

GLUKAZONE®

Blood Glucose Monitoring System

Dear GlukAZone System User,

Thank you for choosing the GlukAZone system! The GlukAZone blood glucose monitoring system is designed for easy testing of blood glucose and helps you to keep your blood glucose under control. The GlukAZone system is fully compliant with the new EN ISO 15197:2015 International Standard.

Read this User Manual carefully before you use your meter system. This manual will help you to become familiar with using the GlukAZone blood glucose monitoring system and get reliable test results. Please keep your User Manual in a safe place; you may want to refer to it in the future.

Thank you again for choosing the GlukAZone System.

Principle and Intended Use

The GlukAZone system (Meter Model: GAM001) is designed to quantitatively measure the glucose concentration in fresh capillary whole blood. The GlukAZone blood glucose test is based on the measurement of an electric current caused by the reaction of glucose with the reagents on the electrode of the test strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample then reacts with an enzyme and mediator, generating electrons, which produce a current that is proportional to the glucose concentration in the sample. After the reaction time, the glucose concentration in the sample is displayed. The meter is calibrated to display plasma-like concentration results.

The GlukAZone system is intended for external use (*in vitro* diagnostic use) at home, by people with diabetes and by health care professionals in a clinical setting, as an aid to monitor the effectiveness of diabetes control. The system should not be used for the diagnosis of diabetes.

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CHAPTER 1: UNDERSTANDING YOUR TESTING TOOLS

Your Meter System Overview

The GlukAZone Blood Glucose Meter and Strip



Your Meter Display

The picture below shows all the symbols that appear on your meter display. To make sure the display is working properly, with the meter off, press and hold ◀ and ▶ together for 3 seconds to see the complete display. All display segments will appear for 10 seconds. If you need more than 10 seconds to check the display, press and hold ◀ and ▶ together again. All of the segments should be clear and exactly like the picture below. If not, contact your local distributor for help.



Icon	What it Means
88/88	The top left area on the screen indicates the date.
88:88	The top right area on the screen indicates the time.
d/m/d	Date, month format.
	Indicates the alarms have been set.
A	Indicates the average value.
	Indicates a low battery or it needs to be replaced.
88.8	The centre area on the display, this shows test results or error codes.
	Indicates the system is ready to do a test.
Ketone?	Ketone warning.
	Pre-meal marker.
	Post-meal marker.
	Control test result.
mg/dL mmol/L	Test results are displayed as mg/dL or mmol/L according to local government regulations
	Indicates the temperature is not suitable for testing.
Hypo	Indicates that a low test result may cause hypoglycaemia.

Notes:

Your GlukAZone meter is pre-set with a beep sound function, the meter will beep when:

- You turn on the meter.*
- the test strip is inserted and it is ready for blood or control solution to be applied.*
- sufficient blood or control solution is drawn into the test strip.*
- the test is complete.*
- it is time to perform a test if you set the test alarms.*
- if any error occurs during operation.*

Meter Use and Precautions

- The meter is pre-set to display blood glucose concentration in either millimoles per liter (mmol/L) or milligrams per deciliter (mg/dL) depending on which unit of measurement is standard in your country. This unit of measurement cannot be adjusted.
- Do not get water or other liquids inside the meter.
- Keep the strip port area clean.
- Keep your meter dry and avoid exposing it to extremes of temperature or humidity. Do not leave it in your car.
- Do not drop the meter or get it wet. If you do drop the meter or get it wet, check the meter by running a quality control test. Refer to **Quality Control Test** on page 21 for instructions.
- Do not take the meter apart. Taking the meter apart will void the warranty.
- Refer to the **Caring for Your Meter** section on page 30 for details on cleaning the meter.
- Keep the meter and all associated parts out of reach of children.

Note: Follow proper precautions and all local regulations when disposing of the meter and used batteries.

All Glucose systems preventive warnings with regard to EMC

1. This meter is tested for immunity to electrostatic discharge as specified in IEC 61000-4-2. However, use of this meter in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.) may cause damaging static discharges that may cause inaccurate results.
2. This meter complies with the emission and immunity requirements described in EN61326-1 and EN61326-2-6. Do not use this meter in close proximity to sources of strong electromagnetic radiation as it may interfere with proper operation of the meter.
3. For professional use, the electromagnetic environment should be evaluated prior to operation of this meter.

Important Safety Information

- Always keep the test strips in the original vial. Tightly close the vial immediately after you have removed the test strip.
- Do not use the meter if it is wet.
- Wash and dry your hands well before and after testing.
- Test strips and lancets are for single use only.
- **DO NOT DROP BLOOD DIRECTLY ON TO THE FLAT SURFACE OF THE TEST STRIP.**
- Check the expiry dates and discard dates on your test strips vial label and control solution bottle label.
- Use only GlukAZone test strips with your GlukAZone system.
- Use only GlukAZone control solution with your GlukAZone system.
- Following a self-test always consult your diabetes health care professional before making any adjustments to your medication, diet or activity routines.
- If the system is used in a manner not specified by the manufacturer, the protection provided by the system will be impaired.



Potential Biohazard





Healthcare professionals or persons using this system on multiple patients should follow the infection control procedure approved by their facility. All products or objects, which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral disease.

CHAPTER 2: SETTING UP YOUR SYSTEM

Before you use your meter for the first time or if you change your meter battery, you must check and update your meter settings.

Set the Time and Date

1. Enter the setting mode and set the time

When the meter is off, press and hold  (this is located on the top left corner) until the meter beeps, to enter the set up mode, the number in the hour position will now flash on the display. Press  or  to select the hour and press  to set.



The minute will now flash. Press  or  to select the minute and press  to set.

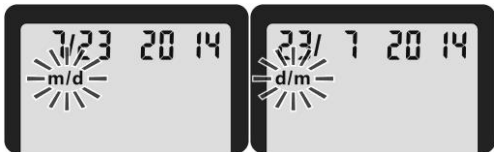


Note:

Before you use the meter for the first time, please adjust the meter settings to set the correct date and time, this is to ensure that the results stored in the memory are shown with the correct date and time.

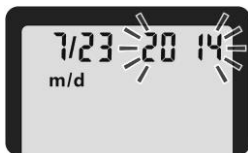
2. Set the Month and Date Format

m/d will now flash on the display. Press  or  to select the format you wish (m/d for month/date format or d/m for date/month format). Press  to set.

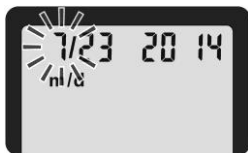


3. Set the Date

The year will be flashing now. Press ◀ or ▶ to select the current year. Press ⏻ to set.



The month will now flash. Press ◀ or ▶ to select the month. Press ⏻ to set.




The date will now flash. Press ◀ or ▶ to select the date. Press ⏻ to set.

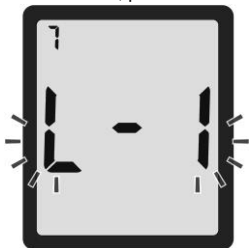





Set up for Basic (L-1) and Advanced (L-2) Modes

Your GlukAZone meter is pre-set with the Basic Mode; it offers the same test procedure in either the Basic or Advanced Mode.


Basic Mode (L-1) Function	Advanced Mode (L-2) Function
7 day average 900 test result memory	7,14 and 30 day average 900 test result memory Meal marker function 30 day Pre and Post-meal average Selectable test alarms Hypo warning Ketone warning

After you have set the date you have now finished basic set up mode set, “L-1” will flash. To keep your meter in Basic Mode, press  to set.



To change your meter to Advanced Mode, press  or  to change to “L-2”, and press  to set.



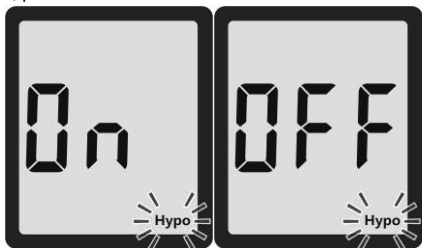
If you are using Basic Mode, you have completed your meter set up. Press  to turn off the meter. You can also insert a test strip into the meter, a symbol of a test strip with a flashing blood drop will appear letting you know the meter is ready to do a test.



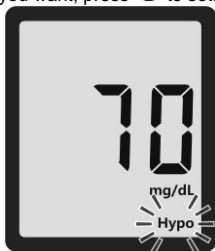
Set the Hypoglycaemia (Hypo) Alarm

If you selected Advanced Mode, you can set the Hypo Alarm to let you know when your blood glucose is possibly too low. You can select the blood glucose level you want the alarm to alert you at (60-80 mg/dL (3,3-4,4 mmol/L)).

After you have confirmed the selection of Advanced Mode, the **Hypo** flashes on the display along with "On" on the display. Press ◀ or ▶ to turn the Hypo alarm function on or off, press ⏻ to set.



If you select the hypo alarm "on", the display shows 70 mg/dL (3,9 mmol/L). Press ◀ or ▶ to select the level you want, press ⏻ to set.

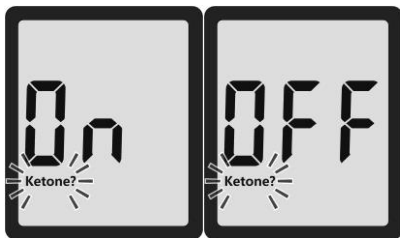


Notes:

- Talk to your doctor or health care professional to help you decide the hypo level that is suitable for your situation.
- For health care professionals, the hypoglycemic level may vary from person to person. It is recommended to turn the hypo alarm function OFF when using the meter in a clinical setting.

Set the Ketone Warning

After you set the Hypo Alarm, the **Ketone?** symbol will flash, along with the word "On" on the display. Press ◀ or ▶ to turn the Ketone warning function on or off, press ⏻ to set.



If you turn this function on, the **Ketone?** symbol will appear when the test result is equal to or above 300 mg/dL (16.7 mmol/L).



Set the Test Alarm Function

The test alarm function reminds you when to test. You can set up to 5 alarms per day. When the alarm sounds, the ⌚ flashes on the display. The alarm will beep 20 times. You can turn the alarm off by inserting a test strip to perform a test or pressing any button to turn the meter off.



Your meter is pre-set with the test alarm function to “OFF”. You can set up to 5 test alarms per day. If you turn 5 test alarms on (A1, A2, A3, A4 and A5), your meter is pre-set with the following times for your convenience. You can adjust each time to suit your needs.

A1 7:00

A2 9:00

A3 14:00

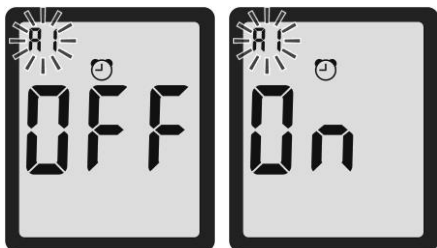
A4 18:00

A5 22:00

Note:

If the meter is on at the test reminder time, the test alarm does not sound.

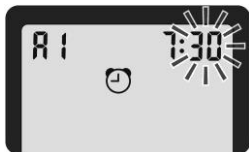
After you set the Ketone Warning, the ☹ and the word “OFF” will be displayed, symbol “A1” flashes. Press ◀ or ▶ to turn the alarm function on or off, and press ⏻ to confirm.



If you select “On”, the hour flashes, “A1” and the ☹ remains on the display. Press ◀ or ▶ to select the hour. Press ⏻ to set.



The minute flashes, press ◀ or ▶ to select 00, 15, 30, or 45. These are the only choices. Press ⏻ to set minutes.



The next alarm “A2” flashes on the display with ☹ and “OFF”.



You can set a second alarm by pressing ◀ or ▶ to turn on the second alarm. Do the same procedures to set the rest of the alarms, you have now completed your GlukAZone meter set up for Advanced Mode. The meter shows L-2 along with advanced function icons.



Press ⏻ to turn off the meter. You can also insert a test strip into the meter, the test strip symbol with a flashing blood drop appears on the display, and you are ready to test.



Note:

If you want to exit the set up mode at any time, please set up at least one item, then press and hold ⏻ until the default operation mode (L-1 or L-2) appears on the display, press ⏻ to exit the set up mode and turn off the meter.

CHAPTER 3: TAKING A TEST

Set up your meter correctly and have all the materials you will need ready before you begin the test. This includes your GlukAZone meter, the GlukAZone test strips and GlukAZone lancing device with GlukAZone lancets.

Preparing the Test Strip

1. Wash and dry your hands well before testing.
2. Remove a test strip from the test strip vial or foil pouch. Tightly close the vial cap immediately after you have removed the test strip.
3. Insert the test strip into the meter in the direction of the arrows. The meter turns on after a beep.



4. A symbol of a test strip with a flashing blood drop will appear letting you know the meter is ready to use.

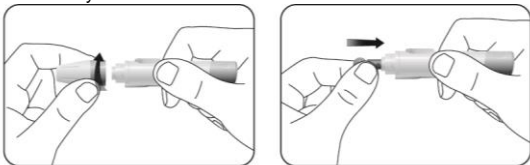


Note: Check the expiry and discard dates on the test strip vial. All expiration dates are printed in Year-Month format. 2022-01 indicates January, 2022. Your GlukAZone test strips have 6 months shelf life after you first open the test strip vial. Write the discard date on the vial label when you first open it. Make sure the test strip does not appear damaged. Prior to testing, wipe the test site with an alcohol swab or wash with soapy water. Using warm water to wash your hands can help to increase blood flow if necessary. Dry your hands and the test site thoroughly. Make sure there is no cream or lotion on the test site.

Preparing the Lancing Device

For fingertip sampling, adjust the depth of penetration to reduce the discomfort. You do not need the clear cap for fingertip sampling.

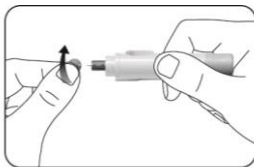
1. Unscrew the lancing device cover from the body of the lancing device. Insert a GlukAZone sterile lancet into the GlukAZone lancing device and push it until the lancet is fully inserted.



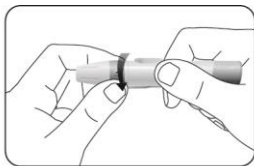
Note:

The GlukAZone lancing device uses ONLY GlukAZone sterile lancets.

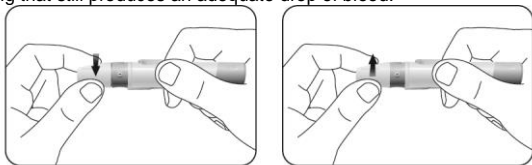
2. Hold the lancet firmly in the lancing device and twist the safety tab of the lancet until it is loose, then pull the safety tab off the lancet. Save the safety tab for disposing of the used lancet.



3. Carefully screw the cover back onto the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully secured on the lancing device.



4. Adjust the puncture depth by rotating the lancing device cover. There are a total of 5 puncture depth settings. To reduce the discomfort, use the lowest setting that still produces an adequate drop of blood.



Adjusting the puncture depth:

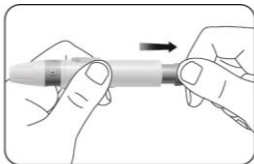
- 1 for delicate skin
- 2 and 3 for normal skin
- 4 and 5 for calloused or thick skin

Note:

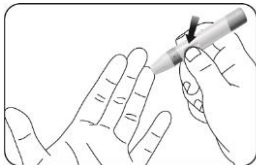
Firm pressure of the lancing device against the finger will also increase the puncture depth

Getting a Blood Drop and Testing

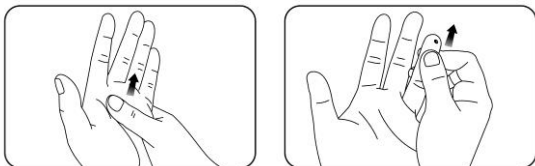
1. Pull the cocking barrel back to prime the lancing device. You may hear a click to indicate the lancing device is now loaded and ready for obtaining a drop of blood.



2. Press the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick your fingertip. You should hear a click as the lancing device is activated.



3. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume. Avoid smearing the blood drop. Lance on the side of the fingertip to help reduce any pain. Test immediately after a good blood drop has formed.



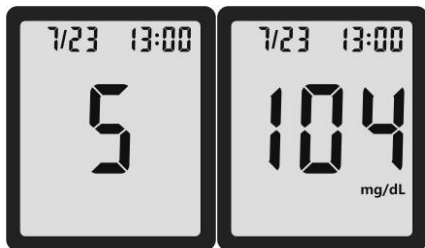
4. Immediately touch the tip of the test strip to the drop of blood. The blood is drawn into the test strip through the tip. Make sure that the blood sample has fully filled the sample tip on the test strip. Hold the tip of the test strip in the blood drop until the meter beeps.



Note:

If the blood sample does not fill the sample tip, do not add a second drop. Discard the test strip and start over with a new test strip.

5. The meter counts down 5 seconds and your result appears on the display after a beep. The test result will automatically be stored in the meter memory. Please do not touch the test strip during the countdown as this may result in an error.



Note:


If you have selected Advanced Mode (L-2) leave the test strip in the meter to mark the blood glucose results. Otherwise, remove the used strip and the meter will turn off automatically. See “Discard used test strip” instructions below. The meter turns off automatically 2 minutes after inactivity. Now wash your hands.







Marking Blood Glucose Results

You can set your meter to use meal marker options by using Advanced Mode (L-2). Your meter will display two markers after you test your blood.



 Pre-meal marker: marks a test result that was taken before the meal.

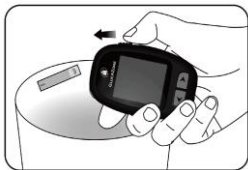
 Post-meal marker: marks a test result that was taken after the meal.

After testing and your blood glucose result is displayed, pre-meal marker  and post-meal marker  appear on the meter display, and pre-meal marker  flashes, press  or  to select the marker you want to set, press  to confirm.

If you do not want to mark the test result, simply remove the used test strip to automatically save the test result in the meter memory without the marker. The meter will turn off automatically. Dispose of the used test strip and lancet properly.

Discard the Used Test Strip

You can discard the used test strip by sliding the strip ejector forwards. The meter turns off automatically after a beep.





Potential Biohazard

Dispose of the used test strips as medical waste.

Expected Diabetes Control Goal:

Blood glucose values will vary depending on food intake, medication dosages, health, stress, or exercise. Ideally, the goal is to control the glucose level as close to a normal (non-diabetic) blood glucose level as you can safely.

The American Diabetes Association suggests the following targets for most non-pregnant adults with diabetes. More or less stringent glycaemic goals may be appropriate for each individual. Consult your doctor or health care professional for the target value that is appropriate for you.

Expected blood glucose levels for most non-pregnant adults with diabetes:¹

Time	Range, mmol/L
Before a meal	3.9 – 7.2
1-2 hours after beginning of the meal	Less than 10

Reference:

1. ADA Clinical Practice Recommendations, 2014.

Warning:

- If your blood glucose reading is under 50 mg/dL (2.8 mmol/L) or you see LO (less than 10 mg/dL (0.6 mmol/L)) on the meter display, contact your doctor or health care professional as soon as possible.
- If your test result is above 250 mg/dL (13.9 mmol/L) or you see HI (greater than 600 mg/dL (33.3 mmol/L)) on the meter display, contact your doctor or health care professional as soon as possible.
- Do not change your medication based on the GlukAZone test result before you consult your doctor or health care professional.
- If you want to mark your result (only in Advanced Mode (L-2)) you will need to do it before removing the test strip.

Questionable or Inconsistent Results:

If your blood glucose result does not match how you feel, please:

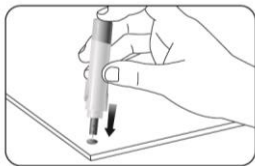
- Check the expiry date and the discard date of the test strip. Make sure that the test strips vial has not been opened for more than 6 months.
- Confirm the temperature in which you are testing is between 5 and 45°C (41-113°F).

- Make sure that the test strip vial has been tightly capped.
- Make sure the test strips have been stored in a cool, dry place.
- Make sure the test strip was used immediately after removing it from the test strip vial or foil pouch.
- Make sure that you followed the testing procedure correctly.
- Perform a control solution test (See Performing a Control Test on page 21 for instructions).

After checking all of the conditions listed above, repeat the test with a new test strip. If you are still unsure of the problem, please contact your local distributor.

Removing the Used Lancet

Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface and carefully insert the lancet needle into the safety tab.



Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward to discard the used lancet. Place the lancing device cover back on the lancing device.



Potential Biohazard

Always dispose of the used lancet properly to prevent injury or contamination to others.



Caution:

- *Do not use the lancet if the safety tab is missing or loose when you take the lancet out of the bag.*
- *Do not use the lancet if the needle is bent.*
- *Take care whenever the lancet needle is exposed.*
- *Never share lancets or the lancing device with other people in order to prevent possible infections.*
- *In order to reduce the risk of infection from prior use of the instrument, always use a new, sterile lancet. Do not reuse lancets.*
- *Avoid getting the lancing device or lancets dirty with hand lotion, oils, dirt or debris.*

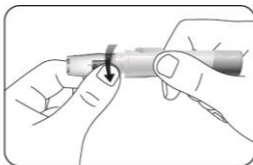
Alternative Site Testing

Blood samples for glucose testing may be taken from sites other than your fingertips. Alternative site testing using blood from the forearm or palm may give glucose results that significantly differ from fingertip blood. Differences occur when blood glucose levels are changing rapidly, such as after a meal, after insulin, and during or after exercise.

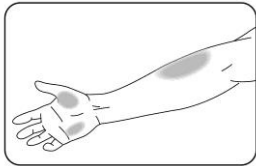
The forearm and palm areas have less nerve endings than the fingertip. You may find obtaining blood from these sites less painful than from the fingertip. The procedure for forearm and palm sampling is different. You need the clear cap to draw blood from these sites. The clear cap is not adjustable for puncture depth.

Follow Step 1 and 2 of “Preparing the Lancing Device” to insert the lancet and load the lancing device.

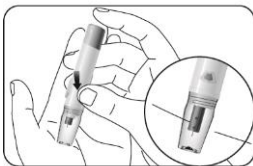
3. Screw the clear cap onto the lancing device.



4. Choose a puncture site on the forearm or palm. Select a soft and fleshy area of the forearm or palm that is clean and dry, away from bone, and free of visible veins and hair. To bring fresh blood to the surface of the puncture site, massage the puncture site vigorously for a few seconds until you feel it getting warm.



5. Place the lancing device against the puncture site. Press and hold the clear cap against the puncture site for a few seconds. Press the release button of the lancing device, but do not immediately lift the lancing device from the puncture site. Continue to hold the lancing device against the puncture site until you can confirm a sufficient blood sample has formed.



Notes:

- Consult your doctor or health care professional to determine if alternative site testing is right for you.
- Alternative site testing is not recommended if you have hypoglycemic unawareness (you do not recognize the symptoms of or cannot tell when you have low blood glucose). Please consult with your doctor or health care professional if you have a low blood glucose level.
- Select a soft, fleshy area of skin that is free from hair, moles and visible veins for alternative site testing. Wash the site with soap and warm water, then rinse and dry thoroughly.
- Use alternative site testing for blood glucose tests only when it is more than 2 hours after:

· A meal · Taking medication · Exercise

Testing with Control Solution

Why Perform Control Tests?

Performing a control test confirms you know that your meter and test strips are working properly and will give reliable test results. You should perform a control test:

- When you open a new box of test strips
- When you want to check the meter and test strips
- If your test strips were stored in extreme temperature or humidity
- After cleaning your meter
- If you dropped the meter
- If your test result does not match with how you feel

About the Control Solutions

- Only use GlucAZone Control Solutions (Low, Normal or High) to practice on the system.
- Your meter automatically recognizes the control solution.
- The control solution results are not included in the average value calculation.
- All expiration dates are printed in Year-Month format. 2017-01 indicates January, 2017.
- Do not use a control solution that is past the expiry date or discard date (the control solution will expire 6 months after the bottle is opened for the first time).
- **Shake the bottle well before use.**
- Close the bottle tightly after use.

Performing a Control Test

1. Remove a test strip from the test strip vial or foil pouch. Tightly close the vial cap immediately after you have removed the test strip.

Note: Check the expiration and discard dates of the test strips. Do not use an expired test strip.

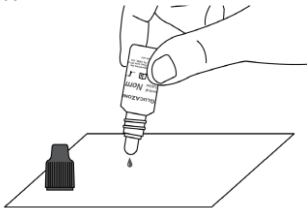
2. Insert a test strip into the meter in the direction of the arrows.



3. The meter turns on after a beep. An image of a test strip with a flashing blood drop will appear letting you know the meter is ready to test.



4. Shake the control solution bottle thoroughly. Squeeze the control solution bottle gently and discard the first drop. Squeeze out a second small drop on a clean nonabsorbent surface.



Note:

Do not apply control solution to the test strip directly from the bottle.

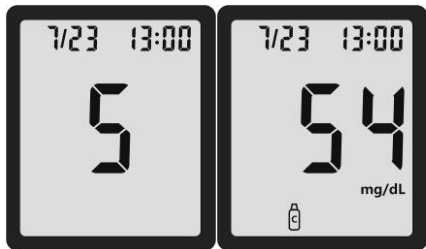
5. Immediately touch the tip of the test strip to the drop of control solution. The control solution is drawn into the test strip through the strip tip.



Note:

If the control solution sample does not fill the sample tip, do not add a second drop. Discard the test strip and start over with a new test strip.

6. Hold the test strip in the control solution until the meter beeps, and then you will see the meter count down on the screen and the control test result will be shown after another beep.

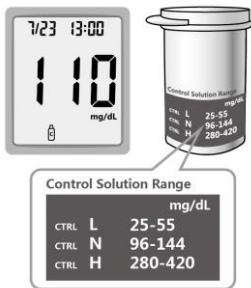


Note:

The meter will automatically recognize and mark the control result for you. Control results are not included in the 7, 14 and 30 day average calculation.

Understanding Your Control Test Result

Compare your control test result with the ranges printed on the test strip vial label or on the foil pouch.



Notes:

If your control test result is out of range:

- *Check the expiry dates and discard dates of the test strips and control solution. Make sure that the test strips vial has not been opened for more than 6 months and the control solution bottle has not been opened for more than 6 months. Discard any expired test strips or control solution.*
- *Confirm the temperature in which you are testing is between 15 and 40°C (59-104°F).*
- *Make sure that the test strip vial and the control solution bottle have been tightly capped.*
- *Make sure the test strip was used immediately after removing it from the test strip vial or foil pouch.*
- *Make sure the control solution was shaken well before use.*
- *Confirm that you are using GlukAZone brand control solution.*
- *Make sure that you followed the test procedure correctly.*

After checking all of the conditions listed above, repeat the control solution test with a new test strip. If your results still fall outside of the range indicated on the test strip vial label or on the foil pouch, your meter or test strips may not be working properly. **DO NOT** use the system to test blood. Contact your distributor for help. To turn your meter off, just remove the test strip. Dispose of the used test strips as medical waste. The result will be automatically marked and stored in the meter memory. Control results will not be included in your blood glucose averages.




Using the Meter Memory

Your meter automatically stores up to 900 results with the time and date. Test results are stored from the newest to the oldest. The meter will also calculate the average values of records from the last 7, 14 and 30 days.

Notes:

- *If there are already 900 records in memory, the oldest record will be erased to make room for a new one.*
- *It is very important to set the correct time and date in the meter, please make sure the time and date are correct after you change your battery.*
- *Control results are not included in the 7, 14 and 30 day average calculation.*

Viewing Basic Mode (L-1) Results

When your meter is off, press  to turn the meter on, after a beep, a symbol of a test strip flashes on the display, press  again, the 7 day average will appear in the centre of the display with the number of results shown at the top right of the display. If you want to review the memory after you have immediately performed a test, with the test result on the display, press  to see the 7 day average.



Press ◀ to review your previous results in order. Results will be shown starting with the most recent. Each result will show the date and time the test was taken. You can press ◀ or ▶ to scroll forward or backward through the results.



When END appears on the display, you have viewed all of the results in the memory.



Viewing Advanced Mode (L-2) Results

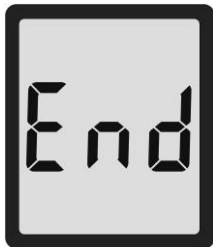
When your meter is off, press ⏻ to turn the meter on. Press ⏻ again to view the 7 day average including the number of results used to obtain the average.



Press ◀ to review previous results. Results will be shown starting with the most recent. Each result will show the date and time the test was taken.



You can press ◀ or ▶ to scroll forward or backward through the results. When END appears on the display, you have viewed all of the results in the memory.



Viewing Advanced Mode (L-2) Averages

When your meter is off, press ⏻ to turn the meter on, press ⏻ again to view the 7 day average including the number of results used to obtain the average.

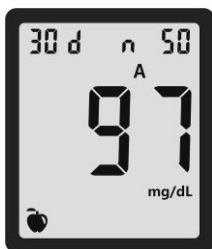
Press ➤ to view the 14 day average. You will see the average in the centre of the display and the number of results along the top.



Press ➤ to review the 30 day average. It will display the average in the centre and the number of readings along the top.



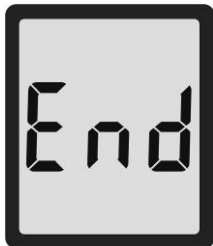
Press ➤ again to view the 30 day average of results marked with a pre-meal marker.



Press ➤ again to view the 30 day average of results marked with a post-meal marker.



Press ➤ again and you will see END on the display. Press ⏻ to turn off the meter or it will automatically turn off after 2 minutes.



Transferring Results to a Computer

You can transfer stored test results from GlukAZone meter to a computer to track, identify patterns and print.

Transferring data directly to a computer requires specialist software and a cable from VivaChek Biotech (Hangzhou) Co., Ltd. Contact your local distributor for purchasing information.



Notes:

- To make the most of the data transfer feature, you must set the time and date in the meter correctly.
- Any external equipment (e.g. PC) connected to the apparatus by data port (Mini USB port) should be approved separately.

CHAPTER 4: MAINTENANCE AND TROUBLESHOOTING

Proper maintenance is recommended for best results.

Changing the Battery

Battery should be replaced when the meter continually displays , or the meter shows  then turns off.



1. Turn off your meter before changing the battery.
2. Press firmly on the battery cover and slide in the direction of the arrow.



Note:

After you change the battery, your meter prompts you to confirm the meter's time and date settings. All the test results are saved in the memory.

3. Lift out the old battery.



4. Place the new battery under the prongs and into the battery compartment with the "+" side up (Use one 3-volt CR 2032 lithium battery).
5. Slide the battery cover back into place, lining up with the open slots, and close firmly.



Warning:

Keep battery away from children. Lithium battery are poisonous. If swallowed, immediately contact your doctor or poison control centre. Discard battery according to your local environmental regulations.

Caring for Your Glucose Monitoring System

Blood Glucose Meter








Your GlukAZone Blood Glucose Meter does not require special maintenance or cleaning. A damp cloth and a mild detergent solution can be used to wipe the outside of the meter. Take care to avoid getting liquids, dirt, blood or control solution into the meter through the strip or data ports. It is recommended that you store the meter in the carrying case after each use.





The GlukAZone Blood Glucose Meter is a precision electronic instrument. Please handle it with care.

Lancing Device

Clean the lancing device using a soft cloth with mild soap and warm water as required. Use 70% Isopropyl Alcohol to disinfect the lancing device. Carefully dry the lancing device. **Do not immerse the lancing device in liquid.**

Troubleshooting Guide

What You See	What It Means	What You Should Do
	Blood or control solution was applied to the test strip before the flashing blood drop appeared on the display	Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing.
	The meter is sensing a used or contaminated test strip.	Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing.
	Incorrect test strip.	Discard the test strip and repeat the test with a new test strip. Make sure that you are using a GlukAZone test strip.
	Incorrect sample.	Discard the test strip and repeat the test with a new test strip. Make sure that only human capillary blood and GlukAZone control solution is used for the test.
	Temperature out of range.	Move to an area that is within the operating range for the meter. Let the meter adjust to this temperature for 20 minutes before performing a test.
	Potential software or hardware issue.	Replace the battery and restart the meter. If the problem continues, contact your local distributor.
	Insufficient sample.	Repeat test and apply enough sample to fill the test strip check window.

	Test result is above 600 mg/dL (33.3 mmol/L).	Wash and dry your hands well and the test site. Repeat the test using a new test strip. If your result still flashes HI, contact your doctor or health care professional as soon as possible.
		
Caution:		
Glucose levels above 250mg/dL(13.9mmol/L) may indicate a potentially serious medical condition.		
	Test result is below 10 mg/dL (0.6 mmol/L).	Repeat the test using a new test strip. If your result still flashes LO, contact your doctor or health care professional as soon as possible.
		
Caution:		
Glucose levels below 50mg/dL(2.8mmol/L) may indicate a potentially serious medical condition.		

Symptoms of High or Low Blood Glucose

You can better understand your test results by being aware of the symptoms of high or low blood glucose. According to the American Diabetes Association, some of the most common symptoms are:

Low blood glucose (Hypoglycaemia):

- shakiness
- sweating
- fast heartbeat
- blurred vision
- confusion
- fainting
- irritability
- seizure
- extreme hunger
- dizziness

High blood glucose (Hyperglycaemia):

- frequent urination
- excessive thirst
- blurred vision
- increased fatigue
- hunger

Ketones (ketoacidosis):

- shortness of breath
- nausea or vomiting
- very dry mouth

Warning:

If you are experiencing any of these symptoms, test your blood glucose. If your test result is under 50 mg/dL (2.8 mmol/L) or above 250 mg/dL (13.8 mmol/L), contact your doctor or health care professional immediately.

System Specifications:

Feature	Specification
Measurement range	10 to 600 mg/dL (0.6-33.3 mmol/L)
Result calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Sample volume:	About 0.5 µL
Test time	About 5 seconds
Power source	One (1) CR 2032 3.0 V coin cell battery
Battery life	12 months or approximately 1,000 tests
Glucose units of measurement	The meter is pre-set to either millimoles per litre (mmol/L) or milligrams per decilitre (mg/dL) depending on the standard of your country
Memory	Up to 900 records with date and time
Automatic shutoff	2 minutes after last action
Dimensions	82.5 mm × 52 mm × 18.2 mm
Display size	31mm × 37 mm
Weight	Approximately 44.2g (with battery installed)
Operating temperature	5-45°C
Operating relative humidity	10-90% (non-condensing)
Hematocrit range	20-70%
Data port	Micro USB

Limitations

The GlukAZone meter, test strips and control solution have been designed, tested and proven to work together effectively to provide accurate blood glucose measurements. Do not use components from other brands.

- Fresh capillary blood may be collected into test tubes containing sodium heparin or lithium heparin if the blood is used within 10 minutes. Do not use sodium fluoride/oxalate or other anticoagulants or preservatives.
- Use only with whole blood. Do not use with serum or plasma samples.
- Very high (above 70%) and very low (below 20%) haematocrit levels can cause false results. Talk to your doctor or health care professional to find out your haematocrit level.
- Abnormally high levels of vitamin C and other reducing substances will produce false high blood glucose measurements.
- The system is tested to accurately read the measurement of glucose in whole blood within the range of 10 to 600 mg/dL (0.6-33.3 mmol/L).
- Fatty substances (triglycerides up to 3,000 mg/dL or cholesterol up to 500 mg/dL) have no major effect on blood glucose test results.
- The GlukAZone Blood Glucose Monitoring System has been tested and shown to work properly up to 10,000ft (3,048 meters).
- Severely ill persons should not run the glucose test with the GlukAZone Blood Glucose Monitoring System.
- Patients using oxygen therapy are not recommended for testing with GlukAZone Blood Glucose Monitoring System.
- Blood samples from patients in shock, with severe dehydration, or from patients in a hyperosmolar state (with or without ketosis) have not been tested and are not recommended for testing with GlukAZone Blood Glucose Monitoring System.
- Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions and obey all local regulations when disposing of materials.

Warranty

Please complete the warranty card that came with this product and mail it to your distributor to register your purchase.

If the meter fails to work for any reason other than obvious abuse within the first five (5) years from purchase, we will replace it with a new meter free of charge. For your records, also write the purchase date of your product here.



















Date of purchase: _____

Note:

This warranty applies only to the meter in the original purchase, and does not apply to the battery supplied with the meter.

Index of Symbols

These symbols may appear on the packaging and in the instructions for the GlukAZone system.

Symbols	Explanation
	Consult instructions for use
	For <i>in vitro</i> diagnostic use only
	Manufacturer
	Temperature limitations
	Contains sufficient for <n> tests
	Use by
	Lot Number
	Authorised Representative
	Sterilised using irradiation
	Control range
	Catalogue number
	Model number
	Do not re-use
	Caution, consult accompanying documents
	Dispose of items according to local relevant laws regarding disposal and recycling
	Use by 6 months from the opening
	Series number
	Keep away from sunlight and heat

Warranty Card

Please complete this warranty card to validate your warranty. Mail it within 30 days of purchase to the local dealer address labeled on the Starter Kit box to process the validation.

If the meter does not work for any reason other than obvious abuse in the first 5 years after purchase, we will replace it with a new or equivalent meter free of charge.

Date of purchase ____ / ____ / ____

Meter serial number (e.g.101A0000001)

Where purchased

Date of birth ____ / ____ / ____ Gender ☐M ☐F

Telephone number

Email address

Year/Age of Diabetes Diagnosis _____ / _____

How many times a week do you test your blood glucose?

What type of diabetes you have:

☐ Type 1 ☐ Type 2 ☐ Pre-diabetes ☐ Gestational

Suggestion/Comments