iHealth®

Wireless Smart Gluco-Monitoring System

Model: BG5S

OWNER'S MANUAL

For in vitro diagnostic use only

Read instructions before use for self-testing

Table of Contents

INTRODUCTION

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

INTENDED USE

The iHealth Wireless Smart Gluco-Monitoring System (BG5S) 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 (BG5S) is intended to be used by a single person and should not be shared.

The iHealth Wireless Smart Gluco-Monitoring System(BG5S) 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 (BG5S) 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).

The AGS-1000I & EGS-2003 test strips are for use with the iHealth BG5S meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh.

The iHealth control solutions are intended for use with the iHealth BG5S Wireless Smart Blood Glucose Monitoring System, to check that the glucose meter and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.

The iHealth Gluco-Smart App is the application for the iHealth Gluco-Monitoring System, and is used for data extraction and analysis.

In order to use the iHealth BG5S Wireless Smart Gluco-Monitoring System, a compatible Android or iOS mobile device with the necessary mobile application installed is required.

IMPORTANT SAFETY INSTRUCTIONS

Please read the following information carefully before using the iHealth system. Always keep these

instructions in a safe place for reference.

- Misuse of the iHealth system can cause electrocution, burns, fire, and other hazards.
- The meter and lancing device are for single patient use.
- Do not use either item on multiple patients.
- Do not share the meter or lancing device with anyone, including other family members.
- Do not place the iHealth system in or near liquid.
- The iHealth system can be used up to an altitude of 3276 meters (10744 feet).
- 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

LIMITATIONS OF USE

The iHealth system is not intended for use on neonates.

- The iHealth system is not intended for use on artery blood, serum, and plasma.
- The 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.

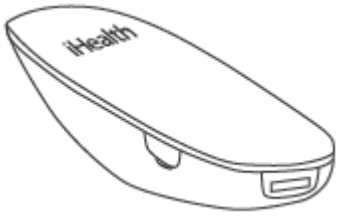
These substances do not affect test results in normal concentrations but may affect test results in high concentrations. Do not use haemolysis samples, icterus samples, or high lipemia samples.

- Patients undergoing oxygen therapy may yield falsely lower results
- The glucose meter and lancing device are for single patient use
- Not for use for patients in a hyperglycemic-hyperosmolar state, with or without ketosis.
- Not for use on critically ill patients.
- This device is not for use in people who are severely dehydrated, in people who are severely hypotensive, or people who are in shock, consult your healthcare professional immediately when this happens.
- Use only fresh 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 Over-the-Counter use
- 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)
- Do not use AST results for insulin dosing calculations
- If you take acetaminophen or acetaminophen containing medications (Tylenol, certain cold and flu remedies, or certain prescription drugs) higher than the recommended levels (>5 mg/dL) then you should know that this medication might affect the reliability of your blood glucose results and you should not use this Blood Glucose Monitoring System. If you are unsure, than ask your doctor.
- Certain conditions may cause your blood level of uric acid to rise. These conditions include gout or kidney disease. Uric acid levels in your blood are measured by a laboratory test that your doctor orders. You should know that if your blood level of uric acid is high ($\geqslant$10 mg/dL) then your blood glucose results may be not reliable. If your doctor tells you that your uric acid level is greater than 10 mg/dL, then do not use this blood glucose monitoring system. If you are unsure, then ask your doctor.
- Vitamin C (Ascorbic acid (>2 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.

CONTENTS OF THE WIRELESS SMART GLUCO-MONITORING SYSTEM

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

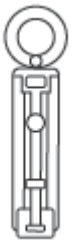
1. iHealth Wireless Smart Glucose Meter (BG5S)



2. iHealth Test Strips *

3. iHealth Lancing Device

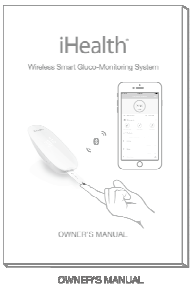
4. Lancet*



5. Clear Cap for Alternative Site Testing

6. iHealth Control Solution(Level II)*

7. Owner’s Manual



8. Quick Start Guide

9. USB Charging Cable

10. Carry case

*The contents in package of item * is vary from the sales area.*

Note:

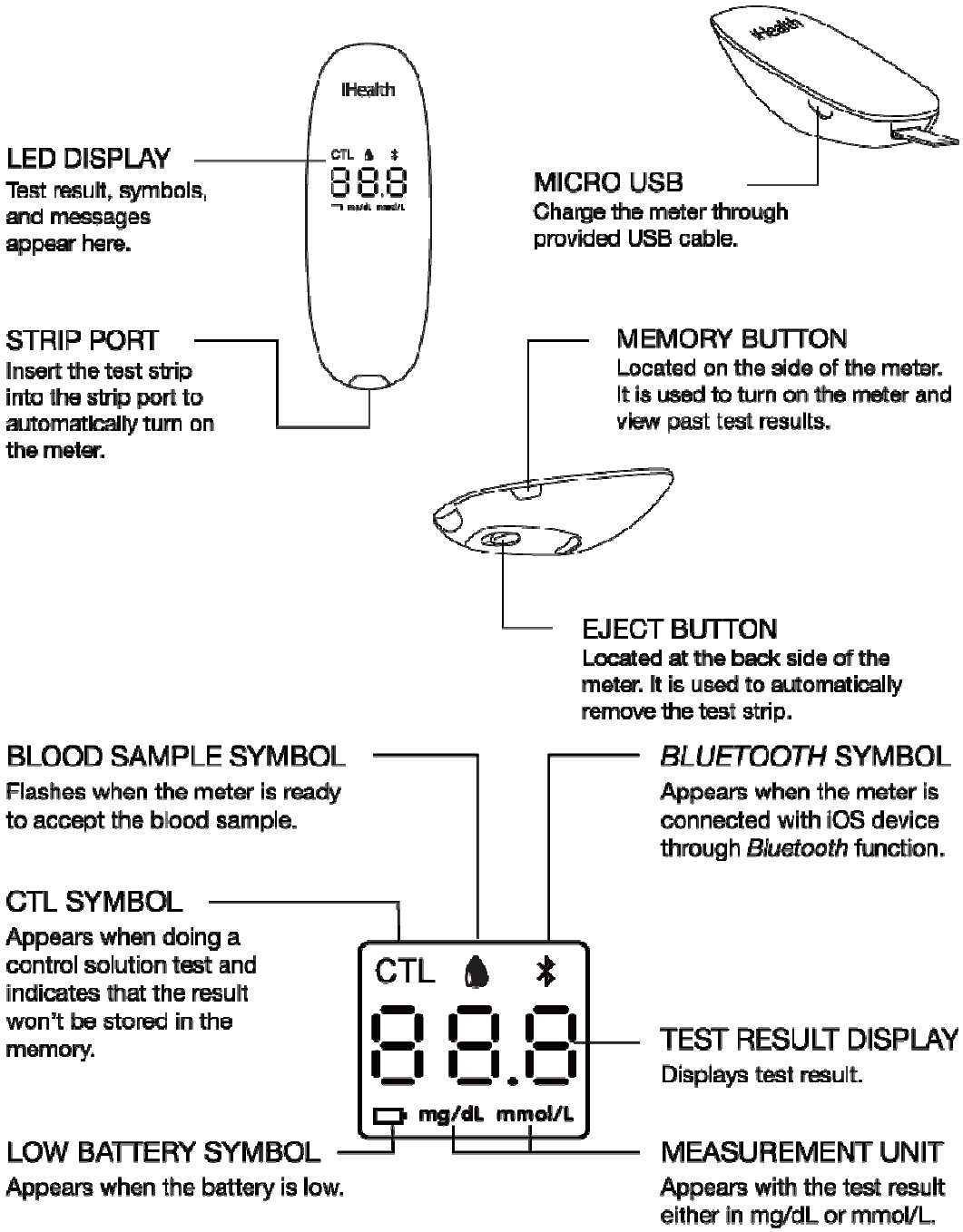
- *There are three levels for the control solutions: Level I, Level II and Level III. Please note that only the level II control solution may be included in the your kit. The level I and level III control solution are not included in the your kit. You can call iHealth Labs Customer Service for additional levels.*
- *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 call iHealth Labs Customer Service.*

- *iHealth Labs Customer Service hotline: 1-855-816-7705*

  (8:30AM – 5:30PM PST, Monday to Friday except holidays)

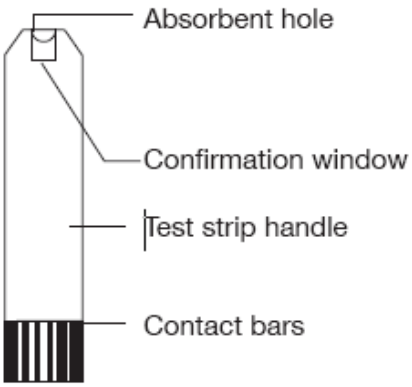
Parts and Displays

➢ iHealth Wireless Smart Glucose Meter (BG5S)

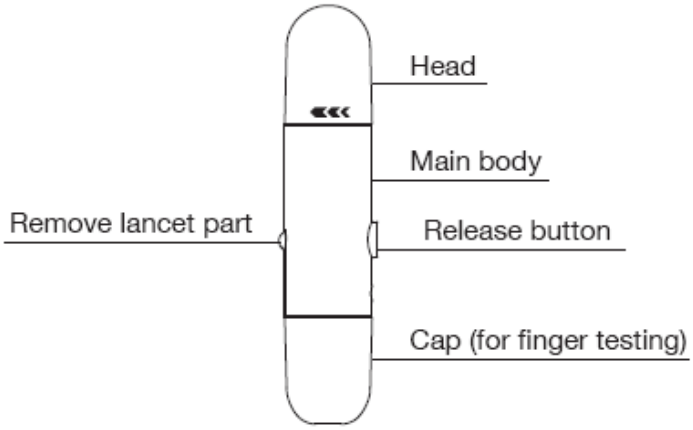


➢ iHealth Test Strips

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



- iHealth Lancing Device



Mobile Device Compatibility

- Works with the iOS version 8.0/9.0 devices, for example:
  iPhone 4S
  iPhone 5
  iPhone 5c
  iPhone 5s
  iPhone 6
  iPhone 6 Plus
  iPhone SE
  iPod Touch 5G
  iPod Touch 6G
  iPad 3
  iPad 4
  iPad Air
  iPad Mini 2G
  iPad mini 3G
  iPad mini 4G
  iPad Air 2
- Works with the Android version 4.2/5.0/6.0 devices, for example:
  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.com

TEST PRINCIPLE

Testing with the iHealth system is based on the measurement of electrical currents generated by the reaction of glucose with the reagent of the test strip. The iHealth system measures the current and converts it to the corresponding blood glucose level.

The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

IMPORTANT TEST INFORMATION

Please read the following:

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

TEST BLOOD GLUCOSE LEVEL

When you get a new BG5S iHealth Wireless Smart Gluco-Monitoring System, please

confirm your test strip type first. And then following the instruction below according the test strip type.

- Test strip type is EGS-2003.
  - About the first time test.
    We recommend you finish the first time test through online mode showing below from ***PROCESS 1 to PROCESS 5***.
    But you can also finish the first time test through offline mode (only following ***PROCESS 5***).
  - About the general time test.
    After you have finished the first time test, you can finish test through online mode (launch your app and then only following ***PROCESS 5***).
    But you can also finish test through offline mode (only following ***PROCESS 5***).

• ***PROCESS 1*** Download the companion app

Prior to first use, download and install the free Gluco-Smart App from the App Store or Google Play Store to your mobile device.

• ***PROCESS 2*** Login in your app

Create an iHealth ID first, and then you can login your app.

Note2: You can create an iHealth ID by following instructions in your app, or go to www.ihealthlabs.com to create.

• ***PROCESS 3*** Activate your meter

Your meter is powered by a built-in, rechargeable battery. When you use this meter first time, activate it as following instruct. Plug one end of the charging cable into the side of the meter and the other end into your computer's USB port.

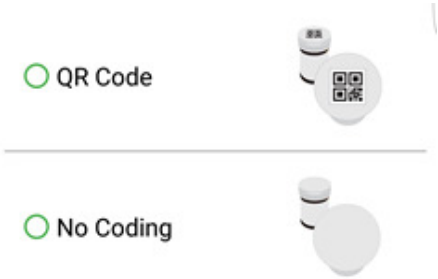
Note 3: About Low battery message

After you have used your meter for some time,  *appears for three seconds when the battery in your meter is low on power. You must recharge the battery before using it again.*

Important: If battery is completely drained, fully charge the battery.

• ***PROCESS 4*** Confirm your test strip model

Keeping your meter is closed to your Android or iOS mobile device within 30cm. And then launch your app and select the "No Coding" model.

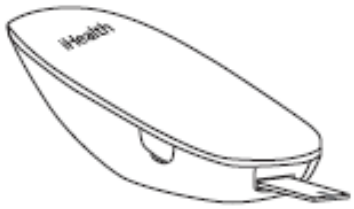


Note 4: •If you want to change the other strip model, you can re-choose anytime in setting pages.

•Must re-confirm your test strip model, once you have changed the model of test strip into the other one.

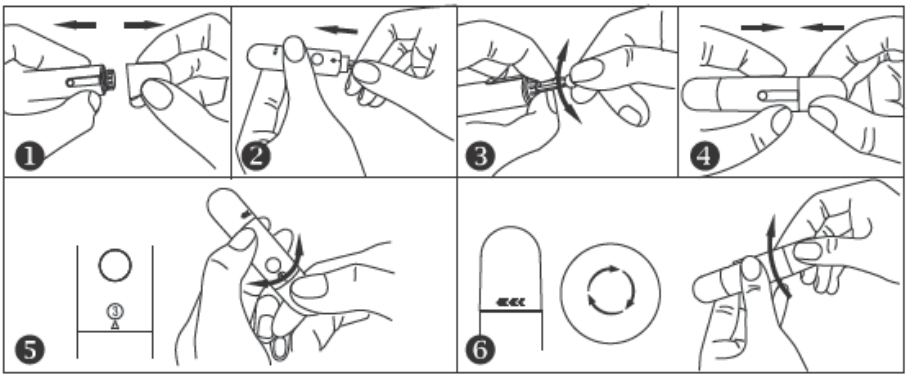
• ***PROCESS 5*** Test blood glucose level

Step 5-1: Insert the test strip into the meter's strip port with the contact bars facing toward you.



Step 5-2: Prepare the lancing device.

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

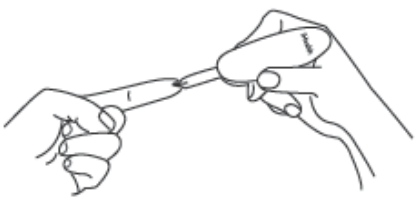


Step 5-3: Obtain a blood sample.

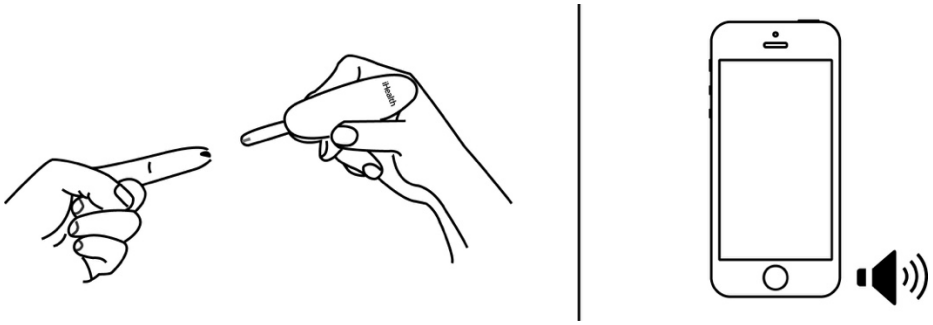
Press the lancing device against the site to be lanced. Press the release button to puncture the site. Gently squeeze your finger until a drop of blood forms. Wipe away the first blood drop and squeeze until a second small blood drops forms.

Step 5-4: 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.

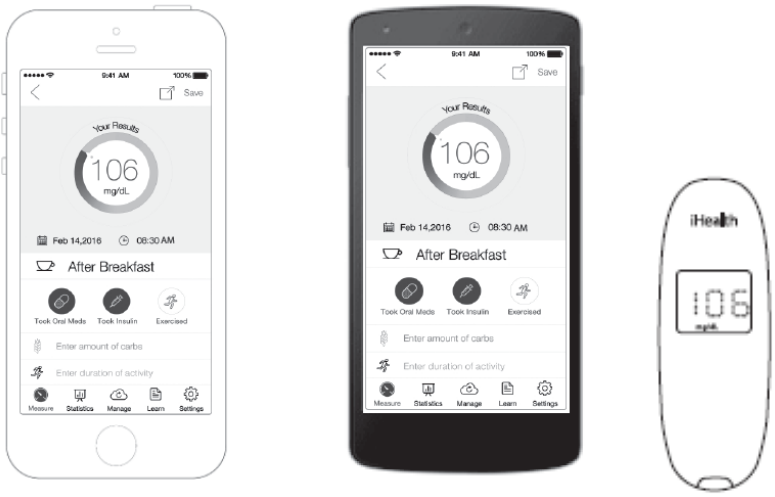


Quickly remove your finger from the test strip when you hear a sound alert from your Android or iOS mobile device, or when the countdown (from 5 to 1) begins on the meter display.

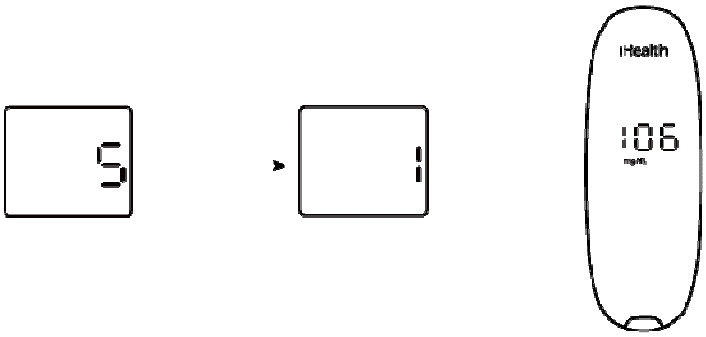


Step 5-5: Read the test results.

Case ①：If the meter is connecting with the app, the test result will appear both on the app and your meter.



Case ②：If the meter is not connecting with the app, the test result will appear on the meter after counting down from 5 to 1.



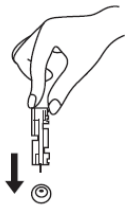
Note 5-5: The results obtained from the glucose meter are plasma-calibrated. This helps you and your physician or other qualified healthcare providers to compare your meter results with laboratory tests. Refer to the instructions given by your physician or other qualified healthcare providers, do not deviate from these instructions on the basis of the result without first consulting your physician.

Step 5-6: Discard the used test strip and lancet.

Remove the used test strip from the meter using a small amount of tissue paper.

Discard the used test strip and lancet properly.

Tip: Prior to disposal, stick the lancet into the cover.



- Test strip type is AGS-1000I.
  - About the first time test.
    You must finish the first time test through online mode showing below from ***PROCESS Ⅰ to PROCESS Ⅴ***.
  - About the general time test.
    After you have finished the first time test, you can finish test through online mode (following ***PROCESS 4 and 5***).
    But you can also finish test through offline mode (following ***step5-2 to step5-7***).

• ***PROCESS Ⅰ*** Download the companion app

Same to PRCESS 1 (above).

• ***PROCESS Ⅱ*** Login in your app

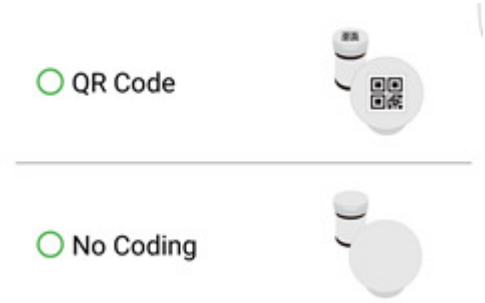
Same to PRCESS 2 (above).

• ***PROCESS Ⅲ*** Activate your meter

Same to PRCESS 3 (above).

• ***PROCESS Ⅳ*** Confirm your test strip model

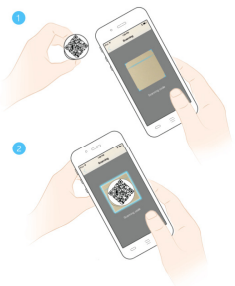
Keeping your meter is closed to your Android or iOS mobile device within 30cm. And then launch your app and select the “QR Code” model.



Note Ⅳ: •If you want to change the other strip model, you can re-choose anytime in setting pages.
•Must re-confirm your test strip model, once you have changed the model of test strip into the other one.

• ***PROCESS Ⅴ*** Test blood glucose level

Step Ⅴ-1: *S*can the QR code on the top of the iHealth test strip vial to calibrate the test strips with the meter.



Note Ⅴ-1: •Please carefully read and follow the App's instructions on the page of scanning-result.

•When you have scanned the QR Code once and you haven't changed strip's model, there's no need to scan for this vial unless you change anther mobile device.

•As soon as your vial is changed, must follow Step Ⅴ-1 which is scanning the QR code on the top of the iHealth test strip vial.

•When your mobile device is changed, please re-scan the QR code on the top of the iHealth test strip vial which you are using.

Step Ⅴ-2~ Step Ⅴ-7: *Corresponding to Step 5-1~Step 5-6* (above), they are same.

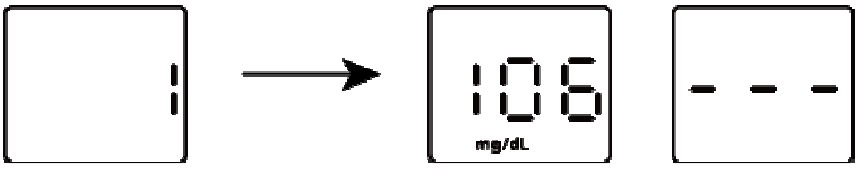
DATA SYNCING

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

The data in your meter will be uploaded to the app as soon as the meter is connected to the app on your mobile device

REVIEWING SAVED TEST RESULTS ON THE METER

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 word "End" will appear, and the meter will shut off automatically. Similarly, the meter will shut automatically when it is idle for three minutes.



CLEANING AND DISINFECTION

The cleaning and disinfection is absolutely necessary for the test procedure, because cleaning can insure the meter works well (for example, display will be clear to see after cleaning); and disinfection can avoid the infection to you or to the other people, and the cross-infection.

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

You can purchase this product from the suppliers listed below:

(1) Visit the website www.metrex.com or contact Metrex at 800-841-1428 for product or technical information.

(2) Visit store like Walmart or Sears holdings.

(3) Visit the following websites:

- Amazon.com : http://www.amazon.com/s/ref=nb_sb_noss?url=search-alias%3Daps&field-keywords=CaviWipes
- Endochoice.cm : http://www.endochoice.com/Equipment?search=wipe
- Metrex corporate and distributor : http://www.metrex.com/how-to-buy

The meter and lancing device are validated to support 10,000 individual tests—and consequently 10,000 cleanings over their 5 year life spans.

Below are the steps on how to clean the meter and lancing device.

(1) After a test, clean and wash your hands.
(2) Use one CaviWipe to carefully clean the entire external surface of the meter.
(3) Then wipe the entire external surface of the meter with another wipe, and keep the surface wet for 2 minutes.
(4) Use the same method with the CaviWipes to clean and disinfect the lancing device.

Note:

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

SIGNS OF POTENTIAL PHYSICAL AND PERFORMANCE DETERIORATION

If you encounter one of the following circumstances, stop using the meter and contact local customer services or the place of purchase for assistance, or call the toll free customer service number 1-855-816-7705 (8:30 AM-5:30PM PST, Monday to Friday).

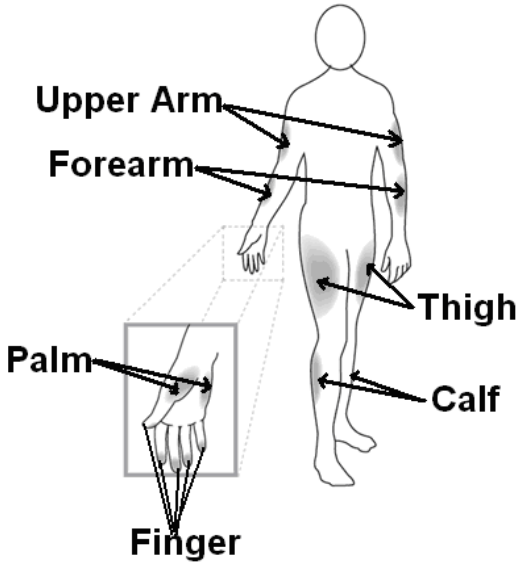
(1) The device does not work; for example, the Android or iOS mobile device can't begin testing when the meter is connected with the Android or iOS mobile device or when a test strip is inserted into the meter.
(2) Discoloration of the meter casing or lancing device; for example, it is difficult to read the labeling 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.

INFORMATION ABOUT ALTERNATIVE SITE TESTING (AST)

What Is Alternative Site Testing?

Alternative site testing (AST) is the use of parts of the body, other than the fingertips, to check blood glucose levels. The iHealth Wireless Smart Gluco-Monitoring System allows you to test on the palm, forearm, upper arm, calf, or thigh with equivalent results to fingertip testing when used at appropriate times.



***Caution**:*

When performing Alternate Site Testing, please remember to change the cap of the lancing device to the clear cap specially designed for AST.

There are limitations for doing AST:

- *Please consult your healthcare professional before you conduct AST.*
- *The iHealth Wireless Smart Gluco-Monitoring System should only be used for AST under steady-state blood glucose conditions.*

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 Should You Use Alternative 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.

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

IMPORTANT INFORMATION ABOUT CONTROL SOLUTION TESTS

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

Materials needed to perform a control solution test:

- iHealth Wireless Smart Glucose Meter (BG5S)
- iHealth Test Strips (AGS-1000I / EGS-2003)
- iHealth Control Solution (Level I, Level II, or Level III)

Perform a control solution test when:

- First receiving or purchasing the meter
- Checking the meter and test strips (which should be done at least once a week)
- Using a new vial of test strips
- You suspect the meter or test strips are not working properly
- Your blood glucose test results are not consistent with your expectation, or you think the results are not accurate
- Practicing the testing process
- The meter has been dropped or damaged

PERFORMING A CONTROL SOLUTION TEST

➢ When the meter is not connected to your app on your Android or iOS mobile device:
You can only perform this test with the test strip whose type is EGS-2003 in this situation, and it is

forbidden to perform a control solution test with test strip AGS-1000I.

***Step** A-1*: Turn on the control solution test (CTL) mode.

Insert the test strip into the meter's strip port to turn on the meter. When the blood sample symbol appears on the meter display, press the memory button to turn on the CTL mode.

When the CTL symbol appears, the meter is in control solution test mode and will not save this test result in memory.

Note:

- *Be sure to set the meter and/or app on the CTL mode before performing a control solution test. The control solution test result will not be saved in the meter.*
- *You can press the memory button again to turn off the CTL mode and switch back to the regular testing mode.*

***Step** A-2*: Apply the control solution.

- Shake the control solution vial before each use.
- Squeeze a drop of control solution into the vial cap. For better results, it is recommended that you use the second drop of the control solution (discard the first drop).
- Hold the meter and move the absorbent hole of the test strip to catch the drop. Once the conformation window fills completely, the meter will start counting down. Remove the control solution sample from the test strip when the countdown begins.

Note:

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

***Step** A-3*: Read and compare the results.

After the meter counts down to "1," the control solution test result will appear on the meter display. The result of the control solution test should be within the range printed on the test strip vial label. If the test result falls outside the specified range, repeat the test, carefully following the steps above.

- When the meter is not connected to your app on your Android or iOS mobile device:

You can perform this test with either EGS-2003 test strip or test strip AGS-1000I.

***Step** B-1*: Launch the app, and select the CTL test mode.

***Step** B-2*: Follow ***Step** A-2* above.

***Step** B-3*: Read and compare the results.

The control solution test result will appear on the app both on your device and meter. The result of the control solution test should be within the range printed on the test strip vial label. If the test result falls outside the specified range, repeat the test, carefully following the steps above.

Out-of-Range Results

Results falling outside the specified range may be caused by:

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

If you continue to get control solution test results that fall outside of the range printed on the vial, the meter may not be working properly. Discontinue use and call iHealth Labs Customer Service at 1-855-816-7705 for assistance.

To purchase additional control solution, call iHealth Labs Customer Service

NOTE:

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

COMPARING GLUCOSE METER TEST RESULTS WITH LABORATORY RESULTS

The iHealth System provides you with whole blood equivalent results. The result you obtain from your glucose meter may differ somewhat from your laboratory results due to normal variation.

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

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

Before the Lab Test

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

While at the Lab

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

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

THE iHealth Wireless Smart Gluco-Monitoring System 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 oxidase or glucose dehydrogenase
4. Result range: 20 mg/dL ~600 mg/dL (1.1 mmol/L ~33.3mmol/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
   The meter -4°F～131° F (-20°C～55°C); Humidity 10%～80%RH
8. Operating conditions: 50°F～104°F (10°C～40°C) , 25%RH～80%RH
9. Blood source: Fresh capillary whole blood
10. Blood volume: Minimum 0.7 micro liter
11. Life span: Five years
12. If you are taking acetaminophen containing drugs (Tylenol and other medicines containing acetaminophen, blood concentrations >5 mg/dL) or Vitamin C (ascorbic acid, blood concentrations >4 mg/dL) at doses higher than recommended, these may interfere with your glucose meter and cause you to get inaccurate results with this system

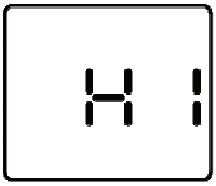
MAINTENANCE AND STORAGE OF YOUR METER

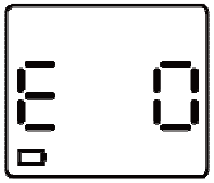
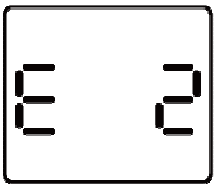
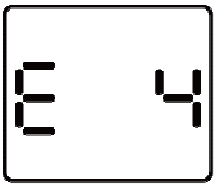
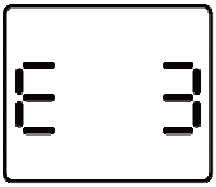
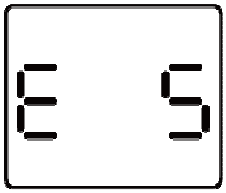
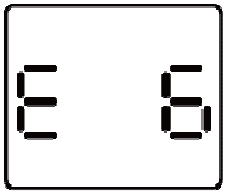
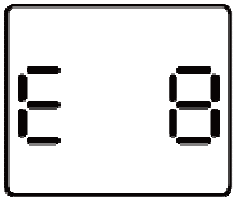
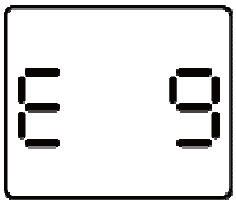
- Always use care when handling the iHealth Wireless Smart Glucose Meter (BG5S). Dropping or throwing the meter may cause damage.
- Always wash your hands with soap and water, and rinse and dry them completely before handling the iHealth Wireless Smart Glucose Meter (BG5S) and test strips.

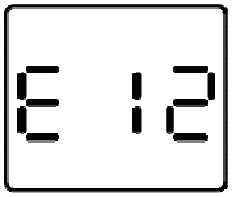
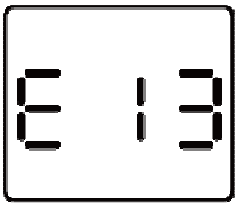
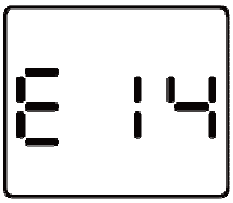
SYSTEM TROUBLESHOOTING

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, **please call iHealth Labs Customer Service at 1-855-816-7705**. Do not attempt to repair the meter by yourself and never try to disassemble the meter under any circumstances.

Display Messages

MESSAGE	WHAT It Means?	ACTION
	Blood glucose level is lower than 20mg/dL (1.1mmol/L)	- Repeat the test using a new test strip. - If your result still flashes Lo, seek medical advice immediately.
	Blood glucose level is higher than 600 mg/dL (33.3mmol/L)	- Wash and dry your hands, and the test site, thoroughly. Repeat the test using a new test strip. - If your result still flashes HI, seek medical advice immediately.

	The battery in your meter in low on power.	Charge the battery.
 	Problem with the meter.	Re-test with a new test strip. If the problem persists, call iHealth Labs Customer Service at 1-855-816-7705 for assistance.
	Problems have occurred that are related to test strip use, such as: - Test strip may be wet or damaged - Test strip may have been removed too soon - You applied more blood	Re-test using a new test strip.
	The environmental temperature is lower than 50°F(10°C)	The operating Temperature is 50°F～104°F (10°C～40°C).
	The environmental temperature is higher than 104°F(40°C).	The operating temperature is 50°F～104°F (10°C～40°C).
	Communication error.	Touch START to re-test.
	Strip is removed during measurement.	Start again using a new test strip.

	Your meter is not synced to the app on your mobile device yet.	Follow the instructions above in the “FIRST TIME SETUP INSTRUCTIONS” to sync your meter.
	The remaining test strip in the vial is “0”.	Scan a new vial of test strips.
	The test strip has expired.	Use a new test strip.

Troubleshooting

Problems	Possible Causes	Solution(s)
Display remains blank after the test strip has been inserted into the meter.	1. Battery power is too low for use. 2. Too much time has passed between inserting the test strip and performing the test. 3. 3. Test strip has not been fully inserted into the meter.	1. Please change 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. 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.

WARRANTY INFORMATION

iHealth Labs, Inc. ("IHealth") warrants the iHealth meter (the "Product"), and only the Product, against defects in materials and workmanship under normal use for a period of three years from the date of purchase by the original purchaser ("Warranty Period"). Under this Limited Warranty, if a defect arises and a valid claim is received by iHealth within the Warranty Period regarding the Product, at its option and to the extent permitted by law, iHealth will either (1) repair the Product using new or refurbished replacement parts or (2) exchange the Product with a new or refurbished Product. In the event of a defect, to the extent permitted by law, these are the sole and exclusive remedies.

iHealth is a trademark of iHealth Labs Inc.

"Made for iPod Touch," "Made for iPad," and "Made for iPhone" mean that an electronic accessory has been designed to connect specifically to the iPod Touch, iPad, and/or iPhone, respectively, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards.

Please note that the use of this accessory with the iPod Touch, iPad, and/or iPhone may a ect wireless performance. iPod Touch, iPad, and iPhone are trademarks of Apple Inc., registered in the U.S. and other countries.

Manufactured for iHealth Labs Inc.

USA:

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

Europe:

EC REP iHealthLabs Europe SARL www.ihealthlabs.eu

3 Rue Tronchet, 75008, Paris, France
+33(0)1 44 94 04 81 (9:00 AM-5:30 PM, Monday to Friday except holidays)
Email: support@ihealthlabs.eu

ANDON HEALTH CO., LTD

No. 3 Jin Ping Street, Ya An Road, Nankai District, Tianjin 300190, China
Tel: +86-22-87611660

If you have questions or need assistance outside the operational days and times, please contact your health care provider.

EXPLANATION OF SYMBOLS

In vitro diagnostic medical device

Serial number

Caution , consult accompanying documents

Consult instructions for use

Manufacturer

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

Authorised representative in the European Community

Catalog number

Storage temperature limit

FCC ID

This device complies with part 15 of the FCC rules.

Bluetooth Sign

Keep dry

Batch Code

Use-by date

Sterilized Using Irradiation

Do not Re-use

CE 0197

Complies with IVD98/79/EC requirements

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.

IC NOTICE

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and

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

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radioexempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

(1) l'appareil ne doit pas produire de brouillage, et

(2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut

fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada. Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

This product is approved in accordance to RED directive.

ELECTROMAGNETIC COMPATIBILITY INFORMATION

Table 1 For All ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration - electromagnetic emissions		
The BG5S is intended for use in the electromagnetic environment specified below. The customer or the user of the BG5S should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The BG5S uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The BG5S is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2 For All ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration - electromagnetic immunity			
The BG5S is intended for use in the electromagnetic environment specified below. The customer or the user of the BG5S should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	± 2 kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 3 For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration - electromagnetic immunity</th></tr>
<tr><td colspan="4">The BG5S is intended for use in the electromagnetic environment specified below. The customer or the user of the BG5S should assure that it is used in such an environment.</td></tr>
<tr><th>IMMUNITY test</th><th>IMMUNITY test</th><th>IMMUNITY test</th><th>IMMUNITY test</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms 150 kHz to 80 MHz</td><td>3 Vrms</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the BG5S, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance：
$d = 1.2\sqrt{P}$

$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz

$d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
Interference may occur in the vicinity of equipment
marked with the following symbol:

  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m 80 MHz to 2,5 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radiOS , amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BG5S is used exceeds the applicable RF compliance level above, the BG5S should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BG5S.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.</td></tr>
</table>

Table 4 For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the 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.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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.

Rev.30 / 03 / 2017