⚠ WARNING:

Turn off the Bluetooth feature in areas where the use of wireless devices is restricted, such as hospitals, some healthcare professional offices, and aeroplanes.

Trademarks

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by i-SENS, Inc. is under license. All other trademarks and trade names are those of their respective owners.

Note

The SmartLog™ mobile app may not be compatible with all smartphones.

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Important Information: Read This First!

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

Intended use:
CareSens Dual Blood Glucose/Blood β-Ketone Monitoring System is used for the quantitative measurement of the glucose/β-ketone level in capillary whole blood as an aid in monitoring diabetes management effectively at home or in clinical settings. Fresh venous whole blood drawn by healthcare professionals can be used only for testing blood glucose. CareSens Dual Blood Glucose/Blood β-Ketone Monitoring System should be used only for self-testing outside the body (*in vitro* diagnostic use only). CareSens Dual Blood Glucose/Blood β-Ketone Monitoring System should not be used for the diagnosis of diabetes or for the diagnosis of diabetic ketoacidosis. Blood glucose testing sites include the traditional fingertip testing along with alternate sites testing on forearm and palm.

Meaning of Symbols Used:

IVD For *in vitro* diagnostic use

CE 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)

Do not discard this product with other household-type waste

Use-by date

Do not reuse

Consult instructions for use

Temperature limitation

LOT Batch code

Manufacturer

SN Serial number

EMC & Safety RCM Mark

- Glucose/β-Ketone in blood samples reacts with the chemical in the test strip to produce a small electrical current. The CareSens Dual meter detects this electrical current and measures the amount of glucose/β-ketone in the blood sample.
- The CareSens Dual Blood Glucose/Blood β-Ketone Meter is designed to minimise code related errors in monitoring by using the no-coding function.
- The CareSens Dual Blood Glucose/Blood β-Ketone Meter should only be used with CareSens PRO blood glucose and KetoSens β-ketone test strips.
- An abnormally high or low red blood cell count (hematocrit level over 65 % or below 15 % for blood glucose and hematocrit level over 60 % or below 20 % for blood β-ketone) may produce inaccurate results.
- If your blood glucose test result is below 3.3 mmol/L or above 13.3 mmol/L, consult a healthcare professional immediately.
- Inaccurate blood glucose results may occur in severely hypotensive individuals or patients in shock. Inaccurate low blood glucose results may occur for individuals experiencing a hyperglycemic- hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose/blood β-ketone meters.
- Do not use during or within 24 hours of receiving xylose absorption testing as it may cause inaccurate results.

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

Specifications & Operating Ranges

Calibration	Plasma-equivalent
Assay method	Electrochemical
Battery life	1,000 tests
Power	Two 3.0 V lithium batteries (disposable, type CR2032)
Memory	1,000 test results
Size	106 x 58 x 17 mm
Weight	72.6 g (with batteries)
Bluetooth® technology	• Frequency range: 2.4–2.4835 GHz • Operating range distance: maximum 10 metres (unobstructed) • Operating channels: 40 channels • Security encryption: 128-bit AES (Advanced Encryption Standard)
Relative humidity	10–90 %

For blood glucose testing

Measurement range	1.1–33.3 mmol/L
Sample size	Minimum 0.4 µL
Test time	5 seconds
Sample type	• Fresh capillary whole blood • Fresh venous whole blood (healthcare professionals only)
Temperature	5–45 °C
Hematocrit	15–65 %

For blood *β*-ketone testing

Measurement range	0.1–8.0 mmol/L
Sample size	Minimum 0.5 µL
Test time	8 seconds
Sample type	Fresh capillary whole blood
Temperature	10–40 °C
Hematocrit	20–60 %

Storage/Transport Conditions

Temperature	Meter (with batteries)	0–50 °C
	Test strip	• Glucose: 1–30 °C • *β*-Ketone: 4–30 °C
	Control solution	8–30 °C
Relative humidity	Test strip	10–90 %

CareSens Dual System includes the following items:

* CareSens Dual Blood Glucose/Blood β-Ketone Meter
* User Manual
* Batteries
* CareSens PRO Blood Glucose Test Strips
* Quick Reference Guide
* Lancets
* Lancing Device
* Logbook
* Carrying Case
* Registration card

- Check all the components after opening the CareSens Dual Blood Glucose/Blood β-Ketone 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

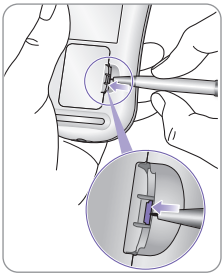
WARNING

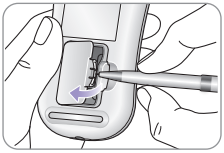
- Chemical burn hazard.
- Keep batteries away from children.
- This product contains lithium button/coin cell batteries. If a new or used lithium button/coin cell battery is swallowed or enters the body, it can cause severe internal burns and can lead to death in as little as 2 hours. Always completely 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 Dual meter uses two CR2032 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.

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.



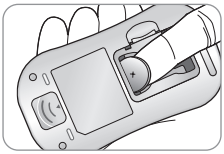


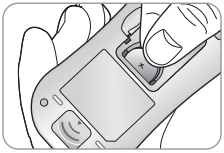
Note

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

Step 2

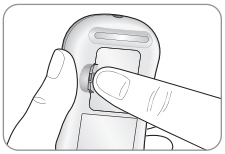
Remove the used batteries one at a time. Slip your index finger under the battery to lift and pull out as shown. Insert two new batteries with the + side facing up and make sure the batteries are inserted firmly.





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 page 21.

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 or acetone, or household and industrial cleaners that may cause irreparable damage to the meter.

Caution:

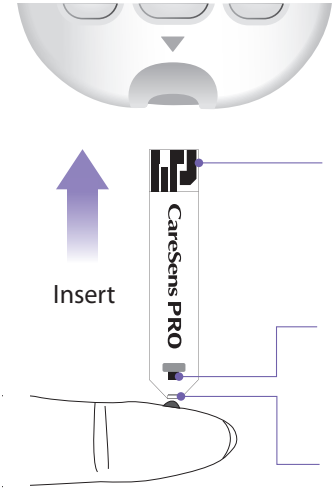
- Do not expose the meter to direct sunlight, heat, or excessive humidity for an extended period of time.
- Do not let dirt, dust, blood, or water enter into the meter's test strip port.
- Do not drop the meter or submit it to strong shock.
- Do not try to fix or alter the meter in any way.
- Strong 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/β-ketone.
- Store all the meter components in the carrying 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*.

CareSens PRO Blood Glucose Test Strip

The CareSens Dual 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

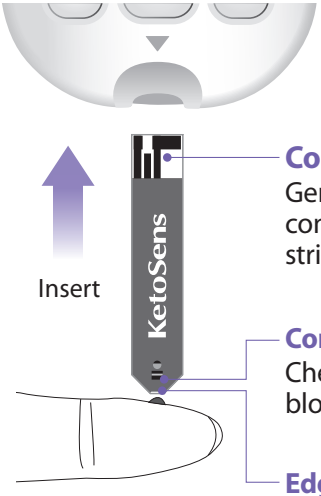
⚠ Caution

- The CareSens PRO Test Strips should be used with fresh capillary whole blood samples, or with fresh venous whole blood if drawn by healthcare professionals.
- Fresh venous whole blood specimens containing the anticoagulants EDTA and Heparin are acceptable. Iodoacetate or fluoride/oxalate are not recommended.

- Do not reuse test strips.
- Do not use test strips past the expiration or discard 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 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.
- 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 PRO test strip package insert.
- 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.

KetoSens Blood β-Ketone Test Strip

The CareSens Dual Blood β-Ketone Monitoring System measures blood β-ketone 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

⚠ Caution

- The KetoSens Blood β-Ketone Test Strips should only be used with fresh capillary whole blood samples.
- Do not reuse test strips.
- Do not use test strips past the expiration or discard date.
- Test strips can be used up until the expiration date printed on the foil packet 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 4–30 °C.
- Keep test strips away from direct sunlight or heat and do not freeze.
- Store test strips only in their original box.
- Open the foil test strip packet to take out a test strip for testing and use the test strip immediately. Do not use the test strip if the foil is damaged or torn.
- 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 KetoSens test strip package insert.
- Keep the meter and testing supplies away from young children.
- The test strips and foil packet may be choking hazards.

CareSens Dual Meter

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

Display
Shows results, messages

◀, ▶ Button
Turns the meter on, selects or changes information

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

Test Strip Port
Insert test strip here

Test Strip Ejector
Slide down to discard the used strips

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 to mmol/L and it cannot be changed by the user.

CareSens Dual Meter Display

① **Test results**
② **Memory recall mode :** appears when test results stored in the memory are displayed
③ **PP2 alarm :** appears when the post-meal alarm has been set
④ **Bluetooth symbol :** appears when Bluetooth® feature is on
⑤ **Mute symbol :** appears only when the sound is set to OFF
⑥ **Control Solution flag :** indicates that the meter is in Control Solution Test Mode and appears when the control solution test results are saved or displayed
⑦ **Decimal point**
⑧ **Blood insertion symbol :** indicates meter is ready for the application of a drop of blood or control solution
⑨ **mmol/L, mg/dL:** unit for blood glucose or blood β-ketone
⑩ **alarm:** appears when the time alarm has been set
⑪ **KETONE :** appears when KetoSens strip is inserted
⑫ **Battery symbol :** indicates meter battery is running low and needs to be replaced
⑬ **Pre-meal test flag :** used for tests done before eating
⑭ **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 **Month/Day/Hour/Minute**

Note

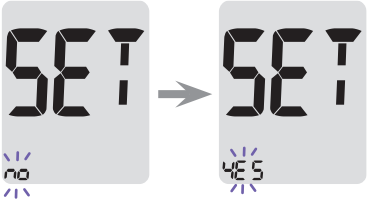
It is recommended to check if the display screen on the meter matches the illustration above every time the meter turns on. Do not use the meter if the display screen does not exactly match the illustration as the meter may show incorrect results.

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 the ◀ or ▶ button to change values. Press and hold the ◀ or ▶ button to scroll faster.

Step 1 Entering 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 show up.
Press the ◀ or ▶ button to select 'YES' and press the **S** button to go to the next step.



Note

Follow steps 2–3 to pair your meter and smartphone. Pairing allows the meter to communicate wirelessly with your smartphone. Ensure that devices are within the maximum Bluetooth range (10 metres). Before pairing your meter and smartphone, download and install the SmartLog™ mobile app on your smartphone.

Setting Up Bluetooth

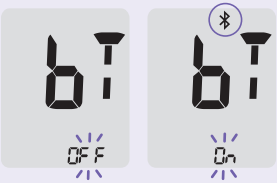
Step 2 Bluetooth Pairing

① If you do not want to connect your meter to your smartphone, press the **S** button when the screen shows on the right. The meter will go to Step 4 Year Setting Mode.

② Press the ◀ or ▶ button. The meter screen shows 'OFF', 'On', and 'PAIr' in turn. To pair your meter with your smartphone, press the **S** button when 'PAIr' blinks on the screen.

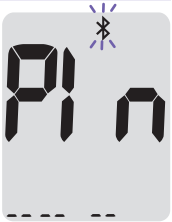
Note

The ✱ symbol will appear on the screen when the Bluetooth feature is on. When the ✱ symbol is not present on the screen, the Bluetooth feature is off. When you need to turn off/on the Bluetooth feature, press the **S** button when OFF/On blinks on the screen.



Step 3 Entering the PIN number

① The ✱ symbol and 'PIn' will appear if you press the **S** button when the meter screen shows 'PAIr'.

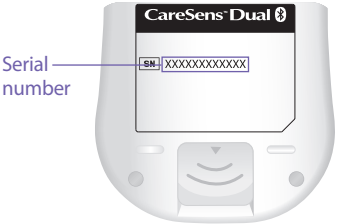


② Launch SmartLog™ mobile app to start pairing the meter with your smartphone. Find the 'Accessories' menu and select the appropriate meter model on SmartLog™ mobile app.

Note

Follow the on-screen instructions on SmartLog™ mobile app to begin searching your meter. Some content or menus may differ depending on your smartphone's operating system or SmartLog™ version.

③ Look for 'CareSens' and the last 4 characters of the meter serial number on the SmartLog mobile app screen to correctly identify your meter.
Touch your meter's ID (CareSens XXXX) on the SmartLog™ mobile app screen.



④ The meter will display six digit PIN number.

⑤ Enter the PIN number into the SmartLog™ mobile app and touch 'OK'. Make sure the PIN you enter on your smartphone matches the PIN on your meter screen.

⑥ When your meter and smartphone are paired and connected, the meter will display 'SUCCESS' and the saved test results will be transferred to your smartphone.

⑦ When the data transfer is finished, the meter will display 'End' on the screen. Press the **S** button to go to Step 10 Sound Setting mode. See page 27. If the meter displays 'FAIL' and then 'OFF', repeat steps 2 to 5.

Note

Some smartphones, especially those that are not tested or approved by i-SENS, may be incompatible with your meter. Visit *www.i-sens.com/smartlog* for more information about supported smartphones. You can also scan the QR code on the back cover of this user manual.

Adjusting the Date and Time

Step 4 Setting the Year

Press the ◀ or ▶ button to adjust until the correct year appears. When the present year appears, press the **S** button to confirm your selection and to go to the next step.

Step 5 Setting the Month

A number indicating the month will blink on the screen.
Press the ◀ or ▶ button until the correct month appears. Press the **S** button to confirm your selection and to go to the next step.

Step 6 Setting the Date

Press the ◀ or ▶ button until the screen displays the correct date. Press the **S** button to confirm the date and to go to the next step.

Step 7 Setting the Time Format

The meter can be set in the AM/PM 12-hour or the 24-hour clock format.
Press the ◀ or ▶ button 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 go to the next step.

Step 8 Setting the Hour

Press the ◀ or ▶ button until the correct hour appears.
After the hour is set, press the **S** button to go to the next step.

Step 9 Setting the Minute

Press the ◀ or ▶ button until the correct minute appears. After setting the minute, press the **S** button to go to the next step.

Setting the Sound On/OFF

Step 10

On pressing the ◀ or ▶ button, 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 a 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 press and hold the ◀ button to set the post-meal (PP2) alarm
- When it is time for a pre-set 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.

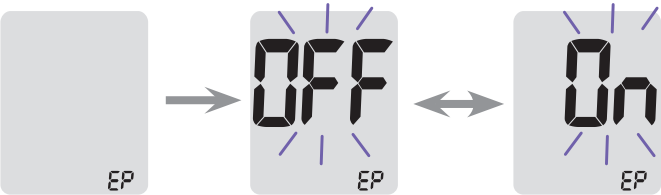
Note

The 🔇 symbol is displayed only when the sound is set to OFF.

Turning on the Strip Expiration Date Indicator

Step 11

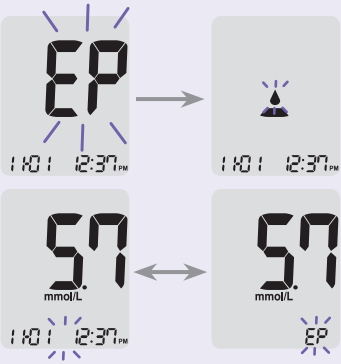
This mode allows you to turn the strip expiration date indicator on or off. This mode turns the function on or off only.
See page 31 to set the strip expiration date.
When 'EP' appears on the screen, press the ◀ or ▶ button. The screen will display 'On' or 'OFF'. Press the **S** button to confirm the 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.

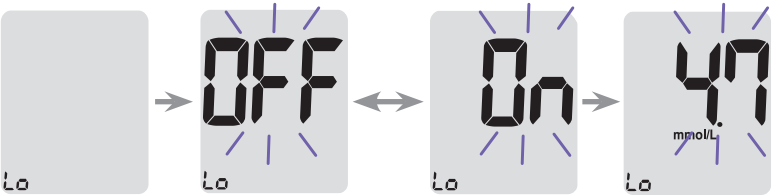
If the expiration date is set to October of 2023, the meter will display EP at the start of November, 2023.



Setting the Hypoglycemia (Lo) Indicator

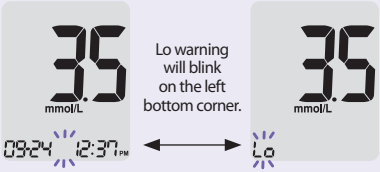
Step 12

This mode allows you to turn the hypoglycemia indicator (possible low blood sugar) On or OFF and to select the desired level for the indicator. You will be alerted any time your test result is lower than the selected level. On pressing the ◀ or ▶ button, the screen will display 'On' or 'OFF'. Press the **S** button when 'On' appears to enter the setting. Press the ◀ or ▶ button until the desired hypoglycemia level between 1.1 and 5.0 mmol/L appears. Press the **S** button to confirm the hypoglycemia 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 the following.



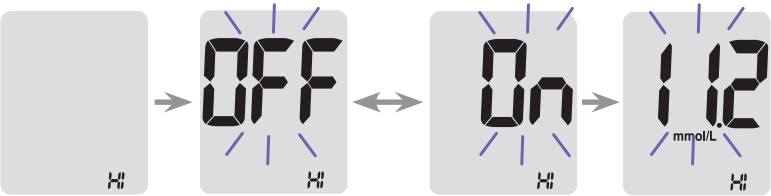
Caution

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

Setting the Hyperglycemia (HI) Indicator

Step 13

This mode allows you to turn the hyperglycemia indicator (possible high blood sugar) On or OFF and to select the desired level for the indicator. You will be alerted any time your test result is higher than the selected level. On pressing the ◀ or ▶ button, the screen will display 'On' or 'OFF'. Press the **S** button when 'On' appears to enter the setting. Press the ◀ or ▶ button until the desired hyperglycemia level between 6.7 and 19.4 mmol/L appears. Press and hold the **S** button to confirm the hyperglycemia level and turn the meter off.



Note

If the test result is higher than the pre-set hyperglycemia level, the meter will display HI on the bottom. KETONE symbol blinks 3 times when the result is higher than 13.3 mmol/L.

Caution

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

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.

Note

The strip expiration date indicator functions only when CareSens PRO test strip is inserted.

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 **S** button to confirm the year and set the month.

Step 3 Setting the Month

A number indicating the month will blink at the bottom of the screen. Press the ◀ or ▶ button until the correct month appears. Press and hold the **S** button for 3 seconds to confirm the month and turn off the meter.

CareSens PRO Control Solution with CareSens PRO Test Strips

You may check your meter and CareSens PRO test strips using the CareSens PRO Control Solution (control L and/or H).
The CareSens PRO Control Solution contains a known amount of glucose and is used to check that the meter and the test strips are working properly.
The CareSens PRO test strip vials have CareSens PRO Control Solution ranges printed on their labels. Compare the result displayed on the meter to the 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 34–35.

KetoSens Control Solution with KetoSens Test Strips

You may check your meter and KetoSens test strips using the KetoSens Control Solutions (control L/M/H).
The KetoSens Control Solution contains a known amount of glucose β-ketone and is used to check that the meter and the test strips are working properly.
KetoSens Control Solution ranges are printed on the KetoSens test strip box. Compare the result displayed on the meter to the KetoSens Control Solution range printed on the test strip box.
Before using a new meter or a new box of test strips, you may conduct a control solution test following the procedure on pages 34–35.

Note

- Use the CareSens PRO Control Solutions and KetoSens Control Solutions only with their corresponding test strips. The control solutions are available for purchase separately.
- Check the expiration date printed on the test strip box.
- 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).
- Before using the control solution, shake the bottle, discard the first few drops and wipe the tip clean.
- Close the control solution bottle tightly and store at a temperature between 8–30 °C.

You may do a control solution test:

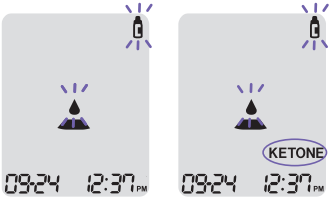
- When you want to practice the test procedure using the control solution instead of blood,
- When using the meter for the first time,
- Whenever you open a new vial or a new box of test strips,
- If the meter or test strips do not function properly,
- If your symptoms are inconsistent with the blood 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 Inserting Test Strip

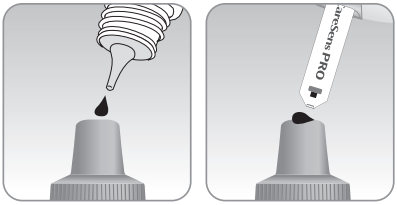
Insert a test strip into the meter's test strip port, with the contact bars facing upwards.
Gently push the test strip into the port until the meter beeps. Be careful not to bend the strip while pushing it in.
The ♟ symbol will show up. 'KETONE' will be displayed on the screen if you insert the KetoSens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

Step 2 Activating Control Solution Test Mode



Press and hold the ▶ button for 3 seconds to activate the Control Solution Test Mode. This will also flag the control solution test result. To undo the control solution flag, press and hold the ▶ button for another 3 seconds.

Step 3 Applying Control Solution to Test Strip

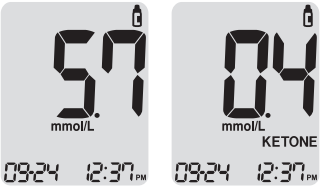


Shake the bottle before each test.
Remove the cap and squeeze the bottle to discard the first drop. Then wipe the tip with a clean tissue or cloth.
Dispense a drop of control solution onto a clean non-absorbent surface. It helps to squeeze a drop onto the top of the cap as shown. After the ♟ symbol appears 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 sample 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.

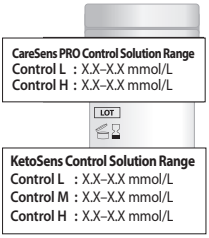
Step 4 Waiting for the Result



The display segments will rotate clockwise and a test result will appear after the meter counts down from 5 to 1 if you test with CareSens PRO test strip and CareSens PRO control solution.
In case of KetoSens test strip and KetoSens control solution, the test result will appear after the meter counts down from 8 to 1.
The test result with control solution flag is stored in the memory but not included in the averages.

Step 5 Comparing the Result

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



Caution

The range printed on the test strip vial or box is for the Control Solution only. It has nothing to do with your blood glucose or your blood β-ketone levels.

Comparing the Control Solution Test Results

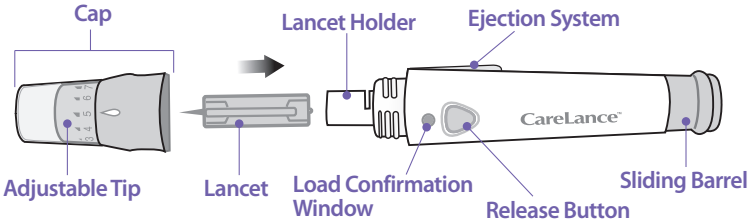
The test result of each control solution should be within the range printed on the label of the test strip vial or on the test strip box. Repeat the control solution test if the test result falls outside of the range. Out of range results may occur in following situations:

Situations	Do This
• When the control solutions are not used with their corresponding test strips, • When the control solution bottle was not shaken well, • 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 meter is not functioning properly.	Repeat the control solution test by referring to the **Note** on page 33.
• When the control solution is past the expiration date printed on the bottle, • When the control solution is past its discard date, • When the control solution is contaminated.	Discard the used control solution and repeat the test using a new bottle of control solution.

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

Using the Lancing Device

You will need a lancing device in order to collect a blood sample.
You may use the lancing device that is included in the CareSens Dual 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.

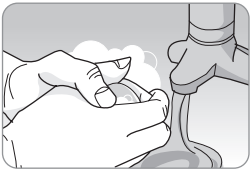
Note

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

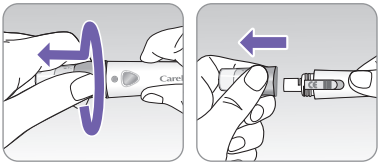
Step 1

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



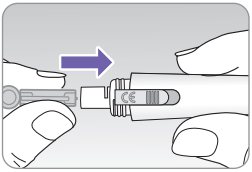
Step 2

Unscrew and remove the lancing device tip.



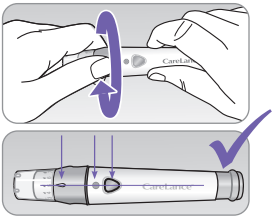
Step 3

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.



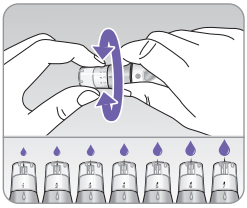
Step 4

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



Step 5

The lancing device has seven puncture depth settings, numbered 1 through 7 (1 for a shallow puncture, 7 for a deeper puncture).
Choose a depth by rotating the top portion of the adjustable tip until the desired number aligns with the arrow.

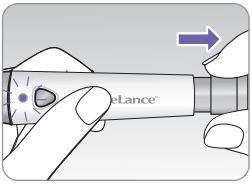


Note

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

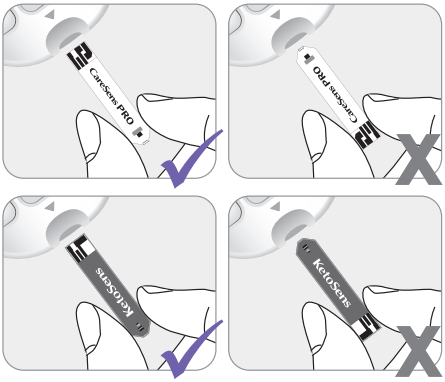
The skin depth to get blood samples will vary for various people at different sample sites. The lancing device's adjustable tip allows the best depth of skin penetration to get an adequate sample size.

Check your ketone:
- When you have an illness,
- When your blood glucose is above 13.3 mmol/L,
- When you and your healthcare professional feel it is necessary.

Preparing the Meter and Test Strip

Step 7

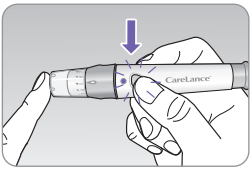
Insert a test strip with the contact bars facing upwards into the meter's test strip port. Push the strip in gently until the meter beeps. Be careful not to bend the test strip. The symbol will appear on the screen. When you insert KetoSens test strip, the meter shows 'KETONE' on the screen.



Applying Blood Sample

Step 8

Obtain a blood sample using the lancing device. Place the device against the pad of the finger. The best puncture sites are on the middle or ring fingers. Press the release button.

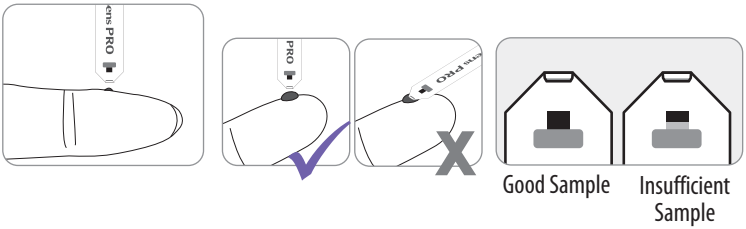


Remove the device from the finger. Wait a few seconds for a blood drop to form. You need a minimum volume of 0.4 microliter for blood glucose test with CareSens PRO test strip and 0.5 microliter (actual size of 0.5 µL: ●) for blood *β*-ketone test with KetoSens test strip.

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 because of abnormal viscosity (thickness and stickiness) or insufficient volume, the Er4 message may appear.

It is recommended to place the test strip vertically into the blood sample site as shown below.

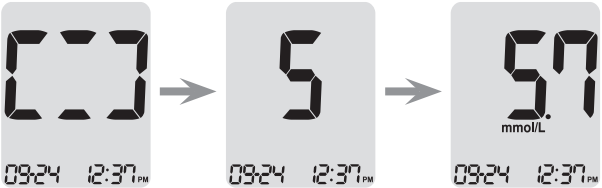


Note

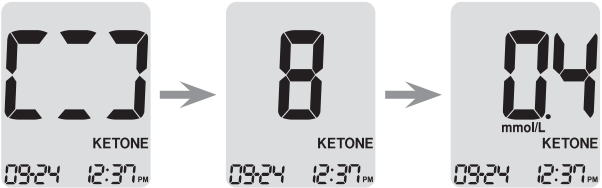
The meter may switch off if the blood sample is not applied within 2 minutes of the symbol appearing on the screen. If the meter turns off, remove the strip and reinsert it, and start from Step 2.

Step 10

At this time, the display segments will rotate clockwise while the blood is going in.
Blood glucose test results will appear after the meter counts down from 5 to 1, and blood β-ketone test results from 8 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. If the Bluetooth feature is activated, the meter will send the test result to the connected smartphone.



Blood glucose test result



Blood β-ketone test result

Note

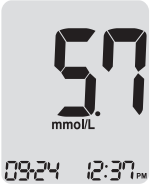
To transmit glucose data using the Bluetooth feature,

- The Bluetooth feature on the meter must be turned on,
- The meter and a smartphone must be paired,
- The SmartLog™ mobile app must be launched.
- The meter will transmit data in the following cases,
- When the strip is ejected after measuring,
- When the meter is turned on (only when untransmitted data exists).

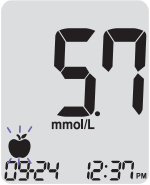
Step 11

You can attach a flag to a blood glucose test 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 ( ), or a fasting 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.

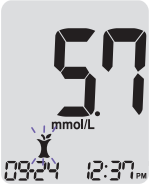
When you test your blood β-ketone, there is no need to attach any flag.



No flag



Pre-meal flag



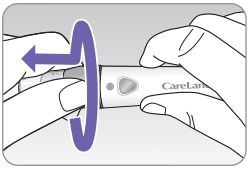
Post-meal flag

Fasting flag

Discarding Used Lancets

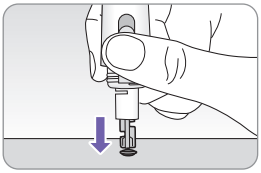
Step 1

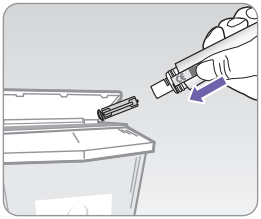
Unscrew the lancing device tip.



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.

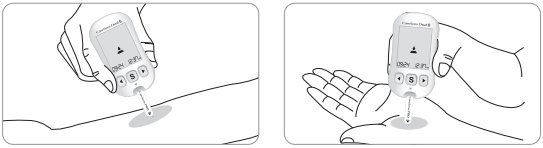
Alternate Site Testing (for glucose only)

Before using AST, please consult your healthcare professional.

What is AST (Alternate Site Testing)?

Usually, we 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 **you should not use AST for your blood β-ketone test.** The following precautions should be observed during testing.

Alternate Sites for Testing



Alternate Site Blood Sampling (forearm and palm)

Select a clean, soft and fleshy sample site area free of visible veins and hair and away from bones. Gently massage the sample site 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 0.4 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 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 use AST for your blood β-ketone test.
- 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.

HI and Lo Messages

HI Message

The meter displays blood glucose 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).
The meter displays blood *β*-ketone results between 0.1–8.0 mmol/L. 'HI' appears when the blood *β*-ketone level is greater than 8.0 mmol/L.

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

Lo Message

'Lo' appears when a blood glucose 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.

Note

In case of blood β-ketone test, 0.0 mmol/L appears when a test result is less than 0.1 mmol/L.

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	
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 Using Cable

Test results stored in CareSens Dual 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.

Note

Test results can also be transferred wirelessly using Bluetooth. To pair the meter and your smartphone, see page 21.

Meter Memory

The CareSens Dual meter can save up to 1,000 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 only calculates and displays the averages of blood glucose test results by 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

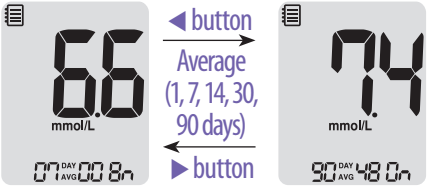
Step 1

Press any 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.

The number of tests within the current day

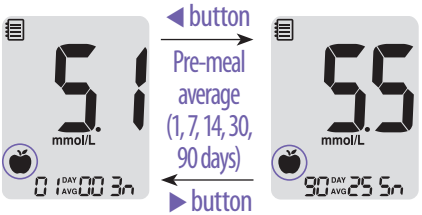
Step 2 Viewing Averages

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



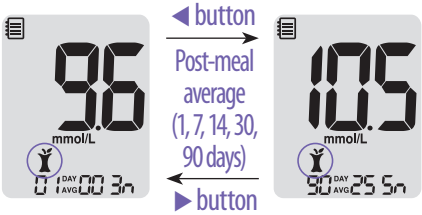
Step 3 Viewing Pre-meal Averages

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



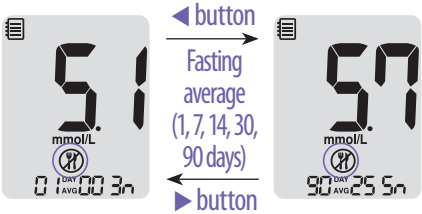
Step 4 Viewing Post-meal Averages

Press the ◀ 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 ◀ 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 **S** button to turn off the meter.

Note

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

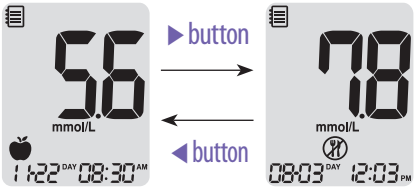
Viewing Test Results Stored in Memory

Step 1

Press any 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

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 results seen previously.
After checking the stored test results, press the **S** button to turn off the meter.



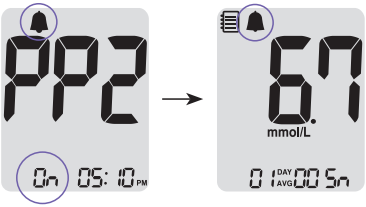
Setting the Alarm Function

Four types of alarms can be set in the CareSens Dual 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 any 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.

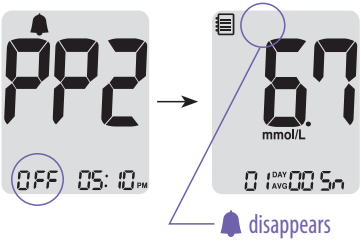


Note

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 **S** buttons simultaneously for 3 seconds to enter the time alarm mode. ‘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 while 'On' blinks to adjust the time of 'alarm 1'. A number indicating 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 **S** button to finish and to go to 'alarm 2' mode.
Repeat steps 2 to 4 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

Er 1	A used test strip was inserted. *> Repeat the test with a new test strip.*
Er2	The blood or control solution sample was applied before the ▲ symbol appeared. *> Repeat the test with a new test strip and wait until the ▲ symbol appears before applying the blood or control solution sample.*
Er3	The temperature during the test was above or below the operating range. *> Move to an area where the temperature is within the operating range for blood glucose test (5–45 °C) or the operating range for blood β-ketone test (10–40 °C) and repeat the test after the meter and test strips have reached a temperature within the operating range.*
Er4	The blood sample has abnormally high viscosity or insufficient volume. *> Repeat the test with a new test strip.*

Er5	This error message may appear when the wrong blood glucose test strip is used instead of CareSens PRO or KetoSens test strip. > *Repeat the test with a CareSens PRO or KetoSens test strip.*
Er6	There is a problem with the meter. > *Do not use the meter. Contact your authorised i-SENS sales representative.*
Er7	There is a problem with Bluetooth communication. > *Contact your authorised i-SENS sales representative.*
Er8	An electronic error occurred during the test, commonly caused by foreign materials in the meter port (e.g., blood, dirt, dust), and/or physical damage to the meter or strips due to incorrect use or storage. > *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.	• 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. • Check if the appropriate test strip was used. • Check whether the batteries are inserted with the + side facing up. • Replace the batteries.
The test does not start even after applying the blood sample on the strip.	• Check if the confirmation window is filled completely. • Repeat the test after inserting a new test strip.
The test result does not match the way you feel.	• Repeat the test after inserting a new test strip. • Check the expiration or discard date of the test strip. • Perform control solution test.

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 Dual Blood Glucose/Blood β-Ketone Monitoring System has been evaluated in laboratory and in clinical tests.

Glucose

Accuracy: The accuracy of the CareSens Dual Blood Glucose Monitoring System (Model: GM01HAC) 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	0.964
Y-intercept	0.199 mmol/L
Correlation coefficient (r)	0.997
Number of tests	600
Range tested	2.6–29.2 mmol/L

System accuracy results for glucose concentration < 5.55 mmol/L

Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
136/204 (66.7 %)	197/204 (96.6 %)	203/204 (99.5 %)

System accuracy results for glucose concentration ≥ 5.55 mmol/L

Within ±5 %	Within ±10 %	Within ±15 %
264/396 (66.7 %)	379/396 (95.7 %)	395/396 (99.7 %)

System accuracy results for glucose concentrations between 2.6 mmol/L and 29.2 mmol/L

Within ±0.83 mmol/L and Within ±15 %
598/600 (99.7 %)

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

Within Run Precision		
Blood average	2.5 mmol/L	0.1 mmol/L
	4.3 mmol/L	0.2 mmol/L
	6.9 mmol/L	CV = 4.2 %
	10.3 mmol/L	CV = 3.3 %
	16.3 mmol/L	CV = 3.0 %

Between Run Precision		
Control average	2.3 mmol/L	0.1 mmol/L
	6.7 mmol/L	CV = 4.1 %
	17.3 mmol/L	CV = 3.1 %

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

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	D,L-arabinose	18 mg/dL
4	Bilirubin	20 mg/dL
5	Cholesterol	500 mg/dL
6	Creatinine	30 mg/dL
7	Dopamine	13 mg/dL
8	EDTA	180 mg/dL
9	Fructose	30 mg/dL
10	Galactose	60 mg/dL
11	Gentisic acid	50 mg/dL
12	Glucosamine	9 mg/dL
13	2-deoxyglucose	8.2 mg/dL
14	Glutathione (Red)	17 mg/dL
15	Hemoglobin	500 mg/dL
16	Heparin	8000 U/dL
17	Ibuprofen	40 mg/dL
18	Icodextrin	1094 mg/dL
19	L-Dopa (L-3,4-dihydroxyphenylalanine)	5 mg/dL

No.	Interferent	Concentration
20	Maltose	1000 mg/dL
21	Maltotriose	240 mg/dL
22	Maltotetraose	120 mg/dL
23	Mannose	9 mg/dL
24	Methyl-DOPA	1.5 mg/dL
25	Pralidoxime Iodide (PAM)	25 mg/dL
26	Salicylate	70 mg/dL
27	Sucrose	500 mg/dL
28	Tolbutamide	100 mg/dL
29	Tolazamide	100 mg/dL
30	Triglycerides	3000 mg/dL
31	Uric acid	20 mg/dL
32	Xylose	9.7 mg/dL

Compounds of xylose ≥ 0.54 mmol/L at glucose concentrations of 2.8–5.6 mmol/L may cause overestimation of blood glucose results.

User Performance Evaluation

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

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

β-Ketone

Accuracy: The accuracy of the CareSens Dual Blood Glucose/ Blood β-Ketone System(Model: GM01HAC) was assessed by comparing blood β-ketone results obtained by patients with those obtained using a Randox Monaco, a laboratory instrument.

Slope	1.012
Y-intercept	-0.0223 mmol/L
Correlation coefficient (r)	0.996
Number of tests	100
Range tested	0.015–7.2 mmol/L

Precision: Precision studies were performed in a laboratory using the CareSens Dual Blood β-Ketone Monitoring Systems.

Within Run Precision		
Blood average	0.5 mmol/L	SD = 0.04 mmol/L
	1.4 mmol/L	SD = 0.05 mmol/L
	3.2 mmol/L	CV = 2.9 %
	5.5 mmol/L	CV = 3.1 %
	7.2 mmol/L	CV = 3.8 %

Between Run Precision		
Control average	0.7 mmol/L	SD = 0.05 mmol/L
	2.4 mmol/L	CV = 4.0 %
	4.7 mmol/L	CV = 4.4 %

This study shows that there could be a variation of up to 4.4 %.

Warranty Information

Manufacturer's Warranty
i-SENS, Inc. warrants that the CareSens Dual 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.

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.

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 fail to be of acceptable quality and the failure does not amount to a major failure.

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