Sensor

Smart Transmitter

Mobile App

eversense™

User Guide

A guide for using the Eversense
Continuous Glucose Monitoring System

Continuous Glucose Monitoring System

Eversense Trademark

Contents

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 every 12 hours.

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 (in the Eversense App) When enabled, smart transmitter will stop providing vibratory and visual notification for non-critical alerts. Critical alerts will still be provided. Many mobile devices have a separate Do Not Disturb Mode. Consult the manufacturer's instructions for more information.

Electromagnetic Interference 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). Outside the US, call your local distributor or visit www.eversensediabetes.com to locate your local distributor.

Eversense CGM System Components

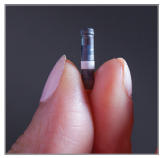
The System includes 1) a small sensor inserted subcutaneously by a physician, 2) a removable smart transmitter worn over the sensor, and 3) a mobile app to display the glucose readings.

Eversense Sensor

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

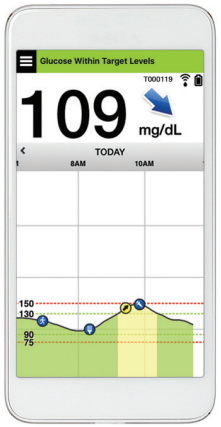
Eversense Smart Transmitter

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.



Sensor

Smart Transmitter



Mobile App

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

Eversense App

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

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

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

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 or during showering/bathing or any other water related activity. The smart transmitter is not water resistant.
- ✓ Make sure your smart transmitter has enough battery power at all times.
- ✓ Perform two blood glucose meter calibration tests each day when prompted.
- ✓ Pay attention to alerts and notifications you receive from your smart transmitter and mobile device.
- ✓ Replace the adhesive patch on your smart transmitter daily.

- ✓ You can remove the smart transmitter from the upper arm at any time, except during calibration. Remember that no data are collected when the smart transmitter is not communicating with the sensor. When you place the smart transmitter back on the sensor site, it will take 10 minutes for sensor communication to re-start and for glucose readings to appear in the app.
- ✓ When the smart transmitter and mobile device are not within range of each other, any data gathered by the smart transmitter is stored and sent to the app when the mobile device and smart transmitter are back within range.
- ✓ It is safe for you to wear your sensor and smart transmitter when you go through metal detectors at airports. While flying, the smart transmitter performs similar to any other Bluetooth device. Be sure to follow the specific safety guidelines mandated by the airline.

Some of the features of the Eversense CGM System:

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

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 and accuracy for the user and are not approved for use by Senseonics.

Indications for Use

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

The system is intended to:

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

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.

Therapeutics products such as mannitol intravenous and irrigation solutions may increase blood mannitol concentrations and cause falsely elevated readings of your sensor glucose results.

What is Included in this Package

This Eversense Smart Transmitter Pack contains the following:

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

Eversense Smart Transmitter

Power Supply (USB cable and AC power adapter)

How to Use this User Guide

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

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

2. Benefits and Risks

2

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 safety and effectiveness of the CGM System has not been established for the following:

- Children or adolescents (younger than 18 years of age).
- Women who are pregnant.

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.

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

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

- **If at any time you have symptoms of a low or high blood glucose level OR if your symptoms are not consistent with the sensor glucose readings, you should test your glucose with a blood glucose meter.**
- **Always test your glucose with your blood glucose meter before making a treatment decision.**
- **If your smart transmitter is damaged or cracked, DO NOT use, as this could create an electrical safety hazard or malfunction, and could result in electrical shock.**
- **Close contact with direct EMI may interfere with the smart transmitter's ability to send data to your mobile device. Move away from the source of EMI and check that your mobile device is connected to your smart transmitter.**
- **High doses of aspirin (over 2000 mg), such as for chronic treatment of inflammatory conditions (e.g., rheumatoid arthritis), may falsely lower Sensor glucose readings.**
- **Until it has healed, always cover the insertion site with a sterile bandage before placing the smart transmitter adhesive over the sensor. Failure to do so could result in infection at the insertion site.**

Warnings (continued)

- Please review this User Guide with your health care provider. For additional Eversense product questions and troubleshooting issues, contact Customer Support toll free in the US at 844-SENSE4U (844-736-7348). Outside the US, call your local distributor or visit www.eversensediabetes.com to locate your local distributor.
- Always calibrate the system using only a fingerstick blood sample. DO NOT use an alternative site (such as forearm or palm) blood glucose reading to calibrate the system.
- DO NOT insert your infusion set within 10.16 cm (4 in) of the sensor site. If the insulin delivery site is within 10.16 cm (4 in) of the sensor site, it may interfere with sensor glucose readings and can cause inaccurate glucose readings.

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

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

Precautions

- DO NOT exchange smart transmitters with another person. Each smart transmitter can be linked to only one sensor at a time.
- The following medical therapies or procedures may cause permanent damage to the sensor particularly if used in close proximity to the device:
  - **Lithotripsy –** The use of lithotripsy is not recommended for people who have an inserted sensor because the effects are unknown.
  - **Diathermy –** DO NOT use diathermy on people who have an inserted sensor. Energy from the diathermy can transfer through the sensor and cause tissue damage in the insertion area.
  - **Electrocautery –** The use of electrocautery near the inserted sensor may damage the device. DO NOT use electrocautery near the sensor.
- 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.

Precautions (continued)

- 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 immerse the smart transmitter in water or use the smart transmitter for any activity where it might be submerged in water. Immersing the smart transmitter in water may result in electrical shock. Always remove the smart transmitter before bathing or swimming.
- DO NOT switch back and forth between smart transmitters. Frequently pairing different smart transmitters with the sensor may result in inaccurate glucose measurements.
- Remove the smart transmitter from your arm before charging the smart transmitter battery. Failure to remove the smart transmitter while it is charging could result in electrical shock.
- DO NOT attempt to use the Eversense App while operating a motor vehicle.
- You should not receive massage therapy near the inserted sensor site. Massage therapy near the sensor site could cause discomfort or skin irritation.
- Use only the AC power adapter and USB cable provided with the smart transmitter when charging the smart transmitter battery. Use of another power supply could damage the smart transmitter, not allowing blood 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 24 hours of use.
- 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.

3. Getting Started

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.

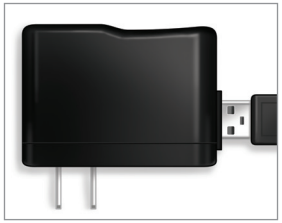
After you receive your smart transmitter it must be fully charged before pairing with the app.

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.

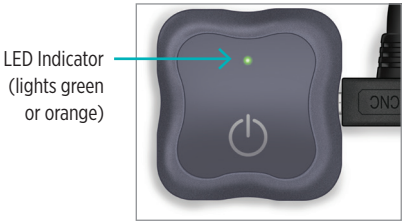
Precaution: Use only the AC power adapter and USB cable provided with the smart transmitter when charging the smart transmitter battery. Use of another power supply could damage the smart transmitter, not allowing glucose readings to be received properly, and could result in voiding your warranty.

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



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

3. **Plug the adapter into an AC power outlet.**
   - Once fully charged, a small green LED light appears on the top front of the smart transmitter (above the power button).
   - Disconnect the power supply from the smart transmitter after it is fully charged.



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.**

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

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.

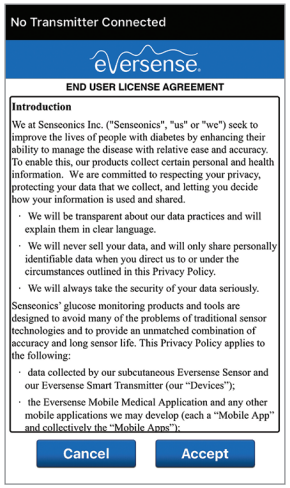
3. **On the install screen, tap Install application and follow the installation instructions.**

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

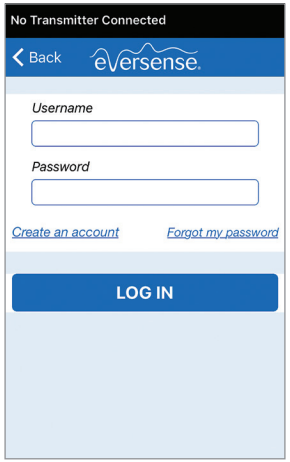
Step 2. Set up the App – Account Creation, Pairing and Settings

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.

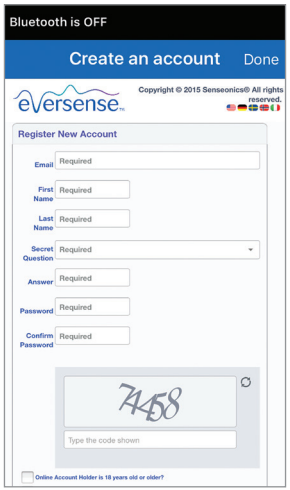


2. **After you accept the Agreement, you will be prompted to create and register an account with a Username and Password.**
   - You must register an account before you are able to log in. Tap **Create an Account**.



Note: If you forget your password, you can reset it via the app. If you forget your username, contact Customer Support.

3. **Enter your account information and then tap Register. The email address you enter will be your username for Login.**



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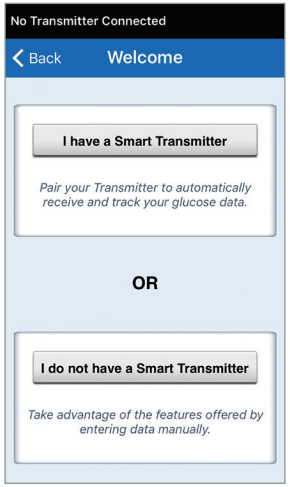
To complete registration check the email address you provided and click the link in the email.

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

4. Enter the email address you registered as your username and your password and tap LOG IN. You will see a confirmation screen. Tap OK.

Note: The password is case sensitive.

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



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

I have a Smart Transmitter

(skip to step 7).

I do not have a Smart Transmitter

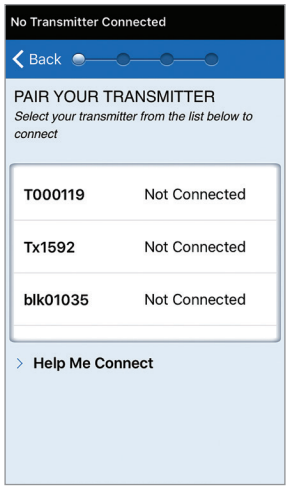
(skip to step 12).

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

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

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

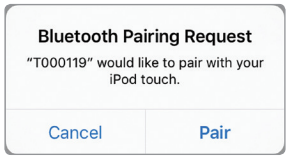
Tap **Not Connected** to begin pairing process.



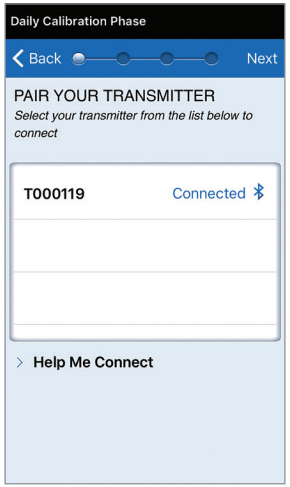
9. **A BLUETOOTH PAIRING REQUEST pop-up screen appears.**

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

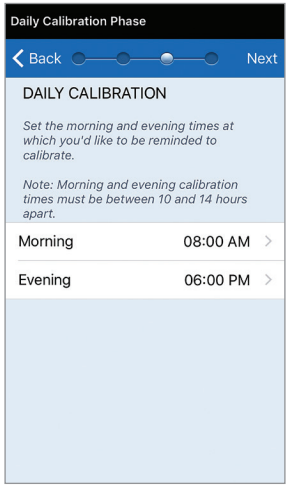
Note: The smart transmitter can only be paired with one mobile device at a time.



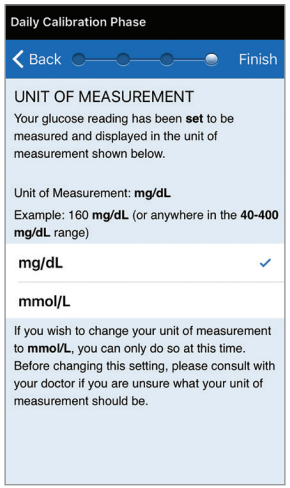
10. "Connected" appears next to the smart transmitter ID once the pairing is complete. The smart transmitter will provide intermittent vibrations until the smart transmitter is linked with the inserted sensor (see *Inserting and Linking the Sensor*).
    - Tap **Next**.



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

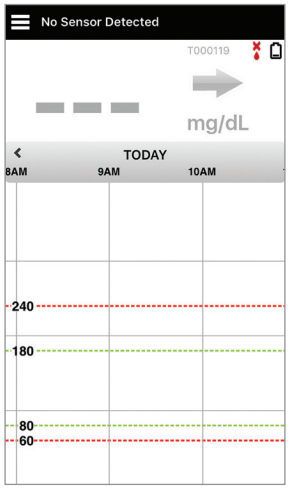


12. The **UNIT OF MEASUREMENT** screen appears and indicates the standard unit of measurement for your region. Your glucose readings will always be displayed in this unit of measurement.



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.

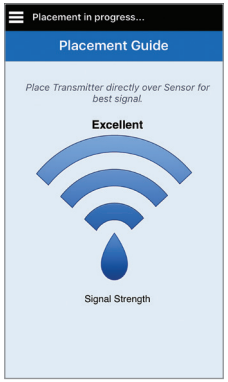
Once the sensor is inserted by your physician and the 24-hour Warm-Up Phase is completed, you can begin calibration. If you have not yet had your sensor inserted, you can review this User Guide to become familiar with the app and its features.

4. Inserting and Linking the Sensor

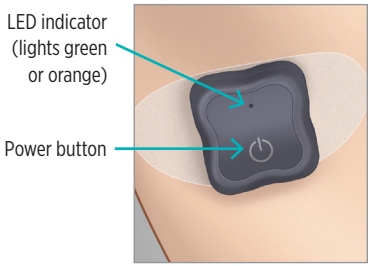
This section describes how to link the sensor and smart transmitter after your physician has inserted the sensor. Only your physician can insert the sensor. See "About the Sensor" to learn more.

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.

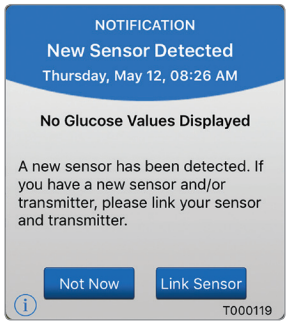
1. **Make sure your smart transmitter is turned ON (see "Using the Smart Transmitter") and that your mobile device has access to the internet.**
   - Position the smart transmitter directly over the inserted sensor until the **Placement Guide** in the app shows some connection. The Placement Guide page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



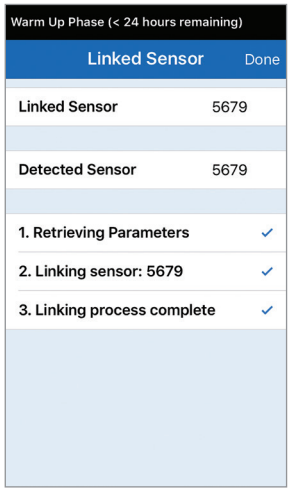
Note: The connection between the sensor and the smart transmitter is sensitive to the orientation of the transmitter. If the smart transmitter is directly over the sensor and the Placement Guide indicates there is no connection, try rotating the smart transmitter slightly to the left or right so the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



2. **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 Sensor.**



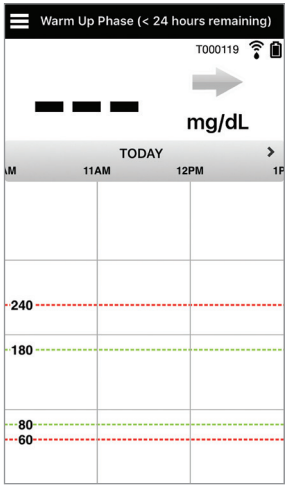
3. When the smart transmitter and sensor are successfully linked, the **LINKED SENSOR** screen appears and displays the sensor ID number.



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.

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, and you are wearing the smart transmitter, the system will prompt you to calibrate using the app.

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



5. Using the Smart Transmitter

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

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

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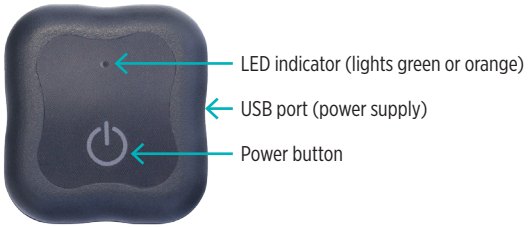
Your Eversense Smart Transmitter does the following:

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



Daily Use

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

- ✓ Wear your smart transmitter at all times except when charging or during showering/bathing or any other water related activity. The smart transmitter is not water resistant.
- ✓ 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:

- **Your smart transmitter is not water resistant. DO NOT wear it during any water-related activities. DO NOT submerge in water.**
- **Always remove the smart transmitter from your body before charging the battery.**

Secure the Smart Transmitter over Inserted Sensor

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

Note: You will receive adhesive patches from your physician.

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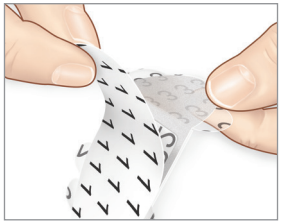
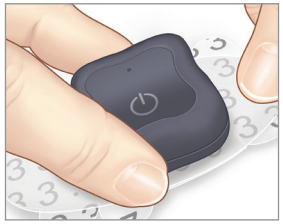
Precaution: If you have any concerns about allergic reaction to silicones, contact your physician prior to use. DO NOT reuse the adhesive patch. Discard the patch after 24 hours of use.

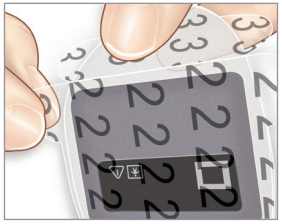
1. **Hold the tabbed side of the patch and remove the backing labeled "1". Try not to touch the sticky portion of the adhesive.**



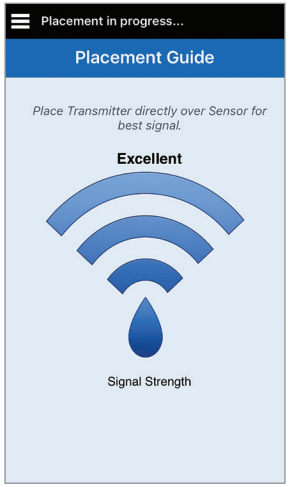
2. **Align the smart transmitter over the sticky side (center) of patch and press firmly to secure.**
   - The smart transmitter should be placed so that its sides face the wings of the patch (as shown).



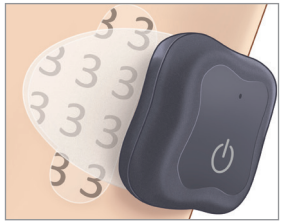
3. **Remove the backing labeled "2" and position the smart transmitter directly over the sensor.**
   - For the maximum signal strength, the smart transmitter must be placed directly over the sensor. Signal strength can also be improved by rotating the smart transmitter over the sensor such that the sensor aligns with the smart transmitter.



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



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



6. **Remove the two remaining clear liner tabs labeled "3" by pulling on the tabs.**
   - Smooth the adhesive onto the skin. Make sure the patch is flat on the skin surface.

Turn the Smart Transmitter ON and OFF

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

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

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

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

Smart Transmitter Care and Maintenance

- Keep the smart transmitter clean (free of visible dirt) and protected when not in use. Wipe the outside with a cloth between uses to keep clean.
- DO NOT spill fluid on the smart transmitter or submerge it in any liquid.
- 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, NOT WET, cloth; dispose of the cloth according to your local regulations.
- Dispose of the smart transmitter 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 is charged. The LED will blink orange once if the battery is low. See the next page for more information on the LED indicators.

LED Status Indicators

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

- **During smart transmitter use:**

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

- **During smart transmitter charging:**

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

6. Calibrating the System

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

Warning: DO NOT use alternative test sites such as your forearm 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 Warm-Up Phase, you must complete 4 fingerstick calibration tests, spaced 2 to 12 hours apart.
Daily Calibration Phase – After the Initialization Phase, you must complete 2 fingerstick calibration tests per day, spaced 10 to 14 hours apart.

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

Tips for ensuring good calibration:

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

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

- ✗ Blood glucose meter reading is less than 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.

Calibration Phases

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

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

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

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

Re-Entering Initialization Phase

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

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

B. Daily Calibration Phase

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

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

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

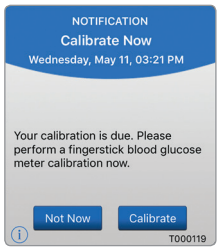
How To Calibrate

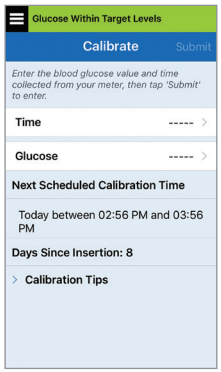
Warning: Always calibrate the system using only a fingerstick blood sample. DO NOT use an alternative site (such as forearm or palm) blood glucose reading to calibrate the system.

Notes

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

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





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