TEE2 Blood Glucose Test Strips

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IMPORTANT
Please read this information and the *TEE2 brand of blood Glucose Meters Owner's Booklet* before using TEE2 Test Strips.

INTENDED USE AND TEST PRINCIPLE

TEE2 Blood Glucose Test Strips work with the TEE2 brand of Blood Glucose Meters to quantitatively measure glucose in whole blood. The TEE2 brand of Blood Glucose Monitoring system is for self-testing outside the body (*in vitro* diagnostic use). The TEE2 brand of Blood Glucose Monitoring System should not be used for the diagnosis of diabetes or for testing newborns. Glucose in blood samples react with the chemical in the test strip to produce a small electrical current. The TEE2 brand of Blood Glucose Meter detects the electrical current which reflects the amount of glucose in the blood sample.

STORAGE AND HANDLING

- Store vial in a cool and dry place between 1-30˚C (34-86˚F). Do not freeze.
- Keep the vial of test strips away from direct sunlight or heat.
- Store unused test strips in their original vial to avoid damage or contamination.
- Push the lid down on the vial immediately after taking out a test strip to fully close the vial and maintain air tightness.
- Handle test strips only with clean and dry hands.
- Use the test strip immediately after taking it out of the vial.
- Do not bend, cut, or alter the test strips in any way.
- Do not force a test strip into the meter. Gently push it into the meter's test strip port.
- Apply only fresh capillary whole blood for testing.
- Use all of the test strips within the expiration date printed on the test strip box and vial label.
- Dispose of test strips past the expiration date immediately. Using test strips past their expiration date can produce incorrect test results.
- Test strips in new, unopened vials and test strips in vials that have been opened can be used up until the expiration date printed on the test strip box and vial label if the test strips are used according to its storage and handling methods.

WARNINGS AND PRECAUTIONS

- Inaccurate results may occur in patients undergoing oxygen therapy.
- Keep test strips and the test strip vial away from children. The test strips and vial cap may be choking hazards. Drying agents in the vial cap may be harmful if inhaled, swallowed, or may cause skin or eye irritation.
- Test strips are for single use only. Do not reuse.
- If test strip does not absorb the blood sample properly, please contact your authorised i-SENS sales representative.

BLOOD SAMPLE COLLECTION PROCEDURE

Wash hands and sample site with soap and warm water. Rinse and dry thoroughly before beginning blood sample collecting with a lancing device.

Fingertip Site Blood Sampling
Unscrew the lancing device tip. Place the loaded lancing device against the side of the fingertip and press the release button. Massage the fingertip to obtain a round drop (at least 0.5 µL, actual size: ●) of blood. Apply test strip tip to the blood sample.

Alternative Site Blood Sampling
Select a clean, soft and fleshy sample site area free of visible veins, hair, and away from bones. Gently massage the sample site to help blood circulation to minimise result differences between fingertip and alternative site sampling. Firmly press and hold the lancing device against sample site. Wait until the skin surface under the lancing device changes color. Then press the release button while continuing to apply pressure. Keep holding the lancing device against your skin until sufficient (at least 0.5 µL, actual size: ●) amount of blood is drawn. Carefully lift the lancing device away from your skin.

CAUTION

Alternative site and fingertip results may differ significantly due to rapid changes in the glucose level after meals or exercise, hypoglycemic symptoms, or effects of drugs such as insulin. Use a fingertip sample site if you suffer from hypoglycemia or have experienced hypoglycemic shock or symptoms.
For instructions on how to obtain samples from alternative sites, please refer to the Alternative Site Testing(AST) section of the *Owner's Booklet* of your meter.

TEST PROCEDURE

1) Wash hands and sample site with soap and warm water. Rinse and dry thoroughly.
2) Insert test strip with contact bars facing up into the port. Push in strip gently until meter beeps.
3) Then the  or ▲ symbol will appear.
4) Use lancing device to get blood sample. Sample must be at least 0.5 µL (actual size: ●) to fill the test strip confirmation window. When the or ▲ symbol appears on display, apply blood sample to edge of the narrow end of the test strip until the meter beeps. If confirmation window is not filled completely, an Er4 message may appear.
5) Meter will count down from five-to-one (5-to-1) on the display. Test results, time, and date will appear and automatically be stored in the meter's memory. Remove used test strip from port. Meter will turn off after three (3) seconds.

TEST RESULTS

The TEE2 brand of Meters will display results between 1.1-33.3 mmol/L.

Normal Blood Glucose Results
The range of a normal fasting* blood glucose level for non-diabetic adults is between 3.9-5.5 mmol/L. Two (2) hours after a meal, the range of a normal blood glucose level for non-diabetic adults is less than 7.8 mmol/L.[1]
*Fasting is defined as no caloric intake for at least eight (8) hours.

Low Blood Glucose Results
If the test result is below 1.1 mmol/L, **Lo** will appear on the display indicating hypoglycemia (low blood glucose). You should follow the appropriate treatment recommendations of your healthcare professional.

High Blood Glucose Results
If the test result is above 33.3 mmol/L, **HI** will appear on the display to indicate hyperglycemia (high blood glucose). If so, follow hyperglycemia treatment recommendations of your healthcare professional.

Unexpected Results
Low or high blood glucose readings can indicate a potentially serious medical condition. If your results are unusually low or high, or don't match the way you feel, repeat the test with a new test strip. If your reading is inconsistent with your symptoms or your result is less than 3.3 mmol/L or higher than 13.3 mmol/L, contact your healthcare professional.

Please note that:

- An abnormally high or low red blood cell count (hematocrit level over 55% or below 30%) may produce inaccurate results.
- Severe dehydration (excessive water loss) may cause inaccurate results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
- Altitude of up to 3,000m (10,000 ft) above sea level has no effect on the performance of the test strip.
- *Interferences:* Acetaminophen, ascorbic acid (vitamin C), uric acid and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurate high results.
- Blood samples that contain a high concentration of dissolved oxygen may lower the test result.
- Discard used test strips properly in an appropriate container.

METER AND TEST STRIP PERFORMANCE CHECK

The TEE2 Control Solution (Control A and/or B) contains a known amount of glucose that reacts with the TEE2 Test Strip in combination with the TEE2 Brand of Meters to make sure they are working properly together and the correct testing procedure is being followed.
You may run a check when you:
- Want to practice the test procedure using the control solution instead of blood.
- Use the meter for the first time.
- Open a new vial of test strips.
- Have symptoms that are inconsistent with your blood glucose test results.
- Believe your test results are not accurate.
- Suspect your meter and test strips are not performing properly.
- Drop or damage the meter.

If your control solution test results do not fall within the range printed on the test strip vial, repeat the test. Out of range results may be due to one or more of the following factors:
- Error in performing the test.
- Expired or contaminated control solution.
- Expired or damaged test strip.
- Failure to shake control solution bottle.
- Failure to discard first drop of control solution and wipe bottle tip clean.

If results continue to fall outside the range printed on the vial, the Test Strip and Meter may not be working properly. If so, do not use your system and contact your authorised i-SENS sales representative.

CHEMICAL COMPOSITION

Each TEE2 Test Strip contains the following reagents:
Glucose oxidase(Aspergillus sp.): 2.7 units
Hexaammineruthenium(III) chloride: 45.7 µg
Other ingredients: 1.6 µg

PERFORMANCE CHARACTERISTICS

The performance of TEE2 Brand of BGM Systems has been evaluated in laboratory and clinical tests.

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ACCURACY

The TEE2 Brand of BGM system is calibrated to yield results equivalent to plasma glucose concentrations. The accuracy of the TEE2 Brand of BGM Systems was evaluated by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyzer, a laboratory instrument. The following results were obtained by diabetic patients at clinic centers.

Slope	0.9805
Y-intercept	0.01 mmol/L
Correlation coefficient (r)	0.995
Number of sample	100
Range tested	1.3-26.2 mmol/L

Accuracy results for glucose concentration < 5.55 mmol/L

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
86/162 (53.1%)	143/162 (88.3%)	162/162 (100%)

Accuracy results for glucose concentration ≥ 5.55 mmol/L

Within ± 5%	Within ± 10%	Within ± 15%
265/438 (60.5%)	395/438 (90.2%)	436/438 (99.5%)

PRECISION

The precision studies were performed in a laboratory using the TEE2 BGM System.

Within Run Precision		
Blood avg.	2.4 mmol/L	SD = 0.1 mmol/L
Blood avg.	3.9 mmol/L	SD = 0.2 mmol/L
Blood avg.	7.4 mmol/L	CV = 3.5%
Blood avg.	11.3 mmol/L	CV = 2.6%
Blood avg.	19.0 mmol/L	CV = 3.2%
Between Run Precision		
Control avg.	2.1 mmol/L	SD = 0.1 mmol/L
Control avg.	6.2 mmol/L	CV = 2.9%
Control avg.	20.1 mmol/L	CV = 3.2%

This study shows that there could be variation of up to 3.5%.

Reference

1. American Diabetes Association. “Standards of Medical Care in Diabetes – 2016.” *Diabetes Care*. January 2016; 39(1):S15, S100.

DESCRIPTION OF SYMBOLS

	Consult instructions for use
	Temperature limitation
IVD	*In vitro* diagnostic medical device
	Manufacturer
EC REP	Authorised representative
CE	CE mark reg. IVDD 98/79/EC
LOT	Batch code
	Use by (unopened or opened test strip vial)
	Cautions for safety and optimum product use
	Do not reuse

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