

iHealth[®] Acacia

Blood Glucose Monitoring System

Model: AG-607



INSTRUCTION MANUAL

For in vitro diagnostic use only.
Read instructions before use for self-testing.

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Introduction

Thank you for purchasing the iHealth Acacia Blood Glucose Monitoring System. This manual provides important information to help you use the system properly. Before using this product, please read the instruction manual thoroughly. If you have questions regarding this product, please contact customer service or your care provider.

Intended Use

The iHealth Acacia Blood Glucose Monitoring System is intended to be used for:

- Quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh.
- Single- person measurement only (it should not be shared).
- Self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.
- The iHealth Acacia Blood Glucose Monitoring System should not be used to diagnose or screen for diabetes or for neonatal use.
- Alternative Site Testing (AST) should be done only during steady-state times when glucose levels are not changing rapidly.
- The Blood Glucose Test Strips (EGS-2003) are intended for use with the iHealth Acacia blood Glucose meter

(AG-607) to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf, or thigh.

- The control solutions (Level II) are intended for use with the iHealth Acacia Blood Glucose Meter (AG-607), to check that the glucose meter and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.

Important Safety Instructions

Please read the following information carefully before using the Acacia Blood Glucose Monitoring System.

Always keep these instructions in a safe place for reference.

- Misuse of the blood glucose monitoring system can cause electrocution, burns, fire, and other hazards.
- The glucose meter and lancing device are for single patient use. Do not use either item on multiple patients.
- Do not share the meter or lancing device with anyone, including other family members.
- Do not place the blood glucose monitoring system in or near liquid.
- Use the blood glucose monitoring system only for the purpose described in the instruction manual.
- Use only accessories (i.e., test strips, control solution, lancing device, and lancets) that are supplied by the manufacturer.
- Do not use the blood glucose monitoring system if it

has sustained any damage or is not working properly.

- Do not block test ports or place the blood glucose monitoring system on soft surfaces that may block them. Keep test ports free from lint, hair, debris, etc.
- Do not place anything on top of the blood glucose monitoring system.
- Do not insert any objects other than test strips into the openings of the blood glucose system.
- Do not use the meter in any manner not specified by the manufacturer.
- All parts of the system are considered biohazards and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Please refer to the resources identified below for detailed information:

“CDC Clinical Reminder: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens”<http://medbox.iiab.me/modules/en-cdc/www.cdc.gov/injectionsafety/fingertick-devicesbgm.html>

“Infection Prevention during Blood Glucose Monitoring and Insulin Administration”

https://www.cdc.gov/cliac/docs/addenda/cliac0313/07B_CLIAC_2013March_GLucose_Monitoring.pdf

Limitations of Use

- The Acacia Blood Glucose Monitoring System is not intended for use on neonates.

- The meter is not intended for use on artery blood, serum, plasma, and venous blood samples.
- The system should be only used with the EGS-2003 test strips.
- The system cannot be used above an altitude of 10,744 feet (3275 meters).
- Drugs containing acetaminophen (e.g., Tylenol® and other medicines containing acetaminophen, blood concentrations >5 mg/dL) and Vitamin C (ascorbic acid, blood concentrations >4 mg/dL), at doses higher than recommended, may interfere with your glucose meter and deliver inaccurate results.
- Not for use for patients in a hyperglycemic-hyperosmolar state, with or without ketosis.
- Not for use on critically ill patients.
- Not to be used for patients who are dehydrated, hypertensive, hypotensive, or in shock.
- Do not use during, or soon after, xylose absorption testing.

Box Contents

Package contents may vary depending on sales channels. Please refer to the contents listed on the package.

1. Blood Glucose Meter (AG-607)
2. 2 × AAA Batteries
3. Test Strips (EGS-2003) *
4. Lancing Device
5. Lancet*

6. Control Solution(Level II)*

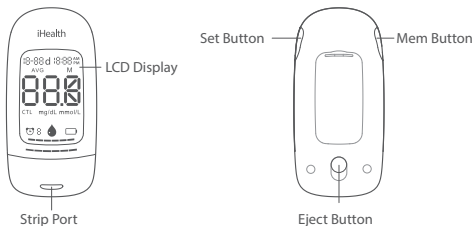
7. Instruction Manual

8. Carrying Bag

* *The package contents may vary across different sales channels.*

Contents and Display Indicators

• Blood Glucose Meter (AG-607)



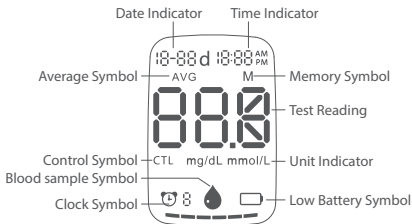
LCD Display: Glucose test results, symbols, and messages appear here.

Strip Port: Insert the test strip into the strip port to automatically turn on the meter.

Set Button: Located on the left side of the meter. It is used to turn on the meter and set the meter's parameters.

Mem Button: Located on the right side of the meter. It is used to turn on the meter and view past test results.

Eject Button: Located on the back side of the meter. It is used to automatically remove the test strip.



Date Indicator: Displays the meter's data.

Time Indicator: Displays the meter's time.

Average Symbol: Displays the 7, 14, 21, 28, 60, 90 day averages.

Memory Symbol: Appears when checking the past test results.

Test Reading: Displays glucose results.

Control Symbol (CTL): Appears when doing a control solution test and indicates that the result will not be stored in the memory.

Unit Indicator: Appears with test results in mg/dL.

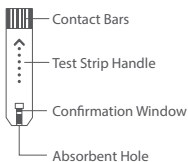
Blood Sample Symbol: Flashes when it is ready to apply the sample.

Clock Symbol: Indicates alarm is set; up to four alarms can be stored.

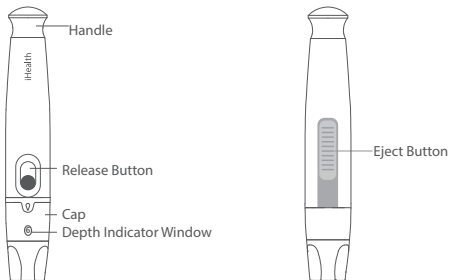
Low Battery Symbol: Appears when the batteries are low to indicate time for replacement.

• Test Strips

Use only iHealth test strips(EGS-2003)with the meter.
Each test strip can be used only once and it consists of the following parts:



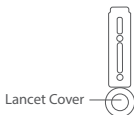
• Lancing Device



• Lancing Device for AST (Optional)



• Lancets



• Control Solution (Level II)



Note:

- 1. If any items printed on the package are missing from your package, or the package appears to have been opened prior to your use, please contact customer service.*
- 2. The package contents may vary across different sales channels. Please verify the contents using your package label.*

Test Principle

Testing with the Acacia Blood Glucose Monitoring System is based on the measurement of electrical currents generated by the reaction of glucose with the reagent of the strip. The system measures the current and converts it to the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

Important Test Information

Please read the following:

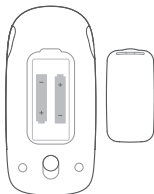
1. Severe dehydration and excessive water loss may cause inaccurate results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
2. Inaccurate results may occur in severely hypotensive individuals or patients who are in shock. Test results that are lower than actual values may occur in individuals who are in a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
3. If you think your blood glucose results are inconsistent with how you are feeling or the symptoms that you are experiencing, repeat the test. If you continue to experience symptoms and get similar results, follow the treatment advice of your healthcare professional.
4. If you are experiencing symptoms that are inconsistent with your blood glucose test, and you have followed all of the instructions provided in this Instruction Manual, contact your healthcare professional immediately.
5. Use only fresh, whole blood samples to test your blood glucose.
6. Do not use test strips that are expired or appear to be damaged, as they may return inaccurate results.
7. The lancing device is for self-use only. Do not share or reuse lancets. Please refer to the Lancing Device Manual for the detailed procedure.

Setup and Operation

Setup

1. Installing battery

- Open the battery cover at the back of the meter.



- Insert two “AAA” batteries. Make sure the batteries are inserted according to the positive and negative marks (“+” and “-”) printed in the battery housing compartment.
- Place the battery cover back on the device.



Disposal – Electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice.

2. Time and date setup

Check and update time and date settings prior to using your system for the first time, or when batteries have been replaced.

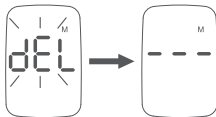
- Press the Set button for two seconds to turn on the meter (a beeping sound will occur) and enter the setting mode.
- With the year display flashing, press the Mem button to cycle through the year values.
- Press the Set button to lock in your choice and proceed to the next setting screen. The order of setting is "Year/Month/Day/Hour/Minute." Refer to the following.



3. Deleting memory (optional)

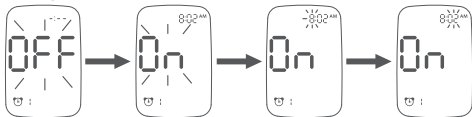
After setting the time and date, the meter will automatically proceed to the memory deletion screen.

- When "dEL" is flashing and the "M" symbol is solid on the screen, press the Mem button to delete all stored memory.
- The meter will then display a flashing "--" and a solid "M" symbol to indicate all memory has been deleted.
- If you do not wish to delete the memory, press the Set button while "dEL" is flashing and the "M" symbol is solid to skip to the alarm settings.

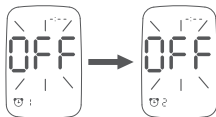


4. Alarm settings (optional)

- When "OFF"/"On" is flashing and the "🕒" symbol is solid on the screen, press the Mem button to toggle between "On" and "OFF" for the first alarm.
- Press the Set button to confirm alarm is on when the flashing "On" and "🕒" symbols appear on the screen.
- When the hour symbol is flashing, press the Mem button to cycle through the numbers, then press the Set button to confirm the hour.
- After setting the hour, press the Mem button to cycle through the minutes. Press and hold the Mem button to fast-cycle through the minutes. Press the Set button to confirm and proceed to the next alarm setting.
- Repeat steps b. through e. for the next alarm. You may set up to four alarms at one time.



- If you do not wish to set an alarm, press the Set button to skip this step.



- To turn off an alarm, enter the setting mode by

pressing the Set button for 2 seconds, then press the Mem button to change the alarm status from “On” to “OFF.” Use the Set button to confirm.

When the alarm activates, the meter will beep and automatically turn on. You can insert a test strip to begin testing. If you do not wish to test at this time, press the Set button to turn off the meter. If you do not press the Set button, the meter will beep for 60 seconds before automatically turning off.

Note:

The data, time, memory deletion, and alarm can only be changed in the setting mode. These parameters cannot be changed when performing blood glucose testing. If the meter is in the setting mode, the meter will turn off automatically if no button is pressed within two minutes.

Operation

1. Prepare your measurement

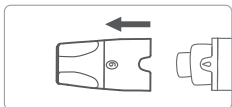
CAUTION:

To reduce the chance of infection:

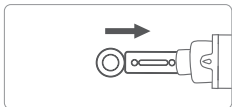
- Choose a clean, dry work surface.
- Never share a lancing device or lancet with another person.
- Always use a new and sterile lancet.
- Always use a new test strip. The test strips are designed for single use only.
- Avoid getting lotion, oils, dirt, or debris in or on the lancet and lancing device.

a. Lay out your Acacia meter, test strips, lancing device, and lancet on a clean, dry work surface.

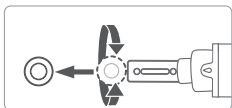
b. Prepare the lancing device:



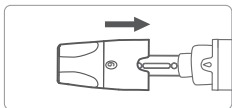
Remove the cap



Insert a lancet



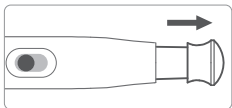
Twist the lancet cover off
(Do **not** discard the lancet cover.)



Place the cap back on



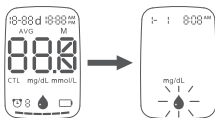
Adjust the puncture depth
(Recommend starting with level 4.)
1~3 for soft skin
4~6 for normal skin
7~9 for thick/rough skin



Pull the handle until it clicks
(A red indicator will appear at the release button.)

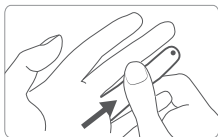
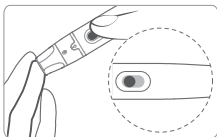
Note: The lancet is for individual use only;
Never share the meter or lancing device with anyone,
including family members.

- c. Wash your hands with warm, soapy water and dry thoroughly.
- d. Take a new test strip out by holding the handle, without touching the absorbent hold or the contact bars.
- e. With the arrow facing the meter, insert the test strip into the meter's strip port. This will power on the device and display all symbols, then the blood sample symbol will be flashing.



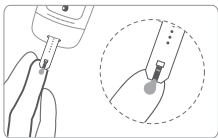
2. Obtain a blood sample

- a. Place the lancing device against your fingertip and press the release button to lance.
- b. Squeeze your finger until a droplet of blood forms. Using your finger, wipe away the first blood droplet and squeeze until a second blood droplet forms.

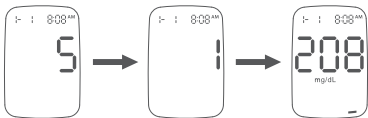


3. Apply the blood sample and read the test results.

- Carefully bring the absorbent hole of the test strip close to the blood droplet at an angle, allowing it to naturally draw in the sample. Make sure the confirmation window of the test strip is filled completely with the blood sample.
- Remove your finger from the test strip when the countdown (from 5 to 1) is displayed on the meter.

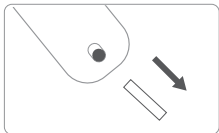


- The test result will appear on the meter after the countdown is complete.

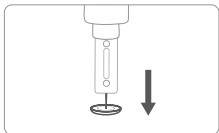


Note: The results obtained from the glucose meter are plasma-calibrated. This helps you and your physician, or other qualified healthcare provider, to compare your meter results with laboratory tests. Refer to the instructions given by your physician, or other qualified healthcare provider. Do not deviate from these instructions on the basis of the result without first consulting your physician.

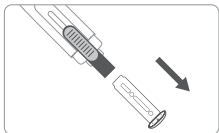
4. Dispose and clean



Push the eject button on the back of the meter and discard the used test strip into a proper container to avoid contaminating other articles.



Remove the lancing device cap and insert the needle into the lancet cover to avoid exposing the needle tip.



Push the eject button slightly and discard the lancet.

To clean, use an isopropyl alcohol pad to wipe the entire surface of the meter and a lancing device for 10 seconds, removing all visible soil from the surface.

5. Interpreting your blood glucose value

a. Reference values

Time of Day	People Without Diabetes
Fasting and before meals	<100 mg/dL
2 hours after meals	<140 mg/dL

Source: American Diabetes Association: Classification and Diagnosis of Diabetes (Position Statement).

Diabetes Care 39 (Supp. 1) S15, 2016.

Please consult your healthcare provider to determine a target range that is best for you.

b. Color bar indication

On the panel of the Acacia Blood Glucose Meter, there is a color bar. It is used for indicating the blood glucose value range. The color bar is shown in.



The black block indicates the present blood glucose value range according to the list below.

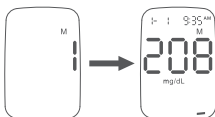
Value of Blood Glucose (mg/dL)	Block in Color Bar (from left to right)
<70	Orange Block
$70 \leq N < 110$	1 st Blue Block
$110 \leq N < 126$	2 nd Blue Block
$126 \leq N < 140$	1 st Purple Block
$140 \leq N < 200$	2 nd Purple Block
≥ 200	3 rd Purple Block

6. Reviewing saved test results

- a. Hold the Mem button for two seconds to view the test results stored in the meter. The first reading displayed will be your recent seven-day average blood glucose result.



- b. Press the Mem button to review 14, 21, 28, 60, and 90-day averages stored in the meter.
- c. After reviewing the 90-day average results, press the Mem button again to see the blood glucose result, along with the date and time.



- d. Continue pressing the Mem button to recall additional test results stored in the meter.

Note: When the memory is full, the oldest result is erased, and the newest result is added.

- e. After reaching the last test result, "End" will display and the meter will turn off automatically.



Cleaning and Disinfection

Cleaning and disinfection are absolutely necessary for this device to ensure the meter works optimally (e.g., display will be visibly clear after cleaning) and to prevent infection and/or cross-contamination.

The meter and lancing device should be cleaned and disinfected following each use. We suggest that you use CaviWipes™ (Metrex® Research Corporation, EPA Reg. No. 46781-8, EPA Est. No. 56952-WI-001). CaviWipes, with isopropanol and diisobutyl-phenoxy-ethoxyethyl dimethyl benzyl ammonium chloride as the active ingredient, have been shown to be safe for use with the meter and lancing device.

You can purchase this product from the suppliers listed below:

- (1) Visit the website www.metrex.com, or contact Metrex at 800-841-1428 for product or technical information.
- (2) Visit retail stores, such as Walmart.
- (3) Visit the following websites:

Amazon.com:

[http://www.amazon.com/s/ref=nb-sb-noss?url=search-alias%3Daps&field-keywords=CaviWipes](http://www.amazon.com/s/ref=nb_sb_noss?url=search-alias%3Daps&field-keywords=CaviWipes)

Metrex corporate and distributor:

<http://www.metrex.com/how-to-buy>

The meter and the lancing device are for single - patient use. If user tests six times per day, the meter and lancing device should be cleaned and disinfected six times per day, which equals 10,950 cycles over the five-year

lifespan of the device. The meter and lancing device were validated for 11,000 cycles, which could support up to six cleaning and disinfection cycles per day. Below are the steps on how to clean and disinfect the meter and lancing device.

1. After testing, clean and wash your hands.
2. Use one CaviWipe to carefully clean the entire external surface of the meter.
3. Then, wipe the entire external surface of the meter with a new wipe, keeping the surface wet for three minutes.
4. Using the same method, use CaviWipes to clean and disinfect the lancing device.

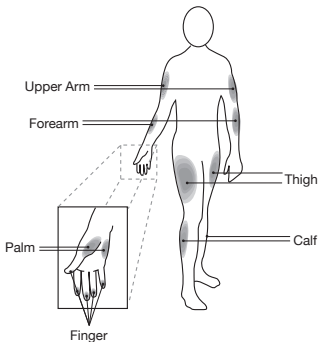
Note:

- ① Wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.
- ② Only the surface of the meter can be cleaned and disinfected with the disinfecting towelette. Do not insert the disinfecting towelette into the test strip port and the metal connector, or the performance of the meter may be negatively affected.
- ③ If you have any questions, call customer service.
- ④ If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected prior to use by the person providing assistance.

Information about Alternative Site Testing (Ast)

What Is AST?

AST is checking blood glucose levels using other parts of the body besides a fingertip. The Acacia Blood Glucose Monitoring System allows you to test on the palm, forearm, upper arm, calf, or thigh, producing equivalent results to fingertip testing when used appropriately.



AST has limitations. Please consult your healthcare professional before you conduct AST. The Acacia Blood Glucose Monitoring System should only be used for AST under steady-state blood glucose conditions.

What Is the Advantage of AST?

The advantage of AST is potential pain reduction. Pain is felt more readily on the fingertips because they are full of nerve endings (receptors). At other body sites where nerve endings are not as condensed, pain is not felt as acutely.

When AST Be Used?

Food, medication, illness, stress, and exercise can affect blood glucose levels. Capillary blood from the fingertips reflects these changes faster than capillary blood from other sites. Therefore, when testing blood glucose levels during or immediately after meals, exercise, or when one of the above-noted conditions applies, take a blood sample from your fingertips only. AST should be used only during steady-state times when glucose levels are not changing rapidly.

Blood glucose results from the forearm, upper arm, hand, thigh, and calf are not always the same as results from fingertips. AST is suitable in the following instances:

- In a pre-meal or fasting state (i.e., two or more hours have passed since last meal).
- Two or more hours after taking insulin.
- Two or more hours after exercising.

Caution: Do not use sites other than the fingertips for testing when blood glucose is rapidly rising or falling, within two hours of eating, after taking insulin, immediately after exercise, or when you are ill or under stress. AST should not be used to calibrate Continuous

Glucose Monitoring Systems (CGMs). Results from AST should not be used in insulin dose calculations. Do not use AST if:

- You think your blood glucose is low.
- You are unaware that you might have hypoglycemia.
- You are testing for hyperglycemia.
- Your AST results do not match the way you feel.
- Your routine glucose results fluctuate often.

***Note:** The Lancing Device for AST is sold separately. If not included in your kit, contact customer service to purchase.*

Important Information about Control Solution Tests

Control solution contains a known amount of glucose that reacts with test strips and is used to check that your meter and test strips are working together properly.

Materials Needed to Perform a Control Solution Test:

- Blood Glucose Meter
- Blood Glucose Test Strip (EGS-2003)
- Control Solution

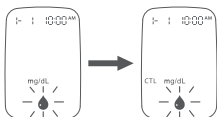
Perform a Control Solution Test When:

- First receiving or purchasing the meter.
- You suspect the meter or test strips are not working properly.
- Your blood glucose test results are not consistent with your expectation, or you think the results are inaccurate.

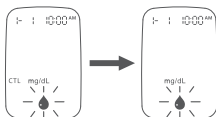
- Practicing the testing process.
- The meter has been dropped or damaged.

Performing a Control Solution Test

1. Take a new test strip out by holding the handle without touching the absorbent hold or the contact bars.
2. With the arrow facing the meter, insert the test strip into the meter's strip port - this will turn on the device. When the blood sample symbol appears on the LCD, press the Set button to enter the control solution (CTL) mode.



Note: Be sure to set the meter on the CTL mode before performing a control solution test. The control test result will not be saved in the meter. Press the Set button again to turn off the CTL mode and switch back to the regular testing mode.



3. Apply the control solution.
 - a. Shake the control solution vial before each use.
 - b. Squeeze a droplet of control solution into the vial cap.

Note: For optimal results, it is recommended that you use the second droplet of the control solution (discard the first droplet).

c. Hold the meter and use the absorbent hole of the test strip to catch the droplet. Once the confirmation window fills completely, the meter will start counting down. Remove the control solution sample from the test strip when the countdown begins.

Note: To avoid contaminating the entire vial of control solution, do not directly apply control solution onto a strip.

4. Read and compare the results.

After the meter counts down to “1” the control solution test result will appear on the meter display.

The result of the control solution test should be within the range printed on the test strip vial label. If the test result falls outside the specified range, repeat the test, carefully following the steps above.

Out-of-Range Results

Results falling outside the specified range may be caused by:

- An error in the test.
- Expired or contaminated control solution.
- An expired or contaminated test strip.
- Meter malfunction.

If you continue to get control solution test results that fall outside of the range printed on the vial, the meter may not be working properly. Discontinue use and

contact customer service.

To purchase additional control solution, please visit www.iHealthlabs.com.

NOTE:

Do not use expired control solution.

The control solution range printed on the test strip vial is for control solution use only. It is not a recommended range for your blood glucose level.

Comparing Glucose Meter Test Results with Laboratory Results

The results obtained from the glucose meter are plasma-calibrated. The result you obtain from your glucose meter may differ somewhat from your laboratory results due to normal variation. Meter results can be affected by factors and conditions that do not affect laboratory results in the same way. To make an accurate comparison between meter and laboratory results, follow the guidelines below.

Before the Lab Test

- Perform a control solution test to make sure that the meter is working properly.
- If possible, fast at least eight hours before conducting a comparison test.
- Take your meter to the lab.

While at the Lab

Make sure that samples for both tests are taken and tested within 15 minutes of each other.

- Wash your hands before obtaining a blood sample.
- Never use your glucose meter with blood samples collected in a test tube.
- Use fresh capillary blood only.

Specifications

1. Model: AG-607
2. Machine size: 4.3" × 2.05" × 0.81"
(110 mm × 52 mm × 20.5 mm)
3. Measuring method: Amperometric technology using glucose dehydrogenase
4. Result range: 20 mg/dL ~ 600 mg/dL
(1.1 mmol/L ~ 33.3mmol/L)
5. Power source: 2×1.5V \Rightarrow SIZE AAA
6. Storage condition: Test Strips 39°F~86°F (4°C~30°C)
and 10%~85% RH
7. Storage condition: The meter -4°F~131°F (-20°C~
55°C) and 10%~80% RH
8. Operating conditions: 50°F~104°F (10°C~40°C) and
25%~80% RH
9. Blood source: Fresh capillary whole blood
10. Blood volume: Minimum 0.7 micro liter
11. Life span: Five years
12. Drugs containing acetaminophen (e.g., Tylenol® and
other medicines containing acetaminophen, blood

concentrations >5 mg/dL) and Vitamin C (ascorbic acid, blood concentrations >4 mg/dL), at doses higher than recommended, may interfere with your glucose meter and deliver inaccurate results.

13. System Accuracy: The System was tested on 350 capillary blood samples, and this is the accuracy in the hands of lay users.

Regression Analysis Between the Meter and YSI Reference

	Finger	Palm	Forearm	Upper Arm	Calf	Thigh
Slope (comparison with YSI)	0.9838	0.9964	0.9809	0.9853	0.9856	0.9955
Y-Intercept (comparison with YSI)	-1.0011	-2.2901	-0.6385	-0.7838	-0.5727	-1.5384
R ² (comparison with YSI)	0.9813	0.9829	0.9844	0.9812	0.985	0.9842

System Accuracy Results for Glucose Concentrations <75mg/dL

Anatomical Site	Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	Within ±20mg/dL
Finger	31/55 (56.4%)	51/55 (91.1%)	55/55 (100%)	55/55 (100%)
Palm	32/56 (57.1%)	55/56 (98.2%)	56/56 (100%)	56/56 (100%)
Forearm	31/55 (56.3%)	54/55 (98.2%)	55/55 (100%)	55/55 (100%)
Upper Arm	33/55 (60%)	53/55 (96.4%)	55/55 (100%)	55/55 (100%)
Calf	29/53 (54.7%)	50/53 (94.3%)	53/53 (100%)	53/53 (100%)
Thigh	32/55 (58.2%)	53/55 (96.4%)	55/55 (100%)	55/55 (100%)

System Accuracy Results for Glucose Concentrations ≥ 75 mg/dL

Anatomical Site	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
Finger	124/295 (42%)	242/295 (82%)	292/295 (99%)	295/295 (100%)
Palm	122/294 (41.5%)	232/294 (78.9%)	286/294 (97.3%)	294/294 (100%)
Forearm	136/295 (46.1%)	235/295 (79.7%)	285/295 (96.6%)	295/295 (100%)
Upper Arm	134/295 (45.4%)	237/295 (80.3%)	287/295 (97.3%)	295/295 (100%)
Calf	122/297 (41.1%)	245/297 (82.5%)	288/297 (97%)	297/297 (100%)
Thigh	136/295 (46.1%)	246/295 (83.4%)	286/295 (96.3%)	295/295 (100%)

Maintenance and Troubleshooting

Maintenance and Storage of Your Meter

- Always use care when handling the Blood Glucose Meter. Dropping or throwing the meter may cause damage.
- Always wash your hands with soap and water, rinse, and dry them completely before handling the AG-607 Blood Glucose Meter and test strips.

Signs of Potential Physical and Performance Deterioration





If you start experiencing one of the following, stop using and contact customer service, or the place of purchase, for assistance.







1. The device does not work.

2. Discoloration of the meter casing or lancing device (e.g., it is difficult to read the labeling information).
3. Corrosion, crazing (fine cracks), embrittlement, and/or cracking of the meter casing or lancing device.

Display Message

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please contact customer service. Do not attempt to repair the meter by yourself and never try to disassemble the meter under any circumstances.

Message	What It Means	What To Do
	Blood glucose level is lower than 20 mg/dL (1.1 mmol/L).	The message indicates very low blood glucose. Consult your healthcare professional.
	Blood glucose level is higher than 600 mg/dL (33.3 mmol/L).	The message indicates severe hyperglycemia (high blood glucose). Seek immediate medical assistance.
	The batteries in your meter are low on power.	Please change the batteries.
	Problem with the meter.	Retest using a new test strip.

	<p>Problems have occurred that are related to test strip use, such as:</p> <ul style="list-style-type: none"> • Test strip may be wet or damaged. • Test strip may have been removed too early. • You applied more blood after testing began. 	<p>Retest using a new test strip.</p>
	<p>Problem with the meter.</p>	<p>Retest using a new test strip.</p>
	<p>The environmental temperature is lower than 50°F(10°C).</p>	<p>The operating temperature is 50°F~104°F (10°C~40°C).</p>
	<p>The environmental temperature is higher than 104°F(40°C).</p>	<p>The operating temperature is 50°F~104°F (10°C~40°C).</p>
	<p>Problem with the meter.</p>	<p>Retest with a new test strip. If the problem persists, contact Customer Service.</p>
	<p>Problem with the meter.</p>	<p>Retest with a new test strip. If the problem persists, contact Customer Service.</p>

Troubleshooting

Problem	Possible Causes	Solution(s)
Display remains blank after the test strip has been inserted into the meter.	<ol style="list-style-type: none"> 1. Battery power is too low for use. 2. Too much time has passed between inserting the test strip and performing the test. 3. Test strip has not been fully inserted into the meter. 	<ol style="list-style-type: none"> 1. Please change the batteries. 2. Reinsert the test strip into the meter. 3. Reinsert the test strip into the meter, pressing firmly.
Test results are inconsistent, or control solution test results are not within the specified range.	<ol style="list-style-type: none"> 1. Not enough sample in the test strip. 2. Test strip or control solution has expired. 3. Test strip has been damaged due to heat or humidity, so that the sample cannot be applied, or the speed of application is too slow. 4. System is not performing due to the environment being above or below room temperature. 	<ol style="list-style-type: none"> 1. Retest with a new test strip and make sure that enough sample has been applied. 2. Retest with a new test strip or new control solution. 3. Perform a control solution test using a new test strip. If the results are still out of range, replace with new vial of test strips. 4. Bring the system to a room-temperature environment and wait approximately 30 minutes before performing a new test.
The meter countdown did not start.	Test strip has not been inserted correctly.	Use a new test strip and retest.

Note: The default setting in US is mg/dL. Please contact customer service if your meter is not set to mg/dL when purchased.

Electromagnetic Compatibility Information

Table 1 For All ME EQUIPMENT and ME SYSTEMS

Guidance and Manufacture's Declaration - Electromagnetic Emissions		
<p>The AG-607 is intended for use in the electromagnetic environment specified below. The customer or the user of the AG-607 should assure that it is used in such an environment.</p>		
Emissions Test	Compliance	Electromagnetic Environment-Guidance
RF emissions CISPR 11	Group 1	The AG-607 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The AG-607 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2 For All ME EQUIPMENT and ME SYSTEMS


Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The AG-607 is intended for use in the electromagnetic environment specified below. The customer or the user of the AG-607 should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME EQUIPMENT or ME SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [ME EQUIPMENT or ME SYSTEM] be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
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NOTE: U_T is the AC main voltage prior to application of the test level.

Table 3 For ME EQUIPMENT and ME SYSTEMS That are not Life-Supporting

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The AG-607 is intended for use in the electromagnetic environment specified below. The customer or the user of the AG-607 should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the AG-607, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

			$d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz to 800MHz $d=1.2\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			
<p>a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts, and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in</p>			

which the AG-607 is used exceeds the applicable RF compliance level above, the AG-607 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AG-607.

- b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4 For ME EQUIPMENT and ME SYSTEMS That are not Life-Supporting

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the AG-607

The AG-607 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AG-607 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AG-607 as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter m		
	150 kHz to 80 MHz $d=1.2\sqrt{p}$	80 MHz to 800 MHz $d=1.2\sqrt{p}$	800 MHz to 2.5 GHz $d=2.3\sqrt{p}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m)

can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 5 Immunity test requirements for equipment intended to be used in a basic electromagnetic environment

Port	Phenomenon	Basic standard	Test value	Performance criterion
Encl- osure	ESD	IEC 61000-4-2	+4 kV contact discharge	B
			+8 kV air discharge	B
	Electromag- netic field	IEC 61000-4-3	3 V/m (80 MHz to 1 GHz)	A
			3 V/m (1.4 GHz to 2 GHz)	A
			1 V/m (2.0 GHz to 2.7 GHz)	A
	Power frequency magnetic field	IEC 61000-4-8	3 A/m (50 Hz, 60 Hz)	A

Table 6 Immunity requirements for IVD medical equipment

Port	Phenomenon	Basic standard	Test value
Encl- osure	Electrostatic discharge (ESD)	IEC 61000-4-2	2 kV and 4kV contact discharge 2 kV, 4 kV and 8 kV air discharge
	Electromagnetic field	IEC 61000-4-3	3 V/m (80 MHz to 1 GHz) 3 V/m (1.4 GHz to 2 GHz) 1 V/m (2.0 GHz to 2.7 GHz)
	Magnetic field	IEC 61000-4-8	3 A/m, (50 Hz, 60 Hz)

NOTE 1: *It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.*

NOTE 2: *It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained, in order that the device will perform as intended.*

Use of this instrument in a dry environment, especially if synthetic materials are present (e.g., synthetic clothing, carpets etc.) may cause damaging static discharge that may cause erroneous results.

Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation.

USA:

iHealth Labs, Inc. www.iHealthlabs.com
880 W Maude Ave, Sunnyvale, CA 94085 USA
+1-855-816-7705 (8:30AM – 5:30PM PST, Monday to
Friday except holidays)
Email: Support@ihealthlabs.com

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EC	REP	iHealth Labs Europe SAS www.ihealthlabs.eu 36 Rue de Ponthieu, 75008, Paris, France Email: support@ihealthlabs.eu
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If you have questions or need assistance outside the operational days and times, please contact your healthcare provider.

Explanation of Symbols

	Serial number		Caution
	Consult instructions for use		
	In vitro diagnostic medical device		
	Storage temperature Limit		

	Manufacturer
	Use-by date
	Batch code
	Do not reuse
	Catalogue number
	Keep in a dry place
	Do not use if packaging is damaged
	Keep away from direct sunlight and other heat sources
	Sterilized using irradiation
	European authorized representative
	Environmental Protection – Electrical products waste should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice.
CE 0197	Complies with the requirements of the European IVD Directive (98/79/EC)

Rev. 12/2024
AG-607-SMSP05 V2.0