



Autonomous Time-in-Range Microsensor Technical Manual



1 CONTACTS AND CONTENTS

Device	Biolinq Shine® Autonomous Time-in-Range Microsensor
Model	82000
Manufacturer	Biolinq Incorporated 10260 Sorrento Valley Rd. San Diego, CA 92121 www.biolinq.com
Customer Support	+1 (833) 317-5518 support@biolinq.com www.biolinq.com/support
Kit Contents	One Sensor (in applicator) One set of instructions One Sensor Cover (medical tape)

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3 GLOSSARY

Word	Definition
App	Software on a compatible mobile device, such as a phone, tablet, or watch.
Applicator	The applicator holds the sensor, which is the wearable part of the device. You use the applicator to place the sensor on your arm.
Base	The bottom part of the applicator that is removed before you place the sensor on your skin.
Blood glucose meter	A medical device used to measure glucose in the blood, typically with fingersticks.
Contraindication	A safety statement about when you should not use the sensor because the risk outweighs the benefit.
Cover	Accessory medical tape that covers the sensor to help it stick to the skin.
Hyperglycemia	High blood glucose.
Hypoglycemia	Low blood glucose.
Indications	A statement about for what and for whom the sensor should be used.
Intradermal	Within the skin. The sensor measures intradermal fluid in the skin.
Medical professional	The person you see for medical treatment, such as a doctor, nurse, or physician assistant.
Medical tape	A type of adhesive used on the skin.
Microarray/ microsensor	The type of sensor in this device. It is shorter than a millimeter and can be seen under a microscope.
mg/dL	Milligrams per deciliter. A standard unit to measure blood glucose.
Precaution	A safety statement about how to avoid injury or device damage when using the sensor.
Sensor	The part of the device that sits in your skin to measure glucose.
Snooze	When the sensor does not show colored lights because you tapped it twice to temporarily turn off the lights.
Warning	A safety statement about how to avoid serious and life-threatening events when using the sensor.
Working time/ wear time	The amount of time you wear a single sensor, up to five days.

4 DEVICE BACKGROUND AND SAFETY

4.1 Device Description

BiolinQ Shine® is a wearable patch applied to the inner forearm that uses microsenors to measure glucose (sugar) in the skin. It can be worn for up to 5 days.

When glucose levels are in range, you will see a blue light on the device. A yellow light will appear on the device when glucose levels rise above the hyperglycemia threshold set at 180 mg/dL. The same colors appear on the app. While you wear it, think about your daily activities and what you can do differently with meal choices to stay in range (blue) longer each day.



blue
IN RANGE
70-180 mg/dL



yellow
ABOVE RANGE
Above 180 mg/dL

4.2 Indications

BiolinQ Shine® Autonomous Time-in-Range Microsensor consists of a continuous intradermal glucose sensor with a color-changing indicator light. It is intended to measure, record, and analyze physiologic data using an array of microsenors combined with an accelerometer and ambient light sensor. The qualitative display communicates real-time changes in glucose levels to aid in the management of a disease or condition related to glycemic control in persons 22 years or older not on insulin. An app provides more granular glucose information. It analyzes and correlates this glucose information with meals, rest, and activity levels. Use of the glucose and activity information is designed to facilitate acute behavior and lifestyle modifications. Interpretation of device readings should be based on glucose and activity trends and patterns. The user is not intended to take medical action based on

the device output without consultation with a qualified healthcare professional.

4.3 Who Can Use It?

4.3.1 User Contraindications

Do not use for hypoglycemia awareness. The sensor must not be used in persons with Type 1 Diabetes or those at significant risk of severe hypoglycemia. It must not be used with Automated Insulin Delivery (AID) Systems.

Do not use if you are taking any form of insulin. The sensor does not provide glucose information below 70 mg/dL, and it does not provide alerts or alarms.

4.3.2 User Precautions

Do not use if you are under 22 years old, are pregnant, on dialysis, or experiencing critical illness. Device performance has not been studied in these populations and may be inaccurate.

Do not use if you have significant color blindness or profound visual impairment that cannot be corrected. The sensor should not be used by people with monochromacy (complete colorblindness) or those who cannot see small objects because the sensor uses small colored lights to show glucose range.

Only one person can use one sensor. You can't share a sensor.

4.4 Other Contraindications



MR Unsafe. This device presents a projectile hazard.

Remove and discard the sensor before magnetic resonance imaging (MRI), computed tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. It has not been tested in these situations, and the magnetic fields and heat could damage its components.

4.5 Warning

Choking hazard. The sensor is small and may be dangerous if swallowed.

4.6 Precautions

Read these instructions for use. Carefully read these instructions before using the sensor. Failure to do so could result in improper device function or user harm.

Pay attention to low and high symptoms. If your symptoms of hypoglycemia or hyperglycemia do not match the color the sensor displays, use a fingerstick blood glucose meter to measure your glucose to make diabetes decisions.

Pay attention when glucose could be changing quickly. Glucose levels in your skin can be different from blood glucose when your glucose is changing quickly, such as after eating or exercising. If you need to know your blood glucose for diabetes decisions, use a fingerstick blood glucose meter.

Unusual skin hydration may cause inaccurate sensor glucose readings. This includes very dry skin (for example, from dehydration or dry weather) and overly wet skin (for example, from sweating, washing, or extreme humidity).

Storage



Do not use past the expiration date. Do not apply or start the sensor past its expiration date because it could be inaccurate. The expiration date is in YYYY-MM-DD (Year-Month-Day) format on the label.

Store at room temperature in moderate climates or in the refrigerator but not in the freezer. Do not use if it has been stored outside 36-86° F (2-30°C).

Keep dry during storage. Do not get the packaging wet.

Inspect Before Use

Do not use the applicator if it has been dropped. Dropping the applicator could result in damage to the applicator or the sensor that may cause it to be inaccurate.

Do not use the applicator if it has cracks. Check the applicator before you use it. The applicator is sealed to keep the sensor sterile and protect the medical tape that holds it to the skin. If the applicator has cracks, leaks, or makes a rattling sound, it might not be sterile, you could get an infection, and the sensor might not work properly.

Do not use the applicator if the base is open before you use it. Inspect the applicator base for any cracks or signs of damage. The base is sealed to keep the sensor sterile. If the base is damaged or loose, it might not be sterile, you could get an infection, and the sensor might not work properly.

Do not use the sensor if it separates from the applicator before use. The applicator places the sensor on your skin. If the sensor comes loose and then you try to use the applicator, it could result in damage and the sensor may be inaccurate.

Do not touch the inside of the applicator. After you remove the applicator's base, the sensor in the middle of the device is exposed. Touching this sensor could result in contamination or damage to the sensor.

Placing the Sensor

Clean and dry skin before wearing. Use plain soap and water or an alcohol wipe to clean the surface of the skin and remove any dirt or oils that may cause infection or prevent the sensor's medical tape from sticking to the skin. Wait for the skin to dry before using the applicator.

Avoid placing on irritated or damaged skin. Examples of skin irritation or damage include scarring, cuts, burns, wounds, or other damage. Do not place the sensor on these areas. The sensor may increase existing skin damage or irritation.

Wear on the inner forearm only. The sensor has only been tested for wear on the inner forearm. The sensor's performance in other wear sites may differ from expected performance.

Avoid placing too close to the elbow or wrist, where arm movement may affect the sensor's medical tape and may cause the sensor to fall off early.

Change the space. If you wear a new sensor soon after removing another sensor, choose a different space on your inner forearm. Using the same space can cause irritation from the medical tape.

Wearing the Sensor

Avoid X-ray machines or millimeter wave scanners. Do not wear the sensor into X-ray machines or Advanced Imaging Technology (AIT) body scanners (millimeter wave scanners), such as the ones at airport security checkpoints. It has not been tested in these, and the magnetic fields could damage it. Hand-wanding, pat-downs, and metal detectors are suitable alternatives.

See section 6.11 Air Travel and International Use

Do not use while taking hydroxyurea. Hydroxyurea is a medication used in the treatment of cancer and sickle cell anemia. Taking hydroxyurea will cause the sensor's readings to be inaccurate, and it will identify glucose excursions higher than the actual glucose in your body. The level of inaccuracy depends on the person and amount of hydroxyurea in your body. If you need to know your blood glucose for diabetes decisions, use a fingerstick blood glucose meter.

Do not use this device during or shortly after a medical test that involves drinking xylose (sometimes called a "D-Xylose absorption test"). Xylose in the body can interfere with glucose results. Ask your doctor how long you should wait after such a test before checking your glucose. This device has not been evaluated for use in people with rare medical conditions that affect xylose metabolism. If you are uncertain whether this applies to you, consult your healthcare provider.

Consider the effect of acetaminophen. Taking acetaminophen may falsely raise the sensor's readings and cause it to show a

higher glucose level than your actual level. Acetaminophen can be found in many medications, including Tylenol®, Excedrin®, and cold medicines. Since this device is intended to provide lifestyle recommendations, not treatment decisions, rely on a fingerstick blood glucose meter if the sensor's output does not match your symptoms or expectations when taking acetaminophen.

Do not try to re-apply. If the sensor falls off or does not place into the skin properly, do not try to re-apply it. Re-applying the sensor won't place it at the correct depth and it can be inaccurate. Discard the sensor.

Remove the sensor if it is causing an allergic reaction. Some people may be sensitive to the medical tape used in the sensor. If you notice a significant allergic reaction around or under the sensor, remove it and contact a medical professional.

Avoid sunscreen and insect repellent. Some chemical products, such as sunscreen and insect repellent, can affect the plastic used on the outside of the sensor. If these products get on it, make sure to remove them with a clean cloth.

Do not attempt to modify the sensor or its applicator. Modifications might affect sterility, you could get an infection, and it might not work properly.

Remove the sensor gently. Removing the sensor's medical tape can cause irritation, similar to removing a bandage or other medical tape. If you remove it before five days, the medical tape might be stronger and more likely to damage your skin. Soaking in a warm bath or shower or using adhesive removal products that can be bought at a pharmacy could make removal easier.

Mobile App

The Bioling Shine® system was not designed to detect and notify you of every event where your glucose increases significantly. Although the app will occasionally display insights for some of these events, it is possible that the device may miss an event when the glucose rose significantly or that it provides insight when one did not occur. You should NOT solely rely on these insights to

assess if a meal or activity has increased your glucose more than expected.

Security

Maintain your device's security. The sensor cannot detect potential security events, so do not let anyone you do not trust place a phone or NFC-capable device directly on top of the sensor while you are wearing it or after you remove it. Be careful to maintain the security of your phone. When using the app, only use a secure internet connection, such as a trusted home WiFi network, cellular connection, or VPN. Don't use unsecured public networks, which could expose the app to viruses or hacking. Check for updates on the Apple App Store, and only install updates from the Apple App Store. Disassembly of the sensor is prohibited, and using the app on a jailbroken phone is prohibited. This could subject you to cybersecurity risks.

After Use

Do not reuse the sensor or its applicator. The device is for single use only. Trying to reuse it may lead to infection, and the device will not display glucose information.

Do not attempt to replace the battery, and do not dispose of the battery in an incinerator or shredder. The battery is for single use only. Dispose of the sensor containing the battery following your local regulations. The battery has been designed to protect it from off-gassing, burns, fires, or explosions. Puncturing or damaging the battery could result in harm.

Skin discoloration after wear may be present. The small section of skin where the sensor was worn may look discolored after removing it. If the discolored skin feels overly sensitive or painful, this is not normal and may mean there is an infection. Contact a medical professional.

If you suspect a broken sensor, check for small pieces of it in the skin. A broken sensor may be more likely if it has been hit from the side. After removing the sensor, check the skin for any broken pieces. The microneedle, if broken, may leave small fragments in the skin that may not require medical intervention to

remove. Gently wiping with a tissue or cloth may help remove small pieces. Gently placing a piece of tape on the skin for about ten seconds and then removing the tape may also help. Use tape that is not so strong that it will damage the skin.

Prescription

Caution: Federal law restricts this device to sale by or on the order of a physician.

5 BENEFITS AND RISKS

5.1 Benefits

Some potential benefits of using BiolinQ Shine are ease of placement, accessibility, and real-time feedback that can provide positive reinforcement.

Ease of Placement. Microarray sensor technology allows for it to be placed in your skin without inserter needles.

Accessibility. The sensor is a self-contained, all-in-one wearable microsensor patch. Placement on the forearm allows you to view your glucose information easily, and the simple color-based display requires minimal training.

Real-time Feedback. The colors display continuous information. This will provide you with an “in the moment” opportunity to think about or change your behavior, which may positively impact your glucose levels. Over time these changes in behavior may result in improvement in your diabetes management.

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Ehrhardt N. et al, The Effect of Real-Time Continuous Glucose Monitoring on Glycemic Control in Patients with Type 2 Diabetes Mellitus, Journal of Diabetes Science and Technology, 2011, Vol 5(3) 668-675.

5.2 Risks

There are some risks with using the sensor. The most significant risk results from use by someone taking insulin. Insulin is an important medication that may cause dangerously low glucose levels. People who need this medication should not use the sensor. If you take insulin, you should use a fingerstick blood glucose meter to measure your glucose to make diabetes treatment decisions.

Hydroxyurea, even at standard doses, will interfere with the sensor's ability to measure glucose, and it will measure glucose higher than the actual glucose in your body. If you are taking hydroxyurea, use a fingerstick blood glucose meter to measure your glucose. At high doses (>450 mg/dL in the body), xylose will interfere. If you are taking a medical test that involves drinking xylose (e.g., D-Xylose absorption test), ask your doctor how long you should wait after such a test before checking your glucose.

If the sensor becomes inaccurate or if it does not display the correct colors, you could be unaware of prolonged high or low glucose levels. Misclassification of the glucose range or misunderstanding trends could reinforce inappropriate lifestyle changes that could result in a higher proportion of time spent in hyperglycemia. Over time, this could contribute to the development of microvascular or macrovascular complications of diabetes that is not optimally controlled. If you suspect inaccuracy, do not make diabetes or lifestyle changes based on the sensor.

Other risks include reactions to the sensor materials, such as an allergic reaction, irritation, or infection caused by the presence of the sensor or its medical tape. Small parts of the sensor could break in your skin and cause irritation. You might also experience skin discoloration that looks like a freckle for days or sometimes weeks after you remove the sensor from your arm.

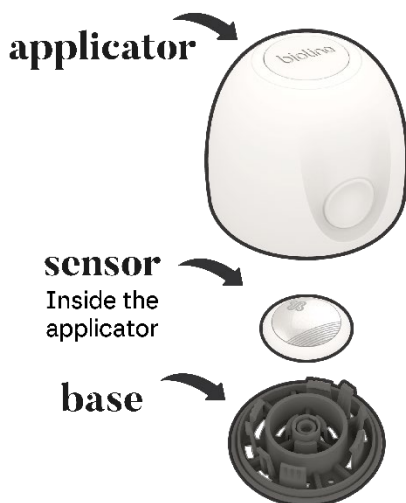
6 INSTRUCTIONS

6.1 Set Up

Before using the sensor, store it between 36 to 86° F (2 to 30°C) and keep it dry.

The sensor is included inside the applicator. You will use the applicator to place the sensor on your arm. The applicator does not use a needle. You will need the applicator, soap and water or an alcohol wipe (that you can buy at a pharmacy), and a solid surface, like a table.

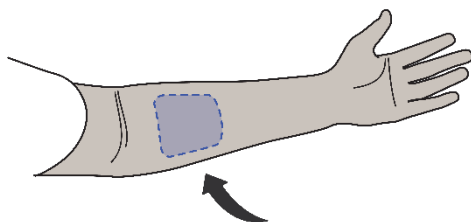
1. Review all the precautions for storing and placing the sensor, in section 4.6.
2. You can watch a video of set up instructions at www.bioling.com/support.
3. Get started by taking the applicator and sensor cover out of the box. The sensor is inside the applicator.



Parts (there is also a cover to secure the sensor after you've applied it)

4. Each sensor and applicator can only be used once. Make sure you start with a new sensor in an unopened applicator.

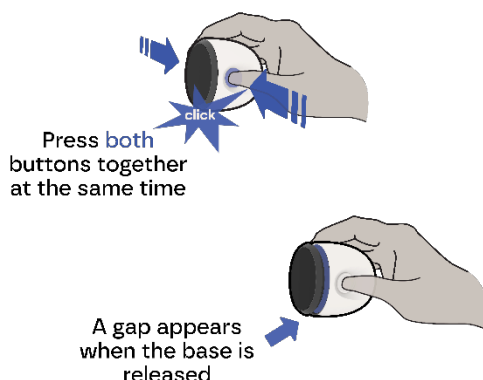
5. Make sure the sensor has not expired before you place it on your body. The package will show the expiration date in YYYY-MM-DD (Year-Month-Day).
6. Inspect the applicator to make sure it has no cracks or damage.
7. Make sure the gray base (the part with a label) is attached to the white applicator top with no gaps between them.
8. If the applicator is damaged or if a gap appears, do not use it. Contact Customer Service.
9. If the applicator is ready for use, put it aside for later.
10. Prepare the inside of your forearm where you will place the sensor.
 - a. Do not use lotions, creams, and sunscreens before or after application.
 - b. Do not place on scar tissue, open wounds, or irritated or damaged skin.
 - c. Do not place on hairy skin. If your inner forearm is hairy, shave it first.
 - d. Clean your forearm with an alcohol wipe or soap and water.
 - e. Allow your skin to dry. Dry skin is important for the device to stick, so be patient and give it extra time to dry completely.
 - f. Prepare to place it on the flattest part of your inner forearm, away from the wrist but not too close to your elbow. It should be in the middle of your forearm slightly closer to the elbow than the wrist as shown in the image below.



Sensor goes on this half of forearm and away from elbow crease

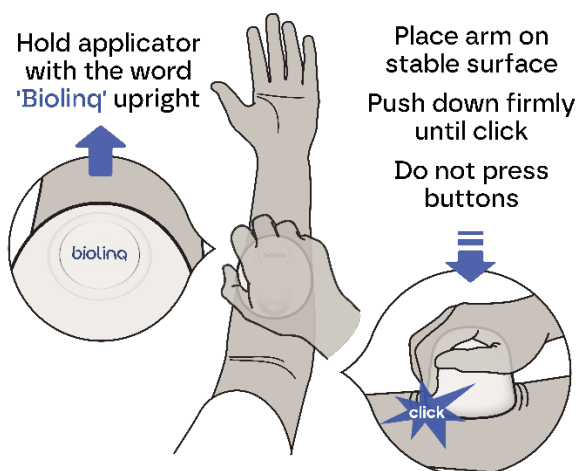
11. Hold the applicator with a finger on each of its two side buttons. Press both side buttons together at the same time to

release the gray applicator base. It will make a “click” sound when it releases.



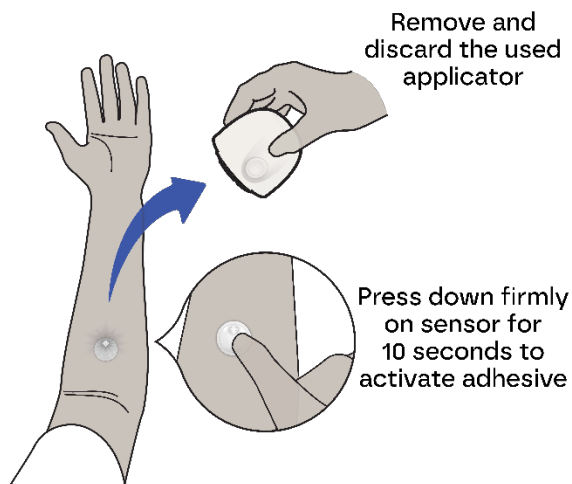
Pressing both buttons at the same time to release the base

12. The base should loosen after you press the buttons. Gently pull the base off with one hand while holding the applicator with the other hand.
 - a. Do not touch the open part of the applicator after the protective base is removed. This could damage the sensor.
 - b. Do not press the applicator firmly against a surface or the sensor might separate too soon.
13. Rest your arm on a table or another flat, stable surface, with your clean forearm facing up.
14. Move the applicator so the name Biolinq is upright when you look at it.
15. Gently place the applicator on the flat part of your inner forearm that you cleaned and allowed to dry.
16. Keeping your arm on the stable surface, use the palm of your hand to press down on the applicator with firm, even pressure. You don't have to push any buttons while you press down. A “pop” sound will let you know it is done.



Using applicator to place sensor on forearm

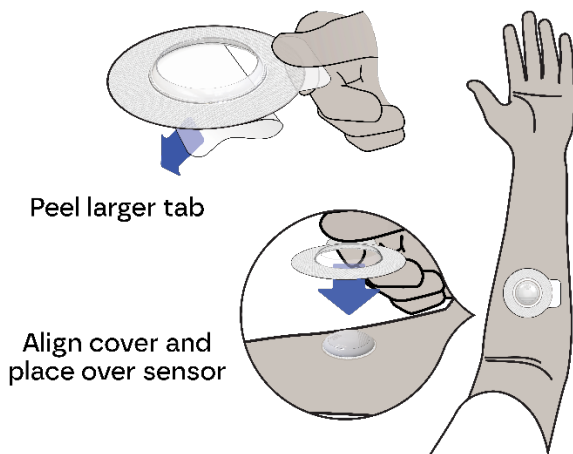
17. To remove the applicator, pull it up, and the sensor will remain on your skin.
18. Press down firmly on the sensor for 10 seconds to activate the adhesive.



Removing applicator and pressing the sensor

19. Save the base with the label for reference and discard the rest of the applicator.

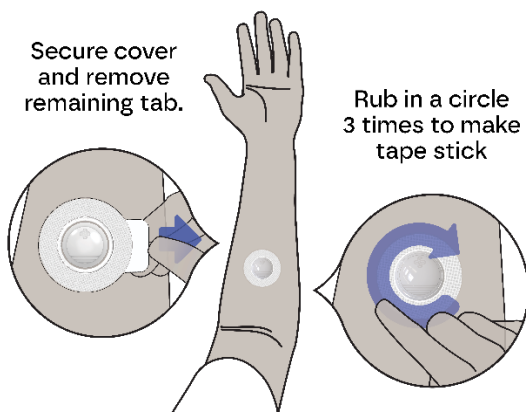
- a. The applicator is not a sharp or biohazard, so it can go in normal waste or recycling, depending on your local rules.
 - b. Each sensor can only be used once, so there is no need to keep the applicator.
20. The sensor cover is a medical tape that helps hold the sensor on your skin.
- a. Hold the sensor cover's smaller tab and peel away the larger tab.
 - b. Do not touch the sticky underside of the tape.



* Do not touch sticky underside of tape

Placing the sensor cover over the sensor

21. Align the sensor cover over the sensor and place it on your skin.
- a. Secure the sensor cover in place.
 - b. Pull the remaining tab to remove it.
 - c. Rub in a circle three times to help the tape stick.



Rubbing the sensor cover to make it stick

22. The sensor will begin to show a softly blinking light in a few seconds.
23. The light will continue to blink white for two hours while it adjusts to your body. If you would like to use the mobile app, you can set it up while you wait for the sensor to adjust. See section 6.6 to set up the app. The sensor works with or without the app.

6.2 Using the Sensor – Colored Lights

The device has a display that shows colored lights. These colors appear continuously throughout the day to inform when glucose levels are in range or when glucose levels are elevated above range. For the first two hours you will see a white light.



The sensor's display has lights

Soon after you place the sensor on your inner forearm, you will see a white light blinking. The light might not turn on for up to 15 seconds. This white light means “Wait – check again later.” This means your glucose can’t be shown now. The Wait light will blink for about two hours while it is getting ready. For these first two hours, the sensor is gathering information to calculate glucose.

After two hours and for the rest of the next five days, the sensor will show distinct colors. You can see examples of these colors in the Quick Start Guide in your kit or at biolinq.com/support.

Learn the Colors

When glucose levels are in range, you will see a blue light on the sensor. A yellow light will appear on the sensor when glucose levels rise above the hyperglycemia threshold set at 180 mg/dL. While you wear the sensor, think about your daily activities and what you can do differently with meal choices to stay in range (blue) longer each day. The same colors appear in the app.

Light Color	What it Means	What You Should Do
Blue	Your glucose is in range (70-180 mg/dL)	Wait and see if you stay in range through daily activities and meals
Blue (top and bottom light both blinking blue)	Your glucose is in range (70-180 mg/dL) and rising quickly	Wait and see if you stay in range through daily activities and meals or consider your eating or meal choices and/or doing a physical activity
Yellow	Your glucose is above range (181-400 mg/dL)	Consider your eating or meal choices and/or doing a physical activity
Yellow with a very rapid blinking light	Your glucose is above 400 mg/dL	Consider your eating or meal choices and/or doing a physical activity. If this very rapid blinking changes to white, and the combination lasts for more than 2 hours, use a fingerstick from a blood glucose meter.

Light Color	What it Means	What You Should Do
White	Wait – check again later. Your glucose can't be shown now (see <i>White Light Means Wait</i> section below for reasons)	Wait – keep the sensor on and use a fingerstick from a blood glucose meter if you need to know your glucose
Red	Your glucose is below 70 mg/dL	Wait – keep the sensor on and use a fingerstick from a blood glucose meter if you need to know your glucose
Purple	Remove and discard – your sensor wear has ended	See Section 6.8 <i>Removing the Sensor</i> and 7 <i>Troubleshooting</i>
No lights	The sensor is in snooze mode because you tapped it twice or are in a dark room	Quickly tap the sensor twice to wake or go to a place with brighter lighting

Blinking patterns:

- If both the top and bottom blue lights blink instead of just one light blinking, this means your glucose levels are in range but rising quickly.
- If the yellow light blinks very rapidly, this means your glucose is above 400 mg/dL.

It's okay if you don't notice these additional blinking patterns. It is more important that you understand the colors. The additional blinking patterns can help identify periods when glucose levels are rising rapidly, and this may be helpful as you learn about your relationship to food choices, physical activity, and medications you may be taking.

The following tips and considerations may help lower glucose levels if your sensor is displaying a yellow light:

- Change the type of food you eat – eat fewer carbohydrates like sugar, rice, and bread.
- Change the timing of your meals – consume carbohydrates after eating vegetables and protein first, or consider eating later, or eat at a different time of day.

- Consider smaller portions or skipping dessert.
- Try physical activity at a different time – walk or exercise after meals.
- Try more physical activity or a different activity.
- Consult with your healthcare professional for medical advice.

White Light Means Wait

If you see the white light this means “Wait – check again later.”

This means the sensor is working but unable to report glucose readings at the moment. In most cases, simply waiting will resolve the issue. Wait times can vary from a few minutes to a few hours. Keep the sensor on your body. Do not remove it.

There are a few reasons you might see White Light:

- The first two hours with the device on your inner forearm is the period of time when the device is preparing to measure glucose levels.
- The sensor may need to readjust. The time to adjust can't be predicted, so check again periodically.

You should not make changes to your meals or activities based on seeing the white light. If you feel unwell or otherwise want to know your glucose at this time, use a fingerstick from a blood glucose meter.

The sensor might show a white light briefly if you press on the device too hard or if its calculations suggest something isn't right and it needs time to gather more data and readjust.

Snoozing the Sensor – Turning Off Lights

You can turn off the sensor's lights when you want privacy.

Quickly tap the sensor twice to turn off the lights for up to four hours. This will “snooze” the lights.

“Tap twice” means tapping the center of the device with your finger quickly and firmly two times, like when you double-click a laptop trackpad or computer mouse. Tap, don't press.

If you snooze the sensor and later your glucose level changes, it will wake up again. For example, if you press snooze while the

sensor is blue, it will wake up to let you know if it changes to yellow.

Dark Mode – Automatic Lights Off in the Dark

The display will automatically turn off the lights when you are in a dark room. If you want to see the lights when you are in a dark room, quickly tap the sensor twice. It will show the lights briefly and then go dark again until you are in a room with more light.

How to Resume Lights During Snooze or in Darkness

The sensor shows a blinking light unless it is in snooze mode or you are in a dark room. This table shows the reasons it might be dark.

Reason sensor is dark	Reason	How to stop snooze
You are in a completely dark room	Peaceful sleep without a bright light; watching a movie	Quickly tap sensor twice to see lights. It will show lights briefly and then go dark again until you are in a space with lighting.
You double-tapped the sensor to make it go dark for 4 hours	For privacy if you do not want people to see it	Sensor will turn back on after 4 hours or if your glucose range changes. You can quickly tap sensor twice to turn it back on before 4 hours.

6.3 How to Know the Sensor is Working

The sensor's light will gently blink when it is working unless it has been placed in snooze mode or you are in a dark room.

If you are not sure if the sensor is snoozed, tap it quickly two times, like when you double-click a laptop trackpad or computer mouse.

- If it was snoozed, this will wake it up, and the light will slowly blink again.
- If it stays dark after tapping it twice and you are in a well-lit place, it may have stopped working. See section 6.4 on *Duration of Use* to learn how long the sensor should work.

If you have difficulty seeing the sensor's light in bright daylight, move it into the shade. You can create shade using your other hand.

6.4 Duration of Use (Useful Life)

The sensor will work for up to five days. The battery is for single use only and cannot be replaced or recharged, so there is no need to monitor the battery status. When five days are over, it will show a purple light, which means that the device has reached the end of its useful life. See section 6.8 *Removing the Sensor* to learn how to remove it.

6.5 Sensor Cover

The sensor cover is a required accessory to help the sensor stick to the skin. It is included in the kit. There are no other required accessories.

6.6 Mobile App

The Biolinq Mobile App can communicate with the sensor and is designed to highlight and reinforce the information you learn from the sensor. The app uses the same colors you see on the sensor. The sensor can work with or without the app. See www.biolinq.com to learn more about the app. Only use the app(s) listed on Biolinq's web page. No other apps are authorized to be used with the sensor.

Download and Set Up the App

The app works on supported Apple® phones. To see a list of supported phones and operating systems, see www.biolinq.com/compatibility. Automatic updates of the app or your phone operating system might shut down the app or change your settings.

1. Make sure your phone is connected to a secure network (your home or office WiFi or cellular). Find the Biolinq Shine app on the Apple App Store by searching for "Biolinq." Download the app. The app can be downloaded

and set up at any time during your sensor wear. A good time to set up the app is just after you apply the sensor.

2. After the mobile app is downloaded, follow the on-screen instructions to set it up. The app will walk you through setting up an account if you don't already have one. It will guide you through setting up your profile.

If you want to make changes to your profile later, press the Profile button at the bottom of the app screen.

Scan the Sensor With Your Phone

The app only receives information from the sensor when you scan it. The information from the sensor does not automatically transfer to your phone without a scan. Only one user may scan a device, so if you plan to use the app, consider scanning soon after you first apply the sensor.

After the app is set up, you can access device information by following the instructions to scan the device. You can do this again any time during the wear session.

1. After you finish the registration process, the app will show a video and then a button to "Start scan" so that you can perform your first scan. If you already have a sensor on your arm, you can press this button. If you don't have a sensor on your arm, follow the instructions in the Quick Start Guide or in section 6.1 to apply the sensor before pressing the Scan button.
2. Watch the video in the app and follow the on-screen instructions to place your phone on top of the sensor. This will transfer sensor information to your phone. If the scan works, you will see a message, "Scan complete." If the transfer doesn't work on the first try, the app will suggest you try again.

The scan should work with most phone cases. If you are having difficulty scanning, consider removing your phone case.

The sensor uses near field communication (NFC) to transfer information to your phone only when you initiate a scan. A single sensor will only pair with one user when a mobile app scan is initiated.

Any time that you want to scan again, press the scan button at the bottom of the app screen and touch your phone to your sensor.

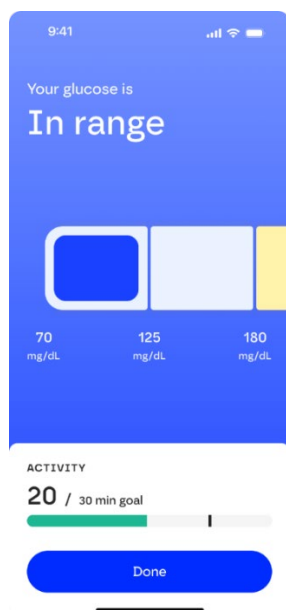
Scan Screen

After you scan a sensor, you will see the scan screen. The app uses the same colors you see on the sensor. The top part of the screen shows the sensor color and a reminder of what this means in words. The boxed region shows the part of the range where your glucose is now. An arrow may sometimes appear on this screen below the words, “In range and rising.” This means that your glucose is in range now, but it is moving towards the yellow and could become out of range. The bottom part of the scan screen sometimes tells you additional information about the amount of minutes of physical activity the sensor has detected so far today.

Scan screen example in range:

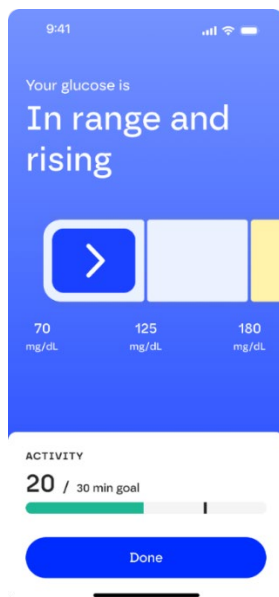
The top part of the screen is blue and shows you are in range. The boxed region shows the part of the range where your glucose is now. The color and box location may change as you scan the sensor depending on your current glucose range.

The bottom part of the screen in white may provide an update on how much physical activity your sensor has tracked so far today.



Scan Screen example in range and rising:

The text and the arrow show that your glucose is rising. This means that your glucose is in range now, but it is moving higher, towards the yellow, and could become out of range.



Insights

Insights provide helpful information about your glucose patterns, tips for how to increase your time in range, and education about how meals, activities, and sleep can affect glucose. Insights appear on different screens in the app.

Precaution: The BiolinQ Shine® system was not designed to detect and notify you of every event where your glucose increases significantly. Although the app will occasionally display insights for some of these events, it is possible that the device may miss an event when the glucose rose significantly or that it provides insight when one did not occur. You should NOT solely rely on these insights to assess if a meal or activity has increased your glucose more than expected.

Home Screen

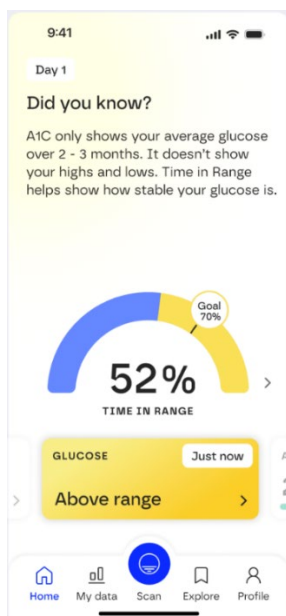
After you click “Done” from the scan screen, you will be taken to the home screen.

Home screen example:

The top part of the screen shows an insight.

The middle part of the screen shows time in range (arch shape).

The bottom part of the screen shows your sensor color. You can click on this glucose card to see more details or swipe to see other topics like activity and sleep.



The home screen shows insights and the sensor color. It also shows your “time in range” for the day so far.

You can get back to the home screen by pressing the Home button at the bottom of your app screen.

Time in Range

Time in range shows the percentage of the day that your glucose is within the target range (blue). This percentage shows how your glucose has stayed in the target range *throughout the day*. It is different from the current glucose color you see on the sensor that shows your glucose *right now*.

The American Diabetes Association recommends staying between 70-180 mg/dL for 70% (17 hours) of the day. The app shows this recommendation as a white bubble with the words, “Goal 70%.”

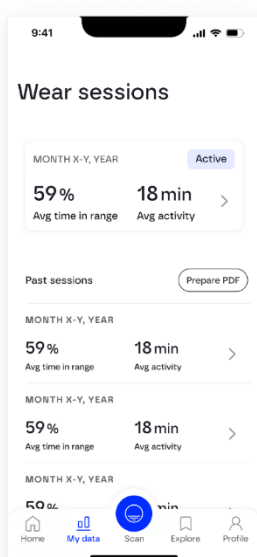
My Data – Wear Sessions

If you want to learn more about how your glucose has performed over time, press the My Data button at the bottom of your app screen.

The My Data screen will show your wear sessions. The sensor lasts for up to five days, and each wear session represents a different sensor. If you are currently wearing a sensor, the current session will be at the top. If you have worn a sensor in the past, those past sessions will appear below the Past Sessions heading.

While you view the My Data screens, think about your daily activities and what you can do differently with meal choices to stay in range (blue) longer each day. The sensor and the app are intended to help you think about activities and meal choices. Always consult a medical professional for medical advice, including for advice regarding your medications. Don't change your medications based on the sensor or the app.

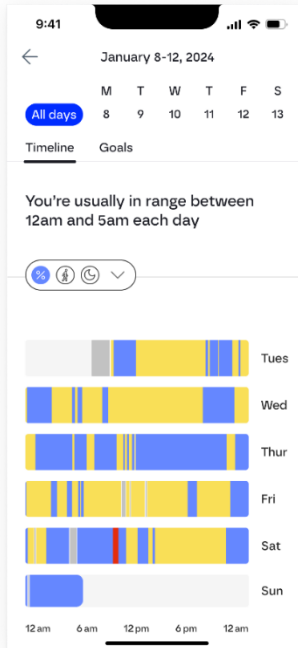
Touch the right arrow (>) next to a session to see more information.



Wear session screen example

My Data – Timeline View

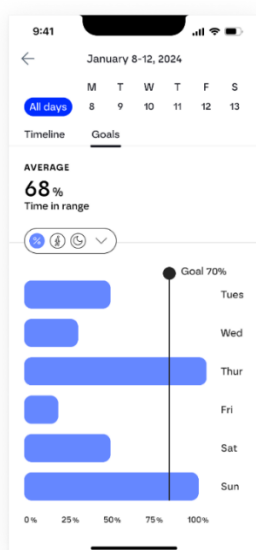
After you press the right arrow (>), you will see the timeline. The timeline shows the sensor ranges that you experienced already in the wear session. This view can help you recognize patterns. For example, in this timeline, the sensor often turns yellow in the late afternoon.



Timeline example

My Data – Goals View

When you are looking at the timeline, you can also press the Goals heading. This will show you how often you met your daily goals throughout the wear session.



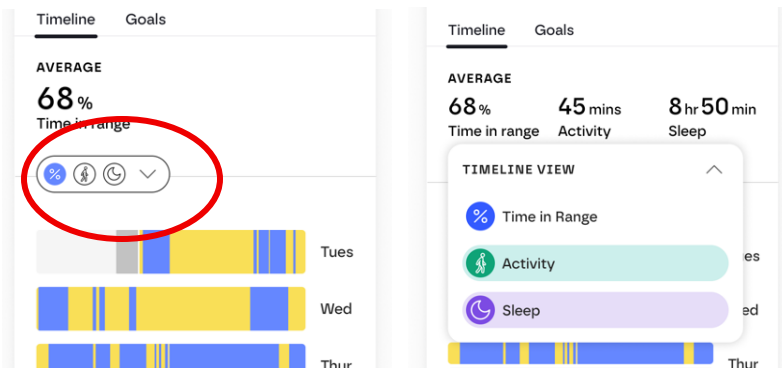
Goals view example

In the Goals view, you can press the Timeline heading to go back into the Timeline view.

You can only change the time –in range and activity goals when you are not wearing an active sensor. Change your goals when you are not wearing a sensor by selecting the Profile button and then selecting Goals.

My Data – Seeing Activity and Sleep

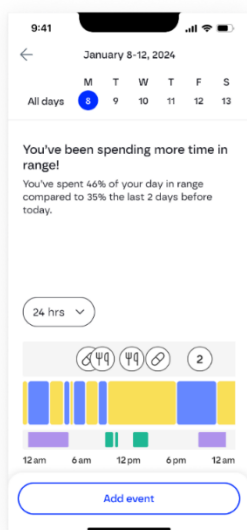
When you first look at the timeline or the goals view, you will see glucose time –in range information. If you press on the down arrow next to the icons, you can select buttons to see activity and sleep or turn off the glucose view.



Arrow next to icon changes view

My Data – Daily View

You can see the Daily view by pressing the date above the Timeline or Goals view. The Daily view shows how your glucose ranges have changed throughout each day. For example, in this Daily view, the glucose range looks higher (yellow) around lunch.



Daily view example

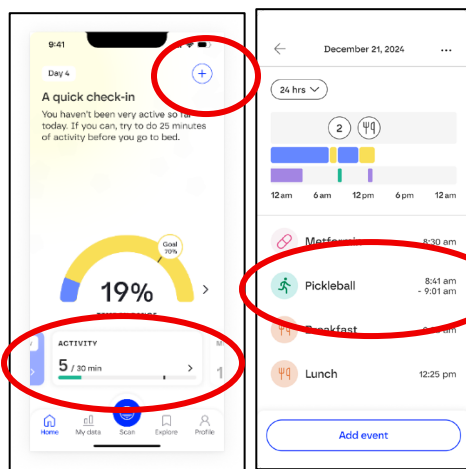
Activity

The sensor automatically measures some forms of activity, like a brisk walk or using an elliptical. After the sensor measures an activity, and after you scan your sensor to upload information to the app, an estimate of the activity will display on the bottom of the scan screen, on the activity card on the bottom of the home screen, and on the My Data screens. If you don't see the activity card on the home screen, swipe the cards at the bottom of the screen until you see activity.

Activity is shown in green as a number of minutes of activity compared to minutes of your activity goal. In the image below, it shows 20 minutes of activity recorded, and the goal is to meet 30 minutes.

Click on the activity to edit it. You can change the time the activity took place, add details like the type of activity, or delete the activity.

You can also add activities that the sensor didn't detect, like bike riding, or strength training. The sensor might not have automatically recognized these activities because they have slower or minimal arm movement. To add new activities, press the + symbol on the home screen or the "add event" button from the Daily View.



Activity example shown as amount of time active

You can only change your activity goal when you are not wearing an active sensor. Change the goal when you are not wearing a sensor by selecting the Profile button and then selecting Goals.

Sleep and Rest

The sensor automatically measures some forms of sleep and rest. After you scan your sensor to upload information to the app, an estimate of the sleep time will display on the sleep card on the bottom of the home screen and on the My Data screens. If you don't see the sleep card on the home screen, swipe the cards at the bottom of the screen until you see sleep. Sleep is shown in hours and minutes.

Click on the sleep event to edit it. You can change the time the sleep took place, add details like the type of sleep (such as a nap), or delete the sleep. You can also add sleep that the sensor didn't detect. The sensor might not recognize sleep events if you move a lot in your sleep. To add a new sleep event, press the + symbol on the home screen or "add event" button from the Daily View.

Food and Drink – Meals

You can log food and drinks in the app. To add food or drinks, press the + symbol on the home screen or "add event" button from the Daily View and select "Food." You can type in the name of the food or drink and add the time of the meal. You can see the food icon on the Daily View and press the food icon in the list to read the details you logged. Since the food and drinks will show up on the Daily View, logging these can help you see and think about the relationship between different meals and your time –in range.

You can also set notifications to remind you an hour after your usual mealtime. For example, if you usually eat dinner at 6 PM, you can enter this time in the reminders list. Then you will receive a reminder every day at 7 PM to scan your sensor and log information about your meal.

Medications

You can set the app to notify you with reminders when it is time to take your medications. This is a calendar reminder setting based on the time you schedule. When you first set up your app, its onboarding screens will guide you to set your reminders. If you would like to add a medication reminder later, you can set up new reminders in the Profile menu.

After adding a list of prescribed medications, you can log that you took these medications. Logging can help you remember if you took your medication and think about the relationship between the days you took or didn't take medication and your time—in range on those days or following days.

To log that you took a medication, press the + symbol on the home screen or “Add event” button from the Daily View and select “Medications.” You can also add medications when viewing the medication card. If you don't see the medication card on the home screen, swipe the cards at the bottom of the screen until you see medication.

Symptoms and Side Effects

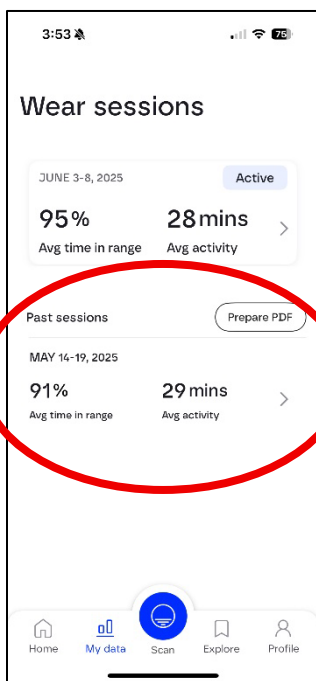
You can log diabetes symptoms and medication side effects in the app. Logging these can help you think about the relationship between the days you didn't take medication and your symptoms on those days or other days of the week.

To add symptoms and side effects, press the + symbol on the home screen or “add event” button from the Daily View and select “side effects.” You can also add side effects when viewing the medication card. If you don't see the medication card on the home screen, swipe the cards at the bottom of the screen until you see medication.

The side effects logging feature is intended to record any sensations or symptoms related to diabetes or medications. This feature is NOT for recording issues related to the sensor or app. To report product issues or medical incidents related to the sensor, contact Customer Support at www.biolineq.com/support.

Wear Summary

You can see the events you entered in the My Data views. When a sensor's wear session ends, you can also see a summary in the app with graphics and insights about your goals and patterns. When you scan a sensor after its wear session ends, the app will remind you to remove the sensor and will give you an option to see the summary. You can also find this summary later by going to the My data button and looking for "Past sessions." Click on the date of the sensor session you'd like to view. At the bottom of the timeline view, you will see a "View wear summary" button. Press the button to see the summary.



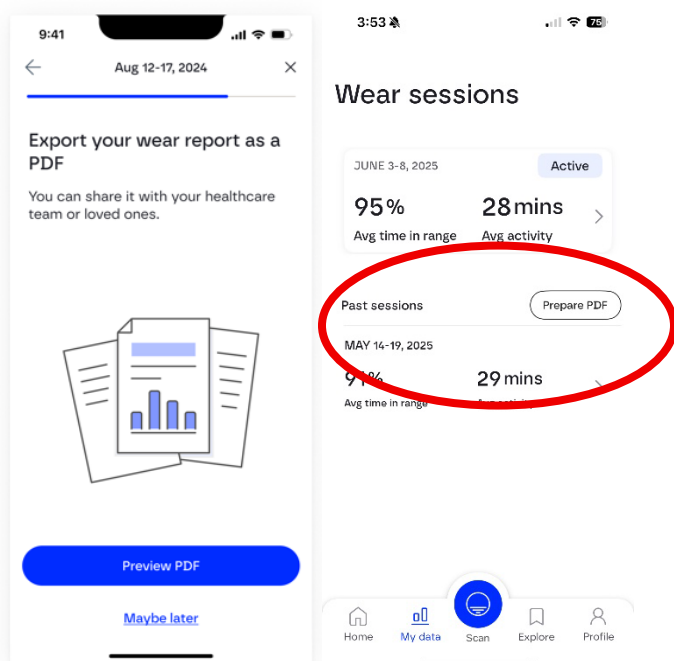
Use past sessions to find wear summary

Shareable PDF Report

You can create a report in PDF format that you can save in your phone's files or share with others. After the sensor's use life ends and you view the wear summary, you might see an option to prepare a PDF report. You can also find this report by pressing

the My data button and looking for a circled “Prepare PDF” button near the “Past sessions.”

You will be able to select the time period that you want to include in the report, such as the last month, last 3 months, or other times. This report will show graphics of glucose and events for the time period you select.



Use Prepare PDF button next to Past sessions

When you press the button to download the report, your phone will provide a menu of options for how to save or share the file.

If you want to see the report before you share it, you can save it to your phone's download files or you can send a text message to yourself.

This report will include sensitive information, including your date of birth, glucose levels, and medication you logged, so you should

take care with how you store or share the report. For example, if you don't have password protection on your phone, you may not want to store a copy in your saved files. If you do not trust the security of an email or communication app, do not use that to share the file. Only share to email or text addresses of people you trust, and only share when you have a secure network connection.

Profile Screen

If you are looking for background information or help, go to the Profile screen by clicking on the Profile button at the bottom of the screen. It includes:

- Links to instructions and guides
- Safety statements (warnings and precautions)
- Contact information for Biolinq support
- Identifier codes in "About your sensor"
- Options to change goals, medications, reminders and notifications, and personal details.

Scan Often

Scan the sensor as often as you want to see updated information on your app. The app only receives information from the sensor when you scan it. The information from the sensor does not automatically transfer to your phone without a scan. Rest assured, the sensor is designed to save your information for up to the full five days of use. It can transfer the next time you scan, up to 24 hours after a session has ended.

6.7 Temperature and Water (Environment)

Temperature

The sensor can be used in temperatures between 50 to 107° F (10 to 42°C).

Water – Bathing and Swimming

The sensor can get wet. It can be submerged up to 6 feet (2 meters) under the water for up to 30 minutes. That means you can swim and bathe. Like any bandage, the medical tape becomes

less sticky when wet. Take care when the sensor is wet not to bump or pull on it.

Activities

See the component specifications to understand if the sensor can function in the environment of extreme activities. It should not be used for SCUBA diving or high altitudes above 10,500 feet (3,200 meters). If the sensor has been exposed to these conditions, stop using it and replace it with another sensor. The sensor can function in a commercial airplane. See section 6.11 for more about air travel.

6.8 Removing the Sensor

The sensor can only be used once. You must remove it after it stops working.

1. Grab one edge of the white medical tape of the sensor cover. Peel it off to remove it like you would remove a bandage.
2. Grab one edge of the white medical tape on the sensor. Peel it off to remove it like you would remove medical tape or a bandage.
3. Discard the sensor and the sensor cover in the trash. See section 6.9 *Disposal* to learn more.
4. If you can feel sticky remnants of the medical tape on your skin, wash with soap and water to remove it. You can also use an adhesive remover purchased from a pharmacy.

6.9 Disposal

The applicator, sensor cover, and the sensor are not considered a sharp or biohazard, so they can be discarded in standard waste, depending on local rules. The sensor is small and may be a choking hazard, so dispose of it where children may not reach it. Do not give a used sensor to another person.

The sensor includes a battery. Do not attempt to replace the battery, and do not dispose of the battery in an incinerator or shredder. The battery is for single use only. Dispose of the sensor containing the battery following your local regulations. The battery has been designed to protect you from off-gassing, burns, fires, or

explosions. Puncturing or damaging the battery could result in harm.

6.10 Starting Another Sensor

After you remove a sensor, you can apply another one. Follow the directions in this manual to apply the sensor and review any precautions. If you wear a new sensor soon after removing another sensor, choose a different space on your inner forearm. If you are using the app, press the scan button and place the phone on top of the sensor as the screens describe. You will not need to do any special app set up for the next sensor.

6.11 Air Travel and International Use

You can wear the sensor on an airplane. Because the sensor is not plugged into an electrical outlet, you do not need a converter when you travel to other countries.

Avoid X-ray machines or millimeter wave scanners. Do not wear the sensor into X-ray machines or Advanced Imaging Technology (AIT) body scanners (millimeter wave scanners), such as the ones at airport security checkpoints. The sensor has not been tested in these, and the magnetic fields could damage it. Hand-wanding, pat-downs, and metal detectors are suitable alternatives.

If you tell the security agents that you are wearing a medical device, they can advise you how to go through the security process. The US Transportation Security Administration (TSA, at www.tsa.gov) has a helpline and email address to answer questions for travelers with medical devices.

Bring a fingerstick blood glucose meter as a backup in case the sensor isn't working properly while you travel.

6.12 Cleaning

Wipe the sensor gently with a clean cloth if it is exposed to household chemicals like sunscreen, insect repellent, or other

cleaners. The sensor is for a single use only, so there is no cleaning of the sensor required before or after you use it.

6.13 Maintenance

The sensor is for single use only, and there is no maintenance.

6.14 Storage

Keep the sensor in its box until you are ready to use it.

Keep the sensor dry during storage. Do not get the box wet.

Store the sensor at room temperature in moderate climates or in the refrigerator but not in the freezer. Do not use if it was stored outside 36 to 86° F (2 to 30°C).

7 TROUBLESHOOTING

If you have any serious medical incidents from using the sensor, contact Biolinq Customer Support.

This table describes common troubleshooting tips. If you still need help after reading, contact Customer Support. Have the package label or applicator base label when you contact Customer Support.

If you feel or see	Do this
Hypoglycemia or hyperglycemia symptoms (e.g., fast heartbeat, shaking, lightheaded, sweating)	Use a fingerstick blood glucose meter to measure glucose. Contact your medical professional for medical advice.
Damage to the applicator or base before use or loose applicator base before use	Do not use. Replace it.
Damage to the sensor (cracks on the surface)	Do not use. Replace it.
A significant allergic reaction	Contact your medical professional for medical advice.
Skin discoloration after sensor removal that does not improve over time	After removal, you might see a colored spot that looks like a freckle. This could last days or sometimes weeks. It should not cause harm and should go away over time. If it becomes painful, contact your medical professional for medical advice about whether you might have an infection.

If you feel or see	Do this
Broken microsensor fragments in the skin after sensor removal	If you suspect a broken sensor, check for small pieces of it in the skin. A broken sensor may be more likely if it has been hit from the side. After removing the sensor, check the skin for any broken pieces. The microneedle, if broken, may leave small fragments in the skin that may not require medical intervention to remove. Gently wiping with a tissue or cloth may help remove small pieces. Gently placing a piece of tape on the skin for about ten seconds and then removing the tape may also help. Use tape that is not so strong that it will damage the skin.
White light (For more on colors see section 6.2)	Wait. Do not remove the sensor. Do not change your meals or activities. Wait for the sensor to readjust. The white Wait light will show during the first 2 hours you wear the sensor. Remove any inadvertent pressure on the device. Use a fingerstick blood glucose meter if you need to measure your glucose.
Blue light that never changes to another color (For more on colors see section 6.2)	This is not a problem unless your symptoms do not match the color. If the symptoms do not match the color, use a fingerstick blood glucose meter if you need to check your glucose levels. If your blood glucose meter and the sensor match, blue means you are in range.
Yellow light that never changes to another color. (For more on colors see section 6.2)	If your symptoms do not match the color, use a fingerstick blood glucose meter to check your glucose levels. If your blood glucose meter and the sensor match, consider following the advice from your healthcare professionals regarding how to manage elevated glucose levels. Contact your medical professional for further advice on improving your time in range.
Red light that never changes to another color. (For more on colors see section 6.2)	Use a fingerstick blood glucose meter to measure your glucose.
Purple light (For more on colors see section 6.2)	The sensor is done. Remove it.

If you feel or see	Do this
No lights	The sensor might be in snooze mode. If you are in a dark room, tap the device twice or turn on the room lights. If you are in bright sunlight, create shade over the device to see the lights better. Quickly tap the sensor twice to see if it was in snooze mode. See section 6.3 <i>How to Know the Sensor is Working</i>. If it stays dark after you try these tips, it has stopped working and can be removed.
Lights appear even though you tapped twice to snooze	Quickly tap twice again after you look at the color and understand what it means. If you snooze the sensor and later your glucose level or status changes, it will wake up again.
The sensor is upside down (the name or symbol is upside down)	Do nothing. This is not a problem, and it will work correctly.
Plastic parts separate from medical tape when removing the sensor	This is not a problem. Remove and discard all parts.
The sensor peels off the skin or peels apart before the normal end of its useful life	Remove it and do not attempt to press it back onto the skin.
Symptoms that do not match the color you see	Use a fingerstick blood glucose meter to measure glucose. Contact Customer Support to further troubleshoot. Contact your medical professional for medical advice about your symptoms if you are not feeling well.
You just exercised and the sensor shows yellow when you expect it to be blue	Sometimes your glucose can rise during or after exercise. This is temporary. Typically, there is no need to change this activity. Exercise is still helpful for lowering your glucose levels throughout the day. If you have concerns, contact your medical professional for advice.

If you feel or see	Do this
Time in range % on the app does not look correct	The time-in-range percentage is based on time blue (in range) for the calendar day divided by the total time blue + red + yellow. White is not included. This means all glucose ranges are used in the calculation, but times when the sensor could not calculate glucose (white light, "Wait") are not used. If your sensor displayed the white light this might make your final time-in-range calculation different than you expected.
Can't change goals in the app for activity or time in range	Goals can't be adjusted while you are in an active sensor session. Wait until the sensor's use life ends. After the sensor's end of use life, scan the sensor so the app can tell that the sensor has ended. Then, press the Profile button and select Goals to change them for the next sensor session.
Activity and rest don't display on the My data weekly view	In the timeline weekly view, press the down arrow next to the % and other icons. You can turn on views for activity and sleep. See the section "My Data – Seeing Activity and Sleep" in this manual.
Can't log events (meal, sleep, activity, medication, side effects) from previous days in the current wear session	Press the My data button, then select the active wear session, and then select the day the event happened. From this view, press the "Add event" button to add the event. Other than medication and side effects, these events can't be added if your sensor is no longer active – that is, if the sensor use life has ended and the sensor is purple.
Can't add meal, sleep, or activity	If you still have an active sensor (showing blue, yellow, red, or white), press the + on the Home screen or "Add Event" in the Daily view to add activities. These events can't be added if your sensor is no longer active – that is, if the sensor use life has ended and the sensor and app home page are purple.
Can't log future events in the app	The app is only intended for logging events that have already happened. Although you can't log future events, you can set reminders for daily activities. In the Profile menu, select "Reminders and notifications."

If you feel or see	Do this
Can't load activities and sleep from other health or wellness apps like Apple Health or Apple Watch	The app does not currently work with other apps or devices. You can manually enter and log events through the app interface.
The app did not automatically recognize and display your activity or sleep	The app estimates activity and sleep based on movements and other information. It may not recognize all types of activity or sleep. Activities with slow or few arm movements, such as biking or strength exercise might not be recognized. Short bursts of activity might not be recognized. Sleep that has excess movement ("tossing and turning") might not be recognized. You can add activity and sleep following the instructions in Section 6.
The app recorded an incorrect time for your activity or sleep	The app estimates activity and sleep based on movements and other information. It is not exact and is meant for general logging. You can edit activity and sleep following the instructions in section 6.
The app's insight text shows a different amount of activity time than expected	The app estimates activity based on movements. Some slower or shorter bursts of movement, such as simple chores, may be measured but not displayed as a green bar on the My data screen or activity card. The words in the insight might include these other movements in the total time.
Can't change the email address in the app / Verification code going to the wrong email	Changing the email address requires contacting customer support because the app uses one-time password email authentication. Contact customer support through the method you prefer. The contact information is on the first page of this manual and at www.biolinq.com/support

You can find these and other instructions and tips at www.biolinq.com/support.

8 DISEASE AND SELF-CARE (WHEN TO GET MEDICAL HELP)

The sensor keeps you aware of glucose ranges and excursions, but it does not give medical advice. Contact your medical professional if any of these events happen:

- You feel major symptoms of hypoglycemia or hyperglycemia, or you feel these symptoms for a long time – fast heartbeat, shaking, lightheaded, excess sweating not from heat.
- Pain during wear or after removal that might suggest an infection.
- Significant allergic reaction, irritation, or itching.

9 COMPONENTS AND MATERIALS

9.1 Component Specifications

Subject	Specification
Glucose range	70 to 400 mg/dL
Glucose assay method	Amperometric electrochemical sensor
Useful life	Up to 5 days
Storage and transport temperature	36 to 86° F (2 to 30°C)
Storage and transport humidity	Do not get the sensor wet during storage.
Sterilization	The part that goes into the skin is sterile by radiation.
Memory	Up to 5 days, stored for up to 24 hours after useful life.
Electrical safety class	Internally powered
Operating conditions	50 to 107° F (10 to 42°C) 10-90% humidity, non-condensing
Operating altitude	-300 to 10,500 ft (-91 to 3200 meters) (pressure 678 hPa to 1025 hPa)
Power source	Internally powered non-replaceable and non-rechargeable battery (follow the operating conditions for the device).
Ingress protection (water resistance and dust)	IP58: dust protection to degree 5 and water protection to 6 feet (2 meters) deep for 30 minutes.
Protection against electrical shock	Type BF applied part
Transmission frequency	Near Field Communication 13.56 MHz, ASK Modulation
Data communication range	0-inch to up to approximately 0.39-inch (0mm to 10mm)

9.2 FCC



This device complies with 47 CFR 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.

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 environment. This equipment generates, uses, and can radiate radio frequency energy and, if not 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 environment. If this equipment does cause harmful interference to radio communications, the user is encouraged to try to correct the interference by increasing separation between the equipment and affected radio communications device.

Note: "Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the Radio Regulations established by the International Telecommunications Union.

9.3 EMC and Electrical Safety

The sensor is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

Electromagnetic interference can occur in the home health care environment even if the other equipment complies with emissions requirements. An interference event can be recognized by gaps in sensor readings or gross inaccuracies.

The expected performance for the sensor is to display yellow when glucose is above range. However, if performance is degraded or lost due to electromagnetic interference, the sensor may falsely display blue or red or may stop working.

Emission test	Compliance / Environment
RF emissions CISPR 11 / FCC Part 15	Group 1 The Spectrum 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.
RF emissions CISPR 11 / FCC Part 15	Class B The sensor 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.
Harmonic emissions IEC 61000-3-2	N/A
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A
RF emissions Aircraft use	RTCA DO-160G Section 21, Category M (Radiated RF Emissions), as per FAA circular AC 91-21-1D. Can be used on aircraft according to the directions provided by the operator of the aircraft

- **WARNING!** Use of this equipment adjacent to or stacked may result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Immunity Test	Compliance / Environment
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 15 kV Air The relative humidity should be at least 5%
Power Frequency Magnetic Field (50 and 60Hz) IEC 61000-4-8	30 A/m Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic environment
Proximity Magnetic Fields IEC 61000-4-39	Tested at 30 kHz, 134.2 kHz & 13.56 MHz
Electrical Fast Transient/Burst IEC 61000-4-4	N/A
Surge IEC 61000-4-5	N/A
Voltage Dips and Interruptions IEC 61000-4-11 IEC 60601-1-11	N/A
Conducted Fields Disturbance IEC 61000-4-6	N/A
Radiated Fields Disturbance IEC 61000-4-3	10 V/m at 80 to 2700 MHz
Radiated and Conducted Fields Aircraft use	RTCA DO-160G Section 20, Category T (Radiated RF Susceptibility), as per FAA circular AC 91-21-1D. Can be used on aircraft according to the directions provided by the operator of the aircraft



WARNING: 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 sensor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Wireless Use Characteristics and Risks: The sensor transfers data to the app using NFC. This allows the app to display information on a compatible phone. The sensor can work with or without the app. The phone can connect to cloud services using WiFi or cellular service. This allows the phone to communicate account information (e.g., logging into the account). The required characteristics of the IT network include the presence of the phone's NFC antenna and secure WiFi or cellular service. No special characteristics, technical specifications, or configurations of the network are required for the system to function. Cybersecurity characteristics and requirements are described in the next section. The sensor shows the current glucose range even during a failure in the IT network to the app or the cloud; however, account services like logging into the app will not work without WiFi or cellular. Connecting to a WiFi or cellular network is not expected to result in risks to other equipment on that network. Connecting additional items to the WiFi or cellular network is not expected to result in risks to the sensor.

Quality of Service: The device wirelessly transfers data from a distance of 0 – 0.39 inches (0.0 – 1.0 cm/0.0 – 10 mm) using an NFC reader. Quality of service is assured when the user presses the scan button in the app and holds the mobile phone to touch the sensor as described in the app. If the expected response is not received, an on-screen message will display.

9.4 Cybersecurity

Access Controls - The sensor does not include any required apps as part of the system, although the Biolinq app may be used if desired. The sensor does not need any external device to control its operation. The sensor provides access to export glucose, step data, and proprietary event logs to the app. The app is only able to receive data from the sensor after an active scan. Data is encrypted with a proprietary format using industry standard encryption with sensor-specific encryption keys and integrity controls. These protection mechanisms are implemented end-to-end. The app can read information from the sensor but cannot write or control the sensor. The app user is only able to change personal information like name and birthdate and cannot change glucose history or amend any data on the sensor.

Connectivity and Wireless Network Controls - The sensor only communicates to the mobile app by short-range Near Field Communication (NFC), which is a form of wireless interfacing that is difficult to intercept or interfere. It does not continuously communicate. It will not transmit radio frequency communications using any other protocols, including Bluetooth. The sensor cannot detect potential security events, so do not let anyone you do not trust place a phone or NFC-capable device directly on top of the sensor while you are wearing it or after you remove it. Although there are other protections in place, this might mean they are trying to take your medical data. If you plan to use the app, consider scanning soon after you first apply the sensor. This will pair your phone to the sensor and help block other unintended users from pairing a phone with the sensor.

The app communicates to the internet using wireless networks (https) through your phone. Although the app can continue to run on the phone without a network connection, the network connection is required to install the app, set up the account, and change account information like name and birthdate. When using the app, only use a secure internet connection, such as a trusted home WiFi network or cellular connection and not an unsecured public network. Be careful to maintain the security of your phone. Only install apps from trusted sources, such as the Apple App Store. Check for updates on the Apple App Store and only install updates from the Apple App Store. To see a list of supported phones and operating systems, see www.biolinq.com/compatibility.

Authentication and Integrity - Authentication between the sensor and the app occurs during pairing using asymmetric cryptography and digital signatures.

Anti-malware - The sensor does not provide a traditional user interface, operating system, or input mechanisms that would be susceptible to common computer malware and viruses. The sensor runs custom firmware tailored to its hardware. The app runs on a mobile phone but does not connect to other apps or programs. Only install apps from trusted sources, such as the Apple App Store.

Updates and Patching – The sensor is a disposable device used for five days. It cannot be updated. There is no servicing, repair, or patching for the sensor. For the app, follow the recommended updates shown in the Apple App Store for software updates and security patches. The app connects to the cloud to store your personal information like name and birthdate. If you replace or update your phone, this information can be restored. Glucose and activity information will not be restored.

After use - If you have the BiolinQ app, scan the sensor to upload the data to the app. You can do this before or after the sensor's end of use life (purple light). This locks the sensor to your personal account so no one else can upload its data. If you are unable to pair your sensor with the app, all data remaining on the sensor is anonymous and encrypted with unique keys. It will retain a record of glucose and activity levels but will not include information like your name or birthdate. You can discard the sensor. Contact customer support if you have further questions.

When users register for a BiolinQ account to use the app, they can see their own glucose and activity information in the app, and they can enter personal information like name, birthdate, and email address. Users can change their personal information but cannot change their glucose information.

Prohibitions - Disassembly of the sensor is prohibited. Using the app on a jailbroken phone is prohibited. This could subject you to cybersecurity risks.

Reporting incidents - Stop using the device if you suspect a security incident. If you suspect a security incident has occurred, are concerned about a security vulnerability, or if you need help to investigate any tampering or activity identified involving the sensor or the app, please contact Customer Support (www.biolinq.com/support). See the contact page near the start of this Manual for other methods to contact support. If your symptoms do not match the color you see on the sensor or the app, use a fingerstick blood glucose meter to check your glucose levels.

SBOM - A Software Bill of Materials is available on request. Visit www.biolineq.com/support

10 CLINICAL RESULTS AND ADVERSE EVENTS

Biolinq performed a clinical study with 202 adult subjects with Type 1 and Type 2 diabetes. The study included subjects on intensive insulin therapy, subjects using basal insulin, and subjects who do not take insulin. Subjects wore at least one device for at least five days on the inner forearm. The device was compared to a laboratory reference method, the Yellow Springs Instrument (YSI) STAT PLUS 2300 Analyzer, to evaluate accuracy. Performance results from 190 devices are presented below.

Demographic	Mean (Median) or n (%)
Age (years)	49.4 (52.6)
Female	96 (47.5%)
Hispanic/Latino	49 (24.3%)
Race*	
White or Caucasian	166 (84.3%)
Black or African American	16 (8.1%)
Asian	12 (6.1%)
Other	9 (4.6%)
Fitzpatrick Skin Type	
Type I	2 (1.0%)
Type II	46 (22.8%)
Type III	69 (34.2%)
Type IV	68 (33.7%)
Type V	15 (7.4%)
Type VI	2 (1.0%)
Height (in)	67.2 (67.1)
Weight (lbs.)	198.9 (192.4)
BMI (kg/m ²)	30.9 (30.4)
BMI Category (kg/m ²)	
Underweight (<18.5)	1 (0.5%)
Normal (18.5-24.9)	36 (17.8%)
Overweight (25.0-29.9)	60 (29.7%)
Obese Class I (30.0-34.9)	62 (30.7%)
Obese Class II (35.0-39.9)	24 (11.9%)
Obese Class III (≥ 40.0)	19 (9.4%)
Diabetes Type	
Type 1	135 (66.8%)
Type 2 on intensive insulin therapy	41 (20.3%)
Type 2 on basal insulin only	12 (5.9%)
Type 2 not on insulin	14 (6.9%)

*N =197 total subjects reported their race. N = 202 total subjects for all other Demographics

For all points when the sensor displays BLUE (reads 70-180 mg/dL), the percentage of YSI values between 55-207 mg/dL was calculated, and the lower one-sided 95% confidence bound is 93%. For all points when the sensor displays YELLOW (reads 181-400 mg/dL), the percentage of YSI values between 154-460 mg/dL was calculated, and the lower one-sided 95% confidence bound is 96%.

Approximately 85% of sensors lasted the entire five-day intended wear period (161/190), with a mean display rate of 94% and a median display rate of 98%.

No device related serious adverse events occurred during the study. In the study, seven subjects experienced skin irritations, such as itchiness, erythema, edema, bruising, and a scabbed wound. They were all classified as mild.

10.1 Concurrence

The following tables show the concurrence of the BiolinQ Shine readings to reference values (YSI). The tables tell you for each glucose range measured by the BiolinQ Shine what percentage of YSI values were in the same glucose range (shaded) or in glucose ranges above or below the BiolinQ Shine. Each table's heading describes whether the ranges shown are those displayed by the wearable sensor or the mobile app. The first two tables show the full wear period, and the following tables show specific days at the beginning, middle, and end of the wear period.

Wearable concurrence table, full wear period

BiolinQ Shine (mg/dL)	YSI (mg/dL)			
	< 70	70-180	181-400	> 400
< 70 (n=674)	73.9%	26.1%	0.0%	0.0%
70-180 (n=7,904)	6.7%	79.8%	13.5%	0.0%
181-400 (n=5,964)	0.0%	12.8%	86.2%	1.0%
> 400 (n=14)	0.0%	0.0%	21.4%	78.6%

App concurrence table, full wear period

Biolog Shine (mg/dL)	YSI (mg/dL)					
	< 70	70-125	126-180	181-300	301-400	> 400
< 70 (n=674)	73.9%	26.1%	0.0%	0.0%	0.0%	0.0%
70-125 (n=4,093)	12.9%	66.9%	17.7%	2.4%	0.0%	0.0%
126-180 (n=3,811)	0.0%	17.7%	56.9%	24.8%	0.6%	0.0%
181-300 (n=5,197)	0.0%	0.3%	14.4%	70.9%	14.2%	0.1%
301-400 (n=767)	0.0%	0.0%	0.0%	20.7%	72.8%	6.5%
> 400 (n=14)	0.0%	0.0%	0.0%	0.0%	21.4%	78.6%

Wearable concurrence table, Day 1 (beginning of wear period)

Biolog Shine (mg/dL)	YSI (mg/dL)			
	< 70	70-180	181-400	> 400
< 70 (n=208)	53.8%	46.2%	0.0%	0.0%
70-180 (n=2,890)	6.7%	80.3%	13.0%	0.0%
181-400 (n=1,828)	0.0%	14.2%	84.4%	1.4%
> 400 (n=10)	0.0%	0.0%	30.0%	70.0%

Wearable concurrence table, Day 3 (middle of wear period)

Biolog Shine (mg/dL)	YSI (mg/dL)			
	< 70	70-180	181-400	> 400
< 70 (n=264)	84.1%	15.9%	0.0%	0.0%
70-180 (n=2,430)	6.8%	79.0%	14.2%	0.0%
181-400 (n=2,300)	0.0%	14.2%	85.1%	0.7%
> 400 (n=0)	N/A	N/A	N/A	N/A

Wearable concurrence table, Day 5 (end of wear period)

Biolinq Shine (mg/dL)	YSI (mg/dL)			
	< 70	70-180	181-400	> 400
< 70 (n=202)	81.2%	18.8%	0.0%	0.0%
70-180 (n=2,584)	6.7%	80.0%	13.4%	0.0%
181-400 (n=1,836)	0.0%	9.8%	89.3%	0.9%
> 400 (n=4)	0.0%	0.0%	0.0%	100.0%

App concurrence table, Day 1 (beginning of wear period)

Biolinq Shine (mg/dL)	YSI (mg/dL)					
	< 70	70-125	126-180	181-300	301-400	> 400
< 70 (n=208)	53.8%	46.2%	0.0%	0.0%	0.0%	0.0%
70-125 (n=1,582)	12.2%	65.8%	19.4%	2.6%	0.0%	0.0%
126-180 (n=1,308)	0.0%	16.0%	58.5%	24.9%	0.6%	0.0%
181-300 (n=1,574)	0.0%	0.1%	16.5%	68.9%	14.6%	0.0%
301-400 (n=254)	0.0%	0.0%	0.0%	11.4%	78.7%	9.8%
> 400 (n=10)	0.0%	0.0%	0.0%	0.0%	30.0%	70.0%

App concurrence table, Day 3 (middle of wear period)

Biolinq Shine (mg/dL)	YSI (mg/dL)					
	< 70	70-125	126-180	181-300	301-400	> 400
< 70 (n=264)	84.1%	15.9%	0.0%	0.0%	0.0%	0.0%
70-125 (n=1,230)	13.4%	65.7%	19.6%	1.3%	0.0%	0.0%
126-180 (n=1,200)	0.0%	18.6%	53.9%	27.3%	0.2%	0.0%
181-300 (n=2,078)	0.0%	0.7%	15.0%	70.1%	13.9%	0.3%
301-400 (n=222)	0.0%	0.0%	0.0%	26.1%	69.8%	4.1%
> 400 (n=0)	N/A	N/A	N/A	N/A	N/A	N/A

App concurrence table, Day 5 (end of wear period)

Biolinq Shine (mg/dL)	YSI (mg/dL)					
	< 70	70-125	126-180	181-300	301-400	> 400
< 70 (n=202)	81.2%	18.8%	0.0%	0.0%	0.0%	0.0%
70-125 (n=1,281)	13.4%	69.4%	13.8%	3.4%	0.0%	0.0%
126-180 (n=1,303)	0.0%	18.7%	58.1%	22.3%	0.8%	0.0%
181-300 (n=1,545)	0.0%	0.2%	11.5%	74.1%	14.2%	0.0%
301-400 (n=291)	0.0%	0.0%	0.0%	24.7%	69.8%	5.5%
> 400 (n=4)	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%

The table below presents the same true concurrence results presented in the tables above. It also includes an evaluation of when the values did not concur, specifically showing the percentage of matched sensor values that were within ± 15 mg/dL/15% of the reference value for both the wearable and mobile app display.

Wearable and app concurrence table, full wear period, 15/15

Display	Biolinq Shine Color Display Range (mg/dL)	n	YSI Range (mg/dL)		
			-15 mg/dL/ -15%	True Concurrence	+15 mg/dL/ +15%
Wearable	BLUE RANGE (70-180)	7,904	55-69 6.1%	70-180 79.8%	181-207 8.9%
	YELLOW RANGE (181-400)	5,964	154-180 9.8%	181-400 86.2%	401-460 0.9%
Mobile App	BLUE RANGE 1 (70-125)	4,093	55-69 11.8%	70-125 66.9%	126-144 10.7%
			107-125 13.2%	126-180 56.9%	181-207 16.9%
	YELLOW RANGE 1 (181-300)	5,197	154-180 11.2%	181-300 70.9%	301-345 11.5%
			256-300 18.0%	301-400 72.8%	401-460 5.7%
	YELLOW RANGE 2 (301-400)	767	< 70 N/A	70-84 73.9%	> 84 19.1%
			> 400 14.3%	> 400 78.6%	N/A
Both ¹	RED RANGE (< 70)	674	N/A	< 70 73.9%	70-84 19.1%
	RAPID YELLOW (> 400)	14	321-400 14.3%	> 400 78.6%	N/A

¹The red range and yellow range are the same in both the wearable and app.

10.2 Sensor Life

Sensors are designed to be worn for up to five days. Some sensors may not survive the full five days for a variety of reasons. To estimate how long a sensor will work over the intended use life, see the table below.

Wear Day	Number of Sensors	Survival Rate (%)
1	183	96.3%
2	178	93.7%
3	173	91.1%
4	169	88.9%
5	161	84.7%

10.3 Glucose Data Availability

The display rate is the number of glucose readings (red, blue, and yellow displays) provided, divided by the number of expected glucose readings for the given sensor lifetime. The sensor warm-up period is excluded from the display rate calculation.

Number of Sensors	Mean $\pm$ SD (Median)	Percent with $\geq$ 85% Display Rate
190	93.9 $\pm$ 13.7 (98.4)	88.9%

10.4 Rate of Change

The device's ability to detect glucose rate of change (displayed by both lights blinking on the wearable or the app description that glucose is "in range and rising") was assessed against the YSI reference rate of change. The analysis is presented in this table:

Wearable Display	YSI					
	> 2	(1,2]	[0,1]	[-1,0]	[-2,-1]	< -2
Bioling Shine in BLUE (70-180 mg/dL) and ROC is > 2 mg/dL/min (n=122)	52 (42.6%)	48 (39.3%)	17 (13.9%)	4 (3.3%)	1 (0.8%)	0 (0.0%)

10.5 Precision

To measure the precision of the sensor, some subjects were randomized to wear two sensors. Precision was evaluated by comparing the glucose readings from the two sensors worn on the same subject at the same time. Sixty-eight subjects were included in the assessment of device precision and wore two devices.

Concurrence analysis for wearable display ranges

Primary (mg/dL)	Secondary (mg/dL)			
	< 70	70-180	181-400	> 400
< 70	916 / 1,727 (53.0%)	806 / 1,727 (46.7%)	5 / 1,727 (0.3%)	0 / 1,727 (0.0%)
70-180	772 / 52,144 (1.5%)	47,339 / 52,144 (90.8%)	4,033 / 52,144 (7.7%)	0 / 52,144 (0.0%)
181-400	25 / 25,972 (0.1%)	5,670 / 25,972 (21.8%)	20,269 / 25,972 (78.0%)	8 / 25,972 (0.0%)
> 400	0 / 42 (0.0%)	0 / 42 (0.0%)	42 / 42 (100.0%)	0 / 42 (0.0%)

Concurrence analysis for mobile app display ranges

Primary (mg/dL)	Secondary (mg/dL)					
	< 70	70-125	126-180	181-300	301-400	> 400
< 70	916 / 1,727 (53.0%)	787 / 1,727 (45.6%)	19 / 1,727 (1.1%)	5 / 1,727 (0.3%)	0 / 1,727 (0.0%)	0 / 1,727 (0.0%)
70-125	731 / 24,985 (2.9%)	19,837 / 24,985 (79.4%)	4,172 / 24,985 (16.7%)	245 / 24,985 (1.0%)	0 / 24,985 (0.0%)	0 / 24,985 (0.0%)
126-180	41 / 27,159 (0.2%)	5672 / 27,159 (20.9%)	17,658 / 27,159 (65.0%)	3,768 / 27,159 (13.9%)	20 / 27,159 (0.1%)	0 / 27,159 (0.0%)
181-300	25 / 24,137 (0.1%)	483 / 24,137 (2.0%)	5,141 / 24,137 (21.3%)	17,739 / 24,137 (73.5%)	749 / 24,137 (3.1%)	0 / 24,137 (0.0%)
301-400	0 / 1,835 (0.0%)	14 / 1,835 (0.8%)	32 / 1,835 (1.7%)	957 / 1,835 (52.2%)	824 / 1,835 (44.9%)	8 / 1,835 (0.4%)
> 400	0 / 42 (0.0%)	0 / 42 (0.0%)	0 / 42 (0.0%)	0 / 42 (0.0%)	42 / 42 (100.0%)	0 / 42 (0.0%)

10.6 Interfering Substances

Acetaminophen Clinical Interference Study

A single-site, single-arm, open-label observational study was conducted to evaluate acetaminophen interference. The study enrolled 31 subjects (with 30 completing device application) who received a single 1000 mg oral dose of acetaminophen. The study compared the device's glucose outputs to a laboratory blood glucose analyzer (YSI STAT Plus 2300) at the pre-dose baseline and every hour after acetaminophen ingestion for up to 6 hours.

Peak plasma concentration is expected 2-3 hours after oral acetaminophen ingestion. Agreement of the semi-quantitative outputs from the sensor with the comparator method (CM) is presented below.

Sensor agreement before and after acetaminophen administration

Time	n	Biolog In Agreement with CM (%)	Biolog In Higher Range than CM (%)	Biolog In Lower Range than CM (%)
Pre-dose	247	81.0%	13.4%	5.7%
1 h Post-dose	117	74.4%	20.5%	5.1%
2 h Post-dose	111	79.3%	14.4%	6.3%
3 h Post-dose	110	83.6%	13.6%	2.7%
4 h Post-dose	114	76.3%	18.4%	5.3%
5 h Post-dose	113	75.2%	15.9%	8.8%
6 h Post-dose	113	79.6%	10.6%	9.7%

Mobile app agreement before and after acetaminophen administration

Time	n	Biolog In Agreement with CM (%)	Biolog In Higher Range than CM (%)	Biolog In Lower Range than CM (%)
Pre-dose	247	67.2%	17.8%	15.0%
1 h Post-dose	117	59.0%	27.4%	13.7%
2 h Post-dose	111	64.0%	23.4%	12.6%
3 h Post-dose	110	60.9%	24.5%	14.5%
4 h Post-dose	114	54.4%	31.6%	14.0%
5 h Post-dose	113	61.9%	22.1%	15.9%
6 h Post-dose	113	64.6%	14.2%	21.2%

11 SYMBOLS GLOSSARY

These symbols might appear on the product label.

Symbol	Definition	Standard
	Manufacturer (name & address)	ISO 15223-1 5.1.1
	Medical device	ISO 15223-1 5.7.7

Symbol	Definition	Standard
	Consult instructions	ISO 15223-1 5.4.3
	Do not use if product is damaged	ISO 15223-1 5.2.8
	Do not reuse	ISO 15223-1 5.4.2
	Expiration date	ISO 15223-1 5.1.4
	Type BF applied part	IEC 60417-5333
	Keep dry	ISO 15223-1 5.3.4
	Temperature limits	ISO 15223-1 5.3.7
	Sterilized by radiation	ISO 15223-1 5.2.4
	Sterile barrier with protective packaging outside	ISO 15223-1 5.2.14
	Requires prescription	--
	Catalog or part number	ISO 15223-1 5.1.6
	Lot number	ISO 15223-1 5.1.5
	Serial number	ISO 15223-1 5.1.7
	Date of manufacture	ISO 15223-1 5.1.3
	MR unsafe: the device should remain outside the MRI scanner room	ASTM F2503
	Unique device identifier number	ISO 15223-1 5.7.10

12 WARRANTY

A copy of the warranty can be found at warranty.shine.biolinq.com

13 TRADEMARK, COPYRIGHT, PATENT

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