Default Device

7

Default Device

If more than 1 device is paired, select the default paired device for the Auto-Send and Sync Time features.



Auto-Send

Select whether data is automatically sent to the default paired device after each test.





Press \blacksquare or \blacksquare to highlight **On** or **Off**. Press \blacksquare to move \checkmark to the option.

Press $\underline{\tt W}$ to set the option and return to the previous menu.



Wireless Communication and Meter Pairing Svnc Time

Sync Time

Select whether to synchronize the time and date to the default paired device.





Press \square or \square to highlight **On** or **Off**. Press \square to move \checkmark to the option.

Press us to set the option and return to the previous menu.



Pairing Additional Devices

Pairing Additional Devices

This procedure is to add another paired device (assumes there is already 1 paired device).

You can pair 5 devices.

If you have 5 paired devices, you must delete a pairing before you can add another device.

The device you choose remains the default until you change it.





Pairing Additional Devices

4 Pairing Pair Device Maximum paired Pair Device devices. **Delete Pairing Delete pairing?** ⑦ Help No Yes Press or to highlight Pair If there are already 5 paired Device, Press devices: If there are less than 5 paired Maximum paired devices devices: appears. You must delete a

Pair Device appears. Proceed to Step 5.





7

Press 🗖 or 🗖 to highlight the device to delete. Press Proceed to Step 5.

Prepare the other device for pairing. Refer to the other device's instructions for information about pairing.



The mobile device displays a list of found devices, including the meter. Select the meter from the list. When prompted, enter the code displayed on the meter from Step 6 into the device to be paired.

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Wireless Communication and Meter Pairing Delete Pairing

Delete Pairing

This procedure is to delete a paired device (assumes there is at least 1 paired device).

You can pair 5 devices. If you have 5 paired devices, you must delete a pairing before you pair to another device.

The device you choose remains the default until you change it.









Wireless Communication and Meter Pairing Delete Pairing

7



If the selected device is not the default device:

The pairing is deleted. The name of the deleted device and \checkmark appear.



If the selected device is the default device:

The meter prompts you to select a new default device. If there is only 1 device remaining, it becomes the default device. The list of paired devices appears.



Highlight the new default device and press [™]. The name of the deleted device and ✓ appear, along with the new default device.





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What is the difference between cleaning and disinfecting?

Cleaning is the removal of dirt from the meter or lancing device.³

Disinfecting is the removal of most, but not all, disease-causing and other types of microorganisms (bloodborne pathogens) from the meter or lancing device.³

Approved Cleaning and Disinfecting Product

The following product has been approved for cleaning and disinfecting the meter and lancing device:

Super Sani-Cloth (EPA* reg. no. 9480-4)

Super Sani-Cloth can be purchased from Amazon.com, Officedepot.com, and Walmart.com.

- Do not use any other cleaning or disinfecting solutions. Using solutions other than the Super Sani-Cloth could result in damage to the meter and lancing device.
- The effect of using more than one product interchangeably to clean and disinfect the meter and lancing device has not been tested. Always use Super Sani-Cloth to clean and disinfect the meter and lancing device.
- Roche has demonstrated that the product is good for 5-year use, after testing in a total of 260 disinfection cycles (equal to cleaning and disinfecting once per week for 5 years).

*Environmental Protection Agency





NOTE

For technical assistance or questions on cleaning and disinfecting, contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

Cleaning and Disinfecting the Meter

WARNING

If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected prior to use by the second person.

To clean and disinfect without damaging the meter, follow these procedures carefully.

When to Clean and Disinfect the Meter

- Clean the meter to remove visible dirt or other material prior to disinfecting.
- Clean and disinfect the meter at least once per week and when blood is present on the surface of the meter.
- Clean and disinfect the meter before allowing anyone else to handle the meter. Do not allow anyone else to use the meter on themselves for testing purposes.

NOTE

Using cleaning and disinfecting products could result in damage to the meter. If you notice any of the following signs of deterioration after cleaning and disinfecting your meter, stop using your meter and contact the Accu-Chek Customer Care Service Center at 1-800-858-8072: residue around buttons, clouding of display, button malfunction, out-of-range control results.

What to Clean and Disinfect

The following parts of the meter should be cleaned and disinfected:

- . The area around slots and openings (do not get any moisture in slots or openings)
- · The meter display
- · The entire meter surface



8

How to Clean and Disinfect the Meter

WARNING

Failure to follow these instructions will damage the meter and stop it from working properly.

- D0 N0T clean or disinfect the meter while performing a blood glucose or control test.
- DO NOT get any moisture in slots or openings.
- D0 NOT spray anything onto the meter.
- D0 NOT immerse the meter in liquid.
- Always use the same product for both cleaning and disinfecting.

2





Wash hands thoroughly with soap and water.



Turn the meter off and wipe the entire meter surface with a Super Sani-Cloth. Carefully wipe around the test strip slot and other openings.

Make sure that no liquid enters any slot or opening.

A separate Super Sani-Cloth should be used for cleaning and disinfection. For disinfecting the meter, get a new cloth and repeat step 2, making sure the surface stays wet for 2 minutes.

3

Make sure that no solution is seen in any slot or opening.

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Wash hands thoroughly with soap and water.



Cleaning and Disinfecting the Lancing Device

To clean and disinfect without damaging the lancing device, follow these procedures carefully.

When to Clean and Disinfect the Lancing Device

- Clean the lancing device to remove visible dirt or other material prior to disinfecting.
- Clean and disinfect the lancing device at least once per week to remove visible dirt or other material for safe handling.
- Clean and disinfect the lancing device before allowing anyone else to handle the lancing device, for instance, if you have someone assisting you. Do not allow anyone else to use the lancing device.

NOTE

- Do not throw away the cap after each use. Use the approved cleaning and disinfecting product on the cap.
- Always remove the lancet drum before cleaning or disinfecting the lancing device.
- Using cleaning and disinfecting products could result in damage to the lancing device. If you notice
 any of the following signs of deterioration after cleaning and disinfecting your lancing device,
 stop using your lancing device and contact the Accu-Chek Customer Care Service Center at
 1-800-858-8072: residue around buttons, difficulty in priming the device, difficulty in inserting the
 lancet drum.
- You might observe a slight discoloration of the lancing device after multiple cleaning and disinfecting cycles. This does not affect the functionality of the lancing device.

What to Clean and Disinfect

The following parts of the lancing device should be cleaned and disinfected:

- The entire lancing device surface
- The cap



8

Meter and Lancing Device Cleaning and Disinfecting

How to Clean and Disinfect the Lancing Device

WARNING

Failure to follow these instructions may damage the lancing device and stop it from working properly.

- DO NOT get any moisture into any openings.
- Always use the same product for both cleaning and disinfecting.









Wash hands thoroughly with soap and water.





Meter Maintenance

The meter automatically tests its own systems every time you turn it on and lets you know if something is wrong. See the **Error Messages** section of this chapter.

If you have problems with the meter or think the results are not accurate, perform a control test with an unexpired test strip and control solution. If the control result is not within the acceptable range, contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

Changing the Batteries



Open the battery door on the back of the meter by pushing the tab in the direction of the arrow and pulling the door up.



Release the old batteries by pressing the 🗃 button. Remove the old batteries.



Slide the new batteries under the black tabs and button, with the (+) side facing up. Put the battery door back in place and snap it closed.

NOTE

- The meter uses two 3-volt lithium batteries, coin cell type CR2032. This type of battery can be found in many stores. It is a good idea to have spare batteries available.
- Always replace both batteries at the same time and with the same brand.
- The logbook data is saved when you replace the batteries.



Meter Maintenance and Troubleshooting

Error Messages

9

- Never make therapy decisions based on an error message.
- If you have any concerns or see any other error message, contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

	Allowed Allowed Remove strip or USB cable.	▲ Connection Lost Reconnect USB cable and retry.
The meter will not turn on or the display is blank.	The meter is connected to a PC and a test cannot be	The connection between the meter and PC was lost.
Batteries are dead.	performed.	Disconnect and reconnect the
Insert new batteries.	EITHER remove the USB cable and perform a test OR remove the test strip and start a data transfer.	USB cable and retry the connection. Contact the Accu-Chek Customer Care Service Center at 1-800-858-8072 if the connection is lost again.
 Display is damaged. / Meter is defective. 		
Contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.		
 Extreme temperatures. 		
Move the meter to a more temperate area.		















Meter Maintenance and Troubleshooting





9

Meter Maintenance and Troubleshooting









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9 Sync Time Meter time has been updated to match time on paired device. The meter time and date have been changed to match the paired device. Meter Maintenance and Troubleshooting





Meter Maintenance and Troubleshooting







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Product Limitations

See the literature packaged with the test strips and control solutions for the latest information on product specifications and limitations.

Specifications	
Blood volume	Refer to the test strip package insert.
Sample type	
Measuring time	
Measuring range	
Test strip storage conditions	
System operating conditions	
Meter storage conditions	Temperature: -13–158 °F
Memory capacity	720 blood glucose results and 32 control results with time and date
Automatic off	90 seconds
Power supply	Two 3-volt lithium batteries (coin cell type CR2032)
Display	LCD
Dimensions	$80 \times 47 \times 20 \text{ mm}$ (LWH)
Weight	Approx. 40 g (with batteries)
Construction	Hand-held
Protection class	III
Meter type	The Accu-Chek Guide meter is suitable for continuous operation.
Control solution storage conditions	Refer to the control solution package insert.
Interfaces	USB: micro-B connector; Bluetooth; Continua Certified [®] to a Continua Certified manager.
Radio frequency connectivity	Bluetooth low energy technology operating in the frequency band of 2402 MHz to 2480 MHz with a maximum transmitted power of 0 dBm (1 mW).



Bluetooth[®] Wireless Technology –The meter uses *Bluetooth* smart class II wireless technology to communicate and transfer information. *Bluetooth* wireless technology is a form or radio frequency (RF) technology that operates in the unlicensed industrial, scientific and medical band at 2.4 to 2.485 GHz. The RF channel utilized for communication between the meter and other devices, such as a smartphone, is not an open channel. The meter can only communicate with the device that

- 1. is Bluetooth smart,
- 2. it is paired with, and
- 3. has an application that can accept the meter's data.

This device complies with United States Federal Communication Commission (FCC) standards. The device complies with FCC Part 15 Rules. Operation of the device is subject to the following conditions:

- 1. This device may not cause harmful interference and
- 2. must accept any interference received, including interference that may cause undesired operation.

Compliance with these guidelines means that under normal, daily circumstances, the device should not affect the operation of other devices. In addition, the device should operate normally in the presence of other devices.

In the event there is interference from another device, it is recommended that you increase the distance between the meter and that device. You can also turn off the interfering device. In addition, you can turn off *Bluetooth* wireless technology on the meter. Changes or modifications to the device not expressly approved by Roche could void the user's authority to operate the device. The device has been tested and found to comply with the limits for a Class B digital device. The device generates, uses, and can radiate radio frequency energy.



Electromagnetic Compatibility – This meter meets the electromagnetic immunity requirements as per EN ISO 15197. The chosen basis for electrostatic discharge immunity testing was basic standard IEC 61000-4-2. In addition, the meter meets the electromagnetic emissions requirements as per EN 61326. The meter's electromagnetic emission is thus low. Interference from the meter to other electrically-driven equipment is not anticipated.

This device complies with Part 15 of the FCC Rules. 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.

This equipment complies with FCC and IC radiation exposure limits set forth for an uncontrolled environment. This equipment is in direct contact with the body of the user under normal operating conditions. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

NOTE

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

- · Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance (i.e. the manufacturer) could void the user's authority to operate the equipment.



Performance Analysis - Refer to the test strip package insert.

Test Principle - Refer to the test strip package insert.



Product Safety Information

WARNING

- This meter meets IEC 61010-1, IEC 61010-2-101 and IEC 60950-1 safety standards.
- Strong electromagnetic fields may interfere with the proper operation of the meter. Do not use the meter close to sources of strong electromagnetic radiation.
- To avoid electrostatic discharge, do not use the meter in a very dry environment, especially one in which synthetic materials are present.

Travel Documentation

If you are traveling on a commercial airline, you may be required to provide documentation certifying that this meter meets environmental conditions and test procedures for Airborne Equipment (RTCA D0-160) section 21 Emission of Radio Frequency Energy. Visit accu-chek.com or contact the Accu-Chek Customer Care Service Center at 1-800-858-8072 to obtain a copy of the document.



Discarding the Meter, Test Strips, Lancing Devices, Lancets, and Batteries

WARNING

- Any product coming in contact with blood is considered contaminated (potentially infectious).*
- During normal testing, any blood glucose meter may come in contact with blood.
- Lancing devices may also be considered sharps. Disposal of sharps is regulated by law in many jurisdictions.

Roche is committed to recycling and sustainability. Comply with any laws or ordinances relating to the disposal of sharps and/or contaminated products. Contact your local health department or other appropriate authorities for proper handling and disposal of used meters, used test strips, used lancets, and used batteries.

Consider the following points when discarding used testing materials: Consider recycling the meters and batteries at an appropriate facility. Be aware the meter is potentially hazardous electronics scrap (e-scrap) and should be disposed of accordingly. The batteries are potentially hazardous also and should be discarded accordingly.

Disinfect the meter before recycling or discarding.

*29 CFR 1910.1030 - Bloodborne pathogens



Explanation of Symbols

	Caution, refer to safety-related notes in the instructions for use accompanying this product.
	Biological Risks – used meters carry a risk of infection.
FCC ID: WX3-126	This device complies with Part 15 of the FCC Rules.
GTIN	Global Trade Item Number
SN	Serial number
(+)	3-volt coin cell type CR2032

Additional Supplies

Test Strips: Accu-Chek Guide test strips

Control Solutions: Accu-Chek Guide control solutions

Lancets: Accu-Chek FastClix 102-ct. lancet drums (17-6 ct. drums)

References

¹ FDA Public Health Notification: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication, (2010). Update 11/29/2010." http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm. Accessed March 20, 2012.

² CDC Clinical Reminder: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens, (2010)." http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html. Accessed March 20, 2012.

³ Healthcare Infection Control Practices Advisory Committee (HICPAC), William A. Rutala, Ph.D., M.P.H., and David J. Weber, M.D., M.P.H. Centers for Disease Control and Prevention, 2008. "Guideline for Disinfection and Sterilization in Healthcare Facilities." Atlanta.







Warranty

Accu-Chek Guide Meter 30-day Money-back Guarantee for Qualifying Consumers

Roche offers qualifying consumers that purchase an Accu-Chek Guide meter, a 30-day money back guarantee. If you are not fully satisfied with your Accu-Chek Guide meter, contact the Accu-Chek Customer Care Service Center toll-free at 1-800-858-8072 to determine whether you qualify to receive a full refund within 30 days of purchase. If you are covered under Medicare, Medicaid, other federal/state programs, or private insurance you are NOT eligible for this money-back offer. Consumers affected by this exclusion may instead request a different Accu-Chek meter/system. The refund will be limited to the amount paid by you net of any rebates. You must have a copy of the dated itemized purchase receipt and the original packaging to obtain this refund.

Accu-Chek Guide Meter Limited 3-Year Warranty

Roche warrants to the original purchaser of the meter that your Accu-Chek Guide meter will be free from defects in materials and workmanship for three years from the date of purchase. If, during this 3-year period, the meter does not work properly because of a defect in materials or workmanship, Roche will replace it with a new Accu-Chek Guide meter or equivalent product free of charge. The warranty on the replacement meter will expire on the date of the original warranty expiration or 90 days after the shipment of a replacement system, whichever period is longer. The purchaser's exclusive remedy with respect to the Accu-Chek Guide meter shall be replacement.

This warranty does not apply to the performance of an Accu-Chek Guide meter that has been damaged by accident or has been altered, misused, tampered with, or abused in any way. Roche will handle meters that show damage or abuse according to its Non-Warranty Service Policy described on the following page.

THE ABOVE WARRANTY IS EXCLUSIVE OF ALL OTHER WARRANTIES, AND ROCHE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE BE LIABLE TO THE PURCHASER OR ANY OTHER PERSON FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL, OR PUNITIVE DAMAGES ARISING FROM OR IN ANY WAY CONNECTED WITH THE PURCHASE OR OPERATION OF THE METER OR ITS PARTS. NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IF ANY IS IMPLIED FROM THE SALE OF THE METER, SHALL EXTEND FOR A LONGER DURATION THAN THRE YEARS FROM THE DATE OF PURCHASE.

Some states do not allow limitations on how long an implied warranty will last or the exclusion of incidental or consequential damages, so the above limitation and exclusion may not apply to you. This warranty gives you specific legal rights, which vary from state to state.



11 License and Warranty

Non-Warranty Service Policy

Roche Non-Warranty Service Policy applies to meters where the above warranty has not become effective, has become inapplicable, or has expired. Roche will replace, at its option, meters returned to it for a service charge (not to exceed \$35).

Replacement will be with the same or similar product. Replacement meters will be warranted for a period of 90 days from shipment under a limited warranty providing for replacement of parts and labor at no charge.

Warranty and Service Instructions

All requests for return of Accu-Chek Guide meters under the above warranty or service policy must be made to the Accu-Chek Customer Care Service Center. You will be mailed a return authorization label, which must be affixed to your carton for shipping the system to Roche. Cartons received without this label will be returned to you at your expense.

Customers experiencing difficulties should review the troubleshooting information in **Meter Maintenance** and **Troubleshooting** of this manual. Further inquiries should be directed to the Accu-Chek Customer Care Service Center.

Be sure to fill out and mail the Warranty Card that comes with the Accu-Chek Guide system.



License and Warranty

Limited License

WARNING

CAUTION – A RESTRICTED LICENSE LIMITS USE OF THE ACCU-CHEK GUIDE SYSTEM (meter and test strips) IN THE UNITED STATES – READ CAREFULLY THE LIMITATIONS RECITED BELOW.

The Accu-Chek Guide system (meter and test strips) and its use are protected by U.S. Patent Nos. 6,645,368 (expires 22-December-2017); 7,276,146 (expires 4-October-2022); 7,276,147 (expires 4-October-2022); 8,349,168 (expires 4-October-2022); 8,425,759 (expires 4-October-2022); 9,017,543 (expires 4-October-2022); 8,329,026 (expires 4-October-2022); 8,384,01 (expires 4-October-2022); 8,303,801 (expires 4-October-2022); 8,329,026 (expires 4-October-2022); 7,407,811 (expires 9-May-2020); 7,452,457 (expires 2-May-2026); 7,488,601 (expires 1-February-2026); 7,494,816 (expires 29-December-2019); 8,377,707 (expires 17-October-2023); 8,859,293 (expires 17-October-2023); 7,569,126 (expires 28-December-2026); and 8,361,291 (expires 8-October-2024). A license to use the Accu-Chek Guide system is required until the expiration of the last-to-expire patent listed above and is only granted when the Accu-Chek Guide meter is used with the Accu-Chek Guide test strips.

Accu-Chek Guide test strips are specifically manufactured for operation with the Accu-Chek Guide meter. Use of other test strips supplied by another manufacturer may prevent or impair the proper function of the Accu-Chek Guide system.

Using the Accu-Chek Guide system indicates your acceptance of the restricted license to use the Accu-Chek Guide system only with Accu-Chek Guide test strips. If you do not agree to the terms and conditions of the restricted license, you may return, at the place of purchase, the unused Accu-Chek Guide system for a full refund. If you have any questions, please call the Accu-Chek Customer Care Services Center at 1-800-858-8072.

Except where prohibited by statute, all warranties covering the Accu-Chek Guide system are voided by use of the Accu-Chek Guide system with any test strips other than Accu-Chek Guide test strips.



11 License and Warranty

WARNING

A RESTRICTED LICENSE LIMITS USE OF THE ACCU-CHEK FASTCLIX SYSTEM (lancing device and lancet drums) IN THE UNITED STATES. READ CAREFULLY THE LIMITATIONS RECITED BELOW.

The Accu-Chek Fastclix system (device and lancet drums) and its use are protected by U.S. Patent Nos. 7,322,998 (expires 3-March-2020); and 7,785,338 (expires 5-January-2026). A license to use the Accu-Chek Fastclix system is required until the expiration of the last-to-expire patent listed above and is only granted when Accu-Chek Fastclix lancet drums are used with the Accu-Chek Fastclix device.

Accu-Chek Fastclix lancet drums are high precision components that are produced to the close tolerances required for satisfactory operation with the Accu-Chek Fastclix device. Use of other lancet drums with the Accu-Chek Fastclix device may prevent or impair proper function of the Accu-Chek Fastclix device.

Using the Accu-Chek Fastclix device indicates your acceptance of the restricted license to use the Accu-Chek Fastclix device only with Accu-Chek Fastclix lancet drums. If you do not agree to the terms and conditions of the restricted license, you may return, at the place of purchase, the unused Accu-Chek Fastclix device for a full refund. If you have any questions, please call the Accu-Chek Customer Care Services Center at 1-800-858-8072.

Except where prohibited by statute, all warranties covering the Accu-Chek Fastclix device are voided by use of the Accu-Chek Fastclix device with any lancet drums other than Accu-Chek Fastclix lancet drums.

Patent Information

U.S. Pat .: http://www.roche-diagnostics.us/patents



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