ACCU-CHEK® Guide Link

User's Manual

Blood Glucose Meter

For use with compatible MiniMed™ Pump with *Bluetooth*® wireless technology

Medtronic

Roche

Contents

Introduction

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

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

The Accu-Chek Guide Link System

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

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

The Accu-Chek Guide Link blood glucose monitoring system is intended to be used to wirelessly transmit glucose values to a compatible MiniMed™ Pump with *Bluetooth*® wireless technology through the use of Bluetooth low energy communication.

Suitable for self-testing

The system includes: Accu-Chek Guide Link 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 Roche.

⚠ WARNING – KEEP BATTERIES OUT OF REACH OF CHILDREN

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

⚠ WARNING

Risk of infection
Any object coming into contact with human blood is a potential source of infection (see: Clinical and Laboratory Standards Institute: Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Fourth Edition; CLSI document M29-A4, May 2014). Healthcare Professionals: see also the Information for Healthcare Professionals section in the chapter Technical Information.

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

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

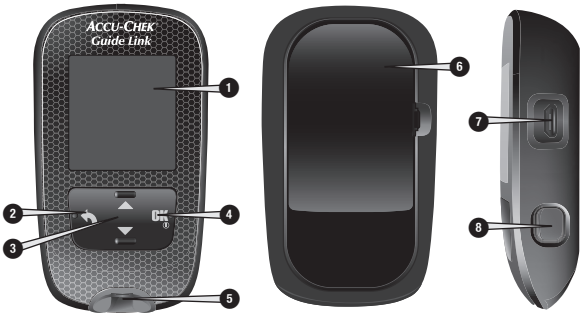
- It is strongly recommended to have a back-up testing method available. Failure to test could cause a delay in therapy decisions and lead to a serious medical condition. Examples of back-up testing methods include a back-up meter and test strips. Ask your healthcare professional or pharmacist about other possible back-up methods.
- The meter may prompt you to choose a language and the time format (12-hour or 24-hour clock) the first time you turn it on.
- Before you begin testing, turn the meter on by briefly pressing OK so the meter can synchronise its time and date with the paired pump.
- 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.

1 Your New Meter

The Accu-Chek Guide Link Meter



Front View Back View Side View

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.

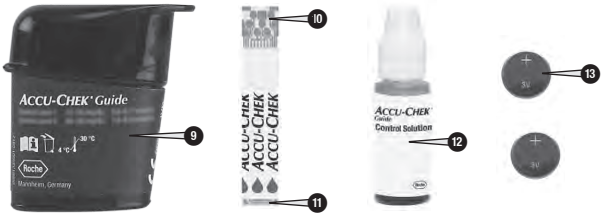
5. **Test Strip Slot with Light**
   Insert test strip here.

6. **Battery Door**
   Flip open to replace batteries.

7. **Micro USB Port**
   USB functionality is not available for this meter.

8. **Test Strip Ejector**
   Press to remove test strip.

1 Your New Meter



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

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

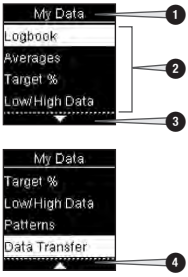
Button Functions

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.

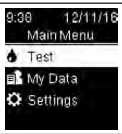
Button	Function
Back Button	Return to the previous screen. Return to the previous field.
Up Arrow and Down Arrow Buttons	Navigate up and down in a menu. Increase or decrease a number.
Power/Set/OK Button	Press briefly to turn the meter on. Press and **hold** to turn the meter off. Press to select an 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. 

1 Your New Meter

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.
	There are more menu options listed above and below the options. Press ▼ or ▲ on the meter to view the options.
	Highlighted option (**Test**) Press OK to enter the **Test** menu.
	Highlighted field (**HH**=Hour) Press ▼ or ▲ to increase or decrease the hour. Press OK to set the hour and move to the minutes field.

1 Your New Meter

Symbols

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

Symbol	Description
	Above target range
	After meal
	Bedtime
	Before meal
	Below target range
	Blood glucose test
	Checkmark / Control test OK / Selected option or setting
	Control bottle
	Control test not OK
	Edit
	Error
	Fasting
	Flight mode
	Help
	Low battery
	My data
	No comment
	Other

Symbol	Description
	Overall
	Settings
	Test reminder
	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.

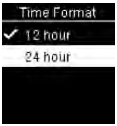
1

Turn the meter on by briefly pressing OK. **Language** appears.

2

Press ▼ or ▲ to highlight the language. Press OK to set the desired language and return to **Main Menu**.

3



If the meter prompts you to set the time format:

Time Format appears. Press ▼ or ▲ to highlight **12 hour** (am/pm) or **24 hour**.

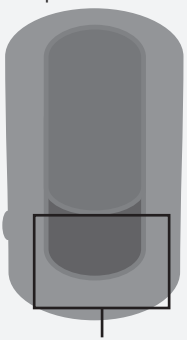
Press OK to set the option and return to **Main Menu**.

NOTE

If you select the wrong language and cannot correct it, contact Roche.

⚠ WARNING

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



mg/dL or mmol/L is printed here

Using the Accu-Chek Guide Link 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 OK. Select **Test** > OK.

1

Wash your hands with warm soapy water and dry thoroughly.

Prepare the lancing device.

2

Check the use by date on the test strip container.

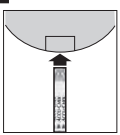
Do not use test strips past the use by date.

3

Remove a test strip from the test strip container.

Close the cap tightly.

4



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

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

5

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

8

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

9

The test result appears on the display.

Note: Press ↩ to automatically send the test result to a paired pump. If ↩ is not pressed, there will be a delay seeing the blood glucose result on the paired pump.

You have the option of adding a comment to the test result by pressing OK OR proceed to Step 12 to complete the test.

10

Add Comment appears. Press ▼ to highlight a comment. Press OK to set the comment for the test result and send the blood glucose result to the paired pump. See the Adding Comments to Blood Glucose Results section of this chapter for details.

11

The final result appears. Press OK or ↩ to set the comment and return to **Main Menu**. Or to change the comment, press ▼ to select the comment.

Press OK 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.

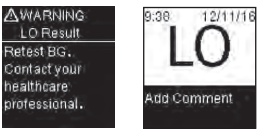
12

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 OK 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

Analysing 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 analyse patterns detected by the meter (see the Patterns section in the chapter Meter Settings for details).
- If Patterns is set to **On**, 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.

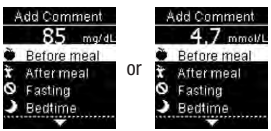
Symbol	Name	Description
	Before meal	If Patterns is **On**, select Before breakfast, lunch, dinner, or snack (see the following page for adding comments with Patterns **On**).
	After meal	If Patterns is **On**, select After breakfast, lunch, dinner, or snack (see the following page for adding comments with Patterns **On**).
	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 Alternative Site Testing (AST) result or exercise.
	No entry	1. You do not want to add a comment. 2. You want to remove a comment for the current blood glucose result.

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

1

After performing a blood glucose test, the test result is displayed on the screen with **Add Comment** highlighted. Press OK to add a comment.

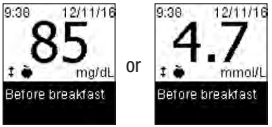
2



The **Add Comment** menu appears. Press ▼ to highlight the desired comment (the example here is **Before meal**). Press OK to select the comment.

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 OK to set the selected meal for the test result.

3



The final result appears with the comment symbol. When automatically sending test results to a paired pump, press OK or ↩ to set the comment, send the test result, and return to **Main Menu**.

To change the comment, press ▼ to select the comment.

Press OK to return to **Add Comment**.

⚠ PRECAUTION

When using a test result for calibrating a continuous glucose monitoring system or to make insulin dosing calculations, confirm that the test result displayed on the pump matches the test result displayed on the meter.

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

⚠ WARNING

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

- Do not use alternative site testing (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 and palm can be used at any time to perform a blood glucose test.

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

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

You may perform a forearm or upper arm test	• immediately before a meal. • while fasting.
You may NOT perform a forearm or upper arm test	• up to 2 hours following a meal, when blood glucose values can rise quickly. • after injecting bolus insulin, when blood glucose values can decrease rapidly. • after exercise. • if you are sick. • if you think your blood glucose is low (hypoglycaemia). • if you sometimes do not notice when your blood glucose is low.

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

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

Unusual Blood Glucose Results

⚠ PRECAUTION

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

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

Symptoms of Low or High Blood Glucose

⚠ WARNING

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

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

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

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

Disease Effects and Prevalence

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

3 Control Tests

When to Perform a Control Test

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

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

About the Control Solutions

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

Performing a Control Test

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

1

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

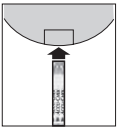
2

Remove a test strip from the test strip container.

Close the cap tightly.

3 Control Tests

3



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.

4

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

5

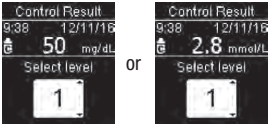
Remove the bottle cap. Wipe the tip of the bottle with a tissue. Squeeze the bottle until a tiny drop forms at the tip.

6

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

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

7



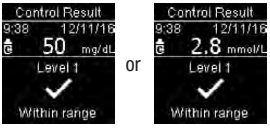
Control Result and the control bottle symbol appear. Press ▼ or ▲ to select the control level you tested. If you do not select a level, the control result is saved without a control level. Press OK.

NOTE

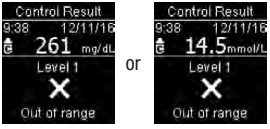
When performing a **control test**: If the **Control Result** screen DOES NOT appear, an error has occurred.

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

8



Within range and ✓ appear if the control result is within range.



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

9

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

Remove and discard the used test strip.

⚠ PRECAUTION

Control results are not transmitted to the pump.

- Do not calibrate your continuous glucose monitoring device from a control result.
- Do not calculate a bolus based on a control result.

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.

3 Control Tests

Understanding Out-of-Range Control Results

⚠ WARNING

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

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

Troubleshooting Checks	Action
Were the test strips or control solutions expired?	Discard the test strips or control solution if either is past the use by date. If the control solution was opened more than 3 months ago, discard it. Repeat the control test with an unexpired test strip and an unexpired control solution.
Did you wipe the tip of the control solution bottle before use?	Wipe the tip of the bottle with a tissue. Repeat the control test with a new test strip and a fresh drop of control solution.
Were the caps on the test strip container and the control solution bottle always closed tightly?	Replace the test strips or control solution if you think either was uncapped for some time. Repeat the control test.
Was the test strip used immediately after it was removed from the test strip container?	Repeat the control test with a new test strip and a fresh drop of control solution.
Were the test strips and control solutions stored in a cool, dry place?	Repeat the control test with a properly stored test strip or control solution.
Did you follow the directions?	Read the chapter Control Tests and repeat the control test.
Did you choose the correct control solution level, either 1 or 2, when you performed the control test?	If you chose the wrong control solution level, you can still compare the control result to the range printed on the test strip container.
Are you still unsure of the problem?	Contact Roche.

4 Meter Settings

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. **NOTE** Feature is only available if the meter is not paired with a pump. If paired with a pump, the meter time and date are automatically set to the pump's time and date during communication.
Beeper	On / Off	Select On or Off.
Wireless	Select wireless communication settings. See the chapter Wireless Communication and Meter Pairing.	
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).
	70–180 mg/dL (pre-set target range) 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.

4 Meter Settings

Setting	Options	Function
Target Ranges	Before Meal Range 70–110 mg/dL (pre-set target range) 3.9–6.1 mmol/L (pre-set target range) After Meal Range 70–180 mg/dL (pre-set target 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.
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.

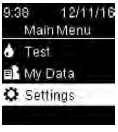
4 Meter Settings

Time/Date

NOTE

Feature is only available if the meter is not paired with a pump. If paired with a pump, the meter time and date are automatically set to the pump's time and date during communication.

1



Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight **Settings**. Press OK.

2

Time/Date is highlighted. Press OK.

3

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

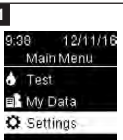
Press OK to save and return to the previous menu.

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).

1



Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight **Settings**. Press OK.

2

Press ▼ to highlight **Beeper**. Press OK.

3

Press ▼ or ▲ to highlight **On** or **Off**. Press OK to move ✓ to the option.

Press OK to set the option and return to the previous menu.

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 60–100 mg/dL (3.3–5.5 mmol/L) to an upper limit of 101–300 mg/dL (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 Range	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).

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

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

NOTE

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

4 Meter Settings

1

Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight **Settings**. Press OK.

2

Press ▼ to highlight **More Options**. Press OK.

3

Target Ranges is highlighted. Press OK.

4

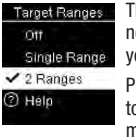
Press ▼ or ▲ to highlight **Off**, **Single Range**, or **2 Ranges**. Press OK to select an option (the example here is **2 Ranges**).

5

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

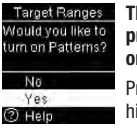
Continue to set the upper limit for the **Before Meal** target range and the lower and upper limits for the **After Meal** target range. Press OK.

6



The ✓ appears next to the option you selected.

Press ↩ to return to the previous menu.



The meter may prompt you to turn on Patterns.

Press ▼ or ▲ to highlight **Yes** or **No**.

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

NOTE

Analysing 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.

1

Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight **Settings**. Press OK.

2

Press ▼ to highlight **More Options**. Press OK.

3

Press ▼ to highlight **Patterns**. Press OK.

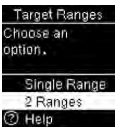
4

Press ▼ to highlight **On**. Press OK to move ✓ to the option. Press OK.

This message appears if Target Ranges is Off:

Press ▼ to highlight **Yes**. Press OK.

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



Target Ranges appears on the display (see the Target Ranges section of this chapter for details on setting target ranges).

NOTE

When automatically sending blood glucose results to a paired pump, select the **View later** option to send the test result without delay.

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 glucose results that make up that pattern.

or

Press OK to highlight **View later**.

Press OK 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 ⚠ is displayed for Reminders set in the meter.

Reminders:

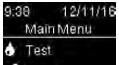
- turn off by inserting a test strip or pressing any button.
- are postponed until the next test reminder if a test was performed within 15 minutes of a test reminder.
- do not appear/beep if the meter is on at the test reminder time.
- do not appear/beep if the meter is connected and communicating to the paired pump.
- 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, 12:00, 18:00, and 22:00. 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).

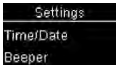
4 Meter Settings

1



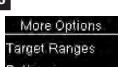
Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight **Settings**. Press OK.

2



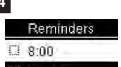
Press ▼ to highlight **More Options**. Press OK.

3



Press ▼ or ▲ to highlight **Reminders**. Press OK.

4



Pre-set reminder times appear on the display. Press ▼ to highlight a reminder time. Press OK.

5

The pre-set reminder time appears. Press ▼ or ▲ to select **On** or **Off**. Press OK to move ✓ to the option.

To change the Reminder time shown:

Press ▼ to highlight **Edit time**. Press OK.

Press ▼ or ▲ to adjust each field. Press OK to move to the next field. Press OK to return to the previous menu.

6

A ✓ indicates the reminder is set for the time shown and automatically set to **On**. To turn the reminder off, press ▼ to highlight **Off**.

Press OK to return to **Reminders**.

7

The reminder time appears.

Press ▼ to continue to set additional reminders or press ↩ to return to **More Options**.

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 ♤ is displayed.

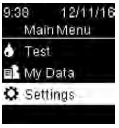
Post Meal reminders:

- 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.
- do not appear/beep if the meter is connected and communicating to the paired pump.
- 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.

1

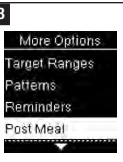


Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight **Settings**. Press OK.

2

Press ▼ to highlight **More Options**. Press OK.

3



Press ▼ to highlight **Post Meal**. Press OK.

4

Press ▼ or ▲ to highlight **On**. Press OK to move ✓ to the option.

5

Press ▼ to highlight **Edit time**. Press OK.

6

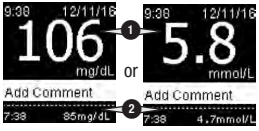
Press ▼ or ▲ to highlight **1 hour**, **1.5 hours**, or **2 hours** after a meal for **Post Meal** reminders to occur.

Press OK to move ✓ to the option.

Press OK to set and return to the previous menu.

Last Result

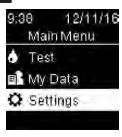
Select whether the previous blood glucose result appears with the current blood glucose result. **Test results older than 24 hours do not appear.**



Off – only the current blood glucose result ❶ appears.

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

1



Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight **Settings**. Press OK.

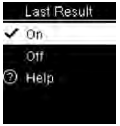
2

Press ▼ to highlight **More Options**. Press OK.

3

Press ▼ to highlight **Last Result**. Press OK.

4



Press ▼ or ▲ to highlight **On** or **Off**. Press OK to move ✓ to the option.

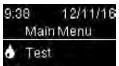
Press OK to set the option and return to the previous menu.

4 Meter Settings

Language

Choose the language that appears on the meter.

1



Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight **Settings**. Press OK.

2

Press ▼ to highlight **More Options**. Press OK.

3

Press ▼ to highlight **Language**. Press OK.

4

Press ▼ or ▲ to highlight the desired language. Press OK to move ✓ to the option.

Press OK to set the language and return to the previous menu.

Time Format

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

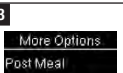
1

Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight **Settings**. Press OK.

2

Press ▼ to highlight **More Options**. Press OK.

3



Press ▼ to highlight **Time Format**. Press OK.

4

Press ▼ or ▲ to highlight **12 hour** (am/pm) or **24 hour**. Press OK to move ✓ to the option.

Press OK to set the time format and return to the previous menu.

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 not included in the averages or blood glucose reports.

⚠ WARNING

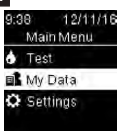
Risk of a serious health incident
Using an individual test result in memory to change your therapy can lead to improper therapy adjustments. Do not change your therapy based on an individual test result in memory. Talk to your healthcare professional before changing therapy based on test results in memory.

NOTE

The meter has time and date auto-sync capability when paired with a pump 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

1

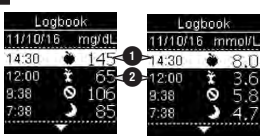


Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight **My Data**. Press OK.

2

Logbook is highlighted. Press OK.

3



Press ▼ or ▲ to scroll through **Logbook**.

The most recent test result ❶.

The 2nd most recent test result ❷.

5 Review Your Data

4

To view details about a test result, press ▼ or ▲ to highlight the test result. Press OK. 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

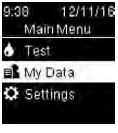
or

The 2nd most recent test result

or

Averages

1



Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight **My Data**. Press OK.

2

Press ▼ to highlight **Averages**. Press OK.

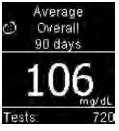
3

Press ▼ to highlight a category (the example here is **Overall**). Press OK.

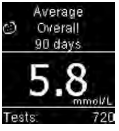
4

Press ▼ to highlight a time period (the example here is **90 days**). Press OK.

5



or



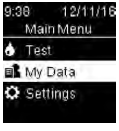
Press ↩ to return to the previous menu if you want to review a different time period OR press ▼ or ▲ to move through different averages.

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.

1



Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight **My Data**. Press OK.

2

Press ▼ to highlight **Target %**. Press OK.

3

Press ▼ to highlight a category (the example here is **Before meal**). Press OK to select the option.

4

Press ▼ to highlight a time period (the example here is **90 days**). Press OK.

5

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

Analysing 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.

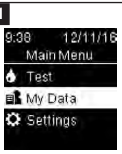
You can select Low BG and High BG test results for Overall, Before meal, After meal, Fasting, or Bedtime blood glucose results.

Symbol	Name	Description
	Overall	Includes low and high blood glucose results based on Target Ranges set in the meter.
	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.*
	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.*
	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**.

5 Review Your Data

1

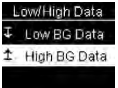


Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight **My Data**. Press OK.

2

Press ▼ to highlight **Low/High Data**. Press OK.

3



If Target Ranges is on:

Press ▼ to select **Low** or **High BG Data** (the example here is **High BG Data**). Press OK.

or

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).

4

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

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 OK.

5

or

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

Analysing 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**.

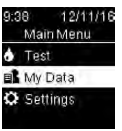
Patterns

- 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:

when a Patterns option is displayed at the bottom of **Main Menu**.

or



from **My Data** on **Main Menu**.

or

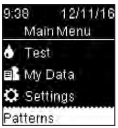
if a **New pattern detected** message appears on the display when performing a blood glucose test.

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

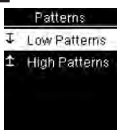
5 Review Your Data

1



Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight the Patterns option at the bottom of the screen (the example here is **Patterns**). Press OK.

2

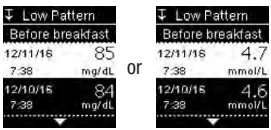


Press ▼ or ▲ to highlight **Low Patterns** or **High Patterns** (the example here is **Low Patterns**). Press OK to select the option.

3

Press ▼ to highlight a category to review (the example here is **Before breakfast**). Press OK.

4



Press ▼ to scroll through test results. Press ↩ to return to the previous menu.

6 Wireless Communication and Meter Pairing

Overview

You can wirelessly and automatically synchronise your diabetes information with a compatible MiniMed™ Pump with *Bluetooth*® wireless technology. The process of creating a connection between the meter and the pump is called pairing.

Setting	Options	Function
Flight Mode	On / Off	Select whether wireless communication is available. On – wireless communication is not available. Off – wireless communication is available.
Auto-Send	On / Off	Select whether data is automatically sent to the paired pump after each test. On – data is automatically sent to the pump. Off – data is not automatically sent to the pump.
Pairing	Pair to Pump / Delete Pairing	Select whether to pair a pump or to delete the paired pump.

Pairing

The meter can automatically send blood glucose results to a compatible MiniMed™ Pump with *Bluetooth*® wireless technology. This feature eliminates the need to manually enter your blood glucose result on the pump. Before the meter can send blood glucose results to a pump, the meter and pump must be paired. Refer to the MiniMed™ System User Guide for pairing instructions.

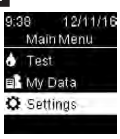
Once the meter and pump are paired, the pairing settings are stored in both devices so that you do not have to repeat the pairing. If communication between the meter and pump is stopped or interrupted for any reason, they will automatically resume communication when both devices are in communication range.

The meter can only be paired with a compatible MiniMed™ Pump. The meter can only be paired with 1 pump at a time. It is not necessary to delete the existing pairing when pairing with a new pump. Any blood glucose results stored on the meter prior to pairing cannot be transferred from the meter to the pump.

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.

1

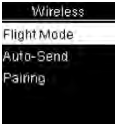


Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight **Settings**. Press OK.

2

Press ▼ to highlight **Wireless**. Press OK.

3

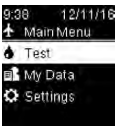


Flight Mode is highlighted. Press OK.

4

Press ▼ or ▲ to highlight **On** or **Off**. Press OK to move ✓ to the option.

Press OK to set the option and return to the previous menu.

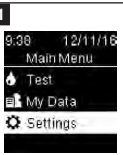


Main Menu with meter in Flight Mode.

Auto-Send

Select whether blood glucose results are automatically sent to the paired pump after each test. Test results sent using Auto-Send can be used by the pump system to calibrate a continuous glucose monitoring system or make insulin dosing calculations.

1

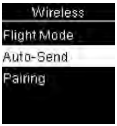


Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight **Settings**. Press OK.

2

Press ▼ to highlight **Wireless**. Press OK.

3



Press ▼ to highlight **Auto-Send**. Press OK.

4

Press ▼ or ▲ to highlight **On** or **Off**. Press OK to move ✓ to the option.

Press OK to set the option and return to the previous menu.

⚠ WARNING

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

- Do not use alternative site testing (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).

Data Transfer

This feature allows you to transfer data wirelessly from your meter to a paired pump. This feature can be used after the meter and paired pump have not been communicating for a period of time, such as when Flight Mode has been enabled or Auto-Send has been disabled. In this case, there may be blood glucose results that have not been sent to the pump.

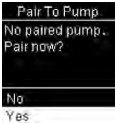
Test results sent using Data Transfer cannot be used by the pump system to calibrate a continuous glucose monitoring system or to make insulin dosing calculations.

1

Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight **My Data**. Press OK.

2

Press ▼ to highlight **Data Transfer**. Press OK.



If a pump is not paired with your meter:

The meter prompts you to pair a pump to the meter (see the Pairing section in the chapter Wireless Communication and Meter Pairing for details).

3

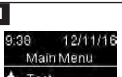
The meter transfers the data to the pump.

Delete Pairing

This procedure is to delete the pairing on the meter, which ends communication between the meter and the pump. For instructions on deleting the pairing information on the pump, refer to the MiniMed™ System User Guide.

The meter can only be paired with 1 pump at a time. It is not necessary to delete the existing pairing when pairing with a new pump.

1

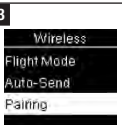


Turn the meter on by briefly pressing OK. From **Main Menu**, press ▼ to highlight **Settings**. Press OK.

2

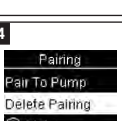
Press ▼ to highlight **Wireless**. Press OK.

3



Press ▼ to highlight **Pairing**. Press OK.

4



Press ▼ or ▲ to highlight **Delete Pairing**. Press OK.

5

Press OK to confirm.

The meter shows the deleted pairing.

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.

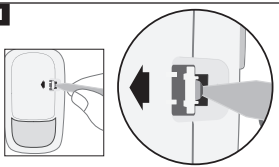
If you drop the meter or think the results are not accurate, contact Roche.

⚠ WARNING

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

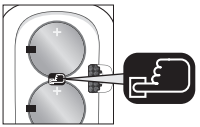
Changing the Batteries

1



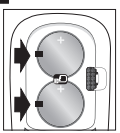
Open the child-resistant battery door by inserting a narrow object, such as a pen, into the slot (see image above). Push the tab in the direction of the arrow and lift the battery door up.

2



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

3



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 batteries.

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.
- The logbook data is saved 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.

⚠ WARNING

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

⚠ WARNING

Risk of a serious health incident

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

When to clean or disinfect the meter:

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

What to clean or disinfect:

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

1

Make sure the meter is turned off.

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

To clean the meter

Mild dishwashing liquid mixed with water

To disinfect the meter

70 % isopropyl alcohol

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

2

Dry the meter thoroughly with a soft cloth.

Error Messages

⚠ WARNING

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

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

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

- Batteries are dead.

Insert new batteries.

- Display is damaged. / Meter is defective.

Contact Roche.

- Extreme temperatures.

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

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

Remove the USB cable and perform a test.

Blood glucose results were not transferred to the paired pump.

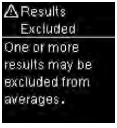
Make sure the paired pump is within range of the meter.

Data cannot be sent to the paired pump because the meter is in Flight Mode.

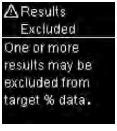
Retry the data transfer when the meter is not in Flight Mode.

USB functionality is not available for this meter.

Remove the USB cable.



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.

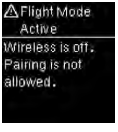
One or more blood glucose results are excluded from the selected low/high data because the test results are invalid.

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 pump cannot be performed while in Flight Mode.

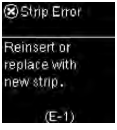
Retry pairing when the meter is not in Flight Mode.

The blood glucose test result has not been sent to the pump.

Manually enter the test result on the pump. For instructions, refer to the MiniMed™ System User Guide.

The meter was unable to pair with a pump.

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.

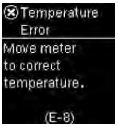
Discard the test strip and repeat the blood glucose or control test.

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.

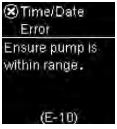
Refer to the test strip package insert for system operating conditions. Move to an area with the appropriate conditions and repeat the blood glucose or control test. Do not artificially heat or cool the meter.

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 time and date setting may be incorrect.

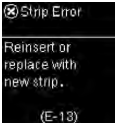
Make sure the pump is in communication range of the meter to update the time and date.

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 Roche.

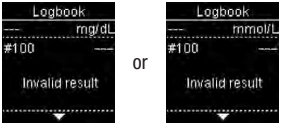
An electronic error has occurred.

Contact Roche.

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

When paired to a pump, the meter time and date cannot be changed using the meter.

There are no results in the Logbook.

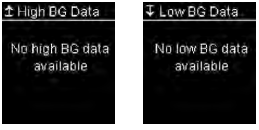


There is an invalid result in the Logbook.

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 Sample type Measuring time Measuring range Test strip storage conditions System operating conditions	Refer to the test strip package insert.
Meter storage conditions	Temperature: -25–70 °C
Memory capacity	720 blood glucose results and 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 Link meter is suitable for continuous operation.
Control solution storage conditions	Refer to the control solution package insert.
Interfaces	*Bluetooth*® low energy technology; USB: micro-B connector (functionality not available)
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).

Electromagnetic Compatibility – The meter meets the electromagnetic emission requirements as per EN 61326-2-6 / EN 60601-1-2. 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 Link 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 Link blood glucose meter has been tested and certified against the Bluetooth Core Specification.

Product Safety Information

NOTE

- 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.

⚠ WARNING

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

Before discarding the meter, remove the battery or batteries.

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

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

Discard used batteries according to local environmental regulations.

This product includes 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.

8 Technical Information

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

Explanation of Symbols

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

	Consult instructions for use or consult electronic instructions for use
	Caution, refer to safety-related notes in the instructions for use accompanying this product.
	The compliance mark indicates that the product complies with the applicable standard and establishes a traceable link between the equipment and the manufacturer, importer or their agent responsible for compliance and for placing it on the Australian and New Zealand market.
	Temperature limit
	Use by
	Keep new and used batteries away from children.
	3-volt coin cell type CR2032
	Biological risks – used meters carry a risk of infection.
	Date of manufacture
	In vitro diagnostic medical device
	Device for self-testing
	Device for near-patient testing
	Manufacturer

8 Technical Information

UDI	Unique device identifier
GTIN	Global Trade Item Number
REF	Catalogue number
SN	Serial number
LOT	Batch code
CE	Complies with the provisions of the applicable EU Legislation

Additional Supplies

Test Strips: Accu-Chek Guide test strips

Control Solutions: Accu-Chek Guide control solutions

Information for Healthcare Professionals

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

⚠ WARNING

Risk of infection
Any object coming into contact with human blood is a potential source of infection. Healthcare professionals should follow the infection control procedures appropriate for your facility. Refer to the test strip package insert for additional healthcare professional information.

Sample Handling

Always wear gloves when handling blood-contaminated items. Always adhere to the recognised procedures for handling objects that are potentially contaminated with human material. Follow the hygiene and safety policy of your laboratory or institution. Prepare the selected blood collection site per facility policy.

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

Recommending Alternative Site Testing to Patients

Decisions about whether to recommend Alternative Site Testing (AST) should take into account the motivation and knowledge level of the patient and his or her ability to understand the considerations relative to diabetes and AST. If you are considering recommending AST for your patients, you need to understand that there is a potential for a significant difference between fingertip or palm test results and test results obtained from the forearm or upper arm. The difference in capillary bed concentration and blood perfusion throughout the body can lead to sample site-to-site differences in blood glucose results. These physiological effects vary between individuals and can vary within a single individual based upon his or her behaviour and relative physical condition.

Our studies involving alternative site testing of adults with diabetes show that most persons will find their glucose level changes more quickly in blood from the fingertip or palm than in blood from the forearm or upper arm. This is especially important when blood glucose levels are falling or rising rapidly. If your patient is used to making therapy decisions based upon fingertip or palm test results, he or she should consider the delay, or lag time, affecting the test results obtained with blood from the forearm or upper arm.

9 Guarantee

Guarantee

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

Index

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

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

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

Hong Kong
Enquiry hotline: +852-2485 7512
(office hours)
www.accu-chek.com.hk

L Y R A ehf.
Hádegismóar 4
110 Reykjavík
Ísland
www.lyra.is

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

Israel
Customer Support:
Tel. 04-6175390
www.dyndiabetes.co.il
patient.care@dyn.co.il

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

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

Roche Diabetes Care South Africa (Pty) Ltd.
Hertford Office Park, 90 Bekker Road
Vorna Valley, 1686
South Africa
Tel: +27 (11) 504 4600
Email: info@accu-chek.co.za
www.rochediabetescaremea.com

LAST UPDATE: 2021-07

HIDF16000080

Complies with
IDA Standards
N4511-17

TA-2017/2714
APPROVED

NTC
Type Approved
ESD-1816643C

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

IVD CE 0123

08159912061A-1121