



# Blood Glucose Monitoring System

**IVD** For *in vitro* diagnostic use only.

2 32°C Store at 2-32°C

## INTENDED USE

Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, up-per arm, or forearm. It is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

## PRINCIPLE OF THE USE

Blood Glucose Test Strip is designed with an electrode that measures glucose levels. Glucose in the blood sample mixes with reagent on the test strip that causes a small electric current. The amount of current that is created depends on how much glucose is in the blood. The meter measures the current that is created and converts the measurement to the amount of glucose that is in the blood. The blood glucose result is displayed on the screen. By touching a drop of blood to the tip of the test strip, the strip's reaction chamber automatically draws the blood into the strip through capillary action. When the chamber is full, the meter starts to measure the blood glucose level. It is a simple and practical system for the daily monitoring of your blood glucose level.

## REAGENT COMPOSITION

### Active Ingredient (per 100 strips)

- Glucose oxidase (GOD) 300 units
- Potassium ferricyanide (mediator) 9.0 mg.

## MATERIALS PROVIDED

- Blood glucose monitoring system (including glucose test, lancing device and lancet).
- Package insert.

## METER SET UP

You should check and update the meter settings such as time and date before using your meter or after changing the meter battery.

The Strip Stand-by screen appears on the display when the ON/OFF button is pressed. Press and hold for 3 seconds on the strip Standby screen to enter the SET mode. You will see the audible beep set mode at the first.

### STEP-1: Setting the Audible Beep

1. Press the ON/OFF buttons in the test strip waiting screen for 3 seconds, and then the beep sound setting screen appears, which is the first stage of setting of a meter.
2. Set the beep mode on or off by pressing the left or right button and then confirm the preferred feature by pressing the ON/OFF button. When the audible signal is activated, a beep is generated; otherwise, if you select the beep off feature, no sound is made.

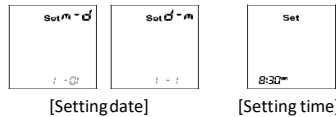
### Step-2: Setting the date and time

#### Date Setting

1. Set the correct year by pressing either the left or right button and then confirm the correct year by pressing the ON/OFF button.
2. The display to set the month and day format. The glucose meter can display the date in the Month-Day (m-d) format or Day-Month (d-m) format. Set your preferred format on the display by pressing the left or right button and then confirm the selection with the ON/OFF button.
3. The display to set the date will appear next. Set the correct month and day on the display by pressing the left or right button and confirming the selection with the ON/OFF button.

#### Time Setting

1. The screen to set the time format will be displayed next. The glucose meter can display the time in the 12 hour or 24 hour format. Set your preferred format on the display by pressing the left or right button and confirm the selection with the ON/OFF button.
2. The display to set the time will appear next. Set the correct time on the display by pressing the left or right button and confirm the selection with the ON/OFF button.



#### Meter Set up



## PRECAUTION AND WARNING

1. This system is not designed to be a substitute for pathology laboratory equipment and should not be used for the diagnosis of diabetes.
2. Do not use this system to test neonates. It has not been validated for neonatal use.
3. Never make significant changes to your diabetes control program or ignore physical symptoms without consulting with your healthcare professional.
4. Do not use this device to measure blood glucose in people who are experiencing cardiovascular collapse (severe shock) or decreased peripheral blood flow.
5. Keep the test strip slot free of dust.
6. If the glucose meter is stored with the battery in, keep it in a low humidity room.
7. Using other test strips can cause inaccurate results.
8. After removing a test strip, close the container tightly.
9. Do not expose strips to heat, moisture or humidity. Temperatures outside the range indicated above as well as humidity (as found, for example, in the bathroom, kitchen, laundry room, car, or garage) can damage the strips and lead to inaccurate results. Severe humidity condition ( $\geq 90\%$ ,  $\leq 15\%$ ) may affect the result.
10. Store test strips in their original container only to avoid damage or contamination. Do not transfer the test strips to any other container and do not store them outside their original container.
11. Do not use test strips from any container that is damaged or left open to air.
12. When you first open the container, write date when the container was first opened on the container's label. Dispose of the test strips after 6 months from date the container was first opened.
13. Do not use the test strips past their expiry date (printed on the package) or disposal date, whichever comes first. Utilizing expired test strips or strips whose container has been open for over six months can lead to inaccurate results.
14. Blood Glucose Test Strips are for a single use only. Never re-use a test strip to which blood or a control solution have already been applied.
15. Pay attention not to contaminate the test strip with dirt, food or liquids. You can touch the test strip over its entire surface with clean and dry hands.
16. Do not bend, cut, or alter in any way the test strip.
17. Use only fresh capillary blood. Do not use serum or plasma or venous whole blood.
18. Severe dehydration (excessive water loss) may cause false low results. If you believe you are suffering from dehydration, consult your healthcare professional right away.
19. Extremes in hematocrit may affect test results. Hematocrit levels less than 20% may cause falsely high readings. Hematocrit levels greater than 60% may cause falsely low readings. If you do not know your HCT, ask your doctor.
20. Interfering substances: the following compounds, elevated levels of ascorbic acid, uric acid, acetaminophen, total bilirubin and triglycerides may affect results.

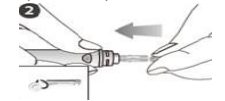
Material	Limitation
Acetaminophen	> 6mg/dL
Ascorbic Acid	> 4mg/dL
Bilirubin	> 40mg/dL
Total cholesterol	> 506mg/dL
Creatinine	> 30mg/dL
Dopamine	> 5mg/dL
EDTA	> 0.1mg/dL
Galactose	> 60mg/dL
Gentisic Acid	> 1.8mg/dL
Glutathione	> 4.6mg/dL
Hemoglobin	> 200mg/dL
Heparin	> 3,000U/L
Ibuprofen	> 50mg/dL
Levodopa	> 4mg/dL
Maltose	> 60mg/dL
Methyl-Dopa	> 2mg/dL
Sodium Salicylate	> 20mg/dL
Tolazamide	> 8.4mg/dL
Tolbutamide	> 4mg/dL
Triglycerides	> 1,026mg/dL
Uric Acid	> 9mg/dL
Xylose	> 60mg/dL
Pralidoxime Iodide	> 1.3mg/dL
Icodextrin	> 750mg/dL
Metformin	> 4mg/dL
Fructose	> 16.5mg/dL
Mannitol	> 810mg/dL
Warfarin	> 1.1mg/dL

21. The needle of lancet is sharp, keep the lancet away from children.
22. Keep the lancet and lancing device dry and avoid their direct exposure to sunlight, intense heat and high humidity areas.
23. The lancet must be used for any purpose other than capillary blood sample collection.
24. The lancet is for single use only. Do not reuse it.
25. Check the conditions of packaging before use; do not use the product in case of anomalies.
26. If a lancet cap is loosed or needle of a lancet is exposed, you should not use it.
27. Dispose of used lancets in order to reduce the risk of infection.

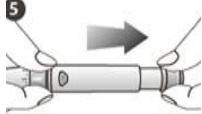
## PROCEDURE

### 1. Blood Collection procedure

1. Unscrew the cap of lancing device to remove it.
2. Insert the lancet into the lancing device holder and push down firmly until it is fully engaged. Twist the lancet cap until it separates from the lancet.
3. Screw the device's cap back on
4. Adjust the pricking depth by rotating the comfort dial. The dial includes positions from 1 to 5. The lowest depth is ideal for delicate skin and pediatric use, the highest depth is ideal for thick and calloused skin.



5. Cock the lancing device back.



**2. Testing procedure**

1. Insert the 3V battery into the housing with "+" side set upwards.



3. Obtain a drop of blood sample using the lancet and lancing device refer to the blood collection procedure



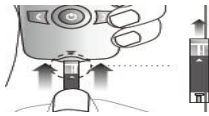
6. Hold the lancing device firmly against the side of finger and then press the release button.



2. Insert the test strip into test strip slot until it will go no further with gold colored bars printed 'G-Mentor' word facing up and toward the meter. Then, the meter turns on automatically.



4. Touch and hold drop of blood to the edge of the strip until the yellow window is completely filled with blood. The blood will be absorbed to the strip automatically.



**TEST RESULT**

- Normal blood glucose result:
  - Expected blood glucose values for non-diabetic adults are as follows.
    - Before meals < 100 mg/dL (5.55 mmol/L)
    - After meals < 140 mg/dL (7.8 mmol/L)
- The meter reads blood glucose results at 10-600 mg/dL.
  - If 'Hi' is displayed, your blood glucose result may be higher than 600 mg/dL. You may have high blood glucose.
  - If 'Lo' is displayed, your blood glucose result may be lower than 10 mg/dL. You may have low blood glucose.

**UNEXPECTED RESULT**

High or low blood glucose results can indicate potentially serious medical conditions. In case of an unexpected result, you should repeat the test immediately using a new test strip. If your reading is still unexpected or the reading is not consistent with how you feel, you should treat as prescribed by your healthcare professional and/or contact your healthcare professional immediately.

**MAINTENANCE AND TROUBLE SHOOTING**

- Replace battery: Battery power is low. Replace the battery immediately. If the ON/OFF button is pressed when the battery is discharged, the icon of battery will flash and the glucose meter will switch off automatically ten seconds later.
- Error message from the glucose meter. Turn off a meter. Then turn on the meter again.
- Strip Error: The test strip is defective or damaged, or is inserted incorrectly. Discard the test strip and repeat the test with a new strip.
- Blood Sample Error An insufficient amount of blood was applied. Discard this test strip and repeat the test with a new strip and proper blood sample.
- Temperature Error If the ambient temperature is higher or lower than the recommended range, the icon of a thermometer will be displayed on the screen. Move to an area between 10- 45°C (50-113°F), wait for 30 minutes, and perform a test. Do not heat or cool the glucose meter artificially.



**Product Technical Information**

<b>Result Range</b>	10 - 600 mg/dL (0.6 - 33.3 mmol/L)	<b>Measurement Unit</b>	mg/dL , mmol/L
<b>Calibration</b>	Plasma-equivalent	<b>Display</b>	LCD
<b>Sample</b>	Fresh capillary whole blood	<b>Control</b>	3 Buttons
<b>Sample Volume</b>	0.9 microliter	<b>Size</b>	44 mm x 92 mm x 18mm
<b>Test Time</b>	5 seconds	<b>Weight</b>	50g (with battery)
<b>Assay Method</b>	Glucose Oxidase	<b>Memory</b>	400 blood glucose tests
<b>Power Source</b>	One replaceable 3 V Lithium Battery (type CR2032)	<b>Operating TEMP.</b>	10 - 45°C (50 - 113°F)
<b>Battery Life</b>	Around 1,000 tests	<b>Hematocrit (%)</b>	20% - 60%

**PERFORMANCE CHARACTERISTIC**

Performance characteristic of the system shall be evaluated with a series of measurements within a short interval of time in accordance with EN ISO 15197:2015.

**Precision**

The acceptable criteria are within standard deviation (STD) 3mg/ dL at the below 100mg/dL(5.55mmol/L), and coefficient of variation(CV) 4% at the above 100mg/dL(5.55mmol/L).

**Repeatability**

Range (mg/dL)	REF (mg/dL)	STD(mg/dL) / CV(%)
30-50	47.8	1.8mg/dL
51 - 110	81.5	2.1mg/dL
111 -150	139.0	3.6%
151-250	212.5	3.5%
251-400	315.0	3.6%

**Intermediate Precision**

< 100mg/dL (5.55mmol/L)	≥ 100mg/dL (5.55mmol/L)	
Level L	Level M	Level H
STD(mg/dL)	CV(%)	CV(%)
1.6mg/dL	3.4%	3.3%

**System Accuracy**

The accuracy of the system was assessed by comparing with the blood glucose test results by YSI 2300 STAT Plus, a glucose laboratory instrument, as the reference. The acceptable criteria for system accuracy are following; 95% of the measured glucose values shall fall within either ±15mg/dL (0.83mmol/L) of the average measured values of the reference measurement procedure at glucose concentrations <100mg/ dL (5.55mmol/L) or within ±15% at glucose concentrations ≥100mg/dL (5.55mmol/L).

Below 100mg/dL (5.55mmol/L)		
Within ±5mg/dL (within ±0.28mmol/L)	Within ±10mg/dL (within ±0.56mmol/L)	Within ±15mg/dL (within ±0.83mmol/L)
100/204 49.0%	185/204 90.7%	200/204 98.0%
Above 100mg/dL (5.55mmol/L)		
Within ±5%	Within ±10%	Within ±15%
290/396 73.2%	376/396 94.9%	394/396 99.5%
Total System Accuracy (35.0-486.5mg/dL (1.94-27.01mmol/L))		
Within ±15mg/dL (0.83mmol/L) or 15%		
594/600 99.0%		

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**PPI1550A01**  
**Rev C (07.05.2022)**

	Catalogue Number		Temperature limit
	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	Batch code		Manufacturer
	Use-by date		Do not use if package is damaged
	Manufacturer fax number		Manufacturer telephone number