CareSens™ PRO Blood Glucose Test Strips

PGL5E0100 REV1 06/2016

IMPORTANT
Please read this information and the CareSens PRO / CareSens Dual *Owner's Booklet* before using the CareSens PRO Test Strips.

INTENDED USE AND TEST PRINCIPLE

CareSens PRO Blood Glucose Test Strips work with the CareSens PRO / CareSens Dual Blood Glucose Meters to quantitatively measure glucose in whole blood. The CareSens PRO / CareSens Dual Blood Glucose Monitoring Systems are for self-testing outside the body (*in vitro* diagnostic use). The CareSens PRO / CareSens Dual Blood Glucose Monitoring Systems should not be used for the diagnosis of diabetes. Glucose in blood samples reacts with the chemical in the test strip to produce a small electrical current. The CareSens PRO / CareSens Dual Blood Glucose Meters detect 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. 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. Fresh venous whole blood may also be used only if drawn by healthcare professionals.
- Use all of the test strips within the expiration date printed on the test strip box and vial label.
- Use test strips within twelve (12) months of opening the vial. Record the discard date (the date the vial was opened plus twelve (12) months) on the vial label.
- Dispose of test strips past the expiration or discard date immediately. Using test strips past their expiration or discard date can produce incorrect test results.

WARNINGS AND PRECAUTIONS

- 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 or swallowed, and may cause skin or eye irritation.
- Test strips are for single use only. Do not reuse.
- If the 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 collecting the blood sample 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 0.4 µL, actual size: ●) of blood. Apply test strip tip to the blood sample.

Alternative Site Blood Sampling (forearm, palm)

Select a clean, soft and fleshy sample site area free of visible veins and 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 0.4 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 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 the test strip into the port with contact bars facing upwards. Push the strip in gently until the meter beeps.
3) The blood insertion symbol will appear. For control solution testing, activate the Control Solution Test Mode by pressing and holding the ▶ button on the meter for 3 seconds.
4) Use lancing device to get blood sample. Sample must be at least 0.4 µL (actual size: ●) to fill the test strip confirmation window. When the blood insertion symbol appears on display, apply blood sample to edge of the narrow end of the test strip until the meter beeps. If the 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 result, 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 CareSens PRO / CareSens Dual Meters will display blood glucose test results between 20 and 600 mg/dL (1.1 and 33.3 mmol/L).

Normal Blood Glucose Results

The range of a normal fasting* blood glucose level for non-diabetic adults is between 70-99 mg/dL (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 140 mg/dL (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 20 mg/dL (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 600 mg/dL (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 high or low, or do not 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 60 mg/dL (3.3 mmol/L) or higher than 240 mg/dL (13.3 mmol/L), contact your healthcare professional.

Please note that:

- An abnormally high or low red blood cell count (hematocrit level over 65% or below 15%) 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 3,000 m (10,000 ft) above sea level has no effect on the performance of the test strip.
- *Interferences:* Paracetamol, 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.
- Discard used test strips properly in an appropriate container.

METER AND TEST STRIP PERFORMANCE CHECK

The CareSens PRO Control Solution (Control L and/or H) contains a known amount of glucose that reacts with the CareSens PRO Test Strip in combination with the CareSens PRO / CareSens Dual 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 CareSens PRO 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 CareSens PRO Test Strip contains the following reagents:

- FAD Glucose Dehydrogenase (*Aspergillus sp.*): 3.4 units
- Mediator: 9.2 µg
- Nonreactive ingredients: 31.5 µg

CareSens™ PRO Blood Glucose Test Strips

PERFORMANCE CHARACTERISTICS

The performance of CareSens PRO BGM Systems has been evaluated in laboratory and in clinical tests.

ACCURACY

CareSens PRO BGM Systems are calibrated to yield results equivalent to plasma glucose concentrations. The accuracy of the CareSens PRO BGM Systems was assessed 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	0.9871
y-intercept	9.504 mg/dL (0.528 mmol/L)
Correlation coefficient (r)	0.9926
Number of sample	600
Range tested	32.4-606 mg/dL (1.8-33.7 mmol/L)

Accuracy results for glucose concentration < 100 mg/dL (5.5 mmol/L)

Within ± 5 mg/dL Within ± 0.28 mmol/L	Within ± 10 mg/dL Within ± 0.56 mmol/L	Within ± 15 mg/dL Within ± 0.83 mmol/L
89/150 (59.3%)	140/150 (93.3%)	150/150 (100%)

Accuracy results for glucose concentration ≥ 100 mg/dL (5.5 mmol/L)

Within ± 5%	Within ± 10%	Within ± 15%
180/450 (40.0%)	352/450 (78.2%)	442/450 (98.2%)

PRECISION

Precision studies were performed in a laboratory using the CareSens PRO BGM Systems.

Within Run Precision		
Blood avg.	41 mg/dL (2.3 mmol/L)	SD = 2.2 mg/dL (0.1 mmol/L)
Blood avg.	73 mg/dL (4.1 mmol/L)	SD = 2.3 mg/dL (0.1 mmol/L)
Blood avg.	124 mg/dL (6.9 mmol/L)	CV = 3.2%
Blood avg.	182 mg/dL (10.1 mmol/L)	CV = 3.0%
Blood avg.	316 mg/dL (17.6 mmol/L)	CV = 2.2%

Total Precision		
Control avg.	35 mg/dL (1.8 mmol/L)	SD = 1.9 mg/dL (0.1 mmol/L)
Control avg.	112 mg/dL (6.9 mmol/L)	CV = 3.4%
Control avg.	319 mg/dL (19.4 mmol/L)	CV = 3.7%

This study shows that there could be a variation of up to 3.7 %.

For the performance data of all other models, please refer to your meter manual. The model number can be found on the back of your meter.

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
CE	CE Mark reg. IVDD 98/79/EC
LOT	Batch code
	Use by
	Cautions for safety and optimum product use
	Do not reuse
EC REP	Authorised representative

i-SENS, Inc.
43, Banpo-daero 28-gil,
Seocho-gu, Seoul 06646, Korea
www.i-sens.com

EC REP Medical Technology Promedt Consulting GmbH
Altenhofstrasse 80, D-66386
St. Ingbert, Germany

CE 0123 IVD