

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 microsensors 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.

Who Can Use It?

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.

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.

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.

Warning

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

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.

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 Biolinq Shine 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.