PrimaryCare:24

STANDARD OPERATING PROCEDURE DOCUMENT (SOP)

Title	**Blood Glucose Monitoring (TEE2 Blood Glucose Monitors)**	**Doc. No.**	**OP0274 / CL072**
Scope	**Operational and Clinical Directorate**		
Purpose	To ensure that the TEE2 Blood Glucose Monitors are used according the manufactures instructions.		
Guidelines	TTE2 manual		

PROCEDURE		**RESPONSIBILITY**
1	TEE2 blood glucose meters should be used in accordance with the manufacturer's instructions (attached)	
2	If the meter or test strips do not function properly or if you drop or damage the meter then you should undertake a control test. Follow the manufacturer's guidance on undertaking the test and comparing the results.	
3	Control tests can be found at Wavertree PC24 Headquarters or at the Litherland site for the Sefton practices.	

i-sens

SPIRIT HEALTHCARE

Owner's Booklet

TEE2™

Blood Glucose Monitoring System

SPIRIT HEALTHCARE

Spirit Healthcare Ltd.
Spirit House, Selbury Drive, Oadby,
Leicester, LE2 5NG
Customer Support Tel : 0800 881 5423
www.spirit-healthcare.co.uk

24/7 NON-AUTOMATED FREE SUPPORT
0800 881 5423

i-SENS, Inc.
27-36, Gwangun-ro, Nowon-gu
Seoul 139-845, Korea
www.i-sens.com

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

CE 0123 IVD

No Coding
Easy & Accurate Testing

0.5 µL
Very Small Sample
(● : actual size shown)

5 Sec
Rapid Test Result

Table of Contents

Welcome to the TEE2 Blood Glucose Monitoring System

Thank you for choosing the TEE2 Blood Glucose Monitoring System. The system provides you with safe, fast, and convenient blood glucose *in vitro* (i.e., outside the body) diagnostic monitoring. You can obtain accurate results in just 5 seconds with a small (0.5 µL) blood sample.

* The information in this manual is correct at the time of printing. However, i-SENS reserves the right to make any necessary changes at any time without notice as our policy is one of continuous improvement.

Important Information: Read this First!

To receive safe and optimum system benefits, please read the entire manual contents before using the system. Please note the following instructions:

Intended use:
TEE2 Blood Glucose Monitoring System is used for the quantitative measurement of the glucose level in capillary whole blood as an aid in monitoring diabetes management effectively at home or in clinical settings.
TEE2 Blood Glucose Monitoring System should be used only for self-testing outside the body (*in vitro* diagnostic use only). A TEE2 Blood Glucose Monitoring System should not be used for the diagnosis of diabetes or for testing newborns. Testing sites include the traditional fingertip testing along with alternate sites testing on forearm, palm, thigh and calf.

The following chart explains the symbols you'll find in the TEE2 Owner's Booklet, product packaging, and product inserts.

For *in vitro* diagnostic use


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


Cautions for safety and optimum product use


Consult instruction for use


Do not discard this product with other household-type waste


Use by (unopened or opened test strip vial)


Manufacturer


Do not reuse

Serial number


Temperature limitations

Batch code

Authorised representative

Important Information

- The TEE2 Blood Glucose Monitoring System is intended for self-testing outside the body (*in vitro* diagnostic use).
- The glucose in the blood sample mixes with special chemicals on the test strip to produce a small electrical current. The TEE2 meter detects this electrical current and measures the amount of glucose in the blood sample.
- The TEE2 Blood Glucose Meter is designed to minimise code related errors in monitoring by using the no-coding function.
- The TEE2 Blood Glucose Meter should be used only with the TEE2 Strip.
- An abnormally high or low red blood cell count (hematocrit level over 60% or below 20%) may produce inaccurate results.
- If your test result is below 3.3 mmol/L or above 13.3 mmol/L, consult a healthcare professional immediately.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycaemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
- Inaccurate results may occur in patients undergoing oxygen therapy.

If you need assistance, please contact the Spirit Healthcare 24/7 Freephone Support Line at 0800 881 5423 or go to www.spirit-healthcare.co.uk.

Specifications

- **Product specifications**

Reported result range	1.1-33.3 mmol/L
Sample size	Minimum 0.5 µL
Test time	5 seconds
Sample type	Fresh capillary whole blood
Calibration	Plasma-equivalent
Assay method	Electrochemical
Battery life	5,000 tests
Power	Two 3.0 V lithium batteries (disposable, type CR2032)
Memory	500 test results
Size	90 X 48.5 X 14 (mm)
Weight	50.1 g (with batteries)

- **Operating ranges**

Temperature	5-50˚C (41-122˚F)
Relative humidity	10-90%
Hematocrit	20-60%

TEE2 Blood Glucose Monitoring System

Components
* TEE2 Blood Glucose Meter
* TEE2 Blood Glucose Test Strips (10)
* Owner's Booklet
* Quick Reference Guide
* Logbook
* Lancing Device
* Lancets (10)
* Batteries (2)
* Carrying Case

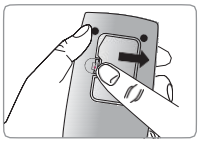
- Certain components may not be included depending on the place of purchase.
- Check all the components after opening the TEE2 blood glucose monitoring system package. The exact contents are listed on the main box.

Inserting or Replacing the Batteries

The TEE2 Meter comes with two 3.0 V lithium batteries.
Before using the meter, check the battery compartment and insert batteries if empty.
When using your meter and seeing the symbol appear on the display for the first time, the batteries should be replaced as soon as possible. The test results might not be saved if the batteries run out.

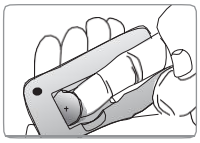
Step 1

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



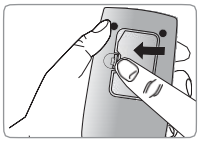
Step 2

Remove the old batteries one by one by lifting with the index finger and pulling it out with your thumb and index fingers as shown in the figure on the right. Insert two new batteries with the + side facing up and make sure the batteries are inserted firmly.



Step 3

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



Caring for Your System

Use a soft cloth or tissue to wipe the meter exterior. If necessary, the soft cloth or tissue might be dipped 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:

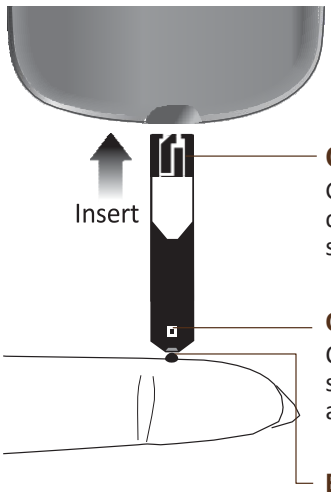
- Do not expose the meter to direct sunlight heat, or excessive humidity for an extended period of time.
- Do not let dirt, dust, blood, or water enter into the meter's test strip port.
- Do not drop the meter or submit it to strong shocks.
- Do not try to fix or alter the meter in any way.
- Keep the meter away from strong electromagnetic fields such as cell phones and microwave ovens.
- TEE2 meter should be used only with TEE2 strips.
- Keep the meter in a cool and well ventilated place.
- Store all the meter components in the portable case to prevent loss and help keep the meter clean.

Note:

- Removing the meter batteries will not affect your stored result. However, you may need to reset your meter settings. See pages 14-16 .

TEE2 Blood Glucose Test Strip

The TEE2 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 TEE2 Test Strip 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 of 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.
- 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 TEE2 Test Strip package insert.

Caution :

- Keep the meter and testing supplies away from young children.
- The test strip vial contains drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.

TEE2 Blood Glucose Meter

Data Port
Used to transfer data from the meter to a computer with the cable available from your authorised i-SENS representative

Display
Shows results, messages

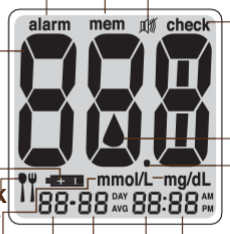
M Button
Turns the meter on/off and confirms menu selections

C Button
Selects or changes information

Test Strip Port
Insert test strip here

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

TEE2 Blood Glucose Meter Display



alarm
appears when the time alarm has been set

Test results
test results displaying panel

Battery symbol
indicates meter battery is running low and needs to be replaced

Post-meal test mark
appears during post-meal testing and when post-meal test results are displayed

mmol/L
unit for measuring blood glucose

mem
appears when test results stored in the memory are displayed

Mute symbol
appears only when the sound is set to OFF

check
appears when the control solution test results are saved or displayed

Blood insertion symbol
indicates meter is ready for the application of a drop of blood or control solution

Decimal point
appears when the blood glucose measuring unit is set to mmol/L

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

Setting up Your System

Press and hold the **M** button for 3 seconds to switch on the meter. After all settings are finished, press and hold the **M** button for 3 seconds to turn off the meter.
Press **C** button to reach the accurate value. Press and hold **C** to scroll faster.

Adjusting the Date and Time

Step 1 Entering the SET Mode

Press and hold the **M** button for 3 seconds to switch on the meter. After all the segments flash across the screen, the 'SET' character will be displayed on the screen. Press the **M** button again to progress to setting the year.

Step 2 Setting the Year

Press and release **C** button to adjust until the correct year appears. Press and hold **C** button to scroll through the numbers quickly. After setting the year, press the **M** button to confirm your selection and progress to setting the month.

Step 3 Setting the Month

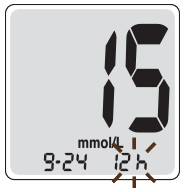
A number indicating the month will be blinking on the left corner of the screen. Press **C** button until the correct month appears. Press the **M** button to confirm your selection and progress to setting the date.

Step 4 Setting the Date

Press **C** button until the screen displays the correct date. Press the **M** button to confirm the date and progress to setting the time.

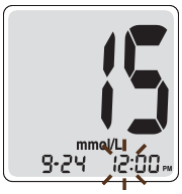
Step 5 Setting the Time

The meter can be set in the AM/PM 12-hour or the 24-hour clock format. Press **C** button to select a format. The AM/PM symbol is not displayed in the 24-hour format.
After selecting the format, press the **M** button to progress to setting the hour.



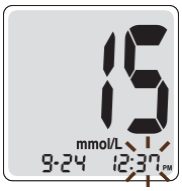
Step 6 Setting the Hour

Press **C** button until the correct hour appears.
After the hour is set, press the **M** button to progress to setting the minute.



Step 7 Setting the Minute

Press **C** button until the correct minute appears. After setting the minute, press the **M** button to progress to setting the sound.



Setting the Sound On/OFF

Step 8

On pressing **C** button, the screen will display the On or OFF. Press the **M** button to confirm the selection.

The meter will beep in the following instances, if set to On.

- 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 push the **M** button or **C** button to turn on the meter
- When you push the **C** button to set the post-meal (PP2) alarm
- When it is time for a preset blood glucose test

If the sound is set to OFF, none of the sound functions will work.
To confirm all settings, press and hold the **M** button and the screen will switch off.

Note :

- Only when the sound is set to OFF, symbol appears on the display.
- At any stage, if the M button is pressed for 3 seconds, Time and Date setting mode will finish and the meter will be turned off. Press and hold C to scroll through numbers quickly.

Checking the System

You may check your meter and test strips using the TEE2 Control Solution(control A and/or B).
The TEE2 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 TEE2 Control Solution ranges printed on their labels. Compare the result displayed on the meter to the TEE2 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 19-20.

Notes:

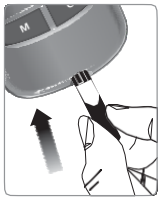
- Use only the TEE2 Control Solution (available for purchase separately).
- Check the expiration dates printed on the bottle. When you first open a control solution bottle, record the discard date (date opened plus three (3) months) in the space provided on the label.
- Make sure your meter, test strips, 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 of 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



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

Shake the TEE2 Control Solution 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. 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 3

A test result will appear after the meter counts down from 5 to 1.
After your control solution result appears on the display, press **C** for 3 seconds till the 'check' symbol appears on the display.
When the 'check' symbol is displayed, the result is stored in the meter's memory and is not included.

Step 4

Compare the result displayed on the meter to the range printed on the test strip vial.
The result should fall within that range.
Used strips should be discarded safely in disposable containers.

Caution:
- The range printed on the test strip vial is for the TEE2 Control Solution only. It does not have any connection to your blood glucose level.

Note:
- The TEE2 Control Solution can be purchased separately. Please contact Spirit Healthcare on 0800 881 5423.

Comparing the Control Solution Test Results

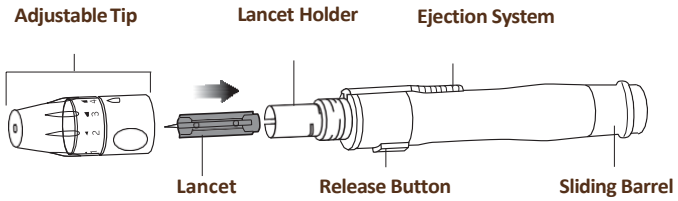
The test result of each control solution should be within the range printed on the label of the test strip vial. Repeat the control solution test if the test result falls outside of this range. Out of range results may occur due to the following factors:

Situations	Actions
• 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 "Notes" on page 18.
• 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 TEE2 Test Strip and Meter may not be working properly. Do not use your system and contact Spirit Healthcare 24/7 Freephone Support Line at 0800 881 5423.

Using the Lancing Device

You will need a lancing device in order to collect a blood sample. You may use the lancing device contained in the TEE2 Blood Glucose Monitoring System or any other medically approved lancing device.



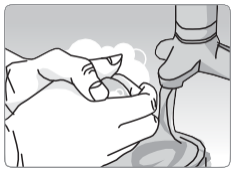
- The lancing device should not be used by more than one individual. Ensure the lancing device is not shared among different users.
- Use a soft cloth or tissue to wipe the lancing device. If necessary, a small amount of alcohol on a soft cloth or tissue may be used.

Caution:
To avoid infection when drawing a sample, use a lancet only one time, and:
- Do not use a lancet that has been used by others.
- Always use a new sterile lancet.
- Keep the lancing device clean.

Preparing the Lancing Device

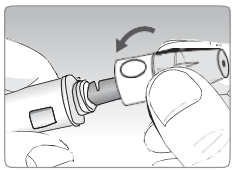
Step 1

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



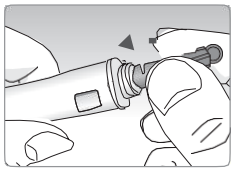
Step 2

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.

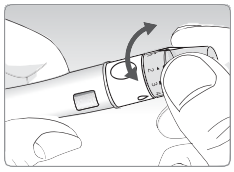


Note:

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

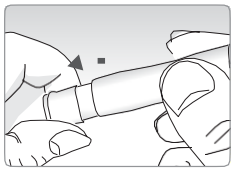
Step 4

Select a desired depth of one-to-five (1- 5) on the lancing device's adjustable tip. Choose a depth by rotating the top portion of the adjustable tip until the setting number matches the arrow.
A beginning setting of three (3) is recommended.



Step 5

To cock the lancing device, hold the body of lancing device in one hand. Pull the sliding barrel with the other hand. The lancing device is cocked when you feel a click.



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 to get an adequate sample size. A beginning setting of three (3) is recommended.

Preparing the Meter and Test Strip

Step 6

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.

Marking Post-meal Test Results

The TEE2 meter allows you to mark a result of a post-meal test with 🍴 symbol. The post-meal test mark (🍴) can be attached just before applying the blood sample. Once you attach the post-meal mark (🍴) to the test results, it cannot be deleted.

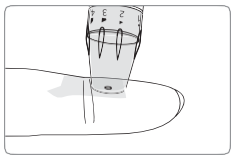
Step 7

If you want to attach a post-meal mark (🍴) to a test result, press and hold **C** for 3 seconds after inserting the test strip. The post-meal mark (🍴) and the ▲ symbol will appear on the screen.
The test result will also be displayed with the post-meal mark (🍴)

If you do not want to save the result as a post-meal test, move on to step 8 after step 6.

Applying Blood Sample

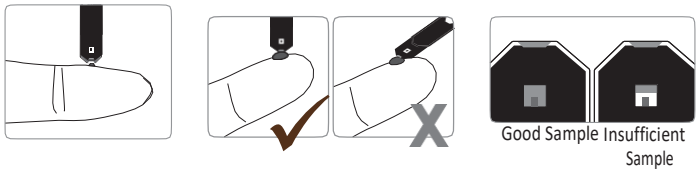
Step 8



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 that the application of blood sample to the test strip be performed virtually vertical to the sample site as shown in the diagram below.



Note:

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

Step 10

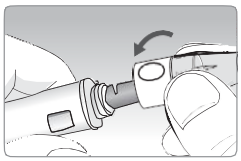
The test result will appear after the meter counts down from 5 to 1. The result will be automatically stored in the meter's memory.

If the test strip is removed after the test result is displayed, the meter will automatically switch off after 3 seconds. Discard used test strips safely in disposable containers.

Discarding Used Lancets

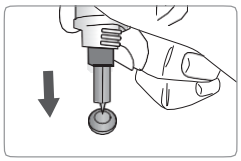
Step 1

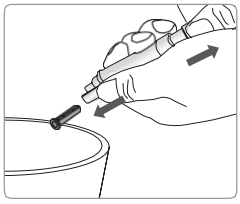
Unscrew lancing device tip.



Step 2

Place protective cover on lancet. Push the lancet ejector forward with the thumb and simultaneously pull out the sliding barrel to dispose of the used lancet in a proper biohazard container.





Caution:

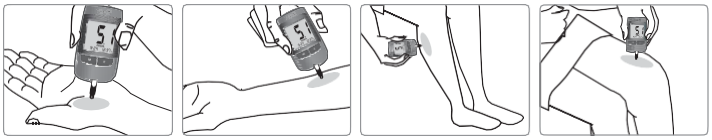
- The lancet is for single use only. Never share or reuse a lancet. Always dispose of lancets properly.

Alternative Site Testing

What is AST(Alternative Site Testing)?

Usually, when someone tests their glucose, they take the blood sample from the tip of the finger. However, since there are many nerve endings distributed there, it is quite painful. When doing a glucose test, using different parts of the body such as the forearms, palms, thighs, and calves can reduce the pain during testing. This method of testing with different parts of the body is called Alternative Site Testing.
While AST may reduce the pain during testing, it may not be simple for everyone and the following precautions should be observed during testing.

Alternative Sites for Testing



Alternative Site Blood Sampling (forearm, palm, thigh, calf)

Select a clean, soft and fleshy sample site area free of visible veins and hair and away from bones. Gently massage the sample site to help blood circulation to minimize result differences between fingertip and alternative site sampling. Firmly press and hold the lancing device against site. Wait until the skin surface under the lancing device changes color. Then press the release button while continuing to apply pressure. Keep holding the lancing device against your skin until sufficient (at least 0.5 µL, actual size:) blood is drawn. Carefully lift the lancing device away from your skin.

Things to know when using AST

Please understand the following before testing at alternative sites (forearms, palms, thighs, and calves).
The capillary whole blood of the fingertips shows changes in glucose levels more rapidly than in alternative sites. Therefore, the test results from the fingertip test and AST may differ. This is because things such as lifestyle and ingested food have an effect on glucose levels.

Acceptable situations for AST

When your blood glucose levels are stable

- Fasting period
- Before a meal
- Before sleeping

Situations requiring fingertip test

When your glucose levels are unstable

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

AST Precautions

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

Note:

- Results from alternative site and fingertip samples may differ from each other as there is a time lag for the glucose levels to reach the same value. Use a fingertip for testing if you suffer from hypoglycaemia or have experienced hypoglycaemic shock or symptoms.

Note:

- If the sample drop of blood runs or spreads due to contact with hair or with a line in your palm, do not use that sample. Try puncturing again in a smoother area.

HI and Lo Messages

HI Message

The meter displays results between 1.1-33.3 mmol/L. "HI" appears when the blood glucose level is greater than 33.3 mmol/L and indicates severe hyperglycaemia (much higher than normal glucose levels).
If "HI" symbol is displayed again on retesting, please contact your healthcare professional immediately.

Lo Message

"Lo" appears when a test result is less than 1.1 mmol/L and indicates severe hypoglycaemia (very low glucose levels).
If "Lo" symbol is displayed again on retesting, please contact your healthcare professional immediately.

Note:

- Please contact the Spirit Healthcare 24/7 Freephone Support Line at 0800 881 5423 or go to www.spirit-healthcare.co.uk, if such messages are displayed even if you do not have hyperglycaemia or hypoglycaemia.

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: The range of a normal fasting* blood glucose level for non-diabetic adults is between 3.9-5.5 mmol/L. Two (2) hours after a meal, the range of a normal blood glucose level for non-diabetic adults is between 5.6-7.7 mmol/L.
*Fasting is defined as no caloric intake for at least eight (8) hours.

Reference

American Diabetes Association. "Standards of Medical Care in Diabetes – 2012." *Diabetes Care.* January 2012; 35(1):S11-S63.

Transferring Test Results

Test results stored in TEE2 meter can be transferred from the meter to a computer using data management software and cable. The 'Pc' is displayed when the data cable connects the meter with a computer. For more information, contact the Spirit Healthcare 24/7 Freephone Support Line at 0800 881 5423 or go to www.spirit-healthcare.co.uk.

Meter Memory

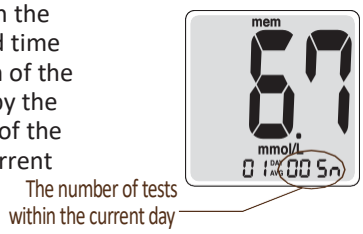
The TEE2 Meter can save up to 500 glucose test results with time and date. If the memory is full, the oldest test result will be deleted and the latest test result will be stored.

The TEE2 Meter calculates and displays the averages of total test results, pre-meal test results, and post-meal test (🍴) results from the last 1, 7, 14, 30 and 90 days.

Viewing Test Results Stored in the Meter's Memory

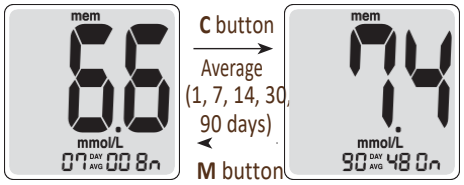
Step 1

Press the **C** or **M** button to turn the meter on. The current date and time will be displayed on the bottom of the screen for 2 seconds, followed by the average value and the number of the test results saved within the current day.



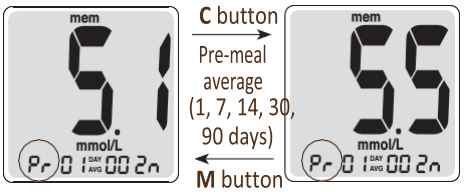
Step 2

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



Step 3

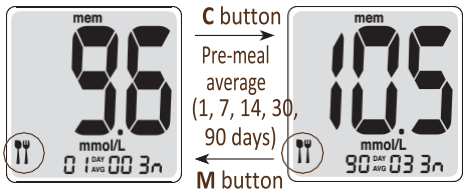
Repeatedly press the **C** to view 1, 7, 14, 30 and 90 day average value and the number of tests performed pre-meals with the 'Pr' symbol for the last test period.



Step 4

Press the **C** 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

Use the **M** button to scroll back through the averages seen previously. Press the M button for 3 seconds to turn the meter off.

Note:

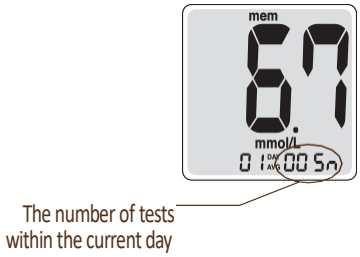
- The control solution test results saved with 'check' symbol are not included in the averages.
- The control solution test results saved with 'check' symbol will be displayed with 'check' symbol when you review the stored test results.

Viewing Test Results Stored in the Meter's Memory

Step 1

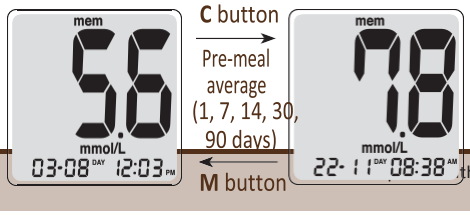
Press the **C** or **M** button to turn the meter on. The current date and time will be displayed on the bottom of the screen for 2 seconds, followed by the 1 day average value and the number

of the test results saved within the current day.



Step 2

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

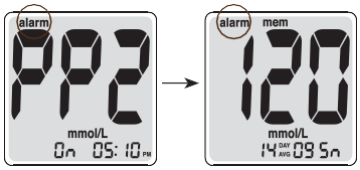


Setting the Post-meal Alarm (PP2 alarm)

The PP2 alarm goes off 2 hours after setting the alarm.
The alarms ring for 15 seconds and can be silenced by pressing **C** or the **M** button or by inserting a test strip.

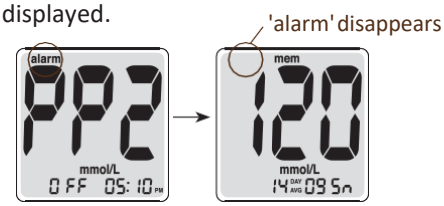
Step 1 Setting the PP2 alarm On

Without inserting a test strip, press and hold **C** for 3 seconds to set the post-meal alarm. The 'PP2' character, the 'alarm' symbol and then the 'On' character will be displayed. The screen will then automatically change to the memory check mode. At this time, the 'alarm' symbol, indicating that the PP2 alarm has been set, will be displayed on the screen.



Step 2 Setting the PP2 alarm OFF

To turn off the PP2 alarm, press and hold **C** for 3 seconds. The 'PP2' character, the 'alarm' symbol and then the 'OFF' character will appear on the screen. Then the screen will change automatically to the memory check mode without the 'alarm' symbol being displayed.



Understanding Error and Other Messages

Message	What It Means	What To Do
	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 (5-50˚C/41-122˚F) and repeat the test after the meter and test strips have reached a temperature within the operating range.

Message	What It Means	What To Do
	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 TEE2 blood glucose test strip.	Repeat test after inserting a TEE2 test strip.
	There is a problem with the meter.	contact the Spirit Healthcare 24/7 Freephone Support Line at 0800 881 5423 or go to www.spirit-healthcare.co.uk.

Note:

- If the error messages persist, contact the Spirit Healthcare 24/7 Freephone Support Line at 0800 881 5423 or go to www.spirit-healthcare.co.uk.

General Troubleshooting

Problem	Troubleshooting
The display is blank even after inserting a test strip.	• Check whether the test strip is inserted with the contact bars facing up. Check if the strip has been inserted completely into the test strip port. • Check if the appropriate test strip was used. • Check whether the batteries are inserted with the '+' side facing up. • Replace the batteries.
The test does not start even after applying the blood sample on the strip.	• Check if the confirmation window is filled completely. • Repeat the test after inserting a new test strip.
The test result doesn't 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 the Spirit Healthcare 24/7 Freephone Support Line at 0800 881 5423 or go to www.spirit-healthcare.co.uk.

Performance Characteristics

The performance of TEE2 Blood Glucose Monitoring System has been evaluated in laboratory and in clinical tests.

Accuracy: The accuracy of the TEE2 BGM System (Model GM505KAB, GM505KBB) was assessed by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyser, a laboratory instrument. The following results were obtained by diabetic patients at clinic centres.

Slope	1.02
Y-intercept	-0.41 mmol/L
Correlation coefficient (r)	0.992
Number of sample	122
Range tested	2.2 ~ 32.1 mmol/L

Accuracy results for glucose concentration < 4.2 mmol/L

Within±0.28mmol/L	Within±0.56mmol/L	Within±0.83mmol/L
11/11 (100%)	11/11 (100%)	11/11 (100%)

Accuracy results for glucose concentration ≥ 4.2 mmol/L

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
47/111 (42%)	89/111 (80%)	109/111 (98%)	111/111 (100%)

Precision: The precision studies were performed in a laboratory using TEE2 BGM Systems.

Within Run Precision		
Blood avg.	2.3 mmol/L	SD = 0.1 mmol/L
Blood avg.	4.4 mmol/L	SD = 0.2 mmol/L
Blood avg.	7.2 mmol/L	CV = 2.6%
Blood avg.	11.2 mmol/L	CV = 3.1%
Blood avg.	19.4 mmol/L	CV = 2.7%

Total Precision		
Control avg.	2.0 mmol/L	SD = 0.07 mmol/L
Control avg.	6.5 mmol/L	CV = 2.3%
Control avg.	17.9 mmol/L	CV = 2.4%

This study shows that there could be variation of up to 3.1%.

Warranty Information

i-SENS,Inc. warrants that the TEE2 Meter shall be free of defects in material and workmanship in normal use for a period of five (5) years. The meter must have been subjected to normal use. The warranty does not cover improper handling, tampering, use, or service of the meter. Any claim must be made within the warranty period.

The i-SENS company 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 Spirit Healthcare. Please contact Customer Support on 0800 881 5423 for further information.

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PrimaryCare:24

STANDARD OPERATING PROCEDURE DOCUMENT (SOP)

Title	**Blood Glucose Monitoring (TEE2 Blood Glucose Monitors)**	**Doc. No.**	**OP0274 / CL072**

Version	v1
Supersedes	N/A – New SOP
Approving Managers/Committee	Clinical Directorate
Date Ratified	5th November 2020
Department of Originator	Medicines Management
Responsible Executive Director	Medical Director
Responsible Manager/Support	Head of Medicines Management
Date Issued	5th November 2020
Next Review Date	November 2021
Target Audience	Operational Clinical Directorate Staff

Version	**Date**	**Control Reason**	**Accountable Person for this Version**
v1	November 2020	New SOP	Head of Medicines Management

Reference documents	**Electronic Locations**	**Locations for Hard Copies**
	Primary Care 24 Intranet / Corporate Policies/ Current SOPS/ ……	Standard Operating Procedures File in the Call Centre.

Document Status: This is a controlled document.
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