



eversense E3 CGM Glucose Monitoring System User Guide

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E3 CGM Glucose Monitoring System



To access additional reference materials, go to: www.eversenseddiabetes.com
Refer to the Eversense E3 CGM User Guide for more detailed information.

Indications for Use

The Eversense E3 CGM System is intended for continually measuring interstitial glucose levels in adults (18 years and older) with diabetes for up to 180 days. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions.

The system is intended to:

- Provide real-time glucose readings.
- Provide glucose trend information.
- Provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia).
- 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 intended for single patient use.

Contraindications

- The system is contraindicated in people for whom dexamethasone or dexamethasone acetate may be contraindicated.
- The smart transmitter is incompatible with magnetic resonance imaging (MRI) procedures. The smart transmitter is MR Unsafe and **MUST BE REMOVED** before undergoing an MRI (magnetic resonance imaging) procedure. The sensor is MR Conditional. For more information on the sensor, see MRI Safety Information in the Eversense E3 CGM System User Guide.
- 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.

Eversense E3 Smart Transmitter

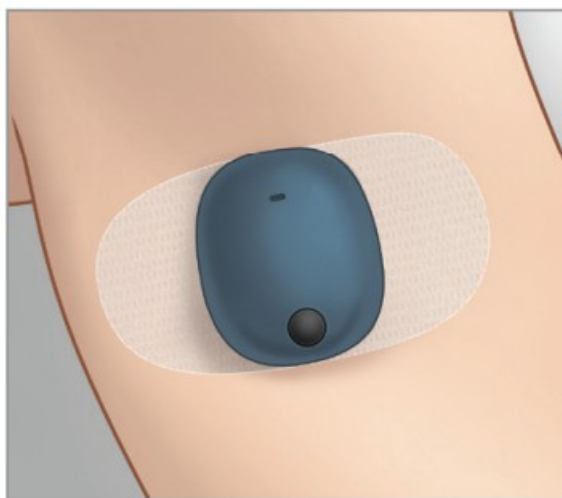
Your rechargeable smart transmitter powers the sensor, calculates glucose readings, and stores and sends data to the app. It also provides on-body vibe alerts. The smart transmitter is secured to your skin with a disposable adhesive patch that is changed daily.



Wearing the Smart Transmitter

- Replace the adhesive patch on your smart transmitter daily.
- The smart transmitter can be removed and reapplied to the skin at any time.

Note: Your smart transmitter is water resistant (IP67) to a depth of 1 meter (3.2 feet) for up to 30 minutes.



Turn the Smart Transmitter ON and OFF

To turn the smart transmitter ON, press and hold the power button for about five seconds.

To turn the smart transmitter OFF, press and hold the power button for about five seconds.

To see if your smart transmitter is ON, press the power button once. If the LED appears, the smart transmitter is ON. If no LED appears, the smart transmitter is OFF.

Getting Started Steps

Charging the Smart Transmitter

Before you begin, you need:

- A compatible mobile device.
 - For a list of compatible devices, visit www.eversenseddiabetes.com/compatibility.

- Wireless internet connection.
- Fully charged Eversense E3 Smart Transmitter.

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 USB port.

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

Once fully charged (about 15 minutes), a small green light appears on the top side of the smart transmitter. Remove the USB cable from the charging cradle after it is fully charged by pulling back on the tab on the cradle, and lifting the smart transmitter out.



IMPORTANT: Use only the AC power adapter and USB cable provided with the smart transmitter when charging the smart transmitter battery, and never stick any object other than the charging cable into the USB port of the transmitter. Use of another power supply could damage the smart transmitter, not allowing glucose readings to be received properly, create the risk of fire, and could result in voiding your warranty. If your Eversense power adapter or USB cable is damaged or lost, contact Customer Support for a replacement to ensure safe operation of the device.

Downloading the Eversense App and Pairing the Smart Transmitter

Download and Install the App

1. 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.

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

2. 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.



IMPORTANT: Make sure that you have a wireless internet connection, the date and time are correct on your mobile device, and that Bluetooth is turned ON before continuing.

Note: When prompted, review and tap Accept to agree to the terms of the License Agreement. A LOG IN screen appears.

Launch the App by Tapping the Eversense Icon

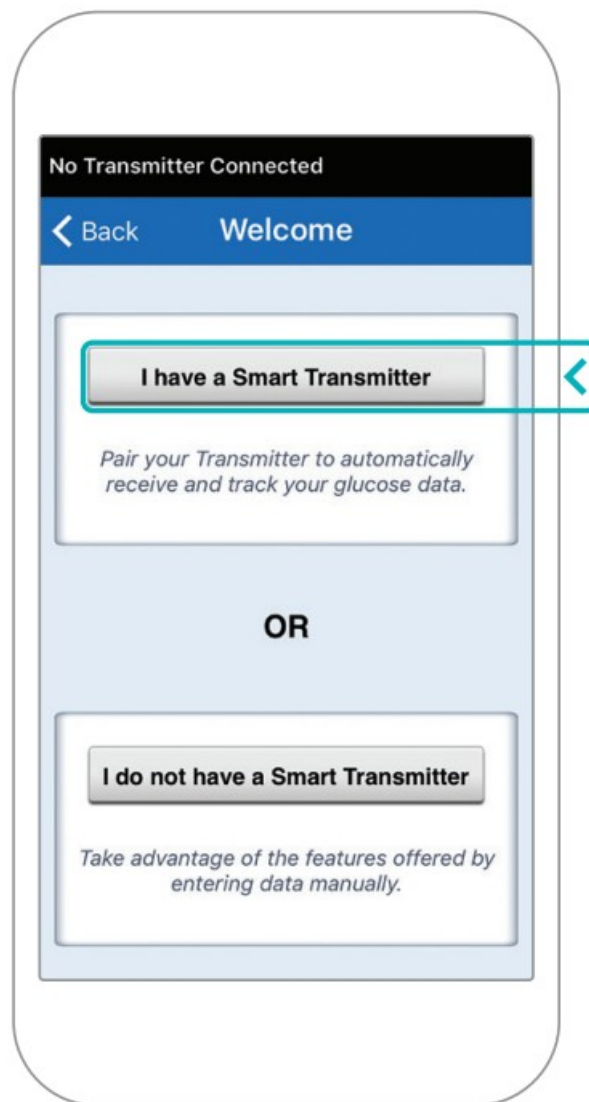
1. Create an account with an Email and Password.

The image shows a mobile app interface for Eversense. At the top, a black banner reads "No Transmitter Connected". Below this is a blue header bar with a back arrow and the text "< Back" on the left, and the "eversense." logo on the right. The main area has a light blue background. It contains two input fields: "Email" and "Password". Below these fields are two links: "Create an account" and "Forgot my password". A large blue button labeled "LOG IN" is centered below the links. At the bottom, there is a link labeled "Delete Account".

2. Enter your account information and tap Submit.

The image shows a mobile app interface for creating a new account. At the top, the browser address bar displays 'us.eversensedms.com'. The Eversense logo is centered at the top of the page. Below the logo, there is a language selector set to 'English'. The main heading is 'Create New Account', followed by a progress bar with three segments, the first of which is filled. The form contains the following fields: 'First Name *' with a placeholder 'First Name', 'Last Name *' with a placeholder 'Last Name', 'Email *' with a placeholder 'sample@email.com', 'Create a password *' with a placeholder 'Eg. abc@1A', and 'Confirm your password *' with a placeholder 'Eg. abc@1A'. A blue 'Next' button is positioned to the right of the password fields. At the bottom of the form, there is a link: 'Have account already? Please go to Sign In'. The footer contains the copyright notice: 'Copyright © 2020 Senseonics® All rights reserved.'

3. Indicate you have your smart transmitter by tapping that option.



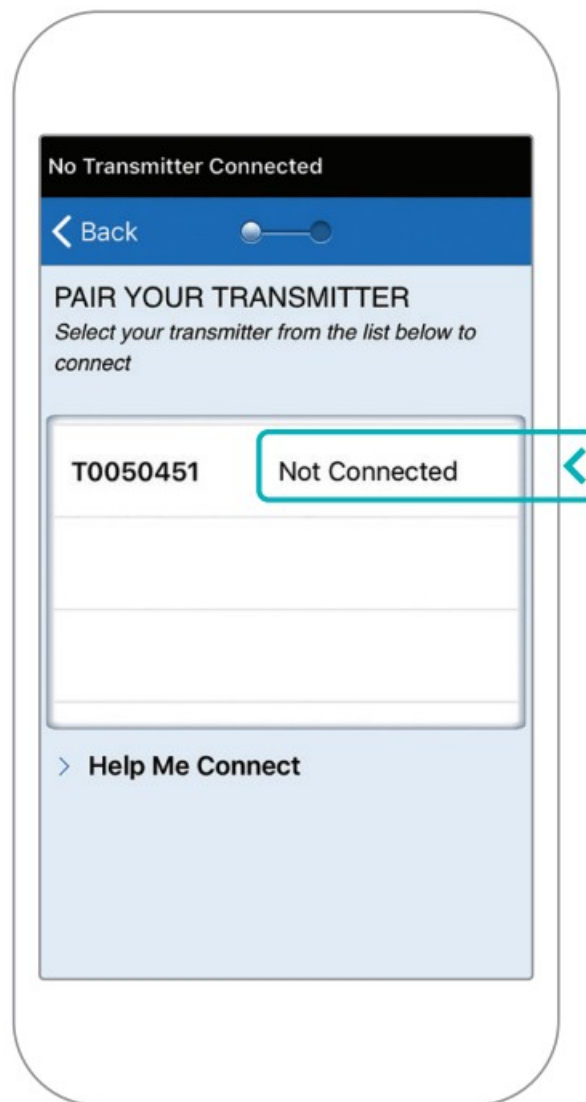
To complete registration check the email address you provided and click the link in the email.

Note: On Android operating systems you will be prompted to acknowledge and enable location or Bluetooth services in order to pair your smart transmitter with your mobile device and receive alerts from the Eversense E3 CGM system.

4. Turn your smart transmitter on and set it to “Discoverable Mode” by pressing the power button three times. The LED light will blink green and orange.

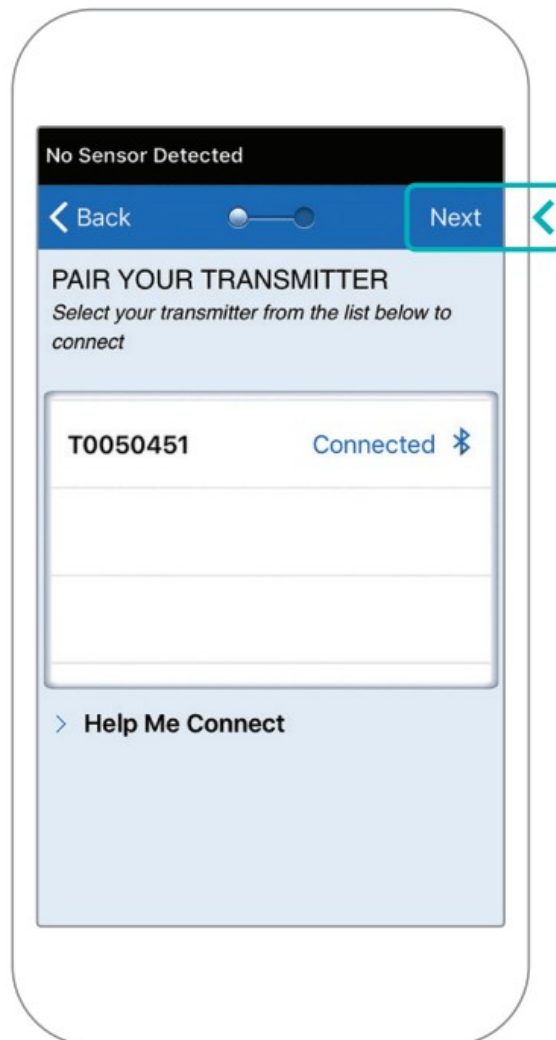
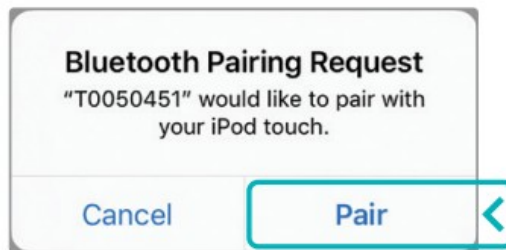


5. Tap Not Connected to begin the pairing **process**.

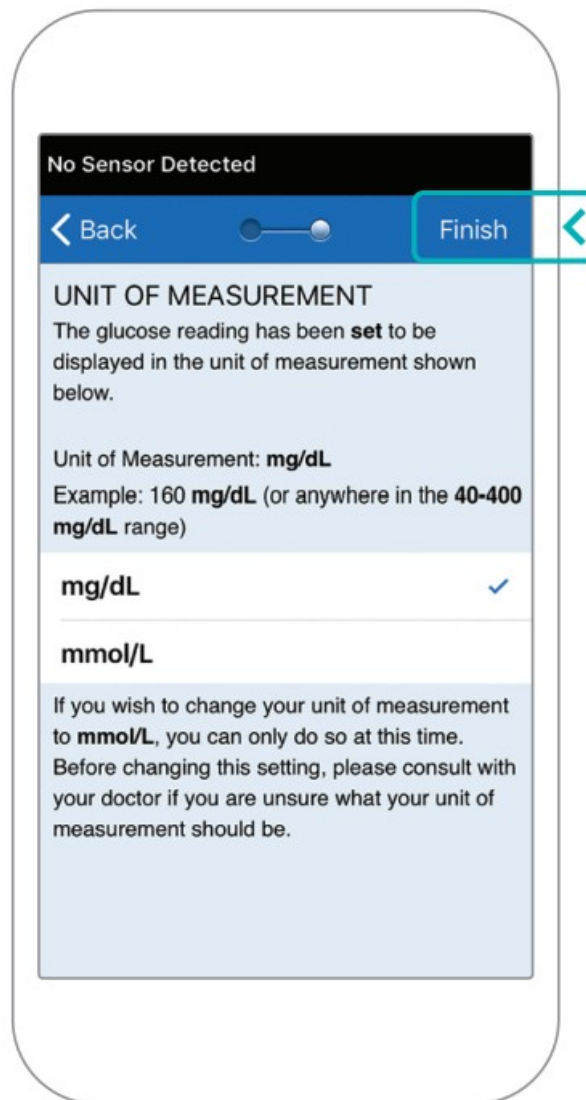


Note: If you do not see your smart transmitter as an option see the User Guide for more information.

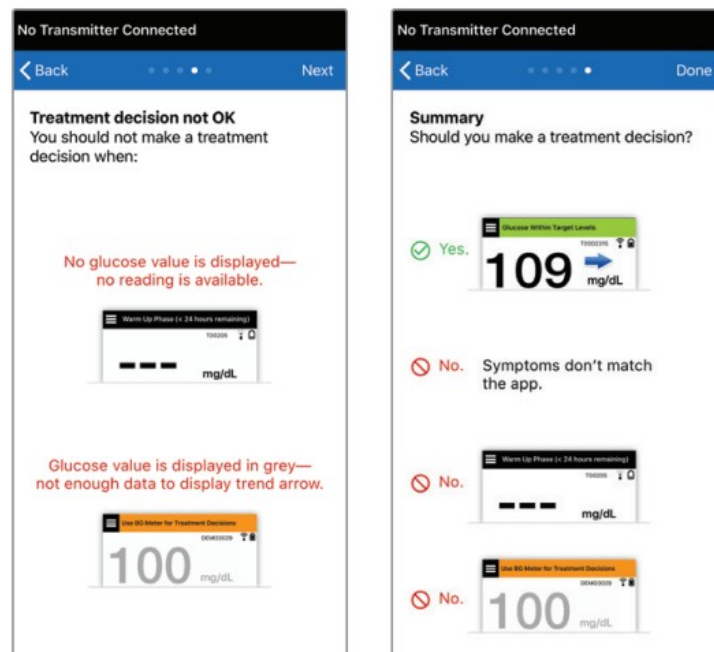
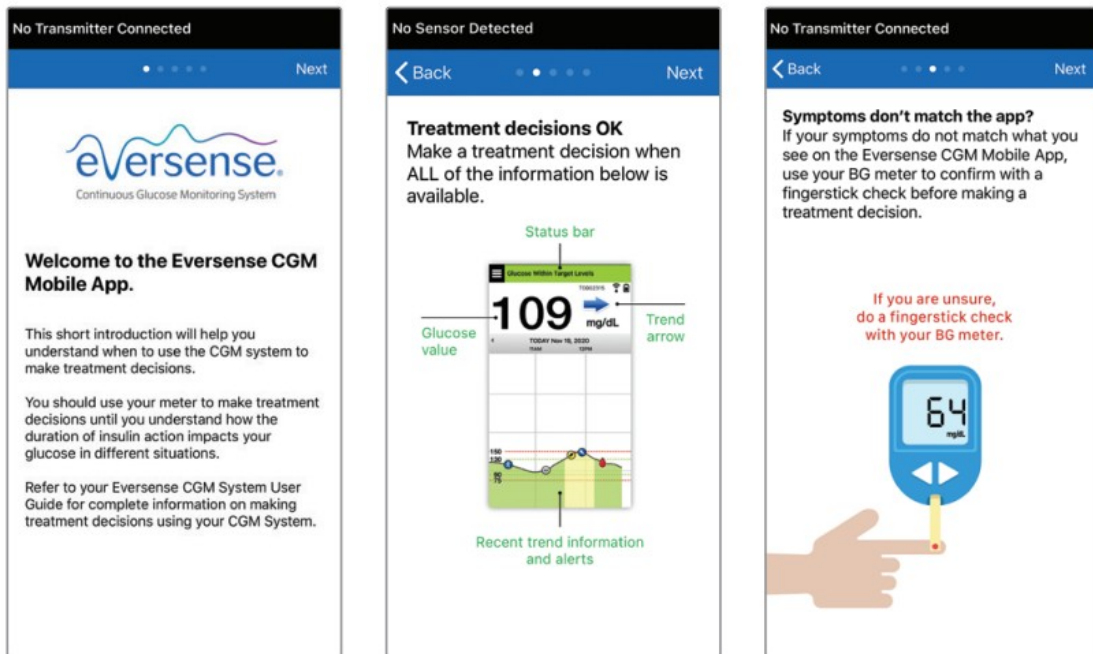
6. Tap Pair and then tap Next to continue when "Connected" appears.



7. The unit of measurement is used for calculating and displaying your glucose readings. DO NOT change the unit of measurement until you consult with your health care provider. Tap Finish to continue.



8. Tap through the introduction screens that provide information about when to make treatment decisions with the Eversense E3 CGM System.



9. Tap the MAIN MENU icon to get access to all app functions from a drop-down menu.

Note: This screen will not have any glucose data to display until your sensor has been inserted and you have started calibrating the system.



Linking the Sensor and Smart Transmitter

Once the sensor has been inserted by your health care provider and you have paired your transmitter and the app, your sensor needs to be linked to your smart transmitter. This will start the 24 hour Warm-Up Phase. There is no need to wear the smart transmitter during the Warm-Up Phase. To link the sensor, your mobile device must be connected to the internet and your transmitter must be charged, turned on, and paired with your mobile device. When you first link the sensor, with the Tegaderm™ bandage over the insertion site, the incision is likely in the center of the Tegaderm. This means the sensor is likely above the center of the Tegaderm. The first time you link the sensor, do not use an Eversense adhesive patch on the smart transmitter. When positioning the smart transmitter over the sensor, it should be slightly above the center of the Tegaderm patch.

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

For details on linking the sensor, please review Linking the Sensor in the Eversense E3 CGM System User Guide.

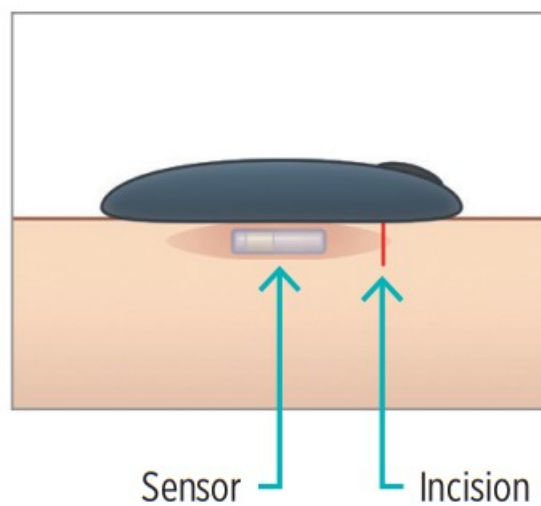
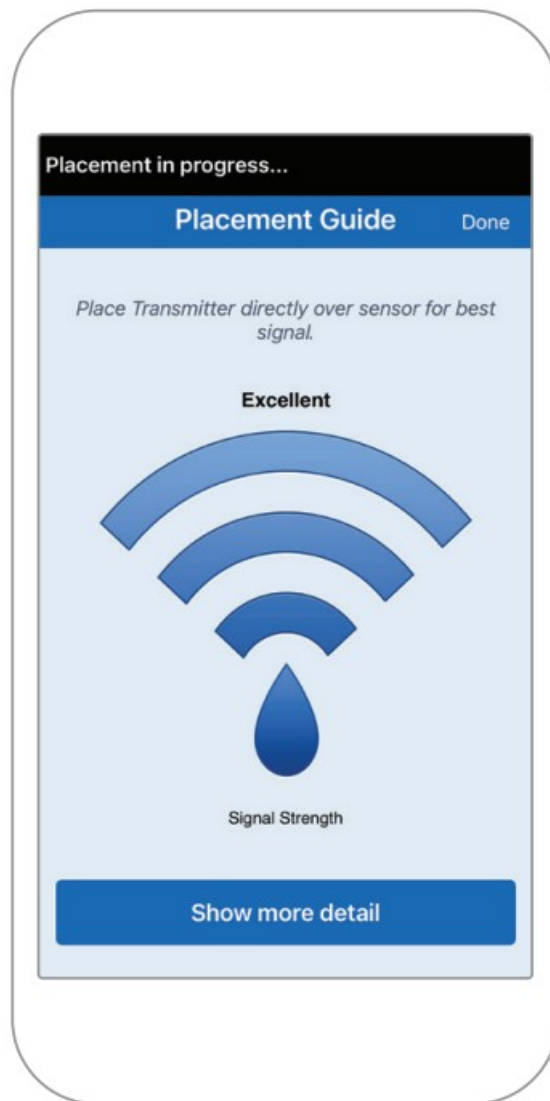
Place Smart Transmitter over Sensor

1. Position the smart transmitter directly over the inserted sensor until the smart transmitter stops vibrating and the New Sensor Detected message appears on the app.
 - Open the placement guide in the app.
 - Using any visible smart transmitter corner marks as a guide, gently place your smart transmitter toward the top half of the bandage.

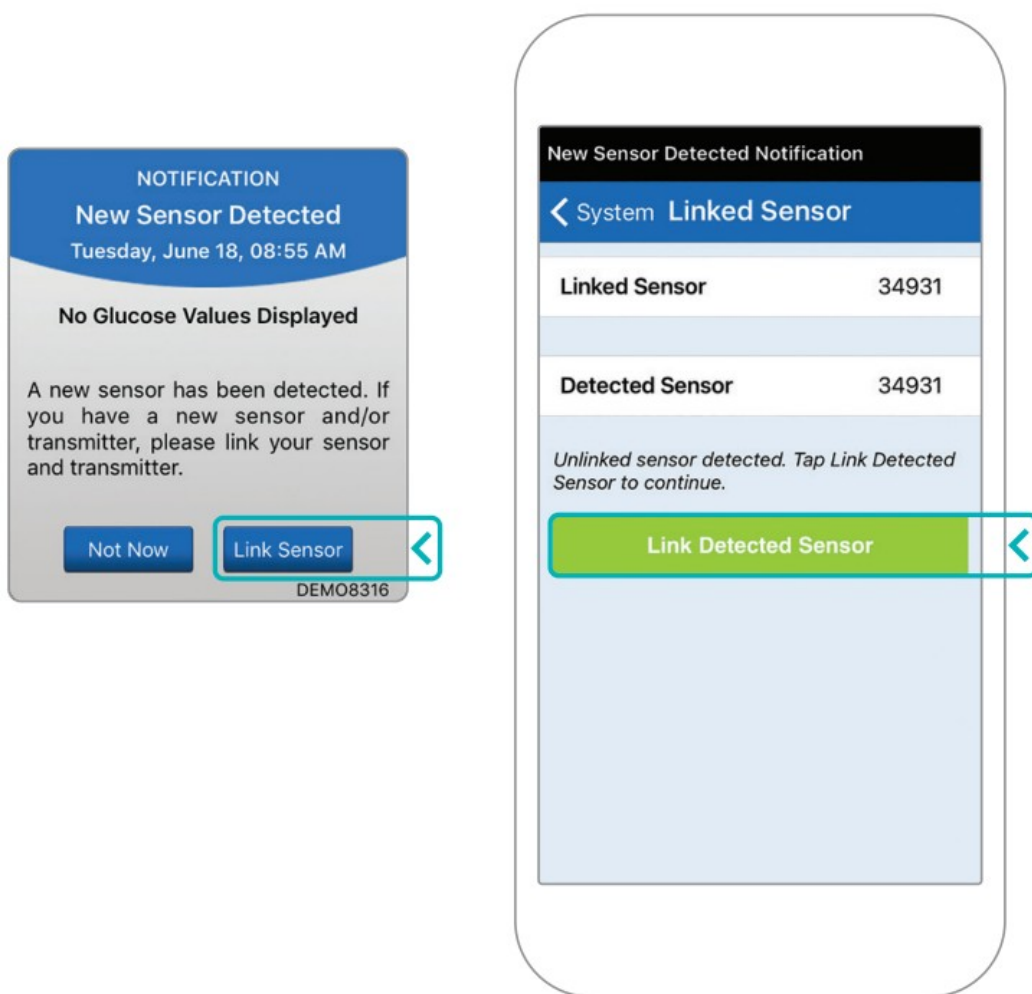
- Watch the placement guide for signal strength – this may take several seconds.
- To get the best signal, gently lift and move the smart transmitter as needed until the placement guide shows 2-3 bars (good to excellent).
- Close the placement guide.

Tip: It may be helpful to look in a mirror as you position your smart transmitter.

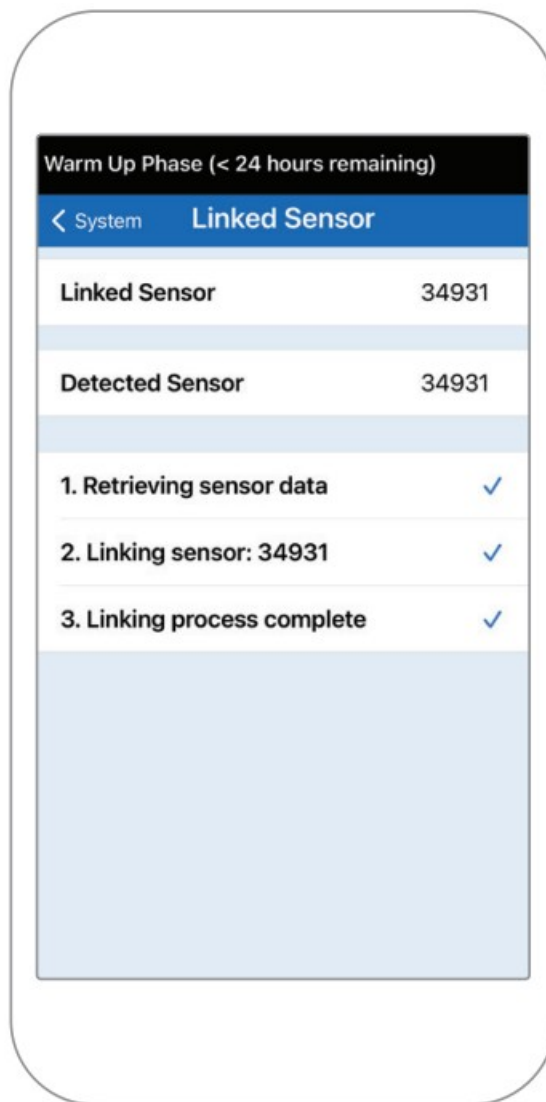




2. Tap Link Sensor and then Link Detected Sensor. DO NOT remove the smart transmitter from your insertion site until the third check mark is displayed.



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



Warm-Up Phase

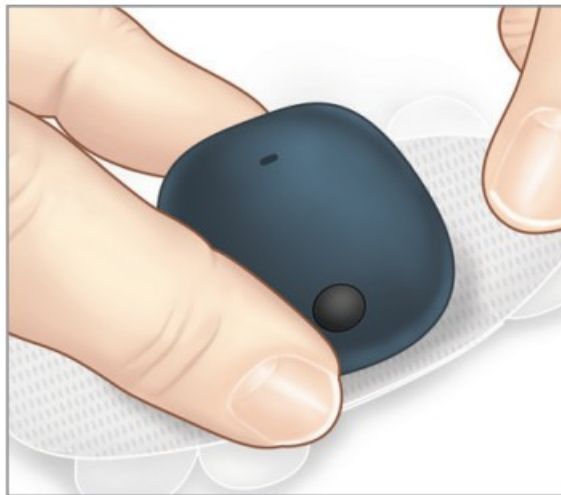
The 24 hour Warm Up Phase begins once you have linked your sensor. Turn off the smart transmitter and do not place it on your arm until the 24-hour Warm Up Phase is over. The sensor requires 24 hours to stabilize in your body before the smart transmitter will calculate glucose values. If you decide to 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. For more information, please review the section titled Calibrating the System in your Eversense E3 CGM System User Guide.

Daily Transmitter Wear and Calibrating the System

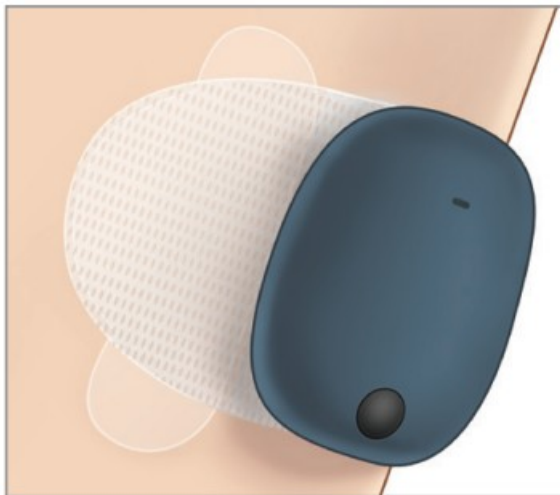
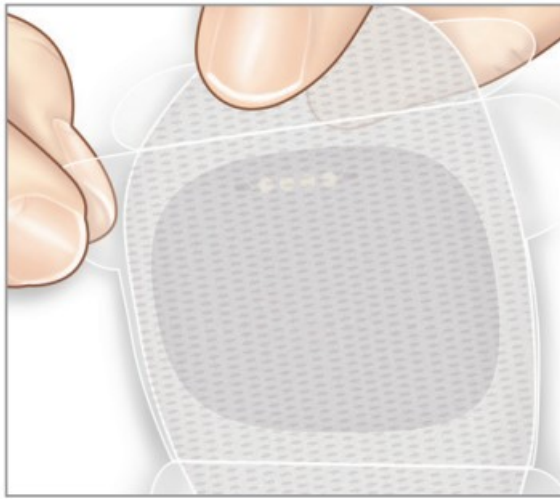
Once the Warm-Up Phase has ended, the Initialization Phase begins, and you're ready to start wearing the smart transmitter. For the first few days, you'll wear the smart transmitter over the Tegaderm™ bandage. Always start with a freshly charged smart transmitter.

Daily Transmitter Wear

1. Peel off the paper backing with the Eversense logo on it and place the smart transmitter in the center.



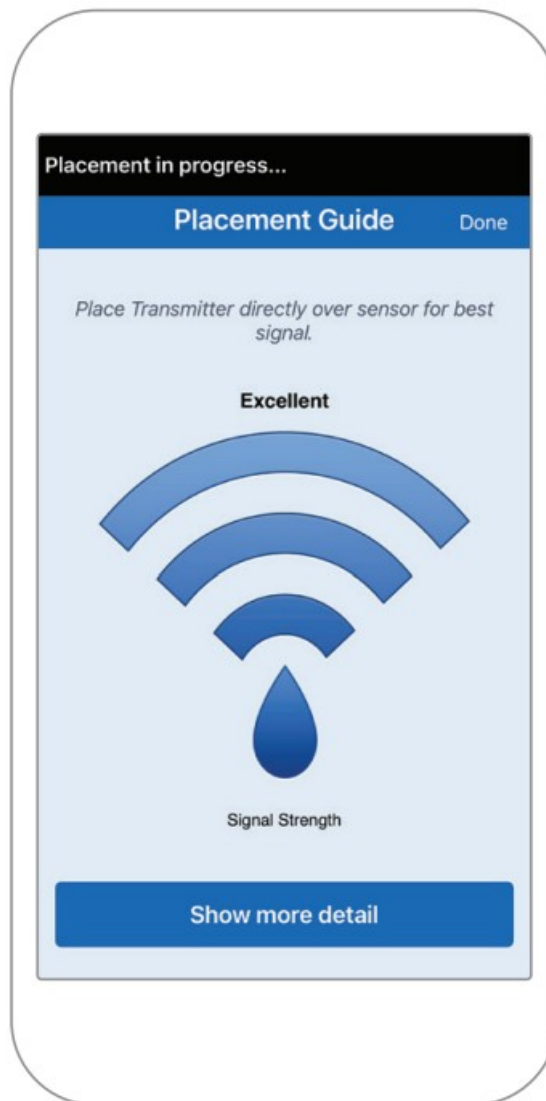
2. Remove the larger clear backing and position the smart transmitter directly over the sensor.



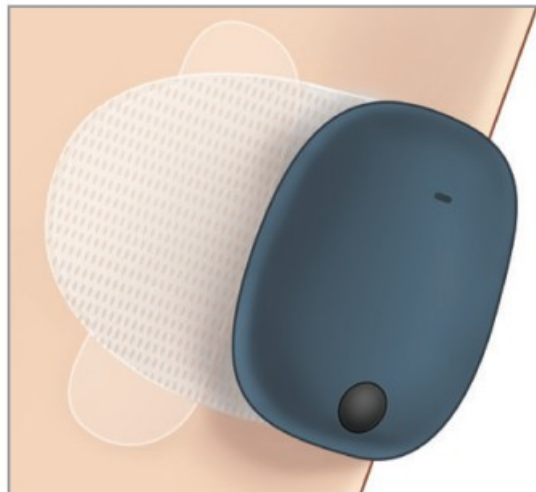
3. Check the connection between the smart transmitter and the sensor.

Select Placement Guide from the Main Menu drop-down to help you determine where to place your smart transmitter.

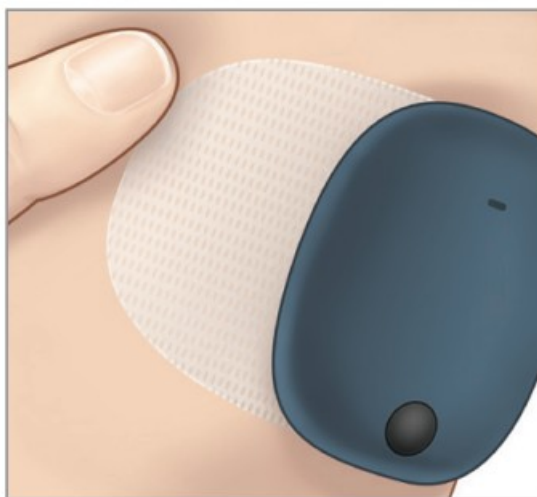
Slide the smart transmitter over the sensor insertion area until you get a good or strong signal on the app.



4. Press the adhesive patch firmly on skin surface over the sensor.



5. Use the tab to pull off the remaining clear liner.



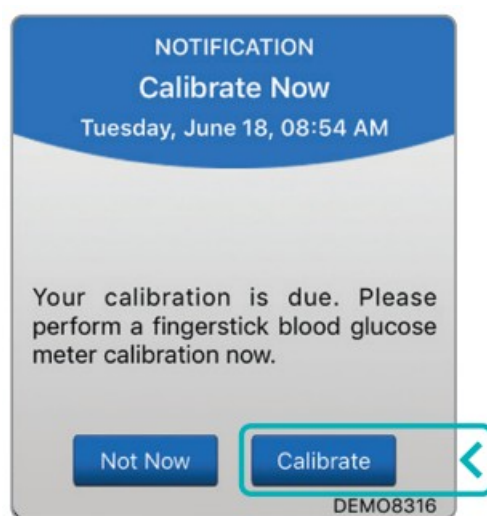
Note: For more information on using the Placement Guide, review Placement Guide – Show More Detail Screen in the Linking the Sensor section of the Eversense E3 CGM System User Guide.

Initialization Phase

About 10 minutes after Initialization Phase begins, the system will display the Calibrate Now Notification.

- Do a fingerstick blood glucose check.
 - ▶ Tap Calibrate on the notification and enter the glucose value into the app.
- You will receive three more calibration prompts during initialization, each 2 hours after the previously completed calibration. You can complete all 4 calibrations in as quickly as 6 hours. All 4 calibrations must be completed within 36 hours.

You can record the times below as a reference.



Calibration times for initialization

Warm-Up Phase ends: _____

1 _____ AM/PM

2 _____ AM/PM*

3 _____ AM/PM

4 _____ AM/PM

*Glucose data available after 2nd calibration

Calibration Tips:

- Wash and dry hands thoroughly.
- Avoid calibrating when glucose may be changing rapidly (such as after meals, after taking insulin, or during/after exercise).

- Always use an actual blood glucose value, and enter calibration within 10 minutes.
- Keep smart transmitter in place over the sensor 5 minutes before and 15 minutes after each calibration.

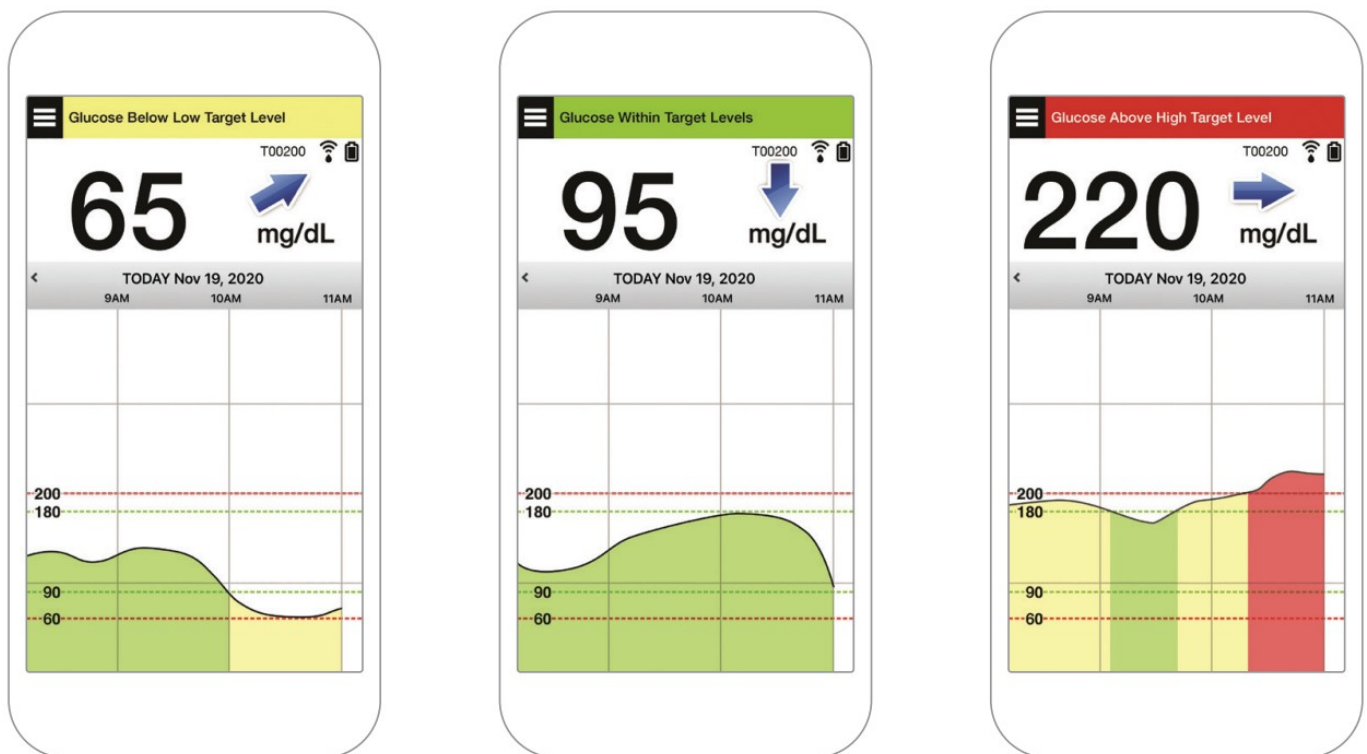
Daily Use

Once the Initialization Phase has passed, the system requires two calibrations each day for the first 21 days. After 21 days, the system will prompt you for calibration either once or twice per day. Please see Calibrating the System in the Eversense E3 CGM System User Guide for more information.

Making Treatment Decisions with Eversense E3

To make a treatment decision, you should consider:

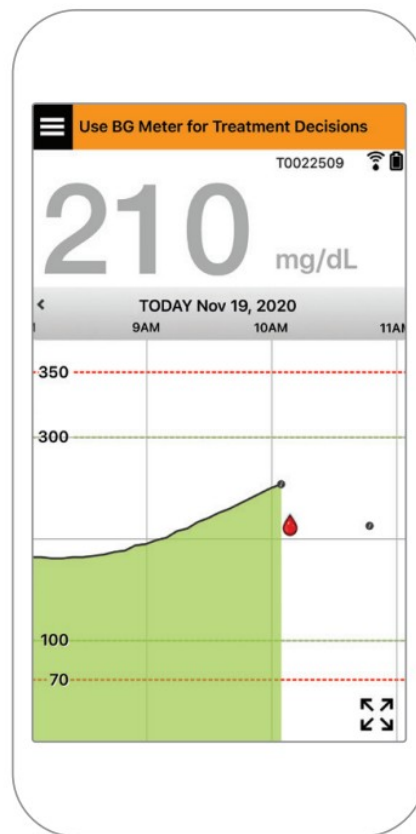
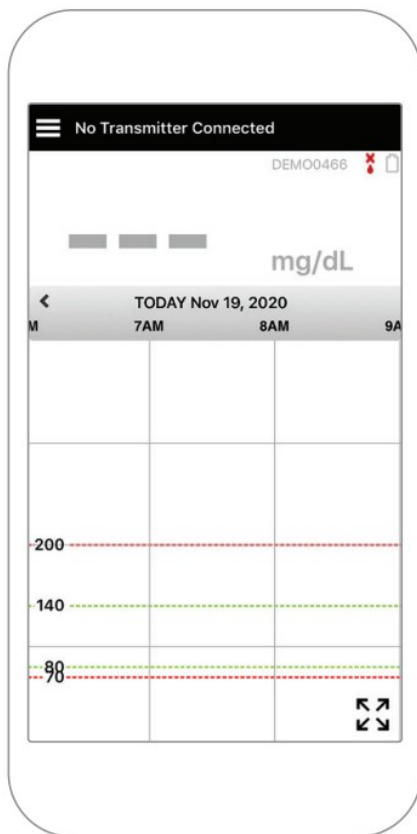
- Status bar information
- Current sensor glucose value – the current glucose value should be displayed in black
- Trend arrow – a trend arrow should be displayed
- Recent trend information and alerts



When to NOT make a treatment decision:

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

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



Use all available CGM information




When to use your blood glucose meter

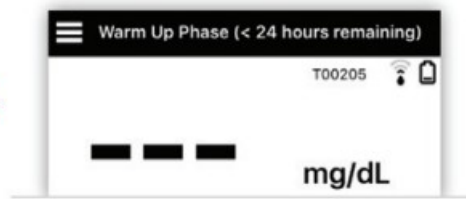
Do not make a treatment decision from your Eversense E3 CGM System if:

- Your symptoms do not match your sensor glucose value.
- No glucose data or trend arrow is displayed.
- "Use BG Meter for Treatment Decisions" appears on the status bar of your My Glucose home screen.

- You are currently taking a medication of the tetracycline class.

 **No.** Symptoms don't match the app.

 **No.**








 **No.**



Additional resource: Eversense E3 CGM System User Guide: Using the App.

Your Diabetes Management

Understand your trend arrows – this can help you make more informed diabetes management decisions.

	Glucose is stable – changing less than 1 mg/dL per minute. A change of 0-30 “points” in 30 minutes.
	Glucose is rising moderately – between 1-2 mg/dL per minute. Up 30-60 “points” in 30 minutes.
	Glucose is falling moderately – between 1-2 mg/dL per minute. Down 30-60 “points” in 30 minutes.
	Glucose is rising rapidly – greater than 2 mg/dL per minute. Up 60 “points” or more in 30 minutes.
	Glucose is falling rapidly – greater than 2 mg/dL per minute. Down 60 “points” or more in 30 minutes.





Understanding Sensor Glucose versus Blood Glucose

- Your sensor measures glucose in the fluid in your skin tissue – called interstitial fluid. Your blood glucose (BG) meter measures glucose in the blood.
- The glucose level in interstitial fluid and blood are usually close. Calibrating your system properly is the best way to ensure they are as close as possible.
- Differences between glucose levels in the interstitial fluid and the blood are especially evident during times of rapid change in blood glucose (after eating, dosing insulin or exercising), and for some people, during the first several days after insertion due to inflammation that may result from the insertion procedure.
- Typically, the difference you see is the sensor glucose level “lags behind” the blood glucose level by several minutes.

Using the Mobile App

Eversense App

The MY GLUCOSE screen will display your glucose data once your sensor has been inserted and you have started calibrating the system.

1. Menu icon (see next page)
2. Temp Profile icon
3. Do Not Disturb icon
4. Current glucose reading
5. Transmitter connection to sensor
6. Transmitter battery power
7. Trend arrow
8. High glucose alert level 
9. High glucose target level 
10. Low glucose target level 
11. Low glucose alert level 
12. Event Log icon



Exercise



Multiple Event



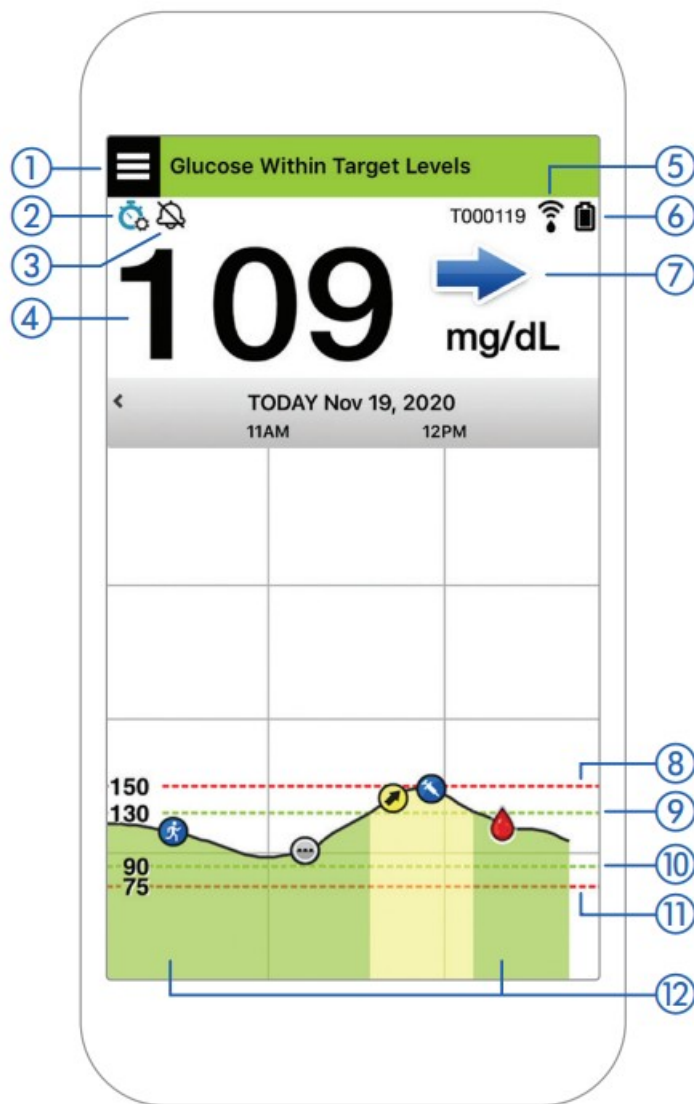
Predicted High
Glucose Alert




Insulin



Calibration

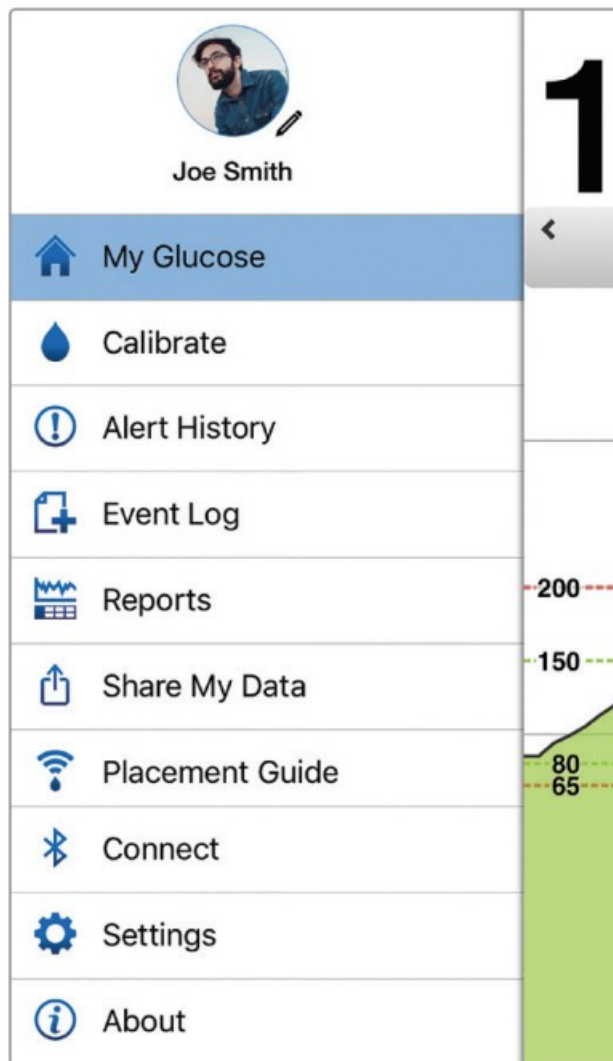


Menu Icon

Tap the MENU icon () on the top left of any screen to navigate to any of the available menu options:



- My Glucose
- Calibrate
- Alert History
- Event Log
- Reports
- Share My Data
- Placement Guide
- Connect
- Settings
- About



Main Menu

Alerts

- BOTH your mobile device and smart transmitter provide alerts to notify you when your CGM readings have reached certain alert settings or if your CGM System requires attention.
- See the User Guide for a complete listing of alerts on your app.

App Status Bar

- Warm-up Phase – applies after linking the smart transmitter and sensor for the first time.

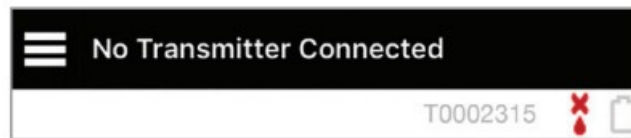


- No Sensor Detected – will appear any time you remove the smart transmitter from over your sensor.



Transmitter powered on
but not over the sensor

- No Transmitter Connected – will appear if the smart transmitter is turned off, in the charging cradle, or out of range of your mobile device.

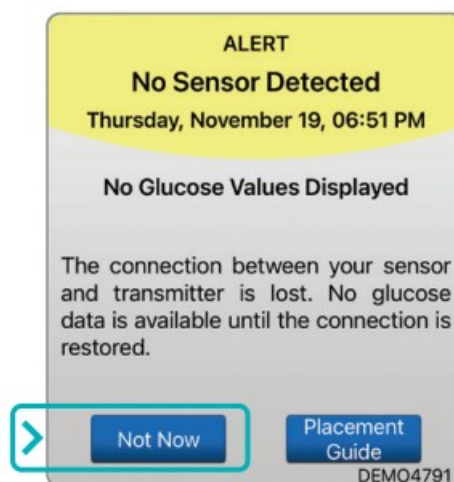


Transmitter powered off

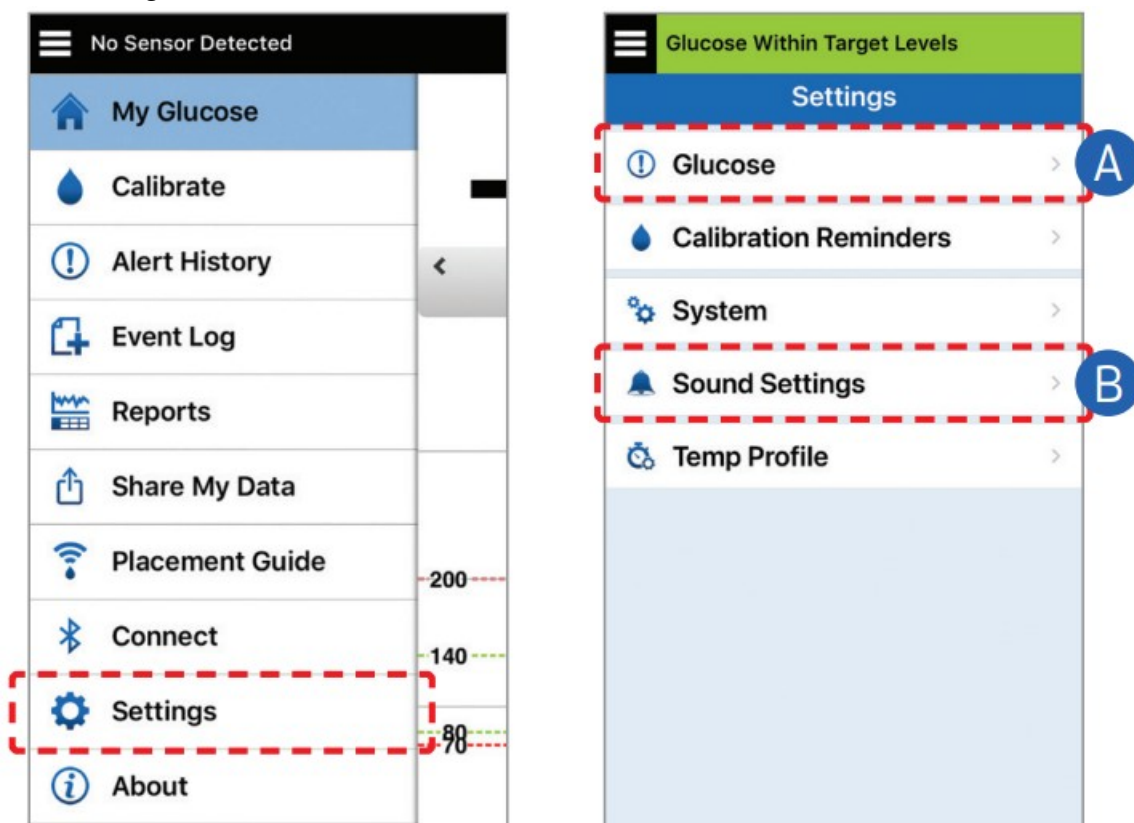
- Use BG Meter for Treatment Decisions – will appear when you should take a confirmatory fingerstick check before making a treatment decision.



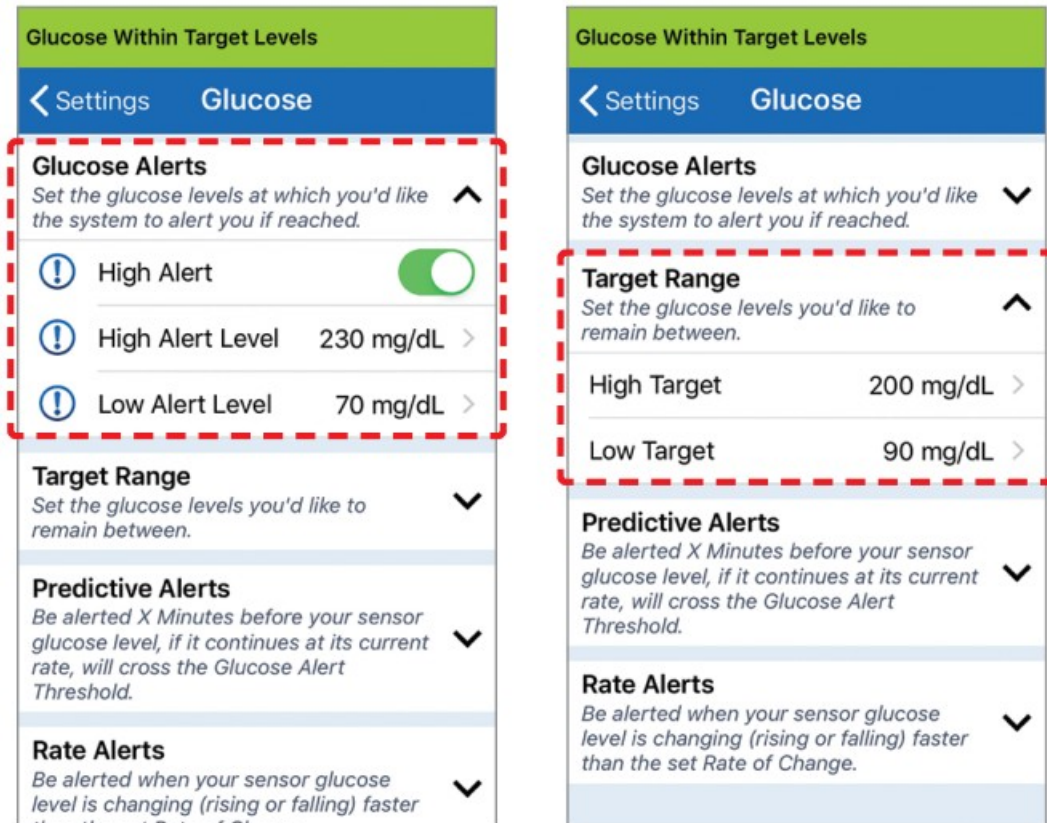
Tip: A “No Sensor Detected” alert may pop-up in your app. This will happen if your smart transmitter is powered on, but not on your arm. Clear the alert by tapping Not Now.



Personalized Settings



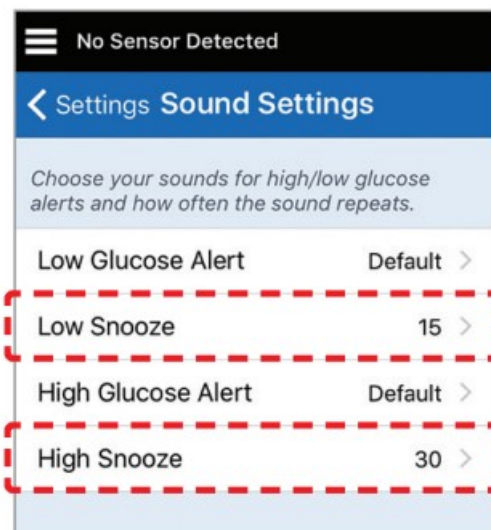
A Set glucose targets and glucose alerts



Tip: If you are new to CGM, wait to set predictive or rate-of-change alerts until you are accustomed to wearing your system.

B. Set how often alerts repeat (snooze)

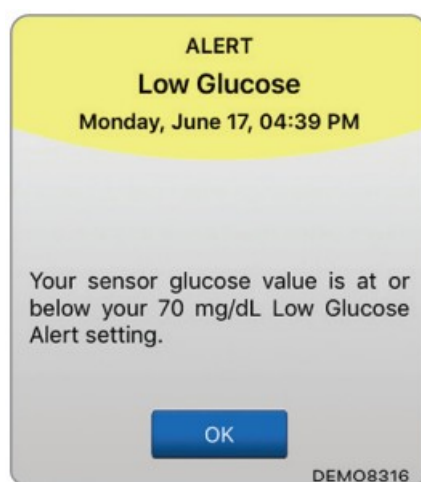
Your alerts sounds are also customizable. See User Guide Section 8.



Alerts and Notifications – See, Hear, Feel

Alerts and notifications	Smart transmitter vibration pattern
Alerts where no glucose values can be displayed or a Battery Error Alert	3 long vibes
Alerts related to Low Glucose	3 short vibes x 3
Alerts related to Predictive Low and Out-of-Range Low Glucose	3 short vibes
Alerts related to High Glucose	1 long vibe then 2 short vibes
Alerts related to smart transmitter charge and low smart transmitter battery	3 quick vibes then 1 long vibe x 2
Alerts related to less critical issues, or notifications	1 short vibe

Tip: If you experience an Ambient Light Alert (more common in early wear), try moving away from direct light, covering the smart transmitter with darker clothing, or placing the smart transmitter slightly higher on the arm over the sensor.

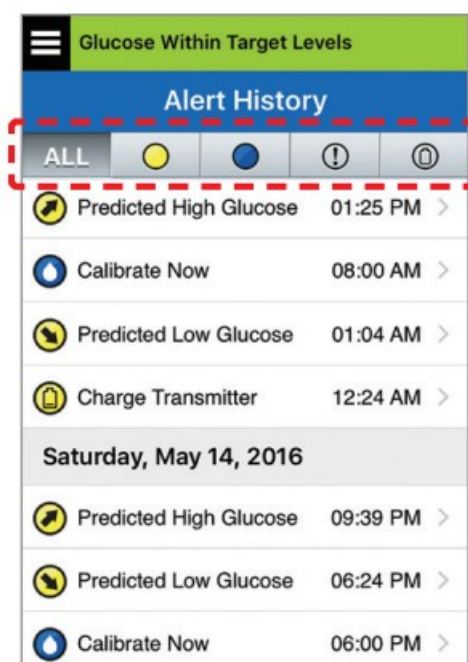


See User Guide Section 9 for more information.

To access alert history:

Menu > Alert History

- Alerts are sortable.



Accessing your DMS Account

You are always logged into your account through the Eversense App, but to get full access to all your data just go to: <https://us.eversensedms.com/> and enter your log-in information. Remember your log-in information is the same as what you used when you created your Eversense account.

Username: _____

Password: _____

Health care provider clinic ID#: _____

Notes: _____

Note: To share your Eversense DMS data with your health care provider, ask them for their Eversense Clinic ID number. See the Eversense DMS User Guide for more information at www.eversenseddiabetes.com/resources.

Contact Information

- Contact your health care provider if you have a medical question or concerns about your diabetes treatment plan.
- Contact Eversense Customer Care if you have technical questions about the Eversense E3 CGM System.

Eversense Customer Care:

1-844-SENSE4U (736-7348)

Support@eversenseddiabetes.com



Distributed by:

Ascensia Diabetes Care US, Inc.

5 Wood Hollow Road

Parsippany, NJ 07054 USA

844.SENSE4U (844.736.7348)

www.ascensia.com/eversense



Manufactured by:

Senseonics, Inc.

20451 Seneca Meadows Parkway

Germantown, MD 20876-7005 USA

www.eversenseddiabetes.com

Patents: www.senseonics.com/products/patents



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Documents / Resources

	<p>eversense E3 CGM Glucose Monitoring System [pdf] User Guide</p> <p>E3 CGM Glucose Monitoring System, E3 CGM, Glucose Monitoring System, Monitoring System</p>
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References

-  [Introducing the Eversense® E3 CGM System | Ascensia Diabetes Care](#)
-  [Introducing the Eversense® E3 CGM System | Ascensia Diabetes Care](#)
-  [Is Eversense® App Compatible with my Android or iOS Devices?](#)
-  [Patents – Senseonics](#)
-  [EDMS](#)

Manuals+.