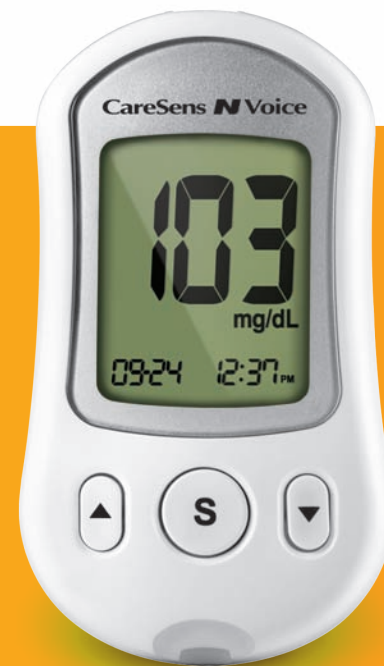


User's Manual

CareSens[®] **N** **Voice**

Blood Glucose Monitoring System



No
Coding



Talking
Function



0.5 μ L



5 Sec

For single user / home use only

PGA1E3217 REV0 01/2013

Para un solo usuario / uso en el hogar sólo



5 Segundos



0,5 μ L



Función
de voz



No
Codificación

Sistema de Monitoreo de Glucosa en Sangre

CareSens[®] **N** **Voice**

Manual del Usuario



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 safe, fast, and convenient blood glucose *in vitro* (i.e., outside the body) 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 minimize 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.

Manufacturer: i-SENS, Inc.
27-36, Gwangun-ro, Nowon-gu,
Seoul 139-845, Korea
www.i-sens.com

Contact Customer Service:

1-800-429-5001

9 am - 9 pm EST, Monday - Saturday

At all other times or in case of emergency,
please contact your healthcare professional or
emergency medical response.

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Bien venido al Sistema de Monitoreo de Glucosa CareSens® N Voice

Gracias por elegir el Sistema de Monitoreo de Glucosa en Sangre CareSens® N Voice. El sistema le provee a Ud. un monitoreo diagnóstico de glucosa en sangre *in vitro* (es decir, de uso externo). La función de voz en dos idiomas de Medidor de CareSens® N Voice se puede utilizar como una ayuda para el uso del medidor. También el Medidor de CareSens® N Voice está diseñado para minimizar los errores relacionados con el código en el monitoreo mediante el uso de la función de autocodificación. Usted recibirá un resultado preciso en cinco segundos con una pequeña muestra de sangre de 0,5 µL. Este manual contiene la información importante sobre el Sistema de Monitoreo de Glucosa de CareSens® N Voice. Por favor, lea con cuidado antes de probar su glucosa en sangre.

1-800-429-5001

Servicio al Cliente:

www.i-sens.com

Fabricante: i-SENS, Inc.
27-36, Gwangun-ro, Nowon-gu,
Seúl 139-845, Corea

09:00 a 21:00 hrs EST, Lunes - Sábado
En diferentes horarios o en casos de
emergencia, favor de ponerse en contacto
con su médico o la contestación médica de
emergencia.

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Important Information: Read This First!

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

- Do not use the system for diagnosis or screening of diabetes.
- Use only fresh capillary whole blood samples for testing.
- Alternative site and fingertip test results may differ significantly due to rapid changes in the blood glucose level after eating, insulin injection or exercise.

Intended Use

The CareSens N Voice Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites such as the forearm, palm, thigh, and calf.

Alternative site testing should be used only during steady-state blood glucose conditions. The CareSens N Voice Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro*) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The system is intended to be used by a single person and should not be shared. It is not intended for use on neonates and is not for the diagnosis or screening of diabetes.

The CareSens N Single Blood Glucose Test Strips are for use with the CareSens N Voice Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites.

The CareSens Control Solutions are for use with the CareSens N Voice Meter and CareSens N Single Test Strips to check that the meter and the test strips are working together properly and that the test is performing correctly.

Important Health-Related Information

- The CareSens N Voice Blood Glucose Monitoring System is intended for *in vitro* (outside the body) diagnostic use only and for the quantitative measurement of glucose in capillary whole blood.
- The CareSens N Voice Blood Glucose Monitoring System is intended for use by a single user only. Do not share the meter and lancing device with another person.
- The CareSens N Voice Blood Glucose Meter is designed to minimize code related errors in monitoring by using the no-coding function.
- The glucose in the blood sample mixes with special chemicals on the test strip to produce a small electrical current. The CareSens N Voice Meter converts this electrical current to glucose concentration.
- The CareSens N Voice Blood Glucose Meter should be used only with the CareSens N Single Test Strip.
- An abnormally high or low red blood cell count (hematocrit level over 60% or below 20%) may produce inaccurate results.
- Inaccurate results may occur in severely hypotensive (having low blood pressure) individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic (high blood sugar) or hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed pre-cleaning and disinfection.
- For questions or concerns, contact Customer Service: 1-800-429-5001 (9 am - 9 pm EST, Mon - Sat). At all other times or in case of emergency, please contact your healthcare professional or emergency medical response.

Specifications

Product specifications	
Measurement Range	20 - 600 mg/dL
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	3.90 x 2.21 x 0.75 in.
Weight	2.47 oz (with batteries)

Operating ranges	
Temperature	50 - 104°F (10 - 40°C)
Relative humidity	10 - 90%
Hematocrit	20 - 60%

CareSens N Voice Blood Glucose Monitoring System

CareSens N Voice System includes the following items:

- ① CareSens N Voice Blood Glucose Meter
- ② User's Manual
- ③ Quick Reference Guide
- ④ Batteries (2)

CareSens N Voice System may include the following items:


- ① CareSens N Single Blood Glucose Test Strips (10)
- ② Lancing Device
- ③ Lancets (10)
- ④ Logbook
- ⑤ 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 CareSens Control Solutions (Control A & B) are necessary but not included. The CareSens Control Solutions and the cable for data management software can be ordered separately. Please contact Customer Service: 1-800-429-5001 (9 am - 9 pm EST, Monday - Saturday).

Caution: The meter and lancing device are only intended for a single user. Do not share them with anyone including other family members. Never use on multiple users.

Inserting or Replacing the 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 use, the batteries should be replaced as soon as possible.

The test results may not be saved if the batteries run out completely.

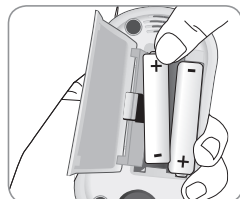
Step 1

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

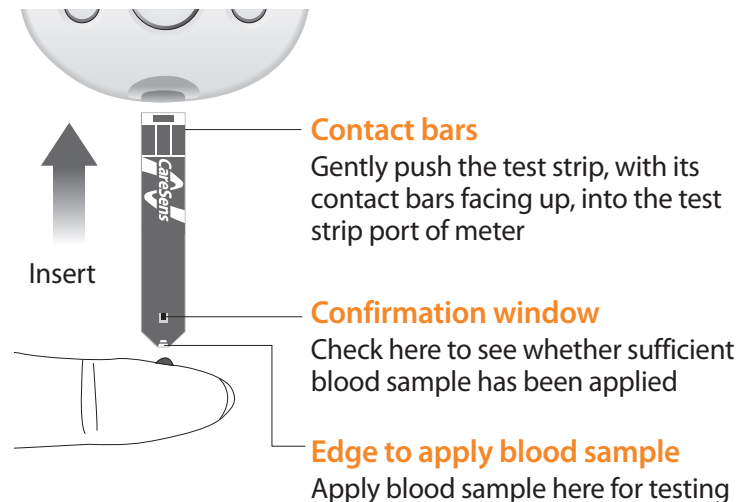
Remove the used batteries and insert the two new batteries. Close the battery cover firmly.



Note: Removing the meter batteries will not affect your stored results. However you may need to reset your meter settings. See page 13.

CareSens N Single 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.



Important Safety Instruction

- All components that come into contact with blood samples should be considered to be biohazards capable of transmitting viral diseases, even after disinfection.
- Do not share the meter or lancing device with another person.
- The CareSens N Single Test Strip should be used only with fresh capillary whole blood samples.

CareSens N Voice Blood Glucose Meter

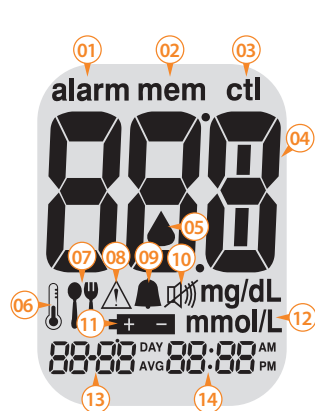
- Do not reuse test strips.
- Do not use CareSens N Single Test Strips beyond the expiration date. This may cause inaccurate results.
- Test strips in new, unopened vial and test strips in vial that have been opened can be used up until the expiration date printed on the test strip box and vial label 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 of 34-86°F (1-30°C).
- 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 Single Test Strip package insert.
- Keep the meter and testing supplies away from young children.

Note: You can get more safety information at FDA Public Health Notification (<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>) or at CDC Clinical Reminder (<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>).



Note: The cable for data management software can be ordered separately. Please contact Customer Service: 1-800-429-5001 (9 am - 9 pm EST, Monday - Saturday).

CareSens N Voice Meter Display



01 **alarm**: appears when the time alarm has been set

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

03 **ctl**: appears during the control solution testing and when the control solution test results are displayed

04 **Test results**: test results are displayed here

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

06 **Temperature symbol**: appears when the temperature is displayed

07 **Post-meal test flag**: appears when post-meal testing and when post-meal test results are displayed

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

09 **Post-meal alarm symbol**: appears when the post-meal alarm has been set

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

11 **Battery symbol**: indicates meter batteries are running low and need to be replaced

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

13 **Date / temperature**

14 **Time**

Note: The unit of measurement for your CareSens N Voice Meter is preset and fixed in mg/dL.

Setting up Your System

You should check and update the meter-settings such as time and date before using your meter or when you change the meter batteries.

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

Adjusting Language, Date, Time and Sound

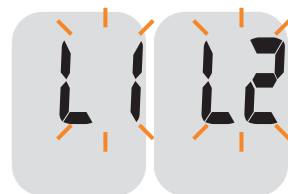
Step 1 Entering the SET Mode

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 select a language.



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 **▲** or **▼** button. Press the **S** button to confirm the language and set the year.



Step 3 Setting the Year

The meter will say "Set year" if the talking function is on. Press ▲ or ▼ button until correct year appears. Press and hold ▲ or ▼ to scroll faster. After setting the year, press the **S** button to confirm your selection and set the month.



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 ▲ or ▼ button until the correct month appears. Press the **S** button to confirm your selection and set the date.



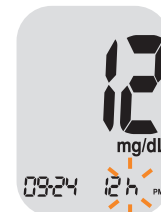
Step 5 Setting the Date

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



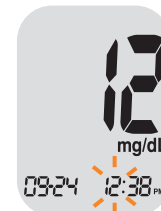
Step 6 Setting the Time Format

The meter can be set in the AM/PM (12-hour) or the 24-hour clock format. If the talking function is on, the meter will say "Set time 12-hour / 24 hour." Press ▲ or ▼ button to select a format. The AM/PM is not displayed in the 24-hour format. After selecting the format, press the **S** button to set the hour.



Step 7 Setting the Hour

If the talking function is on, the meter will say "Set hour." Press ▲ or ▼ button until the correct hour appears. Press the **S** button to confirm the hour and set the minute.




Step 8 Setting the Minute

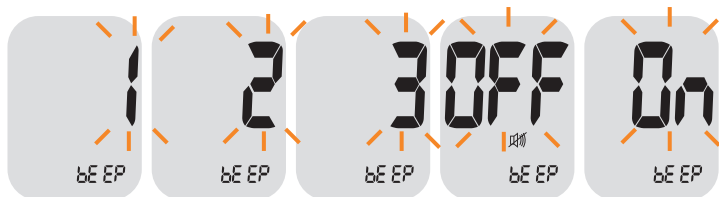
If the talking function is on, the meter will say "Set minute." Press ▲ or ▼ button until the correct minute appears. After setting the minute, press the **S** button to set the sound.




Step 9 Setting or Turning off the Sound

A number showing the sound volume will blink and the meter will say "Set volume." Press ▲ 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 the beep 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 move to the hypoglycemia (low blood glucose) indicator setting mode.




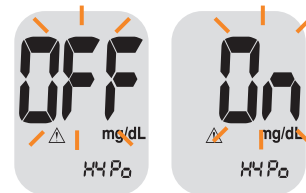
Note: Only when the sound is set to OFF, the  symbol appears on the display.

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 from 60 to 20 mg/dL.

Step 10 Turning on the Hypoglycemia Indicator

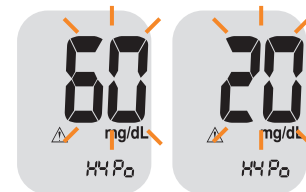
When you enter the hypoglycemia indicator setting mode, the  symbol and HYPo will blink. If the talking function is on, the meter will say "Set hypoglycemia indicator." On pressing ▲ or ▼, the screen will display On or OFF. Press **S** button to set your hypoglycemia level if you choose On. The screen will return to step 2, language selection 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 60 to 20 mg/dL. To set your hypoglycemic level, press ▲ or ▼ button until the level you want to appear. Press the **S** button to confirm. Then the screen will return to step 2, language selection mode (See page 13).



Step 12 Exiting from Set Mode

After completing meter setting, 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 should check your meter and test strips using CareSens Control Solution (Control A and B). The CareSens Control Solutions contain known amounts of glucose and are used to check that the meter and the test strips are working properly. The test strip vials have CareSens Control Solution ranges printed on their labels. Compare the result displayed on the meter to the control solution range printed on the test strip vial. Before using a new meter or a new vial of test strips, you should conduct a control

solution test following the procedure on page 19 with two different levels of solutions (Control A and B).

Notes:

- Use CareSens Control Solutions only.
- 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 solutions are at room temperature before testing. Control solution tests must be done at room temperature (68 - 77°F, 20 - 25°C).
- Before using the control solution, shake the bottle, discard the first 1 or 2 drops and wipe the tip clean.
- Close the control solution bottle tightly and store at a temperature of 46 - 86°F (8 - 30°C).

You should do a control solution test:

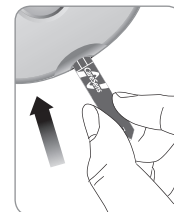
- When you want to practice the test procedure using the control solution instead of blood;
- When using the meter for the first time;

- 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;
- When using the meter for blood glucose test after any disinfection procedure.

Control Solution Testing

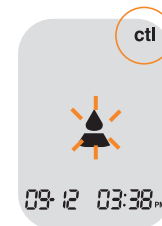
Step 1

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 automatically turns on and the ▲ symbol appears. If the talking function is on, the meter will say "Blood glucose test. Please apply blood onto the test strip."



Step 2

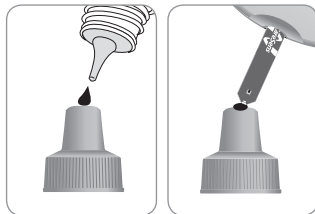
While the blood symbol ▲ blinks, press and hold the ▲ button for 3 seconds till the ctl appears on the display. If the talking function is on, the meter will say "Control solution test. Please apply control solution onto the test strip."



Step 3

Shake the CareSens Control Solution bottle well before each test. Remove the cap and squeeze the bottle to discard the first 1 or 2 drops.

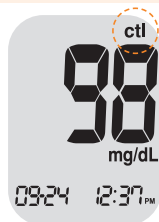
Then wipe the tip with a clean tissue or cloth. While the ▲ symbol blinks, apply the control solution to the narrow edge of the test strip until the meter beeps. Make sure the confirmation window of test strip fills completely.



Note: The meter will 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, press **S** button or ▲ button and start from step 2.

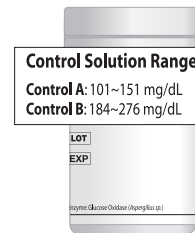
Step 4

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.



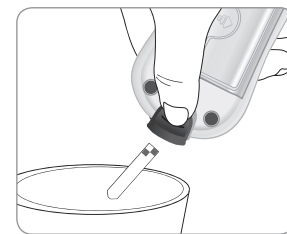
Step 5

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



Step 6

Slide the test strip ejector button to discard the used test strip safely in disposable container.



Caution: The ranges printed on the test strip vial are for CareSens Control Solutions only. They do not have any connection to your blood glucose level.

Using the Lancing Device

Comparing the Control Solution Test Results

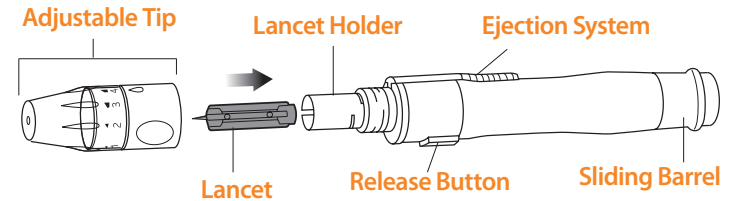
The test result of each control solution should be within the range printed on the label of test strip vial. Repeat the control solution test if the test result falls outside of this range. Out of range results may occur due to the following factors:

Situations	Actions
<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 vial was not wiped clean,• When the meter is not functioning properly.	Repeat the control solution test by referring to the "Notes" on page 18.
<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 CareSens N Voice Meter and CareSens N Single Test Strip may not be working properly. Do not use your system and contact Customer Service: 1-800-429-5001 (9 am - 9 pm EST, Monday - Saturday).

Note: The CareSens Control Solutions can be purchased separately. Contact Customer Service: 1-800-429-5001.

You will need a lancing device in order to collect a blood sample. You may use the lancing device contained 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 including other family members.

CAUTION : To reduce the chance of infection

- All components that come into contact with blood samples should be considered to be biohazards capable of transmitting viral diseases, even after disinfection.
- Do not use a lancet that has been used by another person and never share your meter and lancing device with anyone.
- Wash your hands thoroughly with soap and water after handling your meter, lancing device, or test strips.
- Keep your meter and lancing device clean. See the pre-cleaning and disinfection section on page 41.

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

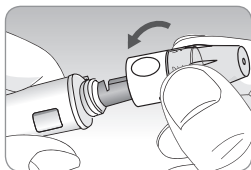
Step 1

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



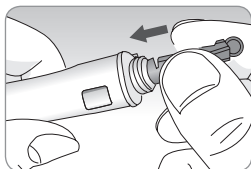
Step 2

Unscrew and remove the adjustable tip.



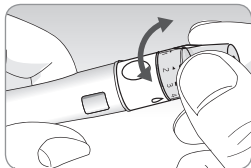
Step 3

Insert a new disposable lancet firmly into the lancet holder. Twist off the protective cover of the lancet and set it aside, then replace the adjustable tip. Keep the protective cover to replace on top of the used lancet after testing.



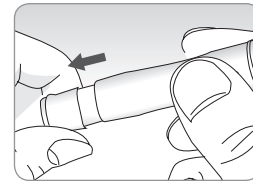
Step 4

The lancing device has five puncture depth settings, numbered 1 through 5. The smaller numbers are for a shallower puncture and the larger numbers are for a deeper puncture. Choose a depth of penetration by rotating the top portion of the adjustable tip until the setting number matches the arrow.



Step 5

Cock the lancing device by holding the body in one hand and pulling on the sleeve with the other hand until the device clicks.

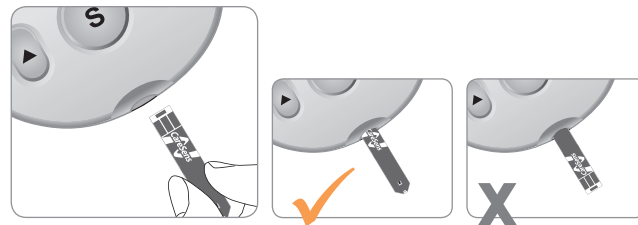


Note: The skin depth to retrieve samples will vary for various people at different sample sites. The lancing device's adjustable tip allows the best depth of skin penetration for an adequate sample size. A beginning setting of three (3) is recommended.




Preparing the Meter and Test Strip

Step 6



Insert a test strip with the contact bars facing up into the meter's test strip port. Push the strip gently into the strip port until the meter automatically turns on and the ▲ symbol appears. 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

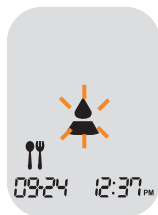
CareSens N Voice Meter allows you to flag a result of a post-meal test with  symbol. The post-meal flag () can be attached and deleted just before applying the blood sample or when the test result is displayed just after testing. Once the test result is saved with the post-meal flag () , it cannot be deleted.

Step 7

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 () .

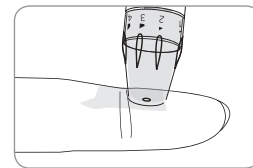
If you do not want to save the result as a post-meal test, move on to Step 8 after Step 6. If you want to delete the post-meal flag () that you attached, press and hold the  button for 3 seconds again before applying the blood sample or when the test result is displayed just after testing.




Applying the Blood Sample

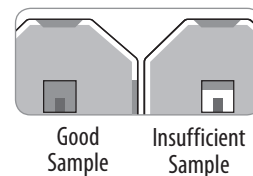
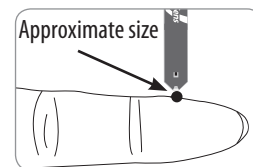
Step 8


Obtain a blood sample using the lancing device. Place the device against the pad of the finger. The best puncture sites are on the middle or ring fingers. Press the release button. Remove the lancing 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.



Step 9

After the  symbol appears on the screen, apply the blood sample to the narrow end of the test strip until the meter beeps. If the blood sample does not fill the confirmation window completely, an Er4 message may appear because of abnormal viscosity or insufficient volume. 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  symbol appears on the screen.

Note: The meter will switch off if the blood sample is not applied within 2 minutes of the ▲ symbol appearing on the screen. If the meter turns off, press **S** button or ▲ button and apply the blood sample after the ▲ symbol appears on the screen.

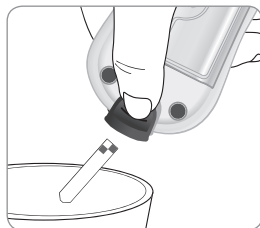
Step 10

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 11

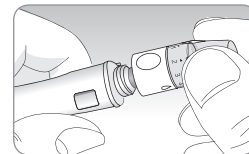
Discard the used test strip safely in disposable container by pushing up the test strip ejector. If the test strip is removed after the test result is displayed, the meter will automatically turn off after 3 seconds.



Discarding Used Lancets

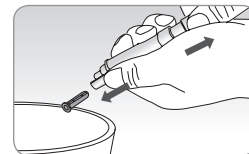
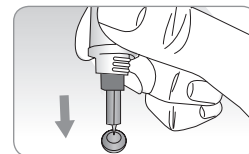
Step 1

Unscrew the lancing device tip.



Step 2

Place the protective cover on the lancet. Push the lancet ejector forward with the thumb and simultaneously pull out the sliding barrel to dispose of the used lancet in a proper biohazard container.



Caution:

- Check for damages before using the lancet. If they have been damaged, please discard it and use other lancet.
- The lancet is very sharp. Please keep away from children.
- Keep the lancets in a cool and dry place.

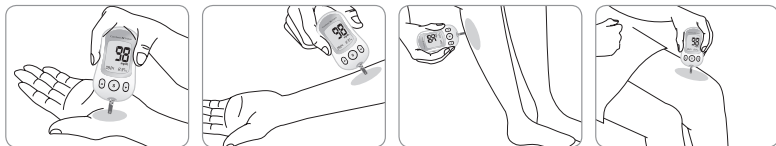
Caution: The lancet is for single use only. Never share or reuse a lancet. Always dispose of lancets properly.

Alternative Site Testing

What is AST(Alternative Site Testing)?

When someone tests their glucose, they usually take the blood sample from the tip of the finger. However, since there are many nerve endings distributed there, it can be quite painful. When doing a glucose test, using different parts of the body, such as the forearms, palms, thighs, and calves, can reduce the pain during testing. This method of testing with different parts of the body is called Alternative Site Testing. While AST may reduce the pain during testing, it may not be simple for everyone and the following precautions should be observed during testing.

Alternative Sites for Testing



Alternative Site Blood Sampling (forearm, palm, thigh, calf)

Select a clean, soft and fleshy sample site area free of visible veins and hair and away from bones. Gently massage the sample site to help blood circulation to minimize result differences between fingertip and alternative 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 μ L) blood is drawn. Carefully lift the lancing device away from your skin.

Caution: AST results should never be used to calibrate Continuous Glucose Monitoring Systems nor entered into an insulin dosing calculator or pump for dosing recommendations.

Things to know when using AST

Please understand the following before testing at sites other than the fingertip (forearms, palms, thighs, and calves).

The capillary whole blood of the fingertips shows changes in glucose levels more rapidly than in alternative sites. Therefore, the test results from the fingertip testing and AST may differ. This is because things such as lifestyle and ingested food having an effect on glucose levels.

Acceptable situations for AST

- Fasting period
- Before a meal

Situations requiring fingertip test

- When the glucose levels are rapidly increasing, such as during the two hours after a meal or exercise
- When sick or when glucose levels seem quite lower than test value
- When hypoglycemia is not well recognized
- When insulin has the biggest effect
- Two hours after an insulin injection

HI and Lo Messages

AST Precautions

- Do not ignore the symptoms of hyperglycemia or hypoglycemia.
- When the results of the test do not reflect the way you feel, retest using the fingertip. If the fingertip result still does not reflect the way you feel on retesting, please consult your healthcare professional.
- Do not rely on the AST results for changing your treatment method.
- The amount glucose in alternative sites differs from person to person.
- Before using AST, please consult your healthcare professional.

Note: Results from alternative site 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.

Note: 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 Message

The CareSens N Voice Meter displays results between 20 - 600 mg/dL. HI appears when the blood glucose level is greater than 600 mg/dL 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."

If HI is displayed again on retesting, please contact your healthcare professional immediately.



Lo Message

Lo appears when a test result is less than 20 mg/dL 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."

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



Note: If messages for hyperglycemia or hypoglycemia are displayed even if you do not have those conditions, please contact Customer Service: 1-800-429-5001 (9 am - 9 pm EST, Monday - Saturday).

Target Blood Glucose Ranges

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

Expected Values: The range of a normal fasting* blood glucose level for non-diabetic adults is between 70 ~ 99 mg/dL. Two (2) hours after a meal, the range of a normal blood glucose level for non-diabetic adults is between 100 ~ 139 mg/dL.

*Fasting is defined as no caloric intake for at least eight (8) hours.

Reference

American Diabetes Association. "Standards of Medical Care in Diabetes – 2012." *Diabetes Care*. January 2012; 35(1):S11-S63.

Transferring Test Results

Test results stored in CareSens N Voice Meter can be transferred from the meter to a computer using PC care software and cable. The 'Pc' is displayed when the data cable connects the meter with computer.

For more information, contact Customer Service at: 1-800-429-5001.



Meter Memory

The CareSens N Voice Meter can save up to 500 test results with time, date and temperature. 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 (Pm) results from the last 1, 7, 14, 30 and 90 days.

Viewing Past Test Averages

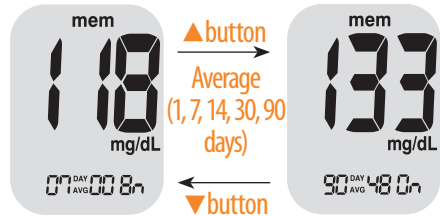
Step 1

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 for 2 seconds, followed by the 1 day average value and the number of the test results saved within the current day.



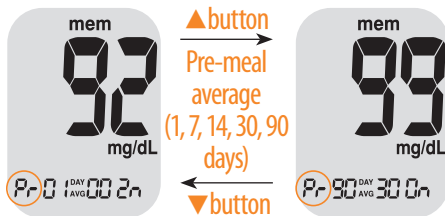
Step 2 Viewing Averages

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



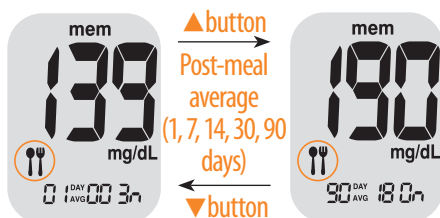
Step 3 Viewing Pre-meal Averages

Continue to 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 for the test period. The pre-meal test averages appear with the Pr symbol.



Step 4 Viewing Post-meal Averages

Continue to repeatedly press the ▲ button; the 1, 7, 14, 30 and 90-day post-meal average values and the number of tests performed post-meals with the 🍴 symbol for the test period will appear on the screen.



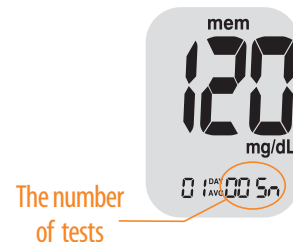
Step 5

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

Viewing Test Results

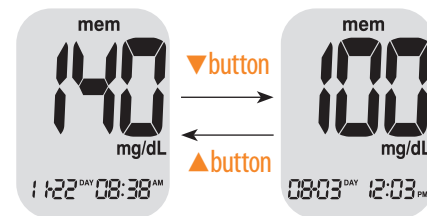
Step 1

Press the S or ▲ button to turn the meter on. The current date and time will be displayed on the bottom of the screen for 2 seconds, 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 result seen previously. The test date and the recorded temperature will display alternately. After checking the stored test result, press the S button to turn off the meter.



Setting the Alarm Function

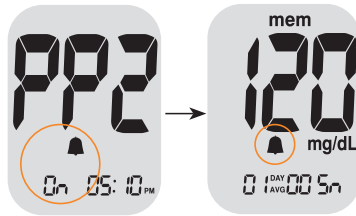
Four types of alarms can be set in the CareSens N Voice Meter: one post-meal alarm (PP2 alarm) and three time set alarms (alarm 1 - 3). The PP2 alarm goes off 2 hours after setting the alarm. The alarms ring for 15 seconds and can be silenced by pressing ▲, ▼ or S button or by inserting a test strip.

Setting the Post-meal Alarm (PP2 alarm)

Step 1 Setting the PP2 alarm On

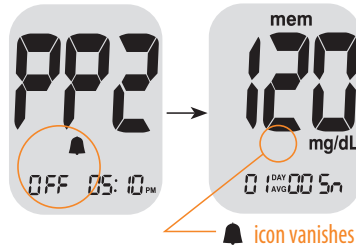
Without inserting a test strip, press and hold the ▲ button for 3 seconds to set the post-meal alarm. PP2, the 📌 symbol and On will be displayed. If the talking function is on, the meter will say "Post-meal alarm is on."

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 📌 symbol being displayed.



Setting the Time Alarms (alarm 1 - 3)

Step 1

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



Step 2

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



Step 3

Press ▲ to adjust the time of alarm 1. A number representing the time will blink on the screen. Press ▼ to set the time. Press ▲ to set the minute.



Caring for Your System

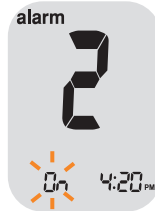
Step 4

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



Step 5

Press the **S** button to finish and to enter the alarm 2 mode.
Repeat steps 2 to 5 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.

- To minimize the risk of transmission of blood-borne pathogens, the pre-cleaning and disinfection procedure should be performed as recommended in the instructions below.
- Wash your hands thoroughly with soap and water after handling the meter, lancing device, or test strips.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be disinfected prior to use by the second person.

Pre-cleaning and Disinfection:


Pre-cleaning procedure is needed to clean dirt as well as blood and other body fluids on the exterior of the meter and lancing device before performing the disinfection procedure. The disinfection procedure is needed to prevent transmission of blood-borne pathogens.

- For the meter and lancing device, this pre-cleaning and disinfection procedure should be performed **once per week**.

Note: The life span of a CareSens N Voice Meter is 5 years. We recommend disinfecting both the meter and lancing device at least once per week. We have validated a total of 260 cleaning and disinfecting cycle (260 pre-cleaning and 260 disinfection cycles) to represent weekly cleaning and disinfecting over the use life of your meter and lancing device.

1 pre-cleaning and 1 disinfection cycles per week * 52 weeks per year * 5 years = 260 pre-cleaning and 260 disinfection cycles

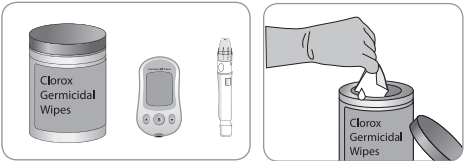
- We have validated **Clorox Germicidal Wipes** with 0.55% sodium hypochlorite as the active ingredient for disinfecting the CareSens N Voice Meter and lancing device. It has been shown to be safe for use with the meter and lancing device. This disinfectant is available commercially in towelette form. In addition to CareSens N Voice BGMS instruction, **please read the instructions provided by the manufacturer of Clorox Germicidal Wipes before using it.**

Name	Clorox® Germicidal Wipes	
Manufacturer	Clorox Professional Products Company [Phone] 1 800 537 1415 [Website] www.cloroxprofessional.com	
EPA registration number	67619-12	
Active ingredients	Sodium Hypochlorite: 0.55%	

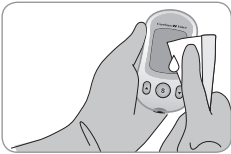
Note: The disinfectant products can be purchased online retailers (e.g. Amazon) or by telephone at the manufacturer. To find out where to purchase the disinfectant product, please contact the manufacturer or visit their website as listed above.

Pre-cleaning and Disinfection Procedures:

- ① **Open the cap of the Clorox Germicidal Wipes container and pull out 1 towelette and close the cap.**



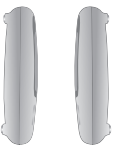
- ② **Wipe the entire surface of the meter 3 times horizontally and 3 times vertically using one towelette to pre-clean blood and other body fluids.**



Front

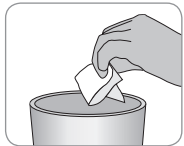


Back

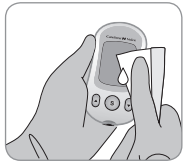
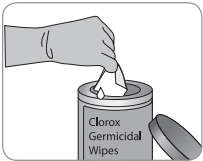


Both sides

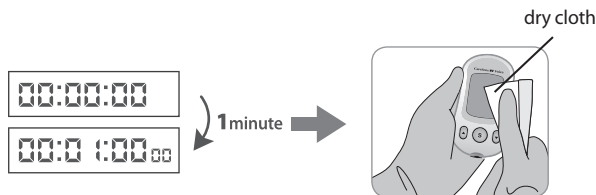
- ③ **Dispose of the used towelette in a trash bin.**



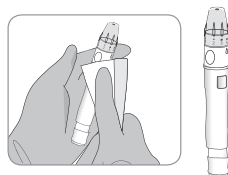
- ④ **Pull out 1 new towelette and wipe the entire surface of the meter 3 times horizontally and 3 times vertically using the new towelette to remove blood-borne pathogens.**



- ⑤ Dispose of the used towelette in a trash bin.
- ⑥ Allow exteriors to remain wet for 1 minute, then wipe the meter using a dry cloth.



- ⑦ Repeat the same procedure for the lancing device (step ① to step ⑥).



※ After the pre-cleaning and disinfection procedure, the control solution should be tested to confirm that the meter works properly before using the meter. Control solution tests should be performed with two different levels of solutions (Control A & B). Verify that the test results are within the range printed on the test strip vial. See page 19 for how to do a control solution test.

Note:

If any of the following deterioration signs appears after pre-cleaning or disinfecting, please stop using the system and contact Customer Service: 1-800-429-5001 (9 am - 9 pm EST, Monday - Saturday).

- When the inscriptions on the exterior of the meter (or lancing device) have been removed,
- When the color of the meter (or lancing device) has changed or faded,
- When cracks or roughness develop on the meter (or lancing device),
- When a part of the segment on the meter display does not flash,
- When control solution test results do not fall within the stated range on the test strip vial.

Caution:





- Do Not use other cleaners or disinfectants because other chemicals have not been validated and may damage the meter.
- Do Not get fluids inside the meter through the test strip port, data transmission port or battery compartment. Never immerse the meter or hold it under running water because this will damage the meter.


Understanding Error and Other Messages





Caution: Storage and Handling

- Do not expose the meter to direct sunlight or heat for extended periods of time.
- Do not let dirt, dust, blood, or water enter into the meter's test strip port.
- Do not drop the meter or subject it to strong shocks.
- Do not try to fix or alter the meter in any way.
- Keep the meter in a cool and airy place.
- Keep the meter away from strong electromagnetic field sources such as cell phones and microwave ovens.
- The CareSens N Voice Meter should be used only with CareSens N Single Test strips.
- Store all meter components in the carrying case to prevent loss.



Note: You can get additional information or technical assistance by calling our Customer Service Center: 1-800-429-5001 (9 am - 9 pm EST, Monday - Saturday).

Message	What is said	What it means	What to do
	"Error 1. Used test strip."	A used test strip was inserted.	Remove the strip and insert 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 ▲ symbol appeared.	Repeat the test with a new test strip and wait until the ▲ symbol appears before applying the blood or control solution sample.
	N/A	The thermometer of meter is not stabilized yet.	Retry the test after about 30 minutes for the thermometer to be stabilized.
	"Error 4. The sample was not enough or too thick."	The blood sample has abnormally high viscosity or insufficient volume.	Repeat the test using a new test strip.

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 the CareSens N Single test strip.	Repeat the test with a CareSens N Single test strip. Insert the strip with the contact bars facing up, and push in gently until the meter turns on.

Message			
			
What is said		What it means	What to do
"Error 6 / Error 7 / Error 8 / Error 9. Meter failure."		There is a problem with the meter.	Do not use the meter. Contact Customer Service: 1-800-429-5001.

Note: If the error messages persist, contact Customer Service: 1-800-429-5001 (9 am - 9 pm EST, Monday - Saturday).

Message	What is said	What it means	What to do
	"The room temperature is too low."	The temperature during the test is below the operating range.	Move to an area where the temperature is within the operating range (50-104°F) 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 the test is above the operating range.	

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 test strip.	<ul style="list-style-type: none">• Check if the confirmation window is filled adequately.• Repeat the test after inserting a new test strip.
The test result does not match the way you feel.	<ul style="list-style-type: none">• Repeat the test after inserting a new test strip.• Check the validity period of the test strip.• Check the meter.

Note: If the problem is not resolved, please contact Customer Service: 1-800-429-5001 (9 am - 9 pm EST, Monday - Saturday).

Performance Characteristics

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

Accuracy: The CareSens N Voice BGM System is calibrated to yield results equivalent to plasma glucose concentrations. The accuracy of the CareSens N Voice System (Model GM505UAA) 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.

	Obtained by healthcare professionals	Obtained by lay users
Slope	1.023	1.032
Y-intercept	-1.86 mg/dL	-3.63 mg/dL
Correlation coefficient(r)	0.995	0.985
Number of sample	110	105
Range tested	30 - 485 mg/dL	67 - 413 mg/dL

Accuracy results for glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
14/17 (82%)	17/17 (100%)	17/17 (100%)

Accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
54/93 (58%)	82/93 (88%)	93/93 (100%)	93/93 (100%)

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

Within Run Precision		
Blood avg.	38 mg/dL	SD = 1.9 mg/dL
Blood avg.	86 mg/dL	SD = 3.2 mg/dL
Blood avg.	125 mg/dL	CV = 4.1%
Blood avg.	189 mg/dL	CV = 2.6%
Blood avg.	334 mg/dL	CV = 2.8%

Total Precision		
Control avg.	35 mg/dL	SD = 1.2 mg/dL
Control avg.	116 mg/dL	CV = 2.4%
Control avg.	324 mg/dL	CV = 2.3%

This study shows that there could be variation of up to 4.1%.

Alternative Sites Testing Evaluation

► Comparison of results using various AST sites with the results of YSI measurements.

Alternative site test results for glucose concentration < 75 mg/dL

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Fingertip	1/2 (50.0%)	2/2 (100%)	2/2 (100%)
Forearm	1/2 (50.0%)	2/2 (100%)	2/2 (100%)
Palm	2/2 (100%)	2/2 (100%)	2/2 (100%)
Thigh	1/2 (50.0%)	2/2 (100%)	2/2 (100%)
Calf	1/2 (50.0%)	2/2 (100%)	2/2 (100%)

Alternative site test results for glucose concentration ≥ 75 mg/dL

	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Fingertip	27/48 (56.3%)	46/48 (95.8%)	48/48 (100%)	48/48 (100%)
Forearm	19/48 (39.6%)	42/48 (87.5%)	47/48 (97.9%)	48/48 (100%)
Palm	28/48 (58.3%)	38/48 (79.2%)	46/48 (95.8%)	48/48 (100%)
Thigh	17/48 (35.4%)	36/48 (75.0%)	46/48 (95.8%)	48/48 (100%)
Calf	27/48 (56.3%)	46/48 (95.8%)	48/48 (100%)	48/48 (100%)

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.

The i-SENS, Inc. will, at its discretion, repair or replace a defective meter or meter part that is covered by this warranty. As a matter of warranty policy, i-SENS will not reimburse the consumer's purchase price.

Obtaining Warranty Service

To obtain warranty service, you must return the defective meter or meter part along with proof of purchase to your nearest i-SENS Authorized Warranty Station.