eversense Continuous Glucose Monitoring System User Guide

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eversense Continuous Glucose Monitoring System

Product Information

The Eversense CGM System is a continuous glucose monitoring system designed for adults (18 years and older) with diabetes. It is intended to measure interstitial glucose levels for up to 90 days. The system replaces the need for fingerstick blood glucose measurements and provides predictions of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia) episodes. It also offers historical data interpretation to aid in therapy adjustments based on patterns and trends seen over time.

The system consists of a sensor, smart transmitter, and mobile app. The sensor is MR Conditional and should be removed before undergoing magnetic resonance imaging (MRI) procedures. The smart transmitter powers the sensor, calculates glucose readings, stores and sends data to the app, and provides on-body vibe alerts. It is secured to the skin with a disposable adhesive patch that needs to be changed daily.

The Eversense CGM System is not recommended for individuals who are contraindicated for dexamethasone or dexamethasone acetate use, or for those undergoing MRI procedures. Additionally, the system may provide falsely elevated sensor glucose results if used in combination with substances containing blood mannitol or sorbitol concentrations.

Product Usage Instructions

1. Wearing the Smart Transmitter:
    - Apply the disposable adhesive patch to secure the smart transmitter to your skin.
    - The smart transmitter can be worn daily and can be removed and reapplied at any time.
    - **Note**: The smart transmitter is water-resistant (IP67) up to a depth of 1 meter (3.2 feet) for up to 30 minutes.
2. Turning 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 check if the smart transmitter is ON, press the power button once. If the LED indicator lights green or orange, it means the smart transmitter is ON. If no LED appears, it means the smart transmitter is OFF.

3. Getting Started Steps:
    - Make sure the smart transmitter is fully charged before pairing it with the mobile app.

Refer to the Eversense CGM User Guide for more detailed information.

For a Spanish version of the User Guide and Quick Reference Guide, please visit **www.eversensediabetes.com.**

Indications for Use

The Eversense CGM System is intended for continually measuring interstitial glucose levels in adults (18 years and older) with diabetes for up to 90 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
- Provide glucose trend
- 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 These adjustments should be based on patterns and trends seen over time.
- The system is intended for single patient

Contraindications

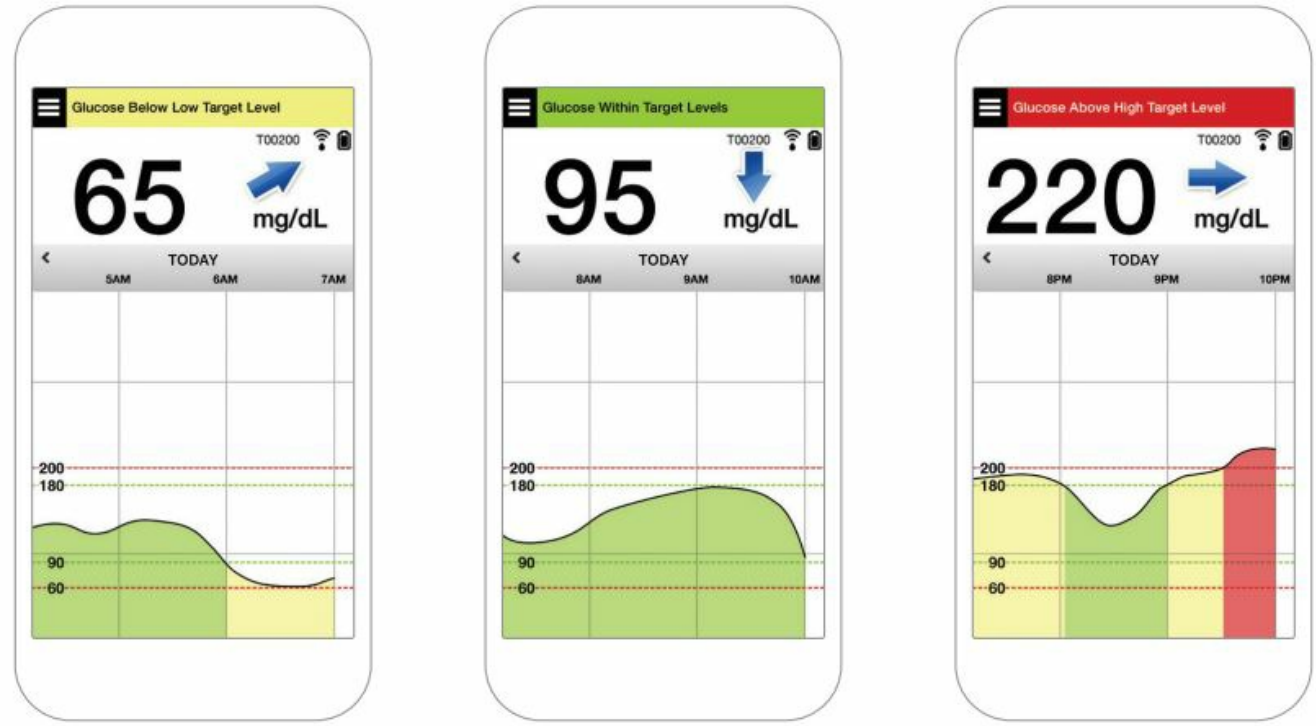
- The system is contraindicated in people for whom dexamethasone or dexamethasone acetate may be
- The smart transmitter is incompatible with magnetic resonance imaging (MRI) The smart transmitter is MR Unsafe and MUST BE REMOVED before undergoing an MRI (magnetic resonance imaging) procedure. The sensor is MR Conditional. For more information on the sensor, see *MRI Safety Information* in the *Eversense 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 Sorbitol is used in some artificial sweeteners, and concentration levels from typical dietary intake do not impact sensor glucose results.

Making Treatment Decisions with Eversense

To make a treatment decision, you should consider:

- Status bar information
- Current sensor glucose value – the current glucose value should be displayed in black

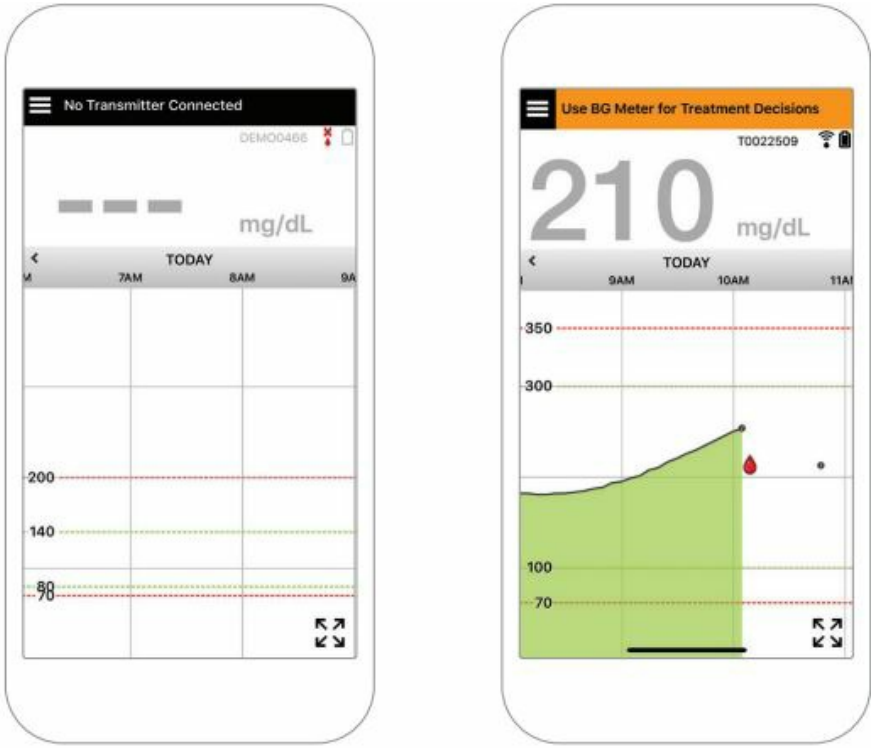
- Trend arrow – a trend arrow should be displayed
- Recent trend information and alerts



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.



Eversense 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
- The smart transmitter can be removed and reapplied to the skin at any

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

Your smart transmitter must be fully charged before pairing with the app.

- Plug the standard end of the USB cable into the adapter on the USB

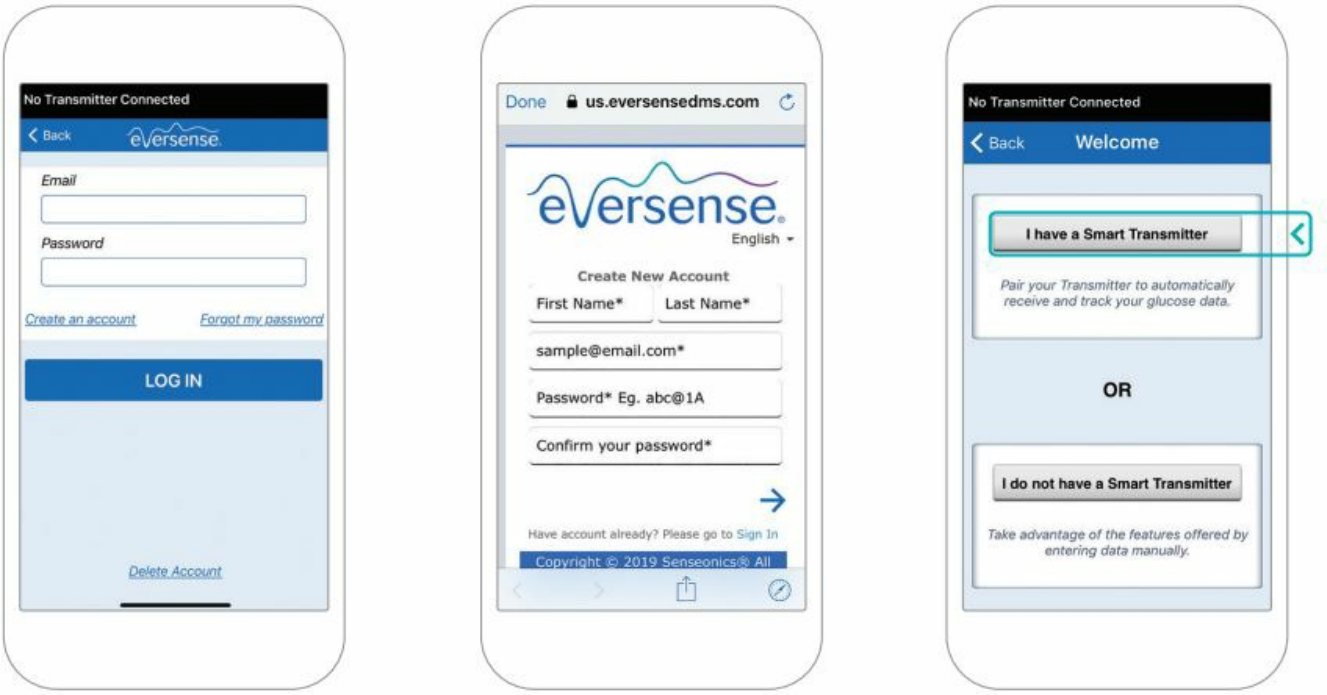
- Plug the micro end of the USB cable into the charging cradle USB port

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

Launch the app by tapping the Eversense icon

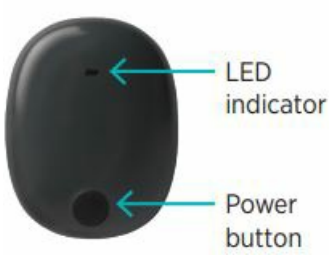
1. Create an account with an Email and
2. Enter your account information and tap **Submit**.
3. Indicate you have your smart transmitter by tapping that option.



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 CGM system.

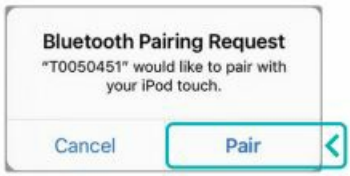
4. Turn your smart transmitter on and set it to “Discoverable Mode” by pressing the power button three times. The LED light will blink green and orange.

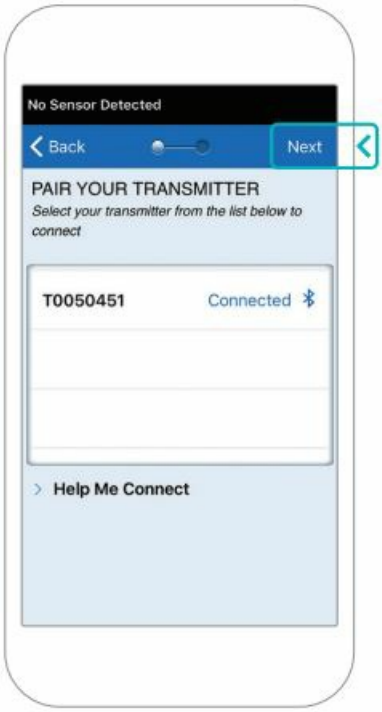


5. Tap Not Connected to begin the pairing process.

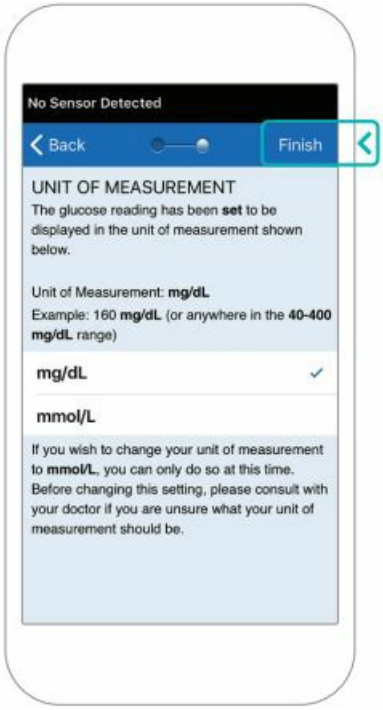
Note: If you do not see your smart transmitter as an option see the User Guide for more information.

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





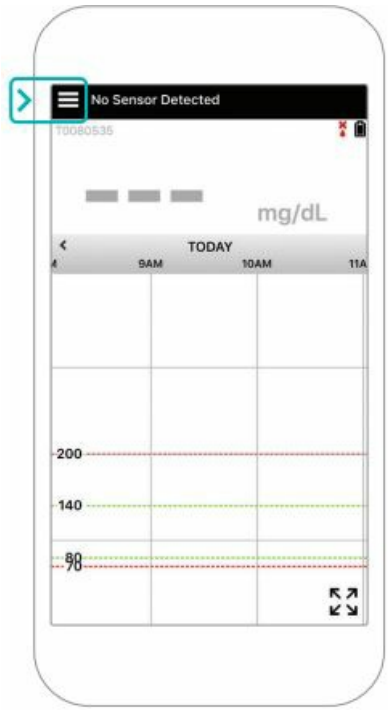
7. The unit of measurement is used for calculating and displaying your glucose readings. DO NOT change the unit of measurement until you consult with your health care provider. Tap Finish to continue



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

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

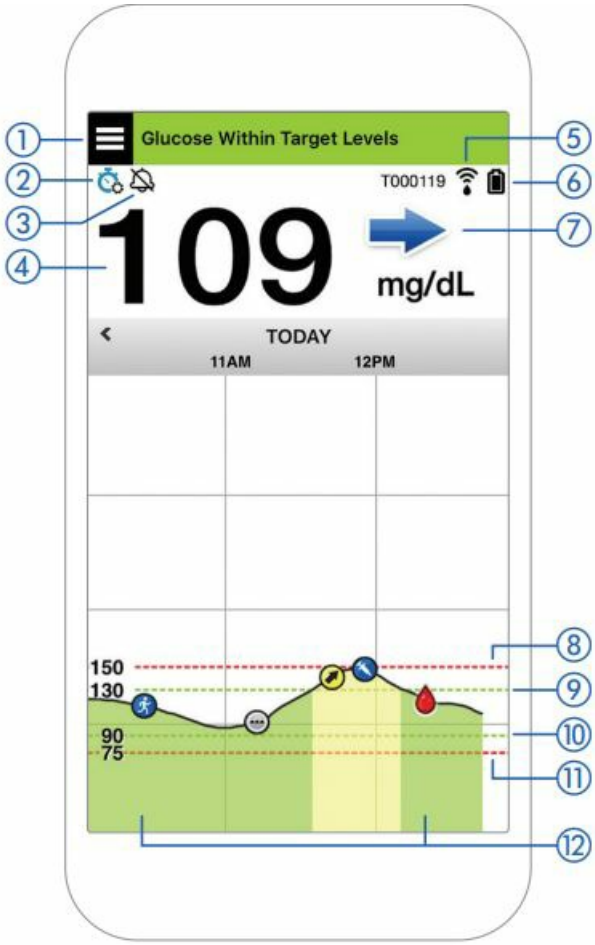
   Note: This screen will not have any glucose data to display until your sensor has been inserted and you have started calibrating the system.



Eversense App

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

- Menu icon (see next page)
- Temp Profile icon
- Do Not Disturb icon
- Current glucose reading
- Transmitter connection to sensor
- Transmitter battery power
- Trend arrow
- High glucose alert level
- High glucose target level
- Low glucose target level
- Low glucose alert level
- Event Log icon

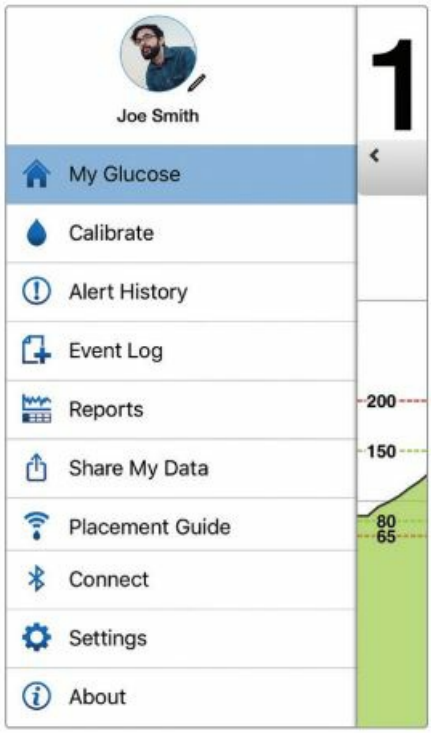


1. Exercise
2. Multiple Event
3. Predicted High Glucose Alert
4. Insulin
5. Calibration

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



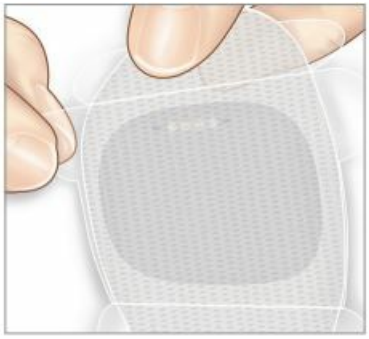
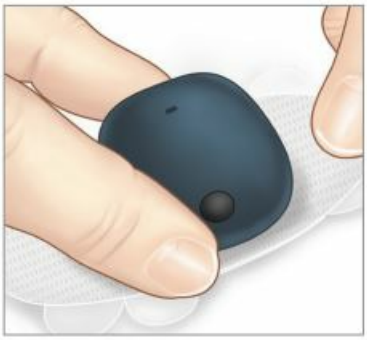
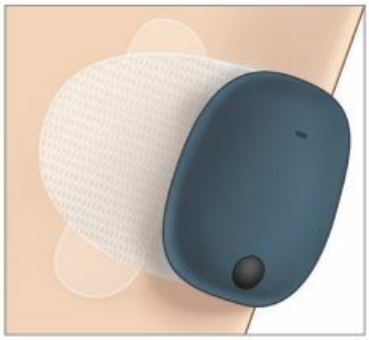
Main Menu

Alerts

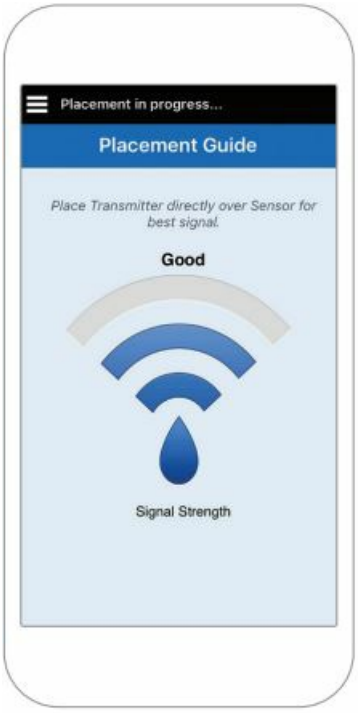
- BOTH your mobile device and smart transmitter provide alerts to notify you when your CGM readings have reached certain target settings or if your CGM System requires attention.
- See the User Guide for a complete listing of alerts on your app.

Placing your Smart Transmitter

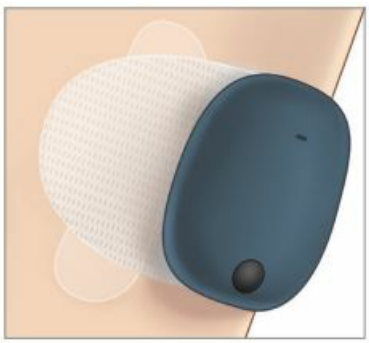
1. Peel off the paper backing with the Eversense logo on it and place the smart transmitter in the center
2. Remove the larger clear backing and position the smart transmitter directly over the sensor.

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.



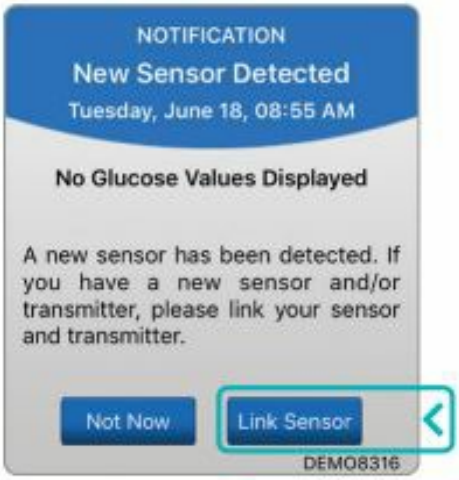
4. Press the adhesive patch firmly on skin surface over the sensor.
5. Use the tab to pull off the remaining clear liner.



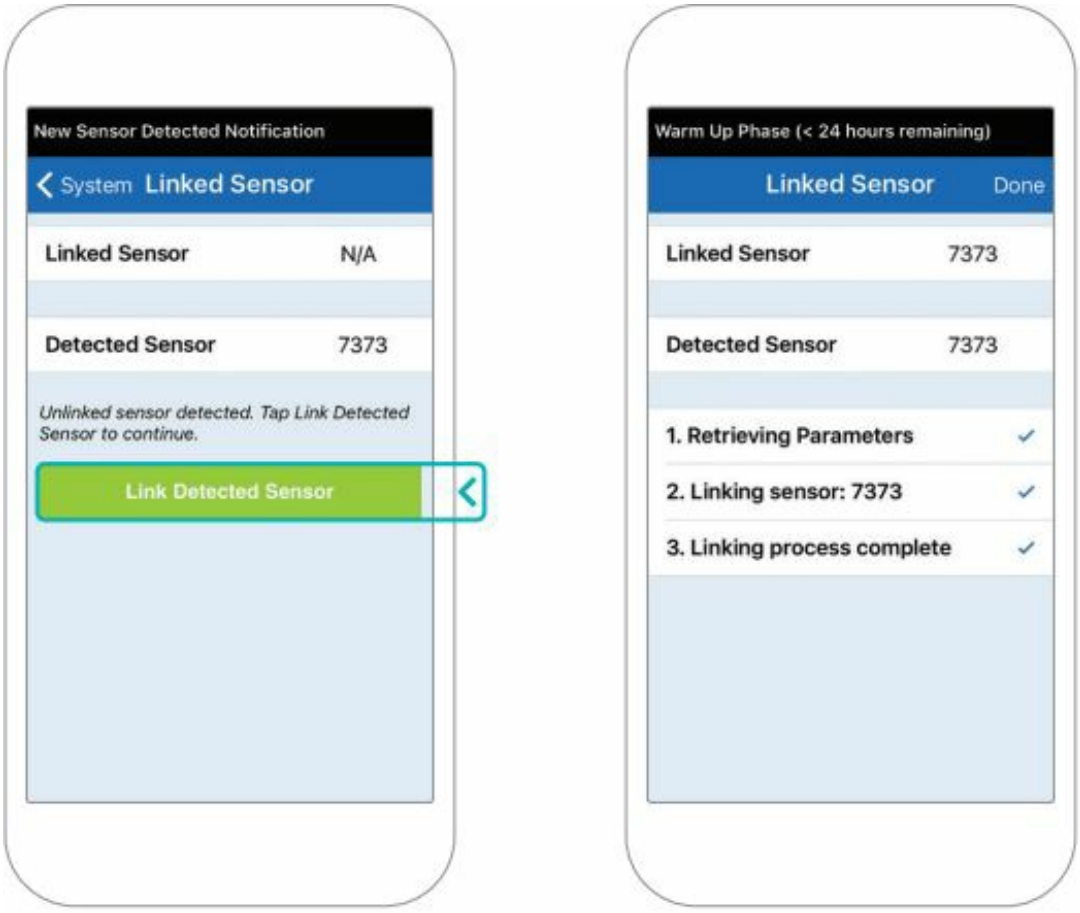

Linking the Sensor and Smart Transmitter

Once the sensor has been inserted by your health care provider, your sensor will need to be linked to your smart transmitter.

1. Position the smart transmitter directly over the inserted sensor until the smart transmitterstops vibrating and the New Sensor Detected message appears on the app.



2. Tap Link Sensor and then Link Detected Sensor.
3. When the smart transmitter and sensor are successfully linked, the LINKED SENSOR screen displays the sensor ID number



The 24 hour Warm Up Phase begins once you have linked your sensor. You can turn off the smart transmitter until the Warm Up Phase is over. The sensor requires 24 hours to stabilize in your body before the smart transmitter will calculate glucose values. For more information, please review the section titled *Calibrating the System* in your *Eversense CGM System User Guide*.

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Patents: www.senseonics.com/products/patents

Rx only

Documents / Resources

	eversense Continuous Glucose Monitoring System [pdf] User Guide Continuous Glucose Monitoring System, Glucose Monitoring System, Monitoring System, System

References

- Introducing the Eversense® E3 CGM System | Ascensia Diabetes Care
- Introducing the Eversense® E3 CGM System | Ascensia Diabetes Care
- Patents – Senseonics