iHealth

Wireless Smart Gluco-Monitoring System

Lecteur de glycémie connecté
Sistema wireless intelligente per il monitoraggio glicemico
Dispositivo inalámbrico conectado para monitorización de glucosa
（iHealth Gluco+）

OWNER'S MANUAL

MANUEL D'UTILISATION
MANUALE DELL'UTENTE
MANUAL DE USUARIO

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

Uniquement pour un usage de diagnostic in vitro
Consultez les instructions d'utilisation avant la réalisation de l'autotest
Unicamente per uso diagnostico in vitro
Leggere le istruzioni prima di iniziare a usare il dispositivo
Exclusivamente para uso diagnóstico in vitro
Lea las instrucciones antes de usarlos para el autoanálisis

EN

Table of Contents

INTRODUCTION

Thank you for purchasing the iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+).
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.eu.

IMPORTANT SAFETY INFORMATION

Intended use

The iHealth Wireless smart Gluco-Monitoring System (iHealth Gluco+) consists of the iHealth Wireless Smart Glucose Meter, iHealth Test Strips (EGS-2003 & EGS-2043), and the iHealth Gluco-Smart 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 iHealth system is not intended for use on neonates, nor for screening or diagnosis.
The iHealth system is not intended for use on arterial or venous whole blood, serum or plasma.

Patients undergoing oxygen therapy may yield falsely lower results.
The meter and lancing device are for single patient use.
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 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.

Important safety instructions

Please read the following information carefully before using the iHealth Wireless Smart Gluco-Monitoring System(iHealth Gluco+). 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.

Misuse of the iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+) can cause electrocution, burns, fire, and other hazards.
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.
Do not swallow & keep away from children.
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

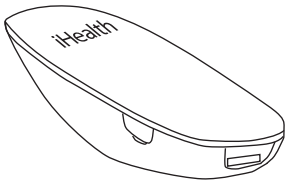
Owner's Manual.
Use only accessories that are supplied by the manufacturer.
Do not use the iHealth system if it has sustained any damage or is not working properly.
Keep the iHealth system away from heat at all times. Do not let the iHealth system come into contact with surfaces that are hot to the touch.
Do not block test port or place the iHealth system on soft surfaces that may block the test port. 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 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

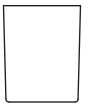
YOUR NEW WIRELESS SMART GLUCOSE METER

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

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



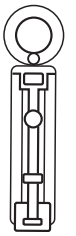
• iHealth Smart Glucose Meter (the meter)



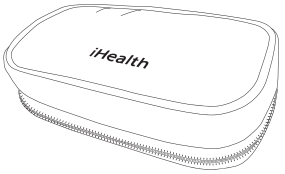
• Clear Cap for Alternate Site Testing

• iHealth Test Strip

• iHealth Lancing Device



• Lancet



• Travel Case

• USB Charging Cable

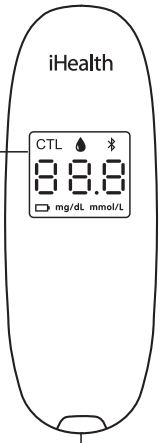
• iHealth Control Solution

• Owner's Manual

• Quick Start Guide

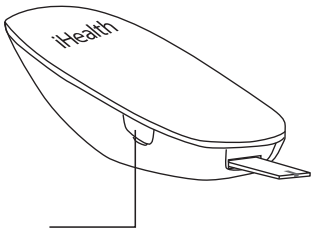
Note: *If any items printed on the package are missing from your package or the package appears to have been opened prior to your use, please contact iHealth Customer Care.*

iHealth Wireless Smart Gluco-Monitoring System:
The meter:



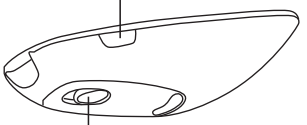
LED DISPLAY
Test result, symbols, and messages appear here.

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



MICRO USB
Charge the meter through provided USB cable.

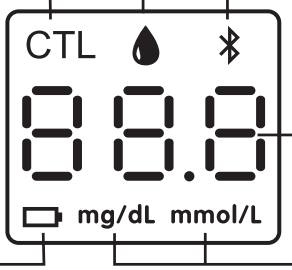
MEMORY BUTTON
Located on the side of the meter. It is used to turn on the meter and view past test results.



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.

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



LOW BATTERY SYMBOL
Appears when the battery is low.

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

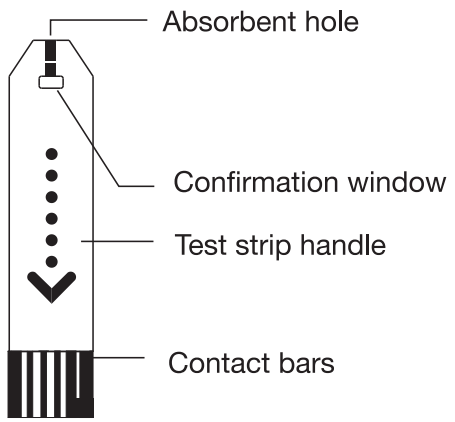
TEST RESULT DISPLAY
Displays test result.

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

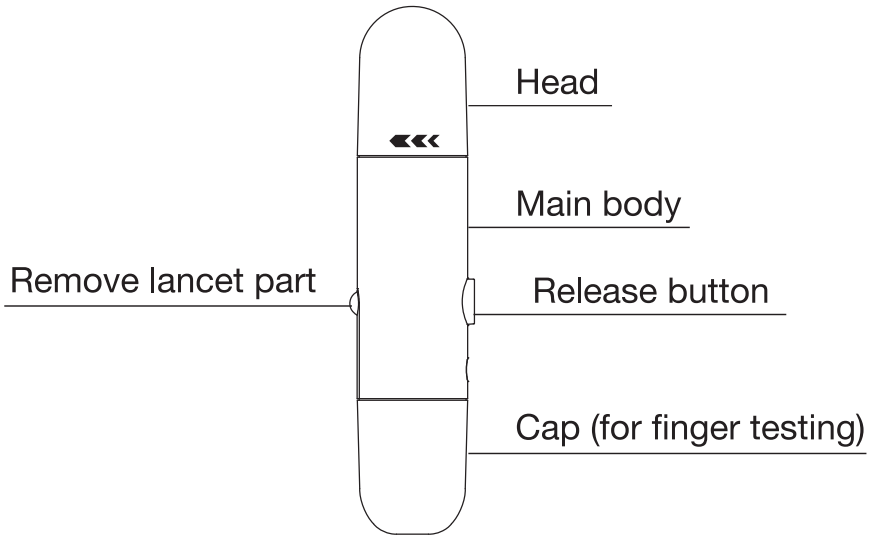
iHealth Test Strips
Use iHealth test strips EGS-2003 & EGS-2043.

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.
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.

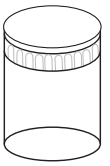
Each test strip can be used only once, and consists of the following parts.
Refer to the test strips Instruction Book to have more details on how to use the test strips with your meter.



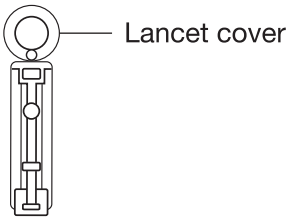
iHealth Lancing Device
Use only with the iHealth lancet.



• 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
Works with both iOS and Android devices: such as iPhone 7/iPhone 7 Plus/Samsung Galaxy S6 Edge/SM-G9250/Samsung Galaxy Note3 SM-N9006/Motorola Nexus 6
For a complete list of compatible devices, visit our support on page on www.ihealthlabs.eu

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 (iHealth Gluco+). 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 & EGS-2043)
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 (iHealth Gluco+) 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.

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 to 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 (iHealth iGluco+) Owner's Manual for further information.

Step 1
Launch the iHealth Gluco-Smart app.
Go to MENU> Settings> Press "Control Solution Testing"

and choose which meter you are using.

Step 2

Insert the test strip into the meter slot.

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 the first drop and use the second to perform your measures.

Then hold your meter and put the test strip reading window into contact with the control solution.

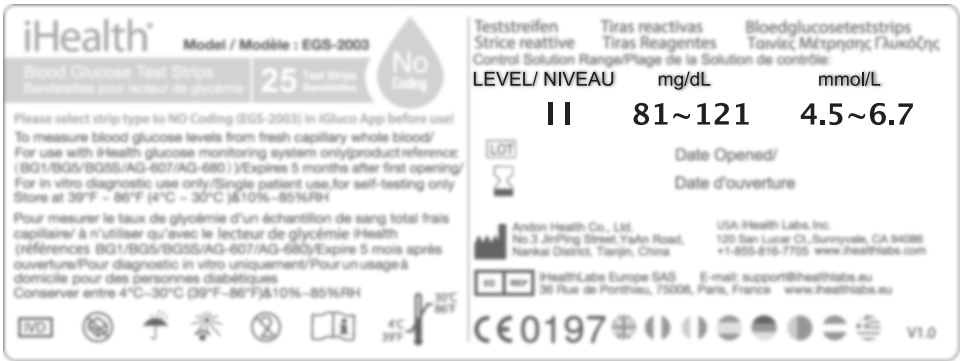
Once the test strip reading window is completely filled, the meter will start counting down, then you can remove the test strip from the control solution sample.

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 (iHealth Gluco+) is failure.

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 (iHealth Gluco+) 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 (iHealth Gluco+) 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 (iHealth Gluco+).

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 to have 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 & EGS-2043)
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 an online test and for an offline test:

About the online-test

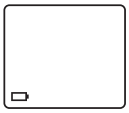
You need the iHealth Gluco-Smart app launched to perform a blood glucose test. When you perform a blood glucose test on an online-test, your results will be synchronized automatically on your iHealth profile.

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

STEP 1 Download the iHealth Gluco-Smart app
Prior to first use, download and install the free iHealth

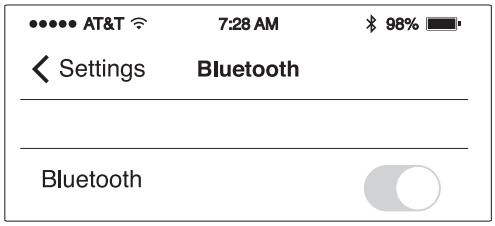
Gluco-Smart (iGluco) app from the App Store or Google Play Store to your mobile device. Follow the on-screen instructions to create your iHealth ID.

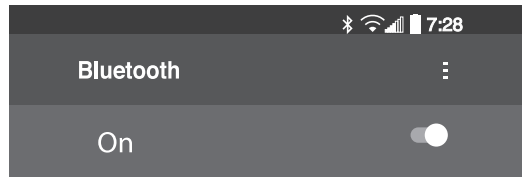
STEP 2 Charge the battery
Your meter is powered by a built-in, rechargeable battery. When you use this meter first time, activate it according to following instructions. Plug one end of the charging cable into the side of the meter and the other end into a USB charging port. Charge it for two to four hours before first use. (A fully charged battery can typically take up to 200 tests depending on your daily usage.)

Note 2: *About Low battery message*
After you have used your meter for some times,  *flash 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 time of the meter before using it again.
Important: This device requires a medical AC adapter with an output of DC 5.0V that complies with IEC 60601-1/UL 60601-1 and IEC 60601-1-2 such as OH-1048A0501000U2 (input: 100-240V, 50/60Hz; output: DC 5V, 1.0A). The charging port is Micro USB and should be used for charging only.

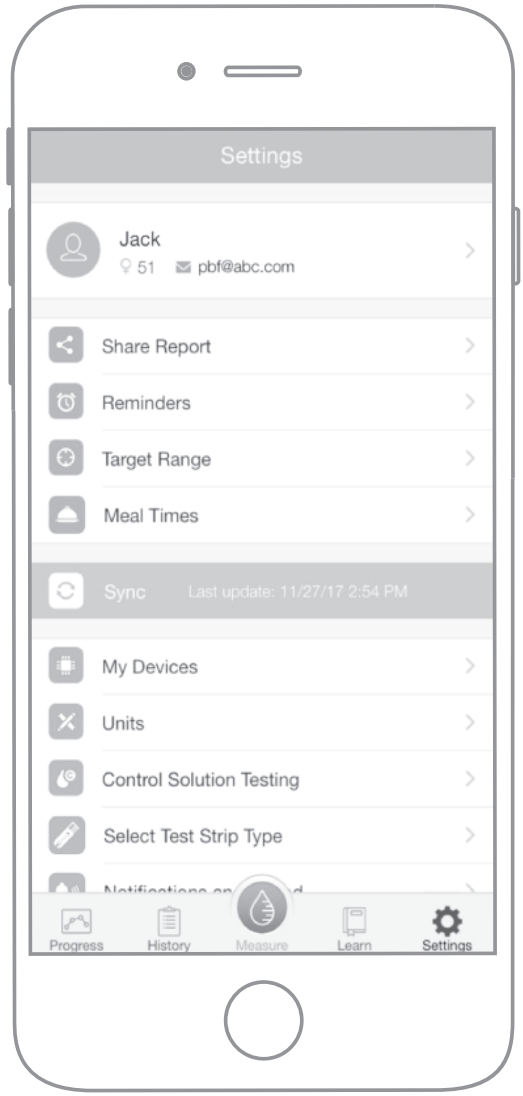
STEP 3 Connect the meter to the app
Prior to first use, follow the steps below to connect the meter to the app on your Android or iOS mobile device to set your meter's time and date. By connecting, the date and time of the meter will be synced with your Android or iOS mobile device.

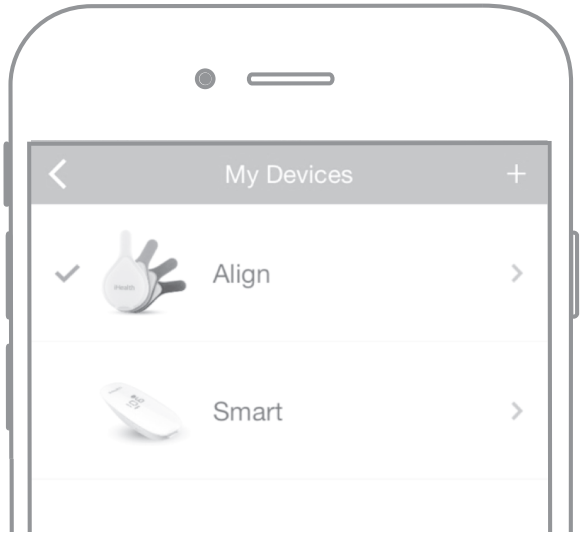
Step 3-1: Turn on the *Bluetooth* switch on your mobile phone.





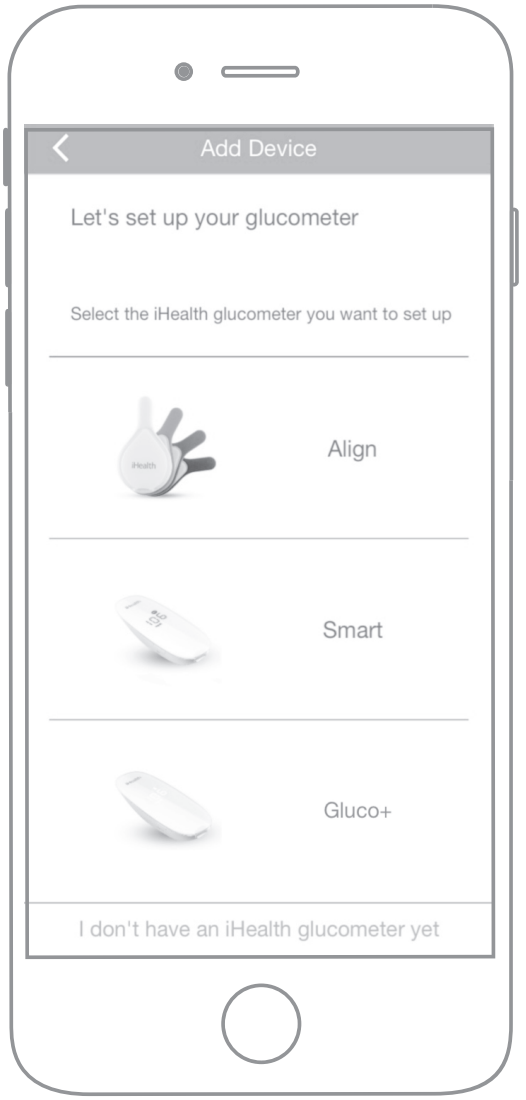
Step 3-2: Connect the meter to the app. Click on “My Devices” in the Settings menu.

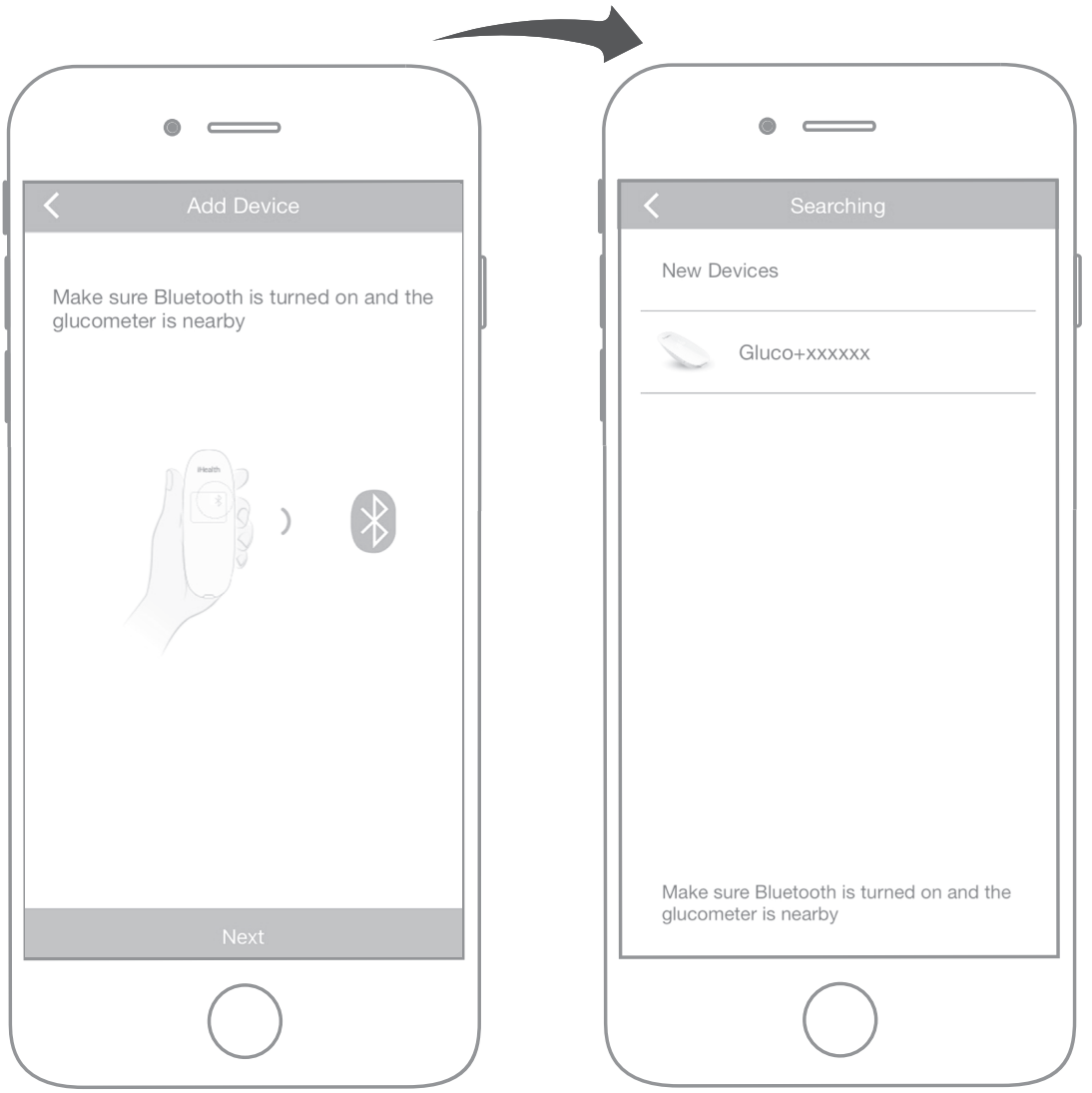


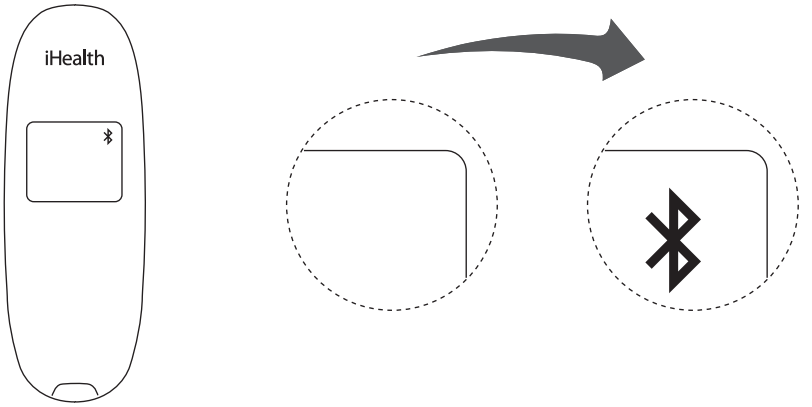


On My Devices screen, click on the '+' icon on the top right corner to add new device.

In "Add Device" screen, select "Gluco+" as the meter. Make sure the *Bluetooth* is turned on and place the meter close to your phone, your phone will start searching automatically for "Gluco+" meter, all "Gluco+" meter nearby will show up in the list, select the one you would like to connect. The *Bluetooth* symbol " ᛒ " on the meter will flash twice, then after three seconds, the meter turns off automatically. (xxxxxx means the last six number of MAC address)





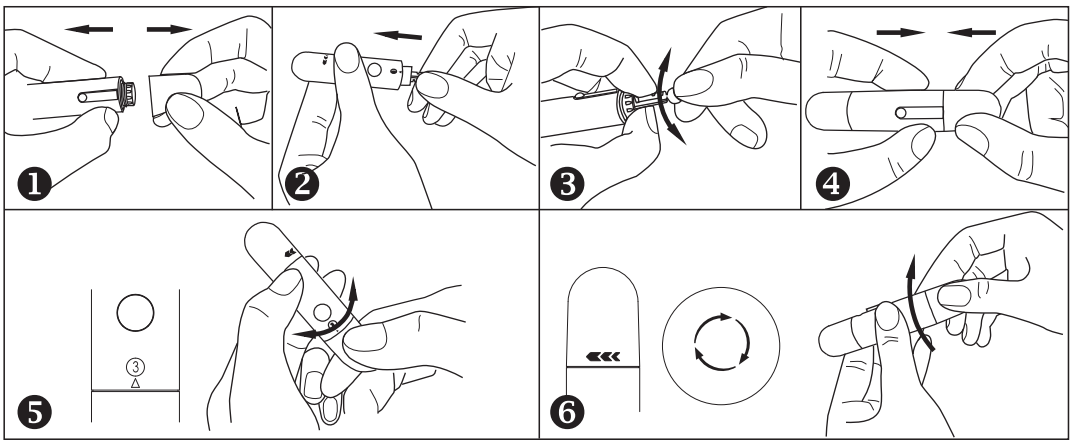


Note 3-2: *Repeat step 3-1 ～ 3-2 when switching to a different Android or iOS mobile device.*

STEP 4 Test your blood glucose level

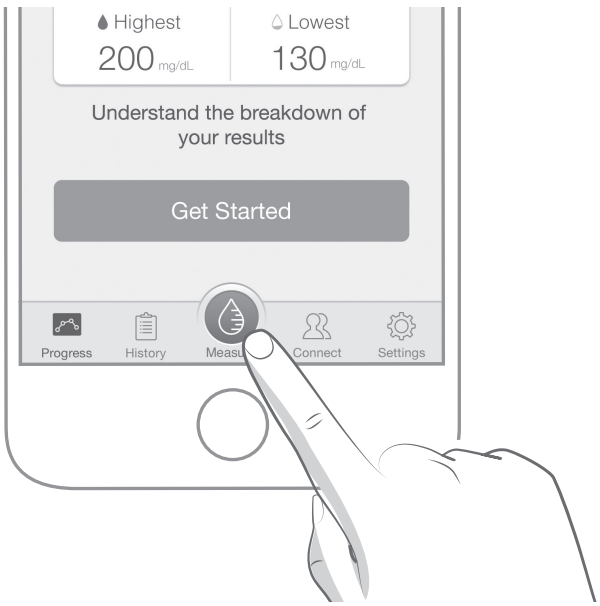
Step 4-1: Prepare the lancing device.

① Remove the lancing device cap
② Insert a new lancet firmly into the lancing holder cup
③ Twist the lancet cover off（Do not discard）
④ Replace the lancing device cap
⑤ Adjust the puncture depth setting. Set the lancing level from level1 (Min.) to 5 (Max)
⑥ Twist until “clicks”



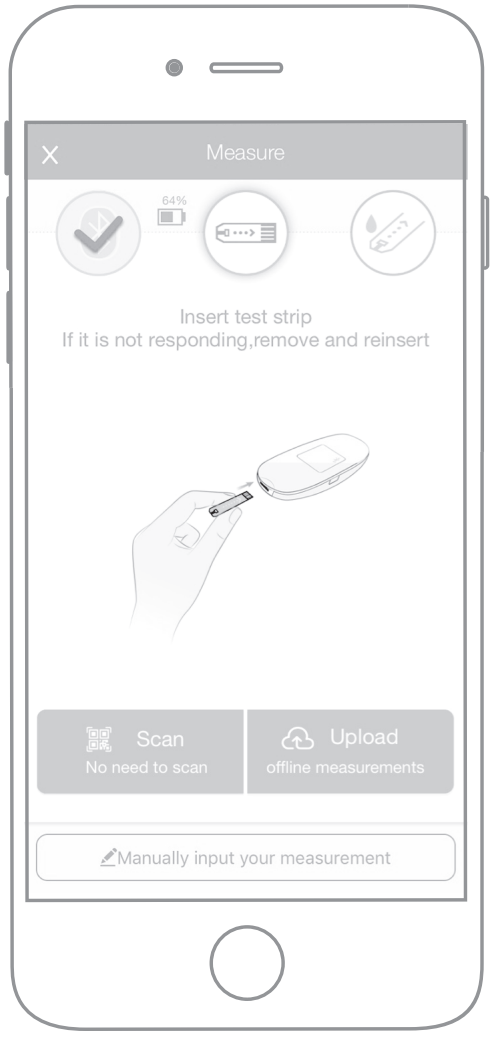
Step 4-2: Wash your hands with warm soapy water and dry thoroughly. Dirty or wet hands could impact test results.

Step 4-3: Open iHealth Gluco-Smart app and click on “Measurement” button.

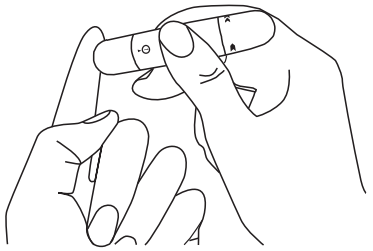


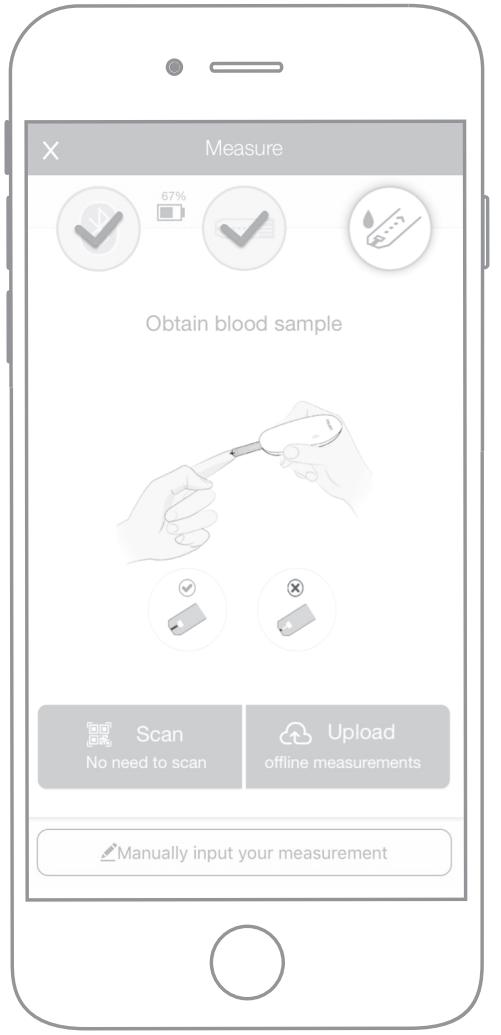
Make sure your *Bluetooth* is turned on, and iHealth Gluco+ is nearby. The connection will be setup automatically.

Follow app instruction to insert test strip. Take a new test strip from the test strip bottle, hold the middle of the test strip, with the arrow facing the meter, insert the test strip into the meter's strip port.

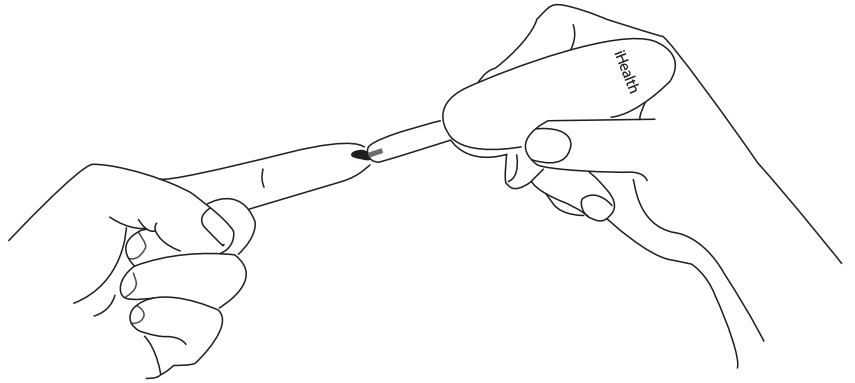


Step 4-4: Obtain a blood sample. Press the lancing device against the site to be lanced. Press the release button to lance the site. Massage your finger until a drop of blood forms.



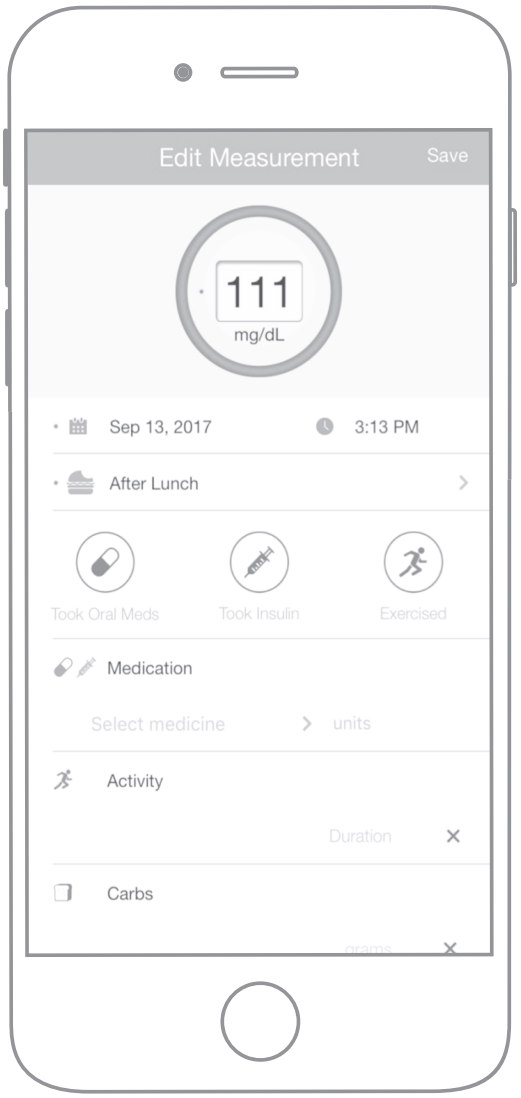


Step 4-5: Apply the blood sample to the test strip. Quickly apply the blood sample to the absorbent hole of the test strip. Make sure the confirmation window of the test strip is completely filled with the blood sample.



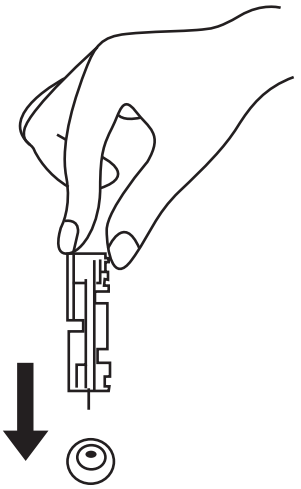
Remove your finger from the test strip when APP starts displaying the ‘Testing’ animation. The test result will appear on the display.

Step 4-6: Read the test results.
The test result will appear on the app.



Note 4-6: *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 4-7: Discard the used test strip and lancet.
Push the eject button on the back side of the meter, 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. Push the remove lancet part slightly and discard the lancet properly.



About the offline-test (you can take a measurement without the app launched)

You can perform a blood glucose test without the iHealth Gluco-Smart app launched. Please insert the test strip to start up measurement. When you perform a blood glucose test without app, your results will be saved on the meter, it can save 500 test results.
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.
To synchronize your result on your iHealth profile, you have to launch the iHealth Gluco-Smart app and click to upload.

Data synchronisation.

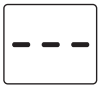
The meter can save as many as 500 of the most recent blood

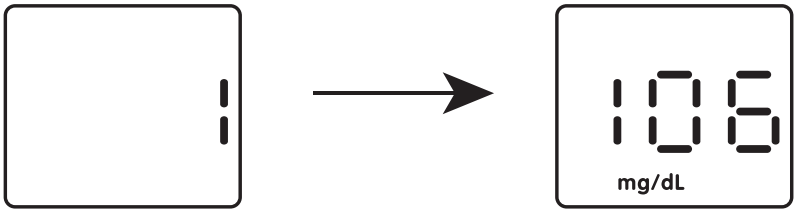
glucose test results. When the meter needs to save a new test result and it has already stored 500 test results, the oldest test result will be overwritten by the new test result.

When the meter is connected to the App on your mobile device, tap the “Upload” button to upload the data from meter to the App and cloud.

Reviewing saved test results on the iHealth Wireless Smart Glucose Meter.

Short press the memory button to view the test results stored in the meter. The first reading you’ll 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 figure  will appear, press the memory button can repetitive view the test results, and the meter will turn off automatically when it is idle for ten second.



Comparing iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+) test results with laboratory results

The iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+) provides you with plasma-calibrated equivalent results. The result you obtain from your meter may differ somewhat from your laboratory results due to normal variation.

The meter results can be affected by factors and conditions that do not affect laboratory results in the same way.

To make an accurate comparison between the meter and laboratory results, follow the guidelines below.

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

While at the Lab
Keep the meter and samples in the same environment at least 30 minutes before performing test.
Wash your hands before obtaining a blood sample.
Never use your meter with blood samples collected in a test tube.
Use fresh capillary blood only.

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.
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 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.
If the 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, clean and wash your hands.
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.

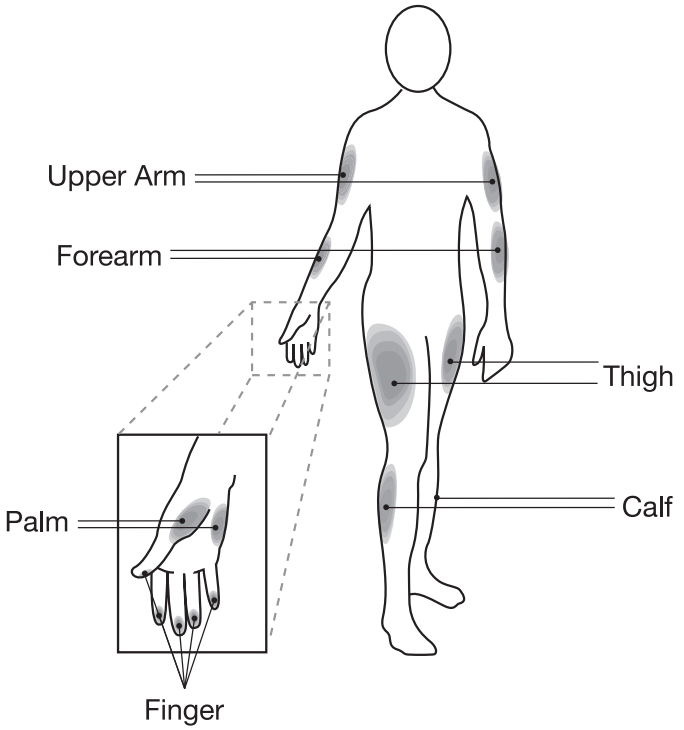
Note:

① *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 wipe. Do not insert the disinfecting wipe into the test strip port.

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

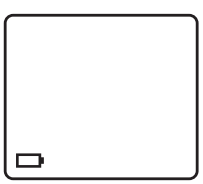
Maintenance and storage of your iHealth Wireless Smart Glucose Meter

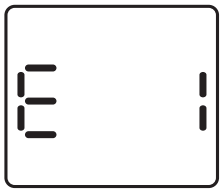
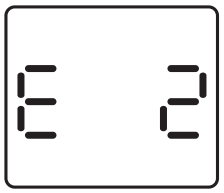
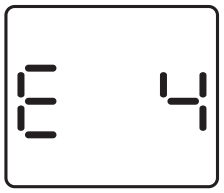
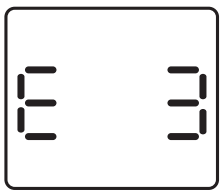
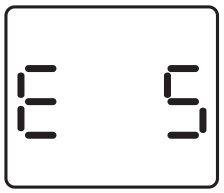
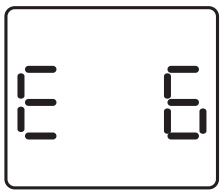
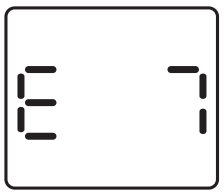
Always use care when handling the meter. Dropping or throwing the meter may cause damage.
Don't expose the meter, test strips, or control solution to extreme conditions such as high humidity, heat, freezing cold, or dust.
Always wash your hands with soap and water, and rinse and dry them completely before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

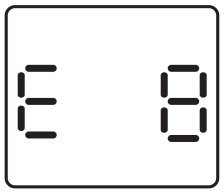
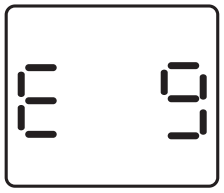
System troubleshooting

If you follow the recommended action 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.

Display messages

MESSAGE	WHAT It Means?	ACTION
	The battery in your meter in low on power.	Charge the battery.

	Strip removed during measurement	Start again using a new test strip
 	Problem with the meter.	Re-test with a new test strip. If the problem persists, call iHealth Labs Customer Service.
	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	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	Keep press MEMORY BUTTON for 7 seconds, then the meter will restore factory settings. Please use the charging line to activate the meter.

	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.

Troubleshooting

Problems	Possible Causes	Solutions
Display remains blank 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. Charge the battery 2. Reinsert the test strip into the meter. 3. Reinsert the test strip into the meter, pressing firmly.
Test results are inconsistent or Control Solution test results are not within the specified range.	1.Not enough sample in the Test Strip. 2.Test strip or Control Solution has expired. 3.Test strip has been damaged due to heat or humidity so that the sample cannot be applied, or the speed of application is too slow. 4.System is not performing due to the environment being above or below room temperature.	1. Re-test with a new Test Strip and make sure that enough sample has been applied. 2. Re-test with a new Test Strip or new Control Solution 3. Perform a Control Solution test using a new Test Strip. If the results are

		still out of range, replace with new vial of Test Strips. 4. Bring the system to a room-temperature environment and wait approximately 30 minutes before performing a new test.
The meter countdown did not start.	Test strip has not been inserted correctly.	Use a new Test Strip and redo the test.
The meter does not respond	System suspend	Keep press MEMORY BUTTON for 7 seconds, then the meter will restore factory settings. Please use the charging line to activate the meter.

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 health care provider.

IHEALTH WIRELESS SMART GLUCO-MONITORING SYSTEM SPECIFICATIONS

Technical specifications

1. Model: BG5S
2. Machine size: 3.85” × 1.37” × 1.09” (98 mm × 35 mm × 27.8 mm)
3. Measuring method: Amperometric technology using glucose dehydrogenase
4. Result range: 20 mg/dL ~ 600 mg/dL
   (1.1 mmol/L ~ 33.3 mmol/L)
5. Power source: DC 3.7V, Li-ion 250 mAh
   Charging condition: DC 5V 250mA
6. Wireless communication: *Bluetooth* V4.1 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: EGS-2003： Min. 0.7 microliter
    EGS-2043： Min. 0.5 microliter
12. Life span: Five years

The blood glucose monitoring system meets the accuracy requirements of standard EN ISO 15197:2015 which states that 95% of the readings less than 100 mg/dL must be within ± 15 mg/dL of the reference value and 95% of the values greater than 100 mg/dL must be within ± 15% of the reference value.

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:
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 conjunction with any other antenna or transmitter.

NOTICE: *Changes or modifications made to this equipment not expressly approved by iHealth Labs, Inc. may void the FCC authorization to operate this equipment.*
This product complies with Industry Canada. IC: RSS-210. This

product is approved in accordance to RED directive. Hereby, Andon Health Co., Ltd. declares that the iHealth Gluco+ is in compliance with the Radio Equipment Directive (RED) 2014/53/EU. The full text of the EU declaration of conformity is available at 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).
Recommended separation distances between portable and mobile RF communications equipment and the BG5S.
The BG5S is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.
The customer or the user of the BG5S can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BG5S as recommended below, according to the maximum output power of the communications equipment.
So the distance between the meter and the radiation source(such as Microwave Oven) should more than 3.25 meters.

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

NOTE 2 *It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.*
Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation.

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 two 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.

This warranty does not apply: (a) to consumable parts, such as the battery that diminish over time, unless failure has occurred due to a defect in materials or workmanship; (b) to cosmetic damage, including but not limited to scratches, dents ; (c) to damage caused by accident, abuse, misuse, contact with liquid; (d) to damage caused by operating the Start by iHealth product outside the user manual, the technical specifications or other Start by iHealth product published guidelines; (e) to damage caused by service performed by anyone who is not a representative of iHealth or one of its representatives.

Manufactured for iHealth Labs, Inc. and iHealthLabs Europe

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+1-855-816-7705 E-mail : support@ihealthlabs.com

Europe:
EC REP iHealthLabs Europe SAS
www.ihealthlabs.eu
36 Rue de Ponthieu, 75008, Paris, France
Customer service: https://ihealthlabs.eu/en/assitance or menu Contact in iGluco App

If you have questions or need assistance outside the operational hours and days, please contact your healthcare provider.

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

LOT Batch code

SN Serial number

REF Catalogue number

Consult instructions for use

Caution

Do not use if the package damaged

 Storage temperature Limit

 Keep in a dry place

 Keep away from direct sunlight or near heat sources.

STERILE R Sterilized using irradiation

 Use by date

 *Bluetooth* sign

 Do not reuse

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

CE 0197 Complies with the requirements of the European IVD Directive (98/79/EC)

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

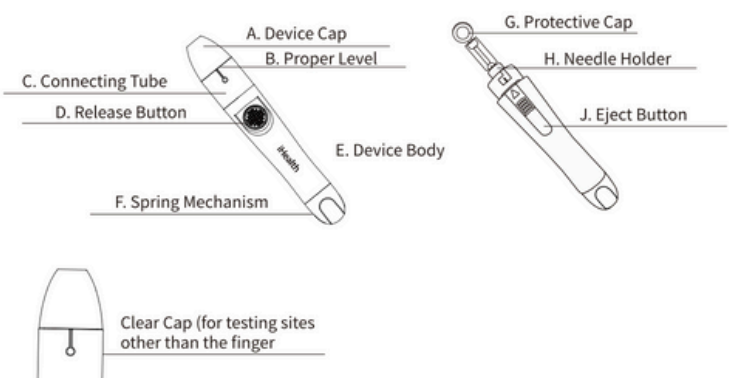
EN

iHealth®
Lancing Device

Intended Use

The iHealth Lancing Device and iHealth Lancets are specifically designed to use with the Gluco-Monitoring System. It is intended for use taking blood samples from fingertips or other sites of the body when testing blood glucose levels.
Important: The iHealth Lancing Device is for, self-use only, and should not be used by healthcare professionals. Do not share or re-use lancets.

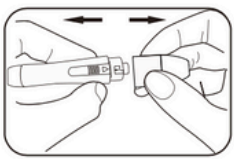
Parts and Display



Using the Lancing Device

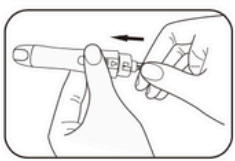
1. Remove Cap

Remove the Device Cap and the Connecting Tube. Turn the Connecting Tube and ensure the "△" is aligned with the "▽" on the Eject Button. At this time, hear the sound of "click", and remove the Device Cap and the Connecting Tube.



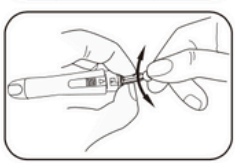
2. Insert Lancet

Insert the lancet into the Needle Holder, and push down firmly until it is fully inserted.



3. Twist Off the Protective Disk (Do not discard)

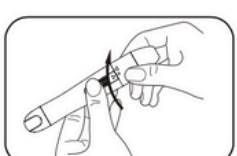
Twist off the Protective Cap and save it for lancet disposal.



4. Replace Lancing Device Cap

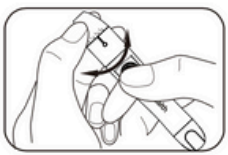
Place the Device Cap and Connecting Tube back on the device. Turn the Connecting Tube and ensure "▽" on the Eject Button is aligned with "○" on the Connecting Tube. At this time, hear the sound of "click".

Use the Device Cap on the lancing device for finger tests. Use the Clear Cap for forearm, upper arm, hand, thigh and calf test sites.



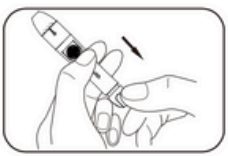
5. Set the Lancing Level

Hold the Device Cap in one hand, and the Device Body in the other, and adjust it to the proper level (usually 3). The depth display window is on the same side as the Release Button.



6. Load the Handle

Pull back on the device' s Spring Mechanism.
You are now ready to perform a blood glucose test.



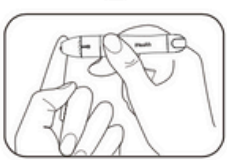
Select Your Preferred Test Site

Warning: If you are testing for hypoglycaemia (low blood glucose) or if you suffer from hypoglycaemia unawareness, we recommend that you test on your fingers.

For Finger Lancing

a. Lightly touch the lancing device (with the cap) against the side of your fingertip. For best results, lance in shaded areas.
b. Press the Release Button.
c. Gently squeeze your finger, if needed, until a blood drop the size of a pinhead forms (example:●).
d. Refer to your Owner's Manual for further information on blood glucose testing with the Gluco-Monitoring System.

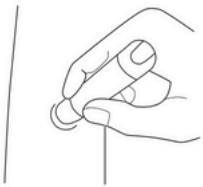
Notes: Blood glucose results from the forearm, upper arm, hand, thigh and calf are not always the same as results from fingertips. Do not use sites other than fingertips for testing when blood sugar is rapidly rising or falling, within 2 hours of eating, after faking insulin, immediately after exercise, or when you are ill or under stress.



Lancing Your Forearm, Upper Arm, Hand, Thigh or Calf

To bring fresh blood to the surface of the test site, rub the test site vigorously for a few seconds until you feel it getting warm. Lance the test site with the lancing device by:

a. Holding the Clear Cap down against the top of your test site. Press the Release Button. Do not lift up.
b. Apply a firm pressure on the lancing device until an adequate blood drop is formed.
c. Lift the lancing device straight up being careful not to smear the blood sample on your test site.



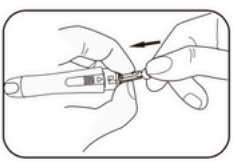
Important:

a. Avoid lancing areas with obvious veins or moles to avoid excess bleeding.
b. Avoid lancing areas with tendons or bones such as hands and ankles.
c. A blood sample of 0.7uL about the size of a pinhead (example: ●) is required.
d. Refer to the Gluco-Monitoring System Owner's Manual for further information.

Removing a Used Lancet

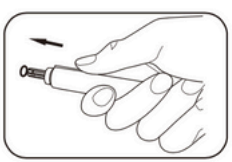
a. Prior to disposal, stick the lancet into the cover.

Remove the Device Cap and the connecting tube and stick the lancet tip into the Protective Cap.



b. Discard the used lancet properly.

Push the Eject Button, then push back the Protective Cap to its original position and discard the used lancet in an appropriate container.



Waring:

- Please avoid the accidental injuries to yourself or others when you use the device.
- Keep the lancing device and the lancet away from children.
- When you install the lancet, please do not press the Release Button if the Device Cap is removed.
- Please do not keep the lancet in the device after using it.
- Please do not share the device with others or reuse the lancet.
- Please disinfect the device before using it, but do not immerse the device into any liquid.
- Please pull the plug of the device gently to avoid shedding.
- The lancing device should press against the skin vertically and firmly, or it will affect the blood taking.

Cleaning and Disinfection

Cleaning and disinfection is absolutely necessary for the test procedure to be accurate because cleaning can insure the lancing device works well and disinfection can avoid infection or cross-infection to you or to other people.
We strongly recommend that the meter and lancing device be cleaned and disinfected following every use. We also suggest you use the following product: CaviWipes (EPA registration number: 46781-8).
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 Glucose Meter and lancing device.
For product and technical information and to purchase this product visit www.metrex.com or contact Metrex at 1-800-841-1428.
a. Before the test, the user should clean and wash hands.
b. After tesing, use the Cavi WipesTM (Metrex® Research Corporation, EPA Reg. No.46781-8, EPA Est. No. 56952-WI-001) to clean and disinfect lancing device for 180 seconds.
Note:
1. Each disinfection step requires a pre-cleaning step.
2. Do not immerse the body of the lancing device in water or any other liquid. Store in a dry, clean well-ventilated room.
3. The users should wash hands thoroughly with soap and water after handling the lancing device.
4. If you have any questions please contact +7-855-816-7705
5. Please refer to the following link for detailed information:

"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk forTransmitting Bloodborne Pathogens: Initial Communication" (2010) http:llwww.fda.govlMedical-DevicesISafetylAlertsandNoticeslucm224025.htm

"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)
htfp:llwww.cdc.govlinjectionsafety/Fingerstick-DevicesBGM.html

Product Model: HH-XVI-T

Manufactured for iHealth Labs, Inc.

USA:

iHealth Labs, Inc. www.ihealthlabs.com
150C Charcot Ave, San Jose, CA 95131, USA
1-855-816-7705
(8:30 AM-5:30 PM PST, Monday to Friday)

Europe:

EC REP Shanghai International Holding Corp.GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Tianjin Huahong Technology Co., Ltd.
A01,Plant B,No. 278 ,Hangkong Road,Tianjin Pilot Free Trade Zone(Air Port Industrial Park) ,Tianjin 300308,China
Made in China

SYMBOLS:

EC REP Authorised reprentative in the European community

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

SN Serial number

MANUFACTURER

Consult instructions for use

Revision date: 2022/04/14
Version: V2.0

iHealth®

Blood Glucose Test Strips
Bandelette
Strisce reattive per il test della glicemia
Tira reactiva de glucosa en la sangre
Blutzuckerteststreifen
Tiras de teste de glicose no sangue
Bloedsuikerteststrips
Ταινίες μέτρησης γλυκόζης του αίματος

INSTRUCTIONS FOR USE
INSTRUCTIONS D'UTILISATION
ISTRUZIONI PER L'USO
INSTRUCCIONES DE USO
BEDIENUNGSANLEITUNG
INSTRUÇÕES DE UTILIZAÇÃO
GEBRUIKSINSTRUCTIES
ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ

EN

iHealth

Blood Glucose Test Strips
Instructions for use
Model: EGS-2003

⚠ **WARNING:** To use these strips (Model: EGS-2003), please select in the Gluco-Smart app (iGluco): Settings > Select Test Strip Type > No coding. If you want to go back to using the AGS-1000l (strips bottle with barcode), select « QR code ». More info here: bit.ly/iHegsENG

Important safety instructions

- The meter and lancing device are for single patient use only. Do not share with anyone including other family members.
- All parts of the BG1/BG5/BG5S/AG-607/AG-680 Blood Glucose Monitoring System are considered bio-hazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

Refer to the following links for more 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
Refer to the Cleaning and Disinfection section of the Owner's Manual for cleaning and disinfection procedures.

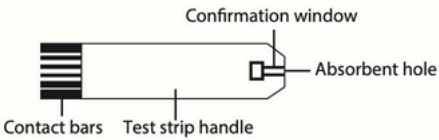
Intended Use

The EGS-2003 Blood Glucose Test Strips are for use with the BG1/BG5/BG5S/AG-607/AG-680 Blood Glucose Monitoring System to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh. They are intended for single patient use only and should not be shared. They should only be used for monitoring and not be used for the diagnosis of or screening for diabetes, or for neonatal use.

Test Principle

The test is based on the measurement of an electrical current generated by the reaction of glucose with the reagent of the test strip. The meter measures the current and converts to the corresponding blood glucose level.

Test Strip Parts



Absorbent hole - Apply a drop of blood here. The blood will be drawn in automatically.

Confirmation window - If sufficient blood has been drawn into the absorbent hole of the test strip this window will be completely covered with blood.

Test strip handle - Hold this part to insert the test strip into the strip port.

Contact bars - Insert this end of the test strip into the meter. Push it in firmly until it will go no further.

Attention: Test results might be inaccurate if the contact bars is not fully inserted into the strip port.

Warning and Precautions

- For in vitro diagnostic use (external use only).
- Do not reuse.
- For self-testing.
- Please review this instruction sheet and the BG1/BG5/BG5S/AG-607/AG-680 Blood Glucose Monitoring System owner's manual before you use EGS-2003 Blood Glucose Test Strips. For reliable results and to maintain the manufacturer's complete service, support, and warranty, please only use

EGS-2003 Test Strips.

- As with all small parts, the test strips and lancets should be kept away from small children. If any parts are swallowed, promptly see a doctor for help.
- If you have questions or need assistance outside the Customer Service days and time, please contact your healthcare provider.
- Please wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.
- The meter and lancing device should be cleaned and disinfected. Please refer to the Cleaning and Disinfection section of the Owner's Manual for cleaning and disinfection procedures.
- Used lancet and test strips may be potentially hazardous. Please discard them carefully according to instructions found in the BG1/BG5/BG5S/AG-607/AG-680 Blood Glucose Monitoring System Owner's Manual.
- Never make significant changes to your diabetes control program or ignore physical symptoms without consulting your healthcare professional.
- You should only adapt the treatment if you has received the appropriate training to do so.

Test Procedure

1. Wash hands or the puncture site using soap and warm water. Rinse and dry thoroughly.

Note: *If you use an alcohol swab, ensure that the puncture site is completely dry*

prior to obtaining a sample.

2. Remove a test strip from its vial and insert the test strip into the strip port of the meter. The contact bars must be all the way into the meter.
3. Puncture the test site using the lancing device and gently squeeze and/or massage the area until a round drop of blood of at least 0.7 microliter forms. Do not squeeze the puncture site excessively.
4. Apply your blood to the absorbent hole of the test strip until the confirmation
   window is fully filled with blood, please refer to the diagram below.

Note: *Make sure the confirmation window of the test strip is completely filled with your blood sample.*

5. Get your blood glucose result.
6. Remove the test strip from the meter. Discard the used lancet directly into a container designed for sharp objects.

Note:

1. *A lancing device is intended only for a single user and should not be shared, otherwise it will bring the risk of blood borne pathogen transmission.*
2. *Lancets are for single use only.*
3. *A new, sterile lancet should be used each time a test is performed.*

Please consult the iHealth Gluco-Monitoring System (BG1/BG5/BG5S/AG-607/AG-680) Owner's Manual for detailed directions and illustrations.

Questionable or Inconsistent Results

If you are receiving test results that are unusual or inconsistent with how you are feeling:

> Make sure that the drop of blood completely covers the confirmation window of the test strip.

> Confirm that the test strips are not expired.

> Check the performance of the meter and test strips using the control solution. Please keep in mind that high or low blood glucose levels can indicate a possibly serious medical condition. If you continue to get results that are unusually high or low, consult your healthcare professional.

Reference Values

Time of day	People without diabetes
Fasting and before meals	<100 mg/dL
2 hours after meals	<140 mg/dL

Source: (1) American Diabetes Association: Classification and Diagnosis of Diabetes (Position Statement). Diabetes Care 39 (Supp. 1) S15, 2016.
Please consult your healthcare provider to determine a target range that is best for you.

Warning: Alternative Site Testing (AST)

Important: There are limitations for doing AST. Please read theBG1/ BG5/BG5S/AG-607/AG-680 Blood Glucose Monitoring System Owner's Manual and consult your healthcare professional before you do AST.

- Alternative site testing (AST) should not be used to calibrate continuous glucose monitoring systems (CGMs).
- Results from alternative site testing should not be used in insulin dose calculations.

Control Solution Testing for Performance Checking

The control solution(Level I, Level II and Level III)contains a known amount of glucose concentrate that reacts with test strips. By comparing your control solution test results with the expected range printed on the test strip vial label, you can check that the meter and the test strips are working together as a system and that you are performing the test correctly. It is very important that you do this simple check routinely to make sure you get accurate results. Read the BG1/BG5/BG5S/AG-607/AG-680 Blood Glucose Monitoring System Owner's Manual for complete testing details.

Control solution test should be performed:

> When your test strips are exposed to extreme environmental conditions (See Warning and Precautions section of this document).
> When your blood glucose test results are not consistent with how you feel, or when you think your results are inaccurate.
> Whenever you suspect the meter or test strips are not working properly.
> At least once a week.
> When you want to practice testing with the meter.
> When you drop or damage the meter.
> Each time a new vial of test strips is opened.

Caution: The control range can change with each new vial of test strips. Always use the control range on the label of your current vial of test strips.

If the control solution test result falls outside the specified range printed on the test strip vial:

(1) Repeat the Quality Control Test.
(2) Review the Quality Control Section of the Owner's Manual to confirm your procedure and techniques.
(3) Check the expiration date of your test strips and control solution.
(4) Check your meter for damage (dropping the meter, immersing in liquid).

Test Results

Your blood glucose test results are displayed in mg/dL or mmol/L.
If your result is below 20mg/dL, repeat your test with a new test strip to confirm this reading. This indicates very low blood glucose levels or severe hypoglycemia. You should immediately treat hypoglycemia by following the recommendations of your healthcare professional.
If your result is above 600mg/dL, repeat your test with a new test strip to confirm this reading. This indicates very high blood glucose levels, or severe hyperglycemia. You should seek immediate medical attention.

Storage and Handling

In order to ensure that your test strips are effective, please use them according to the following recommendations.
IMPORTANT: Do not use the test strips if expired or results will be inaccurate.
To keep your test strips in the best possible condition, read the following recommendations thoroughly:

- Test strips expire 5 months after opening. Write the expiry date on the test strip vial when first opening.
  Store the test strip vial between 39°F ~ 86°F(4° C to 30° C) and 10% ~ 85% relative humidity.
- Do not refrigerate or freeze.

- Keep the test strips away from direct sunlight. Do not store the test strips in areas of high humidity.
- Test strips must be stored in their original vial only. Do not transfer them to a new vial or other 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 strip. Doing so will lead to inaccurate results.
- Do not use if vial is damaged.

Chemical Components in Each Test Strip

1. FAD-GDH >0.04mg
2. Other ingredients

(Electron shuttle, enzyme protector, non-reactive ingredients etc.) >0.05mg

Limitations

> Hematocrit: The glucose result is not affected when hematocrit is between 20% and 60%. Please consult your healthcare professional if you do not know your hematocrit level.

> Neonatal Use: The EGS-2003 Blood Glucose Test Strips are not intended for

neonatal testing.

> Metabolites: Uric acid , bilirubin and hemoglobin at normal blood concentration does not significantly affect glucose readings. High concentrations of acetaminophen and ascorbic acid may cause inaccurate test results. Blood glucose readings should be interpreted with caution.

> Lipemic Effects: Elevated blood triglycerides up to 2000 mg/dL do not significantly affect the results.

>The below table of substances shows the highest concentration without significant interference (± 10% error).

Compounds	Limitation
Ascorbic acid	>4mg/dL
Uric acid	>10mg/dL
Acetaminophen	>5mg/dL
Bilirubin	>40mg/dL
Hemoglobin	>450mg/dL

> Do not use during or soon after xylose absorption testing.

> If you are a patient on peritoneal dialysis, check with your doctor before testing your blood glucose. The dialysis solution may lead to incorrect 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.
> Altitude Effects: Test strips may be used at altitudes up to 10,744 feet (3,275 meters) without an effect on test results.

Performance Characteristics

System Measurement Range: 20 to 600mg/dL (1.1 ~ 33.3 mmol/L)
Hematocrit Range: 20% ~ 60%
Sample: Whole blood, capillary
Not less than Blood Sample Size: 0.7μL
Test Time: 5 seconds
Calibration: plasma equivalents

Precision

These studies were performed in the laboratory with whole blood. The blood glucose level was adjusted to five ranges.

Glucose concentration(mg/dL)	30-50	51-110	111-150	151-250	251-400
Number	100	100	100	100	100
Average	41.5	88.7	118.9	200.0	311.5
SD (mg/dL)	2.1	2.3	2.5	3.1	4.4
CV (%)	5.0	2.6	2.1	1.5	1.4

System Accuracy

The System was tested on 100 capillary blood samples. The system accuracy was compared to the laboratory method(The laboratory method traceability and validation of calibration are traceable to NIST standard reference material (SRM) 917c). The tables below show how well the two methods compared.

Table 1 represents samples for glucose results < 100mg/dL.

Difference range in values between blood glucose monitoring system's value and the laboratory value	Within 5mg/dL	Within 10mg/dL	Within 15mg/dL*
blood glucose monitoring system	39/56 (70%)	54/56 (96%)	56/56 (100%)

Table 2 represents samples for glucose results ≥100mg/dL.

Difference range in values between blood glucose monitoring system's value and the laboratory value	Within 5%	Within 10%	Within 15% *
blood glucose monitoring system	79/144 (55%)	113/144 (78%)	139/144 (97%)

*Acceptance criteria in ISO 15197: 2013 are that 95% of all differences in glucose values should be within 15mg/dL for glucose values less than 100mg/dL or within 15% for glucose values greater than 100mg/dL.

Testing Accuracy of the Alternative Sites

100 subjects were tested on the alternative sites: the palm, the forearm, the upper arm, the calf and the thigh. The tables show differences in glucose values between alternative sites and laboratory values (finger stick sample).

Table 3 represents samples for glucose results < 100mg/dL.

Difference range in values between the alternative sites' value and the laboratory value	Within 5mg/dL	Within 10mg/dL	Within 15mg/dL*
Palm	8/12 (67%)	9/12 (75%)	12/12 (100%)
Forearm	7/12 (58%)	11/12 (92%)	12/12 (100%)
Upper arm	8/12 (67%)	10/12 (83%)	12/12 (100%)
Calf	9/12 (75%)	11/12 (92%)	12/12 (100%)
Thigh	7/12 (58%)	10/12 (83%)	12/12 (100%)

Table 4 represents samples for glucose results ≥ 100mg/dL.

Difference range in values between the alternative sites' value and the laboratory value	Within 5%	Within 10%	Within 15% *
Palm	38/88(43%)	67/88(76%)	86/88(98%)
Forearm	39/88(44%)	71/88(81%)	86/88(98%)
Upper arm	37/88(42%)	73/88(83%)	85/88(97%)
Calf	37/88(42%)	71/88(81%)	85/88(97%)
Thigh	38/88(43%)	72/88(82%)	85/88(97%)

Lay user performance:
A study evaluating glucose values from fingertip capillary blood samples obtained by 100 lay persons showed the following results:
100% within ±15mg/dL(±0.83mmol/L) of the medical laboratory values at glucose concentrations below 100mg/dL (5.55mmol/L), and 100% within ±15% of the medical laboratory values at glucose concentrations at or above 100mg/dL (5.55mmol/L).
The blood glucose test strips EGS-2003 met the EN ISO 15197:2015 standard.

USA:
Manufactured for iHealth Labs, Inc. www.ihealthlabs.com
120 San Lucar Ct., Sunnyvale, CA 94086, USA
+1-855-816-7705(8:30 AM to 5:30 PM PST, Monday to Friday)
If you have questions or need assistance outside the operational days and times, please contact your health care provider.

Europe:

EC REP

iHealthLabs Europe SAS www.ihealthlabs.eu
36 Rue de Ponthieu, 75008, Paris, France
E-mail: support@ihealthlabs.eu

Andon Health Co., Ltd.
No.3 JinPing Street, YaAn Road, Nankai District,Tianjin, China

Made in China

Symbols in use

Do not Reuse

Consult Instructions for Use

IVD In Vitro Diagnostic Medical Device

 Keep dry

 Storage Temperature Limitation

REF Catalogue number

LOT Lot Number

 Use by

 Manufacturer

 Keep away from sunlight

 Do not use if package is damage

EC REP Authorised Representative in the European Community

CE0197 Complies with IVD98/79/EC requirements