ACCU-CHEK[®] Aviva Connect Blood Glucose Monitoring System

Blood Glucose Meter

User's Manual for Single Patient Use Only



ACCU-CHEK® Aviva Connect

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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 fingertip. 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 fingertip.

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 a.m. and 8:00 p.m. 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.



Important Safety Information

WARNING

- During normal testing, any blood glucose meter or lancing device may come in contact with blood. All parts
 of the kit are considered biohazardous and can potentially transmit infectious diseases from bloodborne
 pathogens, even after you have performed cleaning and disinfecting.¹²
- The meter and lancing device should never be used by more than one person. Do not share the meter and lancing device with anyone, including family members, due to the risk of infection from bloodborne pathogens.¹² 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.



Important Safety Information

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.



Important Safety Information



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The ACCU-CHEK Aviva Connect Meter



Front View

1. Back Button

Returns to a previous display or field.

2. Up Arrow and Down Arrow Button

Press to move between menu options or to increase or decrease numbers.

3. Display

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

4. Power/Set/OK Button

Turns meter on or off and sets options.

5. Test Strip Slot

Insert test strip here.



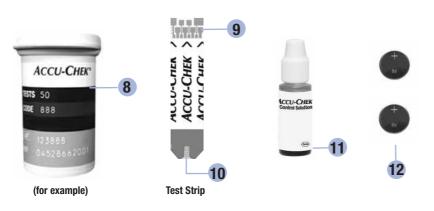
Back View

Side View

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

DRAFT

1





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.

1

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.



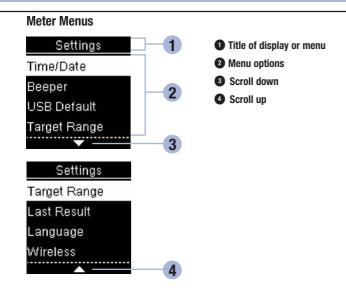
Your New System

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





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



Display	Description
9:38am 12/11/12 Main Menu Test I My Data Settings	Highlighted option (Test) Press III to enter the Test menu.
Time/Date HH MM A/P 9:38 am MM DD YY 12/11/12	Highlighted field (Hour) Press ▲ or ► to increase or decrease the hour. Press ▲ to set the hour and move to the minutes field.



Icons

Here is a list of the icons on the display.

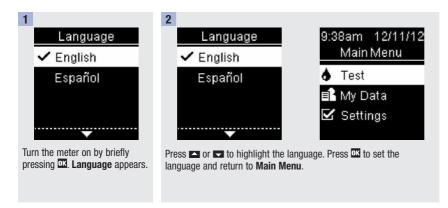
lcon	Description
1	Above target range
1 ř	After meal
┝═┥	Bedtime
♥ ↓	Before meal
Ţ	Below target range
	Blood glucose test
\checkmark	Checkmark
Ċ	Control bottle
×	Control test not OK
~	Control test OK
\bigotimes	Error
\bigcirc	Fasting
DRAF	15

lcon	Description
	Flight mode
?	Help
1	Low battery
i	My data
	No comment
*	Other
* © ~	Overall
\checkmark	Selected setting
	Settings
	Temperature warning
⚠ 1	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 accu-chek.com to order online.



Performing a Control Test

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





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.

Control Tests

2



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.

5



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.



Test

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



2 Control Tests

6



Control Result and the control bottle icon appear.

Press rightarrow or rightarrow 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.



Press OK.

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

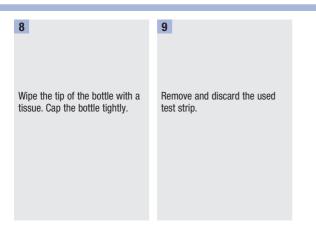


 And Out of range appear if the control result is out of range.

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Control Tests

2



NOTE

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



Understanding Out-of-Range Control Results

WARNING

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

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



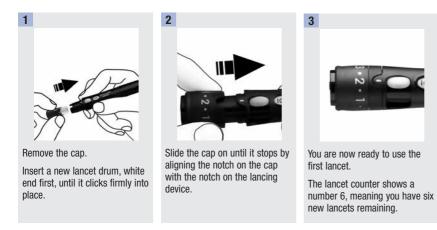
Using the ACCU-CHEK FastClix Lancing Device

1 - 2 - 1	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.
9 +2+1-	 The penetration depth indicator on the comfort dial shows the current depth setting. The higher the number, the deeper the penetration. The best depth setting is the lowest number that lets you get enough blood for a test. Try different depth settings to find the one that is right for you. For soft skin, we suggest a depth setting of 2. For thick skin, try a higher depth setting.



Inserting a Lancet Drum

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



NOTE

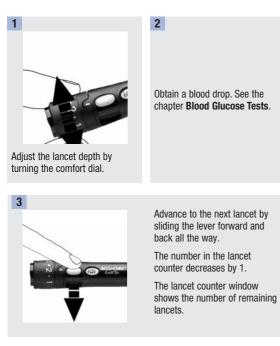
Once the lancet drum is inserted into the lancing device, do not remove the lancet drum until completely used. The lancet drum cannot be reused once it has been removed from the lancing device.

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



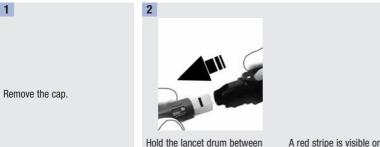
NOTE

- 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.



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.



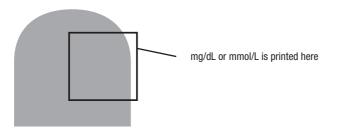
Insert a new lancet drum, white end first, until it clicks firmly into place.

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:

- D0 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 $\overline{\mathbf{OK}}$. Select **Test** > $\overline{\mathbf{OK}}$.





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



2

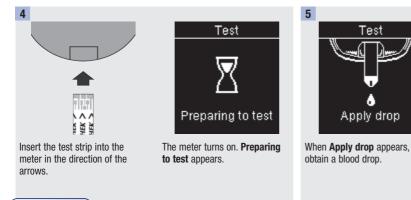
Adjust the comfort dial.



3

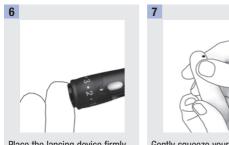
test strip container.

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







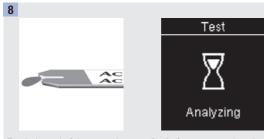


Place the lancing device firmly against the side of your fingertip.

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.



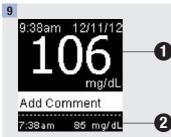
Touch the end of the test strip to the blood drop. Do not put blood on top of the test strip.



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



4



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 **CK**.

10 Add Comment 106 mg/dL Before meal After meal Fasting Bedtime

Add Comment appears. Press or to highlight the comment. Press of.

The final result appears.



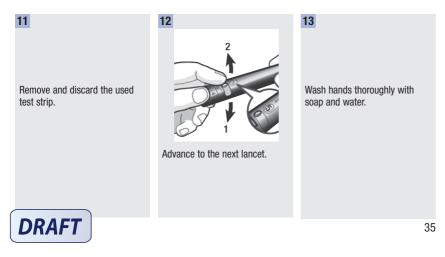
With the comment highlighted, either press I to set the comment or press I to return to Add Comment to change the comment. If the result field is highlighted, press II to set the option and return to Main Menu.



4

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

lcon	Description	
Ù	Before meal	
Ì	After meal	
	Fasting	
ŀ ≕ı	Bedtime	
*	Other	
	No entry	 You do not want to add a comment. You want to remove a comment for the current blood glucose result.



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If you see either of these results:

9:38am 12/11/12	Blood glucose may be lower than the measurement range of the system. See Unusual Blood Glucose Results in this chapter.
Add Comment 7:38am 85 mg/dL	
9:38am 12/11/12	Blood glucose may be higher than the measurement range of the system. See Unusual Blood Glucose Results in this chapter.
Add Comment 7:38am 85 mg/dL	



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.

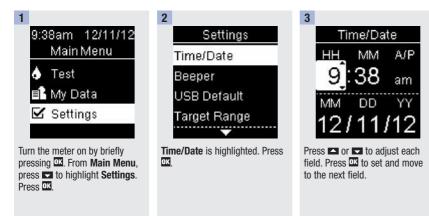


5 Meter Settings

Last Result	On / Off	Select whether the previous blood glucose result (within the past 24 hours) 2 appears with the current blood glucose result On – the previous blood glucose result appears with the current blood glucose result. Off – only the current blood glucose result appears. 9:38am 12/11/12 1066 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)





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



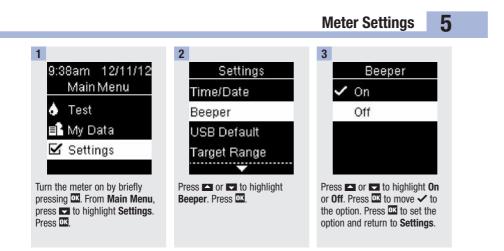
5 Meter Settings

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.
- 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).







5 Meter Settings

USB Default (Main Menu > Settings > USB Default)

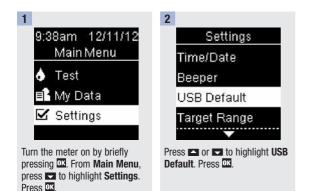
The USB Default option determines how the data in the meter is handled whenever you plug the USB cable into the meter and a PC. Your default option remains the same until you change it.

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.



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