ACCU-CHEK® Guide Me



User's Manual

Blood Glucose Meter





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The Accu-Chek Guide Me System

The Accu-Chek Guide Me blood glucose monitoring system is comprised of the Accu-Chek Guide Me meter and Accu-Chek Guide test strips.

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

The Accu-Chek Guide test strips with the Accu-Chek Guide Me meter are intended for in vitro diagnostic use 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.

♠ WARNING



- Choking hazard. Small parts. Keep away from children under the age of 3 years.
- 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.
- 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).

MARNING - 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.

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.

The Accu-Chek Guide Me Meter





Front View

Back 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).



- 8. Test Strip Container*
- Test Strip* Metallic End Insert this end into meter.
- Test Strip* Yellow Edge
 Touch blood drop or control solution here.
- 11. Control Solution Bottle*
- 12. Batteries
- 13. USB Cable*

Connects meter to a PC.

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

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
	Turn the meter on or off.	Press and release.
[power/set button]	Navigate to an option or set a selection.	
	Check the meter display.	With the meter off, press and hold
	3888 3888 527 ⊕ 1	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.

Symbols

Symbol	Description
Ti day I ave	7-day average symbol. This indicates that you are viewing the 7-day average of your blood glucose results.
II_I day I I ave	14-day average symbol. This indicates that you are viewing the 14-day average of your blood glucose results.
III day	30-day average symbol. This indicates that you are viewing the 30-day average of your blood glucose results.
IIII day	90-day average symbol. This indicates that you are viewing the 90-day average of your blood glucose results.
8	Bluetooth symbol
Ĉ	Control bottle symbol
1	Drop symbol
X	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.
Û	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.

Setting the Time and Date



Press and release

to turn the meter on.

The flashing test strip symbol appears on the

2



Press and **hold** (1) until **set-up** appears on the display. The hour flashes.

Press or locrease the hour.

3



Press ① to set the hour and move to the next field.

4



Repeat steps 2 and 3 to adjust each field. Press and hold ① 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.
- 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.

WARNING WARNING

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 vou, contact your healthcare professional. Using the wrong unit of measurement may cause misinterpretation of your actual blood glucose level and may lead to improper therapy.



mg/dL or mmol/L is printed here

Using the Accu-Chek Guide Me System

WARNING

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

1



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

device.

Prepare the lancing

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.

6



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



Touch the vellow 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 X appears. Failure to move your finger

away from the test strip could give inaccurate test results.

9



or



The test result appears on the display. Remove and discard the used test strip. Performing a Blood Glucose Test with Blood from Your Palm. Forearm, or Upper Arm (Alternative Site Testing, AST)

WARNING

- Do not use alternative site testing to calibrate a continuous glucose monitoring system.
- Do not use alternative site testing to make insulin dosing calculations.

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 alucose 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 vou to misinterpret vour 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.

2 Blood Glucose Tests

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.

Unusual Blood Glucose Results

If your blood glucose result does 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.

2 Blood Glucose Tests

Troubleshooting Checks	Action
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.

Symptoms of Low or High Blood Glucose

⚠ WARNING

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.

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.

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.

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 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.





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





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.

10:38 12:11



The meter turns on.

A flashing drop symbol appears.

3 Control Tests

4



Select the control solution to test. You will confirm 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 \blacksquare appears when there is enough control solution in the test strip.

B Signal A Company of the company of







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

or

Press or to alternate between L1 and L2

9





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.

Understanding Out-of-Range Control Results



♠ WARNING

The control ranges are printed on the test strip container label. If the control result is out of range, check this 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.

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

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



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



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

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



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



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



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.

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's 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.



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 ❸ appears. Both ᅟ and ୬ appear and

flash on the display.



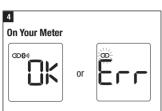
Locate the 6-digit PIN on the back of your meter.



On Your Mobile Device

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

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



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.



With the meter off, press
The last stored test result appears on the display.



Press and hold **(1)** 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.



With the meter off, press
The last stored test result appears on the display.





or



Press and hold ① 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.





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





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.

Meter Maintenance and Troubleshooting

Meter Maintenance

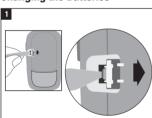
The meter automatically tests its own systems every time you turn it on and lets you know if something is wrong. See the Error Messages section in this chapter.

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



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



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.

NOTE

- · Always have a spare set of batteries.
- Battery life may vary due to factors such as temperature and battery manufacturer.
- 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.

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.

հ

↑ WARNING

- 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.
- . 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.



Dry the meter thoroughly with a soft cloth.

Error Messages

WARNING

- 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 within the stated temperature limits.



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.



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.



(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.



(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.



(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

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	Refer to the test strip package insert.
Sample type	
Measuring time	
Measuring range	
Test strip storage conditions	
System operating conditions	
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 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 Technical Information

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 – Roche hereby declares that the Accu-Chek Guide Me blood glucose meter conforms with the basic requirements and other relevant regulations of the European Directive 2014/53/EU. The conformity declaration may be found at the following website: 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

↑ WARNING

- 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.

Discarding the Meter

⚠ WARNING

- During blood glucose testing, the meter itself may come into contact with blood. Used meters therefore carry a risk of infection. Before discarding the meter, remove the battery or batteries. Discard used meters according to the regulations applicable in your country. Contact the local council and authority for information about correct disposal.
- Keep new and used batteries away from children. See the warning in the Introduction of this User's Manual for additional information.
- 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.

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.

[]i	Consult instructions for use
	Biological Risks – used meters carry a risk of infection.
\triangle	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.
1	Temperature limitation (store at)
\square	Use by
•••	Manufacturer
REF	Catalogue number
LOT	Batch code
IVD	In vitro diagnostic medical device
GTIN	Global Trade Item Number
SN	Serial number
(6 0123	This product fulfils the requirements of the European Directive 98/79/EC on in vitro diagnostic medical devices.
+ 1	3-volt coin cell type CR2032
*	Keep new and used batteries away from children.

Additional Supplies

Test Strips: Accu-Chek Guide test strips

Control Solutions: Accu-Chek Guide control solutions

Information for Healthcare Professionals



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

Sample Handling

Always wear gloves when handling blood-contaminated items. Always adhere to the 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.

8 Guarantee

Guarantee

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

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Accu-Chek Guide Me

R-C-WX3-905



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