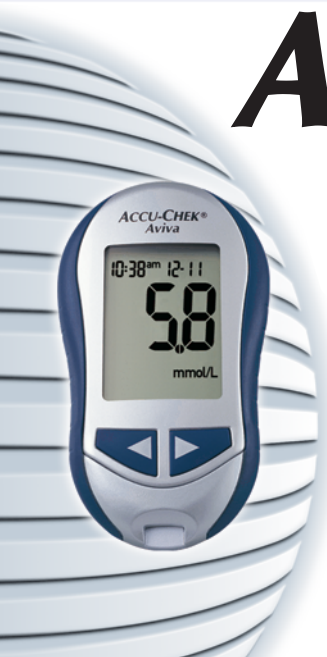


ACCU-CHEK® Aviva

BLOOD GLUCOSE METER / GLYCOMÈTRE

User's Manual
Manuel de l'utilisateur

Roche

Whether the Accu-Chek Aviva Meter is your first blood glucose meter or you have used a meter for some time; please take the time to read this manual carefully before you use your new meter. To use it correctly and dependably, you need to understand its operation, screen displays, and individual features.

This User's Manual may tell you a lot of what you already know, but it will also introduce many new features.

Please see the package insert included with the Accu-Chek Multiclix Lancing Device for important information regarding the lancing device.

Should you have any questions, please contact Accu-Chek Customer Care at 1-800-363-7949 or visit us at www.accu-chek.ca.

The Accu-Chek® Aviva System

The Accu-Chek Aviva Meter is for quantitative blood glucose testing using Accu-Chek Aviva Test Strips. The Accu-Chek Aviva Meter may be used by patients who test their own blood glucose as well as by healthcare professionals for monitoring patients' blood glucose values. Suitable for self-testing.

The system includes:

- **Accu-Chek Aviva Meter with battery**
- **Accu-Chek Aviva Test Strips and code chip (sold separately)**
- **Accu-Chek Aviva Control Solution (sold separately)**

Any object coming into contact with human blood is a potential source of infection (see: Clinical and Laboratory Standards Institute: Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Third Edition; CLSI document M29-A3, 2005).

Why Regular Blood Glucose Testing Is Important

Testing your blood glucose regularly can make a big difference in how you manage your diabetes every day. We have made it as simple as possible.

Need Help?

Call Accu-Chek Customer Care at 1-800-363-7949.

Our address:
Roche Diagnostics
201, Boulevard Armand Frappier
Laval, Québec (CANADA) H7V 4A2

Please complete the warranty card and mail it to the address above, so you receive the best customer service possible and product update news.

Important Information About Your New Meter

- Your new meter is designed for testing fresh capillary whole blood samples (for example, blood from your fingertip or forearm). The meter is for outside the body *(in vitro)* use. It should not be used to diagnose diabetes.
- Only use Accu-Chek Aviva Test Strips. Other test strips will give inaccurate results.
- The meter comes with a pre-set time and date. You may need to change the time to your time zone.
- If you have followed the steps in this manual, but still have symptoms that do not seem to match your test results—or if you have questions—talk to your healthcare professional.

Contents

The Accu-Chek Aviva Meter

Infrared (IR) Window – Transfers data from the meter to a computer or PDA.

Display – Shows results, messages, and results stored in memory.

Right and Left Arrow Buttons – Press to enter memory, adjust settings, and scroll through results.

Test Strip Slot – Insert test strip here.

On/Off/Set Button – Turns the meter on or off and sets options.

Code Chip Slot – Insert code chip into this opening.

Battery Door – Flip open the battery door by pushing the tab in the direction of the arrow.

Golden End – Insert this end of the test strip into the meter.

Yellow Window – Touch blood drop or control solution here.

Test Strip

Test Strip Container

Control Solution Bottle

On/Off/Set Button

Infrared (IR) Window

Top View

Code Chip (for example)

Battery – Insert with (+) symbol facing up.

Coding the Meter

1. Make sure the meter is off.

2. Turn the meter over.

3. Remove the old code chip (if there is one in the meter) and discard it.

Change the code chip every time you open a new box of test strips!

4. Turn the code chip over so the code number faces away from you. Push it into the code chip slot until it stops.

5. Leave the code chip in the meter until you open a new box of test strips.

Notes:

- Do not force the code chip into the meter—it is designed to go into the meter only one way.
- If you see a code "- - -" on the display, insert a code chip into the meter.

Adjusting the Time and Date—First Time Use

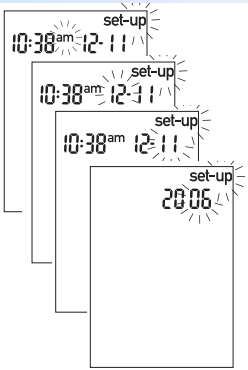
Setting the correct time and date in the meter is important if you use the meter memory or if you want to download your results to a computer.

1. Press and release ⏻ to turn the meter on. The time and date appear on the display. “Set-up” and the hour flash.

2. Press and release ◀ or ▶ to decrease or increase the hour. Press and **hold** ◀ or ▶ down to scroll faster.

3. Press and release ⏻ to set the hour. The minutes flash.

Note: When you install a new battery, the meter automatically prompts you to check the time and date when you turn it on.



4. Press and release ◀ or ▶ to adjust the minutes. Press ⓘ to set the minutes.

5. Repeat to set the am/pm, month, day, and year.

6. Once you set the year, press and **hold** ⓘ until the flashing test strip symbol appears. The time and date are now set.

7. See Chapter 3 “Meter Set-up” to set other options.

Using the Accu-Chek Aviva System

- Only use Accu-Chek Aviva Test Strips.
- Change the code chip every time you open a new box of test strips.
- Store the unused test strips in their original container.
- Close the container tightly immediately after you take a test strip out. This helps keep the test strips dry.
- Use the test strip immediately after you take it out of the container.
- Be sure to check the expiry date on the test strip container. Do not use the test strips after that date.
- Store the test strip container and meter in a cool dry place, such as a bedroom.
- Store the test strips at 2°C to 32°C. Do not freeze.
- Do not apply blood or control solution to the test strip before you insert it into the meter.

Do not store test strips in high heat and moisture areas (bathroom, kitchen, laundry room, car)! Heat and moisture can damage the test strips.

Chapter 2: Testing Your Blood Glucose

Performing a Blood Glucose Test

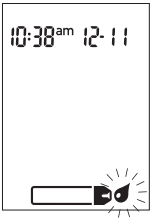
Before you perform your first blood glucose test, set up the meter correctly. You need the meter, a test strip, a lancing device, and a lancet.

1. Wash and dry your hands.

2. Prepare the lancing device.

3. Insert the test strip into the meter in the direction of the arrow. The meter turns on.

Performing a Blood Glucose Test (continued)



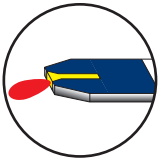
4. Make sure the code number on the display matches the code number on the test strip container. If you miss seeing the code number, remove the test strip and reinsert it into the meter.

5. A test strip and flashing blood drop symbol appear on the display.

6. Poke your fingertip with the lancing device.

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

Performing a Blood Glucose Test (continued)



8. Touch the blood drop to the **front edge** of the yellow window of the test strip. Do not put blood on top of the test strip. When you see ⌛ flash, you have enough blood in the test strip. If you applied blood but do not see the flashing ⌛, you may reapply more blood within five seconds.

Note: After a successful test, the meter turns itself off five seconds after the test strip is removed.

9. The result appears on the display. If you want to flag the test result for a special event, leave the test strip in the meter. (See the next section.) Otherwise, remove and discard the used test strip.

Flagging Test Results

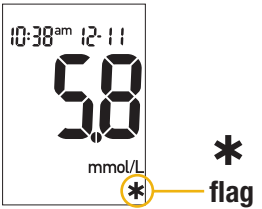
If you wish, you can “flag” your test result with an asterisk (✱) to mark a special result. For example, you might want to flag an event such as an AST result or exercise. When you review the results in memory, this “flag” can help you remember what was different about the result.

Here is how to flag a result:

1. Perform a test.

2. With the test result on the display, and the test strip STILL IN THE METER, press ◀ or ▶ once. The ✱ appears in the lower right corner.

3. Remove and discard the used test strip.

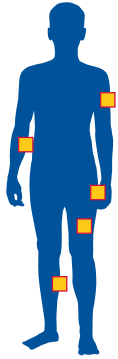


Alternate Site Testing (AST)

You have the option of testing other sites on your body besides the fingertip. Blood obtained from a fingertip can be used at any time to measure blood glucose. If blood from an alternate site—palm, forearm, upper arm, thigh, or calf—is used, there are certain times when testing is not appropriate (see next page). This is because your glucose level changes quicker in your fingertip than in the alternate sites. These differences may cause you to make the wrong therapeutic decision producing adverse health effects. Please read the following section before you try testing from other sites.

IMPORTANT

- Talk to your healthcare professional about Alternate Site Testing.
- See the package insert included with the Accu-Chek Multiclix Lancing Device for important information regarding the lancing device.



Do not change your treatment because of just one result.

NEVER ignore symptoms of high or low blood glucose.

If your blood glucose result does not match how you feel, perform a fingertip test to confirm your result. If your fingertip result still does not match how you feel, see Chapter 2 "Unusual Test Results."

Alternate site testing may be done:

- Immediately before a meal
- Fasting

DO NOT test from an alternate site:

- Two hours or less after eating
- After exercising
- If you are sick
- If you think your blood glucose is low
- If you often don't notice when your blood glucose is low
- During peak action time of short-acting insulin or rapid-acting insulin analogues
- Up to two hours after injecting a short-acting insulin or a rapid-acting insulin analogue

You need the meter, a test strip, a lancing device designed for AST, and a lancet.

1. Prepare the lancing device.
2. Insert the test strip into the meter in the direction of the arrow. The meter turns on.
3. Make sure the code number on the display matches the code number on the test strip container. If you miss seeing the code number, remove the test strip and reinsert it into the meter.

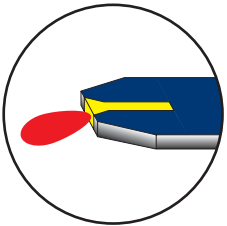
Alternate Site Testing (AST) (continued)

4. A test strip and flashing blood drop symbol appear on the display.

5. Press the lancing device firmly against a fleshy area on the alternate site. Press the lancing device up and down in a slow pumping motion to assist the flow of blood.

Note: If the blood drop is too small, reapply pressure to get a sufficient blood drop.

6. Trigger the lancing device while keeping steady pressure on the site. Apply pressure to the site with the lancing device to assist the flow of blood.



7. Touch the blood drop to the **front edge** of the yellow window of the test strip. When you see ⌛ flash, you have enough blood in the test strip. If you applied blood but do not see the flashing ⌛, you may reapply more blood within five seconds. Flag the result or remove and discard the used test strip.

Normal Blood Glucose Values

These test strips are calibrated to deliver plasma-like results. The normal fasting blood glucose range for an adult without diabetes as related to plasma is 4.1–5.9 mmol/L.[1]
For people with diabetes: Please consult your diabetes team for the blood glucose range appropriate for you.

You should treat your low or high blood glucose as recommended by your healthcare professional.

Unusual Test Results

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

Troubleshooting Checks	Action
1. ***Check if the test strips were expired.***	**Discard the test strips if they are past the expiry date.**
2. ***Check if the cap on the test strip container was always closed tightly.***	**Replace the test strips if you think they were uncapped for some time.**
3. ***Check if the test strip was out of the container for a long time.***	**Repeat the test with a new test strip.**
4. ***Check if the test strips were stored in a cool, dry place.***	**Repeat the test with a properly stored test strip.**

Troubleshooting Checks	Action
5. *Check if you followed the testing steps.*	**Read Chapter 2 "Testing Your Blood Glucose" and test again. If you still have problems, call Accu-Chek Customer Care at 1-800-363-7949.**
6. *Check if the code number on the meter display matches the code number on the test strip container.*	**If they do not match, insert the correct code chip into the meter and test again.**
7. *If you are still unsure of the problem…*	**Repeat the test with a new test strip and run a control test (see Chapter 4). If you still have problems, call Accu-Chek Customer Care at 1-800-363-7949.**

Symptoms of High or Low Blood Glucose

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

High blood glucose (hyperglycemia): fatigue, increased appetite or thirst, frequent urination, blurred vision, headache, or general aching.

Low blood glucose (hypoglycemia): sweating, trembling, blurred vision, rapid heartbeat, tingling, or numbness around mouth or fingertips.

If you are experiencing any of these symptoms, test your blood glucose. If your blood glucose result is displayed as LO or HI, contact your healthcare professional immediately.

Chapter 3: Meter Memory, Set-up, and Downloading

Memory

Storing Test Results

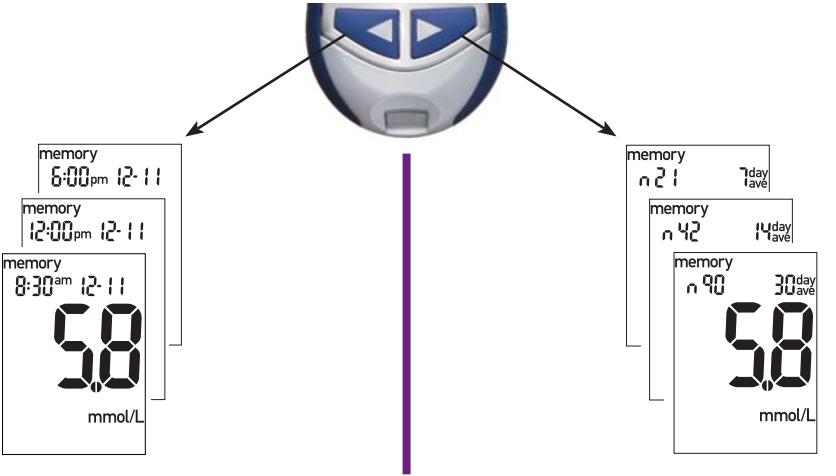
The meter automatically stores up to 500 blood glucose test results with the time and date of the test. You can review them at any time. Test results are stored from the newest to the oldest, so it is very important to set the correct time and date in the meter. Having the correct time and date setting helps ensure appropriate interpretation of stored blood glucose results by you and your healthcare team.

Notes:

- **Do not change your therapy based on one individual result in memory.**
- The memory is not lost when you replace the battery. You do need to check that the time and date are correct after you replace the battery. See Chapter 1 “Adjusting the Time and Date.”
- Once 500 results are in memory, adding a new result causes the oldest one to be deleted.
- Hold  or  down to scroll through the results faster.
- Up to 20 control results are stored in memory, but cannot be reviewed on the meter. The stored control results must first be downloaded to a compatible software application. For product availability, please contact Accu-Chek Customer Care.
- Control results are not included in the 7, 14, and 30 day averages.

Viewing Test Results

Press either ◀ or ▶ to view the memory. The most recent result appears.
Press ◀ to view previous results in order.
OR
Press ▶ to look at the 7, 14, or 30 day averages, in that order.



Meter Set-up

Using the Set-up Mode

By using the set-up mode, you can personalize the meter to suit your lifestyle. Here are the features you can customize—

Time and Date—set the time and date.

Beeper—select on or off.

Alarm clock—select on or off. If you choose on, select 1 to 4 times a day for a reminder to test.

Hypo alarm—select on or off. If you choose on, choose the blood glucose level for the alarm.

Using the set-up mode is easy. The ⓘ has three functions for the set-up mode.

- With the meter on, press and **hold** ⓘ to enter the set-up mode—about four seconds—until "set-up" flashes on the display.
- Press and release ⓘ to set the feature you have chosen.
- You can exit the set-up mode at any time by pressing and **holding** ⓘ for about four seconds until you see the flashing test strip symbol.

You are here

TIME / DATE (hrs, min, am/pm, month, day, year) → **BEEPER** (on/off) → **ALARM CLOCK** (A-1, A-2, A-3, A-4) → **HYPO ALARM** (off, on, level)

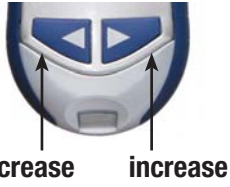
Setting the Time and Date

1. Press ⏻ to turn the meter on. The flashing test strip symbol appears.

2. Enter the set-up mode (press and **hold** ⏻ for about four seconds). "Set-up" and the hour flash on the display.

3. Press and release ◀ or ▶ to decrease or increase the hour.

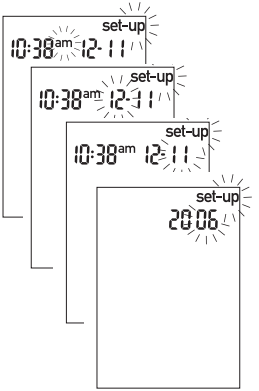
Note: Press and **hold** ◀ or ▶ down to scroll faster.



4. Press and release ⓘ to set the hour. The minutes flash.

5. Press and release ◀ or ▶ to adjust the minutes. Press ⓘ to set the minutes.

Setting the Time and Date (continued)



6. Repeat to set the am/pm, month, day, and year.

7. If you want to set up more options, press and release ⏻. If you want to exit, press and **hold** ⏻ until you see the flashing test strip symbol.

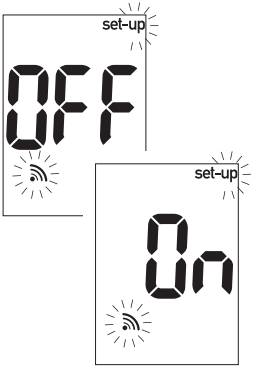
Setting the Beeper On/Off

Your new meter has the beeper pre-set to "On." You can set the beeper to "OFF," if you prefer—this will not affect your test results.

The beeper is helpful because it prompts you:

- To apply blood or control solution to the test strip
- When enough blood or control solution is drawn into the test strip
- When the test is complete
- When a button is pressed
- When it is time to test (if you set the alarm clock)
- If an error occurred while testing (even if the beeper is set to off, it still beeps for an error)

Setting the Beeper On/Off (continued)



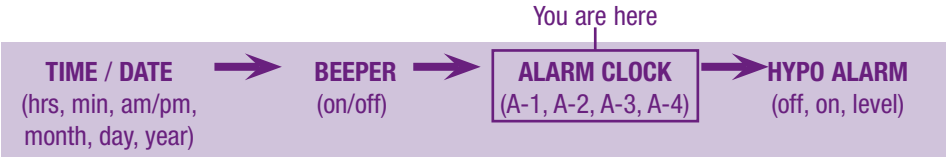
1. Press ⏻ to turn the meter on. The flashing test strip symbol appears.

2. Enter the set-up mode (press and **hold** ⏻ for about four seconds). “Set-up” and the hour flash on the display.

3. Press and release ⏻ repeatedly until you reach the display with the flashing beeper symbol and “On” or “OFF.”

4. Press ◀ or ▶ to switch between "On" or "OFF."

5. If you want to set up more options, press and release ⏻. If you want to exit, press and **hold** ⏻ until you see the flashing test strip symbol.



Setting the Alarm Clock Function

The alarm clock function is a handy way to remind you to test. You can set up to four alarms per day. The meter beeps every two minutes—up to three times. You can turn the alarm off by inserting a test strip or pressing any button. You must have the beeper set to "On" for the alarm to sound.

Your new meter is pre-set with the alarm clock function set to "OFF." You must turn it "On" to use this feature.

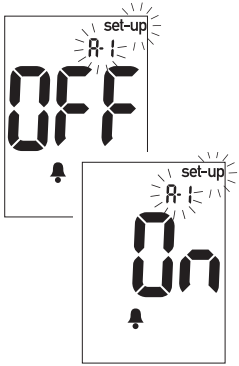
If you turn A-1, A-2, A-3, and A-4 on, the meter is pre-set with the following times for your convenience. You can adjust the times to suit your needs.

A-1 8:00 am **A-2** 12:00 pm (noon) **A-3** 6:00 pm **A-4** 10:00 pm

Notes:

- If you tested within 30 minutes of an alarm, the alarm does not occur.
- If the meter is on at the alarm time, the alarm does not occur.
- Exposure to cold conditions may disable alarms until the meter is turned on.

When you are setting the time for the alarm clock function, the bell symbol remains on the display and "set-up" flashes continuously.

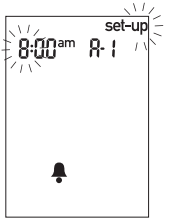


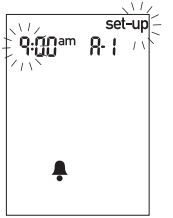
1. Press ⏻ to turn the meter on. The flashing test strip symbol appears.

2. Enter the set-up mode (press and **hold** ⏻ for about four seconds). "Set-up" and the hour flash on the display.

3. Press and release ⏻ repeatedly until you reach the display with the bell symbol, "OFF," and the flashing "set-up" and "A-1."

Setting the Alarm Clock Function (continued)

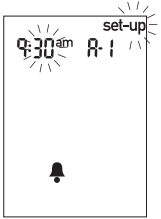


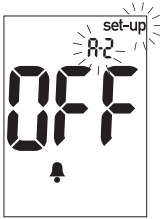


4. Press and release ◀ or ▶ to switch between "On" or "OFF." Press and release ⏻ to set your choice.

5. If you select "On," the hour flashes. "A-1" and the bell symbol remain on the display.

6. Press and release ◀ or ▶ to select the hour. Press and release ⏻ to set the hour.





7. The minutes flash. Press and release ◀ or ▶ to select 00, 15, 30, or 45. These are the only choices.

8. Press and release ⓘ to set the minutes. “Am” or “pm” flashes on the display. Press ◀ or ▶ to switch between am and pm. Press and release ⓘ to set am or pm.

9. The next alarm “A-2” and “set-up” flash on the display with “OFF” and the bell symbol. You can either set a second alarm or press and **hold** ⓘ until you see the flashing test strip symbol to exit the set-up mode.

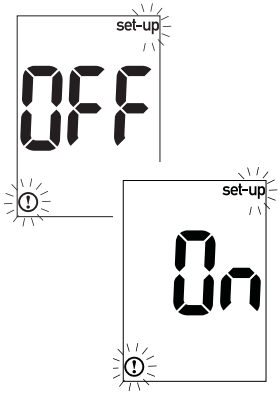
You are here

TIME / DATE (hrs, min, am/pm, month, day, year) → **BEEPER** (on/off) → **ALARM CLOCK** (A-1, A-2, A-3, A-4) → **HYPO ALARM** (off, on, level)

Setting the Hypoglycemic (Hypo) Alarm Function

You can set the meter to let you know when your blood glucose is possibly too low. You can also select what blood glucose level you want this alarm to have (3.3 to 4.4 mmol/L). Before you set the hypo alarm, talk to your healthcare professional to help you decide what blood glucose level is your hypo level. Your new meter is pre-set to "OFF" for the hypo alarm. If you want to turn it "On," follow these steps.

1. Press ⏻ to turn the meter on. The flashing test strip symbol appears.

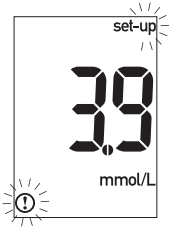


2. Enter the set-up mode (press and **hold** ⓘ for about four seconds). “Set-up” and the hour flash on the display.

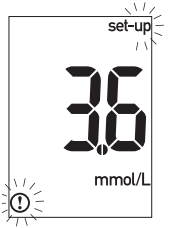
3. Press and release ⓘ repeatedly until you reach the display with “OFF” and the flashing “set-up” and ⓘ.

4. Press and release ◀ or ▶ to switch between “On” and “OFF.” Press and release ⓘ to set your choice.

Setting the Hypoglycemic (Hypo) Alarm Function (continued)



5. If you select “On,” “set-up” and ⓘ flash. The display shows 3.9 mmol/L.



6. Press and release ◀ or ▶ to select the level you want. Press and release ⓘ to set it.

7. Press and **hold** ⓘ until you see the flashing test strip symbol to exit the set-up mode.

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

Downloading Your Results to a Computer or PDA

You can transfer your stored results to a computer to track, identify patterns, and print.

Transferring Data Directly to a Computer or PDA Using Specialized Software and Infrared Cable

1. Install the software according to the instructions. To transfer the results to a computer, connect the infrared meter cable according to the instructions.
2. Run the software program and follow the instructions about how to download information. Make sure the software is ready to accept data from the meter.
3. With the meter off, press and **hold** both ◀ and ▶ until two arrows on the display alternately flash.
4. Locate the infrared (IR) window on the top of the meter.
5. Locate the IR window on either the infrared cable (computer) or PDA.

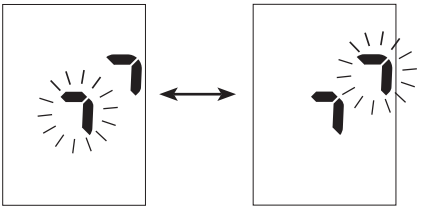
Downloading Your Results to a Computer or PDA (continued)

6. Put the meter on a flat surface. Point the two IR windows toward each other. They should be 3 to 10 cm apart.

7. Do not move the infrared cable (computer), PDA, or meter during the transfer.

8. Follow the prompts on the software.

9. The software program may shut off the meter automatically when the data transfer is complete.



Notes:

- If the data did not transfer successfully, try again. If you still have problems, call Accu-Chek Customer Care at 1-800-363-7949.
- To make the most of the download feature, you must set the time and date in the meter correctly.

Chapter 4: Control Testing

Why Perform Control Tests

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

- You open a new box of test strips
- You left the test strip container open
- You want to check the meter and test strips
- Your test strips were stored in extreme temperatures and/or humidity
- You dropped the meter
- Your test result does not agree with how you feel
- You want to check if you are testing correctly

About the Control Solutions

- Only use Accu-Chek Aviva Control Solutions.
- The meter automatically recognizes the Accu-Chek Aviva Control Solution.
- The control solution results are not displayed in memory.
- Write the date you opened the bottle on the bottle label. The solution is good for three months from that date or until the expiry date on the bottle label, whichever comes first.
- Do not use control solution that is past the expiry date.
- The solution can stain clothing. If you spill it, wash your clothes with soap and water.
- Close the bottle tightly after each use.
- Store the bottle at 2°C to 32°C. Do not freeze.

Performing a Control Test

You need the meter, a test strip, and control solution Level 1 or Level 2. The control level is printed on the bottle label.

1. Insert the test strip into the meter in the direction of the arrow. The meter turns on.

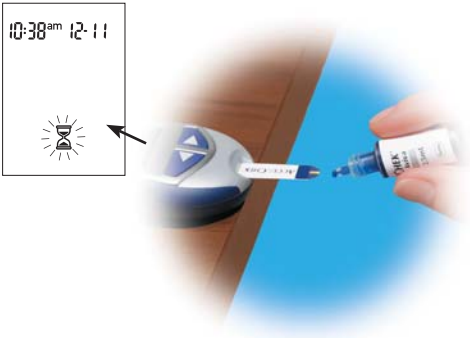
2. Make sure the code number on the display matches the code number on the test strip container. If you miss seeing the code number, remove the test strip and reinsert it into the meter.

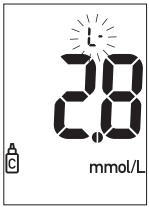
Performing a Control Test (continued)

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

4. Put the meter on a flat surface, like a table.

5. Remove the control bottle cap. Wipe the tip of the bottle with a tissue.

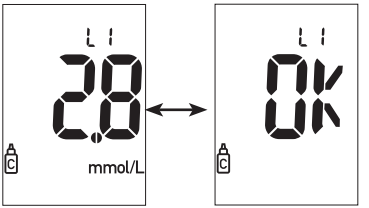




6. Squeeze the bottle until a tiny drop forms at the tip. Touch the drop to the **front edge** of the yellow window of the test strip. When you see ⌛ flash, you have enough control solution in the test strip. Wipe the tip of the bottle with a tissue, then cap the bottle tightly.

7. The result appears on the display, along with the control bottle symbol and flashing "L." Do not remove the test strip yet. Press ▶ once to mark the result as a Level 1. If you tested the Level 2 control, press ▶ a second time.

Performing a Control Test (continued)



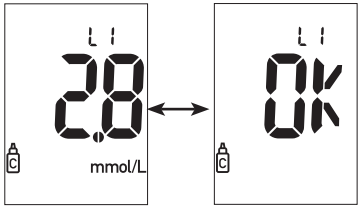
8. Press ⓘ to set the control level in the meter.

9. "OK" and the control result alternate on the display if the result is in range. The range is printed on the test strip container label. "Err" and the control result alternate on the display if the result is not in range. Remove and discard the used test strip.

Understanding Control Test Results

	Range (mmol/L)
Level 1	1.4–3.1
Level 2	14.2–19.1

Example



The label on the test strip container shows the acceptable ranges for both the Level 1 and Level 2 control solutions. The result you get should be inside this range. Make sure you compare the result to the correct level of control.

When the control result is inside the range on the test strip container, the test strips and meter are working properly.

If the control result is not inside the acceptable range, here are some things you can do to solve the problem:

Troubleshooting Checks	Action
1. ***Check if the test strips or control solutions were expired.***	**Discard the test strips or control solutions if either is past the expiry date. If the control solution was opened more than three months ago, discard it.**
2. ***Check if you wiped the tip of the control solution bottle before and after 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.**
3. ***Check if the caps on the test strip container and the control solution bottle were always closed tightly.***	**Replace the test strips or control solutions if you think either was uncapped for some time.**
4. ***Check if the test strip was out of the container for a long time.***	**Repeat the control test with a new test strip.**
5. ***Check if the test strips and control solutions were stored in a cool, dry place.***	**Repeat the control test with a properly stored test strip or control solution.**

Troubleshooting Checks	Action
6. ***Check if you followed the testing steps.***	**Read Chapter 4 “Control Testing” and test again. If you still have problems, call Accu-Chek Customer Care.**
7. ***Check if you chose 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.**
8. ***Check if the code number on the meter display matches the code number on the test strip container.***	**If they do not match, insert the correct code chip into the meter and test again.**
9. ***If you are still unsure of the problem…***	**Repeat the control test with a new test strip. If you still have problems, call Accu-Chek Customer Care.**

Chapter 5: Maintenance and Troubleshooting

Changing the Battery

1. Open the battery door on the back of the meter by pushing the tab in the direction of the arrow and pulling the door up. Remove the old battery.
2. Insert the new battery with the + side up.
3. Put the battery door back in place and snap it closed.

Notes:

- The meter uses one 3-volt lithium battery, type 2032. This type of battery can be found in many stores. It is a good idea to have a spare battery on hand.
- Be sure the battery goes in + side up or facing you.
- After you change the battery, the meter prompts you to confirm the meter's time and date settings. See Chapter 1 "Adjusting the Time and Date." All test results are saved in memory.

Cleaning the Meter

Caring for the Accu-Chek Aviva Meter is easy—just keep it free of dust. If you need to clean it, follow these guidelines carefully to help you get the best performance possible:

Do

- Make sure the meter is off
- Gently wipe the meter's surface with a soft cloth slightly dampened (wring out any excess liquid) with one of these cleaning solutions:
  - Super Sani-Cloth®
  - 70% isopropyl alcohol
  - Mild dishwashing liquid mixed with water
  - 10% household bleach solution (1 part bleach plus 9 parts water) made the same day

Do Not

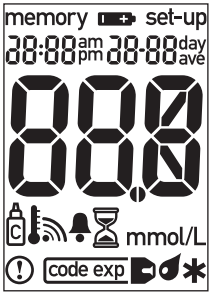
- Get any moisture in the code chip slot or test strip slot
- Spray any cleaning solution directly onto the meter
- Put the meter under water or liquid
- Pour liquid into the meter

Maintenance and Troubleshooting

The meter needs little or no maintenance with normal use. It automatically tests its own systems every time you turn it on and lets you know if something is wrong. (See Chapter 5 on “Screen Messages and Troubleshooting.”)

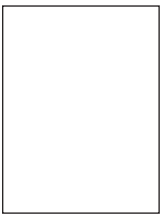
If you drop the meter or think it is not giving accurate results, call Accu-Chek Customer Care at 1-800-363-7949.

To make sure the display is working properly, turn the meter off, then press and **hold** ⏻ to see the complete display. All the segments should be clear and look exactly like the picture below. If not, call Accu-Chek Customer Care at 1-800-363-7949.



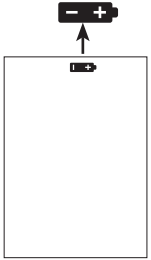
Screen Messages and Troubleshooting

Never make treatment decisions based on an error message. If you have any concerns, call Accu-Chek Customer Care at 1-800-363-7949.

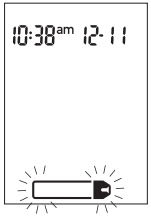


The meter will not turn on or the display is blank.

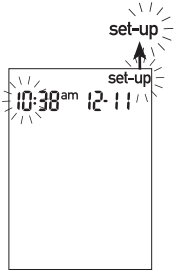
- Battery is dead — Insert new battery
- Display is damaged — Call Accu-Chek Customer Care
- Meter is defective — Call Accu-Chek Customer Care
- Extreme temperatures — Move the meter to a more temperate area



Battery power is low. Change the battery soon. See Chapter 5 “Changing the Battery.”



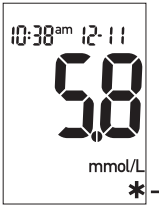
The meter is ready for you to insert a test strip.



The meter is in set-up mode, waiting for you to change or confirm settings. See Chapter 3 “Meter Set-up.”

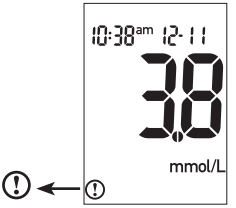
The meter is ready for a drop of blood or control solution.

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



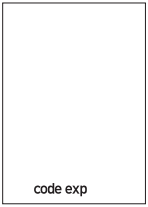
The test result was flagged. See Chapter 2 “Flagging Test Results.”

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



Blood glucose is below the defined hypo (low blood glucose) level.

The meter is not coded or the code chip is not inserted. Turn off the meter and recode it. See Chapter 1 “Coding the Meter.”



The test strips expire at the end of the current month. Before the end of the month, insert a new code chip from a new box of test strips and ensure the code chip number matches the code number on the test strip container. Make sure the time and date in the meter are correct.

Your blood glucose level may be extremely low, or the test strip may be damaged or not properly inserted. If you see this error message **after** you applied blood to the test strip, see Chapter 2 “Unusual Test Results.” If you see this error message **before** you applied blood to the test strip, remove the test strip and reinsert it, or replace it if damaged. If the message reappears, call Accu-Chek Customer Care.

The code chip is incorrect. Turn the meter off and insert a new code chip. If this does not fix the problem, call Accu-Chek Customer Care.

An error occurred during the test. Discard the test strip and repeat the test. See Chapter 1 “Understanding Your New System.”

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 test.

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

The code chip is from an expired lot of test strips. Ensure the code chip number matches the code number on the test strip container. Make sure the time and date in the meter are correct.

An electronic error occurred or, in rare cases, a used test strip was removed and reinserted. Turn the meter off and on or take the battery out for 10 seconds and reinsert it. Perform a blood glucose or control test. If the problem persists, call Accu-Chek Customer Care.

The temperature is above or below the proper range for the meter (6°C to 44°C). Move to an area between 6°C and 44°C, wait five minutes and repeat the test. Do not artificially heat or cool the meter.

The battery is almost out of power. Change the battery now. See Chapter 5 “Changing the Battery.”

The time and date settings may be incorrect. Make sure the time and date are correct and adjust, if necessary. See Chapter 3 “Setting the Time and Date.”

Note: If you see any other error screen, please call Accu-Chek Customer Care at 1-800-363-7949.

Chapter 6: Technical Information

Product Limitations

Please read the literature packaged with your test strips to find the latest information on product specifications and limitations.

Specifications

Blood volume	0.6 µL
Sample type	Fresh capillary whole blood
Measuring time	5 seconds
Measuring range	0.6–33.3 mmol/L
Test strip storage conditions	2°C to 32°C
Meter storage conditions	Temperature: -25ºC to 70ºC
System operating conditions	6°C to 44°C 10% to 90% relative humidity
Relative humidity operating range	10% to 90%

Memory capacity	500 blood glucose and 20 control results with time and date
Automatic power off	2 minutes
Power supply	One 3-volt lithium battery (type 2032)
Display	LCD
Dimensions	94 x 53 x 22 mm (LWH)
Weight	Approx. 60 g (with battery)
Construction	Hand-held
Protection class	III
Meter type	The Accu-Chek Aviva Meter is suitable for continuous operation
Control solution storage conditions	2°C to 32°C

Electromagnetic Compatibility

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

Performance Analysis

The performance data for the Accu-Chek Aviva System (Accu-Chek Aviva Meter with Accu-Chek Aviva Test Strips) were obtained using capillary blood from diabetic patients (method comparison, accuracy), venous blood (repeatability) and control solution (reproducibility). The system is calibrated with venous blood containing various levels of glucose. The reference values are obtained using the hexokinase method. For method comparison, the results were compared with results obtained using the hexokinase method with deproteinization (automatic analyzer). The hexokinase method is traceable to an NIST standard.

The Accu-Chek Aviva System meets the EN ISO 15197 requirements.

Blood glucose concentrations may be measured in whole blood or plasma. Although you always apply whole blood to the test strip, the meter displays blood glucose results that relate either to whole blood or plasma. To see whether your blood glucose meter displays results relating to whole blood or plasma, see the package insert that came with your test strips. You will also find information on how the system works, on the test principle and on reference methods.

Product Safety Information

Strong electromagnetic fields may interfere with the proper operation of the meter. Do not use this 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.

Disposing of the Meter

During blood glucose measurement, the meter itself may come into contact with blood. Used meters therefore carry a risk of infection. Please dispose of your used meter—after removing the battery—according to the regulations applicable in your country. For information about correct disposal, please contact your local council and authority.

The meter falls outside the scope of the European Directive 2002/96/EC—Directive on waste electrical and electronic equipment (WEEE).

Explanation of Symbols

On packaging, on the back of meter, and in the instructions for your Accu-Chek Aviva Meter, you may encounter the following symbols, shown here with their meaning.

Consult the instructions for use

Caution (refer to accompanying documents). Please refer to safety-related notes in the manual accompanying this instrument.

Store at

Manufacturer

REF Catalogue number

Listed by Underwriter's Laboratories, Inc.© in accordance with UL 61010A-1 and CAN/CSA C22.2 No.1010-1.

IVD For in vitro diagnostic use

This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.

Dispose in domestic waste

3V type 2032

Warranty and Service

Roche Diagnostics warrants the meter against any material and manufacturing defects that may arise during proper use of the instrument. For precise terms and conditions please see the warranty card in the box.

This warranty does not affect any statutory or other rights.

The warranty ceases to apply if the instrument has been misused or tampered with.

Roche undertakes to replace faulty components free of charge or, at their discretion, to provide fault-free replacement meter.

Statutory and other rights: This manufacturer's warranty is in addition to any statutory or other rights which may be acquired by the customer through his dealings with the instrument supplier.

The statutory guarantee provisions governing the sale of consumer goods in the country of purchase shall prevail.

Be sure to fill out the warranty card that came with your system and return to Roche Diagnostics.

Additional Supplies

The following supplies and accessories are available from your authorized Roche Diagnostics Diabetes Healthcare Center, pharmacies, or your medical/surgical supply dealer:

Test Strips

Accu-Chek Aviva Test Strips

Control Solutions

Accu-Chek Aviva Control Solutions

Catalogue numbers

Accu-Chek Aviva Care Kit	**04422058164**
Accu-Chek Aviva Test Strips (10ct)	**04454316164**
Accu-Chek Aviva Test Strips (50ct)	**04454308164**
Accu-Chek Aviva Test Strips (100ct)	**04538412164**
Accu-Chek Aviva Control Solution (2 Level)	**04455215001**

References

1. Stedman, TL, *Stedman's Medical Dictionary,* 27th Edition, 1999, p. 2082.

Information for Healthcare Professionals

Healthcare Professionals: Follow the infection control procedures appropriate for your facility.

WARNING: Patients receiving peritoneal dialysis using solutions containing Icodextrin (e.g. Extraneal, Icodial) should not use the Accu-Chek Aviva Test Strip. It could cause an overestimation of glucose results.

Decisions about whether to recommend alternate site testing (AST) should take into account the motivation and knowledge level of the patient and his or her ability to understand the considerations relative to diabetes and AST. If you are considering recommending AST for your patients, you need to understand that there is a potential for a significant difference between fingertip and alternate site blood glucose test results. The difference in capillary bed concentration and blood perfusion throughout the body can lead to sample site-to-site differences in glucose results. These physiological effects vary between individuals and can vary within a single individual based upon his or her behaviour and relative physical condition. Our studies involving AST of adults with diabetes show that most persons will find their glucose level changes more quickly in the fingers' blood than the alternate sites' blood. * This is especially important when glucose levels are falling or rising rapidly. If your patient is used to making treatment decisions based upon fingertip readings, he or she should consider the delay, or lag-time, affecting the reading obtained from an alternate site.

*Data on file

Index