

Owner's Booklet

CareSens™ NPOP

Blood Glucose Monitoring System



i-SENS, Inc.

43, Banpo-daero 28-gil, Seocho-gu,

Seoul 06646, Korea

www.i-sens.com

[EC] [REP]

Medical Technology Promedt
Consulting GmbH
Altenhofstrasse 80,
66386 St. Ingbert, Germany



For self-testing

Welcome to the CareSens N POP Blood Glucose Monitoring System

Thank you for choosing the CareSens N POP 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.

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* The information in this manual is correct at the time of printing. However, i-SENS reserves the right to make any necessary changes at any time without notice as our policy is one of continuous improvement.

Table of Contents

Information

Important Information: Read This First!	4
Specifications	6
CareSens N POP Blood Glucose Monitoring System	7
Inserting or Replacing the Batteries	8
Caring for Your System	9
CareSens N Blood Glucose Test Strip	10
CareSens N POP Blood Glucose Meter	12
CareSens N POP Blood Glucose Meter Display	13

Preparation

Setting Up Your System	14
Adjusting the Date and Time	14
Setting the Sound On/OFF	17
Turning on the Strip Expiration Date Indicator	18
Turning on the Hypoglycemia (HYPo) Indicator	19
Setting the Strip Expiration Date Indicator	20
Checking the System	21
Control Solution Testing	22
Comparing the Control Solution Test Results	24

Testing

Using the Lancing Device	25
Preparing the Lancing Device	26
Preparing the Meter and Test Strip	28
Flagging Post-meal Test Results	28
Applying Blood Sample	29
Discarding Used Lancets	31
Alternate Site Testing	32
Hi and Lo Messages	35
Target Blood Glucose Ranges	36
Transferring Test Results	37

Additional Functions

Meter Memory	38
Viewing Averages	38
Viewing Test Results Stored in the Meter's Memory	40
Setting the Post-meal Alarm (PP2 Alarm)	41

Maintenance

Understanding Error Messages	42
General Troubleshooting	44
Performance Characteristics	45
Warranty Information	49

Important Information: Read This First!

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

Intended use:

CareSens N POP 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 POP Blood Glucose Monitoring System should be used only for self-testing outside the body (*in vitro* diagnostic use only). CareSens N POP 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 and palm.

Meaning of Symbols Used:

 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

 Use by (unopened or opened test strip vial)

 Do not discard this product with other household-type waste

 Do not reuse

 Consult instruction for use

 Temperature limitation

 Authorised representative

Important Information

- Glucose in blood samples reacts with the chemical in the test strip to produce a small electrical current. The CareSens N POP meter detects this electrical current and measures the amount of glucose in the blood sample.
- The CareSens N POP Blood Glucose Meter is designed to minimise code related errors in monitoring by using the no-coding function.
- The CareSens N POP Blood Glucose Meter should be used only with the CareSens N test strips.
- An abnormally high or low red blood cell count (hematocrit level over 65% or below 15%) may produce inaccurate results.
- If your test result is below 3.3 mmol/L or above 13.3 mmol/L, consult a healthcare professional immediately.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a 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.

Specifications

CareSens N POP Blood Glucose Monitoring System

Product specifications

Measurement range	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	2,000 tests
Power	Two 3.0 V lithium batteries (disposable, type CR2032)
Memory	1,000 test results
Size	95 X 33 X 19 (mm)
Weight	41.4 g (with batteries)

Operating ranges

Temperature	5-50°C (41-122°F)
Relative humidity	10-90%
Hematocrit	15-65%

Storage Conditions

Meter (with batteries)	0-50°C (32-122°F)
Test strip	1-30°C (34-86°F)

Components

CareSens N POP BGM System includes the following items:

- * CareSens N POP Blood Glucose Meter
- * Owner's Booklet
- * Quick Reference Guide
- * Batteries

Optional items:

- * CareSens N Blood Glucose Test Strips
- * Lancets
- * Lancing Device
- * Logbook
- * Carrying Case

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

Inserting or Replacing the Batteries

The CareSens N POP meter uses two 3.0 V lithium batteries. Before using the meter, check the battery compartment and insert batteries if empty.

When the  symbol appears on the display while the meter is in use, the batteries should be replaced as soon as possible. The test results may not be saved if the batteries run out.

Step 1

Make sure the meter is turned off. Press down and slide off the battery compartment cover.



Step 3

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

Note: Removing the meter batteries will not affect your stored results. However, you may need to reset your meter settings. See page 14.

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 household and industrial cleaners that may cause irreparable damage to the meter.

Caution:

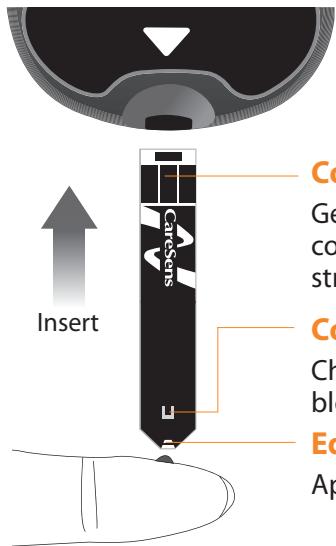
- Do not expose the meter to direct sunlight, heat, or excessive humidity for an extended period of time.
- Do not let dirt, dust, blood, or water enter into the meter's test strip port.
- Do not drop the meter or submit it to strong shocks.
- Do not try to fix or alter the meter in any way.
- Strong 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.
- Store all the meter components in the carrying case to prevent loss and help keep the meter clean.

Disposal of the meter

If you need to throw your meter away, you should follow existing policies and procedures of your own country or region. For information about correct disposal, please contact your local council or authority. If you need assistance, contact your authorised i-SENS sales representative or visit www.i-sens.com.

CareSens N Blood Glucose Test Strip

The CareSens N POP 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 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 N test strip package insert.

Caution:

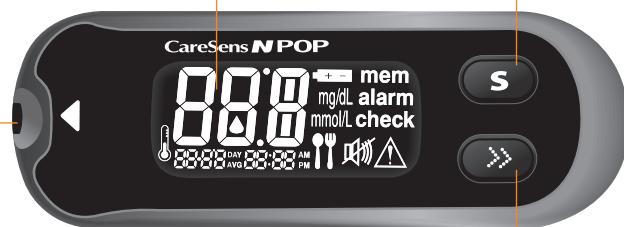
- Keep the meter and testing supplies away from young children.
- Drying agents in the vial cap may be harmful if inhaled or swallowed and may cause skin or eye irritation.

CareSens N POP Blood Glucose Meter

CareSens N POP Blood Glucose Meter Display

Display

Shows results, messages



Test Strip Port
Insert test strip here

>> Button
Selects or changes information

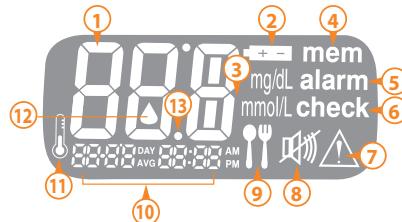
Data Port
Used to transfer data from the meter to a computer with a cable

Note:

- The cable for data management software can be ordered separately. Please contact your authorised i-SENS sales representative.
- The unit of measurement is fixed and it cannot be changed by the user.

S Button

Turns the meter on/off, confirms menu selections, and changes information



① Test results : test results displaying panel

② Battery symbol : indicates meter battery is running low and needs to be replaced

③ mmol/L, mg/dL : unit for measuring blood glucose

④ mem : appears when test results stored in the memory are displayed

⑤ alarm : appears when the post-meal alarm has been set

⑥ check : appears when the control solution test results are saved or displayed

⑦ Hypoglycemia symbol : appears when the test result is below the hypoglycemic level

⑧ Mute symbol : appears only when the sound is set to OFF

⑨ Post-meal test flag : used for tests done after eating

⑩ Month/Day/Hour/Minute

⑪ Temperature symbol : displays recorded temperature when blood glucose levels were tested

⑫ Blood insertion symbol : indicates meter is ready for the application of a drop of blood or control solution

⑬ Decimal point : appears when the blood glucose measuring unit is set to mmol/L

Note: It is recommended to check if the display screen on the meter matches the illustration above 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.

Setting Up Your System

Press and hold the **S** button for 3 seconds to enter SET mode. After all settings are finished, press and hold the **S** button for 3 seconds to turn off the meter. Press the **>>** button to change values. Press and hold the **>>** button to scroll faster.

Adjusting the Date and Time

Step 1 Entering the SET Mode

Press and hold **S** button for 3 seconds to enter SET mode. After all the segments flash across the screen, 'SET' will show up. Press the **S** button again to go to the next step.



Step 2 Setting the Year

Press the **>>** button to adjust until the correct year appears. When the present year appears, press the **S** button to confirm your selection and to go to the next step.



Step 3 Setting the Month

A number indicating the month will blink on the left corner of the screen. Press the **>>** button until the correct month appears. Press the **S** button to confirm your selection and to go to the next step.



Step 4 Setting the Date

Press the **>>** button until the correct date appears. Press the **S** button to confirm your selection and to go to the next step.



Step 5 Setting the Time Format

The meter can be set in the AM/PM 12-hour or the 24-hour clock format. Press the **>>** button 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 go to the next step.



Step 6 Setting the Hour

Press the  button until the correct hour appears. After the hour is set, press the  button to go to the next step.



Step 7 Setting the Minute

Press the  button until the correct minute appears. After setting the minute, press the  button to go to the next step.



Setting the Sound On/OFF

Step 8

On pressing the  button, the screen will display 'On' or 'OFF'. Press the  button to confirm the selection.



The meter will beep in the following instances if the sound is set to On:

- When you press the  or  button to turn on the meter,
- When the test strip is inserted in the meter,
- When the blood sample is absorbed into the test strip and the test starts,
- When the test result is displayed,
- When you press and hold the  button to set the post-meal (PP2) alarm,
- When it is time for a pre-set blood glucose test.



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

After setting the sound, press the  button to go to the next step.

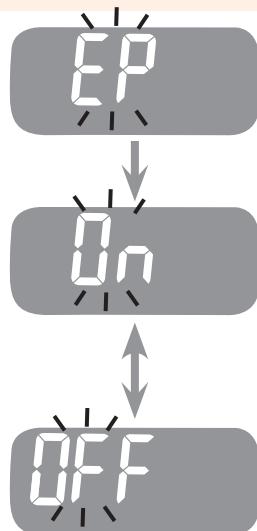
Note: The  symbol is displayed only when the sound is set to OFF.

Turning on the Strip Expiration Date Indicator

Step 9

This setting allows you to turn the strip expiration date indicator on or off. This setting turns the function on or off only. See page 20 to set the strip expiration date.

When 'EP' blinks on the screen, press the  button. The screen will display 'On' or 'OFF'. Press the  button to confirm the setting and to go to the next step.



Turning on the Hypoglycemia (HYPo) Indicator

Step 10

This setting allows you to turn the hypoglycemia indicator (possible low blood sugar) on or off and to select the desired level for the indicator.

'HYPo' will be displayed with hypoglycemia symbol (\triangle).

On pressing the  button, the screen will display 'On' or 'OFF'. Press the  button when 'On' appears to enter the setting.

Press the  button until the desired hypoglycemia level between 1.1 and 5.0 mmol/L is displayed. Press the  button to confirm the hypoglycemia level.

If you do not want to set the indicator, press the  button while the screen displays 'OFF'. Then, the screen will return to step 2. See page 14.

To confirm all settings, press and hold the  button for 3 seconds and the screen will switch off.

Note: If the test result is lower than the pre-set hypoglycemia level, the meter will display the following.



Caution: Ask your healthcare professional to help you decide what your hypoglycemia level is before setting your level.

Setting the Strip Expiration Date Indicator

Step 1 Entering the Expiration Date Setting

Press and hold the and buttons at the same time for 3 seconds to enter the expiration date settings. After all segments flash across the screen, 'EP' will show up.

Press the button to set the strip expiration date.

Note: The strip expiration date is printed on the test strip vial.



Step 2 Setting the Year

A number indicating the year will blink at the bottom left corner of the screen.

Press the button until the correct year appears. Press the button to confirm the year and set the month.



Step 3 Setting the Month

A number indicating the month will blink at the bottom of the screen. Press the button until the correct month appears.

After finishing the setting, press and hold the button for 3 seconds to turn off the meter.



Note: If the pre-set expiration date reached, the meter will display the following. For example, in the case when the expiration date is set to October of 2020, the meter displays 'EP' in the beginning of November of 2020.



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 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 22-23.

Notes:

- Use only the CareSens Control Solutions.
- 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 or a new box 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 show up.



Step 2

Shake the 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.

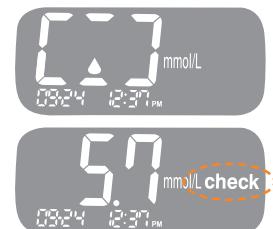
After the  symbol appears on the display, apply the solution to the narrow edge of the test strip until the meter beeps. Make sure the confirmation window fills completely.



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

The display segments will rotate clockwise and a test result will appear after the meter counts down from 5 to 1. After your control solution result appears on the display, press and hold the  button for 3 seconds till 'check' appears on the display. When 'check' is displayed, the result is not stored in the memory and is not included in the averages.



Step 4

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



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

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

Using the Lancing Device

Comparing the Control Solution Test Results

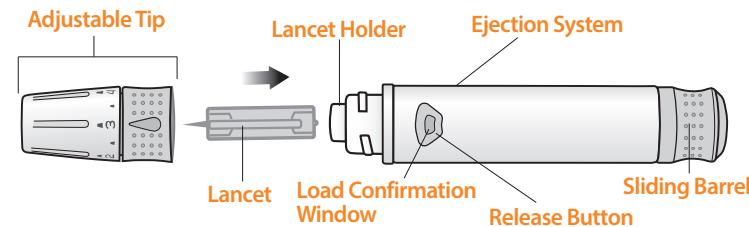
The test result of each control solution should be within the range printed on the label of the test strip vial. Repeat the control solution test if the test result falls outside of the range. Out of range results may occur in following situations:

Situations	Do This
<ul style="list-style-type: none">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 21.
<ul style="list-style-type: none">When the control solution is past the expiration date printed on the bottle,When the control solution is past its discard date,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 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 that is included in the CareSens N POP Blood Glucose Monitoring System or any other medically approved lancing device.



- 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.

Caution: To avoid infection when drawing a sample, do not use a lancet more than once, 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

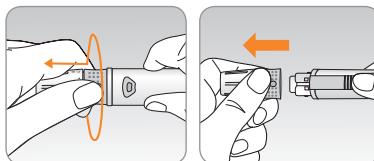
Step 1

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



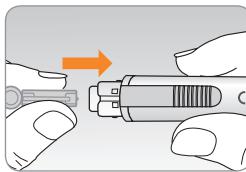
Step 2

Unscrew and remove the lancing device tip.



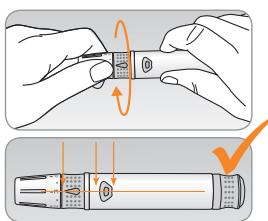
Step 3

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.



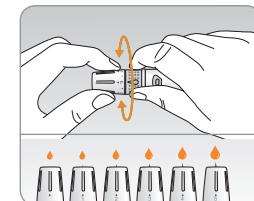
Step 4

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



Step 5

The lancing device has six puncture depth settings (0 for a shallow puncture, 5 for a deeper puncture). Choose a depth by rotating the top portion of the adjustable tip until the desired number aligns with the arrow.

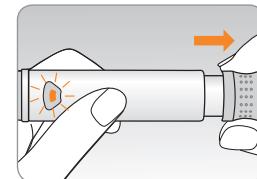


Note:

0 = a shallow puncture for softer skin
5 = a deeper puncture for thick or calloused skin

Step 6

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

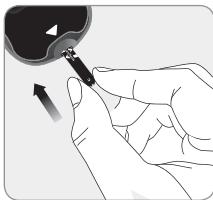


Note: The skin depth to get blood samples will vary for various people at different sample sites. The lancing device's adjustable tip allows the best depth of skin penetration to get an adequate sample size.

Preparing the Meter and Test Strip

Step 7

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.



Flagging Post-meal Test Results

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

Step 8

If you want to attach a post-meal flag () to a test result, press and hold the  button for 3 seconds after inserting the test strip. The post-meal flag () and the  symbol will appear on the screen.

The test result will also be displayed with the post-meal flag () . If you do not want to save the result as a post-meal test, move on to step 9 after step 7.

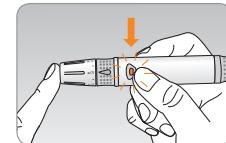


Caution: If 'EP' blinks on the screen when a test strip is inserted, check your strip expiration date. ('EP' only appears when the setting of notifying expiration date feature is ON. Please read page 18 or page 20 for further information on setting strip expiration date.)

Applying Blood Sample

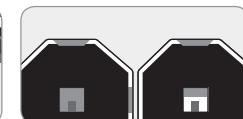
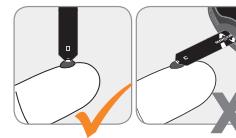
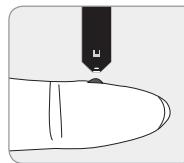
Step 9

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. Remove the device from the finger. Wait a few seconds for a blood drop to form. You need a minimum volume of 0.5 microliter for blood glucose test with CareSens N test strip (Actual size of 0.5 μ L: ).



Step 10

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

Caution:

Do not allow any foreign substances, such as dirt, blood, or water, enter into the meter. The meter may be damaged or may malfunction. Follow the warning information provided below to prevent possible damage to the meter.

- Do not apply the blood sample directly to the test strip port.
- Do not apply the blood sample to the test strip while holding the meter in a way that the tip of the test strip faces upwards. The blood sample may run down the surface of the test strip and flow into the test strip port.
- Do not store your meter in unsanitary or contaminated sites.

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 start from Step 7.

Step 11

Apply the blood sample to the narrow end of the test strip until you hear a beep. At this time, the display segments will rotate clockwise while the blood is going in.

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.

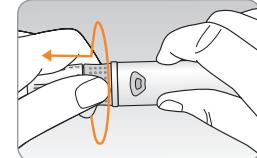
Discard used test strips safely in disposable containers.



Discarding Used Lancets

Step 1

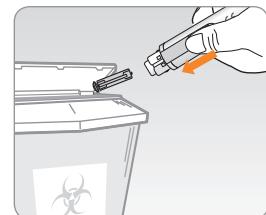
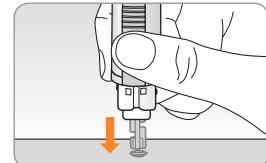
Unscrew the lancing device tip.



Step 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.



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

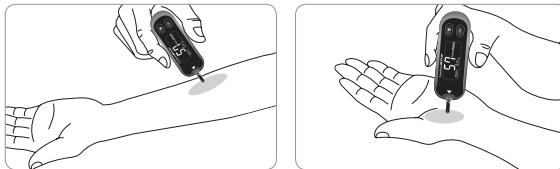
Alternate Site Testing

Before using AST, please consult your healthcare professional.

What is AST (Alternate Site Testing)?

Usually, we 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 and palms 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)

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 and palms).

The capillary whole blood of 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 going to bed

Situations Requiring Fingertip Test

When your blood glucose levels are unstable

- During two (2) 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

Hi and Lo Messages

AST Precautions

- Before using AST, please consult your healthcare professional.
- 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.

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.
- 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 Message

The meter displays blood glucose results between 1.1-33.3 mmol/L. 'Hi' appears when the blood glucose level is greater than 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 blood glucose test result is less than 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.



* When hypoglycemia indicator is on, symbol also appears.



Note: Please contact your authorised i-SENS sales representative if such messages are displayed even though 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 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 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 – 2017. *Diabetes Care*, January 2017, vol. 40, Supplement 1, S11-S24)

Transferring Test Results

Test results stored in CareSens N POP meter can be transferred from the meter to a computer using PC care/ 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 at www.i-sens.com.



Meter Memory

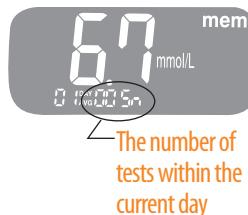
The CareSens N POP meter can save up to 1,000 test results with time and date. If the memory is full, the oldest test result will be deleted and the latest test result will be stored.

The meter calculates and displays the averages of total test results, pre-meal test (Pr) results, and post-meal test (🍴) results from the last 1, 7, 14, 30, and 90 days.

Viewing Averages

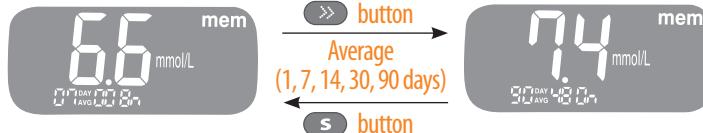
Step 1

Press the ➤ or s button to turn the meter on. The current date and time will be displayed at the bottom of the screen followed by the 1 day average value and the number of the test results saved within the current day.



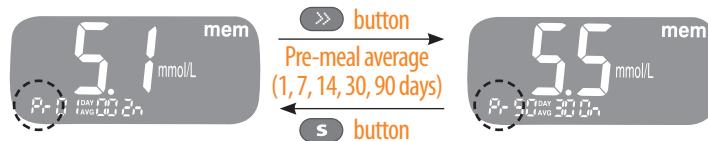
Step 2 Viewing Averages

Press the ➤ button to view 7, 14, 30, and 90-day average values and the number of tests performed for the last test period.



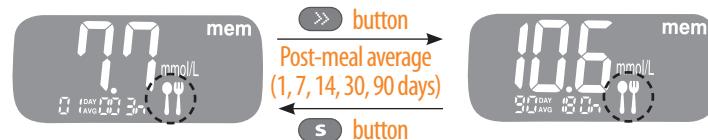
Step 3 Viewing Pre-meal Averages

Repeatedly press the ➤ button to view 1, 7, 14, 30, and 90-day average values and the number of tests performed pre-meals with the 'Pr' symbol for the last test period.



Step 4 Viewing Post-meal Averages

On pressing the ➤ button again, 1, 7, 14, 30, and 90-day average values and the number of tests performed post-meals for the last test period will appear on the screen.



Use the s button to scroll back through the averages seen previously.

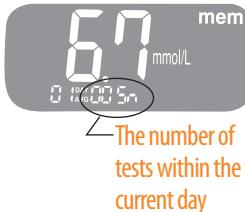
Press and hold the s button to turn off the meter.

Setting the Post-meal Alarm (PP2 Alarm)

Viewing Test Results Stored in Memory

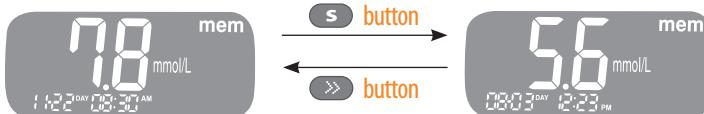
Step 1

Press the **S** button to turn the meter on. The current date and time will be displayed on the bottom of the screen followed by the 1 day average value and the number of the test results saved within the current day.



Step 2

Use the **S** button to scroll through the test results, starting from the most recent and ending with the oldest. Press the **>>** button to return to the results seen previously. The test date and the recorded temperature will display alternately. After checking the stored test results, press and hold the **S** button to turn off the meter.



The PP2 alarm activates 2 hours after setting the alarm. The alarms ring for 15 seconds and can be silenced by pressing the **>>** or **S** button or by inserting a test strip.

Step 1 Turning the PP2 alarm On

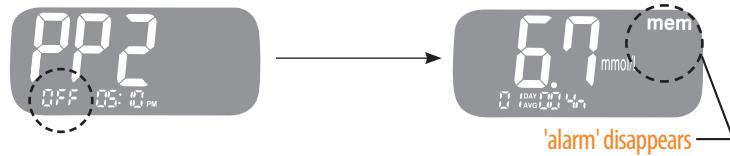
Without inserting a test strip, press and hold the **>>** button for 3 seconds to set the post-meal alarm. 'PP2', 'alarm', and 'On' will be displayed.

The screen will then automatically change to the memory recall mode. At this time, 'alarm' indicating that the PP2 alarm has been set will be displayed on the screen.



Step 2 Turning the PP2 alarm OFF

To turn off the PP2 alarm, press and hold the **>>** button for 3 seconds. 'PP2' and 'OFF' will appear on the screen. Then the screen will change automatically to the memory recall mode without 'alarm' displayed.



Understanding Error Messages

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 blood sample has abnormally high viscosity or insufficient volume.	Repeat the test with a new test strip.
	This error message may appear when the wrong blood glucose test strip is used instead of the CareSens N test strip.	Repeat the test with a CareSens N test strip.
	There is a problem with the meter.	Do not use the meter. Contact your authorised i-SENS sales representative.

Message	What It Means	What To Do
	An electronic error occurred during the test.	Repeat the test with a new test strip. If the error message persists, contact your authorised i-SENS sales representative.
	The temperature during the test was above the operating range.	Move to an area where the temperature is within the operating range (5-50°C/41-122°F) and repeat the test.
	The temperature during the test was below the operating range.	Move to an area where the temperature is within the operating range (5-50°C/41-122°F) and repeat the test.

Note: 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.	<ul style="list-style-type: none">Check whether the test strip is inserted with the contact bars facing upwards. 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 upwards.Replace the batteries.
The test does not start even after applying the blood sample on the strip.	<ul style="list-style-type: none">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.	<ul style="list-style-type: none">Repeat the test with a new test strip.Check the expiration or discard 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 N POP Blood Glucose Monitoring System has been evaluated in laboratory and in clinical tests.

Accuracy: The accuracy of the CareSens N POP Blood Glucose Monitoring System (Model: GM505WAC, GM505WBC) 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	1.0009
Y-intercept	0.10 mmol/L
Correlation coefficient (r)	0.995
Number of samples	600
Range tested	2.0–26.4 mmol/L

System accuracy results for glucose concentration < 5.55 mmol/L

Within \pm 0.28 mmol/L	Within \pm 0.56 mmol/L	Within \pm 0.83 mmol/L
74/156 (47.4%)	133/156 (85.3%)	155/156 (99.4%)

System accuracy results for glucose concentration \geq 5.55 mmol/L

Within \pm 5%	Within \pm 10%	Within \pm 15%
288/444 (64.9%)	413/444 (93.0%)	443/444 (99.8%)

System accuracy results for glucose concentrations between 2.0 mmol/L and 26.4 mmol/L

Within \pm 0.83 mmol/L and Within \pm 15%
598/600 (99.7%)

Precision: The precision studies were performed in a laboratory using CareSens N POP Blood Glucose Monitoring Systems.

Within Run Precision

*Blood avg.	2.1 mmol/L	SD = 0.1 mmol/L
*Blood avg.	4.6 mmol/L	SD = 0.2 mmol/L
*Blood avg.	6.9 mmol/L	CV = 3.0%
*Blood avg.	11.7 mmol/L	CV = 3.2%
*Blood avg.	17.1 mmol/L	CV = 2.6%

Total Precision

*Control avg.	2.1 mmol/L	SD = 0.1 mmol/L
*Control avg.	6.6 mmol/L	CV = 3.8%
*Control avg.	17.4 mmol/L	CV = 3.3%

This study shows that there could be variation of up to 3.8%.

Packed Cell Volume (Hematocrit)

The hematocrit levels (15–65%) were tested to evaluate the effect of hematocrit level on measurement of glucose concentration.

Range (mmol/L)	Average of difference (Hct 15–65%)
1.7 to 2.8	-0.2–0.1 mmol/L
5.3 to 8.0	-1.5–7.1%
15.5 to 23.3	-5.4–1.1%

Interferences

The effect of various interfering substances was evaluated in whole blood samples on glucose measurements.

No.	Interferent	Difference Averages	
		Interval1 (2.8–5.5 mmol/L)	Interval 2 (13.9–19.4 mmol/L)
1	Acetaminophen	-0.1 mmol/L	-3.3%
2	Ascorbic acid	0.4 mmol/L	-0.9%
3	Bilirubin (unconjugated)	-0.01 mmol/L	1.4%
4	Ceftriaxone	0.1 mmol/L	2.4%
5	Cholesterol	-0.1 mmol/L	-1.8%
6	Creatinine	0.01 mmol/L	0.7%
7	Dopamine	0.1 mmol/L	0.4%
8	EDTA	0.1 mmol/L	1.4%
9	Galactose	-0.1 mmol/L	-0.1%
10	Gentisic acid	-0.1 mmol/L	-4.4%
11	Glutathione (Red)	-0.2 mmol/L	0.6%
12	Hemoglobin	-0.01 mmol/L	-0.5%
13	Heparin	0.1 mmol/L	2.8%
14	Hydrocortisone	0.02 mmol/L	1.9%
15	Ibuprofen	-0.1 mmol/L	2.8%
16	Icodextrin	-0.2 mmol/L	-0.5%

Warranty Information

No.	Interferent	Difference Averages	
		Interval1 (2.8–5.5 mmol/L)	Interval 2 (13.9–19.4 mmol/L)
17	L-Dopa	0.04 mmol/L	0.5%
18	Maltose	-0.4 mmol/L	-1.1%
19	Mannitol	0.1 mmol/L	-0.7%
20	Methyldopa	-0.03 mmol/L	0.2%
21	Pralidoxime Iodide	0.0 mmol/L	1.4%
22	Salicylate	0.1 mmol/L	-0.1%
23	Tolazamide	-0.3 mmol/L	-2.8%
24	Tolbutamide	-0.3 mmol/L	-7.3%
25	Triglycerides	-0.1 mmol/L	4.7%
26	Uric acid	-0.1 mmol/L	0.5%
27	Xylose	-0.04 mmol/L	-1.0%

User Performance Evaluation

A study evaluating glucose values from fingertip capillary blood samples obtained by 100 lay persons showed the following results:

100% within ± 0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L and 98.3% within $\pm 15\%$ of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L.

Manufacturer's Warranty

i-SENS, Inc. warrants that the CareSens N POP 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.

i-SENS 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 sales or customer service representative.

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