

## User Manual

### INDEX

01 Important Information: Read This First!	2
02 Specifications	3
03 CareSens N Eco Blood Glucose Monitoring System	4
04 Inserting or Replacing the Battery	5
05 Caring for Your System	6
06 CareSens N Blood Glucose Test Strip	6
07 CareSens N Eco Blood Glucose Meter	8
08 CareSens N Eco Blood Glucose Meter Display	9
09 Setting Up Your System	10
10 Setting the Strip Expiration Date Indicator	14
11 Checking the System	15
12 Using the Lancing Device	18
13 Alternate Site Testing	23
14 HI and Lo Messages	25
15 Target Blood Glucose Ranges	26
16 Transferring Test Results	26
17 Meter Memory	27
18 Setting the Alarm Function	29
19 Understanding Error Messages	31
20 General Troubleshooting	33
21 Performance Characteristics	33
22 Warranty Information	36

PGUAA-0000047 REV1 2019/02

### 01 Important Information: Read This First!

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

#### Intended use:

CareSens N Eco Blood Glucose Monitoring System is used for the quantitative measurement of the glucose level in capillary whole blood as an aid in monitoring diabetes management effectively at home or in clinical settings. CareSens N Eco Blood Glucose Monitoring System should be used only for self-testing outside the body (*in vitro* diagnostic use only). CareSens N Eco Blood Glucose Monitoring System should not be used for the diagnosis of diabetes or for testing newborns. Testing sites include the traditional fingertip testing along with alternate site testing on forearm and palm.

#### Meaning of Symbols Used:

	For <i>in vitro</i> diagnostic use		Authorised representative
	This product fulfills the requirements for Directive 98/79/EC on <i>in vitro</i> diagnostic medical devices		Do not discard this product with other household-type waste
	Cautions for safety and optimum product use		Do not reuse
	Use by (unopened or opened test strip vial)		Batch code
	Temperature limitation		Consult instructions for use
			Manufacturer
			Serial number

- Glucose in blood samples reacts with the chemical in the test strip to produce a small electrical current. The CareSens N Eco meter detects this electrical current and measures the amount of glucose in the blood sample.
- The CareSens N Eco Blood Glucose Meter is designed to minimise code related errors in monitoring by using the no-coding function.

- The CareSens N Eco Blood Glucose Meter should be used only with the CareSens N Test Strips.
- An abnormally high or low red blood cell count (hematocrit level over 65% or below 15%) may produce inaccurate results.
- If your test result is below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), consult a healthcare professional immediately.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
- Inaccurate results may occur in patients undergoing oxygen therapy.

If you need assistance, please contact your authorised i-SENS sales representative or visit [www.i-sens.com](http://www.i-sens.com) for more information.

### 02 Specifications

#### Product specifications

Measurement range	20–600 mg/dL (1.1–33.3 mmol/L)
Sample size	Minimum 0.5 µL
Test time	5 seconds
Sample type	Fresh capillary whole blood
Calibration	Plasma-equivalent
Assay method	Electrochemical
Battery life	1,000 tests
Power	One 3.0 V lithium battery (disposable, type CR2032)
Memory	1,000 test results
Size	95 x 49 x 18(mm)
Weight	49 g (with battery)

#### Operating ranges

Temperature	5–45 °C (41–113 °F)
Relative humidity	10–90 %
Hematocrit	15–65 %

#### Storage Conditions

Glucose meter (with battery)	0–50 °C (32–122 °F)
Test strip	1–30 °C (34–86 °F)

### 03 CareSens N Eco Blood Glucose Monitoring System

#### CareSens N Eco BGM System includes the following items:

- \* CareSens N Eco Blood Glucose Meter
- \* Battery

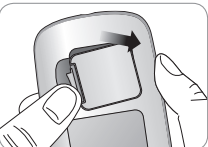
#### Optional items:

- \* CareSens N Blood Glucose Test Strips
- \* User Manual
- \* Lancets
- \* Lancing Device
- \* Quick Reference Guide
- \* Logbook
- \* Carrying Case

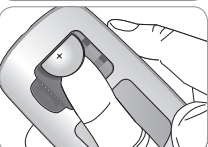
- Check all the components after opening the CareSens N Eco Blood Glucose Monitoring System package. The exact contents are listed on the main box.
- The cable for data management software can be ordered separately. Please contact your authorised i-SENS sales representative.

### 04 Inserting or Replacing the Battery

The CareSens N Eco Meter uses one 3.0 V lithium battery. Before using the meter, check the battery compartment and insert a battery if empty. When the symbol appears on the display while the meter is in use, the battery should be replaced as soon as possible. The test results may 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**  
Remove the used battery and your index finger under the battery to lift and pull out as shown. Insert a new battery 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 battery will not affect your stored results. However, you may need to reset your meter settings. See page 10.

### 05 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:

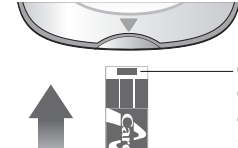
- Do not expose the meter to direct sunlight, heat, or excessive humidity for an extended period of time.
- Do not let dirt, dust, blood, or water enter into the meter's test strip port.
- Do not drop the meter or submit it to strong shocks.
- Do not try to fix or alter the meter in any way.
- Strong 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.
- Keep the meter in a cool and well ventilated place.
- 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 or visit [www.i-sens.com](http://www.i-sens.com).

### 06 CareSens N Blood Glucose Test Strip

The CareSens N Eco 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.



#### Contact bars

Gently push the test strip, with its contact bars facing up, into the test strip port of meter

#### Confirmation window

Check here to see whether sufficient blood sample has been applied

#### Edge to apply blood sample

Apply blood sample here for testing

#### Warning!

- The CareSens N Test Strips should be used only with fresh capillary whole blood samples.
- Do not reuse test strips.
- Do not use test strips past the expiration date.
- Test strips in new, unopened vials and test strips in vials that have been opened can be used up until the expiration date printed on the test strip box and vial label if the test strips are used and stored according to its storage and handling methods.
- Store test strips in a cool and dry place at a temperature between 1–30 °C.
- Keep test strips away from direct sunlight or heat and do not freeze.
- Store test strips only in their original vial.
- Close the vial tightly after taking out a test strip for testing and use the strip immediately.
- Handle test strips only with clean and dry hands.
- Do not bend, cut, or alter test strips in any way.
- For detailed storage and usage information, refer to the CareSens N Test Strip package insert.

#### Caution:

- Keep the meter and testing supplies away from young children.
- Drying agents in the vial cap may be harmful if inhaled or swallowed and may cause skin or eye irritation.

### 07 CareSens N Eco Blood Glucose Meter

#### Data Port

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

#### Display

Shows results and messages

#### S Button

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

#### <> Button

Turns the meter on, selects or changes information

#### Test Strip Ejector

Slide down to discard the used strips

#### 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 and it cannot be changed by the user.

### 08 CareSens N Eco Blood Glucose Meter Display

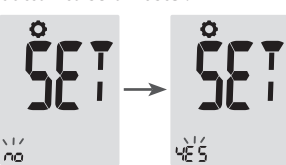
- Test results** : test results displaying panel
- Memory recall mode** : appears when test results stored in the memory are displayed
- Setting symbol** : appears when in SET mode
- PP2 alarm** : appears when the post-meal alarm has been set
- Mute symbol** : appears only when the sound is set to OFF
- Control Solution flag** : appears when the control solution test results are saved or displayed
- Hi** : appears when the test result is greater than the selected hyperglycemia level
- Smile symbol** : appears when the test result is within the selected normal blood glucose range
- Lo** : appears when the test result is lower than the selected hypoglycemia level
- alarm** : appears when the time alarm has been set
- mmol/L, mg/dL** : unit for measuring blood glucose
- Pre-meal test flag** : used for tests done before eating
- Post-meal test flag** : used for tests done after eating
- Fasting test flag** : used for tests done after fasting for at least 8 hours
- Battery symbol** : indicates meter battery is running low and needs to be replaced
- Blood insertion symbol** : indicates meter is ready for the application of a drop of blood or control solution
- Month/Day/Hour/Minute**

**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.

### 09 Setting Up Your System

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

Press the **< or >** button to change values. Press and hold the **< or >** button to scroll faster.



#### 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, 'SET' will be displayed on the screen. Press the **S** button again to go 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 go to the next step.



#### Step 3 Setting the Month

A number indicating the month will blink on the left corner of the screen. Press **< or >** until the correct month appears. Press the **S** button to confirm your selection and go 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 go 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 is not displayed in the 24-hour format. After selecting the format, press the **S** button to go 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 go 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 go to the next step.



#### Step 8 Setting the Sound On/OFF

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** or **<** 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 press 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.

After setting the sound, press the **S** button to go to the next step.

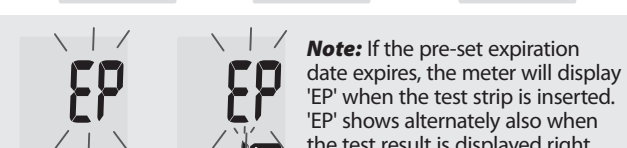
#### Note:

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

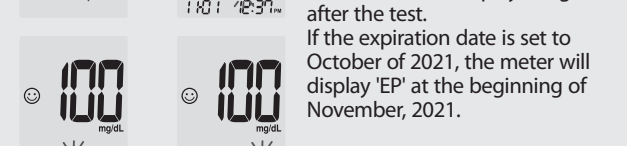
#### Step 9 Turning on the Strip Expiration Date Indicator

This setting allows you to turn the strip expiration date indicator on or off. This setting turns the function on or off only. See page 14 to set the strip expiration date.

When 'EP' appears on the screen, press the **< or >** button. The screen will display 'On' or 'OFF'. Press the **S** button to confirm the setting. If you do not want to set the indicator, press the **S** button while the screen displays 'OFF'.



**Note:** If the pre-set expiration date expires, the meter will display 'EP' when the test strip is inserted. 'EP' shows alternately also when the test result is displayed right after the test. If the expiration date is set to October of 2021, the meter will display 'EP' at the beginning of November, 2021.



#### Step 10 Setting the Hypoglycemia (Lo) Indicator

This setting allows you to select the desired level for the hypoglycemia indicator (possible low blood sugar). You will be alerted any time your test result is lower than the selected level. Press the **< or >** button until the desired hypoglycemia level between 20 and 90 mg/dL (1.1 and 5.0 mmol/L) appears. Then, press the **S** button to confirm the level and to go to the next step.



**Note:** If the test result is lower than the pre-set hypoglycemia level, the meter will display 'Lo'.

#### Caution:

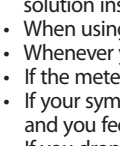
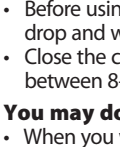
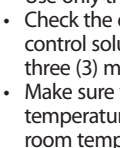
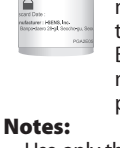
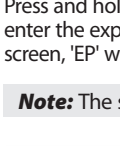
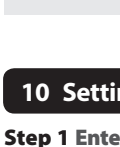
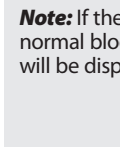
Ask your healthcare professional to help you decide what your hypoglycemia level is before setting your level.



#### Step 11 Setting the Hyperglycemia (Hi) Indicator

This setting allows you to select the desired level for the hyperglycemia indicator (possible high blood sugar). You will be alerted any time your test result is higher than the selected level. Press the **< or >** button until the desired hyperglycemia level between 120 and 349 mg/dL (6.7 and 19.4 mmol/L) appears. Press and hold the **S** button to confirm the hyperglycemia level and turn the meter off.

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

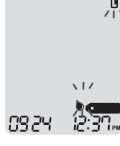


#### Control Solution Testing



#### 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 will be displayed on the screen.



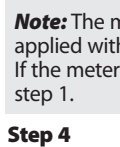
#### Step 2

You can flag the control solution test result by pressing the **>** button for 3 seconds. To undo the control solution flag, press the **>** button for 3 seconds again.



#### Step 3

Shake the bottle well before each test. Remove the cap and squeeze the bottle to discard the first drop. Then wipe the tip with a clean tissue or cloth. After the 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.

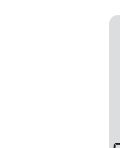


#### Note:

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

#### Step 4

The display segments will rotate clockwise and a test result will appear after the meter counts down from 5 to 1. When flagged, the result is stored in the meter's memory but it is not included in the averages.



#### Step 5

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



#### Caution:

The range printed on the test strip vial is for the CareSens Glucose Control Solution only. It has nothing to do with your glucose level.

**Note:** The CareSens Glucose Control Solution can be purchased 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 this range. Out of range results may occur in following situations:

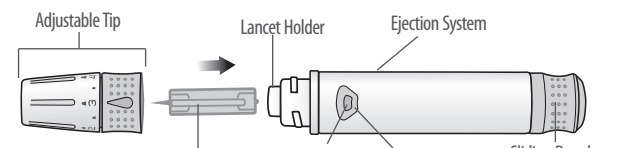
Situations	Do This
• When the control solution bottle was not shaken well,	Repeat the control solution test by referring to the 'Notes' on page 15.
• When the meter, test strip, or the control solution were exposed to high or low temperatures,	
• When the first drop of the control solution was not discarded or the tip of the bottle was not wiped clean,	
• When the control solution is contaminated.	

• When the meter is not functioning properly.	
• When the control solution is past the expiration date printed on the bottle,	Discard the used control solution and repeat the test using a new bottle of control solution.
• When the control solution is past its discard date (the date the bottle was opened plus three (3) months),	
• When the control solution is contaminated.	

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

### 12 Using the Lancing Device

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



- The lancing device is for use by a single user only and should not be shared with anyone.
- Use a soft cloth or tissue to wipe the lancing device. If necessary, a small amount of alcohol on a soft cloth or tissue may be used.



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

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

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

#### Preparing the Lancing Device

**Step 1**  
Wash hands and sample site with soap and warm water. Rinse and dry thoroughly.

**Step 2**  
Unscrew and remove the lancing device tip.

**Step 3**  
Firmly insert a new lancet into the lancet holder. Hold the lancet firmly. Gently twist to pull off protective disk. Save disk to recap lancet after use. Replace lancing device tip.

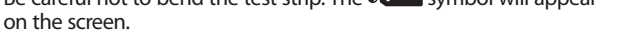
**Step 4**  
Turn the adjustable tip until it is aligned with the load confirmation window and release button as shown in the diagram.

**Step 5**  
The lancing device has six puncture depth settings (0 for a shallow puncture, 5 for a deeper puncture). Choose a depth by rotating the top portion of the adjustable tip until the desired number aligns with the arrow.

**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

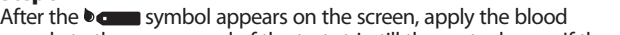
**Step 7**  
Insert a test strip with the contact bars facing upwards into the meter's test strip port. Push the strip in gently until the meter beeps. Be careful not to bend the test strip. The  symbol will appear on the screen.

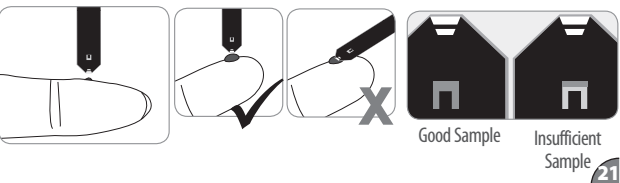
**Caution:** Do not allow any foreign substances, such as dirt, blood, or water, enter into the meter. The meter may be damaged or may malfunction. Follow the warning information provided below to prevent possible damage to the meter.


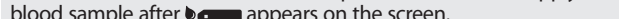
- Do not apply the blood sample directly to the test strip port.
- Do not apply the blood sample to the test strip while holding the meter in a way that the tip of the test strip faces upwards. The blood sample may run down the surface of the test strip and flow into the test strip port.
- Do not store your meter in unsanitary or contaminated sites.

#### Applying Blood Sample

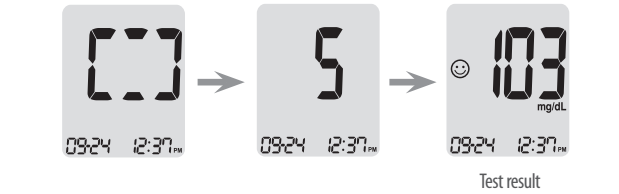
**Step 8**  
Obtain a blood sample using the lancing device. Place the device against the pad of the finger as shown in the diagram. Press the release button. Remove the device from the finger. Wait a few seconds for a blood drop to form. A minimum volume of 0.5 microliter is needed to fill the confirmation window. (Actual size of 0.5 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 in time due to 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.

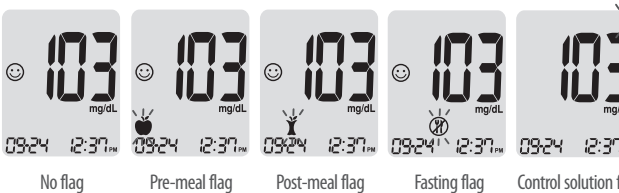


**Note:** The meter may switch off if the blood sample is not applied within 2 minutes of the  appearing on the screen. If the meter turns off, remove the strip and reinsert it and apply blood sample after  appears on the screen.

**Step 10**  
Apply the blood sample to the narrow end of the test strip until you hear a 'beep'. At this time, the display segments will rotate clockwise while the blood is going in. 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**  
You can attach a flag to a result to indicate particular situations while the strip is still in the meter. When the result is displayed right after a test, press the  or  button to select a pre-meal flag () , a post-meal flag () , a fasting flag () , or a control solution flag (). When you remove the test strip while the desired flag is blinking, the test result is stored with the flag. If you do not want to add any flags on the test result, remove the strip after the test result is displayed.



#### Discarding Used Lancets

**Step 1**  
Unscrew the lancing device tip.

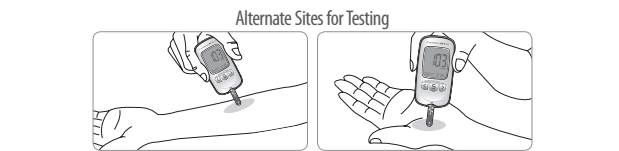
**Step 2**  
Stick the lancet into the saved protective disk. Push the lancet ejector forward with the thumb to dispose of the used lancet in a proper biohazard container.


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

#### 13 Alternate Site Testing

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

**Acceptable Situations for AST**  
When your blood glucose levels are stable

- Fasting period
- Before a meal
- Before going to bed

**Situations Requiring Fingertip Test**  
When your blood glucose levels are unstable

- During two (2) hours after a meal or exercise
- When sick or when glucose levels seem quite lower than test value
- When hypoglycemia is not well recognised
- When insulin has the biggest effect
- During two (2) hours after an insulin injection

#### AST Precautions

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

**Note:**

- Results from alternate sites and fingertip samples may differ from each other as there is a time lag for the glucose levels to reach the same value. Use a fingertip for testing if you suffer from hypoglycemia or have experienced hypoglycemic shock or symptoms.
- If the sample drop of blood runs or spreads due to contact with hair or with a line in your palm, do not use that sample. Try puncturing again in a smoother area.

#### 14 HI and Lo Messages

**HI Message**  
The meter displays results between 20-600 mg/dL (1.1-33.3 mmol/L). 'HI' appears when the blood glucose level is greater than 600 mg/dL (33.3 mmol/L) and indicates severe hyperglycemia (much higher than normal glucose levels). If 'HI' is displayed again upon retesting, please contact your healthcare professional immediately.

**Lo Message**  
'Lo' appears when a test result is less than 20 mg/dL (1.1 mmol/L) and indicates severe hypoglycemia (very low glucose levels). If 'Lo' is displayed again upon retesting, please contact your healthcare professional immediately.

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

#### 15 Target Blood Glucose Ranges

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

**Expected Values :** Normal blood glucose levels for an adult without diabetes are below 100 mg/dL (5.5 mmol/L) before meals and fasting\* and are less than 140 mg/dL (7.8 mmol/L) two hours after meals.

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




#### Reference

American Diabetes Association (Standards of Medical Care in Diabetes - 2018. *Diabetes Care*, January 2018, vol. 41, Supplement 1, S13-S27)


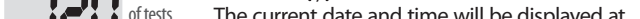

#### 16 Transferring Test Results




**PC**  
Test results stored on CareSens N Eco meter can be transferred from the meter to a computer using SmartLog software and cable. The meter screen displays 'PC' when it is connected to the computer using the data cable. For more information, contact your authorised i-SENS sales representative or visit [www.i-sens.com](http://www.i-sens.com).





#### 17 Meter Memory

The CareSens N Eco 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 meter calculates and displays the averages of total test results, Pre-meal () test results, Post-meal test () , and Fasting test results () from the last 1, 7, 14, 30 and 90 days.





#### Viewing Averages Stored in Memory

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





**Step 2 Viewing Averages**  
Press the ,  or  button to view 7, 14, 30 and 90-day average values and the number of tests performed for the last test period.



**Step 3 Viewing Pre-meal Averages**  
Press the ,  or  button to view 1, 7, 14, 30 and 90-day average values and the number of tests performed premeals with the  symbol for the last test period.


#### Step 4 Viewing Post-meal Averages

Press the ,  or  button to view 1, 7, 14, 30 and 90-day average values and the number of tests performed post-meals with the  symbol for the last test period.




#### Step 5 Viewing Fasting Averages




Press the ,  or  button to view 1, 7, 14, 30 and 90-day average values and the number of tests performed during fasting with the  symbol for the last test period.

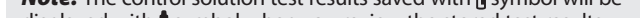
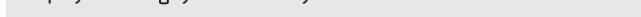
**Step 6**  
Use the  button to scroll back through the averages seen previously. Press the  button to turn off the meter.

**Note:** The control solution test results saved with the  symbol are not included in the averages.




#### Viewing Test Results Stored in Memory

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



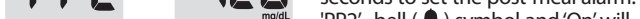
**Step 2**  
Use the  button to scroll through the test results, starting from the most recent and ending with the oldest. Press the  button to return to the result seen previously. After checking the stored test results, hold the  button to turn off the meter.

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




#### 18 Setting the Alarm Function

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




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



**Step 1 Turning the PP2 alarm On**  
Without inserting a test strip, press and hold the  button for 3 seconds to set the post-meal alarm. 'PP2', bell () symbol and 'On' will be displayed. The screen will then automatically change to the memory recall mode. At this time, bell () symbol, indicating that the PP2 alarm has been set, will be displayed on the screen.

**Note:** The PP2 alarm will automatically turn off if the meter's time setting is adjusted to more than two hours before or just past the currently activated PP2 alarm time.

**Step 2 Turning the PP2 alarm OFF**  
To turn off the PP2 alarm, press and hold the  button for 3 seconds. 'PP2', bell () symbol and 'OFF' will appear on the screen. Then the screen will change automatically to the memory recall mode without bell () symbol displayed.


#### Setting the Time Alarms (alarm 1-3)


**Step 1**  
Without inserting a test strip, press the ,  and  buttons simultaneously for 3 seconds to enter the time alarm setting. 'alarm 1' will be displayed while 'OFF' blinks on the screen.

**Step 2**  
On pressing the  button, 'alarm 1' is set and 'On' is displayed on the screen. Press the  button again to cancel 'alarm 1'. 'OFF' will blink on the screen.

**Step 3**  
Press the  button to adjust the time of 'alarm 1'. A number representing the hour will blink on the screen. Press the  button to set the hour.



**Step 4**  
On pressing the  button, the number indicating the minute will start blinking. Press the  button to set the minute.

**Step 5**  
Press the  button to finish and to go to 'alarm 2' setting. Repeat steps 2 to 4 to set the remaining time alarms (alarm 2-3).

**Step 6**  
Press and hold the  button for 3 seconds to finish and turn the meter off.

#### 19 Understanding Error Messages

**Er 1**  
A used test strip was inserted.  
→ Repeat the test with a new test strip.

**Er 2**  
The blood or control solution sample was applied before the  appeared.  
→ Repeat the test with a new test strip and wait until the  appears before applying the blood or control solution sample.

**Er 3**  
The temperature during the test was above or below the operating range.  
→ Move to an area where the temperature is within the operating range (5-45 °C/41-113 °F) and repeat the test after the meter and test strips have reached a temperature within the operating range.

**Er 4**  
The blood sample has abnormally high viscosity or insufficient volume.  
→ Repeat the test with a new test strip.

**Er 5**  
This error message may appear when the wrong blood glucose test strip is used instead of CareSens N Blood Glucose Test Strip.  
→ Repeat the test with a CareSens N test strip.

**Er 6**  
There is a problem with the meter.  
→ Do not use the meter.  
Contact your authorised i-SENS sales representative.

**Er 8**  
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.

#### 20 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 battery is inserted with the + side facing up.</li><li>• Replace the battery.</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 with a new test strip.</li></ul>
The test result does not match the way you feel.	<ul style="list-style-type: none"><li>• Repeat the test with 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.

#### 21 Performance Characteristics

The performance of CareSens N Eco Blood Glucose Monitoring System has been evaluated in laboratory and in clinical tests.  
**Accuracy:** The accuracy of the CareSens N Eco BGM System (Model: GM01WAA) 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	1.0057
Y-intercept	4.2352 mg/dL (0.24 mmol/L)
Correlation coefficient (r)	0.9957
Number of samples	600
Range tested	36.4-471.1 mg/dL (2.0-26.1 mmol/L)

Accuracy results for glucose concentration < 100 mg/dL (5.55 mmol/L)		
Within ± 5 mg/dL (Within ± 0.28 mmol/L)	Within ± 10 mg/dL (Within ± 0.56 mmol/L)	Within ± 15 mg/dL (Within ± 0.83 mmol/L)
96/168 (57.1 %)	150/168 (89.3 %)	162/168 (96.4 %)

Accuracy results for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)		
Within ± 5 %	Within ± 10 %	Within ± 15 %
293/432 (67.8 %)	402/432 (93.1 %)	432/432 (100 %)

System accuracy results for glucose concentrations between 36.4 mg/dL (2.0 mmol/L) and 471.1 mg/dL (26.1 mmol/L)

Within ± 15mg/dL (0.83 mmol/L) and Within ± 15 %
594/600 (99.0 %)

**Precision:** The precision studies were performed in a laboratory using CareSens N Eco BGM Systems.

Within Run Precision		
Blood avg.	40 mg/dL (2.2 mmol/L)	SD = 1.3 mg/dL (0.1 mmol/L)
Blood avg.	73 mg/dL (4.1 mmol/L)	SD = 2.5 mg/dL (0.1 mmol/L)
Blood avg.	126 mg/dL (7.0 mmol/L)	CV = 2.5 %
Blood avg.	212 mg/dL (11.8 mmol/L)	CV = 2.4 %
Blood avg.	320 mg/dL (17.8 mmol/L)	CV = 2.3 %

Between Run Precision		
Control avg.	38 mg/dL (2.1 mmol/L)	SD = 1.4 mg/dL (0.1 mmol/L)
Control avg.	131 mg/dL (7.3 mmol/L)	CV = 2.7 %
Control avg.	349 mg/dL (19.4 mmol/L)	CV = 3.0 %

This study shows that there could be variation of up to 3.0%

#### Packed Cell Volume (Hematocrit)

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

Range	Average difference (Hct 15-65 %)
30 to 50 mg/dL (1.7 to 2.8 mmol/L)	2.6 to 6.4 mg/dL (0.1 to 0.4 mmol/L)
96 to 144 mg/dL (5.3 to 8.0 mmol/L)	0.2 to 4.3 %
280 to 420 mg/dL (15.5 to 23.3 mmol/L)	-0.3 to 3.4 %

#### Interferences

The effect of various interfering substances was evaluated in whole blood samples on glucose measurements.

NO	Interferent	Difference Averages	
		Interval 1 50-100 mg/dL (2.8-5.5 mmol/L)	Interval 2 250-350 mg/dL (13.9-19.4 mmol/L)
1	Acetaminophen	-1.6 mg/dL (-0.1 mmol/L)	-2.0 %
2	Ascorbic acid	-1.2 mg/dL (-0.1 mmol/L)	-1.4 %
3	Bilirubin (unconjugated)	1.4 mg/dL (0.1 mmol/L)	-0.8 %
4	Cholesterol	-1.1 mg/dL (-0.1 mmol/L)	-1.3 %
5	Creatinine	2.7 mg/dL (0.1 mmol/L)	0.9 %
6	Dopamine	4.7 mg/dL (0.3 mmol/L)	0.6 %
7	EDTA	-5.6 mg/dL (-0.3 mmol/L)	-2.8 %
8	Galactose	7.5 mg/dL (0.4 mmol/L)	-0.5 %
9	Genitric acid	-1.8 mg/dL (-0.1 mmol/L)	-5.6 %
10	Glutathione(Red)	3.8 mg/dL (0.2 mmol/L)	-0.2 %
11	Hemoglobin	-1.0 mg/dL (-0.1 mmol/L)	-4.8 %
12	Heparin	1.2 mg/dL (-0.1 mmol/L)	2.9 %
13	Ibuprofen	0.7 mg/dL (0.04 mmol/L)	-1.4 %
14	Icodextrin	2.2 mg/dL (0.1 mmol/L)	-6.2 %
15	L-Dopa	0.8 mg/dL (0.04 mmol/L)	0.2 %
16	Maltose	-4.2 mg/dL (-0.2 mmol/L)	-1.3 %
17	Methyldopa	7.9 mg/dL (0.4 mmol/L)	0.9 %
18	Pralidoxime iodide	-1.7 mg/dL (-0.1 mmol/L)	0.3 %
19	Salicylate	1.8 mg/dL (0.1 mmol/L)	0.2 %
20	Tolazamide	1.3 mg/dL (0.1 mmol/L)	-0.6 %

21	Tolbutamide	-5.5 mg/dL (-0.3 mmol/L)	-5.5 %
22	Triglycerides	-3.0 mg/dL (-0.2 mmol/L)	-0.5 %
23	Uric acid	3.8 mg/dL (0.2 mmol/L)	-2.6 %
24	Xylose	4.1 mg/dL (0.2 mmol/L)	1.7 %