Sensor Smart Transmitter Mobile App

eversense®

User Guide

A guide for using the Eversense
Continuous Glucose Monitoring System

Continuous Glucose Monitoring System

Eversense Trademark

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Glossary

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

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

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

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

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

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

CT Computed Tomography

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

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

EULA End User License Agreement

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

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

FAQ Frequently Asked Questions

"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.

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

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

LED Light Emitting Diode

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

"LO" Reading Indicates sensor glucose reading is < 40 mg/dL.

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

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

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

MRI Magnetic Resonance Imaging

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

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

Snooze Setting Used to set how often an alert repeats.

Subcutaneous Located beneath the skin.

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

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

I. Introduction

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

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

Help and Support

Please review this User Guide with your health care provider. For additional Eversense product questions and troubleshooting issues, contact Customer Support toll free in the US at 844-SENSE4U (844-736-7348). To download a copy of this User Guide in Spanish, please visit www.eversensediabetes.com.

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Eversense CGM System Components

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

Eversense Sensor

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

Sensor

Eversense Smart Transmitter

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

Smart Transmitter

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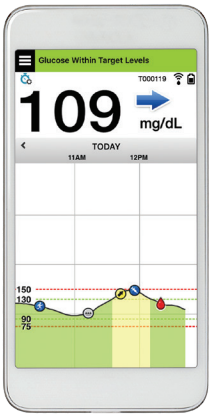
Eversense App

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

The Eversense App screens layout will vary based on your mobile device's model and/or operating system. Throughout this User Guide, we have included some examples of these differences.

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



iOS

Android

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

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

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Eversense System Overview

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

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

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

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Some of the features of the Eversense CGM System:

- Wireless communication with the sensor, smart transmitter and app.
- Long-term sensor wear in the upper arm for up to 90 days.
- Alerts when pre-set Low or High Glucose Alert levels (hypoglycemia or hyperglycemia) are reached.
- Predictive Alerts let you know ***before*** reaching pre-set Low or High Glucose Alert levels.
- Use of mobile device (e.g., smartphone) to display glucose readings.
- On-body vibe alerts with the smart transmitter even when mobile device is not nearby.
- Provides readings within 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.

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System Requirements

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

End User License Agreement and Privacy Policy

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

Jailbroken Devices

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

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 Eversense System and you may miss low or high glucose events.

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Indications for Use

The Eversense CGM System is indicated for continually measuring glucose levels in adults (18 years or older) with diabetes for up to 90 days.

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).

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

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

Contraindications

The sensor and smart transmitter are incompatible with magnetic resonance imaging (MRI) procedures. DO NOT undergo an MRI procedure while the sensor is inserted or when wearing the smart transmitter. Should an MRI be required, please contact your physician to arrange for sensor removal before the procedure.

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.

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What is Included in this Package

This Eversense Smart Transmitter Pack contains the following:

Eversense Smart Transmitter

Charging Cradle

Power Supply
(USB cable and AC power adapter)

Also included in this package is this User Guide, Quick Reference Guide 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.

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2. Benefits and Risks

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

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

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

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

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

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

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Risks and Side Effects

The glucose alerts and notifications will not audibly notify the user 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. The system's calculated glucose can be slightly different from your blood glucose meter. This may cause an alert to activate at a different time than they would have if the system's values always matched the blood glucose meter values. If you do not take frequent blood glucose measurements and miss an alert, you may not be aware of high or low glucose levels. You may need medical attention in the event that you have high or low glucose and are unaware of it.

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

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

Warnings

- **The Eversense CGM System has not been tested using insertion sites other than the upper arm.**
- **If at any time you have symptoms of a low or high blood glucose level OR if your symptoms are not consistent with the sensor glucose readings, you should test your glucose with a blood glucose meter.**
- **Always test your glucose with your blood glucose meter before making a treatment decision.**
- **If your smart transmitter is damaged or cracked, DO NOT use, as this could create an electrical safety hazard or malfunction, and could result in electrical shock.**

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Warnings (continued)

- 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 Eversense 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.
- DO NOT insert your infusion set or inject insulin within 10.16 cm (4 in) of the sensor site. If the insulin delivery site is within 10.16 cm (4 in) of the sensor site, it may interfere with sensor glucose readings and can cause inaccurate glucose readings.
- Always follow your physician's instructions for care after the sensor insertion or removal. Contact your physician if any of the following events occur:
  - You have pain, redness, or swelling at the incision site(s) later than 5 days after the sensor insertion or removal.

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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 –** The use of lithotripsy is not recommended for people who have an inserted sensor because the effects are unknown.
  - **Diathermy –** DO NOT use diathermy on people who have an inserted sensor. Energy from the diathermy can transfer through the sensor and cause tissue damage in the insertion area.
  - **Electrocautery –** The use of electrocautery near the inserted sensor may damage the device. DO NOT use electrocautery near the sensor.
- 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 physician knows about your smart transmitter.
- The sensor and smart transmitter should be linked the day of insertion. Failure to link the sensor and smart transmitter could result in a delay in receiving glucose readings.
- If the sensor, insertion site or smart transmitter feels warm, remove the smart transmitter immediately and contact your physician for further advice. A warm sensor could mean there is an infection or a sensor malfunction.
- DO NOT attempt to use the Eversense App while operating a motor vehicle.

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Precautions (continued)

- You should not receive massage therapy near the inserted sensor site. Massage therapy near the sensor site could cause discomfort or skin irritation.
- Use only the AC power adapter and USB cable provided with the smart transmitter when charging the smart transmitter battery. Use of another power supply could damage the smart transmitter, not allowing glucose readings to be received properly, and could result in voiding your warranty.
- If you have any concerns about allergic reaction to adhesive products containing silicone, contact your physician prior to use. Discard the Eversense adhesive patch after each use of up to 24 hours.
- DO NOT change the unit of measurement unless you have discussed it with your physician. 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.
- The Eversense CGM System has not been tested in the following populations: women who are pregnant or nursing, people under the age of 18, critically ill or hospitalized patients, people receiving immunosuppressant therapy, chemotherapy or anti-coagulant therapy, those with another active implantable device, e.g., an implantable defibrillator (passive implants are allowed, e.g., cardiac stents), those with known allergies to or using systemic glucocorticoids (excluding topical, optical or nasal, but including inhaled). 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 Eversense CGM data and should not be used in place of the primary Eversense CGM display.

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3. Getting Started

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

To get started you need:

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

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

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

2 easy start-up steps:

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

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

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.

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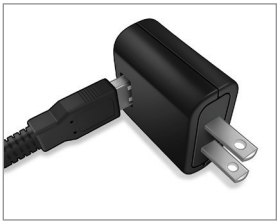
Charge your Smart Transmitter

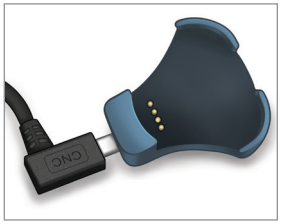
It is important to charge the smart transmitter battery daily to ensure data is collected from the sensor and sent to the app. The smart transmitter does not collect information from the sensor or send it to the app while charging. You may also charge your smart transmitter by connecting the USB cable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

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, and could result in voiding your warranty.

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



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



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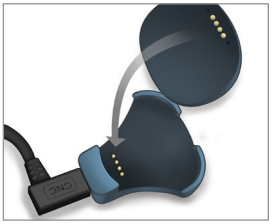
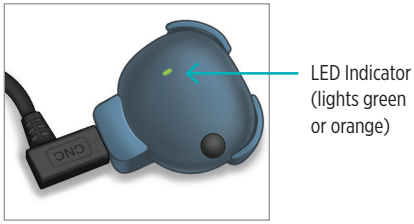
3. Line up the four gold pins on the bottom of the smart transmitter with the four gold pins on the charging cradle.

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



4. Plug the adapter into an AC power outlet.

- Once fully charged, a small green LED light appears on the top front of the smart transmitter (above the power button).
- Disconnect the power supply from the smart transmitter after it is fully charged.



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Step I. Download and Install the App

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

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

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

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

Eversense App Icon

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

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

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

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

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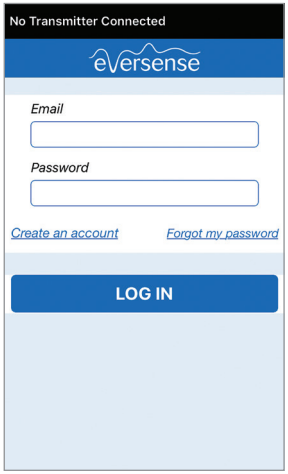
Step 2. Set up the App – Account Creation, Pairing and Settings

3

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

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

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



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

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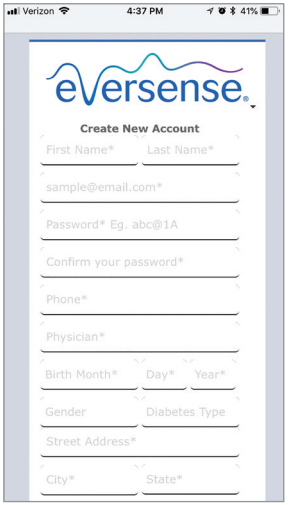
3. Enter your account information and then tap **Register**.



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

Note: The password is case sensitive.

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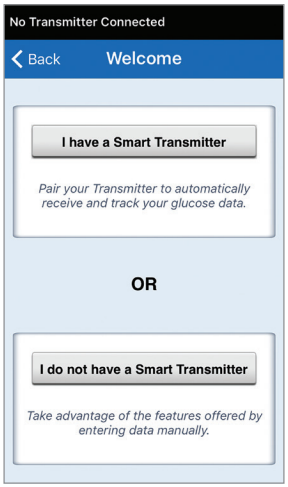
5. When you complete registration and log in, a **WELCOME** screen appears.



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

I have a Smart Transmitter

(skip to step 7).

I do not have a Smart Transmitter

(skip to step 12).

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

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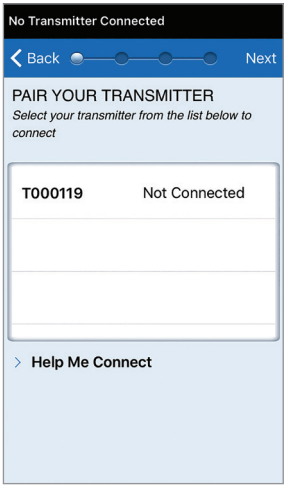
Note: If you press the power button on the smart transmitter and no LED appears, press and hold the power button for about 5 seconds to turn it on.

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

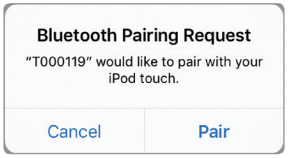
   Tap **Not Connected** to begin pairing process.



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

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

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



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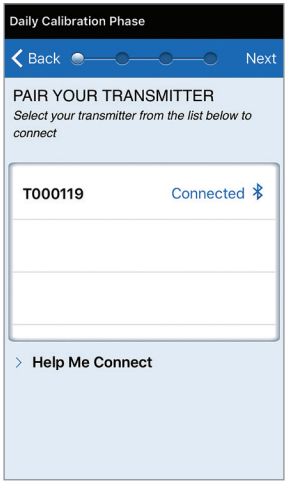
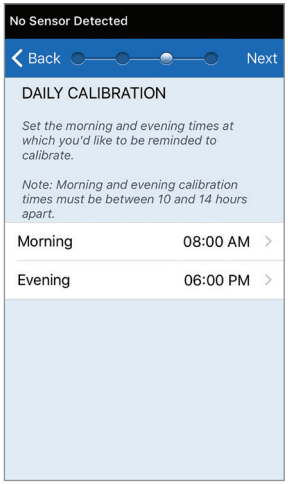
10. "Connected" appears next to the smart transmitter ID once the pairing is complete. The smart transmitter will provide intermittent vibrations until the smart transmitter is linked with the inserted sensor (see *Inserting and Linking the Sensor*).
    - Tap **Next**.



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



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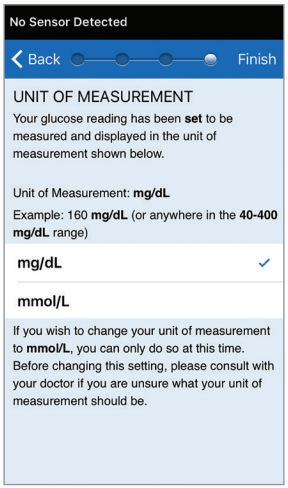
12. The **UNIT OF MEASUREMENT** screen appears and indicates the standard unit of measurement for your region. Your glucose readings will always be displayed in this unit of measurement.



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

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

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

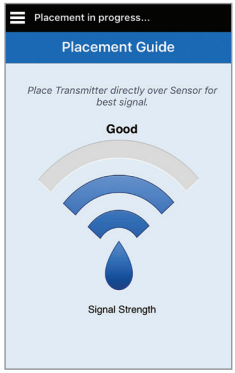
Once the sensor is inserted by your physician and the 24-hour Warm-Up Phase is completed, you can begin calibration. If you have not yet had your sensor inserted, you can review this User Guide to become familiar with the app and its features.

4. Inserting and Linking the Sensor

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

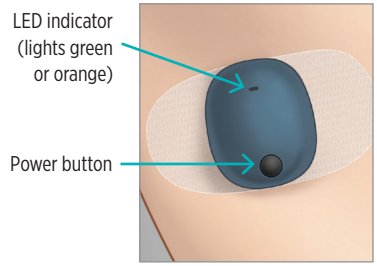
If the smart transmitter was sent directly to you, be sure to bring it and your mobile device to your insertion appointment. Once your physician has inserted your sensor, the smart transmitter and the sensor must be linked in order to start the Warm-Up Phase. Your smart transmitter can only be linked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

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



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

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



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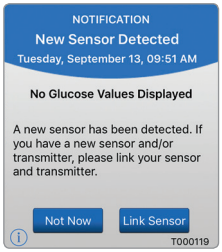
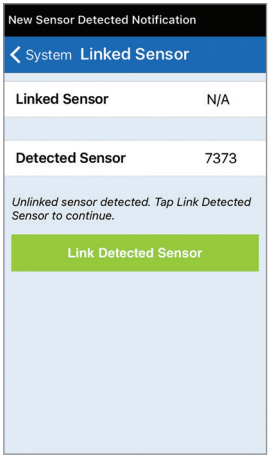
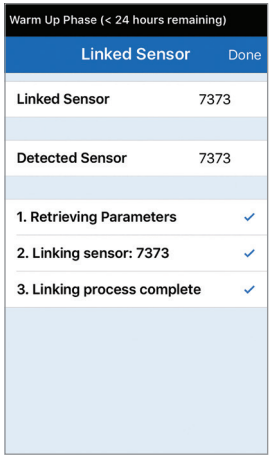
3. To link the smart transmitter and sensor, tap **Link Sensor** on either the **New Sensor Detected** pop-up screen or by tapping **Menu** > **Settings** > **System**> **Linked Sensor** and then tap **Link Detected Sensor**.

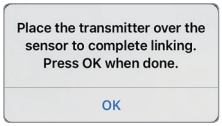


Note: It may take up to 5 minutes for the New Sensor Detected notification to be displayed.



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





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

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.

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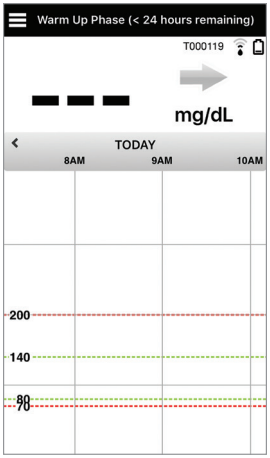
Note: The sensor requires a 24-hour Warm-Up Phase to stabilize in your body before glucose values will be collected by the smart transmitter. During the Warm-Up Phase, you do not need to wear the smart transmitter. If you decide to wear the smart transmitter over the sensor during this time, you will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



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

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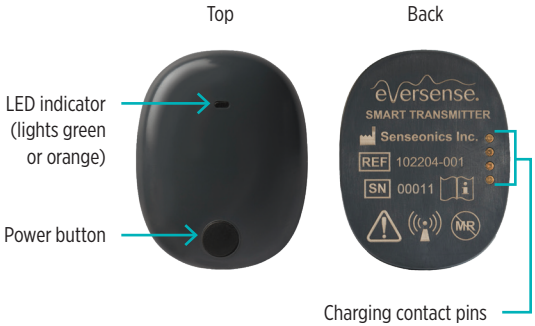
5. Using the Smart Transmitter

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

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

Your Eversense Smart Transmitter does the following:

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



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Daily Use

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

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

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

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

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Secure the Smart Transmitter over Inserted Sensor

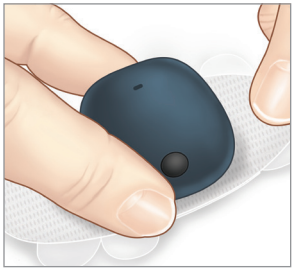
The smart transmitter must be secured on the skin directly over the sensor with the disposable adhesive patch. Each adhesive patch is designed to be replaced daily and has an adhesive side that attaches to the back of the smart transmitter and a silicone adhesive side that attaches to the skin. Both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

Note: You will receive adhesive patches from your physician.

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

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

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



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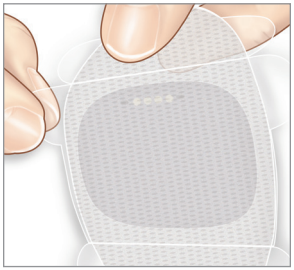
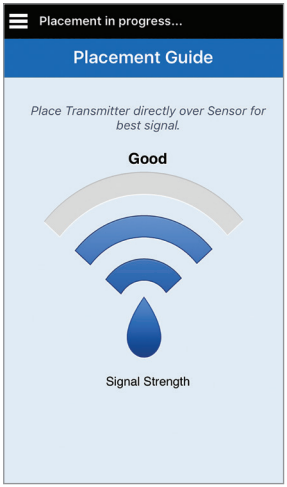
3. **Remove the larger clear backing and position the smart transmitter directly over the sensor.**
   - For the optimal signal strength, the smart transmitter must be placed directly over the sensor. Signal strength can also be improved by rotating the smart transmitter over the sensor such that the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



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



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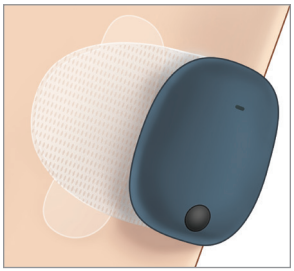
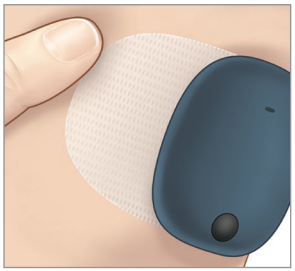
5. **Press the adhesive patch firmly on skin surface over the sensor.**
   - The smart transmitter should be positioned so that the patch wings lay horizontally on the arm.



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



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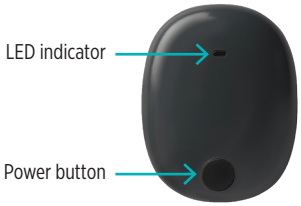
Turn the Smart Transmitter ON and OFF

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

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

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



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

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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.
- 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.

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

With the smart transmitter:

- With the smart transmitter ON, press and release the power button. The LED will blink green once if the battery has at least 10% power. It is recommended to always charge the smart transmitter for a full 15 minutes using a wall outlet to ensure a full charge. See the next page for more information on the LED indicators

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LED Status Indicators

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

- **During smart transmitter use:**

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

- **During smart transmitter charging:**

LED Status	Battery Status	Action
Solid or flashing orange when connected to the USB cable	0% - 65% charged	Charge for 15 minutes before disconnecting from power supply
Solid green when connected to the USB cable	65% - 100% charged	Charge for 15 minutes before disconnecting from power supply

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6. Calibrating the System

This section describes the calibration procedure and schedule of your Eversense CGM 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 for calibration. Once your sensor has been inserted and linked to your smart transmitter, the system begins a 24-hour Warm-Up Phase. No calibration is required during this phase.

There are two calibration phases:

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

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

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

Tips for ensuring good calibration:

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

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

- ✗ Blood glucose meter reading is less than 40 mg/dL.
- ✗ Blood glucose meter reading is greater than 400 mg/dL.
- ✗ Blood glucose meter reading was taken more than 10 minutes before entering the result in the Eversense App.
- ✗ Sensor glucose reading is significantly different than the blood glucose meter reading.
- ✗ Your smart transmitter was being charged during the 15 minutes after you entered your calibration value.

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Calibration Phases

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

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

- The 4 calibration tests must be spaced 2 to 12 hours apart, and all 4 tests must be completed within a 36 hour period. After 8 hours without a calibration entry, no glucose data will be displayed.
  - 1st calibration = 24 hours after sensor insertion.
  - 2nd calibration = 2 to 12 hours after 1st successful calibration.
  - 3rd calibration = 2 to 12 hours after 2nd successful calibration.
  - 4th calibration = 2 to 12 hours after 3rd successful calibration.
- Glucose readings will start displaying in the app a few minutes after the 2nd calibration is successfully completed.

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

Re-Entering Initialization Phase

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

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

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B. Daily Calibration Phase

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

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

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

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How To Calibrate

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

Note:

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

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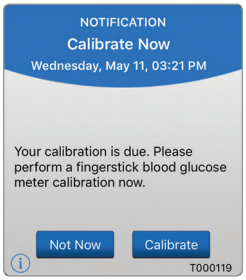
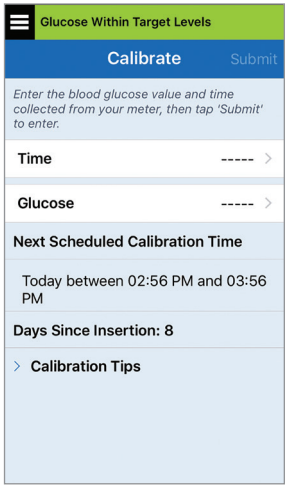
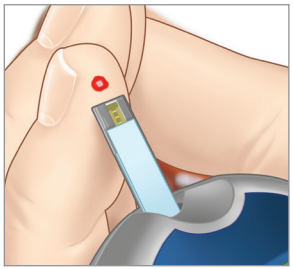
1. **When it is time for calibration, the app displays the CALIBRATE NOW screen.**
   - Tap **Calibrate**.
   - The **CALIBRATE** screen appears.
   - Tap **Not Now** if you want to wait until later.





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



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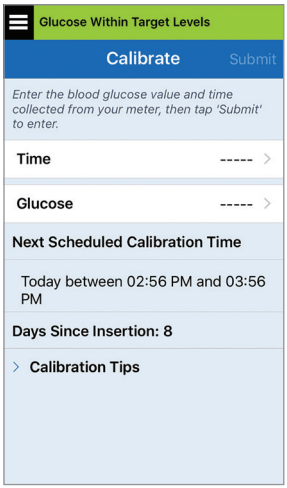
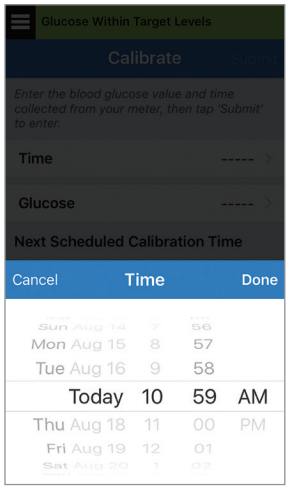
3. Tap **Time** and enter the time of day when the fingerstick blood glucose test was taken.

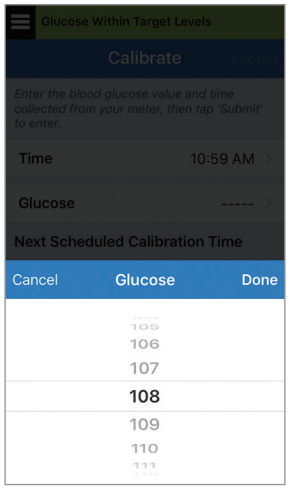
- Tap **Done**.





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

- Tap **Done**.



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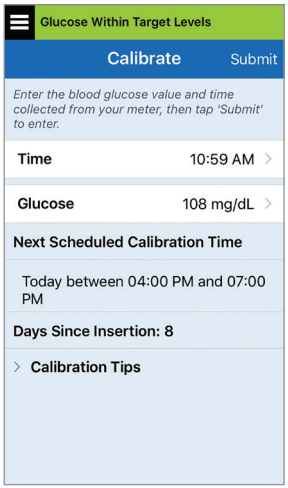
5. The **CALIBRATE** screen now shows the time and glucose reading you entered. If not correct, repeat steps 3 and 4.
   - When correct, tap **Submit**.



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

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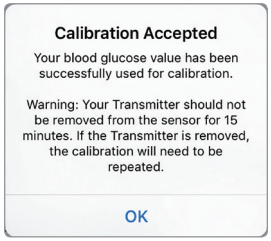
7. The **CALIBRATION ACCEPTED** screen appears.

- Tap **OK**.



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

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

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

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7. Using the App

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

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

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

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

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

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

Check Your Mobile Device Settings

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

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

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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.

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Note:

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

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

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

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Trend Arrows

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

→	Gradually rising or falling glucose levels, falling or rising at a rate between 0.0 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.
↑	Very rapidly rising glucose levels, rising at a rate more than 2.0 mg/dL per minute.
↓	Very rapidly falling glucose levels, falling at a rate more than 2.0 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 for the calculation, the arrow is displayed in gray.

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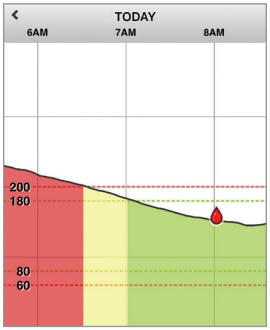
Trend Graph

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

There are several ways you can use the trend graph:

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



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

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

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Menu Options

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

Menu Options		Description
	My Glucose	Main app screen that displays current CGM reading, direction and rate of change, trend graph, events and alerts.
	Calibrate	Enter calibration test values. The **CALIBRATION** screen automatically appears when it is time to calibrate but you can also enter additional calibration values using this menu option.
	Alert History	Review past alerts and notifications. See *Alert Descriptions* for more information.
	Event Log	Enter information about activities such as blood glucose tests, meals, insulin, health and exercise. See *Event Log* for more information.
	Reports	Review a variety of reports about your CGM data. See *Glucose Reports and Sharing* for more information.
	Share My Data	Download or export your CGM data via a .csv file.

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Menu Options		Description
	Placement Guide	Check the communication between the smart transmitter and sensor. Use this screen whenever you are attaching the smart transmitter to be sure communication is established.
	Connect	Check the connection between the smart transmitter and mobile device. A Bluetooth connection is required to send data to the app.
	Settings	Customize settings such as glucose target levels, alert levels, sounds, temporary profile and calibration reminder times. See *Customizing your Settings* for more information.
	About	View information about your CGM System, including sensor and smart transmitter ID numbers.

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8. Customizing your Settings

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

Areas where you can customize app settings include:

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

Glucose Levels

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

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Warning:

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

IMPORTANT:

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

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Setting Glucose Alert Levels

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

Default setting	Low: 70 mg/dL High: 200 mg/dL You can change these alert levels based on what you and your physician agree are the right levels for you. Your Low Glucose Alert cannot be set above your Low Glucose Target, and your High Glucose Alert cannot be set below your High Glucose Target.
Allowable setting	Low: 60 - 115 mg/dL High: 125 - 350 mg/dL
On/Off setting	Always ON (cannot be turned OFF)
Notes	Audio notification and visual alerts on your mobile device and smart transmitter on-body vibe alerts.

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*.

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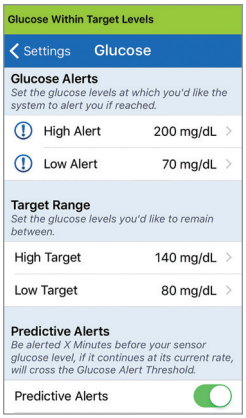
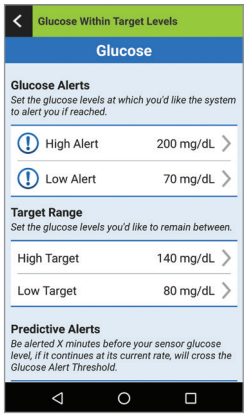
1. Tap **Menu** > **Settings** > **Glucose** to display the **GLUCOSE SETTINGS** screen.



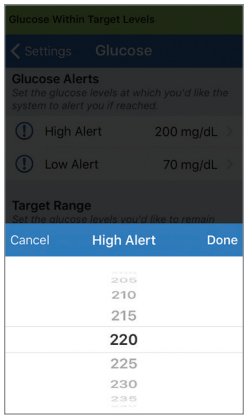
iOS

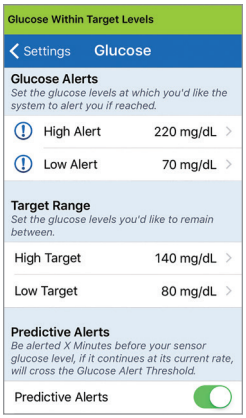


Android

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: 80 mg/dL High: 140 mg/dL You can change this target range based on what you and your physician agree are the right target levels for you.
Allowable setting	Low: 65 - 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.

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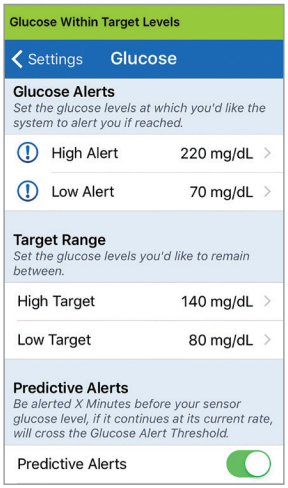
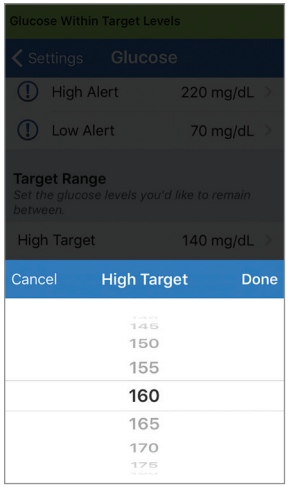
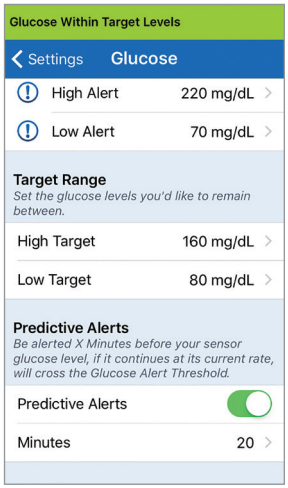
1. Tap **Menu** > **Settings** > **Glucose** to display the **GLUCOSE SETTINGS** screen.



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 mobile app gives an audible alert as well as displays a message on the screen. You should immediately perform a fingerstick blood glucose test before making a treatment decision.

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

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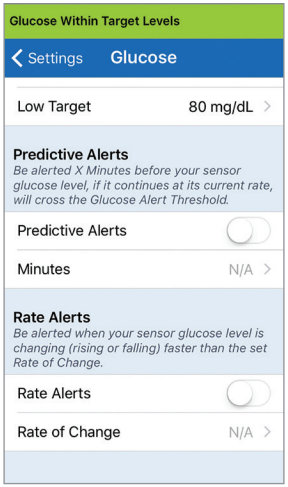
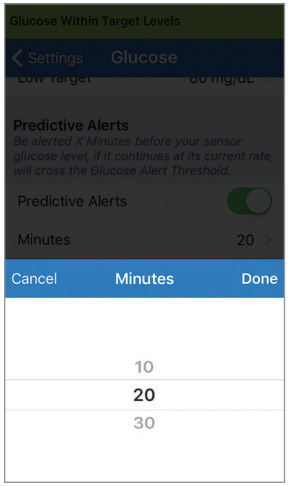
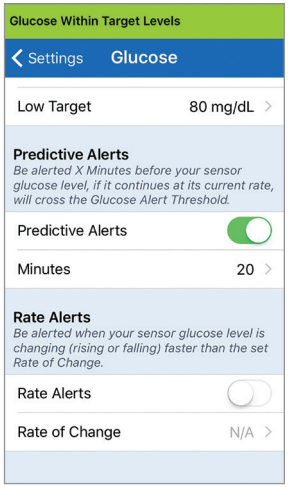
1. To turn this feature ON, tap **Menu** > **Settings** > **Glucose** to display the **GLUCOSE SETTINGS** screen.



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

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





Setting Rate of Change Alerts

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

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

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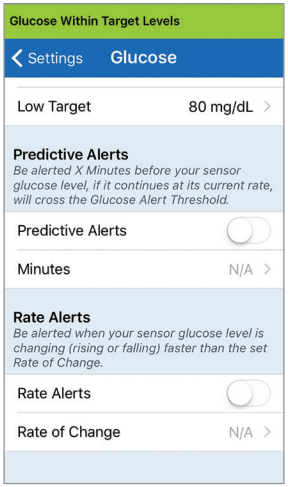
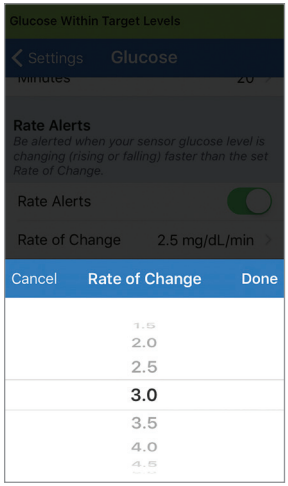
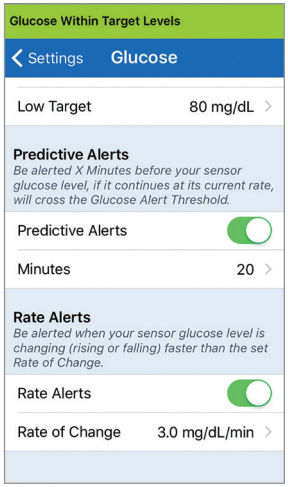
1. To turn this feature ON, tap **Menu** > **Settings** > **Glucose** to display the **GLUCOSE SETTINGS** screen.



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

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



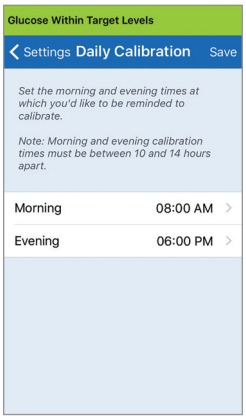


8

Setting Daily Calibration Times

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

1. Tap Menu > Settings > Daily Calibration.

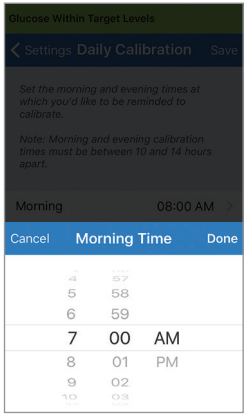


2. Tap Morning to set your morning calibration time.

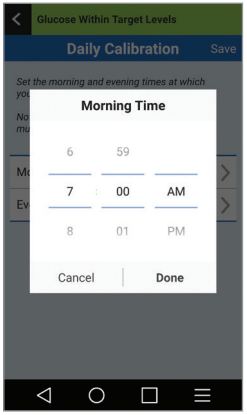
- Tap **Done** when complete.

3. Tap Evening to set your evening calibration time.

- Tap **Done** when complete.

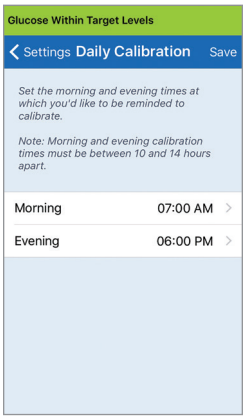


iOS



Android

4. When both times are correct, tap Save.



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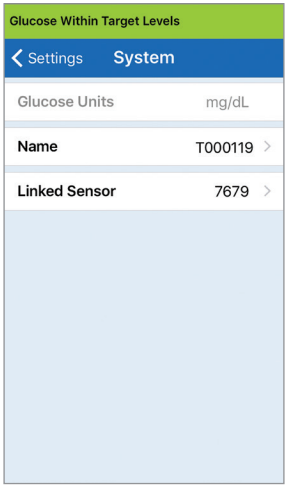
Setting System Information

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

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



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

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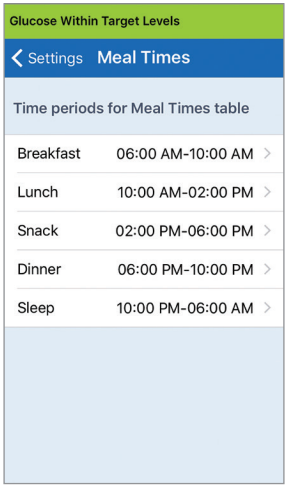
Setting Mealtimes Schedule

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

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

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



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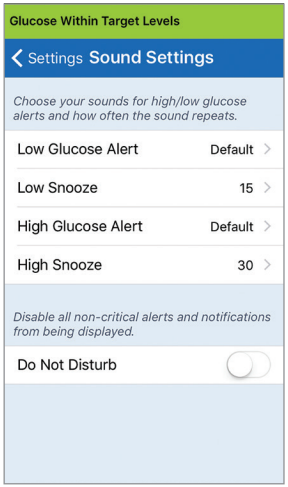
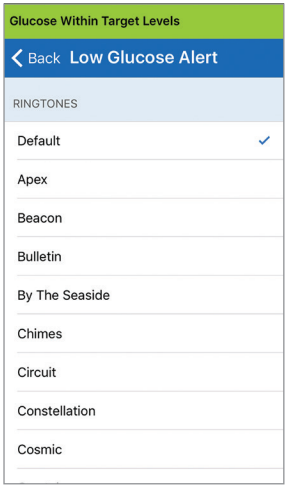
Setting Sounds

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

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



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



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

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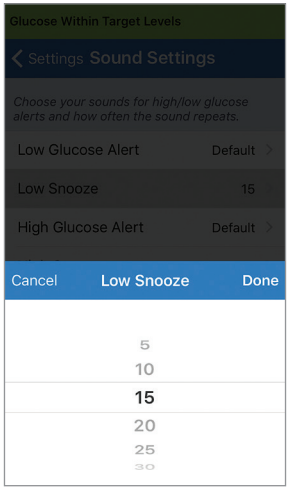
By setting the snooze alert, you can set how often an alert repeats after you have received a Low Glucose and High Glucose alert.

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



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

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

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

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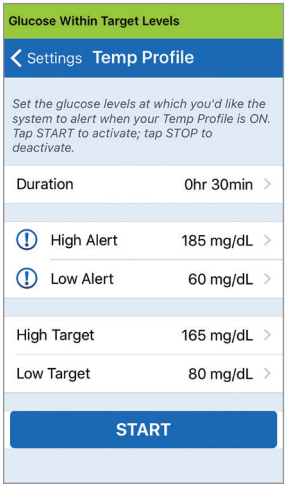
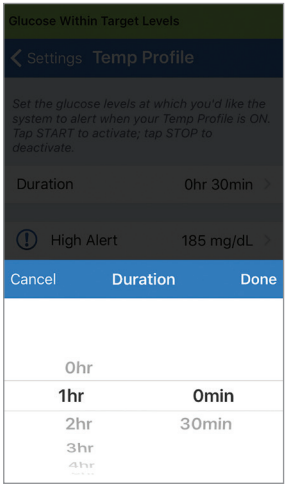
Setting Temporary Profile

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

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



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



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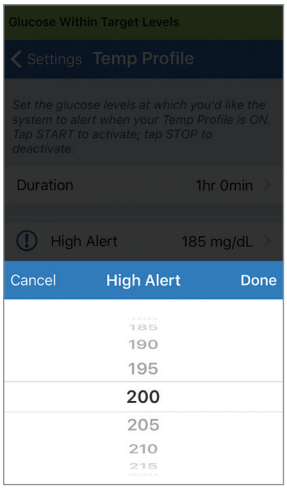
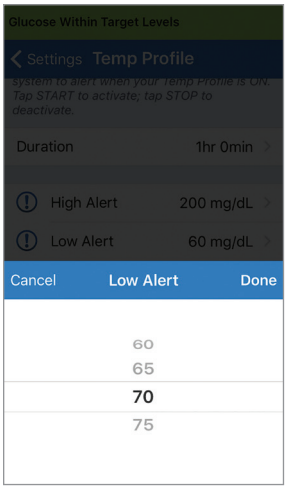
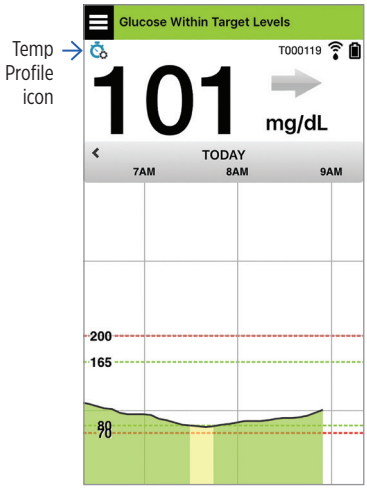
3. Set the High and Low Alerts and High and Low Target levels desired. Tap **START**.





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.



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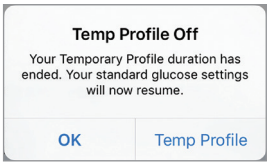
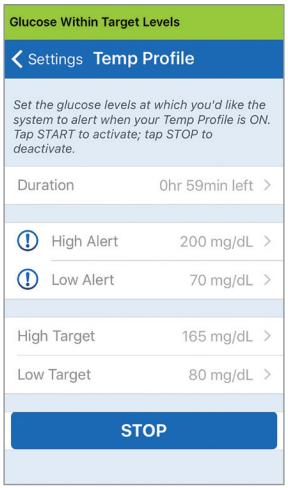
When the Temp Profile duration is finished, the app displays a notice and the Temp Profile icon is no longer displayed on the **MY GLUCOSE** screen.



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



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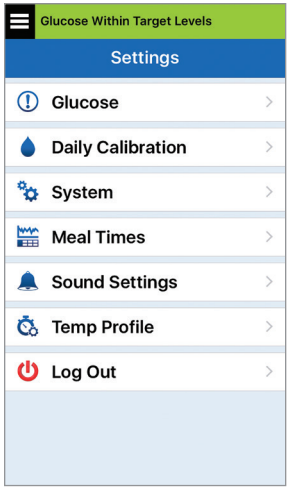
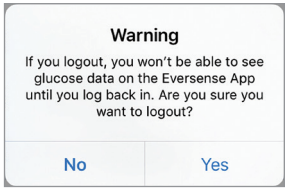
Logging out

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





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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.

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9. Alert Descriptions

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

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

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

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Alert History

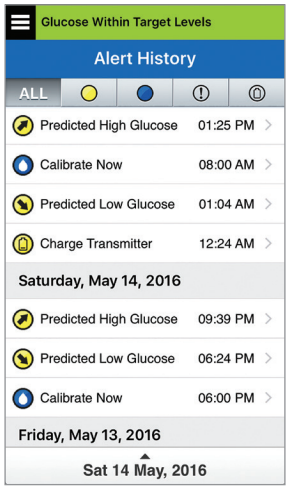
The **ALERT HISTORY** screen lists alerts and notifications you have received.

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

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

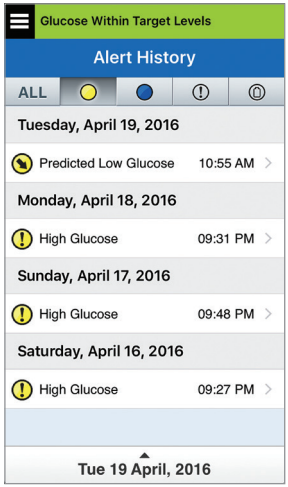
Note: When you receive 2 or more alerts that have not been acknowledged, the app will display an option to **Dismiss All**. This can happen when your mobile device has been out of range of your smart transmitter and then re-syncs. You can review each alert in **Alert History**.

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



Example of ALL

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



Example of alerts only

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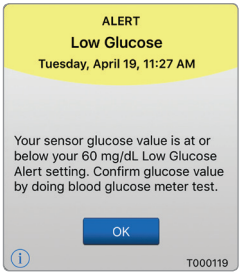
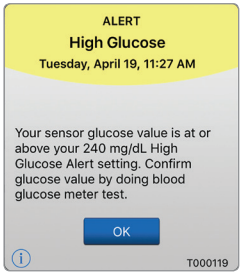
Alert Descriptions and Actions

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

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

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

Alerts

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

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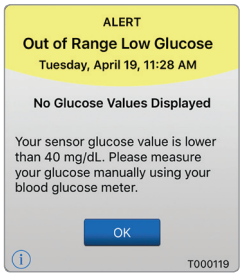
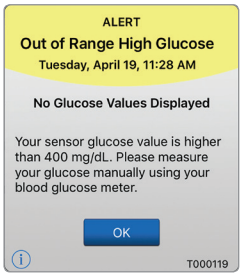
Alerts

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

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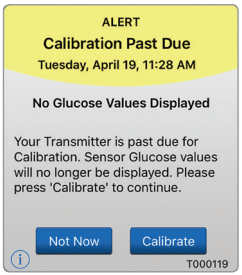
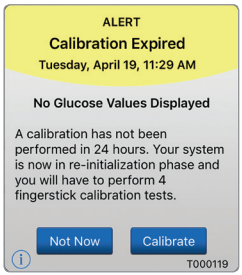
Alert Descriptions and Actions (continued)

Alerts

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

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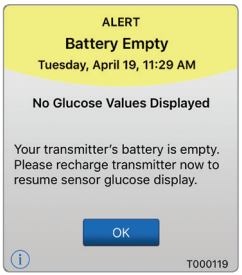
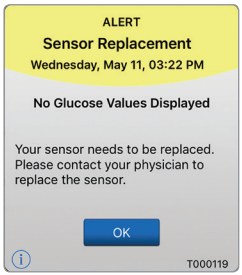
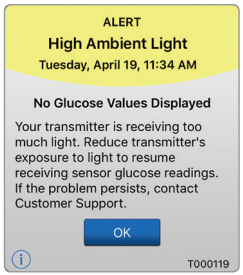
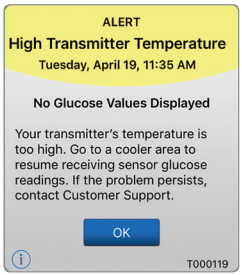
Alert Descriptions and Actions (continued)

Alerts

App Display		
Description	**Battery Empty*** Appears once when your smart transmitter battery is empty and needs to be charged. No glucose reading can be displayed until the smart transmitter is charged.	**Sensor Replacement*** Appears once when your sensor needs to be replaced. No glucose reading can be displayed until the sensor is replaced.
Actions	Charge the smart transmitter immediately. Remove the smart transmitter from your body before connecting it to the power supply.	Contact your physician to have your sensor replaced.

Alerts

App Display		
Description	**High Ambient Light** Appears every 60 minutes when your smart transmitter is receiving too much ambient light, affecting its ability to communicate with the sensor. No glucose reading can be displayed until ambient light is reduced.	**High Smart Transmitter Temperature*** Appears every 20 minutes when your smart transmitter temperature is too high. No glucose reading is displayed until the smart transmitter temperature is within normal operating conditions.
Actions	Reduce ambient light by doing one or more of the following: • Move to an area where there is less light exposure. • Place a dark material over the smart transmitter. • Wear the smart transmitter under clothing.	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.

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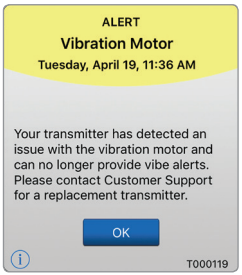
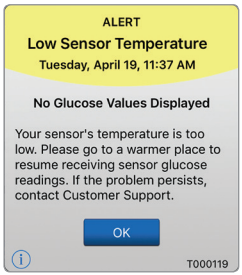
Alerts

App Display		
Description	**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.	**Low Sensor Temperature*** Appears every 20 minutes when the sensor temperature is too low. No glucose reading is displayed until the sensor temperature is within normal operating conditions.
Actions	Contact Customer Support to have your smart transmitter replaced immediately.	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).

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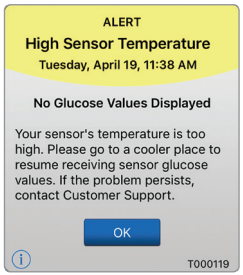
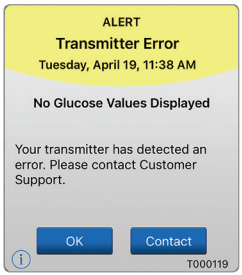
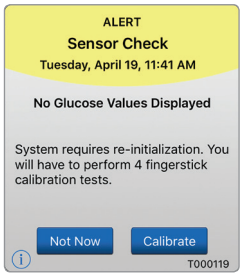
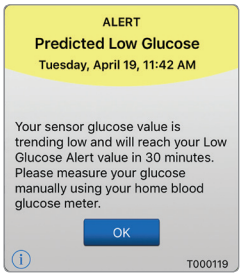
Alert Descriptions and Actions (continued)

Alerts

App Display		
Description	**High Sensor Temperature*** Appears every 20 minutes when the sensor temperature is too high. No glucose reading is displayed until the sensor temperature is within normal operating conditions.	**Smart Transmitter Error*** Appears when the system's internal checks detect a smart transmitter error. No glucose reading is displayed until the error is corrected.
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.	Follow the steps shown in the Troubleshooting section to reset your smart transmitter. If you are unable to complete the reset, contact Customer Support.

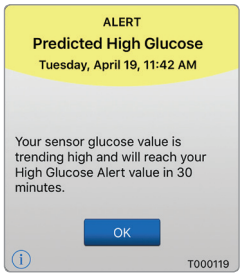
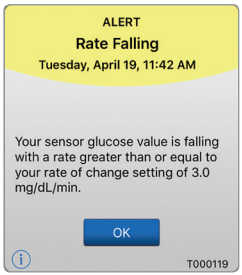
LBL-1602-01-001 Rev B_Eversense User Guide_mgdL_R1.indd 85 7/13/18 11:32 AM

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.	**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.
Actions	In the Initialization Phase, you must perform 4 fingerstick calibration tests spaced 2 - 12 hours apart. Display of glucose readings will resume after the 2nd successful fingerstick calibration test.	Pay close attention to your glucose values, symptoms, and trends. Confirm your glucose value with a blood glucose meter test before making a treatment decision.

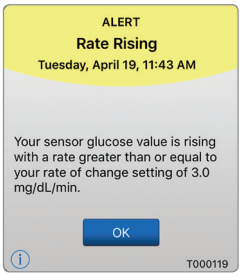
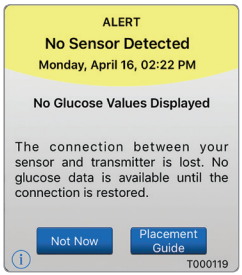
LBL-1602-01-001 Rev B_Eversense User Guide_mgdL_R1.indd 86 7/13/18 11:32 AM

Alerts

App Display		
Description	**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.	**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. Confirm your glucose value with a blood glucose meter test before making a treatment decision.	Pay close attention to your glucose values, symptoms, and trends. Confirm your glucose value with a blood glucose meter test before making a treatment decision.

LBL-1602-01-001 Rev B_Eversense User Guide_mgdL_R1.indd 87 7/13/18 11:32 AM

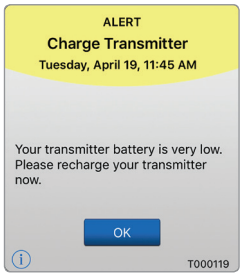
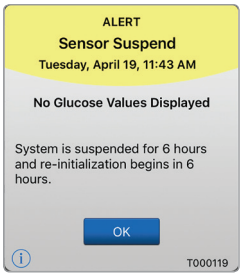
Alerts

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.	**No Sensor Detected** Appears when the connection between your sensor and transmitter is lost. No glucose data is available until the connection is restored.
Actions	Pay close attention to your glucose values, symptoms and trends. Confirm your glucose value with a blood glucose meter test before making a treatment decision.	Using the Placement Guide for reference, place the smart transmitter over the sensor until it shows there is a connection.

LBL-1602-01-001 Rev B_Eversense User Guide_mgdL_R1.indd 88 7/13/18 11:32 AM

Alert Descriptions and Actions (continued)

Alerts

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

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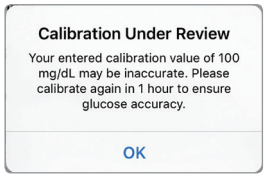
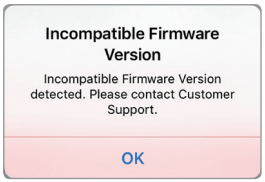
Alerts

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

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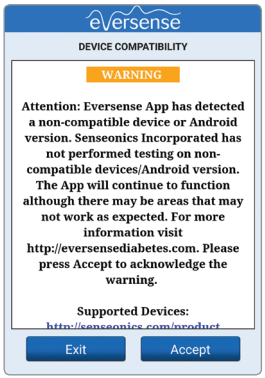
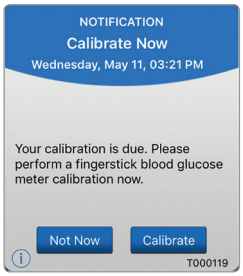
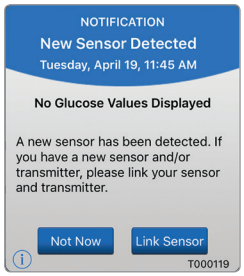
Alerts

App Display	
Description	**Incompatible Device/Operating System** Appears when an incompatible device/operating system is being used with the app.
Actions	For a list of compatible devices/operating systems visit eversensediabetes.com.

Alert Descriptions and Actions (continued)

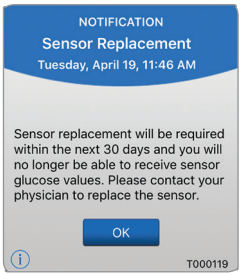
Notifications

App Display		
Description	**Calibrate Now** Appears every 60 minutes when it is time for you to calibrate.	**New Sensor Detected** Appears when the smart transmitter detects a new sensor. The inserted sensor and the smart transmitter must be linked to begin communication.
Actions	Do a fingerstick blood glucose test and enter the reading as your calibration value. DO NOT use an alternative site (such as forearm) to obtain your blood glucose reading.	Tap **Link Sensor** to complete the linking process and begin the 24-hour Warm-Up Phase. You do not need to wear your smart transmitter over the sensor until the Warm-Up Phase is complete.

LBL-1602-01-001 Rev B_Eversense User Guide_mgdL_R1.indd 92 7/13/18 11:32 AM

Alert Descriptions and Actions (continued)

Notifications

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

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10. Event Log

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

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

10

Types of Events:

- Glucose
- Meals
- Insulin
- Health
- Exercise

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

View Events

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

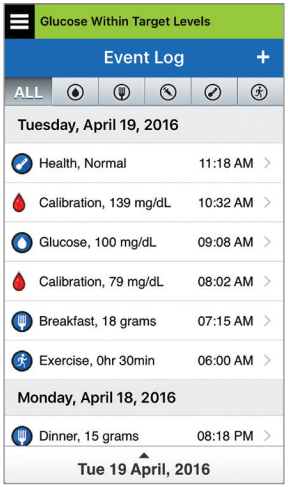
1. **Tap Menu > Event Log.**

   The **EVENT LOG** screen will appear.

2. **All your entered events will be listed.**

   You can also select specific event types to view by tapping a selected event type.

   - Tap **ALL**, then tap icons on top of the screen to select only the types of events you want displayed.



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Log Specific Events

Glucose

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

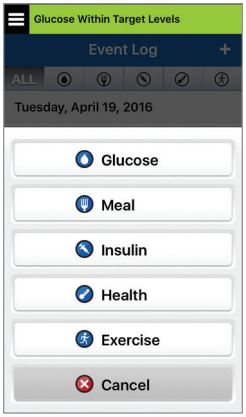
1. Tap **Menu** > **Event Log**.

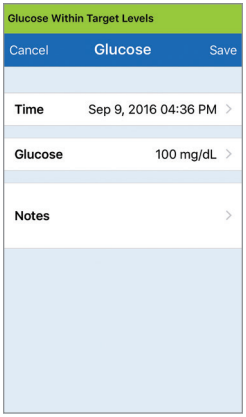
2. Add an event using the event icon "**+**" > **Glucose**.

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

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

   Note: You can enter a BG value between 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.

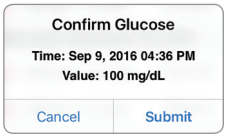




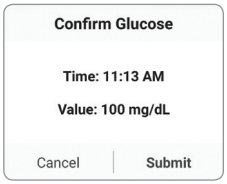
5. Tap **Save**.

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

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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**.

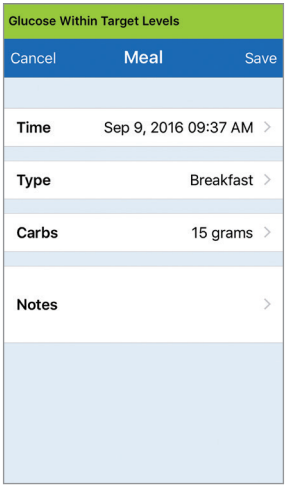
3. Tap **Time** to enter the correct date and time.
   Tap **Done**.

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.



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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**.

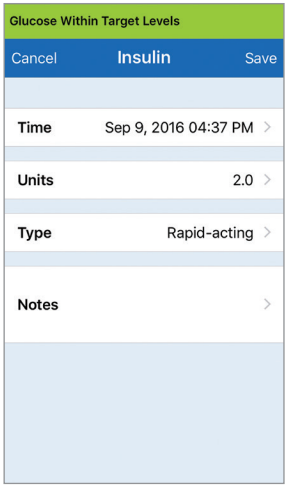
4. Tap **Units** to enter the correct number of Units.
   Tap **Done**.

   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.



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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**.

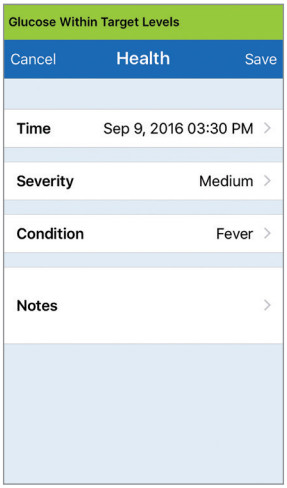
3. Tap **Time** to enter the correct date and time.
   Tap **Done**.

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.



LBL-1602-01-001 Rev B_Eversense User Guide_mgdL_R1.indd 98 7/13/18 11:32 AM

Exercise

Enter exercise type, duration, and intensity.

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

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

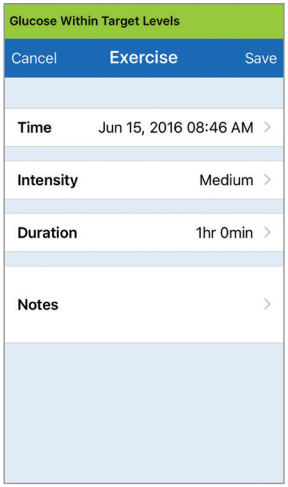
3. Tap **Time** to enter the correct date and time.
   Tap **Done**.

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.



10

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II. Reports

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

Types of reports

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

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

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.

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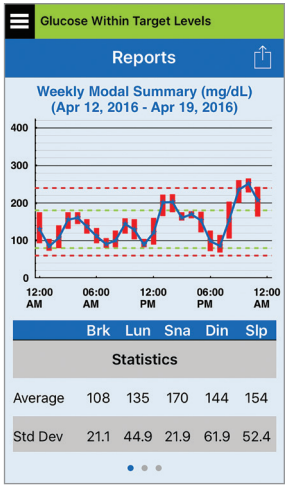
Weekly Modal Summary

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

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

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

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



11

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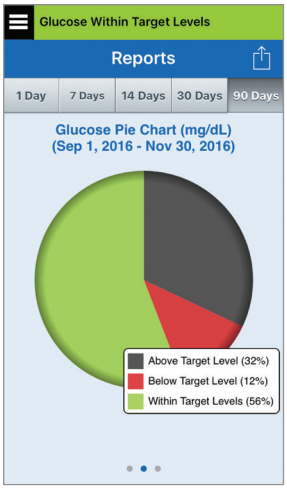
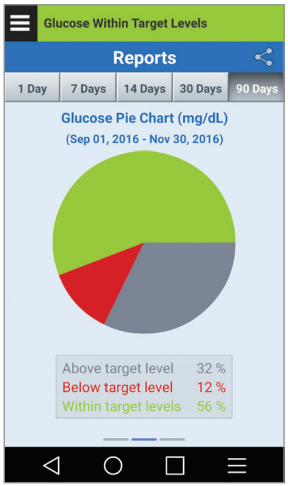
Glucose Pie Chart

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.



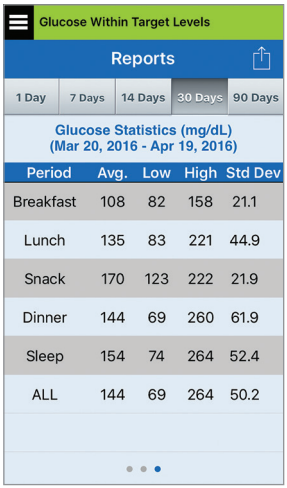
iOS



Android

Glucose Statistics

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



Period	Avg.	Low	High	Std Dev
Breakfast	108	82	158	21.1
Lunch	135	83	221	44.9
Snack	170	123	222	21.9
Dinner	144	69	260	61.9
Sleep	154	74	264	52.4
ALL	144	69	264	50.2

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12. Share My Data

Eversense Data Management Software (DMS) Program

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

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

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

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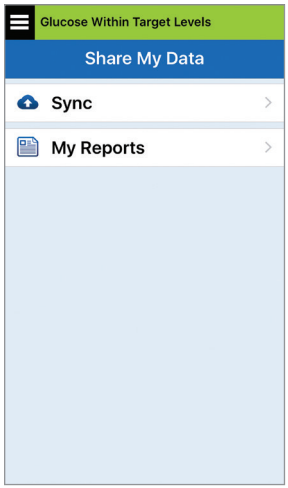
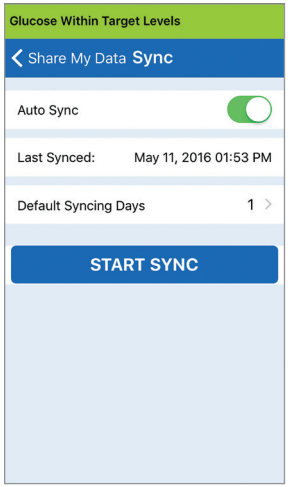
Sync

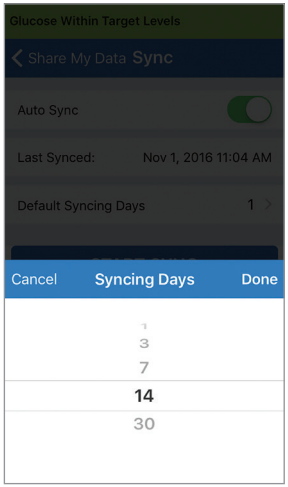
As long as you have an internet connection, Auto Sync is turned on, and you are logged into the app, your glucose readings sync to your Eversense DMS account about every 2 hours. You can turn off Auto Sync.



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

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





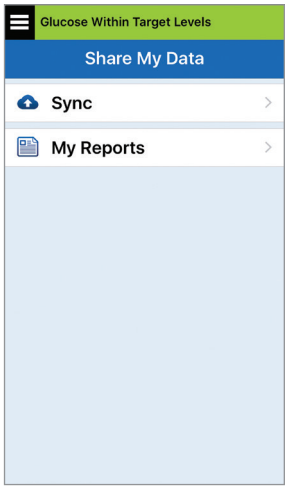
IMPORTANT: If you turn off Auto Sync your historical glucose data will not be stored in your DMS account.

My Reports

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

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

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



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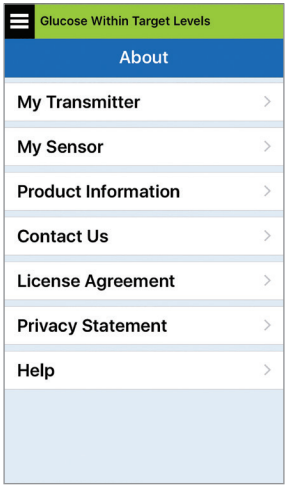
13. Product and General Information on the App

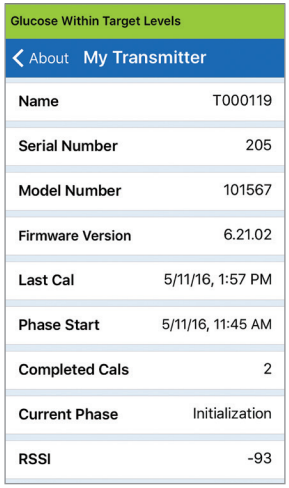
This section describes the information available from the About section of the Main Menu.

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

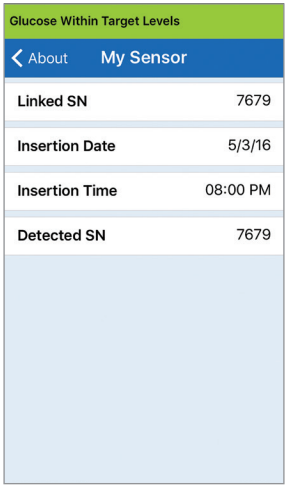
1. Tap **Menu** > **About** and then tap **My Transmitter**, **My Sensor** or **Product Information.**



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



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



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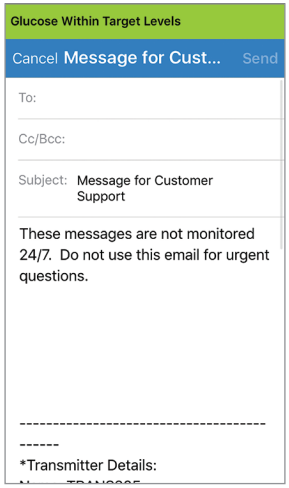
On the **PRODUCT INFORMATION** screen, you can view information about the mobile app software version and Senseonics, Inc., the manufacturer of the Eversense CGM System.

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

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



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

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

To find your local distributor on our website, tap **Help**.

14. Viewing Eversense Data on the Apple Watch

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

The Apple Watch is a secondary display of Eversense CGM data and should not be used in place of the primary Eversense CGM display.

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 test your glucose with a blood glucose meter before making a treatment decision.

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Glance View

The Eversense Apple Watch Glance is not available for Apple Watch users running watchOS 3.0 or higher.

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

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

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

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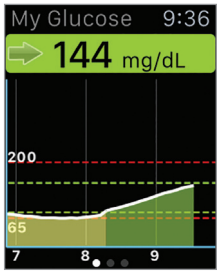
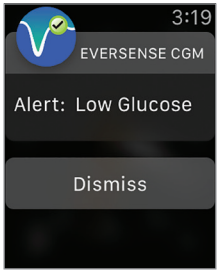
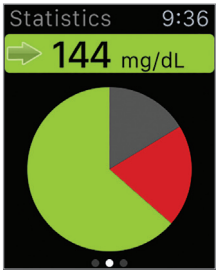
The **My Glucose** screen shows your current glucose with trend arrow, and a trend graph of your last three hours of CGM data.



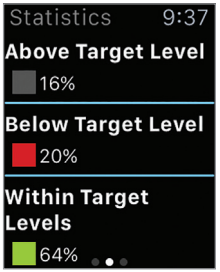
You can also access the **MY GLUCOSE** screen if you turn on notifications from Eversense in your Apple Watch settings. When you receive a notification, you can also tap on the message to see the **MY GLUCOSE** screen.



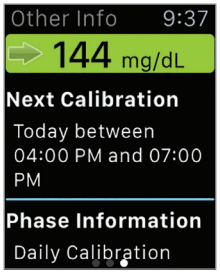
Swipe left to the next screen showing a pie chart of your total time within and outside your target range for the past 24 hours.



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 scheduled calibration time, and the current system calibration phase.



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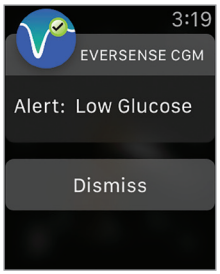
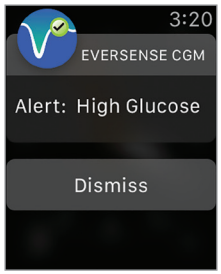
Alerts and Notifications Displayed on the Apple Watch

The Apple Watch is a secondary display to the Eversense CGM mobile app. Any alerts or notifications received on the Apple Watch should be confirmed on the Eversense CGM mobile app before any action is taken.

If you dismiss an alert on the watch, the alert display will disappear from the phone lock screen. Once the mobile app is opened, the alert will be displayed with all of its information.

The following table lists the alerts and notifications you may receive on the Apple Watch from the Eversense app. Some alerts and notifications are affected by the sound settings in the mobile app, and the Do Not Disturb function in the mobile app. See *Setting Sounds* and *Alert Descriptions and Actions* for more information.

Apple Watch 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.	**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.
Actions	**Confirm the alert on your Eversense CGM mobile app.** Pay close attention to your glucose values, symptoms, and trends. Confirm your glucose value with a blood glucose meter test before making a treatment decision.	**Confirm the alert on your Eversense CGM mobile app.** Pay close attention to your glucose values, symptoms, and trends. Confirm your glucose value with a blood glucose meter test before making a treatment decision.

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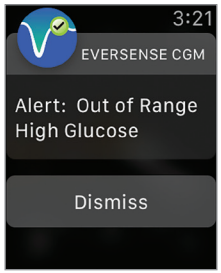
Alerts

Apple Watch Display		
Description	**Out of Range Low Glucose** Appears when your glucose reading is lower than 40 mg/dL. No glucose reading can be displayed.	**Out of Range High Glucose** Appears when your glucose value is higher than 400 mg/dL. No glucose reading can be displayed.
Actions	**Confirm the alert on your Eversense CGM mobile app.** Measure your glucose manually by using your blood glucose meter. Always confirm your glucose value with a blood glucose meter test before making a treatment decision. Once the sensor glucose value is at or higher than 40 mg/dL, glucose readings will resume on the display.	**Confirm the alert on your Eversense CGM mobile app.** Measure your glucose manually by using your blood glucose meter. Always confirm your glucose value with a blood glucose meter test before making a treatment decision. Once the sensor glucose value is at or lower than 400 mg/dL, glucose readings will resume on the display.

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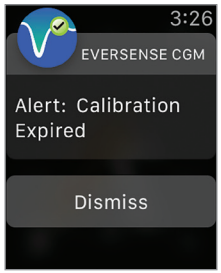
Alerts and Notifications Displayed on the Apple Watch (continued)

Alerts

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

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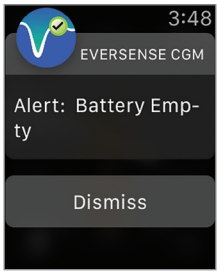
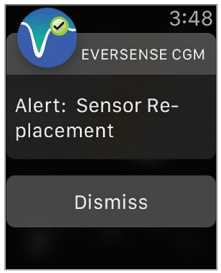
Alerts and Notifications Displayed on the Apple Watch (continued)

Alerts

Apple Watch Display		
Description	**Battery Empty** Appears once when your smart transmitter battery is empty and needs to be charged. No glucose reading can be displayed until the smart transmitter is charged.	**Sensor Replacement** Appears once when your sensor needs to be replaced. No glucose reading can be displayed until the sensor is replaced.
Actions	**Confirm the alert on your Eversense CGM mobile app.** Charge the smart transmitter immediately. Remove the smart transmitter from your body before connecting it to the power supply.	**Confirm the alert on your Eversense CGM mobile app.** Contact your physician to have your sensor replaced.

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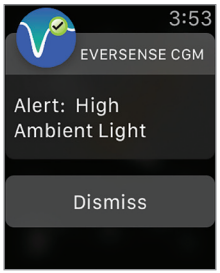
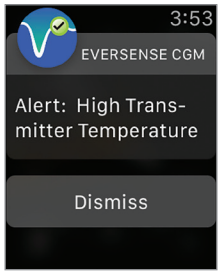
Alerts and Notifications Displayed on the Apple Watch (continued)

Alerts

Apple Watch Display		
Description	**High Ambient Light** Appears every 60 minutes when your smart transmitter is receiving too much ambient light, affecting its ability to communicate with the sensor. No glucose reading can be displayed until ambient light is reduced.	**High Transmitter Temperature** Appears every 20 minutes when your smart transmitter temperature is too high. No glucose reading is displayed until the smart transmitter temperature is within normal operating conditions.
Actions	**Confirm the alert on your Eversense CGM mobile app.** Reduce ambient light by doing one or more of the following: • Move to an area where there is less light exposure. • Place a dark material over the smart transmitter. • Wear the smart transmitter under clothing.	**Confirm the alert on your Eversense CGM mobile app.** 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.

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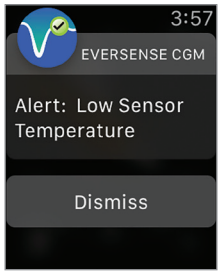
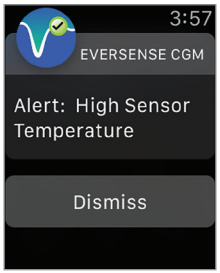
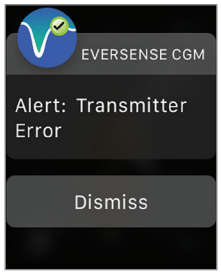
Alerts

Apple Watch Display		
Description	**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.	**Low Sensor Temperature** Appears every 20 minutes when the sensor temperature is too low. No glucose reading is displayed until the sensor temperature is within normal operating conditions.
Actions	**Confirm the alert on your Eversense CGM mobile app.** Contact Customer Support to have your smart transmitter replaced immediately.	**Confirm the alert on your Eversense CGM mobile app.** 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 and Notifications Displayed on the Apple Watch (continued)

Alerts

Apple Watch Display		
Description	**High Sensor Temperature** Appears every 20 minutes when the sensor temperature is too high. No glucose reading is displayed until the sensor temperature is within normal operating conditions.	**Transmitter Error** Appears when the system's internal checks detect a smart transmitter error. No glucose reading is displayed until the error is corrected.
Actions	**Confirm the alert on your Eversense CGM mobile app.** 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.	**Confirm the alert on your Eversense CGM mobile app.** Follow the steps shown in the *Troubleshooting* section to reset your smart transmitter. If you are unable to complete the reset, contact Customer Support.

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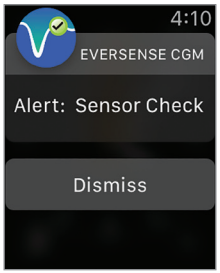
Alerts and Notifications Displayed on the Apple Watch (continued)

Alerts

Apple Watch 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.	**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.
Actions	**Confirm the alert on your Eversense CGM mobile app.** In the Initialization Phase, you must perform 4 fingerstick calibration tests spaced 2 - 12 hours apart. Display of glucose readings will resume after the 2nd successful fingerstick calibration test.	**Confirm the alert on your Eversense CGM mobile app.** Pay close attention to your glucose values, symptoms, and trends. Confirm your glucose value with a blood glucose meter test before making a treatment decision.

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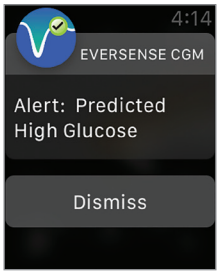
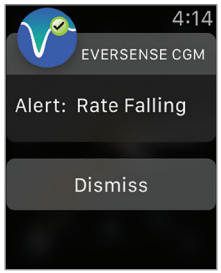
Alerts and Notifications Displayed on the Apple Watch (continued)

Alerts

Apple Watch Display		
Description	**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.	**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	**Confirm the alert on your Eversense CGM mobile app.** Pay close attention to your glucose values, symptoms, and trends. Confirm your glucose value with a blood glucose meter test before making a treatment decision.	**Confirm the alert on your Eversense CGM mobile app.** Pay close attention to your glucose values, symptoms, and trends. Confirm your glucose value with a blood glucose meter test before making a treatment decision.

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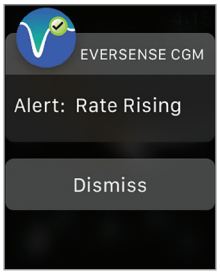
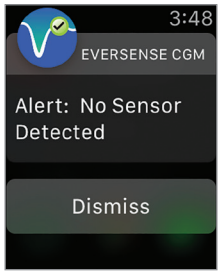
Alerts and Notifications Displayed on the Apple Watch (continued)

Alerts

Apple Watch 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.	**No Sensor Detected** Appears when the connection between your sensor and transmitter is lost. No glucose data is available until the connection is restored.
Actions	**Confirm the alert on your Eversense CGM mobile app.** Pay close attention to your glucose values, symptoms, and trends. Confirm your glucose value with a blood glucose meter test before making a treatment decision.	**Confirm the alert on your Eversense CGM mobile app.** Using the Placement Guide for reference, place the smart transmitter over the sensor until it shows there is a connection.

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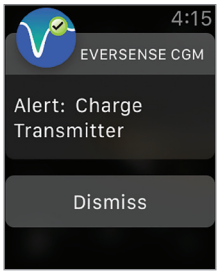
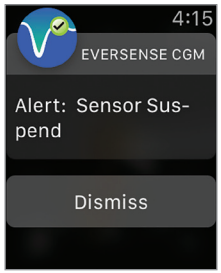
Alerts and Notifications Displayed on the Apple Watch (continued)

Alerts

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

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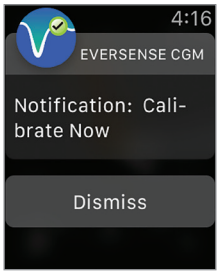
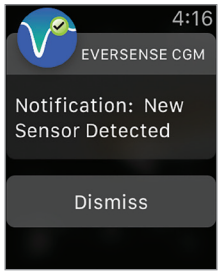
Alerts and Notifications Displayed on the Apple Watch (continued)

Notifications

Apple Watch Display		
Description	**Calibrate Now** Appears every 60 minutes when it is time for you to calibrate.	**New Sensor Detected** Appears when the smart transmitter detects a new sensor. The inserted sensor and the smart transmitter must be linked to begin communication.
Actions	**Confirm the alert on your Eversense CGM mobile app.** Do a fingerstick blood glucose test and enter the reading as your calibration value in the mobile app. DO NOT use an alternative site (such as forearm) to obtain your blood glucose reading.	**Confirm the alert on your Eversense CGM mobile app.** In your mobile app, 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.

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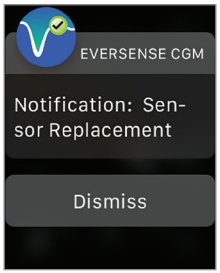
Alerts and Notifications Displayed on the Apple Watch (continued)

Notifications

Apple Watch Display	
Description	**Sensor Replacement** Appears 30, 14, 7, 3, 2, and 1 day before your sensor has completed its 90-day wear period as a reminder to replace your sensor.
Actions	**Confirm the alert on your Eversense CGM mobile app.** Contact your physician to schedule the removal and replacement of your sensor.

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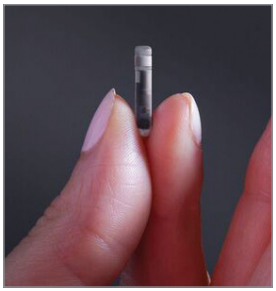
15. About the Sensor

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

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

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

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



Eversense Sensor

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Insertion Steps

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

Insertion site:

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

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 replacing the transmitter**.

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

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Removal Steps

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

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

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

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

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

16. Travel

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

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

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

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

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

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17. Troubleshooting

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

Smart Transmitter

Q: How do I turn my smart transmitter OFF?

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

Q: How do I turn my smart transmitter ON?

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

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

A: There are two ways to ensure proper positioning:

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

Q: My smart transmitter will not vibrate. Why?

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

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

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

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

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

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

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

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

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

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

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

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

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

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Smart Transmitter Battery and Charging

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

A: A fully charged smart transmitter battery typically lasts approximately 24 to 36 hours.

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

A: It takes approximately 15 minutes to fully charge a smart transmitter when plugged into a wall outlet. It may take longer if charging via a computer USB port 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. Tap **Menu** > **About** > **My Transmitter**. Scroll down to the Battery Level line that indicates amount of battery power left.
2. Check the battery symbol in the upper right corner on the **MY GLUCOSE** screen. A red battery icon indicates the smart transmitter battery is empty.
3. Power ON the smart transmitter. Press and release the smart transmitter power button. An orange LED on the smart transmitter indicates low battery. A green LED indicates the battery is at least 10% charged.

Q: On the About > My Transmitter page, the battery level shows 65% and then drops to 35%. Why is that?

A: The rate battery levels discharge varies widely based on use; the same battery model in two devices will not discharge at the same rate. This is why we show battery level indicators on this screen in large increments: 100%, 65%, 35%, 10% and 0%. Our testing shows that the “Low Battery” alert is triggered consistently at the point the smart transmitter still has approximately 2 hours of power left (at about the 10% indicator level). It is important to charge your battery when you receive the “Low Battery” alert.

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Connection with Smart Transmitter

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

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

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

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

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

- Make sure the Bluetooth setting on your mobile device is ON and the smart transmitter's name or serial number appears on the device list.
- The condition may only be temporary. Tap **Menu** > **Connect**.
  If your smart transmitter name indicates **Disconnected**, tap the smart transmitter name to connect manually.
- Your smart transmitter and mobile device may be out of wireless range. Move your mobile device closer to the smart transmitter.
- Your smart transmitter may be turned off, out of battery power or is currently being charged. You may need to restart the Bluetooth (BLE) function on the smart transmitter by following the steps below.
  1. Power off the smart transmitter – Press and hold the power button for 5 seconds and wait for the vibration to confirm it is powered off.
  2. Wait 2 seconds and press the power button three times to restart BLE. **(Note: When doing a BLE restart, do not remove/forget the paired device via your mobile device's Bluetooth Settings.)**

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

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

Q: How do I reset my smart transmitter?

A: Follow the steps below.

1. Place the smart transmitter into the charging cradle and connect the USB cable. Plug the cable into the wall outlet. (You can also plug the standard USB end of the cable directly into a USB port on your computer.)
2. Press and hold the power button (for approx. 14 seconds) on the smart transmitter while connected to the USB. Release the power button.
3. The LED will start blinking in about two 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 a steady green or orange LED will stay on.
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.
6. Disconnect the smart transmitter from the USB cable and proceed with pairing. Once paired, the system will be in the Initialization Phase. If you are unable to complete the reset, contact Customer Support.

Q: Can other people connect to my smart transmitter?

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

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

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

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

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

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

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

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

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

Q: What is “Discoverable” (Pairing) mode?

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

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

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

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

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

A: If other Eversense 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 unlink the old one and link the new one to my sensor?

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

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Calibration

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

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

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

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

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

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

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

Q: 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 Eversense App.
- The last sensor glucose value is significantly different than the blood glucose reading entered.
- It is not time for your calibration.

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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.
- The blood glucose reading entered is significantly different from the last sensor glucose reading.

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

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

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

Q: Can I calibrate earlier than my scheduled time?

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

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

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

Q: What are the different types of calibration phases?

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

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Alerts and Notifications

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

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

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

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

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

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

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

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

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

Q: What are rate of change alerts?

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

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Q: What are predictive alerts?

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

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.

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Glucose Readings

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

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

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

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

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

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

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

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Trend Arrows

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

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

Q: My trend arrow is gray instead of blue.

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

App

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

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

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

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

Q: How will my app be updated?

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

Q: What devices are compatible with the Eversense App?

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

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

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

Q: What is the Do Not Disturb option?

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

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

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Sensor

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

A: The Eversense CGM System was only tested in the upper arm during clinical studies, 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 90 days. You will receive periodic notices (30, 14, 7, 3, 2, and 1 day prior) to remind you when the sensor needs to be replaced. Contact your physician to schedule a sensor replacement.

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

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

Q: Where can I find the sensor serial number?

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

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

A: It may take up to 10 minutes for the linking process to complete. Be sure the smart transmitter is on top of the sensor. Confirm the **LINKED SENSOR** screen shows a check mark for Linking Process Complete. Navigate to the **MY GLUCOSE** screen and wait about 2 minutes. Return to the **MY SENSOR** screen.

If the correct insertion date and time are still not displayed, follow these steps:

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

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

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

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

A: Yes. The Eversense Sensor and Smart Transmitter are contraindicated for people undergoing an MRI.

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Events

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

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

Sync

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

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

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

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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.

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18. Device Performance

This section lists Device Performance Characteristics.

Clinical Study Performance

The safety and effectiveness of the Eversense CGM System has been evaluated in several prospective feasibility and pivotal studies. Two studies – PRECISE II (2016) and PRECISION (2018) – were conducted in the U.S. to evaluate the Eversense CGM System performance in terms of safety and effectiveness. Accuracy assessments were made at various points during the studies and subjects were asked to report any adverse events throughout the studies. The data collected was analyzed post-hoc using a new algorithm, SW 602.

PRECISE II Study

PRECISE II was a multi-site, non-randomized single-arm pivotal clinical study. Ninety (90) adults (18 years and older) with type 1 or type 2 diabetes participated in the study across 8 sites in the U.S. Each had a sensor inserted in the upper arm to collect glucose data but not be displayed to the subject. Some participants had a sensor inserted into each arm for clinical data collection. Participants interacted with the system to calibrate and address notifications not related to glucose data. Accuracy was measured during day-long clinic visits, with blood taken about every 15 minutes. These visits occurred on Days 1, 30, 60, and 90. At each visit, sensor accuracy was evaluated relative to a standard laboratory analyzer known as the YSI. Glucose readings were compared at the same moment in time between the reference analyzer and the continuous device. A safety follow-up visit occurred at Day 100, or ten days after the sensor was removed.

PRECISION Study

PRECISION was a second non-randomized single-arm pivotal clinical study conducted in the U.S. in 3 sites. Thirty-five (35) adults (18 years and older) with type 1 or type 2 diabetes participated in the study which was similar in study design as PRECISE II, except glucose readings and high/low glucose alerts were not blinded to the participants, and study visits on days 7 and 14 were added. The table below characterizes accuracy of the system by assessing the sensor glucose values against the YSI reference values.

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Table 1 - Accuracy to YSI in PRECISE II* and PRECISION*

Study	Number of Participants	Total Number of Paired CGM and YSI Values	Percent Within 15/15%	Percent Within 20/20%	Percent within 30/30%	Percent within 40/40%	MARD
PRECISE II	90 adults (18 years and older)	15,753	87%	94%	99%	100%	8.5%
PRECISION	35 adults (18 years and older)	15,170	85%	93%	98%	99%	9.6%

*Data is from primary sensors only; glucose values between 40 and 400 mg/dL.

Since the two studies are similar, the PRECISION study is included in this report. For detailed report on the PRECISE II results, please go to our website www.eversensediabetes.com.

Eversense Accuracy to YSI in PRECISION Study

Accuracy was measured by comparing the Eversense sensor glucose values to YSI blood glucose values. 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.

Table 2 – Accuracy to YSI in PRECISION Study

YSI Glucose Ranges (mg/dL)	Paired CGM-YSI (n)	Mean Absolute Relative Difference (%)
Overall	15,170	9.6
< 40	15	16.2
40 - 60	1,267	8.1
61 - 80	2,212	8.6
81 - 180	5,685	9.7
181 - 300	3,210	7.7
301 - 350	1,527	6.8
351 - 400	1,174	6.5
> 400	80	11.2

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Performance was also measured by calculating the percentage of sensor glucose readings within 15 mg/dL or 15% of the YSI reference. These tables show the percent agreement at multiple levels, at different glucose ranges, and at different days during the sensor wear. Results in the glucose ranges of 80 mg/dL or less reflect the percentage of values within mg/dL, and results in the glucose ranges over 80 mg/dL reflect the percentage within reference. As an example, glucose values between 40 and 60 mg/dL were within 15 mg/dL of the reference value 91.9% of the time.

Table 3 - Eversense Percentage of Readings in Agreement Overall

CGM System Glucose Range (mg/dL)	Paired CGM and YSI References	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	> 40/40% of Reference
Overall	15,170	85.4%	92.8%	98.1%	99.3%	0.7%
40 - 60	1,236	91.9%	96.0%	98.4%	99.3%	0.7%
61 - 80	2,003	87.3%	94.1%	99.1%	99.6%	0.4%
81 - 180	5,786	80.5%	89.9%	97.2%	99.0%	1.0%
181 - 300	3,566	84.8%	92.8%	98.1%	99.2%	0.8%
301 - 350	1,628	92.8%	97.5%	99.1%	99.9%	0.1%
351 - 400	951	91.5%	95.8%	98.6%	99.8%	0.2%

Table 4 - Eversense Percentage of Readings in Agreement on Day 1

CGM System Glucose Range (mg/dL)	Paired CGM and YSI References	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	> 40/40% of Reference
Overall	2,665	79.1%	88.9%	95.8%	98.5%	1.5%
40 - 60	274	86.5%	91.2%	96.4%	97.8%	2.2%
61 - 80	378	81.7%	87.8%	97.1%	98.7%	1.3%
81 - 180	962	76.7%	87.8%	95.6%	98.9%	1.1%
181 - 300	585	80.3%	91.1%	96.1%	97.8%	2.2%
301 - 350	250	77.6%	90.4%	95.2%	99.2%	0.8%
351 - 400	216	74.5%	85.2%	94.0%	99.1%	0.9%

Table 5 - Eversense Percentage of Readings in Agreement on Day 7

CGM System Glucose Range (mg/dL)	Paired CGM and YSI References	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	> 40/40% of Reference
Overall	2,926	86.1%	93.3%	98.1%	99.0%	1.0%
40 - 60	214	93.0%	98.1%	99.5%	100.0%	0.0%
61 - 80	404	87.6%	94.3%	99.3%	99.8%	0.2%
81 - 180	1,053	80.0%	89.3%	96.7%	97.9%	2.1%
181 - 300	630	84.6%	93.5%	97.5%	99.2%	0.8%
301 - 350	385	94.3%	97.4%	99.7%	100.0%	0.0%
351 - 400	240	95.0%	97.5%	100.0%	100.0%	0.0%

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Table 6 - Eversense Percentage of Readings in Agreement on Day 14

CGM System Glucose Range (mg/dL)	Paired CGM and YSI References	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	> 40/40% of Reference
Overall	2,997	88.1%	94.6%	98.8%	99.6%	0.4%
40 - 60	269	87.0%	92.6%	96.7%	98.9%	1.1%
61 - 80	407	84.0%	93.4%	99.5%	100.0%	0.0%
81 - 180	999	82.0%	91.7%	98.0%	99.1%	0.9%
181 - 300	663	91.3%	95.9%	99.4%	99.8%	0.2%
301 - 350	383	97.1%	99.0%	99.5%	100.0%	0.0%
351 - 400	276	96.7%	99.6%	100.0%	100.0%	0.0%

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Table 7 - Eversense Percentage of Readings in Agreement on Day 30

CGM System Glucose Range (mg/dL)	Paired CGM and YSI References	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	> 40/40% of Reference
Overall	2,284	88.0%	94.3%	98.9%	100.0%	0.0%
40 - 60	209	98.6%	99.5%	100.0%	100.0%	0.0%
61 - 80	416	92.8%	97.6%	100.0%	100.0%	0.0%
81 - 180	936	81.1%	90.0%	97.4%	100.0%	0.0%
181 - 300	492	87.4%	94.7%	99.8%	100.0%	0.0%
301 - 350	183	99.5%	100.0%	100.0%	100.0%	0.0%
351 - 400	48	100.0%	100.0%	100.0%	100.0%	0.0%

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Table 8 - Eversense Percentage of Readings in Agreement on Day 60

CGM System Glucose Range (mg/dL)	Paired CGM and YSI References	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	> 40/40% of Reference
Overall	2,133	86.9%	93.7%	98.5%	99.6%	0.4%
40 - 60	165	98.2%	100.0%	100.0%	100.0%	0.0%
61 - 80	176	89.2%	96.6%	100.0%	100.0%	0.0%
81 - 180	880	85.9%	94.2%	98.3%	99.4%	0.6%
181 - 300	592	79.1%	86.8%	97.1%	99.5%	0.5%
301 - 350	239	96.7%	100.0%	100.0%	100.0%	0.0%
351 - 400	81	98.8%	100.0%	100.0%	100.0%	0.0%

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Table 9 - Eversense Percentage of Readings in Agreement on Day 90

CGM System Glucose Range (mg/dL)	Paired CGM and YSI References	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	> 40/40% of Reference
Overall	2,165	83.9%	92.2%	98.5%	99.3%	0.7%
40 - 60	105	93.3%	100.0%	100.0%	100.0%	0.0%
61 - 80	222	90.5%	96.8%	99.1%	99.1%	0.9%
81 - 180	956	77.7%	86.7%	97.5%	99.2%	0.8%
181 - 300	604	85.9%	94.9%	98.8%	99.2%	0.8%
301 - 350	188	89.9%	98.9%	100.0%	100.0%	0.0%
351 - 400	90	95.6%	98.9%	100.0%	100.0%	0.0%

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Glucose values below 40 mg/dL or above 400 mg/dL are shown on the mobile app as “LO” or “HI”. The table below shows, as a percentage, agreement of sensor glucose values when outside the display range of 40 mg/dL to 400 mg/dL.

Table 10 – Eversense Agreement when “LO” or “HI” is Displayed

		Reference mg/dL					
CGM Readings	CGM-Ref pairs	< 50	< 60	< 70	< 80	> 80	Total
‘LO’	n	6	7	9	9	0	9
	%	66.7%	77.8%	100%	100%	0%	100%

		Reference mg/dL					
CGM Readings	CGM-Ref pairs	> 340	> 320	> 280	> 240	< 240	Total
‘HI’	n	359	383	399	404	1	405
	%	88.6%	94.6%	98.5%	99.8%	0.2%	100%

Eversense Alert Performance

The tables in this section show an alert performance assessment. The Confirmed Event Detection Rate shows the percentage of time the Eversense CGM 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 Eversense CGM 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 CGM 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 CGM system was not confirmed by a reference value within a 15 minute window of the alert being presented.

The table below shows an assessment of the ability of the Eversense CGM System to detect high and low glucose levels, and assess true positive alerts vs false positive alerts. These are shown as a percentage of alerts provided compared to the YSI reference values at various thresholds.

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

Alert Setting (mg/dL)		Confirmed Event Detection Rate	Missed Detection Rate	True Alert Rate	False Alert Rate
Low Alert	60	76%	24%	81%	19%
	70	90%	10%	95%	5%
	80	94%	6%	96%	4%
	90	96%	4%	95%	5%
High Alert	120	99%	1%	96%	4%
	140	99%	1%	96%	4%
	180	98%	2%	95%	5%
	200	98%	2%	95%	5%
	220	98%	2%	95%	5%
	240	98%	2%	95%	5%
	300	93%	7%	94%	6%

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The table below shows an assessment of the ability of the Eversense CGM System to detect high, low, and predictive high and low alerts, and assess true positive alerts vs false positive alerts. These are shown as a percentage of alerts provided compared to the YSI reference values at various thresholds.

Table 12 – Eversense High, Low, and Predictive Alert Performance (Threshold and Predictive)

Alert Setting (mg/dL)		Confirmed Event Detection Rate	Missed Detection Rate	True Alert Rate	False Alert Rate
Low Alert	60	89%	11%	77%	23%
	70	95%	5%	92%	8%
	80	97%	3%	93%	7%
	90	98%	2%	93%	7%
High Alert	120	99%	1%	96%	4%
	140	99%	1%	94%	6%
	180	99%	1%	93%	7%
	200	98%	2%	94%	6%
	220	98%	2%	94%	6%
	240	99%	1%	94%	6%
	300	95%	5%	92%	8%

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Eversense Trend Agreement

The shaded area of the table below shows agreement between the Eversense 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, Eversense glucose trends are in agreement with the reference trends 89% of the time.

Table 13 – Eversense Trend Agreement

CGM Trend (mg/dL/min)	Reference Rate of Change (mg/dL/min) Percent of Matched Pairs in Each Reference Trend Range for Each CGM ROC Range							
	< -3	[-3, -2)	[-2, -1)	[-1, 1]	(1, 2]	(2, 3]	> 3	Total
< -3	14%	20%	30%	36%	0%	0%	0%	135
[-3, -2)	5%	12%	38%	44%	1%	1%	0%	338
[-2, -1)	1%	3%	24%	71%	1%	0%	0%	1,115
[-1, 1]	0%	1%	5%	89%	5%	1%	0%	10,655
(1, 2]	0%	0%	1%	55%	35%	8%	1%	997
(2, 3]	0%	0%	2%	36%	41%	18%	4%	354
> 3	0%	1%	0%	25%	35%	30%	10%	175
Total	57	155	990	11,137	1,085	288	57	13,769

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Eversense Concurrence with YSI Values

The shaded areas of the tables below show what percentage of YSI reference values were in the same range as the sensor glucose values. As an example, when sensor glucose is between 81 and 120 mg/dL, YSI reference values are in the same range 71% of the time.

Table 14 - Concurrence with YSI Range All Days

Percent of Matched Pairs in Each YSI Glucose Range for Each CGM Glucose Range												
		YSI (mg/dL)										
CGM (mg/dL)	Paired CGM-YSI (n)	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400
40 - 60	1,236	1%	63%	34%	2%	0%	0%	0%	0%	0%	0%	0%
61 - 80	2,003	0%	22%	67%	10%	0%	0%	0%	0%	0%	0%	0%
81 - 120	2,524	0%	2%	17%	71%	10%	0%	0%	0%	0%	0%	0%
121 - 160	2,342	0%	0%	0%	18%	71%	11%	0%	0%	0%	0%	0%
161 - 200	1,727	0%	0%	0%	1%	24%	59%	16%	0%	0%	0%	0%
201 - 250	1,502	0%	0%	0%	0%	1%	19%	65%	14%	1%	0%	0%
251 - 300	1,257	0%	0%	0%	0%	0%	1%	18%	51%	27%	3%	0%
301 - 350	1,628	0%	0%	0%	0%	0%	0%	1%	10%	57%	32%	1%
351 - 400	951	0%	0%	0%	0%	0%	0%	0%	2%	26%	65%	7%

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Table 15 - Concurrence with YSI Range Day 1

Percent of Matched Pairs in Each YSI Glucose Range for Each CGM Glucose Range												
		YSI (mg/dL)										
CGM (mg/dL)	Paired CGM-YSI (n)	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400
40 - 60	274	1%	59%	36%	4%	0%	0%	0%	0%	0%	0%	0%
61 - 80	378	0%	14%	65%	19%	1%	0%	0%	0%	0%	0%	0%
81 - 120	516	0%	1%	23%	63%	12%	0%	0%	0%	0%	0%	0%
121 - 160	332	0%	0%	0%	17%	70%	12%	1%	0%	0%	0%	0%
161 - 200	226	0%	0%	0%	1%	23%	58%	17%	0%	0%	0%	0%
201 - 250	268	0%	0%	0%	0%	4%	25%	55%	15%	0%	0%	0%
251 - 300	205	0%	0%	0%	0%	0%	2%	25%	57%	14%	1%	0%
301 - 350	250	0%	0%	0%	0%	0%	0%	4%	27%	42%	26%	1%
351 - 400	216	0%	0%	0%	0%	0%	0%	1%	9%	46%	40%	4%

Calibration Stability Agreement

The table below compares the percentage of sensor glucose values to the YSI reference at various time points after a calibration entry. As an example, in the table below, 88% of the Eversense values were within 15 mg/dL (for reference readings of 80 mg/dL or less), and within 15% (for reference readings over 80 mg/dL) of the reference value 8 to 10 hours after a calibration entry.

Table 16 – Eversense Calibration Stability Agreement

Time from Calibration	Number of Paired CGM-YSI	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	> 40/40% of Reference
0 - 2 Hours	4,034	86.0%	93.6%	98.0%	99.3%	0.7%
2 - 4 Hours	3,979	85.6%	92.8%	98.4%	99.5%	0.5%
4 - 6 Hours	2,308	84.3%	92.2%	97.7%	99.0%	1.0%
6 - 8 Hours	1,614	84.3%	92.7%	97.8%	99.4%	0.6%
8 - 10 Hours	1,372	88.0%	94.4%	98.5%	99.6%	0.4%
10 - 12 Hours	1,295	86.1%	92.9%	98.1%	99.2%	0.8%

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PARD (Paired Absolute Relative Difference) and Percent Coefficient of Variation

In the PRECISION Study, 27 participants had two sensors inserted. The table below shows the precision of the sensor's performance by comparing readings between the two sensors worn by each participant. As an example, the absolute relative difference between the sensors worn by each person is 9.9%, and the percent coefficient of variation is 7.0%, showing the sensor values generally in agreement throughout the 90 day study period.

PARD	9.9%
PCV	7.0%

Sensor Life

Sensor life measured the percentage of sensors being able to function through the intended 90 day durations of each study. In the PRECISE II study, nine sensors did not function through the 90 day period. Function stopped at days 10, 30, 53, 67, 70, 80, 81, 83, and 85. The sensor failure on day 10 was due to a software anomaly that has since been resolved. Overall, the analysis estimated that 91% of sensors remained functioning through 90 days. In the PRECISION study, all sensors functioned through 90 days.

Percentage of sensors that lasted 30, 60, and 90 days

Table 16A PRECISE II

Days	Sensor Life
30	99%
60	97%
90	91%

Table 16B PRECISION

Days	Sensor Life
30	100%
60	100%
90	100%

Table 16C PRECISE II

Mean # of Days	Median # of days
88	91

Table 16D PRECISION

Mean # of Days	Median # of days
92	91

Data Availability

A total of 97% (821,296 out of expected 842,814) glucose values were available during the 90 day study.

Table 17 – Eversense Data Availability

	Days 1 - 30	Days 31 - 60	Days 61 - 90	All Days
Number of Displayed Glucose Values	279,674	274,727	266,895	821,296
Expected Number of Glucose Values	285,579	280,478	276,757	842,814
% of Displayed Glucose Values	98%	98%	96%	97%

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Safety

Both the PRECISE II and PRECISION studies lasted 90 days, and the number of related adverse events was recorded. The Eversense CGM System was well tolerated in the studies. During the studies' 15,921 sensor wear days, there were no unanticipated adverse events. Twenty-two adverse events were reported in 12 participants, including one serious adverse event related to the removal procedure. There were no infections. Mild irritation, pain and redness at the insertion sensor site were observed at a low rate of occurrence. None of the adverse events resulted in hospitalization.

Table 18 – Adverse Events

Event Type	Number of Events	Patients (n = 125)
Pain/Discomfort	6	5 (4.0%)
Redness/Erythema	2	1 (0.8%)
Dermatitis at Patch Location	2	1 (0.8%)
Bruising	2	1 (0.8%)
Skin Hyperpigmentation	2	1 (0.8%)
Paresthesia	1	1 (0.8%)
Syncope-vasovagal	1	1 (0.8%)
Pain	1	1 (0.8%)
Device Fragment Not Recovered	2	2 (1.6%)
Additional Procedure to Remove Sensor Following First Attempt	3	2 (1.6%)
TOTAL	22	12 (9.6%)

19. Technical Specifications

Sensor

Characteristic	Description
Dimensions	Length: 18.3 mm Diameter: 3.5 mm
Materials	Homopolymer polymethylmethacrylate (PMMA), Hydroxyethylmethacrylate (HEMA) based Hydrogel, Platinum, Silicone, Dexamethasone Acetate, epoxy 301-2
Glucose Range	40 - 400 mg/dL
Sensor Life	Up to 90 days
Calibration	Commercially available self-monitoring blood glucose meter
Calibration Range	40 - 400 mg/dL
Sterilization	Sterile by Ethylene Oxide

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Smart Transmitter

Characteristic	Description
Dimensions	Length: 37.6 mm Width: 48.0 mm Thickness: 8.8 mm
Materials	Body: polycarbonate
Weight	11.3 g
Power Supply	Rechargeable lithium polymer batteries (not replaceable)
Operational Conditions	5 - 40 °C (41 - 104 °F)
Operational Life	12 months
Storage Conditions	0 - 35 °C (32 - 95 °F)
Moisture Protection	IP67: submerged up to 1 meter of water for up to 30 minutes
Protection Against Electrical Shock	Type BF applied part
Charge time using AC adapter	15 minutes to fully charge
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)
Moisture Protection (charging cradle)	IP22

USB Cable* for Charging and Downloading

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

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

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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.

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Electrical and Safety Standards (continued)

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

System Electromagnetic Immunity Specifications

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

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

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

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Guidance and Manufacturer's Declaration – Electromagnetic Emissions

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

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

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

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

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Symbols on the Eversense Mobile App

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

Symbols on the Eversense Mobile App (continued)

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

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Symbols on Packaging and Devices

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

Symbol	Explanation
CE 0086	Marking certifies that the device meets the European Council Directive 90/385/EEC
REF	Part number
SN	Serial number
	Type BF Applied Part
	Non-ionizing electromagnetic radiation
LATEX	Not made with natural rubber latex
FCC ID	FCC ID is assigned to all devices subject to certification
NON STERILE	Non-sterile

Symbols on Packaging and Devices (continued)

Symbol	Explanation
MR	Magnetic Resonance Imaging (MRI) procedures are contraindicated for this device.
	European Union WEEE Directive 2012/19/EU
2	Single use only
2 STERILIZE	Do not re-sterilize
	Do not use if package is damaged
STERILE EO	Sterilized using Ethylene Oxide
Rx only	U.S. (Federal) law restricts the sale of the Eversense CGM System to sale by or on the order of a physician

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Eversense Smart Transmitter Limited Warranty

1. Coverage and duration of limited warranty.

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

2. Exclusions to the limited warranty.

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

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

3. Senseonics' obligations under the limited warranty.

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

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

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

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

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

System component	Part Number
Eversense Smart Transmitter Kit	FG-3300-01-001
Charging Cable	FG-6100-00-301
Charging Adapter	FG-6201-91-301
Charging Cradle	FG-6600-00-301
Eversense Adhesive Patches, White, 30 Pack Eversense Adhesive Patches, Clear, 30 Pack	FG-6402-01-300 FG-6401-01-300
Eversense Quick Reference Guide	LBL-1603-01-001
Eversense CGM User Guide	LBL-1602-01-001
Eversense Data Management Software Application	FG-5700-01-300
Eversense Mobile Application iOS	FG-5500-01-300
Eversense Mobile Application Android	FG-5600-01-300

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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.

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FCC Information

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

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

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

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

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

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

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

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Rx only

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CGM Sensor Insertion and Removal Instructions

IMPORTANT:

- Only physicians who have successfully completed the Eversense CGM Insertion and Removal Training Program and have read and understood the Eversense CGM Sensor Insertion and Removal Instructions may perform the insertion and removal procedure on patients. Contact Senseonics (in the US toll free at 844-SENSE4U (844-736-7348)) if training has yet to be conducted or if you experience any difficulty or issues with the insertion or removal procedure. Calls received after business hours (8am to 8pm Eastern US time) will be returned within two business days.
- All symptoms of infection (e.g., increased temperature, inflammation, redness, pain, tenderness, warmth, swelling or purulence) at the insertion or removal area should be reported. If any of the above occurs, please advise patients to contact their physician immediately.
- Store the sensor pack refrigerated at the labeled temperature range.
- Review the Eversense CGM System User Guide to help facilitate your patient's understanding of their new Eversense CGM System and determining their personalized glucose settings.

I. Overview of the Eversense Continuous Glucose Monitoring (CGM) System

Congratulations on having the latest diabetes technology to assist your patients in managing their diabetes. The Eversense CGM System is for people with diabetes to continually measure glucose levels for up to 90 days from the time of sensor insertion.

Some of the features of the Eversense CGM System:

- Wireless communication with the sensor, smart transmitter and app.
- Long-term sensor wear in the upper arm for up to 90 days.
- Alerts when pre-set Low or High Glucose Alert levels (hypoglycemia or hyperglycemia) are reached.
- Predictive alerts to alert the patient before reaching pre-set Low or High Glucose Alert levels.
- Use of mobile device (e.g., smartphone) to display glucose readings.
- On-body vibe alerts with the smart transmitter even when mobile device is not nearby.
- Provides readings within 40-400 mg/dL (2.2-22.2 mmol/L) range every 5 minutes.
- Trend arrows that show whether glucose values are rising or falling and how fast.
- Graphs and statistics that show 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.

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Eversense CGM System Components

The System includes:

1) a small sensor inserted subcutaneously by a doctor,

2) a removable smart transmitter worn over the sensor, and

3) a mobile app to display the glucose readings.

Eversense Sensor

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

The Eversense Sensor lasts up to 90 days. The sensor has a silicone ring that contains a small amount of dexamethasone acetate, an anti-inflammatory steroid drug. The dexamethasone acetate minimizes inflammatory responses, very similar to common medical devices, such as pacemakers.

Specially designed sensor insertion tools are provided for subcutaneous insertion of the sensor. Other equipment necessary for the procedure, but not included in the Eversense Insertion Tool Pack, is listed in *Section 4*.

Eversense Smart Transmitter

The removable smart transmitter is worn externally over the sensor and powers the sensor. It wirelessly sends glucose data (via Bluetooth) to the mobile device app. The smart transmitter also provides on-body vibe alerts based on the pre-set glucose level settings. It has a rechargeable battery and is reusable for up to one year. Adhesive patches included with the Eversense Insertion Tools Pack are provided for the patient to replace daily.

Eversense App

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

Sensor

Smart Transmitter

Eversense App

Note: Not actual size

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2. Benefits and Risks

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

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

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

Indications for Use

The Eversense CGM System is indicated for continually measuring glucose levels in adults (18 years or older) with diabetes for up to 90 days.

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).

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

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

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Contraindications

The sensor and smart transmitter are incompatible with magnetic resonance imaging (MRI) procedures. DO NOT undergo an MRI procedure while the sensor is inserted or when wearing the smart transmitter. Should an MRI be required, please contact your physician to arrange for sensor removal before the procedure.

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.

Risks and Side Effects

The glucose alerts and notifications will not audibly notify the user when the sound on their mobile device is turned off. If the system cannot display a glucose value, it also cannot provide glucose alerts. If the patient is unable to feel the vibration of the smart transmitter he/she may not notice the alerts. The system's calculated glucose can be slightly different from a blood glucose meter. This may cause an alert to activate at a different time than they would have if the system's values always matched the blood glucose meter values. If the patient does not take frequent blood glucose measurements and misses an alert, he/she may not be aware of high or low glucose levels. Medical attention may be needed in the event that he/she has high or low glucose and is unaware of it. If the patient does not test their glucose with a blood glucose meter when symptoms of a low or high blood glucose level appear OR when symptoms are not consistent with the sensor glucose readings, he/she may miss a high or low glucose event. If a patient does not always test glucose with a blood glucose meter before making a treatment decision, he/she may inadvertently cause a high or low blood glucose value because actual glucose values can be slightly different than the system's displayed values.

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.

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Warnings

- The Eversense CGM System has not been tested using insertion sites other than the upper arm.
- Patients should always test glucose with a blood glucose meter before making a treatment decision. Using the sensor glucose value to make a treatment decision could result in a high or low blood glucose.
- If at any time there are symptoms of a low or high glucose level OR if patient symptoms are not consistent with the sensor glucose readings, patients should test glucose levels with a blood glucose meter.
- Patients should not use a smart transmitter if it is damaged or cracked as this could result in electrical shock.
- Patients should avoid close contact with electromagnetic interference (EMI) while wearing the 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.
- The system should only be calibrated using a fingerstick blood sample. Alternative sites (such as forearm or palm) should not be used to calibrate the system.
- Insulin should not be injected and infusion sets for insulin pumps should not be inserted within 10.16 cm (4 in) of the sensor site. If the insulin delivery site is within 10.16 cm (4 in) of the sensor site, it may interfere with sensor glucose readings and can cause inaccurate glucose readings.

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Precautions

- The sensor and sensor holder are sterile in the unopened, undamaged, sterile package. The sensor should not be used if the sterile package has been opened or damaged.
- A sensor should not be inserted if it has been dropped from a height greater than 30 cm.
- Use only the insertion tools provided in the insertion tool kit to insert the sensor. Other insertion tools may damage the sensor.
- Instruct patients to notify airport security personnel of the presence of the device when going through the security system.
- Patients should 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 a single patient in the home environment.
- The following medical therapies or procedures have not been tested with the Eversense Sensor and may cause permanent damage to the sensor particularly if used in close proximity to the device:
  - **Lithotripsy** – The use of lithotripsy is not recommended for people who have an inserted sensor because the effects are unknown.
  - **Diathermy** – DO NOT use diathermy on people who have an inserted sensor. Energy from the diathermy can transfer through the sensor and cause tissue damage in the insertion area.
  - **Electrocautery** – The use of electrocautery near the inserted sensor may damage the device. DO NOT use electrocautery near the sensor.
- Patients should NOT wear the smart transmitter during medical x-rays or computed tomography (CT) scans. To avoid interference with results, remove the smart transmitter before undergoing medical x-ray or CT scans. Make sure your physician knows about your smart transmitter.
- The sensor and smart transmitter should be linked the day of insertion. Failure to link the sensor and smart transmitter could result in a delay in receiving glucose readings.
- Steroid use – It has not been determined whether the risks usually associated with injectable dexamethasone acetate apply to the use of this dexamethasone acetate elution ring, a highly localized, controlled-release device. The dexamethasone acetate ring could cause other adverse events not listed or previously seen.
- If the sensor, insertion site or smart transmitter feels warm, the patient should remove the smart transmitter immediately and contact his/her physician for further advice. A warm sensor could mean there is an infection or a sensor malfunction.

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Precautions (continued)

- Patients should NOT attempt to use the Eversense App while operating a motor vehicle.
- Patients should not receive massage therapy near the inserted sensor site. Massage therapy near the sensor site could cause discomfort or skin irritation.
- Patients should use only the AC power adapter and USB cable provided with the smart transmitter when charging the smart transmitter battery. Use of another power supply could damage the smart transmitter, not allowing glucose readings to be received properly, and could result in voiding the warranty.
- If the patient has any concerns about allergic reaction to adhesive products containing silicone, he/she should contact the physician prior to use. The Eversense adhesive patch should be discarded after each use of up to 24 hours.
- Patients should not change the unit of measurement unless they have discussed it with their physician. 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 the user missing a high or low glucose event.
- Patients should follow their health care provider's recommendation for setting their glucose alerts. Incorrectly setting the glucose alerts can result in the user missing a high or low glucose event.
- Patients should pay attention to the glucose alerts the system provides. Failure to appropriately respond to an alert might result in the user missing a high or low glucose event.
- The Eversense CGM System has not been tested in the following populations: women who are pregnant or nursing, people under the age of 18, critically ill or hospitalized patients, people receiving immunosuppressant therapy, chemotherapy or anti-coagulant therapy, those with another active implantable device, e.g., an implantable defibrillator (passive implants are allowed, e.g., cardiac stents), those with known allergies to or using systemic glucocorticoids (excluding topical, optical or nasal, but including inhaled). The system's accuracy hasn't been tested in these popuations, and sensor glucose readings may be inaccurate, resulting in missing a severe low or high glucose event.

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3. Eversense CGM System Candidates and Pre-Insertion Activities

Candidate Selection

Per ACE/AACE guidelines*, potential candidates for CGM include those patients:

- Taking insulin to treat their T1 or T2 diabetes, and motivated to optimize their blood glucose management with the addition of new glucose monitoring technology.
- Able to follow device labeling and use their blood glucose meter results to make treatment decisions.
- Have hypoglycemic unawareness/frequent hypoglycemia.
- With their hemoglobin A1c (HbA1c) over target, or with excess glycemic variability – requiring HbA1c lowering without increased hypoglycemia.

Eversense CGM System Candidates

- Must have a compatible Android or IOS device, be familiar with its functionality and have WiFi connectivity. For a list of compatible devices, visit eversensediabetes.com.
- Not planning on having an MRI in the next 90 days.
- Willing to enter a calibration blood glucose (BG) into the app twice a day.
- Discuss appropriate placement of sensor insertion and smart transmitter wear.
- No known contraindication to dexamethasone acetate.

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- Is not receiving mannitol or sorbitol, administered intravenously, or as a component of an irrigation solution or peritoneal dialysis solution, as this may increase blood mannitol or sorbitol concentrations and cause falsely elevated readings of sensor glucose results. Sorbitol is used in some artificial sweeteners, and concentration levels from typical dietary intake do not impact sensor glucose results.
- Is not pregnant or under the age of 18.

* Blevins T, Bode B, Garg S, Grunberger G, Hirsch I, Jovanovic L, et al. Statement by the American Association of Clinical Endocrinologists Consensus Panel on Continuous Glucose Monitoring. Endocrine Practice, 2010; 16(5): A.

Pre-Insertion Training Activities for Patient

- Download Eversense App to compatible mobile device (requirements are listed in User Guide) and become familiar with functionality.
- Discuss the importance of setting the correct "Unit of Measure" in the Eversense App.
- Go to eversensediabetes.com – view insertion animation video, download Quick Reference Guide (QRG) and/or User Guide for review.

To pair Smart Transmitter with Compatible Mobile Device

- Confirm the patient has downloaded the Eversense CGM App from the App Store or Google Play store.
- Charge smart transmitter for 15 minutes
- Pair smart transmitter to mobile device.
- Set system preferences according to doctor recommendations.
- Instruct patients to bring smart transmitter and mobile device to clinic if it was shipped to patient's home.

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4. Eversense CGM System Kit

The Eversense CGM System Kit comes in three packages: 1) Sensor Pack, 2) Insertion Tools Pack, and the 3) Smart Transmitter Pack.

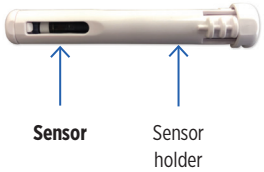
IMPORTANT: The Sensor Pack and Insertion Tools Pack contain components that are packaged sterile. Both packs are designed for single patient-use only. DO NOT re-use, re-process or re-sterilize the sensor, blunt dissector, or insertion tool.

Items Not Included: Other procedure instruments, tools and equipment are not included and must be provided by the clinic.

1. Eversense Sensor Pack (Sensor in holder)

The **Sensor** is shipped sterile inside a protective holder for safe handling purposes. You will need to transfer the sensor to the insertion tool before use. The pouch that holds the sensor is not sterile.

The sensor is approximately 3.5 mm x 18.3 mm and is subcutaneously inserted using the insertion tool. The sensor has a silicone ring that contains an anti-inflammatory steroid drug (dexamethasone acetate). Upon exposure to body fluids the dexamethasone acetate is eluted from the ring in the area near the sensor. The dexamethasone acetate minimizes inflammatory responses, very similar to some already available medical devices (e.g., pacemaker leads).



IMPORTANT: Store the sensor pack refrigerated at the labeled temperature range.

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2. Eversense Insertion Tools Pack

(Incision Template , Blunt Dissector, Insertion Tool, Tray, Adhesive Patches, and Insertion/Removal Instructions)

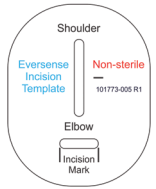
The **Incision Template** is used to guide and mark the incision area on the skin surface by aligning the marking template to the marked outer edges of the smart transmitter when placed in a comfortable position.

The **Blunt Dissector** is used to create the subcutaneous pocket for insertion of the sensor. This tool has two depth guards to help prevent the pocket from being made too deep in the skin. The depth guards have guide marks to assist in determining the length of the subcutaneous pocket for placing the sensor.

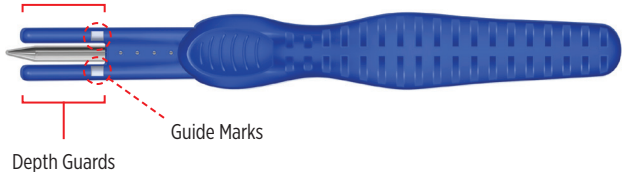
The **Insertion Tool** is used to insert the sensor inside the subcutaneous pocket created with the blunt dissector. It has two guide marks on the cannula to assist in proper placement.

The **Adhesive Patch** (90 patches in pack) has an adhesive side that attaches to the back of the smart transmitter and a silicone adhesive side that attaches to the skin intended to be changed daily.

Incision Point Marking Template



Blunt Dissector



Insertion Tool

3. Eversense Smart Transmitter Pack

(Smart Transmitter, Power Supply, User Guide, Quick Reference Guide)

The **Smart Transmitter** is the reusable and rechargeable device worn externally over the sensor. The smart transmitter wirelessly powers the sensor. Use only the **Power Supply** included in this kit to charge the smart transmitter.

The **User Guide** and **Quick Reference Guide** are designed for the patient to learn about their Eversense CGM System.

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5. Product Handling

The sensor package, blunt dissector, and insertion tool have been sterilized by the method indicated on the package labels.

Inspect the condition of the sterile package before opening and using the contents.

- DO NOT use the contents if the package is broken or torn, or if contamination is suspected because of a defective sterile package seal.
- DO NOT re-sterilize the sensor or the components by any sterilization method.
- DO NOT use the product if the labeled “Use By” date has passed.

Handling and Storage

- Handle the sensor and all other components with care, using appropriate aseptic technique.
- DO NOT open any of the sterile packages until ready for use.
- Keep sharp instruments away from the kit components.
- DO NOT use the sensor or any kit component if it has been dropped on a hard surface from a height of more than 30 cm.
- Store the sensor package refrigerated at the labeled temperature range.
- Dispose of product packaging in accordance with clinic, administrative and/or local government policy.

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6. Suggested Equipment

Items Not Included: Other procedure instruments, tools and equipment are not included in insertion tool kit and must be provided by the clinic. Please see list of suggested equipment below.

Materials (or equivalent) suggested for sensor insertion/removal:

- Chlorhexidine OR Betadine solution
- 2-3 Sterile Gauze Pads
- 1 Disposable Sterile Scalpel (e.g., Disposable Sterile Scalpel, #15)
- 1 Sterile Syringe and Needle (for lidocaine injection)
- Steri-Strip Adhesive Skin Closure and/or available sutures (physician preference)
- 1 sterile scissors (e.g., disposable) to cut steri strips
- 1 Sterile Towel Drape
- 1 Sterile Drape with aperture approximately 22 in x 25 in
- 2 Tegaderm™ + Pad Film Dressing
- 1 Lidocaine HCL without epinephrine (1-2 mL)
- 1 Surgical skin marker
- 3 Sterile, non-latex surgical gloves, physician-preferred size
- 1 10 mL sterile saline filled syringe (for insertion only)
- 1 Sterile surgical clamp 10-16cm

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7. Insertion Procedure

Before inserting the sensor, confirm that the patient:

- Does not plan to have an MRI within 90 days after sensor insertion.
- Does not have allergies to the antiseptic and local anesthetic to be used during insertion.

Note: The procedure below assumes a right handed physician with the patient facing (left arm insertion) or looking away from (right arm insertion) the physician. The dimensions indicated in the instructions are approximate to give a conceptual context of the insertion.

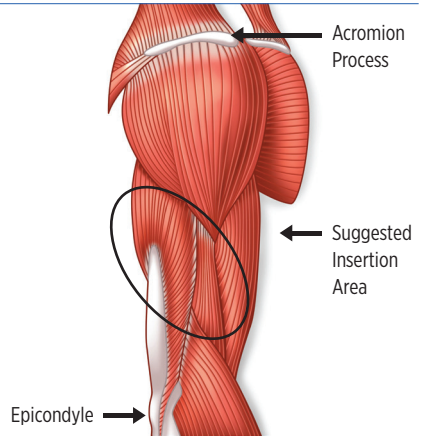
A. Prep the Insertion Area

1. **With the subject seated on the procedure table, position the smart transmitter on the patient's arm to select the insertion location for the sensor. It is recommended to alternate arms for subsequent insertion sites.**

   Suggested insertion location is approximately at the midway point between the acromion process and the lateral epicondyle.

   Things to consider when choosing insertion location:

   - It must be comfortable for the user to wear 24/7 for 90 days. Place the smart transmitter on the intended site and confirm that the patient is comfortable with the placement.
   - Not too lateral such that patient cannot easily apply adhesive patch.
   - Avoid area with loose skin such as back of arm.
   - Avoid areas with scar tissue, tattoo, nevus, or apparent or noticeable blood vessels that could be incised.



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2. Once the position for the smart transmitter is selected, mark the corners on the skin.

3. Using the non-sterile incision template, align the template inside the marked lines and mark the skin for the incision using the incision template's slot.

4. Position the patient in a reclined position preferably on their side, with the elbow flexed up to 90 degrees and the palm resting on the chest or abdomen.

B. Open the Sensor Pack and Insertion Tools Pack

Over the prepared sterile field, remove the sensor holder from the Sensor pouch and remove the sterile inner tray with tools from the Insertion Tools Pack and place in the sterile procedure field created for the procedure. Note that the inner tray of the Sensor Insertion Package is sterile and can be placed within the sterile procedure field.

Precautions

- The sensor and sensor holder are sterile in the unopened, undamaged, sterile package. The sensor should not be used if the sterile package has been opened or damaged.
- DO NOT insert a sensor if it has been dropped from a height of 30 cm or more.
- Use only the insertion tools provided in the insertion tool kit to insert the sensor. Other insertion tools may damage the sensor.

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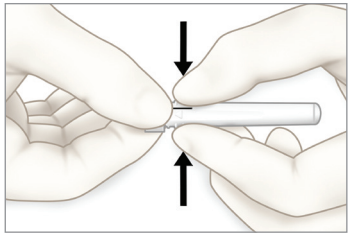
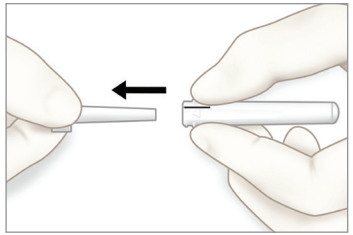
C. Prepare the Sensor

1. **Remove the cap from the end of the sensor holder by pressing the ridged portion and pulling the cap.**

   Discard the cap.

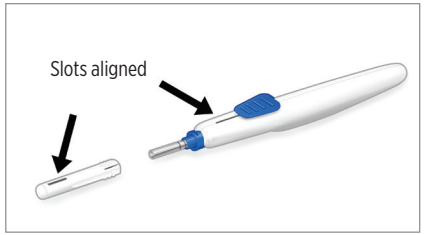




2. **Align the insertion tool cannula and sensor holder.**

   Ensure that the blue thumb slide is still in the retracted position.

   Align the slot of the sensor holder with the exposed slot of the thumb slide and the triangle on the side of the sensor holder with the triangle on the insertion tool.



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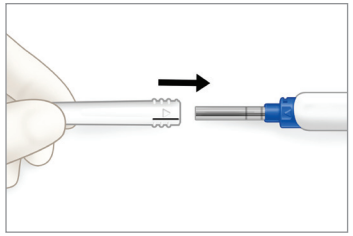
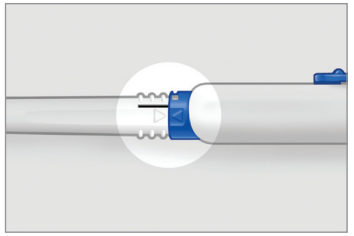
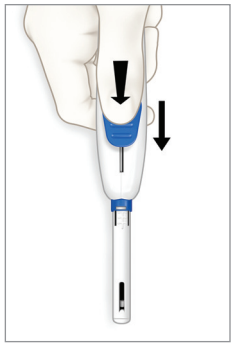
3. **Slide the sensor holder over the insertion tool cannula so that the two triangles are touching at the tip.**

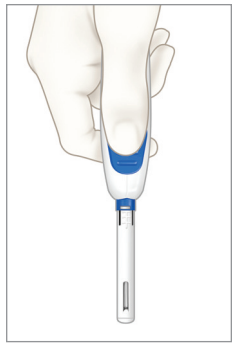


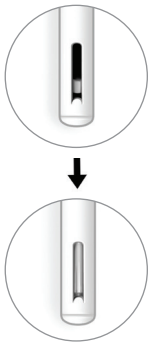


4. **Depress the blue thumb slide down to unlock and advance it all the way forward until it stops.**

   This action secures the sensor inside the cannula. The cannula is now visible through the slot in the sensor holder. DO NOT RETRACT the thumb slide at this step.







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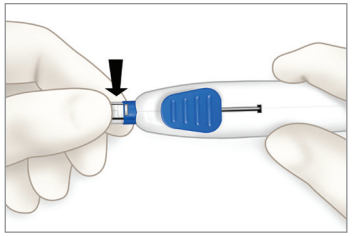
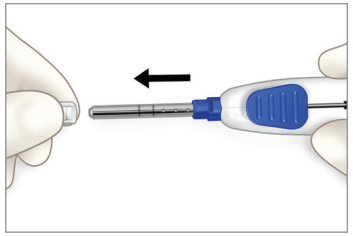
5. **Depress the ridged portion of the sensor holder to remove it from the insertion tool.**

Discard the sensor holder. You should see the tip of the sensor at the end of the insertion tool.

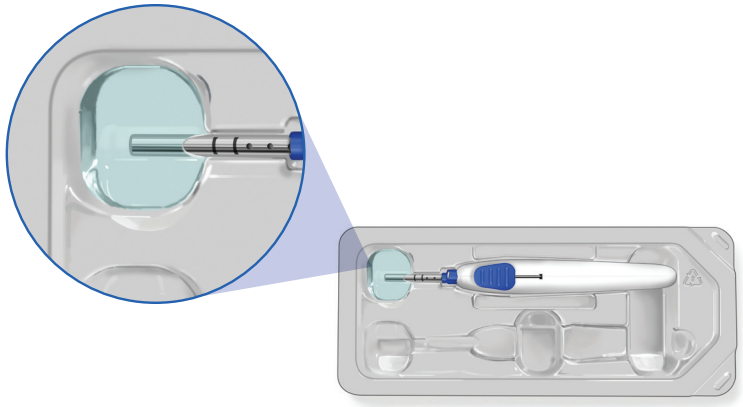




6. **Place the insertion tool back in its original placement in the tray.**

The insertion tool will snap into position in the insertion kit inner tray and the tip of the cannula with the sensor will be positioned in the preformed well in the tray.

7. **Wet the cannula and sensor by filling the preformed well with enough sterile saline (0.95 sterile saline for injection) to completely cover the cannula and sensor (approximately 10 mL). To ensure proper hydration, submerge the tip in the well for a few minutes (approximately 5 minutes).**



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D. Clean and Anesthetize the Insertion Area

1. **If not done previously, position the patient in a reclined position, preferably on their side, with the elbow flexed up to 90 degrees and the palm resting on the chest or abdomen.**

2. **Clean and disinfect the insertion area.**

   Apply disinfectant chlorhexidine to marked area. Cover the arm with sterile drape so opening is around incision site.

3. **Anesthetize the insertion area as appropriate.**

   Local anesthesia (approximately 2 mL of Lidocaine) should be injected approximately 5 mm along the planned incision (along AB) and approximately 30 mm perpendicular to the planned incision (along CD) which is the planned track of the blunt dissector tool. (Figure 1).

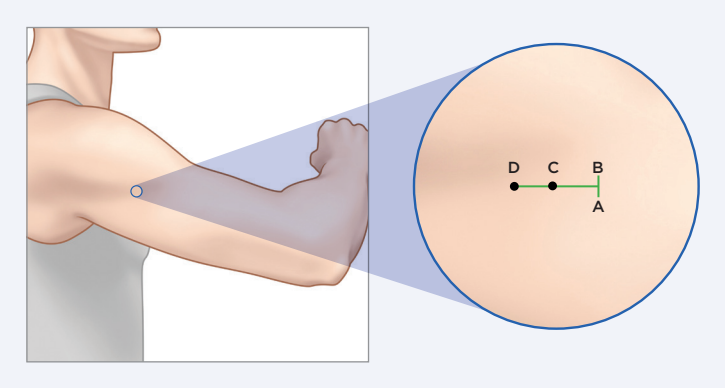

Figure 1

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E. Make Incision and Subcutaneous Pocket

1. **Once the insertion area is sufficiently anesthetized, make an approximately 5 mm incision at the insertion location such that you will be able to create an appropriately sized subcutaneous pocket approximately 3-5 mm below the skin surface.**

   Start incision at point B (Figure 1) and go towards point A, until the incision is approximately 5 mm.

2. **Remove the blunt dissector from the tray and introduce the blunt dissector at approximately a 45 degree entry angle at the midline between A and B (Figures 1 & 2) so that the tip and tapered portion of the blunt dissector are under the skin, and until the depth guards are touching the skin.**

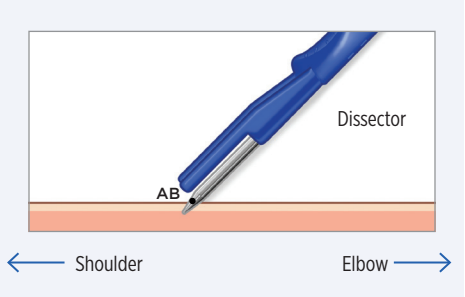

Figure 2

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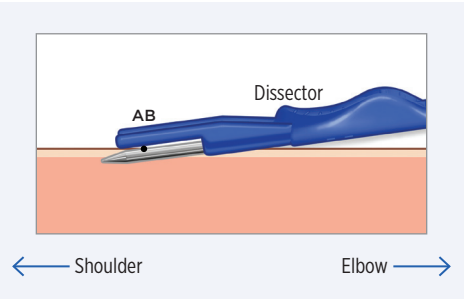
3. **With the tips of the depth guards on the skin and the blunt dissector at the subcutaneous space, lower the angle of skin entry to approximately 5-10 degrees (Figure 3) taking care to ensure that the fingers are not under the metal rod or plastic portions of the tool which would cause a steeper angle.**



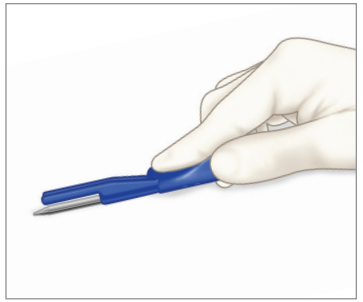


Figure 3

4. **Move the blunt dissector toward the shoulder, while maintaining the metallic and plastic parts of the tool in close contact with the skin to ensure the smallest possible angle of the pocket with respect to the skin (Figure 3).**

   Continue advancing the tool until the incision between A and B is within the white guide marks on the depth guards (Approximately 25-30 mm) (Figure 4). Completely retract the blunt dissector and set aside.

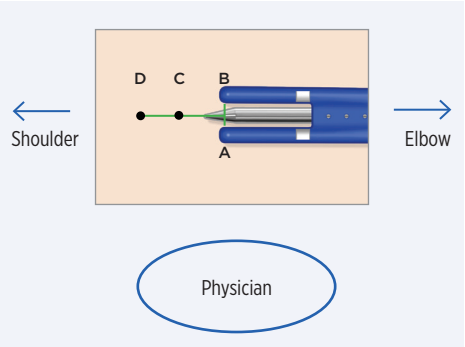


Figure 4

Note:

- Pinching and tenting the skin can aid in forming a small space in the skin for insertion.
- Slight rotation of the blunt dissector along the axis of the tool while advancing may be helpful.
- DO NOT create a pocket more than 3-5 mm below the skin. If the sensor is placed too deep, it may be difficult to communicate with the smart transmitter or to later remove.
- It is important to ensure that the subcutaneous pocket is parallel to and along the same axis as the humerus bone. When you place the sensor, it should be level in the pocket, which will facilitate communication between the sensor and the smart transmitter.

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F. Sensor Placement and Incision Closure

1. **Using approximately a 45 degree entry angle, place the tip of the insertion tool into the incision opening such that the tip of the cannula is beneath the incision.**

2. **Similar to steps E3 & E4, lower the entry angle to about 5-10 degrees and advance toward the shoulder following the pocket created by the blunt dissector.**

3. **Advance the tool until the incision line is between the first and second marked lines on the cannula.**

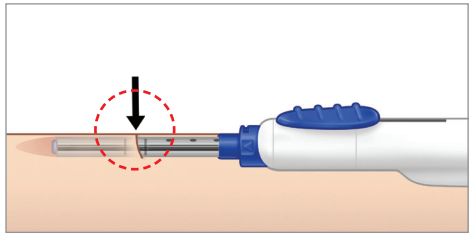
   If necessary, re-use the blunt dissector or widen the incision if excessive force is encountered. DO NOT force the insertion tool into the incision site.

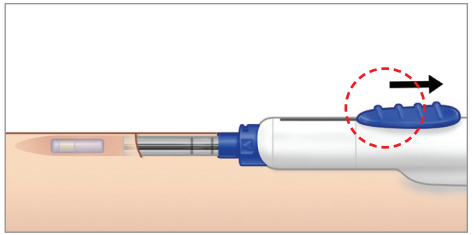
4. **Pushing down on the back of the thumb slide to unlock it, retract the thumb slide to deploy the sensor into the pocket.**

   The slide locks into place when it has reached the end point. DO NOT re-advance the thumb slide.

5. **Lightly palpate the insertion area to confirm that the sensor is in place; remove the insertion tool from the incision.**

6. **Close and dress the incision in the appropriate manner using adhesive skin closure (e.g., Steri-Strip™) or suture and dressing, making sure the two sides of the incision are closed together.**





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G. Insertion Tool and Blunt Dissector Disposal

Dispose of used insertion tool and blunt dissector in accordance with clinic, administrative and/or local government policy.

H. Connecting the Eversense CGM System

1. **Confirm the patient's mobile device has been paired with the Eversense App and has an internet connection.**

2. **Link the sensor to the smart transmitter.**
   a. Place the smart transmitter directly over the bandage.
   b. On the Eversense App, use the Placement Guide screen to confirm there is a signal.
   c. Navigate away from the Placement Guide page once you have confirmed there is a signal.

Note: It may take up to 5 minutes to receive the notification for "New Sensor Detected". DO NOT remove the smart transmitter from over the insertion site until the linking process is complete. You may use the Eversense adhesive to place the smart transmitter over the bandage of the insertion site.

Refer to the *Eversense CGM System User Guide, Inserting and Linking the Sensor* for additional information.

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8. Post-Insertion Patient CGM Start-Up

Your patients may need assistance in getting started with the Eversense CGM System. Refer to the User Guide and Quick Reference Guide that is included in the smart transmitter pack for information on getting the smart transmitter and mobile device ready for use.

This includes:

- Charging the smart transmitter.
- Downloading the Eversense App to their mobile device.
- Personalizing the patient's glucose settings.
- Pairing (connecting) the smart transmitter and app.
- Linking the smart transmitter with the sensor after the sensor is inserted.

Note:

- All but the linking step can be completed before the sensor is inserted.
- Patients do not need to secure the smart transmitter over the sensor during the first 24 hours after insertion. After the sensor is linked to the smart transmitter, the sensor requires 24 hours to stabilize in the body before glucose values can be calculated by the smart transmitter.
- If the smart transmitter is secured over the sensor within the first 24 hours after insertion, the patient will receive a message indicating a Warm-Up Phase status of the system and will provide the patient with a 24-hour countdown.
- If the smart transmitter is not secured over the sensor and turned off to avoid vibrations, patient must remember to turn smart transmitter back on at the 24th hour. It will take about 5 minutes after the smart transmitter is placed over the sensor for the first calibration prompt to be displayed. After calibration is completed, the smart transmitter should not be removed for 15 minutes.
- Glucose readings will appear on screen after successfully completing the 2nd calibration.

Review the Eversense User Guide to help facilitate your patient's understanding of their new Eversense CGM System and determining their personalized glucose settings.

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9. Sensor Removal Procedure

A. Locate the Sensor

1. **Using the initial incision point as a guide, palpate and locate the sensor to determine an appropriate incision location. For reference, mark both ends of the sensor if possible to palpate.**

   Note: If the sensor cannot be located by palpating, the smart transmitter may be used to aid in locating the sensor. To use the smart transmitter to locate the sensor, open the Placement Guide page in the App. Move the smart transmitter around the sensor insertion area until the screen displays the greatest signal strength. Mark the edges of the smart transmitter at this location and use the incision template to determine the proper incision location.

2. **Mark the incision point on the skin.**

   If the site of the original incision is within 3-5 mm of the distal tip of the sensor, removal can be accessed through the same location.

B. Prep the Removal Area

1. **Position the patient in a reclined position, preferably on their side, with the elbow flexed up to 90 degrees and the palm resting on the chest or abdomen.**

2. **Clean and disinfect the insertion area.**

   Prepare the insertion site and surrounding area, using aseptic technique.

3. **Anesthetize the insertion area as appropriate for the patient similar to step D3 in section 7.**

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C. Incision and Pocket Opening

1. Push down on the skin over the expected location of the proximal end of the sensor to stabilize it.
2. Create approximately a 5-6 mm incision through the dermis at the location determined in A1.

D. Remove the Sensor

1. Carefully dissect the subcutaneous tissue until the end of the sensor distal to the incision can be grasped by a small surgical clamp (such as 10 -16cm). Spreading of the tissue through the incision using the clamp both parallel and perpendicular to the incision may be required to enable visualization and grasping of the sensor with the clamp.
2. Put gentle pressure on the proximal end of the sensor through the skin to help stabilize and facilitate grasping the distal end of the sensor. Use a clamp to grasp the distal end of the sensor and remove it from the pocket. Rotation of the sensor with the clamp may aide in freeing the sensor from any attached tissue.
3. If the sensor is encapsulated, further dissection may be necessary to grasp and remove the sensor.

E. Close and Dress the Incision in the Appropriate Manner

1. Close and dress the incision in the appropriate manner using adhesive skin closure (e.g., Steri-Strip™) or suture, making sure the two sides of the incision are closed together.

F. Sensor Disposal

1. Dispose of sensor according to your area's local regulations.

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10. Potential Complications

The insertion and removal of the Eversense Sensor is a minor procedure and requires aseptic technique to minimize the possibility of infection. Please review this document for complete training.

A. During Insertion Process

1. Unable to insert blunt dissector through incision

a. Incision may be too small

Increase incision size by 2-3 mm and re-insert the blunt dissector.

b. Refer to tips for proper insertion technique in this document

– Pinching or tenting the skin can aid in forming a small pocket for the insertion.

– Slight rotation of the blunt dissector along the axis of the tool may be helpful.

– DO NOT create a pocket more than 3-5 mm below surface of skin.

2. Unable to advance the insertion tool into the subcutaneous pocket

a. Ensure the insertion tool is below the incision when advancing into subcutaneous pocket

b. Incision size may be too small

Increase incision size by 3-5 mm with scalpel and re-insert the insertion tool.

3. Unable to locate the subcutaneous pocket with the insertion tool when inserting the sensor

Re-insert the blunt dissector into incision to ensure subcutaneous pocket is adequate.

4. Subject experiences pain during the procedure

Administer additional local anesthetic as required.

5. Excessive bleeding after incision is made

Apply pressure until bleeding subsides.

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B. During Removal Process

1. Unable to palpate/locate the sensor

Use the Placement Guide on the app and the smart transmitter to find the sensor. Once the location of the sensor is made with the Placement Guide, mark the position of the smart transmitter on the skin and use the incision template to mark the point of incision. In some cases, an ultrasound may be required to locate the proper point of the incision.

2. Excessive bleeding after the sensor is removed

Apply pressure and, if necessary, use sutures to close incision in place of Steri-Strips™.

3. Subject experiences pain during the procedure

Administer additional local anesthetic as required.

4. Tissue encapsulation prevents sensor from moving

Dissect encapsulation by spreading the tissue using the clamp/or other desired instrument as required. Gently rotate the clamp with the secured sensor to release any small fibrous tissue encapsulation.

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II. Device Performance

This section lists Device Performance Characteristics.

Clinical Study Performance

The safety and effectiveness of the Eversense CGM System has been evaluated in several prospective feasibility and pivotal studies. Two studies – PRECISE II (2016) and PRECISION (2018) – were conducted in the U.S. to evaluate the Eversense CGM System performance in terms of safety and effectiveness. Accuracy assessments were made at variouspoints during the studies and subjects were asked to report any adverse events throughout the studies. The data collected was analyzed post-hoc using a new algorithm, SW 602.

PRECISE II Study

PRECISE II was a multi-site, non-randomized single-arm pivotal clinical study. Ninety (90) adults (18 years and older) with type 1 or type 2 diabetes participated in the study across 8 sites in the U.S. Each had a sensor inserted in the upper arm to collect glucose data but not be displayed to the subject. Some participants had a sensor inserted into each arm for clinical data collection. Participants interacted with the system to calibrate and address notifications not related to glucose data. Accuracy was measured during day-long clinic visits, with blood taken about every 15 minutes. These visits occurred on Days 1, 30, 60, and 90. At each visit, sensor accuracy was evaluated relative to a standard laboratory analyzer known as the YSI. Glucose readings were compared at the same moment in time between the reference analyzer and the continuous device. A safety follow-up visit occurred at Day 100, or ten days after the sensor was removed.

PRECISION Study

PRECISION was a second non-randomized single-arm pivotal clinical study conducted in the U.S. in 3 sites. Thirty-five (35) adults (18 years and older) with type 1 or type 2 diabetes participated in the study which was similar in study design as PRECISE II, except glucose readings and high/low glucose alerts were not blinded to the participants, and study visits on days 7 and 14 were added. The table below characterizes accuracy of the system by assessing the sensor glucose values against the YSI reference values.

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Table 1 - Accuracy to YSI in PRECISE II* and PRECISION*

Study	Number of Participants	Total Number of Paired CGM and YSI Values	Percent Within 15/15%	Percent Within 20/20%	Percent within 30/30%	Percent within 40/40%	MARD
PRECISE II	90 adults (18 years and older)	15,753	87%	94%	99%	100%	8.5%
PRECISION	35 adults (18 years and older)	15,170	85%	93%	98%	99%	9.6%

*Data is from primary sensors only; glucose values between 40 and 400 mg/dL.

Since the two studies are similar, the PRECISION study is included in this report. For detailed report on the PRECISE II results, please go to our website www.eversensediabetes.com.

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Eversense Accuracy to YSI in PRECISION Study

Accuracy was measured by comparing the Eversense sensor glucose values to YSI blood glucose values. 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.

Table 2 – Accuracy to YSI in PRECISION Study

YSI Glucose Ranges (mg/dL)	Paired CGM-YSI (n)	Mean Absolute Relative Difference (%)
Overall	15,170	9.6
< 40	15	16.2
40 - 60	1,267	8.1
61 - 80	2,212	8.6
81 - 180	5,685	9.7
181 - 300	3,210	7.7
301 - 350	1,527	6.8
351 - 400	1,174	6.5
> 400	80	11.2

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Performance was also measured by calculating the percentage of sensor glucose readings within 15 mg/dL or 15% of the YSI reference. These tables show the percent agreement at multiple levels, at different glucose ranges, and at different days during the sensor wear. Results in the glucose ranges of 80 mg/dL or less reflect the percentage of values within mg/dL, and results in the glucose ranges over 80 mg/dL reflect the percentage within reference. As an example, glucose values between 40 and 60 mg/dL were within 15 mg/dL of the reference value 91.9% of the time.

Table 3 - Eversense Percentage of Readings in Agreement Overall

CGM System Glucose Range (mg/dL)	Paired CGM and YSI References	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	> 40/40% of Reference
Overall	15,170	85.4%	92.8%	98.1%	99.3%	0.7%
40 - 60	1,236	91.9%	96.0%	98.4%	99.3%	0.7%
61 - 80	2,003	87.3%	94.1%	99.1%	99.6%	0.4%
81 - 180	5,786	80.5%	89.9%	97.2%	99.0%	1.0%
181 - 300	3,566	84.8%	92.8%	98.1%	99.2%	0.8%
301 - 350	1,628	92.8%	97.5%	99.1%	99.9%	0.1%
351 - 400	951	91.5%	95.8%	98.6%	99.8%	0.2%

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Table 4 - Eversense Percentage of Readings in Agreement on Day 1

CGM System Glucose Range (mg/dL)	Paired CGM and YSI References	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	> 40/40% of Reference
Overall	2,665	79.1%	88.9%	95.8%	98.5%	1.5%
40 - 60	274	86.5%	91.2%	96.4%	97.8%	2.2%
61 - 80	378	81.7%	87.8%	97.1%	98.7%	1.3%
81 - 180	962	76.7%	87.8%	95.6%	98.9%	1.1%
181 - 300	585	80.3%	91.1%	96.1%	97.8%	2.2%
301 - 350	250	77.6%	90.4%	95.2%	99.2%	0.8%
351 - 400	216	74.5%	85.2%	94.0%	99.1%	0.9%

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Table 5 - Eversense Percentage of Readings in Agreement on Day 7

CGM System Glucose Range (mg/dL)	Paired CGM and YSI References	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	> 40/40% of Reference
Overall	2,926	86.1%	93.3%	98.1%	99.0%	1.0%
40 - 60	214	93.0%	98.1%	99.5%	100.0%	0.0%
61 - 80	404	87.6%	94.3%	99.3%	99.8%	0.2%
81 - 180	1,053	80.0%	89.3%	96.7%	97.9%	2.1%
181 - 300	630	84.6%	93.5%	97.5%	99.2%	0.8%
301 - 350	385	94.3%	97.4%	99.7%	100.0%	0.0%
351 - 400	240	95.0%	97.5%	100.0%	100.0%	0.0%

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Table 6 - Eversense Percentage of Readings in Agreement on Day 14

CGM System Glucose Range (mg/dL)	Paired CGM and YSI References	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	> 40/40% of Reference
Overall	2,997	88.1%	94.6%	98.8%	99.6%	0.4%
40 - 60	269	87.0%	92.6%	96.7%	98.9%	1.1%
61 - 80	407	84.0%	93.4%	99.5%	100.0%	0.0%
81 - 180	999	82.0%	91.7%	98.0%	99.1%	0.9%
181 - 300	663	91.3%	95.9%	99.4%	99.8%	0.2%
301 - 350	383	97.1%	99.0%	99.5%	100.0%	0.0%
351 - 400	276	96.7%	99.6%	100.0%	100.0%	0.0%

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Table 7 - Eversense Percentage of Readings in Agreement on Day 30

CGM System Glucose Range (mg/dL)	Paired CGM and YSI References	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	> 40/40% of Reference
Overall	2,284	88.0%	94.3%	98.9%	100.0%	0.0%
40 - 60	209	98.6%	99.5%	100.0%	100.0%	0.0%
61 - 80	416	92.8%	97.6%	100.0%	100.0%	0.0%
81 - 180	936	81.1%	90.0%	97.4%	100.0%	0.0%
181 - 300	492	87.4%	94.7%	99.8%	100.0%	0.0%
301 - 350	183	99.5%	100.0%	100.0%	100.0%	0.0%
351 - 400	48	100.0%	100.0%	100.0%	100.0%	0.0%

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Table 8 - Eversense Percentage of Readings in Agreement on Day 60

CGM System Glucose Range (mg/dL)	Paired CGM and YSI References	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	> 40/40% of Reference
Overall	2,133	86.9%	93.7%	98.5%	99.6%	0.4%
40 - 60	165	98.2%	100.0%	100.0%	100.0%	0.0%
61 - 80	176	89.2%	96.6%	100.0%	100.0%	0.0%
81 - 180	880	85.9%	94.2%	98.3%	99.4%	0.6%
181 - 300	592	79.1%	86.8%	97.1%	99.5%	0.5%
301 - 350	239	96.7%	100.0%	100.0%	100.0%	0.0%
351 - 400	81	98.8%	100.0%	100.0%	100.0%	0.0%

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Table 9 - Eversense Percentage of Readings in Agreement on Day 90

CGM System Glucose Range (mg/dL)	Paired CGM and YSI References	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	> 40/40% of Reference
Overall	2,165	83.9%	92.2%	98.5%	99.3%	0.7%
40 - 60	105	93.3%	100.0%	100.0%	100.0%	0.0%
61 - 80	222	90.5%	96.8%	99.1%	99.1%	0.9%
81 - 180	956	77.7%	86.7%	97.5%	99.2%	0.8%
181 - 300	604	85.9%	94.9%	98.8%	99.2%	0.8%
301 - 350	188	89.9%	98.9%	100.0%	100.0%	0.0%
351 - 400	90	95.6%	98.9%	100.0%	100.0%	0.0%

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Glucose values below 40 mg/dL or above 400 mg/dL are shown on the mobile app as “LO” or “HI”. The table below shows, as a percentage, agreement of sensor glucose values when outside the display range of 40 mg/dL to 400 mg/dL.

Table 10 – Eversense Agreement when “LO” or “HI” is Displayed

		Reference mg/dL					
CGM Readings	CGM-Ref pairs	< 50	< 60	< 70	< 80	> 80	Total
‘LO’	n	6	7	9	9	0	9
	%	66.7%	77.8%	100%	100%	0%	100%

		Reference mg/dL					
CGM Readings	CGM-Ref pairs	> 340	> 320	> 280	> 240	< 240	Total
‘HI’	n	359	383	399	404	1	405
	%	88.6%	94.6%	98.5%	99.8%	0.2%	100%

Eversense Alert Performance

The tables in this section show an alert performance assessment. The Confirmed Event Detection Rate shows the percentage of time the Eversense CGM 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 Eversense CGM 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 CGM 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 CGM system was not confirmed by a reference value within a 15 minute window of the alert being presented.

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The table below shows an assessment of the ability of the Eversense CGM System to detect high and low glucose levels, and assess true positive alerts vs false positive alerts. These are shown as a percentage of alerts provided compared to the YSI reference values at various thresholds.

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

Alert Setting (mg/dL)		Confirmed Event Detection Rate	Missed Detection Rate	True Alert Rate	False Alert Rate
Low Alert	60	76%	24%	81%	19%
	70	90%	10%	95%	5%
	80	94%	6%	96%	4%
	90	96%	4%	95%	5%
High Alert	120	99%	1%	96%	4%
	140	99%	1%	96%	4%
	180	98%	2%	95%	5%
	200	98%	2%	95%	5%
	220	98%	2%	95%	5%
	240	98%	2%	95%	5%
	300	93%	7%	94%	6%

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The table below shows an assessment of the ability of the Eversense CGM System to detect high, low, and predictive high and low alerts, and assess true positive alerts vs false positive alerts. These are shown as a percentage of alerts provided compared to the YSI reference values at various thresholds.

Table 12 – Eversense High, Low, and Predictive Alert Performance (Threshold and Predictive)

Alert Setting (mg/dL)		Confirmed Event Detection Rate	Missed Detection Rate	True Alert Rate	False Alert Rate
Low Alert	60	89%	11%	77%	23%
	70	95%	5%	92%	8%
	80	97%	3%	93%	7%
	90	98%	2%	93%	7%
High Alert	120	99%	1%	96%	4%
	140	99%	1%	94%	6%
	180	99%	1%	93%	7%
	200	98%	2%	94%	6%
	220	98%	2%	94%	6%
	240	99%	1%	94%	6%
	300	95%	5%	92%	8%

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Eversense Trend Agreement

The shaded area of the table below shows agreement between the Eversense 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, Eversense glucose trends are in agreement with the reference trends 89% of the time.

Table 13 – Eversense Trend Agreement

	Reference Rate of Change (mg/dL/min) Percent of Matched Pairs in Each Reference Trend Range for Each CGM ROC Range							
CGM Trend (mg/dL/min)	< -3	[-3, -2)	[-2, -1)	[-1, 1]	(1, 2]	(2, 3]	> 3	Total
< -3	14%	20%	30%	36%	0%	0%	0%	135
[-3, -2)	5%	12%	38%	44%	1%	1%	0%	338
[-2, -1)	1%	3%	24%	71%	1%	0%	0%	1,115
[-1, 1]	0%	1%	5%	89%	5%	1%	0%	10,655
(1, 2]	0%	0%	1%	55%	35%	8%	1%	997
(2, 3]	0%	0%	2%	36%	41%	18%	4%	354
> 3	0%	1%	0%	25%	35%	30%	10%	175
Total	57	155	990	11,137	1,085	288	57	13,769

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Eversense Concurrence with YSI Values

The shaded areas of the tables below show what percentage of YSI reference values were in the same range as the sensor glucose values. As an example, when sensor glucose is between 81 and 120 mg/dL, YSI reference values are in the same range 71% of the time.

Table 14 – Concurrence with YSI Range All Days

Percent of Matched Pairs in Each YSI Glucose Range for Each CGM Glucose Range YSI (mg/dL)												
CGM (mg/dL)	Paired CGM-YSI (n)	< 40	40 - 60	61 - 80	81 - 120	121 - 160	161 - 200	201 - 250	251 - 300	301 - 350	351 - 400	> 400
40 - 60	1,236	1%	63%	34%	2%	0%	0%	0%	0%	0%	0%	0%
61 - 80	2,003	0%	22%	67%	10%	0%	0%	0%	0%	0%	0%	0%
81 - 120	2,524	0%	2%	17%	71%	10%	0%	0%	0%	0%	0%	0%
121 - 160	2,342	0%	0%	0%	18%	71%	11%	0%	0%	0%	0%	0%
161 - 200	1,727	0%	0%	0%	1%	24%	59%	16%	0%	0%	0%	0%
201 - 250	1,502	0%	0%	0%	0%	1%	19%	65%	14%	1%	0%	0%
251 - 300	1,257	0%	0%	0%	0%	0%	1%	18%	51%	27%	3%	0%
301 - 350	1,628	0%	0%	0%	0%	0%	0%	1%	10%	57%	32%	1%
351 - 400	951	0%	0%	0%	0%	0%	0%	0%	2%	26%	65%	7%

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Table 15 - Concurrence with YSI Range Day 1

Percent of Matched Pairs in Each YSI Glucose Range for Each CGM Glucose Range YSI (mg/dL)												
CGM (mg/dL)	Paired CGM-YSI (n)	< 40	40 - 60	61 - 80	81 - 120	121 - 160	161 - 200	201 - 250	251 - 300	301 - 350	351 - 400	> 400
40 - 60	274	1%	59%	36%	4%	0%	0%	0%	0%	0%	0%	0%
61 - 80	378	0%	14%	65%	19%	1%	0%	0%	0%	0%	0%	0%
81 - 120	516	0%	1%	23%	63%	12%	0%	0%	0%	0%	0%	0%
121 - 160	332	0%	0%	0%	17%	70%	12%	1%	0%	0%	0%	0%
161 - 200	226	0%	0%	0%	1%	23%	58%	17%	0%	0%	0%	0%
201 - 250	268	0%	0%	0%	0%	4%	25%	55%	15%	0%	0%	0%
251 - 300	205	0%	0%	0%	0%	0%	2%	25%	57%	14%	1%	0%
301 - 350	250	0%	0%	0%	0%	0%	0%	4%	27%	42%	26%	1%
351 - 400	216	0%	0%	0%	0%	0%	0%	1%	9%	46%	40%	4%

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Calibration Stability Agreement

The table below compares the percentage of sensor glucose values to the YSI reference at various time points after a calibration entry. As an example, in the table below, 88% of the Eversense values were within 15 mg/dL (for reference readings of 80 mg/dL or less), and within 15% (for reference readings over 80 mg/dL) of the reference value 8 to 10 hours after a calibration entry.

Table 16 – Eversense Calibration Stability Agreement

Time from Calibration	Number of Paired CGM-YSI	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	> 40/40% of Reference
0 - 2 Hours	4,034	86.0%	93.6%	98.0%	99.3%	0.7%
2 - 4 Hours	3,979	85.6%	92.8%	98.4%	99.5%	0.5%
4 - 6 Hours	2,308	84.3%	92.2%	97.7%	99.0%	1.0%
6 - 8 Hours	1,614	84.3%	92.7%	97.8%	99.4%	0.6%
8 - 10 Hours	1,372	88.0%	94.4%	98.5%	99.6%	0.4%
10 - 12 Hours	1,295	86.1%	92.9%	98.1%	99.2%	0.8%

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PARD (Paired Absolute Relative Difference) and Percent Coefficient of Variation

In the PRECISION Study, 27 participants had two sensors inserted. The table below shows the precision of the sensor's performance by comparing readings between the two sensors worn by each participant. As an example, the absolute relative difference between the sensors worn by each person is 9.9%, and the percent coefficient of variation is 7.0%, showing the sensor values generally in agreement throughout the 90 day study period.

PARD	9.9%
PCV	7.0%

Sensor Life

Sensor life measured the percentage of sensors being able to function through the intended 90 day durations of each study. In the PRECISE II study, nine sensors did not function through the 90 day period. Function stopped at days 10, 30, 53, 67, 70, 80, 81, 83, and 85. The sensor failure on day 10 was due to a software anomaly that has since been resolved. Overall, the analysis estimated that 91% of sensors remained functioning through 90 days. In the PRECISION study, all sensors functioned through 90 days.

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Percentage of sensors that lasted 30, 60, and 90 days

Table 16A PRECISE II

Days	Sensor Life
30	99%
60	97%
90	91%

Table 16B PRECISION

Days	Sensor Life
30	100%
60	100%
90	100%

Table 16C PRECISE II

Mean # of Days	Median # of days
88	91

Table 16D PRECISION

Mean # of Days	Median # of days
92	91

Data Availability

A total of 97% (821,296 out of expected 842,814) glucose values were available during the 90 day study.

Table 17 – Eversense Data Availability

	Days 1 - 30	Days 31 - 60	Days 61 - 90	All Days
Number of Displayed Glucose Values	279,674	274,727	266,895	821,296
Expected Number of Glucose Values	285,579	280,478	276,757	842,814
% of Displayed Glucose Values	98%	98%	96%	97%

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Safety

Both the PRECISE II and PRECISION studies lasted 90 days, and the number of related adverse events was recorded. The Eversense CGM System was well tolerated in the studies. During the studies' 15,921 sensor wear days, there were no unanticipated adverse events. Twenty-two adverse events were reported in 12 participants, including one serious adverse event related to the removal procedure. There were no infections. Mild irritation, pain and redness at the insertion sensor site were observed at a low rate of occurrence. None of the adverse events resulted in hospitalization.

Table 18 – Adverse Events

Event Type	Number of Events	Patients (n = 125)
Pain/Discomfort	6	5 (4.0%)
Redness/Erythema	2	1 (0.8%)
Dermatitis at Patch Location	2	1 (0.8%)
Bruising	2	1 (0.8%)
Skin Hyperpigmentation	2	1 (0.8%)
Paresthesia	1	1 (0.8%)
Syncope-vasovagal	1	1 (0.8%)
Pain	1	1 (0.8%)
Device Fragment Not Recovered	2	2 (1.6%)
Additional Procedure to Remove Sensor Following First Attempt	3	2 (1.6%)
TOTAL	22	12 (9.6%)

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12. Technical Specifications

Sensor	Description
Length	18.3 mm
Diameter	3.5 mm
Materials	Homopolymer polymethylmethacrylate (PMMA), Hydroxyethylmethacrylate (HEMA) based Hydrogel, Platinum, Silicone, Dexamethasone Acetate, epoxy 301-2
Storage Temp	Between 36° F (2° C) and 46° F (8° C)
Sterilization	Sterile by Ethylene Oxide

Blunt Dissector	Description
Materials	Acrylonitrile butadiene styrene (ABS), Stainless Steel
Storage Temp	Between 50° F (10° C) and 86° F (30° C)
Sterilization	Sterile by Ethylene Oxide

Insertion Tool	Description
Materials	Acrylonitrile butadiene styrene (ABS) and Polytetrafluoroethylene (PTFE); Cyanoacrylate adhesive and Stainless Steel
Storage Temp	Between 50° F (10° C) and 86° F (30° C)
Sterilization	Sterile by Ethylene Oxide

Sensor Holder	Description
Materials	Acrylonitrile butadiene styrene (ABS) and Polytetrafluoroethylene (PTFE)

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

USB Cable* for Charging and Downloading	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.

System component	Part Number
Eversense Smart Transmitter Kit	FG-3300-01-001
Charging Cable	FG-6100-00-301
Charging Adapter	FG-6201-91-301
Charging Cradle	FG-6600-00-301
Eversense Adhesive Patches, White, 30 Pack	FG-6402-01-300
Eversense Adhesive Patches, Clear, 30 Pack	FG-6401-01-300
Eversense Quick Reference Guide	LBL-1603-01-001
Eversense CGM User Guide	LBL-1602-01-001
Eversense Data Management Software Application	FG-5700-01-300
Eversense Mobile Application iOS	FG-5500-01-300
Eversense Mobile Application Android	FG-5600-01-300
Eversense Sensor Kit	FG-4200-00-301
Eversense Insertion Tools Kit	FG-8211-01-201

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Symbols on Packaging and Device

Symbol	Explanation
	Consult accompanying documents
	Caution, consult accompanying documents
	Use by
	Manufacturer
EC REP	Authorized representative in the European Community
	Date of manufacture
	Storage temperature limits

Symbol	Explanation
LOT	Lot number
CE 0086	Marking certifies that the device meets the European Council Directive 90/385/EEC
REF	Part number
SN	Serial number
	Type BF Applied Part
	Non-ionizing electromagnetic radiation
LATEX	Not made with natural rubber latex

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Symbol	Explanation
	Universal Serial Bus (USB)
FCC ID	FCC ID is assigned to all devices subject to certification
MR	Magnetic Resonance Imaging (MRI) procedures are contraindicated for this device.
	European Union WEEE Directive 2012/19/EU
2	Single use only
2 STERILIZE	Do not re-sterilize

Symbol	Explanation
	Do not use if package is damaged
STERILE EO	Sterilized using Ethylene Oxide
NON STERILE	Non-sterile
Rx only	U.S. (Federal) law restricts the sale of the Eversense CGM System to sale by or on the order of a physician

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File name: LBL-1614-01-201 Rev B_Insertion Tools Kit PI_EN_R1	
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Project Manager: Erin Moody	**Art Director:** Ivy Tsang

Dimensions	
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