ACCU-CHEK® Active

Roche

USER'S MANUAL

BLOOD GLUCOSE METER

Contents

This User's Manual contains warnings, precautions, and notes:

⚠ WARNING	⚠ PRECAUTION	NOTE
A **WARNING** indicates a foreseeable serious hazard.	A **PRECAUTION** describes a measure you should take to use the product safely and effectively or to prevent damage to the product.	A **NOTE** draws your attention to important information to help you get the most out of using the product.

Introduction

Intended Use

The Accu-Chek Active system consists of the Accu-Chek Active meter, the Accu-Chek Active test strips, and the Accu-Chek Active control solutions.

The device with the dedicated test strips is intended to quantitatively measure glucose in fresh capillary, venous, arterial and neonatal blood. It is indicated for self-testing by people with diabetes and for near-patient testing by healthcare professionals.

The Accu-Chek Active system is indicated to monitor blood glucose in diabetes mellitus.

The dedicated test strips are the Accu-Chek Active test strips.

Important Information

- Use only the Accu-Chek Active test strips when you test blood glucose using the Accu-Chek Active meter.
- Use only the Accu-Chek Active control solutions when you perform control tests using the Accu-Chek Active meter and the Accu-Chek Active test strips.
- The system must not be used to diagnose or rule out diabetes.
- The system is only suitable for use outside the body.
- The meter must only be used for its intended purpose; if used otherwise preventive measures could be ineffective.

Limitations

Visually impaired people must not use the blood glucose meter, the test strips, and the control solutions.

Testing Procedure

People with diabetes may use fresh capillary blood from the fingertip or alternative sites.

Healthcare professionals may also use venous blood anticoagulated with lithium heparin or ammonium heparin or EDTA, arterial blood, and blood from neonates.

People with diabetes may apply blood to the test strip while the test strip is inside or outside the meter. Healthcare professionals must apply blood to the test strip while the test strip is outside the meter. The system can be used in doctors' offices, general wards, in suspected cases of diabetes and in emergency cases.

Further limitations can be found in the package insert for the test strips.

AST Testing

The system is suitable for testing blood glucose with blood obtained from alternative sites. Due to the different perfusion, alternative site testing might not be a true reflection of the physiological blood glucose level.

Capillary blood obtained from alternative sites must not be used to test blood glucose:

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

Contraindications

There are no contraindications.

⚠ WARNING

- **Risk of suffocation**
  • This product contains small parts that can be swallowed. Keep the small parts away from small children and people who might swallow small parts.
  • If the battery compartment does not close securely, stop using the product and keep it away from children. Contact Roche.
- **Risk of life-threatening injuries**
  Keep new and used batteries away from children. Ingestion or insertion into the body may cause chemical burns, perforation of soft tissues, and death. Severe burns may occur within 2 hours of swallowing. If you think a battery might have been swallowed or placed inside any part of the body, seek medical attention immediately.
- **Risk of infection**
  Any object coming into contact with human blood is a potential source of infection.*
  Healthcare professionals must also read the instructions and notes in the Testing in More Than One Patient chapter.
- **Risk of a serious health incident**
  Wrong test strips deliver incorrect results. Only use the Accu-Chek Active meter with the Accu-Chek Active test strips that are approved by Roche.

About this User's Manual

Read this User's Manual carefully and completely before testing blood glucose for the first time.

If you have questions about the meter or its operation, or need assistance understanding technical terms, contact customer support.

For more information, see chapter 14 in the section *Customer Support*.

This User's Manual will provide you with all the information you need to operate, troubleshoot, and care for your blood glucose meter. Follow the correct operating procedures for the meter and comply with all instructions for use. You can turn the beep tone of the meter on or off. This User's Manual assumes that the beep is on.

Note: Sample data screens are shown throughout the manual. Your data will differ.

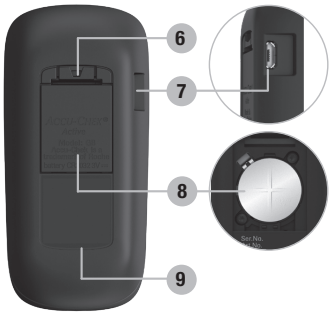
The Main Features

- **No coding**
  No code chip is required for coding the meter.
- **Additional dosing option**
  To perform a test, the meter requires 1–2 µL blood. The meter detects if the amount of blood is insufficient, and more blood can be applied.
- **Marking test results**
  You can mark test results with different symbols which indicate particular situations during the test.
- **Memory**
  The meter automatically saves up to 500 test results with the time and date of the test and all other information that is important for the test.
- **Integrated data analysis**
  From the stored test results your meter can calculate your averages for the last 7, 14, 30, and 90 days.
- **Data transfer**
  The meter has a USB port. You can transfer stored test results to a computer.
- **Flexible blood application**
  You can apply blood to the test strip while the test strip is in the meter or after you have removed it from the meter.

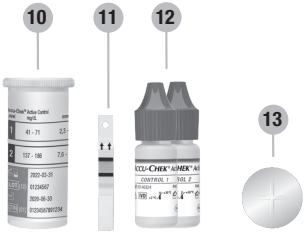
*See: Clinical and Laboratory Standards Institute: Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Fourth Edition; CLSI document M29-A4, May 2014

1 Your New System

The Accu-Chek Active Meter and its Components



1. **Display**
   shows the current and stored test results or device messages
2. **Buttons**
   see the Button Functions section in this chapter
3. **Cover**
   covers the measurement window
4. **Measurement Window**
   underneath the cover
5. **Test Strip Guide**
   insert test strip here
6. **Locking Catch**
   opens the battery door
7. **USB Port**
   the USB cable is inserted here in order to transfer data to a computer
8. **Battery Compartment**
   right: open battery compartment, battery type CR2032
9. **Type Plate**



10. **Test Strip Container***
11. **Test Strip***
    apply blood drop or control solution to the center of the test area (green square)
12. **Control Solution Bottles***
13. **Battery**

* Some items may not be included in the kit. They are a separate purchase.

1 Your New System

Using the Meter Buttons

When instructed to press a meter button, press it briefly and release it.

When instructed to press and **hold** a meter button, press and hold it for 2 or more seconds.

Button Functions

Button / Action	Function
Press M to	turn the meter on and retrieve stored test results mark the test result after a test change settings retrieve the previous stored test result change from the earliest stored test result to the averages retrieve the previous average
Press S to	turn the meter on and access settings mark the test result after a test go to the next setting retrieve the next stored test result change from the averages to the stored test results retrieve the next average
Press M and S at the same time to	perform a display check save settings after the final screen is shown and turn the meter off turn the meter off
Press M or S to	turn the test reminder beep off

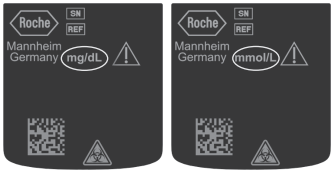
2 Before You Get Started

Unpacking the Contents

Check that the contents of the package are complete. You will find a list with the contents on the box.

If any content is missing, contact customer support.

Checking the Unit of Measurement



Test results can be displayed in two different units of measurement (mg/dL or mmol/L). Check if your meter displays the unit of measurement you are accustomed to. You can find the unit of measurement that your meter displays on the type plate on the back of your meter. If you do not know which unit of measurement is correct for you, contact your healthcare professional.

NOTE

The Accu-Chek Active blood glucose meter has a fixed preset unit of measurement. The unit of measurement cannot be changed on the meter.

⚠ WARNING

Risk of a serious health incident

An incorrect unit of measurement could lead to a false interpretation of the test results and to the wrong therapy recommendations, and thus produce serious adverse health effects. Never use a blood glucose meter with an incorrect unit of measurement.

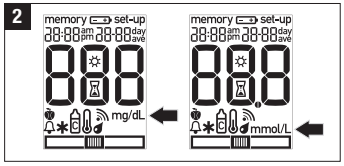
Checking the Display

You can check if all of the display segments are properly displayed by carrying out a full display check.

1

With the meter off, press and hold the M and S buttons at the same time to turn the meter on.

2



Check the meter display for missing segments. All segments should look like the picture above.

If any segments are missing from the display or the unit of measurement shown for the blood glucose results is not the correct one, ask your dealer to exchange the meter.

Press the M and S buttons at the same time to end the display check and turn the meter off.

3 Changing Settings

You can change the meter settings for the time format, time, date, and beep. The meter is delivered with pre-set time and date. You may need to adjust the settings to your time zone. In order to analyze your stored test results properly, it is necessary to set the correct time and date.

Press and hold the S button until set-up appears on the display. The setting that can be changed flashes.

Press the M button to change the setting, if required.

Press the S button to move to the next setting. The meter settings are in the following order: time format (24h, 12h), hours, minutes, year, month, day, beep (on, off).

Press the S button repeatedly until the final screen appears on the display. Only then will the modified settings be saved when you turn the meter off.

Press the M and S buttons at the same time to turn the meter off.

NOTE

If you do not press any buttons, the meter turns off automatically after approx. 30 seconds. If you have not reached the final screen, all changes are lost and the original settings remain unchanged.

Time Format

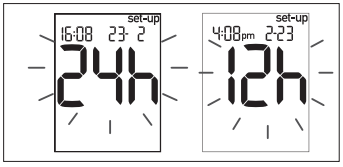
When you change the time format, the time and date are changed accordingly. You can choose between two formats:

24-hour format

Time from 0:00 to 23:59, date in the day-month format (DD-MM)

12-hour format

Time from 12:00 to 11:59 followed by am or pm, date in the month-day format (MM-DD)



The time format flashes on the display.

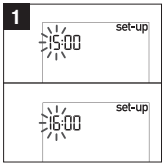
Press the M button to switch from one format to the other.

Press the S button.

Time and Date

Setting the time and date is explained in the following examples using the 24-hour format.

1

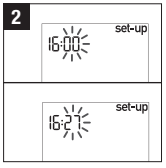


The hours flash on the display.

Press the M button to set the hours.

Press the S button.

2

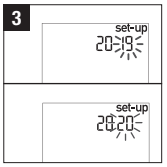


The minutes flash on the display.

Press the M button to set the minutes.

Press the S button.

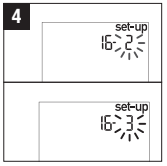
3 Changing Settings



The year flashes on the display.

Press the M button to set the year.

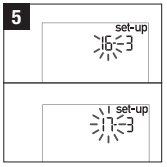
Press the S button.



The month flashes on the display.

Press the M button to set the month.

Press the S button.

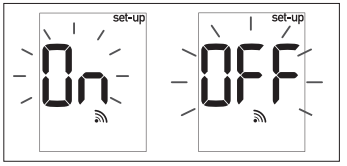


The day flashes on the display.

Press the M button to set the day.

Press the S button.

Beep



The beep symbol appears together with On or OFF on the display.

Press the M button to turn the beep on or off.

Press the S button.

Final Screen

At the end of the setting procedure, the meter displays the final screen with the current settings.

Press the M and S buttons at the same time to turn the meter off.

4 Blood Glucose Tests

There are **2 ways to perform a blood glucose test** with the Accu-Chek Active meter. You can either apply the blood drop to the test area while the test strip is in the meter, or you can remove the test strip from the meter and then apply the blood drop to the test area.

You need the meter, a test strip, and a lancing device with a lancet inserted to perform a blood glucose test.

⚠ WARNING

Risk of wrong therapy decisions

An incorrectly performed blood glucose test may lead to falsely elevated blood glucose results.

Only perform a blood glucose test if the testing site has been washed and dried and is not soiled or sticky (for example, due to glucose residue from food or drink).

1

Wash your hands with warm water and soap, and dry them well.

Prepare your lancing device.

2

Check the use by date on the test strip container.

Use only test strips which are within the use by date.

3

Remove a test strip from the test strip container. Close the cap tightly.

Hold the test strip so that the arrows printed on it and the test area face upwards.

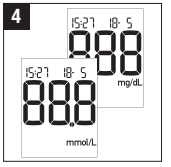
Insert the test strip into the test strip guide.

NOTE

Do not bend or move the test strip before or during the test.

The test strip must lie flat on the measurement window cover.

4

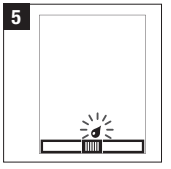


The meter turns on and performs a default display check (approx. 2 seconds).

Check that all the segments are displayed.

If any segments are missing, contact customer support.

5

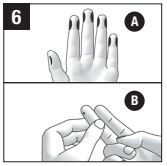


The test strip symbol and the flashing drop symbol appear on the display. The meter beeps.

The meter is ready to perform a blood glucose test. You have approx. 90 seconds to apply blood to the test strip.

4 Blood Glucose Tests

Applying Blood



Lance the side of a fingertip with your lancing device.

Figure Ⓐ shows the recommended sites for obtaining blood.

Massage the finger in the direction of the fingertip to encourage a blood drop to form (see Ⓑ).

If you want to apply the blood drop to the test area while the test strip is in the meter, proceed to step 7.

If you want to apply the blood drop to the test area while the test strip is outside the meter, proceed to step 8.

Test Strip in the Meter

Apply the blood drop to the center of the test area and then remove your finger from the test strip.

As soon as the meter detects the blood, the meter beeps.

The flashing hourglass symbol ⌛ indicates that the test is in progress.

If the amount of blood you applied is insufficient, 3 beeps will sound after a few seconds. You can apply an additional amount of blood.

The test is over in approx. 5 seconds.

Proceed to step 11.

Test Strip outside the Meter

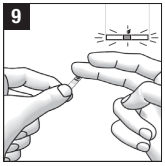
⚠ WARNING

Risk of a serious health incident

Using the wrong test strip can result in significantly incorrect blood glucose results.

Always insert the correct test strip when using the test strip outside the meter.

When the test strip symbol and the flashing drop symbol appear: Remove the test strip from the meter.



The test strip and drop symbol flash on the display. You have approx. 20 seconds to apply blood to the test strip and to reinsert it into the meter.

Apply the blood drop to the center of the test area.

Insert the test strip into the test strip guide in the direction of the arrows with the test area facing up.

The test strip must lie flat on the measurement window cover.

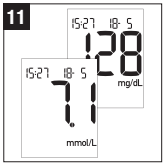
If you do not reinsert the test strip moistened with blood into the meter within the available time, a beep sounds once per second during the last 5 seconds.

The test starts. The flashing hourglass symbol ⌛ indicates that the test is in progress.

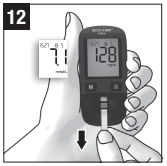
The test is over in approx. 8 seconds.

4 Blood Glucose Tests

Test Result



The test result appears on the display and the meter beeps. The meter automatically saves the test result.



Remove the test strip from the meter.

The meter turns off.

⚠ WARNING

Risk of infection

A used test strip can transmit infections.

Discard a used test strip as infectious material according to the regulations applicable in your country.

Healthcare professionals must discard used test strips according to the hygiene and safety policy of their laboratory or institution.

Notes on Blood Glucose Testing

⚠ WARNING

Risk of a serious health incident

Incorrect test results can lead to wrong therapy recommendations and thus produce serious adverse health effects. Follow the instructions below to perform a blood glucose test correctly.

Risk of a serious health incident

A test strip that is not stored or used properly can deliver an incorrect test result. This can lead to a serious health incident.

- Store the test strips at temperatures between +2 and +30 °C in a dry place away from direct sunlight.
- Use a test strip only once. Test strips are for single use only.

- Use only test strips which are within the use by date.
- Close the test strip container tightly with its original cap immediately after removing a test strip.
- If you have not applied blood to the test strip within the available time and the meter has turned off: Remove the test strip from the meter and discard it.
- If an error message appears and you have not yet applied any blood, you must not use this test strip.
- Do not rub or smear the blood drop onto the test area when applying blood. Repeat the test with a new test strip if necessary.
- Do not store used test strips in a test strip container which still contains unused test strips.
- Do not bend or move the test strip before or while applying blood, or while the test is in progress.

NOTE

If you want to apply the blood drop to the test area while the test strip is outside the meter: Do not remove the test strip until the drop symbol flashes on the display. If you remove the test strip before the drop symbol flashes, the meter turns off.

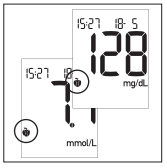
4 Blood Glucose Tests

Marking Test Results

You can mark test results to describe certain events connected to the test result or particular characteristics of the test result. You can only mark a test result while the test strip is still in the meter and the test result is displayed.

You can choose from 5 markers:

Symbol	Meaning
	Before meal (apple symbol)
	After meal (apple core symbol)
	Test reminder (apple + bell symbol)
	Other (asterisk symbol): You can define the meaning of this marker yourself.
	Control (bottle symbol)



Press the M button or S button repeatedly until the desired marker appears at the bottom of the display (the example here is symbol).

If you press the S button, the markers appear in the following order: 1 Before meal; 2 Test reminder; 3 After meal; 4 Other; 5 Control.

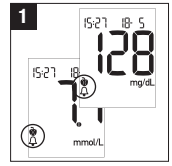
If you press the M button, the markers appear in the reverse order.

If you decide not to mark the test result, press the M button or S button repeatedly until no marker is displayed.

The test result is saved together with the marker.

Setting a Test Reminder

1

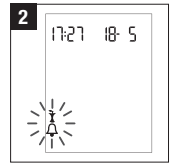


You can only mark a test result while the test strip is still in the meter and the test result is displayed.

Press the M button or S button repeatedly until the test reminder marker (symbol) appears.

The test result is saved together with the symbol.

2



In two hours, you will be reminded to perform a blood glucose test. The flashing symbol appears on the display. At the same time, a beep sounds once per second.

You can now perform a blood glucose test.

As soon as you insert the test strip into the meter, the test reminder turns off.

The test result is saved together with the symbol.

NOTE

If the meter is on at the time of the test reminder, the meter cancels the test reminder.

If you perform a blood glucose test up to 1 hour before a test reminder, the meter cancels the test reminder.

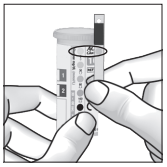
If you do not perform a blood glucose test at the time of the test reminder, you can still perform the blood glucose test within half an hour of the test reminder.

In both cases, the test result is saved together with the symbol.

Checking your Test Results

The test strip itself allows you to estimate the test result through color comparison and thus check the displayed test result in addition.

Before the blood glucose test



On the back of the test strip, there is a round, colored control window.

Compare the color of this window with the colored dots on the label of the test strip container.

The color of the control window must match the color of the top dot (0 mg/dL, 0 mmol/L). If the control window is a different color, you must not use the test strip.

After the blood glucose test

The label on the test strip container shows blood glucose values in mg/dL and mmol/L next to each colored dot.

Within 30 to 60 seconds after applying blood to the test strip, compare the color of the control window on the back of the test strip with the dot that comes closest to your test result.

If the color deviates significantly, repeat the test. If the color still deviates in further tests, contact customer support.

The color comparison serves only as a plausibility check of the test result.

Lo or Hi Screen

The Lo or Hi screen may appear instead of a test result.

Lo may indicate that your blood glucose is lower than the measuring range of the system.

Hi may indicate that your blood glucose is higher than the measuring range of the system.

For more information about the symbols that can appear on the display before, during, or after a test, refer to the Symbols and Troubleshooting chapter.

NOTE

Lo or Hi Display

Lo may indicate that your blood glucose value is very low (possibly a severe hypoglycemia). Hi may indicate that your blood glucose value is very high (possibly a severe hyperglycemia).

If Lo or Hi reflects the way you feel, follow your healthcare professional's instructions immediately. If Lo or Hi does not reflect the way you feel, perform a control test with control solution. Repeat the blood glucose test. If the new test result still does not reflect the way you feel, contact your healthcare professional.

Evaluating Test Results

Blood glucose results are influenced, amongst others, by nutritional choices, medicine taken, state of health, stress, and physical activity.

⚠ WARNING

Risk of a serious health incident

- Do not change your therapy without talking to your healthcare professional first.
- If the blood glucose result is above or below the target range that you have set together with your healthcare professional, contact your healthcare professional.
- If the test result reflects the way you feel, follow your healthcare professional's instructions.

- Perform a control test with control solution and repeat the blood glucose test. If the new test result still does not reflect the way you feel, contact your healthcare professional.
- Contact your healthcare professional immediately if your blood glucose values are too low or too high.
- The test result does not reflect the way you feel.

⚠ PRECAUTION

Risk of a serious health incident

Always check plausibility of the shown test result with your physical perception.

If test results repeatedly do not reflect the way you feel, check the points in the section Sources of Implausible Test Results.

Sources of Implausible Test Results

⚠ PRECAUTION

Risk of a serious health incident

If your meter repeatedly displays implausible test results or error messages, check the following points. If your responses to the questions are different from those given, make the respective corrections when you perform the next test.

⚠ WARNING

Risk of a serious health incident

If you drop the meter, the meter could be damaged. It can no longer be certain that the meter is functioning properly.

Perform a control test with control solution. Repeat the blood glucose test.

If you have taken all of these points into account and still obtain implausible test results or error messages, contact customer support.

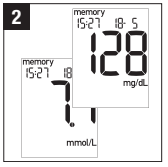
Did you perform the blood glucose test following the instructions in the User's Manual?	yes
Did you wash your hands with warm water and soap and dry them well?	yes
Did you use a used test strip?	no
Did you apply blood after the beep sounded and the drop symbol began to flash on the display?	yes
Did you bend the test strip while inserting it into the meter?	no
Did you apply the blood drop immediately after it had formed on your finger?	yes
Did you bend or move the test strip before or during the test?	no
Are the test strips past their use by date (check next to the symbol on the label of the test strip container)?	no
Are the test strip guide and measurement window clean?	yes
Did you perform the blood glucose test within the acceptable temperature range (+8 to +42 °C)?	yes
Did you follow the storage conditions for the meter and the test strips?	yes
Did you read the *Limitations* section in the test strip package insert?	yes

5 Using the Meter as a Diary

The meter can save up to 500 test results with time and date and calculate averages from the stored test results. If the memory is full, the oldest test result is deleted to create space for the new one, when you perform a new blood glucose test.

Retrieving Test Results from the Memory

With the meter off, press the M button to turn the meter on and retrieve stored test results.



The most recent test result appears together with the time, the date and memory.

If you marked the test result with a marker, the marker is also displayed.

No stored test result

If there are no stored test results in the meter, this screen appears on the display.

Order of the stored test results

Press the M button to view previous test results from the most recent to the oldest. Press the S button to retrieve the stored test results in the reverse order.

As long as you press the M button or S button, the memory location number is displayed. When you release the button, the corresponding test result is displayed. If you press and hold the M button or S button, the occupied memory locations are displayed in quick succession. When you release the button, the corresponding test result is displayed.

When the oldest stored test result is displayed and you press the M button again, the meter beeps. When the most recent stored test result is displayed and you press the S button again, you reach the averages.

Retrieving Averages

The meter calculates the 7, 14, 30, and 90-day averages for 3 groups of test results:

- All test results
- Test results marked with the symbol
- Test results marked with the symbol

Control results (marked with), test results without a valid time or date as well as test results that were displayed as Lo or Hi are not included in the calculation.

With the meter off, press the M button to turn the meter on.

The most recent test result appears.

Press the S button.

The first average, the 7-day average of all test results, appears.

The upper left corner of the display shows the number of test results included in the average. The upper right corner of the display shows the number of days included in the average.

5 Using the Meter as a Diary

Order of the averages

All test results / Test results marked with / Test results marked with	
Press S	**Press M**
7 day ave	90 day ave
14 day ave	30 day ave
30 day ave	14 day ave
90 day ave	7 day ave

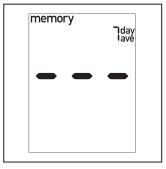
Press the S button to retrieve the averages in the order shown in the table. Press the M button to retrieve the averages in the reverse order.

If you press the S button repeatedly, the 14, 30, and 90-day averages for all test results are displayed after the 7-day average for all test results.

If you continue to press the S button, the averages for “Before meal” and “After meal” are displayed in the same order. When the last average is displayed (= 90-day average marked with) and you press the S button again, the meter beeps.

If you press and hold the M button or S button, the averages are displayed in quick succession.

No average



If there are no stored test results for the selected average, three dashes are displayed.

If you changed the date or time, performed a test, and then reset the date or time, the chronological order of the test results is interrupted. As the meter can only calculate averages based on test results in an uninterrupted chronological order, it therefore does not take into account test results prior to the interruption.

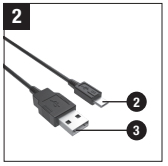
6 Analyzing Test Results on a PC

The meter has a built-in USB port for transferring stored test results to a computer (PC) that is equipped accordingly. Roche offers a variety of special diabetes management hardware and software which enhance the integrated diary functions of your meter. With these diabetes management hardware and software, you and your healthcare professional can manage your test results more effectively and use graphs and tables to understand them better. For more information on diabetes management software, contact customer support.

1

The USB port ❶ is located on the left side of the meter.

2



To connect the meter to the computer, you need a USB cable that is not longer than 1.5 m. ❷ = small end (micro B connector) ❸ = large end (USB A connector).

3

Plug the small end into the USB port on the meter.

Plug the large end into a USB port on your computer.

4

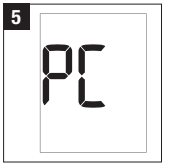
If the meter is off, it turns on.

Read the instructions for use of the diabetes management software in use.

If necessary, start the diabetes management software on your computer.

While the connection is being established, PC flashes on the meter display.

5

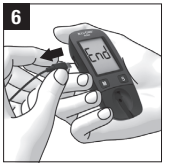


The meter transfers all stored test results.

During the data transfer, PC does not flash.

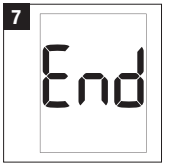
The test results remain in the meter memory after being transferred.

6



To turn the meter off, unplug the small end of the USB cable from the meter once the data transfer is complete.

7



For approx. 3 seconds, End is displayed.

The meter turns off.

NOTE

- If you already have a diabetes management software from Roche, it may not recognize more recent meters and the results will therefore not be transferred. You may need a more recent version of your diabetes management software. In this case, contact customer support.
- You cannot perform a test during the data transfer. You have to unplug the small end of the USB cable from the meter in order to perform a test.

7 Control Tests

Performing a control test lets you know the meter and test strips are working properly.

Perform a control test after you clean the test strip guide and the measurement window, or if you are in doubt about a test result.

A control test is performed in the same way as a blood glucose test, except that you apply control solution to the test strip instead of blood.

You need the meter, a test strip, the Accu-Chek Active control solution Control 1 (low glucose concentration) or Control 2 (high glucose concentration), a clean, dry paper towel, and the concentration table for the control solutions (see label of the test strip container).

Ask customer support where you can obtain control solutions.

⚠ PRECAUTION

Control solutions which are not properly stored or used can deliver results that are outside the specified control range.

Refer to the information in the *Storing and using control solutions properly* section of the Accu-Chek Active control solution package insert.

Use control solution only for application to the test field. Do not ingest or inject the control solution or use the control solution as eye drops.

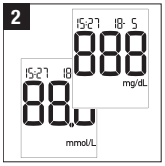
1

Read the package insert which comes with the control solutions.

Insert the test strip into the test strip guide in the direction of the arrows with the test area facing up.

The test strip must lie flat on the measurement window cover.

2

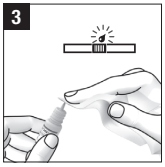


The meter turns on and performs a default display check (approx. 2 seconds).

Check that all the segments are displayed.

If any segments are missing, contact customer support.

3



When test strip symbol and the flashing drop symbol appear on the display and the beep sounds, you have approx. 90 seconds to apply control solution to the test strip.

Open a bottle of control solution.

Wipe the tip of the bottle with a clean, dry paper towel.

4

Hold the bottle downwards at an angle.

Squeeze the bottle gently until a small drop without air bubbles is suspended from the tip of the bottle.

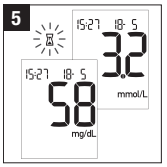
Apply one drop of control solution to the center of the test area without touching the test area with the tip of the bottle.

The test area must be completely covered with control solution.

As soon as the meter detects the control solution, the meter beeps.

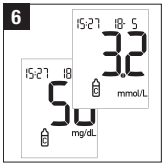
Do not remove the test strip from the meter.

7 Control Tests



The test starts. The flashing hourglass symbol ⌛ indicates that the test is in progress. The test is over in approx. 5 seconds and the meter beeps. The control result appears on the display.

To distinguish this control result from blood glucose results at a later date, you need to mark it as a control test.

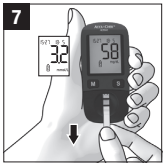


While the control result is displayed: Press the M button.

The 🔒 symbol for control is displayed.

Compare the control result with the concentration table on the label of the test strip container.

The control result must be within the acceptable control range.



Remove the test strip from the meter.

Discard used test strips according to local regulations.

⚠ WARNING

Risk of a serious health incident

Incorrect test results can lead to wrong therapy recommendations.

If the control result is not within the acceptable control range, it is no longer certain that the meter and test strips are working properly.

Follow the questions and instructions below for sources of out-of-range control tests.

Sources of Out-of-Range Control Results

If the control result is not within the acceptable control range, repeat the control test.

If the second control result is still not within the acceptable control range, check the following points.

If you have taken all of these points into account and the control results are still not within the acceptable control range, contact customer support.

Did you perform the control test following the instructions in the User's Manual?	yes
Did you use a used test strip?	no
Did you wipe the tip of the bottle before you applied control solution to the test strip?	yes
Did you apply a suspended drop of control solution?	yes
Did you apply only **one** drop of control solution?	yes
Were there air bubbles in the drop?	no
Did you apply control solution after the beep sounded and the drop symbol began to flash on the display?	yes
Was the test area completely covered with control solution?	yes
Did you bend or move the test strip before or during the test?	no
Did you perform the control test within the acceptable temperature range (+8 to +42 °C)?	yes
Did you compare the control result to the control range for the control solution you used?	yes

7 Control Tests

Did you compare the control result to the control range printed on the test strip container that you removed the test strip from?	yes
Are the test strip guide and measurement window clean?	yes
Has the control solution been open for less than 3 months? The control solutions are valid for 3 months after they were opened for the first time. The control solutions must not be used after this period.	yes
Did you read the *Storing and Using Control Solutions Properly* section in the control solution package insert?	yes
Did you follow the storage conditions for the meter, the test strips, and the control solutions?	yes
Are the test strips or the control solution past their use by date? The use by date is printed next to the symbol on the label of the test strip container or next to the symbol on the bottle label.	no

8 Cleaning the Meter

If the meter is dirty, it may be necessary to clean it.

⚠ WARNING

Risk of infection

- Any object coming into contact with human blood is a potential source of infection.
- Follow the cleaning instructions to avoid self-infection and infection of third parties by contaminated material.

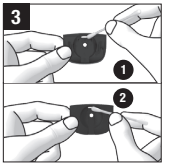
Healthcare professionals using the same meter to test blood glucose in more than one patient must also read the instructions on disinfection (see the Disinfecting the Meter section in the Testing in More Than One Patient chapter).

NOTE

- Use only cold water as a cleaning agent.
- Clean the meter using a lightly moistened cloth or a lightly moistened cotton swab.
- Do not spray anything onto the meter and do not immerse it in liquid.
- Do not allow liquid to enter any openings in the meter.
- Avoid scratching the measurement window.

Wipe the meter surface using a cloth lightly moistened with cold water.

Remove the cover in the direction of the arrow.



Dab the cover and the test strip guide on the inside ❶ and the outside ❷ using a lightly moistened cloth or cotton swab.

Carefully dab the measurement window and its surrounding area using a lightly moistened cloth or cotton swab.

Remove any fluff or lint that may remain.

Dry the areas you have cleaned thoroughly.

Place the cover straight and centered onto the meter.

Slide the cover closed.

Perform a control test.

9 Changing the Battery

When the battery symbol appears on the display for the first time, the battery is almost empty. You can perform approx. 50 more tests with the battery. Change the battery as soon as possible.

⚠ WARNING

Risk of injury from acid

Avoid any direct contact with the battery acid. Wash the affected areas of the body with plenty of water if you have come into contact with battery acid.

Risk of suffocation

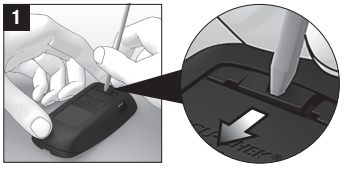
Keep new and used batteries away from children. See the warning in the Introduction of this User's Manual for additional information.

You need 1 battery type CR2032.

Remove the used battery right before inserting the new battery into the meter so that the time and date settings are not lost.

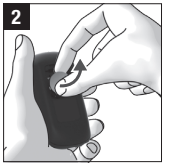
The battery door has a safety mechanism. This prevents small children, for example, from removing the battery and swallowing it.

1



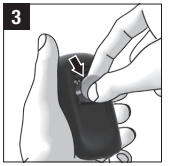
Open the child-resistant battery door by inserting a narrow object, such as a pen, into the recess. Push the tab in the direction of the arrow and lift the battery door up.

2



Remove the used battery.

3



Place the new battery in the battery compartment, with the (**+**) side facing up.

4

Place the battery door back on again.

5

Press the battery door closed.

NOTE

Discard used batteries according to local environmental regulations.

10 Testing in More Than One Patient

Information for Healthcare Professionals

Only healthcare professionals are allowed to perform blood glucose tests on more than one patient using the same Accu-Chek Active meter.

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.

⚠ WARNING

Risk of infection

Any object coming into contact with human blood is a potential source of infection.

- Used lancets, single-use lancing devices or test strips can transmit infections. Healthcare professionals must discard used lancets, single-use lancing devices and test strips according to the hygiene and safety policy of their laboratory or institution.
- **Any patient with an infection or suffering from an infectious disease and any patient who is a carrier of a multi-resistant microorganism must be assigned his/her own meter. This also applies if it is suspected that a patient has one of the above. During this time the meter must not be used to test any other patient.**
- Patients and healthcare professionals are potentially at risk of becoming infected if the same Accu-Chek Active meter is used to test blood glucose in more than one patient.

Risk of wrong therapy decisions

Residues of water or disinfectant on the skin can dilute the blood drop and thus produce incorrect test results.

Wash and dry your hands thoroughly before testing.

- Wear protective gloves.
- The patients' hands should be washed with soap and warm water and dried thoroughly.
- Use only a lancing device approved for use by healthcare professionals. Follow the handling instructions in the instructions for use of the lancing device.
- Apply blood to the test strip while it is **outside** the meter.

Disinfecting the Meter

The following parts of the meter may become contaminated:

- the surface
- the cover
- the measurement window

The meter, the cover, and the measurement window must be carefully cleaned and disinfected after every use. Remember to also clean recesses, grooves, and gaps.

Cotton swabs, pads, or cloths which are lightly moistened with 70 % isopropanol are suitable for disinfecting.

Follow the instructions of the disinfectant manufacturer.

Wipe the meter surface using a cloth lightly moistened with 70 % isopropanol.

10 Testing in more than one patient

Carefully dab the measurement window and its surrounding area as well as the cover from both sides using a lightly moistened cloth or cotton swab.

NOTE

- Do not spray anything onto the meter and do not immerse it in liquid.
- Do not allow liquid to enter any openings in the meter.

11 Test and Storage Conditions

The meter can only work properly if you adhere to the following test and storage conditions.

⚠ WARNING

Risk of injury from acid

A meter that is not stored properly can lead to leaking battery.

Avoid any direct contact with the battery acid. Wash the affected areas of the body with plenty of water if you have come into contact with battery acid.

Temperature

- Only perform blood glucose tests and control tests at temperatures between +8 and +42 °C.
- If the temperature is at the limits of the permitted range (between +5 and +8 °C or between +42 and +45 °C), the meter still allows you to perform a test. The thermometer symbol will be displayed.
- Tests cannot be performed at temperatures below +5 °C and above +45 °C. In this case the following appears on the display:

- Store the meter without battery at temperatures between -25 and +70 °C.
- Store the meter with battery at temperatures between -20 and +50 °C.

NOTE

- Do not use test results obtained at the limits of the permitted temperature range as a basis for making therapy decisions. These test results could be incorrect. Incorrect test results can cause the wrong therapy recommendation to be made and thus produce serious adverse health effects.
- Never try to speed up warming or cooling of the meter, e.g. in a refrigerator or on a radiator.
- At temperatures above +50 °C the battery could leak and damage the meter.
- At temperatures below -20 °C the battery does not have enough power to keep the internal clock functioning.

Atmospheric Humidity

- Only perform blood glucose tests and control tests when relative atmospheric humidity is below 85 %.
- Store the meter below 93 % relative atmospheric humidity.

NOTE

Sudden changes in temperature cause condensation to form in or on the meter. If this has occurred, do not turn the meter on. Let the meter slowly cool down or warm up at ambient temperature. Do not store the meter in high heat and moisture areas (bathroom or kitchen).

Light Conditions

Do not perform a test when the meter and the test strips are exposed to direct sunlight. Go to a shaded place or shade the meter, for example with your body.

If the meter is exposed to too much light, the meter does not allow any tests to be performed. In this case the following error message appears on the display:

NOTE

- Avoid sudden changes in light conditions while testing. The flash of a camera, for example, can lead to incorrect test results.
- Keep the meter away from very strong light sources (e.g. direct sunlight). Such light sources may stop the meter from functioning correctly and lead to error messages.

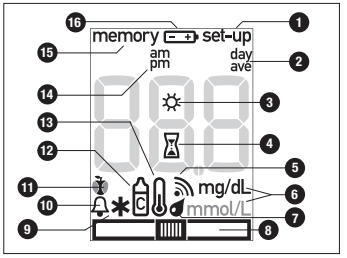
Sources of Environmental Interference

Do not use the meter close to sources of strong electromagnetic radiation.

- Strong electromagnetic fields may interfere with the proper operation of the meter.
- To avoid electrostatic discharge, do not use the meter in a very dry environment, especially one in which synthetic materials are present.

12 Symbols and Troubleshooting

Symbols on the Display

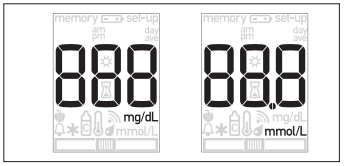


In addition to test results, time, and date, other symbols and error messages also appear on the meter display. Pay attention to all symbols and error messages when you use the meter.

❶	You are in the settings for the time format, time, date, and beep.
❷	When an average is displayed (memory): the symbol is preceded by the number of days taken into account.
❸	Sun symbol – Together with error message E-5: The meter is exposed to too much light.
❹	Flashing hourglass symbol – A test is in progress or an average is being calculated.
❺	The beep is on.
❻	The unit of measurement your meter uses to display test results, either mg/dL or mmol/L depending on the meter.
❼	Flashing drop symbol – Now you can apply blood or control solution to the test strip.
❽	Flashing test strip and drop symbol – The test strip was removed from the meter before blood or control solution was applied, for example to apply blood outside the meter.
❾	Asterisk symbol – Other marker
❿	Bell and apple core symbol – Reminds you to perform an after meal blood glucose test.
⓫	Apple symbol – Before meal marker Apple core symbol – After meal maker
⓬	Bottle symbol – Control test marker
⓭	Thermometer symbol – The temperature during the test is at the limits of the permitted range (between +5 and +8 °C or between +42 and +45 °C).
⓮	Additional time information if 12-hour time format is set.
⓯	You are in the meter memory. Either a stored test result or an average is displayed.
⓰	The battery is almost empty. When the symbol first appears, you can perform approx. 50 more tests.

12 Symbols and Troubleshooting

Symbols Appearing in the Numeric Field



Symbol	Meaning
memory	Averages cannot be calculated because • you have not set the time and date, • only test results without a time and date are saved, • only test results that are not included in the calculation are saved, e.g. control results, • no test results were saved in the period in question, e.g. all test results in memory are more than 7 days old, • the chronological order of the test results in the memory has been interrupted.
memory 000	No test results have been saved.
memory 00	The test result has been lost from memory.
8.2	The decimal point displayed by mmol/L meters is part of the test result (e.g. 8.2 mmol/L is displayed as 82).

Symbol	Meaning
PC	The meter is connected to a computer (PC).
End	The meter has been disconnected from the computer (PC).
Hi	The test result is higher than 600 mg/dL (33.3 mmol/L).
Lo	The test result is lower than 10 mg/dL (0.6 mmol/L).

Troubleshooting

The meter will not turn on:

- The battery is empty or there is no battery in the meter.

  Insert a new battery.

- You have inserted the battery the wrong way round.

  Remove the battery and place it in the battery compartment, with the (**+**) side facing up.

- The ambient temperature is low.

  Ensure that the ambient temperature is between +8 and +42 °C and wait for the meter to adjust to that temperature.

- The electronics have become damp through condensation.

  Allow the meter to dry slowly.

- The meter is defective.

  Contact customer support.

12 Symbols and Troubleshooting

The time is shown as 0:00 or 0:00am and the date as 0- 0:

- The meter was exposed to a temperature below -20 °C and the battery is beginning to freeze.

  Turn the meter off. Ensure that the ambient temperature is between +8 and +42 °C and wait for the meter to adjust to that temperature.

- The meter was without a power supply for too long.

  Insert a new battery and set the time and date.

Error Messages

When an error occurs, an error message appears on the display and two beeps sound. Turn the meter off. Depending on the situation, you can turn the meter off either by pressing the M button and S button at the same time or removing the test strip from the meter.

If your meter has been dropped, this can also lead to error messages.

If error messages occur frequently, contact customer support.

- You did not insert the test strip into the meter correctly or completely.

  Hold the test strip so that the arrows printed on it and the test area face upwards. Without bending it, insert the test strip into the test strip guide in the direction of the arrows. You must feel the test strip lock into place.

- You inserted a used test strip into the meter.
- You applied blood or control solution to the test strip too soon, i.e. before the drop symbol flashed on the display.

  Repeat the blood glucose test or control test with a new test strip.

- The measurement window is dirty.

  Clean the measurement window.

- Your blood glucose value may be very low.

  If you have typical symptoms of very low blood glucose, follow your healthcare professional's instructions immediately. Repeat the blood glucose test with a new test strip.

- You removed the test strip from the meter in order to apply blood and did not reinsert it within 20 seconds.
- The test strip was bent or moved while the test was in progress.
- You applied too little blood or control solution to the test strip.
- You waited too long before applying a second drop of blood or control solution.

  Repeat the blood glucose test or control test with a new test strip.

12 Symbols and Troubleshooting

- While the test was in progress, you connected the meter to a computer that was on.

  Remove the USB cable and repeat the blood glucose test or control test with a new test strip.

- The meter was exposed to a strong electromagnetic field.

  Change your position or turn the source of electromagnetic radiation off.

- The meter is exposed to too much light.

  Go to a shaded place or shade the meter, for example with your body.

- A meter error has occurred.

  Repeat the blood glucose test or control test with a new test strip. If the error message appears again, the meter is defective. Contact customer support.

- The ambient temperature or the meter temperature is too low or too high for a test.

  Ensure that the ambient temperature is between +8 and +42 °C and wait for the meter to adjust to that temperature.

13 Technical Information

Technical Data

Meter type

Accu-Chek Active (Model GB)

Catalogue no./Serial no.

See type plate on the back of the meter

Test principle

Determination of glucose in fresh capillary blood by reflectance photometry. For more information, refer to the Accu-Chek Active test strip package insert.

Measuring range

Refer to the test strip package insert.

Blood volume

1–2 µL (1 µL (microliter) = 1 thousandth of a milliliter)

Test time

Refer to the test strip package insert.

Power supply

1 battery (type CR2032)

Battery life

Approx. 1000 tests or approx. 1 year

Automatic off

After 30 or 90 seconds depending on operating status

Memory

500 test results with time and date, as well as 7, 14, 30, and 90-day averages

Temperature

During testing: +8 to +42 °C

During storage without battery: -25 to +70 °C

During storage with battery: -20 to +50 °C

Atmospheric humidity

During testing: up to 85 % relative humidity

During storage: up to 93 % relative humidity

Altitude

Sea level to 4000 m

Dimensions

97.8 × 46.8 × 19.1 mm

Weight

Without battery: approx. 46 g

With battery: approx. 50 g

Display

96-segment liquid crystal display (LCD)

Interface

USB (Micro B); Continua Certified® to a Continua Certified manager

Protection class

III

Electromagnetic compatibility

The meter meets the electromagnetic emissions requirements as per EN 61326-2-6. Its electromagnetic emission is thus low. Interference on other electrically-driven equipment is not anticipated.

Performance analysis

Refer to the test strip package insert.

Calibration and traceability

Refer to the test strip package insert.

13 Technical Information

System Components

The Accu-Chek Active blood glucose monitoring system comprises the following components in addition to the meter:

Accu-Chek Active test strips
Use only these test strips when you test blood glucose using the Accu-Chek Active meter.
Accu-Chek Active control solutions
Use only these control solutions when you perform control tests using the Accu-Chek Active meter and the Accu-Chek Active test strips.

Ask customer support where you can obtain test strips and control solutions.

Explanation of Symbols

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

	Consult instructions for use or consult electronic instructions for use
	Caution, refer to safety-related notes in the instructions for use accompanying this product.
	Biological Risks – used meters carry a risk of infection.
	Temperature limit
	Use by
	Date of manufacture
IVD	In vitro diagnostic medical device
	Device for self-testing
	Device for near-patient testing
	Manufacturer
UDI	Unique device identifier
REF	Catalogue number
LOT	Batch code
SN	Serial number
CE	Complies with the provisions of the applicable EU Legislation
	Keep new and used batteries away from children.

Discarding the Meter

Used meters carry a risk of infection. Before discarding the meter, remove the battery. Discard used meters according to the regulations applicable in your country. Contact the local council and authority for information about correct disposal.

Healthcare professionals must discard used meters according to the hygiene and safety policy of their laboratory or institution.

The meter falls outside the scope of the European Directive 2012/19/EU (Directive on waste electrical and electronic equipment (WEEE)).

 Discard used batteries according to local environmental regulations.

This product includes internal constituents containing a Substance of Very High Concern (SVHC) 1,2-Dimethoxyethane (CAS 110-71-4), Lead Titanium Trioxide (CAS 12060-00-3) and/or Lead Titanium Zirconium Oxide (CAS 12626-81-2), in a concentration above 0.1% weight by weight, as identified under REACH regulation and added to the Candidate List.

Currently there is no alternative substance leading to the same functionality as needed within this specific article.

There is no direct exposure to the substance and therefore no risk when the instrument is operated according to the instructions for use.

14 Customer Information

Disease Effects and Prevalence

For information on the effects and prevalence of diabetes in your area, visit the International Diabetes Federation website at www.idf.org or send an email to info@idf.org. For further advice or helpline information, refer to the national diabetes organization for your country.

Reporting of Serious Incidents

For a patient/user/third party in the European Union and in countries with identical regulatory regime, if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

Customer Support

For questions on how to operate your Accu-Chek Active meter, or regarding implausible test results, or if you suspect the meter or test strips to be defective, contact the customer support. Do not attempt to repair or modify the meter yourself. Our staff will help you solve any problems you might be experiencing with the meter or test strips from Roche.

Central America and the Caribbean
Local contact information at:
www.accu-chekcac.com

India
Accu-Chek Customer Care Helpline:
1800 120 6020 (Toll-free)
(Monday to Saturday, 7:30 AM to 9:30 PM)
SMS 'HELP' to 5757535*
*Charges applicable as per your network provider
Email: india.accu-chek@roche.com
www.accu-chek.in

Indonesia
Customer Support and Service Centre
Hotline: 0-800-1-222-999
www.accu-chek.co.id

Malaysia
Customer Support and Service Centre:
Toll-Free Line: 1-800-88-1313
www.accu-chek.com.my

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Vivian Corporation
29, Sanitas Building
Tower Street
Msida MSD1824
Freephone: 80073102

Pakistan
Roche Pakistan Limited
37-B, 1st Floor, Block 6,
PECHS Karachi - 75400 Pakistan
Contact: 0800-76243
www.accu-chek.com.pk

Philippines
Accu-Chek Customer Hotline:
Phone: (02) 7718 7575 / (02) 7718 7588 /
+63 917 8978000
www.accu-chek.com.ph

Singapore
Accu-Chek ExtraCare line:
6272 9200
www.accu-chek.com.sg

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Vorna Valley, 1686 South Africa
Tel: +27 (11) 504 4600
Email: info@accu-chek.co.za
www.accu-chek.co.za

Thailand
Customer Service Line:
+66 (0) 2791 2222
www.accu-chek.co.th

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ACCU-CHEK® Active

CE 0123

IN VITRO DIAGNOSTIC MEDICAL DEVICE

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