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 PGA1E3303 REV2 11/2012 CE 0123 IVD

The Biosensor Expert

Owner's Booklet

CareSens™ N

Blood Glucose Monitoring System

No Coding
Easy & Accurate Testing

0.5 μL
Very Small Sample
(● : actual size shown)

5 Sec
Rapid Test Result

Welcome to the CareSens N Blood Glucose Monitoring System

Thank you for purchasing the CareSens N Blood Glucose Monitoring System. The system provides you with safe, fast, and convenient blood glucose *in vitro* (i.e., outside the body) diagnostic monitoring. You can obtain accurate results in just 5 seconds with a small (0.5 µL) blood sample.

Table of Contents

Important Information:Read this First!

To receive safe and optimum system benefits, please read the entire manual contents before using the system. Please note the following instructions:

Intended use:
CareSens N Blood Glucose Monitoring System is used for the quantitative measurement of the glucose level in capillary whole blood as an aid in monitoring diabetes management effectively at home or in clinical settings.
CareSens N Blood Glucose Monitoring System should be used only for self-testing outside the body (*in vitro* diagnostic use only).
CareSens N Blood Glucose Monitoring System should not be used for the diagnosis of diabetes or for testing newborns.
Testing sites include the traditional fingertip testing along with alternate sites testing on forearm, palm, thigh and calf.

The following chart explains the symbols you'll find in the CareSens N Owner's Booklet, product packaging, and product inserts.

For *in vitro* diagnostic use

This product fulfills the requirements for Directive 98/79/EC on *in vitro* diagnostic medical devices


Cautions for safety and optimum product use


Consult instruction for use


Do not discard this product with other household-type waste


Use by (unopened or opened test strip vial)


Manufacturer


Do not reuse

Serial number


Temperature limitations

Batch code

Authorized representative

Important Information

- The CareSens N Blood Glucose Monitoring System is intended for self-testing outside the body (*in vitro* diagnostic use).
- The glucose in the blood sample mixes with special chemicals on the test strip to produce a small electrical current. The CareSens N meter detects this electrical current and measures the amount of glucose in the blood sample.
- The CareSens N Blood Glucose Meter is designed to minimize code related errors in monitoring by using the no-coding function.
- The CareSens N Blood Glucose Meter should be used only with the CareSens N Strip.
- An abnormally high or low red blood cell count (hematocrit level over 60% or below 20%) may produce inaccurate results.
- If your test result is below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), consult a healthcare professional immediately.
- Inaccurate results may occur in severely hypotensive (having low blood pressure) individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic (high blood sugar) or hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.

If you need assistance, please contact your authorized i-SENS sales representative or visit www.i-sens.com for more information.

- **Product specifications**

Reported result range	20-600 mg/dL (1.1-33.3 mmol/L)
Sample size	Minimum 0.5 µL
Test time	5 seconds
Sample type	Fresh capillary whole blood
Calibration	Plasma-equivalent
Assay method	Electrochemical
Battery life	1,000 tests
Power	Two 3.0 V lithium batteries (disposable, type CR2032)
Memory	250 test results
Size	93 X 47 X 15 (mm)
Weight	51.5 g (with batteries)

- **Operating ranges**

Temperature	10-40˚C (50-104˚F)
Relative humidity	10-90%
Hematocrit	20-60%

CareSens N BGM System includes the following items:
* CareSens N Blood Glucose Meter
* Owner's Booklet
* Quick Reference Guide
* Carrying Case
* Batteries

CareSens N BGM System may include the following items:
* CareSens N Blood Glucose Test Strips
* Lancets
* Lancing Device
* Logbook

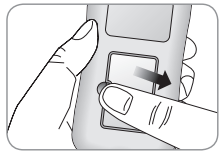
- Check all the components after opening the CareSens N blood glucose monitoring system package. The exact contents are listed on the main box.
- The cable for data transmission can be ordered separately. Please contact your authorized i-SENS sales representative.

Inserting or Replacing the Batteries

The CareSens N Meter comes with two 3.0 V lithium batteries. Before using the meter, check the battery compartment and insert batteries if empty.
When using your meter and seeing the -•- symbol appear on the display for the first time, the batteries should be replaced as soon as possible. The test results might not be saved if the batteries run out.

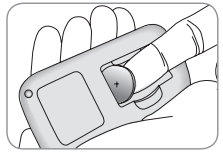
Step 1

Make sure the meter is turned off. Push the cover in the direction of the arrow to open the battery compartment.



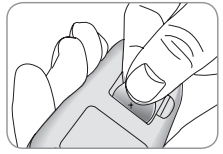
Step 2

Remove the old batteries one by one by lifting with the index finger and pulling it out with your thumb and index fingers as shown in the figure on the right. Insert two new batteries with the + side facing up and make sure the batteries are inserted firmly.



Step 3

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



Note: Removing the meter batteries will not affect your stored result. However, you may need to reset your meter settings. See pages 14-16.

Caring for Your System

Use a soft cloth or tissue to wipe the meter exterior. If necessary, the soft cloth or tissue might be dipped in a small amount of alcohol.

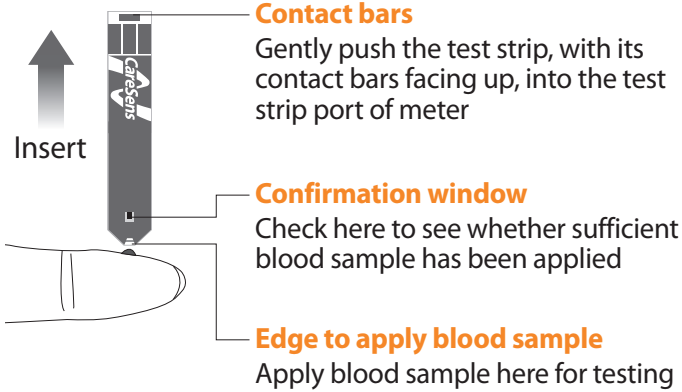
Do not use organic solvents such as benzene, or acetone, or household and industrial cleaners that may cause irreparable damage to the meter.

Caution:

- Do not expose the meter to direct sunlight or heat for an extended period of time.
- Do not let dirt, dust, blood, or water enter into 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.
- CareSens N meter should be used only with CareSens N strips.
- Keep the meter in a cool and well ventilated place.
- Store all the meter components in the portable case to prevent loss.

CareSens N Blood Glucose Test Strip

The CareSens N blood glucose monitoring system measures blood glucose quickly and accurately. It automatically absorbs the small blood sample applied to the narrow edge of the strip.



Contact bars
Gently push the test strip, with its contact bars facing up, into the test strip port of meter

Confirmation window
Check here to see whether sufficient blood sample has been applied

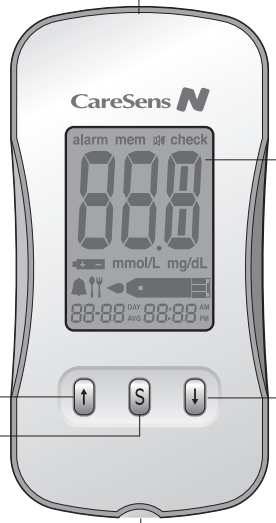
Edge to apply blood sample
Apply blood sample here for testing

Warning!

- The CareSens N Test Strip should be used only with fresh capillary whole blood samples.
- Do not reuse test strips.
- Do not use test strips past the expiration date.
- 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.
- Store test strips in a cool and dry place at a temperature of 1-30˚C (34-86˚F).
- Keep test strips away from direct sunlight or heat and do not freeze.
- Store test strips only in their original vial.
- Close the vial tightly after taking out a test strip for testing and use the strip immediately.
- Handle test strips only with clean and dry hands.
- Do not bend, cut, or alter test strips in any way.
- For detailed storage and usage information, refer to the CareSens N Test Strip package insert.

Caution: Keep the meter and testing supplies away from young children.

CareSens N Blood Glucose Meter



Data Port
Used to transfer data from the meter to a computer with a cable

Display
Shows results, messages

⬆ Button
Selects or changes information

⬇ Button
Selects or changes information

S Button
Turns the meter on/off and confirms menu selections

Test Strip Port
Insert test strip here

Note: The cable for data transmission to PC can be ordered separately. Please contact your authorized i-SENS sales representative.

CareSens N Blood Glucose Meter Display

mem
appears when test results stored in the memory are displayed

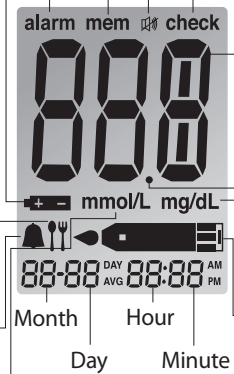
alarm
appears when the time alarm has been set

Battery symbol
indicates meter battery is running low and needs to be replaced

Post-meal test mark
appears during post-meal testing and when post-meal test results are displayed

Alarm symbol
appears when the post-meal alarm has been set

mmol/L
unit for measuring blood glucose



Mute symbol
appears only when the sound is set to OFF

check
means test results have not been saved

Test results
test results displaying panel

Decimal point
appears when the blood glucose measuring unit is set to mmol/L

mg/dL
unit for measuring blood glucose

Blood insertion symbol
indicates meter is ready for the application of a drop of blood or control solution

Note: The unit on the meter may be fixed for your meter, so that you will not be able to change the unit of measurement.

Press and hold the **S** button for 3 seconds to switch on the meter. After all settings are finished, press and hold the **S** button for 3 seconds to turn off the meter.
Press ⬆ or ⬇ to reach the accurate value. Press and hold ⬇ to scroll faster.

Adjusting the Date, Time and Unit

Step 1 Entering the SET Mode

Press and hold the **S** button for 3 seconds to switch on the meter. After all the segments flash across the screen, the 'SET' character will be displayed on the screen. Press the **S** button again to progress onto the next step.

Step 2 Setting the Year

Press and release ⬆ or ⬇ to adjust until the correct year appears. Press and hold ⬇ button to scroll through the numbers quickly. After setting the year, press the **S** button to confirm your selection and progress onto the next step.

Step 3 Setting the Month

A number indicating the month will be blinking on the left corner of the screen. Press ⬆ or ⬇ until the correct month appears. Press the **S** button to confirm your selection and progress onto the next step.

Step 4 Setting the Date

Press ⬆ or ⬇ until the screen displays the correct date. Press the **S** button to confirm the date and progress onto the next step.

Step 5 Setting the Time

The meter can be set in the AM/PM 12-hour or the 24-hour clock format. Press ⬆ or ⬇ to select a format. The AM/PM symbol is not displayed in the 24-hour format.
After selecting the format, press the **S** button to progress onto the next step.

Step 6 Setting the Hour

Press ⬆ or ⬇ until the correct hour appears. After the hour is set, press the **S** button to progress onto the next step.

Step 7 Setting the Minute

Press ⬆ or ⬇ until the correct minute appears. After setting the minute, press the **S** button to progress onto the next step.

Step 8 Setting the Measurement Unit

The CareSens N can display results in mg/dL or mmol/L. You may change the unit by pressing the ⬆ or ⬇. After selecting the unit, press **S** button to confirm your setting. Your meter was preset to the unit generally used in your country. It should be changed only on the recommendation of your healthcare professional.

Caution:
Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment.

Setting the Sound On/OFF

Step 9

On pressing ⬆ or ⬇, the screen will display the On or OFF. Press the **S** button to confirm the selection.

The meter will beep in the following instances, if set to On.

- When the test strip is inserted in the meter
- When the blood or control solution sample is absorbed into the test strip and the test starts
- When the test result is displayed
- When you push the **S** button or ⬆ button to turn on the meter
- When you push the ⬆ button to set the post-meal (PP2) alarm
- When it is time for a preset blood glucose test

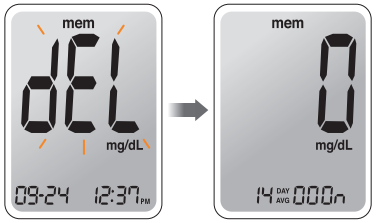
If the sound is set to OFF, none of the sound functions will work.

Note: Only when the sound is set to OFF, 🔇 symbol appears on the display.

Setting the 'Test Result Reset' (Deleting all the saved test results)

Step 10

In this mode all the test results stored in the meter can be deleted. Please note that if you select YES, all the stored test results will be deleted and can not be restored.
After the beeper mode is set, press the **S** button to enter the 'Test Result Reset' mode. The 'dEL' character will blink on the screen. Press ⬆ or ⬇ to alternate between 'YES' or 'no'. To delete all the stored test results, press the **S** button while the screen displays 'YES'. Then, all the test results stored in the meter will be deleted and the screen will be similar to the picture on the right.



If you do not want to delete the results, press the **S** button while the screen displays 'no'. Then, the screen will return to step 2.
See page 14.

Note: At any stage, if the **S** button is pressed for 3 seconds, Date, Time and Unit setting mode will finish and the meter will be turned off. Press and hold ⬇ to scroll through numbers quickly.

You may check your meter and test strips using the CareSens Control Solution(control A and/or B).
The CareSens Control Solution contains a known amount of glucose and is used to check that the meter and the test strips are working properly.
The test strip vials have CareSens Control Solution ranges printed on their labels. Compare the result displayed on the meter to the CareSens Control Solution range printed on the test strip vial.
Before using a new meter or a new vial of test strips, you may conduct a control solution test following the procedure on pages 20-21.

Notes:

- Use only the CareSens Control Solution (available for purchase separately).
- Check the expiration dates printed on the bottle. When you first open a control solution bottle, record the discard date (date opened plus three (3) months) in the space provided on the label.
- 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).
- Before using the control solution, shake the bottle, discard the first few drops and wipe the tip clean.
- Close the control solution bottle tightly and store at a temperature of 8-30˚C (46-86˚F).

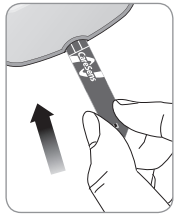
You may do a control solution test:

- When you want to practice the test procedure using the control solution instead of blood,
- When using the meter for the first time,
- Whenever you open a new vial of test strips,
- If the meter or test strips do not function properly,
- If your symptoms are inconsistent with the blood glucose test

results and you feel that the meter or test strips are not working properly,
- If you drop or damage the meter.

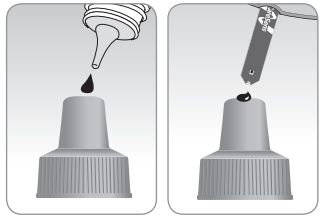
Control Solution Testing

Step 1



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

Step 2



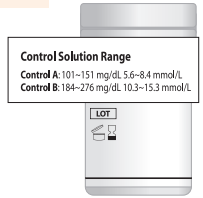
Shake the CareSens Control Solution bottle before each test. Remove the cap and squeeze the bottle to discard the first drop. Then wipe the tip with a clean tissue or cloth. After the ◂▬ symbol appears on the display, apply the solution to the narrow edge of the test strip until the meter beeps. Make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

Note: The meter may switch off, if the control solution sample is not applied within 2 minutes of the ◂▬ symbol appearing on the screen. If the meter turns off, remove the strip, reinsert, and start from step 1.

Step 3

A test result will appear after the meter counts down from 5 to 1.
After your control solution result appears on the display, press ⬇ for 3 seconds till the 'check' symbol appears on the display.
When the 'check' symbol is displayed, the result is not stored in the meter's memory and is not included in the 14-day averages.

Step 4



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 disposable 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.

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

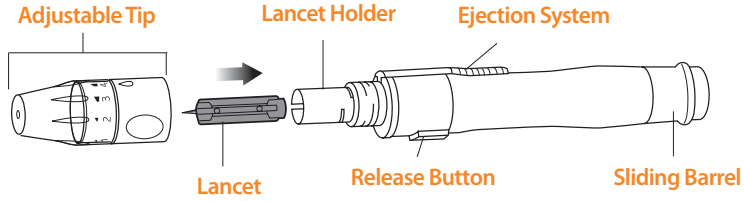
Comparing the Control Solution Test Results

The test result of each control solution should be within the range printed on the label of the test strip vial. Repeat the control solution test if the test result falls outside of this range. Out of range results may occur due to the following factors:

Situations	Actions
• When the control solution bottle was not shaken well, • When the meter, test strip, or the control solution were exposed to high or low temperatures, • When the first drop of the control solution was not discarded or the tip of the bottle was not wiped clean, • When the meter is not functioning properly.	Repeat the control solution test by referring to the "Notes" on page 19.
• When the control solution is past the expiration date printed on the bottle, • When the control solution is past its discard date (the date the bottle was opened plus three (3) months), • When the control solution is contaminated.	Discard the used control solution and repeat the test using a new bottle of control solution.

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. Do not use your system and contact i-SENS sales representative.

You will need a lancing device in order to collect a blood sample.
You may use the lancing device contained in the CareSens N Blood Glucose Monitoring System or any other medically approved lancing device.



- The lancing device may not be used by more than one individual. Ensure the lancing device is not shared among different users.
- 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.

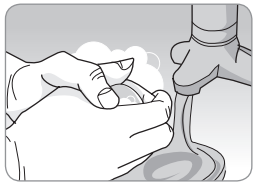
Caution: To avoid infection when drawing a sample, use a lancet only one time, and:
- Do not use a lancet that has been used by others.
- Always use a new sterile lancet.
- Keep the lancing device clean.

Note: Repeated puncturing at the same sample site may cause pain or skin calluses (thick hard skin). Choose a different site each time you test.

Preparing the Lancing Device

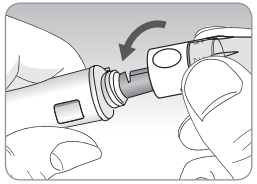
Step 1

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



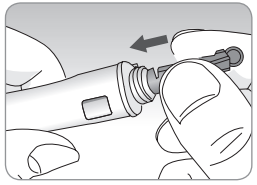
Step 2

Unscrew and remove the lancing device tip.



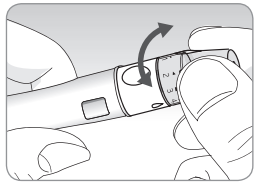
Step 3

Firmly insert a new lancet into the lancet holder. Hold the lancet firmly. Gently twist to pull off protective disk. Save disk to recap lancet after use. Replace lancing device tip.



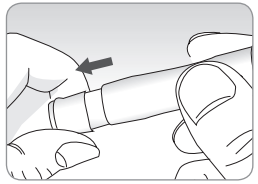
Step 4

Select a desired depth of one-to-five (1- 5) on the lancing device's adjustable tip. Choose a depth by rotating the top portion of the adjustable tip until the setting number matches the arrow. A beginning setting of three (3) is recommended.



Step 5

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

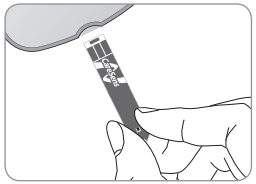


Note: The skin depth to get blood samples will vary for various people at different sample sites. The lancing device's adjustable tip allows the best depth to get an adequate sample size. A beginning setting of three (3) is recommended.

Preparing the Meter and Test Strip

Step 6

Insert a test strip with the contact bars facing upwards into the meter's test strip port. Push the strip in gently until the meter beeps. Be careful not to bend the test strip. The ◂▬ symbol will appear on the screen.



Marking Post-meal Test Results

The CareSens N meter allows you to mark a result of a post-meal test with 🍴 symbol. The post-meal test mark (🍴) can be attached just before applying the blood sample. Once you attach the post-meal mark (🍴) to the test results, it cannot be deleted.

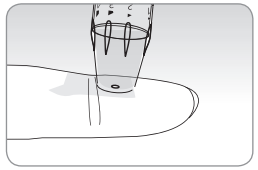
Step 7

If you want to attach a post-meal mark (🍴) to a test result, press and hold ⬇ for 3 seconds after inserting the test strip. The post-meal mark (🍴) and the ◂▬ symbol will appear on the screen. The test result will also be displayed with the post-meal mark (🍴).
If you do not want to save the result as a post-meal test, move on to step 8 after step 6.

Applying Blood Sample

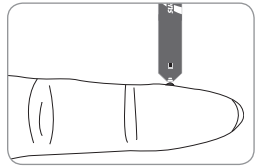
Step 8

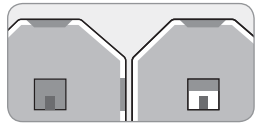
Obtain a blood sample using the lancing device. Place the device against the pad of the finger. The best puncture sites are on the middle or ring fingers. Press the release button. Remove the device from the finger. Wait a few seconds for a blood drop to form. A minimum volume of 0.5 microliter is needed to fill the confirmation window. (Actual size of 0.5 µL : ●)



Step 9

After the ◂▬ symbol appears on the screen, apply the blood sample to the narrow end of the test strip till the meter beeps. If the confirmation window is not filled before the meter finishes counting down then discard the test strip and insert a new one.
If the confirmation window is not filled in time because of abnormal viscosity (thickness and stickiness) or insufficient volume, the Er4 message will appear.





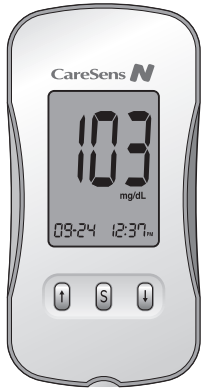
Good Sample Insufficient Sample

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, reinsert it and apply blood sample after ◂▬ symbol appears on the screen.

Step 10

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.

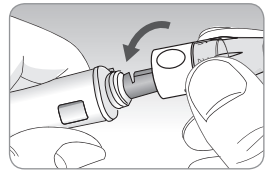
If the test strip is removed after the test result is displayed, the meter will automatically switch off after 3 seconds. Discard used test strips safely in disposable containers.



Discarding Used Lancets

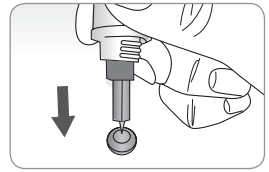
Step 1

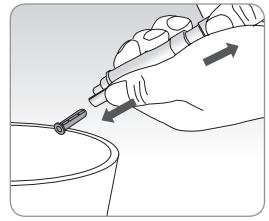
Unscrew lancing device tip.



Step 2

Place protective cover on lancet. Push the lancet ejector forward with the thumb and simultaneously pull out the sliding barrel to dispose of the used lancet in a proper biohazard container.





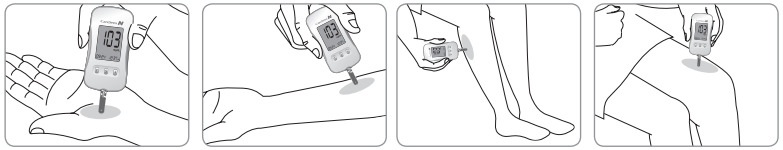
Caution: The lancet is for single use only. Never share or reuse a lancet. Always dispose of lancets properly.

Alternative Site Testing

What is AST(Alternative Site Testing)?

Usually, when someone tests their glucose, they take the blood sample from the tip of the finger. However, since there are many nerve endings distributed there, it is quite painful. When doing a glucose test, using different parts of the body such as the forearms, palms, thighs, and calves can reduce the pain during testing. This method of testing with different parts of the body is called Alternative Site Testing.
While AST may reduce the pain during testing, it may not be simple for everyone and the following precautions should be observed during testing.

Alternative Sites for Testing



Alternative Site Blood Sampling (forearm, palm, thigh, calf)

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 minimize result differences between fingertip and alternative site sampling. Firmly press and hold the lancing device against 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: •) blood is drawn. Carefully lift the lancing device away from your skin.

Things to know when using AST

Please understand the following before testing at alternative sites (forearms, palms, thighs, and calves).
The capillary blood of the fingertip shows the change in glucose more rapidly than AST. Therefore, the test results from the fingertip test and AST may differ. This is because things such as lifestyle and ingested food have an effect on glucose levels.

Acceptable situations for AST

When your blood glucose levels are stable

- Fasting period
- Before a meal
- Before sleeping

Situations requiring fingertip test

When your glucose levels are unstable

- During the two (2) hours after a meal or exercise
- When sick or when glucose levels seem quite lower than test value
- When hypoglycemia is not well recognized
- When insulin has the biggest effect
- Two (2) hours after an insulin injection

AST Precautions

- Do not ignore the symptoms of hyperglycemia or hypoglycemia.
- When the results of the test do not reflect your opinion, retest using the fingertip test. If the fingertip result still does not reflect the way you feel, please consult your healthcare professional.
- Do not rely on the AST results for changing your treatment method.
- The amount of glucose in alternative sites differs from person to person.
- Before using AST, please consult your healthcare professional.

Note: Results from alternative site and fingertip samples may differ from each other as there is a time lag for the glucose levels to reach the same value. Use a fingertip for testing 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.

HI and Lo Messages

HI Message

The meter displays results between 20-600 mg/dL (1.1-33.3 mmol/L). "HI" appears when the blood glucose level is greater than 600 mg/dL (33.3 mmol/L) and indicates severe hyperglycemia (much higher than normal glucose levels).

If "HI" is displayed again on retesting, please contact your healthcare professional immediately.

Lo Message

"Lo" appears when a test result is less than 20 mg/dL (1.1 mmol/L) and indicates severe hypoglycemia (very low glucose levels).

If "Lo" is displayed again on retesting, please contact your healthcare professional immediately.

Note: Please contact your authorized i-SENS sales representative, if such messages are displayed even if you do not have hyperglycemia or hypoglycemia.

Target Blood Glucose Ranges

Reminders *Time of day*	*Your target ranges from your healthcare professional*
Before breakfast	
Before lunch or dinner	
1 hour after meals	
2 hours after meals	
Between 2 a.m. and 4 a.m.	

Expected Values : 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 between 100-139 mg/dL (5.6-7.7 mmol/L).
*Fasting is defined as no caloric intake for at least eight (8) hours.

Reference
American Diabetes Association. "Standards of Medical Care in Diabetes – 2012." *Diabetes Care.* January 2012; 35(1):S11-S63.

Transferring Test Results

Test results stored in CareSens N meter can be transferred from the meter to a computer using PC care software and cable. The 'Pc' is displayed when the data cable connects the meter with a computer. For more information, contact your authorized i-SENS sales representative or visit at www.i-sens.com.

Meter Memory

The CareSens N Meter can save up to 250 glucose test results with time and date. If the memory is full, the oldest test result will be deleted and the latest test result will be stored.

The CareSens N Meter calculates and displays the averages of total test results, pre-meal test results, and post-meal test ( ) results from the last 14 days.

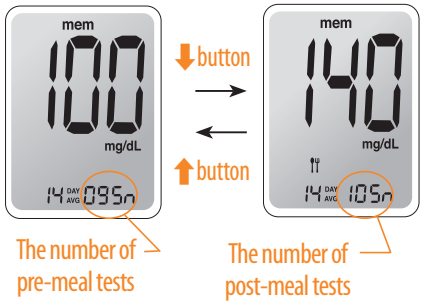
Viewing Test Results Stored in the Meter's Memory

Step 1

Press the ⬆ or **S** button to turn the meter on. The current date and time will be displayed on the bottom of the screen for 2 seconds, followed by the average value and the number of the test results saved within the last 14 days.

Step 2

Press ⬇ to view the average value and the number of tests performed before eating a meal for the last 14 days.
On pressing ⬇ again, the average value and the number of tests performed post-meals for the same period will appear on the screen.



Step 3

Use the ⬇ button to scroll through the test results, starting from the most recent and ending with the oldest. Press ⬆ to return to the result seen previously.
After checking the stored test result, press the **S** button to turn off the meter.

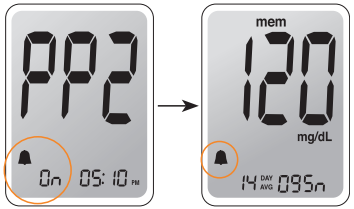
Note: On pressing ⬇, the latest test result saved in the meter's memory will be displayed on the screen along with the date and time. Press and hold ⬇ to scroll through the test results.

Four types of alarms can be set in the CareSens N Meter: one post-meal alarm (PP2 alarm) and three time set alarms (alarm1-3). The PP2 alarm goes off 2 hours after setting the alarm.
The alarms ring for 15 seconds and can be silenced by pressing ⬆, ⬇ or the **S** button or by inserting a test strip.

Setting the Post-meal Alarm (PP2 alarm)

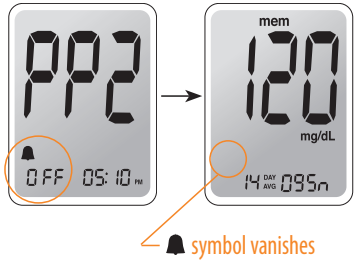
Step 1 Setting the PP2 alarm On

Without inserting a test strip, press and hold ⬆ for 3 seconds to set the post-meal alarm. The 'PP2' character, the bell (🔔) symbol and then the 'On' character will be displayed. The screen will then automatically change to the memory check mode. At this time, the bell (🔔) symbol, indicating that the PP2 alarm has been set, will be displayed on the screen.



Step 2 Setting the PP2 alarm OFF

To turn off the PP2 alarm, press and hold ⬆ for 3 seconds. The 'PP2' character, the bell (🔔) symbol and then the 'OFF' character will appear on the screen. Then the screen will change automatically to the memory check mode without the bell (🔔) symbol being displayed.



Setting the Time Alarms (alarm 1-3)

Step 1

Without inserting a test strip, press ⬆ and the **S** button simultaneously for 3 seconds to enter the time alarm mode. The 'alarm1' will be displayed while the 'OFF' character blinks on the screen.

Step 2

On pressing ⬇, the 'alarm1' is set and the 'On' character is displayed on the screen. Press ⬇ again to cancel the 'alarm1'. The 'OFF' symbol will blink on the screen.

Step 3

Press ⬆ to adjust the time of the 'alarm1'. A number representing the time will blink on the screen. Press ⬇ to set the time. Press ⬆ to end.

Step 4

On pressing ⬆, the number indicating the minute will start blinking. Press ⬇ to set the accurate minute.

Step 5

Press the **S** button to finish and to enter the 'alarm2' mode.
Repeat steps 2 to 5 to set the remaining time alarms (alarm2-3).

Step 6

Press the **S** button for 3 seconds to finish and turn the meter off.

Message	What It Means	What To Do
	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 or control solution 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.

Message	What It Means	What To Do
	The blood sample has abnormally high viscosity or insufficient volume.	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 test after inserting a CareSens N test strip.
	There is a problem with the meter.	Do not use the meter. Contact your authorized i-SENS sales representative.

Note: If the error messages persist, contact your authorized i-SENS sales representative.

Problem	Troubleshooting
The display is blank even after inserting a test strip.	• Check whether the test strip is inserted with the contact bars facing up. Check if the strip has been inserted completely into the test strip port. • Check if the appropriate test strip was used. • Check whether the batteries are inserted with the '+' side facing up. • Replace the batteries.
The test does not start even after applying the blood sample on the strip.	• Check if the confirmation window is filled completely. • Repeat the test after inserting a new test strip.
The test result doesn't match the way you feel.	• Repeat the test after inserting a new test strip. • Check the expiration date of the test strip. • Check the meter.

Note: If the problem is not resolved, please contact your authorized i-SENS sales representative.

Performance Characteristics

The performance of CareSens N Blood Glucose Monitoring System has been evaluated in laboratory and in clinical tests.

Accuracy: The accuracy of the CareSens N BGM System (Model GM505NA, GM505NB, GM505NC) 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	0.961
Y-intercept	3.5 mg/dL (0.194 mmol/L)
Correlation coefficient (r)	0.995
Number of sample	110
Range tested	30-485 mg/dL (1.7-26.9 mmol/L)

Accuracy results for glucose concentration < 75 mg/dL (4.2 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)
13/17 (76%)	16/17 (94%)	17/17 (100%)

Accuracy results for glucose concentration ≥ 75 mg/dL (4.2 mmol/L)

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
45/93 (48%)	88/93 (96%)	93/93 (100%)	93/93 (100%)

Precision: The precision studies were performed in a laboratory using CareSens N BGM Systems.

Within Run Precision		
Blood avg.	38.1 mg/dL (2.1 mmol/L)	SD = 1.9 mg/dL (0.1 mmol/L)
Blood avg.	86.1 mg/dL (4.8 mmol/L)	SD = 3.2 mg/dL (0.2 mmol/L)
Blood avg.	124.5 mg/dL (6.9 mmol/L)	CV = 4.1%
Blood avg.	189.1 mg/dL (10.5 mmol/L)	CV = 2.6%
Blood avg.	334.5 mg/dL (18.6 mmol/L)	CV = 2.8%

Total Precision		
Control avg.	43.1 mg/dL (2.4 mmol/L)	SD = 2.0 mg/dL (0.1 mmol/L)
Control avg.	113.4 mg/dL (6.3 mmol/L)	CV = 3.3%
Control avg.	381.2 mg/dL (21.2 mmol/L)	CV = 4.2%

This study shows that there could be variation of up to 4.2%.

Warranty Information

Manufacturer's Warranty
i-SENS, Inc. warrants that the CareSens N 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 improper handling, tampering, 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 nearest i-SENS Authorized Warranty Station.