iHealth®

Wireless Smart Gluco-Monitoring System (BG1S)

OWNER'S 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 Wireless Smart Gluco-Monitoring System (BG1S).
This manual provides important information to help you to use the system properly. Before using this product, please read the Owner's Manual thoroughly.
If you have questions regarding this product, please visit www.iHealthlabs.com, contact your place of purchase, or call iHealth Labs Customer Service at 1-855-816-7705 (Mon.-Fri. 8:30AM-5:30PM PST, Monday to Friday except holidays)
If you have questions or need assistance outside the operational hours and days, please contact your healthcare provider.

IMPORTANT SAFETY INFORMATION

Intended use

The iHealth Wireless smart Gluco-Monitoring System (BG1S) consists of the iHealth Wireless Smart Glucose Meter (BG1S), iHealth Test Strips (EGS-2003), and the iHealth App mobile application.
The iHealth Wireless Smart Gluco-Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh.
The iHealth Wireless Smart Gluco-Monitoring System is intended to be used by a single person and should not be shared.
The iHealth Wireless Smart Gluco-Monitoring System is intended for 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 Wireless Smart Gluco-Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

Limitations of use

The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
The iHealth system is not intended for use on neonates, nor for screening or diagnosis.
Not for use on critically ill patients.
This device is not for use on people who are severely dehydrated, on people who are severely hypotensive, or people who are in shock, consult your healthcare professional immediately when this happens.
Use only fresh capillary whole blood samples to test your blood glucose.
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 healthcare provider.
For self-testing only.
Do not perform (Alternative Site Testing) AST if you think your 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.
Do not use AST results to calibrate a continuous glucose monitor (CGM) or for insulin dosing calculations.
AST should only be used during times when blood sugar is not fluctuating rapidly,

i.e. Within 2 hours of eating, exercising or taking medication.
If you take acetaminophen or acetaminophen containing medications (Tylenol, certain cold and flu remedies, or certain prescription drugs) this medication might affect the reliability of your blood glucose results (blood concentrations >5 mg/dL). If you are unsure, then ask your healthcare professional.

Certain conditions may cause your blood level of uric acid to rise. These conditions include gout or kidney disease. You should know that if your blood level of uric acid is high (≥10 mg/dL) then your blood glucose results may be not reliable. If you are unsure, then ask your healthcare professional.

Vitamin C (Ascorbic acid (>4 mg/dL) naturally in your blood or from food or taking Vitamin C supplements might cause inaccurate blood glucose results when using this blood glucose monitoring system.
Do not use this device during or shortly after receiving xylose absorption therapy since xylose may cause inaccurate blood glucose results.
This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus(HCV), Hepatitis B Virus(HBV), or other bloodborne pathogens.
For over-the-counter use.

Important safety instructions

Please read the following information carefully before using the iHealth Wireless Smart Gluco-Monitoring System (BG1S). Always keep these instructions in a safe place for reference.

Do not change your therapy based on a test result that does not match what you feel or if you believe that your test result could be incorrect.
If your blood glucose result does not match what you feel and you have followed the instructions in this Owner's Manual, follow your healthcare professional's instructions, or contact your healthcare professional.
Always use a new, sterile lancet each time you test to avoid infection. For safety reasons, once you use a new lancet, you cannot go back to a used lancet, never reuse any lancet.
Swallowing battery can be extremely dangerous. Keep the batteries and the unit out of the reach of children and disabled persons.
The meter and lancing device are for single patient use.
Do not use either item on multiple patients.
Never share the meter or lancing device with anyone, including family members.
Do not place the iHealth system in or near liquid.
The iHealth system can be used up to an altitude of 10744 feet (3275 meters).
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 test port free from lint, hair, debris, etc.
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 kit are considered biohazards and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

Remove the batteries if the blood glucose meter will not be used for a month or more to avoid relevant damage of battery leakage.

Please refer to the resources identified below for 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

YOUR NEW WIRELESS SMART GLUCOSE METER

Contents of the iHealth Wireless Smart Gluco-Monitoring System (BG1S)

Package contents vary from country to country. Please refer to the package contents listed on the package you purchased.

• iHealth Smart Glucose Meter (the meter)

• Clear Cap for Alternate Site Testing

• Pry Plate

• iHelath Test Strip

• iHealth Lancing Device

• Lancet

• iHealth Control Solution

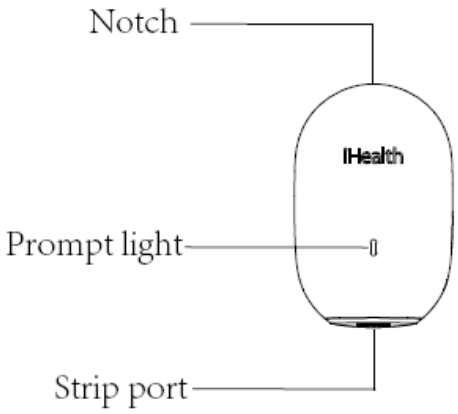
• Owner's Manual

• Quick Start Guide

Note: If any item s printed on the package are missing from your package or the package appears to have been opened prior to y our use, please contact iHealth Customer Care.

iHealth Wireless Smart Gluco-Monitoring System:

The meter:

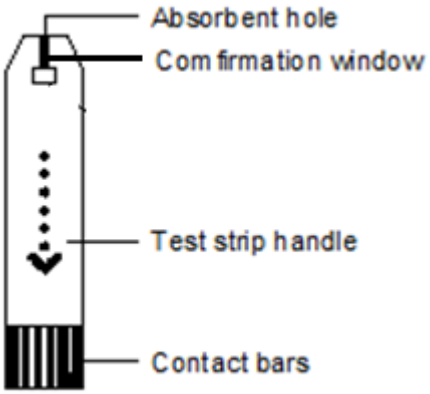


iHealth Test Strips
Use iHealth test strips EGS-2003.

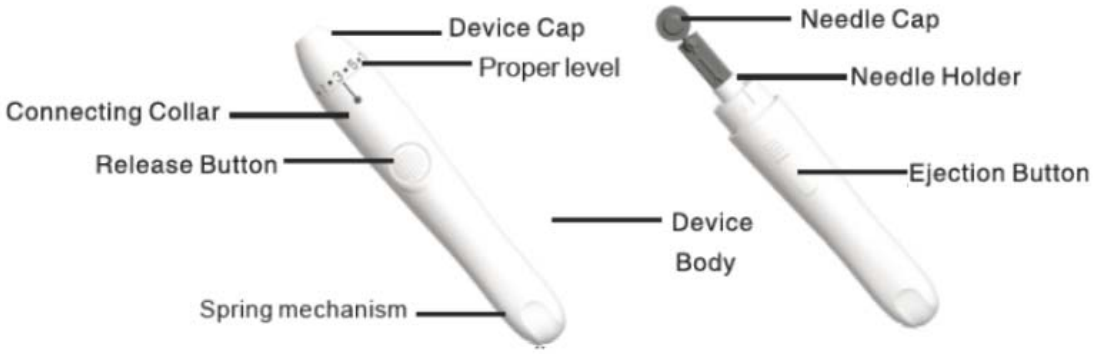
Do not use the test strips if expired.
To keep your test strips in the best possible condition, read the following recommendations thoroughly:
Write the expiry date on the test strips vial when first opening. The expiration date can be found at the bottom of the box in which the vial was received in.

Store the test strips vial between 39°F ~ 86°F (4° C to 30° C) and 10% ~ 85% relative humidity.
Keep the test strips away from direct sunlight.
Test strips must be stored in their original vial only. Do not transfer them to a new vial or another container.
Do not touch the test strips when your hands are wet.
Use each strip promptly after removing it from the vial. Close the vial lid quickly after removing a new test strip.
Keep the vial lid closed at all times.
Do not bend, cut or alter the test strips. Doing so will lead to inaccurate results.
Do not use if vial is damaged.

Each test strip can be used only once, and consists of the following parts.
Refer to the test strips Instruction Book to have more details on how to use the test strips with your meter.

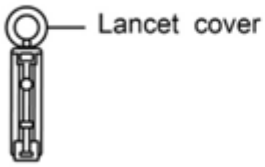


iHealth Lancing Device
Use only with the iHealth lancet.



• Clear Cap for Alternate Site Testing

• Lancet



• iHealth Control Solution

Use only iHealth Control Solution.
Keep the control solution at a temperature between 2°C and 30°C (36°F - 86°F) and at a humidity rate of 10 to 85%.

Do not expose to direct sunlight or place near heat sources.
Use before the expiry date mentioned on the vial.
Use the control solution within 90 days of initial opening of the vial.
Close the vial immediately after each use.
To avoid contamination of the control solution, do not apply directly it to the test strip from the bottle.
Dispose of used equipment according to regulations applicable in your country.

Refer to the Control Solution tests part to know how to use the Control Solution with your meter.

Mobile device compatibility

iOS device with iOS 9 and above, Android Phone with Android 5 and above.
For a complete list of compatible devices, visit our support on page on
https://ihealthlabs.com/ihealth-compatibility-list

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.

CONTROL SOLUTION TESTS

The iHealth Control Solution is intended to be used with the iHealth Wireless Smart Gluco-Monitoring System (BG1S). The iHealth Control Solution contains a specific quantity of glucose concentrate which reacts with the test strips, it's used to verify the accuracy of blood glucose test results.

Materials needed to perform a control solution test:
iHealth Wireless Smart Glucose Meter
iHealth Test Strips (EGS-2003)
iHealth Control Solution (Level I, Level II, or Level III)

Perform a control solution test when:
The iHealth Control Solution is used to ensure the iHealth Wireless Smart Gluco-Monitoring System (BG1S) are working correctly together and are not defective.
It should also be used in the following situations:
First receiving or purchasing the meter.
Each time you open a new vial of test strips.
If you suspect a dysfunction of the meter or test strips.
To familiarize yourself with the practice of testing.
If you suspect that the results are not accurate.
After the meter has been dropped.
Users should perform a control solution test at least once a week.

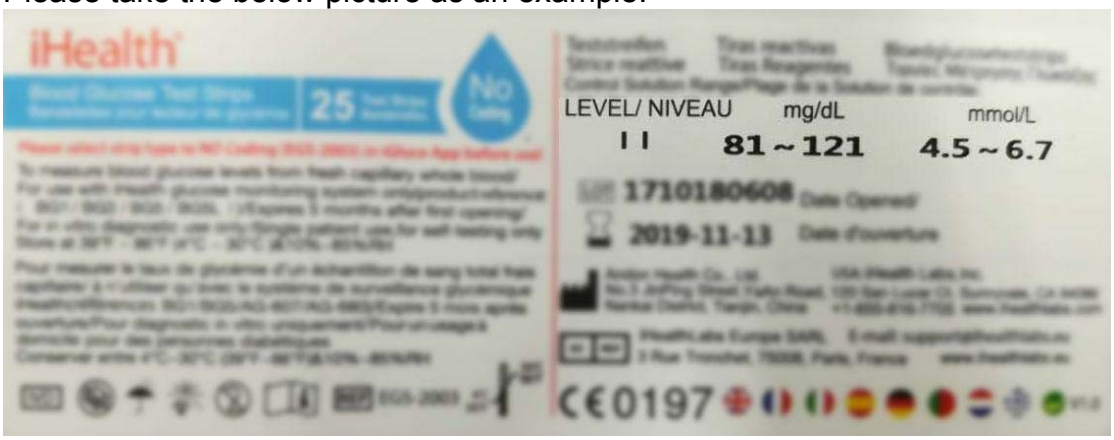
Warning and precautions

The iHealth control solution is intended to be used for in vitro diagnostic only.
Do not swallow or ingest the control solution.
The iHealth control solution is recommended to confirm the performance of the system and can't under any circumstances be substituted for a capillary blood test to test your blood glucose level.
The control solution should be used before the expiry date printed on the bottle label.

The control solution must be used within 90 days of opening the vial
(Shelf-life after opening)
Do not use the control solution after the expiry date or after the shelf-life after opening, whichever comes first, at the risk of getting erroneous results.

Test procedures
Follow these instructions and refer to the iHealth Wireless Smart Gluco-Monitoring System (BG1S) Owner's Manual for further information.

Step 1
Follow instructions on App's user guide to operate the iHealth App
Step 2
Insert the test strip into the strip port.
Step 3
Shake the control solution vial vigorously before each use.
Press a drop of control solution onto a clean plastic surface (for example, the bottle cap). For best results, we recommend to throw out the first drop and use the second to perform your measures.
Then hold your meter and put the test strip absorbent hole into contact with the control solution.
Once the test strip confirmation window is completely filled, the meter will start counting down, then you can remove the test strip from the control solution sample.
Note: To avoid contamination of the control solution, do not apply it directly to the test strip from the bottle.
Step 4
The test result with the control solution is displayed on your smartphone screen.
Compare the result with the range of values printed on the test strips vial label. Please take the below picture as an example.



The result must be within the specified range. If the test result is out of range, please repeat the test.

Expected values
Refer to the specified range on the test strips vial label. Several factors can cause out-of-range test results, including:
The previously mentioned test instructions have not been followed.
The control solution is contaminated, out-of-date or its shelf-life after opening is exceeded.
The test strip is damaged or out-of-date.
The plastic surface that received the drop of control solution during measurement

was not wiped.
The storage temperature of the control solution (between 2°C and 30°C) has not been observed.
iHealth Wireless Smart Gluco-Monitoring System (BG1S) is faulty.

Important
If test results with the control solution continue to fall outside the range of values printed on the iHealth Test Strips vial, do not use the meter, test strips, or control solution and contact iHealth Customer Care.

BLOOD GLUCOSE TEST

Testing with the iHealth Wireless Smart Gluco-Monitoring System (BG1S) is based on the measurement of electrical currents generated by the reaction of glucose with the reagent of the test strips. The iHealth Wireless Smart Gluco-Monitoring System (BG1S) 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 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 individual who are in a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with iHealth Wireless Smart Gluco-Monitoring System (BG1S).
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.
Do not use test strips that are expired or appear to be damaged at the risk of receiving inaccurate results. Please refer to the test strips Instruction Book for the detailed procedure.
The iHealth lancing device is for self-use only. Do not share or re-use lancets. Please refer to the Lancing 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/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

First time setup instructions

Warning
Blood glucose results should be displayed in mg/dL, please contact Customer Service if your meter is not set to mg/dL when you first turn on the meter.
Using the wrong unit of measurement may cause misinterpretation of your actual blood glucose level and may lead to improper therapy.
Before you perform your first blood glucose test, perform a control test to ensure the meter and test strips are working correctly together and are not defective.

Materials needed to perform a blood glucose test:
iHealth Wireless Smart Glucose Meter
iHealth Test Strips (EGS-2003)
iHealth Lancing device with a lancet loaded
iHealth clear cap for alternate site testing (in case of you perform on an AST)

The iHealth Wireless Smart Glucose Meter can be used for online test only.
About the online test
You need the app launched to perform a blood glucose test. When you perform a blood glucose test, your results will be synchronized automatically on your iHealth profile.

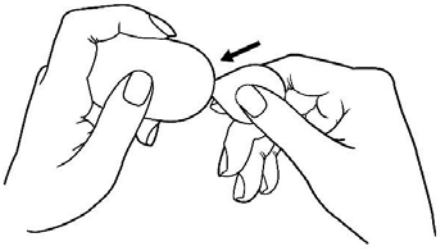
WARNING
①When you get a new meter and you want to finish a first-time test, follow ***STEP 1*** to ***STEP 4*** below.
②When you have already done the first-time test, please go directly to ***STEP 4***.

STEP 1 Download the app
Prior to first use, scan the QR code below or follow the instructions of the customer service personnel to download and install the free app,or The ability to scan the code will depend on the operating system on your mobile device. You can also find the app by searching the name “iHealth Gluco-Smart” in your Apple app store or Google play store. Follow the instructions on app’s guide to register and login. You can download this file from the iHealth website.

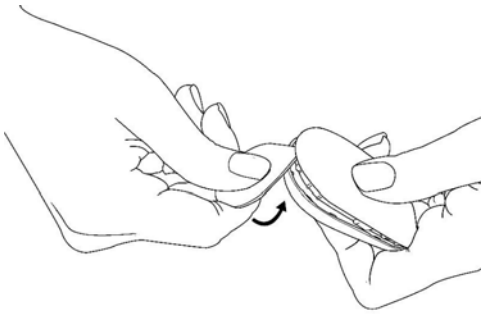
Android iOS

⚠ ***STEP 2*** Install the battery
Your meter is powered by a 3V CR2032 battery. When you use this meter for the first time, load the battery according to the following instructions.
1. Turn the meter over with the iHealth logo facing down.

2. Insert the narrow end of the pry plate into the machine groove (close to the iHealth Logo), and press the inner surface of the groove.



3. Push against the inner surface of the groove and lift up the machine shell.(parts with iHealth Logo)



4. Insert the battery with the "+" side facing up and snap it into place.
5. Press the back panel back in place. Green LED (on the side with iHealth logo) on the meter will light up for 3sec after installation of battery.

⚠ *After you have used your meter for a while, a Red LED flash will appear when the battery in your meter is low on power. After three seconds, the meter shuts off automatically. The meter does not take any measurement when the battery is low. You must replace the battery* according to following instructions *before using it again.*

1. Turn the meter over with the iHealth logo facing down.
2. Insert the narrow end of the pry plate into the machine groove (close to the iHealth Logo), and press the inner surface of the groove.
3. Push against the inner surface of the groove and lift up the machine shell.(parts with iHealth Logo)
4. Remove the exhausted battery.
4. Insert the new battery with the "+" side facing up and snap it into place.
5. Press the back panel back in place

Disposal – Electrical product should not be disposed of with household waste. Please recycle device elements at the existing designated facilities. Check with your local authority or retailer for more information on how and where to properly dispose of or recycle electronic devices and batteries.

STEP 3 Add the meter to the app
Prior to first use, add the meter to the app on your Android or iOS mobile device.

Do not try to pair the device directly to your phone's Bluetooth. The meter is no-connectable to your mobile device. It can only be paired through the app once the devices is entered in.Refer to the app's guide to add your meter to the app.

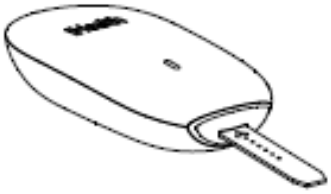
STEP 4 Test your blood glucose level

Step 4 a. Prepare the lancing device.
First read the manual of the lancing device for the instructions on how to prepare the lancing device.

Step 4 b. Wash your hands with warm soapy water for 20 seconds and dry thoroughly. Residues on skin or wet hands could impact test results. Try to avoid touching other surfaces, besides your meter and lacing device, after washing your hands.

Step 4 c. Open app and click "start".
Make sure the app is already open before blood sample collection and make sure your *Bluetooth* is turned on, and BG1S is nearby.

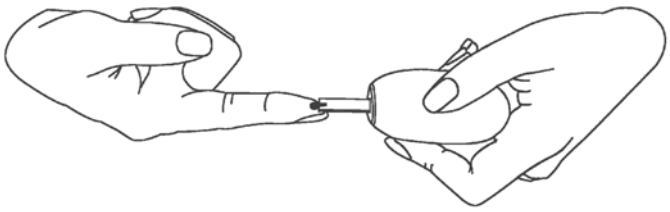
Step 4 d. Follow app instructions to insert test strip.
Take a new test strip from the test strip vial, hold the middle of the test strip, with the arrow facing the meter, and insert the test strip into the meter's strip port. Do not hold the end of the test strip. A Green LED on the meter will start to blink, which indicates that the strip has been inserted and the meter works properly. Otherwise a red LED will light up for 30 seconds to indicate an error with the meter or strip. The connection will be setup automatically once the strip is inserted. Wait until the app prompts you to obtain a blood sample and the green LED on the meter remains lit. To resolve a red light issue, see "Maintenance and Troubleshooting" section below.



Step 4-5**:** Obtain a blood sample.
Press the lancing device against the site to be lanced. Press the release button to lance the site. Massage your finger below the site lanced until a drop of blood forms.

Step 4-6: Apply the blood sample to the test strip.

Quickly apply the blood sample to the absorbent hole of the test strip. Make sure the confirmation window of the test strip is completely filled with the blood sample. Do not let blood sample sit for too long before applying to the test strip.



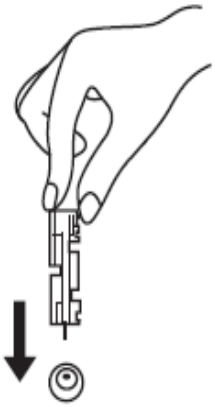
Remove your finger from the test strip when APP indicating the beginning of blood sample analysis. The test result will appear on the display within 5s.

Step 4-7: Read the test results.
The test result will appear on the app.

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

Step 4-8: Discard the used test strip and lancet.
Discard the used test strip into proper container to avoid contaminating other articles. □

Insert the used lancet into the lancet cover to avoid exposing the needle tip. Slide the “remove lancet” sliding component of the lancing device to push lancet out and into the proper waste container □Check with your local authority for more information on how and where to properly dispose of contaminated sharps.



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. The cleaning and disinfection is absolutely necessary for the test procedure, because cleaning can ensure the meter works well (for example, the display will be clear to see after cleaning).
Disinfection can avoid the infection to you or to the other people, and the cross-infection. Cleaning removes dirt and debris but does not eliminate bacteria or virus, while disinfection is to eliminate bacteria or virus on the meter.
Clean and disinfect the meter and lancing device each time before the measurement.
Cleaning is to wipe the whole surface of the meter for 10 seconds, until there is no soil on the surface.
Disinfection is to wipe the whole surface of the meter with a gentle disinfecting solution for 2 min, and keep the surface wet during the 2min.

The iHealth Wireless Smart Glucose Meter and the iHealth lancing device should be cleaned and disinfected at a minimum of once per week.

The iHealth Wireless Smart Glucose Meter and the iHealth lancing device are validated to support 10,000 individual tests—and consequently 10,000 cleanings over their 5 years life spans. The meter and the lancing device are for single-patient use. If the user tests 6 times every day, the meter and lancing device should be cleaned and disinfected 6 times per day which equals 10950 cycles over the 5 year life of the devices. The meter and lancing device were validated for 11,000 cycles which could support up to 6 cleaning and disinfection cycles per day.
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 disinfected prior to use by the second person.

Find below, how to clean the meter and lancing device.
1. After a test, wash your hands thoroughly with soap and water after handling the meter, lancing device, or test strips.
2. Use the clean wipe to carefully clean the meter, front and back.
3. Then, disinfect the meter with another wipe and allow the surface to dry naturally: the meter should remain wet for 2 minutes.
4. Use the same method with the clean wipes to clean and disinfect the lancing device.
Note:

1 You should always perform a cleaning step prior the a disinfection step. Wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

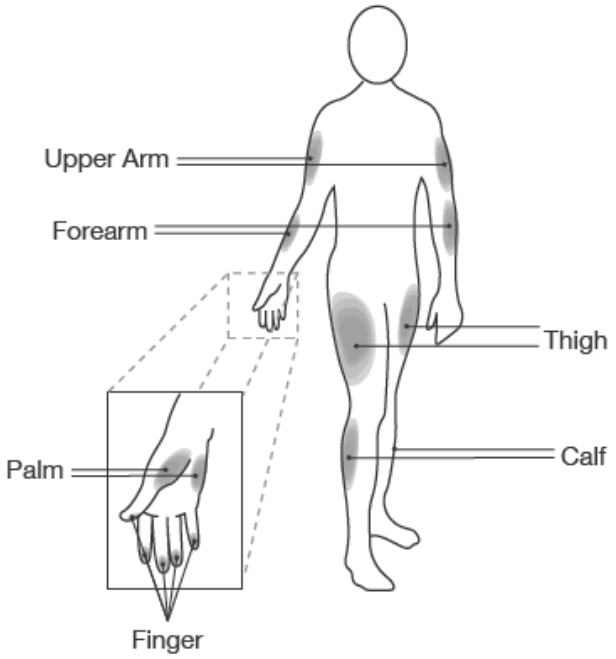
2 Only the surface of the meter can be cleaned and disinfected with the disinfecting wipe. Do not insert the disinfecting wipe into the test strip port.

3 Avoid getting moisture inside the meter through the strip port at all times.

4 If you have any questions you can call the number: 1-855-816-7705

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 meter 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 AST should only be used 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 (hypoglycemia)
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

MAINTENANCE AND TROUBLESHOOTING

Maintenance and storage of your iHealth Wireless Smart Glucose Meter

Always use care when handling the meter. Dropping or throwing the meter may cause damage.
Don't expose the 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 meter and test strips.

System troubleshooting

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

Troubleshooting

Problems	Possible Causes	Solutions
Prompt light doesn't flash after the test strip has been inserted into the meter.	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.	1. Replace the battery 2. Reinsert the test strip into the meter. 3. Reinsert the test strip into the meter, pressing firmly without bending the strip.
Test results are inconsistent or Control Solution test results are not within the specified range.	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. 4. System is not performing due to the environment being above or below room temperature.	1. Re-test with a new Test Strip and make sure that enough sample has been applied. 2. Re-test with a new vial of 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 does not respond, and red LED lights up	System suspend	The meter will recover to default state in 10s after system suspend automatically. Please wait until the green LED remains lit for 3sec
Red LED flash 3sec after the test strip has been inserted into the meter	Battery power is too low for use.	repalce the battery
Red LED lights up 30sec after the test strip has been inserted into the meter	An error occur in testing process	Connect the meter to app to get error message and further information

Signs of potential physical and performance deterioration

If you encounter one of the following circumstances, stop using the meter and contact iHealthlabs customer services

1. The device does not work; for example, the Android or iOS mobile device can't begin testing when the meter is connected with the Android or iOS 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 labelling information.
3. Corrosion, crazing (any cracks), embrittlement, and/or cracking of the meter casing or lancing device.

If you have questions or need assistance outside the operational days and times, please contact your healthcare provider. If deterioration is observed, please stop using and contact local customer services or place of purchase for assistance, or toll free service hotline: 1-855-816-7705.

iHealth WIRELESS SMART GLUCO-MONITORING SYSTEM SPECIFICATIONS

Technical specifications

1. Model: BG1S
2. Machine size: 2.38'' × 1.55'' × 0.63'' (60.5mm × 39.4mm × 16.1 mm)
3. Measuring method: Amperometric technology using glucose dehydrogenase
4. Result range: 50 mg/dL ~ 600 mg/dL (2.8 mmol/L ~ 33.3 mmol/L)
5. Power source: DC 3.0V (CR2032)
6. Wireless communication: *Bluetooth* V4.2 BLE Only Mode (EIRP: <3dBm)

Frequency Band: 2.402-2.480 GHz

7.Storage condition: Test Strips 39° F ~ 86° F (4° C ~ 30° C), Humidity 10% ~ 85% RH

8.Storage condition: The meter -4°F ~ 131° F (-20°C ~ 55°C); Humidity 10% ~ 80%RH

9. Operating conditions: 50°F ~ 104°F (10° C ~ 40° C),Humidity 25% ~ 80%RH
10. Blood source: Fresh capillary whole blood
11. Blood volume: Min. 0.7 microliter
12. Life span: Five years
13. Reference Values

Expected glucose values for people Without diabetes; Time of day	Glucose Range
Fasting and before meals	< 100 mg/dL
2 hours after meals	< 140 mg/dL

Source: American Diabetes Association (Standard of Medical Care in Diabetes – 2018. Diabetes Care, January 2018, vol. 41, Supplement 1, S13 – S27).

Important information required by the FCC

This device complies with Part 15 of 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 interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by iHealth Labs Inc. 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 are designed to provide reasonable protection against harmful interference 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 interference 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 different from that to which the receiver is connected.

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

Radiofrequency radiation exposure Information: The device has been evaluated to meet general RF exposure requirement,

The device can be used in portable exposure condition without restriction

Federal Communication Commission (FCC) Radiation Exposure Statement

Power is so low that no RF exposure calculation is needed.

FCC ID:SLRBG1S
IC:10913A-BG1S
This product com plies with Industry Canada IC: RSS-210. This produc t is approved in accordance to RED directve. Hereby, Andon Health Co., Ltd.declares that the BG1S is in co mpliance with the Radio Equipment Directive (RED) 2014/53/EU. The full text of the EU declar ation of conformity is available a t the following internet address: www.iHealthlabs.eu

Electromagnetic compatibility information

The Quality of the product has been proofed and complies with the requirements of IEC 60601-1-2(electromagnetic compliance and tests). To avoid interferences with a mobile phone we recommend to keep a distance of 3.25 m between the mobile phone and the meter or to shut off the mobile phone.

EMI & EMS Compliance Table

Table 1 - Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class B	Home healthcare environment
Harmonic distortion	IEC 61000-3-2 Class A	Home healthcare environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Home healthcare environment

EMS Compliance Table

Table 2 - Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Home Healthcare Environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3 – Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m

1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

WARNING:

①Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

② Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

③Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the BG1S,including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Warranty information

iHealthlabs Europe. ("iHealth") warrants the iHealth Wireless Smart Glucose Meter (the "Product"), and only the Product, against defects in materials and workmanship under normal use for a period of 3 years from the date of purchase by the original purchaser ("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 are the sole and exclusive remedies.

iHealth is a trademark of iHealth Labs Inc.

“Made for iPod,” “Made for 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. and iHealthLabs Europe.

USA:
iHealth Labs, Inc. www.iHealthlabs.com
120 San Lucar Ct. Sunnyvale, CA 94086, USA
1-855-816-7705 (Mon.-Fri. 8:30AM-5:30PM PST, Monday to Friday except holidays)

If you have questions or need assistance outside the operational hours and days, please contact your healthcare provider.
E-mail : support@iHealthlabs.com

Europe:

EC REP iHealthLabs Europe SAS
36 rue de Ponthieu, 75008, Paris, France
www.iHealthlabs.eu
Customer service: https://helpcenter.ihealthlabs.eu/hc/en-gb/requests/new or menu Contact in App
If you have questions or need assistance outside the operational hours and days, please contact your healthcare provider.
Please feedback to the customer service if the app cannot be opened.

ANDON HEALTH CO., LTD.
No. 3 Jin Ping Street, Ya An Road, Nankai District, Tianjin 300190, China.
Phone number: +86-22-87611660

EXPLANATION OF SYMBOLS

Manufacturer

EC REP European Authorized Representative

IVD In vitro diagnostic medical device

SN Serial number

Consult instructions for use

Do not use if the package damaged

LOT Batch code

REF Catalogue number

Caution

Use by date

Storage temperature Limit

Keep away from direct sunlight or near heat sources

Keep in a dry place

Do not reuse

STERILE R Sterilized using irradiation

Bluetooth sign

CE0197 Complies with the requirements of the European IVD Directive (98/79/EC)

FCC ID This device complies with part 15 of the FCC Rules

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.

Rev.06/2020

IC statements:

Radiation Exposure Statement:
This equipment complies with IC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.

Déclaration d'exposition aux radiations:
Cet équipement est conforme aux limites d'exposition aux rayonnements IC établies pour un environnement non contrôlé. Cet équipement doit être installé et utilisé avec un minimum de 20 cm de distance entre la source de rayonnement et votre corps.

This device complies with Industry Canada license-exempt RSS standard(s).
Operation is subject to the following two conditions:
this device may not cause interference, and
this device must accept any interference, including interference that may cause undesired operation of the device.

Cet appareil est conforme avec Industrie Canada RSS exemptes de licence standard(s).
Son fonctionnement est soumis aux deux conditions suivantes:
(1) cet appareil ne peut pas provoquer d'interférences, et
(2) cet appareil doit accepter toute interférence, y compris celles pouvant causer un mauvais fonctionnement de l'appareil.

This Class B digital apparatus complies with Canadian ICES-003.
Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.