cobas h 232 POC system

Operator's Manual

Roche

cobas®

Life needs answers

Manual version	Revision date	Changes
Version 1.0	2006-10	New document
Version 2.0	2009-09	Minor revisions from internal review
Version 3.0	2011-09	Update to SW 03; enhanced error messages
Version 4.0	2014-05	Added description of new OTS functionality, miscellaneous minor revisions

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Operator's Manual

Version 4.0

0 4880889001 (04) 2014-05 EN

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

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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 instructions for use accompanying this instrument.

Temperature limitation (Store at)

Manufacturer

Catalogue number

In vitro diagnostic medical device

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

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

Laser class 1 according to IEC 60825-1
(applies only to meters with a barcode scanner, meter S/N greater than 200000)

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

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1 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 provides more reliable results by eliminating the 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 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 has the ability to connect to a data management system (DMS) through the Handheld Base Unit from Roche (available separately). The **cobas h** 232 meter supports data exchange via the POCT1A standard. Data management systems may have the ability to expand the security features of the meter, such as enabling operator lockouts. Data management systems may also enable data transfer to an LIS or HIS. Refer to the manuals of the Handheld Base Unit and of your DMS for technical details.

Read this operator's manual, as well as the package inserts for all relevant consumables, before using the system for the first time. You must configure the **cobas h** 232 meter according to your needs before initial use. Refer to Chapter 5, “Meter Setup”. Be sure to read the “Important safety instructions and additional information” section in this chapter before operating the system.

For all questions about the **cobas h** 232 system that are not answered in this manual, contact your Roche representative (see Chapter 12). In order to expedite troubleshooting, please have ready your **cobas h** 232 meter, its serial number, this manual, and all related consumables when you call.

If you connect your **cobas h** 232 meter to a **cobas IT** 1000 data management system or another 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.

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). 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 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 English
- CD-ROM with operator's manual in other languages

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

- Roche Handheld Battery Pack (rechargeable) for temporary operation without the handheld power supply
- Handheld Base Unit (docking station) for data transfer within a network or via USB (Universal Serial Bus)

For a personal printout of the operator's manual in your language, contact your local Roche organization (see Chapter 14).

1.1 Important safety instructions and additional information

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

⚠	The safety alert symbol alone (without a signal word) promotes awareness to hazards which are generic or directs the reader to related safety information.
⚠ **WARNING**	Indicates a hazardous situation which, if not avoided, could result in death or serious injury.
⚠ **CAUTION**	Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.
NOTICE	Indicates a hazardous situation which, if not avoided, may result in damage to the system.

Important information that is not safety relevant is presented against a colored background (without a symbol). Here you will find additional information on correct use of the meter or useful tips.

All illustrations in this manual show hands wearing gloves.

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.

Protection against infection and blood-borne pathogens

WARNING

Healthcare professionals using the **cobas h** 232 meter to perform tests must be aware that any object coming into contact with human blood is a potential source of infection. Operators need to adhere to Standard Precautions when handling or using the **cobas h** 232 meter. All parts of this system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and between patients and healthcare professionals.

- Use gloves.
- Dispose of used syringes, tubes, pipettes, test strips, and all other materials coming into contact with blood according to your institution's infection control policy.
- Follow all health and safety regulations in force locally.

Allergy or injury caused by reagents and other working solutions

CAUTION

Direct contact with reagents, detergents, cleaning/disinfection solutions, or other working solutions may cause skin irritation or inflammation.

- Always use protective gloves.
- Observe the cautions given in the package inserts of the reagents and cleaning/disinfection solutions.
- If a reagent, control, or cleaning/disinfection solution comes into contact with your skin, wash it off immediately with water.
- Follow all health and safety regulations in force locally.

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.

Do not dispose of the battery pack with normal domestic waste. As a component of the **cobas h** 232 meter, it must be deemed as potentially biohazardous. Treat it accordingly. See safety message “Infection by a potentially biohazardous instrument” above.

General care

NOTICE

Clean the meter only with the solutions recommended (see page 139). Using other solutions may result in incorrect operation and possible failure of the system. Make sure that the meter is thoroughly dried after cleaning and disinfecting.

Laser scanner

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

WARNING

A barcode does not need to be present for the laser scanner to become active. 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.

Local Area Network: protection from unauthorized access

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

Wired network connection

If connected to a local area network, the **cobas h** 232 Handheld Base Unit must be protected against unauthorized access by means of a **strong password management**. Observe your own facility guidelines on password management where available, or apply the following rules:

Characteristics of strong passwords

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

Examples of weak passwords

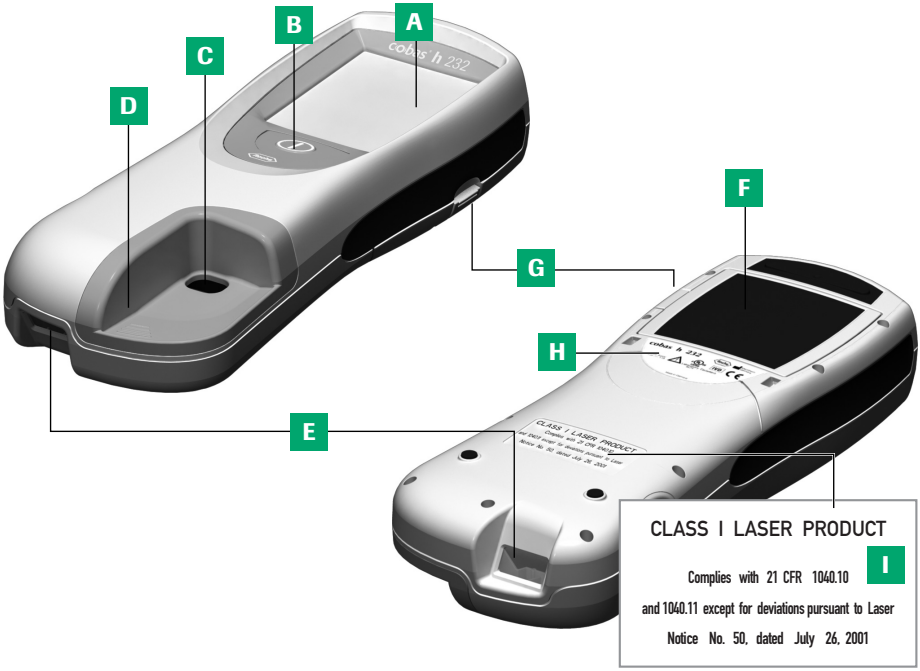
- **uhxwze11** contains no upper case letter.
- **UHXW13SF** contains no lower case letter.
- **uxxxxx7F** contains the same character more than four times.
- **x12useridF** contains a substring of the user ID longer than four characters.

To ensure that your **cobas h** 232 meter functions properly, observe the operating and storage conditions as given in the chapter "General Product Specifications", starting on page 147.

2 The cobas h 232 POC System

2.1 Overview of the meter and its accessories

Meter



A **Touchscreen**
Shows results, information, icons and results saved in the memory. To select an option, simply touch the button lightly.

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

C **Opening for sample application**
Opening in the test strip guide cover that enables you to apply blood once the test strip is inserted.

D **Test strip guide cover**
Remove this cover to clean the area underneath (if it has become soiled, e.g., with blood).

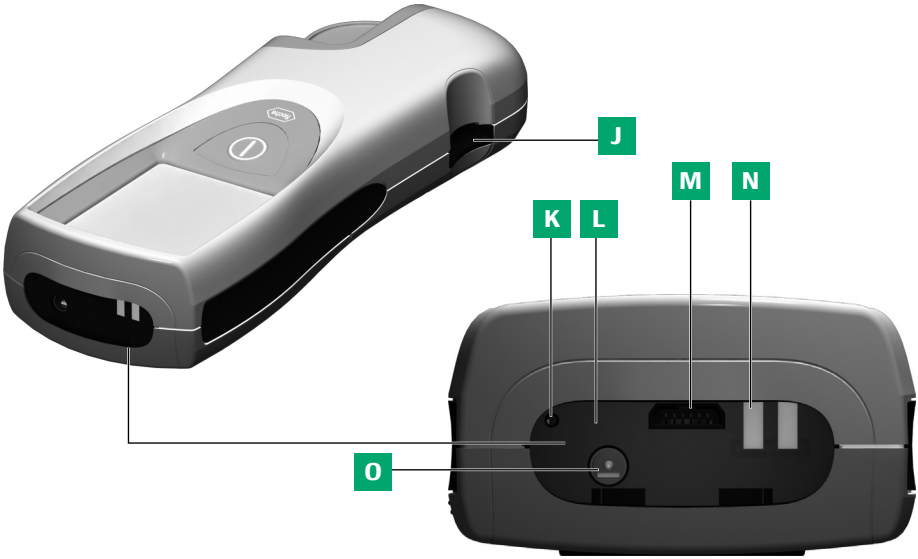
E **Barcode scanner (Laser)**
Operator and patient IDs can be read into the meter using the integrated barcode scanner (only meter versions with a serial number greater than 200 000).

F **Battery compartment**
A cover closes the empty battery compartment if meter is operated without the Handheld Battery Pack; alternatively insert battery pack.

G **Tab of the battery compartment cover**
Used to open the battery compartment.

H **Meter identification plate**
See page 4 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.

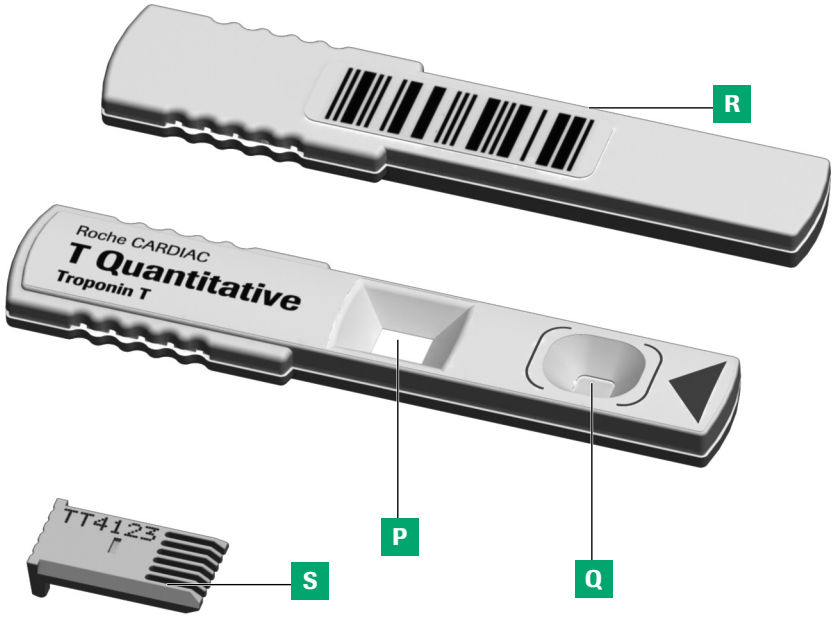
L **Infrared (IR) window**
Supports data communication (covered by the semi-transparent rear panel).

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 **Sample 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 (IR) 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 Data Management System (DMS).

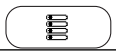
Y **Connection socket for the power supply unit**
Here you can plug in the power supply unit provided with the meter.

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

The Handheld Base Unit can be ordered separately. For detailed information on usage and configuration please consult the operator's manual of the Handheld Base Unit and the Technical Note stored on the Handheld Base Unit itself.

3 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 145.

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 cannot 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)
	Add a comment
 	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 sample amount)
	Apply QC sample (the time left to apply sample is counted down in the screen alongside the required sample amount)

Button/Icon	Meaning
	Insert code chip
	Open test strip guide 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 an error message or a warning (see Chapter 11 "Troubleshooting")
	Room or meter temperature is outside the acceptable range.
	The test strip guide cover is open.
QC!	In a QC lockout condition, this icon indicates that one or more parameters are locked, while others still can be measured.

4 Putting the Meter into Operation

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

1 Connect the handheld power supply

2 If present, insert the handheld battery pack for recharging (see page 25)

3 Set the current date and time as well as the appropriate display format (see Chapter “Meter Setup” starting on page 29)

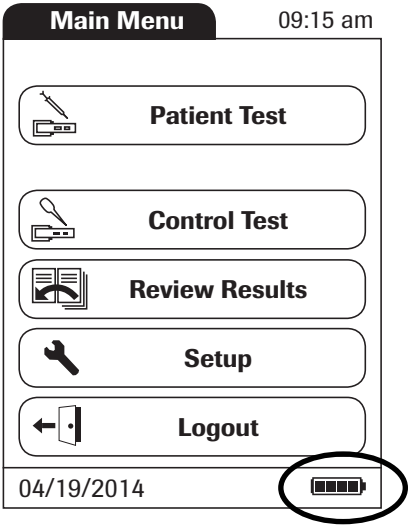
4 Enter the settings of choice (language, quality controls – where necessary, user administration, etc.)

If the meter has **no date/time settings** (either because you are powering on the meter for the first time or because the handheld battery pack was removed from the meter for more than 24 hours), you cannot perform a test (see page 24 “Power supply”). In that case powering on the meter takes you immediately to the Setup mode, where you must set the date and time. See “Setting the date” on page 39 and “Setting the time” on page 41.

Power supply

The meter can be operated with either the handheld power supply (adapter/charger) 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 power itself off after a programmable period of time, if no buttons are pressed or new test strips are inserted. When the meter powers 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 48).



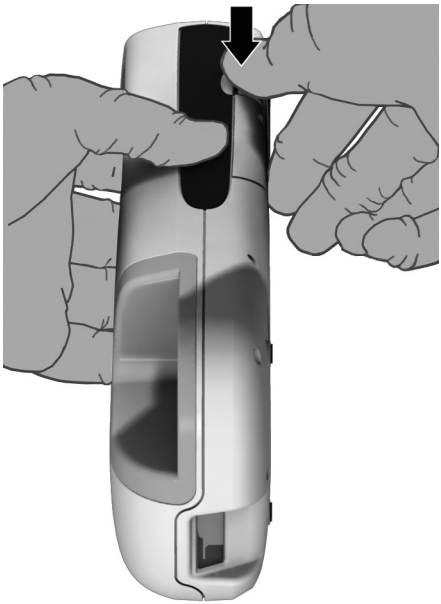
During battery operation, the meter always displays the power level of the handheld battery pack. The battery icon is divided into four segments which correspond to the battery power level.

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.

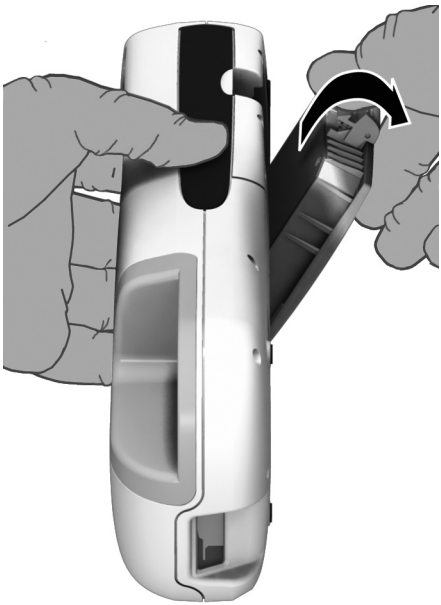
Dispose of used battery packs in an environmentally responsible manner in accordance with applicable local regulations and directives. See “Infection by a potentially biohazardous instrument” on page 13.

Inserting the handheld battery pack



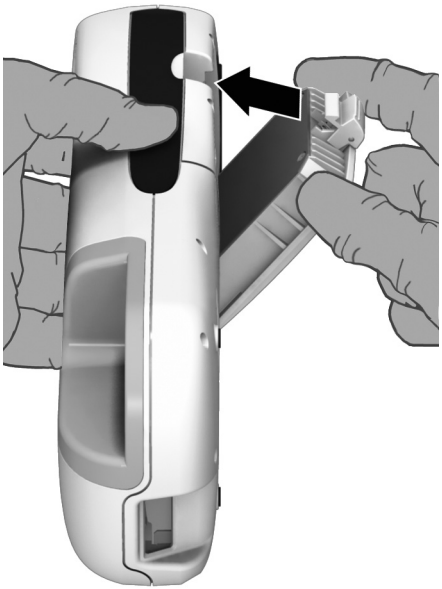
1 With the meter powered off, hold it so that the tab on the handheld battery pack points upward.

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 battery compartment cover upward and remove it.

Note: The battery compartment 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 powers 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.

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*.

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.

Powering the meter on and off

1 Power the meter on by pressing the ⏻ button for approximately 1 second.

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

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

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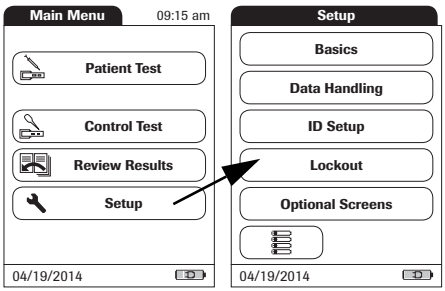
5 Meter Setup

Buttons are screen prompts that cause something to happen when touched. The names of all buttons are either shown as **bold** text or as the icon used on the button (e.g., ✔ for **OK**).

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

You can open any displayed function by touching (or tapping) the button for it with your finger (or a special pen for this purpose). “Tap” means: Touch the button, then remove your finger from the touchscreen. The next screen appears once you remove your finger.



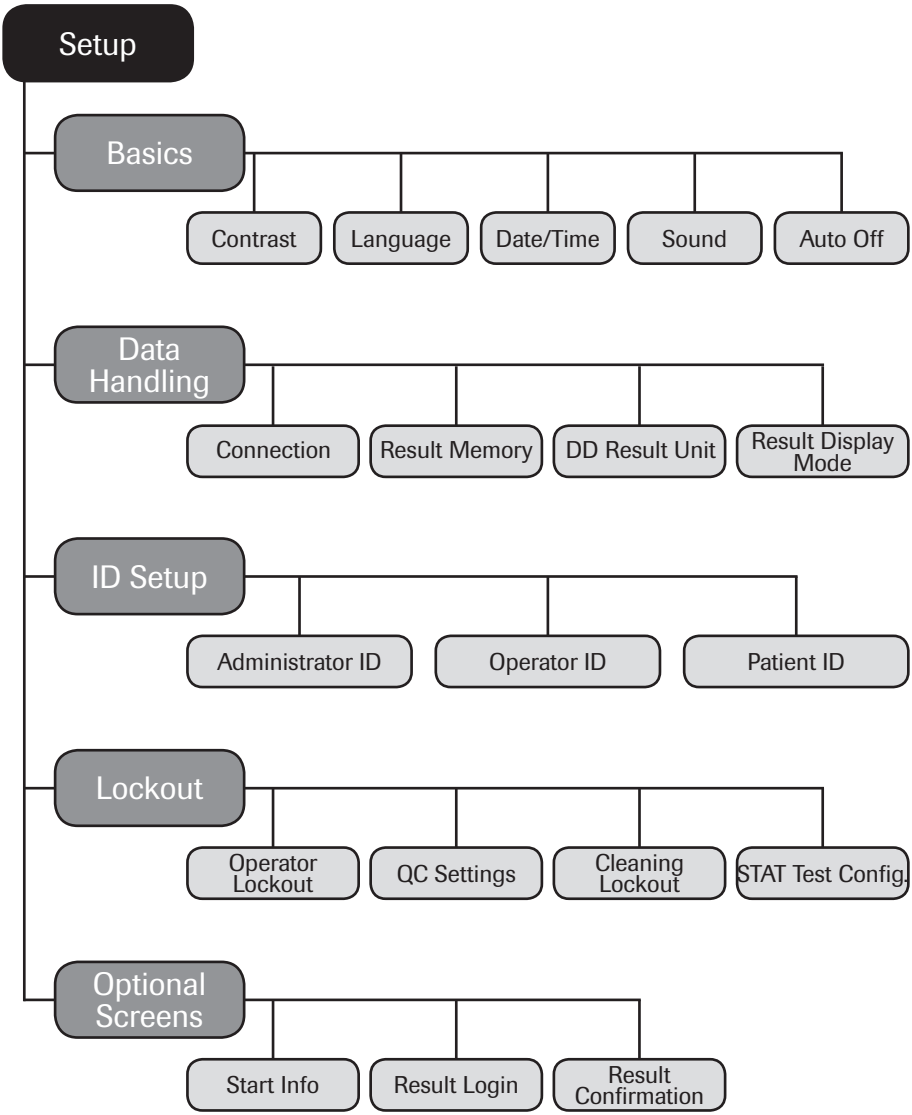
1 Touch **Setup** to call up the *Setup* menu.

2 Select the group of settings of choice (see the Settings summary following this section).

For a description of the buttons and icons used on screen see page 21.

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 *
			Español
			Français
			Italiano
			Nederlands
			Norsk
			Português
			Svenska
			An installable language
	Date/Time	Date	01/01/2011 *
		Time	12:00 am *
		Date formats	Day.Month.Year (31.12.2011)
			Month/Day/Year (12/31/2011) *
			Year-Month-Day (2011-12-31)
		Time formats	24-hour time format (24H)
			12-hour time format (12H), with am/pm *
	Sound (Beeper)	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

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

Group	Subgroup	Setting	Values *
Data Handling	Connection		Off *
			Computer
			Printer
	Result Memory	Result Display Filter	All results *
			Current Op. Res.
		Result Storage Mode	No results deletion *
			Delete oldest result
	DD Result Unit		µg/mL *
			ng/mL
			mg/L
			µg/L
	Result Display Mode		Static *
			Flashing
ID Setup	Administrator ID		Blank (off) *
	Operator ID		None *
			Optional
			Required
			Scan Only
	Patient ID		None
			Optional *
			Required
			Hidden List

* Default settings 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	QC Lockout	New Lot: Yes/No *
			No *
			Daily
			Weekly
			Monthly
		IQC Lockout	No *
			Daily
			Weekly
			Monthly
		QC Result Format	Pass/Fail *
			Value
			Value & Pass/Fail
		Custom Range Trop T	Default Range*
			Custom Range
		Reset Test Param.	Do Reset
			No Reset *
	Cleaning Lockout		No *
			Daily
			Weekly
			Monthly
	STAT Test Config.		Enable
			Disable *

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

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

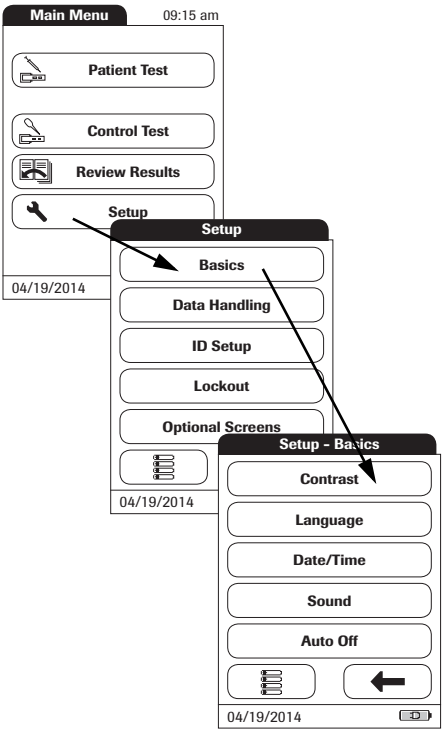
* Default settings are labelled with an asterisk (*).

5.1 *Basics* setup

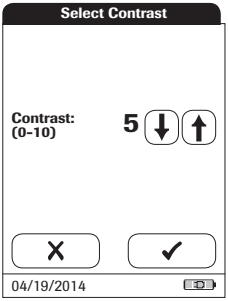
The *Basics* setup area contains the basic options for changing the user interface.

Contrast

Use the *Contrast* menu to adjust the display to your ambient light conditions and make it easier to read.



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



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

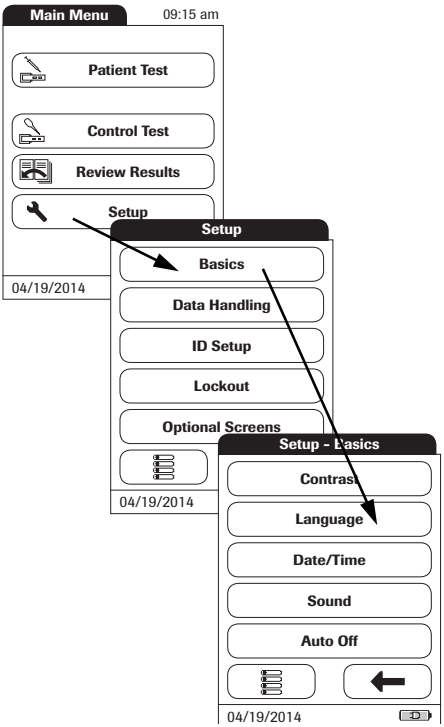
- Contrast “0” makes the screen very dark.
- Contrast “10” makes the screen very light.

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



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

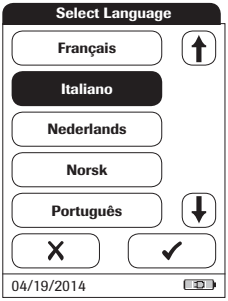
2 From the *Setup* menu, touch **Basics**.

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

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

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

An optional language can be installed upon request (either directly at the plant or later by an authorised Roche Diagnostics service technician).



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 respective direction.

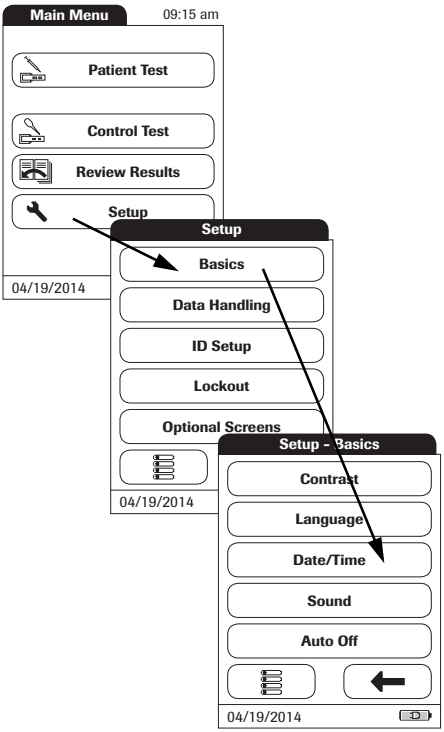
5 Touch the button to select the language of choice. Your selection is now highlighted.

6 Touch ✓ to save this setting, or:

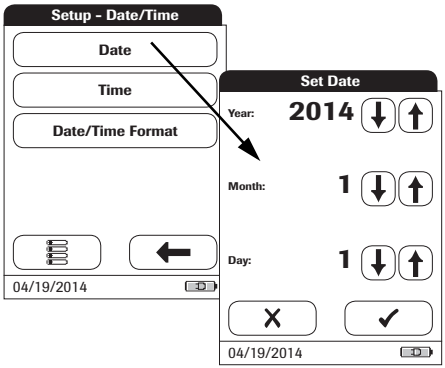
Touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

Setting the date

Use this menu to set the date of the meter.



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

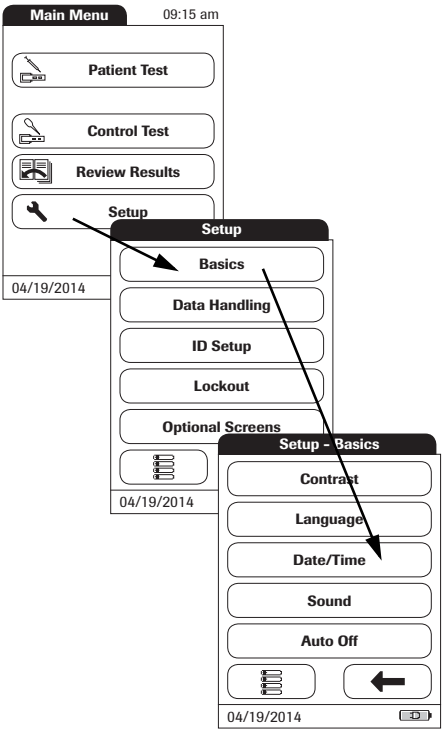
Touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

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

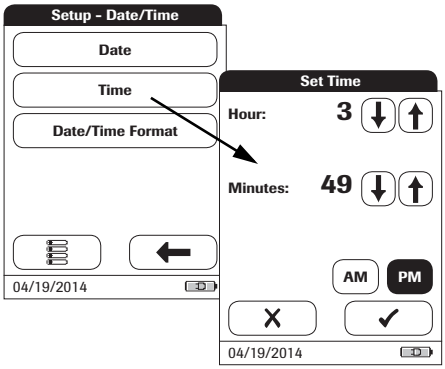
7 In the *Setup-Date/Time* menu, touch ← to return to the *Setup-Basics* menu or touch **Time** to move to the time setting.

Setting the time

Use this menu to set the time of the meter.



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

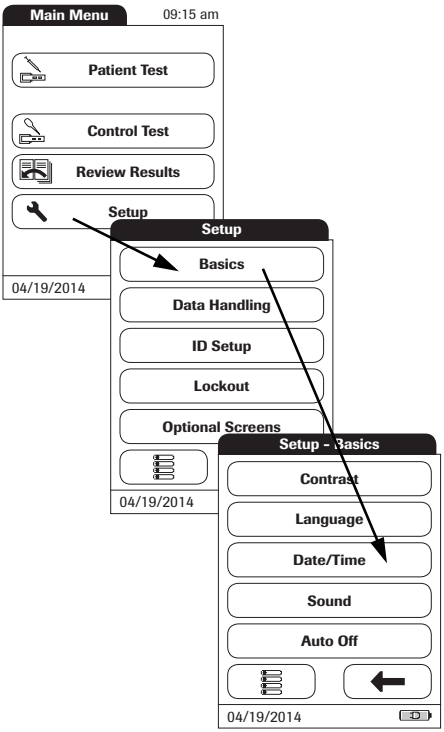
Touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

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.

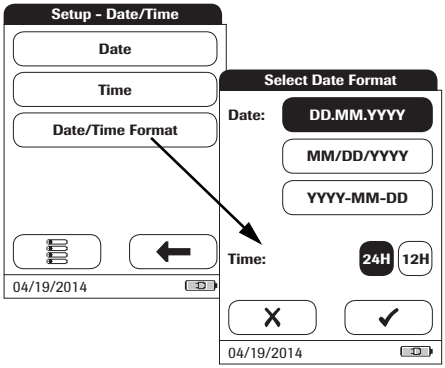
7 Touch ← to return to the *Setup-Basics* menu or touch **Date/Time Format** to move to the display options.

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** to open the meter settings.
2. From the *Setup* menu, touch **Basics**.
3. From the *Setup-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 blue background). You can select one of the following display formats for the date:

- Day.Month.Year, e.g., 31.12.2011
- Month/Day/Year, e.g., 12/31/2011
- Year-Month-Day, e.g., 2011-12-31

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.

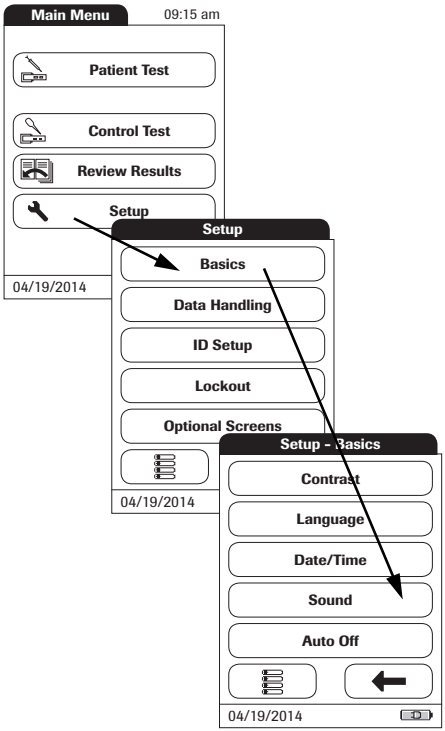
Sound

The **cobas h** 232 meter can display information visually and alert you to special circumstances with a beep sound. When the *Sound* is activated, the meter beeps when:

- it is powered 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 positive test result can be expected, while the measurement still is in progress (a long beep)

We recommend that you keep the *Sound* (beeper) activated at all times.

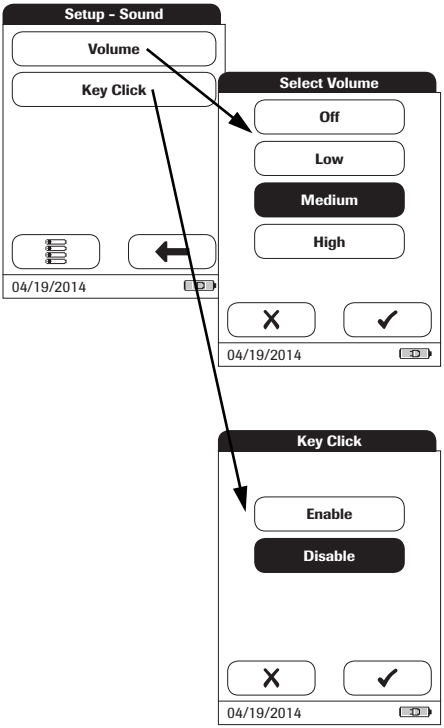
You can also activate a *Key Click*. When the *Key Click* is activated, the meter clicks briefly every time a button is touched, facilitating the input of information.



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

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 of the beeper.

The current setting is highlighted (white type on a blue 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

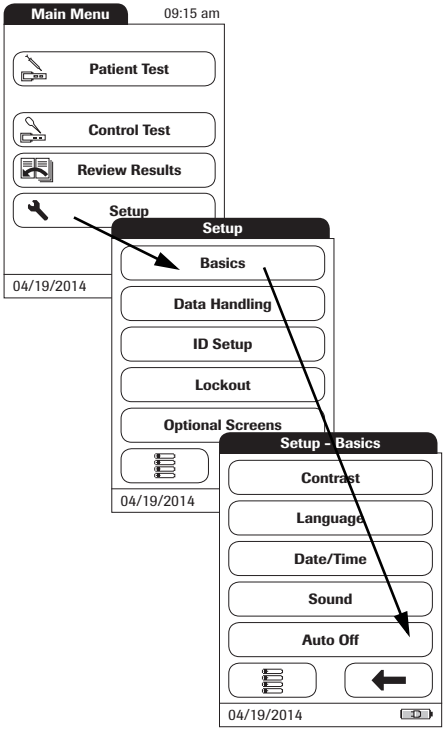
6 Touch ✓ to save this setting, or:

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 powers itself off automatically if it has not been used (no buttons touched or tests run) for a preselected time period. Use this feature to save power and extend the life of the batteries.

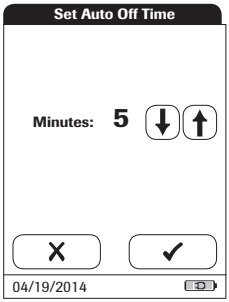


1. From the *Main Menu*, touch **Setup** to open the meter settings.
2. From the *Setup* menu, touch **Basics**.
3. In the *Setup-Basics* menu, touch **Auto Off**.

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

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

For information on *Operator ID*, see “Operator ID” on page 68.



You may select from the following options:

- Off (meter never powers itself off)
- Time until meter powers itself off:
  1…10, 15, 20, 25, 30, 40, 50, 60 minutes

4 Touch ↑ and ↓ to select the time of choice in minutes or to deactivate the feature.

5 Touch ✓ to save this setting, or:

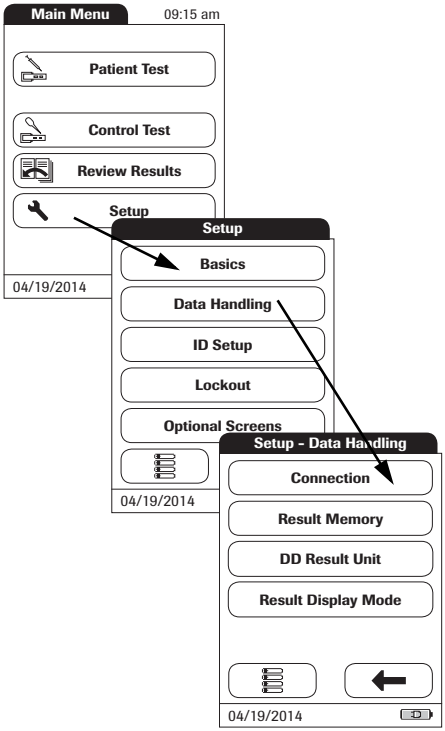
Touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

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

5.2 *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.



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

Computer

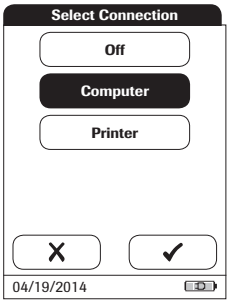
The **cobas h** 232 meter can connect with a computer or host system running appropriate software (that is, a DMS must be installed). To use this connectivity feature, however, you need the optional Handheld Base Unit. The connection is established in two steps.

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

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

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

This eliminates the need for manual entry of these data. In addition, you can transfer test results stored in the meter to other systems for archiving or further evaluation. The option *Computer* controls the meter's ability to communicate with a computer or a network.



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

5 Touch ✓ to save this setting, or:

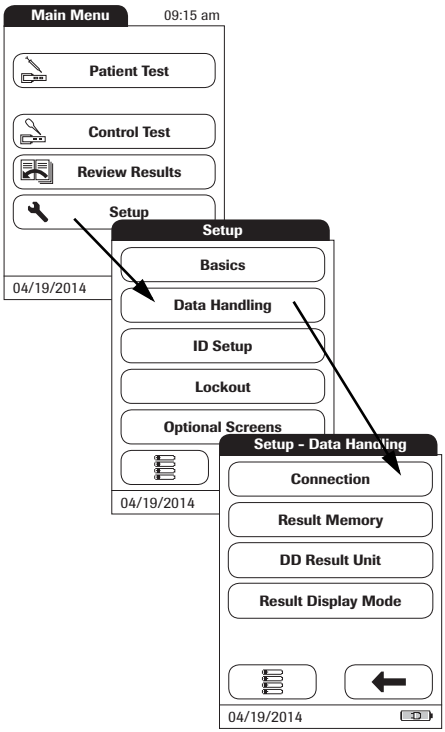
Touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

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

Printer

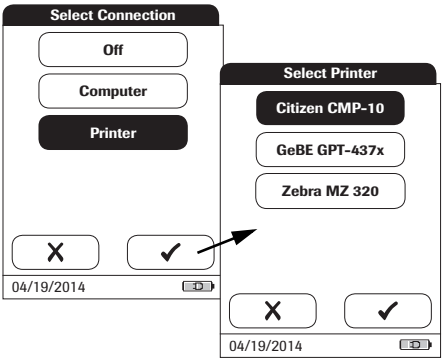
The meter can connect directly with three different infrared printers. The Handheld Base Unit cannot be used for this purpose.

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** to open the meter settings.
2. From the *Setup* menu, touch **Data Handling**.
3. From the *Setup-Data Handling* menu, touch **Connection**.

Connection to a printer can only be established via infrared.

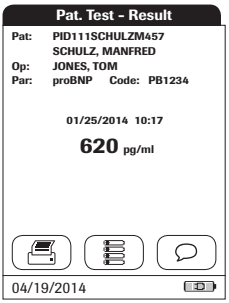


4 Touch **Printer**. Your selection is now highlighted.

5 Touch ✓ to confirm the selection. The next screen allows you to choose the type of printer you are using.

6 Touch ✓ to save this setting, or:

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



To print :

- Align the meter with the IR printer
- At any test or memory screen, touch .

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

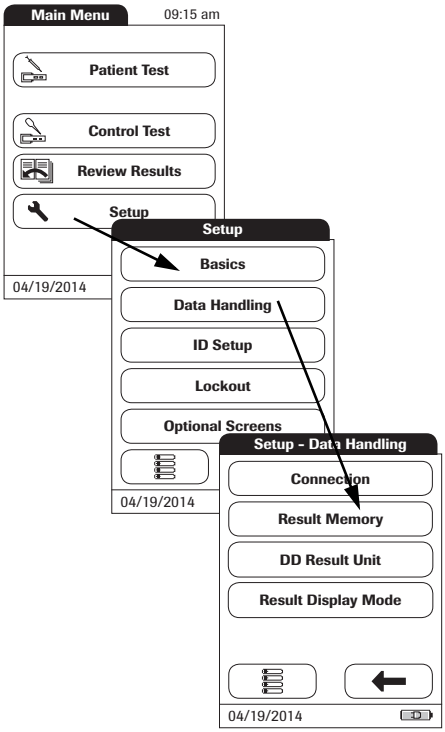
Note: (Only applies if you are working with the meter in a language other than English.) With the exception of information you have entered (such as patient ID and name, operator ID, comments), the printout will be in English.

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

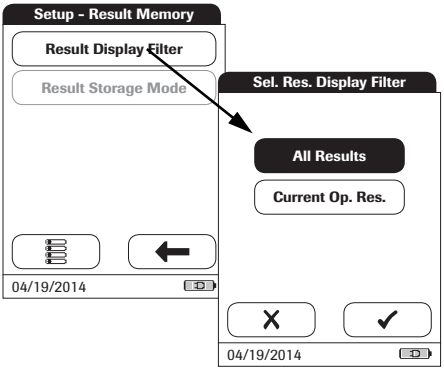
Result memory

Result memory settings allow to apply a *Result Display Filter* and to set the *Result Storage Mode* (see page 56).

All results recorded by the meter (patient results and quality controls) are stored automatically. Use the *Sel. Res. Display Filter* 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** to open the meter settings.
2. From the *Setup* menu, touch **Data Handling** .
3. From the *Setup-Data Handling* menu, touch **Result Memory**.



4 From the *Setup-Result Memory* menu, touch **Result Display Filter** to select the results to display.

The current setting is highlighted (white type on a blue 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.

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

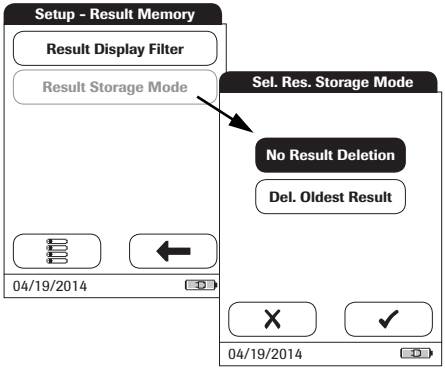
The meter memory can store a maximum of 500 patient tests, 500 liquid controls, and 200 instrument quality controls.

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 cannot perform a new measurement. Further measurements will only be possible if stored data are transferred to the data management system (DMS) 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 DMS (i.e. no data will be transferred and archived).

The option *No Result Deletion* is available only when you are using a DMS. For more details see "Extended Functionalities", starting on page 132. If you are not working with a DMS, this option is set to *Del. Oldest Result*.

However, you only can select between these two options, if the meter is used together with a DMS 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.



6 From the *Setup-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**

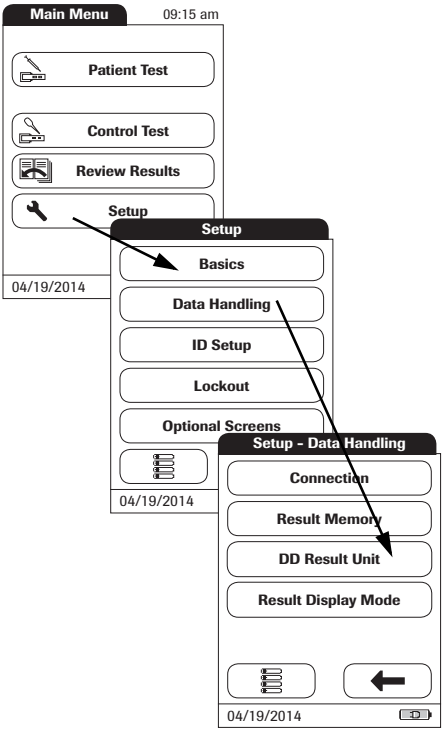
7 Touch ✓ to save this setting, or:

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

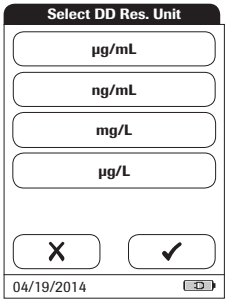
8 Touch ← to return to the *Setup-Data Handling* menu.

Result unit

The result unit setting applies to the result display of **D-Dimer** tests only.



1. From the *Main Menu*, touch **Setup** to open the meter settings.
2. From the *Setup* menu, touch **Data Handling**.
3. From the *Setup-Data Handling* menu, touch **DD Result Unit**.



4 From the *Select DD Res. Unit* menu, select the unit to be used for the D-Dimer result display.

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

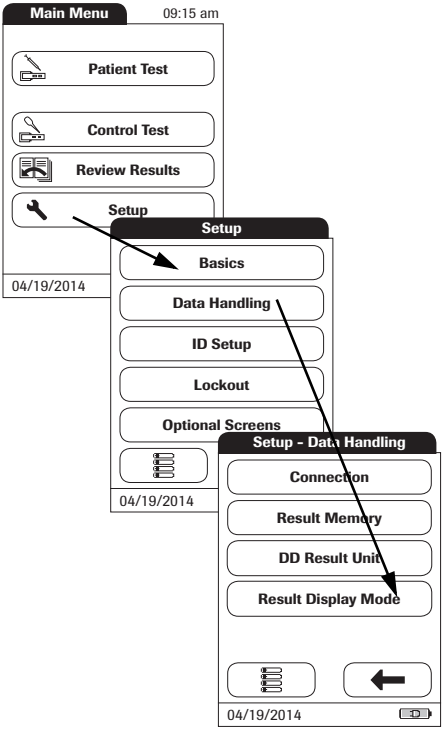
- **µg/mL**
- **ng/mL**
- **mg/L**
- **µg/L**

5 Touch ✓ to save this setting, or:

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

Result display mode

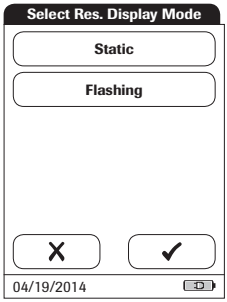
Test results may be displayed either with a static or a flashing display, the latter visually indicating that the measurement process has been finished. Once a result is available, the display starts flashing. Depending on the settings, this may be either a quantitative or qualitative result screen or an operator login screen.



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

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

3 From the *Setup-Data Handling* menu, touch **Result Display Mode**.



4 From the *Select Res. Display Mode* menu, select your display mode.

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

- **Static**
- **Flashing**

5 Touch ✓ to save this setting, or:

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

5.3 *ID Setup* setting

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

There are three types of identification used with the meter:

- **System Administrator:** The administrator has special rights to enter certain meter settings and is the only one who can enter and change these settings. It is not necessary for administrator identification to be activated to use the **cobas h** 232 meter. However, it might be desired or necessary, depending on the regulatory environment and the site of use.
- **Operator:** The *Operator ID* is assigned to persons who use the meter to run tests. If you want to use *Operator IDs*, you have several options:
  - You may use *Operator IDs* to restrict the use of the meter to qualified personnel or a predefined group of users. In this case an operator list created on a DMS must be transferred to the meter, enabling you to select an *Operator ID* when logging in. For more details see “Data handling”, starting on page 132.
  - You may use *Operator IDs* for informational purposes only, in order to assign stored measurement results to the users who performed the test. In this case *Operator IDs* may directly be entered on the meter (by keypad or scanner), with or without an operator list being available.
- **Patient:** The *Patient ID* is assigned to the person, whose test results are recorded. You can either:
  - block input of a unique *Patient ID* (in this case, every test is simply numbered in consecutive order)
  - allow a unique *Patient ID* as optional, or
  - require a unique *Patient ID* for every test. Patient lists created on a DMS can also be transferred to the meter, enabling you to select *Patient ID*s for a test from these lists. For more details see “Data handling”, starting on page 132.

Operator IDs can be selected from a list (if available) or read by the barcode scanner on the front of the meter. If passwords were created, they **must** be entered via the onscreen keypad. *Patient IDs* can be entered by using the onscreen keypad or the barcode scanner on the front of the meter.

Administrator ID

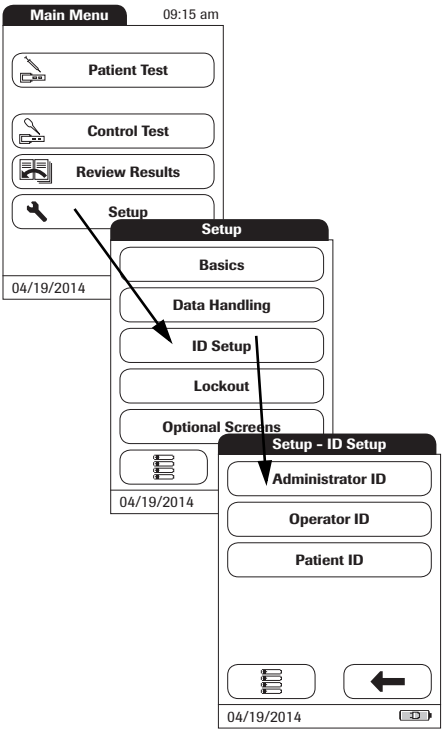
In the default setting, the meter is not protected with an *Administrator ID*, and all setup options are accessible to every user. If you set up an *Administrator ID*, the following setup areas are automatically reserved only for the administrator (i.e., the person who knows the password):

- 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.

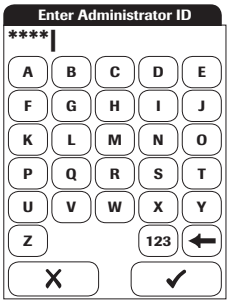
When you enter an *Administrator ID*, this ID must be entered from this point forward before any future IDs can be set up (anywhere in the *ID Setup* menu). The *Administrator ID* must also be entered before you can delete or change the *Administrator ID*.

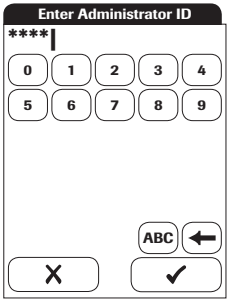
If you forget the *Administrator ID*, the meter setup may be unlocked via the external data management system (e.g., cobas IT 1000). If you don't use such a system and need to reset the *Administrator ID*, contact your Roche representative (see Chapter 12).



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

1. From the *Main Menu*, touch **Setup** to open the meter settings.
2. From the *Setup* menu, touch **ID Setup**.
3. From the *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 can consist of up to 20 alphanumeric characters.

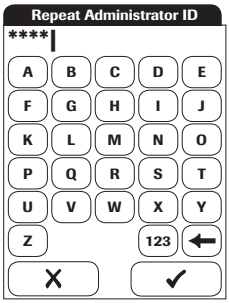
Pay close attention to the buttons you press, because the characters are not displayed on the screen. Asterisks are displayed instead (as if entering a password on a computer).

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

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

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.

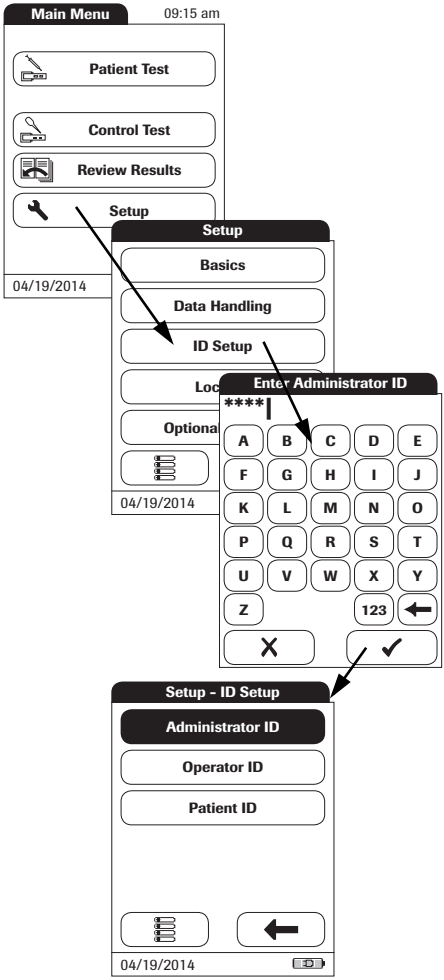


9 Enter the *Administrator ID* again (the onscreen keypad is automatically displayed again) to confirm the first entry.

Touch ✓ to save this entry, (the A*dministrator ID* is now set), or

Touch ✗ to exit this menu, the *Administrator ID* is not set and is therefore still inactive.

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 IDs.



Changing an existing *Administrator ID*:

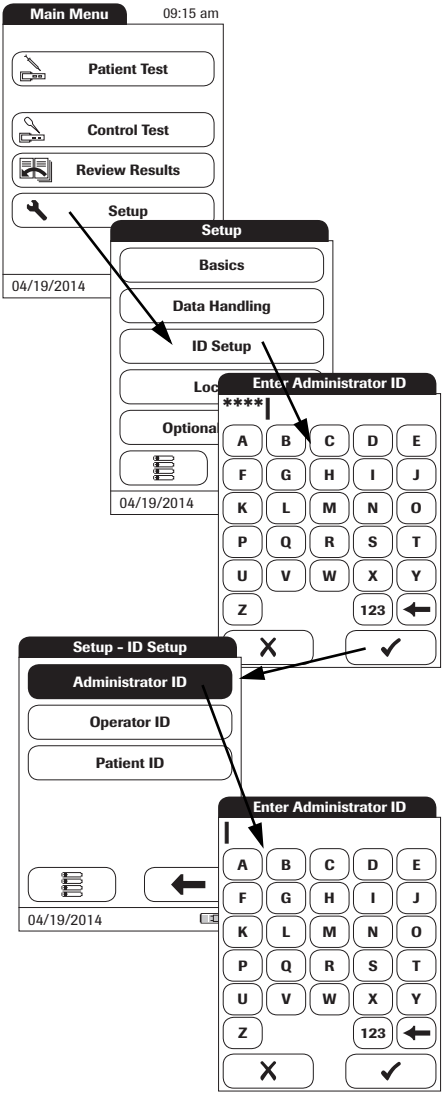
1 From the *Main Menu*, touch **Setup** to open the meter settings.

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** to open the meter settings.

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.

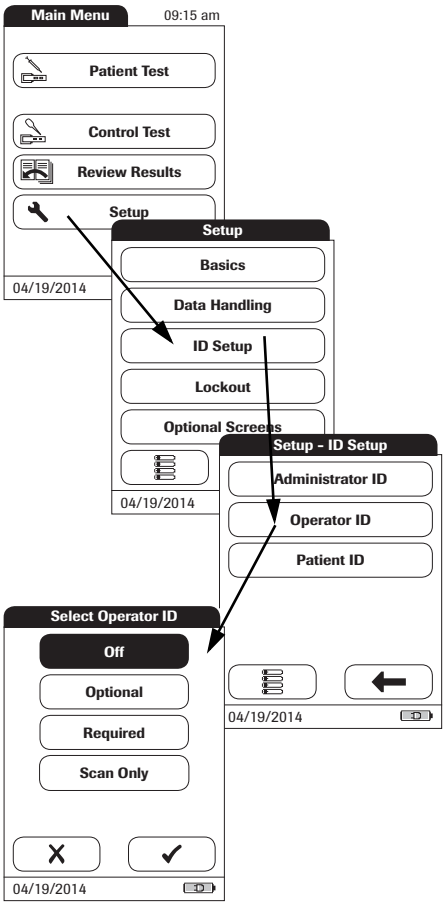
4 Touch **Administrator ID**.

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

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:

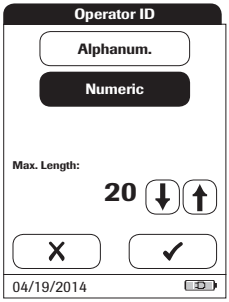
- **Off** (*Operator ID* cannot be entered)
- **Optional** (*Operator ID* can be entered, but is not required)
- **Required** (An *Operator ID* must be entered)
- **Scan Only** (An *Operator ID* must be scanned)

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:

- **Alphanum.** (alphanumeric)
  Enter any combination of letters and numbers, e.g., “J. DOE 3378”
- **Numeric**
  Enter numbers only, e.g., “3387”
- **Max. Length**
  Enter 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.

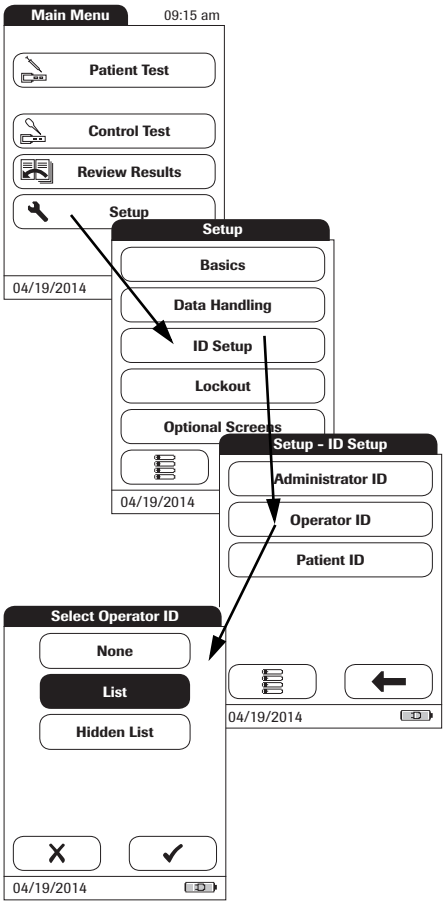
9 Touch ✓ to save this setting, or:

Touch ✗ to exit this menu without saving any changes.

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

If you want to create a list of *Operator IDs* from which you can select an operator, additional software (a data management system) and the Handheld Base Unit are required (for more details see “Data handling”, starting on page 132).

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** to open the meter settings.

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)
- **Hidden List** (*Operator ID* must be entered using the barcode scanner or the onscreen keypad)

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

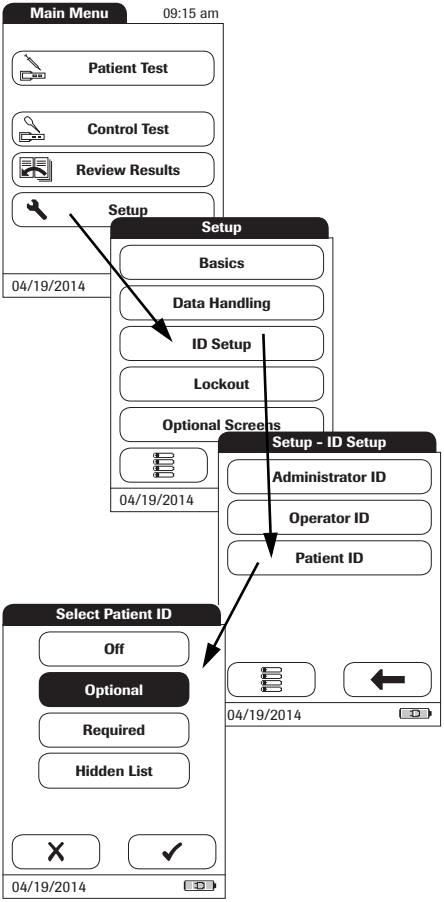
5 Touch ✓ to save this setting, or:

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

Patient ID

Patient IDs help you to assign stored results to individual patients. In the default setting, input of *Patient IDs* is set to *No*. This means that a consecutive number is assigned to each test. However, you can require that a *Patient ID* must be entered or make it optional.

If you want to create a list of *Patient IDs* from which you can select a patient for testing, additional software (a data management system) and the Handheld Base Unit are required (see page 132).



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

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:

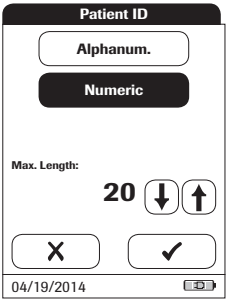
- **Off** (*Patient ID* cannot be entered)
- **Optional** (*Patient ID* can be entered, but is not required)
- **Required** (The operator must enter the *Patient ID*)
- **Hidden List** (Only available when working with a DMS. The list will not be shown. The operator needs to enter the *Patient ID* manually or via barcode scan.)

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:

- **Alphanum.** (alphanumeric)
  Enter any combination of letters and numbers, e.g., “J. DOE 3378”
- **Numeric**
  Enter numbers only, e.g., “3387”
- **Max. Length**
  Enter the maximum number of characters (1 … 20) the Patient ID 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.

5.4 *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*
  - *Custom Range Trop T*
- *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 locked 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.

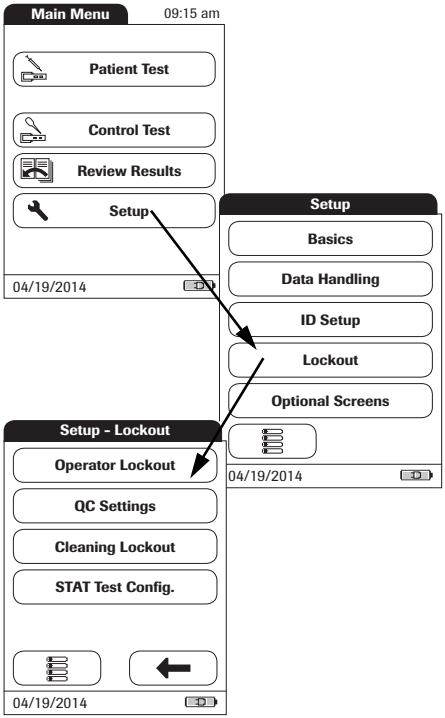
The option of setting up lockouts for operators is available only when the meter is set up for operator logins (see page 68) and operator lists are stored in the meter.

In case of an emergency, there may not be the time to first complete the required quality control test if a lockout has been triggered and the meter is "locked". For such cases you may set up so-called *STAT Tests* (STAT = **S**hort **T**urn**A**round **T**ime). This option allows to perform a limited number of tests when an operator lockout or QC 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.

STAT tests cannot be performed if IQC lockout is in place or a new lot has not (yet) passed a quality control test (New Lot Lockout).

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.

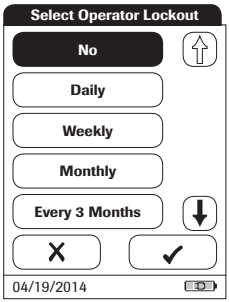


1. From the *Main Menu*, touch **Setup** to open the meter settings.
2. From the *Setup* menu, touch **Lockout**.
3. From the *Setup-Lockout* menu, touch **Operator Lockout**.
   If this button appears in gray (inactive), the option *Operator ID* is deactivated.

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

You may select from the following options:

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



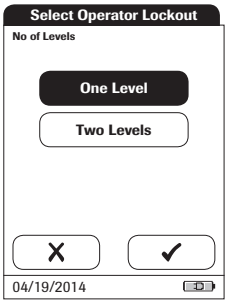
5 Touch ⇧ and ⇩ to display the option of choice on the screen. If the arrow is just an outline ⇧ ⇩, this means no other options are available in the direction indicated.

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.

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**).

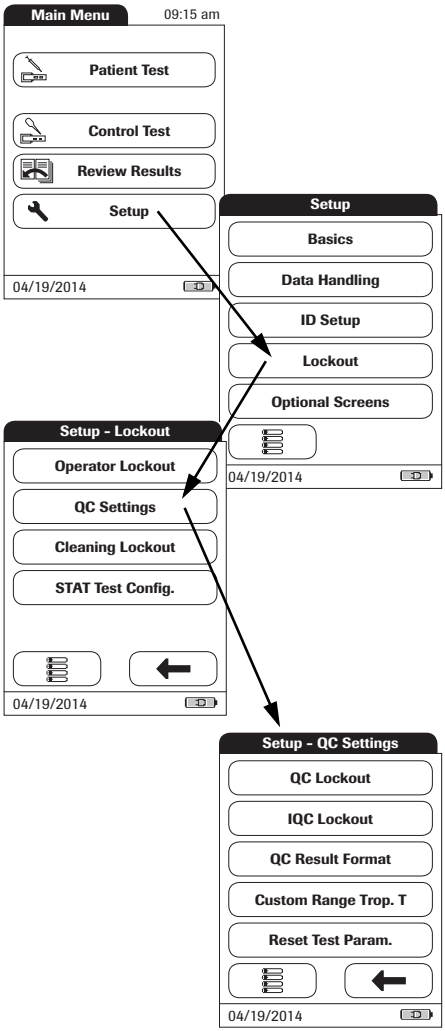
9 Touch ✓ to save this setting, or:

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:

- *QC Lockout* (time-based), with the additional option of a *New Lot Lockout* (applies every time a new test strip lot is used)
- *IQC Lockout* (time-based)
- *Custom Range Trop. T* (customize the QC Range in accordance with applicable local guidelines)
- *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** to open the meter settings.

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

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

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:

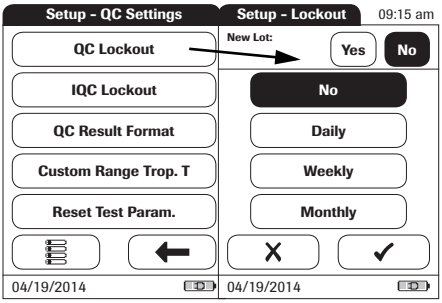
- **New Lot: Yes/No** (applies every time a new test strip lot is used)

The general intervals are:

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

All enabled QC Lockouts, if the time period has elapsed, are activated at 8:00 a.m. (default setting, time can be changed with a DMS).

See page 78 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. New Lot: Touch **Yes** if you want to force a control test every time a new test strip lot is used. Otherwise touch **No**.
3. Time intervals: Touch the button to select the time interval of choice (e.g., **Daily**). Your selection is now highlighted.
4. Touch ✓ to save this setting, or:

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

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

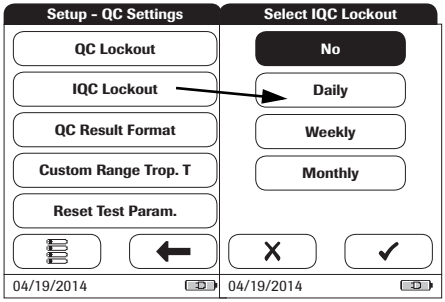
Instrument quality control (IQC) lockout

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 IQC Lockouts, if the time period has elapsed, are activated at 8:00 a.m. (default setting, time can be changed with a DMS).

See page 78 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:

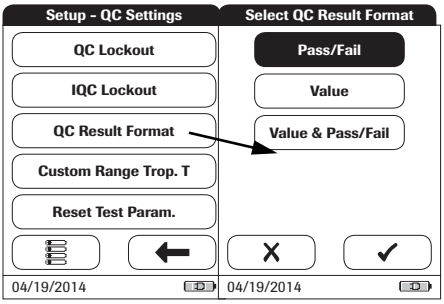
   Touch ✗ to exit this menu without saving any changes.
   The display automatically returns to the previous screen.

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 78 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:

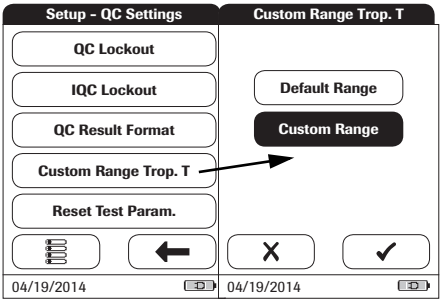
Touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

Custom Range Troponin T

The quality control range for Troponin T can be customized to comply with local guidelines. The *Custom Range Trop. T* function enables you to narrow the default range.

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

See page 78 on how to access the *Setup-QC Settings* menu.



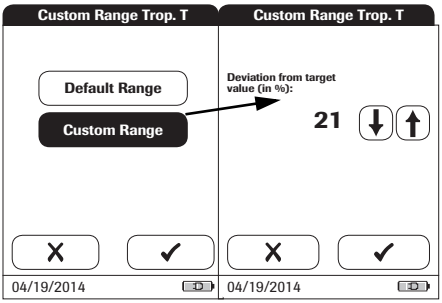
1 Touch **Custom Range Trop. T** to set the quality control range.

You may select from the following options:

- **Default Range** (Range provided in the code chip is selected and displayed.)
- **Custom Range** (The allowed percentage deviation from target value can now be customized).

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

- If you selected **Default Range**, touch ✓ to save this setting, or:
  Touch ✗ to exit this menu without saving any changes.
- If you selected **Custom Range**, touch ✓ to proceed with corresponding settings, or:
  Touch ✗ to exit this menu without saving any changes.
  The display automatically returns to the previous screen.



If you selected **Custom Range**, the *Custom Range* screen opens and offers you the option of customizing the deviation from target value (percentage value).

For the control solutions, the target value always comes from the information stored in the code chip. If you have chosen **Custom Range**, you can now select an allowed deviation from target value in the range of 0 to 50% (in the illustration, 21%).

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

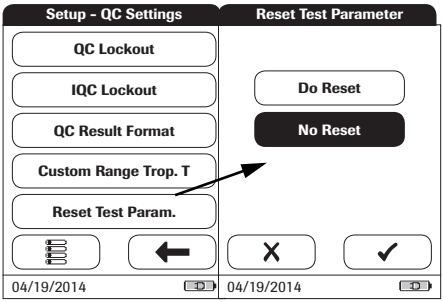
■ Touch ✓ to save this setting, or:

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

Reset test parameters

Under certain circumstances, it may be necessary to delete the test parameters stored in the meter (for example, if a lockout exists for a test strip lot that is no longer available). However, do not use this method for overriding lockouts in general because, after resetting the test parameters, the meter may go into a QC lockout (if configured). If the meter or a parameter is locked by a QC lockout or an operator lockout, use STAT tests for emergency tests. STAT tests cannot be performed if IQC lockout is in place or a new lot has not (yet) passed a quality control test (New Lot Lockout).

See page 78 on how to access the *Setup-QC Settings* menu.



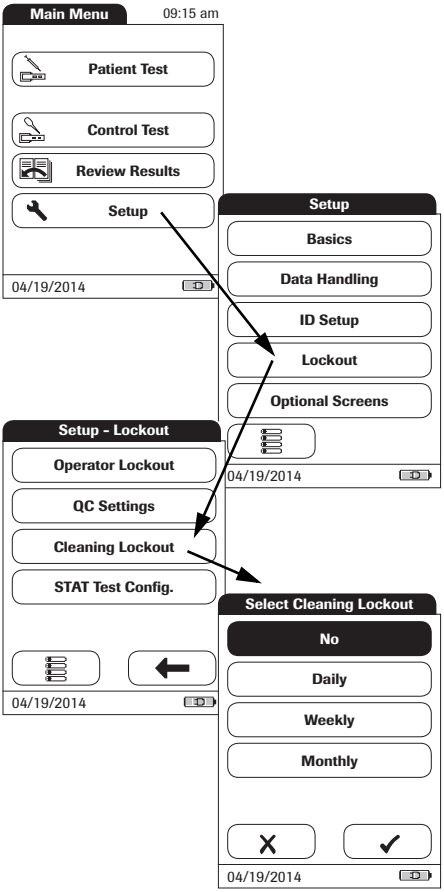
4 Touch **Reset Test Param.** to reset all stored test parameters and QC lockouts.

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** to open the meter settings.

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.

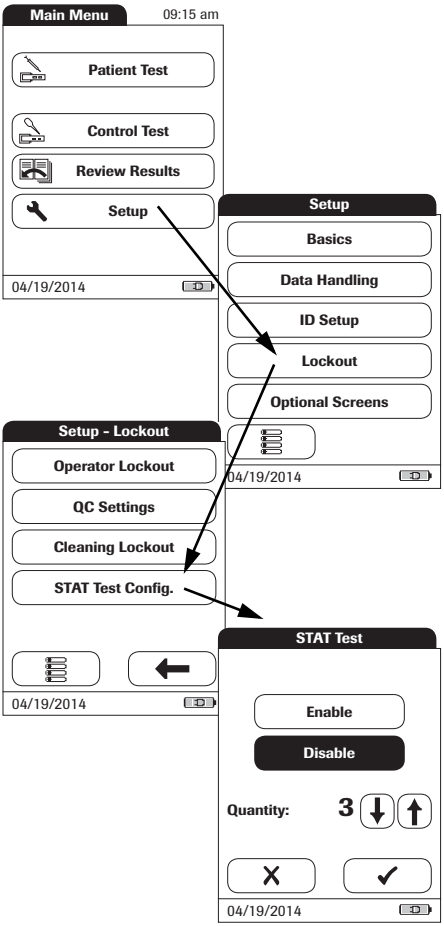
STAT test configuration

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). STAT tests cannot be performed if IQC lockout is in place or a new lot has not (yet) passed a quality control test (New Lot Lockout).

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 locked until you successfully perform a quality control test.

STAT Tests will be counted separately for each test parameter. Thus the actual availability of *STAT Tests* may differ for each parameter.

STAT tests are labelled accordingly in the result window.



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

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.

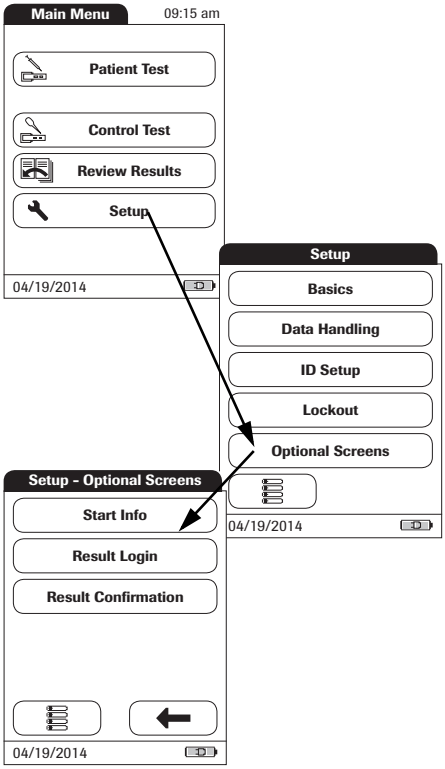
5 If you have enabled the option, touch ⬆ and ⬇ to set the number of additional tests.

6 Touch ✓ to save this setting, or:

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

5.5 *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.



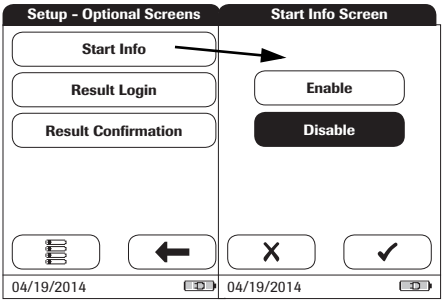
1 From the *Main Menu*, touch **Setup** to open the meter settings.

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

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



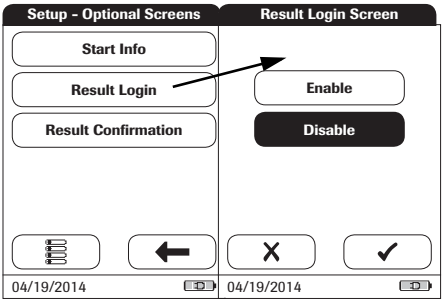
3 Touch **Start Info**.

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.



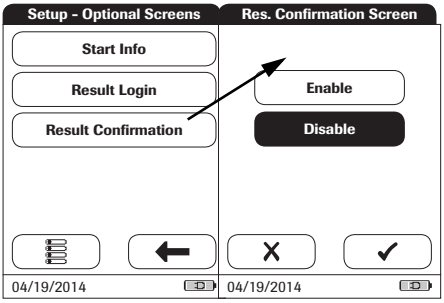
6 Touch **Result Login**.

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 **Result Confirmation**.

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.

6 Performing a Test

What you need:

- Suitable blood sampling system to collect venous whole blood

Only heparinized blood collection tubes are allowed. Refer to test strip package insert.

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

The Roche CARDIAC family includes several strips. Always ensure that the disposables you are using (e.g., test strips) are intended for use with the **cobas h** 232 meter. Some tests might require a minimum software version. Ensure that the software version on the **cobas h** 232 meter is compatible with the test you are running (refer to the corresponding package insert for details). 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 147).
- … follow the information on correct handling of test strips in the package insert.
- … place the meter on a level, vibration-free surface when applying the sample to the sample application area of the test strip. Once the sample has been completely absorbed by the test strip, you can move the meter.
- … keep the meter clean. See “Cleaning and Disinfecting the Meter” on page 139.

Never …

- … use Roche CARDIAC pipettes for collecting blood from the patient.
- … 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

Heparinized venous whole blood is used as sample material. For each test use exactly 150 µL of sample.

Use a suitable sampling system to collect the blood sample. Use only heparinized blood collection tubes. Do not use blood collection tubes containing EDTA, citrate, sodium fluoride or other additives. For details refer to the test strip package insert.

IMPORTANT NOTE: Do not use Roche CARDIAC pipettes for blood sampling from the vein or for injections. Roche CARDIAC pipettes are intended only for drawing the sample from the blood collection tube and applying it to the test strip. See page 106.

- Observe the applicable regulations and directives for hygiene and safety when collecting blood samples.
- Observe the applicable regulations and directives for disposing of potentially infectious samples and materials.
- Dispose of used consumables in line with the disposal policy of your hospital, institute or medical practice.
- See safety message “Protection against infection and blood-borne pathogens” on page 12.

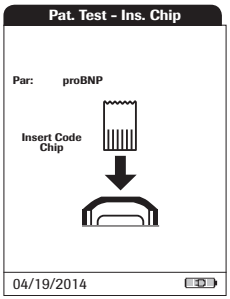
6.1 Preparing to test

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

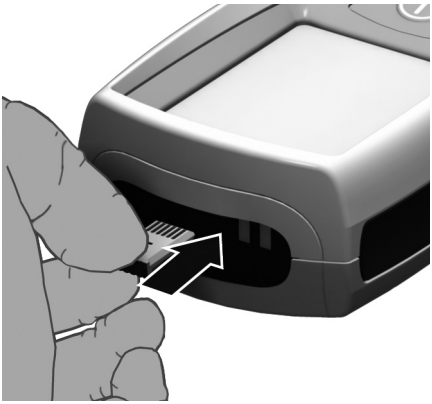
The code chip provides the meter with important information on the manufacturer-specific parameters of the respective test strip lots. It contains information about the test method, the lot number and the expiration date.



- Each test strip box 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.

Roche recommends keeping the code chip in the meter to protect the contacts from becoming dirty. Protect the code chip from moisture and equipment which produces magnetic fields. Once the test strip lot is used up, dispose of the old code chip promptly to prevent mix-ups.

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.

If the code chip is missing or incorrectly inserted, an error message appears in the display (see “Troubleshooting” starting on page 145).

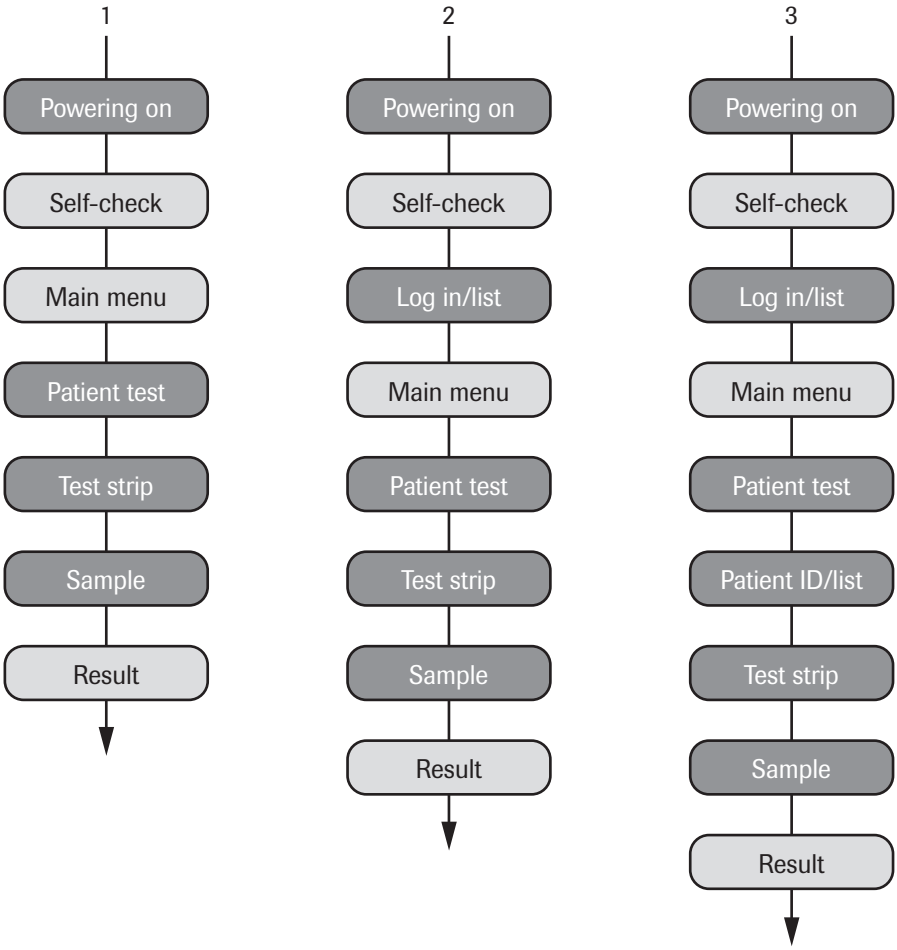
Test steps (overview)

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)

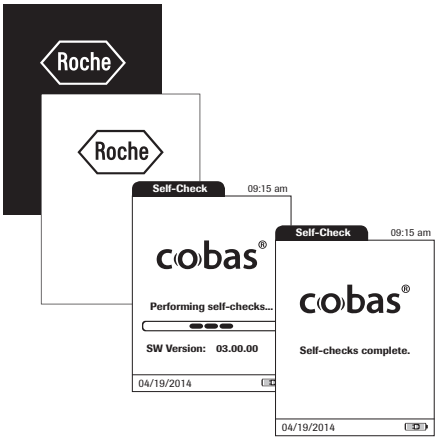
3 With operator and patient list (or operator and patient ID enabled)



Powering on the meter

1 Power the meter on by pressing the ⏻ button for approximately 1 second.

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

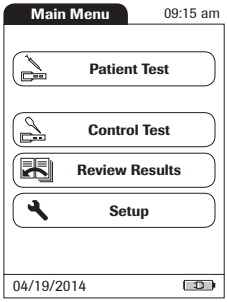


The meter performs a self-check at startup.

Logging in

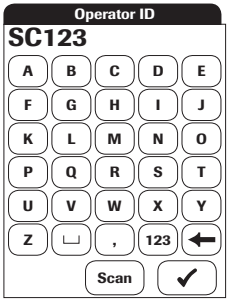
The initial steps until the *Main Menu* is displayed depend on the configuration and are performed as follows:

Without operator login required



2 Wait until the main menu is displayed.

With operator login (no operator list)

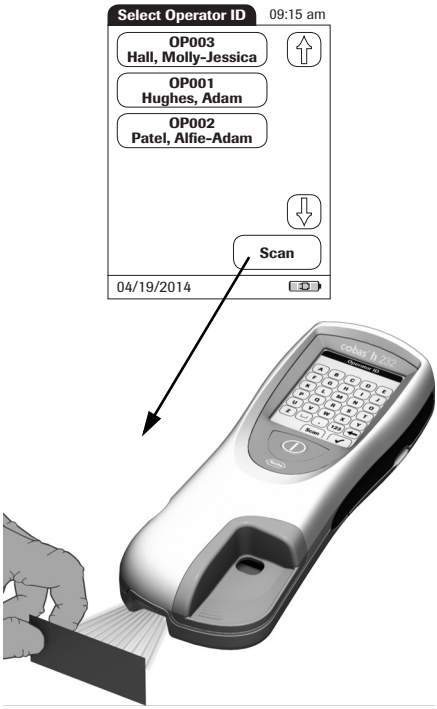


2 Enter or scan your *Operator ID*.

3 Touch ✓ to confirm your entry.

4 Wait until the main menu is displayed.

With operator login (list available)

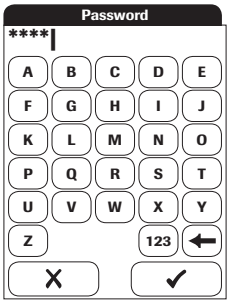


2 If an operator list exists, wait until this list is displayed.

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

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

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

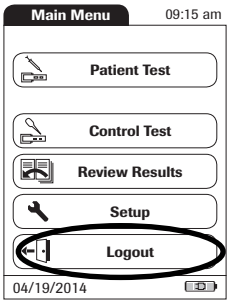


4 Enter the password.

5 Touch ✓ to confirm your entry, or:

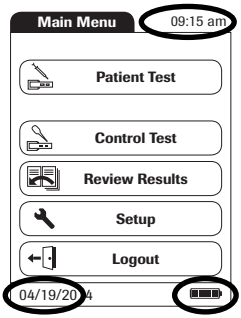
Touch ✗ to display the operator list again.

6 Wait until the main menu is displayed.



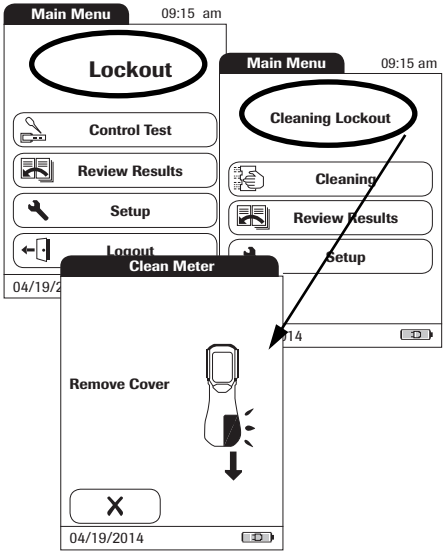
When the tests are completed or another operator wants to perform additional tests, touch **Logout** to log out. The meter returns to the display of the operator list.

6.2 Performing a test



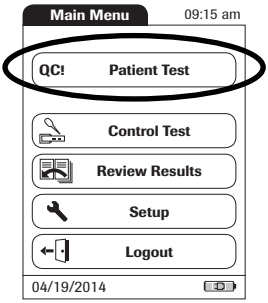
1 Check the charge level of the handheld battery pack. If there are no bars left in the battery icon, you cannot perform any more tests.

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 “Control Testing and Quality Control” starting on page 113). If the meter is locked, a test can only be performed as a STAT test (if this function is enabled and if there are still STAT tests available).

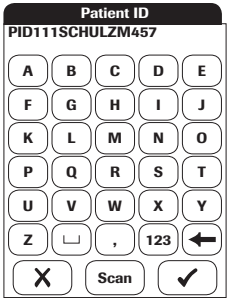
If a *Cleaning Lockout* is displayed instead of **Patient Test**, you must touch **Cleaning** and follow the instructions on the screen and clean the meter. See “Cleaning and Disinfecting the Meter” beginning on page 139. Once you have re-attached the test strip guide cover and powered the meter on again, the meter is no longer locked.



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.

Without patient list

3 Touch **Patient Test**.



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

5 Touch ✓ to confirm the ID, or:

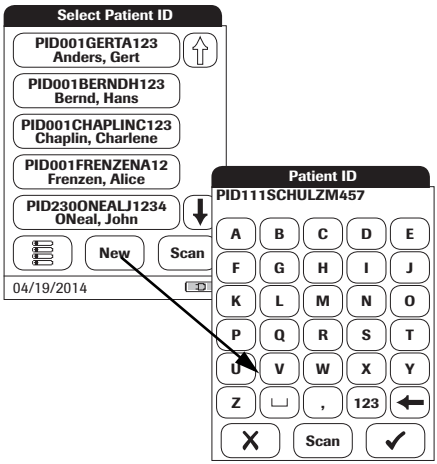
Touch ✗ to cancel the ID entry.

Continue reading on page 104.

With patient list

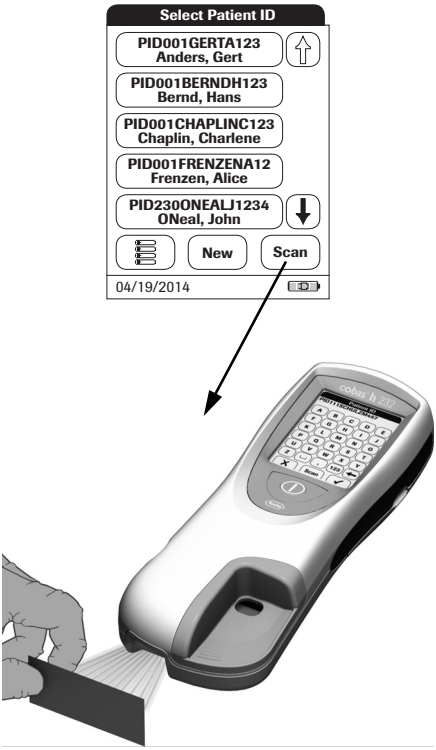
3 Touch **Patient Test**.

Patient lists can only be created on a DMS 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* manually or scan it using the barcode scanner.

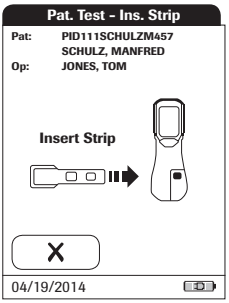


The *Patient ID* can also be entered via barcode (meters with a barcode scanner only). Touch **Scan** and hold either

- 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. 10 seconds).

Inserting a test strip

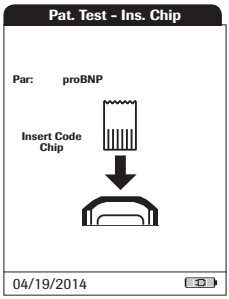


1. The test strip icon prompts you to insert a test strip. Remove the test strip from its foil pouch.
2. Hold the test strip so that the application and test area is facing up.
3. Hold the test strip straight and flat. Insert it in the test strip guide of the meter. It is important that you insert the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

Inserting the test strip too slowly or too fast can cause a barcode reading error.

Slide the test strip in as far as it will go. A beep tone indicates that the meter has detected the test strip (provided the beeper is enabled).

Exposure to external influences (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.

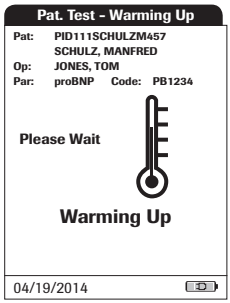


If you use a new test strip lot, you must insert the corresponding code chip once.
See “Code chip” on page 93.

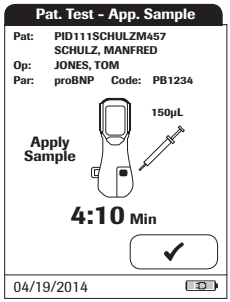
Depending on the meter setting, you may also be required to run a quality control test at this point.

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

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



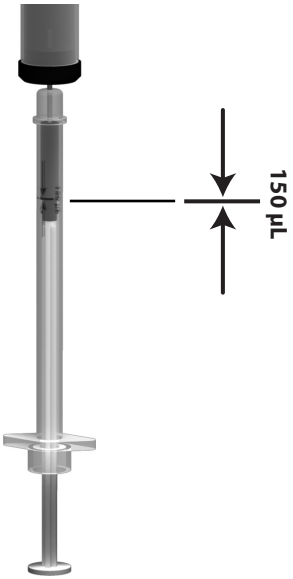
The thermometer icon shows that the test strip is warming up. A beep tone indicates when the warming-up process is complete (provided the beeper is enabled).



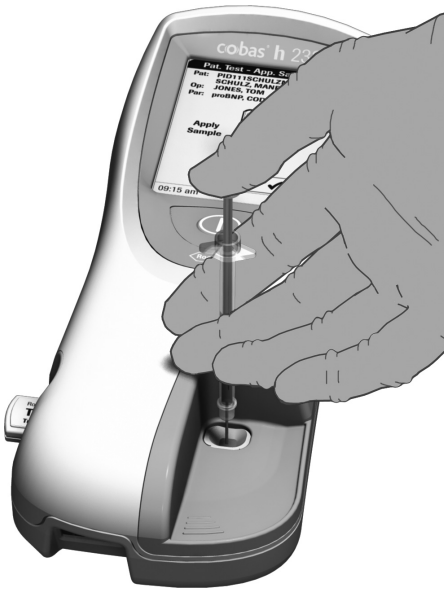
The pipette icon indicates that the meter is ready to perform the test and is waiting for blood to be applied.

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 145.



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



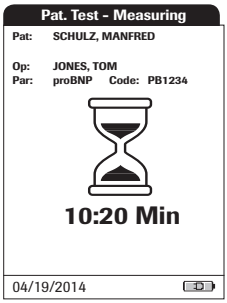
5 Apply the entire sample to the sample application area of the test strip.

Always place the meter on a level, vibration-free surface when applying the sample to the sample application area of the test strip. Once the sample has been completely absorbed by the test strip, you can move the meter.

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.

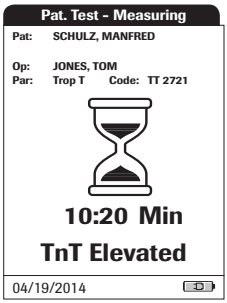
After you confirm that the sample has been applied, or if the meter automatically recognises that the sample has been applied, the ✔ button disappears.



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

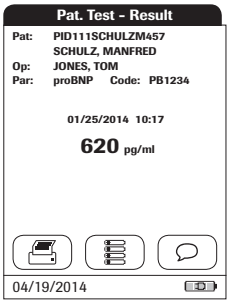
Measurement time:
The time needed to run a test depends on the test parameter (refer to package insert for details). Typically, **8 to 12 minutes** are required.

Do not add more blood. Do not touch the test strip until the result is displayed.



For Troponin T only:
As soon as the meter detects a signal (this may take a few minutes), a qualitative result *(TnT Elevated)* appears under the hourglass icon (see illustration).

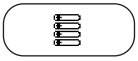
The quantitative result is displayed when the test is completed. Refer to the Roche CARDIAC T Quantitative package insert for more details.



The test result is shown and stored automatically.

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

Print button:
Print results (infrared interface)



Menu button:
Return to main menu

Comment button:
Add predefined or custom comments to the test result

7 Remove the test strip from the meter.

8 Power the meter off by pressing the ⏻ button for approximately 1 second.

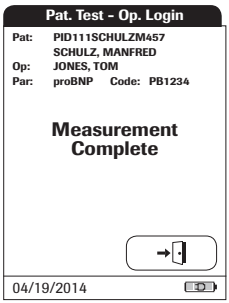
9 Discard the used disposable item and test strip in compliance with the disposal policy of your hospital or medical practice.

10 Clean the meter if necessary. See “Cleaning and Disinfecting the Meter” on page 139).

Displaying, confirming or adding comments to results

As described in the chapter “Optional Screens setup” starting on page 88, there are many options for displaying results that can be activated:

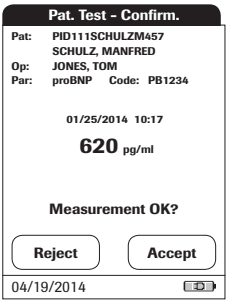
If a new *Operator Login* is required to display the result:



1 Touch the button for *Operator Login*.

2 Log in as described on page 98.

The result is now displayed.

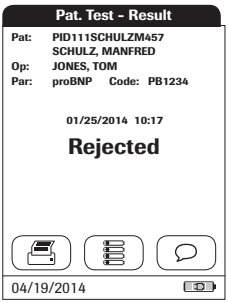


If the test result requires a confirmation:

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

You can choose to either

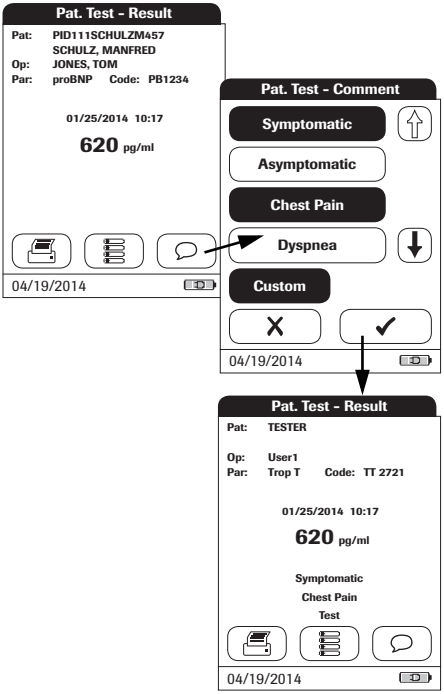
- **Reject**
- **Accept**



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

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

If you want to add a comment, do not remove the test strip. Once the strip is removed, the meter automatically returns to *Main Menu* and a comment can no longer be added.



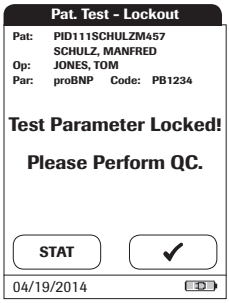
If you want to add a comment to a test result:

1. In the result screen, touch 💬.
2. Select a predefined comment from the list and/or
3. Touch **Custom** to enter your own comment using the onscreen keypad.

The comments are stored with the test result.

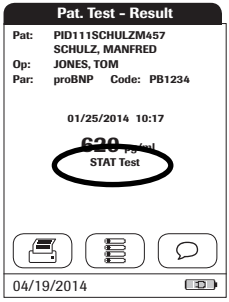
STAT tests

STAT tests are a limited number of tests that can be performed in emergency situations, see page 86. If the meter is configured to perform STAT tests, you have the option of performing a test by choosing STAT even though a QC Lockout is in place.



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 performed, the specified number of STAT tests is available again in case of a new lockout.

7 Control Testing and Quality Control

The **cobas h** 232 POC system employs several methods to check that the meter and test strips are working properly and that the operator is performing the test correctly.

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

- A self-check of the electronic components and functions every time the meter is powered on.
- A check of test temperature when warming up and during the test.
- A check of the expiration date and lot information on the test strip using the information from the code chip.

In addition, the **cobas h** 232 POC system provides:

- Configurable, prescribed quality control tests using Roche CARDIAC IQC test strips for internal functionality tests.
- Definable, prescribed control tests using Roche CARDIAC Control materials for the available test parameters.

7.1 Preparing to run a quality control test

Prepare for a quality control test in the same way you would prepare to perform a test with a patient sample. The only difference is the use of control solution instead of blood.

To perform a quality control test using control solutions, you need:

- **cobas h** 232 meter
- Test strips for the desired tests, with the supplied code chip
- Roche CARDIAC pipettes (or other suitable pipettes with pipetting volume of 150 µL)
- Control set containing two vials of Roche CARDIAC Control material and code chip

Always refer to the package insert provided with the control material for specific handling and testing instructions.

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 73).

If you encounter a lockout for a test strip lot that no longer exists, see “Reset test parameters” on page 84. Please note that, when you use this method, **all** saved test parameters and QC lockouts will be deleted.

7.2 Performing a quality control test

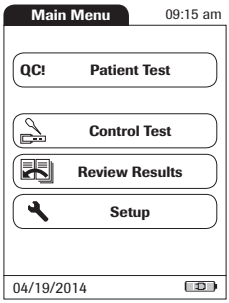
Quality control (QC)

1 Power the meter on by pressing the ⏻ button for approximately 1 second.

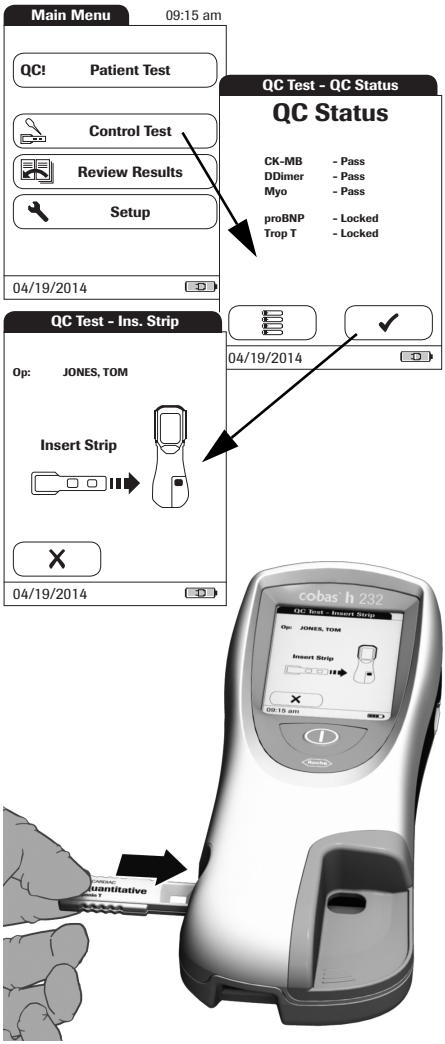
You can also power on the meter directly by connecting the handheld power supply.

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

Depending on the system settings the operator my have to log in and/or enter a password. Follow the procedures as described on page 98.



2 Wait until the main menu is displayed.



3 Touch **Control Test**.

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

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

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

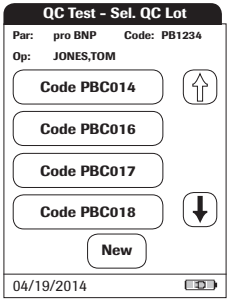
7 Hold the test strip straight and flat. Insert it in the test strip guide of the meter. It is important that you insert the test strip using one smooth movement.

Inserting the test strip too slowly or too fast can cause a barcode reading error.

Slide the test strip in as far as it will go. A beep tone indicates that the meter has detected the test strip (provided the beeper is enabled).

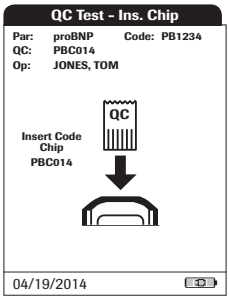
Exposure to external influences (e.g., humidity) may deteriorate the test strips and may lead to error messages! Remove the test strip from its foil pouch only when you are ready to perform a test.

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.

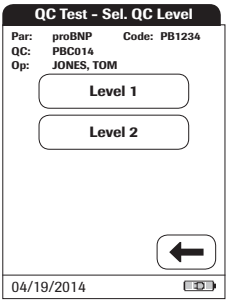


As with the test strips, a code chip is also provided with the control materials. The information on the code chip is stored in the memory so you can use the same control materials again at any time.

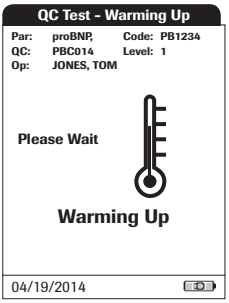
8 Select the code stored for your current control material, or touch **New** to use a new control material.



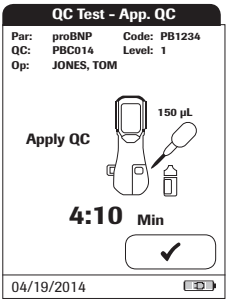
If you are using a new control material, remove the code chip from the meter and insert the code chip that came with the control material instead.



9 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 beeper is enabled).



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 145.

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

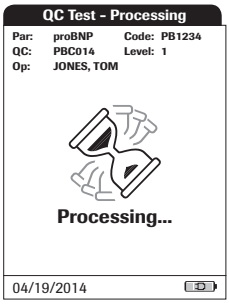
11 Apply the sample (exactly 150 µL) to the application area of the test strip.

Always place the meter on a level, vibration-free surface when applying the sample to the sample application area of the test strip. Once the sample has been completely absorbed by the test strip, you can move the meter.

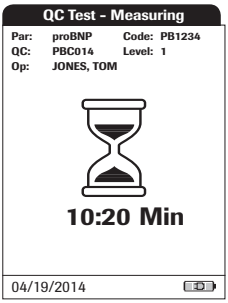
12 Touch ✔ to confirm that the sample has been applied.

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.

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

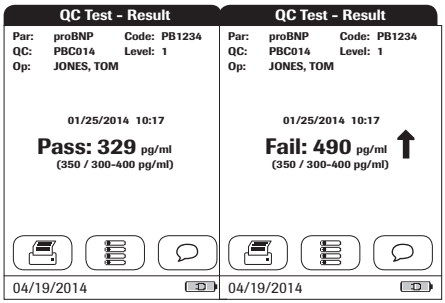


The hourglass icon spins until the sample has been detected and the test begins.
Unlike regular tests, this procedure can be very short and therefore might not be displayed (especially in case of a lack of or delay in confirmation, see step **12**).



The time remaining for the test is displayed.

Measurement time:
The time needed to run a test depends on the test parameter (refer to package insert for details). Typically, **8 to 12 minutes** are required.



The result of this quality control test is displayed 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.

There are three options for displaying a QC test result:

- Pass/Fail
- Value
- Value & Pass/Fail

For details refer to “QC result format” on page 81 and “Settings summary” on page 33.

Print button:
Print results (infrared interface)

Menu button:
Return to main menu

Comment button:
Add predefined or custom comments to the test result

14 Remove the test strip from the meter.

15 Power the meter off by pressing the ⏻ button for approximately 1 second.

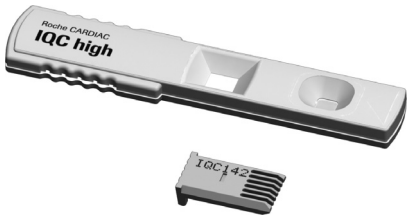
16 Discard the used disposable item and test strip in compliance with the disposal policy of your hospital or medical practice.

17 Clean the meter if necessary (see “Cleaning and Disinfecting the Meter” on page 139).

Instrument quality control (IQC)

The Roche CARDIAC IQC test serves as a performance check for the optical system of the **cobas h** 232 POC system. The instrument determines the reflectance value of the signal and displays “Pass”, “Fail” or the percentage of remission depending on your settings.

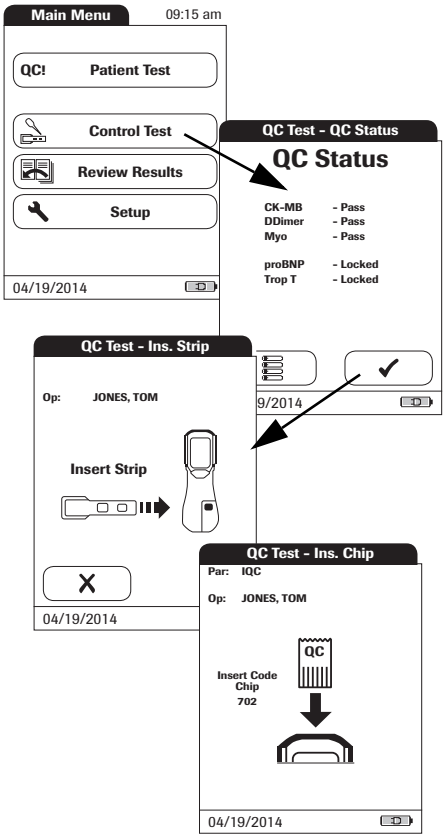
“Pass” means that the optical system of the **cobas h** 232 POC system is functioning properly. If “Fail” appears, the measured reflectance value is outside the confidence interval.



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 115. The following description therefore starts at the main menu.



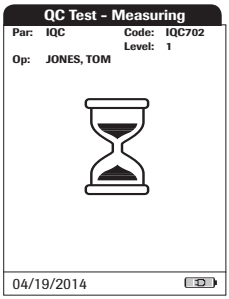
3 Touch **Control Test**.

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.

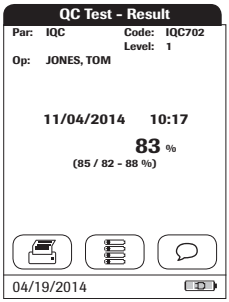
5 Remove the test strip from its IQC test strip container.

6 Insert the test strip as described before, see page 116.

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 displayed as *Pass* or *Fail* (default setting) or in the format selected in the QC result format setting.

There are three options for displaying an IQC test result:

- Pass/Fail
- Value
- Value & Pass/Fail

For details refer to “QC result format” on page 81 and “Settings summary” on page 33.

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8 Review Results

The cobas h 232 meter can save 500 patient test results as well as 500 quality control tests to memory, together with time, date, lot number and, if applicable, IDs and comments.

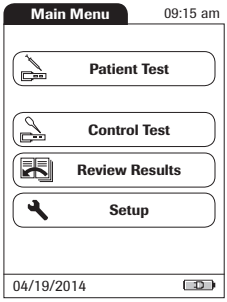
Reviewing test results

1 Power the meter on by pressing the ⏻ button for approximately 1 second.

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

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

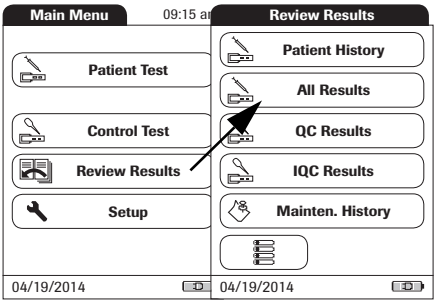
Depending on the system settings the operator my have to log in and/or enter a password. Follow the procedures as described on page 98.



2 Wait until the main menu is displayed.

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

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



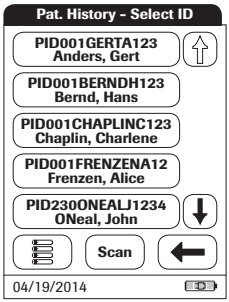
3 Touch **Review Results**.

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

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

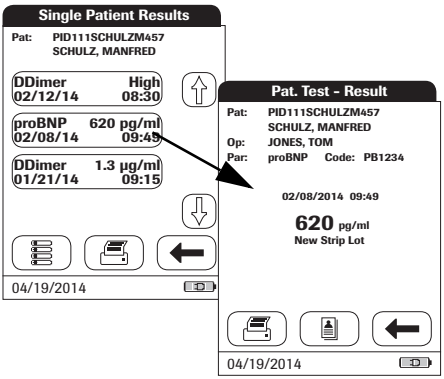
Patient history

This memory area contains a list of all patients, sorted by *Patient ID*. 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.

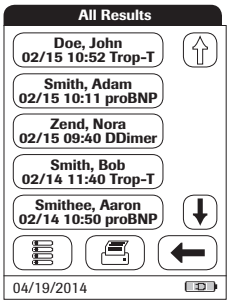


3 Touch ⇧ and ⇩ to display the test result of choice on the screen.

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

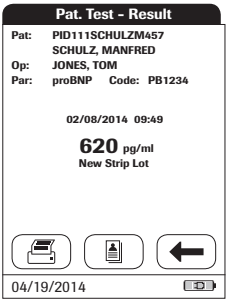
All results

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.

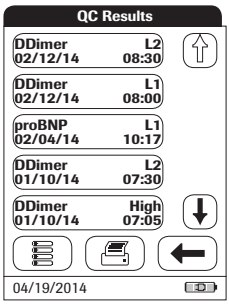


The selected test result dialog box will appear.

When you touch 📋, a list of results for the selected patient is displayed (see page 127).

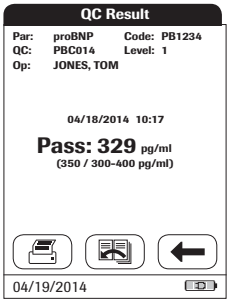
Quality control (QC) results

This memory area contains all test parameter-specific quality control tests (QC, starting on page 115) 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.

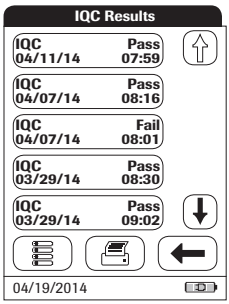
2 Touch the entry you want to open.



The entry is displayed.

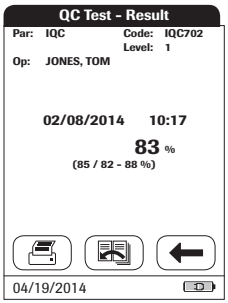
Instrument quality control (IQC) results

This memory area contains all instrument quality control tests (IQC, starting on page 121) 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.

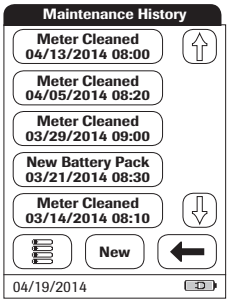
2 Touch the entry you want to open.



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 the default preset comments in the meter or enter a custom comment.



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

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.

9 Extended Functionalities

Data handling

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

When used in conjunction with the Handheld Base Unit from Roche (available separately), the **cobas h** 232 meter can conveniently connect to a data management system (DMS). The main advantages of such a connection between meter and DMS may include:

- Transferring patient lists, operator lists, and settings from the DMS to the meter. In this way the setup for daily work as well as general meter setup can be performed (for one or more meters) quickly and conveniently.
- Transferring all stored test results with the corresponding *Patient ID*, *Operator ID,* and comments from the meter to the DMS. This transfer of data permits further evaluation or proper archiving according to your needs.

Through the DMS the system administrator (such as the POC coordinator) may specify what settings are to be applied to a set of meters within a site or unit (e.g., hospitals or wards). All meters assigned to a specific site and/or unit would consequently share the same settings. The different operator and patient lists (that match a site or unit) are then made available on their respective meters. Other settings such as *QC Lockout* and *Operator Lockout* may easily be set (once) and distributed to all meters.

The option of setting up an *Operator Lockout* is available **only** when operator lists are created on the DMS, stored in the meter, and *Operator* login is activated. For more details on *Operator* login see page 68, for details on *Operator Lockout* see page 74.

Computer (Setup option)

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

- In the *Setup* menu, the *Connection* option must be set to *Computer* (see page 51).
- The Handheld Base Unit must be configured correctly. (For details please refer to the manual of the Handheld Base Unit and the Technical Note stored on the Handheld Base Unit itself.)
- Place the meter on a Handheld Base Unit that is connected to the network. The meter will automatically be recognized by the DMS and may now be assigned to a site and/or unit managed by the DMS (if your DMS has that functionality).
- Depending on DMS functionality available, the DMS may transfer settings and lists to the meter as well as enable test results to be transferred from the meter to the DMS.

Operator lists

After powering the meter on, an *Operator* login may be configured. If no list is available, the options described on page 68 apply.

- *Operator* is set to *Optional* or *Required*:
  The *Operator* can either log in via the onscreen keypad or a barcode scan. The use of the meter is not restricted to a predefined *Operator* group, so *Operator* IDs are entered via the onscreen keypad or read from the barcode and stored with test results for informational purposes only.
- *Operator* is is set to *Scan Only*:
  The display of the meter's onscreen keypad is blocked. The *Operator* can only log in via a barcode scan as there is no onscreen keypad. The use of the meter is not restricted to a predefined *Operator* group, so *Operator* IDs are read from the barcode and stored with test results for informational purposes only.

Meters which are managed by a DMS may receive an *Operator* list.

- *Operator ID* is set to *List*, a list is available and displayed on the login screen:
  The *Operator* selects the ID from the displayed list. If so configured by the *Administrator*, the *Operator* may also be required to enter a password to log in.
- *Operator ID* is set to *Hidden List:*
  The *Operator* can login via a barcode scan or the onscreen keypad. If so configured by the *Administrator*, the *Operator* may also be required to enter a password to log in.

When working with operator lists: The use of the meter is restricted to the operators on this list.

Patient lists

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

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

- The *Patient ID* is set to *Optional* or *Required*, and there is no list available:
  A *Patient ID* can be entered manually via the onscreen keypad or read in via a barcode scan. The Patient ID is stored with the test result.
- The *Patient ID* is set to *No*, but there is a list available:
  The list of Patient IDs is always shown when starting a test. You may now
  - select a patient from the list;
  - scan a *Patient ID* using the barcode scanner;
  - create a new patient entry by touching **New**. Instead of an ID a consecutive number will be assigned to this result.
- The *Patient ID* is set to *Optional* or *Required*, and there is a list available:
  The list of Patient IDs is always shown when starting a measurement. You may now
  - select a patient from the list;
  - scan a *Patient ID* using the barcode scanner;
  - create a new patient entry by touching **New**. You may either read the ID using the barcode scanner or enter a new ID via the onscreen keypad.
- The *Patient ID* is set to *Hidden List* (only possible with a data management system), and there is a list available:
  An empty list is shown when starting a measurement. You may now
  - scan a *Patient ID* using the barcode scanner;
  - create a new patient entry by touching **New**. You may either read the ID using the barcode scanner or enter a new ID via the onscreen keypad.

When working with *Patient* lists, you have the following options:

- A *Patient ID* does not have to be on the list to be scanned and used.
- The meter displays a warning that the *Patient ID* scanned is not on the list.
- The meter displays an error message that the ID was not found on the list of valid *Patient IDs*. You must enter a valid ID to proceed.

Barcode scanner

Using a DMS, the barcode scanner may be configured to accept only selected barcode symbologies. Furthermore, it is possible to define a barcode mask for *Patient ID* and *Operator ID*. With masks being defined, the meter checks a barcode after scanning and rejects it, if it does not match the mask. See “Example of barcode symbologies” on page 151 for further information.

Stored test results and comments

When performing a test, the test result will be stored along with additional information, including the *Patient ID*, *Operator ID*, the kind of test performed, and optional *Comments*. The meter comes with a default set of *Comments* that can be assigned to each test result. If you are working with a DMS, these comments can be replaced by the comments in the DMS. The new wording will then be available for selection from the *Comments* list in the meter.

Up to 3 comments can be assigned to each result.

The *Comment* function may be configured to be either optional, required for test results which are out of range, or always required. If the user is required to enter/select a comment, completely empty comments will not be accepted by the meter.

The default preset comments in the meter are:

Patient and QC Result comments

- Symptomatic
- Asymptomatic
- Chest Pain
- Dyspnea
- Intermediate Zone
- Doctor Notified
- RN Notified
- Under Medication
- Will Repeat Test
- No Action
- New Strip Lot
- New Strip/Kit Lot
- New Lot Number
- Lab Draw
- Cleaned Meter
- Switched QC Vial
- Repeat Control Test
- Acceptable Control
- New Control Lot
- Procedure Error

Maintenance comments

- Meter Cleaned
- Samp. App. Area Cl. (Sample Application Area Cleaned)
- Test Strip Guide Cl. (Test Strip Guide Cleaned)
- New Battery Pack

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10 Cleaning and Disinfecting the Meter

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

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

- Make sure the meter is powered off. Unplug the power supply unit and remove the hand-held battery pack.
- Use only ordinary lint-free cotton swabs/buds and lint-free tissues.
- Ensure that cloth or swab/bud is only damp, not wet, to protect against moisture entering the meter.
- Do not spray anything onto the meter and do not immerse it in liquid.

Recommended cleaning/disinfecting solutions

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

- Ammonium chloride solution (2 %)
- Diluted bleach solution (1:10)
- Mild soapy water
- Citric acid (2.5 %)
- Hydrogen peroxide (0.5 %)
- Sodium hypochlorite solution (0.6 %)
- 70 % isopropyl alcohol

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

Refer to the **safety information** provided on the packaging of the products when using the chemical cleaning agents mentioned above. Some of the agents must not be used together as this may result in undesirable reactions. Follow the manufacturer's instructions.

Cleaning/disinfecting the exterior (meter housing)

Clean the meter whenever it becomes dirty. You can also use the device-specific “Cleaning Lockout” function (see page 85) to ensure regular checks are performed.

Use only the solutions recommended above.

Basic sequence of steps for cleaning

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

Cleaning after contamination due to mispipetting

Observe the following precautions to prevent instrument damage

- Do not move the meter to prevent liquids from creeping and penetrating the meter.
- Dab away all visible blood (also on the test strip, but not in the application area).
- Do not use the meter before the liquid/moisture has been completely removed. While it is drying, the meter must not be moved as this may soil the optical components.

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.

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

Cleaning the test strip guide cover

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

2 Remove the test strip guide cover by pulling it forward horizontally (in the direction of the arrow).

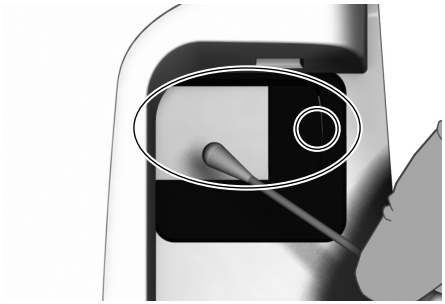
Move the cover safely away from the meter and wipe it clean using the solutions recommended above.

In case of significant soiling or contamination, you can rinse the test strip guide cover with warm water, dry it with a fresh tissue, and then disinfect it using the solutions recommended on page 140.

Always ensure that the test strip guide cover is completely dry before re-attaching it to the meter.

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

Cleaning the visible area of the test strip guide



1 Clean the easily accessible and visible **pipetting field area** of the test strip guide with a moistened cotton swab/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 test strip guide as this will 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 swab/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 test strip guide cover to the housing. Make sure that the cover is properly attached. You will feel it snap into place.

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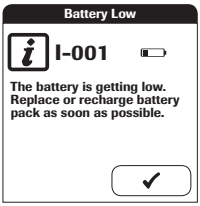
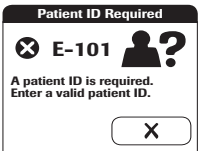
11 Troubleshooting

The **cobas h** 232 meter continually checks its systems for unexpected and unwanted conditions. These may arise for technical reasons (defective components or consumables, environmental factors) or due to handling and procedure errors.

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

Take the action suggested on screen to resolve the problem. If the error disappears, you may continue using the meter as desired. If the problem persists, contact Roche (see page 152).

The two different message types are illustrated below:

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

Errors and unusual behavior without error messages

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

Message	Description
No message or unusual behavior	
Meter display does not power on	■ Wait 10 seconds and try powering on the unit again. ■ Check that the meter has power. ▪ If you are using the external power supply unit, is it connected properly to the meter? Or: ▪ Place the meter in the Handheld Base Unit. Or: ▪ If you are using the Handheld Battery Pack, is it properly installed in the meter?
Meter displays an unexpected result	Refer to the package insert for the test strips.
Automatic shutdown	
	The meter powers off after a configurable time without activity (e.g., pressing a key, touching the screen) to conserve energy. Reactivate the meter/screen as described in the following:
Shutdown after time specified by system administrator (default is 5 minutes, configurable by system administrator)	■ Press the On/Off button of the meter.

12 General Product Specifications

12.1 Operating conditions and technical data

Technical data

Temperature range	18-32 °C
Relative humidity	10-85% (no condensation)
Maximum altitude	4000 m
Position	Always place the meter on a level, vibration-free surface when applying the sample to the sample application area of the test strip. Once the sample has been completely absorbed by the test strip, you can move the meter.
Measuring range	Depends on test parameters
Memory	500 Patient Test Results 500 QC Test Results 200 IQC Test Results 100 Strip Code Chips 100 QC Code Chips 500 Patient List entries 200 Operator List entries
Interface	Infrared interface, LED/IRED Class 1
Battery operation	Handheld battery pack
Mains connection	Power supply adapter: Input: 100-240 V AC (± 10%) / 50-60Hz / 350-150 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

Sample material

Sample type	Heparinized 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)

12.2 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 Control Troponin T (Germany only)	Control set for use with Roche CARDIAC T Quantitative (control set for 2 x 6 quality control checks, level 2, and code chip)	05453879190
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 (measuring range 60 - 9,000 pg/mL for meter software version ≥ 01.04.01)	05533643190

Item	Description	REF
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
Test strip guide cover		04990315001
Battery compartment cover		04990307001
Handheld power supply		04805666001
Handheld Base Unit		04805658001
cobas h 232 meter	Standard version without scanner	04901126190
cobas h 232 meter 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 Operator's Manual	Printed manual (German)	05056683001
cobas h 232 Manual CD	Contains Operator's Manuals and Quick Reference Guides in all available languages (PDF)	04880820001
Printer **cobas h** 232 (CMP-10) ROW	for most North American, Latin American and Asian countries	05404495001
Printer **cobas h** 232 (CMP-10) EMEA	for most European, Middle East and African countries	05404517001
Printer **cobas h** 232 (CMP-10) JAP	for Japan	05404509001
Normal thermal paper roll	5 rolls per package, 50 mm diameter	03666751001
Thermal paper roll (self-adhesive)	10 rolls per package, 50 mm diameter	05412951001

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.

Information about software licenses

This product incorporates software modules developed under open source licenses. The source code of this software can be requested on a standard data exchange medium from the manufacturer at the following address:

Roche Diagnostics GmbH
Sandhofer Str. 116
68305 Mannheim, Germany

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

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

Repairs

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

Contact Roche

For all questions about the **cobas h** 232 POC system that are not answered in this manual, contact your Roche representative. If you do not already have contact details, a list of Roche Diagnostics offices is provided in the appendix or visit our website at www.Roche.com. Select “Roche in your country” at the top of the page and then select your country to find the appropriate local office contact information.

13 Warranty

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

14 Appendix

14.1 Example of barcode symbologies

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

 1234567890	Codabar
 1234567890	Code 39
 1234567890	Code 93
 1234567890	Code 128
 1234567890	Interleaved 2 of 5

14.2 Contact Roche

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

Argentina	Productos Roche SAQeI Rawson 3150 B1610BAL Ricardo Rojas, Tigre Buenos Aires — Argentina Tel.: +54 (11) 5129 8000
Australia	Roche Diagnostics Australia Pty Ltd. ABN 29 003 001 205 31 Victoria Avenue Castle Hill, NSW, 2154 Telephone 02-9860 2222 or 1800 645 619
Austria	Roche Diagnostics GmbH Engelhorngasse 3 A-1211 Wien Tel. +43-1-27787-555 www.roche.at
Belgium	Roche Diagnostics Belgium Schaarbeeklei 198 BE-1800 Vilvoorde Tel : +32 2 247 47 47 Fax : +32 2 247 46 80 www.roche-diagnostics.be
Brazil	Roche Diagnóstica Brasil Ltda. Av. Engenheiro Billings, 1729 — prédio 38 05321-900 São Paulo, SP, Brasil Tel. +55 11 3719 8888 Fax +55 11 3719 8555
Canada	Roche Diagnostics 201 Armand-Frappier Boulevard Laval, Quebec (Canada) H7V 4A2 Technical Support for Healthcare Institutions: Region of Montreal 450-686-7111 Roche Care Center (toll free) 1-877-273-3433 www.rochediagnostics.ca
Central America & The Caribbean	Roche Diagnostics Central America & The Caribbean Edificio Capital Plaza, Piso 18 Calle Paseo del Mar, Costa del Este Panama, Rep. de Panama Tel. + 507 378 1295

Chile	Roche Chile Ltda. Avda. Quilín 3750 Macul, Santiago Tel.: +56 (2) 4413200
China	罗氏诊断产品 （上海）有限公司 Roche Diagnostics (Shanghai) Limited 上海市淮海中路 1045 号淮海国际广场 12 楼 12/F, Huaihai Plaza, No. 1045, Central Huaihai Road Shanghai, 200031, P.R. China Tel. +86 21 2412 1000 Fax +86 21 2412 1188
Colombia	Productos Roche S.A. Carrerra. 44 No. 20-21 Apartado Aéreo 80372 Bogota, D.C.
Croatia	Dobavljač MEDICAL INTERTRADE d.o.o. Dr. F. Tuđmana 3 10431 Sveta Nedelja, Hrvatska Tel.: 00385 1 3374 010 Dodatne informacije: Roche Diagnostics Deutschland GmbH Predstavništvo u Republici Hrvatskoj Banjavčićeva 22/II 10000 Zagreb, Hrvatska Tel.: 00385 1 4628 360
Czech Republic	Roche s.r.o., Diagnostics Division Karlovo náměstí 17 120 00 Praha 2 Česká republika www.roche-diagnostics.cz Tel.: +420 220 382 500
Denmark	Roche Diagnostics A/S Industriholmen 59 2650 Hvidovre Danmark Tel.: 36 39 98 98 Fax: 36 39 99 79 www.roche.dk
Ecuador	Roche Ecuador S.A. Av. 10 de Agosto N36-239 y Naciones Unidas Quito Tel.:+593 (2) 2434347

Estonia	Surgitech AS Pirita tee 20T 10127 Tallinn Tel: +372 6460660
Finland	Roche Diagnostics Oy Klovinpellontie 3, PL 160, 02181 Espoo Puhelinvaihde: 010 554511 Suomi
France	Roche Diagnostics 2, Avenue du Vercors, B.P. 59 38242 Meylan Cedex Tel : +33 4 76 76 30 00 www.rochediagnostics.fr
Germany	Roche Diagnostics Deutschland GmbH Kundenservice Center Sandhofer Straße 116 68305 Mannheim Tel.-Nr. +49 (0) 621 759 4747
Greece	Roche Diagnostics (Hellas) A.E. Ακακιών 54Α 151 25 Μαρούσι Αττικής, Ελλάδα Τηλ.: +30-210-8174000 Γραμμή Υποστήριξης: +30 801 11 61008 & +30 210 8174199
Hungary	Roche Magyarország Kft. 2040 Budaörs, Edison u. 1 Magyarország Tel:+36-23-446-886 Fax:+36-23-446-890 Meghibásodás esetén hívható ingyenes zöld szám (2014. szeptembertől): 06 80 200 089
Italy	Roche Diagnostics SpA Viale G. B. Stucchi 110 20052 Monza (MI) Italia Numero Verde: 800-610619 www.roche-diagnostics.it
Latvia	SIA „Medilink“ Viskaļu iela 11, Rīga, LV 1026 Tālr. 67840379, 67840380

Lithuania	UAB „Roche Lietuva“ Diagnostikos padalinys J.Jasinskio g. 16B LT-01112 Vilnius, Lietuva Tel. +370 5 254 6777 Faks. +370 5 254 6778
Mexico	Productos Roche, S.A. de C.V. Cerrada de Bezares 9 Col. Lomas de Bezares Del. Miguel Hidalgo México D.F., 11910 Tel.: +52 55 50 81 58 00
Netherlands	Roche Diagnostics Nederland BV Transistorstraat 41 1322 CK Almere, Nederland Tel.: 0800 2 882 882 www.roche-diagnostics.nl
New Zealand	Roche Diagnostics N.Z. Ltd, 15 Rakino Way, Box 62-089 Mt. Wellington, Auckland Telephone +64 9 276 4157 Toll Free 0800 652 634
Norway	Roche Diagnostics Norge AS Brynsengfaret 6B Pb 6610 Etterstad 0607 Oslo, Norge Tel. +47-23373300 www.roche.no
Poland	Roche Diagnostics Polska Sp. z o.o. ul. Wybrzeże Gdyńskie 6 B 01-531 Warszawa, Polska Tel. +48-22-481 55 55 www.roche.pl
Portugal	Roche Sistemas de Diagnósticos, Lda Estrada Nacional, 249-1 2720-413 Amadora, Portugal Telefone: +351-21-417 1717 www.roche.pt

Russia	ООО «Рош Диагностика Рус» Официальный дистрибьютор «Ф. Хоффманн Ля Рош Лтд.» (Швейцария) Россия, 115114, г. Москва, ул. Летниковская, д. 2, стр. 2, Бизнес Центр «Вивальди Плаза» Тел.: +7 (495) 229-69-99, +7 (495) 229-29-99 Факс: +7 (495) 229-62-64 http://www.rochediagnostics.ru
Slovakia	Roche Slovensko, s.r.o. Diagnostics Division Lazaretská 12 811 08 Bratislava, Slovenská republika www.roche-diagnostics.com Tel.: +421-2-5710 3680 Fax: +421-2-5263 5213
Slovenia	Roche farmacevtska družba d.o.o. Divizija za diagnostiko. Vodovodna cesta 109 1000 Ljubljana, Slovenija Telefon Centra za pomoč uporabnikom in servis: 080 12 32
South Africa	Roche Products (Pty) Ltd. South Africa Diagnostics Division 9, Will Scarlet Road / Ferndale P.O. Box 1927, Randburg 2125 Telephone +27 -11 504-4600
Spain	Roche Diagnostics S.L. Avda. de la Generalitat, 171, 173 08174 Sant Cugat del Vallès (Barcelona) Teléfono: 902 43 33 33 Internet: www.roche.es
Sweden	Roche Diagnostics Scandinavia AB Box 147 16126 Bromma, Sverige Phone Nr.: +46 (0)8 404 88 00 www.roche.se
Switzerland	Roche Diagnostics (Schweiz) AG Industriestraße 7 CH-6343 Rotkreuz Tel. +41-41-799 61 61 www.roche-diagnostics.ch

Turkey	Roche Diagnostik Sistemleri Ticaret A.Ş. Gazeteciler Sitesi – Matbuat Sokak No. 3 34394 Esentepe – Istanbul Türkiye Tel: +90-212-306.06.06
United Kingdom	Roche Diagnostics Ltd. Charles Avenue Burgess Hill, RH15 9RY UK Freephone: 0808 100 99 98 Rep. of Ireland Freephone: 1800 509 586
Uruguay	Roche International Ltd. (Diagnostics Division) Solferino 4096 11400 Montevideo Tel.: +598 (2) 6137888
USA	Roche Diagnostics 9115 Hague Road Indianapolis, IN 46256 Service information For technical assistance or information, contact the Accu-Chek® Customer Care Service Center at 1-800-440-3638, 24 hours a day, 365 days a year.

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15 Supplement for Observed Test Sequence

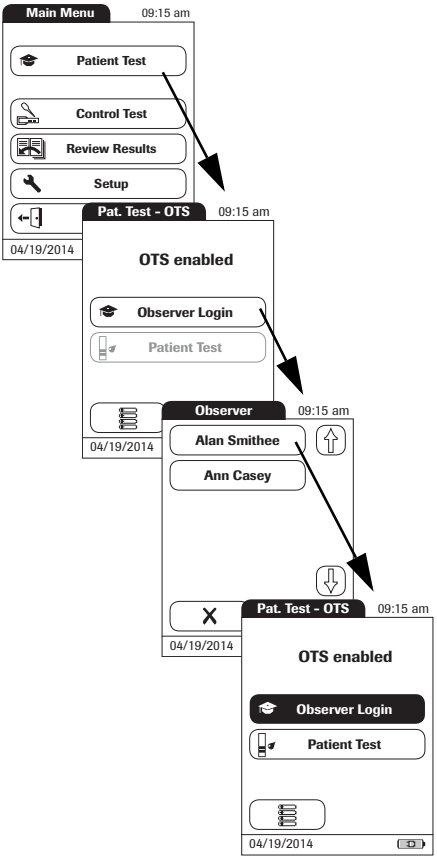
Observed Test Sequence (OTS)

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

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

Using the OTS function

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



Observer:

1 Touch **Patient Test**.

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

2 Touch **Observer Login**.

3 Wait until the observer list is displayed.

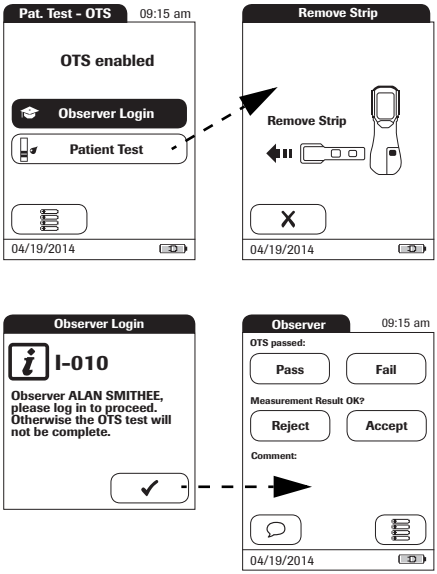
4 Select your observer ID by touching the corresponding button, or scan your operator ID (which is also your observer ID in this case)..

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

5 Enter the (optional) password.

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

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



Operator:

1 Touch **Patient Test**.

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

2 Hand the meter back to the observer.

Observer:

3 Touch ✓ to log in again.

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

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

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

7 Touch 💬 to add a comment.

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

The OTS information is saved together with the test result.

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CE

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