cobas h 232

Supplement Version 2.0 to the Operator's Manual V6.0

Roche

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Document version	Date	Content
1.0	2019-06	New Document, created as an amendment to Operator's Manual Version 6.0
2.0	2021-05	Added information about new features in SW 04.02.xx

Purpose of document

This document provides a description of changes to the Operator's Manual version 6.0 for SW 04.01.xx and SW 04.02.xx. This supplement is valid for and intended to be used in conjunction with the **cobas h** 232 Operator's Manual version 6.0. It is not a replacement for the complete **cobas h** 232 Operator's Manual version 6.0. Changes or additions to the information in the **cobas h** 232 Operator's Manual version 6.0 are shown in colour.

Be sure to read the complete **cobas h** 232 Operator's Manual version 6.0.

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What is new in SW 04.01.xx and SW 04.02.xx

EN

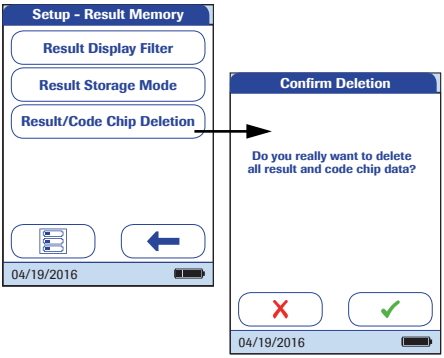
Functions introduced with SW 04.01.xx

Result memory

The following information has been added to page 71 with SW 04.01.xx:

Result memory settings allow to apply a *Result Display Filter*, to set the *Result Storage Mode* (see page 73), and to delete stored test results and code chip data (see page 74).

The following information has been added to page 74 with SW 04.01.xx:



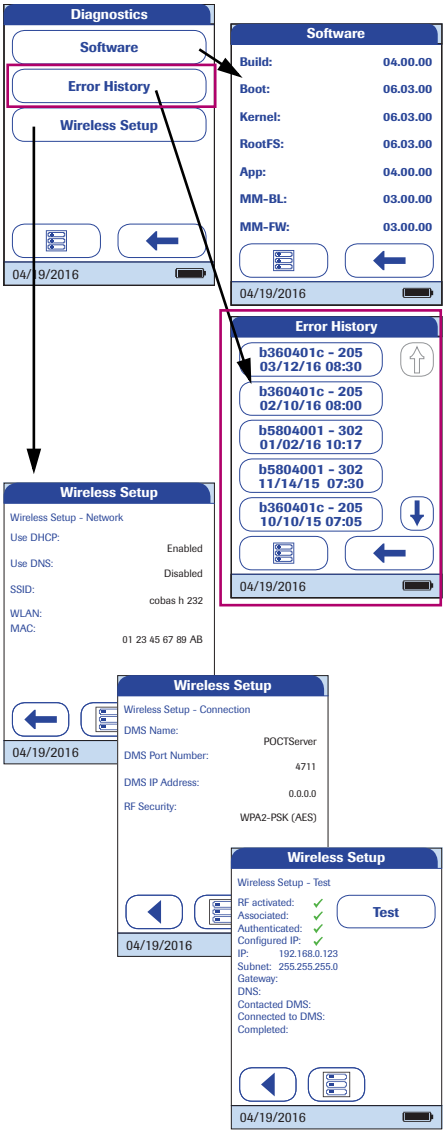
10 From the *Setup-Result Memory* menu, touch **Result/Code Chip Deletion** to delete stored test results and code chip data.

11 Touch ✓ to delete all data, or touch ✗ to exit this screen without deleting any data. The display automatically returns to the previous screen.

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

Diagnostics

The following information has been added on page 81 with SW 04.01.xx:



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

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

15 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.

Functions introduced with SW 04.02.xx

The following information has been added or changed on page 106ff with SW 04.02.xx:

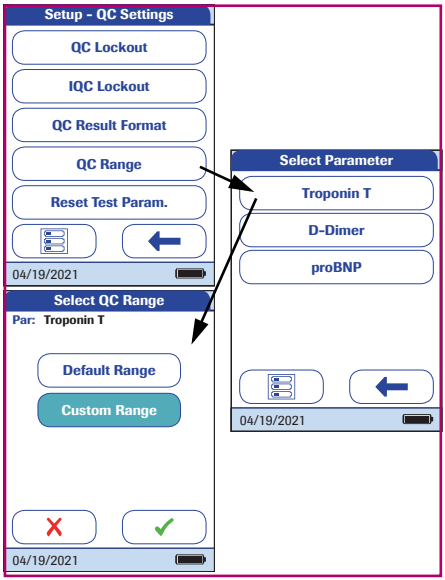
Custom Range

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 101 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 **Custom Range** to set the quality control range.

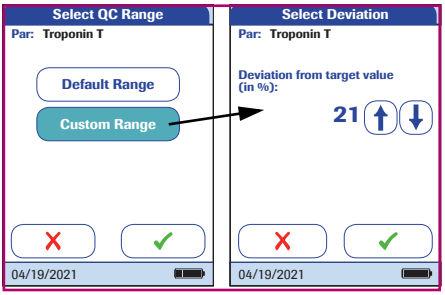
2 Touch the button with the parameter you wish to set.

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.



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.

Amendments to Operator's Manual version 6.0

Revised sections

Symbols

The following information has been added or changed on page 5:

	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
	Batch code/ Lot number
	Catalogue number
	Global Trade Item Number
	Serial Number
	In vitro diagnostic medical device
	This product fulfills the requirements of the European Directives 98/79/EC on *in vitro* diagnostic medical devices and 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio 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.

Battery pack

The following information has been added or changed on page 17:

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.

Power supply

The following information has been added on page 40:

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.

2.1 Installing or replacing the battery pack

The following information has been added or changed on page 36:

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. To start the charging process immediately put the meter into standby mode by pressing the On/Off button for approximately 1 second.

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 41**.

Removing the battery pack

The following information has been changed on page 37:

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 41).

The following information has been added on page 41:

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 supply 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 supply 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 182) and date and time will be lost.

Automatic shutdown

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

The following information has been added on page 183:

Technical data

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

The following information has been changed on page 186:

…	…	…
Power adapter *		08692432001

The following information has been added on page 186:

*** 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 supply has no effect on product performance. Type: FW7555M/12 and Type: FW8001M/12 can be used in parallel.

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