ACCU-CHEK®
Performa

BLOOD GLUCOSE METER / 血糖機

Owner's Booklet
使用者手冊

Roche

Roche USA – 50705
V6/1 – 05853397002 – Schwarz –
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Roche USA – 50705
V6/2 – 05853397002 – Cyan –
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Roche USA – 50705
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Whether the Accu-Chek Performa meter is your first blood glucose meter or you have used a meter for some time, please read this booklet carefully before you use your new meter. To use it correctly and dependably, you need to understand its operation, displays, and all individual features.

If you have any questions, please contact one of our customer support and service centers. Contact information is at the back of this booklet.

The Accu-Chek Performa System

The Accu-Chek Performa meter is designed to be used with the Accu-Chek Performa 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 fingertip and approved alternative sites (for example, forearm). Refer to the Alternative Site Testing (AST) section of this booklet for approved alternative sites and associated limitations. The Accu-Chek Performa meter with the Accu-Chek Performa test strips provide 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 Performa test strips and control solutions

Suitable for self-testing

The system includes (some items may be sold separately):

- **Accu-Chek Performa meter with battery**
- **Accu-Chek Performa test strips and code chip**
- **Accu-Chek Performa control solutions**

⚠ WARNING

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

The meter comes with a preset time and date. You may need to change the time to your time zone.

If you follow the steps in this booklet but still have symptoms that do not seem to match your test results, or if you have questions, talk to your healthcare professional.

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Chapter 1: Understanding Your New System

The Accu-Chek Performa Meter

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

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

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

Test Strip Slot
Insert test strip here.

Power/Set Button
Turns the meter on or off and sets options.

Code Chip Slot
Insert code chip here.

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

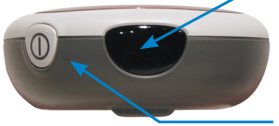
Golden End
Insert this end into the meter.

Yellow Window
Touch blood drop or control solution here.

Test Strip

Test Strip Container

Control Solution Bottle



Infrared (IR) Window

Power/Set Button

Top View

Code Chip
(for example)

Battery
Insert into battery compartment with **(+) side facing up**.

NOTE

The code chips that come with Accu-Chek Performa test strips are changing from white to **black**. Once you receive a **black** code chip, insert it into the meter. You do not need to change the **black** code chip again, even if new test strip boxes contain different colored code chips or different code numbers.

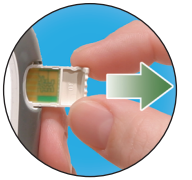
Preparing the Meter for a Test

NOTE

The code chips that come with Accu-Chek Performa test strips are changing from white to **black**. Once you receive a **black** code chip, insert it into the meter. You do not need to change the **black** code chip again, even if new test strip boxes contain different colored code chips or different code numbers.

1. Make sure the meter is off.

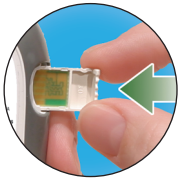
2. Turn the meter over.



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

NOTE

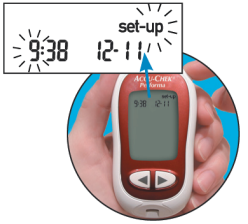
- If you see **code** and a flashing **- - -** on the display, insert a code chip into the meter.
- Do not force the code chip into the meter. There is only one correct way to insert the code chip.
- Leave the code chip in the meter until you open a new test strip box. Once you receive a **black** code chip, you do not need to change the code chip again.

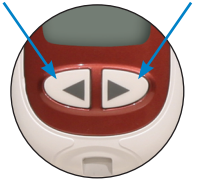


4. Position the new code chip so the code number faces away from you. Push the code chip into the code chip slot until the code chip snaps into place.

Adjusting the Time and Date for First Time Use

The meter is preset with the time and date which may need to be adjusted to the local time zone. It is important to set the correct time and date in the meter to use the meter memory or to transfer results to a computer.





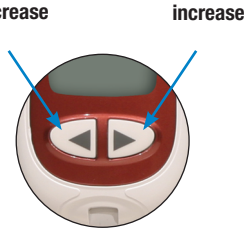
1. Press and release ◉ to turn the meter on.

   The time and date appear on the display with the hour and **set-up** flashing. 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.

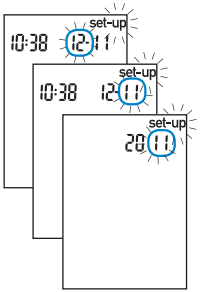
3. Press and release ◉ to set the hour.

   The minutes flash.



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

5. Press and release ◉ to set the minutes.



6. Repeat steps 4 and 5 to adjust and set the day, month, and year.

7. Press and **hold** ◉ until the flashing test strip symbol appears on the display.

   The time and date are now set.

NOTE

- After you change the battery, the meter automatically prompts a time and date confirmation when it is turned on.
- To set more options on the meter, see Chapter 3, Meter Setup.

Using the Accu-Chek Performa System

- Use only Accu-Chek Performa test strips.
- Use the test strip immediately after removing it from the test strip container.
- Do not apply blood or control solution to the test strip before you insert it into the meter.
- Close the test strip container tightly immediately after removing a test strip to protect the test strips from humidity.
- Store the unused test strips in their original test strip container with the cap closed.
- Check the use by date on the test strip container. Do not use the test strips after that date.
- Store the test strip container and meter in a cool, dry place such as a bedroom.
- Refer to the test strip package insert for test strip storage and system operating conditions.

⚠ WARNING

Do not store test strips in high heat and moisture areas (bathroom or kitchen)! Heat and moisture can damage test strips.

NOTE

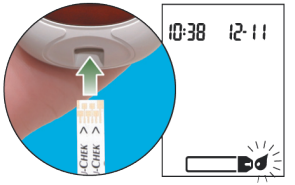
The code chips that come with Accu-Chek Performa test strips are changing from white to **black**. Once you receive a **black** code chip, insert it into the meter. You do not need to change the **black** code chip again, even if new test strip boxes contain different colored code chips or different code numbers.

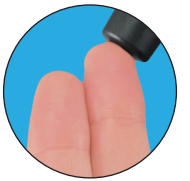
Performing a Blood Glucose Test

NOTE

- Set up the meter before you perform your first blood glucose test.
- Blood samples taken from the palm are equivalent to blood samples taken from the fingertip. For detailed information on how to obtain blood from the palm, refer to the Alternative Site Testing (AST) section, steps 4 and 5.

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



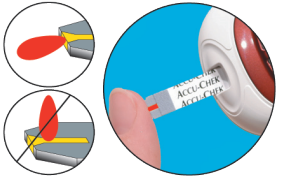


1. Wash and dry your hands.
2. Prepare the lancing device.
3. Check the use by date on the test strip container. Do not use test strips past the use by date.
4. Insert the test strip into the meter in the direction of the arrows.

   The meter turns on. A test strip symbol and a flashing blood drop symbol appear on the display.
5. Perform a fingerstick with the lancing device.

6. Gently squeeze your finger to assist the flow of blood.

   This helps you get a blood drop.



7. 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, there is enough blood in the test strip.

or

8. The test result appears on the display. Leave the test strip in the meter to mark a special event (see the next section, Marking Blood Glucose Results). Otherwise, remove and discard the used test strip.

NOTE

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

Marking Blood Glucose Results

You can mark a test result with an asterisk (∗) to indicate a special event such as exercise or an AST result. When you review the test results in memory, the ∗ can help you remember what was different about the test result.

Here is how to mark a test result:

1. Perform a blood glucose test.

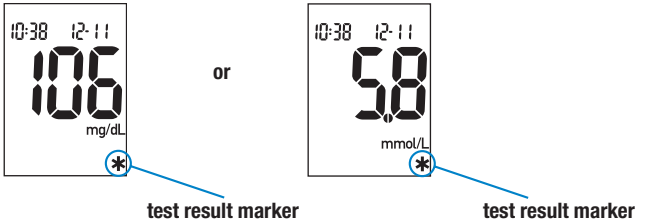
   The blood glucose result appears on the display.

2. Leave the test strip in the meter. Press ◀ or ▶ once.

   In the lower right corner of the display, an ∗ appears.

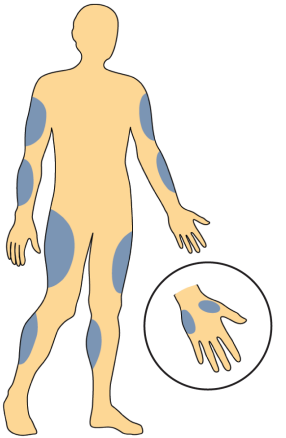
3. Remove and discard the used test strip.

   The test result is marked.



Alternative Site Testing (AST)

You have the option of obtaining a blood sample from other sites on your body besides the fingertip. Alternative sites include the palm, forearm, upper arm, thigh, and calf. The two palm testing sites are the fleshy areas under the thumb (thenar) and under the little finger (hypothenar). Blood obtained from the fingertip and palm can be used at any time to test blood glucose. If blood from the forearm, upper arm, thigh, or calf is used, there are certain times when testing is not appropriate (see the following section). This is because your blood glucose level changes faster in your fingertip and palm than in the forearm, upper arm, thigh, and calf. These differences may cause you to make the wrong therapeutic decision, producing adverse health effects. Please read the following section before you test from alternative sites.



approved alternative sites

IMPORTANT

Talk to your healthcare professional before you perform an alternative site test.

⚠ WARNING

- Do not change your therapy because of just one blood glucose result.
- NEVER ignore symptoms of low or high blood glucose.
- If your blood glucose result does not match how you feel, perform a fingertip or palm test to confirm your test result. If the fingertip or palm test result still does not match how you feel, contact your healthcare professional.

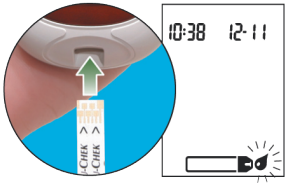
Tests from the forearm, upper arm, thigh, or calf may be performed:

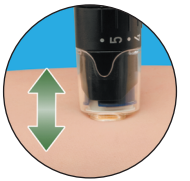
- immediately before a meal.
- fasting.

Tests from the forearm, upper arm, thigh, or calf may NOT be performed:

- up to 2 hours following a meal, when blood glucose values can rise quickly.
- up to 2 hours after injecting bolus insulin, when blood glucose values can decrease rapidly.
- after exercise.
- if you are sick.
- if you think your blood glucose is extremely low.
- if you often do not notice when your blood glucose is low.

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





1. Prepare the lancing device.

2. Check the use by date on the test strip container. Do not use test strips past the use by date.

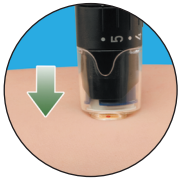
3. Insert the test strip into the meter in the direction of the arrows.

   The meter turns on. A test strip symbol and a flashing blood drop symbol appear on the display.

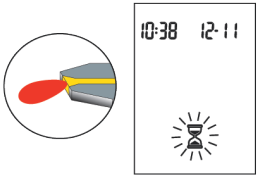
4. Press the lancing device firmly against a fleshy area on the alternative site. Press the lancing device up and down in a slow pumping motion to assist the flow of blood.

NOTE

- If the blood drop is too small, reapply pressure to get a sufficient blood drop.
- After a successful test, the meter turns off 5 seconds after the test strip is removed.

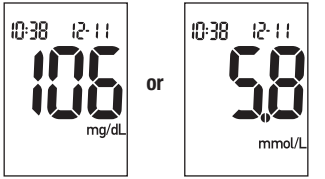


5. Trigger the lancing device while keeping steady pressure on the site. Apply pressure to the site with the lancing device to assist the flow of blood.



6. 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, there is enough blood in the test strip.



7. The test result appears on the display. Leave the test strip in the meter to mark a special event (see Marking Blood Glucose Results). Otherwise, remove and discard the used test strip.

Unusual Blood Glucose Results

If your blood glucose result does not match how you feel, check this list to help solve the problem.

Troubleshooting Checks	Action
1. Check if the test strips were expired.	Discard the test strips if they are past the use by date. Repeat the blood glucose test with an unexpired test strip.
2. Check if the cap on the test strip container was always closed tightly.	Replace the test strips if you think the test strip container was uncapped for some time and repeat the blood glucose test.
3. Check if the test strip was used immediately after removing it from the test strip container.	Repeat the blood glucose test with a new test strip.
4. Check if the test strips were stored in a cool, dry place.	Repeat the blood glucose test with a properly stored test strip.
5. Check if you followed the directions.	See Chapter 2, Testing Your Blood Glucose, and repeat the blood glucose test. Contact Roche if you still have problems.

6. Check if the meter and test strips are working properly.	Perform a control test. See Chapter 4, Performing a Control Test, for instructions.
7. If you are still unsure of the problem …	Contact Roche.

Symptoms of Low or High Blood Glucose

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

Symptoms of low blood glucose (hypoglycemia) may include, but are not limited to: anxiety, shakiness, sweating, headache, increased hunger, dizziness, pale skin color, sudden change in mood or irritability, fatigue, difficulty concentrating, clumsiness, palpitations, and/or confusion.

Symptoms of high blood glucose (hyperglycemia) may include, but are not limited to: increased thirst, frequent urination, blurred vision, drowsiness, and/or unexplained weight loss.

⚠ WARNING

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

Chapter 3: Meter Memory, Setup, and Data Transfer

Memory

Storing Blood Glucose and Control Results

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

NOTE

- The memory is not lost when the battery is replaced; however, confirm that the time and date are still correct (see Chapter 3, Setting the Time and Date).
- Once 500 blood glucose or 20 control results are in memory, adding a new result causes the oldest one to be deleted.
- Press and **hold** ◁ or ▷ to scroll through the test results faster.
- Up to 20 control results are stored in memory but cannot be reviewed on the meter. To view stored control results, first transfer them to a compatible software application. Contact Roche for product availability.
- Control results are not included in the 7, 14, and 30 day averages.

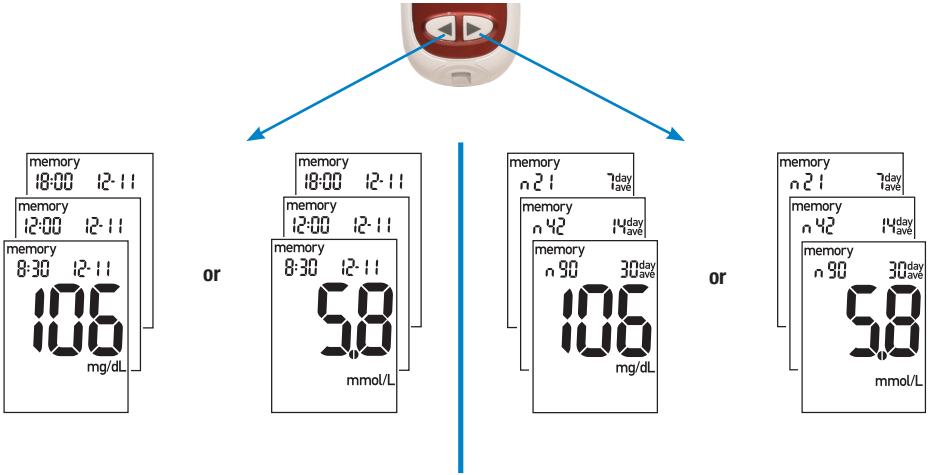
⚠ WARNING

Do not change your therapy based on one individual blood glucose result in memory. Talk to your healthcare professional before changing therapy based on test results in memory.

Viewing Blood Glucose Results

With the meter on or off, press and release ◀ or ▶ to enter memory. The most recent test result appears on the display.

- To view previous test results in order, press ◀.
- To view the 7, 14, or 30 day averages, press ▶.



Meter Setup

Using the Set-Up Mode

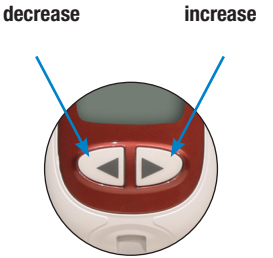
The following features can be customized as required.

	Time and date	Set the time and date.
	Beeper	Select **On** or **OFF**.
	Test reminders	Select **On** or **OFF**. If you select **On**, choose 1 to 4 times a day for a test reminder.
	Hypo alert	Select **On** or **OFF**. If you select **On**, choose the blood glucose level for the hypo alert.

Here is a general overview of the function that each button performs in set-up mode.

	Enter the set-up mode	Turn the meter on. Press and **hold** until **set-up** appears on the display.
	Exit the set-up mode at any time	Press and **hold** until the flashing test strip symbol appears on the display.
	Set the chosen feature	Press and release .
or	Adjust settings	Press and release or .

Setting the Time and Date



1. Press and release ⏻ to turn the meter on.

   The flashing test strip symbol appears on the display.

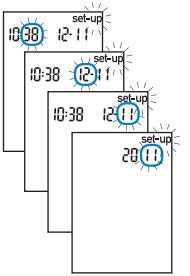
2. Press and **hold** ⏻ until **set-up** appears on the display.

   The hour flashes.

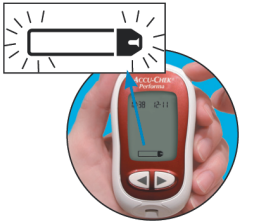
3. Press and release ◀ or ▶ to decrease or increase the hour.

4. Press and release ◉ to set the hour.

   The minutes flash.



5. Repeat steps 3 and 4 to adjust and set the minutes, day, month, and year.



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 or Off

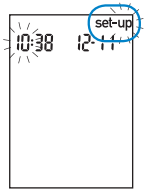
The meter has the beeper preset to **On**. Setting the beeper to **OFF** does not affect test results.

The beeper is helpful because it prompts you:

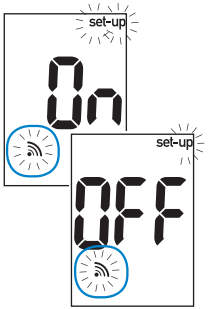
- to apply blood or control solution to the test strip.
- when enough blood or control solution is drawn into the test strip.
- when the blood glucose or control test is complete.
- when a button is pressed.
- when it is time to perform a test (if you set the test reminders).
- if an error occurred while performing a blood glucose or control test (even if the beeper is off, it still beeps for an error).

1. Press and release ⏻ to turn the meter on.

   The flashing test strip symbol appears on the display.



2. Press and **hold** ⏻ until **set-up** appears 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** and **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

A test reminder:

- beeps at the same time each day to remind you to perform a test.
- beeps every 2 minutes up to 3 times.
- turns off by inserting a test strip or pressing any button.
- is preset to **OFF**. You must turn a test reminder on to use this feature.

You can set up to 4 test reminders per day. You can adjust the times to suit your needs. Here are the symbols and preset times for the test reminders.

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

NOTE

- 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.
- If a test reminder is off in set-up mode, any subsequent test reminders are also off. For example, if you set A-1 but turn off A-2, then A-3 and A-4 will automatically be off.

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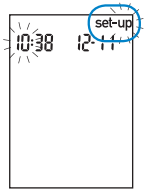
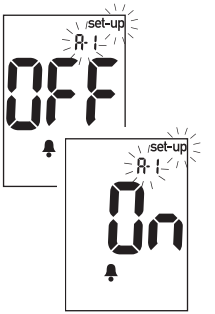
When setting the time for a test reminder, the bell symbol and **set-up** remain on the display.

1. Press and release ◉ to turn the meter on.

   The flashing test strip symbol appears on the display.

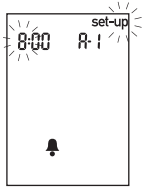


2. Press and **hold** ◉ until **set-up** appears on the display.



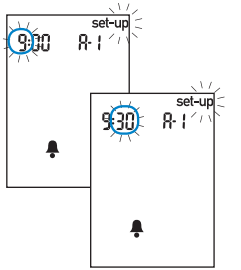
3. Press and release ◉ repeatedly until the bell symbol, **OFF**, and the flashing **A-1** appear on the display.

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



5. Press and release ◉ to set your choice.

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

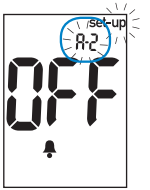


6. Press and release ◀ or ▶ to adjust the hour.

7. Press and release ◉ to set the hour.

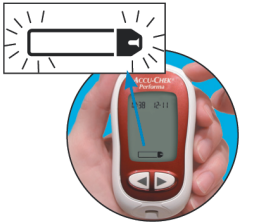
   The minutes flash.

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



9. Press and release ◉ to set the minutes.

   The bell symbol, **OFF**, and the flashing **A-2** appear on the display.



10. To adjust and set additional test reminders, follow steps 4–9. To exit, press and **hold** ◉ until the flashing test strip symbol appears on the display.

Setting the Hypoglycemic (Hypo) Alert

The hypo alert can be set to a level between 60 and 80 mg/dL or 3.3 and 4.4 mmol/L to let you know when your blood glucose is possibly too low.

⚠ WARNING

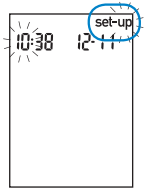
This function is not a substitute for hypoglycemia training by your healthcare professional.

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

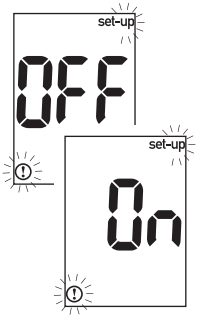
Healthcare Professionals: The hypoglycemic level may vary from person to person. It is recommended to turn the hypo alert **OFF** when using the meter in a professional facility.

1. Press and release ⏻ to turn the meter on.

   The flashing test strip symbol appears on the display.

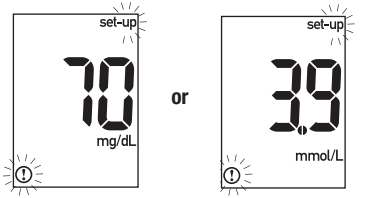


2. Press and **hold** ⏻ until **set-up** appears on the display.



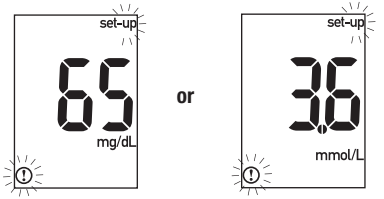
3. Press and release ⏻ repeatedly until **OFF** and the flashing ⏻ appear on the display.

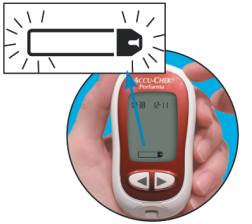
4. Press and release ◀ or ▶ to switch between **On** and **OFF**.



5. Press and release ◉ to set your choice.

   If you select **On**, ⓘ flashes. The display shows 70 mg/dL or 3.9 mmol/L.





6. Press and release ◀ or ▶ to adjust the level.

7. Press and release ◉ to set the level.

8. Press and **hold** ◉ until the flashing test strip symbol appears on the display.

   The set-up mode is complete. To turn the meter off, press and release ◉.

Transferring Your Results to a Computer or PDA

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

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

⚠ WARNING

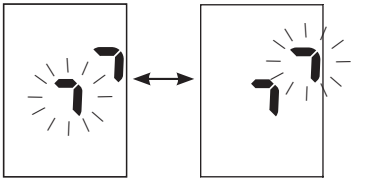
Individual patient results cannot be identified, so transferring data from meters used for multiple-patient testing is NOT recommended.

1. Install the software according to the instructions.

2. To transfer the results to a computer, connect the infrared cable according to the instructions.

3. Run the software program and follow the instructions for data transfer. Make sure the software is ready to accept data from the meter.

4. With the meter off, press and **hold** both ◄ and ► until 2 arrows on the display alternately flash.



5. Locate the infrared (IR) window on the top of the meter.

6. Locate the IR window on either the infrared cable (computer) or PDA.

7. Put the meter on a flat surface and point the 2 IR windows toward each other. They should be 3–10 cm apart.

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

9. Follow the prompts on the software.

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

infrared (IR) window

NOTE

- If the data did not transfer successfully, try again. Contact Roche if you still have problems.
- To make the most of the data transfer feature, you must set the time and date in the meter correctly.

Chapter 4: Control Testing

Why Perform Control Tests

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

- you open a new test strip box.
- you left the test strip container open.
- you want to check the meter and test strips.
- the test strips were stored in extreme temperatures, humidity, or both.
- you dropped the meter.
- your test result does not match how you feel.
- you want to check if you are performing the test correctly.

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About the Control Solutions

- Use only Accu-Chek Performa control solutions.
- Close the control solution bottle tightly after use.
- Write the date you opened the control solution bottle on the bottle label. The control solution is good 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.
- Refer to the control solution package insert for control solution storage conditions.
- The meter automatically recognizes the Accu-Chek Performa control solution.
- The control results are not displayed in memory.
- The control solution can stain fabric. Remove stains by washing with soap and water.

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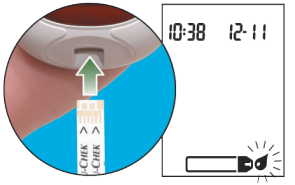
Performing a Control Test

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

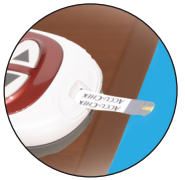
1. Check the use by date on the test strip container. Do not use test strips past the use by date.



2. Insert the test strip into the meter in the direction of the arrows.

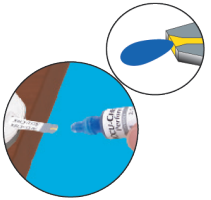
   The meter turns on. A test strip symbol and a flashing blood drop symbol appear on the display.

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



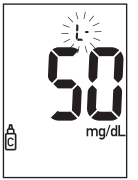
4. Put the meter on a flat surface, such as a table.

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

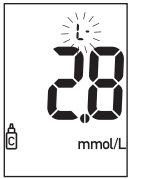


6. Squeeze the bottle until a tiny drop forms at the tip. Touch the drop to the **front edge** of the yellow window of the test strip. Do not put control solution on top of the test strip.

   When you see ⊠ flash, there is enough control solution in the test strip.

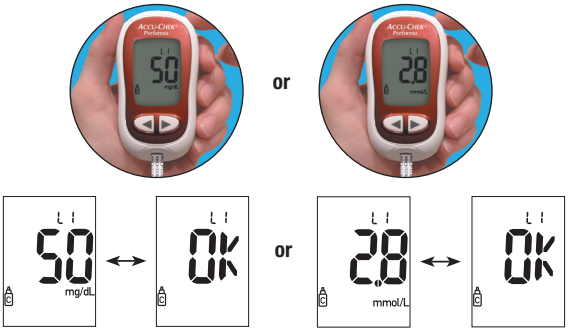


or



7. Wipe the tip of the bottle with a tissue. Cap the bottle tightly.

8. The control 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 control result as a Level 1. Press ▶ a second time to mark the control result as a Level 2.



9. Press and release ⓘ to set the control level in the meter.

   OK and the control result alternate on the display if the control result is in range. **Err** and the control result alternate on the display if the control result is not in range.

10. Remove and discard the used test strip.

NOTE

- The ranges for the Level 1 and Level 2 control solutions are printed on the test strip container label. When the control result is inside the range on the test strip container, the test strips and meter are working properly.
- After a successful test, the meter turns off 5 seconds after the test strip is removed.

Understanding Out-of-Range Control Results

If the control result is out of range, check this list to help solve the problem.

Troubleshooting Checks	Action
1. Check if the test strips or control solutions were expired.	Discard the test strips or control solutions if either is past the use by date. If the control solution was opened more than 3 months ago, discard it. Repeat the control test with an unexpired test strip and an unexpired control solution.
2. Check if you wiped the tip of the control solution bottle before use.	Wipe the tip of the bottle with a tissue. Repeat the control test with a new test strip and a fresh drop of control solution.
3. Check if the caps on the test strip container and the control solution bottle were always closed tightly.	Replace the test strips or control solutions if you think either was uncapped for some time and repeat the control test.
4. Check if the test strip was used immediately after removing it from the test strip container.	Repeat the control test with a new test strip and a fresh drop of control solution.
5. Check if the test strips and control solutions were stored in a cool, dry place.	Repeat the control test with a properly stored test strip and control solution.

6. Check if you followed the directions.	See Chapter 4, Control Testing, and repeat the control test. Contact Roche if you still have problems.
7. Check if you chose the correct control solution level, either 1 or 2, when you performed the control test.	If you chose the wrong control solution level, you can still compare the control result to the range printed on the test strip container.
8. If you are still unsure of the problem …	Contact Roche.

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Chapter 5: Maintenance and Troubleshooting

Meter Maintenance

The meter needs little or no maintenance with normal use. It automatically tests its own systems every time you turn it on and lets you know if something is wrong (see Chapter 5, Display and Error Messages).

If you drop the meter or think it is not giving accurate results, contact Roche.

To make sure the display is working properly, turn the meter off, then press and **hold** ⏻ to see the complete display. All the segments should be clear and look exactly like the picture below. If not, contact Roche.

or

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.
2. Remove the old battery.
3. Insert the new battery with the **(+) side facing up**.
4. Put the battery door back in place and snap it closed.

NOTE

- The meter uses one 3-volt lithium battery, coin cell type CR2032. This battery can be found in many stores. It is a good idea to have a spare battery available.
- Be sure the battery is inserted **(+) side facing up**.
- After the battery is changed, the meter automatically prompts a time and date confirmation when it is turned on.
- All results remain saved in the memory.

Cleaning the Meter

Make sure to keep the meter 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 (wring out any excess liquid) 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

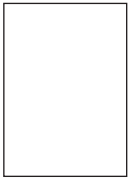
Do Not

- Allow any liquid to enter the slots in the meter
- Spray cleaning solution directly onto the meter
- Immerse the meter in liquid

Display and Error Messages

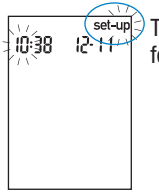
⚠ WARNING

Never make therapy decisions based on an error message. Contact Roche if you have any concerns.

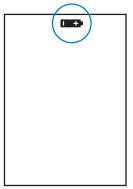


The meter will not turn on or the display is blank.

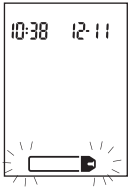
- Battery is dead. Insert new battery.
- Display is damaged. Contact Roche.
- Meter is defective. Contact Roche.
- Extreme temperatures. Move the meter to a more temperate area.



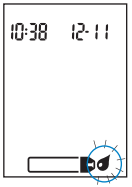
The meter is in set-up mode, waiting for you to change or confirm settings.



Battery power is low. Change the battery soon.



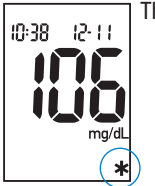
The meter is ready for you to insert a test strip.



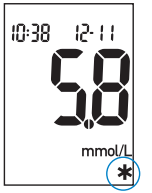
The meter is ready for a drop of blood or control solution.

Blood glucose may be lower than the measuring range of the system (see Chapter 2, Unusual Blood Glucose Results).

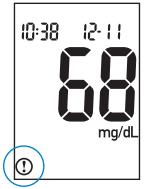
Blood glucose may be higher than the measuring range of the system (see Chapter 2, Unusual Blood Glucose Results).



or

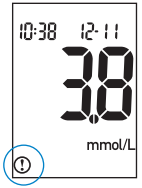


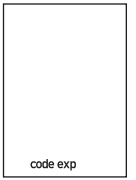
The test result was marked.



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

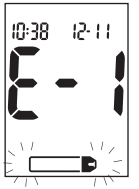
or





This message may appear when using a white code chip in the meter. It means the test strips 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, unexpired test strip box. Make sure the time and date in the meter are correct.

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



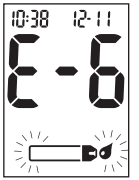
The test strip may be damaged or the code chip is incorrect. Remove and reinsert the test strip. If the message reappears, turn the meter off and insert a new code chip.

The code chip is incorrect. Turn the meter off and insert a new code chip.

Your blood glucose may be extremely high or a meter or a test strip error has occurred.

- If your test result matches how you feel, contact your healthcare professional immediately.
- If your test result does not match how you feel, repeat the blood glucose test and see Chapter 2, Unusual Blood Glucose Results.
  - 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 second test result does not match how you feel, 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 control result is not within the acceptable range, see Chapter 4, Understanding Out-of-Range Control 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.



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.

This message may appear when using a white code chip in the meter. It means the code chip is from an expired lot of test strips. Turn the meter off and insert a new code chip. 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.

The temperature is above or below the proper range for the system. 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 blood glucose or control test. Do not artificially heat or cool the meter.

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

The battery is almost out of power. Change the battery now.

NOTE

- Contact Roche if a display or error message reappears.
- Contact Roche if any other error message appears.

Chapter 6: Technical Information

Product Limitations

Read the literature packaged with the test strips and control solutions for the latest information on product specifications and limitations.

Specifications

Blood volume	Refer to the test strip package insert.
Sample type	Refer to the test strip package insert.
Test time	Refer to the test strip package insert.
Measurement range	Refer to the test strip package insert.
Test strip storage conditions	Refer to the test strip package insert.
Meter storage conditions	Temperature: -25–70 °C
System operating conditions	Refer to the test strip package insert.
Relative humidity operating range	Refer to the test strip package insert.
Memory capacity	500 blood glucose results and 20 control results with time and date

Automatic power off	2 minutes
Power supply	One 3-volt lithium battery (coin cell type CR2032)
Display	LCD
Dimensions	93 × 52 × 22 mm (LWH)
Weight	Approx. 62 g (with battery)
Construction	Hand-held
Protection class	III
Meter type	The Accu-Chek Performa meter is suitable for continuous operation.
Control solution storage conditions	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, the meter meets the electromagnetic emissions requirements as per EN 61326. The meter's electromagnetic emission is thus low. Interference from the meter to other electrically-driven equipment is not anticipated.

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Performance Analysis
Refer to the test strip package insert.

Test Principle
Refer to the test strip package insert.

Product Safety Information

⚠ WARNING

- Choking hazard. Small parts. Keep away from children under the age of 3 years.
- Strong electromagnetic fields may interfere with the proper operation of the meter. Do not use the 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.

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Discarding the Meter

⚠ WARNING

- During blood glucose testing, the meter itself may come into contact with blood. Used meters therefore carry a risk of infection. Before discarding the meter, remove the battery or batteries. Discard used meters according to the regulations applicable in your country. Contact the local council and authority for information about correct disposal.
- The meter falls outside the scope of the European Directive 2002/96/EC – Directive on waste electrical and electronic equipment (WEEE).
- Discard used batteries according to local environmental regulations.

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Explanation of Symbols

These symbols may appear on the packaging, on the type plate, and in the instructions for the Accu-Chek Performa meter.

	Consult instructions for use
	Caution, refer to safety-related notes in the instructions for use accompanying this product.
	Temperature limitation (store at)
	Manufacturer
REF	Catalogue number
IVD	In vitro diagnostic medical device
CE 0088	This product fulfils the requirements of the European Directive 98/79/EC on in vitro diagnostic medical devices.
	3V coin cell type CR2032

Guarantee

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

Additional Supplies

Test Strips

Accu-Chek Performa test strips

Control Solutions

Accu-Chek Performa control solutions

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Information for Healthcare Professionals

⚠ WARNING

Healthcare Professionals: Follow the infection control procedures appropriate for your facility. Refer to the test strip package insert for additional healthcare professional information.

Sample Handling

Always wear gloves 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.

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

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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 or palm test results and test results obtained from the forearm, upper arm, thigh, or calf. The difference in capillary bed concentration and blood perfusion throughout the body can lead to sample site-to-site differences in blood 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 blood from the fingertip or palm than in blood from the forearm, upper arm, thigh, or calf.* This is especially important when blood glucose levels are falling or rising rapidly. If your patient is used to making therapy decisions based upon fingertip or palm test results, he or she should consider the delay, or lag time, affecting the test results obtained with blood from the forearm, upper arm, thigh, or calf.

*Data on file

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ZHT

台灣核准品名：**羅氏優勝血糖機組**
香港核准品名：**卓越血糖機**

不論Accu-Chek Performa（羅氏優勝/卓越）血糖機是您的第一台血糖機，或您曾經使用過其他的血糖機，使用新的血糖機之前，都請您務必仔細閱讀本手冊。為了能正確操作本血糖機，您必須瞭解血糖機的操作方式、顯示幕及所有個別的特殊功能。

如有任何問題，請與羅氏糖尿病照護部門/客戶服務部聯繫。聯絡資訊請見本手冊封底。

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V4/1 – 05853397002 – Schwarz –

Roche USA – 50705
V4/2 – 05853397002 – Cyan –

Roche USA – 50705
V4/3 – 05853397002 – Magenta –

Roche USA – 50705
V4/4 – 05853397002 – Yellow –

Accu-Chek Performa System（羅氏優勝/卓越）血糖機系統

Accu-Chek Performa（羅氏優勝/卓越）血糖機設計為搭配Accu-Chek Performa（羅氏優勝/卓越）試紙使用，適用於定量檢測新鮮靜脈血、動脈血、新生兒血和微血管全血中的血糖，作為有效的血糖監控之用。檢測用的微血管檢體樣本可採自指尖和被准許的其它部位（例如前臂）。請參閱本手冊「其它部位採血檢測法（AST）」一節，以瞭解准許的其它部位和相關限制。Accu-Chek Performa（羅氏優勝/卓越）血糖機配合Accu-Chek Performa（羅氏優勝/卓越）血糖試紙提供完整的檢測系統，供醫護專業人員於臨床環境下或糖尿病患者於家居環境中，進行體外診斷檢測。本系統並不適用於診斷或篩檢各類型糖尿病之用。專業醫護人員採集血樣和準備工作，請參閱試紙包裝盒內的仿單/說明書。

僅可搭配Accu-Chek Performa（羅氏優勝/卓越）試紙和品管/質控液使用。

適用於血糖自我檢測

本系統配備（有些物品可能需要另購）包括：

- **Accu-Chek Performa（羅氏優勝/卓越）血糖機（含電池）**
- **Accu-Chek Performa（羅氏優勝/卓越）試紙和密碼晶片/密碼牌**
- **Accu-Chek Performa（羅氏優勝/卓越）品管/質控液**

⚠警告

任何曾與人類血液接觸的物體，都會是潛在的感染源（請參閱：Clinical and Laboratory Standards Institute：Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Third Edition; CLSI document M29-A3, 2005）。

為什麼定期檢測血糖很重要

若能定期檢測您的血糖，對您每天的糖尿病管理將能發揮顯著的功效。我們已將檢測血糖的方法儘可能簡化。

關於新血糖機的重要資訊

本血糖機出廠時已設定好時間與日期。使用前請將時間改為您的當區時間。

如果您已依照手冊中的步驟進行檢測，但發現自己似乎有與檢測值不符合的症狀，或是有任何疑問，都請與專業醫護人員聯絡。

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第1章：瞭解您的新血糖機

Accu-Chek Performa（羅氏優勝/卓越）血糖機

紅外線（IR）傳輸埠
用來從血糖機傳輸資料到電腦或PDA。

顯示幕
顯示幕—顯示檢測值、訊息和儲存在記憶裡的檢測值。

右箭頭鍵和左箭頭鍵
按壓以便輸入記憶項目、調整設定，並用來捲動瀏覽檢測值。

試紙槽
在此插入試紙。

電源/設定鍵
開啟或關閉血糖機及設定選項。

密碼晶片/密碼牌槽
於此處插入密碼晶片/密碼牌。

電池蓋
依箭頭方向推一下電池蓋上的凸起部分即可翻開電池蓋。

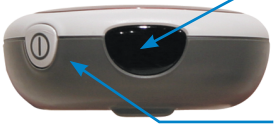
金屬端(電極)
將試紙的金屬端插入血糖機。

黃色反應區
黃色反應區一用此處碰觸血滴或品管/質控液。

試紙

試紙瓶

品管/質控液瓶



紅外線（IR）傳輸埠

電源/設定鍵

俯視圖

密碼晶片/密碼牌
（範例）

電池
將新電池「+」面朝上，放入電池盒內。

備註

Accu-Chek Performa（羅氏優勝/卓越）血糖試紙隨附的密碼晶片/密碼牌已從白色改為**黑色**。首次拿到**黑色**密碼晶片/密碼牌時，請將其插入血糖機。使用**黑色**密碼晶片/密碼牌之後，您無須再次改換密碼晶片/密碼牌，即使新的試紙盒裡有其它不同顏色的密碼晶片/密碼牌或不同的密碼。

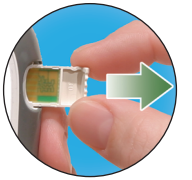
檢測前準備血糖機

備註

Accu-Chek Performa（羅氏優勝/卓越）血糖試紙隨附的密碼晶片/密碼牌已從白色改為**黑色**。首次拿到**黑色**密碼晶片/密碼牌時，請將其插入血糖機。使用**黑色**密碼晶片/密碼牌之後，您無須再次改換密碼晶片/密碼牌，即使新的試紙盒裡有其它不同顏色的密碼晶片/密碼牌或不同的密碼。

1. 確定血糖機為關機狀態。

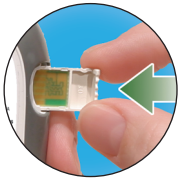
2. 把血糖機翻轉至背面。



3. 移除並丟棄白色密碼晶片/密碼牌（如果血糖機上有白色密碼晶片/密碼牌）。

備註

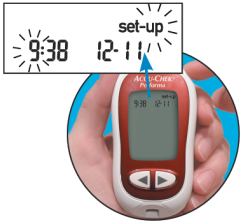
- 看到顯示幕上顯示code（密碼）並閃爍- - -時，請將密碼晶片/密碼牌插入血糖機。
- 請勿強力將密碼晶片/密碼牌壓入血糖機。正確插入密碼晶片/密碼牌的方式只有一種。
- 讓密碼晶片/密碼牌留在血糖機裡，除非您要使用另一盒新的試紙。使用**黑色**密碼晶片/密碼牌之後，您無須再次改換密碼晶片/密碼牌。

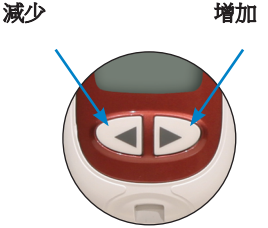


4. 翻轉新的密碼晶片/密碼牌，使其密碼朝向外側。將密碼晶片/密碼牌插入密碼晶片/密碼牌槽，直到卡入定位為止。

首次使用調整設定時間與日期

血糖機已預先設定時間和日期，可能需要更改為當地時區。若要使用血糖機的記憶功能或將檢測值下載至電腦，正確設定血糖機的時間與日期非常重要。





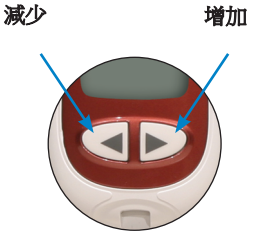
1. 按下又放開◉(電源/設定鍵)以開啟血糖機。

   時間和日期會顯示在顯示幕上，小時和**set-up**（設定）開始閃爍。如果顯示的時間和日期正確，按下並**按住**◉以跳出設定。

2. 按下又放開◀或▶以減少或增加「小時」。按下並**按住**◀或▶不放，以快速捲動數值。

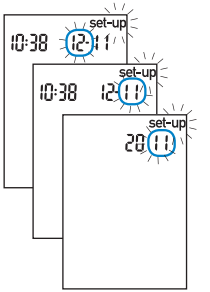
3. 按下又放開◉以完成設定「小時」。

   隨後「分鐘」開始閃爍。



4. 按下又放開◀或▶即可調整分鐘。

5. 按下又放開◉以完成設定「分鐘」。



6. 調整和設定日、月和年，步驟與上述步驟4和5同。

7. 按下並**按住** ◉直到顯示幕上出現閃爍的試紙符號為止。

   現在已完成設定時間和日期。

備註

- 更換電池並開機後，血糖機會提醒您確認血糖機的時間和日期設定。
- 請參閱第3章「血糖機設定」以在血糖機上設定更多選項。

使用Accu-Chek Performa（羅氏優勝/卓越）血糖機系統

- 只能使用Accu-Chek Performa（羅氏優勝/卓越）血糖試紙。
- 試紙從試紙瓶取出後，應立即使用。
- 試紙插入血糖機前，請勿將血液或品管/質控液滴在試紙上。
- 每次取出試紙後，應立即蓋緊試紙瓶蓋，以免試紙受潮。
- 請將未用過的試紙保存在原包裝試紙瓶中，並密閉瓶蓋。
- 檢查試紙瓶上的有效期限。請勿使用過期試紙。
- 請將試紙瓶與血糖機存放在乾燥涼爽之處，例如臥室。
- 請參閱試紙包裝內仿單/說明書上的存放條件和系統操作條件。

⚠警告

請勿將試紙存放在高溫和潮濕的地方（如浴室或廚房）！高温和潮濕會損壞試紙。

備註

Accu-Chek Performa（羅氏優勝/卓越）血糖試紙隨附的密碼晶片/密碼牌已從白色改為**黑色**。首次拿到**黑色**密碼晶片/密碼牌時，請將其插入血糖機。使用**黑色**密碼晶片/密碼牌之後，您無須再次改換密碼晶片/密碼牌，即使新的試紙盒裡有其它不同顏色的密碼晶片/密碼牌或不同的密碼。

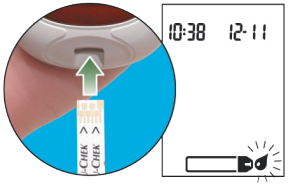
第2章：檢測您的血糖

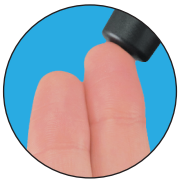
執行血糖檢測

備註

- 執行首次血糖檢測前，請設定血糖機。
- 從手掌採集的血樣與從指尖採集的血樣具有同等效用。有關從手掌採集血樣的詳情，請參閱「其他部位採血檢測法」(AST) 章節，步驟4和5。

用品準備：血糖機、一片試紙、採血筆及採血針。



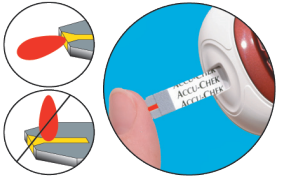


1. 洗淨並擦乾您的雙手。
2. 準備採血筆。
3. 檢查試紙瓶上的有效期限。請勿使用過期的試紙。
4. 依箭頭方向將試紙插入血糖機。

   血糖機會自動開機。顯示幕上會出現試紙符號和閃爍的血滴符號。
5. 以採血筆扎一下手指。

6. 輕輕擠壓指尖，使血液容易流出。

   使其凝聚成血滴。



7. 將血滴碰觸試紙黃色反應區**前緣**。請勿將血滴放在試紙上方。

   看到⌛閃爍時，表示試紙已經吸入足夠的血液。

或

8. 檢測值會顯示在顯示幕上。讓試紙留在血糖機內，以標記一個特殊的事件（見下一章節的「標記血糖檢測值」）。若不需標記，則移除並丟棄用過的試紙。

備註

檢測成功後，血糖機會在試紙移除後5秒內自動關閉。

標記血糖檢測值

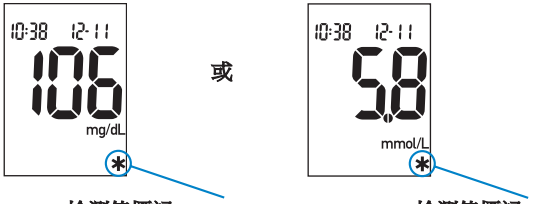
您可使用星號（*）標記來標記一個特殊的事件，例如運動後或其他部位採血檢測法（AST）的檢測值。當您審閱儲存在記憶中的檢測值時，*可以幫助您記起該次檢測和其他檢測值不同的原因。

以下說明如何標記檢測值：

1. 執行血糖檢測。
   血糖檢測值會顯示在顯示幕上。

2. 讓試紙留在血糖機內。按下◀ or ▶一次。
   顯示幕右下角會出現*。

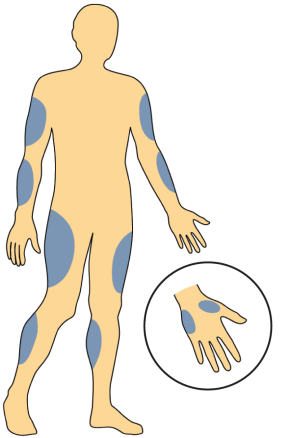
3. 移除並丟棄用過的試紙。
   此檢測值已標記。



檢測值標記　　檢測值標記

其他部位採血檢測法（AST）

您可選擇指尖以外身體其他部位採取血樣。其他部位可為手掌、前臂、上臂、大腿或小腿肚。手掌的兩個採血部位是在拇指和小指下，多肉的「拇指球」和「小指球」掌丘上。從指尖和手掌採集的血樣皆可隨時用來檢測血糖。但從前臂、上臂、大腿或小腿肚等其他部位所採集的血樣，有些時候並不適合檢測血糖之用（見下一章節）。這是因為指尖或手掌血液中的血糖濃度變化，較前臂、上臂、大腿或小腿肚等其他部位血液中的血糖濃度變化更快。這種差異可能導致您錯誤的治療判斷，而產生不良的健康影響。從其它部位採取血樣進行檢測之前，請先閱讀下一節。



允許的其他部位採血檢測法

重要

進行其它部位採血檢測法之前，請諮詢您的專業醫護人員。

⚠警告

- 請勿只因一次的檢測值而改變您的糖尿病治療方式。
- 切勿忽視任何低血糖或高血糖症狀。
- 如果您的血糖檢測值與自己感覺的症狀不符，請採取指尖或手掌的血樣進行檢測以確認結果。如果指尖或手掌血樣檢測的結果仍與您的感覺不符，請聯絡您的專業醫護人員。

可從前臂、上臂、大腿或小腿肚採血進行檢測的情況為：

- 直接在飯前。
- 空腹時。

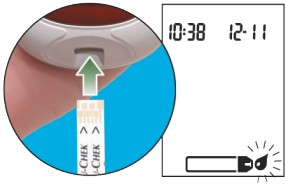
不可從前臂、上臂、大腿或小腿肚採血進行檢測的情況為：

- 飯後2小時內，此時血糖值可能會快速升高。
- 注射胰島素追加量2小時內，此時血糖值可能會快速降低。
- 運動後。
- 生病時。
- 如果您認為自己的血糖極低時。
- 如果您經常不能覺察到自己的血糖過低時。

用品準備：血糖機、一片試紙、其他採血部位（AST）專用的採血筆和採血針。

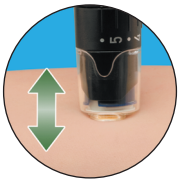
1. 準備採血筆。

2. 檢查試紙瓶上的有效期限。請勿使用過期的試紙。



3. 依箭頭方向將試紙插入血糖機。

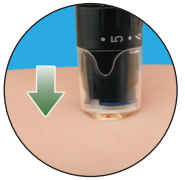
   血糖機會自動開機。顯示幕上會出現試紙符號和閃爍的血滴符號。



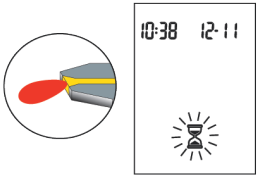
4. 將採血筆緊緊壓到其它部位的多肉區域上。以緩慢的按壓動作，上下按壓採血筆，使血液容易流出。

備註

- 如果血滴太小，請再對採血部位按壓，以取得足夠的血液。
- 檢測成功後，血糖機會在試紙移除後5秒內自動關閉。

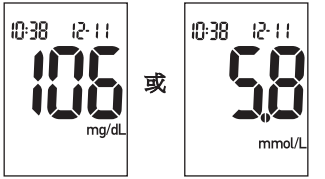


5. 維持採血部位平穩壓力的同時按壓採血筆。使用採血筆對採血部位施壓，使血液容易流出。



6. 將血滴碰觸試紙黃色反應區**前緣**。請勿將血滴放在試紙上方。

   看到⌛閃爍時，表示試紙已經吸入足夠的血液。



7. 檢測值會顯示在顯示幕上。讓試紙留在血糖機內，以標記一個特殊的事件（見「標記血糖檢測值」）。若不需標記，則移除並丟棄用過的試紙。

不正常的血糖檢測值

如果您的血糖檢測值不符合您自己的感覺，檢查以下項目將有助於解決問題。

排解疑難檢索	行動
1. 檢查試紙的有效期限。	過期試紙請丟棄。使用未過期的試紙再次檢測。
2. 檢查試紙瓶蓋是否總是密蓋。	如果您認為試紙瓶已有一段時間沒有密閉，請更換別的試紙再次進行血糖檢測。
3. 檢查試紙是否從試紙瓶中取出後立即使用。	使用新的試紙再次檢測。
4. 檢查試紙原先是否存放在涼爽、乾燥環境下。	使用適當存放的試紙再次檢測。
5. 檢查您是否按照操作流程進行檢測。	請見第2章「檢測您的血糖」並再次進行血糖檢測。如果您還有疑問，請聯絡羅氏糖尿病照護部門/客戶服務部。
6. 檢查血糖機和試紙功能是否正常。	執行品管/質控檢測。相關說明，請見第4章「執行品管/質控檢測」。
7. 如果您仍不確定問題…	聯絡羅氏糖尿病照護部門/客戶服務部。

低血糖或高血糖的症狀

知道低血糖或高血糖的症狀有助於您瞭解檢測值，以及在這些異常狀況發生時決定如何處理。

低血糖（血糖過低）的症狀包括：焦慮、顫抖、出汗、頭痛、飢餓感、暈眩感、膚色蒼白、心情突然改變或易怒、疲倦、注意力難集中、遲鈍笨拙、心悸及/或茫然困惑。

高血糖（血糖過高）的症狀包括：口渴增加、頻尿、視力模糊、昏昏欲睡及/或不明原因體重下降。

⚠警告

如果您有上述任何一種症狀，請從您的指尖或手掌採血檢測血糖。如果血糖檢測值顯示為「LO」（低）或「HI」（高），請立即與您的專業醫護人員聯繫。

第3章：血糖機記憶功能、設定和資料傳輸

記憶功能

儲存血糖檢測和品管/質控檢測值

血糖機自動儲存最多500個帶有檢測時間和日期的血糖檢測值。您可隨時檢視儲存的檢測值。顯示幕會出現你最近的檢測值。正確設定血糖機的時間與日期是非常重要的。正確的時間與日期設定有助於您和您的糖尿病照護團隊正確解讀血糖檢測值。參閱下頁的備註。

備註

- 更換電池時已記憶的檢測值不會遺失，但於更換電池後，請確認時間與日期是正確的（見第3章「設定時間和日期」）。
- 儲存500個血糖檢測值或20個品管/質控檢測值後，如新增一個檢測值，則最早的一個檢測值會被刪除。
- 按下並**按住** ◀或▶，可更快速捲動檢測值。
- 記憶功能會儲存最多至20個品管/質控檢測值，但不能在血糖機上檢視。若要檢視品管/質控檢測值，必須先將其傳輸到相容的軟體應用程式上。請聯絡羅氏查詢產品供應情況。
- 品管/質控檢測值不包含在7天、14天、及30天的平均檢測值中。

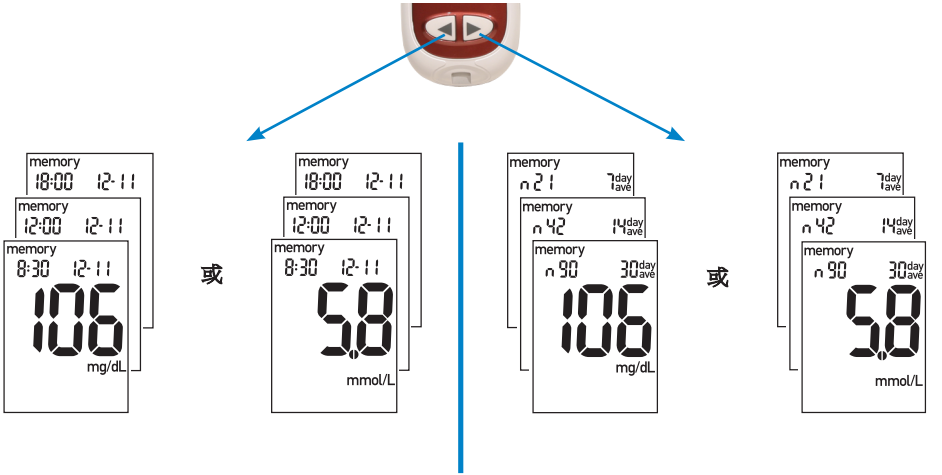
⚠警告

請勿根據記憶中單次的個別檢測值而改變您的糖尿病治療方式。根據記憶中的檢測值改變治療方式之前，請諮詢您的專業醫療人員。

檢視血糖檢測值

無論血糖機開機或關機，按壓又放開◀或▶即可進入記憶功能。最近的檢測值會出現在顯示幕上。

- 按下◀即可依序檢視先前的檢測值。
- 按▶即可查閱7天、14天或30天的平均檢測值。



血糖機設定

使用設定模式

以下功能需要時可自訂。

	時間與日期	設定時間與日期。
	嗶聲	選擇「On」（開啟）或「OFF」。
	檢測提醒鬧鈴功能	選擇「On」（開啟）或「OFF」。如果選擇On，請選擇一天一到四次嗶聲檢測提醒鬧鈴時間。
	血糖過低警示	選擇「On」（開啟）或「OFF」。如果選擇「On」，請選擇要執行血糖過低警示的血糖濃度值。

以下是設定模式中每一個按鍵執行的功能一覽表。

	進入設定模式	開啟血糖機。按下並**按住** 直到顯示幕上出現「set-up」（設定）為止。
	隨時離開**設定**模式	按下並**按住** 直到顯示幕上出現閃爍的試紙符號為止。
	設定選擇的功能	按下又放開。
或	調整設定	按下又放開或。

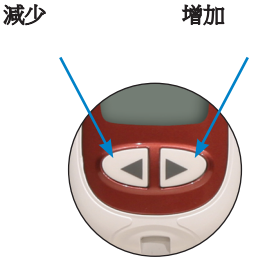
設定時間與日期

1. 按下又放開◉（電源/設定鍵）以開啟血糖機。

   顯示幕上出現閃爍的試紙符號。

2. 按下並**按住**◉直到顯示幕上出現「**set-up**」（設定）為止。

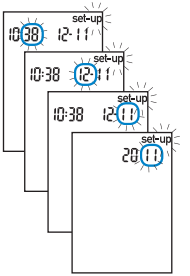
   接著「小時」會閃爍。



3. 按下又放開◀或▶以減少或增加「小時」。 和年，步驟與上述步驟

4. 按下又放開◉以完成設定「小時」。

   隨後「分鐘」開始閃爍。



5. 調整和設定分鐘、日、月和年，步驟與上述步3和4同。

6. 按下又放開◉即可設定其它選項。按下並**按住**◉直到顯示幕上出現閃爍的試紙符號為止，即可離開設定模式。

設定嗶聲「On」（開啟）或「Off」（關閉）

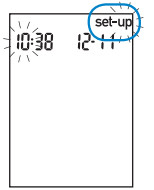
血糖機的嗶聲預設值為On。將嗶聲設定為「OFF」不會影響檢測值。

嗶聲可提醒您：

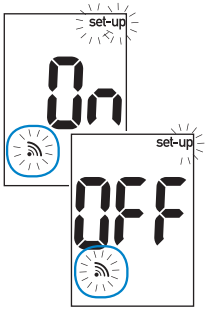
- 將血液或品管/質控液碰觸到試紙上。
- 已有足夠的血液或品管/質控液碰觸到試紙。
- 已完成血糖或品管/質控檢測。
- 已按下按鍵。
- 何時進行檢測（在已設定檢測提醒鬧鈴功能）。
- 如果在血糖或品管/質控檢測時發生錯誤（即使嗶聲設定為「OFF」，血糖機仍會發出嗶聲提醒您發生錯誤）。

1. 按下又放開◉（電源/設定鍵）以開啟血糖機。

   顯示幕上出現閃爍的試紙符號。



2. 按下並**按住**◉直到顯示幕上出現「**set-up**」（設定）為止。



3. 按下又放開◉數次，直到顯示幕上出現閃爍嗶聲符號和「**On**」或「**OFF**」為止。

4. 按下又放開◀或▶即可在「On」和「OFF」之間切換。

5. 按下又放開◉即可設定其它選項。按下並**按住**◉直到顯示幕上出現閃爍的試紙符號為止，即可離開設定模式。

設定檢測提醒鬧鈴功能

檢測提醒鬧鈴功能：

- 每天在同一時間發出嗶聲提醒您進行檢測。
- 每2分鐘發出一次嗶聲，最多發出3次。
- 插入一支試紙或按下任何按鍵即可關閉嗶聲。
- 預設值為「OFF」（關閉）。為了使用這個功能，您必須將鬧鈴設定為「ON」（開啟）。

您可設定每天4個檢測提醒鬧鈴。您可依據您的需求調整檢測提醒鬧鈴時間。以下是檢測提醒的符號和預設的時間。

檢測提醒鬧鈴1	🔔 A-1	8:00
檢測提醒鬧鈴2	🔔 A-2	12:00
檢測提醒鬧鈴3	🔔 A-3	18:00
檢測提醒鬧鈴4	🔔 A-4	22:00

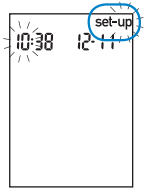
備註

- 若在檢測提醒鬧鈴前30分鐘內進行檢測，則不會再發出嗶聲提醒。
- 若在檢測提醒鬧鈴時間到時血糖機已開機，則不會再發出嗶聲提醒。
- 血糖機暴露在極冷的環境下可能會使檢測提醒功能停止，直到血糖機開機後功能才會恢復。
- 若有一檢測提醒鬧鈴在設定模式中被設為「OFF」，則其後的檢測提醒也會被設為「OFF」。例如，如果您設定了A-1但關閉了 A-2，則A-3和A-4會自動設為「OFF」。

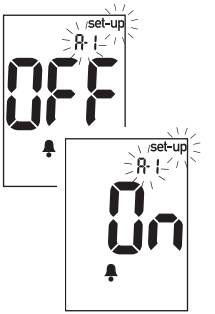
在設定檢測提醒鬧鈴的時間時，鬧鈴符號和「set-up」會停留在顯示幕上。

1. 按下又放開◉（電源/設定鍵）以開啟血糖機。

   顯示幕上出現閃爍的試紙符號。

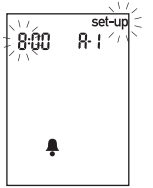


2. 按下並**按住**◉直到顯示幕上出現「set-up」（設定）為止。



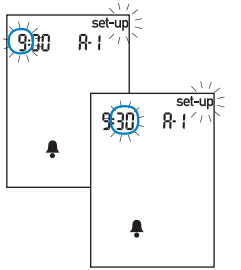
3. 按下又放開◉數次，直到顯示幕上出現鬧鈴符號、「OFF」和閃爍的「A-1」為止。

4. 按下又放開◀或▶即可在「On」和「OFF」之間切換。



5. 按下又放開◉以設定您的選擇。

   若選擇「On」，則「小時」會閃爍。「A-1」和鬧鈴符號仍在顯示幕上。

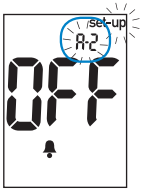


6. 按下又放開◀或▶即可調整「小時」。

7. 按下又放開◉以完成設定「小時」。

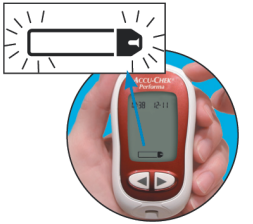
   隨後「分鐘」開始閃爍。

8. 按下又放開◀或 ▶即可選擇00、15、30或45分鐘。只可選擇這些分鐘。



9. 按下又放開◉以完成設定「分鐘」。

   鬧鈴符號、「OFF」和閃爍的「A-2」出現在顯示幕上。



10. 調整和設定其它檢測提醒，請遵循步驟4到9。按下並**按住** ◉直到顯示幕上出現閃爍的試紙符號為止，即可離開設定模式。

設定血糖過低（Hypo）警示

血糖過低警示可設定在60和80 mg/dL或3.3和4.4 mmol/L之間，讓您知道您的血糖濃度可能過低。

⚠警告

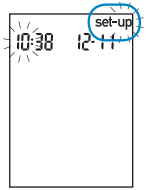
此功能不可取代專業醫護人員為您提供的低血糖訓練。

使用者：設定血糖過低警示之前，請先諮詢專業醫護人員，以協助您判定何種血糖濃度是自己的血糖過低濃度。

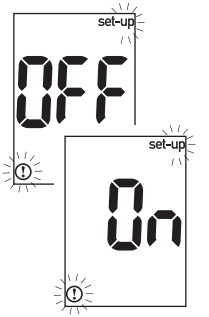
專業醫護人員：低血糖濃度可能人人不同。因此，建議在專業醫療場所，應**關閉**血糖過低警示功能。

1. 按下又放開◉（電源/設定鍵）以開啟血糖機。

   顯示幕上出現閃爍的試紙符號。

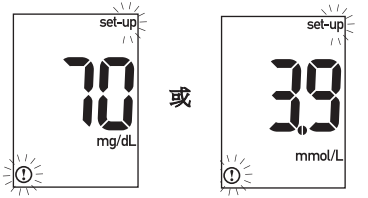


2. 按下並**按住** ◉直到顯示幕上出現「**set-up**」（設定）為止。



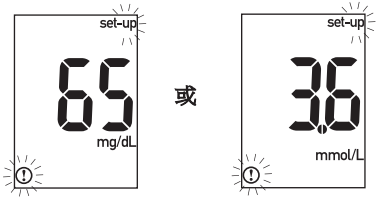
3. 按下又放開◉數次，直到顯示幕上出現「**OFF**」和閃爍的①為止。

4. 按下又放開◀或▶即可在「On」和「OFF」之間切換。



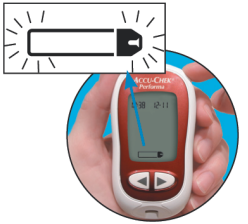
5. 按下又放開◉以設定您的選擇。

若選擇「On」，則①會閃爍。顯示幕上顯示 70 mg/dL 或 3.9 mmol/L。



6. 按下又放開◀或▶即可調整血糖濃度。

7. 按下又放開◉即可設定血糖濃度。



8. 按下並**按住** ◉直到顯示幕上出現閃爍的試紙符號為止。

   設定模式於此完成。按下又放開◉即可關閉血糖機。

傳輸您的檢測值到電腦上或PDA。

您可將儲存的檢測值傳輸到電腦，以便追蹤、判斷血糖濃度週期及列印。

使用專用軟體和紅外線接收器(需另外購買)直接傳輸資料到電腦或PDA

⚠警告

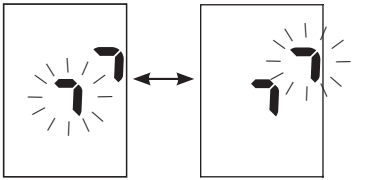
由於無法辨別個別病患的檢測值，因此不建議傳輸多位病患所共用的同一血糖機的資料。

1. 依照使用說明安裝所需的軟體。

2. 為了傳輸檢測值到電腦，請依照使用說明連接紅外線接收器(需另外購買)。

3. 執行軟體程式，依照如何傳輸資料的相關說明進行操作。確定軟體已準備好接收血糖機的資料。

4. 血糖機在關機狀態下，同時按下並**按住◁**和**▷**，直到顯示幕上交替閃爍兩個箭頭。



5. 找到血糖機頂端的紅外線（IR）傳輸埠。

6. 找到紅外線纜線（電腦）或PDA的IR傳輸埠。

7. 將血糖機放在平坦處，並對齊兩者的IR傳輸埠。兩者距離應為3到10公分。

8. 傳輸資料時，請勿移動紅外線接收器（電腦），PDA或血糖機。

9. 遵照軟體上的提示操作。
   資料傳輸完成後，軟體程式會自動將血糖機關機。

紅外線（IR）傳輸埠

備註

- 如果未能順利傳輸資料，請再試一次。如果您還有疑問，請聯絡羅氏糖尿病照護部門/客戶服務部。
- 為了能發揮資料傳輸功能的最大效用，您必須正確設定時間與日期。

第4章：品管/質控檢測

為什麼要執行品管/質控檢測

執行品管/質控檢測可讓您瞭解血糖機與試紙的功能是否正常。您應在下列情況發生時執行品管/質控檢測：

- 開啟一盒新試紙。
- 試紙瓶開啟後沒有關上。
- 您想檢查血糖機與試紙的性能。
- 試紙存放在極端的溫度或濕度環境下。
- 血糖機摔到地上。
- 您的血糖檢測值與您認為的結果不符
- 您想檢查自己的血糖檢測是否正確。

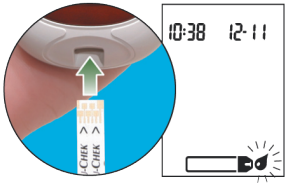
關於品管/質控液

- 僅可使用Accu-Chek Performa（羅氏優勝/卓越）品管/質控液。
- 使用後請蓋緊品管/質控液瓶子。
- 在品管/質控液瓶身標籤上記錄打開品管/質控液瓶的日期。品管/質控液可以在開瓶日期後3個月內，或是瓶子標籤上的有效期限內（以先到者為準）使用。
- 請勿使用過期品管/質控液。
- 請參閱品管/質控液仿單/說明書上有關品管/質控液的存放條件。註：如需執行品管/質控檢測，台灣用戶請與羅氏糖尿病照護部門或洽全省羅氏特約經銷商聯繫，香港用戶請致電客戶服務部訂購。
- 您的血糖機會自動辨識Accu-Chek Performa（羅氏優勝/卓越）品管/質控液。
- 品管/質控液的檢測值不會顯示在記憶功能中。
- 品管/質控液會沾染紡織品。請使用肥皂與清水清洗。

執行品管/質控檢測

用品準備：血糖機、一片試紙、品管/質控液control 1 及/或control 2。瓶子標籤上會註明品管/質控液編號。

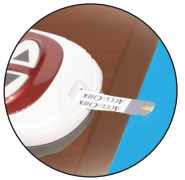
1. 檢查試紙瓶上的有效期限。請勿使用過期的試紙。



2. 依箭頭方向將試紙插入血糖機。

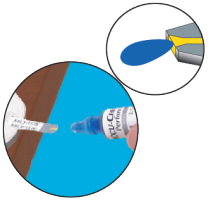
   血糖機會自動開機。顯示幕上會出現試紙符號和閃爍的血滴符號。

3. 選擇要使用的品管/質控檢測。檢測後您須輸入品管/質控液編號（1或2）。



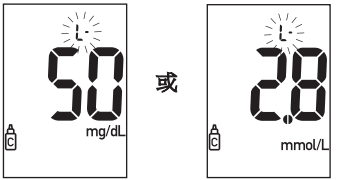
4. 將血糖機放在平坦的表面上，如桌子上。

5. 移除瓶蓋。用面紙擦拭瓶口。



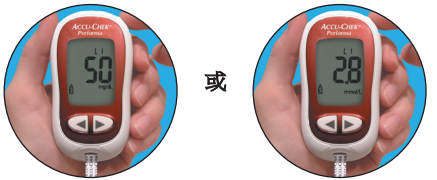
6. 擠壓瓶子，直到品管/質控液在瓶口形成一小滴為止。讓小滴碰觸試紙黃色反應區的**前緣**。請勿將品管/質控液滴在試紙上方。

   看到閃爍時，表示試紙已經吸入足夠的品管/質控液。

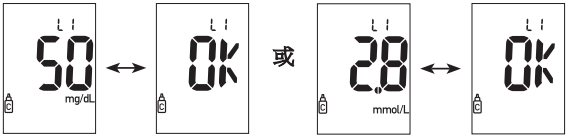


7. 用面紙擦拭瓶口。然後蓋緊蓋子。

8. 顯示幕上會出現檢測值、品管/質控液符號及閃爍的**L**。請先不要取出試紙。按一下▶可標記為品管/質控液 1。 再按一下▶可標記為品管/質控液 2。



或



9. 按下又放開◐以在血糖機上完成設定品管/質控編號（1或2）。
   如果檢測值在可接受範圍之內，則顯示幕上會交替顯示OK和品管/質控檢測值。如果檢測值超出可接受範圍，則顯示幕上會交替顯示「Err」和品管/質控檢測值。

10. 移除並丟棄用過的試紙。

備註

- 試紙瓶標籤上印有品管/質控液1和2的可接受範圍。品管/質控液的檢測值若在試紙瓶上列示的標準範圍內，表示試紙與血糖機的功能正常。
- 檢測成功後，血糖機會在試紙移除後5秒內自動關閉。

瞭解超出範圍的品管/質控檢測值

如果品管/質控檢測值超出可接受範圍，可執行下列動作解決問題：

排解疑難檢索	行動
1. 檢查試紙或品管/質控液是否過期。	其中任何一樣過期，請將其丟棄。如果品管/質控液開封超過3個月以上，請將其丟棄。使用未過期的試紙和未過期的品管/質控液，再進行一次品管/質控檢測。
2. 檢查使用品管/質控液之前和之後，是否皆已用面紙擦拭瓶口處。	用面紙擦拭瓶口。使用新的試紙與新的一小滴品管/質控液，再進行一次品管/質控檢測。
3. 檢查試紙瓶蓋與品管/質控瓶蓋是否一直保持在蓋緊狀態。	更換試紙或品管/質控液，如果您覺得試紙或品管/質控液瓶已打開一段時間。
4. 檢查試紙是否從試紙瓶中取出後立即使用。	使用新的試紙與新的一小滴品管/質控液，再進行一次品管/質控檢測。
5. 檢查試紙與品管/質控液是否存放在涼爽乾燥的環境中。	使用正確存放的試紙和品管/質控液，再進行一次品管/質控檢測。
6. 檢查您是否遵守了檢測步驟。	請參閱第4章「品管/質控檢測」，然後再次檢測。如果您還有疑問，請聯絡羅氏糖尿病照護部門/客戶服務部。

7. 檢查在執行品管/質控檢測時，是否選擇正確的品管/質控液（品管/質控液1或品管/質控液2）。	如果選擇了錯誤的品管/質控液，您仍可將檢測值與試紙瓶上列示的範圍進行比對。
8. 如果您仍不確定問題…	聯絡羅氏糖尿病照護部門/客戶服務部。

第5章：維護與疑難排解

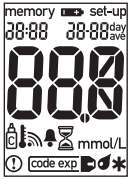
血糖機維護

在正常使用血糖機的情形下，血糖機不太需要維護或甚至不需要維護。每次開機時，血糖機都會自動檢查系統的功能是否正常，如有異常，血糖機會告知您（見第5章「顯示幕訊息與錯誤訊息」）。

如果您將血糖機掉在地上，或您認為檢測值不正確，請與羅氏糖尿病照護部門/客戶服務部聯繫。

若要確定顯示幕功能是否正常，請先將血糖機關機，然後按壓並**按住** ◉，查看整個顯示幕的影像。所有的影像段落都必須清晰可見，如同下圖所示。若非如此，請與羅氏糖尿病照護部門/客戶服務部聯繫。

或



更換電池

1. 依照箭頭方向推一下電池蓋上凸起的部分，將蓋子向上拉，打開血糖機背後的電池蓋。
2. 取出舊電池。
3. 將新電池**「+」面朝上**，放入電池盒內。
4. 放回電池蓋，咯嗒一聲將它關緊。

備註

- 血糖機使用一顆3伏特的鈕扣型鋰電池，型號為CR2032。許多商店都有此類型電池可購。備妥備用電池是明智之舉。
- 確定安裝電池時，電池的**「+」面朝上**。
- 更換電池並開機後，血糖機會提醒您確認血糖機的時間和日期設定。
- 記憶功能會保留所有的檢測值。

清潔血糖機

確定血糖機不受灰塵影響。如果有需要清潔或消毒血糖機，請仔細遵守以下指導原則，如此有助於維持血糖機的最佳效果。

請

- 確定血糖機在關機狀態下
- 使用下列的任一種清潔溶劑濕潤軟布，然後輕輕地以微濕的軟布擦拭血糖機表面（擰出任何多餘液體）：
  - 70 %異丙醇（isopropyl alcohol）
  - 以水稀釋的中性洗碗精
  - 當天稀釋的10 %家用漂白水（漂白劑與清水比例1:9）

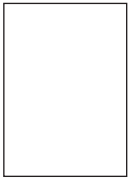
請勿

- 讓任何液體進入血糖機的插槽內
- 直接對血糖機噴灑清潔溶劑
- 將血糖機放入液體中

顯示幕訊息與錯誤訊息

⚠警告

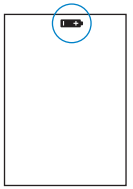
絕對不要根據錯誤的訊息做出治療決定。如有任何疑慮，請聯絡羅氏糖尿病照護部門/客戶服務部。



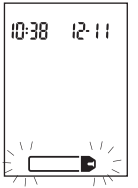
如果血糖機無法開機，或是螢幕顯示空白，表示：

- 電池沒電。請插入新電池。
- 顯示幕受損。聯絡羅氏糖尿病照護部門/客戶服務部。
- 血糖機損壞。聯絡羅氏糖尿病照護部門/客戶服務部。
- 極端的環境溫度。請將血糖機移往溫度較正常的地方。

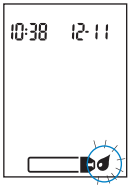
血糖機處於設定模式，正等候您變更或確認設定。



電池電力不足，請儘快更換電池。



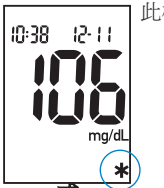
血糖機已準備好讓您插入試紙。



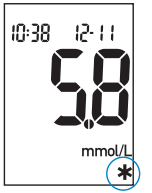
血糖機已準備好接受一滴血液或品管/質控液。

血糖濃度可能低於系統可檢測的範圍（見第2章「不正常的血糖檢測值」）。

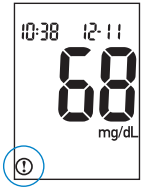
血糖濃度可能高於系統可檢測的範圍（見第2章「不正常的血糖檢測值」）。



或

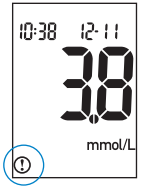


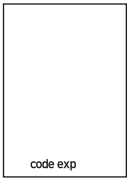
此檢測值已標記。



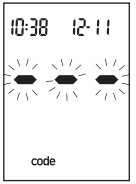
血糖低於設定的血糖濃度過低提醒值。

或

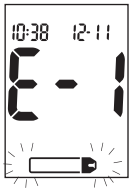




若使用白色密碼晶片/密碼牌，有可能顯示這則訊息。這表示這些試紙將於本月底過期。月底時請丟棄密碼晶片/密碼牌及任何剩餘的試紙。插入一個從新的且尚未過期的試紙盒拿出的新密碼晶片/密碼牌。確認血糖機的時間、日期正確。



未更換血糖機的晶片/密碼牌，或未插入密碼晶片/密碼牌。將血糖機關機後更換密碼晶片/密碼牌。



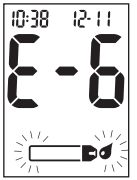
試紙可能已經受損，或是密碼晶片/密碼牌不正確。移除試紙再重新插入。如果還出現同樣錯誤訊息，先關閉血糖機，再插入一個新的密碼晶片/密碼牌。

密碼晶片/密碼牌不正確。關閉血糖機並插入新的密碼晶片/密碼牌。

您的血糖可能非常高或已經發生血糖機或試紙錯誤。

- 如果檢測值證實了您的感覺，請立即聯絡專業醫護人員。
- 如果檢測值與您的自己感覺不符，請再次檢測血糖並參閱第2章「不正常的血糖檢測值」。
  - 如果在血糖檢測時仍出現E-3符號，您的血糖可能非常高且超過系統的讀取範圍。**請立即聯絡專業醫護人員。**
  - 如果第二次檢測值不符合您自己的感覺，請用品管/質控液和一支新的試紙進行品管/質控檢測。
    - 如果品管/質控檢測值在可接受的範圍內，檢視檢測步驟是否正確並再使用新的試紙重新進行血糖檢測。
    - 如果品管/質控檢測值沒有在可接受的範圍內，參考第4章「瞭解超出範圍的品管/質控檢測值」。

試紙吸血量或吸入品管/質控液量不足，或在開始檢測後才滴入血液。請更換一片新試紙並重新檢測。



血滴符號閃爍前，就已將血液或品管/質控液滴到了試紙上。請更換一片新試紙並重新檢測。

若使用白色密碼晶片/密碼牌，會顯示這則訊息。這表示密碼晶片/密碼牌來自於過期批號的試紙。關閉血糖機並插入新的密碼晶片/密碼牌。確認血糖機的時間、日期正確。

電子故障，或偶爾也可能出現用過的試紙被取出後又重新放入的情況。關閉血糖機再重新打開或將電池拆下20秒後再重新裝上。再執行血糖檢測或品管/質控檢測。

溫度低於或高於合適的檢測溫度。參考試紙包裝內仿單/說明書上的系統操作條件。移到適當操作條件的環境，等5分鐘過後再重新進行血糖或品管/質控檢測。請勿刻意將血糖機加熱或降溫。

時間與日期設定可能不正確。若有需要，請檢查時間與日期是否正確，必要時請修改。

電池量幾乎耗盡。請立即更換電池。

備註

- 如有顯示幕訊息或錯誤訊息一再出現，請聯絡羅氏糖尿病照護部門/客戶服務部。
- 如有其它錯誤訊息出現，請聯絡羅氏糖尿病照護部門/客戶服務部。

第6章：技術資訊

產品限制

請閱讀試紙及品管/質控液包裝隨附仿單/説明書，以取得產品規格與限制的最新資訊。

規格

血量	請參閱試紙包裝隨附仿單/説明書。
檢體類型	請參閱試紙包裝隨附仿單/説明書。
檢測時間	請參閱試紙包裝隨附仿單/説明書。
檢測範圍	請參閱試紙包裝隨附仿單/説明書。
試紙存放環境	請參閱試紙包裝隨附仿單/説明書。
血糖機存放環境	溫度：-25至70 ˚C
系統操作環境	請參閱試紙包裝隨附仿單/説明書。
操作環境相對濕度範圍	請參閱試紙包裝隨附仿單/説明書。
記憶容量	500個血糖檢測值和20個品管/質控檢測值，含時間與日期
自動關機	2分鐘
電源供應	一個3伏特的鋰電池（鈕釦型電池類型CR2032）
顯示螢幕	液晶螢幕（LCD）

尺寸	93 × 52 × 22 mm（長寬高）
重量	約62公克（含電池）
結構	攜帶式
觸電防護等級	III
血糖機類型	Accu-Chek Performa（羅氏優勝/卓越）血糖機適宜長時間持續操作。
品管/質控液存放環境	請參閱品管/質控液包裝隨附仿單/說明書。

電磁相容性

本血糖機符合ISO 15197附件A要求的電磁抗擾性標準，其所選的靜電放電抗擾度試驗基準為IEC 61000-4-2基本標準。此外，本血糖機也符合EN 61326所要求的電磁輻射標準，因此電磁輻射極低。本血糖機使用時，預期不會對其他電子驅動設備造成干擾。

性能分析
請參閱試紙包裝隨附仿單/説明書。

檢測原理
請參閱試紙包裝隨附仿單/説明書。

產品安全性資訊

⚠警告

- 小物品，有窒息危險。請保存於3歲以下孩童接觸不到的地方。
- 電磁場若過於強大，會干擾血糖機的正確運作。請勿在接近電磁輻射強烈的地方使用本血糖機。
- 為了避免產生靜電放電，請勿在非常乾燥的環境中使用本血糖機，特別是在有人工合成材料的環境中。

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血糖機廢棄處理

⚠警告

- 在血糖檢測期間，血糖機本身可能接觸到血液。因此，使用過的血糖機具有傳染疾病的風險。廢棄處理血糖機之前，請移除所有的電池。請依據當地法令廢棄處理血糖機。有關廢棄處理規定的資訊，請向當地相關機構查詢。
- 血糖機不在歐盟2002/96/EC指令『電氣電子設備報廢指令（WEEE）』的規範範圍內。
- 請依據當地環境法規廢棄處理用過的電池。

符號說明

下列符號可能出現在包裝、設備名牌以及Accu-Chek Performa（羅氏優勝/卓越）血糖機操作說明上。

	使用時請參閱使用者手冊
	請注意，務必參閱本產品隨附的使用者手冊裡有關安全方面的備註說明。
	溫度限制（保存於）
	製造商
REF	料號
IVD	體外診斷醫療器材
CE 0088	本產品符合歐盟體外診斷用醫療裝置指令98/79/EC的規定。
	3伏特鈕扣型電池型號CR2032

保固/保養

適用購買地國家法定的消費產品銷售保證條款。

其他耗材

下列耗材和配件請聯絡羅氏特約經銷商。

試紙

Accu-Chek Performa（羅氏優勝/卓越）試紙

品管/質控液

Accu-Chek Performa（羅氏優勝/卓越）品管/質控液

專業醫護人員注意事項

⚠警告

專業醫護人員：請依照貴機構的疾病感染控制程序進行作業。其它專業醫療人員資訊，請參閱試紙仿單/說明書。

檢體處理

處理受到血液污染的物品時，務必穿戴手套。請務必遵循處理可能受到人體物質污染物品的一般程序。請按照您所在實驗室或醫療機構的衛生和安全規定操作。請依據貴機構政策準備好採集選擇血樣的部位。

其它有關可接受的樣本類型、抗凝血劑以及處理方面的指示資訊，請參閱試紙包裝隨附仿單/說明書。

向病患建議其它部位採血法（AST）

決定是否建議患者採用其它部位採血法（AST）時，應考慮患者的動機與知識水準，以及對糖尿病與AST相關注意事項的理解能力。如果您考慮建議患者使用AST，您必須瞭解，從指尖或手掌採血與從前臂、上臂、大腿或小腿肚採血檢測，其血糖濃度可能會有顯著的不同。微血管中與全身血液流通的不同部位上的血糖濃度會有差異，這是導致採集不同部位血樣檢測值會有差異的原因。這些生理效應因人而異，甚至在同一個人身上也會因單一個人的行為與相對產生之生理狀況不同而有所不同。

從我們對罹患糖尿病的成人使用其它部位採血法的研究發現，大多數人指尖或手掌血液中血糖濃度的變化比其他採血部位（AST）血液中血糖濃度的變化更快。*這在血糖濃度急遽上升或下降時特別明顯。如果您的病患一向根據指尖或手掌血液的檢測值做醫療判斷，則在從前臂、上臂、大腿或小腿肚採血檢測採血時應考慮，所取得的結果讀數是否受到血糖濃度變化延遲（即遲滯時間）的影響。

*內部存檔資料

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