Manufactured by
All Medicus Co., Ltd.
#7102~7107, #7402, #7403, #7406, 140,
Beolmal-ro, Dongan-gu, Anyang-si,
Gyeonggi-do REPUBLIC OF KOREA
www.allmedicus.com

B312DA300
11/2015

BLOOD GLUCOSE MONITORING SYSTEM

AGM-513S

User Manual

GlucoDr.S™

Blood Glucose Monitoring System

CE 0123

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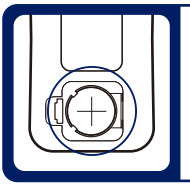
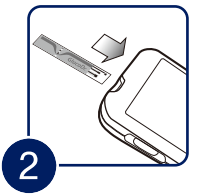
TEST SUMMARY

This summary is intended only as a quick reference and is not a substitute for GlucoDr.S Blood Glucose Monitoring System User Manual. Please read the entire User Manual before you begin the test.

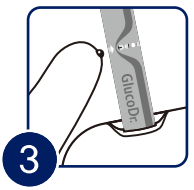


Remove the battery cover and put the battery with "+" sign facing up.

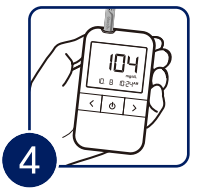
Check the expiration date printed on the strip vial label.



Insert a test strip. The meter will automatically turn on.



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



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

“Thank you for using GlucoDr.S™
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: GlucoDr.S Blood Glucose Monitoring System is intended for self-testing outside the body (*in vitro* diagnostic use) for quantitative measurement of glucose in fresh capillary whole blood drawn from fingertips. The GlucoDr.S Blood Glucose Monitoring System is intended for use by diabetic lay users as an aid to monitor their blood glucose level. The GlucoDr.S Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes mellitus, or for neonatal use.
For professional use: GlucoDr.S Blood Glucose Monitoring System is intended for testing outside the body (*in vitro* diagnostic use) for the quantitative measurement of glucose in venous whole blood and fresh capillary whole blood drawn from fingertips. The GlucoDr.S Blood Glucose Monitoring System is intended for use by healthcare professionals as an aid to monitor patients' blood glucose level.
The GlucoDr.S 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 GlucoDr.S Blood Glucose Monitoring System is based on measurement of electric currents caused by the reaction of glucose with the reagents on the gold electrode 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 on the test strip. This reaction creates electric currents. The consequent electric currents are proportional to the glucose concentration in the blood and converted to the equivalent glucose concentration by the algorithm programmed in the GlucoDr.S Meter.

Precautions for Use

Carefully read and follow the instructions in the User Manual and package inserts for the test strips and control solution and practice the testing procedures before using the GlucoDr.S Blood Glucose Monitoring System. It is very important to follow the instructions in order to avoid an incorrect test result that leads to improper therapy.
Take note of information and cautions throughout this User Manual.

- The GlucoDr.S Meter is designed for use only with GlucoDr.S Test Strips. (manufactured by All Medicus Co., Ltd.)
- The GlucoDr.S Blood Glucose Monitoring System is calibrated to produce values equivalent to the results on plasma specimens on a laboratory analyzer (YSI 2300 STAT Plus).
- The GlucoDr.S 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.
- The GlucoDr.S Blood Glucose Monitoring System is for *in vitro* diagnostic use.
- 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 65%) or very low (below 20%) can cause false test results.
- Handle all the reagents with care knowing that they are capable of transmitting infection.
- Used test strips, lancets and meter may be considered bio-hazardous waste in your area. Be sure to follow your local regulation for proper disposal of used strips, lancets and meter.

Precautions for Test Strip

- Store test strip vials in dry place with room temperature 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 test strips only in their original vial and do not transfer them to a new bottle or any other container.
- Do not touch the test strip with wet hands.
- Do not use the test strip beyond the expiration date printed on the vial.
- Do not bend, cut, or damage the test strips.
- Do not insert the same test strip into the test port multiple times. It may cause an improper operation.

Safekeeping

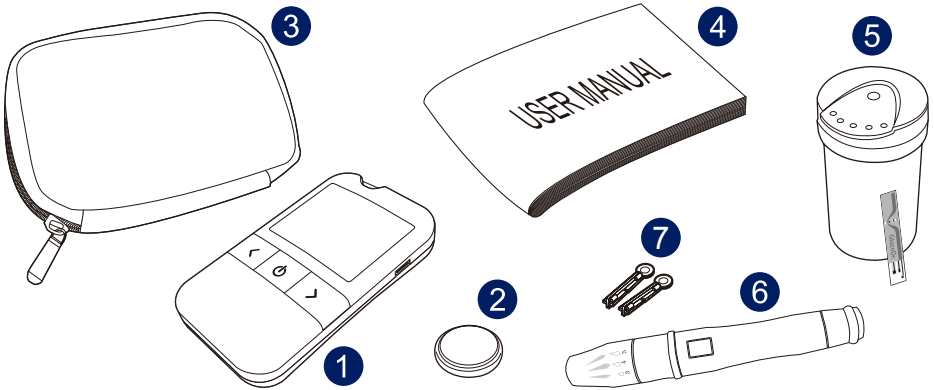
- Store the GlucoDr.S Meter in a room temperature between 0~40℃ (32~104℉).
- Store the GlucoDr.S Meter where relative humidity is between 15~85%.
- Keep the GlucoDr.S Meter in sanitary environment.
- Keep the meter away from direct sunlight for a long time.
- Keep the test port away from dirt, blood 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.

INFORMATION Please read the literature packaged with test strip and meter to find the product specification and limitations.

INFORMATION If the meter does not work properly and you have followed the storage and handling instructions in this User Manual, contact your local distributor.

Table of Contents

GlucoDr.S™ Blood Glucose Monitoring System



GlucoDr.S Blood Glucose Monitoring System includes the following items:

1. GlucoDr.S™ Meter
2. Battery
3. Carrying case
4. User Manual

Upon request of distributor, GlucoDr.S Blood Glucose Monitoring System may include the following items:

5. GlucoDr.S™ Test Strips
6. Lancing Device
7. Lancets

All the including items are listed on the main box.
Check the items after opening GlucoDr.S Blood Glucose Monitoring System package.
If any of the items are missing from your kit, Contact your local distributor.

❶ LCD Display

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

❷ </> Button

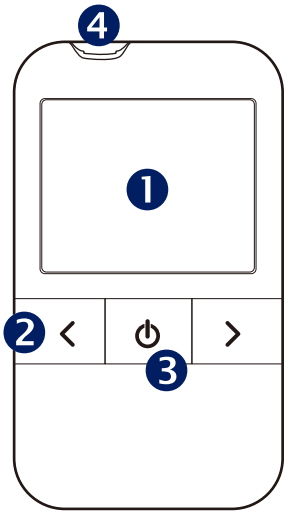
- Recall the stored test result in the MEMORY MODE.
- Select an event in the EVENT RECORD MODE.
- Change the date, time and options in the SET MODE.

❸ Power Button

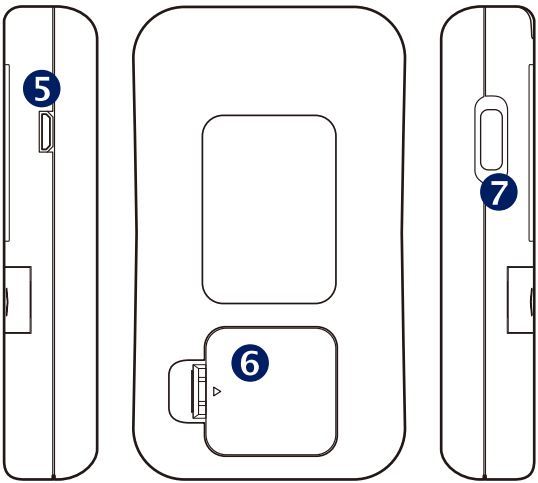
- Turn the meter on/off.
- Enter into SET MODE while pressing the power button for more than 3 seconds.
- Delete all the stored test results in the AVERAGE MODE.
- Delete each test results in the MEMORY MODE.

❹ Test Port

- Insert the GlucoDr.S Test Strip for testing. Then the meter turns on and BLOOD DROP ICON will blink.



GlucoDr.S™ Meter

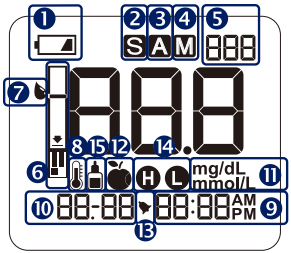


5 Micro USB Port

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

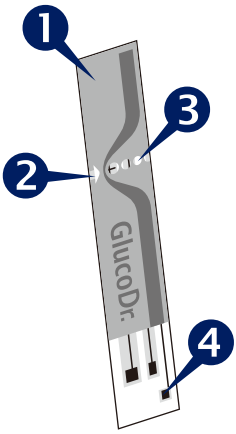
6 Battery Cover

7 Test Strip Eject Button



1. BATTERY LIFE.
2. SET MODE.
3. AVERAGE MODE.
4. MEMORY MODE.
5. MEMORY NUMBER.
   The meter displays the current memory order number in the MEMORY MODE.
6. STRIP ICON.
   When the STRIP ICON blinks, insert a test strip to the meter.
7. BLOOD DROP ICON.
   When the BLOOD DROP ICON blinks, apply blood sample.
8. TEMPERATURE ICON.
   When the meter is not used at a recommended temperature range, "Er1" and TEMPERATURE ICON appear.
9. CURRENT TIME and TEST TIME in the MEMORY MODE.
10. CURRENT DATE and TEST DATE in the MEMORY MODE.
11. UNIT OF MESUREMENT.
12. EVENT ICON.
    If you choose an event icon which correlates to test results, it helps to manage glucose level more effectively.
13. ALARM.
    You can set up to four different alarms. Each alarm rings for 10 seconds.
14. HYPERGLYCEMIC, HYPOGLYCEMIC WARNING ICON.
15. CONTROL SOLUTION ICON.
    The meter automatically recognizes the difference between the control solution and blood.

GlucoDr.S™ Test Strip



❶ Grip

- Hold this part to insert a test strip.

❷ Yellow Side-edge

- Apply blood sample here; blood is absorbed automatically.

❸ Confirmation window (Reaction chamber)

- Confirm if enough blood entered the confirmation window.

❹ Gold electrodes

- Insert this part into the meter's test port.

Checking Your System with GlucoDr.S™ Control Solution

Control solution test is to check the performance of your meter and test strips. GlucoDr.S Control Solution contains a measured amount of glucose that reacts with the GlucoDr.S 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.

INFORMATION

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

CAUTION

- Use only the GlucoDr.S 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 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, meter, and test strips should be kept at a room temperature prior to the use.

Checking Your System with GlucoDr.S™ Control Solution

CAUTION

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

1 Check the expiration date printed on the test strip vial.

Do not use the test strip beyond the expiration date.

2 Insert a Test Strip

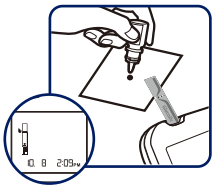
Insert a test strip, with the printed side facing up, into the test port of the meter. Gently push it all the way in until it goes no further.
The meter will turn on automatically and beep. Then the BLOOD DROP ICON will appear.

CAUTION

- If the BLOOD DROP ICON does not appear, remove the test strip and insert it again.
- If the BLOOD DROP ICON still does not appear, contact your local distributor.

CAUTION

Do not force the test strip into your meter. This may cause malfunction.

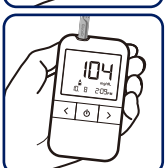


3 Apply Control Solution

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. 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.



4 Test Result Appears in 5 seconds

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

Checking Your System with GlucoDr.S™ Control Solution

CAUTION

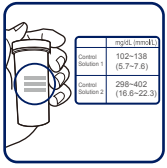
CONTROL SOLUTION ICON

Check the CONTROL SOLUTION ICON ' ' to appear. If CONTROL SOLUTION ICON ' ' is not displayed, repeat the test with a new test strip.

If the ICON ' ' still does not appear, contact your local distributor.

CAUTION

The Control Solution range printed on the test strip vial is for the GlucoDr.S 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.



5 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 GlucoDr.S Test Strip Instruction for the use.

INFORMATION

Out-of-range test results may be caused by one or more of the followings:
- Expired or contaminated control solution,
- Expired or damaged test strip,
- Use of control solution or test strip past its discarding date,
- Error in performing the test,
- Failure to shake the control solution vial well,
- Meter, test strips or control solution are kept too warm or too cold,
- or Meter malfunction

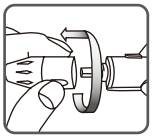
CAUTION

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

INFORMATION

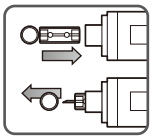
All the control solution test results are record with CONTROL SOLUTION ICON '  ' to distinguish them from those of actual blood glucose tests in the meter memory. Recorded control solution test results will not be calculated in your result averages.

Preparing the Lancing Device



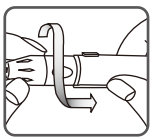
1 Remove the cap

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.

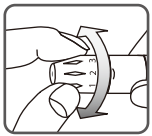


3 Replace the cap

Turn the cap of lancing device clockwise until it fits.

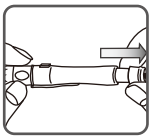
! CAUTION

- 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.



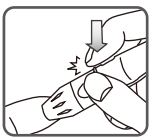
4 Adjust the Puncture Depth Setting

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.

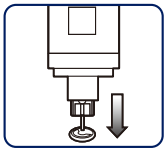
Draw back the end part of lancing device until it clicks, and then release it.



6 Lance your Finger

Place the lancing device carefully on the tip of your finger and press the release button.

Preparing the Lancing Device



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 to dispose the used lancet in a proper bio-hazardous container.

RECOMMENDED AVALIABLE LANCETS

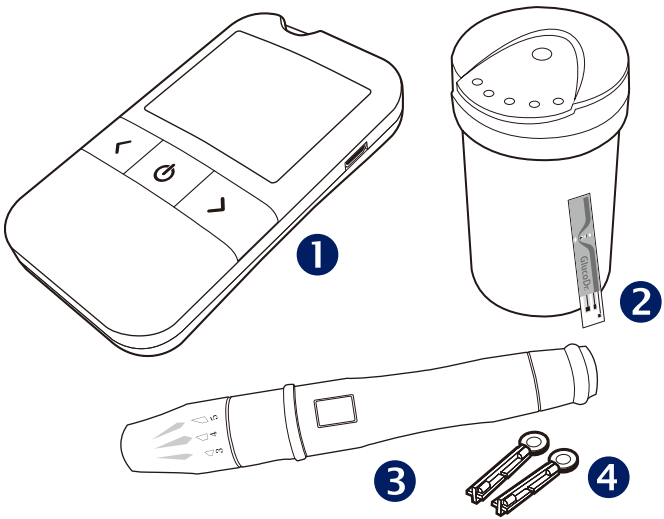
Some general sterilized lancets are BD-Ultra Fine, E-Z Ject, G-P Lite, Microlet, Monolet, Soft Touch, Ultra TLC, Unilet GP and Greenlan.
Note: Not recommended lancets in the above list may not work properly with the lancing device due to their dimensions. Please contact your supplier to make sure you are using proper lancets.

! 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 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
CE
GMMC
1112, 130, Digital-ro, Geumcheon-gu, Seoul, Korea

Lancet Manufactured by
CE$_{1370}$
SAEHANMED CORP.
Na-dong, Ga-dong, 331 Seongseok-ro, Ilsandong-gu, Goyang-si, Gyeonggi-do, Korea



1. GlucoDr.S™ Meter
2. GlucoDr.S™ Test Strip
3. Lancing Device
4. Lancets

Performing the Blood Glucose Test with GlucoDr.S™

1 Check the expiration date printed on the test strip vial.

Do not use the test strip beyond the expiration date.

2 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.

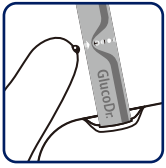
! CAUTION Do not force the test strip into the meter. This may cause malfunction of the meter.

3 Obtain a Blood Drop

Obtain a blood drop from your fingertip using the lancing device (see pages 11-13). The blood sample must be at least 0.5 micro liters in volume.

TIP

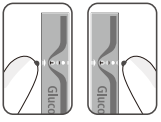
- Before puncturing, gently massage the fingertip to obtain a round drop of blood.
- Do not squeeze the finger to obtain a drop of blood.
- Do not smear the blood sample.



4 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



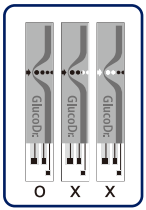
O X

You should apply blood to the left side edge of the test strip as directed.

- Do not put blood on the top of the test strip.

Peforming the Blood Glucose Test with GlucoDr.S™

CAUTION



- If insufficient blood is inserted, error message (Er8) will be displayed.
  See the picture in the left for proper application of the required blood volume to perform the test properly.
- 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.

5 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 a new test strip into your meter to restart the test.

TIP

After the test, press any of </> button in the EVENT RECORD MODE before removing the test strip from your meter. Recording your condition will lead you to more effective diabetes management.

Entering the EVENT RECORD MODE

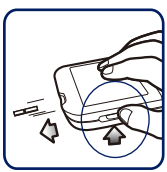
For effective diabetes management, stored test results with your condition will help you and your healthcare professional to track changes in your blood glucose level.

1 Press </> Button after the Test

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 2 different EVENT ICONs: Post Meal and Pre Meal. 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 left 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.

Understanding Your Test Results

The GlucoDr.S Meter will display test result 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 meter display. If your test result is higher than 600 mg/dL (33.3 mmol/L), "HI" will appear on the meter 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 GlucoDr.S Control Solution. If your meter and test strip 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 ~ 100 mg/dL (3.9 ~ 5.6 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.

CAUTION

If your test result is lower than 70 mg/dL (3.9 mmol/L) or hypoglycemic warning limit, "L" will appear on the meter display.

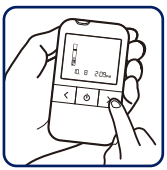
If your result is higher than 140 mg/dL (7.8 mmol/L) or hyperglycemic warning limit, "H" will appear on the meter display.

INFORMATION

The meter is pre-set with a low limit of 70 mg/dL (3.9 mmol/L) and a high limit of 140 mg/dL (7.8 mmol/L). If you need to change the pre-set limits, please go the SET MODE (page 29).

Recalling the Previous Test Results

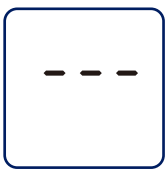
The GlucoDr.S Meter has a memory capacity to store up to 500 most recent test results with date, time and event. It also provides you averages of your blood glucose test results over a period of time (Options: 7d, 14d, 30d, 60d, or 90d average). You can review the test results stored in the memory by the following steps.



1 **Press </> Button**

To enter the MEMORY MODE, press </> button with the meter turned on.

INFORMATION



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

2 Indicate the Average Value

You can select the number of days for the average (7d, 14d, 30d, 60d, or 90d) in the SET MODE. "7d" shown in the left side indicates that the value 96 is a calculated average for the past 7 days. The meter is pre-set with the average day of 7d.

INFORMATION

When the whole test results' average is calculated, individual event records are not considered and "Lo" and "Hi" are not included.

TIP

You can delete all the stored test results in the meter memory after the average value is displayed. Press and hold the power button for 5 seconds until "CLr" flashes and "---"appears.

Recalling the Previous Test Results

3 Recall your Test Results

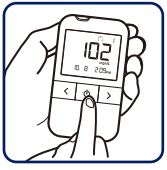
Press and release </> button once to make the most recent test result appear on the meter display. Every time you press and release </> button, the meter will display the next result up to 500 test results.

TIP

Press and hold </> button in the MEMORY MODE in order to view the test results faster.

TIP

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

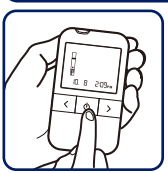


4 Exit the MEMORY MODE

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

The GlucoDr.S Meter comes with date (1. 1), date format(dd.mm) time (12:00AM), time format (12h), alarm(0), average day(7d), hypoglycemic[<70 mg/dL (3.9 mmol/L)], hyperglycemic[>140 mg/dL (7.8 mmol/L)] and unit of measurement (mg/dL), beep (On) preset. However, if you need to change the setting of the meter, or if you replace the battery, you need to enter the SET MODE and reset them. 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.

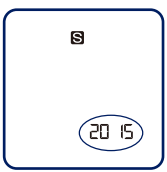


1

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. The Year flashes.

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

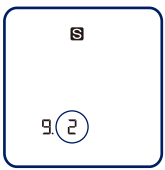
Set the Year

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, the meter advances next to the Month Setting.

Setting GlucoDr.S™ Meter

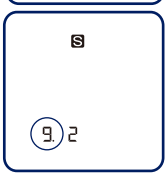
TIP

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.



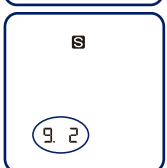
3 Set the Month

The Month flashes. Press and release </> button until you get the correct month. If you press and release the power button, the meter advances next 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 advances next 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 advances next to the Hour Setting.

6 Set the Hour

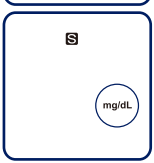
The Hour flashes. Press and release </> button until you get the correct hour. If you press and release the power button, the meter advances next to the Minutes Setting.

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 advances next to the Time Format Setting.

8 Set the Time Format

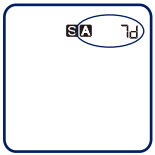
The "12h" or "24h" flashes. Press and release </> button to adjust until you get the correct time format. If you press and release the power button, the meter advances next to the Unit of Measurement Setting.



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 that you want. If you press and release power button, the meter advances next to the Average Period Setting.

Setting GlucoDr.S™ Meter



10 Set the Average Period

The Average Period flashes. Press and release </> button until you get the period of average setting that you want (7,14,30,60,or 90). If you press and release the power button, the meter advances next to the Hypoglycemic Warning Limits Setting.

11 Set Hypoglycemic Warning Limit

"70 mg/dL (3.9 mmol/L)" flashes, press </> button to select the hypo (lower) blood glucose level. If you press and release power button, the meter advances next to the Hyperglycemic Warning Limits Setting.

12 Set Hyperglycemic Warning Limit

"140 mg/dL (7.8 mmol/L)" flashes, press </> button to select the hyper (upper) blood glucose level. If you press and release power button, the meter advances next to the Beep Setting.

CAUTION

- Hypoglycemic warning limit cannot be higher than hyperglycemic warning limit.
- Hyperglycemic warning limit cannot be lower than hypoglycemic warning limit.

CAUTION

This function is no substitute for hyperglycemia or hypoglycemia training by your healthcare professional.

13 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. And then the meter advances next to the Alarm Setting.
If you set it "Off", you don't need to set the alarm and the meter exits the SET MODE.

14 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 advances next to the Alarm Time Setting.
If you set it "0", the meter exits the SET MODE.

15 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).

16 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

Totally 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.

Installing Battery

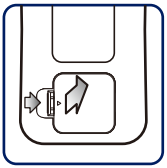
A battery (CR2032) will provide you enough power to perform about 1,000 tests.
The meter will alert you when the energy level is getting low by displaying the message ( ). In this case you can test a few more times but the battery should be replaced to new one as soon as possible. If "bAt" appears on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

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.

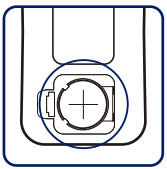
1 **Turn off the Meter.**

Press the power button to turn off the meter.



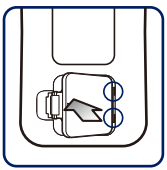
2 Remove the Battery Cover

Remove the battery door from the back of the meter by pushing the tab in the direction of the arrow and pulling up the door.



3 Replace the Battery

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



4 Close the Battery Cover

Put the battery door back in place and snap it closed.

How to Use LinkDr. 2.0

GlucoDr.S is designed to connect with PC using Micro USB cable and to transfer test results to PC. Through diabetes management software LinkDr. 2.0, you can review your test results and print the report.
To learn more about LinkDr. 2.0, please contact your distributor.

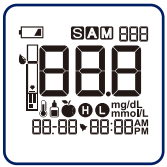
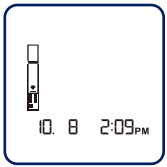
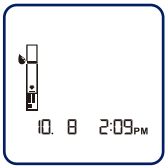
1. Visit www.allmedicus.com and download LinkDr. 2.0. And set up LinkDr. 2.0 in your PC.
2. Run LinkDr. 2.0.
3. Connect the meter with your PC using Micro USB cable.
   If the meter is connected with PC, "USb" appears on meter display.
4. Select Date Range and click "Yes".
   Meter data will be transferred to your PC.
5. After the download is completed, you can see the summary report and the meter turns off.

INFORMATION

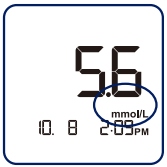
LinkDr. 2.0 PC requirements
- CPU : Pentium4 2.4GHz or higher
- Memory : 256 MB or higher
- HDD : 500 MB or higher
- OS : Windows XP or higher

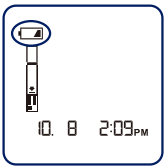
CAUTION

Until the download is completed, do not disconnect the meter with PC and do not turn off the meter.

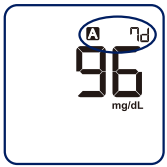
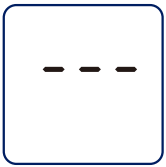
Message				
What it means.	System check. This display always appears when you press the power button to turn on the meter.	The system is ready for you to insert a test strip.	The meter is ready for a blood drop or control solution.	The meter displays countdown from 5 to 1, while calculating a blood glucose 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 your local distributor.	Insert a test strip into the test port of your meter.	Apply a blood sample to the test strip.(See pages 14-18 for how to test your blood glucose level)	No action is required.

Display Message Guide

Message				
What it means.	A blood glucose test result in mg/dL	A blood glucose test result in mmol/L	System is ready to record the EVENT ICON which correlates with your test result.	Your blood glucose result is higher than 600 mg/dL (33.3 mmol/L).
Action	No action is required.	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 GlucoDr.S Control Solution. If the test result is "HI" again even though your system is working correctly, contact your healthcare professional immediately.

				
Your blood glucose result is lower than 20 mg/dL (1.1 mmol/L).	Your blood glucose result is higher than the hyperglycemic warning limit.	Your blood glucose result is lower than the hypoglycemic warning limit.	A blood glucose test result stored in the memory.	Battery is low but you can still perform a few more tests.
Repeat the test using a new test strip and/or check the system with the GlucoDr.S Control Solution. If the test result is "Lo" again even though your system is working correctly, contact your healthcare professional immediately.	No action is required.	No action is required.	No action is required.	Turn off the meter and replace the battery as soon as possible.

Display Message Guide

Message				
What it means.	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.	The meter is connected with PC using Micro USB cable.	No test result in memory
Action	Turn off the meter and replace the battery immediately.	No action is required.	Transfer meter data to PC. (page 33)	No action is required.

				
The meter is used outside the proper range of temperature.	The used test strip was inserted in the test port.	The test strip was removed during testing.	The blood sample or control solution was improperly applied or there was an electrical noise during the test.	The meter has an internal electric circuit problem.
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.	Contact your local distributor.

Display Message Guide

Message				
What it means.	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 is applied to wrong direction into the test strip.
Action	Contact your local distributor.	Contact your local distributor.	Retest with a new test strip.	Apply blood to right direction into a new test strip.

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 your local distributor.
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 your local distributor.

Specifications

Product Name	GlucoDr.S™ Blood Glucose Monitoring System
Model Name	AGM-513S
Assay Method	Electrochemical method
Sample Type	Fresh capillary and 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: 10~40°C (50~104°F)
	Relative Humidity: 15~85%
	Altitude: Up to 3,048m (10,000 feet)
	Hematocrit: 20~65%
Dimension	50 X 87.3 X 17.5 (mm), 2.0 X 3.4 X 0.69 (inches)
Weight	Approximately 47.2g or 1.7 oz. (with battery)
Display	44.0 X 38.0 (mm) LCD, 1.7 X 1.5 (inches) LCD
Memory Capacity	500 test results (with date, time & event)
Data Management	Micro USB
Automatic Shutoff	5 minutes after last action

The performance of the GlucoDr.S Test Strips 3 lots has been evaluated in clinical tests.

Accuracy:
The accuracy of the GlucoDr.S 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 < 100mg/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	49/64 (76.6%)	64/64 (100%)	64/64 (100%)
2nd Lot	48/64 (75%)	64/64 (100%)	64/64 (100%)
3rd Lot	49/64 (76.6%)	63/64 (98.4%)	64/64 (100%)
Total (3Lots)	146/192 (76%)	191/192 (99.5%)	192/192 (100%)

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

Lot	Within ± 5 %	Within ± 10 %	*Within ± 15 %*
1st Lot	103/136 (75.7%)	133/136 (97.8%)	136/136 (100%)
2nd Lot	92/136 (67.6%)	131/136 (96.3%)	136/136 (100%)
3rd Lot	95/136 (69.9%)	132/136 (97.1%)	136/136 (100%)
Total (3Lots)	290/408 (71.1%)	396/408 (97.1%)	408/408 (100%)

Performance Characteristics

System accuracy results for glucose concentrations between 25 mg/dL (1.39 mmol/L) and 512 mg/dL (28.4 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	**STD**	**CV**	**Level**	**STD**	**CV**
35.3 mg/dL	2.1 mg/dL	5.9%	38 mg/dL	1.4 mg/dL	3.7%
72.9 mg/dL	2.5 mg/dL	3.5%	119 mg/dL	2.6 mg/dL	2.2%
113 mg/dL	4.2 mg/dL	3.7%	353 mg/dL	7.4 mg/dL	2.1%
191 mg/dL	9.3 mg/dL	4.9%	514 mg/dL	13.3 mg/dL	2.6%
300 mg/dL	13.7 mg/dL	4.6%			

User Performance Evaluation:
A study evaluating glucose values from fingertip capillary blood samples obtained by 146 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 xylose were tested at more than their therapeutic concentrations and their effects on GlucoDr.S 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	Therapeutic concentration (mg/dL)	Test concentration (mg/dL)	No.	Interference	Therapeutic concentration (mg/dL)	Test concentration (mg/dL)
1	Acetaminophen	23.3	25.0	13	Ibuprofen	42.7	50.0
2	Ascorbic acid	3.0	3.5	14	Icodextrin	468	468
3	Bilirubin (C,UC)	12.0	25.0	15	L-DOPA	0.2	2.0
4	Cholesterol	250.0	309.0	16	Maltose	100.0	1000.0
5	Creatinine	5.0	10.0	17	Methyl-DOPA	1.2	1.5
6	Dopamine	0.1	0.2	18	PAM	57.0	60.0
7	EDTA	0.1	200.0	19	Salicylic acid	70.4	80.0
8	Galactose	4.9	10.0	20	Tolazamide	0.1	16.0
9	Gentisic acid	2.1	10.0	21	Tolbutamide	48.0	100.0
10	Glutathione	18.5	20.0	22	Triglycerides	500.0	550.0
11	Hemoglobin	500.0	600.0	23	Uric acid	9.0	10.0
12	Heparin(140u/mg)	0.7	7.1	24	Xylose	20.0	20.0

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

Xylose > 20 mg/dL (1.33 mmol/L)

Explanation of Symbols

	CAUTION
	This product fulfils 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
	Manufacturer
	Store at
	Direct Current

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