BLOOD
GLUCOSE
MONITORING
SYSTEM

# GlucoZen.*auto*™

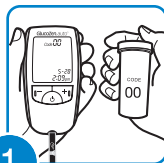Blood Glucose Monitoring System

## User Manual

**AGM-4000**

# QUICK START GUIDE

This summary is intended only as a quick reference and is not a substitute for GlucoZen.auto Blood Glucose Monitoring System User Manual. Please read the entire User Manual before you begin testing.
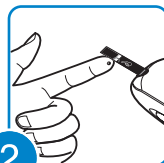
**1** Insert a test strip. The meter will automatically turn on. Check the code number. The code number displayed on the meter must match the one on the test strip vial.

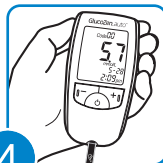**2** Apply the blood drop to the side edge of the yellow window of the test strip.
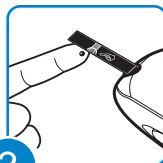
**3** Wait for the blood drop to completely fill the yellow window of the test strip, then the meter will begin the countdown.

**4** The blood glucose result will be displayed on the meter in just 5 seconds.

"Thank you for using **GlucoZen**.*auto*™
Blood Glucose Monitoring System"

This User Manual will tell you all you need to know
about the system and how it works.
Please read this carefully before using the meter.

# *PRECAUTIONS

## Intended Use

**For Self-testing:** GlucoZen.auto Blood Glucose Monitoring System is for quantitative blood glucose testing in fresh capillary whole blood drawn from the fingertips. The GlucoZen.auto Blood Glucose Monitoring System is for testing outside the body (*in vitro* diagnostic use). The GlucoZen.auto Blood Glucose Monitoring System is intended for use by diabetic lay users for self testing to improve management of their blood glucose level. The GlucoZen.auto Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes mellitus, or for neonatal use.

**For professional use:** GlucoZen.auto Blood Glucose Monitoring System is for quantitative blood glucose testing in venous whole blood and fresh capillary whole blood drawn from the fingertips.
The GlucoZen.auto Blood Glucose Monitoring System is for testing outside the body (*in vitro* diagnostic use). The GlucoZen.auto Blood Glucose Monitoring System is intended for use by healthcare professionals to improve management of patient's blood glucose level. The GlucoZen.auto Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes mellitus, or for neonatal use.

## Test Principle

The blood sample is drawn into the test strip's reaction chamber through capillary action. Glucose in the sample reacts with glucose dehydrogenase and mediator in the test strip. This reaction creates electrical currents. The electrical currents produced are proportional to the glucose concentration in the blood and converted to the equivalent glucose concentration values calculated based on the algorithm programmed in GlucoZen.auto Meter.

## Precautions for Use

- The GlucoZen.auto Meter is designed for use with GlucoZen.auto Test Strips
  (manufactured by **All Medicus Co., Ltd.**) only.
- The GlucoZen.auto Blood Glucose Monitoring System is calibrated to produce values equivalent to results on plasma specimens obtained from a laboratory analyzer (YSI 2300 STAT Plus).
- The GlucoZen.auto Blood Glucose Monitoring System should not be used for the diagnosis of diabetes.

- Rapid change in temperature may cause inaccurate test results in reading. When taking the meter from cold to warm area or from warm to cold area, let the meter sit for about 30 minutes to adjust to the room temperature.
- Do not drop the meter.
- Do not disassemble, repair or remodel without consultation. The sensitive parts could be damaged and the warranty will then become invalid.
- A hematocrit that is either very high (above 60%) or very low (below 20%) can cause false test results.

## Precautions for Test Strip

- Store test strip vials in dry place with temperature ranging between 1~32℃ (34~90℉).
- Avoid direct sunlight, heat and excessive humidity.
- Always close the vial cap immediately after removing a test strip from the vial. If the test strip vial is left open for a long time, the test strips will become unusable.
- Use the test strip immediately after removing it from the vial.
- Use all the test strips within 4 months after the first opening.
- Store your test strips only in their original vial and do not transfer them to a new bottle or any other container.
- Do not handle the test strip with wet hands.
- Do not use the test strip after the expiration date printed on the vial.
- Do not bend, cut, or alter the test strips.
- Do not insert the same test strip into the test port multiple times. It can lead to an improper operation.

## Safekeeping

- Store the GlucoZen.auto Meter at a temperature between 0~40℃ (32~104℉).
- Store the GlucoZen.auto Meter at a place where relative humidity is less than 85%.
- Keep the GlucoZen.auto Meter in sanitary environment.
- Keep the meter away from direct sunlight.
- Keep the test port away from dirt, blood or water.
- Do not store your meter and test strips in the car, the bathroom, or the refrigerator. (sensitive to temperature and humidity)
- Keep the meter, test strip vials and lancing materials away from children.
- Clean the outside of the meter using a moist (not wet) cloth or tissue with isopropyl alcohol or mild detergent with water. Do not immerse the meter in water or other liquid.
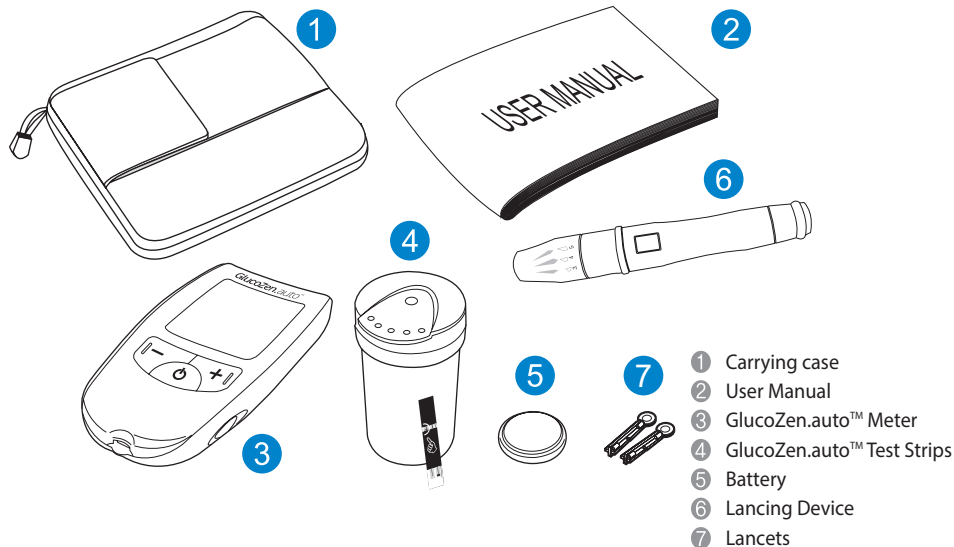
# Table of Contents

1  Carrying case
2  User Manual
3  GlucoZen.auto™ Meter
4  GlucoZen.auto™ Test Strips
5  Battery
6  Lancing Device
7  Lancets

# GlucoZen.auto™ Meter

**❶ LCD Display**

- Test results, icons, symbols and simple messages appear here.
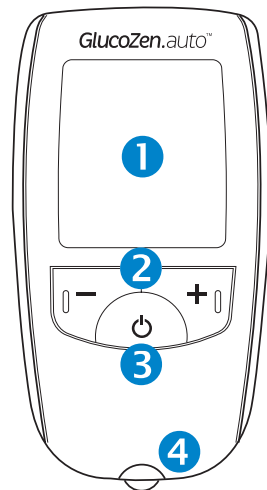
**❷ +/- Button**

- Recall the stored test result in the MEMORY MODE.
- Select an event in the EVENT RECORD MODE.
- Change the date and time in the SET MODE.

**❸ Power Button**

- Turn the meter on/off.
- Enter into different MODEs while pressing the power button.
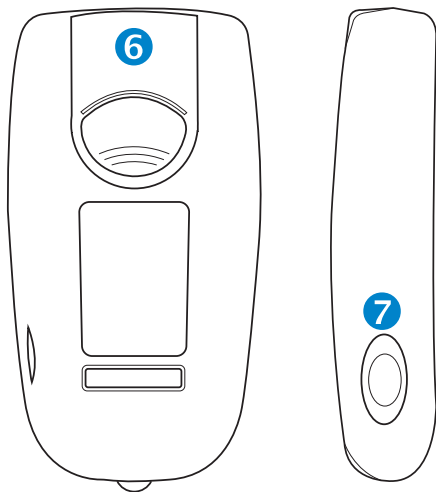 (3 seconds : SET MODE)

**❹ Test Port**

- Insert the GlucoZen.auto Test Strip for testing. Then the meter
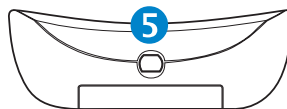 turns on and displays the code number automatically.

**⑤ Data Port**
 - Transfer your test results from  the meter
   to a computer.

**⑥ Battery Cover**

**⑦ Test Strip Ejector Button**

1 Battery life.

2 SET MODE.

3 AVERAGE MODE.

4 MEMORY MODE.

5 CODE MODE

6 MEMORY and CODE NUMBER.

The meter displays the current memory order number in the MEMORY MODE.

The meter displays the current code number in the CODE MODE.

7 STRIP ICON.

When the STRIP ICON blinks, insert a test strip to the meter.

8 BLOOD DROP ICON.

When the BLOOD DROP ICON blinks, apply blood sample.

9 TEMPERATURE ICON.

When the meter is not used at a recommended temperature range, "Er1" and TEMPERATURE ICON appear.

10 CURRENT TIME and TEST TIME in the MEMORY MODE.

11 CURRENT DATE and TEST DATE in the MEMORY MODE.

12 UNIT OF MESUREMENT mmol/L.

13 EVENT ICON.

If you choose an event icon which correlates to test results, it helps to manage glucose level more effectively.

14 ALARM.

You can set up to four different alarms. Each alarm rings for 10 seconds.
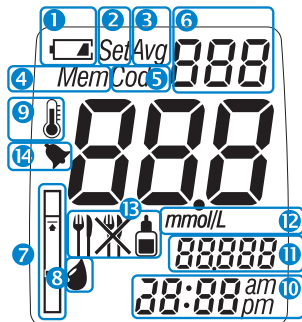
① **Grip**

- Hold this part to insert or remove test strip.

② **Yellow Side-edge**

- Apply blood sample here; blood is absorbed automatically.

③ **Confirmation window (Reaction chamber)**

- Make sure the confirmation window fills completely.

④ **Gold electrodes**

- Insert into test port.

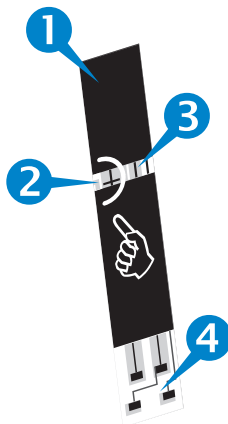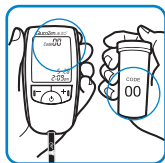# Checking the Code Number

Code numbers are used to calibrate your meter with the test strips for accurate test results. Whenever you test, you must check if the code number displayed on the meter matches the one on the test strip vial. All GlucoZen.auto meters and Test Strips distributed in the UK and Republic of Ireland  have been calibrated for code 00.

**1** **Insert a GlucoZen.auto Test Strip**

Insert a GlucoZen.auto Test Strip into the test port and the GlucoZen.auto Meter will turn on automatically. Then the code number, STRIP ICON and BLOOD DROP ICON will appear.

**2** **Check the Code Number**

Make sure that the code number displayed on the meter matches the one on the test strip vial. The meter will display code 00 which will match with code 00 printed on the test strip vial, you can now begin the test.

**⚠ CAUTION** Only use genuine GlucoZen.auto Test Strips showing code 00 on the label. If the label on your test strips shows a different numbered code DO NOT USE the test strips , please contact Glucozen as soon as possible on Freephone 0800 773 4865 or email care@glucozen.co.uk

Control solution test is to check the performance of your meter and test strips. GlucoZen.auto Control Solution contains a measured amount of glucose that reacts with the GlucoZen.auto Test Strips. The control solution test confirms that your meter and test strips are working correctly. Compare your control solution test results with the range printed on the test strip vial label. It is very important that you do this simple test routinely to make sure you get accurate test results. If you have registered your GlucoZen.auto Meter. Please contact GlucoZen for your control solution. Tel: 0800 773 4865 or Email: care@glucozen.co.uk or Address: UK Distributor, GlucoZen Ltd, Unit 20, Primrose Hill Tr.Est. Cradley Road, Netherton, Dudley, DY2 9SA. UK

| INFORMATION | Check your system with the GlucoZen.auto Control Solution under the following situations.<br>- When you want to check the performance of the meter and test strip.<br>- When you leave your test strip vial cap open for a long time.<br>- When you open a new vial of test strips.<br>- When you think that the test results are not accurate.<br>- When you drop the meter.<br>- When you suspect your meter or test strips are not working properly.<br>- When your blood glucose test results are not consistent. |
|---|---|
| CAUTION | - Use only the GlucoZen.auto Control Solution for the test.<br>- Check the expiration date printed on the control solution vial. Do not use if the expiration date is past. Discard the control solution on the expiration date printed on the vial or three months after first opening whichever comes first. When you first open a new vial of the control solution, count three months forward and write the expected discarding date on the label of the control solution vial for your convenience.<br>- The control solution, meter, and test strips should be kept at a room temperature prior to use. |

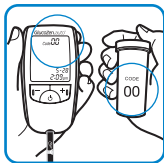| ⚠ CAUTION | - Do not drink the control solution.<br>- Tightly close the cap of control solution vial and store at a room temperature after the test. |
|---|---|
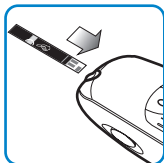
**1** **Insert a Test Strip**

Insert a test strip, with the printed side facing up, into the test port of the meter. Gently push it all the way in until it goes no further.
The meter will turn on automatically and beep. Then the code number and the BLOOD DROP ICON will appear. Make sure that the code number displayed on the meter matches the one on the test strip vial. If the code numbers match, you can start the test. If the code number on the meter doesn't match the one on the test strip vial, insert a new test strip and check the code number again.

| ⚠ CAUTION | Do not force the test strip into your meter.<br>This may cause malfunction. |
|---|---|
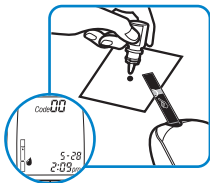
## 2 Apply Control Solution

Shake the control solution vial well. Prepare a drop of the control solution on a clean plate. Slowly let the side edge of the yellow window of the test strip touch the drop of the control solution following the finger symbol. Once the confirmation window fills completely, your meter will begin the countdown.

**TIP**

To ensure accurate test results
- Gently shake the control solution (vial) to ensure the control solution is mixed well before each test.
- Squeeze the vial to discard the first drop before the test.

## 3 Test Result Appears in 5 seconds

Your meter will display countdown from "5" to "1", then the test result will appear.

**INFORMATION**

Do not remove the test strip from your meter before you select the CONTROL SOLUTION ICON in the EVENT RECORD MODE. If you remove the test strip before making the selection, you cannot save the test result marked as the control solution test. See page 19-20 for more details.

| ⚠️ CAUTION | The Control Solution range printed on the test strip vial is for the GlucoZen.auto Control Solution only. It is used to check the performance of your meter and test strips. It is NOT a recommended range for your blood glucose level. |
| --- | --- |

**④ Compare Control Solution Test Results**

Compare the control solution test result to the control solution range printed on the test strip vial. The test result should fall within this range. Each vial of test strips may have a different control solution range. If the test result you get is not within this range, the meter and test strips may not be working properly. Repeat the control solution test. Refer to the GlucoZen.auto Test Strip Instruction for the use.

| 🔍 INFORMATION | Out-of-range test results may be caused by one or more of the following:<br>- Expired or contaminated control solution,<br>- Expired or damaged test strip,<br>- Use of control solution or test strip past its discarding date,<br>- Error in performing the test,<br>- Failure to shake the control solution vial well,<br>- Code number printed on the test strip vial does not match the one displayed on the meter,<br>- Meter, test strips or control solution are kept too warm or too cold,<br>- or Meter malfunction |
| --- | --- |

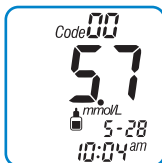| ⚠ CAUTION | If your control solution test results continue to fall outside the range printed on the test strip vial, the GlucoZen.auto Blood Glucose Monitoring System may not be working properly.<br>- If this is the case, do not use the system to test your blood glucose levels.<br>- Contact GlucoZen on customer care line: 0800 773 4865 or email: care@glucozen.co.uk |
|---|---|
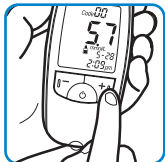
**⑤ Record the Control Solution Test Results in the Meter**

To record the control solution test results, press the +/- button of the meter to select CONTROL SOLUTION ICON. Press and release the power button if selection is completed. The control solution test results will be saved.
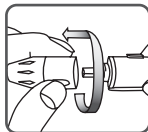
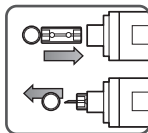| 🔍 INFORMATION | Record all the control solution test results with CONTROL SOLUTION ICON ' 🕮 ' to distinguish them from those of actual blood glucose tests in the meter memory. Recorded control solution test results will not be calculated in your result averages. |
|---|---|

### 1 Remove the cap

Turn the cap of the lancing device counter-clockwise to remove the cap.

### 2 Insert a Lancet into the Lancet Holder.

Insert the lancet firmly into the holder until it comes to a full stop. When the lancet is placed in the lancing device, twist off the protective disk of the lancet. Do not discard the protective disk of the lancet; it will be used to dispose the lancet safely after its use.
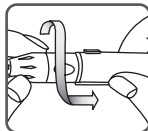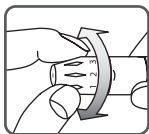
### 3 Replace the cap

Turn the cap of lancing device clockwise until it fits.

**⚠ CAUTION**

- Before using the lancing device, wash your hands in warm water with soap. Make sure to rinse and dry them thoroughly. Perspiration, dirt or water remaining on your hands may cause incorrect test results.
- Avoid using hand lotion or any other oily products before using the lancing device.

**4** **Adjust the Puncture Depth Setting**

The dial for setting the puncture depth is at the tip of the lancing device. Higher number indicates deeper puncture. Thus, dial to the lower number for thin skin.
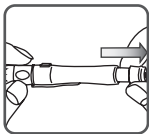
**5** **Charge the Lancing Device.**

Draw back the end part of lancing device until it clicks, and then release it.
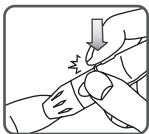
**6** **Lance your Finger**

Place the lancing device carefully on the tip of your finger and press the release button.
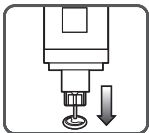
**7** **Remove the Used Lancet**

Place the protective disk on a flat surface. With the used lancet still in the lancing device, push the lancet needle completely into the protective disk. Push the lancet ejector forward with your thumb and simultaneously pull out the sliding barrel to dispose the used lancet in a proper bio-hazardous container.

| ⚠ CAUTION | - To reduce the risk of infection, never share a lancet or lancet pen with another person.<br>- Lancets are for single use only. Always use a new sterile lancet.<br>- Used strips, lancets and meter may be considered bio-hazardous waste in your area. Make sure to follow your healthcare professional's recommendations or local regulations for proper disposal. |
|---|---|

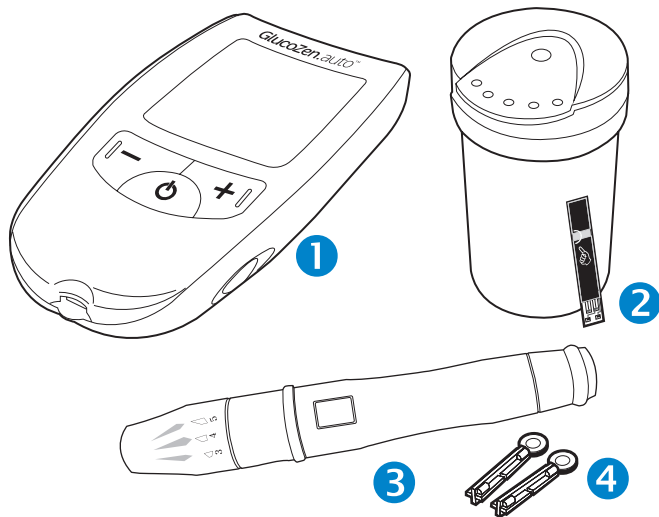| 🏭 Lancing Device Manufactured by<br>**CE**<br>GMMC<br>1112, 130, Digital-ro, Geumcheon-gu, Seoul, Korea | 🏭 Lancet Manufactured by<br>**CE**₁₃₇₀<br>SAEHANMED CORP.<br>Na-dong, Ga-dong, 331 Seongseok-ro, Ilsandong-gu, Goyang-si, Gyeonggi-do, Korea |
|---|---|

## RECOMMENDED AVAILABLE LANCET
GlucoZen Lancet available on prescription.

① GlucoZen.auto™ Meter
② GlucoZen.auto™ Test Strip
③ Lancing Device
④ GlucoZen Lancets

**1 Insert a Test Strip**

Insert a test strip, with the printed side facing up, into the test port of the meter. Push it all the way in until it goes no further. The meter will turn on automatically and beep. Then the code number and the BLOOD DROP ICON will appear. Make sure the code number displayed on your meter and the test strip code number match.

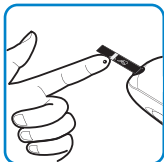| ⚠ CAUTION | Do not force the test strip into the meter. This may cause malfunction of the meter. |
|---|---|

**2 Obtain a Blood Drop**

Obtain a blood drop from your fingertip using the lancing device (see page 12-14) The blood sample must be at least 0.5 micro liters in volume [actual size ● ].

| TIP | Gently massage the fingertip to obtain a round drop of blood. Do not smear the blood sample. |
|---|---|

**3** **Apply the Blood Sample**

Apply the round drop of blood to the side edge of the yellow window of the test strip and then blood drop will be absorbed into the narrow channel. Touch and hold the blood drop to the side edge of the yellow window of test strip until blood completely fills the confirmation window and the meter beeps. Then, your meter will start the countdown.
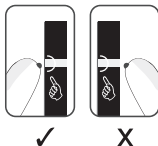
| ⚠ CAUTION | You should apply blood to the finger symbol on the test strip as directed.<br>- Do not put blood on the top of the test strip.<br>- Apply the blood drop to the side edge of the yellow window of the test strip. |
|---|---|

| ⚠ CAUTION | - If insufficient blood is inserted, Error message will be displayed. See the picture in the left for proper application of the required blood volume to perform the test properly.<br>- Even if the meter begins the countdown despite the fact that the confirmation window is not completely filled, do not apply more blood to the test strip. Discard the test strip and repeat the test with a new test strip. |
|---|---|
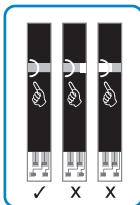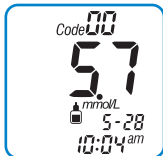
**4**

## Test Results Appear in 5 seconds

Once the meter completes the countdown from "5" to "1", your test result will appear on the meter display. If you remove the test strip immediately, only the test result (without recording the event) will be automatically saved in the meter memory. Recording the event with each test result may help with effective diabetes management. To enter the EVENT RECORD MODE, you may press +/- button of the meter before removing the test strip from the meter (See pages 19-20 for more details).

**INFORMATION** | If you do not apply a blood drop within 5 minutes, your meter will turn off automatically. Once the meter turns off, remove the test strip and then insert it back into your meter to turn on the meter.

**TIP** | After the test, press any of +/- button in the EVENT RECORD MODE before removing the test strip from your meter. Recording the event will lead you to more effective diabetes management.

For effective diabetes management, stored test results with your condition will help you and your healthcare professional to track changes in your blood glucose level.

**1**  **Press +/- Button after the Test**

Once the test result appears on the meter
display, press any of +/- button to enter the EVENT RECORD MODE.
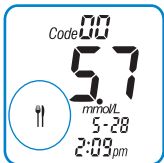
**2**  **Select the EVENT ICON**

There are 3 different EVENT ICONs: Post Meal, Pre Meal, and Control Solution.
Press +/- button to select an icon which correlates with the test result.
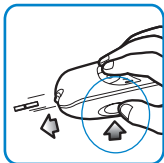
**3**  **Remove the Test Strip**

After the selection of an EVENT ICON, remove the used test strip. The used test strip will be discharged automatically by pushing the Ejector Button on the side of the meter. After discharging the used test strip, the test result with the EVENT ICON will be saved in the meter memory automatically.

| ⚠ CAUTION | Once you remove the test strip from the meter, you cannot go back to the EVENT RECORD MODE. Do not remove the test strip from the meter until selecting an EVENT ICON is completed. |
|---|---|

**POST MEAL ICON**

Select this icon when you have a test after meal (food intake).

**PRE MEAL ICON**

Select this icon when you have a test before meal.

**CONTROL SOLUTION ICON**

Select this icon in performing control solution tests or improper blood glucose test. Record all control solution tests with CONTROL SOLUTION ICON to distinguish them from blood glucose tests in the meter memory. Recorded control solution test results will not be calculated in your result averages.

The GlucoZen.auto Meter will display test result between 1.1~33.3 mmol/L.
If your test result is lower than 1.1 mmol/L, "Lo" will appear on the meter display.
If your test result is higher than 33.3 mmol/L, "HI" will appear on the meter display.

⚠ **CAUTION**

*Code* 00
*H1*
5-28
2:09pm

*Code* 00
*Lo*
5-28
2:09pm

- If "HI" or "Lo" appears instead of a test result, retest your blood glucose level immediately with a new test strip. If the same message appears, check the system with the GlucoZen.auto Control Solution. If your meter and test strip are working correctly, you must contact your healthcare professional immediately.

Blood glucose targets
It is important that the blood glucose levels being aimed for are as near normal as possible (that is in the range of those of a person who does not have diabetes).

These are: 3.5 ~ 5.5 mmol/I* before meals
less than 8 mmol/l, two hours after meals.

There are many different opinions about the ideal range to aim for. As this is so individual to each person, the target levels must be agreed between the person and their diabetes team. (Ref Diabetes UK, http://www.diabetes.org.uk)

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

The GlucoZen.auto Meter has a memory capacity to store up to 500 most recent test results with date, time and event.* It also provides you averages of your blood glucose test results over a period of time (Options: 0d, 7d, 14d, 21d, 28d, 60d, or 90d average). You can review the test results stored in the memory by the following steps.

**1** **Press +/- Button**

To enter the MEMORY MODE, press +/- button with the meter turned on.

*GlucoZen.auto does not allow you to delete test results

**INFORMATION**

Mem
- - -

If there is no test result, the meter will not display anything and +/- button will not operate.

**Avg  7d**

**5.7**

mmol/L

## 2 Indicate the Average Value

You can select the number of days for the average (0d, 7d, 14d, 21d, 28d, 60d, or 90d) in the SET MODE. "7d" shown in the left side indicates that the value 5.7 is a calculated average for the past 7 days.

**INFORMATION** When the whole test results' average is calculated, individual event records are not considered. The GlucoZen.auto Blood Glucose Monitoring System will use (33.3 mmol/L) for "HI" results, and (1.1 mmol/L) for "Lo" results.

## 3 Recall your Test Results

Press and release +/- button once to make the most recent test result appear on the meter display. Every time you press and release +/- button, the meter will display the next result up to 500 test results.

**TIP**   Press and hold +/- button in the MEMORY MODE in order to view the test results faster.

**INFORMATION**

Mem    1
5.7 mmol/L
5-28
2:09pm

Code 00
5.7 mmol/L
5-28
2:09pm
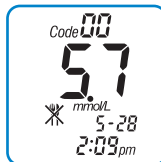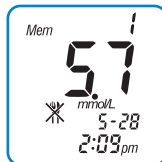
Without any button action for 3 seconds in the MEMORY MODE, then code number will be displayed.

**4** **Exit the MEMORY MODE**

Press and release the power button once to exit from the MEMORY MODE.

It is important to set the correct time and date. Having the correct time and date of each blood glucose test result will help you and your healthcare professional to track changes in your blood glucose level.

**INFORMATION** After replacing the battery, you should update the time and date setting.

**1** **Press and Hold the Power Button for 3 seconds**
With the meter turned on, press and hold the power button until "SET" appears on the meter. Release the power button to enter the SET MODE.

**INFORMATION** To exit the SET MODE at any time, press and hold the power button for 3 seconds. The settings you have already made will be saved.
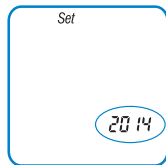
**2** **Set the Year**
The Year flashes, press and release +/- button to adjust the year until the correct year  appears on the meter display. If you press and release the power button in SET MODE, the meter will advance to the Month Setting.

**TIP** Press and release the power button in order to advance to the next setting steps in the SET MODE. Press and release +/- button to adjust the number in the SET MODE. To move faster, press and hold +/- button.

**3 Set the month**

The Month flashes. Press and release +/- button until you get the correct month. If you press and release the power button, the meter will advance to the Day Setting.
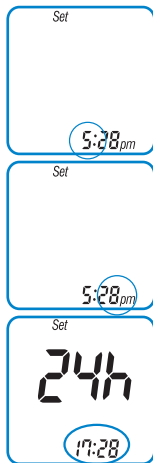
**4 Set the Day**

The Day flashes. Press and release +/- button until you get the correct day. If you press and release the power button, the meter will advance to the Date Format Setting.

**5 Set the Date Format**

The Date flashes. Press and release +/- button until you get the date format that you want. If you press and release the power button, the meter will advance to the Hour Setting.

**6** Set the Hour

The Hour flashes. Press and release +/- button until you get the correct hour. If you press and release the power button, the meter will save hour and advance to the Minutes Setting.

**7** Set the Minutes

The Minutes flash. Press and release +/- button until you get correct minute. If you press and release power button, the meter will advance to the Time Format Setting.

**8** Set the Time Format

The "12H" or "24H" flashes. Press and release +/- button to adjust until you get the correct time format.

**9** ### Set the Average Period

The Average Period flashes. Press and release +/- button until you get the period of average setting that you want (0,7,14,21,28,60,or 90). If you press and release the power button, the meter will advance to the Beep Setting.

**10** ### Set the Beep

When "ON" or "OFF" flashes, press +/- button, then you can set the beeper 'On' or 'Off'. If you set it 'On', Press and release the power button, the meter will advance to the Alarm Setting.
If you set it 'Off', you don't need to set the alarm and just finish the SET MODE.
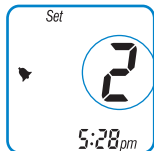
**11** ### Set the Alarm (up to 4 different Alarms a day)

The Alarm times flash. Press and release +/- button until you get the alarm times (0 to 4th) setting that you want. If you press and release the power button, the meter will advance to the Alarm Time Setting.
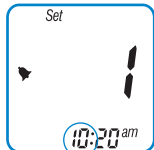
**12** ### Set the Alarm Time

The Hour of the Alarm Time flashes. Press and release +/- button to set the alarm time the same as the Time Setting (⑥-⑦).

**13** ### Save the Setting Information

Press and release the power button, and then the meter will turn off. The setting information you entered will be saved.

**TIP**

Four different alarms can be set. You can continually set alarm right after the first setting. Press and release the power button after you complete the first alarm time setting. Then "2" appears, you can repeat to set the next alarm time.

A battery(CR2032) will provide you enough power to perform about 1,000 tests.
The meter will alert you when the energy level is getting low by displaying the message
( 🔋 ). In this case you can test a few more times but the battery should be replaced to
new one as soon as possible. If "bAt" appears on the meter display, the meter will not
operate. The battery must be immediately replaced.
If you have previously registered your meter please contact GlucoZen Ltd for a
free replacement battery.

**⚠ CAUTION** Always turn off the meter before replacing the battery. Replacing the battery with the meter power on may lead to malfunction of the meter.

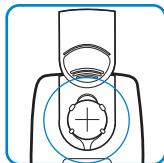① **Turn off the Meter.**
Press the power button to turn off the meter.
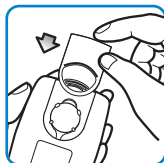
**2** **Remove the Battery Cover**

Press down on the battery cover then slide it out. The battery cover will be released.

**3** **Replace the Battery**

Remove the old battery and put the new one with "+" sign facing up.

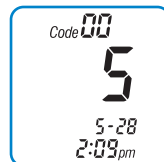**4** **Close the Battery Cover**

Slide the battery cover back into place until it clicks into the meter.

**Message**

| | | | |
|---|---|---|---|
| SetAvg MemCode 888 mmol/L 88888 88:88 am/pm | 5-28 2:09pm | Code 00 5-28 2:09pm | Code 00 5 5-28 2:09pm |
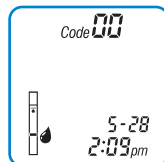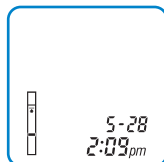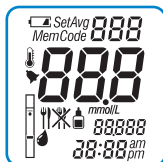
**What it means.**

| System check. This display always appears when you press the power button to turn on the meter. | The meter is ready for you to insert a test strip. | The meter is ready for a blood drop or control solution. (This is an example of a code number stored in the meter.) | The meter displays countdown from 5 to 1, while calculating a blood glucose test result. |
|---|---|---|---|

**Action**

| You should check that your meter matches the example exactly every time your meter turns on. Do not use the meter if the display check screen does not exactly match the example. Please contact GlucoZen.* | Insert a test strip into the test port of your meter. Make sure the code number displayed on the meter matches the one on the test strip vial. | Apply a blood sample to the test strip.(See pages 15-18 for how to test your blood glucose level) | No action is required. |
|---|---|---|---|

*Contact GlucoZen on customer care line: 0800 773 4865 or email: care@glucozen.co.uk
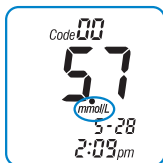
| | | | |
|---|---|---|---|
| *Code* 00 5.7 mmol/L 5-28 2:09pm | *Code* 00 5.7 mmol/L 5-28 2:09pm | *Code* 00 HI 5-28 2:09pm | *Code* 00 Lo 5-28 2:09pm |
| A blood glucose test result in mmol/L | System is ready to record the EVENT ICON  which correlate with your test result. | Your blood glucose result is higher than 33.3 mmol/L. | Your blood glucose result is lower than 1.1 mmol/L. |
| No action is required. | Select an EVENT ICONs using +/- button before discarding the used test strip. | Repeat the test using a new test strip and/or check the system with the GlucoZen.auto Control Solution. If the test result is "HI" again even though your system is working correctly, contact your healthcare professional immediately. | Repeat the test using a new test strip and/or check the system with the GlucoZen.auto Control Solution. If the test result is "Lo" again  even though your system is working correctly, contact your healthcare professional immediately. |

|  | Mem **5.7** mmol/L 5-28 10:24 am | 5-28 2:09 pm | **bAt** 5-28 2:09 pm | Avg 7d **5.7** mmol/L |
|---|---|---|---|---|
| **Message** | | | | |
| **What it means.** | A blood glucose test result stored in the memory. | Battery is low but you can still perform a few more tests. | The energy level of the battery is too low to provide accurate test results. | The average of blood glucose test results for the past 7 days. |
| **Action** | No action is required. | Turn off the meter and replace the battery as soon as possible. | Turn off the meter and replace the battery immediately. | No action is required. |
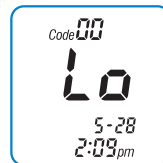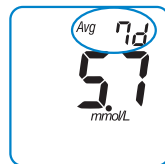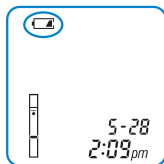
Mem
- - -

Er 1

Er2

Er3

Er4
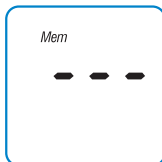
| No test result in memory. | The meter is used outside the proper range of temperature. | A used test strip was inserted in the test port. | There may be a problem with the test strip. It may have been damaged or removed during testing. | The blood sample or control solution was improperly applied. |
|---|---|---|---|---|
| No action is required. | Leave the meter at a temperature between 10~40℃ (50~104℉) for at least 30 minutes before repeating the test. | Retest with a new test strip. | Retest with a new test strip. Do not remove the test strip until test result appears on the meter display. | Retest with a new test strip. |

| $Er5$ | $Erb$ | $Er7$ | $Er8$ | $Er9$ |
|---|---|---|---|---|
| The meter has an internal electric circuit problem. | The meter has a problem with strip connection. | The meter has a problem with strip connection. | Not enough blood or control solution was drawn into the test strip for a test or was applied after the test was started. | Blood has been applied to the wrong side of the test strip |
| Contact GlucoZen* | Contact GlucoZen* See Troubleshooting Guide. | Contact GlucoZen* See Troubleshooting Guide. | Retest with a new test strip. | Apply blood to the correct side of a new test strip. |

*Contact GlucoZen on customer care line: 0800 773 4865 or email: care@glucozen.co.uk

**Troubleshooting Guide**

| Troubleshooting | Cause | Action |
|---|---|---|
| 1. The meter does not turn on after inserting a test strip. | Battery is dead. | Replace the battery. |
| | The battery is installed incorrectly or there is no battery in the meter. | Check if battery is correctly installed with the positive "+" sign facing up. (See pages 31-32) |
| | The test strip is inserted upside down or incompletely. | Insert the test strip correctly with the printed side facing up. |
| | The meter may not be working properly. | Contact GlucoZen*. |
| 2. The meter does not start after applying the blood sample. | Not enough blood sample. | Retest with a new test strip. |
| | The test strip may be damaged. | Retest with a new test strip. |
| | Blood sample is applied after the meter was automatically turned off (5 minutes after last action). | Retest with a new test strip. |
| | The meter may not be working properly. | Contact GlucoZen*. |

*Contact GlucoZen on customer care line: 0800 773 4865 or email: care@glucozen.co.uk

| | |
|---|---|
| Product Name | GlucoZen.auto™ Blood Glucose Monitoring System |
| Model Name | AGM-4000 |
| Assay Method | Electrochemical method |
| Sample Type | Fresh capillary, venous whole blood |
| Sample Volume | 0.5 $\mu\ell$ |
| Measurement Range | 1.1~33.3 mmol/L |
| Measurement Time | 5 seconds |
| Calibration | Plasma-equivalent |
| Battery Type | One 3-volt lithium battery (coin cell type CR2032) |
| Battery Life | Approximately 1,000 tests |
| Unit of Measurement | mmol/L |
| Operating Ranges | Temperature: 10~40℃ (50~104℉) |
| | Relative Humidity: Less than 85% |
| | Altitude: Up to 2500m (8202 feet) |
| | Hematocrit: 20~60% |
| Dimension | 3.5 X 49.0 X 17.5 (mm), 3.7 X 1.9 X 0.69 (inches) |
| Weight | Approximately 40g or 1.4 oz. (with battery) |
| Display | 37.0 X 42.0 (mm) LCD, 1.5 X 1.7 (inches) LCD |
| Memory Capacity | 500 test results (with date, time & event) |
| PC Interface | USB |
| Automatic Shutoff | 5 minutes after last action |

The GlucoZen.auto Blood Glucose Monitoring System complies with the requirements of EN ISO 15197:2015. The performance of the GlucoZen.auto Test Strips 3 lots has been evaluated in clinical tests.

Accuracy:
The accuracy of the GlucoZen.auto Blood Glucose Monitoring System was assessed by comparing blood glucose test results obtained from 100 diabetic patients with those obtained using a YSI Model 2300 STAT Plus Glucose Analyzer.

**For glucose concentration < 5.55 mmol/L**

| Lot | Within ± 0.28 mmol/L | Within ± 0.56 mmol/L | *Within ± 0.83 mmol/L* |
|---|---|---|---|
| **1st Lot** | 36/56 (64.3%) | 55/56 (98.2%) | 56/56 (100%) |
| **2nd Lot** | 39/56 (69.6%) | 55/56 (98.2%) | 56/56 (100%) |
| **3rd Lot** | 35/56 (62.5%) | 56/56 (100%) | 56/56 (100%) |
| **Total(3Lots)** | 110/168 (65.5%) | 166/168 (98.8%) | 168/168 (100%) |

**For glucose concentration ≥ 5.55 mmol/L**

| Lot | Within ± 5 % | Within ± 10 % | *Within ± 15 %* |
|---|---|---|---|
| **1st Lot** | 98/144 (68.1%) | 139/144 (96.5%) | 143/144 (99.3%) |
| **2nd Lot** | 82/144 (56.9%) | 132/144 (91.7%) | 142/144 (98.6%) |
| **3rd Lot** | 92/144 (63.9%) | 140/144 (97.2%) | 144/144 (100%) |
| **Total(3Lots)** | 272/432 (63%) | 411/432 (95.1%) | 429/432 (99.3%) |

**System accuracy results for glucose concentrations
between 1.52 mmol/L and 26.14 mmol/L**

| *Within ± 0.83 mmol/L or ± 15 %* |
| --- |
| 597/600 (99.5%) |

Measurement precision:

| Measurement Repeatability (using venous whole blood): | | | Intermediate Measurement Precision (using control soution): | | |
| --- | --- | --- | --- | --- | --- |
| Level (mmol/L) | STD (mmol/L) | CV (%) | Level (mmol/L) | STD (mmol/L) | CV (%) |
| 2.22 | 0.17 | 7.9 | 2.06 | 0.13 | 6.4 |
| 4.31 | 0.24 | 5.6 | 6.00 | 0.19 | 3.2 |
| 6.83 | 0.24 | 3.5 | 18.33 | 0.38 | 2.1 |
| 10.94 | 0.37 | 3.3 | | | |
| 17.33 | 0.59 | 3.4 | | | |

User Performance Evaluation:
A study evaluating glucose values from fingertip capillary blood samples obtained by 112 lay persons showed the following results:
100 % within ± 0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L,
and 100 % within ± 15 % of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L.

Interfering Substances:
The table below shows the list of the tested electro-oxidizable constituents of blood, which are potential interferences. The interferences except Acetaminophen, PAM, uric acid, and xylose were tested at more than their therapeutic concentrations and their effects on GlucoZen.auto test results were less than ± 0.55 mmol/L at glucose concentrations below 5.55 mmol/L and less than ± 10% at glucose concentrations above 5.55 mmol/L.

| No. | Interference | Upper Limit of Therapeutic concentration (mmol/L) | Test concentration (mmol/L) | No. | Interference | Upper Limit of Therapeutic concentration (mmol/L) | Test concentration (mmol/L) |
|---|---|---|---|---|---|---|---|
| 1 | Acetaminophen | 0.20 | 0.93 | 13 | Ibuprofen | 0.34 | 2.43 |
| 2 | Ascorbic acid | 0.11 | 0.34 | 14 | Icodextrin | 0.29 | 0.29 |
| 3 | Bilirubin (UC) | 0.02 | 0.43 | 15 | L-DOPA | 0.01 | 0.10 |
| 4 | Cholesterol, total | 5.20 | 13.06 | 16 | Maltose | 2.92 | 29.21 |
| 5 | Creatinine | 0.11 | 0.88 | 17 | Methyl-DOPA | 0.03 | 0.07 |
| 6 | Dopamine | 0.002 | 0.01 | 18 | PAM | 3.03 | 0.38 |
| 7 | EDTA | 0.34 | 6.85 | 19 | Salicylate | 2.17 | 5.79 |
| 8 | Galactose | 0.28 | 0.89 | 20 | Tolazamide | 0.001 | 0.51 |
| 9 | Gentisic acid | 0.04 | 0.65 | 21 | Tolbutamide | 0.40 | 3.70 |
| 10 | Glutathione | 1.05 | 3.03 | 22 | Triglycerides | 3.73 | 37.75 |
| 11 | Hemoglobin | 0.03 | 3.10 | 23 | Uric acid | 0.48 | 0.59 |
| 12 | Heparin(140u/mg) | 0.05 | 0.51 | 24 | Xylose | 1.33 | 0.60 |

Depending on the concentration, below substances may affect the test results.

    Acetaminophen         > 0.93 mmol/L
    PAM                   > 0.38 mmol/L
    Uric acid             > 0.59 mmol/L
    Xylose                > 0.60 mmol/L

CAUTION

This product fulﬁlls the requirements of Directive 98/79/EC on in vitro diagnostic medical device.

For in vitro diagnostic use

Do not dispose the instrument in the urban waste.

Consult User Manual

# MEMO

# MEMO

A812DE601
08/2017

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www.glucozen.com

⬛ Manufactured by
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