CE 0123

EC REP

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G1 Advance

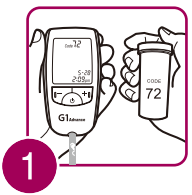
Blood Glucose Monitoring System

User Manual

AGM-4000

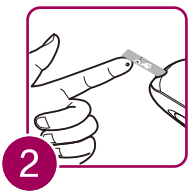
* TEST SUMMARY

This summary is intended only as a quick reference and is not a substitute for the **G1 Advance** Blood Glucose Monitoring System User Manual. Please read the entire User Manual before you begin testing.



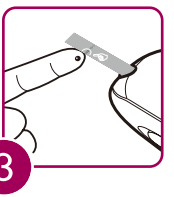
1

Insert a test strip. The monitor will automatically turn on. Check the code number. The code number displayed on the monitor 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 monitor will begin the countdown.

4

The blood glucose result will be displayed on the monitor in just 5 seconds.

Thank you for using the G1 Advance 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 monitor.

* PRECAUTIONS

Intended Use

For Self-testing: **G1 Advance** Blood Glucose Monitoring System is for quantitative blood glucose testing in fresh capillary whole blood drawn from the fingertips. **G1 Advance** Blood Glucose Monitoring System is for testing outside the body (in vitro diagnostic use). **G1 Advance** Blood Glucose Monitoring System is intended for self-testing by diabetic lay users to improve management of their blood glucose level. **G1 Advance** Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes mellitus, or for neonatal use.

For professional use: **G1 Advance** Blood Glucose Monitoring System is for quantitative blood glucose testing in venous whole blood and fresh capillary whole blood drawn from the fingertips. **G1 Advance** Blood Glucose Monitoring System is for testing outside the body (in vitro diagnostic use). **G1 Advance** Blood Glucose Monitoring System is intended for near-patient testing by healthcare professionals to improve management of patient's blood glucose level. **G1 Advance** Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes mellitus, or for neonatal use.

Healthcare Professionals

Blood glucose determination with venous blood must be performed within 15 minutes of sample collection to avoid error from glycolysis. In order to avoid the effects of sample temperature, keep the venous blood sample to body temperature. The blood should be collected in EDTA or heparin containing tubes. Do not shake the tube vigorously.

Test Principle

The **G1 Advance** Blood Glucose Monitoring System is based on measurement of electrical currents caused by the reaction of glucose with the reagents on the gold electrodes of the test strip. 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 the **G1 Advance** Blood Glucose Monitor.

Precautions for Use

- The **G1 Advance** Blood Glucose Monitor is designed for use with the **G1 Advance** Test Strips (manufactured by All Medicus Co., Ltd.) only.
- The **G1 Advance** 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 **G1 Advance** 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 monitor from a cold to warm area or from a warm to cold area, let the monitor sit for about 30 minutes to adjust to the room temperature.
- Do not drop the monitor.
- 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 a dry place with temperature ranging between 2°C~30°C (36°F~86°F).
- 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 strips with wet hands.
- Do not use the test strips 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 **G1 Advance** Blood Glucose Monitor at a temperature between 0°C~40°C (32°F~104°F).
- Store the **G1 Advance** Blood Glucose Monitor at a place where relative humidity is less than 85%.
- Keep the **G1 Advance** Blood Glucose Monitor in a sanitary environment
- Keep the monitor out of direct sunlight.
- Keep the test port away from dirt, blood or water.
- Do not store your monitor and the test strips in the car, bathroom or refrigerator (sensitive to temperature and humidity).
- Keep the monitor, test strip vials and lancing materials away from children.
- Clean the outside of the monitor using a moist (not wet) cloth or tissue with isopropyl alcohol or mild detergent with water. Do not immerse the monitor in water or other liquid.

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G1 Advance Blood Glucose Monitoring System

1. Carrying case
2. User Manual
3. **G1 Advance** Blood Glucose Monitor
4. **G1 Advance** Test Strips
5. Battery
6. Lancing Device
7. Lancets

Upon request of distributor, actual package may consist of all or part of items described above.

❶ LCD Display

- Test results, icons, symbols and simple messages appear here.

❷ +/- Button

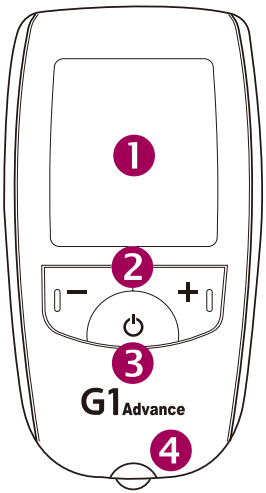
- Recall the stored test results in the MEMORY MODE.
- Select the event in the EVENT RECORD MODE.
- Change the date and time in the SET MODE.

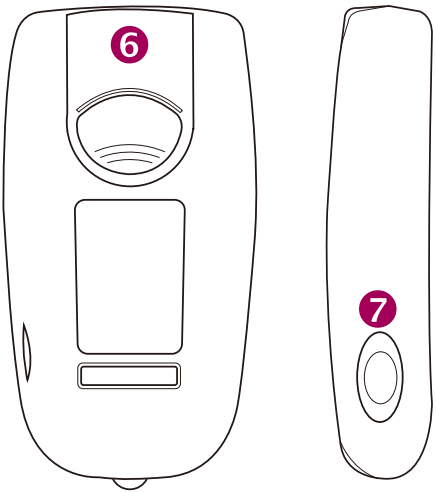
❸ Power Button

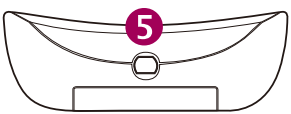
- Turn the monitor on/off.
- Enter into SET MODE while pressing the power button for the 3 seconds.
- Delete all the stored test results in the MEMORY MODE.

❹ Test Port

- Insert the **G1 Advance** Test Strip for testing. Then the monitor turns on and displays the code number automatically.







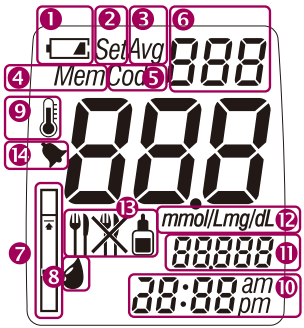
5 Data Port

- Transfer your test results from the monitor to a computer.

6 Battery Cover

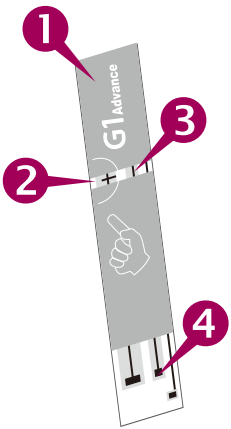
7 Test Strip Ejector Button

G1 Advance Blood Glucose Monitor LCD Display



1. Battery life.
2. SET MODE.
3. AVERAGE MODE.
4. MEMORY MODE.
5. CODE MODE
6. MEMORY and CODE NUMBER.
   The monitor displays the current memory order number in the MEMORY MODE.
   The monitor displays the current code number in the CODE MODE.
7. STRIP ICON.
   When the STRIP ICON blinks, insert a test strip into the monitor.
8. BLOOD DROP ICON.
   When the BLOOD DROP ICON blinks, apply blood sample.
9. TEMPERATURE ICON.
   When the monitor 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 MEASUREMENT.
13. EVENT ICON.
    If you choose the event icon which relates to test results, it helps to manage glucose levels more effectively.
14. ALARM.
    You can set up to four different alarms. Each alarm rings for 10 seconds.

G1 Advance Test Strip



❶ Grip

- Hold this part to insert or remove the test strip.

❷ Yellow Side-edge

- Apply blood sample here; blood is absorbed automatically.

❸ Confirmation window (Reaction chamber)

- Make sure the confirmation window fills completely.

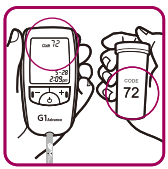
❹ Gold electrodes

- Insert into the test port.

The code numbers are used to calibrate your monitor with the test strips for accurate test results. Whenever you test, you must check if the code number displayed on the monitor matches the one on the test strip vial.

1 Insert the G1 Advance Test Strip

Insert a test strip into the test port and the monitor 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 monitor matches the one on the test strip vial. If the code numbers match, you can begin the test.

! CAUTION

- If the code number on the monitor doesn't match the one on the test strip vial, insert a new test strip and check the code number again.
- If they do not match again, please contact your local distributor.

Checking Your System with the G1 Advance Control Solution

The control solution test checks the performance of your monitor and test strips. The **G1 Advance** Control Solution contains a measured amount of glucose that reacts with the **G1 Advance** Test Strips.

The control solution test confirms that your monitor and test strips are working correctly. Compare your control solution test results with the ranges 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.

INFORMATION

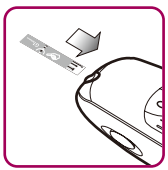
Check your system with the **G1 Advance** Control Solution under the following situations.
- When you want to check the performance of the monitor and test strips.
- When you leave your test strip vial cap open for a long time.
- When you open a new vial of the test strips.
- When you think that the test results are not accurate.
- When you drop the monitor.
- When you suspect your monitor or test strips are not working properly.
- When your blood glucose test results are not consistent.

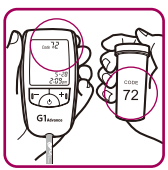
CAUTION

- Use only the **G1 Advance** Control Solution for the test.
- 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 the 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.
- The control solution, monitor and test strips should be kept at room temperature prior to use.

CAUTION

- Do not drink the control solution.
- Tightly close the cap of control solution vial and store at room temperature after the test.





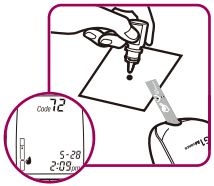
1 Insert a Test Strip

Insert a test strip, with the printed side facing up, into the test port of the monitor. Gently push it all the way in until it goes no further.

The monitor 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 monitor matches the one on the test strip vial. If the code numbers match, you can start the test. If the code number on the monitor 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 monitor. This may cause a malfunction



2 Apply Control Solution

Shake the control solution vial well. Put 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 monitor 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 monitor will display countdown from “5” to “1”, then the test result will appear.

INFORMATION

Do not remove the test strip from your monitor 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 **G1 Advance** Control Solution only. It is used to check the performance of your monitor 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 the test strips may have a different control solution range. If the test result you get is not within this range, the monitor and test strips may not be working properly. Repeat the control solution test. Refer to the **G1 Advance** Test Strips Package Insert.

INFORMATION

Out-of-range test results may be caused by one or more of the following:

- Expired or contaminated control solution,
- Expired or damaged test strip,
- Use of control solution or test strip past its expiration date,
- Error in performing the test,
- Failure to shake the control solution vial well,
- Code number printed on the test strip vial does not match the one displayed on the monitor,
- Monitor, test strips or control solution are kept too warm or too cold,
- or Monitor malfunction.

CAUTION

If your control solution test results continue to fall outside the range printed on the test strip vial, the **G1 Advance** Blood Glucose Monitoring System may not be working properly.
- If this is the case, do not use the system to test your blood glucose level.
- Contact your local distributor.

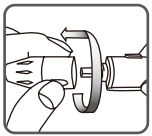
5 Record the Control Solution Test Results in the Monitor

To record the control solution test results, press any of +/- buttons on the monitor 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 the CONTROL SOLUTION ICON ‘ ’ to distinguish them from those of actual blood glucose tests in the monitor memory. Recorded control solution test results will not be calculated in your result averages.

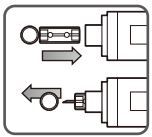
* The reference values of the control solutions are obtained using a validated test method. This test method is referenced to the glucose oxidase method and is traceable to a NIST Reference material 917c.



1

Remove the cap

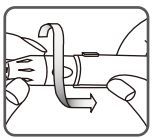
Turn the cap of the lancing device counter-clockwise to remove the cap.



2

Insert a Lancet into the Lancet Holder.

Insert a 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

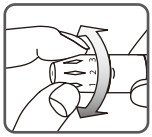
Replace the cap

Turn the cap of lancing device clockwise until it fits.

! CAUTION

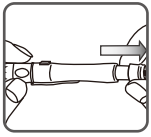
– Before using the lancing device, wash your hands in warm water with soap. Make sure to rinse and dry them thoroughly. Perspiration, dirt or water remaining on your hands may cause incorrect test results.

- Avoid using hand lotion or any other oily products before using the lancing device.



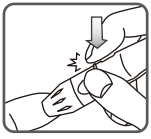
4 Adjust the Puncture Depth Setting

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.



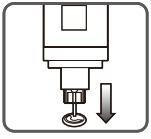
5 Charge the Lancing Device.

Pull back the end part of the 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

Push the lancet ejector forward with the thumb, and then easily can remove the used lancet. Also you can dispose of the used lancet in a proper biohazard container.

CAUTION

- To reduce the risk of infection, never share a lancet with another person.
- Lancets are for single use only. Always use a new sterile lancet.
- Used test strips, lancets and monitor 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

CE

Sterilance Medical (Suzhou) Inc.
No.168 PuTuoShan Road, New District, 215153, Suzhou, Jiangsu, China

EC REP

Emergo Europe B.V.
Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands

Lancet Manufactured by

CE 0197

Tianjin Hua Hong Technology Co.,Ltd.
A01, Plant B, No.278 Hangkong Road, Tianjin Pilot Free Trade Zone (Air Port Industrial Park) Tianjin China, 300308, China

EC REP

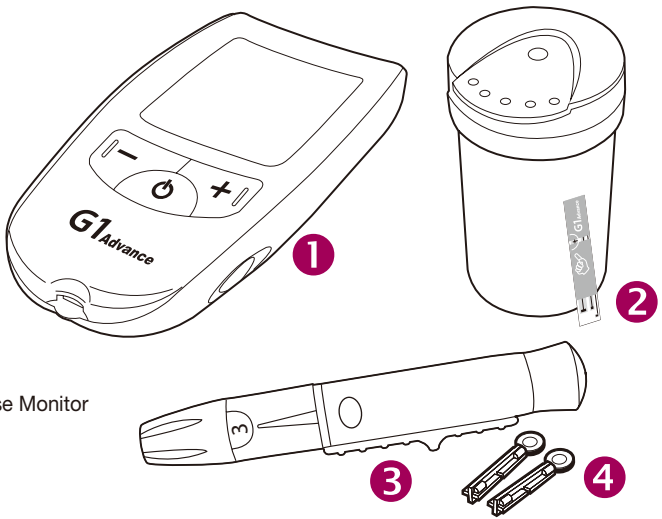
Shanghai International Holding Corporation GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, Germany

RECOMMENDED AVAILABLE LANCETS

Some general sterilized lancets are BD-Ultra Fine, E-Z Ject, G-P Lite, Microlet, Monolet, Soft Touch, Ultra TLC, Unilet GP and Greenlan.

Note: Lancets that are not recommended in the above list may not work properly with the lancing device due to their dimensions. Please contact your supplier to make sure you are using proper lancets.

Performing the Blood Glucose Test



1. **G1 Advance** Blood Glucose Monitor
2. **G1 Advance** Test Strip
3. Lancing Device
4. Lancets

1 Insert a Test Strip

Insert a test strip, with the printed side facing up, into the test port of the monitor. Push it all the way in until it goes no further. The monitor 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 monitor and the test strip code number match.

CAUTION

Do not force the test strip into the monitor. This may cause malfunction of the monitor.

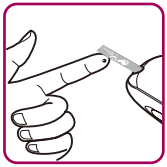
2 Obtain a Blood Drop

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

Before puncturing, gently massage the fingertip to obtain a round drop of blood.
Do not smear the blood sample.

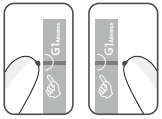
Performing the Blood Glucose Test



3 Apply the Blood Sample

Apply the round drop of blood sample to the side-edge of the yellow window of the test strip and the blood sample will be absorbed into the narrow channel. Hold until the blood sample completely fills the confirmation window and the monitor beeps. Then your monitor will start the countdown.

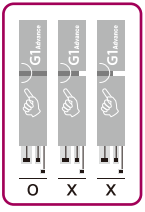
! CAUTION



You should apply the blood to the finger symbol on the test strip as directed.

- Do not put blood on the top of the test strip.
- Apply the blood drop to the side-edge of the yellow window of the test strip.

! CAUTION



- If there is an insufficient amount of blood in the confirmation window, you may get an inaccurate test result. See the picture on the left for proper application of the required blood volume to perform the test properly.
- Even if the monitor begins the countdown without the confirmation window 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 monitor completes the countdown from “5” to “1”, your test result will appear on the monitor display. If you remove the test strip immediately, only the test result (without recording the event) will be automatically saved in the monitor memory. Recording the event with each test result may help with effective diabetes management. To enter the EVENT RECORD MODE, press +/- button of the monitor before removing the test strip from the monitor (See pages 19-20 for more details).

INFORMATION

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

TIP

After the test, press any of +/- buttons in the EVENT RECORD MODE before removing the test strip from your monitor. Recording the event with the test result can lead you to more effective diabetes management.

Entering the EVENT RECORD MODE

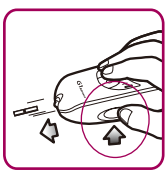
For effective diabetes management, stored test results with the event will help you and your healthcare professional to track changes in your blood glucose level.

1 Press +/- Button after the Test

Press +/- button after the test. Once the test result appears on the monitor display, press any of +/- buttons 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 relates to the test result.



3 Remove the Test Strip

After the selection of the 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 monitor. After discharging the used test strip, the test result with the EVENT ICON will be saved in the monitor memory automatically.

CAUTION

Once you remove the test strip from the monitor, you cannot go back to the EVENT RECORD MODE. Do not remove the test strip from the monitor until selecting the EVENT ICON is completed.

POST MEAL ICON

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

PRE MEAL ICON

Select this icon when you have a test before a meal.

CONTROL SOLUTION ICON

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

Understanding Your Test Results

The **G1 Advance** Blood Glucose Monitor will display test results between 20 and 600 mg/dL (1.1~33.3 mmol/L). If your test result is lower than 20 mg/dL (1.1 mmol/L), "Lo" will appear on the monitor display. If your test result is higher than 600 mg/dL (33.3 mmol/L), "HI" will appear on the monitor display.

CAUTION

- 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 **G1 Advance** Control Solution. If your monitor and test strips are working correctly, you must contact your healthcare professional immediately.

Expected Values[1]

Criteria for the diagnosis of non-diabetes
Fasting plasma glucose (FPG) 70 ~ 99 mg/dL (3.9 ~ 5.5 mmol/L)
Two hours after meals plasma glucose < 140 mg/dL (7.8 mmol/L)

Criteria for the diagnosis of diabetes
Fasting plasma glucose (FPG) >126 mg/dL (7.0 mmol/L)
Two hours after meals plasma glucose >200 mg/dL (11.1 mmol/L)

Categories of increased risk for diabetes (prediabetes)
Fasting plasma glucose (FPG) 100~ 125 mg/dL (5.6 ~ 6.9 mmol/L)
Two hours after meals plasma glucose 140 ~ 199 mg/dL (7.8 ~ 11.0 mmol/L)

Reference

1. American Diabetes Association: Clinical Practice Recommendations (2013) Diabetes Care, Vol 36, Supplement 1, p. S1-S100.

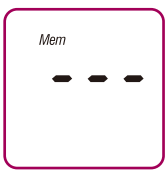
The **G1 Advance** Blood Glucose Monitor has a memory capacity to store up to 500 most recent test results with the date, time and event. It also provides you the averages of your blood glucose test results over a period of days (Options: 0d, 7d, 14d, 21d, 28d, 60d or 90d average). You can review the test results stored in the memory by the following steps.

1

Press +/- Button

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

INFORMATION



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

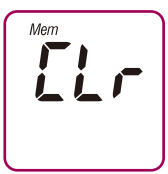
2 Indicate the Average Value

You can select the number of days for the average (0d, 7d, 14d, 21d, 28d, 60d or 90d) in the SET MODE. “7d” shown on the left side indicates that the value 96 is the calculated average for the past 7 days.

INFORMATION

When the test results' average is calculated, individual event records are not considered. The **G1 Advance** Blood Glucose Monitoring System will use 600 mg/dL (33.3 mmol/L) for “HI” results, and 20 mg/dL (1.1 mmol/L) for “Lo” results.

TIP



You can delete all the stored test results in the monitor memory after the average value is displayed. Press and hold the power button for 5 seconds until “CLr” flashes.

3 Recall your Test Results

Press and release +/- button once to make the most recent test result appear on the monitor display. Every time you press and release +/- button, the monitor 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

Without any button action for 3 seconds in the MEMORY MODE, the code number will be displayed.

TIP

To delete an individual test result in the MEMORY MODE, press and hold the power button for 5 seconds until "dEL" flashes 3 times.

4 Exit the MEMORY MODE

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

The **G1 Advance** Blood Glucose Monitor comes with the date, time, alarm (0), average day (7d) and unit of measurement (mg/dL) preset. However, if you need to change the setting of the monitor, or if you replace the battery, you need to enter the SET MODE and reset. It is important to set the correct date and time. Having the correct date and time 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 date and time setting.

1 Press and Hold the Power Button for 3 seconds

With the monitor turned on, press and hold the power button until "SET" appears on the monitor. Release the power button to enter the SET MODE.

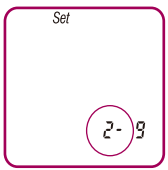
INFORMATION To exit the SET MODE at any time, press and hold the power button for 3 seconds. The settings you have already made will be saved.

2 Set the Year

The Year flashes. Press and release +/- button until the correct year appears on the monitor display. If you press and release the power button, the monitor will save and advance to the Month Setting.

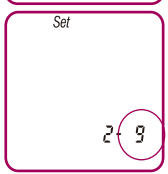
TIP

Press and release the power button 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.



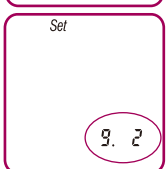
3 Set the month

The Month flashes. Press and release +/- button until you get the correct month. If you press and release the power button, the monitor will save and 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 monitor will save and advance to the Date Format Setting.



5 Set the Date Format

The Date Format flashes. Press and release +/- button until you get the date format of your choice. If you press and release the power button, the monitor will save and advance to the Time Setting.

6 Set the Hour

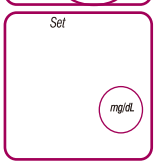
The Hour flashes. Press and release +/- button until you get the correct hour. If you press and release the power button, the monitor will save and advance to the Minutes Setting.

7 Set the Minutes

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

8 Set the Time Format

The “12H” or “24H” flashes. Press and release +/- button until you get the time format of your coice. If you press and release the power button, the monitor will save and advance to the Unit of Measurement Setting.



9 Set the Unit of Measurement

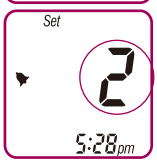
The Unit of Measurement (mg/dL or mmol/L) flashes. Press and release +/- button until you get the unit measurement of your choice. If you press and release power button, the monitor will save and advance to the Average Period Setting.

10 Set the Average Period

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

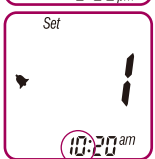
11 Set the Beep

When “ON” or “OFF” flashes, press +/- button to set the beeper 'On' or 'Off'. If you set it 'On', press and release the power button, then the monitor will save and advance to the Alarm Setting.
If you set it 'Off', you don't need to set the alarm and just finish the SET MODE.



12 Set the Alarm Frequency (up to 4 different Alarms a day)

The Alarm Frequency flashes. Press and release +/- button until you get the alarm frequency (0 to 4 times) of your choice. If you press and release the power button, the monitor will save and advance to the Alarm Time Setting.



13 Set the Alarm Time

The Hour of the Alarm Time flashes. Follow the Time Setting steps (⑥-⑦) to set the Hour and the Minutes of the Alarm Time.

14 Save the Setting Information

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

TIP

A total of four different alarms can be set. You can continually set the alarm right after setting the first one. Press and release the power button after you set the first alarm time, then “2” appears on your monitor display. You can repeat the steps to set the next alarm time.

Installing Battery

A battery (CR2032) will provide you enough power to perform about 1,000 tests. The monitor will alert you when the battery is getting low by displaying the message ( ). You can still perform additional tests with this low battery message, but the battery should be replaced as soon as possible. If the "bAt" message appears on the monitor display, the monitor will no longer operate. The battery must be replaced immediately.

CAUTION

Always turn off the monitor before replacing the battery. Replacing the battery with the monitor on may lead to malfunction of the monitor.

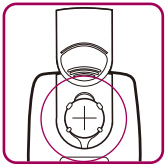
1

Turn off the Monitor.

Press the power button to turn off the monitor.

2 Remove the Battery Cover

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



3 Replace the Battery

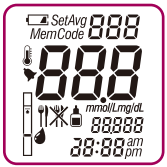
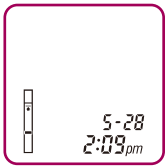
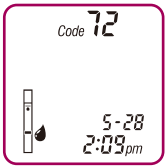
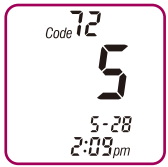
Remove the old battery and place the new one with "+" sign facing up.

4 Close the Battery Cover

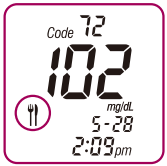
Slide the battery cover back in until it clicks into the monitor.

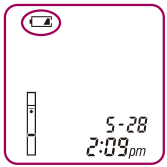
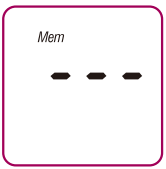
NOTE: *Used batteries are special waste and should not be disposed of in general household waste. Please dispose of used batteries according to applicable local guidelines and regulations.*

Display Message Guide

Message				
What it means	System check. Always appears when you press the power button to turn on the monitor.	The monitor is ready for you to insert a test strip.	The monitor is ready for a drop of blood sample or control solution. (This is an example of a code number stored in the monitor.)	The monitor displays countdown from 5 to 1, while calculating a blood glucose test result.
Action	You should always check that this exact display message appears every time your monitor turns on. Do not use the monitor if the display message does not match exactly as shown above. In such case, please contact your local distributor.	Insert a test strip into the test port of your monitor. Make sure the code number displayed on the monitor 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.

The meter programmed for mmol/L, or the meter programmed for mg/dL shows its own unit measurements only.

				
A blood glucose test result in mg/dL.	A blood glucose test result in mmol/L.	The system is ready to record the EVENT ICON which relates to your test result.	Your blood glucose result is higher than 600 mg/dL (33.3 mmol/L).	Your blood glucose result is lower than 20 mg/dL (1.1 mmol/L).
No action is required. (The meter programmed for mmol/L measurement does not apply in this case.)	No action is required. (The meter programmed for mg/dL measurement does not apply in this case.)	Select the EVENT ICON using +/- button before discharging the used test strip from the monitor.	Repeat the test using a new test strip and/or check the system with the **G1 Advance** Control Solution. If the system is working properly but your test result is still “HI”, contact your healthcare professional immediately.	Repeat the test using a new test strip and/or check the system with the **G1 Advance** Control Solution. If the system is working properly but your test result is still “Lo”, contact your healthcare professional immediately.

				
A blood glucose test result stored in the memory.	The battery is low but you can still perform additional tests.	The battery level is too low to perform a blood glucose test.	The average of blood glucose test results for the past 7 days.	No test result in the memory.
No action is required.	Turn off the monitor and replace the battery as soon as possible.	Turn off the monitor and replace the battery immediately.	No action is required.	No action is required.

				
The monitor is used outside of the operating range of temperature.	The used test strip was inserted in the test port of the monitor.	There may be a problem with the test strip. It may have been damaged or removed during the testing.	The blood sample or control solution was improperly applied or there was an electronical noise during the test.	The monitor has an internal electric circuit problem.
Leave the monitor at a temperature between 10°C~40°C (50°F~104°F) 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 monitor display.	Retest with a new test strip.	Contact your local distributor.

			
The monitor has a problem with the strip connection.	The monitor has a problem with the strip connection.	Not enough blood sample or control solution was drawn into the test strip for a test or was applied after the test was started.	The blood sample is applied to the wrong side of the test strip.
See Troubleshooting Guide or contact your local distributor.	See Troubleshooting Guide or contact your local distributor.	Retest with a new test strip.	Retest by applying the blood sample to the right side of a new test strip.

Troubleshooting	Cause	Action
1. The monitor does not turn on after inserting a test strip.	The battery may be dead.	Replace the battery.
	The battery is installed incorrectly or there is no battery in the monitor.	Check if the 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 monitor may not be working properly.	Contact your local distributor.
2. The monitor 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.
	The blood sample is applied after the monitor was automatically turned off (5 minutes after last action).	Retest with a new test strip.
	The monitor may not be working properly.	Contact your local distributor.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Specifications

Product Name	**G1 Advance** 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	20 ~ 600 mg/dL (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	mg/dL or mmol/L
Operating Ranges	Temperature: 10°C~40°C (50°F~104°F)
	Relative Humidity: Less than 85%
	Altitude: Up to 3,048 m (10,000 ft)
	Hematocrit: 20~60%
Dimension	93.5 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 summary of safety and performance (SSP) is available in the EUDAMED (https://ec.europa.eu/tools/eudamed/#/screen/home).

The G1 Advance Blood Glucose Monitoring System complies with the requirements of EN ISO 15197:2015. The performance of the G1 Advance Test Strips 3 lots has been evaluated in clinical tests.

Accuracy:
The accuracy of the G1 Advance 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 < 100 mg/dL (< 5.55 mmol/L)

Lot	Within ± 5 mg/dL (Within ± 0.28 mmol/L)	Within ± 10 mg/dL (Within ± 0.56 mmol/L)	*Within ± 15 mg/dL (Within ± 0.83 mmol/L)*
1st Lot	33/54 (61.1%)	52/54 (96.3%)	54/54 (100%)
2nd Lot	35/54 (64.8%)	54/54 (100%)	54/54 (100%)
3rd Lot	40/54 (74.1%)	54/54 (100%)	54/54 (100%)
Total(3Lots)	108/162 (66.7%)	160/162 (98.8%)	162/162 (100%)

For glucose concentration ≥ 100 mg/dL (≥ 5.55 mmol/L)

Lot	Within ± 5 %	Within ± 10 %	*Within ± 15 %*
1st Lot	68/146 (46.6%)	127/146 (87%)	146/146 (100%)
2nd Lot	76/146 (52.1%)	130/146 (89%)	146/146 (100%)
3rd Lot	75/146 (51.4%)	122/146 (83.6%)	146/146 (100%)
Total(3Lots)	219/438 (50%)	379/438 (86.5%)	438/438 (100%)

System accuracy results for glucose concentrations between 23.7 mg/dL (1.32 mmol/L) and 497 mg/dL (27.6 mmol/L)

Within ± 15 mg/dL or ± 15 % (Within ± 0.83 mmol/L or ± 15 %)
600/600 (100%)

Measurement precision:

Measurement Repeatability (using venous whole blood):			**Intermediate Measurement Precision (using control solution):**		
Level (mg/dL)	**STD (mg/dL)**	**CV (%)**	**Level (mg/dL)**	**STD (mg/dL)**	**CV (%)**
49.8	3.2	6.4	40.4	2.6	6.5
72.6	3.2	4.4	120.6	3.4	2.8
127.8	4.9	3.9	339.8	10.8	3.2
177.6	6.5	3.7	485.9	13.3	2.7
288.8	10.0	3.5			

User Performance Evaluation:
A study evaluating glucose values from fingertip capillary blood samples obtained by 104 lay persons showed the following results:
100 % within ± 15 mg/dL (± 0.83 mmol/L) of the medical laboratory values at glucose concentrations below 100 mg/dL (5.55 mmol/L), and 100 % within ± 15 % of the medical laboratory values at glucose concentrations at or above 100 mg/dL (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 uric acid and xylose were tested at more than their therapeutic concentrations and their effects on **G1 Advance** test results were less than ± 10 mg/dL at glucose concentrations below 100 mg/dL and less than ± 10% at glucose concentrations above 100 mg/dL.

No.	Interference	Upper Limit of Therapeutic concentration (mg/dL)	Test concentration (mg/dL)	No.	Interference	Upper Limit of Therapeutic concentration (mg/dL)	Test concentration (mg/dL)
1	Acetaminophen	3.0	20.0	13	Ibuprofen	7.0	50.0
2	Ascorbic acid	2.0	6.0	14	Icodextrin	NA	1100.0
3-1	Bilirubin (C)	0.3	28.8	15	L-DOPA	NA	0.75
3-2	Bilirubin (UC)	1.2	20.0	16	Maltose	NA	480.0
4	Cholesterol	201.1	502.7	17	Methyl-DOPA	0.75	2.0
5	Creatinine	1.3	15.0	18	PAM	3.8	3.8
6	Dopamine	0.03	0.09	19	Salicylate	30.0	60.0
7	EDTA	NA	0.1	20	Tolazamide	0.03	9.0
8	Galactose	5.0	60.0	21	Tolbutamide	10.8	72.0
9	Gentisic acid	0.6	1.8	22	Triglycerides	329.5	3333.0
10	Glutathione	32.3	93.0	23	Uric acid	8.0	23.5
11	Hemoglobin	20000.0	20000.0	24	Xylose	NA	20.0
12	Heparin(140u/mg)	0.7	2.1				

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

Uric acid	> 12.0 mg/dL (0.71 mmol/L)
Xylose	> 8.0 mg/dL (0.53 mmol/L)

Explanation of Symbols

	CAUTION
CE 0123	This product fulfills the requirements of Regulation (EU) 2017/746 on in vitro diagnostic medical device.
IVD	For *in vitro* diagnostic use
	Do not dispose the instrument in the urban waste.
	Consult User Manual
	For self-testing
	For near-patient testing

MEMO

MEMO

MEMO

MEMO

MEMO

Business Reply Card

Affix appropriate value of postage stamps

Name:

Date of Birth (DD MM YYYY): Gender: M F

Address:

City: State: Pin:

Tel: Mob:

Email: @

Diabetes Diagnosed (year): Prescribing doctor:

Medication: Insulin Tablets Both None

Testing frequency: Once every Day/ Week/ 2 Weeks/ Month/ Year

I would like to receive information on various product related offers and updates. Yes No

I would like to receive information about diabetes management and related awareness and educational programs. Yes No

Customer's signature:

11 digit **G1** Advance Blood Glucose Monitor Serial Number:
(See back of the monitor)