iHealth®

Wireless Smart Gluco-Monitoring System

OWNER'S MANUAL

For in vitro diagnostic use only
Read instructions before use for self-testing
iHealth® Wireless Smart Gluco-Monitoring System
OWNER'S MANUAL

Table of Contents

• INTRODUCTION

Thank you for purchasing the iHealth Wireless Smart Gluco-Monitoring System (the iHealth system). This manual provides important information to help you use the system properly. Before using this product, please read the Owner's Manual thoroughly.

• INTENDED USE

The iHealth 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 system should not be used for the diagnosis of or screening for diabetes, or for neonatal use.

• IMPORTANT SAFETY INSTRUCTIONS

Please read the following information carefully before using the iHealth system. Always keep these instructions in a safe place for reference.

. Misuse of the iHealth system can cause electrocution, burns, fire, and other hazards.

. The 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 iHealth system in or near liquid.

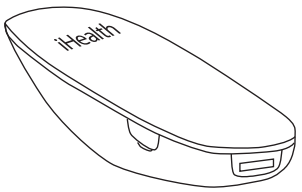
. Use the iHealth system only for the purpose described in the Owner's Manual.

. Use only accessories that are supplied by the manufacturer.

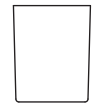
. Do not use the iHealth system if it has sustained any damage or is not working properly.
. Keep the iHealth system away from heat at all times. Do not let the iHealth system come into contact with surfaces that are hot to the touch.
. Do not block test port or place the iHealth system on soft surfaces that may block them. Keep test port free from lint, hair, debris, etc.
. Do not place anything on top of the iHealth system.
. Do not place foreign objects into any opening in the iHealth system.
. Do not use the meter in a manner not specified by the manufacturer.
. All parts of the iHealth 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 fo r detailed information:
"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)
http ://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm
"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens"(2010)
http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

• CONTENTS OF THE WIRELESS SMART GLUCO-MONITORING SYSTEM

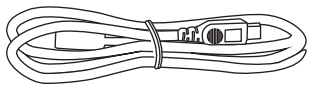
Package contents vary by region. Please refer to the package contents listed on the package you purchased.



• iHealth Smart Glucose Meter (the meter)

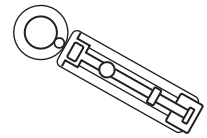


• Clear Cap for Alternate Site Testing



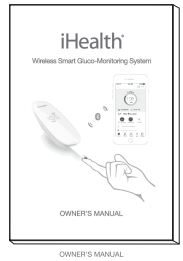
• USB Charging Cable

• iHealth Lancing Device



• Lancet

• Travel Case

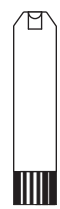


• Owner's Manual

• Quick Start Guide

iHealth control solution and iHealth test strips sold separately.

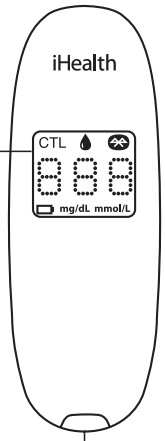
• iHealth Control Solution



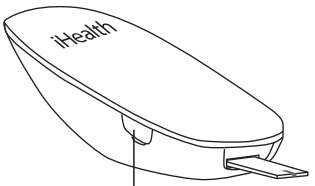
• iHealth Test Strip

• Parts and Displays

• iHealth Blood Glucose Meter(the meter)



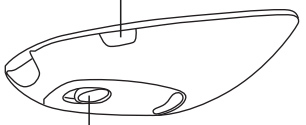
LED DISPLAY
Test result, symbols, and messages appear here.



MICRO USB
Charge the meter through provided USB cable.

STRIP PORT
Insert the test strip into the strip port to automatically turn on the meter.

MEMORY BUTTON
Located on the side of the meter. It is used to turn on the meter and view past test results.

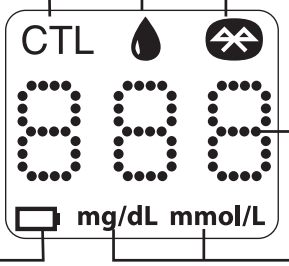


EJECT BUTTON
Located at the back side of the meter. It is used to automatically remove the test strip.

BLOOD SAMPLE SYMBOL
Flashes when the meter is ready to accept the blood sample.

BLUETOOTH SYMBOL
Appears when the meter is connected with iOS device through *Bluetooth* function.

CTL SYMBOL
Appears when doing a control solution test and indicates that the result won't be stored in the memory.



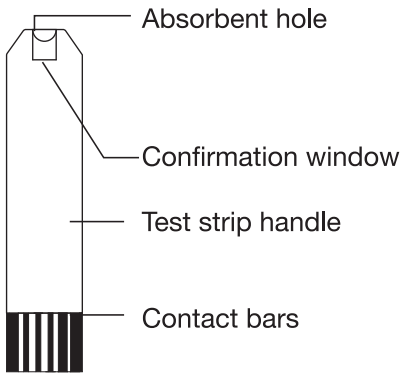
TEST RESULT DISPLAY
Displays test result.

LOW BATTERY SYMBOL
Appears when the battery is low.

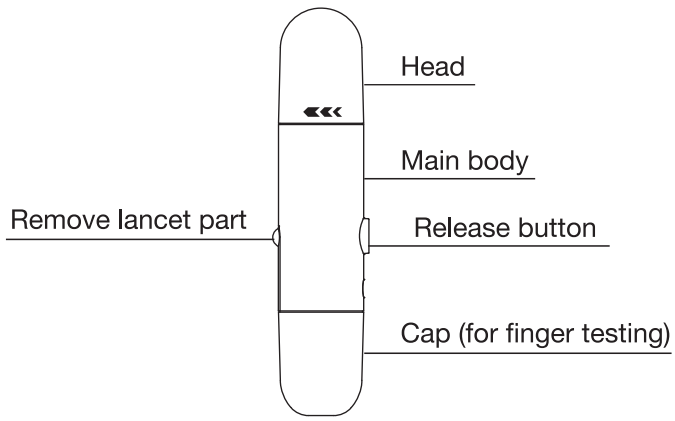
MEASUREMENT UNIT
Appears with the test result either in mg/dL or mmol/L.

• iHealth Test Strips (sold separately)

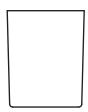
Use only iHealth test strips with the meter. Each test strip can be used only once, and consists of the following parts:



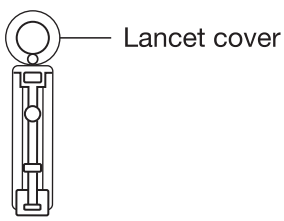
• iHealth Lancing Device



• Clear Cap for Alternate Site Testing



• Lancet



• iHealth Control Solution (sold separately)

• **Mobile Device Compatibility**

Works with the following devices:
iPhone 4+
iPad 2+
iPad Mini+
iPad Air+
iPod Touch (5th generation)
Select Android devices

Requires iOS version 7.0+ or Android version 4.0+

• TEST PRINCIPLE

Testing with the iHealth system is based on the measurement of electrical currents generated by the reaction of glucose with the reagent of the test strip. The iHealth 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:
. Severe dehydration and excessive water loss may cause inaccurate results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
. 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-hyper-osmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
. If your blood glucose results are lower or higher than usual, and you do not have symptoms of illness, first repeat the test. If you have symptoms or continue to get results that are higher or lower than usual, follow the treatment advice of your healthcare

professional.
. If you are experiencing symptoms that are inconsistent with your blood glucose test, and you have followed all of the instructions provided in this Owner's Manual, contact your healthcare professional immediately.
. Use only fresh whole blood samples to test your blood glucose.
. Do not use test strips that are expired or appear to be damaged as they may return inaccurate results.
. The lancing device is for self-use only. Do not share or re-use lancets. Please refer to the La ncing Device Manual for the detailed procedure.
For more detailed information, please refer to the resources identified below:
"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)
http ://www.fda.gov/MedicaIDevices/Safety/AlertsandNotices/ucm224025.htm
"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens"(2010)
http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

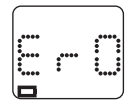
• FIRST TIME SETUP INSTRUCTIONS

. Download the companion app
Prior to first use, download and install the free iHealth Gluco-Smart App from the Apple App Store or Google Play Store. Follow the on-screen instructions to create your iHealth account.
. Access iHealth Cloud
You can use your iHealth ID to gain access to free and secure Cloud Services. Go to www.ihealthlabs.com and click on "Sign In".
. Charge the battery

Out of the box

Your meter is powered by a built-in, rechargeable battery. Plug one end of the charging cable into the side of the meter and the other end into an USB charger port. Charge it for two to four hours before first use. A fully charged battery can typically last up to 200 tests depending on your daily usage.

Low battery message

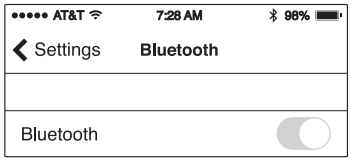
After you have used your meter for some time,  appears for three seconds when the battery in your meter is low on power. You must recharge the battery before using it again. After three seconds, the meter shuts off automatically. The meter does not take any measurement when the battery is low.

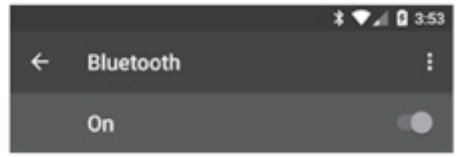
Important: If battery is completely drained, fully charge the battery and launch the app to sync the meter before using it again.

. Sync the meter

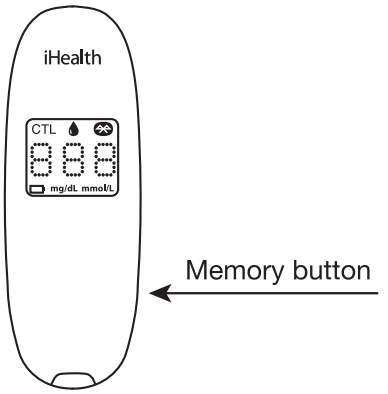
Prior to first use, follow the steps below to connect the meter to the app on your smart device to set your meter's time and date. By connecting the two, the date and time of the meter will be synced with your smart device.

1. Enable *Bluetooth* on your iOS or Android device.

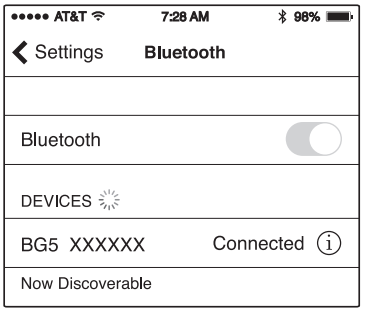


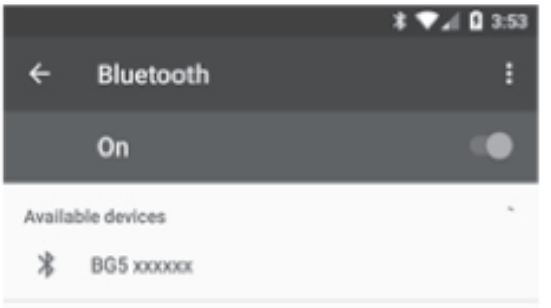


2. Press and hold the "Memory" button for three seconds to turn the meter on.

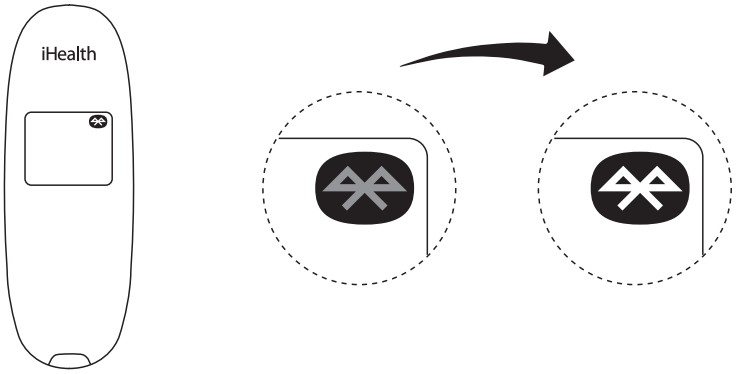


3. Select the model name "BG5xxxxxx" in the *Bluetooth* menu to pair and connect.





4. Launch the app to connect the meter to the app. The *Bluetooth* symbol will flash and remain lit on the meter.



Note: Repeat steps 1-4 when switching to a different iOS or Android device, making sure to un-pair or forget the meter on the previous device..

. Scan the test strip vial
Connect your mobile device to the Internet and open the

Gluco-Smart App. When the glucose meter is connected to the mobile device, scan the QR code on the top of the iHealth test strip vial to calibrate the test strips with the meter. You must scan the QR code each time a new vial is opened.
When all 25 strips in a vial have been used, 

appears on the meter to alert you that it is time to open a new vial, and the meter will shut off automatically. The meter does not take any measurement when "Er d" appears on the meter.

. Test blood glucose level

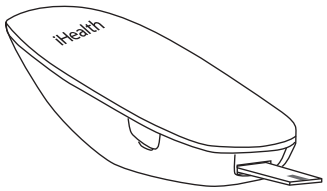
If you have synced your meter to the app on your mobile device, scanned the QR code of a test strip vial, and want to take a reading with the app:

[1] Make sure *Bluetooth* is turned on to connect the meter to the app on your mobile device.

If you have synced your meter to the app on your mobile device, scanned the QR code of test strip vial, and want to take a reading without the app launched: Skip step [1].

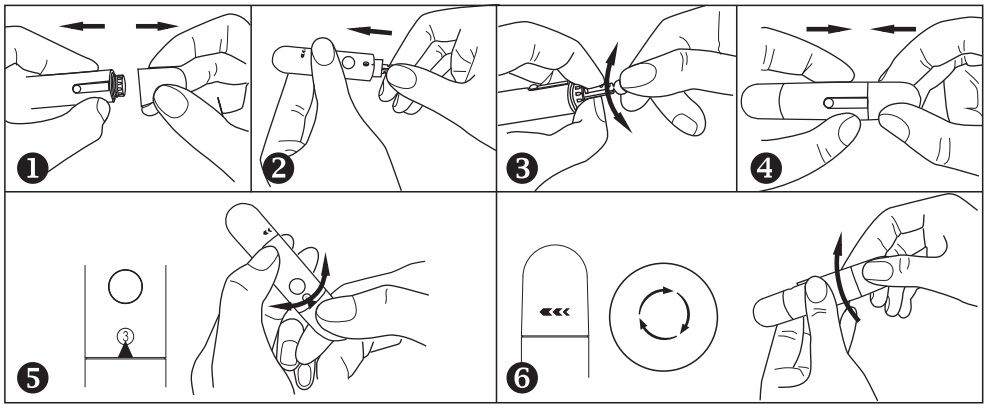
[2] Insert the test strip into the meter's strip port.

Insert the test strip into the strip port with the contact bars facing toward you.



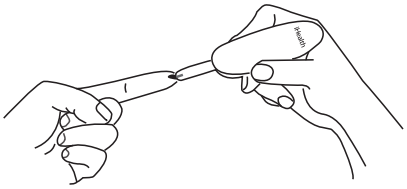
[3] Prepare the lancing device.

① Snap off the lancet device cap
② Insert a new lancet firmly into the lancing holder cup
③ Twist the lancet cover off
④ Replace the lancing device cap
⑤ Set the lancing level
⑥ Cock the handle until it clicks

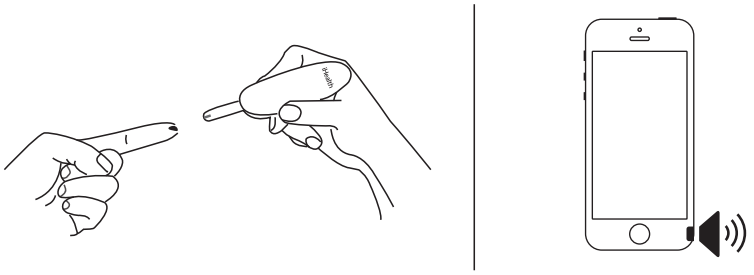


[4] Obtain a blood sample.
Press the lancing device against the site to be lanced. Press the release button to puncture the site. Gently squeeze your finger until a drop of blood forms. Wipe away the first blood drop and squeeze until a second small blood drops forms.

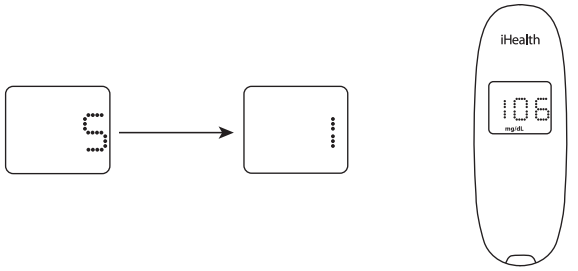
[5] Apply the blood sample to the test strip.
Quickly apply the blood sample to the absorbent hole (tip) of the test strip. Make sure the confirmation window of the test strip is completely filled with the blood sample.



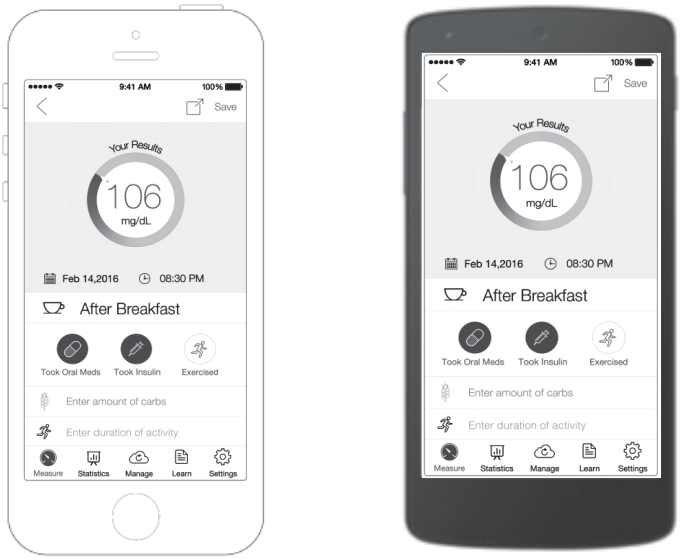
Quickly remove your finger from the test strip when the countdown (from 5 to 1) begins on the meter display, or when you hear a sound alert from your mobile device.



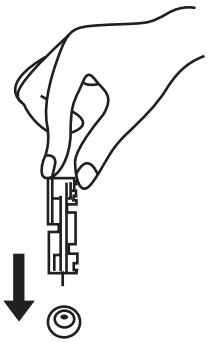
[6] Read the test results.
-If the meter is not connected to the app, the test result will appear on the meter after counting down from 5 to 1 .



- If the meter is connected to the app, the test result will appear on the app.



[7] Discard the used test strip and lancet.
Remove the used test strip from the meter using a small amount of tissue paper. Discard the used test strip and lancet properly.
(Tip: Prior to disposal, stick the lancet into the cover)



• DATA SYNCING

The meter can save up to 500 of the most recent blood glucose test results. When the meter needs to save a new test result and has already stored 500 test results, the oldest test result will be overwritten by the new test result.

When the meter is connected to the app on your mobile device, tap the "Upload" button to upload the saved data from the meter to the app.

• REVIEWING SAVED TEST RESULTS ON THE METER

Press the memory button to view the test results stored in the meter. The first reading you see is your most recent blood glucose result. To review earlier test results, press the memory button repeatedly.

When you reach the last test result, the word "End" will appear, and the meter will shut off automatically. Similarly, the meter will shut off automatically when it is idle for three minutes.

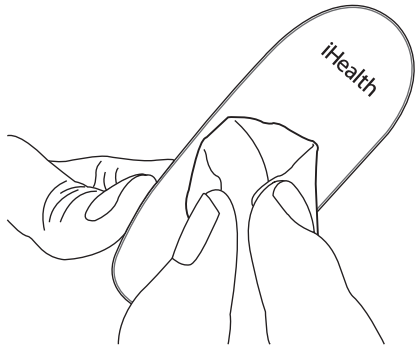
• CLEANING AND DISINFECTION

Cleaning and disinfection is a necessary and important part of the test procedure. It can help to prevent infection, the potential spread of infection, and cross-contamination. Cleaning can also ensure that the meter works properly and that the display is clear and readable.

The meter and lancing device should be cleaned and disinfected following each use. We suggest that you use CaviWipesTM (Metrex~ Research Corporation, EPA Reg. No. 46781-8, EPA Est. No. 56952-WI-O01). 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 the website http://www.endochoice.com/Equipment?search=wipe
The meter and lancing device are validated to support 10,000 individual tests and consequently 1 0,000 cleanings over their 5 year life spans.

Below are the steps on how to clean the meter and lancing device.
1. After a test, clean and wash your hands.
2. Use one CaviWipe to carefully clean the meter, front and back
3. Then, disinfect the meter with another wipe and allow the surface to dry naturally: this should take approximately 2 minutes.



4. Use the same method with the CaviWipes to clean and disinfect the lancing device.
Note:
① Each disinfection step requires a pre-cleaning step. 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, or else the perfo rmance of the meter may be affected.

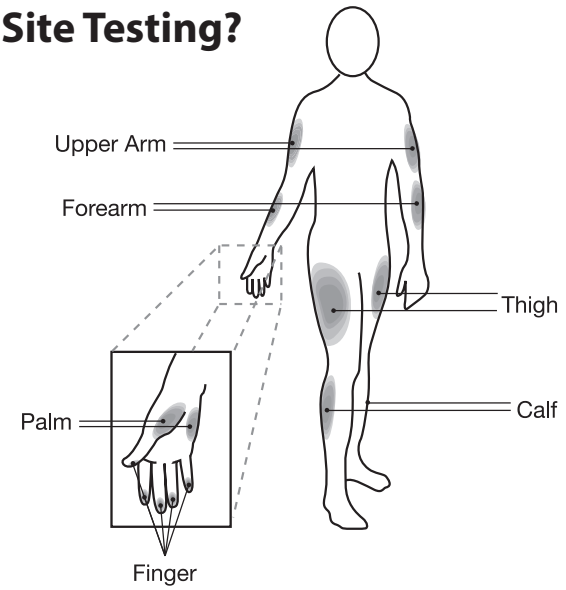
• SIGNS OF POTENTIAL PHYSICAL AND PERFORMANCE DETERIORATION

If you encounter one of the following circumstances, stop using the meter and contact iHealth Customer Support by email (support@ihealthlabs.com) phone (1-855-816-7705):

1. The device does not work; for example, the mobile device can not begin testing when the meter is connected with the mobile device or when a test strip is inserted into the meter.
2. Discoloration of the meter casing or lancing device; for example, it is difficult to read the labeling information.
3. Corrosion, crazing (fine cracks), embrittlement, and/or cracking of the meter casing or lancing device.

• INFORMATION ABOUT ALTERNATE SITE TESTING (AST)

What is Alternate Site Testing?



Alternate Site Testing (AST) is the use of parts of the body, other than the fingertips, to check blood glucose levels. The iHealth system allows you to test on the palm, forearm, upper arm, calf, or thigh with equivalent results to fingertip testing when used at appropriate times.

Caution: When performing Alternate Site Testing, please

remember to change the cap of the lancing device to the clear cap specially designed for AST.
There are limitations for doing AST. Please consult your healthcare professional before you conduct AST. The iHealth system should only be used for AST under steady-state blood glucose conditions.

• What is the Advantage of Alternate Site Testing?

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 so condensed, pain is not felt as acutely.

• When Should You Use Alternate Site Testing?

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 or exercise, or when another 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.

Alternate Site Testing is suitable in the following instances:
. In a pre-meal or fasting state (two hours or more after the last meal)
. Two hours or more after taking insulin
. Two hours or more after exercising

Caution: Alternate Site Testing should not be used to calibrate continuous glucose monitoring systems (CGMs). Results from Alternate Site Testing 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 fee
. Your routine glucose results fluctuate often

• IMPORTANT INFORMATION ABOUT CONTROL SOLUTION TESTS

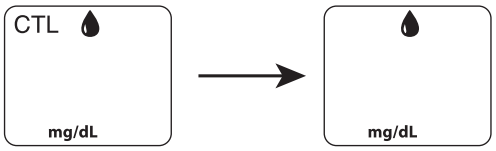
Control solution contains a known amount of glucose that reacts with test strips and is used to check that your meter and test strips are working together properly.
Materials needed to perform a control solution test:
. iHealth Blood Glucose Meter (the meter)
. iHealth Test Strip
. iHealth Control Solution
Perform a control solution test when:
. First receiving or purchasing the meter
. Checking the meter and test strips (which should be done at least once a week)
. Using a new vial of test strips
. You suspect the meter or test strips are not working properly
. Your blood glucose test results a re not consistent with you expectation, or you think the results are not accurate
. Practicing the testing process
. The meter has been dropped or damaged

• PERFORMING A CONTROL SOLUTION TEST

[1] When the meter is not connected to your iHealth Gluco-Smart App on your mobile device:
Step 1: Turn on the control solution test (CTL) mode. Insert the test strip into the meter's strip port to turn on the meter. When the blood sample symbol appears on the meter display, press the memory button to turn on the CTL mode. When the CTL symbol appears, the meter is in control solution test mode and will not save this test result in memory.

Note: Be sure to set the meter and/or app on the CTL mode before performing a control solution test. The control solution test result will not be saved in the meter.

Step 2: Press the memory button again to turn off the CTL mode and switch back to the regular testing mode.



Step 3: Apply the control solution.

. Shake the control solution vial before each use.

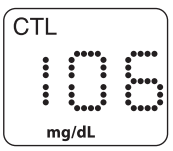
. Squeeze a drop of control solution into the vial cap. For better results, it is recommended that you use the second drop of the control solution (discard the first drop).

. Hold the meter and move the absorbent hole of the test strip to absorb the drop. 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.

Step 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 la bel. If the test result falls outside the specified range, repeat the test, carefully following the steps above.

[2] When the meter is connected to your iHealth Gluco-Smart App on your mobile device:

Step l: Launch the app.

Step 2: Tap the CTL button to switch to control (CTL) mode.

Step 3: Follow Steps 3-4 above in section [1].

Step 4: The control solution test result will appear on the app on your mobile device.

• **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 call iHealth Labs Customer Service at 1-855-816-7705 for assistance or email at support@ihealthlabs.com.

Control solution is available for purchase directly on the iHealth website store at www.ihealthlabs.com and other select retailers.

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 iHealth system provides you with whole blood equivalent results. The result you obtain from your glucose meter may differ somewhat from your laboratory results due to normal variation. The iHealth system results can be affected by factors and conditions that do not affect laboratory results in the same way. To make an accurate comparison between the iHealth system 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 the iHealth system 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.

• TEST STRIP VIAL LABEL

iHealth®

25 Test Strips Bandelettes

Model / Modèle : AGS-1000I

Blood Glucose Test Strips
Bandelettes pour lecteur de glycémie

To measure blood glucose levels from fresh capillary whole blood/For use with Smart Gluco-Monitoring System and Wireless Smart Gluco-Monitoring System only/Expires 90 days after first opening/For in vitro diagnostic use only/Consult instructions for use/Do not reuse/Single patient use, for self-testing only
Pour mesurer le taux de glycémie d'un échantillon de sang total frais capillaire/Pour utilisation avec le Système intelligent de surveillance de la glycémie et Système intelligent de surveillance de la glycémie sans fil, uniquement/Expire 90 jours après ouverture/Pour diagnostic in vitro uniquement/Consultez les instructions d'utilisation/Usage unique/Pour un usage à domicile pour des personnes diabétiques
Store at 39°F ~ 86°F (4°C ~ 30°C)/Do not refrigerate/Keep away from direct sunlight
Conserver entre 4°C ~ 30°C (39°F ~ 86°F)/Ne pas réfrigérer/Ne pas exposer à la lumière directe du soleil

Note: Scan QR code before first use/Remarque: Lire le code QR avant la première utilisation de ce flacon
Control Solution Range/Plage de la Solution de contrôle:
LEVEL/ NIVEAU mg/dL mmol/L

Lot No./Lot N°.
Use by/Utiliser avant le
Date Opened/Date d'ouverture

Manufactured for/Fabriqué pour iHealth Lab Inc.
USA:
iHealth Lab Inc. www.ihealthlabs.com
Mountain View, CA 94043, USA
1-855-816-7705
(8:30 AM – 5:00 PM PST, Monday to Friday)
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3 Rue Tronchet, 75008, Paris, France
+33(0)1 44 94 04 81 (9:00 AM – 5:30 PM, Monday to Friday)

CE 0197

V2.0

• IHEALTH WIRELESS SMART GLUCO-MONITORING SYSTEM SPECIFICATIONS

1. Model: BG5
2. Machine size: 3.8" x 1.35"x 0.75" (96 mm x 34.5 mm x19 mm)
3. Measuring method: Amperometric technology using glucose oxidase
4. Result range: 20 mg/d L - 600 mg/d L (1.1 mmol/L - 33.3 mmol/L)
5. Power source: DC 3.7V , li-ion 250 mAh
6. Wireless communication:
   Bluetooth V3.O+EDR Class2 SPP
   Frequency Band: 2.402-2.480 GHz
7. Storage condition: Test strips 39.2° F - 86° F(40℃ - 300℃), Humidity 10% - 80% RH
8. Storage condition: The meter -4° F - 131° F (-20℃ - 55℃) Humidity 10 - 80% RH
9. Operating conditions: 50° F - 104° F (1 0℃ - 40℃)
10. Blood source: Fresh capillary whole blood
11. Blood volume: Min. 0.7 micro-liter
12. Life span: Five years
13. The table of substances below shows the highest concentration without significant interfe rence (± 10% error)

Compounds	Limitation
Ascorbic acid	2mg/dL
Uric acid	10mg/dL
Acetaminophen	5mg/dL
Bilirubin	15mg/dL
Dopamine	0.03mg/dL
L-dopa	0.45mg/dL
Methyldopa	0.75mg/dL
Tolbutamide	24mg/dL
Triglycerides	2000mg/dL
Hemoglobin	250mg/dL

• MAINTENANCE AND STORAGE OF YOUR IHEALTH SYSTEM

. Always use care when handling the iHealth Smart Glucose Meter. Dropping or throwing the meter may cause damage.
. Don't expose the iHealth Smart Glucose Meter, test strips, or control solution to extreme conditions such as high humidity heat, freezing cold, or dust.
. Always wash your hands with soap and water, and rinse and dry them completely before handling the iHealth Smart Glucose Meter and test strips.

• LIMITATIONS OF USE

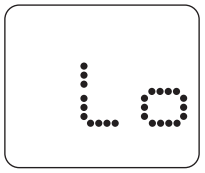
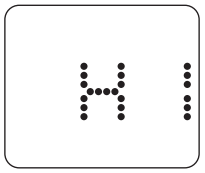
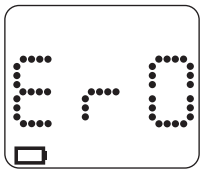
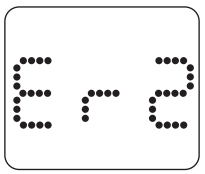
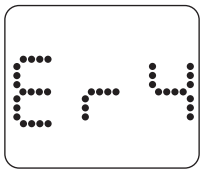
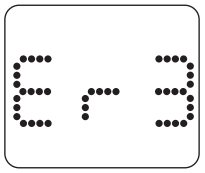
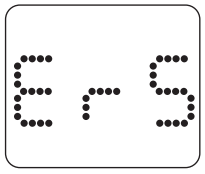
. The iHealth system is not intended for use on neonates.
. The iHealth system is not intended for use on artery blood, serum, and plasma.
. The iHealth system should only be used with iHealth test strips.
. The iHealth system can be used up to an altitude of 3276 meters(10744 feet).

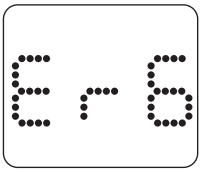
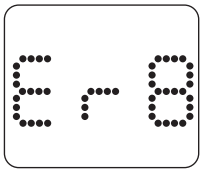
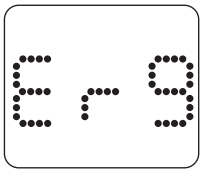
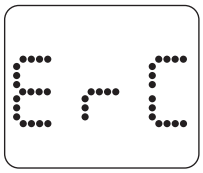
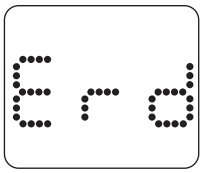
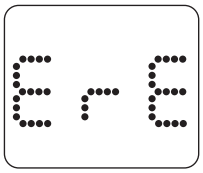
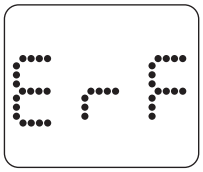
. The following substances at levels grreater than normal or therapeutic levels may cause significant interference (affect the result by greater than 10%), resulting in an inaccurate result: ascorbic acid, uric acid, acetaminophen, dopamine, L-dopa, etc. These substances do not affect test results in normal concentrations but may affect test results in high concentrations. Do not use haemolysis samples, icterus samples, or high lipemia samples.
. Patients undergoing oxygen thera py may yield falsely lower 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.
. Very low or very high red blood cell count (hematocrit) can lead to incorrect test results. If you do not know your hematocrit level, please consult your healthca re provider.
We recommend periodic comparison of the iHealth system to another monitoring system known to be well maintained and monitored by a healthcare provider.

• SYSTEM TROUBLESHOOTING

If you follow the recommended action but the problem persists or error messages other than the ones below appear, please call iHealth Labs Customer Service at l-855-816-7705. Do not attempt to repair the meter by yourself and never try to disassemble the meter under any circumstances.

• DISPLAY MESSAGES

Message	What It Means	What To Do
	Blood glucose level is lower than 20mg/dL (1.1mmol/L).	- Repeat the test using a new test strip. - If your result still flashes Lo, seek medical advice immediately.
	Blood glucose level is higher than 600 mg/dL (33.3mmol/L).	- Wash and dry your hands, and the test site, thoroughly. Repeat the test using a new test strip. - If your result still flashes HI, seek medical advice immediately.
	The battery in your meter in low on power.	Charge the battery.
 	Problem with the meter.	Re-test with a new test strip. If the problem persists, call iHealth Labs Customer Service at 1-855-816-7705 for assistance.
	Problems have occurred that are related to test strip use, such as: - Test strip may be wet or damaged - Test strip may have been removed too soon - You applied more blood after testing began	Re-test using a new test strip.
	The environmental temperature is lower than 50°F(10°C).	The operating temperature is 50°F～104°F (10°C～40°C).

	The environmental temperature is higher than 104°F(40°C).	The operating temperature is 50°F～104°F (10° C～40° C).
	Communication error.	Touch START to re-test.
	Strip removed during measurement.	Start again using a new test strip.
	Your meter is not synced to the app on your iOS device yet.	Follow the instructions above in the ‘FIRST TIME SETUP INSTRUCTIONS” to sync your meter.
	The remaining test strip in the vial is “0”.	Scan a new vial of test strips.
	The test strip has expired.	Use a new test strip.
	Charging does not allow measurement.	Unplug the charging cable.

• TROUBLESHOOTING

Problem	Possible Causes	Solution(s)
Display remains blank after the test strip has been inserted into the meter.	1. Battery power is too low for use.	1. Charge the battery.
	2. Too much time has passed between inserting the test strip and performing the test.	2. Reinsert the test strip into the meter.
	3. Test strip has not been fully inserted 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.	1. Not enough sample in the test strip.	1. Re-test with a new test strip and make sure that enough sample has been applied.
	2. Test strip or control solution has expired.	2. Re-test with a new test strip or new control solution.
	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.	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. iHealth system is not performing due to the environment being above or below room temperature.	4. Bring the iHealth 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 redo the test.

• INTERNATIONAL BLOOD GLUCOSE MEASUREMENTS UNITS

Country	Unit of Measure Used	Country	Unit of Measure Used
Algeria	mg/dL	Australia	mmol/L
Argentina	mg/dL	Canada	mmol/L
Austria	mg/dL	China	mmol/L
Bahrain	mg/dL	Czech Republic	mmol/L
Bangladesh	mg/dL	Denmark	mmol/L
Belgium	mg/dL	Finland	mmol/L
Brazil	mg/dL	Germany	mmol/L
Caribbean Countries	mg/dL	Hong Kong	mmol/L
Chile	mg/dL	Ireland	mmol/L
Colombia	mg/dL	Kazakhstan	mmol/L
Ecuador	mg/dL	Malaysia	mmol/L
Egypt	mg/dL	Malta	mmol/L
France	mg/dL	Netherlands	mmol/L
Georgia	mg/dL	New Zealand	mmol/L
Greece	mg/dL	Norway	mmol/L
India	mg/dL	Qatar	mmol/L
Indonesia	mg/dL	Russia	mmol/L
Israel	mg/dL	Singapore	mmol/L
Italy	mg/dL	Slovakia	mmol/L
Japan	mg/dL	South Africa	mmol/L
Jordan	mg/dL	Sub-Saharan Africa	mmol/L
Korea	mg/dL	Sweden	mmol/L
Kuwait	mg/dL	Switzerland	mmol/L
Lebanon	mg/dL	Ukraine	mmol/L

Luxembourg	mg/dL	United Kingdom	mmol/L
Mexico	mg/dL	Vietnam	mmol/L
Oman	mg/dL		
Peru	mg/dL		
Philippines	mg/dL		
Poland	mg/dL		
Portugal	mg/dL		
Saudi Arabia	mg/dL		
Spain	mg/dL		
Syria	mg/dL		
Taiwan	mg/dL		
Thailand	mg/dL		
Tunisia	mg/dL		
Turkey	mg/dL		
United Arab Emirates (UAE)	mg/dL		
United States	mg/dL		
Uruguay	mg/dL		
Venezuela	mg/dL		
Yemen	mg/dL		

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

• WARRANTY INFORMATION

iHealth Labs, Inc. ("iHealth") warrants the iHealth meter (the “Product"), and only the Product, against defects in materials and workmanship under normal use for a period of three years from the date of pu rchase by the original pu rchaser ("Warranty Period"). Under this Limited Warranty, if a defect arises and a valid claim is received by iHealth within the Warranty Period regarding

the Product, at its option and to the extent permitted by law, iHealth will either (1) repair the Product using new or refurbished replacement parts or (2) exchange the Product with a new or refurbished Product. In the event of a defect, to the extent permitted by law, these a re the sole and exclusive remedies.

iHealth is a trademark of iHealth Labs Inc.
"Made for iPod," "Made fo r iPad," and "Made for iPhone" mean that an electronic accessory has been designed to connect specifically to the iPod, iPad, and/or iPhone, respectively, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards.
Please note that the use of this accessory with the iPod, iPad, and/or iPhone may affect wireless performance. iPod Touch, iPad, and iPhone are trademarks of Apple Inc., registered in the U.S. and other countries.
Manufactured for iHealth Labs Inc

USA:
iHealth Labs Inc. www.ihealthlabs.com
Mountain View, CA 94043, USA
855-816-7705
(8:30 AM - 5:30 PM PST, Monday to Friday except holidays)
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Email: support@ihealthlabs.eu

ANDON HEALTH CO., LTD.
No. 3 Jin Ping Street, Ya An Road, Nankai District, Tianjin
300190, China
Tel: +86-22-60526161

• EXPLANATION OF SYMBOLS

IVD In vitro diagnostic medical device

SN Serial number

Caution, consult accompanying documents

Consult instructions for use Manufacturer

Manufacturer

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.

EC REP Authorised representative in the European Community

FCC ID THIS DEVICE COMPLIES WITH PART 15 OF THE FCC RULES

Bluetooth sign

Keep away from rain

LOT Lot Number

Use by date

STERILE R Sterilized Using Irradiation

Do not Reuse

CE 0197 Complies with IVD98/79/EC requirements

• IMPORTANTINFORMATION REQUIRED BY THE FCC

This device complies with Part 15 0f the FCC Rules. Its operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interfe rence received, including interfe rence that may cause undesired operation.

Changes or modifications not expressly approved by iHealth LabInc. would void the user's authority to operate the product.

NOTE: This product has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits a re designed to provide reasonable protection against harmful interfe rence in a residential installation. This product generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interfe rence to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this product does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit dffeerent from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

Radiofrequency radiation exposure Information: This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance of [20] cm between the radiator and your body. This transmitter must not be co-located or

operating in conj unction with any other antenna or transmitter.
NOTICE: Changes or modifications made to this equipment not expressly approved by iHealth Lab Inc. may void the FCC authorization to operate this equipment.
This product complies with Industry Canada. IC: RSS-21 0
This product is approved in accordance to R&TTE directive transmitter.

IC NOTICE

This device complies with Industry Canada licence-exempt RSS standard (s). Operation is subject to the following two conditions

(1) this device may not cause interference, and

(2) this device must accept any interference, including interference that may cause undesired operation of the device.