glucoCheck KEY

Version 1.0 2025/06
311-4231300-034

BLOOD GLUCOSE MONITORING SYSTEM

Operation Instructions

Dear glucoCheck KEY Blood Glucose Monitoring System Owner:

Thank you for purchasing the **glucoCheck KEY** Blood Glucose Monitoring System. This manual provides important information to help you use the system.

Please read the owner's manual thoroughly before using this product. If you have any additional questions regarding this product, please contact the place of purchase or Homemed (Pty) Ltd customer service on 0861 106 150.

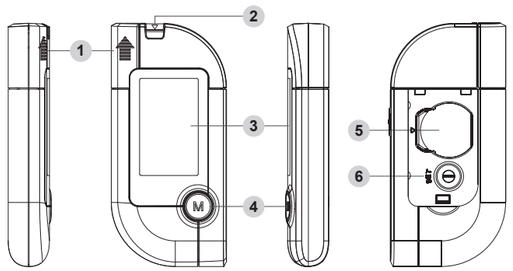
Intended Use

This system is intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home and by healthcare professionals in clinical settings as an aid in monitoring the effectiveness of diabetes control. It is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples (from the finger, palm, forearm or upper arm).

This system provides you with plasma equivalent results.

METER OVERVIEW

The standard kit of this system includes:



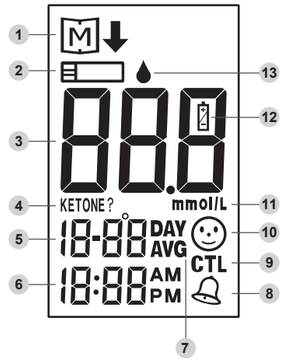
1. Test Strip Ejector
Eject the used strip by sliding this button up.
2. Test Strip Slot
Insert test strip here to switch the meter on for testing.
3. Display Screen
4. MAIN Button (M)
Enter the meter memory and silence a reminder alarm.
5. Battery Compartment
6. SET Button (S)
Enter and confirm the meter settings.

NOTE

The meter will switch off automatically after 3 minutes if not in use. Alternatively hold **M** for 3 seconds to switch the meter off.

METER DISPLAY

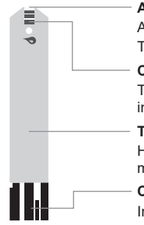
1. Memory Mode
2. Test Strip Symbol
3. Test Result
4. Ketone Warning
5. Date
6. Time
7. Day Average
8. Alarm Symbol
9. Control Solution Mode
CTL-control solution test
10. Face Symbol
11. Measurement Unit
12. Low Battery Symbol
13. Blood Drop Symbol



TEST STRIP

Your system measures the amount of sugar (glucose) in whole blood. Blood is applied to the absorbent hole of the test strip and is automatically drawn into the reaction cell where the reaction takes place.

The test strip consists of the following parts:



Absorbent Hole
Apply a drop of blood here.
The blood will automatically be absorbed.

Confirmation Window
This is where you confirm if enough blood has been drawn into the absorbent hole of the strip.

Test Strip Handle
Hold this part to insert the test strip into the slot of the glucose meter.

Contact Bars
Insert this end of the test strip into the meter.
Push it in firmly until it will go no further.

NOTE

The **glucoCheck KEY** meter should only be used with **glucoCheck KEY** Test Strips. Using other test strips with this meter will produce inaccurate results.

SETTING THE METER

Before using your meter for the first time or after changing the meter battery, you should check and update the settings. Start with the meter off (no test strip inserted). Open the battery compartment and press the SET button **(S).**

STEP 1: Setting the Date
YEAR / MONTH / DAY flashing in sequence, press the **Main Button (M)** until the correct year/month/day appears. Press **S**.

STEP 2: Setting the Time
Press **M** to select the desired time format (12h or 24h). Press **S.**
With the HOUR / MINUTE flashing in sequence, press **M** until the correct hour/minute appears. Press **S.**

STEP 3: Deleting the memory
With "dEL" and "M" on the display, press **M** to select "no" to keep the results in memory then press **S** to skip. To delete all the results, press **M** to select "yes", and then press **S** to delete all the memory records.

STEP 4: Setting the reminder alarm
Your meter has one reminder alarm. The meter will display "On" or "OFF" and "🔔". If you don't want to set an alarm, press **M** to select "OFF", and then press **S** to skip this step. Or select "On" and press **S** to proceed.
With the hour/minute flashing in sequence, press **M** to select the correct hour/minute.
Press **S** to finish the alarm setting.

NOTE

If the meter is idle for 2 minutes during the setting mode, it will switch off automatically.

MEASURING MODES

The meter provides you with TWO modes for measuring, General and QC.

MODES	USE WHEN
General	Any time of day without regard to time since last meal
QC (displays CTL)	Testing with the control solution

CONTROL SOLUTION TESTING

Our Control Solution contains a known amount of glucose that reacts with test strips. By comparing the result of your control solution test with the expected range printed on the test strip vial label, you can check that the meter and test strips are working together as a system and that you are performing the test correctly. Routinely perform a control solution test to ensure accurate results.

Performing a control solution test

To perform a control solution test, you will need:

1) Meter 2) Test Strip 3) Control Solution

STEP 1: Insert Test Strip
Insert a test strip into the test strip slot. The meter will automatically switch on. With the 🩸 symbol flashing on the display, press **M.** "**CTL**" will appear on the display. In this mode the test result will not be stored in the meter memory. If you decide not to perform a control solution test, press **M** again, to exit QC (CTL) mode.

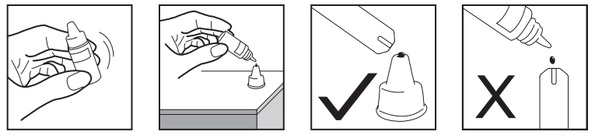
CAUTION

When performing a control solution test, you have to mark it accordingly to ensure that the test result is not stored in the meter memory. Failure to do so will result in the control solution test result being included with your blood glucose test results in memory.

STEP 2: Apply Control Solution
Shake the control solution bottle thoroughly before use. Squeeze out the first drop and wipe it off, then squeeze out another drop and place it on the tip of the bottle cap. Hold the meter to move the absorbent hole of the test strip to touch the drop. Once the confirmation window fills completely, the meter will start counting down.

NOTE

To avoid contaminating the control solution, do not directly apply control solution onto a strip.



STEP 3: Read and Compare the Result
After counting down to 0, the control solution test result will appear on the display. Compare this result with the range printed on the test strip vial. The result should fall within this range.

Out-of-range results
If the meter continues to display results outside the range printed on the test strip vial, the meter and/or strips may be faulty. Please contact Homemed (Pty) Ltd customer service on 0861 106 150 for assistance.

TESTING WITH A BLOOD SAMPLE

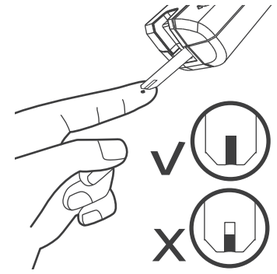
Preparing the Lancing Device for Blood Testing
Please follow the instructions in the lancing device insert for collecting a blood sample.

STEP 1: Insert a Test Strip to switch the Meter On.
Wait for the meter to display 🩸.

STEP 2: Select the Appropriate Measuring Mode by Pressing M
For selecting the measurement mode, please refer to the **"Measuring Mode"** section.

STEP 3: Obtaining a Blood Sample
Use the pre-set lancing device to puncture the desired site. Wipe off the first drop of blood that appears with a clean cotton swab. Gently squeeze the punctured area to obtain another drop of blood. Be careful not to smear the blood sample. The size of the drop should be at least 0.7 microliter (μL) of volume.

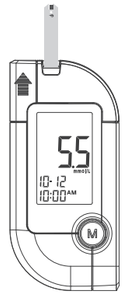
STEP 4: Apply the Blood Sample
Gently insert the test strip into the blood sample, at a tilted angle. The absorbent hole of the test strip will absorb the blood sample until the confirmation window is completely filled. Do **NOT** remove your finger until the meter starts counting down.



NOTE

- If you do not apply a blood sample to the test strip within 3 minutes, the meter will automatically switch off. You will need to remove and reinsert the test strip to start a new test.
- The confirmation window should be filled with blood before the meter starts counting down.
- Adding blood to the test strip should be done in one single action. **NEVER** try to add more blood to the test strip once it has been removed from the test site or the "🩸" sign has disappeared from the screen. Discard the used test strip and retest with a new one.
- If you experience issues whilst performing the test procedure, please contact your healthcare professional or Homemed (Pty) Ltd for assistance.

STEP 5: Read your Result
The result of your blood glucose test will appear after the meter counts down to 0. The blood glucose test result will automatically be stored in the meter memory.



STEP 6: Remove the Test Strip
Switch the meter off by removing the test strip. Discard the used test strip and lancet carefully according to your local regulations.

ALTERNATIVE SITE TESTING

You can test on a variety of locations on your body.

Important: There are limitations with Alternative Site Testing (AST). Please consult with your healthcare professional before you perform AST.

When to use AST?

Food, medication, illness, stress and exercise can affect blood glucose levels. Capillary blood at the fingertip reflects these changes faster than capillary blood at other sites. Thus, when testing blood glucose during or immediately after a meal, physical exercise, or any other event, **take a blood sample from your finger only.**

We strongly recommend that you perform AST **ONLY** at the following times:

- In a pre-meal or fasting state (more than 2 hours since the last meal)
- Two hours or more after taking insulin
- Two hours or more after exercise

Do NOT use AST if:

- You think your blood glucose is low
- You are unaware of hypoglycemia
- You are testing for hyperglycemia
- Your AST results do not match the way you feel
- Your routine glucose results often fluctuate

METER MEMORY

The meter stores the 450 most recent blood glucose test results along with respective dates and times in its memory. To enter the meter memory, start with the meter switched off.

Reviewing Test Results

1. Press and release M.

" M " will appear on the display and the first reading you see is the last blood glucose result along with date, time and the measuring mode.

2. Press **M** to recall the test results stored in the meter each time you press. Press and hold **M** to switch the meter off.

Reviewing Blood Glucose Day Average Results

1. Press and release **M** to enter memory mode for average results with " M " and " DAY AVG " displayed on the screen. Release **M** and your 7-day average result will appear on the display.
2. Press **M** again to also view your 14-, 21-, 28-, 60- and 90- day average results stored in the meter memory.
3. Keep pressing **M** to exit the meter memory. The meter will switch off after displaying the last test result.

NOTE

- Any time you wish to exit the memory, press and hold **M** for 3 seconds or leave it without any action for 3 minutes. The meter will switch off automatically.
- Control solution results are **NOT** included in the day average.

SYSTEM TROUBLESHOOTING

Herewith a summary of error messages and how to resolve them. If the problem persists, please contact Homemed (Pty) Ltd customer service on 0861 106 150.

Message	What it means	Action
E-b	Appears when the battery cannot provide enough power for a test.	Replace the battery immediately.
E-U	Appears when a used test strip is inserted.	Repeat with a new test strip.
E-t	Appears when ambient temperature is above or below system operation range.	System operation range is 10°C to 40°C. Repeat the test when the meter and test strip are at the desired temperature.
E-E **E-0** **E-A** **E-C**	Problem with the meter.	Review the instructions and try again with a new test strip. If the problem persists, please contact the local customer service for assistance.
E-F	Appears when test strip is removed while counting down.	Review the instructions and repeat test with a new test strip. If the problem persists, please contact the local customer service for assistance.

For questionable results, please see test strip package insert for important information.

SYMBOL INFORMATION

Symbol	Referent	Symbol	Referent
IVD	*In vitro* diagnostic medical device		Manufacturer
	Consult instructions for use	SN	Serial number
	Temperature limit	REF	Catalogue number
	Use-by date	CE 0123	CE mark
LOT	Batch code		Humidity limitation
	Caution	RoHS	RoHS compliance
	Keep away from sunlight		Keep dry
EC REP	Authorized representative in the European Community		Do not use if package is damaged and consult instructions for use
	This device does not belong to household waste and must be returned to a collection point for recycling electric and electronic devices according to local laws. If it contains batteries, the batteries should be removed and disposed in accordance with locations for separate collection of spent batteries.		

SPECIFICATIONS

Dimensions: 96 (L) x 46 (W) x 17 (H) mm
Weight: 41.4g (exclude battery)
Power source: One CR2032 3V lithium battery
Display: LCD
Memory: 450 measurement results with date and time
Automatic detection of electrode insertion
Automatic reaction time count-down
Auto switch-off after 3 minutes without action
Temperature warning
Operating Condition: 10°C ~ 40°C, between 10% and 85% R.H.
Meter Storage / Transportation condition: -20°C ~ 60°C, between 10% and 93% R.H.
Strip Storage / Transportation Conditions: 4°C ~ 40°C, between 10% and 85% R.H.
Measurement Units: mmol/L
Measurement Range: 1.1 - 33.3 mmol/L
Expected Service Life: 5 years
Operating Altitude: Up to 2000m, for indoor use
Degree of Pollution: Pollution degree 2

The device has been tested to meet the electrical and safety requirements of:
IEC/EN 61010-1, IEC/EN 61010-2-101, IEC/EN 61326-1, IEC/EN 61326-2-6, EN 300 328.

CARING FOR YOUR METER

To avoid the monitor and test strips attracting dirt, dust or other contaminants, wash and dry your hands thoroughly before use.

Cleaning

1. To clean the meter exterior, wipe it with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft dry cloth. Do NOT rinse with water.
2. Do NOT use organic solvents to clean the meter.

Meter Storage

- Storage conditions: -20°C to 60°C between 10% and 93% relative humidity.
- Always store or transport the meter in its original storage case.
- Avoid dropping and heavy impact.
- Avoid direct sunlight and high humidity.

Meter Disposal

The used meter should be treated as contaminated that may carry a risk of infection during measurement. The batteries in this used meter should be removed and the meter should be disposed of in accordance with local regulations.
The meter falls outside the scope of the European Directive 2012/19/EU-Directive on waste electrical and electronic equipment (WEEE).

Replacing the Battery

Your meter comes with one 3V CR2032 lithium battery. The " " symbol will appear with E-b and Low on the screen when the battery is too low and it is time to replace the battery.

To replace the battery, make sure the meter is switched off.
1. Press the edge of the battery cover and lift it up.
2. Remove the old battery and replace with a new 3V CR2032 lithium battery.
3. Close the battery cover. Make sure the battery is inserted correctly.

NOTE

- Replacing the battery does not affect the test results stored in the memory.
- As with all small batteries, these batteries should be kept away from children. If swallowed, promptly seek medical assistance.
- Battery might leak chemicals if unused for a long time. Remove the battery if you are not going to use the device for an extended period (i.e. 3 months or more).
- Dispose of the battery according to your local environmental regulations.

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Co Reg 2003/022932/07
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For self-testing.
REF TD-4231 IVD CE 0123