## **ACCU-CHEK** \* **Guide**Blood Glucose Monitoring System



# **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 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.

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).

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:

Accu-Chek Guide 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.

#### 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-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 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.

#### 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. 12

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. Do not use on multiple patients!

Cleaning and disinfecting the meter and lancing device destroys most, but not necessarily all, bloodborne pathogens.  $^{\circ}$ 

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. 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



Front View



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

#### 2. Back Button

Returns to a previous display or field.

- 3. 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 the meter to a computer (PC).

#### 8. Test Strip Ejector

Press to remove test strip.



- 9. Test Strip Container\* (for example)
- **10. Test Strip\* Metallic End** Insert this end into meter.
- **11. Test Strip\* Yellow Edge**Touch blood drop or control solution here.

- 12. Control Solution Bottle\*
- 13. Batteries
- 14. USB Cable\*
  Connects the meter to a PC.

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

### 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

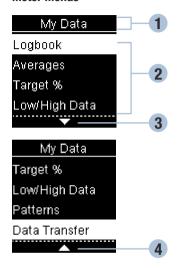
Some items may be sold separately.

#### **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.

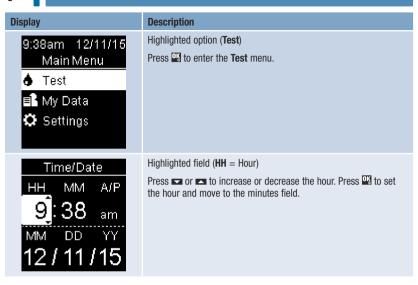
Button	Function	
4	Return to the previous display.  Return to the previous field.	
Back Button		
Up Arrow and Down Arrow Buttons	Navigate up and down in a menu. Increase or decrease a number.	
Power/Set/OK Button	Press briefly to turn the meter on.  Press and hold to turn the meter off.  Press to select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

#### **Meter Menus**



- Title of display or menu
- Menu options
- Scroll down
- Scroll up

Display	Description
	There are more menu options listed beneath the last option. Press $\blacksquare$ on the meter to view the options.
	There are more menu options listed above the first option. Press $\blacksquare$ on the meter to view the options.
	There are more menu options listed above and below the options. Press $\blacksquare$ or $\blacksquare$ on the meter to view the options.



## **Symbols**

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

Symbols	Description
1	Above target range
Ì	After meal
Č	Bedtime
Ď	Before meal
Ţ	Below target range
	Blood glucose test
<b>/</b>	Checkmark / Control test OK / Selected option or setting
C	Control bottle
X	Control test not OK
0	Edit
×	Error
0	Fasting

Symbols	Description
<b>†</b>	Flight mode
?	Help
<u>:</u>	Low battery
	My data
	No comment
*	Other
* •	Overall
<b>\$</b>	Settings
$\Diamond$	Test reminder
<u>(1</u>	Warning
<b>1</b>	Within target range

#### **Set the Language**

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



#### NOTE

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

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



- The black cap is for fingertip testing only.
- Remember that the opening where the lancet comes out is not in the center of the cap.
- Remove the cap by pulling it straight off. Do not twist the cap.



• A new lancet drum is dark gray with a white end.



- A used lancet drum has a visible red stripe on the white end.
- You cannot reuse a used lancet drum.
- Do not remove the lancet drum until you have used all 6 lancets.



- 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.

## 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.

#### **Using the Accu-Chek FastClix Lancing Device**



Adjust the lancet depth by turning the comfort dial.

2

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



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.

#### **Changing the Lancet Drum**

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





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.

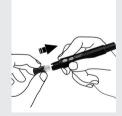
2



Throw the old lancet drum away.

Always discard according to local regulations.

3

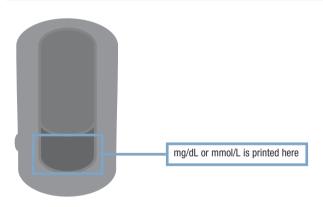


Insert a new lancet drum, white end first, until it clicks firmly into place.

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

#### 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.



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

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

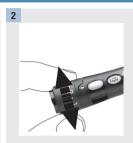
Refer to the Important Safety Information section at the beginning of this manual.

#### 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 drum loaded to perform a blood 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  $\square$ . Select **Test** >  $\square$ .



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



Adjust the comfort dial.

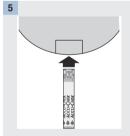


Check the **Use By** date on the test strip container.

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.



The meter turns on. **Preparing to test** appears.

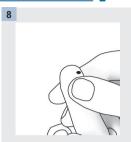


When **Apply drop** appears, obtain a blood drop.

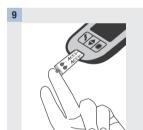


Press the lancing device firmly against the side of your fingertip.

Press the release button all the way down to prick your finger.



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



Test Remove finger Analyzing

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

10 7:38am 12/11/15 mg/dL Add Comment

The test result appears on the display.

You have the option of adding a comment to the test result by pressing W OR proceed to Step 13 to complete the test.



11

## Add Comment 85 mg/dL

Before meal

🕻 Aftermeal **S** Fasting

Fasting

Bedtime

Add Comment appears. Press
to 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.

12



The final result appears. Press or to set the comment and return to Main Menu. Or to change the comment, press to select the comment.

Press (15) to return to Add Comment.

13



Press here to eject test strip

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



Advance to the next lancet.

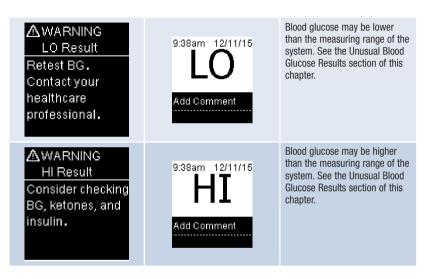


Wash hands with soap and water and dry thoroughly.



#### **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 display.



#### **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 results.



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

Symbols	Name	Description
ď	Before meal	If Patterns is ${\bf 0n}$ , select Before breakfast, lunch, dinner, or snack (see the following page for adding comments with Patterns ${\bf 0n}$ ).
Ĭ	After meal	If Patterns is $\mathbf{0n}$ , select After breakfast, lunch, dinner, or snack (see the following page for adding comments with Patterns $\mathbf{0n}$ ).
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	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-2016.



After performing a blood glucose test, the test result is displayed on the screen with Add Comment highlighted.
Press to add a comment.



The Add Comment menu appears. Press 

to highlight the desired comment (the example here is Before meal). Press 

to 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 of to set the comment and return to **Main Menu**.

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 next section before you try testing from alternative sites.

You may perform a palm or upper arm test	<ul><li>immediately before a meal.</li><li>while fasting.</li></ul>
You may NOT perform a palm or upper arm test	<ul> <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.

3

### Blood Glucose Tests

#### **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.

### 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.

#### 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-chek.com to order online.

# **Control Tests**

# **Performing a Control Test**

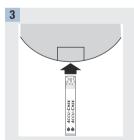
You need the meter, a test strip, and control solution Level 1 or Level 2.



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.



7



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 control result is saved without a control level.

Press OK.

Control Result
9:38am 12/11/15
5 50 mg/dL
Level 1
Within range



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

or

**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.

# **Control Tests**

# **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.



### 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 communication settings. See the chapter Wireless Communication and Meter 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 blood glucose result. Patterns is <b>Off</b> (see the Patterns section of this chapter for details).	
	70–160 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 70–160 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.	

Setting	Options	Function
Patterns	On / Off	On – a pattern is detected when 2 below-target or 3 above-target 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
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 appears.
Language		Select the language for the meter.

### Time/Date



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

Press ☑ Fress ☑ Fress



Time/Date is highlighted. Press



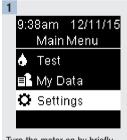
Press or to adjust each field. Press to set and proceed to the next field. Set am or pm if necessary.

Press of 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).



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

Press ♥️ B.



Press to highlight **Beeper**. Press .



Press ightharpoonup or ightharpoonup or ightharpoonup off. Press ightharpoonup to the option.

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

# **Target Ranges**

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

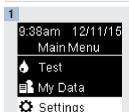
Options	Function	
Off	Arrow symbols for above, within, or below target ranges do not appear with the blood glucose results.	
Single Range	Set lower limit and upper limit for the target range.	
	You will be prompted to turn on Patterns if desired (see the Patterns section of this chapter for details).	
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).	

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.
1	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 ☑.



Press to highlight More Options. Press .

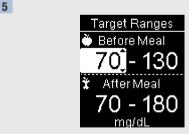


Target Ranges is highlighted. Press OK.



Press or to highlight Off, Single Range, or 2 Ranges.

Press to select an option (the example here is 2 Ranges).



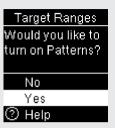
Press or to adjust the lower limit of the **Before Meal** target range. Press to set and move to the next field.

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 ✓ 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 to highlight Yes or No.

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

#### NOTE

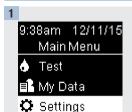
Analyzing your blood glucose results stored in the meter is an effective way for you and your healthcare professional to determine how well you are controlling your diabetes. This analysis is a valuable tool for making improvements to your diabetes management. Use care when adding comments to blood glucose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

#### **Patterns**

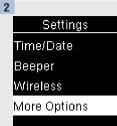
A Pattern is detected by the meter when 2 below-target (Low Pattern) or 3 above-target (High Pattern) test results with the same comment are detected within a 7-day period.

- 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
  vou to set it.

**Patterns** 



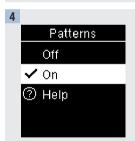
Turn the meter on by briefly pressing <sup>™</sup>. From **Main Menu**, press <sup>™</sup> to highlight **Settings**. Press <sup>™</sup>.



Press to highlight More Options. Press ...



Press to highlight **Patterns**. Press OK.

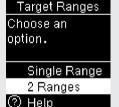




This message appears if Target Ranges is Off:
Press ■ to highlight Yes. Press

OK.

(To turn Patterns **Off**, select **No**. Press **DK** to return to **Patterns**.)



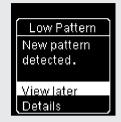
Target Ranges appears on the display (see the Target Ranges section of this chapter for details on setting target ranges).



If Patterns is **On** 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.



or

Press W to highlight View later.

Press to return to the previous screen.

#### Reminders

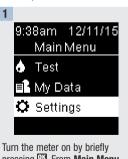
You can set up to 4 general test Reminders per day to remind you to test. A series of beeps sound and  $\diamondsuit$  is displayed for Reminders set in the meter.

#### 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 ☑. From Main Menu, press ☑ to highlight Settings. Press ☑.



Press to highlight More Options. Press .



# **Meter Settings**

Patterns

4

Reminders

🗆 12:00pm

🖾 6:00pm 🖾 10:00pm

Pre-set reminder times appear on the display. Press 

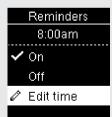
to highlight a reminder time. Press

... 5

Reminders 8:00am ✓ On
Off

Edit time

The pre-set reminder time appears. Press 
or 
to select 0n or 0ff. Press 
to move 
✓ to the option.



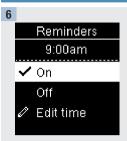
# To change the Reminder time shown:

Press to highlight **Edit time**. Press **S**.



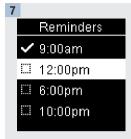
Press or to adjust each field. Press to move to the next field. Press to return to the previous menu.

Reminders



A ✓ indicates the reminder is set for the time shown and automatically set to **0n**. To turn the reminder off, press **□** to highlight **0ff**.

Press of to return to Reminders.



The reminder time appears.

Press 

to continue to set
additional reminders or press
to return to More Options.

# Meter Settings Post Meal Reminders

#### **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  $\diamondsuit$  is displayed.

#### Post Meal reminders:

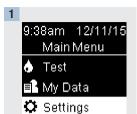
- turn off by inserting a test strip or pressing any button.
- are postponed until the next test reminder if a test was performed within 15 minutes of a test reminder.
- do not appear/beep if the meter is on at the test reminder time (including when the meter is connected to a USB cable).
- do not appear/beep 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.

5

Post Meal Reminders



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

Settings
Time/Date
Beeper
Wireless

Press to highlight More Options. Press .

More Options



Press to highlight Post Meal, Press .



# **Meter Settings**

Post Meal Reminders

4

# Post Meal

✓ On

Off

Edit time

② Help

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

5

# Post Meal

✓ On Off

Edit time

② Help

Press to highlight Edit time. Press OK

6

# Post Meal Remind after:

1 hour

1.5 hours.

2 hours

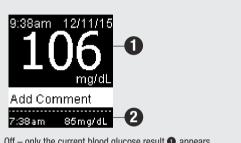
Press or to highlight 1 hour, 1.5 hours, or 2 hours after a meal for Post Meal reminders to occur.

Press to move 
to the option.

Press to set and return to the previous menu.

### Last Result

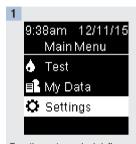
Select whether the previous blood glucose result appears with the current blood glucose result. Test results older than 24 hours do not appear.



Off – only the current blood glucose result 

appears.

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



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



2

# Settings

Time/Date

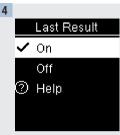
Beeper Wireless

More Options

Press to highlight More Options. Press .

More Options
Patterns
Reminders
Post Meal
Last Result

Press to highlight Last Result. Press ...

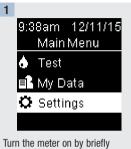


Press to set the option and return to the previous menu.

Language

### Language

Choose the language that appears on the meter.



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

Press ☑ I



Press **□** to highlight **More Options**. Press **□**.



Press to highlight Language. Press .



Press 

or 

to highlight the desired language. Press 

to move

to the option.

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

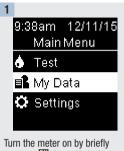
#### Overview

- 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.

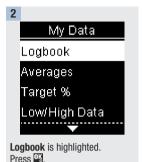
## **∴** WARNING

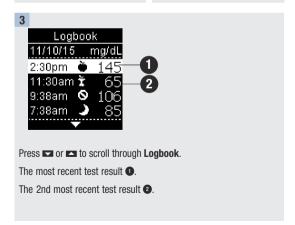
Do not change your therapy based on an individual test result in memory. Talk to your healthcare professional before changing therapy based on test results in memory.

# Logbook



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





Logbook



To view details about a test result, press or to highlight the test result. Press II. Test result details shown below only appear if **Target Ranges** is on or comments were added to a test result.





The most recent test result.

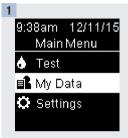




The 2nd most recent test result.

# U

# **Averages**



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

Press ☑.



Press to highlight **Averages**. Press .



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

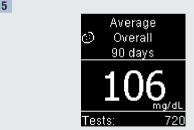


Press 

to highlight a time period (the example here is 

days). Press 

...



Press 

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

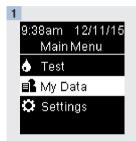
or 

to move through different averages.

### **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.

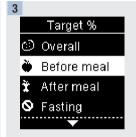
- Target % results can be viewed for 7, 14, 30, or 90-day time periods.
- Target Ranges must be set in the meter to review Target % results.



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



Press  $\blacksquare$  to highlight **Target** %. Press  $\blacksquare$ 



Press 

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

to select the option.

Target Percent (%)

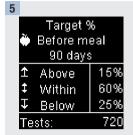


Press 

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 at the bottom of the display.

Press to return to the previous menu.

Low/High Data

#### 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.

# 6

# **Review Your Data**

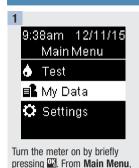
Low/High Data

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 high and low 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.*
Ĭ	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 high or low fasting blood glucose results marked as Fasting in comments.
)	Bedtime	Includes high or low 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.

Low/High Data

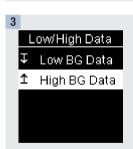


press to highlight My Data.

Press OK



Press to highlight Low/High Data. Press .



Low/High Data
No data available.

or

Enable target ranges to track low/high BG data.

If Target Ranges is on:

Press to select Low or High BG Data (the example here is High BG Data). Press .

If Target Ranges has NOT been on within the last 30 days:

This message appears on the meter (to turn on Target Ranges see the Target Ranges section in the chapter Meter Settings for details).

Low/High Data

1 High BG Data

3 Overall

3 Before meal

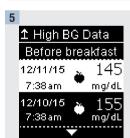
3 After meal

5 Fasting

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



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



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

Press to return to the previous menu.

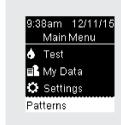
#### NOTE

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**.

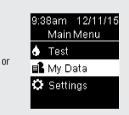
#### **Patterns**

- 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**.



from My Data on Main Menu.



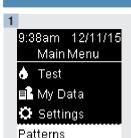
or

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

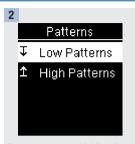
Patterns detected by the meter may be displayed on the Main Menu as:

Patterns	High and low patterns have been detected	Patterns may include the	
High Pattern(s)	One or more high patterns have been detected	following blood glucose results marked with	
Low Pattern(s)	One or more low patterns have been detected	comments:	
No Patterns	No active pattern based on test results from last 7 days	Before breakfast, After breakfast, Before lunch, After lunch, Before dinner, After 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>		

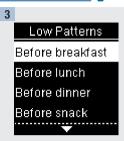
Patterns



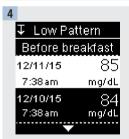
Turn the meter on by briefly pressing ☑. From **Main Menu**, press ► to highlight the Patterns option at the bottom of the screen (the example here is **Patterns**). Press ☑3.



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



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

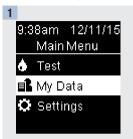


Press **t** to scroll through test results.

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.



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

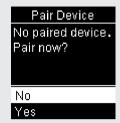
Press ♥️ .





**Data Transfer Using Wireless** 





If a device has not been paired with your 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.

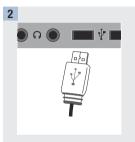
Data Transfer Using USB Cable

#### **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 USB 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.



Start the software for data analysis and initiate a data transfer.

Data Transfer Using USB Cable







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 other 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.

7

# Wireless Communication and Meter Pairing

First-Time Pairing

#### **First-Time Pairing**

The steps below are for first-time pairing.

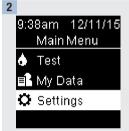
Up to 5 devices can be paired with the meter at any time.

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 ☑.



Press 

to highlight Wireless.

Press 

.

First-Time Pairing

4

Pair Device No paired device. Pair now? No Yes

5

Pair Device 123456 Enter code on device.

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.

7



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

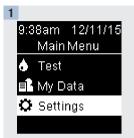
Press to return to the previous menu.

# Wireless Communication and Meter Pairing

Flight Mode

#### Flight Mode

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



Turn the meter on by briefly pressing 

I. From Main Menu, press 

to highlight Settings.

Press 

I.



Press to highlight Wireless. Press ok.



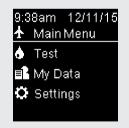
**Flight Mode** is highlighted. Press **OK**.





Press  $\blacksquare$  or  $\blacksquare$  to highlight  $\mathbf{0n}$  or  $\mathbf{0ff}.$  Press  $\blacksquare$  to move  $\checkmark$  to the option.

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

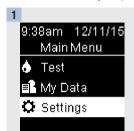


**Main Menu** with meter in Flight Mode.



#### **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 <sup>™</sup>3. From **Main Menu**, press <sup>™</sup>4 to highlight **Settings**. Press <sup>™</sup>5.



Press to highlight **Wireless**. Press .



Press to highlight **Default Device**. Press of



A list of paired devices appears.

Press to highlight the device you want as the default device.

Press to move 
to the option.

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

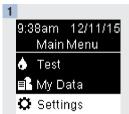
7

# Wireless Communication and Meter Pairing

Auto-Send

#### **Auto-Send**

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



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

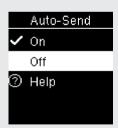


Press to highlight Wireless. Press .



Auto-Send Press OK





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

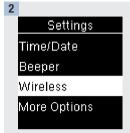
Press to set the option and return to the previous menu.

#### **Sync Time**

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



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



Press to highlight **Wireless**. Press .





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

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

# 7

# Wireless Communication and Meter Pairing

**Pairing Additional Devices** 

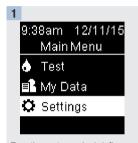
#### **Pairing Additional Devices**

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

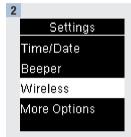
You can pair 5 devices.

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

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



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



Press 

to highlight Wireless.

Press 

K.



Press **t** to highlight **Pairing**. Press **t**.

Pairing
Pair Device
Delete Pairing

Help

Press or to highlight Pair Device. Press of.

If there are less than 5 paired devices:

**Pair Device** appears. Proceed to Step 5.

Pair Device Maximum paired devices. Delete pairing? No

If there are already 5 paired devices:

Yes

Maximum paired devices appears. You must delete a paired device before you can proceed to Step 5. Press 

to highlight Yes. Press 

to highlight Yes.

Delete Pairing

✓ Device1234

Device2345

Device3456 Device4567

Press or to highlight the device to delete. Press of.

Proceed to Step 5.

5

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

Pair Device
123456

Enter code on device.

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.



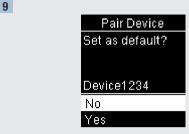
**Wireless Communication and Meter Pairing** 

Pairing Additional Devices



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

Device1234



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 of 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.



pressing . From Main Menu, press to highlight Settings. Press .



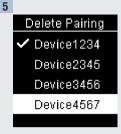
Press **□** to highlight **Wireless**. Press **□**.



**Delete Pairing** 



Delete Pairing. Press ...



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

6

# Delete Pairing Deleted: Device1234

# If the selected device is not the default device:

The pairing is deleted. The name of the deleted device and 
✓ appear.

# Delete Pairing Press OK to choose new default device.

# If the selected device is the default device:

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



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

#### What is the difference between cleaning and disinfecting?

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

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

<sup>\*</sup>Environmental Protection Agency

### Meter and Lancing Device Cleaning and Disinfecting

#### 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.

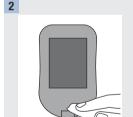
- DO NOT clean or disinfect the meter while performing a blood glucose or control test.
- DO NOT get any moisture in slots or openings.
- DO NOT spray anything onto the meter.
- DO NOT immerse the meter in liquid.
- . Always use the same product for both cleaning and disinfecting.







Wash hands with soap and water and dry thoroughly.



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.



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 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 lancing 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

#### How to Clean and Disinfect the Lancing Device

#### WARNING

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

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



Wash hands 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.



#### Meter Maintenance

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

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

#### **Changing the Batteries**



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



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



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

#### NOTE

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

#### **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 within the stated temperature limits.



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.

#### A No Connection

Connect USB cable to continue.

There is no connection between the meter and PC. Connect the USB cable and retry the connection.

#### ↑ Transfer Failed

Ensure paired device is within range and turned on.

Blood alucose results were not transferred to a paired device.

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

#### ∧ Connection Failed Check PC or USB cable.

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

Check the PC or USB cable.

#### ▲Transfer Not Allowed

Mireless communication not allowed in flight mode.

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.

# **∧**Results

Excluded One or more results may be excluded from averages.

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

#### ▲ Results Excluded

One or more results may be excluded from tardet % data.

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

#### \_\_Results Excluded

One or more results may be excluded from low/high data.

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

## **∆**Invalid Date

Check the date.

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

#### **∆** Flight Mode Active

Wireless is off. Selected setting was saved.

A meter setting was changed while in Flight Mode.

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

#### ▲Flight Mode Active Wireless is off.

Pairing is not allowed.

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.

#### ▲Pairing Failed

Retry pairing.

meter was unable to p

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.



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 on 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 reading 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.



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 are out of power.

Change the batteries now. 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.



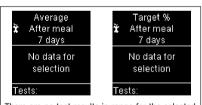
The meter time and date have been changed to match the paired device.



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 %

No data available. Enable target ranges to track target data.

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

#### Low/High Data

No data available. Enable target ranges to track low/high BG data.

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

## 1 High BG Data

No high BG data available



No low BG data available

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

9

#### Patterns

No active patterns based on last 7 days of data.

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

#### Patterns No data available. Turn on Patterns in Settings to

in Settings to show patterns for results marked

Patterns is Off.



# 9:38am 12/11/16

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.



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.

#### **Product Limitations**

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

Specifications			
Blood volume	Refer to the test strip package insert.		
Sample type			
Measuring time			
Measuring range			
Test strip storage conditions			
System operating conditions			
Meter storage conditions	Temperature: -13-158 °F		
Memory capacity	720 blood glucose results and 32 control results with time and date		
Automatic off	90 seconds		
Power supply	Two 3-volt lithium batteries (coin cell type CR2032)		
Display	LCD		
Dimensions	$80 \times 47 \times 20$ mm (LWH)		
Weight	Approx. 40 g (with batteries)		
Construction	Hand-held		
Protection class	III		
Meter type	The Accu-Chek Guide meter is suitable for continuous operation.		
Control solution storage conditions	Refer to the control solution package insert.		
Interfaces  Continua	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 2.402 GHz to 2.480 GHz with a maximum transmitted power of 0 dBm (1 mW).		

# 10

## Technical Information

**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
- 3. 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 of the device is subject to the following conditions:

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

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

In the event there is interference from another device, it is recommended that you increase the distance between the meter and that device. You can also turn off the interfering device. In addition, you can turn off Bluetooth 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.

## **Technical Information**

**Electromagnetic Compatibility** – This meter meets the electromagnetic immunity requirements as per 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:

- 1. 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 guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

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

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# Technical Information

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.

## **Technical Information**

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

#### WARNING

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

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

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

Disinfect the meter before recycling or discarding.

\*29 CFR 1910.1030 - Bloodborne pathogens

#### **Explanation of Symbols**

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

#### **Additional Supplies**

Test Strips: Accu-Chek Guide test strips

Control Solutions: Accu-Chek Guide control solutions

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

#### References

- 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 June 1, 2016.
- <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/odf/guidelines/disinfection-guidelines.pdf. Accessed January 17, 2018.

#### Warranty

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

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

#### **Accu-Chek Guide Meter Limited 3-Year Warranty**

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

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

THE ABOVE WARRANTY IS EXCLUSIVE OF ALL OTHER WARRANTIES, AND ROCHE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE BE LIABLE TO THE PURCHASER OR ANY OTHER PERSON FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL, OR PUNITIVE DAMAGES ARISING FROM OR IN ANY MAY 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.

# 11 License and Warranty

#### **Non-Warranty Service Policy**

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

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

#### **Warranty and Service Instructions**

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

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

Be sure to 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. 6,645,368 (expires 22-December-2017); 7,276,146 (expires 4-October-2022); 7,276,147 (expires 4-October-2022); 8,349,168 (expires 4-October-2022); 8,425,759 (expires 4-October-2022); 9,017,543 (expires 4-October-2022); 9,017,544 (expires 4-October-2022); 8,298,401 (expires 4-October-2022); 8,303,801 (expires 4-October-2022); 8,329,2026 (expires 4-October-2022); 7,407,811 (expires 9-May-2020); 7,452,457 (expires 2-May-2026); 7,488,601 (expires 1-February-2026); 7,494,816 (expires 29-December-2019); 8,377,707 (expires 17-October-2023); 8,859,293 (expires 17-October-2023); 7,569,126 (expires 28-December-2026); and 8,361,291 (expires 8-October-2024). A license to use the Accu-Chek Guide system is required until the expiration of the last-to-expire patent listed above and is only granted when the Accu-Chek Guide meter is used with the Accu-Chek Guide test strips.

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

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

# 11 License and Warranty

#### WARNING

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

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

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

Using the Accu-Chek FastClix lancing device indicates your acceptance of the restricted license to use the Accu-Chek FastClix lancing device only with Accu-Chek FastClix lancet drums. If you do not agree to the terms and conditions of the restricted license, you may return, at the place of purchase, the unused Accu-Chek FastClix lancing device 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 FastClix lancing device are voided by use of the Accu-Chek FastClix lancing device with any lancet drums other than Accu-Chek FastClix lancet drums.

#### **Patent Information**

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

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# **Notes**

# Notes

# **Notes**

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