

User Manual

INDEX

01 Preparing Lancing Device for Blood Sampling	2
02 Using Lancing Device at Fingertip Sample Site	3
03 Testing Your Blood Glucose Level	4
04 Viewing Test Results in Meter Memory	6
05 Checking the System	6
06 "HI" and "Lo" Messages	8
07 Error Messages and Troubleshooting	10
08 Replacing Battery	11
09 Please Note	12
10 CareSens N Mini Blood Glucose Monitoring System Specifications	13
11 Warranty Information	14

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01 Preparing Lancing Device for Blood Sampling



Step1
Wash your hands and the sample site with soap and warm water. Rinse and dry thoroughly.



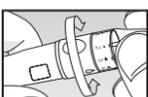
Step2
Unscrew and remove the adjustable tip.



Step3
Insert a new disposable lancet firmly into the carrier.



Step4
Twist off and set aside the protective cover of the disposable lancet and replace the adjustable tip.



Step5
Choose a depth of penetration by rotating the top portion of the adjustable tip until the setting number matches the arrow.

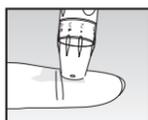


Step6
To cock the lancing device, hold the tip in one hand. Pull the sliding barrel on with the other hand. The lancing device is cocked when you feel a click.

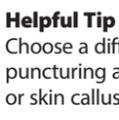
Helpful Tip

The skin depth varies for various people at different sample sites. The lancing device adjustable tip allows the best depth of skin penetration for an adequate sample size. A beginning setting of three (3) is recommended.

02 Using Lancing Device at Fingertip Sample Site



Step1
Place the cocked lancing device against the pad of the finger. The best puncture sites are on the middle or ring fingers.



Step2
Press the release button. Remove the device from the finger. Wait a few seconds for a blood drop to form.

- The lancing device should be used by one individual.
- Use a soft cloth or tissue to wipe the lancing device. If necessary, a small amount of alcohol on a soft cloth or tissue may be used.

03 Testing Your Blood Glucose Level



Step1
Insert a test strip with contact bars facing up into the test strip port. Push the strip gently until the meter beeps. Then the symbol will appear.



Step2
Use your lancing device to get blood sample. A minimum volume of 0.5 microliter is needed to fill the confirmation window (actual size of 0.5 µL : ●). After the symbol appears on the screen, apply the blood sample to the narrow end of the test strip until the meter beeps.

To avoid infection when drawing a sample, use a lancet only one time, and :

- Do not use a lancet that has been used by others.
- Always use a new sterile lancet.
- Keep the lancing device clean.



If the confirmation window is not filled in time because of abnormally high viscosity or insufficient volume, Er4 message will appear.

NOTE

If the test strip does not take in the blood sample, please contact your authorized i-SENS sales representative.



Step3

The test result will appear after the meter counts down from 5 to 1. The result will be automatically stored in the meter's memory. If the test strip is removed after the test result is displayed, the meter will automatically switch off after 3 seconds. Discard used test strips safely in biohazard containers.

NOTE

The meter may switch off if the blood sample is not applied within 2 minutes of the symbol appearing on the screen. If the meter turns off, remove the strip and reinsert it, and apply the blood sample after symbol appears on the screen.

NOTE

Results from alternative site and fingertip samples may appear different as there is a time lag for the glucose levels to reach the same value. Use a fingertip for drawing if you suffer from hypoglycemia or have experienced hypoglycemic shock or symptoms.

NOTE

If the sample drop of blood runs or spreads due to contact with hair or with a line in your palm, do not use that sample. Try puncturing again in a smoother area.

04 Viewing Test Results in Meter Memory

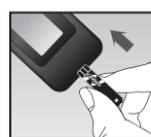
The meter memory can store up to ten (10) results at one time. The results will be saved in the order it was measured, and you can view stored results by pushing the button. When the button is pushed, number "1" will appear on the screen for one second, and then the result will be shown. This is the most recent test result that is saved in the memory. To go on to the second recent result, press the button again. Now number "2" will appear for one second and the next result will be displayed. By repeating this process, you can go through to result number 10 which is the oldest data saved in the memory.

To exit from the memory mode, press and hold down the button for about two (2) seconds. The meter will turn off.

05 Checking the System

You may check your meter and test strips using the CareSens Control Solution(control A and/or B).

Control Solution Testing



Step1
Insert a test strip into the meter's test strip port, with the contact bars facing upwards until the meter beeps. Be careful not to bend the strip while pushing it in. The symbol will be displayed on the screen.



Step2

Shake the CareSens Control Solution bottle before each test. Remove the cap and squeeze the bottle to discard the first drop. Then wipe the tip with a clean tissue or cloth. After the symbol appears on the display, apply the solution to the narrow edge of the test strip until the meter beeps. Make sure the confirmation window fills completely.



NOTE

The meter may switch off if the control solution drop is not applied within 2 minutes of the symbol appearing on the screen. If the meter turns off, remove the strip, reinsert it. Then start from step 1.

Step3

A test result will appear after the meter counts down from 5 to 1.



Step4

Compare the result displayed on the meter to the range printed on the test strip vial. The result should fall within that range. Used strips should be discarded safely in biohazard containers.

Caution

The range printed on the test strip vial is for the CareSens Control Solution only. It does not have any connection to your blood glucose level.

CareSens Control Solution Storage and Handling

For accurate results:

- Close the control solution bottle tightly and store at a temperature of 8-30°C/46-86°F.
- Do not refrigerate or freeze.
- Make sure your meter, test strips, and control solution are at room temperature before testing. Control solution tests must be done at room temperature (20-25°C/68-77°F).

The CareSens Control Solution can be purchased separately. Please contact your authorized i-SENS sales representative.

06 "HI" and "Lo" Messages

The CareSens N Mini Meter displays test results between 20 to 600 mg/dL (1.1-33.3 mmol/L), and a "HI" or "Lo" message outside this range.



HI Message

If your test result is above 600 mg/dL (33.3 mmol/L), "HI" appears on the display. A test result above 600 mg/dL (33.3 mmol/L) indicates hyperglycemia (high blood glucose).



Lo Message

If your test result is below 20 mg/dL (1.1 mmol/L), "Lo" will appear on the display. This indicates hypoglycemia (low blood glucose).

✖ If a "Lo" message blinks when the meter is turned on or a test strip is inserted, it means the battery needs to be replaced. It may also appear when the meter battery seems temporarily discharged due to exposure to cold or low temperature. Take the meter to an area where the temperature is within the operating range (10-40°C/50-104°F) and repeat the test after the meter and test strips have reached a temperature within the operating range.

If you get a "HI" or "Lo" message, repeat the test. If the "HI" or "Lo" message is displayed again on retesting, please contact your healthcare professional immediately.

If "HI" or "Lo" message appear irrespective of your condition, contact your authorized i-SENS sales representative.

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.

07 Error Messages and Troubleshooting



A used test strip was inserted.
→ Repeat the test with a new test strip.



The blood or control solution sample was applied before the symbol appeared.
→ Repeat the test with a new test strip and wait until the symbol appears before applying the blood sample.



The temperature during the test was above or below the operating range.
→ Move to an area where the temperature is within the operating range(10-40°C/50-104°F) and repeat the test after the meter and test strips have reached a temperature within the operating range.



The blood sample has abnormally high viscosity or is insufficient.
→ Repeat the test after inserting a new test strip.



This error message may appear when the wrong blood glucose test strip is used instead of CareSens N blood glucose test strip.
→ Repeat the test with a CareSens N test strip.



There is a problem with the meter.
→ Do not use the meter. Contact your authorized i-SENS sales representative.

08 Replacing Battery

If "Lo" message blinks when the meter is turned on or a test strip is inserted, it means there is not enough power for tests. So, the battery needs to be changed. Use only non-rechargeable, replaceable, type CR2032 lithium battery with 3 V nominal voltage, 220 mAh nominal capacity, and a 0.2 mA nominal standard discharge.



Step1

To replace the battery, make sure that the meter is turned off. Turn the meter over, press down slightly and push the battery compartment cover in the direction of arrow shown to remove it.



Step2

Remove the old battery by gently pushing the edge of the battery. Insert a new battery and make sure the positive (+) side of the battery is facing up.

✖The meter will not operate if the battery is placed upside down.



Step3

Place the cover over the battery compartment. Push it down until you hear the tab click into place.

Caution

There is a risk of explosion if the battery is replaced with an incorrect type. Please dispose of the used battery according to your local regulations.

09 Please Note

The unit of measurement is fixed.

Caring for the Meter

- Do not expose the meter to direct sunlight or heat for an extended period of time.
- Prevent the entry of dirt, dust, blood or water at the meter's test strip port.
- Do not drop the meter or submit it to strong shocks.
- Do not try to fix or alter the meter in any way.
- Keep the meter away from strong electromagnetic fields such as cell phones and microwave ovens.
- Keep the meter in a cool and well ventilated place.

CareSens N Mini BGM System Components

- CareSens N Mini Blood Glucose Meter
- CareSens N Blood Glucose Test Strips
- Lancing Device
- User Manual
- Quick Reference Guide
- Battery
- Lancets
- Carrying Case

- Certain components may not be included depending on the place of purchase.
- Check all the components after opening the CareSens N Mini Blood Glucose Monitoring System package. The exact contents are listed on the main box.
- Please contact your authorized i-SENS sales representative if any component is missing or damaged.

The device can be sent back to the manufacturer for recycling or proper disposal after its useful life. Alternatively the device should be disposed in accordance with national laws after its useful life.

10 CareSens N Mini Blood Glucose Monitoring System Specifications

- Model : GM505VAA
- Test Range : 20-600 mg/dL (1.1-33.3 mmol/L)
- Sample Size : Minimum 0.5 µL
- Test Time : 5 seconds
- Test Sample : Fresh capillary whole blood
- Calibration : Plasma-equivalent
- Assay Method : Electrochemical
- Operating Range
Temperature : 10-40°C/50-104°F
Relative Humidity : 10-90%
Hematocrit : 20-60%

11 Warranty Information

Manufacturer's Warranty
i-SENS, Inc. warrants that the CareSens N Mini Meter shall be free of defects in material and workmanship in normal use for a period of five (5) years. The meter must have been subjected to normal use. The warranty does not cover tampering, improper handling, use, or service of the meter. Any claim must be made within the warranty period. The i-SENS company will, at its discretion, repair or replace a defective meter or meter part that is covered by this warranty. As a matter of warranty policy, i-SENS will not reimburse the consumer's purchase price.

Obtaining Warranty Service
To obtain warranty service you must return the defective meter or meter part along with proof of purchase to your authorized i-SENS sales representative.



Strip information

IMPORTANT
Please read this information and the CareSens N Mini User Manual before using CareSens N Test Strips.

INTENDED USE AND TEST PRINCIPLE
The CareSens N Test Strips work with the CareSens N Mini Blood Glucose Meter to quantitatively measure glucose in capillary whole blood. The CareSens N Mini Blood Glucose Monitoring Systems are for self-testing outside the body (*in vitro* diagnostic use). The CareSens N Mini Blood Glucose Monitoring Systems should not be used for the diagnosis of diabetes or for testing newborns. The glucose in a blood sample mixes with special test strip chemicals where a small electrical current is produced. The CareSens N Mini 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 vials of test strips away from direct sunlight or heat.
• Store unused test strips in their original vials to

- avoid damage or contamination.
- Close the vials tight immediately after taking out a test strip in order to maintain airtightness. Exposing test strips to humidity for a long period of time can produce incorrect test results even if the test strips are new.
- 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 because 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 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 or 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 authorized i-SENS sales representative.

- Please note that:**
- An abnormally high or low red blood cell count (hematocrit level over 60% or below 20%) may produce inaccurate results.
 - Severe dehydration (excessive water loss) may cause false low results. If you believe you are suffering from severe dehydration, consult your physician immediately.
 - There is no effect from altitude up to 3,000 m (10,000 ft) above sea level.

METER AND TEST STRIP PERFORMANCE CHECK
The CareSens Control Solution contains a known amount of glucose that reacts with the CareSens N Test Strip in combination with the CareSens N Mini Meter to make sure they are working properly together and the correct testing procedure is being followed.

- You may run a check with the control solution 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 properly performing.

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 test strip vial, the CareSens N Test Strip and Meter may not be working properly. If so, do not use your system and contact your authorized i-SENS sales representative.

CHEMICAL COMPOSITION
• Glucose oxidase : 2.7 units
• Hexaamineruthenium(III) chloride : 45.7 µg
• Other ingredients : 1.6 µg

PERFORMANCE CHARACTERISTICS
The performance of CareSens N Mini BGM System has been tested in laboratory and clinical studies. The testing range of the CareSens N Mini BGM System is 20-600 mg/dL (1.1-33.3 mmol/L).

ACCURACY
The accuracy of the CareSens N Mini BGM System (Model GM505VAA) 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. The results were:

• Slope -----	1.0132
• Y-intercept -----	1.0053 mg/dL (0.0559 mmol/L)
• Correlation coefficient(r) --	0.9864
• Number of Sample -----	600
• Range tested -----	33-455 mg/dL (1.8333–25.278 mmol/L)

Accuracy results for glucose concentration < 75 mg/dL (4.2 mmol/L)
CareSens N Mini (Model GM505VAA)

Within ± 5 mg/dL (Within ± 0.28 mmol/L)	71/84 (85%)
Within ± 10 mg/dL (Within ± 0.56 mmol/L)	84/84 (100%)
Within ± 15 mg/dL (Within ± 0.83 mmol/L)	84/84 (100%)

Accuracy results for glucose concentration ≥ 75 mg/dL (4.2 mmol/L)
CareSens N Mini (Model GM505VAA)

Within ± 5%	268/516 (52%)
Within ± 10%	461/516 (89%)
Within ± 15%	511/516 (99%)
Within ± 20%	516/516 (100%)

PRECISION
The precision studies were performed in a laboratory using CareSens N Mini BGM Systems.

Within Run Precision

• Blood avg. ----	35 mg/dL (1.9 mmol/L) SD = 1.9 mg/dL (0.1 mmo/L)
• Blood avg. ----	83 mg/dL (4.6 mmol/L) SD = 2.3 mg/dL (0.1 mmo/L)
• Blood avg. ----	128 mg/dL (7.1 mmol/L) CV = 3.5%
• Blood avg. ----	288 mg/dL (16.0 mmol/L) CV = 3.3%
• Blood avg. ----	347 mg/dL (19.3 mmol/L) CV = 2.7%

Total Precision

• Control avg. -----	37 mg/dL (2.1 mmol/L) SD = 1.7 mg/dL (0.1 mmol/L)
• Control avg. -----	122 mg/dL (6.8 mmol/L) CV = 2.8%
• Control avg. -----	394 mg/dL (21.9 mmol/L) CV = 3.1%

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.

	For <i>in vitro</i> diagnostic use
	Consult instruction for use
	Manufacturer
	Do not reuse
	Temperature limitations
	Use by (unopened or opened test strip vials)
	Batch code
	Serial number
	Do not discard this product with other household-type waste

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