Owner's Booklet

CareSens™ II

Blood Glucose Monitoring System

Accurate, complete blood glucose monitoring through advanced biosensor technology

FASTER, EASIER, LESS PAINFUL

RAPID TEST RESULT (5 sec.)

VERY SMALL SAMPLE SIZE (0.5 μℓ)

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CE 0123 IVD

 PGA1E3011 REVx 02/2012

Welcome to the **CareSens II** Blood Glucose Monitoring System

Thank you for purchasing the CareSens II Blood Glucose Monitoring System. The system provides you with fast, safe, and convenient blood glucose *in vitro* (i.e., outside the body) diagnostic monitoring.

You will receive an accurate results in only five seconds with a small 0.5 $\mu\ell$ blood sample.

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Important Information: Read This First!

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

- Do *not* use the system for the diagnosis of diabetes or for testing newborns.
- The CareSens II blood glucose monitoring system is intended for self-testing outside the body (*in vitro* diagnostic use).
- Use *only* fresh capillary whole blood samples for testing.
- The glucose in the blood sample mixes with special chemicals on the test strip to produce a small electrical current. The CareSens II meter detects this electrical current and measures the amount of glucose in the blood sample.
- Alternative site and fingertip results may differ significantly due to rapid change in the glucose level after meal, insulin or exercise.
- Use alternative site samples only for testing prior to, or more than two hours after, meal, insulin dose, or physical exercise.
- The average hematocrit range is between 30 and 50%. However, people with severe anemia and newborns may have higher hematocrit and this can affect the test results.
- Very high (60% or more) or very low (20% or less) hematocrit can lead to incorrect test results.

The following chart explains the symbols you will find in the *CareSens II User Manual,* product packaging, and product inserts.

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

IVD	For *in vitro* diagnostic use
CE 0123	This product fulfills the requirements for Directive 98/79/EC on *in vitro* diagnostic medical devices.
	Cautions for safety and optimum product use
	Do not discard this product with other household-type waste
	Consult instruction for use
	Manufacturer
EC REP	Authorized representative
	Do not reuse
SN	Serial number
LOT	Batch code
	Use by (unopened or opened test strip container)
	Temperature limitations

CareSens II Blood Glucose Monitoring System

Verify that all the following components are included in the system box.

1. CareSens II Blood Glucose Meter
2. Battery (1)
3. CareSens Blood Glucose Test Strip
4. CareSens Check Strip
5. Lancing Device
6. Lancet
7. Carrying Case
8. Owner's Booklet
9. Quick Reference Guide
10. Logbook

* CareSens Glucose Control Solution (Optional)

The components of the product is identical to what's listed in the meter manual, however you need to check the meter box for the quantity of the strip.

• Helpful Tip

See page 40 for battery information and replacement instructions.

Use only CareSens Test Strips with the **CareSens II** Blood Glucose Monitoring System.

- Please contact your authorized i-SENS sales representative if any component is missing or damaged.

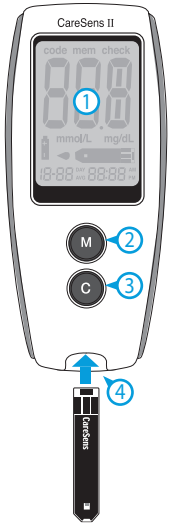
CareSens II Blood Glucose Meter

[1] Meter Display
Test result, symbol and simple message display.

[2] M Button
On-off power button. Also used to call memory or setting modes.

[3] C Button
Power button to review previous test results or change code, date, time, year or measurement units.

[4] Test Strip Port
Insert test strip here.



Meter Display

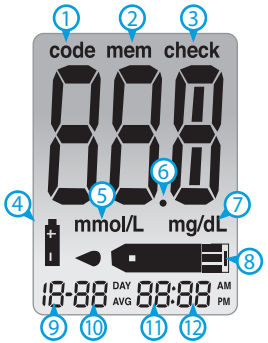
[1] code
Shows code for three (3) seconds after test strip insertion

[2] mem
Shows previously stored test results

[3] check
Appears during meter testing

[4] Battery Symbol
Indicates low battery

[5] mmol/L
Appears when test result is set to mmol/L



[6] Decimal Point
Appears when the blood glucose measuring unit is set to mmol/L

[7] mg/dL
Appears when test result is set to mg/dL

[8] Blood Drop Symbol
Indicates meter is ready to receive blood sample

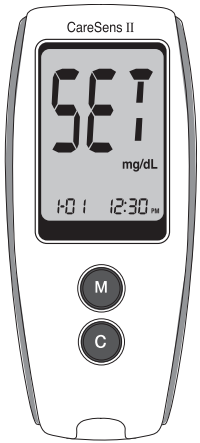
[9] Month [10] Day [11] Hour [12] Minute

Setting the Meter

When you turn on your CareSens II Meter the first time, its display will show the following setting:

- Display format for the date: MM-DD (Month-Date)
- Display format for the time: 12 h (AM/PM)
- Year: year of manufacture

To set the display, press and hold the M Button for three (3) seconds.



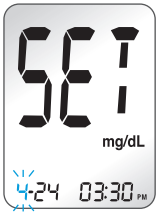
• Helpful Tip

To set any date, time, or unit of measurement, you must begin by setting the month and date mode and consecutively go through the process.

Setting the Month and Date

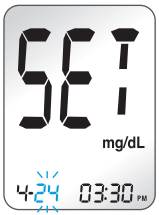
[1] Setting the Month

Press and hold the **M** Button for three (3) seconds. A blinking number indicating the month will appear on the lower left display corner. Press and release the **C** Button until correct month appears. Press the **M** Button to set. You are now ready to set the date.



[2] Setting the Date

Press the **C** Button until blinking number represents correct date. Press the **M** Button to set and move to time setting mode.



• Helpful Tip

Press and hold the **M** Button for three (3) seconds to begin and end the setting of the date, time, year or measurement unit on the meter. Use the **C** Button for scrolling. To scroll more quickly, hold the **C** Button down.

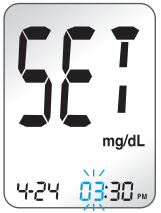
Setting the Time

[3] Setting the Time

The meter can be set in an AM/PM 12-hour or 24-hour format. Press the **C** Button to select format.

[4] Setting the Hour

Press the M Button to move to hour setting mode. Press the **C** Button until correct hour appears. After hour is set, press the **M** Button to enter minute setting mode.



[5] Setting the Minute

Press the **C** Button until correct minute appears. After minute is set, press the **M** Button to move to year setting mode.

Setting the Year and Measurement Unit

[6] Setting the Year

Press the **C** Button until correct year appears. After setting the year, press the **M** Button to move to unit setting mode.

[7] Setting the Measurement Unit

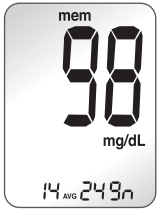
The meter is set to mg/dL. Press the **C** Button to change to mmol/L or return to mg/dL. After selecting measurement unit, press the **M** Button for three (3) seconds to exit setting mode.

• Helpful Tip

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

Storing Test Results in Meter Memory

The **CareSens II** Meter provides storage for up to 250 blood glucose test results. It also stores the 14-day average and number of tests performed. The following procedure lets you store your test results.



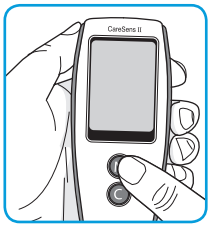
[1] Press the **M** Button to turn on meter. The current date and time will appear at the bottom of the screen for two (2) seconds, followed by the 14-day average and number of tests performed.

[2] Press the **C** Button. The most recent test result, its date and time will appear.

• Helpful Tip

Each time you press the **C** Button, you'll see previous test results, dates and times displayed in chronological order. To see test results displayed more quickly, press and hold the **C** Button.

[3] Press the **M** Button to turn the meter off.



Deleting Stored Test Results from Meter Memory

To delete all past stored test results, follow this procedure.

[1] Begin with meter off. Enter time and unit setting mode (see *Setting the Meter* pages 10-13). Press the **M** Button seven times to set meter to memory deleting mode. Press the **C** Button to call up Yes or no.

[2] To delete all memory, choose Yes. Press the **M** Button. All past stored test results and their dates and times will be deleted. The number zero will appear. Or, If you do not wish to delete the memory, choose no. Press the **M** Button to enter Step 1 of the time and unit setting mode.

• Helpful Tip

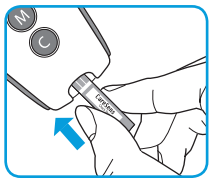
The meter will turn off if you press the **M** Button for more than three (3) seconds at any stage of the setting. The meter will turn itself off after two (2) minutes if the **M** Button is not pressed.

Checking the Meter with the CareSens II Check Strip

The **CareSens II** Check Strip is used to determine if the meter is functioning properly. To perform the test, start with the meter turned off.
Perform a **CareSens II** Check Strip when:

- the **CareSens II** meter is used for the first time
- the battery is replaced
- the test result seems inaccurate or does not reflect how you feel
- the **CareSens II** meter seems to be not working properly
- the **CareSens II** meter is dropped or banged

[1] Start with meter off.
Remove **CareSens II** Check Strip from the package.
Insert **CareSens II** Check Strip contact end into test strip port.

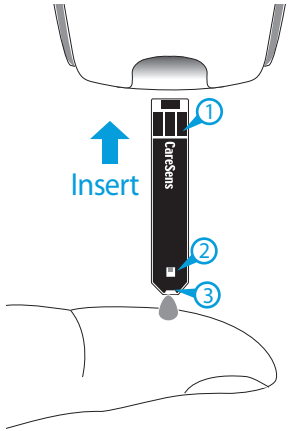


[2] After a few seconds, meter displays 'YES'.
'YES' in the display of the meter means the meter is functioning properly.
Remove the **CareSens II** Check Strip.
Return to the package.

• Helpful Tip
If segments are missing from display or 'no' appear, do not use meter for testing. Contact your authorized i-SENS representative.

CareSens II Blood Glucose Test Strip

The CareSens Test Strip supports the accurate measurement of glucose levels in a capillary whole blood sample.



[1] Contact Bars
Gently push the test strip, with its contact bars facing up, into the test strip port of meter.

[2] Confirmation Window
Check here to see whether sufficient blood sample has been applied.

[3] Edge to apply blood sample
Apply blood sample here for testing.

Warning!

- The CareSens 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 containers and test strips in containers that have been opened can be used up until the expiration date printed on the test strip box and container label if the test strips are used and stored 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 away test strips from direct sunlight or heat and do not refrigerate or freeze.
- Store test strips only in their original vial.
- Close the vial tightly after removing 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 test strip package insert.

• Helpful Tip

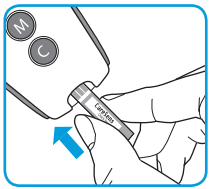
For detailed storage and usage information, refer to the CareSens Test Strip package insert.

⚠ Keep test strips and the test strip bottle away from children. The test strips and bottle cap may be choking hazards. Drying agents in the bottle cap may be harmful if inhaled or swallowed and may cause skin or eye irritation.

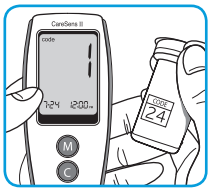
Coding Meter to Match Test Strips

For accurate results, the code numbers on the CareSens II Meter and CareSens Test Strips must match. You must code your meter before using it for the first time and each time you open a new bottle of test strips. The code number on the meter display must match the one on the test strip bottle.

[1] Gently push test strip in until meter beeps. Code numbers will appear for three (3) seconds. Code number 1 will appear when the meter is first used.

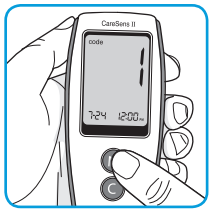


[2] Code numbers on display and test strip bottle should match. If so, wait until the symbol appears on the screen to begin the test.
If not, follow Step 3.

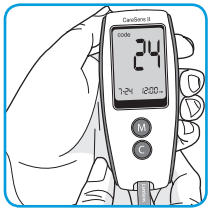


⚠ You must code your meter before using it for the first time and each time you open a new bottle of test strips. The code numbers on the display and test strip bottle must match. If the meter is not correctly coded, you will get inaccurate results.

[3] Press the **M** or the **C** Button to select the correct code number. Each time you press the **M** button, the number will increase by one, and each time you press the **C** Button, the number will decrease by one. Press and hold the **C** Button to scroll code numbers down.



[4] After selecting correct code number, wait for three (3) seconds until the symbol appears on display.



[5] When the symbol appears, meter is ready for testing.

Checking the System

CareSens Control Solution:

You may check your meter and test strips using the CareSens Control Solution.
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, conduct a control solution test following the procedure on page 23.

Note:

- Use only the CareSens Control Solution.
- Check the expiration dates printed on the vial. When you first open a control solution vial, record the discard date (date opened plus three 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 vial, discard the first few drops and wipe the tip clean.
- Close the control solution vial tightly and store at a temperature of 8 ~ 30˚C (46 ~ 86˚F).

Do a control solution test:

- 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.

⚠ If all the results you get on testing three times continuously are within the range printed on the test strip, the meter and test strips are working properly and you may use them for your blood glucose test.

CareSens Gloucose Control Solution Storage and Handling

Discard the CareSens Control Solution after its expiration date on the bottle or discard date, whichever comes first. Add three (3) months to the date you open the bottle and write it on the bottle label. This is the discard date. *Do not* use the solution after the discard or expiration date, whichever comes first.

For accurate results:

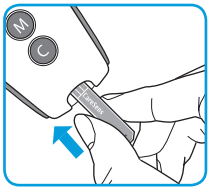
- Store control solution in tightly capped bottle at temperature 8-30°C /46-86°F.
- Do not refrigerate or freeze.
- Keep the control solution, meter, and test strips at room temperature (20-25°C/68-77°F) for at least 30 minutes before testing.

⚠ Do not use the control solution after the expiration or discard date, whichever comes first. Only use **CareSens** Control Solution to test **CareSens** Test Strips and the **CareSens II** Meter.

Testing Meter and Test Strip Performance

Perform the following steps to check the combined performance of your **CareSens II** Meter and Test Strips or to assess proper testing procedure performance.

[1] Insert test strip contact bars facing up into the meter's test strip port. Gently push test strip into the port until meter beeps. A code number will appear for three (3) seconds.
The symbol will show on the display. Confirm matching code numbers on display and test strip bottle. If code numbers do not match, see Coding Meter to Match Test Strips on pages 19-20.

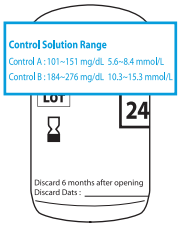


[2] Shake the bottle well. Discard first drop of the control solution.
Wipe off the bottle tip.
After the symbol appears on the display, apply the solution to narrow top edge of the test strip until the meter beeps.

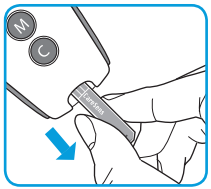
⚠ The glucose level printed on the bottle is for the **CareSens** Control Solution only.
It does not refer to your blood glucose level.

[3] Test results appear after the meter counts down from five-to-one (5-to-1). To mark test result, press and hold the **C** Button for three (3) seconds. Check will appear on the display. Marked test results will not be shown in your averages.

[4] Compare results with range printed on test strip bottle. If results fall within range, you are ready to test your blood.



[5] Remove used test strip. The Meter will turn off.



Comparing the Control Solution Test Results

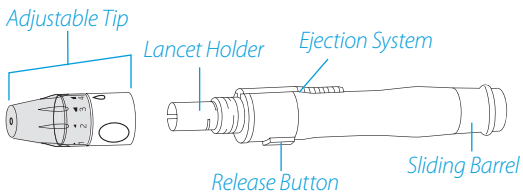
Repeat the control test if the test result falls outside the range printed on label of the test strip vial. Out of range results may occur due to the following factors:

- When the control solution vial was not shaken well,
- When the control solution is past its expiration date or is contaminated,
- When the meter, the strip or the control solution were exposed to high or low temperatures,
- When the first few drops of the control solution were not discarded or the tip of the vial was not wiped clean,
- When the test strip is past its expiration date,
- When the meter is not functioning properly.

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

Using the Lancing Device

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



- The lancing device should be used by one individual and communal use is strongly discouraged.
- 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.

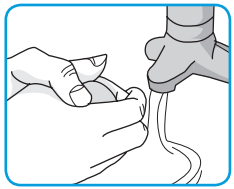
⚠ To avoid infection when drawing a sample, use a lancet only one time, and:
- Do not use a lancet that has been used by others.
- Always use a new sterile lancet.
- Keep the lancing device clean.

• Helpful Tip

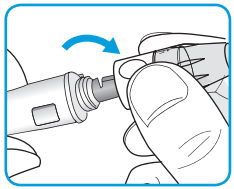
Repeated puncturing at the same sample site may cause pain or skin calluses. Choose a different site each time you test.

Preparing the Lancing Device for Blood Sample Retrieval

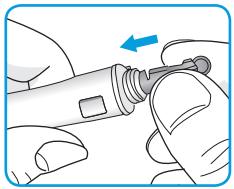
[1] Wash hands and fingertip sample site with soap and warm water. Rinse and dry thoroughly.



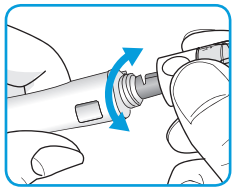
[2] Unscrew lancing device tip.



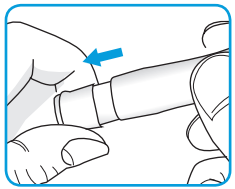
[3] Firmly insert new lancet into carrier. Hold lancet firmly. Gently twist to pull off protective disk. Save disk to recap lancet after use. Replace lancing device tip.



[4] Select a desired depth of one-to-five (1-5) on lancing device's adjustable tip. Rotate ring to align desired number with the arrow.
A beginning setting of three (3) is recommended.



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

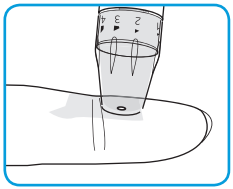


• Helpful Tip

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

Using the Lancing Device at Fingertip Sample Site

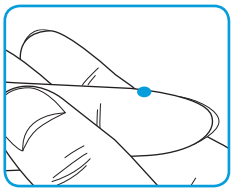
[1] Place cocked lancing device against fingertip side.



• Helpful Tip

Choose a different fingertip each time you retrieve a sample to minimize discomfort.

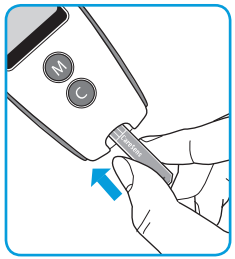
[2] Press release button. Massage fingertip to obtain a round drop (at least 0.5 µl , actual size: ●) of blood. Apply test strip tip to blood sample.



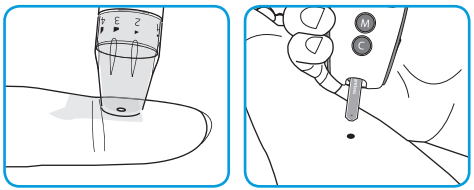
⚠ Abnormally viscous blood or insufficient amount of blood may result in Er4 on the display after the measurement (See Error Messages and Troubleshooting on page 44).

Testing Your Blood Glucose Levels

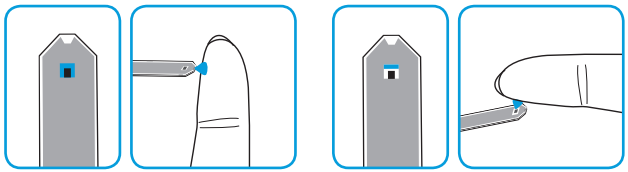
[1] Insert test strip with contact bars facing up into a port. Push strip gently until meter beeps. A code number will appear for three (3) seconds.
The ▬▬ symbol will appear.
Display code number should match the one on the test strip bottle. If not, see Coding Meter to Match Test Strips on pages 19-20.



[2] Use lancing device to get blood sample. Sample must be at least 0.5 μℓ (actual size: ●) to fill the test strip reaction cell.
When the symbol appears on display, apply blood sample to narrow top edge of test strip until meter beeps.
When testing from forearm, hold the meter as shown.



If confirmation window has not filled in time because of abnormal viscosity or insufficient volume, Er4 message will appear.
If the confirmation window is not completely filled when results appear, it is recommended that you perform a second test for more accurate results.



• Helpful Tip

If the test strip dose not receive a blood sample, please contact your authorized i-SENS sales representative.

[3] Meter will count down from five-to-one (5-1) on the display. Test results, time, and date will appear and automatically store in meter memory. Remove used test strip from the port. Meter will turn off after three (3) seconds.

⚠ The meter will automatically turn off if a sample is not applied within two (2) minutes. If this happens, remove the test strip from the port. Reinsert the test strip to restart the meter.

⚠ Alternative site and fingertip results may differ significantly due to rapid changes in the glucose level after meals or exercise, hypoglycemic symptoms, dehydration or effects of drugs such as insulin. Rubbing the site before drawing the sample reduces these differences. If you suffer from hypoglycemia or have experienced hypoglycemic shock, secure blood samples from your fingertips.

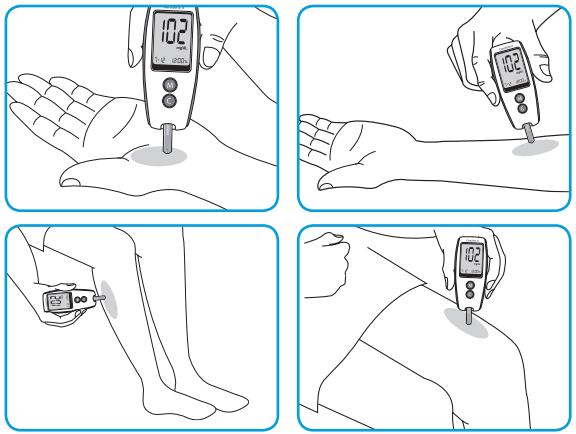
⚠ Discard used test strips and lancets properly in a container for sharp objects.

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 arms, 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 Site for Testing



Things to know when using AST

Please understand the following things before testing outside of the fingertip (arms, thighs, 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

- Fasting period
- Before a meal
- Before sleeping

Situations requiring fingertip test

- When the glucose levels are rapidly increasing during the two 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
- 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 one's opinion, retest using the fingertip test. If the test results do not reflect one's opinion, please consult a doctor.
- Do not rely on the AST results for changing one's treatment method.
- The amount glucose in alternative sites differs from person to person.
- Before using AST, please consult your regular physician.

• Helpful Tip

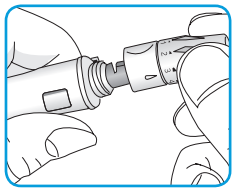
Results from alternative site and fingertip samples may appear differently as there is a time lag for the glucose levels to reach the same value. Use a fingertip for drawing if you suffer from hypoglycemia or have experienced hypoglycemic shock or symptoms.

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

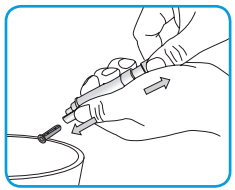
Discarding Used Lancets

Proper discarding of used lancets protects you and others from infection and injury. The following shows the correct process.

[1] Unscrew general lancing device tip.



[1] 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.



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

Target Blood Glucose Ranges

Reminders

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

Source : *Diagnosis of Diabetes*, NIH Publication No. 05-4642, January 2005

Hi and Lo Messages

The **CareSens II** Meter displays test results between 20 to 600 mg/dL (1.1-33.3 mmol/L). Please refer to the instructions below if you receive a Hi or Lo message.

- *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) may indicate hyperglycemia (high blood glucose).

- *Lo Message*

If your test result is below 20 mg/dL (1.1 mol/L), **Lo** will appear on the display.
This may indicate hypoglycemia (low blood glucose).

⚠ If you receive a Hi or Lo message, repeat the test. If the result is the same, contact your physician immediately.

⚠ If Hi or Lo message does not reflect how you feel, contact your authorized i-SENS sales representative.

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, acetone, or household and industrial cleaners that may cause irreparable damage to the meter.
Store all the meter components in the portable case to prevent loss.

Caution :

- 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 in a cool and airy place.
- Keep the meter away from strong electromagnetic fields such as cell phones and microwave ovens.
- **CareSens II** meter should be used only with **CareSens** test strips.

• Helpful Tip

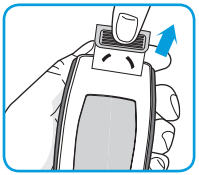
Keep all system components in the carrying case to prevent loss.

⚠ Do not clean the meter with household or industrial cleaning solvents, benzene or acetone.

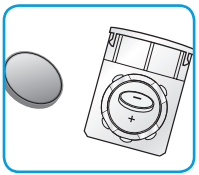
Replacing the Batteries

When the icon appears on the display for the first time, the battery should be replaced as soon as possible.
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.

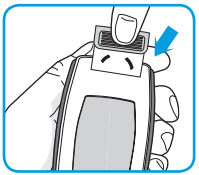
[1] Turn the meter over and at the top you see the recess for openning the battery compartment cover. Slide the cover out of the meter.



[2] Remove the battery. Insert new battery negative (-) side facing up.



[3] Slide cover down until it clicks.



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

Specifications

- 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
- Meter Test: Check Strip
- Power: One (1) 3.0 V lithium battery
- (non-rechargeable, replaceable, type CR2032)
- Battery Life: 1,000 tests
- Memory: 250 blood glucose values
- Dimension: 95 x 41.5 x 17.5 (mm)
- Weight: 42.4 g (with battery)
- Operating Range
  - Temperature: 10-40˚C/50-104˚F
  - Relative Humidity: 10-90%
  - Hematocrit: 20-60%

Performance Characteristics

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

Accuracy: **CareSens II BGM Systems** are calibrated to yield results equivalent to plasma glucose concentrations. The accuracy of the CareSens II System 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 115 diabetic patients at clinic centers.

Slope	0.961
Y-intercept	3.5 mg/dL
Correlation coefficient (r)	0.995
Number of samples	115
Range tested	40-521 mg/dL

Accuracy results for glucose concentration < 75 mg/dL (4.2 mmol/L)
CareSens II (Model GM505C)

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)
13/19 (68%)	18/19 (95%)	19/19 (100%)

Accuracy results for glucose concentration ≧75 mg/dL (4.2 mmol/L)
CareSens II (Model GM505C)

Within ± 5%	Within ±10%	Within ± 15%	Within ± 20%
66/96 (69%)	92/96 (96%)	96/96 (100%)	96/96 (100%)

Precision:

Precision studies were performed in a laboratory using the **CareSens II BGM System.**

CareSens II BGM System (Model GM505C)

Within Run Precision		
Blood average	42 mg/dL (2.3 mmol/L)	SD=1.7 mg/dL (0.1 mmol/L)
Blood average	98 mg/dL (5.4 mmol/L)	SD=2.9 mg/dL (0.2 mmol/L)
Blood average	142 mg/dL (7.9 mmol/L)	CV=2.9%
Blood average	209 mg/dL (11.6 mmol/L)	CV=3.3%
Blood average	339 mg/dL (18.8 mmol/L)	CV=3.6%

Total Precision		
Blood average	44 mg/dL (2.4 mmol/L)	SD=1.7 mg/dL (0.1 mmol/L)
Blood average	137 mg/dL (7.6 mmol/L)	3.7%
Blood average	355 mg/dL (19.7 mmol/L)	4.0%

This study shows that there could be variation of up to 4.0%

Understanding Error and Other Messages

Message	What It Means	What To Do
	*Test strip has been used.*	Use a new strip.
	*Blood sample applied before the symbol appeared. Repeat test with a new strip.*	Wait until the symbol appears before applying sample.
	*Temperature recommended system range during test.*	Take system where temperature is within operating range (10-40˚C/ 50-104˚F) and repeat test after 30 minutes.

Message	What It Means	What To Do
	*The blood sample did not fill the confirmation window of the test strip during measurement because of abnormally high viscosity or insufficient volume.*	Repeat test with new test strip and adequate blood sample.

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

General 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 till the end.
- 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 test strip confirmation window for adequate blood sample.
- Repeat test with a new test strip.

The test result doesn't match your expectation.

- Ensure test strip bottle and meter code numbers match. Repeat the test with a new test strip.
- Make sure the blood sample was applied in time. Repeat the test with a new test strip.
- Draw the blood sample from another fingertip or alternate site. Repeat the test with a new test strip.
- Check the validity period of the test strip.
- Check the meter.

Warranty Information

Manufacturer's Warranty

i-SENS, Inc. warrants that the **CareSens II** 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.

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