

Your Welcome Kit includes:

- Livongo Connected Meter (1)
- Livongo Lancing Device (1)
- Livongo Lancets (150)
- Livongo Blood Glucose Test Strips (150)
- Livongo Blood Glucose Control Solution (2)
- Livongo User Guide / Instructions for Use (1)
- AC Adapter (Wall Charger) and USB Cable (Set)
- Travel Case (1)



Livongo for Diabetes User Guide



Welcome to the Livongo for Diabetes program.
This guide will help you get started in less than
5 minutes. If you have any questions, please call
Member Support at **(800) 945-4355** or email us
at **membersupport@livongo.com**. We're available
24 hours a day, seven days a week.

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The Livongo for Diabetes Program

The Livongo for Diabetes program is a new approach to diabetes management designed to empower you to make better decisions. The program includes: the Livongo connected blood glucose meter, unlimited test strips and lancets, access to coaches at any time, personalized insights, and much more. Get started to discover all the benefits.

Getting Started

The Livongo meter comes ready to use right out of the box and is already charged and ready for your first blood sugar check.

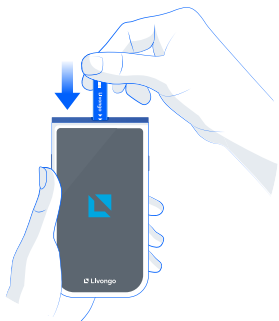
Note: *If you have cellular connectivity, your meter's date and time will be automatically updated after you do your first check.*



Before checking your blood sugar and to ensure accurate results, wash your hands with soap and water and dry them thoroughly.

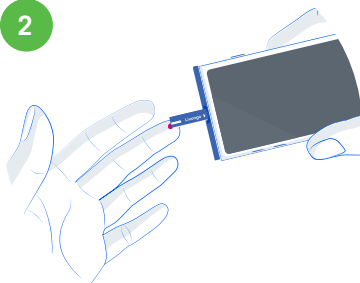
Checking Your Blood Sugar

1



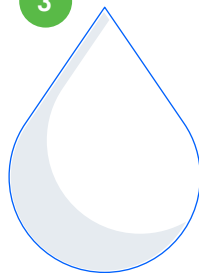
Place your meter on a flat surface, then insert a test strip.

2



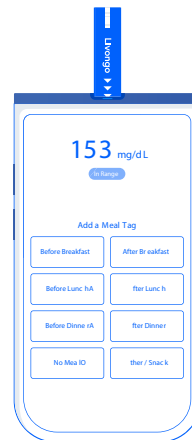
When your meter displays “Apply blood to the strip,” apply a drop of blood into the strip chamber. (See page 11 for instructions on how to use the lancing device.)

3



Wait while your meter checks your blood sugar. (Do not move or touch the screen of your meter during this time.)

4



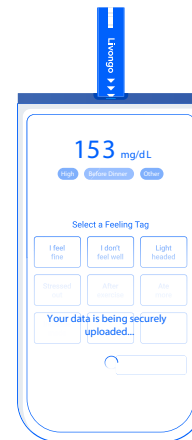
Choose a meal tag.

5



Select a tag that describes how you're feeling.

6



Click “Submit” to securely upload your blood sugar reading and tags (meals and feelings) to your Livongo account.

Accessing Your Data

You can access your data on the Livongo meter by tapping **See More** on the home screen data card.

Charging the Livongo Meter

Your Livongo meter is powered by a rechargeable battery. You'll receive a notification on the meter when your battery level is low. To charge it, plug the charger cord with power adapter attached into the port on the left side of the meter. The meter will show the progress on the screen. Please note that you won't be able to perform a blood sugar check while it's charging. Do not plug in your charging cord while performing a blood sugar check.

 **Please wait for 30 minutes after charging the Livongo meter to check your blood sugar.**

The service life of the battery depends on the service time and frequency. It can generally be charged and discharged at least 400 times.

Use only the Livongo-supplied AC adapter and USB cable to charge the Livongo meter. Avoid charging your meter in extreme high or low temperatures.

Power On / Power Off / Sleep Mode

- To power on your Livongo meter when it is completely off, press and hold the power button for 2 seconds.
- To conserve battery, your Livongo meter will go to sleep automatically after a period of inactivity. You can also put the meter to sleep by tapping the power button.
- To completely power off your Livongo meter for extended periods of non-use or storage, press and hold the power button for 2 seconds and then select **Power Off** on the screen.

To ensure the best experience possible, we recommend keeping your Livongo meter in sleep mode instead of completely powered down during normal usage periods. In sleep mode, your Livongo meter will wake up automatically when you insert a test strip.

Storing the Livongo Meter

The Livongo meter is best stored in the Livongo travel case included in the Welcome Kit. The case is designed to protect the device and help you carry everything you need to check your blood sugar. You can even check without removing the meter from the case.

Using the Livongo Lancing Device

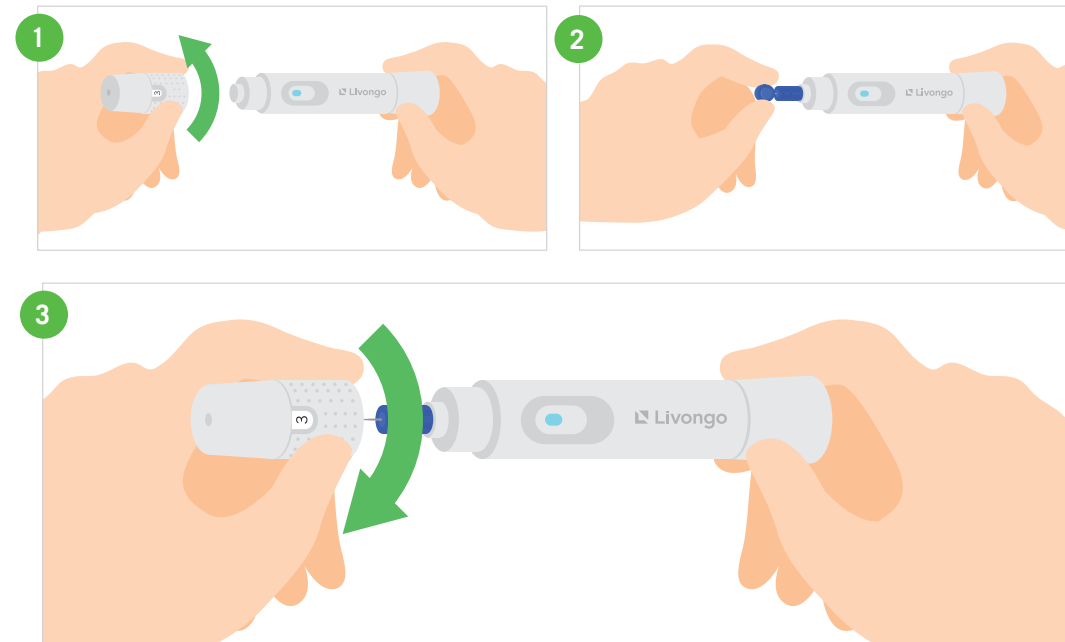
The Livongo lancing device is simple to use. Please follow these instructions:

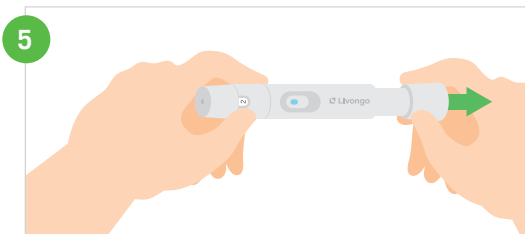
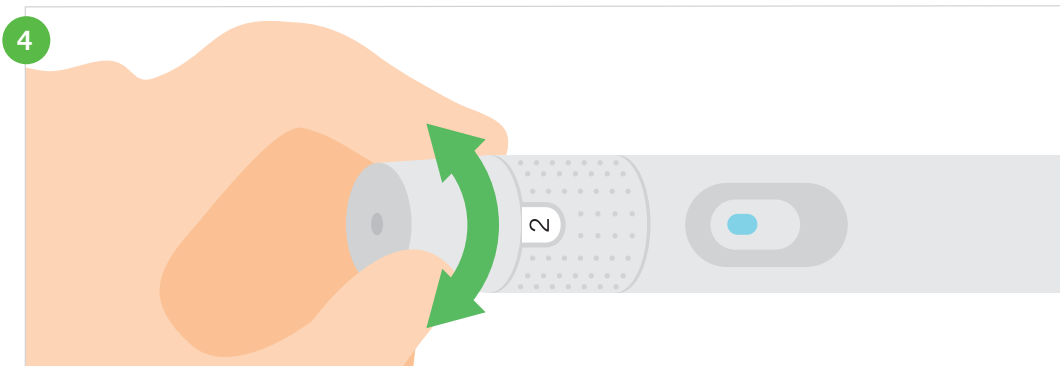
- 1. Remove the lancing device cap:** Remove the cap by turning it counterclockwise and then pulling it straight off the lancing device.
- 2. Insert a lancet:** Align the lancet so that it fits into the lancet holder. Push the lancet into the device until it snaps into place. Twist the protective cover until it separates from the lancet.
- 3. Replace the lancing device cap:** Place the cap on the lancing device and turn clockwise to secure the cap. Avoid contact with the exposed lancet.



Useful Tips:

- Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume.
- Rotating fingers helps avoid callus build up, which will make drawing blood easier.
- Prior to checking, wash your hands with soap and water and dry them thoroughly. Use warm water to increase blood flow in your fingers.





Using the Livongo Lancing Device (Cont.)

4. Adjust the depth setting: The lancing device has 11 puncture depth settings, numbered 0 through 5. Smaller numbers are for a shallower puncture. Turn the depth wheel to choose the setting.

Tip: A shallower puncture may reduce discomfort. It is recommended that you start with a shallower setting and increase the depth until you get an adequate drop of blood. Greater pressure of the lancing device against your finger will also increase the puncture depth.

5. Cock the lancing device: Pull the cocking barrel back to set the lancing device. The release button will turn light blue and you may hear a click.

6. Puncture your finger: Hold the lancing device firmly against the side of your finger. Press the release button to prick your finger. Remove the lancing device from your finger.

Important Safety Instructions

Please take a minute to read through this important safety information. Remember, this is a medical device and it needs to be used with caution and care.

Warnings

- ❑ Keep your Livongo meter and supplies away from children at all times. The blood glucose test strips and lancets are choking hazards and could be inhaled or swallowed. The USB charging cable could get entangled with your child and cause strangulation or asphyxiation.
- ❑ Do NOT puncture, drop, crush, microwave, incinerate, paint, or insert foreign objects into the Livongo meter.
- ❑ Do NOT use fire to dispose of your Livongo meter. The battery may explode and may cause serious injury.
- ❑ The Livongo meter and lancing device are for single patient use. For safety reasons, do not share them with anyone, including your family members.
- ❑ All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after being cleaned and disinfected.
- ❑ Always wash your hands thoroughly with soap and water and dry well after handling your Livongo meter, test strips, lancets, or lancing device.
- ❑ Do NOT try to open and change the Livongo meter's battery. It is built in and not changeable.

- ❑ Do NOT use your meter in close proximity to sources of strong electromagnetic radiation.
- ❑ Other equipment could interfere with the Livongo meter, even if the other equipment complies with CISPR8 emission requirements.

Precautions

- ❑ Do NOT use with any accessories that are not specified or certified by Livongo. If the equipment is used in a manner not specified by Livongo, the protection provided by the equipment may be impaired.
- ❑ Use only the Livongo-supplied AC adapter and USB cable to charge the Livongo meter. Avoid charging your meter in extreme high or low temperatures. For replacement of the AC adapter or USB cable, contact Livongo Member Support.
- ❑ Do NOT open, tamper with, repair, disassemble, or abuse your Livongo meter. There are NO user serviceable parts inside your device.
- ❑ Do NOT attempt to clean or use the Livongo meter while it is being charged.
- ❑ Your device can be used indoors or outdoors, but avoid exposing your device to high temperatures, humidity, moisture, cold, dust, or dirt. If your device is exposed to temperatures outside the stated operating and storage temperatures, move it to a room environment, and wait 30 minutes before using.
- ❑ Dispose of the Livongo meter and accessories according to local regulations after their service lives. They can also be returned to the manufacturer for recycling or proper disposal.
- ❑ Use of the Livongo meter in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.) may cause damaging static discharges that may hinder in the transfer of the readings.

Important Symbols

	Biological risks		Includes control solution
	Consult instructions for use		Temperature limitation
	In vitro diagnostic medical device		Use by date
	Caution, consult accompanying documents		Humidity limitation
	Catalog number		Atmospheric pressure limitation
	Keep away from sunlight		Keep dry
	Direct current		

Troubleshooting Error Messages

In the event of an error while checking your blood sugar, an error message will appear on your meter screen. Before troubleshooting, ensure your supplies are within the expiration date and have not been open for more than six months.

Blood Applied Too Quickly	Blood was applied to the test strip prior to the meter displaying "Ready to Check Blood Sugar." Please use a new test strip and try again. If the error persists, please contact Member Support.
Test Strip Contaminated/ Used or Blood Applied Too Quickly	The test strip that you are using is contaminated or used, or the blood sample was applied too quickly. Ensure that blood was not applied to the test strip prior to inserting it into the meter. Also ensure that blood was not applied to the strip prior to the meter displaying "Ready to Check Blood Sugar." Please use a new test strip and try again. If the error persists, please contact Member Support.
Insufficient Blood Sample or Late Re-dosing	Not enough blood was applied to the test strip to give an accurate reading. Ensure that you do not re-dose blood to the strip after applying your initial sample. Please use a new test strip and try again. If the error persists, please contact Member Support.
Glucose Strip Coding Error	Please remove and re-insert the test strip. If the error is repeated, please insert a new test strip from the same vial and try again. If the error persists, please contact Member Support.

Troubleshooting Error Messages (Cont.)

In the event of an error while checking your blood sugar, an error message will appear on your meter screen.

Temperate Too High	The temperature is above 113°F, which is too high to give an accurate reading.
Temperature Too Low	The temperature is below 41°F, which is too low to give an accurate reading.
Test Strip Removed	If the strip is removed before a reading can be obtained, you'll receive this error message. Please fully remove the strip and try again with a new strip.
Hematocrit Error	This error may occur when an air bubble gets trapped in the siphon while blood is being applied to the test strip, or when your hematocrit level is below 20% or above 70%. Please use a new test strip and try again. If the error persists, talk to your doctor to learn more about your hematocrit level. The Livongo meter operates in the hematocrit range of 20% to 70%. Very high (above 70%) and very low (below 20%) hematocrit levels can cause false results.
Severely High: > 600 mg/dL	The Livongo meter can measure blood glucose accurately from 40 mg/dL to 600 mg/dL. If your blood glucose is higher than 600 mg/dL, the screen will display this message. Please use a new test strip and try again. If you see this message after testing again, please call your doctor.

Troubleshooting Error Messages (Cont.)

In the event of an error while checking your blood sugar, an error message will appear on your meter screen.

Severely Low: < 40 mg/dL	The Livongo meter can measure blood glucose accurately from 40 mg/dL to 600 mg/dL. If your blood glucose is lower than 40 mg/dL the screen will display this message. Please use a new test strip and try again. If you see this message after testing again, please call your doctor.
Internal Calibration Error	Please turn off the meter for 30 seconds and turn it back on. If the error persists, contact Member Support.
Internal Meter Error	Please turn off the meter for 30 seconds and turn it back on. If the error persists, contact Member Support.
Meter CRC Error	Repeat the blood glucose check with the same test strip. If the error persists, contact Member Support.
Communication Error	If you are not in cellular range, your blood glucose results will not be transmitted. The results will be stored in the meter's memory and transmitted once the meter is in cellular range and able to establish a connection.

If you have any questions about your Livongo meter, please contact Member Support at **(800) 945-4355** or email us at **membersupport@livongo.com**. We are available 24 hours a day, seven days a week.

Cleaning and Disinfecting the Livongo Meter

CAUTION: Do NOT disinfect the meter with any product containing bleach.

Pre-Cleaning and Disinfection of the Meter

Before disinfecting the meter, please first use a PDI Super Sani-Cloth Germicidal Disposable Wipe (EPA Registration No. 9480-4) to pre-clean the entire meter surface by removing any stains or debris. This pre-cleaning process is for preparing the meter surface to be ready for disinfection process.

After pre-cleaning, please use another wipe to disinfect the meter. Wipe the entire meter thoroughly and leave the surface wet according to the contact time listed below.

Disinfection Wipe	EPA Registration No.	Contact Time
PDI Super Sani-Cloth Germicidal Disposable Wipe	9408-4	2 minutes

NOTE: Only the disinfectant listed should be used on the device for the lifespan of the device. The effect of using more than one disinfectant interchangeably has not been evaluated.

After disinfection wiping, please allow the meter to air dry completely before using the meter again.

Avoid inserting any wipes into the inside of the strip port and data port when performing the pre-cleaning and disinfection procedure.

Intended Use for Disinfection and Pre-Cleaning Before Disinfection

The disinfection process is for preventing potential transmitting of infectious diseases through bloodborne pathogens. The pre-cleaning process is to ensure the removal of any stains or debris so that effective disinfection can be achieved for the meter surface.

You should also wash your hands thoroughly with soap and water after handling the meter and test strips.

Disinfection Wipes Material and Where to Buy Them

The materials suitable for the Livongo meter pre-cleaning and disinfection are listed on the next page.

Cleaning and Disinfecting the Livongo Meter (Cont.)

Disinfection Wipe	EPA Registration No.	Active Ingredients	Where to Purchase
PDI Super Sani-Cloth Germicidal Disposable Wipe	9408-4	Isopropyl alcohol 55%,n-alkyl dimethyl benzyl ammonium chlorides 0.25%, n-alkyl dimethyl ethyl benzyl ammonium chloride 0.25%	Available through online retailers such as www.amazon.com

Pre-Cleaning and Disinfection Frequency

Your Livongo meter should be cleaned and disinfected once a week. If someone else is helping you test, the meter should be disinfected prior to operation by that person. Your meter has been tested for 260 cycles of the cleaning and disinfection process (one disinfection cycle per week for 5 years).

Your meter has been tested to withstand the pre-cleaning and disinfection process during the 5-year meter life based on the operation frequency mentioned above.

However, if you have any problem with your meter, please contact Member Support at **(800) 945-4355** or email us at membersupport@livongo.com.

Note: All parts of the kit are considered bio-hazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection. Please follow proper precautions when handling your meter.

No signs of meter deterioration in appearance or performance were observed after 260 cycles of the recommended pre-cleaning and disinfection procedure. However, you should always inspect your meter after performing the cleaning and disinfection procedure. External signs of meter deterioration might include polymer crazing (thin silver streaks), cracking, swelling, dissolving, softening, or becoming brittle. Signs of meter performance deterioration might include buttons not functioning properly, audio not working, missing display segments, error messages during testing, or control solution test results that are out of range.

If any signs of external or performance deterioration are observed on your meter after cleaning and disinfection, please stop using your meter and lancing device and contact Member Support at **(800) 945-4355** for assistance.

If you have any questions about your Livongo meter, please contact Member Support at **(800) 945-4355** or email us at **membersupport@livongo.com**. We are available 24 hours a day, seven days a week.

Appendix

Specifications and Limitations

Specifications

- Test measured: Blood glucose
- Glucose methodology: Glucose oxidase biosensor
- Glucose test results: mg/dL (Plasma values)
- Result Calibration: Plasma-equivalent, calibrated by using YSI (Model 2300 STAT PLUS) Glucose Analyzer reference instrument, which is traceable to NIST reference standard.
- Sample: Capillary whole blood from fingertip
- Measuring range: 40–600 mg/dL
- Acceptable hematocrit range: 20% to 70%
- Length of test: 5 seconds
- Test strip volume: 0.6 µL
- Weight: 5.0 oz (142 g) (Batteries included)
- Size 5.0 x 2.5 x 0.5 in (130 x 60 x 12.7 mm)
- Livongo-supplied AC adapter
 - Input voltage range: 100~240 Vac
 - Input frequency: 50~60 Hz
 - AC input current 0.2A(rms) Max. @115Vac
 - Output Voltage 5V  1A
- Livongo BG1000 Firmware

Operating

- Temperature (blood): 41°F to 113°F (5°C to 45°C)
- Temperature (control): 50°F to 104°F (10°C to 40°C)
- Humidity: 10% to 90% relative humidity
- Altitude: up to 10,000 ft (3,048 m)
- Meter data storage: 1,000 results

Electrical & Power Ratings

- Rechargeable Li-ion Battery, 3.85V, 2400mAh, 9.24Wh
- Maximum current (Battery): 2A peak
- USB charging input: 5V  1A continuous

Environmental

- The storage temperature range for the meter: 36°F to 95°F (2°C to 35°C).
- The storage temperature range for the test strips and control solution: 36°F to 95°F (2°C to 35°C).
- The storage humidity range: 10% to 90% non-condensing.

FCC Statement



This device, model BG1000, complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by Livongo Health, Inc. could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to

provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

- Consult Livongo Health or an experienced radio/TV technician for help.

Interference from external equipment has not been found to affect the Livongo meter.

Radiofrequency radiation exposure Information:

The device uses cellular radio frequency technology to accomplish required communications with Livongo's server. The device communicates with Livongo's server only in three circumstances: when used to check blood glucose (which typically happens up to 8 times per day); before the device goes to sleep

(which follows every blood glucose check); when used to share a summary report (which typically happens every 1-3 months).

The average human exposure to such radio frequency radiation remains far below the regulatory limits set by the US Federal Communications Commission (FCC) provided that the device is used at positions as instructed in this manual during communication with Livongo's server.

California Proposition 65 Warning

THIS PRODUCT CONTAINS CHEMICALS KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER AND BIRTH DEFECTS OR OTHER REPRODUCTIVE HARM.

Warranty

Your Livongo connected meter is guaranteed to be free of material and workmanship defects for one (1) year from the date of receipt (except as noted below). If at any time during the first year after purchase, your meter does not work for any reason (other than as described below), it will be replaced with a new meter free of charge.

Limitations On Warranty

This warranty is subject to the following exceptions and limitations:

- This warranty is applicable only to the original purchaser.
- This warranty does not apply to units

that malfunction or are damaged due to obvious abuse, misuse, alteration, neglect, unauthorized maintenance or failure to operate meter in accordance with instructions.

- We have no knowledge of the performance of the Livongo meter when used with test strips other than Livongo Strips. Therefore, we make no warranty as to the performance of the Livongo meter when used with any test strips other than Livongo Test Strips.
- There is no other express warranty for this product. The option of replacement, described above, is Livongo's only obligation under this warranty.

For Warranty Service

Please contact Member Support at (800) 945-4355.

Privacy Policy

As the manufacturer of Livongo meter, we are committed to securing your personal information responsibly and in compliance with the law. Learn more at: <https://my.livongo.com/common/docs/privacy-practices.pdf>



BLOOD GLUCOSE MONITORING SYSTEM

Instructions for Use

Materials Provided

- Test Strips
- Lancing Device
- Meter
- Sterile Lancets
- Control Solution

Contents

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BLOOD GLUCOSE MONITORING SYSTEM

PRINCIPLE AND INTENDED USE

The Livongo Blood Glucose Monitoring System is comprised of the Livongo Blood Glucose Meter and Livongo Blood Glucose Test Strips. The Livongo Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips. The Livongo Blood Glucose Monitoring System is intended for self-testing by people with diabetes at home as an aid to monitoring the effectiveness of diabetes control programs. The Livongo Blood Glucose Monitoring System is intended for single-patient use and should not be shared. The Livongo Blood Glucose Monitoring System is for in vitro diagnostic use. The Livongo Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes, nor intended for use on neonates.

The Livongo Blood Glucose Monitoring Systems use electrochemical methodologies that use a reagent system that includes glucose dehydrogenase (FAD-GDH) and a mediator that reacts with the glucose in the whole blood sample obtained from the fingertip, forearm, and/or palm to produce an electrical current signal. This current is measured using an amperometric detection method. The meter then calculates and displays the blood glucose concentration reading, calibrated to plasma reference.

BLOOD GLUCOSE TEST STRIPS

PRINCIPLE AND INTENDED USE

The Livongo blood glucose test strips are used with the Livongo meter in the quantitative measurement of glucose in fresh whole capillary blood from the fingertip. The Livongo meter is intended for use by people with diabetes at home as an aid to monitor the effectiveness of a diabetes control program and should not be used for the diagnosis of or screening for diabetes mellitus or for neonatal use. The blood glucose test strips are thin strips. The strips have a chemical reagent system. They work with the Livongo meter to measure the glucose level in whole blood. Blood is applied to the end tip of the test strip. The blood is then absorbed into the reaction cell. This is where the reaction takes place. A transient electrical current is formed during the reaction and detected by the meter. The amount of glucose is then calculated based on this current. The result is shown on the meter display. The meters are calibrated to display plasma equivalent results. The system is used to monitor how well a diabetes control program works. The blood glucose test strips can be used only outside the body. They are to be used by persons with diabetes for self-testing purposes.

BLOOD GLUCOSE TEST STRIPS

Composition

Each test strip has reactive and non-reactive chemicals. These chemicals are: FAD-dependent Glucose Dehydrogenase <25 IU, Mediator <300 µg, Buffer, and Non-reactive Ingredient. Each test strip vial contains a drying agent.

Storage and Handling

- Test strips should be kept in their vial. The cap must be tightly closed to keep the test strips in working condition.
- Store in a cool, dry place between 36°F–95°F (2°C–35°C) and 10%–90% relative humidity and keep out of direct sunlight.
- Do not freeze or refrigerate.
- For accurate results use the test strips at room temperature.
- Keep the text side up and blank side down when you insert the strip into the strip port.
- Do not store or use the test strips in a humid place such as a bathroom.

BLOOD GLUCOSE TEST STRIPS

- Do not store any part of the system near bleaches or cleaners that contain bleaches.
- Do not move the test strips to a new vial or any other container.
- Repeated insertion and removal of a test strip into the meter strip port may cause errors.
- Replace the vial cap as soon as you take a test strip out.
- Use the test strip as soon as it is taken out of the vial.
- Do not use your test strips past the unopened expiration date printed on the vial. Using test strips past the expiration date may cause inaccurate results.
Note: All expiration dates are printed in Year-Month-Date format. 2020-01-30 means January 30, 2020.
- A new vial of test strips may be used for 6 months after first being opened. After 6 months they will expire. Write the opened vial expiration date on the vial label after opening.

Precautions

- For in vitro diagnostic use. The test strips are to be used only outside the body for testing purposes.
- Your Blood Glucose Meter is for single patient use. Do not share it with others including family members. Remember to follow the required pre-cleaning and disinfection procedure. This procedure is important to prevent the potential transmission of infectious diseases.

BLOOD GLUCOSE TEST STRIPS

- Do not use test strips after the expiration date that is shown on the vial. Expired test strips may give an incorrect result.
- Do not use test strips that are torn, bent, or damaged.
- Do not reuse test strips.
- Apply sample only to the tip of the test strip. Do not apply to the top of the test strip. This may result in a false reading.
- Discard the vial and any unused test strips 6 months after you first open it. Constant exposure to air may destroy chemicals in the test strip. This can cause false readings.
- Keep the test strip vial away from children and animals.
- Consult your doctor before making any changes to your treatment plan.

Please contact Member Support at **800.945.4355** for information about ordering more test strips.

BLOOD GLUCOSE TEST STRIPS

Instructions for Use

1. Open the cap of the test strip vial and take out a test strip. Replace the cap to protect the other test strips.
2. Run the test following the instructions on page 7.
3. The blood glucose test result will be shown on the meter display. This result should fall within the target range recommended by your doctor. If your blood glucose test results are higher or lower, ask your doctor what to do. Always consult your doctor before changing your treatment plan.
Note: The system reads glucose in whole blood within the range of 40 mg/dL–600 mg/dL. If a result is below 40 mg/dL, the meter will display “Severely Low.” If a result is above 600 mg/dL, the meter will display “Severely High.”

Range of Expected Values

Blood glucose monitoring requires the help of a doctor. Together you can set your own range of expected blood glucose values. You can also arrange your testing times. In addition, you should discuss the meaning of your blood glucose results together. Expected blood glucose levels for people without diabetes:¹

BLOOD GLUCOSE TEST STRIPS

Time	Range, mg/dL	Range, mmol/L
Fasting and Before Meals	70 – 100	3.9 – 5.6
2 Hours After Meal	Less than 140	Less than 7.8

Checking the System

Be careful with your blood glucose meter. Do a quality control test to make sure that the meter and test strips are working well together. Two ranges CTRL 1 and CTRL 2 are shown on the test strip vial label. Control Solution 1 is sufficient for most all self-testing needs. If you think your meter or strips may not be working correctly, you may also want to do a level 2 test. Contact Customer Support for information on purchasing control solution.

You should confirm your control solution results. Make sure the Control Solution 1 tests fall within the CTRL 1 range. Make sure the Control Solution 2 tests fall within the CTRL 2 range. When testing with Control Solution 1, make sure you are matching the results to the CTRL 1 range on the vial label.

Caution: If your quality control test result falls outside the control range shown on the test strip vial, DO NOT use the system to test your blood. The system may not be working properly. If you cannot correct the problem, contact Customer Support for help.

BLOOD GLUCOSE TEST STRIPS

Limitations

- The Livongo meter, test strips, and other components have been designed, tested and proven to work together effectively to provide accurate blood glucose measurements. Do not use components from other brands.
- The Livongo meter should not be used to test critically ill patients, and the Livongo meter should not be used to test neonates.
- The Livongo blood glucose test strips test fresh capillary whole blood from the fingertip. Do not use with serum or plasma samples.
- The Livongo Blood Glucose Monitoring System is for self-testing by users to test fresh capillary blood from the fingertip.
- Very high (above 70%) and very low (below 20%) hematocrit levels can cause false results. Talk to your doctor to find out your hematocrit level.
- The system is tested to accurately read the measurement of glucose in whole blood within the range of 40 mg/dL–600 mg/dL.
- Fatty substances have no major effect on test results. These include triglycerides up to 3,000 mg/dL or cholesterol up to 500 mg/dL.

BLOOD GLUCOSE TEST STRIPS

- Acetaminophen, uric acid, and ascorbic acid (vitamin C) (when occurring in blood at normal or high therapeutic concentration) do not significantly affect results. However, abnormally high concentration in blood may cause inaccurately high results.
- The Livongo Blood Glucose Monitoring System has been tested to work properly up to 10,000 ft (3,048 meters).
- Blood samples from patients in shock, severe dehydration, or a hyperosmolar state (with or without ketosis) have not been tested. It's not recommended to test those samples with The Livongo Blood Glucose Monitoring System.
- Dispose of blood samples and materials with care. Treat all blood samples as if they are infectious materials. Follow all local regulations.
- All parts of the kit are considered biohazardous and potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

Performance Characteristics

The precision and accuracy of the Livongo meter is calibrated by using an YSI (Model 2300 STAT PLUS) Glucose Analyzer as the reference instrument. It is traceable to the NIST reference standard.

BLOOD GLUCOSE TEST STRIPS

Reproducibility, Precision

[X] replicate assays were each run on [X] Livongo meters. Heparinized venous blood samples at [X] concentration levels were used in the testing. The results of all [X] lots combined provided the following estimates.

MEAN Blood Glucose, mg/dL	SD	%CV
[X]	[X]	[X]
[X]	[X]	[X]
[X]	[X]	[X]
[X]	[X]	[X]
[X]	[X]	[X]

Intermediate Precision

[X] replicate assays from [X] strip lots were run on [X] Livongo meters. These tests were run each day for a total of [X] days. Control solutions at [X] concentration levels were used in the testing. The results combined from the [X] strip lots provided the following estimates.

BLOOD GLUCOSE TEST STRIPS

#	MEAN	Standard Deviation mg/dL or Coefficient of Variation (CV)
All [X] Lots Combined	[X] mg/dL	[X] mg/dL
	[X] mg/dL	[X]%
	[X] mg/dL	[X]%

System Accuracy

System accuracy studies were conducted independently using lay users. Each individual subject obtained their own fingertip sample and self-tested their blood glucose with the Livongo meter on [X] lots of test strips. Blood was taken from [X] users. The fingertip samples from the same subjects were then analyzed on an YSI Model 2300 STAT PLUS Glucose Analyzer that served as the reference standard to determine the system accuracy of the Livongo meter in the hands of lay persons. The results presented below are the results from the first replicates obtained by lay persons using the Livongo meter and Livongo blood glucose test strips.

BLOOD GLUCOSE TEST STRIPS

Linear Regression Results: Livongo™ (y) vs. YSI Reference (x) Lay User					
Sample Site	Slope	Intercept	R	R ²	N
Fingertip	[X]	[X]	[X]	[X]	[X]

The sample range was [X] to 391.5 mg/dL for Livongo meter testing with blood sampled from fingertip sites.

Lay User Fingertip Site: System Accuracy Results for Glucose Concentration ≥75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
[X]/[X] ([X]%)	[X]/[X] ([X]%)	[X]/[X] ([X]%)	[X]/[X] ([X]%)
Lay User Fingertip Site: System Accuracy Results for Glucose Concentration <75mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
[X]/[X] ([X]%)	[X]/[X] ([X]%)	[X]/[X] ([X]%)	

For additional questions or issues with this product, please contact Member Support at **800.945.4355**. Member Support is available 24 hours a day, 365 days a year.

BLOOD GLUCOSE CONTROL SOLUTION

Principle and Intended Use

Livongo control solution contains a known concentration of glucose. It is used to confirm that your Livongo meter and test strips are properly working together. It also confirms that you are performing the test correctly.

You should perform a quality control test:

- Before you use your meter for the first time. This will help you get used to this test.
- Before using a new box of test strips.
- When you suspect that the meter or test strips are not working properly.
- When you suspect that your test results are inaccurate. Or if they do not match with how you feel.
- If you suspect your meter is damaged.
- At least once a week.
- After cleaning your meter.

BLOOD GLUCOSE CONTROL SOLUTION

Two levels of control solution are available. They are Control Solution 1 and Control Solution 2. Control Solution 1 is sufficient for most self-testing needs. If you think your meter or strips may not be working correctly, you may also want to do a level 2 test.

Composition

Control solution 1 contains less than 0.2% glucose (active ingredient). Control Solution 2 contains less than 0.4% glucose (active ingredient). Both have preservatives in an aqueous based mixture.

Storage and Handling

- Store the control solution at 36°F–95°F (2°C–35°C).
- If the control solution is cold, do not use until it has warmed to room temperature.
- Use before the unopened expiration date that is shown on the bottle.

Note: All expiration dates are printed in Year/Month format. 2020/01 indicates January 2020.

- Use the control solution only for 6 months after you first open it. The control solution will expire 6 months after the bottle is opened for the first time. Record this opened expiration date on the bottle label.

BLOOD GLUCOSE CONTROL SOLUTION

Precautions

- For in vitro diagnostic use. Use the control solution to test only outside the body. Do not swallow or inject. For self-testing use.
- Shake well before using.
- To get accurate results, do control solution testing between 50°F and 104°F (10°C–40°C).
- The control ranges shown on the test strip vial are not a recommended range for your blood glucose level. Figure out your personal blood glucose target ranges with your doctor.
- Do not touch the end of the test strip to the control solution bottle. This could cause contaminants to enter the bottle.
- Use only Livongo brand control solution with your Livongo meter and test strips.

Please contact Member Support at **800.945.4355** for more information on obtaining a control solution kit.

BLOOD GLUCOSE CONTROL SOLUTION

INSTRUCTIONS FOR USE

1. Insert a new test strip to turn on the meter.
2. Shake the control solution bottle thoroughly.
3. Squeeze the control solution bottle gently. Discard the first drop. If the tip clogs, tap the tip gently on a clean, hard surface. Shake again, and then use.
4. Squeeze out a second small drop on a clean nonabsorbent surface. Touch the sample tip of the test strip to the control solution drop. Ensure the strip gets enough sample.

Notes: Do not apply control solution to the test strip straight from the bottle. If the control solution sample does not completely fill the check window, do not add a second drop. Discard the test strip and start over with a new test strip.

5. Read the result from the meter display. The meter will automatically detect the control solution and mark it as a control test separate from normal blood glucose test results.

EXPECTED RESULTS

Make sure the control solution test results are in the control range. The ranges for both CTRL 1 and CTRL 2 are displayed on the test strip vial. For confirmation of results, Control Solution 1 tests should fall within

BLOOD GLUCOSE CONTROL SOLUTION

the CTRL 1 range. Control Solution 2 tests should fall within the CTRL 2 range. If the test results are in the respective ranges, this means your Livongo Blood Glucose Monitoring System is working right and you are doing the procedure correctly.

If the control solution test results do not fall within the respective ranges:

- Check the expiration date of the test strip and control solution. Make sure that the test strip vial and the control solution bottle have not been open for more than 6 months. Throw away any expired test strips or control solution.
- Make sure you are testing at a temperature between 50°F and 104°F (10°C–40°C).
- Make sure that the test strip vial and the control solution bottle have been tightly capped.
- Confirm that you are using Livongo control solution.
- Make sure that you followed the test procedure correctly.

After checking everything listed above, repeat the control solution test with a new test strip. If your results still fall outside the range indicated on the test strip vial label, your meter may not be working properly. DO NOT use the system to test blood. For questions or issues with this product, please contact

LANCING DEVICE



Member Support at **800.945.4355**. Member Support is open 24 hours a day, 365 days a year.

Principle and Intended Use

The Livongo lancing device is used with compatible disposable sterile lancets to draw capillary blood from the fingertip for blood glucose testing. The lancing device is intended to be used by a single patient and should not be shared.

Instructions for Use

Before testing, choose a clean, dry work surface. Familiarize yourself with the procedure and make sure you have all the items needed to obtain a drop of blood.

Important: Prior to testing, wipe the test site with an alcohol swab or soapy water. Use warm water to increase blood flow if

LANCING DEVICE

necessary. Then dry your hands and the test site thoroughly. Make sure there is no alcohol, soap or lotion on the test site.

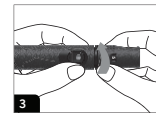
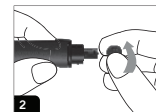
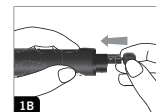
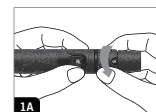
The lancing device is for fingertip sampling only. Adjust the depth penetration to reduce the discomfort.

1A-1B Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancing device and push it until the lancet comes to a complete stop in the lancing device.

2. Hold the sterile lancet firmly in the lancing device and twist the safety tab of the lancet until it loosens, then pull the safety tab off the lancet. Save the safety tab for lancet disposal.

3. Carefully screw the cover back onto the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully sealed on the lancing device.

LANCING DEVICE



4A-4B. Adjust the puncture depth by rotating the lancing device cover. There are a total of 11 puncture depth settings. To reduce discomfort, use the lowest setting that still produces an adequate drop of blood.

ADJUSTMENT:

0–1.5 for delicate skin • 2–3.5 for normal skin • 4–5 for calloused or thick skin

Note: Greater pressure of the lancing device against the finger will also increase the puncture depth.

5. Pull the cocking barrel back to set the lancing device. The release button will turn yellow and you may hear a click. The lancing device is now loaded and ready for obtaining a drop of blood.

6A-6B. Prior to testing, wipe your hands with an alcohol swab or wash your hands with soap. Use warm water to increase blood flow



LANCING DEVICE

in your fingers if necessary. Then dry your hands thoroughly. Massage the hand from the wrist up to the fingertip a few times to encourage blood flow.

7A-7B. Hold the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick your fingertip. You should hear a click as the lancing device activates. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume. Avoid smearing the drop of blood.

For the greatest reduction in pain, lance on the sides of the fingertips. Rotation of sites is recommended. Repeated punctures in the same spot can make your fingers sore and callused.

8. Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface and carefully insert the lancet needle into the safety tab.
9. Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward to discard the used lancet. Place the lancing device cover back on the lancing device.

LANCING DEVICE

CARE OF THE LANCING DEVICE

Cleaning and Disinfection

First use DisCide Ultra Disinfecting Towelettes to clean the entire device surface. This pre-cleaning is to prepare the device surface for a disinfection process. Then use another fresh DisCide Ultra Disinfecting Towelette to wipe the entire lancing device surface. Make sure the lancing surface is thoroughly damp. This disinfection process has been validated through repeated disinfection cycles equivalent to 5 years of lancing device usage.

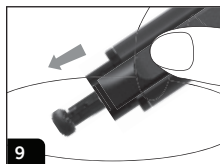
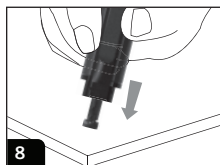
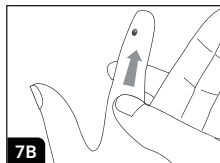
DisCide Ultra Disinfecting Towelettes are available at internet retailers such as **www.amazon.com**.

Precautions

- Do not use the lancet if the safety tab is missing or loose when you take the lancet out of the bag.
- Do not use the lancet if the needle is bent.
- Use with caution whenever the lancet needle is exposed.

LANCING DEVICE

- Do not share with anyone 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.
- In order to reduce the risk of infection from prior use of the instrument, always use a new, sterile lancet. Do not reuse lancets.
- Avoid getting the lancing device or lancets dirty with hand lotion, oils, dirt, or debris.



REFERENCES

1. American Diabetes Association (Standards of Medical Care in Diabetes – 2018. Diabetes Care, January 2018, vol. 41, Supplement 1, S13-S27).
2. “FDA Public Health Notification: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication,” <http://wayback.archive-it.org/7993/201701111013014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>, 2010.
3. “Infection Prevention during Blood Glucose Monitoring and Insulin Administration,” <http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>.

LIMITED WARRANTY

If the lancing device does not work for any reason other than obvious abuse in the first 5 years after purchase, we will replace it with a new or equivalent lancing device free of charge. Please contact Member Support at **800.945.4355** for more information.

CONTACT INFORMATION

Meter Manufactured by Livongo Health

**Test Strips, Lancing Device, Lancets, and Control
Solution Manufactured for Livongo Health by:**

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Made in China

Distributed by:



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