NFC antenna in the back of the meter

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 PGA1E3422 REV2 2019/08 CE 0123 IVD

i-sens

Owner's Booklet

NFC

CareSens™ N

Blood Glucose Monitoring System

NFC
Near Field
Communication

SmartLog App
Free Download

Android
Smartphone

Welcome to the CareSens N NFC Blood Glucose Monitoring System

Thank you for choosing the CareSens N NFC 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.

In addition, you can send your results to your smartphone using the SmartLog application which is very helpful in managing your blood glucose levels.
To use the NFC function in your smartphone, you need to install the SmartLog application. Please search "SmartLog" or "i-SENS" in GooglePlay.

SMART LOG

Android

How to Tag Your Meter to Your Smartphone

❶ Antenna located in the middle section of your smartphone

❷ Antenna located in the mid-lower section of your smartphone

❸ Antenna located in the lower-right section of your smartphone

❹ Antenna located in the lower-left section of your smartphone

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

Meaning of Symbols Used:

IVD For *in vitro* diagnostic use

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

Cautions for safety and optimum product use

Consult instructions for use

Do not discard this product with other household-type waste

Use by (unopened or opened test strip vial)

Manufacturer

Temperature limitation

Do not reuse

LOT Batch code

SN Serial number

EC REP Authorised representative

- Glucose in blood samples reacts with the chemical in the test strip to produce a small electrical current. The CareSens N NFC meter detects this electrical current and measures the amount of glucose in the blood sample.
- The CareSens N NFC Blood Glucose Meter is designed to minimise code related errors in monitoring by using the no-coding function.
- The CareSens N NFC 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 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 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.

Product specifications

Measurement range	20–600 mg/dL (1.1–33.3 mmol/L)
Sample size	Minimum 0.5 µL
Test time	5 seconds
Sample type	Fresh capillary whole blood
Calibration	Plasma-equivalent
Assay method	Electrochemical
Battery life	2,000 tests
Power	One 3.0 V lithium battery (disposable, type CR2032)
Memory	500 test results
Size	93 X 47 X 15 (mm)
Weight	51.5 g (with battery)

Operating ranges

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

Storage Conditions

Glucose meter (with battery)	0–50 ˚C (32–122 ˚F)
Test strip	1–30 ˚C (34–86 ˚F)

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

Optional items:
* CareSens N Blood Glucose Test Strips
* Lancets
* Lancing Device
* Logbook
* Carrying Case

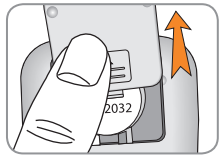
- Check all the components after opening the CareSens N NFC Blood Glucose Monitoring System package. The exact contents are listed on the main box.
- The cable for data management software can be ordered separately. Please contact your authorised i-SENS sales representative.

Inserting or Replacing the Battery

The CareSens N NFC Meter comes with one 3.0 V lithium battery. Before using the meter, check the battery compartment and insert battery 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 battery runs out.

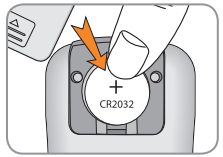
Step 1

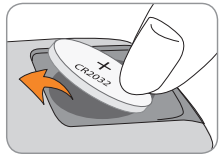
Make sure the meter is turned off. Push the cover in the direction of the arrow to open the battery compartment.



Step 2

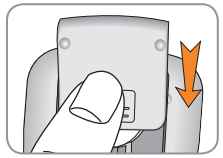
Remove the old battery by pushing it out with your thumb as shown in the figure on the right. Insert a new battery with the + side facing up and make sure the battery is inserted firmly.





Step 3

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



Note: Removing the meter battery will not affect your stored results. However, you may need to reset your meter settings. See pages 14-20.

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:

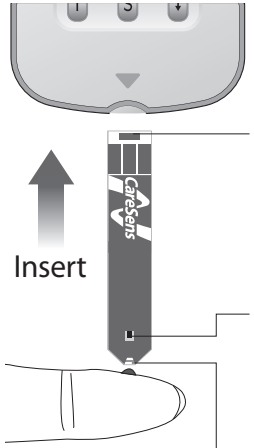
- Do not expose the meter to direct sunlight or heat for an extended period of time.
- Do not let dirt, dust, blood, or water enter into the meter's test strip port.
- Do not drop the meter or submit it to strong shocks.
- Do not try to fix or alter the meter in any way.
- Strong electromagnetic radiation 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.
- Keep the meter in a cool and well ventilated place.
- Store all the meter components in the portable 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 NFC 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

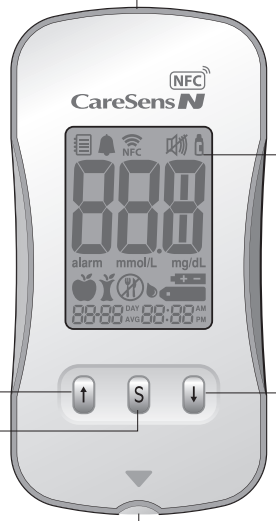
Warning!

- 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 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 NFC Blood Glucose Meter



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

Display
Shows results, messages

⬆ Button
Selects or changes information

⬇ Button
Selects or changes information

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

Test Strip Port
Insert test strip here

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

CareSens N NFC Blood Glucose Meter Display

PP2 alarm
appears when the post-meal alarm has been set

Memory recall mode
appears when test results stored in the memory are displayed

Test results
test results displaying panel

alarm
appears when the time alarm has been set

Pre-meal flag
appears when pre-meal test results are saved or displayed

Post-meal flag
appears when post-meal test results are saved or displayed

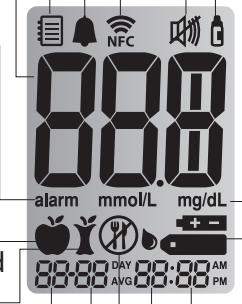
NFC icon
appears when NFC Time Synchronization function is performed

Mute symbol
appears only when the sound is set to OFF

Control solution flag
appears when the control solution test results are saved or displayed

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

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

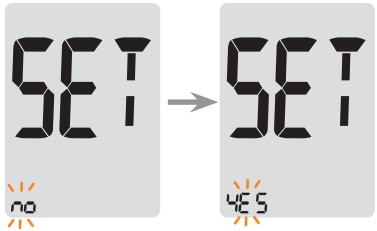


Fasting flag
appears when fasting test results are saved or displayed

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.

Step 1 Entering the SET Mode

Press and hold the **S** button for 3 seconds to enter SET mode. After all the segments flash across the screen, "SET" will show up.
Press the ⬆ or ⬇ button to select "YES" and press the **S** button to go to the next step.



Adjusting the Date and Time

Step 2 Setting the Year

Press the ⬆ or ⬇ 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 screen.
Press the ⬆ or ⬇ 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 ⬆ or ⬇ button until the screen displays the correct date. Press the **S** button to confirm the date 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 ⬆ or ⬇ 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 ⬆ or ⬇ button until the correct hour appears.
After the hour is set, press the **S** button to go to the next step.

Step 7 Setting the Minute

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

Setting the Sound On/OFF

Step 8

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

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

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

If the sound is set to OFF, none of the sound functions will work. After setting the sound, press the **S** button to progress to the next step.

Note:

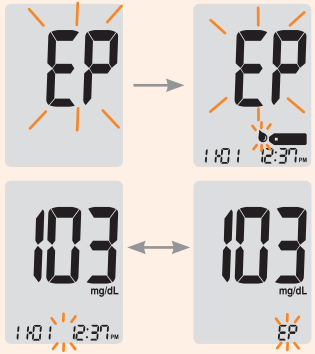
- The 🔇 symbol is displayed only when the sound is set to OFF.
- At any stage, press the **S** button for 3 seconds to exit SET mode and turn off the meter.

Turning on the Strip Expiration Date Indicator

Step 9

This mode allows you to turn the strip expiration date indicator on or off. This mode turns the function on or off only. See page 20 to set the strip expiration date.
When "EP" blinks on the screen, press the ⬆ or ⬇ button. The screen will display "On" or "OFF". Press the **S** button to confirm the setting. If you do not want to set the indicator, press the **S** button while the screen displays "OFF".

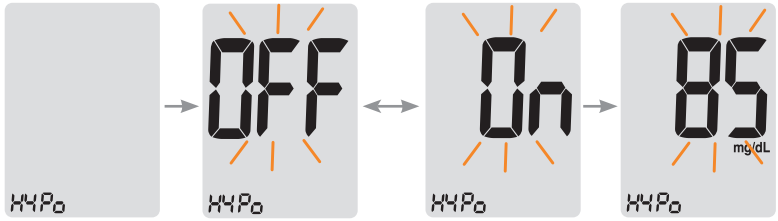
Note: If the pre-set expiration date expires, the meter will display "EP" when the test strip is inserted. EP shows alternately also when the test result is displayed right after the test.
If the expiration date is set to October of 2021, the meter will display "EP" at the start of November, 2021.



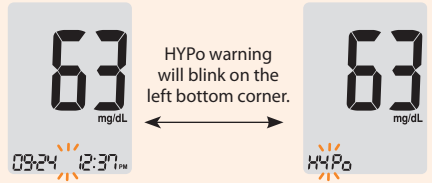
Turning on the Hypoglycemia (HYPo) Indicator

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. You will be alerted any time your test result is lower than the selected level. On pressing the ⬆ or ⬇ button, the screen will display "On" or "OFF". Press the **S** button when "On" appears to enter the setting. Press the ⬆ or ⬇ button until the desired hypoglycemia level between 20 and 90 mg/dL (1.1–5.0 mmol/L) appears. Press the **S** button to confirm the hypoglycemia level and go to the next step.



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 hypoglycemic 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.

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 ⬆ or ⬇ button until the correct year appears. Press the **S** 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 ⬆ or ⬇ button until the correct month appears.
Press and hold the **S** button for 3 seconds to confirm the month and turn off the meter.

Checking the System

You may check your meter and test strips using the CareSens Control Solution(control A, B and/or C).
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 22–24.

Notes:

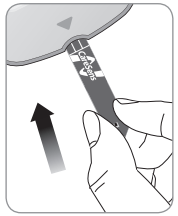
- Use only the CareSens Control Solutions.
- Check the expiration date printed on the bottle. When you first open a control solution bottle, record the discard date (date opened plus three (3) months) in the space provided on the label.
- Make sure your meter, test strips, and control solution are at 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 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

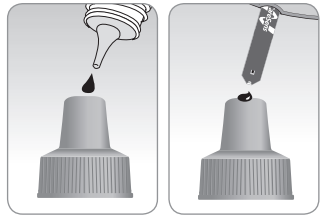


Insert a test strip into the meter's test strip port, with the contact bars facing upwards.
Gently push the test strip into the port until the meter beeps. Be careful not to bend the strip while pushing it in.
The symbol will show up.

Step 2

You can flag the control solution test result by pressing the ↓ button for 3 seconds. To undo the control solution flag, press the ↓ button for 3 seconds again.

Step 3



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. Dispense a drop of control solution onto a clean non-absorbent surface. It helps to squeeze a drop onto the top of the cap as shown. 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.

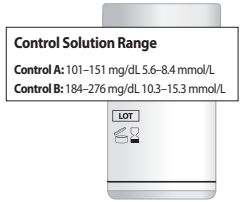
Note: The meter may switch off if the control solution sample is not applied within 2 minutes of the symbol appearing on the screen. If the meter turns off, remove the strip, reinsert, and start from step 1.

Step 4

The display segments will rotate clockwise on the meter display and a test result will appear after the meter counts down from 5 to 1.
The test result with control solution flag is stored in the memory but not included in the averages.

Step 5

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



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.

Comparing the Control Solution Test Results

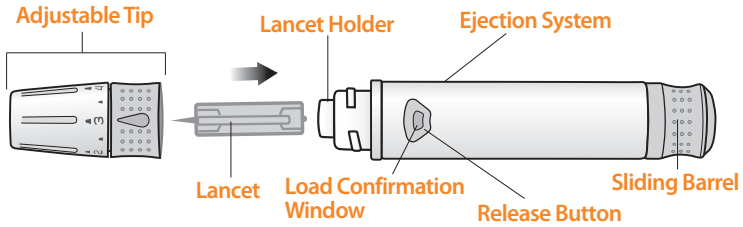
The test result of each control solution should be within the range printed on the label of the test strip vial. Repeat the control solution test if the test result falls outside of the range. Out of range results may occur due to following factors:

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 21.
• When the control solution is past the expiration date printed on the bottle, • When the control solution is past its discard date (the date the bottle was opened plus three (3) months), • When the control solution is contaminated.	Discard the used control solution and repeat the test using a new bottle of control solution.

If results continue to fall outside the range, the CareSens N Test Strip and CareSens N NFC 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 that is included in the CareSens N NFC 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.

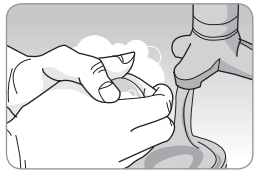
Caution: To avoid infection when drawing a sample, do not use a lancet more than once, and:
- Do not use a lancet that has been used by others.
- Always use a new sterile lancet.
- Keep the lancing device clean.

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

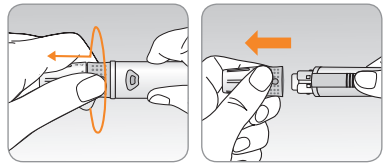
Step 1

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



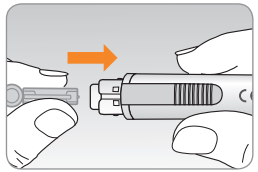
Step 2

Unscrew and remove the lancing device tip.



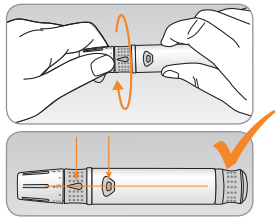
Step 3

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.



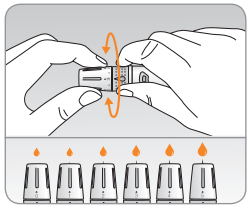
Step 4

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



Step 5

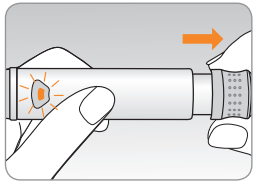
The lancing device has six puncture depth settings (0 for a shallow puncture, 5 for a deeper puncture). Choose a depth by rotating the top portion of the adjustable tip until the desired number aligns with the arrow.



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.

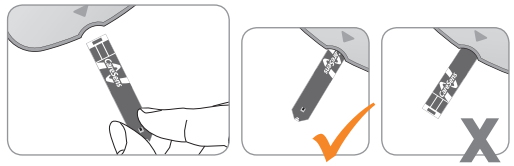


Note: The skin depth to get blood samples will vary for various people at different sample sites. The lancing device's adjustable tip allows the best depth of skin penetration to get an adequate sample size.

Preparing the Meter and Test Strip

Step 7

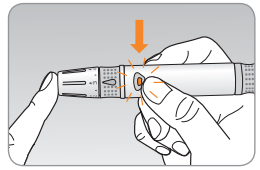
Insert a test strip with the contact bars facing upwards into the meter's test strip port. Push the strip in gently until the meter beeps. Be careful not to bend the test strip. The  symbol will appear on the screen.



Applying Blood Sample

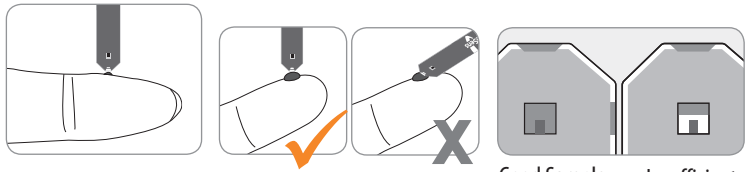
Step 8

Obtain a blood sample using the lancing device. Place the device against the pad of the finger as shown in the diagram. Press the release button. Remove the device from the finger. Wait a few seconds for a blood drop to form. A minimum volume of 0.5 microliter is needed to fill the confirmation window (Actual size of 0.5 µL : ●).



Step 9

After the symbol appears on the screen, apply the blood sample to the narrow end of the test strip till the meter beeps.
If the confirmation window is not filled in time due to 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.



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 apply blood sample after the symbol appears on the screen.

Step 10

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.

Test result

Step 11

You can attach a flag to a blood glucose test result to indicate particular situations while the strip is still in the meter. When the result is displayed right after a test, press the ⬆ or ⬇ button to select a pre-meal flag ( ), a post-meal flag ( ), a fasting flag ( ), or a control solution flag ( ). When you remove the test strip while the desired flag is blinking, the test result is stored with the flag.
If you do not want to add any flags on the test result, remove the strip after the test result is displayed.

No flag

Pre-meal flag

Post-meal flag

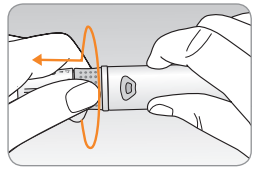
Fasting flag

Control solution flag

Discarding Used Lancets

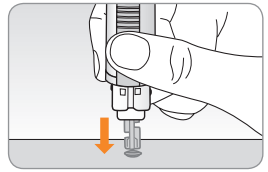
Step 1

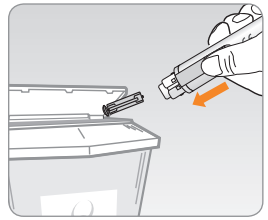
Unscrew the lancing device tip.



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.



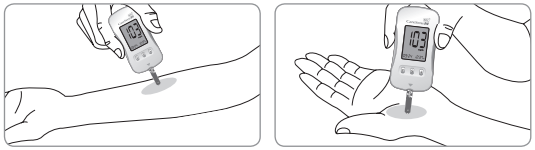


Caution: The lancet is for single use only. Never share or reuse a lancet. Always dispose of lancets properly.

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 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 and 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 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 Situation for AST

When your blood glucose levels are stable

- Fasting period
- Before a meal
- Before sleeping

Situations Requiring Fingertip Test

When your glucose levels are unstable

- During 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.
- 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 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 : Normal blood glucose levels for an adult without diabetes are below 100 mg/dL (5.5 mmol/L) before meals and fasting* and are less than 140 mg/dL (7.8 mmol/L) two hours after meals.

*Fasting is defined as no caloric intake for at least eight hours.

Reference

American Diabetes Association. "Standards of Medical Care in Diabetes – 2018. *Diabetes Care*, January 2018, vol. 41, Supplement 1, S13-S27.

Transferring Test Results

Test results stored on the CareSens N NFC 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.

NFC(Near Field Communication)

NFC(Near Field Communication)

NFC as an acronym for Near Field Communication is a function which allows transmission of glucose test results to smartphones installed with an NFC chip when a glucose meter is closely placed to the receiving device. By using the NFC function, saving and reviewing the glucose test results in devices such as smartphones can be convenient. The NFC function of i-SENS' blood glucose meters is designed in accordance with the RF protocol of ISO15693 and ISO18000-3 mode 1.

Precautions of the NFC Function

- The NFC function operates on Android based smartphone V4.1 or later (Does not operate on Apple iOS system). It is possible to confirm the installation of NFC antenna and its position in your smartphone by visiting the manufacturer's website or manual.
- To use the NFC function, please set the NFC function ON on the smartphone.
- When using the NFC function, the function may not operate correctly if your meter is placed farther than the fixed distance. The communication distance may differ on the type of smartphones used.

Methods to Use the NFC Function

Step 1

When transmitting glucose test results, the position of the NFC antenna in the smartphone should be confirmed.

Step 2

To transmit glucose data using the NFC function, you need to launch the SmartLog mobile app. When you tag your smart phone, NFC communication will start and Glucose test result will be transferred.

Step 3

After the transfer is completed, the glucose test result is saved.

Note:

- To use NFC function in your smartphone, you need to install the SmartLog application in your smartphone.
- To download the smartphone application, search "SmartLog" or "i-SENS" in GooglePlay.

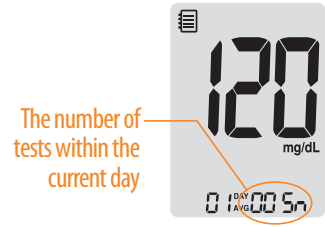
The CareSens N NFC Meter can save up to 500 glucose test results with time and date. If the memory is full, the oldest test result will be deleted and the latest test result will be stored.

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

Viewing Averages Stored in the Memory

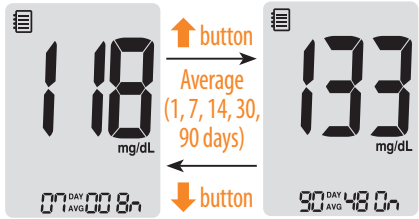
Step 1

Press any 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.



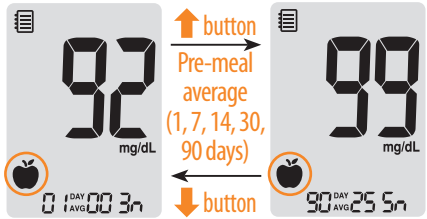
Step 2 Viewing Averages

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



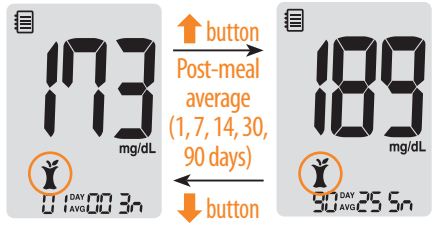
Step 3 Viewing Pre-meal Averages

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 symbol for the last test period.



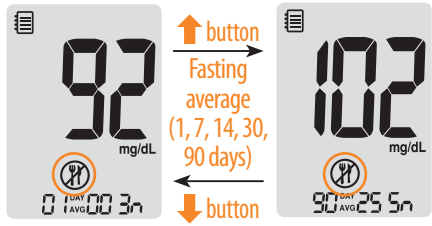
Step 4 Viewing Post-meal Averages

Press the ⬆ button to view 1, 7, 14, 30 and 90-day average values and the number of tests performed post-meals with the symbol for the last test period.



Step 5 Viewing Fasting Averages

Press the ⬆ button to view 1, 7, 14, 30 and 90-day average values and the number of tests performed fastings with the symbol for the last test period.



Step 6

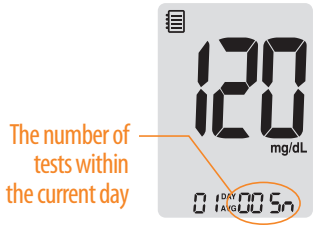
Use the ⬇ button to scroll back through the averages seen previously.
Press the **S** button to turn off the meter.

Note: The control solution test results saved with the symbol are not included in the averages.

Viewing Test Results Stored in the Memory

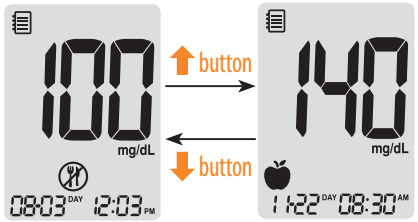
Step 1

Press any 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 ⬇ 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. After checking the stored test results, hold the **S** button to turn off the meter.



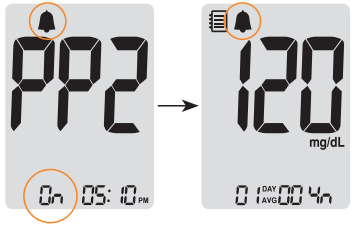
Setting the Alarm Function

Four types of alarms can be set in the CareSens N NFC Meter: one post-meal alarm (PP2 alarm) and three time set alarms (alarm 1-3). The PP2 alarm goes off 2 hours after setting the alarm. The alarms ring for 15 seconds and can be silenced by pressing any button or by inserting a test strip.

Setting the Post-meal Alarm (PP2 alarm)

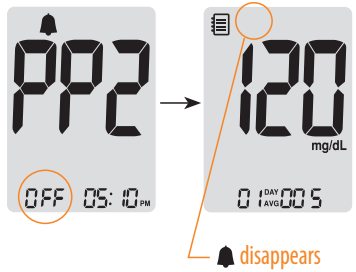
Step 1 Setting the PP2 Alarm On

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



Step 2 Setting the PP2 Alarm OFF

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



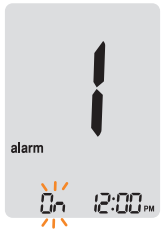
Setting the Time Alarms (alarm 1–3)

Step 1

Without inserting a test strip, press the ⬆ button and the **S** button simultaneously for 3 seconds to enter the time alarm mode. 'alarm 1' will be displayed while 'OFF' blinks on the screen.

Step 2

On pressing the ⬇ button, 'alarm 1' is set and 'On' is displayed on the screen. Press the ⬇ button again to cancel 'alarm 1'. 'OFF' will blink on the screen.



Step 3

Press the ⬆ button to adjust the time of 'alarm 1'.
A number representing the time will blink on the screen. Press the ⬇ button to set the time.
Press the ⬆ button to end.

Step 4

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

Step 5

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

Step 6

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

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 temperature during the test was above or 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 after the meter and test strips have reached a temperature within the operating range.

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

Message	What It Means	What To Do
	There is a problem in saving the test results to the NFC chip.	Contact your authorised i-SENS sales representative.
	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.

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

Problem	Troubleshooting
The display is blank even after inserting a test strip.	• Check whether the test strip is inserted with the contact bars facing up. Check if the strip has been inserted completely into the test strip port. • Check if the appropriate test strip was used. • Check whether the batteries are inserted with the '+' side facing up. • Replace the batteries.
The test does not start even after applying the blood sample on the strip.	• Check if the confirmation window is filled completely. • Repeat the test 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 N NFC Blood Glucose Monitoring System has been evaluated in laboratory and in clinical tests.

Accuracy: The accuracy of the CareSens N NFC BGM System (Model GM505PAG, GM505PBG, GM505PCG) 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	0.9859
Y-intercept	1.8724 mg/dL (0.10 mmol/L)
Correlation coefficient (r)	0.996
Number of sample	600
Range tested	27.9–479 mg/dL (1.6–26.6 mmol/L)

Accuracy results for glucose concentration < 100 mg/dL (5.55 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)
112/180 (62.2 %)	172/180 (95.6 %)	180/180 (100 %)

Accuracy results for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)

Within ± 5 %	Within ± 10 %	Within ± 15 %
304/420(72.4 %)	413/420(98.3 %)	420/420(100 %)

System accuracy results for glucose concentrations between 27.9 mg/dL (1.6 mmol/L) and 479 mg/dL(26.6 mmol/L)

Within ± 15 mg/dL (Within ± 0.83 mmol/L) and Within ± 15 %
600/600 (100 %)

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

Within Run Precision		
*Bloodav avg.	35 mg/dL (1.9 mmol/L)	SD = 1.7 mg/dL (0.1 mmo/L)
*Bloodav avg.	65 mg/dL (3.6 mmol/L)	SD = 2.0 mg/dL (0.1 mmo/L)
*Bloodav avg.	129 mg/dL (7.2 mmol/L)	CV = 3.0 %
*Bloodav avg.	175 mg/dL (9.7 mmol/L)	CV = 3.0 %
*Bloodav avg.	330 mg/dL (18.3 mmol/L)	CV = 2.1 %

Between Run Precision		
*Controlav avg.	38 mg/dL (2.1 mmol/L)	SD = 1.4 mg/dL (0.1 mmol/L)
*Controlav avg.	120 mg/dL (6.7 mmol/L)	CV = 3.2 %
*Controlav avg.	318 mg/dL (17.7 mmol/L)	CV = 2.4 %

This study shows that there could be variation of up to 3.2 %.

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

Range	Average of difference (Hct 15–65 %)
30 to 50 mg/dL (1.7 to 2.8 mmol/L)	-3.1–1.9 mg/dL (-0.2–0.1 mmol/L)
96 to 144 mg/dL (5.3 to 8.0 mmol/L)	-1.5–7.1 %
280 to 420 mg/dL (15.5 to 23.3 mmol/L)	-5.4–1.1 %

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

NO	Interferent	Difference Averages	
		Interval 1 50–100 mg/dL (2.8–5.5 mmol/L)	Interval 2 250–350 mg/dL (13.9–19.4 mmol/L)
1	Acetaminophen	-2.3 mg/dL (-0.1 mmo/L)	-3.3 %
2	Ascorbic acid	7.3 mg/dL (0.4 mmol/L)	-0.9 %
3	Bilirubin (unconjugated)	-0.1 mg/dL (-0.01 mmol/L)	1.4 %
4	Ceftriaxone	2.1 mg/dL (0.1 mmol/L)	2.4 %
5	Cholesterol	-1.3 mg/dL (-0.1 mmol/L)	-1.8 %
6	Creatinine	0.1 mg/dL (0.01 mmol/L)	0.7 %
7	Dopamine	1.0 mg/dL (0.1 mmol/L)	0.4 %
8	EDTA	1.1 mg/dL (0.1 mmol/L)	1.4 %
9	Galactose	-1.0 mg/dL (-0.1 mmol/L)	-0.1 %
10	Gentisic acid	-1.0 mg/dL (-0.1 mmol/L)	-4.4 %
11	Glutathione(Red)	-4.1 mg/dL (-0.2 mmol/L)	0.6 %
12	Hemoglobin	-0.1 mg/dL (-0.01 mmol/L)	-0.5 %
13	Heparin	1.1 mg/dL (0.1 mmol/L)	2.8 %
14	Hydrocortisone	0.4 mg/dL (0.02 mmol/L)	1.9 %
15	Ibuprofen	-1.5 mg/dL (-0.1 mmol/L)	2.8 %
16	Icodextrin	-2.7 mg/dL (-0.2 mmol/L)	-0.5 %
17	L-Dopa	0.7 mg/dL (0.04 mmol/L)	0.5 %
18	Maltose	-6.3 mg/dL (-0.4 mmol/L)	-1.1 %
19	Mannitol	1.1 mg/dL (0.1 mmol/L)	-0.7 %
20	Methyldopa	-0.6 mg/dL (-0.03 mmol/L)	0.2 %
21	Pralidoxime Iodide	0.0 mg/dL (0.0 mmol/L)	1.4 %
22	Salicylate	0.9 mg/dL (0.1 mmol/L)	-0.1 %
23	Tolazamide	-5.3 mg/dL (-0.3 mmol/L)	-2.8 %
24	Tolbutamide	-4.5 mg/dL (-0.3 mmol/L)	-7.3 %
25	Triglycerides	-1.0 mg/dL (-0.1 mmol/L)	4.7 %
26	Uric acid	-2.6 mg/dL (-0.1 mmol/L)	0.5 %
27	Xylose	-0.8 mg/dL (-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 ±15 mg/dL(± 0.83 mmol/L) of the medical laboratory values at glucose concentrations below 100 mg/dL(5.55 mmol/L), and 100 % within ±15 % of the medical laboratory values at glucose concentrations at or above 100 mg/dL(5.55 mmol/L).

Warranty Information

Manufacturer's Warranty
i-SENS, Inc. warrants that the CareSens N NFC 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.

- 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.

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