## User Manual

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### 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 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 Eco 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.

Do not discard this product with other household to

Consult instructions for use

waste

② Do not reuse

Manufacturer

LOT Batch code

with other household-type

Meaning of Symbols Used: IVD For in vitro diagnostic use EC REP Authorised representative

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

Cautions for safety and optimum product use

🛮 🖵 Use by (unopened or opened test strip vial)

Temperature limitation

**SN** Serial number • Glucose in blood samples reacts with the chemical in the test strip to produce a small electrical current. The CareSens N Fco 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

If you need assistance, please contact your authorised i-SENS sales entative or visit <u>www.i-sens.com</u> 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 %

#### ago/transport conditions

Storage/transport conditions			
Temperature	Glucose meter (with battery)	0–50 °C (32–122 °F	
	Test strip	1-30 °C (34-86 °F)	
	Control solution	8-30 °C (46-86 °F)	
Relative humidity	Test strip	10–90 %	

### 03 CareSens N Eco Blood Glucose Monitoring System

CareSens N Eco Blood Glucose Monitoring System includes the following items

- \* CareSens N Eco Blood Glucose Meter \* Battery
- CareSens N Eco Blood Glucose Monitoring System may include the following 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

#### 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.



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



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



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

2

Removing the meter battery will not affect your stored results. ever, 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

### Caution:

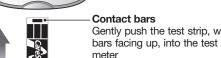
- Do not expose the meter to direct sunlight, heat, or excessive humidity for an extended period of time
- Do not let dirt, dust, blood, or water enter into the meter's test strip port.
- Do not drop the meter or submit it to strong shocks.
- Do not try to fix or alter the meter in any way. · Avoid getting 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. 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 représentative or visit 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.



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

 Confirmation window Check here to see whether sufficient blood sample has been applied

Edge to apply blood sample Apply blood sample here for testing

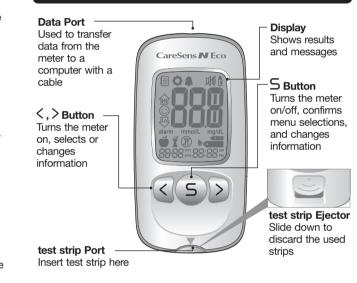
#### Warning

- The CareSens N test strips should be used only with fresh capillary whole
- 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
- 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.
- 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. 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



### 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

### 08 CareSens N Eco Blood Glucose Meter Display



1 Memory symbol: appears when test results stored in the memory are displayed **3 2 Setting symbol:** appears when in SET mode

3 PP2 alarm: appears when the post-meal alarm has been set (4) Mute symbol: appears only when the sound is set to OFF

(5) Control Solution flag: appears when the control solution test results are saved or displayed 6 Test results: test results displaying panel

(7) Hi: appears when the test result is greater than the selected hyperglycemia level

- (8) Smile symbol: appears when the test result is within the selected normal blood glucose range (9) Lo: appears when the test result is lower than the selected
- hypoglycemia level (10) alarm: appears when the time alarm has been set
- ) mmol/L, mg/dL: unit for measuring blood glucose
- Battery symbol: indicates meter battery is running low and needs to be replaced
- (13) Pre-meal test flag: used for tests done before eating Post-meal test flag: used for tests done after eating
- (15) Fasting test flag: used for tests done after fasting for at least 8 hours (16) Blood insertion symbol: indicates meter is ready for the application of a drop of blood or control solution
- (17) Month/Day/Hour/Minute: appears date and time

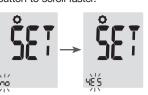
### Note Note

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.

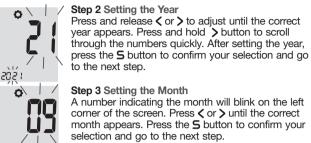
## 09 Setting Up Your System

Press and hold the **5** button for 3 seconds to enter SET mode. After all settings are finished, press and hold the 5 button for 3 seconds to turn off the meter

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



Step 1 Entering the SET Mode Press and hold the 5 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 **5** button again to go to the next step.

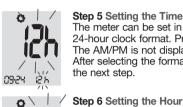


09:01 IS:00 ...

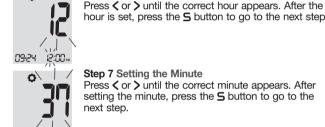
0954 15:00~

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.



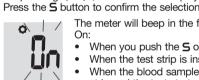
Step 5 Setting the Time Format The meter can be set in the AM/PM 12-hour or the 24-hour clock format. Press  $\langle$  or  $\rangle$  to select a format. The AM/PM is not displayed in the 24-hour format. After selecting the format, press the S button to go to the next step.



Step 7 Setting the Minute Press < or > until the correct minute appears. After setting the minute, press the 5 button to go to the next step.

hour is set, press the **5** button to go to the next step.

Step 8 Setting the Sound On/OFF On pressing < or >, the screen will display 'On' or 'OFF'.



68 EP

- The meter will beep in the following instances if set to When you push the S or < to turn on the meter,</li>
- 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.

88 EP

 The □ symbol is displayed only when the sound is set to OFF. • At any stage, press the **5** button for 3 seconds to exit SET mode and turn off the meter. Press and hold > to quickly scroll through the

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 **5** button to confirm the setting. If you do not want to set

the indicator, press the **5** button while the screen displays 'OFF'.





\ | / 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 2023, the meter will display 'EP' at the beginning of November, 2023.

Ø\ /

山门



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

### O 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.

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

## Note

If the test result is within the selected normal blood glucose range, the smile symbol will be displayed on the screen as shown.



09-24 12:30~

### 10 Setting the Strip Expiration Date Indicator

Step 1 Entering the Expiration Date Setting Press and hold the < and > buttons at the same time for 3 seconds to enter the expiration date settings. After all segments flash across the screen, 'EP' will show up.

### O Note

The strip expiration date is printed on the test strip vial.



Step 2 Setting the Year A number indicating the year will blink in the left corner of the screen. Press the < or > button until the correct year appears. Press the 5 button to confirm the year and set the

2023 10

Step 3 Setting the Month A number indicating the month will blink at the bottom of the screen. Press the  $\langle$  or  $\rangle$  button until the correct month appears. After setting, press and hold the **5** button for 3 seconds to turn off the meter.

## 11 Checking the System



You may check your meter and test strips using the CareSens Control Solutions(control A and/or B) The CareSens Control Solution contains a known amount of glucose and is used to check that the meter and the est strips are working properly. The test strip vials have CareSens Control Solution ranges

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 16–17. O Note

se only the CareSens Control Solutions

 Check the expiration date printed on the bottle. When you first open a control solution bottle, record the discard date (date opened plus three (3) months) in the space provided on the label.

 Make sure your meter, test strips, and control solution are at room temperature before testing. Control solution tests must be done at room temperature (20-25°C, 68-77°F).

• Before using the control solution, shake the bottle, discard the first drop and wipe the tip clean. Close the control solution bottle tightly and store at a temperature

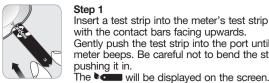
#### between 8-30 °C (46-86 °F). You may do a control solution test:

When you want to practice the test procedure using the control solution instead of blood,

results and you feel that the meter or test strips are not working

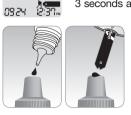
- · When using the meter for the first time, Whenever you open a new vial of test strips. If the meter or test strips do not function properly. If your symptoms are inconsistent with the blood glucose test
- If you drop or damage the meter.

#### Control Solution Testing



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

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.



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

#### O 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.

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.



09-24 12:30... 09-24 12:30... 09-24 12:30...

Compare the result displayed on the meter to the range printed on Control A: XX-XX mg/dL (X.X-X.X mmol/L) the test strip vial. The result Control B: XX-XX mg/dL (X.X-XX mmol/L) should fall within the range.

Control Solution Range

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.

### separately. Please contact your authorised i-SENS sales

The CareSens Glucose Control Solution can be purchased

**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 Repeat the control

When the meter, test strip, or the control referring to the **Note** solution were exposed to high or low on page 15. temperatures When the first drop of the control

When the meter is not functioning

the bottle was not wiped clean,

solution was not discarded or the tip of

properly When the control solution is past the expiration date printed on the bottle, • When the control solution is past its discard date (the date the bottle was opened plus three (3) months),

When the control solution is

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

Discard the used

solution.

control solution and

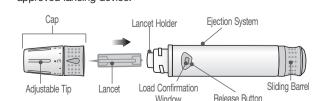
new bottle of control

repeat the test using a

## 2 Using the Lancing Device

authorised i-SENS sales representative.

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.



- 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.

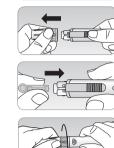
### O Note

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**



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



 $\mathsf{MMMMM}$ 

appear on the screen

damage to the meter.

into the test strip port.

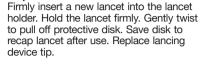
**Applying Blood Sample** 

message may appear.

the diagram below.

Note

Unscrew and remove the lancing device



deeper puncture).

The skin depth to get blood samples will vary for various people at

best depth of skin penetration to get an adequate sample size.

Insert a test strip with the contact bars facing upwards into the

beeps. Be careful not to bend the test strip. The symbol will

meter's test strip port. Push the strip in gently until the meter

Do not allow any foreign substances, such as dirt, blood, or water,

• Do not apply the blood sample directly to the test strip port.

• Do not store your meter in unsanitary or contaminated sites.

• 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

(actual size of 0.5 µL: ●).

After the symbol appears on the screen, apply the blood

sample to the narrow end of the test strip till the meter beeps. If

viscosity (thickness and stickiness) or insufficient volume, the Er4

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 confirmation window is not filled in time due to abnormal

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 microlite

is needed to fill the confirmation window

enter into the meter. The meter may be damaged or may malfunction.

Follow the warning information provided below to prevent possible

Preparing the Meter and test strip

different sample sites. The lancing device's adjustable tip allows the

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

The lancing device has six puncture depth

settings (0 for a shallow puncture, 5 for a

Choose a depth by rotating the top

portion of the adjustable tip until the

desired number aligns with the arrow.

To cock the lancing device, hold the body

of lancing device in one hand and pull the

sliding barrel with the other hand. The

the load confirmation window turns red.

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

Note

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.



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 postmeal flag( $\Upsilon$ ), a fasting flag( $\Re$ ), or a control solution flag( $\P$ ). When you remove the test strip while the desired flag is blinking, the test result is stored with the flag.

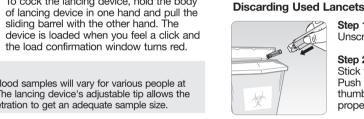
If you do not want to add any flags on the test result, remove the strip after the test result is displayed.

The meter displays results between 20-600 mg/dL (1.1-33.3 mmol/L). 'HI' appears when the blood normal alucose levels).

## 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). f 'Lo' is displayed again upon retesting, please contact your healthcare professional immediately. 89-24 I2:37<sub>m</sub>

## Pre-meal flag Post-meal flag Fasting flag Control solution flag



Unscrew the lancing device tip.

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.

The lancet is for single use only. Never share or reuse a lancet. Always

### 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.

### Note

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
- The amount of glucose in alternate sites differs from person to person.

#### O 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

### 14 HI and Lo Messages

glucose level is greater than 600 mg/dL (33.3 mmol/L) and indicates severe hyperglycemia (much higher than

### 19324 (2:37... If 'HI' is displayed again upon retesting, please contact your healthcare professional immediately.

## O Note

Please contact your authorised i-SENS sales representative if such nessages are displayed even though you do not have hyperglycemia

### 15 Target Blood Glucose Ranges

_	-
Reminders Time of day	Your target ranges from your healthcare professional
Before breakfast	
Before lunch or dinner	
1 hour after meals	
2 hours after meals	

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.

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

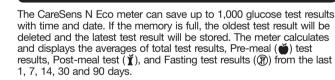
### 16 Transferring Test Results

Between 2 a.m. and 4 a.m.



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

### 17 Meter Memory

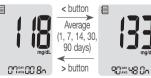


### Viewing Averages Stored in Memory



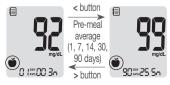
The number  $\frac{1}{2}$  Press the  $\frac{1}{2}$ ,  $\frac{1}{2}$  or  $\frac{1}{2}$  button to turn the meter on. The current date and time will be displayed within the at the bottom of the screen followed by the 1 day average value and the number of the test results saved within the current day.

### **Step 2** Viewing Averages

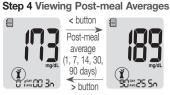


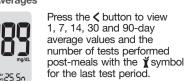
Press the **<** button to view 7, 14, 30 and 90-day average values and the number of tests performed for the last test period.

### Step 3 Viewing Pre-meal Averages

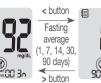


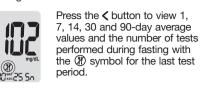
Repeatedly press the < button to view 1, 7, 14, 30 and 90-day average values and the number of tests performed premeals with the 🍏 symbol for the last test period. 21





#### Step 5 Viewing Fasting Averages





### Use the > button to scroll back through the averages seen previously. Press the **5** button to turn off the meter.

The control solution test results saved with the 🛊 symbol are not

#### **Viewing Test Results Stored in Memory**



within the

Press the <, > or 5 button to turn the meter The number on. The current date and time will be displayed on the bottom of the screen followed by the 1 day average value and the current day number of the test results saved within the current day.

< button T +22°\*\* 08:30\*\* 08-03<sup>m</sup> 12:03<sup>m</sup>

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 **5** button to turn off the meter

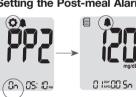
### O Note

The control solution test results saved with  $\hat{\mathfrak{g}}$  symbol will be displayed with  $\hat{\mathfrak{g}}$  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 5 button or by inserting a test strip.

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

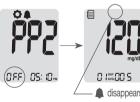


Step 1 Turning the PP2 alarm On Without inserting a test strip, press and hold the < button for 3 seconds to set the post-meal

'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)



**S** buttons simultaneously for 3 seconds to enter the time alarm setting. 'alarm 1' will be displayed while 'OFF' blinks on the screen



is displayed on the screen. Press the > button again to cancel 'alarm 1'. 'OFF' will blink on the screen.

On pressing the button, 'alarm 1' is set and 'On'

### Step 3

Step 2



Press the **<** button to adjust the time of 'alarm 1'.

On pressing the \( \) button, the number indicating the minute will start blinking. Press the > button to set the minute.



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

### Press and hold the **5** button for 3 seconds to finish and turn the

### 19 Understanding Error Messages

the operating range.

insufficient volume

N Blood Glucose test strip

> Do not use the meter.

There is a problem with the meter.

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

strip port.

completely.

The test result does • Repeat the test with a new test strip.

not match the way • Check the expiration date of the test strip.

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

The performance of CareSens N Eco Blood Glucose Monitoring

Accuracy: The accuracy of the CareSens N Eco Blood Glucose

a YSI Model 2300 Glucose Analyzer, a laboratory instrument. The

Monitoring System (Model: GM01WAA) was assessed by comparing

blood glucose results obtained by patients with those obtained using

following results were obtained by diabetic patients at clinic centers.

System has been evaluated in laboratory and in clinical tests.

21 Performance Characteristics

**System Accuracy and Measurement Precision** 

Perform control solution test.

the + side facing up.

Replace the battery

20 General Troubleshooting

**Problem** 

even after inserting a

The test does not

applying the blood

sample on the strip.

start even after

O Note

test strip.



A used test strip was inserted. > Repeat the test with a new test strip.



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

The temperature during the test was above or below

Move to an area where the temperature is within the

test after the meter and test strips have reached a

The blood sample has abnormally high viscosity or

This error message may appear when the wrong

> Repeat the test with a CareSens N test strip.

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

**Troubleshooting** 

the contact bars facing up. Check if the strip

Check whether the test strip is inserted with

has been inserted completely into the test

• Check if the appropriate test strip was used.

Check whether the battery is inserted with

Check if the confirmation window is filled

Repeat the test with a new test strip.

blood glucose test strip is used instead of CareSens

Contact your authorised i-SENS sales representative.

temperature within the operating range.

> Repeat the test with a new test strip

operating range (5-45 °C/41-113 °F) and repeat the

#### Influence Quantities

average

average

Y-intercept

Range tested

Correlation coefficient (r)

Number of samples

Within ±5 mg/dL

96/168 (57.1 %)

293/432 (67.8 %)

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 %.

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

4.2352 mg/dL (0.24 mmol/L)

Accuracy results for glucose concentration < 100 mg/dL (5.55 mmol/L)

Within ±10 mg/dL

(Within  $\pm 0.28$  mmol/L) (Within  $\pm 0.83$  mmol/L) (Within  $\pm 0.83$  mmol/L)

150/168 (89.3 %)

Within ±10 %

402/432 (93.1 %)

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

**Precision:** The precision studies were performed in a laboratory using

40 mg/dL (2.2 mmol/L) SD = 1.3 mg/dL (0.1 mmol/L)

73 mg/dL (4.1 mmol/L) SD = 2.5 mg/dL (0.1 mmol/L)

38 mg/dL (2.1 mmol/L) SD = 1.4 mg/dL (0.1 mmol/L)

System accuracy results for glucose concentrations between

36.4 mg/dL (2.0 mmol/L) and 471.1 mg/dL (26.1 mmol/L)

CareSens N Eco Blood Glucose Monitoring Systems.

126 mg/dL (7.0 mmol/L)

212 mg/dL (11.8 mmol/L)

320 mg/dL (17.8 mmol/L)

131 mg/dL (7.3 mmol/L)

349 mg/dL (19.4 mmol/L)

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

Accuracy results for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)

36.4-471.1 mg/dL (2.0-26.1 mmol/L)

162/168 (96.4 %)

432/432 (100 %)

CV = 2.5 %

CV = 2.4 %

CV = 2.3 %

CV = 2.7 %

CV = 3.0 %

NO	Interferent	Concentration
1	Acetaminophen (paracetamol)	20 mg/dL
2	Ascorbic acid	3 mg/dL
3	Bilirubin (Unconjugated)	40 mg/dL
4	Cholesterol	500 mg/dL
5	Creatinine	30 mg/dL
6	Dopamine	13 mg/dL
7	EDTA	200 mg/dL
8	Galactose	60 mg/dL
9	Gentisic acid	100 mg/dL
10	Glutathione (Red)	92 mg/dL
11	Hemoglobin	500 mg/dL
12	Heparin	8000 U/dL
13	Ibuprofen	50 mg/dL
14	Icodextrin	1094 mg/dL
15	L-Dopa (L-3,4-dihydroxyphenylalanine)	5 mg/dL
16	Maltose	2500 mg/dL
17	Methyl-DOPA	1.5 mg/dL
18	Pralidoxime Iodide (PAM)	25 mg/dL
19	Salicylate	60 mg/dL
20	Tolbutamide	100 mg/dL

#### Concentration Interferent 100 mg/dL 3300 mg/dL Triglycerides 25 mg/dL Uric acid 300 mg/dL **Xylose**

### **User Performance Evaluation**

A study evaluating glucose values from fingertip capillary blood samples obtained by 100 lay persons showed the following results: 95.8 % within ±15 mg/dL (±0.83 mmol/L) of the medical laboratory values at glucose concentrations below 100 mg/dL (5.55 mmol/L), and 100 % within ±15 % of the medical laboratory values at glucose concentrations at or above 100 mg/dL (5.55 mmol/L).

## 22 Warranty Information

### Manufacturer's Warranty

i-SENS. Inc. warrants that the CareSens N Eco 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 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 sales or customer service representative. EC REP

## www.i-sens.com

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Without inserting a test strip, press the < and



A number representing the hour will blink on the screen. Press the > button to set the hour.

# 30