ACCU-CHEK Guide



USER'S MANUAL

BLOOD GLUCOSE METER



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Introduction

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



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 System

The Accu-Chek Guide 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 meter with the Accu-Chek Guide test strips provides a complete test system that is meant for in vitro diagnostic use by a single person and should not be shared.

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

Suitable for self-testing

The system includes: Accu-Chek Guide 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



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 Accu-Chek Customer Care at 1-800-363-7949.

⚠ 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).

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

The lancing device is for single patient use only and should not be shared

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.

Introduction

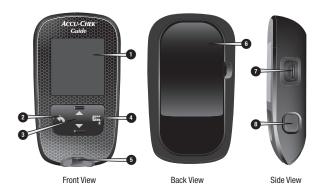
Important Information About Your New Meter

- 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 may prompt you to choose a language and the time format (12-hour or 24-hour clock) 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.

The Accu-Chek Guide Meter



1. Display

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

2. Back Button

Returns to a previous screen or field.

3. Up Arrow and Down Arrow Buttons

Press to move between menu options or to increase or decrease numbers.

4. Power/Set/OK Button

Turns meter on or off and sets options.

5. Test Strip Slot with Light

Insert test strip here.

6. Battery Door

Flip open to replace batteries.

7. Micro USB Port

Transfers data from meter to a computer (PC).

8. Test Strip Ejector

Press to remove test strip.



ACTI-CHE Grate facilities

- 9. Test Strip Container* (for example)
- 10. Test Strip* Metallic End Insert this end into meter.
- 11. Test Strip* Yellow Edge Touch blood drop or control solution here.
- 12. Control Solution Bottle*
- 13. Batteries
- 14. USB Cable*

Connects the meter to a PC.

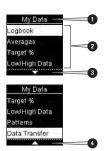
*Some items may not be included in the kit. They are a separate purchase.

Button Functions

Here are the functions of the back, arrow, and Power/Set/OK buttons on the meter. These functions are used throughout this manual. See the chapter Meter Settings for specific instructions on setting up the meter.

Button	Function		
Back Button	Return to the previous screen. Return to the previous field.		
Up Arrow and Down Arrow Buttons	Navigate up and down in a menu. Increase or decrease a number.		
Power/Set/OK Button	Press briefly to turn the meter on. Press and hold to turn the meter off. Press to select an option. Press to move to the next field or screen. Press to save an option. With the meter off, press and hold to check the meter display. Display Check		

Meter Menus



- 1. Title of screen or menu
- 2. Menu options
- 3. Scroll down
- 4. Scroll up

Screen	Description			
	There are more menu options listed beneath the last option. Press on the meter to view the options.			
	There are more menu options listed above the first option. Press on the meter to view the options.			
A	There are more menu options listed above and below the options. Press or on the meter to view the options.			
9:38am 12/11/15 Main Menu ♣ Test ■ My Data ♣ Settings	Highlighted option (Test) Press ™ to enter the Test menu.			
Time/Date HH MM A/P 9: 38 am DD MM YY 12 / 11 / 15	Highlighted field (HH=Hour) Press or to increase or decrease the hour. Press to set the hour and move to the minutes field.			

Symbols

Here is a list of the symbols on the meter display.

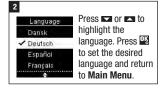
Symbol	Description
1	Above target range
Ì	After meal
)	Bedtime
Ď	Before meal
Ţ	Below target range
•	Blood glucose test
\	Checkmark / Control test OK / Selected option or setting
C	Control bottle
×	Control test not OK
0	Edit
×	Error
0	Fasting
†	Flight mode
?	Help
<u>-</u>	Low battery
4	My data
	No comment
*	Other

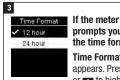
Symbol	Description
⊙	Overall
₩	Settings
\Diamond	Test reminder
<u>^</u>	Warning
‡	Within target range

Setting the Language and Time Format

The meter may prompt you to choose a language and time format (12-hour or 24-hour clock) the first time you turn it on.







prompts you to set the time format:

Time Format appears. Press or **t** to highlight

12 hour (am/pm) or 24 hour.

Press us to set the option and return to Main Menu.

NOTE

If you select the wrong language and cannot correct it, contact Accu-Chek Customer Care at 1-800-363-7949.

↑ 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. Meters for use in Canada have mmol/L as the unit of measurement. If the meter shows the wrong unit, contact Accu-Chek Customer Care at 1-800-363-7949. If you do not know which unit of measurement is correct for you.



mg/dL or mmol/L is printed here

Using the Accu-Chek Guide 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 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 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 up the meter correctly.
- 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.
- . There are 2 ways to start a blood glucose test.
 - . Insert a test strip into the meter.
 - Turn the meter on by briefly pressing $\frac{\text{OK}}{\text{N}}$. Select **Test** $> \frac{\text{OK}}{\text{N}}$.





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.





Insert the metallic end of the test strip into the meter.



The meter turns on. Preparing to test appears.





Wash your hands with warm soapy water and dry thoroughly.

Prepare the lancing device.



Apply drop

When Apply drop appears, poke your fingertip with the lancing device.



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



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





Remove your finger from the test strip when **Analyzing** appears.



The test result appears on the display.

You have the option of adding a comment to the test

result by pressing OR proceed to Step 12 to complete the test.



Add Comment

appears. Press to highlight a comment. Press to set the comment for the test result.

See the Adding Comments to Blood Glucose Results section of this chapter for details.



Before meal

The final result appears. Press or to set the comment and return to Main

Menu. Or to change the comment, press

to select the comment.

Press to return to Add Comment.

NOTE

When performing a **blood glucose test**: If the **Control Result** screen appears, 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.

12

Remove and discard the used test strip by pulling the test strip out of the meter or by pressing the test strip ejector on the side of the meter.



Press here to eject test strip

Blood Glucose Warnings

If your blood glucose result is outside the measuring range of the meter, a warning is displayed. Press to acknowledge the LO or HI warning, OR the meter automatically moves to the LO or HI result screen.





Blood glucose may be lower than the measuring range of the system. See the Unusual Blood Glucose Results section of this chapter.





Blood glucose may be higher than the measuring range of the system. See the Unusual Blood Glucose Results section of this chapter.

Adding Comments to Blood Glucose Results

NOTE

Analyzing your blood glucose results stored in the meter is an effective way for you and your healthcare professional to determine how well you are controlling your diabetes. This analysis is a valuable tool for making improvements to your diabetes management. Use care when adding comments to blood glucose results. Incorrect comments can cause inaccurate patterns to be detected by the meter if Patterns is **On**.

Overview

It is very important to have the correct time and date set in the meter. Having the correct time and date setting helps ensure accurate interpretation of information by you and your healthcare professional.

- You may add comments to blood glucose results to help you and your healthcare professional analyze patterns detected by the meter (see the Patterns section in the chapter Meter Settings for details).
- If Patterns is set to **0n**, once a pattern is detected you may NOT change the comment attached to a blood glucose result (see the Patterns section in the chapter Meter Settings for details).
- Adding a comment saves the comment and the symbol with the blood glucose results.

Here is a list of comment symbols that can be added to a blood glucose result.

Symbol	Name	Description
ď	Before meal	If Patterns is 0n , select Before breakfast, lunch, dinner, or snack (see the following page for adding comments with Patterns 0n).
Ĭ	After meal	If Patterns is 0n , select After breakfast, lunch, dinner, or snack (see the following page for adding comments with Patterns 0n).
0	Fasting	Select Fasting for no caloric intake for at least 8 hours.*
)	Bedtime	
*	Other comment	You can use this comment to mark an event such as an AST result or exercise.
	No entry	You do not want to add a comment. You want to remove a comment for the current blood glucose result.

^{*}American Diabetes Association: Standards of Medical Care in Diabetes-2020.

7:38am 12/11/15 4.7 mmol/L

After performing a blood glucose test, the test result is displayed on the screen with Add Comment

highlighted. Press ut to add a comment

Add Comment



The Add Comment menu appears.

Press to highlight the desired comment (the example here is

Before meal). Press to select the comment.

Before Meal Breakfast Lunch Dinner Snack If Patterns is On:
If Patterns is On
and you select
Before meal or
After meal, press
to select a

specific meal (Breakfast, Lunch, Dinner, or Snack). Press W to set the selected meal for the test result.

3



The final result appears with the comment symbol. Press ☐ or ☐ to set the comment and return to Main Menu.

To change the comment, press to select the comment.

Press to return to **Add Comment**.

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 than in the
palm, forearm, and upper arm.
Performing a blood glucose test with
blood from the palm, forearm, or
upper arm may cause you to
misinterpret your actual blood
glucose level, leading to improper
therapy and potential adverse health
effects.

- Do not use alternative site testing (AST) 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).

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 can be used at any time to perform a blood glucose test.

If blood from the palm, forearm, or upper arm is used, there are certain times when testing is not appropriate.

Read the following section before you try testing from the palm, forearm, or upper arm.

You may perform a palm, forearm, or upper arm test	immediately before a meal. while fasting.
You may NOT perform a palm, 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 (hypoglycemia). 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 Accu-Chek Customer Care at 1-800-363-7949.

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 Accu-Chek Customer Care at 1-800-363-7949 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 Accu-Chek Customer Care at 1-800-363-7949.

Symptoms of Low or High Blood Glucose

♠ WARNING

Risk of hypoglycemia

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 the following symptoms, or other unusual symptoms, test your blood glucose from the fingertip.
- If your blood glucose result is displayed as LO or HI, contact your healthcare professional immediately.

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

High blood glucose (hyperglycemia): Symptoms of hyperglycemia 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 organization for your country.

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 recognizes 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.



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



The meter turns on. **Preparing to test** appears.



Apply drop appears.





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.



Analyzing appears when there is enough control solution in the test strip. 7



Control Result and the control bottle symbol appear. Press ▼ or ▼ to select the control level you tested. If

you do not select a level, the control result is saved without a control level. Press

NOTE

When performing a **control test**: If the **Control Result** screen DOES NOT appear, 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.

Control Result
9:38am 12/11/15
2.8 mmo//L
Level 1
Within range

Within range and
✓ appear if the

control result is within range.



Out of range and appear if the control result is out of range.





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

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 Accu-Chek Customer Care at 1-800-363-7949.

Overview

You can adjust the following settings in the meter for your personal preferences. Refer to the sections later in this chapter for details and how to set the options.

Setting	Options	Function
Time/Date	Time / Date	Set the time and date.
Beeper	On / Off	Select On or Off.
Wireless	Select wireless communi Communication and Mete	
Target Ranges	Off / Single Range / 2 Ranges	Select the blood glucose target range appropriate for you.
		NOTE
		Consult your healthcare professional for the appropriate target range for you.
		Off – no target range arrow symbols appear with the blood glucose result. Patterns is Off (see the Patterns section of this chapter for details).
	3.9–10.0 mmol/L (pre-set target range)	Single Range – blood glucose results are marked as above, within, or below range based on the single target range set in the meter.
	Before Meal Range 3.9–6.1 mmol/L (pre-set target range) After Meal Range 3.9–10.0 mmol/L (pre-set target range)	2 Ranges – set Before Meal and After Meal ranges. Blood glucose results are marked as above, within, or below range based on the 2 target ranges (Before Meal and After Meal) set in the meter.
Patterns	On / Off	On – a pattern is detected when 2 below-target or 3 above-target test results with the same comment are detected within a 7-day period.
Reminders	On / Off / Edit time	On – set up to 4 reminders per day to remind you to test.
Post Meal	On / Off / Edit time	On – reminds you to perform an after meal blood glucose test.

Setting	Options	Function
Last Result	On / Off	Select whether the previous blood glucose result (within the past 24 hours) appears with the current blood glucose result.
		On – the previous blood glucose result appears with the current blood glucose result.
		Off – only the current blood glucose result appears.
Language		Select the language for the meter.
Time Format	12 hour / 24 hour	Select the clock format for the meter.

Time/Date



Turn the meter on by briefly pressing

☐. From Main Menu, press ☐ to highlight Settings. Press ☐.



Time/Date is highlighted. Press 23.



Press or to adjust each field.
Press to set and move to the next field. Set am or pm if necessary.

Press to save and return to the previous menu.

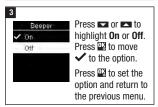
Beeper

The beeper prompts you:

- when a test strip is inserted.
- to apply blood or control solution to the test strip.
- when enough blood or control solution is drawn into the test strip.
- when the blood glucose or control test is complete.
- when the meter is turned on.
- when a button is pressed.
- when it is time to perform a test (if Reminders or Post Meal reminders are On)
- · when the batteries are inserted.
- when there are no stored blood glucose results or there is an invalid record in the logbook.
- when there are no errors in the error log.
- if an error occurred (even if the beeper is off, it still beeps for an error).







Target Ranges

Your healthcare professional can tell you what blood glucose range is appropriate for you. It is very important to stay within your target range.

Target Ranges can be set from a lower limit of 3.3–5.5 mmol/L to an upper limit of 5.6–16.6 mmol/L.

Options	Function
Off	Arrow symbols for above, within, or below target ranges do not appear with the blood glucose results.

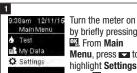
Single Set lower limit and upper limit for the Target Range. You will be prompted to turn on Patterns if desired (see the Patterns section of this chapter for details). 2 Ranges Set lower limits and upper limits for Before Meal and After Meal target ranges. You must mark your blood glucose results with a comment for the meter to detect above, within, or below Before Meal or After Meal test results (see the Adding Comments to Blood Glucose Results section in the chapter Blood Glucose Tests for details). You will be prompted to turn on Patterns if desired (see the Patterns section of this chapter for details).		
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(see the Patterns section of this chapter for details).		
of this chapter for details).		
details).		
, ,		
	/hon Target	,

When Target Ranges is on, the following symbols appear with blood glucose results

Symbol	Meaning
Ţ	The blood glucose result is below the target range.
‡	The blood glucose result is within the target range.
1	The blood glucose result is above the target range.

WARNING

This function is no substitute for hypoglycemia training by your healthcare professional.



by briefly pressing From Main Menu. press to highlight Settings. Press OK



3 More Options Target Ranges is highlighted. Target Ranges Press OK Patterns Reminders Post Meal





Press or to adjust the lower limit of the Before Meal target range. Press to set and move to the next field.

Continue to set the upper limit for the Before Meal target range and the lower and upper limits for the After Meal target range, Press





(?) Help

The meter may prompt you to turn on Patterns.

Press or to highlight Yes or No.

Press to set the option and return to the previous menu (see the Patterns section of this chapter for details).

NOTE

Analyzing your blood glucose results stored in the meter is an effective way for you and your healthcare professional to determine how well you are controlling your diabetes. This analysis is a valuable tool for making improvements to your diabetes management. Use care when adding comments to blood glucose results. Incorrect comments can cause inaccurate patterns to be detected by the meter if Patterns is **On**

Patterns

A Pattern is detected by the meter when 2 below-target (Low Pattern) or 3 above-target (High Pattern) test results with the same comment are detected within a 7-day period.

- The meter does NOT detect a pattern for the "other" comment added to blood glucose results.
- It is very important to have the correct time and date set in the meter. Having the correct time and date setting helps ensure accurate interpretation of information by you and your healthcare professional.
- Only blood glucose results marked with comments will be included in Patterns. If LO or HI test results are marked with comments, the test results become part of Patterns (see the chapter Blood Glucose Tests for more details).
- Target Ranges must be set in the meter to use Patterns. If Target Ranges is not set, the meter prompts you to set it.



Turn the meter on by briefly pressing

☑3. From Main
Menu, press

to highlight Settings.
Press

☐4

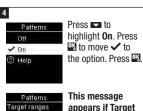


Press to highlight More Options. Press .



Press to highlight Patterns.

Press S.



must be set up. Set up now? No YAS

Ranges is Off:

Press to hiahliaht Yes. Press OK

(To turn Patterns Off, select No. Press (1) to return to Patterns.)

Target Ranges Choose an ontion. Single Range 2 Ranges (2) Help

Target Ranges appears on the display (see the Target Ranges section of this chapter for details

on setting target ranges).

If Patterns is **On** and a new pattern is detected with a blood glucose result, a message appears on the display.



Press to select Details to view the blood alucose results that make up that pattern.

٥r



Press to highlight View later

Press to return to the previous screen.

Reminders

You can set up to 4 general test Reminders per day to remind you to test. A series of beeps sound and \triangle is displayed for Reminders set in the meter.

Reminders:

- . turn off by inserting a test strip or pressing any button.
- are postponed until the next test reminder if a test was performed within 15 minutes of a test reminder.
- do not appear/beep if the meter is on at the test reminder time (including when the meter is connected to a USB cable).
- do not appear/beep if the meter is connected and communicating to a Continua Certified® manager.
- do not beep if the meter beeper is set to off
- do not appear/beep if the batteries need to be replaced.

Set Reminders

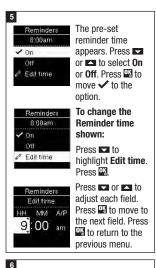
- Reminder times are pre-set in the meter for 8:00 am. 12:00 pm. 6:00 pm, and 10:00 pm. You may change reminder times by following the instructions below.
- If a general test Reminder is set for the same time as a Post Meal reminder, the Post Meal reminder will appear/beep instead of the general Reminder (see the Post Meal Reminders section of this chapter for details).

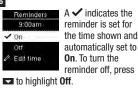


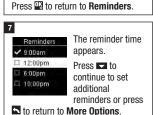




Reminders
□ 8:00am times appear on the
□ 12:00pm display. Press to highlight a reminder
□ 10:00pm time. Press ...







Post Meal Reminders

Post Meal reminders can be set to remind you to test again later when you add a Before meal comment to a blood glucose result. When a reminder occurs, a series of beeps sound and \diamondsuit is displayed.

Post Meal reminders:

- turn off by inserting a test strip or pressing any button.
- are postponed until the next test reminder if a test was performed within 15 minutes of a test reminder.
- do not appear/beep if the meter is on at the test reminder time (including when the meter is connected to a USB cable).
- do not appear/beep if the meter is connected and communicating to a Continua Certified® manager.
- do not beep if the meter beeper is set to off.
- do not appear/beep if the batteries need to be replaced.

Set Post Meal Reminders

- Adding a Before meal comment to a blood glucose result sets a Post Meal reminder in the meter.
- Marking blood glucose results with an After meal comment provides more information about your test results to help you and your healthcare professional in the management of your diabetes.
- Talk to your healthcare professional to determine your Post Meal test time.
- Select 1 hour, 1.5 hours, or 2 hours for Post Meal reminders to occur.



Turn the meter on by briefly pressing

☐3. From Main

Menu, press

to highlight Settings.

Press
☐4



Press to highlight More Options. Press .







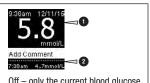


Press To move 🗸 to the option.

Press to set and return to the previous menu.

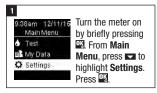
Last Result

Select whether the previous blood glucose result appears with the current blood glucose result. **Test results older than 24 hours do not appear.**



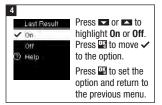
Off – only the current blood glucose result • appears.

On – the previous blood glucose result 2 appears with the current blood glucose result.



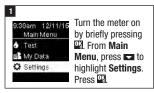






Language

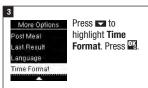
Choose the language that appears on the meter.















Time Format

menu.

Choose the time format (12-hour or 24-hour clock) that appears on the meter.



5 Review Your Data

Overview

- Blood glucose results are stored from the newest to the oldest.
- The meter automatically stores up to 720 blood glucose results in memory with the time and date of the test and any test result comments.
- Once 720 blood glucose results are in memory, adding a new blood glucose result deletes the oldest blood glucose result.
- Only test results that have been marked with a fasting, before meal, after meal, or bedtime comment are included in the average for that comment
- All test results are included in the overall 7, 14, 30, and 90-day averages regardless of what comment is added.
- Control results are stored in memory but cannot be reviewed on the meter.
 To view stored control results, transfer them to a compatible software application.
- Control results are not included in the averages or blood glucose reports.
- Once 32 control results are in memory, adding a new control result deletes the oldest control result.

♠ 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.

Logbook



Turn the meter on by briefly pressing

☐. From Main
Menu, press ☐ to highlight My Data.

Press ☐.



5 Review Your Data



Press or to scroll through **Logbook**.

The most recent test result .

The 2nd most recent test result a.

To view details about a test result, press □ or ■ to highlight the test result. Press □. Test result details shown below only appear if Target Ranges is on or comments were added to a test result.

The most recent test result



The 2nd most recent test result



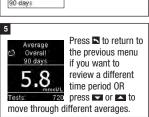
Averages











Target Percent (%)

Target Percent (%) allows you to view the percentage of your Overall, Before meal, After meal, Fasting, and Bedtime blood glucose results that are above, within, or below your target ranges.

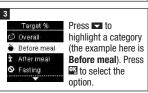
- Target % results can be viewed for 7, 14, 30, or 90-day time periods.
- Target Ranges must be set in the meter to review Target % results.



Turn the meter on by briefly pressing

☐. From Main
Menu, press
☐ to highlight My Data.
Press ☐.









The **Target** % appears (for the **Before meal** example). The number of total tests included in the

Target % appears at the bottom of the display.

Press to return to the previous menu.

NOTE

Analyzing your blood glucose results stored in the meter is an effective way for you and your healthcare professional to determine how well you are controlling your diabetes. This analysis is a valuable tool for making improvements to your diabetes management. Use care when adding comments to blood glucose results. Incorrect comments can cause inaccurate patterns to be detected by the meter if Patterns is **On**.

Low/High Data

Your healthcare professional can tell you what blood glucose range is appropriate for you. It is very important to stay within your target range.

- Target Ranges must be set in the meter to track Low/High Data test results (see the Target Ranges section in the chapter Meter Settings for details).
- Low BG or High BG Data includes only test results that fall above or below the target ranges set in the meter.
- Low BG or High BG Data is tracked in the meter for 30 days.

You can select Low BG and High BG test results for Overall, Before meal, After meal, Fasting, or Bedtime blood glucose results.

Symbol	Name	Description
\odot	Overall	Includes low and high blood glucose results based on Target Ranges set in the meter.
ď	Before meal	You may view low or high test results marked with a Before meal comment for Overall, Before breakfast, Before lunch, Before dinner, and Before snack blood glucose results.*
Ť	After meal	You may view low or high test results marked with an After meal comment for Overall, After breakfast, After lunch, After dinner, and After snack blood glucose results.*
0	Fasting	Includes low or high fasting blood glucose results marked as Fasting in comments.
)	Bedtime	Includes low or high bedtime blood glucose results marked as Bedtime in comments.

^{*}Test results for Before and After specific meals are only available if Patterns is set to **On**.





Low/High Data

↓ Low BG Data

† High BG Data

If Target Ranges is on:

Press To select
Low or High BG
Data (the example
here is High BG

Data). Press .

or

Low/High Data No data available. Enable target ranges to track low/high BG data. If Target Ranges has NOT been on within the last 30 days:

This message appears on the

meter (to turn on Target Ranges see the Target Ranges section in the chapter Meter Settings for details).

1 ± High BG Data

② Overall
③ Before meal

↑ After meal
⑤ Fasting

Press to highlight a category (the example here is **Before meal**).



If test results with detailed meal comments are saved in the Logbook:

The meter may prompt you to select detailed categories to view. Press ■ to highlight a category (the example here is before **Breakfast**). Press ■ 3.

The selected data appears (the example here is High BG Data).
Press

to scroll through the test results

Press to return to the previous menu.

NOTE

Analyzing your blood glucose results stored in the meter is an effective way for you and your healthcare professional to determine how well you are controlling your diabetes. This analysis is a valuable tool for making improvements to your diabetes management. Use care when adding comments to blood glucose results. Incorrect comments can cause inaccurate patterns to be detected by the meter if Patterns is On

Patterns

- Patterns displays only active Low Patterns or High Patterns based on comments added to blood glucose results within the last 7 days.
- A Pattern is generated when 2 below-target or 3 above-target test results with the same comment are detected within a 7-day period.

Patterns may be viewed on the meter in 3 ways:



Patterns detected by the meter may be displayed on the Main Menu as:

Patterns	High and low patterns have been detected	Patterns may include the following blood glucose results
High Pattern(s)	One or more high patterns have been detected	marked with comments: Before breakfast, After
Low Pattern(s)	One or more low patterns have been detected	breakfast, Before lunch, After lunch, Before dinner, After
No Patterns	No active pattern based on test results from last 7 days	dinner, Before snack, After snack, Fasting, or Bedtime (see the Adding Comments to Blood Glucose Results section in the chapter Blood Glucose Tests).
Blank	Patterns feature is set to Off	



example here is **Patterns**). Press **2**.





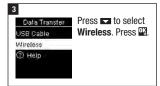


Data Transfer Using Wireless

This feature allows you to transfer data wirelessly from your meter to another device.







If a device has not been paired with your meter:

Pair Device No paired device. Pair now?

The meter prompts you to pair a device to the meter (see the First-Time Pairing section in the chapter Wireless

Communication and Meter Pairing for details).

or

Yes

If the meter has already been paired with at least one device:



Choose Device Press ▼ or ▲ to choose a wireless device for data transfer.



The meter transfers the data to the device.

Data Transfer Using 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.



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

If the meter is off, it turns on.

3

4

Start the diabetes management software and initiate a data transfer.







The meter transfers the data to the software.

Overview

You can wirelessly and automatically synchronize your diabetes information with a mobile device. The process of creating a connection between the meter and the other device is called pairing. You need an application on your mobile device that can accept the meter data.

Setting	Options	Function
Flight Mode	On / Off	Select whether wireless
		communication is available.
		On – wireless communication is not available.
		Off – wireless communication is available.
Default Device	List of devices paired with the meter	If more than 1 device is paired, select the device with which the Auto-Send and Sync Time features will communicate.
Auto-Send	On / Off	Select whether data is automatically sent to the default paired device after each test.
		On – data is automatically sent to the default paired device.
		Off – data is not automatically sent to the default paired device.
Sync Time	On / Off	Select whether to synchronize the time and date to the default paired device.
		On – the time and date on the meter synchronize to the time and date on the default paired device.
		Off – the time and date on the meter do not synchronize to the time and date on the default paired device.
Pairing	Pair Device / Delete Pairing	Select whether to pair a device or to delete a paired device.

6

First-Time Pairing

The steps below are for first-time pairing.

Up to 5 devices can be paired with the meter at any time.

Each device must be paired with the meter one at a time.

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

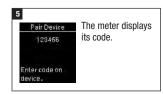
1

Prepare the device for pairing. Refer to the device's instructions for information about pairing.









The mobile device displays a list of found devices, including the meter. Select the meter from the list. When prompted, enter the code displayed on the meter from Step 5 into the device to be paired.



When pairing is complete, \checkmark and the name of the paired device appear.

Press to return

to the previous menu.

Flight Mode

Select whether wireless communication is available or not. When Flight Mode is on, appears in the title bar and wireless communication is not available.









Default Device

If more than 1 device is paired, select the default paired device for the **Auto-Send** and **Sync Time** features.









Press

to move

to the option.

Press

to set the option and return to the previous menu.

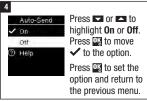
Auto-Send

Select whether data is automatically sent to the default paired device after each test.









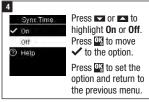
Sync Time

Select whether to synchronize the time and date to the default paired device.









Pairing Additional Devices

This procedure is to add another paired device (assumes there is already 1 paired device).

You can pair 5 devices.

If you have 5 paired devices, you must delete a pairing before you can add another device.

The device you choose remains the default until you change it.

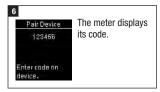








Prepare the other device for pairing. Refer to the other device's instructions for information about pairing.

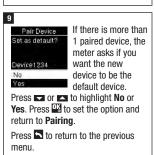


7

The mobile device displays a list of found devices, including the meter. Select the meter from the list. When prompted, enter the code displayed on the meter from Step 6 into the device to be paired.



When pairing is complete, ✓ and the name of the paired device appear. Press ...



Delete Pairing

This procedure is to delete a paired device (assumes there is at least 1 paired device).

You can pair 5 devices. If you have 5 paired devices, you must delete a pairing before you pair to another device.

The device you choose remains the default until you change it.



Turn the meter on by briefly pressing

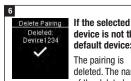
☐ From Main
Menu, press
to highlight Settings.
Press
☐ Press ☐ Fress ☐ Fr







(2) Help



device is not the default device:

The pairing is deleted. The name of the deleted

device and \checkmark appear.



Delete Pairing If the selected device is the default device:

> The meter prompts you to select a new default device. If

there is only 1 device remaining, it becomes the default device. The list of paired devices appears.



Highlight the new default device and press OK. The name of the deleted device and < appear, along with the new default device.

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 of this chapter.

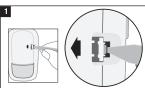
If you drop the meter or think the results are not accurate, contact Accu-Chek Customer Care at 1-800-363-7949.

⚠ 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



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.





Release the old batteries by pressing the button. Remove the old button. Semove the old between button and hold the Power/Set/OK button on the front of the meter for at least 2 seconds.





Slide the new batteries under the black tabs and the button, with the (+) side facing up.
Put the battery door

back in place and snap it closed.
Immediately discard the old
hatteries

NOTE

- Always have a spare set of hatteries
- 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.
- The logbook data is saved when you replace the batteries.

Meter Cleaning and Disinfecting

What is the difference between cleaning and disinfecting?

Cleaning is the removal of dirt from the meter.

Disinfecting is the removal of most, but not all, disease-causing and other types of microorganisms (bloodborne pathogens) from the meter.

Approved Cleaning and Disinfecting Product

The following active ingredients have been approved for cleaning and disinfecting the meter:

 A mixture of alkyl dimethyl ethylbenzyl ammonium chloride (0.125 %), benzalkonium chloride (0.125 %), and isopropyl alcohol (14.85 %).

We recommend Sani-Cloth Plus Germicidal Disposable Cloths. This product contains the approved active ingredients and is licensed for use in Canada.

Roche has tested the approved product for a total of 520 cleaning and disinfecting cycles (260 cleaning and 260 disinfection cycles), which is equal to cleaning and disinfecting once per week for a 5-year period.

For more information see:

 FDA Public Health Notification: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication, (2010). Update 11/29/2010." http://wayback. archive-it.org/7993/20161022010458/ http://www.fda.gov/MedicalDevices/ Safety/AlertsandNotices/ucm224025. htm.

Accessed January 17, 2018.

 CDC website on "Infection Prevention during Blood Glucose Monitoring and Insulin Administration". http://www. cdc.gov/injectionsafety/bloodglucose-monitoring.html Accessed November 09, 2015.

NOTE

- Always wash hands thoroughly with soap and water before handling the meter, lancing device, or test strips.
- For technical assistance or questions on cleaning and disinfecting, contact Accu-Chek Customer Care at 1-800-363-7949.

Cleaning and Disinfecting the Meter

To clean and disinfect without damaging the meter, follow these procedures carefully.

When to Clean and Disinfect the Meter

- Clean the meter to remove visible dirt or other material prior to disinfecting.
- Clean and disinfect the meter at least once per week and when blood is present on the surface of the meter.
- Clean and disinfect the meter before allowing anyone else to handle the meter. Do not allow anyone else to use the meter on themselves for testing purposes.

What to Clean and Disinfect

The following parts of the meter should be cleaned and disinfected:

- The area around slots and openings (do not get any moisture in slots or openings)
- · The meter display
- · The entire meter surface

How to Clean and Disinfect the Meter

♠ WARNING

Failure to follow these instructions will damage the meter and stop it from working properly.

- DO NOT clean or disinfect the meter while performing a blood alucose or control test.
- D0 N0T get any moisture in slots or openings.
- DO NOT spray anything onto the meter.
- DO NOT immerse the meter in liquid.
- Always use the same product for both cleaning and disinfecting.







Wash hands thoroughly with soap and water.



Turn the meter off and wipe the entire meter surface with a Sani-Cloth Plus. Carefully wipe around the test

strip slot and other openings.

Make sure that no liquid enters any slot or opening.



A separate Sani-Cloth Plus should be used for cleaning and disinfection. For disinfecting the meter, get a new cloth and repeat step 2, making sure the surface stays wet for 3 minutes.

Make sure that no solution is seen in any slot or opening.





Wash hands thoroughly with soap and water.

Error Messages



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 Accu-Chek Customer Care at 1-800-363-7949.



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

· Batteries are dead.

Insert new batteries.

 Display is damaged. / Meter is defective.

Contact Accu-Chek Customer Care at 1-800-363-7949.

• Extreme temperatures.

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



The meter is connected to a PC and a test cannot be performed.

EITHER remove the USB cable and perform a test OR remove the test strip and start a data transfer.



The connection between the meter and PC was lost.

Disconnect and reconnect the USB cable and retry the connection.

Contact Accu-Chek Customer Care at 1-800-363-7949 if the connection is lost again.



There is no connection between the meter and PC.

Connect the USB cable and retry the connection.



Blood glucose results were not transferred to a paired device.

Make sure the paired device is within range of the meter and turned on.



Data could not be transferred from the meter to the PC. Check the PC or USB cable.



Data cannot be sent to a paired device because the meter is in Flight Mode

Retry the data transfer when the meter is not in Flight Mode.



One or more blood glucose results are excluded from the selected averages because the results are invalid or outside the system measuring range.



One or more blood glucose results are excluded from the selected target % data because the test results are invalid.



One or more blood glucose results are excluded from the selected low/ high data because the test results are invalid



The date entered is not valid. Enter the correct date.



A meter setting was changed while in Flight Mode.

The setting change will not take effect until Flight Mode is turned off.



Pairing to a device cannot be performed while in Flight Mode. Retry pairing when the meter is not in Flight Mode.



The blood glucose result has not been sent to the default paired device. The transfer is still pending. Place meter and paired device closer together.



The meter was unable to pair with a device.

Retry the pairing.



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.



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.



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.



Blood or control solution was applied to the test strip before **Apply drop** appeared.

Discard the test strip and repeat the blood glucose or control test.



An electronic error occurred.

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



The temperature is above or below the proper range for the system.

Refer to the test strip package insert for system operating conditions.

Move to an area with the appropriate conditions and repeat the blood glucose or control test. Do not artificially heat or cool the meter.



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/OK button for at least 2 seconds, then reinsert the batteries



The time and date setting may be incorrect.

Make sure the time and date are correct and adjust, if necessary.



The test strip may be damaged. Retest with a new test strip.



Your blood sample may contain a high level of ascorbate.

Contact your healthcare professional.



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 problem persists, contact Accu-Chek Customer Care at 1-800-363-7949.



An electronic error has occurred. Contact Accu-Chek Customer Care at 1-800-363-7949.



The meter time and date have been changed to match the paired device.



There are no results in the Logbook.



There is an invalid result in the Logbook.





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



Target Ranges is **Off** and there are no results for the Target % data stored in the meter.



Target Ranges is **Off** and there are no results for the low/high data stored in the meter.





There are no results stored in the meter for the selected data.



Patterns is **On** but there are no active patterns stored in the meter.





Patterns is Off.



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/OK button for at least 2 seconds, then reinsert the batteries.

8 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 32 control results with time and date
Automatic off	90 seconds
Power supply	Two 3-volt lithium batteries (coin cell type CR2032)
Display	LCD
Dimensions	80 × 47 × 20 mm (LWH)
Weight	Approx. 48 g (with batteries)
Construction	Hand-held
Protection class	III
Meter type	The Accu-Chek Guide meter is suitable for continuous operation.
Control solution storage conditions	Refer to the control solution package insert.
Interfaces	USB: micro-B connector; Bluetooth® low
200	energy technology; Continua Certified® to a
Continua	Continua Certified manager.
Radio frequency connectivity	Bluetooth low energy technology operating in the frequency band of 2.402 GHz to 2.480 GHz with a maximum transmitted power of 0 dBm (1 mW).

Bluetooth Wireless Technology

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

Industry Canada ICES-003 Compliance Label:

CAN ICES-3 (B)/NMB-3(B)

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 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 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 2014 Continua Design Guidelines which include the Blood Glucose specification for Bluetooth, Bluetooth SIG, Glucose Profile, Version 1.0 and Bluetooth SIG, Glucose Service, Version 1.0.

Product Safety Information

♠ WARNING

- 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

-

Risk of infection

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

Before discarding the meter, remove the battery or batteries.

Discard used meters according to the regulations applicable in your country. Contact the local council and authority for information about correct disposal.

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

Discard used batteries according to local environmental regulations.

This product includes internal constituents containing a Substance of Very High Concern (SVHC), 1,2-Dimethoxyethane (CAS 110-71-4), Hexabromocyclododecane (CAS 25637-99-4), Lead Titanium Trioxide (CAS 12060-00-3) and/or Lead Titanium Zirconium Oxide (CAS 12626-81-2), in a concentration above 0.1 % weight by weight, as identified under REACH 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.

8 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 meter.

Caution, refer to safety-related notes in the instructions for use accompanying this product. 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
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
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Biological risks – used meters carry a risk of infection. Date of manufacture
Date of manufacture
IVD In vitro diagnostic medical device
Device for self-testing
Device for near-patient testing
Manufacturer
Unique device identifier
GTIN Global Trade Item Number
REF Catalogue number
SN Serial number
LOT Batch code
Complies with the provisions of the applicable EU Legislation

8 Technical Information

Additional Supplies

Test Strips: Accu-Chek Guide test strips Control Solutions: Accu-Chek Guide control solutions

9 Guarantee

Guarantee

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

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Canada

Accu-Chek Customer Care: 1-800-363-7949

www.accu-chek.ca



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





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