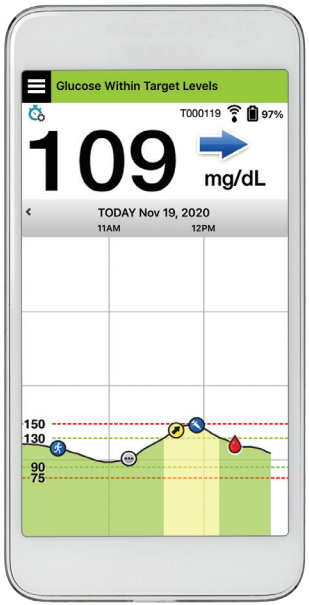
eversense® 365

Continuous Glucose Monitoring System

User Guide

Sensor

Smart Transmitter



App

eversense® 365

Integrated Continuous Glucose Monitoring System
with Sensor Containing Dexamethasone Acetate

Contents

Glossary

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

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

Bluetooth® (BLE) 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 365 App to check the accuracy of the system. With the Eversense 365 CGM System, there are three phases: Initialization Phase during which 4 fingerstick calibrations are required, the 1 Daily Calibration Phase during which a fingerstick calibration is required once daily, and the 1 Weekly Calibration Phase during which a fingerstick calibration is required once a week.

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 365 App) When enabled, the app will stop displaying lower priority alerts, and the smart transmitter will stop providing vibratory notifications for those alerts. Higher priority alerts will still be provided. Many mobile devices have a separate Do Not Disturb Mode. Consult the manufacturer's instructions for more information.

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

EULA End User License Agreement

Eversense 365 App Software program that is installed on a mobile device and is used to display CGM glucose data sent from the Eversense 365 Smart Transmitter.

Eversense 365 Sensor A device inserted subcutaneously for continually measuring interstitial fluid glucose levels.

Eversense 365 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 365 App.

Eversense DMS A web-based application compatible with the Eversense 365 App where your glucose data is stored and can be viewed.

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

FAQ Frequently Asked Questions

Health Care Provider A physician, physician assistant, and/or nurse practitioner who has successfully completed the Eversense 365 CGM Sensor Insertion and Removal Training Program and has read and understood the Eversense 365 CGM Sensor Insertion and Removal Instructions.

"HI" Reading Indicates a sensor glucose reading is > 400 mg/dL.

Hyperglycemia An episode of high blood glucose.

Hypoglycemia An episode of low blood glucose.

Integrated Continuous Glucose Monitoring (iCGM) iCGM devices may be used as part of an integrated system with other compatible medical devices, which may include automated insulin dosing systems, insulin pumps, or other electronic devices used for diabetes management.

Interstitial Fluid (ISF) The fluid between cells in the body. The Eversense 365 CGM System 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 < 40 mg/dL.

Mobile Device A handheld device built on a mobile operating system that runs the Eversense 365 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 365 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 365 CGM System.

MRI Magnetic Resonance Imaging

MR Conditional An item with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields.

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 app they download to a compatible mobile device.

Rooted Device A device (Android) that has been modified to remove controls and limits set by the original manufacturer.

Snooze Setting Used to set how often an alert repeats.

Subcutaneous Located beneath the skin.

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 your new Eversense 365 Continuous Glucose Monitoring (CGM) System.

Your Eversense 365 CGM System is intended to continually measure glucose levels for up to 1 year after your sensor is inserted. Glucose information collected by the system is automatically sent to your mobile device. You must contact your health care provider to schedule the insertion and removal of your sensor.

Throughout this *User Guide*, any mention of "system", "sensor", "smart transmitter", "app", or "adhesive patches" refers specifically to one or more components of the "Eversense 365 CGM System".

Help and Support

Please review this *User Guide* with your health care provider. For additional product questions and troubleshooting issues, contact Customer Support toll free in the US at 844-SENSE4U (844-736-7348).

For additional information on getting started with your system, access to the onboarding videos and training materials, and to check for the most recent version of the this *User Guide*, visit www.eversensediabetes.com.

System Components

The System includes 1) a small sensor inserted under the skin by a health care provider, 2) a removable smart transmitter worn over the sensor, and 3) an app to display the glucose readings.

Sensor

The sensor is inserted under the skin (upper arm) and measures glucose in interstitial fluid for up to 1 year. These glucose levels are then calculated by the smart transmitter and sent to the app.

Sensor

Transmitter

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

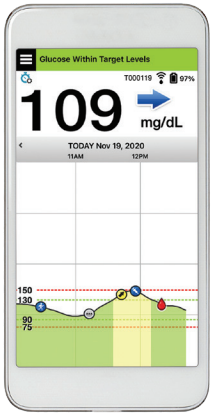
Smart Transmitter

App

The 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.

The app screen layouts will vary based on your mobile device's model and/or operating system. We have included some examples in this *User Guide*.

Make sure your mobile device is using the latest operating system that is listed as compatible. For supported smart devices and operating systems, go to www.eversensediabetes.com/compatibility.



iOS

Android

IMPORTANT: In order to use the system, you must have an understanding of downloading and using apps on your mobile device. Data from the smart transmitter is sent wirelessly via Bluetooth. Carefully read the instructions in this *User Guide* for downloading and installing the app, and for pairing your mobile device with the smart transmitter. If there is anything you do not understand in this *User Guide*, please consult your health care provider. For product questions, contact Customer Support.

Disposable adhesive patches for daily use will be provided by your health care provider 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.

System Overview

A separate blood glucose monitoring system (not provided by Senseonics) is required for calibrating the system, and to make treatment decisions under certain conditions. See *Understanding Treatment Decisions with CGM*. When used properly, these components work together to help ensure you get continuous glucose monitoring for up to 1 year.

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 blood glucose meter calibrations 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. No data is 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 up to 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 similarly to any other Bluetooth device. Be sure to follow the specific safety guidelines mandated by the airline.

Some of the features of the system:

- Wireless communication with the sensor, smart transmitter and app.
- Long-term sensor wear in the upper arm for up to 1 year.
- 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 to display glucose readings.
- On-body vibe alerts with the smart transmitter even when mobile device is not nearby.
- Provides readings within 40 - 400 mg/dL 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 App.

System Requirements

- The Eversense 365 CGM System.
- A compatible smartphone for Android or Apple iPhone® or iPod® or iPad® that has Bluetooth Smart (or Bluetooth Low Energy). The Eversense 365 App also works with the Apple Watch®.
- For a list of compatible devices and operating systems, please go to www.eversensediabetes.com.
- The Eversense 365 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 system is subject to the terms and conditions of the most current Eversense End User License Agreement and Eversense Privacy Policy. These documents are updated from time to time and are posted at www.eversensediabetes.com.

Broken Screen or Button

If the screen of your mobile device is broken, or the buttons do not work, then you may not be able to use your system and you may miss low or high glucose events.

Device Modifications

DO NOT modify the system for use with products, accessories, or peripheral equipment not furnished or approved in writing by Senseonics. Unauthorized modifications void your transmitter warranty and may impact system performance.

Indications for Use

The Eversense 365 Continuous Glucose Monitoring (CGM) System is indicated for continually measuring glucose levels for up to 1 year in people (18 years or older) with diabetes. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions.

The system is intended to:

- 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 Eversense 365 CGM System is also intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems. The Eversense 365 CGM System can be used alone or in conjunction with these digitally connected medical devices for the purpose of managing diabetes.

The system is intended for single patient use and requires a prescription.

MRI Safety Information

The Eversense 365 Smart Transmitter is MR Unsafe and MUST BE REMOVED before undergoing an MRI procedure. Before you undergo an MRI procedure, tell the MRI staff that you have an Eversense 365 Sensor and Smart Transmitter.

Non-clinical testing has demonstrated the Eversense 365 Sensor is MR Conditional.

Implanted Sensor MRI Safety Information

For Whole-Body MR Examinations: A person implanted with the Eversense 365 Sensor may be safely scanned anywhere in the body at 1.5T or 3.0T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Eversense 365 Sensor
Device Configuration	Sensor implanted
Static Magnetic Field Strength (Bo)	1.5T and 3T
Type of Nuclei	Hydrogen
MR Scanner Type	Cylindrical
Bo Field Orientation	Horizontal
Maximum Spatial Field Gradient	30 T/m (3000 gauss/cm)
Maximum Gradient Slew Rate	200 T/m/s
RF Excitation	Circularly polarized
RF Transmit Coil Type	Body and Head or any local coil not positioned directly over the sensor
RF Receive Coil Type	Any receive coil
Operating Mode	Normal Operating Mode
RF Conditions	**For 1.5 T and 3T MR Scanner:** Whole-body SAR ≤ 2 W/kg
Scan Duration	60 minutes of continuous scanning
Scan Regions	No restrictions
Image Artifact	The presence of the Eversense 365 Sensor may produce an image artifact

Contraindications

The smart transmitter is incompatible with magnetic resonance imaging (MRI) procedures. The smart transmitter is MR Unsafe and MUST BE REMOVED before undergoing an MRI (magnetic resonance imaging) procedure. For information on the sensor, please see *MRI Safety Information*.

The system is contraindicated in people for whom dexamethasone or dexamethasone acetate may be contraindicated.

Mannitol or sorbitol, when administered intravenously, or as a component of an irrigation solution or peritoneal dialysis solution, may increase blood mannitol or sorbitol concentrations and cause falsely elevated readings of your sensor glucose results. Sorbitol is used in some artificial sweeteners, and concentration levels from typical dietary intake do not impact sensor glucose results.

What is Included in this Kit

The smart transmitter kit contains the following:

Eversense 365 Smart Transmitter

Power Supply
(USB cable and AC power adapter)

Also included in this package is this *User Guide*, *Quick Reference Guide*, *Next Steps* sheet, and a wallet card (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 **precautions** 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 365 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. Your Eversense 365 CGM System and BG meter measure glucose differently. Glucose levels in ISF lag behind glucose levels in blood. Differences are more likely to be seen when your glucose is changing rapidly (e.g., after eating, dosing insulin, or exercising). For some people, there may be differences during the first several days after insertion due to inflammation that may result from the procedure.

IMPORTANT: If your symptoms do not match the glucose alerts and readings from the Eversense 365 CGM System, a fingerstick blood glucose check with a home blood glucose meter should be performed prior to making treatment decisions.

Failure to use the system in accordance with the instructions for use may result in you missing a hypoglycemic or hyperglycemic glucose event, which may result in injury.

The sensor has a silicone ring that contains 1.75mg 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 ring on the sensor. The elution ring releases approximately 0.4 mg of dexamethasone acetate over 365 days 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 health care provider.

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.

Caution: Federal (US) law restricts this device to sale by or on the order of a licensed practitioner.

Risks and Side Effects

The glucose alerts and notifications will not audibly notify you when the sound on the 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. You may need medical attention in the event that you have high or low glucose and are unaware of it.

IMPORTANT: If you do not test your glucose with a blood glucose meter when your symptoms are not consistent with the sensor glucose readings, you may miss a high or low glucose event.

Treatment decisions should be made based on a review of sensor glucose value, trend arrow, recent glucose trend graph, and system alerts/notifications. You should not make a treatment decision unless you have considered all this information.

Be sure you talk with your health care provider about insulin action, so you understand how its impact on your glucose may factor into your treatment decisions.

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. Dizziness, fainting and nausea were reported in small numbers during clinical studies, as were instances of the sensor breaking or not being removed on first attempt. Any medical issue related to the procedure or use of the device should be reported to your health care provider.

Warnings

- The system has not been tested using insertion sites other than the upper arm.
- If at any time your symptoms are not consistent with the sensor glucose readings, you should test your glucose with a blood glucose meter.
- Before making a treatment decision, you should take into account the sensor glucose value, the trend graph, the trend arrow and any alerts from the system. If no trend arrow is displayed, the system does not have enough data to display direction and rate of change. You should not make a treatment decision based solely on the sensor glucose value.
- 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.
- Antibiotics of the tetracycline class may falsely lower sensor glucose readings. You should not rely on sensor glucose readings while taking tetracyclines.
- The bandage should remain covering the incision for 48 hours as this is a standard of care to allow formation of a water-tight seal to help protect against infection. 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 product questions and troubleshooting issues, contact Customer Support toll free in the US at 844-SENSE4U (844-736-7348).
- 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.

Warnings (continued)

- DO NOT insert your infusion set or inject insulin within 4 in (10.16 cm) of the sensor site. If the insulin delivery site is within 4 in (10.16 cm) of the sensor site, it may interfere with sensor glucose readings and can cause inaccurate glucose readings.
- Always follow your health care provider's instructions for care after the sensor insertion or removal. Contact your health care provider 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, or if the incision has not healed within 5 to 7 days.
- If your sensor glucose is very low (below 40 mg/dL) or very high (above 400 mg/dL), you should perform a fingerstick blood glucose test prior to making a treatment decision.
- The system requires calibration in order to provide accurate readings. You should not use CGM readings to make treatment decisions unless you have followed the instructions for calibration.
- The system will not provide readings during the 24 hour Warm-Up Phase and until a second calibration is successful during the Initialization Phase. During this time, you should monitor your glucose using a home blood glucose monitor.
- Certain conditions and alerts will prevent glucose data from being displayed. During these times, you should use a home blood glucose monitor to make treatment decisions. You should carefully read the *Alerts and Notifications* section of the *User Guide* to understand these conditions.
- The glucose alerts and notifications will not audibly notify you 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.
- When the smart transmitter is not worn over the sensor, such as during charging, the system will not provide alerts and notifications on the mobile device or through vibration alerts from the smart transmitter.
- If you are allergic to any of the materials used in the sensor, insertion tools or smart transmitter that are listed in the *Technical Specifications* of this *User Guide*, DO NOT use the system.

Precautions

- DO NOT exchange smart transmitters with another person. Each smart transmitter can be linked to only one sensor at a time. The system is to be used by one person in the home environment.
- The following medical therapies or procedures may cause permanent damage to the sensor particularly if used in close proximity to the device:
  - **Lithotripsy (Therapeutic Ultrasound) –** The use of lithotripsy is not recommended for people who have an inserted sensor because the effects are unknown. DO NOT use lithotripsy near the sensor.
  - **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.
  - **Vaccinations –** DO NOT have vaccines injected in the same arm as the sensor. Ingredients in vaccines may damage the sensor.
- 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.
- 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 health care provider 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.
- If the sensor, insertion site or smart transmitter feels warm, remove the smart transmitter immediately and contact your health care provider for further advice. A warm sensor could mean there is an infection or a sensor malfunction.

Precautions (continued)

- DO NOT attempt to use the 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.
- Remove the smart transmitter from your arm before charging the smart transmitter battery. Failure to remove the transmitter before charging could result in discomfort in the event the transmitter overheats during charging.
- 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, create the risk of fire, and could result in voiding your warranty. If your AC power adapter or USB cable is damaged or lost, contact Customer Support for a replacement to ensure safe operation of the device.
- Never stick any object other than the charging cable into the USB port of the transmitter. Doing so may damage the transmitter and void your warranty.
- If you have any concerns about allergic reaction to adhesive products containing silicone, contact your health care provider prior to use. Discard the adhesive patch after each use of up to 24 hours.
- DO NOT change the unit of measurement unless you have discussed it with your health care provider. Using the incorrect unit of measure could result in missing a high or low glucose event.
- Entering incorrect blood glucose values for calibration can result in inaccurate sensor glucose readings, which may result in you missing a high or low glucose event.
- Follow your health care provider's recommendation for setting your glucose alerts. Incorrectly setting your glucose alerts can result in you missing a high or low glucose event.
- Pay attention to the glucose alerts the system provides. Failure to appropriately respond to an alert might result in you missing a high or low glucose event.

Precautions (continued)

- The Eversense NOW Remote Monitoring App does not replace the monitoring regimen as directed by your health care provider.
- The 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). The system's accuracy hasn't been tested in these populations, and sensor glucose readings may be inaccurate, resulting in missing a severe low or high glucose event.
- The Apple Watch is a secondary display of data and should not be used in place of the primary CGM display.
- If using headphones with your mobile device, keep them in your ears. If you are not using headphones or speakers that are connected to your mobile device, you may not hear audible alerts from your CGM system. Always disconnect headphones or speakers when not using.

3. Getting Started

This section describes steps required before you can begin using your new Eversense 365 CGM System on a daily basis. You may perform these steps before your health care provider inserts the sensor.

To get started you need:

- Your compatible mobile device to download the Eversense 365 App.
- Wireless internet connection.
- The Eversense 365 Smart Transmitter box that includes your smart transmitter and power supply.

Note: If you have not received your smart transmitter box, skip to instructions on downloading and installing the app to your compatible mobile device later in this section.

Fully charge your smart transmitter before pairing with the app.

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.

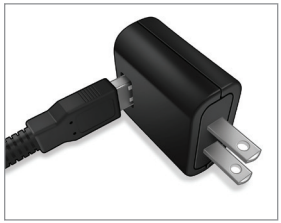
Your smart transmitter comes with a 12 month warranty. The system will alert you when the transmitter warranty exceeds 365 days.

Charge your Smart Transmitter

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 can 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.

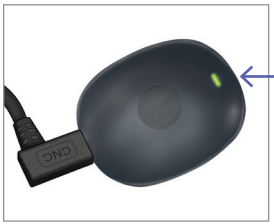
Precaution: Use only the AC power adapter and USB cable provided with the smart transmitter when charging the smart transmitter battery. Use of another power supply could damage the smart transmitter, not allowing glucose readings to be received properly, create the risk of fire, and could result in voiding your warranty. If your AC power adapter or USB cable is damaged or lost, contact Customer Support for a replacement to ensure safe operation of the device.

1. **Plug the USB cable into the adapter on the wall plug.**



2. **Plug the micro end of the USB cable into the USB port of the smart transmitter.**

3. **Plug the adapter into an AC power outlet.**
   - Once fully charged, a small green LED light appears on the top front of the smart transmitter (above the button).
   - Disconnect the USB cable from the smart transmitter after it is charged for at least 15 minutes and the LED flashes green.

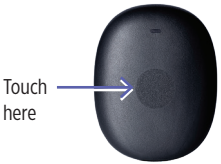


Using the Smart Transmitter

This smart transmitter has a soft-touch button. To use the smart transmitter, touch and hold or tap your finger on the soft-touch button (similar to using a smartphone). The smart transmitter provides information about system status by vibration and by LED lights.

1. **To turn on the smart transmitter, touch and hold the soft-touch button for about 3 seconds.**
   - You will feel a quick vibe, and the LED will blink once, indicating the power is ON.
   - You can tap the soft-touch button to see if it is ON. If you feel a quick vibe and the LED appears, the smart transmitter is ON.

2. **To turn the smart transmitter OFF, touch and hold your finger on the soft-touch button for about 5 seconds – the LED will turn on.**
   - You will feel a quick vibe, and the LED will turn off, indicating the power is OFF.



If your smart transmitter is turned off or the battery is completely empty, there will be no vibration or LED response when you tap the soft-touch button. Plug the smart transmitter into the USB cable and charge it for a few minutes.

Note: You must touch the button directly with your finger – it cannot detect a touch through clothing.

Downloading, Installing and Setting up the App

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 365 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 365 App Icon

Note: Make sure your mobile device is using the latest compatible operating system and turn on automatic updates in your mobile device's settings so you are notified when the latest version of the app is available.

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 365 App icon.

IMPORTANT:

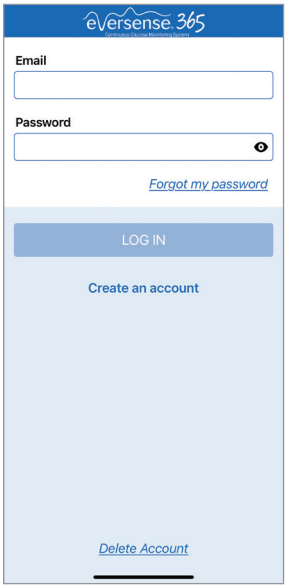
- Make sure that you have a wireless internet connection, the date and time are correct on your mobile device, and that Bluetooth is turned ON before continuing.
- DO NOT add the app to Private Space or similar mobile device features that will prevent it from providing notifications or communicating with the rest of the system.

Set up the App – Account Creation and Enabling Bluetooth and Notifications

Once the app is downloaded, create your Eversense account. You will be prompted to enable Bluetooth for pairing your smart transmitter to your mobile device, and enabling notifications.

1. **Launch the app by tapping the Eversense 365 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.

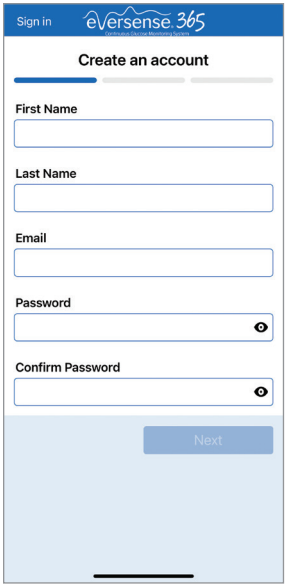
2. **Tap Create an account.**

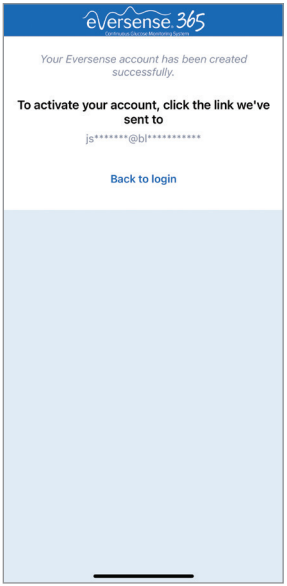


Note: If you already have an Eversense account, log in from this page. If you forget your password, you can reset it via the app. If you forget your email associated with your account, go to **Main Menu** > **About** > **My Account**.

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

- To activate your Eversense account, click the link in the email sent from donotreply@eversensediabetes.com.



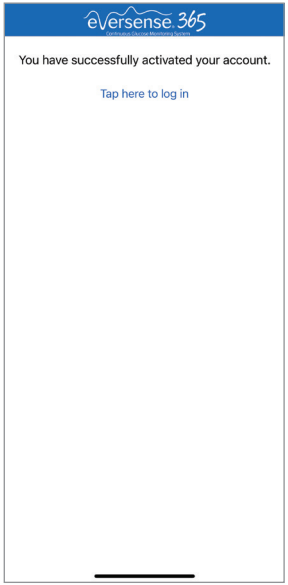


Note: If you have not received the confirmation email with the link to activate your account within a few minutes, check your spam folder. After clicking the link in the email, the app will display that the account was successfully activated.

4. The app will open. Tap the link to log in.

- Enter your email address and password and tap **LOG IN**.

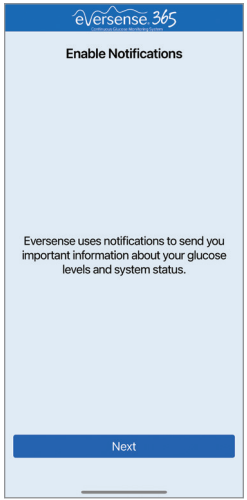
Note: The password is case sensitive.

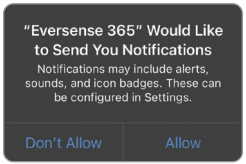


Note: Clicking the link from a laptop or a device other than the smartphone with the app installed will display a page with information on how to complete system setup.

5. The app will ask you to enable notifications and Bluetooth. The prompts may differ slightly between iOS and Android.

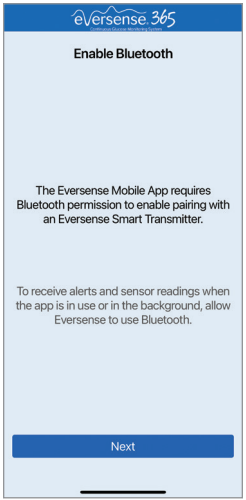
- Tap **Allow** to ensure you receive alerts when the app is in use or in the background.

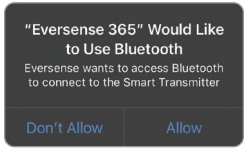




Note: Make sure to Allow Notifications from the app to receive alerts and notifications to your mobile device.

- Tap **OK** to enable Bluetooth for pairing the smart transmitter to the mobile device.



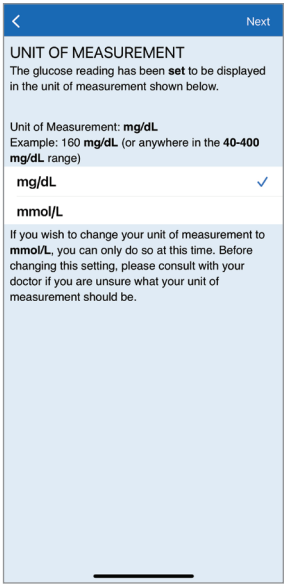


Unit of Measurement and Treatment Decisions

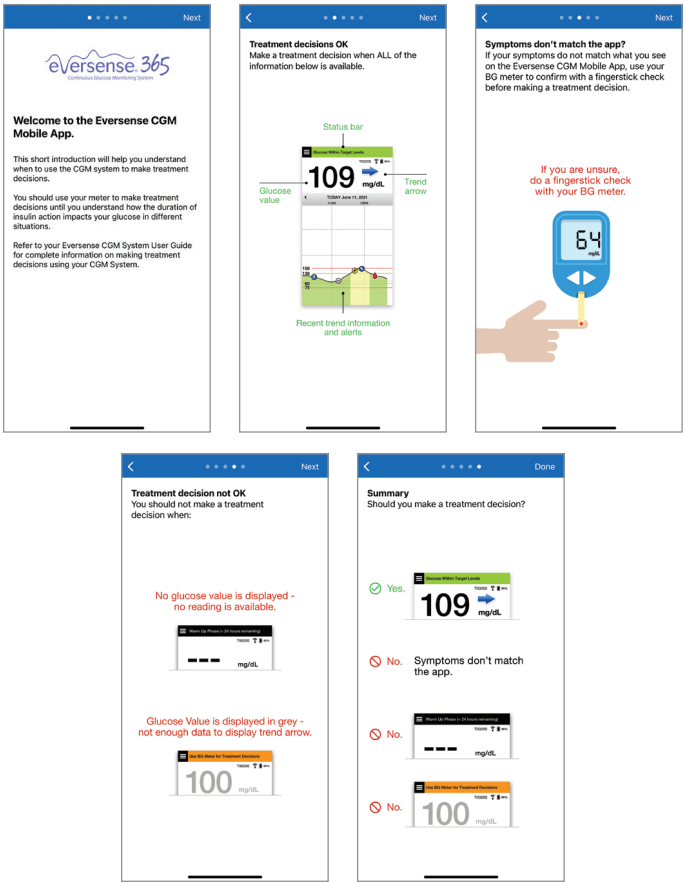
You will need to confirm that the default unit of measurement that will display glucose values is correct for you and your region. The app will provide you with general information about when to make treatment decisions with the Eversense 365 CGM System.

1. **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.**
   - When the unit of measurement is confirmed, tap **Finish**.

Precaution: DO NOT change the unit of measurement unless you have discussed it with your health care provider.



2. Tap through the introduction screens that provide information about when to make treatment decisions with the system.



3. **Choose one of the two options for pairing your smart transmitter.**
   - If you select **I have a Smart Transmitter**, you will begin System Setup to pair the smart transmitter to your mobile device.
   - If you select **I do not have a Smart Transmitter**, you will be taken to the Home Screen.

System Setup

System Setup Menu

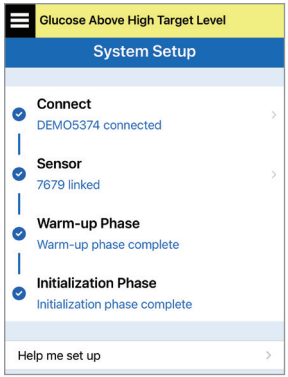
The System Setup Menu will be your guide for setting up your system. Check marks will be displayed after completing each step.

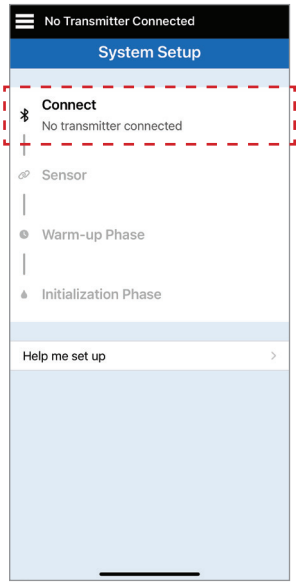
- **Connect:** Pair your smart transmitter to the mobile device.
- **Sensor:** Link your inserted sensor with the smart transmitter.
- **Warm-up Phase:** The 24-hour period after the sensor is linked with the smart transmitter.
- **Initialization Phase:** Enter 4 calibrations 2 to 12 hours apart.

Connect

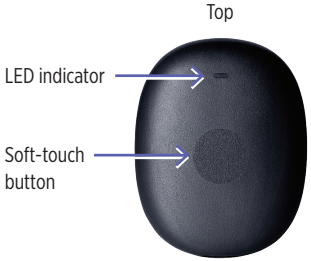
On the System Setup Menu, tap **Connect** to pair your transmitter.

Note: Make sure your smart transmitter is turned on and not plugged into the power supply. If the LED on the smart transmitter does not light up when you tap the soft-touch button, press and hold it for about 5 seconds to turn it on. The transmitter must be within 6 feet of the mobile device to pair.

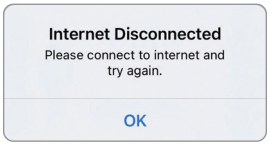




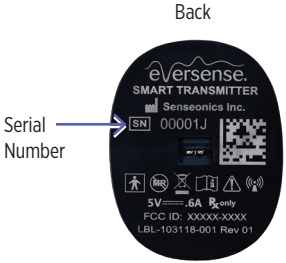
1. **With the smart transmitter turned on, press the soft touch button three times to start pairing mode:**
   - The LED will blink blue to indicate the smart transmitter is in pairing mode.

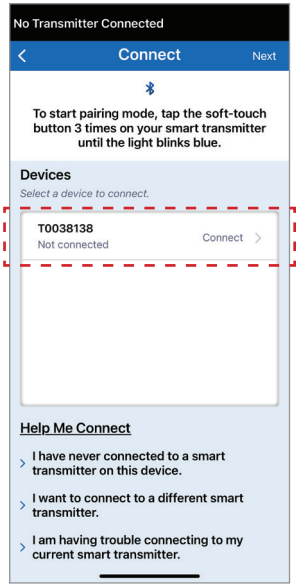


Note: Your mobile device must be connected to the internet in order to pair with the smart transmitter. Internet is only required at pairing.



2. **On the Connect screen, tap your smart transmitter serial number. (Your smart transmitter serial number can be found on the back of the smart transmitter.)**

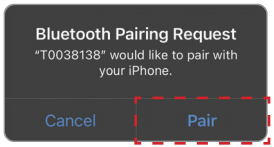




3. A **Bluetooth Pairing Request** pop-up screen appears.

   • Tap **Pair**.

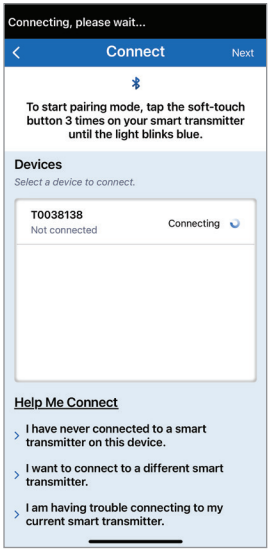
   Note: The smart transmitter can only be paired with one mobile device at a time.

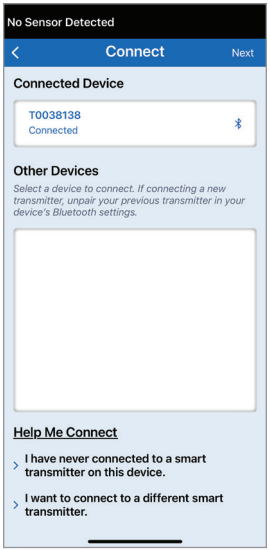


Note: The transmitter will only connect via BLE with compatible software apps. If the system detects unauthorized apps trying to connect with the transmitter, communication with the device will be prevented.

4. The smart transmitter serial number and **Connected** will be displayed under Connected Devices once the pairing is complete. The smart transmitter will provide intermittent vibrations until the smart transmitter is linked with the inserted sensor.

   • Tap **Next**.





Note: The smart transmitter can only be paired with one mobile device at a time. The text next to the smart transmitter serial number you selected will display **Connecting** while the mobile device is trying to connect.

Link sensor

Once pairing is complete, you are ready to link the sensor to your smart transmitter.

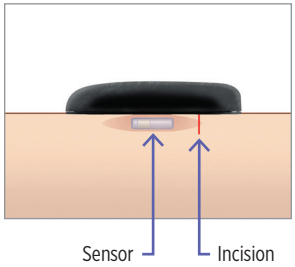
Considerations before linking the sensor

Once your health care provider has inserted your sensor, the smart transmitter and the sensor must be linked to start the **24-hour** Warm-Up Phase. Your smart transmitter can only be linked to one sensor at a time.

IMPORTANT: Please read this entire section before linking your sensor.

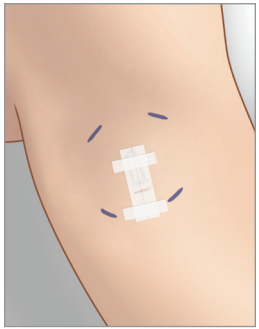
You can link your sensor to the smart transmitter any time after the sensor is inserted and the smart transmitter is paired with the app. To link the sensor, your mobile device must be connected to the internet and your transmitter must be charged, turned on, and paired with your mobile device.

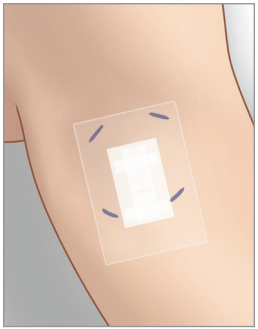
The incision site is closed using Steri Strips and an adhesive bandage, such as Tegaderm is placed over the top. It's important to understand how the smart transmitter should be positioned over the sensor to ensure linking can be completed. The smart transmitter should be centered over the sensor as shown to ensure linking can be completed.



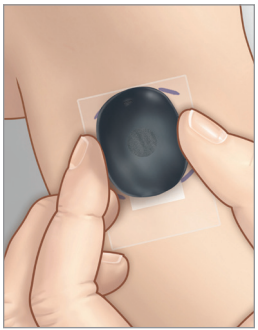
3

When you first link the sensor, with the Tegaderm bandage over the insertion site, the incision is likely in the center of the Tegaderm. This means the sensor is likely above the center of the Tegaderm.

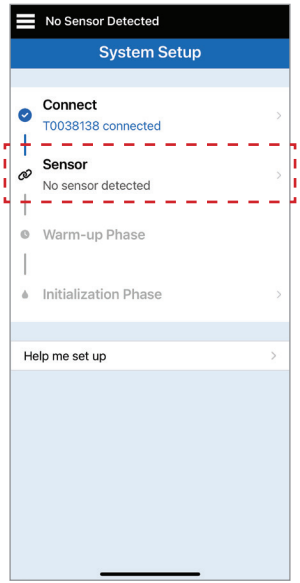




The first time you link the sensor, do not use an adhesive patch on the smart transmitter. Position the smart transmitter over the sensor, slightly above the center of the Tegaderm.



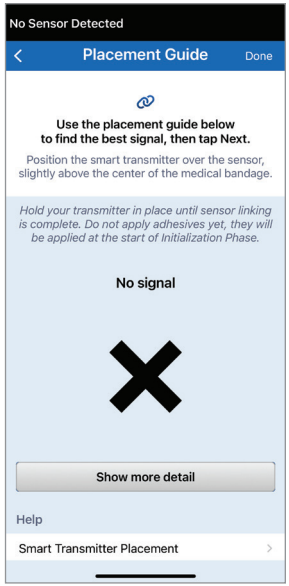
Tap **Sensor** to display the Placement Guide.



Placement Guide

Use the Placement Guide, to find the best signal between the smart transmitter and the sensor.

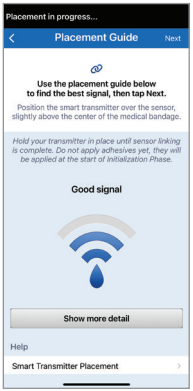
1. **Make sure your smart transmitter is turned ON and that your mobile device has access to the internet.**
   - Position the smart transmitter directly over the inserted sensor until the **Placement Guide** in the app shows some connection and keep in position without applying pressure.

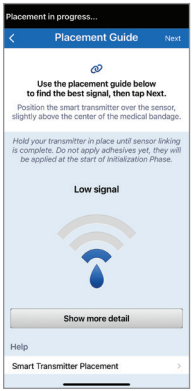


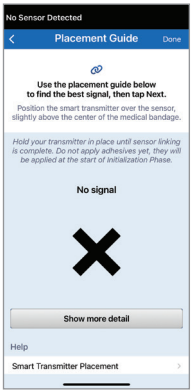
Placement Guide – Signal Strength Screen

Below are the various signal strength levels that may be displayed.

✓ **Tip:** You do not need Excellent signal strength in order to link the sensor or use your system.



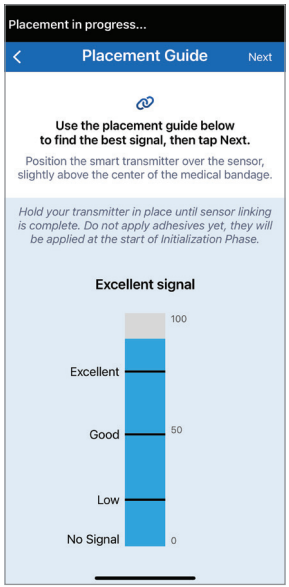




Placement Guide – Show More Detail Screen

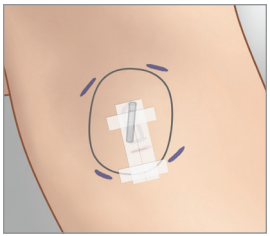
Tapping Show More Detail displays a higher resolution signal strength indicator.

- This may assist you in properly positioning the transmitter over the sensor.



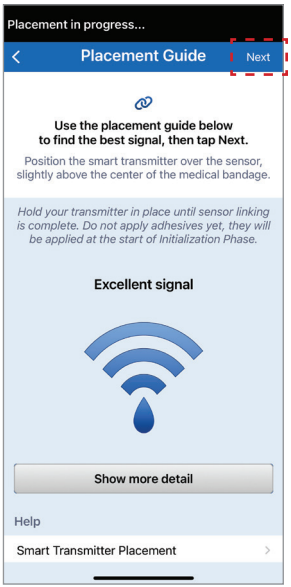
✓ **Tip:** Your sensor may not be precisely perpendicular to the incision. If you find it difficult to get a Good or Excellent signal in the Placement Guide, DO NOT apply pressure. Do try slightly rotating the smart transmitter over the sensor. Wait about 1 second for the Placement Guide to refresh between each adjustment to the smart transmitter's position over the sensor.

Outside of setup, you can access the Placement Guide anytime you want to check the signal between the smart transmitter and the sensor by tapping **Menu** > **Placement Guide**.



2. **Tap Next on the top right corner of the app once you have confirmed there is a signal.**

Note: DO NOT use an adhesive patch with the transmitter if you have not completed the 24-hour Warm-Up Phase. They will be applied at the start of Initialization Phase.

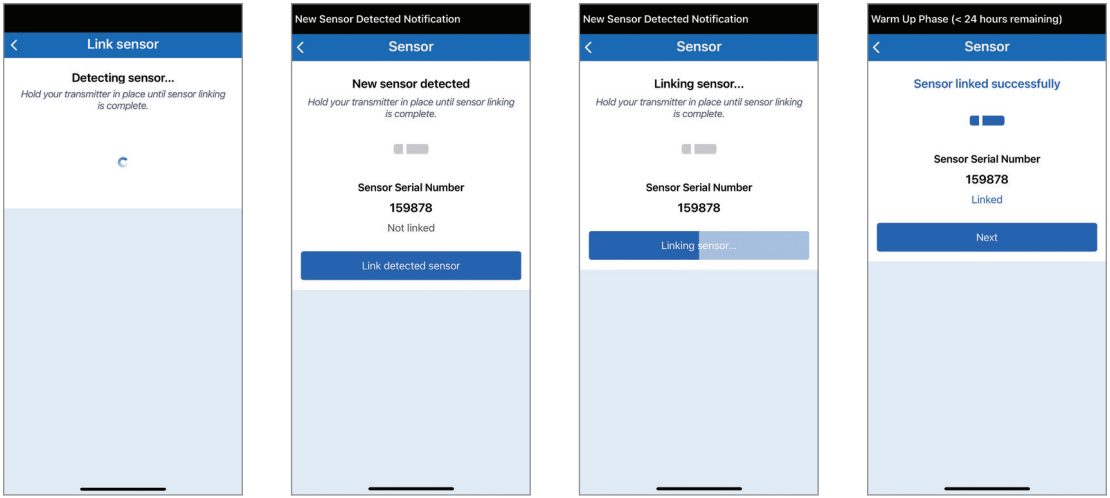


Link Detected Sensor

After establishing the signal using the Placement Guide, you can now link the sensor.

1. **The app will display Detecting sensor. During this time, continue to hold your transmitter in place.**
2. **When the New sensor detected screen is displayed, tap Link detected sensor.**

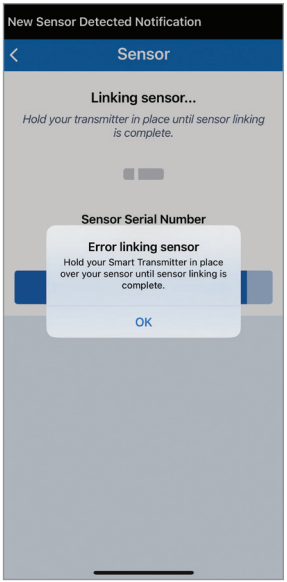
   Note: It may take up to 5 minutes for the **New sensor detected** screen to be displayed.



The linking process will begin. It may take up to 10 minutes for the process to complete. DO NOT remove the smart transmitter from your sensor site until the progress bar is completed and **Sensor linked successfully** is displayed.

3. **Tap Next.**

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

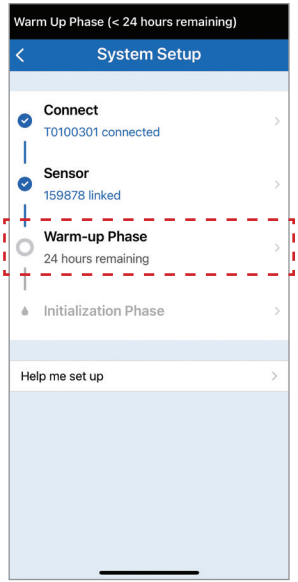


After the sensor is linked, you can remove the smart transmitter and charge for the next 24 hours.

Precaution: 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.

Warm-Up Phase

The sensor requires a 24-hour Warm-Up Phase before glucose values will be collected by the smart transmitter. **During the Warm-Up Phase, you do not need to wear the smart transmitter.** Once the Warm-Up Phase is complete, you will receive a notification to let you know that you can continue with the next step in your system setup. At that time, you can turn ON the smart transmitter and place it over the sensor with the adhesive patch. The system will prompt you to calibrate using the app.



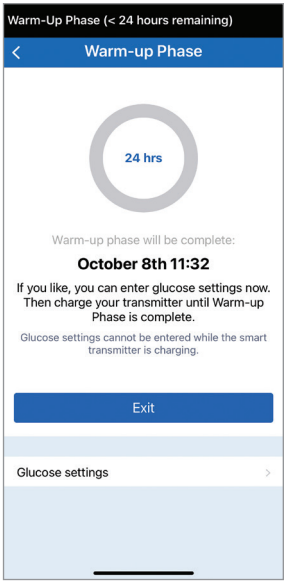
Warning: The system will not provide readings during the 24-hour Warm-Up Phase and until a second calibration is successful during the Initialization Phase. During this time, you should monitor your glucose using a home blood glucose monitor.

In the System Setup Menu, tap **Warm-up Phase** to see details about Warm-up Phase duration.

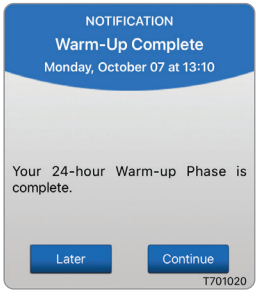
- Tap **Exit** to go to the Home Screen

  or

- Tap **Glucose settings** to set your target and alert settings. See *Glucose Settings* for more information.



Once the 24-hour Warm-Up Phase is complete, the app will notify you to begin Initialization Phase.

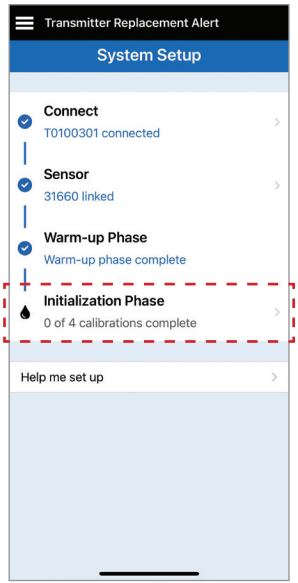


Initialization Phase

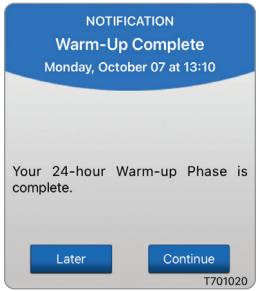
During this phase, 4 fingerstick blood glucose meter calibrations are required.

- The 4 calibrations must be spaced 2 to 12 hours apart, and all 4 calibrations must be completed within a 36 hour period. After 8 hours without a calibration entry, no glucose data will be displayed.
  - 1st calibration = 24 hours after sensor is linked.
  - 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: Your smart transmitter must be turned on, paired with the app, and linked to your sensor in order to calibrate.

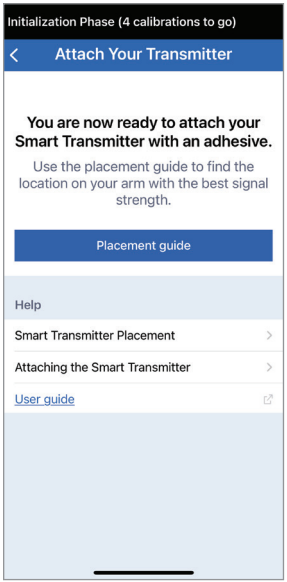


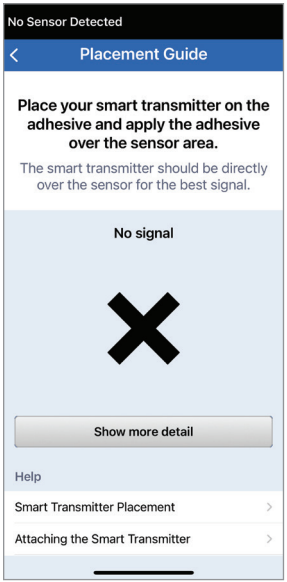
1. On the Warm-Up Complete notification, tap **Continue** to begin the Initialization Phase.



2. Tap on **Placement Guide**.

Until the transmitter is secured over the sensor and a signal is established, the **Placement Guide** screen will show **No signal**. See next section to *Secure the Smart Transmitter over Inserted Sensor*.





Using the Adhesive Patches

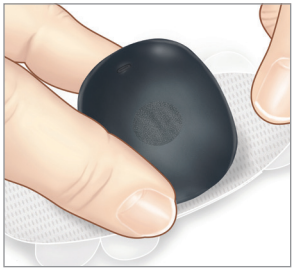
The smart transmitter must be positioned on the skin directly over the sensor with the disposable adhesive patch. Each adhesive patch is designed to be replaced daily. There is an adhesive side that attaches to the back of the smart transmitter and a silicone adhesive side that attaches to the skin. Both the skin and smart transmitter surfaces should be clean and dry to secure the adhesive patch. During the first few days after insertion, you will wear the smart transmitter over the Tegaderm. Leave the Tegaderm in place for as long as your health care provider instructs.

Note: You will receive adhesive patches from your health care provider.

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

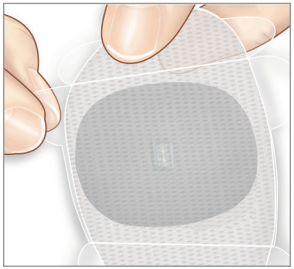
1. **Peel off the paper backing with the smart transmitter outline on it. Try not to touch the sticky portion of the adhesive in the center.**

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.

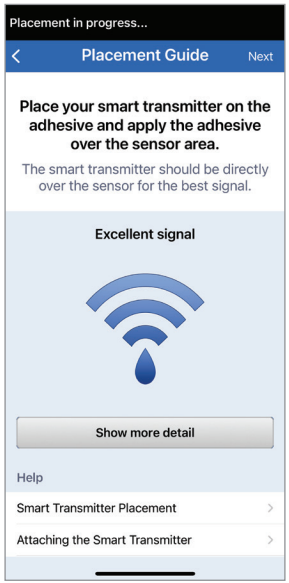
- For the best signal, the smart transmitter must be placed directly over the sensor. Signal strength can be improved by rotating the smart transmitter over the sensor.



You may wear the smart transmitter over the Tegaderm with the adhesive patch after the 24-hour Warm-Up Phase is complete.

4. Check the connection between the smart transmitter and the sensor.

- Use the **Placement Guide** when attaching your smart transmitter to ensure connection between the sensor and smart transmitter.

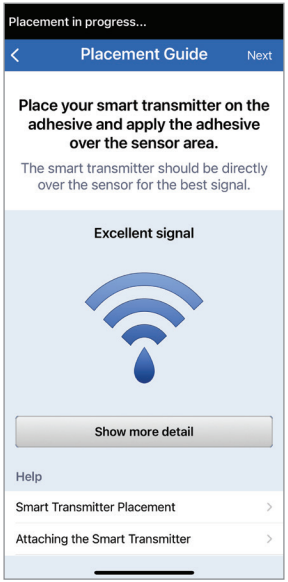


Note: To see more information about signal strength and transmitter positioning, see *Placement Guide – Show More Detail Screen* in the *Linking the Sensor* section.

5. **Once a signal is achieved, press the adhesive patch firmly on skin surface over the sensor. DO NOT use excessive pressure for the first several days after insertion.**
   - 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.

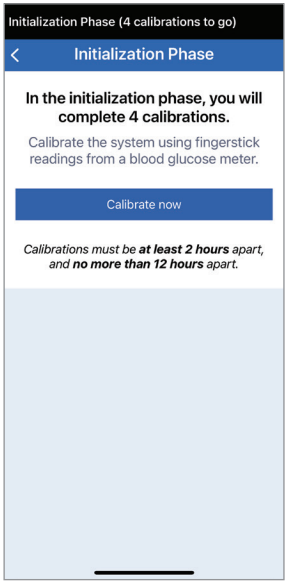
7. Tap **Next**.
   - Confirm there is a signal before continuing with the next step.



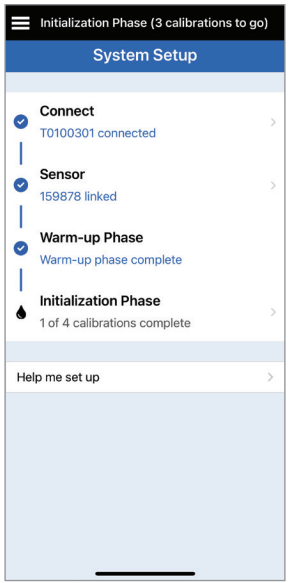
8. **Tap Calibrate now. Enter your blood glucose reading from your meter. See *Calibrating the System* for more details on entering calibrations.**

Note: The app will remind you when to enter calibrations with a Calibrate Now Notification or Alert.

During the Initialization Phase, glucose readings will start displaying in the app a few minutes after the 2nd calibration is successfully completed.



Once Initialization Phase has concluded your System Setup is complete.



Note: Under certain conditions, the system may re-enter the Re-Initialization Phase. See *Calibrating the System* for more information.

4. Calibrating the System

This section describes the steps for calibrating the system.

Warning: DO NOT use alternative test sites such as your forearm when entering BG values for calibration.

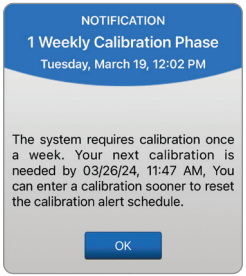
To ensure best performance, routine calibration is required using fingerstick readings from a blood glucose meter. Any commercially available meter may be used. Once your sensor has been inserted and linked to your smart transmitter, the system begins a 24-hour Warm-Up Phase. No calibration is required during this phase.

There are three calibration phases:

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

1 Daily Calibration Phase – After the Initialization Phase, you must complete a fingerstick calibration every 24 hours for 13 days.

1 Weekly Calibration Phase – In the 1 Weekly Calibration Phase, you must complete a fingerstick calibration once a week.



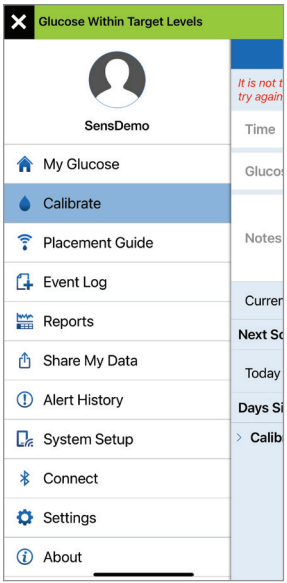
Warning: In the 1 Daily Calibration Phase, the system requires calibration every 24 hours in order to provide accurate readings. In the 1 Weekly Calibration Phase, the system requires calibration once a week. You should not use CGM readings to make treatment decisions unless you have followed the instructions for daily and weekly calibration.

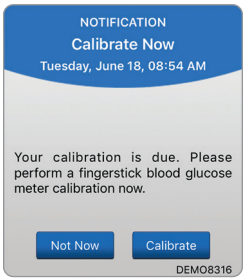
How To Calibrate

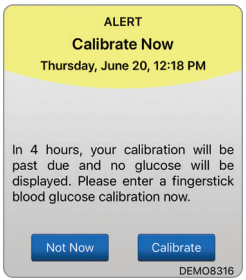
Warning: **Always calibrate the system using only a fingerstick blood sample. DO NOT use an alternative site (such as forearm or palm) blood glucose reading to calibrate the system.**

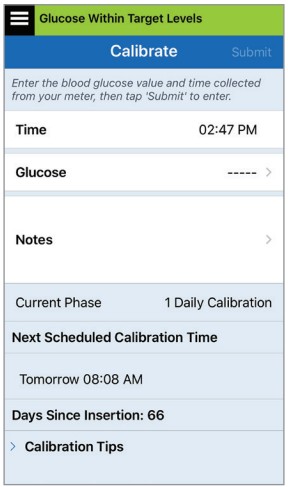
Note: You can enter additional calibration readings as long as each calibration is at least one hour apart.

1. **You can enter the calibration value by tapping Calibrate from the main menu or from the Calibrate Now Notification or Alert.**

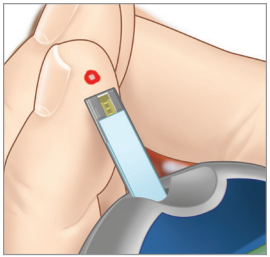




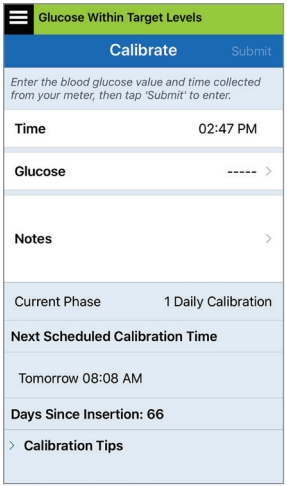


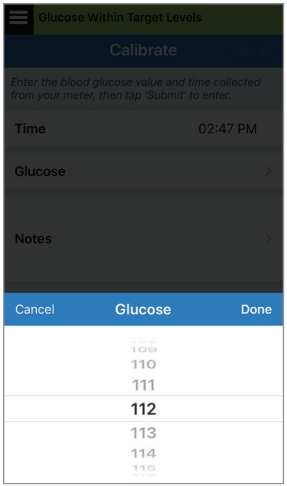


2. Obtain a fingerstick reading from your blood glucose meter.



3. Tap **Glucose** and enter the value from your fingerstick blood glucose meter.
   - Tap **Done**.
   - Tap **Notes** to enter any notes.
   - Tap **Done**.

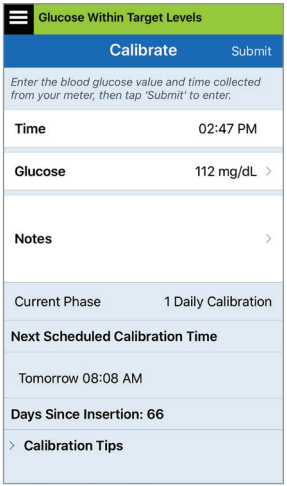




Note: DO NOT enter a calibration value that is older than 10 minutes.

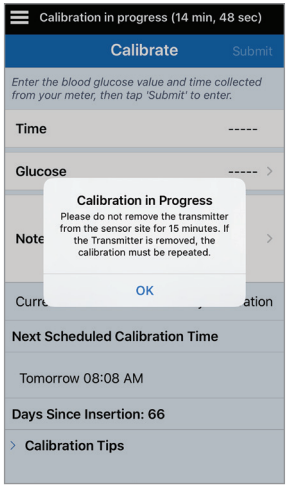
4. The **CALIBRATE** screen now shows the time and glucose reading you entered. If not correct, repeat steps 3.

- When correct, tap **Submit**.



5. The **CALIBRATION IN PROGRESS** screen appears.

- Tap **OK**.



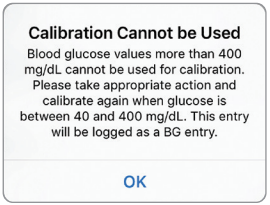
IMPORTANT: The smart transmitter should not be removed from over the sensor for at least 5 minutes before the entry to 15 minutes after the entry while calibration is in progress. The Status Bar at the top of the screen lets you know when calibration will be complete. If the smart transmitter is removed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

6. The **MY GLUCOSE** screen appears with a grey blood drop icon to identify your fingerstick calibration. The blood drop will turn red when the calibration value is accepted.

Note: There may be conditions when your calibration is NOT accepted.

Calibration will *NOT* be accepted if:

- ✖ Blood glucose meter reading is less than 40 mg/dL.
- ✖ Blood glucose meter reading is greater than 400 mg/dL.



- ✖ Your smart transmitter was removed or could not collect sensor glucose data during the 15 minutes after you entered your calibration value.

Routine calibration is critically important to ensuring the best performance of the 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. Dry thoroughly before taking a blood glucose meter reading. It is very important to have clean, dry hands when you measure 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 40 mg/dL.
- ✘ Blood glucose meter reading is greater than 400 mg/dL.
- ✘ Your smart transmitter was removed or could not collect sensor glucose data 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 calibrations are required.

- The 4 calibrations must be spaced 2 to 12 hours apart. All 4 calibrations must be completed within a 36 hour period. After 8 hours without a calibration entry, no glucose data will be displayed.

IMPORTANT: If your smart transmitter is not turned on and paired with the app and linked to the 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 within a 12-hour period during the Initialization Phase.
- Not completing all 4 calibrations within 36 hours during the Initialization Phase.
- Not completing required calibration entries during the Daily or Weekly Calibration Phase.
  - 1 calibration every 24 hours when the system is in 1 Daily Calibration Phase.
  - 1 calibration a week when the system is in 1 Weekly Calibration Phase.
- When the last several blood glucose meter measurements are significantly different than the sensor glucose values.
- When you receive a Sensor Check Alert.

B. 1 Daily Calibration Phase

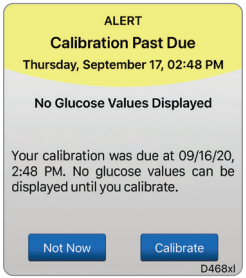
The 1 Daily Calibration Phase requires a blood glucose fingerstick calibration every 24 hours once the initialization phase is complete, and lasts through day 13.

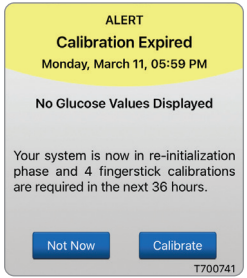
- 24 hours after your last successful calibration, the system prompts you to calibrate.
- You may enter calibrations more frequently. Daily calibration entries must be spaced at least one hour apart.
- If you do not calibrate within 48 hours, the system will display a Calibration Past Due Alert and no glucose values will be available until a calibration value is entered. After 72 hours without a calibration value entered, the system will display a Calibration Expired Alert and the system returns to Initialization Phase.

C. 1 Weekly Calibration Phase

The 1 Weekly Calibration Phase requires a blood glucose fingerstick calibration once a week after day 13.

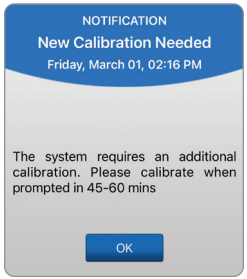
- 1 week after your last successful calibration, the system prompts you to calibrate.
- You may enter calibrations more frequently. Calibration entries must be spaced at least one hour apart.
- If you do not calibrate within 8 days from the time of your last successful calibration, the system will display a Calibration Past Due Alert and no glucose values will be available until a calibration value is entered. After 9 days without a calibration value entered, the system will display a Calibration Expired Alert and the system returns to Initialization Phase.





Warning: **Certain conditions and alerts will prevent glucose data from being displayed. During these times, you should use a home blood glucose monitor to make treatment decisions. You should carefully read the *Alerts and Notifications* section of this *User Guide* to understand these conditions.**

Note: After a calibration is complete, in some cases the system may request an additional calibration.



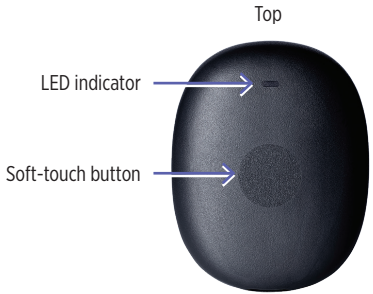
5. Daily Transmitter Wear

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

Once the Warm-Up Phase has ended, the Initialization Phase begins. Now you're ready to start wearing the smart transmitter. For the first few days, you'll wear the smart transmitter over the Tegaderm. Always start with a transmitter that has been charged for at least 15 minutes. Your smart transmitter communicates with both the sensor and the app to provide CGM information.

Your smart transmitter does the following:

- Powers the sensor.
- Calculates and stores 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 USB port in the transmitter and the charging cable.
- Uses USB port with charging cable to download data to compatible external applications.
- Multi-color LED to indicate various system conditions.
- 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 3.2 feet (1 meter) 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 a blood glucose meter calibration when prompted.
- ✓ Pay attention to alerts and notifications you receive from your smart transmitter and mobile device.
- ✓ Replace the 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 can take up to 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 similarly to any other Bluetooth device. Be sure to follow the specific safety guidelines mandated by the airline.
- ✓ Until the smart transmitter has received the first glucose value after positioning over the sensor, the status bar on the app will display Collecting Data. You may see this status bar just after charging the smart transmitter.

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.

Smart Transmitter Care and Maintenance

- Keep the smart transmitter clean (free of visible dirt) and protected when not in use. Wipe the outside with a cloth between uses to keep clean.
- Contact Customer Support for a replacement transmitter if you receive a Battery Error Alert.
- Charge the smart transmitter whenever 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.
- Never stick any object other than the charging cable into the USB port of the transmitter. Doing so may damage the transmitter and void your warranty.
- If the USB port appears to be obstructed, contact Customer Support for a replacement.

IMPORTANT: DO NOT insert the charging cable into the charging port while the port is wet.

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 power left.

  Or

- Check the battery icon and percentage 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, tap the soft-touch button in the center of the smart transmitter once. The LED will blink green once if the battery has ~ 24 hours of power. Charging for 15 minutes each day will ensure the transmitter has ~24 hours of power. See the following chart for more information on the LED indicators. For more information on using the smart transmitter's soft-touch feature, see *Daily Transmitter Wear*.

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
Blinking blue when the button is tapped 3 times in 5 seconds	Pairing mode	Pair smart transmitter with mobile device.
Does not blink when the button is tapped	Smart transmitter off	Touch and hold the button for 3 seconds to turn on.
Blinks green (once) when the button is tapped	~24 hours battery power remaining	No immediate action required.
Blinks orange (once) when the button is tapped	Low battery, less than ~24 hours 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.
Blinks orange	Transmitter and sensor communication interrupted or not yet linked	Position transmitter over sensor site. If prompted, link sensor.

- **During smart transmitter charging:**

LED Status	Battery Status	Action
Glowing orange when connected to the USB cable	Less than 24 hours of power available	Charge for at least 15 minutes or until the LED flashes green.
Flashing green when connected to the USB cable	About 24 hours of power available	Use or continue charging until LED is solid green.
Solid green when connected to the USB cable	100% charged	Ready to use.

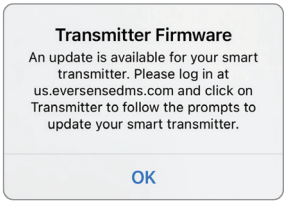
Upgrading your Eversense Smart Transmitter

As an Eversense CGM System user, you have access to the Eversense Data Hub that is designed to upgrade the software in your smart transmitter, giving you access to new features and upgrades for your eligible smart transmitter.

You will see this icon (!) on the Main menu, next to **About**, when an upgrade is available.

From the **About** screen, go to **My Transmitter** > **Firmware Version**, and tap on the icon to confirm an upgrade is available.

For information on how to download and install the Eversense Data Hub, go to www.eversensediabetes.com to see the *Eversense Data Hub User Guide*.



6. Help Me Set Up Menu

Help Me Set Up includes resources to guide you through the steps for replacing your smart transmitter and sensor, either individually or both at the same time.

You can also access helpful tools such as system tutorials, this *User Guide*, and onboarding videos.

- Tap **Menu** > **System Setup** > **Help me set up**

I have a new transmitter

When you receive a new or replacement smart transmitter and are ready to start using that transmitter, tap **I have a new transmitter**. Follow the prompts to begin the pairing process and link to your existing sensor. Once linking is complete, the system will be in initialization phase.

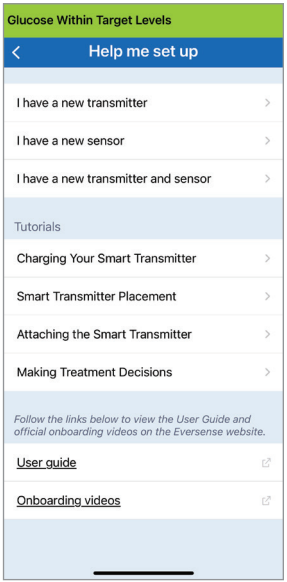
I have a new sensor

When you receive a new or replacement sensor, tap **I have a new sensor** to link the new sensor to your current smart transmitter. The system will begin the 24-hour Warm-Up Phase followed by Initialization Phase.

I have a new transmitter and sensor

When you receive a new or replacement sensor and a new or replacement smart transmitter, tap **I have a new transmitter and sensor** and follow the prompts. Once linking is complete, the system will begin the 24-hour Warm-Up Phase followed by Initialization Phase.

For more information on system setup, see *System Setup*.



Tutorials

During system setup, you may have seen these tutorials. The tutorials are helpful resources you may access at any time.

Additional Resources

The *User Guide* and system onboarding videos can be accessed by tapping the link. An internet connection is required to access these resources.

7. Using the App

This section describes the Eversense 365 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 app, your smart transmitter will not send glucose data to the app until you log back in.

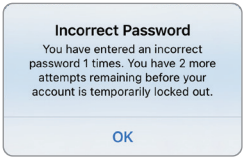
On the **MY GLUCOSE** screen, you have easy access to:

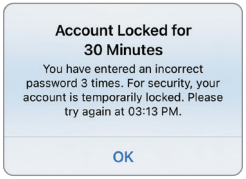
- Real-time sensor glucose measurements.
- Rate and direction of your changing glucose levels.
- Graphical trends of your glucose levels.
- Alerts (hypoglycemia or hyperglycemia).
- Events such as meals, exercise, and medications.

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

Eversense Account Management

For security purposes if you enter an incorrect password three consecutive times in the app, your account will be locked for 30 minutes. During this time, you will not have access to your CGM data on the app.

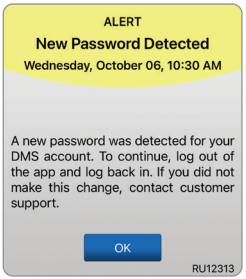


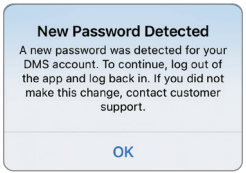


Precaution: If you cannot access your CGM data, you should monitor your glucose using a home blood glucose monitor.

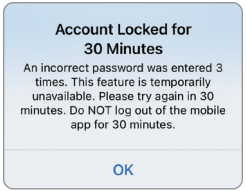
The app will periodically check to confirm your log in information has not been changed via your Eversense DMS account.

If you change your account password from your DMS log in screen or the DMS Change Password page, you must log out of the app and log back in using the new password. If the passwords do not match, the app will notify you. Some features are not available, including not being able to sync your data to your DMS account, not being able to add Eversense NOW users to your Circle, and not being able to make changes to your profile picture.





If you enter an incorrect password three times on your DMS log in page, some app features may be unavailable for 30 minutes, including no data syncing to your DMS account, no Eversense NOW users can be added to your Circle, and no changes to your profile picture can be made. You should not log out of the app during this time.



Check Your Mobile Device Settings

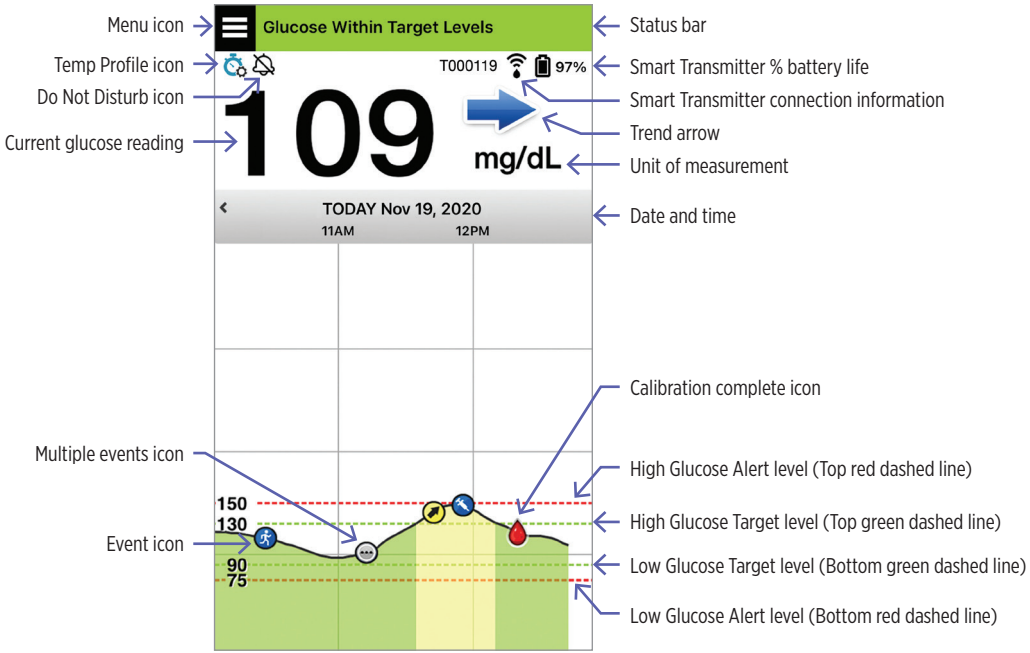
You will need a mobile device (such as your smartphone) to use the system. It is very important that your mobile device is set up properly to ensure accurate display of your glucose data in the app. Follow the manufacturer's instructions for your mobile device to set up the following:

- 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, some apps and settings such as Driving Mode may automatically enable Do Not Disturb. Please refer to your mobile device instructions for more information.
- If you have your mobile device set to Do Not Disturb, you will not hear any notifications from the app.*

*** For iOS 12 and above, and Android 6 and above, you can allow the Low Glucose and Out of Range Low Glucose Alerts to override your phone sound settings. See *Sound Settings* for more information.**

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.



Before making a treatment decision, you should take into account the sensor glucose value, the trend graph, the trend arrow and any alerts from the system. If no trend arrow is displayed, the system does not have enough data to display direction and rate of change. You should not make a treatment decision based solely on the sensor glucose value.

Note:

- You can view a snapshot of system information on your iOS or Android devices. For information on managing widgets, consult your mobile device *User Guide*. The Eversense Widget is not available on all operating systems.
- You can view the **MY GLUCOSE** screen in landscape orientation 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 life	Indicates battery power left in the smart transmitter with both an icon and percentage.
Smart Transmitter connection	Indicates the strength of your smart transmitter connection with the sensor or with the mobile device.
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 icon	Indicates multiple events have occurred at the same time.
Event icon	Indicates manually entered events (e.g., exercise). See *Logging Events* for more information.

Calibration icons	Indicates calibration entry status.
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 app: My Glucose Calibrate Alert History Event Log Reports Share My Data Placement Guide Connect Settings About

Smart Transmitter Connection Icons

	When the icon is a grey blood drop with an X, no smart transmitter is detected. You will see this icon before you pair your smart transmitter to your app and any time the BLE connection between the smart transmitter and your app is interrupted.
	When the icon is a red blood drop with an X, no sensor is detected. You will see this icon before you link a sensor to your transmitter and any time a linked sensor cannot be detected.
	When the icon is a grey or black blood drop with bars on top, the NFC connection between the sensor and smart transmitter has been established. The bars indicate the strength of the connection. Signal strength information is also displayed in **Main Menu** > **Placement Guide** in the app. **Reminder: You cannot link to a sensor until your transmitter is paired with the app.**

Trend Arrows

There are 7 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 0.0 mg/dL and 1.0 mg/dL per minute.
	Moderately rising glucose level, rising at a rate between 1.0 mg/dL and 2.0 mg/dL per minute.
	Moderately falling glucose levels, falling at a rate between 1.0 mg/dL and 2.0 mg/dL per minute.
	Rapidly rising glucose levels, rising at a rate between 2.0 mg/dL and 3.0 mg/dL per minute.
	Rapidly falling glucose levels, falling at a rate between 2.0 mg/dL and 3.0 mg/dL per minute.
	Very rapidly rising glucose levels, rising at a rate more than 3.0 mg/dL per minute.
	Very rapidly falling glucose levels, falling at a rate more than 3.0 mg/dL 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 to calculate a trend arrow, it is not displayed and the glucose value is grey instead of black.

Before making a treatment decision, you should take into account the sensor glucose value, the trend graph, the trend arrow and any alerts from the system. If no trend arrow is displayed, the system does not have enough data to display direction and rate of change. You should not make a treatment decision based solely on the sensor glucose value.

Understanding Treatment Decisions with CGM

Read this entire *User Guide* and be sure you are familiar with when you should and should not make treatment decisions based on your CGM information. Before you begin using the system to make treatment decisions, talk with your health care provider about understanding how food, insulin, medications, stress, and exercise impact your glucose.

IMPORTANT:

- If your symptoms do not match the sensor glucose information displayed, or the app is not displaying both a number and a trend arrow, then use your BG meter to make treatment decisions.
- Use your BG meter to make treatment decisions until you understand how the system works for you. It may take days, weeks, or even months for you to be comfortable using your CGM data to make treatment decisions.

Take your time and follow your health care provider's recommendation for when to use the system instead of your BG meter.

Sensor Glucose and Blood Glucose

Sensor glucose is measured in the interstitial fluid, not in blood. Because of this, sensor glucose values may lag behind blood glucose values. For example, when your CGM trend arrow shows rapidly falling glucose, your blood glucose may be lower than the number shown; or when your CGM trend arrow shows a rapid rise, your blood glucose may be higher than the number shown. These examples are more likely when your glucose is changing rapidly, such as after a meal, after dosing insulin, or during and after exercise. Stress, illness, and even some medications you take can also impact your glucose. Sometimes the right treatment decision is to wait and check your CGM data frequently before taking action.

Early Wear Time

During the 24-hour Warm up Phase, glucose values are not displayed. Also, during early wear time as your insertion site heals, your sensor glucose values may not match your blood glucose values as closely as they will when healing is complete. Use your BG meter to make treatment decisions during the Warm up Phase and until you are confident with your CGM values. Always remember, if the way you feel does not match the glucose value and trend arrow, use your BG meter.

Bluetooth Communication

The smart transmitter communicates wirelessly with your mobile device via Bluetooth to display your glucose reading. If the connection between your smart transmitter and your mobile device is interrupted, you will not see a glucose value or a trend arrow. Use your BG meter to make treatment decisions if your smart transmitter is not communicating with your mobile device.

On-body Vibe Alert

Your smart transmitter vibrates when you have passed the glucose alert levels you set. However, do not use on-body vibe alerts to make treatment decisions. When you receive an on-body vibe alert, check your glucose reading and trend arrow on your app. See *Alert Description* for information.

Remote Monitoring with Eversense NOW

Treatment decisions must not be made based on CGM information displayed on the Eversense NOW Remote Monitoring App. Remote monitoring relies on data being sent from your mobile device through the Eversense cloud and then to the Eversense NOW App. Interruptions in any of these connections will delay data being displayed in Eversense NOW. Only the CGM information sent directly from the smart transmitter to your mobile device can be used to make treatment decisions.

Discuss with Your Health Care Provider

Meals

Different types of meals and foods can impact your glucose levels and trend arrows in different ways, as can conditions such as delayed gastric emptying. Some foods will raise your glucose more rapidly than others. Before using CGM data to make treatment decisions, discuss with your health care provider about how to manage insulin dosing for different types of food, and how to accurately calculate carbohydrates.

Insulin

Insulin takes time to work. For example, depending on the brand of rapid-acting insulin used, onset of action can be from 5 to 15 minutes, peak effect in 1-2 hours and duration of action of 4-6 hours. Be sure to understand when you can expect the insulin you take to start lowering your glucose, when its maximum effectiveness is, and how long it lasts in your body continuing to lower your glucose. Working with your health care provider to understand the onset, peak, and duration of your insulin action to help you avoid stacking insulin. Stacking insulin is when you take a dose of insulin while a previous dose is still working at lowering your glucose. Hypoglycemia, sometimes severe, can result. Rather than reacting and taking insulin based on a high CGM value, be sure to consider whether insulin from your most recent dose is still actively lowering your glucose.

Exercise

Even relatively mild exercise, if it is not part of your normal routine, may cause your glucose to change more rapidly than usual. If your symptoms do not match your CGM value, or if your CGM value and trend arrow are not what you expect, use your BG meter to make treatment decisions. Some people experience delayed-onset hypoglycemia hours after exercise. You should follow your health care provider's recommendation on dosing insulin following exercise to avoid low glucose.

Illness & Stress

When you are ill or stressed, your glucose can be impacted, and this may be a consideration for making treatment decisions. Keep in mind that stress is not always negative. You could find your glucose levels changing while headed on vacation or going to a fun social event. Your health care provider can help you create a plan for treatment decisions when you are sick or in stressful situations.

Medications

Understand how the medications you take impact your glucose. Some diabetes medications work to decrease your glucose, and some medications, like steroids, may increase your glucose levels. With the Eversense 365 CGM System, medications of the Tetracycline class, such as tetracycline, doxycycline, minocycline, tigecycline, may falsely lower glucose and you should not rely on CGM readings when taking drugs in this class. Talk with your health care provider about the medications you take and what to consider about them when making treatment decisions.

Mannitol or sorbitol, when administered intravenously, or as a component of an irrigation solution or peritoneal dialysis solution, may increase blood mannitol or sorbitol concentrations and cause falsely elevated readings of your sensor glucose results. Sorbitol is used in some artificial sweeteners, and concentration levels from typical dietary intake do not impact sensor glucose results.

Glucose Alerts

Your health care provider will help you determine the target range and glucose alert levels that are right for you. Pay careful attention to your CGM glucose alerts – you may need to make a treatment decision. When you receive an Out of Range Glucose Alert, the sensor glucose value is below 40 mg/dL with LO displayed instead of a number, or above 400 mg/dL with HI displayed instead of a number. Ask your health care provider about how treating very low and very high glucose may be different from the way you otherwise treat. Always use your BG meter to make a treatment decision when LO or HI is displayed.

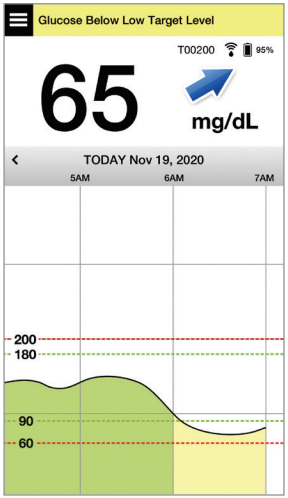
Planning Ahead

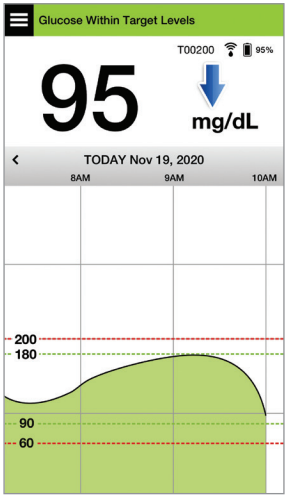
Carefully consider the time of day when making treatment decisions, just like you do when using your BG meter. For example, if your glucose is high and rising just before bedtime, adjust your insulin dose according to your health care provider's recommendation. Also think about how to treat if you are planning to exercise or will be sitting in a meeting all day. Your health care provider may recommend adjusting your treatment decision based on what is about to happen in order to avoid high or low glucose.

Making Treatment Decisions

To make a treatment decision, you should consider:

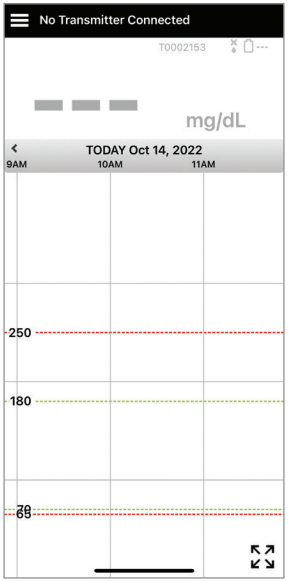
- Status bar information.
- Current sensor glucose value – the current glucose value should be displayed in black.
- Trend arrow – a trend arrow should be displayed.
- Recent trend information and alerts.

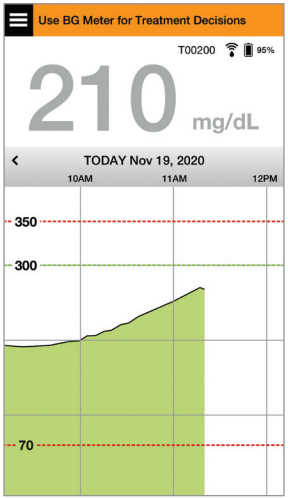




When to NOT make a treatment decision:

- No glucose value is displayed.
- No trend arrow is displayed.
- Your symptoms do not match the glucose information displayed.
- The current sensor glucose value is displayed in grey.
- The status bar is displayed in orange.
- You are taking medications of the tetracycline class.





Note: Always refer to the glucose information on your Eversense 365 App on your smartphone to make treatment decisions. Do not use a secondary display like the Apple Watch or Eversense NOW.

Trend Arrows and Treatment Decisions

Trend arrows show the direction and rate of change of your glucose to give you an idea of where your glucose is headed. Talk with your health care provider about using trend arrows to help you make treatment decisions. Generally, if the arrow is going down, you may consider taking less insulin, and if the trend arrow is going up, you may take more. Be careful not to take too much insulin in a short time, as that could result in low glucose from stacking insulin. The trend arrows are listed below, along with how you may use them when considering treatment. Talk with your health care provider about making adjustments to treatment based on trend arrows. **Never make a treatment decision using CGM if there is no arrow displayed.**

Trend Arrow		What it Indicates	Low Glucose	High Glucose	Glucose in Range
No trend arrow		Not enough data to calculate glucose trend direction or rate of change.	**Do a fingerstick blood glucose check with your BG meter before making a treatment decision, even if your glucose is in range.**		
	Glucose is changing gradually (1.0 mg/dL/ minute or less).	Your glucose could rise or fall up to 15 mg/dL within 15 minutes.	Consider treating with carbs. If you've recently taken insulin, check your CGM value and trend arrow frequently.	If you've recently taken insulin or are about to exercise, wait and check your CGM value and trend arrow frequently. If you have not recently taken insulin, consider adjusting insulin correction dose up.	No treatment, but if you've recently taken insulin or are about to exercise, check your CGM value and trend arrow frequently.

Trend Arrow		What it Indicates	Low Glucose	High Glucose	Glucose in Range
	Glucose is falling at a moderate rate (between 1.0 and 2.0 mg/dL/minute).	Your glucose could drop between 15 and 30 mg/dL within 15 minutes.	Treat with carbs and consider if you recently have finished exercising or if you may have taken too much insulin.	If you've recently taken insulin or are about to exercise, wait and check your CGM value and trend arrow frequently before making a treatment decision.	Treat with carbs and consider if you recently have finished exercising or if you may have taken too much insulin.
	Glucose is falling at a rapid rate (between 2.0 and 3.0 mg/dL/minute).	Your glucose could drop between 30 and 45 mg/dL within 15 minutes.			
	Glucose is falling at a very rapid rate (> 3.0 mg/dL/minute)	Your glucose could drop 45 mg/dL **or more** within 15 minutes.			

Trend Arrow		What it Indicates	Low Glucose	High Glucose	Glucose in Range
	Glucose is rising at a moderate rate (between 1.0 and 2.0 mg/dL/minute).	Your glucose could rise between 15 and 30 mg/dL within 15 minutes.	If you've recently taken insulin or are about to exercise, wait and check your CGM value and trend arrow frequently before making a treatment decision.	If you've recently taken insulin or are about to exercise, wait and check your CGM value and trend arrow frequently. If you have not recently taken insulin, and are not about to exercise, consider adjusting insulin correction dose up.	If you've recently taken insulin or are about to exercise, wait and check your CGM value and trend arrow frequently before making a treatment decision. If you have not recently taken insulin or finished exercise, consider adjusting insulin correction dose up.
	Glucose is rising at a rapid rate (between 2.0 and 3.0 mg/dL/minute).	Your glucose could rise between 30 and 45 mg/dL within 15 minutes.			
	Glucose is rising at a very rapid rate (> 3.0 mg/dL/minute).	Your glucose could rise 45 mg/dL **or more** within 15 minutes.			

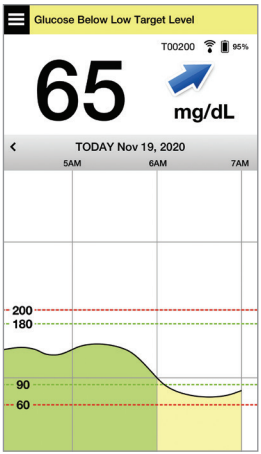
What Would You Do

This section provides examples of some situations you may encounter. It's important to consider what has happened and what is about to happen when making treatment decisions with CGM. Review these examples carefully, and think about what you would consider before making a treatment decision. If you're not sure, always check your BG with a fingerstick before making a treatment decision.

Glucose below target at 65, but rising moderately. Your glucose could reach 120 within 30 minutes.

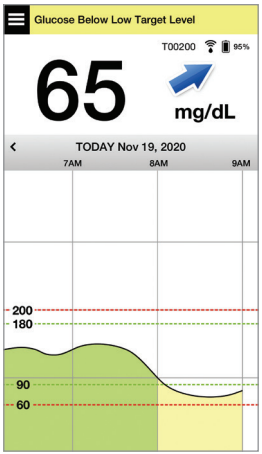
It's 7am, and you're about to eat breakfast, and you drank a small glass of orange juice when you first woke up.

- Should you consider taking a little less insulin than you usually would for your meal?
- Should you take the amount of insulin you typically would for this breakfast, and keep an eye on your glucose value, the arrow and how you feel?



It's 9am, and you dosed insulin for your breakfast about 2 hours ago.

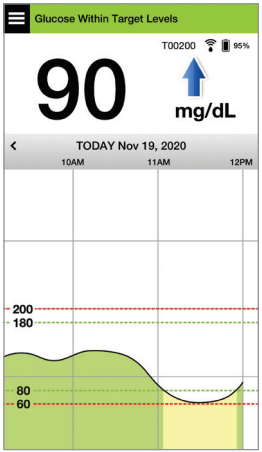
- Should you wait and keep an eye on your glucose value and the arrow before making a treatment decision?
- Should you consider taking carbs to treat the low now?



Glucose in target at 90, but rising rapidly. Your glucose could reach 180 or higher within 45 minutes.

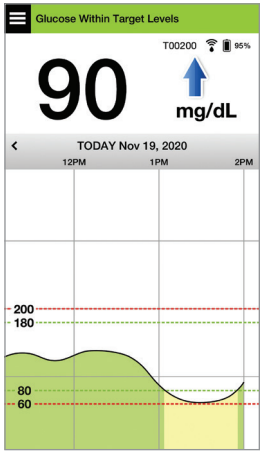
It's noon, and you're about to have lunch.

- What might be causing this rise in glucose?
- Should you consider taking more insulin than you usually would for your meal?
- What does your health care provider recommend for adjusting your insulin in this situation?



It's 2pm, and you dosed insulin to cover your lunch, plus a little extra because of the rapidly rising arrow, about 90 minutes ago.

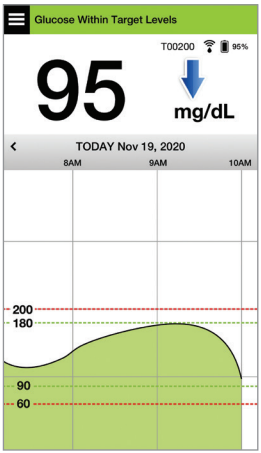
- Since it's only been 90 minutes since you dosed insulin, should you wait and keep an eye on your glucose number and trend arrows?
- How long does your health care provider recommend you wait between insulin doses to help prevent stacking insulin?



Glucose in target at 95, but falling rapidly. Your glucose could reach 65 or lower within 15 minutes.

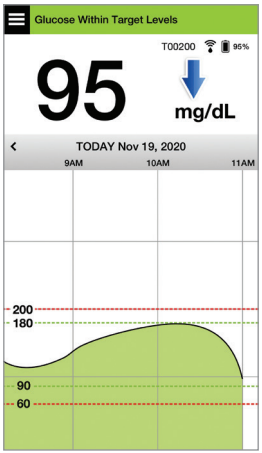
You're about to start your workout.

- What might be causing this rapid drop in glucose?
- Consider a snack to prevent a low glucose event.
- Consider postponing your workout until your trend and glucose are more steady. Keep a close eye on your glucose number, trend arrow and how you feel.



You've just finished your workout.

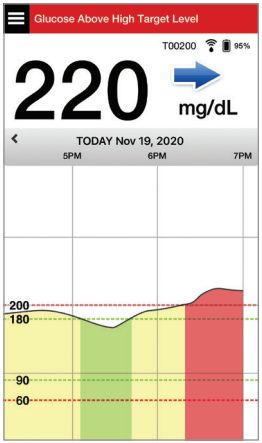
- How does your health care provider recommend you prevent low glucose after a workout?
- Consider a snack to prevent a low glucose event.
- Keep a close eye on your glucose number and trend arrow, and how you feel.



Glucose above high alert level at 220, and changing gradually. Your glucose could drop to 190 or rise to 250 within 30 minutes.

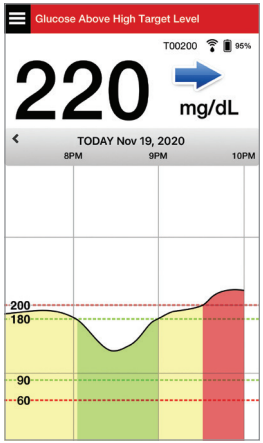
It's 7pm, and you're about to eat dinner. It's been 6 hours since you dosed insulin for lunch.

- What might be causing this high glucose so long after your last meal?
- Are you having a stressful day; are you not feeling well?
- Should you consider taking more insulin or eating fewer carbs than you typically would for this meal?



It's 10pm, and you're about to go to bed. It's been two and a half hours since you last dosed insulin.

- What might be causing this high glucose?
- How long does it usually take for the insulin you use to finish lowering your glucose?
- What bedtime glucose value is recommended by your health care provider?
- How do you typically treat for a high glucose at bedtime?



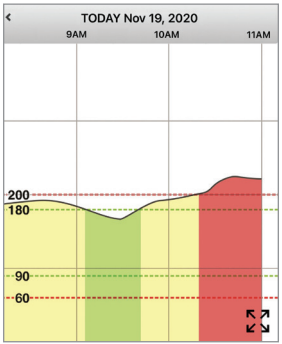
Remember, if you are not sure, always do a fingerstick check with your blood glucose meter before making a treatment decision.

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., calibrations 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, you can 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 fingerstick blood glucose calibration values.
	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.
	Event Log	Enter information about activities such as blood glucose values, meals, insulin, health and exercise. See *Event Log* for more information.
	Reports	Review a variety of reports about your CGM data. See *Reports* for more information.
	Share My Data	Allow others to view your glucose data through the Eversense NOW App.
	Alert History	Review past alerts and notifications. See *Alert Descriptions* for more information.
	System Setup	Connect or link your CGM System components and complete Warm Up and Initialization phases.
	Connect	Establish or 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, and temporary profile. See *Customizing your Settings* for more information.
	About	View information about your CGM System, including sensor and smart transmitter ID numbers. Change or delete your profile picture and log out of the app.

8. Customizing your Settings

This section describes how to customize settings in your Eversense 365 CGM System.

Areas where you can customize app settings include:

- **Glucose –** glucose levels and change rates that will trigger an alert.
- **Calibration Reminders –** optionally set calibration reminder times.
- **System –** identifies or lets you enter personalized information about your system.
- **Sound Settings –** change the sounds for some glucose alerts, set snooze times and Do Not Disturb.
- **Temp Profile –** set a temporary glucose profile.

Glucose Levels

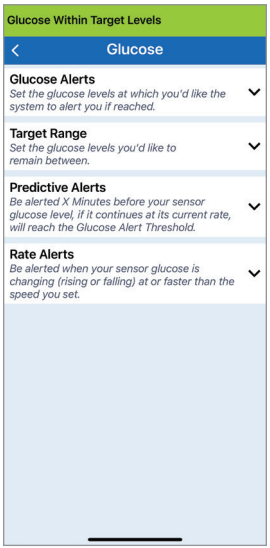
The system is designed to provide alerts on your smart transmitter and mobile device when your glucose level has reached the alert levels you set. You will decide the settings for your glucose alerts, targets, and rates of change based on input from your health care provider.

Warning: 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 reached 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.
  - Predictive Low and High Glucose alerts notify you on your mobile device and smart transmitter when your glucose is likely to reach the Low and High Glucose Alert levels you have set.

On the **Glucose Settings** screen, tap the "carat symbols" ⌄ to expand and collapse the settings options.



Setting Glucose Alert Levels

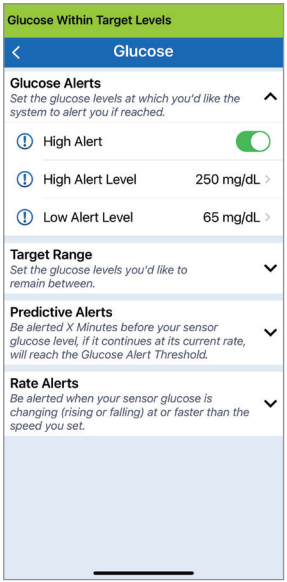
Your system will alert you when your glucose levels are outside the alert settings you choose. When you have passed your low and high glucose alert levels, the smart transmitter vibrates, and the app gives an audible alert as well as displays a message on the screen.

Default setting	Low: 65 mg/dL High: 250 mg/dL You can change these alert levels based on what you and your health care provider 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: 55 - 115 mg/dL High: 125 - 350 mg/dL
On/Off setting	Low Glucose Alert setting is Always ON High Glucose Alert setting can be turned ON and OFF. No High Glucose alerts will display or vibe on the smart transmitter if this feature is turned off.
Notes	Audio notification and visual alerts on your mobile device and smart transmitter on-body vibe alerts.

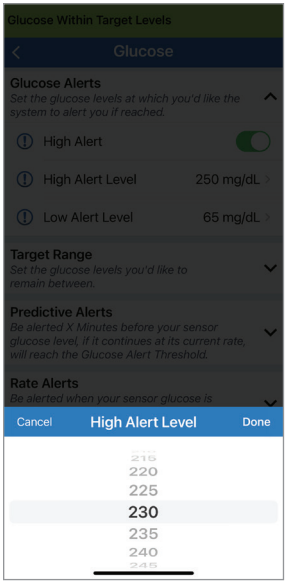
IMPORTANT:

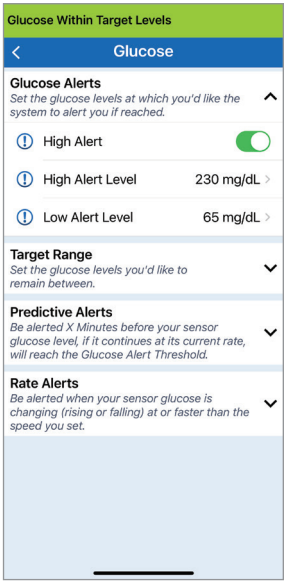
- The Low and High Glucose Alert levels you set are the same levels used to provide Predictive Alerts. See this section, *Setting Predictive Alerts*.
- For iOS 12 and above, and Android 6 and above, you can allow the Low Glucose and Out of Range Low Glucose Alerts to override your phone sound settings. See *Sound Settings* for more information.

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.



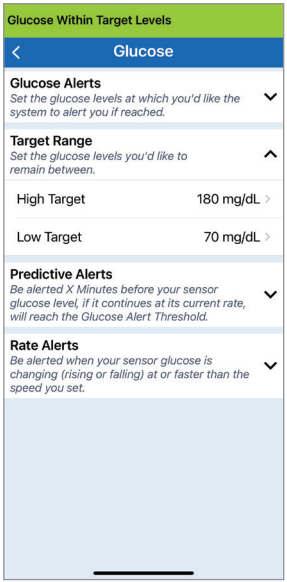


Setting Glucose Target Levels

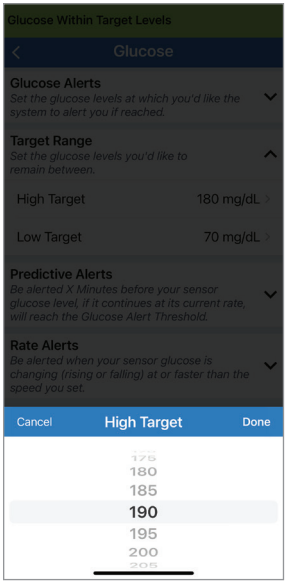
Glucose Targets are the low and high levels of the range you are aiming for throughout the day. These settings are used in the app to indicate when glucose values are in your target range.

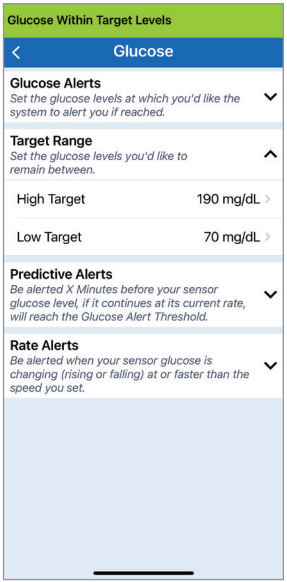
Default setting	Low: 70 mg/dL High: 180 mg/dL You can change this target range based on what you and your health care provider agree are the right target levels for you.
Allowable setting	Low: 60 - 120 mg/dL High: 120 - 345 mg/dL
On/Off setting	Always ON (cannot be turned OFF)
Notes	Used in graphs and 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.





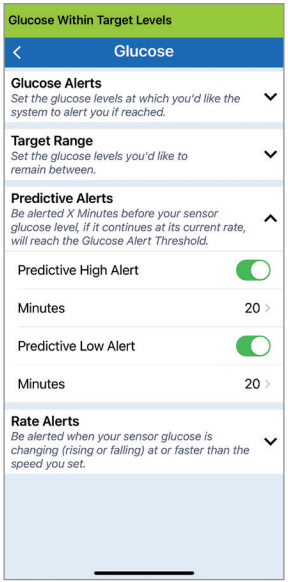
Setting Predictive Alerts

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 previously set to provide an "early" warning. You set the early warning time (10, 20, or 30 minutes) to alert you in advance of reaching your alert levels, based on current glucose trends. When you have reached the early warning time, the smart transmitter vibrates, and the app gives an audible alert as well as displays a message on the screen.

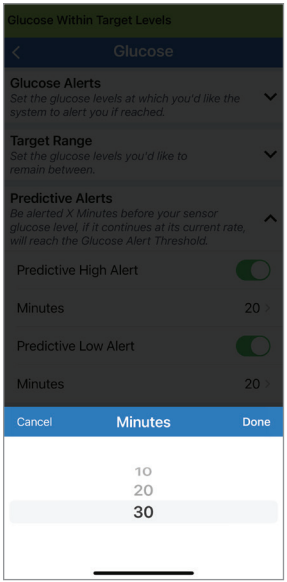
Default setting	OFF
Allowable setting	10, 20, or 30 minutes prior
On/Off setting	You can turn these alerts ON and OFF. No predictive alerts will occur until this feature is turned ON. The default is 20 minutes.
Notes	Audio notification and visual alerts on your mobile device and smart transmitter on-body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

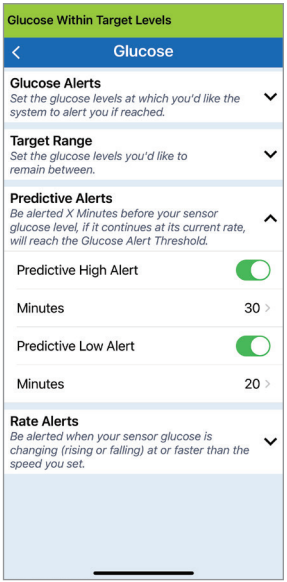
1. To turn this feature ON, tap **Menu > Settings > Glucose** to display the **GLUCOSE SETTINGS** screen.



2. Next to **the High and Low Predictive Alerts**, slide the **OFF** button to **ON.**

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



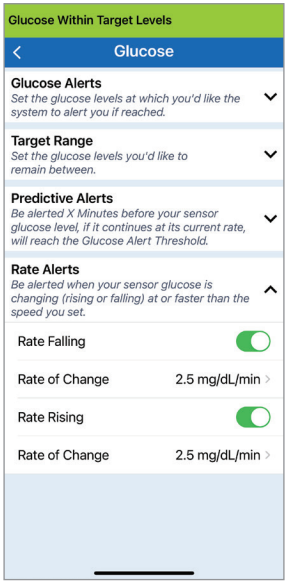


Setting Rate of Change Alerts

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

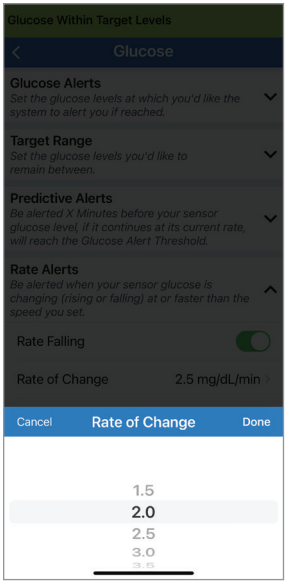
Default setting	OFF
Allowable setting	1.5 - 5 mg/dL per minute
On/Off setting	You can turn these alerts ON and OFF. No rate of change alerts will occur until this feature is turned ON.
Notes	Audio notification and visual alerts on your mobile device and transmitter vibration alerts.

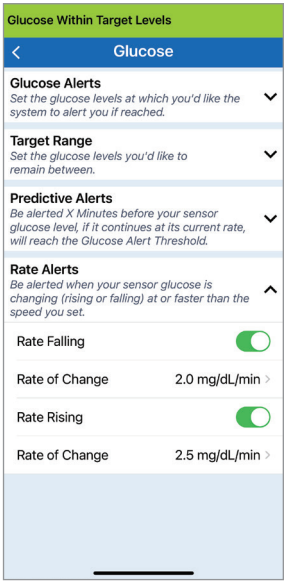
1. To turn this feature ON, tap **Menu** > **Settings** > **Glucose** to display the **GLUCOSE SETTINGS** screen.



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

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





Setting Calibration Reminders

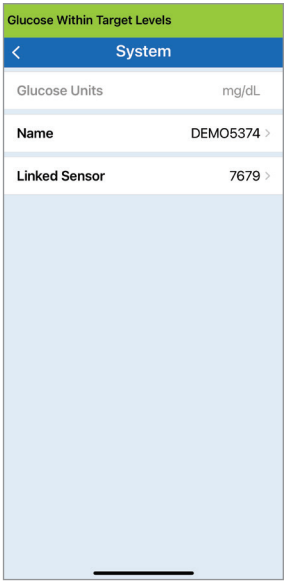
You can optionally set daily or weekly calibration reminders at times most convenient for you. You will still receive the system generated calibration notifications and alerts.

Default setting	OFF
Allowable setting	Daily: Time of day in increments of 1 minute. Weekly: Day of the week, and time of day in increments of 1 minute.
On/Off setting	You can turn this feature ON or OFF. No reminders will display unless this feature is turned ON.
Notes	You can set daily or weekly reminders. The daily reminders will repeat at the set time of day. The weekly reminders will repeat on the day of the week and time of day that is set. Audio notification and visual alerts on your phone screen only – no transmitter vibrations. If you delete the app and re-install, these reminders must be reset. These reminders are not stored in Alert History. If you pair a new transmitter with the existing app, the settings will remain the same. See *Do Not Disturb on Eversense 365 App and Mobile Devices* for more information.

Setting System Information

The **SYSTEM** screen lets you view and edit other settings in your 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:

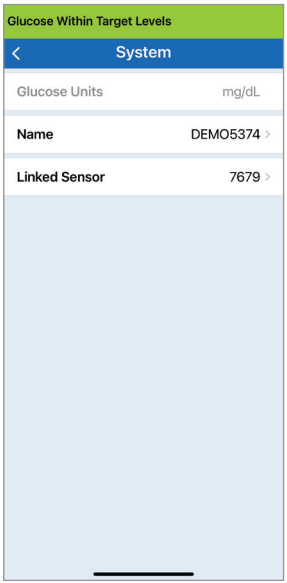
- **Glucose Units.** The unit of measurement for your glucose readings. The app must be reinstalled to edit this setting.
- **Name.** The serial number of your smart transmitter. You can also tap on the serial number displayed here and give your smart transmitter a custom name.
- **Linked Sensor.** The 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.

Re-linking a Sensor

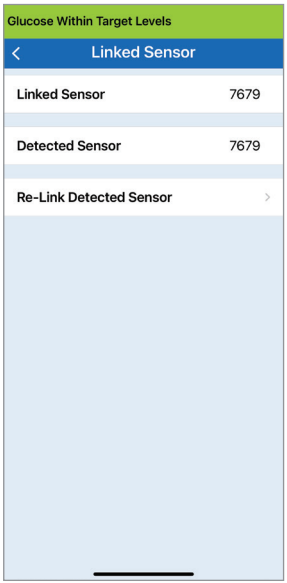
IMPORTANT: Do not re-link your sensor unless instructed by Customer Support. Re-linking the sensor returns the system to Initialization Phase, requiring 4 blood glucose fingerstick calibrations within 36 hours. Re-linking does not impact the life of your sensor.

1. Confirm with Customer Support that you should re-link your sensor.

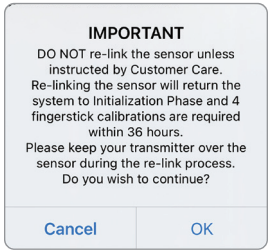
2. Tap **Linked Sensor**.



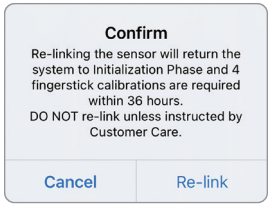
3. Tap **Re-link detected sensor**.



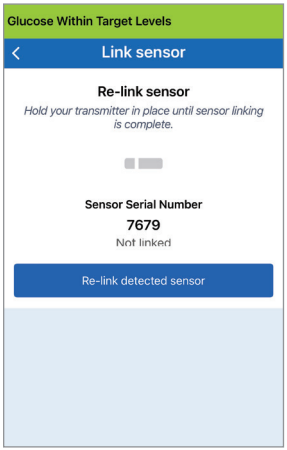
4. Tap **Cancel** or **OK** to continue.

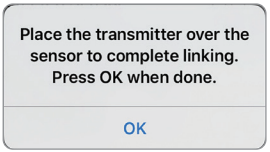


5. Tap **Cancel** or **Re-link**.

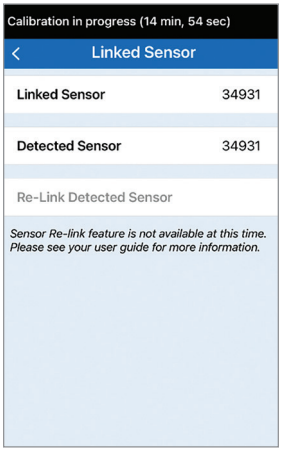


6. Tap **Re-link detected sensor** on the next screen. The re-linking process will begin. It may take up to 10 minutes for the process to complete. DO NOT remove the smart transmitter from your sensor site until the process is complete





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



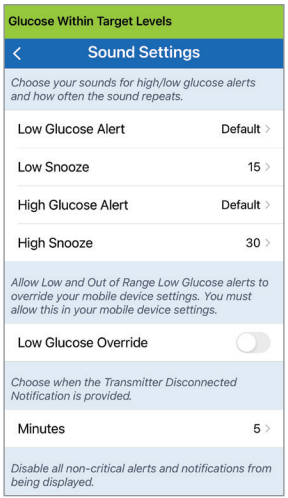
Note: The re-link button will not be available under the following conditions:

- Your transmitter battery needs to be charged or is empty.
- While calibration is in progress.
- Before a sensor has been linked.
- Certain sensor replacement alerts.
- If no sensor is detected.
- If any of the below alerts are active:
  - Transmitter End of Life
  - System Time Error

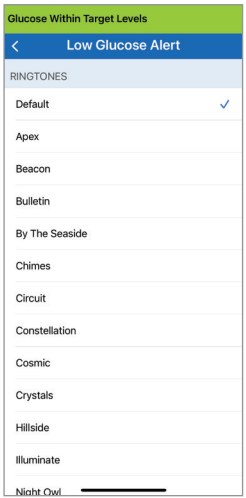
Setting Sounds

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, and the option to have Low and Out of Range Low Glucose Alerts to override your phone sound settings (iOS 12 and above, and Android 6 and above).

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



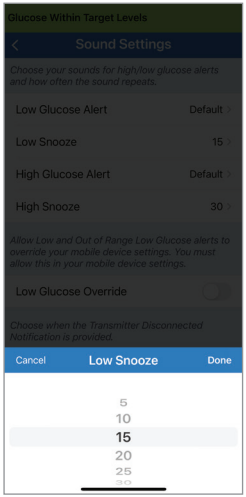
2. **Tap each alert to select the alert sound. Tap Back to get back to the SOUND SETTINGS screen.**



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.

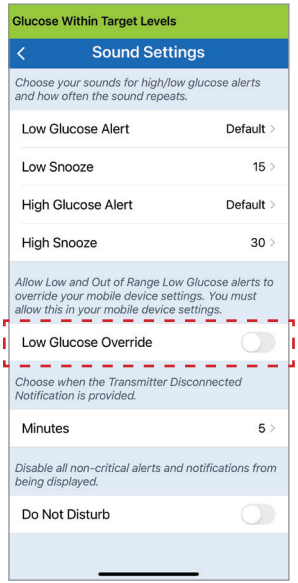


Low Glucose Override Setting

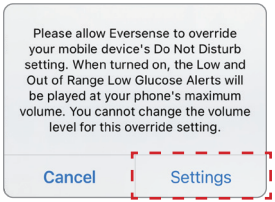
If your mobile device is running iOS 12 and above or Android 6 and above, you can optionally allow Low and Out of Range Low Glucose alerts to always override your mobile device sound settings. When turned on, the Low and Out of Range Low Glucose alerts will be played at your phone's maximum volume. You cannot change the volume level for this override setting. This allows you to still receive Low and Out of Range Low Glucose alerts on your phone, even if your phone's Silent Mode is on, or Do Not Disturb is on. You must allow this in your mobile device settings.

iOS Devices

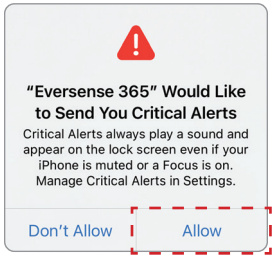
1. Tap the button to turn on the override.



2. Tap Settings.

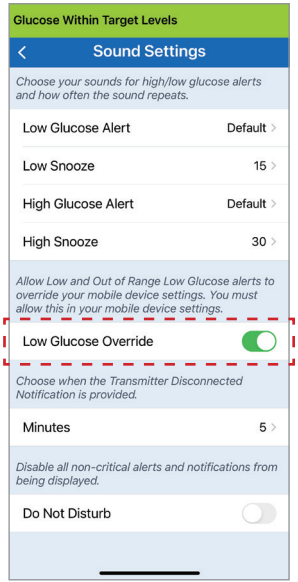


3. Tap Allow.



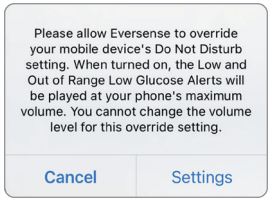
4. The switch for Low Glucose Override can now be turned on.

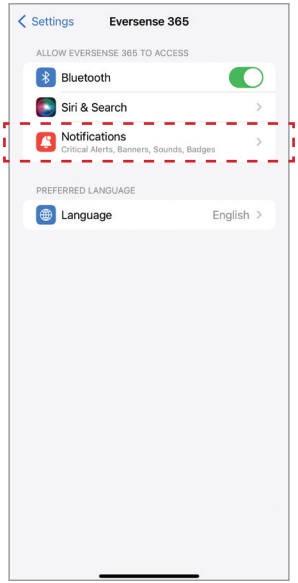
Your system will now alert you of Low and Out of Range Low Glucose alerts at maximum volume even if your Apple device's Silent/Vibration Mode is on, or Do Not Disturb is on.

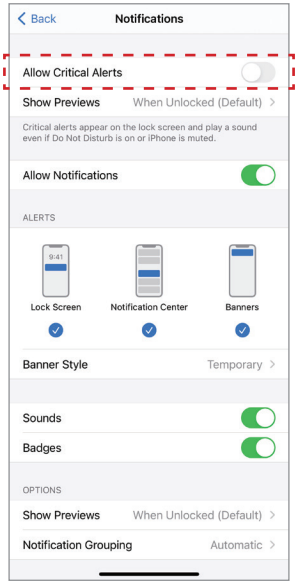


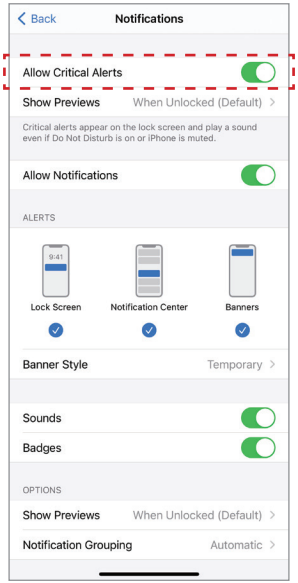
Note: This feature works similar to apps with an alarm clock feature that will always sound regardless of your phone sound settings.

Note: If you tap **Don't Allow** in Step 3, you cannot turn on the Low Glucose Override setting. To turn this setting on at another time, when you tap **Settings** from Step 2, the Eversense settings in your mobile device settings page will be displayed. Tap **Notifications > Allow Critical Alerts**. Then you can turn on the switch for Low Glucose Override in the Eversense 365 App.





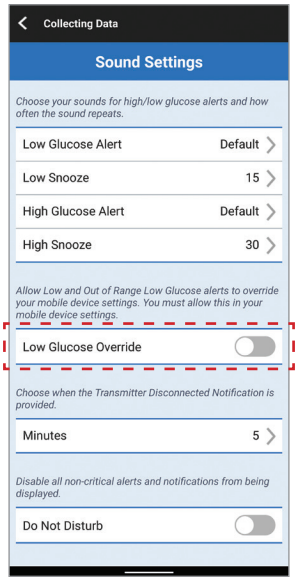




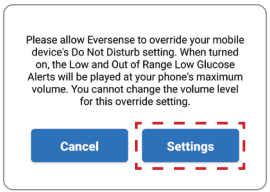
Android Devices

For devices with Android 6 and above:

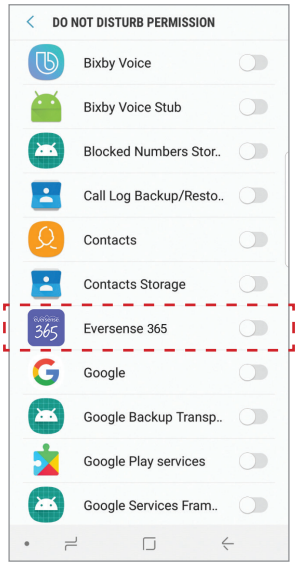
1. Tap the button to turn on the override.



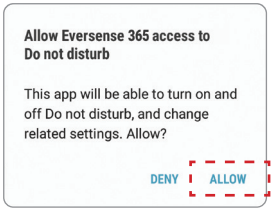
2. Tap **Settings**.



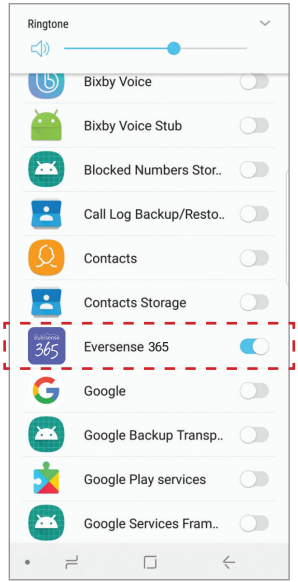
3. Tap on Eversense 365 from the Do Not Disturb access page.



4. Tap **Allow**.

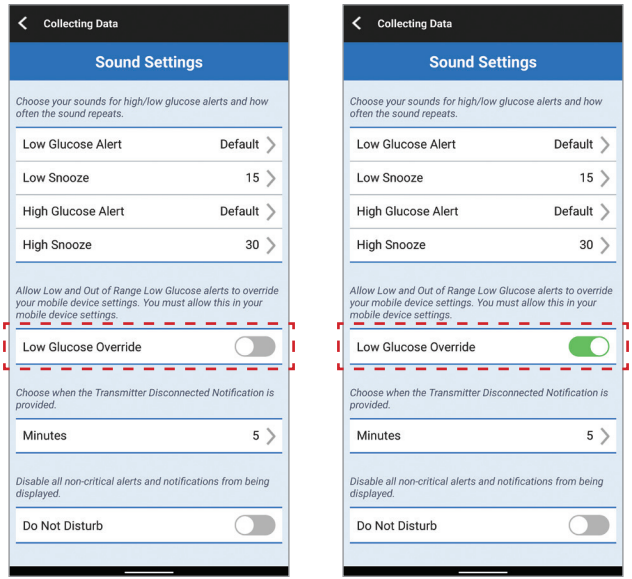


5. Tap the button next to Eversense 365 to allow the app to override the Do Not Disturb settings.



6. Return to the Eversense 365 App.

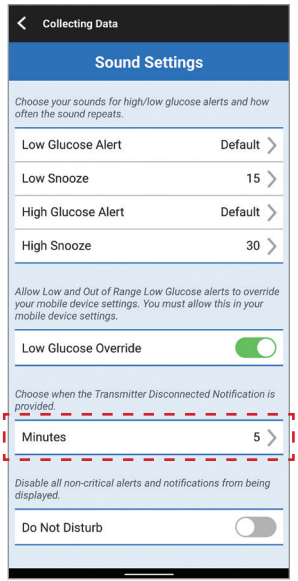
7. Tap on the Low Glucose Override switch to sound the Low and Out of Range Low Glucose alerts at maximum volume even if your device's Silent Mode, Vibration Mode, or Do Not Disturb is on.



Note: This feature works similar to apps with an alarm clock feature that will always sound regardless of your phone sound settings.

Transmitter Disconnect Setting

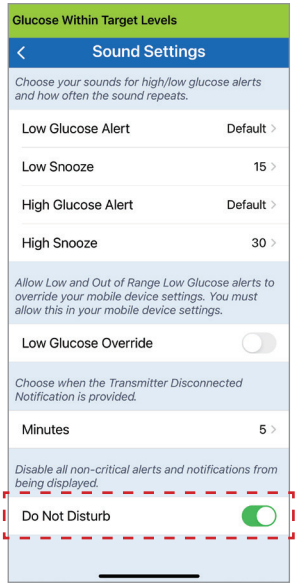
There may be times when the Bluetooth connection between your smart transmitter and mobile device is interrupted. This may be due to the devices being out of range, smart transmitter battery empty, or the Bluetooth feature is turned off in your phone settings. You can customize how long before the system notifies you of a communication interruption. You can set the time to alert you 5 to 30 minutes after a connection is lost. When there is no communication between the smart transmitter and the app, you will only receive vibratory alerts from the smart transmitter. See next section regarding Do Not Disturb mode.



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

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

Note: When you enable Do Not Disturb mode on your mobile device you will not receive any alerts or notifications from the app. The DND icon will appear on the Home Screen. For a list of alerts, please see Alert Descriptions.



Do Not Disturb on Eversense 365 App and Mobile Devices

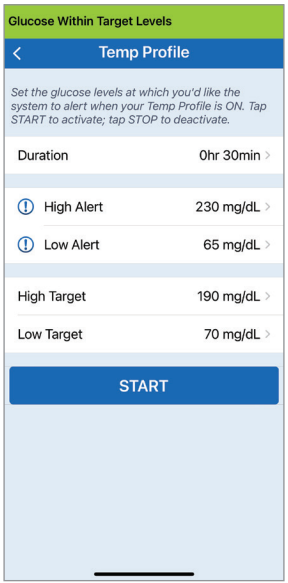
	Eversense 365 App DND off; Mobile device DND off	Eversense 365 App DND on; Mobile device DND off	Eversense 365 App DND off; Mobile device DND on	Eversense 365 App DND on; Mobile device DND on
Transmitter Vibration (Low Priority Alerts and Notifications)	Yes	No	Yes	No
Eversense 365 App Display, Phone Sound and Phone Vibration (Low Priority Alerts and Notifications)	Yes	No	No	No
Transmitter Vibration (High Priority Alerts)	Yes	Yes	Yes	Yes
Eversense 365 App Display, Phone Sound and Phone Vibration (High Priority Alerts)	Yes	Yes	No	No
Calibration Reminders (Phone notification)	Yes	Yes	No	No
Low Glucose Alert (Override turned ON)	Yes	Yes	Yes	Yes

IMPORTANT: Certain phone operating systems allow you to enable Low Glucose Alerts to override your phone sound setting. See *Sound Settings* for more information.

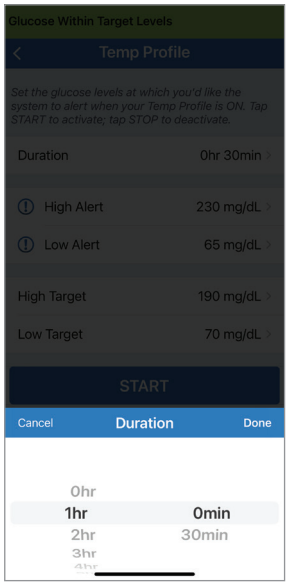
Setting Temporary Profile

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.

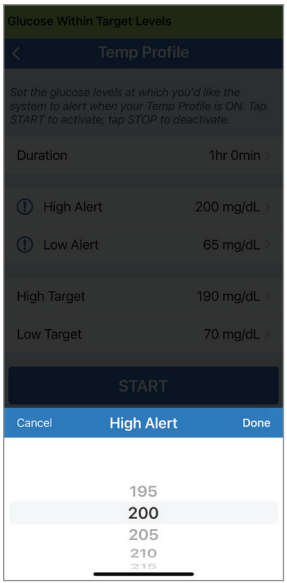
1. Tap **Menu** > **Settings** > **Temp Profile** to display the **TEMP PROFILE** screen.

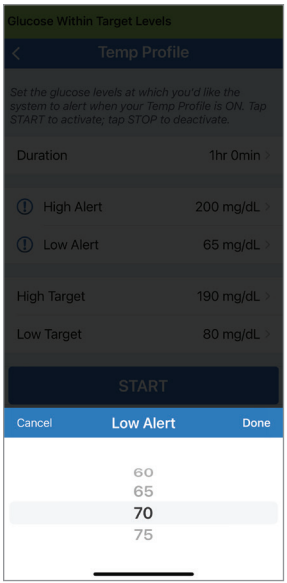


2. Select the duration. You can set a Temp Profile for up to 36 hours in 30 minute increments.



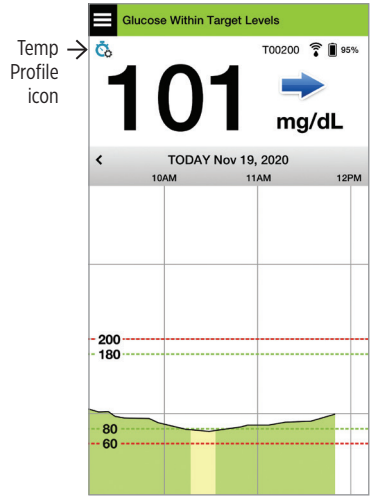
3. Set the High and Low Alerts and High and Low Target levels desired. Tap **START**.



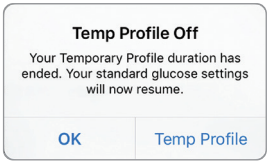


The Temp Profile selections cannot be changed when the duration has been started.

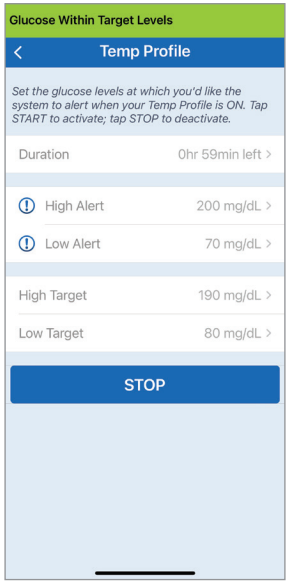
While a Temp Profile is active, the Temp Profile icon will be displayed on the **MY GLUCOSE** screen.



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**.



9. Alert Descriptions

This section describes the various alerts and notification messages you may see on the 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 when no glucose values can be displayed and to indicate the transmitter battery is empty Requires immediate and appropriate action.	3 long vibes	**MESSAGE APPEARS IN YELLOW**
Low Glucose and Out of Range Low Glucose Alert Requires immediate and appropriate action.	3 short vibes x 3	**MESSAGE APPEARS IN YELLOW**
Alerts related to Predictive Low Glucose Requires immediate and appropriate action.	3 short vibes	**MESSAGE APPEARS IN YELLOW**
Alerts related to High Glucose High Glucose Alert, Predictive High, and Out-of-Range High. Requires immediate and appropriate action.	1 long vibe then 2 short vibes	**MESSAGE APPEARS IN YELLOW**

Alerts and Notifications	Smart Transmitter Vibration Pattern	App Alert Indicators
Alerts related to lower priority issues Requires some action but may lower priority in nature. See following section for examples.	1 short vibe	MESSAGE APPEARS IN YELLOW
Charge Smart Transmitter Alert Your smart transmitter battery has approximately 10 hours of power available and should be charged.	3 quick vibes then 1 long vibe x 2	MESSAGE APPEARS IN YELLOW
Sensor Sync Confirmed Your smart transmitter has successfully synced with your sensor.	2 quick vibes x 3	MESSAGE APPEARS IN YELLOW
Notifications Requires some action but is lower priority 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

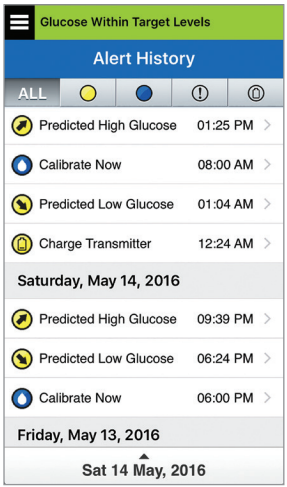

Notifications


Glucose-related alerts


Battery Alerts

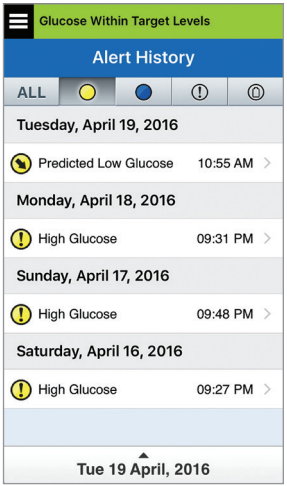
Note: When you receive 2 or more alerts that have not been acknowledged, the app will display an option to **Dismiss All**. This can happen when your mobile device has been out of range of your smart transmitter and then re-syncs. You can review each alert in **Alert History**.

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.



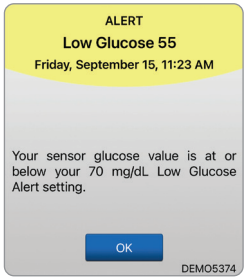
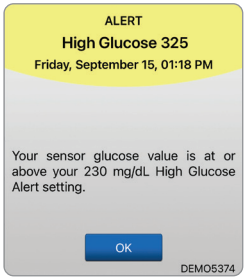
Example of alerts only

Alert Descriptions and Actions

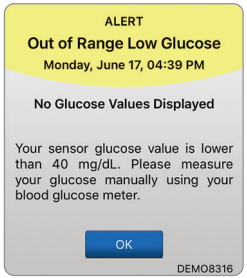
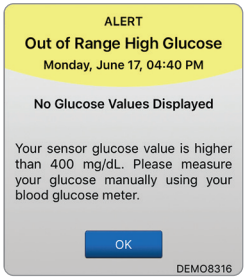
The following table lists the alerts and notifications you may receive on the app.

IMPORTANT: Alerts marked with a * are considered higher priority and cannot be turned off in the app or in the smart transmitter using the DND in the app settings.

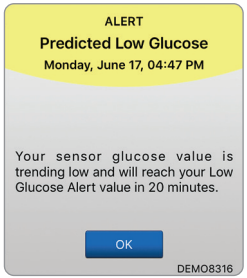
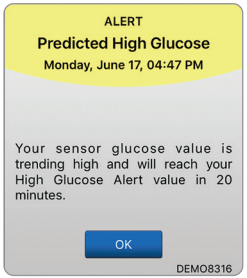
Alerts

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. The glucose value at the time the alert was triggered is displayed in the pop-up.	**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. The glucose value at the time the alert was triggered is displayed in the pop-up.
Actions	Pay close attention to your glucose values, symptoms, and trends. If your symptoms do not match the sensor glucose value, confirm your glucose value with a blood glucose meter before making a treatment decision.	Pay close attention to your glucose values, symptoms, and trends. If your symptoms do not match the sensor glucose value, confirm your glucose value with a blood glucose meter before making a treatment decision.

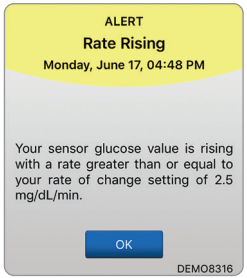
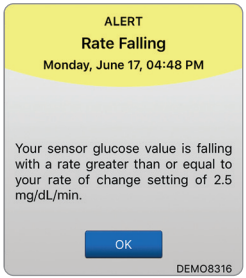
Alerts

App Display		
Description	**Out of Range Low Glucose*** Appears when your glucose reading is lower than 40 mg/dL. No glucose readings 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 400 mg/dL. No glucose readings can be displayed (only **HI** is displayed on the **MY GLUCOSE** screen).
Actions	Confirm your glucose value with a blood glucose meter before making a treatment decision. Once the sensor glucose value is at or higher than 40 mg/dL, glucose readings will resume on the display.	Confirm your glucose value with a blood glucose meter before making a treatment decision. Once the sensor glucose value is at or lower than 400 mg/dL, glucose readings will resume on the display.

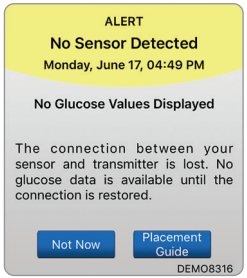
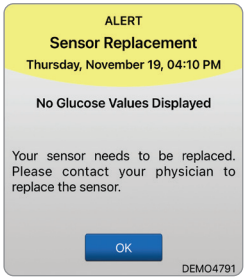
Alerts

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. If your symptoms are different than the sensor glucose values or what the alert indicates, confirm your glucose value with a blood glucose meter before making a treatment decision.	Pay close attention to your glucose values, symptoms, and trends. If your symptoms are different than the sensor glucose values or what the alert indicates, confirm your glucose value with a blood glucose meter before making a treatment decision.

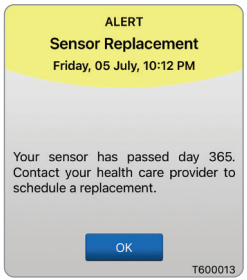
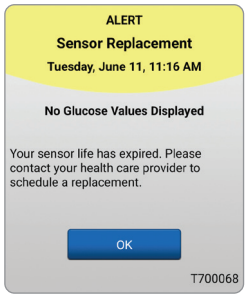
Alerts

App Display		
Description	**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.	**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.
Actions	Pay close attention to your glucose values, symptoms and trends. If your symptoms are different than the sensor glucose values or what the alert indicates, 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. If your symptoms are different than the sensor glucose values or what the alert indicates, confirm your glucose value with a blood glucose meter test before making a treatment decision.

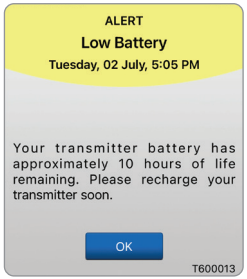
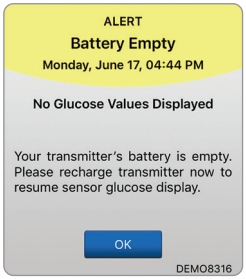
Alerts

App Display		
Description	**No Sensor Detected*** Appears when the connection between your sensor and transmitter is lost. No glucose data is available until the connection is restored.	**Sensor Replacement*** Appears once when system self-checks detect the sensor is no longer able to provide glucose values. No glucose readings can be displayed until the sensor is replaced.
Actions	Using the Placement Guide for reference, place the smart transmitter over the sensor until it shows there is a connection.	Contact your health care provider to have your sensor replaced.

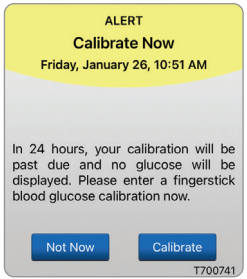
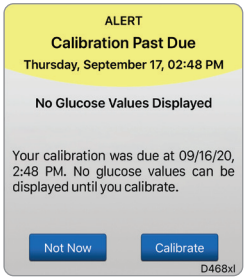
Alerts

App Display		
Description	**Sensor Replacement*** Appears once when your sensor has passed day 365. Your system may continue providing sensor glucose readings for up to 10 days after day 365.	**Sensor Replacement*** Appears once when your sensor life has expired. No glucose readings can be displayed until the sensor is replaced.
Actions	Contact your health care provider to have your sensor replaced as soon as possible.	Contact your health care provider to have your sensor replaced.

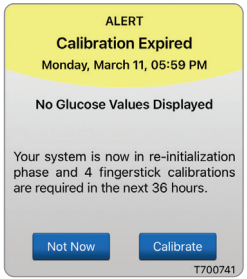
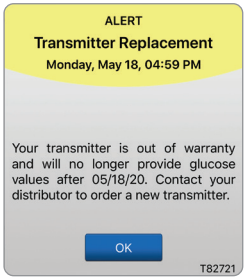
Alerts

App Display		
Description	**Low Battery*** Appears once when smart transmitter battery power is very low (less than 10 hours remaining) and you need to charge your battery very soon.	**Battery Empty*** Appears once when your smart transmitter battery is empty and needs to be charged. No glucose readings can be displayed until the smart transmitter is charged.
Actions	Charge your smart transmitter as soon as possible.	Charge the smart transmitter immediately. Remove the smart transmitter from your body before connecting it to the power supply.

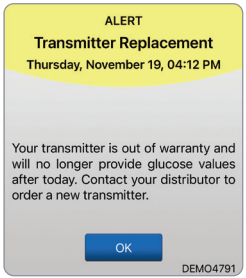
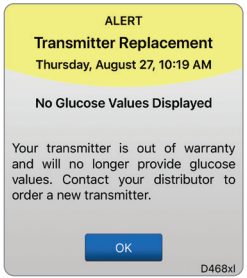
Alerts

App Display		
Description	**Calibrate Now** Appears to alert you that your calibration is due. If you do not calibrate within 24 hours, glucose values will no longer be displayed.	**Calibration Past Due** Appears when your system is past due for calibration (48 hours in 1 Daily Calibration Phase or 8 days in 1 Weekly Calibration Phase). No glucose readings can be displayed until calibration is performed.
Actions	Tap **Calibrate** to enter a calibration value.	Perform a fingerstick calibration in order to resume displaying glucose values.

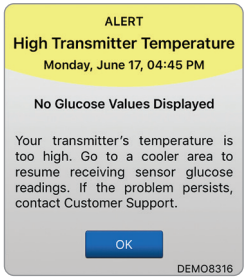
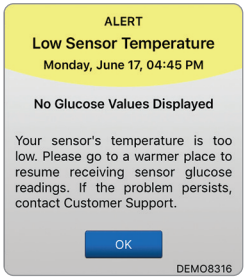
Alerts

App Display		
Description	**Calibration Expired** Appears when a calibration has not been performed within 72 hours while in 1 Daily Calibration Phase or 9 days in 1 Weekly Calibration Phase. The system returns to the Initialization Phase. No glucose readings can be displayed until calibration is performed.	**Transmitter End of Life Day 366*** Appears once every 7 days when your transmitter has been in use for 365 days and is out of warranty. After 395 days of use, your transmitter will no longer provide glucose readings.
Actions	In the Initialization Phase, you must perform 4 fingerstick calibrations spaced 2 - 12 hours apart. Glucose readings will display after the 2nd successful calibration.	Contact your distributor to order a new transmitter.

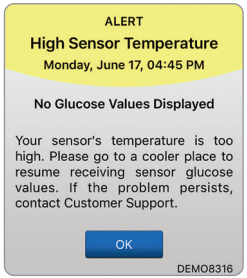
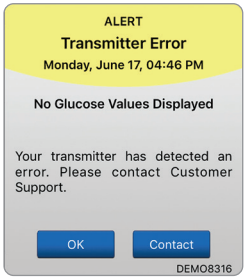
Alerts

App Display		
Description	**Transmitter End of Life Day 395*** Appears once your transmitter has been out of warranty for 30 days. Glucose readings cannot be displayed after the date of this alert until you replace your transmitter.	**Transmitter End of Life Day 396*** Appears once your transmitter has been in use for 395 days of use. Glucose readings cannot be displayed until you replace your transmitter. If your transmitter has reached its end of life it cannot be linked to a sensor.
Actions	Contact your distributor to order a new transmitter.	Contact your distributor to order a new transmitter.

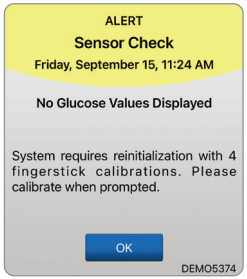
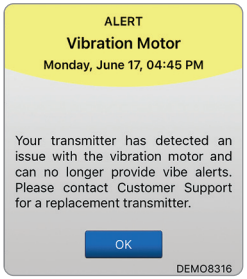
Alerts

App Display		
Description	**High Smart Transmitter Temperature*** Appears every 20 minutes when your smart transmitter temperature is too high. No glucose readings can be displayed until the smart transmitter temperature is within normal operating conditions.	**Low Sensor Temperature*** Appears every 20 minutes when the sensor temperature is too low. No glucose readings can be displayed until the sensor temperature is within normal operating conditions.
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.	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).

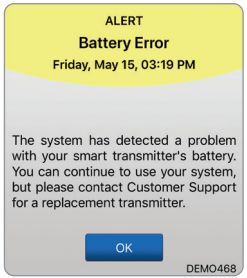
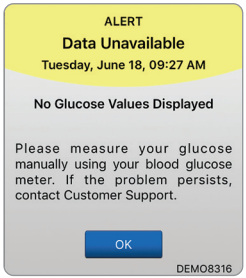
Alerts

App Display		
Description	**High Sensor Temperature*** Appears every 20 minutes when the sensor temperature is too high. No glucose readings can be displayed until the sensor temperature is within normal operating conditions.	**Smart Transmitter Error*** Appears when the system's internal checks detect a smart transmitter error. No glucose readings can be displayed until the error is corrected.
Actions	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.	Contact Customer Support.

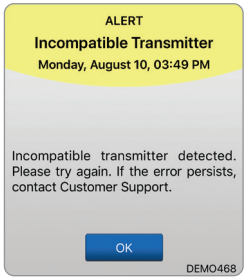
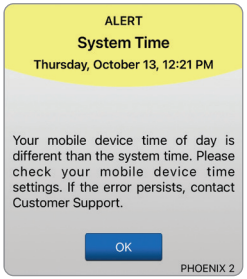
Alerts

App Display		
Description	**Sensor Check** Appears once when the system's internal checks detect instability with the sensor which requires a return to calibration Initialization Phase. No glucose readings can be displayed until the second successful calibration has been entered.	**Vibration Motor*** Appears every 60 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	In the Initialization Phase, you must perform 4 fingerstick calibrations spaced 2 - 12 hours apart. Display of glucose readings will resume after the 2nd successful fingerstick calibration.	Contact Customer Support to have your smart transmitter replaced immediately.

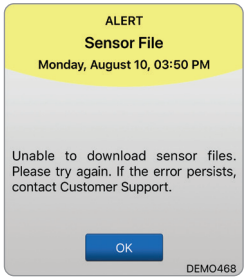
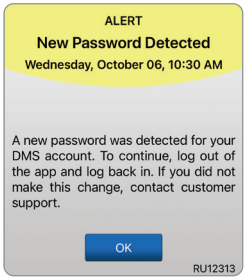
Alerts

App Display		
Description	**Battery Error*** Appears when the system's internal checks detect an error with your smart transmitter battery. Glucose readings will continue to be displayed, but your smart transmitter will need to be replaced.	**Data Unavailable** Appears when the system's internal checks detect a system error. No glucose readings can be displayed until the error is corrected.
Actions	Contact your distributor to order a new transmitter.	Plug the charging cable into a wall outlet or USB port. Plug the cable into the smart transmitter and remove it. If the condition persists, follow the steps shown in the Troubleshooting section to reset your smart transmitter. If you are unable to complete the reset, contact Customer Support.

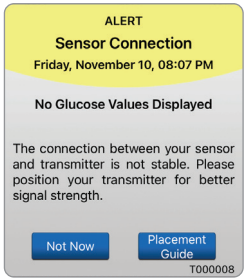
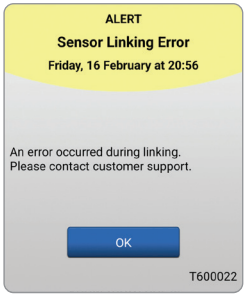
Alerts

App Display		
Description	**Incompatible Transmitter Detected*** Appears during linking when the system detects the transmitter is incompatible with the sensor.	**System Time Error** Appears when your system detects a discrepancy in time between your mobile device clock and the system clock.
Actions	Try linking again. If the error is displayed on the second attempt, contact Customer Support.	Set your mobile device clock to your current local time. If the error persists, contact Customer Support.

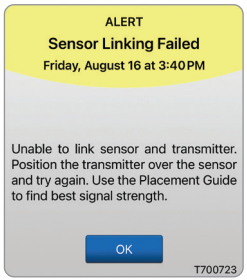
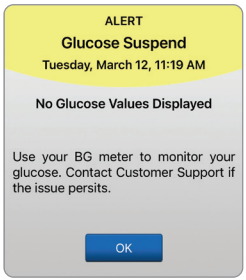
Alerts

App Display		
Description	**Sensor File Error*** Appears when the system detects a problem during linking.	**New Password Detected** Appears once when the system detects the password was changed via your Eversense DMS account.
Actions	Try linking again. If the error is displayed on the second attempt, contact Customer Support.	Log out of the app and log back in with the new password.

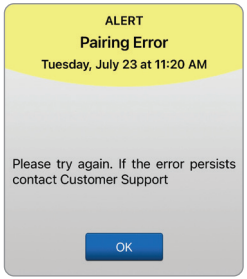
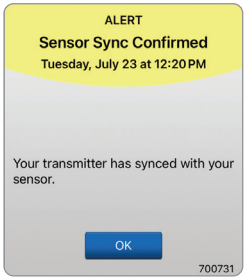
Alerts

App Display		
Description	**Sensor Connection*** Appears when the transmitter needs to be repositioned over the sensor.	**Sensor Linking Error*** Appears when there is an error during sensor linking.
Actions	Use the placement guide to establish a better signal strength.	Contact Customer Support.

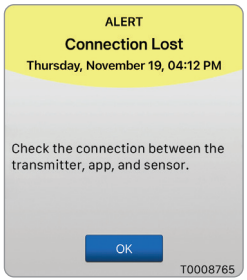
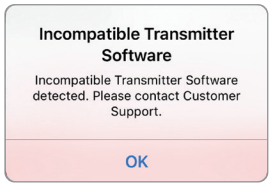
Alerts

App Display		
Description	**Sensor Linking Failed*** Appears when there is an error during sensor linking.	**Glucose Suspend*** Appears when system checks determine that no glucose can be displayed.
Actions	Try again. If the error persists, contact Customer Support.	Confirm your glucose value with a blood glucose meter before making a treatment decision until the values begin being displayed again.

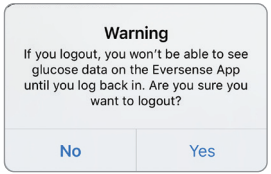
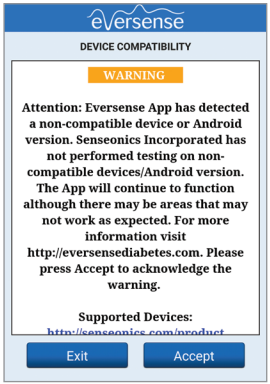
Alerts

App Display		
Description	**Pairing Error*** Appears if pairing the mobile device with the transmitter fails.	**Sensor Sync Confirmed*** Appears when the transmitter has successfully synced with the sensor.
Actions	Follow the steps to pair the transmitter again. If the error persists, contact Customer Support.	No action needed.

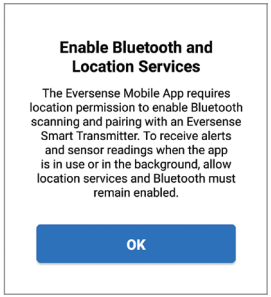
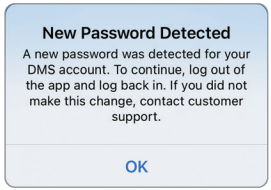
Alerts

App Display		
Description	**Connection Lost*** Appears before linking when the transmitter or sensor connection disconnects.	**Incompatible Transmitter Software** Appears when the software in your smart transmitter is incompatible with the app version on your mobile device.
Actions	Ensure your transmitter is connected to your mobile device and remains over top of your sensor to complete linking.	Contact Customer Support.

Alerts

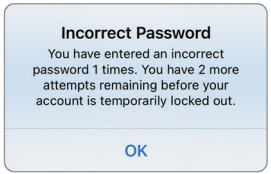
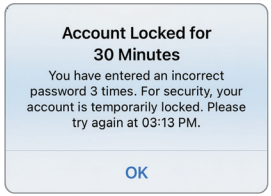
App Display		
Description	**Log Out Warning** Appears when you attempt to log out of the app. If you log out, you will not be able to view glucose data in the app.	**Incompatible Device/Operating System** Appears when an incompatible device/operating system is being used with the app.
Actions	Remain logged in to the app to continue viewing your glucose data. If you log out, you must log back in with your username and password to continue using the app.	For a list of compatible devices/operating systems visit www.eversensediabetes.com.

Alerts

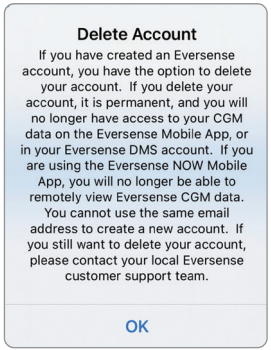
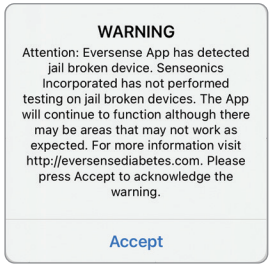
App Display		
Description	**Enable Bluetooth and Location Services** **For Android only.** Explains the use of location services is required to enable Bluetooth connection and to receive alerts.	**New Password Detected** Appears once when the system detects the password was changed via your Eversense DMS account.
Actions	Tap **OK** to acknowledge.	Log out of the app and log back in with the new password.

Alert Descriptions and Actions (continued)

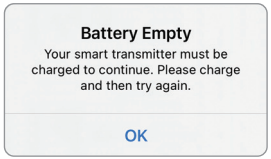
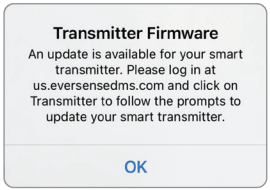
Alerts

App Display		
Description	**Incorrect Password** Appears when the system detects one or two incorrect passwords have been entered consecutively via your app.	**Account Locked** Appears after three incorrect passwords have been entered consecutively via your app.
Actions	Use the correct password to log in to the app.	Wait 30 minutes. Log in with correct password or reset your password.

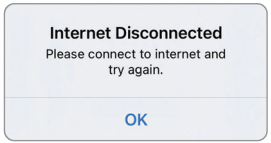
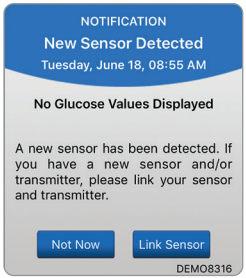
Alerts

App Display		
Description	**Delete Account** Appears when Delete Account is tapped on the log in page.	**Jailbroken Modal** Appears when the system detects an iOS device has been modified to remove the controls and limits set by the original manufacturer.
Actions	Contact Customer Support if you wish to proceed.	Devices that have been jailbroken should not be used with the app. The app may not work as expected and your device may be vulnerable to outside cyber attack.

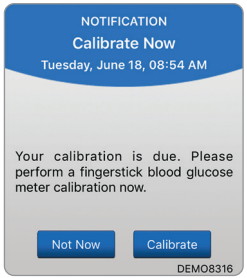
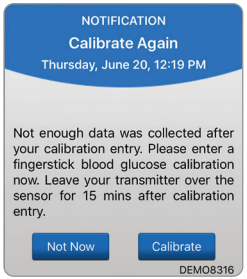
Alerts

App Display		
Description	**Battery Empty** Appears when the battery does not have enough charge to complete an action.	**Transmitter Upgrade Available** Appears when an upgrade is available for your Eversense Smart Transmitter.
Actions	Charge your smart transmitter and try the action again.	Go to us.eversensedms.com, log in and follow the prompts to download the Eversense Upgrade Application to upgrade your smart transmitter.

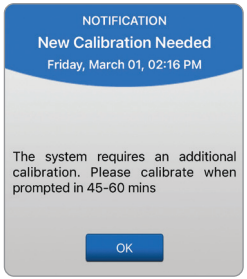
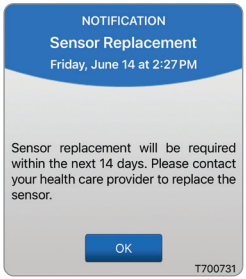
Notifications

App Display		
Description	**Internet Disconnected** Appears when the mobile device is disconnected from the internet, and an internet connection is required to complete an action.	**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	Connect the mobile device to the internet and try the action again.	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.

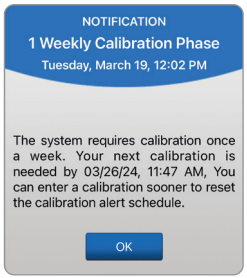
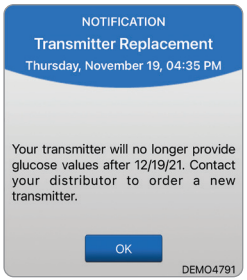
Notifications

App Display		
Description	**Calibrate Now** Appears when it is time for you to calibrate when the system is in Initialization Phase or after a calibration has been entered that is very different from the sensor glucose.	**Calibrate Again** Appears when not enough data has been collected during calibration.
Actions	Do a fingerstick blood glucose calibration. DO NOT use an alternative site (such as forearm) to obtain your blood glucose reading.	Tap **Calibrate** to enter a new calibration value.

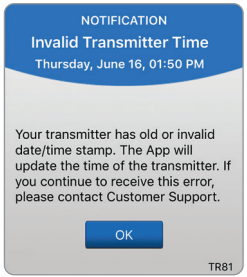
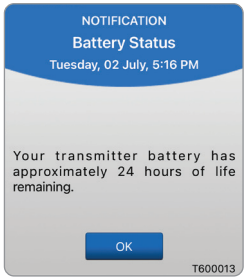
Notifications

App Display		
Description	**New Calibration Needed** Appears if the system requires another calibration. After about 1 hour, you will receive a Calibrate Now notification.	**Sensor Replacement** Appears 60, 30, 14, 7, 3, and 1 day before your sensor has completed its wear period as a reminder to replace your sensor.
Actions	Enter a new calibration value when prompted.	Contact your health care provider to schedule the removal and replacement of your sensor.

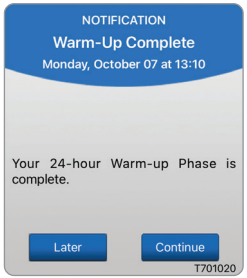
Notifications

App Display		
Description	**1 Weekly Calibration Phase** Appears once when the system requires calibration once a week.	**Transmitter End of Life Day 330** Appears once 35 days before your transmitter warranty expires.
Actions	Enter a new calibration value when prompted.	Contact your distributor to order a new transmitter.

Notifications

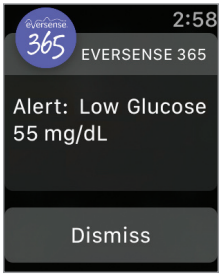
App Display		
Description	**Invalid Transmitter Time** The time on the smart transmitter is out of sync with your app.	**Battery Status** Transmitter has approximately 24 hours of life remaining.
Actions	If the error persists, contact Customer Support.	Charge transmitter soon.

Notifications

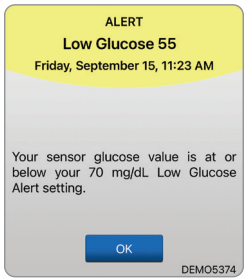
App Display	
Description	**Warm Up Complete** Appears when 24 hours have passed since your sensor has been linked with your transmitter, and the system is ready to use.
Actions	Calibrate when prompted.

Alerts and Notifications Displayed on the Wearable Device

Wearable devices are a secondary display to the Eversense 365 App. Any alerts or notifications received on the wearable should be confirmed on the Eversense 365 App before any action is taken. Screen shape format may vary based on the wearable device. If you dismiss an alert on the watch, the alert display will disappear from the phone lock screen. Once the app is opened, the alert will be displayed with all of its information. To see a list of the alerts and notifications you may receive from your system, see *Section 9 Alert Descriptions*. Some alerts and notifications are affected by the sound settings in the app, and the Do Not Disturb function in the app. See *Setting Sounds and Alert Descriptions and Actions* for more information.



Low Glucose Alert displayed on wearable



Low Glucose Alert displayed on app

10. Event Log

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

The 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.

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.

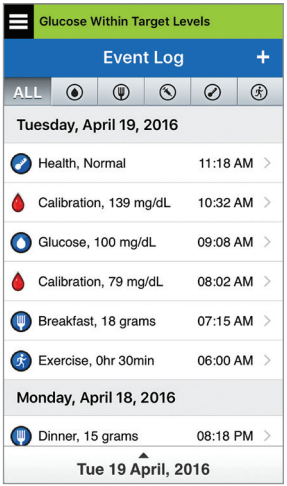
1. **Tap Menu > Event Log.**

   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 entries (entries other than calibrations).

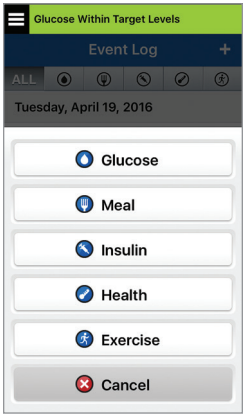
1. Tap **Menu** > **Event Log**.

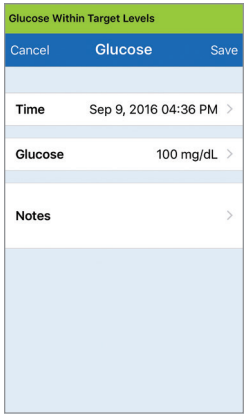
2. Add an event using the event icon "**+**" > **Glucose**.

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 20 and 600 mg/dL. Entries < 20 mg/dL will be converted to 20, and entries above 600 mg/dL will be converted to 600 for calculation and display purposes.

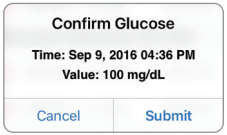




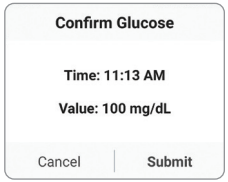
5. Tap **Save**.

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.



iOS



Android

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**.

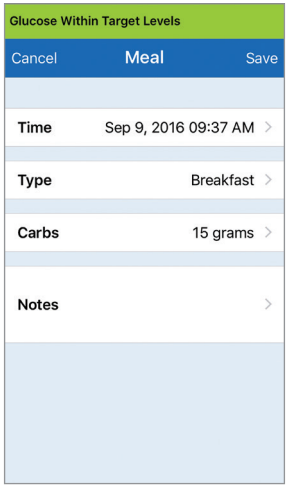
3. Tap **Time** to enter the correct date and time.
   Tap **Done**.

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**.

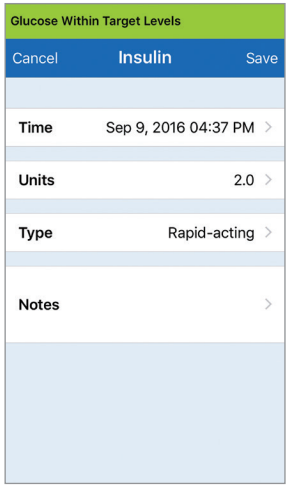
4. Tap **Units** to enter the correct number of Units.
   Tap **Done**.

   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**.

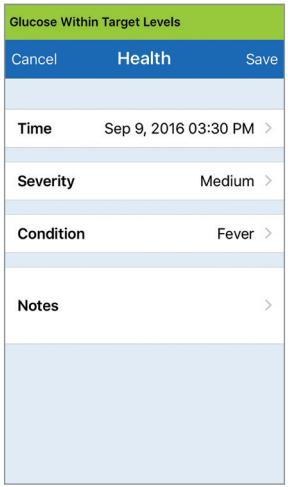
3. Tap **Time** to enter the correct date and time.
   Tap **Done**.

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**.

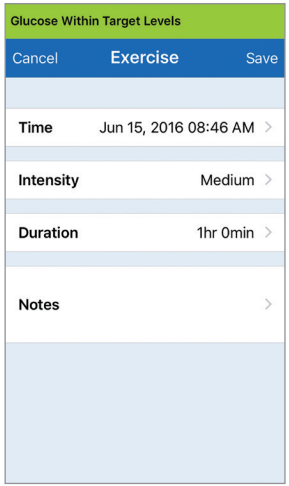
3. Tap **Time** to enter the correct date and time.
   Tap **Done**.

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

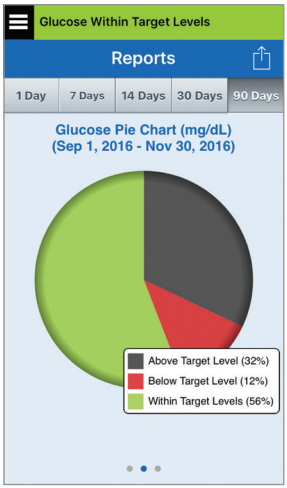
- Glucose Pie Chart
- Time in Range
- Weekly Modal Summary
- Glucose Statistics

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.

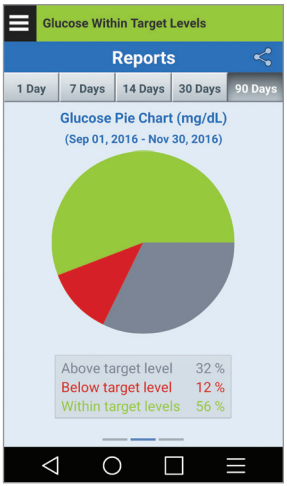
To view the glucose reports tap **Menu** > **Reports** and swipe to move across the three different reports. You can also email each report as a pdf file by tapping the email icon in the top right hand corner.

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.



iOS



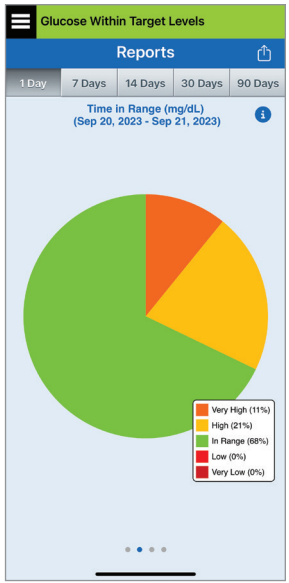
Android

Time in Range

This report shows the percentage of time spent in fixed, standard, glucose ranges.

- Very High: > 250 mg/dL
- High: 181 mg/dL - 250 mg/dL
- In Range: 70 mg/dL - 180 mg/dL
- Low: 54 mg/dL - 69 mg/dL
- Very Low: < 54 mg/dL

Source: http://www.agpreport.org/agp/agpreports

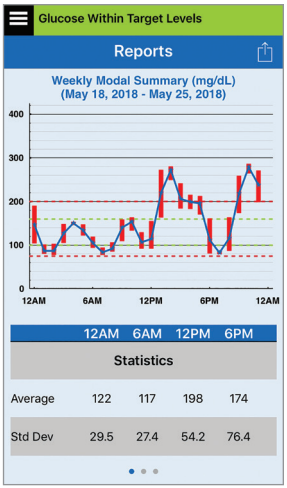


Weekly Modal Summary

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.

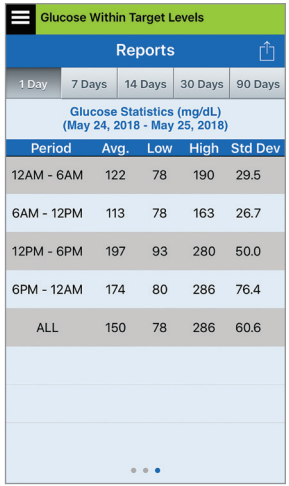
- The **blue line** is the average of the last seven days of your readings in an hour time block.
- The **red bars** show the highest and lowest actual readings in the same hour time block.
- The **red horizontal dotted lines** are your pre-set High and Low Glucose Alert levels.
- The **green horizontal 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 6 hour time slots.



Glucose Statistics

This report shows your average, low and high glucose readings, along with standard deviation within 6 hour time periods. You can choose the last 1, 7, 14, 30 or 90 days.



12. Sharing Data

You can share data multiple ways with Eversense.

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 smart transmitter or the app.

This program is offered at no cost to you. 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 365 App, an Eversense DMS account is automatically created for you. The *Eversense NOW App User Guide* has more information on how to remotely view glucose data from the Eversense 365 CGM System.

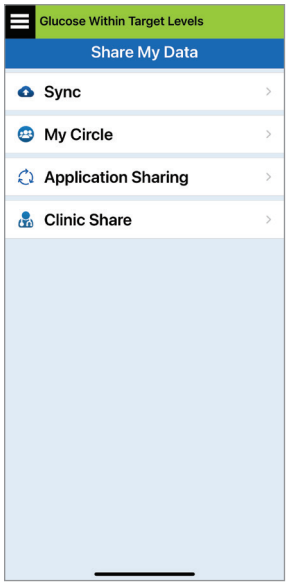
IMPORTANT: EVERSENSE DATA MANAGEMENT SYSTEM DOES NOT PROVIDE MEDICAL ADVICE. CHANGES TO YOUR TREATMENT PLAN SHOULD ONLY BE MADE BY YOUR HEALTH CARE TEAM.

Share My Data

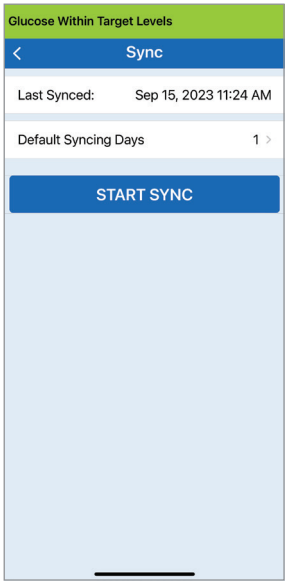
The Share My Data feature in the app allows you to manually sync data to your Eversense DMS account, invite friends and family to remotely view your CGM data via the Eversense NOW App, invite your health care provider to review your glucose data via Eversense DMS Pro, and to connect with other compatible health applications.

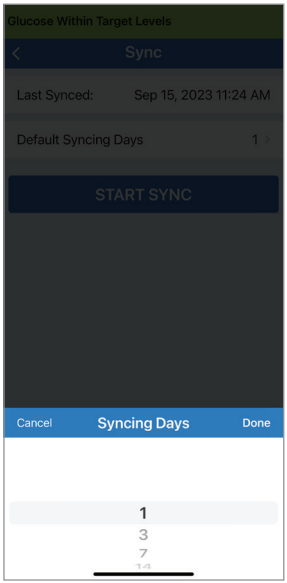
Sync

As long as you have an internet connection, and you are logged into the app, your glucose readings sync to your Eversense DMS account about every 5 minutes.



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.

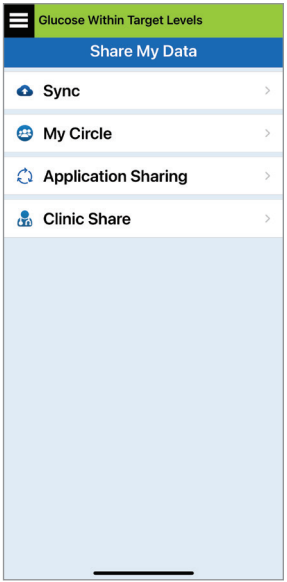




My Circle

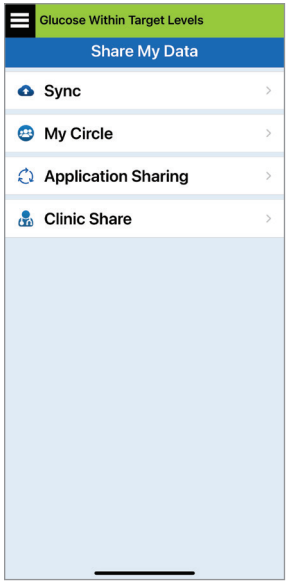
My Circle is an optional feature that allows you to activate remote monitoring of your CGM data. For more information on this feature, see *My Circle - Remote Monitoring*.

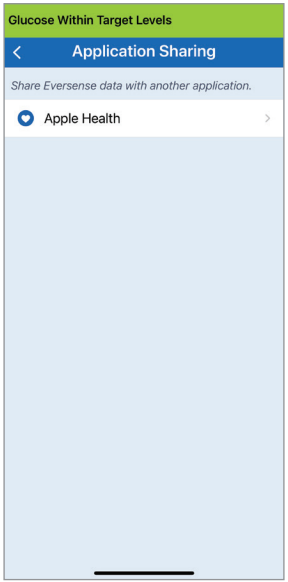
IMPORTANT: Both the Eversense 365 App and the Eversense NOW Remote Monitoring App must be downloaded from the US App Store in order for them to communicate.

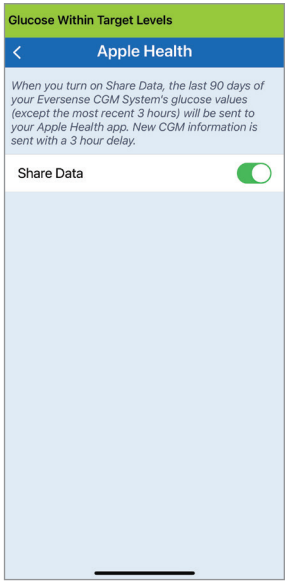


Application Sharing

Application Sharing is an optional feature that allows you to share certain Eversense data with another compatible health application. Tap the application and turn on **Share Data**. You may need to also allow sharing via the health application.





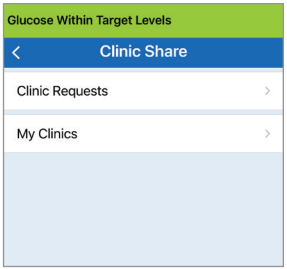


Clinic Share

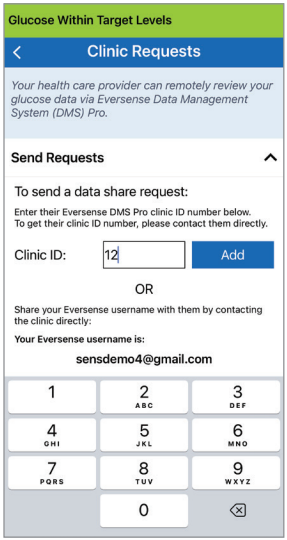
Clinic Share is an optional feature that allows you to either invite or accept an invitation from your health care provider's clinic via Eversense DMS Pro. This will allow them to review your Eversense DMS glucose reports.

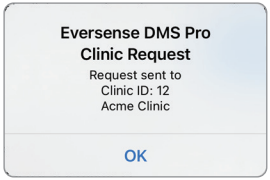
To invite your health care provider:

In order to send an invitation to your health care provider's clinic, you will need their Eversense DMS Pro Clinic ID number. They will need to provide this number to you.



1. Tap **Menu** > **Share My Data** > **Clinic Share**.
2. Tap **Clinic Requests** > **Send Requests**.
3. Enter your health care provider's Eversense DMS Pro Clinic ID number.
4. Tap **Add**.
5. Tap **OK** to confirm the invitation.





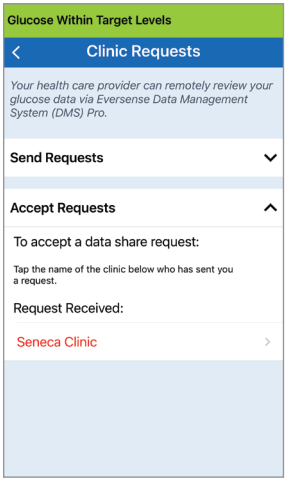
Once the clinic has accepted the invitation, they will be listed on the My Clinics page. To access this page, tap **Menu** > **Share My Data** > **Clinic Share** > **My Clinics**.

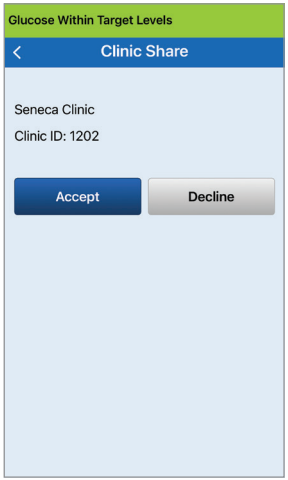
To accept an invitation from your health care provider:

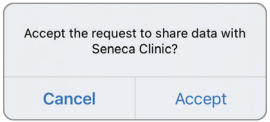
Your health care provider can also send you an invitation for them to have access to your glucose reports. You can accept this invitation directly in the app.

1. Tap **Menu** > **Share My Data** > **Clinic Share**.
2. Tap **Clinic Requests**.
3. Under Accept Requests, tap on the clinic name.
4. Tap **Accept**.
5. Tap **Accept** on the pop-up.

Once you have accepted the invitation, the clinic will be listed on the My Clinics page. To access this page, tap **Menu** > **Share My Data** > **Clinic Share** > **My Clinics**.





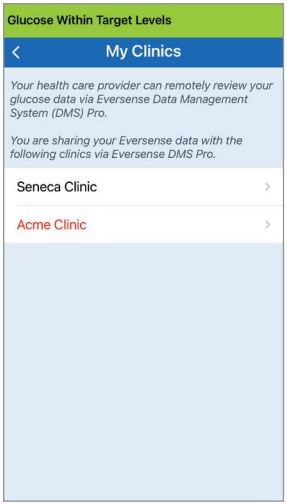


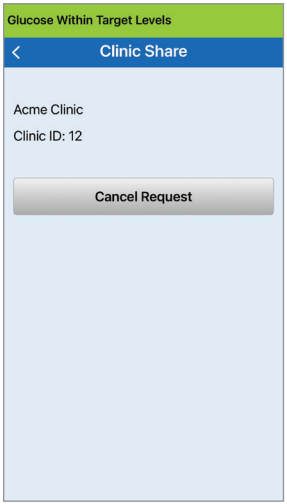
To stop sharing data with a clinic:

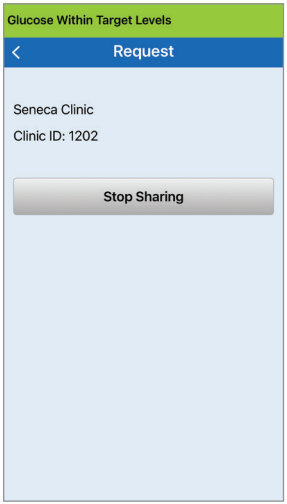
You can cancel an invitation to a clinic or stop sharing data with a clinic.

1. Tap **Menu** > **Share My Data** > **Clinic Share**.
2. Tap **Clinic Requests**.
3. Tap **My Clinics**.
4. Tap on the clinic name.
5. Tap **Cancel Request** or **Stop Sharing**.

This will remove you from the clinic's Eversense DMS Pro list of patients. You can send this clinic another invitation in the future, or the clinic may send you an invitation in the future.





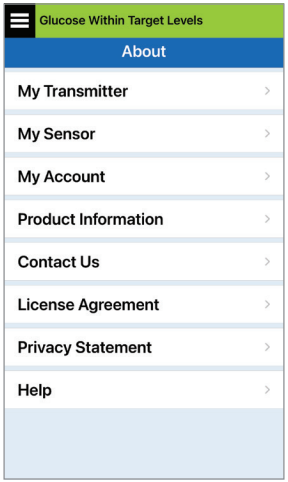


13. Product and General Information on the App

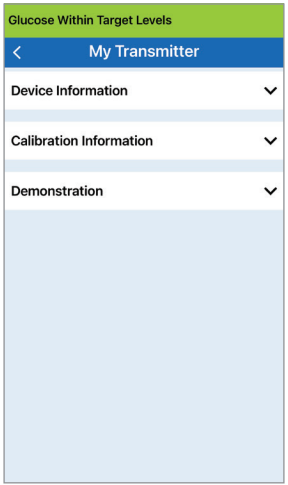
This section describes the information available from the About section of the Main Menu.

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

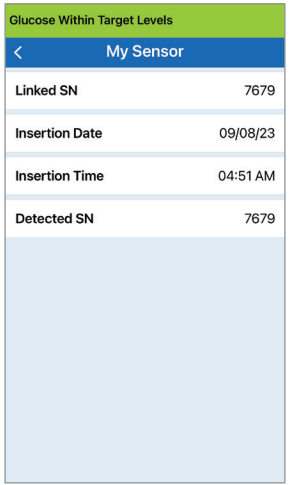
1. Tap **Menu** > **About** and then tap **My Transmitter**, **My Sensor** or **Product Information**.



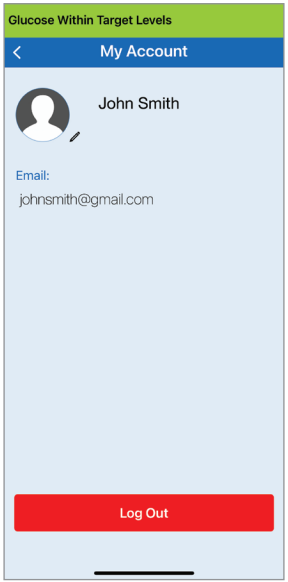
On the **MY TRANSMITTER** screen, you can find information that includes the serial number, calibration information and battery level. You can also demonstrate the vibration feature of the smart transmitter.



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



On the **My Account** screen, you can edit your profile picture, view the email address used to create your Eversense account, and log out of the app.

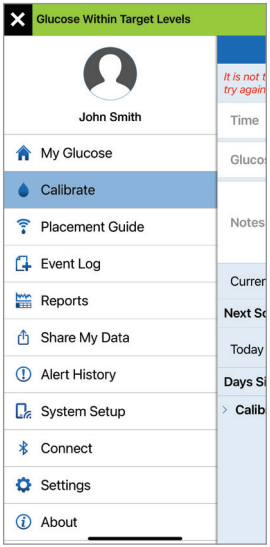


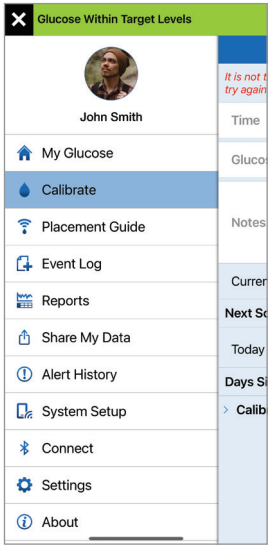
Profile Picture

You can update the profile picture in your Eversense account, which will be displayed in your app and in your Eversense DMS account.

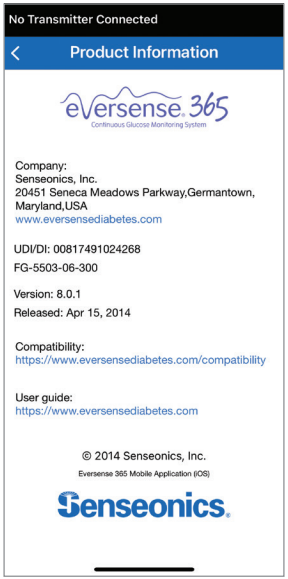
- Go to **About** > **My Account** and tap on the picture. You can also tap on the picture from the main menu.
- Follow the prompt to either update or delete the image. You can either take a new photo or choose an existing photo that is saved on your device.
- The photo you select will be displayed on 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.



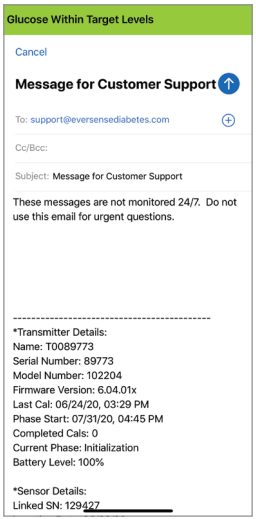


On the **Product Information** screen, you can view information about the app software version and Senseonics, Inc., the manufacturer of the Eversense 365 CGM System.



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 your local Customer Support team.



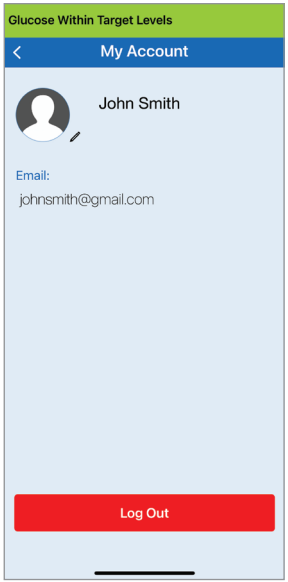
IMPORTANT: This email is not monitored 24/7. **DO NOT** use this email for health-related or any urgent issues.

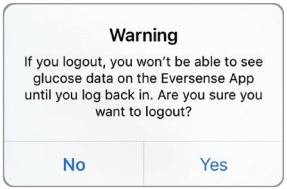
To read the End User License Agreement and the Privacy Policy, tap either option.

For more product information, tap **Help**.

Logging out

To log out of your app, tap **My Account** > **Log Out**.





13

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.

14. Viewing Eversense Data on Wearables

You can view a snapshot of your CGM data on your Apple Watch. Once you've downloaded and installed the Eversense 365 App on your mobile device, follow the device's instructions for adding the app to your watch.

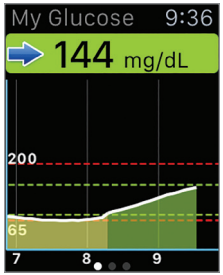
The wearable is a secondary display of Eversense data and should not be used in place of the primary CGM app display. Any alerts and notifications described in *Section 9* that appear on your Apple Watch should be confirmed within the mobile device app.

Any problems with mobile devices, wireless internet, data connection, the Eversense Data Management System (DMS), the CGM user's smart transmitter out of range of their mobile device, or charging their smart transmitter may cause data transfer to be delayed or not to be displayed.

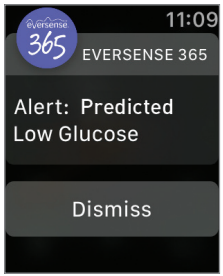
If at any time you have symptoms of a low or high blood glucose level OR if your symptoms are not consistent with the sensor glucose readings, you should measure your glucose with a blood glucose meter before making a treatment decision.

To access additional app features, tap the **Eversense 365** icon on your watch **HOME** screen to open the app.

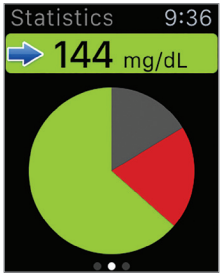
The **My Glucose** screen shows your current glucose with trend arrow, and a trend graph of your last three hours of CGM data.



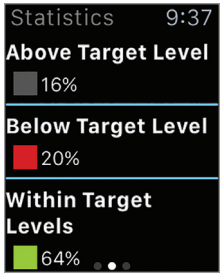
You can also access the **MY GLUCOSE** screen if you turn on notifications from the Eversense 365 App in your Apple Watch settings. When you receive a notification, you can also tap on the message to see the **MY GLUCOSE** screen.



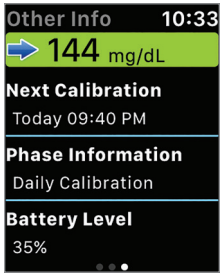
Swipe left to the next screen showing a pie chart of your total time within and outside your target range for the past 24 hours.



Swipe up to display the same data shown as percentages.

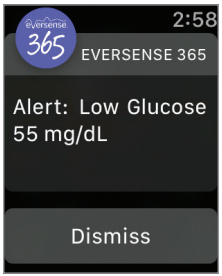


Swipe left to the next screen showing your current glucose with trend arrow, your next calibration time, the current system calibration phase, and battery level of your smart transmitter.

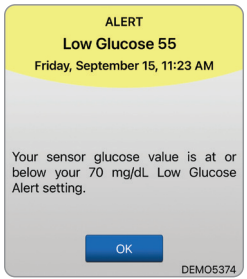


Alerts and Notifications Displayed on the Wearable Device

Wearable devices are a secondary display to the Eversense 365 App. Any alerts or notifications received on the wearable should be confirmed on the Eversense 365 App before any action is taken. Screen shape format may vary based on the wearable device. If you dismiss an alert on the watch, the alert display will disappear from the phone lock screen. Once the app is opened, the alert will be displayed with all of its information. To see a list of the alerts and notifications you may receive from your system, see *Section 9 Alert Descriptions*. Some alerts and notifications are affected by the sound settings in the app, and the Do Not Disturb function in the app. See *Setting Sounds and Alert Descriptions and Actions* for more information.



Low Glucose Alert displayed on wearable



Low Glucose Alert displayed on app

15. My Circle

Remote Monitoring with Eversense 365 CGM System and Eversense NOW App

The Eversense 365 App interacts with the Eversense NOW App to allow other people to view your 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 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 App are not a replacement for the primary display on your Eversense 365 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 365 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. The Eversense NOW App is a secondary display of your CGM data and should not be used in place of the primary Eversense 365 App display.
- You should not rely on those who are remotely monitoring your glucose to notify you about high or low glucose events.

Precautions

- The Eversense NOW App does not replace the monitoring regimen as directed by your health care provider.
- If you and the members of your Circle do not have an internet connection, or the mobile device has shut down due to a low or empty battery, your Eversense 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 365 Sensor and/or with the Eversense 365 Smart Transmitter.
- The Eversense NOW App cannot change the settings on the Eversense 365 App.
- If the Eversense NOW user does not allow notifications from the Eversense NOW App, they will not receive glucose related alerts from you.
- If you have your mobile device set to Do Not Disturb, you will not hear any notifications from the Eversense NOW App.

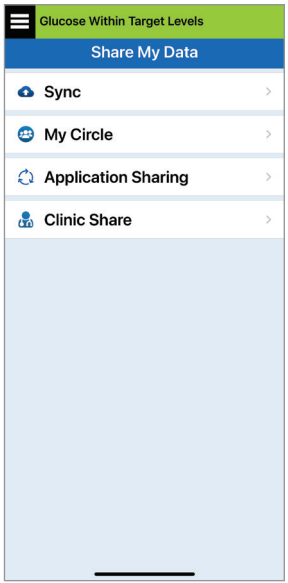
Through the **MY CIRCLE** screen on your Eversense 365 App, you can invite as many people as you wish to view your data. When you invite someone to join your Circle, an invitation will be sent to the email address you entered. Once the invitation is accepted, and the Eversense NOW App is downloaded, members of your Circle can view your recent glucose data, events and alerts.

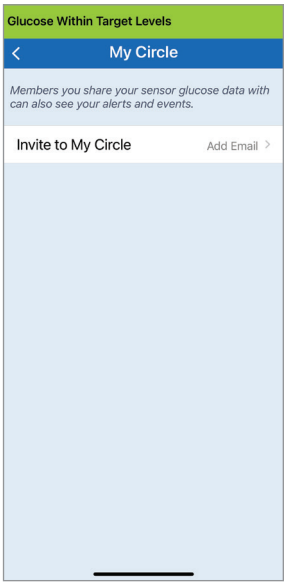
IMPORTANT: Members of your Circle who do not have the Eversense NOW App will not be able to see your data.

As long as your Eversense 365 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.

1. From the Main Menu, tap **Share My Data** > **My Circle** to display the **MY CIRCLE** screen.

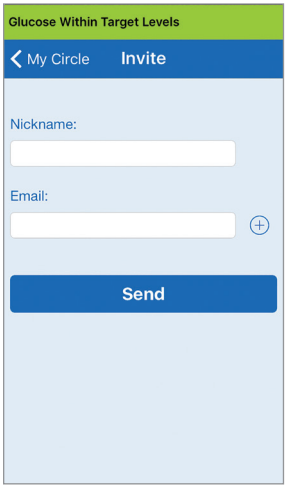
2. To invite a new member to view your glucose data, tap **Invite to My Circle.**





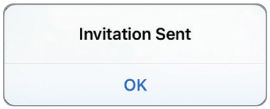
3. **Enter the email for the person you would like to invite to your Circle, and tap Send when complete.**

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

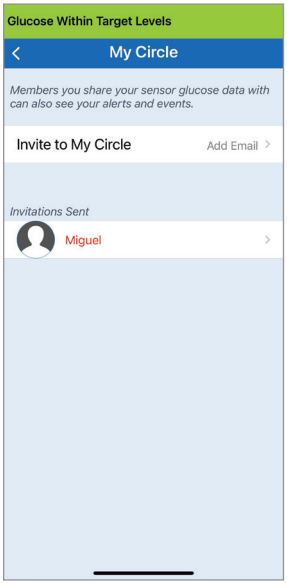


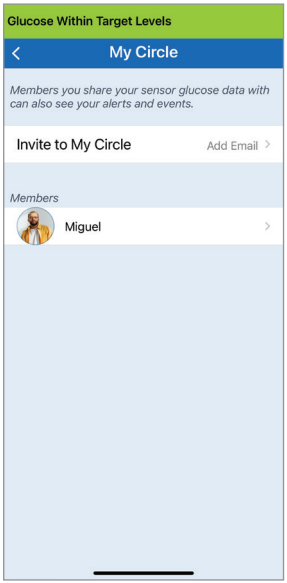
Tip: Nicknames are optional, and are used to help you easily manage your Circle Members. If you choose not to give a nickname to a Circle Member, their email address will show in place of a nickname.

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.

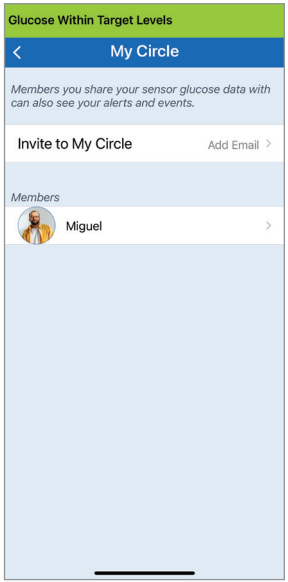




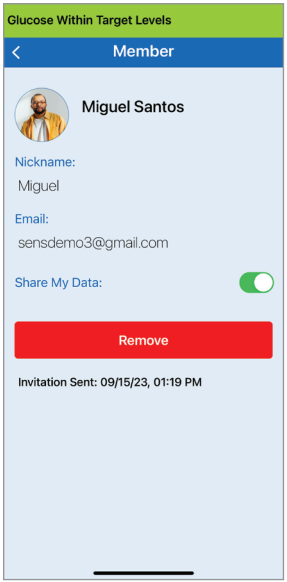
Note: Profile pictures of those remotely viewing your glucose data are set up in the DMS account by the account owner. You cannot change profile pictures of those you have invited to your Circle.

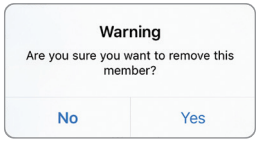
Remove a Member from Your Circle

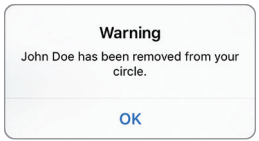
1. To remove a member or an invitation, tap the person's name in the Members List or the Invitations Sent List on the **MY CIRCLE** screen.



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





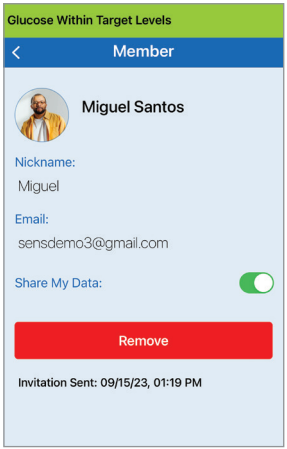


The member you remove will be notified on their Eversense NOW App if they have already accepted.

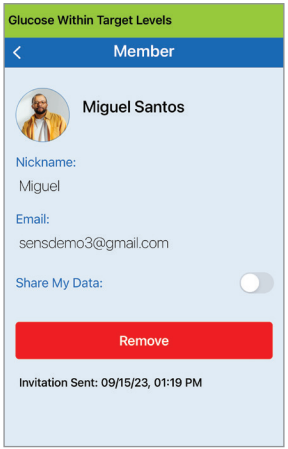
Temporarily Stop Sharing Data

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.



15

IMPORTANT: If you have disabled the Share My Data feature for a member, that member will not see any of your 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.

16. About the Sensor

This section describes the Eversense 365 Sensor and how it is inserted by your health care provider.

The sensor uses fluorescence to measure glucose in interstitial fluid. It is inserted under the skin and provides glucose readings for up to 1 year.

The sensor uses a unique fluorescent, glucose indicating polymer to measure glucose concentration based on the changes in light.

The sensor is approximately 3.5 mm x 18.3 mm and contains a small amount of dexamethasone acetate, an anti-inflammatory steroid drug. The dexamethasone acetate minimizes inflammatory responses, very similar to pacemakers.

Eversense 365 Sensor

Insertion Steps

Your health care provider 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 on the upper arm that is comfortable for you to wear the sensor and smart transmitter for up to 1 year. 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. It is recommended to alternate arms for the next sensor insertion.

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. Steri Strips™ are typically used to close the incision.

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 wearing the transmitter**.

Removal Steps

Similarly to the insertion steps, your health care provider 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 Strips™ (sutures may be used depending on provider's preference).

17. Travel

This section describes the safety issues when traveling with your Eversense 365 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 365 CGM System is safe for use on U.S. commercial airlines. The Eversense 365 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.

18. Troubleshooting

This section lists information about troubleshooting your Eversense 365 CGM System and includes a list of frequently asked questions (FAQs).

Smart Transmitter

Q: How do I turn my smart transmitter OFF?

A: Touch and hold the soft-touch button in the center of the transmitter for 5 seconds. Release the button when you feel a quick vibe and the LED turns off.

Q: How do I turn my smart transmitter ON?

A: Touch and hold the soft-touch button in the center of the transmitter for 3 seconds. Release the button when you feel a quick vibe and the LED turns on.

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 button 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.

Note: To see more information about signal strength and transmitter positioning, see *Placement Guide – Show More Detail Screen* in the *Linking the Sensor* section.

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 paired 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.
- Go to **About** > **My Transmitter** and tap **Demonstration**.

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

Q: Can I remove and replace the same adhesive patch more than once a day?

A: Repeated removal and replacement may reduce adhesion strength.

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.

Q: Why does my smart transmitter show a pulsating red LED?

A: The system has detected a transmitter error. Contact Customer Support.

Smart Transmitter Battery and Charging

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

A: Charging daily for 15 minutes provides about 24 hours of battery life when plugged into a wall outlet. It may take longer if charging via a computer USB port, if you don't charge daily, or when the battery is empty.

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. Check the battery icon and percentage in the upper right corner on the **MY GLUCOSE** screen. A red battery icon indicates the smart transmitter battery is empty.
2. Tap **Menu** > **About** > **My Transmitter**. Scroll down to the Battery Level line that indicates amount of battery power left.
3. Power on the smart transmitter. Tap in the center of the transmitter once. The LED will blink once. Orange indicates less than 24 hours battery life remaining. Green indicates about 24 hours or more battery life remaining.

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 365 App.
2. Tap the soft-touch button three times to activate pairing mode.
3. When the smart transmitter blinks blue, tap the smart transmitter ID on the **CONNECT** screen. The app will then begin the searching process.
   - Your smart transmitter ID is 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 your smart transmitter is not being charged, that it is turned on, and the battery is not very low or empty.
- Make sure your smart transmitter is within wireless range of your mobile device.
- Make sure your mobile device has the Bluetooth setting turned ON.

The condition may be temporary.

1. On the Eversense 365 App, tap **Menu** > **Connect**. If your smart transmitter name indicates **Disconnected**, tap the smart transmitter name to connect. If still not connected, go to next step.
2. Close the app.
3. Remove/forget the smart transmitter in your mobile device's Bluetooth settings.
4. Turn off the smart transmitter and then turn it back on.
5. Open the app.
6. Tap **Pair** if prompted. If not prompted, in the app, go to **Menu** > **Connect**. If your smart transmitter serial number (or name, if you gave it a custom name) indicates **Disconnected**, tap the smart transmitter name. If you don't see your transmitter listed, go to step 7.

7. Tap the smart transmitter's soft-touch button 3 times to activate pairing mode. When your transmitter is displayed on the **CONNECT** screen, tap it.
8. Tap **Pair** when prompted. If you are not prompted to Pair, contact Customer Support.

Q: How do I reset my smart transmitter?

A: Follow the steps below.

1. Charge the smart transmitter. Wait until the LED is blinking green or solid green.
2. While connected to the charger, touch and hold the transmitter's soft-touch button (for approx. 14 seconds). The LED will be white. Remove your finger from the transmitter when the LED changes from white to orange.
3. The LED will start blinking in a few seconds indicating the smart transmitter is going through a self-test sequence. The LED will blink in various colors. Once the self test is complete, the smart transmitter will vibrate and blink green indicating it is now charging.
4. If the self-test does not complete, repeat steps 1 through 3.
5. If step 3 is successfully completed, the smart transmitter is now ready for use.

Q: Can other people connect to my smart transmitter?

A: The 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 5 to 30 minutes, based on your sound settings, until the app is launched or the smart transmitter is reconnected. Once the connection is re-established, the data collected will sync with the 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.

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 pairing mode?

A: Pairing 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: 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.
- 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: Why do I see other smart transmitters listed on the CONNECT screen?

A: If other Eversense 365 CGM users are around you, then the app may find those devices. 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: I just received a new smart transmitter. How do I unpair the old one and connect the new one to my system?

A: On the Main Menu, tap **Connect** or **System Setup** > **Help me set up** > **I have a new transmitter**. Tap and hold the name of your old smart transmitter. Tap **OK** to stop the app from automatically connecting with the old smart transmitter. Forget the old smart transmitter from your phone's Bluetooth settings. Follow the steps in this *User Guide* for pairing the new smart transmitter with the app and linking it to your sensor.

Calibration

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 40 mg/dL.
- The blood glucose reading entered is greater than 400 mg/dL.

If another calibration is needed, the system will prompt you.

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 40 mg/dL.
- The blood glucose reading is greater than 400 mg/dL.
- The blood glucose reading was taken more than 10 minutes prior to entering it in the app.
- The last sensor glucose value is significantly different than the blood glucose reading entered.

- A calibration is in progress.
- It is less than 1 hour since the last successful calibration.
- Your transmitter is disconnected.
- Transmitter is not linked to your sensor.
- Your sensor needs to be replaced.

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 system has three types of Calibration Phases: the Initialization Phase, 1 Daily Calibration Phase, and 1 Weekly Calibration Phase. Initialization Phase begins 24 hours after sensor insertion and requires 4 fingerstick blood glucose calibrations.

Alerts and Notifications

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

A: Smart transmitter vibe patterns 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: Can I change the number of alerts I receive?

A: If you feel that you are getting too many alerts, you should discuss the alert settings with your health care provider. If you need to change your glucose alert settings, tap **Menu** > **Settings** > **Glucose**.

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**.

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

A: A Notification is a 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 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 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. If your symptoms do not match the sensor glucose value, or what the alerts indicate, you should immediately perform a fingerstick blood glucose measurement before making a treatment decision.

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: 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: 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: 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.

Glucose Readings

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

A: The system measures glucose in interstitial fluid (ISF) between the body's cells. Your Eversense 365 CGM System and BG meter measure glucose differently. Glucose levels in ISF lag behind glucose levels in blood. Differences are more likely to be seen when your glucose is changing rapidly (e.g., after eating, dosing insulin, or exercising). For some people, there may be differences during the first several days after insertion due to inflammation that may result from the procedure. Until you are aware of what these differences are, confirm sensor readings with a fingerstick blood glucose check. Also, if your symptoms do not match the sensor glucose readings, you should confirm with a fingerstick blood glucose check.

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.
- Sensor Check.
- High Smart Transmitter Temperature.
- High Sensor Temperature.
- Empty Battery.
- Calibration Past Due.
- New Sensor Detected.
- Sensor Replacement.
- Calibration Expired.
- Smart Transmitter Error.
- Transmitter Replacement Alert
- Glucose Suspend Alert.

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

Making Treatment Decisions

Q: What information should be considered before I make a treatment decision?

A: Take into account the sensor glucose value, the trend graph, the trend arrow and any alerts from the system. If no trend arrow is displayed, the system does not have enough data to display direction and rate of change. You should not make a treatment decision based solely on the sensor glucose value.

Q: Why is my glucose value grey?

A: When the system does not have enough data to provide a trend arrow, the sensor glucose value may be displayed in grey. You should not make a treatment decision based solely on the sensor glucose value.

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

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

- When it is time to calibrate.
- No glucose value is displayed.
- No trend arrow is displayed.
- Your symptoms do not match the glucose information displayed.
- The current sensor glucose value is displayed in grey.
- The status bar is displayed in orange.
- You are taking medications of the tetracycline class.

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 missing.

A: The 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 not displayed. You should not make treatment decisions unless you see a glucose value, a trend arrow, and consider recent trends and alerts.

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: Follow the process of keeping your app up to date via the Apple App Store or the Google Play Store.

Q: What devices are compatible with the Eversense 365 App?

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

Q: Can I delete my Eversense account?

A: If you delete your account, it is permanent, and you will no longer have access to your CGM data on the app, or in your Eversense DMS account. If you are using the Eversense NOW App, you will no longer be able to remotely view Eversense data. You cannot use the same email address to create a new account. To initiate account deletion, tap Delete Account on the log in page.

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 365 App Settings, the app will stop displaying lower priority alerts. The smart transmitter will also stop providing vibratory alerts for those alerts. High priority alerts will still be provided by the smart transmitter and the 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. However with certain phone operating systems you can enable Low Glucose Alerts to override your phone sound setting. See *Sound Settings* for more information. Be aware that some apps may automatically enable Do Not Disturb on your phone.

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.

Q: My Glucose Settings and Temp Profile Settings are grayed out and I cannot adjust them.

A: Your app must be paired to a smart transmitter to be able to adjust your Glucose and Temp Profile settings.

Q: Can I edit a manual BG entry event?

A: Manual BG entries and calibration entries cannot be edited.

Q: If I hide an event, can I restore later?

A: Event entries that have been hidden cannot be restored.

Q: What repeat intervals can I set for High and Low Glucose?

A: For High Glucose, the repeat interval can be 15 to 180 minutes, in 15-minute increments. For Low Glucose, the repeat interval can be 5 to 30 minutes in 5-minute increments.

Sensor

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

A: The system was tested only in the upper arm during clinical studies, and the sensor should not be inserted in other locations.

Q: When do I need to replace my sensor?

A: Your sensor lasts up to 1 year. You will receive periodic notices (60, 30, 14, 7, 3, and 1 day prior) to remind you when the sensor needs to be replaced. Contact your health care provider to schedule a sensor replacement.

Q: Can I extend the life of the sensor?

A: No, however the sensor may continue to provide glucose readings after day 365, for up to 10 days.

Q: Where can I find the sensor serial number?

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

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

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

- Calibration period has expired without you having entered a fingerstick value.
- 3 or more blood glucose readings are significantly different than the current sensor glucose readings.
- If you manually change the time on your mobile device your smart transmitter will sync and reinitialize to your mobile device.
- A new transmitter has been linked to your existing sensor. For example, if you have replaced your existing transmitter.
- If you were instructed by Customer Support to re-link your sensor.

Q: Is it okay for an MRI technician to wear the Eversense 365 CGM System?

A: Yes, MRI technicians can wear the Eversense 365 CGM System. However, for people undergoing an MRI with a static magnetic field of 1.5T or 3.0T, the sensor can stay in place under the skin, but the smart transmitter must be removed and left outside the room. See *MRI Safety Information* for more details.

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 app completely and re-launched it.
- Your mobile device lost battery power and was recharged.

Shortcuts

Q: Is there a way to select a date to view on the MY GLUCOSE screen, instead of scrolling backwards?

A: Yes, tap the **"**Today**"** bar right above the graph. A pop-up will appear for you to select the desired date to be displayed on the graph.

Q: If I'm viewing a date/time in the past on the MY GLUCOSE screen, is there a short cut back to the current date and time?

A: Yes, tap the glucose value/trend arrow to return to the current date/time on the **MY GLUCOSE** screen.

Q: Is there a shortcut to the ALERT HISTORY screen?

A: If your smart transmitter is connected to the app, you can tap the status bar at the top of the screen to display the **ALERT HISTORY** screen.

Q: Is there a shortcut to the CONNECT screen?

A: If your smart transmitter is disconnected from the app, when you tap the status bar at the top of the screen, the **CONNECT** screen is displayed.

Q: Is there a shortcut to enter an event, like meals or exercise?

A: From the **MY GLUCOSE** screen, tap on the graph to display the **EVENT ENTRY** screen.

19. Device Performance

This section lists Device Performance Characteristics.

Clinical Study Performance

The safety and effectiveness of the Eversense 365 CGM System has been evaluated in the ENHANCE clinical study conducted in the U.S. Accuracy assessments were made at various points during the study and subjects were asked to report any adverse events throughout the study.

ENHANCE Study

The ENHANCE study was a prospective, multi-site non-randomized pivotal clinical study. One hundred and ten (110) people (18 years and older) with type 1 or type 2 diabetes participated in the study across 4 sites in the U.S. (Table 1). Participants interacted with the system to calibrate and address notifications not related to glucose data. All diabetes care decisions were based on blood glucose values and clinical standard of care. Accuracy was measured during 8-12 hour clinic visits. These visits occurred on Days 1, 7, 14, 22, 30, 60, 90, 120, 150, 210, 240, 270, 300, 330, and 365. At each visit, sensor accuracy was evaluated relative to a standard laboratory analyzer known as the YSI 2300. Glucose readings were compared between the reference analyzer and the CGM.

Table 1 – Study Demographics

Demographic	Data Capture Rate (%)
Gender n (%)	
Male	69 (62.7%)
Female	41 (37.3%)
Age (years)	
[Mean (SD)]	47.2 (13.7)
Min, Max	18, 77
Ethnicity n (%)	
Non-Hispanic	86 (78.2%)
Hispanic	24 (21.8%)
Race n (%)	
Caucasian	102 (92.7%)
Black or African American	4 (3.6%)
More than One Race	2 (1.8%)
American Indian or Alaska Native	1 (0.9%)
Asian	1 (0.9%)
Native Hawaiian or Other Pacific Islander	0 (0.0)%
Body Mass Index Class	
[Mean (SD)] kg/m^2	32.0 (6.8)
Min, Max	19.0, 52.0
Normal (< 25 kg/m^2) n (%)	12 (10.9%)
Overweight (> 25 and < 30) n (%)	30 (27.3%)
Obese (> 30) n (%)	68 (61.8%)

Table 2– Accuracy to YSI Overall

YSI Glucose Range (mg/dL)	Total Number of Paired CGM and YSI Values	Percent Within 20/20% of Reference	Percent Within 20/20% of Reference on Day 1	MARD (%)
Overall	40,497	93.4	88.6	8.8

CGM values are within 40 to 400 mg/dL.

20/20% results: For blood glucose values less than or equal to 80 mg/dL, the mean absolute difference between the two results was calculated. For values greater than 80 mg/dL, the mean absolute relative difference was calculated.

MARD result: The result is derived from the mean absolute relative difference (%) across the entire measuring range of the device over 365 days.

MAD result: The result is derived from the mean absolute difference (mg/dL).

Accuracy was measured by comparing the CGM glucose values to YSI blood glucose values in various glucose ranges.

Table 3 – Sensor Accuracy to YSI by YSI Glucose Range

YSI Glucose Range (mg/dL)	Total Number of Paired CGM and YSI Values	MARD (%)	MAD (mg/dL)
< 54	358	15.8	7.7
54 - 69	2,446	12.5	7.8
70 - 180	23,130	9.0	---
181 - 250	7,997	7.8	---
> 250	6,566	7.5	---

Performance was also measured by calculating the percentage of sensor glucose readings within a certain range of the YSI reference by CGM glucose ranges (Table 4), and by YSI glucose ranges (Table 5). These tables show the percent agreement at multiple levels, at different glucose ranges. As an example, in Table 4, CGM glucose values between 54 and 69 mg/dL were within 20 mg/dL of the reference value 94.8% of the time.

Table 4 – Sensor Accuracy to YSI by CGM Glucose Range

CGM Glucose Range (mg/dL)	Total Number of Paired CGM and YSI Values	Percent Within 15 mg/dL	Percent Within 20 mg/dL	Percent Within 40 mg/dL	Percent Within 15% of Reference	Percent Within 20% of Reference	Percent Within 40% of Reference	Mean Bias	MARD (%)	MAD (mg/dL)
< 54	687	76.3	88.2	98.3	---	---	---	-11.0	17.9	11.6
54 - 69	2,353	90.4	94.8	99.2	---	---	---	-3.8	11.1	7.8
70 - 180	23,049	---	---	---	81.9	90.9	99.4	-1.9	9.0	---
181 - 250	8,198	---	---	---	88.0	94.9	99.7	-2.4	7.7	---
> 250	6,210	---	---	---	91.1	97.1	99.8	5.3	7.2	---

Table 5 – Sensor Accuracy to YSI by YSI Glucose Range

YSI Glucose Range (mg/dL)	Total Number of Paired CGM and YSI Values	Percent Within 15 mg/dL	Percent Within 20 mg/dL	Percent Within 40 mg/dL	Percent Within 15% of Reference	Percent Within 20% of Reference	Percent Within 40% of Reference	Mean Bias	MARD (%)	MAD (mg/dL)
< 54	358	90.2	95.0	99.4	---	---	---	3.9	15.8	7.7
54 - 69	2,446	89.8	96.7	99.6	---	---	---	0.8	12.5	7.8
70 - 180	23,130	---	---	---	82.4	91.4	99.4	-0.3	9.0	---
181 - 250	7,997	---	---	---	87.1	94.5	99.9	-3.1	7.8	---
> 250	6,566	---	---	---	89.5	95.9	100.0	-2.9	7.5	---

Table 6 shows the percentage of sensor glucose values that concur to YSI within CGM ranges.

Table 6 – Sensor Glucose Concurrence within CGM ranges

		Percent of Matched Pairs in Each YSI Glucose Range for Each CGM Glucose Range YSI (mg/dL)										
CGM (mg/dL)	Number of Paired CGM-YSI	< 40	40 - 60	61 - 80	81 - 120	121 - 160	161 - 200	201 - 250	251 - 300	301 - 350	351 - 400	> 400
< 40	76	14.5%	71.7%	9.2%	5.3%							
40 - 60	1,411	0.2%	52.0%	44.6%	3.0%	0.1%						
61 - 80	3,449		13.0%	61.8%	24.7%	0.6%						
81 - 120	9,149		0.3%	6.8%	76.1%	16.4%	0.5%	0.0%				
121 - 160	8,638		0.0%	0.1%	14.2%	71.2%	13.7%	0.8%	0.0%			
161 - 200	6,292				0.1%	17.0%	65.0%	17.2%	0.7%	0.0%		
201 - 250	5,348					0.4%	15.8%	66.0%	16.8%	1.0%		
251 - 300	3,494					0.1%	0.4%	17.5%	63.8%	17.4%	0.7%	
301 - 350	2,052							0.5%	28.1%	64.5%	6.6%	0.2%
351 - 400	664								3.3%	61.3%	34.0%	1.4%
> 400	156								0.6%	22.4%	55.1%	21.8%

Table 7 shows the percentage of sensor glucose values that concur to YSI within YSI ranges. As an example, when CGM readings are between 81 and 120 mg/dL, blood glucose values were in that same range 76.5% of the time.

Table 7 – Sensor Glucose Concurrence within YSI ranges

		Percent of Matched Pairs in Each CGM Glucose Range for Each YSI Glucose Range CGM (mg/dL)										
YSI (mg/dL)	Number of Paired CGM-YSI	< 40	40 - 60	61 - 80	81 - 120	121 - 160	161 - 200	201 - 250	251 - 300	301 - 350	351 - 400	> 400
< 40	14	78.6%	21.4%									
40 - 60	1,261	4.3%	58.2%	35.4%	2.0%	0.1%						
61 - 80	3,392	0.2%	18.6%	62.8%	18.2%	0.2%						
81 - 120	9,098	0.0%	0.5%	9.4%	76.5%	13.5%	0.1%					
121 - 160	8,755		0.0%	0.2%	17.1%	70.2%	12.2%	0.2%	0.0%			
161 - 200	6,179				0.7%	19.1%	66.2%	13.7%	0.2%			
201 - 250	5,308				0.0%	1.4%	20.4%	66.5%	11.5%	0.2%		
251 - 300	3,774					0.0%	1.1%	23.8%	59.1%	15.3%	0.6%	0.0%
301 - 350	2,427						0.0%	2.1%	25.1%	54.5%	16.8%	1.4%
351 - 400	473								5.3%	28.8%	47.8%	18.2%
> 400	48									10.4%	18.8%	70.8%

LO and HI Agreement

The system displays values from 40 to 400 mg/dL. Values lower than 40 are displayed as LO. Values higher than 400 are displayed as HI. Table 8 shows a comparison of HI/LO readings compared to the YSI value. As an example, of the 76 LO readings, 93.4% of the YSI values were below 70 mg/dL.

Table 8 – Distribution of Comparator Glucose for CGM Readings

CGM Readings	CGM Comparator Readings	< 55	< 60	< 70	< 80	>= 80	Total
LO	N Cumulative Percent	54 71.1%	64 84.2%	71 93.4%	72 94.7%	4 5.3%	76
CGM Readings	**CGM Comparator Readings**	**> 340**	**> 320**	**> 280**	**> 250**	**>= 250**	**Total**
HI	N Cumulative Percent	134 85.9%	143 91.7%	156 100.0%	156 100.0%	0 0.0%	156

Performance was evaluated at various points during the study. Table 9 shows results at 30 day intervals during sensor wear.

Table 9 – Sensor Accuracy over Time

Time after Insertions (Days)	Total Number of Paired CGM and YSI Values	Percent of CGM System Readings Within				
		15/15% of Reference	20/20% of Reference	30/30% of Reference	40/40% of Reference	MARD
1 - 30	9,129	81.5	90.6	97.4	99.3	9.7
31 - 60	3,283	84.0	93.4	98.7	99.7	9.0
61 - 90	2,858	82.7	90.9	97.4	99.4	9.9
91 - 120	3,561	88.1	95.1	98.8	99.6	8.4
121 - 150	2,745	89.0	96.0	99.2	99.7	7.8
151 - 180	2,727	86.2	93.7	99.4	100.0	8.1
181 - 210	3,076	88.7	95.5	99.6	100.0	7.9
211 - 240	2,855	88.2	95.0	98.8	99.6	8.2
241 - 270	1,951	82.7	91.3	98.2	99.9	9.4
271 - 300	2,718	88.3	95.4	99.5	99.9	7.9
301 - 330	2,257	89.0	94.9	99.2	99.9	8.1
331 - 365	3,337	86.9	94.8	99.1	99.8	8.8

Alert Performance

The tables in this section show an alert performance assessment. The Confirmed Event Detection Rate shows the percentage of time the system confirmed the reference value by presenting an alert within a 15 minute window of a reference value beyond the alert setting threshold. The Missed Detection Rate shows the percentage of time the system did not present an alert within a 15 minute window of a reference value beyond the alert setting threshold. The True Alert Rate shows the percentage of time the alert from the system was confirmed by a reference value within a 15 minute window of the alert being presented. The False Alert Rate shows the percentage of time the alert from the system was not confirmed by a reference value within a 15 minute window of the alert being presented.

Table 10 – Sensor High and Low Glucose Alert Performance (Threshold and Predictive)

Alert Setting (mg/dL)		Confirmed Event Detection Rate	Missed Event Detection Rate	True Alert Rate	False Alert Rate
Low Alert	55	88.6%	11.4%	51.0%	49.0%
	60	90.5%	9.5%	66.7%	33.3%
	70	96.6%	3.4%	81.5%	18.5%
	80	97.2%	2.8%	84.6%	15.4%
	90	97.4%	2.6%	88.0%	12.0%
High Alert	120	98.6%	1.4%	96.7%	3.3%
	140	98.4%	1.6%	96.0%	4.0%
	180	97.9%	2.1%	94.0%	6.0%
	200	97.2%	2.8%	93.5%	6.5%
	220	96.4%	3.6%	93.0%	7.0%
	240	95.8%	4.2%	92.1%	7.9%
	300	93.5%	6.5%	83.0%	17.0%

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Table 11 – Sensor High and Low Glucose Alert Performance (Threshold)

Alert Setting (mg/dL)		Confirmed Event Detection Rate	Missed Event Detection Rate	True Alert Rate	False Alert Rate
Low Alert	55	76.9%	23.1%	54.5%	45.5%
	60	78.2%	21.8%	72.0%	28.0%
	70	91.4%	8.6%	86.7%	13.3%
	80	94.0%	6.0%	88.8%	11.2%
	90	94.0%	6.0%	91.7%	8.3%
High Alert	120	97.6%	2.4%	97.5%	2.5%
	140	97.4%	2.6%	97.2%	2.8%
	180	96.4%	3.6%	95.5%	4.5%
	200	95.3%	4.7%	95.4%	4.6%
	220	94.5%	5.5%	95.3%	4.7%
	240	93.7%	6.3%	94.5%	5.5%
	300	89.6%	10.4%	87.8%	12.2%

Rate of Change Trend Agreement

The shaded areas in Table 12 shows agreement between the CGM glucose trends and the YSI reference trends while glucose is trending at different rates (mg/dL per minute). As an example, when glucose is trending at a rate of between -1 and 1 mg/dL/minute, CGM glucose trends are in agreement with the reference trends 85.3% of the time.

Table 12 – Sensor Rate of Change Trend Agreement

Comparator Trend (mg/dL/Min)	CGM Rate of Change (mg/dL/Min) Percent of Matched Pairs in Each CGM Trend Range for Each Reference Trend Range					
	< -2	[-2, -1)	[-1, 1]	(1, 2]	> 2	Total
< -2	41.4%	37.1%	21.0%	0.5%	0.0%	210
[-2, -1)	13.4%	40.2%	44.2%	1.8%	0.4%	2,026
[-1, 1]	1.1%	6.5%	85.3%	5.8%	1.3%	32,531
(1, 2]	0.2%	0.7%	43.9%	36.9%	18.2%	2,861
> 2	0.0%	0.4%	21.7%	28.6%	49.3%	803

Calibration Stability

Table 13 compares the percentage of sensor glucose values to the YSI reference at various time points after a calibration entry. As an example, 95.5% of the sensor values were within 20 mg/dL (for reference readings of less than 70 mg/dL or less), and within 20% (for reference readings greater than or equal to 70 mg/dL) of the reference value 24 to 36 hours after a calibration entry.

Table 13 – Sensor Calibration Stability

Time from Calibration	Number of Paired CGM and YSI Reference	Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent Greater than 40/40% of Reference
0 - 12 hours	10,440	85.0	92.7	97.9	99.3	0.7
12 - 24 hours	4,345	85.9	93.1	98.5	99.8	0.2
24 - 36 hours	1,953	87.1	95.5	99.3	99.8	0.2
36 - 48 hours	2,628	87.0	94.4	99.3	99.8	0.2
48 - 60 hours	1,431	86.8	94.0	98.9	100.0	0.0
60 - 72 hours	2,299	86.3	94.3	99.0	99.9	0.1
72 - 84 hours	1,465	82.9	90.5	97.7	99.4	0.6
84 - 96 hours	2,309	87.7	94.8	98.6	99.7	0.3
96 - 108 hours	1,534	86.1	93.9	98.7	99.7	0.3
108 - 120 hours	2,567	84.5	93.6	98.4	99.5	0.5
120 - 132 hours	2,095	84.8	93.1	99.0	99.8	0.2
132 - 144 hours	2,750	85.6	93.3	99.0	99.9	0.1
144 - 156 hours	1,978	83.9	93.7	99.5	100.0	0.0
156 - 168 hours	2,627	85.8	93.8	98.6	99.6	0.4
168 - 174 hours	76	86.8	96.1	97.4	100.0	0.0

Data Availability

The system is designed to capture and display a glucose value every 5 minutes, or up to 288 readings per day, after Warm Up Phase. The table below shows the Eversense 365 Sensors captured readings at least 99.9% of the time.

Table 14 – Data Availability

Date Range	Number of Sensors	Data Capture Rate (%)
Day 1 - 30	103	99.9
Day 31 - 60	101	99.9
Day 61 - 90	97	100.0
Day 91 - 120	96	99.9
Day 121 - 150	97	100.0
Day 151 - 180	95	100.0
Day 181 - 210	91	99.9
Day 211 - 240	90	100.0
Day 241 - 270	86	99.9
Day 271 - 300	87	99.9
Day 301 - 330	84	100.0
Day 331 - 365	81	99.9

Sensor to Sensor Precision

For subjects who had two Eversense 365 Sensors (one inserted in each arm), CGM data from both sensors was evaluated for precision. The overall PARD (paired absolute relative difference) of 8.0% and PCV (percent coefficient of variation) of 5.7% demonstrate high precision.

Table 15 – Sensor to Sensor Precision

Range of Mean CGM Glucose (mg/dL)	Number (CGM, CGM) pairs	Number of subjects	SD (mg/dL)	PAD (mg/dL)	PARD (%)	PCV (%)
Overall	82,731	32	17.5	12.3	8.0	5.7
< 70	3,911	28	10.1	7.4	12.6	8.9
70 - 180	50,997	32	14.0	10.2	8.2	5.8
> 180	27,823	32	23.2	16.8	7.0	4.9

Sensor Life

Sensor life measured the percentage of sensors being able to function through the intended 365 day duration. In the ENHANCE study, 90.0% of sensors functioned through the 365 day period.

Table 16 – Sensor Survival by Day

Days since Sensor Insertion	Survival Rate (%)
1	97.0
30	97.0
60	97.0
90	96.0
120	96.0
150	96.0
180	96.0
210	95.0
240	95.0
270	93.0
300	92.0
330	92.0
365	90.0

Safety

Table 17 shows the number of related adverse events through 365 days. The system was well tolerated in the study. During the study's 37,895 sensor wear days, there were no unanticipated adverse events. Twenty three adverse events were reported in 17 of the participants. None of the adverse events resulted in hospitalization.

Table 17 – Adverse Events

Event Type	Number of Events	Number of Subjects (% of Subjects)
	23	17 (15.5)
Infection, insertion site	4	4 (3.6)
Prolonged/Delayed wound healing	3	3 (2.7)
Skin irritation, adhesive location	2	2 (1.8)
Skin irritation, sensor site	2	2 (1.8)
Skin atrophy/discoloration/hyperpigmentation	4	3 (2.7)
Insertion site pain	3	2 (1.8)
Vasovagal episode	3	2 (1.8)
Nausea	1	1 (0.9)
Bleeding, excessive, removal site	1	1 (0.9)

20. Technical Specifications

Sensor

Characteristic	Description
Dimensions	Length: 18.3 mm Diameter: 3.5 mm
Tissue Contacting Materials	Polymethylmethacrylate (PMMA); Hydroxyethylmethacrylate (HEMA) based Hydrogel; Silicone Dexamethasone Acetate (DXA) Collar; EPO-TEK 301-2; Platinum, Iridium, Molybdenum
Glucose Range	40 - 400 mg/dL
Sensor Life	Up to 1 year
Calibration	Commercially available self-monitoring blood glucose meter
Calibration Range	40 - 400 mg/dL
Sterilization	Sterile by Ethylene Oxide
Non-pyrogenic	Free from fever-causing substances

Blunt Dissector

Characteristic	Description
Materials	Acrylonitrile butadiene styrene (ABS), 304 Stainless Steel (an alloy of Carbon, Manganese, Phosphorus, Sulfur, Silicon, Chromium and Nickel)
Storage Temp	Between 50 °F (10 °C) and 86 °F (30 °C)
Sterilization	Sterile by Ethylene Oxide
Non-pyrogenic	Free from fever-causing substances

Insertion Tool

Characteristic	Description
Materials	Acrylonitrile butadiene styrene (ABS) and Polytetrafluoroethylene (PTFE); Cyanoacrylate adhesive and 304 Stainless Steel (an alloy of Carbon, Manganese, Phosphorus, Sulfur, Silicon, Chromium and Nickel)
Storage Temp	Between 50 °F (10 °C) and 86 °F (30 °C)
Sterilization	Sterile by Ethylene Oxide
Non-pyrogenic	Free from fever-causing substances

Smart Transmitter

Characteristic	Description
Dimensions	Length: 48.0 mm Width: 37.7 mm Height: 9.2 mm
Materials	Body: polycarbonate
Weight	14.0 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 for up to 30 minutes
Protection Against Electrical Shock	Type BF applied part
Communication Distance	Between app and smart transmitter is up to 24.9 feet Wireless communication to the app will not function well when communicating through water. The range will decrease if you are in a bathtub, water bed, pool, etc.
Cabin Pressure	700 hPa to 1060 hPa
Relative Humidity Range (non-condensing)	15% to 90%
Altitude	10,000 ft

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)

IMPORTANT: Use only the AC power adapter and USB cable provided with your smart transmitter. Use of another power supply could damage the smart transmitter and create the risk of fire.

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.

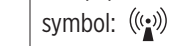
Transmitter Electromagnetic Immunity Specifications

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 365 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)	10 V/m	

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 365 CGM System is used exceeds the applicable RF compliance level above, the Eversense 365 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 365 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 365 CGM 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 365 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 365 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 365 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.
	**Predicted Low or Rate Falling Alert** Indicates a Rate Falling or Predicted Low Alert occurred. The icon appears in the **ALERT HISTORY** screen and on the home screen trend line.
	**Predicted High or Rate Rising Alert** Indicates a Rate Rising or Predicted High Alert occurred. The icon appears in the **ALERT HISTORY** screen and on the home screen trend line.
	**Empty Battery Alert** Appears when the smart transmitter battery is empty.
	**Low Battery Alert** Appears when the smart transmitter battery has less than 24 hours of power available.
	**Smart Transmitter/Sensor Alert** The icon appears in the **ALERT HISTORY** screen.
	**Smart Transmitter/Sensor Notifications** Appears when there are notifications related to the smart transmitter or sensor.
	**Calibration Alert** Appears when there are calibration-related alerts.
	**Calibration Notification** Appears in **ALERT HISTORY** when there are calibration-related notifications. The icon also appears on the My Glucose trend line and Event Log when a manual BG entry is logged.

Symbols on the Eversense 365 App (continued)

Symbol	Explanation
	**Calibration Accepted** Appears on the glucose trend line and **EVENT LOG** when a calibration is entered and accepted.
	**Calibration in Progress** Appears on the glucose trend line and the Event Log during the ~15 minutes while a calibration is in progress. The icon will turn either red, black or blue when calibration is no longer in progress.
	**Calibration Incomplete** Appears on the glucose trend line and the Event log when not enough data is not collected to complete the calibration. For example, when the transmitter is removed from over the sensor during the ~15 minute calibration period.
	**Calibration Cannot be Used** Appears on the glucose trend line and the Event Log when a calibration has been entered that cannot be used. For example, the value entered is less than 40 mg/dL or more than 400 mg/dL. In this case, the calibration value is stored as a manual BG entry.
	**System Connection Successful** Appears when the smart transmitter is connected to the smartphone and the sensor is linked to the smart transmitter. The bars indicate the strength of the connection.
	**Transmitter and Sensor Connection** Appears before a transmitter is linked to a sensor and when the connection between a transmitter and sensor is interrupted.
	**Transmitter and App Connection** Appears when the BLE connection between the transmitter and app is interrupted.

Symbols on the Eversense 365 App (continued)

Symbol	Explanation
	**Multiple Alerts (more than one alert or event)** Appears when there are two or more alerts or events in a short interval.
	**Event Icons** Appear on the glucose trend line and in the **EVENT LOG** after an event is entered. The events that can be entered are:  Glucose  Insulin  Exercise  Meals  Health
	**Temp Profile** Appears when the Temp Profile is active.
	**Do Not Disturb (DND)** Appears when the DND setting is active.
	**Battery Power Icons and Percentage** Indicates approximate battery power remaining.  No battery power remaining  Full battery power remaining

Symbols Glossary

The symbols glossary for the Eversense 365 CGM System can be found here:
www.eversensediabetes.com/symbols_glossary

Security Information and Quality of Service

The Eversense 365 CGM System components are designed to securely connect with compatible devices using industry standard communication protocols, as well as additional security measures. The sections below provide information on security and quality of service for the various system components. A software bill of materials is available upon request by contacting Customer Support.

If you believe the security of your system has been compromised, contact Customer Support, and use your BG meter to monitor your glucose until the issue is resolved.

Transmitter and App Communication

The app and the smart transmitter communicate via Bluetooth Low Energy (BLE) when the devices are within 24.9 feet, without obstructions. The BLE connection provides an industry standard level of security.

- In addition to the security provided by the BLE connection via the use of encryption, data sent from your smart transmitter to your app is further protected by using authentication between the devices. The system checks for secure BLE communication. If a problem is detected, the BLE communication will be stopped, and the Transmitter Disconnected banner is displayed.
- To provide added security during pairing of the smart transmitter and app, Eversense uses a Pass Key, proximity pairing and authentication between the devices.
- To help reduce cybersecurity risks such as “Bluesnarfing” and “Eavesdropping”, it is recommended that you only pair your smart transmitter and app in a private or safe location.
- If the connection between the smart transmitter and mobile device is lost, the app will display a Transmitter Disconnected message and no glucose values will be displayed. When the connection is restored, any data collected by the transmitter from the sensor will be sent to the app.

Transmitter and Sensor Communication

The smart transmitter and the sensor communicate via short-range Near Field Communication (NFC). NFC allows the wireless exchange of data between two devices that are very close together, making it difficult to intercept or interfere with data transmission.

NFC is often used for tap-to-pay credit cards and mobile wallets such as Apple Pay and Google Pay.

- The sensor is designed to connect and communicate with only one smart transmitter at a time. The smart transmitter must be worn directly over the implanted sensor in order to communicate via NFC.
- If the communication between the sensor and transmitter is lost, the app will display a No Sensor Detected Alert and no glucose values will be displayed.
- In addition to the security provided by short range NFC, data from the sensor to your smart transmitter is protected using a proprietary raw data format.

Data Transfer

Data sent from your app to Eversense servers is protected through the use of industry standard security measures, including encryption and authentication. The servers are constantly monitored to protect against intrusion using industry standard tools and protocols. All monitoring logs are encrypted, and only authorized personnel can access.

Device, Network, and Internet Security

It is your responsibility to use your devices in a secure manner. As with other apps you use that include your personal information, only install Eversense 365 Apps from Google Play or the Apple App Store to ensure their authenticity.

- Use a strong password when creating your Eversense account and turn on the screen auto-lock feature in your mobile device settings. Do not share your username or password with other people. Your username and password are encrypted and stored securely on your mobile device. They are used by the system to be sure that only you can access your data.
- If the system detects the username or password does not match what is stored, no data will be sent to the cloud, and a password error will be displayed.

- Do not use the app on mobile devices that have been rooted (Android) or jailbroken (Apple), etc. Devices that have been jailbroken or rooted may function differently than the manufacturer intended, which can affect the performance of the apps running on the device, and could cause failures of the app. Additionally, your mobile device may be vulnerable to outside attack if you have compromised it by jailbreaking or rooting.
- Sideloading apps not obtained from the Apple App Store or Google Play Store can interfere with the way the app functions, including possible disruption of BLE communication with your smart transmitter.
- If connecting your smart transmitter to a computer to upload data, always be sure the network is secure/trusted, and the computer's anti-virus software, and virus definition files are up to date. Virus definition files are used to detect viruses and spyware on your computer. Viruses and spyware continue to evolve, so these files need to be updated regularly. Some anti-virus software products will automatically update these files. Check the user manual of your anti-virus software for more information. Do not use unsecured public internet access such as guest networks in hotels, restaurants, schools, airplanes, airports, etc.

Back up and Recovery

Your CGM data is securely stored in the Eversense cloud. If data is lost on the app due to mobile device operating system crash, or accidental uninstall of the app, you can reinstall the app and pair to your transmitter. The past 3 days of glucose data will be displayed in the app.

When you delete and reinstall the app, or get a new mobile device, once you pair your transmitter, glucose settings are restored to the app.

Eversense 365 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 365 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 health care provider ("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 health care provider, 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 health care provider 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 365 CGM 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.

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.

The FCC term "harmful interference" is different than physical harm. Harmful interference is defined by the FCC as interference which may seriously obstruct or interrupt communication between the transmitter and sensor and app. FCC 47 CFR §2.1 provides a detailed definition of "harmful interference".

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Senseonics®

℞ only

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