

Rightest™ GS100 BLOOD GLUCOSE TEST STRIP INSERT

Intended Use

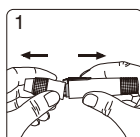
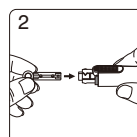
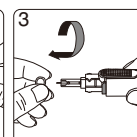
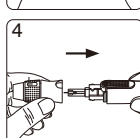
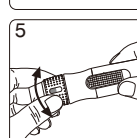
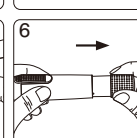
The **Rightest™** Blood Glucose Monitoring System is used by individuals with diabetes. It's for checking on glucose levels in capillary whole blood (CB) from the fingertip, palm and forearm. It's as an aid in management of diabetes at home and clinical sites. **Please only purchase the test strips in your country, the use of the test strips of different countries is not suggested and might get deviated test results under such circumstance.**

Rightest™ Blood Glucose test Strips are intended for testing outside the body (*in vitro* diagnostic use) (For self-testing) only.

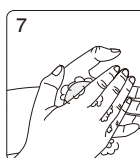
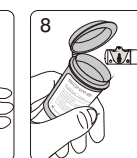
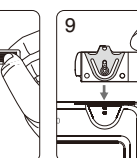
The **Rightest™** System tests the CB and provides results equivalent to a laboratory instrument. (plasma equivalent)

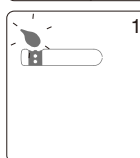
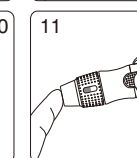
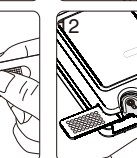
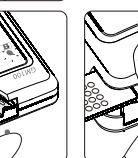
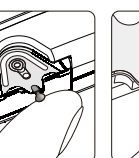
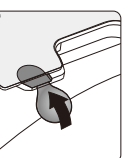
- The **Rightest™** Blood Glucose Test Strip GS100 is designed for use only with the **Rightest™** Blood Glucose Meter GM100.
- The **Rightest™** Blood Glucose Monitoring System includes meter, test strips, control solutions, lancing device and lancets.

Preparing the Lancing Device

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6) Hold the hub in one hand and pull on the plunger in the other hand. The device will be cocked. Release the plunger, it will automatically move back to its original position near the hub.

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10) While the blood drop symbol flashing, you are ready to apply the blood sample.
11) Place the lancing device against the pad of your fingertip and press the release button. The best puncture sites are on the middle or ring fingers. Press the release button.

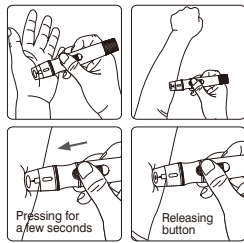
Sample Size Example



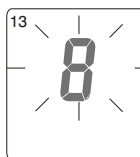
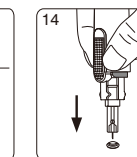
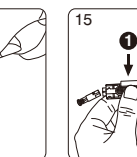
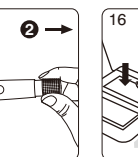
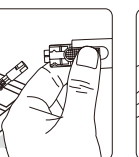
Please take a minimum of 1.4 µL to do the test on glucose monitoring system. Blood sample size above 4.0 µL might contaminate the Smart Code Key.

Alternative site testing-palm or forearm blood sampling

- To perform a test using samples obtained from alternative sites, install the clear cap on the lancing device (For more information on how to install, see the Instructions for the lancing device).
- To increase the blood flow, massage the puncture area of palm or forearm for a few seconds.
- Immediately after massaging the puncture area, press and hold the lancing device with the clear cap against palm or forearm.
- Then press the release button.
- Continue holding the lancing device against palm or forearm and gradually increase pressure for a few seconds until the blood sample size is sufficient (Refer to Instructions for the lancing device)



12) Touch and hold the drop to the edge of sample entry until you hear a " beep " and the view window is totally filled with blood. If the view window is not totally filled with blood or the test does not start. Please discard the test strip and repeat the test with a new test strip.

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- 13) You will see the countdown mode on the screen. After 8 seconds, the test result appears.
- 14) Pull off the depth adjustable cap. Without touching the used disposable lancet, stick the lancet tip into the protective cover.
- 15) Hold the release button in one hand and pull on the plunger in the other hand will safely eject the used disposable lancet.
- 16) Discard the used disposable lancet into an appropriate puncture-proof or biohazard container.
- 17) Replace the depth adjustable cap after finishing the test.

For more information on how to use your meter and understand your test results, see the Instructions for use.

Test Result

- Blood glucose test results are shown on the meter as mg/dL.
- If your blood glucose result is unusually high or low, or if you question your results, repeat the test with a new test strip. You can also run a quality control test with your **Rightest™** Control Solutions to check your meter and strip. If the test result still remains unusually high or low, contact your doctor immediately.
- If you are experiencing symptoms that are not consistent with your blood glucose test results and you have followed all the instructions in this manual, contact your doctor immediately.
- The **Rightest™** Meter displays results between 0.6 and 33.3 mmol/L. If your test result is below 0.6 mmol/L, " Lo " will appear on the screen. Please repeat your test again with another strip. If you still get a " Lo " result, you should immediately contact your doctor.
- If your test result is above 33.3 mmol/L, " Hi " will appear on the screen. Please repeat your test again with another strip. If you still get a " Hi " result, you should immediately contact your doctor.

Expected values ⁽¹⁾

Fasting Blood Glucose	
GLUCOSE LEVEL	INDICATION
From 70 to 99 mg/dL (3.9 to 5.5 mmol/L)	Normal fasting glucose
From 100 to 125 mg/dL (5.6 to 6.9 mmol/L)	Pre-diabetes (Impaired fasting glucose)
126 mg/dL (7.0 mmol/L) and above on more than one testing occasion	Diabetes

Precautions

- Check the expiration date printed on the package every time you use the strip. Do not use expired test strips.
- Close the vial cap immediately after taking test strip out from the vial.
- Do not perform quality control test with expired control solution.
- Do not bend or twist the test strip. Damage of test strip may cause wrong result.
- Do not reuse test strips.
- Do not reuse lancets. Discard used lancets properly.
- Wait at least 30 minutes to perform a test if you have moved the meter to an area of different temperature.
- If you want to purchase a new control solution, please contact your authorized Bionime representative.

Warning

- Keep the test strips or vial cap away from children. They may cause a choking hazard. If a test strip or vial cap is swallowed, contact your physician immediately.

Limitations

- Grossly lipemic (fatty) samples may interfere with some methodologies. To be aware of such interferences, patients under the supervision of their physician should have baseline glucose values established by a clinical laboratory method prior to starting home glucose monitoring. These baseline values should be checked periodically thereafter.
- Meter read capillary blood glucose values may be significantly lower than " true glucose levels " in the hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested by the **Rightest™** System, or tested with extreme caution.
- Caution is advised in the interpretation of glucose values below 2.8 mmol/L or above 13.9 mmol/L. Consult a physician as soon as possible if values in this range are obtained.

- Doctors should evaluate their technique and their patients' technique at periodic intervals. To accomplish this, it is recommended that meter results be compared with a concurrently obtained laboratory measurement on the same blood sample. A well characterized clinical laboratory method employing hexokinase or glucose oxidase should be used as the comparative method.
- Fluoride should not be used as a preservation for venous specimens when using blood glucose monitors.
- Hands and fingers contaminated with sugar from foods or beverages may cause falsely elevated results.
- Differences in whole blood and serum/plasma values may cause variability in results.
- Storage of strips near bleach as well as bleach containing products will affect results of glucose oxidase strips.
- The use of cellular phones and other radio transmitting devices should be prohibited in areas where testing occurs.
- **Rightest™** Blood Glucose Test Strips are designed for use with capillary whole blood samples. Do not use serum or plasma samples.
- Incorrect test results may be obtained at high altitude more than about 3,048 meters (10,000 feet) above sea level.
- Hematocrits should be between 35 % ~ 48 %. If you do not know your hematocrits, ask your healthcare professional.
- Severe dehydration and excessive water loss may cause inaccurately low results.
- **Rightest™** Blood Glucose Monitoring System has not been validated for use on neonates. Therefore, it should not be used for neonates.
- Do not perform the blood glucose test at temperatures below 10°C (40 °F) or above 50 °C (104 °F) , below 10 % or above 90 % relative humidity.

NOTE

- Suggest not to use this meter close to source of strong electromagnetic radiation, to avoid interference with proper operation.
- Suggest to keep meter free of dust, water or any liquid.

Storage and Handling

- Store the strips in the original capped vial at temperatures between 4 °C to 30 °C (39 °F to 86 °F), and relative humidity between 10 % to 90 %.
- Replace the vial cap immediately and close tightly after taking test strip out from the vial. Do not leave the cap of vial opened. If the strip is exposed in the air too long, it will absorb the moisture and cause wrong test result.
- Use test strips within 3 months after first opening.

Measurement Range

The measurement range of the **Rightest™** System is 0.6 to 33.3 mmol/L.

Quality Control Section

Please refer to the Quality Control section of the Instructions for use.

Troubleshooting and Customer Service

For more information on error messages and trouble shooting, please refer to the Error Messages and Trouble Shooting section of the **Rightest™** Instructions for use. You may also contact customer service by calling local distributor or email to rightest@bionime.com. (At all other times, you could contact your healthcare professional for assistance)

Additional Information for Healthcare Professionals

Detection Principle ⁽²⁾

The glucose oxidase and potassium ferricyanide in the strip react with the glucose in the sample to produce an electrical current which is proportional to the amount of glucose in the sample. The meter measures the current and converts it to the corresponding glucose concentration.

Performance Characteristics

Precision

The precision was evaluated including (i) venous whole blood sample (ii) 3 levels glucose control solution in period of 10 days, by 10 meters and 3 batches of strips.

(i) Venous whole blood sample:

Glucose levels	P-01	P-02	P-03	P-04	P-05
(1) Total test numbers (n)	300	300	300	300	300
(2) Mean mg/dL (mmol/L)	47.1 (2.6)	104.3 (5.8)	133.0 (7.4)	227.5 (12.6)	349.2 (19.4)
(3) SD mg/dL (mmol/L)	1.5 (0.08)	2.9 (0.16)	2.7 (0.15)	3.8 (0.21)	5.1 (0.28)
(4) CV (%)	3.2 %	2.8 %	2.1 %	1.7 %	1.5 %

(ii) Control solution:

Glucose levels	CS-L	CS-N	CS-H
(1) Total test numbers (n)	300	300	300
(2) Mean mg/dL (mmol/L)	59.1 (3.3)	109.9 (6.1)	299.4 (16.6)
(3) SD mg/dL (mmol/L)	1.8 (0.10)	2.4 (0.13)	5.3 (0.29)
(4) CV (%)	3.1 %	2.2 %	1.8 %

Accuracy

The accuracy of the test study of the **Rightest™** Blood Glucose Meter was demonstrated by comparing whole blood (plasma equivalent) glucose values on the **Rightest™** meter with plasma glucose values on a lab instrument.

A total of 111 patients were enrolled. Each patient collected and tested their own blood samples (from the fingertip, palm and forearm) using the **Rightest™** System. Then the blood samples were centrifuged immediately after collection to obtain plasma. Analyze the plasma by the lab instrument - YSI 2300. 100 % of **Rightest™** meter values were within ± 15 mg/dL (0.83 mmol/L) of the YSI values at glucose concentrations < 100 mg/dL (5.55 mmol/L) and within ± 15 % at glucose concentrations ≥ 100 mg/dL (5.55 mmol/L).

The results and differences between the two methods, **Rightest™** System and YSI 2300 (as the reference method) are proved in the tables below.

Table 1: represents samples for glucose concentrations < 100 mg/dL (5.55 mmol/L).

Difference range in values between the YSI value and the Rightest™ meter value	The percent (and number) of samples of alternative site were the difference between the Rightest™ and the YSI value within the range shown in the side row.		
	Fingertip	Palm	Forearm
Within ± 5 mg/dL (0.28 mmol/L)	58.8 % (40/68)	63.2 % (43/68)	60.3 % (41/68)
Within ± 10 mg/dL (0.56 mmol/L)	91.2 % (62/68)	92.6 % (63/68)	88.2 % (60/68)
Within ± 15 mg/dL (0.83 mmol/L)	100 % (68/68)	100 % (68/68)	100 % (68/68)

Table 2: represents samples for glucose concentrations ≥ 100 mg/dL (5.55 mmol/L).

Bias range in values between the YSI value and the Rightest™ meter value	The percent (and number) of samples of alternative site were the bias between the Rightest™ and the YSI value within the range shown in the side row.		
	Fingertip	Palm	Forearm
Within ± 5 %	61.0 % (94/154)	61.0 % (94/154)	59.1 % (91/154)
Within ± 10 %	84.4 % (130/154)	85.1 % (131/154)	87.7 % (135/154)
Within ± 15 %	100 % (154/154)	100 % (154/154)	100 % (154/154)

* Acceptance criteria in ISO15197 : 2013 are that 95 % of all differences in glucose values should be within ± 15 mg/dL (0.83 mmol/L) at glucose concentrations < 100 mg/dL (5.55 mmol/L), and within ± 15 % at glucose concentrations ≥ 100 mg/dL (5.55 mmol/L).

Note: For glucose concentrations < 100 mg/dL (5.55 mmol/L), difference values are expressed in mg/dL (mmol/L), and for glucose concentrations ≥ 100 mg/dL (5.55 mmol/L), difference values are compared in percentage.

Interferences

The following compounds may interfere with the glucose measurement at the concentrations listed:












Ascorbic Acid ≥ 5 mg/dL (0.28 mmol/L)	Dopamine HCl ≥ 2 mg/dL (0.11 mmol/L)
L-Dopa ≥ 3 mg/dL (0.15 mmol/L)	Tolazamide ≥ 15 mg/dL (0.48 mmol/L)
Cholesterol ≥ 500 mg/dL (12.93 mmol/L)	Glutathione reduced ≥ 60 mg/dL (1.93 mmol/L)
Hemoglobin $\geq 6,000$ mg/dL (0.94 mmol/L)	Uric acid ≥ 9 mg/dL (0.54 mmol/L)

Each Blood Glucose Test Strip contains the following reagents:

Glucose Oxidase (GOD)	8.5 %
Potassium Ferricyanide	48.5 %
Non-reactive Ingredients	43.0 %

References

- 1) Diabetes Information - American Association for Clinical Chemistry (AACC) (Electronic Version) Retrieved Aug 21, 2015 from www.labtestsonline.org/understanding/analytes/glucose/test.html
- 2) In Vitro Diagnostics in Diabetes : Meeting the Challenge. Clinical Chemistry 45:9, 1596-1601 (1999).

 Consult instructions for use	 EU Representative	 Manufacturer
 For in vitro diagnostic use	 For single use only	 Use by
 Reference number	 Temperature limitations	 Lot number
 CE Mark with number of Notified Body		 Biological risks

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BIONIME

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