ACCU-CHEK* **Aviva Connect** Blood Glucose Monitoring System



User's Manual for Single Patient Use Only

Blood Glucose Meter



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The ACCU-CHEK Aviva Connect System

The ACCU-CHEK Aviva Connect blood glucose monitoring system is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The ACCU-CHEK Aviva Connect blood glucose monitoring system is intended to be used by a single person and should not be shared.

The ACCU-CHEK Aviva Connect blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The ACCU-CHEK Aviva Connect blood glucose monitoring system should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The ACCU-CHEK Aviva Plus test strips are for use with the ACCU-CHEK Aviva Connect blood glucose meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

This system is intended to be used by a single person and should not be shared.

The ACCU-CHEK Aviva Connect blood glucose monitoring system includes:

ACCU-CHEK Aviva Connect meter with batteries, ACCU-CHEK Aviva Plus test strips,* ACCU-CHEK Aviva 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 displays are shown throughout the manual. Your data will differ.

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 complete the warranty card and mail it, 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.^{1,2}
- 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.^{1,2} Do not use on multiple patients!
- Cleaning and disinfecting the meter and lancing device destroys most, but not necessarily all, bloodborne pathogens.³
- 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 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

- Do not use the meter system to measure blood glucose in people who are experiencing cardiovascular collapse (severe shock) or decreased peripheral blood flow.
- 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.
- Not for use on critically ill patients, patients in shock, dehydrated patients, or hyperosmolar patients.

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 Aviva Connect system.

NOTE

- The meter prompts 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 Aviva Connect Meter

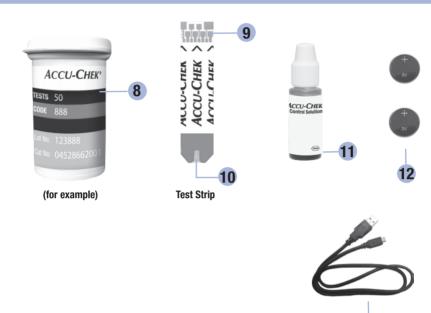


Front View

- 1. Back Button
 Returns to a previous display or field.
- Up Arrow and Down Arrow Button
 Press to move between menu options or to increase or decrease numbers.
- Display
 Shows results, messages, and test results stored in memory.
- **4. Power/Set/OK Button**Turns meter on or off and sets options.
- Test Strip Slot Insert test strip here.



- **6. Battery Drawer**Pull out to replace batteries.
- 7. Micro USB Port
 - Transfers data from the meter to a computer (PC).



8. Test Strip Container*

9. Insert this end into meter.

10. Yellow Window

Touch blood drop or control solution here.

11. Control Solution Bottle*

12. Batteries

13. USB Cable*

Connects the meter to a PC.

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

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

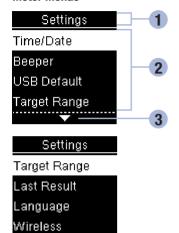
Some items may be sold separately.

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		
	Return to the previous display.		
Back Button	Return to the previous field.		
Dack Bullott	Navigate up and down in a menu.		
	Increase or decrease a number.		
Up Arrow and Down Arrow Button			
OK	Press briefly to turn the meter on.		
Power/Set/OK Button	Press and hold to turn the meter off.		
rower/ser/or button	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		
	Display Check		
	Display Check		

Meter Menus



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



Icons

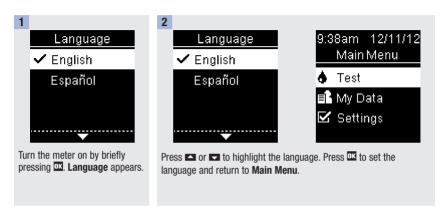
Here is a list of the icons on the display.

lcon	Description
1	Above target range
Ť	After meal
	Bedtime
ď	Before meal
Ţ	Below target range
♦	Blood glucose test
✓	Checkmark
C	Control bottle
X	Control test not OK
★ ✓ ×	Control test OK
×	Error
0	Fasting

lcon	Description
†	Flight mode
?	Help
<u>:</u>	Low battery
1	My data
	No comment
*	Other
ⓒ	Overall
* * * * * * * * * * * * * * * * * * * *	Selected setting
\checkmark	Settings
I	Temperature warning
<u> </u>	Warning
‡	Within target range

Set the Language

The meter prompts 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.

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

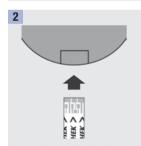
- Use only ACCU-CHEK Aviva control solutions.
- Close the control solution bottle tightly after use.
- Write the date you open the control solution bottle on the bottle label. The control solution must be
 discarded 3 months from the date the control solution bottle was opened (discard date) or on the 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
 accur-chek com to order online.

Performing a Control Test

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



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



Insert the test strip into the meter in the direction of the arrows. 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 **front edge** of the yellow window 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.

6



Control Result and the control bottle icon appear.

Press or to select the control level you tested. If you do not select a level, the control level is saved as --

If any other action is taken at this time, the control result is saved with no control level.

7



Press OK

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



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



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 Use By 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.

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



2

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



turning the comfort dial.

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

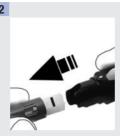
- ALWAYS use a new, sterile lancet each time you test to avoid infection.
- For safety reasons, once you advance to a new lancet, you cannot go back to a used lancet.
- . NEVER reuse a lancet.
- NEVER share your lancing device with anyone.

Changing the Lancet Drum

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

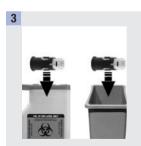
1

Remove the cap.



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

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



Throw the old lancet drum away.

Always discard according to local regulations.

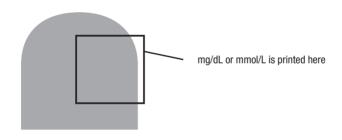


Insert a new lancet drum, white end first, until it clicks firmly into place.

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.^{1,2} 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. 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 Aviva Connect System

- Use only ACCU-CHEK Aviva Plus 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

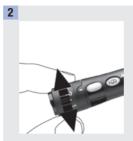
Refer to the **Important Safety Information** section at the beginning of this manual.

NOTE

- A blood glucose test cannot be performed while the meter is connected to a PC with a USB cable.
- . Before you perform your first blood glucose test, set up the meter correctly and perform a control test.
- You need the meter, a test strip, and a lancing device with a lancet drum loaded to perform a blood test.
- There are 2 ways to start a blood glucose test.
 - . Insert a test strip into the meter.
 - Turn the meter on by briefly pressing ok. Select Test > ok.



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

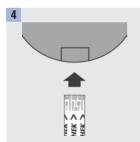


Adjust the comfort dial.



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

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



Insert the test strip into the meter in the direction of the arrows.



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.



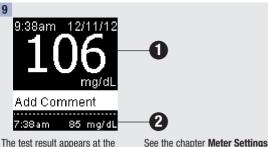
Gently squeeze your finger to assist the blood flow. This helps you get a blood drop.



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



Analyzing appears when there is enough blood in the test strip.



The test result appears at the top of the display **1**. If **Last Result** is on, the previous result appears at the bottom of the display **2**.

See the chapter **Meter Settings** for details on **Last Result**.

To add a comment to the test result, press .

10



Add Comment appears. Press

or
to highlight the comment. Press

™.

The final result appears.



With the comment highlighted, either press ☑ to set the comment or press ☑ to return to Add Comment to change the comment. If the result field is highlighted, press ☑ to set the option and return to Main Menu.

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

Icon	Description	
ď	Before meal	
Ĭ	After meal	
0	Fasting	
	Bedtime	
○ ∺	Other	
	No entry	You do not want to add a comment. You want to remove a comment for the current blood glucose result.



Remove and discard the used test strip.



Advance to the next lancet.

13

Wash hands thoroughly with soap and water.

If you see either of these results:



7:38am - 85 mg/dL

Blood glucose may be lower than the measurement range of the system. See **Unusual Blood Glucose Results** in this chapter.

Blood glucose may be higher than the measurement range of the system. See **Unusual Blood Glucose Results** in this chapter.

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 call 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. If you receive a numerical value below 20 mg/dL or above 600 mg/dL and it does not match how you feel, contact the ACCU-CHEK Customer Care Service Center toll-free at 1-800-858-8072.

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 **Unusual Blood Glucose Results**.

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.

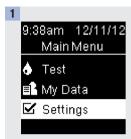
Overview

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.	
USB Default	Data Transfer / PC Reports	Select the desired activity for the data in the meter when the USB cable is plugged into the meter and a PC.	
		Data Transfer – copies the data in the meter to a compatible software program.	
		PC Reports – the meter generates data reports that open in an Internet browser and can be printed.	
Target Range	On / Off	Set Markers	
		Select On or Off.	
		On – blood glucose results are marked as above, within, or below based on the target range set in the meter.	
		Off – no target range markers appear with a blood glucose result.	
	70–160 mg/dL (pre-set target range)	Set Range	
		Select the blood glucose target range appropriate for you.	
		Consult your healthcare professional for the appropriate target range for you.	

Setting	Options	Function
Last Result	On / Off	Select whether the previous blood glucose result (within the past 24 hours) ② appears with the current blood glucose result ①
		On – the previous blood glucose result appears with the current blood glucose result.
		Off – only the current blood glucose result appears.
		9:38am 12/11/12 106 mg/dL Add Comment 7:38am 85 mg/dL
Language		Select the language for the meter.
Wireless		Select wireless communication settings. See the chapter Wireless Communication and Meter Pairing.

Time/Date (Main Menu > Settings > Time/Date)



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





Press or to adjust each field. Press to set and move to the next field.

4

Press ox to save and return to **Settings**.

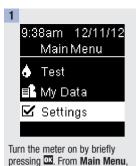
5

Meter Settings

Beeper (Main Menu > Settings > Beeper)

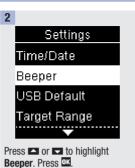
The beeper prompts you:

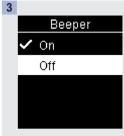
- when a test strip is inserted.
- to apply blood or control solution to the test strip.
- \bullet when enough blood or control solution is drawn into the test strip.
- when the blood glucose or control test is complete.
- when the meter is turned on.
- when a button is pressed.
- · when the batteries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



press to highlight Settings.

Press OK





Press or to highlight On or Off. Press to move to the option. Press to set the option and return to Settings.

USB Default (Main Menu > Settings > USB Default)

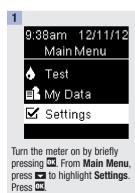
The USB Default option determines how the data in the meter is handled whenever you plug the USB cable into the meter and a PC. Your default option remains the same until you change it.

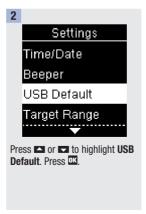
There are 2 options to display and analyze results on a PC.

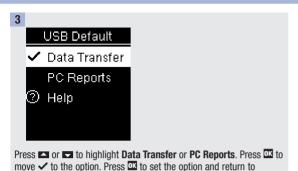
Data Transfer – the data is read by special software for diabetes management on the computer.

PC Reports – the meter generates data reports that open in an Internet browser and can be printed.

See the chapter **Data Transfer and PC Reports** for detailed information on data management.







Target Range (Main Menu > Settings > Target Range > Set Markers / Set Range)

Set Markers

Settings.

- If Set Markers is off, the markers do not appear with the blood glucose results.
- Any marker remains with the blood glucose result in the Logbook, even if you later turn Set Markers off.
- If **Set Markers** is on, the following markers appear with blood glucose results.

Marker	Meaning	
Ţ	The blood glucose result is below the target range.	
‡	The blood glucose result is within the target range.	
1	The blood glucose result is above the target range.	

5

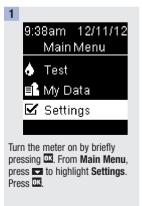
Meter Settings

Set Range

- Consult your healthcare professional for the appropriate target range for you.
- The target range can be set from a lower limit of 50-100 mg/dL to an upper limit of 101-200 mg/dL.

WARNING

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





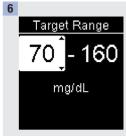


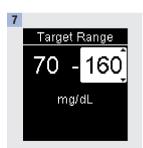


Press or to highlight On or Off. Press to move ✓ to the option. Press to set the option and return to Target Range.



Press to highlight **Set Range**. Press **S**.





Press or to adjust the upper limit of the range. Press to set the option. Target Range appears. Press to return to Settings.

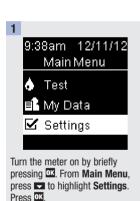
Meter Settings

Last Result (Main Menu > Settings > Last Result)

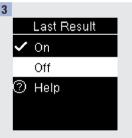
Select whether the previous blood glucose result appears with the current blood glucose result. Test results older than 24 hours do not appear.

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

Off - only the current blood glucose result appears.







Press or or to highlight On or Off. Press ox to move ✓ to the option. Press ox to set the option and return to Settings.

Language (Main Menu > Settings > Language)

Choose the language that appears on the meter.







Overview

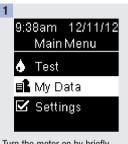
- Blood glucose results are stored from the newest to the oldest.
- The meter automatically stores up to 750 blood glucose results in memory with the time and date of the test and any test result markers.
- Once more than 750 blood glucose results are in memory, adding a new blood glucose result deletes the oldest blood glucose result.
- Only test results that have been assigned a fasting, before meal, after meal, or bedtime marker are included in the average for that marker.
- All test results are included in the overall 7-, 14-, 30-, and 90-day averages regardless of what comment is assigned.
- 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 more than 30 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.

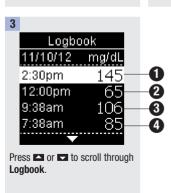
6

Logbook (Main Menu > My Data > Logbook)







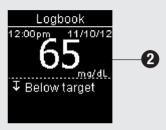


4

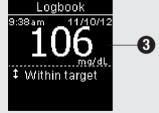
To view details about a result, press or to highlight the result. Press . These details only appear if **Target Range** and **Markers** are on or comments are added to the test result.



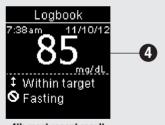
most recent result



2nd most recent result

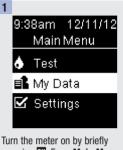


3rd most recent result



4th most recent result

Averages (Main Menu > My Data > Averages)



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

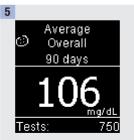


Press or to highlight Averages. Press .



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





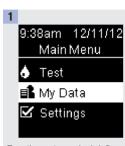
Press

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

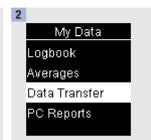
to move through different averages.

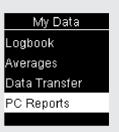
Transfer Data (Main Menu > My Data > Data Transfer/PC Reports)

This menu allows you to choose either **Data Transfer** or **PC Reports**, regardless of what the **USB Default** setting is or if you do not set the **USB Default**. For example, if the **USB Default** is **PC Reports**, but your healthcare professional wants to transfer your data, navigate to this menu and select **Data Transfer**. If the **USB Default** is not set, you can use this menu to select where to view your data each time.



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





Logbook is highlighted. Press ☐ or ☐ to highlight either Data

Transfer or PC Reports. Press ☐



Connect the USB cable to the meter.

Overview

You can wirelessly and automatically synchronize your diabetes information with a mobile device and your personal ACCU-CHEK Connect online account. The process of creating a connection between the meter and the other device is called pairing. You need an application that can accept the meter's 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.

Wireless Communication and Meter Pairing

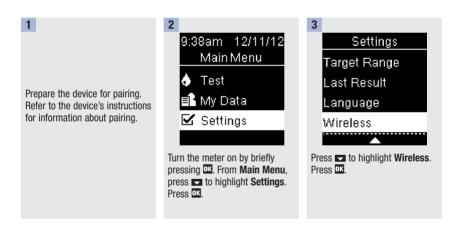
Wireless (Main Menu > Settings > Wireless)

The steps below are for first time pairing.

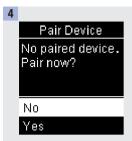
Up to 5 devices can be paired with the meter at any time.

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

The meter and the device to be paired should be within 1 meter (3 feet) of each other.



6



Pair Device appears. Press

to highlight Yes. Press OK



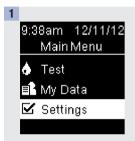
The other device displays a list of found devices, including the meter. Select Accu-Chek from the list. When prompted, enter the meter code from Step 5 into the device to be paired.



Wireless Communication and Meter Pairing

Flight Mode (Main Menu > Settings > Wireless > Flight Mode)

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



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





Flight Mode is highlighted. Press .

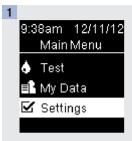


Press or to highlight On or Off. Press to move to the option. Press to set the option and return to Wireless.

Default Device (Main Menu > Settings > Wireless > Default Device)

Press OK.

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



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





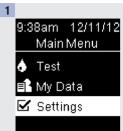


Press or to highlight the device you want as the default device. Press to set the option and return to Wireless.

Wireless Communication and Meter Pairing

Auto-Send (Main Menu > Settings > Wireless > Auto-Send)

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

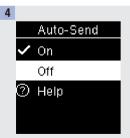


Turn the meter on by briefly pressing [™]. From **Main Menu**, press [™] to highlight **Settings**. Press [™].





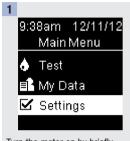
Auto-Send.



Sync Time (Main Menu > Settings > Wireless > Sync Time)

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

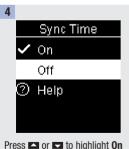
Press OK



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







or **Off**. Press to migning to or **Off**. Press to move ✓ to the option. Press to set the option and return to **Wireless**.

Wireless Communication and Meter Pairing

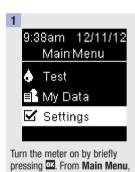
Pairing Additional Devices (Main Menu > Settings > Wireless > Pairing > Pair Device)

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 as the default until you change it.



press to highlight Settings.

Press OK







Press or to highlight Pair Device. Press .

If there are less than 5 paired devices, **Pair Device** appears. Go to Step 5.



✓ NOKIA1234
NOKIA2345
NOKIA3456
NOKIA4567

If there are already 5 paired devices, **Pair Device** appears. You must delete a paired device before you can proceed to Step 5. Select **Yes**. Press ☐ or ☐ to highlight the device to delete. Press ☐. Proceed to Step 5.

5

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

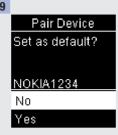


The meter displays its code.

7

The other device displays a list of found devices, including the meter. Select Accu-Chek from the list. When prompted, enter the meter code from Step 6 into the device to be paired.





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

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

Press to return to Wireless.

Delete Pairing (Main Menu > Settings > Wireless > Pairing > Delete Pairing)

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

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

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



Press OK.







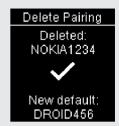




If the selected device is not the default device, the pairing is deleted. ✓ and the name of the deleted device appear.



If the selected device is the default device, you are asked 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 록. ✓ and the name of the deleted device appear, along with the new default device.

Overview

You have 2 options to display and analyze blood glucose results on a PC.

- 1. Data Transfer this option transfers the data to special software for diabetes management in a PC.
- 2. PC Reports the meter generates data reports that open in an Internet browser and can be printed.

The option you select remains as the default until you change it.

NOTE

- You cannot perform a blood glucose test while the meter is connected to a computer with a USB cable.
 If you connect the meter to a PC when a test is in progress, the test is cancelled.
- The meter has a port on the side for the small end of the USB cable. The large end of the USB cable is
 inserted into the USB port of a PC.

Set Data Transfer as the Default (Main Menu > Settings > USB Default > Data Transfer)

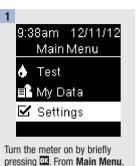






Press o r to highlight Data
Transfer. Press to move ✓
to the option. Press to set the
option and return to Settings.

Set PC Reports as the Default (Main Menu > Settings > USB Default > PC Reports)



press to highlight Settings.

Press OK





option and return to Settings.

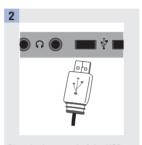
View the Data in Compatible Diabetes Management Software

These steps assume that the USB default option is set to **Data Transfer**.

The meter can be off or on.



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



Plug the large end of the USB cable into a USB port on a PC.

If the meter is off, it turns on.



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



The meter transfers the data to the software.





Data Transfer and PC Reports

NOTE

If you would like to view the data in **PC Reports** instead, follow these steps:

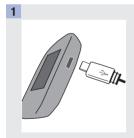
- 1. Unplug the USB cable. **Connection Lost** appears.
- 2. Press to return to Main Menu.
- 3. Select My Data>PC Reports.
- 4. Reconnect the USB cable.
- 5. PC Reports appears.

View the Data on a PC (in an Internet Browser)

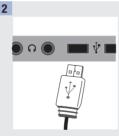
These steps assume that USB Default is set to PC Reports.

The meter can be off or on.

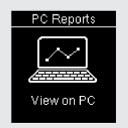
Once the meter is disconnected from the PC, the data disappears from the PC (but not the meter) unless you save it on the PC.



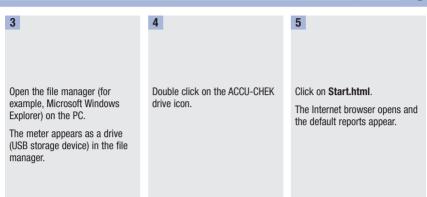
Plug the small end of the USB cable into the meter.



Plug the large end of the USB cable into a USB port on a PC.



If the meter is off, it turns on and displays **PC Reports**.



NOTE

If you would like to view the data in special diabetes management software instead, follow these steps:

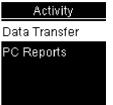
- 1. Unplug the USB cable. Connection Lost appears.
- 2. Press to return to Main Menu.
- 3. Select My Data>Data Transfer>USB Cable.
- 4. Reconnect the USB cable.
- 5. Data Transfer appears.

Data Transfer and PC Reports

Shortcut

Here is a shortcut to get to **Data Transfer** or **PC Reports**. This is a quick way to transfer the data to software or to view the meter's data on a PC.

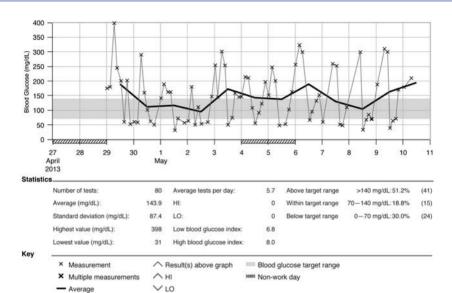
- 1. Turn the meter off.
- 2. Press and hold both and until Activity appears.
- 3. Select either Data Transfer or PC Reports.



View PC Reports

Overview

- An Internet connection is not necessary to view PC Reports.
- When the meter and PC successfully connect, the following reports are displayed in the Internet browser:
 - Trend Report This report shows the trend for several test results over the selected time period (past 3, 7, 14, 30, or 90 days).
 - Standard Day Report This report shows all data in a 24-hour grid.
 - Standard Week Report This report shows all blood glucose results according to the time when the
 test was performed and the day of the week.
 - List Report The list report (record list) shows the test results sorted by date and time of the test.



Data Transfer and PC Reports

Statistics

Below the chart of a report, you will find a statistical analysis of all test results plotted with the following information:

- · Number of tests
- Average
- Standard deviation The standard deviation is the variance of the analyzed results.
- · Highest value
- Lowest value
- Average tests per day Average number of blood glucose tests per day
- HI or LO Blood glucose results outside the measuring range
- Low blood glucose index or High blood glucose index Further information can be found in References
- Above target range Blood glucose results above the target range
- Within target range Blood glucose results within the target range
- Below target range Blood glucose results below the target range

Key

х	Blood glucose result	
X	Several blood glucose results	
	Average blood glucose results in the selected time period	
٨	Blood glucose result above the chart range	
^ (red caret)	Blood glucose may be higher than the measurement range of the system	
٧	Blood glucose may be lower than the measurement range of the system	
(green)	Your personal blood glucose target range (shown as a green bar on the PC monitor)	
(black)	Non-work days	

Print Report

Do not use the print function of the Internet browser. Use the **Print reports** button instead.



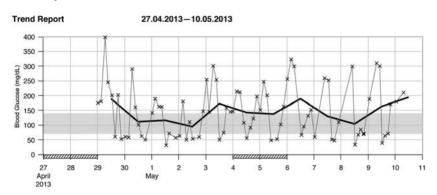
Excluded Data

The following blood glucose results are not included in a report:

- Test results outside the selected time period
- · Control results
- . LO or HI test results

Data Transfer and PC Reports

Trend Report



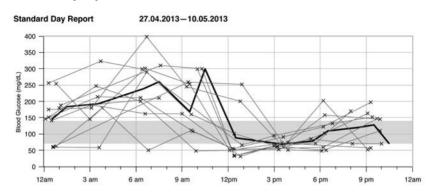
The Trend Report shows the trend of blood glucose results over the selected time period.

The date appears on the horizontal x-axis. The blood glucose results appear on the vertical y-axis. The test results are connected by a thin black line in chronological order.

If you set a target range in the meter, it appears as a green bar on the chart. Non-work days are marked with diagonal slashes on the horizontal x-axis.

The trend of the day-to-day average blood glucose result is represented by a thick black line.

Standard Day Report

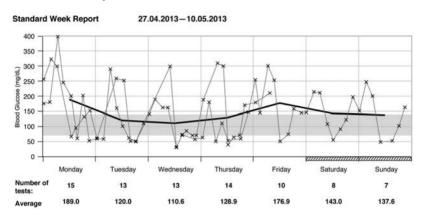


The Standard Day Report makes it easier to recognize daily patterns. All blood glucose results are placed on a 24-hour grid. Therefore, all tests performed at (approximately) the same time are shown at the same position on the horizontal time axis.

Blood glucose results are connected by a thin black line in chronological order. A thick black line represents the trend of the average level (in intervals of 1 hour if a test result falls in each interval).

Data Transfer and PC Reports

Standard Week Report



The Standard Week Report makes it easier to recognize weekly patterns. For example, you might find trends brought about by your occupation.

All blood glucose results are plotted on the chart according to the time and day the test was performed. Blood glucose results are connected by a thin black line in chronological order. A thick black line represents the trend of the average level for each day.

The number of tests and the daily blood glucose average are listed below the chart.

List Report

List Report

05/08/2013-05/10/2013

Date and Time		Blood Glucose (mg/dL)	Events
05/10/2013	07:30am	210	Before meal
	01:01am	179	
05/09/2013	08:00pm	170	After meal
	05:45pm	71	Before mea
	03:00pm	64	After meal
	12:27pm	39	Before mea
	10:18am	300	After meal
	07:37am	310	Before mea
	01:10am	188	
05/08/2013	10:00pm	70	After meal
	08:10pm	70	After meal
	05:27pm	85	Before mea
	03:17pm	67	After meal
	12:25pm	33	Before mea
	10:01am	299	After meal

The List Report shows the test results sorted by date and time of the test. All blood glucose results are listed chronologically with any additional information about the test result.

The list contains the following columns:

- · Date and Time
- Blood Glucose
- . Events Event connected to this test result

Data Transfer and PC Reports

Working with Reports

Analyzing Data in External Applications

If you want to analyze the test results using external software, you can save the data as a CSV file (Comma Separated Values). CSV files can be opened with a text editor or spreadsheet program.

The CSV file contains all test results saved in the meter. Test results transferred at an earlier date are transferred again.

- Press the Save file button on the user interface.
 Depending on the configuration of the PC, the CSV file may be directly opened in a spreadsheet program. In this case, you can save the data using the Save function of the spreadsheet program.
- In the dialog box that opens, select the option to save the file.Where you find the CSV file on the PC depends on the settings in the operating system for data download.

The CSV file contains the following information:

- Serial number: Serial number of the meter.
- Download date, download time: date and time when the meter transferred the test results to the computer.
- · Date, time, result and unit of the results saved in the meter.
- Flags added to the results, indicated by an X.

In the CSV file, the date is always displayed as DD.MM.YYYY and the time as 24-hour format (hh:mm). The time format set in the meter has no influence on the format of the date and time in the CSV file.

Security Settings within the Internet Browser

The settings of the Internet browser can influence working with reports. The reports use pages with active content (JavaScript). This active content can be suppressed by security settings in the browser, causing warnings or restricted functionality. If this happens, check the Internet browser settings.

In many cases, you can create different security settings for using the Internet and working with reports (for example, at user login to the PC or by defining user profiles in the browser).

If you select the Internet browser security settings appropriately (for example, **Allow active content to run in files on My Computer**), you can work with reports without any restrictions.

NOTE

Some newer Internet browsers do not allow the **Save** function (e.g., Mozilla Firefox version 15 and higher). The files can be saved from Windows Explorer and subsequently opened using programs that are compatible with *.CSV files.

Troubleshooting

Troubleshooting Check	Action
The ACCU-CHEK drive symbol with the start.html file does not appear on the PC.	Check whether PC Reports is selected as the default.
	Check whether the PC or operating system supports data transfer via USB.
	Check whether the USB connector is firmly plugged into the correct port on the PC.
The meter is still not detected as a drive.	Plug the meter into a different USB port on the PC.



What is the difference between cleaning and disinfecting?

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

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

Approved Cleaning and Disinfecting Product

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

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

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

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

*Environmental Protection Agency

NOTE

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

Cleaning and Disinfecting the Meter

WARNING

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

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

When to Clean and Disinfect the Meter

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

NOTE

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

What to Clean and Disinfect

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

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

How to Clean and Disinfect the Meter

WARNING

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

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







Wash hands thoroughly with soap and water.



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

Make sure that no liquid enters any slot or opening.

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 thoroughly with soap and water.

Cleaning and Disinfecting the Lancing Device

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

When to Clean and Disinfect the Lancing Device

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

NOTE

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

What to Clean and Disinfect

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

- · The entire lancing device surface
- · The cap

How to Clean and Disinfect the Lancing Device

WARNING

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

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



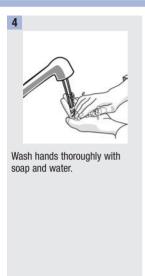
Wash hands thoroughly with soap and water.



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



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.



Meter Maintenance

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

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

Changing the Batteries



Use your thumb to slide the battery drawer out of the meter.



Remove the old batteries and place the new ones in the battery drawer with the (+) side facing down.



Slide the battery drawer back into position until it locks into place.

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.

10 Meter Maintenance and Troubleshooting

Error Messages

WARNING

Never make therapy decisions based on an error message.

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

Batteries are dead.

Insert new batteries.

Display is damaged or meter is defective.

Contact the ACCU-CHEK **Customer Care Service Center** at 1-800-858-8072.

Extreme temperatures.

Move the meter to a more temperate area.



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

FITHER 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 if the connection is lost again.



There is no connection between the meter and PC

Connect the USB cable and retry the connection.



Ensure paired device is within range and turned on.

Blood glucose results were not transferred to a paired device.

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



Data could not be transferred from the meter to the PC

Check the PC or USB cable.

___Transfer Not Allowed

Wireless 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 glucose results are excluded from the selected averages because the results are invalid or out of the system measurement range.

▲Invalid Date

Check the date.

The date entered is not valid.

Enter the correct date.

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Meter Maintenance and Troubleshooting

▲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.

AFlight 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 ${\bf Flight\ Mode}.$

▲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.

The meter was unable to pair with a device.

Retry the pairing.



The test strip may be damaged or not properly inserted.

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



A meter or test strip error has occurred.

Your blood glucose may be extremely high or a meter or a test strip error has occurred.

- If your test result matches how you feel, contact your healthcare professional immediately.
- If your test result does not match how you feel, 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, your blood glucose result may be extremely high

- and above the system's reading range. Contact your healthcare professional immediately.
- If the second test result does not match how you feel, 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.

Meter Maintenance and Troubleshooting



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

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



The blood or control drop was applied to the test strip too late.

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.

© Electronic
Error
Remove
batteries, press
any button,
reinsert batteries.
(F-7)

An electronic error occurred, or in rare cases, a used test strip was removed and reinserted.

Remove the batteries, press any button, 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, wait 5 minutes, 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, slide the battery drawer out of the meter, press any meter button, then reinsert the battery drawer into position.



The time and date setting may be incorrect.

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

Sync Time Meter time has been changed by more than 5 minutes to match

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

paired device.



There are no results in the Loabook.



There is an invalid result in the Loabook.

Meter Maintenance and Troubleshooting



There are no results in range for the selected average.



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

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



Add Comment 7:38am 85 mg/dL

Blood glucose may be lower than the measurement 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	
Measurement range	
Test strip storage conditions	
System operating conditions	
Meter storage conditions	Temperature: -13-158 °F
Memory capacity	750 blood glucose results and 30 control results with time and date
Automatic off	90 seconds
Power supply	Two 3-volt lithium batteries (coin cell type CR2032)
Display	LCD
Dimensions	$80 \times 47 \times 19$ mm (LWH)
Weight	Approx. 40 g (with batteries)
Construction	Hand-held
Protection class	III
Meter type	The ACCU-CHEK Aviva Connect meter is suitable for continuous operation.
Control solution storage conditions	Refer to the control solution package insert.

11 Technical Information

Bluetooth® Wireless Technology

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

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

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

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

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

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

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

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

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

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

NOTE

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

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

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

Performance Analysis – Refer to the test strip package insert.

Test Principle – Refer to the test strip package insert.

11 Technical Information

Product Safety Information

WARNING

- This meter meets IEC 61010-1, IEC61010-101 and IEC 609501-1 safety standards.
- Strong electromagnetic fields may interfere with the proper operation of the meter. Do not use the meter close to sources of strong electromagnetic radiation.
- To avoid electrostatic discharge, do not use the meter in a very dry environment, especially one in which synthetic materials are present.

Travel Documentation

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

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

WARNING

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

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

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

Disinfect the meter before recycling or discarding.

*29 CFR 1910.1030 - Bloodborne pathogens

Explanation of Symbols



Caution, refer to safety-related notes in the instructions for use accompanying this product.



3-volt coin cell type CR2032

Additional Supplies

Test Strips: ACCU-CHEK Aviva Plus test strips

Control Solutions: ACCU-CHEK Aviva control solutions

Lancets: ACCU-CHEK FastClix 102-ct. lancet drums (17-6 ct. drums)

Low Blood Glucose Index or High Blood Glucose Index 4.5.6

These figures represent the frequency and the resulting risk of blood glucose values being too low or too high. Figures should be as low as possible.

The following table provides an overview to assess the risk of blood glucose values being too low or too high:

Risk	Low blood glucose index	High blood glucose index
minimal	≤1.1	≤5.0
low	1.1–2.5	5.0-10.0
medium	2.5-5.0	10.0–15.0
high	>5.0	>15.0

WARNING

The index values for low blood glucose or high blood glucose in the table are not blood glucose values. Ask your healthcare professional if you want to change your therapy based on the index values.

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://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm. Accessed March 20, 2012.
- ² CDC Clinical Reminder: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens, (2010)." http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html. Accessed March 20, 2012.
- ³ Healthcare Infection Control Practices Advisory Committee (HICPAC), William A. Rutala, Ph.D., M.P.H., and David J. Weber, M.D., M.P.H. Centers for Disease Control and Prevention, 2008. "Guideline for Disinfection and Sterilization in Healthcare Facilities." Atlanta.
- ⁴ Boris P. Kovatchev, Martin Straume, Daniel J. Cox, Leon S. Farhy (2001) "Risk analysis of blood glucose data: a quantitative approach to optimizing the control of insulin dependent diabetes." *Journal of Theoretical Medicine*, 3: pp 1-10.
- ⁵ Boris P. Kovatchev, Daniel J. Cox, Anand Kumar, Linda Gonder-Frederick, William L. Clarke (2003)
- "Algorithmic Evaluation of Metabolic Control and Risk of Severe Hypoglycemia in Type 1 and Type 2 Diabetes Using Self-Monitoring Blood Glucose Data." *Diabetes Technology & Therapeutics*, 5(5): pp 817-828.
- ⁶ Boris P. Kovatchev (2006) "Is Glycemic Variability Important to Assessing Antidiabetes Therapies." *Current Diabetes Reports*, 6: pp 350-356.

Warranty

ACCU-CHEK Aviva Connect Meter 30-day Money-back Guarantee for Qualifying Consumers

Roche offers qualifying consumers that purchase an ACCU-CHEK Aviva Connect meter, a 30-day money back quarantee. If you are not fully satisfied with your ACCU-CHEK Aviva Connect 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 Aviva Connect Meter Limited 3-Year Warranty

Roche warrants to the original purchaser of the meter that your ACCU-CHEK Aviva Connect 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 Aviva Connect 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 Aviva Connect meter shall be replacement.

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

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

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

12 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 Aviva Connect meters under the above warranty or service policy must be made to the ACCU-CHEK Customer Care Service Center. You will be mailed a return authorization label, which must be affixed to your carton for shipping the system to Roche. Cartons received without this label will be returned to you at your expense.

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

Be sure to fill out and mail the Warranty Card that comes with the ACCU-CHEK Aviva Connect system.

Limited License

WARNING

CAUTION – A RESTRICTED LICENSE LIMITS USE OF THE ACCU-CHEK AVIVA CONNECT SYSTEM IN THE UNITED STATES – READ CAREFULLY THE LIMITATIONS RECITED BELOW.

The ACCU-CHEK Aviva Connect 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); 7,407,811 (expires 9-May-2020); 8,298,401 (expires 4-October-2022); 8,329,026 (expires 4-October-2022); 7,452,457 (expires 2-May-2026); 7,488,601 (expires 1-February-2026); 7,494,816 (expires 29-December-2019); 7,569,126 (expires 28-December-2026); and 7,604,721 (expires 12-August-2026). A license to use the ACCU-CHEK Aviva Connect system is required until the expiration of the last-to-expire patent listed above and is only granted when the ACCU-CHEK Aviva Connect meter is used with the ACCU-CHEK Aviva Plus test strips.

ACCU-CHEK Aviva Plus test strips are specifically manufactured for operation with the ACCU-CHEK Aviva Connect meter. Use of other test strips supplied by another manufacturer may prevent or impair the proper function of the ACCU-CHEK Aviva Connect system.

Using the ACCU-CHEK Aviva Connect system indicates your acceptance of the restricted license to use the ACCU-CHEK Aviva Connect system only with ACCU-CHEK Aviva Plus 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 Aviva Connect 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 Aviva Connect system are voided by use of the ACCU-CHEK Aviva Connect system with any test strips other than ACCU-CHEK Aviva Plus test strips.

WARNING

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

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

12 License and Warranty

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

Using the ACCU-CHEK FastClix device indicates your acceptance of the restricted license to use the ACCU-CHEK FastClix device only with ACCU-CHEK FastClix lancet drums. Further, if you have purchased an ACCU-CHEK FastClix device that includes this restricted license, then this restricted license applies regardless of any additional offers found in ACCU-CHEK FastClix device packages. If you do not agree to the terms and conditions of the restricted license, you may return, at the place of purchase, the unused ACCU-CHEK FastClix device for a full refund. If you have any questions, contact the ACCU-CHEK Customer Care Services Center at 1-800-858-8072.

Except where prohibited by statute, all warranties covering the ACCU-CHEK FastClix device are voided by use of the ACCU-CHEK FastClix device with any lancet drums other than ACCU-CHEK FastClix lancet drums.

Patent Information

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

A averages 54 B batteries, changing 95 battery drawer 95 battery type 95 blood glucose index 107 blood glucose results, unusual 37 blood glucose test, performing 31 button, functions 12	L lancet drum, changing 28 lancet drum, inserting 26 lancing device, cleaning and disinfecting 91 lancing device, using 27 logbook 52 low blood glucose 38 M maintenance, meter 95 meter, cleaning and disinfecting 88
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Notes

Notes



Continua Certified signifies that this product complies with applicable IEEE 11073-10417 standards and that it has been tested and certified against the 2014 Continua Design Guidelines.

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