INTENDED USE AND TEST PRINCIPLE
CareSens N Blood Glucose Test Strips work with the CareSens N Brand of Blood Glucose Meters to quantitatively measure glucose in whole blood. The CareSens N Brand of Blood Glucose Monitoring Systems* should not be used for the diagnosis of diabetes or for testing newborns. Glucose in blood samples reacts with the chemical in the test strip to produce a small electrical current. The CareSens N Brand of Blood Glucose Meters detect the electrical current which reflects the amount of glucose in the blood sample.

* CareSens N Brand of BGMS: CareSens N, CareSens N POP, CareSens N Voice, CareSens N Mini, CareSens N NFC, CareSens N Premier

TEST PROCEDURE
1) Use lancing device to get blood sample. Sample must be at least 0.5 µL (actual size: 5 µL). Apply test strip tip to the blood sample.
2) Insert the test strip into the port with contact bars facing upwards. Push the strip in gently until the meter beeps.
3) The or symbol will appear. If the test result is above 600 mg/dL (33.3 mmol/L), will appear on the display to indicate hyperglycemia (high blood glucose). Follow the appropriate treatment recommendations of your healthcare professional.
4) Wash hands and sample site with soap and warm water. Rinse and dry thoroughly before collecting the blood sample with a lancing device.

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 0.5 µL, actual size: 5 µL). Apply test strip tip to the blood sample.

Alternative Site Blood Sampling (forearm and 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 0.5 µL, actual size: 5 µL). 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 RESULTS
If the test result is below 20 mg/dL (1.1 mmol/L), 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). Follow the appropriate 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.

• Blood samples that contain a high concentration of dissolved oxygen may lower the test result.

• Discard used test strips properly in an appropriate container.

**The hematocrit range may vary depending on the meter model. Please refer to the meter manual for the corresponding range.

METER AND TEST STRIP PERFORMANCE CHECK
The CareSens Control Solution (Control A and/or B) contains a known amount of glucose that reacts with the CareSens N Test Strip in combination with the CareSens N 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 CareSens N Test Strip and Meter may not be working properly. If so, do not use your system and contact your authorised i-SENS sales representative.
CareSens™ N Blood Glucose Test Strips

CHEMICAL COMPOSITION
Each CareSens N Test Strip contains the following reagents:
- Glucose oxidase (Aspergillus sp.): 2.7 units
- Hexammineruthenium(III)chloride: 45.7 μg
- Other ingredients: 1.6 μg

PERFORMANCE CHARACTERISTICS
The performance of CareSens N Brand of BGM Systems has been evaluated in laboratory and in clinical tests.

ACCURACY
CareSens N BGM Systems are calibrated to yield results equivalent to plasma glucose concentrations. The accuracy of the CareSens N BGM Systems (Model GM505PAD, GM505PBD, GM505PCD) 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.

<table>
<thead>
<tr>
<th>CareSens N</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Slope</td>
<td>0.946</td>
</tr>
<tr>
<td>Y-intercept</td>
<td>6.696 mg/dL (0.37 mmol/L)</td>
</tr>
<tr>
<td>Correlation coefficient (r)</td>
<td>0.994</td>
</tr>
<tr>
<td>Number of samples</td>
<td>600</td>
</tr>
<tr>
<td>Range tested</td>
<td>25.5-487 mg/dL (1.6-27.1 mmol/L)</td>
</tr>
</tbody>
</table>

Accuracy results for glucose concentration < 100 mg/dL (5.55 mmol/L)

<table>
<thead>
<tr>
<th></th>
<th>Within ± 5 mg/dL</th>
<th>Within ± 10 mg/dL</th>
<th>Within ± 15 mg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood avg.</td>
<td>100/186 (53.8%)</td>
<td>169/186 (90.9%)</td>
<td>180/186 (96.8%)</td>
</tr>
<tr>
<td>SD</td>
<td>2.0 mg/dL (0.1 mmol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CV</td>
<td>3.6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood avg.</td>
<td>121 mg/dL (6.7 mmol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CV</td>
<td>3.6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood avg.</td>
<td>174 mg/dL (9.7 mmol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CV</td>
<td>2.8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood avg.</td>
<td>303 mg/dL (16.8 mmol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CV</td>
<td>3.2%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Accuracy results for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)

<table>
<thead>
<tr>
<th></th>
<th>Within ± 5%</th>
<th>Within ± 10%</th>
<th>Within ± 15%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control avg.</td>
<td>266/414 (64.3%)</td>
<td>395/414 (95.4%)</td>
<td>409/414 (98.8%)</td>
</tr>
</tbody>
</table>

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

**Within Run Precision**

| Blood avg. | 37 mg/dL (2.1 mmol/L) | SD = 2.0 mg/dL (0.1 mmol/L) |
| Blood avg. | 57 mg/dL (3.2 mmol/L) | SD = 2.2 mg/dL (0.1 mmol/L) |
| Blood avg. | 121 mg/dL (6.7 mmol/L) | CV = 3.6% |
| Blood avg. | 174 mg/dL (9.7 mmol/L) | CV = 2.8% |
| Blood avg. | 303 mg/dL (16.8 mmol/L) | CV = 3.2% |

**Between Run Precision**

| Control avg. | 39 mg/dL (2.2 mmol/L) | SD = 1.5 mg/dL (0.1 mmol/L) |
| Control avg. | 121 mg/dL (6.7 mmol/L) | CV = 3.5% |
| Control avg. | 318 mg/dL (17.7 mmol/L) | CV = 2.6% |

This study shows that there could be a variation of up to 3.6%.

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

DESCRIPTION OF SYMBOLS

- ![Consult instructions for use](image)
- ![Temperature limitation](image)
- ![In vitro diagnostic medical device](image)
- ![Manufacturer](image)
- ![CE Mark reg. IVDD 98/79/EC](image)
- ![Batch code](image)
- ![Use by (unopened or opened test strip vial)](image)
- ![Cautions for safety and optimum product use](image)
- ![Do not reuse](image)
- ![Authorised representative](image)

- No part of this document may be reproduced in any form or by any means without the prior written consent of i-SENS.
- The information in this manual is correct at the time of printing. However, i-SENS reserves the right to make any necessary changes at any time without notice as our policy is one of continuous improvement.