Sensor Smart Transmitter Mobile App

eversense®

User Guide

A guide for using the Eversense
Continuous Glucose Monitoring System

Eversense Trademark

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Glossary

Alert An alert warns you that a situation needs your attention and that you should respond/take appropriate action.

Blood Glucose Meter A commercially available device used to measure glucose using a blood sample from a fingerstick.

Bluetooth® A brand name for a wireless networking technology that uses short wave radio frequencies (RF) to connect mobile devices and other wireless electronic devices.

Calibration Blood glucose reading from a fingerstick sample entered in the Eversense App to check the accuracy of the system. With the Eversense System, there are two phases: Initialization Phase during which 4 fingerstick tests are required, and the Daily Calibration Phase, during which 1 fingerstick test is required twice daily.

CGM Continuous Glucose Monitoring. Continuously monitoring your glucose levels from interstitial fluid every few minutes.

Contraindication A condition or circumstance in which a person should not use the device.

CT Computed Tomography

Do Not Disturb Mode (DND in the Eversense App) When enabled, the smart transmitter will stop providing vibratory notifications for non-critical alerts. The Do Not Disturb feature in the Eversense App only controls the smart transmitter and will not mute or hide smartphone notifications. Many mobile devices have a separate Do Not Disturb Mode. Consult the manufacturer's instructions for more information.

Electromagnetic Interference A strong field of energy generated by electrical or magnetic devices.

EULA End User License Agreement

Eversense App Software program that is installed on a mobile device and is used to display CGM glucose data sent from the smart transmitter.

Eversense DMS A web-based application compatible with the Eversense app where your glucose data is stored and can be viewed.

Eversense Now A remote monitoring mobile application that allows you to share your glucose data with other people.

FAQ Frequently Asked Questions

"HI" Reading Indicates a sensor glucose reading is > 22.2 mmol/L.

Hyperglycemia An episode of high blood glucose.

Hypoglycemia An episode of low blood glucose.

Interstitial Fluid (ISF) The fluid between cells in the body. The Eversense CGM measures glucose from an interstitial fluid sample, versus glucose in a blood sample obtained from a fingerstick.

Jailbroken Device A device (iPhone or iPod) that has been modified to remove the controls and limits set by the original manufacturer.

LED Light Emitting Diode

Linked Sensor A sensor that is connected to a smart transmitter.

"LO" Reading Indicates sensor glucose reading is < 2.2 mmol/L.

Mobile Device A handheld device built on a mobile operating system that runs the Eversense App and communicates with the smart transmitter.

mg/dL Milligrams per deciliter, a unit of measure that shows the concentration of a substance in a specific amount of fluid. In some countries, including the United States, glucose test results are reported as mg/dL, indicating how much glucose is in the blood when using a blood glucose meter, or how much glucose is in the interstitial fluid when using some CGM systems, like the Eversense CGM System.

mmol/L Millimoles per liter, a unit of measure that shows the concentration of a substance in a specific amount of fluid. In many countries, glucose test results are reported as mmol/L, indicating how much glucose is in the blood when using a blood glucose meter, or how much glucose is in the interstitial fluid when using some CGM systems, like the Eversense CGM System.

MRI Magnetic Resonance Imaging

Rate of change/trend arrows Indicators of direction and speed of change of your glucose levels.

Remote Monitoring An optional feature that allows you to invite others to view your CGM data using Eversense Now, a separate mobile app they download to a compatible mobile device.

Sensor A device inserted subcutaneously for continually measuring interstitial fluid glucose levels.

Snooze Setting Used to set how often an alert repeats.

Subcutaneous Located beneath the skin.

Smart Transmitter A reusable device worn externally over the inserted sensor that powers the sensor and sends glucose information to the mobile device for display in the Eversense App.

Warm-Up Phase The period the sensor requires to adjust after the sensor has been inserted and before calibrations.

I. Introduction

This section reviews how to use this guide and describes your new Eversense CGM System, including its components and intended purpose.

Congratulations on having the latest technology to assist you in managing your diabetes. Your Eversense CGM System is intended to continually measure glucose levels for up to 90 days after your sensor is inserted. Glucose information collected by the system is automatically sent to your mobile device. You must contact your physician's office to schedule the insertion and removal of your sensor.

Help and Support

Please review this User Guide with your health care provider. For additional Eversense product questions and trouble shooting issues, contact Customer Support toll free in the US at 844-SENSE4U (844-736-7348). Outside the US, call your local distributor or visit www.eversensediabetes.com to locate your local distributor.

Eversense CGM System Components

The system includes 1) a small sensor inserted subcutaneously by a physician, 2) a removable smart transmitter worn over the sensor, and 3) a mobile app to display the glucose readings.

Eversense Sensor

The sensor is inserted under the skin (upper arm) and measures glucose in interstitial fluid for up to 90 days. These glucose levels are then calculated by the smart transmitter and sent to the app.

Sensor

Eversense Smart Transmitter

The removable smart transmitter is worn externally over the sensor and powers the sensor. It wirelessly sends glucose data (via Bluetooth) to the mobile device app. The smart transmitter also provides on-body vibe alerts based on the glucose settings you choose. It has a rechargeable battery and is reusable for up to one year.

Smart Transmitter

Eversense App

The Eversense App is a software application that runs on a mobile device (e.g., smartphone or tablet) and displays glucose data in a variety of ways. It also provides alerts based on the glucose settings you choose.

IMPORTANT: In order to use the Eversense CGM System, you must have an understanding of downloading and using mobile apps on your handheld device. Data from the Eversense Smart Transmitter is sent wirelessly via Bluetooth. Carefully read the instructions in this User Guide for downloading and installing the Eversense mobile app, and for pairing your mobile device with the smart transmitter. If there is anything you do not understand in this User Guide, please contact your local distributor.

Disposable adhesive patches for daily use are also included as part of the system, and will be provided to you by your physician after your sensor has been inserted. The patch has an acrylic adhesive side that attaches to the back of the smart transmitter, and a silicone adhesive side that attaches to the skin.

Mobile App

Make sure your mobile device is using the latest operating system.

Eversense System Overview

A separate blood glucose monitoring system (not provided by Senseonics) is required for calibrating the CGM System, and to make treatment decisions. When used properly, these components work together to help ensure you get continuous glucose monitoring for up to 90 days.

To ensure you receive continuous glucose readings and other information, follow these daily use tips:

- ✓ Wear your smart transmitter all the time except when charging.
- ✓ The smart transmitter is water-resistant to a depth of 1 meter (3.2 feet) for 30 minutes. Exposing the smart transmitter to conditions beyond this will result in damage and void your warranty.
- ✓ Make sure your smart transmitter has enough battery power at all times.
- ✓ Perform two blood glucose meter calibration tests each day when prompted.
- ✓ Pay attention to alerts and notifications you receive from your smart transmitter and mobile device.
- ✓ Replace the adhesive patch on your smart transmitter daily.
- ✓ You can remove the smart transmitter from the upper arm at any time, except during calibration. Remember that no data are collected when the smart transmitter is not communicating with the sensor. When you place the smart transmitter back on the sensor site, it will take 10 minutes for sensor communication to re-start and for glucose readings to appear in the app.
- ✓ When the smart transmitter and mobile device are not within range of each other, any data gathered by the smart transmitter is stored and sent to the app when the mobile device and smart transmitter are back within range.
- ✓ It is safe for you to wear your sensor and smart transmitter when you go through metal detectors at airports. While flying, the smart transmitter performs similar to any other Bluetooth device. Be sure to follow the specific safety guidelines mandated by the airline.

Some of the features of the Eversense CGM System:

- Wireless communication with the sensor, smart transmitter and app.
- Long-term sensor wear in the upper arm for up to 90 days.
- Alerts when pre-set Low or High Glucose Alert levels (hypoglycemia or hyperglycemia) are reached.
- Predictive Alerts let you know ***before*** reaching pre-set Low or High Glucose Alert levels.
- Use of mobile device (e.g., smartphone) to display glucose readings.
- On-body vibe alerts with the smart transmitter even when mobile device is not nearby.
- Provides readings within 2.2 - 22.2 mmol/L range every 5 minutes.
- Trend arrows that show whether your glucose values are rising or falling and how fast.
- Graphs and statistics that show your glucose results in easy-to-understand formats.
- Removable and rechargeable smart transmitter.
- Event entry capabilities (like meals, exercise and insulin).
- Stores glucose data in the app and on the smart transmitter.
- Provides remote monitoring capability to others using the Eversense Now mobile app.

System Requirements

- The Eversense CGM System.
- A compatible smartphone for Android (version 4.4 or higher) or Apple iPhone® or iPod® or iPad® (iOS version 8.0 or higher) that has Bluetooth Smart (or Bluetooth Low Energy). The Eversense App also works with the Apple Watch®.
- For a list of compatible devices, please go to www.eversensediabetes.com.
- The Eversense CGM App downloaded to your mobile device from the Apple App Store or on Google Play™.

End User License Agreement and Privacy Policy

Use of the Eversense App is subject to the terms and conditions of the most current Eversense App End User License Agreement and Eversense App Privacy Policy. These documents are updated from time to time and are posted at www.eversensediabetes.com.

Jailbroken Devices

DO NOT use the Eversense apps on jailbroken iPhones or iPods. Jailbroken devices do not provide an acceptable level of security and accuracy for the user and are not approved for use by Senseonics.

Indications for Use

The Eversense CGM System is indicated for continually measuring interstitial fluid glucose levels in adults (18 years and older) with diabetes for the operating life of the sensor.

The system is intended to:

- Aid in the management of diabetes.
- Provide real-time glucose readings.
- Provide glucose trend information.
- Provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia).

Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns and trends seen over time.

The system is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices.

Contraindications

The sensor and smart transmitter are incompatible with magnetic resonance imaging (MRI) procedures. Patients should not undergo an MRI procedure while the sensor is inserted or when wearing the smart transmitter. Should an MRI be required the sensor must be removed before the procedure.

- The system is contraindicated in people for whom dexamethasone or dexamethasone acetate may be contraindicated.
- Therapeutics products such as mannitol intravenous and irrigation solutions may increase blood mannitol concentrations and cause falsely elevated readings of sensor glucose results.

What is Included in this Package

This Eversense Smart Transmitter Pack contains the following:

Eversense Smart Transmitter

Charging Cradle

Power Supply
(USB cable and AC power adapter)

Also included in this package is this User Guide and a Quick Reference Guide (not shown).

How to Use this User Guide

This guide describes how to use your CGM System. Read the entire guide before using the system.

- Any **warnings** or **cautions** are highlighted in a box.
- User tips are preceded by the ✓ symbol.

2. Benefits and Risks

This section describes the benefits, expectations and risks associated with using the Eversense CGM System.

Continuous glucose monitoring aids in the management of diabetes and glucose control, which can improve your quality of life. Best results are achieved when you are fully informed about the risks and benefits, insertion procedure, follow-up requirements, and self-care responsibilities. You should not have the sensor inserted if you cannot properly operate the CGM System.

The CGM System measures glucose in interstitial fluid (ISF) between the body's cells. Physiologic differences between ISF and blood from a fingerstick may result in differences in glucose measurements. These differences are especially evident during times of rapid change in blood glucose (e.g., after eating, dosing insulin, or exercising). Glucose levels in ISF lag behind glucose levels in blood by several minutes.

The sensor has a silicone ring that contains a small amount of an anti-inflammatory drug (dexamethasone acetate). It has not been determined whether the risks associated with injectable dexamethasone acetate apply to the dexamethasone acetate elution ring inside the sensor. The elution ring releases a small amount of dexamethasone acetate when the sensor comes in contact with body fluids and serves to minimize the body's inflammatory response to the inserted sensor. Dexamethasone acetate in the ring may also cause other adverse events not previously seen with the injectable form. For a listing of potentially adverse effects related to dexamethasone acetate, contact your physician.

Unauthorized modifications of the equipment, improperly accessing information within it or "jailbreaking" your system, and taking any other unauthorized actions may cause the CGM system to malfunction and may put you at risk. Unauthorized modification of the equipment is not permitted and voids your warranty.

Risks and Side Effects

The glucose alerts and notifications will not audibly notify the user when the sound on your mobile device is turned off. If the system cannot display a glucose value, it also cannot provide glucose alerts. If you are unable to feel the vibration of the smart transmitter you may not notice the alerts. The system's calculated glucose can be slightly different from your blood glucose meter. This may cause an alert to activate at a different time than it would have if the system's values always matched the blood glucose meter values.

If you do not take frequent blood glucose measurements and miss an alert, you may not be aware of high or low glucose levels. You may need medical attention in the event that you have high or low glucose and are unaware of it.

If you do not test your glucose with a blood glucose meter when you have symptoms of a low or high blood glucose level OR when your symptoms are not consistent with the sensor glucose readings, you may miss a high or low glucose event. Treatment decisions made without confirming with a blood glucose meter check may result in a high or low glucose event, since blood glucose values can be slightly different than your sensor glucose values measured in interstitial fluid.

The sensor is inserted by making a small incision and placing it under the skin. This process may cause infection, pain or skin irritation. Additionally, the adhesive may cause a reaction or skin irritation.

Warnings

- **If at any time you have symptoms of a low or high blood glucose level OR if your symptoms are not consistent with the sensor glucose readings, you should test your glucose with a blood glucose meter.**
- **Always test your glucose with your blood glucose meter before making a treatment decision.**
- **If your smart transmitter is damaged or cracked, DO NOT use, as this could create an electrical safety hazard or malfunction, and could result in electrical shock.**
- **Close contact with direct EMI may interfere with the smart transmitter's ability to send data to your mobile device. Move away from the source of EMI and check that your mobile device is connected to your smart transmitter.**

Warnings (continued)

- High doses of aspirin (over 2000 mg), such as for chronic treatment of inflammatory conditions (e.g., rheumatoid arthritis), may falsely lower Sensor glucose readings.
- Until it has healed, always cover the insertion site with a sterile bandage before placing the smart transmitter adhesive over the sensor. Failure to do so could result in infection at the insertion site.
- Please review this User Guide with your health care provider. For additional Eversense product questions and troubleshooting issues, contact Customer Support toll free in the US at 844-SENSE4U (844-736-7348). Outside the US, call your local distributor or visit www.eversensediabetes.com to locate your local distributor.
- Always calibrate the system using only a fingerstick blood sample. DO NOT use an alternative site (such as forearm or palm) blood glucose reading to calibrate the system.
- DO NOT insert your infusion set within 10.16 cm (4 in) of the sensor site. If the insulin delivery site is within 10.16 cm (4 in) of the sensor site, it may interfere with sensor glucose readings and can cause inaccurate glucose readings.

Always follow your physician's instructions for care after the sensor insertion or removal. Contact your physician if any of the following events occur:

- You have pain, redness, or swelling at the incision site(s) later than 5 days after the sensor insertion or removal.

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Cautions

- DO NOT exchange smart transmitters with another person. Each smart transmitter can be linked to only one sensor at a time.
- The following medical therapies or procedures may cause permanent damage to the sensor particularly if used in close proximity to the device:
  - **Lithotripsy –** The use of lithotripsy is not recommended for people who have an inserted sensor because the effects are unknown.
  - **Diathermy –** DO NOT use diathermy on people who have an inserted sensor. Energy from the diathermy can transfer through the sensor and cause tissue damage in the insertion area.
  - **Electrocautery –** The use of electrocautery near the inserted sensor may damage the device. DO NOT use electrocautery near the sensor.
- DO NOT wear the smart transmitter during medical x-rays or computed tomography (CT) scans. To avoid interference with results, remove the smart transmitter before undergoing medical x-ray or CT scans. Make sure your physician knows about your smart transmitter.
- The sensor and smart transmitter should be linked the day of insertion. Failure to link the sensor and smart transmitter could result in a delay in receiving glucose readings.
- Steroid use – It has not been determined whether the risks usually associated with injectable dexamethasone acetate apply to the use of this dexamethasone acetate elution ring, a highly localized, controlled-release device. The dexamethasone acetate ring could cause other adverse events not listed or previously seen.
- If the sensor or smart transmitter feels warm, remove the smart transmitter immediately and contact your physician for further advice. A warm sensor could mean there is an infection or a sensor malfunction.
- Remove the smart transmitter from your arm before charging the smart transmitter battery. Failure to remove the smart transmitter while it is charging could result in electrical shock.

Cautions (continued)

- DO NOT attempt to use the Eversense App while operating a motor vehicle.
- You should not receive massage therapy near the inserted sensor site. Massage therapy near the sensor site could cause discomfort or skin irritation.
- Use only the AC power adapter and USB cable provided with the smart transmitter when charging the smart transmitter battery. Use of another power supply could damage the smart transmitter, not allowing glucose readings to be received properly, and could result in voiding your warranty.
- If you have any concerns about allergic reaction to silicones, contact your physician prior to use.
- Discard the patch after 24 hours of use.
- The Eversense Now Remote Monitoring App does not replace the monitoring regimen as directed by your health care provider.
- The Eversense CGM System has not been tested in the following populations: women who are pregnant or nursing, people under the age of 18, critically ill or hospitalized patients, people receiving immunosuppressant therapy, chemotherapy or anti-coagulant therapy, those with another active implantable device, e.g., an implantable defibrillator (passive implants are allowed, e.g., cardiac stents), those with known allergies to or using systemic glucocorticoids (excluding topical, optical or nasal, but including inhaled).

3. Getting Started

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This section describes the initial start-up steps required before you can begin using your new Eversense CGM System on a daily basis. You may perform these steps before your physician inserts the sensor.

To get started you need:

- Your mobile device to download the Eversense App.
- Wireless internet connection.
- This Eversense Smart Transmitter Pack that includes your smart transmitter and power supply.

  Note: If you have not received your Smart Transmitter Pack skip to instructions on downloading and installing the Eversense App to your mobile device later in this section.

  You may complete the following start-up steps before your sensor is inserted so that you can familiarize yourself with the system.

Note: Your smart transmitter is set to "sleep" status for shipping. When you charge the smart transmitter for the first time, the status changes to active.

2 easy start-up steps:

1. Download the Eversense App to your mobile device.
2. Set up the app – Create an Account, Pairing and Settings.

After you receive your smart transmitter it must be fully charged before pairing with the app.

Charge your Smart Transmitter

It is important to charge the smart transmitter battery daily to ensure data is collected from the sensor and sent to the app. The smart transmitter does not collect information from the sensor or send it to the app while charging. You may also charge your smart transmitter by connecting the USB cable to a computer USB port instead of the AC power adapter. Using a computer may take longer to fully charge the smart transmitter battery.

Caution: Use only the AC power adapter and USB cable provided with the smart transmitter when charging the smart transmitter battery. Use of another power supply could damage the smart transmitter, not allowing glucose readings to be received properly, and could result in voiding your warranty.

1. **Plug the standard end of the USB cable into the adapter on the USB port.**

2. **Plug the micro end of the USB cable into the charging cradle on the USB port.**

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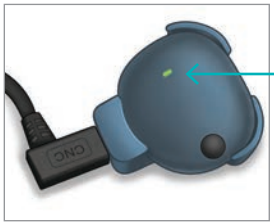
3. Line up the four gold pins on the bottom of the smart transmitter with the four gold pins on the charging cradle.

- Slide the smart transmitter into place in the charging cradle.
- Once positioned, push down on the smart transmitter until it snaps into place.

4. Plug the adapter into an AC power outlet.



Step 1. Download and Install the App

The app is designed to work with the smart transmitter to automatically receive and display sensor glucose data.

1. **Select the mobile device you would like to use to display your glucose readings. In most cases, this would be a smartphone.**

2. **Download the free Eversense App from the Apple App Store or on Google Play.**

   The prompts to install the app will vary between iOS and Android operating systems.

Eversense App Icon

Note: Make sure your mobile device is using the latest operating system.

3. **On the install screen, tap Install application and follow the installation instructions.**

   After 1 - 2 minutes, check your mobile device display for the Eversense App icon (as shown to the left).

IMPORTANT: Make sure that you have a wireless internet connection and that Bluetooth is turned ON before continuing.

Step 2. Set up the App – Account Creation, Pairing and Settings

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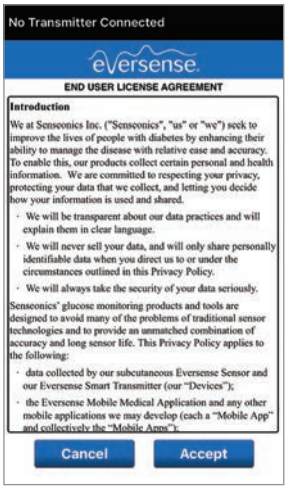
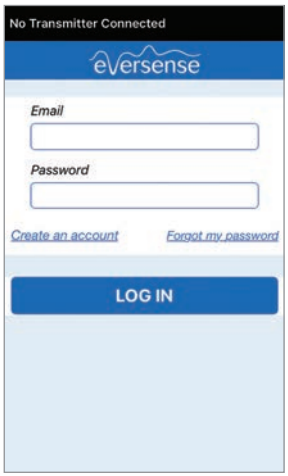
Once the app is downloaded, connect the app and smart transmitter by pairing the smart transmitter with your mobile device.

1. **Launch the app by tapping the Eversense App icon on your mobile device. The END USER LICENSE AGREEMENT will appear.**
   - Review the Agreement and tap **Accept** to agree to the terms of the License Agreement.

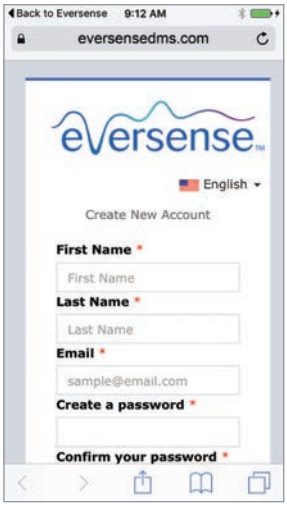


2. **After you accept the Agreement, you will be prompted to create and register an account with an Email and Password.**
   - You must register an account before you are able to log in. Tap **Create an Account**.



Note: If you forget your password, you can reset it via the app. If you forget your email associated with your account, contact Customer Support.

3. **Enter your account information and then tap Register.**



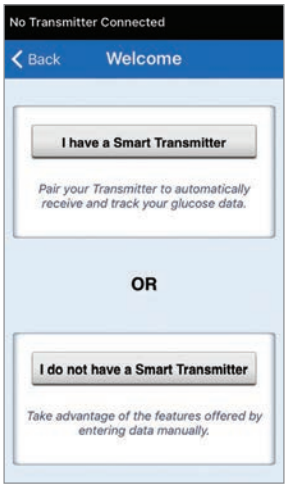
To complete registration check the email address you provided and click the link in the email.

- Tap **Done** to return to the **Eversense LOGIN** screen.

4. **Enter your email address and password and tap LOG IN. You will see a confirmation screen. Tap OK.**

Note: The password is case sensitive.

5. When you complete registration and log in, a **WELCOME** screen appears.



6. Choose one of the two options depending on whether you already have your smart transmitter or not:

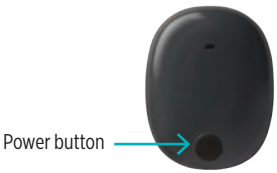
I have a Smart Transmitter

(skip to step 7).

I do not have a Smart Transmitter

(skip to step 12).

7. With the smart transmitter turned on, and when the **PAIR YOUR TRANSMITTER** screen appears on your mobile device, set your smart transmitter to "Discoverable" mode for the mobile device to find the smart transmitter:
   - Press the smart transmitter power button three times. Make sure your smart transmitter is not plugged into the power supply.
   - The LED will blink green and orange to indicate the smart transmitter is in Discoverable mode.



Note: If you press the power button on the smart transmitter and no LED appears, press and hold the power button for about 5 seconds to turn it on.

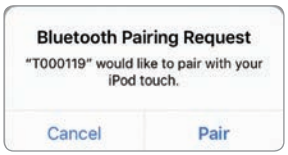
8. **On the PAIR YOUR TRANSMITTER screen, the smart transmitter ID detected by the app is listed as "Not Connected". (Your smart transmitter ID matches the serial number found on the back of the smart transmitter.)**

Tap **Not Connected** to begin pairing process.

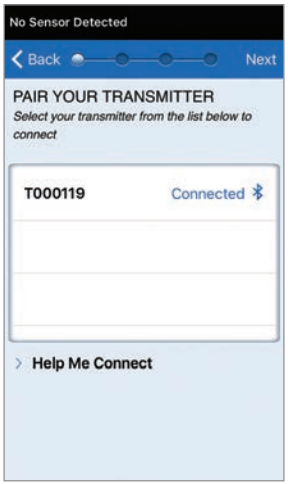
9. **A BLUETOOTH PAIRING REQUEST pop-up screen appears.**

Tap **Pair** to complete the pairing process.

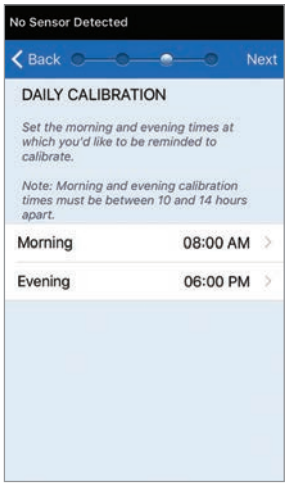
Note: The smart transmitter can only be paired with one mobile device at a time.



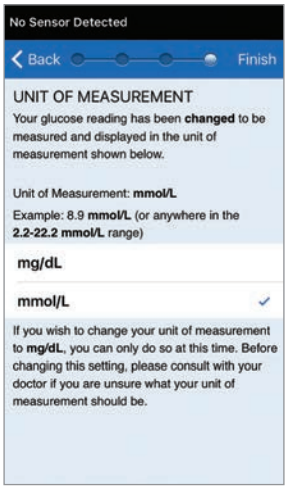
10. **"Connected" appears next to the smart transmitter ID once the pairing is complete. The smart transmitter will provide intermittent vibrations until the smart transmitter is linked with the inserted sensor (see *Inserting and Linking the Sensor*).**
    - Tap **Next**.



11. **The DAILY CALIBRATION screen appears for you to set your morning and evening reminder times for your twice-a-day calibrations. You will automatically receive a notification when it is time to make a calibration entry.**
    - Tap **Morning** to change the time and repeat for **Evening**.
    - Tap **Next** when done.



12. The **UNIT OF MEASUREMENT** screen appears and indicates the standard unit of measurement for your region. Your glucose readings will always be displayed in this unit of measurement.



Note: DO NOT change the unit of measurement unless you have discussed it with your physician. When the unit of measurement is confirmed, tap **Finish**.

13. Next, the **MY GLUCOSE** screen appears. The screen will not have any glucose data to display at this time.

Note: Once the sensor is linked to the smart transmitter, the red blood drop with the X will no longer appear and a black blood drop with signal bars will be displayed.

Once the sensor is inserted by your physician and the 24-hour Warm-Up Phase is completed, you can begin calibration. If you have not yet had your sensor inserted, you can review this User Guide to become familiar with the app and its features.

4. Inserting and Linking the Sensor

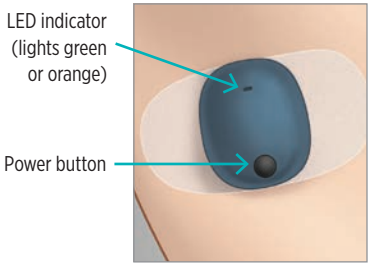
This section describes how to link the sensor and smart transmitter after your physician has inserted the sensor. Only your physician can insert the sensor. See "About the Sensor" to learn more.

If the smart transmitter was sent directly to you, be sure to bring it and your mobile device to your insertion appointment. Once your physician has inserted your sensor, the smart transmitter and the sensor must be linked in order to start the Warm-Up Phase. Your smart transmitter can only be linked to one sensor at a time.

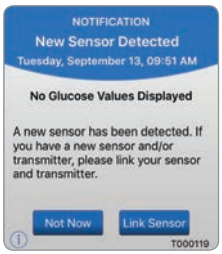
1. **Make sure your smart transmitter is turned ON (see *Using the Smart Transmitter*) and that your mobile device has access to the internet.**
   - Position the smart transmitter directly over the inserted sensor until the **Placement Guide** in the app shows some connection. The Placement Guide page is located in **Menu** > **Placement Guide**.

2. **Navigate away from the Placement Guide page to the Main Menu screen once you have confirmed there is a signal.**

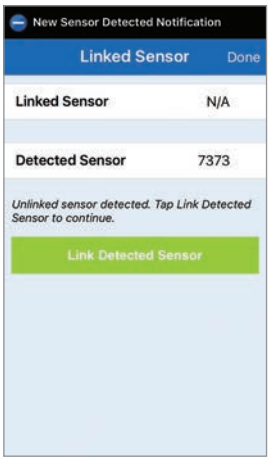
Note: The connection between the sensor and the smart transmitter is sensitive to the orientation of the transmitter. If the smart transmitter is directly over the sensor and the Placement Guide indicates there is no connection, try rotating the smart transmitter slightly to the left or right so the power icon and LED are parallel to the sensor.



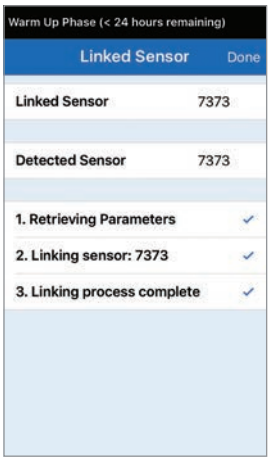
3. To link the smart transmitter and sensor, tap **Link Sensor** on either the **New Sensor Detected** pop-up screen or by tapping **Menu > Settings > System> Linked Sensor** and then tap **Link Detected Sensor.**

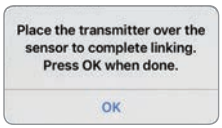


Note: It may take up to 5 minutes for the New Sensor Detected notification to be displayed.



4. The linking process will begin. Each step will show a check mark when finished. It may take up to 10 minutes for the process to complete. DO NOT remove the smart transmitter from your insertion site until the third check mark is displayed.



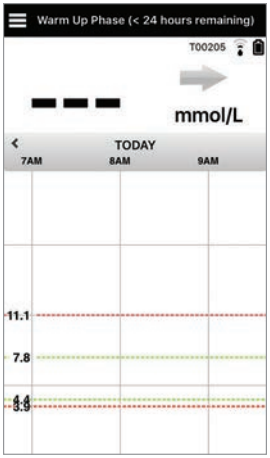


If the smart transmitter is removed from the sensor site, the system will display a notification.

Caution: The sensor and smart transmitter should be linked the day of the sensor insertion. Failure to link the sensor and smart transmitter could result in a delay in receiving glucose readings.

4

Note: The sensor requires a 24-hour Warm-Up Phase to stabilize in your body before glucose values will be collected by the smart transmitter. During the Warm-Up Phase, you do not need to wear the smart transmitter. If you decide to wear the smart transmitter over the sensor during this time, you will receive a message on the app indicating the Warm-Up Phase is in progress. Once the Warm-Up Phase is complete, turn ON the smart transmitter and place it over the sensor with the Eversense adhesive patch. The system will prompt you to calibrate using the app.



IMPORTANT: If your smart transmitter is not turned on and paired with the Eversense App and linked to the sensor, the system is not able to prompt you to calibrate.

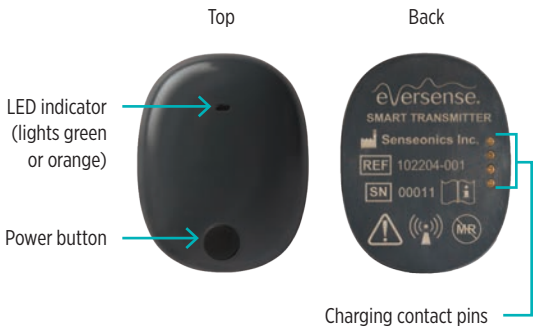
5. Using the Smart Transmitter

This section describes the many features of the smart transmitter and how to get uninterrupted and continuous monitoring of your glucose levels.

Your smart transmitter communicates with both the sensor and the app to provide CGM information.

Your Eversense Smart Transmitter does the following:

- Powers the sensor.
- Calculates and stores up to 90 days of glucose data.
- Provides on-body vibe alerts when you have reached the glucose alert levels you set.
- Sends glucose data to the app via Bluetooth.
- Can be recharged using the charging cradle.
- USB port to download data to compatible external applications.
- Multi-color LED to indicate various modes of the smart transmitter.
- Communicates with mobile device.
- Can be powered ON or OFF.



Daily Use

To receive continuous glucose readings and information, keep the following in mind when using your smart transmitter:

- ✓ Wear your smart transmitter at all times except when charging.
- ✓ The smart transmitter is water-resistant to a depth of 1 meter (3.2 feet) for 30 minutes. Exposing the smart transmitter to conditions beyond this will result in damage and void your warranty.
- ✓ Make sure your smart transmitter has enough battery power at all times.
- ✓ Perform two blood glucose meter calibration tests each day when prompted.
- ✓ Pay attention to alerts and notifications you receive from your smart transmitter and mobile device.
- ✓ Replace the smart transmitter with a new adhesive patch on a daily basis.
- ✓ You can remove the smart transmitter from the upper arm at any time, except during calibration. Remember that no data are collected when the smart transmitter is not communicating with the sensor. When you place the smart transmitter back on the sensor site, it will take about 10 minutes for sensor communication to re-start and for glucose readings to appear in the app.
- ✓ When the smart transmitter and mobile device are not within range of each other, any data gathered by the smart transmitter is stored and sent to the app when the mobile device and smart transmitter are back within range.
- ✓ It is safe for you to wear your sensor and smart transmitter when you go through metal detectors at airports. While flying, the smart transmitter performs similar to any other Bluetooth device. Be sure to follow the specific safety guidelines mandated by the airline.

Warning: If your smart transmitter is damaged or cracked, DO NOT use, as this could create an electrical safety hazard or malfunction, and could result in electrical shock.

Caution: Always remove the smart transmitter from your body before charging the battery.

Secure the Smart Transmitter over Inserted Sensor

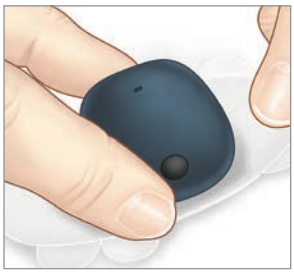
The smart transmitter must be secured on the skin directly over the sensor with the disposable adhesive patch. Each adhesive patch is designed to be replaced daily and has an adhesive side that attaches to the back of the smart transmitter and a silicone adhesive side that attaches to the skin. Both the skin and smart transmitter surfaces should be clean and dry to secure the adhesive surfaces of the patch.

Note: You will receive adhesive patches from your physician.

Caution: If you have any concerns about allergic reaction to silicones, contact your physician prior to use. Discard the patch after 24 hours of use.

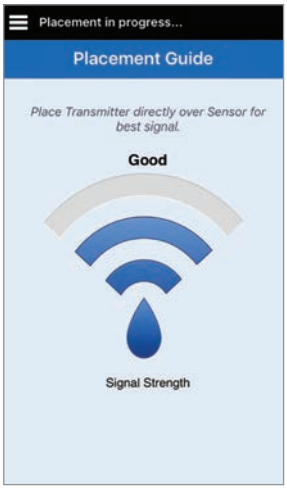
1. **Peel off the paper backing with the Eversense Smart Transmitter outline on it. Try not to touch the sticky portion of the adhesive in the center.**

2. **Align the smart transmitter over the sticky side (center) of patch and press firmly to secure.**
   - The smart transmitter should be placed so that its sides face the wings of the patch (as shown).

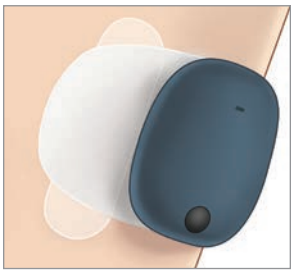


3. **Remove the larger clear backing and position the smart transmitter directly over the sensor.**
   - For the optimal signal strength, the smart transmitter must be placed directly over the sensor. Signal strength can also be improved by rotating the smart transmitter over the sensor such that the sensor aligns with the smart transmitter.

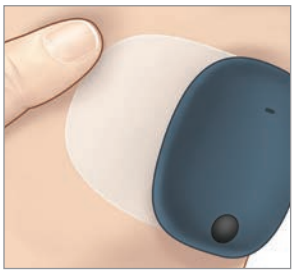
4. **Check the connection between the smart transmitter and the sensor.**
   - Tap **Menu** > **Placement Guide**.
   - Refer to the **Placement Guide** when attaching your smart transmitter to ensure there is some connection between the sensor and smart transmitter.



5. **Press the adhesive patch firmly on skin surface over the sensor.**
   - The smart transmitter should be positioned so that the patch wings lay horizontally on the arm.



6. **Use the tab to pull off the remaining clear liner.**
   - Smooth the adhesive onto the skin. Make sure the patch is flat on the skin surface.

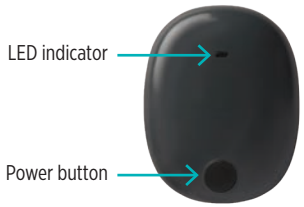


Turn the Smart Transmitter ON and OFF

The smart transmitter has a power button to turn the device on and off. The power button and two light emitting diodes (LED) lights are also used to indicate the remaining battery power.

1. **To turn the smart transmitter ON, press and hold the power button for about five seconds.**
   - The smart transmitter will vibrate once.
   - Release the power button and the LED will blink once indicating the power is ON.

   At any time, you can press the power button once to see if the smart transmitter is ON. If the LED appears, the smart transmitter is ON. If no LED appears, the smart transmitter is OFF.



2. **To turn the smart transmitter OFF, press and hold the power button for about five seconds.**
   - The smart transmitter will vibrate once.
   - Release the power button and an orange light will blink once, indicating the power is OFF.

Smart Transmitter Care and Maintenance

- Keep the smart transmitter and charging cradle clean (free of visible dirt) and protected when not in use. Wipe the outside with a cloth between uses to keep clean.
- Charge the smart transmitter when the battery power is low.
- Use only the power supply supplied with your system to charge the smart transmitter battery. Using a power supply other than one provided by Senseonics may void your smart transmitter warranty. DO NOT use the power supply if it is damaged in any way.

To clean your smart transmitter, wipe it down with a water dampened cloth; dispose of the cloth according to your local regulations. Dispose of the smart transmitter and all other system components according to local regulations.

Battery Indicator

The smart transmitter battery power can be checked using the app, or on the smart transmitter itself.

With the app:

- Tap **Menu** > **About** > **My Transmitter**. Scroll down to the Battery Level line that indicates amount of battery left.

  Or

- Check the battery icon on the upper right corner on the **MY GLUCOSE** screen. A red battery icon indicates the smart transmitter battery is empty.

With the smart transmitter:

- With the smart transmitter ON, press and release the power button. The LED will blink green once if the battery is charged. The LED will blink orange once if the battery is low. See the next page for more information on the LED indicators.

LED Status Indicators

The smart transmitter communicates several different states based upon the color of the LED.

- **During smart transmitter use:**

LED Status	Status	Action
Alternating green and orange when power button is pressed 3 times in 5 seconds	Discoverable mode	Pair smart transmitter with mobile device
Does not blink when power button is pressed	Smart transmitter off	Hold down power button for 5 seconds to turn on
Blinks green (once) when power button is pressed	10% - 90% battery power	No immediate action required
Blinks orange (once) when power button is pressed	Low battery, less than 10% battery power remaining	Charge battery soon
LED is orange for one minute	An alert has been triggered	Check the app on your mobile device to understand the alert

- **During smart transmitter charging:**

LED Status	Battery Status	Action
Solid orange when connected to the USB cable	Not yet fully charged	Continue charging until complete
Solid green when connected to the USB cable	100% charged	Disconnect from power supply

6. Calibrating the System

This section describes the calibration procedure and schedule of your Eversense CGM System.

To ensure best performance, routine calibration is required using fingerstick readings from a blood glucose meter. DO NOT use alternative test sites such as your forearm when entering BG values for calibration. Any commercially available meter may be used for calibration. Once your sensor has been inserted and linked to your smart transmitter, the system begins a 24-hour Warm-Up Phase. No calibration is required during this phase.

There are two calibration phases:

Initialization Phase – After the 24 Warm-Up Phase, you must complete 4 fingerstick calibration tests, spaced 2 to 12 hours apart.

Daily Calibration Phase – After the Initialization Phase, you must complete 2 fingerstick calibration tests per day, spaced 10 to 14 hours apart.

Routine calibration is critically important to ensuring the best performance of the Eversense CGM System. The following tips can help you improve your calibration measurements:

Tips for ensuring good calibration:

- ✓ Calibrate at times when glucose is NOT changing rapidly (e.g., before meals, before dosing insulin).
- ✓ Calibrate when you know you will not be removing the smart transmitter during the next 15 minutes.
- ✓ Wash your hands with warm, soapy water and dry thoroughly before taking a blood glucose meter reading. It is very important to have clean, dry hands when you test your blood glucose.
- ✓ Always follow the blood glucose meter manufacturer's instructions to get accurate blood glucose readings for calibration.
- ✓ Be sure the code on test strip vial matches the code on your blood glucose meter (if coding is required).

Calibration will *NOT* be complete or results *NOT* accepted if:

- ✗ Blood glucose meter reading is less than 2.2 mmol/L.
- ✗ Blood glucose meter reading is greater than 22.2 mmol/L.
- ✗ Blood glucose meter reading was taken more than 10 minutes before entering the result in the Eversense App.
- ✗ Sensor glucose reading is significantly different than the blood glucose meter reading.
- ✗ Your smart transmitter was being charged during the 15 minutes after you entered your calibration value.

Calibration Phases

A. Initialization Phase (after 24-hour Warm-Up Phase)

During this phase, 4 fingerstick blood glucose meter tests are required.

- The 4 calibration tests must be spaced 2 to 12 hours apart, and all 4 tests must be completed within a 36 hour period.
  - 1st calibration = 24 hours after sensor insertion.
  - 2nd calibration = 2 to 12 hours after 1st successful calibration.
  - 3rd calibration = 2 to 12 hours after 2nd successful calibration.
  - 4th calibration = 2 to 12 hours after 3rd successful calibration.
- Glucose readings will start displaying in the app a few minutes after the 2nd calibration is successfully completed.

IMPORTANT: If your smart transmitter is not turned on and paired with the Eversense App and sensor, the system is not able to prompt you to calibrate.

Re-Entering Initialization Phase

The following will cause the system to re-enter Initialization Phase.

- Not completing a calibration test within a 12-hour period during the Initialization Phase.
- Not completing all 4 calibration tests within 36 hours during the Initialization Phase.
- Not completing 2 calibration tests within a 24-hour period during the Daily Calibration Phase (see *B. Daily Calibration Phase*).
- When the last several blood glucose meter measurements are significantly different than the sensor glucose values.
- If the smart transmitter is out of battery power for more than 16 hours.
- When you receive a Sensor Check Alert.
- Six hours after you receive a Sensor Suspend Alert.

B. Daily Calibration Phase

The Daily Calibration Phase requires 2 blood glucose meter tests at the scheduled morning and evening calibration times. The first Daily Calibration Phase will begin after successful completion of the Initialization Phase.

- Your system will automatically tell you when it is time to perform the twice-daily calibration test.
- Daily Calibration times must be spaced 10 to 14 hours apart.
- The system allows the calibration test to be taken up to 2 hours ***before*** the scheduled time. If you miss your scheduled calibration time, the system will prompt you hourly.
- The **CALIBRATE** screen provides the next allowable calibration time.

Note: If a Daily Calibration test is missed, no additional CGM readings will be displayed after 16 hours have elapsed since the last accepted calibration result. If a calibration test result is not entered within 24 hours from the last accepted calibration, the system will re-enter the Initialization Phase.

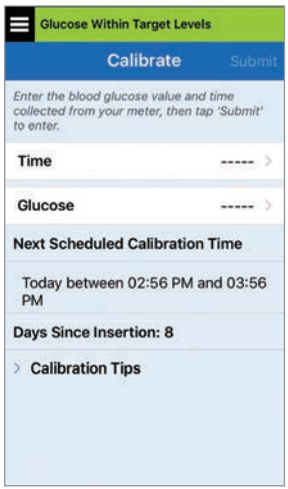
How To Calibrate

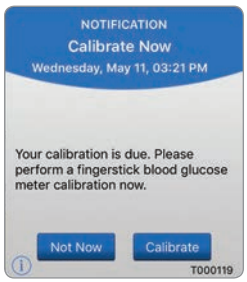
Warning: Always calibrate the system using only a fingerstick blood sample. DO NOT use an alternative site (such as forearm or palm) blood glucose reading to calibrate the system.

Note:

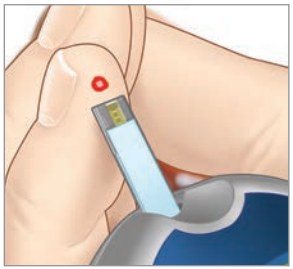
- For daily calibrations your CGM System will alert you when it is time to calibrate based on your scheduled calibration times.
- You can change your scheduled calibration times to better fit your schedule. Tap **Menu** > **Settings** > **Daily Calibration**.
- You can calibrate up to 2 hours before your scheduled calibration time. If you miss your scheduled calibration time, the system will prompt you hourly.
- You can enter additional calibration readings as long as each calibration is at least one hour apart. Tap **Menu** > **Calibrate**.
- If the time chosen is not within the calibration time frame, the **CALIBRATE** screen will indicate that it is not yet time for a calibration test.

1. When it is time for calibration, the app displays the **CALIBRATE NOW** screen.
   - Tap **Calibrate**.
   - The **CALIBRATE** screen appears.
   - Tap **Not Now** if you want to wait until later.

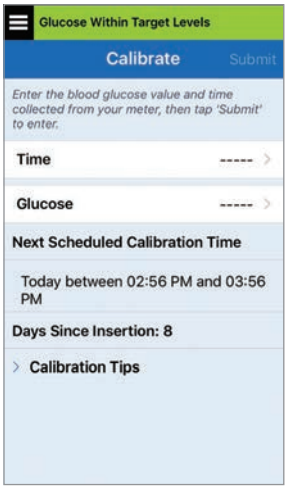


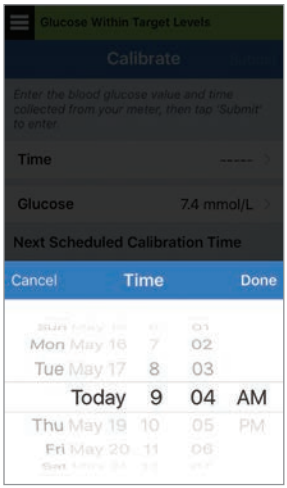


2. Obtain a fingerstick reading from your blood glucose meter.

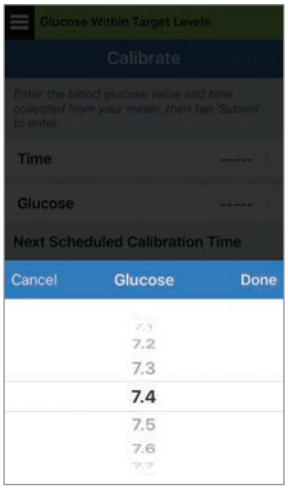


3. Tap **Time** and enter the time of day when the fingerstick blood glucose test was taken.
   - Tap **Done**.

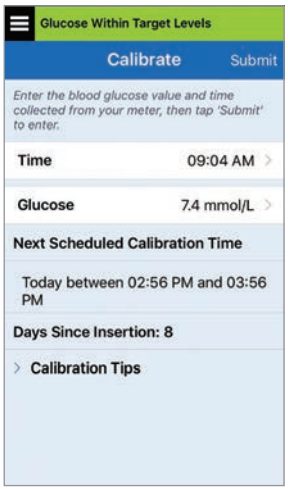




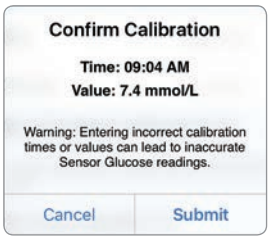
4. Tap **Glucose** and enter the value from your fingerstick blood glucose test.
   - Tap **Done**.



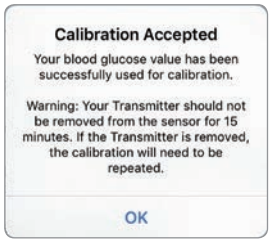
5. The **CALIBRATE** screen now shows the time and glucose reading you entered. If not correct, repeat steps 3 and 4.
   - When correct, tap **Submit**.



6. A **CONFIRM CALIBRATION** screen appears. Make sure that the fingerstick blood glucose test result you entered is correct.
   - Tap **Cancel** to go back and re-enter the correct time or glucose test result.
   - When correct, tap **Submit**.



7. **The CALIBRATION ACCEPTED screen appears.**
   - Tap **OK**.



Note: There may be conditions when your calibration result is NOT accepted. See *Calibrating the System* for more information.

8. **The MY GLUCOSE screen appears with a red blood drop icon to identify your fingerstick calibration.**

IMPORTANT: The smart transmitter should not be removed from over the sensor for at least 5 minutes before the test to 15 minutes after the test while calibration is in progress. The Status Bar at the top of the screen lets you know when calibration will be complete.

7. Using the App

This section describes the Eversense App including the main screen, trend graph, trend arrows, and the menu screen.

The app communicates with the smart transmitter to receive and then display glucose data, trends, graphs and alerts. The app also stores your glucose history with up to 90 days of stored data.

Note: When you log out of the Eversense App, your smart transmitter will not send glucose data to the app until you log back in.

On the **MY GLUCOSE** screen, you have easy access to:

- Real-time sensor glucose measurements.
- Rate and direction of your changing glucose levels.
- Graphical trends of your glucose levels.
- Alerts (hypoglycemia or hyperglycemia).
- Events such as meals, exercise, and medications.

Note: A wireless internet connection is required to download or update the Eversense App.

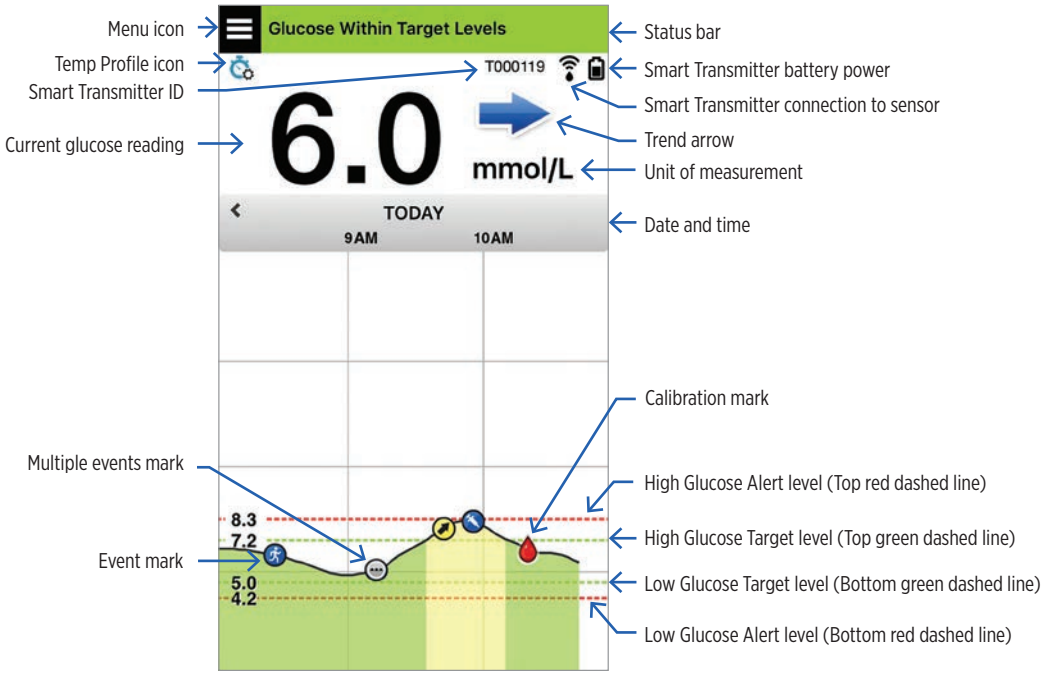
Check Your Mobile Device Settings

You will need a mobile device (such as your smartphone) to use the Eversense CGM System. It is very important that your mobile device is set up properly to ensure accurate display of your glucose data in the app. Follow the manufacturer's instructions for your mobile device to set up the following:

- Time and date.
- Bluetooth turned ON (enabled).
- Notifications turned on.
- Battery is charged.
- Geographic zone.
- Language.
- Mobile device sound should not be on vibrate.
- Do Not Disturb should be OFF.
  If you have your mobile device set to Do No Disturb, you will not hear any notifications from the Eversense App.

Get To Know the “My Glucose” Screen

The **MY GLUCOSE** screen is the main display screen for the app. It displays a variety of data, including sensor glucose readings, direction and rate of change arrow, trend graph, events, calibrations, alerts and notifications.



Note:

- If your sensor is not linked to a smart transmitter the smart transmitter connection to sensor icon will appear as a red blood drop with a red X.
- You can view a snapshot of the Home screen on your iOS device if you add the Eversense App widget to your widget page. For information on managing widgets, consult your iOS device user guide.
- You can view the **MY GLUCOSE** screen in landscape orientation to access short cut buttons to view the last 7, 14, 30 or 90 days and you can email this view with a single tap.

Status bar	Provides important information about your current glucose and system status.
Smart Transmitter ID	This is the smart transmitter you are now using. You can change the name by tapping **Settings** > **System**.
Current glucose reading	Current real-time glucose level. This is updated every 5 minutes.
Date and time	Current date and time. You can scroll left or right to see different dates and times.
Smart Transmitter battery power	Indicates battery power left in the smart transmitter.
Smart Transmitter connection to sensor	Indicates the strength of your smart transmitter connection with the sensor.
Trend arrow	Shows the direction your glucose levels are moving.
Unit of measurement	This is the unit of measurement used to display all glucose data.
High/Low Glucose *alert* level	The levels set for the high and low glucose alerts.
High/Low Glucose *target* level	The levels set for the high and low glucose targets (target range).

Multiple events mark	Indicates multiple events have occurred at the same time.
Event mark	Indicates manually entered events (e.g., exercise). See *Logging Events* for more information.
Calibration mark	Indicates a blood glucose calibration entry.
Glucose trend graph	Glucose levels over time. You can scroll back and forth to see trends or zoom in to display as few as 3 hours of data, or zoom out to see up to 3 days.
Menu	Provides easy navigation to various sections of the Eversense App: My Glucose Calibrate Alert History Event Log Reports Share My Data Placement Guide Connect Settings About

Trend Arrows

There are 5 different trend arrows that show the current direction of your glucose levels, and how fast they are changing.

	Gradually rising or falling glucose levels, falling or rising at a rate between 0.00 mmol/L and 0.06 mmol/L per minute.
	Moderately rising glucose level, rising at a rate between 0.06 mmol/L and 0.11 mmol/L per minute.
	Moderately falling glucose levels, falling at a rate between 0.06 mmol/L and 0.11 mmol/L per minute.
	Very rapidly rising glucose levels, rising at a rate more than 0.11 mmol/L per minute.
	Very rapidly falling glucose levels, falling at a rate more than 0.11 mmol/L per minute.

The app uses the **last 20 minutes of continuous glucose data** for calculating glucose trends.

When there are not enough sensor values available for the calculation, the arrow is displayed in gray. 

Trend Graph

The trend graph is used to review and analyze historical data and trends in your glucose values over time. It also displays marks for events you have manually logged in the app (e.g., calibration tests and exercise).

There are several ways you can use the trend graph:

- Quickly review how well you are doing when compared to the glucose targets and alert levels you set. The red dashed lines indicate your High and Low Glucose Alert levels, and the green dashed lines indicate your high and low glucose target levels (your target range).
- Shaded areas of the graph are color coded as follows depending on the glucose settings you enter:
  - Glucose values that are ***outside of your glucose alert levels*** will be red.
  - Glucose values that are ***within your glucose target levels*** will be green.
  - Glucose values that are ***between your glucose target and alert levels*** will be yellow.

- Press and hold any point in the line graph to view a specific glucose reading for that point in time.
- Tap any of the marks on the app screen to get more information about the event or alert.
- Pinch in and out on the screen to display different day/time ranges on the trend graph. You can zoom in and out to display as few as 3 hours or up to 3 days of information.
- To view trend graph data for a different date, tap the date on the screen and enter the desired date.
- You can view the trend graph in either portrait or landscape mode. In landscape mode, there are shortcut buttons to see 7, 14, 30 and 90 day views.

Note: All of your glucose data will be stored in the app as long as you have memory available on your mobile device.

Menu Options

The Menu icon (☰) appears at the top left corner of all app screens and provides easy navigation to other app features. The following menu items are available:

Menu Options		Description
	My Glucose	Main app screen that displays current CGM reading, direction and rate of change, trend graph, events and alerts.
	Calibrate	Enter calibration test values. The **CALIBRATION** screen automatically appears when it is time to calibrate but you can also enter additional calibration values using this menu option.
	Alert History	Review past alerts and notifications. See *Alert Descriptions* for more information.
	Event Log	Enter information about activities such as blood glucose tests, meals, insulin, health and exercise. See *Event Log* for more information.
	Reports	Review a variety of reports about your CGM data. See *Glucose Reports and Sharing* for more information.
	Share My Data	Download or export your CGM data via a .csv file, or allow others to view your glucose data through the Eversense Now mobile app. **Note:** The Eversense Now App is only available for iOS devices.
	Placement Guide	Check the communication between the smart transmitter and sensor. Use this screen whenever you are attaching the smart transmitter to be sure communication is established.
	Connect	Check the connection between the smart transmitter and mobile device. A Bluetooth connection is required to send data to the app.
	Settings	Customize settings such as glucose target levels, alert levels, sounds, temporary profile and calibration reminder times. See *Customizing your Settings* for more information.
	About	View information about your CGM System, including sensor and smart transmitter ID numbers.

Profile Picture

You can add or change the profile picture in your Eversense account, which will be displayed in your Eversense CGM mobile app and in your Eversense DMS account.

- Go to the **Main Menu** and tap on the picture of the silhouette.
- Follow the prompt to either take a new photo or choose an existing photo that is saved on your device.
- The photo you select will be displayed on the **Main Menu** screen.

Note: You can also change your profile picture from your Eversense DMS account. See the Eversense DMS User Guide for more information.

8. Customizing your Settings

This section describes how to customize settings in your Eversense CGM System.

Areas where you can customize app settings include:

- **Glucose –** glucose levels and change rates that will trigger an alert.
- **Daily Calibration –** your morning and evening calibration reminders.
- **System –** identifies or lets you enter personalized information about your system.
- **Mealtimes –** your times for each meal so that glucose reports can help show how meals may affect readings.
- **Sound Settings –** change the sounds for some glucose alerts, set snooze times and Do No Disturb for the Eversense App.
- **Temp Profile –** set a temporary glucose profile.
- **Log Out –** log out of your Eversense Account.

Glucose Levels

The Eversense CGM System is designed to provide alerts on your smart transmitter and mobile device when your glucose level has reached the alert levels you set. You will decide the settings for your glucose alerts, targets, and rates of change based on input from your health care provider.

Warning:

- Before making a dosing decision, perform a fingerstick blood glucose test to confirm the sensor glucose result.
- The Low and High Glucose Alerts are designed to assist you in managing your diabetes and should not be exclusively used to detect hypoglycemia or hyperglycemia. The alerts should always be used in conjunction with other indications of glycemic state such as your glucose level, trend, line graph etc.

IMPORTANT:

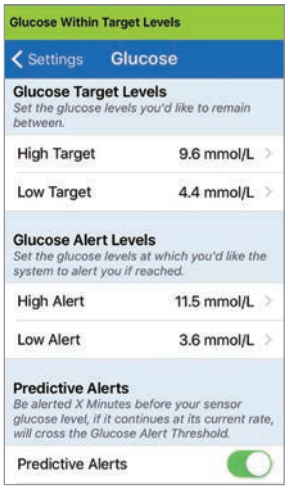
- **Low and High Glucose Alerts are different from your Low and High Glucose Targets.**
  - Low and High Glucose Alerts notify you on your mobile device and smart transmitter when you have crossed a certain low or high value.
  - Glucose Targets are used in the reports and line graphs to show how your glucose levels have been performing compared to the targets you set. You will not receive an alert when you have reached your Glucose Target levels.

Setting Glucose Target Levels

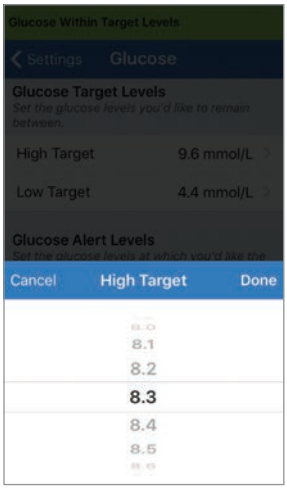
Glucose Targets are the low and high levels of the range you are aiming for throughout the day. These settings are used in the app to indicate when glucose values are in your target range.

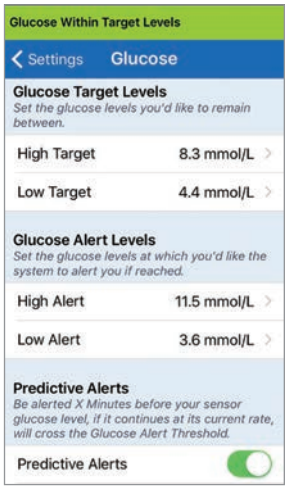
Default setting	Low: 4.4 mmol/L High: 7.8 mmol/L You can change this target range based on what you and your physician agree are the right target levels for you.
Allowable setting	Low: 3.6 - 6.7 mmol/L High: 6.7 - 19.3 mmol/L
On/Off setting	Always ON (cannot be turned OFF)
Notes	Used in graphs and charts on the app to show time spent in target range.

1. Tap **Menu > Settings > Glucose** to display the **GLUCOSE SETTINGS** screen.



2. Under **Glucose Target Levels**, tap **High Target** and select the appropriate High Glucose Target level.
   - Tap **Done** when complete.
   - Repeat step to make your **Low Target** selection.



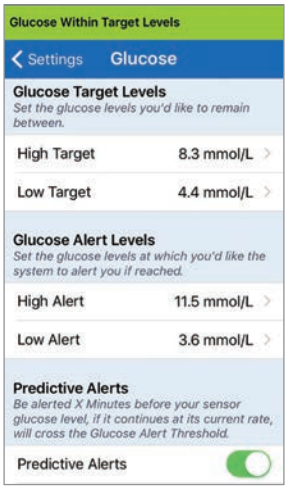


Setting Glucose Alert Levels

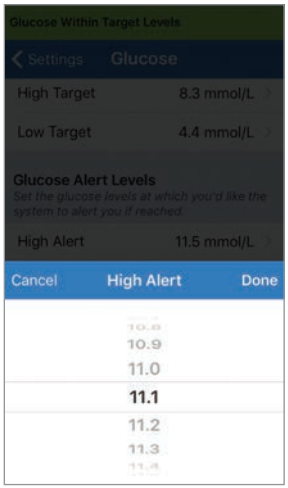
Your Eversense CGM System will alert you when your glucose levels are outside the alert settings you choose. When you have reached your low and high glucose alert levels, the smart transmitter vibrates, and the mobile app gives an audible alert as well as displays a message on the screen. You should immediately perform a fingerstick blood glucose test before making a treatment decision.

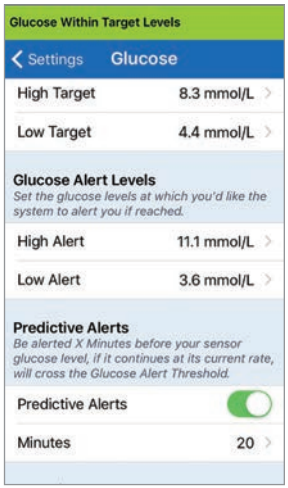
Default setting	Low: 3.9 mmol/L High: 11.1 mmol/L You can change these alert levels based on what you and your physician agree are the right levels for you. Your Low Glucose Alert cannot be set above your Low Glucose Target, and your High Glucose Alert cannot be set below your High Glucose Target.
Allowable setting	Low: 3.3 - 6.4 mmol/L High: 6.9 - 19.4 mmol/L
On/Off setting	Always ON (cannot be turned OFF)
Notes	Audio notification and visual alerts on your mobile device and smart transmitter on-body vibe alerts.

1. Tap **Menu > Settings > Glucose** to display the **GLUCOSE SETTINGS** screen.



2. Under **Glucose Alert Levels**, tap **High Alert** and select the appropriate High Glucose Alert level.
   - Tap **Done** when complete.
   - Repeat step to make your **Low Alert** selection.





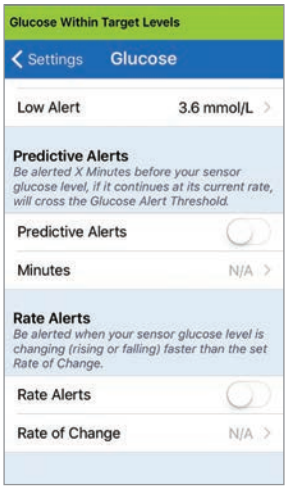
Setting Predictive Alerts

Predictive Alerts let you know in advance that a high or low glucose event is likely to occur if current trends continue.

Predictive Alerts use the Low and High Glucose Alert levels to provide an "early" warning. When you have reached the early warning time, the smart transmitter vibrates, and the mobile app gives an audible alert as well as displays a message on the screen. You should immediately perform a fingerstick blood glucose test before making a treatment decision.

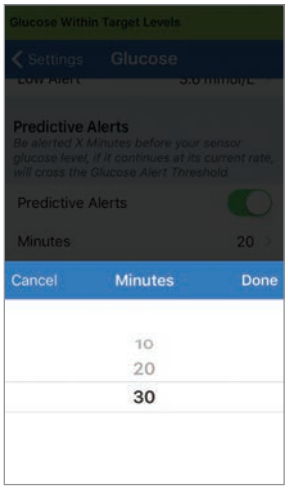
Default setting	OFF
Allowable setting	10, 20, or 30 minutes prior
On/Off setting	You can turn this feature ON. No predictive alerts will occur until this feature is turned ON. The default is 20 minutes.
Notes	Audio notification and visual alerts on your mobile device and smart transmitter on-body vibe alerts.

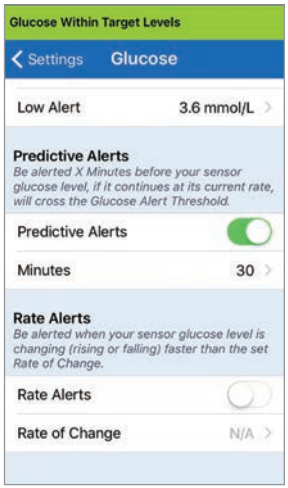
1. To turn this feature ON, tap **Menu** > **Settings** > **Glucose** to display the **GLUCOSE SETTINGS** screen.



2. Next to **Predictive Alerts**, slide the **OFF** button right to **ON**.

3. Tap **Minutes** to select the amount of advance warning
   - Tap **Done** when complete.



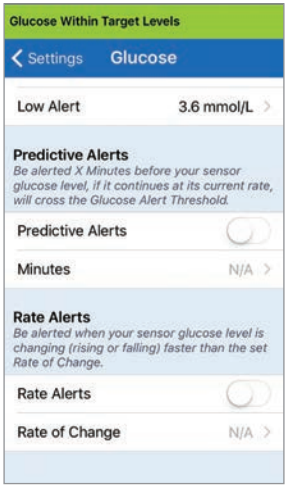


Setting Rate of Change Alerts

The Rate of Change Alerts let you know when your glucose level is falling or rising faster than the Rate Alert setting you choose.

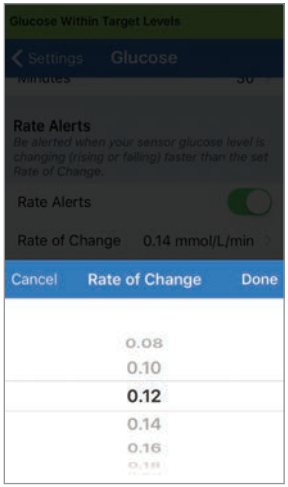
Default setting	OFF
Allowable setting	0.08 - 0.28 mmol/L per minute.
On/Off setting	You can turn this feature ON. No rate of change alerts will occur until this feature is turned ON.
Notes	Audio notification and visual alerts on your mobile device and transmitter vibration alerts.

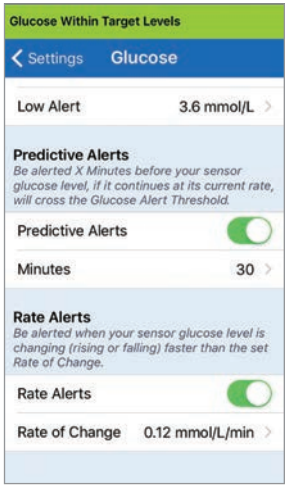
1. To turn this feature ON, tap **Menu** > **Settings** > **Glucose** to display the **GLUCOSE SETTINGS** screen.



2. Next to **Rate Alerts**, slide the **OFF** button right to **ON**.

3. Tap **Rate of Change** to select the rate.
   - Tap **Done** when complete.





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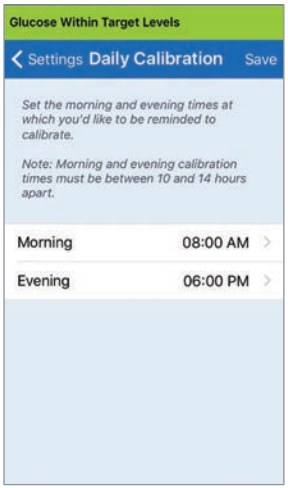
Setting Daily Calibration Times

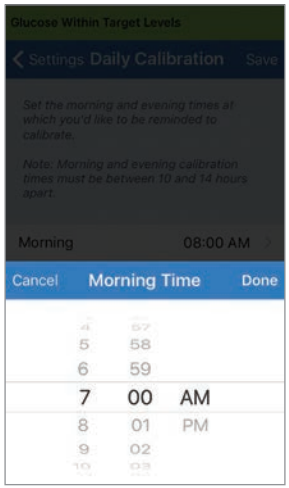
The morning and evening calibration times are set to remind you when to calibrate. You can calibrate up to 2 hours before your scheduled calibration time. Your morning and evening calibration times must be between 10 and 14 hours apart.

1. Tap **Menu** > **Settings** > **Daily Calibration**.

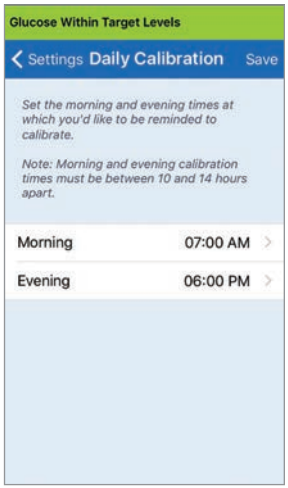


2. Tap **Morning** to set your morning calibration time.
   - Tap **Done** when complete.

3. Tap **Evening** to set your evening calibration time.
   - Tap **Done** when complete.



4. When both times are correct, tap **Save**.



Setting System Information

The **SYSTEM** screen lets you view and edit other settings in your Eversense CGM System.

1. Tap **Menu > Settings > System** to display the **SYSTEMS** screen.

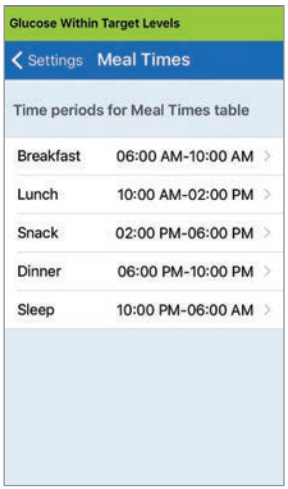
2. **On the SYSTEMS screen, you can tap each of the following to set:**
   - **Glucose Units.** The unit of measurement for your glucose readings. The app must be reinstalled to edit this setting.
   - **Name.** The serial number of your smart transmitter. You can also tap on the serial number displayed here and give your smart transmitter a custom name.
   - **Linked Sensor.** The serial number of the sensor currently linked with the smart transmitter. Tap this feature to access the ability to link or re-link a sensor.

Setting Mealtimes Schedule

The **MEAL TIMES** screen displays the time slots for your Breakfast, Lunch, Snack, Dinner and Sleep times. The time intervals set in the **MEAL TIMES** screen are used on the Reports graph view to indicate the high, low and average CGM values during each mealtime interval.

1. Tap **Menu** > **Settings** > **Meal Times** to display the **MEAL TIMES** screen.

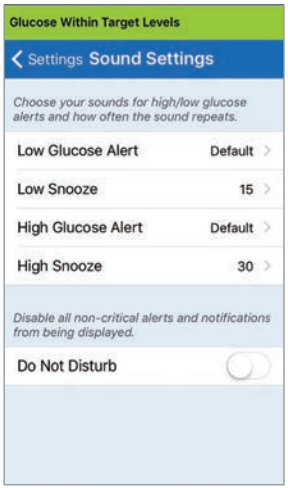
2. Tap each meal time listed, then tap **Start** and **End** to set a beginning and end mealtime.



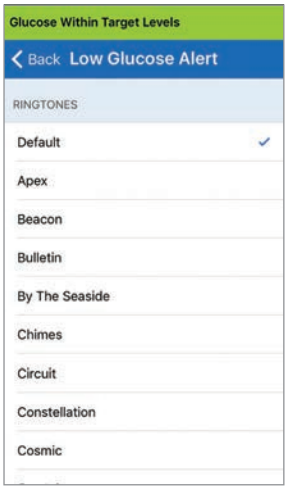
Setting Sounds

The **SOUND SETTINGS** screen displays the alert sound settings for Low Glucose and High Glucose. This screen also allows you to enter a snooze setting for the alerts listed.

1. Tap **Menu** > **Settings** > **Sound Settings** to display the **SOUND SETTINGS** screen.



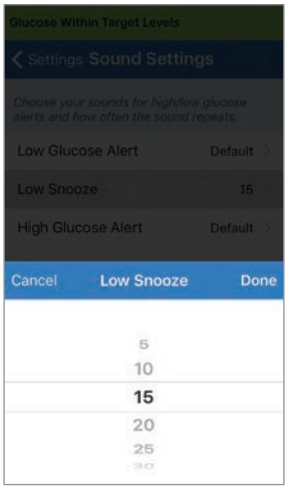
2. Tap each alert to select the alert sound. Tap **Back** to get back to the **SOUND SETTINGS** screen.



IMPORTANT: Be sure the sound on your mobile device is turned on. If you turn the sound on your mobile device off, you will not hear any sounds from the app.

By setting the snooze alert, you can set how often an alert repeats after you have received a Low Glucose and High Glucose alert.

3. **Tap each snooze alert to set how often the alert repeats.**
   Tap Done when complete.



The **SOUND SETTINGS** screen also allows you to enable and disable the Do Not Disturb mode.

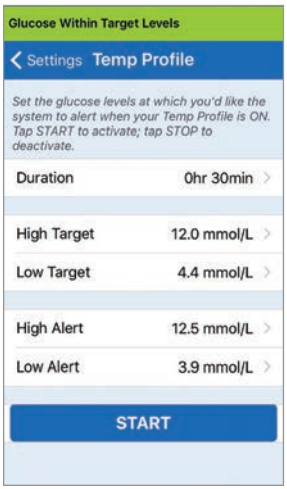
- **Do Not Disturb.** Places the smart transmitter in a "Do Not Disturb" mode.
- **OFF –** ALL notifications – alerts and notifications – regardless of critical nature will be provided by the smart transmitter and app.
- **ON –** ONLY critical alerts will be provided by the smart transmitter's on-body vibe alerts. All alerts will continue to be provided on the mobile app.

Note: When you enable Do Not Disturb mode on your mobile device you will not receive any alerts or notifications from the Eversense App. For a list of alerts, please see *Alert Descriptions.*

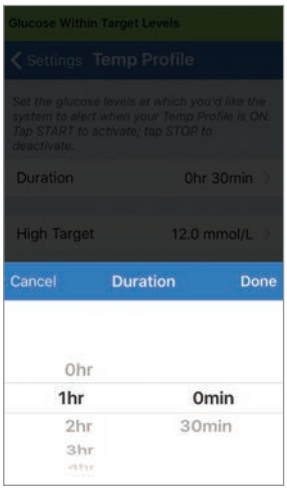
Setting Temporary Profile

During activities or conditions outside your normal routine, you may wish to temporarily use glucose settings that are different from the standard glucose settings you have entered. The **TEMP PROFILE** screen allows you to temporarily change glucose target and alert settings for the duration you choose. When the Temp Profile duration is over, the standard glucose settings you entered in **Settings** > **Glucose** will automatically resume.

1. Tap **Menu > Settings > Temp Profile** to display the **TEMP PROFILE** screen.



2. Select the duration. You can set a Temp Profile for up to 36 hours in 30 minute increments.



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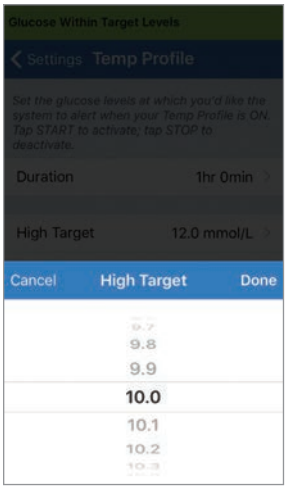
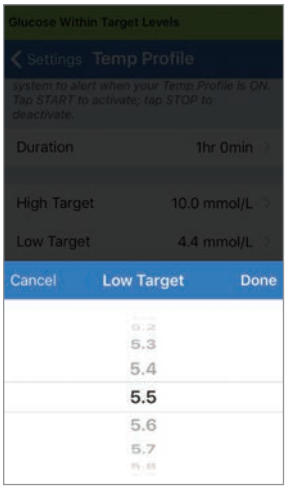
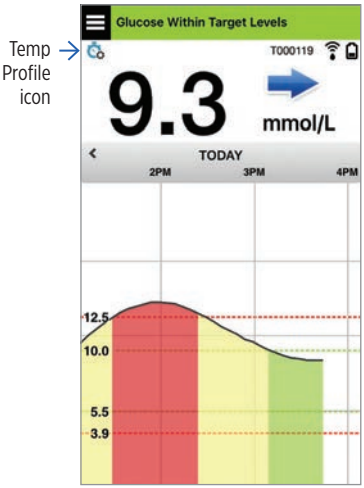
3. Set the High and Low Targets and High and Low Alert levels desired. Tap **START**.



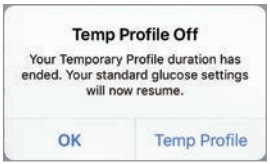


The Temp Profile selections cannot be changed when the duration has been started.

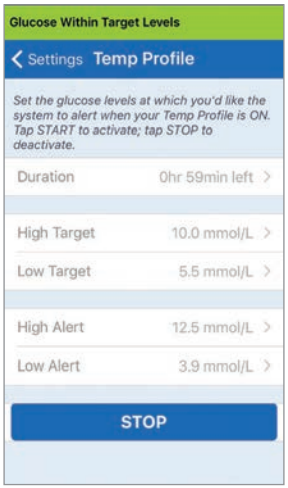
While a Temp Profile is active, the Temp Profile icon will be displayed on the **MY GLUCOSE** screen.



When the Temp Profile duration is finished, the app displays a notice and the Temp Profile icon is no longer displayed on the **MY GLUCOSE** screen.

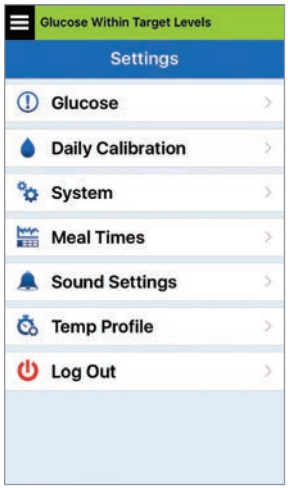


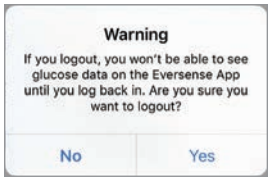
To end the Temp Profile earlier than the time you set, go to **Settings** > **Temp Profile** and tap **STOP**.



Logging out

To log out of your Eversense account, tap **Settings** > **Log Out**.





IMPORTANT: If you log out, no glucose data will be displayed on the app until you log back in using the email and password you entered when you set up your account for the first time.

9. Alert Descriptions

This section describes the various alerts and notification messages you may see on the Eversense App screens and actions you may need to take.

Your CGM System provides you with alerts and notifications related to glucose readings and system status on both your smart transmitter and mobile device. The smart transmitter provides on-body vibe alerts when an alert level has been reached. The mobile device app sounds an alert and displays messages on the **MY GLUCOSE** screen.

The table below describes the vibration patterns on the smart transmitter and the indicators on your app.

Alerts and Notifications	Smart Transmitter Vibration Pattern	App Alert Indicators
Alerts where no glucose values can be displayed Requires immediate and appropriate action.	3 long vibes	**MESSAGE APPEARS IN YELLOW**
Alerts related to Low readings Low Glucose Alert and Out-of-Range Low. Requires immediate and appropriate action.	3 short vibes x 3	**MESSAGE APPEARS IN YELLOW**
Alerts related to High readings High Glucose Alert and Out-of-Range High. Requires immediate and appropriate action.	1 long vibe then 2 short vibes	**MESSAGE APPEARS IN YELLOW**
Alerts related to less critical issues Requires some action but may not be as critical in nature. See following section for examples.	1 short vibe	**MESSAGE APPEARS IN YELLOW**
Notifications Requires some action but not critical in nature. See following section for examples.	1 short vibe	**MESSAGE APPEARS IN BLUE**

Alert History

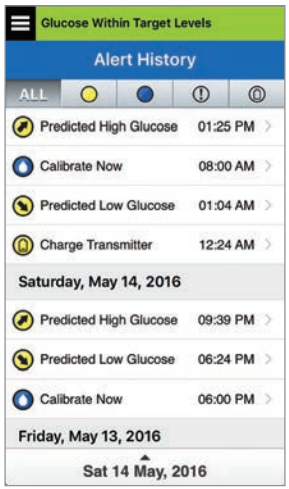
The **ALERT HISTORY** screen lists alerts and notifications you have received.

The following icons are used to indicate the severity level of messages.

- Alerts
- Notifications
- More than 1 Alert in Same Period
- Battery Alerts

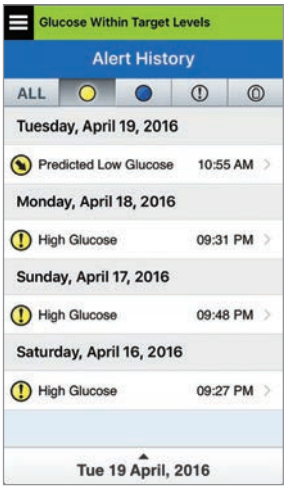
Note: When you receive 2 or more alerts that have not been acknowledged, the app will display an option to **Dismiss All**. This can happen when your mobile device has been out of range of your smart transmitter and then re-syncs. You can review each alert in **Alert History**.

1. **Tap Menu > Alert History.**
   - The **ALERT HISTORY** screen will list ALL alerts and notifications for that day.
   - Tap on any message to get more information.



Example of ALL

2. **You can choose to include only certain messages (alerts and notifications, etc.) for review by tapping selected alert icons.**
   - Tap **ALL**, then tap icons on top of the screen to select only the types of alerts you want displayed.
   - Tap **Menu** when done.



Example of alerts only

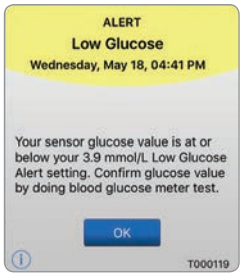
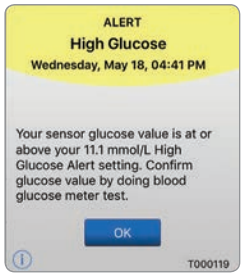
Alert Descriptions and Actions

The following table lists the alerts and notifications you may receive on the Eversense App.

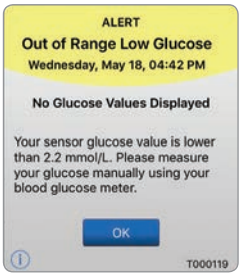
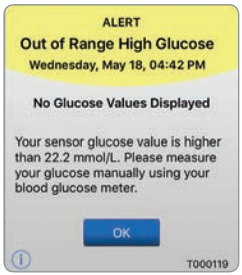
Note: For each message, you can also tap the information icon ⓘ to receive additional details about the message.

IMPORTANT: On-body vibe alerts for the alerts marked with a * cannot be turned off using DND in the app.

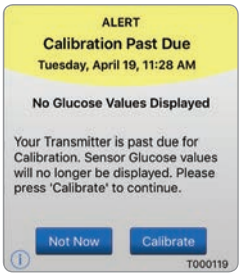
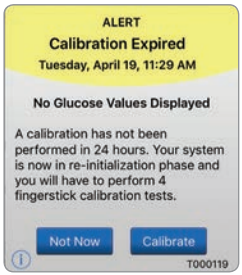
Alerts

App Display		
Description	**Low Glucose*** Appears at the interval you enter in sound settings when your sensor glucose reading is at or below the low glucose alert level you set. The default repeat interval is 15 minutes.	**High Glucose*** Appears at the interval you enter in sound settings when your sensor glucose reading is at or above the high glucose alert level you set. The default repeat interval is 30 minutes.
Actions	Pay close attention to your glucose values, symptoms, and trends. Confirm your glucose value with a blood glucose meter test before making a treatment decision.	Pay close attention to your glucose values, symptoms, and trends. Confirm your glucose value with a blood glucose meter test before making a treatment decision.

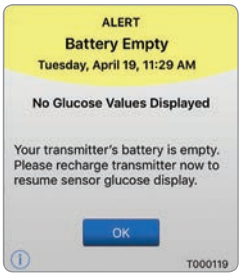
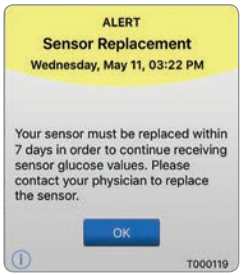
Alerts

App Display		
Description	**Out of Range Low Glucose*** Appears when your glucose reading is lower than 2.2 mmol/L. No glucose reading can be displayed (only **LO** is displayed on the **MY GLUCOSE** screen).	**Out of Range High Glucose*** Appears when your glucose value is higher than 22.2 mmol/L. No glucose reading can be displayed (only **HI** is displayed on the **MY GLUCOSE** screen).
Actions	Confirm your glucose value with a blood glucose meter test before making a treatment decision. Once the sensor glucose value is at or higher than 2.2 mmol/L, glucose readings will resume on the display.	Measure your glucose manually by using your blood glucose meter. Always confirm your glucose value with a blood glucose meter test before making a treatment decision. Once the sensor glucose value is at or lower than 22.2 mmol/L, glucose readings will resume on the display.

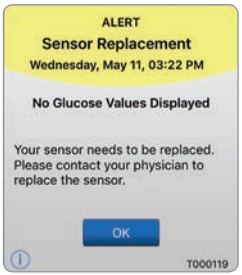
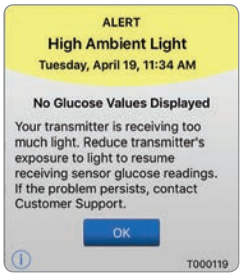
Alerts

App Display		
Description	**Calibration Past Due** Appears when your system is past due for calibration. No glucose readings can be displayed until calibration is performed.	**Calibration Expired** Appears when a calibration has not been performed in 24 hours. The system returns to the Initialization Phase. No glucose reading can be displayed until calibration is performed.
Actions	Perform a fingerstick calibration in order to resume displaying glucose values.	In the Initialization Phase, you must perform 4 fingerstick calibration tests spaced 2 - 12 hours apart. Display of glucose readings will resume after the 2nd successful fingerstick calibration test.

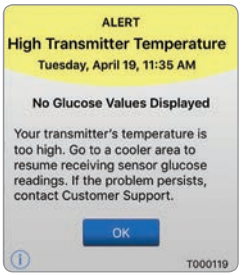
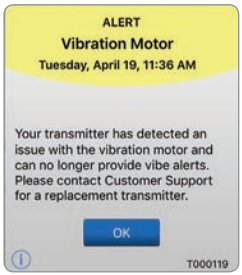
Alerts

App Display		
Description	**Battery Empty*** Appears once when your smart transmitter battery is empty and needs to be charged. No glucose reading can be displayed until the smart transmitter is charged.	**Sensor Replacement (7 days)** Appears when your sensor will stop collecting glucose data in 7 days.
Actions	Charge the smart transmitter immediately. Remove the smart transmitter from your body before connecting it to the power supply.	Contact your physician to schedule your sensor removal and insertion of new sensor.

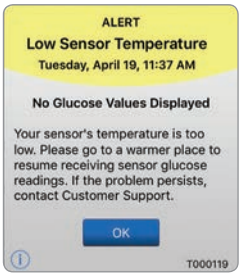
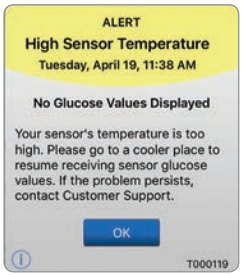
Alerts

App Display		
Description	**Sensor Replacement*** Appears once when your sensor needs to be replaced. No glucose reading can be displayed until the sensor is replaced.	**High Ambient Light** Appears every 20 minutes when your smart transmitter is receiving too much ambient light, affecting its ability to communicate with the sensor. No glucose reading can be displayed until ambient light is reduced.
Actions	Contact your physician to have your sensor replaced.	Reduce ambient light by doing one or more of the following: • Move to an area where there is less light exposure. • Place a dark material over the smart transmitter. • Wear the smart transmitter under clothing.

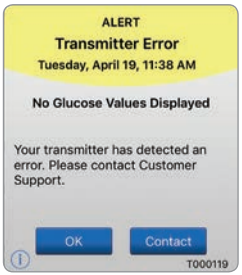
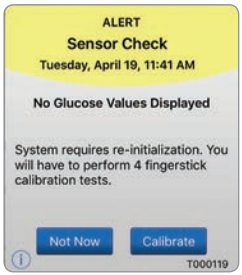
Alerts

App Display		
Description	**High Smart Transmitter Temperature*** Appears every 20 minutes when your smart transmitter temperature is too high. No glucose reading is displayed until the smart transmitter temperature is within normal operating conditions.	**Vibration Motor** Appears every 20 minutes when the vibration motor on your smart transmitter can no longer provide on-body vibe alerts. You will continue to get glucose readings up to 72 hours after receiving the alert message. After 72 hours, you will receive a Transmitter Error Alert every 20 minutes until you replace the smart transmitter.
Actions	Reduce the smart transmitter temperature by moving to a cooler environment. Once the smart transmitter temperature is below 42 °C (108 °F), it will resume displaying glucose values. You may temporarily remove the smart transmitter to cool it down. Once the smart transmitter is back to a lower temperature, be sure to replace it over the sensor.	Contact Customer Support to have your smart transmitter replaced immediately.

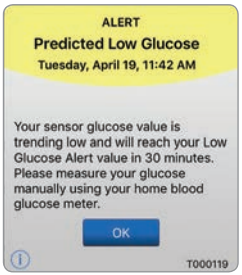
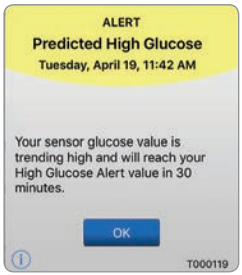
Alerts

App Display		
Description	**Low Sensor Temperature*** Appears every 20 minutes when the sensor temperature is too low. No glucose reading is displayed until the sensor temperature is within normal operating conditions.	**High Sensor Temperature*** Appears every 20 minutes when the sensor temperature is too high. No glucose reading is displayed until the sensor temperature is within normal operating conditions.
Actions	Go to a warmer environment to increase the sensor temperature. Keep your smart transmitter turned on so you will start receiving glucose values when the sensor temperature is between 26 - 40 °C (81 - 104 °F).	Go to a cooler environment to reduce the sensor temperature. Briefly remove the smart transmitter while the sensor temperature cools to between 26 - 40° C (81 - 104 °F). Then put the smart transmitter back on to start receiving glucose values again from the sensor.

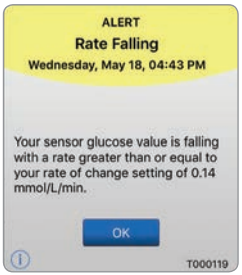
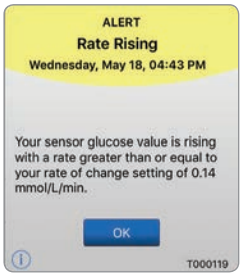
Alerts

App Display		
Description	**Smart Transmitter Error*** Appears when the system's internal checks detect a smart transmitter error. No glucose reading is displayed until the error is corrected.	**Sensor Check** Appears once when the system's internal checks detect instability with the sensor which requires a return to calibration Initialization Phase.
Actions	Follow the steps shown in the Troubleshooting section to reset your smart transmitter. If you are unable to complete the reset, contact Customer Support.	In the Initialization Phase, you must perform 4 fingerstick calibration tests spaced 2 - 12 hours apart. Display of glucose readings will resume after the 2nd successful fingerstick calibration test.

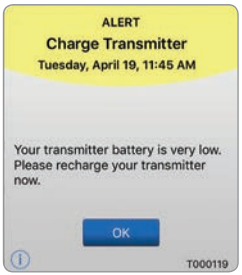
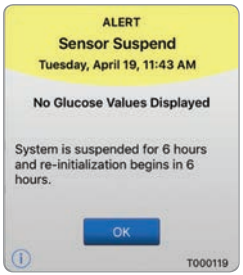
Alerts

App Display		
Description	**Predicted Low Glucose** Appears every 60 minutes when your glucose values are trending low and will reach your Low Glucose Alert level within the time you entered in Settings.	**Predicted High Glucose** Appears every 60 minutes when your glucose values are trending high and will reach your High Glucose Alert level within the time you entered in Settings.
Actions	Pay close attention to your glucose values, symptoms, and trends. Confirm your glucose value with a blood glucose meter test before making a treatment decision.	Pay close attention to your glucose values, symptoms, and trends. Confirm your glucose value with a blood glucose meter test before making a treatment decision.

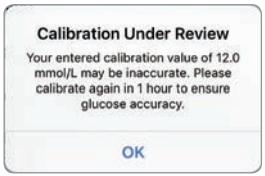
Alerts

App Display		
Description	**Rate Falling** Appears every 60 minutes when your glucose values are falling at a rate equal to or faster than the rate of change you entered in Settings.	**Rate Rising** Appears every 60 minutes when your glucose value is rising at a rate equal to or faster than the rate of change you entered in Settings.
Actions	Pay close attention to your glucose values, symptoms, and trends. Confirm your glucose value with a blood glucose meter test before making a treatment decision.	Pay close attention to your glucose values, symptoms and trends. Confirm your glucose value with a blood glucose meter test before making a treatment decision.

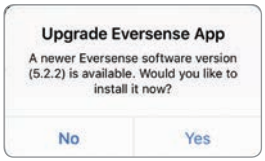
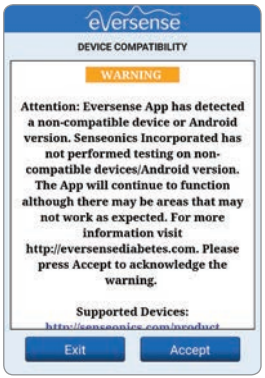
Alerts

App Display		
Description	**Charge Smart Transmitter** Appears when smart transmitter battery power is very low and you need to charge your battery very soon.	**Sensor Suspend** Appears when the system's internal checks detect a need to restart the Initialization Phase for additional calibrations. Glucose values will be displayed a few minutes after the second successful calibration during the Initialization Phase.
Actions	Charge your smart transmitter as soon as possible.	Re-initialization of the system begins in 6 hours.

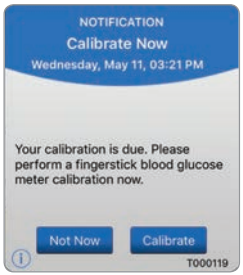
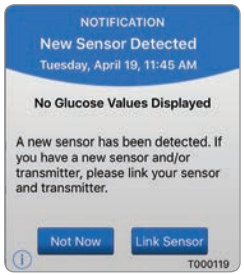
Alerts

App Display		
Description	**Calibration Under Review** Appears when your calibration value is significantly different from your sensor glucose value.	**Incompatible Firmware Version** Appears when the firmware in your smart transmitter is incompatible with the Eversense mobile app version on your mobile device.
Actions	Re-calibrate when prompted.	Contact Customer Support.

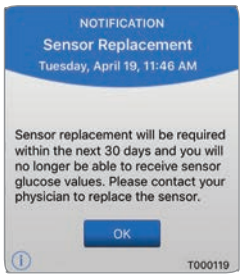
Alerts

App Display		
Description	**Upgrade Eversense App** Appears when a newer version of the Eversense App is available to download.	**Incompatible Device/Operating System** Appears when an incompatible device/operating system is being used with the app.
Actions	Tap **Yes** to install the update.	For a list of compatible devices/operating systems visit eversensediabetes.com.

Notifications

App Display		
Description	**Calibrate Now** Appears when it is time for you to calibrate.	**New Sensor Detected** Appears when the smart transmitter detects a new sensor. The inserted sensor and the smart transmitter must be linked to begin communication.
Actions	Do a fingerstick blood glucose test and enter the reading as your calibration value. DO NOT use an alternative site (such as forearm) to obtain your blood glucose reading.	Tap **Link Sensor** to complete the linking process and begin the 24-hour Warm-Up Phase. You do not need to wear your smart transmitter over the sensor until the Warm-Up Phase is complete.

Notifications

App Display	
Description	**Sensor Replacement** Appears 30, 14, 7, 3, 2, and 1 day before your sensor has completed its 90-day wear period as a reminder to replace your sensor.
Actions	Contact your physician to schedule the removal and replacement of your sensor.

10. Event Log

This section describes how to review and log events to help better track glucose patterns.

The Eversense CGM System allows you to log and track events in addition to continually monitoring glucose levels. You can manually enter events that will appear on the trend graph and glucose reports to help you find patterns in your glucose profile.

10

Types of Events:

- Glucose
- Meals
- Insulin
- Health
- Exercise

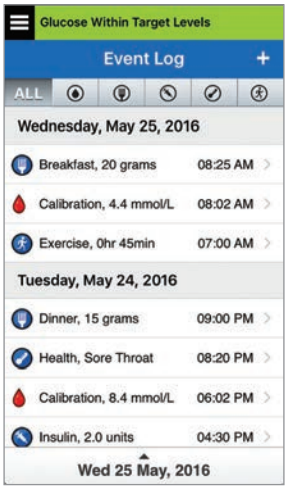
Note: You can also access the **ADD EVENT** screen directly from the **MY GLUCOSE** screen with a single tap anywhere on the graph area.

View Events

You can view past events entered from the **EVENT LOG** screen.

1. **Tap Menu > Event Log.**
   The **EVENT LOG** screen will appear.

2. **All your entered events will be listed.**
   You can also select specific event types to view by tapping a selected event type.
   - Tap **ALL**, then tap icons on top of the screen to select only the types of events you want displayed.



Log Specific Events

Glucose

Enter and track blood glucose meter tests (test results other than calibrations).

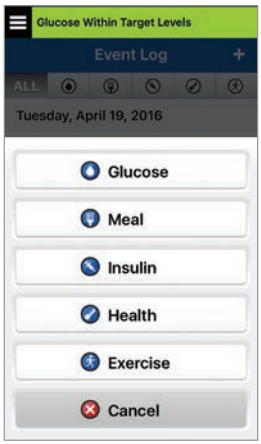
1. Tap **Menu > Event Log.**

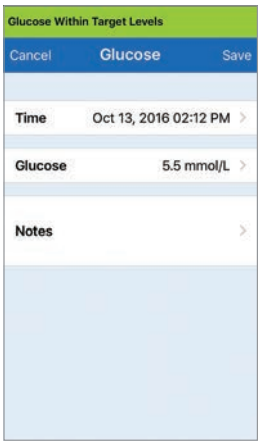
2. Add an event using the event icon "**+**" > **Glucose.**

3. Tap **Time** to enter the correct date and time.
   Tap **Done.**

4. Tap **Glucose** to enter the correct blood glucose value.
   Tap **Done.**

   Note: You can enter a BG value between 1.1 and 33.3 mmol/L. Entries < 1.1 mmol/L will be converted to 1.1, and entries above 33.3 mmol/L will be converted to 33.3 for calculation and display purposes.

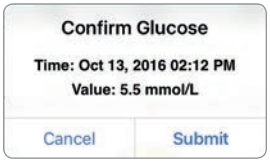




5. Tap **Save**.

6. On the Confirm Glucose pop up box, tap **Submit** to confirm the glucose event and return to the **EVENT LOG** screen, or tap **Cancel** to exit without saving changes or to edit the information before saving.

   Note: Glucose Events do not replace calibration measurements. You will still have to enter calibration readings.



Meals

Enter the type of meal, date and time and carbohydrate count.

1. Tap **Menu** > **Event Log**.

2. Add an event using the event icon "**+**" > **Meals**.

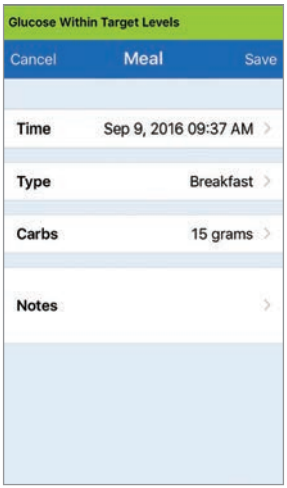
3. Tap **Time** to enter the correct date and time.
   Tap **Done**.

4. Tap **Type** to enter the type of meal.
   Tap **Done**.

5. Tap **Carbs** to enter correct number of carbohydrates.
   Tap **Done**.

6. Tap **Notes** to enter any notes.
   Tap **Done**.

7. Tap **Save** to save entry and return to **EVENT LOG** screen. Tap **Cancel** to exit without saving changes.



Insulin

Enter the units of insulin according to Time and Insulin type.

1. Tap **Menu** > **Event Log**.

2. Add an event using the event icon "**+**" > **Insulin**.

3. Tap **Time** to enter the correct date and time.
   Tap **Done**.

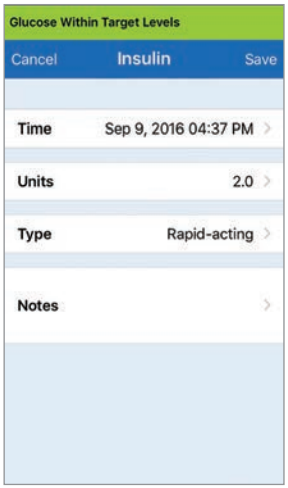
4. Tap **Units** to enter the correct number of Units.
   Tap **Done**.

   Note: The maximum insulin units that can be entered is 200U.

5. Tap **Type** to enter the correct Type of Insulin.
   Tap **Done**.

6. Tap **Notes** to enter any notes.
   Tap **Done**.

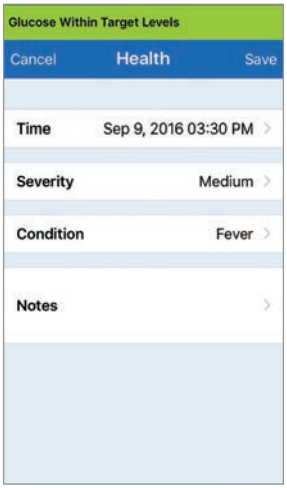
7. Tap **Save** to save entry and return to **EVENT LOG** screen. Tap **Cancel** to exit without saving changes.



Health

Enter the type of health condition, severity, and date and time.

1. Tap **Menu** > **Event Log**.
2. Add an event using the event icon "**+**" > **Health**.
3. Tap **Time** to enter the correct date and time.
   Tap **Done**.
4. Tap **Severity** to enter Low, Medium or High.
   Tap **Done**.
5. Tap **Condition** to enter the health condition.
   Tap **Done**.
6. Tap **Notes** to enter any notes.
   Tap **Done**.
7. Tap **Save** to save entry and return to **EVENT LOG** screen. Tap **Cancel** to exit without saving changes.



Exercise

Enter exercise type, duration, and intensity.

1. Tap **Menu** > **Event Log**.

2. Add an event using the event icon "**+**" > **Exercise**.

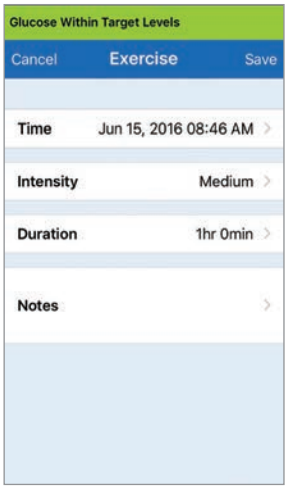
3. Tap **Time** to enter the correct date and time.
   Tap **Done**.

4. Tap **Intensity** to enter Low, Medium or High.
   Tap **Done**.

5. Tap **Duration** to enter the duration.
   Tap **Done**.

6. Tap **Notes** to enter any notes.
   Tap **Done**.

7. Tap **Save** to save entry and return to **EVENT LOG** screen. Tap **Cancel** to exit without saving changes.



II. Reports

This section describes the different glucose reports available for a summary of your glucose profile. You may choose specific dates or select pre-selected time ranges.

Types of reports

- Weekly Modal Summary.
- Glucose Pie Chart.
- Glucose Statistics.

Note: Be sure to set the mobile device date and time correctly. The accuracy of the graphs and reports depends upon the date and time being correct.

11

To view the glucose reports tap **Menu** > **Reports** and swipe to move across the three different reports. You can also email each report as a pdf file by tapping the email icon in the top right hand corner.

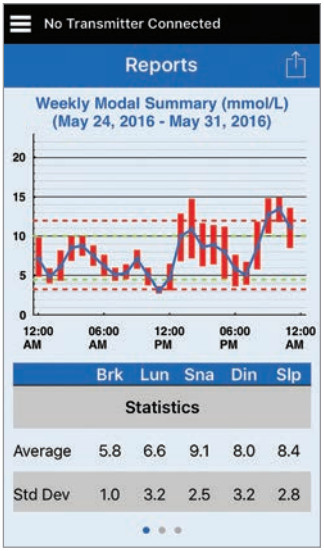
Weekly Modal Summary

This report shows your last seven days of glucose readings summarized in a 24-hour line graph format to help find patterns during the day.

- The **blue line** is the average of the last seven days of your readings in an hour time block.
- The **red bars** show the highest and lowest actual readings in the same hour time block.
- The **red horizontal dotted lines** are your pre-set High and Low Glucose Alert levels.
- The **green horizontal dotted lines** are your pre-set High and Low Glucose Target levels.

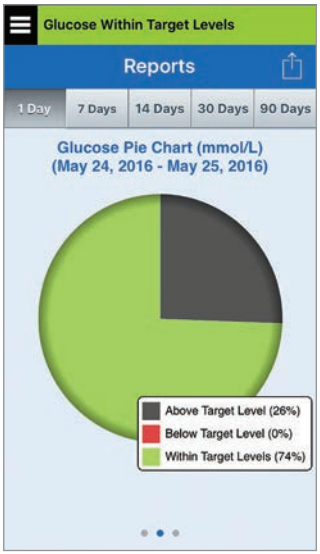
This report also provides summary statistics (average readings, standard deviation of readings), glucose target performance (percent within, above and below glucose target levels), and glucose reading highs and lows (percent of readings that fall within the low and high glucose target levels). The information is shown based on mealtime slots.

Note: To review or change the mealtime slots, please see *Setting Mealtimes Schedule*.



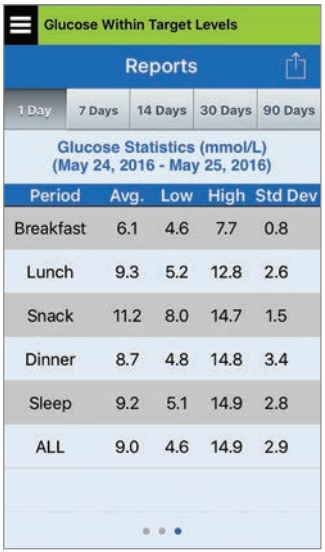
Glucose Pie Chart

This report shows in graphical format what percent of your readings within a given time period are within, below or above your Glucose Target levels. You can choose the last 1, 7, 14, 30 or 90 days.



Glucose Statistics

This report shows your average, low and high glucose readings, along with standard deviation within a mealtime slot period. You can choose the last 1, 7, 14, 30 or 90 days.



12. Share My Data

Eversense Data Management Software (DMS) Program

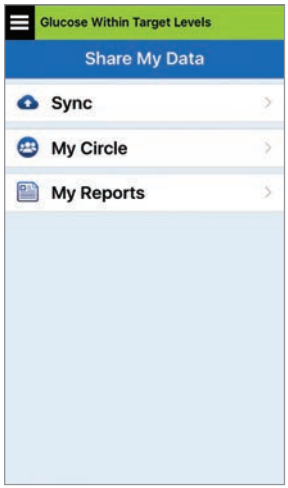
The Eversense DMS Program is a web-based application that enables patients, caregivers, and health care professionals to view and analyze glucose data that has been transmitted from the Eversense Smart Transmitter or the Eversense CGM System mobile app.

This program is offered at no cost to users of the Eversense CGM System. To learn about the Eversense DMS Program, go to www.eversensediabetes.com. When you create and register your account during the installation of the Eversense mobile app, an Eversense DMS account is automatically created for you.

IMPORTANT: THE EVERSENSE DATA MANAGEMENT SYSTEM DOES NOT PROVIDE MEDICAL ADVICE. CHANGES TO YOUR TREATMENT PLAN SHOULD ONLY BE MADE BY YOUR HEALTH CARE TEAM.

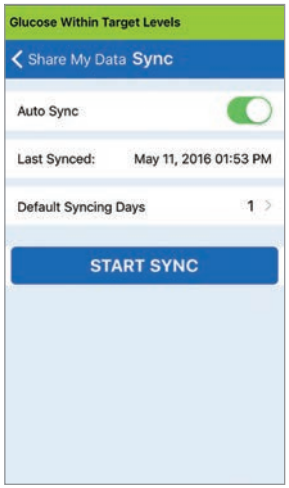
Sync

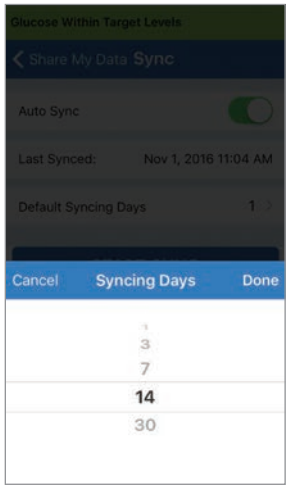
As long as you have an internet connection, Auto Sync is turned on, and you are logged into the app, your glucose readings sync to your Eversense DMS account about every 5 minutes. You can turn off Auto Sync.



To turn off Auto Sync, tap **Sync** on the **SHARE MY DATA** screen. Tap the Auto Sync button to off.

To manually sync your data, tap the Start Sync button. Data for the number of days set as your default will be synced. You can set the Default Syncing Days to 1, 3, 7, 14 or 30 days.





IMPORTANT: If you turn off Auto Sync, your data will not be sent to anyone using the Eversense Now App to remotely monitor your glucose data, and your historical glucose data will not be stored in your DMS account.

My Circle

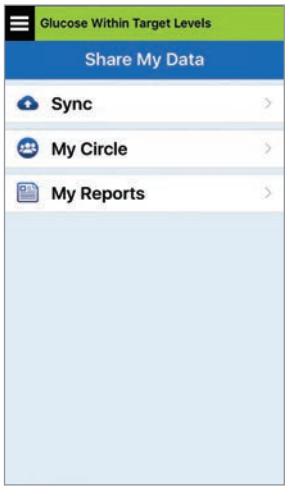
My Circle is an optional feature that allows you to activate remote monitoring of your Eversense CGM data. For more information on this feature, see *My Circle - Remote Monitoring*.

My Reports

You may also choose to export your glucose readings in a CSV-file format.

Tap **Menu** > **Share My Data** > **My Reports**

- Select the number of days of your glucose readings you want to export then tap **Done**.
- Tap **Export**.
- Email the CSV-file format by tapping the email icon on the top right hand corner.

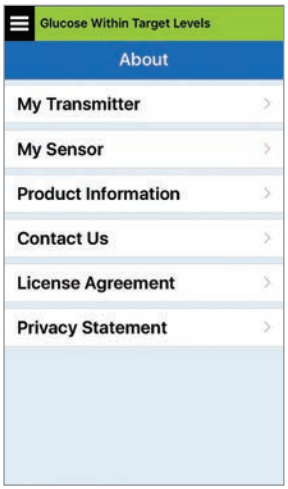


13. Product and General Information on the App

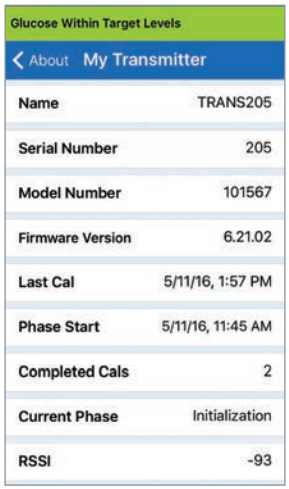
This section describes the information available from the About section of the Main Menu.

You can view product information about your smart transmitter, your sensor and your Eversense mobile app.

1. Tap **Menu** > **About** and then tap **My Transmitter**, **My Sensor** or **Product Information**.



On the **MY TRANSMITTER** screen, you can find information that includes the serial number, calibration information and battery level.

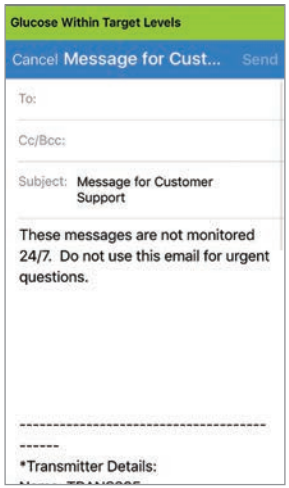


On the **MY SENSOR** screen, you can view the sensor serial number and insertion details.

On the **PRODUCT INFORMATION** screen, you can view information about the mobile app software version and Senseonics, Inc., the manufacturer of the Eversense CGM System.

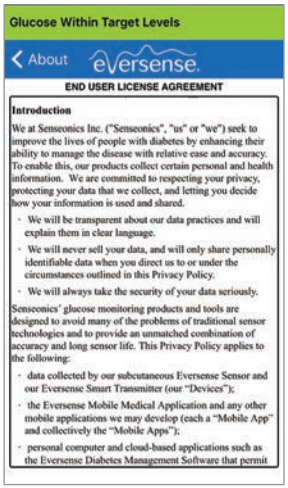
You can also send feedback or view the End User License Agreement and Privacy Policy from the About menu.

- Tap **Contact Us** to send an email to Senseonics, Inc.



IMPORTANT: This email is not monitored 24/7. **DO NOT** use this email for health-related or any urgent issues.

To read the End User License Agreement and the Privacy Policy, tap either option.



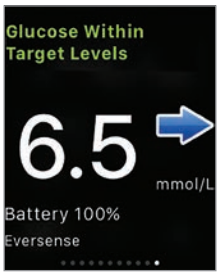
14. Viewing Eversense Data on the Apple Watch

You can view a snapshot of your Eversense CGM data on your Apple Watch. Once you've downloaded and installed the Eversense mobile app on your mobile device, follow the Apple Watch instructions for adding the app to your watch.

Glance View

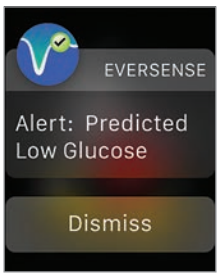
If your Apple Watch operating system supports the Glance view, and you have already set the Eversense App on your mobile device to *Show in Glances* under the Apple Watch settings, simply swipe up on the watch **HOME** screen to display the Eversense App Glance View.

Status bar information, your current glucose value with trend arrow, and the battery life remaining in your smart transmitter appear.



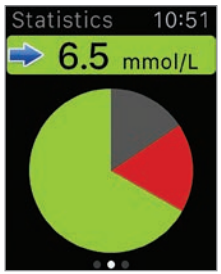
To access additional app features, tap the **Eversense** icon on your watch **HOME** screen to open the app.

You can also access the **MY GLUCOSE** screen if you turn on notifications from Eversense in your Apple Watch settings. When you receive a notification, you can also tap on the message to see the **MY GLUCOSE** screen.

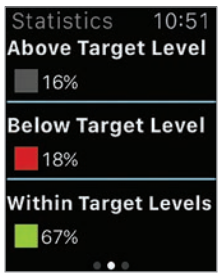


The **My Glucose** screen shows your current glucose with trend arrow, and a trend graph of your last three hours of CGM data.

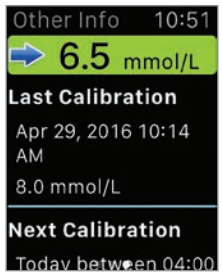
Swipe left to the next screen showing a pie chart of your total time within and outside your target range for the past 24 hours.



Swipe up to display the same data shown as percentages.



Swipe left to the next screen showing your current glucose with trend arrow, your next scheduled calibration time, and the current system calibration phase.



15. My Circle

Remote Monitoring with Eversense CGM System and Eversense Now App

The Eversense CGM App includes an optional remote monitoring feature. The Eversense CGM App interacts with the Eversense Now Remote Glucose Monitoring App to allow other people to view your data.

Note: The Eversense Now Remote Monitoring App is only available for iOS. If you invite a member to your Circle who does not use an iOS mobile device, they will not be able to use the Eversense Now App to view your glucose data.

Risks

There may be times when glucose data cannot be sent to the Eversense Now App. If a member of your Circle is not receiving glucose data from your Eversense CGM System, they cannot assist you in the event of a high or low glucose value. The secondary display and notifications on the Eversense NOW mobile app are not a replacement for the primary display on your Eversense CGM System mobile app.

Members of your Circle may not always have a connection to support data transfer such as internet/wifi or 3G/4G/LTE. If you or a member of your Circle does not have an internet connection, your glucose data will not be available for viewing on a secondary display. Any problems with mobile devices, wireless internet, data connection, the Eversense Data Management System (DMS) System, having your smart transmitter out of range of your mobile device, or charging your smart transmitter may prevent data from being displayed to members of your Circle. You should not rely on people remotely monitoring your glucose data to assist you in the event of a high or low glucose event.

The remote monitoring feature provides a secondary display of notifications and data to those in your Circle. It is not a real-time remote monitoring system.

Benefits

The Eversense CGM System used with the Eversense Now Remote Monitoring App may provide CGM users with additional confidence, knowing that others can also view their CGM data.

Warnings

- Glucose information displayed on the Eversense Now App should not be used to make treatment decisions. Always use blood glucose values from your meter to make treatment decisions. Using a sensor glucose value to make a treatment decision could result in a high or low blood glucose. The Eversense Now App is a secondary display of Eversense CGM data and should not be used in place of the primary Eversense CGM display.
- You should not rely on those who are remotely monitoring your glucose to notify you about high or low glucose events.

Cautions

- The Eversense Now Remote Mobile App does not replace the monitoring regimen as directed by your health care provider.
- If you do not have Auto Sync (the feature that enables data to automatically be sent to your Eversense Now app) turned on, you cannot share data with those in your Circle and they will not see high or low glucose trends and events.
- If you and the members of your Circle do not have an internet connection, or the mobile device has shut down due low or empty battery, your Eversense CGM data cannot be displayed on the Eversense Now App.
- If the members of your Circle turn off the sounds on their mobile device, they will not receive audible alerts about your CGM data on their Eversense Now App.
- If you set your status to offline with any of the members of your Circle, they will not receive any of your CGM data on their Eversense Now App. DO NOT set your status to offline if you want members of your Circle to see your CGM data.
- The Eversense Now app does not communicate directly with the Eversense Sensor and/or with the Eversense Smart Transmitter.
- The Eversense Now app cannot change the settings on the Eversense CGM App.
- If you do not Allow notifications from the Eversense Now app, you will not receive glucose related alerts from Eversense CGM users.

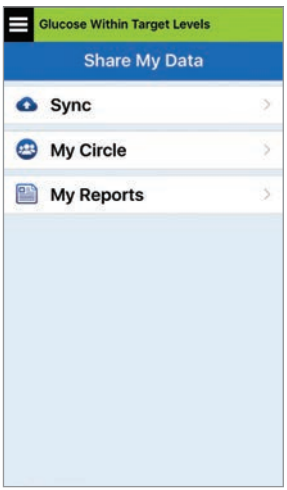
Through the **MY CIRCLE** screen on your Eversense mobile app, you can invite up to five people to view your data. When you invite someone to join your Circle, an invitation will be sent to the email address you entered. Once the invitation is accepted, and the Eversense Now App is downloaded, members of your Circle can view your recent glucose data, events and alerts.

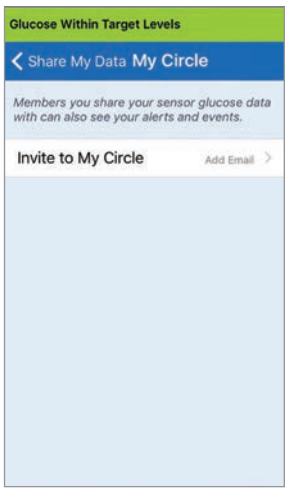
IMPORTANT: Members of your Circle who do not have the Eversense Now App will not be able to see your data.

As long as your Eversense CGM System App and the Eversense Now App have an internet connection, your glucose data is synced to the Eversense Now App approximately every 5 minutes. Calibration values may take longer to sync to the Eversense Now App.

Note: If you have turned off Auto Sync, your glucose data will NOT be available on the Eversense Now Remote Monitoring App.

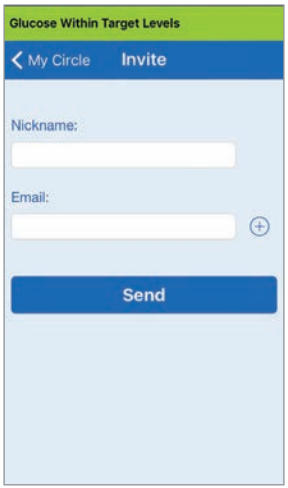
1. From the Main Menu, tap **Share My Data** > **My Circle** to display the **MY CIRCLE** screen.
2. To invite a new member to view your glucose data, tap **Invite to My Circle**.





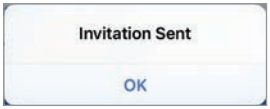
3. **Enter the email for the person you would like to invite to your Circle, and tap Send when complete.**

Note: You can tap the "**+**" next to the email field to select an email address from your Contact list.

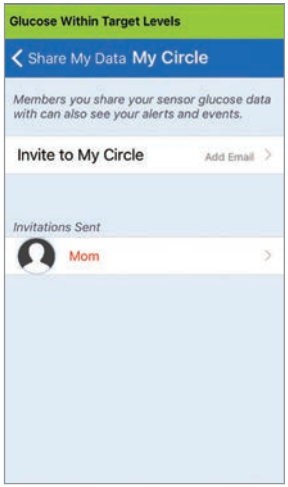


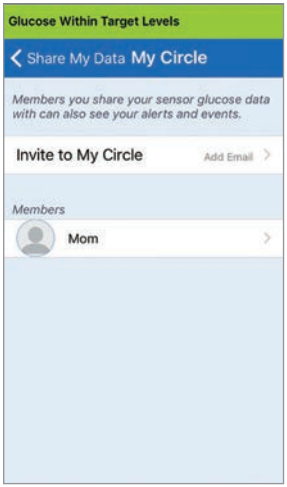
Tip: Nicknames are optional, and are used to help you easily manage your Circle Members. If you choose not to give a nickname to a Circle Member, their email address will show in place of a nickname.

4. **An Invitation Sent screen appears. Tap OK.**



When the invitation has been accepted, the member's name will appear in your Members List on the **MY CIRCLE** screen in your app.

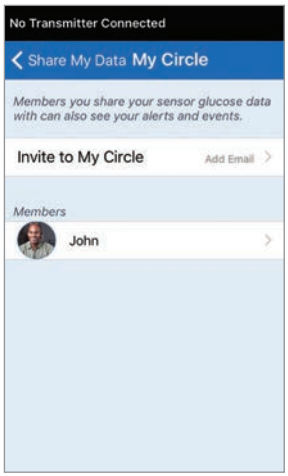




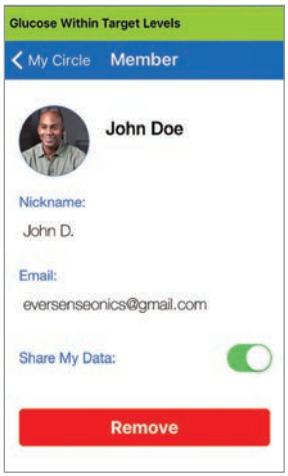
Note: Profile pictures of those remotely viewing your glucose data are set up in the DMS account by the account owner. You cannot change profile pictures of those you have invited to your Circle.

Remove a Member from Your Circle

1. To remove a member or an invitation, tap the person's name in the Members List or the Invitations Sent List on the **MY CIRCLE** screen.



2. Tap **Remove** to remove the member from your circle. Tap **Yes** when prompted.

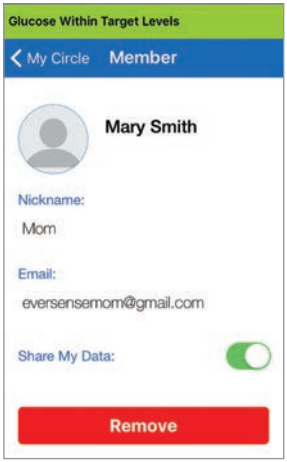


The member you remove will be notified on their Eversense Now App if they have already accepted.

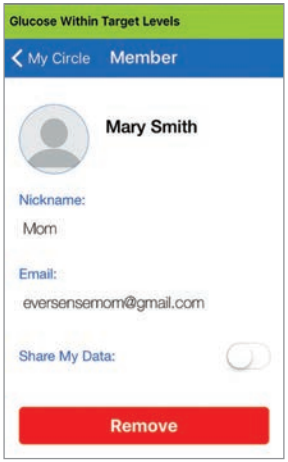
Temporarily Stop Sharing Data

There may be times when you wish to temporarily stop sharing data with a member, but not remove them from your Circle.

1. Tap the member's name in the My Circle list to open the **MEMBER** screen.



2. Tap the **Share My Data** button to turn on/off data share with this member.



IMPORTANT: If you have disabled the Share My Data feature for a member, that member will not see any of your Eversense CGM System glucose data, alerts or event history. Members will see your status as Offline on their Eversense Now App when you have disabled the Share my Data feature. It can take up to 10 minutes for the change to display on the Eversense Now user's app.

Note: The Eversense Now user can also remove you from their app. It can take up to 2 hours for these changes to display on your Eversense CGM App.

For more information about the Eversense Now App, please visit eversensediabetes.com or contact your local distributor.

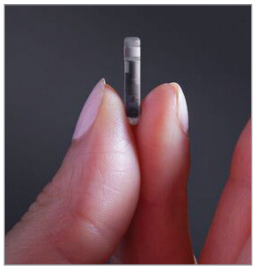
16. About the Sensor

This section describes the Eversense Sensor and how it is inserted by your physician.

The Eversense Sensor is a miniaturized fluorometer that uses fluorescent intensity to measure glucose in interstitial fluid. The sensor is implanted subcutaneously (under the skin) on the upper arm, leaving no part of the sensor protruding from the skin. The sensor remains in place and provides CGM measurements for up to 90 days.

The sensor is encased in a biocompatible material and utilizes a unique fluorescent, glucose indicating polymer. A light emitting diode embedded in the sensor excites the polymer, and the polymer then rapidly signals changes in glucose concentration via a change in light output. The measurement is then relayed to the smart transmitter. Measurements are completed automatically and require no action by the user.

The sensor is approximately 3.5 mm x 18.3 mm and has a silicone ring that contains a small amount of dexamethasone acetate, an anti-inflammatory steroid drug. The dexamethasone acetate minimizes inflammatory responses, very similar to common medical devices, such as pacemakers.



Eversense Sensor

Insertion Steps

Your physician will explain and perform the simple and quick steps to insert the sensor. You will be fully awake during the approximately 5-minute insertion procedure.

Insertion site:

It is important to choose a site that is comfortable for you to wear the sensor and smart transmitter for the entire 90 day period. It is recommended to have the sensor inserted toward the back of the upper arm. Placement in this area minimizes the chance of the sensor and smart transmitter being bumped by doorways, walls or other narrow passages. If possible, avoid areas with loose skin, scars, tattoos, nevus, or blood vessels that could be incised during the procedure.

Step 1: **Site preparation –** the insertion site will be cleaned, disinfected, then anesthetized using lidocaine.

Step 2: **Incision –** a small (less than 1 centimeter) incision will be made at the insertion site.

Step 3: **Sensor insertion –** a subcutaneous pocket will be created under the skin and the sensor will be inserted in this pocket.

Step 4: **Site closure –** the incision will be closed with an adhesive bandage. Sutures are not usually required.

Step 5: **Sensor and smart transmitter linking –** link the sensor and smart transmitter to begin the 24-hour Warm-Up Phase.

Note: **After insertion, link the smart transmitter and the sensor and then allow the incision site to heal 24 hours before replacing the transmitter**.

The sensor requires 24 hours to stabilize within the insertion site, this period is known as the Warm-up Phase. After the first 24 hours of sensor insertion, position and secure the smart transmitter over the sensor and ensure you have a connection. (See *Secure the Smart Transmitter over Inserted Sensor*.) Then you can perform your Initialization Phase calibration of 4 fingerstick blood glucose tests to start getting glucose readings.

Removal Steps

Similarly to the insertion steps, your physician will explain the simple and quick steps for the sensor removal and you will be fully awake during the 5-minute (approximate) removal process.

Step 1: **Site preparation –** the sensor site will be cleaned, disinfected, then anesthetized using lidocaine.

Step 2: **Incision –** a small (less than 1 centimeter) incision will be made at the sensor site.

Step 3: **Sensor removal –** the sensor will be removed and discarded.

Step 4: **Site closure –** once removed, the incision will be closed with a steri-strip (sutures may be used depending on provider's preference).

17. Travel

This section describes the safety issues when traveling with your Eversense smart transmitter and sensor.

When traveling, your smart transmitter and sensor are safe to go through airport security without removing them. You may inform security that you have an implanted medical device.

Your smart transmitter will automatically sync to your smartphone's current time and date when time zones are changed.

The Eversense CGM System is safe for use on U.S. commercial airlines. The Eversense Smart Transmitter is a Medical Portable Electronic Device (M-PED) with emission levels that meet FAA mandates for use in all modes while in flight. (Reference FAA Advisory, Circular #21-16G, dated 6.22.2011.) To use, turn your mobile device's Bluetooth feature on after you have put your mobile device in airplane mode. For flights outside the US, follow local security regulations for use of medical devices in flight.

IMPORTANT: When traveling to different time zones, check your calibration reminder settings to ensure the times are convenient for you in the local time zone.

18. Troubleshooting

This section lists information about troubleshooting your Eversense CGM System and includes a list of frequently asked questions (FAQs).

Smart Transmitter

Q: How do I turn my smart transmitter OFF?

A: Press and hold the smart transmitter power button for 5 seconds. Release the button when the smart transmitter begins to vibrate.

Q: How do I turn my smart transmitter ON?

A: Press and hold the smart transmitter power button for 5 seconds. Release the button when the smart transmitter begins to vibrate.

Q: How do I properly position the smart transmitter over the sensor?

A: There are two ways to ensure proper positioning:

1. When using the adhesive patch to secure the smart transmitter, make sure the power button symbol and the LED are lined up in parallel with your arm.
2. Use the **PLACEMENT GUIDE** screen on the app to confirm connection between the sensor and the transmitter.
   - Tap **Placement Guide**.
   - Position the smart transmitter over the sensor so that a connection is confirmed.

Q: My smart transmitter will not vibrate. Why?

A: If the smart transmitter does not vibrate, try the following steps:

- Check that the smart transmitter is connected to your mobile device.
- Check that the **Do Not Disturb** is disabled by tapping **Menu** > **Settings** > **Sound Settings**.
- Check that your smart transmitter has enough battery power and charge if necessary.

If the smart transmitter still will not vibrate, contact Customer Support or your local distributor for further troubleshooting.

Q: Can I use the same adhesive patch more than once a day?

A: The individual adhesive patch is intended to be used for a 24-hour period.

Q: What is the serial number and model number of my smart transmitter?

A: You can find the serial number and model on the back of your smart transmitter. Once you have paired your smart transmitter and mobile device, you can also find the serial number and model by tapping **Menu** > **About** > **My Transmitter**.

Q: How do I customize the name of my smart transmitter?

A: Tap **Menu** > **Settings** > **System** > **Transmitter Name**. Type in the name you desire. The updated name of the smart transmitter will appear in your connection status screen.

Q: Why does my smart transmitter show a continuous solid orange LED?

A: Follow the steps below to troubleshoot the smart transmitter:

1. Make sure the smart transmitter is paired with your mobile device.
2. Make sure the smart transmitter is charged.
3. Check your app for any alerts or notifications.
4. Remove the smart transmitter from your arm and wait for a few minutes. A **No Sensor Detected** message will appear and the smart transmitter should vibrate more frequently as it searches for a sensor. If the smart transmitter does not vibrate or if the app does not show **No Sensor Detected**, contact Customer Support in the US. Outside the US, contact your local distributor. Place the smart transmitter back over the sensor to see if the orange LED disappears and observe any notifications on the app.

If the orange LED continues to stay lit, contact Customer Support.

Smart Transmitter Battery and Charging

Q: How long does a fully charged smart transmitter battery last?

A: A fully charged smart transmitter battery typically lasts about a day and half.

Q: How long does it take to charge a smart transmitter?

A: It takes approximately 15 minutes to fully charge a smart transmitter when plugged into a wall outlet. It may take longer if charging via a computer USB port.

Q: What happens if my smart transmitter battery is completely drained?

A: No glucose readings will be displayed. Always charge immediately when the smart transmitter battery is completely drained.

Q: How do I check the smart transmitter battery status?

A: There are three ways to check battery status:

1. Tap **Menu** > **About** > **My Transmitter**. Scroll down to the Battery Level line that indicates amount of battery power left.
2. Check the battery symbol in the upper right corner on the **MY GLUCOSE** screen. A red battery icon indicates the smart transmitter battery is empty.
3. Power ON the smart transmitter. Press and release the smart transmitter power button. An orange LED on the smart transmitter indicates low battery. A green LED indicates the battery is at least 10% charged.

Connection with Smart Transmitter

Q: How do I pair my mobile device and smart transmitter for the first time?

A: Follow the steps below to pair your mobile device and smart transmitter. Please read this User Guide for more detailed information.

1. Launch the Eversense App.
2. Press the smart transmitter power button three times to get it into "Discoverable" mode.
3. When the smart transmitter blinks green and orange, tap the smart transmitter ID on the **CONNECT** screen. The app will then begin the searching process.
   - Your smart transmitter ID is the same as the serial number listed on the back of the smart transmitter.
4. When the app finds your smart transmitter, a **BLUETOOTH PAIRING REQUEST** pop-up screen appears.
5. Tap **Pair** to confirm the pairing.
6. The app will display **Connected** next to the smart transmitter ID once the pairing is completed.

Q: My smart transmitter and mobile device do not appear to be connected.

A: There may be several reasons why you do not have a connection.

- Make sure the Bluetooth setting on your mobile device is ON and the smart transmitter's name or serial number appears on the device list.
- The condition may only be temporary. Tap **Menu** > **Connect**. If your smart transmitter name indicates **Disconnected**, tap the smart transmitter name to connect manually.
- Your smart transmitter and mobile device may be out of wireless range. Move your mobile device closer to the smart transmitter.
- Your smart transmitter may be turned off, out of battery power or is currently being charged. You may need to restart the Bluetooth (BLE) function on the smart transmitter by following the steps below.

1. Power off the smart transmitter – Press and hold the power button for 5 seconds and wait for the vibration to confirm it is powered off.
2. Wait 2 seconds and press the power button three times to restart BLE. **(Note: When doing a BLE restart, do not remove/forget the paired device via your mobile device's Bluetooth Settings.)**

3. Press the power button 3 times again to place the smart transmitter in discoverable mode and pair with your mobile device. Tap **Menu** > **Connect** to see if your smart transmitter is connected. If not connected, tap to select your smart transmitter from the list.

If these steps do not resolve the problem, you may need to go to the Bluetooth Settings feature on your mobile device and unpair or forget the smart transmitter and then press the smart transmitter power button 3 times to re-pair. If the problem still exists, you may need to reset your smart transmitter.

Q: How do I reset my smart transmitter?

A: Follow the steps below.

1. Connect the smart transmitter to the USB cable and adapter that came with your smart transmitter. Plug the cable into the wall outlet. (You can also plug the standard USB end of the cable directly into a USB port on your computer.)
2. Press and hold the smart transmitter's power button for about 10 seconds until it begins to vibrate. Do not release the power button until the vibration stops.
3. Once the vibration stops, release the power button. The orange LED should be on. Quickly (within about 2 seconds) unplug the smart transmitter from the USB cable. The LED should be off.
4. To verify the first part of the reset is complete, press the power button multiple times. The LED should not light up. If the LED lights up, repeat steps 1 through 4.
5. After 30 seconds, reconnect the transmitter to the USB cable. The smart transmitter will complete a series of self-tests that lasts about 90 seconds. During this time, the LED will blink green and orange. When the self-test is complete, the transmitter will vibrate and the LED (either green or orange) will stay on. If the self-test doesn't complete, repeat steps 1 through 5.
6. Disconnect the smart transmitter from the USB cable and proceed with pairing. Once paired, the system will be in the Initialization Phase. If you are unable to complete the reset, contact Customer Support.

Q: Can other people connect to my smart transmitter?

A: The Eversense CGM System utilizes a secure Bluetooth connection and will not allow others to connect.

Q: What happens if my smart transmitter is disconnected from my mobile device or app?

A: The smart transmitter will vibrate and the app will provide a "Transmitter Disconnected" notification every 30 minutes until the app is launched or the smart transmitter is reconnected. Once the connection is re-established, the data collected will sync with the mobile app.

Q: Why am I unable to connect my mobile device to my smart transmitter (No Transmitter Connected is displayed in the app status bar)?

A: The smart transmitter may fail to connect with your mobile device for any of the following reasons:

- The smart transmitter is currently charging.
- The smart transmitter is turned OFF.
- The smart transmitter battery is completely drained.
- Bluetooth on your mobile device is turned OFF.
- Smart transmitter pairing to your mobile device has not been established or has been "un-paired". You must re-establish pairing. See *Troubleshooting* for more information.

Q: Why do I see Searching on the CONNECT screen?

A: The app will continue to show **Searching** for any of the following reasons:

- The smart transmitter is currently charging.
- The smart transmitter is turned OFF.
- The smart transmitter battery is completely drained.
- Bluetooth on your mobile device is turned OFF.
- Smart transmitter pairing to your mobile device has not been established or has been "un-paired". You must re-establish pairing.

Q: What is "Discoverable" (Pairing) mode?

A: Discoverable mode is the smart transmitter state that enables it to be located by your mobile device for pairing. See *Getting Started* for more information.

Q: Why do I see other smart transmitters listed on the CONNECT screen?

A: The app may find other Bluetooth enabled devices in the vicinity. However, the app connects only to the smart transmitter that was paired with your mobile device. DO NOT attempt to pair your mobile device to other smart transmitters that are not yours.

Q: My smart transmitter is not listed on the CONNECT screen?

A: The smart transmitter will not be listed on the **CONNECT** screen for any of the following reasons:

- The smart transmitter is currently charging via USB.
- The smart transmitter is turned OFF.
- The smart transmitter battery is completely drained.
- Bluetooth on your mobile device is turned OFF.
- Smart transmitter pairing to your mobile device has not been established or has been "un-paired". You must re-establish pairing.

Q : I just received a new smart transmitter. How do I unlink the old one and link the new one to my sensor?

A: On the Main Menu, tap **Connect**. Tap and hold the name of your old smart transmitter. Tap **OK** to stop the app from automatically connecting with the old smart transmitter. Follow the steps in this User Guide for pairing the new smart transmitter with the app and linking it to your sensor.

Calibration

Q: Will doing more than 2 fingerstick calibrations per day affect the accuracy of the system?

A: The accuracy will not be negatively impacted if you do more than the required 2 calibrations per day.

Q: When should I do a fingerstick test with a blood glucose meter?

A: You should perform a blood glucose test on a meter:

- When it is time to calibrate.
- When you cannot get sensor glucose readings.
- Any time you have reached your low or high glucose alert thresholds.
- Any time you have symptoms of low or high blood glucose.
- Any time your symptoms are not consistent with the sensor glucose readings.
- Prior to making treatment decisions, such as dosing insulin or consuming carbohydrates.

Q: Why am I unable to calibrate?

A: You may not be able to calibrate for any of the following reasons:

- Not enough sensor glucose data has been collected, which may take up to 5 minutes.
- Sensor glucose values are changing rapidly, such as after eating or taking insulin.
- The blood glucose reading is less than 2.2 mmol/L.
- The blood glucose reading is greater than 22.2 mmol/L
- The blood glucose reading was taken more than 10 minutes prior to entering it in the Eversense App.
- The last sensor glucose value is significantly different than the blood glucose reading entered.
- It is not time for your calibration.

Q: How do I change my scheduled morning and evening Daily Calibration times?

A: Tap **Menu** > **Settings** > **Daily Calibration**. Select the morning or evening time to change. Morning and evening times must be set a minimum of 10 hours apart and maximum of 14 hours apart.

Q: Why was my calibration rejected?

A: The system will reject the calibration for the any of the following reasons:

- The blood glucose reading entered is less than 2.2 mmol/L.
- The blood glucose reading entered is greater than 22.2 mmol/L.
- The blood glucose reading entered is significantly different from the last sensor glucose reading.

If the calibration is rejected, you must re-calibrate. You may need to wait up to 60 minutes before re-calibrating.

Q: Can I calibrate earlier than my scheduled time?

A: You can calibrate up to 2 hours before the scheduled time. If you miss your scheduled time, the system will send an hourly calibration prompt. To view the next available calibration time, tap **Menu** > **Calibrate**. The next scheduled calibration time is displayed.

Q: What time should I enter on the CALIBRATE screen when I am notified to calibrate?

A: Enter the time you tested your blood glucose with your meter. You must enter the blood glucose reading within 10 minutes of doing the test.

Q: Where can I find details for Calibration Phase, number of calibrations and last calibration date and time?

A: You can view calibration details by tapping **Menu** > **About** > **My Transmitter**.

Q: What are the different types of calibration phases?

A: The Eversense CGM System has two types of Calibration Phases, the Initialization Phase and the Daily Calibration Phase. Initialization Phase begins 24 hours after sensor insertion and requires 4 fingerstick blood glucose tests for calibration. The Daily Calibration Phase occurs after the Initialization Phase and requires 2 daily calibrations (morning and evening) for the life of the sensor.

Alerts and Notifications

Q: Can I change the vibration alert pattern on my smart transmitter?

A: Smart transmitter vibe patterns are fixed and cannot be changed. The repeat interval can be changed for some alerts in **Settings** > **Sound Settings**.

Q: Can I increase the volume of the app sounds coming from my mobile device?

A: You may increase the volume of the app sounds by connecting your mobile device to an external device to amplify the sound.

Q: How do I silence glucose alerts?

A: Glucose alerts can be silenced by confirming the alert on your mobile device and taking the appropriate action if necessary.

Q: Can I change the number of alerts I receive?

A: If you feel that you are getting too many alerts, you should first discuss the alert settings best suited for you with your physician. If you need to change your glucose alert settings, tap **Menu** > **Settings** > **Glucose**.

Q: What is the difference between a notification and alert?

A: A Notification is a non-critical, low priority message (e.g., calibration reminder).

An Alert is an important message that needs your attention and may require you to respond/take action.

Q: What are rate of change alerts?

A: Rate of Change Alerts notify you when your glucose level is falling or rising faster than the setting you entered in **Settings** > **Glucose**. You should immediately perform a fingerstick blood glucose test to confirm your glucose value.

Q: What happens to the notifications if my app is disconnected from my smart transmitter?

A: If the app is disconnected from your smart transmitter, but you have been wearing your smart transmitter over your sensor, the alerts received during that time will be sent to the app once it is reconnected and synced with the smart transmitter.

Q: Why am I unable to see notifications when the app is in the background?

A: Refer to your mobile device instructions to enable the notifications in the background.

Q: How can I sort the notifications on the ALERT HISTORY screen?

A: The **ALERT HISTORY** screen has a sort filter at the top. You can sort based on the severity levels (yellow and blue), and alert type. Tap the desired sort filter icon.

Q: What are predictive alerts?

A: Predictive Alerts notify you in advance of an event that is likely to occur if current trends continue. Predictive Alerts use High and Low Glucose Alert levels you set to determine when the Predictive Alerts occur. You can set the alerts to notify you at 10, 20, or 30 minutes in advance of when the CGM System anticipates you reaching the alert levels you set. Your smart transmitter will vibrate, and your app will sound an alert and display a message on the **MY GLUCOSE** screen to notify you of a predicted high or low glucose. You should immediately perform a fingerstick blood glucose test to confirm your glucose value.

Glucose Readings

Q. Why is my sensor reading different from my blood glucose meter reading?

A: The Eversense CGM System measures glucose in interstitial fluid (ISF) between the body's cells. Physiologic differences between ISF and blood from a fingerstick may result in differences in glucose measurements. These differences are especially evident during times of rapid change in blood glucose (e.g., after eating, dosing insulin, or exercising). On average, glucose levels in ISF lag behind glucose levels in blood by several minutes.

Q: I am getting "-- -- --" in place of sensor glucose readings on the app.

A: You may not get any sensor glucose readings when there is no connection between your smart transmitter and your sensor or smart transmitter and mobile device.

You may also not get any readings when one of the alerts below is activated:

- No sensor detected.
- Out of Range High or Out of Range Low Glucose Sensor reading.
- Low Sensor Temperature.
- High Ambient Light.
- Sensor Check.
- High Smart Transmitter Temperature.
- High Sensor Temperature.
- Empty Battery.
- Calibration Past Due.
- New Sensor Detected.
- Sensor Replacement.
- Calibration Expired.
- Smart Transmitter Error.
- Sensor Suspend Alert.

Please follow the instructions provided in the notification message to clear the Alert.

Trend Arrows

Q: My trend arrows and glucose alerts do not match.

A: Trend arrows indicate the rate and direction of change in glucose levels. For example, you may have a trend arrow that points up or down (indicating slow or rapid changes). Glucose alerts notify you when your current glucose level reaches the alert level you set, regardless of the rate or direction of change.

Q: My trend arrow is gray instead of blue.

A: The CGM System uses the **last 20 minutes of continuous glucose data** for calculating and displaying the trend arrow. When there are not enough sensor values available for the calculation, the arrow is displayed in gray.

App

Q: What will happen if I re-install the app?

A: Upon re-installing the app, the app will download historical data only from the last 3 days.

Q: What version of the app is installed on my mobile device?

A: You can find the app software version by tapping **Menu** > **About** > **Product Information**.

Q: How will my app be updated?

A: Visit www.eversensediabetes.com for instructions on updating the app software.

Q: What devices are compatible with the Eversense App?

A: Visit www.eversensediabetes.com for a list of compatible devices.

Q: Can I still use the same smart transmitter if I switch to a new mobile device?

A: You will need to install the app on your new mobile device and pair it with your smart transmitter. The last 3 days of historical data will be synced to the app on the new mobile device.

Q: What is the Do Not Disturb option?

A: When Do Not Disturb is enabled in the Eversense App Settings, the smart transmitter will stop providing vibratory notifications for non-critical alerts. Critical alerts will still be provided via on-body vibe alerts. All alerts and notifications will continue to be provided on the mobile app.

Note that the Do Not Disturb feature on your smartphone overrides the Do Not Disturb option in the app. So if the Do Not Disturb feature on your smartphone is turned on, you will not receive the alerts on the smart transmitter or in the app.

Q: Why does my status bar say "syncing"?

A: "Syncing" will appear in the status bar when the app on your mobile device is connecting to your smart transmitter.

Sensor

Q: Can the sensor be inserted in another body part besides my upper arm?

A: The Eversense CGM System was only tested in the upper arm during clinical studies.

Q: When do I need to replace my sensor?

A: Your sensor lasts up to 90 days. You will receive periodic notices (30, 14, 7, 3, 2, and 1 day prior) to remind you when the sensor needs to be replaced. Contact your physician to schedule a sensor replacement.

Q: Can I extend the 90 day life of the sensor?

A: The sensor will no longer provide glucose readings after 90 days of wear and must be replaced.

Q: Where can I find the sensor serial number?

A: You can view the sensor serial number by tapping **Menu** > **About** > **My Sensor**.

Q: Why do I see a "New Sensor Detected" notification?

A: This message appears when your smart transmitter detects a new sensor so you may link the smart transmitter and sensor. The smart transmitter can only be linked to one sensor at a time. If you see a **New Sensor Detected** message and you already have a sensor inserted and linked to your smart transmitter, tap **Not Now**. If unsure, contact Customer Support for more information.

Q: I have just linked a sensor and smart transmitter for the first time, but the insertion date and/or time do not show when I tap About > My Sensor.

A: It may take up to 10 minutes for the linking process to complete. Be sure the smart transmitter is on top of the sensor. Confirm the **LINKED SENSOR** screen shows a check mark for Linking Process Complete. Navigate to the **MY GLUCOSE** screen and wait about 2 minutes. Return to the **MY SENSOR** screen. If the correct insertion date and time are still not displayed, follow these steps:

1. Remove the smart transmitter from the insertion site. Connect it with the charging cable and power supply. Plug the power supply into the wall outlet and then unplug it and disconnect it from charging cable.
2. Replace smart transmitter over sensor. Navigate to **About** > **My Sensor** and confirm correct insertion date and time. If problem persists, contact Customer Support.

Q: I have just linked a sensor and smart transmitter but the About > My Transmitter does not show the correct Current Phase.

A: It may take up to 10 minutes for the linking process to complete. Be sure the smart transmitter is on top of the sensor. Confirm the **LINKED SENSOR** screen shows a check mark for Linking Process Complete. Navigate to the **MY GLUCOSE** screen and wait about 2 minutes. Return to the **MY SENSOR** screen. If the correct insertion date and time are still not displayed, follow these steps:

1. Remove the smart transmitter from the insertion site.
2. Connect it with the charging cable and power supply.
3. Plug the power supply into the wall outlet and then unplug it and disconnect it from charging cable.
4. Replace the smart transmitter over the sensor.
5. Navigate to **About** > **My Transmitter** and confirm Current Phase is correct. If the problem continues, contact Customer Support.

Q: Why did my CGM System re-enter Initialization Phase?

A: You will re-enter Initialization Phase for any one of the following reasons:

- Calibration period has expired without you having entered a fingerstick test value.
- 3 or more blood glucose readings are significantly different than the current sensor glucose readings.
- Your smart transmitter has not been charged within 16 hours of the empty battery alert.
- If you manually change the time on your mobile device your smart transmitter will sync and reinitialize to your mobile device.

Events

Q: How can I sort my events on the EVENT LOG screen?

A: The **EVENT LOG** screen has a sort filter at the top of the screen. Tap the desired sort filter icon to include and exclude events from the list. The default sort option is to show ALL events.

Sync

Q: Why do I sometimes see a blue and white progress bar across the top of my screen?

A: You will see this syncing progress bar for several reasons.

- Your smart transmitter was out of range of your sensor for a while and it is re-syncing.
- You closed the Eversense App completely and re-launched it.
- Your mobile device lost battery power and was recharged.
- Your data is being uploaded to your Eversense DMS account.

19. Device Performance

This section lists Device Performance Characteristics.

Clinical Study Performance

The performance of the Eversense CGM System was evaluated in a multi-site, non-randomized clinical study. Adult (older than 17 years old) subjects with diabetes were enrolled at 7 different sites in 3 different countries. Each subject had 2 separate sensors inserted, one in each upper arm. One sensor was used to display glucose data on the subject's mobile device and the other sensor was used to collect glucose data but was not displayed to the subject. Forty-four (44) subjects were followed for 90 days following the insertion of the sensor. Accuracy assessments were made at various points during the study, and subjects were asked to report any adverse events throughout the study. The Mean Absolute Relative Difference (MARD) measured throughout the 90 days was 11.4% for glucose values over 4.2 mmol/L.

Overall System Performance Compared to YSI

The study demonstrated that 83.8% of overall CGM System readings were within ± 20% of YSI values, 93.9% were within ± 30% of YSI values, and 97.5% were within ± 40% of YSI values. The chart below provides a percentage breakdown by glucose range.

Difference between CGM System readings and YSI Measurements by Glucose Level

YSI Glucose Range (mmol/L)	Number of paired CGM-YSI Readings	Percent within 20% of YSI	Percent within 30% of YSI	Percent within 40% of YSI
≤ 3.9*	422	80.6%	93.4%	96.7%
3.9 - 10.0	6633	80.6%	92.2%	96.7%
> 10.0	3387	90.4%	97.3%	99.1%
Overall	10442	83.8%	93.9%	97.5%

*The absolute difference from the YSI reading is measured in mmol/L if the YSI reading is ≤ 3.9 mmol/L.

Although device measurement errors may have been present in either YSI or sensor readings, and interstitial values (sensor) are known to have time lags in responses to changing blood glucose levels compared to blood values (YSI), it was demonstrated that 80% or greater of differences were within 20%/1.1 mmol/L (20% for YSI values greater than 3.9 mmol/L, within 1.1 mmol/L for YSI values ≤ 3.9 mmol/L). The level of agreement increased to above 92% for differences within 30%/1.7 mmol/L and above 96% for differences within 40%/2.2 mmol/L.

Clarke Error Grid Analysis

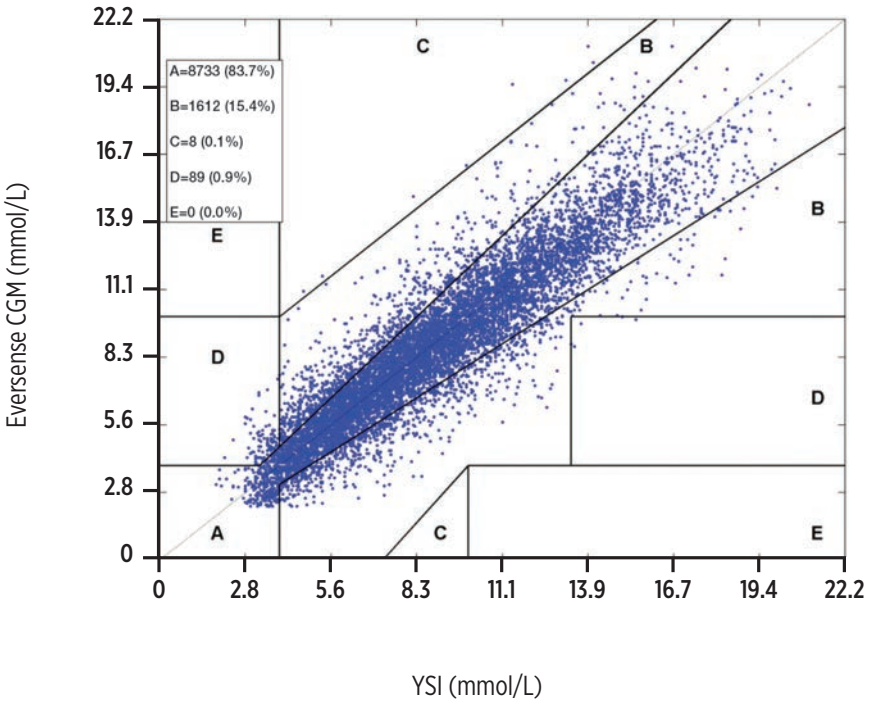
The Clarke Error Grid Analysis (EGA) is one of the standards for quantifying the accuracy of CGM systems. Clarke EGA measures accuracy by comparing subject glucose values taken from their CGM system to reference values taken in a lab.

Clarke EGA calculates accuracy by looking at the number and percentage of data points that fell into 5 "clinical risk" zones. Data is presented in both graph and chart formats.

- **Zone A** (no risk) contains CGM values that fell **within** ±20% of the reference values.
  - Zone A values are considered to be within the acceptable accuracy range of CGM systems.
- **Zone B** (no risk) contains CGM values that fell **outside** ±20% of the reference values.
  - Zone B values are not considered to be within the acceptable accuracy range, but their difference from the reference values would not lead a subject to making an inappropriate treatment decision.
- **Zone C** (low risk) contains CGM values that differed enough from the reference values that a subject might make an unnecessary treatment decision based on the CGM information.
- **Zone D** (medium risk) contains CGM values that were correctly identified as hypoglycemic or hyperglycemic by the reference system but not the CGM system.
  - Not correctly identifying a CGM value as hypoglycemic or hyperglycemic is a potentially dangerous situation.
- **Zone E** (high risk) contains CGM values that were incorrectly identified as hypoglycemic when the reference system correctly identified them as hyperglycemic (and vice versa).
  - Mistakenly identifying a CGM value as hypoglycemic when it is actually hyperglycemic (or vice versa) is a potentially dangerous situation.

Clarke Error Grid Scatterplot

Clarke Error Grid percentages were calculated by glucose range, and at certain "wear duration" points in the study.



Clarke Error Grid Accuracy by Glucose Level

YSI Glucose Range (mmol/L)	Number of paired CGM-YSI Readings	Clarke Score				
		A	B	C	D	E
≤ 3.9	422	77.2%	2.4%	0.0%	20.4%	0.0%
3.9 - 10.0	6633	80.6%	19.4%	0.0%	0.0%	0.0%
> 10.0	3387	90.4%	9.4%	0.1%	0.1%	0.0%
Overall	10442	83.6%	15.4%	0.1%	0.9%	0.0%

Overall, 83.6% of CGM readings fell within zone A. This indicates CGM readings were in close agreement with reference values for the great majority of readings.

Clarke Error Grid Accuracy by Duration of Wear

Percent values are reported to single precision.

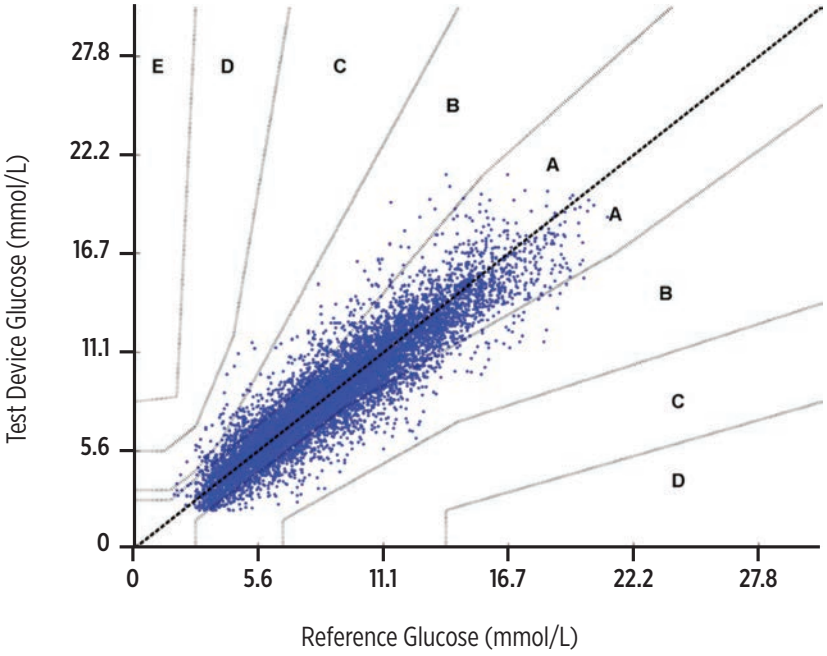
Period of Wear	Number of paired CGM-YSI Readings	Clarke Score				
		A	B	C	D	E
Days 1-30	6784	82.9%	16.0%	0.1%	1.1%	0.0%
Days 1-60	9529	83.5%	15.6%	0.1%	0.9%	0.0%
Days 1-90	10442	83.6%	15.4%	0.1%	0.9%	0.0%

Overall, 83.6% of CGM readings fell within zone A. This indicates CGM readings were in close agreement with reference values for the great majority of readings. Also, there were no real differences in zone A percentages as the duration of wear increased.

Consensus (Parkes) Error Grid Analysis

The Consensus Error Grid Analysis (CEG) is another standard for quantifying the accuracy of CGM systems. CEG is similar to the Clarke EGA in that it assigns the differences (errors) between the CGM system values and reference values to one of 5 “clinical risk” regions. But the CEG differs from the Clarke EGA in that the risk regions are continuous (A through E), whereas with the Clarke EGA they are not continuous (e.g., A is next to D).

CEG percentages were calculated for the total number of CGM readings.



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Consensus Error Grid Accuracy by Glucose Level

Zone	Frequency	Percent
A	8922	85.4%
B	1481	14.2%
C	39	0.4%
D	0	0.0%
E	0	0.0%
Total	10442	100.0%

Overall, 85.4% of CGM readings fell within zone A. This indicates CGM readings were in close agreement with reference values for the great majority of readings.

Calibration Performance

Calibration performance looks at whether accuracy is affected by how much time has elapsed since the last system calibration with a blood glucose value.

CGM System Performance by Time Since Last Calibration

Time from Calibration	Number of paired CGM-YSI Readings	Percent within 20%	Percent within 30%	Percent within 40%
0-4 hrs	6043	83.1%	93.1%	97.0%
4-8 hrs	2479	85.0%	94.5%	97.7%
8-12 hrs	1663	83.6%	95.6%	98.6%
Total	10185	83.6%	93.8%	97.4%

Overall, there is no real difference in accuracy based on how long after the last blood glucose calibration the CGM readings were recorded.

Sensor Life

Sensor life measured how many days out of the intended 90-day duration period subjects were able to continue using the sensor to record CGM readings.

Overall, the analysis estimated that 87.5% of sensors remained functioning through 90 days.

Smart Transmitter Wear

Smart transmitter wear measured how many hours of the day subjects wore the smart transmitter. Overall, subjects wore their smart transmitters an average of 22.3 hours per day, with a median of 23.5 hours.

Safety

The number of adverse events were recorded over the first 90 days of the study period.

The CGM system was extremely well tolerated in the study. There were no serious adverse events reported that were related to use of the system or the insertion procedure. A total of 37 adverse events were reported in 26 subjects, all recorded as mild. Twelve (12) of these were related to the sensor insertion procedure. None of the adverse events resulted in hospitalization due to hypoglycemia, hyperglycemia, or ketoacidosis.

20. Technical Specifications

Sensor

Characteristic	Description
Dimensions	Length: 18.3 mm Diameter: 3.5 mm
Materials	Homopolymer polymethylmethacrylate (PMMA), Hydroxyethylmethacrylate (HEMA) based Hydrogel, Platinum, Silicone, Dexamethasone Acetate, epoxy 301-2
Glucose Range	2.2 - 22.2 mmol/L
Sensor Life	Up to 90 days
Calibration	Commercially available self-monitoring blood glucose meter
Calibration Range	2.2 - 22.2 mmol/L
Sterilization	Sterile by Ethylene Oxide

Smart Transmitter

Characteristic	Description
Dimensions	Length: 37.6 mm Width: 48.0 mm Thickness: 8.8 mm
Materials	Body: polycarbonate
Weight	11.3 g
Power Supply	Rechargeable lithium polymer batteries (not replaceable)
Operational Conditions	5 - 40 °C (41 - 104 °F)
Operational Life	12 months
Storage Conditions	0 - 35 °C (32 - 95 °F)
Moisture Protection	IP67: submerged up to 1 meter of water for up to 30 minutes
Protection Against Electrical Shock	Type BF applied part
Charge time using AC adapter	about 15 minutes
Communication Distance	Between app and smart transmitter is up to 7.6 meters (25 feet)
Cabin Pressure	700hPa to 1060hPa
Relative Humidity Range (non-condensing)	15% to 90%

Power Supply and Charger

Characteristic	Description
Class	II
Input	AC Input, 100-240Vac, 50/60Hx, 0.3-0.15A
DC Output	5V DC, 1A (5.0 watts)
Moisture Protection (charging cradle)	IP22

USB Cable* for Charging and Downloading

Characteristic	Description
Input/Output	5V DC, 1A
Type	USB-A to USB micro-B
Length	36 inches (91 cm)

*If misused, the USB cable can pose a strangulation risk. The USB cable can be connected to the power supply/charger and charged using an AC power outlet. To isolate the system, unplug the charger/power supply from the outlet. If you charge the smart transmitter using a USB port on your personal computer, ensure the personal computer complies the IEC 60950-1 (or equivalent) safety standard.

Electrical and Safety Standards

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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.

Transmitter Electromagnetic Immunity Specifications

Immunity Test	Immunity Test	Transmitter Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 15 kV Air	± 8 kV Contact ± 15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power Frequency (110VAC/60Hz, 230VAC/50 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Electrical and Safety Standards (continued)

The Eversense CGM System is intended to be used in the electromagnetic environment detailed in the table below. Users of the System should ensure it is used according to these specifications.

System Electromagnetic Immunity Specifications

Immunity Test	IEC 60601 Test Level	Transmitter Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6 (Smartphone only (Receiving Device))	≥ 3 Vrms (150 kHz to 80 MHz)	3 Vrms	Interference may occur in the vicinity of equipment marked with following symbol:
Radiated RF IEC 61000-4-3	≥ 10 V/m at 80 MHz to 2700 MHz (AM Modulation)	3 Vrms	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Eversense CGM System is used exceeds the applicable RF compliance level above, the Eversense CGM System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Eversense CGM System.

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

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

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

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	The Eversense CGM System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Eversense CGM System is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Recommended Separation Distances Between Other Portable/Mobile RF Communications Equipment and the Smartphone (Receiving Device)

Follow the smartphone (or other receiving device) manufacturer's instructions for separation distances. The customer or the user of the smartphone (or other receiving device) can help prevent electromagnetic interference by maintaining a minimum distance between other portable/mobile RF communications equipment (transmitters) and the smartphone of at least 30 cm (about 12 inches). Portable/mobile RF equipment include: baby monitors, Bluetooth wireless headsets, wireless routers, microwave ovens, laptops with internal Wi-Fi adapters, GSM cell phones, RFID scanners and hand-held security metal detector often used by security screeners.

Symbols on the Eversense Mobile App

Symbol	Explanation
	**Glucose Alert** Appears when the glucose is above the high glucose alert range and below the low glucose alert range. The icon appears in the **ALERT HISTORY** screen.
	**Falling Rate Alert** Appears when the glucose value is falling beyond a defined rate.
	**Rising Rate Alert** Appears when the glucose value is rising beyond a defined rate.
	**Empty Battery Alert** Appears when the smart transmitter battery is empty.
	**Low Battery Alert** Appears when the smart transmitter battery is less than 10% charged.
	**Smart Transmitter/Sensor Alert** The icon appears only in the **ALERT HISTORY** screen.
	**Smart Transmitter/Sensor Notifications** Appears when there are notifications related to the smart transmitter or sensor.

Symbols on the Eversense Mobile App (continued)

Symbol	Explanation
	**Calibration Alert** Appears when there are calibration-related alerts.
	**Calibration Notification** Appears when there are calibration-related notifications.
	**Calibration Failure** Appears when the smart transmitter rejects the user-entered calibration value.
	**Connection Failure** Appears when the smart transmitter is disconnected from the smartphone or when the sensor is not linked to the smart transmitter.
	**Multiple alerts (more than one alert or event)** Appears when there are two or more alerts or events in a short interval.
	**Temp Profile** Appears when the Temp Profile is active.

Symbols on Packaging and Devices

Symbol	Explanation
	Consult accompanying documents
	Caution, consult accompanying documents
	Use by
	Manufacturer
	Authorized representative in the European Community
	Date of manufacture
	Storage temperature limits
	Lot number
	Universal Serial Bus (USB)

Symbol	Explanation
	Marking certifies that the device meets the European Council Directive 90/385/EEC
	Part number
	Serial number
	Type BF Applied Part
	Non-ionizing electromagnetic radiation
	Not made with natural rubber latex
FCC ID# 2AHYA-3401	FCC ID is assigned to all devices subject to certification
	Non-sterile

Symbols on Packaging and Devices (continued)

Symbol	Explanation
	Magnetic Resonance Imaging (MRI) procedures are contraindicated for this device.
	European Union WEEE Directive 2012/19/EU
	Single use only
	Do not re-sterilize
	Do not use if package is damaged
	Sterilized using Ethylene Oxide
	Follow instructions for use

Eversense Smart Transmitter Limited Warranty

1. Coverage and duration of limited warranty.

Senseonics, Incorporated ("Senseonics") warrants to the original patient end user ("you") of the Eversense Smart Transmitter (the "Smart Transmitter") that the Smart Transmitter shall be free from defects in material and workmanship under normal use for a period of one year (365 days) commencing on the date that you first received the Smart Transmitter from your physician ("Limited Warranty Period"). This warranty gives you specific legal rights, and you may also have other rights which vary from jurisdiction to jurisdiction. This limited warranty is made on the condition that you provide Senseonics with written notice of any defects in material and/or workmanship immediately upon discovery, and provided that Senseonics determines that your claim is due to defects in original material and/or workmanship. If Senseonics provides you with a replacement Smart Transmitter pursuant to the terms of this limited warranty, any remaining warranty on the original Smart Transmitter will transfer to the replacement Smart Transmitter, the warranty period for the replacement Smart Transmitter shall end on the one year anniversary of the date that you first received the Smart Transmitter from your physician, and this warranty will be void with respect to the original Smart Transmitter.

2. Exclusions to the limited warranty.

The limited warranty applies only to the Smart Transmitter manufactured by Senseonics, and is conditioned upon proper use of the product by you. The limited warranty does not cover a) cosmetic damage, scratching or other damage to surfaces and exposed parts due to normal use; b) damage resulting from accident, neglect and other negligence, misuse, unusual physical, electrical or electromechanical stress, or modification of any part of the product; c) equipment that has been altered to remove, alter or otherwise make illegible the ID number; d) malfunctions resulting from use with products, accessories or peripheral equipment not furnished or approved in writing by Senseonics; e)consumables (batteries), f) equipment that has been dissembled; and g) damage caused by improper operation, testing, maintenance, installation or adjustment.

The Smart Transmitter is water-resistant to the specification listed in the User Guide. This limited warranty does not cover water damage if the Smart Transmitter housing is cracked, or otherwise damaged. This limited warranty does not apply to collateral services, equipment or software that may be used with the Smart Transmitter.

3. Senseonics' obligations under the limited warranty.

Your sole and exclusive remedy, and the sole and exclusive obligation of Senseonics under this limited warranty is to repair or replace, at its sole discretion, without charge to you, any defective Smart Transmitter, provided that the defect arises and a valid claim is received by Senseonics within the Limited Warranty Period. You must return the defective Smart Transmitter to an authorized Senseonics Customer Service Department in an appropriate shipping container that will adequately protect the Smart Transmitter from further damage, accompanied by your name and address, the name and address of the physician from whom you obtained the Smart Transmitter, and the date and the ID number of the Smart Transmitter. To find out where to send the Smart Transmitter, please visit our website www.eversensediabetes.com. Upon receipt, if Senseonics determines that the Smart Transmitter is covered by the limited warranty and that coverage is not excluded, Senseonics will promptly replace the Smart Transmitter. If Senseonics determines that the Smart Transmitter is not covered by the limited warranty, you may purchase a replacement or if you want the original Smart Transmitter returned, you must prepay all shipping charges.

A repaired or replacement Smart Transmitter assumes the remaining warranty of the original Smart Transmitter, or [30] days from the date of replacement or repair, whichever is longer.

4. Limits of Senseonics' obligations under the limited warranty.

THE LIMITED WARRANTY OF SENSEONICS DESCRIBED ABOVE IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, STATUTORY OR OTHERWISE, AND SENSEONICS EXPRESSLY EXCLUDES AND DISCLAIMS ALL SUCH OTHER WARRANTIES, INCLUDING WITHOUT LIMITATION, ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, SATISFACTORY QUALITY, NON-INTERFERENCE, ACCURACY OF INFORMATIONAL CONTENT, OR ARISING FROM A COURSE OF DEALING, LAW, USAGE, OR TRADE PRACTICE.. EXCEPT TO THE EXTENT PROHIBITED BY APPLICABLE LAW, SENSEONICS SHALL NOT BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, ARISING IN ANY WAY OUT OF THE SALE, USE, MISUSE OR INABILITY TO USE THE SMART TRANSMITTERS OR ANY SENSEONICS EVERSENSE SYSTEM. THIS LIMITATION SHALL APPLY EVEN IF SENSEONICS OR ITS AGENT HAS BEEN ADVISED OF SUCH DAMAGES AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF THIS LIMITED REMEDY.

THIS LIMITED WARRANTY SHALL NOT EXTEND TO ANYONE OTHER THAN YOU, THE ORIGINAL END USER OF THIS PRODUCT AND IT STATES YOUR EXCLUSIVE REMEDY. IF ANY PORTION OF THIS LIMITED WARRANTY IS ILLEGAL OR UNENFORCEABLE BY REASON OF ANY LAW, TO THE EXTENT THAT SENSEONICS MAY NOT, AS A MATTER OF APPLICABLE LAW, DISCLAIM ANY IMPLIED WARRANTY OR LIMIT ITS LIABILITIES, THE SCOPE AND DURATION OF SUCH WARRANTY AND THE EXTENT OF LIABILITY OF SENSEONICS SHALL BE THE MINIMUM PERMITTED UNDER SUCH APPLICABLE LAW.

System component	Part Number
Eversense Smart Transmitter Kit	FG-3300-01-001
Charging cable	FG-6100-00-301
Charging Adapter	FG-6301-93-301 (PSM03E-050Q)
Charging Cradle	FG-6500-00-301
Eversense Adhesive Patches	FG-6400-00-301
Eversense Quick Reference Guide	LBL-0303-01-001
Eversense CGM User Guide	LBL-0302-01-001
Eversense Data Management Software Application	FG-5200-01-300
Eversense Mobile Application iOS	FG-5100-01-300
Eversense Mobile Application Android	FG-5300-01-300

Legal Notices

Apple Legal Notice

"Made for iPod touch", "Made for iPhone" and "Made for iPad" mean that an electronic accessory has been designed to connect specifically to iPod touch, iPhone or iPad, respectively, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards. Please note that the use of this accessory with iPod touch, iPhone or iPad may affect wireless performance.

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Google Legal Notice

The "Android" name, the Android logo, and Google Play are trademarks of Google Inc.

About Bluetooth®

Bluetooth® is a type of wireless (RF) communication. Mobile devices like smartphones use Bluetooth® technology as do many other devices. Your smart transmitter uses Bluetooth® Smart to pair with the mobile device and to send results to the app.

Bluetooth® Trademark

The Bluetooth® word mark and logos are owned by the Bluetooth® SIG, Inc. and any use of such marks by Senseonics, Inc. is under license.

FCC Information

Your smart transmitter complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference.
(2) This device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by Senseonics, Inc., could void the user's authority to operate the equipment.

These guidelines help ensure that your smart transmitter will not affect the operation of other nearby electronic devices. Additionally, other electronic devices should not affect the use of your smart transmitter.

With the exception of your mobile device, other electronic wireless devices that are in use nearby, such as a cell phone, microwave or a wireless network, may prevent or delay the transmission of data from your smart transmitter to the app. Moving away from or turning off these electronic devices may allow communication.

The smart transmitter has been tested and found to be appropriate for use at home. In most cases, it should not interfere with other home electronic devices if used as instructed. However, this smart transmitter gives off RF energy. If not used correctly, your smart transmitter may interfere with your TV, radio or other electronic devices that receive or transmit RF signals.

If you experience smart transmitter interference problems, try moving away from the source of the interference. You can also move the electronic device or its antenna to another location to solve the problem.

If you continue to experience interference, contact customer service for the manufacturer of the electronic device causing the interference.

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Notes

eversense®

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