

Owner's Booklet

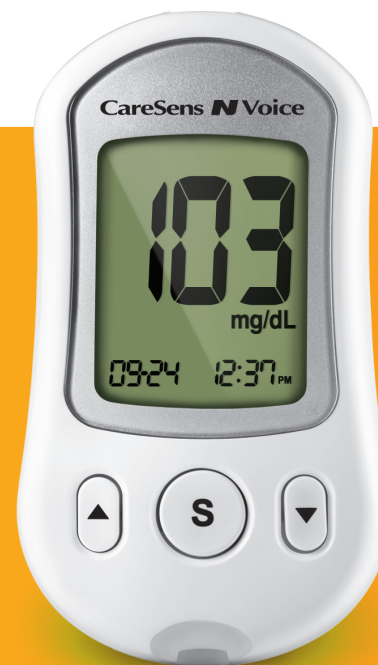
CareSens™ **N** Voice

Blood Glucose Monitoring System

i·sens

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No Coding

Easy & accurate testing



Talking Function

Easy to use



0.5 µL

Very small sample
(● : actual size shown)



5 Sec

Rapid test results



Welcome to the CareSens N Voice Blood Glucose Monitoring System

Thank you for choosing the CareSens N Voice Blood Glucose Monitoring System. The system provides you with rapid and convenient blood glucose *in vitro* (i.e., outside the body) diagnostic monitoring. The bilingual talking function of CareSens N Voice Meter can be used as an aid for using the meter. The CareSens N Voice Meter is also designed to minimise code related errors in monitoring by using the auto coding function. You'll receive an accurate result in five seconds with a small 0.5 µL blood sample. This booklet contains important information about the CareSens N Voice Glucose Monitoring System. Please read it carefully before testing your blood glucose.

- No part of this document may be reproduced in any form or by any means without the prior written consent of i-SENS.
- 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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Important Information: Read This First!

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

Intended use:

CareSens N Voice Blood Glucose Monitoring System is used for the quantitative measurement of the glucose level in capillary whole blood as an aid in managing diabetes effectively at home or in clinical settings. CareSens N Voice Blood Glucose Monitoring System should be used only for self-testing outside the body (*in vitro* diagnostic use only). CareSens N Voice 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:

 For *in vitro* diagnostic use  Authorised representative



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



Batch code



Consult instructions for use  Manufacturer



Temperature limitation



Serial number

Important Information

- Glucose in blood samples reacts with the chemical in the test strip to produce a small electrical current. The CareSens N Voice Meter detects this electrical current and measures the amount of glucose in the blood sample.
- The CareSens N Voice Blood Glucose Meter is designed to minimise code related errors in monitoring by using the auto-coding function.
- The CareSens N Voice 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.

Specifications

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	1,000 tests
Power	Two alkaline AAA batteries
Memory	500 test results
Size	100 x 56 x 19 (mm)
Weight	70 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)

CareSens N Voice Blood Glucose Monitoring System

CareSens N Voice BGM System includes the following items:

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

Optional items:

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

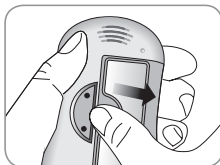
- Check all the components after opening the CareSens N Voice Blood Glucose Monitoring System package. The exact contents are listed on the main box.
- The cable for data management software can be ordered separately. Please contact your authorised i-SENS sales representative.

Inserting or Replacing Batteries

The CareSens N Voice Meter uses two AAA alkaline 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.

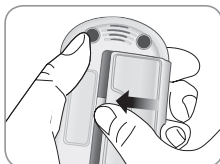
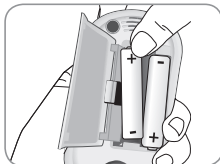
Step 1

Make sure the meter is turned off. Press firmly on the battery cover and slide in the direction of the arrow. And then swing it open.



Step 2

Remove the used batteries and insert two new batteries. Close the battery cover firmly.



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

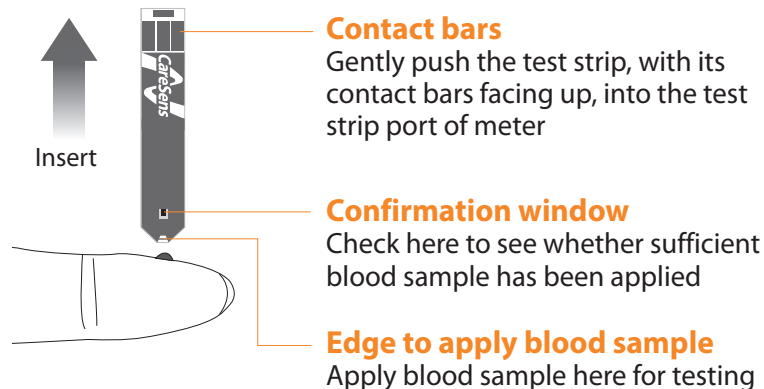
Use a soft cloth or tissue to wipe the meter exterior. If necessary, dip the soft cloth or tissue in a small amount of alcohol. Do not use organic solvents such as benzene or acetone, or household and industrial cleaners that may cause irreparable damage to the meter.

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 shock.
- 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 portable case to prevent loss and help keep the meter clean.

CareSens N Blood Glucose Test Strip

The CareSens N Voice 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.



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 Voice Blood Glucose Meter

Data Port

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

▲ Button

Turns the meter on, selects or changes information

S Button

Turns the meter on/off, confirms menu selections

Test Strip Port

Insert test strip here

Speaker

Announces each step

Display

Shows results and messages

▼ Button

Selects or changes information

Test Strip Ejector

Slide down to discard the used strips

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.

CareSens N Voice Blood Glucose Meter Display



- alarm** : appears when the time alarm has been set
- mem** : appears when test results stored in the memory are displayed
- ctl** : appears during the control solution testing and when the control solution test results are displayed
- Test results** : test results displaying panel
- Blood insertion symbol**: indicates meter is ready for the application of a drop of blood or control solution
- Temperature symbol** : displays recorded temperature when blood glucose levels are tested
- Post-meal test flag** : appears when post-meal testing and when post-meal test results are displayed
- Hypoglycemia symbol** : appears when the test result is below the hypoglycemic level
- Post-meal alarm symbol** : appears when the post-meal alarm has been set.
- Mute symbol** : appears only when the sound is set to OFF
- Battery symbol** : indicates meter batteries are running low and needs to be placed
- mg/dL, mmol/L** : unit for measuring blood glucose
- Date / temperature**
- Time**

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

You should check and update the meter-settings such as time and date before using your meter or after changing the meter batteries.

Press and hold the **S** button for 3 seconds to enter SET mode. While you are setting the meter, current settings will appear on the display. The meter will also announce each function when the talking function is on. Press and hold the **▲** or **▼** button to scroll faster. Whenever you want to complete the settings and exit from SET mode, press and hold the **S** button for 3 seconds again.

Adjusting Date, Time and Sound

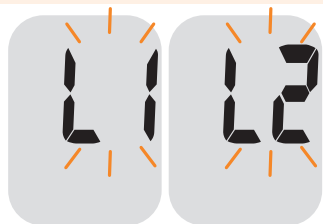
Step 1 Entering the SET Mode

Press and hold the **S** button for 3 seconds. After all the segments flash across the screen, "SET" is displayed on the screen. If the talking function is on, the meter will say "Set meter." Press the **S** button again to go to the next step.



Step 2 Selecting a Language

The meter has a bilingual talking function that can be used as a verbal aid for using the meter and hearing test results. When you enter the language selection mode for the first time, L1 will be blinking and the meter will announce "Language Selection" in the default language (English). To select another language (L2, Spanish), press the **▲** or **▼** button. Press the **S** button to confirm the language and to go to the next step.



Step 3 Setting the Year

If the talking function is on, the meter will say "Set year." Press the **▲** or **▼** button until correct year appears. After setting the year, press the **S** button to confirm your selection and to go to the next step.



Step 4 Setting the Month

A number indicating the month will blink on the bottom left corner of the screen. If the talking function is on, the meter will say "Set month." Press the **▲** or **▼** button until the correct month appears. Press the **S** button to confirm your selection and to go to the next step.



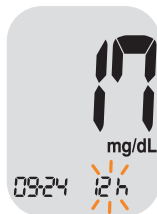
Step 5 Setting the Date

The meter will say "Set date" when the talking function is on. Press the **▲** or **▼** button until blinking number shows the correct date. Press the **S** button to set the date and to go to the next step.



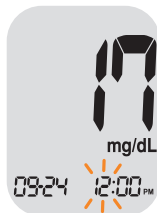
Step 6 Setting the Time Format

The meter can be set in the AM/PM (12-hour) or 24-hour clock format. If the talking function is on, the meter will say "Set time 12-hour(24 hour)". 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.



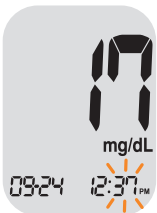
Step 7 Setting the Hour

If the talking function is on, the meter will say "Set 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.



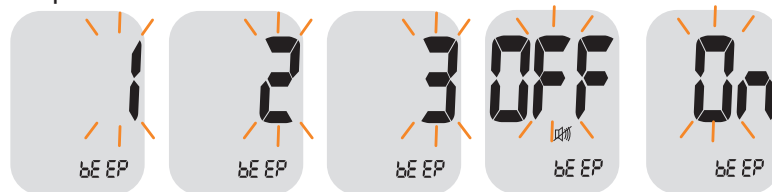
Step 8 Setting the Minute

If the talking function is on, the meter will say "Set minute." Press the ▲ or ▼ button until the correct minute appears. After setting the minute, press the **S** button to go to the next step.



Step 9 Turning the Sound On/Off

A number showing the sound volume will blink and the meter will say "Set volume." Press the ▲ or ▼ button to adjust the volume from 1 (lowest) to 3 (highest) or to turn the sound off or the beep sound on. When you select "On", the meter will beep instead of announcing messages. To turn off the sound, press the **S** button when "OFF" blinks on the display. Then the 🔊 symbol will appear on the display and the meter will be muted. Press the **S** button to save the setting and to go to the next step.



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




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. Press and hold the ▼ button hold to quickly scroll through the numbers.

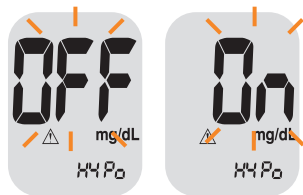
Setting the Hypoglycemia Indicator

You can set the meter to let you know when your test result indicates a possible low blood glucose (hypoglycemia). You can also select the hypoglycemia level.

Step 10 Turning on the Hypoglycemia Indicator



When you enter the hypoglycemia indicator setting mode, the  symbol and HYPo will blink. If the talking function is on, the meter will say "Set hypoglycemia indicator." On pressing the  or  button, the screen will display "On" or "OFF". Press the **S** button to set your hypoglycemia level if you choose "On".

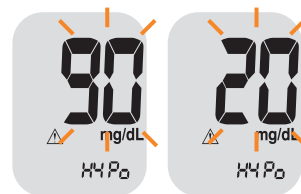
The screen will return to step 3, year setting mode, if you choose "OFF".



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

Step 11 Setting Your Hypoglycemic Level

The hypoglycemic level can be set from 20 to 90 mg/dL (1.1 to 5.0 mmol/L). To set your hypoglycemic level, press the  or  button until the level you want appears. Press the **S** button to confirm. Then the screen will return to step 2, language selection mode. See page 14.



Note:

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



Step 12 Exiting from Set Mode

After completing the meter settings, press and hold the **S** button for 3 seconds to confirm all your selections and exit from SET mode. If the talking function is on, the meter will announce the set date and time for your confirmation.

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 21–23.

Notes:

- Use only the CareSens Control Solution (available for purchase separately).
- Check the expiration dates printed on the bottle. When you first open a control solution bottle, record the discard date (date opened plus three (3) months) in the space provided on the label.
- Make sure your meter, test strips and control solution are at room temperature before testing. Control solution tests must be done at room temperature (20–25°C/68–77°F).
- Before using the control solution, shake the bottle, discard the first few drops and wipe the tip clean.
- Close the control solution bottle tightly and store at a temperature of 8–30°C (46–86°F).

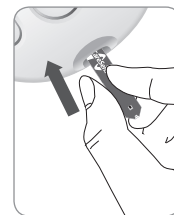
You may do a control solution test:

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

Control Solution Testing

Step 1

Insert a test strip into the meter's test strip port, with the contact bars facing upwards. Gently push the test strip into the port. The ▲ symbol will blink on the screen. If the talking function is on, the meter will say "Blood glucose test. Please apply blood onto the test strip."



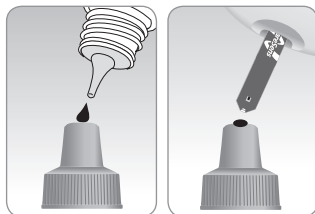
Step 2

While the ▲ symbol blinks, press and hold the ▲ button for 3 seconds till the "ctl" appears on the display. If the talking function is on, the meter will say "Control solution test. Please apply control solution onto the test strip."



Step 3

Shake the bottle well 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.



While the ▲ symbol blinks, apply the control solution to the narrow edge of the test strip until the meter beeps. Make sure the confirmation window of test strip fills completely.

Note: The meter may switch off if the control solution 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 2.

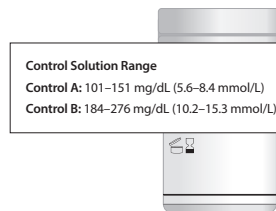
Step 4

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. If the talking function is on, the test result will be announced. If you missed step 2, you can mark the test result as a control solution test result by pressing and holding the ▲ button for 3 seconds until the "ctl" appears on the display. When the "ctl" is displayed, the result is stored in the meter's memory but is not included in the averages.



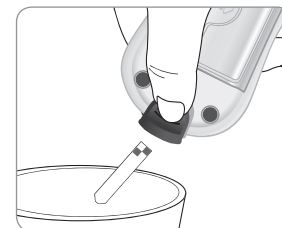
Step 5

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



Step 6

Slide the test strip ejector button to discard the used test strip 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

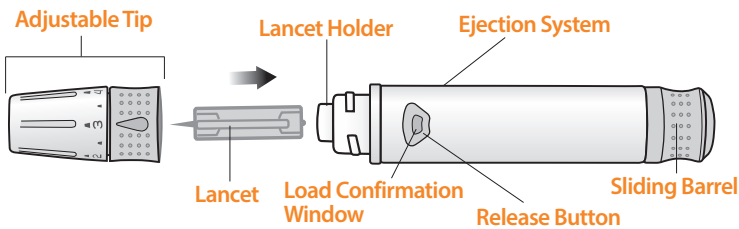
The test result of each control solution should be within the range printed on the label of the test strip vial. Repeat the control solution test if the test result falls outside of this range. Out of range results may occur in following situations:

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 20.
<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 (the date the bottle was opened plus three (3) months),• When the control solution is contaminated.	Discard the used control solution and repeat the test using a new bottle of control solution.

If results continue to fall outside the range printed on the test strip vial, the test strip and meter may not be working properly. Do not use your system and contact your authorised i-SENS sales representative.

You will need a lancing device in order to collect a blood sample.

You may use the lancing device included in the CareSens N Voice 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:

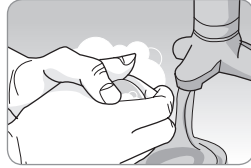
- Do not use a lancet that has been used by others.
- Always use a new sterile lancet.
- Keep the lancing device clean.

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

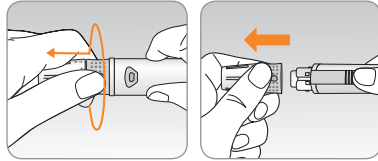
Step 1

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



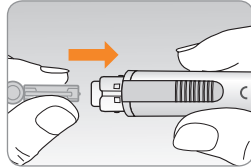
Step 2

Unscrew and remove the lancing device tip.



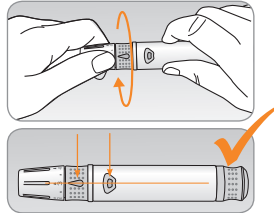
Step 3

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.



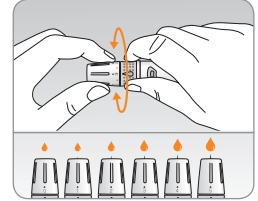
Step 4

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.

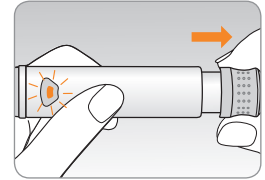


Note:

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 automatically turns on and the ▲ symbol appears. Be careful not to bend the test strip. If the talking function is on, the meter will say "Blood glucose test. Please apply blood onto the test strip."



Flagging Post-meal Test Results

The CareSens N Voice meter allows you to flag a result of a post-meal test with the 🍴 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. If the talking function is on, the meter will say "Post-meal test. Please apply blood onto the test strip." The test result will also be displayed with the post-meal flag (🍴).

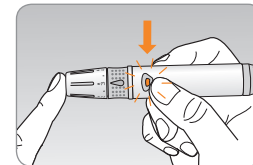


If you do not want to save the result as a post-meal test, move on to Step 9 after Step 7. If you want to delete the post-meal flag (🍴) that you have attached, press and hold the ▼ button for 3 seconds again before applying the blood sample or when the test result is displayed just after testing.

Applying Blood Sample

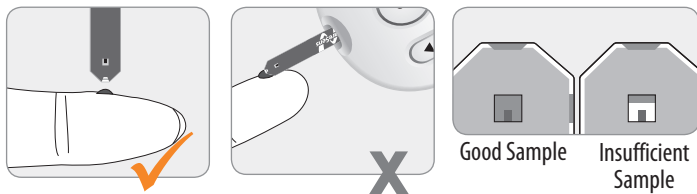
Step 9

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 μ L : ●)



Step 10

After the ▲ symbol appears on the screen, apply the blood sample to the narrow end of the test strip. If the confirmation window is not filled in time because of abnormal viscosity (thickness and stickiness) or insufficient volume, the Er4 message may appear. If the talking function is on, the meter will say "Error four. The sample was not enough or too thick." Then discard the test strip, insert a new one, and apply the blood sample again after the ▲ symbol appears on the screen. 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 ▲ appears on the screen.

Step 11

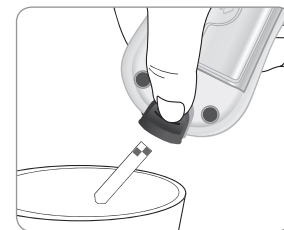
Apply the blood sample to the narrow end of the test strip until you hear a 'beep'. At this time, the display segments will rotate clockwise on the meter display implying that the blood sample is being inserted.

The test result will appear after the meter counts down from 5 to 1. If the talking function is on, the result will be announced. The result will be automatically stored in the meter memory.



Step 12

Discard the used test strip safely in a disposable container by sliding the test strip ejector. If the test strip is removed after the test result is displayed, the meter will automatically turn off after 3 seconds.

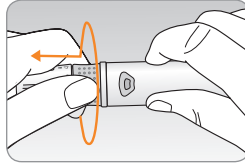


Alternate Site Testing

Discarding Used Lancets

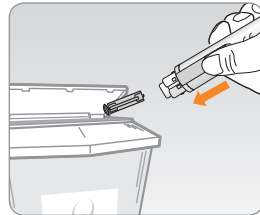
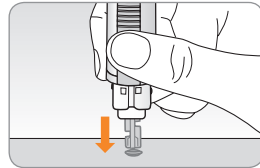
Step 1

Unscrew the lanceting 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.

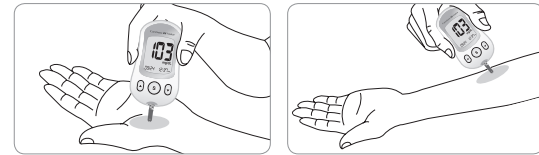


Caution: The lancet is for single use only. Never share or reuse a lancet. Always dispose of lancets properly.

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, 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 lanceting device against site. Wait until the skin surface under the lanceting device changes color. Then press the release button while continuing to apply pressure. Keep holding the lanceting device against your skin until sufficient (at least 0.5 μ L, actual size: ●) blood is drawn. Carefully lift the lanceting 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 sleeping

Situations Requiring Fingertip Test

When your blood glucose levels are unstable

- During two (2) hours after a meal or exercise
- When sick or when glucose levels seem 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

- 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:

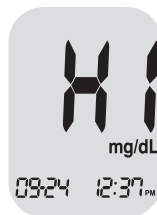
- Results from alternate sites and fingertip samples may differ from each other, as there is a time lag for the glucose levels to reach the same value. Use a fingertip sample if you suffer from hypoglycemia or have experienced hypoglycemic shock or symptoms.
- If the sample drop of blood runs or spreads due to contact with hair or with lines on 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 the talking function is on, the meter will say "Your blood glucose reading is above 600 mg/dL (33.3 mmol/L)."

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 the talking function is on, the meter will say "Your blood glucose reading is below 20 mg/dL (1.1 mmol/L)."

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



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

Target Blood Glucose Ranges

Reminders

Time of day

*Your target ranges
from your healthcare 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 in CareSens N Voice 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, please contact your authorised i-SENS sales representative or visit www.i-sens.com.



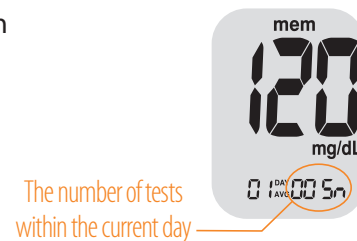
Meter Memory

The CareSens N Voice Meter can save up to 500 test results with temperature, time and date. If the memory is full, the oldest test result will be deleted and the latest test result will be stored. The CareSens N Voice Meter calculates and displays the averages of total test results, pre-meal test (Pr) results, and post-meal test (Pp) results from the last 1, 7, 14, 30 and 90 days.

Viewing Averages Stored in Memory

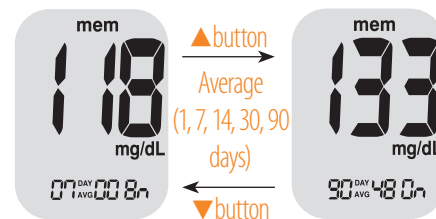
Step 1

Press the **S** or **▲** button to turn on the meter. If the talking function is on, the meter will say "Memory recall." 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.



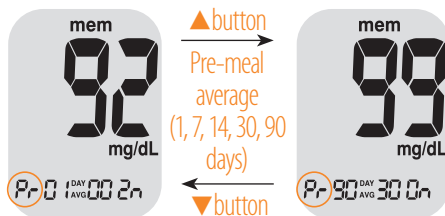
Step 2 Viewing Averages

Press the **▲** button to view the 7, 14, 30 and 90 day average values and the number of tests performed for that test period.



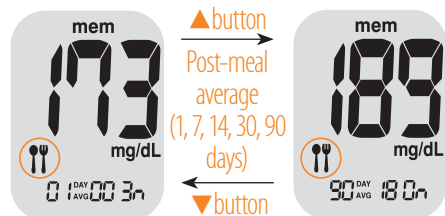
Step 3 Viewing Pre-meal Averages

Repeatedly press the ▲ button to view the 1, 7, 14, 30 and 90 day pre-meal average values and the number of tests performed pre-meals with the "Pr" symbol for that 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.



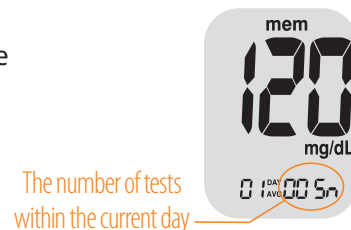
Step 5

Use the ▼ button to scroll back through the averages seen previously. To turn off the meter, press the S button.

Viewing Test Results

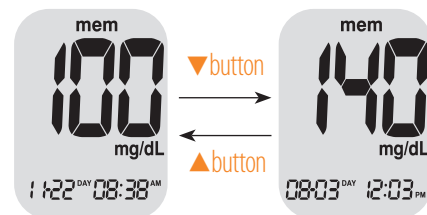
Step 1

Press the S or ▲ 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 stored 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 the S button to turn off the meter.



Note: The control solution test results saved with 'ctl' will be displayed with 'ctl' when you review the stored test results.

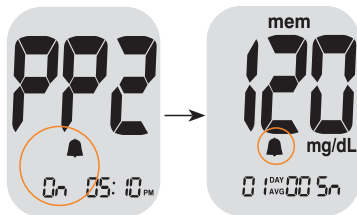
Setting the Alarm Function

Four alarms can be set in the CareSens N Voice 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 the ▲, ▼ or S button or by inserting a test strip.

Setting the Post-meal Alarm (PP2 Alarm)

Step 1 Setting the PP2 Alarm On

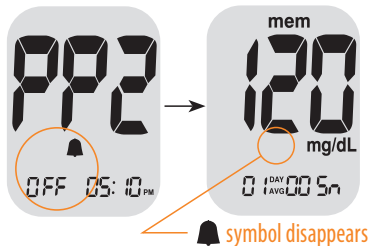
Without inserting a test strip, press and hold the ▲ button for 3 seconds to set the post-meal alarm. "PP2", the 🔔 symbol and "On" will be displayed. If the talking function is on, the meter will say "Post-meal alarm is on."



The screen will then automatically change to the memory check mode. At this time, the 🔔 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", the 🔔 symbol and "OFF" will appear on the screen. If the talking function is on, the meter will say "Post-meal alarm is off." Then the screen will change automatically to the memory check mode without the 🔔 symbol displayed.



Setting the Time Alarms (Alarm 1-3)

Step 1

Without inserting a test strip, press the ▲ and S buttons simultaneously for 3 seconds to enter the time alarm mode. "alarm 1" will be displayed while "OFF" blinks on the screen. If the talking function is on, the meter will say "Set alarm one."



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" and "OFF" will blink on the screen.



Step 3

Press the ▲ button to adjust the time of "alarm 1". A number indicating the hour will blink on the screen. Press the ▼ button to set the hour. Press the ▲ button to end.



Understanding Error Messages

Step 4

On pressing the ▲ button, the number indicating the minute will start blinking. Press the ▼ button to set the minute.



Step 5

Press the S button to finish and to go to "alarm 2" mode.
Repeat steps 2 to 4 to set the remaining time alarms (alarm 2 and 3).








Step 6

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

Message	What is said	What it means	What to do
	"Error 1. Used test strip."	A used test strip was inserted.	Repeat the test with a new test strip.
	"Error 2. The sample has been applied before the blood symbol appeared."	The blood or control solution sample was applied before the ▲ appeared.	Repeat the test with a new test strip and wait until the ▲ appears before applying the blood or control solution sample.
	"Error 4. The sample was not enough or too thick."	The blood sample has abnormally high viscosity or insufficient volume.	Repeat the test with a new test strip.

Other Important Messages

Message	What is said	What it means	What to do
	"Error 5. Strip insertion error. Please insert a CareSens N strip properly."	This error message may appear when the wrong blood glucose test strip is used instead of CareSens N blood glucose test strip.	Repeat the test with a CareSens N test strip.
	"Error 6 Meter failure."	There is a problem with the meter.	Do not use the meter. Contact your authorised i-SENS sales representative.
	"Error 8 Meter failure."	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.

Message	What is said	What it means	What to do
	"The room temperature is too low."	The temperature during testing was below the operating range.	Move to an area where the temperature is within the operating range (5-50°C) and repeat the test after the meter and test strips have reached a temperature within the operating range.
	"The room temperature is too high."	The temperature during testing was above the operating range.	

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 up. Check if the strip has been inserted completely into the test strip port.• Check if the appropriate test strip was used.• Check if the batteries are inserted correctly.• 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 after inserting a new test strip.
The test result doesn't match the way you feel.	<ul style="list-style-type: none">• 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 Voice Blood Glucose Monitoring System has been evaluated in laboratory and in clinical tests.

Accuracy: The accuracy of the CareSens N Voice BGM System (Model GM505UAB) was tested by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyzer, a lab instrument. The results below were obtained by diabetic patients at clinic centers.

Slope	0.9637
Y-intercept	1.9258 mg/dL (0.11 mmol/L)
Correlation coefficient (r)	0.993
Number of samples	600
Range tested	27.9-478 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)
128/186 (68.8%)	179/186 (96.2%)	186/186 (100%)

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

Within ± 5%	Within ± 10%	Within ± 15%
226/414 (54.6%)	359/414 (86.7%)	413/414 (99.8%)

System accuracy results for glucose concentrations between 27.9 mg/dL (1.6 mmol/L) and 478 mg/dL (26.6 mmol/L)

Within ± 15 mg/dL (Within ± 0.83 mmol/L) and Within ± 15 %
599/600 (99.8%)

Precision: Precision studies were performed in a laboratory using the CareSens N Voice BGM Systems.

<i>Within Run Precision</i>		
*Blood avg.	35 mg/dL (1.9 mmol/L)	SD = 1.7 mg/dL (0.1 mmol/L)
*Blood avg.	83 mg/dL (4.6 mmol/L)	SD = 2.3 mg/dL (0.1 mmol/L)
*Blood avg.	131 mg/dL (7.3 mmol/L)	CV = 3.2%
*Blood avg.	196 mg/dL (10.9 mmol/L)	CV = 2.7%
*Blood avg.	302 mg/dL (16.8 mmol/L)	CV = 3.4%

<i>Between Run Precision</i>		
*Control avg.	39 mg/dL (2.2 mmol/L)	SD = 1.4 mg/dL (0.1 mmol/L)
*Control avg.	121 mg/dL (6.7 mmol/L)	CV = 3.5%
*Control avg.	316 mg/dL (17.6 mmol/L)	CV = 2.9%

This study shows that there could be variation of up to 3.5%.

Packed Cell Volume (Hematocrit)

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

Range mg/dL (mmol/L)	Average of difference (Hct 15-65%)
30 to 50 (1.7 to 2.8)	-3.3 to 1.7 mg/dL (-0.2 to 0.1 mmol/L)
96 to 144 (5.3 to 8.0)	-1.5 to 7.1%
280 to 420 (15.5 to 23.3)	-5.4 to 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 mmol/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%

Warranty Information

Manufacturer's Warranty

i-SENS, Inc. warrants that the CareSens N Voice Meter shall be free of defects in material and workmanship in normal use for a period of 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.

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)
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 ± 0.83 mmol/L of the medical laboratory values at glucose concentrations below 100 mg/dL (5.55 mmol/L) and 97.4% within $\pm 15\%$ of the medical laboratory values at glucose concentrations at or above 100 mg/dL (5.55 mmol/L).

MEMO