

Owner's Booklet

# CareSens™ N

## Blood Glucose Monitoring System

No Coding   
Easy & Accurate Testing

0.5  $\mu$ L   
Very Small Sample  
(: actual size shown)

5 Sec   
Rapid Test Result



## Welcome to the CareSens™ N Blood Glucose Monitoring System

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

- No part of this document may be reproduced in any form or by any means without the prior written consent of i-SENS.
- The information in this manual is correct at the time of printing. However, i-SENS reserves the right to make any necessary changes at any time without notice as our policy is one of continuous improvement.

# Table of Contents

## Information

Important Information: Read This First! _____	4
Specifications _____	6
CareSens N Blood Glucose Monitoring System _____	7
Inserting or Replacing the Batteries _____	8
Caring for Your System _____	11
CareSens N Blood Glucose Test Strip _____	12
CareSens N Blood Glucose Meter _____	14
CareSens N Blood Glucose Meter Display _____	15

## Preparation

Setting Up Your System _____	16
Adjusting the Date and Time _____	16
Setting the Sound On/OFF _____	19
Checking the System _____	20
Control Solution Testing _____	21
Comparing the Control Solution Test Results _____	23

## Testing

Using the Lancing Device _____	24
Preparing the Lancing Device _____	25
Preparing the Meter and Test Strip _____	27
Flagging Post-meal Test Results _____	27
Applying Blood Sample _____	28
Discarding Used Lancets _____	30
Alternate Site Testing _____	31
HI and Lo Messages _____	34
Target Blood Glucose Ranges _____	35
Transferring Test Results _____	36

## Additional Functions

Meter Memory _____	37
Viewing Averages Stored in the Meter's Memory _____	37
Viewing Test Results Stored in the Meter's Memory _____	39
Setting the Alarm Function _____	40
Setting the Post-meal Alarm (PP2 Alarm) _____	40
Setting the Time Alarms (alarm 1-3) _____	41

## Maintenance

Understanding Error Messages _____	43
General Troubleshooting _____	45
Performance Characteristics _____	46
System Accuracy and Measurement Precision _____	46
Influence Quantities _____	47
User Performance Evaluation _____	49
Warranty Information _____	50

## Important Information: Read This First!


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


### Intended use:


CareSens N Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the fingertip. Alternate site testing from the forearm and palm may also be used to measure glucose levels. The CareSens N Blood Glucose Monitoring System is intended for use outside the body (*in vitro* diagnostic use) and is intended for use as an aid to monitor the effectiveness of diabetes management. The system is for self-testing or healthcare professional use and should not be used for the diagnosis of or screening for diabetes or for testing newborns.

### Meaning of Symbols Used:

 For *in vitro* diagnostic use

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

 Caution, Warning (consult instructions for use for cautions and warnings)

 Warning (Contains coin battery)

 Use by (unopened or opened test strip vial)

 Do not reuse


 Batch code

 Consult instruction for use

 Manufacturer

 Temperature limitations

 Serial number

 Do not discard this product with other household-type waste

## Important Information

---

- The CareSens N Blood Glucose Monitoring System is intended for self-testing outside the body (*in vitro* diagnostic use).
- Glucose in blood samples reacts with the chemical in the test strip 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 minimise 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 Test Strips.
- An abnormally high or low red blood cell count (hematocrit level over 65 % or below 15 %) may produce inaccurate results.
- If your test result is below 3.3 mmol/L or above 13.3 mmol/L, consult a healthcare professional immediately.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
- Inaccurate results may occur in patients undergoing oxygen therapy.

*If you need assistance, please contact your authorised i-SENS sales representative.*

# Specifications

## Product specifications

Measurement range	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	3,000 tests
Power	Two 3.0 V lithium batteries (disposable, type CR2032)
Memory	1,000 test results
Size	93 x 47 x 15 mm
Weight	51.5 g (with batteries)

## Operating ranges

Temperature	5–50 °C
Relative humidity	10–90 %
Hematocrit	15–65 %

## Storage/Transport conditions

Temperature	Glucose meter (with batteries)	0–50 °C
	Test strip	1–30 °C
	Control solution	8–30 °C
Relative humidity	Glucose meter (with batteries), Test strip, Control solution	10–90 %

# CareSens N Blood Glucose Monitoring System



## Components

- |                                   |  |
|-----------------------------------|--|
| 01 CareSens N Blood Glucose Meter | 07 Registration Card                         |
| 02 CareLance (Lancing Device)     | 08 Carrying Case                             |
| 03 Lancets (50)                   | 09 CareSens N Blood Glucose Test Strips (10) |
| 04 Owner's Booklet                | 10 Batteries (2)                             |
| 05 Quick Reference Guide          |  |
| 06 Logbook                        |  |

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

## Inserting or Replacing the Batteries




### WARNING

- Chemical burn hazard.
- Keep batteries away from children.
- This product contains lithium button/coin cell batteries. If a new or used lithium button/coin cell battery is swallowed or enters the body, it can cause severe internal burns and can lead to death in as little as 2 hours. Always completely secure the battery compartment. If you think batteries might have been swallowed or placed inside any part of the body, seek immediate medical attention.
- The cells shall be disposed of properly, including keeping them away from children, and even used cells may cause injury.
- If you suspect your child has swallowed a button/coin cell battery immediately call the Poisons Information Centre on 13 11 26 in Australia, or 0800 764 766 in New Zealand.



The CareSens N Meter uses two 3.0 V lithium batteries. Before using the meter, check the battery compartment and insert batteries if empty.

When the  symbol appears on the display while the meter is in use, the batteries should be replaced as soon as possible. The test results may not be saved if the batteries run out completely.

### Step 1

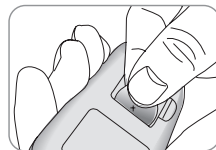
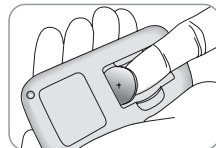
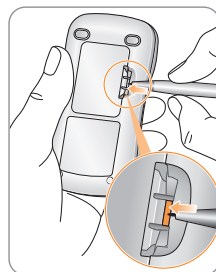
Make sure the meter is turned off. To open the battery cover, insert a narrow object, such as a ballpoint pen into the slot, and lift the cover up.

#### Note

Please take care when opening the battery compartment – the cover may spring up.

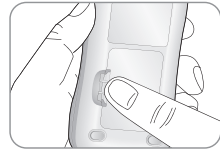
### Step 2

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



### Step 3

Place the cover on the battery compartment, and push it down until it clicks into place.



### Note

Removing the meter batteries will not affect your stored results. However, you may need to reset your meter settings. See pages 16–19.

## Caring for Your System

Use a soft cloth or tissue to wipe the meter exterior. If necessary, dip the soft cloth or tissue in a small amount of alcohol.

Do not use organic solvents such as benzene, acetone, or any household and industrial cleaners that may cause irreparable damage to the meter.

### Caution:

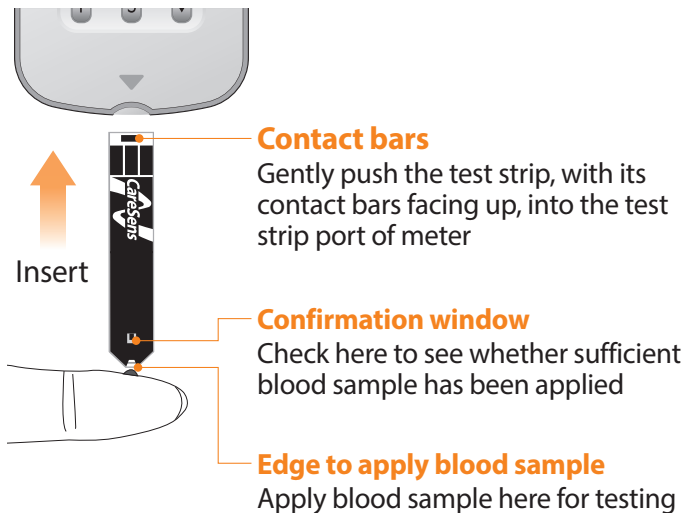
- Do not expose the meter to direct sunlight, heat, or excessive humidity for an extended period of time.
- Do not let dirt, dust, blood, or water enter into the meter's test strip port.
- Do not drop the meter or submit it to strong shocks.
- Do not try to fix or alter the meter in any way.
- Strong electromagnetic radiation may interfere with the proper operation of this device. Keep the device away from sources of strong electromagnetic radiation, especially when measuring your blood glucose.
- CareSens N meter should be used only with CareSens N test strips.
- Store all the meter components in the portable case to prevent loss and help keep the meter clean.

### Disposal of the meter

If you need to throw your meter away, you should follow existing policies and procedures of your own country or region. For information about correct disposal, please contact your local council or authority. If you need assistance, contact your authorised i-SENS sales representative.

## CareSens N Blood Glucose 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.



 **Caution**

- The CareSens N Test Strips should be used only with fresh capillary whole blood samples.
- Do not reuse test strips.
- Do not use test strips past the expiration date.
- Test strips in new, unopened vials and test strips in vials that have been opened can be used up until the expiration date printed on the test strip box and vial label if the test strips are used and stored according to its storage and handling methods.
- Store test strips in a cool and dry place at a temperature of 1–30 °C.
- Keep test strips away from direct sunlight or heat and do not freeze.
- Store test strips only in their original vial.
- Avoid getting any liquid or moisture in the test strip vial. This can affect the test strips and cause inaccurate test results.
- Do not apply samples other than capillary whole blood or control solution to the test strip.
- Close the vial tightly after taking out a test strip for testing and use the strip immediately.
- Handle test strips only with clean and dry hands.
- Do not bend, cut, or alter test strips in any way.
- For detailed storage and usage information, refer to the CareSens N Test Strip package insert.
- Keep the meter and testing supplies away from young children.
- The test strip vial contains drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.

# CareSens N Blood Glucose Meter

## Data Port

Used to transfer data from the meter to a computer with the cable available from your authorised i-SENS representative

## ↑ Button

Selects or changes information

## S Button

Turns the meter on/off, confirms menu selections, and changes information

## Display

Shows results, messages

## ↓ Button

Selects or changes information



**Test Strip Port**  
Insert test strip here

## Note

- The cable for data management software can be ordered separately. Please contact your authorised i-SENS sales representative.
- The unit of measurement is fixed in mmol/L and it cannot be changed by the user.

# CareSens N Blood Glucose Meter Display

## mem

appears when test results stored in the memory are displayed

## alarm

appears when the time alarm has been set

## Battery symbol

indicates meter battery is running low and needs to be replaced

## Post-meal test flag

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

## Alarm symbol

appears when the post-meal alarm has been set

## mmol/L

unit for measuring blood glucose

## Sound symbol

appears only when the sound is set to OFF

## check

appears when the control solution test results are saved or displayed

## Test results

test results displaying panel

## Decimal point

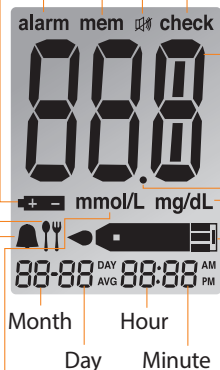
appears when the blood glucose measuring unit is set to mmol/L

## mg/dL

unit for measuring blood glucose

## Blood insertion symbol

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



## Note

It is recommended to check if the display screen on the meter matches the illustration above every time the meter turns on. Do not use the meter if the display screen does not exactly match the illustration as the meter may show incorrect results.

## Setting Up Your System

Press and hold the **S** button for 3 seconds to enter the SET mode. After all settings are finished, press and hold the **S** button for 3 seconds to turn off the meter.

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

### Adjusting the Date and Time

#### Step 1 Entering the SET Mode

Press and hold the **S** button for 3 seconds to enter the SET mode. After all the segments flash across the screen, the 'SET' will be displayed on the screen.

Press the **S** button again to progress to the next step.



#### Step 2 Setting the Year

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 progress to the next step.





### 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 progress to the next step.



### Step 4 Setting the Date

Press **↑** or **↓** until the screen displays the correct date. Press the **S** button to confirm the date and progress to the next step.



### Step 5 Setting the Time Format

The meter can be set in the AM/PM 12-hour or the 24-hour clock format. Press **↑** or **↓** to select a format. The AM • PM symbol is not displayed in the 24-hour format. After selecting the format, press the **S** button to progress to the next step.



### Step 6 Setting the Hour

Press **↑** or **↓** until the correct hour appears. After the hour is set, press the **S** button to progress to the next step.



### Step 7 Setting the Minute

Press **↑** or **↓** until the correct minute appears. After setting the minute, press the **S** button to progress to the next step.



## Setting the Sound On/OFF

### Step 8

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

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


- When you push the **S** button or **↑** button to turn on the meter
- 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 **↑** 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.

To confirm all settings, press and hold the **S** button and the screen will switch off.

### Note

-  symbol is displayed only when the sound is set to OFF.
- At any stage, press the **S** button for 3 seconds to exit SET mode and turn off the meter. Press and hold **↓** to quickly scroll through the numbers.

## Checking the System



You may check your meter and test strips using the CareSens Control Solutions (control A, B and/or C). The CareSens Control Solution contains a known amount of glucose and is used to check that the meter and the test strips are working properly. The test strip vials have CareSens Control Solution ranges printed on their labels. Compare the result displayed on the meter to the CareSens Control Solution range printed on the test strip vial.

Before using a new meter or a new vial of test strips, you may conduct a control solution test following the procedure on pages 21–22.

### Note

- Use only the CareSens Control Solutions.
- 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.
- Control solution tests must be done between 20–25 °C. Make sure your meter, test strips, and control solution have adjusted to the above temperature ranges well before testing.
- Before using the control solution, shake the bottle, discard the first drop and wipe the tip clean.
- Close the control solution bottle tightly and store at a temperature of 8–30 °C.


### You may do a control solution test:

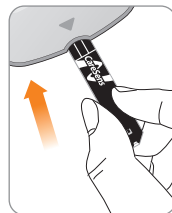
- When you want to practice the test procedure using the control solution instead of blood,
- When using the meter for the first time,
- Whenever you open a new vial of test strips,
- If the meter or test strips do not function properly,

- If your symptoms are inconsistent with the blood glucose test results and you feel that the meter or test strips are not working properly,
- If you drop or damage the meter.


## Control Solution Testing

### Step 1

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




### Step 2

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



### Note

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

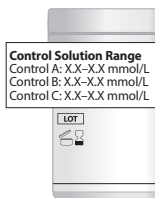
### Step 3

The display segments will rotate clockwise on the meter display and a test result will appear after the meter counts down from 5 to 1. After your control solution result appears on the display, press  $\downarrow$  for 3 seconds till the 'check' appears on the display. When the 'check' is displayed, the result is stored in the meter's memory but it will not be included in the averages.



### Step 4

Compare the result displayed on the meter to the range printed on the test strip vial. The result should fall within the range. Used strips should be discarded safely in appropriate containers.



### ⚠ Caution

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.

### 🔍 Note

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

## Comparing the Control Solution Test Results

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

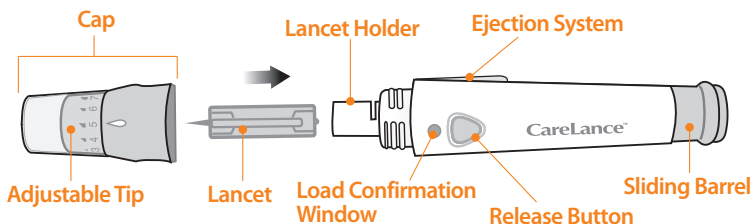
Situations	Actions
<ul style="list-style-type: none"><li>• When the control solution bottle was not shaken well,</li><li>• When the meter, test strip, or the control solution were exposed to high or low temperatures,</li><li>• When the first drop of the control solution was not discarded or the tip of the bottle was not wiped clean,</li><li>• When the meter is not functioning properly.</li></ul>	Repeat the control solution test by referring to the <b>Note</b> on page 20.
<ul style="list-style-type: none"><li>• When the control solution is past the expiration date printed on the bottle,</li><li>• When the control solution is past its discard date (the date the bottle was opened plus three (3) months),</li><li>• When the control solution is contaminated.</li></ul>	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 Test Strip and Meter may not be working properly. Do not use your system and contact your authorised i-SENS sales representative.

## Using the Lancing Device

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

You may use CareLance contained in the CareSens N Blood Glucose Monitoring System or any other medically approved lancing device.



- The lancing device should not be used by more than one individual. Ensure the lancing device is not shared among different users.
- Use a soft cloth or tissue to wipe the lancing device. If necessary, a small amount of alcohol on a soft cloth or tissue may be used.

### Caution

To avoid infection when drawing a sample, do not use a lancet more than once, and:

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

### Note

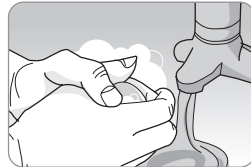
Repeated puncturing at the same sample site may cause pain or skin calluses (thick hard skin). Choose a different site each time you test.



## Preparing the Lancing Device

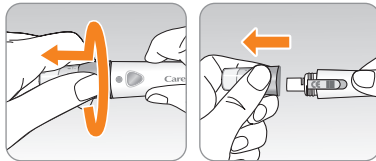
### Step 1

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



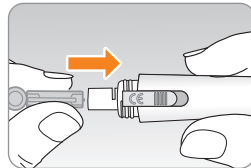
### Step 2

Unscrew and remove the lancing device tip.



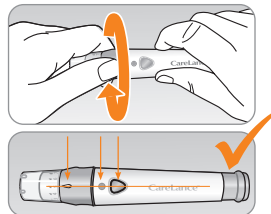
### Step 3

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



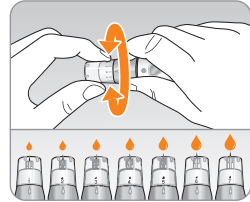
### Step 4

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



## Step 5

Select a desired depth of one-to-seven (1–7) on the lancing device's adjustable tip. Choose a depth by rotating the top portion of the adjustable tip until the setting number matches the arrow.

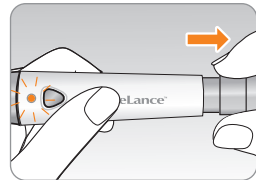


### Note

- 1 = least penetration of lancet into the skin.
- 7 = most penetration of lancet into the skin.

## Step 6

To cock the lancing device, hold the body of lancing device in one hand and pull the sliding barrel with the other hand. The device is loaded when you feel a click and the load confirmation window turns red.




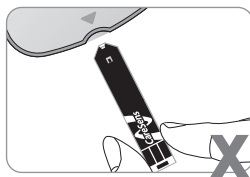
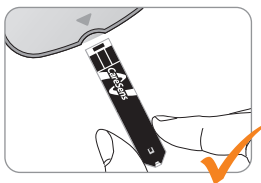
### Note

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




## Preparing the Meter and Test Strip

### Step 7






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



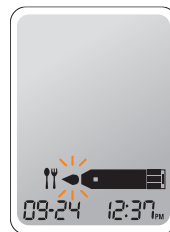
## Flagging Post-meal Test Results

The CareSens N meter allows you to flag a result of a post-meal test with  symbol. The post-meal test flag () can be attached just before applying the blood sample. Once you attach the post-meal flag () to the test results, it cannot be deleted.

### Step 8

If you want to attach a post-meal flag () to a test result, press and hold  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 ()

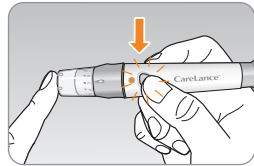
If you do not want to save the result as a post-meal test, move on to step 9 after step 7.




## Applying Blood Sample

### Step 9

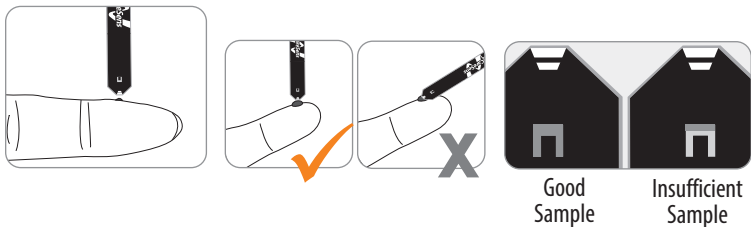
Obtain a blood sample using the lancing device. Place the device against the pad of the finger as shown in the diagram. Press the release button. Remove the device from the finger. Wait a few seconds for a blood drop to form. A minimum volume of 0.5 microliter is needed to fill the confirmation window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





### Step 10

After the  symbol appears on the screen, apply the blood sample to the narrow end of the test strip till the meter beeps. If the confirmation window is not filled in time because of abnormal viscosity (thickness and stickiness) or insufficient volume, the Er4 message may appear.

It is recommended that the application of blood sample to the test strip be performed virtually vertical to the sample site as shown in the diagram below.



### Note

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

### Step 11

After the blood sample has been applied, the display segments will rotate clockwise on the meter display.

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.

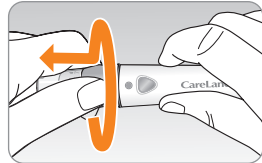
If the test strip is removed after the test result has been displayed, the meter will automatically switch off after 3 seconds. Discard used test strips safely in appropriate containers.



## Discarding Used Lancets

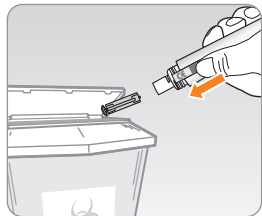
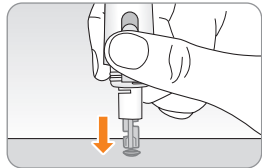
### Step 1

Unscrew lanceting device tip.



### Step 2

Place protective cover on lancet. Push the lancet ejector forward with the thumb to dispose of the used lancet in a proper biohazard container.



### Caution

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

## Alternate Site Testing

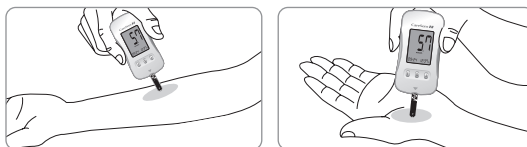
**Before using AST, please consult your healthcare professional.**

### What is AST (Alternate Site Testing)?

Usually, when someone tests their glucose, they take the blood sample from the tip of the finger. However, since there are many nerve endings in the fingertip, it can be quite painful. When doing a glucose test, using different parts of the body such as the forearms and palms can reduce the pain during testing. This method of testing with different parts of the body is called Alternate Site Testing.

While AST may reduce the pain during testing, it may not be simple for everyone and the following precautions should be observed during testing.

#### Alternate Sites for Testing



### Alternate Site Blood Sampling (forearm, palm)

Select a clean, soft and fleshy sample site area free of visible veins and hair and away from bones. Wash the area with soap and water and dry thoroughly. Gently massage the sample site with clean hands to help blood circulation to minimise result differences between fingertip and alternate site sampling. Firmly press and hold the lancing device against site. Wait until the skin surface under the lancing device changes color. Then press the release button while continuing to apply pressure. Keep holding the lancing device against your skin until sufficient (at least 0.5  $\mu\text{L}$ , actual size: ●) blood is drawn. Carefully lift the lancing device away from your skin.

## Things to Know When Using AST

Please read the following before testing at alternate sites (forearms and palms).

The capillary whole blood of the fingertips reflects changes in glucose levels more rapidly than in alternate sites. The test results from the fingertip testing and AST may differ due to factors such as lifestyle and ingested food which affect glucose levels.

### Note

#### Acceptable Situations for AST

When your blood glucose levels are stable

- Fasting period
- Before a meal
- Before sleeping

#### Situations Requiring Fingertip Test

When your blood glucose levels are unstable

- During 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 recognised
- When insulin has the biggest effect
- 2 hours after an insulin injection



## AST Precautions

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

### Note

Results from alternate 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 for testing if you suffer from hypoglycemia or have experienced hypoglycemic shock or symptoms.

### Note

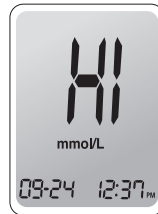
If the sample drop of blood runs or spreads due to contact with hair or with a line in your palm, do not use that sample. Try puncturing again in a smoother area.

## HI and Lo Messages

### HI Message

The meter displays results between 1.1–33.3 mmol/L. "HI" appears when the blood glucose level is greater than 33.3 mmol/L and indicates severe hyperglycemia (much higher than normal glucose levels).

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



### Lo Message

"Lo" appears when a test result is less than 1.1 mmol/L and indicates severe hypoglycemia (very low glucose levels).

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



## 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 :** Normal blood glucose levels for an adult without diabetes are: below 5.5 mmol/L before meals and fasting\*, and less than 7.8 mmol/L two hours after meals.

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

### Reference

American Diabetes Association (Standards of Medical Care in Diabetes - 2021. *Diabetes Care*, January 2021, vol 44 (Supplement 1): S15-S33.

## Transferring Test Results

Test results stored in CareSens N meter can be transferred from the meter to a computer using PC care/SmartLog software and cable. 'Pc' is displayed on the meter screen when the data cable connects the meter with a computer. For more information, contact your authorised i-SENS sales representative.



# Meter Memory

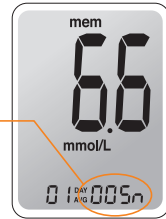
The CareSens N Meter can save up to 1,000 glucose test results with time and date. If the memory is full, the oldest test result will be deleted and the latest test result will be stored. The CareSens N Meter calculates and displays the averages of total test results, pre-meal test results, and post-meal test (  $\uparrow$  ) results from the last 1, 7, 14, 30 and 90 days.

## Viewing Averages Stored in the Meter's Memory

### Step 1

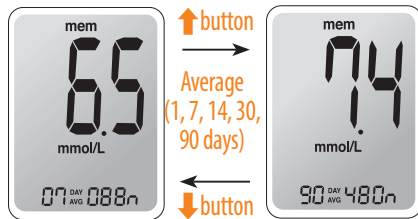
Press the  $\uparrow$  or **S** button to turn the meter on. The current date and time will be displayed on the bottom of the screen followed by the 1 day average value and the number of the test results saved within the current day.

The number of tests within the current day



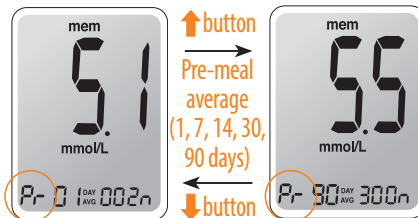
### Step 2

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



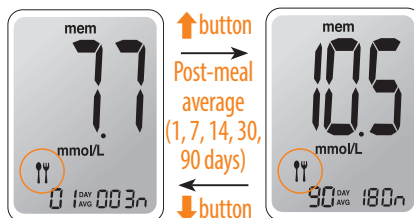
### Step 3

Repeatedly press the **↑** to view 1, 7, 14, 30 and 90-day average values and the number of tests performed pre-meals with the 'Pr' symbol for the last test period.



### Step 4

Press the **↑** to view 1, 7, 14, 30 and 90-day average values and the number of tests performed with the post meal flag (🍴) for the last test period.



### Step 5

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

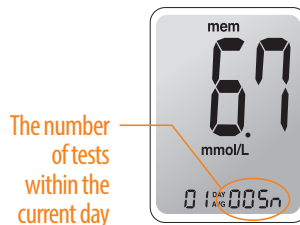
### Note

The control solution test results saved with 'check' are not included in the averages.

## Viewing Test Results Stored in the Meter's Memory

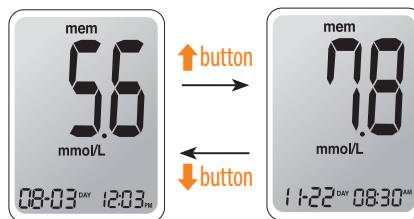
### Step 1

Press the **↑** or **S** button to turn the meter on. The current date and time will be displayed on the bottom of the screen followed by the 1 day average value and the number of the test results saved within the current day.



### Step 2

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



### Note

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

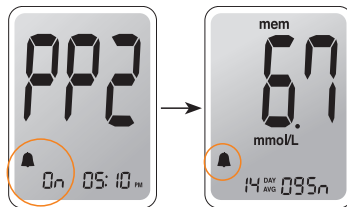
## Setting the Alarm Function

Four types of alarms can be set in the CareSens N Meter: one post-meal alarm (PP2 alarm) and three time set alarms (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 the **S** button or by inserting a test strip.

### Setting the Post-meal Alarm (PP2 Alarm)

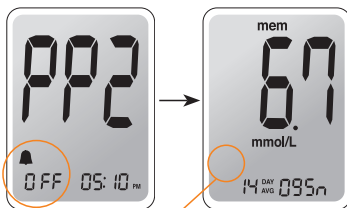
#### Step 1 Setting the PP2 Alarm On

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



#### Step 2 Setting the PP2 Alarm OFF

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



🔔 symbol disappears



## 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. The 'alarm 1' will be displayed while the 'OFF' blinks on the screen.



### Step 2

On pressing **↓**, the 'alarm1' is set and the 'On' is displayed on the screen. Press **↓** again to cancel the 'alarm 1' and the 'OFF' will blink on the screen.



### Step 3

Press **↑** to adjust the time of the 'alarm 1'. 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.

## Understanding Error Messages

	<p>A used test strip was inserted. &gt; Repeat the test with a new test strip.</p>
	<p>The blood or control solution sample was applied before the  symbol appeared. &gt; Repeat the test with a new test strip and wait until the  symbol appears before applying the blood or control solution sample.</p>
	<p>The temperature during the test was above or below the operating range. &gt; Move to an area where the temperature is within the operating range (5–50°C) and repeat the test after the meter and test strips have reached a temperature within the operating range.</p>
	<p>The blood sample has abnormally high viscosity or insufficient volume. &gt; Repeat the test after inserting a new test strip.</p>



This error message may appear when the wrong blood glucose test strip is used instead of CareSens N blood glucose test strip.  
> *Repeat test after inserting a CareSens N test strip.*



There is a problem with the meter.  
> *Do not use the meter. Contact your authorised i-SENS sales representative.*



An electronic error occurred during the test.  
> *Repeat the test with a new test strip. If the error message persists, contact your authorised i-SENS sales representative.*

#### **Note**

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

## General Troubleshooting

Problem	Troubleshooting
The display is blank even after inserting a test strip.	<ul style="list-style-type: none"><li>• 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.</li><li>• Check if the appropriate test strip was used.</li><li>• Check whether the batteries are inserted with the '+' side facing up.</li><li>• Replace the batteries.</li></ul>
The test does not start even after applying the blood sample on the strip.	<ul style="list-style-type: none"><li>• Check if the confirmation window is filled completely.</li><li>• Repeat the test after inserting a new test strip.</li></ul>
The test result doesn't match the way you feel.	<ul style="list-style-type: none"><li>• Repeat the test after inserting a new test strip.</li><li>• Check the expiration date of the test strip.</li><li>• Perform control solution test.</li></ul>

### Note

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

## Performance Characteristics

### System Accuracy and Measurement Precision

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

**Accuracy:** The accuracy of the CareSens N Blood Glucose Monitoring System (Model GM505PAD, GM505PBD, GM505PCD) was assessed by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyzer, a laboratory instrument. The following results were obtained by diabetic patients at clinic centers.

Slope	0.946
Y-intercept	0.37 mmol/L
Correlation coefficient (r)	0.994
Number of samples	600
Range tested	1.6–27.1 mmol/L

Accuracy results for glucose concentration < 5.55 mmol/L

Within $\pm 0.28$ mmol/L	Within $\pm 0.56$ mmol/L	Within $\pm 0.83$ mmol/L
100/186 (53.8 %)	169/186 (90.9 %)	180/186 (96.8 %)

Accuracy results for glucose concentration  $\geq 5.55$  mmol/L

Within $\pm 5$ %	Within $\pm 10$ %	Within $\pm 15$ %
266/414 (64.3 %)	395/414 (95.4 %)	409/414 (98.8 %)

System accuracy results for glucose concentrations between 1.6 mmol/L and 27.1 mmol/L

Within $\pm 0.83$ mmol/L and Within $\pm 15$ %
589/600 (98.2 %)

**Precision:** The precision studies were performed in a laboratory using CareSens N Blood Glucose Monitoring Systems.

<i>Within Run Precision</i>		
Blood average	2.1 mmol/L	SD = 0.1 mmol/L
	3.2 mmol/L	SD = 0.1 mmol/L
	6.7 mmol/L	CV = 3.6 %
	9.7 mmol/L	CV = 2.8 %
	16.8 mmol/L	CV = 3.2 %

<i>Between Run Precision</i>		
Control average	2.2 mmol/L	SD = 0.1 mmol/L
	6.7 mmol/L	CV = 3.5 %
	17.7 mmol/L	CV = 2.6 %

This study shows that there could be variation of up to 3.6 %.

## **Influence Quantities**

### **Packed Cell Volume (Hematocrit)**

Packed cell volume evaluation was conducted in various hematocrit levels. The range of hematocrit levels within the acceptance criteria is 15–65 %.

## Interferences

The effect of various interfering substances was evaluated in whole blood samples. The presence of the following substances within the given concentrations does not affect blood glucose measurements. Higher concentrations of the substances shown below may cause inaccurate blood glucose results.

No.	Interferent	Concentration
1	Acetaminophen (paracetamol)	20 mg/dL
2	Ascorbic acid	3 mg/dL
3	Bilirubin	20 mg/dL
4	Ceftriazone	81 mg/dL
5	Cholesterol	500 mg/dL
6	Creatinine	3 mg/dL
7	Dopamine	13 mg/dL
8	EDTA	180 mg/dL
9	Galactose	60 mg/dL
10	Gentisic acid	50 mg/dL
11	Glutathione (Red)	17 mg/dL
12	Hemoglobin	500 mg/dL
13	Heparin	8000 U/dL
14	Hydrocortisone	1 mg/dL
15	Ibuprofen	40 mg/dL
16	Icodextrin	2 mg/dL



No.	Interferent	Concentration
17	L-Dopa (L-3,4-dihydroxyphenylalanine)	5 mg/dL
18	Maltose	1000 mg/dL
19	Mannitol	600 mg/dL
20	Methyl-DOPA	1.5 mg/dL
21	Pralidoxime Iodide (PAM)	25 mg/dL
22	Salicylate	60 mg/dL
23	Tolbutamide	100 mg/dL
24	Tolazamide	100 mg/dL
25	Triglycerides	3000 mg/dL
26	Uric acid	20 mg/dL
27	Xylose	25 mg/dL

### User Performance Evaluation

A study evaluating glucose values from fingertip capillary blood samples obtained by 100 lay persons showed the following results:

100 % within  $\pm 0.83$  mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L and 99.1 % within  $\pm 15$  % of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L.

## 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 authorised Warranty Station.

### For Australian Consumers

Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and compensation for any other reasonable foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fails to be of acceptable quality and the failure does not amount to a major failure.

#### NZ Distributor:

Pharmaco (NZ) Ltd  
Auckland  
Phone: 0800 GLUCOSE (0800 458267)  
Website:  
[www.pharmacodiabetes.co.nz](http://www.pharmacodiabetes.co.nz)

#### Australian Distributor:

Pharmaco (Australia) Ltd  
Gordon, NSW 2072  
Phone: 1800 114 610  
Website:  
[www.pharmacodiabetes.com.au](http://www.pharmacodiabetes.com.au)