



## User's Manual for Single Patient Use Only

**BLOOD GLUCOSE METER** 



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#### The Accu-Chek Guide System

The Accu-Chek Guide blood glucose monitoring system is comprised of the Accu-Chek Guide meter and the Accu-Chek Guide test strips.

The Accu-Chek Guide blood glucose monitoring system is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip, palm, and upper arm as an aid in monitoring the effectiveness of glucose control.

The Accu-Chek Guide blood glucose monitoring system is intended for in vitro diagnostic single-patient use by people with diabetes at home.

The Accu-Chek Guide blood glucose monitoring system is intended to be used by a single person and should not be shared.

This system is not for use in diagnosis or screening of diabetes mellitus, nor for neonatal use.

Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The Accu-Chek Guide control solutions are for use with the Accu-Chek Guide blood glucose monitoring system to check that the meters and test strips are working together properly and that the test is performing correctly.

The system includes:

The Accu-Chek Guide meter with batteries, the Accu-Chek Guide test strips,\* the Accu-Chek Guide control solutions,\* the Accu-Chek Softclix lancing device,\* the Accu-Chek Softclix lancets.\*

\*Some items may not be included in the kit. They are a separate purchase.

#### WARNING



- Choking hazard. Small parts. Keep away from children under the age of 3 years.
- Keep new and used batteries away from children. Ingestion or insertion into the body may cause chemical burns, perforation of soft tissues, and death. Severe burns may occur within 2 hours of swallowing. If you think a battery might have been swallowed or placed inside any part of the body, seek medical attention immediately.
- If the battery compartment does not close securely, stop using the product and keep it away from children.
   Contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

#### NOTE

- The term "blood glucose" is used when referring to "blood sugar."
- Sample data screens are shown throughout the manual. Your data will differ.

#### Limitations

- Do not use the meter at high hematocrit levels above 65 % or low hematocrit levels below 10 %.
- Not for use in diagnosis or screening of diabetes mellitus.
- Not for neonatal use.
- Abnormally high concentrations (greater than 5 mg/dL) of ascorbic acid (vitamin C) may cause inaccurate results. High-dose vitamin C therapy that would result in abnormally high concentrations is typically prescribed by a healthcare professional. If you are not sure if this applies to you, please check with your healthcare professional.
- Do not use the meter system to measure blood glucose in people who are experiencing cardiovascular collapse (severe shock) or decreased peripheral blood flow.
- Do not use during or soon after xylose absorption testing since xylose may cause inaccurate results. Xylose absorption testing is performed under the supervision of a healthcare professional. Ask your healthcare professional how long to wait after xylose testing before performing a blood glucose test.
- Not for use on critically ill patients, patients in shock, dehydrated patients, or hyperosmolar patients with or without ketosis.
- This system has not been tested at altitudes higher than 10,150 feet.

#### **Need Help?**

For questions, contact the Accu-Chek Customer Care Service Center toll-free at 1-800-858-8072. Hours of operation are Monday through Friday between 8:00 am and 8:00 pm eastern time (ET). We offer assistance in many languages. You can also visit accu-chek.com for diabetes management tools and product demonstrations.

Please register your warranty online at accu-chek.com/register, so you receive the best customer service possible and product update news.

#### **About Testing Yourself or Others**

#### WARNING

DO NOT CHANGE YOUR THERAPY BASED ON A TEST RESULT THAT DOES NOT MATCH HOW YOU FEEL OR IF YOU BELIEVE THAT YOUR TEST RESULT COULD BE INCORRECT.

It is strongly recommended to have a back-up testing method available. Failure to test could cause a delay in therapy decisions and lead to a serious medical condition. Examples of back-up testing methods include a back-up meter and test strips. Ask your healthcare professional or pharmacist about other possible back-up methods.

If your blood glucose result does not match how you feel and you have followed the instructions in this User's Manual, follow your healthcare professional's instructions, or contact your healthcare professional.

During normal testing, any blood glucose meter or lancing device may come in contact with blood. All parts of the kit are considered biohazardous and can potentially transmit infectious diseases from bloodborne pathogens, even after you have performed cleaning and disinfecting.<sup>1,2</sup>

The meter and lancing device should never be used by more than one person. Do not share the meter and lancing device with anyone, including family members, due to the risk of infection from bloodborne pathogens. <sup>1,2</sup> Do not use on multiple patients!

Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

Cleaning and disinfecting the meter and lancing device destroys most, but not necessarily all, bloodborne pathogens.<sup>3</sup>

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.

Disinfect the meter and lancing device before allowing anyone else to handle them. Do not allow anyone else to test with the meter or lancing device.

It is important to keep the meter and lancing device clean and disinfected. For instructions on how to clean and disinfect the meter and lancing device, see the chapter Meter and Lancing Device Cleaning and Disinfecting.

Wash hands and dry thoroughly before and after handling the meter, lancing device, or test strips.

#### NOTE

- Perform a control test when you open a new test strip box or if you think that a test result is incorrect. Performing a control test lets you know that the meter and test strips are working properly.
- Refer to the test strip and control solution package inserts for additional health-related information.
- Blood glucose and BG are interchangeable and mean the same thing.

#### **Special Information for Caregivers**

- Consult your healthcare professional to determine if it is appropriate for your child to be taught how to use the meter system or any other medical products.
- Some people with diabetes do not experience symptoms of low blood glucose (hypoglycemia). Others, such as children or people who are unconscious or have certain disabilities, may not be able to communicate their symptoms to caregivers. For these reasons, do not change any therapy without first talking to a healthcare professional.

#### **Before You Start Testing**

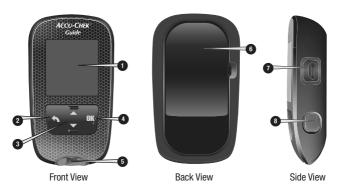
#### WARNING

- Carefully read and follow the instructions in the User's Manual and package inserts for the test strips and control solutions. It is very important to follow the instructions in order to avoid an incorrect test result that leads to improper therapy.
- Inspect the test strip container before using the test strips for the first time. If you see any damage to the container cap or if anything prevents the cap from closing properly, do not use the test strips. Contact the Accu-Chek Customer Care Service Center at 1-800-858-8072. Damaged test strips can cause inaccurate results, which could lead to improper therapy.
- The meter, test strips, and control solution are only for use outside the body (in vitro). Do not eat the test strips. Do not swallow or inject the control solution or use the control solution for any purpose other than testing the Accu-Chek Guide system.

#### NOTE

- The meter may prompt you to choose a language the first time you turn it on
- Check the time and date on the meter before you begin testing. Adjust the time and date if necessary.

#### The Accu-Chek Guide Meter



#### 1. Display

Shows results, messages, and test results stored in memory.

#### 2. Back Button

Returns to a previous screen or field.

- Up Arrow and Down Arrow Buttons
   Press to move between menu options
   or to increase or decrease numbers.
- Power/Set/OK Button
   Turns meter on or off and sets options.

## 5. Test Strip Slot with Light Insert test strip here.

## 6. Battery Door

Flip open to replace batteries.

#### 7. Micro USB Port

Transfers data from meter to a computer (PC).

#### 8. Test Strip Ejector

Press to remove test strip.



- 9. Test Strip Container\*
- Test Strip\* Metallic End Insert this end into meter.
- Test Strip\* Yellow Edge
   Touch blood drop or control solution here.
- 12. Control Solution Bottle\*
- 13. Batteries
- 14. USB Cable\*
  Connects meter to a PC.

\*Some items may not be included in the kit. They are a separate purchase.

#### The Accu-Chek Softclix Lancing Device



- Cap with Comfort Dial Depth Selection
  For fingertip testing.
- For tingertip testing.

  2. Eiector
- Slide to release lancet.
- Release Button Press to prick.

- **4. Priming Button** Press to prime.
- 5. Lancet

#### NOTE

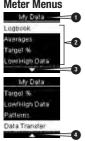
Some items may be sold separately.

#### **Button Functions**

Here are the functions of the back, arrow, and Power/Set/OK buttons on the meter. These functions are used throughout this manual. See the chapter Meter Settings for specific instructions on setting up the meter.

Button	Function
Back Button	Return to the previous screen. Return to the previous field.
Up Arrow and Down Arrow Buttons  Navigate up and down in a menu. Increase or decrease a number.	
Power/Set/OK Button	Press briefly to turn the meter on. Press and <b>hold</b> to turn the meter off. Press to select an option. Press to move to the next field or screen. Press to save an option. With the meter off, press and <b>hold</b> to check the meter display.

#### **Meter Menus**



- Title of screen or menu.
- 2 Menu option
- Scroll down
- Scroll up

Screen	Description
	There are more menu options listed beneath the last option. Press on the meter to view the options.
	There are more menu options listed above the first option. Press on the meter to view the options.
	There are more menu options listed above and below the options.  Press  o or  o on the meter to view the options.
9:36am 12/11/15 Main Menu  Test  My Data  Settings	Highlighted option ( <b>Test</b> )  Press <b>1</b> to enter the <b>Test</b> menu.
Time/Date HH MM A/P 9:38 am MM DD YY 12/11/15	Highlighted field ( <b>HH</b> = Hour)  Press   or  to increase or decrease the hour. Press  the hour and move to the minutes field.

#### **Symbol**

Here is a list of the symbols on the meter display.

Symbol	Description	
Above target range		
Ť	After meal	
)	Bedtime	
ď	Before meal	

Symbol	Description
Ţ	Below target range
•	Blood glucose test
<b>~</b>	Checkmark / Control test OK / Selected option or setting
C	Control bottle

Symbol	Description
×	Control test not OK
0	Edit
*	Error
0	Fasting
<b>†</b>	Flight mode
?	Help
<u>-</u>	Low battery
1	My data
	No comment
*	Other
<b>ⓒ</b>	Overall
₽	Settings
<u></u>	Test reminder
<u></u>	Warning
1	Within target range

#### **Setting the Language**

The meter may prompt you to choose a language the first time you turn it on.



Turn the meter on by briefly pressing ☑.

Language appears.

Press ☑ or ☑ to highlight the language.



Press of to set the desired language and return to Main Menu.

#### NOTE

If you select the wrong language and cannot correct it, contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

## 2 The Accu-Chek Softclix Lancing Device

#### Using the Accu-Chek Softclix Lancing Device



- The black cap is for fingertip testing only.
- Remove the cap by pulling it straight off. Do not twist the cap.



- The penetration depth indicator on the comfort dial shows the current depth setting. The higher the number, the deeper the penetration. The best depth setting is the lowest number that lets you get enough blood for a test. Try different depth settings to find the one that is right for you.
- For soft skin, we suggest a depth setting of 2. For thick skin, try a higher depth setting.

#### **Inserting a Lancet**

You must first insert a lancet into the lancing device to get it ready for use.





Remove the lancing device cap. Do not twist the cap.

2



Insert a new lancet into the lancing device until it clicks.

3



Twist off the lancet's protective cap.

4



Place the cap back on the lancing device. Make sure the notch on the cap lines up with the notch on the lancing device.

## 2 The Accu-Chek Softclix Lancing Device

#### Using the Accu-Chek Softclix Lancing Device





Adjust the lancet depth by turning the comfort dial.

2



Press the priming button in as far as it will go, like a pen.

The release button turns yellow when the lancing device is ready.

3

Obtain a blood drop. See the chapter Blood Glucose Tests.

#### NOTE

- DO NOT press the release button while pressing the priming button.
- ALWAYS use a new, sterile lancet each time you test to avoid infection.
- · NEVER reuse a lancet.
- NEVER share your lancing device with anyone.

#### WARNING

- The meter and lancing device should never be used by more than one person. Do not share the meter and lancing device with anyone, including family members, due to the risk of infection from bloodborne pathogens.<sup>1,2</sup> Do not use on multiple patients!
- Blood glucose results can be displayed in either mg/dL or mmol/L. The back label of the meter shows the unit of measurement. This meter is set to mg/dL. If the meter shows the wrong unit, contact the Accu-Chek Customer Care Service Center at 1-800-858-8072. The correct unit of measurement in the US is mg/dL. If you do not know which unit of measurement is correct for you. contact your healthcare professional. Using the wrong unit of measurement may cause misinterpretation of your actual blood glucose level and may lead to improper therapy.



mg/dL is printed here

#### **Using the Accu-Chek Guide System**

- The Accu-Chek Guide test strips are for testing fresh capillary whole blood.
- Use only the Accu-Chek Guide test strips.
- Use the test strip immediately after removing it from the test strip container.
- Do not apply blood or control solution to the test strip before inserting it into the meter. If you applied blood or control solution before inserting the test strip into the meter, retest with a new test strip. If a result appears before applying blood or control solution, do not act on that result.
- Close the test strip container tightly immediately after removing a test strip.
   Moisture can damage the test strips and produce incorrect results.
- Store the unused test strips in their original container with the cap tightly closed.
- Discard the test strips if they are past the Use By date printed on the test strip container. If the Use By date is missing or cannot be read, do not use the test strips. Contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.
- Refer to the test strip package insert for test strip storage and system operating conditions.
- Do not remove test strips from the test strip container and put them into another container, such as a plastic bag, pocket, purse, wallet, etc.
- Do not reuse test strips. Once control solution or blood has been applied to a test strip, discard it. If a retest is necessary, use a new test strip.
- Perform a control test every time you open a new test strip box.

#### WARNING

To prevent inaccurate results:

- DO NOT expose test strips to heat, moisture, or humidity. Temperatures outside the required range, as well as moisture and humidity, can damage the test strips and lead to inaccurate results
- DO NOT bend, cut, or alter the test strips.
- DO NOT get dirt, food, or other material on the test strip.

## Performing a Blood Glucose Test with Blood from Your Fingertip

Refer to the Important Safety Information section at the beginning of this manual.

#### NOTE

Before you perform your first blood glucose test, set up the meter correctly.

- You need the meter, a test strip, and a lancing device with a lancet inserted to perform a blood glucose test.
- A blood glucose test cannot be performed while the meter is connected to a PC with a USB cable.
- There are 2 ways to start a blood glucose test.
  - Insert a test strip into the meter.
  - Turn the meter on by briefly pressing . Select Test > ...

#### 1



Wash your hands with warm soapy water and dry thoroughly. Dirty or wet hands could affect test results.

#### 2



Adjust the lancet depth to a comfortable penetration level.

#### 3



Check the **Use By** date on the test strip container.

Do not use test strips past the **Use By** date.

#### 4



Remove a test strip from the test strip container.

Close the cap tightly.

5





Insert the metallic end of the test strip into the meter.

The meter turns on. Preparing to test appears.

6



When Apply drop appears, obtain a blood drop.

7



Press the lancing device firmly against the side of your fingertip.

Press the vellow release button to prick your finger.

8



Gently squeeze your finger to assist the blood flow. This helps you get a blood drop.

9



Touch the vellow edge of the test strip to the blood drop. Do not put blood on top of the test strip.

10





Remove your finger from the test strip when Analyzing appears.

11



The test result appears on the display.

You have the option of adding a comment to the test result by

pressing OR proceed to Step 14 to complete the test.

12



Add Comment

appears. Press **t** highlight a comment. Press to set the comment for the test

result. See the Adding Comments to Blood Glucose Results section of this chapter for details.



The final test result appears. Press a or to set the comment and return to Main Menu. Or to change

the comment, press to select the comment

Press to return to Add Comment.

#### NOTE

When performing a **blood glucose test**: If the **Control Result** screen appears, an error has occurred.

- Do not act on the blood glucose result.
- Discard the test strip and repeat the blood glucose test with a new test strip.

#### 14

Remove and discard the used test strip by pulling the test strip out of the meter or by pressing the test strip ejector on the side of the meter.



Press here to eject test strip

#### 15



Discard the used lancet. Remove the lancing device cap. Point the lancet away from you.

Slide out the ejector to release the lancet into a puncture-proof container.

Always discard according to local regulations.

#### 16



Wash your hands with warm soapy water and dry thoroughly.

#### **Blood Glucose Warnings**

If your blood glucose result is outside the measuring range of the meter, a warning is displayed. Press to acknowledge the LO or HI warning, OR the meter automatically moves to the LO or HI result screen.





Blood glucose may be lower than the measuring range of the system. See the Unusual Blood Glucose Results section of this chapter.





Blood glucose may be higher than the measuring range of the system. See the Unusual Blood Glucose Results section of this chapter.

#### Adding Comments to Blood Glucose Results

#### NOTE

Analyzing your blood glucose results stored in the meter is an effective way for you and your healthcare professional to determine how well you are controlling your diabetes. This analysis is a valuable tool for making improvements to your diabetes management. Use care when adding comments to blood glucose results. Incorrect comments can cause inaccurate patterns to be detected by the meter if Patterns is **On** 

#### Overview

It is very important to have the correct time and date set in the meter. Having the correct time and date setting helps ensure accurate interpretation of information by you and your healthcare professional.

- You may add comments to blood glucose results to help you and your healthcare
  professional analyze patterns detected by the meter (see the Patterns section in the
  chapter Meter Settings for details).
- If Patterns is set to **0n**, once a pattern is detected you may NOT change the comment attached to a blood glucose result (see the Patterns section in the chapter Meter Settings for details).
- Adding a comment saves the comment and the symbol with the blood glucose result.

Here is a list of comment symbols that can be added to a blood glucose result.

Symbol	Name	Description
ď	Before meal	If Patterns is <b>On</b> , select Before breakfast, lunch, dinner, or snack (see the following page for adding comments with Patterns <b>On</b> ).
Ť	After meal	If Patterns is <b>0n</b> , select After breakfast, lunch, dinner, or snack (see the following page for adding comments with Patterns <b>0n</b> ).
0	Fasting	Select Fasting for no caloric intake for at least 8 hours.*
)	Bedtime	
*	Other comment	You can use this comment to mark an event such as an AST result or exercise.
	No entry	1. You do not want to add a comment.
		You want to remove a comment for the current blood glucose result.

<sup>\*</sup>American Diabetes Association: Standards of Medical Care in Diabetes-2020.



After performing a blood glucose test, the test result is displayed on the screen with

Add Comment

highlighted. Press ut to add a comment.



The Add Comment menu appears. Press ■ to highlight the desired comment (the example here is

**Before meal**). Press uto select the comment.

#### If Patterns is On:



If Patterns is On and you select Before meal or After meal, press

■ to select a specific meal (**Breakfast**,

**Lunch**, **Dinner**, or **Snack**). Press to set the selected meal for the test result.



The final result appears with the comment symbol. Press or to set the comment and return to Main

To change the comment, press to select the comment. Press to return to **Add Comment**.

Performing a Blood Glucose Test with Blood from Your Palm or Upper Arm (Alternative Site Testing, AST)

#### WARNING

- Do not use Alternative Site Testing to calibrate a continuous glucose monitoring system or to make insulin dosing calculations.
- Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

You have the option of obtaining a blood sample from other sites on your body besides the fingertip. Alternative sites include the palm and upper arm.

Blood obtained from the fingertip can be

used at any time to test blood glucose. If blood from an alternative site is used, there are certain times when testing is not appropriate. This is because your blood glucose level changes faster in your fingertip than in the alternative sites. These differences may cause you to misinterpret your actual blood glucose level, leading to improper therapy and potential adverse health effects

Read the following section before you try testing from alternative sites.

account from automative cited		
You may perform a palm or upper arm test	immediately before a meal.     while fasting.	
You may NOT perform a palm or upper arm test	up to 2 hours following a meal, when blood glucose values can rise quickly.     after injecting bolus insulin, when blood glucose values can decrease rapidly.     after exercise.     if you are sick.     if you think your blood glucose is low (hypoglycemia).     if you sometimes do not notice when your blood glucose is low.	

If you are interested in AST, talk to your healthcare professional first.

#### **Unusual Blood Glucose Results**

If your blood glucose result does not match how you feel, follow these steps:

- Perform a control test. See the chapter Control Tests.
- 2. Repeat the blood glucose test.

If your blood glucose result still does not match how you feel, follow your healthcare professional's instructions or contact your healthcare professional immediately.

#### NOTE

Always follow your healthcare professional's instructions. For example, if your healthcare professional has advised you to immediately treat a low blood glucose result (such as by eating something), then do that first.

#### WARNING

- Do not change your treatment because of one blood glucose result.
- NEVER ignore symptoms of low or high blood glucose.

## Symptoms of Low or High Blood Glucose

#### WARNING

The meter is designed to provide a numerical value for blood glucose in the range of 20–600 mg/dL.

Being aware of the symptoms of low or high blood glucose can help you understand your test results and decide what to do if they seem unusual.

Low blood glucose (hypoglycemia): Symptoms of hypoglycemia may include, but are not limited to, anxiety, shakiness, sweating, headache, increased hunger, dizziness, pale skin color, sudden change in mood or irritability, fatigue, difficulty concentrating, clumsiness, palpitations, and/or confusion.

High blood glucose (hyperglycemia): Symptoms of hyperglycemia may include, but are not limited to, increased thirst, frequent urination, blurred vision, drowsiness, and/or unexplained weight loss.

If you are experiencing any of these symptoms, or other unusual symptoms, test your blood glucose from the fingertip. If your blood glucose result is displayed as L0 or HI, follow your healthcare professional's instructions or contact your healthcare professional immediately. If your blood glucose result does not match how you feel, follow the steps in the Unusual Blood Glucose Results section of this chapter.

#### Comparing Your Meter Result to a Laboratory Result

A common question is how the blood glucose results on the meter compare to the laboratory results. Your blood glucose can change quickly, especially after eating, taking medication, or physical activity. If you test yourself in the morning, then go to your healthcare professional's office for a blood glucose test, your test results will probably not match, even if you are fasting. This is typically not a problem with the meter, it just means that time has elapsed and your blood glucose level has changed.

Although you always apply fresh capillary whole blood to the test strip, the system has been calibrated to deliver plasma-like values for easier comparison to laboratory results.

If you want to compare your meter result to the laboratory result, **you must be fasting**. Take the meter to your healthcare professional's office and test yourself by fingerstick within 5 minutes of having blood drawn from your arm by a healthcare professional. Keep in mind that the laboratory uses different technology than the meter.

#### When to Perform a Control Test

Performing a control test lets you know the meter and test strips are working properly. You should perform a control test when:

- vou open a new test strip box.
- vou left the test strip container open.
- you think the test strips are damaged.
- vou want to check the meter and test strips.
- the test strips were stored in extreme temperatures, humidity, or both.
- you dropped the meter.
- · vour test result does not match how you feel.
- vou want to check if you are performing the test correctly.

#### About the Control Solutions

- Use only the Accu-Chek Guide control solutions.
- Close the control solution bottle tightly after use.
- Write the date you open the control solution bottle on the bottle label. The control solution must be discarded 3 months from the date the control solution bottle was opened (discard date) or on the Use By date on the bottle label, whichever comes first.
- Do not use control solution that is past the Use By or discard date.
- Refer to the control solution package insert for control solution storage conditions.
- . The meter automatically recognizes the difference between the control solution and blood
- The control results are not displayed in memory.

- The control solution can stain fabric. Remove stains by washing with soap and water.
- Control solution is available for purchase. To order the control solution. talk to your pharmacist or visit accu-chek com to order online.

#### **Performing a Control Test**

You need the meter, a test strip, and control solution Level 1 or Level 2.



Check the Use By date on the test strip container. Do not use test strips past the Use By date.



Remove a test strip from the test strip container.

Close the cap tightly.



Insert the metallic end of the test strip into the meter. Place the meter on a flat surface.



The meter turns on. Preparing to test appears.



Apply drop appears.



Select the control solution to test. You will enter the level later in the test.



Remove the bottle cap. Wipe the tip of the bottle with a tissue. Squeeze the bottle until a tiny drop forms at the tip.



Touch the drop to the **yellow edge** of the test strip. Do not put control solution on top of the test strip.



Analyzing appears when there is enough control solution in the test strip.

Control Resul 9:38am 12/11/ \$ 50 mg

Control Result and the control bottle symbol appear.

Press or to select the control level you tested. If you do not select a level, the

(example)

control result is saved without a control level

level. Press 🍱.

#### NOTE

When performing a **control test**: If the **Control Result** screen DOES NOT appear, an error has occurred.

- . Do not act on the control result.
- Discard the test strip and repeat the control test with a new test strip.

# 8 Control Result 9:38am 12/11/ \$ 50 mg

Control Result.
9:38am 12/11/15
6 261 me/dt.
Or Level 1

Could of range

Within range and ✓ appear if the control result is within range.

**Out of range** and **X** appear if the control result is out of range.





Wipe the tip of the bottle with a tissue. Cap the bottle tightly. Remove and discard the used test strip.

#### NOTE

- Most people just test the Level 1 control. If you wish, you can also test a Level 2 control. A set of Level 1 and Level 2 control solutions is available for purchase.
- The ranges for Level 1 and Level 2 control solutions are printed on the test strip container label.
- The meter turns off 90 seconds after a successful test or 15 seconds after the test strip is removed, provided no other action is taken

#### Understanding Out-of-Range Control Results

#### WARNING

The control range applies only to a control result. It only indicates that the test strips and meter are working properly. Do not use a control result to interpret blood glucose results.

If the control result is out of range, do not use the meter until you solve the problem. Check the following list to help solve the problem.

Troubleshooting Checks	Action
Were the test strips or control solutions expired?	Discard the test strips or control solution if either is past the <b>Use By</b> date. If the control solution was opened more than 3 months ago, discard it. Repeat the control test with an unexpired test strip and an unexpired control solution.
Did you wipe the tip of the control solution bottle before use?	Wipe the tip of the bottle with a tissue. Repeat the control test with a new test strip and a fresh drop of control solution.
Were the caps on the test strip container and the control solution bottle always closed tightly?	Replace the test strips or control solution if you think either was uncapped for some time. Repeat the control test.
Was the test strip used immediately after it was removed from the test strip container?	Repeat the control test with a new test strip and a fresh drop of control solution.
Were the test strips and control solutions stored in a cool, dry place?	Repeat the control test with a properly stored test strip or control solution.
Did you follow the directions?	Read the chapter Control Tests and repeat the control test.
Did you choose the correct control solution level, either 1 or 2, when you performed the control test?	If you chose the wrong control solution level, you can still compare the control result to the range printed on the test strip container.
Are you still unsure of the problem?	Contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

#### **Overview**

You can adjust the following settings in the meter for your personal preferences. Refer to the sections later in this chapter for details and how to set the options.

Setting	Options	Function
Time/Date	Time / Date	Set the time and date.
Beeper	On / Off	Select On or Off.
Wireless	Select wireless commu Communication and Me	inication settings. See the chapter Wireless eter Pairing.
Target Ranges	Off / Single Range / 2 Ranges	Select the blood glucose target range appropriate for you.
		NOTE  Consult your healthcare professional for the appropriate target range for you.
		Off – no target range arrow symbols appear with the blood glucose result. Patterns is <b>Off</b> (see the Patterns section of this chapter for details).
	70–180 mg/dL (pre-set target range)	Single Range – blood glucose results are marked as above, within, or below range based on the single target range set in the meter.
	Before Meal Range 70–110 mg/dL (pre-set target range) After Meal Range 70–180 mg/dL (pre-set target range)	2 Ranges – set Before Meal and After Meal ranges. Blood glucose results are marked as above, within, or below range based on the 2 target ranges (Before Meal and After Meal) set in the meter.
Patterns	On / Off	On – a pattern is detected when 2 below-target or 3 above-target test results with the same comment are detected within a 7-day period.
Reminders	On / Off / Edit time	On – set up to 4 reminders per day to remind you to test.

Setting	Options	Function
Post Meal	On / Off / Edit time	On – reminds you to perform an after meal blood glucose test.
Last Result	On / Off	Select whether the previous blood glucose result (within the past 24 hours) appears with the current blood glucose result.  On – the previous blood glucose result appears with the current blood glucose result.  Off – only the current blood glucose result
Language		appears.  Select the language for the meter.
Language		Select the language for the meter.

#### Time/Date



Turn the meter on by briefly pressing ☑ S.
From Main Menu, press ☑ to highlight Settings. Press ☑ S.



Time/Date is highlighted. Press 록.



Press or to to adjust each field. Press to set and proceed to the next field. Set am or pm if necessary.

Press to save and return to the previous menu.

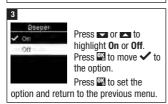
#### **Beeper**

The beeper prompts you:

- · when a test strip is inserted.
- to apply blood or control solution to the test strip.
- when enough blood or control solution is drawn into the test strip.
- when the blood glucose or control test is complete.
- when the meter is turned on.
- when a button is pressed.
- when it is time to perform a test (if Reminders or Post Meal reminders are On).
- · when the batteries are inserted.
- when there are no stored blood glucose results or there is an invalid record in the logbook.
- when there are no errors in the error log.
- if an error occurred (even if the beeper is off, it still beeps for an error).







#### **Target Ranges**

Consult your healthcare professional before changing the target range. It is very important to stay within your target range.

Target Ranges can be set from a lower limit of 60–100 mg/dL to an upper limit of 101–300 mg/dL.

Options	Function
Off	Arrow symbols for above, within, or below target ranges do not appear with the blood glucose results.

Single Range  Set lower limit and upper limit for the target range. You will be prompted to turn on Patterns if desired (see the Patterns section of this chapter for details).  2 Ranges  Set lower limits and upper limits for Before Meal and After Meal target ranges. You must mark your blood glucose results with a comment for the meter to detect above, within, or below Before Meal or After Meal test results (see the Adding Comments to Blood Glucose Results section in the chapter Blood Glucose Tests for details). You will be prompted to turn on Patterns if desired (see the Patterns section of this chapter for details).		
limits for Before Meal and After Meal target ranges. You must mark your blood glucose results with a comment for the meter to detect above, within, or below Before Meal or After Meal test results (see the Adding Comments to Blood Glucose Results section in the chapter Blood Glucose Tests for details). You will be prompted to turn on Patterns if desired (see the Patterns section of		limit for the target range. You will be prompted to turn on Patterns if desired (see the Patterns section of
	2 Ranges	limits for Before Meal and After Meal target ranges. You must mark your blood glucose results with a comment for the meter to detect above, within, or below Before Meal or After Meal test results (see the Adding Comments to Blood Glucose Results section in the chapter Blood Glucose Tests for details). You will be prompted to turn on Patterns if desired (see the Patterns section of

When Target Ranges is on, the following symbols appear with blood glucose results.

Symbol	Meaning
Ţ	The blood glucose result is below the target range.
<b>‡</b>	The blood glucose result is within the target range.
1	The blood glucose result is above the target range.

#### WARNING

This function is no substitute for hypoglycemia training by your healthcare professional.



Turn the meter on by briefly pressing 

From Main Menu, press 

to highlight 
Settings. Press 

Turn the meter on by briefly pressing.



Press to highlight More Options.
Press .



Target Ranges is highlighted. Press ...



Press or to highlight Off, Single Range, or 2 Ranges. Press to select an option (the example here is 2 Ranges).



Press or to adjust the lower limit of the **Before Meal** target range. Press to set and move to the next field

Continue to set the upper limit for the **Before Meal** target range and the lower and upper limits for the **After Meal** target range. Press



The  $\checkmark$  appears next to the option you selected.

Press to return to the previous menu.



The meter may prompt you to turn on Patterns.

Press or No.

Press to set the

option and return to the previous menu (see the Patterns section of this chapter for details).

#### **Patterns**

#### NOTE

Analyzing your blood glucose results stored in the meter is an effective way for you and your healthcare professional to determine how well you are controlling your diabetes. This analysis is a valuable tool for making improvements to your diabetes management. Use care when adding comments to blood glucose results. Incorrect comments can cause inaccurate patterns to be detected by the meter if Patterns is **On** 

A Pattern is detected by the meter when 2 below-target (Low Pattern) or 3 above-target (High Pattern) test results with the same comment are detected within a 7-day period.

- The meter does NOT detect a pattern for the "Other" comment added to blood glucose results.
- It is very important to have the correct time and date set in the meter. Having the correct time and date setting helps ensure accurate interpretation of information by you and your healthcare professional.
- Only blood glucose results marked with comments will be included in Patterns. If LO or HI test results are marked with comments, the test results become part of Patterns (see the chapter Blood Glucose Tests for more details).
- Target Ranges must be set in the meter to use Patterns. If Target Ranges is not set, the meter prompts you to set it.



Turn the meter on by briefly pressing O.S.
From Main Menu, press to highlight Settings. Press O.S.



Press to highlight More Options.
Press .



Press to highlight



Sel up now?

Yes

Press ■ to highlight

On. Press ☑ to move

✓ to the option. Press

☑

This message appears if Target Ranges is Off:

Press to highlight Yes. Press ...
(To turn Patterns Off.)

select No. Press (10 turn Patterns of Select No. Press (10 turn Patterns of Select No. Patterns of Select No. Press (10 turn Patterns of Select No

# Target Ranges Choose an option. Single Range 2 Ranges ① Help

Target Ranges appears on the display (see the Target Ranges section of this chapter for details on setting target ranges).

If Patterns is **0n** and a new pattern is detected with a blood glucose result, a message appears on the display.





Press to select **Details** to view the blood glucose results that make up that pattern.

Press us to highlight View later.

Press to return to the previous screen.

#### Reminders

You can set up to 4 general test Reminders per day to remind you to test. A series of beeps sound and  $\diamondsuit$  is displayed for Reminders set in the meter.

#### Reminders:

- turn off by inserting a test strip or pressing any button.
- are postponed until the next test reminder if a test was performed within 15 minutes of a test reminder.
- do not appear/beep if the meter is on at the test reminder time (including when the meter is connected to a USB cable).
- do not appear/beep if the meter is connected and communicating to a Continua Certified® manager.
- do not beep if the meter beeper is set to off.
- do not appear/beep if the batteries need to be replaced.

#### Set Reminders

- Reminder times are pre-set in the meter for 8:00 am, 12:00 pm, 6:00 pm, and 10:00 pm. You may change reminder times by following the instructions below.
- If a general test Reminder is set for the same time as a Post Meal reminder, the Post Meal reminder will appear/beep instead of the general Reminder (see the Post Meal Reminders section of this chapter for details).



Turn the meter on by briefly pressing ☑3.
From Main Menu, press ☑ to highlight Settings. Press ☑3.



Press 

to highlight

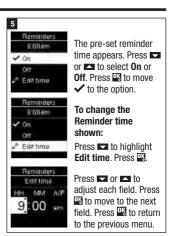
More Options.

Press 

.









A ✓ indicates the reminder is set for the time shown and automatically set to **On**. To turn the reminder

off, press **t** to highlight **Off**.

Press **t** to return to **Reminders**.



The reminder time appears.

Press to continue to set additional reminders or press

to return to More Options.

#### Post Meal Reminders

Post Meal reminders can be set to remind you to test again later when you add a Before meal comment to a blood glucose result. When a reminder occurs, a series of beeps sound and & is displayed.

#### Post Meal reminders:

- turn off by inserting a test strip or pressing any button.
- are postponed until the next test reminder if a test was performed within 15 minutes of a test reminder.
- do not appear/beep if the meter is on at the test reminder time (including when the meter is connected to a USB cable).
- do not appear/beep if the meter is connected and communicating to a Continua Certified® manager.
- do not beep if the meter beeper is set to off.
- do not appear/beep if the batteries need to be replaced.

#### Set Post Meal Reminders

 Adding a Before meal comment to a blood glucose result sets a Post Meal reminder in the meter.

- Marking blood glucose results with an After meal comment provides more information about your test results to help you and your healthcare professional in the management of your diabetes.
- Talk to your healthcare professional to determine your Post Meal test time.
- Select 1 hour, 1.5 hours, or 2 hours for Post Meal reminders to occur.



Turn the meter on by briefly pressing ...
From Main Menu, press to highlight Settings. Press ...



Press to highlight More Options.

Press

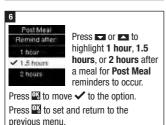


Press to highlight Post Meal. Press



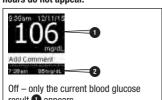
Press or to highlight **On**. Press to move to the option.





#### Last Result

Select whether the previous blood glucose result appears with the current blood alucose result. Test results older than 24 hours do not appear.



result 1 appears.

On – the previous blood glucose result 2 appears with the current blood alucose result.



Turn the meter on by briefly pressing . From Main Menu. press **t** to highlight Settings. Press







#### Language

Choose the language that appears on the meter.



Turn the meter on by briefly pressing ☑. From **Main Menu**, press ☑ to highlight **Settings**. Press ☑.



Press to highlight More Options.

Press (18).

More Options
Reminders
Post Meal
Last Result
Language

Press to highlight Language. Press .



Press 
or 
to
highlight the desired
language. Press 
to
move 
to the option.

Press 
to set the

language and return to the previous menu.

#### Overview

- Blood glucose results are stored from the newest to the oldest.
- The meter automatically stores up to 720 blood glucose results in memory with the time and date of the test and any test result comments.
- Once 720 blood glucose results are in memory, adding a new blood glucose result deletes the oldest blood glucose result.
- . Only test results that have been marked with a fasting, before meal, after meal, or bedtime comment are included in the average for that comment.
- · All test results are included in the overall 7. 14. 30. and 90-day averages regardless of what comment is added.
- · Control results are stored in memory but cannot be reviewed on the meter. To view stored control results, transfer them to a compatible software application.
- · Control results are not included in the averages or blood glucose reports.
- . Once 32 control results are in memory. adding a new control result deletes the oldest control result

#### WARNING

Do not change your therapy based on an individual test result in memory. Talk to vour healthcare professional before changing therapy based on test results in memory.

### NOTE

The meter has time and date auto-sync capability when paired with a mobile device that will update the meter time and date automatically. Even if you use your meter in multiple time zones. results are stored from newest to oldest and not by time and date.

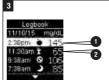
### Logbook



Turn the meter on by briefly pressing . From Main Menu, press **t** to highlight My Data. Press ...



Logbook is highlighted. Press OK

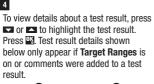


Press or to scroll through Loabook.

The most recent test result 1. The 2nd most recent test result 2.











# Averages



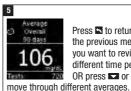




Press to highlight a category (the example here is Overall). Press DX



Press to highlight a time period (the example here is 90 days). Press .



Press to return to the previous menu if you want to review a different time period OR press or to

## **Target Percent (%)**

Target Percent (%) allows you to view the percentage of your Overall, Before meal, After meal, Fasting, and Bedtime blood glucose results that are above, within, or below your target ranges.

- Target % results can be viewed for 7. 14, 30, or 90-day time periods.
- Target Ranges must be set in the meter to review Target % results.



Turn the meter on by briefly pressing ... From Main Menu. press to highlight My Data. Press ...



Press **to** highlight Target %. Press ...



Press to highlight a category (the example here is **Before meal**). Press to select the option.



Press 

to highlight a time period (the example here is 

days). Press 

...



The **Target %** appears (for the **Before meal** example). The number of total tests included in the Target % appears

Press to return to the previous menu.

at the bottom of the display.

#### NOTE

Analyzing your blood glucose results stored in the meter is an effective way for you and your healthcare professional to determine how well you are controlling your diabetes. This analysis is a valuable tool for making improvements to your diabetes management. Use care when adding comments to blood glucose results. Incorrect comments can cause inaccurate patterns to be detected by the meter if Patterns is **On**.

### Low/High Data

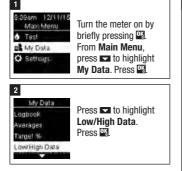
Your healthcare professional can tell you what blood glucose range is appropriate for you. It is very important to stay within your target range.

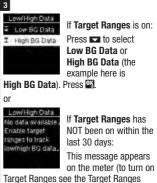
- Target Ranges must be set in the meter to track Low/High Data test results (see the Target Ranges section in the chapter Meter Settings for details).
- Low BG or High BG Data includes only test results that fall above or below the target ranges set in the meter.
- Low BG or High BG Data is tracked in the meter for 30 days.

You can select Low BG and High BG test results for Overall, Before meal, After meal, Fasting, or Bedtime blood glucose results.

Symbol	Name	Description
<b>ⓒ</b>	Overall	Includes low and high blood glucose results based on Target Ranges set in the meter.
ď	Before meal	You may view low or high test results marked with a Before meal comment for Overall, Before breakfast, Before lunch, Before dinner, and Before snack blood glucose results.*
Ť	After meal	You may view low or high test results marked with an After meal comment for Overall, After breakfast, After lunch, After dinner, and After snack blood glucose results.*
0	Fasting	Includes low or high fasting blood glucose results marked as Fasting in comments.
)	Bedtime	Includes low or high bedtime blood glucose results marked as Bedtime in comments.

<sup>\*</sup>Test results for Before and After specific meals are only available if Patterns is set to **On**.





section in the chapter Meter Settings for

details).



Press to highlight a category (the example here is **Before meal**).



If test results with detailed meal comments are saved in the Logbook:

The meter may prompt

you to select detailed categories to view.

Press 

to highlight a category (the example here is before Breakfast).

Press 

A.



The selected data appears (the example here is **High BG Data**). Press To scroll through the test results.

Press to return to the previous menu.

### NOTE

Analyzing your blood glucose results stored in the meter is an effective way for you and your healthcare professional to determine how well you are controlling your diabetes. This analysis is a valuable tool for making improvements to your diabetes management. Use care when adding comments to blood glucose results. Incorrect comments can cause inaccurate patterns to be detected by the meter if Patterns is **On**.

#### **Patterns**

- Patterns displays only active Low Patterns or High Patterns based on comments added to blood glucose results within the last 7 days.
- A Pattern is generated when 2 below-target or 3 above-target test results with the same comment are detected within a 7-day period.

Patterns may be viewed on the meter in 3 ways:



when a Patterns option is displayed at the bottom of **Main Menu**.



٥r



from My Data on Main Menu.



if a New pattern detected message appears on the display when performing a blood glucose test.

Patterns detected by the meter may be displayed on the Main Menu as:

Patterns	High and low patterns have been detected	Patterns may include the following blood glucose
High Pattern(s)	One or more high patterns have been detected	results marked with comments:  Before breakfast, After
Low Pattern(s)	One or more low patterns have been detected	breakfast, Before lunch, After lunch, Before dinner, After
No Patterns	No active pattern based on test results from last 7 days	dinner, Before snack, After snack, Fasting, or Bedtime (see the Adding Comments to Blood Glucose Results section in the chapter Blood Glucose Tests).
Blank	Patterns feature is set to <b>Off</b>	



the bottom of the screen (the example here is **Patterns**). Press



Press or to highlight Low Patterns or High Patterns (the example here is Low Patterns).

Press us to select the option.



Press to highlight a category to review (the example here is **Before breakfast**). Press .



Press to scroll through test results. Press to return to the previous menu.

### **Data Transfer Using Wireless**

This feature allows you to transfer data wirelessly from your meter to another device.









If a device has not been paired with vour meter:



The meter prompts you to pair a device to the meter (see the First-Time Pairing section in the chapter

Wireless Communication and Meter Pairing for details).

or

If the meter has already been paired with at least one device:



Press or to choose a wireless device for data transfer.







The meter transfers the data to the device.

## **Data Transfer Using USB Cable**

This feature allows you to transfer data from your meter to special software for diabetes management on a PC using a IISB cable



Plug the small end of the USB cable into the meter.



Plug the large end of the USB cable into a USB port on the PC. If the meter is off, it turns on.

3

Start the diabetes management software and initiate a data transfer.







The meter transfers the data to the software.

### Overview

You can wirelessly and automatically synchronize your diabetes information with a mobile device. The process of creating a connection between the meter and the mobile device is called pairing. You need an application on your mobile device that can accept the meter data.

Setting	Options	Function
Flight Mode	On / Off	Select whether wireless communication is available.
		On – wireless communication is not available.
		Off – wireless communication is available.
Default Device	List of devices paired with the meter	If more than 1 device is paired, select the device with which the Auto-Send and Sync Time features will communicate.
Auto-Send	On / Off	Select whether data is automatically sent to the default paired device after each test.
		On – data is automatically sent to the default paired device.
		Off – data is not automatically sent to the default paired device.
Sync Time	On / Off	Select whether to synchronize the time and date to the default paired device.
		On – the time and date on the meter synchronize to the time and date on the default paired device.
		Off – the time and date on the meter do not synchronize to the time and date on the default paired device.
Pairing	Pair Device / Delete Pairing	Select whether to pair a device or to delete a paired device.

### **First-Time Pairing**

The steps below are for first-time pairing. Up to 5 devices can be paired with the meter at any time.

Each device must be paired with the meter one at a time.

The meter and the device to be paired should be within 3 feet of each other.



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



Turn the meter on by briefly pressing ♣. From **Main Menu**, press ► to highlight **Settings**. Press ♣.





Pair Device appears.
To pair a device, press to highlight Yes.
Press OK.



The meter displays its code.

6

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 5 into the device to be paired.



When pairing is complete,  $\checkmark$  and the name of the paired device appear.

Press to return to

the previous menu.

## Flight Mode

Select whether wireless communication is available or not. When **Flight Mode** is on, appears in the title bar and wireless communication is not available.



Turn the meter on by briefly pressing .
From Main Menu, press to highlight Settings. Press .







#### **Default Device**

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



Turn the meter on by briefly pressing □.
From Main Menu, press □ to highlight Settings. Press □.







the previous menu.

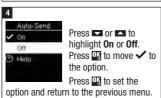
#### Auto-Send

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









### **Sync Time**

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



Turn the meter on by briefly pressing 

Table 1. From Main Menu, press 

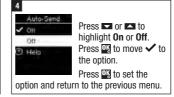
To highlight

Settings. Press 

Table 2. Settings.







### **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.









Press or to highlight Pair Device.

Press or

If there are less than 5 paired devices:

Pair Device appears. Proceed to Step 5.



If there are already
5 paired devices:
Maximum paired
devices appears. You
must delete a paired



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 meter displays its code.

7

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.



When pairing is complete, ✓ and the name of the paired device appear.

Press ☑.



If there is more than 1 paired device, the meter asks if you want the new device to be the default device.

Press or to highlight No or Yes.
Press to set the option and return to
Pairing.

Press to return to the previous menu.

### **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.



Turn the meter on by briefly pressing OS.
From Main Menu, press to highlight Settings. Press OS.



Press to highlight Wireless. Press ...



Press to highlight Pairing. Press .



Press or to highlight **Delete**Pairing. Press



Press or to highlight the device to delete. Press to set the option.



If the selected device is not the default device:

The pairing is deleted. The name of the

deleted device and 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

# What is the difference between cleaning and disinfecting?

Cleaning is the removal of dirt from the meter or lancing device.<sup>3</sup>

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

# 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

#### How to Clean and Disinfect the Meter

#### WARNING

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

- DO NOT clean or disinfect the meter while performing a blood glucose or control test.
- DO NOT get any moisture in slots or openings.
- . DO NOT spray anything onto the meter.
- DO NOT immerse the meter in liquid.

Always use the same product for both cleaning and disinfecting.









Wash hands with soap and water and dry thoroughly.

2



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.

#### 3

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.

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

## 4



Wash hands with soap and water and dry thoroughly.

## 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 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 lancing device, difficulty in inserting the lancet.
- 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

### 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.

- D0 N0T get any moisture into any openings.
- Always use the same product for both cleaning and disinfecting.



Wash hands with soap and water and dry thoroughly.



Wipe the entire surface of the lancing device and the inside of the cap with a Super Sani-Cloth.

#### 3

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



Wash hands with soap and water and dry thoroughly.

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## Meter Maintenance and Troubleshooting

#### **Meter Maintenance**

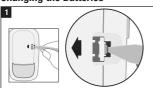
The meter automatically tests its own systems every time you turn it on and lets you know if something is wrong. See the Error Messages section of this chapter.

If you have problems with the meter, drop 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

#### WARNING

Keep new and used batteries away from children. See the warning in the Important Safety Information section at the beginning of this manual for additional information.

## **Changing the Batteries**



Open the child-resistant battery door by inserting a narrow object, such as a pen, into the slot. Push the tab in the direction of the arrow and lift the battery door up.



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

Press and hold the Power/Set/OK button on the front of the meter for at least 2 seconds.



Slide the new batteries under the black tabs and the button, with the (+) side facing up. Put the battery

door back in place and snap it closed. Immediately discard the old batteries.

### NOTE

- Always have a spare set of batteries.
- Battery life may vary due to factors such as temperature and battery manufacturer
- The meter uses two 3-volt lithium batteries, coin cell type CR2032. This type of battery can be found in many stores
- Always replace both batteries at the same time and with the same brand
- The logbook data is saved when you replace the batteries.

### **Error Messages**

#### WARNING

- 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.



The meter will not turn on or the display is blank

Batteries are dead.

Insert new batteries.

 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 location with a more moderate temperature.



The meter is connected to a PC and a test cannot be performed.

EITHER remove the USB cable and perform a test OR remove the test strip and start a data transfer.



The connection between the meter and PC was lost

Disconnect and reconnect the 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.



There is no connection between the meter and PC.

Connect the USB cable and retry the connection.



Blood glucose results were not transferred to a paired device.

Make sure the paired device is within range of the meter and turned on.



Data could not be transferred from the meter to the PC.

Check the PC or USB cable.



Data cannot be sent to a paired device because the meter is in Flight Mode. Retry the data transfer when the meter is not in Flight Mode.



One or more blood glucose results are excluded from the selected averages because the results are invalid or outside the system measuring range.



One or more blood glucose results are excluded from the selected target % data because the test results are invalid.



One or more blood glucose results are excluded from the selected low/high data because the test results are invalid.



The date entered is not valid. Enter the correct date.



A meter setting was changed while in Flight Mode.

The setting change will not take effect until Flight Mode is turned off.



Pairing to a device cannot be performed while in Flight Mode.

Retry pairing when the meter is not in Flight Mode.

Auto-Send
Not Complete
Transfer still
pending. Ensure
paired device
is within range
and turned on.

The blood glucose result has not been sent to the default paired device. The transfer is still pending.

Place meter and paired device closer together.



The meter was unable to pair with a device.

Retry the pairing.



The test strip may be damaged, not properly inserted, or was previously used.

Remove and reinsert the test strip or replace it if damaged or previously used.

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## **Meter Maintenance and Troubleshooting**



A meter or test strip error has occurred. This error message could appear if the cap on the test strip container was not closed tightly. The test strips may have been damaged due to improper storage or handling.

# Never make therapy decisions based on an error message.

Repeat the blood glucose test. If a second E-3 error message appears, perform a control test with the control solution and a new test strip. See the section Performing a Control Test in the chapter Control Tests. If you continue to receive an E-3 error message, use an alternate method for testing your blood glucose, such as a back-up meter and test strip. If the alternate method gives an extremely high blood glucose result, or if an alternate method is not available, contact your healthcare professional immediately.

In rare cases, an E-3 error message may indicate that your blood glucose is extremely high and above the system's measuring range. See the Unusual Blood Glucose Results section in the chapter Blood Glucose Tests for other possible causes of the error

message.



Not enough blood or control solution was drawn into the test strip for measurement or was applied after the test had started.

Discard the test strip and repeat the blood glucose or control test.



Blood or control solution was applied to the test strip before **Apply drop** appeared.

Discard the test strip and repeat the blood glucose or control test.



An electronic error occurred.

Remove the batteries, press and hold the Power/Set/OK button for at least 2 seconds, and reinsert the batteries.

Perform a blood glucose or control test.



The temperature is above or below the proper range for the system.

Refer to the test strip package insert for system operating conditions. Move to an area with the appropriate conditions and repeat the blood glucose or control test. Do not artificially heat or cool the meter.



The batteries may be out of power. Turn the meter back on. If you are in a cold environment, move to a location with a more moderate temperature and retest. If the message continues to appear after several attempts, replace the batteries. If the message reappears after the batteries have been replaced, remove the batteries, press and hold the Power/Set/OK button for at least 2 seconds, then reinsert the batteries.



The time and date setting may be incorrect.

Make sure the time and date are correct and adjust, if necessary.



The test strip may be damaged. Retest with a new test strip.



Your blood sample may contain a high level of ascorbate.

Contact your healthcare professional.



Fluid or foreign material may be present in the test strip slot.

Remove and reinsert the test strip or repeat the blood glucose or control test with a new test strip. If the problem persists, contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.





An electronic error has occurred. Contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

> Synt 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.



There are no results in the Logbook.



There is an invalid result in the Logbook.





There are no test results in range for the selected data.



Target Ranges is **Off** and there are no results for the Target % data stored in the meter



Target Ranges is **Off** and there are no results for the low/high data stored in the meter.





There are no results stored in the meter for the selected data.



Patterns is **On** but there are no active patterns stored in the meter.





Patterns is Off.



Blood glucose may be higher than the measuring range of the system (higher than 600 mg/dL).

See the Unusual Blood Glucose Results section in the chapter Blood Glucose Tests.



Blood glucose may be lower than the measuring range of the system (lower than 20 mg/dL).

See the Unusual Blood Glucose Results section in the chapter Blood Glucose Tests.



The batteries are almost out of power. Change the batteries now. If the symbol reappears after the batteries have been replaced, remove the batteries again, press and hold the Power/Set/OK button for at least 2 seconds, then reinsert the batteries.

#### **Product Limitations**

Considinations

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
Sample type	package insert.
Measuring time	
Measuring	
range	
Test strip	
storage	
conditions	
System	
operating conditions	
Meter storage	Temperature:
conditions	-13–158 °F
Memory	720 blood glucose
capacity	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	I CD
Display	80 × 47 × 20 mm
Difficusions	(LWH)
Weight	Approx. 48 g (with
· · · · · · · · · · · · · · · · · · ·	batteries)
Construction	Hand-held
Protection class	III
Meter type	The Accu-Chek Guide
	meter is suitable for
	continuous operation.

Control solution	Refer to the control
storage	solution package insert.
conditions	
Interfaces	USB: micro-B
100	connector; Bluetooth
Continua	Low Energy technology;
	Continua Certified® to a
	Continua Certified
	manager.
Radio	Bluetooth low energy
frequency	technology operating in
connectivity	the frequency band of
	2.402 GHz to
	2.480 GHz with a
	maximum transmitted
	power of 0 dBm
	(1 mW).

Bluetooth Wireless Technology — The meter uses Bluetooth® low energy 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. utilizes Bluetooth low energy technology,
- 2. it is paired with, and
- has an application that can accept the meter data.

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

- This device may not cause harmful interference, and
- this device 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 low energy 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 – The meter meets the electromagnetic emission 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 61326-2-6 / EN 60601-1-2. 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:

- This device may not cause harmful interference, and
- 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 quarantee 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.

#### Communication Protocol - The

Accu-Chek Guide blood glucose meter is Continua Certified. Continua Certified signifies that this product complies with applicable ISO/IEEE 11073-10417, Health informatics — Personal health device communication — Part 10417: Device specialization — Glucose meter standards and that it has been tested and certified against the Continua Design Guidelines 2015 which include the Blood Glucose specification for Bluetooth low energy technology, Bluetooth SIG, Glucose Profile, Version 1.0 and Bluetooth SIG, Glucose Service, Version 1.0.

### **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.
- Dispose of sharps according to local regulations.

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. Follow the instructions provided by your healthcare professional.

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**

$\bigcap_{\mathbf{i}}$	Consult instructions for use or consult electronic instructions for use
$\triangle$	Caution, refer to safety-related notes in the instructions for use accompanying this product.
	Use by
STERILE R	Sterilized using irradiation
<b>(2)</b>	Use only once
(ii)	Single patient multiple use
6	Wash your hands
₩	Biological risks
( <del>+</del> 1	3-volt coin cell type CR2032

<b>X</b>	Keep new and used batteries away from children.
~M	Date of manufacture
MD	Medical device
***	Manufacturer
FCC ID: WX3-126	This device complies with Part 15 of the FCC Rules.
UDI	Unique device identifier
REF	Catalogue number
SN	Serial number
LOT	Batch code
GTIN	Global Trade Item Number
CE	Complies with the provisions of the applicable EU Legislation

#### **Additional Supplies**

Test Strips: Accu-Chek Guide test strips Control Solutions: Accu-Chek Guide control solutions

**Lancets:** Accu-Chek Softclix 100-ct. lancets

#### References

<sup>1</sup>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." https://downloads. regulations.gov/FDA-2016-M-0035-0003/ content.pdf Accessed December 13, 2021. <sup>2</sup>Klonoff DC. Improving the safety of blood glucose monitoring. J Diabetes Sci Technol. 2011 Nov 1;5(6):1307-11. doi:10.1177/193229681100500601. PMID: 22226247; PMCID: PMC3262696.

<sup>3</sup> 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, 2019. "Guideline for Disinfection and Sterilization in Healthcare Facilities." Atlanta. https://www.cdc.gov/ infectioncontrol/guidelines/disinfection/. Accessed July 23, 2021.

### Warranty

### The 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.

### The 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 in the following section.

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 MERCHANTARII ITY OR FITNESS FOR A PARTICULAR PURPOSE JE ANY IS IMPLIED FROM THE SALE OF THE METER, SHALL EXTEND FOR A LONGER DURATION THAN THREE 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.

#### **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.

## **11** License and Warranty

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 register your warranty online at accu-chek.com/register for the Accu-Chek Guide system.

#### 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. 7.452.457 (expires 2-May-2026): 7.488.601 (expires 1-February-2026): 7.569.126 (expires 28-December-2026): 7.604.721 (expires 12-August-2026) 9.395.322 (expires 13-March-2034): 10.119.931 (expires 11-August-2035): 10.809.221 (expires 13-March-2034): 9.594.052 (expires 13-March-2034): 9.797.859 (expires 29-October-2034): 10.295.494 (expires

28-August-2035): 9.594.045 (expires 13-March-2034). 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.

The 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 the 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, contact the Accu-Chek Customer Care Service 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 the Accu-Chek Guide test strips.

#### Patent Information

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

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