

iHealth™

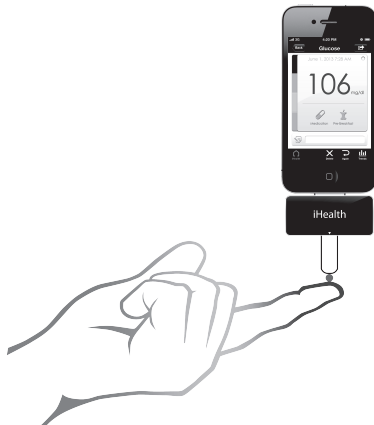
Smart Gluco-Monitoring System

Système intelligent de surveillance de la glycémie

Sistema intelligente di monitoraggio del glucosio

Sistema de glucomonitorización inteligente

Smart-Blutzuckermesssystem



OWNER'S MANUAL

MODE D'EMPLOI

MANUALE D'ISTRUZIONI

MANUAL DEL PROPIETARIO

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iHealth™ Smart Gluco-Monitoring System (AG-631)

OWNER'S MANUAL

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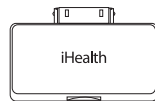
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INTRODUCTION

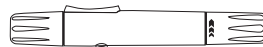
Thank you for purchasing the iHealth Smart Gluco-Monitoring System. This Manual provides important information to help you use the system properly. Before using this product, please read the Owner's Manual thoroughly. Regular monitoring of your blood glucose levels can help you and your doctor gain better control of your diabetes. Due to its compact size and easy operation, you can use the Smart Glucose Meter to easily monitor your blood glucose levels by yourself anywhere, anytime.

If you have questions regarding this product, please visit www.ihealthlabs.com, contact your place of purchase, or call Customer Service at 1-855-816-7705.

PACKAGE CONTENTS



• Smart Glucose Meter



• Lancing Device



• Test Strips*



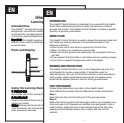
• Clear Alternate Site Testing Device Cap



• Lancets*



- Travel Case
- Control Solution*
- Owner's Manual



- Reference Guide



- Quick Start Guide

Note: *These contents may vary according to geographic markets. You must check your package.

If any items printed on the package are missing from your package or the package is opened prior to use, please contact the place of purchase for assistance.

The lancing device can be used several times, however, the lancet should be changed after each use.

SET UP REQUIREMENTS

The iHealth Smart Gluco-Monitoring System is designed to be used with the following iPod touch and iPhone models:

iPod touch 4

iPhone 4S

iPhone 4

iPhone 3GS

The iOS version of these devices should be V4.0 or higher.

INTENDED USE

The iHealth Smart Gluco-Monitoring System should be used

for:

- quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf or thigh
- single person measurement only and should not be shared
- self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control

The iHealth Smart Gluco-Monitoring System should not be used for the diagnosis of or screening for diabetes, or for neonatal use.

The blood glucose test strips are intended for use with the iHealth Smart Gluco-Monitoring System to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh.

Alternative Site Testing (AST) should be done only during steady – state times when glucose levels are not changing rapidly.

Control Solutions are intended for use with the Smart Gluco-Monitoring System. Control solutions can be used to check that the glucose meter and test strips are working properly and the measurement is accurate. These control solutions contain a known amount of glucose as indicated on the bottles. If you need the Control Solution, you can call Customer Service at 1-855-816-7705.

TEST PRINCIPLE

Testing with the iHealth Smart Gluco-Monitoring System is based on the measurement of electrical currents generated by the reaction of glucose with the reagent of the strip. The glucose meter measures the current and converts 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 SAFETY INSTRUCTIONS

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

- Misuse of the Smart Gluco-Monitoring System can cause electrocution, burns, fire and other hazards
- The glucose meter and lancing device are for single patient use. Do not use on multiple patients. Do not share meter or lancing device with anyone including other family members.
- Do not place the glucose meter in or near liquid.
- Use the glucose meter only for the purpose described in the Owner's Manual.
- Do not use accessories that are not supplied by the manufacturer.
- Do not use the glucose meter if it is not working properly, or if it has suffered any damage.
- Do not let the glucose meter come into contact with surfaces that are too hot to touch.
- Do not block test ports or place the glucose meter on soft surfaces that may block them. Keep test ports free from lint, hair, fluff, etc.
- Do not place anything on top of the glucose meter.
- Do not drop or put anything into any opening in the glucose meter.
- Please make sure it is not used by children or people who cannot express their own volition to use it, and do not put the glucose meter in a place where it can easily be reached by children.
- Do not use the glucose meter where aerosol sprays are

being used, or where oxygen is being administered.

- Do not use in a manner not specified by the manufacturer.
- When not in use, please disconnect the glucose meter from the iOS device.

IMPORTANT TESTING INFORMATION

- Severe dehydration and excessive water loss may cause results that are lower than actual values. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- 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.
- Use only fresh whole blood samples to test your blood glucose. Using other substances will result in inaccurate results.
- If you are experiencing symptoms that are inconsistent with your blood glucose test results and you have followed all the instructions provided in this Owner's Manual, contact your healthcare professional.
- Inaccurate results may occur in severely hypotensive individuals or patients who are in shock. Test results that are lower than actual values may occur in individuals who are in a hyperglycemic-hyperosmolar state, with or without ketosis. Please consult your healthcare professional before use.

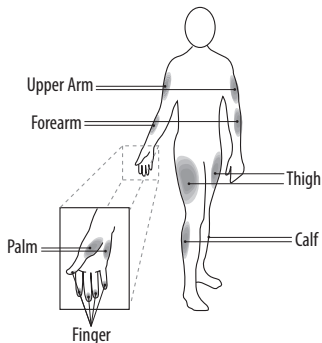
INFORMATION ABOUT ALTERNATIVE SITE TESTING (AST)

There are limitations for doing AST. Please consult your healthcare professional before you conduct AST. The Smart

Gluco-Monitoring System limits usage to steady-state blood glucose conditions only.

What is Alternative Site Testing?

Alternative site testing (AST) means that people use parts of the body, other than the fingertips, to check their blood glucose levels. The Smart Gluco-Monitoring System allows you to test on the palm, forearm, upper arm, calf, or thigh with equivalent results to fingertip testing.



What is the Advantage of Alternative 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 to Use Alternative Site Testing?

Food, medication, illness, stress and exercise can affect blood glucose levels. Capillary blood from the fingertips reflect these changes faster than capillary blood from other sites. Therefore, when testing blood glucose levels during or

immediately after one of the above listed events, such as meals or exercise, take a blood sample from your fingertips only. Alternative Site Testing (AST) should be done only during steady-state times when glucose levels are not changing rapidly.

Alternative Site Testing is suitable in the following instances:

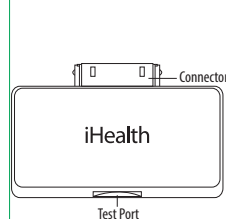
- In a pre-meal or fasting state (two hours or more after the last meal)
- Two hours or more after taking insulin
- Two hours or more after exercising

Caution: *Alternative Site Testing should not be used to calibrate continuous glucose monitoring systems (CGMs). Results from Alternative Site Testing should not be used in insulin dose calculations. Do not use AST if:*

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

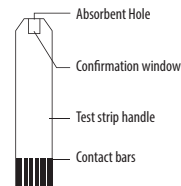
PARTS AND DISPLAY INDICATORS

Glucose Meter



Test Strip

Each test strip can be used only once. Test strips consist of the following parts:



SET UP PROCEDURES

Download the Free iHealth App

Prior to first use, download and install the free iHealth App from the App Store. Use keyword search terms “iHealth”, “BG3” or “Smart Gluco-Monitoring System”

Use the following procedure to download the free iHealth App from the App Store.

Account Set Up and Registration

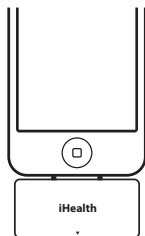
Follow the on-screen instructions to register and set up your personal account.

Clean Your Hands

Wash hands using soap and warm water.

Connect the Glucose Meter to your iOS Device and Launch the App

Connect your glucose meter to your iOS device, and the App will launch automatically once the meter is connected.



MEASUREMENT PROCEDURES

CAUTION:

To reduce the chance of infection:

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

Note: *Before testing, please read the following steps thoroughly. Changing the test procedure may produce inaccurate results.*

Scan QR Code on Top of the Test Strip Vial

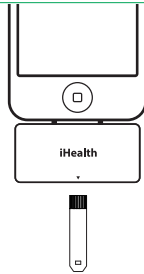
When you are ready to open a new test strip vial, you must scan the QR Code on its top. It is unnecessary to scan the QR Code for each test

By this scan, the App can determine whether the test strips are a match with the iHealth Smart Glucose Meter, the expiration date of the test strips and how many strips remain in the vial. Using this information the App can help the user better monitor their blood glucose levels.

Apply the Test Strip

Take a test strip from its vial. You may touch the test strip anywhere on its surface with clean dry hands. Do not bend, cut or modify the test strips in any way. Use each test strip immediately after removing it from the vial.

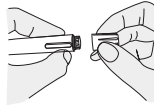
Insert the test strip into the test port of the glucose meter.



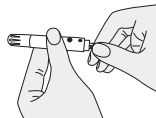
Obtain a Blood Sample

A sample may be obtained from the fingertip by the following steps:

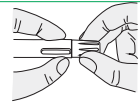
1) Remove the cap by twisting it off.



2) Insert the lancet into the cup holder and push in firmly. Twist the protective disk until it separates from the lancet and save the disk for later use.



3) Replace the cap until it clicks into place. Be careful not to touch the exposed needle on the lancet.



4) The lancing device offers five different settings. Level 1 is the shallowest depth and Level 5 is the deepest. Twist cap to the desired setting as shown in the depth indicator window.



5) Twist the cocking handle according to the arrow direction until you hear a click and cannot twist it further.



6) Puncture your fingertip.



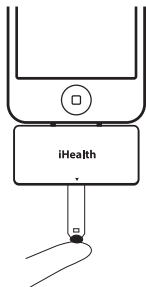
7) Gently squeeze and/or massage your fingertip until a round drop of blood of at least 0.7 micro liter forms on your fingertip.

Note: If you want to puncture your forearm, upper arm, hand, thigh or calf, consult the Lancing Device Manual for instructions.

Caution: A lancing device is intended only for a single user and should not be shared as it may bring risk of blood-borne pathogen transmissions.

Apply Your Blood Sample

Apply your blood to the blood sample area of the test strip, making sure the sample area is fully covered with your blood sample. Your iOS device will beep when you should remove the test strip from the blood sample.



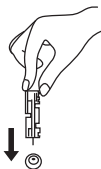
Read the Test Results

Your blood glucose results will be displayed on the iOS device.

Note: The results obtained from the glucose 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.

Discard the Used Lancet

Remove the test strip from the glucose meter. Discard the used lancet directly into a container designed for sharp objects. To remove the test strip from the glucose meter for proper disposal, we



recommend using a tissue paper. Please wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

Note: Please consult a healthcare professional for interpretation of blood glucose measurements.

For additional information, please visit:
www.ihealthlabs.com

REFERENCE VALUE OF THE IHEALTH SMART GLUCOSE METER

Time of day	People without diabetes
Fasting glucose	<110 mg/dL
2 hours glucose	<140 mg/dL (not specified but implied)

Source: World Health Organization, DEFINITION AND DIAGNOSIS OF DEABETES MELLITUS AND INTERMEDIATE HYPERGLYCAEMIA, (REPORT OF A WHO/IDF CONSULTATION), International Diabetes Federation, 2006, pg.36

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

COMPARING GLUCOSE METER WITH LABORATORY RESULTS

The glucose meter provides you with whole blood equivalent results. The result you obtain from your glucose meter may differ somewhat from your laboratory results due to normal variation. Glucose 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 glucose meter and laboratory results, follow

the guidelines below.

Before Going to the Lab

- Perform a Control Solution Test to make sure that the meter is working properly.
- If possible, fast for at least eight hours before conducting a comparison test.
- Take your glucose meter with you to the Lab.

While at the Lab

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

IMPORTANT INFORMATION ABOUT CONTROL SOLUTION TESTS

When you are ready to use the control solution to check your Glucose-Monitoring System, you must select the control solution test on the App so that the test result will not be recorder in your test result list which maybe interfere to monitor your blood glucose levels actually.

When to do a Control Solution Test?

The control solution is used to check that the glucose meter and the test strips are working correctly together. You might need to do a Control Solution Test if one or more situations below apply:

- When you open a new vial of test strips
- When you suspect that the glucose meter or test strips are not working properly
- If your blood glucose test results are not consistent with how you feel
- After the test strips are exposed to extreme conditions
- After dropping or damaging the meter

If you need control solution, contact Customer Service at 1-855-816-7705.

To perform a Control Solution Test, you need:

- Glucose Meter
- Test Strips
- Control Solution

Note: *Please consult a healthcare professional for interpretation of blood glucose measurements.*

Read the Control Solution Test Results

The results of the control solution test appear on the iOS device screen. The results should be within the range printed on the test strip vial label. If the test results fall outside the specified range, repeat the test. Results falling outside the specified range may be caused by:

- Error in performing the test
- Expired or contaminated control solution
- Expired or contaminated test strip
- Meter malfunction

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

Note: *Do not use expired control solution.*

IHEALTH SMART GLUCO-MONITORING SYSTEM SPECIFICATIONS

1. Model: BG3
2. Machine size: 2.1" x 1.43" x 0.36" (54 mm x 36.4 mm x 9.2 mm)
3. Measuring method: Amperometric technology using glucose oxidase
4. Result range: 20 mg/dL~600 mg/dL (1.1 mmol/L)

~33.3mmol/L)

5. Power source: DC 3.3V $\overline{\text{---}}$, powered by iOS device
6. Storage condition: Blood Glucose Monitoring System (Meter and Test Strips): 39.2° F~86° F (4° C~30° C), Humidity < 80% RH
7. Storage condition (meter): -4° F - 131° F (-20° C~55° C); Humidity<80%RH
8. Operating conditions: 50°F~95°F (10° C~35° C)
9. Blood source: Fresh capillary whole blood
10. Blood volume: min. 0.7 micro liter
11. Useful life: five years

CARE AND STORAGE OF YOUR GLUCOSE METER

- Maintain care when handling the glucose meter. Dropping or throwing the meter may cause damage .
- Don't expose the glucose meter, test strip, and control solution to extreme conditions such as high humidity, heat, freezing cold or dust. The storage conditions for the test strips are 39.2°F~86°F (4° C~30° C), Humidity<80%RH. Storage conditions for the glucose meter are -4°F~131°F(-20° C~55° C), Humidity< 80%RH.
- Always wash your hands with soap and water, and rinse and dry them completely before handling the glucose meter and test strips.

LIMITATIONS OF USE

- The iHealth Smart Glucose Meter is not intended for use on newborns.
- The iHealth Smart Glucose Meter is not intended for use on artery blood, serum and plasma.
- The iHealth Smart Glucose Meter should only be used with iHealth Test Strips (AGS-1000I).
- The iHealth Smart Glucose Meter can be used up to an

altitude of 3276 meters (10744feet).

- The following substances at levels greater than normal or therapeutic levels may cause significant interference (affect the result by greater than 10%) resulting in an inaccurate result: ascorbic acid, uric acid, acetaminophen, Dopamine, L-dopa, etc. These substances do not affect test results in normal concentration but may affect test results in high concentrations. Do not use haemolysis sample, icterus sample or high lipemia samples.
- Patients undergoing oxygen therapy may yield falsely lower results.
- Not for use for patients in a hyperglycemic-hyperosmolar state, with or without ketosis.
- Not for use on critically ill patients.
- Not to be used for patients who are dehydrated, hypertensive, hypotensive or in shock.
- Very low or very high red blood cell count (hematocrit) can lead to incorrect test results.

If you do not know your hemarocrit level, please consult your healthcare provider.

We recommend periodic comparison of the iHealth Smart Gluco-Monitoring System to another monitoring system known to be well maintained and monitored by a healthcare provider.

TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSES	SOLUTIONS
The meter does not respond after the test strip has been inserted into the glucose meter.	The Smart Glucose Meter is not correctly connected to an iOS device	Remove the Smart Glucose Meter from the iOS device and reconnect.
	Too much time has passed between inserting the test strip and performing the test.	Reinsert the test strip into the glucose meter.
Test results are inconsistent or Control Solution Test results are not within the specified range.	Test strip has not been fully inserted into the glucose meter.	Reinsert the test strip into the glucose meter.
	Not enough blood sample on the test strip.	Redo test with new test strip and make sure that enough sample has been used.
	Test strip or control solution has expired.	Redo test with new test strip.
	Test strip has been damaged due to heat or humidity so that sample cannot be applied or the speed of applying sample is too slow.	Perform a Control Solution Test using a new test strip. If results are still out of range, replace with new vial of test strips.
After blood sample has been applied to the test strip, testing doesn't start.	System is not performing due to the environment being above or below room temperature.	Bring Monitoring System to room temperature and wait approximately 30 minutes before performing a new test.
	Test strip has not been inserted correctly.	Redo test with new test strip.


 In vitro diagnostic medical device

 Serial Number

 Consult instructions for use

 Consult instructions for use

 Manufacturer

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

 Authorised representative in the European Community

 "This Device Complies With Part 15 Of The FCC Rules


 Keep Dry

 **0197** Complies With IVD98/79/EC Requirements

iHealth is a trademark of iHealth Lab Inc.

"Made for iPod" and "Made for iPhone" mean that an electronic accessory has been designed to connect specifically to iPod, 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 iPod, iPhone may affect wireless performance. iPod touch and iPhone are trademarks of Apple Inc., registered in the U.S. and other countries.

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