Abbott

Lingo
GLUCOSE SYSTEM

User's Manual

English

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Abbott

User's Manual

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 healthcare professional.

Compatible Devices

For a list of compatible devices that can be used with the Lingo Biosensor, please go to: http://www.support.hellolingo.com

Getting to Know Your Lingo Glucose System

The Lingo Glucose System has two main parts: a disposable Lingo Biosensor and the Lingo app. When they're in range of each other, the Lingo Biosensor will automatically communicate to the Lingo app and display your glucose readings. When the Lingo Biosensor is out of range or unable to communicate with the Lingo app, the Lingo Biosensor will store glucose data for the whole wear duration of the Lingo Biosensor, and automatically send the data to the App when the devices are back within range.

Lingo Count helps you track your meals, exercise and other activities in correlation to your glucose exposure allowing you to meet your health and wellness goals.

Lingo Biosensor Kit

Note: When opening your Lingo Biosensor Kit, check that the contents are undamaged and that you have all parts listed. If any parts are missing or damaged, contact Customer Service. Customer Service is available at 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.

The Lingo Biosensor Kit includes:

- Lingo Biosensor Pack
- Lingo Biosensor Applicator
- Product Insert

Follow the provided instructions for use to apply the Lingo Biosensor to the back of your upper arm. The Lingo Biosensor measures and stores glucose readings when worn on your body. The Lingo Biosensor has a small, flexible tip that is inserted just under the skin. The Lingo Biosensor can be worn for up to the wear duration specified by your Lingo Biosensor instructions.

Note: The Lingo Biosensor Pack is sterile and non-pyrogenic unless opened or damaged. Using a non-sterile biosensor may cause infection.

Important Safety Information

Warnings

- 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 (HCP) 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 HCP 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.

Cautions and Limitations

What to know about using the System:

- Before using the System, review all product information and take standard precautions to avoid contamination through transmission of blood borne pathogens.
- 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.
- **Choking hazard:** The System contains small parts that may be dangerous if swallowed.

Who should not use the System:

- You can only use the system if you are 18 years of age and older and not on insulin.
- Do not use the System 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 System when used with other implanted medical devices,

such as pacemakers, has not been evaluated.

⚠ What should you know about wearing a Lingo Biosensor:

- The Lingo Biosensor can be worn for up to the wear duration specified within your Lingo Biosensor instructions. Remember to always have your 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.
- 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 System. Consult your HCP before applying a new Lingo Biosensor.
- 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.
- 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.
- 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)
- If a Lingo Biosensor breaks inside your body, call your HCP.

How to Store the Biosensor Kit:

- Store the Lingo Biosensor Kit between 36°F and 82°F. Storage outside of this range may cause inaccurate biosensor glucose readings.
- If you suspect that the temperature may exceed 82°F (for example, in an un-airconditioned home in summer), you should refrigerate your Lingo Biosensor Kit. Do not freeze your Lingo Biosensor Kit.
- Store your Lingo Biosensor Kit in a cool, dry place. Do not store your Lingo Biosensor Kit in a parked car on a hot day.
- Store the Lingo Biosensor Kit between 10-90% non-condensing humidity.

When not to use the System:

- Do NOT use if the Lingo Biosensor Kit package, Lingo Biosensor Pack, or Lingo Biosensor Applicator appear to be damaged or already opened due to risk of no results and/or infection.
- Do NOT use if Lingo Biosensor Kit contents are past expiration date.
- The Lingo Biosensor Pack is sterile and non-pyrogenic unless opened or damaged. Using a non-sterile or pyrogenic Lingo Biosensor might cause infection.

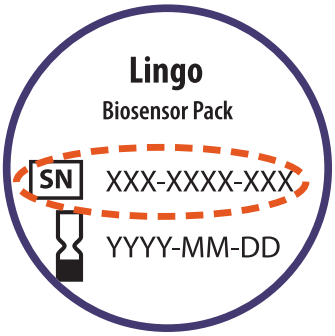
What to know about the System:

- 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.

What to know before you apply the Lingo Biosensor:

- Biosensor insertion under the skin may cause bruising or bleeding.
- Clean hands prior to biosensor handling/insertion to help prevent infection.
- Wash application site on the back of your upper arm using a plain soap, dry, and then clean with an 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. Carefully preparing the site according to these instructions will help the Lingo Biosensor stay on your body for the full wear period and help prevent it from falling off early.

- 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.



- 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.
- Select an appropriate Lingo Biosensor site to help the biosensor stay attached to the body and prevent discomfort or skin irritation. Avoid areas with scars, moles, stretch marks, or lumps. Select an area of skin that generally stays flat during normal daily activities (no bending or folding).

⚠ What to know about X-Rays:

- 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 biosensor you are wearing and apply a new one after the appointment.

⚠ When to remove the Lingo Biosensor:

- 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.

- 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.

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 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.

Applying your Lingo Biosensor

CAUTION: Intense exercise may cause your Lingo Biosensor to loosen due to sweat or movement of the biosensor. 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 low readings. 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.

IMPORTANT: Before using your Lingo Biosensor Applicator, make sure you have an alcohol wipe (70% isopropyl alcohol) on hand to prepare the application site. This is not included in the Biosensor Kit.

When opening your kit, check that the contents are undamaged and that you have all parts listed. If any parts are missing or damaged, contact Customer Service. Customer Service is available at 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.

The Lingo Biosensor (only visible after applied) is initially in two parts: one part is in the Lingo Biosensor Pack and the other part is in the Lingo Biosensor Applicator. Once prepared and applied to your body, the Lingo Biosensor measures your glucose using a small, flexible tip that inserts just under the skin. The biosensor can be worn for up to 14 days. 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.

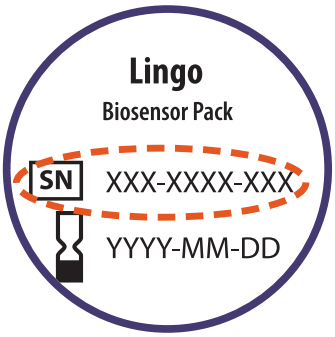
Note: The Lingo Biosensor Pack is sterile and non-pyrogenic unless opened or damaged. Using a non-sterile or pyrogenic biosensor might cause infection.

Lingo Biosensor Pack. Used with the Lingo Biosensor Applicator to prepare the Lingo Biosensor for use.

Lingo Biosensor Applicator. Applies the biosensor to your body.

CAUTION:

- The Lingo Biosensor Pack and Lingo Biosensor Applicator are packaged together 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.



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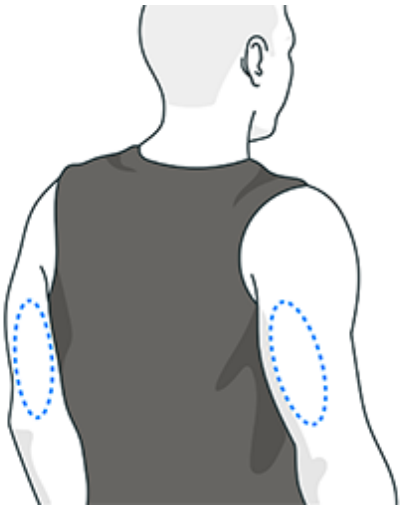
1. Apply Lingo Biosensors only on the back of your upper arm. If placed in other areas, the Lingo Biosensor may not function properly and could give inaccurate readings. Avoid areas with scars, moles, stretch marks or lumps. Select an area of skin that generally stays flat during your normal daily activities (no bending or folding). To prevent discomfort or skin irritation, you should select a different site other than the one most recently used.

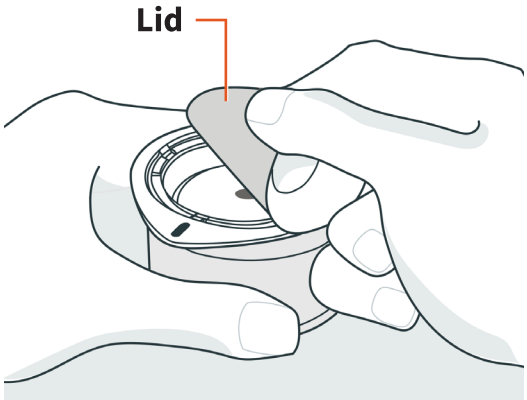


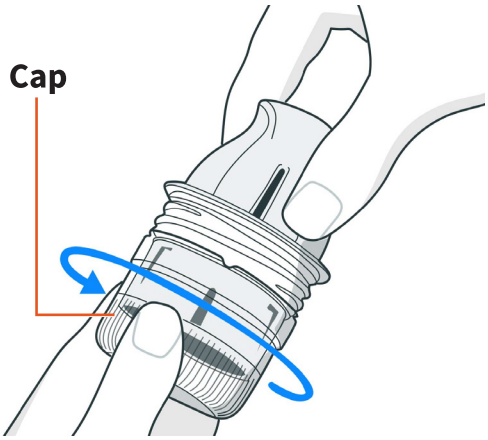
2. Wash application site using a plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the Lingo Biosensor from sticking properly. Allow site to air dry before proceeding.

   Note: The area **MUST** be clean and dry following these instructions, or the Lingo Biosensor may not stay on for the full wear duration.

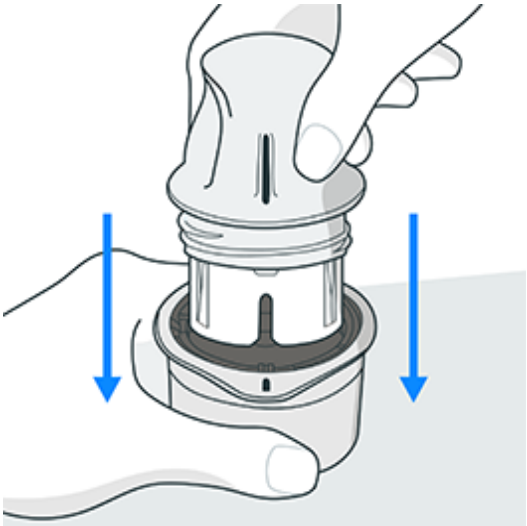
3. Open the Lingo Biosensor Pack by peeling the lid off completely. Unscrew the cap from the Lingo Biosensor Applicator and set the cap aside.

   CAUTION: Do NOT use if the Lingo Biosensor Pack or Lingo Biosensor Applicator seem to be damaged or already opened. Do NOT use if past expiration date.

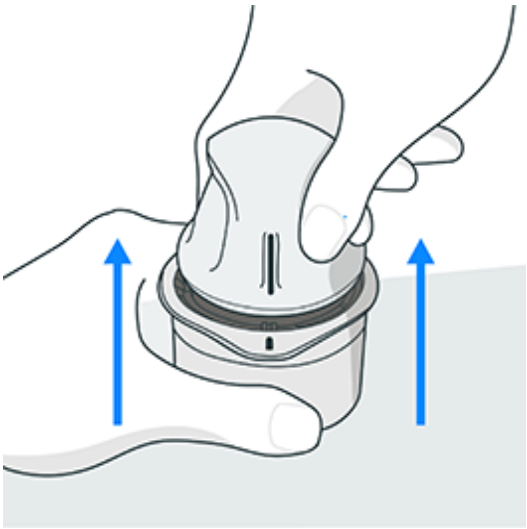




4. Line up the dark mark on the Lingo Biosensor Applicator with the dark mark on the Lingo Biosensor Pack. On a flat hard surface, press down firmly on the Lingo Biosensor Applicator until it comes to a stop.



5. Lift the Lingo Biosensor Applicator out of the Lingo Biosensor Pack.

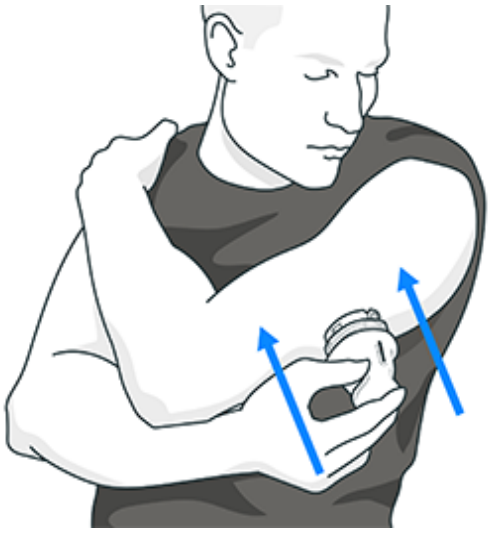


6. The Lingo Biosensor Applicator is prepared and ready to apply the biosensor.

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

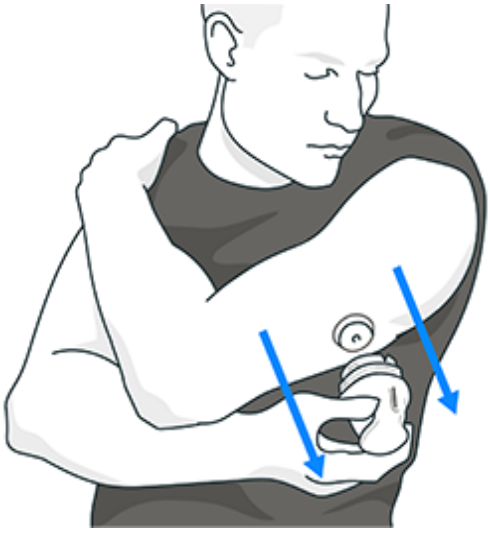
7. Place the Lingo Biosensor Applicator over the prepared site and push down firmly to apply the biosensor to your body.

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



8. Gently pull the Lingo Biosensor Applicator away from your body. The Lingo Biosensor should now be attached to your skin.

   Note: Applying the Lingo Biosensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the Lingo Biosensor, and contact your health care professional.

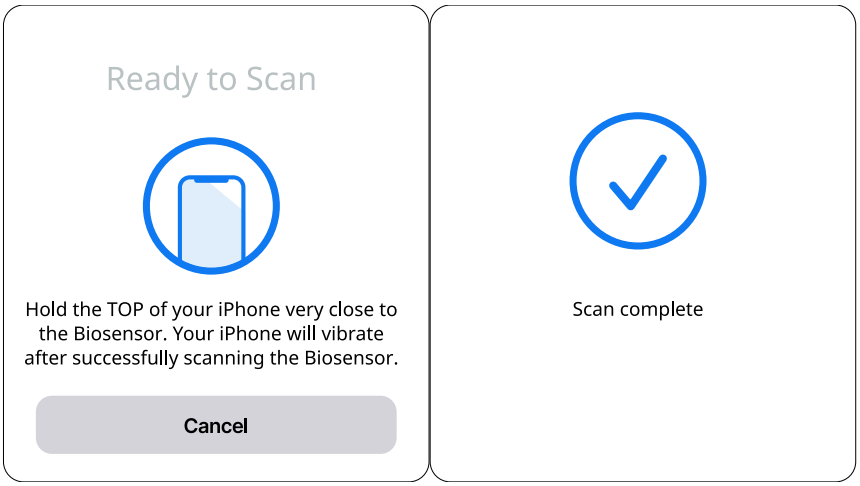


9. Make sure Lingo Biosensor is secure after application. Put the cap back on the Lingo Biosensor Applicator. Discard the used Lingo Biosensor Applicator and Lingo Biosensor Pack according to local regulations.

Pairing Your Lingo Biosensor

The **NFC** (Near Field Communication) antenna is on the top edge of your iPhone. Hold this area near your Lingo Biosensor when you are pairing. You may need to adjust your pair distance based on what clothing you are wearing. In addition to proximity and orientation, other factors can affect **NFC** performance. For example, a bulky or metallic case can interfere with the NFC signal. Keep in mind that the ease of scanning a biosensor may vary between phone models.

1. Make sure that your phone is connected to a network (WiFi or cellular). You can then download Lingo app from the App Store.
2. Open the App and follow onscreen instructions to complete setup and accept the requested permissions.
3. Once app setup is completed, your phone is now ready to pair the Lingo Biosensor to start it.
4. Hold the TOP of your phone very close to the Lingo Biosensor. You will receive a tone and vibration after you have successfully started the biosensor. If your phone’s volume is turned off, you will not hear the tone.

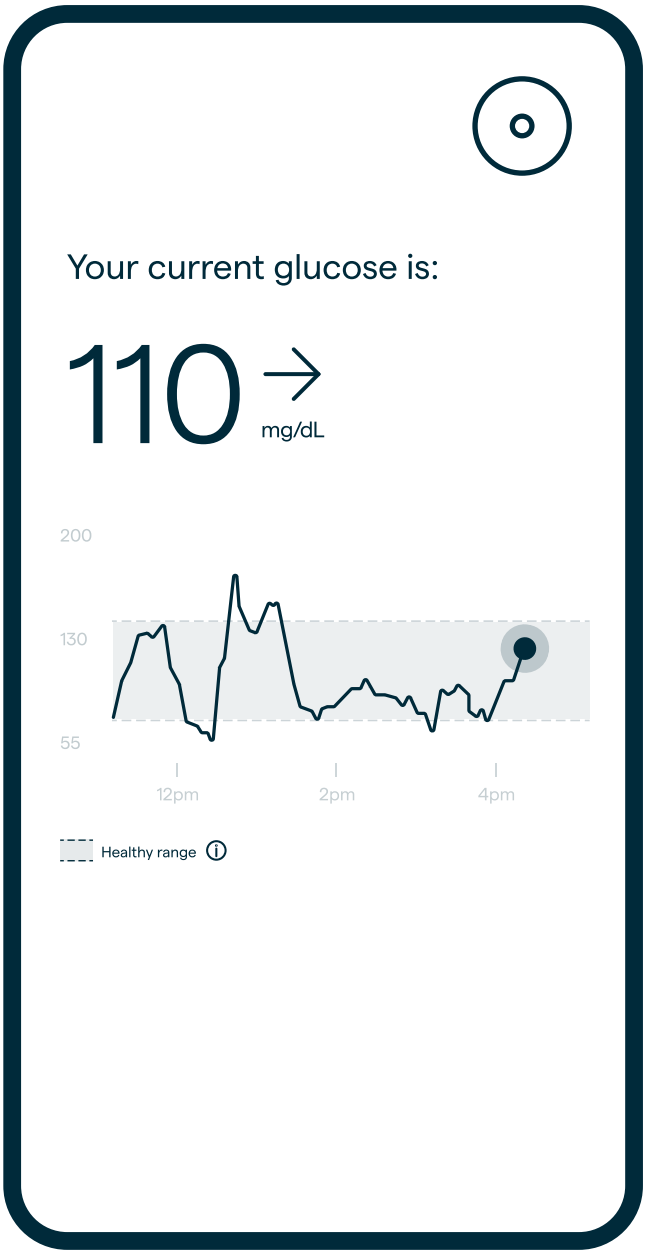


5. The Lingo Biosensor can be used to check your glucose 60 minutes after a successful pairing. If notifications are enabled, you will see a notification when the Lingo Biosensor is ready.

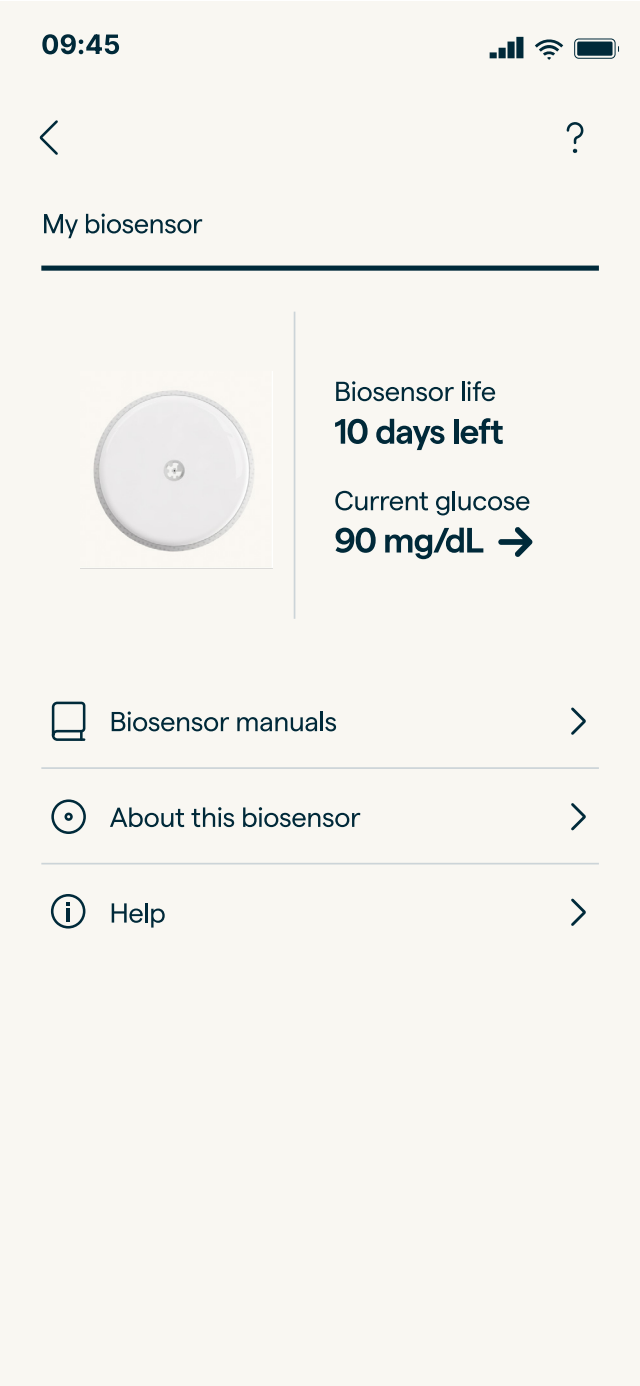
Checking your Glucose

Glucose information gives you visibility into your overall metabolic health and helps you understand how your body reacts to nutrition, exercise and daily activities. There are two ways to check your glucose if you have an active Lingo Biosensor:

1. The first way is by just opening the App to see your glucose reading! It will automatically update every minute. Your glucose reading includes your Current Glucose, a Glucose Trend Arrow indicating which way your glucose is going, and a graph of your current and stored glucose readings.



2. The second way is by tapping the Lingo Biosensor icon located on the top right corner of the App. Tapping this will take you to the My biosensor page, which shows your Current Glucose, Glucose Trend Arrow, and remaining life of the Lingo Biosensor.



The Glucose Trend Arrow indicates the direction your glucose is going.

↑ Your glucose is rising quickly

↗ Your glucose is rising

→ Your glucose is changing slowly

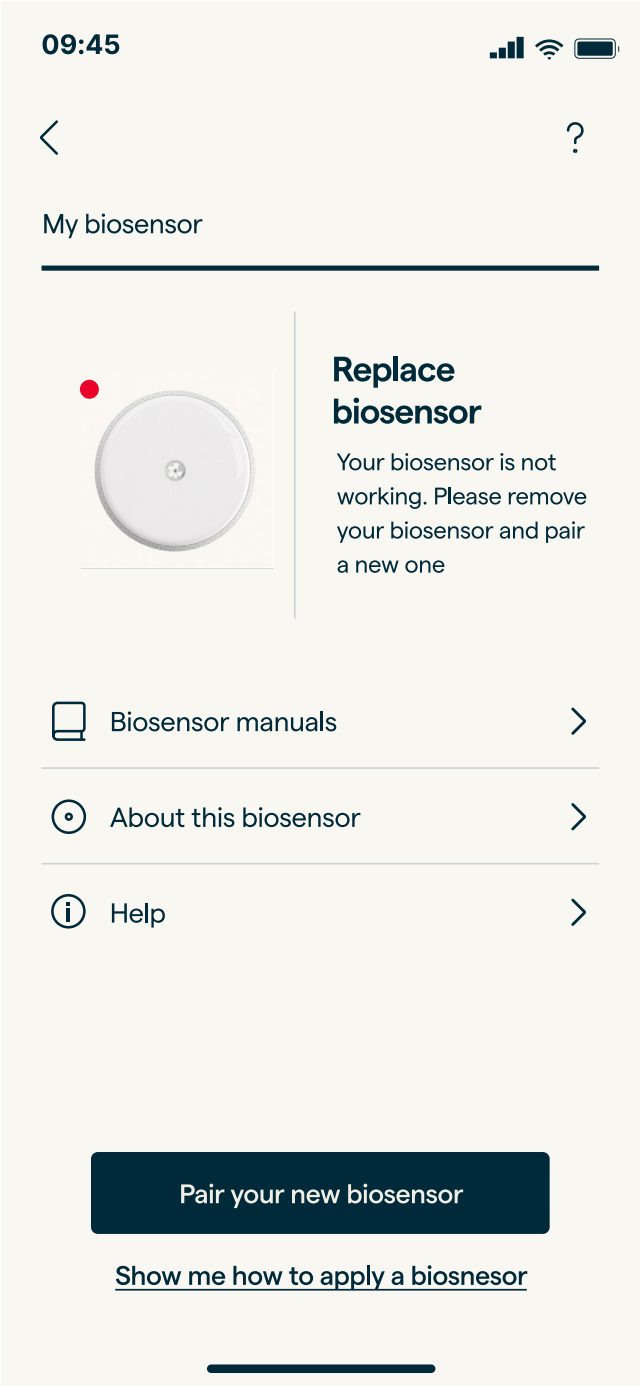
↘ Your glucose is falling

↓ Your glucose is falling quickly

The Lingo Biosensor provides a glucose measurement range of 55-200 mg/dL. This system is **NOT** intended to be used in the diagnosis of any disease including diabetes. You must not take medical action without consulting a qualified health care professional.

Note:

- If your current glucose value does not match how you feel, contact your health care professional before you take medical action.
- If your Lingo Biosensor is not successfully paired, you may receive an error message. Follow the instructions in the message. Picture below is an example of an error message.



- See Troubleshooting for error messages.

Living with your System

Activities

Bathing, Showering, and Swimming: Your Lingo Biosensor is water-resistant and can be worn while bathing, showering, or swimming. Do NOT take your Lingo Biosensor deeper than 3 ft (1 meter) or immerse it longer than 10 minutes

in water. Bluetooth performance may be impacted if using the System while underwater.

Traveling by Air: You may use your System while on an aircraft, following any requests from the flight crew.

You can continue to get Lingo Biosensor readings after you put your phone in airplane mode and enable Bluetooth.

- Some airport full-body scanners include x-ray or millimeter radio-wave, which you cannot expose your Lingo Biosensor to. The effect of these scanners has not been evaluated and the exposure may damage the Lingo Biosensor or cause inaccurate readings. To avoid removing your Lingo Biosensor, you may request another type of screening. If you do choose to go through a full-body scanner, you must remove your Lingo Biosensor.
- The Lingo Biosensor can be exposed to common electrostatic (ESD) and electromagnetic interference (EMI), including airport metal detectors.

Lingo App Options

Biosensor manual - View the User's Manual and the Lingo Biosensor instructions.

About this biosensor - Learn more about the Lingo Biosensor.

Biosensor history - View a log of errors.

End biosensor - End the Lingo Biosensor early.

Removing Your Lingo Biosensor

1. Pull up the edge of the adhesive that keeps your Lingo Biosensor attached to your skin. Slowly peel away from your skin in one motion.

   Note: Any remaining adhesive residue on the skin can be removed with warm soapy water or isopropyl alcohol.

2. Discard the used Lingo Biosensor according to local regulations. See Maintenance and Disposal. When you are ready to apply a new Lingo Biosensor, follow the instructions in Applying your Lingo Biosensor and Pairing Your Lingo Biosensor.

Note: After removing your Lingo Biosensor you may observe a slight bump at the insertion site. This goes away quickly, usually in a day or two.

Replacing Your Lingo Biosensor

Your Lingo Biosensor automatically stops working after the wear duration and must be replaced. You should also replace your Lingo Biosensor if you notice any irritation or discomfort at the application site or if you get a notification there is a problem with the Lingo Biosensor currently in use. Taking action early can keep small problems from turning into larger ones.

Maintenance and Disposal

Maintenance: The Lingo Biosensor has no serviceable parts.

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.

Troubleshooting

This section lists problems that you may experience, the possible cause(s), and recommended actions.

Problems at the Lingo Biosensor Application Site

Problem: **The Lingo Biosensor is not sticking to your skin.**

What it may mean: The site is not free of dirt, oil, hair, or sweat.

What to do:

1. Remove the Lingo Biosensor.
2. Clean the site with a plain soap and water and then clean with an alcohol wipe.
3. Follow the instructions in Applying your Lingo Biosensor and Pairing Your Lingo Biosensor. Consider shaving the site, avoiding use of lotions prior to insertion, and applying the Lingo Biosensor to your non-dominant arm.

Problem: **Skin irritation at the Lingo Biosensor application site.**

What it may mean: Seams or other constrictive clothing or accessories causing friction at the site **OR** you may be sensitive to the adhesive material.

What to do: Ensure that nothing rubs on the site. If the irritation is where the adhesive touches skin, contact your health care professional to identify the best solution.

Problems Starting Your Lingo Biosensor

Display: **Pairing error**

What it may mean: The phone was unable to pair the Lingo Biosensor.

What to do: Try pairing the Lingo Biosensor again. The NFC antenna is on the top edge of the phone. Pair your Lingo Biosensor by holding the TOP of your phone very close to the biosensor. Move your phone around slowly if needed. Proximity, orientation, and other factors can affect NFC performance. For example, a bulky or metallic case can interfere with the NFC signal.

Display: **Biosensor Already in Use**

What it may mean: The Lingo Biosensor was started by another device.

What to do: Check again with the device that started it. Or, apply and start a new Lingo Biosensor.

Display: **Enable Bluetooth**

What it may mean: The Bluetooth setting on your phone is turned off.

What to do: Go to your phone settings and enable Bluetooth.

Display: **Biosensor incompatible**

What it may mean: The biosensor cannot be used with the App. Check that you have installed the app that is compatible with your biosensor. You may need to download a different app if your biosensor is not compatible.

What to do: Tap **Learn More** to find out what biosensors can be used. If you still have questions about compatibility, call Customer Service.

Display: **Replace Biosensor**

What it may mean: The App has detected a problem with your Lingo Biosensor.

What to do: Apply and start a new Lingo Biosensor.

Display: **Biosensor Ended**

What it may mean: Your Lingo Biosensor has ended.

What to do: Apply and start a new Lingo Biosensor.

Problems Receiving Lingo Biosensor Readings

Display: **Check Biosensor**

What it may mean: The Lingo Biosensor tip may not be under your skin.

What to do: Try to start your Lingo Biosensor again. If you see “Check biosensor” again, your Lingo Biosensor was not applied properly. Remove this Lingo Biosensor and apply and start a new Lingo Biosensor.

Display: **Replace Biosensor**

What it may mean: The App has detected a problem with your Lingo Biosensor.

What to do: Apply and start a new Lingo Biosensor.

Display: **Biosensor Ended**

What it may mean: Your Lingo Biosensor has ended.

What to do: Apply and start a new Lingo Biosensor.

Display: **Signal Loss**

What it may mean: The Lingo Biosensor has not automatically communicated with the App in the last 5 minutes.

What to do: Make sure your phone is within 33 feet (10 meters) of the Lingo Biosensor and you have not force closed the App. Try turning Bluetooth OFF then ON again. If that doesn't work, try turning your phone OFF then ON again.

Display: **Enable Bluetooth**

What it may mean: The Bluetooth setting on your phone is turned off.

What to do: Go to your phone settings and enable Bluetooth.

Display: **Biosensor Too Cold**

What it may mean: Your Lingo Biosensor is too cold to provide a reading. Tap the

? symbol for more information.

What to do: Move to a location where the temperature is appropriate and check again in a few minutes.

Display: **Biosensor Too Hot**

What it may mean: Your Lingo Biosensor is too hot to provide a reading. Tap the ? symbol for more information.

What to do: Move to a location where the temperature is appropriate and check again in a few minutes.

Display: **Biosensor Error**

What it may mean: The Lingo Biosensor is unable to provide a reading. Tap the ? symbol for more information.

What to do: Check again after the duration specified in the message.

Customer Service

Customer Service is available to answer any questions you may have about your Lingo System. Customer Service is available at 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. The latest version of the user's manual is available at www.support.hellolingo.com and a printed copy is available upon request.

System Specifications

Lingo Biosensor glucose assay method: Amperometric electrochemical biosensor

Lingo Biosensor glucose reading range: 55 to 200 mg/dL

Lingo Biosensor size: 5mm height and 35mm diameter

Lingo Biosensor power source: One silver oxide battery

Lingo Biosensor data: Up to 14 days[1] (glucose readings stored every 5 minutes)

Lingo Biosensor transmission range: 33 ft (10 meters) unobstructed

Lingo Biosensor memory: Up to 14 days[1] (glucose readings stored every 5 minutes)

Atmospheric pressure: 700 hPa to 1060 hPa

Operating temperature: 50°F to 113°F

Lingo Biosensor Applicator and Lingo Biosensor Pack storage temperature: 36°F to 82°F

Operating and storage relative humidity: 10-90%, non-condensing

Lingo Biosensor water resistance and ingress protection: IP27: Can withstand immersion into 3 ft (1 meter) of water for up to 30 minutes. Protected against insertion of objects > 12mm diameter.

Operating and storage altitude: -1,250 ft to 10,000 ft (-381 to 3048 meters)

Radio Frequency: Near Field Communication (13.56 MHz ± 7 KHz RFID); ASK Modulation; 2.402-2.480 GHz BLE; GFSK; 0dBm EIRP

Note: [1] 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.

Security Measures and Quality of Service

Security measures: The communication between the Lingo App and Lingo Biosensor during an activation pair is a short range Near Field Communication (NFC) method which makes it difficult to interfere with or intercept during transmission. The communication between the Lingo App and Lingo Biosensor for glucose data is a standard Bluetooth Low Energy (BLE) connection. Mutual authentication is performed between the Lingo App and Lingo Biosensor during the pairing process using application certificates, and an authenticated login procedure using NFC. This prevents unauthorized devices from connecting to the Lingo Biosensor. The transmitted data is protected by encryption. This prevents unauthorized devices from accessing the data if they are within range and intercept the transmission. Under normal operation, the industry standard BLE protocols allow for many users to be in the same vicinity. In the case where the connection is lost due to out-of-range or interference, only the authenticated Lingo App that is paired with the Lingo Biosensor will be able to reconnect and

receive glucose data.

Quality of Service (QoS): QoS for the Lingo App and Lingo Biosensor wireless communication using NFC (for biosensor activation) is assured when the TOP of the phone is held very close to the Lingo Biosensor. The communication for activation takes place within 1 second. If the expected response is not received, the phone will continue to retry. QoS for the Lingo App and Lingo Biosensor wireless communications using BLE for normal operation (receiving glucose readings) is assured at regular 1-minute intervals. If connection is lost between the Lingo App and Lingo Biosensor for 5-minutes, the Lingo App will display an indication of “Signal Loss” on the Lingo App screen. If connection is lost between the Lingo Biosensor and the Lingo App, all lost glucose data will be automatically retrieved when the connection is restored. The Lingo App is designed to only accept BLE data from recognized and paired Lingo Biosensors. The transmission range for BLE communication is 33 feet (10 meters) unobstructed. If the phone and Lingo Biosensor are seeing frequent signal loss at longer distances, bring them closer together.

Labeling Symbols and Definitions

	Consult instructions for use
	Temperature limit
	Manufacturer
LOT	Batch code
	Type BF applied part
	Do not re-use
	Use-by date
REF	Catalog number
SN	Serial number

	Caution
STERILE R	Sterilized by irradiation
	Humidity limitation
	Do not use if package is damaged
MR	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.

Performance Characteristics

Accuracy Results

A pivotal, non-randomized, single arm, multi-center, prospective study was conducted for significant risk evaluation of the System. A total of 149 adult subjects had CGM paired with YSI reference and were considered as evaluable. Accuracy of the System was measured by comparing paired System Glucose Measurement (CGM) and YSI blood glucose values. The percentage of total System readings that were within 20 mg/dL for YSI blood glucose values < 70 mg/dL or 20% of YSI for blood glucose values ≥ 70 mg/dL is displayed in **Table 1a**.

Subject group	Number of CGM reference pairs	Number of Subjects	Percent within 20% or 20mg/dL
Adults	11086	149	91.2

Table 1a: Overall Accuracy to YSI

The accuracy of different CGM glucose ranges versus YSI reference was assessed by calculating the percentage of System readings that were within 15%, 20%, and 40% for reference values ≥ 70 mg/dL, and within 15 mg/dL, 20 mg/dL, and 40 mg/dL for values < 70 mg/dL. The results categorized within YSI glucose ranges are presented in **Table 1b**.

YSI Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Percent Within ± 15mg/dL	Percent Within ± 20mg/dL	Percent Within ± 40mg/dL	Percent Within ± 15%	Percent Within ± 20%	Percent Within ± 40%	Mean bias (mg/dL)	MARD(%)
<70	2386	96.9	98.5	99.6				1.4	8.9
70-180	7564				81.4	90.0	99.1	-5.8	9.7
>180	1136				77.5	84.0	98.9	-21.9	10.7

Table 1b: Accuracy to YSI within YSI Glucose Ranges

Concurrence of iCGM values compared to the comparator method across the entire measuring range was also evaluated. iCGM glucose ranges of <55, 55-70, 71-90, 91-120, 121-160, 161-200, and >200 mg/dL were evaluated against the comparator glucose ranges and the percentages of iCGM values within those ranges were reported in the following table.

iCGM (mg/dL) N (Column %)	Comparator Glucose Values (mg/dL)						
	<55	**55-70**	**71-90**	**91-120**	**121-160**	**161-200**	**>200**
<55	279 (52.6%)	342 (13.2%)	70 (3.7%)	13 (0.6%)	1 (0.0%)	1 (0.1%)	0 (0.0%)
55-70	244 (46.0%)	1920 (74.2%)	683 (36.1%)	55 (2.6%)	11 (0.4%)	0 (0.0%)	0 (0.0%)
71-90	7 (1.3%)	305 (11.8%)	971 (51.3%)	525 (24.7%)	42 (1.7%)	1 (0.1%)	0 (0.0%)
91-120	0 (0.0%)	18 (0.7%)	163 (8.6%)	1380 (64.9%)	599 (23.8%)	38 (2.0%)	2 (0.0%)
121-160	0 (0.0%)	1 (0.0%)	5 (0.3%)	150 (7.1%)	1691 (67.1%)	471 (25.0%)	37 (0.5%)
161-200	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.1%)	173 (6.9%)	1201 (63.6%)	391 (5.2%)
>200	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.2%)	175 (9.3%)	7064 (94.3%)
Total	530	2586	1892	2125	2521	1887	7494

Table 1c: Concurrence of iCGM and Comparator by Comparator Glucose Range

Glucose Rate of Change Accuracy

The System's glucose rate of change accuracy presented in Table 2 was assessed by the concurrence rate of glucose rate of change (changes in mg/dL of glucose per minute) determined by the iCGM values and the corresponding comparator values for each iCGM-comparator measurement pair. For example, when the actual glucose levels in the body was changing slowly downward (-1 to 0 mg/dL/min), Lingo Biosensor glucose were falling quickly (<-2 mg/dL/min) 0.5% of the time, falling (-2 to -1 mg/dL/min) 3.1% of the time, changing slowly downward (-1 to 0 mg/dL/min) 80.8% of the time, changing slowly upward (0 to 1 mg/dL/min) 15.2% of the time, rising (1 to 2 mg/dL/min) 0.2% of the time, and were rising quickly (>2 mg/dL/min) 0.1% of the time.

iCGM Rate (mg/dL/min)	Comparator Rate (mg/dL/min)					
	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2
<-2	41 (48.2%)	61 (10.5%)	28 (0.5%)	5 (0.1%)	2 (0.2%)	1 (0.2%)
-2 to -1	22 (25.9%)	197 (33.8%)	166 (3.1%)	23 (0.7%)	5 (0.6%)	2 (0.4%)
-1 to 0	18 (21.2%)	280 (48.1%)	4294 (80.8%)	1261 (37.8%)	101 (11.2%)	52 (10.4%)
0 to 1	4 (4.7%)	43 (7.4%)	807 (15.2%)	1907 (57.1%)	486 (53.9%)	203 (40.5%)
1 to 2	0 (0%)	1 (0.2%)	13 (0.2%)	122 (3.7%)	205 (22.8%)	103 (20.6%)
>2	0 (0%)	0 (0%)	5 (0.1%)	21 (0.6%)	102 (11.3%)	140 (27.9%)
Number of Paired iCGM-Comparator (N)	85	582	5313	3339	901	501

Table 2: Concurrence Analysis by Glucose Rate of Change

Glucose Reading Availability

The System is designed to show a glucose reading throughout the wear period after the start-up time. **Table 3** shows the glucose reading capture rate for each day of the wear duration.

Day of Wear	Number Of Biosensors	Capture Rate (%)
1	146	96.4
2	146	97.4
3	146	97.7
4	142	97.8
5	143	97.9
6	141	97.9
7	136	98.1
8	135	98.1
9	130	98.2
10	127	98.3
11	125	98.2
12	123	98.2
13	118	98.2
14	116	98.2

Table 3: Glucose Reading Capture Rate Over Wear Duration

Biosensor Wear Duration

Table 4 below indicates that the estimated probability of a biosensor remaining functional and not being knocked or pulled off throughout the 14-day wear duration. 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.

Day of Wear	Number Of Biosensors	Survival Rate (%)
1	150	100.0
2	150	100.0
3	149	99.3
4	147	98.0
5	142	94.7
6	139	93.3
7	138	92.7
8	131	88.0
9	129	86.6
10	127	85.3
11	125	83.9
12	122	81.9
13	118	79.9
14	111	77.1

Table 4: Biosensor Survival Rate Over Wear Duration

Electromagnetic Compatibility (EMC)

Lingo Biosensor - FCC ID: QXS-LINBS1

- The biosensor needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect the System.
- Use of accessories, transducers, and cables other than those specified or provided by Abbott could result in increased electromagnetic emissions or decreased electromagnetic immunity of the System and result in improper operation.
- The System should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the System should be observed to verify normal operation in the configuration in which it will be used.
- The device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) The device may not cause harmful interference, and (2) the device must accept any interference received, including interference that may cause undesired operation.
- 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 the dealer or an experienced radio/TV technician for help.

- Changes or modifications not approved by Abbott could void the user's authority to operate the equipment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.

Emissions test: RF emissions; CISPR 11

Compliance: Group 1

Electromagnetic environment – guidance: The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Emissions test: RF emissions; CISPR 11

Compliance: Class B

Electromagnetic environment – guidance: The System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.

Immunity test: Electrostatic discharge (ESD); IEC 61000-4-2

IEC 60601 test level: ± 8 kV contact; ± 2 kV, 4 kV, 8 kV, 15 kV air

Compliance level: ± 8 kV contact; ± 2 kV, 4 kV, 8 kV, 15 kV air

Electromagnetic environment – guidance: Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Immunity test: Power frequency (50/60 Hz) magnetic field IEC 61000-4-8

IEC 60601 test level: 30 A/m; 50 Hz or 60 Hz

Compliance level: 30 A/m; 50 Hz or 60 Hz

Electromagnetic environment – guidance: Power frequency magnetic fields should be at levels

characteristic of a typical location in a typical domestic, commercial, or hospital environment.

Immunity test: Radiated RF; IEC 61000-4-3

IEC 60601 test level: 10 V/m; 80 MHz to 2.7 GHz; 80% AM at 1 KHz

Compliance level: 10 V/m; 80 MHz to 2.7 GHz; 80% AM at 1 KHz

Immunity test: Proximity fields from RF wireless communications equipment; IEC 61000-4-3

IEC 60601 test level: See table below

Compliance level: Compliance to the tested levels

Electromagnetic environment - guidance:

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the System. Otherwise, degradation of the performance of the System could result.

The table below lists the immunity test levels at specific test frequencies for testing the effects of some wireless communications equipment. The frequencies and services listed in the table are representative examples in various locations where the System may be used.

Test frequency (MHz)	**Band** [a)] (MHz)	**Service** [a)]	**Modulation** [b)]	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)
385	380 –390	TETRA 400	Pulse modulation [b)] 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM [c)] ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation [b)] 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b)] 18 Hz	2	0.3	28
870						
930						
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b)] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b)] 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation [b)] 217 Hz	0.2	0.3	9
5500						
5785						

[a)] For some services, only the uplink frequencies are included.

[b)] The carrier is modulated using a 50% duty cycle square wave signal.

[c)] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[d] should be less than the compliance level in each frequency range.[e]

Interference may occur in the vicinity of equipment marked with the following symbol:

[d] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the

location in which the System is used exceeds the applicable RF compliance level above, the System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the System.

[e] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

www.HelloLingo.com

The circular shape of the Lingo Biosensor housing and Lingo are marks of Abbott.

Patent: https://www.abbott.com/patents

Manufacturer:

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