CareSens™ S Fit BT
Blood Glucose Monitoring System

User Manual

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01 Important Information: Read This First!

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

Intended use:
CareSens S Fit BT Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the fingertip.
The CareSens S Fit BT Blood Glucose Monitoring System is intended for use outside the body (*in vitro* diagnostic use) and is intended for use as an aid to monitor the effectiveness of diabetes management. The system is for self-testing or healthcare professional use and should not be used for the diagnosis of or screening for diabetes or for testing newborns.

Meaning of Symbols Used:

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

- Glucose in blood samples reacts with the chemical in the test strip to produce a small electrical current. The CareSens 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 minimise code related errors in monitoring by using the no-coding function.

Bluetooth® technology	• Frequency range: 2.4–2.4835 GHz • Operating range distance: maximum 10 meters (unobstructed) • Operating channels: 40 channels • Security encryption: 128-bit AES (Advanced Encryption Standard)

Operating ranges

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

Storage/Transport Conditions

Temperature	Meter (with battery)	0–50 °C (32–122 °F)
	Test strip	1–30 °C (34–86 °F)
	Control solution	8–30 °C (46–86 °F)
Relative Humidity	Test strip	10–90 %

03 CareSens 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 Manual

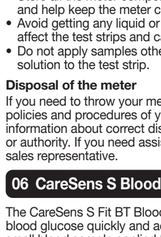
CareSens S Fit BT Blood Glucose Monitoring System may include the following items:

* CareSens S Blood Glucose Test Strips
* Lancing Device
* Battery
* Logbook
* Quick Guide
* Carrying Case
* Lancets

- 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 your authorised i-SENS sales representative.

04 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 10.

05 Caring for Your System

Use a soft cloth or tissue to wipe the meter exterior. If necessary, dip the soft cloth or tissue in a small amount of alcohol.
Do not use organic solvents such as benzene or acetone, or household and industrial cleaners that may cause irreparable damage to the meter.

Caution:

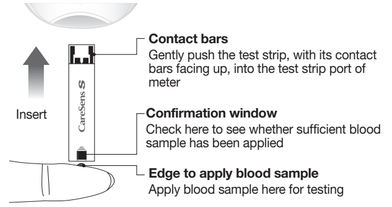
- Do not expose the meter to direct sunlight, heat, or excessive humidity for an extended period of time.
- Do not let dirt, dust, blood, or water enter into the meter's test strip port.
- Do not drop the meter or submit it to strong shock.
- Do not try to fix or alter the meter in any way.
- Strong 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.
- Keep the meter away from strong electromagnetic field sources, such as cell phones and microwave ovens.
- Store all the meter components in the carrying case to prevent loss and help keep the meter clean.
- 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.

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.

06 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 tip of the strip.



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.
- Store test strips in a cool and dry place at a temperature between 1–30 °C (34–86 °F).
- 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 S test strip package insert.

Caution

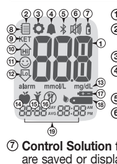
- Keep the meter and testing supplies away from young children.
- Drying agents in the vial cap may be harmful if inhaled or swallowed and may cause skin or eye irritation.

07 CareSens S Fit BT Blood Glucose Meter

Note

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

08 CareSens S Fit BT Blood Glucose Meter Display

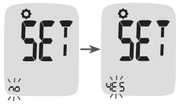


① **Test results:** test results displaying panel
② **Memory symbol:** appears when test results stored in the memory are displayed
③ **Setting symbol:** appears when in SET mode
④ **PP2 alarm:** appears when the post-meal alarm has been set
⑤ **Bluetooth Symbol**
⑥ **Mute symbol:** appears only when the sound is set to OFF
⑦ **Control Solution flag:** appears when the control solution test results are saved or displayed
⑧ **KET symbol:** appears when the test result is greater than 240 mg/dL (13.3 mmol/L)
⑨ **Hi:** appears when the test result is greater than the selected hyperglycemia level
⑩ **Smile symbol:** appears when the test result is within the selected normal blood glucose range
⑪ **Lo:** appears when the test result is lower than the selected hypoglycemia level
⑫ **alarm:** appears when the time alarm has been set
⑬ **mmol/L, mg/dL:** unit for measuring blood glucose
⑭ **Pre-meal test flag:** used for tests done before eating
⑮ **Post-meal test flag:** used for tests done after eating
⑯ **Fasting test flag:** used for tests done after fasting for at least 8 hours
⑰ **Battery symbol:** indicates meter battery is running low and needs to be replaced
⑱ **Blood insertion symbol:** indicates meter is ready for the application of a drop of blood or control solution
⑲ **Month/Day/Hour/Minute:** appears date and time

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

09 Setting Up Your System

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

If you do not want to connect your meter to your smartphone, press the **S** button when the screen display 'bT' while 'OFF' is blinking on the bottom of the screen. Then, the meter will go to Step 4 Adjusting the Date and Time mode.

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 **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.

② **Smartphone:** Select the CareSens S Fit model from the meters list, and then tap **Bluetooth Register** > **Next**.

③ **Meter:** With your 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. Press the **S** button to select 'YES'.

④ **Smartphone/Meter:** Tap **1** on your smartphone to set the Bluetooth® pairing type setting while Bluetooth symbol and 'tYPE 1' are displayed on the meter's screen.

⑤ **Smartphone/Meter:** Follow the on-screen instructions on SmartLog mobile app to begin searching your meter. 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.

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

Step 3 Entering the PIN number
① **Meter/Smartphone :** The ᛒ symbol and 6-digit PIN number will appear on the meter's screen.

② **Smartphone:** 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.

③ **Meter:** When your meter and smartphone are paired and connected, the meter will display 'SYNC' and the saved test results will be transferred to your smartphone.

④ **Meter:** When the data transfer is finished, the meter will be display 'End' on the screen and it will be automatically turned off after 3 seconds. If the data transfer is failed, the meter will display 'FAIL' and it will be automatically turned off after 3 seconds. Then, repeat Step 2 to 5 to connect your meter with smartphone.

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.

Step 4 Adjusting the Date and Time

Press the ◀ or ▶ button to adjust the date and time. Following images will appear in order of year, month, date, time format, hour, and minutes. Press the **S** button to confirm your selection and to go to the next step.

10 Setting the Sound On/OFF

Step 5
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.

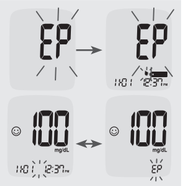
If the sound is set to OFF, none of the sound functions will work.
After setting the sound, press the **S** button to go to the next step.

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

11 Turning on the Strip Expiration Date Indicator

Step 6
This setting allows you to turn the strip expiration date indicator on or off. This setting turns the function on or off only. See page 14 to set the strip expiration date. When 'EP' appears on the screen, press the ◀ or ▶ button. The screen will display 'On' or 'OFF'. Press the **S** button to confirm the setting. If you do not want to set the indicator, press the **S** button while the screen displays 'OFF'.

Note
If the pre-set expiration date expires, the meter will display 'EP' when the test strip is inserted. 'EP' shows alternately also when the test result is displayed right after the test.
If the expiration date is set to October of 2023, the meter will display 'EP' at the beginning of November, 2023.



12 Setting the Hypoglycemia (Lo) Indicator

Step 7
This setting allows you to select the desired level for the hypoglycemia indicator (possible low blood sugar). You will be alerted any time your test result is lower than the selected level. Press the ◀ or ▶ button until the desired hypoglycemia level between 20 and 90 mg/dL (1.1–5.0 mmol/L) appears. Then, press the **S** button to confirm the level and to go to the next step.

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

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

13 Setting the Hyperglycemia (Hi) Indicator

Step 8
This setting allows you to select the desired level for the hyperglycemia indicator (possible high blood sugar). You will be alerted any time your test result is higher than the selected level. Press the ◀ or ▶ button until the desired hyperglycemia level between 120 and 349 mg/dL (6.7–19.4 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 greater than the pre-set hyperglycemia level, the meter will display 'Hi'.
If the test result is greater than 240 mg/dL (13.3 mmol/L), '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.

14 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 is printed on the test strip vial.

Step 2 Setting the Year
A number indicating the year will blink in the left corner of the screen. Press the ◀ or ▶ button until the correct year appears.
Press the **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 ▶ Press button until the correct month appears. Press and hold the **S** button for 3 seconds to confirm the month and turn off the meter.

15 Checking the System

You may check your meter and test strips using the CareSens S Glucose Control Solution (control A and/or B). The CareSens S 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 Control Solution ranges printed on their labels. Compare the result displayed on the meter to the CareSens S 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 17–19.

Note

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

You may do a control solution test:

- When you want to practice the test procedure using the control solution instead of blood,
- 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 be displayed on the screen.

Step 2 Activating Control Solution Test Mode
You can flag the control solution test result by pressing and holding the ▶ button for 3 seconds. To undo the control solution flag, press and hold the ▶ button for 3 seconds again.

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 tip 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 6 to 1.
When flagged, the result is stored in the meter's memory but it is 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 Control Solution only. It has nothing to do with your blood glucose level.

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

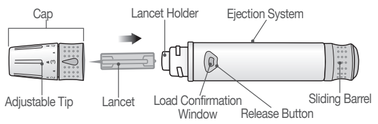
Comparing the Control Solution Test Results
The test result of each control solution should be within the range printed on the label of the test strip vial. Repeat the control solution test if the test result falls outside of the range. Out of range results may occur in following situations:

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, • 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 17.
• 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 your authorised i-SENS sales representative.

16 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.



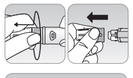
- The lancing device is for use by a single user only and should not be shared with anyone.
- Use a soft cloth or tissue to wipe the lancing device. If necessary, a small amount of alcohol on a soft cloth or tissue may be used.

⚠ 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.

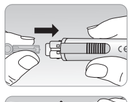
Note
Repeated puncturing at the same sample site may cause pain or skin calluses (thick hard skin). Choose a different site each time you test.

Preparing the Lancing Device

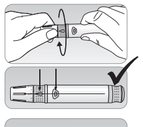
Step 1
Wash hands and sample site with soap and warm water. Rinse and dry thoroughly.



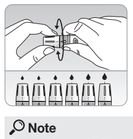
Step 2
Unscrew and remove the lancing device tip.



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.

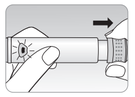


Step 4
Turn the adjustable tip until it is aligned with the load confirmation window and release button as shown.



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

Note
0 = least penetration of lancet into the skin
5 = most penetration of lancet into the skin



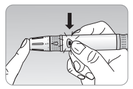
Step 6
To cock the lancing device, hold the body of lancing device in one hand and pull the sliding barrel with the other hand. The device is loaded when you feel a click and the load confirmation window turns red.

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.

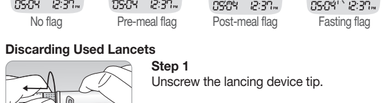
Preparing the Meter and Test Strip

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. 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 tip of the test strip till the meter beeps. At this time, the display segments will rotate clockwise while the blood is going in.
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.

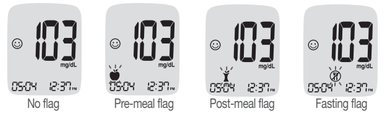
⚠ Caution
Do not apply blood on top surface of the test strip.

⚠ 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.

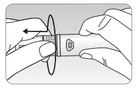
Note
The meter may switch off if the blood sample is not applied within 2 minutes of the ▮▬ symbol appearing on the screen. If the meter turns off, remove the strip and reinsert it, and start from Step 2.

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.

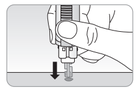
Step 11
You can attach a flag to a result to indicate particular situations while the strip is still in the meter. When the result is displayed right after a test, press the ◄ or ► button to select a pre-meal flag ( ), a post-meal flag ( ), or a fasting flag ( ). When you remove the test strip while 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.



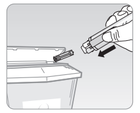
Discarding Used Lancets



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.

17 HI and Lo Messages

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

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

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

18 Target Blood Glucose Ranges

Expected Values : Normal blood glucose levels for an adult without diabetes are below 100 mg/dL (5.5 mmol/L) before meals and fasting* and are less than 140 mg/dL (7.8 mmol/L) two hours after meals.
*Fasting is defined as no caloric intake for at least eight hours.

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

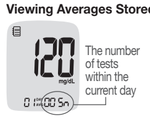
19 Transferring Test Results

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. For more information, contact your authorised i-SENS sales representative or visit *www.i-sens.com*.

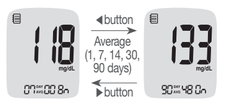
20 Meter Memory

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.



Step 2 Viewing Averages
Press the ◄ button to view the average values of 7, 14, 30 and 90 days and the number of tests performed. (For the average values of Pre-meal, Post-meal or fasting, each representative symbol will be appeared on the screen with the average values and the number of tests peformed.)

Step 3
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

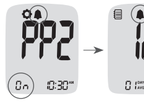
Step 1
Press the ◄, ► or **S** button to turn the meter on. The current date and time will be displayed on the bottom of the screen followed by the 1 day average value and the number of the test results saved within the current day.

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 symbol will be displayed with symbol when you review the stored test results.

21 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 (alarm 1–3). The PP2 alarm goes off 2 hours after setting the alarm. The alarms ring for 15 seconds and can be silenced by pressing the ◄, ► or **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 ◄ and the **S** button simultaneously for 3 seconds to enter the time alarm mode. The 'alarm 1' will be displayed while the 'OFF' is blinking on the screen.
On pressing the ► button, the 'alarm 1' is set and 'On' is displayed on the screen. Press the ► button again to cancel the 'alarm 1'. The 'OFF' will blink on the screen.

Step 2
Press the ◄ button to set the time of 'alarm 1'.
A number representing the hour will blink on the screen. Press the ► button to set the hour.
On pressing the ◄ button, the number indicating the minute will start blinking. Press the ► button to set the minute.

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

Step 4
Press and hold the **S** button for 3 seconds to finish and turn the meter off.

22 Understanding Error Messages

Er1
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 ▮▬ appeared.
→ *Repeat the test with a new test strip and wait until the ▮▬ 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 (5–45 ℃/41–113 ℉) 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 S blood glucose test strip.
→ *Repeat the test with a CareSens S 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.
→ *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, please contact your authorised i-SENS sales representative.

23 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 with a new test strip.
The test result does not match the way you feel.	• Repeat the test with 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 your authorised i-SENS sales representative.

24 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 Blood Glucose Monitoring System (Model: GM01NBE) 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	0.998
Y-intercept	2.338
Correlation coefficient (r)	0.9962
Number of samples	600
Range tested	26.2–447 mg/dL (1.5–24.8 mmol/L)

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

Within ±5 mg/dL (±0.28 mmol/L)	Within ±10 mg/dL (±0.56 mmol/L)	Within ±15 mg/dL (±0.83 mmol/L)
118/180 (65.6 %)	172/180 (95.6 %)	180/180 (100 %)

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

Within ±5 %	Within ±10 %	Within ±15 %
298/420 (71.0 %)	403/420 (96.0 %)	417/420 (99.3 %)

System accuracy results for glucose concentrations between 26.2 mg/dL (1.5 mmol/L) and 447 mg/dL (24.8 mmol/L)

Within ±15 mg/dL (±0.83 mmol/L) and Within ±15 %
597/600 (99.5 %)

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

Within Run Precision		
Blood average	36.3 mg/dL (2.0 mmol/L)	SD = 1.9 mg/dL (0.1 mmol/L)
	68.7 mg/dL (3.8 mmol/L)	SD = 2.7 mg/dL (0.1 mmol/L)
	134.6 mg/dL (7.5 mmol/L)	CV = 3.0 %
	212 mg/dL (11.8 mmol/L)	CV = 2.6 %
	296.1 mg/dL (16.5 mmol/L)	CV = 3.0 %

Between Run Precision		
Control solution average	40.9 mg/dL (2.3 mmol/L)	SD = 1.1 mg/dL (0.1 mmol/L)
	130 mg/dL (7.2 mmol/L)	CV = 2.3 %
	355.1 mg/dL (19.7 mmol/L)	CV = 3.7 %

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

Influence Quantities

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

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

No.	Interferent	Concentration
1	Acetaminophen (paracetamol)	20 mg/dL
2	Ascorbic acid	3 mg/dL
3	Bilirubin (Unconjugated)	20 mg/dL
4	Cholesterol	500 mg/dL
5	Creatinine	30 mg/dL
6	Dopamine	13 mg/dL
7	EDTA	180 mg/dL
8	Galactose	60 mg/dL
9	Gentisic acid	50 mg/dL
10	Glutathione (Red)	92 mg/dL
11	Hemoglobin	500 mg/dL
12	Heparin	8000 U/dL
13	Ibuprofen	50 mg/dL
14	Icodextrin	1094 mg/dL
15	L-Dopa (L-3,4-dihydroxyphenylalanine)	5 mg/dL
16	Maltose	1000 mg/dL
17	Methyl-DOPA	1.5 mg/dL
18	Pralidoxime Iodide	25 mg/dL
19	Salicylate	70 mg/dL
20	Tolbutamide	100 mg/dL
21	Tolazamide	100 mg/dL
22	Triglycerides	3300 mg/dL
23	Uric acid	25 mg/dL
24	Xylose	300 mg/dL

25 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.

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EC REP
Medical Technology Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert, Germany

User Performance Evaluation
A study evaluating glucose values from fingertip capillary blood samples obtained by 100 lay persons showed the following results:
100 % within ±15 mg/dL (±0.83 mmol/L) of the medical laboratory values at glucose concentrations below 100 mg/dL (5.55 mmol/L), and 97.2 % within ±15 % of the medical laboratory values at glucose concentrations at or above 100 mg/dL (5.55 mmol/L).

26 Warranty Information

CE 0123 IVD

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