Hangzhou Sejoy Electronics & Instruments Co., Ltd.

BS-602 Blood Glucose Test Strips
Instruction Manual

Cautions:

- For Use with the Sejoy BG-707, BG-707b, BG-709, BG-709b Blood Glucose Meter.
- Read the Owner's Manual of the Sejoy BG-707, BG-707b, BG-709, BG-709b 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.
- The patient should only adapt the treatment if he has received the appropriate training to do so.

【Product Name】

Generic Name: Blood Glucose Test Strips

【Model】

BS-602

【Packing Type】

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

【Product Description】

BS-602 Blood Glucose Test Strips

【Intended Use】

The Sejoy BS-602 Test Strips are used with the Sejoy BG-707, BG-707b, BG-709, BG-709b Blood Glucose Meters to quantitatively measure glucose with fresh capillary whole blood or venous blood or neonatal 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.

【Test Principle】

The Sejoy BS-602 Test Strip is a plastic strip containing chemistries and electrodes.The strip measures glucose by using amperometric technology employing a glucose dehydrogenase 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 dehydrogenase ≥ 1.6 IU; Potassium Ferricyanide ≥ 0.2 mg; Stabilizer ≥ 0.1 mg ; other elements 68%.

Each package contains desiccating agent.

【Storage and Handling】

- Store the test strip and control solution in a dry place at temperature between 1℃～30℃ (33.8℉～86℉).
- Use the test strips at temperatures between 5℃～45℃ (41℉～113℉), humidity between 10%～90%.
- Do not store the test strips in high heat and moisture environments. Avoid exposure test strips to sunshine.
- Do not freeze or refrigerate.
- Test strips must be store in original vial with cap tightly sealed.
- Test strip are valid before either 24 months after produced or 6 months past the opened date; write the first opened date on the package.
- Control solution are valid before either 24 months after produced or 3 months past the opened date; write the first opened date on the package.
- Immediately recap vial after removing a strip.
- Use the test strip immediately after it removed out from package.

【Accessories】

- Blood Glucose Meters BG-707, BG-707b, BG-709, BG-709b
- Control Solution CS-201
- Lancing Device
- Lancet

【Blood Sample Requirement】

- Use fresh capillary whole blood or venous blood or neonatal blood; Applying anticoagulant in blood sample may affect test results.
- Capillary, venous and neonatal blood samples containing these anticoagulants are acceptable: EDTA, sodium heparin. Othter anticoagulants are not recommended.
- Venous and neonatal whole samples collection and preparation should be obtained by healthcare professionals.
- To minimize the effect of glycolysis, venous blood glucose tests need to be performed within 20 minutes of the blood samples. If collected blood samples cannot be tested immediately, please centrifuge and store them in a refrigerator.
- Test strip has been tested with neonatal blood. As a matter of good clinical practice, caution is advised in the interpretation of neonatal blood glucose values below 2.8 mmol/L (50mg/dL).
- Remaining water or alcohol on blood sample puncture site causes inaccurate results.

【Precautions】

- Test Strips are for in vitro (external) testing of Capillary, venous and neonatal 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-707, BG-707b, BG-709, BG-709b Owner's Booklet thoroughly before test.

1) Prepare system components:

BG-707, BG-707b, BG-709, BG-709b Blood Glucose Meter

BS-602 Test Strips

Lacing 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 if 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.
- Hole 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,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 result can be known within 5 seconds after the blood sample or control solution is added.
- The blood glucose meter can accurately measure blood glucose concentrations between 0.5 to 33.3mmol/L (9 to 600 mg/dL). "Lo" and "HI" messages indicate results outside of this range.
- "Lo" symbol will appear on screen if blood glucose is below 0.5 mmol/L (9 mg/dL).
- "HI" symbol means test result is higher than 33.3 mmol/L (600 mg/dL).
- The blood glucose monitoring system needs at least 0.6 μl sample. "E-4" error code will appear when samples are insufficient.
- 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	3.9-5.8 mmol/L (70-105mg/dL)
Before lunch or supper	3.9-6.1mmol/L (70-110mg/dL)
1 hour after meal	Less than 8.9mmol/L (≤160mg/dL)
2 hour after meal	Less than 6.7mmol/L (≤120mg/dL)
Between 2 AM and 4 AM	Greater than 3.9mmol/L (≥70 mg/dL)

【Limitations】

- The sejoy blood glucose monitoring system BG-707, BG-707b, BG-709, BG-709b is designed for using with capillary, venous and neonatal blood samples.
- Hematocrit range: 0% to 70%. Hematocrit above 70% may cause deviated 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. Blood samples tested at the following substance concentration levels will not interfere.

Substance	Concentration	Substance	Concentration
Acetaminophen	1.11 mmol/L (20 mg/dL)	Ascorbic acid	0.17 mmol/L (3 mg/dL)

Bilirubin	2.22 mmol/L (40 mg/dL)	Cholesterol	27.78 mmol/L (500 mg/dL)
Creatinine	0.56 mmol/L (10 mg/dL)	Dopamine	1.1 mmol/L (20 mg/dL)
Gentisic acid	1.25 mmol/L (22.5 mg/dL)	Glutathione	2.17 mmol/L (39 mg/dL)
Haemoglobin	1111.11 mol/L (20000 mg/dL)	Heparin	500 IU/dL
Ibuprofen	2.78 mmol/L (50 mg/dL)	Icodextrin	60.8 mmol/L (1094.4 mg/dL)
L-Dopa	0.03 mmol/L (0.5 mg/dL)	Maltose	555.56 mmol/L (10000 mg/dL)
Methyl-DOPA	0.22 mmol/L (4 mg/dL)	Salicylate	3.33 mmol/L (60 mg/dL)
Tolbutamide	5.55 mmol/L (100 mg/dL)	Tolazamide	0.56 mmol/L (10 mg/dL)
Triglycerides	83.33 mmol/L (1500 mg/dL)	Uric acid	1.33 mmol/L (24 mg/dL)
Xylose	2.78 mmol/L (50 mg/dL)	Pralidoxime Iodide	0.83 mmol/L (15 mg/dL)
EDTA	11.11 mmol/L (200 mg/dL)	Galactose	0.83 mmol/L (15 mg/dL)

【Traceability】

The calibrator of the Sejoy Blood Glucose Monitoring System BG-707, BG-707b, BG-709, BG-709b is control solution. The traceability of the control solution is referenced to the YSI Glucose Analyzer. The YSI Glucose Analyzer 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) 917b (D-Glucose). Concentration is 200 mg/dL.

【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 0.5 to 33.3mmol/L (9 to 600 mg/dL). "Lo" and "HI" 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 YSI Glucose Analyzer, a laboratory instrument.

Table1. System accuracy results for glucose concentration < 5.55mmol/L (100mg/dL)

Within ±0,28 mmol/L (5 mg/dL)	Within ±0,56 mmol/L (10 mg/dL)	Within± 0,83 mmol/L (15 mg/dL)
118/150(78.7%)	150/150 (100%)	150/150 (100%)

Table 2. System accuracy results for glucose concentration ≥ 5.55 mmol/L (100mg/dL)

Within ±5 %	Within ±10 %	Within ±15 %
277/450(61.6%)	400/450(88.9%)	446/450 (99.1%)

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

- Precision:

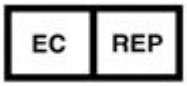
Intermediate Precision	Control Solution$_{av}$ 2.20 mmol/L CV=3.69% Control Solution$_{av}$ 4.89 mmol/L CV=2.82% Control Solution$_{av}$ 7.19 mmol/L CV=1.97% Control Solution$_{av}$ 10.99 mmol/L CV=1.77% Control Solution$_{av}$ 18.09 mmol/L CV=1.36%
Repeatability	Blood $_{av}$ 2.55 mmol/L CV=4.3% Blood $_{av}$ 4.79 mmol/L CV=4.2% Blood $_{av}$ 7.34 mmol/L CV=2.3% Blood $_{av}$ 11.42 mmol/L CV=2.6% Blood $_{av}$ 20.5 mmol/L CV=1.6%

【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		Sufficient for
	In vitro diagnostic medical device		Temperature limitation
	Caution		Keep dry
	Batch code		Do not reuse
	Manufacturer		Use by
	Authorized representative in the European Community		
	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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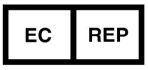

【EU Representative】

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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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