RIGHTEST™ GT100 BLOOD GLUCOSE TEST STRIP INSERT

Intended Use

The GT100 Blood Glucose Monitoring System is used:

By diabetics for checking glucose levels in capillary whole blood (CB) from the fingertip, palm and forearm.

As an aid in management of diabetes at home and clinical sites.

GT100 Blood Glucose Test Strips:

Are intended for testing outside the body (*in vitro* diagnostic use for self-testing only).

Are designed for use only with GT100 Blood Glucose Meter to assure accurate results.

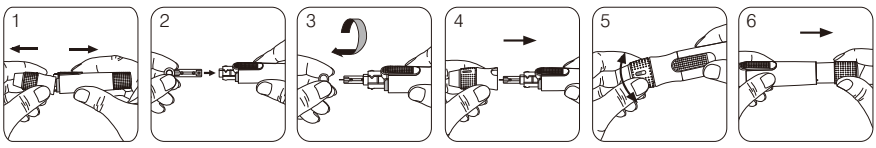
GT100 Blood Glucose Monitoring System includes meter, test strips, control solutions, lancing device and lancets.

Special conditions for use statement(s): GT100 System provides plasma equivalent results.

Test Procedure

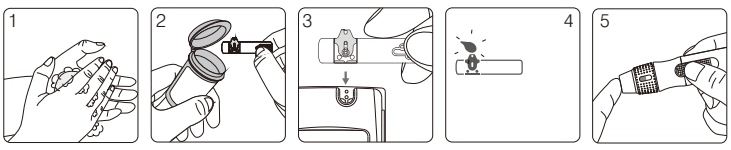
Preparing the Lancing Device

1) Hold the depth adjustable cap in one hand and hold the hub in the other hand. Bend the cap towards the down side, until a gap appears between the cap and hub. Pull the cap and hub off in opposite directions, remove the cap.
2) Insert a new disposable lancet firmly into lancet carrier.
3) Twist off and set aside the protective cover of the disposable lancet.
4) Replace the depth adjustable cap.
5) Choose a depth of penetration by rotating the top portion of the depth adjustable cap until your desired setting is visible in the window. Settings are based on skin type: " ▮▮▯ " for soft or thin skin; " ▮▮▮▯ " for average skin; " ▮▮▮▮▯ " for thick or calloused skin.
6) Hold the hub in one hand and pull on the plunger with the other hand. The device will be cocked. Release the plunger and it will automatically move back to its original position near the hub.



Performing a Test

1) Wash your hands in warm soapy water and dry.
2) Take one test strip from the vial. Close the vial cap immediately.
3) Insert the strip into the strip port of the meter with the indication symbol facing up. Push the strip in until it snaps and stops. The meter will automatically detect the code number.
4) When the blood drop icon is flashing on the display window, you are ready to apply the blood sample within 2 minutes.
5) Place the lancing device to the side of your fingertip and press the release button.



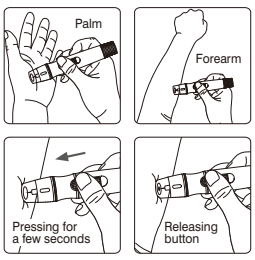
Sample Size Example

0.75 µL	1.0 µL	1.5 µL	2.0 µL	3.0 µL
•	●	●	●	●

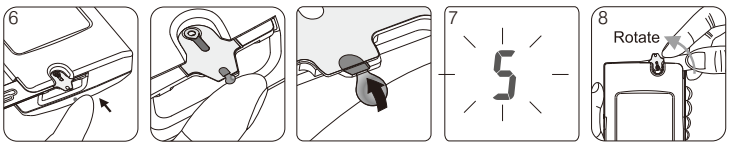
Please take a minimum of 0.75 µL to perform the test on glucose monitoring system. Blood sample size above 3.0 µL might contaminate the test strip port and the meter.

Alternative site testing: palm or forearm blood sampling

- To perform a test using samples obtained from alternative sites, choose the clear cap and follow step 1 through step 4.
- Massage the puncture area of your palm or forearm for a few seconds.
- Immediately after massaging the puncture area, press and hold the lancing device with the clear cap against your palm or forearm.
- Press the release button.
- Continue holding the lancing device against your palm or forearm and gradually increase pressure for a few seconds until the blood sample size is sufficient (Refer to Instruction manual for the lancing device).



6) Touch and hold the drop to the edge of sample entry until you hear a " beep " (if volume is turned on) and the view window is completely filled with blood. If the view window is not completely filled with blood the test will not start. Please discard the test strip and repeat the test with a new test strip.
7) The countdown mode will begin on the display window. After 5 seconds your test result will appear.
8) Remove the test strip from the meter. Please follow your local regulations to discard the used strip properly.
9) To remove the lancet, pull off the depth adjustable cap of the lancing device. Without touching the used disposable lancet, insert the lancet tip into the protective cover. Hold the release button of the lancing device in one hand and pull on the plunger with the other hand to safely eject the used disposable lancet into an appropriate puncture-proof or biohazard container.



For more information on how to use your meter and understand your test results, see the User's manual.

Test Result

- Blood glucose test results are shown on the meter as mg/dL or mmol/L, based on your setting (refer to User's manual for unit setting).
- 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 the GC550 Control Solutions to check your meter and Test 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 Blood Glucose Meter displays results between 10 and 600 mg/dL (0.6 and 33.3 mmol/L). If your test result is below 10 mg/dL (0.6 mmol/L), " Lo " will appear on the screen. Please repeat your test with a new strip. If you still get a " Lo " result, you should immediately contact your doctor.
- If your test result is above 600 mg/dL (33.3 mmol/L), " Hi " will appear on the screen. Please repeat your test with a new strip. If you still get a " Hi " result, you should immediately contact doctor.

Expected glucose values without diabetes[1)]

Status	Range
Fasting	70 - 99 mg/dL (3.9 - 5.5 mmol/L)

Precautions

- Check the expiration date printed on the strip vial. 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 and lancets.
- Discard the used disposable lancet and strip into an appropriate puncture-proof or biohazard container.
- If the RIGHTEST Blood Glucose Meter and strips are exposed to a high temperature difference, please wait 30 minutes before measurement.
- If you want to purchase new normal or high level control solutions, please contact Customer Service.
- Test results may vary if blood samples are taken from different sites or under certain conditions where glucose levels can change such as: following a drink, a meal, an insulin dose or exercise. In these cases, only the fingertip should be used.

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 doctor instantly.

Limitations

- The meter readings of the blood glucose 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 RIGHTEST Blood Glucose Monitoring System, or tested with extreme caution.
- Caution is advised when glucose values are below 50 mg/dL (2.8 mmol/L) or above 250 mg/dL (13.8 mmol/L). Consult a doctor as soon as possible, if values in this range are obtained.
- Healthcare professionals should evaluate their technique and their patients' technique at periodic intervals. To accomplish this, it is recommended that BGM (blood glucose monitoring) 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.
- Flouoride should not be used as a preservative when collecting blood glucose samples.
- Hands and fingers contaminated with sugar from foods or beverages may cause false elevated results.
- The results of blood glucose measurements are different for measurements with whole blood and plasma.
- Storage of strips near bleach as well as bleach containing products will affect the results of RIGHTEST Blood Glucose Test Strips.
- 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 3048 meters (10000 feet) above sea level.
- 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 (50°F) or above 40°C (104°F), below 10% or above 90% relative humidity.
- Not intended for screening or diagnosis of diabetes.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock.

NOTE
- In order to ensure proper operation, do not use this meter close to sources of strong electromagnetic radiation.
- Keep meter free of dust and liquids including water.

Storage and Handling
- Store the strips in the original capped vial at temperatures between 4°C - 30°C (39°F - 86°F) and relative humidity below 90%. Do not freeze.
- Replace the vial cap immediately and close tightly after taking test strip out from the vial. If the strip is exposed to the air too long, it will absorb the moisture and cause inaccurate test results.
- When you open a new vial of test strips please write the opening date on the label. Use test strips within 12 months after first opening or until the expiration date printed on the label (whichever comes first).

Measurement Range
The measurement range of RIGHTEST Blood Glucose Monitoring System is 10 to 600 mg/dL (0.6 to 33.3 mmol/L).

Quality Control Section
Please refer to the Quality Control section of the User's Manual.

Troubleshooting and Customer Service
For more information on error messages and trouble shooting, please refer to the Error Messages and Trouble Shooting section of RIGHTEST GT100 User's Manual.
If you have any questions or in case of problems with the RIGHTEST products, please contact local Bionime authorized distributor or email to rightest@bionime.com.

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
Measurement Range
The measurement range of RIGHTEST Blood Glucose Monitoring System is 10 and 600 mg/dL (0.6 and 33.3 mmol/L).

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 1 batch of strip.

(i) Venous whole blood sample:

Meters	P-01	P-02	P-03	P-04	P-05
(1) Total test numbers	300	300	300	300	300
(2) Mean mg/dL (mmol/L)	45.8 (2.5)	95.9 (5.3)	136.5 (7.6)	241.3 (13.4)	357.5 (19.9)
(3) SD mg/dL (mmol/L)	1.4 (0.08)	1.9 (0.10)	2.8 (0.15)	4.0 (0.22)	5.2 (0.29)
(4) CV	3.1%	1.9%	2.0%	1.7%	1.5%

(ii) Control solution:

Glucose levels	CS-L	CS-N	CS-H
(1) Total test numbers	300	300	300
(2) Mean mg/dL (mmol/L)	52.3 (2.9)	103.5 (5.8)	267.1 (14.8)
(3) SD mg/dL (mmol/L)	1.5 (0.09)	2.0 (0.11)	3.9 (0.22)
(4) CV	3.0%	2.0%	1.5%

Accuracy
For the alternative site:
The accuracy of the alternative site test study of RIGHTEST GT100 System was proved by comparing whole blood (plasma equivalent) glucose values on RIGHTEST GT100 meter with plasma glucose values on a lab instrument. A total of 110 patients were enrolled. A trained healthcare professional collected blood samples (from the fingertip, palm and forearm) using RIGHTEST GT100 Meter. 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 concentrations < 100 mg/dL (5.55 mmol/L) and within ± 15 % at concentrations ≧ 100 mg/dL (5.55 mmol/L)
The results and differences between the two methods, RIGHTEST GT100 System and YSI 2300 Analyzer (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 2300 value and meter value	The percent (and number) of samples for which the difference between RIGHTEST Meter value (Alternative site) and the YSI 2300 value were within the difference range shown in the side row.		
	Fingertip	Palm	Forearm
Within ± 5 mg/dL (0.28 mmol/L)	57.4 % (39/68)	58.8 % (40/68)	64.7 % (44/68)
Within ± 10 mg/dL (0.56 mmol/L)	92.6 % (63/68)	94.1 % (64/68)	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 mmool/L).

Difference range in values between the YSI 2300 value and Meter value	The percent (and number) of samples for which the difference between RIGHTEST Meter value (Alternative site) and the YSI 2300 value were within the difference range shown in the side row.		
	Fingertip	Palm	Forearm
Within ± 5 %	69.1 % (105/152)	61.2 % (93/152)	63.2 % (96/152)
Within ± 10 %	92.1 % (140/152)	94.7 % (144/152)	90.1 % (137/152)
Within ± 15 %	100 % (152/152)	100 % (152/152)	100 % (152/152)

Table 3: System accuracy results of RIGHTEST BGMS (combine 3 lots) VS. YSI (fingertip) results.

Difference range in values between the YSI value and the RIGHTEST BGMS	Fingertip	Palm	Forearm
Test range in mg/dL (mmol/L)	30 - 570(1.67 - 31.67)	30 - 562(1.67 - 31.22)	30 - 569(1.67 - 31.61)
Within ± 15 mg/dL (0.83 mmol/L) or within ± 15 %	660/660(100.0%)	660/660(100.0%)	660/660(100.0%)

*Acceptance criteria in ISO 15197 : 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.

Hematocrit(Hct)
Hematocrit(Hct) should be between 30 - 57%. If you do not know your hematocrit, ask your healthcare professional.

Interferences
26 toxic amount tested substances (Acetaminophen, Ascorbic acid, Dopamine, EDTA, Gentisic acid, Heparin, Ibuprofen, L-dopa, Methyldopa, Pralidoxime iodide, Salicylic Acid, Tetracycline, Tolazamide, Tolbutamide, Bilirubin, Cholesterol, Creatinine, Glutathione, Haemoglobin, Triglycerides, Uric acid, Maltose, Xylose, Galactose, Lactose, Icodextrin) in two blood sample concentrations.
Substance and possible level may interfere the glucose measurement:
Ascorbic acid ≧ 6 mg/dL (0.34 mmol/L)
Glutathione reduced ≧ 70 mg/dL (2.28 mmol/L)
Uric Acid ≧ 16 mg/dL (0.95 mmol/L)

Reagents
Each Blood Glucose Test Strip contains the following reagents:

Glucose Oxidase (Aspergillus niger) (GOD)	18.8 %
Potassium ferricyanide	37.7 %
Non-reactive ingredients	43.5 %

References

1) Diabetes Information-American Association for Clinical Chemistry (AACC)〔Electronic Version〕 Retrieved February 08, 2006 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).

IVD For *in vitro* diagnostic use | Manufacturer | Expiry date | LOT Lot number
For single use only | 4°C–30°C Store between temperature 4°C and 30°C (39°F and 86°F)
Consult the instruction for use | Biological risks | CE 0197 CE-mark (with No. of notified body)

Rev. Date: 2019-10

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