



Blood Glucose Test Strips BG01



For self-testing and in vitro diagnostic use only.

IMPORTANT:

Read this package insert and the user's manual of the **isaw**® Multi-Monitoring Meter and Systems for quantitatively measuring blood glucose in fresh capillary whole blood or Venous blood. **isaw**® Blood Glucose Test Strips are intended for self-testing outside the body (in vitro diagnostic use) by people at home and health care professionals in the clinical setting.

Intended Use

isaw® Blood Glucose Test Strips are used with the **isaw**® Multi-Monitoring Meter and Systems for quantitatively measuring blood glucose in fresh capillary whole blood or Venous blood. **isaw**® Blood Glucose Test Strips are intended for self-testing outside the body (in vitro diagnostic use) by people at home and health care professionals in the clinical setting.

STORAGE AND HANDLING

- Store the test strip package in 2°C-30°C. Keep away from direct sunlight and heat. Do not refrigerate.
- Store your test strips in their original vial only; do not transfer them to a new vial or any other container.
- After removing a **isaw**® Blood Glucose Test Strip from the vial, immediately replace the vial cap and close it tightly.
- Use each test strip immediately after removing it from the vial.
- Write the date opened on the vial label. Discard remaining test strips 3 months after first opening the vial.
- Avoid getting dirt or food on the test strips.
- Do not use test strips beyond the expiration date printed on the package since they may cause inaccurate results.
- Do not bend, cut or alter a **isaw**® Blood Glucose Test Strip in any way.
- Use universal blood precautions when handling and disposing of blood glucose monitoring materials. All patient samples are materials with which they come in contact are considered biohazards and should be handled as if capable of transmitting infection. Follow proper precautions in accordance with local regulations when disposing of all materials.

WARNING: Keep the test strip vial away from children; the cap is a choking hazard. Also, the vial or cap may contain drying agent that are harmful if inhaled or swallowed and may cause skin or eye irritation.

PRECAUTIONS TO OBTAIN ACCURATE RESULTS

- Code the **isaw**® Brand Meter to match the code number printed on the **isaw**® Blood Glucose Test Strips vial.
- Use only **isaw**® BG01 Blood Glucose Test Strips with **isaw**® LBM-01 Multi-Monitoring Meter to obtain accurate and consistent blood glucose results.
- If you are experiencing symptoms that are not consistent with your blood glucose test results and you have followed all instructions described in your **isaw**® LBM-01 Multi-Monitoring Meter User's Manual.
- Never make significant changes to your diabetes control program or ignore physical symptoms without speaking with your healthcare professional.



TEST PROCEDURE FOR BLOOD GLUCOSE MEASUREMENT

Materials provided: **isaw**® Blood Glucose Test Strips.
Materials required but not provided: **isaw**® LBM-01 Multi-Monitoring Meter with User's Manual, Adjustable Lancing Device, New Sterile Lancet.

BLOOD SAMPLE COLLECTION

To obtain a drop of blood, follow these steps.

Step 1: You may obtain a blood drop from a fingertip. Wash your hands with warm, soapy water. Dry them thoroughly.

Step 2: Lance the fingertip. Hold the sampler firmly against the side of your finger. Press the release button. Massage the fingertip to obtain a round drop of blood. Do not squeeze the puncture site excessively. The blood sample should be at least 1.5µL in volume or you may get an inaccurate result.

BLOOD GLUCOSE TESTING

Step 1: Insert a test strip. Remove a test strip from the vial. Recap the vial immediately. Insert a test strip, contact bars end first and facing up, into the test port. Push it in until it will go no further. The meter will turn on and the display check will appear briefly. Then the code number will appear, followed by the symbol. Be sure the meter and test strip codes match. If they do not, code the meter correctly.

Step 2: Apply sample. Using the adjustable blood sampler, obtain a blood sample large enough to fill the confirmation window. When the symbol appears on the display, touch and hold the drop of blood to the narrow channel in the top edge of the strip.

DO NOT:

- Apply sample to the front and back of the test strip.
- Push your finger against the test strip.
- Apply a smeared sample.

Hold the blood drop to the top edge of the test strip until the confirmation window is full before the meter begins to count down. If the confirmation window does not fill completely before the meter begins to count down, do not add more blood to the test strip; discard the strip and retest. If the confirmation window is not full you may get an Er5 message or an inaccurate test result.

Step 3: Get accurate results in just 5 seconds. Your blood glucose result will appear after the meter counts down from 5 to 0. Blood glucose test results are automatically stored in the meter memory. Turn the meter off by removing the test strip.

For detailed information on the test procedure and coding your meter, please refer to your **isaw**® LBM-01 Multi-Monitoring Meter User's Manual.

TEST RESULTS

isaw® LBM-01 Multi-Monitoring Meter displays results between 1.1 and 33.3mmol/L (20-600 mg/dL). If your test result is lower than 1.1mmol/L (20mg/dL), "Lo" will appear on the meter display. This indicates severe hypoglycaemia (low blood glucose). You should immediately treat hypoglycaemia as recommended by your healthcare professional. If your test result is above 33.3mmol/L (600mg/dL), "Hi" will appear on the meter display. This indicates severe hyperglycaemia (high blood glucose). You should seek immediate medical assistance.

RANGE OF EXPECTED VALUES

Blood glucose management requires the help of a health care professional. Together you can set your own range of expected blood glucose value, arrange your testing times, and discuss the meaning of your blood glucose results. Expected blood glucose levels for people without diabetes.

Time	Range, mmol/L	Range, mg/dL
Before breakfast	3.90-6.10	70-110
2 hours after meals	Less than 7.80	Less than 140
Unit conversion formula	1mmol/L=18mg/dL	

IF YOU GET UNEXPECTED RESULTS

IMPORTANT: Low or high blood glucose readings can indicate a potentially serious medical condition. If your blood glucose reading is unusually low or high, or you do not feel the way your reading indicates, repeat the test with a new test strip. If your reading is not consistent with your symptoms or if your blood glucose result is less than 3.3mmol/L (60mg/dL) or higher than 13.3 mmol/L (240mg/dL), you should contact your healthcare professional and follow his or her treatment advice.

Never ignore symptoms or make significant changes to your diabetes control program without speaking to your health care professional.

QUALITY CONTROL: CHECKING THE SYSTEM

Do a Control Solution Test:

- When you begin using a new vial of test strips
- When your blood glucose test results are not consistent with how you feel, or when you think your results are not accurate
- At least once a week
- Whenever you suspect that the meter or test strips are not working properly
- If you drop the meter

When control solution is applied to the top edge of **isaw**® blood glucose test strip, you should get result within the expected range printed on the test strip vial. If control solution test result fall outside this range, repeat the test. Results that fall outside the range may be caused by:

- Error in performing the test
- Test strip deterioration
- Failure to shake the control solution vial well enough (must shake vigorously)
- Meter malfunction
- Control solution is too warm or too cool
- Expired or contaminated control solution
- Failure to discard the first drop of control solution
- Improper coding of the meter

IMPORTANT: If you continue to get **isaw®** Control Solution test results that fall outside the range printed on the vial, the **isaw®** Multi-Monitoring Meter may not be functioning properly. DO NOT use the meter to test your blood until you get a control solution test result that falls within the range.

LIMITATIONS

- isaw®** Blood Glucose Test Strips give accurate results when the following limitations are observed:
- The test strips should not be used for the testing of newborns.
 - The test strips are for single use only. Do not reuse.
 - The test strips are specific to D-glucose and do not react to other sugars which may be present in blood.
 - Use only fresh capillary whole blood. Do not use serum or plasma.
 - Extremes in haematocrit may affect test results. Haematocrit levels less than 30% may cause falsely high readings and haematocrit levels greater than 55% may cause falsely low readings. If you do not know your haematocrit level, consult your healthcare professional.
 - In-vitro Diagnosis.

Healthcare professionals-please note these additional limitations:

- Fresh capillary blood may be collected into heparin-containing test tubes if the blood is used within 10 minutes. Do not use other anticoagulants or preservatives.
- Interferences: Acetaminophen, salicylates, uric acid, ascorbic acid (vitamin C), and other reducing substance (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.
- Patients undergoing oxygen therapy may yield falsely lower results.
- Test results may be falsely low if the patient is severely dehydrated, in shock, or in a hyperosmolar state (with or without ketosis).
- Critically ill patients should not be tested by Multi-Monitoring Meter.
- Lipemic samples: Cholesterol levels up to 18.1mmol/L (700mg/dL) and triglycerides up to 33.9 mmol/L (3,000mg/dL) do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with **isaw®** Multi-Monitoring Meter.
- High Altitude : High Altitude(>2400 meters) affect on accuracy of Multi-Monitoring Meter.

TEST PRINCIPLE

Glucose in the blood sample mixes with special chemicals on the test strip and a small electrical current is produced. This current is measured by the **isaw®** Multi-Monitoring Meter and displayed as your blood glucose results. The strength of these current changes with the amount of glucose in the blood sample.

REAGENT COMPOSITION

Each **isaw®** Blood Glucose Test Strip contains: Glucose oxidase (*Aspergillus niger*)≥0.8IU; Other ingredient (mediator, buffer, etc.) ≥0.05mg. The vial or vial cap contains approximately 1.4g silica gel or 2.8g of molecular sieve.

PERFORMANCE CHARACTERISTICS

The performance of **isaw®** Blood Glucose Test Strips have been evaluated both in laboratory and in clinical tests. Measurement range: The measurement range of **isaw®** Multi-Monitoring Meter is 1.1 to 33.3 mmol/L (20-600mg/dL).

Accuracy: the accuracy of **isaw®** Multi-Monitoring Meter was assessed by comparing blood glucose results obtained using a reference method. The following results were obtained by 107diabetic patients.

Table 1 Regression Analyses

Slope	0.9859
y-intercept	0.14 mmol/L
correlation coefficient	0.9915
no.of samples	107
range tested	2.71-30.24 mmol/L

Figure 1 Regression Plot

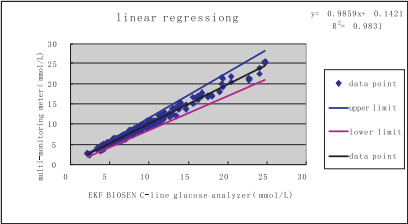


Table 2 System Accuracy Results for Glucose Concentration <5.55mmol/L (100mg/dL)

Within ±0.28mmol/L (±5mg/dL)	Within ±0.56mmol/L (±10mg/dL)	Within ±0.83mmol/L (±15mg/dL)
54/114(47.4%)	91/114(79.8%)	113/114(99.1%)

Table 3 System Accuracy Results for Glucose Concentration ≥5.55mmol/L (100 mg/dL)

Within ±5%	Within ±10%	Within ±15%
281/528(53.2%)	466/528(88.2%)	519/528(98.3%)

Table 4 System Accuracy Results for Glucose Concentration Between 2.71mmol/L (49 mg/dL) and 30.24mmol/L (544 mg/dL)

Within ±0.83mmol/L or ±15% (Within ±15mg/dL or ±15%)
632/642(98.4%)

This study shows that the **isaw®** system compare well with a laboratory method.

Repeatability:

Table 5 Measurement Repeatability

	BIOSEN C-line average value	Meter test average value	Meter test standard deviation	Meter test variable coefficient
sample 1	1.92	1.93	0.193	10.00%
sample 2	4.58	4.75	0.210	4.42%
sample 3	7.44	7.28	0.193	2.65%
sample 4	10.60	10.59	0.377	3.56%
sample 5	18.81	17.75	0.449	2.53%

This study shows variability from strip to strip in blood tests of 3.5% or less.

User performance evaluation

A study evaluating glucose values from fingertip capillary blood samples obtained by 110 lay persons showed the following results: 100% within ±0.83 mmol/L (±15 mg/dL) of the medical laboratory values at glucose concentrations below 5.55 mmol/L (100 mg/dL), and 98.9 % within ±15 % of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L (100 mg/dL).

Bibliography

1. American Diabetes Association, www.diabetes.org
2. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline CTThird Edition Clinical and Laboratory Standards Institute (CLSI), document M29-A3, (ISBN 1-56238-567-4). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2005.
3. American Diabetes Association: Standards of Medical Care in Diabetes (Position Statement). Diabetes Care 29 (Suppl. 1):S10, 2006.

Notes on Symbols and Marks

	Blood Glucose Test Strips
	Consult instructions for use
	In vitro diagnostic medical device
	Temperature limit
	Keep away from sunlight
	Do not re-use
	Contains sufficient for < n > tests
	Manufacturer
	Date of manufacture
	Batch code
	Use-by date
	Conformity with Directive 98/79/EC
	Authorized representative in the European Community / European Union

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