cobas h 232
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
Version 5.0	2016-06	Transition to new meter hardware: updated meter housing; 2D barcode scanner; wireless LAN option; new battery pack. Update to SW 04.00. Update of cleaning and disinfection section; added safety information on battery packs; deleted appendix for addresses; misc. editorial revisions.
Version 6.0	2016-06	Updated safety information, added information on TnT Elevated message, minor editorial revisions.
Version 6.1	2021-11	Implementation of supplements for SW features for SW 04.01 and SW 04.02 and implementation of IVDR-related requirements (IVDR: in vitro diagnostics regulation).
Version 7.0	2022-11	Biohazard symbol added to meter housing; Update to SW 04.03; Status communication indicator icon; TLS authentication; TLS setup; Data Deletion; Meter credential download; added information about Roche CARDIAC Pipettes.

cobas h 232

Operator's Manual

Version 7.0

Electronic user documentation can be downloaded using the eLabDoc e-service on Dialog:

www.dialog.roche.com/

For more information, contact your local affiliate or Roche Service representative.

ROCHE CARDIAC, COBAS, COBAS H and IQC are trademarks of Roche.

 The Wi-Fi CERTIFIED Logo is a certification mark of the Wi-Fi Alliance.

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
	Date of manufacture
LOT	Batch code/ Lot number
REF	Catalogue number
GTIN	Global Trade Item Number
UDI	Unique device identifier
SN	Serial Number
IVD	In vitro diagnostic medical device
	Device for near-patient testing
	Device not for self-testing
	Biohazardous
CE	Complies with the provisions of the applicable EU regulations.

The **cobas h** 232 meter meets the requirements laid down in:

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

Directive 2011/65/EU (including 2015/863) of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

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).

Eurasian Conformity. Demonstrates that the product meets the Eurasian Economic Union (EAEU)'s regulations and standards for customs clearance and trading.

cobas h 232 meter

Power adapter

Manual

Content

On meters with WLAN capability:

This device complies with Part 15 of the FCC Rules and with RSS-210 of Industry Canada

For other WLAN certifications, see label on bottom of battery compartment and addendum for information on WLAN registration.

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

What is new in publication version 7.0?

Amendments

■   Information about Roche CARDIAC Pipettes added, see page 36.

SW 04.03

■   TLS authentication, see page 72.

■   TLS and communication status icons, see page 35.

■   Battery fill state during charging, see page 34.

■   Improved functions for automatic data deletion, see page 79.

■   Certificate handling, see page 88.

■   Downloading meter credentials, see page 93.

This page intentionally left blank.

1 Introduction

Intended Use

The **cobas h** 232 is an in vitro diagnostic instrument intended for the quantitative evaluation of immunoassays using the Roche CARDIAC test strips in human whole blood. The **cobas h** 232 is intended for near-patient testing. Not for self-testing.

Summary

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) by means of wireless communication (if the meter is equipped with WLAN functionality) or through the Handheld Base Unit from Roche Diagnostics (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 a hospital information system (HIS) or to a laboratory information system (LIS). 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 3, "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 "Contact Roche" on page 219). 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

■   Power adapter

■   Universal Battery Pack

■   Battery compartment cover

■   Torx screw driver for mounting the battery compartment cover

■   Operator's Manual

■   Quick Reference Guide

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

■   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 A).

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.

Illustrations in this manual show two different kinds of hands:
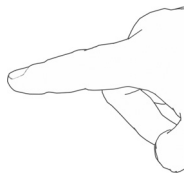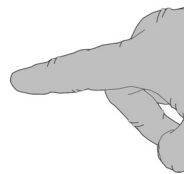
Hand without glove   Hand with glove

Safety information

⚠

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

⚠

Incident reporting
Inform your Roche representative and your local competent authority about any serious incidents which may occur when using this product.

⚠
WARNING

QC and IQC Lockouts
QC and IQC lockouts are disabled by default. For routine confirmation of system reliability it is strongly recommended to enable this feature. See QC recommendations on page 156.

⚠
WARNING

Protection against infection and blood-borne pathogens
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. Wear a new pair of clean gloves for testing each patient.

■ Wash hands thoroughly with soap and water before putting on a new pair of gloves and performing the next patient test.

■ 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.

⚠️ **CAUTION**

Allergy or injury caused by reagents and other working solutions

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.

⚠️ **WARNING**

Avoidance of electrical shock, fire, and explosions

■ Only use Roche Diagnostics original accessories (cables, power adapters, battery packs, and spare parts). Third-party cables, power adapters, and battery packs can cause the battery pack to explode or the meter to become damaged.

■ Do not use loose power sockets or damaged power adapters, cables, plugs, or battery packs.

■ Do not short circuit the power adapter, the handheld base unit contacts, or the battery pack.

■ Do not drop the **cobas h** 232 meter, the power adapter, or the battery pack and protect these against shaking and vibrations.

Disposal of the system

	Infection by a potentially biohazardous instrument
⚠ **WARNING**	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. Always remove the battery pack before thermal disinfection. For more information, contact your Roche representative.

Battery pack

The meter contains a rechargeable battery pack that can be charged if the power adapter is connected or the meter is placed on an active Handheld Base Unit (i.e., one connected to a power adapter). The charging process starts as soon as the meter goes into standby mode.

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

⚠️
WARNING

Possible hazards posed by the lithium-ion battery pack

Damaged or swollen lithium-ion (Li-ion) battery packs can overheat, catch fire, or leak. Immediately cease use of **cobas h** 232 meters with damaged or swollen Li-ion battery packs. Under no circumstances recharge meters with damaged or swollen Li-ion battery packs by placing them in the handheld base unit or connecting them to the power adapter.

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

■ Never throw the battery pack or the meters onto a fire. Do not dismantle, compress, or pierce the battery pack as this could cause an internal short circuit that leads to overheating.

■ Do not place either the battery pack or the **cobas h** 232 meter on or in heating appliances, such as a microwave, conventional oven, or radiator.

■ Avoid prolonged exposure to direct sunlight, e.g., when the meter is docked in the Handheld Base Unit. Keep this in mind when positioning the Handheld Base Unit.

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

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

Handle and dispose of battery packs with care.

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

Observe the following general safety instructions for handling the battery pack:

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

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

Save or download data from the meter prior to replacing the battery pack to prevent loss of data (see Chapter 7).

■ Always power the meter **off** before removing the battery pack.

■ When the *Battery Low* warning is displayed, the meter must be returned **as soon as possible** to the Handheld Base Unit or connected to the power adapter for recharging.

■ When the battery capacity is too low for further tests, the meter must be returned **immediately** to the Handheld Base Unit or connected to the power adapter for recharging.

General care

NOTICE
Clean the meter only with the solutions recommended (see page 187). 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.

Electrical safety

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

Electromagnetic interference

The meter fulfills the IEC 61326-2-6 requirements for emitted interference and interference immunity.

⚠	Do not use the meter near strong electromagnetic fields, which could interfere with the proper operation of the meter.
	Electrostatic discharges may cause malfunction 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.

■ If you use a customized data management system solution, ensure that sensitive data transmitted via the POCT1-A interface is protected by appropriate security measures.

■ Ensure that the instrument is protected against unauthorized physical access and theft.

■ Do not use shared user or operator accounts on meter, DMS and network.

■ Whether working in a wired or wireless environment, use a strong password for user or operator accounts on the meter, DMS, and network. Observe your own facility guidelines on password management where available, or apply the rules for strong passwords, see "Characteristics of strong passwords" below.

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 197.

Wireless connectivity

If the meter is equipped with WLAN functionality:
Wireless connectivity allows the meter to send data (test results, patient IDs, operator IDs, etc.) to the data management system without the need to return the meter to the Handheld Base Unit. This feature must be configured by the system administrator. Observe the guidelines of your facility for using wireless local area network connections. For a description of the **cobas h** 232 meter's ability to connect to Wireless Local Area Networks (WLAN, Wi-Fi), see appendix B.

Radiofrequency radiation exposure information

Glossary:

■ "FCC" stands for "Federal Communications Commission" (USA).
■ "RF" stands for "radio frequency"
■ "RSS" stands for "Radio Standards Specification" (Canada).
■ "WLAN" stands for "Wireless Local Area Network"

The Industrial, Scientific and Medical (ISM) radio frequencies may contain emissions from microwave ovens, heaters, and other noncommunication devices. While these types of devices usually pose no threat of interference as they are low-powered devices, the possibility exists that some industrial high power systems may wipe out any attempted communication use of a WLAN. Therefore, perform a site survey and interference analysis with a spectrum analyzer to view the entire spectrum, looking for signals that might not only be within the frequency range of the intended WLAN but also could be near or at the same frequency and cause interference.

Roche Diagnostics supports industry wireless standards and recommends using products that have Wi-Fi certification. This certification tests products to the 802.11 industry standards for basic connectivity, security, authentication, Quality of Service (QoS), interoperability and reliability. The Wi-Fi CERTIFIED logo is an assurance that the Wi-Fi Alliance has tested a product in numerous configurations and with a diverse sampling of other devices to ensure compatibility with other Wi-Fi CERTIFIED equipment that operates in the same frequency band. The Wi-Fi Alliance network of independent test labs conducts interoperability testing programs to ensure that wireless devices work together and support secure connections.

The **cobas h** 232 system complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance of 20 cm (8 inches) between the radiator and your body.

This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.

Changes or modifications made to this equipment not expressly approved by Roche Diagnostics may void the FCC authorization to operate this equipment.

This device complies with Part 15 of the FCC Rules and with RSS-210 of Industry Canada. Operation is subject to the following two conditions:

(1) this device may not cause harmful interference,

and

(2) this device must accept any interference received, including interference that may cause undesired operation.

The **cobas h** 232 system complies with the emission and immunity requirements described in EN 61326-2-6. It has been designed and tested to CISPR 11 Class B.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by powering the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

■　　　　Reorient or relocate the receiving antenna.

■　　　　Increase the separation between the equipment and receiver.

■　　　　Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

■　　　　Consult the dealer or an experienced radio/TV technician for help.

This Class B digital apparatus complies with Canadian ICES-003.

1.2   Overview of the meter and its accessories

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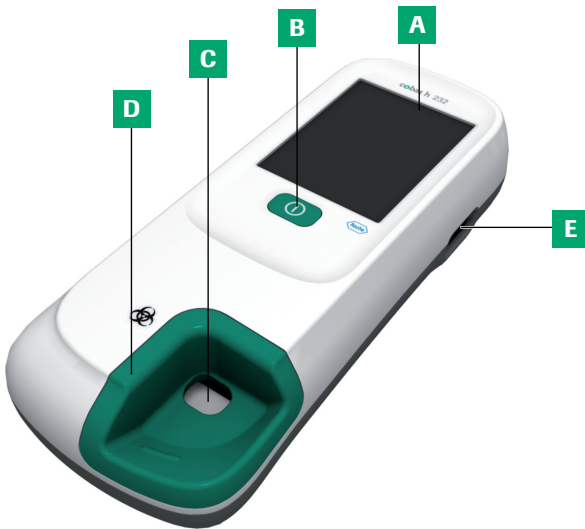
A   **Touchscreen**
Shows results, information, icons and results saved in the memory. To select an option, simply touch the button lightly.

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**
Operator and patient IDs can be read into the meter using the integrated barcode scanner. *

* To determine if your meter has this function compare the REF number on the meter identification plate to the corresponding ordering information (list of REF numbers) on page 200.

F   **Battery compartment cover**
Remove to insert the battery pack.

G   **Meter identification plate**
See page 5 for symbol explanation.

H   **Wireless LAN label**
If the meter supports wireless connectivity: This label displays registration numbers that are specific to the meter RF hardware. *

* To determine if your meter has this function compare the REF number on the meter identification plate to the corresponding ordering information (list of REF numbers) on page 200.
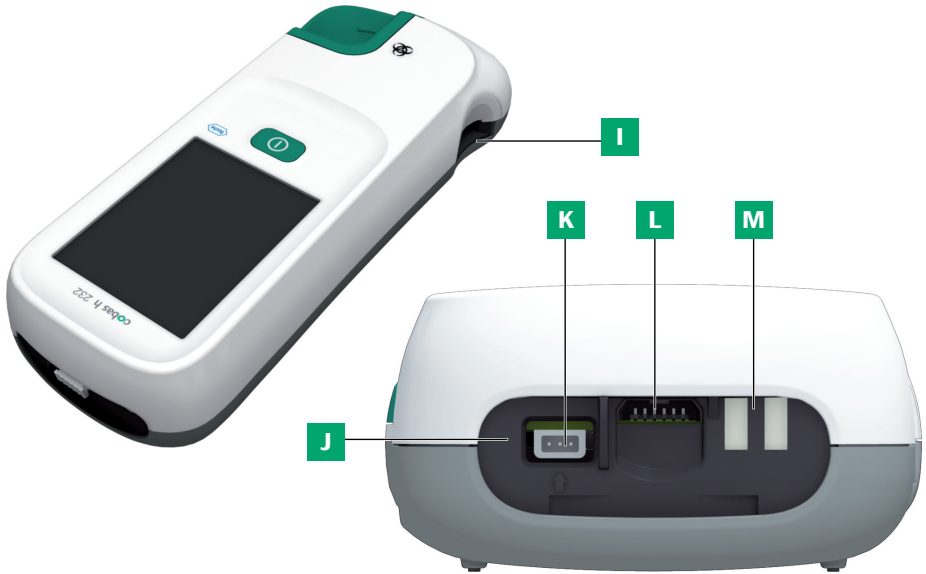
I **Test strip guide**
Insert the test strip here.

J **Infrared (IR) window**
Supports data communication with the
(optional) Handheld Base Unit. Covered
by the semi-transparent rear panel.

K **Connection socket for power adapter**
Plug in the power adapter here.

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

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

Power adapter
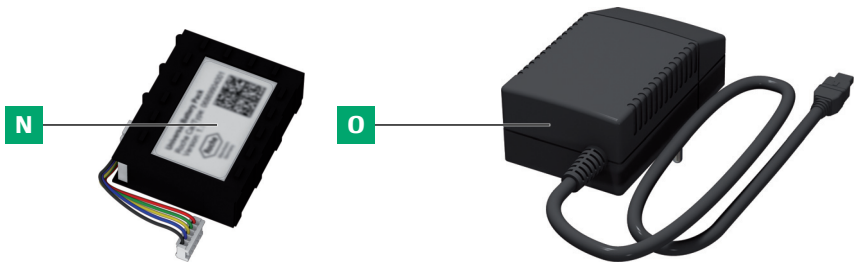
N **Universal Battery Pack**
Powers the device.

O **Power adapter**
Powers the device and charges the
battery pack.

The meter can be operated with the rechargeable battery pack only or together with the power adapter or the (optional) Handheld Base Unit, which both can charge the battery pack when inserted. Insert the battery pack even when always using the power adapter or the Handheld Base Unit. This ensures that you will not lose the date and time settings if the power goes out. Results are retained in the memory together with the corresponding date and time, as well as all other settings, even when no battery pack is inserted.

In general, it is not recommended to detach the external power adapter or undock the meter from the Handheld Base Unit during a measurement. When the meter is connected to an external power adapter and the battery level is low, measurements cannot be completed if the external power adapter is detached. In this case a message is displayed not to remove the external power adapter.

To save power, the meter can automatically power itself off or go into standby mode, 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 65).

Main Menu	09:15 am

Patient Test

Control Test

Review Results

Setup

Logout

04/19/2023
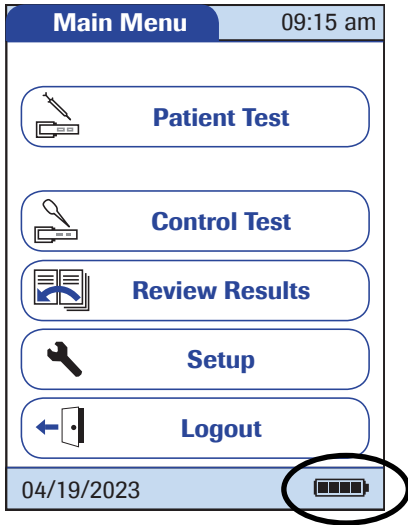
During battery operation, the meter always displays the power level of the battery pack. The battery icon is divided into four segments which correspond to the battery power level.

When **replacing the battery pack**, insert the new battery pack within 24 hours of removing the old one. Otherwise you may need to re-enter date and time.

⚠️ 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 19.

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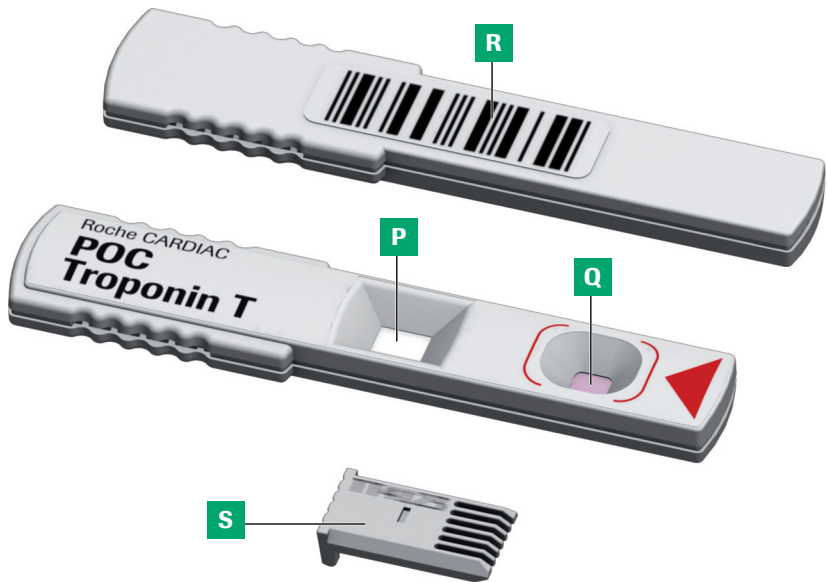
P **Test area**
This area is evaluated by the meter via the camera.

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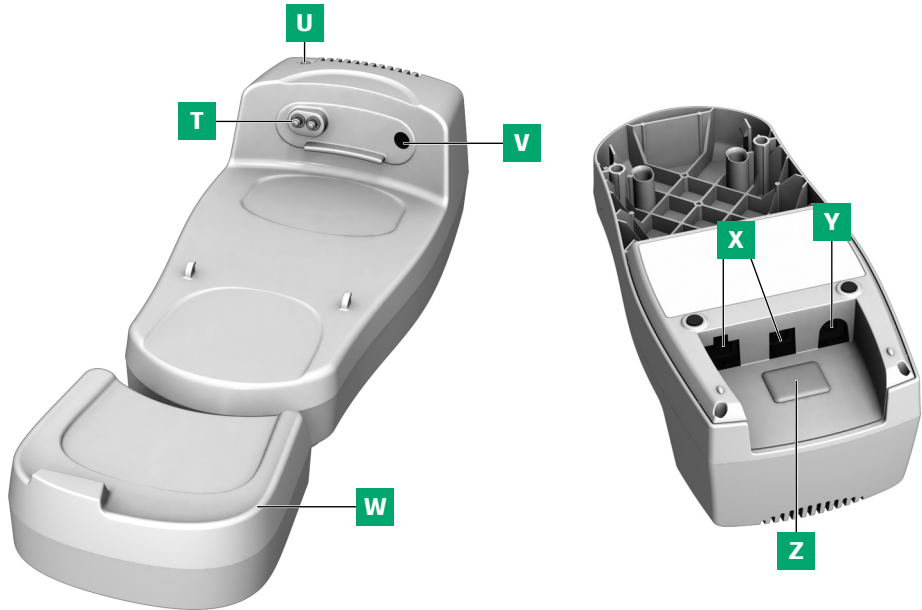
T **Charging contacts**
Used for power adapter and/or charging
the battery pack.

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, optional.

X **Data ports (Ethernet/RJ45 and USB)**
For connecting the device to a Data
Management System (DMS).

Y **Connection socket for the
power adapter**
Here you can plug in the power adapter of
the Handheld Base Unit.

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.

1.3   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 193.

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)
▦	Display test result as QR code
💬	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)

Button/Icon	Meaning
	Apply QC sample (the time left to apply sample is counted down in the screen alongside the required sample amount)
	Insert code chip
	Open test strip guide cover for cleaning
	Battery status: ▪ If the battery pack still has its full charge, all segments are lit ▪ Individual segments disappear one by one as the 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 adapter ▪ Individual segments appear one by one as the battery pack is charged ▪ If the battery pack is fully charged, all segments are lit
am	Time between midnight and noon (in 12-hour time format)
pm	Time between noon and midnight (in 12-hour time format)
	Marks an information message
	Marks an error message or a warning (see Chapter 9 "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.

The following icons may appear when using the meter in conjunction with a data management system (DMS).

🔊	Infrared interface is enabled (for communication with the computer and/or printer)
🔊✓	Infrared interface is enabled, the last attempt to communicate with the data management system was successful and terminated according to the communication protocol
🔊✗	Infrared interface is enabled, the last attempt to communicate with the data management system was not successful or was unintentionally terminated. If this icon persists, contact your system administrator.
📡	Communication is taking place via WLAN
📡✓	Communication is taking place via WLAN, the last attempt to communicate with the data management system was successful and terminated according to the communication protocol
📡✗	Communication is taking place via WLAN, the last attempt to communicate with the data management system was not successful or was unintentionally terminated. If this icon persists, contact your system administrator.
🔓	The last communication with the data management system was neither TLS encrypted nor TLS authenticated
🔒	The last communication with the data management system was TLS encrypted, but not TLS authenticated.
🛡	The last communication with the data management system was both TLS encrypted and TLS authenticated.
🎓	An OTS request is pending
✋	Cleaning/Disinfection necessary

The communication security icon 🔓 🔒 🛡 indicates the security status of current or last communication with the data management system. The icon is shown permanently after the initial communication of a brand new meter has taken place.

1.4   Roche CARDIAC Pipettes

Intended use

The Roche CARDIAC Pipettes are intended only for drawing the sample from the blood collection tube and application of the sample onto the Roche CARDIAC test strips. The Roche CARDIAC Pipettes are intended for near-patient testing. Not for self-testing.

Handling

Remove the protective caps and use the Roche CARDIAC Pipettes to draw exactly 150 μL (to the blue mark on the pipette) heparinized blood from the blood collection tube.

Precautions and Warnings

Before use, visually check if the packaging of the Cardiac pipettes and/or the pipettes are intact. If the needle falls off or gets stuck during use, do not try to re-cap it. Stop using the pipette immediately and dispose of it in a sturdy sharps container (in accordance with applicable local regulations and directives and your facility's guidelines).

Never use Roche CARDIAC Pipettes for blood sampling directly from the vein nor for administering injections. They are not sterile-packaged and do not contain anti-coagulants. Roche CARDIAC Pipettes are intended only for drawing the sample from the blood collection tube and applying it to the test strip.

2   Putting the Meter into Operation

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

1   Install the battery pack (see page 40).

2   Connect the power adapter to charge the battery pack.

3   Set the current date and time as well as the appropriate display format (see Chapter "Meter Setup" starting on page 45).

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 battery pack was removed from the meter for more than 24 hours), you cannot perform a test. In that case powering on the meter takes you immediately to the *Setup* mode, where you must set the date and time.

2.1 Installing or replacing the battery pack

When shipped, the battery pack is not installed in the meter. When the battery pack is not installed, the meter cannot be used.

Unused battery packs lose their charge over time and have to be recharged before they can be used. After installing a new battery pack, the meter should be charged at least 4 hours before testing, preferably overnight.

Whenever the meter is placed on an active Handheld Base Unit or powered by the power adapter, the icon is displayed. This icon shows that power is available and the meter can be charged if necessary. Charging starts automatically after 10 minutes when switching into standby mode. To start the charging process immediately put the meter into standby mode by pressing the On/Off button for approximately 1 second. The meter will only charge while in standby mode. The meter will not continue to charge when woken up from standby mode.

Make sure that the permitted temperature range for charging the battery pack (12-32 °C or 54-90 °F) is maintained during installation and initial setup.

Replace the battery pack within approximately 24 hours to retain the date and time settings. Beyond this period of time, you may have to re-enter date and time. **Replace the battery pack only in shutdown mode, see page 44.**

Removing the battery pack
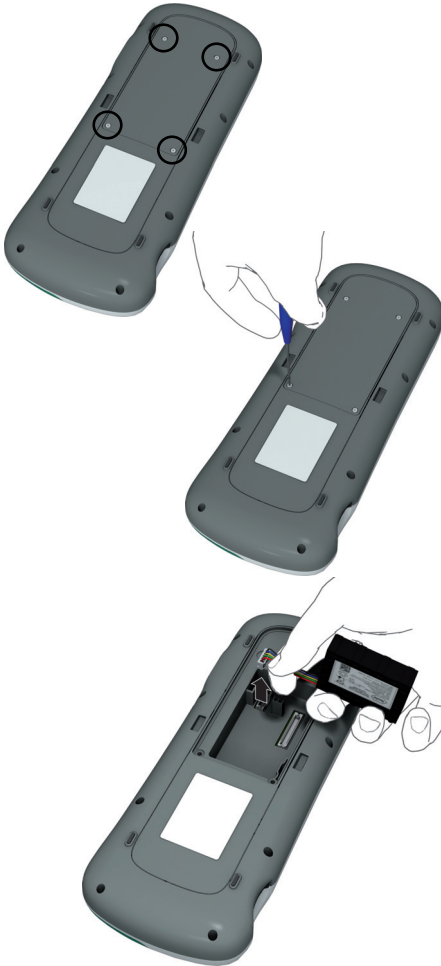
1   If a battery pack is already installed, make sure that the meter is shut down to prevent damage to the meter or potential data loss (see page 44).

Always disconnect the external power adapter before removing the battery pack.

2   Place the meter face down on a level surface.

3   Use the starshaped Torx screw driver (delivered with the **cobas h** 232 product pack/kit) to remove the four screws holding the battery compartment cover in place.

4   Remove the battery compartment cover from the meter. The battery pack now visible is connected to the meter by a plug.

5   Carefully lift the battery pack and remove the plug connector.

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

Installing the battery pack
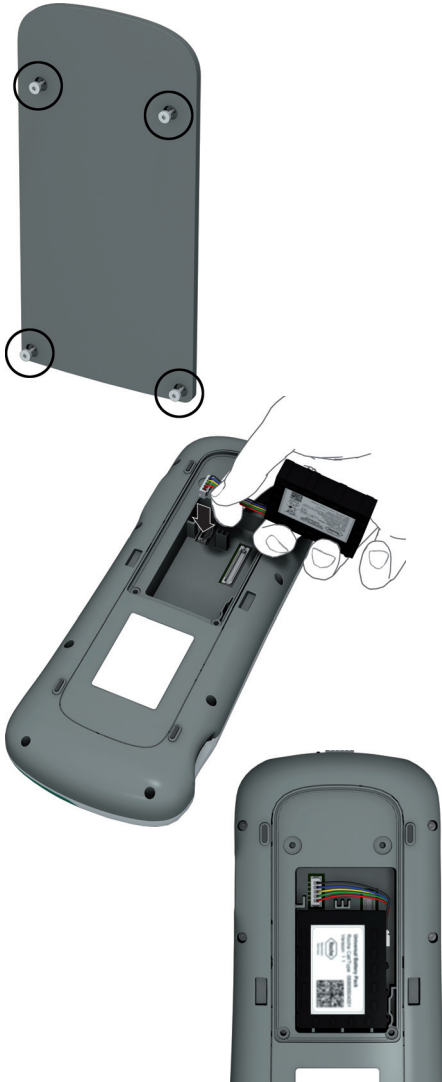
1 Loosen the screws on the battery com-
   partment cover until they are protruding
   about 4-5 mm (2/10 in).

Always disconnect the external power adapter
before inserting the battery connector plug.

2 Hold the battery pack in your hand, with
   the wires and the plug pinched between
   your thumb and index finger.

3 Plug the connector plug into the socket
   and make sure it is fully inserted.

4 Place the battery pack inside the battery
   compartment as shown.

To position the battery pack correctly, always
align the ridges on the side of the battery pack
with the ridges on the inside of the battery
compartment.

Preferably use the battery pack that was
shipped with the meter. When the battery
pack is installed, the meter checks if battery
pack and meter are compatible.

5 Place the cover on the battery compartment. Make sure that the plug connector wires do not get pinched between meter and cover.

6 Tighten all four screws until snug (do not overtighten).
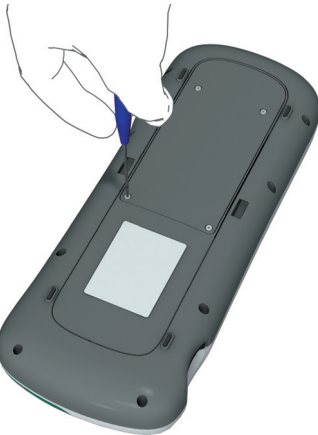
After inserting a new battery pack, the meter should be charged overnight before testing.
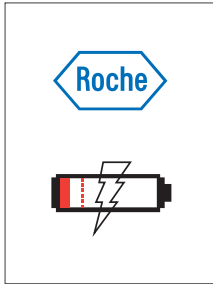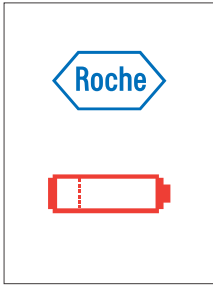
The meter powers on automatically and the Roche logo is displayed. If the meter does not start up automatically, the battery pack may be empty. In this case either a red battery symbol or a charging symbol is displayed. When the battery pack is charged sufficiently, the meter starts up automatically.
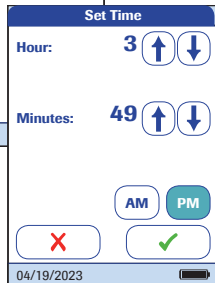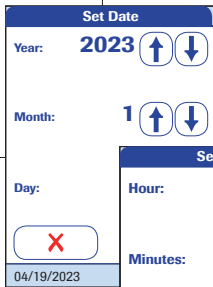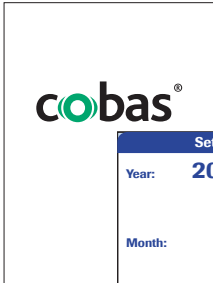
7 If the meter has been without power for too long, you have to re-enter the date and time settings. After you have entered the correct information, confirm each screen with ✓.

Powering the meter on and off

1   Power the meter on by pressing the ⏻ button.

You can also power on the meter directly by connecting the power adapter or by placing the meter on the Handheld Base Unit.

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

Shut down / restart meter

Shutting down the meter shuts down wireless communication and all other functionalities. Date and time, however, are maintained.

1   Device is not connected to the external power adapter or HBU:

To shut down the meter, press the ⏻ button for about 5 seconds and release the button as soon as the Roche logo is displayed and the meter beeps. The screen goes blank and the meter is shut down.

Use meter shutdown when you want to remove or replace the battery pack (see page 36).

2   Device is connected to the external power adapter or HBU:

To restart the meter, press the ⏻ button for about 5 seconds and release the button as soon as the Roche logo is displayed and the meter beeps. The screen goes blank and the meter powers itself off and on.

Use meter restart if the meter does not respond to user actions (like touching buttons).

> If you press the ⏻ button for too long, a meter reset will be triggered after about 12 seconds (see page 196) and date and time will be lost.

Automatic shutdown

If the battery pack is critically low, the meter willl shut down automatically.

3   Meter Setup

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

When text refers to other screen elements (e.g., Menu titles), these 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.
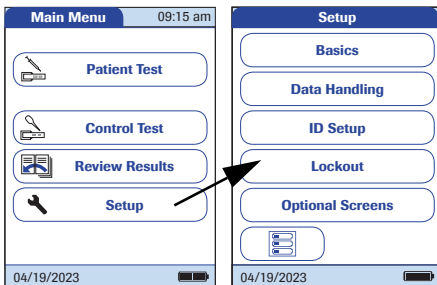
1 Touch **Setup** to call up the *Setup* menu.

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 33.

45

Settings summary

The diagram below gives an overview of the setup areas that can be accessed on the meter.
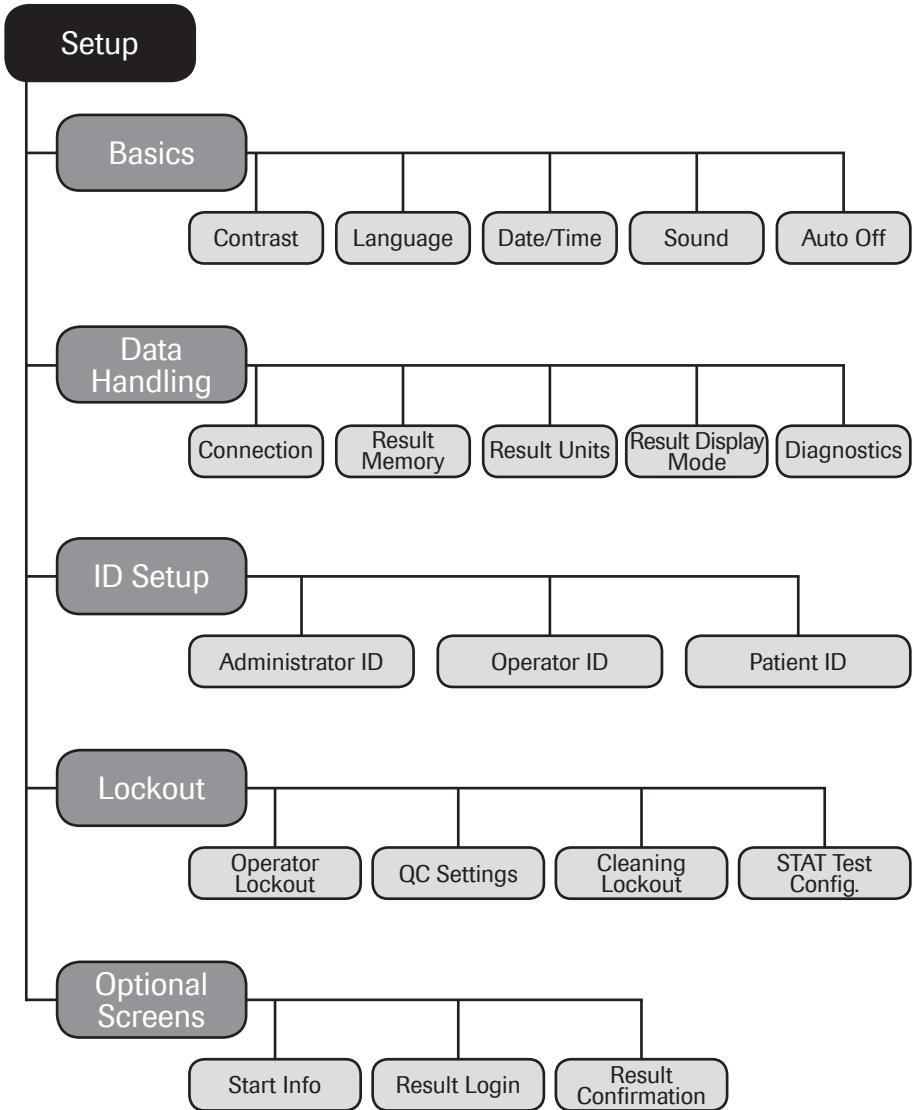
Group	Subgroup	Setting	Values *
Basics	Contrast		0 – 10 (5*)
	Language		Dansk
			Deutsch
			English *
			Español
			Français
			Italiano
			Nederlands
			Norsk
			Português
			Svenska
			An installable language
	Date/Time	Date	01/01/2011 *
		Time	12:00 am *
		Date formats	Day.Month.Year (31.12.2011)
			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		QR Code
			Off *
			Computer and TLS setup
			Printer
	Result Memory	Result Display Filter	All results *
			Current Op. Res.
		Result Storage Mode	No results deletion *
			Delete oldest result
		Result Retention	On, Off* & Value (30*)
		Delete Database	Selection of Results, Code Chip Data or Entire Database
	Result Units	Select DD Res. Unit	µg/mL *
			ng/mL
			mg/L
			µg/L
		Select TT Res. Unit	ng/L *
			pg/mL
			ng/mL
			µg/L
	Result Display Mode		Static *
			Flashing
	Diagnostics	Software	Display of existing settings, parameters, and information only
		Error History	
		Wireless Setup	
		Certificates, Client	Display and Renewal
		Certificates, Server	Display, Approval and Deletion
		Certificates, Root CA	Display and Deletion
		Credential Download	Download of meter credentials

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

Group	Subgroup	Setting	Values *
ID Setup	Administrator ID		Blank (off) *
	Operator ID	(with DMS and list available on meter)	None *
			List
			Hidden List
		(No list available on meter)	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 (*).

3.1 *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.
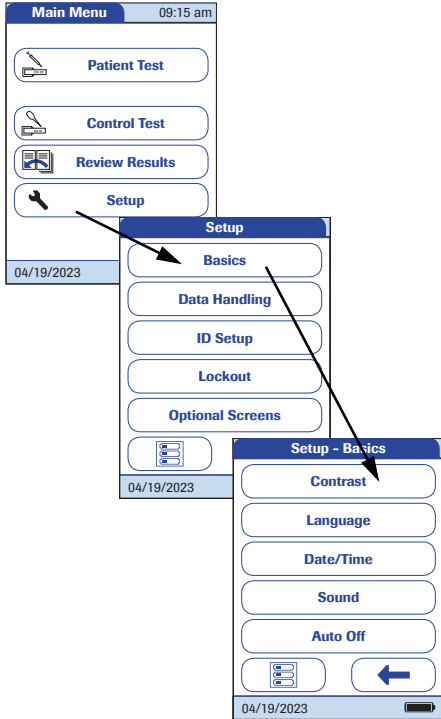
1 From the *Main Menu*, touch **Setup** to open the meter settings.

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

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

Select Contrast

Contrast:
(0-10)   5 ⬆ ⬇

❌   ✔

04/19/2023
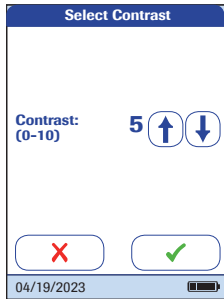
4   Touch ⬆ or ⬇ to change the contrast in a range from 0 to 10.

■   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.

53

Language

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

Main Menu	09:15 am
Patient Test	
Control Test	
Review Results	
Setup	
04/19/2023	

Setup
Basics
Data Handling
ID Setup
Lockout
Optional Screens
04/19/2023

Setup - Basics
Contrast
Language
Date/Time
Sound
Auto Off
04/19/2023

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).

54

Select Language

Français	⬆
Italiano	
Nederlands	
Norsk	
Português	⬇
✗	✓

04/19/2023

4 Touch ⬆ or ⬇ to display the language of choice on the screen.

If the arrow is just an outline ⬆ ⬇ , you have reached the end of the list in the respective direction.

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

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

Setting the date

Use this menu to set the date of the meter.
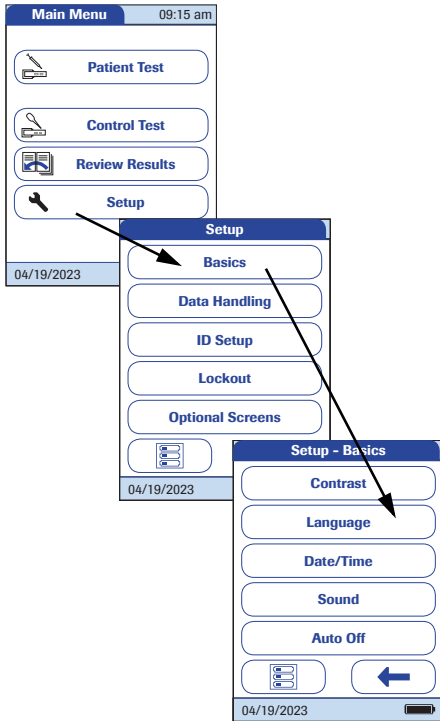

1 From the *Main Menu*, touch **Setup** to open the meter settings.

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

3 From the *Setup-Basics* menu, touch **Date/Time**.

Setup - Date/Time
Date
Time
Date/Time Format

04/19/2023

Set Date
Year: **2023**
Month: **1**
Day: **1**
✗   ✓

04/19/2023
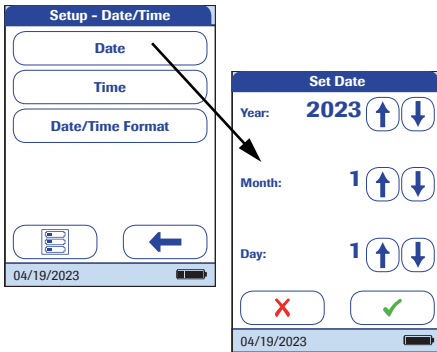
4 From the *Setup-Date/Time* menu, touch **Date** to set the date.

5 Touch ↑ or ↓ 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

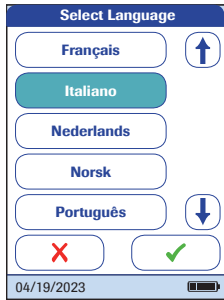Use this menu to set the time of the meter.

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**.

Setup - Date/Time

Date

Time

Date/Time Format

04/19/2023

Set Time

Hour: 3

Minutes: 49

AM PM

04/19/2023
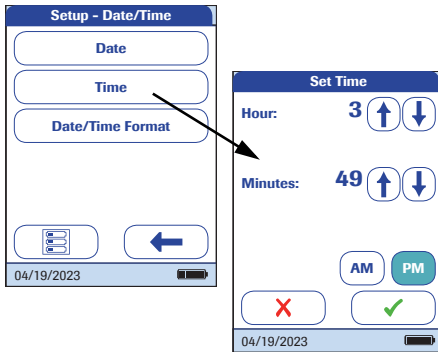
4 From the *Date/Time* menu, touch **Time** to set the time.

5 Touch ⬆ or ⬇ 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**.
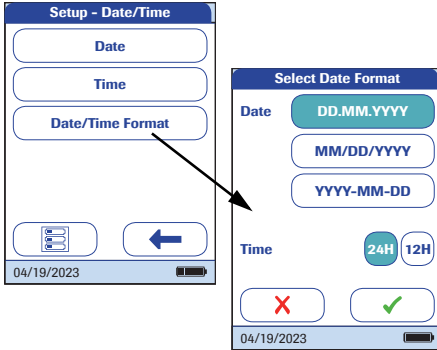
4 From the *Setup-Date/Time* menu screen, touch **Date/Time Format** to set the display format.

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

■ it detects a blood sample

■ the test is completed and the results are displayed (a long beep)

■ an error occurs (three short beeps)

■ the power adapter 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)

■ a test result requires operator confirmation and the meter will soon power off automatically (three short beeps)

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.
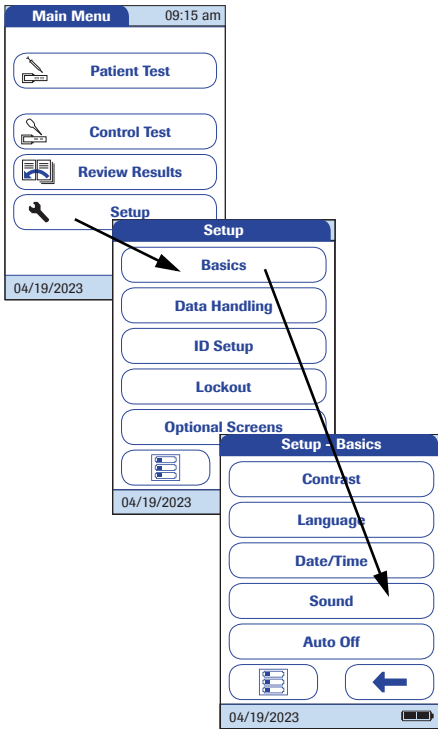
Main Menu 09:15 am

Patient Test

Control Test

Review Results

Setup

04/19/2023

Setup

Basics

Data Handling

ID Setup

Lockout

Optional Screens

04/19/2023

Setup - Basics

Contrast

Language

Date/Time

Sound

Auto Off

04/19/2023

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

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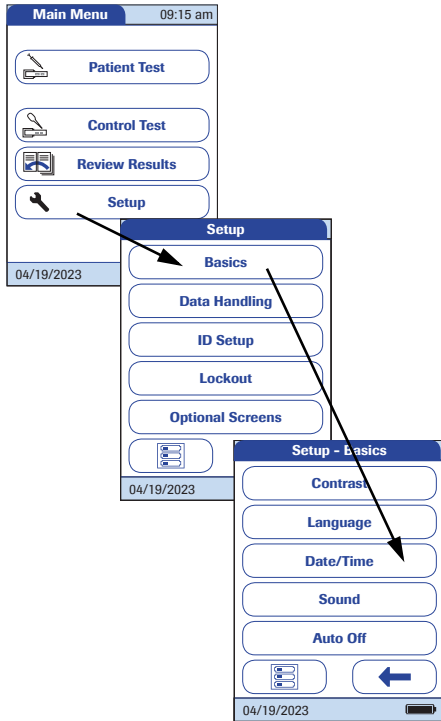
3 From the *Setup-Basics* menu, touch **Sound**.

Setup – Sound

Volume

Key Click

04/19/2023

Select Volume

Off

Low

Medium

High

✕   ✓

04/19/2023

Key Click

Enable

Disable

✕   ✓

04/19/2023
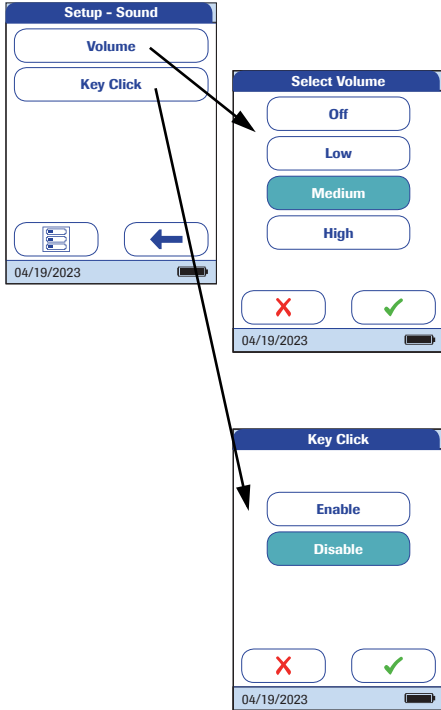
4   From the *Setup-Sound* menu, touch **Volume** to set the volume level of the beeper.

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 time of usage before having to recharge the battery pack.
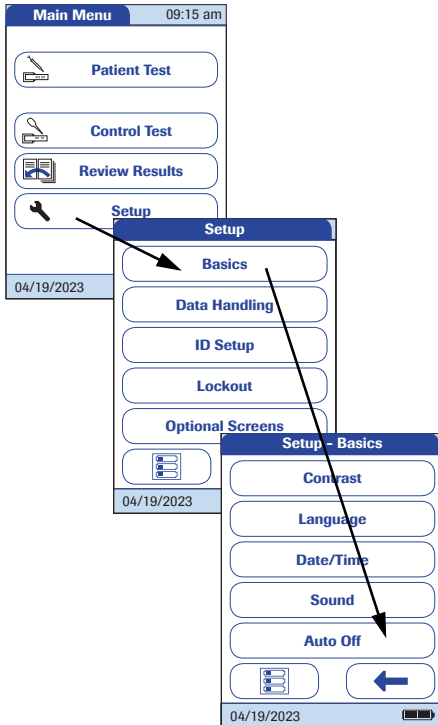
1 From the *Main Menu*, touch **Setup** to open the meter settings.

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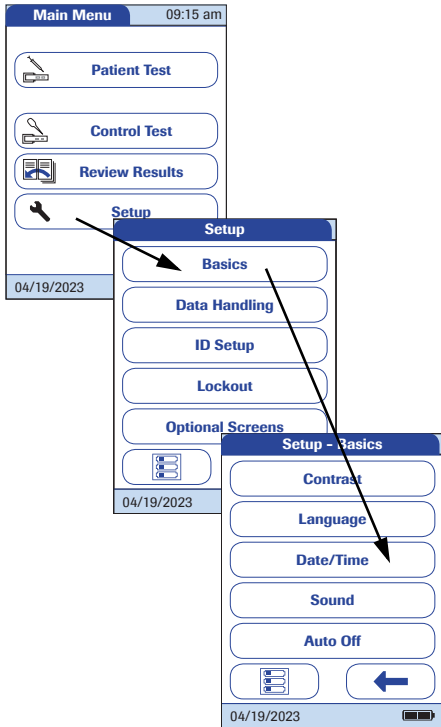
3 In the *Setup-Basics* menu, touch **Auto Off**.

Main Menu 09:15 am	
Patient Test	
Control Test	
Review Results	
Setup	
04/19/2023	

Setup
Basics
Data Handling
ID Setup
Lockout
Optional Screens
04/19/2023

Setup - Basics
Contrast
Language
Date/Time
Sound
Auto Off
04/19/2023

If connected to the power adapter or the Handheld Base Unit, the meter goes into standby mode instead of powering off if it has not been used for 10 minutes. Furthermore the meter can perform a maintenance reboot on a regular basis. The latter will only occur during meter inactivity.

Set Auto Off Time

Minutes: **5** ⬆️⬇️

❌ ✔️

04/19/2023
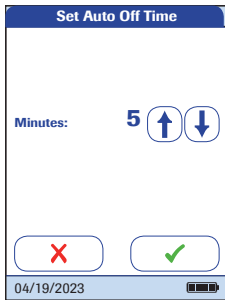
You may select from the following options:

■ Off (meter never powers itself off)

■ Time until meter powers itself off:
1…10, 15, 20, 25, 30, 40, 50, 60 minutes

4 Touch ⬆️ or ⬇️ to select the time of choice in minutes or to 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.

3.2 *Data Handling* setup

Connection

In the *Connection* menu you can configure the data exchange with external devices. The meter can be connected either to a computer or a printer. In addition to this direct data output, test results may also be encoded as QR codes, which can be scanned to be used with other applications.
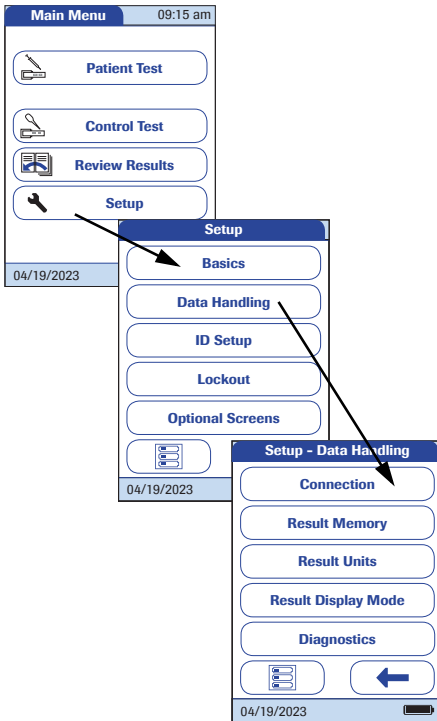
1 From the *Main Menu*, touch **Setup** to open the meter settings.

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

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

QR Code
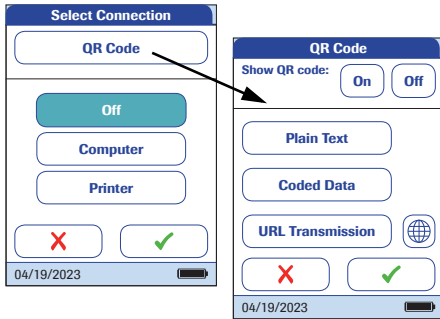
4. From the *Select Connection* menu, touch **QR Code**.

5. Touch **On** to enable, or touch **Off** to disable QR code display. Your selection is now highlighted.

■ If you have enabled this feature, select the style of the QR code to be displayed:

■ *Plain Text*
Use this option to scan the result into a PC hosted application (e.g. electronic medical record). In order to do so, you need an external 2D barcode scanner attached to your PC. Once scanned, the test result and related meta-information (e.g. date, time, comments) will appear as plain text in your PC application.

■ *Coded Data*
Use this option to scan the result into a smartphone or tablet app, or a PC hosted application.

■ *URL Transmission*
Use this option to upload the result to a web based service (e.g. such as an electronic health record, etc.). For this option further parameters (URL, encryption key) must be set.

Ensure that your environment for reading QR codes (QR code reader, operating system, text processing application) is appropriate for your language. Disregard may lead to unpredictable behavior of your receiving component (PC, mobile device).

For the options *Coded Data* and *URL Transmission* dedicated software programs or apps are required in order to use this feature. If you are a customer or a 3rd party IT provider, and you are interested to use this feature, contact your local Roche Diagnostics representative for additional information.
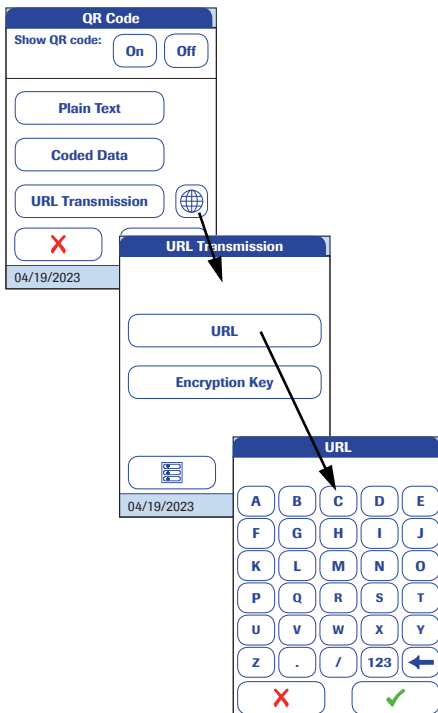
6 Touch **Plain Text**, **Coded Data** or **URL Transmission**, depending on the intended use. Your selection is now highlighted.

If you have selected *URL Transmission*, the ⊕ button will become active. Use this button to set the additional parameters.

7 Touch ⊕ to open the *URL Transmission* menu.

8 Touch **URL** to enter the URL to which the test result data will be uploaded (note: the URL will be provided by your specialized service provider).

■ Use (123) to switch to input of numbers.

■ Use (ABC) to switch back to input of text.

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

9 Touch ✔ to save this setting, or touch ✘ to exit this menu without saving any changes. The display automatically returns to the previous screen.

URL Transmission

URL

Encryption Key

04/19/2023

Encryption Key

Key:
JD5G29F6U8V2WC4L
Serial No.:
KQ0327832

Note: The encryption key and the serial number are required to decrypt QR code messages from this meter. Ensure they are available on the target system.

04/19/2023
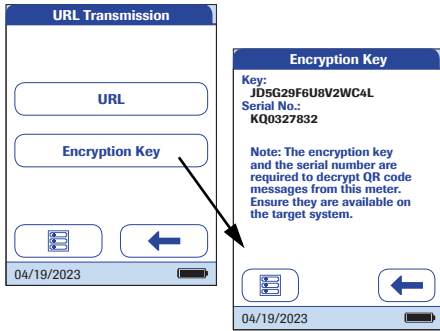
10 Touch **Encryption Key** to display the *Encryption Key* menu.

The *Encryption Key* menu displays two types of information which are required in order to identify and decode the transmitted test result. This information is required by the IT system, to which the test result is transmitted via the defined URL.

■ *Key*
This key is auto-generated by the meter and is required to decrypt the QR code information.

■ *Serial No.*
The meter's serial number is required to map the test result to the encryption key.

Touch the **New** button, if you want the meter to generate a new encryption key.

11 Touch ← twice to return to the *QR Code* menu.

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

The *Encryption Key* information needs to be exchanged once with your specialized service provider prior to using the URL transmission method. Contact your specialized service provider in order to exchange this information.

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 or the meter must be configured for wireless communication. If no wireless communication is configured, 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.

<div style="float:left">

Select Connection

QR Code

Off

Computer

Printer

✗   ✓

04/19/2023

</div>
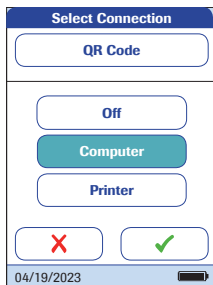
13 From the *Select Connection* menu, touch **Computer**. Your selection is now highlighted.

14 Touch ✓ to save this setting and proceed to the *TLS* menu (see page 72), or touch ✗ to exit this menu without saving any changes. The display automatically returns to the previous screen.

TLS menu

This menu allows you to configure the TLS Communication between meter and DMS.

TLS	
TLS Encryption:	On Off
TLS Authentication:	On Off
✗	✓
04/19/2023	
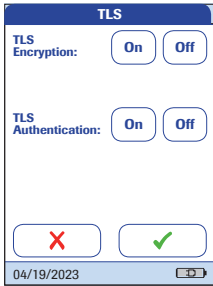
15 Touch the desired configuration.

■ TLS Encryption

- *On:* activates an end-to-end TLS tunnel from the meter to the DMS

- *Off:* the communication is not encrypted and no TLS authentication is possible

■ TLS Authentication

- *On:* ensures the end-to-end TLS tunnel is only initiated between an authenticated meter and an authenticated DMS

- *Off:* TLS authentication is deactivated

16 Touch ✓ to save this setting, or touch ✗ to exit this menu without saving any changes. The display automatically returns to the *Setup - Data Handling* menu.

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.

Connection to a printer can only be established via infrared.

Enabling the connection to a printer disables the connection to a computer (and vice versa).
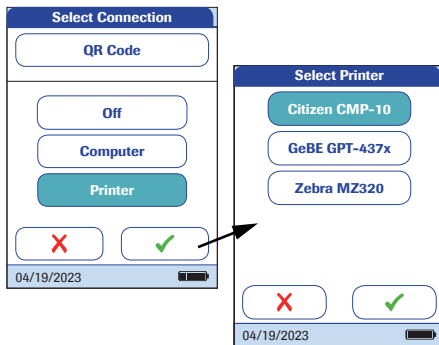
17 From the *Select Connection* menu, touch **Printer**. Your selection is now highlighted.

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

19 Touch ✔ to save this setting, or touch ✘ to exit this menu without saving any changes. The display automatically returns to the *Setup-Data Handling* menu.

Pat. Test – Result
Pat: PID111SCHULZM457
SCHULZ, MANFRED
Op: JONES, TOM
Par: proBNP **Code: PB1234**
04/19/2023 10:17
620 pg/mL

04/19/2023
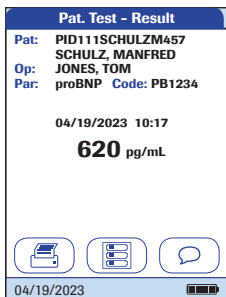
To print :

■   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.

Result memory

Result memory settings allow to apply a *Result Display Filter* and to set the *Result Storage Mode* (see page 77), and to delete stored test results, code chip data or the entire database (see page 80).

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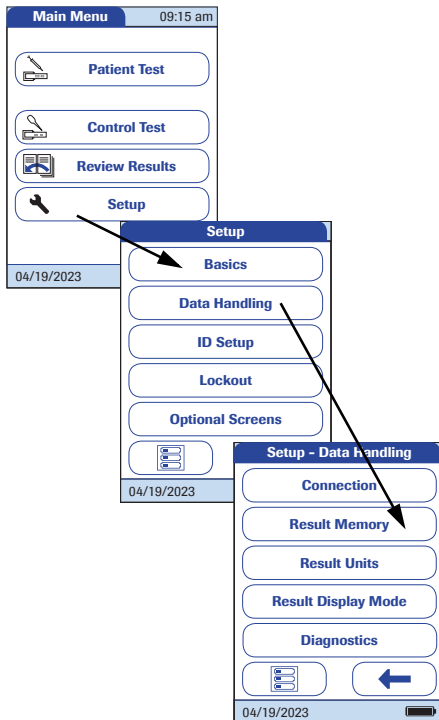
1   From the *Main Menu*, touch **Setup** to open the meter settings.

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

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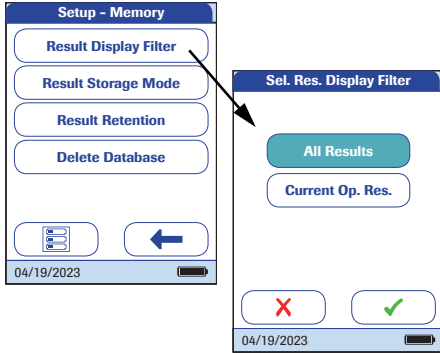
4 From the *Setup-Memory* menu, touch **Result Display Filter** to select the results to display.

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.

6 Touch ⬅ to return to the *Setup-Data Handling* menu.

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 2000 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 177. 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.

Setup – Memory
Result Display Filter
Result Storage Mode
Result Retention
Delete Database

04/19/2023

Sel. Res. Storage Mode
No Result Deletion
Del. Oldest Result

✗   ✓

04/19/2023
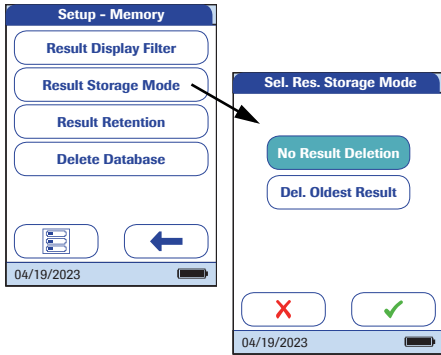
7 From the *Setup-Memory* menu, touch **Result Storage Mode** to select your storage mode.

You may select from the following options:

■ **No Result Deletion**

■ **Del**(ete) **Oldest Result**

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

9 Touch ← to return to the *Setup-Data Handling* menu.
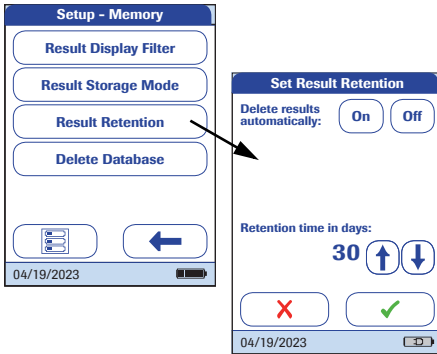
10 From the *Setup-Memory* menu, touch **Result Retention** to configure automatic deletion and setting a retention time.

Touch the desired configuration:

■ Delete patient and QC results automatically (On/Off)

- *On*: Results will be deleted automatically after the set retention time has elapsed.

- *Off*: Results will not be deleted automatically based on a time interval. (Automatic deletion as per the *Sel. Res. Storage Mode* setting will still be performed.)

11 If automatic deletion is enabled, set the *Retention time in days* (1…1000), after which the automatic deletion will be performed.

12 Touch ✔ to save this setting, or touch ✘ to exit this menu without saving any changes. The display automatically returns to the previous screen.

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

Setup – Memory

- Result Display Filter
- Result Storage Mode
- Result Retention
- Delete Database

04/19/2023

Delete Database

- Results
- Code Chip Data
- Entire Database

04/19/2023

Confirm Deletion

Do you really want to delete all results?

04/19/2023

Confirm Deletion

Do you really want to delete all code chip data?

04/19/2023

Confirm Deletion

Do you really want to delete the entire database?

04/19/2023
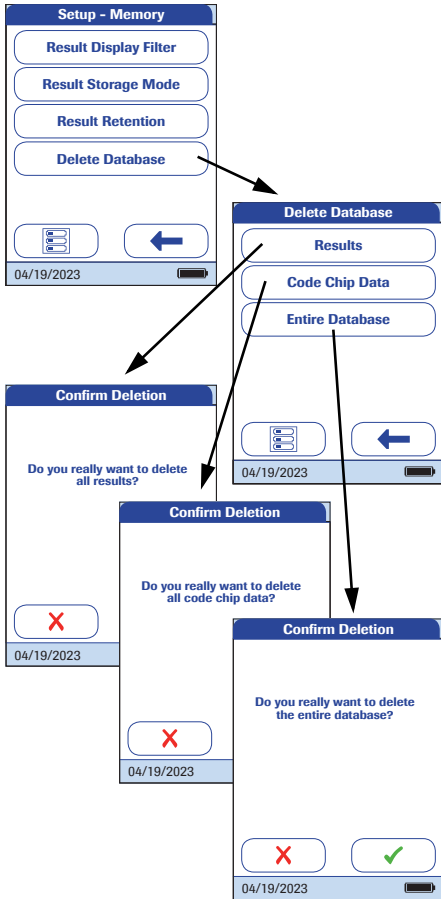
14 From the *Setup-Memory* menu, touch **Delete Database** to delete stored test results, code chips or the complete database (including operators, patients, code chips, test results and comments).

15 From the *Delete Database* menu, touch either **Results**, **Code Chip Data** or **Entire Database**, depending on the type of data you want to delete.

16 Touch ✔ to delete the selected data, or touch ✗ to exit this screen without deleting any data. The display automatically returns to the previous screen.

17 Touch ⬅ to return to the *Setup-Data Handling* menu.

Result units

The result unit setting applies to the result display of **D-Dimer** and **Troponin T** tests only.
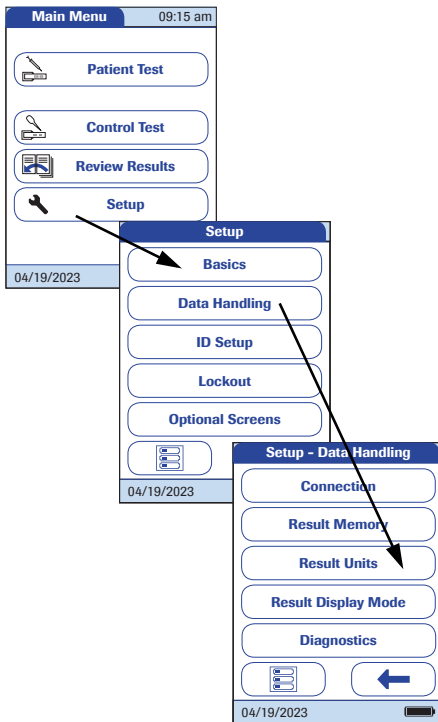
1 From the *Main Menu*, touch **Setup** to open the meter settings.

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

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

Setup - Result Units
DD Result Units
TT Result Units
🗒️   ⬅️
04/19/2023   🔋

Select DD Res. Unit
µg/mL
ng/mL
mg/L
µg/L
❌   ✔️
04/19/2023   🔋
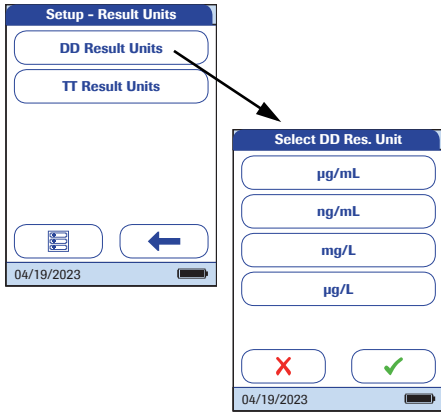
4 From the *Setup-Result Units* menu, touch **DD Result Units**.

5 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**

6 Touch ✔️ to save this setting, or touch ❌ to exit this menu without saving any changes. The display automatically returns to the previous screen.

Setup – Result Units

| DD Result Units |
| TT Result Units |

04/19/2023

Select TT Res. Unit

| ng/L |
| pg/mL |
| ng/mL |
| µg/L |

❌   ✔️

04/19/2023

7 From the *Setup-Result Units* menu, touch **TT Result Units**.

8 From the *Select TT Res. Unit* menu, select the unit to be used for the Troponin T result display.

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

- **ng/L**
- **pg/mL**
- **ng/mL**
- **µg/L**

9 Touch ✔️ to save this setting, or touch ❌ to exit this menu without saving any changes. The display automatically returns to the previous screen.

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

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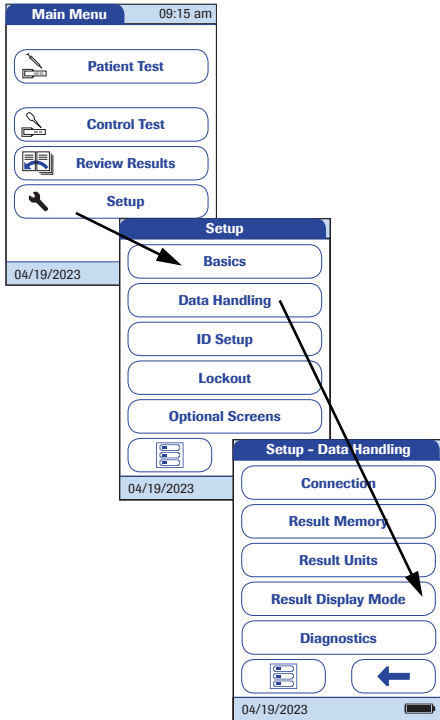
1 From the *Main Menu*, touch **Setup** to open the meter settings.

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

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

Main Menu 09:15 am

- Patient Test
- Control Test
- Review Results
- Setup

04/19/2023

Setup

- Basics
- Data Handling
- ID Setup
- Lockout
- Optional Screens

04/19/2023

Setup – Data Handling

- Connection
- Result Memory
- Result Units
- Result Display Mode
- Diagnostics

04/19/2023

```
┌────────────────────────────────┐
│   Select Res. Display Mode     │
│  ┌──────────────────────────┐  │
│  │         Static           │  │
│  └──────────────────────────┘  │
│  ┌──────────────────────────┐  │
│  │        Flashing          │  │
│  └──────────────────────────┘  │
│                                │
│                                │
│                                │
│   ┌─────────┐    ┌─────────┐   │
│   │    ✗    │    │    ✓    │   │
│   └─────────┘    └─────────┘   │
│  04/19/2023            ▭▭▭▭    │
└────────────────────────────────┘
```
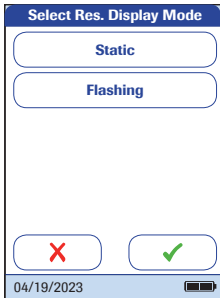
4 From the *Select Res. Display Mode* menu, select your display mode.

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.

6 Touch ⬅ to return to the *Setup-Data Handling* menu.

Diagnostics

Under *Diagnostics,* you will find information about the system, such as software version and wireless configuration details. The *Diagnostics* menu contains functions relevant for installation, maintenance and troubleshooting purposes. In case of technical problems the firmware version (Build) is an important information for the Roche Diagnostics customer support.

The diagnostics screens shown here are for illustration purposes only. The Information shown on your meter may differ.

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 **Diagnostics**.

Diagnostics

- Software
- Error History
- Certificates
- Wireless Setup

04/19/2023

Software

Build:	04.00.00
Boot:	06.03.00
Kernel:	06.03.00
RootFS:	06.03.00
App:	04.00.00
MM-BL:	03.00.00
MM-FW:	03.00.00

04/19/2023

Error History

- b360401c - 205
03/12/23 08:30
- b360401c - 205
02/10/23 08:00
- b5804001 - 302
01/02/23 10:17
- b5804001 - 302
11/14/22 07:30
- b360401c - 205
10/10/22 07:05

04/19/2023

Wireless Setup

Wireless Setup - Network

Use DHCP:
Enabled

Use DNS:
Disabled

SSID:
cobas h 232

WLAN:
MAC:
01 23 45 67 89 AB

04/19/2023

Wireless Setup

Wireless Setup - Connection

DMS Name:
POCTServer

DMS Port Number:
4711

DMS IP Address:
0.0.0.0

RF Security:
WPA2-PSK (AES)

04/19/2023

Wireless Setup

Wireless Setup - Test

RF activated: ✓
Associated: ✓
Authenticated: ✓
Configured IP: ✓
IP: 192.168.0.123
Subnet: 255.255.255.0
Gateway:
DNS:
Contacted DMS:
Connected to DMS:
Completed:

Test

04/19/2023

4 From the *Diagnostics* menu, touch the button of the diagnostics screen you want to display.

See chapter 3.3 "Certificates setup" for detailed information about the *Certificates* menu.

5 Use ◀ and ▶ to toggle between the *Wireless Setup* screens.

6 In either diagnostics screen, touch ← to return to the *Diagnostics* menu.

Note: The **Wireless Setup** button is only available if the meter is equipped with WLAN functionality.

3.3 *Certificates* setup

Use the *Certificates* menu to manage the required certificates for TLS communication between meter and the DMS:

■   renew the client certificate

■   activate or delete server certificates

■   delete Root CAs

TLS (Transport Layer Security) supports many different methods for exchanging keys, encrypting data and authenticating message integrity. Using the TLS encryption and authentication provides an end-to-end TLS tunnel from meter to DMS. Activate these options as the most effective measure to ensure secure communication.
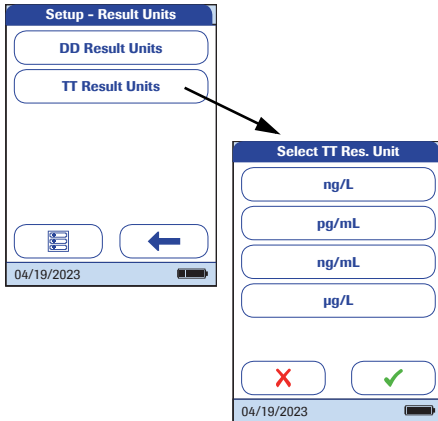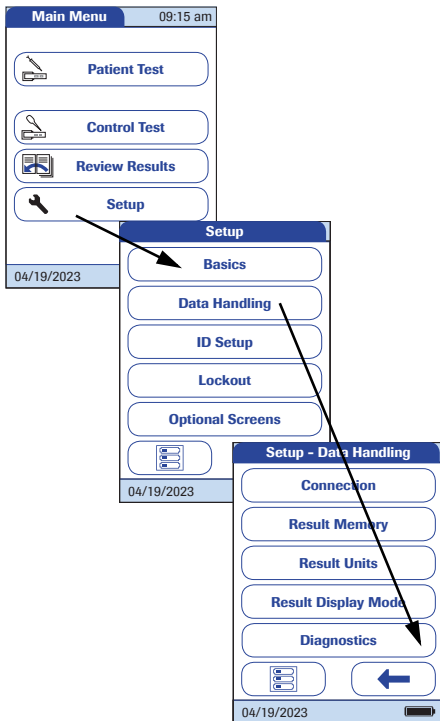

1 From the *Main Menu*, touch **Setup** to open the meter settings.

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

3 From the *Setup-Data Handling* menu, touch **Diagnostics**.
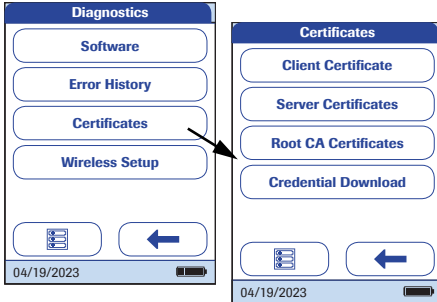
4   From the *Diagnostics* menu, touch **Certificates** to display the *Certificates* menu.

5   In either diagnostics screen, touch ← to return to the *Diagnostics* menu.

Certificate status symbols

In any of the certificate screens described below (Client, Server, Root CA) the status of a certificate is indicated by the following symbols:

✅	Indicates that the server or root CA certificate status is **approved**.
⊗	Indicates that the server certificate status is **not approved**.
⚠	Indicates that the server or root CA certificate is **expired**.
⬇	Download; for downloading credentials.

Managing the client certificate

You can display and renew the client certificate.
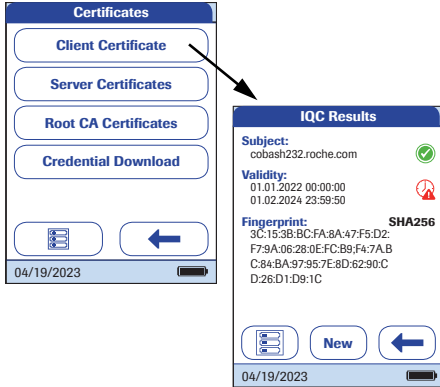
1. Touch **Client Certificate** to display the *Client* screen.

The *Client* screen contains the following information:

- *Subject:* shows the common name of the certificate and its approval status.

- *Validity:* shows the time range of the certificate's validity. When the time range is exceeded the expired icon ⊘ is displayed.

- *Fingerprint:* shows the fingerprint type and the fingerprint. The fingerprint is the unique identifier of the certificate.

2. Touch **New** to renew the client certificate.

3. In the following message, touch ✔ to confirm that you want to renew the certificate, or touch ✗ to cancel the process without renewing the certificate.

4. Touch ◀— to return to the *Certificates* menu.

Managing server certificates

You can display and review existing server certificates, activate not yet approved certificates and delete expired or invalid certificates.
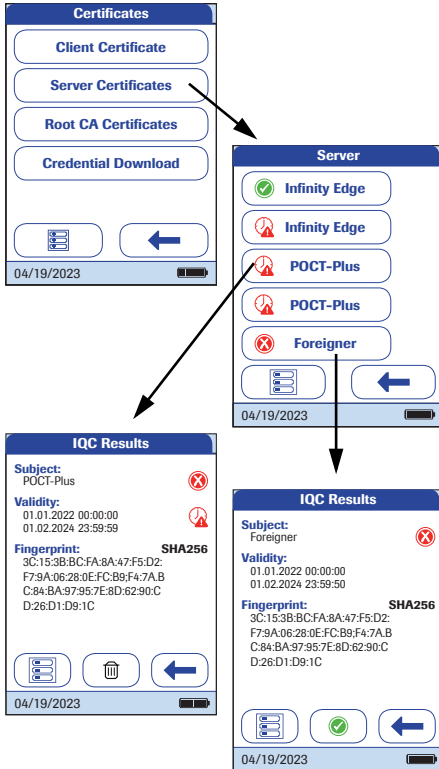
1 Touch **Server Certificate** to display the *Server* screen with a list of certificates.

2 Touch the server certificate you wish to display.

The *Server* screen contains the following information:

■ *Subject:* shows the common name of the certificate and its approval status.

■ *Validity:* shows the time range of the certificate's validity. When the time range is exceeded the expired icon is displayed.

■ *Fingerprint:* shows the fingerprint type and the fingerprint. The fingerprint is the unique identifier of the certificate.

3 Manage certificates as follows:

   ▪ Touch to approve a server certificate which is not yet approved.

   ▪ Touch to delete a certificate.

4 In the following message, touch ✔ to confirm that you want to approve or delete the certificate, or touch ✗ to cancel the process without changing the certificate status.

5 Touch ← to return to the *Server* menu.

Managing Root CA certificates

You can display and review existing Root CA certificates, and delete expired or invalid certificates.
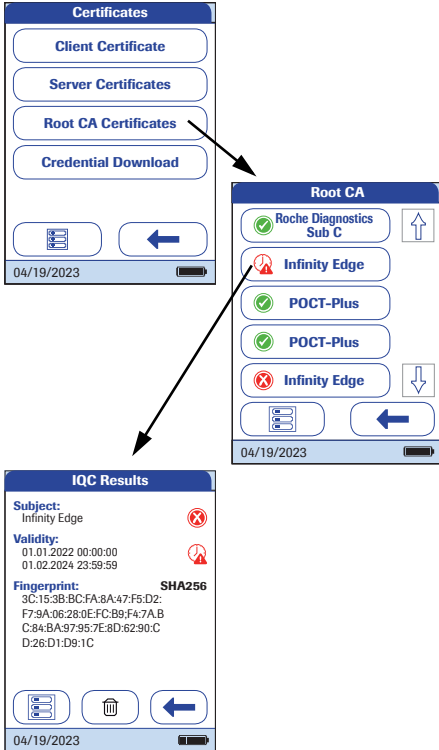
1 Touch **Root CA Certificates** to display the *Root CA* screen with a list of certificates.

2 Touch ⬆ or ⬇ to scroll through the list.

3 Touch the Root CA certificate you wish to display.

The *Root CA* screen contains the following information:

■ *Subject:* shows the common name of the certificate, its approval status, and the text *built in* if the certificate is built-in.

■ *Validity:* shows the time range of the certificate's validity. When the time range is exceeded the expired icon 🔺 is displayed.

■ *Fingerprint:* shows the fingerprint type and the fingerprint. The fingerprint is the unique identifier of the certificate.

4 Touch 🗑 to delete a customer installed certificate. Built-in certificates can not be deleted.

5 In the following message, touch ✔ to confirm that you want to approve or delete the certificate, or touch ✖ to cancel the process without changing the certificate status.

6 Touch ⬅ to return to the *Root CA* menu.

Downloading credentials

For downloading meter credentials the meter must be placed in a configured Handheld Base Unit.
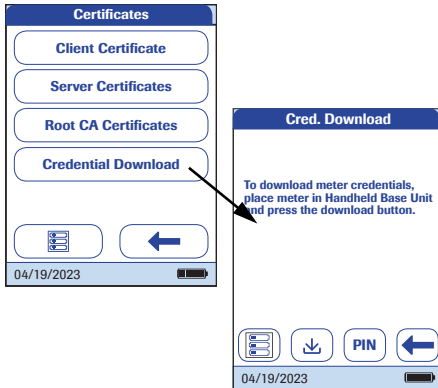
1. Touch **Credential Download** to display the *Cred. Download* screen.

2. Touch **PIN** to enter the required pin.

3. Touch ⤓ to download a new meter credential via the Handheld Base Unit.

4. Touch ⬅ to return to the *Certificates* menu.

3.4   *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 177.

–   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 177.

Operator IDs can be selected from a list (if available) or read by the barcode scanner. 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.

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 10).

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**.

Main Menu 09:15 am

Patient Test

Control Test

Review Results

Setup

04/19/2023

Setup

Basics

Data Handling

ID Setup

Lockout

Optional Screens

04/19/2023

Setup - ID Setup

Administrator ID

Operator ID

Patient ID

04/19/2023

Enter Administrator ID

****|

A	B	C	D	E
F	G	H	I	J
K	L	M	N	O
P	Q	R	S	T
U	V	W	X	Y
Z			123	←

✗   ✓

Enter Administrator ID

****|

0	1	2	3	4
5	6	7	8	9
			ABC	←

✗   ✓
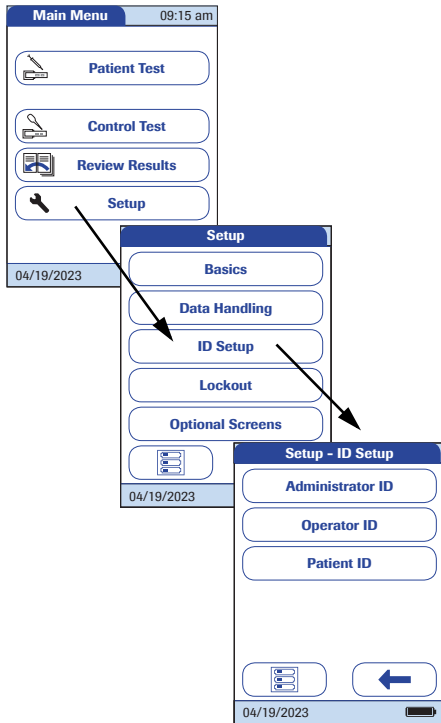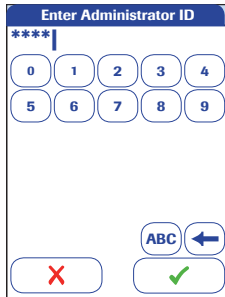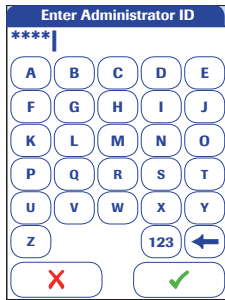
4 Using the onscreen keypad, enter the *Administrator ID* of choice (or the password provided by Roche Diagnostics). The ID can consist of up to 20 alphanumeric characters.

Alphanumeric characters are any combination of A - Z and 0 - 9. Additionally "." (period), or "-" (hyphen) may be used.

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.

97

Repeat Administrator ID

****|

A	B	C	D	E
F	G	H	I	J
K	L	M	N	O
P	Q	R	S	T
U	V	W	X	Y
Z		123	←	

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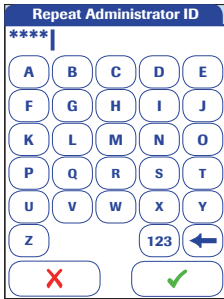
9 Enter the *Administrator ID* again (the onscreen keypad is automatically displayed again) to confirm the first entry.

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.

Main Menu   09:15 am

Patient Test

Control Test

Review Results

Setup

04/19/2023

Setup

Basics

Data Handling

ID Setup

Lockout

Optional S

04/19/2023

Enter Administrator ID

****|

A	B	C	D	E
F	G	H	I	J
K	L	M	N	O
P	Q	R	S	T
U	V	W	X	Y
Z		123	←

✗   ✓

Setup - ID Setup

Administrator ID

Operator ID

Patient ID

04/19/2023
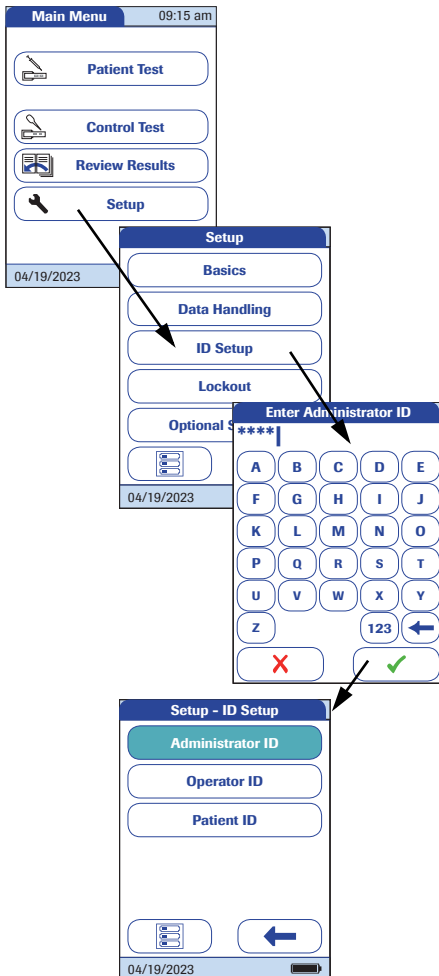
Changing an existing *Administrator ID*:

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).
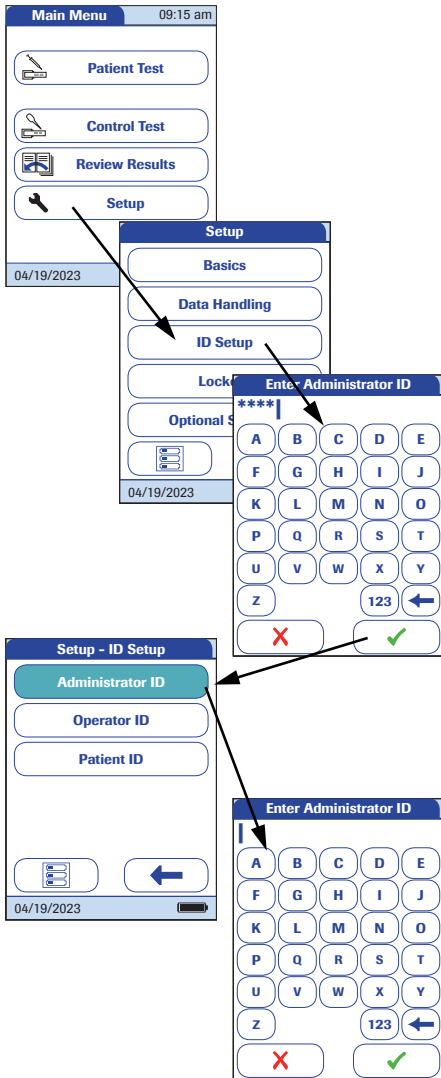
Disabling an existing *Administrator ID*:

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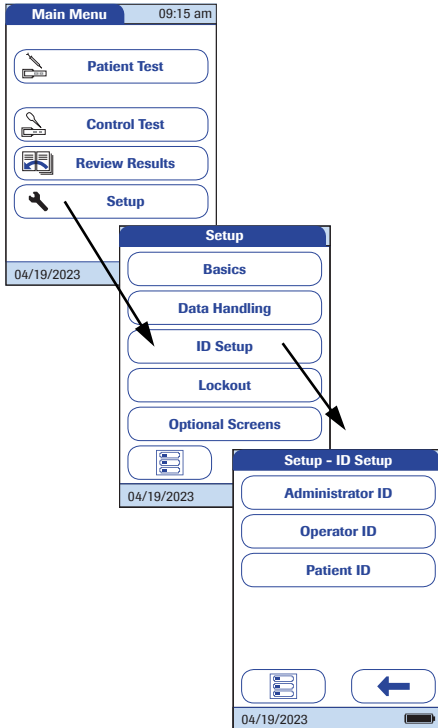
1 From the *Main Menu*, touch **Setup** to open the meter settings.

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)
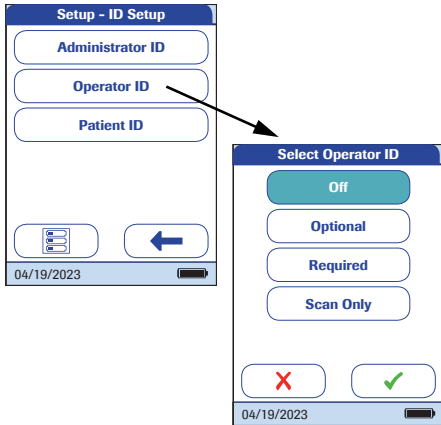
Setup – ID Setup
Administrator ID
Operator ID
Patient ID

04/19/2023

Select Operator ID
Off
Optional
Required
Scan Only

04/19/2023

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.

Operator ID

Alphanum.

Numeric

Max. Length:

20 ↑ ↓

✗ ✓

04/19/2023

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

You may select from the following options:

■ **Alphanum.** (alphanumeric)
Enter any combination of A - Z and 0 - 9. Additionally "." (period), or "-" (hyphen) may be used.

■ **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 ↑ or ↓ to set the number of characters (length) of choice.

9 Touch ✓ to save this setting, or touch ✗ to exit this menu without saving any changes.

The 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 a WLAN connection or the Handheld Base Unit are required (for more details see "Data handling", starting on page 177).

With an *Operator* list being transferred to the meter, the *Operator ID* options are different from the options in "standalone" mode.
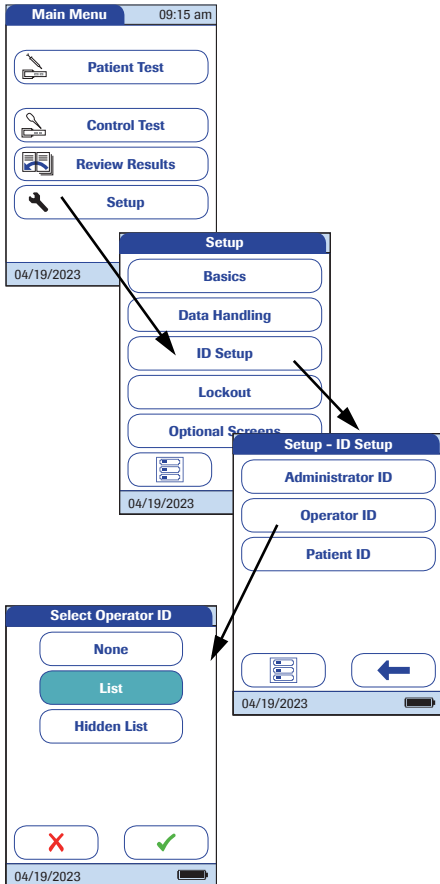
1 From the *Main Menu*, touch **Setup** to open the meter settings.

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 a WLAN connection or the Handheld Base Unit are required (see page 177).
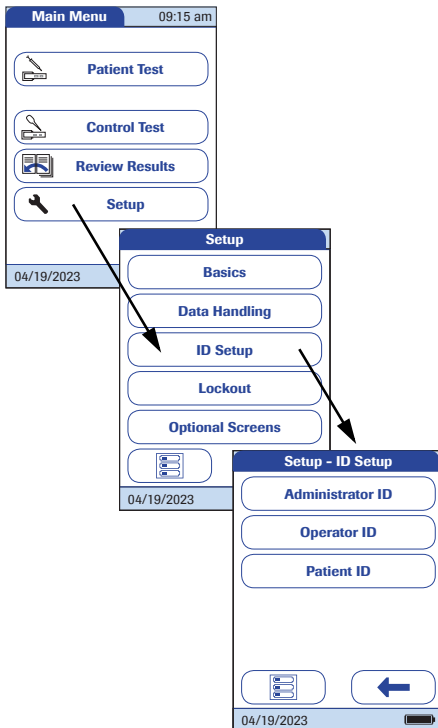
1 From the *Main Menu*, touch **Setup** to open the meter settings.

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.)
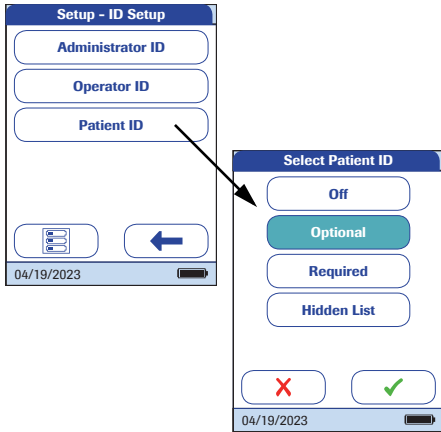
Setup – ID Setup
Administrator ID
Operator ID
Patient ID

04/19/2023

Select Patient ID
Off
Optional
Required
Hidden List

04/19/2023

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.

Patient ID

Alphanum.

Numeric

Max. Length:

20

✗   ✓

04/19/2023

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 A - Z and 0 - 9. Additionally "." (period), or "-" (hyphen) may be used.

■ **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 ↑ or ↓ to set the number of characters (length) of choice.

9   Touch ✓ to save this setting, or touch ✗ to exit this menu without saving any changes.

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

107

3.5 *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 101) 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.
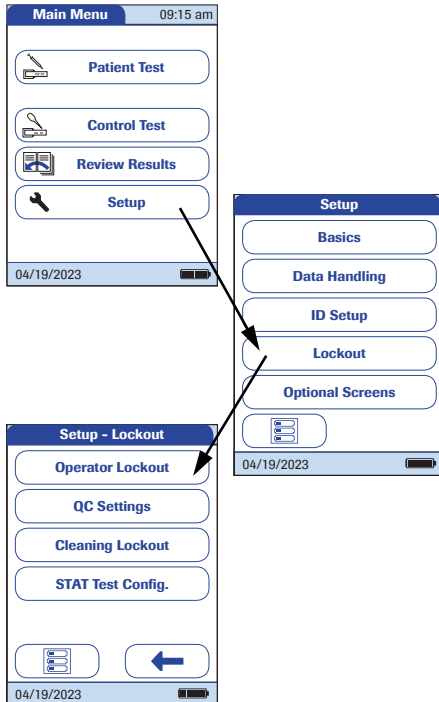
1 From the *Main Menu*, touch **Setup** to open the meter settings.

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**

Select Operator Lockout
No
Daily
Weekly
Monthly
Every 3 Months
✕   ✓
04/19/2023
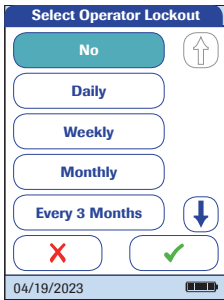
5 Touch ⬆ or ⬇ to display the option of choice on the screen. If the arrow is just an outline ⬆ ⬇, this means no other options are available in the direction indicated.

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.

Select Operator Lockout

No of Levels

One Level

Two Levels

❌   ✔️

04/19/2023
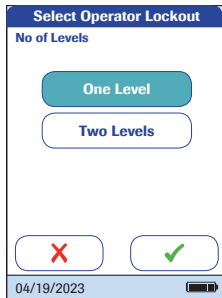
8 Quality control tests may include one or two levels. Select the number of levels which must be performed (not applicable, if you selected **No**).

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)
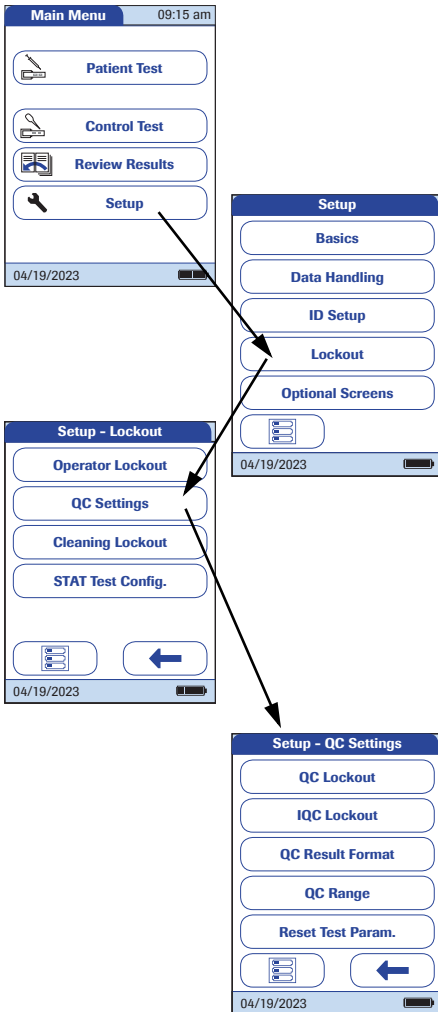
Main Menu	09:15 am
Patient Test	
Control Test	
Review Results	
Setup	
04/19/2023	

Setup
- Basics
- Data Handling
- ID Setup
- Lockout
- Optional Screens

04/19/2023

Setup – Lockout
- Operator Lockout
- QC Settings
- Cleaning Lockout
- STAT Test Config.

04/19/2023

Setup – QC Settings
- QC Lockout
- IQC Lockout
- QC Result Format
- QC Range
- Reset Test Param.

04/19/2023

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**.

113

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 113 on how to access the *Setup-QC Settings* menu.

Setup - QC Settings
QC Lockout
IQC Lockout
QC Result Format
QC Range
Reset Test Param.
▤   ←
04/19/2023 ▬

Setup - Lockout
New Lot: Yes   No
No
Daily
Weekly
Monthly
✗   ✓
04/19/2023 ▬
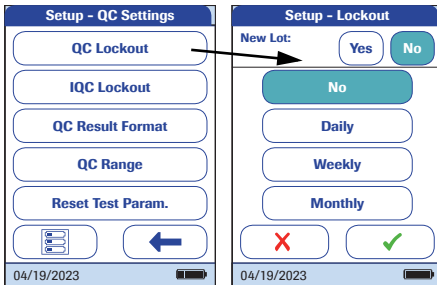
1. Touch **QC Lockout** to set regularly recurring quality control tests for available test parameters.

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**).

> If you select two levels, two **different** control levels are required for every parameter. It is not possible to unlock a QC lockout by performing multiple tests with the same control level.

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 113 on how to access the *Setup-QC Settings* menu.

Setup - QC Settings	Select IQC Lockout
QC Lockout	No
IQC Lockout	Daily
QC Result Format	Weekly
QC Range	Monthly
Reset Test Param.	
🗏 ←	✗ ✓
04/19/2023 ▭	04/19/2023 ▭

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 113 on how to access the *Setup-QC Settings* menu.

Setup - QC Settings	Select QC Result Format
QC Lockout	Pass/Fail
IQC Lockout	Value
QC Result Format	Value & Pass/Fail
QC Range	
Reset Test Param.	
04/19/2023	04/19/2023
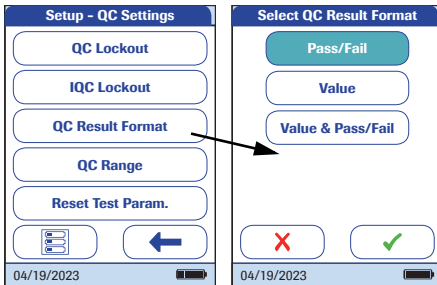
1. Touch **QC Result Format** to set the display format.

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

The quality control range for Troponin T, D-Dimer and proBNP can be customized to comply with local guidelines. The *Custom Range* 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 113 on how to access the *Setup-QC Settings* menu.

> Do not use the *Custom Range* option when using level 1 controls. The target value is outside of the quantitative measuring range.
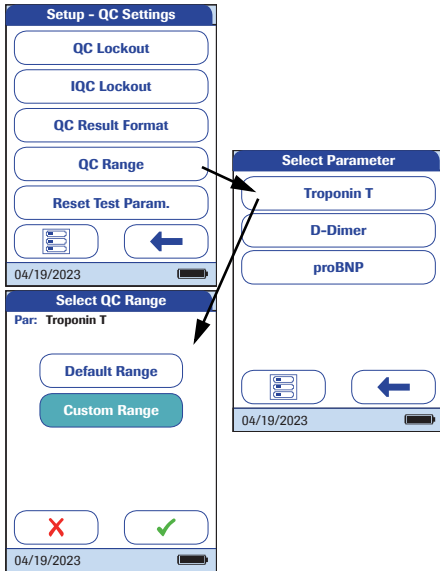
1 Touch **QC Range** to set the quality control range.

2 Touch the button with the parameter you wish to set.

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).

3 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.

Select QC Range
Par: **Troponin T**

Default Range

Custom Range

✗ ✓

04/19/2023

Select Deviation
Par: **Troponin T**

Deviation from target value
(in %):

21 ⬆ ⬇

✗ ✓

04/19/2023
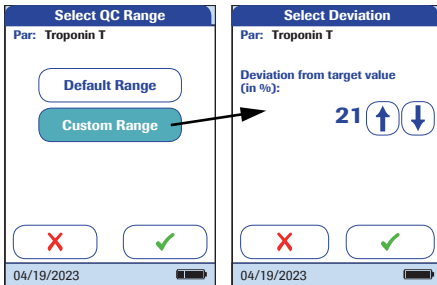
If you selected **Custom Range**, the *Select Deviation* screen opens and offers you the option of customizing the deviation from target value (percentage value).

> 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%).

4 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 113 on how to access the *Setup-QC Settings* menu.
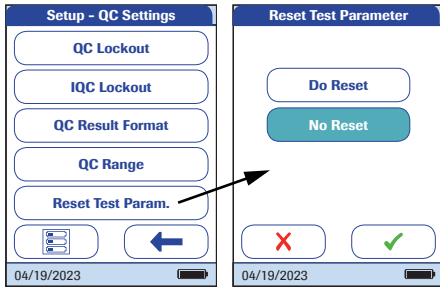
5 Touch **Reset Test Param.** to reset all stored test parameters and QC lockouts.

6 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.
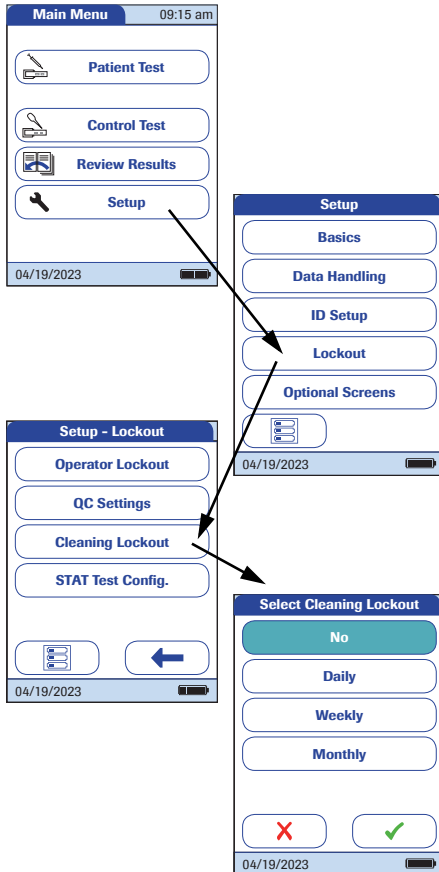
Main Menu	09:15 am
Patient Test	
Control Test	
Review Results	
Setup	
04/19/2023	

Setup
Basics
Data Handling
ID Setup
Lockout
Optional Screens
04/19/2023

Setup - Lockout
Operator Lockout
QC Settings
Cleaning Lockout
STAT Test Config.
04/19/2023

Select Cleaning Lockout
No
Daily
Weekly
Monthly
✗   ✓
04/19/2023

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.

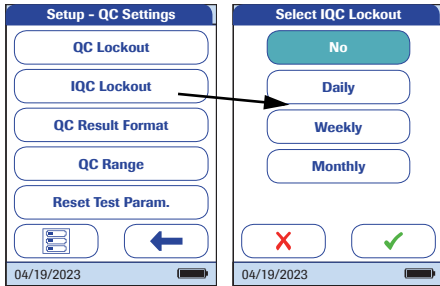**STAT test configuration**

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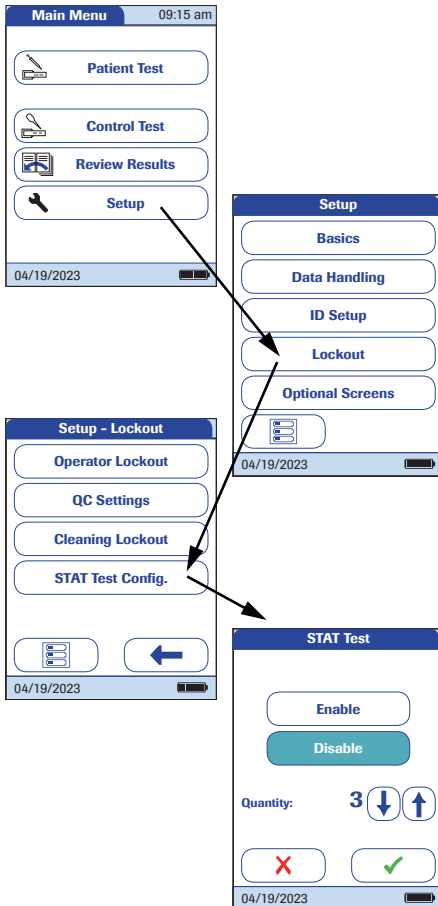
1 From the *Main Menu*, touch **Setup** to open the meter settings.

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 ⬆ or ⬇ 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.

3.6 *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.

Main Menu	09:15 am

- Patient Test
- Control Test
- Review Results
- Setup

04/19/2023

Setup

- Basics
- Data Handling
- ID Setup
- Lockout
- Optional Screens

04/19/2023

Setup – Optional Screens

- Start Info
- Result Login
- Result Confirmation

04/19/2023
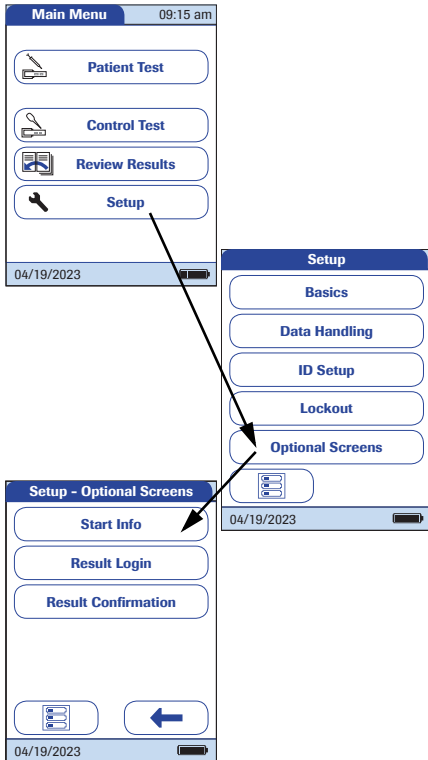
1 From the *Main Menu*, touch **Setup** to open the meter settings.

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.
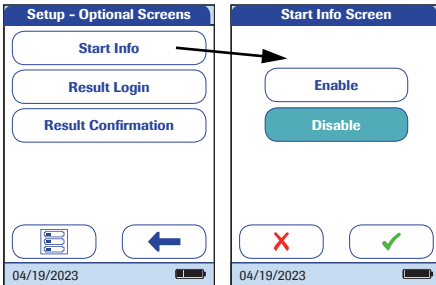
3 Touch **Start Info**.

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.
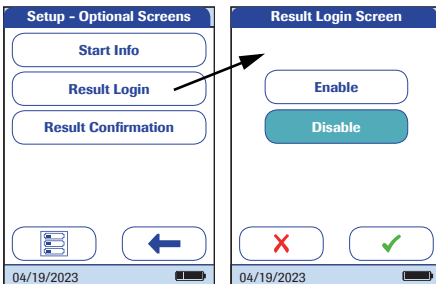
6 Touch **Result Login**.

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.

Setup – Optional Screens	Res. Confirmation Screen
Start Info	
Result Login	Enable
Result Confirmation	Disable
04/19/2023	04/19/2023
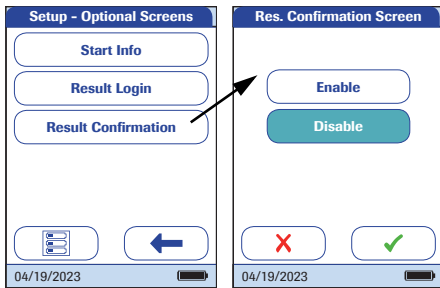
9 Touch **Result Confirmation**.

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.

4   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

⚠   Before use, visually check if the packaging of the Cardiac pipettes and/or the pipettes are intact. If the needle falls off or gets stuck during use, do not try to re-cap it. Stop using the pipette immediately and dispose of it in a sturdy sharps container (in accordance with applicable local regulations and directives and your facility's guidelines). This information applies to the following products:

■   Cardiac pipettes 150 µL 20 pc. (int.) (REF 11622889190)
■   Syringe 150 µL 5 pc. Japan (REF 05904528001)

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 197).

■ … 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 "Maintenance and Care" on page 183.

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.

■ … store the meter in a dusty environment 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

⚠️
WARNING

Proper sample collection
In order to avoid false test results which may lead to inaccurate thera-peutic decisions adhere to the following when collecting blood samples:

■ Only use **heparinized venous whole blood** 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: Never use Roche CARDIAC pipettes for blood sampling directly from the vein nor for administering injections. They are not sterile-packaged and do not contain anti-coagulants. Roche CARDIAC pipettes are intended only for drawing the sample from the blood collection tube and applying it to the test strip. See page 145.

⚠️

■ 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 17.

4.1   Preparing to test

1 Prepare the required test strips (shown here: Roche CARDIAC POC 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.
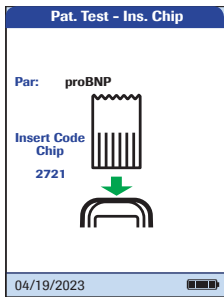
- Each test strip box contains its own code chip. Make sure you have the code chip at hand before performing the first test with a new test strip lot.

- 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 and electrostatic discharges. 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.

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 does not match the test strip lot, is missing or incorrectly inserted, an error message appears in the display (see "Troubleshooting" starting on page 193).

Test steps (overview)

The following illustration shows the steps performed during testing. The steps you actively per-
form 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 dif-
ferent, 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)

1	2	3
Powering on	Powering on	Powering on
Self-check	Self-check	Self-check
Main menu	Log in/list	Log in/list
Patient test	Main menu	Main menu
Test strip	Patient test	Patient test
Sample	Test strip	Patient ID/list
Result	Sample	Test strip
	Result	Sample
		Result
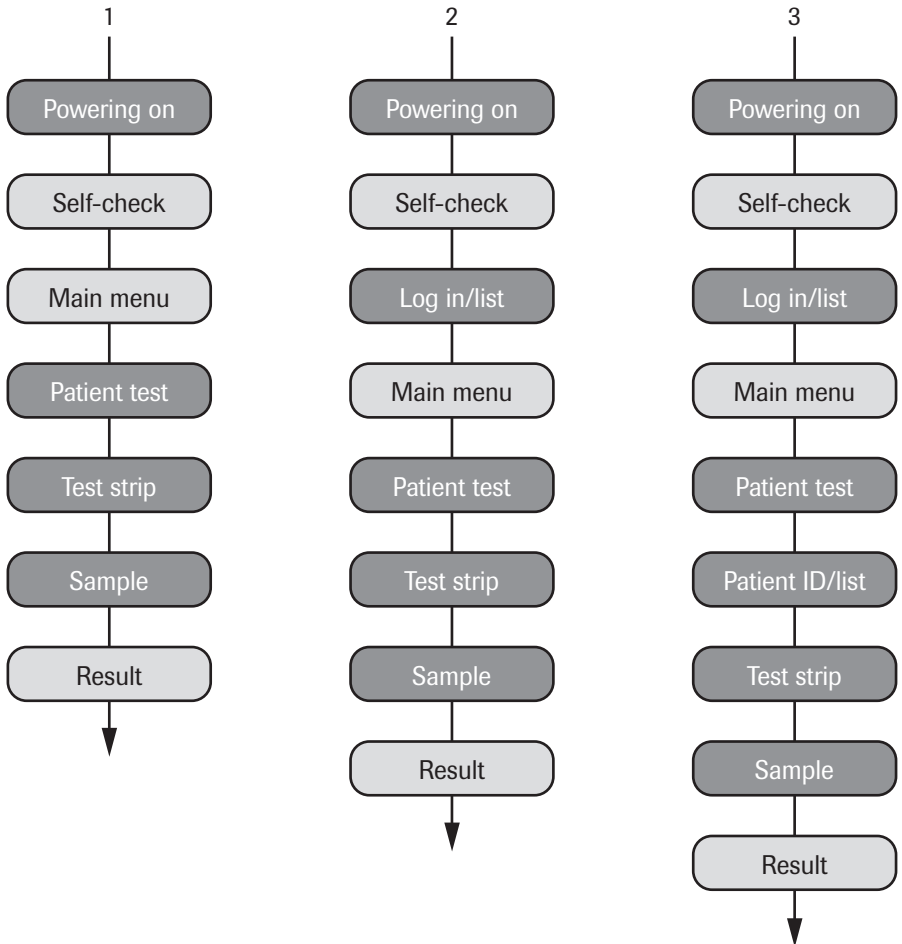
Powering on the meter

1   Power the meter on by pressing the ⏻ button.

> You can also power on the meter directly by connecting the power adapter or by placing the meter on the Handheld Base Unit.
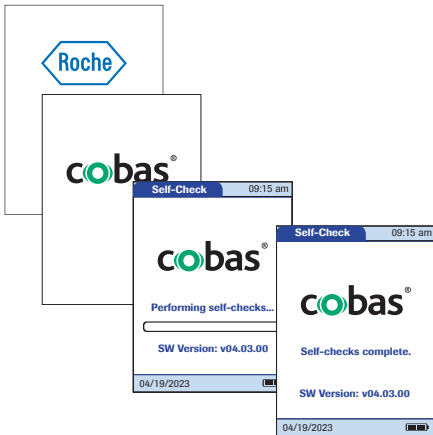
The meter performs a self-check at startup.

Logging in

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

Without operator login required

Main Menu 09:15 am Patient Test Control Test Review Results Setup 04/19/2023	**2** Wait until the main menu is displayed.
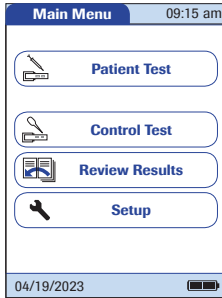
With operator login (no operator list)
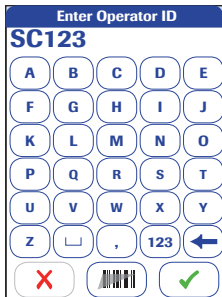
Enter Operator ID **SC123** A B C D E F G H I J K L M N O P Q R S T U V W X Y Z ⎵ , 123 ← ✗ ‖‖‖ ✓	**2** Enter or scan your *Operator ID*. **3** Touch ✓ to confirm your entry. **4** Wait until the main menu is displayed.

With operator login (list available)
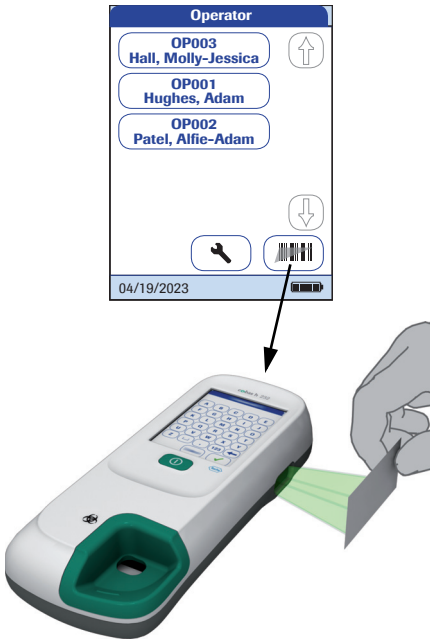
2 If an operator list exists, wait until this list is displayed.

3 Touch ⬆ or ⬇ 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 📇

■ Hold the card with the barcode approx. **15 cm (6 in) from the scanner**.

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

The scanner equipped **cobas h** 232 meter described in this manual provides a camera based 2D barcode scanner, instead of the laser scanner used in previous meter versions. Established scanning procedures may need some corresponding adjustments:

■ the nominal distance between scanner and barcode is slightly different

■ avoid reflections on the barcode (e.g. by reflective foils etc.)

■ ensure an adequate size and quality of barcodes

See Appendix A for further details on barcode handling.
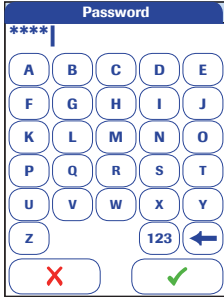
4 Enter the password.

5 Touch ✓ to confirm your entry, or touch ✗ to display the operator list again.

6 Wait until the main menu is displayed.

With operator login (list hidden)
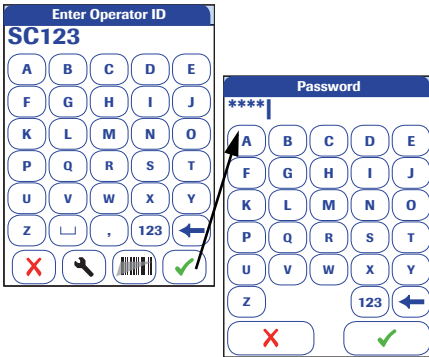
2 Enter or scan an existing *Operator ID* from the hidden list.

3 Touch ✓ to confirm your entry.

4 Wait until the main menu is displayed.

5 Enter the password.

6 Touch ✓ to confirm your entry, or touch ✗ to display the operator list again.

7 Wait until the main menu is displayed.

In the *Operator* login screens with list or hidden list you can touch 🔧 to open the *Configuration Manager*. The *Configuration Manager* is required to renew expired TLS certificates in case of missing administrator access to the meter setup. For more information, contact your local affiliate or Roche Service representative.

Main Menu	09:15 am
Patient Test	
Control Test	
Review Results	
Setup	
Logout	
04/19/2023	
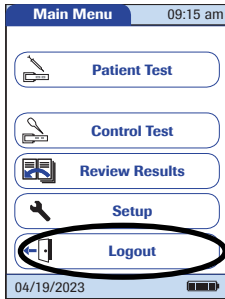
When the tests are completed or another operator wants to perform additional tests, touch **Logout** to log out. The meter returns to the display of the operator list.

4.2 Performing a test
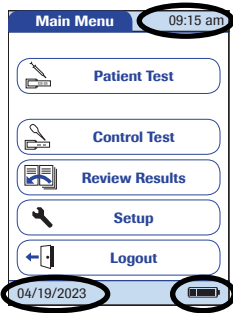
1 Check the charge level of the battery pack. If there are no bars left in the battery icon, you cannot perform any more tests. For further details see page 29.

2 Check that the date and time are correct. Correct any incorrect settings as described in the chapter entitled "Meter Setup/Setting the date".
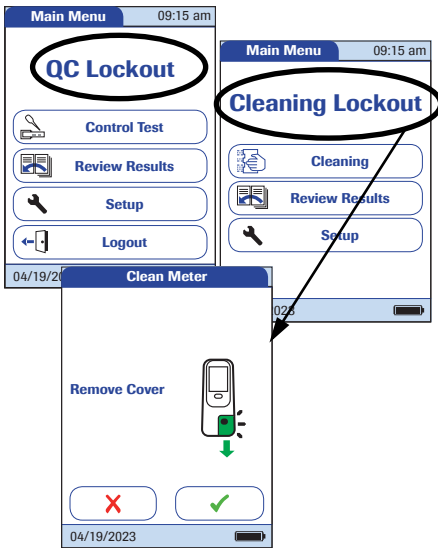
If a *QC lockout* is displayed instead of **Patient Test**, you must run a quality control test before you can perform a test (see "Control Testing and Quality Control" starting on page 155). If the meter is locked, a test can only be performed as a STAT test (if this function is enabled and if there 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 "Maintenance and Care" beginning on page 183. Once you have re-attached the test strip guide cover and powered the meter on again, the meter is no longer locked.
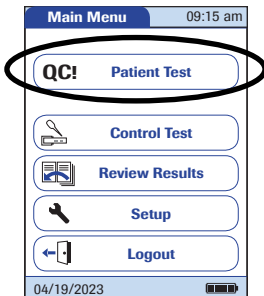
If the **Patient Test** button is available, but a lockout is displayed, you must first perform a quality control test for certain test parameters. Other test parameters are not affected.

Without patient list

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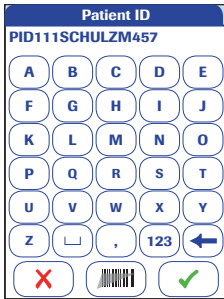
4 If you selected the *Patient ID* as *optional*, you **can** enter or scan a *Patient ID*. If you selected the *Patient ID* as *required*, you **must** enter or scan the *Patient ID*. If you selected no *Patient ID* (*None*), the meter automatically proceeds to the next step.

5 Touch ✓ to confirm the ID, or touch ✗ to cancel the ID entry.

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.
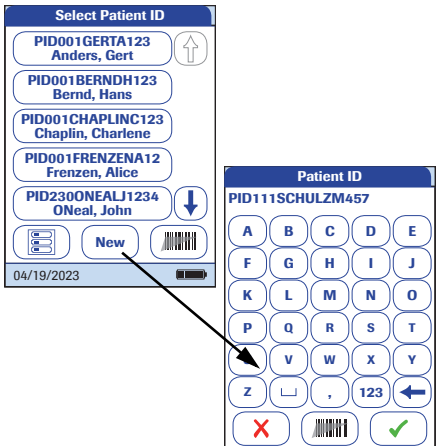
4 Touch ⬆ or ⬇ to scroll through the list. Select the patient to be tested by touching the corresponding button.

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.

141

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

■ a card with the barcode approx. 15 cm (6 in) 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

Pat. Test – Ins. Strip

Pat: PID111SCHULZM457
        SCHULZ, MANFRED
Op: JONES, TOM

Insert Strip

✕

04/19/2023
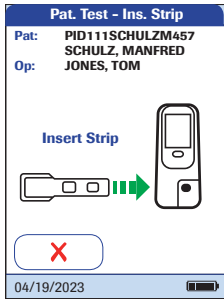
1 The test strip icon prompts you to insert a test strip. Remove the test strip from its foil pouch.

2 Hold the test strip so that the application area and test area are facing up.

3 Hold the test strip straight and flat. Insert it in the test strip guide of the meter. Be careful that the strip is not shifted, angled or tilt during insertion. It is also 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).

⚠ **WARNING**

Test strip deterioration
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 130.

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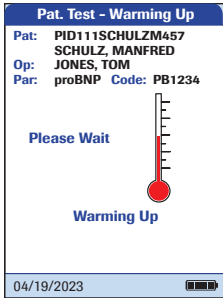
The thermometer icon shows that the test strip is warming up. A beep tone indicates when the warming-up process is complete (provided the beeper is enabled).

Select Operator ID

Pat: PID111SCHULZM457
SCHULZ, MANFRED
Op: JONES, TOM
Par: proBNP Code: PB1234

150 µL

Apply
Sample

4:10 Min

✓

04/19/2023
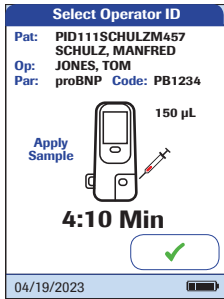
The pipette icon indicates that the meter is ready to perform the test and is waiting for blood to be applied.

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). The test strip is now unusable, repeat the test with a new test strip.

In case of errors, see "Troubleshooting" on page 193.
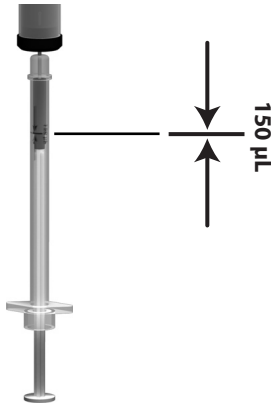
4   Use the Roche CARDIAC Pipette (or other suitable pipettes with a pipetting volume of 150 µL). Draw **exactly 150 µL** (to the blue mark on the pipette) heparinized blood from the blood collection tube.

150 µL

⚠
WARNING

Potential risk of incorrect patient results

In order to avoid inaccurate test results, make sure the blood sample is homogenized (by gently swirling the blood collection tube several times) and ensure the blood sample contains no air bubbles when it is in the pipette.

Inaccurate test results may lead to inappropriate therapeutic decisions.

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.

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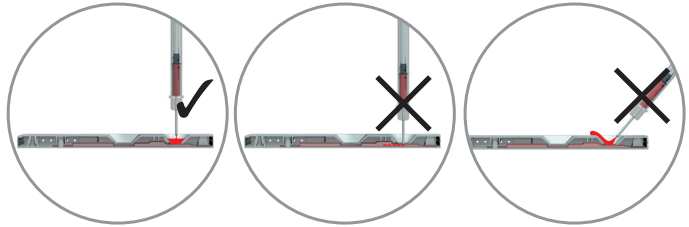
5 Apply the entire sample to the sample application area of the test strip.

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

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

After you confirm that the sample has been applied, or if the meter automatically recognises that the sample has been applied, the ✔ button disappears.
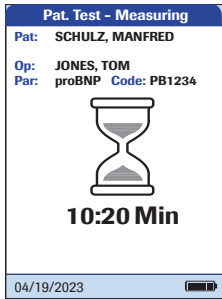
The hourglass icon spins until the sample has been detected and the test begins. The time remaining for the test is displayed.

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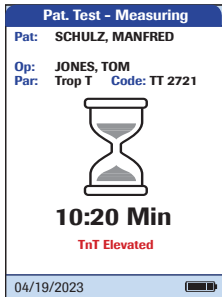
For Troponin T only:
As soon as the meter detects a signal (this may take a few minutes), a qualitative message *(TnT Elevated)* appears under the hourglass icon (see illustration).

The final quantitative result is displayed when the test is completed. Decisions on further treatment of the patient should be based on the final result only. Refer to the Roche CARDIAC T Quantitative or Roche CARDIAC POC Troponin T package insert for more details.

```
┌─────────────────────────┐
│    Pat. Test – Result   │
│ Pat:  PID111SCHULZM457  │
│       SCHULZ, MANFRED   │
│ Op:   JONES, TOM        │
│ Par:  proBNP  Code: PB1234 │
│                         │
│    04/19/2023  10:17    │
│     620 pg/mL           │
│                         │
│                         │
│                         │
│  (▤)    (▤)    (○)      │
│ 04/19/2023        ▭▭▭   │
└─────────────────────────┘
```

The test result is shown and stored automatically.

When interpreting your result, please read the test strip package insert carefully.
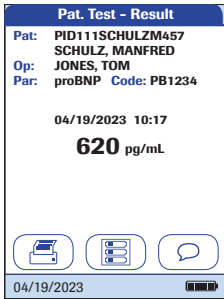
Print button:
Print results (infrared interface)

QR Code button:
Display result as QR code

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 ① button for approximately 1 second if you do not wish to perform any further tests.

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 "Maintenance and Care" on page 183).

Displaying, confirming or adding comments to results

As described in the chapter "Optional Screens setup" starting on page 124, there are many options for displaying results that can be activated:

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

```
┌─────────────────────────────┐
│    Pat. Test – Op. Login     │
├─────────────────────────────┤
│ Pat:  PID111SCHULZM457       │
│       SCHULZ, MANFRED        │
│ Op:   JONES, TOM             │
│ Par:  proBNP  Code: PB1234   │
│                              │
│                              │
│    Measurement Complete      │
│                              │
│                              │
│                              │
│                  ┌───────┐   │
│                  │  →▯   │   │
│                  └───────┘   │
├─────────────────────────────┤
│ 04/19/2023          ▭▭▭      │
└─────────────────────────────┘
```

1 Touch the button for *Operator Login*.

2 Log in as described on page 136.

The result is now displayed.

```
   Pat. Test - Confirm.
Pat:  PID111SCHULZM457
      SCHULZ, MANFRED
Op:   JONES, TOM
Par:  proBNP  Code: PB1234


      04/19/2023  10:17
         620 pg/mL


      Measurement OK?

  ┌────────┐   ┌────────┐
  │ Reject │   │ Accept │
  └────────┘   └────────┘
04/19/2023          ▭▭▭
```
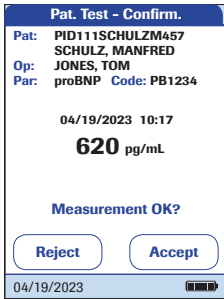
If the test result requires a confirmation:

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

You can choose to either

■ **Reject**

■ **Accept**

```
    Pat. Test - Result
Pat:  PID111SCHULZM457
      SCHULZ, MANFRED
Op:   JONES, TOM
Par:  proBNP  Code: PB1234


      04/19/2023  10:17
         Rejected




  ┌───┐  ┌───┐  ┌───┐
  │ 🖨 │  │ 📋 │  │ 💬 │
  └───┘  └───┘  └───┘
04/19/2023          ▭▭▭
```
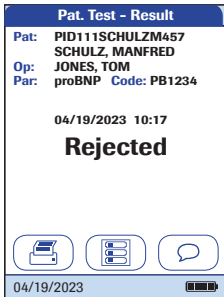
If you reject the result, the result value is no longer displayed. However, the test entry is stored.

If you miss to finish a required confirmation before the meter is powered off automatically, the test result will be stored and displayed along with a "Result not validated" comment. However, if a confirmation is required, the meter reminds you to do so with a series of triple beeps (once a minute for the last 3 minutes) before powering off.

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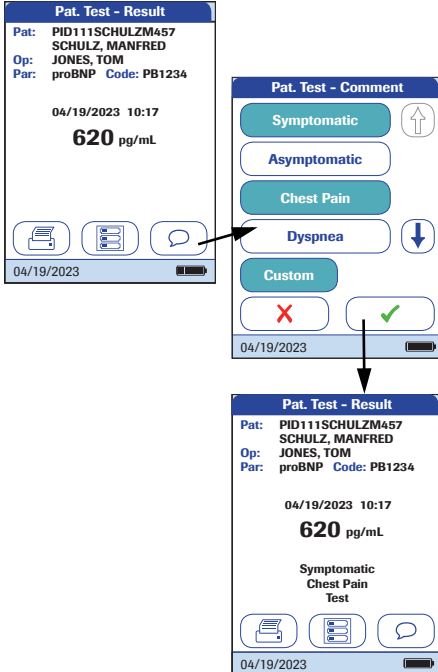
If you want to add a comment to a test result:

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.

Displaying the test result as QR code

> The QR code button only appears if the QR code display function is activated (see page 68 and following). Otherwise it is not displayed.
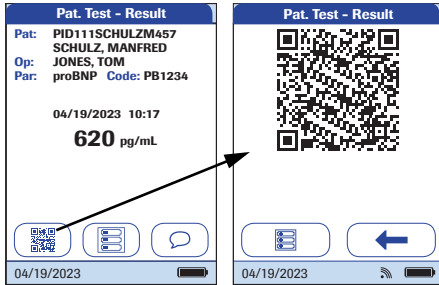
1   Touch to display the result as QR code.

2   Touch ⬅ to return to the standard result display.

The size of the QR code displayed on the screen varies according to the amount of data encoded.

STAT tests

STAT tests are a limited number of tests that can be performed in emergency situations, see page 122. 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.
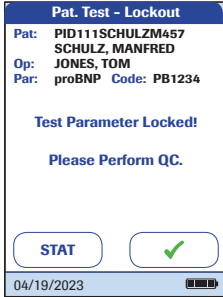
1 To perform the measurement **without** performing a quality control test, touch **STAT**, or:

2 Touch ✓ to perform the quality control test before the measurement.
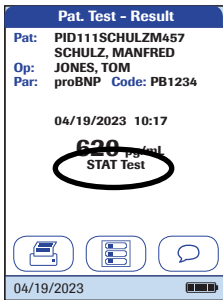
When a STAT test is performed, this information is stored with the result. The number of permissible STAT tests is reduced by 1. After all pending quality control tests are performed, the specified number of STAT tests is available again in case of a new lockout.

This page intentionally left blank.

5 Control Testing and Quality Control

The **cobas h** 232 meter 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 meter 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.

⚠️ **WARNING**

Potential risk of incorrect patient results
Failure to check the system regularly by performing quality control tests may lead to incorrect results and therefore to inappropriate therapy decisions. To ensure that the system is functioning properly adhere to the manufacturer recommendations on quality control testing given in the tables below.

Manufacturer recommended frequency of quality control tests:

Frequency	Material to test	Reason	Release criteria
Daily*	CARDIAC IQC High and CARDIAC IQC Low	Verification of the proper functioning of the optical system	Both levels are "Pass"

*only on days when the **cobas h** 232 meter is used for measurements

Manufacturer recommended use:

Frequency	Material to test	Reason	Release criteria
Once a month	Roche CARDIAC Controls	To verify adequate storage at customer site	Results are within the range provided by the manufacturer
With each new shipment of test strips		To verify proper functioning after transportation to customer site	
When an implausible result is obtained			
When an operator uses the **cobas h** 232 system (meter with or without scanner) for the first time		To qualify the new operator; to verify proper handling and sample dosing	
After adverse events such as dropping the meter or other strong mechanical shocks.	Roche CARDIAC Controls and CARDIAC IQC High and CARDIAC IQC Low	To verify proper functioning of the meter	Results are within the range provided by the manufacturer

QC recommendations by national associations or local hospital guidelines take precedence over manufacturer recommendations

5.1   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

<table>
<tr>
<td>⚠</td>
<td>Always refer to the package insert provided with the control material for specific handling and testing instructions.</td>
</tr>
</table>

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 108).

If you encounter a lockout for a test strip lot that no longer exists, see "Reset test parameters" on page 120. Please note that, when you use this method, **all** saved test parameters and QC lockouts will be deleted.

5.2   Performing a quality control test

Quality control (QC)

1   Power the meter on by pressing the ① button.

You can also power on the meter directly by connecting the power adapter or by placing the meter on the Handheld Base Unit.

Depending on the system settings the operator my have to log in and/or enter a password. Follow the procedures as described on page 136.
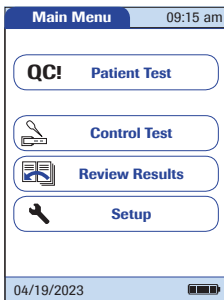
2   Wait until the main menu is displayed.
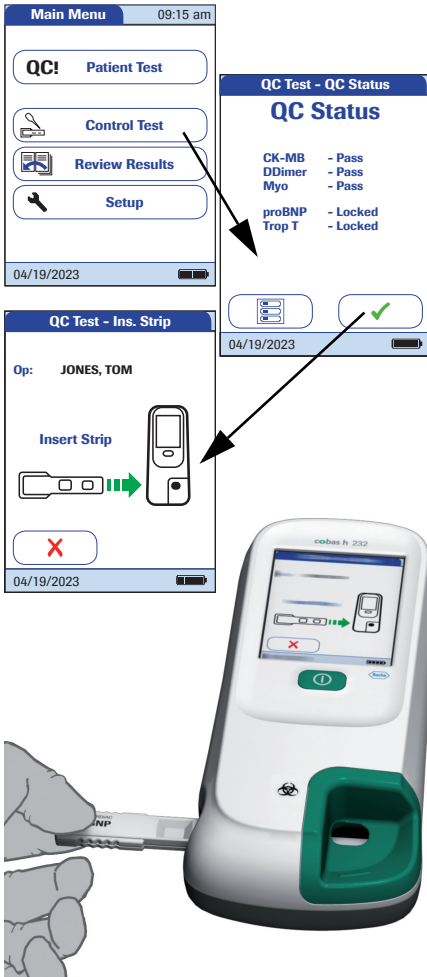
3 Touch **Control Test**.

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 area and test area are facing up.

7 Hold the test strip straight and flat. Insert it in the test strip guide of the meter. Be careful that the strip is not shifted, angled or tilt during insertion. It is also 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).

⚠ **CAUTION**

Test strip deterioration
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.

159

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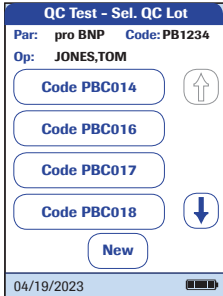
As with the test strips, a code chip is also provided with the control materials. The information on the code chip is stored in the memory so you can use the same control materials again at any time.

QC Test - Sel. QC Lot

Par: pro BNP	Code: PB1234
Op: JONES,TOM	

Code PBC014

Code PBC016

Code PBC017

Code PBC018

New

04/19/2023

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

QC Test - Ins. Chip

Par: proBNP	Code: PB1234
QC: PBC014	
Op: JONES, TOM	

QC

Insert Code Chip

PBC014

04/19/2023
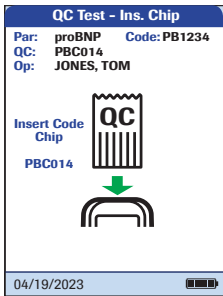
If you are using a new control material, remove the code chip from the meter and insert the code chip that came with the control material instead.

160

QC Test – Sel. QC Level

Par:	proBNP Code: PB1234
QC:	PBC014
Op:	JONES, TOM

Level 1

Level 2

←

04/19/2023
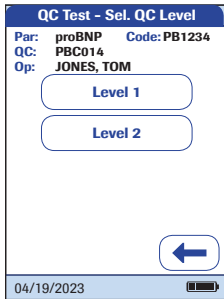
9 If the control material box contains more than one level, select the level of choice for this measurement.
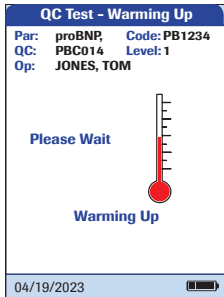
QC Test – Warming Up

Par:	proBNP, Code: PB1234
QC:	PBC014 Level: 1
Op:	JONES, TOM

Please Wait

Warming Up

04/19/2023

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).

QC Test – App. QC

Par:	proBNP Code: PB1234
QC:	PBC014 Level: 1
Op:	JONES, TOM

150 µL

Apply QC

4:10 Min

✓

04/19/2023
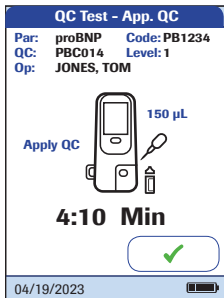
The pipette icon indicates that the meter is ready to perform the test and is waiting for the sample to be applied.

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 193.

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.

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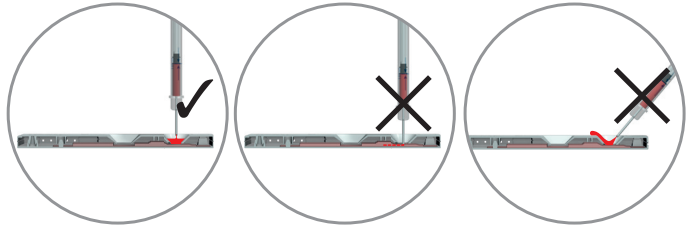
10 Using the pipette, draw up the dissolved contents of the vial.

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

12 Touch ✔ to confirm that the sample has been applied.
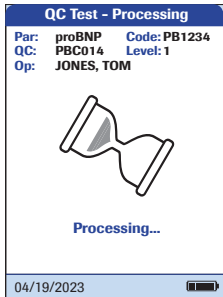
QC Test – Processing

Par:	proBNP	Code:	PB1234
QC:	PBC014	Level:	1
Op:	JONES, TOM		

Processing...

04/19/2023

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.
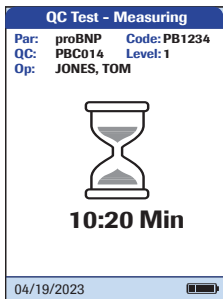
QC Test – Measuring

Par:	proBNP	Code:	PB1234
QC:	PBC014	Level:	1
Op:	JONES, TOM		

10:20 Min

04/19/2023

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.

QC Test – Result	
Par: proBNP	**Code:** PB1234
QC: PBC014	**Level:** 1
Op: JONES, TOM	
04/19/2023 10:17	
Pass: 329 pg/mL	
(350 / 300–400 pg/mL)	

QC Test – Result	
Par: proBNP	**Code:** PB1234
QC: PBC014	**Level:** 1
Op: JONES, TOM	
04/19/2023 10:17	
Fail: 490 pg/mL ↑	
(350 / 300–400 pg/mL)	
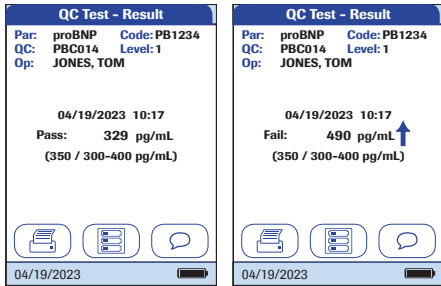
The result of this quality control test is displayed and is automatically saved to memory.

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 117 and "Settings summary" on page 50.

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 ⓵ button for approximately 1 second if you do not wish to perform any further tests.

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 "Maintenance and Care" on page 183).

Instrument quality control (IQC)

The Roche CARDIAC IQC test serves as a performance check for the optical system of the **cobas h** 232 meter. 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 meter is functioning properly. If "Fail" appears, the measured reflectance value is outside the confidence interval.
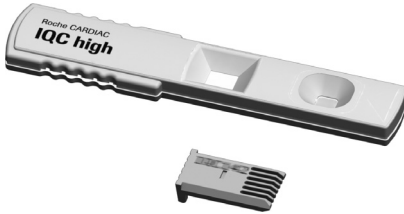
1 Prepare the required IQC test strips (shown here: Roche CARDIAC IQC high).

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 158. The following description therefore starts at the main menu.
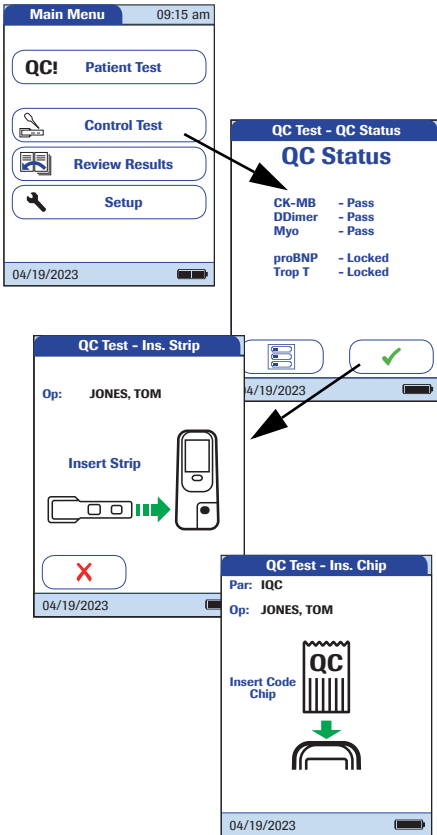
3 Touch **Control Test**.

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 159.

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.

167

```
┌─────────────────────────────────┐
│     QC Test – Measuring         │
│ Par:  IQC          Code: IQC702 │
│                    Level:  1    │
│ Op:   JONES, TOM                │
│                                 │
│            ⏳                    │
│                                 │
│                                 │
│ 04/19/2023              ▮▮▮▯    │
└─────────────────────────────────┘
```
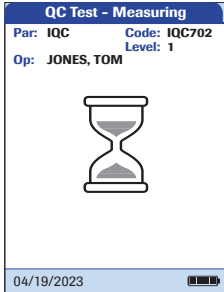
The hourglass icon is displayed and the (internal) measurement begins.

```
┌─────────────────────────────────┐
│     QC Test – Result            │
│ Par:  IQC          Code: IQC702 │
│                    Level:  1    │
│ Op:   JONES, TOM                │
│                                 │
│       19/04/2023    10:17       │
│           83 %                  │
│        (85 / 82 – 88 %)         │
│                                 │
│   🖨      ▤▤       💬            │
│ 04/19/2023              ▮▮▮▯    │
└─────────────────────────────────┘
```
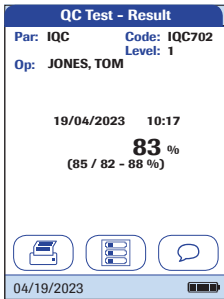
The result of this IQC quality control test is displayed as *Pass* or *Fail* (default setting) or in the format selected in the QC result format setting.

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 117 and "Settings summary" on page 50.

6   Review Results

The **cobas h** 232 meter can save 2000 patient test results as well as 500 quality control and 200 IQC 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 $\textcircled{\textbf{I}}$ button.

> You can also power on the meter directly by connecting the power adapter or by placing the meter on the Handheld Base Unit.

> Depending on the system settings the operator my have to log in and/or enter a password. Follow the procedures as described on page 136.

2   Wait until the main menu is displayed.

169
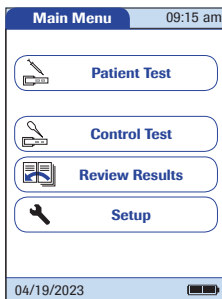
From the *Main Menu* you have access to all stored results, sorted by selectable criteria:

■   **Patient History**

■   **All Results**

■   **QC Results** (Quality Control)

■   **IQC Results** (Instrument Quality Control)

■   **Maintenance History**
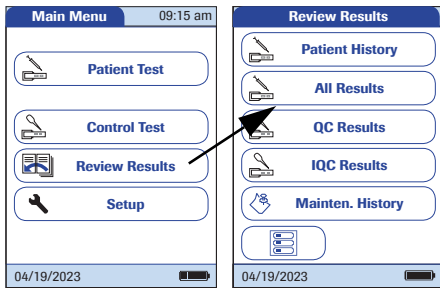
3   Touch **Review Results**.

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

🖨 The print button only appears if the printer function is activated. Otherwise it is not displayed.

▦ **Patient results only:** The QR code button only appears if the QR code display function is activated. Otherwise it is not displayed.

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.
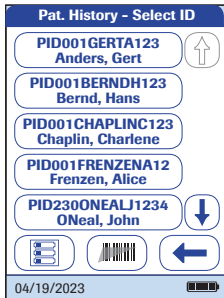
Pat. History – Select ID

- PID001GERTA123
  Anders, Gert
- PID001BERNDH123
  Bernd, Hans
- PID001CHAPLINC123
  Chaplin, Charlene
- PID001FRENZENA12
  Frenzen, Alice
- PID230ONEALJ1234
  ONeal, John

04/19/2023

1 Touch ⬆ or ⬇ 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.

Single Patient Results

Pat: PID111SCHULZM457
      SCHULZ, MANFRED

- DDimer High
  02/12/23 08:30
- proBNP 620 pg/mL
  02/08/23 09:49
- DDimer 1.3 µg/mL
  01/21/23 09:15

04/19/2023

Patient Result

Pat: PID111SCHULZM457
      SCHULZ, MANFRED
Op: JONES, TOM
Par: proBNP Code: PB1234

02/08/2023 09:49

620 pg/mL

New Strip Lot

04/19/2023
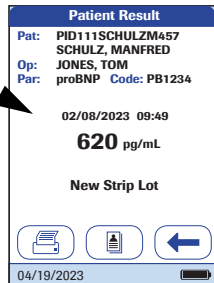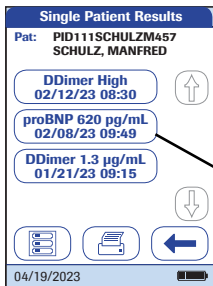
3 Touch ⬆ or ⬇ to display the test result of choice on the screen.

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

171

All results

This memory area contains a list of all patient tests, sorted chronologically. From here, you can call up results for specific times.
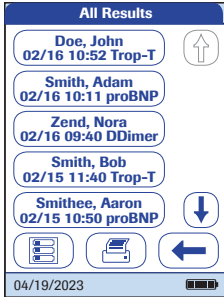
1 Touch ⬆ or ⬇ to display the entry of choice on the screen.

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 171).

Quality control (QC) results

This memory area contains all test parameter-specific quality control tests (QC, starting on page 158) that were run, sorted chronologically. The most recent results are at the top of the list.
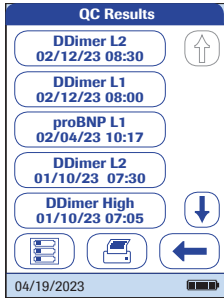
1 Touch ⬆ or ⬇ to display the entry of choice on the screen.

2 Touch the entry you want to open.

The entry is displayed.

173

Instrument quality control (IQC) results

This memory area contains all instrument quality control tests (IQC, starting on page 166) that were run, sorted chronologically. The most recent results are at the top of the list.

IQC Results IQC Pass 04/11/23 07:59 IQC Pass 04/07/23 08:16 IQC Fail 04/07/23 08:01 IQC Pass 03/29/23 08:30 IQC Pass 03/29/23 09:02 04/19/2023	**1** Touch ⬆ or ⬇ to display the entry of choice on the screen. **2** Touch the entry you want to open.
QC Test – Result Par: IQC Code: IQC702 Level: 1 Op: JONES, TOM 04/19/2023 07:59 **83** % (85 / 82 – 88 %) 04/19/2023	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.

Maintenance History
Meter Cleaned 04/13/2023 08:00
Meter Cleaned 04/05/2023 08:20
Meter Cleaned 03/29/2023 09:00
New Battery Pack 03/21/2023 08:30
Meter Cleaned 03/14/2023 08:10
04/19/2023
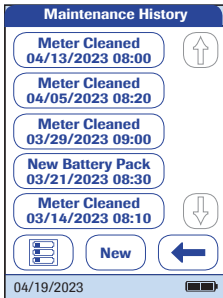
1 Touch ⬆ or ⬇ to display the entry of choice on the screen.

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 ⬆ or ⬇ 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.

This page intentionally left blank.

7 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 either with WLAN (if the meter is equipped with WLAN) or with the (optional) Handheld Base Unit from Roche Diagnostics, 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.

> Preferably use incremental list updates instead of complete list updates, if your DMS supports this setup option.

■ 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 101, for details on *Operator Lockout* see page 109.

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 71).

■ For wired communication, 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.

For wireless communication, additional installation steps via DMS are required. Please contact your local Roche representative for further information. For further details on WLAN configuration see Appendix B.

Software updates

Software updates are installed via DMS. The meter accepts updates triggered by the DMS only when it is idle and when the battery icon shows at least three segments. The screen on the left will be displayed when an update is in progress.

Operator lists

After powering the meter on, an *Operator* login may be configured. If no list is available, the options described on page 101 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 205 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

8   Maintenance and Care

8.1   Conditions for storage and shipping

Storage

■   Store the system and test strips in the same environment in which they are used.

■   Do not store the meter in direct sunlight or under extreme temperature conditions.

■   Observe the limits for temperature and humidity when storing and using the meter (see Chapter 10).

Shipping

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

■ If the meter is shipped or transported over long distances, always remove the battery pack from the meter. This eliminates the possibility of the battery pack overheating due to a short-circuit in the meter. It also prevents deep discharge and other damage to the battery pack or meter.

■ Only ship undamaged battery packs. Damaged battery packs must be disposed of locally. See page 20 for the risks associated with damaged battery packs and disposal information.

■ Package the battery pack for shipping so that it cannot move around in the packaging. Also observe any other applicable national regulations.

■ When shipping via third parties (e.g., by air or parcel service), work with the carrier to check whether specific requirements need to be met in relation to the lithium-ion battery packs on the basis of national or international laws on hazardous goods and, where applicable, if special packaging and labeling requirements apply.

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

Transport safety of the Handheld Battery Pack is proven to meet the requirements of each test in the UN *Manual of Tests and Criteria*, Part III, subsection 38.3.

8.2 Cleaning and disinfecting the meter

Difference between cleaning and disinfecting

Cleaning is the physical removal of organic soiling (e.g., dirt, or other foreign material) from the meter surface.

Disinfecting is the removal of most, but not all, disease-causing and other types of micro-organisms (blood-borne pathogens) from the meter.

When should the meter be cleaned and disinfected?

■　Clean the meter to remove visible soil and organic material for safe handling and/or prior to disinfecting.

■　You can use the *Cleaning Lockout* function (see page 121) to ensure regular checks are performed.

What to clean and disinfect?

The following parts of the meter may be cleaned/disinfected:

■　The visible area of the test strip guide

■　The test strip guide cover

■　The meter housing (entire meter surface including display)

⚠ ■　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.

⚠️
WARNING

Instrument damage due to moisture

Ensure that no liquid enters the meter. If moisture enters the meter, it may cause malfunction of the instrument.

- Make sure the meter is powered off. Unplug the power adapter.
- Do not spray anything onto the meter housing.
- Do not spray into the test strip guide.
- Do not immerse the meter in liquid.
- Use only ordinary lint-free tissues.
- Do not use cloths that are saturated. Squeeze off excess solution or blot on a dry paper towel to remove any excess solution before wiping the surface of the meter.
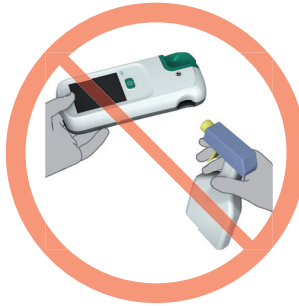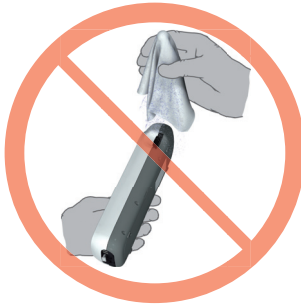
Recommended cleaning/disinfecting agents

Before using a cleaning/disinfecting solution on the meter refer to the product labeling for required contact time for cleaning/disinfecting and to ensure that the active ingredients are acceptable for use. Prepare all solutions per the manufacturer's product labeling.

Acceptable active ingredients are listed below.

Recommended cleaning agents

■   mild soapy water

■   70 % (or less) solution of isopropyl alcohol in water

Recommended disinfecting agents

■   70 % (or less) solution of isopropyl alcohol in water

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

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 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.

■　　　　With the meter powered off, 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 meter

Only use the **cleaning agents** recommended on page 187. Procede as follows for cleaning the meter.

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 dry and fresh tissue.

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

4 Clean the easily accessible and visible **pipetting field area** of the test strip guide with moistened lint-free tissues.

⚠
WARNING

Protection against instrument damage

In order to avoid instrument damage, adhere to the following:

- Clean **only the visible area** (large circle) 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.

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

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

7 Continue with disinfecting the meter.

Disinfecting the meter

Follow the procedures described above for cleaning the meter, with the following differences: Only use the **disinfecting agents** recommended on page 187.

1   Wipe the **test strip guide cover**, the **outside of the meter** and **only the visible area** of the test strip guide three times horizontally and three times vertically with a lightly moistened tissue.

2   Wait for the **disinfection time** according to the instructions of the used disinfection agent.

3   Dry the test strip guide cover and the outside of the meter with a dry and fresh tissue.

Adhere to the following:

■   Do not insert dry tissues into the test strip guide.

■   Do not insert any objects into the concealed areas of the test strip guide. That would damage the optical components of the meter.

4   Re-attach the test strip guide cover to the housing.

⚠
CAUTION

Protection against instrument damage
To avoid instrument damage, always ensure that the test strip guide cover is completely dry before reattaching it. Make sure that the cover is properly attached. If so, you will hear it snap into place.

This page intentionally left blank.
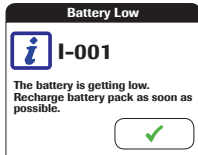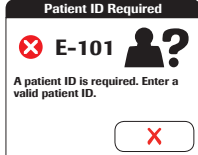
9 Troubleshooting

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 [i] 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 219).

The two different message types are illustrated below:

Display/symptom	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.

193

Errors and unusual behavior without error messages

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

Display/symptom	Description
No message or unusual behavior	
If you notice any issues with the display functionality (e.g. unexpected lines/marks on the meter display) stop using the system and contact your Roche representative.	
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 adapter, is it connected properly to the meter? Or: ▪ Place the meter in the Handheld Base Unit. Or: ▪ Is the Handheld Battery Pack 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.	■ Press the On/Off button to reactivate the meter/screen.

Display/symptom	Description
Communication Problems with the Data Management System via RF	
The **cobas h** 232 meter is unable to communicate with the Data Management System.	■ Check WLAN functionality on the meter (see the *Wireless Setup* screens in section "Diagnostics" starting on page 86). ■ Dock the RF enabled meter into a hard-wired base unit to transfer the data. ■ Reset the meter. ■ If the error persists, contact your Roche representative.

Meter reset

A hard reset should only be performed if all other remedies have failed.
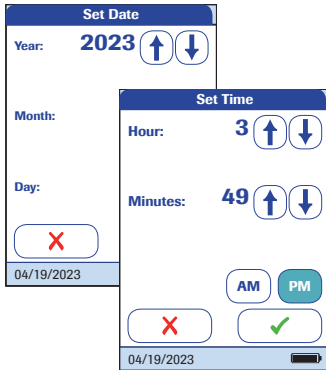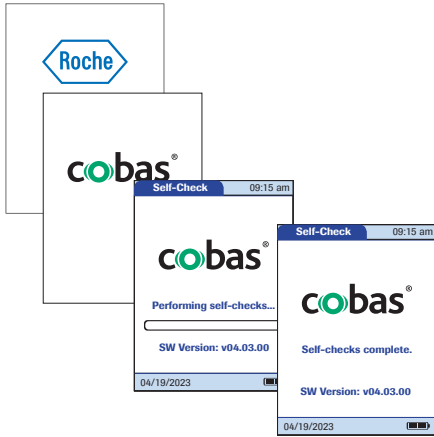
1   Place the meter on a level surface.

2   Press the (I) button for at least 12 seconds.

■   The meter powers off and on again.

■   The Roche logo is displayed.
    If the Roche logo does not appear within 60 seconds, place the meter in the Handheld Base Unit for a minimum of 15 minutes to recharge the battery pack.

■   The meter performs a system check.

■   The screens for entering the date and the time appear.

3   Enter the date and time. After you have entered the correct information, confirm each screen with ✓.

■   Unless all lockouts are disabled (see chapter 3.5), the meter will now be in QC Lockout due to the manually entered date/time.

4   Synchronize the meter's date/time with the date/time of your facility via the Handheld Base Unit or, if working wirelessly, wait at least ten minutes for the next WLAN synchronization before performing any further tests.

> Even if your configuration does not require it, we recommend always performing a QC test after a meter reset.

10 General Product Specifications

10.1 Operating conditions and technical data

Technical data

Temperature range	18-32 °C
Relative humidity	10-85% (no condensation)
Maximum altitude	4300 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	2000 Patient Test Results 500 QC Test Results 200 IQC Test Results 100 Strip Code Chips 100 QC Code Chips 4000 Patient List entries 5000 Operator List entries
Interface	Infrared interface, LED/IRED Class 1
Supported barcodes	Code 128, Code 39, Code 93, EAN 13, Interleaved 2/5, Codabar, GS1 DataBar Limited, QR Code, DataMatrix, PDF417, Aztec
Battery operation	Handheld battery pack
Mains connection	Power adapter (REF 07006098001) Input: 100-240 V AC (± 10%) / 50-60Hz / 350-150 mA Output: 12 V DC / 1.25A Power adapter (REF 08692432001) Input: 100-240 V AC (± 10%) / 50-60Hz / 400-200 mA Output: 12 V DC / 1.5A
Number of tests with fully charged battery	approx. 10 tests
Safety class	III
Automatic power-off	Programmable 1 … 60 minutes
Dimensions	244 × 105 × 51 mm
Weight	approx. 526 g incl. battery pack and scanner

Sample material

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

Storage conditions

Temperature range Meter (without battery pack)	–5 °C to +45 °C (+23 °F to +113 °F)
Temperature range Meter (with installed battery pack)	–5 °C to +35 °C (+23 °F to +95 °F)
Relative humidity	10 to 85% (no condensation)

Transport conditions

Temperature range Meter (without battery pack)	–25 °C to +70 °C
Temperature range Meter (with battery pack contained in the kit)[a]	–25 °C to +70 °C
Relative humidity	10 to 85% (no condensation)

a.   At temperatures above +70 °C/158 °F the battery pack could leak and damage the meter. At temperatures below -10 °C/+14 °F the battery pack does not have enough power to keep the internal clock functioning.

10.2 Further information

List of available assays, accessories and consumables

Below is a list of available accessories and consumables. For ordering information, contact your local sales representative.

Item	Description	REF
Roche CARDIAC POC Troponin T	10 tests for quantitative detection of cardiac Troponin T	07007302XXX
Roche CARDIAC POC Troponin T Control	Control set for use with Roche CARDIAC POC Troponin T (control set for 2 x 6 quality control checks, level 2, and code chip)	07089643190

Item	Description	REF
Roche CARDIAC POC Troponin T 2 Level Control	Control set for use with Roche CARDIAC POC Troponin T (control set for 2 x 6 quality control checks, level 1/2, and code chip)	07831005190
Roche CARDIAC POC Troponin T Control (Germany only)	Control set for use with Roche CARDIAC POC Troponin T (control set for 2 x 6 quality control checks, level 2, and code chip)	07912218190
Roche CARDIAC M Myoglobin	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	04877802XXX
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)	05533643XXX
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 POC NT-proBNP	10 tests for quantitative detection of NT-proBNP (measuring range 60 - 9,000 pg/mL for meter software version ≥ 01.04.01)	09213074XXX
Roche CARDIAC POC NT-proBNP Control	Control set for use with Roche CARDIAC POC NT-proBNP 10 tests (control set for 2 x 6 quality control checks, level 1/2, and code chip)	09302344190
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

Item	Description	REF
Universal battery pack	Rechargeable battery pack for **cobas h** 232 meter	06869904001
Test strip guide cover		07751109001
Battery compartment cover		07751125001
Power adapter *		08692432001
Handheld Base Unit		04805658001
cobas h 232 meter	Version without scanner/without WLAN	04901126XXX
cobas h 232 meter	Version with scanner/with WLAN	04901142XXX
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

* **Important note**

Power adapter REF 07006098001 (International edition), Type: FW7555M/12,
Input: 100-240V/50-60Hz/350-150 mA, Output: 12V ===1.25A has been discontinued and replaced by:

Power adapter REF 08692432001 (International edition), Type: FW8001M/12,
Input: 100-240V/50-60Hz/400-200 mA, Output: 12V ===1.50A

The change in power adapter has no effect on product performance. Type: FW7555M/12 and Type: FW8001M/12 can be used in parallel.

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.

11　Warranty

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

This page intentionally left blank.

A   Appendix

A.1   Working with barcodes

<table>
<tr>
<td>

⚠️

WARNING

</td>
<td>

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

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 15416 and 15415) are adequate. Inadequate print size and/or quality may lead to erroneous decoding. In addition every user must carry out a plausibility check on all data scanned into and displayed by the instrument.

</td>
</tr>
</table>

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

■   check ID against list or

■   check ID for length[1]

■   check if the scanned bar code type is allowed and activated in the DMS

■   use barcodes with check digits

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

Always make sure that the entire barcode is covered by the green light frame when scanning.

---

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

A.2   Operator and patient ID barcode masks

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

The allowed maximum length of a barcode mask is 300 characters for 1D and 2D barcodes.

A.3   Example of barcode symbologies

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

EAN 13 and Interleaved 2/5 barcodes, although widely used, are not recommended for patient/operator barcodes.

If an EAN 13 or Interleaved 2/5 barcode is read incorrectly, this may lead to patient misidentification and therefore to inappropriate therapy decisions. If used nonetheless:

■ make sure that the very highest quality standards of barcode creation and reproduction are applied

■ for EAN13: do not use the start sequences 978 (ISBN) and 979 (ISMN) as they will be ignored as a part of any ID code

The barcode samples shown here are for illustration purposes only. If printed out, they can be used to check the barcode scanner. However, they are not meant to be used as a reference for size or resolution of real patient or operator ID barcodes. When creating patient or operator barcodes always refer to the relevant standards ISO/IEC 15416 and 15415 for size and resolution requirements and to the specification listed below.

	Recommended Specification	**Remarks**
Print resolution	300 dpi preferred 200 dpi minimum	At 200 dpi issues with the wide-to-narrow ratio may exist.
Reflective contrast	70% or greater	Matte finish is preferred over gloss finish.
Symbol grade	Grade C or above Grade B is preferred Symbol grades are A-F based on analysis of several quality elements.	Depending on quality grade parameters for a specific bar code, grade C may not be sufficient when motion, reflection, or poor lighting occur.
Module width (minimum)	0.16 mm (linear barcodes) 0.20 mm (2D barcodes)	

1234567890	Codabar	1234567890	Code 39
ABC123-/+	Code 93	1234567890	Code 128
1 112223 334448	EAN 13	1234567890	Interleaved 2/5 without checksum
Roche Diagnostics	PDF417	(01)01234567890128	RSS (GS1 DataBar Limited)
Roche Diagnostics	Aztec	Roche Diagnostics	DataMatrix
Roche Diagnostics	QR Code		

A.4 Supported characters in 2D barcodes

The 2D barcode scanner is able to read characters from the following unicode ranges:

■   Basic Latin (0021-007E)

■   Latin-1 Supplement (00A1-00FF)

■   Latin Extended-A (0100-017F)

The 2D barcode scanner does not support Asian characters.

This page intentionally left blank.

B   Appendix

B.1   Option: Wireless network (WLAN)

Preliminary note

Appendix B has been developed to explain the wireless communication principles of the **cobas h** 232 system[1] and to help your facility's information technology/management team(s) in effectively deploying the **cobas h** 232 system on your wireless network.

Whether your meter is equipped with WLAN functionality or not depends on the system configuration that you purchased.

For information on WLAN registration see the addendum "WLAN registration information, Addendum to the Operator's Manual for **cobas h** 232" which can be downloaded from the "Point of Care testing" area at www.cobas.com.

Background

The **cobas h** 232 meter can only be configured through a data management system to communicate wirelessly. The data management system is also used to set-up and configure the meter to connect to one hospital specific Wireless Local Area Network (WLAN[2]). WLANs use electromagnetic waves in the 2.4 and/or 5.0 GHz frequency range to wirelessly transmit data[3]. The **cobas h** 232 system adheres to IEEE Standard 802.11g (2.4 GHz range)[4]. The system is backwards compatible to 802.11b. During wireless communication to an Access Point (AP), the **cobas h** 232 meter recognizes the existent AP WLAN protocol configuration (802.11b or 802.11g) and automatically transmits data using the appropriate communication protocol[5].

---

1.   The **cobas h** 232 system is certified by the Wi-Fi Alliance.
2.   WLAN is also commonly referred to as wireless LAN or Wi-Fi.
3.   For the wireless functionality to work properly, the wireless module must first be configured by your system administrator.
4.   While the **cobas h** 232 system adheres to the 802.11g standard, it uses only channels 1-11. Channels 12-14 are not used by the system.
5.   WLANs are organized in cells. A typical WLAN cell consists of Access Point(s) that are connected to the (wired) Local Area Network and one or more clients, e.g., **cobas h** 232 meters along with other clients such as portable computers.

The loss of signal or access to bandwidth of one particular client may vary depending on one or more of the following situations: the type and number of other clients, the performance of the Access Point, the presence of electromagnetic disturbances, and other potential interfering factors, e.g., concrete walls.

The **cobas h** 232 meter uses a burst-like communication protocol that will only consume bandwidth if there is actually data to be transferred. Compared to other applications, such as Voice over Internet Protocol (VoIP) or multi-media applications, the meter's bandwidth consumption is minimal. If the WLAN that the **cobas h** 232 meter seeks to connect to is degraded, the meter design minimizes the impact on functionality.

Technical implementation

Prior to connecting any wireless device to a wireless network, it is recommended that a WLAN site survey be performed. The goal of a WLAN site survey is to ensure that Access Points will provide enough coverage and performance to support any new radio frequency (RF) application or device. The survey will also detail RF signals, including all existing WLANs along with any competing RF signals and interferences (building structure related and other wireless equipment / devices).

As part of an RF implementation of the **cobas h** 232 system, it is recommended that at minimum one base unit be hard wired per floor. A networked base unit provides redundancy if a wireless network malfunctions or loses service. If the **cobas h** 232 meter with RF is used in an area with low signal or interferences, it is recommended to install a connected base unit for redundancy. The redundancy of the connected base unit allows immediate transmission of patient results when the meter is docked.

The current RF system consists of an antenna and a WLAN system-on-chip (SoC) along with other components. The WLAN system-on-chip is the core of the WLAN system. The RF system used in the **cobas h** 232 meter specifically adheres to the following specifications:

■ Its WLAN system-on-chip supports IEEE 802.11b and 802.11g. It works seamlessly together with other Wi-Fi certified transceivers. It also implements the Wi-Fi Protected Access (WPA™ - Enterprise and WPA™ - Personal), Wi-Fi Protected Access 2 (WPA2™ - Enterprise and WPA2™ - Personal), and Wired Equivalent Privacy (WEP) security mechanisms with Temporal Key Integrity Protocol (TKIP) and Advanced Encryption Standard (AES).
In addition, the system supports the extensible authentication protocol (EAP) with EAP-TLS, EAP-TTLS/MSCHAPv2 and PEAPv0/EAP-MSCHAPv2. The **cobas h** 232 meter interoperability Wi-Fi certificate can be accessed at http://certifications.wi-fi.org/search_products.php.
Further information including a glossary of terms, frequently asked questions, and other topics related to Wi-Fi technology can be found on the Wi-Fi Alliance site (http://www.wi-fi.org/).

■ The used channels in the 2.4 GHz-band are channels 1-11. (Channels 12-14 are not used by the **cobas h** 232 meter.)

■ RF output power is approximately 15 dBm at a data rate of 54 MBPS.

Note: For technical reasons, only client certificates in a *.pem file format are acceptable for EAP-TLS authentication. In a Windows-based network environment, *.pfx files need to be converted to *.pem format. It is in the responsibility of the customer / customer's IT department to convert *.pfx certificates to the required *.pem format.

Important Note:

■ WEP is an obsolete cryptographic data confidentiality algorithm which is not considered secure. It should not be used anymore.

■ TKIP is an old cryptographic data confidentiality algorithm which is not considered secure. It should not be used anymore, with exception of a backwards compatibility option as a group cipher when connecting to access points that use AES/TKIP mixed mode.

RF specific functionalities and effective performance claims

The **cobas h** 232 system offers the option of wireless network connectivity (WLAN/Wi-Fi). If you purchase a system with this option, the WLAN function is enabled during production.

This module can only be configured by a data management system (DMS), which activates the meter's wireless communication and data transfer capabilities. Wireless connectivity can help to ensure that updates to information in the DMS are sent immediately to all networked meters. Communication takes place when the meter is idle, but will be interrupted during the performance of a test.

Meters with an integrated and activated wireless option use the base unit for recharging and/or as a redundant communication option to exchange data with the DMS.

The meter also has to be docked if the hospital changes security protocols. When this change occurs, it may lock out all meters until docked and reconfigured with the new protocol.

As described above, the **cobas h** 232 meter supports the 802.11g standard. This translates into the following RF specific performance claims:

■   The **cobas h** 232 meter is capable of transferring to a suitable DMS, via WLAN, a data set of up to 1000 result records, 100 reagent records, and 500 operator ID records in less than 15 minutes, when operated in a typical WLAN environment (correct WLAN administration, typical population of other clients present, any of the supported security models enabled).

■   A **cobas h** 232 meter with wireless connectivity enabled will communicate results after every test or when the meter is idle; it will automatically attempt to communicate with the DMS every 10 minutes. In line with the industry communication standard POCT1-A, the DMS must acknowledge the meter's request for connection and actively query for the result. Only upon receipt of this DMS query, the meter will send the result. Hence the effective time for transmitting results depends on infrastructure, DMS workload, etc. Once the DMS sends a query, however, the meter will respond within a few seconds.

A typical range for direct connection between the **cobas h** 232 meter and the access point (air, direct view, low disturbances) is up to 15 to 20 meters (49 to 66 feet). The actual range depends on the positioning of the access point's antennas and other topological properties of the space between WLAN device and AP. Additionally, dynamic control of the transmitting power of the access point may reduce the maximum distance between WLAN device and AP within which communication can be guaranteed.

The **cobas h** 232 system is designed such that it coexists with other wirelessly communicating devices. The **cobas h** 232 system does NOT include any real-time or even time critical wireless functionality. It communicates exclusively single, digital data fields. It does NOT communicate continuous waveform data.

> Note: A degraded Quality of Service (QoS) of the WLAN communication will not impact the functionality of the meter but may delay the communication of results to the DMS. Users should be aware that **real-time communication** of test result readings **cannot be guaranteed** by the **cobas h** 232 meter.

This page intentionally left blank.

C   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.
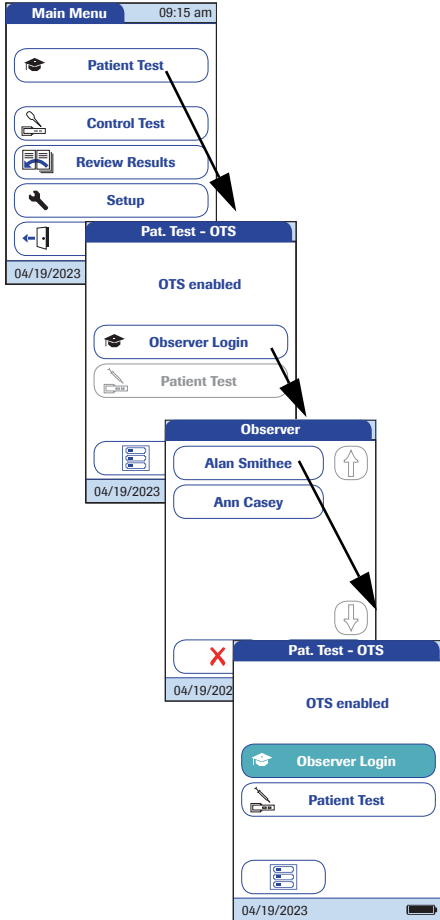
Observer:

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.

Pat. Test – OTS

OTS enabled

🎓 **Observer Login**

⌨ **Patient Test**

▤

04/19/2023

Remove Strip

Remove Strip

◀▥▯ ⬛

04/19/2023

Observer Login

i **I-010** 🧾

Observer Alan Smithee, please log in to proceed. Otherwise the OTS test will not be complete.

✓ -

Observer

OTS passed:

Pass   **Fail**

Measurement Result OK?

Reject   **Accept**

Comment:

💬   ▤

04/19/2023
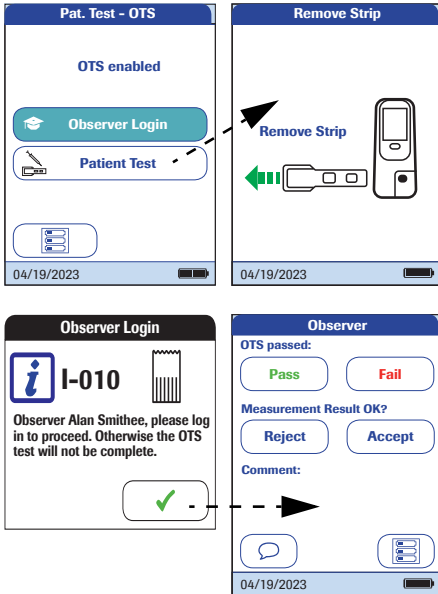
Operator:

1 Touch **Patient Test**.

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

2 Hand the meter back to the observer.

Observer:

3 Touch ✓ to log in again.

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

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

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

7 Touch 💬 to add a comment.

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

The OTS information is saved together with the test result.

This page intentionally left blank.

D   Contact Roche

For all questions about the **cobas h** 232 system that are not answered in this manual, contact your Roche representative. If you do not already have contact details:

■   Visit our website at www.roche.com.

■   Click on "Menu", then select "Worldwide" to find the appropriate local office contact information.

In Australia and New Zealand, the **cobas h** 232 system is manufactured for and distributed by:

Roche Diagnostics Australia Pty Limited
ABN 29 003 001 205
2 Julius Avenue
North Ryde, NSW, 2113

This page intentionally left blank.

Index

This page intentionally left blank.

This page intentionally left blank.

This page intentionally left blank.

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany

www.roche.com
www.cobas.com

0 7469101001 (04) 2022-11 EN