ACCU-CHEK® Inform II

Roche

Accu-Chek® Inform II

BLOOD GLUCOSE MONITORING SYSTEM

Operator's Manual

ACCU-CHEK®

Revision History

Manual version	Revision date	Changes
Version 1.0	2008-01	New document
Version 2.0	2009-08	Update, new SW version 02.00
Version 3.0	2010-09	Update, new SW version 03.00
Version 4.0	2012-11	Update, new SW version 03.04 (OTS, OTE), revision Cleaning/Disinfection section; misc. editorial revisions

ACCU-CHEK ® Inform II System

Operator's Manual

Version 4.0

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

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

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)
	Manufacturer
REF	Catalog number
IVD	In vitro diagnostic medical device
CE	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).
FC	This device complies with Part 15 of the FCC Rules and with RSS-210 of Industry Canada.
N20091	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.
C (UL) US LISTED	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)
7.5V ⎓ 1.7A	Power supply connection

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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 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 either directly on the meter or by using a suitable data management system. Refer to Chapter 9 "Initial setup on the meter" for on-meter configuration. Refer to Appendix A for configuration via a data management system.

⚠️

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

11

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.
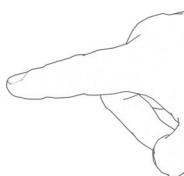
For all questions about the Accu-Chek Inform II system that are not answered in this manual, contact your Roche representative (see Chapter 12). In order to expedite troubleshooting, please have ready your Accu-Chek Inform II meter, its serial number, this manual, and all related consumables when you 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
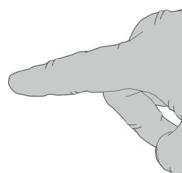
Unless otherwise specified, the term "base unit" refers to both the Accu-Chek Inform II Base Unit and the Accu-Chek Inform II Base Unit Light.

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 appli-
cation, 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

■ 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

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.

⚠
WARNING

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

⚠
CAUTION

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

NOTICE

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 on more than one patient 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 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 per-
forming the next patient test.

■ Use an auto-disabling single-use lancing device
for each patient.

■ Dispose of used lancets in a sturdy sharps con-
tainer 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.

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.

NOTICE 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 16.

Automatic power-off

■ Unless otherwise configured, the system automatically powers off 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.

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.

Observe the following general safety instructions for handling batteries:

Do not dispose of the battery pack with normal domestic waste. As a component of the Accu-Chek Inform II system, it must be deemed as potentially biohazardous. Treat it accordingly. See "Disposal of the system" on page 16.

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

■   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.

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.

Laser scanner

The built-in barcode scanner emits a laser beam when activated.

The built-in barcode scanner is a Class 1 laser, according to IEC 60825-1/A2:2001.

⚠
WARNING

A barcode does not need to be present for the laser scanner to become active. Do not stare directly into the laser beam.

Electrostatic discharge (ESD)

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 EN ISO 15197 Annex A. The system also complies with the electrostatic discharge (ESD) immunity requirements as specified in IEC 61000-4-2 and complies with applicable electromagnetic emissions requirements according to EN 61326-1. The system's emissions of the energy used are low and not likely to cause interference in nearby electronically driven equipment.

Electrostatic discharge (ESD) is an electrical charge at rest, most commonly known as static electricity. 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. 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, or near electronic equipment that is a source of electromagnetic radiation.

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** that applies 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.

Wireless network connection (RF card)

The optional RF card for a wireless network connection 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 35. 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 Com-
mission" (USA).
■ "RSS" stands for "Radio Standards Specification"
(Canada).

Note: The following table provides an overview of the
classifications for electromagnetic compliance (EMC,
according to CISPR 11) for different combinations of
Accu-Chek Inform II system components. Refer to the
explanatory texts following the table for more infor-
mation on these classifications.

Classification acc. to CISPR 11	Meter with RF, docked, serial number < UU11030000	Meter with RF, docked, serial number ≥ UU11030000
Accu-Chek Inform II Base Unit, serial number < UU41030000 and connected to network / a PC via a cable	Class A	Not allowed
Accu-Chek Inform II Base Unit, serial number ≥ UU41030000	Class B	Class B

No operating limitations apply to meters without an RF
card or to meters with an RF card that are not docked.

Note: The following Classification B applies to all
hardware combinations except those specified on
page 25.

The Industrial, Scientific and Medical (ISM) frequencies (802.11b and 802.11g use 2.4 GHz) 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.

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

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

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

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

(1) this device may not cause harmful interference,

and

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

The Accu-Chek Inform II system complies with the emission and immunity requirements described in EN 61326-2-6. It has been designed and tested to CISPR 11 Class B.

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

■   Reorient or relocate the receiving antenna.

■   Increase the separation between the equipment and receiver.

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

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

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

Note on systems with older hardware

⚠
WARNING

Possibility of Electromagnetic Interference
Under certain conditions, a specific combination of hard-ware equipment may emit electromagnetic radiation of such high energy that it can interfere with the proper functioning of other electronic or medical equipment. Therefore it is not allowed to dock an Accu-Chek Inform II meter with a serial number above or equal to UU11030000, which is equipped with an RF card, into an Accu-Chek Inform II Base Unit with a serial number below UU41030000 if this Accu-Chek Inform II Base Unit is connected to a network directly or through a PC via a cable.

Note: The following classification applies if an Accu-Chek Inform II meter (with RF card) with a serial number below UU11030000 is docked in an Accu-Chek Inform II Base Unit with a serial number below UU41030000 if this Accu-Chek Inform II Base Unit is connected to a network directly or through a PC via a cable.

The Accu-Chek Inform II system complies with the emission and immunity requirements described in EN 61326-2-6. It has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference. The electro-magnetic environment in which the Accu-Chek Inform II device is to be operated should be thoroughly evaluated prior to operation of the device.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interfer-ence when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

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

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 with power supply

D   Accessory box (shown with consumables, not included)

The system 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 Accu-Chek Inform II Base Unit (LAN)

1.   Barcodes on test strips vials/control solutions may not be available in all countries.
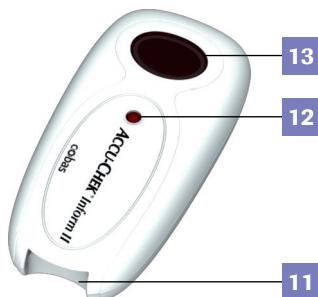
1.4   Overview of the meter

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 (laser)
The integrated barcode scanner can be used to read operator and patient IDs.

5   RF card label
This label displays registration numbers that are specific to the RF card used in the meter.

6   Battery pack
Powers the device.

7   Reset button
Use this button to reset the device. Reset will not alter configuration.

8   Charging contacts
These contacts are used to charge the batteries when the meter is in the base unit.

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

10   Cover for RF card
If your meter is equipped with this option, the RF card for the wireless network (WLAN) is located behind this cover.

28

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:
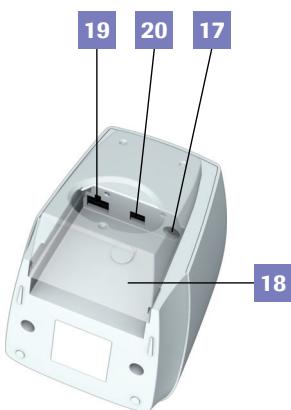
11   Code key slot

12   LED for displaying status

13   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 code key reader LED status light 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.

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

1.6   Overview of the 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 also supports:

■   communication with a data management system.

■   communication with a computer.

Both versions of the base unit have the following elements:

14   Charging contacts

15   Infrared window for communication with the meter

16   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)

17   Jack for the power supply unit provided

18   Removable mount for wall installation

The Accu-Chek Inform II Base Unit has the following additional elements:

19   Network connection — LAN, Ethernet (RJ45)

20   USB connection

Electrical connections are located on the back of the base unit (for a better view the removable wall mount is shown as transparent).

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

1.7   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.

1.8   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.

1.9   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).
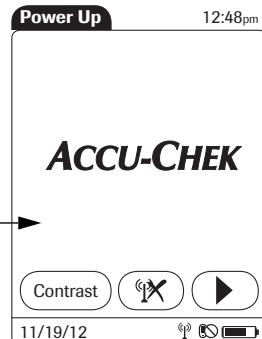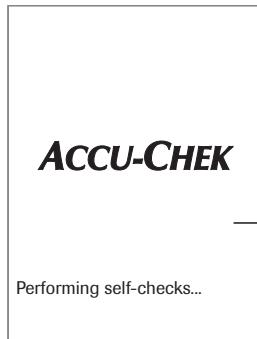
To ensure standardized configuration within a facility, the meter-based *Setup Menu* may be disabled.

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.

ACCU-CHEK

Performing self-checks...

| Power Up | 12:48pm |

ACCU-CHEK

Contrast   ⁽ⁱ⁾🗙   ▶

11/19/12
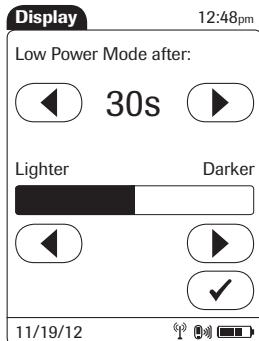
■   If during self-check an error is detected, the appropriate error message appears on-screen.

■   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 🔋.

Adjusting the display

Using the *Display* options, you can adjust display parameters to your needs:

■   Adjust the display contrast to the ambient light conditions.

■   Set the time interval for activating the *Low Power Mode*, which reduces the display contrast after a configurable time without activity (e.g., touching the screen) to conserve energy.

Display	12:48pm
Low Power Mode after:	
◀ 30s ▶	
Lighter Darker	
◀ ▶	
✓	
11/19/12	📶 📢 🔋

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

2   Touch ◀ or ▶ to set the time until *Low Power Mode* is activated.

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

4   Touch ✓ to confirm the setting.

Adjusting the display on meters with older hardware

> The following description applies to meters with a serial number below UU11030000.

While the meter is powered on, you can switch the backlight on or off at any time by pressing ① for more than 1.5 seconds and releasing it.

■   You can adjust the display contrast as described above.

■   The function *Low Power Mode* is not available.

34
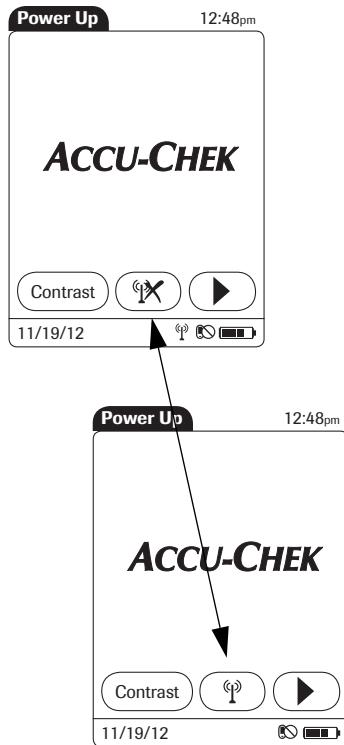
Enabling/disabling the RF card

If the unit is equipped with an RF card, you can temporarily enable or disable this functionality as required.

The RF card 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 running the RF card is 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.

Power Up	12:48pm

ACCU-CHEK

Contrast (📶✖) ▶

11/19/12

Power Up	12:48pm

ACCU-CHEK

Contrast (📶) ▶

11/19/12

If the RF card 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 the RF card is enabled.

■ 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 39).

35
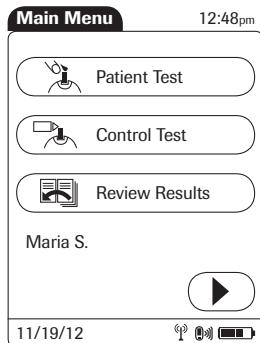
Closing startup

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.

```
┌─────────────────────────────┐
│ Main Menu        12:48pm     │
│ ┌─────────────────────────┐ │
│ │  🖐  Patient Test        │ │
│ │ ─────────────────────── │ │
│ │  🖐  Control Test        │ │
│ │ ─────────────────────── │ │
│ │  📖  Review Results      │ │
│ │                         │ │
│ │  Maria S.               │ │
│ │              ┌───────┐  │ │
│ │              │   ▶   │  │ │
│ │              └───────┘  │ │
│ │ 11/19/12      📶 📶 🔋   │ │
│ └─────────────────────────┘ │
└─────────────────────────────┘
```

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 only

■   Manually or optionally via barcode scanner
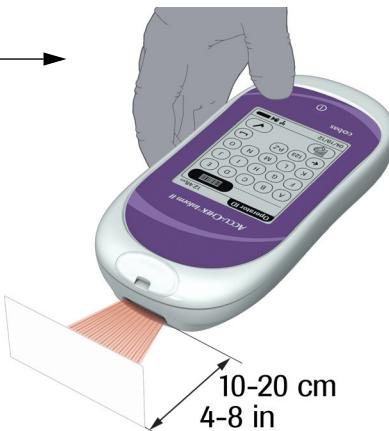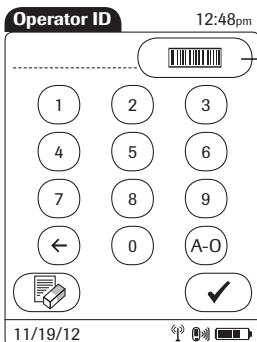
Operator IDs can consist of up to 20 alphanumeric characters.

Alphanumeric characters are any combination of A - Z and 0 - 9, additionally "." (period), or "-" (hyphen) may be used. See also page 38.

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 158.

Entering an operator ID with barcode scanner
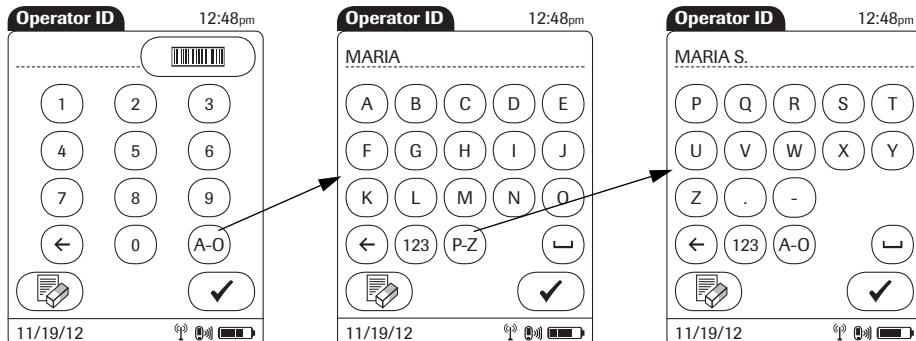
When the screen for entering the operator ID is displayed:

Operator ID		12:48pm
1	2	3
4	5	6
7	8	9
←	0	A-O
🗑		✓

11/19/12

10-20 cm
4-8 in

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.

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 config-ured). 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

| Power Up | 12:48ₚₘ |

ACCU-CHEK

QC Due: Immediately

(Contrast) (📵) (▶)

11/19/12

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. 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 63).

⚠

■ 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:
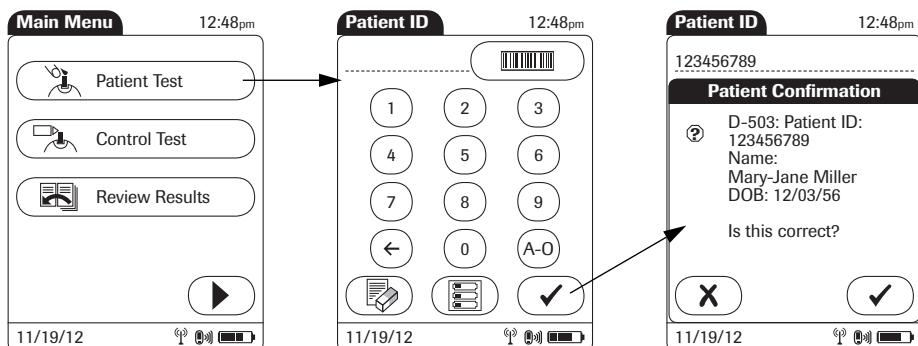
■   Enter the patient ID. This can be done either man-
         ually or by using the barcode scanner.

■   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 187).

As mentioned previously, the following steps must be
completed already:

1   The meter is switched on.

2   You have entered your operator ID.

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

***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 informa-
         tion, after you entered or selected the ID.

40

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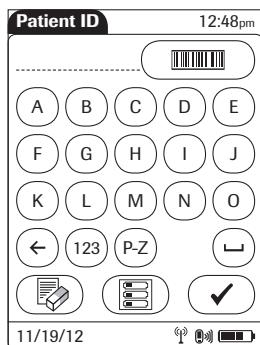
Alphanumeric characters are any combination of A - Z and 0 - 9, additionally "." (period), or "-" (hyphen) may be used.

■ Enter patient ID via barcode scanner.
■ Select a patient from a list. *

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. *
■ 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 158.

* Depending on the DMS you are using, this feature may be disabled.
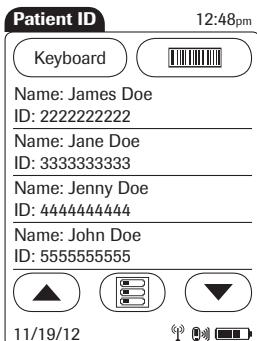
Entering the patient ID manually

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

| Patient ID | 12:48pm |

A B C D E
F G H I J
K L M N O
← 123 P-Z ␣

11/19/12

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

5   Touch (☰) to cancel this procedure and return to the *Main Menu*.

If the patient ID you have entered is not valid (or the patient is not found in the downloaded list), an error message is displayed. Confirming the message allows you to enter the ID again.

Selecting the patient ID from a list

Patient ID	12:48pm

Keyboard · ▐▐▌▐▌▐▐▌

Name: James Doe
ID: 2222222222

Name: Jane Doe
ID: 3333333333

Name: Jenny Doe
ID: 4444444444

Name: John Doe
ID: 5555555555

▲   ▤   ▼

11/19/12
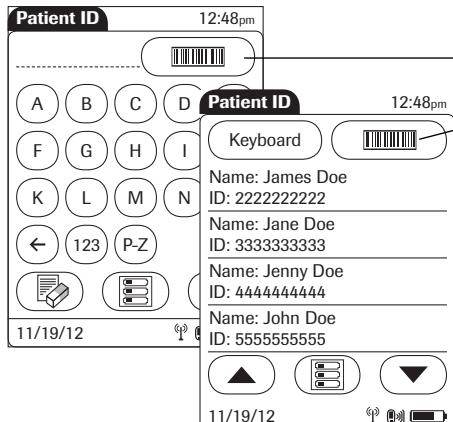
Choose the patient ID from a list*, if a list has been down-loaded to the meter (from the data management system).
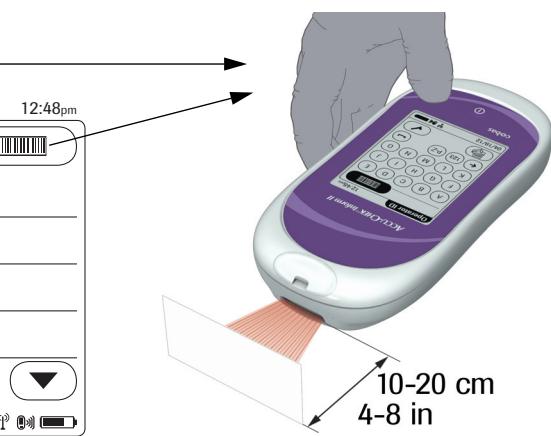
1   Touch ▲ or ▼ to scroll up or down in the list.

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

3   Touch ▤ to cancel this procedure and return to the *Main Menu*.

* Depending on the DMS you are using, this feature may be disabled.

Entering a patient ID with barcode scanner
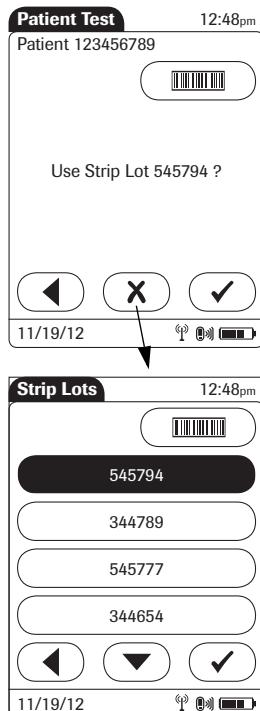
When the screen for entering the patient ID is displayed:


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. The barcode information appears in the patient ID field. The barcode scanner turns off after 10 seconds, if a barcode is not scanned.

Confirming or selecting the test strip lot

Patient Test   12:48pm

Patient 123456789

Use Strip Lot 545794 ?

◀   ✗   ✓

11/19/12

Strip Lots   12:48pm

545794

344789

545777

344654

◀   ▼   ✓

11/19/12

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 ✗ to display a list of stored lot numbers. Select the desired lot number from the list.

■   To read the lot number from the test strip vial via barcode scanner, press and release ▭. Follow the instructions for scanning IDs (see note below).

2   Touch ✓ to confirm the selected or scanned 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 (see note below).
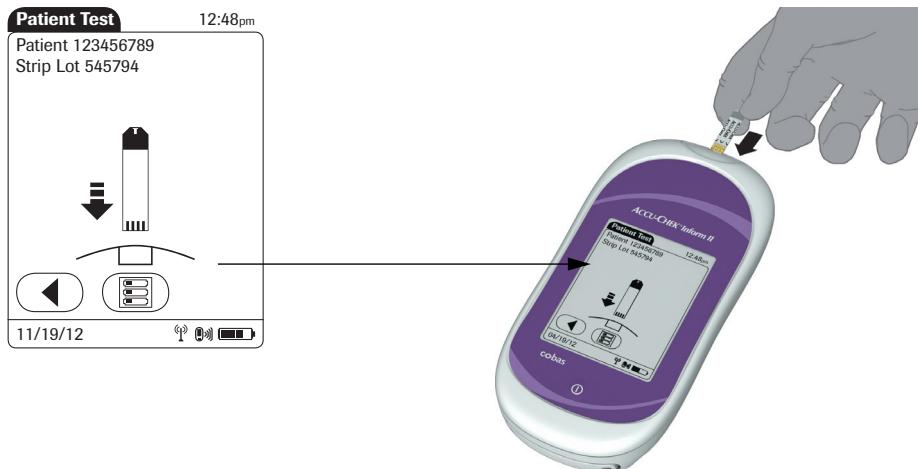
For additional information about storing lot numbers for test strips, see page 67.

Note: Barcodes on test strips vials/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).

45

Inserting test strips
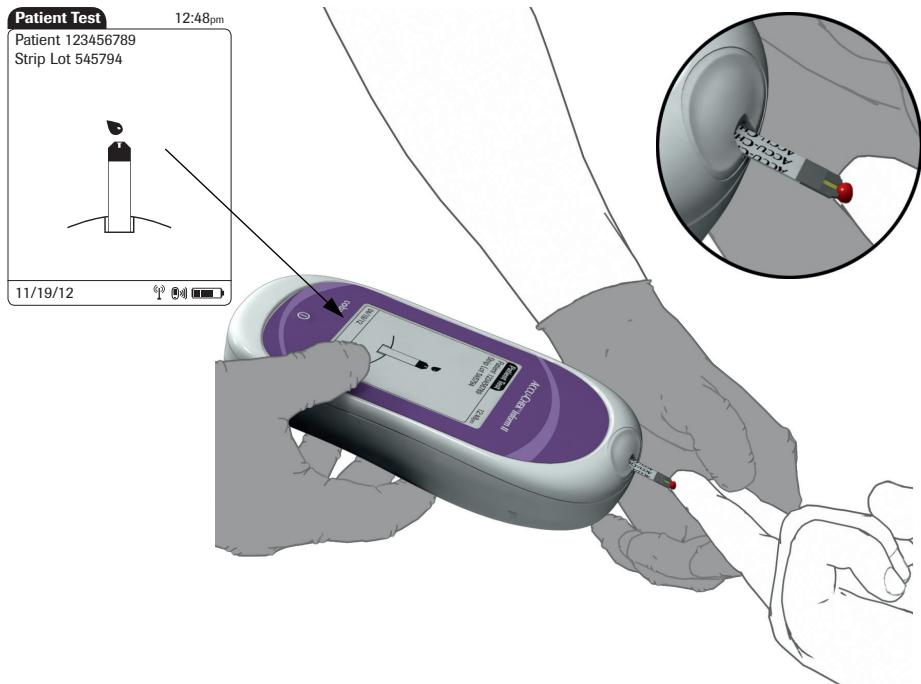
After confirming the test strip lot, you are prompted to insert the test strip.

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.

46

Applying a blood sample

Once the meter has detected the test strip, you are prompted to apply a blood sample.
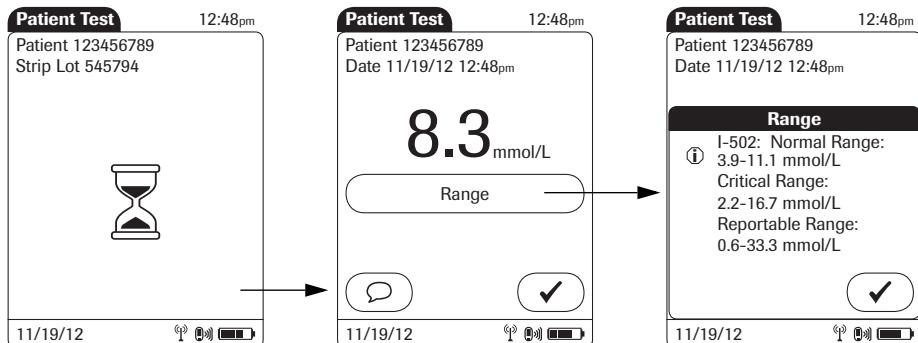
When applying the sample, position the meter so that the test strip port is always higher or on the same level as the blood drop. This prevents any excess blood from flowing down the strip and entering the meter.

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

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

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

47

Results screen

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

Patient Test	12:48pm
Patient 123456789	
Strip Lot 545794	

| 11/19/12 | |

Patient Test	12:48pm
Patient 123456789	
Date 11/19/12 12:48pm	

8.3 mmol/L

Range

| 11/19/12 | |

Patient Test	12:48pm
Patient 123456789	
Date 11/19/12 12:48pm	

Range
ⓘ I-502: Normal Range:
3.9-11.1 mmol/L
Critical Range:
2.2-16.7 mmol/L
Reportable Range:
0.6-33.3 mmol/L

| 11/19/12 | |
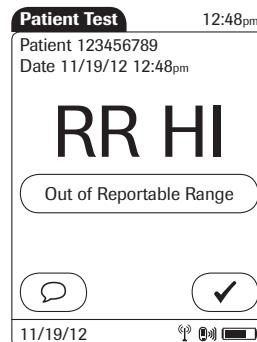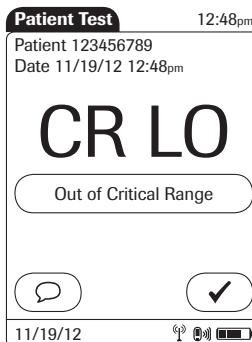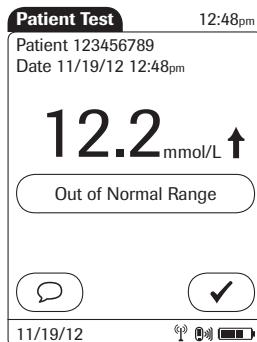
When the result is displayed, a message or warning may also appear (depending on system configuration) notifying you if the result exceeds the specified limit values. Additionally, a **red flashing arrow** next to the test result indicates that a result is out of range.

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

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

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.

Patient Test ⬛ 12:48pm	Patient Test ⬛ 12:48pm	Patient Test ⬛ 12:48pm
Patient 123456789 Date 11/19/12 12:48pm	Patient 123456789 Date 11/19/12 12:48pm	Patient 123456789 Date 11/19/12 12:48pm
12.2 mmol/L ↑	CR LO	RR HI
(Out of Normal Range)	(Out of Critical Range)	(Out of Reportable Range)
(⬭) (✓)	(⬭) (✓)	(⬭) (✓)
11/19/12 ⌖ ▯» ▰▰▰	11/19/12 ⌖ ▯» ▰▰▰	11/19/12 ⌖ ▯» ▰▰▰

■　The System Measurement 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 10 to 600 mg/dL (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 properly.

■　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.

49

The following messages may appear in addition to the standard 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.

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 also saved when the meter is powered off in the results screen or when it powers off automatically.
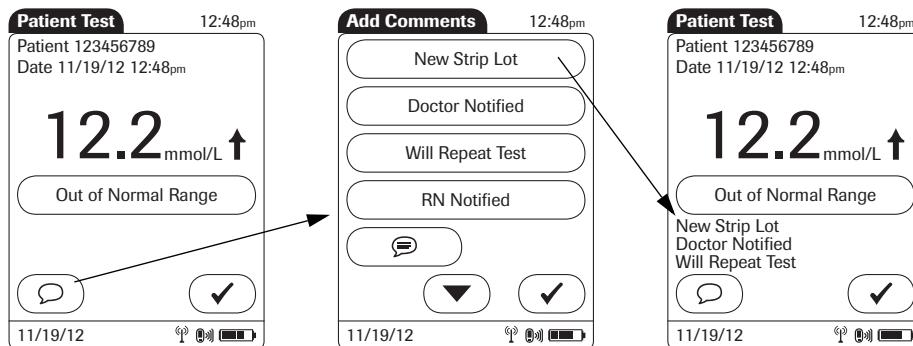
Remove the test strip and dispose of it in accordance with applicable regulations and directives for disposal of potentially infectious samples and materials.

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.

Patient Test 12:48pm	Add Comments 12:48pm	Patient Test 12:48pm
Patient 123456789 Date 11/19/12 12:48pm 12.2 mmol/L ↑ Out of Normal Range	New Strip Lot / Doctor Notified / Will Repeat Test / RN Notified / 💬 / ▼ / ✓	Patient 123456789 Date 11/19/12 12:48pm 12.2 mmol/L ↑ Out of Normal Range New Strip Lot Doctor Notified Will Repeat Test

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

3   Touch 💬 to enter up to one custom comment (if custom commenting is enabled). Use the keypad (as with login) to enter your comment(s).

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

5   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 after 10 minutes of inactivity (no screen touches). See "Automatic power-off" on page 17.

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

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 16.

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 switched on and when the *Glucose Test* function is selected.

```
┌─────────────────────────────────┐
│ ▐Power Up▌          12:48pm      │
│  ┌───────────────────────────┐   │
│  │                           │   │
│  │                           │   │
│  │      ACCU-CHEK            │   │
│  │                           │   │
│  │   QC Due: Immediately     │   │
│  │                           │   │
│  │ (Contrast) (📶✕)  ( ▶ )   │   │
│  │ 11/19/12         📶 🚫▪▪▪  │   │
│  └───────────────────────────┘   │
└─────────────────────────────────┘
```

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 in the illustration on the left), 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 63).

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:

| Main Menu   12:48pm |
| Patient Test |
| Control Test |
| Review Results |
| ▶ |
| 11/19/12 |

| Control Test   12:48pm |
| ▮▮▮▮▮▮ |
| Level 1 (Lo) |
| Level 2 (Hi)   Required |
| ◀ ▤ |
| 11/19/12 |
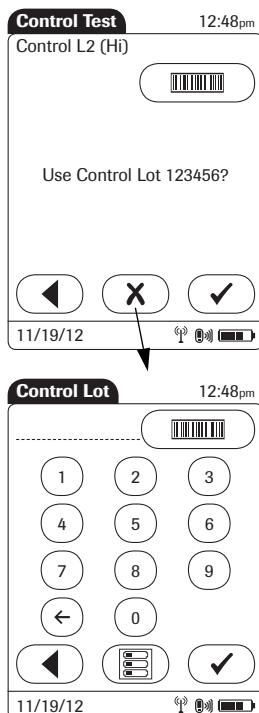
1   From the *Main Menu* screen touch *Control Test*.

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 ✗ 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 37). *

2   Touch ✓ to confirm the selected test strip lot number.
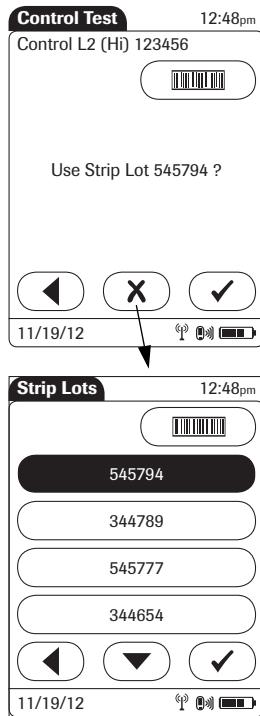
The meter can be configured so that manual confirmation is not necessary. In this setup, only the lot number is displayed. Additional options are not available.

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 73.

* Barcodes on test strips vials/control solutions may not be available in all countries (see page 45).

58

Confirming or selecting the test strip lot

Control Test 12:48pm
Control L2 (Hi) 123456

[||||||||||||]

Use Strip Lot 545794 ?

(◀) (✗) (✓)
11/19/12 📶 📢 🔋

Strip Lots 12:48pm

[||||||||||||]

545794

344789

545777

344654

(◀) (▼) (✓)
11/19/12 📶 📢 🔋

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 (✗) 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. *
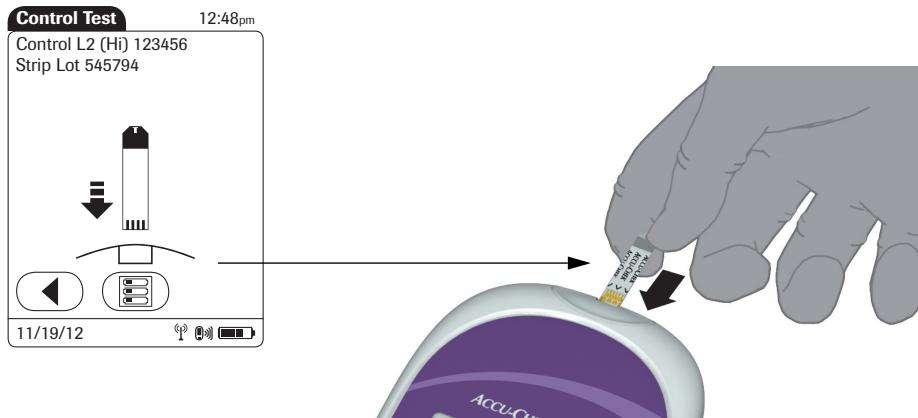
The meter can be configured so that lot numbers can only be selected from a list.

For additional information about storing lot numbers for test strips, see page 67.

* Barcodes on test strip vials/control solutions may not be available in all countries (see page 45).

59

Inserting test strips

After confirming the test strip lot, you are prompted to insert the test strip.

Control Test	12:48pm

Control L2 (Hi) 123456
Strip Lot 545794

11/19/12
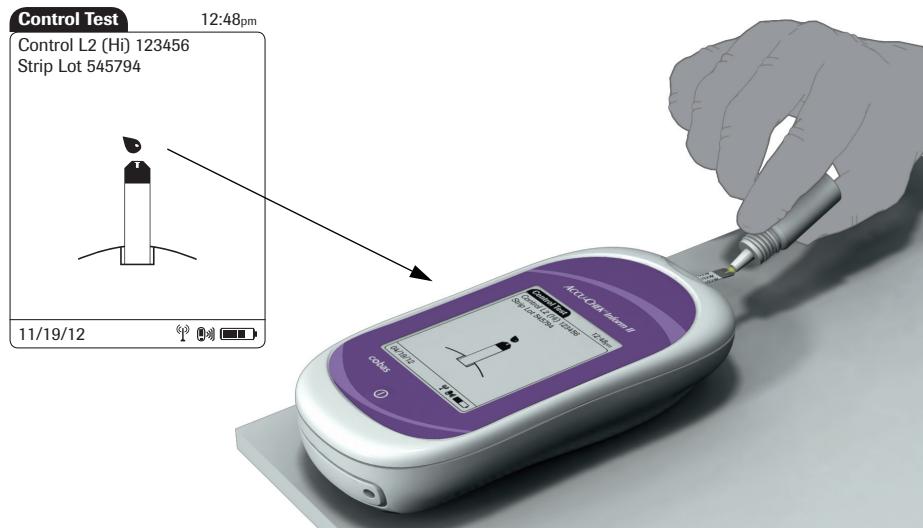
1   Remove the test strip from the test strip vial and close the vial with the cap.

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.

Applying the control solution

Once the meter has detected the test strip, you are prompted to apply the control solution.

Control Test	12:48pm
Control L2 (Hi) 123456	
Strip Lot 545794	
11/19/12	
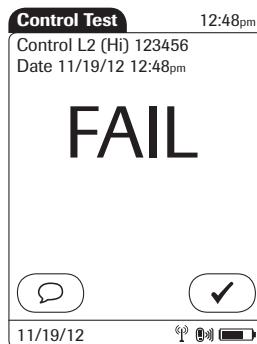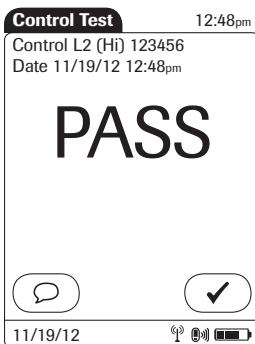
1 Wait until the flashing drop appears in the display before applying the control solution.

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.

Control Test 12:48pm	Control Test 12:48pm	Control Test 12:48pm
Control L2 (Hi) 123456	Control L2 (Hi) 123456	Control L2 (Hi) 123456
Date 11/19/12 12:48pm	Date 11/19/12 12:48pm	Date 11/19/12 12:48pm
17.1 mmol/L	PASS	FAIL
Range		
⬭ ✓	⬭ ✓	⬭ ✓
11/19/12	11/19/12	11/19/12

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.
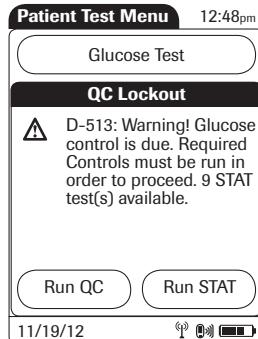
You can add comments to a test result (as with blood glucose tests) (see page 51).

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

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:

```
┌─────────────────────────────────┐
│ Patient Test Menu   12:48pm      │
│  ┌───────────────────────────┐   │
│  │      Glucose Test         │   │
│  └───────────────────────────┘   │
│  ┌───────────────────────────┐   │
│  │       QC Lockout          │   │
│  │ ⚠ D-513: Warning! Glucose │   │
│  │   control is due. Required│   │
│  │   Controls must be run in │   │
│  │   order to proceed. 9 STAT│   │
│  │   test(s) available.      │   │
│  │                           │   │
│  │ ┌────────┐  ┌──────────┐  │   │
│  │ │ Run QC │  │ Run STAT │  │   │
│  │ └────────┘  └──────────┘  │   │
│  └───────────────────────────┘   │
│ 11/19/12         📶 📳 🔋         │
└─────────────────────────────────┘
```

■   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 (see page 125).

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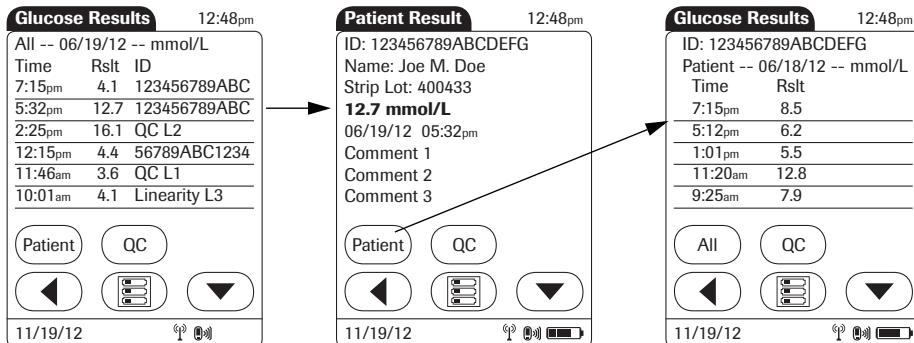
Maintenance results (for documentation of maintenance activities) are stored and displayed with date and time only if comments were added.

List of results stored in the memory

To display the results from the memory as a list:

Main Menu	12:48pm
Patient Test	
Control Test	
Review Results	
	▶
11/19/12	

Glucose Results	12:48pm
All -- 06/19/12 -- mmol/L	

Time	Rslt	ID
7:15pm	4.1	123456789ABC
5:32pm	12.7	123456789ABC
2:25pm	16.1	QC L2
12:15pm	4.4	56789ABC1234
11:46am	3.6	QC L1
10:01am	4.1	Linearity L3

(Patient)   (QC)

◀   ▦   ▼

11/19/12

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.

Glucose Results	12:48pm

All -- 06/19/12 -- mmol/L

Time	Rslt	ID
7:15pm	4.1	123456789ABC
5:32pm	12.7	123456789ABC
2:25pm	16.1	QC L2
12:15am	4.4	56789ABC1234
11:46am	3.6	QC L1
10:01am	4.1	Linearity L3

(Patient)   (QC)

◀   ▤   ▼

11/19/12   ⦿

Patient Result	12:48pm

ID: 123456789ABCDEFG
Name: Joe M. Doe
Strip Lot: 400433
12.7 mmol/L
06/19/12 05:32pm
Comment 1
Comment 2
Comment 3

(Patient)   (QC)

◀   ▤   ▼

11/19/12   ⦿

Glucose Results	12:48pm

ID: 123456789ABCDEFG
Patient -- 06/18/12 -- mmol/L

Time	Rslt
7:15pm	8.5
5:12pm	6.2
1:01pm	5.5
11:20am	12.8
9:25am	7.9

(All)   (QC)

◀   ▤   ▼

11/19/12   ⦿

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.

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

8   Touch ▤ to return to the *Main Menu*.

66

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:
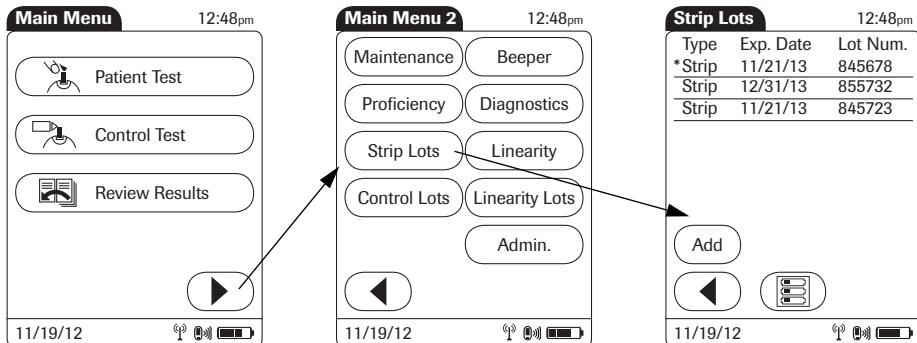
■   Expiration date (can be set to a date **before** the date stored in the key)

■   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 pow-
ered on and the *Main Menu* is displayed.

Main Menu	12:48pm
🖊 Patient Test	
🖊 Control Test	
📖 Review Results	
▶	
11/19/12	〰 ◑)) ▬▬

Main Menu 2	12:48pm
(Maintenance)	(Beeper)
(Proficiency)	(Diagnostics)
(Strip Lots)	(Linearity)
(Control Lots)	(Linearity Lots)
	(Admin.)
◀	
11/19/12	〰 ◑)) ▬▬

Strip Lots		12:48pm
Type	Exp. Date	Lot Num.
*Strip	11/21/13	845678
Strip	12/31/13	855732
Strip	11/21/13	845723
(Add)		
◀	📋	
11/19/12		〰 ◑)) ▬▬

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.
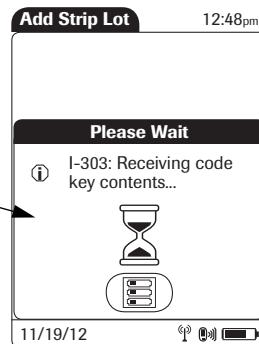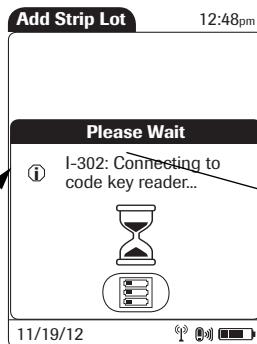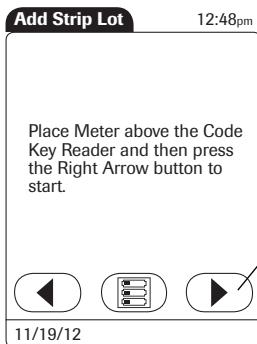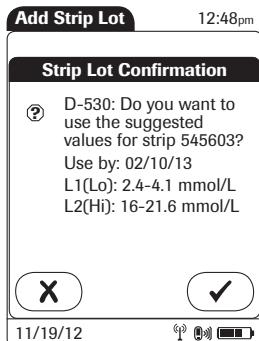
10-15 cm
4-6 in

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.

Add Strip Lot 12:48pm	**Add Strip Lot** 12:48pm	**Add Strip Lot** 12:48pm
Place Meter above the Code Key Reader and then press the Right Arrow button to start.	**Please Wait** ⓘ I-302: Connecting to code key reader...	**Please Wait** ⓘ I-303: Receiving code key contents...
◀ ▤ ▶	▤	▤
11/19/12	11/19/12	11/19/12
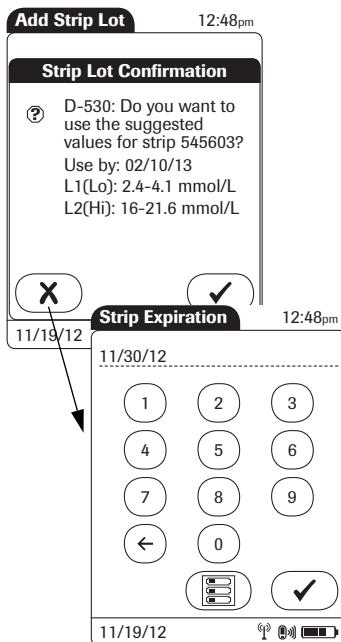
Information about the expiration date and parameters for control solutions is subsequently displayed.

1   Touch ✓ to store the data for this lot number in the meter without changes, or

2   Touch ✗ to modify the data for this lot number before storing it in the meter.

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.

3   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.

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

The parameters for control solutions consist of four sepa-
rate values.

Strip Expiration 12:48pm	Control L2 Min 12:48pm	Control L2 Max 12:48pm
11/30/12	16 mmol/L	21.6 mmol/L
1 2 3	1 2 3	1 2 3
4 5 6	4 5 6	4 5 6
7 8 9	7 8 9	7 8 9
← 0	← 0	← 0
11/19/12	11/19/12	11/19/12

5   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

6   Touch (▶) to confirm each separate entry and
continue to the next entry.
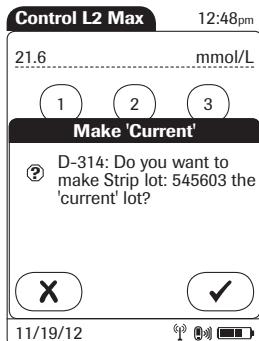
```
┌─────────────────────────────────┐
│ Control L2 Max        12:48pm    │
│ ─────────────────────────────   │
│ 21.6                  mmol/L     │
│   ( 1 )    ( 2 )    ( 3 )        │
│ ▌ Make 'Current'        ▐        │
│ ⑦  D-314: Do you want to         │
│    make Strip lot: 545603 the    │
│    'current' lot?                │
│                                  │
│  ( X )              ( ✔ )        │
│ 11/19/12          ⌄⁾ ▣⟫ ▰▰▱      │
└─────────────────────────────────┘
```

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.
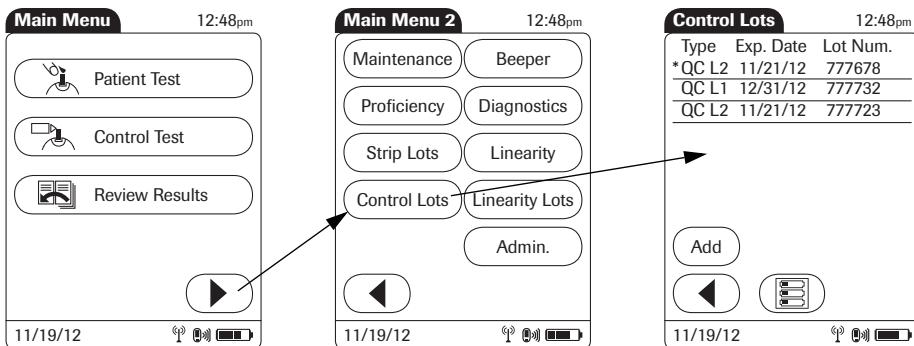
7   Touch (✔) to confirm that you want this lot number to be the lot number currently in use, or

8   Touch (X) to store the entries without making the lot number the current lot number.

9   Continue entering additional lot numbers, or

10 Touch (▤) to return to the *Main Menu*.

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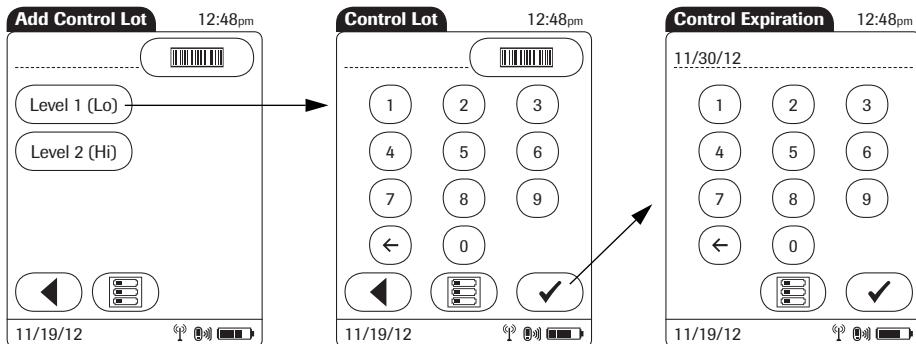
Glucose control solution lot information can be entered before testing, if lot editing has been allowed at the meter level in the setup, and appears in a list for operators to refer to. Use the following procedure to add glucose control lot numbers to the Control Lot list.

Entering the lot number of the control solution

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

Main Menu	12:48pm
Patient Test	
Control Test	
Review Results	
11/19/12	

Main Menu 2	12:48pm
Maintenance	Beeper
Proficiency	Diagnostics
Strip Lots	Linearity
Control Lots	Linearity Lots
	Admin.
11/19/12	

Control Lots		12:48pm
Type	Exp. Date	Lot Num.
*QC L2	11/21/12	777678
QC L1	12/31/12	777732
QC L2	11/21/12	777723
Add		
11/19/12		

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.

73
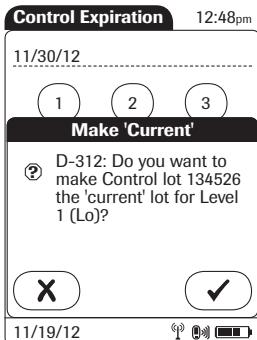
4   Select the level (L1/Lo or L2/Hi).

5   Use the keypad to enter the lot number. Touch ✓ to confirm the entered lot number, or

6   Press and release ▭ to read the lot number from the control solution bottle via barcode scanner. Follow the instructions for scanning IDs (see page 37). *

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

8   Touch ✓ to confirm the entered expiration date.

* Barcodes on test strip vials/control solutions may not be available in all countries (see page 45).

Control Expiration 12:48pm

11/30/12
- -

(1)   (2)   (3)

Make 'Current'

⑦ D-312: Do you want to make Control lot 134526 the 'current' lot for Level 1 (Lo)?

(✗)   (✓)

11/19/12   📶 📳 🔋
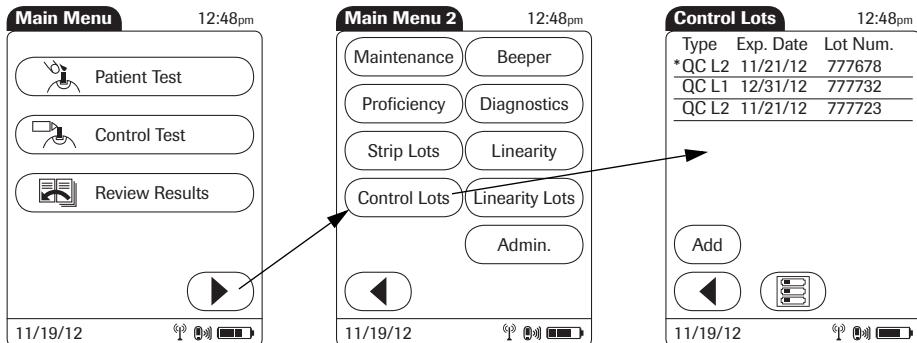
Once you have finished updating the control solution information, you can use the next screen to select the lot number you are currently editing as the current lot number.
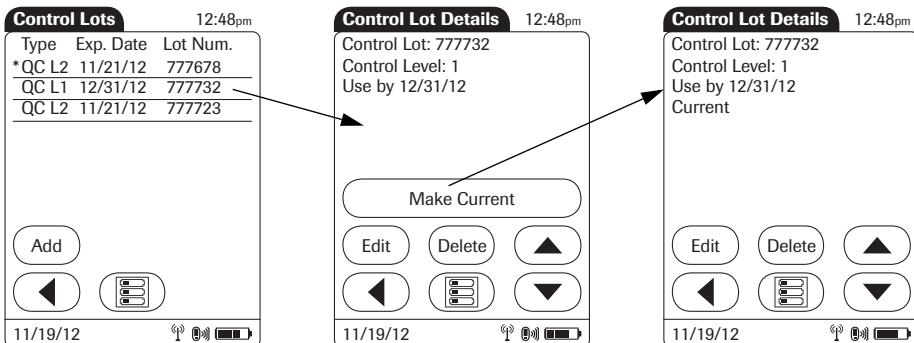
The current lot number is provided automatically for use with subsequent tests.

9   Touch (✓) to confirm that you want this lot number to be the lot number currently in use, or

10   Touch (✗) to store the entries without making the lot number the current lot number.

11   Continue entering additional lot numbers, or

12   Touch (📋) to return to the *Main Menu*.

75

Selecting a stored lot number as the current lot number

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

Main Menu	12:48pm
Patient Test	
Control Test	
Review Results	
	▶
11/19/12	

Main Menu 2	12:48pm
Maintenance	Beeper
Proficiency	Diagnostics
Strip Lots	Linearity
Control Lots	Linearity Lots
	Admin.
◀	
11/19/12	

Control Lots		12:48pm
Type	Exp. Date	Lot Num.
*QC L2	11/21/12	777678
QC L1	12/31/12	777732
QC L2	11/21/12	777723
Add		
◀		
11/19/12		

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 (*).

76

Control Lots	12:48pm

Type	Exp. Date	Lot Num.
*QC L2	11/21/12	777678
QC L1	12/31/12	777732
QC L2	11/21/12	777723

Add

Control Lot Details	12:48pm

Control Lot: 777732
Control Level: 1
Use by 12/31/12

Make Current

Edit   Delete

Control Lot Details	12:48pm

Control Lot: 777732
Control Level: 1
Use by 12/31/12
Current

Edit   Delete

11/19/12
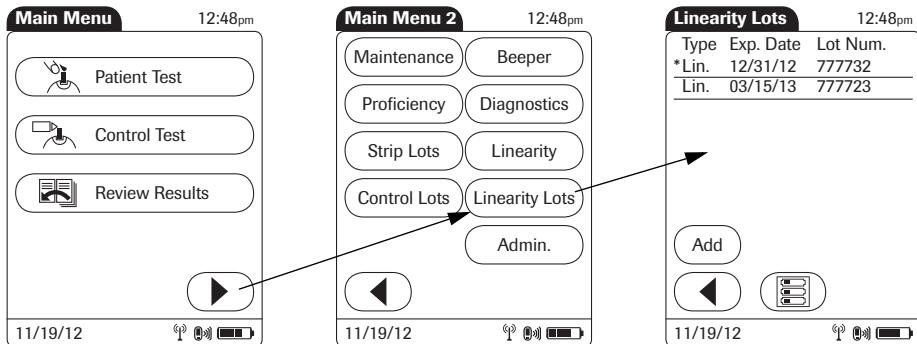
3   Touch the lot number you wish to select as the current lot number. This opens the related detail view.

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

6   Touch 🗐 to return to the *Main Menu*.

77

6.3 Storing linearity test information
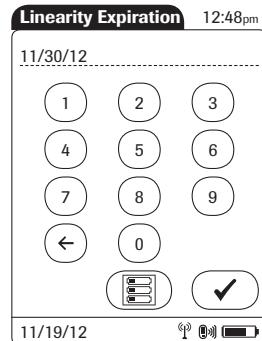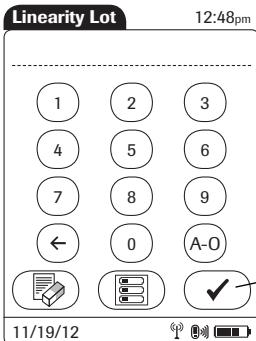
Observe the applicable regulations and directives of the responsible regulatory agencies when performing linearity tests.

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.

Linearity Lot   12:48pm

1 2 3
4 5 6
7 8 9
← 0 A-O

11/19/12

Linearity Expiration   12:48pm

11/30/12

1 2 3
4 5 6
7 8 9
← 0

11/19/12
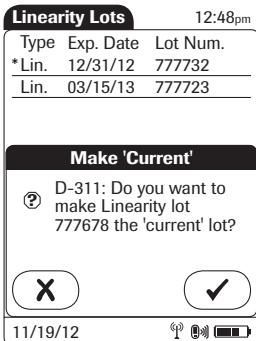
4   Use the keypad to enter the lot number.

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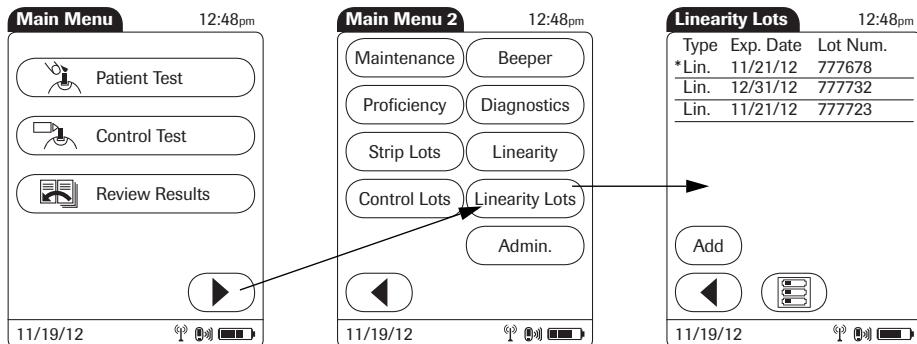
Once you have finished updating the linearity test information, you can use the next screen to select the lot number you are currently editing as the current lot number.

Linearity Lots   12:48pm

Type	Exp. Date	Lot Num.
*Lin.	12/31/12	777732
Lin.	03/15/13	777723

Make 'Current'

⍰ D-311: Do you want to make Linearity lot 777678 the 'current' lot?

✗   ✓

11/19/12
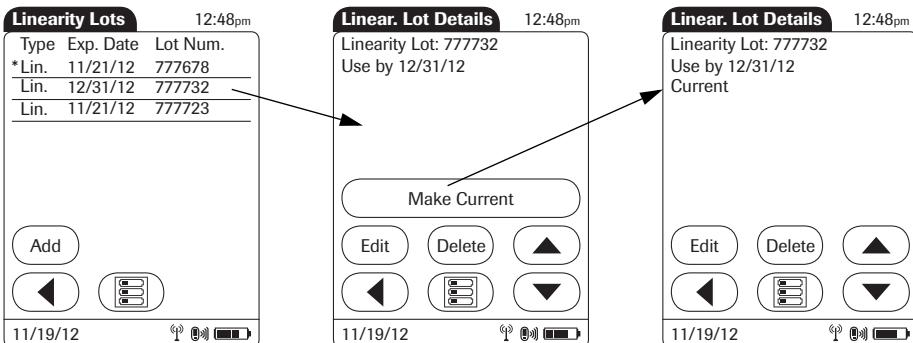
The current lot number is provided automatically for use with subsequent tests.

7   Touch ✓ to confirm that you want this lot number to be the lot number currently in use, or

8   Touch ✗ to store the entries without making the lot number the current lot number.

9   Continue entering additional lot numbers, or

10   Touch 🗐 to return to the *Main Menu*.

79

Selecting a stored lot number as the current lot number

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

Main Menu	12:48pm
Patient Test	
Control Test	
Review Results	
▶	
11/19/12	

Main Menu 2	12:48pm
Maintenance	Beeper
Proficiency	Diagnostics
Strip Lots	Linearity
Control Lots	Linearity Lots
	Admin.
◀	
11/19/12	

Linearity Lots		12:48pm
Type	Exp. Date	Lot Num.
*Lin.	11/21/12	777678
Lin.	12/31/12	777732
Lin.	11/21/12	777723
Add		
◀		☰
11/19/12		

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 (*).

80

Linearity Lots	12:48pm

Type	Exp. Date	Lot Num.
*Lin.	11/21/12	777678
Lin.	12/31/12	777732
Lin.	11/21/12	777723

Add

11/19/12

Linear. Lot Details	12:48pm

Linearity Lot: 777732
Use by 12/31/12

Make Current

Edit   Delete

11/19/12

Linear. Lot Details	12:48pm

Linearity Lot: 777732
Use by 12/31/12
Current

Edit   Delete

11/19/12

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

6   Touch (☰) to return to the *Main Menu*.

81

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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 16. 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
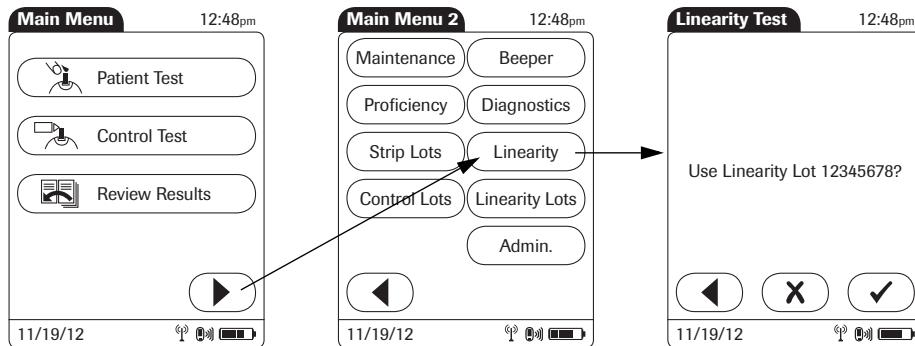
Overview of test procedure   A linearity test comprises the following steps:

■   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.
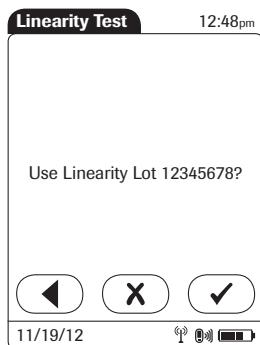
Starting a linearity test   The following description assumes that the meter is powered on and the *Main Menu* is displayed.

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.

Linearity Test	12:48pm

Use Linearity Lot 12345678?

◀ ✕ ✓

11/19/12

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 78).

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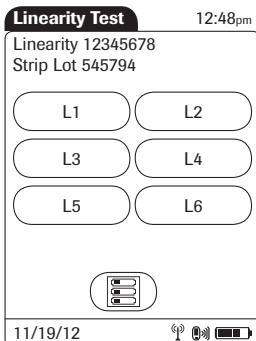
Once you have entered and confirmed the lot number of the linearity test kit, you are asked to choose the lot number of the test strips. Compare the number displayed by the meter to the number on the label of the test strip vial.

Linearity Test	12:48pm

Linearity 12345678

|||||||

Use Strip Lot 545794 ?

◀ ✕ ✓

11/19/12

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 67). *

* Barcodes on test strip vials/control solutions may not be available in all countries (see page 45).

86

```
┌─────────────────────────────┐
│ ▐ Linearity Test ▌  12:48pm │
│ ┌─────────────────────────┐ │
│ │ Linearity 12345678      │ │
│ │ Strip Lot 545794        │ │
│ │                         │ │
│ │ ( L1 )        ( L2 )    │ │
│ │                         │ │
│ │ ( L3 )        ( L4 )    │ │
│ │                         │ │
│ │ ( L5 )        ( L6 )    │ │
│ │                         │ │
│ │        ( ▤ )            │ │
│ │ 11/19/12    ⌔ ⍩ ▭       │ │
│ └─────────────────────────┘ │
└─────────────────────────────┘
```
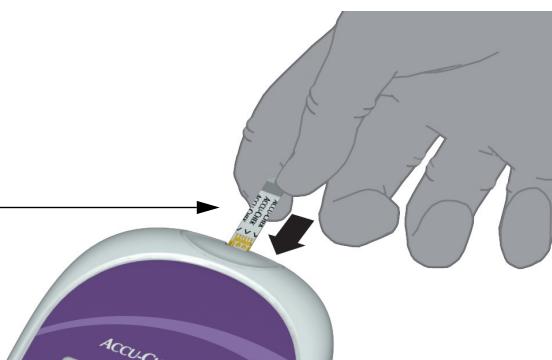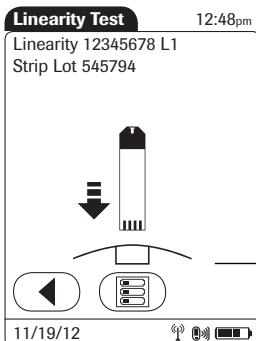
In the *Linearity Test* menu, the levels available for the linearity test are displayed.

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

Inserting test strips
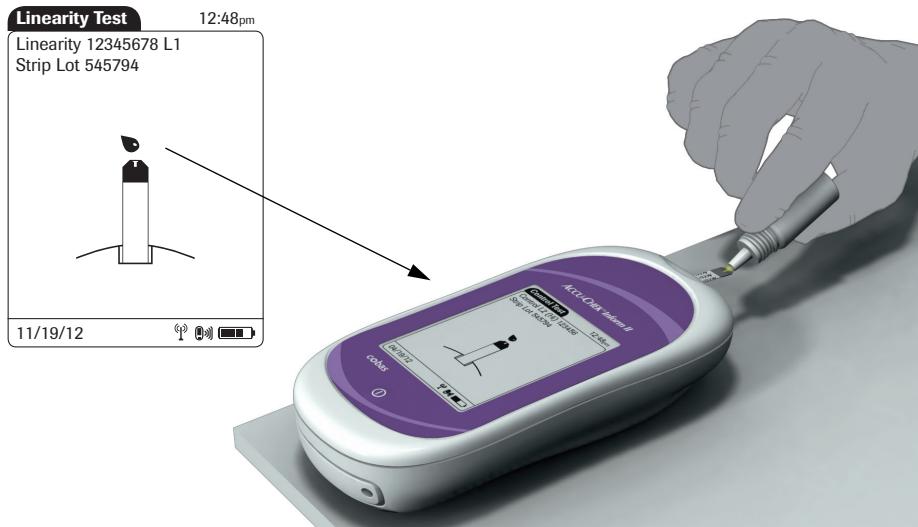
After selecting the level, you are prompted to insert the test strip.

```
┌─────────────────────────────┐
│ ▐ Linearity Test ▌  12:48pm │
│ ┌─────────────────────────┐ │
│ │ Linearity 12345678 L1   │ │
│ │ Strip Lot 545794        │ │
│ │          ▮              │ │
│ │          ▼              │ │
│ │                         │ │
│ │      ╱───────╲          │ │
│ │ ( ◀ )  ( ▤ )            │ │
│ │ 11/19/12    ⌔ ⍩ ▭       │ │
│ └─────────────────────────┘ │
└─────────────────────────────┘
```


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.

Applying a linearity test sample

Once the meter has detected the test strip, you will be prompted to apply the linearity solution.


```
Linearity Test          12:48pm
Linearity 12345678 L1
Strip Lot 545794




11/19/12          ⊻ 📶 🔋
```
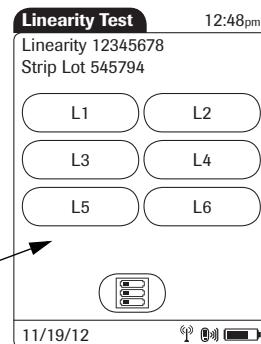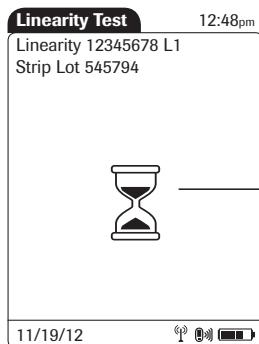
1   Wait until the flashing drop appears in the display before applying the solution.

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.

Linearity Test 12:48pm	Linearity Test 12:48pm	Linearity Test 12:48pm
Linearity 12345678 L1 Strip Lot 545794	Linearity 12345678 L1 Date 11/19/12 12:48pm	Linearity 12345678 Strip Lot 545794
⧗	2.5 mmol/L	L1 L2 L3 L4 L5 L6
	◯ ✓	☰
11/19/12	11/19/12	11/19/12

You can add comments to a test result (as with blood glucose tests, see page 51).

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

89

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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
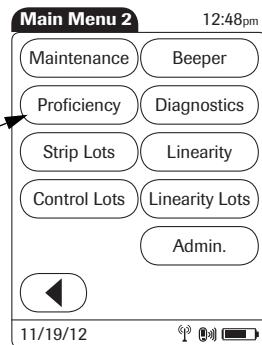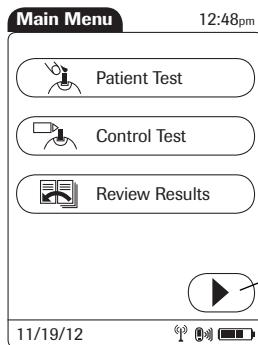
Overview of test procedure   A proficiency test comprises the following steps:

■   Enter a sample ID for the proficiency sample.

■   Check the lot number of the test strips.

■   Perform the actual test with the proficiency sample.
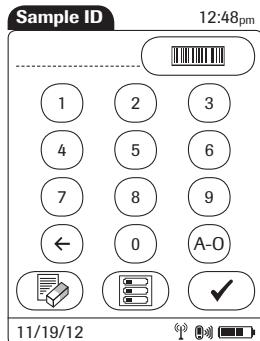
Starting a proficiency test   The following description assumes that the meter is powered on and the *Main Menu* is displayed.

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

2   Press and release ⬛ to read the sample ID from the sample vial via barcode scanner (see page 37). Make sure in this case that the proficiency sample has a compatible barcode (see Appendix A).

3   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.

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 67). *

* Barcodes on test strips vials/control solutions may not be available in all countries (see page 45).

94

Inserting test strips
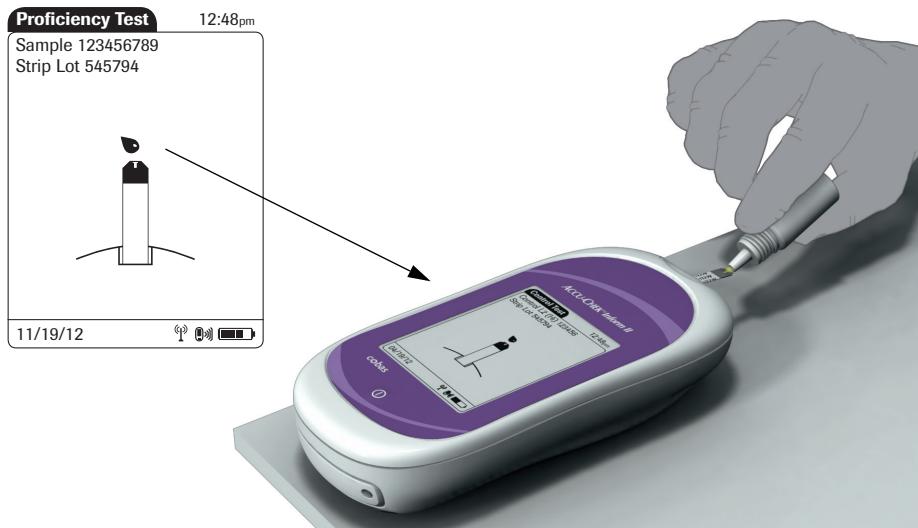
After confirming the test strip lot, you will be prompted to insert the test strip.

```
┌──────────────────────────────┐
│ Proficiency Test     12:48pm  │
│ Sample 123456789              │
│ Strip Lot 545794              │
│                               │
│                               │
│                               │
│                               │
│                               │
│                               │
│  ◀     ▤                      │
│ 11/19/12        ⌁ ▣ ▬▬▬       │
└──────────────────────────────┘
```


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.

95

Applying a proficiency sample   Once the meter has detected the test strip, you are
prompted to apply the proficiency sample.
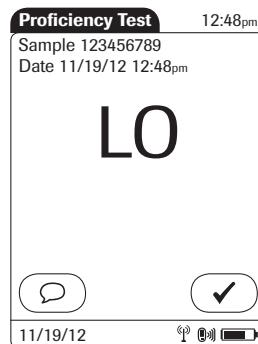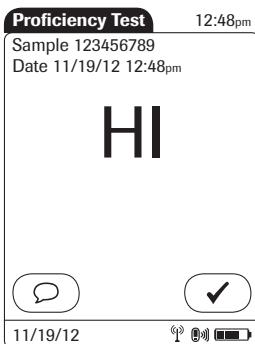
1   Wait until the flashing drop appears in the display
before applying the sample.

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.

Proficiency Test 12:48pm	Proficiency Test 12:48pm	Proficiency Test 12:48pm
Sample 123456789 Date 11/19/12 12:48pm 8.3 mmol/L	Sample 123456789 Date 11/19/12 12:48pm HI	Sample 123456789 Date 11/19/12 12:48pm LO
11/19/12	11/19/12	11/19/12

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 51).

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

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 145).

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

2   Connect the power cord to the proper outlet.

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.

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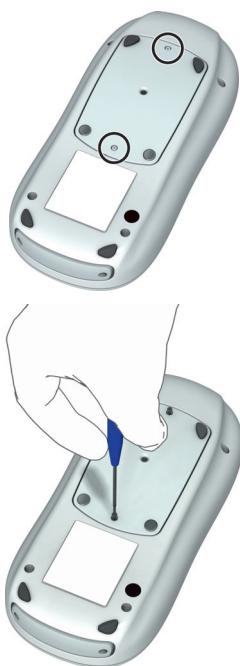
When shipped, the battery pack is not installed in the Accu-Chek Inform II meter.

After installing a new battery pack, the meter should be charged for three hours 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 (3-40 °C or 37-104 °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.

Removing the battery pack

1   If a battery pack is already installed, make sure that the meter is switched off.

2   Place the meter face down on a level surface.

3   Using a Torx screwdriver size T5, remove the two screws holding the battery pack in place.

4   Carefully remove the battery pack from the meter. The battery pack is still connected to the meter by the plug.

5   Remove the plug connector.
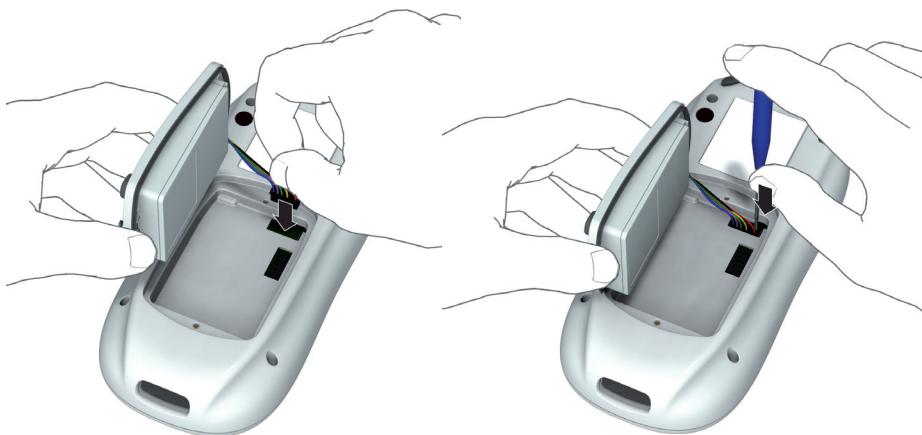
Dispose of used battery packs in an environmentally responsible manner in accordance with applicable local regulations and directives.

101

Installing the battery pack

1   Loosen the screws on the battery pack until they are protruding about 4-5 mm (2/10 in).
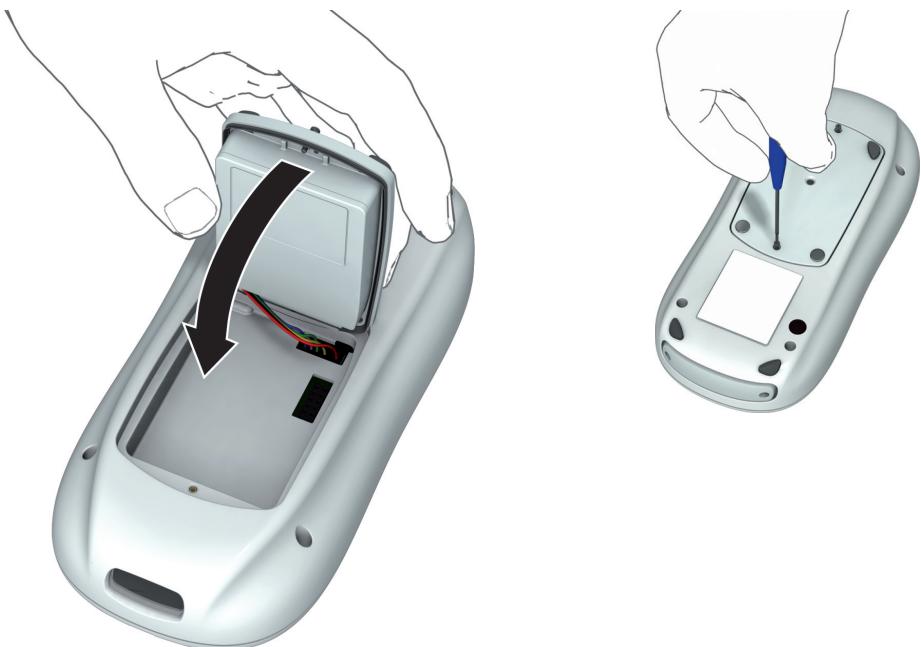
2   Position the battery pack alongside the meter so that the plug connector is level with the socket inside the meter.
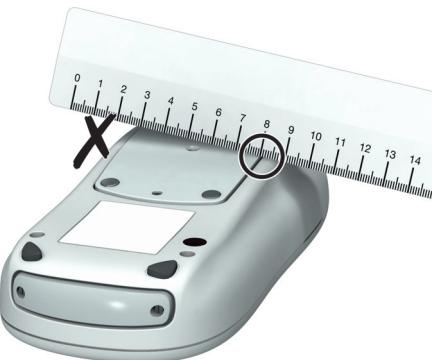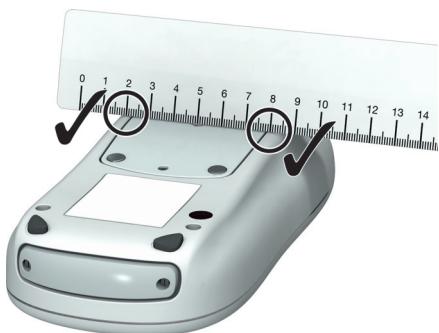
3   Plug the connector plug into the socket.

4   If necessary, use a suitable tool (such as the Torx screwdriver) to push the plug completely into the socket.

5   Place the tapering end of the battery pack on the small ledge of the opening and push down like a lid to close (as shown in the illustration below). Make sure that the plug connector wires slide into the groove provided for them on the battery pack. Gently pushing down the "lid" as described here helps to align the wires properly so that they do not get pinched or bent.

6   The battery pack should now fit neatly inside the meter. If this is not the case, check whether the screws have been loosened enough or if the wires are caught between the sides of the battery pack and the meter.

7   Tighten both screws until snug (do not over-tighten). Until then, the cover will have some play due to the inner gasket and the o-rings around the screws. After you have tightened the screws, the cover should be flush with the sides of the meter.

103
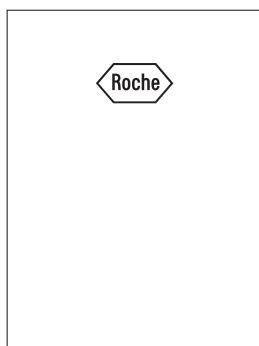
8   Place a ruler across the back of the meter to check
     that the battery pack is properly positioned. The
     ruler should lie completely flat, touching both sides
     of the meter on the left and right of the battery pack
     (see left image above). If this is not the case (as
     shown in the right image above), carefully loosen
     the screws again and start over with step 1.

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

■   The Roche logo is displayed. If the meter does not
     power on automatically, perform a reset. To do this,
     press the reset button in the middle of the battery
     pack using a tool such as a screwdriver or a paper
     clip.

■   Within a short period of time, the start screen
     should appear.

■   Depending on how long the meter was without
     power, a time/date verification message may
     appear. If the time and date is correct, touch ✓.
     If it is not correct, touch ← and update the infor-
     mation accordingly. Follow the prompts on screen
     or contact the system administrator.

After installing a new battery pack, the meter should be
charged for three hours in the base unit before testing.
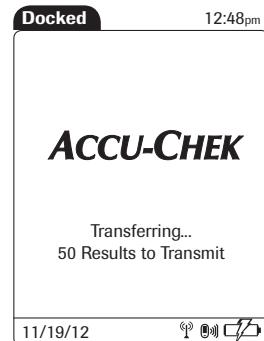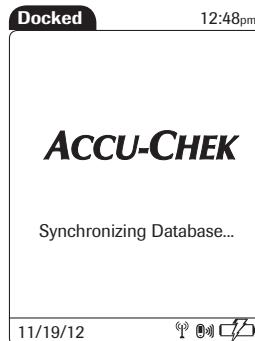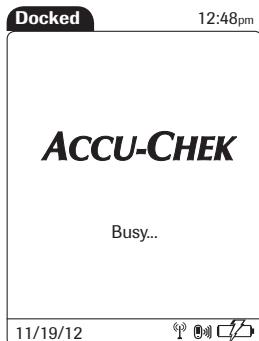
9.3   Docking the meter

Docking the meter in the base unit allows you to charge the battery. When docked, the meter shows different messages according to the current meter status.
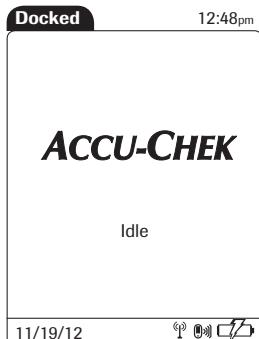
The following displays are visible while the meter connects to the data management system and transfers stored data:

Note: 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 RF card (wireless connection).

Docked 12:48pm	Docked 12:48pm	Docked 12:48pm
ACCU-CHEK	**ACCU-CHEK**	**ACCU-CHEK**
Connecting…	Synchronizing Database…	Transferring… 50 Results to Transmit
11/19/12	11/19/12	11/19/12

105

Docked	12:48pm

ACCU-CHEK

Busy…

11/19/12   〔symbols〕

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.

Docked	12:48pm

ACCU-CHEK

Idle

11/19/12   〔symbols〕

This display is visible when no communication is taking place.

Docked	12:48pm

ACCU-CHEK

Updating Software…

11/19/12   〔symbols〕

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

Note:

■ 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.

106

9.4   Initial setup on the meter

There are two ways to customize the setup of the meter: directly on the meter (see the following menu overview) or via the data management system (see Appendix A). The two methods differ according to the range of options available.

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. These options then appear grayed out on the display.

The meter is delivered with preconfigured default settings. The following settings can be configured on the meter:

■   Date and time format

■   Date and time editing enabled

■   Units

■   Test types

■   Lot information editing enabled

■   Methods for verifying lot information

■   Enable barcode scanner

■   Normal, critical, and reportable ranges

■   Operator ID options

■   Patient ID options

■   Settings for glucose controls and QC Lockout

■   Beeper

Menu overview

The following tables contain a brief overview of the menu structure. The menus can be used to operate the meter fully and enter the most important basic settings.
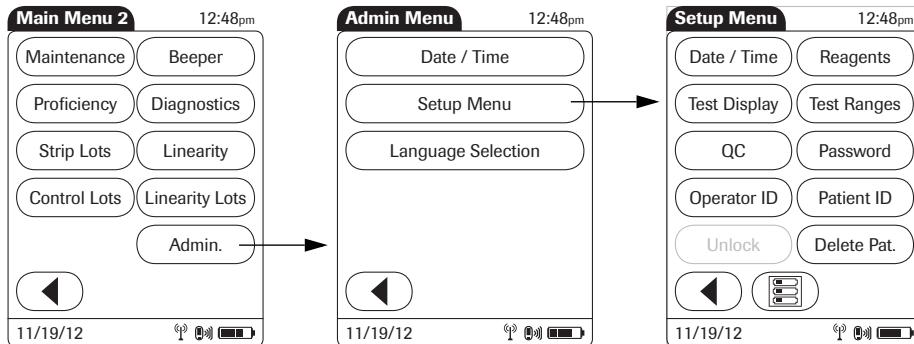
Main Menu		
Patient Test	**Observer Login**	– Enter Observer ID – Enter Observer Password
	Glucose Test	– Enter Patient ID – Verify Test Strip Lot – Insert Test Strip – Apply Sample – View Test Results – Add Comments
	Other Test	– Pregnancy – Visual Urinalysis (UA) – Rapid Streptococcus – Rapid Drugs of Abuse Tests (DAT) – Fecal Occult – Gastric Occult – Ketones – Rapid-Acting Insulin – Regular Insulin – Intermediate-Acting Insulin – Long-Acting Insulin – Insulin Mixtures
Control Test	**Glucose Control Test**	– Select Level – Verify Control Lot – Verify Test Strip Lot – Insert Test Strip – Apply Control Solution – View Test Results – Add Comments
	Other Control Tests	– Select Type of Control – Enter Date/Time tested – Enter/Confirm Kit or Test Strip Lot Number – Enter Kit or Test Strip Expiration Date – Enter/Confirm Control Lot Number – Enter Control Lot Expiration Date – Select Control Result(s).
Review Results	**Review Glucose Test**	– Review All Test Results
	Review Other Test	– Review All OTE Results

Main Menu 2	
Maintenance	– Add Comment – Maintenance Result
Proficiency	– Enter Sample ID – Verify Test Strip Lot – Insert Test Strip – Apply Sample – View Test Results – Add Comments
Strip Lots	– View Lot List – Add Lot – Enter Expiration Date – Set Control Ranges – View Lot Details – Make Lot Current – Edit/Delete Lot
Control Lots	– View Lot List – Select Control Level – Add Lot – Enter Expiration Date – Make Lot Current – Edit/Delete Lot
Linearity Lots	– View Lot List – Add Lot – Enter Expiration Date – Make Lot Current – Edit/Delete Lot
Linearity	– Verify Linearity Lot – Verify Strip Lot – Select Linearity Level – Insert Test Strip – Apply Linearity Solution – View Test Results – Add Comments
Beeper	– Set Beeper Volume
Diagnostics	– List Software Versions – Test Barcode Scanner – Meter Events Log – Statistics – Configuration – Ranges – Wireless Setup – Wireless Status – Wireless Test

Admin Menu		
Admin	– Language – Date/Time – Setup	
Language	– German – French – Spanish – Italian – Dutch – Swedish – English – Danish – Portuguese	
Date/Time	– Enter Current Date – Enter Current Time	
Setup Menu	**Date/Time Options**	– Date/Time Editing – Time Format – Date Format
	Test Display Options	– Result Unit – Enable Tests – Number of STAT Tests (if enabled)
	Reagent Options	– Reagent Editing – Lot Verification Mode
	QC Frequency	– Control Frequency
	Test Ranges	– Normal – Critical – Reportable
	Operator ID Entry	– Operator Entry – Operator Validation – Barcode
	Patient ID	– Patient Entry – Patient Validation – Barcode
	Setup Password	– Change Setup Password
	Delete Patient	– Delete all patient-related data (patient list and results)
Touch ✓ to confirm and save any changes to the settings.		
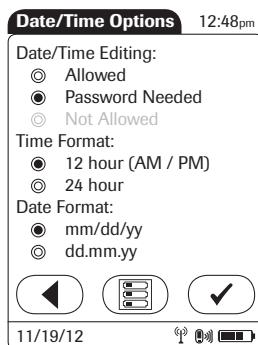
9.5 Opening the Setup Menu

All settings described here are configured via the *Setup Menu*. To open the *Setup Menu*, proceed as follows:

Main Menu 2	12:48pm
Maintenance	Beeper
Proficiency	Diagnostics
Strip Lots	Linearity
Control Lots	Linearity Lots
	Admin.
◀	
11/19/12	📶 📳 🔋

Admin Menu	12:48pm
Date / Time	
Setup Menu	
Language Selection	
◀	
11/19/12	📶 📳 🔋

Setup Menu	12:48pm
Date / Time	Reagents
Test Display	Test Ranges
QC	Password
Operator ID	Patient ID
Unlock	Delete Pat.
◀	☰
11/19/12	📶 📳 🔋

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

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

3   Touch *Setup Menu* to open the *Setup Menu*.

4   Enter the *Setup* password if requested.

111

9.6   Date and time format

```
Date/Time Options    12:48pm

Date/Time Editing:
  ◎   Allowed
  ◉   Password Needed
  ◎   Not Allowed
Time Format:
  ◉   12 hour (AM / PM)
  ◎   24 hour
Date Format:
  ◉   mm/dd/yy
  ◎   dd.mm.yy

 (  ◀  )  (  ▤  )  (  ✓  )

11/19/12          📶 🔊 🔋
```
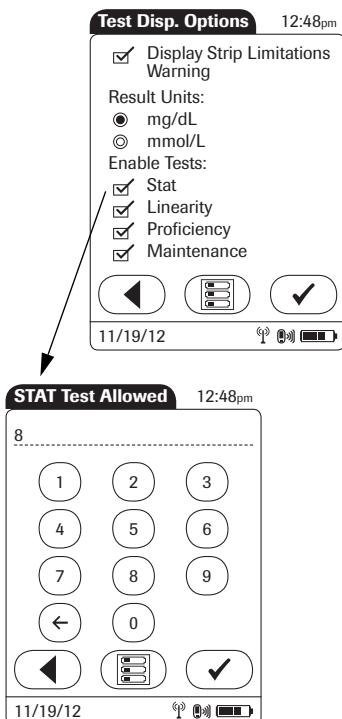
Use this menu to select the date and time format for the display. You can also choose whether the operator is allowed to edit date and time (optionally with password required).

1   Touch the desired option to enable it:

■   Date/Time Editing

   –   *Allowed*: Enables the operator to edit the date and time

   –   *Password Needed*: Enables the operator to edit the date and time only after entering a password

■   Time Format

   –   *12 hour (AM/PM)*

   –   *24 hour*

■   Date Format

   –   *mm/dd/yy*: The date is displayed in two-digit month/day/year format

   –   *dd.mm.yy*: The date is displayed in two-digit day/month/year format

2   Touch (✓) to save the settings, or

3   Touch (◀) to exit this menu without saving any changes.

The display returns in both cases to the *Setup Menu*.

When using a data management system for configuration, it is possible to fully disable the *Date/Time Editing* option.

9.7   Display options and optional tests

```
┌─────────────────────────────┐
│ Test Disp. Options  12:48pm │
│  ☑  Display Strip Limitations│
│       Warning               │
│  Result Units:              │
│  ◉  mg/dL                   │
│  ◎  mmol/L                  │
│  Enable Tests:              │
│  ☑  Stat                    │
│  ☑  Linearity               │
│  ☑  Proficiency             │
│  ☑  Maintenance             │
│                             │
│  ◄      [≡]       ✓          │
│  11/19/12      ⌜⁾ ⌐» ▭▭▭    │
└─────────────────────────────┘
```

```
┌─────────────────────────────┐
│ STAT Test Allowed   12:48pm │
│  8                          │
│  ─────────────────────────  │
│  (1)    (2)    (3)          │
│  (4)    (5)    (6)          │
│  (7)    (8)    (9)          │
│  (←)    (0)                 │
│  ◄      [≡]       ✓          │
│  11/19/12      ⌜⁾ ⌐» ▭▭▭    │
└─────────────────────────────┘
```
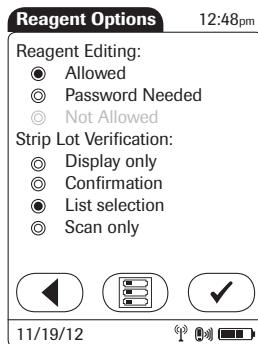
Use this menu to select the unit of measure for test results and enable or disable optional tests.

1   Touch the desired option to enable it:

■   Result Units

   –   *mg/dL*

   –   *mmol/L*

■   Enable Tests

   –   *STAT*: STAT tests may be performed. When this option is enabled, you must enter the number of STAT tests allowed (after confirming the settings).

   –   *Linearity* is displayed in the *Main Menu 2* screen

   –   *Proficiency* is displayed in the *Main Menu 2* screen

   –   *Maintenance* is displayed in the *Main Menu 2* screen

2   Touch ✓ to save the settings. If the *STAT* option is enabled, enter the number of STAT tests allowed, or

3   touch ◄ to exit this menu without saving any changes.

The display returns in both cases to the *Setup Menu* (after entering the number of STAT tests allowed).

113
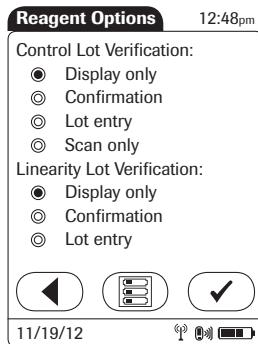
9.8   Options for test strips

```
┌─────────────────────────────────┐
│ ▐ Reagent Options ▌    12:48pm   │
│ ┌─────────────────────────────┐ │
│ │ Reagent Editing:            │ │
│ │  ◉    Allowed               │ │
│ │  ◎    Password Needed       │ │
│ │  ◎    Not Allowed           │ │
│ │ Strip Lot Verification:     │ │
│ │  ◎    Display only          │ │
│ │  ◎    Confirmation          │ │
│ │  ◉    List selection        │ │
│ │  ◎    Scan only             │ │
│ │                             │ │
│ │                             │ │
│ │  ◀      ▤       ✓           │ │
│ └─────────────────────────────┘ │
│ 11/19/12          📶 📢 ▮▮▮     │
└─────────────────────────────────┘
```

This menu allows you to select options for handling lot numbers and specify whether the operator is allowed to edit the expiration date and limit values on the meter (optionally with password required).

1   Touch the desired option to enable it:

■   Reagent Editing

–   *Allowed*: Enables the operator to edit the expiration date and limit values

–   *Password Needed*: Enables the operator to edit the expiration date and limit values only after entering a password

■   Strip Lot Verification

–   *Display only*: The lot number is shown on-screen but the operator cannot confirm it or select a different lot number.

–   *Confirmation*: The operator must confirm the lot number displayed and can enter alternative lot numbers manually or via barcode scanner.

–   *List selection*: The operator can also select from a list of stored lot numbers.

–   *Scan only*: Lot numbers can be verified via barcode scanner only.

2   Touch ✓ to change to the second screen of options, or

3   Touch ◀ to exit this menu without saving any changes.
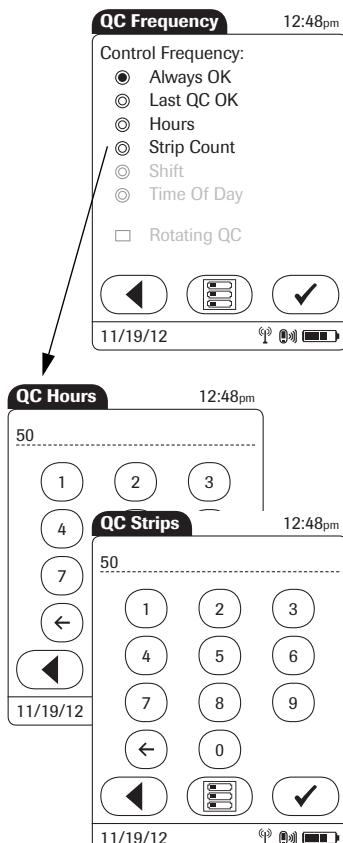
When using a data management system for configuration, it is possible to fully disable the *Reagent Editing* option.

Reagent Options   12:48pm

Control Lot Verification:
- ◉ Display only
- ◎ Confirmation
- ◎ Lot entry
- ◎ Scan only

Linearity Lot Verification:
- ◉ Display only
- ◎ Confirmation
- ◎ Lot entry

(◀) (☰) (✓)

11/19/12

On the second settings screen, you can select options for handling lot numbers with glucose control and linearity tests.

1   Touch the desired option to enable it:

■   Control Lot Verification

– *Display only*: The lot number is shown on-screen but the operator cannot confirm it or select a different lot number.

– *Confirmation*: The operator must confirm the lot number displayed and can enter alternative lot numbers manually or via barcode scanner.

– *Lot entry*: The operator must enter the lot number.

– *Scan only*: Lot numbers can be verified via barcode scanner only.

■   Linearity Lot Verification

– *Display only*: The lot number is shown on-screen but the operator cannot confirm it or select a different lot number.

– *Confirmation*: The operator must confirm the lot number displayed and can enter alternative lot numbers manually or via barcode scanner.

– *Lot entry*: The operator must enter the lot number.

2   Touch (✓) to save the settings (for both settings screens), or

3   Touch (◀) to return to the first settings screen.

115

9.9   Options for glucose control tests
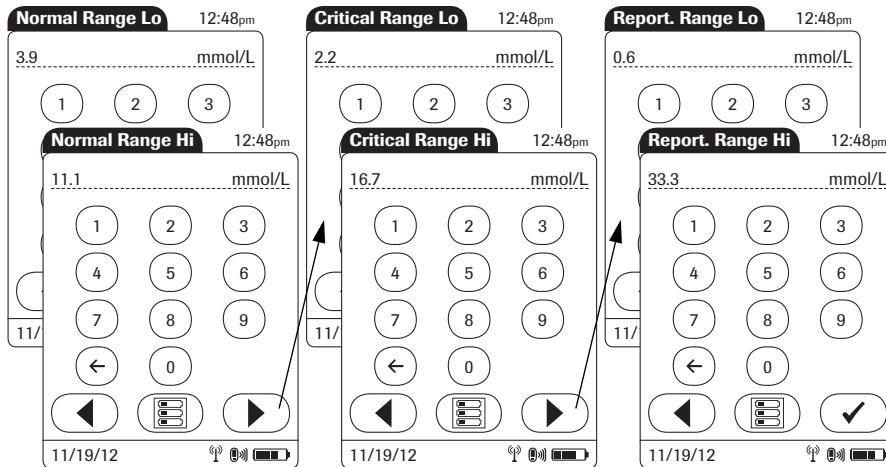
This menu contains options that allow you to specify whether and at what intervals glucose control tests are performed. If you require control tests, check your settings for STAT tests (see page 113).

1   Touch the desired option to enable it:

■   Control Frequency

–   *Always OK*: QC Lockout is disabled, patient tests can be performed at any time. This applies regardless of the result of running glucose control tests.

–   *Last QC OK*: QC Lockout is activated only when the last glucose control test is out of range or a control test is not available (e.g., when changing the test strip lot).

–   *Hours*: QC Lockout is activated after the specified time. When a glucose control test is run successfully, the counter is reset to "0".

–   *Strip Count*: QC Lockout is activated after reaching the specified number of tests. When a glucose control test is run successfully, the test strip counter is reset to "0".

–   *Shift*: QC Lockout is activated per shift.

–   *Time Of Day:* QC Lockout is activated at the specified time of day. (Up to six times per day can be configured.)

–   *Rotating QC:* QC tests require alternating use of L1 and L2 controls, instead of requiring both controls when performing a QC test.

2   Touch ✓ to save the settings. If the *Hours* or *Strip Count* option is enabled, enter the desired number, or

3   touch ◀ to exit this menu without saving any changes.

The display returns in both cases to the *Setup Menu*.

116

9.10   Value ranges (normal, critical, reportable)
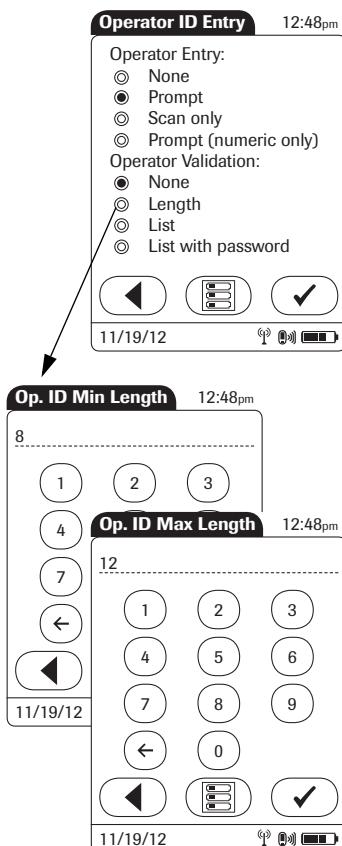
This menu allows you to set limit values for results as *Normal*, *Critical,* or *Reportable*. Results outside these limits will be flagged to alert you of this event. The *Reportable Range* allows the system administrator to set an institution defined range for reporting patient results.

Values for range limits are entered one directly after the other in the following order:

- ■   Normal (low/high limit value)

- ■   Critical (low/high limit value)

- ■   Reportable (low/high limit value)

1   Use the keypad to enter the first value.

2   Touch (▶) to enter the following value, or

3   Touch (◀) to return to the previous view.

4   After entering the last value, touch (✓) to save all the previous settings.

9.11   Options for Operator ID Entry

Operator ID Entry   12:48pm

Operator Entry:
- ◎ None
- ◉ Prompt
- ◎ Scan only
- ◎ Prompt (numeric only)

Operator Validation:
- ◉ None
- ◎ Length
- ◎ List
- ◎ List with password

◀   ▤   ✓

11/19/12   📶 🔊 🔋

Op. ID Min Length   12:48pm

8 -

1   2   3

4   7   ←   ◀

11/19/12

Op. ID Max Length   12:48pm

12 -

1   2   3

4   5   6

7   8   9

←   0

◀   ▤   ✓

11/19/12   📶 🔊 🔋
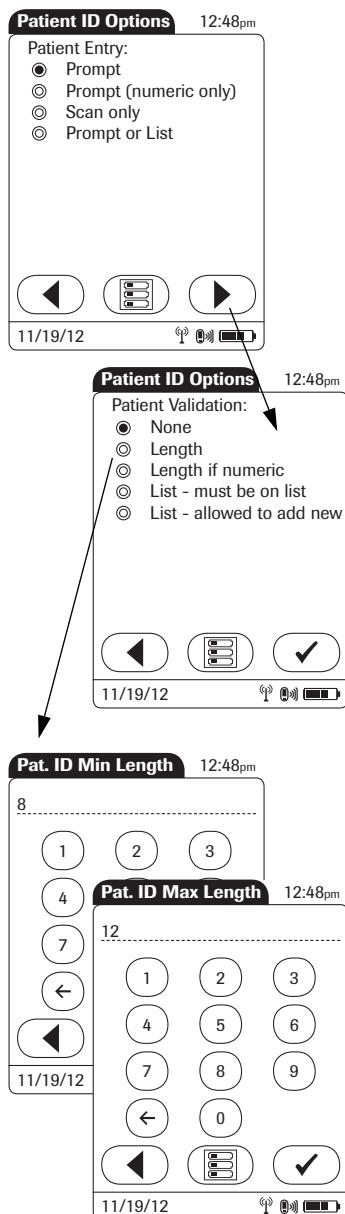
This menu allows you to specify if and how operator login is performed.

1   Touch the desired option to enable it:

■   Operator Entry

–   *None*: The meter can be used without operator login.

–   *Prompt* or *Prompt (numeric only)*: Operator login is required. The Operator ID can be entered manually via keypad or via barcode scanner.

–   *Scan only*: Operator login is required. Entry of ID via barcode scanner only.

■   Operator Validation

–   *None*: The operator ID can have any length.

–   *Length*: The operator ID must be a specified length (up to 20 characters). Enter the minimum and maximum lengths after selecting this option.

–   *List:* The operator ID must be on a list received from the data management system (DMS).

–   *List with password:* The operator ID must be on a list received from the data management system (DMS). Additionally, a password must be entered.

2   Touch ✓ to save the settings. If the *Length* option is enabled, enter the desired numbers, or

3   touch ◀ to exit this menu without saving any changes.

The display returns in both cases to the *Setup Menu*.

9.12 Patient ID options

Patient ID Options 12:48pm

Patient Entry:
- ◉ Prompt
- ◎ Prompt (numeric only)
- ◎ Scan only
- ◎ Prompt or List

◀ ▤ ▶

11/19/12

Patient ID Options 12:48pm

Patient Validation:
- ◉ None
- ◎ Length
- ◎ Length if numeric
- ◎ List - must be on list
- ◎ List - allowed to add new

◀ ▤ ✓

11/19/12

Pat. ID Min Length 12:48pm

8

1 2 3
4 7
←
◀

11/19/12

Pat. ID Max Length 12:48pm

12

1 2 3
4 5 6
7 8 9
← 0
◀ ▤ ✓

11/19/12

This menu allows you to specify the criteria for entering a patient ID.
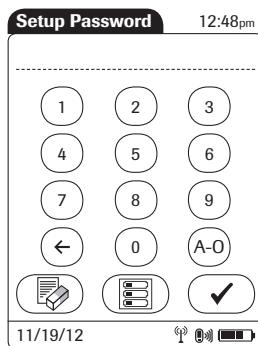
1   Touch the desired option to enable it:

■   Patient Entry

- *Prompt* or *Prompt (numeric only):* The Patient ID can be entered manually via keypad or via barcode scanner.

- *Scan only*: Enter of ID via barcode scanner only.

- *Prompt or List:* The Patient ID can be entered manually via keypad or via barcode scanner, or can be picked from a list received from the DMS.

■   Patient Validation

- *None*: The patient ID can have any length.

- *Length*: The patient ID must be a specified length (up to 20 characters). Enter the minimum and maximum lengths after selecting this option.

- *Length if numeric:* Only numeric patient IDs are validated for their length. Alphabetic patient IDs are not validated.

- *List - must be on list:* The patient ID must be on a list received from the DMS.

- *List - allowed to add new:* The patient ID will be checked against a list received from the DMS. However, it is allowed to create a new patient ID using the meter.

2   Touch ✓ to save the settings. If the *Length* option is enabled, enter the desired numbers, or

3   touch ◀ to exit this menu without saving any changes.

The display always returns to the *Setup Menu* (after entering the desired numbers).

119

9.13 Creating a setup password

This screen allows you to create a password for all the settings described in this chapter. The password ensures that only authorized persons can make changes to the setup.
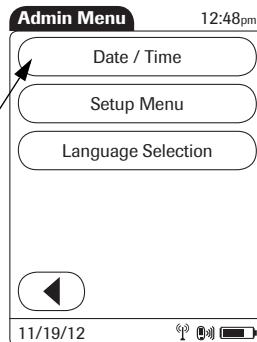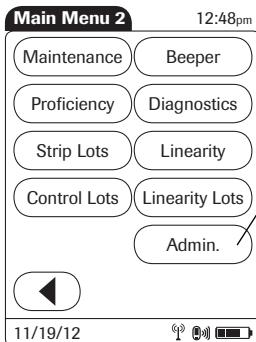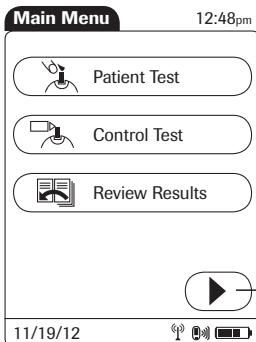
Please note that password protection can only be reset or modified after entering the current password. Proper authentication is required to access the *Setup Menu*. Store your password in a safe place.

Setup Password 12:48pm

```
   1    2    3
   4    5    6
   7    8    9
   ←    0   A-O
11/19/12
```
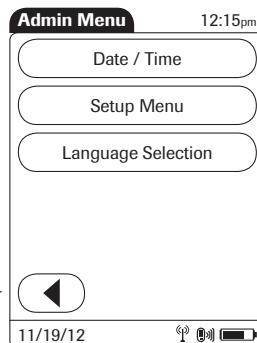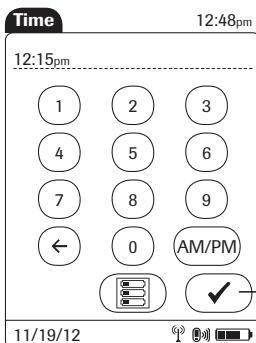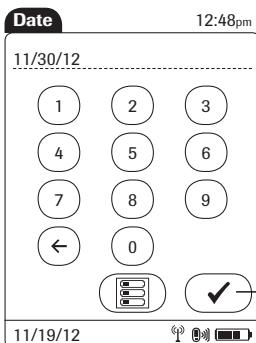
1 Use the keypad to enter the password.

2 Touch ✓ to save the password and enable password protection. (Password protection will take effect only after the next power on.) The display returns to the *Setup Menu*, or

3 touch 📋 to exit this screen without saving any changes. The display returns to the *Main Menu*.

To disable password protection:

1 Open the *Setup Menu* (you must enter the current password).

2 Touch *Password*.

3 Delete the current password by touching 📝.

4 Touch ✓ to disable password protection.

9.14   Setting the date and time

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

Main Menu 12:48pm	Main Menu 2 12:48pm	Admin Menu 12:48pm
Patient Test	Maintenance / Beeper	Date / Time
Control Test	Proficiency / Diagnostics	Setup Menu
Review Results	Strip Lots / Linearity	Language Selection
	Control Lots / Linearity Lots	
	Admin.	
▶	◀	◀
11/19/12	11/19/12	11/19/12

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.

Date 12:48pm	Time 12:48pm	Admin Menu 12:15pm
11/30/12	12:15pm	Date / Time
1 2 3	1 2 3	Setup Menu
4 5 6	4 5 6	Language Selection
7 8 9	7 8 9	
← 0	← 0 AM/PM	
☰ ✓	☰ ✓	◀
11/19/12	11/19/12	11/19/12
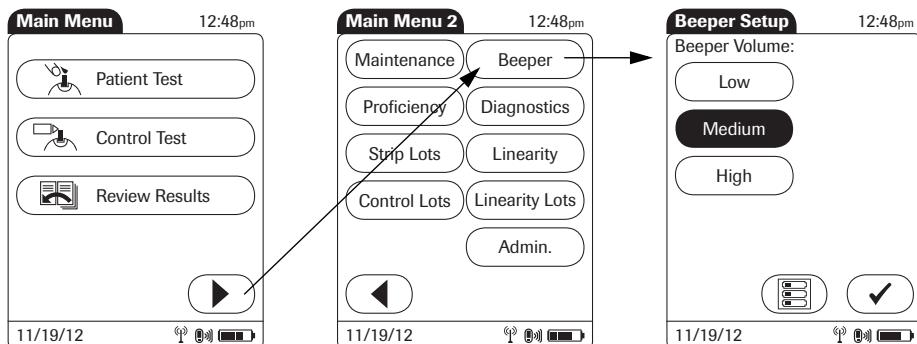
4   Enter the date first, then time (all values are two-digit with a leading zero, if necessary) by touching ✓.

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

121

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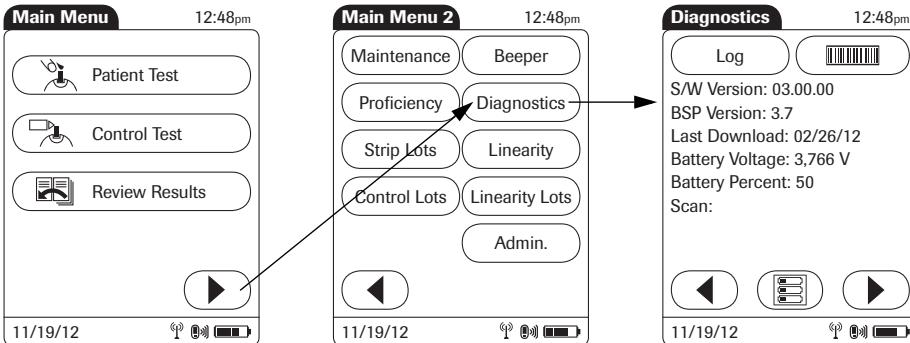
This setting can be used to set the volume of the beeper.

Main Menu 12:48pm	Main Menu 2 12:48pm	Beeper Setup 12:48pm
Patient Test	Maintenance · Beeper	Beeper Volume:
Control Test	Proficiency · Diagnostics	Low
Review Results	Strip Lots · Linearity	Medium
▶	Control Lots · Linearity Lots	High
	Admin.	
	◀	☰ · ✓
11/19/12	11/19/12	11/19/12
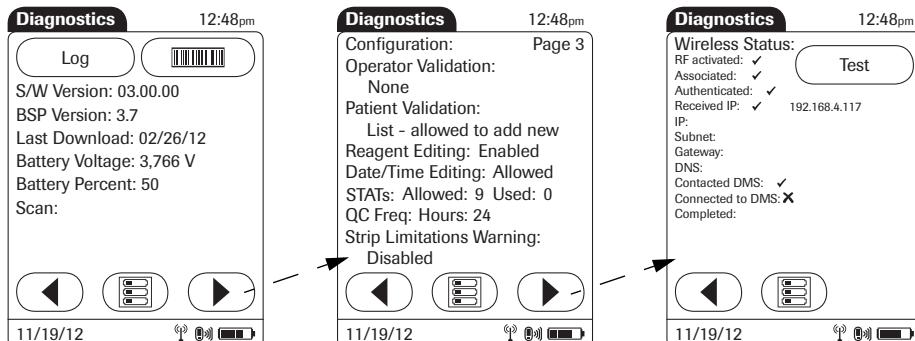
1   Touch ▶ in the *Main Menu* to open the *Main Menu 2* screen.

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.

anceProficiency

9.16 Diagnostics view

Under *Diagnostics* you can find information about the system, such as software version, number of data records stored, and settings. Use this menu to display stored error messages and test the barcode scanner.

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.

123

Diagnostics 12:48pm	Diagnostics 12:48pm	Diagnostics 12:48pm
Log ▐▌█▐▌█	Configuration: Page 3	Wireless Status:
S/W Version: 03.00.00	Operator Validation:	RF activated: ✓ Test
BSP Version: 3.7	None	Associated: ✓
Last Download: 02/26/12	Patient Validation:	Authenticated: ✓
Battery Voltage: 3,766 V	List - allowed to add new	Received IP: ✓ 192.168.4.117
Battery Percent: 50	Reagent Editing: Enabled	IP:
Scan:	Date/Time Editing: Allowed	Subnet:
	STATs: Allowed: 9 Used: 0	Gateway:
	QC Freq: Hours: 24	DNS:
	Strip Limitations Warning:	Contacted DMS: ✓
	Disabled	Connected to DMS: ✗
		Completed:
◀ ▤ ▶	◀ ▤ ▶	◀ ▤
11/19/12	11/19/12	11/19/12

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*.

9.17   Unlocking a Download Lockout

When using a data management system for configuration, a *Download Lockout* can be configured. This lockout prevents a meter from being used for testing, if the meter data have not been downloaded for a defined period of time. If a download lockout occurs, the operator may use a STAT test to temporarily override the lockout. If no STAT test is configured or left, the meter cannot be used until the stored data is downloaded via network (either wireless or by docking the meter).

In cases of e.g., network failures (which make a download impossible), or other emergencies, it may be necessary to unlock a meter without access to the data management system. Since unlocking is a function of the *Setup Menu*, it is restricted to persons who know the setup password.

To unlock a meter:

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

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

3   Touch *Setup Menu* to open the *Setup Menu*.

4   Enter the *Setup* password if requested.

5   Touch *Unlock* to reset the lockout timer.

The meter switches off, and is ready for testing after powering up again.

125

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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 128.

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.

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

Healthcare professionals should wear gloves and follow their institution's infection control procedures when handling blood glucose testing equipment. See also safety messages "Protection against infection and blood-borne pathogens" on page 15 and "Allergy or injury caused by reagents and other working solutions" on page 16.

The gloves worn during cleaning and disinfecting should be removed and hands washed thoroughly with soap and water before performing the next patient test. Dispose of acceptable cleaning and disinfection solutions per facility guidelines.

NOTICE

Do not use cleaning/disinfecting solutions containing the chemicals ether, polyhexanide, or prepared solutions or wipes containing a mixture of bleach and detergent on the system components. Use of cleaning/disinfecting solutions containing these chemicals could result in damage to the system components

***Acceptable cleaning/
disinfecting agents***

Before using a cleaning/disinfecting solution on the meter, base unit, code key reader, or accessory box refer to the product labeling for required contact time for cleaning/disinfecting and to ensure that the active ingredients are acceptable for use. Prepare all solutions per the manufacturer's product labeling.

Acceptable active ingredients are listed below.

Recommended cleaning agents

■   mild soapy water

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

■   0.625 % (or less) solution of sodium hypochlorite in water

Recommended disinfecting agents

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

■   ammonium chloride (up to 0.25 % of each quaternary ammonium compound) with isopropyl alcohol (up to 55 %)*

■   0.05 % solution of a phenol compound in water*

*   Exception: Do not use the disinfecting agents marked with an asterisk for disinfecting the accessory box. For disinfection, use only 0.625 % (or less) solution of sodium hypochlorite in water (bleach). See also page 133.

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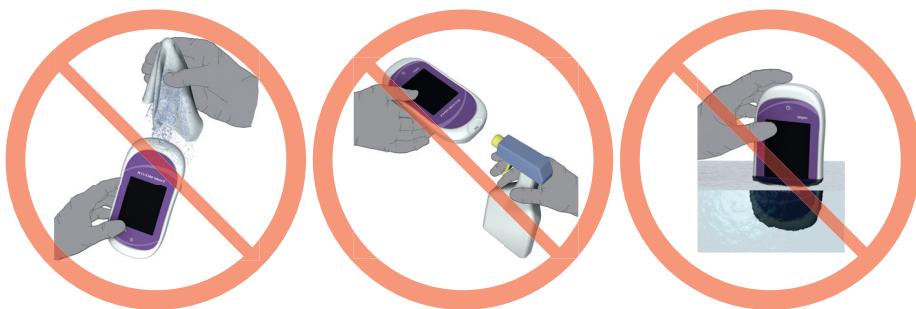
■ Clean the meter to remove visible soil and organic material for safe handling and/or prior to disinfecting.

■ Disinfect the meter when it is soiled and per your facility's guidelines.

⚠
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, 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. **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 damp-
        ened (not wet).

        If spraying the accessory box, place it on a flat sur-
        face or table. Ensure that it is completely empty.
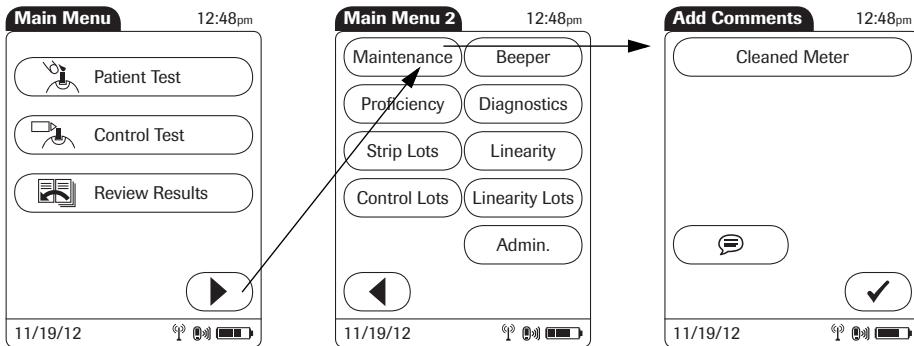
2   Allow the accessory box to air dry for the recom-
        mended contact time according to the cleaning/
        disinfecting solution product labeling. Do not place
        the meter in the accessory box until all cleaning/
        disinfecting steps are completed.

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.

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 switching on the meter.

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

Main Menu 12:48pm	Main Menu 2 12:48pm	Add Comments 12:48pm
Patient Test	Maintenance Beeper	Cleaned Meter
Control Test	Proficiency Diagnostics	
Review Results	Strip Lots Linearity	
	Control Lots Linearity Lots	
	Admin.	💬
▶	◀	✓
11/19/12	11/19/12	11/19/12

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*.

Maintenance Test   12:48pm
Cleaned Meter
NEW BATTERY PACK
💬   ✓
11/19/12

You can add up to three comments. For details see section "Adding comments" on page 51.

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	
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.
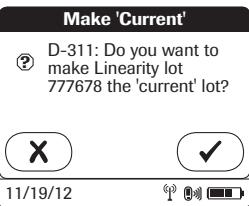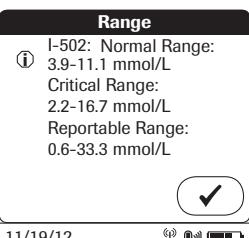
Display/symptom	Possible solution
Test result **LO/HI**	The glucose result may be below (LO) or above (HI) the measurement range of the system. – Refer to the package insert for the test strips. – Check that you are performing the test correctly (see Chapter 3). – Run a glucose control test with a new 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). – Press the On/Off button on the top of the meter. – Reset the meter by pressing the reset button (see page 141). – 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 – Reset the meter by pressing the reset button (see page 141) – 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 123. – Reset the meter by pressing the reset button (see page 141) – 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 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.
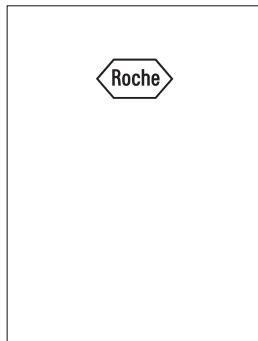
Display/symptom	Possible solution
Automatic shutdown (power-off)	
	The meter powers off after a configurable time without activity (e.g., pressing a key, touching the screen) to conserve energy. In addition, the meter may power off automatically for the reasons listed below. Reactivate the meter/screen 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 top of 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.

Error messages 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. All messages, including purely informative messages, are preceded by a letter, identifying the message type, and a number. The different message types are illustrated in the following table.

Sample message type	Description
Linearity Lots 12:48pm Type Exp. Date Lot Num. *Lin. 12/31/12 777732 Lin. 03/15/13 777723 **Make 'Current'** ⑦ D-311: Do you want to make Linearity lot 777678 the 'current' lot? (X) (✓) 11/19/12	– **D**: Decision; To confirm, touch (✓). To reject, touch (X).
Patient Test 12:48pm Patient 123456789 Date 11/19/12 12:48pm **Range** ⓘ I-502: Normal Range: 3.9-11.1 mmol/L Critical Range: 2.2-16.7 mmol/L Reportable Range: 0.6-33.3 mmol/L (✓) 11/19/12	– **I**: Information; touch (✓) to confirm.

Sample message type	Description
Operator ID　　　　12:48pm ‐ ‐ ‐ ‐ ‐ ‐ ‐ ‐ ‐ ‐ [‖‖‖‖‖‖] (1)　(2)　(3) **Invalid Scan** ❌ E-314: Invalid Scan. The scan returned an entry > 20 characters. Please see your System Administrator. (✓) 11/19/12　　　　 📶 🔊 🔋	– **E**: Error; touch (✓) to confirm. To resolve the problem, take the actions suggested.
Patient Test　　　12:48pm Patient 123456789 Date 11/19/12 12:48pm 17.2 mmol/L Out of Critical Range **Out of Critical Range** ⚠ W-511: Out of Critical Range. (✓) 11/19/12　　　　 📶 🔊 🔋	– **W**: Warning; touch (✓) to confirm.

Meter reset

A meter reset can be performed to correct a number of unspecified errors (e.g., "frozen" screen, etc.). Use the following steps to perform a meter reset.

1   Place the meter face down on a level surface.

2   Press the reset button in the middle of the battery pack using a tool such as a screwdriver or a paper clip.

3   Turn over the meter.

■   The Roche logo is displayed.
    If the Roche logo does not appear within 60 seconds, place the meter on a base unit for a minimum of 15 minutes to recharge the battery.

■   Within a short period of time, the *Versions* screen will appear, displaying the version numbers of the meter components. (The Versions screen shown here is for illustration purposes only. Version numbers on your meter may differ.)

4   The screens for entering the date and the time appear if date and time need to be set. After you have entered the correct information, confirm each screen with (✓).

Depending on the configuration of your system, the meter may have to be docked in the base unit for synchronization of the meter's date/time with the date/time of your facility.

■   Finally, the *Power Up* screen and the *Main Menu* are displayed as usual.

Versions	
Build:	03.02.00
Boot:	00.16.28
Kernel:	00.21.28
RootFS:	00.15.00
App:	03.02.00

141

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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.)	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.)	118 mm / 4.65 in (max.)	51 mm / 2.01 in
Length	193 mm / 7.60 in (max.)	103 mm / 4.06 in (max.)	87 mm / 3.43 in
Weight	approx. 361 g (with rechargeable battery) approx. 376 g (with rechargeable battery AND RF card)	Accu-Chek Inform II Base Unit 615 g with wall mount Accu-Chek Inform II Base Unit Light 573 g with wall mount	N/A
User interface	Touchscreen and barcode scanner	LED (tricolor: red, green, blue) *	N/A
Display resolution (touchscreen)	320 x 240 pixel	N/A	N/A
Memory	– 1,000 Results – 3,000 Operator IDs – 4,000 Patient IDs – 300 Predefined comments – 20 Code Files (= test strip lots) – 100 Reagent Lots (= control, linearity, OTE)	N/A	N/A
Operating temperature	3 to 50 °C 37 to 122 °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)		
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

* Accu-Chek Inform II Base Unit Light: only red, green.

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	+7.5 V DC	100 to 240 V AC
Input frequency	DC	DC	50 to 60 Hz
Input current	1.7 A (max)	1.7 A (max)	350 to 150 mA
Battery capacity	100 (subsequent) measurements possible after 360 min of charging	N/A	N/A
Interfaces	Charge contacts IR port Barcode scanner RF card (Channel 1-11 only)	Charge contacts IR port RJ45 Ethernet * USB type B *	DC connector Replaceable AC input contacts
Data transfer rate	RF card: up to 54 Mbps	IR: 9.6K - 115K bps * Ethernet: 10 Mbps * USB: 12 Mbps *	N/A
Min. barcode width	4 mil (1 mil = 0.0254 mm)	N/A	N/A
CDRH/IEC	CDRH Class I	N/A	N/A
Supported barcodes	Code 128, Code 39, Code 93, EAN 13, Inter-leaved 2 of 5, Codabar, GS1 DataBar Limited	N/A	N/A

* Not applicable to Accu-Chek Inform II Base Unit Light

Specification	Accessory box	Code key reader	
Height	85 mm / 3.35 in	18.4 mm / 0.72 in	
Width	280 mm / 11.02 in	34.8 mm / 1.37 in	
Length	272 mm / 10.71 in	70.7 mm /2.78 in	
Weight	1100 g	28 g	
Storage temperature	-25 to 70 °C -13 to 158 °F	2 to 25 °C 36 to 77 °F	
Relative humidity (storage)	< 93%	< 93%	
Battery voltage/type	N/A	Not replaceable	
Interfaces	N/A	IR port Code key socket	

12.2   Further Information

Ordering

Item	Description	REF/Catalog Number
Accu-Chek Inform II Meter	Meter only	05060311001
Accu-Chek Inform II Meter	Meter, equipped with RF card	05060303001
Accu-Chek Inform II Base Unit	Equipped with charging and connectivity functionality	05060290001
Accu-Chek Inform II Base Unit Light	Equipped with charging functionality	05920353001
Accu-Chek Inform II Base Unit Wall Mount	Wall Mount for Base Unit/Base Unit Light	05404878001
Accu-Chek Inform II Base Unit Hub	Equipped with power and connectivity function-ality for the Accu-Chek Inform II Base Unit Light	05888760001
Accu-Chek Inform II Battery Pack		04882326001
Accu-Chek Inform II Code Key Reader		04884671001
Accu-Chek Inform II RF Card Kit	Wi-Fi card replacement for optional wireless functionality	05112699001
Power Supply	Power supply for Base Unit (international edition)	04805666001
Power Supply	Power supply for Base Unit (North America)	05388805001
Power Cord	Required to power the Base Unit Hub (North America)	03868133001
Power Cord	Required to power the Base Unit Hub (United Kingdom)	03034933001
Power Cord	Required to power the Base Unit Hub (international)	11800515001
Accu-Chek Inform II Accessory Box		05060281001

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.

***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 file "ROCHE HBU-BU Technical Note.pdf".

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.

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 on www.roche.com. Select "Roche Worldwide" at the top of the page and then select your country to find the appropriate local office contact information.

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

In the United States:

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46256

In Australia:

Roche Diagnostics Australia Pty Limited
ABN 29 003 001 205
31 Victoria Avenue
Castle Hill, NSW, 2154

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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				
Shutdown timeout (meter powers off if no activity)	30 – 3,600 s	300	N	Y
Display: Low Power Mode after [0 = feature disabled)	0 – 120 s	30	Y	Y
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

Subject/Attribute	Range	Default	Device	DMS
Custom comments	0: enabled 1: disabled	0	N	Y
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	10 – 600 mg/dL 0.6 – 33.3 mmol/L	600 mg/dL 33.3 mmol/L	Y	Y
Critical range LO limit	10 – 600 mg/dL 0.6 – 33.3 mmol/L	10mg/dL 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	""	N	Y
Normal range HI limit	10 – 600 mg/dL 0.6 – 33.3 mmol/L	600 mg/dL 33.3 mmol/L	Y	Y
Normal range LO limit	10 – 600 mg/dL 0.6 – 33.3 mmol/L	10mg/dL 0.6 mmol/L	Y	Y
STAT tests allowed	0: no 1: yes	1	Y	Y
Number of STAT tests allowed	0 – 9	9	Y	Y
Reportable range HI limit	10 – 600 mg/dL 0.6 – 33.3 mmol/L	600 mg/dL 33.3 mmol/L	Y	Y
Reportable range LO limit	10 – 600 mg/dL 0.6 – 33.3 mmol/L	10mg/dL 0.6 mmol/L	Y	Y
Reportable range message	Whether to display a reportable range message (1) or not (0)	1	N	Y
Reportable range message text	0 – 100 characters	""	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

Subject/Attribute	Range	Default	Device	DMS
Linearity lot verification	0: display only 1: yes/no confirmation 2: prompt for lot entry	1	Y	Y
Display				
Low Power Mode time (only serial numbers ≥ UU11030000)	0 - 120 sec (0 = Low Power Mode off)	30 sec	Y	Y
Contrast	1 - 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
Glucose result units	0: mg/dL 1: mmol/L	0	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
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

Subject/Attribute	Range	Default	Device	DMS
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
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: no (always) 1: yes (on controls only)	0	Y	Y
Operator ID validation (Allowed characters: a-z, 0-9, "." [period], "-" [hyphen])	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 that an operator remains logged in after power-off). 0 = feature disabled.	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 – 60 characters*	""	N	Y
Patient ID barcode mask (see separate table at the end of this chapter)	0 – 60 characters*	""	N	Y
* The number of characters in the unmasked barcode may not exceed 20.				
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.				

Subject/Attribute	Range	Default	Device	DMS
Patient ID entry mode	0: Keyboard / Scan 1: List / Keyboard / Scan 2: Scan only 3: Prompt (numeric)	0	Y	Y
Patient ID validation (Allowed characters: a-z, 0-9, "." [period], "-" [hyphen])	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"	0-20	20	Y	Y
Patient ID minimum length (used to validate a patient ID if patient ID validation mode is set to "Length"	0-20	0	Y	Y
Patient name length	0-25 characters	N/A	N	N
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")	0 – 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

Subject/Attribute	Range	Default	Device	DMS
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
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 can be deleted automatically if result deletion algorithm is set to "automatic" and no more memory is available).	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)	5 – 6,000 s	60	N	Y
WLAN settings (general)				
WLAN enabled	0: disabled 1: enabled	1	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 – 20 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

Subject/Attribute	Range	Default	Device	DMS
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
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: WEP2 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)	"0000000000"	N	Y
WEP-authentication	0: open system authentication 1: shared key authentication	0	N	Y

155

Subject/Attribute	Range	Default	Device	DMS
WPA Key Type	0: Passphrase 1: Key	0	N	Y
WPA Key	string of 64 characters (HEX)	"0000000000 0000000000 0000000000 0000000000 0000000000 0000000000"	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.				

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 - WEP2	4 - WEP40	0 - open / 1 - shared	10 characters HEX	-	-	-
3 - WEP2	5 - WEP40	0 - open / 1 - shared	26 characters HEX	-	-	-
4 - EAP	-	-	-	-	-	-

Operator and patient ID barcode masks

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

A.2   Example of barcode symbologies

Codabar

1234567890

Code 39

1234567890

Code 93

ABC123-/+

Code 128

1234567890

EAN 13

1 112223 334448

Interleaved 2/5

1234567890

GS1 DataBar
Limited

(01)01234567890128

B   Appendix

B.1   Option: Wireless network (WLAN)

Preliminary note

Appendix B has been developed to explain the wireless communication protocols of the Accu-Chek Inform II system[1]. The connectivity specifications described in this section are designed to assist your facility's information technology / management team(s) in effectively deploying the Accu-Chek Inform II system on your wireless network.

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 2.4 GHz frequency range to wirelessly transmit data[3]. Two of the currently recognized IEEE standards for WLANs are 802.11b and 802.11g. 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[4].

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.

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, RF cards are also commonly called Wi-Fi cards.
3.   For the wireless functionality to work properly, the wireless module must first be configured by your system administrator.
4.   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 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 a base unit be hard wired via an RJ-45 network jack per floor. A networked base unit provides redundancy if a wireless network that the Accu-Chek Inform II meter is using malfunctions or looses 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 Accu-Chek Inform II meter uses a wireless (RF) card in compact flash (CF) card format to implement the WLAN functionality. Depending on the system configuration that you purchased, the meter will either already be equipped with a WLAN card or you may purchase the card later.

The current RF card 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 card used in the Accu-Chek Inform II specifically adheres to the following specifications:

■　　Its WLAN system-on-chip supports IEEE 802.11b Direct Sequence Spread Spectrum and 802.11g Orthogonal Frequency Division Multiplexing base-band modulation, and Media Access Control (MAC). It works seamlessly together with WLAN RF 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/pdf_certificate.php?cid=WFA9981.
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 12-13 are not used by the Accu-Chek Inform II meter.)

■　　RF output power is approximately 13dBm at a data rate of 54 MBPS.

Location and type of RF card　　The location of the RF card is described on page 28.

Only Roche-approved RF cards may be used. All Roche-approved RF cards comply with FCC standards.

Note: As technology evolves, the RF card may be updated.

RF specific functionalities and effective performance claims

The Accu-Chek Inform II system includes an optional module for wireless network connectivity (RF card). This module can only be configured by a data management system (DMS), which enables 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 RF card and wireless enabled 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 2000 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. Upon receipt of this DMS query, the meter will re-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 an RF card and wireless enabled will communicate results after every test or, when the meter is idle; it will automatically attempt to communicate with the DMS every 10 minutes.

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 49 to 66 feet (15 to 20 meters). 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 35). 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.

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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.

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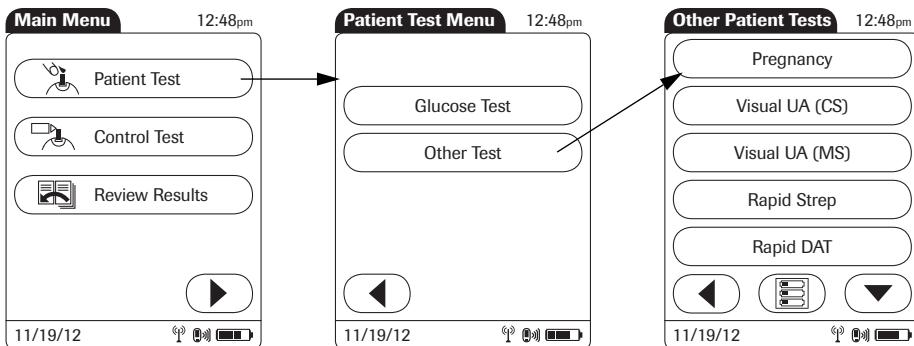
This can be done either manually or by using the barcode scanner (if a barcode is available).

■   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.
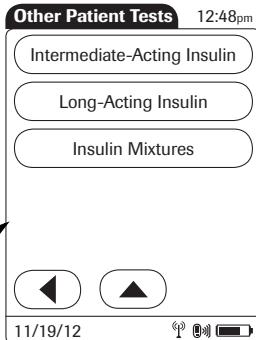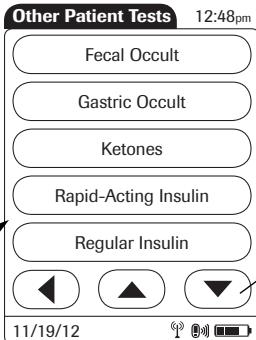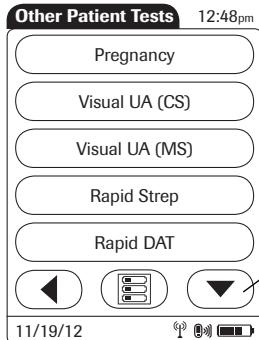
C.3   Recording Other Patient Tests

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.

Main Menu 12:48pm	Patient Test Menu 12:48pm	Other Patient Tests 12:48pm
Patient Test		Pregnancy
Control Test	Glucose Test	Visual UA (CS)
Review Results	Other Test	Visual UA (MS)
		Rapid Strep
		Rapid DAT
▶	◀	◀ ▤ ▼
11/19/12	11/19/12	11/19/12

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.

Other Patient Tests 12:48pm	Other Patient Tests 12:48pm	Other Patient Tests 12:48pm
Pregnancy	Fecal Occult	Intermediate-Acting Insulin
Visual UA (CS)	Gastric Occult	Long-Acting Insulin
Visual UA (MS)	Ketones	Insulin Mixtures
Rapid Strep	Rapid-Acting Insulin	
Rapid DAT	Regular Insulin	
◀ 🔳 ▼	◀ ▲ ▼	◀ ▲
11/19/12	11/19/12	11/19/12

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.
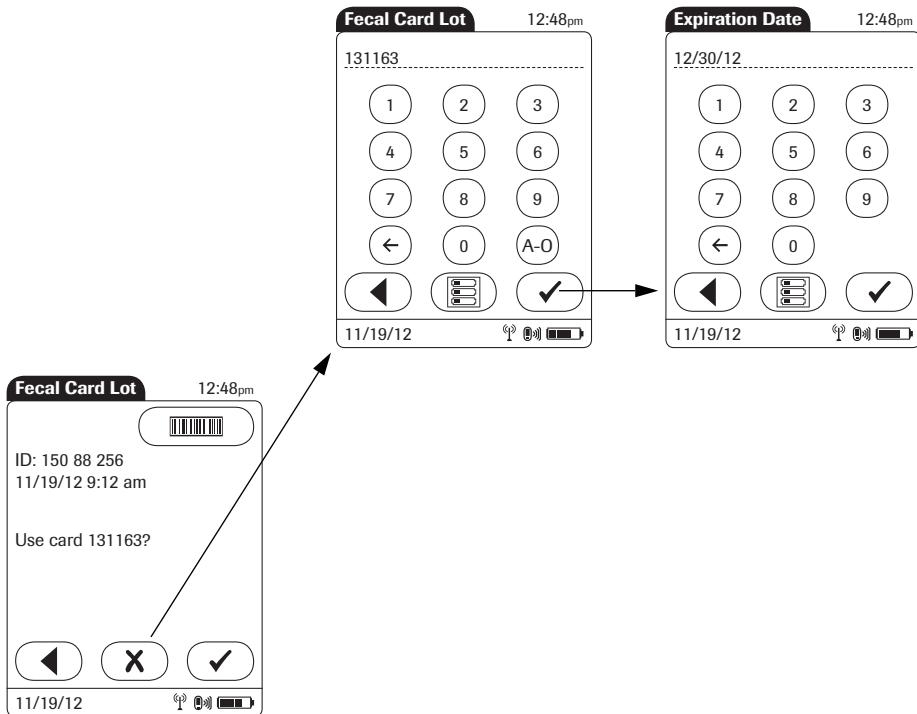
Other Patient Tests	12:48pm		Patient ID	12:48pm

Other Patient Tests 12:48pm

- Fecal Occult
- Gastric Occult
- Ketones
- Rapid-Acting Insulin
- Regular Insulin

◀ ▲ ▼

11/19/12

Patient ID 12:48pm

IIIIIIII

1 2 3
4 5 6
7 8 9
← 0 A-O

11/19/12

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

Date Tested 12:48pm

11/19/12

1 2 3
4 5 6
7 8 9
← 0

◀ ✓

11/19/12

Time Tested 12:48pm

12:48 pm

1 2 3
4 5 6
7 8 9
← 0 AM/PM

◀ ✓

11/19/12

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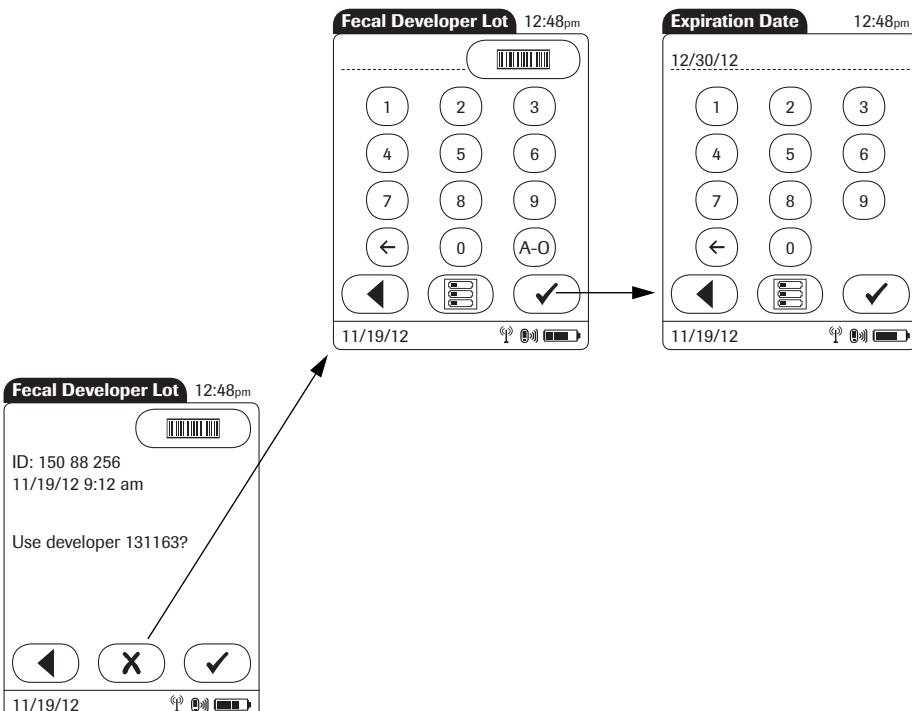
1.   See also section "Entering or selecting the patient ID" in Chapter 3.

171

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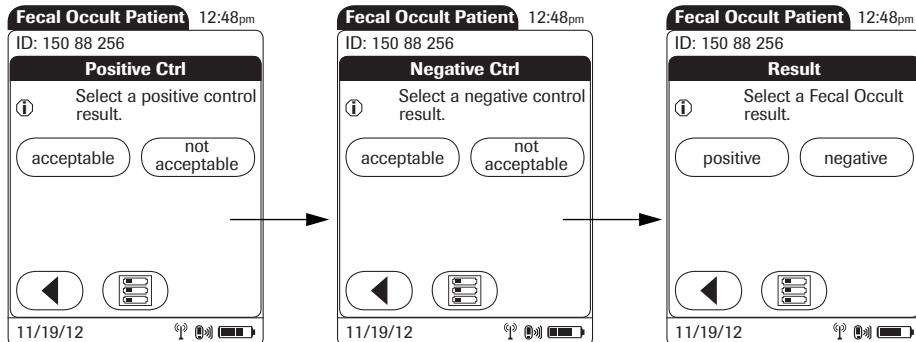
9   Use the keypad to enter the *Fecal Card Lot* expiration date. Touch ✓ to proceed to the next screen.

Fecal Developer Lot 12:48pm

ID: 150 88 256
11/19/12 9:12 am

Use developer 131163?

11/19/12

10   Use the keypad or the barcode scanner (if a bar-
code 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.

Fecal Occult Patient 12:48pm	Fecal Occult Patient 12:48pm	Fecal Occult Patient 12:48pm
ID: 150 88 256	ID: 150 88 256	ID: 150 88 256
Positive Ctrl	**Negative Ctrl**	**Result**
ⓘ Select a positive control result.	ⓘ Select a negative control result.	ⓘ Select a Fecal Occult result.
(acceptable) (not acceptable)	(acceptable) (not acceptable)	(positive) (negative)
◀ 𝄇	◀ 𝄇	◀ 𝄇
11/19/12 📶 🔊 🔋	11/19/12 📶 🔊 🔋	11/19/12 📶 🔊 🔋

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.

Fecal Occult Patient 12:48pm	**Fecal Occult Patient** 12:48pm	**Fecal Occult Patient** 12:48pm
ID: 150 88 256	ID: 150 88 256	ID: 150 88 256
(D/T Tested) *11/19/12 9:12 am*	(Result) negative	(Result) negative
(Card Lot #) *1283 12/30/12*		
(Dev Lot #) *45233 07/30/13*		Doctor Notified
(Positive Ctrl) acceptable		
(Negative Ctrl) acceptable		
(🗩) (▶)	(◀) (🗩) (✓)	(◀) (🗩) (✓)
11/19/12	11/19/12	11/19/12

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

18   Touch (🗩) to enter your own custom comment. Use the keypad (as with login) to enter your comment.

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

20   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.
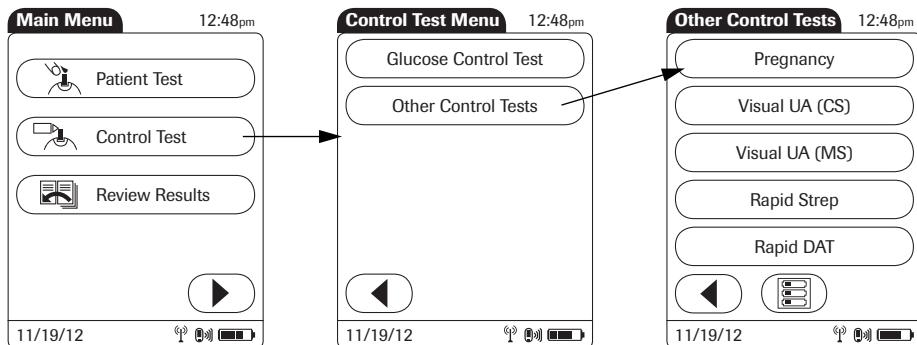
This can be done either manually or by using the barcode scanner (if a barcode is available).

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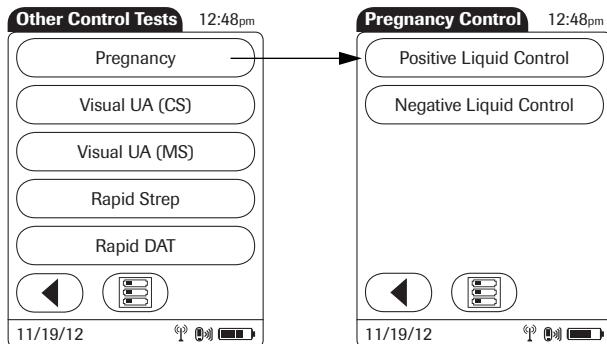
The control solution results must fall into the acceptable range indicated on the test kit or reagent packaging, or as defined by your institution, before being considered successful.

177

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.

Main Menu 12:48pm	Control Test Menu 12:48pm	Other Control Tests 12:48pm
Patient Test	Glucose Control Test	Pregnancy
Control Test	Other Control Tests	Visual UA (CS)
Review Results		Visual UA (MS)
		Rapid Strep
▶		Rapid DAT
11/19/12	◀ 11/19/12	◀ 🗒 11/19/12

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

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

Other Control Tests 12:48pm	Pregnancy Control 12:48pm
Pregnancy	Positive Liquid Control
Visual UA (CS)	Negative Liquid Control
Visual UA (MS)	
Rapid Strep	
Rapid DAT	
◀ 🗒 11/19/12	◀ 🗒 11/19/12

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.

| Pregnancy Ctrl Lot	12:48pm		Expiration Date	12:48pm

5   Use the keypad or the barcode scanner (if a bar-code 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.

Date Tested	12:48pm		Time Tested	12:48pm
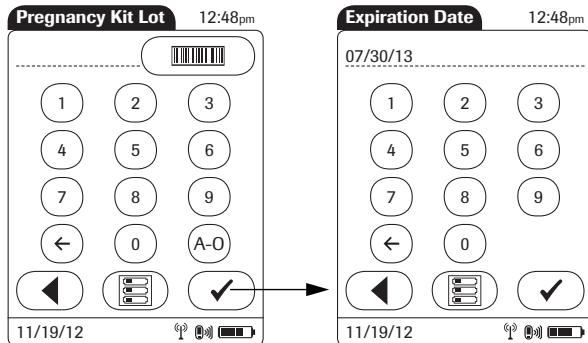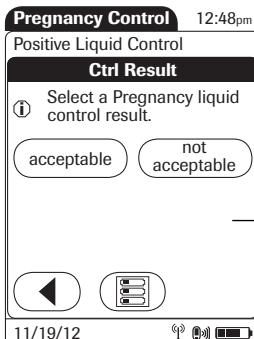
7   Use the keypad to enter the date the test was performed. For single digit numbers, add a leading zero. Touch ✓ to proceed to the next screen.

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.

179

9   Use the keypad or the barcode scanner (if a bar-
code 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.

Pregnancy Control 12:48pm	Pregnancy Control 12:48pm	Pregnancy Control 12:48pm
Positive Liquid Control	Positive Liquid Control	Positive Liquid Control
Control Bar	**Ctrl Result**	D/T Tested *11/19/12 8:30 am*
ⓘ Select a Pregnancy control bar result.	ⓘ Select a Pregnancy liquid control result.	Control Lot # *1283 12/30/12*
acceptable / not acceptable	acceptable / not acceptable	Kit Lot # *45233 11/30/13*
		Control Bar acceptable
		Ctrl Result acceptable
◀ ▤	◀ ▤	💬 ✓
11/19/12	11/19/12	11/19/12

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

16 Touch 💬 to enter your own custom comment(s). Use the keypad (as with login) to enter your comment.

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

18 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.

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 "Error 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.
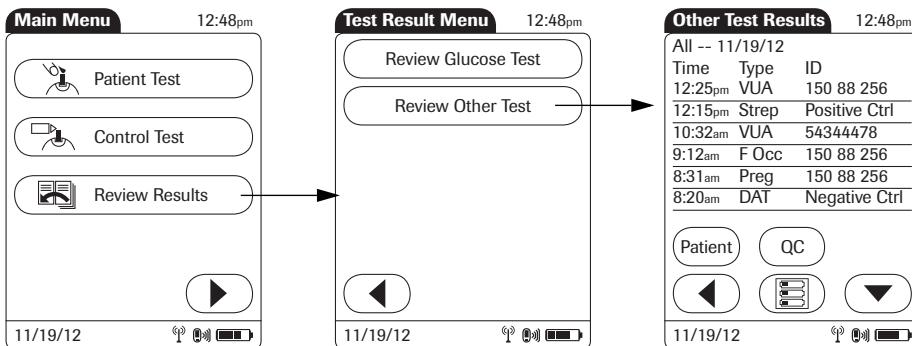
C.5   Reviewing Other Test Results

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):

Main Menu 12:48pm	Test Result Menu 12:48pm	Other Test Results 12:48pm
Patient Test	Review Glucose Test	All -- 11/19/12
Control Test	Review Other Test	Time Type ID
Review Results		12:25pm VUA 150 88 256
		12:15pm Strep Positive Ctrl
		10:32am VUA 54344478
		9:12am F Occ 150 88 256
		8:31am Preg 150 88 256
		8:20am DAT Negative Ctrl
		Patient QC
11/19/12	11/19/12	11/19/12

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.

Other Test Results	12:48pm

All -- 11/19/12

Time	Type	ID
12:25pm	VUA	150 88 256
12:15pm	Strep	Positive Ctrl
10:32am	VUA	54344478
9:12am	F Occ	150 88 256
8:31am	Preg	150 88 256
8:20am	DAT	Negative Ctrl

(Patient) (QC)

(◀) (▤) (▼)
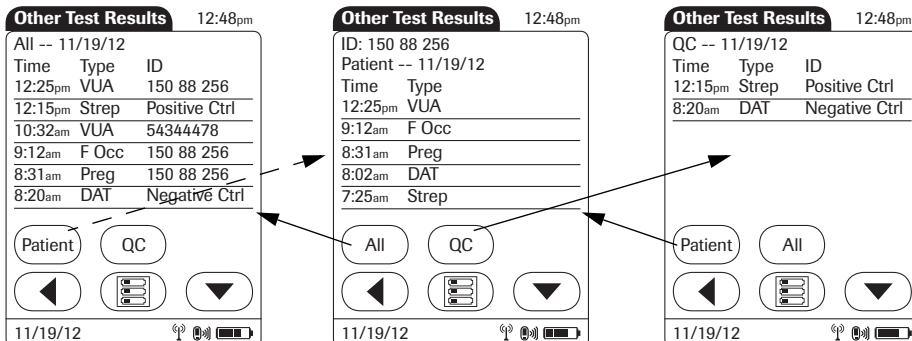
11/19/12   ⟨ᵖ⟩ 🕪 ▦

Fecal Occult Patient	12:48pm

Page 1/2

ID: 150 88 256
Name: Helen Schneider
11/19/12 9:12 am

Card Lot #   *1283*
                      12/30/12

Dev Lot #   *45233*
                      11/30/12

(Patient) (QC) (▲)

(◀) (▤) (▼)

11/19/12   ⟨ᵖ⟩ 🕪 ▦

Fecal Occult Patient	12:48pm

Page 2/2

ID: 150 88 256

Positive Ctrl   acceptable

Negative Ctrl   acceptable

Result   negative

Doctor Notified

(Patient) (QC) (▲)

(◀) (▤) (▼)

11/19/12   ⟨ᵖ⟩ 🕪 ▦

---

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.

Other Test Results	12:48pm

All -- 11/19/12

Time	Type	ID
12:25pm	VUA	150 88 256
12:15pm	Strep	Positive Ctrl
10:32am	VUA	54344478
9:12am	F Occ	150 88 256
8:31am	Preg	150 88 256
8:20am	DAT	Negative Ctrl

(Patient) (QC)

◀ ▤ ▼

11/19/12

Other Test Results	12:48pm

ID: 150 88 256
Patient -- 11/19/12

Time	Type
12:25pm	VUA
9:12am	F Occ
8:31am	Preg
8:02am	DAT
7:25am	Strep

(All) (QC)

◀ ▤ ▼

11/19/12

Other Test Results	12:48pm

QC -- 11/19/12

Time	Type	ID
12:15pm	Strep	Positive Ctrl
8:20am	DAT	Negative Ctrl

(Patient) (All)

◀ ▤ ▼

11/19/12

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 barcode 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

10   Touch ▤ to return to the *Main Menu*.

185

C.6   Other Test Entry Configuration Options
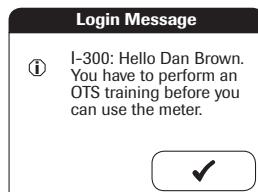
Other Test Entry options can only be configured using a DMS. The availability of configuration options will thus vary according to the data management software utilized by your institution. Consult your system administrator.

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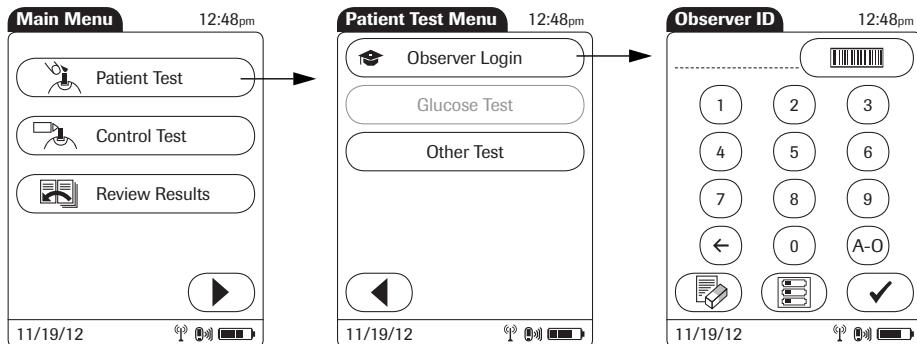
> This function needs to be configured by the system administrator and depends on available DMS settings. Electronic configuration options will thus vary according to the data management software utilized by your institution.

Login Message

ⓘ I–300: Hello Dan Brown. You have to perform an OTS training before you can use the meter.

✓

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.

Main Menu 12:48pm
- Patient Test
- Control Test
- Review Results

11/19/12

Patient Test Menu 12:48pm
- Observer Login
- Glucose Test
- Other Test

11/19/12

Observer ID 12:48pm

1 2 3
4 5 6
7 8 9
← 0 A-O

11/19/12
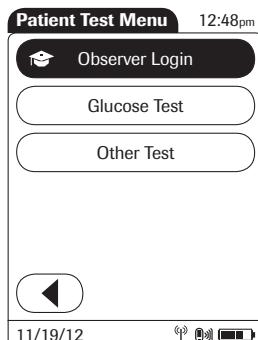
Observer:

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.

Patient Test Menu 12:48pm
- Observer Login
- Glucose Test
- Other Test

11/19/12

Operator:

1   Touch *Glucose Test*.

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

2   Hand the meter back to the observer.

Patient Test – OTS	12:48pm
Patient 123456789	
Date 11/19/12 12:48pm	

$$8.3_{mmol/L}$$

Range

◯   ✓

11/19/12

Observer Login

ⓘ   I-301: Observer Alan Smithee, please log in to proceed. Otherwise the OTS test will not be complete.

✓

OTS	12:48pm

Valid Glucose Result:
◎   Yes
◎   No
OTS:
◎   Pass
◎   Fail

◯   ✓

11/19/12

Observer:

3   Touch ✓ to log in again.

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

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

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

7   Touch ◯, if you want to add a comment.

8   Touch ✓ to return to the *Main Menu* screen.

The OTS information is saved together with the test result.

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Index

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