



LinkSun G-425-3 Blood Glucose Monitoring System

User Manual



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 finger. 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.
- 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.
- 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.
- The meter and lancing device are for single patient use. Do not share them with any including other family members! 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.

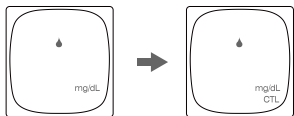
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You can switch between each mode by:

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



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.

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Dear G-425-3 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.

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

- A Meter
- Owner's Manual
- Two AAA Alkaline Batteries (Optional)
- Test Strips
- Lancing Device
- Sterile Lancet
- Control Solution (Optional)

NOTE:

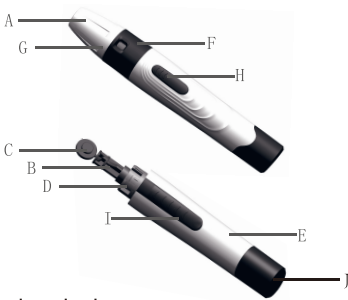
- The Lancing Device can be used for several times, however the sterile lancet should be changed after each use.
- There are three levels for the control solutions: level 1, level 2 and level 3 available, please contact the place of purchase for more information.

If any items are missing from your kit or opened prior to use, please contact local customer services (Toll Free: 302-6089028) or place of purchase for assistance.

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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.

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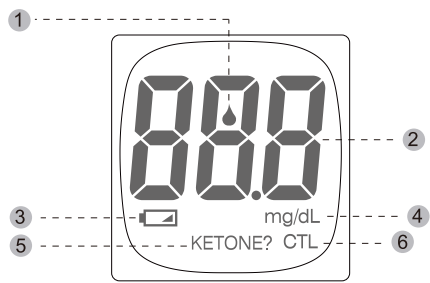
Important safety instructions

- 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.

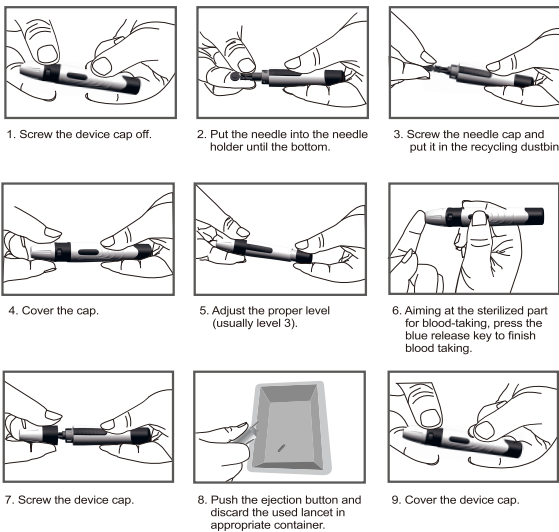
Meter Screen Display Message



- 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.
- 5 KETONE?
Ketone warning. The symbol of "KETONE?" will appear when the test result is equal to or above 240 mg/dL.
- 6 CTL Symbol
Appears when doing a control test and indicates that the result won't be stored in the memory.

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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

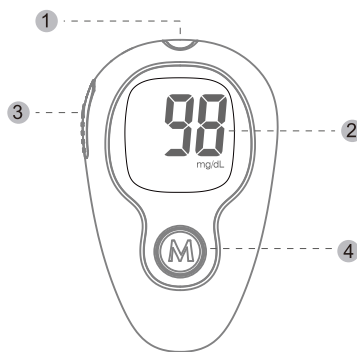
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The following basic safety notice should always be taken:

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

Blood Glucose Meter



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

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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

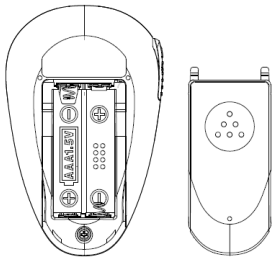
Hold the lancing device firmly against the side of your finger. Press the release key. You will hear a click, indicating that the puncture is complete.



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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 2 new (AAA) batteries with correct +/- direction.
4. Close the battery cover.



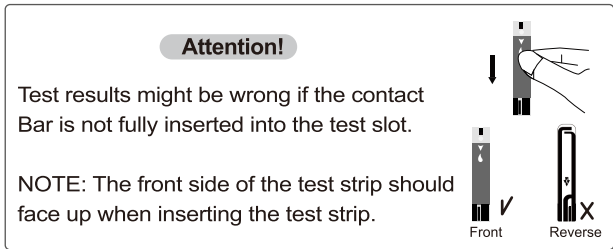
Environment Protection – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice.

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Test Strip

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

- 1 1-Absorbent hole
Apply a drop of blood here. The blood will be drawn in automatically.
- 2 2-Confirmation window
This is where you confirm if enough blood has been drawn into the absorbent hole of the strip.
- 3 3-Test strip handle
Hold this part to insert the test strip into the slot.
- 4 4-Contact bars
Insert this end of the test strip into the meter. Push it in firmly until it will go no further.



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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.
- The lancing device is intended only for a single user and should not be shared.
- You should clean their hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

Performing a Blood Glucose Test

Step 1

Wash hands with soap and water and drying the skin before taking a blood sample.

NOTE: If there are contaminants on the skin, which may be affect results.

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.

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INTRODUCTION TO THE SYSTEM

ABOUT YOUR SYSTEM

Intended Use

- The LinkSun G-425-3 Blood Glucose Monitoring System is comprised of LinkSun G-425-3 Blood Glucose Meter and LinkSun Blood Glucose Test Strips.

- The LinkSun G-425-3 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 LinkSun G-425-3 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 LinkSun G-425-3 Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The LinkSun G-425-3 Blood Glucose Monitoring System is not for use in neonates.

SETTING THE METER AND DELETING THE MEMORY

1. Memory Function:

Short press "M" button, then device will appear the most recent test result after full display for 1 Sec.; Short press "M" button to appear the next most recent test result, you can use such way to review all 500 memories.

2.Deleting the memory

Press and hold "M" button for 5 seconds, device will appear "dEL", release "M" button, "dEL" will flash, press "M" button within 5 seconds to delete all memories, otherwise device 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.

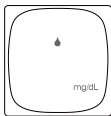
Modes	Use when
General test (not display)	Any time of day without regard to time since last meal
CTL	Testing with the control solution

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NOTE: Be sure to use LinkSun 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:** Make sure the confirmation window of the Test Strip is completely filled with your blood sample.



Step 7

Your blood glucose level will appears on the display. Blood glucose results are automatically stored in the memory.



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NOTE:

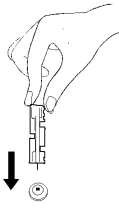
- The results obtained from this meter are plasma-calibrated. This helps you and your physician or other qualified healthcare provider to compare your meter results with laboratory tests. Reference to the instructions given by your physician or other qualified healthcare provider, do not deviate from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

- When your glucose value is less than 20 mg/dL, you will see the following error code “Lo”; When your glucose value is high than 600 mg/dL, you will see the following error code “Hi”.

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.



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.

Specification

1. Model: G-425-3
2. Machine size: 91mm (L)x57mm (W)x22mm(H)
3. Weight: 42.08g(Excluding Batteries)
4. Measuring method: Amperometric technology using glucose oxidase
5. Measuring range: 20mg/dL–600mg/dL
6. Memory: 500 blood glucose tests
7. Power source: DC 3V (AAAx2 alkaline batteries)
8. Battery Life: Approx. 500 normal tests
9. Storage Condition (system: meter and test strips): 39.2°F~104°F(4°C~40°C), Humidity: 10%~85%RH
10. Storage Condition (meter): -4°F~131°F(-20°C~55°C), Humidity≤93%RH
11. Operating conditions: 50°F~104°F(10°C~40°C), Humidity: ≤80%RH
12. Blood Source: Fresh capillary whole blood
13. Blood Volume: Minimum 0.7 micro liter.
14. Use life: five years

Lay-user performance study

Your G-425-3 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-425-3 meter to test their blood glucose level. In this study, the G-425-3 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-425-3 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 G-425-3 Blood Glucose Monitoring System were compared to parallel results obtained on YSI-2300, which is the manufacturer's standard measurement procedure.

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.
- Fast for at least eight hours and then do comparison tests, if possible.
- Take your meter with you to the lab.

Limitations of use:

- The blood Monitoring System is not intended for use on neonates.
- The blood Monitoring System is not intended for use on artery blood, neonates' serum and plasma.
- The system can be used up to an altitude of 10744 feet (3275 meters).
- Patients undergoing oxygen therapy may yield falsely lower 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°C) may lead to incorrect test results.
- High humidity (more than 80%) may lead to incorrect test results

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 61326-1 or IEC 61326-2-6.

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.

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.
- Never use your meter with blood that has been collected in a gray top test tube.
- Use fresh capillary blood only.

Quality control Procedure

Material needed:

- Blood Glucose Meter
- Blood Glucose Test strips
- 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.
- 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.

DISPLAY MESSAGE

Message	What it means	Trobleshooting procedure
	Blood glucose level is lower than 20mg/dL.	The message indicates very low blood sugar. You should consult with your healthcare professional.
	Blood glucose level is higher than 600mg/dL.	This indicates sever hyperglycemia (high blood glucose). You should seek immediate medical assistance.
	Meter is ready to test control solution under the CTL state.	Please place a drop of control solution onto the test well of test strip.
	Battery power is low.	Please change the battery.
	Use a used test strip.	Please use a new strip and re-test.
	Error message indicates that you may remove prematurely the strip after applying blood to the absorbent hole.	Try again with a new test strip.
	Problem with the meter.	Re-test with a new test strip. If the problem is still unsolved, please call the customer care line for help.
	Environmental temperature is lower than 50°F~104°F.	Please test at an environmental temperature within 50°F~104°F operation range.

How to perform quality control 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 directlyapply 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

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 for 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 inconsistent or Control Solution test results are not within the 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 performing 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 performing a new test.
The Meter countdown did not start.	Test Strip has not been inserted correctly.	Use a new Test Strip and redo the test.

If you continue to get quality control 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 (Toll Free: 302-6089028).

NOTE:

- Do not use the expired control solution. Only use the LinkSun 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.

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 Blood Glucose Monitoring System, Test strip, and 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(4°C~40°C), Humidity:10%~85%RH. Storage conditions for the meter are -4°F~131°F(-20°C~55°C), Humidity≤93%RH.
- Always wash your hands with soap and water and rinse and dry completely before handling the blood gucose monitoring system.
- Use CaviWipes (see below) to clean the blood glucose monitoring system.
- Discard the used lancet into a container for sharp objects.

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(%)	6.6%	3.5%	3.5%	3.6%	3.4%
	Mean (mg/dL)	40.2	90.2	130.0	199.9	323.2
Lot 2	SD	2.7	3.1	4.7	6.5	10.9
	CV(%)	6.7%	3.5%	3.6%	3.3%	3.4%
	Mean (mg/dL)	40.0	89.9	130.7	201.3	320.9
Lot 3	SD	2.5	3.1	4.6	7.0	10.1
	CV(%)	6.3%	3.4%	3.5%	3.5%	3.1%
	Mean (mg/dL)	40.1	89.9	130.5	200.4	322.1
Pooled	SD	2.6	3.1	4.6	6.9	10.7
	CV(%)	6.5%	3.5%	3.6%	3.4%	3.3%

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. We strongly warn that the device should be cleaned and disinfected following use on every patient. 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 LinkSun G-425-3 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 disinfected at least once per week.

1. Before the test, the user should clean and wash hands. If you are a caregiver, (not the patient), the please use disposable gloves.
2. After test, take one wipe to clean the meter's housing, buttons, lens and mark, including its front and back for 10 seconds for cleaning until there is no soil on the surface. Then disinfect the meter's housing, buttons, lens, mark, usb cover and support block use another wipe for 2 min, keep the surface wet for 2 min.
3. Take off the glove; discard carefully according to your healthcare provider's instruction.

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%
	Mean (mg/dL)	40.1	90.3	116.9	192.4	314.2
Lot 2	SD	2.0	2.7	3.2	4.6	6.2
	CV(%)	5.1%	3.0%	2.8%	2.4%	2.0%
	Mean (mg/dL)	40.0	89.8	117.3	192.1	315.0
Lot 3	SD	1.9	2.5	2.9	4.0	6.0
	CV(%)	4.9%	2.8%	2.5%	2.1%	1.9%
	Mean (mg/dL)	40.1	90.2	117	192.5	314.9
Pooled	SD	2.0	2.6	3.1	4.5	6.2
	CV(%)	5.0%	2.9%	2.7%	2.3%	2.0%

Manufacturer:
BIOLAND TECHNOLOGY LTD.
No.A6B7 (Block G), Shangrong Industrial Zone,
No.5 Baolong Road, Baolong Community Longgang District, 518116 Shenzhen, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Authorized Representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80,20537 Hamburg, Germany
Tel: +49-40-2513175 Fax: +49-40-255726
E-mail: shholding@hotmail.com

Toll-free Service Line:
As your partner in diabetes care, we welcome you to contact us anytime
Telephone: 302-6089028

US Agent Email:
regrek.cs@hotmail.com

After-sales Email:
Health@LinkSun-co.com

