

iHealth[®]

Blood Glucose Test Strips

INSTRUCTIONS FOR USE



iHealth

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

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 iHealth 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.

These test strips can be used with the following systems:

- **iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+ with BG55 meter)**
- **iHealth Align Gluco-Monitoring System (BG1)**
- **iHealth Wireless Smart Gluco-Monitoring System (BG5)**
- **iHealth Blood Glucose Monitoring System (AG-607)**

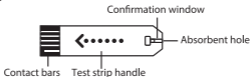
Intended Use

iHealth Blood Glucose Test Strips (EGS-2003) are 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 Blood Glucose Test Strips (EGS-2003)** 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).

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.

Limitations

- This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or longterm care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures.

Use of this device on multiple patients may lead to transmission of Human

Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

- Xylose will interfere test result from EGS-2003 test strip. Do not use during or soon after xylose absorption testing.
- The Blood Glucose Monitoring System including EGS-2003 test strips is not intended for use on neonates nor for diagnosis or screening.
- Patients undergoing oxygen therapy may show results lower than actual levels.
- 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
- 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.
- The test strip cannot be used above than the altitude of 10744 feet (3275 meters).
- 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.
- 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.
- For in vitro diagnostic use (external use only).
- Do not reuse.
- For self-testing.
- Please review this instruction sheet and the iHealth Gluco-Monitoring System (BG1/BG5/BG5S/AG-607) owner's manual before you use iHealth Blood Glucose Test Strips(EGS-2003)(abbreviated as EGS-2003 test strip below). 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 iHealth Gluco-Monitoring System (BG1/BG5/BG5S/AG-607) Owner's Manual.

- Never make significant changes to your diabetes control program or ignore physical symptoms without consulting your healthcare professional.

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.

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. The used lancet and test strip should

be disposed according to their healthcare provider's instructions.

Note: 1. The blood glucose meter and 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) 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

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

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

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 the iHealth Gluco-Monitoring System (BG1/BG5/BG5S/AG-607) 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.
- Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

Control Solution Testing for Performance Checking

The iHealth 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 iHealth Gluco-Monitoring System (BG1/BG5/BG5S/AG-607) 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 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 (The standard unit of measure in the United States is mg/dL and using the wrong units could lead to hyper- or hypoglycemia). Please contact their healthcare provider immediately if your result is below Lower limit of measurement range.

If your result is above Upper limit of measurement range, 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.*
- 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. Biological source of enzyme used: *Aspergillus niger*

3. Other ingredients

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

Performance Characteristics

Measurement range for iHealth Wireless Smart Gluco-Monitoring System (iHealth Gluco+ with BG55 meter) = 50 to 600 mg/dL

Measurement range for iHealth Align Gluco-Monitoring System (BG1) = 20 to 600 mg/dL

Measurement range for iHealth Wireless Smart Gluco-Monitoring System (BG5) = 20 to 600 mg/dL

Measurement range for iHealth Blood Glucose Monitoring System (AG-607) = 20 to 600 mg/dL

Hematocrit Range: 20% ~ 60%

Sample: Whole blood, capillary

Not less than Blood Sample Size: 0.7 μ L

Test Time: 5 seconds

Calibration: plasma equivalents

Precision

These studies were performed in the laboratory with whole blood using the iHealth Wireless Smart Gluco-Monitoring System (BG5) with EGS-2003 test strips.

Glucose concentration(mg/dL)	30-50	51-110	111-150	151-250	251-400
Number	100	100	100	100	100
Average	47.3	98.3	126.3	177.8	360.2
SD (mg/dL)	2.1	3.5	5.7	6.7	12.6
CV (%)	4.3	3.5	4.5	3.7	3.5

Intermediate precision

Glucose concentration(mg/dL)	Level I	Level II	Level III
Number	300	300	300
Average	47.3	111.0	332.8
SD (mg/dL)	3.7	5.2	16.4
CV (%)	7.8	4.7	4.9

System Accuracy

The iHealth Wireless Smart Gluco-Monitoring System (BG5) using EGS-2003 test strips was tested on 350 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 linear regression

	Finger	Palm	Foreare	Upper arm	Calf	Thigh
Slope (comparison with YSI)	0.9896	0.9733	1.0139	0.9825	0.9975	1.0000
Y-Intercept(comparison with YSI)	-0.8667	1.0008	-4.2613	0.0885	-2.3566	-3.3990
R2(comparison with YSI)	0.9843	0.9832	0.9841	0.9827	0.9838	0.9837

Table 2 represents samples for glucose results ≤ 75 mg/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	33/53 (62.3%)	51/53 (96.2%)	53/53 (100%)

Table 3 represents samples for glucose results > 75 mg/dL.

Difference range in values between blood glucose monitoring system's value and the laboratory value	Within 5%	Within 10%	Within 15%	Within 20%
blood glucose monitoring system	131/297 (44.1%)	239/297 (80.5%)	289/297 (97.3%)	297/297 (100%)

Testing Accuracy of the Alternative Sites

350 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 4 represents samples for glucose results $\leq 75\text{mg/dL}$.

Difference range in values between the alternative sites' value and the laboratory value	Within 5mg/dL	Within 10mg/dL	Within 15mg/dL
Palm	34/54 (63.0%)	54/54 (100%)	54/54 (100%)
Forearm	28/55 (50.9%)	55/55 (100%)	55/55 (100%)
Upper arm	35/54 (64.8%)	54/54 (100%)	54/54 (100%)
Calf	34/51 (66.7%)	51/51 (100%)	51/51 (100%)
Thigh	36/54 (66.7%)	53/54 (98.1%)	54/54 (100%)

Table 5 represents samples for glucose results > 75mg/dL.

Difference range in values between the alternative sites' value and the laboratory value	Within 5%	Within 10%	Within15%	Within 20%
Palm	132/296 (44.6%)	245/296 (82.8%)	287/296 (97.0%)	296/296 (100%)
Forearm	132/295 (44.7%)	239/295 (81.0%)	287/295 (97.3%)	295/295 (100%)
Upper arm	124/296 (41.9%)	244/296 (82.4%)	292/296 (98.6%)	296/296 (100%)
Calf	127/299 (42.5%)	249/299 (83.3%)	292/299 (97.7%)	299/299 (100%)
Thigh	127/296 (42.9%)	231/296 (78.0%)	289/296 (97.6%)	296/296 (100%)

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Symbols in use



Do not Reuse



Consult Instructions for Use



In Vitro Diagnostic Medical Device



Keep in a dry place



Storage Temperature Limitation



Lot Number



Use by



Manufacturer



Keep away from
direct sunlight



Do not use if package is damage



Triman recycling logo



Authorised Representative in the European Community

CE0197

Complies with IV98/79/EC requirements

EGS-2003-SMSP02 V1.0

