

# MediSure®

## Blood Glucose Test Strips

The MediSure® Blood Glucose Test Strips are used with the MediSure® Blood Glucose Meters to quantitatively measure glucose in capillary whole blood.

### INDICATIONS FOR USE:

The MediSure® Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the fingertip. The MediSure® Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

### TEST PRINCIPLE

The measurement is based on amperometric technology. When the blood sample or control solution is drawn into the reaction zone, glucose in the sample reacts with glucose oxidase and produces an electrical current. Your meter measures the electronic current and converts it into your blood glucose result. The results provided will be capillary whole blood equivalent.

### QUALITY CONTROL

You can use the Glucose Control Solution to check the performance of your meter and/or test strips.

#### Material for quality control:

Meter  
Strip  
Glucose Control Solution

#### When do you need the quality control?

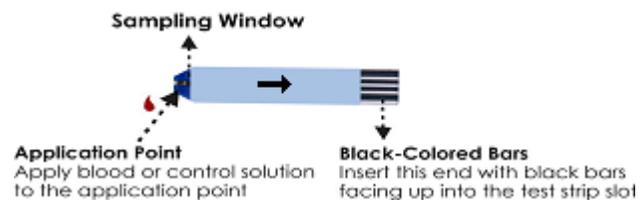
When you open a new vial of test strips.  
If you leave the vial of test strips opened.  
When you drop your meter.

If you have repeated a test, the result is still out of the expected range.  
(Please read your User's Guide for more detailed information.)

### BLOOD SAMPLE COLLECTION

Select the puncture area :

1. Wash the selected puncture site with warm water and soap, rinse well and **DRY** thoroughly.
2. You can also use an alcohol prep. If an alcohol pad is used, the puncture site must be allowed to dry thoroughly before sampling.
3. Hold the lancing device firmly against the side of your finger. Press the release button. To help blood drop form, lower your hand below your waist and gently massaging finger.



### NOTE

1. The blood-borne pathogen (e.g. HBV, HCV, or HIV) will be outbreak if using shared use of medical device.
2. The lancing device is intended to be used by a single person and should not be shared.
3. The meter or lancing device should be cleaned whenever it is visibly dirty. It should be disinfected periodically, such as once per week.
4. Please refer to the section of "How to Clean and Disinfect Your Device in User's Guide for more detailed information.
5. You should wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

### TESTING YOUR BLOOD GLUCOSE

Please read your User's Guide for more detailed information.

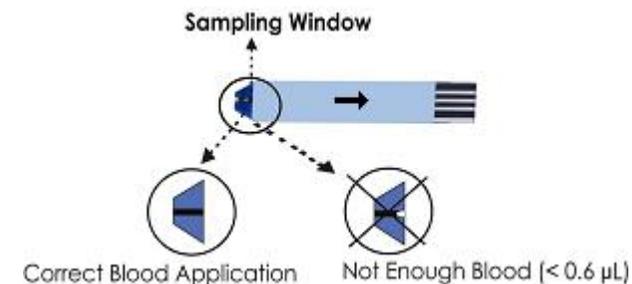
1. Insert a test strip into the test strip slot of your meter.
2. Obtain a good drop of blood from your fingertip.
3. Apply the drop of blood to the application point of the test strip. Allow the blood drop to be drawn into the test

strip until your meter beeps and blood fully fills in the application point.

4. Your test result will appear on the display in 6 seconds.
5. Record the result in your Log Book.
6. Remove the test strip from your meter. Discard the used test strip and lancet.

- The unit of the glucose result is in mmol/L.

### HOW TO ASSESS THAT ENOUGH BLOOD HAS BEEN SAMPLED?



- Look at the sampling window on the test strip. If you have enough blood on the strip, you will not see any white. The sampling window will be completely filled with blood.
- If it doesn't have enough blood, it will look like the one on the right above.

### STORAGE AND HANDLING

1. Store between 36 and 86 °F (2~30°C).
2. Keep away from direct heat and sunlight.
3. Store test strips in their original vial with the cap tightly closed. When taking a test strip out of the vial, replace the vial cap immediately and close it tightly.
4. When you first open the test strip vial, write the date on the vial label. The test strips should be used within 90 days after first opening.
5. Do not use the test strips beyond the expiry date.
6. Do not bend, cut, or alter the test strips in any way.

### CAUTIONS

1. For testing outside the body (*in vitro* diagnostic use)

only.

- The MediSure® Blood Glucose Test Strips are for single use only. Do not reuse.
- To obtain accurate results, only use the MediSure® Blood Glucose Test Strips with the MediSure® Blood Glucose Meters and the Glucose Control Solutions.
- Use the test strip within three minutes after taking it out from the vial or the test strip may get damped, and your result may be wrong.
- Do not use test strips that are wet, scratched, or damaged in any way.
- Do not smear the blood drop onto the application point above the reaction zone of test strips.
- The self-test results are for reference only. Do not change your diabetes control program based on the results without advice of your doctor.

### LIMITATIONS

- Use only fresh capillary blood from the finger. Do not use venous or arterial blood, plasma, or serum.
- Abnormal red blood cell counts (hematocrit levels below 25% and above 60%) may cause inaccurate test results.
- Neonates: Do not use the MediSure® Blood Glucose Test Strips to test neonates. The performance of the MediSure® Blood Glucose Monitoring System has not been validated with neonatal blood.
- Therapeutic levels of acetaminophen, normal to high levels of uric acid and high levels of ascorbic acid / vitamin c in blood may result in inaccurate glucose reading. Blood glucose readings from these cases should be interpreted with caution.
- Therapeutic levels of L-dopa or dopamine may result in inaccurate glucose readings with the system.
- Clinical testing demonstrates that altitude up to 10183 feet (3104 meters) above sea level do not affect results with MediSure® Blood Glucose Monitoring System.
- Not for patients who are dehydrated, in shock or in a hyperosmolar state.
- Critically ill patients should not be tested with blood glucose meters.
- Not intended for the screening or diagnosis of diabetes.

10. For In Vitro Diagnostics use only.

### PERFORMANCE CHARACTERISTICS

Accuracy :

Two different lots of the MediSure® Blood Glucose Test Strips were tested to assess the accuracy of the MediSure® Blood Glucose Monitoring System by comparing to the reference method using venous whole blood concentrations between 1.1 and 41.7 mmol/L. The linear regression correlations are as follows:

Lot	N	Regression equation	R <sup>2</sup>
1	100	Y=1.0106X-1.001	0.9961
2	100	Y=1.0029X-0.4772	0.9970

Y= MediSure® Blood Glucose method

X= Reference Method

The table below was based on a study done on 150 patients to see how well the MediSure® Blood Glucose Monitoring System compared to laboratory results:

Results for glucose concentration < 4.2mmol/L

Within±0.28 mmol/L	Within±0.56 mmol/L	Within±0.83 mmol/L
21/21(100%)	21/21(100%)	21/21(100%)

Results for glucose concentration ≥ 4.2mmol/L

Within±5%	Within±10%	Within±15%	Within±20%
89/129 (69.0%)	129/129 (100%)	129/129 (100%)	129/129 (100%)

Note:

- When meter results are compared to the laboratory results, results below 4.2 mmol/L are compared in mmol/L.
- In the accuracy study, the hematocrit range of the samples is within 25~60%

### Precision:

Two different lots of MediSure® Blood Glucose Test Strips were tested to assess the precision and repeatability of the MediSure® Blood Glucose Monitoring System using capillary whole blood between 1.1 and 41.7 mmol/L. The coefficient of variation for one lot of test strip is shown below:

### Precision table:

Level	Mean (mmol/L)	Within-run precision SD	Between-run precision SD	CV (%)
1	1.7	0.22	0.19	16.2
2	2.8	0.08	0.21	11.9
3	4.1	0.17	0.18	6.0
4	6.7	0.17	0.17	4.5
5	12.1	0.31	0.24	3.2
6	18.4	0.63	0.31	3.7

### REAGENT COMPOSITION

Each cm<sup>2</sup> of the test strip contains the following ingredients:

- Glucose Oxidase (*A. niger*) 8%
- Potassium Ferricyanide 45%
- Buffer 42%
- Non-reactive ingredients 5%

### CONTENTS

Each pack contains test strips and strip instruction.

### ADDITIONAL INFORMATION

- If you have questions or need assistance, please call our Customer Assistance line at (855)634-7873. For customer assistance outside the operational days and times, please contact your health care provider with questions.

### EXPECTED VALUES<sup>1</sup>

Expected blood glucose levels for people without diabetes:		
Time	Range (mg/dL)	Range (mmol/L)
Fasting	< 126	< 7.0
Two hours after meals	< 200	< 11.1

<sup>1</sup> American Diabetes Association: Diabetes Care, Volume 35, Supplement 1, January 2012, S4



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