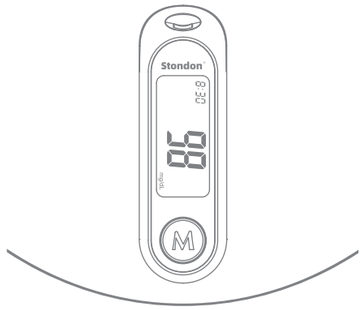


Svnuoik G-520 Blood Glucose Monitoring System

User Manual

Stondon®

Dear Stondon G-520 Blood Glucose Monitoring System Owner:

Thank you for choosing this system!
This manual contains important information you must know about the system.
Please read it thoroughly and carefully.
The system provides No Code function which means that you don't need to calibrate your meter making it easier for the user to monitor blood glucose at home.

Important safety instructions

- The meter and lancing device are for single patient use. Do not share them with anyone including other family member! Do not use on multiple patients!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases even after you have performed cleaning and disinfection.
- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Read this before using

DANGER - Misuse of this electrical device can cause electrocution, burns, fire and other HAZARDS.
Basic safety precautions should always be taken, including all those listed below.
Close supervision is necessary when equipment is used by, on, or near children, handicapped persons or invalids.

The following basic safety notice should always be taken:

1. Do not place the device in liquid, nor put it where it could fall into liquid.
2. The following basic safety notice should always be taken.
3. Use the device only for the intended use described in this manual.
4. Do not use adjunct which are not supplied by the producer.
5. Do not make the device come into contact with surfaces which are too hot to touch.
6. Do not use the device where aerosol sprays are being used.
7. Do not use the device if it is not working properly, or if it has been damaged.
8. Read all the manual, and practice the test, and then use the product to test your blood glucose. Do all quality control checks as directed and consult with a diabetes expert.

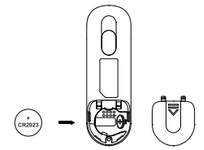
KEEP THESE INSTRUCTION IN A SAFE PLACE

Limitations of use:

- The Stondon G-520 Blood Glucose Monitoring System is not intended for use on neonates.
- Altitudes above 10744 feet (3275 meters) may cause inaccurate results.
- Not for use for patients in a hyperglycemic-hyperosmolar state, with or without ketosis.
- Not for use on critically ill patients.
- Not to be used for patients who are dehydrated, hypertensive, hypotensive or in shock.
- Very low (less than 20%) or very high (more than 60%) red blood cell count (hematocrit) can lead to incorrect test results. If you do not know your hemarocrit level, please consult your health care provider.
- High temperature (more than 104°F) and low temperature (less than 50°F) may lead to incorrect test results.
- High humidity (more than 85%) and low humidity (less than 10%) may lead to incorrect test results.
- These following substances do not affect test results in normal concentration but may affect test results in high concentration.
- Acetaminophen in your blood (>8.0mg/dL) might affect the reliability of your blood glucose results. If you are taking Tylenol, or other acetaminophen containing drugs, your glucose results may not be reliable. If you are unsure, then ask your healthcare professional.
- If you have a disease or condition that elevates your blood uric acid level (>8.0mg/dL), such as gout, your blood glucose results may not be reliable. If you are unsure, then ask your healthcare professional.
- Xylose: Do not test blood glucose during or soon after a xylose absorption test.
  Xylose in the blood can give falsely elevated results.

Before Your Begin

Installing the battery



1. Open the battery cover on the back of meter.
2. If replacing the batteries, please remove the used batteries.
3. Insert a button cell with correct +/- direction.
4. Close the battery cover.



Environment Protection – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice.

INTRODUCTION TO THE SYSTEM

Intended Use

- The Stondon G-520 Blood Glucose Monitoring System is comprised of Stondon G-520 Blood Glucose Meter and Stondon Blood Glucose Test Strips.
- The Stondon G-520 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip. The Stondon G-520 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Stondon G-520 Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes.The Stondon G-520 Blood Glucose Monitoring System is not for use in neonates.

Warnings

- The system is intended for use outside the body (in vitro diagnostic use). It is for single-patient use. It should be used only for testing glucose (sugar) and only with fresh capillary whole blood samples taken from the fingertips. The system is intended for use at home. It should not be used for the diagnosis of diabetes or for the testing of newborns.
- The System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.
- The Stondon Blood Glucose Test Strips are for use with the Stondon G-520 Blood Glucose Meter Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from fingertips.
- This device is not intended for use in healthcare or assisted -use settings such as hospitals, physician's offices, or long-term care facilities because it has not been determined to be safe and effective for use in these settings, including for routine assisted testing or as part of glycemic control procedures.
- The Stondon G-520 Blood Glucose Monitoring System are for over-the-counter (OTC) use by lay-users.
- Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.
- When the following phenomenon happens, the user should stop using meter and contact customer service:
  - The test result of control solution exceeds the range of vial labeled.
  - The meter failure to display relative information;
  - The meter does not respond when insert test strips;
  - The meter damaged severely (eg. Case broken, screen chalkboard)

Test principle

The System uses electrochemical methodologies. The System quantitatively measures blood glucose levels using an Amperometric method. The method involves detecting the current produced from glucose oxidation. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample. The electrons generated during this reaction are transferred from the blood to the electrodes. The magnitude of the resultant current is proportional to the concentration of glucose in the specimen. The current level is converted into a readout displayed on the meter.

Contents of the kits

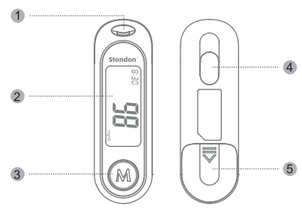
- One Stondon G-520 Blood Glucose Meter
- Owner's Manual
- A CR2032 button cell
- Stondon Blood Glucose Test Strips（Sold separately）
- Lancing Device (Model:HH-XIII-T)
- Sterile Lancet（Sold separately , Model: I）
- Stondon Glucose Control Solutions（Sold separately）

NOTE:

- The Lancing Device can be used for several times, however the sterile lancet should be changed after each use.The Lancing device (Model:HH-XIII-T) and Lancet (Model: I)are produced by the Tianjin Huahong Technology Co., Ltd.
- Stondon Blood Glucose Test Strips, Sterile lancet and Stondon Glucose Control Solutions are not included in the standard kit.
- There are three levels for the control solutions: Level 1, Level 2 and Level 3 available, please contact the place of purchase for more information.

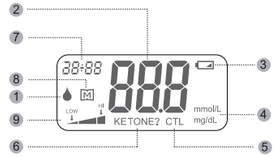
If any items are missing from your kit or opened prior to use, please contact local customer services or place of purchase for assistance.

Blood Glucose Meter



1. Strip port
   Where you insert the test strip into strip port, the meter will turn on automatically.
2. LCD Display
   It guides you through the test using symbols and simple messages
3. "M" Button
   It is used to turn on the meter enter the memory mode
4. Strip ejector
   Slide forward to eject the test strip after test.
5. Battery cover

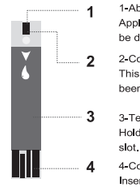
Meter Screen Display Message



1. BLOOD DROP SYMBOL
   Flashes when it is ready to apply the blood sample
2. TEST RESULT AREA
   Displays glucose results
3. LOW BATTERY SYMBOL
   Appears when the battery power is low
4. MEASUREMENT UNIT
   Appears with the test result in mg/dL or mmol/L
5. CTL SYMBOL
   Appears when doing a control test and indicates that the result won't be stored in the memory.
6. KETONE WARNING
   Appears when your result >240mg/dL
7. DATE AND TIME
8. MEMORY SYMBOL
9. BLOOD GLUCOSE LEVEL

Test Strip

Each strip can be used only once. The test strip consists of the following parts:



1-Absorbent hole
Apply a drop of blood here. The blood will be drawn in automatically.

2-Confirmation window
This is where you confirm if enough blood has been drawn into the absorbent hole of the strip.

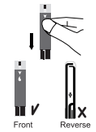
3-Test strip handle
Hold this part to insert the test strip into the slot.

4-Contact bars
Insert this end of the test strip into the meter. Push it in firmly until it will go no further.

Attention!

Test results might be wrong if the contact Bar is not fully inserted into the test slot.

NOTE: The front side of the test strip should face up when inserting the test strip.



Setting the meter and deleting the memory

1. Setting the date and time

In shutdown state, long press "M" key to enter the year, month, day and time setting mode. Start to set the year, short press "M" key, the current blinking number increase by 1;Long press "M" key to enter the month setting, short press "M" key to modify the month; Long press "M" key to enter the date setting, short press "M" key to modify the date; Long press "M" key to enter the hour setting, short press "M" key to change the hour; Long press "M" key to enter the minute setting, short press "M" key to modify the minute.

2. Deleting the memory

After the time setting is complete, long press "M" key to enter the Empty memory mode del interface, short press "M" key, you can switch no or yes to decide whether to delete the memory. When no is displayed, long press "M" key or do not perform any operation, then "OFF" will appear and the memory will not be deleted. When yes is displayed, long press "M" key to delete all memories.



3. Memory Function

In shutdown state, short press "M" key, then device will appear the most recent test result after full display 1 second, short press "M" key to appear the next most recent test result, you can use such way to review all 500 memories.

4. Setting Measurement Unit

After setting the date and time, long press the "M" button to enter the measurement unit mode. Short press the"M" button to switch between mmol/L and mg/dL.

NOTE:

- The date, time, unit and memory deletion can ONLY be set in the setting mode.
- When the meter is in setting mode, if no button is pressed within 3 minutes, the meter will turn off.

The two measuring modes

The meter provides you with two modes for measuring, General and CTL. The CTL mode should be used when a control solution is being tested. See the table below.

Modes	Use when
General test (not display)	Any time of day without regard to time since last meal
CTL	Testing with the control solution

You can switch between each mode by:

1. Start with the meter turned off. Insert a test strip to turn on the meter, the screen will display a flashing blood drop and Bluetooth symbol, time and date.



2. Press "M" to select General or CTL mode.



Testing with blood sample

CAUTION:

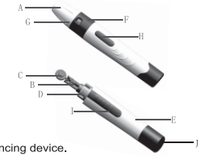
To reduce the chances of infection:

- Choose a clean, dry work surface.
- Never share a lancing device and lancet with another person.
- Always use a new and sterile lancet. Lancets are for single use only.
- Always use a new test strip. Test strip are for single use only.
- Avoid getting lotion, oils, dirt or debris in or on the lancet and lancing device.

Note: Before testing, please read the following steps thoroughly and carefully, please relax and do the test step by step. Simplifying or changing the test procedure may produce inaccurate results.

Overview of the Lancing Device

A.Device Cap
B.Handle
C.Needle Cap
D.Needle Holder
E.Device Body
F.Connecting Collar
G.Adjustable tip
H.Release Button
I .Ejection Button
J .Device control cap on the lancets and the lancing device.



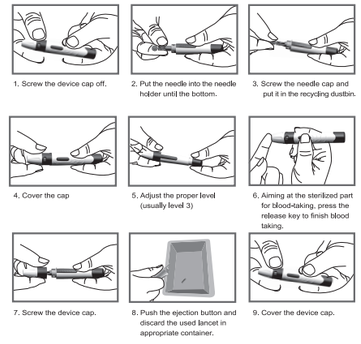
If your lancing device differs from the one shown here, please refer to the manufacturer's manual to ensure proper usage.

NOTE:

To reduce the chance of infection:

- Never share a lancet or the lancing device.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotion, oils, dirt, or debris when handling the lancets.

Setting Up the Lancing Device



NOTE:

The adjustable tip offers 5 levels of skin penetration. Twist the adjustable tip to the proper level:
1-2 level for soft or thin skin
3 level for average skin
4-5 level for thick or calloused skin

Preparing the puncture site

Stimulating blood perfusion by rubbing the puncture site prior to blood extraction has a significant influence on the glucose value obtained. Blood from a site that has not been rubbed exhibits a measurably different glucose concentration than blood from the finger. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced.

Please follow the suggestions below before obtaining a drop of blood:

- Rub the puncture site for about 20 seconds before penetration.
- Select the puncture site at the fingertips.
- Clean the puncture site using cotton moistened with 70% alcohol and let it air dry.

Fingertip testing

Hold the lancing device firmly against the side of your finger. Press the release key. You will hear a click, indicating that the puncture is complete.



NOTE:

- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
- It is recommended to discard the first drop of blood as it might contain tissue fluid, which may affect the test result.

Performing a Blood Glucose Test

Step 1
Wash hands with soap and warm water.

Step 2
Remove a test strip from its vial. With clean, dry hands, you may touch the test strip anywhere on its surface. Do not bend, cut or modify the test strips in any way. Remove the test strip from the vial and use it instantly.

Step 3
Insert the test strip into the meter's test port and the meter is turned on. The screen will display a flashing blood drop and time and date.

NOTE: Be sure to use G-520 blood glucose test strips, other test strips may not produce an accurate result.

Step 4
When the blood drop symbol flashes on the screen, you may select the appropriate measurement mode, for selecting the measurement mode of Control (CTL) or General, please refer to the "The two measuring modes" section.



Step 5
Apply your blood to the absorbent hole of the test strip. For collecting blood sample, please refer to the "Preparing the puncture site" section.

Step 6
As soon as enough blood has filled the confirmation window of the test strip, you will hear a beep letting you know the test has begun. A countdown of 5 seconds starts.

NOTE: You must wait for the end of 5-second count down to see the data display

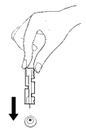
Note: make sure the confirmation window of the Test Strip is completely filled with your blood sample.

Step 7
Your blood glucose level, along date and time appears on the display. Blood glucose results are automatically stored in the memory.



NOTE:
The results obtained from this meter are plasma-calibrated. This helps you and your physician or other qualified healthcare provider to compare your meter results with laboratory tests. Reference to the instructions given by your physician or other qualified healthcare provider, do not deviate from these instructions on the basis of the result without first consulting your physician.

Step 8
Eject the used test strip and remove the lancet. To eject the test strip, point the strip at a disposal container for sharp objects. The meter will switch itself off automatically after the test strip is ejected. Please wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.



Reference value

Time of day	Normal plasma glucose rang for people without
Before breakfast (fasting)	<100 mg/dL
Two hours after meals	<140 mg/dL

Source: American Diabetes Association. Standards of Medical Care in Diabetes—2021 Volume 42 | Supplement 1
Note: Please work with your doctor to determine a target range that works best for you.

Comparing Meter and Laboratory Results

The meter provides you with whole blood equivalent results. The result you obtain from your meter may differ somewhat from your laboratory result due to normal variation. Meter results can be affected by factors and conditions that do not affect laboratory results in the same way. To make an accurate comparison between meter and laboratory results, follow the guidelines below.

Before going to the lab:

- Do a control solution test to make sure that the meter is working properly.
- Comparisons are best when your blood is not changing rapidly; therefore, consult with your physician to determine whether it would be appropriate for you to fast prior to having your blood drawn.

While staying at the lab:

Make sure that the samples for both tests are taken and tested within 15 minutes of each other.
- Wash your hands and then obtain a blood sample.
- Use fresh capillary blood only.

CONTROL SOLUTION TEST

Material needed:
- Stondon G-520 Blood Glucose Meter
- Stondon Blood Glucose Test Strips
- Stondon Glucose Control Solution

When to do a control solution test

- When you suspect that the meter or test strips are not working properly.
- If your blood glucose test results are not consistent with how you feel.
- After the test strips are exposed to extreme conditions (temperature:>104°F or <39.2°F,humidity:>85% or <10%).
- After dropping the meter.
  The control solution is to check that the meter and the test strips can work together as a system and work correctly.

How to do a control solution test

Step 1
Insert the test strip into the meter. Wait for the meter to display the drop symbol.

Step 2
You may press "M" button to select CTL mode, for selecting the CTL mode, please refer to the "The two measuring modes" section.

Step 3
Apply the control solution
Shake the control solution vial thoroughly before use.
Squeeze out a drop and wipe it off, then squeeze another drop and place it on the tip of the vial cap.
Hold the meter to move the absorbent hole of test strip so it touches the drop. Once the confirmation window fills completely, the meter will begin counting down.
To avoid contaminating the control solution, do not directly apply control solution onto a strip.

Step 4
The result of the control solutions test appears on the display. The result will not be stored under CTL mode.
The result of the control solutions test should be within the range printed on the test strip vial label. If the test results falls outside the specified range printed on test strip vial label, repeat the test.
Results falling outside the specified range may be caused by:
- Error in performing the test
- Expired or contaminated Control Solution
- Expired or contaminated Test Strip
- Malfunction of your Meter

If you continue to get control solution test results that fall outside of the range printed on the vial, the system may not be working properly, Do not use the meter. Please contact your customer support immediately.

NOTE:
- Do not use the expired control solution. Only use the Stondon blood glucose control solution.
- Users should periodically review their technique and compare a result obtained with their meter to a result obtained using a laboratory method or a well-maintained and monitored system used by your healthcare provider.

Viewing Results on the Meter

Your meter stores the 500 most recent blood glucose test results with dates and times.
Note: The control solution readings are not included in the average of your results.

Recalling the Stored Test Results

1. Start with the meter off, press the "M" button to turn on the meter. The "M" symbol will flash with the time and date displayed on the screen.

2. Press "M" again, the most recent test results with date and time will display. Press "M" once more and the next most recent test results will appear. Each time you press and release "M", the meter will recall up to your last 500 test results in order. Press the "M" to turn off the meter. When the memory is full, the oldest result is added.

Note: The control solution readings are not included in the average of your results.
When your glucose value is less than 20mg/dL, you will see the following message "Lo"; When your glucose value is high than 600mg/dL, you will see the following message "HI"

Care and storage for your system

- Handle the meter with care. Dropping or throwing the meter may cause damage to the device.
- Don't expose the Stondon G-520 Blood Glucose Monitoring System, Stondon Blood Glucose Test strips and Stondon Blood Glucose Control Solution to extreme conditions, such as high humidity, heat, freezing cold or dust. The storage conditions for the test strips are 39.2°F~104°F, 10%~85%RH. Storage conditions for the meter are-4°F~131°F, ≤93±3%RH.
- Always wash your hands with soap and water and rinse and dry completely before handling the Stondon G-520 Blood Glucose Monitoring System and Test strip.
- Use CLOROX Healthcare® Bleach Germicidal Wipes to clean the Stondon G-520 Blood Glucose Monit oring System.
- Discard the used lancet into a container for sharp objects.

Cleaning and Disinfection

The cleaning and disinfection is absolutely necessary for the test procedure, because cleaning can insure the meter works well (for example, display will be clear to see after cleaning); and disinfection can avoid the infection to you or to the other people, and the cross-infection.
The meter should be cleaned and disinfected at least once a week or when visibly dirty. And we suggest you use the following product: CLOROX Healthcare® Bleach Germicidal Wipes. You can purchase this product according to the following information: visit the web site:https://www.cloroxpro.ca or contact CLOROX

Healthcare at 1-888-200-5674 for product or technical information. You are also available at www.amazon.com or at Walmart store.
The Stondon G-520 blood glucose meter can be cleaned and disinfected by the user twice per day over the 5 year use life of the device, up to 3,650 times. The meter should be cleaned and disinfectedat least once per week.
FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication (2010)
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.html
CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person
Poses Risk for Transmitting Bloodborne Pathogens (2010)
http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

Cleaning procedure
The purpose of cleaning is to remove the dust or organic/inorganic contaminations from the glucose meters. To clean the meter, wipe the entire outer crust of the meters gently with disinfectant towels.
For cleaning procedure, we recommend use CLOROX Healthcare® Bleach Germicidal Wipes. In addition, we recommend cleaning the meters every time after use.
As for the cleaning procedure, please follow the steps below:
Wiping the entire outer crust (including test strips port, data port, strip ejector, LCD Display, M button, and S button) of the meter with CLOROX Healthcare® Bleach Germicidal Wipes.
Air dried the meters and lancing devices carefully in room temperature.

Disinfection procedure
A disinfection procedure is a procedure intended to remove the bloodborne pathogens on the meters. Disinfecting the entire outer crust of the meter with CLOROX Healthcare® Bleach Germicidal Wipes carefully, including screen and button. In order to ensure the blood-borne pathogens were removed by the disinfectant infallibly, it is necessary to keep disinfectant (disinfectant is a chemical that is applied to kill microbes) on the meter for one minute. As for the disinfecting procedure, please follow the steps below:
Wiping the entire outer crust of the meter with CLOROX Healthcare® Bleach Germicidal Wipes and keeps the disinfectant on the meter for one minute.
Carefully air dried the meters in room temperature.
1. Before the test, the user should clean and wash hands. If you are a caregiver, (not the patient), please use disposable gloves.
2. After test, take one wipe to clean the meter's housing, buttons, mark and support block, including its front and back for 10seconds for cleaning until there is no soil on the surface. Then disinfect the meter's housing, buttons, mark and support block use another wipe for 1 min, keep the surface wet for 1 min.

Note:
1. Each disinfection step requires a pre-cleaning step.
2. If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device shall be cleaned and disinfected first.
3. The users should wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.
4. After cleaning / disinfection procedures, the user should look for as signs of physical deterioration, e.g., cracking, swelling, polymer crazing, dissolving,softening, smooth, ridged, brittle & color change and should do a control solution test to check its accurate performance. If these signs of deterioration or out-of-range control solution test results are noted, you should, stop using the device and call toll-free customer support line: 1-800-218-2838,9AM-5PM, Monday through Friday, EST. Call your healthcare professional when it is outside of the above-mentioned hours.

Specification

1. Model: G-520
2. Machine size: 102mm (L)×32mm (W)×13mm(H)
3. Weight: 29.5g (Including batteries)
4. Measuring method: Amperometric technology using glucose oxidase
5. Measuring range: 20mg/dL~600mg/dL(1.1mmol/L~33.3mmol/L)
6. Memory: 500 blood glucose tests
7. Display: LCD display
8. Power source: DC 3V (1*CR2032)
9. Battery Life: Approx. 500 normal tests
10. Storage Condition (system: meter and test strips): 39.2°F~104°F, Humidity:10%~85%RH
11. Storage Condition (meter): -4°F~131°F, Humidity＜93±3%RH
12. Operating conditions: 50°F~104°F, Humidity:10%~85%RH
13. Blood Source: Fresh capillary whole blood from the fingertip
14. Blood Volume: Minimum 0.7 micro liter.
15. Use life: Five years.

DISPLAY MESSAGE

MESSAGE	WHAT IT MEANS	ACTION
	Blood glucose level is lower than 1.1mmol/L (20mg/dL)	The message indicates very low blood sugar. You should consult with your healthcare professional.
	Blood glucose level is higher than 33.3mmol/L (600mg/dL)	This indicates sever hyperglycemia (high blood glucose). You should seek immediate medical assistance.
	Battery power is low.	Please change the battery.
	Use a used test strip.	Please use a new strip and re-test.
	Pull out strip during the testing.	Re-test with a new test strip.
	The meter self-inspection is failure.	Turn on the meter after calibration again.
	Environmental temperature is lower than 10℃(50 ℉) or higher than 40 ℃(104 ℉)	Please test at an environmental temperature within 10~40 ℃ (50~104 ℉) operation range.

Problems

Problems	Causes	Solutions
Display remains blank after the test strip has been inserted into the Meter.	1. Battery may be installed improperly. 2. Battery power is too low tor use. 3. Too much time has passed between inserting the Test Strip and perfor- ming the test. 4. Test Strip has not been fully inserted into the Meter.	1.Install the Battery correctly. 2.Replace with new Battery. 3.Reinsert the Test Strip into the Meter. 4.Reinsert the Test Strip into the Meter.
Test results are incon sistent or Control Solution test results are not withinthe specified range.	1. Not enough sample in the Test Strip. 2. Test Strip or Control Solution has expired. 3. Test Strip has been damaged due to heat or humidity so that sample cannot be applied or the speed of applying sample is too slow. 4. System is not per- forming due to the environment being above or below room temperature.	1. Redo test with new test strip and make sure that enough sample has been added. 2. Redo test with new test strip. 3. Perform a Control Solution test using a new Test Strip. If results are still out of range, replace with new vial of Test Strips. 4. Bring System to a room temperature environment and wait approximately 30 minutes before per- forming a new test.
The Meter countdown did not start.	1.Test Strip has not been inserted correctly. 2.The blood sample volume is not enough .	Use a new Test Strip and redo the test.

Performance Characteristics

Precision

Within Run Precision (300 Venous Blood Tests per Glucose Level)

Glucose concentration interval（mg/dL）		30~50	51~110	111~150	151~250	251~400
YSI Mean (mg/dL)		40,3	89,9	131,5	199,3	323,8
Lot 1	Mean (mg/dL)	40,0	89,7	130,8	200,0	322,1
	SD	2,7	3,1	4,6	7,2	11,1
	CV(%)	6,8%	3,5%	3,5%	3,6%	3,4%
Lot 2	Mean (mg/dL)	40,2	90,2	130,0	199,9	323,2
	SD	2,7	3,1	4,7	6,5	10,9
	CV(%)	6,7%	3,5%	3,6%	3,3%	3,4%
Lot 3	Mean (mg/dL)	40,0	89,9	130,7	201,3	320,9
	SD	2,5	3,1	4,6	7,0	10,1
	CV(%)	6,3%	3,4%	3,5%	3,5%	3,1%
Pooled	Mean (mg/dL)	40,1	89,9	130,5	200,4	322,1
	SD	2,6	3,1	4,6	6,9	10,7
	CV(%)	6,5%	3,5%	3,6%	3,4%	3,3%

Results show that the greatest variability observed between test strips when tested with blood is 3,6% or less.

Between-run Precision

Glucose concentration interval（mg/dL）		30~50	51~110	111~150	151~250	251~400
YSI Mean (mg/dL)		41,9	94,0	131,1	199,2	325,3
Lot 1	Mean (mg/dL)	40,1	90,5	116,8	193,0	315,6
	SD	2,0	2,5	3,2	4,8	6,3
	CV(%)	5,1%	2,8%	2,8%	2,5%	2,0%
Lot 2	Mean (mg/dL)	40,1	90,3	116,9	192,4	314,2
	SD	2,0	2,7	3,2	4,6	6,2
	CV(%)	5,1%	3,0%	2,8%	2,4%	2,0%
Lot 3	Mean (mg/dL)	40,0	89,8	117,3	192,1	315,0
	SD	1,9	2,5	2,9	4,0	6,0
	CV(%)	4,9%	2,8%	2,5%	2,1%	1,9%
Pooled	Mean (mg/dL)	40,1	90,2	117	192,5	314,9
	SD	2,0	2,6	3,1	4,5	6,2
	CV(%)	5,0%	2,9%	2,7%	2,3%	2,0%

Results show that the greatest variability observed between test strips when tested with blood is 2,9% or less.

Lay-user performance study

Your G-520 Meter result may vary slightly from you actual blood glucose value. This may be due to slight differences in technique and the natural variation in the test technology. The chart below shows the results of a study where 351 typical users used the G-520 meter to test their blood glucose level. In this study, the G-520 meter gave result within 15% of their true blood glucose level 346 out of 351 times.

Difference range between the true blood glucose level and the G-520 meter result	Within ±5%	Within ±10%	Within ±15%	Within ±20%
The percent (and number) of meter results that match true blood glucose level within x%	49.29% (173/351)	83.48% (293/351)	98.58% (346/351)	100% (351/351)

Traceability of glucose monitoring system

The results of Stondon G-520 Blood Glucose Monitoring System were compared to parallel results obtained on YSI-2300, which is the manufacturer's standard measurement procedure.

Electrical and safety standards

This meter complies with CISPR 11: Class B (Radiated Only). Emissions of the energy used are low and not likely to cause interference in nearby electronic equipment. The meter has been tested for immunity to Level 3 electrostatic discharge as specified in IEC 61326. This meter complies with immunity to radio frequency interference over the frequency range 80MHz to 2.5GHz at 3V/m as specified in IEC 60601-1-2.

The meter meets the requirements for immunity to electrical interference at the frequency range and test level specified in international standard ISO 15197.

Use of this meter near electrical or electronic equipment that are sources of electromagnetic radiation, may interfere with proper operation of this meter. It is advisable to avoid testing in close proximity to sources of electromagnetic radiation.

Common sources of electromagnetic radiation include mobile phones, walkie talkies or garage door openers.

Do Not use the equipment where aerosol sprays are being used, or when oxygen is being administered.

Symbols

	Consult instructions for use or consult electronic instructions for use		Manufacturer
IVD	In vitro diagnostic medical device		Caution
⚠ Warning	If the instructions are not followed properly, operation may lead to hazards for the product or the user/patient.		

Manufacturer:
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As your partner in diabetes care,
we welcome you to contact us anytime
Telephone: 302-6089028

Date of issue: 2023.10.23
revision control

Item	Version	Description	Release date
1	V1.0	First issued	2023.10.23
2			

611.GS2008-000P