

BS-102 Blood Glucose Test Strips

Instruction Manual

**Cautions:**

- For Use with the Sejoy BG-201, BG-202, BG-203, BG-205 and BG-208 Blood Glucose Meter.
- Read the Owner's Manual of the Sejoy BG-201, BG-202, BG-203, BG-205 and BG-208 Blood Glucose Monitoring System before using the product.
- The user should not take any decision of medical relevance without first consulting his or her medical practitioner.

【Product Name】

Generic Name: Blood Glucose Test Strips

【Model】

BS-102

【Packing Type】

1 Strip/Bag, 10 Strips/Vial, 25 Strips/Vial, 50 Strips/Vial

【Product Description】

BS-102 Blood Glucose Test Strips

【Intended Use】

The Sejoy BS-102 Test Strips are used with the Sejoy BG-201, BG-202, BG-203, BG-205 and BG-208 Blood Glucose Meters to quantitatively measure glucose with fresh capillar whole blood or venous whole blood. The system is intended for in vitro diagnostic home-use and by healthcare professional in a clinical setting as an aid to monitor the effectiveness of diabetes control. This system is not for use in the diagnosis of diabetes mellitus, screening nor for testing newborns.

【Test Principle】

The Sejoy BS-102 Test Strip is a plastic strip containing chemistries and electrodes. The strip measures glucose by using amperometric technology employing a glucose oxidase reaction. When whole blood or control solution is drawn into the tip of a test strip, glucose in the sample reacts with chemicals and produces an electrical current. The meter measures electrical current and calculates amount of glucose. The glucose result is displayed as a calculated plasma value.

【Chemical Composition】

Glucose Oxides $\geq$ 0.3 IU; Potassium Ferricyanide $\geq$ 0.2 ug; other elements 68%.

Each package contains desiccating agent.

【Storage and Handling】

- Store the test strip in a dry place at temperature between 1°C ~ 30°C (33.8°F ~ 86°F).
- Test strips must be store in original vial with cap tightly sealed.
- Do not exposure test strips to sunshine. Avoid moisture.
- Test strip are valid before either 24 months after produced or 3 months past the opened date; write the first opened date on the package.
- Do not freeze or refrigerate.
- Immediately recap vial after removing a strip.
- Use the test strip immediately after it removed out from package.

【Accessories】

- Blood Glucose Meters BG-201, BG-202, BG-203, BG-205 and BG-208
- Control Solution CS-101
- Lancing Device
- Lancet

【Blood Sample Requirement】

- Use fresh capillary whole blood or venous whole blood; Applying anticoagulant in blood sample may affect test results.
- Venous blood sample collection and preparation should be obtained by healthcare professionals.
- Do not use arterial blood, serum or plasma.
- Remaining water or alcohol on blood sample puncture site causes inaccurate results.

【Precautions】

- Test Strips are for in vitro (external) testing of whole blood.
- Operate the Blood Glucose Monitoring System at room temperature.
- Test strips are for single use only. Do not use test strips that are torn, bent, or damaged in any way.
- Lancing device can only be used for single person, exclusively; lancet is for single use only.
- Do not use expired test strips as it caused incorrect test results.
- Never use iodine solution to disinfect puncture site.
- Keep puncture site dry.
- Second drop of blood sample is recommended for measurement.
- If the test strip is cold, do not use until it has warmed to room temperature.
- To eliminate any chance of infection, discard the used test strips, lancing device and lancet properly follow the local environmental affairs regulation.

**Warnings:**

- Do not swallow test strips. Not for human consumption.
- Test strips have a sharper edge that may cause a small scratch.
- Keep the test strip vial or the foil pouch away from children

【How to Test Your Blood Glucose】

Read the BG-201, BG-202, BG-203, BG-205 and BG-208 Owner's Booklet thoroughly before test.

1) Prepare system components:

BG-201, BG-202, BG-203, BG-205 and BG-208 Blood Glucose Meter

BS-102 Test Strips

Code Chip

Lancing Device, Lancet

2) Measuring blood sample

1. Blood Sampling

The blood glucose system requires a tiny of blood sample from your fingertip to test the blood glucose. Before sampling your blood, wash your hands and the puncture site with an alcohol swab or soapy water. Rinse and dry thoroughly.

- Turn the cap anti-clockwise to remove it. Insert a new sterilized lancet into the lancet holder and push it down firmly until it stops.
- Twist off the protective disk until it separates from the lancet
- Slide the cap on until it stops (Avoid contact with the lancet pin)
- Adjust puncture depth by turning the Depth Adjusting Knob. The Depth Indicator shows the current depth selection. There are 5 optional depths. The higher of the number, the deeper of penetration
- After slide the Ejection Spring Controller back until it clicks. The Lancing Device is ready to use.
- Wash your hands and the puncture site with an alcohol swab or soapy water. Rinse and dry thoroughly.
- Hold the Lancing device firmly against the side of your fingertip. Press the Release Button. Gently squeeze your finger to assist the blood flow. This will help you to get a drop of blood.
Note: Choose two sides of your finger for the blood sampling site as it can reduce pain.
- Put the Protective Disk back on the lancet. Discard it properly.

2. Testing your blood glucose

- Insert a test strip, contact bar end first and facing up, into Strip Port. Push it in until stops. The meter will automatically turn on and shortly display symbols on screen. Make sure all the symbols are completely displayed.
- After the meter run self check, a test strip symbol will appear in the top-right corner of the screen

The Blood Sample Reminder symbol flashes to remind applying blood. 

- Touch the blood drop to Top Edge at the end of test strip. Hold until the Confirmation Window is full. The meter begins testing with display countdown.

Note: "E-4" error will appear when the test strip moved during measurement.

- At the end of the countdown, one beep sound to remind you test finished. The screen will display test result.

Note: To avoid inaccurate test results affect 7, 14, 28 day average, user may delete the last test result by simultaneously pressing "S" Button and "M" Button.

- Remove the used test strip. The meter will store the test result and automatically turn off.

Note: To prolong battery life, remove the test strip to turn the meter off.

【Understand your test results】

- If you have symptoms that are not consistent with your test results, consult the system Owner's Booklet to check for common testing errors. If the problem persists, contact your healthcare professional immediately.
- The blood glucose meter can accurately measure blood glucose concentrations between 2.2 to 33.3mmol/L (40 to 600 mg/dL). "HI" and "Lo" messages indicate results outside of this range.
- "LO" symbol will appear on screen if blood glucose is below 40 mg/dl (2.2 mmol/L).
- "HI" symbol means test result is higher than 600 mg/dl (33.3 mmol/L).
- If the screen displays error symbols, refer to Owner's Booklet for the troubleshooting.

【Blood Glucose Range Information】

Time	Normal Blood Glucose Range
Before breakfast	70-105mg/dL(3.9-5.8mmol/L)
Before lunch or supper	70-110mg/dL (3.9-6.1mm)
1 hour after meal	Less than 160mg/dL ($\leq$ 8.9mmol/L)
2 hour after meal	Less than 120mg/dL ($\leq$ 6.7mmol/L)
Between 2 AM and 4 AM	Greater than 70 mg/dL ($\geq$ 3.9mmol/L)

【Limitations】

- The sejoy blood glucose monitoring system BG-201, BG-202, BG-203, BG-205 and BG-208 is designed for using with whole blood samples. Do not use serum or plasma samples.
- DO NOT test on neonatal samples (new born).
- Inaccurate test results may be obtained at high altitude more than about 2,000 meters above sea level.
- Hematocrit range: 30% to 55%. Hematocrit below 30% may cause higher results, and hematocrit above 55% may cause lower results.
- Severe dehydration and excessive water loss may cause false low results. If you think you may be dehydrated, consult your healthcare professional immediately.
- The interferent listed below were tested. The interferent at the normal therapy levels or higher shown has no apparent influence on results.

Substance	Concentration	Substance	Concentration
Acetaminophen	2.0 mg/dL	Levodopa	No clear range of effective drug concentration
Ascorbic acid	2.0 mg/dL	Creatinine	1.5 mg/dL
Ibuprofen	4.2 mg/dL	Dopamine	0.04 mg/dL

Other interfering substances are not verified, it may affect the test results
eg. Galactose, Salicylate, Haemoglobin etc.

【Traceability】

The calibrator of the Sejoy Blood Glucose Monitoring System BG-201, BG-202, BG-203, BG-205 and BG-208 is control solution. The traceability of the control solution is referenced to the EKF BIOSEN C line-Clinic glucose analyzer. The EKF is the reference method used to assess the accuracy with which glucose results are obtained using the system. The value of the calibrator for glucose is traceable to the

National Institute of Standards and Technology (NIST) Standard Reference Material (SRM) 917c (D-Glucose).

Concentration: 12 mmol/L $\pm$ 0.25mmol/L, diluted 51-fold, ready for use.

【Performance Characteristics】

The performance of the system has been evaluated both in laboratory and in clinical tests.

- Range: The display range of the meter is 2.2 to 33.3 mmol/L (40 to 600 mg/dL). "HI" and "Lo" messages indicate results outside of this range.
- Accuracy: The accuracy of the system was assessed by comparing blood glucose results obtained by patients with those obtained using a EKF Glucose Analyzer, a laboratory instrument.

Table1. System accuracy results for glucose concentration < 5.55mmol/L

Within $\pm$ 0.28 mmol/L	Within $\pm$ 0.56 mmol/L	Within $\pm$ 0.83 mmol/L
107/156(68.6%)	156/156(100.0%)	156/156(100.0%)

Table 2. System accuracy results for glucose concentration $\geq$ 5.55 mmol/L

Within $\pm$ 5 %	Within $\pm$ 10 %	Within $\pm$ 15 %
426/444(95.9%)	444/444(100.0%)	444/444(100.0%)

This study shows that the system compares well with a laboratory method and meets the minimum acceptable performance criteria defined in ISO 15197.

- Precision:

Intermediate Precision	Control Solution _{av} 2.5 mmol/L SD=0.12 mmol/L Control Solution _{av} 7.0 mmol/L CV=2.4% Control Solution _{av} 20.0 mmol/L CV=3.7%
Repeatability	Blood _{av} 2.5 mmol/L SD=0.12 mmol/L Blood _{av} 4.1 mmol/L CV=2.9% Blood _{av} 7.1 mmol/L CV=1.9% Blood _{av} 10.6 mmol/L CV=1.9% Blood _{av} 19.9 mmol/L CV=3.8%

【Literature Reverences】

1. Clin Chem 51, 2005:1573-1576
2. Stedmans Medical Dictionary, 27th Edition, 2000:2802
3. American Diabetes Association: Clinical Practice Recommendation 2007 Diabetes Care 30 (Suppl.1), 2007: S4-S41

【Symbol Index】

On the packaging, you may encounter the following symbols shown below. They have the following meanings:

	Consult instructions for use
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	In vitro diagnostic medical device
	Caution
	Batch code
	Manufacturer
	Authorized representative in the European Community
	Sufficient for
	Temperature limitation
	Keep dry
	Do not reuse
	Use by
	The product conforms to the requirements of the EC Directive IVDD (98/79/EC) on in vitro diagnostic medical devices.

【Manufacturer】



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0197 The product conforms to the requirements of the EC Directive IVDD 98/79/EC on in vitro diagnostic medical devices, “0197” is the identification number of notify body.

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