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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 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 LINK User Manual, product packaging, and product inserts.

IVD — For in *vitro* diagnostic use

CE 0123 — 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

Use by

EC REP — Authorized representative

+30°C / +8°C — Temperature limitations

Do not reuse.

LOT — Batch code

Do not discard this product with other household-type waste

SN — Serial number

Important Information

- The CareSens LINK 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 LINK meter detects this electrical current and measures the amount of glucose in the blood sample.
- The CareSens LINK blood glucose meter is designed to minimize code related errors in monitoring by using the no-coding function.
- The CareSens LINK blood glucose meter should be used only with the CareSens LINK 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 μℓ
Test time	5 seconds
Sample type	Fresh capillary whole blood
Calibration	Plasma-equivalent
Assay method	Electrochemical
Battery life	1,000 tests
Power	Two 1.5 V alkaline batteries (AAA)
Memory	250 test results
Size	93 x 47 x 26 (mm)
Weight	77.5 g (with battery)

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

CareSens LINK Blood Glucose Monitoring System

Components

① CareSens LINK Blood Glucose Meter
② Lancing Device
③ Lancet (10)
④ Owner's Booklet
⑤ Quick Reference Guide
⑥ Logbook
⑦ Carrying Case
⑧ CareSens N Blood Glucose Test Strip (10)
⑨ Battery (2)

- 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.

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CareSens LINK Blood Glucose Meter

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

Display
Shows results, messages

Button
Selects or changes information

Button
Selects or changes information

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

Test Strip Port
Insert test strip here

Note
The 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 LINK Blood Glucose Meter Display

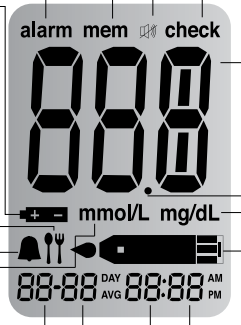
mem
appears when test results stored in the memory are displayed

Sound icon
appears only when the sound is set to OFF

alarm
appears when the time alarm has been set

check
appears when test results have not been saved

Battery icon
indicates meter battery is running low and needs to be replaced



Test results
test results displaying panel

Post-meal test flag
appears during post-meal testing and when post-meal test results are displayed

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

mg/dL
unit for measuring blood glucose

Alarm icon
appears when the post meal alarm has been set

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

mmol/L
unit for measuring blood glucose

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 the ⬆ or ⬇ to scroll faster.

Adjusting 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. 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 **S** button to enter the hour setting mode.

Step 6 Setting the Hour

Press ⬆ or ⬇ 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 ⬆ or ⬇ until the correct minute appears. After setting the minute, press the **S** button to enter the unit setting mode

Note

The unit setting on the meter may be fixed for your meter, so that you may not be able to change the setting.

Setting the Sound On/OFF

Step 8

On pressing ⬆ or ⬇, 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 ⬆ button to check the memory
- When you push the ⬆ button to set the post-meal (PP2) alarm
- When it is time for a preset blood glucose test

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

Note

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

Step 9 Setting the Bluetooth

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 can 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 ⬆ or ⬇ 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.

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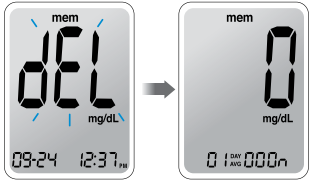
Setting the 'Test Result Reset' (Deleting all the saved test results)

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 can not be restored.



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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, Time, Date and Unit setting mode will finish and the meter will be turned off. Press and hold ⬇ to scroll through numbers quickly.

Step 11

Discard the used test strip by pushing the strip ejection button on the right side of the meter as shown in the picture on the right to a proper disposal container. The meter will turn off automatically in three seconds after the test strip has been removed.
When the Bluetooth mode is activated, follow the next step (Step 12)

Step 12

If the Bluetooth mode has been activated, 'bT' will appear on the display and try to connect with a Bluetooth device when the test strip has been removed.
Depending on the user's Bluetooth settings PIN Code input may be necessary in order to register the external Bluetooth device. In this case, type in '0000' in the input box. When the measured glucose value has been transmitted via Bluetooth, the transmitted data in the meter will be automatically deleted and the meter will turn itself off.

Note

In case, the measured glucose value has NOT been transmitted even with the Bluetooth activated, 'con' and 'check' icon will appear on the display. When measuring the glucose level at a Bluetooth ready environment later, previous values stored in the meter and the most recent value will be transmitted altogether.

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 20.

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 solution 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

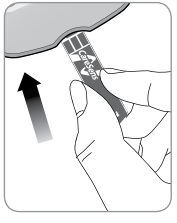
Caution

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

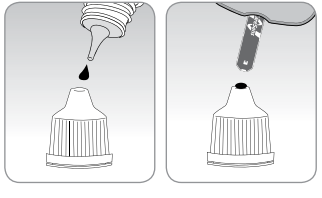
Step 1

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. Be careful 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, 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.

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 expiration 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 expiration date,
- When the meter is not functioning properly.

Note

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

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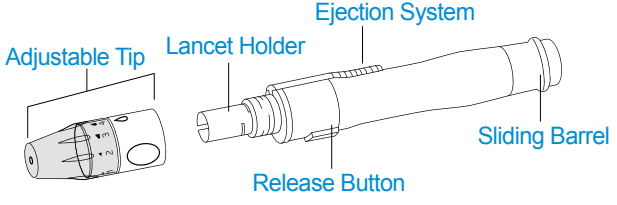
Using the Lancing Device

You will need a lancing device in order to collect a blood sample. You may use the lancing device contained in the CareSens LINK Blood Glucose Monitoring System or any other medically approved lancing device.



- The lancing device should be used by one individual and communal use is strongly discouraged.
- Use a soft cloth or tissue to wipe the lancing device. If necessary, a small amount of alcohol on a soft cloth or tissue may be used.

Caution

To avoid infection when drawing a sample, use a lancet *only* one time, and:
- Do not use a lancet that has been used by others.
- Always use a new sterile lancet.
- Keep the lancing device clean.

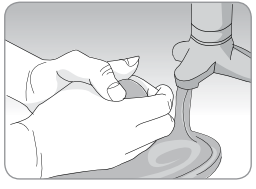
Note

Repeated puncturing at the same sample site may cause pain or skin calluses. Choose a different site each time you test.

Preparing the Lancing Device for Blood Sample Retrieval

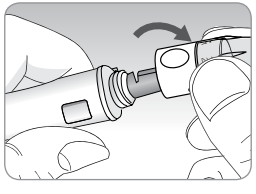
Step 1

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



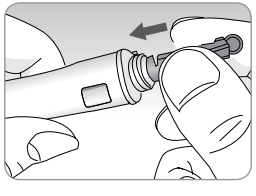
Step 2

Unscrew lancing device tip.



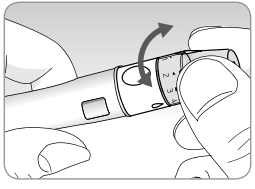
Step3

Firmly insert new lancet into carrier. Hold lancet firmly. Gently twist to pull off protective disk. Save disk to recap lancet after use. Replace lancing device tip.



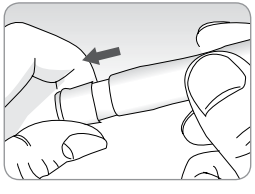
Step 4

Select a desired depth of one-to-five (1-5) on lance's adjustable tip. Rotate ring to align desired number with arrow.
A beginning setting of three (3) is recommended.



Step 5

To cock the lancing device, hold the tip in one hand. Pull the sliding barrel on with the other hand. The lancing device is cocked when you feel a click.



Note

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

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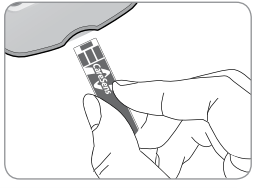
Preparing the Meter and Test Strip

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. Be careful 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.

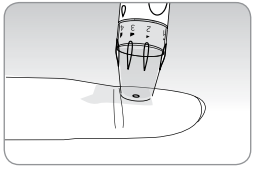
Press the ▼ button to change the measurement modes, and the number will be repetitively changed from '1' to '3' on the display. Each number means the post-meal time.

Within 2 hours after a meal (within 1 hr. 45 min.): '1' displayed
About 2 hours after a meal (1 hr. 45 min. to 2 hr. 15 min.) : '2' displayed
After 2 hours after a meal (2 hr. 15 min. to 8 hr.): '3' displayed

Applying Blood Sample

Step 8

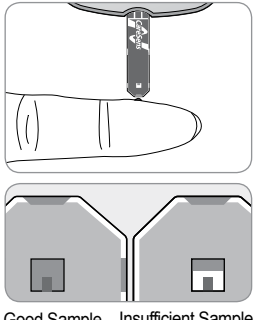
Obtain a blood sample using the lancing device. Place the device against the pad of the finger. The best puncture sites are on the middle or ring fingers. Press the release button. Remove the device from the finger. Wait a few seconds for a blood drop to form. A minimum volume of 0.5 microliter is needed to fill the confirmation window. (actual size of 0.5 μℓ : ●)



Step 9

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

Step 10

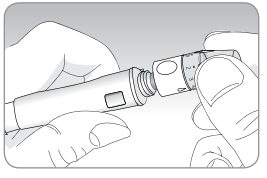
The test result will appear after the meter counts down from 5 to 1. The result will be automatically stored in the meter's memory. If the test strip is removed after the test result is displayed, the meter will automatically switch off after 3 seconds.

Discard used test strips safely in disposable containers.

Discarding Used Lancets

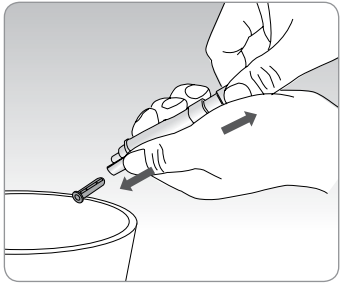
Step 1

Unscrew general lancing device tip.



Step 2

Place protective cover on 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

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

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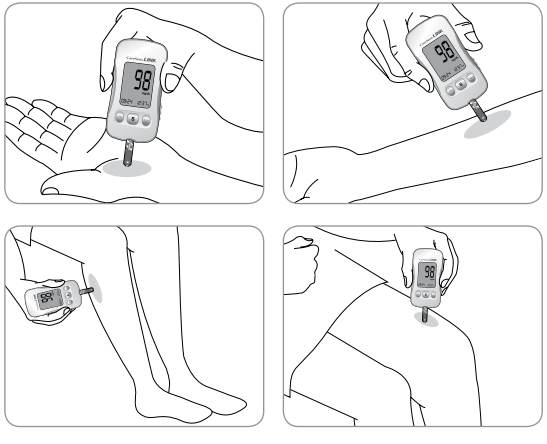
Alternative Site Testing

What is AST(Alternative Site Testing)?

Usually, when someone tests their glucose, they take the blood sample from the tip of the finger. However, since there are many nerve endings distributed there, it is quite painful. When doing a glucose test, using different parts of the body such as the arms, 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 Site for Testing



Things to know when using AST

Please understand the following things before testing outside of the fingertip (arms, thighs, calves).
The capillary blood of the fingertip shows the change in glucose more rapidly than AST. Therefore, the test results from the fingertip test and AST may differ. This is because things such as lifestyle and ingested food have an effect on glucose levels.

Acceptable situations for AST

- Fasting period
- Before a meal
- Before sleeping

Situations requiring fingertip test

- When the glucose levels are rapidly increasing 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
- 2 hours after an insulin injection

AST Precautions

- Do not ignore the symptoms of hyperglycemia or hypoglycemia.
- When the results of the test do not reflect one's opinion, retest using the fingertip test.
  If the test results do not reflect one's opinion, please consult a doctor.
- Do not rely on the AST results for changing one's treatment method.
- The amount glucose in alternative sites differs from person to person.
- Before using AST, please consult your regular physician.

Note

Results from alternative site and fingertip samples may appear differently as there is a time lag for the glucose levels to reach the same value. Use a fingertip for drawing 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 a line in you palm, do not use that sample.
Try puncturing again in a smoother area.

Hi and Lo Messages

Hi Message

The meter displays results between 20 ~ 600 mg/dL (1.1 ~ 33.3 mmol/L). 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.

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Target Blood Glucose Ranges

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

Source : *Diagnosis of Diabetes*, NIH Publication No. 05-4642, January 2005

Meter Memory

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

The 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.

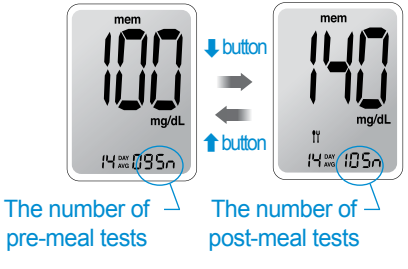
Viewing Test Results Stored in the Meter's Memory

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.

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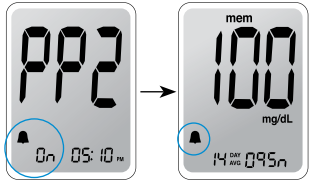
Setting the Alarm Function

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)

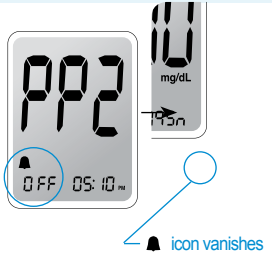
Step 1 Setting the PP2 alarm On

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.



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.

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Bluetooth Paring

When the meter is off, hold the ⬇ buttons for 2 seconds to pair the meter and the other Bluetooth device. ‘bT’ will be blinked on the display, and the Bluetooth connection will be available.
Depending on the user’s Bluetooth settings PIN Code input may be necessary in order to register the external Bluetooth device. In this case, type in ‘0000’ in the input box.
When the measured glucose value has been transmitted via Bluetooth, the transmitted data in the meter will be automatically deleted and the meter will turn itself off.

Note

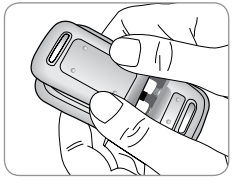
Blinking ‘bT’ on the display means that the search of the Bluetooth device is available. The meter will be automatically turned off after entering the mode. If the meter is turned off before finishing Bluetooth paring, retry the paring by holding the ⬇ button.

Replacing the Batteries

The CareSens LINK meter comes with two 1.5 V AAA alkaline batteries. 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 runs out.

Step 1

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

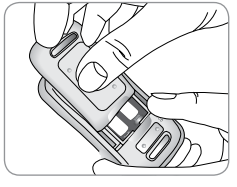


Step 2

Replace the old batteries with new batteries. Remove the old battery by lifting the battery with the index finger and pulling out the battery with your thumb and index fingers as shown in the figure on the right one by one. Insert two new batteries with the + side facing up and make sure the battery is inserted firmly.

Step 3

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



Note

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

Caring for Your System

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:

- 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 LINK meter should be used only with CareSens LINK 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 LINK test strip was used. Test strip was not inserted properly.	Repeat the test with a CareSens LINK 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.	• 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.	• 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.	• Repeathe 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 6 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 GM505LE) 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 LINK BGM System.

Within Run Precision		
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%

Total Precision		
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%

Warranty Information

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.

MEMO

FCC Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference. and
(2) This device must accept any interference received, including interference that may cause undesired operation.

Caution

Any changes or modifications (including the antenna) made to this device that are not expressly approved by the manufacturer may void the user's authority to operate the equipment.

This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.