i·sens

CareSens™ II
Blood Glucose Monitoring System

Accurate, complete blood glucose monitoring through advanced biosensor technology

FASTER, EASIER, LESS PAINFUL

5sec. **RAPID TEST RESULT (5 sec.)**

0.5 µL **VERY SMALL SAMPLE SIZE (0.5µL)**

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IVD

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

Thank you for choosing the **CareSens II** 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!

For optimum safety and benefits, please read the entire manual contents before using the system.

Intended use: **CareSens II** 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 II Blood Glucose Monitoring System should be used only for self-testing outside the body (*in vitro* diagnostic use only).
CareSens II 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.

Meaning of Symbols Used:

IVD	For *in vitro* diagnostic use
⚠	Cautions for safety and optimum product use
	Use by (unopened or opened test strip vial)
	Do not discard this product with other household-type waste
	Do not reuse
	Consult instructions for use
LOT	Batch code
	Temperature limitation
	Manufacturer
SN	Serial number

- Glucose in blood samples reacts with the chemical in 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.
- The **CareSens II** blood glucose meter should be used only with the **CareSens** 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 hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
- Inaccurate results may occur in patients undergoing oxygen therapy.

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

CareSens II Blood Glucose Monitoring System

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

Optional items:
* **CareSens** Blood Glucose Test Strips
* Lancets
* Lancing Device
* Logbook
* **CareSens** Check Strip

* Check all the components after opening the **CareSens II** Blood Glucose Monitoring System package. The exact contents are listed on the main box.
* The data transmission cable can be ordered separately. Please contact your authorised i-SENS sales representative.

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.

[5] Data Port
Used to transfer data from the meter to a computer with a cable.

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

CareSens II Blood Glucose Meter Display

Display Segment Check
It is recommended to check if the display screen on the meter matches the illustration (below, above, etc.) every time the meter turns on. Do not use the meter if the display screen does not exactly match the illustration as the meter may show incorrect results.

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

[2] mem
appears when test results stored in the memory are displayed

[3] check
appears when test results have not been saved and the **CareSens** Check Strip is inserted

[4] Battery Symbol
indicates meter battery is running low and needs to be replaced

[5] mmol/L
unit for measuring blood glucose

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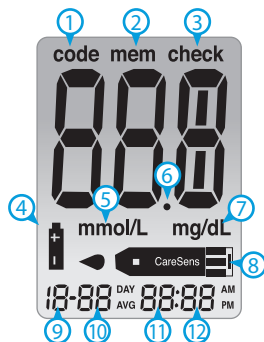appears when the blood glucose measuring unit is set to mmol/L

[7] mg/dL
unit for measuring blood glucose

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

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

Setting up Your System

Press and hold the **M** button for 3 seconds to enter the set mode. After all settings are finished, press and hold the **M** button for 3 seconds to turn off the meter.
Press **C** button to reach the accurate value. Press and hold **C** button to scroll faster.

Adjusting the Date, Time and Unit
[1] Setting the Month
Press and hold the **M** button for 3 seconds to enter the set mode. After all the segments flash across the screen, the 'SET' character will be displayed on the screen.
Then, a number indicating the month will be blinking on the left corner of the screen. Press **C** button until the correct month appears. Press the **M** button to confirm your selection and progress to the next step.

[2] Setting the Date
Press **C** button until the screen displays the correct day. Press the **M** button to confirm your selection and progress to the next step.

• Note
It is recommended to check if the display screen on the meter matches the illustration on the page 8 every time the meter turns on. Do not use the meter if the display screen does not exactly match the illustration as the meter may show incorrect results.

[3] Setting the Time Format

The meter can be set in the AM/PM (12-hour) or the 24-hour clock format.
Press **C** button to select a format. The AM/PM symbol is not displayed in the 24-hour format. Press the **M** button to confirm your selection and progress to the next step.

[4] Setting the Hour

Press **C** button until the correct hour appears. Press the **M** button to confirm your selection and progress to the next step.

[5] Setting the Minute

Press **C** button until the correct minute appears. Press the **M** button to confirm your selection and progress to the next step.

[6] Setting the Year

Press and release **C** button to adjust until the correct year appears. Press the **M** button to confirm your selection and progress to the next step.

[7] Setting the Measurement Unit

The **CareSens II** can display results in mg/dL or mmol/L. You may change the unit by pressing the **C** button. After selecting the unit, press **M** 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.

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

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

In this mode all the 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 unit is set, press the **M** button to enter the 'Test Result Reset' mode. The 'dEL' character will blink on the screen. Press **C** button to alternate between 'YES' or 'no'. To delete all the stored test results, press the **M** 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 **M** button while the screen displays 'no'. Then, the screen will return to step 1. See page 9.

mem
dEL
4-24   03:30 PM

mem
0
mg/dL
14 DAY AVG 00.0 n

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

Meter Memory

The **CareSens II** 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 II** Meter calculates and displays the averages of total test results from the last 14 days.

[1] Press the **M** 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 14-day.

[2] Use the **C** button to scroll through the test results, starting from the most recent to the oldest.

[3] After checking the stored test results, press **M** button to turn off the meter.

mem
120
mg/dL
14 AVG 249 n

mem
103
mg/dL
6-23   03:30 PM
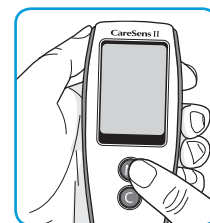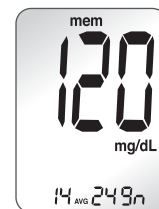
Checking the Meter
with the CareSens Check Strip

The **CareSens** Check Strip is used to determine if the meter is functioning properly. To perform the test, start with the meter turned off.
Use the **CareSens** 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] When the meter is turned off, insert the **CareSens** Check Strip all the way into the test strip port.
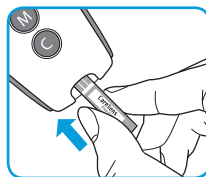
[2] It means the meter is functioning properly. Remove the **CareSens** Check Strip and return to the package.
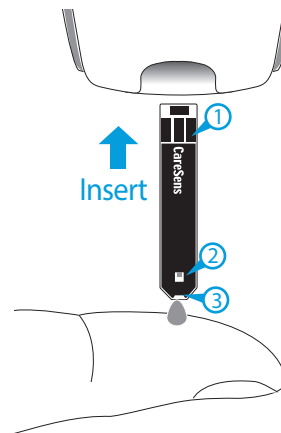
• Note
If segments are missing from display or 'no' appears, do not use meter for testing. Contact your authorised i-SENS sales representative.

CareSens Blood Glucose Test Strip

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

Insert

[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 Strips 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 and stored according to its storage and handling methods.
- Store test strips in a cool and dry place at a temperature between 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** test strip package insert.

> ⚠ • Keep the meter and testing supplies away from young children.
> • The test strip vial contains drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.

Coding Meter to Match Test Strips

For accurate results, the code number 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 vial of test strips. The code number on the meter display must match the one on the test strip vial.

[1] Gently push test strip in until meter beeps. A code number will appear for three (3) seconds. Code number 1 will appear when the meter is first used.
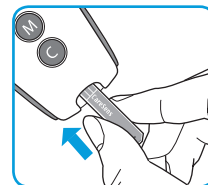
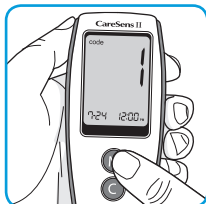**[2]** The code number on display and test strip vial should match. If so, wait until the ◂▭▭ symbol appears on the screen to begin the test. If not, follow Step 3.
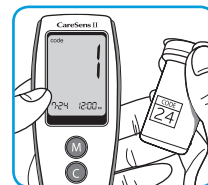

> ⚠ You must code your meter before using it for the first time and each time you open a new vial of test strips. The code number on the display and test strip vial must match. If the meter is not correctly coded, you will get inaccurate results.

[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.
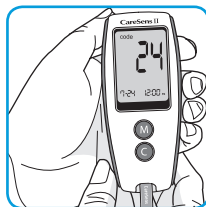
[5] When the ◀▭ symbol appears, meter is ready for testing.
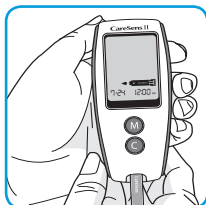
Checking the System

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 21-22.

Notes:

- Use only the **CareSens** Control Solution (available for purchase separately).
- Check the expiration date 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 between 8-30˚C (46-86°F).

You may do a control solution test:
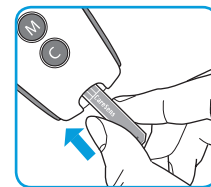
- When you want to practice the test procedure using the control solution instead of blood
- When using the meter for the first time
- Whenever you open a new vial of test strips
- If the meter or test strips do not function properly
- If your symptoms are inconsistent with the blood glucose test results and you feel that the meter or test strips are not working properly
- If you drop or damage the meter

Control Solution Testing

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

[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 code number will appear for three (3) seconds. Then, the ◄▭ symbol will be displayed on the screen.
Confirm matching the code number on display and test strip vial. If the code number does not match, see Coding Meter to Match Test Strips on pages 17-18.

[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.

> ⚠ 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.

[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 C button for 3 seconds till the 'check' appears on the display.
When the 'check' symbol is displayed, the result is stored in the meter's memory but it is not included in the averages.

[4] Compare the result displayed on the meter to the range printed on the test strip vial. The result should fall within that range.

Control Solution Range
Control A: 101-151 mg/dL (5.6-8.4 mmol/L)
Control B: 184-276 mg/dL (10.2-15.3 mmol/L)

⚠️ The range printed on the test strip vial is for the **CareSens** Control Solution only. It has nothing to do with your glucose level.

• Note
The **CareSens** Control Solution can be purchased separately.
Please contact your authorised 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 in following situations:
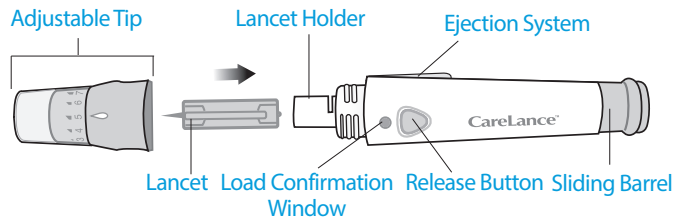
Situations	Do This
• When the control solution bottle was not shaken well, • When the meter, test strip, or the control solution were exposed to high or low temperatures, • When the first drop of the control solution was not discarded or the tip of the bottle was not wiped clean, • When the meter is 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.
• When the code number of the meter does not match with the test strip vial.	See 'Coding Meter to Match Test Strips' on pages 17-18.

If results continue to fall outside the range printed on the test strip vial, the Test Strip and Meter may not be working properly. Do not use your system and contact your authorised 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 included in the CareSens II Blood Glucose Monitoring System or any other medically approved lancing device.

Adjustable Tip   Lancet Holder   Ejection System

Lancet Load Confirmation Release Button Sliding Barrel
Window

- The lancing device is for use by a single user only and should not be shared with anyone.
- 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.
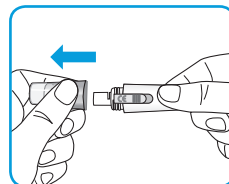
• Note
Repeated puncturing at the same sample site may cause pain or skin calluses (thick hard skin). Choose a different site each time you test.
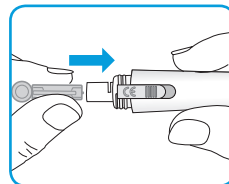
Preparing the Lancing Device

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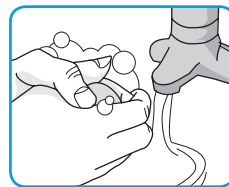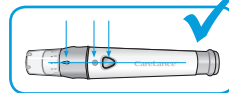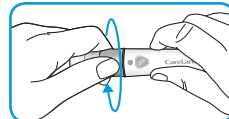

[2] Unscrew and remove the lancing device tip.

[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.

[4] Turn the adjustable tip until it is aligned with the load confirmation window and release button as shown in the diagram.

[5] Select a desired depth of one-to-seven (1-7) 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.
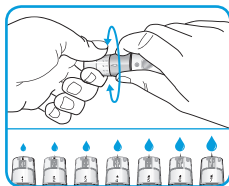
• Note
1 = least penetration of lancet into the skin.
7 = most penetration of lancet into the skin.

[6] To cock the lancing device, hold the body of lancing device in one hand. Pull the sliding barrel with the other hand. The device is loaded when you feel a click and the load confirmation window turns red.
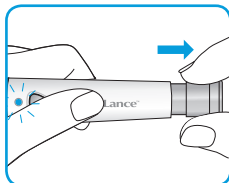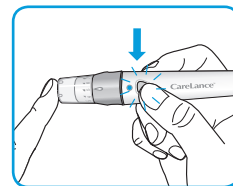

• Note
The skin depth to get blood samples will vary for various people at different sample sites. The lancing device's adjustable tip allows the best depth of skin penetration to get an adequate sample size.

Applying Blood Sample

[7] Obtain a blood sample using the lancing device. Place the device against the pad of the finger as shown in the diagram. 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 microlitre is needed to fill the confirmation window (actual size of 0.5 μL: ●)

[8] 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 in time because of abnormal viscosity (thickness and stickiness) or insufficient volume, the Er4 message may appear.
It is recommended to place the test strip vertically into the blood sample site as shown below.

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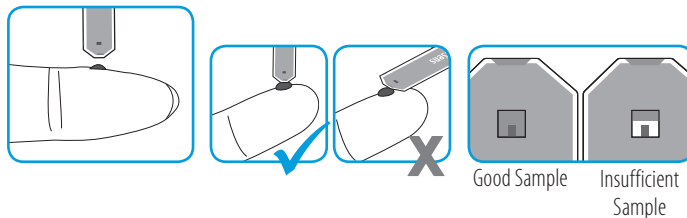
• Note
The meter may switch off if the blood sample is not applied within 2 minutes of the ( ) symbol appearing on the screen. If the meter turns off, remove the strip and reinsert it, and apply the blood sample after ( ) symbol appears on the screen.

[9] 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 appropriate containers.

Discarding Used Lancets
[1] Unscrew the lancing device tip.
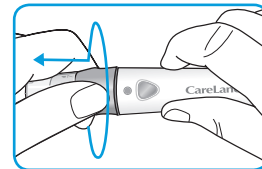
[2] Stick the lancet into the saved protective disk. Push the lancet ejector forward with the thumb to dispose of the used lancet in a proper biohazard container.

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

Alternate Site Testing

What is AST (Alternate 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 in the fingertip, it can be quite painful.
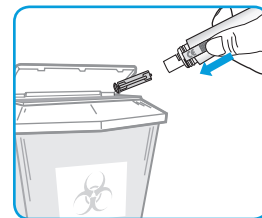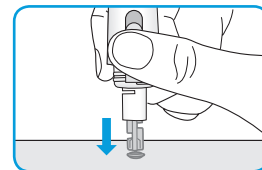When doing a glucose test, using different parts of the body such as the forearms, palms, thighs, and calves can reduce the pain during testing. This method of testing with different parts of the body is called Alternate Site Testing. While AST may reduce the pain during testing, it may not be simple for everyone and the following precautions should be observed during testing.

[Alternate Sites for Testing]
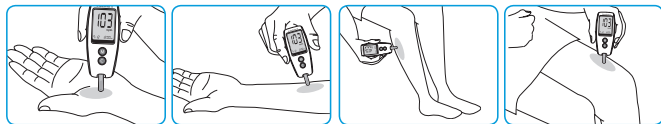
Alternate Site Blood Sampling (forearm, palm, thigh, calf)
Select a clean, soft and fleshy sample site area free of visible veins and hair and away from bones. Gently massage the sample site to help blood circulation to minimise result differences between fingertip and alternate site sampling.
Firmly 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 read the following before testing at alternate sites (forearms, palms, thighs, and calves).
The capillary whole blood at the fingertips reflects changes in glucose levels more rapidly than in alternate sites. The test results from the fingertip testing and AST may differ due to factors such as lifestyle and ingested food which affect 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 blood glucose levels are unstable
- During 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 recognised
- When insulin has the biggest effect
- During 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 alternate sites differs from person to person.
- Before using AST, please consult your healthcare professional.

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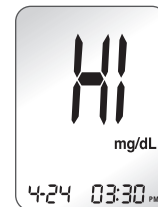
• Note
If the sample drop of blood runs or spreads due to contact with hair or with a line in your palm, do not use that sample. Try puncturing again in a smoother area.

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 upon 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 upon retesting, please contact your healthcare professional immediately.

• Note
Please contact your authorised 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 expert
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 less than 140 mg/dL (7.8 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 – 2016." *Diabetes Care*. January 2016; 39(1):S15, S100.

Transferring Test Results

Test results stored on **CareSens II** meter can be transferred from the meter to a computer using SmartLog software and cable. The meter screen displays 'Pc' when it is connected to the computer using the data cable.

For more information, contact your authorised i-SENS sales representative or visit www.i-sens.com.

Caring for Your System

Use a soft cloth or tissue to wipe the meter exterior. If necessary, dip the soft cloth or tissue in a small amount of alcohol.
Do not use organic solvents such as benzene, acetone, or any 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.
- Strong electromagnetic radiation may interfere with the proper operation of this device. Keep the device away from sources of strong electromagnetic radiation, especially when measuring your blood glucose.
- The **CareSens II** meter should be used only with **CareSens** strips.
- Keep the meter in a cool and well ventilated place.
- Store all the meter components in the carrying case to prevent loss.

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

Inserting or Replacing the Battery

When the 🔋 symbol 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 3.0 V nominal voltage, 220 mAh nominal capacity, and a 0.2 mA nominal standard discharge.

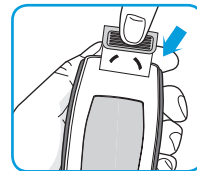[1] Turn the meter over and at the top you see the recess for openning the battery compartment cover. Slide the cover out of the meter.
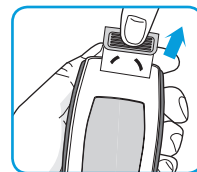
[2] Remove the battery. Insert new battery negative (-) side facing up.
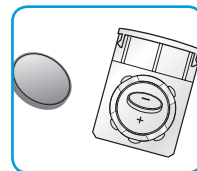
[3] Slide cover down until it clicks.

⚠ 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 42 X 18 (mm)
- Weight: 42.4 g (with battery)
- Operating Range
  - Temperature: 10-40°C/50-104°F
  - Relative Humidity: 10-90%
  - Hematocrit: 20-60%

Understanding Error and Other Messages

Message	What It Means	What To Do
Er 1	*A used test strip was inserted.*	Repeat the test with a new test strip.
Er2	*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.
Er3	*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
Er4 (display)	*The blood sample has abnormally high viscosity or insufficient volume.*	Repeat the test with a new test strip.

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

General Troubleshooting

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 with a new test strip.
The test result does not match the way you feel.	• Repeat the test after inserting a new test strip. • Check the expiration date of the test strip. • Perform control solution test.

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

Performance Characteristics

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

Accuracy: The accuracy of the **CareSens II** BGM System (Model GM505C) 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 (0.2 mmol/L)
Correlation coefficient (r)	0.995
Number of samples	115
Range tested	40-521 mg/dL (2.2-28.9 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)
13/19 (68%)	18/19 (95%)	19/19 (100%)

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

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

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

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

Total Precision		
Control avg.	44 mg/dL (2.4 mmol/L)	SD=1.7 mg/dL (0.1 mmol/L)
Control avg.	137 mg/dL (7.6 mmol/L)	CV=3.7%
Control avg.	355 mg/dL (19.7 mmol/L)	CV=4.0%

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

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 Authorised Warranty Station.

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