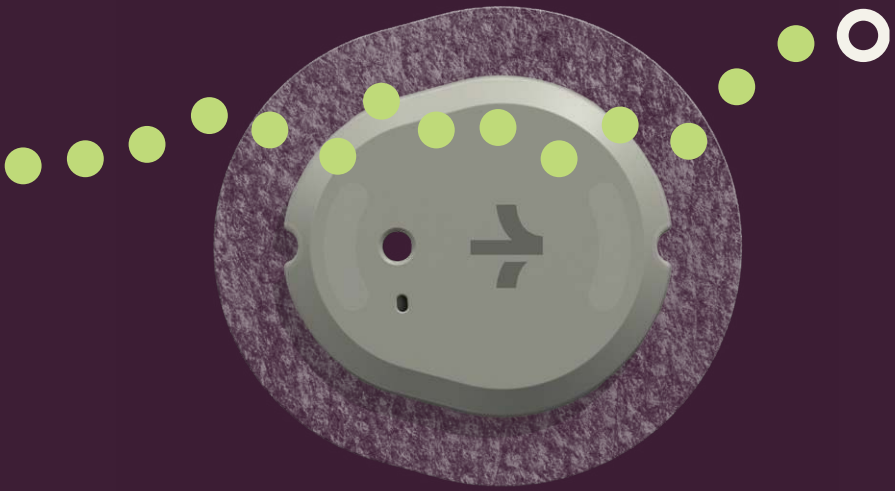
stelo



by Dexcom

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Welcome

Thanks for choosing the Stelo Glucose Biosensor™ System (Stelo).

You're here. We're so glad you've joined a community of bold, brave people like you who are interested in taking the lead when it comes to health.

You care about how your lifestyle choices affect your health, especially when it comes to your glucose, and you want to make the best choices possible.

Wearing Stelo means you'll get glucose levels delivered to your smartphone 24/7. No need to test your blood glucose any other way throughout the day.

Why Stelo?

- Stelo allows you to experience the confidence consistent glucose tracking brings.
- Knowing how your choices with diet, activity, medication, or even stress affect your glucose levels gives you the power to make decisions that count.

Remember: Personal insights lead to personal success. You're now on your way to optimal glucose health.

User guide

This *Stelo User Guide* introduces you to your app, provides troubleshooting tips, and shows you how to move to your next sensor session. Each sensor session lasts up to 15 days[1].

[1]A study was conducted to assess the sensor life where 77.9% of sensors lasted the full 15 days. In other words, when using the product per the package labeling, approximately 20% of sensors may not last for the full 15 days, 10% of these sensors may last less than 12 days.

You can find the latest *Stelo User Guide* at:

- App: **Settings > Help**
- Print: Order a free copy at **stelo.com**
- Web: **stelo.com/guides**

Contact

Stelo has support teams to help you. Go to **stelo.com/contact** to connect with them.

In the app, go to **Settings > Contact** to get help.

Corporate office

Dexcom address:

6340 Sequence Drive, San Diego, CA 92121

Compatibility

The app works on Apple® and Android™ smartphones. For Stelo app operating system compatibility, go to **stelo.com/compatibility**.

Safety information

Safety statements

Indications for use

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

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

Contraindications

No MRI/CT/diathermy — MR unsafe: Don't wear any Stelo Glucose Biosensor System component during magnetic resonance imaging (MRI) or high-frequency electrical heat (diathermy) treatment. However, it's safe to have a CT scan if you keep the sensor out of the scanned area and cover the sensor with a lead apron during the scan.



The Stelo Glucose Biosensor System hasn't been tested in those situations when used during an MRI scan, diathermy, or in the scanned area of a CT scan. The magnetic fields and heat could damage Stelo Glucose Biosensor System components, which may cause inaccurate sensor readings.

Warnings

Choking hazard: The Stelo Glucose Biosensor System contains small parts and may pose a choking hazard if swallowed.

Don't use if you are on insulin: The Stelo Glucose Biosensor System hasn't been designed for these populations. Consult with your healthcare provider to discuss which Dexcom product is right for you.

Don’t use if you have problematic hypoglycemia: The Stelo Glucose Biosensor System hasn’t been designed for these populations. Consult with your healthcare provider to discuss which Dexcom product is right for you.

Don’t use if you are on dialysis: The Stelo Glucose Biosensor System performance hasn’t been evaluated in this population and sensor readings may be inaccurate.

Don’t ignore low/high symptoms: Consult your healthcare provider when your sensor readings are not consistent with your symptoms of low or high glucose.

Don’t change medications: Consult your healthcare provider before making any medication adjustments based on your sensor readings.

Cautions

What to know before using the Stelo Glucose Biosensor System:

- Review product instructions before using the Stelo Glucose Biosensor System.
- Balanced nutrition supports glucose management and provides essential nutrients and energy for the body.
- Consult your healthcare provider before using Stelo if you have a history of disordered eating or eating disorders.

What to know before applying the sensor:

- Don't start a sensor past its Use By Date (YYYY-MM-DD) because it may give incorrect results. You can start a new sensor on or before its Use By Date. This gives you full wear.
- Do not use any damaged or cracked Stelo Glucose Biosensor System components because they may not work correctly and could cause injuries from electrical shocks. If the applicator and/or sterile cap has been damaged or opened, it might cause an infection. Don't remove cap until ready for insertion.
- Clean and dry your hands prior to handling your sensor and clean your insertion site with alcohol wipes to prevent infections. If your insertion site and hands aren't clean and dry, you run the risk of infection and the sensor not sticking well. Before insertion, don't apply insect repellent, sunscreen, perfume, or lotion on your insertion site or sensor. This may cause the sensor to not stick well.
- Only insert your sensor on the back of your upper arm. Don't wear your sensor on other sites (such as your abdomen), as it may not work as expected.
- The Stelo Glucose Biosensor System insertion safety guard is enabled until you press the Stelo Glucose Biosensor System applicator down against your skin. Only do this when ready to insert.
- Change your insertion site with each sensor to allow the skin to heal. Avoid areas:
    - With loose skin or without enough fat to avoid muscles and bones.
    - That get bumped, pushed, or you lie on when sleeping.
    - Within 3 inches of an injection site.
    - With irritations, scarring, tattoos, or lots of hair. If needed, trim site with electric clippers.

What to know while using your sensor:

- Make sure your smartphone's Bluetooth is on and keep your smartphone battery charged to prevent missed readings.
- Keep your sensor and smartphone within 20 feet with no obstacles between them. Otherwise, they might not be able to communicate.
- Don't use the Stelo Glucose Biosensor System to diagnose or indicate your risk of developing diabetes. Don't use information from Stelo alone to determine the risk of problematic hypoglycemia.
- If you need to track your glucose levels when the Stelo Glucose Biosensor System readings don't match how you feel, don't show a number, or during the 30 minute sensor warmup period, a blood glucose meter may be an option as needed.
- Don't ignore broken or detached sensor wires. If this happens, contact 24/7 technical support (in the app, go to **Settings > Contact**). If a sensor wire breaks off or detaches under your skin and you can't see it, don't try to remove it. Contact your healthcare provider if you have symptoms of infection or inflammation — redness, swelling, or pain — at the insertion site.
- During your sensor session, don't apply insect repellent, sunscreen, perfume, or lotion on your insertion site or sensor. This may cause the sensor to not stick well or could damage the Stelo Glucose Biosensor System.

- When going through a security check point, you can wear the Stelo Glucose Biosensor System sensor for the walk-through metal detector and Advanced Imaging Technology (AIT) body scanner. If you do, don't use the Stelo Glucose Biosensor System until you leave the security area. This is because the Stelo Glucose Biosensor System hasn't been tested with every x-ray and security scanner and you may not be able to bring a smartphone. You can also ask for hand-wanding or full-body pat-down and visual inspection instead of going through any walk-through body scanners or putting any part of the Stelo Glucose Biosensor System in the baggage scanning machine.

What to know about the Stelo Glucose Biosensor System:

- No modifications to the Stelo Glucose Biosensor System are allowed.
- Stelo Glucose Biosensor components aren't compatible with any other Dexcom products. Don't mix with any other Dexcom products.
- Only use a cellular internet connection, a trusted Wi-Fi network (like your home or office), or use a secure internet connection such as a VPN service when using the Stelo Glucose Biosensor System. Don't use unsecured public Wi-Fi such as guest networks in other's homes, restaurants, schools, libraries, hotels, airports, airplanes, etc. Those could expose the Stelo Glucose Biosensor to viruses or hacking.
- Before upgrading your smartphone or its operating system, check for compatibility at **stelo.com/compatibility**. Automatic updates of the app or your smartphone operating system can change settings or shut down the app. Always update manually and verify correct device settings afterward.
- While connected to the internet, the app periodically checks compatibility and will display a message if it's not compatible (or no longer compatible) with your smartphone or your smartphone's operating system (OS). The message may include a timeframe for updates.

- Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches to any part of the Stelo Glucose Biosensor System. Otherwise, degradation of the performance of this equipment could result in improper operation. Use of this equipment adjacent to, or stacked with, other equipment should be avoided because it could result in improper operation.

How to store the sensor:

- You can store your sensors at room temperature or in your refrigerator, between 36°F and 86°F, but not in the freezer.

Interfering substance risks

Hydroxyurea

Hydroxyurea is a medication used in the treatment of diseases including cancer and blood disorders; it is known to interfere with sensor readings.

If you are taking hydroxyurea, your sensor readings will be higher than your actual glucose. The level of inaccuracy depends on the amount of hydroxyurea in your body. Talk to your physician about alternative glucose monitoring approaches.

Acetaminophen

With the Stelo Glucose Biosensor System, you can take a standard or maximum acetaminophen dose of 1 gram (1,000 mg) every 6 hours and still use the Stelo Glucose Biosensor System. Taking higher than the maximum dose of acetaminophen (e.g. > 1 gram every 6 hours in adults) may affect the sensor readings and make them look higher than they really are.

Risks and benefits

The risks and benefits of your Stelo Glucose Biosensor System are discussed below. Avoid any risks and enjoy the Stelo Glucose Biosensor System's benefits by following the product instructions.

Risks

The risks with using the Stelo Glucose Biosensor System are:

- Sensor insertion issues
  - Adhesive reactions
  - Retained sensor wire
- Interfering substances
- Inaccurate sensor readings, nutrition information, or insights

Sensor insertion issues

In rare cases, inserting the sensor can cause infection, bleeding, or pain, and wearing the adhesive patch can irritate your skin. For most people, the adhesive reactions are mild and resolve within a week. Only a few participants in the clinical studies got slight redness and swelling. Although uncommon, some people get a significant reaction from the sensor adhesive that may take weeks to resolve. If a sensor wire breaks off or detaches under your skin and you can't see it, don't try to remove it. Contact your healthcare provider if you have symptoms of infection or inflammation — redness, swelling, or pain — at the insertion site.

Interfering substances

Acetaminophen

With the Stelo Glucose Biosensor System you can take a standard or maximum acetaminophen dose of 1 gram (1,000mg) every 6 hours and still use the Stelo Glucose Biosensor System. Taking higher than the maximum dose of acetaminophen (e.g. > 1 gram every 6 hours in adults) may affect the sensor readings and make them look higher than they really are.

Hydroxyurea

Hydroxyurea makes your sensor readings look higher than they really are. How much higher depends on the amount of hydroxyurea in your body. If you're taking hydroxyurea, talk to your healthcare provider about alternative glucose monitoring approaches.

Inaccurate sensor readings, nutrition information, or insights

Inaccurate sensor readings, nutrition information, or insights may lead to inappropriate lifestyle decisions or dietary changes. For more reliable decisions, review your readings and trends over time. Always consult your healthcare provider before making any changes to your medication based on your sensor readings, nutrition information, or insights.

Benefits

Some benefits of using your Stelo Glucose Biosensor System are:

- No fingersticks
- Knowing your glucose trends
- Making healthy lifestyle decisions
- Informing a medication regimen

No fingersticks

There's no need to take fingersticks to track your glucose levels as Stelo Glucose Biosensor System provides accurate and reliable glucose measurements. In addition, the Stelo Glucose Biosensor provides functions not feasible using traditional blood glucose monitoring. Traditional blood glucose meters only provide information about discrete, intermittent blood glucose levels and therefore are unable to provide information regarding patterns of glycemic excursions throughout the day and night when people may be unable to test their blood glucose (go to Glucose to find out more).

Knowing your glucose trends

The Stelo Glucose Biosensor System can help you analyze past glucose data. You can look at trends and patterns over days, weeks, and even months to better understand how your glucose changes over time. This lets you see the overall picture and how changes to your daily habits impact your glucose levels over time. This information may prompt you to discuss your glucose trends with your healthcare provider which can be useful for early detection of abnormal glucose control and behavior modification (Holzer et al., 2022).

Making healthy lifestyle decisions

The Stelo Glucose Biosensor System empowers you to make lifestyle decisions on your own. Clinical studies (Erhhardt et al., 2020 and Holzer et al., 2022) suggest that continuous glucose monitoring can be helpful for people with or without diabetes in connecting the dots of an individual's lifestyle choices and their glucose control. Many users felt that continuous glucose monitoring contributed to a healthier lifestyle, such as being more likely to go for a walk or do physical activity if they saw a rise in their glucose, and modifying their food choices. Glucose is one of the key signals of metabolic health. Stelo helps make metabolic health visible by showing the impact of your daily habits, including food, sleep, stress, and activity, on glucose patterns and trends over time. Insights translate the complexity of glucose data with multiple lifestyle variables into understandable and actionable signals of glucose and metabolic health. Monitoring the way behavioral and lifestyle factors impact your glucose can also help inform a conversation with your healthcare provider.

Informing a medication regimen

Continuous glucose monitoring can be important in understanding the impact of medications, such as diabetes and non-diabetes related pills or injections and in adherence to those medications (Ehrhardt, et al., 2020). In addition, review of sensor readings with a healthcare provider can address any changes to medication needs, especially if target goals can't be met through lifestyle changes.

References

Ehrhardt, N., & Al Zaghal, E. (2020). Continuous glucose monitoring as a behavioral modification tool. Clinical Diabetes, 38(2), 126-131. https://doi.org/10.2337/cd19-0037

Holzer, R., Bloch, W., & Brinkmann, C. (2022). Continuous glucose monitoring in healthy adults—Possible applications in health care, wellness, and sports. Sensors, 22(5), 2030. https://doi.org/10.3390/s22052030

Glossary

Accessory device	Hardware connected to your smart device. For example, a Bluetooth headset, Apple Watch®, or other smartwatch.
Airplane mode	A setting on a smartphone where certain features are disabled to comply with airline regulations.
Alternative site testing	Testing a blood sample from non-fingertip (alternate) sites for blood glucose meter values.
Android	Operating system used for Android smartphones.
App or application	Software installed on a smartphone. The Stelo by Dexcom app is a display for continuous glucose monitoring.
App Store® or Google Play store	Internet stores for downloading applications to a smartphone.
Apple Watch	A watch that communicates with and extends an Apple smartphone, such as an iPhone®.
Biosensor (sensor)	A sensor inserted under the skin that checks glucose levels in interstitial fluid and sends sensor readings (readings) to a smartphone. The transmitter and adhesive patch are built into the sensor.
Blood glucose (BG) meter	A medical device used to measure how much glucose is in the blood.

Blood glucose (BG) value	The amount of glucose in the blood measured by a BG meter.
Bluetooth	A technology that allows devices to wirelessly communicate with each other.
Caution	The special care necessary for the safe and effective use of the Stelo Glucose Biosensor System and the care necessary to avoid damage to the device that may occur as a result of use or misuse.
Compatible	Works with the Stelo Glucose Biosensor System. A smartphone and operating system is compatible with the Stelo System when Dexcom has tested it to ensure it works as designed with the Stelo Glucose Biosensor System.
Continuous glucose monitoring (CGM)	A sensor inserted under the skin checks glucose levels in interstitial fluid and sends sensor readings to a smartphone.
Contraindication	A situation where the Stelo Glucose Biosensor System shouldn't be used because it may be harmful to you. The risk of use outweighs the benefit.
Default	A manufacturer's preset option for a smartphone setting.
Display device	A device with a screen used for monitoring your glucose information, for example, a smartphone app.

Grace period	An extra 12-hour period after the sensor session that gives you more time to replace your sensor. Your system works exactly as it did during your sensor session.
Glucose Response Score	A 1–10 score that reflects how logged meals impact your glucose levels. Higher scores point to meals that kept your glucose levels stable after eating. Lower scores indicate that your glucose levels increased in response to the meal.
Hyperglycemia	High BG. Same as high or high blood sugar. Hyperglycemia is characterized by an excess of glucose in the bloodstream. Symptoms include: extreme thirst, dry mouth, weakness, frequent urination, blurry vision, nausea, confusion, shortness of breath. It's important to treat hyperglycemia. If left untreated, hyperglycemia can lead to serious complications.
Hypoglycemia	Low BG. Same as low or low blood sugar. Hypoglycemia is characterized by a low level of glucose in the bloodstream. Symptoms include: hunger, irritability, trouble concentrating, fatigue, sweating, confusion, fast heartbeat, shaking. It's important to treat hypoglycemia. If left untreated, hypoglycemia can lead to serious complications.
Indications	How, for what purposes, and under what circumstances you should use the Stelo Glucose Biosensor System.

Insights	Some Insights use AI. For example, Insights that surface and summarize patterns about your glucose, sleep, nutrition and activity data use AI to generate messages. Dexcom marks AI-generated content with the acronym "AI". AI can make mistakes and is not intended as a medical device. Consult your healthcare provider or registered dietitian for recommendations appropriate for your needs and health conditions.
iOS	Operating system used for Apple smartphones.
Jailbroken or rooted	The removal of limitations and security measures set by the manufacturer on a smartphone. The removal poses a security risk and your data may become vulnerable. Don't install the Stelo by Dexcom app on a jailbroken (Apple) or rooted (Android) smartphone. It won't work correctly.
mg/dL	Milligrams per deciliter. A unit of measure for BG values.
Notification	A message that appears on a smartphone screen. Notifications may also include a sound or vibration, depending on the device settings. The Stelo by Dexcom app has notifications on the lock screen and within the app.

Notifications (system)	Notifications not related to your glucose, including: App Bluetooth is Off, App Stopped Working: Phone Storage Full, Brief Sensor Issue, Incompatible Sensor, Pairing Complete, Pairing Unsuccessful, Phone Bluetooth is Off, Phone Storage Low, Phone Storage Very Low, Readings Stop Soon, Replace Sensor Now, Searching for Sensor, Sensor Expired, Sensor Expires in 2 Hours, Sensor Expires in 24 Hours, Session Ended Early, Sensor Not Found Yet, Sensor Paired, Sensor Warmup Complete, Sensor reconnecting.
Notifications (lock screen)	These notifications will appear on your smartphone's lock screen: App is Closed, App Running (Android Only), Insights: Spike detection, Morning check-in, Sleep summary, Glucose Response Score.
Safety statement	A statement of the intended uses of the Stelo Glucose Biosensor System and relevant warnings, cautions, and contraindications.
Sensor reading	The glucose concentration measured in the interstitial fluid by the sensor.
Sensor session	The period of wear for a sensor. During this period, you'll get glucose updates on your smartphone every 15 minutes.
Sensor warmup	Sensor warmup happens right after you insert and pair the sensor. It takes about 30 minutes for the sensor and your body to adjust to each other. You won't get readings until sensor warmup is done.

Simultaneous voice and data	The ability to make a phone call and access the Internet on the same cellular connection at the same time.
Smartphone (phone)	An electronic, handheld phone that's cordless, mobile, and connected to a cellular network and the internet.
Smartwatch (watch)	A watch that communicates with and extends a smartphone. For example, an Apple Watch.
Target range	Stelo recommends two pre-set target ranges: For people with diabetes, the international consensus for target range is 70–180 mg/dL. For people without diabetes (or with prediabetes) the target range is set to 70–140 mg/dL. You can also customize your own target range.
Time in range	The percentage of time your glucose is in target range. For most people with diabetes, the target range is usually 70–180 mg/dL. For people without diabetes (or with prediabetes), the target range is set to 70–140 mg/dL.
Transmitter	Sends sensor readings to the smartphone. The Stelo Glucose Biosensor transmitter is built into the sensor.
Warning	Describes serious and life-threatening circumstances, the consequences, and how to avoid the hazard while using the Stelo Glucose Biosensor System.

Insertion

Download app

To set up your Stelo Glucose Biosensor System, download the app and follow the onscreen instructions (also available below and in your *Stelo Glucose Biosensor Essentials* guide).

You must have secure internet access for the entire setup. For Stelo app operating system compatibility, go to **stelo.com/compatibility**.

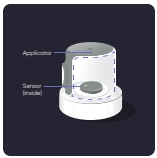
- Go to the app store on your phone and search for “Stelo by Dexcom”. You can also use the QR code below.
- Download and open the app, then follow onscreen instructions.



Stelo by Dexcom



Stelo basics



The applicator inserts the built-in biosensor (sensor) under your skin. Each sensor session lasts up to 15 days[1], plus a 12-hour grace period at the end.



The sensor sends glucose sensor readings (readings) to your smartphone. You'll get glucose updates every 15 minutes.



After you insert the sensor, you must apply an overpatch to keep the sensor on your skin.

[1]A study was conducted to assess the sensor life where 77.9% of sensors lasted the full 15 days. In other words, when using the product per the package labeling, approximately 20% of sensors may not last for the full 15 days, 10% of these sensors may last less than 12 days.

Inserting your sensor

Open the app and follow the onscreen instructions to set up and use Stelo.

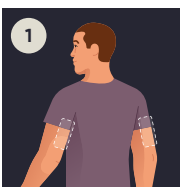
1. Choose sensor site

Insert your sensor on **the back of your upper arm**.

Don't wear your sensor on other sites (such as your abdomen), as it may not work as expected.

Avoid areas:

- With loose skin or without enough fat to avoid muscles and bones
- That get bumped, pushed, or you lie on while sleeping
- Within 3 inches of injection site
- With irritations, scarring, tattoos, or lots of hair



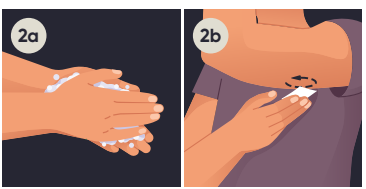
To keep sensor attached see **stelo.com/support**.

2. Clean and dry site

a. Wash hands with soap and water. Dry.

b. Rub site with an alcohol wipe to get rid of all oils.

c. Let dry completely so sensor will stick.



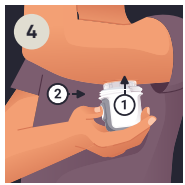
3. Unscrew cap



The applicator uses a needle to insert a tiny sensor wire under your skin. The needle stays in the applicator, not your skin.

- Don't touch inside applicator
- Don't use if damaged or previously opened

4. Use applicator to insert sensor



Relax any muscles near site.

1. Press and hold applicator firmly against skin until clear safety guard is pushed in.
2. Press the button while the guard is pushed in. **Tip: Pressing applicator firmly against the skin unlocks the button.**

5. Remove applicator



a. Move applicator away from your body. Sensor stays on skin.

b. Save applicator because you'll need its pairing code.

c. Screw cap back on applicator.

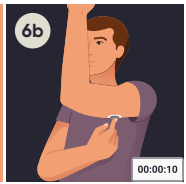
6. Rub patch

To help keep the patch on your skin:

a. Rub firmly around patch 3 times.

b. Gently press on top of sensor for 10 seconds.





7. Apply overpatch

The overpatch keeps the sensor on your skin. It's bundled with the instructions in the sensor box.

a. Carefully pull off both clear liners, one at a time. Don't touch white adhesive area.

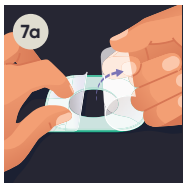
b. Use colored tab to place overpatch around sensor.

c. Rub around overpatch.

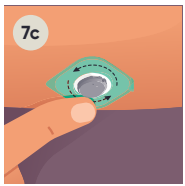
d. Use tab to peel off colored liner.

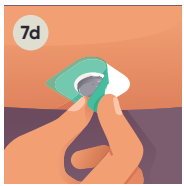
e. Rub around overpatch.

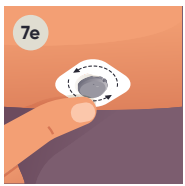
Go back to app to finish setup.











App overview

How Stelo uses AI

Stelo uses artificial intelligence (AI) in the following areas:

- **Daily tab:** Helps you uncover patterns relevant to today.
- **Trends tab:** Shows how glucose and other lifestyle factors interact over time.
- **Log tab:** Describes meals and estimates nutrition facts.
- **Coach tab:** Provides explanations of how nutrition, activity, stress and sleep impact your glucose to help support metabolic health.

An AI icon appears whenever AI is used in the app.

Note

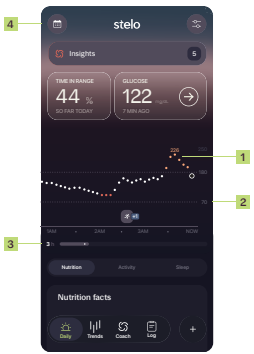
- Consult with your healthcare provider or registered dietitian for recommendations appropriate for your needs and health conditions.
- AI can make mistakes and is not considered medical advice.

Daily

The Daily tab shows your current reading, time in range, and trend information.

Images are representational. Your display device screens may look different.

Trend graph



1. **Trend graph dots:** The smaller dots show past readings. The bigger black dot on the right is the most recent reading.

   The dots will change color depending on if your glucose is in, above, or below target range.

2. **Target range:** This is where you want your glucose to be.

   You can choose yours in > **Target range**.

3. **Time band:** Change the number of hours shown on the trend graph. You can choose from a 3, 6, 12, or 24 hour view.

4. Use the to select data from previous days.

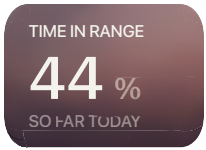
The Stelo by Dexcom app may compete with other apps for battery and storage capacity and may require certain phone settings to function.

Readings and trend arrows

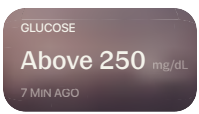
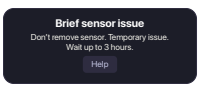
Where your glucose is now

Your latest glucose reading and time in range percentage are near the top of your Daily tab. Both numbers update every 15 minutes. The app tells you how recent both numbers are. You can tap both numbers for more information.





Sometimes you don't get a number. Your readings may be above or below the trend graph, or your system may have an issue.

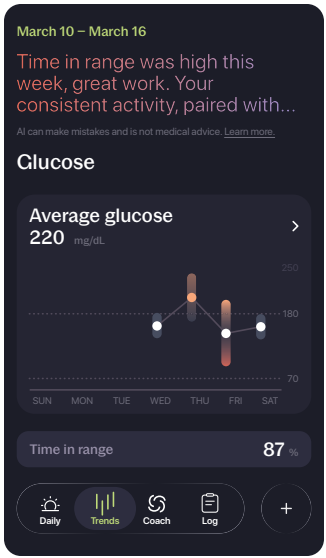
What you see	What it means
	Sensor reading is below 70 mg/dL.
	Sensor reading is above 250 mg/dL.
	Sometimes your system may have an issue, such as Brief Sensor Issue shown here. These issues aren't related to your glucose.

Where your glucose is heading

Trend arrows help you predict where your glucose will be within the next 30 minutes.

What you see	What it means
	**Steady:** Changing less than 30 mg/dL in 30 minutes.
 	**Slowly rising or falling:** Changing 30–60 mg/dL in 30 minutes.
 	**Rising or falling:** Changing 60–90 mg/dL in 30 minutes.
 	**Rapidly rising or falling (double arrows):** Changing more than 90 mg/dL in 30 minutes.
	No arrow: Can't determine glucose trend.

Trends



The Trends tab surfaces patterns (including Insights) about your glucose, activity, sleep, and nutritional data.

Note:

Time in range is the percentage of time your glucose is in target range.

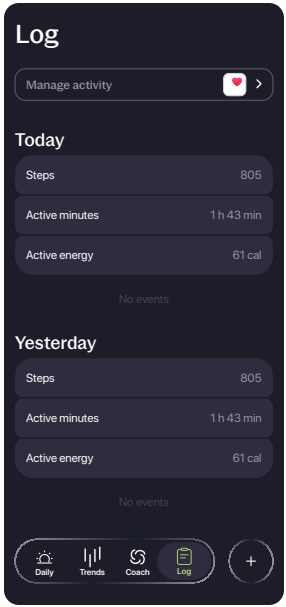
Stelo recommends two pre-set target ranges:

- 70–180 mg/dL
- 70–140 mg/dL

You can also customize your own target range. Stelo recommends at least 50 mg/dL between the top and bottom of your target range.

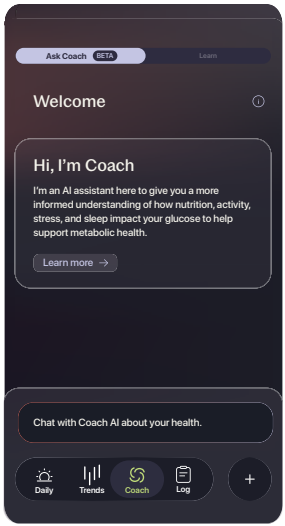
You can change your range in **Settings > Target range**.

Log



The Log tab is where you can find your event log, connect an activity tracker, or link events to glucose rises. Tap the + to get started.

Coach



Learn: Explore articles that can help you understand how and why your glucose changes throughout the day.

Coach: Health Coach is an AI assistant that provides personalized guidance. Chat with Coach to get a more informed understanding of how nutrition, activity, stress, and sleep impact your glucose to help support metabolic health.

Please note that Health Coach is unable to answer questions not related to your health journey.

Responses provided by Health Coach are not intended as medical advice, and do not replace your healthcare provider.

Consult your healthcare provider or registered dietitian for recommendations appropriate to your needs and health conditions.

AI can make mistakes and is not intended as medical advice.

Settings

Tap  on the Daily tab to adjust your settings or get help.

- **Sensor:** Get information on your sensor, find your pairing code, and end your sensor session.
- **App Settings:**
  - Customize your target range and health status.
  - Send glucose data to health apps.
- **Phone Settings:** Avoid phone settings that stop your app from working.
- **Support:**
  - Review your software and account information.
  - Contact technical support (in the app, go to **Settings > Contact**).
  - Get help (**Settings > Help**).
  - Give Dexcom feedback.
  - Learn more about AI-powered features.
- In **Settings > Help** you'll find:
  - Answers to your questions
  - Instructions
    - Inserting and removing sensors
    - Sensor readings
  - Links to product guides
  - Safety information

Understanding glucose

Reviewing your trends

Stelo empowers you to better understand how your glucose changes over time. It can help you analyze your past glucose data to think about questions like:

- How much does my glucose change after a walk or meal?
- Does a full night's sleep have an impact on my glucose?

It can also help you see trends and patterns in your glucose levels. For example, if your readings are consistently outside the target range (for people with diabetes, this means lower than 70 mg/dL or above 180 mg/dL) you may need to consult your healthcare provider (HCP) for guidance.

Time in range

Time in range is the percentage of time glucose levels are in target range.

Stelo recommends two pre-set target ranges:

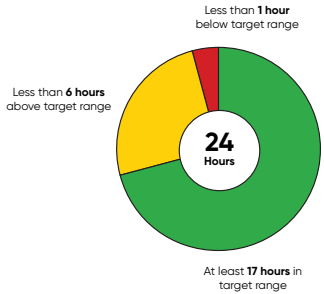
- 70–180 mg/dL
- 70–140 mg/dL

You can also customize your target range.

	People with diabetes	People without diabetes (or with prediabetes)
Target range	Between 70–180 mg/dL.	Between 70–140 mg/dL.
Time in range goal	70% of your day, or at least 17 hours in target range. Less than 1 hour of the day below target range (less than 70 mg/dL). Less than 6 hours of the day above target range (above 250 mg/dL).	Set to 96% of the day.

It's always important to talk to your HCP to find your individual target range, and time in range goal. Consider working with your HCP to customize your target range.

For people with diabetes:



Reference: Battelino, T., Danne, T., Bergenstal, R. M., Amiel, S. A., Beck, R., Biester, T., Bosi, E., Buckingham, B. A., Cefalu, W. T., Close, K. L., Cobelli, C., Dassau, E., DeVries, J. H., Donaghue, K. C., Dovc, K., Doyle, F. J., III, Garg, S., Grunberger, G., Heller, S., ... Phillip, M. (2019). Clinical targets for continuous glucose monitoring data interpretation: Recommendations from the international consensus on time in range. Diabetes Care, 42(8), 1593-1603. https://doi.org/10.2337/dci19-0028

Glucose and your HCP

Stelo empowers you to make lifestyle decisions on your own.

Consult your healthcare provider (HCP) if you have any questions around medication.

People with diabetes

If you have type 2 diabetes, it can change over time, so you may need to change your diabetes management strategies.

If your readings are consistently outside target range (70–180 mg/dL), you may need to consult your HCP for guidance.

Talk to your HCP about changes that are needed to bring your glucose where you want it to be.

Medications

Don't make any medication adjustments based on your readings without talking to your HCP first. Increasing, decreasing, or stopping your medications can cause changes to your glucose or overall health. Consider reviewing your sensor readings with your HCP to address any changes to your medication needs.

People without diabetes (or with prediabetes)

Glucose changes during the day. Monitoring the way food, physical activity, or other lifestyle factors impact your glucose can help inform a conversation with your HCP.

If your readings are consistently outside target range (70–140 mg/dL), you may need to consult with your HCP for guidance.

Glucose and behavior

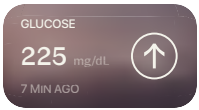
The Stelo by Dexcom app shows you readings and glucose trends over time. You can use this information to help you uncover what causes your glucose to change.

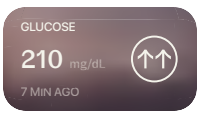
For example:

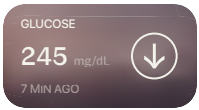
- Does your glucose go down after a walk around the neighborhood?
- How does your glucose react to your favorite meal?

Using your number and trend arrows

The number in the card is your most recent glucose reading. The trend arrow(s) tell you where your glucose is headed, and how quickly. There are many factors that can cause your glucose to go up or down.

What you see	Situation	Think about
	You ate a sandwich for dinner.	**Number** - The bread made your glucose go high. **Arrow** - The high carbohydrate content of the bread makes your glucose rise. *Consider:* Next time you have a sandwich for dinner, eat a smaller portion. See what happens to your glucose.

What you see	Situation	Think about
	You had a glass of orange juice before breakfast.	**Number** - The amount of juice made your glucose go high. **Arrows** - The orange juice on an empty stomach made your glucose rise quickly. *Consider:* Try swapping orange juice for a fresh orange. The fiber from the orange may limit how high your glucose goes.

What you see	Situation	Think about
	You ate lunch, then decided to take your dog for a walk. 15–20 minutes into your walk, you notice your glucose trending down.	**Number** - The lemonade you had for lunch made your glucose start off high. **Arrow** - The walk is making your glucose fall. *Consider:* Physical activity can help bring your glucose into target range. Watch the arrow to see how your glucose changes during activity.

Stelo and BG meters

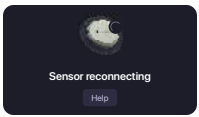
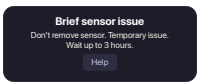
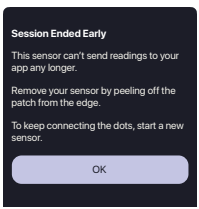
A BG meter may be an option (as needed) if you need to track glucose levels when your readings:

- Don't match how you feel
- Don't show a number
- Aren't present (for example, during the 30-minute sensor warmup)

Sometimes you might feel off even when your readings show you're in range. Always pay attention to symptoms of low or high glucose, and don't ignore how you're feeling.

Notifications

Stelo sends you notifications when new insights are ready for you, or if the app isn't working as planned.

What you see	What it means
	**Sensor reconnecting** Your smartphone temporarily stops getting readings because there's an issue with the connection.
	**Brief Sensor Issue** The sensor can't read your glucose right now.
	**Session Ended** Notifications like Session Ended Early and Replace Sensor Now mean you're not getting readings.

For a list of notifications, go to the Glossary.

Tips

- Follow Stelo's recommended settings. Certain phone settings or features such as Android's Digital Wellbeing and Apple's Screen Time may prevent notifications if enabled.
- Allow the app's notifications to show on your lock screen. This will ensure you receive notifications and allow you to see notifications without unlocking your phone.
- Make sure your smartphone volume is turned up, not muted, and the speaker works. All app notifications will match your smartphone settings. They will not override your phone settings.
- When you have headphones connected, notifications will only sound through the headphones, not on your smartphone speaker.
- When using multiple accessories such as headphones, Bluetooth speakers, or smartwatches, you may get your notifications on only one, not all. After connecting any accessories, make sure that your smartphone settings allow you to continue receiving notifications.

Responding to in-app notifications

Sometimes your app will show a notification on the daily tab to let you know there's an issue with the app.

These notifications will tell you how to fix the issue.

If you have a smartwatch, it may display notifications. Tapping **OK** on your smartwatch lock screen will acknowledge the notification in your app too.

For most issues, you won't get readings until the situation has been fixed.

Tips

- Notification vibrations feel the same as notifications you get from other apps on your smartphone. The only way to know if it's from the Stelo by Dexcom app is to look at your smartphone.
- In the app, you see notifications on your lock screen and Apple Watch. If you're not seeing any data, open your app.
- If your smartwatch battery gets too low to show your glucose information, use the app on your smartphone.

Smartphone setup

App

You can set up the Stelo by Dexcom app on only one smartphone. Download the Stelo by Dexcom app from your app store and follow the instructions on the screen.

You'll need the pairing code. Find it on the applicator:



For Stelo app operating system compatibility, go to **stelo.com/compatibility**.

Internet requirements

You need secure Wi-Fi or cellular internet access for:

- **Setup:** Internet is required to download the app and create and/or login to your account.
- **Sharing data:** To smoothly share data with other apps, you need a steady internet connection.
- **Some app help features:** A few app help features use the internet, including FAQs, app technical support, the Learn tab, and the Spike detection insight.

Internet connections lost without warning, failure to establish internet connections, or the degradation of service prevent those features from working.

While you don't need Wi-Fi or cellular internet services to pair your sensor, get readings, or use other features not listed above, you do need Bluetooth.

Smartwatch (Apple)

Check your Stelo Glucose Biosensor on your Apple smartwatch.

Suggested use

Using a smartwatch with your Stelo Glucose Biosensor may change how you get notifications.

- Your smartwatch communicates with your smartphone, not the sensor.
- You won't get notifications or readings on your watch unless it's connected to your smartphone and your smartphone is connected to your sensor.
- Make sure you understand how you get notifications when a watch is connected.
- You must wear the watch to see notifications and feel their vibrations.

- In your smartphone settings, make sure notifications are sent to both your phone and watch.
- Don't disable or block notifications from the app.

Waking up your watch updates your Stelo Glucose Biosensor data from your phone. There may be a brief delay before your watch app shows current information.

Go to **stelo.com/compatibility** to make sure your smartwatch works with the Stelo Glucose Biosensor.

Apple Watch setup (iPhone)

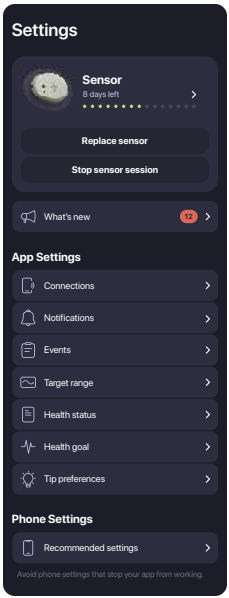
To install the app, use the Watch app on your iPhone.

Refer to your watch instructions for details about installing apps.

What you see	What it means
	**Sensor reading and arrow** 1. Sensor reading 2. Trend arrow **Trend graph** 3. Target range 4. Current sensor reading 5. Shows past 3 hours 6. Time

Tap the graph to change the number of hours shown: 1, 3, or 6 hours.

Connections



From **Settings**, you can:

- Get information about your sensor session
- Replace your sensor
- Upload your glucose information to your health apps

Active connections — like your sensor — appear in **Settings > Connections**. Connections to features you're not currently using are in the Available Connections list.

Tap each connection to learn more.

Sensor

In **Settings > Sensor**, you can also:

- Check how much time is left in your sensor session
- Replace a sensor (for more, go to Next sensor session) or stop the sensor session
- Get your pairing code

Health apps

Health apps like Apple Health and Google Health Connect consolidate health data from your smartphone and third party apps, including Stelo. Activate your smartphone's health app, and Stelo will send data to the health app with a 3-hour delay. Stelo sends glucose data between 70–250 mg/dL.

Clarity Clinic

Dexcom Clarity provides a holistic view of your glucose management by highlighting patterns, trends, and statistics. It can help you identify glucose patterns and, with your healthcare provider, determine the potential causes of those patterns.

Through the Clarity Clinic feature, you can connect Stelo to Dexcom Clarity.

To get started, go to **Settings > Connections** and follow the onscreen instructions.

Clarity Clinic requires your healthcare provider to provide you with their clinic code.

Events

Overview

The Stelo by Dexcom app gives you a graph showing where your glucose has been. Events can help you understand why your glucose changed. For example, what happened to your glucose level when you took a walk after breakfast? You can use these reflections to find even more ways to manage your glucose.

You can see the events you've tracked on your smartphone.

Daily tab: Events logged in the app can be found below your trend graph (for more, go to App overview).

Log tab: Lists events logged in the app in the last 15 days.

Glucose Response Score

After each meal or snack, you'll get a personalized Glucose Response Score showing how your food affected your glucose level.

After you eat, Stelo tracks the changes in your glucose levels. After about two hours, you'll get a Glucose Response Score from 1 to 10.

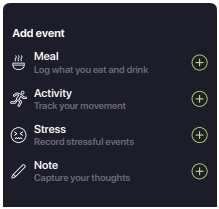
Higher scores point to meals that kept your glucose levels stable after eating. Lower scores indicate that your glucose levels increased in response to the meal.

Tracking events

In the Log tab, you can track meals, activity, sleep, stress, and more. In addition, you can enable the automatic transfer of Activity and Sleep data when you connect to your health app.

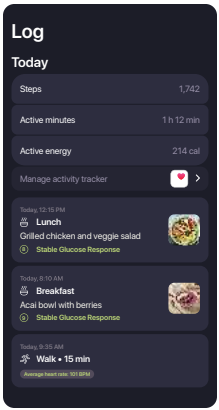
You can track events as they occur and for up to 15 days in the past.

To add an event:



Tap + in the tab.

Tap the event you want to add and follow the instructions on the screen.



To edit or delete a logged event, select the event on your Log tab. Tap the ••• icon, the follow the onscreen instructions.

Insights

Stelo uses AI to provide insights on your Daily, Log, and Trends tabs to help you understand the connection between your glucose and daily habits.

Daily tab insights help you in the moment. For example, you may get an insight in the morning that recaps your previous day so you'll be set up for success.

Log tab insights are relevant to specific events. For example, if you log a meal, you may get an insight that provides information about the meal's nutritional content, and then another about how your glucose level was impacted.

Trends tab insights look across time to reveal patterns across metrics. For example, you can explore the connection between your steps and average glucose over a six-month timeframe.

The following insights do not use AI.

Meal detection

After your glucose rises, you may get a message on your app's Daily tab that a possible meal has been detected.

Spike detection

After your glucose has a notable rise, you may get a message on your smartphone's lock screen or the app's glucose tab that a glucose spike has started.

You'll be able to log why the spike may have started, and can view tips for lowering the spike. If you want to add information later, your spike start time will be in the Events tab.

Spike detection can help you understand what might cause them to happen. This can be a first step to making changes for the future.

Spike pattern

You'll get this insight if your glucose spikes around the same time for several days in a row.

It's designed to help you find any routine food, activities, or events that might be causing a pattern of glucose spikes so you can start to make a change in your habits.

Low pattern

If your glucose has a pattern of going below 54 mg/dL, you may get this insight.

This is designed to help people with type 2 diabetes recognize patterns of low glucose they may not have noticed before.

Most insights require an active internet connection.

Next sensor session

What is a sensor session?

Each sensor session lasts up to 15 days[1], plus a 12-hour grace period at the end. The grace period gives you more time to replace your sensor so you can do it when it's convenient for you. The time left in the grace period shows on your screen. During the grace period, your sensor continues to work as it did during the sensor session.

You can choose to wear the sensor until the grace period ends or end the session early. To find out how much time you have left in your sensor session, go to **Settings > Sensor**. When the sensor expires, the 12-hour grace period starts.

[1]A study was conducted to assess the sensor life where 77.9% of sensors lasted the full 15 days. In other words, when using the product per the package labeling, approximately 20% of sensors may not last for the full 15 days, 10% of these sensors may last less than 12 days.

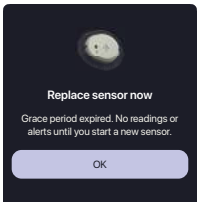
Sensor transition

You must end the sensor session or grace period before you start a new sensor. You can end it two ways:

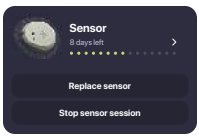
- Automatically, when the grace period ends (a notification lets you know)
- Manually, before the grace period ends

Automatically: End sensor when grace period ends

At the end of the grace period, you'll get a Start New Sensor notification:

What you see	What it means
	Tap **OK** and follow instructions on the screen.

Manually: End sensor before grace period ends

What you see	What it means
	To end your session early from the app, go to **Settings > Sensor** Tap either: • **Replace Sensor:** If you want to start a new sensor immediately • **Stop Sensor Session:** If you want to stop this sensor without starting a new one Then, follow the instructions on the app screens.

Remove your sensor

Before inserting a new sensor, remove the old one. You can use only one sensor at a time. After your sensor session ends, peel off the patch like a bandage. To make it easier and to avoid irritating your skin, try these tips:

- Loosen edge and soak patch in body oil, like baby oil or an adhesive remover for skin (see product instructions before using)
- Use adhesive removal wipes for skin, rubbing exposed skin as you peel back the patch
- Try different pulling techniques:
  - Pull off the patch slowly, folding it over itself, in the same direction of hair growth
  - Stretch the loosened edge, and push your fingers under the patch to pull it off skin

For more tips, go to **stelo.com/support**.

Throw out the used sensor following local guidelines for blood-contacting components.

Remove from Bluetooth

Before inserting a new sensor, remove old sensors from your smartphone's list of Bluetooth connections.

There may be more than one sensor listed because your smartphone saves each sensor as a new device in the Bluetooth connections list.

Apple

1. Go to **Phone Settings > Bluetooth**.
2. Find a used sensor in My Devices list. Stelo names start with DXCM.
3. Tap **i** to see details about this sensor.
4. Tap **Forget This Device**.

Android

1. Go to **Phone Settings > Connections > Bluetooth**.
2. Find your used sensors in the list of paired devices. Stelo names start with DXCM.
3. Tap **Settings** ⚙ to see details about the connection.
4. Tap **Unpair**.

Remove while using sensor

To remove old sensors from the Bluetooth connections list while you're wearing a sensor, follow the above steps and keep these tips in mind:

- All Stelo sensors are listed as not connected, even the current one. The current sensor's status changes to connected during the few seconds every 5 minutes when it's sending your sensor reading to your smartphone. If you watch the list for up to 5 minutes, you'll see which sensor is the current one.
- Don't worry if you remove the current sensor. Within 15 minutes, the sensor will send your next sensor reading to your smartphone and the sensor will reappear in the Bluetooth connections list (if you use an iPhone, it will prompt you to re-pair the sensor — no pairing code needed. Android phones do this automatically).

Appendix

Troubleshooting

This section has brief instructions for the most common issues.

- Accuracy
- Adhesive patch
- Common notifications
- Gap in graph
- Travel and Stelo
- App updates
- Water and Stelo
- Medical equipment and Stelo

For more troubleshooting information, find the frequently asked questions section on the Stelo website (**stelo.com/support**), or contact technical support (in the app, go to **Settings > Contact**).

Accuracy

Issue

BG meter and readings aren't the exact same number.

Solution

Accuracy

One reason is they're measuring glucose in different fluids. The BG meter measures blood glucose while the sensor measures interstitial fluid. And if your healthcare provider did a lab test at the same time, the lab result might give you a third number. The lab test is considered the most accurate number.

Other reasons there could be a difference between your BG meter and Stelo are:

- **Hand cleanliness:** Wash your hands with soap and water (not hand sanitizer) and dry them. Then test. Many inaccurate BG meter values are from hands not being washed thoroughly before testing.
- **Sensor's first day:** With newly inserted sensors, the differences between your BG meter and the sensor reading might be greater. Generally, the numbers get closer over the first 24 hours.
- **Pressure on sensor:** Sometimes when something is pressing on your sensor, for example, if you're lying on it, it can affect your sensor readings. Relieve the pressure and the numbers should get closer.
- **Glucose changing quickly:** When your glucose is rapidly changing, it can be more difficult to compare your BG meter value and sensor reading because blood glucose changes a little before interstitial glucose. The numbers should get closer when your glucose stabilizes.
- **Test strips:** Make sure your test strips are stored as directed and not expired. Also, make sure to use enough blood on the test strip.

Adhesive patch

Issue

The adhesive patch is peeling off your body.

Solution

Follow the insertion instructions carefully. Extra care may help you keep your sensor on for the entire sensor session.

Site preparation

- **Site:** Sensor site should be flat, clean, and completely dry before you insert the sensor. There should be some fat under the skin at the sensor site.
- **Extra adhesive:** Put on additional adhesive over the patch before applying the overpatch. Let dry. For more recommendations, go to **stelo.com/support**.
- **Avoid hair:** Apply the patch to areas without much hair. If needed, shave site with electric clippers.
- **Old adhesive:** Remove any adhesive residue from previous sensors. Consider using a body oil or adhesive remover for skin (such as Uni-solve, Detachol, or Tac Away).

Patch care

- The longer you keep it dry and sweat-free in the first 12 hours, the longer it may stick to your skin.
- When it gets wet, gently pat it dry as soon as you can.
- If it peels off your skin, trim the peeled parts and put on an overpatch or medical tape.

Issue

Skin irritation around sensor site.

Solution

Some people are sensitive to the sensor adhesive. Extra care can help. Follow insertion instructions carefully. In addition to the site preparation tips above, consider these:

Site preparation

- **New site:** Don't use the same sensor site twice in a row.
- **Healthy skin:** Consider moisturizing skin between sensor sessions to avoid dry skin. Don't use moisturizer on the sensor site the day you insert the sensor.

If you have significant skin irritation (itching, burning and/or rashes at the site of the adhesive patch), contact your healthcare provider. Go to **stelo.com/support** for more tips.

Issue

Applicator won't detach after inserting sensor.

Solution

1. Gently peel off adhesive patch with applicator attached.
2. Check insertion site to make sure the sensor isn't left in the skin.
3. Don't reuse applicator.
4. Contact technical support (in the app, go to **Settings > Contact**).

Issue

Removing sensor.

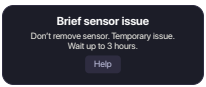
Solution

Go to Next sensor session or **stelo.com/support** for tips.

Common notifications

Issue

Brief Sensor Issue: Sensor is temporarily unable to measure glucose.



Solution

Your sensor has a temporary issue. This issue often happens during the first day of a sensor session, but it can happen anytime. It usually fixes itself within 3 hours.

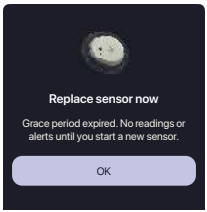
Check your sensor. Tap **Help** in app for more information on troubleshooting.

If Brief Sensor Issue continues for more than 3 hours, contact technical support (in the app, go to **Settings > Contact**).

Brief Sensor Issue may lead to Session Ended Early.

Issue

Session Ended Early



Solution

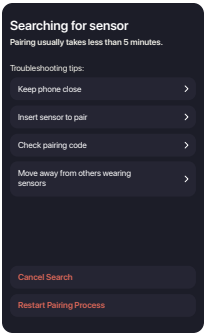
This issue may happen anytime during a sensor session.

You won't get readings until you start a new sensor.

1. Remove sensor now.
   Tip: Peel off patch from edge.
2. Insert and pair new sensor.
3. Review Step 1 in Insertion.

Issue

Searching for sensor: Pairing is taking longer than expected. (Help screen shown here.)



Solution

If you get this notification, go to its Help screen for more information.

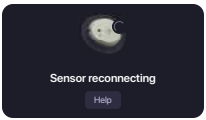
Pairing usually takes less than 5 minutes. If it takes longer, use these troubleshooting tips.

- **Keep phone close:** Always keep smartphone within 20 feet of sensor.
- **Insert sensor to pair:** Make sure your sensor is inserted. If it isn't, insert sensor now.
- **Check pairing code:** Check that pairing code you entered is the pairing code on the applicator. If it isn't, edit pairing code.
- **Move away from others wearing sensors:** To reduce potential interference, stay more than 20 feet from other sensors until pairing is complete. For pairing, you may have to go to a different area to get far enough away from other people wearing sensors.
- **Check display device:** Sensor can be paired with only one smartphone.
- **Keep app open:** Don't close the app by swiping it off during pairing.

Issue

Sensor reconnecting: Smartphone temporarily stops getting readings from Bluetooth. This displays on your screen after a few minutes of not getting readings.

You won't get readings until fixed. When your sensor readings resume, up to 24 hours of missed readings can fill in on the trend graph.



Solution

Troubleshooting tips:

(It will take up to 5 minutes for any of these to work).

- Turn Bluetooth off. Then turn it back on and leave it on.
- Keep the app open and displayed on your screen. Don't swipe it closed.
- Keep your smartphone within 20 feet of the sensor with nothing between them, including your body, walls, and water.
- Keep your smartphone on the same side of your body as your sensor. Bluetooth works best when the sensor and smartphone are in sight of each other.
- If these solutions don't work, restart your smartphone and app.

To help prevent Sensor reconnecting:

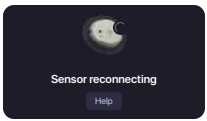
- Use recommended phone settings listed in the app at **Settings > Phone Settings**.
- Keep your smartphone battery charged to at least 20%.

If Sensor reconnecting continues for more than 30 minutes, contact technical support (in the app, go to **Settings > Contact**).

Gap in graph

Issue

When you aren't getting readings, your trend graph may show a gap in the trend dots.



Solution

When your readings resume, up to 24 hours of missed readings can fill in on the trend graph.

Travel and Stelo

Issue

You want to use Stelo when going through security or flying.

Solution

TSA Security check point

You can wear Stelo for the walk-through metal detector and Advanced Imaging Technology (AIT) body scanners. Or you can also ask for hand-wanding or full-body pat-down and visual inspection. Ask for visual inspection of any part of the Stelo Glucose Biosensor System in the baggage scanning machine.

Most security check points require you to temporarily give up your smartphone.

Prepare for airport security checks and screening procedures for your air travel. Review airport website and travel updates before your trip.

On the plane

To use your app to get sensor glucose information while on the plane, switch phone to airplane mode, then turn Bluetooth on.

Contact your airline for their policies. Always follow instructions from the airplane crew while on the plane.

For more information

Visit the TSA website at **tsa.gov**.

App updates

Issue

You want to know how and when to update your app.

Solution

Keep app updated

You'll get a notification when an app update is available while connected to the internet. Go to the App Store or Google Play and download the updated Stelo by Dexcom app.

Water and Stelo

Issue

You want to shower, swim, or bathe wearing the Stelo Glucose Biosensor.

Solution

Once inserted, the sensor is waterproof up to 8 feet. You can swim, shower, and take a bath with the sensor.

If you're in or near water, your smartphone may need to be closer than 20 feet to get readings. If you're in water, you may not get readings until you get out.

The patch stays on longer if kept dry. For more, go to Adhesive patch.

Medical equipment and Stelo

Issue

You need an x-ray, CT scan, or radiation therapy while wearing the sensor.

Solution

Discuss these safeguards with your healthcare provider:

- Avoid including the sensor in the scanned area during the procedure
- Cover the sensor with a lead apron

Taking care of Stelo

Maintenance

Sensor

- Keep in box until ready for use.
- Don't unscrew applicator cap until ready to insert.

All Stelo components

- Stelo components work together. Don't mix with any other Dexcom products.
- Don't use damaged components.

Storage

Storing the Stelo correctly helps prevent system failures.

Sensor

- Keep in its sterile packaging until you're ready to use it.
- Store at temperatures between 36°F and 86°F.
- Store between 10% and 90% relative humidity.

Disposal

Different regions have different requirements for disposing of electronics (sensor) and parts that have come in contact with blood or other bodily fluids (applicator and sensor). Follow your area's local requirements.

Stelo user terms

Dexcom sensor limited warranty

To the extent allowed by law, the Stelo Glucose Biosensor is provided to you without any warranty by Dexcom. Dexcom hereby disclaims all warranties (express, implied, and statutory) with respect to the sensor, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. There are no warranties which extend beyond the description herein.

App terms of use

By using the Stelo Glucose Biosensor System, you are acknowledging that you have read and agreed to the Dexcom App Terms of Use and the included provisions for binding individual arbitration, as well as the Privacy Policy, including what personal information Dexcom collects from you and how Dexcom uses your personal information.

Open source software code

This product may include open source software code. Third Party notices, terms, and conditions pertaining to third party software included in this product can be found at **stelo.com/notices**.

Technical information

Performance characteristics

NOTE: We recommend you review this information to understand how well the Stelo Glucose Biosensor System performs.

The Stelo Glucose Biosensor System uses a glucose sensor to continuously measure and monitor your glucose levels. The Stelo Glucose Biosensor System records glucose readings (sensor readings) every 5 minutes. All the sensor readings are then displayed on the mobile app every 15 minutes. The Stelo Glucose Biosensor System's performance was evaluated in a clinical study in which sensor readings were assessed against blood glucose values tested by a comparator method for subjects 18 years of age and older. The performance characteristics of the Stelo Glucose Biosensor System presented in the following sections conform to the guidance for devices in the same classification.

Clinical study overview

To demonstrate the safety and effectiveness of the Stelo Glucose Biosensor System, a prospective clinical study was conducted at six (6) centers across the United States with a total of 130 participants. The study included adult (18 years and older) participants with Type 1 or Type 2 diabetes. Participants wore the sensors for up to 15.5 days with one approximately 12-hour clinic session at the beginning (Day 1 to 3), early middle (Day 4 to 7), late middle (Day 9 to 12), and end (Day 13 to the first half of Day 15) of the sensor wear period.

In the clinic sessions, subjects had their blood glucose measured every 10–15 minutes with a comparator method, the Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer. This instrument is referred to as the YSI. Sensor readings were reported every 5 minutes and paired with YSI values to characterize the accuracy of the sensor reading.

Accuracy

The Stelo Glucose Biosensor System accuracy was assessed with paired sensor readings to YSI blood glucose values. For YSI blood glucose values less than 70 mg/dL, the absolute difference in mg/dL between the two glucose results was calculated. For values greater than or equal to 70 mg/dL, the absolute difference (%) relative to the YSI value was calculated. In addition, the mean absolute relative difference (MARD) shows the average amount the sensor readings differ from the YSI glucose. The percentages of total readings within 20 mg/dL or 20% (20/20%) are provided in Table 1-A. The tables are further categorized within Biosensor glucose ranges (Table 1-B) and categorized within YSI glucose ranges (Table 1-C). When you see a sensor reading on your mobile app, these tables show you how likely it is that the reading matches your blood glucose level (measured by YSI in the study).

For example, the total number of data pairs considered in the analysis was 20,330. Of these, 94.0% of the sensor readings fall within ± 20 mg/dL of the YSI blood glucose values < 70 mg/dL and within ± 20% of YSI blood glucose values ≥ 70 mg/dL.

Table 1-A. Overall accuracy to comparator method (n=130)

Population	Number of subjects	Number of paired Biosensor[1]-YSI	Percent within 20/20% YSI	Percent within 20/20% YSI on Day 1	MARD (%)
Adults	130	20,330	94.0	88.6	8.3

[1]Biosensor readings are within 40–400 mg/dL, inclusive.

Table 1-B. Accuracy to comparator method within Biosensor glucose ranges (adults; n=130)

Biosensor glucose range[1] (mg/dL)	Number of paired Biosensor [1]-YSI	Percent within 15 mg/dL YSI	Percent within 20 mg/dL YSI	Percent within 40 mg/dL YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean bias (mg/dL)	MARD (%)
<70	1,807	89.0	94.6	99.5	---	---	---	-3.5	10.5
70–180	10,902	---	---	---	84.8	93.3	99.6	-1.1	8.5
180–250	3,301	---	---	---	84.3	91.5	100.0	-11.3	8.3
>250	4,320	---	---	---	91.6	96.8	100.0	-9.2	6.8

[1]Biosensor readings are within 40–400 mg/dL, inclusive.

Table 1-C. Accuracy to comparator method within comparator method glucose ranges (adults; n=130)

YSI glucose range (mg/dL)	Number of paired Biosensor 1-YSI	Percent within 15 mg/dL YSI	Percent within 20 mg/dL YSI	Percent within 40 mg/dL YSI	Percent within 15% YSI	Percent within 20% YSI	Percent within 40% YSI	Mean bias (mg/dL)	MARD (%)
<70	2,008	93.5	97.3	99.9	---	---	---	2.3	10.5
70–180	10,463	---	---	---	86.2	93.8	99.7	-0.3	8.2
180–250	2,988	---	---	---	88.0	94.9	99.9	-6.5	7.4
>250	4,871	---	---	---	86.1	92.5	99.9	-15.8	8.0

[1]Biosensor readings are within 40–400 mg/dL, inclusive.

Concurrence of Stelo Glucose Biosensor and comparator method

Table 2 describes (column percent), for each range of YSI values, what percentage of paired Biosensor readings was in the same glucose range (shaded) or in glucose ranges above and below the paired YSI values. For example, Table 2 shows that when YSI values are within 70 to 120 mg/dL, you can expect your Biosensor readings to be within 70 to 120 mg/dL 85.1% of the time.

Table 2. Concurrence of Biosensor readings and YSI values by YSI Glucose Range (n=130)

Biosensor Glucose Range (mg/dL) (Column %)	Comparator Glucose Values (mg/dL)					
	<70	70–120	121–160	161–200	201–250	>250
<70	1,432 (72.9%)	410 (6.9%)	1 (0.0%)	---	---	---
70–120	532 (27.1%)	5,029 (85.1%)	506 (14.7%)	13 (0.6%)	1 (0.0%)	3 (0.1%)
121–160	---	469 (7.9%)	2,584 (75.0%)	468 (21.5%)	23 (1.1%)	3 (0.1%)
161–200	---	3 (0.1%)	353 (10.2%)	1,487 (68.5%)	444 (22.2%)	33 (0.7%)
201–250	---	---	1 (0.0%)	204 (9.4%)	1,350 (67.4%)	697 (14.1%)
>250	---	---	---	---	185 (9.2%)	4,196 (85.1%)
Total	1,964	5,911	3,445	2,172	2,003	4,932

[1]Biosensor readings are within 40–400 mg/dL, inclusive.

Trend accuracy

Trend accuracy explains how well Stelo Glucose Biosensor System captures the time-dependent characteristics of glucose fluctuation. The following examples quantify the trend accuracy:

1. When the Biosensor rate of change is rapidly rising (> 2 mg/dL/min), how often is reference glucose also trending up (>0 mg/dL/min)? The answer is 96.9% of the time.
2. When the Biosensor rate of change is rapidly falling (< -2 mg/dL/min), how often is reference glucose also falling (< 0 mg/dL/min)? The answer is 92.9% of the time.
3. When the Biosensor rate of change is stable (≥ -1 mg/dL/min and ≤ 1 mg/dL/min), how often is reference glucose changing rapidly (> 2 mg/dL/min or < -2 mg/dL/min)? The answer is only 0.8% of the time.

Table 3. Trend accuracy rate of change (adults; n=130)

Biosensor rate range (mg/dL/min)	YSI rate range (mg/dL/min)						Biosensor-YSI pairs (n)
	<-2	[-2,-1)	[-1,0)	[0,1]	(1,2]	>2	
<-2	31.5%	39.0%	22.4%	5.5%	0.8%	0.8%	254
[-2,-1)	7.0%	45.0%	41.8%	5.6%	0.5%	0.1%	1,373
[-1,0)	0.4%	6.6%	73.2%	18.6%	1.1%	0.1%	8,970
[0,1]	0.2%	1.1%	24.2%	64.0%	9.5%	1.0%	6,859
(1,2]	0.1%	0.5%	4.9%	31.8%	48.3%	14.4%	1,703
>2	0.0%	0.4%	2.7%	11.6%	31.1%	54.2%	673

[1]Biosensor readings are within 40–400 mg/dL, inclusive.

Sensor life

A subsequent study was conducted in 108 participants in the intended user population to assess the sensor life. A total of 110 sensors were evaluated. 77.9% of the sensors lasted until Day 15. In other words, when using the product per the package labeling, approximately 20% of sensors may not last for the full 15 days, 10% of these sensors may last less than 12 days.

Number of readings provided

Stelo Glucose Biosensor System is capable of recording up to 288 valid sensor readings per day. For a variety of reasons, Stelo Glucose Biosensor System may be unable to provide a valid sensor reading. The percentage of valid sensor readings you can expect from Stelo Glucose Biosensor System over the sensor life is 99.3% (data not presented in a table). All sensors (100%) had valid sensor readings available at least 90% of the time (data not presented in a table). Table 4 below describes the data availability rate by each wear day over the sensor life.

Table 4. Data availability rate by wear day — adults (n=130)

Wear day	Number of sensors	Data availability rate (%)
1	130	99.4
2	130	99.7
3	130	99.7
4	128	99.6
5	124	99.8
6	124	99.7
7	123	99.8
8	121	99.6
9	120	99.5
10	119	99.2
11	115	98.9
12	112	98.6
13	107	98.9
14	104	97.8
15	75	97.1

Sensor insertion experience

Enrolled subjects in the clinical study were asked to complete questionnaires on comfort and ease of use of sensor insertion. The questionnaires were completed by the subjects.

Ninety-six percent (96%) of subjects responded that the sensor insertion was painless. A total of 98% subjects found that the device was easy to use and 96% of subjects found the IFU easy to understand.

Table 5. Survey of sensor insertion experience (n=130)

Question	Number of subjects	Percent
Comfort: painless (mild, no pain)	130	96%*
Ease of use: easy (somewhat or very)	128	98%
IFU ease of use: easy (somewhat or very)	108	96%

*The percentage was based on the evaluation of 171 sensors.

Adverse events

No device-related serious adverse events (AEs) occurred during the clinical studies. There was a total of four mild to moderate device related AEs. Two AEs were due to local infection, 1 was due to pain or discomfort, and 1 AE was due to skin irritation, specifically edema (swelling) at the sensor needle insertion area or around the adhesive area.

Product specifications

Use electrical equipment as directed:

> Use of accessories, cables, adapters, and chargers other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches to any part of the Stelo Glucose Biosensor System including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result in improper operation.

Use of this equipment adjacent to, or stacked with, other equipment should be avoided because it could result in improper operation.

Sensor with built-in transmitter product specifications

Model	Stelo Glucose Biosensor System sensor/transmitter
Glucose Range	40–400 mg/dL
Useful Life	Up to 15.5 days
Sterilization	Ethylene Oxide gas
Memory Storage	Minimum 24 hours of glucose data
Data Backfill for User Display	24 hours

Model	Stelo Glucose Biosensor System sensor/transmitter
Power Source	Internally/battery powered
Battery Longevity (Typical)	Sufficient to support 15-day wear period plus a 12-hour grace period
Battery Charging Time	Non-rechargeable
Operational Temperature	Temperature: 50°F–107.6°F
Operating and Storage Humidity	Humidity: 10%–90% RH
Storage Temperature	Temperature: 35.6°F–86°F Store sensors in a cool, dry place
Operating and Storage Altitude	-1,253 feet to 16,406 feet
Ingress Protection	IP58: Protected from ingress of dust; Protected from submersion in the water up to depth of 8 feet for 24 hours
Applied Part	Type BF applied part
Alert Audible Output	N/A

Model	Stelo Glucose Biosensor System sensor/transmitter
TX/RX Frequencies	2.402–2.480 GHz
Bandwidth	1.07 MHz
Maximum Output Power	1.0 mW EIRP
Modulation	Gaussian Frequency-Shift Keying
Data Rate	1 Mbps
Data Communication Range	20 feet

The maximum surface temperature of Applied part = 109.4°F.

Essential performance

The Stelo Glucose Biosensor System measures users' glucose sensor readings with specified accuracy under the stated operating conditions. The Stelo Glucose Biosensor System's essential performance also includes reporting the corresponding measured glucose sensor readings on the display device.

Quality of service summary

Quality of service for the Stelo Glucose Biosensor System's wireless communication using Bluetooth Low Energy is assured within the effective range of 20 feet, unobstructed, between the Stelo Glucose Biosensor transmitter and paired display device at regular 5-minute intervals. If connection is lost between the transmitter and display device, upon re-connection any missed packets (up to 24 hours) will be transmitted from the transmitter to the display device. The Stelo Glucose Biosensor System is designed to only accept radio frequency (RF) communications from recognized and paired display devices.

Security measures

The Stelo Glucose Biosensor System uses the following interfaces and communication protocols:

- **Transmitter:** BLE.
- **App:** BLE to transmitter. TLS to Dexcom data platform using cellular data or Wi-Fi.

The Stelo Glucose Biosensor System is designed to transmit data between the transmitter and designated display devices in accordance to the industry standard Bluetooth Low Energy (BLE) protocols. It will not accept radio frequency (RF) communications using any other protocol, including Bluetooth classic communication protocols.

Don't pair your sensor over Bluetooth in public or populated areas. Bluetooth pairing should be done in a private and safe location to reduce cyber risks such as eavesdropping.

Critical function protection

In addition to the security provided by the BLE connection, communication between the Stelo Glucose Biosensor transmitter and mobile applications is protected by additional levels of security and safety mitigations using an encrypted and proprietary data format. This format embeds various industry standard encryption protocols and methods to protect data, verify data integrity, and to detect and prevent data tampering.

The communication between the transmitter and the app uses PKI (Public Key Infrastructure) to authenticate and verify that the transmitter is an authentic Dexcom device.

Critical functionality is protected by run-time protections that detect security violations and anomalies and take action to protect against an attack. In addition, the app includes integrity verification to detect app modifications and malware injection that could be used in an attack.

Furthermore, the binary of the app is obfuscated to make reverse engineering more difficult. This prevents an attacker from gaining insight into how the app works, making it more difficult for attackers to exploit the system.

Communication between the app and the cloud uses industry standard encryption protocols and methods to protect data, verify data integrity, and to detect and prevent data tampering

You are responsible for securing your display devices. If security is compromised, it may affect the Dexcom data shown on the display device.

Use these tips to help secure a smart device:

- **Secure network:** Only connect to a trusted/secure network
- **Secure smart device:** Don't use the Stelo by Dexcom app on a jailbroken (Apple) or rooted (Android) smart device

- **App sources:** Only install apps from trusted sources, such as Google Play or the App Store
- **Auto-lock:** In smart device settings, turn on auto-lock and use a strong password

Backup and restore

The Stelo Glucose Biosensor System does not backup or restore configurations such as settings or preferences.

If you suspect your display device security is compromised and affecting your Dexcom data, contact technical support (in the app, go to **Settings > Contact**) and consider using a BG meter as needed until the issue is resolved.

Unless disabled, the Stelo by Dexcom app regularly communicates with Dexcom Servers. Both the Stelo by Dexcom app and communication between the Stelo Glucose Biosensor applications and Dexcom Servers are protected by a number of mechanisms, designed to safeguard data integrity and data confidentiality.

SBOM (Software bill of materials)

An SBOM can help you understand the software components within your system. You can learn more at **account.stelo.com**.

Security events

The Stelo by Dexcom app will notify the user when a security issue is detected, such as attempting to use the app on a jailbroken (Apple) or rooted (Android) smart device, or when the transmitter is not reachable.

Additionally, Dexcom publishes system-impacting cybersecurity events users should be aware of at **dexcom.com/dexcom-security**.

End of product support

Transmitter

The transmitter firmware is provided in the single-use disposable transmitter with the built-in sensor. Each sensor session lasts up to 15 days[1], plus a 12-hour grace period at the end.

[1]A study was conducted to assess the sensor life where 77.9% of sensors lasted the full 15 days. In other words, when using the product per the package labeling, approximately 20% of sensors may not last for the full 15 days, 10% of these sensors may last less than 12 days.

App

Dexcom supports the original Major Operating system (OS) for the App version release as well as up to 2 subsequent major OS releases. Therefore, the expected lifetime of an app version is estimated to be approximately 3 years.

When an app or OS version is obsoleted, the user is given at least 30 days to update their software before it becomes incompatible and no longer supported.

For Stelo app operating system compatibility, go to **stelo.com/compatibility**.

Securely deleting the app

Deleting the app will remove all Stelo by Dexcom app information from your smart device.

iOS

- Touch and hold the app icon on the Home Screen
- Tap **Remove App**
- Tap **Delete App** to confirm

Android

- Touch and hold the app icon on the home screen
- Tap **Uninstall**
- Confirm you want to remove the app

Securely disposing the sensor

Dispose the used sensor following local guidelines for blood contacting components. No identifiable data is stored on the sensor.

Electromagnetic immunity and emissions declaration and guidance

The transmitter is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the transmitter should ensure that it is used in such an environment.

Immunity test	Transmitter compliance level
Electrostatic Discharge (ESD) **IEC 61000-4-2**	± 8 kV Contact ± 15 kV Air
Magnetic Field (50Hz) **IEC 61000-4-8**	30 A/m
Electrical Fast Transient/Burst **IEC 61000-4-4**	N/A

Immunity test	Transmitter compliance level
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 MHz to 2700 MHz (AM Modulation)
Radiated and Conducted Fields **Aircraft use**	Meets RTCA /DO-160 edition G Section 20, Category T

Electromagnetic interference can still occur in the home health care environment as control over the EMC environment cannot be guaranteed. An interference event can be recognized by gaps in sensor readings or gross inaccuracies. The user is encouraged to try to mitigate these effects by one of the following measures:

- If your symptoms do not match your sensor readings, consider using a BG meter as needed. If sensor readings do not consistently match your symptoms or BG meter values, talk to your healthcare provider. Your healthcare provider can help you decide how you should best use this device.
- If the display device temporarily misses sensor glucose data, the Sensor reconnecting error displays. To resolve, follow the onscreen instructions.

Electromagnetic emissions specifications

Emission test	Compliance
Radio Frequency Emissions **CISPR 11**	Group 1, Class B
Radio Frequency Emissions **Aircraft Use**	Meets RTCA /DO-160 edition G Section 21, Category M for in-cabin use as per FAA circular AC 91-21-1D Use of Portable Electronic devices aboard Aircraft.

Radio regulations compliance

FCC information

The Stelo Glucose Biosensor System is classified as a Class B medical digital device and complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Transmitter FCC ID: PH29788

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 [ITU] Radio Regulations.

Symbols

Symbols on the Stelo packaging show proper and safe use of the device. You may also reference the symbols glossary at **stelo.com/symbols**.

Below is a list of each symbol and its meaning.

Symbol	Definition
	Catalogue number
	Lot number
	Unique device identifier
	Date of manufacture
	Manufacturer
	Country of manufacture
	Do not use if package is damaged



Keep dry



Temperature limit



Humidity limitation



Use by date



Do not reuse



Sterilized using ethylene oxide



Single sterile barrier system with protective packaging outside



Consult instructions for use



Caution

MD	Medical device
MR	MR (magnetic resonance) unsafe
	Type BF applied part
IPXX	IPXX degree of ingress protection (see Technical information for product detail)

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