

Lingo Glucose Biosensor

**READ ALL THE LABELING PROVIDED WITH THIS PRODUCT
BEFORE HANDLING THE LINGO BIOSENSOR KIT PARTS.**

Glucose is used by the body for energy, and glucose levels in the blood naturally rise and fall in response to food and activity. Continuous glucose tracking can help users understand the impact of food, exercise and other lifestyle factors on glucose levels.¹ The Lingo Biosensor provides continuous glucose measurements for up to 14 days.² For more information, visit www.helloingo.com

Indications for Use

The Lingo Glucose System is an over-the-counter (OTC) integrated Continuous Glucose Monitor (iCGM) intended to continuously measure, record, analyze and display glucose values in people 18 years and older not on insulin. The Lingo Glucose System helps to detect euglycemic and dysglycemic glucose levels. The Lingo Glucose System may also help the user better understand how lifestyle and behavior modification, including diet and exercise, impact glucose excursion.

The user is not intended to take medical action based on the device output without consultation with a qualified health care professional.

Compatible Devices

For a list of compatible devices that can be used with the Lingo Biosensor and to view the User's Manual, please go to:
www.support.hellolingo.com

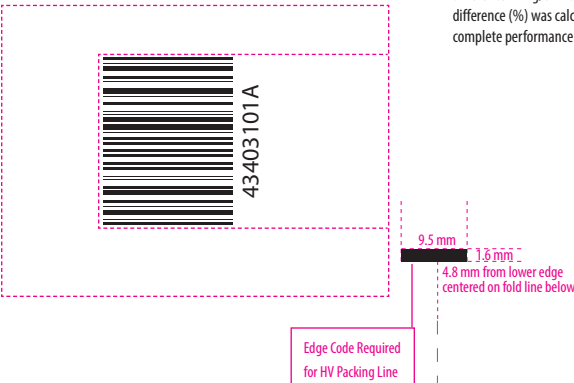
WARNING:

- This System must **NOT** be used for diagnosis of disease including diabetes.
 - Do not take medical action based on your data without health care professional oversight.
- Medical action is defined as activities undertaken in consultation with or under the guidance of a licensed health care professional to screen, diagnose, treat, cure, mitigate, prevent or monitor a disease or other medical condition.
- Consult your health care professional before making changes to your diet or exercise regime or if you have an eating disorder or a history of eating disorders.
 - Don't use if you have problematic hypoglycemia. The Lingo Glucose System hasn't been designed for these populations.
- Consult with your health care provider to discuss which Abbott product is right for you.
- **⚠️** If you have a medical appointment that includes strong magnetic or electromagnetic radiation, for example an X-ray, MRI (Magnetic Resonance Imaging), diathermy or CT (Computed Tomography) scan, remove the Lingo Biosensor you are wearing and apply a new one after the appointment.

CAUTION:

- **Choking hazard:** The Lingo Biosensor contains small parts that may be dangerous if swallowed.
- Before using the Lingo Biosensor, review all product information and take standard precautions to avoid contamination through transmission of blood borne pathogens.
- You can only use the system if you are 18 years of age and older and not on insulin.
- Biosensor insertion under the skin may cause bruising or bleeding.
- Clean your hands prior to handling or applying the Lingo Biosensor to prevent infection.

- Your Lingo Biosensor may become loose if you bump it, play contact sports, or sweat a lot. If the Lingo Biosensor is becoming loose or if the Lingo Biosensor tip is coming out of your skin, you may get no readings or unreliable readings; the Lingo Biosensor may self-terminate in this instance. Remove and replace your Lingo Biosensor if it starts to loosen and follow the instructions to select an appropriate application site. Do not attempt to reinsert the Lingo Biosensor. Contact Customer Service if your Lingo Biosensor becomes loose or falls off before the end of the wear period.
- If you believe your glucose readings are not correct or are inconsistent with how you feel, contact your HCP. If the problem continues, remove the current biosensor, apply a new one, and contact Customer Service.
- Do not reuse Lingo Biosensors. The Lingo Biosensor and Lingo Biosensor Applicator are designed for single use. Reuse may result in no glucose readings and infection. Not suitable for re-sterilization.
- The Lingo Biosensor Pack and Lingo Biosensor Applicator are packaged as a set and have the same biosensor serial number. All digits must match. Check that the biosensor serial numbers match before using your Lingo Biosensor Pack and Lingo Biosensor Applicator. Do not use Lingo Biosensor Packs and Lingo Biosensor Applicators with different biosensor serial numbers together as this will result in incorrect glucose readings.
- Some individuals may be sensitive to the adhesive that keeps the Lingo Biosensor attached to the skin. If you notice significant skin irritation around or under your Lingo Biosensor, remove the biosensor and stop using the biosensor. Consult your health care professional before applying a new Lingo Biosensor.
- Change the application site for the next Lingo Biosensor application to prevent discomfort or skin irritation.
- Only apply the Lingo Biosensor to the back of the upper arm. If placed in other areas, the Lingo Biosensor may not function properly.
- Make sure that your devices and Lingo Biosensor kits are kept in a safe place, and maintain your devices under your control during use. This is important to help prevent anyone from accessing or tampering with the System.
- If a Lingo Biosensor breaks inside your body, call your health care professional.
- The Lingo Biosensor can be worn for up to the wear duration specified. Remember to always have a new next Lingo Biosensor available before your current one ends so you can keep getting your glucose readings.
- The System is designed to detect certain conditions which may occur where the Lingo Biosensor is not working as intended and shut it off, telling you to replace your Lingo Biosensor. This may occur if the Lingo Biosensor gets knocked off from the skin or if the System detects that the Lingo Biosensor may not be performing as intended. Contact Customer Service if you receive a Replace biosensor message before the end of the wear duration specified by your Lingo Biosensor instructions.
- Do not use the Lingo Biosensor if you are on dialysis or critically ill. It is not known how different conditions or medications common to these populations may affect performance of the System.
- Performance of the Lingo Biosensor when used with other implanted medical devices, such as pacemakers, has not been evaluated.



User Safety, Storage, and Handling

- The Lingo Biosensor Pack is sterile and non-pyrogenic unless opened or damaged. Using a non-sterile or pyrogenic biosensor might cause infection.
- Store the Lingo Biosensor package between 36°F (2°C) and 82°F (28°C). Storage outside of this range may cause inaccurate biosensor glucose readings.
- If you suspect that the temperature may exceed 82°F (28°C) (for example, in an air-conditioned home in summer), you should refrigerate your Lingo Biosensor package. Do not freeze your Lingo Biosensor package
- Store the Lingo Biosensor package between 10-90% non-condensing humidity.
- Store your Lingo Biosensor package in a cool, dry place. Do not store your Lingo Biosensor package in a parked car on a hot day.
- Your Lingo Biosensor is water-resistant and can be worn while bathing, showering, or swimming. Your Lingo Biosensor has been tested to withstand immersion into 3 feet (1 meter) of water for up to 30 minutes. It is also protected against insertion of objects >12 mm diameter. (IP27)
- Do NOT use if Lingo Biosensor package contents are past expiration date.
- The System is intended for use by a single person. It must not be used by more than one person due to the risk of misinterpreting glucose information.

Security Information

- You are responsible for properly securing and managing your phone. If you suspect an adverse cybersecurity event related to the Lingo app, please contact customer service.
- The Lingo app is not intended for use on a phone that has been altered or customized to remove, replace, or circumvent the manufacturer's approved configuration, use restrictions, or otherwise violates the manufacturer's warranty.
- The Lingo app should only be downloaded and/or updated through the official Apple App Store.
- Please contact customer service if you suspect your Biosensor or its packaging have been tampered with.

Interfering Substances

- Taking more than 1000 mg of Vitamin C per day may falsely raise your Lingo Biosensor readings. Vitamin C can be found in supplements including multivitamins and cold remedies such as Airborne® and Emergen-C®. See your health care professional to understand how long Vitamin C is active in your body.

Disposal

This product should be disposed of in accordance with all applicable local regulations related to the disposal of electronic equipment, batteries, sharps, and materials potentially exposed to body fluids.

Accuracy Summary

The following table shows the System's accuracy at different CGM glucose ranges vs. YSI (Yellow Springs Instrument) blood glucose values in the adult population. For blood glucose values < 70 mg/dL, the difference in mg/dL was calculated. For values ≥ 70 mg/dL, the relative difference (%) was calculated. Please refer to the User's Manual for complete performance data.

Accuracy to YSI within CGM Glucose Ranges

CGM Glucose Level	Percent Within ± 15 mg/dL	Percent Within $\pm 15\%$	Percent Within ± 20 mg/dL	Percent Within $\pm 20\%$
<70	91.5		95.2	
70-180		82.1		90.0
>180		86.5		91.8

System range is 55-200 mg/dL

Reference and Note:

¹Thomas, F., C. G. Pretty, T. Desai, J. G. Chase. 2016. Blood glucose levels of subelite athletes during 6 days of free living. *Journal of Diabetes Science and Technology*. 10(6):1335-1343. <https://pubmed.ncbi.nlm.nih.gov/27301981/>

² A study was conducted to assess the biosensor life where 77.1% of biosensors lasted the full 14 days. In other words, when using the product per the package labeling, approximately 22.9% of biosensors may not last for the full 14 days. 14.7% of biosensors may last less than 11 days.

2.17"

2.33"

2.17"

2.17"

2.33"

2.17"

IMPORTANT: Before using your Lingo Biosensor Pack and Lingo Biosensor Applicator, make sure you have an alcohol wipe (70% isopropyl alcohol) on hand to prepare the application site.

- 1:** Select site on back of upper arm. Do not use other sites as these may result in inaccurate glucose readings. Avoid areas with scars, moles, stretch marks, or lumps.
- 2:** Wash site using a plain soap, dry, and then clean with alcohol wipe. This will help remove any oily residue that may prevent the Lingo Biosensor from sticking properly. Allow site to air dry before proceeding.
- Note:** The area **MUST** be clean and dry following these instructions, or the Lingo Biosensor may not stay on for the full wear duration.

- 3:** Peel lid completely off Lingo Biosensor Pack. Unscrew cap from Lingo Biosensor Applicator.

CAUTION: Biosensor serial numbers must match on Lingo Biosensor Pack and Lingo Biosensor Applicator. All digits must match. Do NOT use if damaged or already opened.

- 4:** Line up dark marks on Lingo Biosensor Applicator and Lingo Biosensor Pack. On a flat hard surface, press down firmly on Lingo Biosensor Applicator until it comes to a stop.

- 5:** Lift Lingo Biosensor Applicator out of Lingo Biosensor Pack.

- 6:** Lingo Biosensor Applicator is ready to apply biosensor.

CAUTION: Lingo Biosensor Applicator now contains a needle. Do not touch inside Lingo Biosensor Applicator or put it back into Lingo Biosensor Pack.

Note:

- Step 6 shows the loaded applicator, the Lingo Biosensor is now ready to be applied.
- It has a small, flexible tip that inserts just under your skin to measure your glucose for up to 14 days.²
- No calibration with blood glucose values is needed!

- 7:** Place Lingo Biosensor Applicator over site. Push down firmly to apply biosensor.

CAUTION: Do NOT push down on Lingo Biosensor Applicator until placed over prepared site to prevent unintended results or injury.

- 8:** Gently pull Lingo Biosensor Applicator away.
- Note:** Applying the Lingo Biosensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the Lingo Biosensor, and consult your doctor.

- 9:** Make sure Lingo Biosensor is secure. Put the cap back on the Lingo Biosensor Applicator. Discard used Lingo Biosensor Applicator and Lingo Biosensor Pack according to local regulations.

Note: Review all labeling provided with the Lingo Biosensor and compatible product before use.

Starting your Lingo Biosensor with the App

1. Check that your phone is connected to a network (WiFi or cellular). You can then download Lingo app from the App Store (iPhone).
2. Open the App and follow onscreen instructions to complete setup and accept the requested permissions.
3. When setup is complete, you'll be prompted to scan the Sensor to start it. You can check your glucose after the 60 minute start-up period.

Lingo Biosensor - FCC ID: QXS-LINBS1
This device 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.
Changes or modifications not approved by Abbott could void the user's authority to operate the equipment.

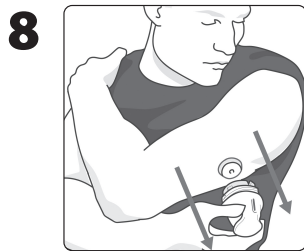
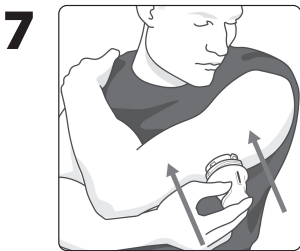
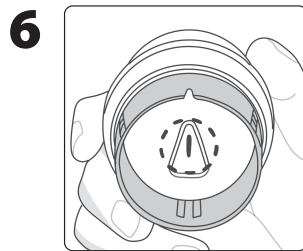
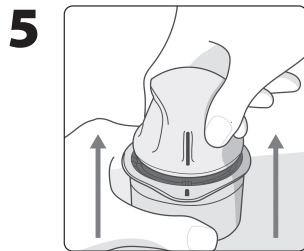
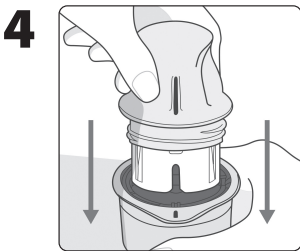
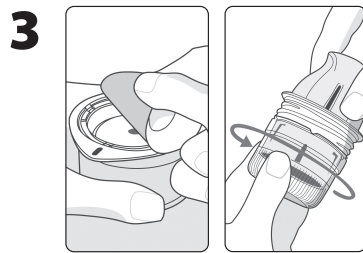
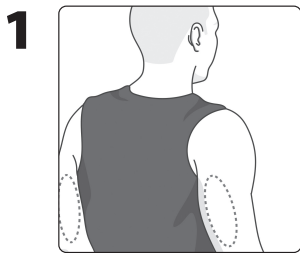


Lingo Biosensor Pack



Lingo Biosensor Applicator

The Lingo Biosensor initially comes in two parts: one part is in the Lingo Biosensor Pack and the other part is in the Lingo Biosensor Applicator. Follow the instructions to prepare and apply the Lingo Biosensor on the back of your upper arm. The Lingo Biosensor has a small, flexible tip that is inserted just under the skin. The Lingo Biosensor can be worn for up to 14 days.² The Lingo Biosensor is intended for use by persons 18 years and older not on insulin.



Labeling Symbols

	Do not use if package is damaged.
	Do not re-use
	Sterilized using irradiation
	Caution
	Use-by date
	Serial number
	Temperature limit
	Type BF applied part
	Manufacturer
	Consult instructions for use
	Batch code
	Catalog number
	Humidity limitation
	MR unsafe
	This product contains electronic equipment, batteries, sharps and materials that may contact bodily fluids during use. Dispose of product in accordance with all applicable local regulations.

To the extent allowed by law, the Lingo Glucose Biosensor is provided to you "as is." Abbott hereby disclaims all warranties (express, implied, and statutory) with respect to the Lingo Biosensor, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. There are no warranties which extend beyond the description on the face hereof.

Customer Service:
1-888-764-7684
7 Days a Week from 9am to 9pm Monday through Friday Eastern Time and 9am to 5pm Saturday and Sunday Eastern Time; excluding holidays
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