eversense ®E3

Continuous Glucose Monitoring System
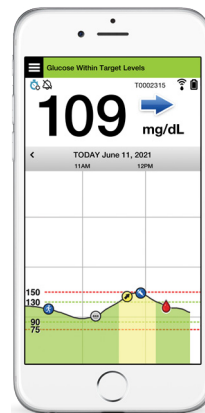
Quick Reference Guide

Sensor

Smart Transmitter

Mobile App

Refer to the *Eversense E3 CGM System 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.
- Aid in the management of diabetes.
- Provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycaemia) and high blood glucose (hyperglycaemia).
- 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. Patients should not undergo an MRI procedure when wearing the smart transmitter. For information on the sensor, please 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.

Top   Back

LED indicator (lights green or orange)

Power button

Charging contact pins
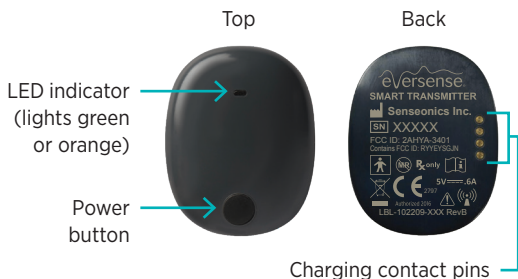
Wearing the Smart Transmitter

• 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 metre (3.2 feet) for up to 30 minutes.
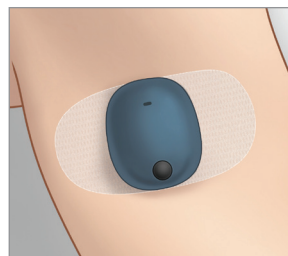
Turn the Smart Transmitter ON and OFF

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
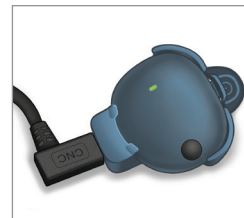
Charging the Smart Transmitter

Before you begin, you need:

- A compatible mobile device.
  - For a list of compatible devices, visit https://global.eversensediabetes.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.

Note: Your smart transmitter kit will include a wall plug appropriate for use in your local region.

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 Licence Agreement. A LOG IN screen appears.
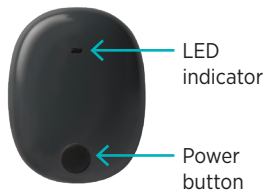
Launch the App by Tapping the Eversense Icon

l. Create an account with an Email and Password.

2. Enter your account information and tap **Submit**.

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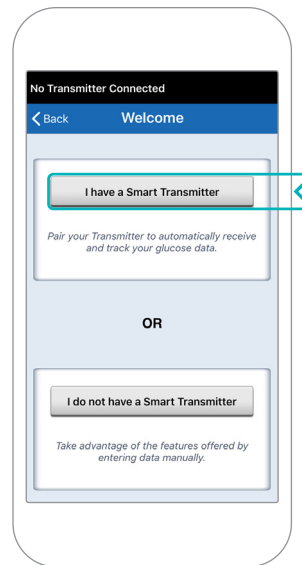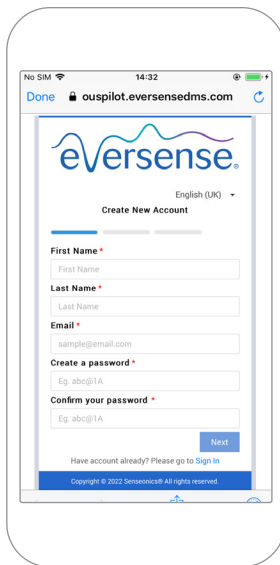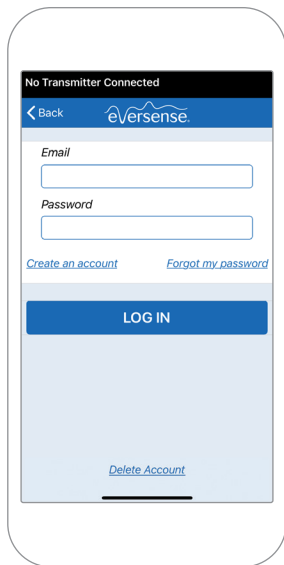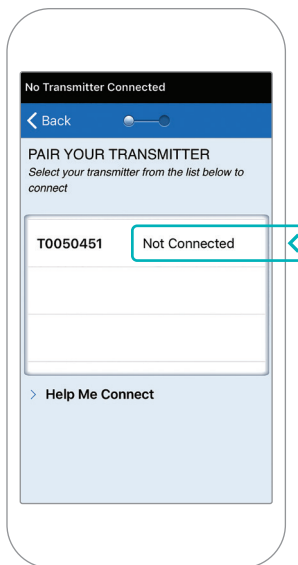
Note: On Android operating systems you will be prompted to acknowledge and enable location or Bluetooth services in order to pair your smart transmitter with your mobile device and receive alerts from the Eversense E3 CGM system.

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.
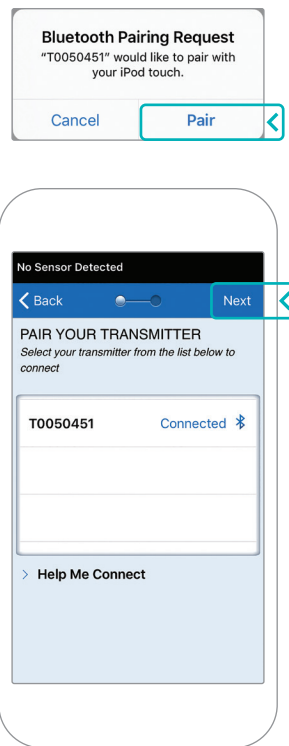
LED indicator

Power button

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

No Transmitter Connected

< Back

PAIR YOUR TRANSMITTER
Select your transmitter from the list below to connect

| T0050451 | Not Connected | < |

> Help Me Connect

Note: If you do not see your smart transmitter as an option, see the *Eversense E3 CGM System User Guide* for more information.

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

Bluetooth Pairing Request
"T0050451" would like to pair with your iPod touch.

Cancel | Pair | <

No Sensor Detected

< Back   Next <

PAIR YOUR TRANSMITTER
Select your transmitter from the list below to connect

| T0050451 | Connected ✳ |

> Help Me Connect

7. The standard unit of measurement for your region is preselected. Your glucose readings will always be displayed in this unit of measurement. DO NOT change your unit of measurement unless you have discussed it with your healthcare provider.

Tap **Finish** to continue.
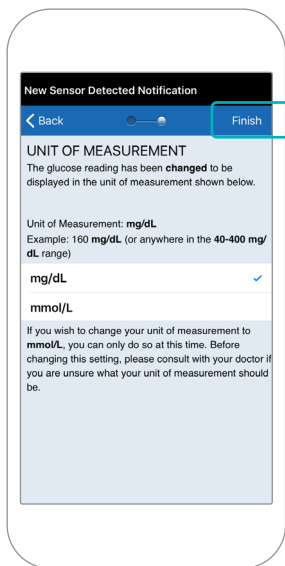
8. Review and tap through the introduction screens that provide information about when to make treatment decisions with the Eversense E3 CGM System.
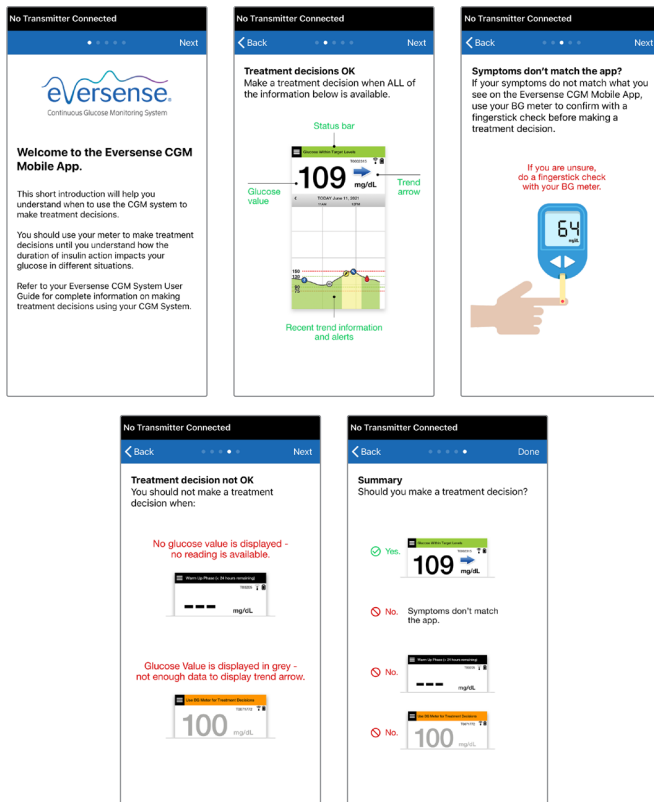
9. Tap the **MAIN MENU** icon to get access to all app functions from a drop-down menu.

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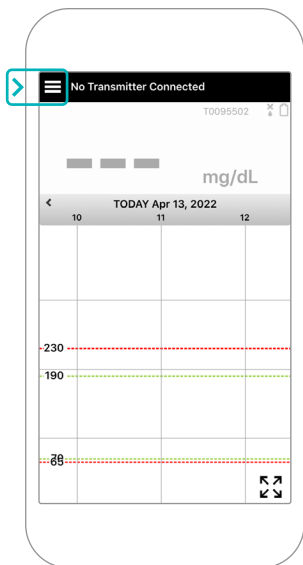
Linking the Sensor and Smart Transmitter

Once the sensor has been inserted by your healthcare 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 to be in the centre of the Tegaderm. This means the sensor is likely to be above the centre 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 centre 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*.
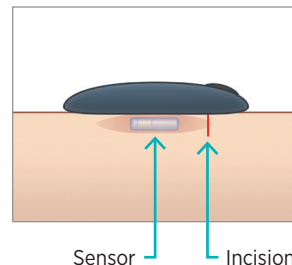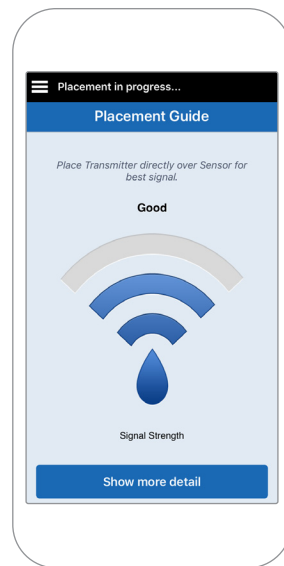
Place Smart Transmitter over Sensor

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 towards 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.

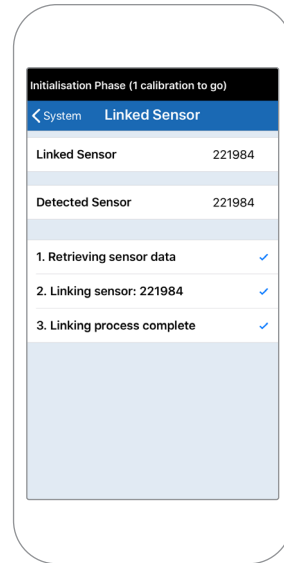**Tip:** It may be helpful to look in a mirror as you position your smart transmitter.

Placement in progress…

Placement Guide

Place Transmitter directly over Sensor for best signal.

Good

Signal Strength

Show more detail

Sensor ⌐   ⌐ Incision

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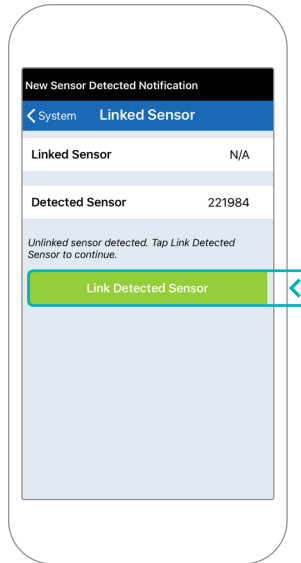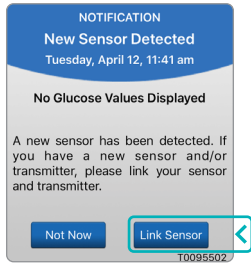
3. When the smart transmitter and sensor are successfully linked, the **LINKED SENSOR** screen displays the sensor ID number.

NOTIFICATION
New Sensor Detected
Tuesday, April 12, 11:41 am

No Glucose Values Displayed

A new sensor has been detected. If you have a new sensor and/or transmitter, please link your sensor and transmitter.

Not Now   Link Sensor
T0095502

New Sensor Detected Notification
❮ System   **Linked Sensor**

Linked Sensor   N/A

Detected Sensor   221984

Unlinked sensor detected. Tap Link Detected Sensor to continue.

Link Detected Sensor

Initialisation Phase (1 calibration to go)
❮ System   **Linked Sensor**

Linked Sensor   221984

Detected Sensor   221984

1. Retrieving sensor data   ✓
2. Linking sensor: 221984   ✓
3. Linking process complete   ✓

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 stabilise 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 Initialisation 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 centre.

2. Remove the larger clear backing and position the smart transmitter directly over the sensor.
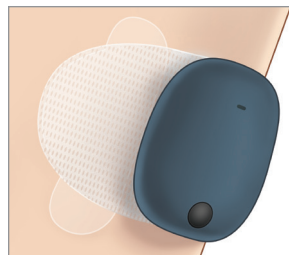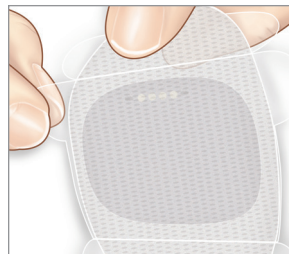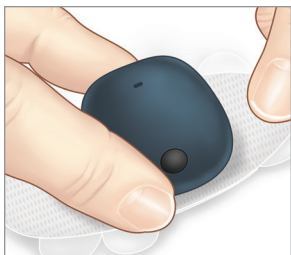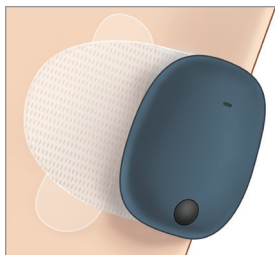
3. Check the connection between the smart transmitter and the sensor.

Select **Placement Guide** from the Main Menu drop-down to help you determine where to place your smart transmitter.
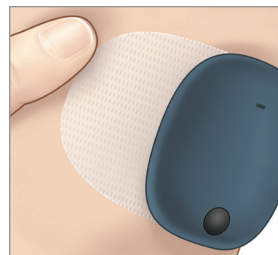
Slide the smart transmitter over the sensor insertion area until you get a good or strong signal on the app.

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

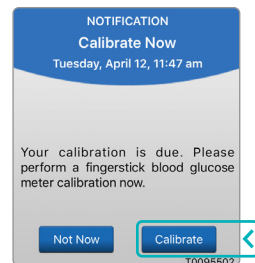

5. Use the tab to pull off the remaining clear liner.

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*.

Initialisation Phase

About 10 minutes after the Initialisation 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 initialisation, every 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.

NOTIFICATION
Calibrate Now
Tuesday, April 12, 11:47 am

Your calibration is due. Please perform a fingerstick blood glucose meter calibration now.

Not Now   Calibrate

T0095502

Calibration times for initialisation

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 the smart transmitter in place over the sensor 5 minutes before and 15 minutes after each calibration.

Daily Use

Once the Initialisation 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.
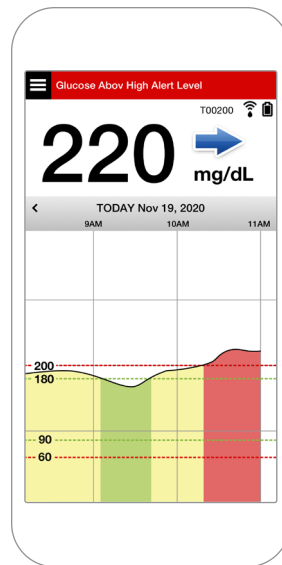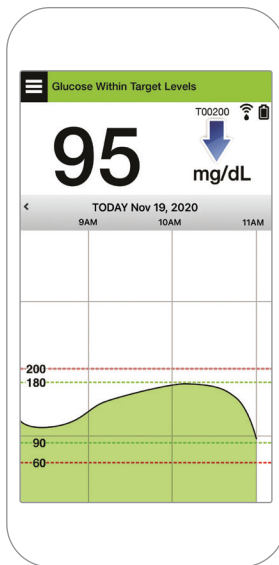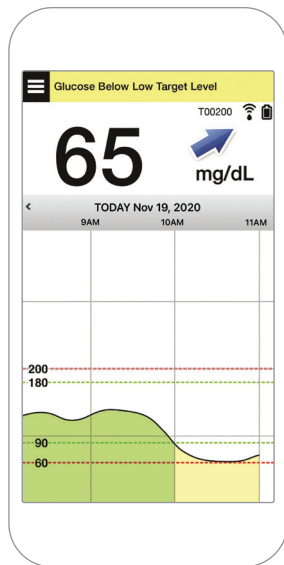
When to NOT make a treatment decision:

- 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 use a secondary display like the Apple Watch or Eversense NOW.**
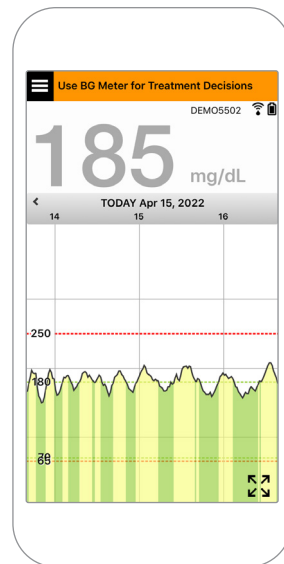
Use all available CGM information

Status bar

Glucose value

Trend arrow

Recent trend information and alerts

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	🔧 Insulin
⊙ Multiple Event	🔴 Calibration
↗ Predicted High Glucose Alert	
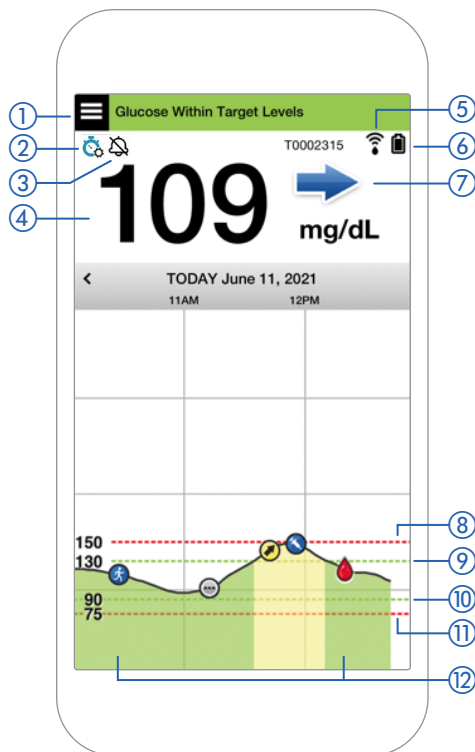
Menu Icon

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

> ☰ **Glucose Within Target Levels**

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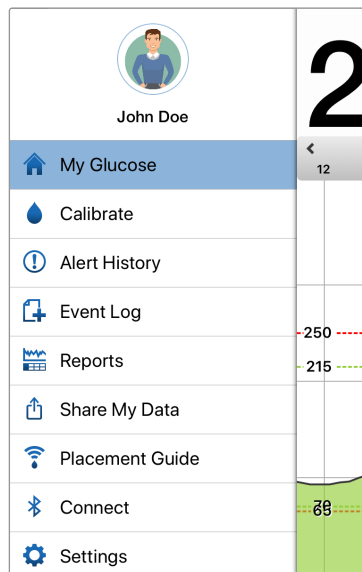
Main Menu

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 *Eversense E3 CGM System 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.

Warm Up Phase (< 24 hours remaining)
T0002315

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

No Sensor Detected
T0002315

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.

No Transmitter Connected
T0002315

Transmitter powered off

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

Use BG Meter for Treatment Decisions
T0071772

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**.

ALERT
No Sensor Detected
Tuesday, April 12, 11:46 am

No Glucose Values Displayed

The connection between your sensor and transmitter is lost. No glucose data is available until the connection is restored.

Not Now | Placement Guide
T0095502
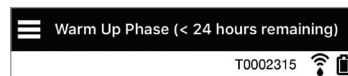
Personalised Settings

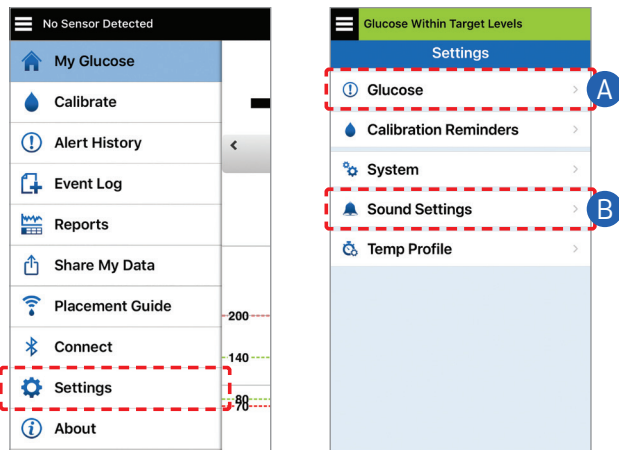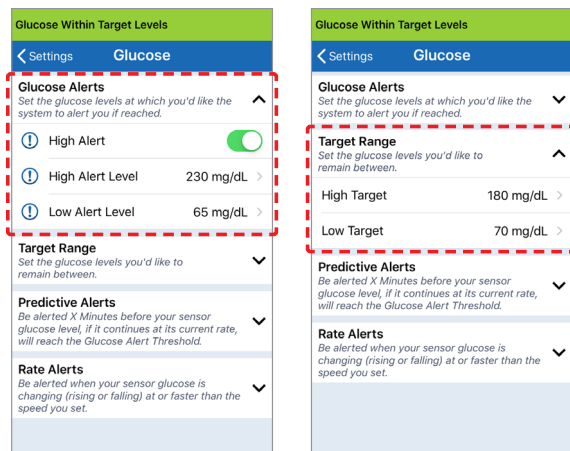**A** Set glucose targets and glucose alerts

Glucose Within Target Levels

< Settings **Glucose**

Glucose Alerts
Set the glucose levels at which you'd like the system to alert you if reached.   ⌃

(!) High Alert ⬤

(!) High Alert Level 230 mg/dL >

(!) Low Alert Level 65 mg/dL >

Target Range
Set the glucose levels you'd like to remain between. ⌄

Predictive Alerts
Be alerted X Minutes before your sensor glucose level, if it continues at its current rate, will reach the Glucose Alert Threshold. ⌄

Rate Alerts
Be alerted when your sensor glucose is changing (rising or falling) at or faster than the speed you set. ⌄

Glucose Within Target Levels

< Settings **Glucose**

Glucose Alerts
Set the glucose levels at which you'd like the system to alert you if reached. ⌄

Target Range
Set the glucose levels you'd like to remain between. ⌃

High Target 180 mg/dL >

Low Target 70 mg/dL >

Predictive Alerts
Be alerted X Minutes before your sensor glucose level, if it continues at its current rate, will reach the Glucose Alert Threshold. ⌄

Rate Alerts
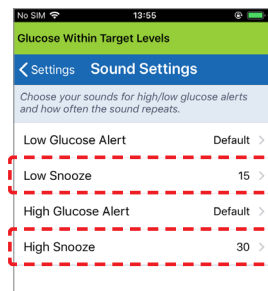*Be alerted when your sensor glucose is changing (rising or falling) at or faster than the speed you set.* ⌄

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 customisable. See *Customising Your Settings* in the *Eversense E3 CGM System User Guide*.

No SIM 🤚 13:55 🔋

Glucose Within Target Levels

< Settings **Sound Settings**

Choose your sounds for high/low glucose alerts and how often the sound repeats.

Low Glucose Alert Default >

Low Snooze 15 >

High Glucose Alert Default >

High Snooze 30 >

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.
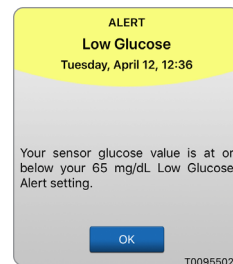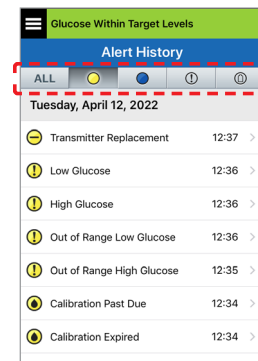

See *Alert Descriptions* in the *Eversense E3 CGM System User Guide* for more information.

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 of your data just go to: **https://www.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: _____

Healthcare provider clinic ID#: _____

Notes: _____

_____

_____

Note: To share your Eversense DMS data with your healthcare provider, ask them for their Eversense Clinic ID number. See the *Eversense DMS User Guide* included in your Eversense Smart Transmitter Kit.

Contact Information

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

Basic UDI/DI:
- Eversense E3 Smart Transmitter Kit: 081749102FG3500T8
- Eversense E3 Adhesive Patches Kit: 081749102FG6400TQ
- Eversense Charging Cradle: 081749102FG6501TX
- Eversense Mobile App iOS: 081749102FG5101T4
- Eversense Mobile App Android: 081749102FG5301TE

Call 04-6175390 for Customer Support.

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CE 2797

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Dimensions	
Trim: 6.75" w x 5.8" h	Bleed: 0.125"
Folded (*Include folded dimensions if applicable*):	

Colors: 4/color
Spot (*Name PMS colors if applicable*): N/A

Paper Weight:
Cover: 65# Gloss Cover
Text: 60# Gloss Text