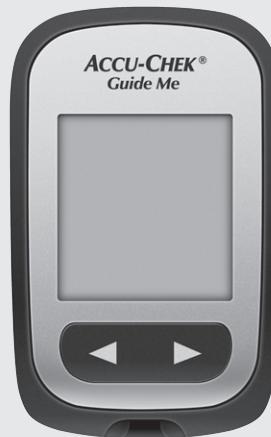


**ACCU-CHEK® Guide Me**



# User's Manual for Single Patient Use Only

Blood Glucose Meter



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## Important Safety Information

### The Accu-Chek Guide Me System

The Accu-Chek Guide Me Blood Glucose Monitoring System is comprised of the Accu-Chek Guide Me meter and Accu-Chek Guide test strips.

The Accu-Chek Guide Me 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 Me Blood Glucose Monitoring System is intended for in vitro diagnostic single-patient use by people with diabetes.

The Accu-Chek Guide Me 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).

Accu-Chek Guide control solutions are for use with the Accu-Chek Guide Me 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:

Accu-Chek Guide Me meter with batteries, Accu-Chek Guide test strips,\* Accu-Chek Guide control solutions,\* Accu-Chek FastClix lancing device, Accu-Chek FastClix lancet drums.\*

\*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.**

#### **NOTE**

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

**DRAFT**

## Important Safety Information

### 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 of ascorbic acid (vitamin C) resulting in blood concentrations in excess of 5 mg/dL may cause inaccurate results. If you are not sure please check with your doctor.
- 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 this system during xylose absorption test.
- Not for use on critically ill patients, patients in shock, dehydrated patients, or hyperosmolar patients.
- 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 standard time (EST). We offer assistance in many languages. You can also visit accu-check.com for diabetes management tools and product demonstrations.

Please register your meter online at accu-check.com/register so you receive the best customer service possible, in addition to product updates.

### 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 always a good idea 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 or testing by a laboratory. 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.

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## Important Safety Information

### ⚠ WARNING

- 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!
- 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.

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## Important Safety Information

### 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

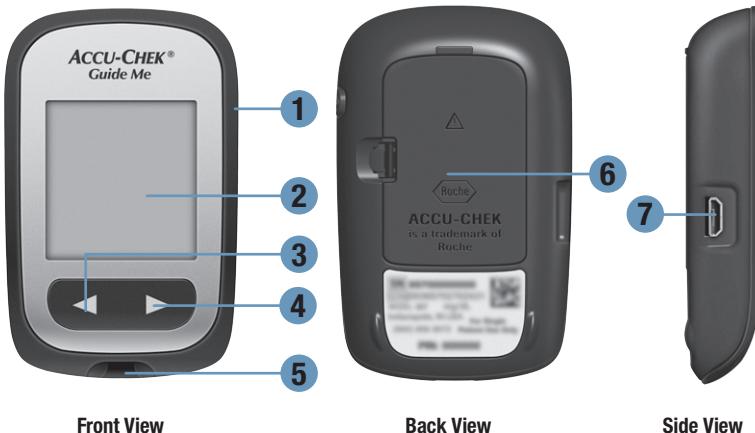
- Carefully read and follow the instructions in the User's Manual and package inserts for the test strips and control solutions. It is very important to follow the instructions in order to avoid an incorrect test result that leads to improper therapy.
- Inspect the test strip container before using the 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. 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 Me system.

#### NOTE

Set the time and date on the meter before you begin testing.

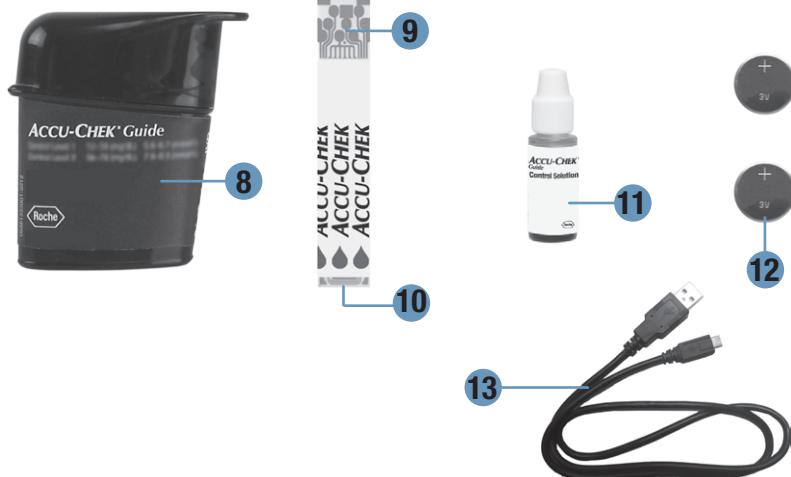
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## The Accu-Chek Guide Me Meter



- 1. Power/Set Button**  
Turns the meter on or off and sets options.
- 2. Display**  
Shows results, messages, and test results stored in memory.
- 3. Left Arrow Button**  
Press to enter memory, adjust settings, and scroll through test results.
- 4. Right Arrow Button**  
Press to enter memory, adjust settings, and scroll through averages.
- 5. Test Strip Slot**  
Insert test strip here.
- 6. Battery Door**  
Open to replace batteries.
- 7. Micro USB Port**  
Transfers data from meter to a computer (PC).

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**8. Test Strip Container\*****9. Test Strip\* – Metallic End**

Insert this end into the meter.

**10. Test Strip\* – Yellow Edge**

Touch blood drop or control solution here.

**11. Control Solution Bottle\*****12. Batteries****13. USB Cable\***

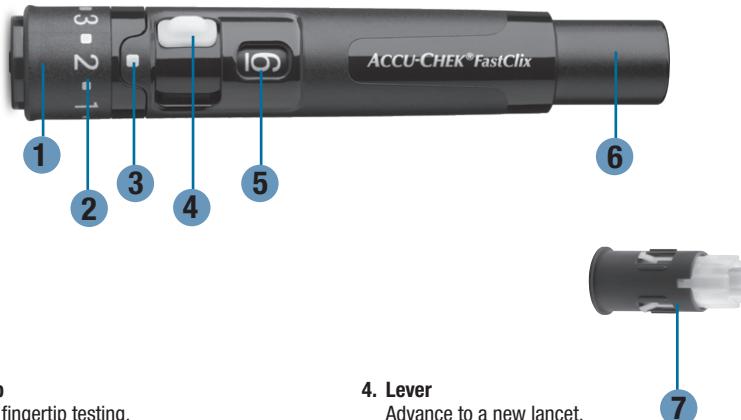
Connects the meter to a PC.

\*Some items may not be included in the kit.

They are a separate purchase.

**DRAFT**

## The Accu-Chek FastClix Lancing Device



- 1. Cap**  
For fingertip testing.
- 2. Comfort Dial with Depth Selection**  
Select penetration depth.
- 3. Penetration Depth Indicator**  
Points to depth setting.
- 4. Lever**  
Advance to a new lancet.
- 5. Lancet Counter Window**  
Shows number of available lancets.
- 6. Release Button**  
Press to prime and prick.
- 7. Lancet Drum**  
Contains 6 lancets.

### NOTE

Some items may be sold separately.

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## Using the Meter Buttons

When instructed to press a meter button, press it briefly and release it.

When instructed to press and **hold** a meter button, press and hold it for 3 or more seconds.

## Button Functions

Here are the functions of the power/set button and arrow buttons on the meter. These functions are used throughout this manual.

Button	Function	Action
 [power/set button]	<p>Turn the meter on or off.</p> <p>Navigate to an option or set a selection.</p> <p>Check the meter display.</p> 	<p>Press and release.</p> <p>With the meter off, press and hold to see the complete meter display. If one of the segments is missing or looks different from this picture, do not use the meter. Contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.</p>
 [right arrow and left arrow buttons]	Adjust settings for time and date, scroll through test results in memory.	Press and release or press and hold to scroll faster.

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## Symbols

Symbol	Description
	7-day average symbol. This indicates that you are viewing the 7-day average of your blood glucose results.
	14-day average symbol. This indicates that you are viewing the 14-day average of your blood glucose results.
	30-day average symbol. This indicates that you are viewing the 30-day average of your blood glucose results.
	90-day average symbol. This indicates that you are viewing the 90-day average of your blood glucose results.
	Bluetooth symbol
	Control bottle symbol
	Drop symbol
	Hourglass symbol
	Low battery symbol
	No data to display
	Pairing symbol. A flashing symbol indicates the meter is attempting to pair with a device. A solid symbol indicates the meter pairing was successful.
	Temperature warning symbol
	Test strip symbol. A flashing symbol indicates the meter is ready for you to insert a test strip.
	Wireless symbol. A flashing symbol indicates the meter is attempting to connect to the paired device. A solid symbol indicates the meter is connected to a paired device.

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# 1

## Your New System

### Setting the Time and Date

The meter prompts you to set the time and date the first time you turn the meter on or if an error occurs.

1



Set-up appears on the display with the hour flashing.

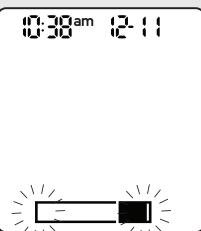
Press **[◀]** or **[▶]** to decrease or increase the hour.

2



Press **(1)** to set the hour and move to the next field.

3



Repeat steps 1 and 2 to set minutes, am or pm, month, day, and year. Press **(1)** until the flashing test strip symbol appears. Insert a test strip to perform a test.

#### NOTE

- Press and hold **(1)** at any time until the flashing test strip symbol appears to perform a test.
- The time and date on the meter synchronizes to the time and date on the paired device each time the meter sends data to the paired device.

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# The Accu-Chek FastClix Lancing Device

2

## Using the Accu-Chek FastClix Lancing Device

	<ul style="list-style-type: none"><li>The black cap is for fingertip testing only.</li><li>Remember that the opening where the lancet comes out is not in the center of the cap.</li><li>Remove the cap by pulling it straight off. Do not twist the cap.</li></ul>
	<ul style="list-style-type: none"><li>A new lancet drum is dark gray with a white end.</li></ul>
	<ul style="list-style-type: none"><li>A used lancet drum has a visible red stripe on the white end.</li><li>You cannot reuse a used lancet drum.</li><li>Do not remove the lancet drum until you have used all 6 lancets.</li></ul>
	<ul style="list-style-type: none"><li>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.</li><li>For soft skin, we suggest a depth setting of 2. For thick skin, try a higher depth setting.</li></ul>

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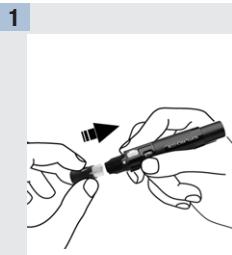
13

## 2

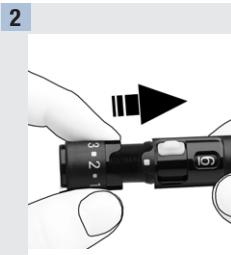
# The Accu-Chek FastClix Lancing Device

## Inserting a Lancet Drum

You must first load the lancet drum into the lancing device to get it ready for use.



Remove the cap.  
Insert a new lancet drum, white end first, until it clicks firmly into place.



Slide the cap on until it stops by aligning the notch on the cap with the notch on the lancing device.



You are now ready to use the first lancet.  
The lancet counter shows a number 6, meaning you have 6 new lancets remaining.

### NOTE

Once the lancet drum is inserted into the lancing device, do not remove the lancet drum until completely used. The lancet drum cannot be reused once it has been removed from the lancing device.

### WARNING

You must not insert the lancet drum into the lancing device and simultaneously press the release button or hold the lancing device with the release button resting on a surface such as a table top. This could release a lancet and inadvertently cause injury.

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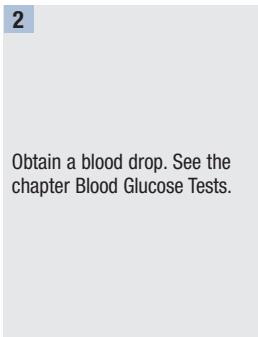
# The Accu-Chek FastClix Lancing Device

2

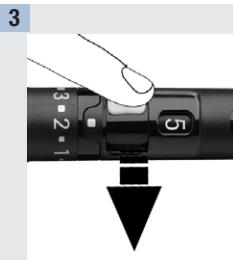
## Using the Accu-Chek FastClix Lancing Device



1  
Adjust the lancet depth by turning the comfort dial.



2  
Obtain a blood drop. See the chapter Blood Glucose Tests.



3  
Advance to the next lancet by sliding the lever forward and back all the way.  
The number in the lancet counter decreases by 1.  
The lancet counter window shows the number of remaining lancets.

### NOTE

- ALWAYS use a new, sterile lancet each time you test to avoid infection.
- For safety reasons, once you advance to a new lancet, you cannot go back to a used lancet.
- NEVER reuse a lancet.
- NEVER share your lancing device with anyone.

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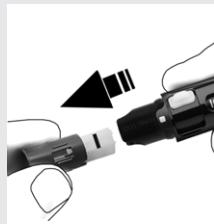
15

## 2 | The Accu-Chek FastClix Lancing Device

### Changing the Lancet Drum

When you have used the sixth and last lancet, change the lancet drum.

1



Remove the cap.

Hold the lancet drum between your thumb and index finger and pull it straight out.

A red stripe is visible on the white part, indicating that the lancet drum has been used.

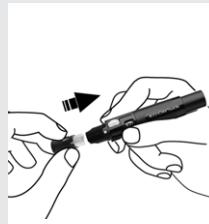
2



Throw the old lancet drum away.

**Always discard according to local regulations.**

3



Insert a new lancet drum, white end first, until it clicks firmly into place.

Slide the cap back on until it stops by aligning the notch on the cap with the notch on the lancing device.

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### 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. If the meter shows the wrong unit, contact the Accu-Chek Customer Care Service Center at 1-800-858-8072. The correct unit of measure 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.



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### Using the Accu-Chek Guide Me System

- The Accu-Chek Guide test strips are for testing fresh capillary whole blood.
- Use only 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.

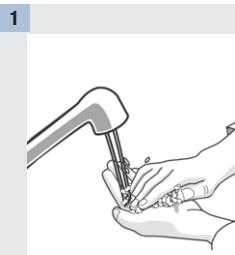
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### Performing a Blood Glucose Test with Blood from Your Fingertip

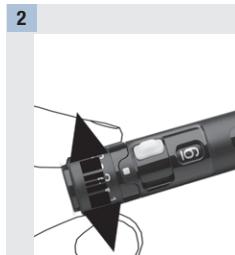
Refer to the Important Safety Information section at the beginning of this manual.

#### NOTE

- Before you perform your first blood glucose test, set the meter time and date.
- You need the meter, a test strip, and a lancing device with a lancet drum loaded 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.
- 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.
- There are 2 ways to start a blood glucose test.
  - Insert a test strip into the meter.
  - Turn on the meter by briefly pressing ① .



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



Rotate the comfort dial until the desired penetration depth lines up with the indicator.



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

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

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### 3

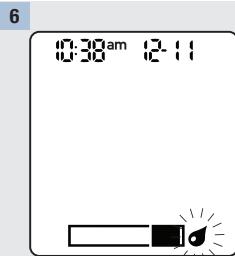
## Blood Glucose Tests



Remove a test strip from the test strip container.  
Close the cap tightly.



Insert the metallic end of the test strip into the meter. The meter turns on.



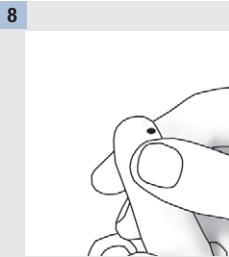
When the flashing drop symbol appears, obtain a blood drop.



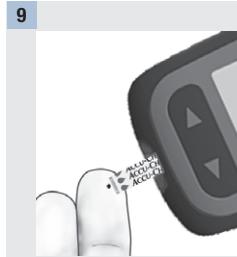
Press the lancing device firmly against the side of your fingertip.  
Press the release button all the way down to prick your finger.

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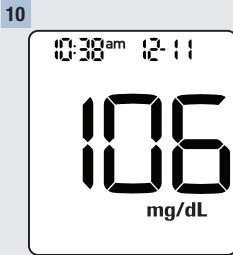
## Blood Glucose Tests | 3



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



Touch the **yellow edge** of the test strip to the blood drop. Remove your finger from the test strip when the flashing appears. Do not put blood on top of the test strip.

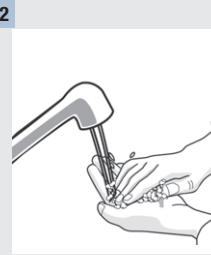


The test result appears on the display.

Remove and discard the used test strip.



Advance to the next lancet by sliding the lever forward and back all the way.



Wash hands with soap and water and dry thoroughly.

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### 3

## Blood Glucose Tests

### 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 next section before you try testing from alternative sites.

You may perform a palm or upper arm test	<ul style="list-style-type: none"><li>• immediately before a meal.</li><li>• while fasting.</li></ul>
You may NOT perform a palm or upper arm test	<ul style="list-style-type: none"><li>• up to 2 hours following a meal, when blood glucose values can rise quickly.</li><li>• after injecting bolus insulin, when blood glucose values can decrease rapidly.</li><li>• after exercise.</li><li>• if you are sick.</li><li>• if you think your blood glucose is low (hypoglycemia).</li><li>• if you sometimes do not notice when your blood glucose is low.</li></ul>

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

To obtain an AST cap and detailed AST instructions, contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

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## Unusual Blood Glucose Results

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

1. 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.

**DRAFT**

## 3 | Blood Glucose Tests

### 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 LO 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 and that blood glucose meters for self-testing generally read somewhat lower

than the laboratory result.

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### 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:

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

### About the Control Solutions

- Use only 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-check.com](http://accu-check.com) to order online.

**DRAFT**

## 4 | Control Tests

### Performing a Control Test

#### 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 controls 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.

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

1



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

2



Remove a test strip from the test strip container.

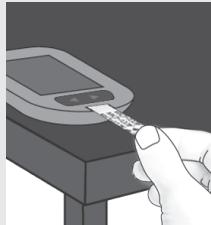
Close the cap tightly.

**DRAFT**

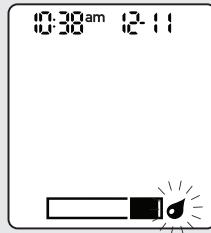
## Control Tests

4

3



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



The meter turns on.  
A flashing drop symbol appears.

4



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

5



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

6



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

**DRAFT**

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## 4

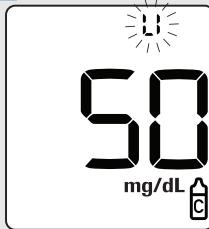
## Control Tests

7

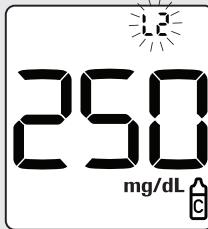


A flashing  appears when there is enough control solution in the test strip.

8



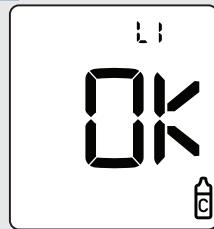
or



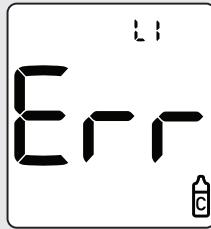
The control result, the bottle symbol, and the flashing L1 or L2 appear on the display. Press  to confirm the control level you tested.

Press the  or  to alternate between L1 and L2.

9



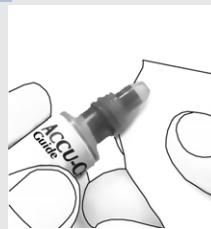
or



**OK** appears if the control result is within range.

**Err** appears if the control result is out of range.

10



Wipe the tip of the bottle with a tissue. Cap the bottle tightly.

Remove and discard the used test strip.

**DRAFT**

## 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 this 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 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.

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**DRAFT**

### Overview

- The meter automatically stores up to 720 blood glucose results in memory with the time and date of the test.
- Once 720 blood glucose results are in memory, adding a new blood glucose result deletes the oldest blood glucose result.
- If more than 720 blood glucose tests are performed within a 90-day period, only the 720 most recent test results are included in the 90-day average.
- The meter automatically stores at least 30 control results in memory, but only the current control result can be viewed on the meter. To view stored control results, transfer them to compatible software.
- Once 30 control results are in memory, adding a new control result deletes the oldest control result.
- Control results are not included in the 7, 14, 30, or 90-day averages.

#### ⚠ WARNING

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

#### NOTE

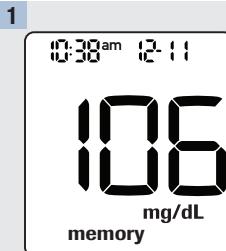
The meter has time and date auto-sync capability when paired with a mobile device that will update the meter time and date automatically. Even if you use your meter in multiple time zones, results are stored from newest to oldest and not by time and date.

**DRAFT**

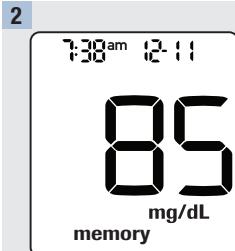
# 5

## Review Your Data

### Reviewing Blood Glucose Results in Memory



With the meter off, press  or  to view blood glucose results stored in memory. The most recent stored blood glucose result appears on the display.



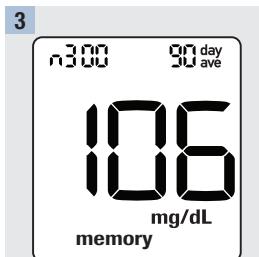
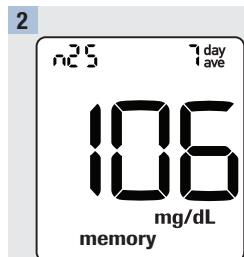
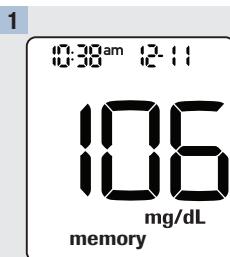
Press  to view previous test results from newest to oldest.

#### NOTE

 scrolls from newest to oldest test result.  scrolls from oldest to newest test result.

**DRAFT**

### Viewing 7, 14, 30, and 90-day Averages



**DRAFT**

5

## Review Your Data

**DRAFT**

## Overview

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

## Pairing

The meter can only pair with 1 device at a time. Pairing with a second device overwrites the first pairing.

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

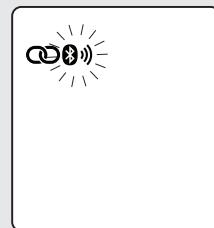
1

### On Your Mobile Device

Ensure Bluetooth is on and open the diabetes management app.

2

### On Your Meter



With meter off, press and **hold**  and  at the same time until  appears. Both  and  appear and flash on the display.



Locate the 6-digit PIN on the back of your meter.

**DRAFT**

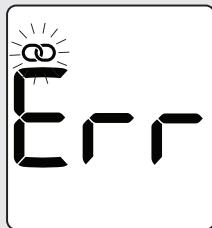
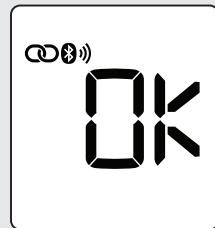
3

**On Your Mobile Device**

Within the app, follow the instructions and select your meter. When prompted, enter the meter's 6-digit PIN.

The meter times out after 30 seconds once you are prompted to enter the PIN.

4

**On Your Meter**

**OK** appears if pairing is successful. **Err** appears if pairing is unsuccessful.

**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.

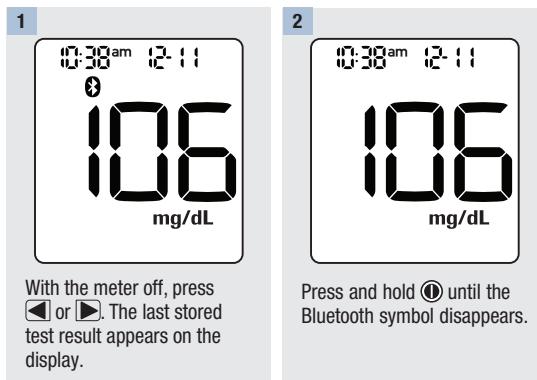
**Transferring Data Wirelessly**

If the meter is paired with a mobile device and Bluetooth is on, your test results will be automatically sent to the paired device.

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### Turning Bluetooth Off

Turn Bluetooth off to disable wireless communication (flight mode). Turning Bluetooth off will not unpair your meter.

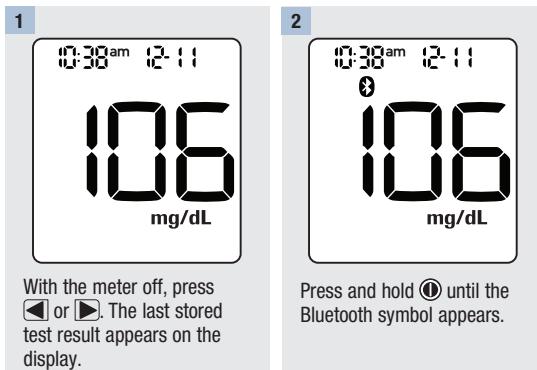


**DRAFT**

## 6 | Wireless Communication, Meter Pairing, and Data Transfer

### Turning Bluetooth On

If you have turned Bluetooth off (flight mode), follow the steps below to turn it back on. This will enable wireless communication with your mobile device.



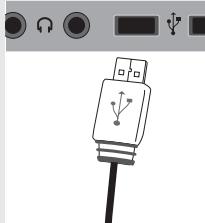
**DRAFT**

## Transferring Data Using a USB Cable

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

**1**

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

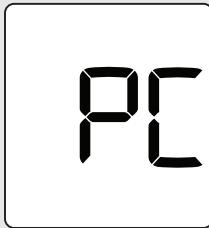
**2**

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 on the PC and initiate a data transfer.

**4**

The meter transfers the data to the software.

**NOTE**

The USB cable does not charge the meter's batteries. Remove the USB cable after you have finished.

**DRAFT**

**DRAFT**

### 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

**DRAFT**

### 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

**DRAFT**

# Meter and Lancing Device Cleaning and Disinfecting

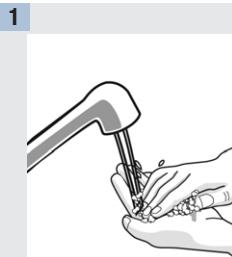
7

## How to Clean and Disinfect the Meter

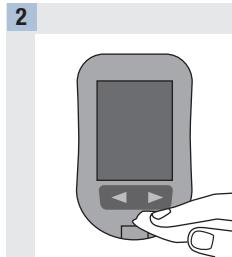
### WARNING

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.

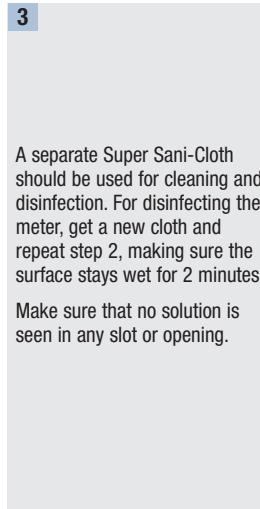


Wash hands with soap and water and dry thoroughly.



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.

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

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4



Wash hands with soap and water and dry thoroughly.

**DRAFT**

## 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

**DRAFT**

### 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.

1



Wash hands with soap and water and dry thoroughly.

2



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.

4



Wash hands with soap and water and dry thoroughly.

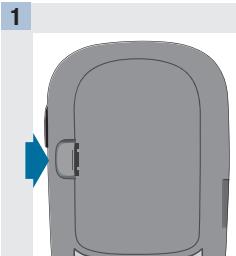
**DRAFT**

## Meter Maintenance

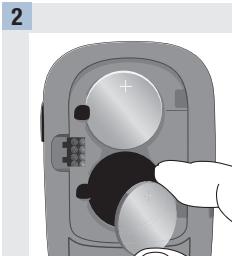
The meter automatically tests its own systems every time you turn it on and lets you know if something is wrong. See the Error Messages section in this chapter.

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.

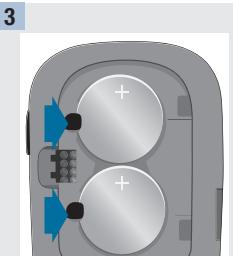
## Changing the Batteries



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.



Remove the old batteries.



Slide the new batteries under the black tabs with the (+) side facing up.

Put the battery door back in place and snap it closed.

### NOTE

- If the E-7 or E-9 error code still appears on the display after you have changed the batteries, remove the batteries again, press ① for at least 2 seconds, then reinsert the batteries.
- 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.
- Meter data is not lost when you replace the batteries.

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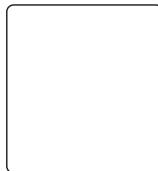
## Error Messages

### 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.

### NOTE

- The error code and Err will alternate on the display for all coded error messages (E-1 through E 14).



The meter will not turn on or the display is blank.

- Batteries are dead.

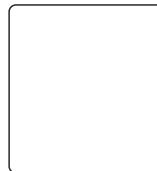
Insert new batteries.

- Display is damaged. / Meter is defective.

Contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

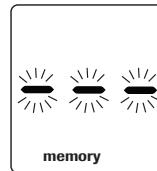
- Extreme temperatures.

Move the meter to a more temperate area.



- The meter has timed out with a USB connection.

Remove the USB cable and press the power/set button to resume testing or review test results.



memory

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

**DRAFT**

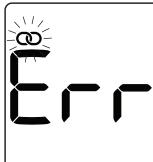
## Meter Maintenance and Troubleshooting

8



The meter is connected to a PC and a blood glucose or control test cannot be performed.

EITHER remove the USB cable and perform a blood glucose or control test OR remove the test strip and start a data transfer.



The meter was unable to pair with a mobile device.

Retry the pairing.

10:38 am 12-11



Blood glucose may be higher than the measuring range of the system.

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

10:38 am 12-11

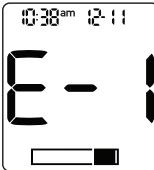


Blood glucose may be lower than the measuring range of the system.

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

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(The error code and **Err** will alternate on the display.)

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.



(The error code and **Err** will alternate on the display.)

A meter or test strip error has occurred.

Repeat the blood glucose test. If a second E-3 code appears, perform a control test with the control solution and a new test strip.

- If the control result is within the acceptable range, review the proper testing procedure and repeat the blood glucose test with a new test strip.
- If the control result is not within the acceptable range, see the Understanding Out-of-Range Control Results section in the chapter Control Tests.

This error could appear if the cap of the test strip container was not closed tightly. The test strips may have been damaged due to improper storage or handling.

In rare cases, an E-3 error code may indicate that your blood glucose is extremely high and above the system's measuring range. If you do not feel like your blood glucose is extremely high, repeat the blood glucose test. See the Unusual Blood Glucose Results section in the chapter Blood Glucose Tests. If the E-3 code still appears for your blood glucose test, **contact your healthcare professional immediately.**

**DRAFT**



(The error code and Err will alternate on the display.)

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.



(The error code and Err will alternate on the display.)

Blood or control solution was applied to the test strip before the flashing drop symbol appeared on the display.

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



(The error code and Err will alternate on the display.)

An electronic error occurred.

Remove the batteries, press and hold the power/set button for at least 2 seconds, and reinsert the batteries. Perform a blood glucose or control test.



(The error code and Err will alternate on the display.)

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.

**DRAFT**



(The error code and Err will alternate on the display.)

The batteries are almost out of power.

Change the batteries now. If the message reappears after the batteries have been replaced, remove the batteries again, press and hold the power/set button for at least 2 seconds, then reinsert the batteries.



(The error code and Err will alternate on the display.)

The time and date setting may be incorrect. A flashing wave symbol appears while the meter attempts to synchronize the time and date with the paired device.

When the wave symbol no longer appears, press the power/set button to turn the meter off. Press the power/set button a second time until the flashing test strip symbol appears. If time and date sync was not successful the meter prompts you to set them the next time you turn it on. See the Setting the Time and Date section in the chapter Your New System.

**DRAFT**

## Meter Maintenance and Troubleshooting

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(The error code and Err will alternate on the display.)

The test strip may be damaged.

Repeat the blood glucose or control test with a new test strip.



(The error code and Err will alternate on the display.)

Your blood sample may contain a high level of ascorbate.

Contact your healthcare professional.



(The error code and Err will alternate on the display.)

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 error persists, contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.



(The error code and Err will alternate on the display.)

An electronic error has occurred.

Contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

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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 30 control results with time and date.
Automatic off	90 seconds after performing a test, 15 seconds after a test strip is removed.
Power supply	Two 3-volt lithium batteries (coin cell type CR2032)
Display	LCD
Dimensions	76 x 48 x 16 mm (LWH)
Weight	Approx. 40 g (with batteries)
Construction	Hand-held
Protection class	III

**DRAFT**

Specifications	
Meter type	The Accu-Chek Guide Me meter is suitable for continuous operation.
Control solution storage conditions	Refer to the control solution package insert.
Interfaces	USB: micro-B connector; Bluetooth low energy; Continua Certified® to a Continua Certified manager. 
Radio frequency connectivity	Bluetooth low energy technology operating in the frequency band of 2.4 GHz (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 of 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
3. has an application that can accept the meter's data.

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**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 EN61326-2-6 / EN60601-1-2. 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:

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

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.

This equipment complies with FCC 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 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.

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.

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**Performance Analysis** – Refer to the test strip package insert.

**Test Principle** – Refer to the test strip package insert.

**Communication Protocol** – The Accu-Chek Guide Me blood glucose meter is Continua Certified. Continua Certified signifies that this product complies with applicable IEEE 11073-10417 standards and that it has been tested and certified against the 2016 Continua Design Guidelines which include the Blood Glucose specification for Bluetooth low energy technology, Bluetooth SIG, Glucose Profile Version 1.0 and Bluetooth SIG Glucose Service, Version 1.1.

### Product Safety Information

#### **WARNING**

- This meter meets IEC 61010-1, IEC61010-2-101, and IEC 609501-1 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.

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### 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

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### Explanation of Symbols

These symbols may appear on the packaging, on the type plate, and in the instructions for the Accu-Chek Guide Me meter.

	Caution, refer to safety-related notes in the instructions for use accompanying this product.
 FCC ID: WX3-801	This device complies with Part 15 of the FCC Rules.
 GTIN	Global Trade Item Number
 SN	Serial number
	3-volt coin cell type CR2032

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### 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

<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.”

<http://wayback.archive-it.org/7993/20161022010458/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>. Accessed January 17, 2018.

<sup>2</sup> 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 January 17, 2018.

<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, 2008. “Guideline for Disinfection and Sterilization in Healthcare Facilities.” Atlanta.  
<https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines.pdf>. Accessed Jan 17, 2018.

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### Warranty

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

Roche offers qualifying consumers that purchase an Accu-Chek Guide Me meter, a 30-day money back guarantee. If you are not fully satisfied with your Accu-Chek Guide Me 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 Me Meter Limited 3-Year Warranty**

Roche warrants to the original purchaser of the meter that your Accu-Chek Guide Me 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 Me 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 Me meter shall be replacement.

This warranty does not apply to the performance of an Accu-Chek Guide Me 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 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.

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## 10 | 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 Me 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 register your warranty online at [www.accu-chek.com/register](http://www.accu-chek.com/register).

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### Limited License

#### WARNING

CAUTION: A RESTRICTED LICENSE LIMITS USE OF THE ACCU-CHEK GUIDE ME SYSTEM IN THE UNITED STATES. READ CAREFULLY THE LIMITATIONS RECITED BELOW.

The Accu-Chek Guide Me system (meter and test strips) and its use are protected by U.S. Patent Nos. 7,276,146 (expires 4-October-2022); 7,276,147 (expires 4-October-2022); 8,298,401 (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); 7,569,126 (expires 28-December-2026); and 7,604,721 (expires 12-August-2026). A license to use the Accu-Chek Guide Me system is required until the expiration of the last-to-expire patent listed above and is only granted when the Accu-Chek Guide Me 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 Me meter. Use of other test strips supplied by another manufacturer may prevent or impair the proper function of the Accu-Chek Guide Me system.

Using the Accu-Chek Guide Me system indicates your acceptance of the restricted license to use the Accu-Chek Guide Me 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 Me 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 Me system are voided by use of the Accu-Chek Guide Me system with any test strips other than Accu-Chek Guide test strips.

#### Patent Information

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

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