

# ACCU-CHEK® Performa

BLOOD GLUCOSE METER / MEDIDOR DE GLUCEMIA

## Owner's Booklet Instrucciones de uso



1

*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 contact one of our customer support and service centers. A list of addresses is at the back of this booklet.*

## 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.

<b>Chapter 1: Understanding Your New System</b> .....	6
The Accu-Chek Performa Meter .....	6
Coding Your Meter .....	8
Adjusting the Time and Date – First Time Use.....	10
Using the Accu-Chek Performa System .....	13
<b>Chapter 2: Testing Your Blood Glucose</b> .....	14
Performing a Blood Glucose Test.....	14
Flagging Test Results .....	19
Alternative Site Testing (AST) .....	20
Unusual Test Results .....	25
Symptoms of High or Low Blood Glucose.....	27
<b>Chapter 3: Meter Memory, Setup, and Downloading</b> .....	28
Memory.....	28
Viewing Test Results .....	29
Meter Setup .....	30
Setting the Time and Date.....	31
Setting the Beeper On/Off.....	34
Setting the Alarm Clock Function .....	37
Setting the Hypoglycemic (Hypo) Alarm Function.....	42
Downloading Your Results to a Computer or PDA.....	45

<b>Chapter 4: Control Testing</b> .....	47
Why Perform Control Tests.....	47
About the Control Solutions .....	48
Performing a Control Test.....	49
Understanding Control Test Results.....	53
<b>Chapter 5: Maintenance and Troubleshooting</b> .....	56
Changing the Battery.....	56
Cleaning Your Meter.....	58
Maintenance and Troubleshooting.....	59
Screen Messages and Troubleshooting .....	60
<b>Chapter 6: Technical Information</b> .....	67
Product Limitations .....	67
Specifications.....	67
Product Safety Information .....	70
Disposing of Your Meter .....	70
Explanation of Symbols .....	71
Guarantee .....	72
Additional Supplies.....	72
Information for Healthcare Professionals .....	73
Index.....	75

# Chapter 1: Understanding Your New System

## The Accu-Chek Performa Meter

6

### 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.

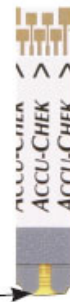


### Golden End –

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



On/Off/Set Button

Top View

Infrared (IR) Window



Code Chip (for example)



Battery – Insert with (+) symbol facing up.

7

# Coding Your Meter

8



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 meter until it stops.



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

9

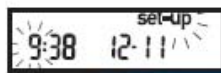
## Notes:

- 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

The meter is preset with the time and date which may need to be adjusted to the local time zone. 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.

10

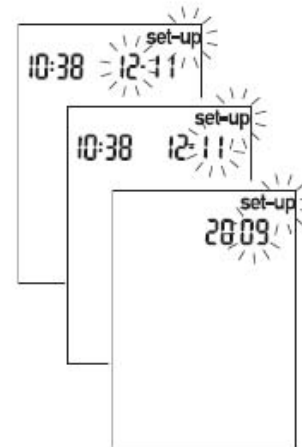


decrease increase





1. Press and release  to turn the meter on. The time and date appear on the display. "Set-up" and the hour flash. If the correct time and date are displayed, press and hold  to exit.
2. Press and release  or  to decrease or increase the hour. Press and hold  or  to scroll faster.




decrease increase



11

3. Press and release  to set the hour. The minutes flash.
4. Press and release  or  to adjust the minutes. Press and release  to set the minutes.
5. Repeat to set 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 unused test strips in their original container with the cap closed.
- 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.
- Refer to the test strip package insert for test strip storage and system operating conditions.
- 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 or kitchen)! Heat and moisture can damage your test strips.**

## Chapter 2: Testing Your Blood Glucose

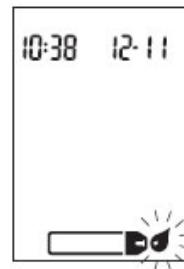
### Performing a Blood Glucose Test

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

14



1. Prepare your lancing device.
2. Wash and dry your hands.
3. Insert a test strip into the meter in the direction of the arrows. The meter turns on.



15

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.



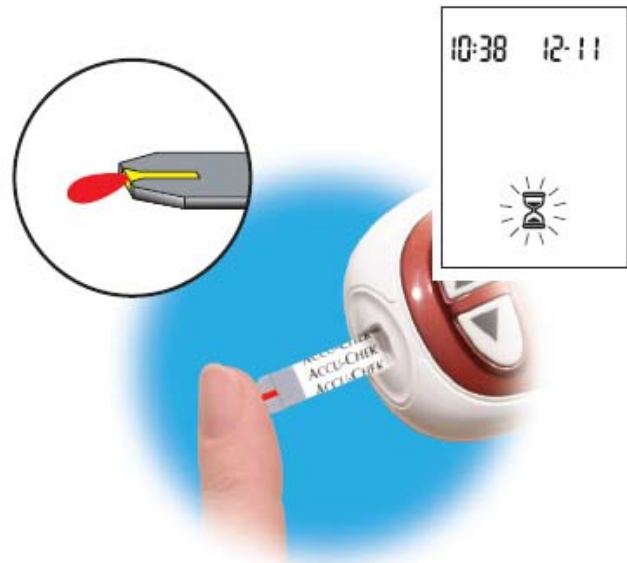
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OR




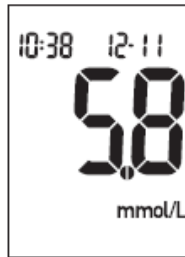
6. Perform a fingerstick with your lancing device. Blood samples taken from the palm are equivalent to blood taken from the fingertip. For detailed information on how to obtain blood from the palm refer to the Alternative Site Testing (AST) section, steps 5 and 6.



17

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

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.



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.

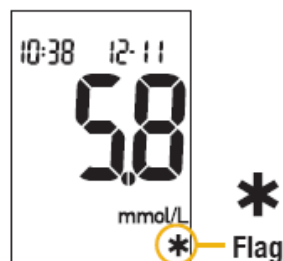
**Note:** After a successful test, the meter turns itself off five seconds after the test strip is removed.

## Flagging Test Results

If you wish, you can “flag” your test result with an asterisk (\*) to mark 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.

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)

20

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 (hypothelar) – 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 result 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
- During peak action time of short-acting insulin or rapid-acting insulin analogues
- Up to two hours after injecting a short-acting insulin or rapid-acting insulin analogue

21

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

22

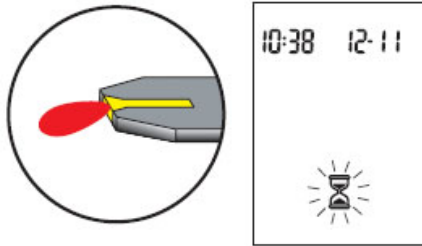



1. Prepare your lancing device.
2. Insert a test strip into the meter in the direction of the arrows. The meter turns on.
3. Make sure the code number on the display matches the code number on the test strip container. If you miss seeing the code number, remove the test strip and reinsert it into the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



23

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 alternative site. Press the lancing device up and down in a slow pumping motion to assist the flow of blood.
6. Trigger the lancing device while keeping steady pressure on the area. Apply pressure to the area 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. Discard the used test strip.

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

## Unusual Test Results

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

Troubleshooting Checks	Action
1. <i>Check the expiry date of the test strips.</i>	If they are past the expiry date, discard the test strips.
2. <i>Ensure that the cap on the test strip container is always closed tightly.</i>	If you think they may have been uncapped for some time, discard the test strips.
3. <i>Check if the test strip was out of the container for a long time.</i>	Repeat the test with a new test strip.
4. <i>Check that your test strips were stored in a cool, dry place.</i>	Repeat the test with properly stored test strips.

## Troubleshooting Checks

## Action

26

5. *Check that you followed the testing steps.*

Read Chapter 2 “Testing Your Blood Glucose” and test again. If you still have problems, call Roche.

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 Roche.

## 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.

27



**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 Control and Blood Glucose 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.

28

#### Notes:

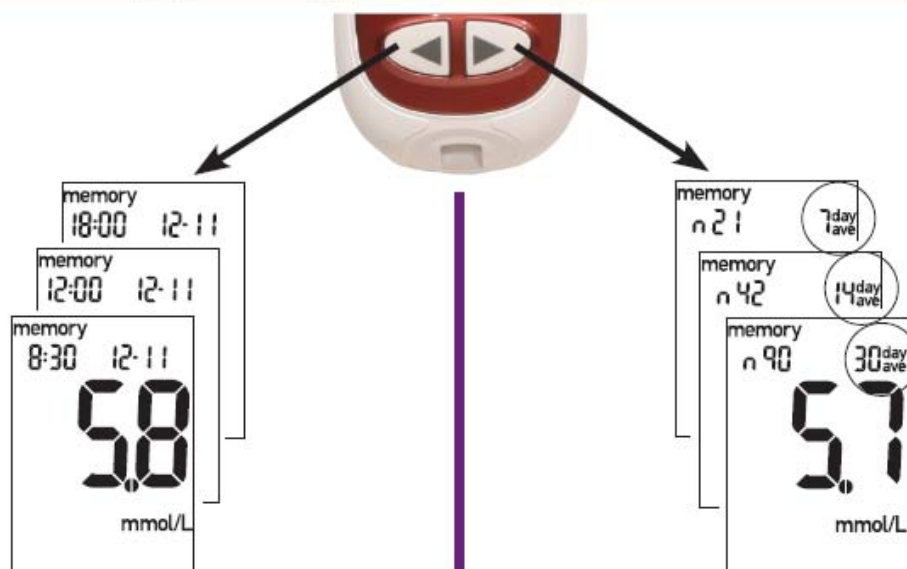
- The memory is not lost when you replace the battery. You do need to check that the time and date are correct after you replace the battery.
- Once 20 control or 500 blood glucose results are in memory, adding a new result causes the oldest one to be deleted.
- Press and **hold** ◀ or ▶ to scroll through the results faster.
- The control results do not appear in memory. They are not included in the 7, 14, and 30 day averages.
- Up to 20 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.

## Viewing Test Results

Press and release either ◀ or ▶ to enter memory. Your most recent result appears. Press and release ◀ to view previous results in order.

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

**! Do not change your therapy based on one individual result in memory.**



29

# 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 “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.

30

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.

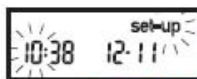
You are here




## Setting the Time and Date





1. Press and release  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.

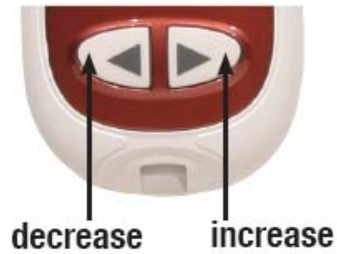



decrease      increase




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



31

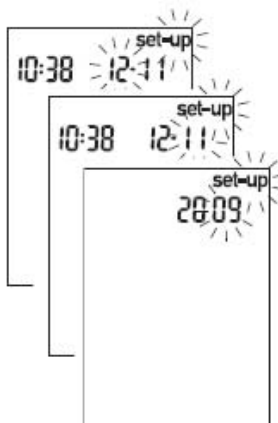






4. Press and release  to set the hour.  
The minutes flash.

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

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



6. Repeat to set 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

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.




34

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)



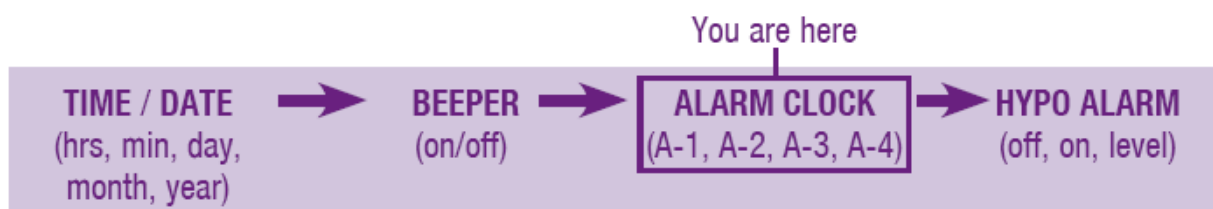
35

1. Press and release  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 and release ◀ 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.

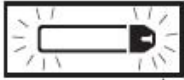
If you turn A-1, A-2, A-3, and A-4 on, your meter is preset with the following times for your convenience. You can adjust the times to suit your needs.

A-1 8:00                      A-2 12:00                      A-3 18:00                      A-4 22:00

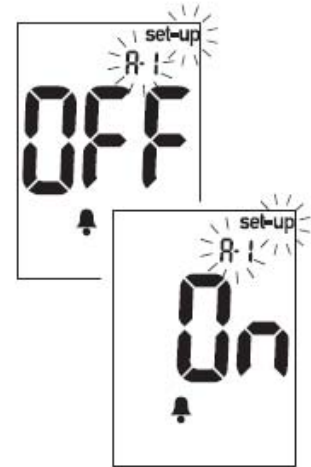
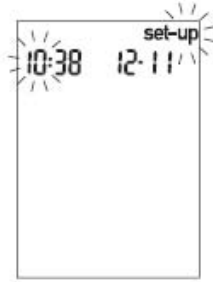
### Notes:


- 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.




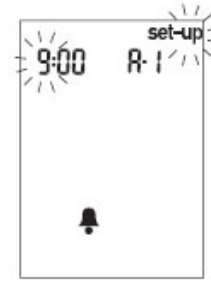
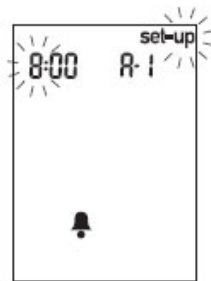
38






1. Press and release  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”.

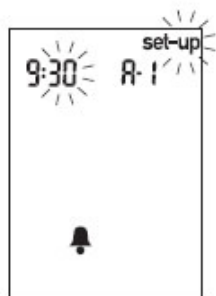




39

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.

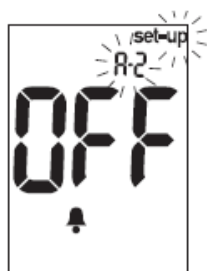
6. Press and release  or  to select the hour. Press and release  to set the hour.




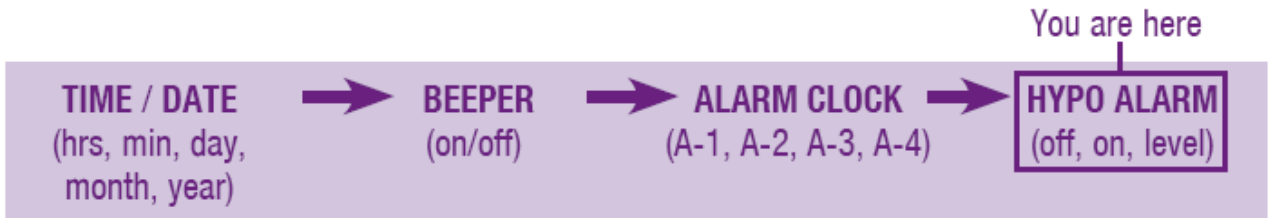
7. The minutes flash. Press and release  or  to select 00, 15, 30, or 45. These are the only choices.



8. Press and release  to set the minutes.



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.



## Setting the Hypoglycemic (Hypo) Alarm Function

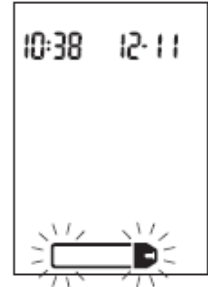
You can set the meter to let you know when your blood glucose is possibly too low. You can also select what blood glucose level you want this alarm to have (3.3 to 4.4 mmol/L).


42

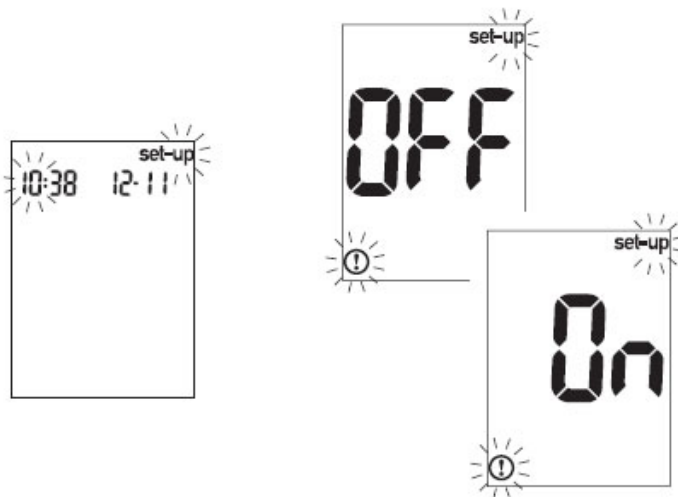
**Consumers:** Before you set the hypoglycemic alarm, talk to your healthcare professional to help you decide what blood glucose level is your hypo level.

**Healthcare professionals:** The hypoglycemic level may vary from person to person. It is recommended to turn the hypo alarm function **off** when using the meter in a professional facility.







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

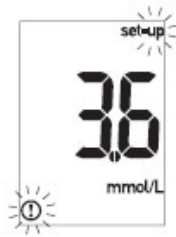







1. Press and release  to turn the meter on. The flashing test strip symbol appears.



43

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

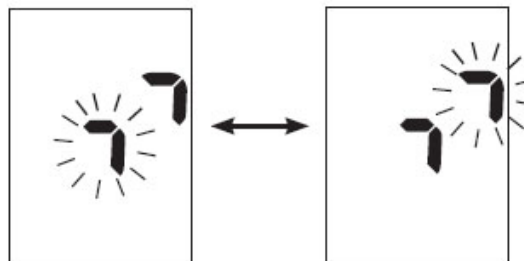
You can transfer your stored results to a computer to track, identify patterns, and print.



Downloading data is not recommended for healthcare facilities since there is no means to identify results by patient.

### 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 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.
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.

46



### Notes:

- If the data did not transfer successfully, try again. If you still have problems, contact Roche.
- 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 temperature 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

47



## About the Control Solutions

- Only use Accu-Chek Performa Control Solutions.
- Your meter automatically recognizes the control solution.
- The control 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.

48

## 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.*



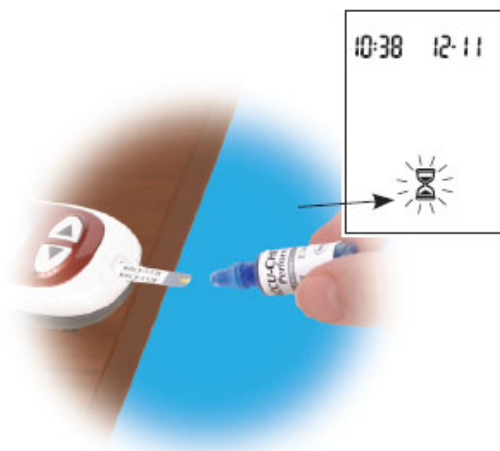
1. Insert a test strip into the meter in the direction of the arrows. The meter turns on.




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.

49




- 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 and release  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



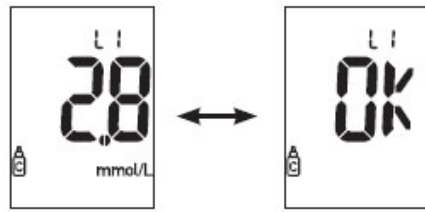
container label. "Err" and the control result alternate on the display if the result is not in range. Remove the test strip and discard it.

## Understanding Control Test Results



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

Example



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.

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:

54

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. <i>Check that you followed the testing steps.</i>	Read Chapter 4 “Control Testing” and test again. If you still have problems, call Roche.
7. <i>Check that you chose the correct control solution level, either 1 or 2, when you performed the test.</i>	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. <i>Check that the code number on the meter display matches the code number on the test strip container.</i>	If they do not match, insert the correct code chip in the meter and test again.
9. <i>If you are still unsure of the problem...</i>	Repeat the control test with a new test strip. If you still have problems, call Roche.

55

## Chapter 5: Maintenance and Troubleshooting

### Changing the Battery



56

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. This type of battery can be found in many stores. 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 are 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 or disinfect 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 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

58

## 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 Roche.

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 Roche.



59

# Screen Messages and Troubleshooting



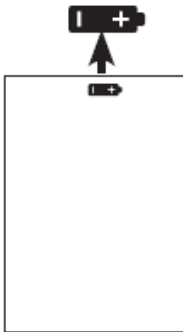
Never make treatment decisions based on an error message. If you have any concerns, call Roche.



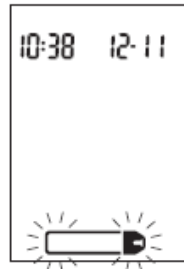
The meter will not turn on or the display is blank.

- Battery is dead –  
Insert new battery
- Display is damaged –  
Call Roche
- Meter is defective –  
Call Roche
- Extreme temperatures –  
Move the meter to a more temperate area

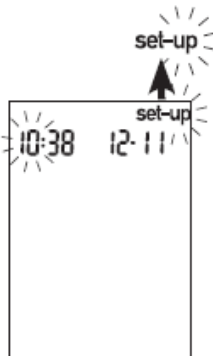
60



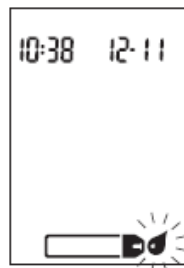
Battery power is low.  
Change the battery soon.



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.

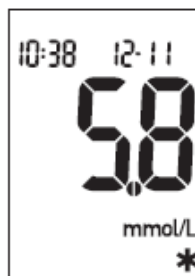


The meter is ready for a  
drop of blood or control  
solution.

61



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



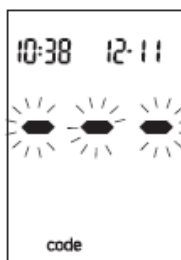
This test result was flagged. See Chapter 2 “Flagging Test Results” for more details.



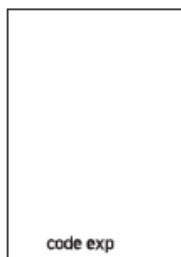
Blood glucose may be lower than the measuring range of the system.



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



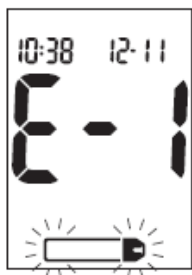
The meter is not coded or the code chip is not inserted. Turn off the meter and recode it.



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.

Make sure the time and date in the meter are correct.





The test strip is damaged. Remove the test strip and reinsert it, or replace it if damaged. Verify that the code number on the test strip container matches the code number printed on the code chip currently inserted in the meter. If the message reappears, call Roche.



Your blood glucose may be extremely high or a meter or a test strip error has occurred. If this confirms how you feel, contact your healthcare professional immediately. If it does not confirm how you feel, repeat the test and refer to Chapter 2 “Unusual Test Results”. If this does not confirm the way you feel, run a control test with your control solution and a new test strip. If the control result is within the acceptable range, review the proper testing procedure and repeat your blood glucose test with a new test strip. If the E-3 code still appears for your blood glucose test, your blood glucose result may be extremely high and above the system’s reading range. **Contact your healthcare professional immediately.** If the control result is not within the acceptable range, see Chapter 4 “Understanding Control Test Results”.

64



The code chip is incorrect. Turn off the meter and insert a new code chip. If this does not fix the problem, call Roche.



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 drop 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 20 seconds and reinsert it.

Perform a blood glucose or control test. If the problem persists, call Roche.

65



The temperature is above or below the proper range for the meter. Refer to the test strip package insert for system operating conditions. Move to an

area with the appropriate conditions, 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 Roche.

# 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

<b>Blood volume</b>	Refer to the test strip package insert
<b>Sample type</b>	Fresh whole blood
<b>Measuring time</b>	Refer to the test strip package insert
<b>Measuring range</b>	Refer to the test strip package insert
<b>Test strip storage conditions</b>	Refer to the test strip package insert
<b>Meter storage conditions</b>	Temperature: -25 °C to 70 °C
<b>System operating conditions</b>	Refer to the test strip package insert
<b>Relative humidity operating range</b>	Refer to the test strip package insert
<b>Memory capacity</b>	20 control and 500 blood glucose results with time and date
<b>Automatic power off</b>	2 minutes
<b>Power supply</b>	One 3-volt lithium battery (type CR 2032)

67

<b>Display</b>	LCD
<b>Dimensions</b>	93 x 52 x 22 mm (LWH)
<b>Weight</b>	Approx. 62 g (with battery)
<b>Construction</b>	Hand-held
<b>Protection class</b>	III
<b>Meter type</b>	The Accu-Chek Performa Meter is suitable for continuous operation
<b>Control solution storage conditions</b>	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 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 EN ISO 15197 requirements.

## Measuring Principle

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.



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.



For in vitro diagnostic use



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



3V type 2032

71

## Guarantee

The statutory provisions on rights in consumer goods sales in the country of purchase shall apply.

## Additional Supplies

The following supplies and accessories are available from your authorized Roche Diabetes Care Office, pharmacies, or your medical/surgical supply company:

### Test Strips

**Accu-Chek Performa Test Strips**

### Control Solutions

**Accu-Chek Performa Control Solutions**

72



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

## Sample Handling

Always wear gloves and follow your facility's infection control procedures when handling blood-contaminated items. Always adhere to the recognized procedures for handling objects that are potentially contaminated with human material. Follow the hygiene and safety policy of your laboratory or institution. Prepare the selected blood collection site per facility policy.

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. For fresh venous blood specimens, refer to the test strip package insert for acceptable anticoagulants.

## Recommending Alternative Site Testing to Patients

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, 37
- alternative site testing, 20, 74
- appetite, increased, 27
- battery, changing, 56
- battery, installing, 56
- battery, type, 57
- beeper, setting, 34
- blood glucose, testing, 14
- blurred vision, 27
- button, on/off/set, 6, 7
- code chip, 7, 8
- computer, connecting your meter to, 45
- control solution, 48
- control test, acceptable range, 53
- control test, performing, 49
- control test, results, 53
- control test results, understanding, 53
- control test, unacceptable range, 54
- display check, 59
- error messages, 60–66
- expiry date, 13, 48
- fatigue, 27
- flagging test results, 19
- frequent urination, 27
- guarantee, 72
- healthcare professionals, 73
- high blood glucose, 27
- hyperglycemia, 27
- hypoglycemia, 27
- hypoglycemic alarm function, setting, 42
- low blood glucose, 27
- maintenance, meter, 59
- memory, meter, 28
- numbness, 27
- product limitations, 67
- product specifications, 67–68
- rapid heartbeat, 27
- settings, meter, 30
- supplies, 72
- sweating, 27
- symbols, 71
- technical information, 67
- test results, unusual, 25
- test strips, Accu-Chek Performa, 7, 13
- thirst, increased, 27
- time and date, setting, 31
- tingling, 27
- trembling, 27
- troubleshooting, 60–66