Fast, Accurate, Easy to Use

Gluco Spark

Blood Glucose Measuring System

USER MANUAL

SENSACORE
Healthcare and Diagnostic Products

ISO 13197:2013   ISO 9001:2015   ISO 13485:2016   CE   IVD

Table of Contents

Important information about your
Gluco Spark blood glucose monitoring system

* The Gluco Spark system is intended for use outside the body (in other words, *in vitro* diagnostic use only).

* The Gluco Spark system is used for measuring blood glucose (also known as blood sugar) from samples taken from the forearm, upper arm, hand, thigh, calf or fingers.

> **Important:**
> The Gluco Spark meter should only be used with Gluco Spark test strips. Using other test strips with this meter can produce inaccurate results.

Do use the Gluco Spark system for:
* Testing blood glucose.
* Testing only with fresh capillary whole blood samples.

> **Warning:**
> The Gluco Spark system contains small parts that may be dangerous if swallowed.

> **Caution:**
> Please read all the instructions provided in this owner 's booklet and practice the testing procedures before using the Gluco Spark system. Blood glucose monitoring should be done with the guidance of a healthcare professional.

Important health-related information

* Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your physician or doctor immediately.

* Test results below 70 mg/dL mean low blood glucose (hypoglycemia).

* Test results greater than 180 mg/dL mean high blood glucose (hyperglycemia).

* If you get results below 70 mg/dL or above 180 mg/dL and do not have symptoms of hypoglycemia or hyperglycemia, repeat the test. If you have symptoms or continue to get results that fall below 70 mg/dL or above 180 mg/dL, follow the treatment/advice of your healthcare professional.

* If you are experiencing symptoms that are not consistent with your blood glucose test and you have followed all instructions described in the Gluco Spark owner's booklet, consult your healthcare professional.

Gluco Spark system uses 0.5 µL sample.
So you can test on a variety of locations

Alternate Test Sites

Suggested Test
Areas for the Hand

Upper arm
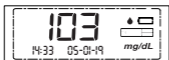
Forearm

Hand

Fingertips

Thigh

Calf
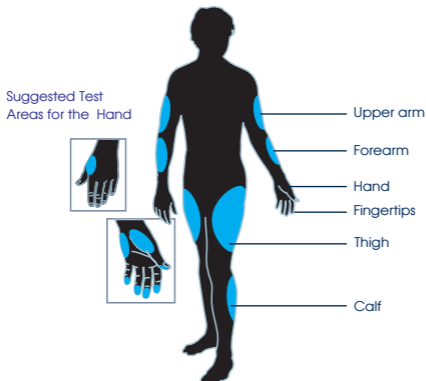
The human figure above shows the areas where you can test with
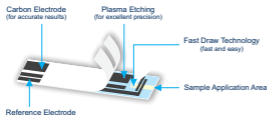the Gluco Spark System. Avoid moles, veins, bones, and tendons.

Warning:
We recommend that you test on your fingers for better results.

Gluco Spark meter and how it works

This screen always appears when the meter is turned on so that you can make sure the display is working properly. Do not use the meter if the system check screen does not match the example here.

◀ (NO) Button
Exit

(Yes) Button ▶
Previous Readings.

Display Screen
Displays your test results and other important information.

Strip Ejector
Press this button to release the used strip after testing.

Sample Area
Apply blood to sample area at end of the strip only.

Test Strip Port
Insert the top end of a new Gluco Spark test strip here. The meter powers on when you insert the test strip.

Carbon Electrode
(for accurate results)

Plasma Etching
(for excellent precision)

Fast Draw Technology
(fast and easy)

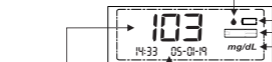Sample Application Area

Reference Electrode

Sensa Core®
Gluco Spark Meter Display

Blood Drop Symbol
This symbol works with strip symbol in an animation to tell you when the meter is ready to apply blood.

Battery Symbol

Strip Symbol
This symbol works with Blood Drop symbol in an animation to indicate that the meter is ready to apply blood.

mg/dL (U.S. Standard)
Indicates unit of measurement.

Time and Date
Shows Time and Date of the Test

Test Result Area
Displays test results.

Gluco Spark test strip

Apply blood to strip sample area per test.

> **Important:**
> Test strips may be used only once. Discard used test strips.
> You can continue to fill the test strip for up to 60 seconds.

Test Strip
Sample Area

> **Warning:**
> The cap or vial contains drying agents that may be harmful if inhaled or swallowed and
> may cause skin or eye irritation.

> **Important:**
> The Gluco Spark Meter should only be used with Gluco Spark Test Strips. Using other test
> strips with this meter can produce inaccurate results.

Important Test Strip Information

* The Gluco Spark system has an operating range of 2° to 50°C.
* Store the test strip package in a cool, dry place between 0° to 50°C.
* Use test strips only within the system operating temperature range.
* Keep away from direct sunlight and heat.
* Store your test strips in their original vial only; never transfer them to another vial or any other container.
* Never store individual test strips outside the vial.
* After removing a Gluco Spark test strip from the vial, immediately close the vial cap tightly.
* With clean, dry hands, you may touch the test strip anywhere when removing it from the vial or inserting it into the meter.
* Do not use test strips beyond the expiration date. This may cause inaccurate results.
* Do not bend, cut, or alter Gluco Spark test strips.

> **Note:**
> For further information, refer to the Gluco Spark Test Strip package insert.

Testing your blood glucose

Important:
To ensure accurate results, wash your hands and test site (for example, your finger) with soap and water. Make sure there is no cream or lotion on the test site. Thoroughly dry your hands and test site.

* With the Gluco Spark meter, you can test your blood glucose on your forearm, fingers, upper arm, hand, thigh, or calf.

* Testing with the Gluco Spark meter requires a very small sample size 0.5 µL of blood; about the size of pinhead

Note
We recommend that you test on your fingers for better results.

Times when you may be checking for low blood glucose include:

* When you are feeling symptoms such as weakness, sweating, nervousness, headache, or confusion.

* When you have delayed a meal after taking insulin.

* When your healthcare professional advises you to do so.
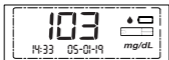
1 Performing a blood glucose test

Prepare your meter
Insert a Gluco Spark Test Strip into the meter till it allows. The meter will power on.

Note:
If you do not start the test within one minute, the meter will turn off. To restart the meter, take out the unused Gluco Spark test strip and reinsert it into the meter.

System Check

System check screen
When the meter powers on, this screen will appear so that you can make sure the display is working properly.

Blood Drop and
Test Strip Symbols

The blood drop and test strip symbols will appear on the display screen. Your meter is now ready to apply blood sample.

Important:
The Gluco Spark meter should only be used with Gluco Spark test strips. using other test strips with this meter can produce inaccurate results

2 Obtain a blood sample

Select a test site. There are differences in testing on fingers versus other alternative sites. Use your lancing device to obtain a blood sample. Refer to the detailed instructions on how to use the Gluco Spark lancing device. (Page 9 to 11)

Note
We recommend that you test on your fingers for better results.

3 Filling the Gluco Spark test strip with blood

a. Make sure that the Gluco Spark Test Strip is in the meter and the meter is powered on. (If the meter is off, take out the test strip and reinsert it into the meter.) You are now ready to apply the blood sample.

b. Bring the Gluco Spark Test Strip to the blood sample at a slight angle.

c. The Gluco Spark Test Strip acts like a sponge and pulls the blood into the strip through the sample area.

* Do not press the Gluco Spark test strip against the test site.
* Do not scrape the blood onto the Gluco Spark test strip.
* Do not apply blood to the top side of the Gluco Spark test strip.
* Do not apply blood to the Gluco Spark test strip when the Gluco Spark test strip is out of the meter.
* Do not put blood or foreign objects into the Gluco Spark test strip port.

4 Waiting for result

★ Do not pull the Gluco Spark test strip away until you hear one beep or see the timer starting on your meter screen. this means you have enough blood and the meter is reading your glucose.

★ If after five seconds your meter does not show a timer starting on the display screen, the sample may be too small or strip might be faulty. Replace the strip.

★ The test result is complete when your blood glucose test result is shown on the display screen and you will hear two beeps.

★ On average, your reading will display in 5 seconds.

Strip Ejection

After getting the result, Press the strip ejector button near a dustbin so that the used strip gets released from the meter and falls in the dustbin.

Instructions for use of Lancing Device

Intended Use

The lancing device is intended for the collection of capillary whole blood sample for testing purposes from the fingertip and from other sites, such as palm, upper arm, and forearm, which is referred to as alternate site testing. The lancing device is for use only on a single patient.

Plunger/Ejector
Cap
Lancet Holder
Release Button
Penetration
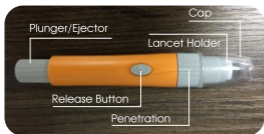
Below are the steps which have to be followed to ensure proper and safe usage of the Lancets and Lancing Device:

Inserting a Lancet

Step 1: Remove the cap from the lancing device.

Step 2: Insert a new lancet firmly into the lancet holder as far as it will go.

Step 3: Twist the protective cap to remove from the lancet. (Don't bend the protective cap)

Step 4: Place the cap back on to the device. The cap must audibly click into place.

To Obtain a Blood Sample

Step 5:
Select the desired depth setting then pull the plunger (on the end of the device) all the way down & you hear a click. Then the device is ready.

Step 6:
Wash your hands & dry them thoroughly. Hold the lancing device against your finger tip, then press the release button. The lancet is released and it penetrates the skin.

Note :
1. The amount of blood that emerges depends on the penetration depth and the pressure used to hold the lancing device against the skin.
2. If not enough blood emerges, apply more pressure on the lancing device when you next obtain blood. If that is not sufficient, increase the penetration depth progressively in addition.
3. If too much blood emerges, decrease the penetration depth.
4. Test your blood glucose immediately after you obtained blood, according to the instructions for use for your blood glucose meter.

Penetration Depth
You can set 3 penetration depths (3.5 to 5). The larger the number, the greater the penetration depth. Penetration depth also depends on the skin thickness If you have sensitive skin set a low penetration depth, such as penetration depth 3.5. Rotate the comfort dial until the desired penetration depth is set.

Ejecting the used lancet
1. Remove the cap from lancing device.
2. Slide/Push the ejector forward. The used lancet is ejected.
3. Place the cap back on to the device.

Instructions for use of Safety Lancets

How to use

Twist and remove the protective cap from the lancet

Place white end of lancet on the test site

Push the lancet down against test site to activate the lancet mechanism

LO and HI Readings

Important:

Low or high blood glucose readings can indicate a potentially serious medical condition. The Gluco Spark Meter displays results from 20 to 800 mg/dL

LO Reading with Symptoms

If you have a reading below 70 mg/dL and have symptoms such as weakness, sweating, nervousness, headache or confusion, then follow your doctor's recommendation to treat hypoglycemia.

HI Reading with Symptoms

If your test result is above 800 mg/dL, this indicates severe hyperglycemia (high blood glucose).

If you feel symptoms such as fatigue, thirst, excess urination, or blurry vision, then follow your doctor's recommendation to treat hyperglycemia.

HI Reading without Symptoms

If you get a HI reading, but have no symptoms of high blood glucose, then re-test with a new test strip. If you still get a HI reading, follow your doctor's recommendation to treat hyperglycemia.

Meter Maintenance

Battery

Your Gluco Spark meter comes with one preinstalled, 3 volt, lithium battery. The battery provides enough power for the meter to perform about 1000 Tests. If your battery runs low, the battery needs to be replaced.
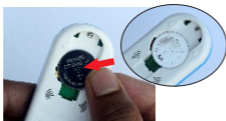
Replacing the Battery

Open the battery cover as shown in the image

Tilt the meter to sideways to release the battery

Insert a new battery with "+" symbol on the top

Close the battery cover

Date and Time Set-Up (On Replacement of Battery)

Your Gluco Spark meter allows you to set the Date and Time as you like. You can view 24 hour time.

To get into set-up mode, remove the battery and replace it. A complete display will briefly appear, then numbers will flash in the bottom left corner of the display.

Steps to set the Year, Date :

Remove battery and replace it to set date and time.

With the number flashing in the position of Year on the display. Press ">" (forward) button until you reach the current year.
Press "<" (backward) button to set.

The number in the month flashes on the display. Press ">" (forward) button until you reach the current month.
Press "<" (backward) button to set.

The number in the day position flashes on the display. Press ">" (forward) button until you reach the current day.
Press "<" (backward) button to set.

Setting the Time

The minute will now flash. Press ">" (forward) button to select the current minute.
Press "<" (backward) button to set.

The number in the hour position will now flash. Press ">" (forward) button until you reach the current hour.
Press "<" (backward) button to set.

Note:

1. To quickly adjust a certain number, keep pressing the > button until the one you want appears.

2. At any steps if you want to shut the meter off, Press< until you complete the cycle and all setting still cab be automatically saved.

Important Notes

Caring for your meter

Taking care of your meter is very simple. Just follow the guidelines shown below

1. Do not disassemble your meter. If you have any questions, please contact your local authorized distributor of Gluco Spark Blood Glucose Monitoring System.
2. Please use your meter carefully. Avoid throwing, shaking, or dropping it, which may damage its internal parts.
3. Clean the meter's surface with a soft tissue slightly dampened with water. Do not use alcohol or abrasive solutions.
4. Do not wash or pour liquid on the meter.

Cleaning of your meter

Avoid getting dirt, dust, blood, water, or any other liquid in the meter's test strip and data ports. Clean the outside of the meter using a cloth dampened with one of the following:

* Mild detergent/mild soap and water.
* 70% isopropyl alcohol.
* A mix of one part household bleach, nine parts water.

> **Important:**
> Never immerse the meter in water or any other liquid.

Handling & Storage

1. Handle your meter with care and protect it from direct sunlight or extremely high or low temperature.
2. Do not expose your meter and test strips to an environment of high humidity, such as in bathrooms, kitchens, etc.
3. Keep your meter free of dust.
4. It is recommended that you use the carrying case that is designed to store and protect your Blood Glucose Monitoring System.
5. Put your system in an appropriate operating environment at least 30 minutes before testing.

System troubleshooting

Error messages

Er
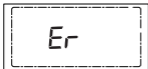
When an error occurs, an error message appears on the display with continuous beep sound. Turn the meter off by ejecting the strip.

If your meter has been dropped, this can also lead to error messages. If error messages occur frequently, contact your customer support and service centre.

Error Message	Cause and Solution
Er	• You slid a used test strip into the meter. • You applied blood or control solution to the test strip too soon, i.e. before the drop symbol flashed on the display. Start the blood glucose test from the beginning with a new test strip.
ErS	When strip is ejected from the meter after applying the blood sample Start the blood glucose test from the beginning with a new test strip and wait until the result appears on the screen.

Troubleshooting

Meter does not enter the test mode after inserting a test strip.	
Probable cause	**What to do**
The battery is dead.	Replace the battery.
The battery is installed incorrectly or there is no battery in the meter.	Check that the battery is installed correctly with the positive (+) sign facing upward, towards you.
Test strip inserted upside down, wrong end in, or incompletely inserted into the meter.	Insert the Gluco Spark Test Strip with the white sheet with sample inlet side up and the top of the strip in the meter.

| Test does not start after applying the blood sample.	
Probable cause	**What to do**
Blood sample too small.	Replace the Strip and apply enough Sample. Do not apply blood to the strip with small Sample.
Defective test strip.	Repeat the test with a new Gluco Spark test strip
Sample applied after meter times out (one minute) and turns off.	Repeat the test using a new test strip. Wait until you see the Blood and Test Strip symbols on the display screen before you apply the blood sample.
Sample applied before the appearance of blood sign	

Technical Specifications

Gluco Spark system specifications

Test Principle	Determination of glucose in fresh capillary whole blood
Assay Method	Amperometric Bio sensor
Automatic Shutoff	After 5 seconds, depending on operating status
Hematocrit	15 % to 65 %
Measurement Units	mg/dL
Strips Storage Temp.	0° to 50° C (Do not refrigerate)
Operating Temperature	2° to 50° C
Operating Relative Humidity	10 % to 95 % (non-condensing)
Memory	1000 Previous Readings
Power Source	One 3 volt lithium battery (CR2032), replaceable
Battery Life	Approximatly 1000 tests
Result Range	20 to 800 mg/dL
Sample	Capillary whole blood
Sample Size	0.5 µL (500 nanoliters)
Meter Size (Centimeters)	Length 10.0 x Width 3.1 x Depth 1.4
Display Size (Millimeters)	48 (diagonally) LCD
Test Time	5 seconds
Weight	34 grams
Strip Ejection	Yes
Construction	Handheld
Protection Class	B

Explanation of Symbols

These symbols may appear on the packaging of Gluco Spark Meter

CE	CE Marking Conformity European Notified Body Reference No. 98/79/EC
	Manufacturer
	Date of Manufacture
	Use by Date
LOT	Batch Code
SN	Serial Number
	Keep Away from Sunlight
	Temperature limit
	Do not reuse
	Consult instructions for use
IVD	In vitro diagnostic medical device
	Caution
	Do Not Use if Package is Damaged

The symbols appear on the screen are

When you insert a test strip into the meter, all symbols will be displayed together for 2 seconds. Then the meter turns on automatically.

	Flashing blood drop symbol – Now you can apply blood or control solution to the test strip.
	The battery is almost empty. When the symbol first appears, you can perform approx. 20 more tests.
mg/dL	The unit your meter uses to display test results, i.e., mg/dL on the meter.
	Strip with flashing symbol.

Target Range for Blood Sugar set with your Healthcare Professional

Wakeup Time _____ Before Meals _____ After Meals _____ At Bed Time _____

Date	BREAKFAST			LUNCH			DINNER			BEDTIME		OTHER	NOTES
	Blood Glucose	Insulin/ Medication		Blood Glucose	Insulin/ Medication		Blood Glucose	Insulin/ Medication		Blood Glucose	Insulin/ Medication	Blood Glucose	
M														
T														
W														
T														
F														
S														
S														
Avg.														

Target Range for Blood Sugar set with your Healthcare Professional

Wakeup Time _____ Before Meals _____ After Meals _____ At Bed Time _____

Date	BREAKFAST		LUNCH		DINNER		BEDTIME		OTHER	NOTES
	Blood Glucose	Insulin/ Medication	Blood Glucose	Insulin/ Medication	Blood Glucose	Insulin/ Medication	Blood Glucose	Insulin/ Medication	Blood Glucose	
M										
T										
W										
T										
F										
S										
S										
Avg.										

Customer Care Number
1800 200 2880