

ACCU-CHEK® *Performa*

BLOOD GLUCOSE METER

Owner's Booklet

A red and white Accu-Chek Performa blood glucose meter is shown on the left side of the image. The device has a digital display showing the time 10:38 AM, the date 12-11, and a glucose reading of 5.8 mmol/L. Below the display are two arrow buttons and a small port at the bottom. The meter is set against a background of white horizontal lines.

Roche

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

Should you have any questions, please call the Accu-Chek Enquiry Line on 1800 251 816.

The Accu-Chek® Performa System

Your new Accu-Chek Performa Meter is for quantitative blood glucose testing using Accu-Chek Performa test strips.

Suitable for self-testing.

The Accu-Chek Performa meter may be used by patients who test their own blood glucose as well as by healthcare professionals for monitoring patients' blood glucose values. The system includes:

- **Accu-Chek Performa Meter with battery**
- **Accu-Chek Performa Test Strips and code chip**
- **Accu-Chek Performa Control Solution**



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.

Important Information About Your New Meter

- Your new meter is designed for testing fresh 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.
- This meter requires Accu-Chek Performa Test Strips. Other test strips will give inaccurate results.
- Your new meter comes with a preset time and date. You may need to change the time to your time zone.
- If you have followed the steps in the booklet, but still have symptoms that do not seem to match your test results—or if you have questions—talk to your healthcare professional.

Contents

Chapter 1: Understanding Your New System	7
The Accu-Chek Performa Meter	7
Coding Your Meter	9
Adjusting the Time and Date—First Time Use	11
Using the Accu-Chek Performa System	13
Chapter 2: Testing Your Blood Glucose	14
Performing a Blood Glucose Test	14
Flagging Test Results	18
Alternative Site Testing (AST)	19
Chapter 3: Meter Memory, Setup, and Downloading	26
Memory	26
Meter Setup	28
Setting the Time and Date	29
Setting the Beeper On/Off	32
Setting the Alarm Clock Function	35
Setting the Hypoglycemic (Hypo) Alarm Function	39
Downloading Your Results to a Computer or PDA	42

Chapter 4: Control Testing	44
Why Perform Control Tests	44
About the Control Solutions	45
Performing a Control Test	46
Understanding Control Test Results	50
Chapter 5: Maintenance and Troubleshooting	53
Changing the Battery	53
Cleaning Your Meter	55
Maintenance and Troubleshooting	56
Screen Messages and Troubleshooting	57
Chapter 6: Technical Information	64
Product Limitations	64
Specifications	64
Product Safety Information	67
Disposing of Your Meter	67
Guarantee	69
Additional Supplies	70
Information for Healthcare Professionals	71
Index	73

Chapter 1: Understanding Your New System

The Accu-Chek Performa Meter

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.



Infrared (IR) Window –

Used to transfer data from the meter to a computer or PDA.

On/Off/Set Button –

Turns the meter on or off and sets options.

Battery Door –

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

Code Chip Slot –

Insert code chip into this opening.

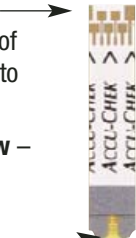


Golden End – →

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



Code Chip
(for example)



Battery – Insert with (+) symbol facing up.

Coding Your Meter



1. Make sure the meter is turned 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 meter until it stops.

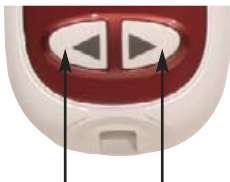
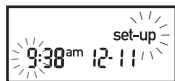
5. Leave the code chip in the meter until you open a new box of test strips.

Notes:

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

Adjusting the Time and Date—First Time Use







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

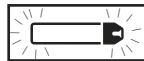
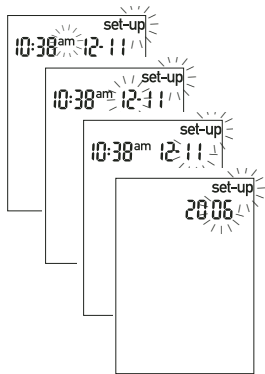
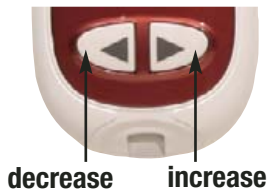






decrease

increase



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.



4. Press and release  or  to adjust the minutes. Press  to set the minutes.
5. Repeat to set am/pm, day, month, 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 Setup” to set other options.

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

Using the Accu-Chek Performa System

- Only use Accu-Chek Performa Test Strips.
- Replace the code chip every time you open a new box of test strips.
- Store the 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 your meter in a cool dry place, such as a bedroom.
- Store the test strips at 2°C to 32°C. Do not refrigerate or 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 (e.g. bathroom or kitchen)! Heat and moisture can damage your test strips.

Chapter 2: Testing Your Blood Glucose

Performing a Blood Glucose Test

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

14



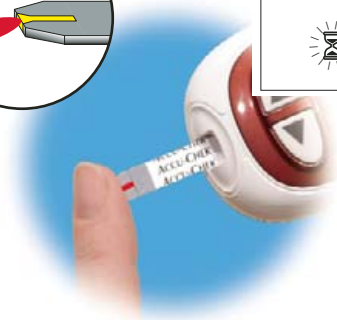
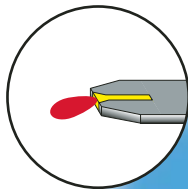
1. Wash and dry your hands.
2. Prepare your lancet device.
3. Insert a test strip into the meter in the direction of the arrows. The meter turns on.
4. Make sure the code number on the display matches the code number on the test strip container. If you miss seeing the code number, remove the test strip and reinsert it into the meter.



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



6. Perform a fingerprick with your lancet device. Blood samples taken from the palm are equivalent to blood taken from the fingertip. For detailed information on how to obtain blood from the palm refer to the Alternative Site Testing section steps 5 and 6.



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



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



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

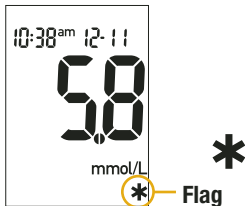
Flagging Test Results

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

18

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 test strip.



Alternative Site Testing (AST)

You have the option of testing other places on your body besides the fingertip. Blood obtained from a fingertip or palm – fleshy part of the hand under the thumb (thenar) and the little finger (hypothenar) – can be used at any time to measure blood glucose. If blood from an alternative site – forearm, upper arm, thigh, or calf - is used, there are certain times when testing is not appropriate (see below). This is because your glucose level changes quicker in your fingertip or palm than in the alternative 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 places.

IMPORTANT

- Talk to your healthcare professional about Alternative Site Testing.



Do not change your treatment because of just one result.

NEVER ignore symptoms of high or low blood glucose.

If your blood glucose does not match how you feel, perform a fingertip/palm test to confirm your result. If the fingertip/palm result still does not match how you feel, call your healthcare professional.

Alternative site testing may be done:

- Immediately before a meal
- Fasting

DO NOT test from an alternative 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
- When basal insulin is most active
- After injecting rapid-acting insulin (two hours or less)

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

20



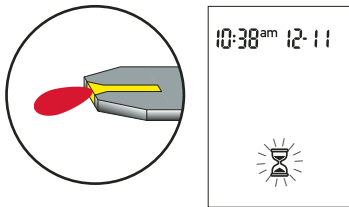
1. Prepare your lancet device.
2. Insert a test strip into the meter in the direction of the arrows. The meter turns on.
3. Make sure the code number on the display matches the code number on the test strip container. If you miss seeing the code number, remove the test strip and reinsert it into the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





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

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

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



7. Touch the 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. Discard the used test strip.

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

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.

These **test strips** are **plasma referenced** in line with the recommendations of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).²

Blood glucose concentrations may be measured in whole blood or in plasma. Although you always apply whole blood to the test strip, when using these test strips your meter will show results that are equivalent to the glucose concentrations in plasma.

Unusual Test Results

If your blood glucose result does not reflect the way you feel, follow these steps:

Troubleshooting Checks

Action

24

1. Check the expiry date of the test strips.	If they are past the expiry date, discard the test strips.
2. Ensure that the cap on the test strip container is always closed tightly.	If you think it may have been uncapped for some time, discard the test strips.
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 that your test strips were stored in a cool, dry place.	Repeat the test with properly stored test strips.
5. Check that you followed the testing steps.	Read Chapter 2 “Testing Your Blood Glucose” and test again. If you still have problems, call the Accu-Chek Enquiry Line on 1800 251 816.
6. Check that 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 in 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. If you still have problems, call the Accu-Chek Enquiry Line on 1800 251 816.

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, Setup, and Downloading



Memory

Storing Test Results

Your meter automatically stores up to 500 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. It is very important to have the correct time and date set in the meter. Having the correct time and date setting helps ensure appropriate interpretation of blood glucose results by you and your healthcare team.

26

Notes:

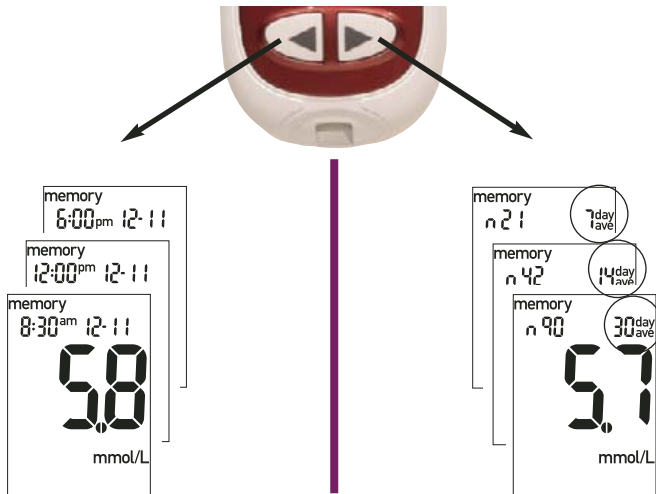
- **Do not change your therapy based on one individual result in memory.**
- The memory is not lost when you replace the battery. You do need to check that the time and date are correct after you replace the battery.
- Once 500 results are in memory, adding a new result causes the oldest one to be deleted.
- Hold  or  down to scroll through the results faster.
- The control results do not appear in memory. They are not included in the 7, 14, and 30 day averages.
- The control results are stored in memory, but cannot be reviewed on the meter. The stored results must first be downloaded to a compatible software application. For product availability, please contact Roche Diagnostics.

Viewing Test Results

Press either ◀ or ▶ to enter memory. Your most recent result appears.

Press ◀ to view previous results in order.

OR, press ▶ to look at your 7, 14, or 30 day averages, in that order.



Meter Setup

Using the Set-up Mode

By using the set-up mode, you can personalize your 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 1–4 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. You see the flashing test strip symbol.

You are here

TIME / DATE

(hrs, min, am/pm,
day, month, year)

BEEPER

(on/off)

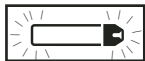
ALARM CLOCK


(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" flashes on the display. The hour flashes.




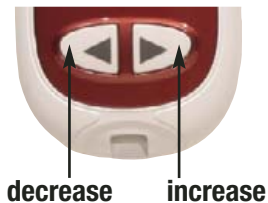
decrease

increase



3. Press and release  to decrease the hour. Press and release  to increase the hour.

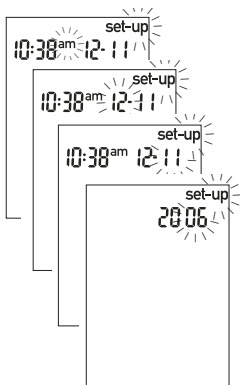


4. Press and release  to set the hour.
The minutes flash.





5. Press and release  or  to adjust the minutes. Press  to set the minutes.

Note: You can press and hold  or  to scroll faster.



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



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



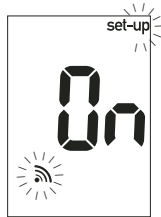
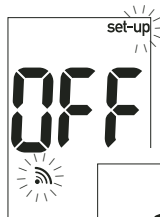
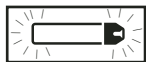
Setting the Beeper On/Off


32

Your new meter has the beeper preset 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)





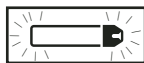
1. Press  to turn the meter on. The flashing test strip symbol appears.



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

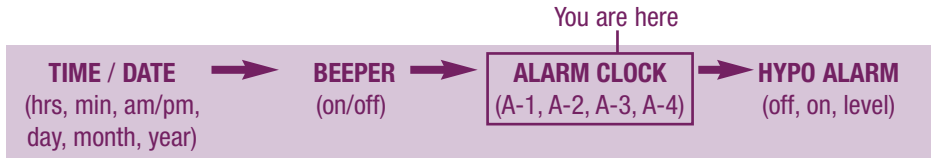
3. Press and release  repeatedly until you reach the display with the flashing beeper symbol and “On.”



4. Press  or  to select “On” or “OFF.”



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



Setting the Alarm Clock Function

The alarm clock function is a handy way to remind you to test. You can set 1 to 4 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 meter is preset with the alarm clock function set to “OFF.” You must turn it “On” to use this feature.

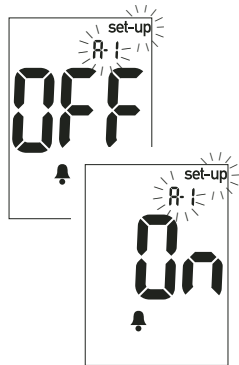
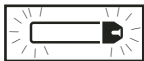
If you turn A-1, A-2, A-3, and A-4 on, your meter is preset with the following times for your convenience. You can adjust the times to suit your needs.




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

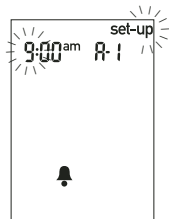
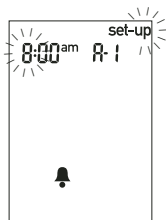
Notes:




- 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.






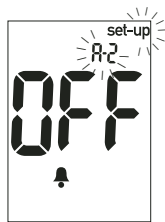
1. Press  to turn the meter on. The flashing test strip symbol appears.
2. Enter the set-up mode (press and **hold**  for about four seconds). “Set-up” flashes on the display.
3. Press and release  repeatedly until you reach the display with the bell symbol, “OFF,” and the flashing “set-up” and “A-1.”



4. Press and release  or  to select “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.

TIME / DATE
(hrs, min, am/pm,
day, month, year)



BEEPER
(on/off)



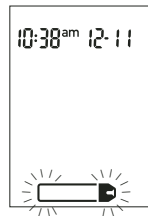
ALARM CLOCK
(A-1, A-2, A-3, A-4)




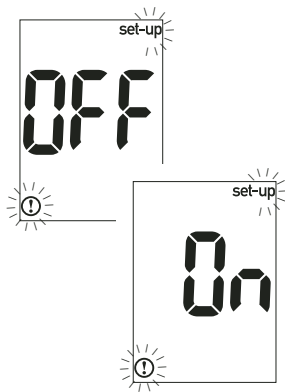
HYPG ALARM
(off, on, level)







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 meter is preset to “OFF” for the hypo alarm. If you want to turn it “On,” follow these steps.

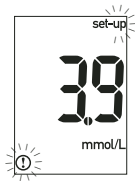


1. Press  to turn the meter on. The flashing test strip symbol appears.

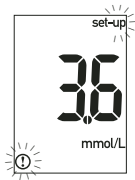


2. Enter the set-up mode (press and **hold**  for about four seconds). “Set-up” flashes on the display.
3. Press and release  repeatedly until you reach the display with “OFF” and the flashing “set-up” and .
4. Press and release  or  to switch between “On” and “OFF.” Press and release  to set your choice.

5. If you select the hypo alarm “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.

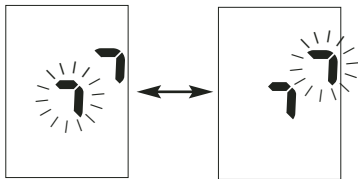
Transferring Data

1. Turn off your meter.
2. Install the software according to the instructions.
3. Connect the infrared meter cable to a 9-pin serial port connector on the back of your computer.
4. 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.
5. Press and hold the ◀ and ▶ on the meter until two arrows flash on the meter display. The meter is ready to transfer data.

Infrared (IR)
Window



6. Put the meter on a flat surface, and then align the infrared windows on the meter and cable or PDA (they should be 3 to 10 cm apart).



7. Do not move the meter or cable during the transfer.
8. Click OK when you are ready to continue.
9. Follow the prompts on the software.
10. 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 the Accu-Chek Enquiry Line on 1800 251 816.
- To make the most of the download feature, you must set the time and date correctly.

Chapter 4: Control Testing

Why Perform Control Tests

Performing a control test lets you know that your 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 or humidity
- You dropped the meter
- Your test result does not reflect how you feel
- You want to check if you are testing correctly

About the Control Solutions

- Only use Accu-Chek Performa Control Solutions.
- Your meter automatically recognizes the 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 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 and/or Level 2.
The control level is printed on the bottle label.*

46



1. Insert a test strip into the meter in the direction of the arrows. 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, take the test strip out and reinsert it into the meter.



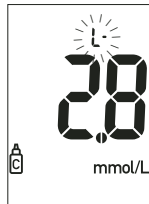
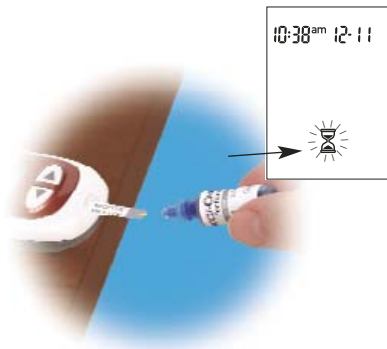
OR






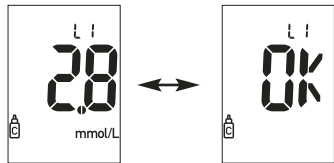
3. Select the control solution you want to test. You will enter the level later in the test.


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



- 8. Press  to set the 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 the test strip and discard it.

Understanding Control Test Results

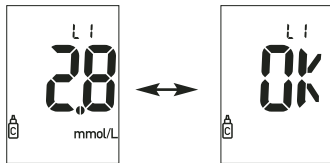
50



	Range (mmol/L)
Level 1	1.7–3.4
Level 2	14.4–19.5

Example

The label on your test strip container shows the acceptable ranges for both the Level 1 and the 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.



Example

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

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

Troubleshooting Checks

Action

1. <i>Check the expiry date of the test strips and control solution.</i>	If either is past the expiry date, discard it. If the control solution was opened more than three months ago, discard it.
2. <i>Check that you wiped the tip of the control solution bottle before and after use.</i>	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. <i>Ensure that the caps on the test strip container and the control solution bottle are always closed tightly.</i>	If you think either may have been uncapped for some time, replace the test strips or control solution.
4. <i>Check if the test strip was out of the container for a long time.</i>	Repeat the control test with a new test strip.
5. <i>Check that your test strips and control solutions were stored in a cool, dry place.</i>	Repeat the control test with properly stored test strips or control solution.

Troubleshooting Checks

Action

6. Check that you followed the testing steps.

Read Chapter 4 “Control Testing” and test again. If you still have problems, call the Accu-Chek Enquiry Line on 1800 251 816.

7. Check that 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 that 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 in 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 the Accu-Chek Enquiry Line on 1800 251 816.

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 CR 2032. It is a good idea to have a spare battery available.
- Be sure the battery goes in + side up or facing you.
- After you change the battery, your meter prompts you to confirm the meter's time and date settings. All test results remain saved in memory.

Cleaning Your Meter

Caring for your Accu-Chek Performa 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 turned off
- Gently wipe the meter's surface with a soft cloth slightly dampened with one of these cleaning solutions:
 - 70 % isopropyl alcohol
 - Mild dishwashing liquid mixed with water
 - 10 % household bleach solution (1 part bleach plus 9 parts water) made the same day
- Make sure you squeeze off excess liquid from the cloth before you wipe the meter's surface


Do Not

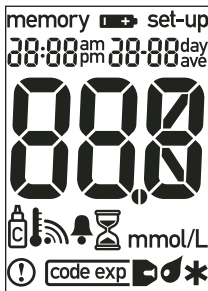
- Get any moisture in the code chip slot or test strip slot
- Spray any cleaning solution directly onto the meter
- Put the meter under water or liquid
- Pour liquid into the meter

Maintenance and Troubleshooting

Your 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.

If you drop the meter or think it is not giving accurate results, call the Accu-Chek Enquiry Line on 1800 251 816.

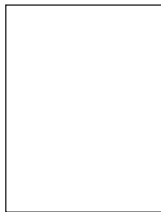
To make sure the display is working properly, turn off the meter, then press and **hold**  to see the complete display. All the segments should be clear and look exactly like the picture below. If not, call the Accu-Chek Enquiry Line on 1800 251 816.



Screen Messages and Troubleshooting

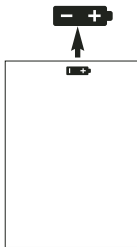


Never make treatment decisions based on an error message. If you have any concerns, please call the Accu-Chek Enquiry Line on 1800 251 816.



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

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



Battery power is low.
Change the battery
soon.



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



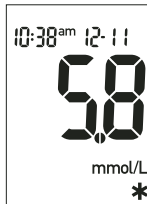
The meter is in set-up
mode, waiting for you to
change or confirm
settings.



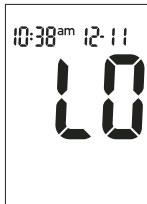
The meter is ready for a
drop of blood or control
solution.



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



This test result was flagged. See Chapter 2 “Flagging Test Results” for more details.



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



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



The test strips will 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.



The meter is not coded or the code chip is not inserted. Turn off the meter and recode it.



The test strip is damaged. Remove the test strip and reinsert it, or replace it if damaged. If the message reappears, call the Accu-Chek Enquiry Line.



An error occurred during the test. Discard the test strip and repeat the test.



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



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.



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 a few seconds and reinsert it. Perform a blood glucose or control test. If the problem persists, call the Accu-Chek Enquiry Line.



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



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.



The time and date settings may be incorrect. Make sure the time and date are correct and adjust, if necessary.

Note:

- If you see any other error screen, please call the Accu-Chek Enquiry Line on 1800 251 816.

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 μ L
Sample type	Fresh whole blood
Measuring time	5 seconds
Measuring range	0.6 to 33.3 mmol/L
Test strip storage conditions	2°C to 32°C
Meter storage conditions	Temperature: -25°C to 70°C
System operating conditions	6°C to 44°C; 10 to 90 % relative humidity
Relative humidity operating range	10 to 90 %
Memory capacity	500 results with time and date
Automatic power off	2 minutes
Power supply	One 3-volt lithium battery (type CR 2032)
Display	LCD
Dimensions	93 x 52 x 22 mm (LWH)

Weight	Approx. 62 g (with battery)
Construction	Hand-held
Protection class	III
Meter type	The Accu-Chek Performa 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 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 Performa system (Accu-Chek Performa meter with Accu-Chek Performa 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 Performa system meets the ISO 15197 requirements.

Measuring Principle

The enzyme on the test strip, glucose dehydrogenase, in the presence of the coenzyme (PQQ), converts the glucose in the blood sample to gluconolactone. This reaction creates a harmless DC electrical current that your meter interprets for your blood glucose. The sample and environmental conditions are also evaluated using a small AC signal.

Blood glucose concentrations may be measured in whole blood or plasma. Although you always apply whole blood to the test strip, your meter displays blood glucose results that relate to plasma. Please refer to the package insert for 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 Your 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 European Directive 2002/96/EC (Directive on waste electrical and electronic equipment (WEEE)).

Explanation of Symbols

You may encounter the following symbols on packaging, on the type plate, and in the instructions for your Accu-Chek Performa meter, shown here with their meaning.



Please consult instructions for use



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



Use by (unopened or opened test strip container)



Store at



IFCC plasma referenced (strips)



Dispose in domestic waste



Manufacturer

REF Catalogue number



For *in vitro* diagnostic use. Do not ingest!



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



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



3V type 2032

Guarantee

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

Additional Supplies

The following supplies and accessories are available from Diabetes Australia, pharmacies, or your surgical supplier:

Accu-Chek Performa Test Strips

Accu-Chek Performa Control Solutions

Accu-Chek Softclix Lancing Device

Accu-Chek Softclix Lancets

Accu-Chek Multiclix Lancing Device

Accu-Chek Multiclix Lancets

References

1. Stedman, Thomas Lathrop. *Stedman's Medical Dictionary, 27th Edition*, 1999, pg. 2082.
2. D'Orazio et al.: IFCC Recommendation on Reporting Blood Glucose Results; *Clinical Chemistry* 51:9 1573-1576 (2005).

Information for Healthcare Professionals



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

A drop of fresh, whole blood is required to perform a blood glucose test. Fresh venous, capillary, arterial, or neonatal blood may be used. Caution should be taken to clear arterial lines before blood is drawn. Caution should be exercised in the interpretation of neonate blood glucose values below 2.8 mmol/L. Blood glucose determination with venous or arterial blood must be performed within 30 minutes of sample collection. Avoid air bubbles with the use of pipettes. Fresh venous blood specimens containing the anticoagulants EDTA or heparin are acceptable. Iodoacetate or fluoride/oxalate are not recommended.

Decisions about whether to recommend alternative 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/palm and alternative 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 behavior and relative physical condition. Our studies

involving alternative site testing of adults with diabetes show that most persons will find their glucose level changes more quickly in the fingers'/palms' blood than the alternative 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/palm readings, he or she should consider the delay, or lag-time, affecting the reading obtained from an alternative site.

*Data on file.

Index

- alarm clock function, setting, 35
- alternative site testing, 19, 71
- appetite, increased, 25
- battery, changing, 53
- battery, installing, 53
- battery, type, 54
- beeper, setting, 32
- blood glucose, testing, 14
- blurred vision, 25
- button, on/off/set, 7
- code chip, 8, 9
- computer, connecting your meter to, 42
- control solution, 45
- control test, acceptable range, 50
- control test, performing, 46
- control test, results, 50
- control test results, understanding, 50
- control test, unacceptable range, 50
- display check, 56
- error messages, 57–63
- expiry date, 13, 45
- fatigue, 25
- flagging test results, 18
- frequent urination, 25
- guarantee, 69
- high blood glucose, 25
- hyperglycemia, 25
- hypoglycemia, 25
- hypoglycemic alarm function, setting, 39
- low blood glucose, 25
- maintenance, meter, 56
- memory, meter, 26
- numbness, 25
- product limitations, 64
- product specifications, 64
- professional caregivers, 71
- rapid heartbeat, 25
- settings, meter, 28
- supplies, 70

sweating, 25

symbols, 68

technical information, 64

test results, unusual, 24

test strips, Accu-Chek
 Performa, 8, 13

thirst, increased, 25

time and date, setting, 29

tingling, 25

trembling, 25

troubleshooting, 57–63

Australia Patent Nos. 738325 and 591160. Australia Patent No. 591160 is licensed from Quadrant Holdings Cambridge Limited.


Distributed by:

Roche Diagnostics
Australia Pty Ltd
31 Victoria Ave, Castle Hill,
NSW 2154, Australia

Accu-Chek Enquiry Line 1800 251 816

ACCU-CHEK® Performa



 Roche Diagnostics GmbH,
D-68298 Mannheim, Germany
www.accu-chek.com

Made in U.S.A.

ACCU-CHEK, ACCU-CHEK PERFORMA, SOFTCLIX, and ACCU-CHEK MULTICLIX are trademarks of Roche.

©2006 Roche Diagnostics. All rights reserved. 04861612001-1006

IVD

CE 0088