ACCU-CHEK® Inform II

Roche

Accu-Chek® Inform II

BLOOD GLUCOSE MONITORING SYSTEM

Operator's Manual

ACCU-CHEK®

Revision History

Manual content version	Revision date	Changes
Version 1.0	2008-01	New document, international launch with document **0 4807839001 (01)** EN 2008-01.
Version 2.0	2009-08	Update, new SW version 02.00; creation document versions **0 5956200001 (01)** 2009-08 EN-CAN/ **0 5956218001 (01)** 2009-08 FR-CAN for Canada
Version 3.0	2010-09	Update, new SW version 03.00. This manual version not available in Canada.
Version 4.0	2012-11	Update, new SW version 03.04 (OTS, OTE), revision Cleaning/Disinfection section; misc. editorial revisions; international launch with document **0 4807839001 (04)** 2012-11 EN. This document not available in Canada.
Version 4.0	2013-11	Creation documents **0 5956200001 (02)** 2013-11 EN-CAN/ **0 5956218001 (02)** 2013-11 FR-CAN containing Canada-specific changes. Additionally, implemented information on barcode symbologies; misc. corrections/amendments to v4.0 international.
Version 5.0	2013-09	Transition to new meter hardware: 2D barcode scanner, modifications to wireless LAN option (separate insertable RF card replaced by integrated WLAN component); new battery pack. Update to SW 04.00; misc. editorial revisions; international launch with document **0 4807839001 (05)** 2013-09 EN. This document not available in Canada.
Version 5.0	2014-09	Creation documents **0 5956200001 (03)** 2014-09 EN-CAN/ **0 5956218001 (03)** 2014-09 FR-CAN containing Canada-specific changes to international master document **0 4807839001 (05)** 2013-09 EN. Additionally, implemented Li-ion battery safety information.
Version 6.0	2017-03	Creation documents **0 5956200001 (04)** 2017-03 EN-CAN/ **0 5956218001 (04)** 2017-03 FR-CAN containing Canada-specific changes to international master document **0 4807839001 (06)** 2017-03 EN. SW 04.01 and low power icons implemented; update to SW 04.02; new Base Unit in “System overview”; new section “What is new…”; new Appendix E for legacy Base Unit; misc. editorial revisions.
Version 6.1	2020-04	Update of C&D information, minor editorial revisions.
Version 6.2	2020-07	Update of intended use information.
Version 7.0	2020-06	Update, new SW version 04.04; implementation of supplements for SW 04.03; misc. editorial revisions
Version 7.1	2021-05	Update of intended use information. Updated section “Automatic deletion”; added information about the maintenance reboot. Updated information on WLAN regulatory registration.

ACCU-CHEK® Inform II System

Operator's Manual

Version 7.1

0 5956200001 (07) 2021-05 EN-CAN

On the packaging, on the identification plate of the meter, the battery pack, the base unit, or the code key reader 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 product.

Temperature limitation (Store at)

Admissible humidity range (Store at)

Manufacturer

Date of manufacture

Catalog number

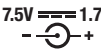
In vitro diagnostic medical device

Global Trade Item Number

Serial Number

This product fulfills the requirements of the European Directives 98/79/EC on in vitro diagnostic medical devices and 1999/5/EC on radio and telecommunications terminal equipment (R&TTE).

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



Power supply connection (Base Unit Light)

Power supply connection (Base Unit)

On meters with WLAN capability:

This device complies with Part 15 of the FCC Rules and with Industry Canada RSS standard(s).

The compliance mark indicates that the product complies with the applicable standard and establishes a traceable link between the equipment and the manufacturer, importer or their agent responsible for compliance and for placing it on the Australian and New Zealand market.

For other WLAN certifications, see label on bottom of battery compartment.

What is new in publication version 7.1?

This section provides an overview of all major changes from Operator's Manual version 6 to version 7.1. Deletions or minor corrections are not listed.

SW 04.03

Description of new features SW 04.03 and amendments from the supplement (English master document 0 8698376001 (02) 2019-03 EN and all derived translations) have been implemented.

- Battery status information in *Docked* screens. For example, see page 128.
- Battery status information in *Diagnostics* screens. For example, see page 149.
- Improved charging performance. See page 129.
- New power management, see "Shut down meter" on page 23 and "Automatic shutdown" on page 24 .
- Improved barcode masking, see "Operator and patient ID barcode masks" on page 188ff.
- Add barcode content to a result, see page 68.
- TLS encrypted WLAN communication, see chapter A.1 "Table of configuration options".
- Data compression of DMS communication, see chapter A.1 "Table of configuration options".

SW 04.04

Based on customer feedback, new features have been added and existing ones improved.

- Order new strips, see page 95.
- Blood sample type selection. Screen allows you to select and document blood sample type used for a patient test. See Supplement E, “Supplement for Enhanced Workflows”.
- Improvement of data privacy. Automatic deletion of outdated patient data, see page 154.
- Audit trail of Operator logins, see page 46.
- Reworked displaying error codes (see page 160f):
  - Replaced the numbers by letters.
  - Removed codes in decision messages.

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1 Introduction

1.1 Before you start

Intended use

The Accu-Chek® Inform II system is intended for *in vitro* diagnostic use in the quantitative determination of blood glucose levels in venous, capillary, arterial, and neonatal whole blood samples for monitoring blood glucose.

The system is also intended for quantitative measurement of glucose (sugar) in venous whole blood, arterial whole blood, and neonate arterial and heel stick whole blood samples throughout all hospital and all professional healthcare settings including patients receiving intensive medical intervention/therapy.

This product is for monitoring hypoglycemia in neonates diagnosed with laboratory glucose methods. The system is indicated for use by healthcare professionals. For healthcare professionals, the system is a bedside unit that can help you provide quality patient care by measuring blood glucose and by automating the record keeping associated with blood glucose and glucose control tests.

Important information regarding use

Read this operator's manual, as well as the package inserts for all relevant consumables, before using the system for the first test.

You must configure the Accu-Chek Inform II system according to your needs **before** initial use. You can configure the system by using a suitable data management system. Refer to Appendix A for configuration via a data management system. The device may not be used in screening for neonatal hypoglycemia.

Be sure to read the “Important safety instructions and additional information” section in this chapter before operating the system.

If you need help

Information about using the system, the screen menus and performing a test can be found in this operator's manual.

Error messages that appear on screen include information or instructions on how to correct the error.

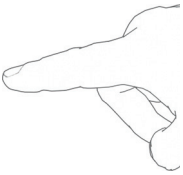
For all questions about the Accu-Chek Inform II system that are not answered in this manual, contact your Roche representative (see Chapter 12). In order to expedite troubleshooting, please have ready your Accu-Chek Inform II meter, its serial number, this manual, and all related consumables when you call. If you suspect a communication error beyond the meter, also have your Accu-Chek Inform II Base Unit serial number ready to help assist our customer care group in troubleshooting.

Note on the use of "base unit" in this manual

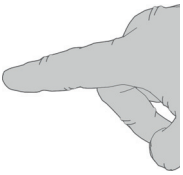
Unless otherwise specified, the term "base unit" refers to both the Accu-Chek Inform II Base Unit and the Accu-Chek Inform II Base Unit Light.

Note on illustrations in this manual

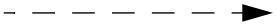
Illustrations in this manual show two different kinds of hands:



Hand without glove



Hand with glove



A dashed arrow between screen illustrations indicates that some screens have been skipped in these illustrations.

What can the system do for you?

The Accu-Chek Inform II system has the following features and properties:

- Perform patient blood glucose tests and glucose control tests with control solution.
- Automatically record all relevant data for the application, which includes:
  - Time and date of test
  - IDs for operator, patient, and samples
  - Information about control solutions, test strips, and linearity
  - Test results and comments
  - Patient sample type based on configuration
- Record patient test results, quality control test results and reagent information for certain off-meter manual tests.
- For purposes of quality assurance, information on the following areas can be collected, stored, and transferred:
  - Meters
  - Test strips
  - Glucose control solutions
  - Linearity solutions
  - Test results

Test principle

An enzyme on the test strip converts the glucose in the blood sample to gluconolactone. This reaction creates a harmless DC electrical current that the meter interprets and converts into a blood glucose result. The sample and environmental conditions are also evaluated using AC and DC signals.

For more details, refer to the test strip package insert.

1.2 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 Accu-Chek Inform II 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.

These symbols and signal words are used for specific hazards:

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.

Important information regarding safety

⚠

Operator qualification

Only trained healthcare professionals may operate the Accu-Chek Inform II system. Operators must also have received comprehensive instruction in the operation, quality control, and care of the Accu-Chek Inform II system.

⚠ WARNING

Protection against infection and blood-borne pathogens

Healthcare professionals using the Accu-Chek Inform II system 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 Accu-Chek Inform II system. 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.
- Use an auto-disabling single-use lancing device for each patient.
- Dispose of used lancets in a sturdy sharps container with lid.
- Dispose of used test strips from patient and proficiency tests 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, linearity, 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 original accessories (cables, power supply units, battery packs, and spare parts). Third-party cables, power supply units, 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 supply units, cables, plugs, or battery packs.
- Do not short circuit the power supply unit, the base unit charging contacts, or the battery pack.
- Do not drop the Accu-Chek Inform II meter, the power supply unit, or the battery pack and protect these against shaking and vibrations.

Disposal of the system

⚠ WARNING

Infection by a potentially biohazardous instrument

The Accu-Chek Inform II system 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 or you may return it to Roche. For more information, contact your Roche representative.

Product safety

Observe the following information to ensure product safety:

- The system is suitable for continuous operation.
- The system is not protected against the harmful ingress of fluids (IP X0 rating according to IEC 60529).

General care

NOTICE

Clean the system only with the solutions recommended. Using other solutions may result in incorrect operation and possible failure of the system. Make sure that the meter and base unit are thoroughly dried after cleaning and disinfecting.

Accessory box

NOTICE

Carry the accessory box carefully by the handle for easy transport. Dropping or hitting the box may damage it.

Meter

Dispose of the meter in accordance with applicable laws and regulations. See “Disposal of the system” on page 21.

Power off meter

When you power off the meter by pressing the On/Off button ⏻ briefly (less than a second) or the meter powers off automatically (see below), the screen goes blank. However, the meter is in standby mode and continues to draw power from the battery pack to maintain date/time and run various functions in the background such as wireless communication.

Automatic power-off

- Unless otherwise configured, the system automatically powers off and goes into standby mode to save power after 5 minutes of inactivity (e.g., no screen touches, strip insertions).
- In measurement mode only: If you are performing a test (patient, control, proficiency, or linearity), the meter will power off after 10 minutes of inactivity (no screen touches), independently of configured automatic power-off time. If a result is already present, the meter will emit three warning beeps every minute after 5 minutes of inactivity and will save the result before powering off after 10 minutes of inactivity. The result will be flagged with a standard comment (“Result not confirmed”) when it is transmitted to the DMS.

Shut down meter

In standby mode ("Automatic power off"), energy continues to be drawn from the battery and it depletes within a day if not docked. Shutting down the meter shuts down wireless communication and all other functionalities. Date and time, however, are maintained. Powering up the meter will take slightly longer than from power-off (standby) mode.

To shut down the meter, press the On/Off 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 124).

If you press the On/Off button for too long, a meter reset will be triggered after about 12 seconds (see page 162) and date and time will be lost.

Automatic shutdown

In case of a *Download Lockout* or if the battery pack is critically low (see page 159), wireless communication and all other functionalities are shut down (although date and time are maintained).

The meter can be configured to automatically shut down 30 minutes after power-off when it is NOT docked. This feature is enabled by default. However, with this configurable automatic shutdown feature, the meter will automatically wake up on a regular basis for wireless communication. The setting for this wake-up timer is configurable (see Appendix A.1, “Table of configuration options”).

If you configure the meter to wake up more often from shutdown for wireless communication (if WLAN is enabled and the meter is not docked), more power will be drawn from the battery pack and the meter will need to be recharged more frequently. If you choose to leave the meter in shutdown until you power it up manually or opt for longer time intervals between waking up for wireless communication, the battery will last longer but synchronization with the DMS may also take longer. In this case however, the meter’s database will probably need to be synchronized before you can start testing.

Which option you choose will be determined by the workflow needs of your institution.

Battery Pack

The meter contains a rechargeable battery pack that begins charging as soon as it is placed in an active base unit (i.e., one connected to a power supply).

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 battery pack

Damaged or swollen battery packs can overheat, catch fire, or leak. Immediately cease use of Accu-Chek Inform II meters with damaged or swollen battery packs and under no circumstances recharge them (do not place in the base unit).

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 Accu-Chek Inform II 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 base unit. Keep this in mind when positioning the 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 batteries:

Disposal of used batteries
Do not dispose of the batteries with normal domestic waste. Dispose of used batteries 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 9).

- Always **shut down** the meter before removing the battery pack (see page 124).
- When the *Battery Low* warning is displayed, the meter must be returned **as soon as possible** to the base unit for recharging.
- The *Battery Critically Low* warning indicates that the meter must be returned **immediately** to the base unit for recharging.

If the meter displays a large red battery icon instead of powering up when you press the On/Off button, this indicates that the battery is empty. Return the meter to the base unit immediately for recharging. See Troubleshooting, "Low power icons" on page 159.

Touchscreen

NOTICE

- Use only your finger to touch the screen elements. Using a sharp-edged object (e.g., tip of a pen) can damage the touchscreen.
- Do not use the system in direct sunlight. Direct sunlight may reduce the life expectancy and functionality of the display, as well as the integrity of test strips.

Electromagnetic compatibility (EMC)

The Accu-Chek Inform II system complies with the emission and immunity requirements described in IEC 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.

The Accu-Chek Inform II system complies with both the electromagnetic immunity requirements and radio interference immunity requirements at the frequency and test levels according to ISO 15197.

Electrostatic discharge (ESD)

The Accu-Chek Inform II system complies with the electrostatic discharge (ESD) immunity requirements as specified in IEC 61326-2-6. Electrostatic discharge (ESD) is an electrical charge at rest, most commonly known as static electricity. If the meter experiences ESD during a blood glucose test, an error message is displayed and no blood glucose result is displayed by the meter or stored in the meter's memory. The blood glucose test will need to be repeated.

To avoid ESD, do not use the meter in a very dry environment, particularly one in which synthetic materials (e.g., carpets) are present that might cause damaging static discharges.

If the Accu-Chek Inform II meter experiences a form of ESD before or after running a blood glucose test, the test result will be stored in the meter memory and transmitted when the meter is docked in a connected base unit or when a wireless connection is established.

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 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 information about how to temporarily enable or disable this function, see page 44. For a description of the Accu-Chek Inform II 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 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.

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 turning 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.

NOTICE

This device complies with Part 15 of the FCC Rules and with Industry Canada licence-exempt RSS standard(s).

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.

NOTICE

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

Radiofrequency radiation exposure Information: This device has been tested and meets the FCC/ISED RF exposure guidelines. Nevertheless, the device should be used in such a manner that the potential for human contact during normal operation is minimized.

⚠ CAUTION

The UNII-1 band (5150-5250 MHz) is only allowed for indoor use in Canada.

Local Area Network: protection from unauthorized access

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

Wired network connection

If connected to a local area network, the Accu-Chek Inform II Base Unit or Accu-Chek Inform II Base Unit Hub must be protected against unauthorized access by means of a **strong password management**. Observe your own facility guidelines on password management where available, or apply the following rules:

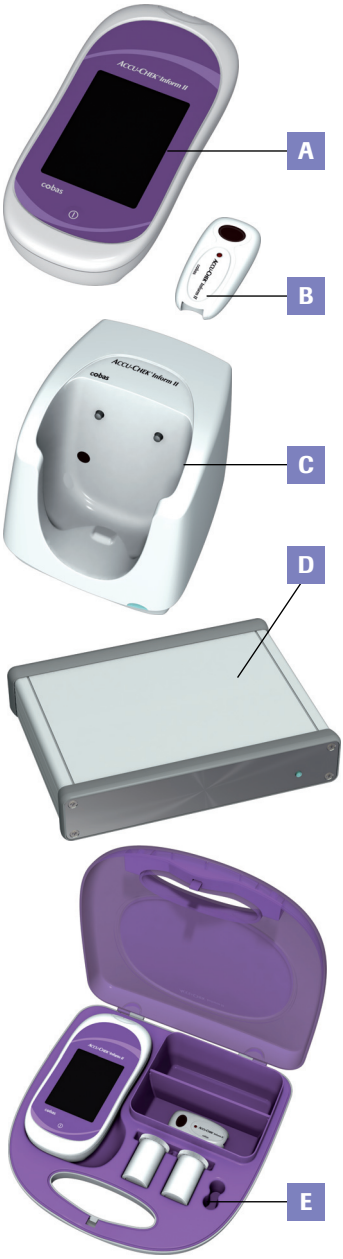
Characteristics of strong passwords

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

Examples of weak passwords

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

1.3 System components



The Accu-Chek Inform II system includes the following components and accessories:

- **A** Meter
- **B** Code key reader
- **C** Base unit (power supply unit not shown)
- **D** Accu-Chek Inform II Base Unit Hub (power supply unit not shown)
- **E** Accessory box (shown with consumables, not included)

The meter can be configured by two different methods:

1. Configuration via the Setup function on the meter (see Chapter 9)
2. Configuration via data management system

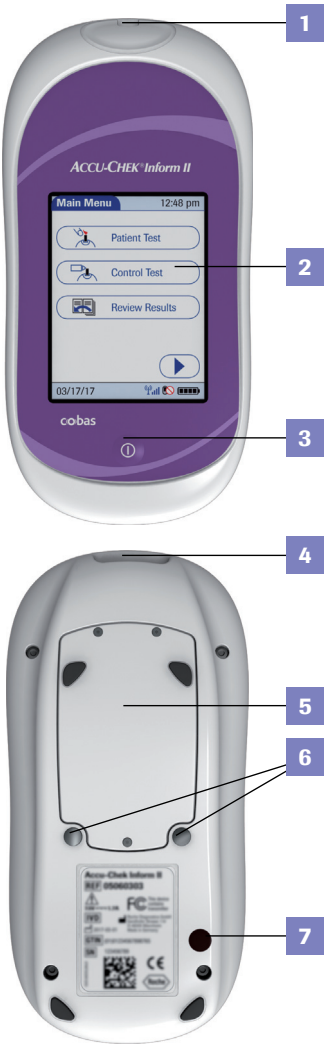
Note: Not all options can be configured using the Setup function on the meter.

The meter performs the following tasks within the system:

- Serves as the primary operator interface through the touchscreen and on/off button
- Performs glucose tests
- Scans barcodes[1] (test strip lots, controls, patient and operator IDs) in a variety of supported formats
- Displays test results from patient tests and control tests
- Transfers stored data to the data management system via wireless communication (WLAN, optional) or the base unit (LAN)

1. Barcodes on control solutions may not be available in all countries. A list of supported barcode symbologies can be found in Appendix A.2.

1.4 Overview of the meter



The meter has the following elements:

1 **Test strip port**
Insert the test strip here.

2 **Touchscreen (touch-sensitive display)**
This screen allows you to perform patient tests, perform controls tests, and review results. To select any of these functions, simply touch the button on the screen.

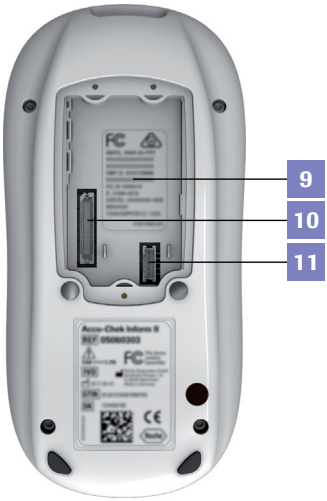
3 **On/Off button**
Press this button to power the meter on or off.

4 **Barcode scanner**
The integrated barcode scanner can be used to read operator and patient IDs.

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

6 **Charging contacts**
These contacts are used to charge the battery pack when the meter is in the base unit.

7 **Infrared window**
Facilitates data communication with code key reader and base unit.



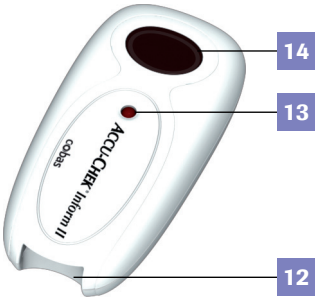
8 **Battery pack**
Powers the device.

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

10 **Interface**
(For manufacturer's use only.)

11 **Battery pack connector socket**
Connect battery pack here.

1.5 Overview of the code key reader



Test strip vials include a code key.[1] This code key is read by the code key reader and the data is sent to the meter. For additional information about the code key reader, see Chapter 6.

The code key reader has the following elements:

12 Code key slot

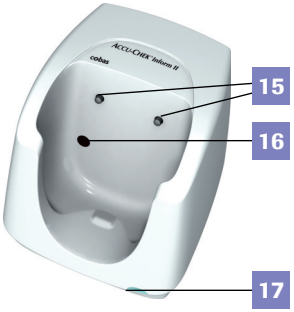
13 LED (green) for displaying status

14 Infrared window for transmitting the code file to the meter

Do not replace code keys while the code key reader is still flashing. If the green LED status light is still flashing, the code key reader will continue to transmit the previously loaded code file and ignore the code file on the newly inserted code key. You may get an error message on the meter.

1. The *code key* is also frequently referred to as a *code chip*. The terms are synonymous.

1.6 Overview of the Accu-Chek Inform II Base Unit



To provide flexibility in line with customer requirements, two versions of the base unit are available.

- The Accu-Chek Inform II Base Unit
- The Accu-Chek Inform II Base Unit Light

Both versions of the base unit can:

- charge the meter battery pack.

In addition, the Accu-Chek Inform II Base Unit supports:

- communication with a data management system.[1]
- communication with a computer.

Both versions of the base unit have the following elements:

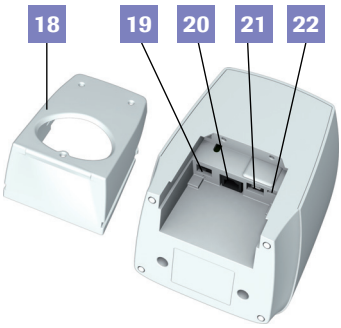
15 Charging contacts

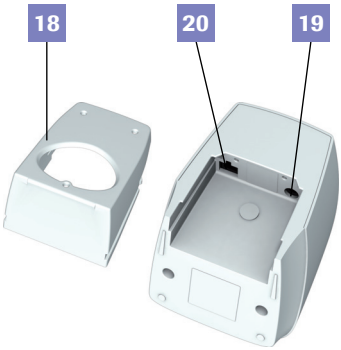
16 Infrared window for communication with the meter

17 Status LED (lights up when power is connected):

- Lights up red: Power supply is connected, application is starting up (Accu-Chek Inform II Base Unit only)
- Lights up green: Ready
- Flashes red: Error
- Lights up blue: Configuration mode (Accu-Chek Inform II Base Unit only)

1. The Accu-Chek Inform II Base Unit Light can support communication with a data management system only when used together with the Accu-Chek Inform II Base Unit Hub.





Electrical connections are located on the back of the Accu-Chek Inform II Base Unit and the Base Unit Light.

Illustration on the left shows the Accu-Chek Inform II Base Unit above, the Accu-Chek Inform II Base Unit Light below.

18 Removable mount for wall installation

19 Power input jack for the power supply unit

20 Network connection

- Base Unit: Ethernet/RJ45 port
- Base Unit Light: RJ25 port (communication via Base Unit Hub)

21 USB port (Base Unit)

22 USB configuration switch (Base Unit, for System Administrator use only)

The following additional elements are provided with the base units:

23 Power supply unit for

- Base Unit: 12V ⎓ 1,25A
- Base Unit Light: 7.5V ⎓ 1.7A (not shown here)

24 USB cable for

- Base Unit: USB A to USB micro B

For instructions on connecting the base unit, see Chapter 9.

For an overview of the Base Unit with older hardware (REF 05060290001), see Appendix F, “Appendix for Accu-Chek Inform II Base Unit (legacy version)”.

1.7 Overview of the Accu-Chek Inform II Base Unit Hub

The Accu-Chek Inform II Base Unit Hub is able to connect up to 4 Accu-Chek Inform II Base Units Light (RJ25) and supports communication to a data management system via Ethernet (RJ45).

The hub also provides power for the Accu-Chek Inform II Base Unit Light. When connected to a hub an Accu-Chek Inform II Base Unit Light does not require a separate power supply. The LED colors of the hub are the same as for the Accu-Chek Inform II Base Unit Light.

17 Status LED (lights up when power is connected)

19 Power input jack for the power supply unit

20 Network connection — Ethernet/RJ45 port

21 USB port

24 Connections for up to 4 Accu-Chek Inform II Base Units Light (RJ25, data transfer, and power)

1.8 Overview of the accessory box

The accessory box provides an area for storing and transporting consumables needed for performing point-of-care blood glucose tests.

1.9 Reagents and consumables

You need the following reagents to perform patient tests and glucose control tests:

- Accu-Chek Inform II Test Strips
- Accu-Chek Performa Control Solutions
- Accu-Chek Linearity Kit (if required by your facility guidelines)

Your facility provides additional consumables such as blood collection supplies. Observe the current rules and safety guidelines for collecting and handling blood samples.

1.10 Instructions for initial setup

The meter must be configured prior to initial use. During this setup, the following parameters are configured:

- Date and time format
- Input mode for Patient ID
- Input mode for Operator ID
- Glucose controls: Type and schedule
- Results screen for glucose control
- Comments for entry after a test
- Settings for data transfer

You can perform these settings on a limited basis directly in the *Setup Menu* of the meter. For more information about configuration using the *Setup Menu*, see Chapter 9, as well as Appendix A. In addition to this option, the meter can be configured using a data management system. Suitable data management systems provide a range of functions for configuring the meter that go beyond what is possible with the meter-based configuration feature.

For questions about using data management systems, contact your Roche representative (see Chapter 12).

To ensure standardized configuration within a facility, the meter-based *Setup Menu* may be disabled.

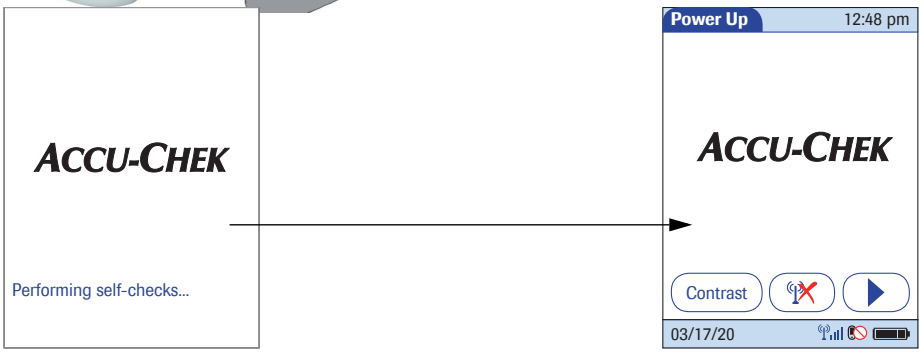
2 Powering Up and Entering an Operator ID

2.1 Powering up the meter

1 Press and release the On/Off button ⏻. The meter is now on.

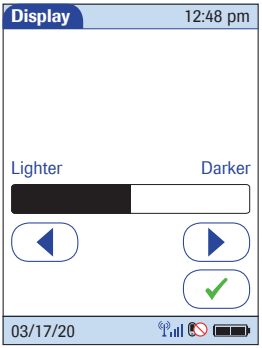
2 The *Power Up* screen appears.

3 Check in the *Power Up* screen whether the date (lower left) and time (upper right) are displayed correctly. If necessary, refer to the instructions for updating these settings in Chapter 9.



- If during self-check an error is detected, the appropriate error message appears on screen.
- If the *QC Lockout* feature is enabled and glucose control is required, a corresponding message is displayed.
- The battery icon shows the current battery level. A completely filled icon indicates a fully charged battery, and a partial charge is displayed as a partially filled battery icon. If the battery is nearly empty, the battery icon turns red.

Adjusting the display



Using the *Display* options, you can adjust the display contrast to the ambient light conditions.

1 In the *Power Up* screen, touch *Contrast*. The *Display* screen appears.

2 Touch ◀ or ▶ to make the display lighter or darker.

3 Touch ✓ to confirm the setting.

After 30 seconds without any activity (e.g., without a screen touch) the meter automatically dims the display backlight to conserve energy (“Low Power Mode”).

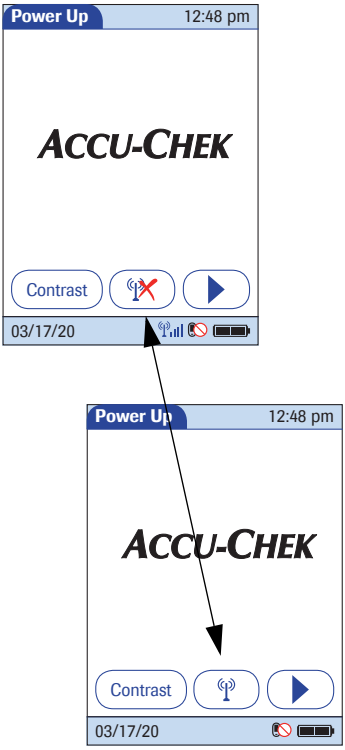
Enabling/disabling wireless connectivity

If the meter supports wireless connectivity, you can temporarily enable or disable this functionality as required.

Wireless connectivity is automatically reactivated the next time you power on the meter. You can then disable it again temporarily, if required.

⚠ WARNING

If you suspect that the RF emissions of wireless communication are harming the patient or affecting other devices, you should carefully reassess the appropriateness of continued use of the WLAN functionality of the Accu-Chek Inform II system using the guidelines of your facility.



If wireless connectivity is activated, the (*RF OFF*) icon is displayed as a button in the *Power Up* screen.

- To temporarily **disable** the wireless network connection, touch (*RF OFF*) in the *Power Up* screen. The icon then changes to (*RF ON*).
- To temporarily **enable** the wireless network connection, touch (*RF ON*) in the *Power Up* screen. The icon then changes to (*RF OFF*).

The *RF ON/RF OFF* button always displays the **option** you currently have. The current communication **status** is displayed in the status bar (bottom line) of the display in all menus and screens.

- The icon is displayed, if wireless connectivity is enabled. Signal strength is shown by 4 bars next to the icon in the status bar. Signal strength can range from “poor” to “excellent”.

The signal strength bars are only displayed when wireless communication is actually taking place. For example, since wireless communication never takes place when a test is being run on the meter, no status bars will be displayed.

- The icon is displayed if the last attempt to communicate with the data management system was successful and was terminated according to the communication protocol.
- The icon is displayed if 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. Ignoring this information may lead to a *Download Lockout* (if configured, see page 49).

Closing startup

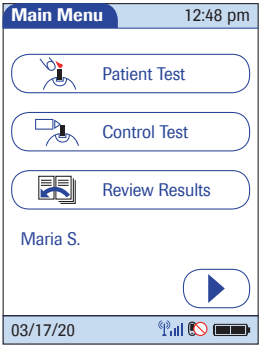
Once you have completed all the necessary changes,

- touch (▶) to proceed to the screen used to enter the operator ID, or
- wait 5 seconds and the meter automatically proceeds to the screen used to enter the operator ID.

2.2 Entering the operator ID

How and when an operator ID is entered and if a password is required, depends on the configuration of the system. It is also, for example, possible to require the operator ID only when starting control tests. In general, the system can manage and check operator IDs as well as make additional functions ID-dependent.

Every successful operator login will be logged as a meter event in an audit trail (ID, date and time).



If an operator name matching the entered operator ID is available on the meter, this name will be displayed in the *Main Menu* (shown here as “Maria S.”).

There are a number of options for entering operator IDs and these depend on the configuration of the system:

- Via barcode scanner[1] only
- Manually or optionally via barcode scanner

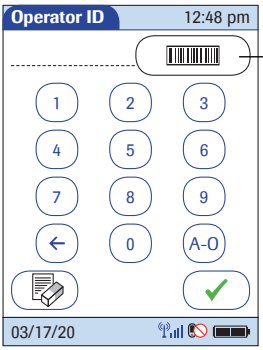
Operator IDs can consist of up to 20 alphanumeric characters.

Alphanumeric characters are any combination of A - Z and 0 - 9, additionally “.” (period), or “-” (hyphen) may be used. See also page 48.

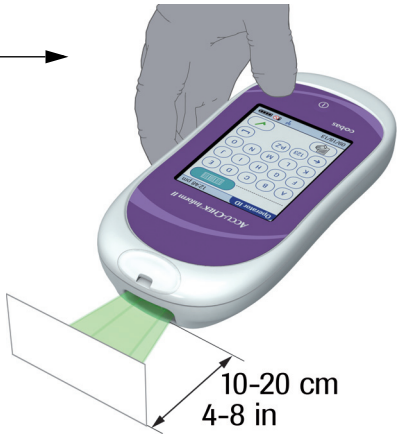
Barcode masking can be used to eliminate any characters not belonging to the Operator ID. See information on “Operator and patient ID barcode masks” on page 188.

1. A list of supported barcode symbologies can be found in Appendix A.2.

Entering an operator ID with barcode scanner



When the screen for entering the operator ID is displayed:



1 Press and release . The button now appears with a black background (during the scan).

2 Hold the meter so that the window of the barcode scanner is approx. 10-20 cm (4-8 in) above the barcode you wish to read.

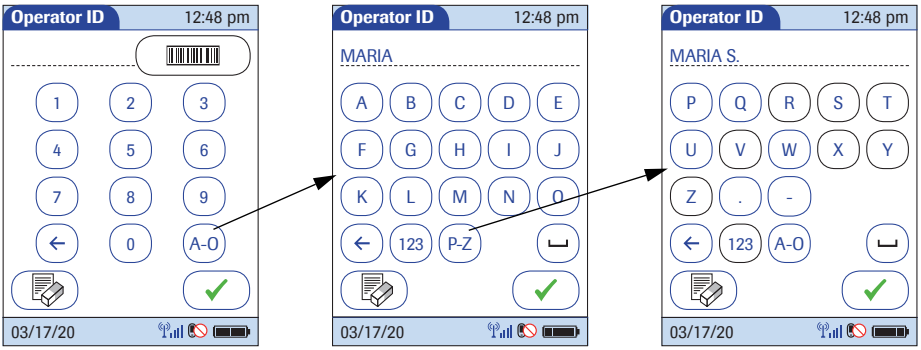
The meter beeps once the barcode has been read successfully. The barcode information appears in the operator ID field. The barcode scanner turns off after 10 seconds, if a barcode is not scanned.

The meter can be configured so that there is a small delay between activating the barcode scanner (green beam) and reading the barcode (red beam). The delay is adjustable and can range from 0 - 10 seconds. (See also table “Barcode Configuration” on page 186.)

This delay gives the operator time to position the barcode scanner and/or the barcode properly, e.g., in case several different barcodes are located very close to each other such as in a list.

Entering the operator ID manually

When the screen for entering the operator ID is displayed:



1 Touch the letters or numbers to enter the ID.

2 Use the following buttons to toggle between ranges of characters:

- (A-O) for letters A-O
- (P-Z) for letters P-Z
- (123) for numbers 0-9

3 Touch (←) to backspace and delete a character entered incorrectly. Touch (🗎) to delete the whole entry. Touch (␣) to enter a space.

4 Touch (✓) to confirm.

If the operator ID you have entered is not valid (or the operator is not stored in the meter), an error message is displayed. Confirming the message allows you to enter the ID again.

Entering a password

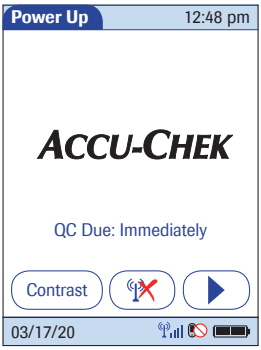
Once the operator ID has been entered correctly, a screen for entering a password may appear (if configured). Enter the password in the same manner as described above for the operator ID.

Once all entries are complete, the *Main Menu* appears.

3 Patient Glucose Testing

3.1 Information regarding blood glucose testing

Preparing to test



The following requirements must be met before you can perform a test:

- The Accu-Chek Inform II test strips are available.
- The code file for the test strip lot in use must be stored in the meter (see Chapter 6).
- An operator ID must be entered (with password, if required), if the meter is configured for login.
- Glucose control tests specified in the system configuration must be run and completed successfully before running patient tests. Information whether glucose control tests are necessary is displayed in the *Power Up* screen.
- If configured, the meter may require downloading stored data to the data management system within defined time intervals. If such a download (either via WLAN or by docking the meter in a base unit) does not happen within the specified time, the meter is locked (*Download Lockout*) and cannot be used for testing.

If a glucose control test is shown as required, patient glucose testing cannot be performed until the controls are run successfully.

Depending on how your meter is configured, QC Lockout occurs when

- patient testing is attempted and controls have not been run in the time interval or frequency established by your facility.
- controls have been run but the control values were not in range.
- new software has been installed.
- a test strip lot other than the “current” lot is selected (default setting).
- you use a new test strip lot for the first time.

For emergencies, STAT (**S**hort **T**urn**A**round **T**ime) tests can be configured in the meter. This option allows the meter to perform a limited number of patient glucose tests, if circumstances require, despite the meter being in QC Lockout or Download Lockout (see page 83).

- 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.

3.2 Performing a patient glucose test

Overview of test procedure

A patient glucose test comprises the following steps:

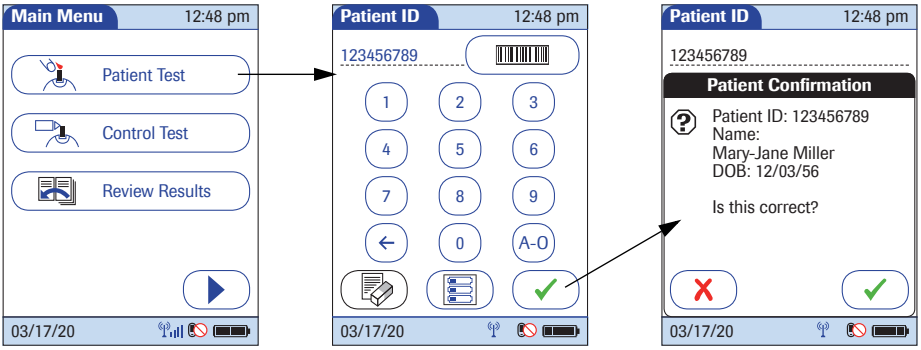
- Enter the patient ID. This can be done either manually or by using the barcode scanner.
- Confirm that the test strip lot matches the test strips in use (if configured).
- Perform the test.
- Optionally a test may be categorized as an *Observed Test Sequence* (see page 223).

Enhanced workflows

The Accu-Chek Inform II system offers enhanced configuration options for adapting the default patient testing workflow to meet a facility's specific requirements or needs. See page 227 for more information.

Entering or selecting the patient ID

After preparing the meter as described, you can proceed to the steps directly related to testing:



1 From the *Main Menu* screen touch *Patient Test*.

2 Enter or select the *Patient ID* as described on the following pages.

3 If the function *Patient Confirmation* is enabled, verify and confirm the displayed patient information, after you entered or selected the ID.

You now have three different options, depending on setup, for assigning the subsequent test to a patient.

The patient ID function can be configured by your system administrator to:

- Enter any combination of up to 20 alphanumeric characters, with specified minimum and maximum lengths.

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

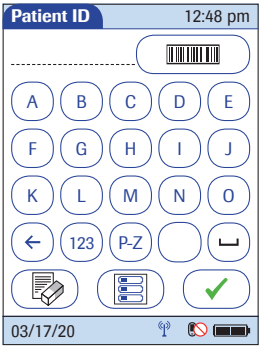
- Enter patient ID via barcode scanner.[1]
- Select a patient from a list.[2]

The following options are available for validating patient IDs:

- Manual entries can be validated based on an downloaded list.
- Confirmation of patient name, date of birth, and ID can be required.[2]
- Barcode masking can be used to eliminate any characters not belonging to the Patient ID. See information on "Operator and patient ID barcode masks" on page 188.

1. A list of supported barcode symbologies can be found in Appendix A.2.
2. Depending on the meter configuration, this feature may be disabled.

Entering the patient ID manually



Use the displayed keypad to enter the patient ID. You can select characters in the same manner as when entering an operator ID.

1 Touch the letters or numbers to enter the ID.

2 Use the following buttons to toggle between ranges of characters:

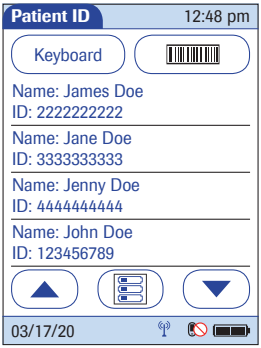
- A-O for letters A-O
- P-Z for letters P-Z
- 123 for numbers 0-9

3 Touch ← to backspace and delete a character entered incorrectly. Touch to delete the whole entry. Touch ␣ to enter a space.

4 Touch ✓ to confirm, or touch to cancel this procedure and return to the *Main Menu*.

- If the patient ID you have entered is **not valid** (does not match configured max/min length) an **error message** is displayed. Confirming the error message allows you to enter the ID again.
- If the patient is **not found** in the downloaded list, a **decision message** may be displayed (depending on configuration, see Appendix A.1). Cancelling the decision message also allows you to enter the ID again.
- Confirming the decision message allows you to perform a test on the patient if the ID complies with the configured maximum/minimum length. However, the patient ID will not be automatically added to the list.

Selecting the patient ID from a list



Choose the patient ID from a list[1], if a list has been downloaded to the meter (from the data management system).

1 Touch ▲ or ▼ to scroll up or down in the list.

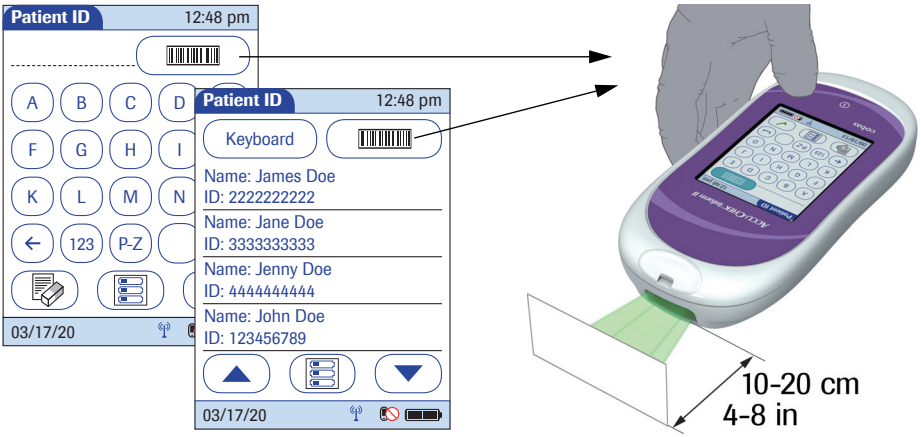
If one of the buttons is hidden, you have reached the top or bottom of the list.

2 Touch the desired entry to select a patient, or touch ☰ to cancel this procedure and return to the *Main Menu*.

1. Depending on the meter configuration, this feature may be disabled.

Entering a patient ID with barcode scanner

When the screen for entering the patient ID is displayed:



1 Press and release . The button now appears with a black background (during the scan).

2 Hold the meter so that the window of the barcode scanner is approx. 10-20 cm (4-8 in) above the barcode you wish to read.

The meter beeps once the barcode has been read successfully.

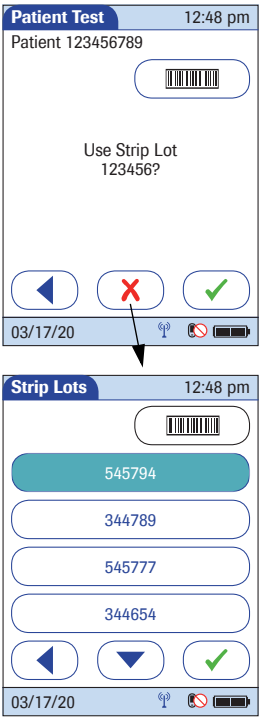
3 If the function *Barcode Confirmation* is enabled, verify and confirm the barcode information.

If the *Barcode Confirmation* screen appears (before or without the *Patient Confirmation* screen), the function to add barcode content to a test result is enabled. See page 68.

The extracted patient ID[1] appears in the patient ID field of the succeeding screens. The barcode scanner turns off after 10 seconds if a barcode is not scanned.

1. See also section “Operator and patient ID barcode masks” starting on page 188.

Confirming or selecting the test strip lot



Once you have entered and confirmed the patient ID, you are asked to choose the lot number for the test strips. Compare the number displayed by the meter to the number on the label of the test strip vial.

1 Select the lot number as follows:

- If you want to use the preselected lot number displayed by the meter, touch (✓) to confirm.
- To use a different lot number than the one displayed, touch (X) to display a list of stored lot numbers. Select the desired lot number from the list.

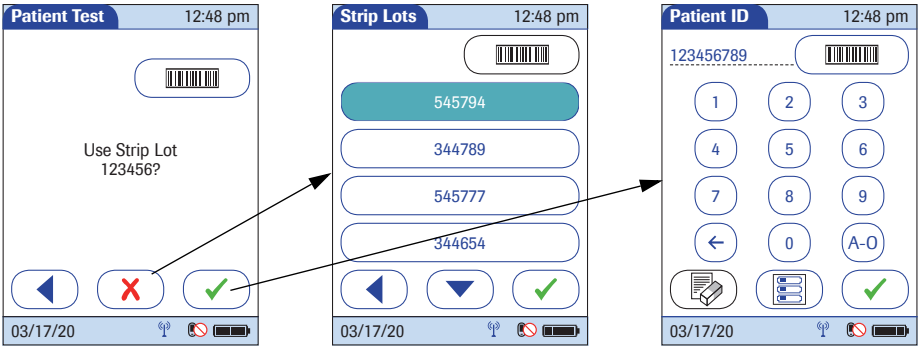
The meter can be configured so that no QC lockout occurs when you switch **between** stored test strip lots. However, the selected test strip lot must already have passed a glucose control test.

A QC Lockout will still occur if a test strip lot is stored in the meter but no glucose control test has been run. A glucose control test must always be performed before using a lot for the first time.

- To read the lot number from the test strip vial via barcode scanner, press and release (▮▮▮). Follow the instructions for scanning IDs (see note on the next page).

2 Touch (✓) to confirm the selected or scanned lot number.

If the meter is configured to use the “Isolation Room Workflow” (see Appendix A.1) the strip lot will be confirmed before a patient ID is entered or selected.



The meter can be configured so that manual confirmation is not necessary. In this setup, only the lot number is displayed. Additional options are not available.

The meter can be configured so that lot numbers are entered via barcode scanner only (see note below).

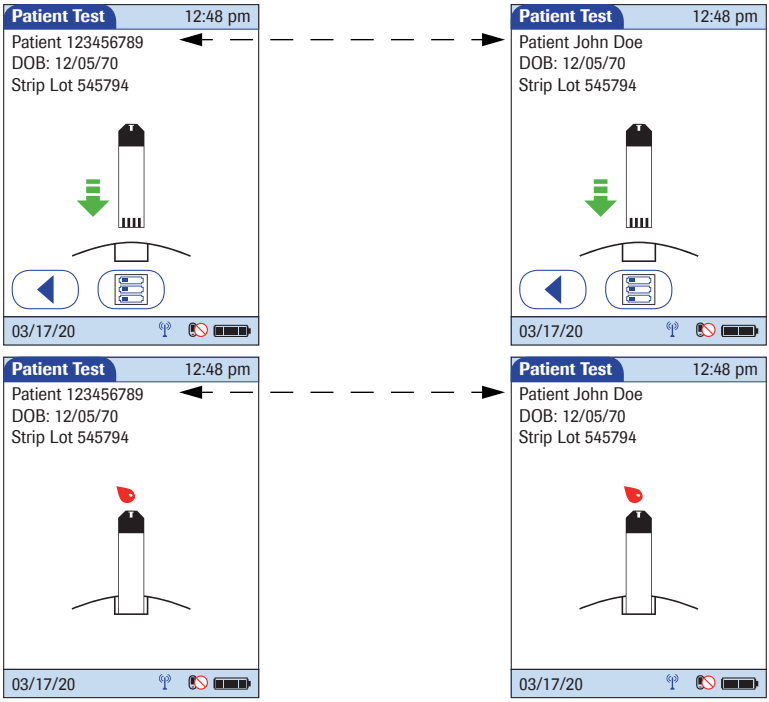
For additional information about storing lot numbers for test strips, see page 89.

Note: Barcodes on control solutions may not be available in all countries. In this case either

- manually enter the lot number each time (recommended),
- pick a previously entered lot number from the list, or
- configure the meter to only display the lot number (without confirmation by the operator).

Patient identification information

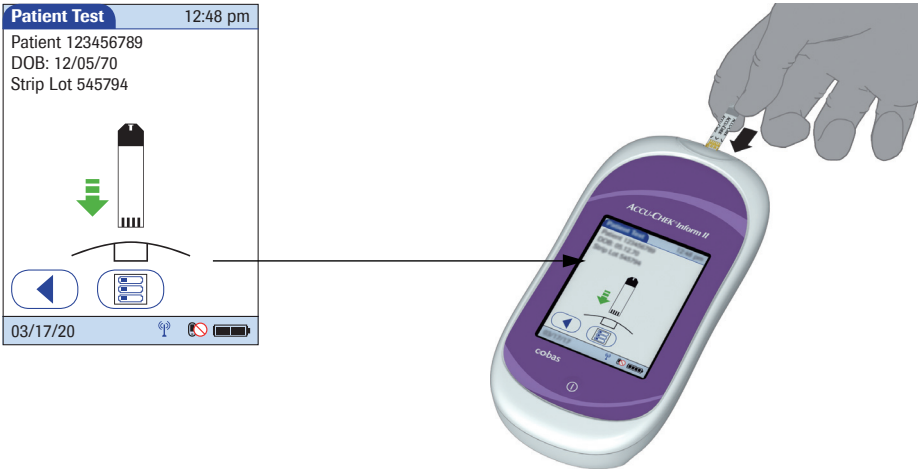
All available patient ID information for the selected patient is displayed on the *Patient Test* screen. Additional patient identifiers such as name and date of birth help verify patient identity. When performing a test, the nurse can easily check whether the gender and age of the patient match the patient details shown on the screen. The display cycles (every second) between displaying patient ID and (if available) patient name. In a second line the date of birth (DOB) is displayed. If no DOB is available, a dash (-) is shown instead. See illustrations below.

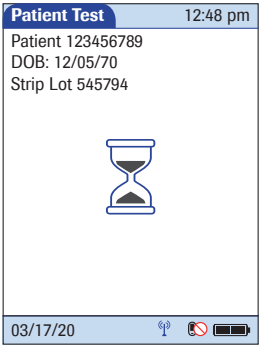


The DOB is not displayed on the patient test result screens, stored test results, or OTE test screens.

Inserting test strips

After confirming the test strip lot, a flashing green arrow appears on screen and prompts you to insert the test strip.





1 Remove the test strip from the test strip vial and close the vial with the cap.

2 Hold the test strip so the lettering “ACCU-CHEK” is facing upward.

3 Slide the test strip into the test strip port as far as it goes in the direction indicated by the arrows on the test strip.

The meter beeps. The hourglass icon appears and indicates that the meter is checking the test strip. Do not apply blood while it is displayed.

Obtaining a blood sample

Prepare the selected blood collection site and obtain blood from the patient per facility policy.

Recommendations for the collection of capillary blood

If no facility policy exists for obtaining capillary blood, the patient's hands (or heel in the case of small children) should be washed with warm water and soap, and then dried thoroughly. If you are using alcohol wipes or other disinfectants when obtaining capillary blood, the patient's skin must be completely dry before you lance the site to obtain blood.

We recommend obtaining the capillary blood sample from the side of the fingertip as this part is the least sensitive to pain.

⚠ WARNING

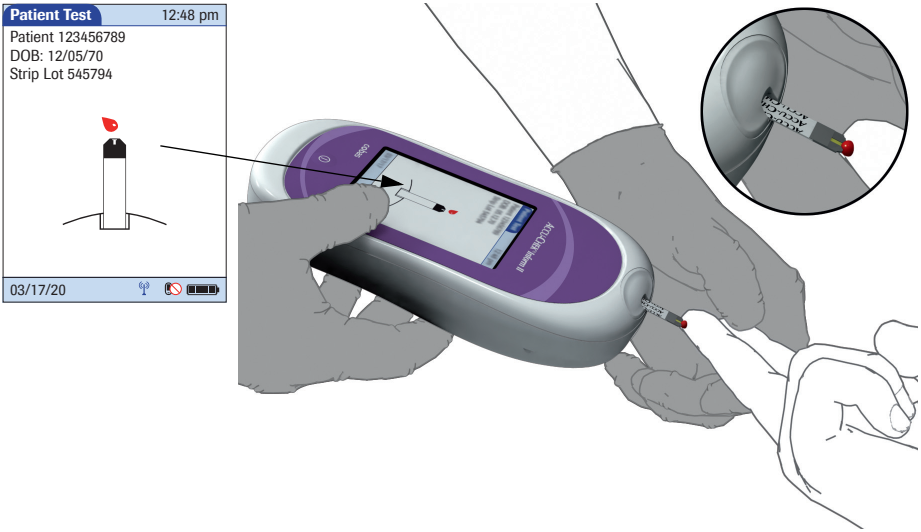
Potential risk of incorrect results due to residues on skin

- Traces of food on the fingers or fatty residues from hand cremes or soap products may contaminate the sample and lead to incorrect results. Wash the puncture site thoroughly and rinse with plenty of water.
- Residues of water or disinfectant on the skin can dilute the drop of blood and lead to incorrect results. After you have washed and disinfected the site, ensure that the patient's skin is completely dry before lancing the site to obtain a capillary blood sample.

Use an auto-disabling single-use lancing device for each patient. The lancing device must be intended for use by healthcare professionals in a multiple patient setting. Follow the manufacturer's instructions for use.

Applying a blood sample

Once the meter has checked the test strip, the hourglass icon disappears and you are prompted to apply a blood sample.



When applying the sample, position the meter so that the test strip port is always higher or on the same level as the blood drop. This prevents any excess blood from flowing down the strip and entering the meter.

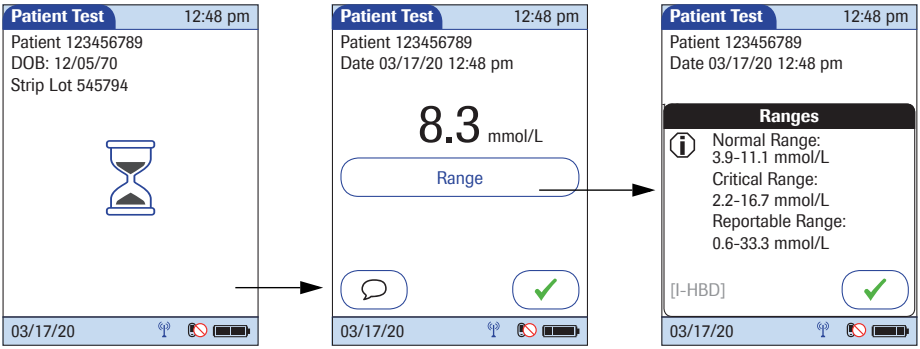
1 Wait until the flashing drop appears in the display before applying the blood. The meter beeps.

2 Apply the **drop of blood** to the **front edge** (yellow dosing area) of the test strip. Blood is pulled into the test strip by capillary action.
Do **not** apply the blood to the top of the strip. Blood on top of the test strip is not available for testing because it will not be pulled into the strip.

Once a sufficient blood sample has been detected, the meter beeps and the measurement begins.

Results screen

The hourglass icon indicates the test is running. When the test is completed and the result is ready, the meter beeps again.



When the result is displayed, a message or warning may also appear (depending on system configuration) notifying you if the result exceeds the specified limit values. Additionally, a **red flashing arrow** next to the test result indicates that a result is out of range.

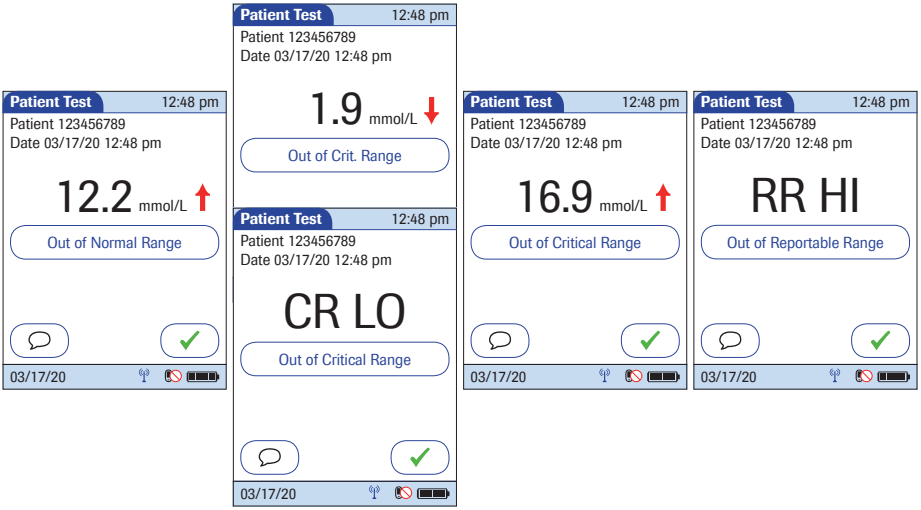
↑: the value is **above** the normal/critical upper range.

↓: the value is **below** the normal/critical lower range.

Example: For the ranges shown above, a value between 2.2 and 3.8 mmol/L would be rated as “below normal range” but “within critical range”.

These limit values define ranges that can either be configured individually by the system administrator in line with facility guidelines, or are the (technical) limits of the system. The characteristics of these ranges are explained on the following page.

The results screen contains a button that changes its name based on the result (*Range* or *Out of ... Range*). Touch this button to display the configured limit values.



- The System Measuring Range refers to the measurement range of the system itself (strips and meter) and is the only range which cannot be configured. With Accu-Chek Inform II test strips this fixed range is 0.6 to 33.3 mmol/L. If a result falls outside this range, the message HI or LO appears, i.e., the result cannot be quantified.
- Glucose results above or below the Reportable Range, as defined by the institution or local regulatory body, are above the highest or below the lowest numerical results to be reported. Results outside this range must not be used for intervention decisions.
- Glucose results above or below the Critical Range, as defined by the institution, require immediate action as defined by hospital policy.
- Glucose results within the Normal Range, as defined by the institution, are considered normal and require no therapeutic action.

The following messages[1] may appear instead of a numeric test result:

- **CR LO** (below the Critical Range threshold, but within the Reportable Range)
- **CR HI** (above the Critical Range threshold, but within the Reportable Range)
- **RR LO** (below the Reportable Range threshold, but within the System Measurement Range)
- **RR HI** (above the Reportable Range threshold, but within the System Measurement Range)
- **LO** (below the System Measurement Range)
- **HI** (above the System Measurement Range)

For test results that lie outside the critical or reportable range, a message (up to 100 characters in length) can be configured during setup. This message is then displayed with the corresponding test results.

Instructions on how to add comments are provided in the following section.

1. Results that are below or above the Critical Range threshold, but within the Reportable Range can be configured to display as either numeric results or as CR LO or CR HI. All other results exceeding specified limit values will always be displayed as RR LO, RR HI, LO, or HI.

If comments are not set as required and you do not wish to add a comment to the test result, touch ✓ to return to the *Main Menu*.

Test results are saved automatically if the meter is powered off or if it powers itself off after 10 minutes of inactivity/no screen touches (see “Automatic power-off” on page 22).

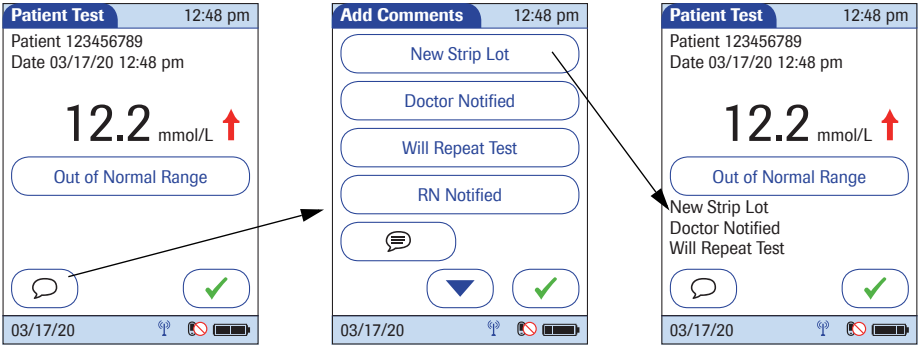
Remove the test strip and dispose of it in accordance with applicable regulations and directives for disposal of potentially infectious samples and materials.

Adding comments

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.

Of these three comments only one can be a custom comment; the others can be selected from the predefined comments list.

The meter can be configured so that comments are always required, required depending on the result range, optional, or disabled. You can call up the function for adding comments directly in the results screen. If comments are set as required, the meter will not accept an empty comment field.



To add comments:

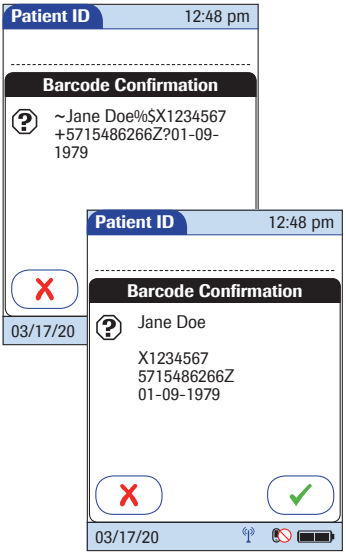
1 In the *Patient Test* screen, touch (💬).

2 Select up to three desired predefined comment(s) from the display list (if configured) or touch (💬) to enter up to one custom comment (if custom commenting is enabled). Use the keypad (as with login) to enter your comment(s).

3 Once you have selected the desired comment(s), touch (✓) to return to the results screen.

4 Touch (✓) to return to the *Main Menu*.

Add barcode content to a result



It is possible to read and display the complete content of a barcode (not only the extracted ID) and add it as a comment to the test result, to be further processed by the DMS. This option can only be configured via a DMS. The following options can be set:

- Barcode content will not be added to the result
- Barcode content will be added to the result
- Barcode content will be displayed for confirmation after scanning and then added to the result

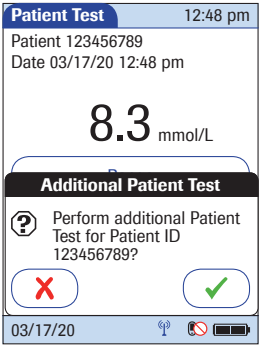
If the meter is set to the last option (enabled with confirmation), you can choose to display the complete barcode content in the confirmation screen as follows:

- The barcode is displayed as a continuous string of characters without any formatting. The separator characters (“~%$+?”) are shown. See example in top screen in the illustration on the left.
- The barcode is divided into separate lines for easier reading. The separator characters (“~%$+?”) are replaced by line breaks. See example in the bottom screen in the illustration on the left.

The replacement of separator characters by line breaks is only applied temporarily for display in the *Barcode Confirmation* screen. The barcode information stored with the test result contains the original separator characters.

During a patient test, the *Barcode Confirmation* screen appears before the *Patient Confirmation* screen, if both are enabled.

Additional Patient Test



It is possible to enable a patient test series (e.g. for plausibility checks). If this function is enabled (only possible via DMS), a pop-up dialog allows the operator to perform another test for the same patient immediately after the first test result is displayed. This function is also available for OTS and OTE workflows.

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4 Glucose Control Testing

4.1 Information regarding glucose control tests

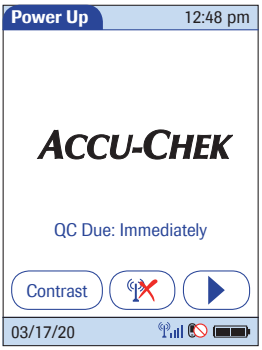
Observe the applicable regulations and directives of the responsible regulatory agencies when performing glucose control tests. See also safety message “Allergy or injury caused by reagents and other working solutions” on page 20.

Accurately testing known levels of glucose ensures that the system and your technique used in testing give accurate results on patient tests. Glucose control solutions have defined (known) values. The results for these solutions must first fall within a certain acceptable range in order to allow valid patient testing.

The system may be configured to require in-range glucose control testing before patient testing is allowed. This is called *QC Lockout*, and the system actually prevents patient and proficiency testing when the control results are not within the accepted range.

Glucose control testing intervals

Intervals between running glucose control tests are determined by your facility. These intervals are entered when the system is configured. At the end of the specified interval (or after a specific event such as starting to test with a new test strip lot), a warning is displayed when the meter is powered on and when the *Glucose Test* function is selected.



Glucose control tests should be run in the following circumstances:

- Before using the meter for patient testing the first time
- At the glucose control intervals established by your facility
- When using a new test strip vial for the first time
- When using a new test strip lot for the first time (and as a result a new test strip code)
- If a test strip vial was left open
- If questionable test results are displayed repeatedly
- If you wish to test the performance of the system

In addition, the following events can be specified during setup as a reason for a glucose control test:

- If a previous control test is out of range
- If glucose control tests were not run at the proper intervals

If a glucose control test is required (as shown on the previous page), you will not be able to test blood glucose until the controls have been run successfully. For emergencies, STAT tests can be configured in the meter. This option allows the meter to perform a limited number of blood glucose tests, if circumstances require, despite the meter being in QC Lockout (see page 83).

Information stored during glucose control testing

The following information is stored for every glucose control test using control solution:

- Glucose control test result
- Lot number of the control solution
- Operator ID (if configured)
- Level of control solution (L1 or L2)
- Lot number of the test strips
- Time and date of test
- Comments (if applicable)
- Out of range measurements

Control solutions

For blood glucose test strips, control solutions have two levels:

- Level 1 (L1): Lo (low values in test results)
- Level 2 (L2): Hi (high values in test results)

Preparing to run a glucose control test

Aside from special preparations (see the following section), a glucose control test is run in the same manner as a patient test:

- At least one code file for test strips must be stored in the meter and match the lot number of the test strips used (see Chapter 6).
- The proper test strips must be available.
- An operator ID must be entered (with password, if applicable), if the meter is configured for login.

4.2 Performing glucose control tests

Overview of test procedure

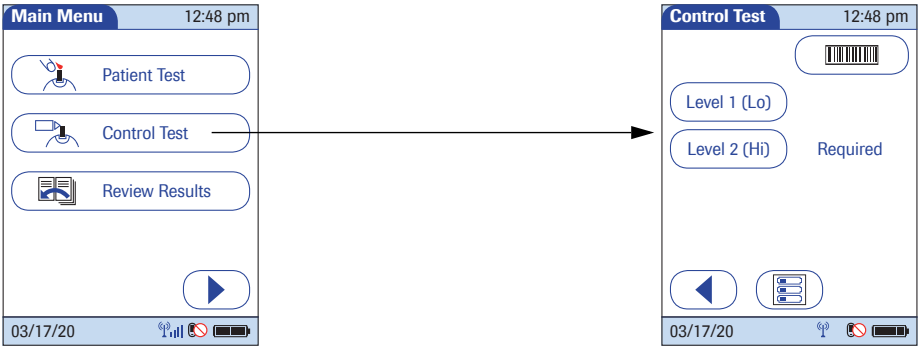
A glucose control test using control solution comprises the following steps:

- Select the desired level of control solution for the test.
- Check the lot number of the control solution.
- Check the lot number of the test strips.
- Perform the test with the control solution.

The result must fall within the specified range (as shown on the label of the test strip vial or defined per configuration) for the control test to be completed successfully. Patient tests can now be performed (again).

Starting a glucose control test

After preparing the meter as described, you can proceed to the steps directly related to control testing:

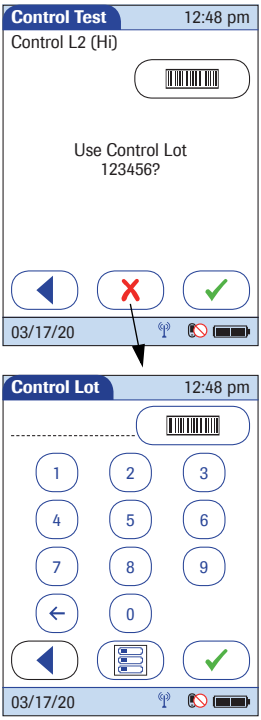


1 From the *Main Menu* screen touch *Control Test*.

In the *Control Test* screen, the levels available for the control solution are displayed. To the right of the buttons, the word *Required* identifies the level at which a glucose control test must be run to remove QC Lockout.

2 Touch *Level 1 (Lo)* or *Level 2 (Hi)* to select the level for the following test. In the example above, *Level 2 (Hi)* is marked.

Confirming or selecting the lot number for control solutions



Once you have selected the level, you are asked to confirm or enter the lot number of the control solution. Compare the number displayed by the meter to the number on the label of the control solution.

1 Select the lot number as follows:

- If you want to use the preselected number displayed by the meter, touch (✓) to confirm.
- If you want to use a different number than the lot number displayed, touch (X) to open the keypad and enter the number manually, or
- To read the lot number from the control solution bottle via barcode scanner, press and release (▮▮▮). Follow the instructions for scanning IDs (see page 47). *

2 Touch (✓) to confirm the selected test strip lot number.

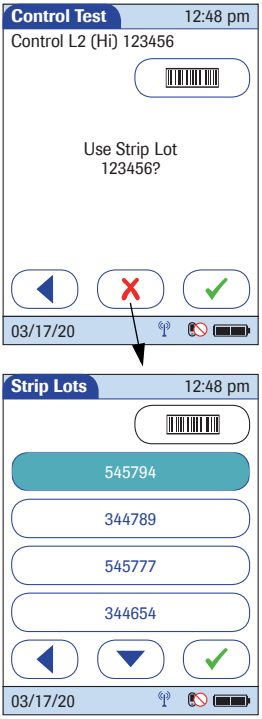
The meter can be configured so that manual confirmation is not necessary. In this setup, only the lot number is displayed. Additional options are not available.

The meter can be configured so that lot numbers are entered via barcode scanner only. *

For additional information about storing lot numbers for control solutions, see page 96.

* Barcodes on control solutions may not be available in all countries (see page 58).

Confirming or selecting the test strip lot



Once you have entered and confirmed the lot number of the control solution, you are asked to choose the lot number for the test strips. Compare the number displayed by the meter to the number on the label of the test strip vial.

1 Select the lot number as follows:

- To read the lot number from the test strip vial via barcode scanner, press and release (▮▮▮). Follow the instructions for scanning IDs. *
- If you want to use the preselected lot number displayed by the meter, touch (✓) to confirm.
- To use a different lot number than the one displayed, touch (X) to display a list of stored lot numbers. Select the desired lot number from the list.

2 Touch (✓) to confirm the selected test strip lot number.

The meter can be configured so that manual confirmation is not necessary. In this setup, only the lot number is displayed. Additional options are not available.

The meter can be configured so that lot numbers are entered via barcode scanner only. *

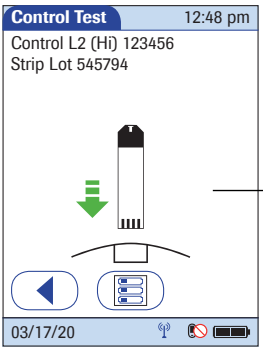
The meter can be configured so that lot numbers can only be selected from a list.

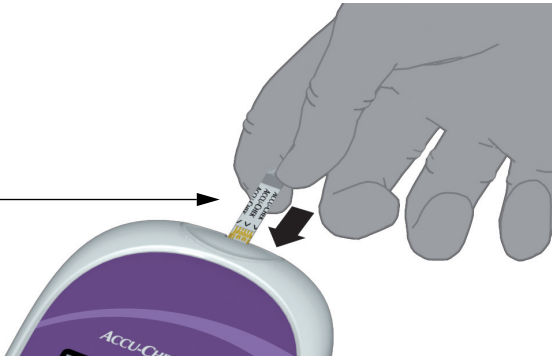
For additional information about storing lot numbers for test strips, see page 89.

* Barcodes on control solutions may not be available in all countries (see page 58).

Inserting test strips

After confirming the test strip lot, a flashing green arrow appears on screen and prompts you to insert the test strip.





1 Remove the test strip from the test strip vial and close the vial with the cap.

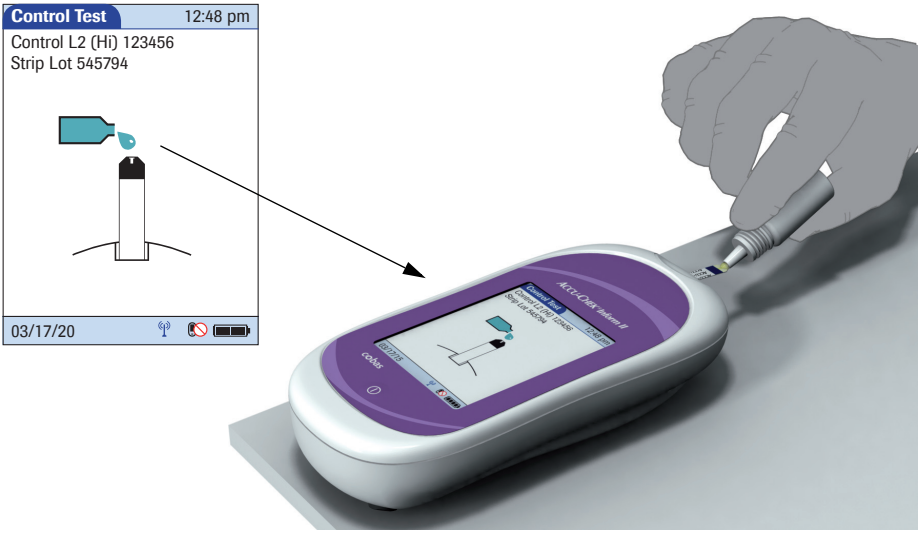
2 Hold the test strip so the lettering “ACCU-CHEK” is facing upward.

3 Slide the test strip into the test strip port as far as it goes in the direction indicated by the arrows on the test strip.

The meter beeps. The hourglass icon appears and indicates that the meter is checking the test strip. Do not apply control solution while it is displayed.

Applying the control solution

Once the meter has checked the test strip, the hourglass icon disappears and you are prompted to apply control solution.



When applying the control solution, position the meter so that the test strip port is always higher or on the same level as the control solution. This prevents any excess solution from flowing down the strip and entering the meter.

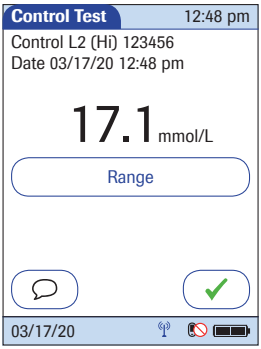
1 Wait until the flashing drop appears in the display before applying the control solution. The meter beeps.

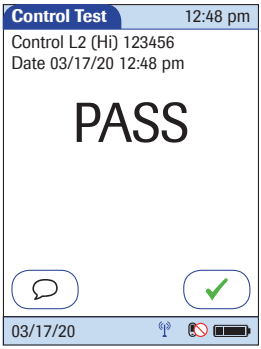
2 Apply a drop of glucose control solution to the **front edge** of the test strip. Do **not** apply the control solution to the top of the strip.
The control solution is pulled into the test strip by capillary action.

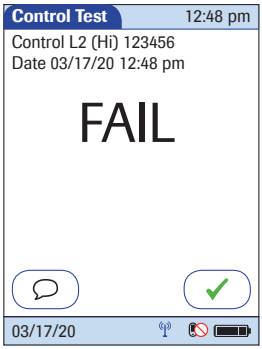
Once sufficient control solution has been detected, the meter beeps and the measurement begins.

Results screen

The hourglass icon indicates the test is running. When the test is completed and the result is ready, the meter beeps again.







Depending on configuration, the result is displayed either as a value or only as a qualitative result *Pass* or *Fail*. Your system may be configured to disallow further testing until all the required glucose control levels are successfully run (QC Lockout).

When the results are displayed as a value, the results screen contains a button that changes its name based on the result (*Range* or *Out of … Range*). Touch this button to display the minimum and maximum target values for the control levels.

You can add comments to a control test result (as with blood glucose tests) (see page 66).

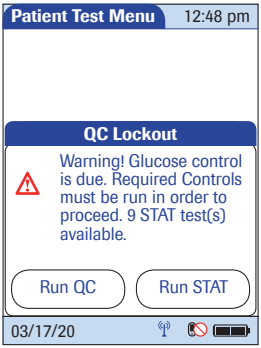
For control tests, comments are only required if the result is outside the specified range (whether this is displayed as a value or as FAIL). If the result is within the specified range (displayed as a value or as PASS), comments are optional.

If you do not wish to add a comment to the test result, touch ✓ to continue to the next level of the control test, if necessary, or to return to the *Main Menu*.

Test results are saved automatically if the meter is powered off or if it powers itself off after 10 minutes of inactivity/no screen touches (see "Automatic power-off" on page 22).

Remove the test strip and dispose of it in accordance with applicable regulations and directives.

Performing a STAT test



The meter can be configured to allow a STAT patient glucose test to be run even if the meter is in QC Lockout or Download Lockout. This option is to be used in situations with critical patients. The system administrator can allow control tests to be delayed one to nine times.

Run STAT appears in the *QC Lockout* warning box under the following conditions:

- You are successfully logged in and have selected *Patient Test* from the *Main Menu*.
- A glucose control test is required (due to specified control intervals or other conditions).
- The administrator has enabled the *STAT test* option during setup.
- The number of STAT tests available has not been exceeded.

If these conditions are fulfilled, two buttons appear in the warning message that allow you to choose the next step:

- Touch *Run QC* to run the required control test instead of a patient test.
- Touch *Run STAT* to perform a patient test even if a glucose control test is required. The status as STAT test is stored with the data record for the test.

If the meter is in a *Download Lockout* status, and no STAT test is available, the meter can be unlocked by a system administrator.

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5 Review Results

5.1 Displaying test results from the memory

Information stored in data records for test results

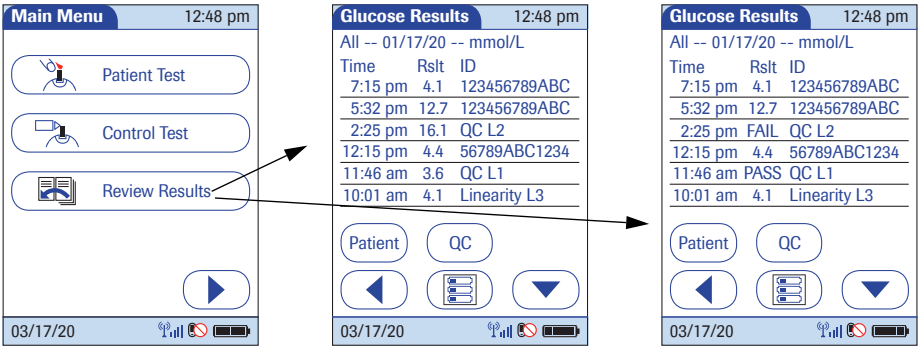
When you retrieve the data record for stored test results, the following information is displayed.

- Patient ID, glucose control, or sample ID
- The test result
- The lot numbers of the reagents used for glucose control and linearity tests
- Date and time of the test
- Comments entered at the time the test was performed

Maintenance results (for documentation of maintenance activities) are stored and displayed with date and time only if comments were added.

List of results stored in the memory

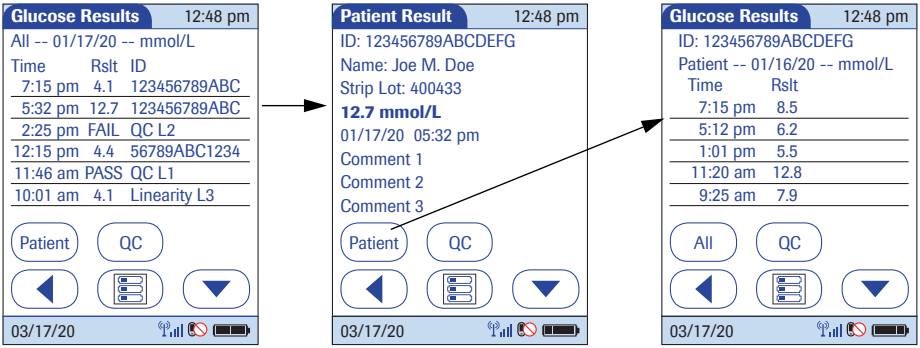
To display the results from the memory as a list:



1 From the *Main Menu* screen touch *Review Results*.

All stored test results are displayed in a sequential list.

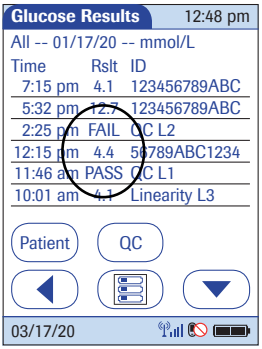
2 Touch ▲ or ▼ to scroll up or down in the list. The results are grouped by date.



3 Touch an entry in the list to display the related details.

4 Touch *Patient*, if you wish to display results for a specific patient only.

- If you touch *Patient* from the full list view, you will be asked to enter the patient ID manually or via bar-code scanner. The list now contains only the results for the selected patient.
- If you touch *Patient* in the *Patient Result* view (middle screen above), the list of test results for this patient will be displayed.



5 Touch *QC*, if you wish to display a list of glucose control tests.

If the meter is configured to show PASS/FAIL instead of a numerical QC result, you can use the list to check whether a meter lockout is due to a failed or overdue control test.

6 Touch *All* in the *Glucose Results* screen to remove the *Patient* or *QC* selection and display all results.

7 Touch ◀ to return to the previous menu screen, or touch ☰ to return to the *Main Menu*.

6 Storing Test Strip, Control Solution, and Linearity Solution Information in the Meter

6.1 Storing information about test strips

Each box of test strips contains a code key.[1] Each code key belongs to a single lot number and provides important information about the lot-specific properties of the test strip. The properties of the test strips are downloaded (as a code file) from the code key using the code key reader and sent to the meter. The code file is stored in the meter.

This procedure also allows the code key information to be stored centrally in the data management system, from where it can be sent to all the meters used in your facility.

Make sure with each test that the code stored (and selected by you) matches the lot number of the test strips in use.

Aside from the unchangeable data directly linked to the lot-specific properties, some of the information from the code key can be modified (depending on your meter setup). This information includes:

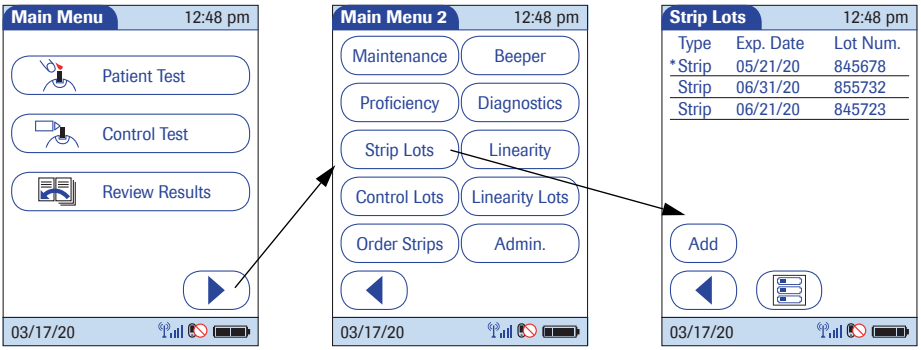
- Expiration date (can be set to a date **before** the date stored in the key)
- Parameters for control solutions (minimum and maximum values for levels L1/Lo and L2/Hi)

When using a data management system for configuration, it is possible to partially or fully disable the functions described in this chapter. In this case, the respective buttons in *Main Menu 2* do not appear. See also Appendix A.

1. The *code key* is also frequently referred to as a *code chip*. The terms are synonymous.

Transferring code key information to the meter

The following description assumes that the meter is powered on and the *Main Menu* is displayed.

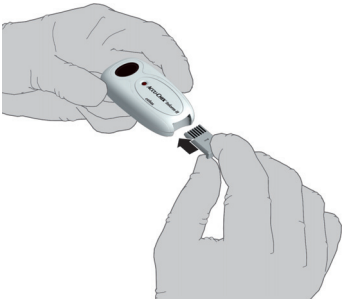


1 Touch ▶ to open the *Main Menu 2* screen.

2 Touch *Strip Lots* to open the related menu.

3 Touch *Add* if you want to add the information for a new test strip lot from a new code key. The *Add Strip Lot* screen opens.

4 Insert the new code key into the opening of the code key reader. The LED starts flashing green and signals that the reader is ready to transfer data.



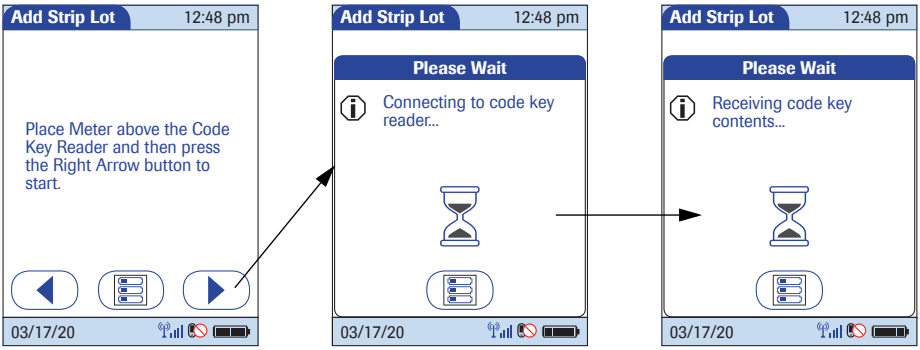
The code key reader remains ready to send for a few seconds after it has transmitted data. As a result, you can perform the following procedure on multiple meters without having to reinsert the code key.

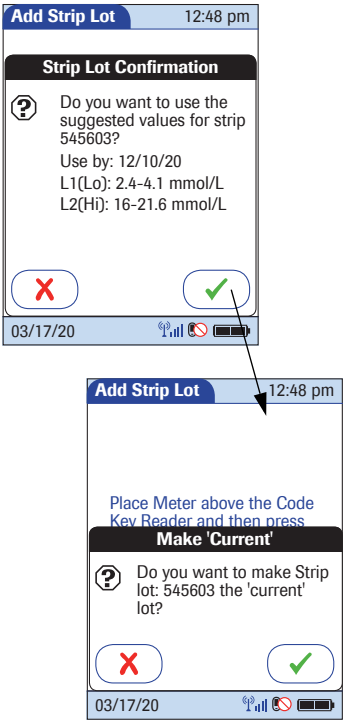
5 Place the code key reader on a level surface such as a bench. Hold the meter 10-15 cm (4-6 in) above the code key reader so that a connection can be made between the two infrared windows.

6 Touch ▶ to begin downloading data.

- The code file is ready for transmission as long as the LED on the code key reader is flashing, even if the code key is removed.
  - After the LED stops flashing, remove the code key and insert a new code key for download, if required.
  - If you get an error message that the download was not successful, re-insert the same code key and try again.
- Do not replace code keys while the code key reader is still flashing. If the code key reader is still flashing, it will continue to transmit the previously loaded code file and ignore the code file on the newly inserted code key. You may get an error message on the meter.

Once the connection is made, the meter provides you with status information on the download.





Information about the expiration date and parameters for control solutions is subsequently displayed.

1 Touch (✓) to store the data for this lot number in the meter without changes, or touch (X) to modify the data for this lot number before storing it in the meter.

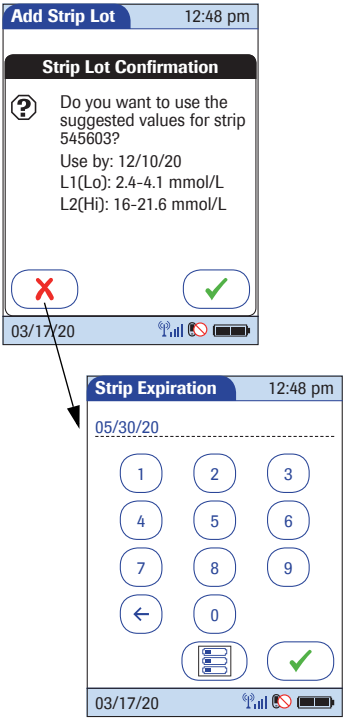
If you accept the suggested values the following screen appears. You can use this screen to select the lot number you have just transmitted as the current lot number.

The current lot number is provided automatically for use with subsequent tests.

2 Touch (✓) to confirm that you want this lot number to be the lot number currently in use, or touch (X) to store the entries without making the lot number the current lot number.

3 Continue entering additional lot numbers, or touch (☰) to return to the *Main Menu*.

Editing test strip data

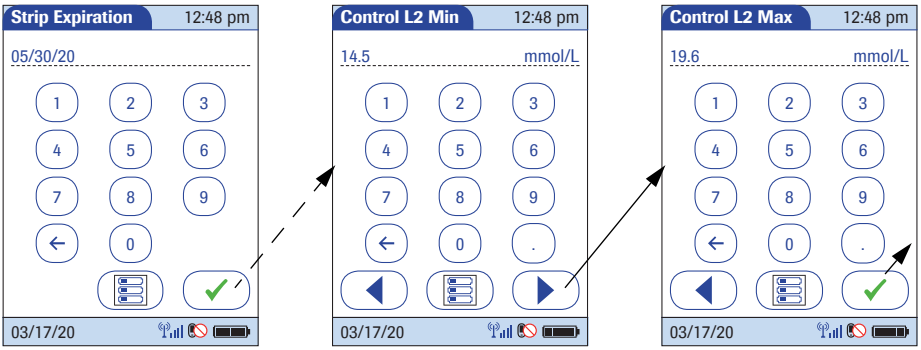


As mentioned at the beginning of this chapter, you can edit several parameters for test strips, the expiration date and the value ranges for control solutions.

1 Use the keypad to enter the desired expiration date (use two digits and leading zero, if necessary). It is **not** possible to enter a date beyond the expiration date stored in the key.

2 Touch ✓ to accept the modified date and continue to the value ranges.

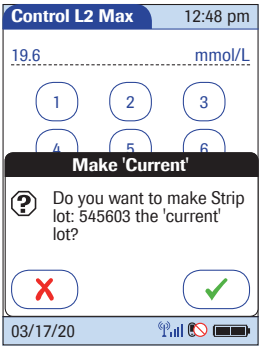
The parameters for control solutions consist of four separate values.



3 Use the keypad to enter the desired values one after another:

- Minimum limit value for Level 1
- Maximum limit value for Level 1
- Minimum limit value for Level 2
- Maximum limit value for Level 2

4 Touch (▶) to confirm each separate entry and continue to the next entry.



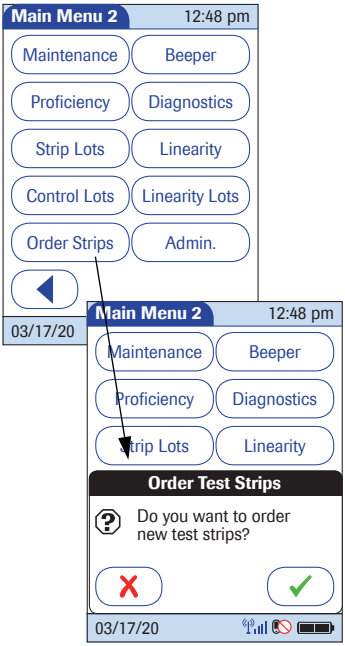
Once you have finished updating the test strip information, you can use the next screen to select the lot number you are currently editing as the current lot number.

The current lot number is provided automatically for use with subsequent tests.

5 Touch ✓ to confirm that you want this lot number to be the lot number currently in use, or touch ✗ to store the entries without making the lot number the current lot number.

6 Continue entering additional lot numbers, or touch ☰ to return to the *Main Menu*.

Order test strips



If you notice that strip lots are running empty or the expiration date is approaching soon, you can inform your system administrator to reorder new test strips.

1 Touch *Order Strips* to open the related menu.

2 Touch ✓ to confirm that you want to inform your system administrator about the order, or touch ✗ to close this dialog without sending the order request.

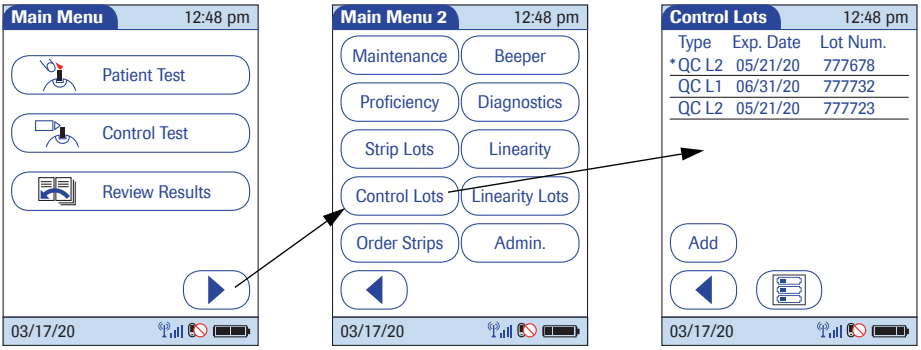
Confirming the *Order Test Strips* dialog creates and sends an order event to the DMS. This does not automatically lead to an order of new test strips. The administrator is informed via the DMS and has to place the order accordingly.

6.2 Storing control solution information

Glucose control solution lot information can be entered before testing, if lot editing has been allowed at the meter level in the setup, and appears in a list for operators to refer to. Use the following procedure to add glucose control lot numbers to the Control Lot list.

Entering the lot number of the control solution

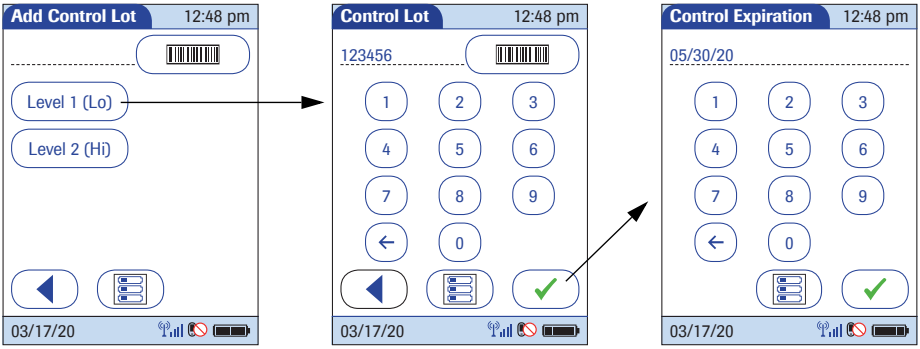
The following description assumes that the meter is powered on and the *Main Menu* is displayed.



1 Touch (▶) to open the *Main Menu 2* screen.

2 Touch *Control Lots* to open the related menu.

3 Touch *Add* to enter a new lot number.



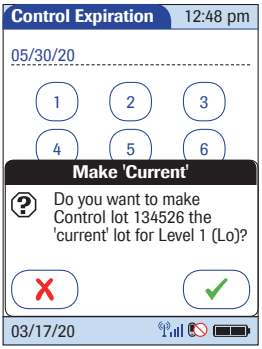
4 Select the level (L1/Lo or L2/Hi).

5 Use the keypad to enter the lot number. Touch (✓) to confirm the entered lot number, or press and release (barcode) to read the lot number from the control solution bottle via barcode scanner. Follow the instructions for scanning IDs (see page 47). *

6 Use the keypad to enter the expiration date as stated on the control solution bottle.

7 Touch (✓) to confirm the entered expiration date.

* Barcodes on control solutions may not be available in all countries (see page 58).



Once you have finished updating the control solution information, you can use the next screen to select the lot number you are currently editing as the current lot number.

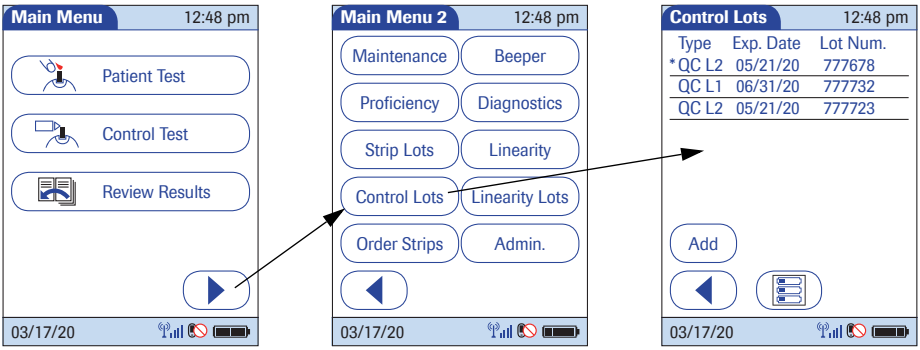
The current lot number is provided automatically for use with subsequent tests.

8 Touch (✓) to confirm that you want this lot number to be the lot number currently in use, or touch (✗) to store the entries without making the lot number the current lot number.

9 Continue entering additional lot numbers, or touch (☰) to return to the *Main Menu*.

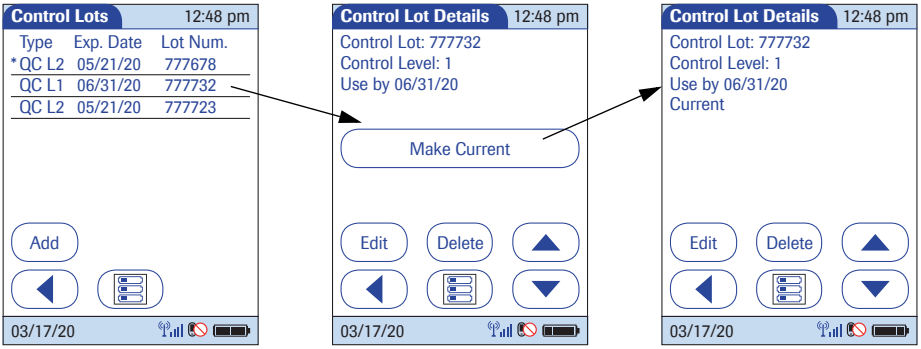
Selecting a stored lot number as the current lot number

You can select any stored lot number as the current lot number.



1 Touch (▶) in the *Main Menu* to open the *Main Menu 2* screen.

2 Touch *Control Lots* to open the related menu. The current lot number is indicated by an asterisk (*).



3 Touch the lot number you wish to select as the current lot number. This opens the related detail view.

4 Touch *Make Current* to make the lot number the current lot number. The information *Current* is then also displayed in the detail view.

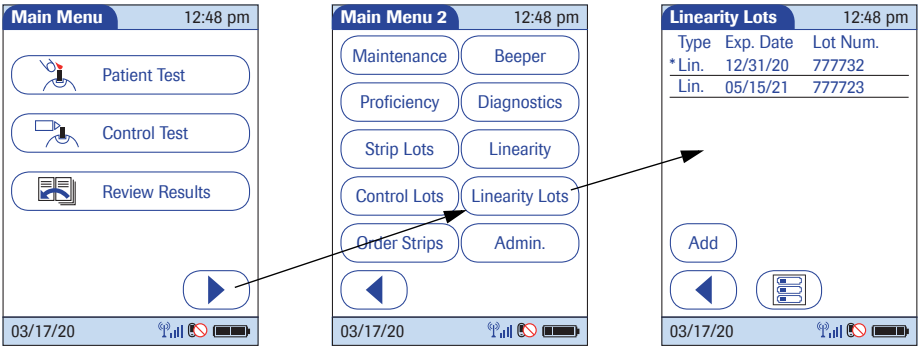
5 Touch ◀ to return to the list of lot numbers, or touch ☰ to return to the *Main Menu*.

6.3 Storing linearity test information

Observe the applicable regulations and directives of the responsible regulatory agencies when performing linearity tests.

Entering the lot number of the linearity test

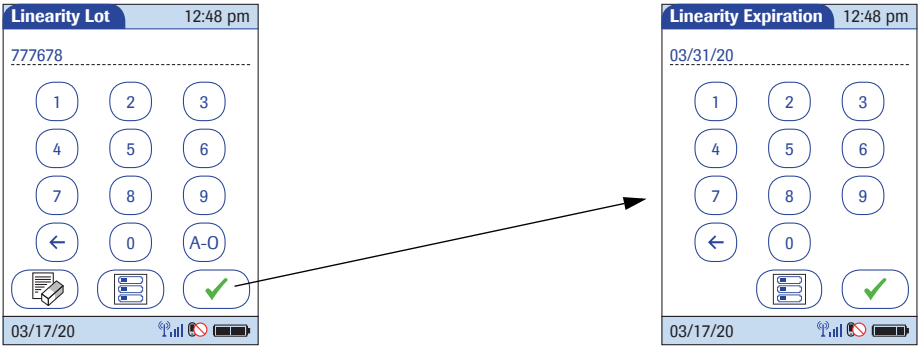
The following description assumes that the meter is powered on and the *Main Menu* is displayed.



1 Touch (▶) to open the *Main Menu 2* screen.

2 Touch *Linearity Lots* to open the related menu.

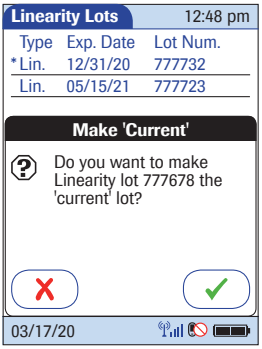
3 Touch *Add* to enter a new lot number.



4 Use the keypad to enter the lot number.

5 Touch (✓) to confirm the entered lot number.

6 Enter the expiration date (use two digits and leading zero, if necessary) and touch (✓) to confirm the expiration date you have entered.



Once you have finished updating the linearity test information, you can use the next screen to select the lot number you are currently editing as the current lot number.

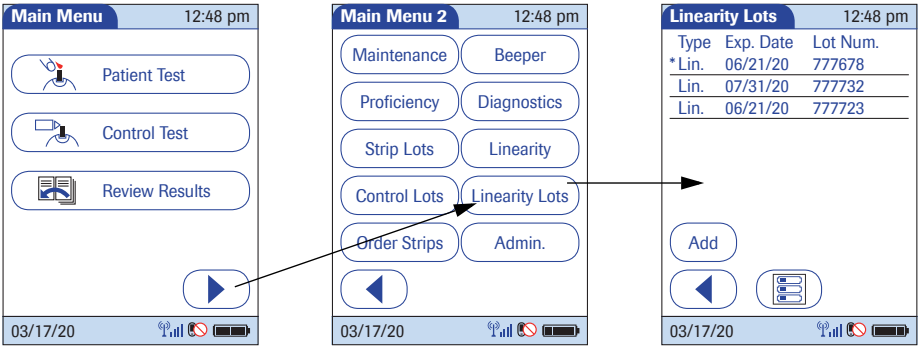
The current lot number is provided automatically for use with subsequent tests.

7 Touch (✓) to confirm that you want this lot number to be the lot number currently in use, or touch (✗) to store the entries without making the lot number the current lot number.

8 Continue entering additional lot numbers, or touch (☰) to return to the *Main Menu*.

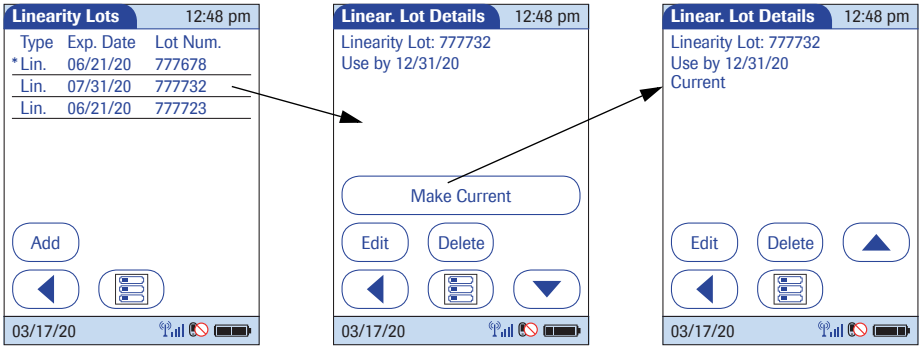
Selecting a stored lot number as the current lot number

You can select any stored lot number as the current lot number.



1 Touch (▶) in the *Main Menu* to open the *Main Menu 2* screen.

2 Touch *Linearity Lots* to open the related menu. The current lot number is indicated by an asterisk (*).



3 Touch the lot number you wish to select as the current lot number. This opens the related detail view.

4 Touch *Make Current* to make this lot number the current lot number. The *Current* information is then also displayed in the detail view.

5 Touch ◀ to return to the list of lot numbers, or touch ☰ to return to the *Main Menu*.

7 Linearity Testing

7.1 Information regarding linearity tests

Observe the applicable regulations and directives of the responsible regulatory agencies when performing glucose control tests. See also safety message “Allergy or injury caused by reagents and other working solutions” on page 20. For information about sources for products required during linearity testing, contact your local Roche representative.

Linearity tests can help you to check the function and accuracy of the entire system over the full range of specified values. Linearity samples should be treated in exactly the same manner as previously described for control solutions used in glucose control testing.

The term “Linearity” describes the ability of the system to maintain a constant accuracy over the full range of specified values. If test results were plotted against reference values as a curve over the full range of these values, the ideal (high linearity) would be a straight line. Linearity is the range of values from the lowest to the highest for which an instrument is proven capable of giving accurate results.

When using a data management system for configuration, it is possible to partially or fully disable the functions described in this chapter. In this case, the respective buttons in *Main Menu 2* do not appear. See also Appendix A.

Linearity testing intervals

The linearity of the system should be checked before it is used the first time for patient testing. The intervals for subsequent linearity tests are determined by the facility that operates the system. Linearity testing can also be run when you want to check the overall performance of the system.

Information stored during linearity testing

The following information is stored for every linearity test:

- Test result
- Lot number of the linearity solution
- Level of linearity solution (L1 to L6)
- Operator ID (if configured)
- Lot number of the test strips
- Time and date of test
- Comments (if applicable)

Linearity test kit

The linearity test kit contains glucose solutions in six levels (6 vials, 2.5 mL each). For additional information about the contents and handling of the kit, refer to the package insert.

Preparing to run a linearity test

Aside from special preparations (see the following section), a linearity test is run the same as a patient test. Please check the following:

- At least one code file for test strips must be stored in the meter and match the lot number of the test strips used (see Chapter 6).
- The proper test strips must be available.
- An operator ID must be entered (with password, if applicable), if the meter is configured for login.

7.2 Performing a linearity test

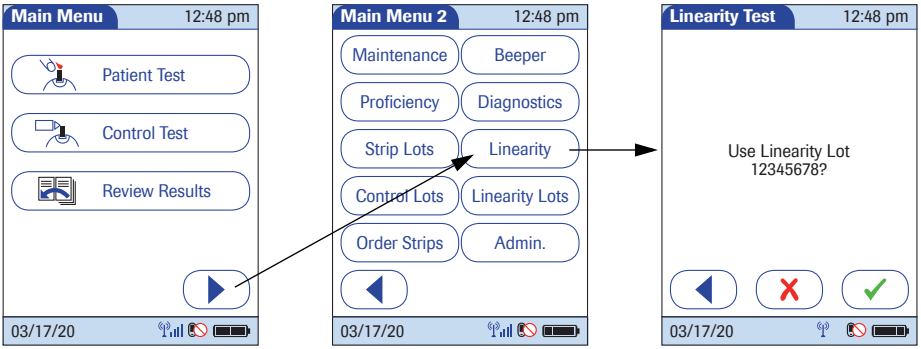
Overview of test procedure

A linearity test comprises the following steps:

- Check the lot number of the linearity solutions.
- Check the lot number of the test strips.
- Perform the test with a minimum of three linearity solutions.

Starting a linearity test

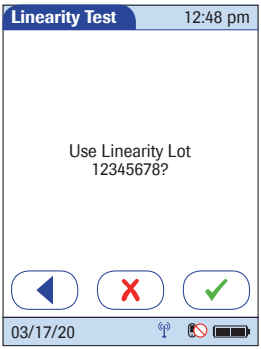
The following description assumes that the meter is powered on and the *Main Menu* is displayed.



1 Touch (▶) in the *Main Menu* to open the *Main Menu 2* screen.

2 Touch *Linearity* to start the linearity test. The *Linearity Test* screen opens.

Confirming or selecting the lot number for linearity test kits



You are now prompted to confirm or enter the lot number of the linearity test kit. Compare the number displayed by the meter to the number on the label of the linearity test kit.

3 If you want to use the preselected number displayed by the meter, touch (✓) to confirm.

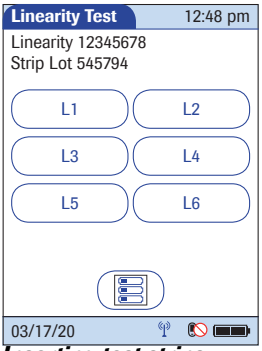
To use a different number than the lot number displayed, touch (✗) to open the keypad and enter the number manually (see page 101).

Confirming or selecting the test strip lot

Once you have entered and confirmed the lot number of the linearity test kit, you are asked to choose the lot number of the test strips. Compare the number displayed by the meter to the number on the label of the test strip vial.

4 If you want to use the preselected number displayed by the meter, touch (✓) to confirm.

To use a different number than the lot number displayed, touch (✗) to select the number from a list, enter the number manually via keypad, or use the barcode scanner to enter the lot number (see page 57).

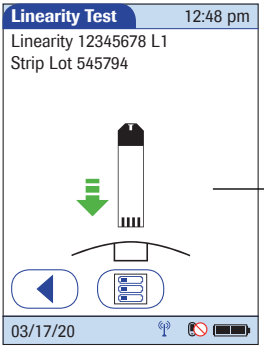


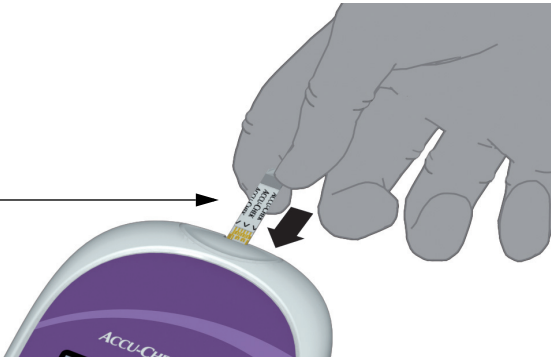
In the *Linearity Test* menu, the levels available for the linearity test are displayed.

5 Touch *L1* to start the subsequent test with this (first) level.

Inserting test strips

After selecting the level, a flashing green arrow appears on screen and prompts you to insert the test strip.





1 Remove the test strip from the test strip vial and close the vial again with the cap.

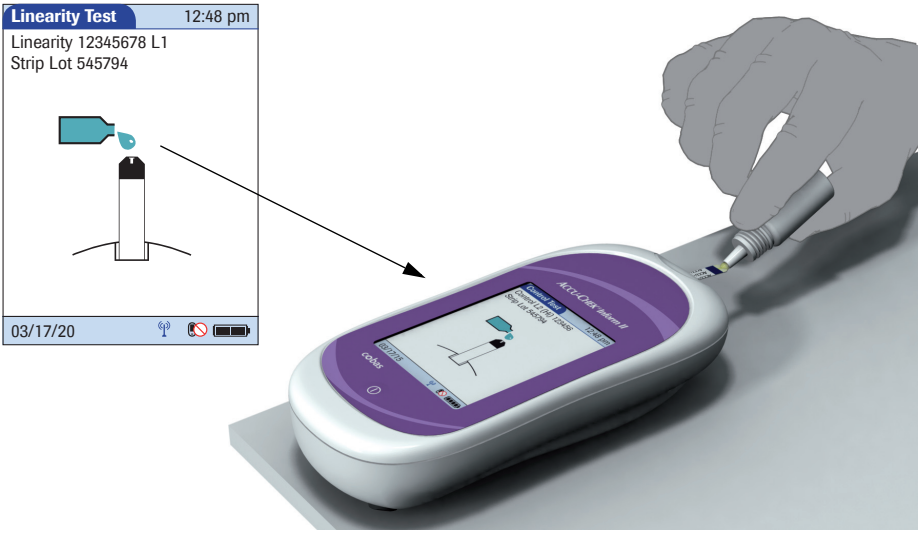
2 Hold the test strip so the lettering “ACCU-CHEK” is facing upward.

3 Slide the test strip into the test strip port as far as it will go in the direction indicated by the arrows on the test strip.

The meter beeps. The hourglass icon appears and indicates that the meter is checking the test strip. Do not apply linearity solution while it is displayed.

Applying a linearity test sample

Once the meter has checked the test strip, the hourglass icon disappears and you are prompted to apply linearity solution.



When applying the linearity solution, position the meter so that the test strip port is always higher or on the same level as the linearity solution. This prevents any excess solution from flowing down the strip and entering the meter.

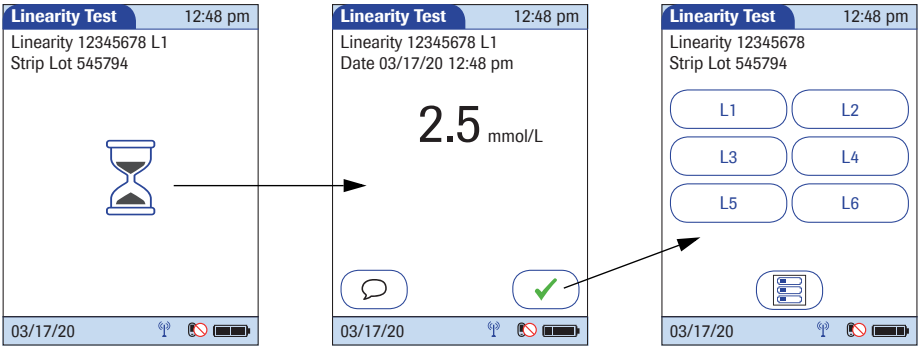
1 Wait until the flashing drop appears in the display before applying the solution. The meter beeps.

2 Apply a drop of the linearity solution to the **front edge** of the test strip. Do **not** apply the solution to the top of the strip.
The linearity solution is pulled into the test strip area by capillary action.

Once sufficient linearity solution has been detected, the meter beeps and the measurement begins.

Results screen

The hourglass icon indicates the test is running. When the test is completed and the result is ready, the meter beeps again.



You can add comments to a test result (as with blood glucose tests, see page 66).

If you do not wish to add a comment to the test result, touch ✓ to continue to the next level of the linearity test.

Remove the test strip and dispose of it in accordance with applicable regulations and directives. Repeat the above steps for all levels of the linearity test.

Test results are saved automatically if the meter is powered off or if it powers itself off after 10 minutes of inactivity/no screen touches (see “Automatic power-off” on page 22).

8 Proficiency Testing

8.1 Information regarding proficiency tests

Observe the applicable regulations and directives of the responsible regulatory agencies when performing proficiency tests.

Blood glucose proficiency tests are run on samples whose values are unknown to the operator performing the test. These samples are provided by an outside source, and the results should be forwarded to the appropriate source after completing the test. The supplied samples are treated in the same manner as regular patient samples.

Blood glucose proficiency testing provides another means to verify that your technique, reagents, system, and testing performance are as they should be. Some regulatory agencies require that these proficiency samples be tested as part of an institution's quality assurance program before certification of the institution is allowed.

When using a data management system for configuration, it is possible to partially or fully disable the functions described in this chapter. In this case, the respective buttons in *Main Menu 2* do not appear. See also Appendix A.

Information stored during proficiency testing

The following information is stored for every proficiency test:

- Test result
- Sample ID
- Lot number of the test strips
- Time and date of test
- Comments (if applicable)
- Operator ID (if configured)

For blood glucose proficiency tests, the sample ID (instead of patient ID) must be stored as identification. Sample IDs with up to 20 characters can be entered.

Preparing a proficiency test

To perform a proficiency test you need the following:

- At least one code file for test strips must be stored in the meter and match the lot number of the test strips used (see Chapter 6).
- The proper test strips must be available.
- An operator ID must be entered (with password, if applicable), if the meter is configured for login.

8.2 Performing a proficiency test

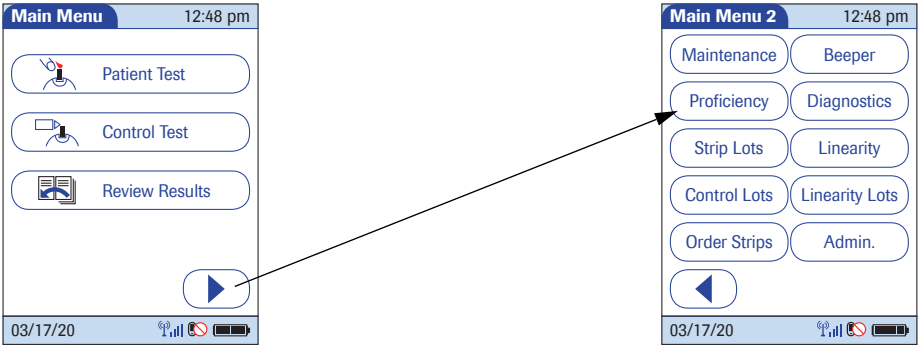
Overview of test procedure

A proficiency test comprises the following steps:

- Enter a sample ID for the proficiency sample.
- Check the lot number of the test strips.
- Perform the actual test with the proficiency sample.

Starting a proficiency test

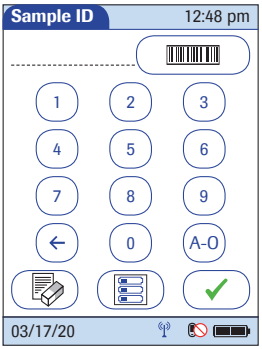
The following description assumes that the meter is powered on and the *Main Menu* is displayed.



1 Touch (▶) in the *Main Menu* to open the *Main Menu 2* screen.

2 Touch *Proficiency* to start the proficiency test.

Entering the proficiency sample ID



You will now be asked to enter the sample ID.

1 Use the keypad to manually enter the sample ID, or press and release (barcode) to read the sample ID from the sample vial via barcode scanner (see page 47). Make sure in this case that the proficiency sample has a compatible barcode (see Appendix A).

2 Touch (✓) to confirm the selected or scanned sample ID.

Confirming or selecting the test strip lot

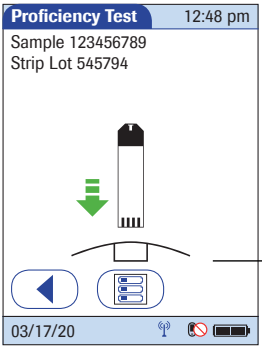
Once you have entered and confirmed the sample ID, you will be asked to choose the test strip lot number. Compare the number displayed by the meter to the number on the label of the test strip vial.

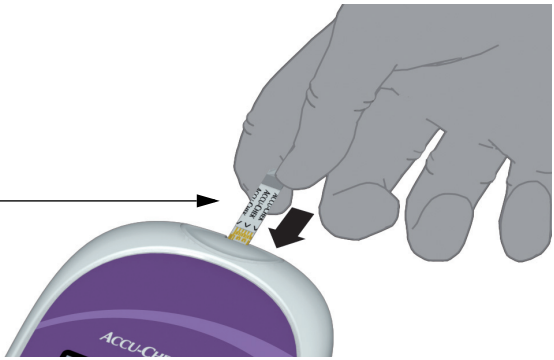
3 If you want to use the preselected number displayed by the meter, touch (✓) to confirm.

To use a different number than the lot number displayed, touch (X) to select the number from a list, enter the number manually via keypad, or use the barcode scanner to enter the lot number (see page 57).

Inserting test strips

After confirming the test strip lot, a flashing green arrow appears on screen and prompts you to insert the test strip.





1 Remove the test strip from the test strip vial and close the vial with the cap.

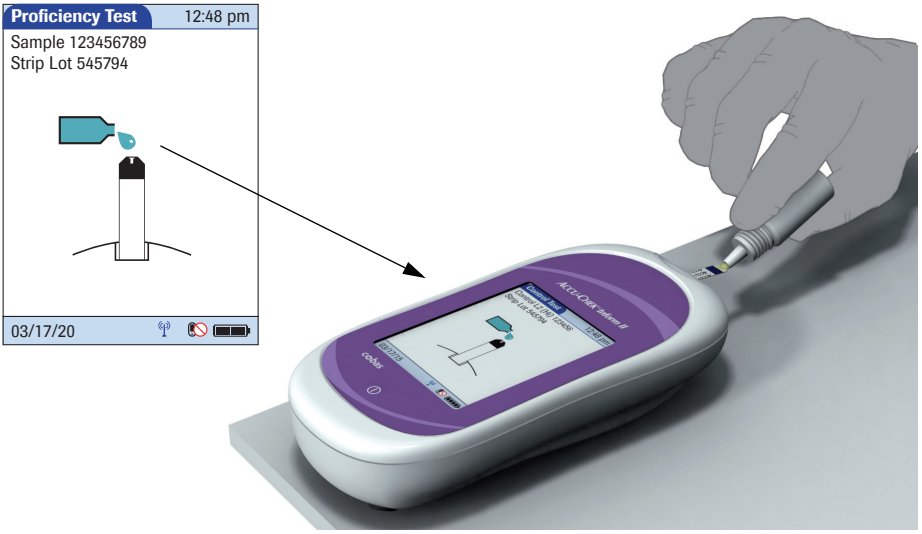
2 Hold the test strip so the lettering “ACCU-CHEK” is facing upward.

3 Slide the test strip into the test strip port as far as it will go in the direction indicated by the arrows on the test strip.

The meter beeps. The hourglass icon appears and indicates that the meter is checking the test strip. Do not apply the proficiency sample while it is displayed.

Applying a proficiency sample

Once the meter has checked the test strip, the hourglass icon disappears and you are prompted to apply the proficiency sample.



When applying the proficiency sample, position the meter so that the test strip port is always higher or on the same level as the sample. This prevents any excess sample from flowing down the strip and entering the meter.

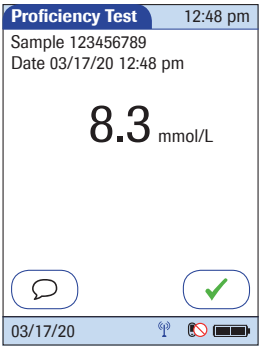
1 Wait until the flashing drop appears in the display before applying the sample. The meter beeps.

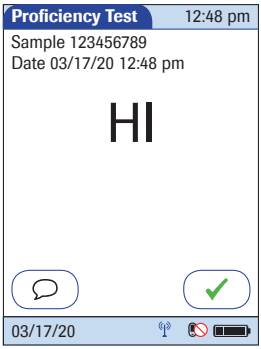
2 Apply a drop of sample to the **front edge** of the test strip. Do **not** apply the sample to the top of the strip. The sample is pulled into the test strip area by capillary action.

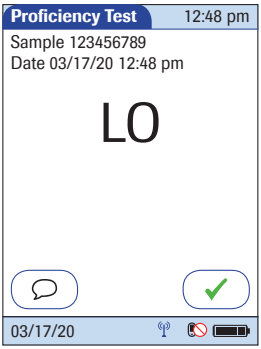
Once sufficient sample has been detected, the meter beeps and the measurement begins.

Results screen

The hourglass icon indicates the test is running. When the test is completed and the result is ready, the meter beeps again.







The result is displayed as a numerical value, unless it falls outside the system measurement range. In this case, the message *Hi* or *Lo* is displayed.

You can add comments to a test result (as with blood glucose tests) (see page 66).

If you do not wish to add a comment to the test results, touch ✓ to complete the test and store the result.

Test results are saved automatically if the meter is powered off or if it powers itself off after 10 minutes of inactivity/no screen touches (see “Automatic power-off” on page 22).

Remove the test strip and dispose of it in accordance with applicable regulations and directives for disposal of potentially infectious samples and materials.

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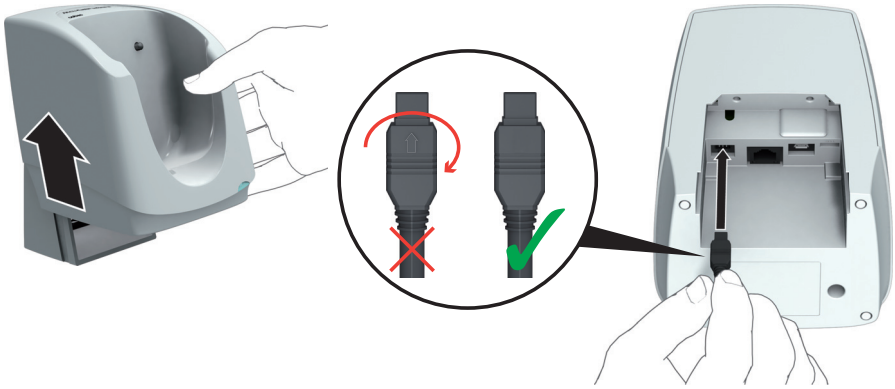
9 Initial Startup

9.1 Connecting the base unit

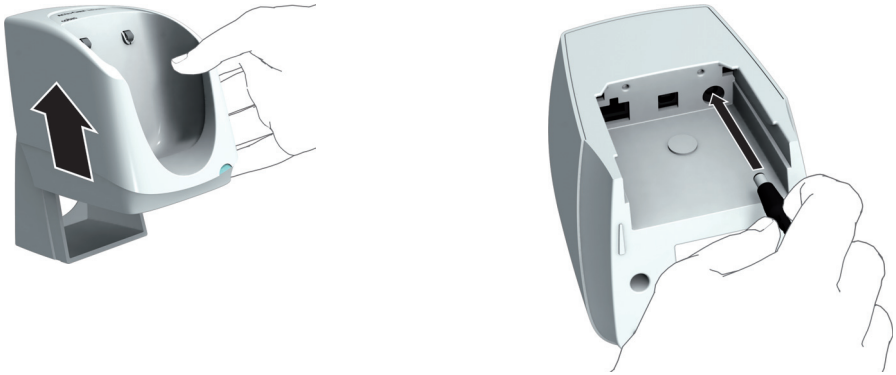
NOTICE

To ensure continuous safe and reliable operation, use only the power supply unit provided for the Accu-Chek Inform II system (for ordering information see page 169).

Accu-Chek Inform II Base Unit:



Accu-Chek Inform II Base Unit Light:



1 Slide the base unit upward and remove it from the wall mount (if in use).

2 Connect the power supply to the power input jack.

3 **If you want to connect the Accu-Chek Inform II Base Unit in a wired environment:** Connect the Ethernet (RJ45) cable or the USB cable to the respective port. Use only the USB cable provided with the Accu-Chek Inform II system.

4 Slide the base unit back onto the wall mount (if in use).

For details on configuring the Accu-Chek Inform II Base Unit, consult your Roche representative.

Note for System Administrator: For further technical information on setting up and configuring the Accu-Chek Inform II Base Unit, consult the package insert accompanying the device and the "Technical Note" stored on the Accu-Chek Inform II Base Unit as a PDF file. You can access this file by connecting the base unit to a PC with the USB cable.

For connecting the Base Unit with older hardware (REF 05060290001), see Appendix F, "Appendix for Accu-Chek Inform II Base Unit (legacy version)".

9.2 Installing or replacing the battery pack

When shipped, the battery pack is not installed in the Accu-Chek Inform II meter.

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 for at least 8 hours (e.g., overnight)** in the base unit before testing.

Whenever the meter is in the base unit, the icon is displayed. This icon shows that power is available and the meter can charge, if necessary.

Make sure that the allowable temperature range for charging the battery pack (3-42 °C or 37-108 °F) is maintained during installation and initial setup.

Replace the battery pack within approximately 10 minutes 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 124.

Data stored in the memory (see section 12.1) is kept when replacing the battery pack even if no battery is inserted. All settings (other than date/time - see above) are also retained.

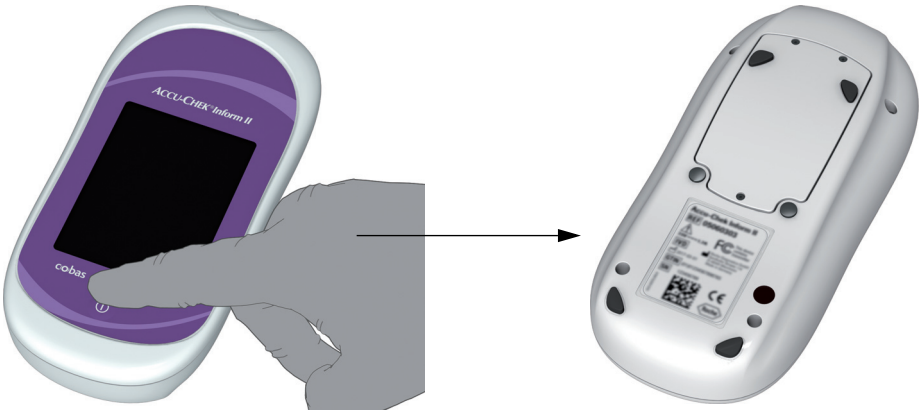
Removing the battery pack

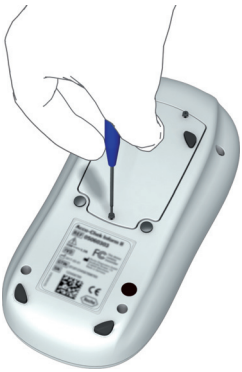
If a battery pack is already installed, make sure that the meter is shut down to prevent damage to the meter or potential data loss.

1 To shut down the meter, press the On/Off button ⏻ **for about 5 seconds** and release the On/Off button as soon as the Roche logo is displayed and the meter beeps.

If you press the On/Off button for too long, a meter reset will be triggered after about 12 seconds (see section “Meter reset” on page 162.)

2 Place the meter face down on a level surface.





3 Using a Torx screwdriver size T5, remove the three 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.

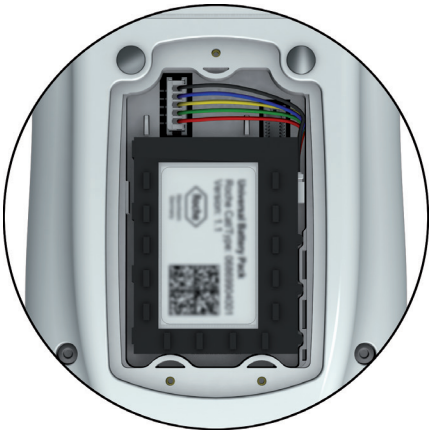
Disposal of used batteries

Do not dispose of the batteries with normal domestic waste. Dispose of used batteries 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 compartment cover until they are protruding about 4-5 mm (2/10 in).

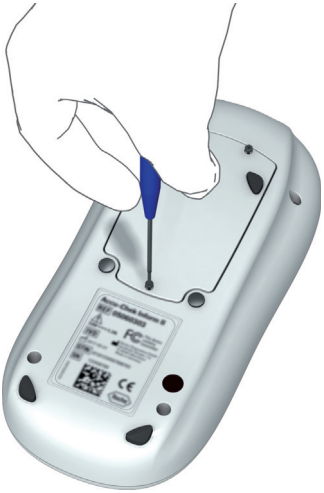
2 Hold the battery pack in your hand, with the wires and the plug pinched between your thumb and index finger.

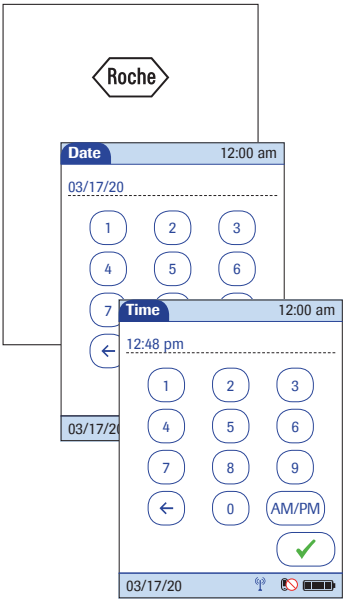


3 Plug the connector plug into the socket.

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

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.





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

6 Tighten all three screws until snug (do not over-tighten).

After inserting a new battery pack, the meter powers on automatically.

- The Roche logo is displayed. If the meter does not power on automatically, the battery pack may be nearly empty. Place the meter in a base unit for a minimum of 15 minutes, then remove the meter and try to power it on. If it powers on, the battery pack is charging properly.
- Within a short period of time, the start screen should appear.
- If the meter has been without power for too long, a message may appear informing you that the date and time settings have been lost due to power loss.
- The screens for entering the date and the time appear.

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

- Unless your QC configuration is *Always OK*, the meter will now be in QC Lockout due to the manually entered date/time.

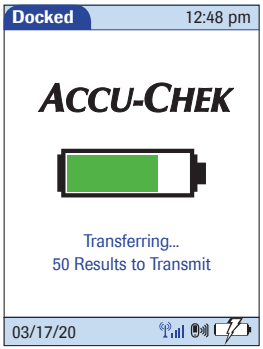
8 Synchronize the meter's date/time with the date/time of your facility via base unit or, if working wirelessly, wait at least ten minutes for the next WLAN synchronization before performing any further tests.

After installing a new battery pack, the meter should be charged for at least 8 hours (e.g., overnight) in the base unit before testing.

9.3 Docking the meter

Docked screen - battery status

Docking the meter in the base unit allows you to charge the battery pack. The *Docked* screen displays a large battery icon showing the current charging status of the battery. This information enables you to choose the meter with the best battery status for the next test.



Battery status is displayed as follows:

Icon	Description
	Battery is empty and device cannot be used.
	Software updates and WLAN disabled.
	Software updates are disabled.
	All functions available

Improved charging performance

After 2 minutes in the base unit, the meter powers off and goes into standby mode. The screen goes blank and the charging process starts. Charging the battery pack in standby mode improves charging performance.

When the screen is blank during the charging process, you can power on the meter at any time **to check** the battery charging status or that the meter is properly docked by touching the screen or pressing the On/Off button ⏻. The screen lights up for 2 minutes and displays the *Docked* screen with the colored battery icon best showing the current battery status.

If the meter is **NOT** properly docked, a short "humming" noise sporadically occurs and the battery charging icon flashes in the status bar.

- Remove the meter from the base unit.
- Redock it by gently pushing it into the base unit to ensure proper contact.

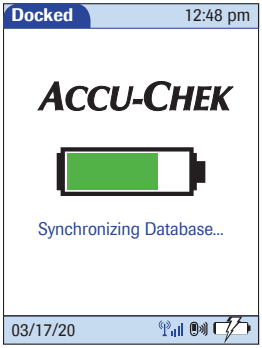
Once the meter is properly docked and charging, the battery charging icon stops flashing. See section "Low power icons" on page 159.

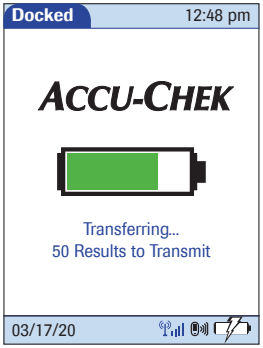
When the battery pack is fully charged, the meter powers on automatically and stays on. The screen displays the green battery icon to show that the battery is fully charged.

Docked screen - meter status

When docked, the meter shows different messages according to the current meter status.

The following displays appear on the meter when it is **docked** in an Accu-Chek Inform II Base Unit or an Accu-Chek Inform II Base Unit Light **and communicating**. The same displays appear whether the meter is transferring data via base unit or via wireless connection.





This display is visible when communication is still active but the meter is busy processing the data received or waiting for the next data message from the DMS.

While being docked and recharging the meter regularly checks the time since the last maintenance reboot. After at least 24 hours another maintenance reboot will be initiated. During this maintenance reboot the integrity of stored data and the function of the measurement module will be checked. Additionally the system searches for outdated results which can be deleted, because the configured retention time for these records has elapsed.

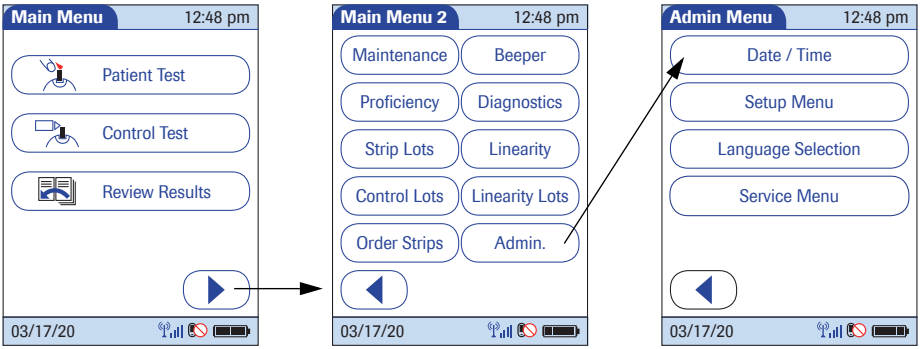
This display is visible when no communication is taking place.

This display is visible when software updates are being transferred to the meter.

- If the meter transfers data wirelessly immediately after a test, this **communication is not visible** on the display. The display remains unchanged (usually in the *Main Menu* view after a test).
- If a meter is in standby (but not docked) and communicating wirelessly, this **communication is not visible** on the display. The display remains blank.

9.4 Setting the date and time

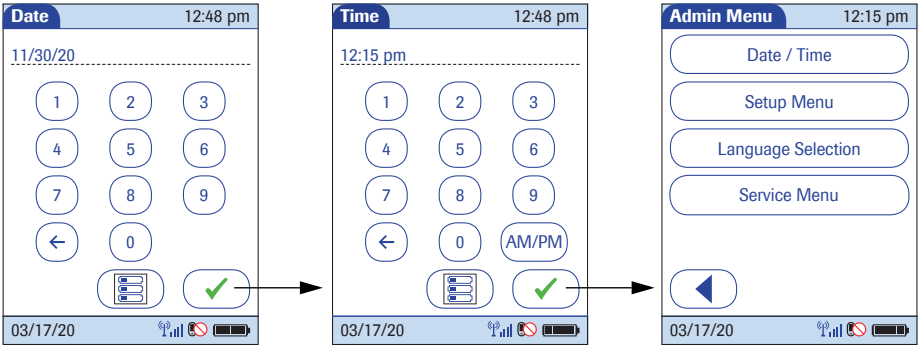
This setting can be hidden or require entry of the setup password, based on configuration.



1 Touch (▶) in the *Main Menu* to open the *Main Menu 2* screen.

2 Touch *Admin.* to open the *Admin Menu*.

3 Touch *Date/Time* to begin entering the date.

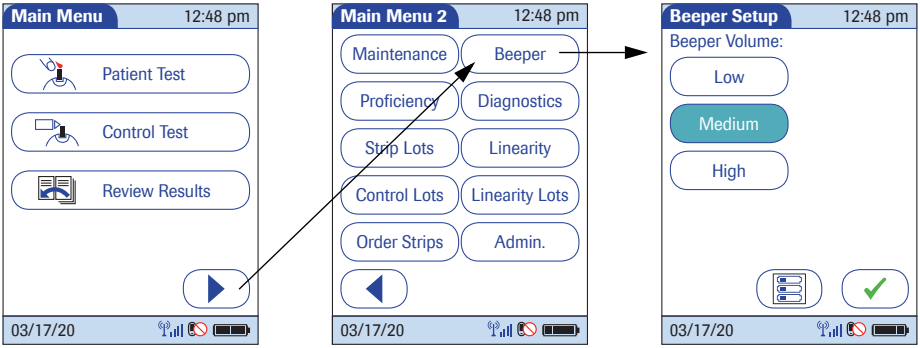


4 Enter the date first, then time (all values are two-digit with a leading zero, if necessary) by touching (✓).

If the time format is “12h”, touch *am/pm* to select the correct time.

9.5 Beeper options

This setting can be used to set the volume of the beeper.



1 Touch (▶) in the *Main Menu* to open the *Main Menu 2* screen.

2 Touch *Beeper* to set the volume.

3 Touch the button with the desired volume. When you touch a button, the meter will beep at the corresponding volume.

4 Touch (✓) to save the setting and return to the *Main Menu 2* screen.

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10 Maintenance and Care

10.1 Conditions for storage and shipping

All information given on maintenance and care of the “base unit” in this chapter applies to both the Accu-Chek Inform II Base Unit and the Accu-Chek Inform II Base Unit Light.

General operating conditions

Please observe the following points to ensure the reliable operation of your system over the long term:

- Handle the meter and its system components with care. Avoid dropping it or banging it.
- Protect the base unit from dripping liquid.
- Do **not** immerse the meter or base unit in any liquid.
- Follow the instructions for cleaning, beginning on page 137.

⚠

Observe the following safety information to ensure the system functions properly. Improper handling can lead to erroneous test results.

- Do not expose the meter to excessive sources of heat for prolonged periods of time when performing a test. Potential sources of heat can be, but are not limited to:
  - Leaving the meter under a bilirubin light or photo therapy light
  - Leaving the meter on a bed warmer
  - Leaving the meter in an isolette

See Chapter 12 for operating and storage temperature ranges.

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 has to be 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. 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 25 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.

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 12).

10.2 Cleaning/disinfecting the Accu-Chek Inform II system

Cleaning and disinfecting the exterior surface of the meter is, at minimum, recommended daily for dedicated patient devices. Meters used with multiple patients may require more frequent cleaning and disinfecting. Follow official recommendations and your facility's policies and procedures for infection control. [1, 2]

The FDA recommends that Point of Care testing devices, such as blood glucose meters, should be used only on one patient and not shared. If dedicating blood glucose meters to a single patient is not possible, the meters must be properly cleaned and disinfected after every use following the guidelines given below. [3]

For technical assistance or questions on cleaning and disinfecting, please contact the Roche Care Center at 1-877-273-3433.

1. FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication, (2010). http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm
2. CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens, (2010). http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html
3. Healthcare Infection Control Practices Advisory Committee (HICPAC), William A. Rutala, Ph.D., M.P.H., and David J. Weber, M.D., M.P.H. Centers for Disease Control and Prevention, 2008. Guideline for Disinfection and Sterilization in Healthcare Facilities. Atlanta, GA.

Guide to cleaning and disinfecting the Accu-Chek Inform II system

Prior to cleaning and disinfecting a blood glucose testing equipment:

1 Follow the infection control procedures of your institution when handling blood glucose testing equipment

2 Wear gloves

3 The gloves worn during cleaning and disinfecting should be removed and hands washed thoroughly with soap and water before performing the next patient test.

Difference between cleaning and disinfecting

Clean the meter to remove visible soil and organic material prior to disinfecting.

Disinfect the meter to destroy pathogenic and other types of microorganisms. Disinfection destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).

When to clean/disinfect

Clean the meter when there are visible signs of soil or per your facility's guidelines.

Disinfect the meter between each patient or per your facility's guidelines

Approved cleaning and disinfecting products

The following active ingredients are tested and approved for cleaning and disinfecting the meter housing:

Active ingredient(s)

- Premoistened disinfecting cloths (active ingredient with a max. concentration of 0,5% quarternary ammonium chlorides and up to 60% isopropanol).

We recommend **Super Sani-Cloth® Germicidal Disposable Wipes**. This product contains the approved active ingredients and is licensed for use in Canada. The use of **Sani-Cloth® Plus Germicidal Disposable Cloths** is not recommended.

NOTICE

Damage to the instrument

Use only products containing the approved active ingredients. Do not use any other cleaning or disinfecting solutions as this could result in damage to the system components.

For technical assistance or questions on cleaning and disinfecting, please contact Roche Care Center at 1-877-273-3433.

Technical Assistance

For technical assistance or questions on cleaning and disinfecting and acceptable products, please contact the Roche Care Center. If you notice any signs of deterioration after cleaning or disinfection of your meter system, stop using the system component and contact the Roche Care Center at 1-877-273-3433.

What to clean/disinfect

The following parts of the meter and system components may be cleaned and disinfected:

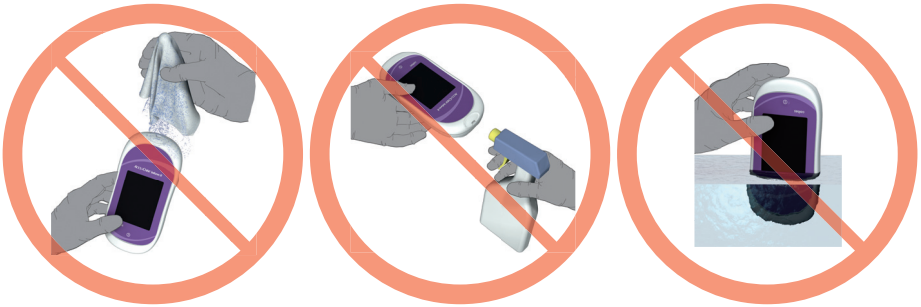
- The area around the test strip port
- The meter display (touchscreen)
- The meter housing (entire meter surface)

⚠ WARNING

Avoid getting liquid into the test strip port!
Moisture in the strip port may lead to incorrect blood glucose results.

- **Do Not** clean/disinfect the meter while performing a blood glucose or control test.
- **Do Not** get any moisture in the test strip port.
- **Do Not** spray into the test strip port.
- **Do Not** immerse the meter in liquid.

If you suspect that moisture may have entered the test strip port, perform a glucose control test.



NOTICE

Do not allow liquid to enter the test strip port or allow pooling of liquid on the touchscreen. If liquid does get into the test strip port, immediately dry the components with a dry cloth or gauze. **If solution is allowed to collect in any meter opening, severe damage to the system can occur.**

How to clean/disinfect

1 Remove the meter from the base unit prior to cleaning/disinfecting.

2 Power off the meter.

3 Place the meter on a level surface.

4 Gently wipe over the surfaces (touchscreen, meter housing) with a soft, lint-free cloth slightly dampened **(not wet)**.

If using commercially available pre-moistened cleaning/disinfection wipes, **squeeze off excess solution** or blot on a dry paper towel to remove any excess solution before wiping the surface of the meter.

5 Carefully wipe over the test strip port area, making sure that no liquid enters the test strip port.

If spraying the meter, place it on a flat surface or table. Wear gloves. Be aware that the meter may become slippery when wet. Do not let the meter drop! Do not spray while the meter is docked in the base unit!

6 Dry the meter thoroughly with a soft cloth or gauze after cleaning. Visually verify that no solution is seen anywhere on the meter at the completion of cleaning.

If you notice streaks on the meter housing or touchscreen, or the touchscreen surface becomes slightly cloudy, wipe clean immediately with a soft, lint-free cloth slightly dampened with water.

Always ensure that the meter is thoroughly dried after cleaning/disinfecting.

Cleaning the barcode scanner window

The barcode scanner window should be cleaned periodically. Use a clean, dry cloth to wipe the barcode scanner window.

Cleaning/disinfecting the base unit

1 Unplug the base unit before cleaning/disinfecting.

2 Wipe over the surfaces with a soft lint-free cloth slightly dampened (wring out any excess).

If using commercially available pre-moistened cleaning/disinfecting wipes, **squeeze off excess solution** or blot on a dry paper towel to remove any excess solution before wiping the surface of the base unit.

Do not wipe the electrical connectors on the back of the base unit.

3 **Dry** the base unit thoroughly after cleaning/disinfecting. Visually verify that no solution is seen in the base unit connectors at the completion of disinfecting. If fluid is allowed to collect in any connector, severe damage can occur to the meter and the base unit.

4 Plug in the base unit.

NOTICE

Ensure meter/base unit (including connectors) are thoroughly dried after cleaning or disinfecting. A flashing LED (red) on the base unit indicates a fault condition.

NOTICE

Do not spray the base unit directly with solutions as this could cause the solution to enter the case and damage the electronic components.

If cleaning/disinfecting solution does get on the connectors or pools in the base unit, unplug the base unit, then **dry the components** with a dry cloth or gauze pad before returning the meter to the base unit.

Cleaning/disinfecting the accessory box

For cleaning, you may wipe the surfaces with a soft cloth slightly dampened (not wet) with 70 % (or less) solution of isopropyl alcohol in water or with 70 % isopropyl alcohol, full strength.

For disinfection: Acceptable active ingredients for disinfecting the accessory box are:

- 0.625 % (or less) solution of sodium hypochlorite in water (bleach).

NOTICE

Use of disinfectants containing other active ingredients could result in damage to the accessory box.

1. Wipe the surface with a soft cloth slightly dampened (not wet).

   If spraying the accessory box, place it on a flat surface or table. Ensure that it is completely empty.
2. Allow the accessory box to air dry for the recommended contact time according to the cleaning/disinfecting solution product labeling. Do not place the meter in the accessory box until all cleaning/disinfecting steps are completed.
3. Dry the accessory box thoroughly with a dry cloth or gauze and visually verify that no solution is seen in the accessory box at the completion of cleaning/disinfecting.

Ensure the accessory box is thoroughly dried before using or filling it again.

Cleaning the code key reader

The code key reader should be cleaned as necessary.

1 Wipe over the surfaces with a clean and soft lint-free cloth slightly dampened with water (wring out any excess).

2 Dry the code key reader with a dry cloth or gauze and visually verify that it is completely dry and no moisture is left on the surfaces after cleaning.

Cleaning the Accu-Chek Inform II Base Unit Hub

The hub should be cleaned as necessary.

1 Unplug the power supply unit and detach all other cables from the hub before cleaning.

2 Wipe over the surfaces with a clean and soft lint-free cloth slightly dampened with water (wring out any excess).

NOTICE

Do not wipe the electrical connectors at the back of the hub. Avoid getting liquid into any opening otherwise it could damage the electronic components.

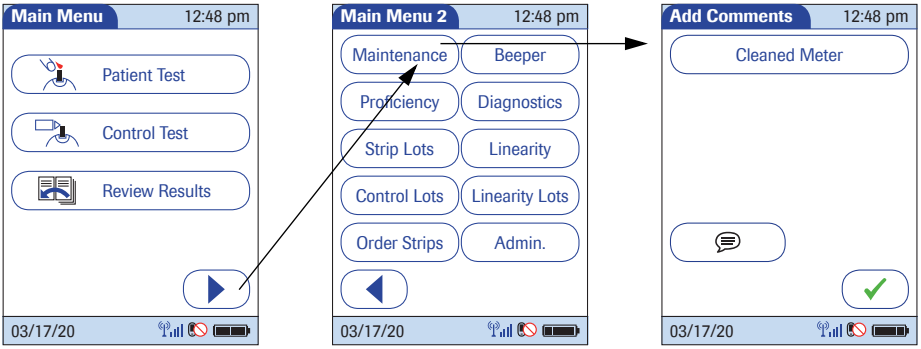
3 Dry the hub with a dry cloth or gauze and visually verify that it is completely dry and no moisture is left on the surfaces after cleaning.

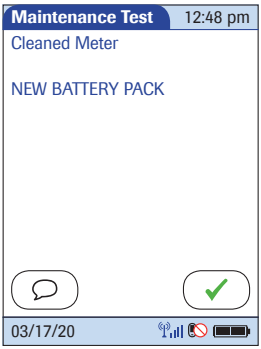
10.3 Logging maintenance activities

Cleaning, disinfecting, and other maintenance activities can be logged in the meter. Make sure that all cleaning activities are complete and the system is thoroughly dry before powering on the meter.

All logged maintenance comments can be reviewed later using the *Review Results* function of the meter (see page 85ff.).

To store cleaning information in the meter, proceed as follows:





1 Touch (▶) in the *Main Menu* to open the *Main Menu 2* screen.

2 Touch *Maintenance* to open the screen for adding comments.

3 Select the desired comment(s) from the list or touch (💬) to enter your own comment via keypad.

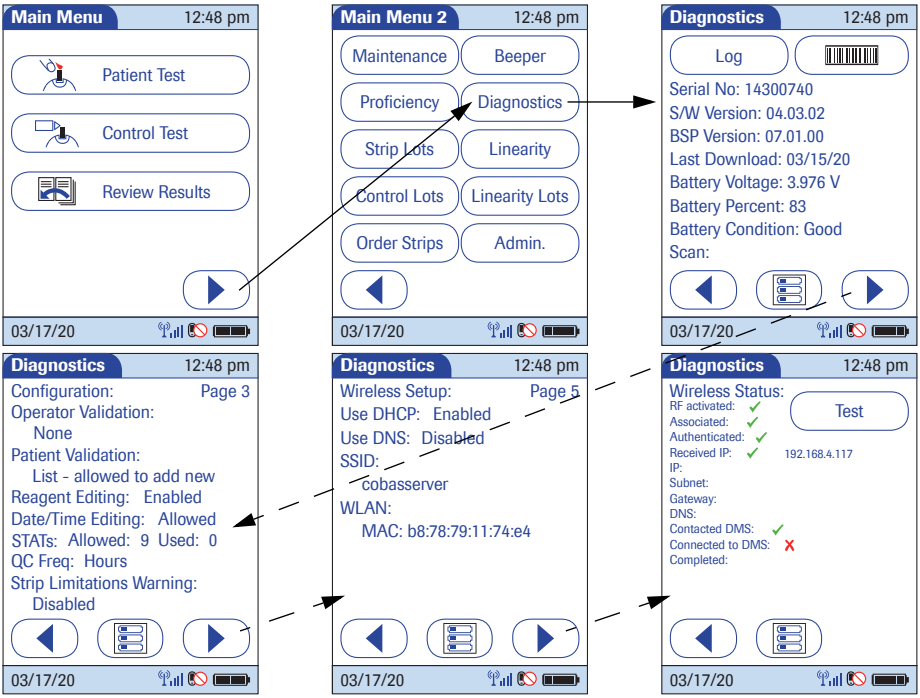
4 Once you have entered your comments, touch (✓) to save the maintenance comments. The *Maintenance Test* screen opens up.

5 Touch (✓) to return to *Main Menu 2*.

You can add up to three comments. For details see section “Adding comments” on page 66.

10.4 Diagnostics view

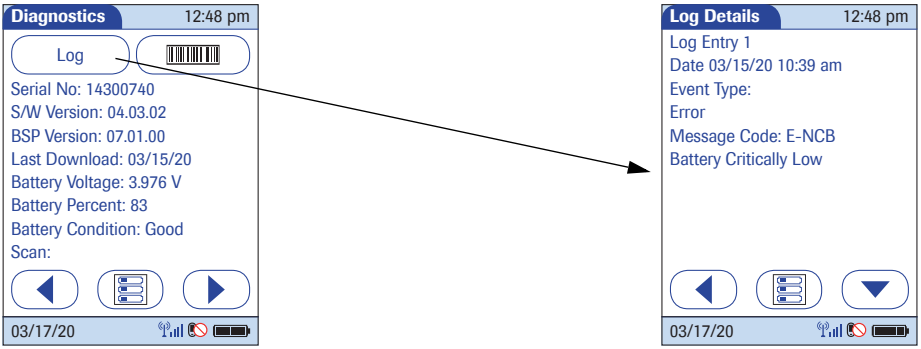
Under *Diagnostics* you can find information about the system, such as software version, number of data records stored, and configuration details. Use this menu to display stored error messages, to test the barcode scanner and the wireless status (if your meter is equipped with the WLAN option), and to check battery health. The *Diagnostics* screens shown here are for illustration purposes only. Information shown on your meter may differ.



1 Touch (▶) in the *Main Menu* to open the *Main Menu 2* screen.

2 Touch *Diagnostics* to call up the main screen for this menu.

3 Touch (◀) or (▶) to scroll between screens.

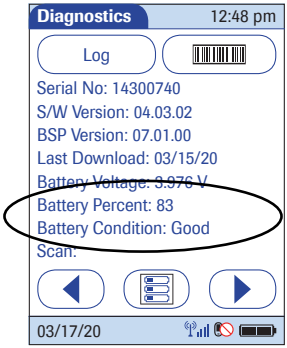


4 Touch *Log* to display stored error messages.

5 Touch  to test the barcode scanner.

6 Touch  to return to the *Main Menu*.

Diagnostics screen – battery condition



The cycle of battery charging, discharging, and recharging ages the battery. Over its lifespan, the battery pack will thus gradually loose capacity. This means, over time, it will power the meter for increasingly shorter periods of time.

In addition to the relative charging status indicated by the battery icon in the Docked screen, the meter provides information about the condition of the battery in the *Diagnostics* screen.

Battery Condition is displayed as follows:

- *Good*: capacity sufficient for normal usage
- *Limited*: capacity reduced due to battery aging

If a battery is no longer providing the expected performance and battery condition is displayed as *Limited*, contact your Roche Support Center.

10.5 Service menu

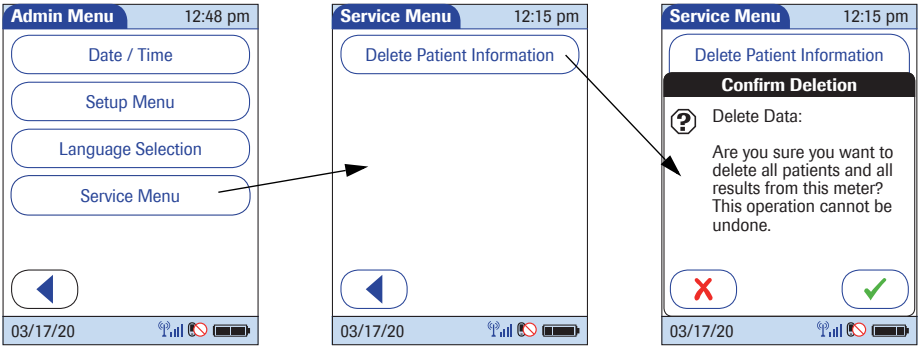
The option *Service Menu* with the feature “Delete Patient Information” is not available in the preconfigured default setting. The *Service Menu* can only be activated via DMS.

Deleting patient information

Deletion of data stored on the meter is not only a maintenance measure to conserve or restore meter memory. It may become necessary to comply with data protection and privacy policies when sending a meter back to the manufacturer or passing it on to another facility. You can delete data manually and/or automatically.

Manual deletion

This feature allows you to delete all patient-related data (patient lists and results) manually.



To ensure deleted data is not transferred back through an unwanted automatic synchronization with the DMS, remove the battery pack immediately after deleting patient data.

Be aware that the function *Delete Patient Information* irrevocably deletes all data once you touch ✓ to confirm. The system will delete any patient results regardless of whether they have been synchronized with a data management system or not. Therefore, always ensure that you have downloaded all relevant patient results before you use this function.

Automatic deletion

If a retention time has been configured via DMS, outdated results will be automatically deleted[1], if they meet the following criteria:

- The result is older than the configured retention time
- The result deletion algorithm is set to automatic
- If the configuration “Result download required” is enabled, the result must already have been transmitted to the DMS

These results will automatically be deleted before each test and/or when the meter is powering up via maintenance reboot. For more information on the maintenance reboot see page 130.

Automatic deletion of patient data is not sufficient when sending a meter back to the manufacturer or passing it on to another facility. Make sure to manually delete **all** data stored in the meter for that purpose.

1. After midnight of the following day.

11 Troubleshooting

The Accu-Chek Inform II meter continually checks its systems for unexpected and unwanted conditions.

A troubleshooting table follows that will help you when the system is not performing as expected. Most concerns can be resolved quickly by referring to this table for help. Take the following steps when an unexpected condition arises:

- Find the displayed message or condition in the Troubleshooting Table.
- Take the action suggested under the column header *Possible Solution*.

If further assistance is required, call your local Roche representative.

Errors and unusual behavior without error messages

Some conditions may arise that have no associated error message. Refer to the following table, if such a condition arises on the Accu-Chek Inform II system.

Display/symptom	Possible solution
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. – Place the meter in the base unit and confirm that it is charging. – Check that the battery pack is correctly installed and connected.
	Follow the instructions in Chapter 9 to avoid data loss when replacing the battery pack.
Meter displays an unexpected result	Refer to the package insert for the test strips.

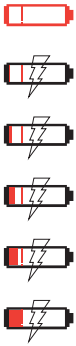
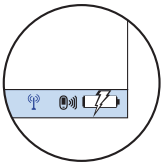
Display/symptom	Possible solution
Test result **LO/HI**	The glucose result may be below (LO) or above (HI) the measurement range of the system. – Refer to the package insert for the test strips. – Check that you are performing the test correctly (see Chapter 3). – Run a glucose control test with a new test strip (see Chapter 4). – Repeat the test or proceed according to the requirements of your facility.
Test result **RR LO/RR HI**	The glucose result may be below/above the reportable range set by system administrator. – Run a glucose control test with a new test strip (see Chapter 4). – Repeat the test or proceed according to the requirements of your facility.
Test result **CR LO/CR HI**	The glucose result may be below/above the critical range set by system administrator. – Run a glucose control test with a new test strip (see Chapter 4). – Repeat the test or proceed according to the requirements of your facility.
Meter displays **Strip defect Error**	The test strip is defective. – Refer to the package insert for the test strips. – Check that you are performing the test correctly (see Chapter 3). – Run a glucose control test with a new test strip (see Chapter 4). – Repeat the test or proceed according to the requirements of your facility. – If the error persists, contact your Roche representative.
Meter displays an error **Type Bad Dose**	Insufficient amount of blood on the test strip. – Refer to the package insert for the test strips. – Review proper testing procedure. – Repeat the test using a new test strip, ensuring proper sample application. – If the error persists, contact your Roche representative.
Meter displays (QC) **FAIL** or **Out of Range**	– Refer to the package insert for the test strips. – Check that you are performing the test correctly (see Chapter 4). – Repeat the glucose control test with a new test strip. – If the error persists, contact your Roche representative.

Display/symptom	Possible solution
Meter displays **Glucose Error**	Detection of an unexpected hardware error – Repeat the test or proceed according to the requirements of your facility. – Run a glucose control test with a new test strip (see Chapter 4). – Power the meter off and on. – Reset the meter by pressing the On/Off button for 12 seconds (see page 162). – If the error persists, contact your Roche representative.
Meter displays **Unexpected SW Error**	Detection of an unexpected software error – Repeat the test or proceed according to the requirements of your facility. – Place meter into a connected base unit to synchronize configurations with the data management system. – If the error persists, contact your Roche representative.
Communication Problems with the Data Management System via RF	
The Accu-Chek Inform II Meter is unable to communicate with the Data Management System	– Check whether WLAN is activated on the meter (see Chapter 2). – Check whether the data transfer icon shows that the last attempt at data transfer was successful (see Chapter 2). – Dock the RF enabled meter into a hard-wired base unit to transfer the data (see Chapter 9). – Check the meter WLAN performance in Diagnostic Screen #7 on the meter. See page 149. – Reset the meter by pressing the On/Off button for 12 seconds (see page 162). – If the error persists, contact your Roche representative.
Base unit	
LED is not illuminated	Not connected to power supply unit or power supply unit is defective, base unit is defective, or mains power outlet not active. – Disconnect and connect the power supply again. – If the error persists, contact your Roche representative.
LED flashes red	Communication or configuration error. – Check the configuration and/or the connection to the Data Management System (DMS). Contact the DMS or IT administrator of your institution. – If the error persists, contact your Roche representative.

Display/symptom	Possible solution
Automatic power-off	
	The meter powers off after a configurable time without activity (e.g., pressing a key, touching the screen) and goes into standby mode to save power. In addition, the meter may power off automatically for the reasons listed below. Reactivate the meter/screen as described in the following:
Power-off after time specified by system administrator (default is 5 minutes, configurable by system administrator)	– Press the On/Off button on the meter.
Battery Low	– Charge the battery by placing the meter in the base unit.
Battery Critically Low	– Charge the battery by placing the meter in the base unit. – Check that the battery pack is correctly installed and connected. – Replace the defective battery pack.
	Follow the instructions in Chapter 9 to avoid data loss when replacing the battery pack.

Low power icons

If the battery pack is running low or not charging properly, the meter will display a series of low power icons. Refer to the following table for their meaning.

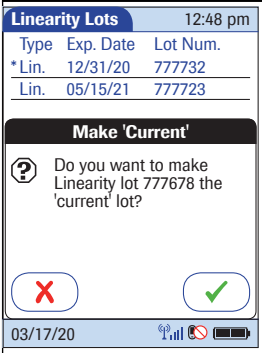
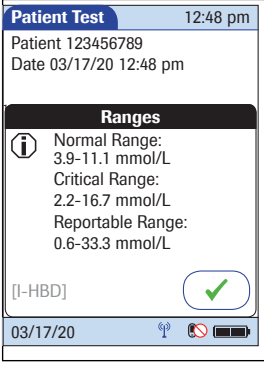
Display/symptom	What it means/Remedy
	Meter displays  when you try to power on: – Battery is empty. Dock the meter. When docked, meter displays  : – Charging status is indicated by a single red segment that grows gradually until the required threshold for booting the meter is reached.
	Avoid using the meter in case of low power to guarantee full functionality. The On/Off button cannot be used. If not docked, the meter will shut down automatically after 1 minute.
Flashing  icon in status bar 	If the meter is not properly docked, a short “humming” noise sporadically occurs and the battery charging icon flashes. – Remove the meter from the base unit. – Redock it by gently pushing it into the base unit to ensure proper contact. Once the meter is properly docked and charging, the battery charging icon stops flashing.

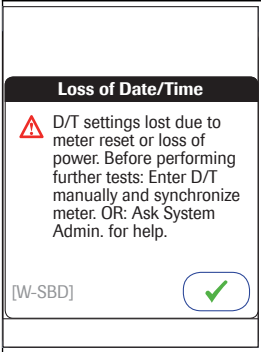
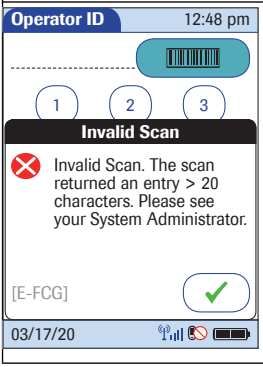
Pop-up messages

There are different message types displayed by the meter, namely decision, information, warning, and error messages. All except the decistion messages contain a letter code on the lower left side of the screen. The first letter of this code identifies the message type (**I**nformation, **W**arning, **E**rror)

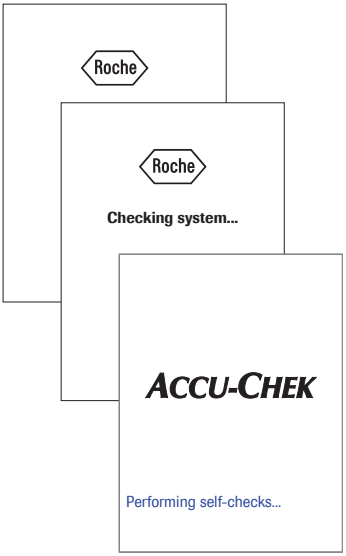
All error messages displayed by the system are accompanied by a description of the error and a possible solution. Take the action suggested on screen to resolve the problem.

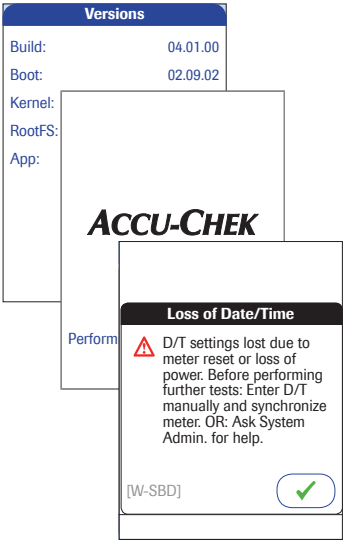
The different message types are illustrated in the following table.

Sample message type	Description
	– Decision; To confirm, touch (✓). To reject, touch (X).
	– Information; touch (✓) to confirm.

Sample message type	Description
	– Warning; touch ✓ to confirm.
	– Error; touch ✓ to confirm. To resolve the problem, take the actions suggested.

Meter reset





A meter reset should only be performed if all other remedies have failed.

1 Place the meter on a level surface.

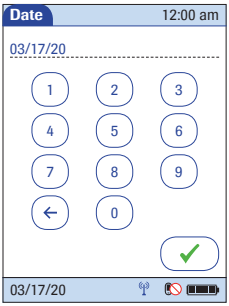
2 Press the On/Off button for at least 12 seconds **and release the button**.

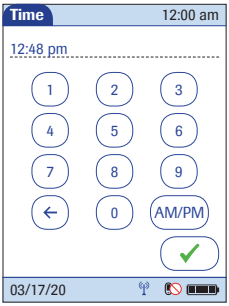
- The meter powers off and on again.
- The Roche logo is displayed.
  If the Roche logo does not appear within 15 seconds, place the meter in a base unit for a minimum of 15 minutes to recharge the battery.
- The meter performs a system check. During the system check, the *Versions* screen appears for a few seconds, then disappears. The *Versions* screen shows the version numbers of the meter components. (The *Versions* screen shown here is for illustration purposes only. Version numbers on your meter may differ.)
- A message appears informing you that the date and time settings have been lost due to the meter reset.

3 Confirm the message *Loss of Date/Time*.

Before performing any further tests, you must now **either** enter date/time manually and then synchronize the meter, **or** contact your system administrator for help.

To enter date/time manually and synchronize the meter, follow the instructions on the next page.





- Once you have confirmed the message *Loss of Date/Time*, the screens for entering the date and the time appear.

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

- Unless your QC configuration is *Always OK*, the meter will now be in QC Lockout due to the manually entered date/time.

5 Synchronize the meter's date/time with the date/time of your facility via 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.

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12 General Product Information

12.1 Technical data

Specification	Meter	Base unit	Power supply unit
Height	44 mm / 1.73 in (max.)	Base Unit: 123 mm / 4.84 in (max.) Base Unit Light: 110 mm / 4.33 in (max.)	35 mm / 1.38 in + AC plug (28-40 mm / 1.1-1.6 in)
Width	95 mm / 3.74 in (max.)	Base Unit: 130 mm / 5.12 in (max.) Base Unit Light: 118 mm / 4.65 in (max.)	51 mm / 2.01 in
Length	193 mm / 7.60 in (max.)	Base Unit: 130 mm / 5.12 in (max.) Base Unit Light: 103 mm / 4.06 in (max.)	87 mm / 3.43 in
Weight	approx. 347 g (with rechargeable battery)	Base Unit: 671 g with wall mount Base Unit Light: 573 g with wall mount	170 g
User interface	Touchscreen and barcode scanner	Base Unit: LED (tricolor: red, green, blue) Base Unit Light: LED (bicolor: red, green)	LED: green
Display resolution (touchscreen)	320 x 240 pixel	N/A	N/A
Memory	– 1,000 Results – 5,000 Operator ID records – 4,000 Patient ID records – 300 Predefined comments – 20 Code Files (test strip lots) – 100 Reagent Lots (control, linearity, OTE) – 250 Events	N/A	N/A

Specification	Meter	Base unit	Power supply unit
Operating temperature	3 to 42 °C 37 to 108 °F	3 to 50 °C 37 to 122 °F	0 to 40 °C 32 to 104 °F
Measurement temperature	Test strip dependent: Refer to the test strip package insert		
Storage conditions (long-term storage)	5 to 40 °C / 41 to 104 °F at 10 - 85% RH (non-condensing) (Remove battery pack from meter for long-term storage.)		
Humidity (operating)	10 - 90 % RH (non-condensing)		
Air pressure	0.7 to 1.06 bar 70 to 106 kPa	0.7 to 1.06 bar 70 to 106 kPa	N/A

Specification	Meter	Base unit	Power supply unit
Battery voltage/type	3.7 volt rechargeable (lithium technology)	N/A	N/A
Input voltage	+7.5 V DC	Base Unit: +12 V DC legacy Base Unit Light: +7.5 V DC NEW Base Unit Light: +12V DC	100 to 240 V AC
Input frequency	DC	DC	50 to 60 Hz
Input current	1.7 A (max)	Base Unit: 1.25 A (max) legacy Base Unit Light: 1.7 A (max) NEW Base Unit Light: 1.25 A (max)	350 to 150 mA (REF 07006098001, 07455976190) 400 to 200 mA (REF 08692432001, 08692432160)
Battery capacity	30 (subsequent) measurements possible after 90 min of charging[1]	N/A	N/A
Interfaces	Charging contacts IR port Barcode scanner WLAN (Channel 1-11 only)	Charging contacts IR port RJ45 Ethernet (Base Unit) RJ25 (Base Unit Light) USB type B *	DC connector Replaceable AC input contacts

1. A fully charged battery pack will provide sufficient power for at least 100 tests within 5 hours including wireless communication (WLAN, if available and enabled).

Specification	Meter	Base unit	Power supply unit
Data transfer rate	WLAN: up to 54 Mbps	IR: 9.6K - 115K bps[1] Ethernet: 10/100 Mbps (auto-negotiate) full-duplex[1] USB: 12 Mbps[1]	N/A
		In combination with the Base Unit Hub: IR: 9.6K - 115K bps[2] Ethernet: 10 Mbps half-duplex[3]	
Supported barcodes	Code 128, Code 39, Code 93, EAN 13, Interleaved 2 of 5 (with or without checksum), Codabar, GS1 DataBar Limited, Aztec, QR Code, DataMatrix, PDF417	N/A	N/A

1. Accu-Chek Inform II Base Unit
2. Accu-Chek Inform II Base Unit Light (NEW and legacy versions)
3. Accu-Chek Inform II Base Unit Hub

Specification	Accessory box	Code key reader	Base unit hub
Height	85 mm / 3.35 in	18.4 mm / 0.72 in	35 mm / 1.38 in
Width	280 mm / 11.02 in	34.8 mm / 1.37 in	169 mm / 6.65 in
Length	272 mm / 10.71 in	70.7 mm / 2.78 in	127 mm / 5 in
Weight	approx. 1100 g	approx. 28 g	approx. 470 g
Operating temperature	N/A	3 to 50 °C 37 to 122 °F	3 to 50 °C 37 to 122 °F
Storage temperature (short-term)	-25 to 70 °C -13 to 158 °F	3 to 50 °C 37 to 122 °F	-25 to 70 °C -13 to 158 °F
Relative humidity (short-term storage)	< 93%	< 93%	< 93%
Battery voltage/type	N/A	Not replaceable	N/A
Interfaces	N/A	IR port Code key socket	LED (red, green, blue)
Input voltage	N/A	N/A	+12 V DC
Input current	N/A	N/A	2.0 A

12.2 Further Information

Ordering

Item	Description	REF/Catalog Number
Accu-Chek Inform II Meter	Meter, equipped with built-in WLAN functionality	05060303001
Accu-Chek Inform II Battery Pack	Rechargeable battery pack (for meters with serial no. above UU14000000)	06869904001
Accu-Chek Inform II Battery Compartment Cover	Replacement cover for meter battery compartment (for meters with serial no. above UU14000000)	06869823001
Accu-Chek Inform II Base Unit (NEW)	Equipped with charging and connectivity functionality	07671717190
Accu-Chek Inform II Base Unit Light (NEW)	Equipped with charging functionality	08376824190
Power Supply*	Power supply (North America) for Base Unit Light (NEW) REF 08376824190/ Base Unit (NEW) REF 07671717190	08692432160

*** Important note**

Power supply REF 07006098001, (International edition) and Power supply REF 07455976190, (North America), Type: FW7555M/12, Input: 100-240V/50-60Hz/350-150 mA, Output: 12V ⎓ 1.25A have been discontinued and replaced by:

Power supply REF 08692432001, (International edition) and Power supply REF 08692432160, (North America), Type: FW8001M/12, Input: 100-240V/50-60Hz/400-150 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.

Item	Description	REF/Catalog Number
Accu-Chek Inform II Base Unit Light (legacy version)	Equipped with charging functionality (discontinued)	05920353001
Power Supply	Power supply (North America) for legacy Base Unit Light REF 05920353001/ legacy Base Unit REF 05060290001	05388805001
Accu-Chek Inform II Base Unit Wall Mount	Wall Mount for Base Unit/Base Unit Light (fits legacy and new versions)	05404878001
Accu-Chek Inform II Base Unit Hub	Equipped with power and connectivity functionality for the Accu-Chek Inform II Base Unit Light	05888760001
Power Cord	Required to power the Base Unit Hub (North America)	03868133001
Accu-Chek Inform II Code Key Reader		04884671001
Accu-Chek Inform II Accessory Box		05060281001
Accu-Chek Inform II Battery Pack	Rechargeable battery pack (for meters with older hardware and serial no. below UU14000000)	04882326001
Accu-Chek Inform II RF Card Kit	Wi-Fi card replacement (for meters with older hardware and serial no. below UU14000000)	05112699001

Accu-Chek Inform II Operator's Manual and Quick Reference Guide	For additional copies of the Accu-Chek Inform II Operator's Manual and Quick Reference Guide or copies in other languages, please contact your local Roche organization.
Reagents and Solutions	Supplies are available through Roche Diagnostics. Contact your local Roche representative.
Product limitations	Read the information in the package insert supplied with the reagents and solutions for detailed product data and limitations.
Warranty	Any customer modification to the system renders the warranty or service agreement null and void. For conditions of warranty, contact your local sales representative or refer to your warranty contract partner.

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 complete license agreements are stored as a text file (file name “license.pdf”) on the Accu-Chek Inform II Base Unit of the Accu-Chek Inform II system. The file “license.pdf” is located in the same folder as the PDF file “ROCHE BU Technical Note UDS5”.[1]

You can access these files by connecting the Accu-Chek Inform II Base Unit to a PC with the USB cable. For detailed instructions on how to do this, see the instruction sheet “Setting Up the Base Unit” included in the Accu-Chek Inform II Base Unit Kit.

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

1. On legacy base units the respective PDF file is called “ROCHE HBU-BU-BUH Technical Note”.

Contact Roche

For all questions about the Accu-Chek Inform II 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.

The Accu-Chek Inform II system is manufactured for and distributed by:

Roche Diagnostics
201 Armand-Frappier Boulevard
Laval, Quebec (Canada) H7V 4A2

Technical Support for Healthcare Institutions:
Region of Montreal 450-686-7111
Roche Care Center (toll free) 1-877-273-3433
www.rochediagnostics.ca

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A Appendix

A.1 Table of configuration options

This section provides an overview of all the settings available.

The two rightmost columns describe the accessibility of a configuration parameter on the device (*Setup Menu*) and via the data management system (DMS).
"Y" (Yes) means, that this parameter is available, "N" (No) means, that this parameter is not available using the respective configuration method.

DEVICE: If the meter is configured by a system administrator using a data management system, the configuration options on the meter may be disabled to avoid conflicts in the settings. This option is indicated by the use of parentheses e.g., (Y).

DMS: Configuration options may vary depending on available DMS settings.

Configuration options

Subject/Attribute	Range	Default	Device	DMS
Timer				
Power-off timeout (meter powers off automatically if no activity)*	30 – 3,600 s	300	N	Y
Shut down (meter automatically shuts down 30 minutes after powering off)	0: disabled 1: enabled	1	N	Y
Time Interval reconnect (0 = disabled)	0: disabled 10 – 1440 minutes (24 hrs)	30	N	Y
* Not applicable in measurement mode (see "Automatic power-off" on page 22).				

Subject/Attribute	Range	Default	Device	DMS
Beeper				
Beeper volume	0: low 1: medium 2: high	2	Y	Y
Measurement Flow				
Comments required*	0: optional 1: out of range 2: required 3: disabled	0	N	Y
Comments requirement level: if out of… (only valid if *Comments required* = 1)*	0: normal range 1: critical range 2: reportable range 3: measurement range	0	N	Y
Custom comments*	0: disabled 1: enabled	1	N	Y
* Does not apply to QC measurement workflow				
Control lot verification	0: display only 1: yes / no confirmation 2: prompt for entry 3: scan only	1	Y	Y
Control result display	0: value (numeric) 1: PASS / FAIL	0	N	Y
Critical range display	0: value (numeric) 1: HI / LO	0	N	Y
Critical range HI limit	0.6 – 33.3 mmol/L	33.3 mmol/L	Y	Y
Critical range LO limit	0.6 – 33.3 mmol/L	0.6 mmol/L	Y	Y
Critical range message enabled	Whether to display the out-of-critical range warning message (1) or not (0)	1	N	Y
Critical range text	0 – 100 characters	“Out of Critical Range”	N	Y
Normal range HI limit	0.6 – 33.3 mmol/L	33.3 mmol/L	Y	Y
Normal range LO limit	0.6 – 33.3 mmol/L	0.6 mmol/L	Y	Y
STAT tests allowed	0: no 1: yes	0	Y	Y
Number of STAT tests allowed	0 – 9	9	Y	Y
Reportable range HI limit	0.6 – 33.3 mmol/L	33.3 mmol/L	Y	Y
Reportable range LO limit	0.6 – 33.3 mmol/L	0.6 mmol/L	Y	Y
Reportable range message	Whether to display a reportable range message (1) or not (0)	1	N	Y

Subject/Attribute	Range	Default	Device	DMS
Reportable range message text	0 – 100 characters	"Out of Reportable Range"	N	Y
Strip limitations warning	Configuration, whether to display the strip limitations warning (1) or not (0).	0	Y	Y
Strip lot verification	0: display only 1: yes/no confirmation 2: list selection 3: scan only	1	Y	Y
Linearity lot verification	0: display only 1: yes/no confirmation 2: prompt for lot entry	1	Y	Y
Additional Patient Test: enables consecutive tests on the same patient (creating a patient test series)	0: disabled 1: enabled	0	N	Y
Isolation Room	0: disable (select patient ID before strip lot selection) 1: enable (select strip lot before patient ID selection)	0	N	Y
Configurable QC Lockout (when switching strip lot)	0: disabled 1: enabled	1	N	Y

Subject/Attribute	Range	Default	Device	DMS
Display				
Contrast	0 - 15	7	Y	Y
Formats and Language				
Date format	1: MM/DD/YY 2: DD.MM.YY	1	Y	Y
Time format	1: 24 hours 2: 12 hours	2	Y	Y
Language setting *	1: German 3: French 4: Spanish 5: Italian 6: Dutch 7: Swedish 8: English (USA) 9: Danish 11: Portuguese	8	Y	Y
* Other languages: For the availability of languages not listed above, contact Roche.				
Power Up				
Location (a string to show where a certain meter ought to be located); to be shown on the Power Up screen.	0 – 20 characters	“”	N	Y

Subject/Attribute	Range	Default	Device	DMS
Meter Functionality				
Date and time editing allowed	0: electronically only (only the DMS can set date and time) 1: anyone (anyone can set date and time) 2: password required (the setup password is required to set date and time)	1	N	Y
Main menu 2 “Linearity” (if enabled, linearity tests are allowed)	0: disabled 1: enable	1	Y	Y
Main menu 2 “Maintenance” (if enabled, maintenance comments are allowed)	0: disabled 1: enable	1	Y	Y
Main menu 2 “Proficiency” allowed (if enabled, proficiency tests are allowed)	0: disabled 1: enable	0	Y	Y
Admin menu “Setup” (if enabled, access to setup screens is possible)	0: disabled 1: enable	1	Y	Y
Setup password	0 – 20 characters	“”	Y	Y
Reagent editing allowed	1: Allowed 2: Password needed 0: Not allowed	1	(Y)	Y
Order test strips	0: disabled 1: enable	0	N	Y

Subject/Attribute	Range	Default	Device	DMS
Operator ID				
Operator ID entry control	0: None 1: Prompt 2: Scan only 3: Prompt (numeric only)	1	Y	Y
Operator ID entry control on Glucose control only	0: yes (on controls only) 1: no (always)	1	Y	Y
Operator ID validation (Any character allowed [except non-printable ones, represented as hexadecimal ASCII values by 0x01 - 0x1F and 0x7F]. Via the meter keyboard only A-Z/a-z, 0-9, "." [period], "-" [hyphen] can be entered.) Remark: leading and trailing spaces are truncated.	0: none 1: length 2: list 3: list & password	0	Y	Y
Operator ID maximum length (used to validate an operator ID if operator ID validation mode is set to "Length")	0 – 20	20	Y	Y
Operator ID minimum length (used to validate an operator ID if operator ID validation mode is set to "Length")	0 – 20	0	Y	Y
Operator ID timeout (determines the time in sec. before the operator is logged out after power-off). 0 = immediately logged out	0 – 3,600sec	0	N	Y
Operator password length	4-20 characters (only a-z, 0-9 allowed)	N/A	N	N
Operator certification expiry warning	0-90 days	0 (=off)	N	Y
Operator Name length	0-25 characters	N/A	N	N
Operator ID and patient ID barcode masks				
Operator ID barcode mask (see separate table at the end of this chapter)	0 – 300 characters*	""	N	Y
Patient ID barcode mask (see separate table at the end of this chapter)	0 – 300 characters*	""	N	Y
* The number of characters in the unmasked barcode may not exceed 20.				

Subject/Attribute	Range	Default	Device	DMS
Patient ID				
Patient ID confirmation	0: disabled 1: name 2: date of birth (DOB)* 3: name/DOB*	0	N	Y
* Depends on available DMS settings.				
Patient ID entry mode	0: Keyboard / Scan 1: List / Keyboard / Scan 2: Scan only 3: Prompt (numeric)	0	Y	Y
Patient ID validation (Any character allowed [except non-printable ones, represented as hexadecimal ASCII values by 0x01 - 0x1F and 0x7F]. Via the meter keyboard only A-Z/a-z, 0-9, "." [period], "-" [hyphen] can be entered.) Remark: leading and trailing spaces are truncated.	0: none 1: length 2: list 3: list allowing entry if not on list 4: length if numeric	0	Y	Y
Patient ID maximum length (used to validate a patient ID if patient ID validation mode is set to "Length" or "List - allowed to add new")	0-20	20	Y	Y
Patient ID minimum length (used to validate a patient ID if patient ID validation mode is set to "Length" or "List - allowed to add new")	0-20	0	Y	Y
Patient name length	0-25 characters	N/A	N	N

Subject/Attribute	Range	Default	Device	DMS
QC algorithm				
QC Algorithm	0: None (always OK) 1: Last result OK 2: Time of day (DMS only) 3: Shift (DMS only) 4: Hours 5: Strip count 6: Time of day rotate (DMS only) 7: Shift rotate (DMS only) 8: Hours rotate (DMS only) 9: Strip count rotate (DMS only)	0	(Y)	Y
QC hours (Number of hours between required control measurements if QC algorithm is set to “Hours” or “hours rotate”)	1 – 9,999 hours	24	Y	Y
QC shift length (a PASS control remains valid for twice this amount in time after shift start if the QC algorithm is set to “Shift” or “Shift rotate”)	1, 2, 3, 4, 6, 8, 12, 24 hours	8	N	Y
QC shift start (time of the shift start if the QC algorithm is set to “Shift” or “Shift rotate”)	0 – 23 hours	6	N	Y
QC strip count (number of tests a PASS control remains valid)	1 – 999	50	Y	Y
QC time of day	6 POCT1-A data fields 00:00 – 23:59	06:00 09:00 12:00 15:00 18:00 22:00	N	Y
QC time of day set	6 POCT1-A data fields 0 or 1	1 0 0 0 0 0	N	Y

Subject/Attribute	Range	Default	Device	DMS
Result deletion				
Result deletion algorithm. Automatic or First in First out.	0: automatic 1: FIFO	1	N	Y
Result retention time: Number of days since a result was measured before it will be deleted automatically if result deletion algorithm is set to “automatic”. Results are then deleted when powering up the meter or performing a test.	1 – 1,000 d	30	N	Y
Result download required	0: disabled 1: enabled	0	N	Y
Electronic communication				
Download warning	0 – 999 h	0: disabled	N	Y
Download Lockout	0 – 999 h	0: disabled	N	Y
Maximum number of list items transferred in one POCT1-A message	1 – 500	75	N	Y
Application timeout (within this time the application expects a response by the DMS to any POCT1-A command)	30 – 3,600 s	60	N	Y
TLS Encryption of communication	0: disabled 1: enabled	0	N	Y
Compression of data communication	0: disabled 1: enabled	0	N	Y

Subject/Attribute	Range	Default	Device	DMS
WLAN settings (general)				
WLAN enabled	0: disabled 1: enabled	0	N	Y
Use DHCP	0: disabled 1: enabled	0	N	Y
IP (the meter's static IP-address if no DHCP is used)	0.0.0.0 – 255.255.255.255	0.0.0.0	N	Y
Subnet Mask (subnet mask to be used by the meter if static IP is used. Note: if DHCP is used; the DHCP-subnet mask will be used.)	0.0.0.0 – 255.255.255.255	0.0.0.0	N	Y
Use DNS	0: disabled 1: enabled	0	N	Y
DMS host (the host's DNS name if DNS is used)	0 – 60 characters	""	N	Y
DMS IP address (the host's IP address if no DNS is used)	0.0.0.0 – 255.255.255.255	0.0.0.0	N	Y
DMS port (the port number to request open socket from the DMS. Roche recommends use of port numbers ≥ 1024.)	0 – 65,535	0	N	Y
DNS IP (IP address of the DNS-server if DHCP is not used and DNS is configured)	0.0.0.0 – 255.255.255.255	0.0.0.0	N	Y
Gate IP (static gateway IP address)	0.0.0.0 – 255.255.255.255	0.0.0.0	N	Y

Subject/Attribute	Range	Default	Device	DMS
WLAN settings (security)				
Cipher Type (encyrption method)	0: None (no cipher type) 1: AES (symmetric key cryptography) 2: TKIP (using dynamic keys) 3: AES | TKIP (AES and TKIP together) 4: WEP40 (WEP with 64 bit key length) 5: WEP104 (WEP with 128 bit key length)	0: disabled	N	Y
Security Type *	0: open (no security/encryption) 1: WEP 2: WPA_PSK (WPA with pre-shared key) 3: - 4: EAP**	0	N	Y
* Note: Only those combinations of cipher type and security type are allowed that are listed below, see table "Allowed combinations of cipher and security type". **Note: When using option 4 ensure that an appropriate WLAN EAP package has already been downloaded from the DMS to the meter. Within this EAP container, the appropriate EAP type (TLS, PEAP or TTLS) and the diverse EAP configuration settings have to be configured.)				
SSID	0 – 32 characters	""	N	Y
WEP-key (40 or 104 bits)	NUL-terminated string of 10 or 26chs (HEX)	""	N	Y
WEP-authentication	0: open system authentication 1: shared key authentication	0	N	Y
WPA Key Type	0: Passphrase 1: Key	0	N	Y
WPA Key	string of 64 characters (HEX)	""	N	Y
WPA pass phrase (Un-encrypted text used to generate the 256-bit preshared key.)	8 – 63 characters	""	N	Y

Subject/Attribute	Range	Default	Device	DMS
Other Test Entry (OTE)				
OTE functionality *	0: disabled 1: enabled	0	N	Y
* Depends on available DMS settings.				
Barcode Configuration				
Code 128	0: disabled 1: enabled	1	N	Y
Code 39	0: disabled 1: enabled	1	N	Y
Code 93	0: disabled 1: enabled	1	N	Y
EAN 13	0: disabled 1: enabled	1	N	Y
Interleaved 2 of 5	0: disabled 1: enabled	1	N	Y
Codabar	0: disabled 1: enabled	1	N	Y
GS1 DataBar Limited	0: disabled 1: enabled	1	N	Y
QR Code	0: disabled 1: enabled	1	N	Y
DataMatrix	0: disabled 1: enabled	1	N	Y
PDF417	0: disabled 1: enabled	1	N	Y
Aztec	0: disabled 1: enabled	1	N	Y
PreAimer Delay (in milliseconds)	0 - 9,999	500	N	Y
Interleaved 2 of 5 checksum validation	0: disabled 1: enabled	0	N	Y
Add barcode to patient test result	0: disabled 1: enabled 2: enabled and confirm	0	N	Y
Barcode Separators: List of separator characters (readable characters, or hexadecimal ASCII values* preceded by a backslash) to be replaced by line breaks on the confirmation screen. Only valid if *Add barcode to patient test result*=2.	0-30 characters	""	N	Y
* See the table of ASCII characters on page 190.				

Allowed combinations of cipher and security type

security_type	cipher_type	wep_auth_type	wep_key	wpa_key_type	wpa_key	wpa_passphrase
0 - open	0 - none	-	-	-	-	-
1 - WEP	4 - WEP40	0 - open / 1 - shared	10 characters HEX	-	-	-
1 - WEP	5 - WEP104	0 - open / 1 - shared	26 characters HEX	-	-	-
2 - WPA_PSK	1 - AES (WPA2)	-	-	0 - passphrase	-	8-63 characters
2 - WPA_PSK	1 - AES (WPA2)	-	-	1 - key	64 characters HEX	-
2 - WPA_PSK	2 - TKIP (WPA)	-	-	0 - passphrase	-	8-63 characters
2 - WPA_PSK	2 - TKIP (WPA)	-	-	1 - key	64 characters HEX	-
2 - WPA_PSK	3 - AES/TKIP (WPA2/WPA)	-	-	0 - passphrase	-	8-63 characters
2 - WPA_PSK	3 - AES/TKIP (WPA2/WPA)	-	-	1 - key	64 characters HEX	-
3 -	-	-	-	-	-	-
4 - EAP	-	-	-	-	-	-

Operator and patient ID barcode masks

Barcode mask character	Definition
A-Z/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/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.
Caret Plus ("^+")	The "^" can be combined with the plus ("+"). This denotes that the scan data character in this position must be an alpha character, A – Z/a-z, and that it is 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 Tilde ("^~")	The "^" can be combined with the tilde ("~"). This denotes that the scan data character in this position must be a number, 0-9, and that it is kept as part of the ID. If the scan data character is not a number, the scan data is not a valid ID.

The barcode mask can be preceded by optional square brackets containing the separator characters - [nC_1mC_2] - to extract the ID from any position within the barcode. The ID to be extracted must start after the n^{th} occurrence of the starting character C_1 and must end after the m^{th} occurrence of the ending character C_2. The extracted string of characters will be processed by the succeeding mask (see page 188) to identify the patient ID.

C_1 and C_2 can be represented by any readable characters, or by any hexadecimal ASCII values if marked by a preceding backslash ("\"). See the table of ASCII characters on page 190.

Example 1:

[1$1+]^+^~^~^~^~^~^~^~^~

Extract the ID between first occurrence of "$" and first occurrence of "+". The ID must start with one alpha character (A-Z/a-z), followed by seven numbers (0-9). This mask will extract the ID X1234567 from the following barcode example:

```
~Jane Doe%$X1234567+5715486266Z?01-09-1979
```

Example 2:

[3\3b1\3b]^+^~^~^~^~^~^~^~^~

Extract the ID between 3^{rd} and 4^{th} semicolon (; = 0x3b). This mask will extract the ID X1234321 from the following barcode example:

```
;Mary Miller;;X1234321;5715486266Z;01-09-1982
```

Table of ASCII characters

Dec	Hex	Char	Dec	Hex	Char	Dec	Hex	Char	Dec	Hex	Char
0	0	[NULL]	32	20	[SPACE]	64	40	@	96	60	`
1	1	[START OF HEADING]	33	21	!	65	41	A	97	61	a
2	2	[START OF TEXT]	34	22	"	66	42	B	98	62	b
3	3	[END OF TEXT]	35	23	#	67	43	C	99	63	c
4	4	[END OF TRANSMISSION]	36	24	$	68	44	D	100	64	d
5	5	[ENQUIRY]	37	25	%	69	45	E	101	65	e
6	6	[ACKNOWLEDGE]	38	26	&	70	46	F	102	66	f
7	7	[BELL]	39	27	'	71	47	G	103	67	g
8	8	[BACKSPACE]	40	28	(	72	48	H	104	68	h
9	9	[HORIZONTAL TAB]	41	29	)	73	49	I	105	69	i
10	A	[LINE FEED]	42	2A	*	74	4A	J	106	6A	j
11	B	[VERTICAL TAB]	43	2B	+	75	4B	K	107	6B	k
12	C	[FORM FEED]	44	2C	,	76	4C	L	108	6C	l
13	D	[CARRIAGE RETURN]	45	2D	-	77	4D	M	109	6D	m
14	E	[SHIFT OUT]	46	2E	.	78	4E	N	110	6E	n
15	F	[SHIFT IN]	47	2F	/	79	4F	O	111	6F	o
16	10	[DATA LINK EXCAPE]	48	30	0	80	50	P	112	70	p
17	11	[DEVICE CONTROL 1]	49	31	1	81	51	Q	113	71	q
18	12	[DEVICE CONTROL 2]	50	32	2	82	52	R	114	72	r
19	13	[DEVICE CONTROL 3]	51	33	3	83	53	S	115	73	s
20	14	[DEVICE CONTROL 4]	52	34	4	84	54	T	116	74	t
21	15	[NEGATIVE ACKNOWLEDGE]	53	35	5	85	55	U	117	75	u
22	16	[SYNCHRONOUS IDLE]	54	36	6	86	56	V	118	76	v
23	17	[ENG OF TRANS. BLOCK]	55	37	7	87	57	W	119	77	w
24	18	[CANCEL]	56	38	8	88	58	X	120	78	x
25	19	[END OF MEDIUM]	57	39	9	89	59	Y	121	79	y
26	1A	[SUBSTITUTE]	58	3A	:	90	5A	Z	122	7A	z
27	1B	[ESCAPE]	59	3B	;	91	5B	[	123	7B	{
28	1C	[FILE SEPARATOR]	60	3C	<	92	5C	\	124	7C	|
29	1D	[GROUP SEPARATOR]	61	3D	=	93	5D	]	125	7D	}
30	1E	[RECORD SEPARATOR]	62	3E	>	94	5E	^	126	7E	~
31	1F	[UNIT SEPARATOR]	63	3F	?	95	5F	_	127	7F	[DEL]

A.2 Example of barcode symbologies

⚠ WARNING

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.

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]
- 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.

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.

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

EAN 13 barcodes, although widely used in retail, are less recommendable for patient/operator barcodes. If used, they demand the very highest quality standards of barcode creation and reproduction.

It is possible to **selectively enable or disable the barcode types used for scanning Patient IDs or Operator IDs**. Barcode types that are not used can be disabled (see "Barcode Configuration" on page 186). This feature is only available via a Data Management System (DMS).

For questions about working with barcodes that are not answered in this manual and for best practice guidelines on creating and reading barcodes, contact your Roche representative (see Chapter 12).

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 standard 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)	

Ensure that your printer can print the module width of the barcode with the required resolution, i.e., that there is no mismatch between print resolution and module width.

1234567890

Codabar

1234567890

Code 39

ABC123-/+

Code 93

1234567890

Code 128

1 112223 334448

EAN 13

(01)01234567890128

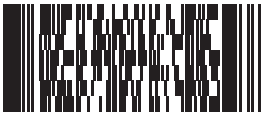
GS1 DataBar Limited

1234567890

Interleaved 2/5 without checksum

012345678905

Interleaved 2/5 with checksum



Roche Professional Diagnostics

PDF417

Roche Professional Diagnostics

Aztec

Roche Professional Diagnostics

DataMatrix

Roche Professional Diagnostics

QR Code

B Appendix

B.1 Option: Wireless network (WLAN)

Preliminary note

Appendix B has been developed to explain the wireless communication principles of the Accu-Chek Inform II system[1] and to help your facility's information technology/ management team(s) in effectively deploying the Accu-Chek Inform II system on your wireless network.

Whether your meter has wireless capability or not depends on the system configuration that you purchased.

Background

The Accu-Chek Inform II 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 2.45 GHz and/or 5.15 - 5.25 GHz and/or 5.725 - 5.850 GHz frequency range to wirelessly transmit data[3]. The Accu-Chek Inform II system adheres to IEEE Standard 802.11g (2.45 GHz range)[4]. The system is backwards compatible to 802.11b. During wireless communication to an Access Point (AP), the Accu-Chek Inform II 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 Accu-Chek Inform II 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 Accu-Chek Inform II 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., Accu-Chek Inform II 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 Accu-Chek Inform II 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 Accu-Chek Inform II 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 Accu-Chek Inform II 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 Accu-Chek Inform II 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 Accu-Chek Inform II 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 Accu-Chek Inform II 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, which are the legally allowed channels in the USA. (Channels 12-14 are not used by the Accu-Chek Inform II 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.

RF specific functionalities and effective performance claims

The Accu-Chek Inform II 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.

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 Accu-Chek Inform II meter supports the 802.11g standard. This translates into the following RF specific performance claims:

- The Accu-Chek Inform II 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).
- Immediately after the operator has initiated the sending of a blood glucose result, the Accu-Chek Inform II meter will attempt to connect to the DMS. 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.
- An Accu-Chek Inform II meter with wireless connectivity enabled will communicate results after every test[1] or, when the meter is idle; it will automatically attempt to communicate with the DMS every 10 minutes.

1. The meter will attempt to transmit the result after touching ✓. If the meter is left to power off automatically (see page 22) or powered off manually using the On/Off button the result will be transmitted only after another 10 minutes in the next communication cycle.

A typical range for direct connection between the Accu-Chek Inform II 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 Accu-Chek Inform II system is designed such that it coexists with other wirelessly communicating devices. The Accu-Chek Inform II 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: The Accu-Chek Inform II meter monitors the Quality of Service (QoS) of the WLAN communication connection. Should the last attempt to communicate have failed, an icon appears on the screen (see page 44). A degraded QoS 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 blood glucose readings **cannot be guaranteed** by the Accu-Chek Inform II meter.

C Supplement for Other Test Entry

C.1 Before you start

Description

The *Other Test Entry (OTE)* feature is designed to allow the professional user to document patient test results from certain off-meter tests or other related information (e.g., prescribed insulin type, number of units).

External controls are entered in the *Control Test* section. The meter facilitates the transfer of this information to a data management system (DMS).

The activation of this feature is only possible via a suitable DMS.

Activating this feature permanently adds an additional step to the *Patient Test* or a *Control Test* sequence. Once this feature is activated, you will have to select the type of test (*Glucose Test/Other Test* or *Glucose Control Test/Other Control Tests*) each time.

The examples in this manual are for illustration purposes only. Consult the instructions that come with the DMS for details and configuration options.

C.2 Overview of Other Test Entry (OTE)

Introduction

The *Other Test Entry (OTE)* feature allows you to enter patient results for the following tests:

- Pregnancy
- Visual Urinalysis (UA)
- Rapid Streptococcus
- Rapid Drugs of Abuse Tests (DAT)
- Fecal Occult
- Gastric Occult
- Ketones

The *Other Test Entry* feature also allows you to add information about prescribed insulin type and number of units:

- Rapid-Acting Insulin
- Regular Insulin
- Intermediate-Acting Insulin
- Long-Acting Insulin
- Insulin Mixtures

In the *Review Results* listing, the test names for the above tests and insulin information will be abbreviated as follows:

- Pregnancy (Preg)
- Visual UA (VUA)
- Rapid Strep (Strep)
- Rapid DAT (DAT)
- Fecal Occult (F Occ)
- Gastric Occult (G Occ)
- Ketones (Ket)
- Rapid-Acting (Rap-I)
- Regular (Reg-I)
- Intermediate-Acting (Int-I)
- Long-Acting (Long-I)
- Insulin Mixtures (Mix-I)

Entering patient test results using the *Other Test Entry* feature comprises the following steps:

- Enter the patient ID.[1]

This can be done either manually or by using the barcode scanner.

- Enter the date and time the test was performed.
- Enter or confirm the test strip, kit and/or other reagent lot numbers.

This can be done either manually or by using the barcode scanner (if a barcode is available).

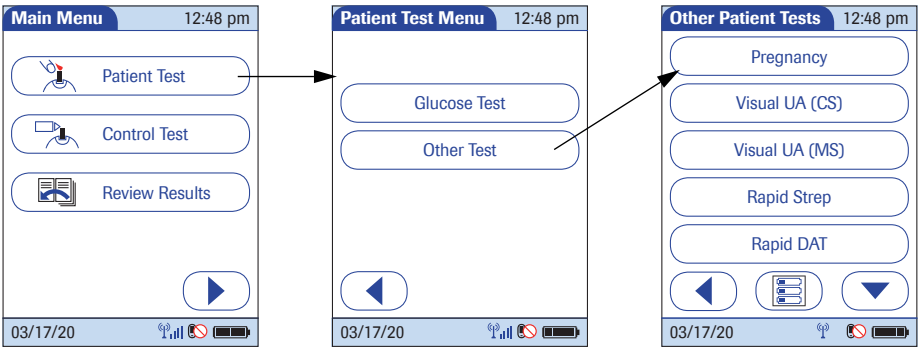
- Enter the test strip, kit and/or other reagent expiration date the first time a lot number is entered.
- Enter the onboard control result(s) if available.
- Enter the test result(s).
- Select appropriate comments.

1. Note: The display of date of birth (DOB) is not available for OTE workflows.

C.3 Recording Other Patient Tests

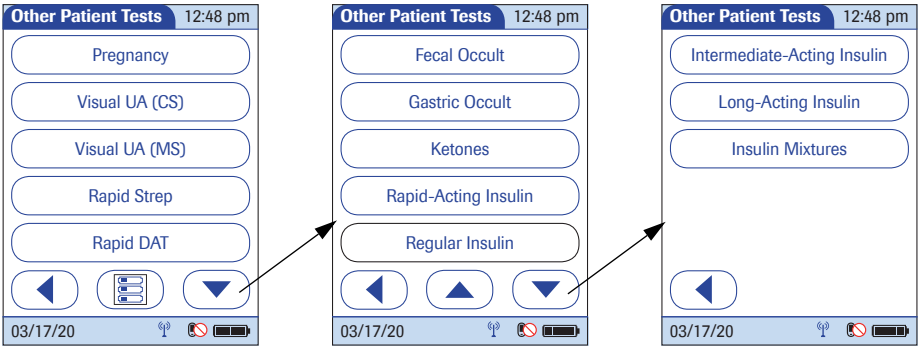
The following steps must be completed already:

- The meter is powered on.
- You have entered your operator ID.
- You have completed login by selecting ✓ and the *Main Menu* screen is displayed.



1 From the *Main Menu* screen touch *Patient Test*.

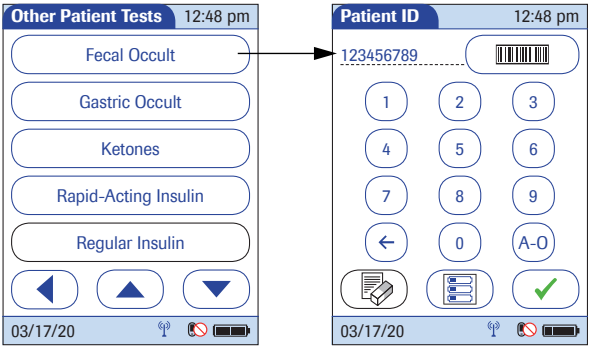
2 From the *Patient Test Menu* touch *Other Test*. The *Other Patient Tests* menu list is displayed.



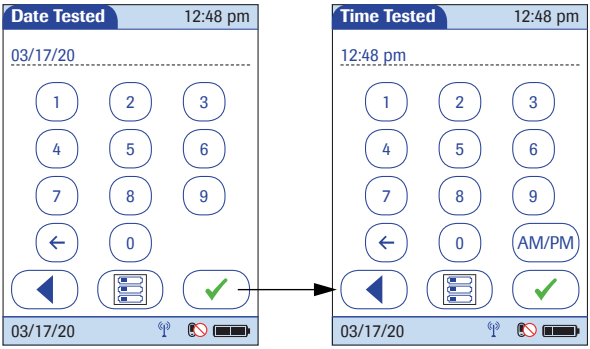
3 Touch ▲ or ▼ to scroll up or down in the list.

4 Select the desired test from the display list.

If you need to change an entry, touch ◀ to return to the previous screen.



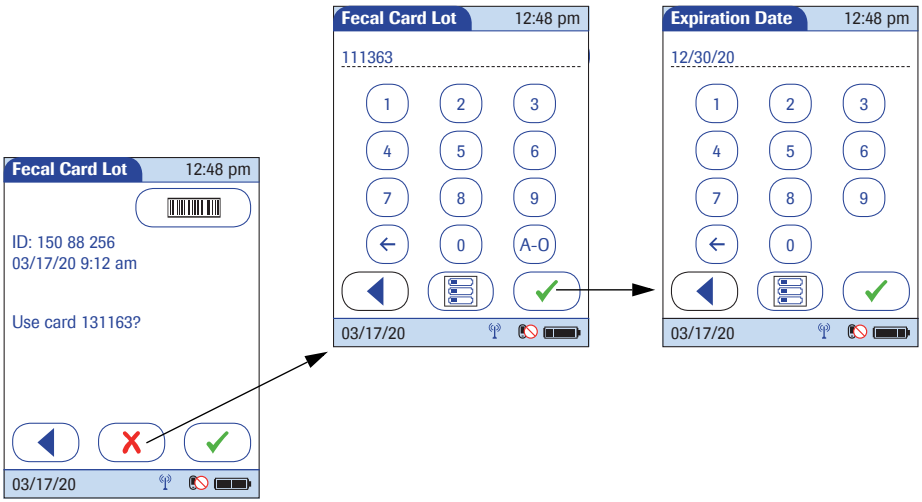
5 Enter or select the *Patient ID*. Touch ▶ to proceed to the next screen[1].



6 Use the keypad to enter the date the test was performed. For single digit numbers, add a leading zero. Touch ▶ to proceed to the next screen.

7 Use the keypad to enter the time the test was performed. For single digit numbers, add a leading zero. Touch ▶ to proceed to the next screen.

1. See also section “Entering or selecting the patient ID” in Chapter 3.

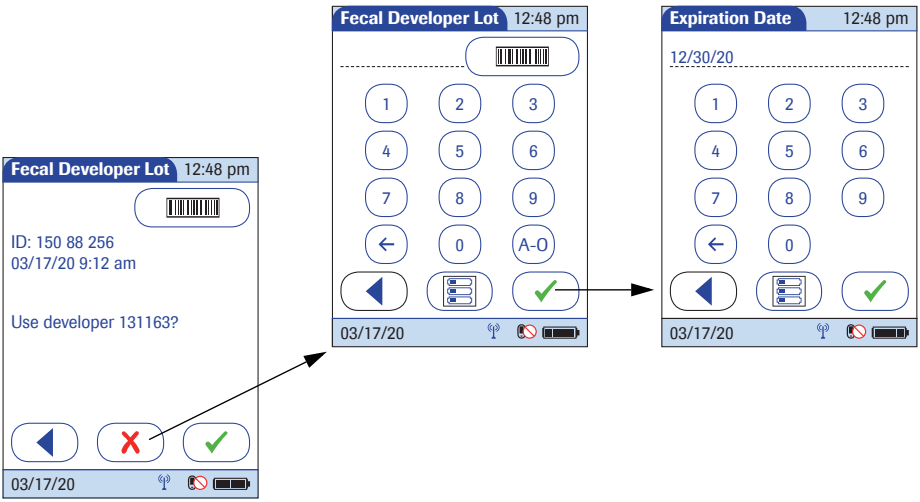


8 Use the keypad or barcode scanner to enter the *Fecal Card Lot* number, and touch (✓) to proceed to the next screen. OR, if configured:

- Touch (✓) to confirm that you want to use the pre-selected lot number displayed by the meter.
- Touch (X) to enter a new lot number, if you want to use a different lot number than the one displayed.

If you touch (✓) to confirm the displayed lot number, the meter will not prompt for expiration date.

9 Use the keypad to enter the *Fecal Card Lot* expiration date. Touch (✓) to proceed to the next screen.

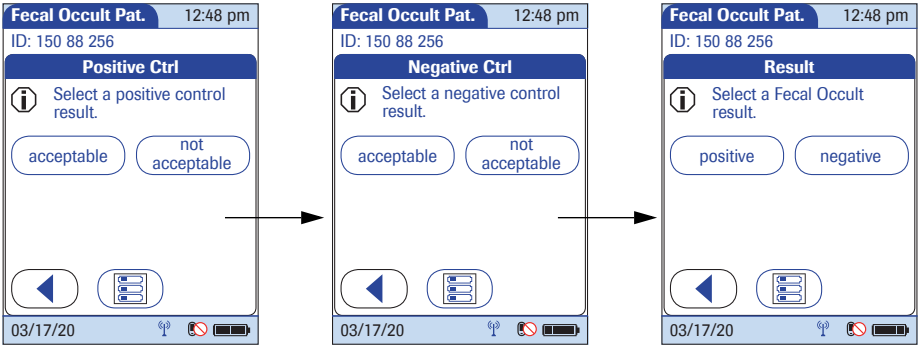


10 Use the keypad or the barcode scanner (if a barcode is available) to enter the *Fecal Developer Lot* number, and touch ✓ to proceed to the next screen. Or, if configured:

- Touch ✓ to confirm that you want to use the preselected lot number displayed by the meter.
- Touch ✗ to enter a new lot number, if you want to use a different lot number than the one displayed.

If you touch ✓ to confirm the displayed lot number, the meter will not prompt for expiration date.

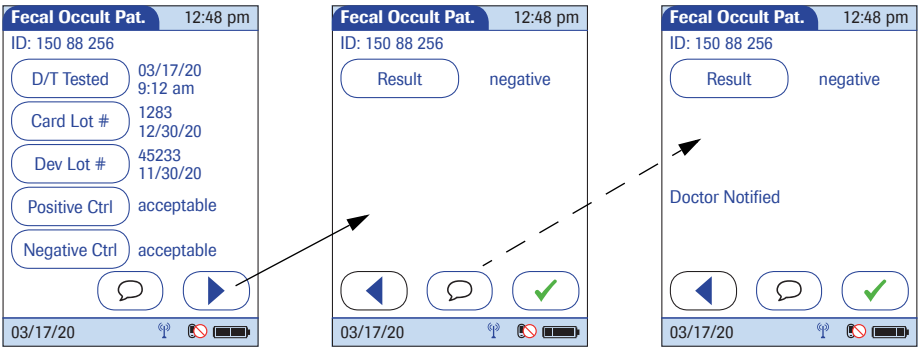
11 Use the keypad to enter the *Fecal Developer Lot* expiration date. Touch ✓ to proceed to the next screen.



12 Select the result of the *Positive Control* as *acceptable* or *not acceptable* by touching the appropriate button.

13 Select the result of the *Negative Control* as *acceptable* or *not acceptable* by touching the appropriate button.

14 Select the patient test result as *positive* or *negative* by touching the appropriate button.



Once the result(s) are entered, the *Fecal Occult Pat.* result screen is displayed.

15 To change an entry or a result, touch the appropriate button.

To add comments[1]:

16 In the result screen, touch (💬).

17 Select the desired predefined comment from the display list (if configured) or touch (💬) to enter your own custom comment. Use the keypad (as with login) to enter your comment.

18 Once you have selected the desired comment(s), touch (✓) to return to the results screen.

19 Touch (✓) to return to the *Main Menu*.

Test results are also saved when the meter is powered off in the results screen or automatically powers off.

1. See also section “Adding comments” in Chapter 3.

C.4 Recording Other Control Tests

Introduction

The *Other Control Tests* feature allows you to enter liquid control results for the following OTE tests:

- Pregnancy (Preg)
- Visual UA (VUA)
- Rapid Strep (Strep)
- Rapid DAT (DAT)

Running controls ensures that your technique used in testing will give accurate results on *Other Patient Tests*. Control solutions have defined (known) values. Commercially prepared control solutions should be used on a regular basis, as established by your institution's quality control protocols. The results for these solutions should be within a certain acceptable range in order to ensure valid OTE testing.

Other Control Testing Intervals

Intervals between running control tests are determined by your institution. Quality control lockout is not available for *Other Test Entry*.

Stored Control Information

The meter can record the following information about *Other Control Tests*:

- Operator ID
- Type of control
- Date tested
- Time tested
- Kit lot number
- Control lot number
- Control test result(s)
- Comment (if applicable)

Entering control test results using the *Other Control Tests* menu comprises the following steps:

- Select the type of control to be recorded.
- Enter the date tested (if required).
- Enter the time tested (if required).
- Enter or confirm the kit or test strip lot number.

This can be done either manually or by using the barcode scanner (if a barcode is available).

- Enter the kit or test strip expiration date.
- Enter or confirm the control lot number.
- Enter the control lot expiration date.
- Select the control result(s).

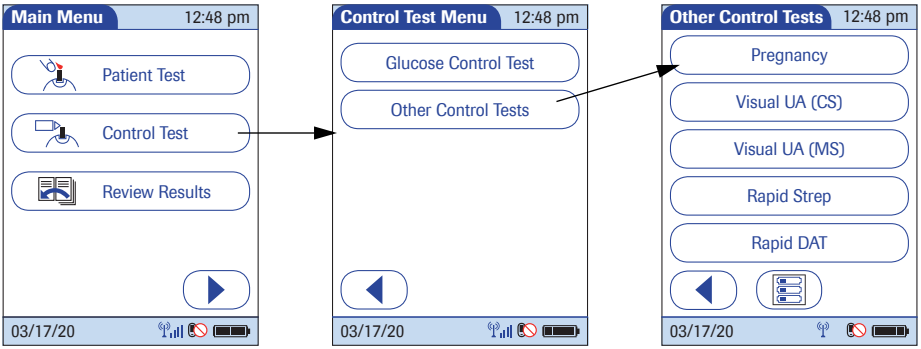
The control solution results must fall into the acceptable range indicated on the test kit or reagent packaging, or as defined by your institution, before being considered successful.

The following steps must be completed already:

1 The meter is powered on.

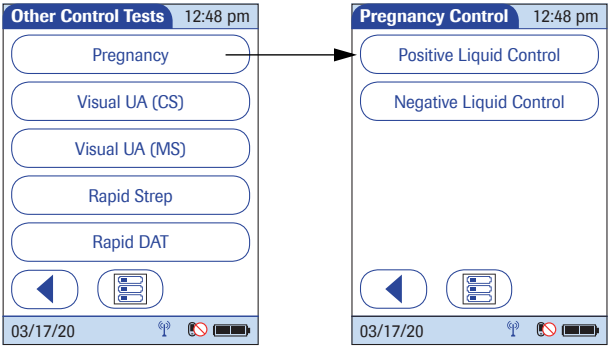
2 You have entered your operator ID.

3 You have completed login by selecting ✓ and the *Main Menu* screen is displayed.



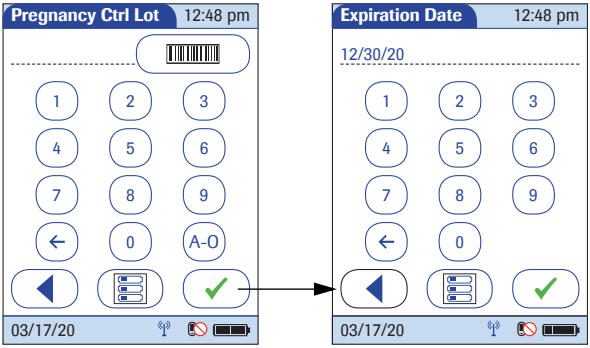
1 From the *Main Menu* screen touch *Control Test*.

2 From the *Control Test Menu* touch *Other Control Tests*.



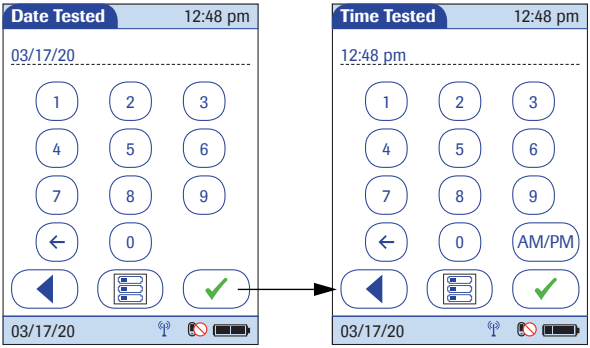
3 Select the desired test from the display list. (*Pregnancy* control will be used as the example.)

4 Select the type (level) of control being used.



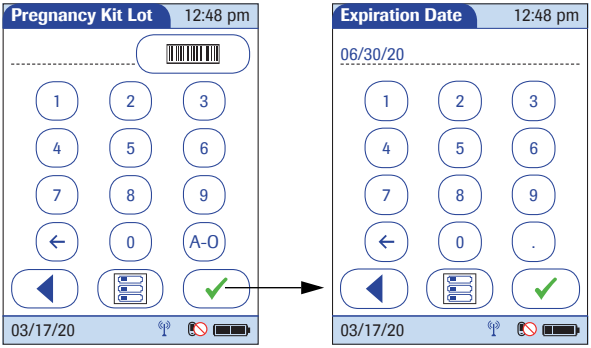
5 Use the keypad or the barcode scanner (if a barcode is available) to enter the *Pregnancy Ctrl Lot* number. Touch (✓) to proceed to the next screen.

6 Use the keypad to enter the *Pregnancy Ctrl Lot* expiration date. Touch (✓) to proceed to the next screen.



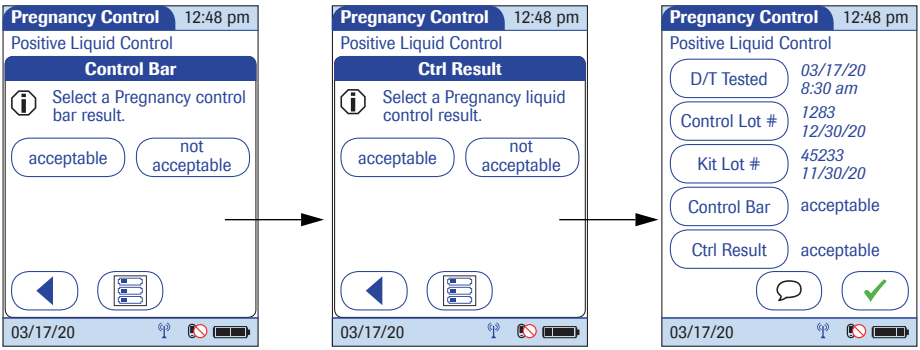
7 Use the keypad to enter the date the test was performed. For single digit numbers, add a leading zero. Touch (✓) to proceed to the next screen.

8 Use the keypad to enter the time the test was performed. For single digit numbers, add a leading zero. Touch (✓) to proceed to the next screen.



9 Use the keypad or the barcode scanner (if a barcode is available) to enter the *Pregnancy Kit Lot* number. Touch (✓) to proceed to the next screen.

10 Use the keypad to enter the *Pregnancy Kit Lot* expiration date. Touch (✓) to proceed to the next screen.



11 Select the result of the *Control bar* test as *acceptable* or *not acceptable* by touching the appropriate button.

12 Select the result of the liquid control test *(Ctrl Result)* as *acceptable* or *not acceptable* by touching the appropriate button.

Once the results are entered, the *Pregnancy Control* result screen is displayed.

13 To change an entry or a result, touch the appropriate button.

To add comments[1]:

14 In the result screen, touch (💬).

15 Select the desired predefined comment(s) from the display list (if configured) or touch (💬) to enter your own custom comment(s). Use the keypad (as with login) to enter your comment.

16 Once you have selected the desired comment(s), touch (✓) to return to the results screen.

17 Touch (✓) to return to the *Main Menu*.

Test results are also saved when the meter is powered off in the results screen or automatically powers off.

Warning messages

The meter may display error or warning messages when you enter *Other Patient Tests* and *Other Control Tests*. These error or warning messages occur when the validity of the recorded result is questionable. These messages caution that test information may not be valid or accurate. (See also “Pop-up messages” in Chapter 11)

When entering other patient and other control test results, the user may be prompted to enter a control test (control bar) result as either acceptable or not acceptable. If the result is entered as not acceptable, subsequent patient results may not be valid due to the invalid control bar result.

1. See also section “Adding comments” in Chapter 3.

C.5 Reviewing Other Test Results

The *Other Test Results* screen displays all stored OTE results. Results can be viewed in three ways: *All*, *Patient*, or *QC*.

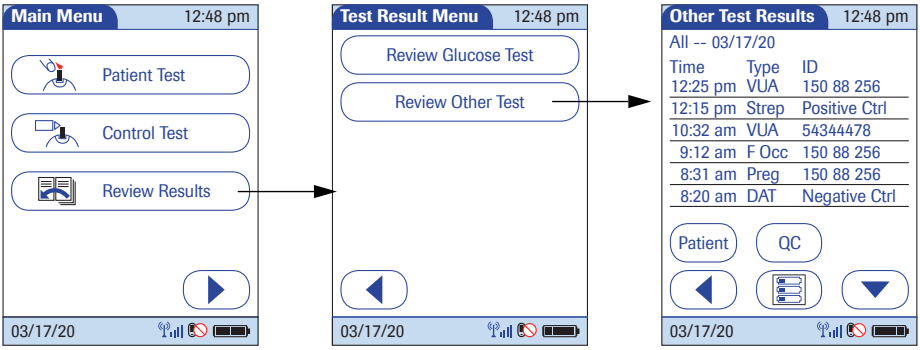
The following steps must be completed already:

1 The meter is powered on.

2 You have entered your operator ID.

3 You have completed login by selecting ✓ and the *Main Menu* screen is displayed.

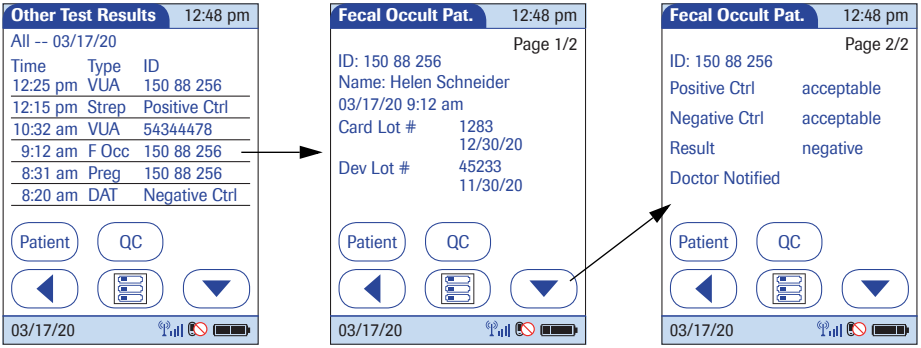
Perform the following steps to *Review Other Test* result(s):



1 From the *Main Menu* screen touch *Review Results*.

2 From the *Test Result Menu* touch *Review Other Test*.

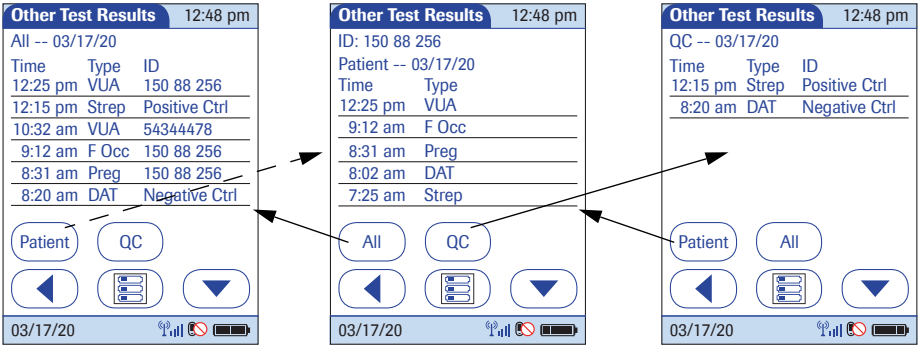
All stored OTE test results are displayed in a sequential list.



3 Touch (▲) or (▼) to scroll up or down in the list. The results are grouped by date.

4 Touch an entry in the list to display the related details.

5 Touch (▲) or (▼) to display all available pages of a test result.



6 Touch *Patient*, if you wish to display results for a specific patient only.

– If you touch *Patient* from the full list view, you will be asked to enter the patient ID manually or via bar-code scanner. The list now contains only the results for the selected patient.

7 Touch *QC*, if you wish to display a list of other control tests.

8 Touch *All* in the *Other Test Results* screen to remove the *Patient* or *QC* selection and display all results.

9 Touch ◀ to return to the previous menu screen, or touch ☰ to return to the *Main Menu*.

C.6 Other Test Entry Configuration Options

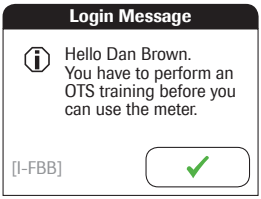
Other Test Entry options can only be configured using a DMS. The availability of configuration options will thus vary according to the data management software utilized by your institution. Consult your system administrator.

D 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 glucose test result and any desired comments.

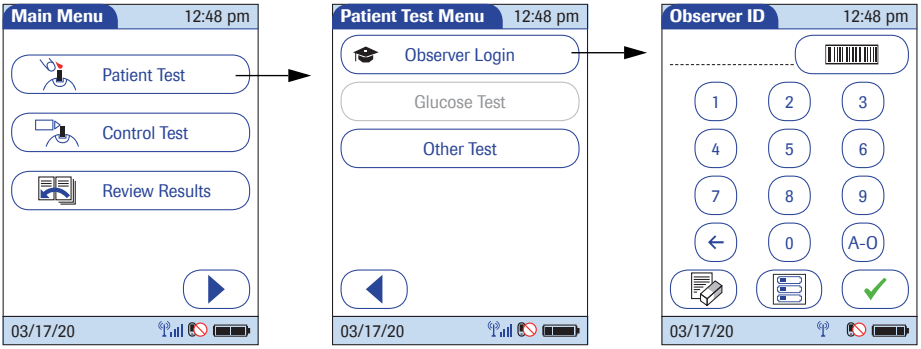
This function needs to be configured by the system administrator and depends on available DMS settings. Electronic configuration options will thus vary according to the data management software utilized by your institution.



If so configured, the operator may receive a message from the DMS when he or she tries to log in to the meter. This message informs the operator that they have to renew their certification. The contents of the message is created on the DMS and may vary. The screen message shown here is for illustration purposes only.

Using the OTS function

A request for an Observed Test Sequence comes from the DMS.



Observer:

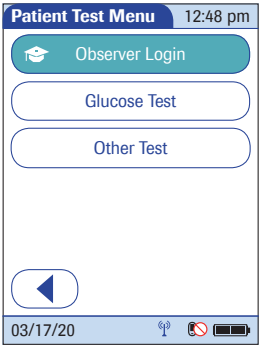
1 Touch *Patient Test*.

In the *Patient Test Menu*, the *Glucose Test* button is grayed out (disabled) until the observer has logged in.

2 Touch *Observer Login*.

3 Wait until the *Observer ID* screen is displayed.

4 Enter your operator ID or scan your operator ID barcode. Enter the (optional) password in the *Observer Password* screen, and touch ✓ to log in.



The *Patient Test Menu* is displayed again. The *Glucose Test* button is now active.

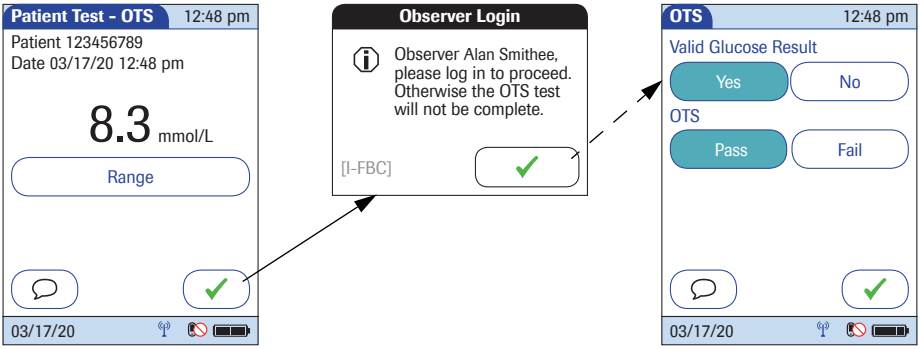
5 Hand the meter to the operator who can now perform the patient test under supervision.

Operator:

6 Touch *Glucose Test*.

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

7 Hand the meter back to the observer.



Observer:

8 Touch (✓) to log in again.

9 After you enter your password, touch (✓) to proceed with the assessment.

10 Assess the test result validity by touching *Yes* or *No*.

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

12 Touch (💬), if you want to add a comment.

13 Touch (✓) to return to the *Main Menu* screen.

The OTS information is saved together with the test result.

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E Supplement for Enhanced Workflows

E.1 Configurable workflows

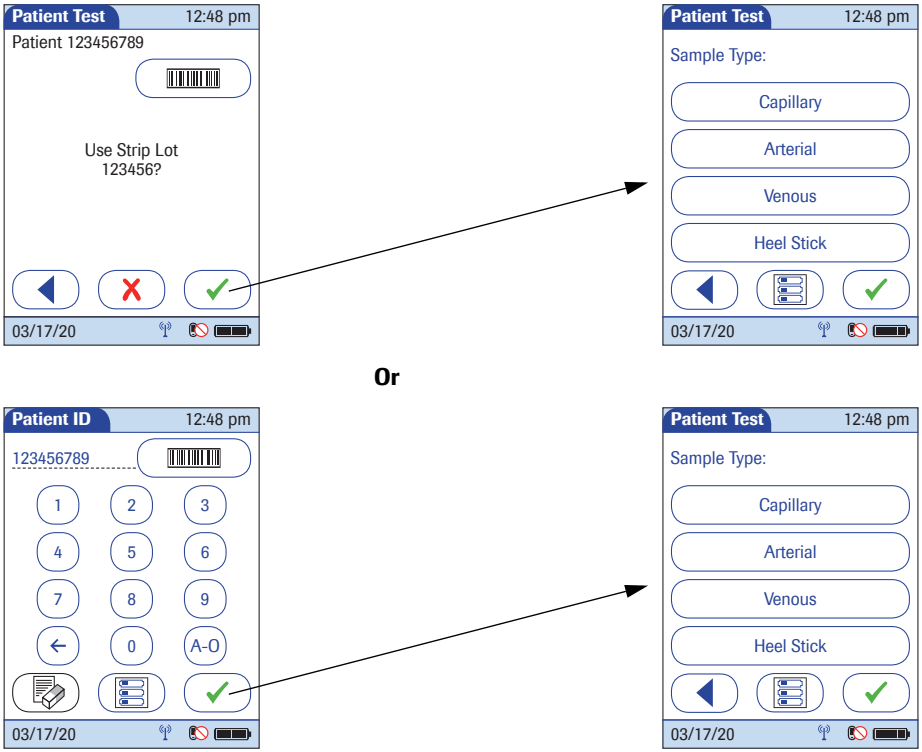
The Accu-Chek Inform II system offers enhanced configuration options for adapting the default patient testing workflow described in chapter 3 “Patient Glucose Testing” to meet a facility’s specific requirements or needs.

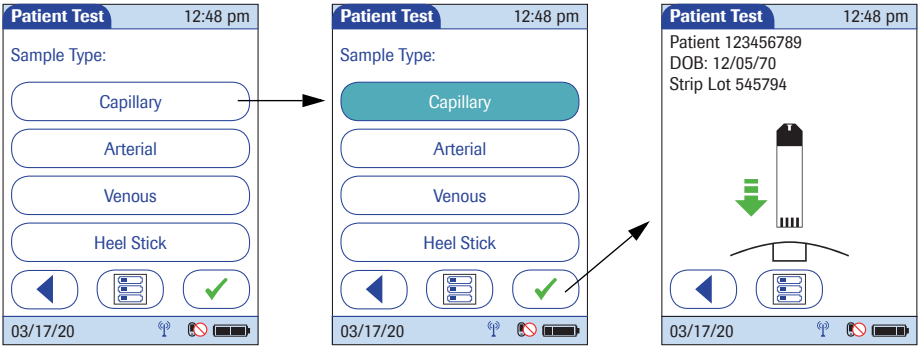
The activation of these features is only possible via a suitable data management System (DMS). See Appendix A.1, “Table of configuration options”.

Blood sample type selection

This feature allows you to select and document the blood sample type used for a patient test.

After you have confirmed or selected the test strip lot (see page 57) **or** Patient ID (in case of the Isolation Room Workflow described below), the blood sample type selection screen appears.





1 Select the blood sample type: *Capillary*, *Arterial*, *Venous*, or *Heel Stick*.

2 Touch (✓) to confirm the selected blood sample type.

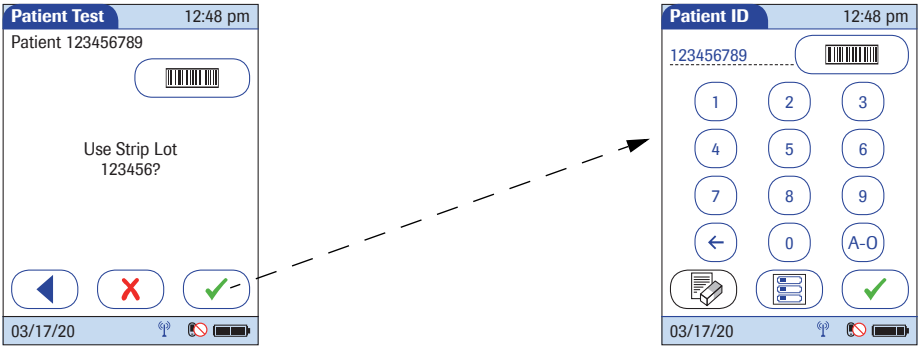
After confirming the selected blood sample type, a flashing green arrow appears on screen and prompts you to insert the test strip.

3 Slide the test strip into the test strip port as far as it goes in the direction indicated by the arrows on the test strip.

Isolation Room Workflow

If configured, this feature allows you to reverse the order of the steps “Entering or selecting the patient ID” and “Confirming or selecting the test strip lot” to avoid contamination issues. This workflow allows you to test a patient in an isolation room without having to take the test strip vial to the patient.

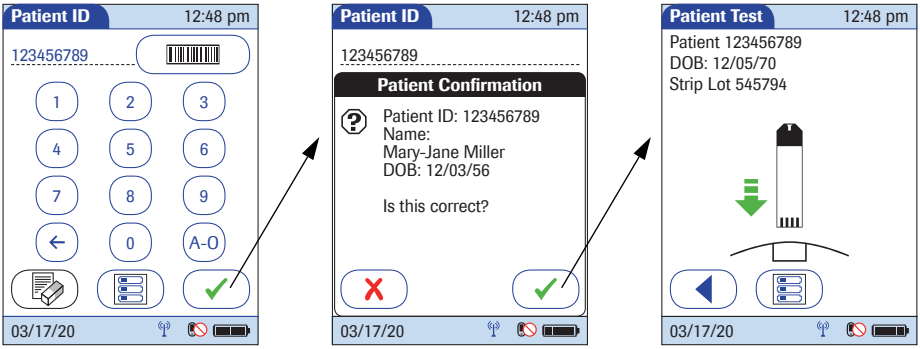
Test procedure for patients in an isolation room



1 Confirm or select the test strip lot. For more details see page 57.

Once a test strip has been removed from the vial, **the blood sample must be applied within 3 minutes**.

2 Take the meter and the test strip to the isolation room.



3 Enter or select the patient ID. For more details see pages 52 - 56.

4 Perform the test. For more details see pages 59 - 62.

The test strips should be used immediately after removing them from the test strip vial (see package insert). However, where this is not possible due to an altered workflow (example: Isolation Room Workflow), studies show that the test strips remain stable for 3 minutes between removing them from the vial and applying a blood sample.

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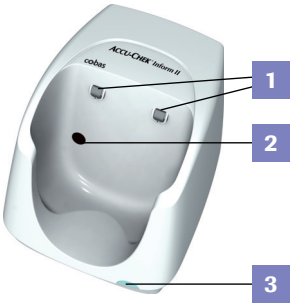
F Appendix for Accu-Chek Inform II Base Unit (legacy version)

The legacy version of the Accu-Chek Inform II Base Unit (REF 05060290001) differs in some technical aspects from the newer Accu-Chek Inform II Base Unit (REF 07671717190) that is described in section 1.6 “Overview of the Accu-Chek Inform II Base Unit”. This chapter describes the elements and technical data of the legacy base unit version with older hardware.

F.1 Overview of the base unit with older hardware



The Accu-Chek Inform II Base Unit (legacy version) can:

- charge the meter battery pack.
- communicate with a data management system.
- communicate with a computer.

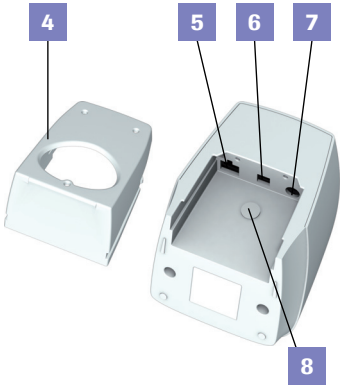
The base unit has the following elements:

1 Charging contacts

2 Infrared window for communication with the meter

3 Status LED (lights up when power is connected):

- Lights up red: Power supply is connected, application is starting up
- Lights up green: Ready
- Flashes red: Error
- Lights up blue: Configuration mode



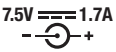
Electrical connections are located on the back of the base unit.

4 Removable mount for wall installation

5 Network connection — Ethernet/RJ45 port

6 USB port

7 Jack for the power supply unit provided

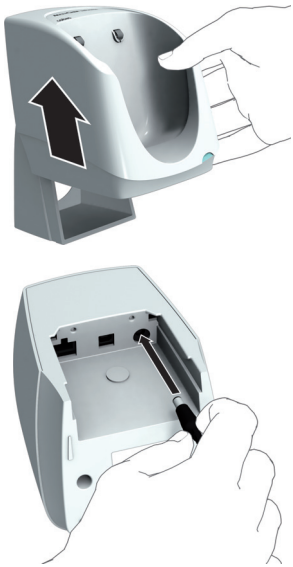


8 USB configuration switch (for System Administrator use only)

F.2 Connecting the base unit (legacy version)

NOTICE

To ensure continuous safe and reliable operation, use only the power supply unit provided for the Accu-Chek Inform II system (for ordering information see page 169).



1 Slide the base unit upward and remove it from the wall mount (if in use).

2 Connect the power supply to the power input jack.

3 **If you want to connect the Accu-Chek Inform II Base Unit in a wired environment:** Connect the Ethernet (RJ45) cable or the USB cable to the respective outlet. Use only the USB cable provided with the Accu-Chek Inform II system.

4 Slide the base unit back onto the wall mount (if in use).

For details on configuring the Accu-Chek Inform II Base Unit, consult your Roche representative.

F.3 Cleaning/disinfecting the base unit (legacy version)

See “Cleaning/disinfecting the base unit” on page 145.
The same instructions apply.

F.4 Technical data

Specification	Base unit (legacy version)	Power supply unit
Height	110 mm / 4.33 in (max.)	35 mm / 1.38 in + AC plug (28-40 mm / 1.1-1.6 in)
Width	118 mm / 4.65 in (max.)	51 mm / 2.01 in
Length	103 mm / 4.06 in (max.)	87 mm / 3.43 in
Weight	Accu-Chek Inform II Base Unit (legacy version) 615 g with wall mount	N/A
User interface	LED (tricolor: red, green, blue)	LED: green
Operating temperature	3 to 50 °C 37 to 122 °F	0 to 40 °C 32 to 104 °F
Storage conditions (long-term storage)	5 to 40 °C / 41 to 104 °F at 10 - 85% RH (non-condensing)	
Humidity (operating)	10 - 90 % RH (non-condensing)	
Air pressure	0.7 to 1.06 bar 70 to 106 kPa	N/A
Input voltage	+7.5 V DC	100 to 240 V AC
Input frequency	DC	50 to 60 Hz
Input current	1.7 A (max)	350 to 150 mA
Interfaces	Charge contacts IR port RJ45 Ethernet USB type B	DC connector Replaceable AC input contacts
Data transfer rate	IR: 9.6K - 115K bps Ethernet: 10 Mbps half-duplex USB: 12 Mbps	N/A

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Notes

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