

# ACCU-CHEK<sup>®</sup> *Performa*

---

**BLOOD GLUCOSE METER**

---

**Operator's Manual**





# The Accu-Chek Performa System

## Intended Use

The Accu-Chek Performa Meter is designed to be used with the Accu-Chek Inform II Test Strip to quantitatively measure glucose in fresh venous, arterial, neonatal, and capillary whole blood as an aid in monitoring the effectiveness of glucose control. Capillary whole blood for testing of blood glucose can be obtained from the fingertip. The Accu-Chek Performa Meter with the Accu-Chek Inform II Test Strips provides a complete test system that is meant for in vitro diagnostic use by healthcare professionals in clinical settings and by people with diabetes at home. The system is not for use in diagnosis or screening of diabetes mellitus. Healthcare professional blood sample collection and preparation is described in the test strip package insert.

For use only with the Accu-Chek Inform II Test Strips and Accu-Chek Performa Control Solutions.

Suitable for self-testing

### **Note:**

The Accu-Chek Performa Meter with the Accu-Chek Inform II Test Strip was found to be safe and accurate for use in a hyperbaric chamber.

The system includes:

- **Accu-Chek Performa Meter with Battery**
- **Accu-Chek Inform II Test Strips and Code Chip**
- **Accu-Chek Performa Control Solutions**



**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).**

# Contents

<b>Chapter 1: Introduction</b> .....	<b>5</b>
The Accu-Chek Performa Meter.....	5
Coding the Meter.....	7
Adjusting the Time and Date – First Time Use.....	9
Using the Accu-Chek Performa System.....	11
<b>Chapter 2: Patient Testing for Healthcare Professionals</b> .....	<b>13</b>
Sample Handling.....	13
Performing a Blood Glucose Test.....	15
Flagging Test Results.....	18
Unusual Test Results.....	19
Disinfecting the Meter.....	21
<b>Chapter 3: Control Testing for Healthcare Professionals</b> .....	<b>23</b>
Introduction.....	23
Testing Intervals.....	23
About the Control Solutions.....	24
Performing a Control Test.....	25
Understanding Out-of-Range Control Test Results.....	28
<b>Chapter 4: Meter Memory, Set-up, and Downloading</b> .....	<b>29</b>
Memory.....	29
Viewing Test Results.....	30
Meter Set-up.....	31
Setting the Time and Date.....	32
Setting the Beeper On/Off.....	34
Setting Test Reminders.....	37

Setting the Hypoglycaemic (Hypo) Alert .....	41
Transferring Data Directly to a Computer or PDA Using Specialised Software and Infrared Cable.....	43
<b>Chapter 5: Maintenance and Troubleshooting .....</b>	<b>45</b>
Changing the Battery .....	45
Cleaning the Meter .....	46
Maintenance and Troubleshooting .....	47
Display Messages and Troubleshooting .....	48
<b>Chapter 6: Technical Information .....</b>	<b>55</b>
Product Limitations.....	55
Specifications .....	55
Product Safety Information .....	57
Disposing of the Meter and Batteries.....	57
Explanation of Symbols.....	58
Guarantee.....	59
Additional Supplies .....	59
<b>Index.....</b>	<b>61</b>

# Chapter 1: Introduction

## 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 –

Transfers data from the meter to a computer or PDA.

### Power/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.



**Test Strip**

**Yellow Window** —  
Touch blood  
drop or control  
solution here.



**Test Strip Container**



**Control Solution  
Bottle  
(example)**



**Code Chip  
(example)**



**Battery —  
Insert with  
(+) symbol facing up.**

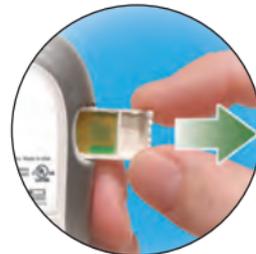
## Coding the Meter



1. Make sure the meter is off.



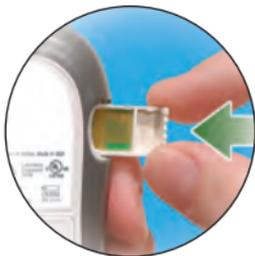
2. Turn over the meter.



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



**Change the code chip every time a new box of test strips is opened!**



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

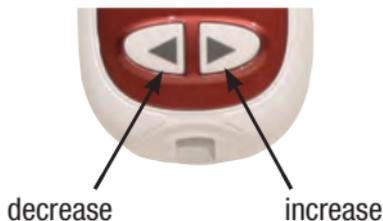
5. Leave the code chip in the meter until a new box of test strips is opened. Change the code chip each time a new box of test strips is opened.

### Notes:

- Do not force the code chip into the meter. It is designed to go into the meter only one way.
- If “code” and a flashing “- -” is displayed, turn off the meter and reinsert a code chip into the meter.

## Adjusting the Time and Date – First Time Use

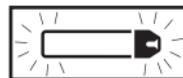
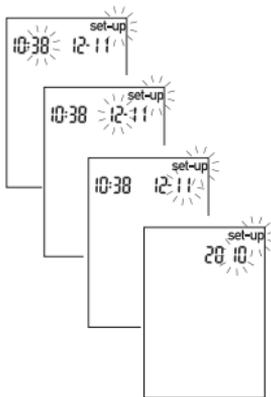
The meter is preset with the time and date which may need to be adjusted to the local time zone. Setting the correct time and date in the meter is important to review the results in memory or to download the results to a computer.



1. Press and release  to turn on the meter. 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 the set-up mode.

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

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



4. Repeat steps 2 and 3 to set the minutes, day, month, and year. The flashing field is the one that is being changed.
5. Once the year is set, press and **hold**  until the flashing test strip symbol appears. The time and date are now set.
6. See Chapter 4, “Meter Set-up” to set other options.

### Note:

After the battery is changed, the meter automatically prompts the operator to confirm the time and date when it is turned on.

## Using the Accu-Chek Performa System

- Only use Accu-Chek Inform II Test Strips.
- Replace the code chip every time a new box of test strips is opened.
- Refer to the test strip package insert for test strip storage and system operating conditions.
- Store unused test strips in the original container with the cap closed.
- Close the container tightly immediately after removing a test strip to protect the test strips from humidity.
- Use the test strip immediately after removing it from the container.
- Check the use by date on the test strip container. Do not use the test strips after that date.
- Do not apply blood or control solution to the test strip before inserting it into the meter.



**Do not store test strips in high heat and humidity! Heat and moisture can damage the test strips.**



# Chapter 2: Patient Testing for Healthcare Professionals

## Sample Handling

Always wear gloves and follow your facility's infection control procedures when handling blood-contaminated items. Always adhere to the recognised 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.

Refer to the test strip package insert for additional information regarding acceptable sample types, anticoagulants, and handling instructions.

## Testing Blood Glucose in Multiple Patients

Only healthcare professionals are allowed to perform blood glucose tests in a multiple patient testing situation.

When using the meter always follow the recognised procedures for handling objects that are potentially contaminated with human material.

Practise the health and safety policy of your laboratory or institution. Also, to stop your meter becoming contaminated, please follow the directions printed on the next few pages.

For healthcare professionals we recommend the Accu-Chek Safe-T-Pro Plus or Accu-Chek Safe-T-Pro Uno disposable lancing devices.



**Patients and healthcare workers are potentially at risk of becoming infected when the same blood glucose meter is used to test blood glucose in several patients.**

**Any patient with an infection or suffering from an infectious disease and any patient who is a carrier of a multi-resistant organism must be assigned his/her own meter. This applies also if a patient is suspected of being one of the above. For as long as the suspicion exists, the meter must not be used to test any other patient.**

**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).**

### **Note:**

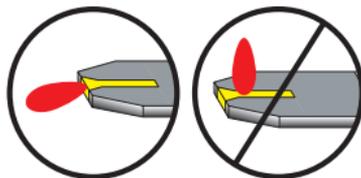
The hypoglycaemic level may vary from person to person. It is recommended to turn **off** the hypo alert function when using the meter in a professional facility.

## Performing a Blood Glucose Test

Before performing a blood glucose test on patients, set up the meter correctly. The meter, a test strip, and a disposable, single-use lancet or blood collection device are required.



1. Wear protective gloves.
2. Wash or disinfect the patient's finger and allow it to dry thoroughly. The blood drop does not spread so easily over dry skin.
3. Use only a lancing device that is approved for use by healthcare professionals.
4. Use a lancing device with adjustable penetration depth settings. If using a Safe-T-Pro Plus Lancing Device, select a penetration depth to suit the nature of the patient's skin. Start with a shallow depth setting.
5. Select a puncture site along the side of a fingertip.
6. Insert a test strip into the meter.



7. Make sure the code number on the meter display matches the code number on the test strip container.
8. Lance the side of the fingertip.
9. Using gentle pressure, massage from the palm to the fingertip to encourage a blood drop to form. A proper but nevertheless small blood drop (approx. 0.6  $\mu$ L) must form.
10. Immediately after the blood drop has formed, 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).
11. The test strip draws up blood.

### Note:

The test strip cannot properly draw up blood that has spread over the skin.



12. When you see  flash, you have enough blood in the test strip.

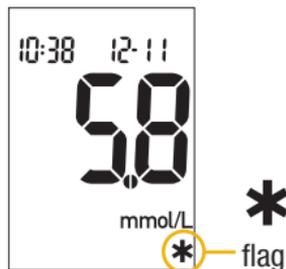
13. The result appears on the display.

14. Remove and discard the used test strip.

## Flagging Test Results

It is possible to flag a test result with an asterisk (\*) for a special result. When the results in memory are reviewed, this flag is a reminder of a special result.

1. Perform a test.
2. With the test result on the display, and the test strip STILL IN THE METER, press ◀ or ▶ once. The \* appears in the lower right corner.
3. Remove and discard the used test strip and blood collection device per facility infection control policy.



**To test blood glucose you require approximately 0.6  $\mu$ L of blood. Avoid producing large blood drops on the patient's finger. Where the blood drops are too large, the meter may come into contact with the blood. Wipe off any large blood drops. Test using the blood drop that forms again at the puncture site.**

**Residues of water or disinfectant on the skin can dilute the blood drop and so produce false results.**

**After a successful test, the meter turns itself off 5 seconds after the test strip is removed.**

**Dispose of used lancets, test strips or disposable lancing devices according to local health and safety regulations.**

## Unusual Test Results

Follow facility policy for reporting or treating blood glucose results.

If the blood glucose result does not reflect the patient's clinical symptoms, or seems unusually high or low, perform a control test. If the control test confirms that the system is working properly, repeat the blood glucose test. If the repeated blood glucose result still seems unusual, follow facility guidelines for further action or refer to the following table for assistance in problem solving.

<b>Troubleshooting Checks</b>	<b>Action</b>
1. Check if the test strips were expired.	Discard the test strips if they are past the use by date.
2. Check if the cap on the test strip container was always closed tightly.	Replace the test strips if you think they were uncapped for some time.
3. Check if the test strip was used immediately after removing it from the container.	Repeat the test with a new test strip.
4. Check if the test strips were stored in a cool, dry place.	Repeat the test with a properly stored test strip.
5. Check if the testing steps were followed.	Read Chapter 2, "Patient Testing for Healthcare Professionals" and test again. If you still have problems, contact Roche.

6. Check if the code number on the meter display matches the code number on the test strip container.	If they do not match, insert the correct code chip into the meter and test again.
7. If the problem does not resolve ...	Repeat the test with a new test strip and perform a control test. If the problem does not resolve, contact Roche.

## Disinfecting the Meter

The Accu-Chek Performa Meter may be disinfected. Disinfection is performed according to the degree of soiling (see “When to Disinfect”).

### What to Disinfect

In the unlikely event that the meter becomes contaminated, the following parts of the meter may be disinfected:

- The area around the test strip slot
- The display
- The outer casing

### How to Disinfect

- Make sure the meter is off.
- Gently wipe the meter’s surface.
- Cotton buds, wipes, and cloths lightly moistened with disinfectant are all suitable for disinfecting the meter.
- Allow areas you have wiped time to dry thoroughly.
- Remove any fluff or lint that may remain.
- Refer to the section “Cleaning the Meter” for further information.

### Notes

- Make sure that no liquid enters the meter.
- Do not spray anything onto the meter and do not immerse it in liquid. Doing so may damage the meter’s internal components and stop it from working properly.

## When to Disinfect

- Each time after you have tested a patient's blood glucose, wipe the area around the test strip slot. If you find blood on the cloth, wipe also the test strip slot itself and the display.
- If there is blood on the meter, wipe the meter.
- If blood has entered the meter, wipe the area around the test strip slot and the display. Allow areas you have wiped time to dry thoroughly.
- The meter, including the test strip slot and display must be thoroughly cleaned and disinfected at least once a day after use. Carefully check all recesses, grooves and gaps.

## Suitable Disinfecting/Cleaning Solutions

### Products suitable for use are:

- 70 % isopropyl alcohol
- Mild dishwashing liquid mixed with water
- 10 % household bleach solution (1 part bleach plus 9 parts water) made the same day

# Chapter 3: Control Testing for Healthcare Professionals

## Introduction

Testing control solutions with known glucose levels establishes that the operator and the system are performing acceptably. Control results must be within the defined acceptable ranges before valid patient testing is allowed.

## Testing Intervals

Follow your facility's policy for control testing intervals.

Control testing should be performed:

- The first time before using the meter for patient testing
- At intervals established by the facility
- When a new box of test strips is opened
- If the test strip container is left open
- If test strips were incorrectly stored
- If there is a question about a patient's glucose result
- To check the performance of the system
- If the meter was dropped

Your facility may require that control testing be successfully performed **after** any of the following occur and **before** patient testing resumes:

- Previous control test results were out of the acceptable range.
- Control tests were not performed at the proper interval.

Control results must be within the designated range on label of the test strip container, or as defined by your facility, before being considered acceptable. Patients can be tested after controls have been acceptably performed at the proper testing interval.

## About the Control Solutions

- Only use Accu-Chek Performa Control Solutions.
- The meter automatically recognises the Accu-Chek Performa Control Solution.
- Write the date the bottle was opened on the bottle label. The control solution is stable for 3 months from that date or until the use by date on the bottle label, whichever comes first.
- Do not use control solution that is past the use by date.
- Control results are not displayed in memory.
- Close the bottle tightly after use.
- Refer to the control solution package insert for control solution storage conditions.
- The solution can stain fabric. Wash with soap and water.

## Performing a Control Test

The meter, a test strip, and control solution are needed.



1. Insert the 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 the code number is overlooked, remove the test strip and reinsert it into the meter.



(example)

3. Select the control solution to be tested. The level is entered later.

### Note:

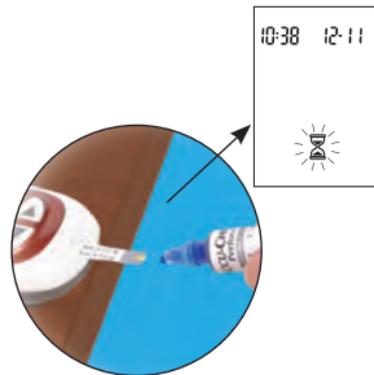
Cap color may vary – refer to the control solution package insert.



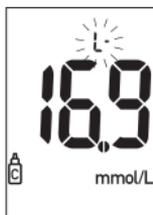
4. Put the meter on a flat surface, such as a table.



5. Remove the control bottle cap. Wipe the tip of the bottle with a lint-free wipe.



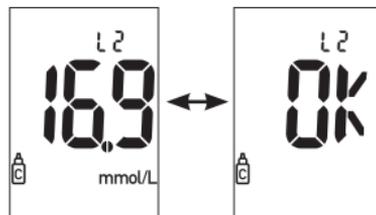
6. Squeeze the bottle until a tiny drop forms at the tip. Touch the drop to the **front edge** of the yellow window of the test strip. When  flashes, sufficient control solution is in the test strip. Wipe the tip of the bottle with a lint-free wipe then cap the bottle tightly.



(example)



(example)



(example)

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

8. Press and release  to set the control level in the meter.

9. “OK” and the control result alternate on the display if the result is in range. The range is printed on the test strip container label. “Err” and the control result alternate on the display if the result is out of range. Remove and discard the used test strip per facility policy.

## Understanding Out-of-Range Control Test Results

The label on the test strip container shows the acceptable ranges for the Level 1 and Level 2 control solutions. Control results must be within the designated range on the test strip container label, or as defined by the facility, before being considered acceptable.

If the control result is not acceptable, review this list for a possible cause.

- Were the test strips or control solutions expired?
- Was the tip of the control solution bottle wiped with a lint-free wipe before and after use?
- Were the test strip container and control solution bottle always closed tightly?
- Was the test strip used immediately after removing it from the container?
- Were the test strips and control solutions stored properly?
- Were the testing steps followed?
- Was the correct control solution level selected when the control test was performed?
- Did the code number on the meter display match the code number on the test strip container?

# Chapter 4: Meter Memory, Set-up, and Downloading

## Memory

### Storing Control and Blood Glucose Results

The meter automatically stores up to 500 blood glucose test results with the time and date of the test. Results can be reviewed at any time. They are stored from the newest to the oldest, so set the time and date correctly in the meter.

#### Notes:

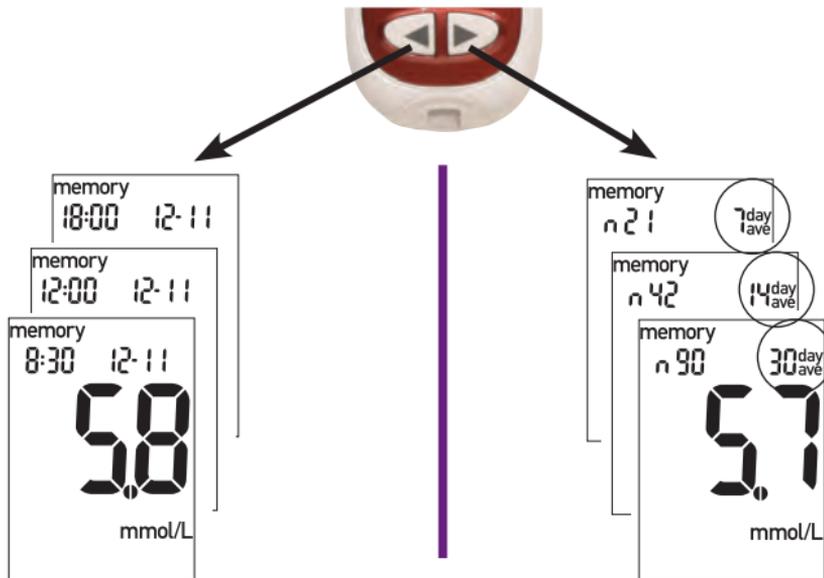
- The memory is not lost when the battery is replaced; however, confirm that the time and date are still correct.
- Once 20 control or 500 blood glucose results are in memory, adding a new result causes the oldest one to be deleted.
- Press and **hold**  or  to scroll through the results faster.
- The control results do not appear in memory.
- 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, contact Roche.



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

## Viewing Test Results

1. Press and release either ◀ or ▶ to enter memory. The most recent result appears.
2. Press and release ◀ to view previous results in order.
3. OR, press and release ▶ to look at 7-, 14-, or 30-day averages in that order.



# Meter Set-up

## Using the Set-up Mode

The following features can be adjusted as required.

Time and Date – set the time and date.

Beeper – select “On” or “OFF.”

Test reminder – select “On” or “OFF.” If “On” is chosen, select 1 to 4 test reminders per day.

Hypo alert – select “On” or “OFF.” If “On” is chosen, select the blood glucose level for the alert.

The  has three functions for the set-up mode:

- To enter the set-up mode, turn on the meter then press and **hold**  until “set-up” flashes on the display. This takes about 4 seconds.
- Press and release  to set the selected option.
- To exit the set-up mode at any time, press and **hold**  for about 4 seconds until the flashing test strip symbol appears on the display.

You are here

**TIME / DATE**  
(hrs, min, day,  
month, year)



**BEEPER**  
(on/off)



**TEST REMINDERS**  
(A-1, A-2, A-3, A-4)



**HYPO ALERT**  
(off, on, level)

## Setting the Time and Date



32

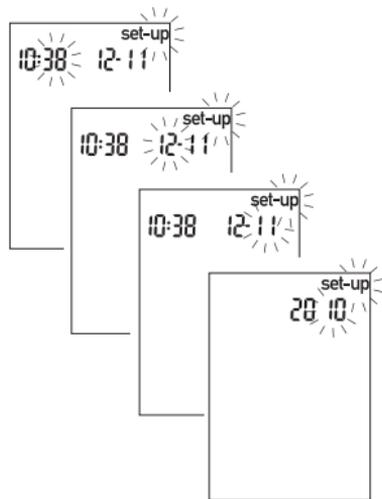
1. Press and release  to turn on the meter. The flashing test strip symbol appears.
2. Press and **hold**  for about 4 seconds to enter the set-up mode. "Set-up" and the hour flash on the display.
3. Press and release  or  to decrease or increase the hour.

### Note:

Press and **hold**  or  to scroll faster.



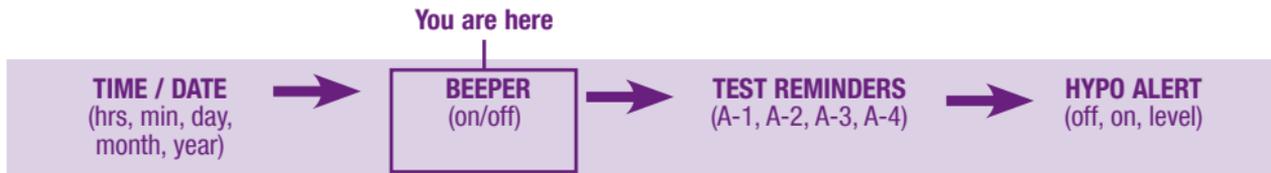
4. Press and release  to set the hour. The minutes flash.



5. Repeat steps 2 and 3 to set the minutes, day, month, and year. The flashing field is the one that is being changed.



6. To set up more options, press and release . To exit, press and **hold**  until the flashing test strip symbol appears on the display.

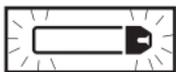


## Setting the Beeper On/Off

The meter beeper is preset to “On.” Setting the beeper to “OFF” does not affect test results.

The beeper prompts the operator:

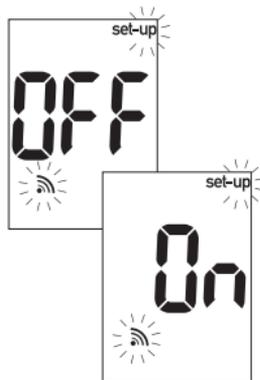
- To apply blood or control solution to the test strip
- When sufficient blood or control solution is drawn into the test strip
- When the test is complete
- When a button is pressed
- If an error occurred while testing (even if the beeper is off, it beeps for an error)
- If a test reminder is set



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



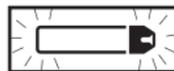
2. Press and **hold**  for about 4 seconds to enter the set-up mode. "Set-up" and the hour flash on the display.



3. Press and release  repeatedly until the flashing beeper symbol and "On" or "OFF" appear on the display.



4. Press and release ◀ or ▶ to switch between “On” or “OFF.”



5. To set up more options, press and release Ⓞ. To exit, press and **hold** Ⓞ until the flashing test strip symbol appears on the display.



## Setting Test Reminders

One to four test reminders can be set per day. The meter beeps every 2 minutes – up to 3 times. Turn off the test reminder by inserting a test strip or pressing any button. The beeper must be set to “On” for the test reminder to sound.

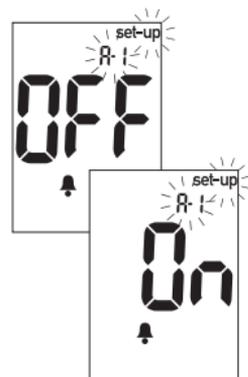
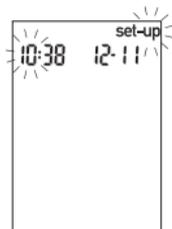
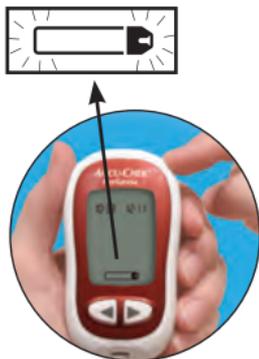
The meter is preset with the test reminder function set to “OFF.” It must be turned “On” to use this feature. If A-1, A-2, A-3, and A-4 are turned on, the meter is preset with the following times which can be adjusted as necessary.

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

### Notes:

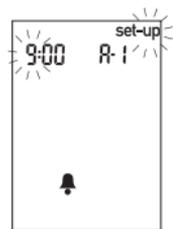
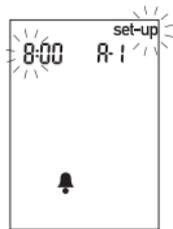
- If a test was performed within 30 minutes of a test reminder, the test reminder does not occur.
- If the meter is on at the test reminder time, the test reminder does not occur.
- Exposure to cold conditions may disable test reminders until the meter is turned on.

When setting the time for the test reminder function, the bell symbol remains on the display and “set-up” flashes continuously.

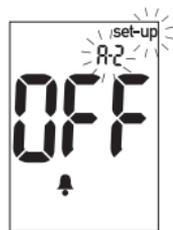
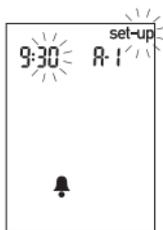


38

1. Press and release  to turn on the meter. The flashing test strip symbol appears.
2. Press and **hold**  for about 4 seconds to enter the set-up mode. “Set-up” and the hour flash on the display.
3. Press and release  repeatedly until the bell symbol, “OFF,” and the flashing “set-up” and “A-1” appear on the display.



4. Press and release ◀ or ▶ to switch between “On” and “OFF.” Press and release Ⓞ to set the option.
5. If “On” is selected, 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.



40

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 reminder “A-2” and “set-up” flash on the display with “OFF” and the bell symbol. A second reminder can be set, or press and **hold** Ⓞ until the flashing test strip symbol appears on the display to exit the set-up mode.

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



BEEPER  
(on/off)



TEST REMINDERS  
(A-1, A-2, A-3, A-4)



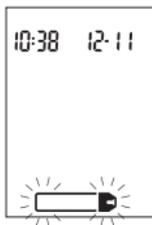
You are here

HYPO ALERT  
(off, on, level)

## Setting the Hypoglycaemic (Hypo) Alert

The meter hypoglycaemic alert is preset to “OFF.” The alert level can be set from 3.3–4.4 mmol/L.

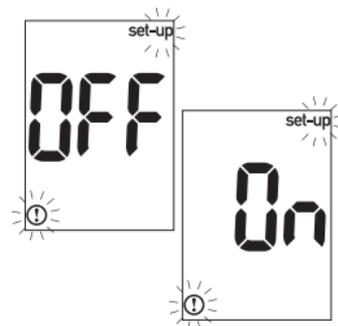
**Healthcare professionals:** The hypoglycaemic level may vary from person to person. It is recommended to turn **off** the hypo alert function when using the meter in a professional facility.



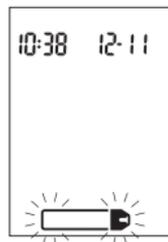
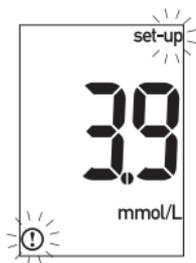
1. Press and release  to turn on the meter. The flashing test strip symbol appears.



2. Press and **hold**  for about 4 seconds to enter the set-up mode. “Set-up” and the hour flash on the display.



3. Press and release  repeatedly until “OFF” and the flashing “set-up” and  appear on the display.



4. Press and release ◀ or ▶ to switch between “On” and “OFF.” Press and release Ⓞ to set the option.

5. If “On” is selected, “set-up” and ⚠ flash. The display shows 3.9 mmol/L (first use) or the current level.

6. Press and release ◀ or ▶ to select the level. Press and release Ⓞ to set the level.

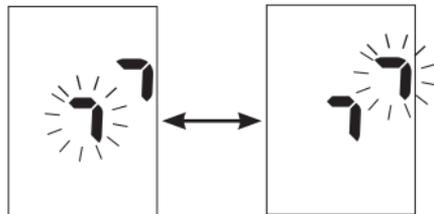
7. To exit, press and **hold** Ⓞ until the flashing test strip symbol appears on the display.

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



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

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



4. Locate the infrared (IR) window on the top of the meter.
5. Locate the IR window on either the infrared cable (computer) or PDA.
6. Put the meter on a flat surface. Point the two IR windows toward each other. They should be 3–10 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.

**Infrared (IR) Window**



### **Notes:**

- If the data did not transfer successfully, try again. Contact Roche if problems persist.
- Be sure to set the time and date in the meter for traceability of results.

# 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.
4. Turn on the meter. Confirm that the time and date are correct.

### Notes:

- The meter uses one 3-volt lithium battery, type 2032.
- All control and blood glucose test results remain saved in memory.

## Cleaning the Meter

Follow these instructions to clean or disinfect the meter:

- Make sure the meter is off
- Gently wipe the meter's surface with a soft cloth slightly dampened (wring out any excess) 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



### **DO NOT**

- **Get any moisture in the code chip and test strip slot**
- **Spray any cleaning solution directly onto the meter**
- **Put the meter in any type of liquid**
- **Pour liquid into the meter**

## Maintenance and Troubleshooting

The meter needs little or no maintenance with normal use. It automatically tests its own systems every time it is turned on and prompts the operator for any errors. See Chapter 5, “Display Messages and Troubleshooting.”

If the meter is dropped or the accuracy is in question, contact Roche.

To check the display, 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, contact Roche.



## Display Messages and Troubleshooting

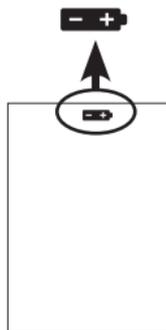


**Never make treatment decisions based on an error message. If you have any concerns, contact Roche.**



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

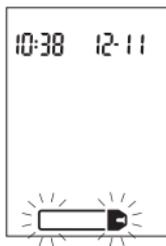
- Battery is dead – Insert new battery.
- Display is damaged – Contact Roche.
- Meter is defective – Contact Roche.
- Extreme temperatures – Move the meter to a more temperate area.



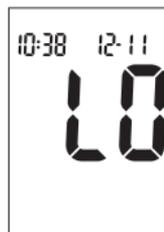
Battery power is low. Change the battery soon.



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



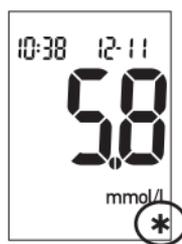
The meter is ready for you to insert a test strip.



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



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



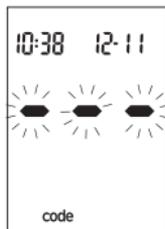
This test result was flagged. See Chapter 2 “Flagging Test Results” for more details.



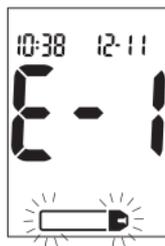
Blood glucose may be higher than the measuring range of the system.



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 strip is damaged. Remove the test strip and reinsert it or replace it if damaged. Or the code chip is incorrect. Turn off the meter and insert a new code chip. If the message reappears, contact Roche.



The test strips will expire at the end of the current month. At the end of the month, discard the code chip and any remaining test strips. 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 code chip is incorrect. Turn off the meter and insert a new code chip. If this does not fix the problem, contact Roche.



The blood glucose may be extremely high or a meter or test strip error has occurred. If this confirms symptoms, **follow your facility policy for treating questionable blood glucose results**. If it does not confirm symptoms, repeat the test and refer to Chapter 2, “Unusual Test

Results.” If this does not confirm symptoms, perform a control test with the control solution and a new test strip. If the control result is within the acceptable range, review the proper testing procedure and repeat the blood glucose test with a new test strip. If the E-3 code still appears for the blood glucose test, the blood glucose result may be extremely high and above the system’s reading range. **Follow facility policy**. If the control result is not within the acceptable range, see Chapter 3, “Understanding Out-of-Range Control Test Results.”



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 20 seconds and reinsert it. Perform a blood glucose or control test. If the problem persists, contact Roche.



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



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 5 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 display, please contact Roche.



# Chapter 6: Technical Information

## Product Limitations

Please read the literature packaged with the test strips and control solutions 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>	Refer to the test strip package insert.
<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>	-25–70 °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 2032)
<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>	Refer to the control solution package insert.

## **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 the meter to other electrically driven equipment is not anticipated.

## **Performance Analysis**

Refer to the test strip package insert.

## **Test Principle**

Refer to the test strip package insert.

## Product Safety Information



**Strong electromagnetic fields may interfere with the proper operation of the meter. Do not use this meter close to sources of strong electromagnetic radiation.**



**To avoid electrostatic discharge, do not use the meter in a very dry environment, especially one in which synthetic materials are present.**

## Disposing of the Meter and Batteries



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



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

**Dispose of used batteries according to local environmental regulations.**

## Explanation of Symbols

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



Consult instructions for use



Caution (refer to accompanying documents)! Please refer to safety-related notes in the instructions for use accompanying this instrument.



Temperature limitation (Store at)



Manufacturer

REF

Catalogue number



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

IVD

In vitro diagnostic medical device



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



3V type 2032

## 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 authorised Roche Diabetes Healthcare Centres, pharmacies, or medical/surgical supply dealers:

### **Test Strips**

Accu-Chek Inform II Test Strips

### **Control Solutions**

Accu-Chek Performa Control Solutions

### **Linearity Kits**

Accu-Chek Linearity Kit



# Index

## B

- battery,
  - changing, 45
  - installing, 45
  - type, 45, 55
- beeper, setting, 34
- blood glucose, testing, 15
- button, power/set, 5–6

## C

- code chip, 6–7
- computer, connecting the meter to, 43
- control solution, 24
- control test, performing, 25
- control test results, understanding out-of-range, 28

## D

- display check, 47
- display messages, 48–53

## E

- error messages, 50–53

## F

- flagging test results, 18

## G

- guarantee, 59

## H

- hyperglycaemia, 19–20
- hypoglycaemia, 19–20
- hypoglycaemic alert, setting, 41

## M

- maintenance, meter, 45
- memory, meter, 29

## P

- product limitations, 55
- product specifications, 55

## S

- sample handling, 13
- settings, meter, 31
- supplies, 59
- symbols, 58

## T

- technical information, 55
- test reminders, setting, 37
- test results, unusual, 19–20
- test strips, Accu-Chek Inform II, 6, 11
- time and date, setting, 32
- troubleshooting, 47–53

## U

- use by date, 11, 24





Roche Diagnostics Limited  
Charles Avenue, Burgess Hill  
West Sussex, RH15 9RY  
United Kingdom

Accu-Chek Customer Careline<sup>1)</sup>

UK Freephone number: 0800 701 000

ROI Freephone number: 1 800 709 600

<sup>1)</sup> calls may be recorded for training purposes

[www.accu-chek.co.uk](http://www.accu-chek.co.uk)

# ACCU-CHEK<sup>®</sup> Performa



Roche Diagnostics GmbH  
Sandhofer Strasse 116  
68305 Mannheim, Germany

[www.accu-chek.com](http://www.accu-chek.com)

ACCU-CHEK, ACCU-CHEK PERFORMA, ACCU-CHEK INFORM, and SAFE-T-PRO are trademarks of Roche.

©2010 Roche Diagnostics. All rights reserved. 05796806001(02)-0710

IVD

CE 0088