ACCU-CHEK® Guide Me

Roche

USER'S MANUAL

BLOOD GLUCOSE METER

This file may not print or view at 100%.
Die lines and color breaks do not print.
"Holding Area" text, box and rules do not print.

Roche USA – 83537
V1/1 -09241493061A
09241493061(01) – Black

PMS-MANUAL FOLD OUT

Approved according to SHR_SOP 04.07.08_Att A **Category 2**

The Signature will not be printed!

LAN	baroudia - Oct 12, 2021
IPM	greenk4 - Oct 13, 2021
PM/LAB	smithk44 - Oct 12, 2021
GD/LAY	curtisd6 - Oct 14, 2021

Contents

Introduction 2

Chapter 1: Your New System.....5

Chapter 2: Blood Glucose Tests.....10

Chapter 3: Control Tests.....16

Chapter 4: Review Your Data.....20

Chapter 5: Wireless Communication, Meter Pairing, and Data Transfer.....22

Chapter 6: Meter Maintenance and Troubleshooting.....25

Chapter 7: Technical Information.....32

Chapter 8: Guarantee and Warranty 37

Index 38

7_09241493061A_09241493061_01.indd 2 10/12/2021 10:21:33 AM

Introduction

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

⚠ WARNING

A **WARNING** indicates a foreseeable serious hazard.

⚠ PRECAUTION

A **PRECAUTION** describes a measure you should take to use the product safely and effectively or to prevent damage to the product.

NOTE

A **NOTE** draws your attention to important information to help you get the most out of using the product.

The Accu-Chek Guide Me System

The Accu-Chek Guide Me meter with the Accu-Chek Guide test strips is intended to quantitatively measure glucose in fresh capillary whole blood from the finger, palm, forearm, and upper arm as an aid in monitoring the effectiveness of glucose control.

The Accu-Chek Guide Me meter with the Accu-Chek Guide test strips is intended for in vitro diagnostic self-testing by people with diabetes.

The Accu-Chek Guide Me meter with the Accu-Chek Guide test strips is intended for in vitro diagnostic near-patient testing by healthcare professionals in clinical settings. Venous, arterial, and neonatal blood testing is limited to healthcare professional use.

This system is not for use in diagnosis of diabetes mellitus, nor for testing neonate cord blood samples.

Suitable for self-testing

The system includes:

Accu-Chek Guide Me meter with batteries, Accu-Chek Guide test strips*, and Accu-Chek Guide control solutions*.

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

7_09241493061A_09241493061_01.indd 2 10/12/2021 10:21:33 AM

⚠ 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.

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.
- If the battery compartment does not close securely, stop using the product and keep it away from children. Contact Roche.

⚠ WARNING

Risk of infection
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 – Fourth Edition; CLSI document M29-A4, May 2014). Healthcare Professionals: see also the Information for Healthcare Professionals section in the chapter Technical Information.

Risk of a serious health incident
Failure to follow testing instructions or test strip storage and handling instructions can lead to an incorrect test result that may lead to improper therapy. Carefully read and follow the instructions in the User's Manual and package inserts for the test strips and control solutions.

⚠ WARNING - KEEP BATTERIES OUT OF REACH OF CHILDREN

- In Australia: If you suspect your child has swallowed or inserted a button battery, immediately call the Australian 24-hour Poisons Information Centre on 13 11 26 for fast, expert advice.

7_09241493061A_09241493061_01.indd 3 10/12/2021 10:21:35 AM

Introduction

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

- It is strongly recommended to have a back-up testing method available. Failure to test could cause a delay in therapy decisions and lead to a serious medical condition. Examples of back-up testing methods include a back-up meter and test strips. Ask your healthcare professional or pharmacist about other possible back-up methods.
- The meter prompts you to set the time and date the first time you turn it on.
- Check the time and date on the meter before you begin testing. Adjust the time and date if necessary.
- Sample data screens are shown throughout the manual. Your data will differ.
- If you follow the steps in this manual but still have symptoms that do not seem to match your test results, or if you have questions, talk to your healthcare professional.

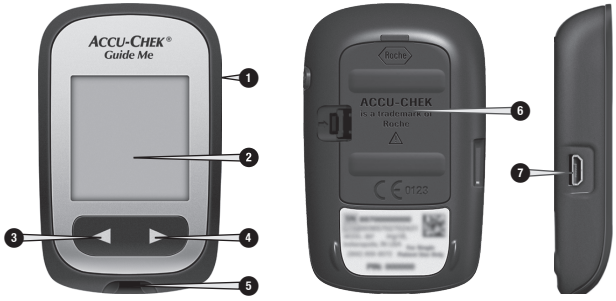
Reporting of Serious Incidents

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.

7_09241493061A_09241493061_01.indd 4 10/12/2021 10:21:35 AM

1 Your New System

The Accu-Chek Guide Me Meter



Front View Back View Side View

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

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

3. **Left Arrow Button**
   Press to enter memory, adjust settings, and scroll through test results.

4. **Right Arrow Button**
   Press to enter memory, adjust settings, and scroll through averages.

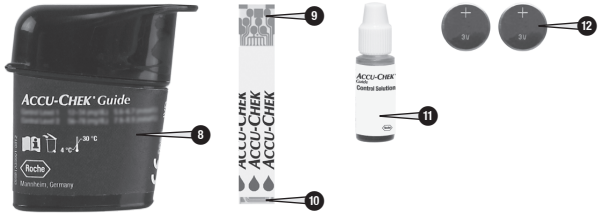
5. **Test Strip Slot**
   Insert test strip here.

6. **Battery Door**
   Open to replace batteries.

7. **Micro USB Port**
   Transfers data from meter to a computer (PC).

7_09241493061A_09241493061_01.indd 5 10/12/2021 10:21:39 AM

1 Your New System



8. Test Strip Container*

9. Test Strip – Metallic End

Insert this end into meter.

10. Test Strip – Yellow Edge

Touch blood drop or control solution here.

11. Control Solution Bottle*

12. Batteries

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

7_09241493061A_09241493061_01.indd 6 10/12/2021 10:21:42 AM

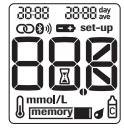
Using the Meter Buttons

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 3 or more seconds.

Button Functions

Here are the functions of the power/set button and arrow buttons on the meter. These functions are used throughout this manual.

Button	Function	Action
[power/set button]	Turn the meter on or off. Navigate to an option or set a selection.	Press and release.
	Check the meter display. or 	With the meter off, press and hold to see the complete meter display. If one of the segments is missing or looks different from this picture, do not use the meter. Contact Roche.
[right arrow and left arrow buttons]	Adjust settings for time and date and scroll through test results in memory.	Press and release or press and hold to scroll faster.

7_09241493061A_09241493061_01.indd 7 10/12/2021 10:21:46 AM

1 Your New System

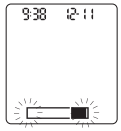
Symbols

Symbol	Description
7 day ave	7-day average symbol. This indicates that you are viewing the 7-day average of your blood glucose results.
14 day ave	14-day average symbol. This indicates that you are viewing the 14-day average of your blood glucose results.
30 day ave	30-day average symbol. This indicates that you are viewing the 30-day average of your blood glucose results.
90 day ave	90-day average symbol. This indicates that you are viewing the 90-day average of your blood glucose results.
	Bluetooth symbol
	Control bottle symbol
	Drop symbol
	Hourglass symbol
	Low battery symbol
	No data to display
	Pairing symbol. A flashing symbol indicates the meter is attempting to pair with a device. A solid symbol indicates the meter pairing was successful.
	Temperature warning symbol
	Test strip symbol. A flashing symbol indicates the meter is ready for you to insert a test strip.
	Wireless symbol. A flashing symbol indicates the meter is attempting to connect to the paired device. A solid symbol indicates the meter is connected to a paired device.

7_09241493061A_09241493061_01.indd 8 10/12/2021 10:21:58 AM

Setting the Time and Date

1



Press and release ⏻ to turn the meter on.

The flashing test strip symbol appears on the display.

2

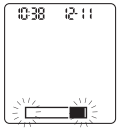
Press and **hold** ⏻ until **set-up** appears on the display. The hour flashes.

Press ◀ or ▶ to decrease or increase the hour.

3

Press ⏻ to set the hour and move to the next field.

4



Repeat steps 2 and 3 to adjust each field. Press and **hold** ⏻ until the flashing test strip symbol appears. Insert a test strip to perform a test.

NOTE

- The meter prompts you to set the time and date the first time you turn the meter on or if an error occurs.
- Press and hold ⏻ at any time until the flashing test strip symbol appears to perform a test.
- The time and date on the meter synchronises to the time and date on the paired device each time the meter sends data to the paired device. See the chapter Wireless Communication, Meter Pairing, and Data Transfer.

7_09241493061A_09241493061_01.indd 9 10/12/2021 10:22:03 AM

⚠ WARNING

Risk of a serious health incident
Using the wrong unit of measurement may cause misinterpretation of your actual blood glucose level and may lead to improper therapy. Blood glucose results can be displayed in either mg/dL or mmol/L. The back label of the meter shows the unit of measurement. If the meter shows the wrong unit, contact Roche. If you do not know which unit of measurement is correct for you, contact your healthcare professional.

mg/dL or mmol/L is printed here

Using the Accu-Chek Guide Me System

⚠ WARNING

Risk of a serious health incident

- If you drop the meter or drop the meter with a test strip inserted, the meter and/or test strip could be damaged. Discard the test strip and perform a control test with control solution and a new, unused test strip to ensure the meter and test strips are both working properly. Then repeat the blood glucose test with a new test strip.
- A test strip that is not stored or used properly can deliver an incorrect test result.
- Do not store test strips in high heat and moisture areas (bathroom or kitchen)! Heat and moisture can damage test strips.

- Use only the Accu-Chek Guide 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 inserting 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.

7_09241493061A_09241493061_01.indd 10 10/12/2021 10:22:04 AM

- 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.

Performing a Blood Glucose Test with Blood from Your Fingertip

NOTE

- Before you perform your first blood glucose test, set the meter time and date.
- You need the meter, a test strip, and a lancing device with a lancet inserted to perform a blood glucose test.
- A blood glucose test cannot be performed while the meter is connected to a PC with a USB cable.
- The meter turns off 90 seconds after a successful test or 15 seconds after the test strip is removed, provided no other action is taken.
- There are 2 ways to start a blood glucose test.
  - Insert a test strip into the meter.
  - Turn the meter on by briefly pressing ⏻ and insert a test strip.

1

Wash your hands with warm soapy water. Rinse and dry thoroughly.

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

Remove a test strip from the test strip container.

Close the cap tightly.

4

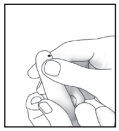
Insert the metallic end of the test strip into the meter. The meter turns on.

5

When the flashing drop symbol appears, prick your finger with the lancing device.

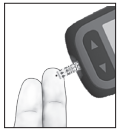
7_09241493061A_09241493061_01.indd 11 10/12/2021 10:22:08 AM

6



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

7



Touch the **yellow edge** of the test strip to the blood drop. Do not put blood on top of the test strip.

8

Remove your finger from the test strip when the flashing ⌛ appears.

9

or

The test result appears on the display.

Remove and discard the used test strip.

NOTE

When performing a **blood glucose test**: If the control bottle symbol and the flashing **L1** or **L2** appear on the display with your blood glucose result, an error has occurred.

- Do not act on the blood glucose result.
- Discard the test strip and repeat the blood glucose test with a new test strip.

Performing a Blood Glucose Test with Blood from Your Palm, Forearm, or Upper Arm (Alternative Site Testing, AST)

⚠ WARNING

Risk of a serious health incident
Your blood glucose level changes faster in your fingertip and palm than in the forearm and upper arm. Performing a blood glucose test with blood from the forearm or upper arm may cause you to misinterpret your actual blood glucose level, leading to improper therapy.

- Do not use alternative site testing to calibrate a continuous glucose monitoring system.
- Do not use alternative site testing to make insulin dosing calculations.
- Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

7_09241493061A_09241493061_01.indd 12 10/12/2021 10:22:14 AM

You have the option of obtaining a blood sample from other sites on your body besides the fingertip. Alternative sites include the palm, forearm, and upper arm.

Blood obtained from the fingertip and palm can be used at any time to perform a blood glucose test.

If blood from the forearm or upper arm is used, there are certain times when testing is not appropriate. This is because your blood glucose level changes faster in your fingertip and palm than in the forearm and upper arm. These differences may cause you to misinterpret your actual blood glucose level, leading to improper therapy and potential adverse health effects. Read the next section before you try testing from the forearm or upper arm.

You may perform a forearm or upper arm test	• immediately before a meal. • while fasting.
You may NOT perform a forearm or upper arm test	• 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 (hypoglycaemia). • if you sometimes do not notice when your blood glucose is low.

If you are interested in AST, talk to your healthcare professional first.

To obtain an AST cap and detailed AST instructions, contact Roche.

7_09241493061A_09241493061_01.indd 13 10/12/2021 10:22:14 AM

Unusual Blood Glucose Results

⚠ Precaution

Risk of a serious health incident
If your blood glucose results do not match how you feel, check the following list to help solve the problem.

Troubleshooting Checks	Action
Did you wash your hands?	Wash your hands with warm soapy water and dry thoroughly. Repeat the blood glucose test with a new test strip.
Were the test strips expired?	Discard the test strips if they are past the use by date. Repeat the blood glucose test with an unexpired test strip.
Was the cap on the test strip container always closed tightly?	Replace the test strips if you think the test strip container was uncapped for some time. Repeat the blood glucose test.
Was the test strip used immediately after it was removed from the test strip container?	Repeat the blood glucose test with a new test strip.
Were the test strips stored in a cool, dry place?	Repeat the blood glucose test with a properly stored test strip.
Did you follow the directions?	Read the chapter Blood Glucose Tests and repeat the blood glucose test. Contact Roche if you still have problems.
Are the meter and test strips working properly?	Perform a control test. See the chapter Control Tests for instructions.
Are you still unsure of the problem?	Contact Roche.

7_09241493061A_09241493061_01.indd 14 10/12/2021 10:22:14 AM

Symptoms of Low or High Blood Glucose

⚠ WARNING

Risk of hypoglycaemia
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.

- If you are experiencing any of these symptoms, or other unusual 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.

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

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

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 organisation for your country.

7_09241493061A_09241493061_01.indd 15 10/12/2021 10:22:14 AM

3 Control Tests

When to Perform a Control Test

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 think the test strips are damaged.
- 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.

About the Control Solutions

- Use only the Accu-Chek Guide control solutions.
- Close the control solution bottle tightly after use.
- Write the date you open the control solution bottle on the bottle label. The control solution must be discarded 3 months from the date the control solution bottle was opened (discard date) or on the use by date on the bottle label, whichever comes first.
- Do not use control solution that is past the use by or discard date.
- Refer to the control solution package insert for control solution storage conditions.
- The meter automatically recognises the difference between the control solution and blood.
- The control results are not displayed in memory.
- The control solution can stain fabric. Remove stains by washing with soap and water.

Performing a Control Test

You need the meter, a test strip, and control solution Level 1 or Level 2.

1

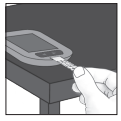
Check the use by date on the test strip container. Do not use test strips past the use by date.

2

Remove a test strip from the test strip container.

Close the cap tightly.

3



Insert the metallic end of the test strip into the meter. Place the meter on a flat surface.

The meter turns on.

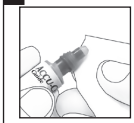
A flashing drop symbol appears.

7_09241493061A_09241493061_01.indd 16 10/12/2021 10:22:15 AM

4

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

5



Remove the bottle cap. Wipe the tip of the bottle with a tissue. Squeeze the bottle until a tiny drop forms at the tip.

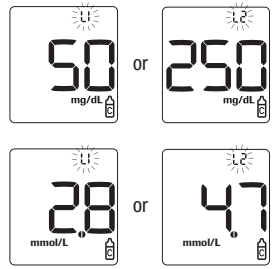
6

Touch the drop to the **yellow edge** of the test strip. Do not put control solution on top of the test strip.

7

A flashing ⌛ appears when there is enough control solution in the test strip.

8



The control result, the bottle symbol, and the flashing **L1** or **L2** appear on the display. Press ⓘ to confirm the control level you tested.

Press ◀ or ▶ to alternate between **L1** and **L2**.

NOTE

When performing a **control test**: If the control bottle symbol and the flashing L1 or L2 DO NOT appear on the display with your control result, an error has occurred.

- Do not act on the control result.
- Discard the test strip and repeat the control test with a new test strip.

7_09241493061A_09241493061_01.indd 17 10/12/2021 10:22:23 AM

9

or

OK appears if the control result is within range.

Err appears if the control result is out of range.

10

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

Remove and discard the used test strip.

NOTE

The meter turns off 90 seconds after a successful test or 15 seconds after the test strip is removed, provided no other action is taken.

7_09241493061A_09241493061_01.indd 18 10/12/2021 10:22:25 AM

Understanding Out-of-Range Control Results

⚠ WARNING

Risk of a serious health incident
Incorrect test results can lead to wrong therapy recommendations.

The control ranges are printed on the test strip container label. If the control result is out of range, check that the meter and test strips are working properly. Check the following list to help solve the problem.

Troubleshooting Checks	Action
Were the test strips or control solutions expired?	Discard the test strips or control solution 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.
Did you wipe 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.
Were the caps on the test strip container and the control solution bottle always closed tightly?	Replace the test strips or control solution if you think either was uncapped for some time. Repeat the control test.
Was the test strip used immediately after it was removed from the test strip container?	Repeat the control test with a new test strip and a fresh drop of control solution.
Were the test strips and control solutions stored in a cool, dry place?	Repeat the control test with a properly stored test strip or control solution.
Did you follow the directions?	Read the chapter Control Tests and repeat the control test.
Did you choose 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.
Are you still unsure of the problem?	Contact Roche.

7_09241493061A_09241493061_01.indd 19 10/12/2021 10:22:26 AM

4 Review Your Data

Overview

- The meter automatically stores up to 720 blood glucose results in memory with the time and date of the test.
- Once 720 blood glucose results are in memory, adding a new blood glucose result deletes the oldest blood glucose result.
- If more than 720 blood glucose tests are performed within a 90-day period, only the 720 most recent test results are included in the 90-day average.
- The meter automatically stores at least 30 control results in memory, but only the current control result can be viewed on the meter. To view stored control results, transfer them to compatible software.
- Once 30 control results are in memory, adding a new control result deletes the oldest control result.
- Control results are not included in the 7, 14, 30, or 90-day averages.

⚠ WARNING

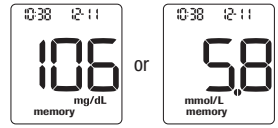
Risk of a serious health incident
Using an individual test result in memory to change your therapy can lead to improper therapy decisions. Do not change your therapy based on an individual test result in memory. Talk to your healthcare professional before changing therapy based on test results in memory.

NOTE

The meter has time and date auto-sync capability when paired with a mobile device that will update the meter time and date automatically. Even if you use your meter in multiple time zones, results are stored from newest to oldest and not by time and date.

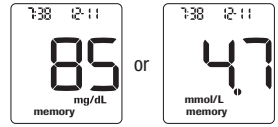
Reviewing Blood Glucose Results in Memory

1



With the meter off, press ◀ or ▶ to view blood glucose results stored in memory. The most recent stored blood glucose result appears on the display.

2



Press ◀ to view previous test results from newest to oldest.

NOTE

◀ scrolls from newest to oldest test result. ▶ scrolls from oldest to newest test result.

7_09241493061A_09241493061_01.indd 20 10/12/2021 10:22:31 AM

Reviewing 7, 14, 30, and 90-day Averages

1

or

With the meter off, press ◀ or ▶ to view blood glucose results stored in memory. The most recent blood glucose result appears on the display.

2

or

With the most recent test result on the display, press ▶. The 7-day average appears on the display.

3

or

Press ▶ to scroll through 7, 14, 30, and 90-day averages. The number of test results in the average = n. Press ◀ to scroll back from 90, 30, 14, and 7-day averages.

To return to the most recent blood glucose result, press ◀ from the 7-day average screen.

NOTE

If the memory contains a result that is HI or LO, or is corrupt, then the time period and **day/ave** will flash to alert you that those results are not included in the average.

7_09241493061A_09241493061_01.indd 21 10/12/2021 10:22:37 AM

Overview

The process of creating a connection between the meter and the mobile device is called pairing. You will need an application on your mobile device that can accept the meter data. You can use this application to wirelessly and automatically synchronise your diabetes information between the meter and the mobile device.

Pairing

The meter can only pair with 1 device at a time. Pairing with a second device overwrites the first pairing.

The meter and the device to be paired should be within 1 metre of each other.

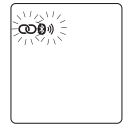
1

On Your Mobile Device

Ensure Bluetooth is on and open the diabetes management app.

2

On Your Meter



With the meter off, press and hold ◀ and ▶ at the same time until ✱ appears. Both ⚭ and))) appear and flash on the display.

6-digit PIN

Locate the 6-digit PIN on the back of your meter.

3

On Your Mobile Device

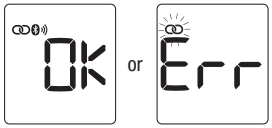
Within the app, follow the instructions and select your meter. When prompted, enter the meter 6-digit PIN.

The meter times out after 30 seconds once you are prompted to enter the PIN.

7_09241493061A_09241493061_01.indd 22 10/12/2021 10:22:40 AM

4

On Your Meter



OK appears if pairing is successful.
Err appears if pairing is unsuccessful.

NOTE

The meter has time and date auto-sync capability when paired with a mobile device that will update the meter time and date automatically. Even if you use your meter in multiple time zones, results are stored from newest to oldest and not by time and date.

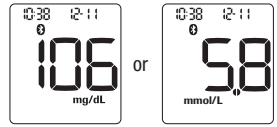
Transferring Data Wirelessly

If the meter is paired with a mobile device and Bluetooth is on, your test results will be automatically sent to the paired device.

Turning Bluetooth Off

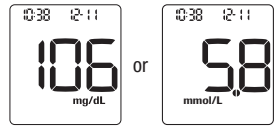
Turn Bluetooth off to disable wireless communication (flight mode). Turning Bluetooth off will not unpair your meter.

1



With the meter off, press ◀ or ▶. The most recent stored test result appears on the display.

2

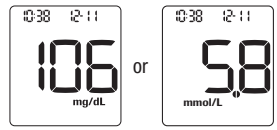


Press and hold ⏻ until the Bluetooth symbol disappears.

Turning Bluetooth On

If you have turned Bluetooth off (flight mode), follow the steps below to turn it back on. This will enable wireless communication with your mobile device.

1



With the meter off, press ◀ or ▶. The most recent stored test result appears on the display.

7_09241493061A_09241493061_01.indd 23 10/12/2021 10:22:45 AM

2

or

Press and hold until the Bluetooth symbol appears.

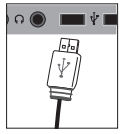
Transferring Data Using a USB Cable

This feature allows you to transfer data from your meter to special software for diabetes management on a PC using a USB cable.

1

Plug the small end of the USB cable into the meter.

2



Plug the large end of the USB cable into a USB port on the PC.

If the meter is off, it turns on.

3

Start the diabetes management software on the PC and initiate a data transfer.

4

The meter transfers the data to the software.

NOTE

The USB cable does not charge the meter batteries. Remove the USB cable after you have finished.

7_09241493061A_09241493061_01.indd 24 10/12/2021 10:22:48 AM

Meter Maintenance

The meter automatically tests its own systems every time you turn it on and lets you know if something is wrong. See the Error Messages section in this chapter.

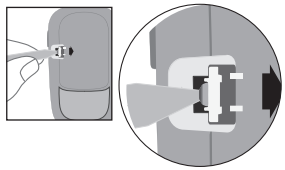
If you drop the meter, or think the results are not accurate, contact Roche.

⚠ WARNING

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

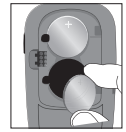
Changing the Batteries

1



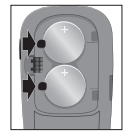
Open the child-resistant battery door by inserting a narrow object, such as a pen, into the slot (see image above). Push the tab in the direction of the arrow and lift the battery door up.

2



Remove the old batteries.

3



Slide the new batteries under the black tabs with the **(+) side facing up**.

Put the battery door back in place and snap it closed. Immediately discard the old batteries.

NOTE

- Always have a spare set of batteries.
- Battery life may vary due to factors such as temperature and battery manufacturer.
- If the E-7 or E-9 error code still appears on the display after you have changed the batteries, remove the batteries again, press ⏻ for at least 2 seconds, then reinsert the batteries.
- The meter uses two 3-volt lithium batteries, coin cell type CR2032. This type of battery can be found in many stores.
- Always replace both batteries at the same time and with the same brand.
- Meter data is not lost when you replace the batteries.

7_09241493061A_09241493061_01.indd 25 10/12/2021 10:22:52 AM

Cleaning and Disinfecting the Meter

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.

⚠ WARNING

Risk of infection
If the meter is being operated by a second person who is providing testing assistance to the user, the meter should be disinfected prior to use by the second person.

⚠ WARNING

Risk of a serious health incident

- Do not clean or disinfect the meter while performing a blood glucose or control test.
- Do not allow liquid to enter any openings in the meter.
- Do not spray anything directly onto the meter.
- Do not immerse the meter in liquid.

When to clean or disinfect the meter:

- Clean the meter to remove visible dirt or other material.
- Disinfect the meter between each patient use.

What to clean or disinfect:

- The area around slots and openings
- The meter display
- The entire meter surface

1

Make sure the meter is turned off.

Gently wipe the meter surface with a soft cloth slightly dampened (wring out any excess liquid) with one of these solutions:

To clean the meter

Mild dishwashing liquid mixed with water

To disinfect the meter

70 % isopropyl alcohol

Note: During disinfection, make sure that the meter surface stays wet with isopropyl alcohol for a minimum of 2 minutes. Additional wiping of the surface with cloths dampened with isopropyl alcohol may be necessary.

2

Dry the meter thoroughly with a soft cloth.

7_09241493061A_09241493061_01.indd 26 10/12/2021 10:22:52 AM

Error Messages

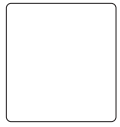
⚠ WARNING

Risk of a serious health incident
Using an error message to change your therapy can lead to improper therapy decisions.

- Never make therapy decisions based on an error message.
- If you have any concerns or see any other error message, contact Roche.

NOTE

The error code and **Err** will alternate on the display for all coded error messages (E-1 through E 14).



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

- Batteries are dead.

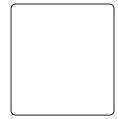
Insert new batteries.

- Display is damaged. / Meter is defective.

Contact Roche.

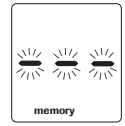
- Extreme temperatures.

Move the meter to a location with a more moderate temperature.



The meter has timed out with a USB connection.

Remove the USB cable and press the power/set button to resume testing or review test results.



There are no test results in range for the selected data.

The meter is connected to a PC and a blood glucose or control test cannot be performed.

EITHER remove the USB cable and perform a blood glucose or control test OR remove the test strip and start a data transfer.

7_09241493061A_09241493061_01.indd 27 10/12/2021 10:22:55 AM

The meter was unable to pair with a mobile device.

Retry the pairing.

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

See the Unusual Blood Glucose Results section in the chapter Blood Glucose Tests.

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

See the Unusual Blood Glucose Results section in the chapter Blood Glucose Tests.

The batteries are almost out of power.

Change the batteries now. If the symbol reappears after the batteries have been replaced, remove the batteries again, press and hold the power/set button for at least 2 seconds, then reinsert the batteries.

(The error code and **Err** will alternate on the display.)

The test strip may be damaged, not properly inserted, or was previously used.

Remove and reinsert the test strip or replace it if damaged or previously used.

7_09241493061A_09241493061_01.indd 28 10/12/2021 10:23:02 AM

(The error code and **Err** will alternate on the display.)

A meter or test strip error has occurred.

This error message could appear if the cap on the test strip container was not closed tightly. The test strips may have been damaged due to improper storage or handling.

Never make therapy decisions based on an error message.

Repeat the blood glucose test. If a second E-3 error message appears, perform a control test with the control solution and a new test strip. See the section Performing a Control Test in the chapter Control Tests. If you continue to receive an E-3 error message, use an alternate method for testing your blood glucose, such as a back-up meter and test strip. If the alternate method gives an extremely high blood glucose result, or if an alternate method is not available, **contact your healthcare professional immediately**.

In rare cases, an E-3 error message may indicate that your blood glucose is extremely high and above the system's measuring range. **See the Unusual Blood Glucose Results section in the chapter Blood Glucose Tests for other possible causes of the error message.**

(The error code and **Err** will alternate on the display.)

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 blood glucose or control test.

(The error code and **Err** will alternate on the display.)

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 blood glucose or control test.

(The error code and **Err** will alternate on the display.)

An electronic error occurred.

Remove the batteries, press and hold the power/set button for at least 2 seconds, and reinsert the batteries. Perform a blood glucose or control test.

7_09241493061A_09241493061_01.indd 29 10/12/2021 10:23:07 AM

(The error code and **Err** will alternate on the display.)

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 and repeat the blood glucose or control test. Do not artificially heat or cool the meter.

(The error code and **Err** will alternate on the display.)

The batteries may be out of power.

Turn the meter back on. **If you are in a cold environment, move to a location with a more moderate temperature and retest.** If the message continues to appear after several attempts, replace the batteries. If the message reappears after the batteries have been replaced, remove the batteries, press and hold the power/set button for at least 2 seconds, then reinsert the batteries.

(The error code and **Err** will alternate on the display.)

The time and date setting may be incorrect. A flashing wireless symbol appears while the meter attempts to synchronise the time and date with the paired device.

When the wireless symbol no longer appears, press the power/set button to turn the meter off. Press the power/set button a second time until the flashing test strip symbol appears. If time and date sync was not successful the meter prompts you to set them the next time you turn it on. See the Setting the Time and Date section in the chapter Your New System.

(The error code and **Err** will alternate on the display.)

The test strip may be damaged.

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

7_09241493061A_09241493061_01.indd 30 10/12/2021 10:23:12 AM

(The error code and **Err** will alternate on the display.)

Your blood sample may contain a high level of ascorbate.

Contact your healthcare professional.

(The error code and **Err** will alternate on the display.)

Fluid or foreign material may be present in the test strip slot.

Remove and reinsert the test strip or repeat the blood glucose or control test with a new test strip. If the error persists, contact Roche.

(The error code and **Err** will alternate on the display.)

An electronic error has occurred.

Contact Roche.

7_09241493061A_09241493061_01.indd 31 10/12/2021 10:23:15 AM

7 Technical Information

Product Limitations

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

Specifications	
Blood volume Sample type Measuring time Measuring range Test strip storage conditions System operating conditions	Refer to the test strip package insert.
Meter storage conditions	Temperature: -25–70 °C
Memory capacity	720 blood glucose results and 30 control results with time and date
Automatic off	90 seconds after performing a test, 15 seconds after a test strip is removed.
Power supply	Two 3-volt lithium batteries (coin cell type CR2032)
Display	LCD
Dimensions	76 × 48 × 16 mm (LWH)
Weight	Approx. 43 g (with batteries)
Construction	Hand-held
Protection class	III
Meter type	The Accu-Chek Guide Me meter is suitable for continuous operation.
Control solution storage conditions	Refer to the control solution package insert.
Continua CERTIFIED Interfaces	USB: micro-B connector; Bluetooth low energy technology; Continua Certified® to a Continua Certified manager.
Radio frequency connectivity	Bluetooth low energy technology operating in the frequency band of 2.4 GHz (2.402 GHz to 2.480 GHz) with a maximum transmitted power of 0 dBm (1 mW).

7_09241493061A_09241493061_01.indd 32 10/12/2021 10:23:16 AM

Electromagnetic Compatibility – The meter meets the electromagnetic emission 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.

Test Principle – Refer to the test strip package insert.

Declaration of Conformity – Hereby, Roche declares that the radio equipment type Accu-Chek Guide Me blood glucose meter is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address:
http//declarations.accu-chek.com

Communication Protocol – The Accu-Chek Guide Me blood glucose meter is Continua Certified. Continua Certified signifies that this product complies with applicable IEEE 11073-10417 standards and that it has been tested and certified against the 2016 Continua Design Guidelines which include the Blood Glucose specification for Bluetooth low energy technology, *Bluetooth SIG, Glucose Profile, Version 1.0* and *Bluetooth SIG, Glucose Service, Version 1.0.*

Product Safety Information

NOTE

- This meter meets IEC 61010-1, IEC 61010-2-101, and IEC 60950-1 safety standards.
- 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.

7_09241493061A_09241493061_01.indd 33 10/12/2021 10:23:16 AM

Discarding the Meter

⚠ WARNING

Risk of infection
During blood glucose testing, the meter itself may come into contact with blood. Used meters therefore carry a risk of infection.

⚠ WARNING

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

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 2012/19/EU (Directive on waste electrical and electronic equipment (WEEE)).

Discard used batteries according to local environmental regulations.

This product includes an internal constituent containing a Substance of Very High Concern (SVHC), Hexabromocyclododecane (CAS 25637-99-4), in a concentration above 0.1 % weight by weight, as identified under REACH and added to the Candidate List.

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

7_09241493061A_09241493061_01.indd 34 10/12/2021 10:23:16 AM

7 Technical Information

Explanation of Symbols

These symbols may appear on the packaging, on the type plate, and in the instructions for the Accu-Chek Guide Me 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.
	The compliance mark indicates that the product complies with the applicable standard and establishes a traceable link between the equipment and the manufacturer, importer or their agent responsible for compliance and for placing it on the Australian and New Zealand market.
	Temperature limit
	Use by
	Keep new and used batteries away from children.
	3-volt coin cell type CR2032
	Biological risks – used meters carry a risk of infection.
	Date of manufacture
IVD	In vitro diagnostic medical device
	Device for self-testing
	Device for near-patient testing
	Manufacturer
UDI	Unique device identifier
GTIN	Global Trade Item Number
REF	Catalogue number
SN	Serial number
LOT	Batch code
CE	Complies with the provisions of the applicable EU Legislation

7_09241493061A_09241493061_01.indd 35 10/12/2021 10:23:22 AM

Additional Supplies

Test Strips: Accu-Chek Guide test strips

Control Solutions: Accu-Chek Guide control solutions

Information for Healthcare Professionals

This system can be used in professional healthcare environments such as doctors' offices, general wards, in suspected cases of diabetes, and in emergency cases.

⚠ WARNING

Risk of infection
Any object coming into contact with human blood is a potential source of infection. Healthcare professionals should 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 recognised procedures for handling objects that are potentially contaminated with human material. Follow the hygiene and safety policy of your laboratory or institution. Prepare the selected blood collection site per facility policy.

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

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 or upper arm. 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 behaviour 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 or upper arm. 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 or upper arm.

7_09241493061A_09241493061_01.indd 36 10/12/2021 10:23:22 AM

8 Guarantee and Warranty

Guarantee

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

Warranty

Be sure to register your warranty online at accu-chek.com.au/warranty for the Accu-Chek Guide Me system.

7_09241493061A_09241493061_01.indd 37 10/12/2021 10:23:23 AM

Index

A
alternative site testing 12, 36
averages, reviewing 21

B
batteries, changing 25
battery type 25, 32
blood glucose results, unusual 14
blood glucose test, performing 11
blood glucose, warning 15, 28
buttons, functions 5, 7

C
cleaning and disinfecting, meter 26
control results, out-of-range 19
control solution 16
control test, performing 16

D
data transfer
    USB 24
    wireless 23

E
error messages 28

G
guarantee 37

H
high blood glucose 15
hyperglycaemia 15
hypoglycaemia 15

L
low blood glucose 15

M
maintenance, meter 25
memory 20

P
pairing 22
product limitations 32
product safety information 33
product specifications 32

S
supplies 36
symbols
    IVD 35
    meter display 8

T
technical information 32
test strips 10
time and date, setting 9

U
USB 24
use by date 11

W
warranty 37
wireless communication
    auto-sync, time and date 20, 23
    pairing 22
    turning off (flight mode) 23

7_09241493061A_09241493061_01.indd 38 10/12/2021 10:23:23 AM

LAST UPDATE: 2021-06

Australia

Roche Diabetes Care Australia Pty. Limited
Accu-Chek Enquiry Line: 1800 251 816
www.accu-chek.com.au

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

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

Roche Diabetes Care GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany
www.accu-chek.com

대한민국
고객 지원 및 서비스 센터
무료상담전화: 080-909-2222
(월-금 오전 9시 ~ 오후 5시)
www.accu-chek.co.kr

Saudi Arabia / United Arab Emirates / Jordan / Kuwait / Lebanon / Qatar
Roche Diabetes Care Middle East FZCO
Tel: +971 (0) 4 816 9165
www.rochediabetescaremea.com
or contact Roche local authorized representative in your country

Accu-Chek Guide Me

R-C-WX3-905

MCMC
HIDF16000080

IVD

CE 0123

ACCU-CHEK, ACCU-CHEK GUIDE, and ACCU-CHEK GUIDE ME are trademarks of Roche.

Continua CERTIFIED

CONTINUA, the CONTINUA logos and CONTINUA CERTIFIED are trademarks, service marks, or certification marks of the Continua Health Alliance. CONTINUA is a registered trademark in some, but not all countries in which this product is distributed.

The *Bluetooth®* word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Roche is under license.

All other product names and trademarks are the property of their respective owners.

© 2021 Roche Diabetes Care

09241493061A-1021
09241493061(01)-1021