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ALL MEDICUS GLUCODR AGM-2100 USER MANUAL



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A112DA302
04/2016

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BLOOD
GLUCOSE
MONITORING
SYSTEM

GlucoDr™

Blood Glucose Monitoring System

User Manual

AGM-2100

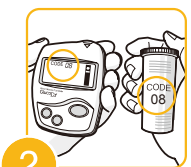


∗TEST SUMMARY

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



Turn on the Meter.
Press the power button to turn on the meter.



Insert a test strip.
Check the code number.
The code number displayed on the meter must match the one on the test strip vial.



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, then the meter will begin the countdown.



The blood glucose result will be displayed on the meter in just 11 seconds.

"Thank you for using GlucoDr™
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 Blood Glucose Monitoring System is for quantitative blood glucose testing in fresh capillary whole blood. The GlucoDr Blood Glucose Monitoring System is for testing outside the body (*in vitro* diagnostic use). The GlucoDr Blood Glucose Monitoring System is intended for use by diabetic lay users for self testing to improve management of their blood glucose level. The GlucoDr Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes mellitus, or for neonatal use.

Test Principle

The blood sample is drawn into the test strip's reaction chamber through capillary action. Glucose in the sample reacts with glucose oxidase 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 GlucoDr Meter.

Precautions for Use

- The GlucoDr Meter is designed for use with GlucoDr Test Strips (manufactured by **All Medicus Co., Ltd.**) only.
- The GlucoDr 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 GlucoDr Blood Glucose Monitoring System should not be used for the diagnosis of diabetes.
- Rapid change in temperature may cause inaccurate test results in reading. When taking the meter from cold to warm area or from warm to cold area, let the meter sit for about 30 minutes to adjust to the room temperature.
- Do not drop the meter.
- Do not disassemble, repair or remodel without consultation. The sensitive parts could be damaged and the warranty will then become invalid.
- A hematocrit that is either very high (above 55%) or very low (below 30%) can cause false test results.

Precautions for Test Strip

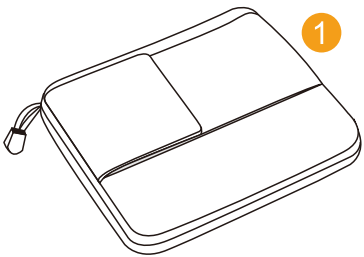
- Store test strip vials in dry place with temperature ranging between 1~30℃ (34~86℉).
- Avoid direct sunlight, heat and excessive humidity.
- Always close the vial cap immediately after removing a test strip from the vial. If the test strip vial is left open for a long time, the test strips will become unusable.
- Use the test strip immediately after removing it from the vial.
- Use all the test strips within 4 months after the first opening.
- Store your test strips only in their original vial and do not transfer them to a new bottle or any other container.
- Do not handle the test strip with wet hands.
- Do not use the test strip after the expiration date printed on the vial.
- Do not bend, cut, or alter the test strips.
- Do not insert the same test strip into the test port multiple times. It can lead to an improper operation.

Safekeeping

- Store the GlucoDr Meter at a temperature between 15~35℃ (59~95℉).
- Store the GlucoDr Meter at a place where relative humidity is less than 85%.
- Keep the GlucoDr Meter in sanitary environment.
- Keep the meter away from direct sunlight.
- Keep the test port away from dirt, blood or water.
- Do not store your meter and test strips in the car, the bathroom, or the refrigerator. (sensitive to temperature and humidity)
- Keep the meter, test strip vials and lancing materials away from children.
- Clean the outside of the meter using a moist (not wet) cloth or tissue with isopropyl alcohol or mild detergent with water. Do not immerse the meter in water or other liquid.

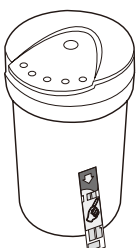
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1. Carrying case
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4. GlucoDr™ Test Strips
5. Batteries
6. Lancing Device
7. Lancets

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

GlucoDr™ Meter

1 LCD Display

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

2 Code Button

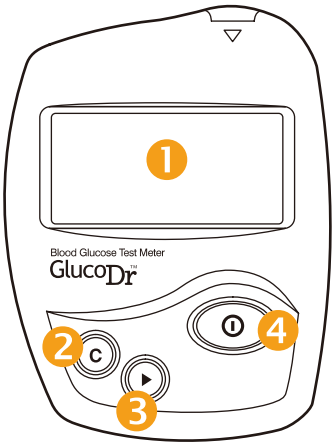
- Enters into the CODE MODE while pressing the code button.

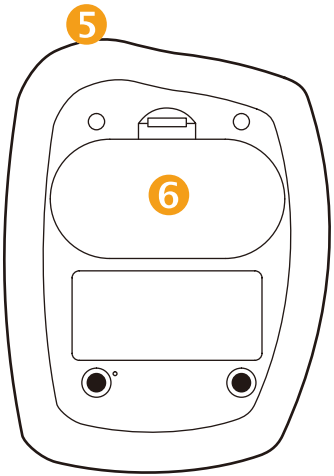
3 Memory Button

- Recall the stored test results in the MEMORY MODE or change the code number in the CODE MODE.

4 Power Button

- Turn the meter on/off.





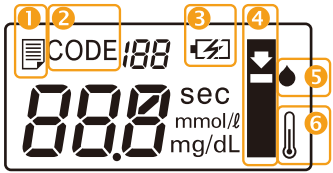
5 Test Port

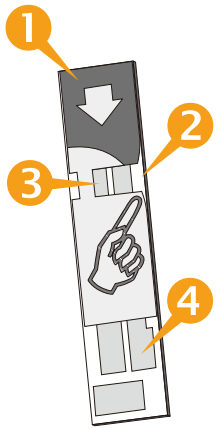
- Insert the GlucoDr Test Strip for testing. Then the meter turns on and displays the code number automatically.

6 Battery Cover

GlucoDr™ Meter LCD Display

1. MEMORY MODE.
2. CODE MODE .
3. Battery life.
4. STRIP ICON.
   When the STRIP ICON blinks, insert a test strip to the meter.
5. BLOOD DROP ICON.
   When the BLOOD DROP ICON blinks, apply blood sample.
6. TEMPERATURE ICON.
   When the meter is not used at a recommended temperature range, "Er1" and TEMPERATURE ICON appear.





1 Grip

- Hold this part to insert or remove test strip.

2 Yellow Side-edge

- Apply blood sample here; blood is absorbed automatically.

3 Confirmation window (Reaction chamber)

- Make sure the confirmation window fills completely.

4 Gold electrodes

- Insert into test port.

Checking the Code Number

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



1 Turn on the Meter

Press the power button to turn on the meter.
Then the code number, STRIP ICON and BLOOD DROP ICON will appear.



2 Check the Code Number

Make sure that the code number displayed on the meter matches the one on the test strip vial. If the code numbers match, you can begin the test.
If they do not match, follow the next step.



3 Enter the CODE MODE

You can enter the CODE MODE by pressing and holding the code button (ⓒ button). Then the code number blinks on the meter display. Do not release the code button(ⓒ button), because it will cause the meter to exit the CODE MODE.

CAUTION

- Check the code number on the test strip vial before inserting the test strip.
- You can not change the code number when the test strip is inserted into the test port.



4 Change the Code Number.

With the code button(ⓒ button) pressed, use ▶ button to adjust the same code number printed on your test strip vial.

TIP

- To change the code number faster, press and hold ▶ button.



5 Save the Code Number

When the code number is correctly adjusted, release the code button(ⓒ button).
A new code number will be saved and appear on the meter display.

Control solution test is to check the performance of your meter and test strips. GlucoDr Control Solution contains a measured amount of glucose that reacts with the GlucoDr 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 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 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.
- Do not drink the control solution.
- Tightly close the cap of control solution vial and store at a room temperature after the test.





1 Insert a Test Strip

Insert a test strip, with the printed side facing up, into the test port of the meter. Gently push it all the way in until it goes no further.
The meter will turn on automatically and beep. Then the code number and the BLOOD DROP ICON will appear. Make sure that the code number displayed on the meter matches the one on the test strip vial. If the code numbers match, you can start the test. If the code number on the meter doesn't match the one on the test strip vial, adjust the code number on your meter.(see page 6~8)

! CAUTION

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



2 Apply Control Solution

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

TIP

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



3 Test Result Appears in 11 seconds

Your meter will display countdown from "11" to "1", then the test result will appear.

CAUTION

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



4 Compare Control Solution Test Results

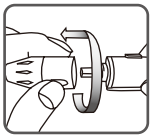
Compare the control solution test result to the control solution range printed on the test strip vial. The test result should fall within this range. Each vial of test strips may have a different control solution range. If the test result you get is not within this range, the meter and test strips may not be working properly. Repeat the control solution test. Refer to the GlucoDr 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,
- Code number printed on the test strip vial does not match the one displayed on the meter,
- Meter, test strips or control solution are kept too warm or too cold,
- or Meter malfunction

CAUTION

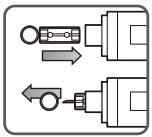
If your control solution test results continue to fall outside the range printed on the test strip vial, the GlucoDr Blood Glucose Monitoring System may not be working properly.
- If this is the case, do not use the system to test your blood glucose levels.
- Contact your local distributor.



1

Remove the cap

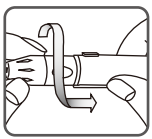
Turn the cap of the lancing device counter-clockwise to remove the cap.



2

Insert a Lancet into the Lancet Holder.

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



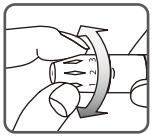
3

Replace the cap

Turn the cap of lancing device clockwise until it fits.

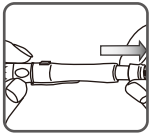
! CAUTION

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



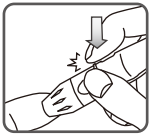
4 Adjust the Puncture Depth Setting

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



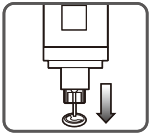
5 Charge the Lancing Device.

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



6 Lance your Finger

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



7 Remove the Used Lancet

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

CAUTION

- To reduce the risk of infection, never share a lancet 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

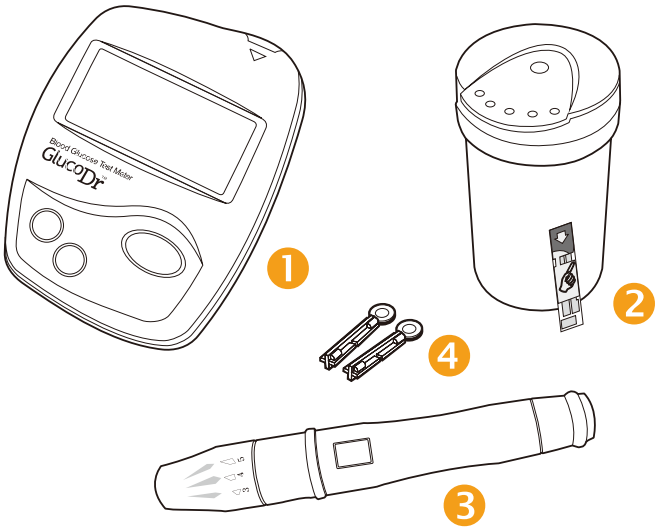
Lancet Manufactured by
CE1370
SAEHANMED CORP.
Na-dong, Ga-dong, 331 Seongseok-ro, Ilsandong-gu, Goyang-si, Gyeonggi-do, Korea

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.

Performing the Blood Glucose Test with GlucoDr™



1. GlucoDr™ Meter
2. GlucoDr™ 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 meter. Push it all the way in until it goes no further. The meter will turn on automatically and beep. Then the code number and the BLOOD DROP ICON will appear. Make sure the code number displayed on your meter and the test strip code number match.

CAUTION

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

2 Obtain a Blood Drop

Obtain a blood drop from your fingertip using the lancing device (see page 15) The blood sample must be at least 4 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.

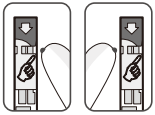


3

Apply the Blood Sample

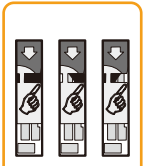
Apply the round drop of blood to the side edge of the yellow window of the test strip and then blood drop will be absorbed into the narrow channel. Touch and hold the blood drop to the side edge of the yellow window of test strip until blood completely fills the confirmation window and the meter beeps. Then, your meter will start the countdown.

CAUTION



You should apply blood to the arrow 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 confirmation window, you may get inaccurate test result. 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.





4

Results in just 11 seconds

Once the meter completes the countdown from "11" to "1", your test result will appear on the meter display. If you remove the test strip, the test result will be automatically saved in the meter memory.

INFORMATION

If you do not apply a blood drop within 3 minutes, your meter will turn off automatically. Once the meter turns off, remove the test strip and then insert it back into your meter to turn on the meter.



5

Remove the Strip

Hold the used strip as shown in the picture. Gently remove it from the meter and discard it properly. Press the power button to turn off the meter, or the meter will be turned off automatically after 3 minutes without any action.

The GlucoDr 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 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.

The GlucoDr Meter has a memory capacity to store up to 100 most recent test results with date and time.



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

Recall Your Test Results

Press and release ▶ button once to make the most recent test result appear on meter display. Every time you press and release ▶ button, the meter will display the next result up to the last 100 test results.

TIP

Press and hold ▶ button in the MEMORY MODE in order to view the test results faster.



3 Exit the MEMORY MODE

Press and release the code button(ⓒ button) once to exit from the MEMORY MODE.

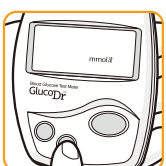
Set the Unit of Measurement.
The GlucoDr Meter can display the test results with the unit of milligrams per deciliter (mg/dL) or millimoles per liter (mmol/L).



1

Press and Hold the Power Button for 3 seconds

To enter the UNIT SELECT MODE, With the meter turned on, press and hold the power button until "mg/dL" or "mmol/L" appears on the meter.



2

Select the Unit of Measurement.

Press and release the ▶ button
until you get the unit measurement that you want. And then press the power button to turn off meter, the setting information you entered will be saved.

Installing Battery

Two batteries(CR2032) will provide you enough power to perform about 4,000 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

Press down the top of the battery cover then pull it out. The battery cover will be released.



3 Replace the Batteries

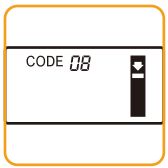
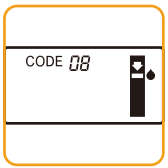
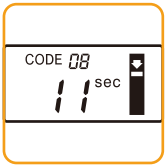
Remove the old batteries and put the new one with "+" sign facing up.

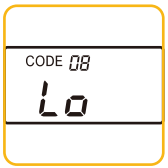


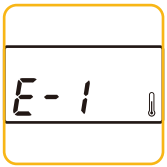
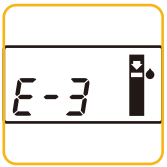
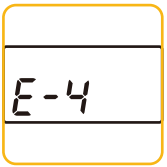
4 Close the Battery Cover

Insert the battery cover tab into the matching hole on the meter, and push down until you hear the cover click into place.

Display Message Guide

Message				
What it means.	The meter is ready for you to insert a test strip.	The meter is ready for a blood drop or control solution. (This is an example of a code number stored in the meter.)	The meter displays countdown from 11 to 1, while calculating a blood glucose test result.	A blood glucose test result in mg/dL
Action	Insert a test strip into the test port of your meter. Make sure the code number displayed on the meter matches the one on the test strip vial.	Apply a blood sample to the test strip.(See pages 18 for how to test your blood glucose level)	No action is required.	No action is required.

Message				
What it means.	A blood glucose test result in mmol/L	A blood glucose test result stored in the memory.	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).
Action	No action is required.	No action is required.	Repeat the test using a new test strip and/or check the system with the GlucoDr Control Solution. If the test result is "HI" again even though your system is working correctly, contact your healthcare professional immediately.	Repeat the test using a new test strip and/or check the system with the GlucoDr Control Solution. If the test result is "Lo" again even though your system is working correctly, contact your healthcare professional immediately.

				
The energy level of the battery is too low to provide accurate test results.	The meter is used outside of the proper range of temperature.	The meter has some problems.	The used test strip was inserted in the test port.	The meter has some problems while testing blood glucose.
Turn off the meter and replace the battery immediately.	Leave the meter at a temperature between 15~35℃ (59~95℉) for at least 30 minutes before repeating the test.	Retest with a new test strip. If this error message displays again, please contact your local distributor.	Retest with a new test strip.	Retest with a new test strip. If this error message displays again, please contact your local distributor.

Troubleshooting	Cause	Action
1. The meter does not turn on after inserting a test strip.	Batteries are dead.	Replace the batteries.
	The batteries are installed incorrectly or there is no battery in the meter.	Check if batteries are correctly installed.(See pages 24~25)
	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 (3 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™ Blood Glucose Monitoring System
Model Name	AGM-2100
Assay Method	Electrochemical method
Sample Type	Fresh capillary whole blood
Sample Volume	4 μℓ (minimum 2.5 μℓ)
Measurement Range	20~600 mg/dL (1.1~33.3 mmol/L)
Measurement Time	11 seconds
Calibration	Plasma-equivalent
Battery Type	Two 3-volt lithium batteries (coin cell type CR2032)
Battery Life	Approximately 4,000 tests
Unit of Measurement	mg/dL or mmol/L
Operating Ranges	Temperature : 15~35℃ (59~95°F)
	Relative Humidity : Less than 85%
	Altitude : Up to 2500m (8202 feet)
	Hematocrit : 30~55%
Dimension	65 X 86.5 X 20 (mm), 2.6 X 3.4 X 0.79 (inches)
Weight	50g or 1.8 oz. (with batteries)
Display	46.0 X 22 (mm) LCD, 1.8 X 0.87 (inches) LCD
Memory Capacity	100 test results
Automatic Shutoff	3 minutes after last action

- The performance of the GlucoDr Test Strips has been evaluated in clinical tests.
  Accuracy:
- The accuracy of the GlucoDr Blood Glucose Monitoring System was assessed by comparing blood glucose test results obtained from 181 diabetic patients with those obtained using YSI Model 2300 STAT Plus Glucose Analyzer.

For glucose concentration < 75 mg/dL (4.2 mmol/L)		For glucose concentration ≥ 75 mg/dL (4.2 mmol/L)	
Accuracy Range	**% of result**	**Accuracy Range**	**% of result**
Within ±5 mg/dL (0.28 mmol/L)	3	Within ±5%	38
Within ±10 mg/dL (0.56 mmol/L)	92	Within ±10%	76
Within ±15 mg/dL (0.83 mmol/L)	100	Within ±15%	95
		Within ±20%	100

Repeatability (using venous whole blood):			Repeatability (using control):		
Level	**SD**	**CV**	**Level**	**SD**	**CV**
32.8 mg/dL	3.7 mg/dL	11.1%	40 mg/dL	3.3 mg/dL	8.2%
83.4 mg/dL	3.3 mg/dL	3.9%	103 mg/dL	3.8 mg/dL	3.7%
114 mg/dL	4.4 mg/dL	3.9%	304 mg/dL	9.6 mg/dL	3.2%
193 mg/dL	6.9 mg/dL	3.6%			
279 mg/dL	9.0 mg/dL	3.2%			

Explanation of Symbols

	CAUTION
	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical device.
	For in vitro diagnostic use
	Do not dispose the instrument in the urban waste.
	Consult User Manual

MEMO

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