⚠ WARNING:

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

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.

FCC Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.
This equipment should be installed and operated with minimum distance 20 cm between the radiator and your body.

Any changes or modifications not expressly approved by the manufacturer could void the user's authority to operate this equipment.

Note

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

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Intended use:

The CareSens S Fit BT Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The CareSens S Fit BT Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro*) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The system is intended to be used by a single person and should not be shared. It is not intended for use on neonates and is not for the diagnosis or screening of diabetes. The CareSens S Blood Glucose Test Strips are for use with the CareSens S Fit BT Blood Glucose Meters to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip.

Important Safety Information

- Please use this device only for the intended use described in this user guide.
- Please follow the suggested cleaning and disinfection procedures described in this user guide.
- CareSens S Blood Glucose Test Strips are intended for single use only. They should be disposed of in an appropriate container

immediately after use.

- "FDA Public Health Notification: Use of Fingerstick Devices on More than One 1314 Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm234889.htm (2010)
- CDC website on "Infection Prevention during Blood Glucose Monitoring and Insulin 1318 http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html Administration"

Limitations of CareSens S Fit BT Blood Glucose Monitoring System

- An abnormally high or low red blood cell count (hematocrit level over 60 % or below 20 %) may produce inaccurate results.
- If you are taking Vitamin C (ascorbic acid) at doses higher than recommended (resulting in blood concentrations greater than 3 mg/dL), it may interfere with your glucose meter and cause you to get inaccurate results with this system.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hypoglycemic hyperosmolar state, with or without ketosis.

- Dehydration (excessive water loss) may cause false low results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
- Altitudes of higher than 10,000 ft. (3,048 m) above sea level may have an effect on the performance of the test strip.
- CareSens S Fit BT test system is for single-patient use only and should not be shared.
- Not for neonatal use.
- Do not use for diagnosis of or screening for diabetes mellitus.
- Not for use on critically ill patients.
- For *in vitro* diagnostic use only.
- For over the counter use.

Important Information

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

- The CareSens S Fit BT blood glucose meter should be used only with the CareSens S Test Strips.
- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients.
- If your test result is below 60 mg/dL or above 240 mg/dL, consult a healthcare professional immediately.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

If you need assistance, please contact Customer Service: 1-800-429-5001 Mon–Sat, 9 am–9 pm EST. At all other times or in case of emergency, contact your healthcare professional or emergency medical response.

Distributor Information

- Company name: i-SENS USA, Inc.
- Address: 2461 W. 205th St., Ste B102, Torrance, CA 90501
- Telephone: 1-310-320-0254
- Email: i-sens-usa@i-sens.com

Specifications

Product specifications

Measurement range	40–600 mg/dL
Sample size	Minimum 0.5 µL
Test time	6 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 17.5 (mm)
Weight	50.5 g (with battery)
Bluetooth®	• Frequency range: technology 2.4–2.4835 GHz • Operating range distance: maximum 32 feet (10 meters) unobstructed • Operating channels: 40 channels • Security encryption: 128-bit AES (Advanced encryption standard)

Operating ranges

Temperature	50–104 °F (10–40 °C)
Relative humidity	10–90 %
Hematocrit	20–60 %

Storage and transport conditions

Temperature	Glucose Meter (with battery)	32–122 °F (0–50 °C)
	Test strip	34–86 °F (1–30 °C)
	Control solution	46–86 °F (8–30 °C)
Relative humidity	Glucose Meter (with battery), Test strip, Control solution	20–80 %

CareSens S Fit BT Blood Glucose Monitoring System

CareSens S Fit BT Blood Glucose Monitoring System includes the following items:

- CareSens S Fit BT Blood Glucose Meter
- User's Manual
- Pairing Quick Guide
- Carrying Case
- Battery

CareSens S Fit BT Blood Glucose Monitoring System may include the following items:

- CareSens S Blood Glucose Test Strips
- Lancets
- Lancing Device

This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

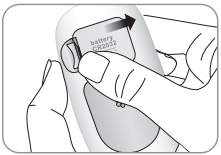
- CareSens S Glucose Control Solution Level A, Level B, or Level A&B packages are sold separately and can be purchased by contacting Customer Service: 1-800-429-5001 Mon–Sat, 9 am–9 pm EST.
- Check all the components after opening the CareSens S Fit BT Blood Glucose Monitoring System package. The exact contents are listed on the main box.
- The cable for data management software can be ordered separately. Please contact Customer Service: 1-800-429-5001 Mon–Sat, 9 am–9 pm EST.

Inserting or Replacing the battery

The CareSens S Fit BT meter uses one 3.0 V lithium battery. Before using the meter, check the battery compartment and insert a battery if empty.
When the + − symbol appears on the display while the meter is in use, the battery should be replaced as soon as possible. The test results may not be saved if the battery runs out.

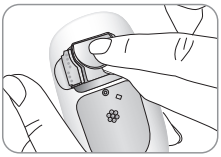
Step 1

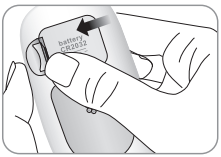
Make sure the meter is turned off. Push the cover in the direction of the arrow to open the battery compartment.



Step 2

Remove the used battery. Slip your thumb finger and pulling it out with your index and thumb finger as shown in the diagram. Insert a new battery with the + side facing up and make sure the battery is inserted firmly.





Step 3

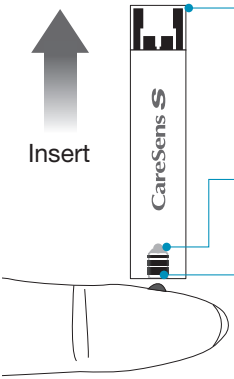
Place the cover on the battery compartment. Push it down until you hear the tab click into place.

Note

Removing the meter battery will not affect your stored results. However, you may need to reset your meter settings. See page 24.

CareSens S Blood Glucose Test Strip

The CareSens S Fit BT Blood Glucose Monitoring System measures blood glucose quickly and accurately. It automatically absorbs the small blood sample applied to the narrow edge of the strip.



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

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

Edge to apply blood sample
Apply blood sample here for testing

Warning!

- The CareSens S Test Strips should be used only with fresh capillary whole blood samples.
- Do not reuse test strips.
- Do not use test strips past the expiration date.
- Test strips in new, unopened vials and test strips in vials that have been opened can be used up until the expiration date printed on the test strip box and vial label if the test strips are used and stored according to its storage and handling methods.
- Record the date when opening a new test strip vial for the first time. Discard the vial of test strips after 5 months from opening.
- Store test strips in a cool and dry place at a temperature between 34–86 °F (1–30 °C) and 20–80 % Relative Humidity.
- Keep test strips away from direct sunlight or heat and do not freeze.
- Store test strips only in their original vial.
- Close the vial tightly after taking out a test strip for testing and use the strip immediately.
- Handle test strips only with clean and dry hands.
- Do not bend, cut, or alter test strips in any way.
- For detailed storage and usage information, refer to the CareSens S 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.

CareSens S Fit BT Blood Glucose 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

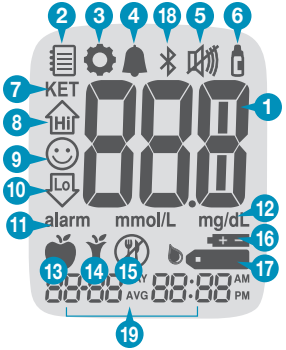
S Button
Turns the meter on/off, confirms menu selections, and changes information

Test Strip Port
Insert test strip here

Note

The cable for data management software can be ordered separately. Please contact Customer Service: 1-800-429-5001 Mon–Sat, 9 am–9 pm EST.

CareSens S Fit BT Blood Glucose Meter Display



❶ **Test results**	test results displaying panel
❷ **Memory recall mode**	appears when test results stored in the memory are displayed
❸ **Setting symbol**	appears when in SET mode
❹ **PP2 alarm**	appears when the post-meal alarm has been set
❺ **Mute symbol**	appears only when the sound is set to OFF
❻ **Control Solution fla**	appears when the control solution test results are saved or displayed
❼ **KET symbol**	appears when the test result is greater than 240 mg/dL

❽ **Hi**	appears when the test result is greater than the selected hyperglycemia level
❾ **Smile symbol**	appears when the test result is within the selected normal blood glucose range
❿ **Lo**	appears when the test result lower than the selected hypoglycemia level
⓫ **alarm**	appears when the time alarm has been set
⓬ **mg/dL**	unit for measuring blood glucose
⓭ **Pre-meal test flag**	used for tests done before eating
⓮ **Post-meal test flag**	used for tests done after eating
⓯ **Fasting test flag**	used for tests done after fasting for at least 8 hours
⓰ **Battery symbol**	indicates meter battery is running low and needs to be replaced
⓱ **Blood insertion symbol**	indicates meter is ready for the application of a drop of blood or control solution

⑱ Bluetooth® symbol
⑲ Month/Day/Hour/Minute

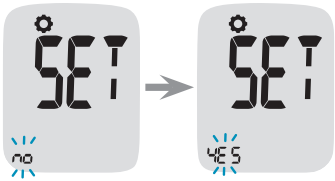
Note

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.

Press and hold the **S** button for 3 seconds to enter SET mode. After all settings are finished, press and hold the **S** button for 3 seconds to turn off the meter. Press the ◀ or ▶ button to change values. Press and hold the ▶ button to scroll faster.

Step 1 Entering the SET Mode

Press and hold the **S** button for 3 seconds to enter SET mode. After all the segments flash across the screen, '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 meters). Before pairing your meter and smartphone, download and install the SmartLog™ mobile app on your smartphone.

Setting Up Bluetooth®

Step 2 Bluetooth® Pairing

Note

For details about the Bluetooth® pairing process, refer to the Bluetooth® Pairing Quick Guide enclosed in the CareSens S Fit BT product box.

① **Meter:** Your CareSens S Fit BT Meter will have Bluetooth® feature turned on. If you want to turn off Bluetooth®, press the ◀ or ▶ button and **S** to confirm your selection. The meter will go to step 3, Setting the Year.

② **Smartphone:** If you **want to pair** (connect) your meter to your smartphone, launch the SmartLog™ mobile app and find the **Accessories** menu on your smartphone.

③ **Smartphone:** Select the CareSens S Fit BT model from the meters list, and then tap **Bluetooth Register** > **Next**.

④ **Meter:** With the meter turned off, press and hold the ▶ button for three seconds to enter pairing mode.

The Bluetooth® symbol and **bT** will appear and **YES** will blink at the bottom of the screen.

⑤ **Meter:** Press the **S** button to select **YES** and set the Bluetooth® pairing type setting.
The pairing type number **2** and **type** will appear, and the Bluetooth® symbol will blink at the top.

⑥ **Smartphone/Meter:** Follow the on-screen instructions on the SmartLog™ mobile app to search your meter, and complete the pairing process.

⑦ **Meter:** When the pairing process is complete, the meter will display **End** and it will be automatically turned off after three seconds.

Note

Some content or menus may differ depending on your smartphone's operating system or SmartLog™ version.

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

Note

- If your meter and smartphone are paired, the meter communicates with the smartphone, automatically synchronizing the current date and time. In this case, continue to press the **S** button to skip the date and time setting and go on to step 9.
- To set the date and time manually, press and hold the **S** button to enter the SET mode, and continue to press the **S** button to go to step 3.

Step 3 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 4 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 5 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 6 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 7 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 8 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 9

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 10 Setting the Year

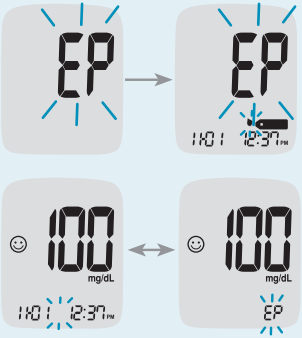
This setting allows you to turn the strip expiration date indicator on or off. This setting turns the function on or off only. See page 36 to set the strip expiration date.

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 beginning of November, 2023.



Setting the Hypoglycemia (Lo) Indicator

Step 11

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 40 and 90 mg/dL appears. Then, press the **S** button to confirm the level and to go to the next step.

Note

If the test result is lower than the pre-set hypoglycemia level, the meter will display the following.

Caution

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

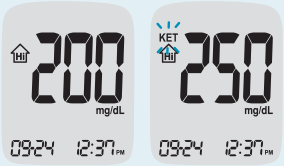
Setting the Hyperglycemia (Hi) Indicator

Step 12

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 appears. Press and hold the **S** button to confirm the hyperglycemia level and turn the meter off.

Note

If the test result is greater than the pre-set hyperglycemia level, the meter will display 'Hi'. If the test result is greater than 240 mg/dL, 'KET' will blink three times on the screen.



⚠ Caution

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

Note

If the test result is within the normal blood glucose level (between the pre-set hypoglycemia and hyperglycemia values), the smile symbol will be displayed on the screen as shown.

Step 13 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 is printed on the test strip vial.

Step 14 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 15 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. After setting, press and hold the **S** button for 3 seconds to turn off the meter.

Checking the System

You may check your meter and test strips using the CareSens S Glucose Control Solution (Level A and/or B).
The CareSens S Glucose Control Solution contains a known amount of glucose and is used to check that the meter and the test strips are working properly.
The test strip vials have CareSens S Glucose Control Solution ranges printed on their labels. Compare the result displayed on the meter to the CareSens S Glucose 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 39–42.

Note

- Use only the CareSens S Glucose Control Solution (Level A and/or B, available for purchase separately).
- 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.

Note

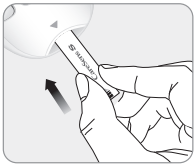
- Make sure your meter, test strips, and control solution are at room temperature before testing. Control solution tests must be done at room temperature 68–77 °F/20–25 °C.
- Before using the control solution, shake the bottle, discard the first few drops and wipe the tip clean.
- Close the control solution bottle tightly and store at a temperature between 46–86 °F (8–30 °C).

You may do a control solution test:

- When you want to practice the test procedure using the control solution instead of blood,
- When using the meter for the first time,
- Whenever you open a new vial of test strips,
- If the meter or test strips do not function properly,
- If your symptoms are inconsistent with the blood glucose test results and you feel that the meter or test strips are not working properly,
- If you drop or damage the meter.

Control Solution Testing

Step 1 Inserting Test Strip

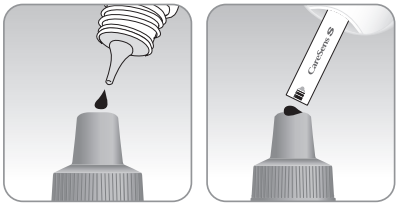


Insert a test strip into the meter's test strip port, with the contact bars facing upwards.
Gently push the test strip into the port until the meter beeps. Be careful not to bend the strip while pushing it in.
The symbol will show up.

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

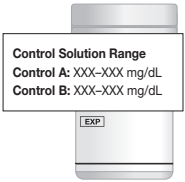
The meter may switch off if the control solution sample is not applied within 2 minutes of the symbol appearing on the screen. If the meter turns off, remove the strip, reinsert, and start from step 1.

Step 4 Waiting for the Result

A test result will appear after the meter counts down from 6 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. The result should fall within the range.



⚠ Caution

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

Note

The CareSens S Glucose Control Solution can be purchased separately. Please contact Customer Service: 1-800-429-5001 Mon–Sat, 9 am–9 pm EST.

Comparing the Control Solution Test Results

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

Situations	Do This
• 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,	Repeat the control solution test by referring to the notes on page 37.

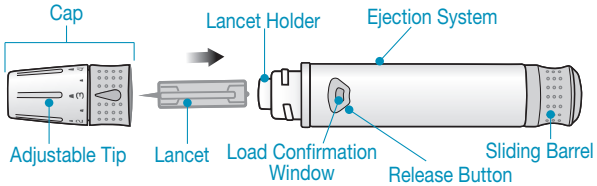
Situations	Do This
• When the first drop of the control solution was not discarded or the tip of the bottle was not wiped clean, • When the meter is not functioning properly.	Repeat the control solution test by referring to the notes on page 37.
• When the control solution is past the expiration date 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 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 printed on the test strip vial, the CareSens S Test Strip and CareSens S Fit BT meter may not be working properly. Do not use your system and contact Customer Service at 1-800-429-5001 Mon–Sat, 9 am–9 pm EST.

At all other times or in case of emergency, contact your healthcare professional or emergency medical response.

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 S Fit BT Blood Glucose Monitoring System or any other medically approved lancing device.



- The lancing device may not be used by more than one individual. Ensure the lancing device is not shared among different users.

⚠ 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.

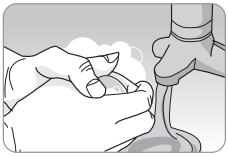
Note

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

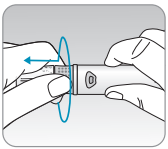
Step 1

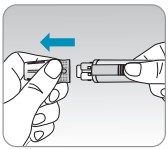
Wash hands and sample site with soap and warm water. Rinse and dry thoroughly.



Step 2

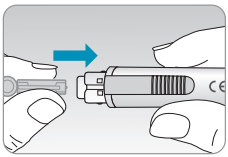
Unscrew and remove the lancing device tip.





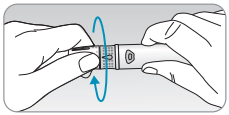
Step 3

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.



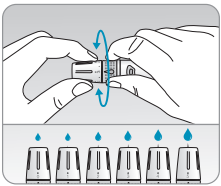
Step 4

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



Step 5

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



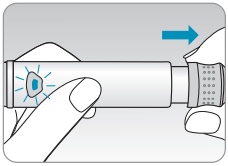
Note

0 = least penetration of lancet into the skin.

5 = most penetration of lancet into the skin.

Step 6

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



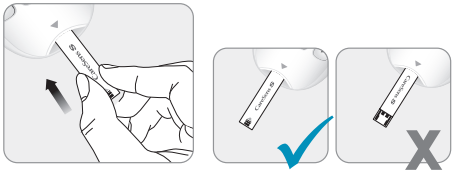
Note

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

Preparing the Meter and Test Strip

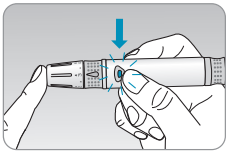
Step 7

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



Applying Blood Sample

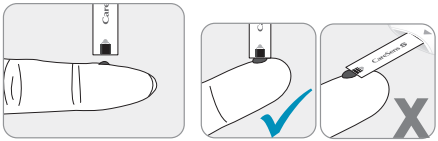
Step 8



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

Step 9

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



⚠ Caution

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

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

Note

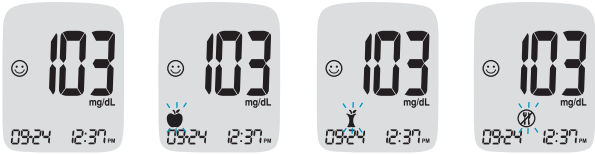
The meter may switch off if the blood sample is not applied within 2 minutes of the symbol appearing on the screen. If the meter turns off, remove the strip and reinsert it, and start from Step 2.

Step 10

The test result will appear after the meter counts down from 6 to 1. The result will be automatically stored in the meter's memory. If the test strip is removed after the test result is displayed, the meter will automatically switch off after 3 seconds. Discard used test strips safely in disposable containers.

Step 11

You can attach a flag to a result to indicate particular situations while the strip is still in the meter. When the result is displayed right after a test, press the ◄ or ► button to select a pre-meal flag ( ), a post-meal flag( ), 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.

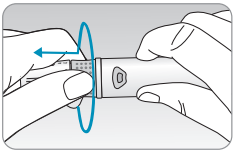


No flag | Pre-meal flag | Post-meal flag | Fasting flag

Discarding Used Lancets

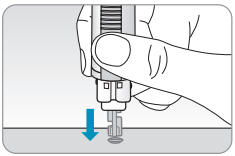
Step 1

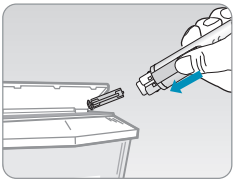
Unscrew the lancing device tip.



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.

HI and Lo Messages

Step 1 HI Message

The meter displays results between 40–600 mg/dL. 'HI' and 'KET' appear when the blood glucose level is greater than 600 mg/dL and indicate severe hyperglycemia (much higher than normal glucose levels).
If 'HI' is displayed again upon retesting, please contact your healthcare professional immediately.

Step 2 Lo Message

'Lo' appears when a test result is less than 40 mg/dL and indicates severe hypoglycemia (very low glucose levels).
If 'Lo' is displayed again upon retesting, please contact your healthcare professional immediately.

Note

If the messages persists, please contact Customer Service: 1-800-429-5001Mon–Sat, 9 am–9 pm EST. At all other times or in case of emergency, contact your healthcare professional or emergency medical response.

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 100 mg/dL before meals and fasting* and are less than 140 mg/dL two hours after meals.[1]

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

Reference

1. American Diabetes Association (Standards of Medical Care in Diabetes – 2019. *Diabetes Care*, January 2019, vol. 42, Supplement 1, S13-S27)

Transferring Test Results Using Cable

Test results stored in the CareSens S Fit BT 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.
You are responsible for properly securing and managing your PC. If you suspect an adverse cybersecurity event related to CareSens S Fit BT meter, contact Customer Service at 1-800-429-5001 Mon–Sat, 9 am–9 pm EST.

Note

- Please note that SmartLog™ stores sensitive health-related information on your PC. We recommend keeping your PC up-to-date with the latest security software. For more information on keeping your PC and information safe, please contact the manufacturer of your PC.
- Test results can also be transferred wirelessly using Bluetooth®. To pair the meter and your smartphone, see page 25.

Meter Memory

The CareSens S Fit BT meter can save up to 1,000 glucose test results with time and date. If the memory is full, the oldest test result will be deleted and the latest test result will be stored.
The meter calculates and displays the averages of total test results, Pre-meal ( ) test results, Post-meal test ( ), and Fasting test results ( ) from the last 1, 7, 14, 30 and 90 days.

Viewing Averages Stored in Memory

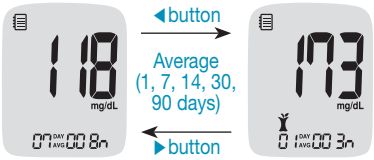
Step 1

Press the ◀, ▶ or **S** 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

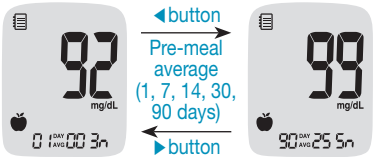
Step 2 Viewing Averages

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



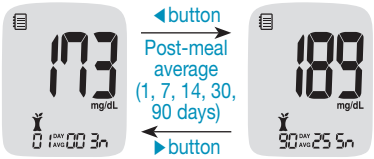
Step 3 Viewing Pre-meal Averages

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.



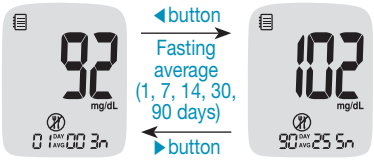
Step 4 Viewing Post-meal Averages

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

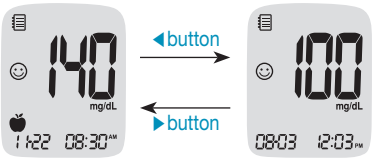
Step 1

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

The number of tests within the current day

Step 2

Use the ▶ button to scroll through the test results, starting from the most recent and ending with the oldest.



Press the ◀ button to return to the result seen previously.

After checking the stored test results hold the **S** button to turn off the meter.

Note

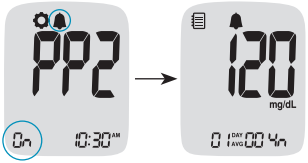
The control solution test results saved with the symbol will be displayed with the symbol when you review the stored test results.

Setting the Alarm Function

Four types of alarms can be set in the CareSens S Fit BT Meter: one post-meal alarm (PP2 alarm) and three time set alarms (alarm1–3). The PP2 alarm goes off 2 hours after setting the alarm. The alarms ring for 15 seconds and can be silenced by pressing the ◀, ▶ or **S** button or by inserting a test strip.

Setting the Post-meal Alarm (PP2 alarm)

Step 1 Turning the PP2 alarm On



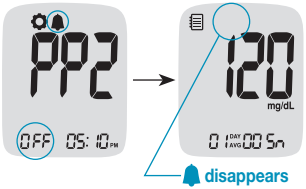
Without inserting a test strip, press and hold the ◀ button for 3 seconds to set the post-meal alarm. 'PP2' , bell (🔔) symbol and 'On' will be displayed. The screen will then automatically change to the memory recall mode. At this time, bell (🔔) symbol, indicating that the PP2 alarm has been set, will 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 settng. 'alarm1' will be displayed while 'OFF' blinks on the screen.

Step 2

On pressing the ▶ button, ‘alarm1’ is set and ‘On’ is displayed on the screen. Press the ▶ button again to cancel ‘alarm1’. ‘OFF’ will blink on the screen.

Step 3

Press the ◀ button to adjust the time of ‘alarm1’.
A number representing the hour will blink on the screen. Press the ▶ button to set the hour.

Step 4

On pressing the ◀ button, the number indicating the minute will start blinking. Press the ▶ button to set the minute.

Step 5

Press the **S** button to finish and to go to ‘alarm2’ setting.
Repeat steps 2 to 4 to set the remaining time alarms (alarm2–3).

Step 6

Press the **S** button for 3 seconds to finish and turn the meter off.

- To minimize the risk of transmission of blood-borne pathogens, the cleaning and disinfection procedure should be performed as recommended in the instructions below.
- Wash your hands thoroughly with soap and water after handling the meter, lancing device, or test strips.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be disinfected prior to use by the second person.

Cleaning and Disinfection:

The cleaning procedure is needed to clean dirt as well as blood and other body fluids on the exterior of the meter and lancing device before performing the disinfection procedure.

The disinfection procedure is needed to prevent transmission of blood-borne pathogens.

- For the meter and lancing device, this cleaning and disinfection procedure should be performed **once per week**.

Note

The life span of a CareSens S Fit BT meter is 5 years. We recommend disinfecting both the meter and lancing device at least once per week. We have validated a total of 260 cleaning and disinfecting cycles (260 cleaning and 260 disinfection cycles) to represent weekly cleaning and disinfecting over the use life of your meter and lancing device.
1 cleaning and 1 disinfection cycles per week * 52 weeks per year * 5 years = 260 cleaning and 260 disinfection cycles.

- We have validated **Clorox Healthcare Bleach Germicidal Wipes,** with 0.55 % sodium hypochlorite as the active ingredient for disinfecting the CareSens S Fit BT meter and lancing device. It has been shown to be safe for use with the meter and lancing device. This disinfectant is available commercially in towelette form. In addition to CareSens S Fit BT Blood Glucose Monitoring System instruction, please read the instructions provided by the manufacturer of Clorox Healthcare Bleach Germicidal Wipes before using it.

Name	**Clorox Healthcare® Bleach Germicidal Wipes**	
Manufacturer	**Clorox® Professional Products Company** [Phone] 1 800 537 1415 [Website] www.cloroxprofessional.com	
EPA registration number	67619-12	
Active ingredients	Sodium Hypochlorite: 0.55 %	

Note

The disinfectant products can be purchased through online retailers (e.g. Amazon or Walmart) or by calling the Clorox® company. To find out where to purchase the disinfectant product, please contact the Clorox® company or visit their website as listed above.

Note

Cleaning procedures should always be performed before the disinfectanting procedures.

Cleaning and Disinfection Procedures

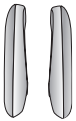
① Open the cap of the Clorox Healthcare Bleach Germicidal Wipes container, and pull out 1 towelette and close the cap.

Cleaning Procedures:

② Wipe the entire surface of the meter 3 times horizontally and 3 times vertically, in a back and forth motion, using one towelette to clean blood and other body fluids.

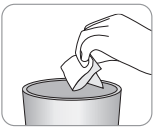
Front

Back



Both sides

③ Dispose of the used towelette in a trash bin.

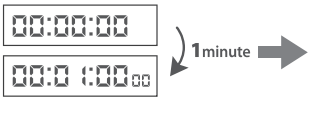


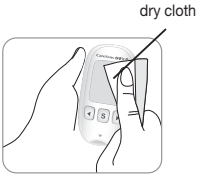
Disinfection Procedures:

④ Pull out 1 new towelette and wipe the entire surface of the meter 3 times horizontally and 3 times vertically using a new towelette to disinfect bloodborne pathogens.

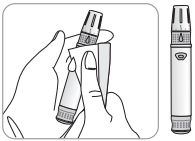
⑤ Dispose of the used towelette in a trash bin.

⑥ Allow exteriors to remain wet for 1 minute, then wipe the meter using a dry cloth.





⑦ Repeat the same procedure for the lancing device (step ① to step ⑥).



* **After the cleaning and disinfection procedure, the control solution should be tested to confirm**

that the meter works properly before using the meter. Control solution tests should be performed with two different levels of control solutions (Level A and B). Verify that the test results are within the range printed on the test strip vial. See pages 39–42 for how to do a control solution test.

Note

If any of the following deterioration signs appear after cleaning or disinfecting, please stop using the system and contact Customer Service at 1-800-429-5001 Mon–Sat, 9 am–9 pm EST. *At all other times or in case of emergency, contact your healthcare professional or emergency medical response.*

- When the inscriptions on the exterior of the meter (or lancing device) have been removed
- When the color of the meter (or lancing device) has changed or faded
- When cracks or roughness develop on the meter (or lancing device)
- When a part of the segment on the meter display does not flash
- When control solution test results do not fall within the stated range on the test strip vial

⚠ Caution

- Do not use other cleaners or disinfectants because other chemicals have not been validated and may damage the meter.
- Do not get fluids inside the meter through the test strip port, data transmission port or battery compartment. Never immerse the meter or hold it under running water because this will damage the meter.

Storage and Handling Caution:

- Do not expose the meter to direct sunlight or heat 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 subject it to strong shock.
- Do not try to fix or alter the meter in any way.
- Keep the meter in a cool and airy place.
- Keep the meter away from strong electromagnetic field sources such as cell phones and microwave ovens.
- The CareSens S Fit BT meter should be used only with CareSens S test strips.
- Store all meter components in the carrying case to prevent loss.

- Record the date when opening a new test strip vial for the first time. Discard the vial of test strips after 5 months from opening.
- Use of the meter adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the meter and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by i-SENS could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF Communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CareSens S Fit BT meter, including cables specified by i-SENS.

Note

You can get additional information or technical assistance by calling our Customer Service at 1-800-429-5001 Mon–Sat, 9 am–9 pm EST. *At all other times or in case of emergency, contact your healthcare professional or emergency medical response.*

Understanding Error Messages

	A used test strip was inserted. > *Repeat the test with a new test strip.*
	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.*
	The temperature during the test was above or below the operating range. > *Move to an area where the temperature is within the operating range (50–104 °F/10–40 °C) and repeat the test after the meter and test strips have reached a temperature within the operating range.*

	The blood sample has abnormally high viscosity or insufficient volume. > *Repeat the test after inserting a new test strip.*
	This error message may appear when the wrong blood glucose test strip is used instead of CareSens S blood glucose test strip. > *Repeat the test with a CareSens S test strip.*
	There is a problem with the meter. > *Do not use the meter. Contact Customer Service at 1-800-429-5001 Mon–Sat, 9 am–9 pm EST. At all other times or in case of emergency, contact your healthcare professional or emergency medical response.*

	There is a problem with Bluetooth® communication > *Contact Customer Service at 1-800-429-5001 Mon–Sat, 9 am–9 pm EST. At all other times or in case of emergency, contact your healthcare professional or emergency medical response.*
	An electronic error occurred during the test. > *Repeat the test with a new test strip. If the error message persists, contact Customer Service at 1-800-429-5001 Mon–Sat, 9 am–9 pm EST. At all other times or in case of emergency, contact your healthcare professional or emergency medical response.*

Note

If the error messages persist, please contact Customer Service: 1-800-429-5001 Mon–Sat, 9 am–9 pm EST. At all other times or in case of emergency, contact your healthcare professional or emergency medical response.

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 battery is inserted with the + side facing up. • Replace the battery.
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 date of the test strip. • Perform control solution test.

Note

If the problem is not resolved, please contact Customer Service: 1-800-429-5001 Mon–Sat, 9 am–9 pm EST. At all other times or in case of emergency, contact your healthcare professional or emergency medical response.

Performance Characteristics

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

Accuracy: The accuracy of the CareSens S Fit BT BGM System 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	0.972
Y-intercept	1.2038
Correlation coefficient (r)	0.9913
Number of Subjects	376
Range tested	55.6–441.5 mg/dL

Method Comparison/User Evaluation results for glucose concentration between 55.6 mg/dL and 441.5 mg/dL

Within ±5 %	Within ±10 %	Within ±15 %	Within ±20 %
235/376 (62.5 %)	343/376 (91.2 %)	369/376 (98.1 %)	376/376 (100 %)

Accuracy Information

Comparison between blood glucose results (376 typical users) of the CareSens S Fit BT BGMS and a laboratory instrument

Accurate Results	369 out of 376 (98.1 % of results)
More Accurate Results	343 out of 376 (91.2 % of results)
Most Accurate Results	235 out of 376 (62.5 % of results)

Accuracy key	Percentages listed are meter result as compared to laboratory result
Accurate Results	Meter result is ±15 % of laboratory result
More Accurate Results	Meter result is ±10 % of laboratory result
Most Accurate Results	Meter result is ±5 % of laboratory result

* Please refer to the Performance Characteristics section for more details.

Within Run Precision			
*Interval 1. 30–50	43.7 mg/dL	SD = 1.8 mg/dL	CV = 4.1 %
*Interval 2. 51–110	62.3 mg/dL	SD = 2.5 mg/dL	CV = 4.0 %
*Interval 3. 111–150	126.1 mg/dL	SD = 3.6 mg/dL	CV = 2.9 %
*Interval 4. 151–250	193.0 mg/dL	SD = 6.0 mg/dL	CV = 3.1 %
*Interval 5. 251–400	303.4 mg/dL	SD = 9.0 mg/dL	CV = 3.0 %

Between Run Precision			
*Interval 1. 30–50	44.7 mg/dL	SD = 0.8 mg/dL	CV = 1.8 %
*Interval 2. 51–110	73.6 mg/dL	SD = 1.5 mg/dL	CV = 2.0 %
*Interval 3. 111–150	121.7 mg/dL	SD = 3.4 mg/dL	CV = 2.8 %
*Interval 4. 151–250	191.6 mg/dL	SD = 6.2 mg/dL	CV = 3.2 %
*Interval 5. 251–400	314.2 mg/dL	SD = 12.7 mg/dL	CV = 4.0 %

Warranty Information

Manufacturer's Warranty

i-SENS, Inc. warrants that the CareSens S Fit BT 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.