

Owner's Booklet

CareSens **N**

Blood Glucose Monitoring System

No Coding 
Easy & Accurate Testing

0.5 μ l 
Very Small Sample
( : actual size shown)

5 Sec 
Rapid Test Result



i-SENS, Inc.

465-6 Wolgye4-dong, Nowon-gu
Seoul 139-845, Korea
www.i-sens.com



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

Warranty Information

Welcome to the CareSens N Blood Glucose Monitoring System

Thank you for purchasing the CareSens N Blood Glucose Monitoring System. The system provides you with safe, convenient and painless blood glucose *in vitro* (i.e., outside the body) diagnostic monitoring. You can obtain accurate results in just 5 seconds with a small (0.5 μ l) blood sample.

Manufacturer's Warranty

i-SENS, Inc. warrants that the CareSens N Meter shall be free of defects in material and workmanship in normal use for a period of five(5) years. The meter must have been subjected to normal use. The warranty does not cover improper handling, tampering, use, or service of the meter. Any claim must be made within the warranty period.

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

Obtaining Warranty Service

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

Table of Contents

Information

Important Information	4
Specifications	6
CareSens N Blood Glucose Monitoring System	7
CareSens N Test Strip	8
CareSens N Blood Glucose Meter	10
CareSens N Meter Display	11

Preparation

Setting up Your System	12
Adjusting the Date, Time and Unit	12
Setting the Sound On/OFF	15
Setting the Test Result Reset	16

Testing

Getting a Blood Sample	17
Preparing the Lancing Device	18
Preparing the Meter and Test Strip	22
Flagging Post-meal Test Results	22
Applying Blood Sample	23
Hi & Lo Messages	25
Blood Glucose Management	26

Additional Functions

Meter Memory	27
Viewing Test Results Stored in the Meter's memory	27
Setting the Alarm Function	29
Setting the Post-meal Alarm (PP2)	29
Setting the Time Alarm (alarm 1-3)	30

Maintenance

Replacing Batteries	32
Checking the System	33
Control Solution Testing	34
Caring for Your System	37
Understanding Error and Other Messages	38
General Troubleshooting	40
Performance Characteristics	41
Warranty Information	43

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 the diagnosis of diabetes without the guidance of a healthcare professional or for testing newborns.
- Use *only* fresh capillary whole blood samples for testing.
- Alternative site and fingertip test results may differ significantly due to rapid change in the glucose level post meal, insulin injection or exercise.

The following chart explains the symbols you'll find in the CareSens N User Manual, product packaging, and product inserts.



For *in vitro* diagnostic use



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



Cautions for safety and optimum product use



Consult instruction for use



Manufacturer



Authorized representative



Do not reuse.



Batch code



Use by



Temperature limitations

Important Information

- The CareSens N blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use).
- The glucose in the blood sample mixes with special chemicals on the test strip where to produce a small electrical current. The CareSens N meter detects this electrical current and measures the amount of glucose in the blood sample.
- The CareSens N blood glucose meter is designed to minimize code related errors in monitoring by using the no-coding function.
- The CareSens N blood glucose meter should be used only with the CareSens N strip.
- The average hematocrit range is between 30 and 50%. However, people with severe anemia, pregnant women and newborns may have higher hematocrit and this can affect the test results.
- Very high (60% or more) or very low (20% or less) hematocrit can lead to incorrect test results.
- A glucose value of less than 70 mg/dL (3.9 mmol/L) may indicate hypoglycemia and a value of more than 240 mg/dL (13.3 mmol/L) may indicate hyperglycemia.

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

Specifications

Product specifications	
Reported result range	20 ~ 600 mg/dL (1.1 ~ 33.3 mmol/L)
Sample size	Minimum 0.5 μ l
Test time	5 seconds
Sample type	Fresh capillary whole blood
Calibration	Plasma-equivalent
Assay method	Electrochemical
Battery life	1,000 tests
Power	Two 3.0 V lithium batteries (disposable, type CR2032)
Memory	250 test results
Size	93 X 47 X 15 (mm)
Weight	50 g (with battery)

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

CareSens N Blood Glucose Monitoring System



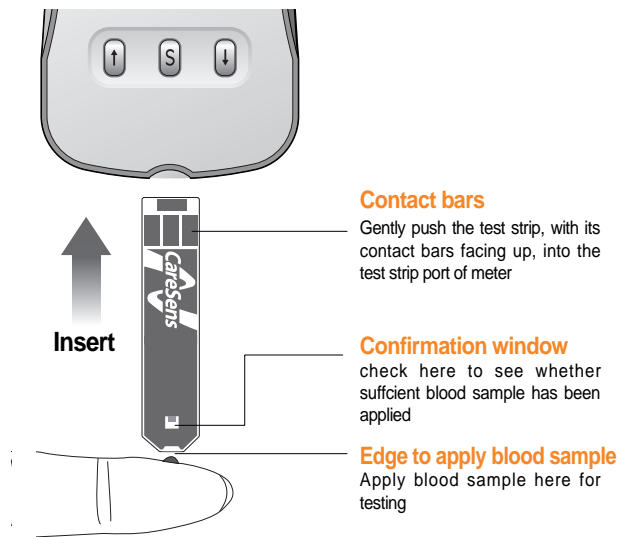
Components

- | | |
|--------------------|-------------------------|
| ① CareSens N Meter | ⑥ Lancing Device (10) |
| ② Test Strips (10) | ⑦ Owner's Booklet |
| ③ Lancing Device | ⑧ Quick Reference Guide |
| ④ AST Clear Cap | ⑨ Logbook |
| ⑤ Battery (2) | ⑩ Portable Case |

- Check all the components after opening the CareSens N blood glucose monitoring system package.
- Please contact your authorized i-SENS sales representative if any component is missing or damaged.
- The CareSens N cable for data transmission can be ordered separately. Please contact your authorized i-SENS sales representative or visit www.i-sens.com.

CareSens N Test Strip

The CareSens N 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.

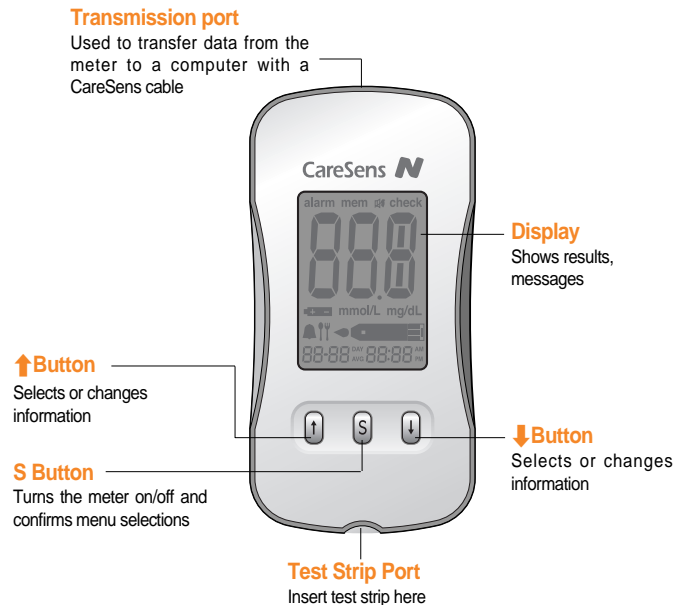


Warning!

- The CareSens N test strip should be used only with fresh capillary whole blood samples.
- Do not reuse test strips.
- Do not use test strips past the expiration or discard date.
- Check the expiration date printed on the vial. When you first open a test strip vial, you must record the discard date (date opened plus three months) in the space provided on the label.
- Store test strips in a cool and dry place at a temperature of 8 ~ 30°C (46 ~ 86°F).
- Keep away test strips from direct sunlight or heat and do not refrigerate or freeze.
- Store test strips only in their original vial.
- Close the vial tightly after removing 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.

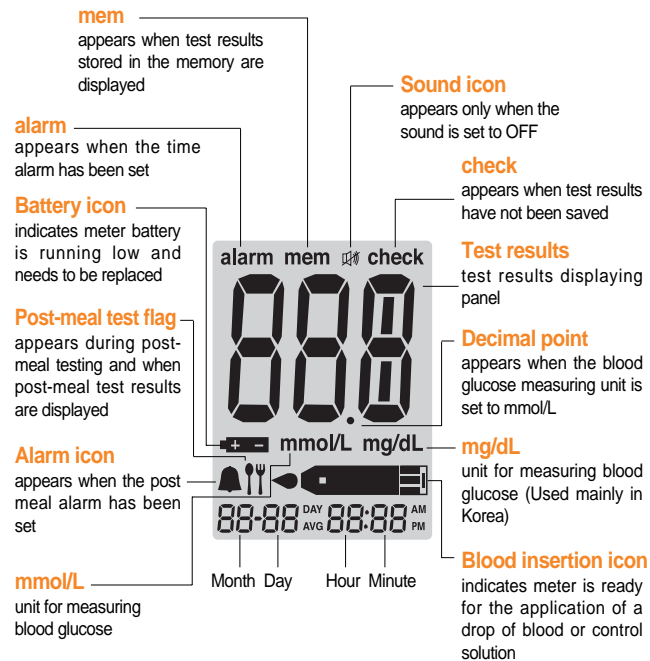
CareSens N Blood Glucose Meter



Note

The CareSens cable for data transmission to PC can be ordered separately. Please contact your authorized i-SENS sales representative or visit www.i-sens.com.

CareSens N Meter Display



Setting up Your System

Press and hold the S button for 3 seconds to switch on the meter. After all settings are finished, press and hold the S button for 3 seconds to turn off the meter.

Press **↑** or **↓** to reach the accurate value. Press and hold **↓** to scroll faster

Ajusting the Date, Time and Unit

Step 1 Entering the SET Mode

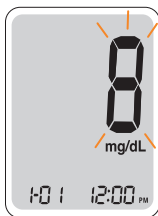
Press and hold the S button for 3 seconds to switch on the meter. After all the segments flash across the screen, the 'SET' character icon will be displayed on the screen.

Press the S button again to enter the year setting mode.



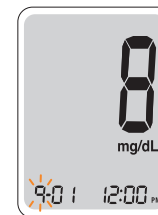
Step 2 Setting the Year

The number that appears on the screen after the meter is turned on indicates the year of manufacture. Press and release **↑** or **↓** to adjust until the correct year appears. Press and hold **↓** button to scroll through the numbers quickly. The meter will count up to 30 (indicating the year 2030) and then return to the year of manufacture. After setting the year, press the S button to confirm your selection and enter the month setting mode.



Step 3 Setting the Month

A number indicating the month will be blinking on the left corner of the screen. Press **↑** or **↓** until the correct month appears. Press the S button to confirm your selection and enter the date setting mode.



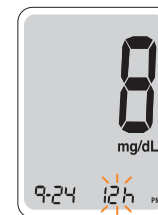
Step 4 Setting the Date

Press **↑** or **↓** until the screen displays the correct date. Press the S button to confirm the date and enter the time setting mode.



Step 5 Setting the Time

The meter can be set in the AM/PM 12-hour or the 24-hour clock format. Press **↑** or **↓** to select a format. The AM • PM icon is not displayed in the 24-hour format. After selecting the format press the M button to enter the hour setting mode.



Step 6 Setting the Hour

Press \uparrow or \downarrow until the correct hour appears. After the hour is set, press the S button to enter the minute setting mode.



Step 7 Setting the Minute

Press \uparrow or \downarrow until the correct minute appears. After setting the minute, press the S button to enter the unit setting mode.



Step 8 Setting the Measurement Unit

The meter is set to mg/dL. Press \uparrow or \downarrow to change to mmol/L or to return to mg/dL. Press the S Button to confirm your selection and to enter the sound setting mode.



Note

The mg/dL is a standard unit in the United states. The most commonly used unit in Australia, Canada, China and in some European countries is mmol/L.

Setting the Sound On/OFF

Step 9

On pressing \uparrow or \downarrow , the screen will display the On or OFF. Press the S button to confirm the selection.


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

- When the test strip is inserted in the meter
- When the blood sample is absorbed into the test strip and the test starts
- When the test result is displayed
- When you push the S button or \uparrow button to check the memory
- When you push the \uparrow button to set the post-meal (PP2) alarm
- When it is time for a preset blood glucose test

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



Note

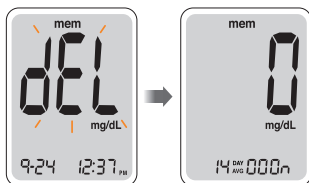
Only when the sound is set to OFF,  icon appears on the display.

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

Step 10

In this mode all the test results stored in the meter can be deleted. Please note that if you select YES, all the stored test results will be deleted and will not be restored.

After the beeper mode is set, press the S button to enter the 'Test Result Reset' mode. The 'dEL' character will blink on the screen. Press \uparrow or \downarrow to alternate between 'YES' or 'no'. To delete all the stored test results press the S button while the screen displays 'YES'. Then, all the test results stored in the meter will be deleted and the screen will be similar to the picture on the right.



If you do not want to delete the results press the S button while the screen displays 'no'. Then, the screen will return to step 2. See page 12.

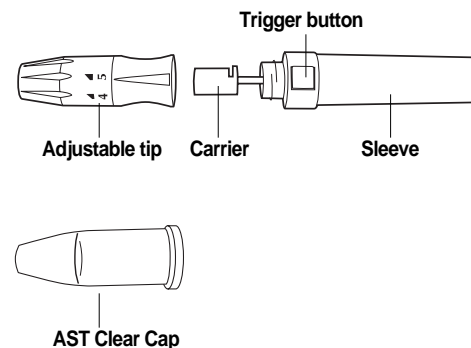
Note

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

Getting a Blood Sample

Repeated punctures in the same spot may cause soreness and calluses. Therefore, it is advisable to choose a different puncture site each time you test.

Lancing Device



Caution

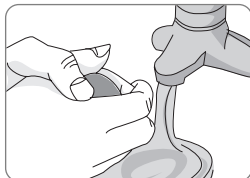
Please follow the instruction given below to prevent infection.

- The lancets are disposable and each lancet should be used only once.
- Do not share the lancing device or the lancets with others.
- Use new sterilized lancets.
- Clean the lancing device before use.

Preparing the Lancing Device

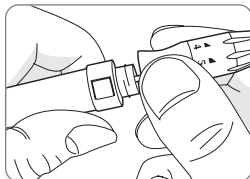
Step 1

Wash your hands and the site from where the blood sample will be drawn thoroughly with warm soapy water. Rinse and dry.



Step 2

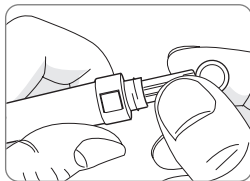
Unscrew and remove the adjustable tip.



Step 3

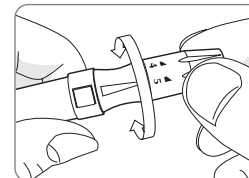
Insert a new disposable lancet firmly into the carrier. Twist off and set aside the protective cover of the disposable lancet and replace the adjustable tip.

Keep the protective cover and replace on top of the used lancet after testing and discard into an appropriate sharps or biohazard container.



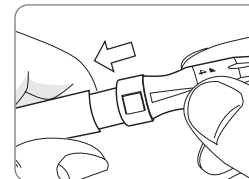
Step 4

CareSens N 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 adjustable tip in one hand and pull on the sleeve with the other hand until the device clicks.



※ **Alternative Site Testing (AST)**

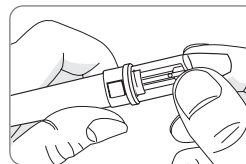
Sampling from an alternate site (forearm, palm, thigh or calf) allows you to use your fingertips less often. You may find that obtaining a blood sample from an alternate site is less painful than using a fingertip.

Alternative Sites for Testing

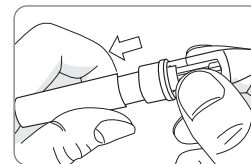


※ **Preparing the Lancing Device for an Alternative Site Testing**

For alternative site testing, follow the steps from 1 to 3 on page 18. After inserting a lancet into the lancing device, install the AST Clear Cap on the lancing device by snapping it on.



AST Clear Cap installation



Cock the lancing device

Do not test on alternative sites when:


- It has been less than two hours after a meal, a rapid-acting insulin injection or you think your glucose level is changing rapidly.
- You think your blood glucose is rapidly falling, such as within two hours of exercise or a rapid-acting insulin injection or insulin pump bolus.
- You are concerned about the possibility of hypoglycemia or an insulin reaction, such as when driving a car. This is especially important if you suffer from hypoglycemia unawareness.

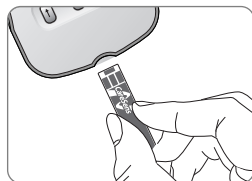
Notes

- You may need to wait a little longer to get a large enough drop of blood from the alternative sites.
- If the sample drop of blood runs or spreads due to contact with hair or with a line in you palm, do not use that sample. Try puncturing again in a smoother area.




Preparing the Meter and Test Strip

Step 6






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



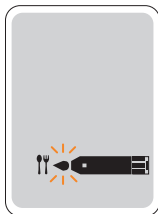
Flagging Post-meal Test Results

The CareSens N meter allows you to flag a result of an post-meal test with () icon. 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 7


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

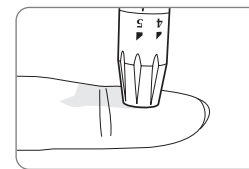
If you do not want to save the result as an post-meal test, move on to the step 8 after the step 6.




Applying Blood Sample

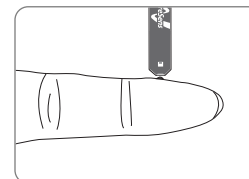
Step 8

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 trigger button. Remove the device from the finger. Wait a few seconds for a blood drop to form. A minimum volume of 0.5 microliter is needed to fill the confirmation window. (actual size of 0.5 μL : )



Step 9

After the  symbol appears on the screen, apply the blood sample to the narrow end of the test strip till the meter beeps. If the confirmation window is not filled before the meter finishes counting down then discard the test strip and insert a new one.




If confirmation window is not filled in time because of abnormal viscosity or insufficient volume, Er4 message will appear.



Good Sample Insufficient Sample

Note

The meter may switch off if the blood sample is not applied within 2 minutes of the  icon appearing on the screen. If the meter turns off, remove the strip and reinsert after switching on the meter.

Hi and Lo Messages

Step 10

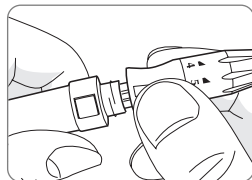
The test result will appear after the meter counts down from 5 to 1. The result will be automatically stored in the meter's memory. If the test strip is removed after the test result is displayed, the meter will automatically switch off after 3 seconds.

Discard used test strips safely in disposable containers.



Step 11

After finishing the test, unscrew and remove the adjustable tip by rotating it in an anti-clockwise direction. Without touching the used disposable lancet, stick the lancet tip into the protective cover. Grip the carrier firmly and pull the lancet safely out. Discard the used disposable lancet into an appropriate sharps or biohazard container.



Caution

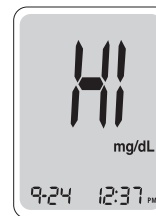
The lancets are for one-time use only and should not be reused or shared.

Discard the used lancet carefully after each use to avoid unintended lancet stick injuries. Used test strips and lancets may be considered biohazardous waste in your area. Be sure to follow your local regulations for proper disposal.

Hi Message

The meter displays results between 20 - 600 mg/dL (1.1 - 33.3 mmol/L). The Hi icon appears when the blood glucose level is more than 600 mg/dL (33.3 mmol/L) and indicates hyperglycemia.

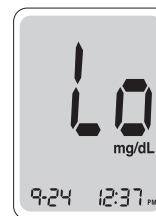
If the Hi icon is displayed again on re-testing, please contact your healthcare professional immediately.



Lo Message

The Lo icon appears when the result is less than 20 mg/dL (1.1 mmol/L) and indicates hypoglycemia.

If the Lo icon is displayed again on re-testing, please contact your healthcare professional immediately.



Note

Please contact your authorized i-SENS sales representative, if such messages are displayed even though you do not have hyperglycemia or hypoglycemia.

Blood Glucose Management

Time	Normal Blood Glucose Range mg/dL (mmol/L)	Your Target Range mg/dL
Before breakfast	70 - 105 (3.9 - 5.8)	
Before lunch or dinner	70 - 110 (3.9 - 6.1)	
1 hour post meal	160 (8.9) or less	
2 hours post meal	120 (6.7) or more	
Between 2-4pm	70 (3.9) or more	

Source: Krall, L.P., and Beaser, R.S.: Joslin Diabetes Manual.
Philadelphia: Lea and Febiger (1989), 138.

Healthcare Professional: _____

Meter Memory

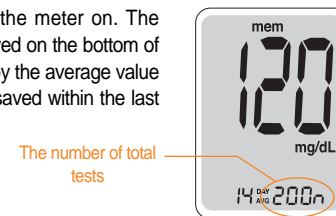
The CareSens N meter can memory up to 250 glucose test results with time and date. If the memory is full, the oldest test result gets deleted and the latest test result gets stored.

The CareSens N meter calculates and displays the averages of total test results, pre-meal test results, and post-meal test (†) results from the last 14 days.

Viewing Test Results Stored in the Meter's Memory

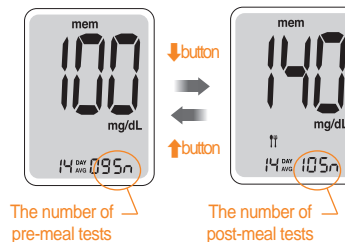
Step 1

Press the **↑** or S button to turn the meter on. The current date and time will be displayed on the bottom of the screen for 2 seconds, followed by the average value and the number of the test results saved within the last 14 days.



Step 2

Press **↓** to view the average value and the number of tests performed before eating a meal for the last 14 days. On pressing **↓** again, the average value and the number of tests performed post meals for the same period will appear on the screen.



Step 3

Use the ↓ button to scroll through the test results, starting from the most recent and ending with the oldest. Press ↑ to return to the result seen previously. After checking the stored test result, press the S button to turn off the meter.

Note

On pressing ↓, the latest test result saved in the meter's memory will be displayed on the screen along with the date and time. Press and hold ↓ to scroll through the test results.

Setting the Alarm Function

Four types of alarms can be set in the CareSens N meter: one post-meal alarm (PP2 alarm) and three time set alarms (alarm1-3).

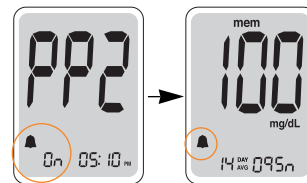
The PP2 alarm goes off 2 hours after setting the alarm.

The alarms ring for 15 seconds and can be silenced by pressing ↑, ↓ or the S button or by inserting a test strip.

Setting the post-meal alarm (PP2 alarm)

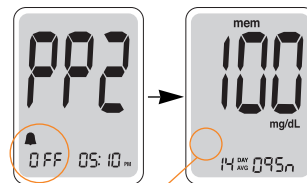
Step 1 Setting the PP2 alarm On

Without inserting a test strip, press and hold ↑ for 3 seconds to set the post-meal alarm. The 'PP2' character, the bell (🔔) icon and then the 'On' character will be displayed. The screen will then automatically change to the memory check mode. At this time, the bell (🔔) icon, 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 ↑ for 3 seconds. The 'PP2' character, the bell (🔔) icon and then the 'Off' character will appear on the screen. Then the screen will change automatically to the memory check mode without the bell (🔔) icon being displayed.

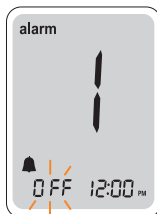


🔔 icon vanishes

Setting the Time Alarms (alarm1-3)

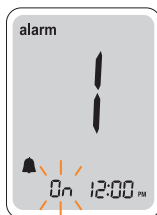
Step 1

Without inserting a test strip, press **↑** and the S button simultaneously for 3 seconds to enter the time alarm mode. The 'alarm1' will be displayed while the 'OFF' character blinks on the screen.



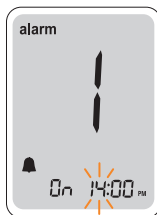
Step 2

On pressing **↓**, the 'alarm1' is set and the 'On' character is displayed on the screen. Press **↓** again to cancel the 'alarm1'. The 'OFF' icon will blink on the screen.



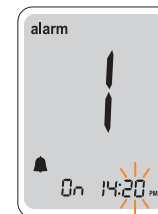
Step 3

Press **↑** to adjust the time of the 'alarm1'. A number representing the time will blink on the screen. Press **↓** to set the time. Press **↑** to end.



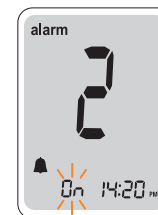
Step 4

On pressing **↑**, the number indicating the minute will start blinking. Press **↓** to set the accurate 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 2-3).



Step 6

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

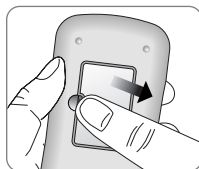
Replacing the Batteries

The CareSens N meter comes with two 3.0 V lithium batteries already installed. Around 50 tests can still be carried out after the  icon appears on the display for the first time, but the battery should be replaced as soon as possible.

The test results might not be saved if the battery gets discharged.

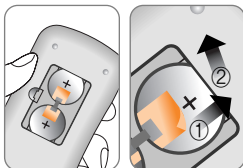
Step 1

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



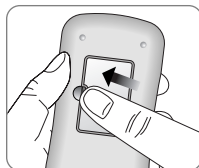
Step 2

Pull the plastic tape up and remove the old batteries. Insert two new batteries with the + side facing up as shown in the figure.



Step 3

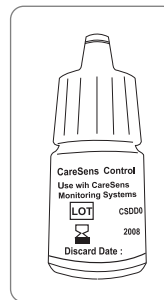
Place the cover over the battery compartment. Push down until you hear the tab click into place.



Note

- Removing the meter battery will not affect your stored result. However, you may need to re-set your meter settings. See pages 12 ~ 14.

Checking the System



You may check your meter and test strips using the CareSens Control Solution.

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, conduct a control solution test following the procedure on page 34.

Notes:

- Use only the CareSens Control Solution.
- Check the expiration dates printed on the vial. When you first open a control solution vial, record the discard date (date opened plus three 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 vial, discard the first few drops and wipe the tip clean.
- Close the control solution vial tightly and store at a temperature of 8 ~ 30°C (46 ~ 86°F).

Do a control test:


- 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

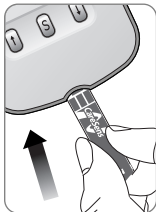
Caution

If all the results you get on testing three times continuously are within the range printed on the test strip, the meter and test strips are working properly and you may use them for your blood glucose test.


Control Solution Testing

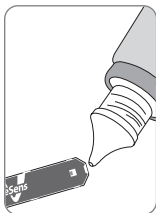
Step 1

Insert a test strip into the meter's strip port, with the contact bars facing upwards. Gently push the test strip into the port until the meter beeps. Take care not to break the strip while pushing it in. The  icon will be displayed on the screen.




Step 2

Shake the CareSens Control Solution vial before each test. Remove the cap and squeeze the vial to discard the first drop. Then wipe the tip with a clean tissue or cloth. After the  symbol appears on the display, apply the solution to the narrow edge of the test strip until the meter beeps. Make sure the confirmation window fills completely.




Note

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

Step 3

A test result will appear after the meter counts down from 5 to 1.

After your control solution result appears on the display, press  for 3 seconds till the 'check' icon appears on the display. When the 'check' icon is displayed, the result is not stored in the meter's memory and is not included in the 14-day averages.



Step 4

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

Used strips should be discarded safely in disposable containers.



Caution

- If the results you get are not within this range, the meter and test strip may not work properly. Then, stop using the meter and contact the nearest i-SENS representative.
- The range printed on the test strip vial is for the CareSens Control Solution only. It does not have any connection to your blood glucose level.

Caring for Your System

Comparing the Control Solution Test Results

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

- When the control solution vial was not shaken well,
- When the control solution is past its expiry date or is contaminated,
- When the meter, the strip or the control solution were exposed to high or low temperatures,
- When the first few drops of the control solution were not discarded or the tip of the vial was not wiped clean,
- When the test strip is past its validity period,
- When the meter is not functioning properly.

Note

The CareSens N Control Solution can be purchased separately. Please contact your authorized i-SENS sales representative.

Use a soft cloth or tissue to wipe the meter exterior. If necessary, the soft cloth or tissue might be dipped 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.




Store all the meter components in the portable case to prevent loss.

Caution:

- Store the meter at a temperature between 10 ~ 40°C.
- Store the meter at a humidity between 10 ~ 90%.
- Do not expose the meter to direct sunlight or heat for an extended period of time.
- Prevent the entry of dirt, dust, blood, or water at the meter's test port.
- Do not drop the meter or submit it to strong shocks.
- Do not try to fix or alter the meter in any way.
- Keep the meter away from strong electromagnetic fields such as cell phones and microwave ovens.
- CareSens N meter should be used only with CareSens N strips.

Understanding Error and Other Messages

Message	What It Means	What To Do
	A used test strip was inserted.	Repeat the test with a new test strip.
	The blood or control solution sample was applied before the  icon appeared.	Repeat the test with a new test strip and wait until the  icon appears before applying the blood sample.
	The temperature during the test was above or below the operating range.	Move to an area where the temperature is within the operating range (10 ~ 40°C/ 50 ~ 104°F) and repeat the test after 30 minutes.

Message	What It Means	What To Do
	The blood sample has abnormally high viscosity or insufficient volume.	Repeat the test after inserting a new test strip.
	A non-CareSens N test strip was used. A test strip was not inserted properly.	Repeat the test with a CareSens N test strip. Insert a test strip with the contacting bars facing upwards and push in gently until the meter beeps.
	There is a problem with the meter.	Do not use the meter. Contact your authorized i-SENS sales representative.

Note

If the error messages persist, contact your authorized 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 till the end. • Check whether the batteries are inserted with the '+' side facing up. • Replace the batteries.
The test does not start even after applying the blood sample on the strip.	<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 doesn't match your expectation.	<ul style="list-style-type: none"> • Repeat the test after inserting a new test strip. • Check the validity period of the test strip. • Check if the strip has passed the discard date (date of opening the test strip vial plus 3 months). • Check the meter.

Note

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

Performance Characteristics

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

Accuracy: The accuracy of the CareSens N BGM System (Model GM505IA, GM505IB, GM505IC) was assessed by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyzer, a laboratory instrument. The following results were obtained by 110 diabetic patients at clinic centers.

Slope	0.961
Y-intercept	3.5 mg/dL
Correlation coefficient(r)	0.995
Number of sample	110
Range tested	30~485 mg/dL

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

Within ± 5 mg/dL (Within ± 0.28 mmol/L)	Within ± 10 mg/dL (Within ± 0.56 mmol/L)	Within ± 15 mg/dL (Within ± 0.83 mmol/L)
13/17 (76%)	16/17 (94%)	17/17 (100%)

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

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
45/93 (48%)	88/93 (96%)	93/93 (100%)	93/93 (100%)

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

<i>Within Run Precision Within Run Precision</i>		
Blood average	38.1 mg/dL (2.1 mmol/L)	SD = 1.9 mg/dL (0.11 mmol/L)
Blood average	86.1 mg/dL (4.8 mmol/L)	CV = 3.7%
Blood average	124.5 mg/dL (6.9 mmol/L)	CV = 4.1%
Blood average	189.1 mg/dL (10.5 mmol/L)	CV = 2.6%
Blood average	334.5 mg/dL (18.6 mmol/L)	CV = 2.8%

<i>Total Precision</i>		
Control average	43.1 mg/dL (2.4 mmol/L)	SD = 2.0 mg/dL (0.11 mmol/L)
Control average	113.4 mg/dL (6.3 mmol/L)	CV = 3.3%
Control average	381.2 mg/dL (21.2 mmol/L)	CV = 4.2%

This study shows that there could be variation of up to 4.2%