Insertion Steps

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

Insertion site:

It is important to choose a site on the upper arm that is comfortable for you to wear the sensor and smart transmitter for up to 180 days. It is recommended to have the sensor inserted toward the back of the upper arm. Placement in this area minimizes the chance of the sensor and smart transmitter being bumped by doorways, walls or other narrow passages. If possible, avoid areas with loose skin, scars, tattoos, nevus, or blood vessels that could be incised during the procedure. It is recommended to alternate arms for subsequent insertion sites.

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

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

Step 3: **Sensor insertion –** a subcutaneous pocket will be created under the skin and the sensor will be inserted in this pocket.

Step 4: **Site closure –** the incision will be closed with an adhesive bandage. Steri Strips™ are typically used to close the incision.

Step 5: **Sensor and smart transmitter linking –** link the sensor and smart transmitter to begin the 24-hour Warm-Up Phase.

Note: **After insertion, link the smart transmitter and the sensor and then allow the incision site to heal 24 hours before wearing the transmitter**.

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

Removal Steps

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

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

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

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

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

17. Travel

This section describes the safety issues when traveling with your Eversense E3 smart transmitter and sensor.

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

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

The Eversense E3 CGM System is safe for use on U.S. commercial airlines. The Eversense E3 Smart Transmitter is a Medical Portable Electronic Device (M-PED) with emission levels that meet FAA mandates for use in all modes while in flight. (Reference FAA Advisory, Circular #21-16G, dated 6.22.2011.) To use, turn your mobile device's Bluetooth feature on after you have put your mobile device in airplane mode. For flights outside the US, follow local security regulations for use of medical devices in flight.

18. Troubleshooting

This section lists information about troubleshooting your Eversense E3 CGM System and includes a list of frequently asked questions (FAQs).

Smart Transmitter

Q: How do I turn my smart transmitter OFF?

A: Touch and hold the soft-touch button in the center of the transmitter for 5 seconds. Release the button when you feel a quick vibe and the LED turns off.

Q: How do I turn my smart transmitter ON?

A: Touch and hold the soft-touch button in the center of the transmitter for 3 seconds. Release the button when you feel a quick vibe and the LED turns on.

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

A: There are two ways to ensure proper positioning:

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

Note: To see more information about signal strength and transmitter positioning, see Placement Guide – Show More Detail Screen in the Linking the Sensor section.

Q: My smart transmitter will not vibrate. Why?

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

- Check that the smart transmitter is paired to your mobile device.
- Check that the **Do Not Disturb** is disabled by tapping **Menu** > **Settings** > **Sound Settings.**
- Check that your smart transmitter has enough battery power and charge if necessary.
- Go to **About** > **My Transmitter** and tap **Demonstration**.

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

Q: Can I remove and replace the same adhesive patch more than once a day?

A: Repeated removal and replacement may reduce adhesion strength.

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

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

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

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

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

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

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

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

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

A: The system has detected a transmitter error. Contact Customer Support.

Smart Transmitter Battery and Charging

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

A: A fully charged smart transmitter battery typically lasts approximately 5 days.

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

A: Charging daily for 15 minutes provides about 24 hours of battery life when plugged into a wall outlet. It may take longer if charging via a computer USB port, if you don't charge daily, or when the battery is empty.

Q: What happens if my smart transmitter battery is completely drained?

A: No glucose readings will be displayed. Always charge immediately when the smart transmitter battery is completely drained.

Q: How do I check the smart transmitter battery status?

A: There are three ways to check battery status:

1. Check the battery icon and percentage in the upper right corner on the **MY GLUCOSE** screen. A red battery icon indicates the smart transmitter battery is empty.
2. Tap **Menu** > **About** > **My Transmitter**. Scroll down to the Battery Level line that indicates amount of battery power left.
3. Power on the smart transmitter. Tap in the center of the transmitter once. The LED will blink once. Orange indicates less than 10% (less than 24 hours) battery life remaining. Green indicates 10% (about 24 hours) or more battery life remaining.

Connection with Smart Transmitter

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

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

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

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

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

- Make sure your smart transmitter is not being charged, that it is turned on, and the battery is not very low or empty.
- Make sure your smart transmitter is within wireless range of your mobile device.
- Make sure your mobile device has the Bluetooth setting turned ON.

The condition may be temporary.

1. On the Eversense App, tap **Menu** > **Connect**. If your smart transmitter name indicates **Disconnected**, tap the smart transmitter name to connect. If still not connected, go to next step.
2. Close the Eversense App.
3. Remove/forget the smart transmitter in your mobile device's Bluetooth settings.
4. Turn off the smart transmitter and then turn it back on.
5. Open the Eversense App.
6. Tap **Pair** if prompted. If not prompted, in the Eversense app, go to **Menu** > **Connect**. If your smart transmitter serial number (or name, if you gave it a custom name) indicates **Disconnected**, tap the smart transmitter name. If you don't see your transmitter listed, go to step 7.

7. Tap the smart transmitter's soft-touch button 3 times to activate pairing mode. When your transmitter is displayed on the **CONNECT** screen, tap it.
8. Tap **Pair** when prompted. If you are not prompted to Pair, contact Customer Support.

Q: How do I reset my smart transmitter?

A: Follow the steps below.

1. Plug the USB cable into the smart transmitter. Plug the cable into the wall outlet. (You can also plug the standard USB end of the cable directly into a USB port on your computer.) Wait until the LED is blinking green or solid green.
2. While connected to the USB, touch and hold your finger on the transmitter's soft-touch button (for approx. 14 seconds). The LED will be white. Remove your finger from the transmitter when the LED changes from white to orange.
3. The LED will start blinking in a few seconds indicating the smart transmitter is going through a self-test sequence. The LED will blink in various colors. Once the self test is complete, the smart transmitter will vibrate and blink green indicating it is now charging.
4. If the self-test does not complete, repeat steps 1 through 3.
5. If step 3 is successfully completed, the smart transmitter is now ready for use.

Q: Can other people connect to my smart transmitter?

A: The Eversense E3 CGM System utilizes a secure Bluetooth connection and will not allow others to connect.

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

A: The smart transmitter will vibrate and the app will provide a "Transmitter Disconnected" notification every 5 to 30 minutes, based on your sound settings, until the app is launched or the smart transmitter is reconnected. Once the connection is re-established, the data collected will sync with the mobile app.

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

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

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

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

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

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

Q: What is pairing mode?

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

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

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

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

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

A: If other Eversense E3 CGM users are around you, then the app may find those devices. However, the app connects only to the smart transmitter that was paired with your mobile device. DO NOT attempt to pair your mobile device to other smart transmitters that are not yours.

Q: I just received a new smart transmitter. How do I unpair the old one and connect the new one to my system?

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

Calibration

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

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

Q: Why was my calibration rejected?

A: The system will reject the calibration for the any of the following reasons:

- The blood glucose reading entered is less than 40 mg/dL.
- The blood glucose reading entered is greater than 400 mg/dL.

If another calibration is needed, the system will prompt you.

Q: Why am I unable to calibrate?

A: You may not be able to calibrate for any of the following reasons:

- Not enough sensor glucose data has been collected, which may take up to 5 minutes.
- Sensor glucose values are changing rapidly, such as after eating or taking insulin.
- The blood glucose reading is less than 40 mg/dL.
- The blood glucose reading is greater than 400 mg/dL.
- The blood glucose reading was taken more than 10 minutes prior to entering it in the Eversense App.
- The last sensor glucose value is significantly different than the blood glucose reading entered.
- A calibration is in progress.
- It is less than 1 hour since the last successful calibration.
- Your transmitter is disconnected.
- Transmitter is not linked to your sensor.
- Your sensor needs to be replaced.

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

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

Q: What are the different types of calibration phases?

A: The Eversense E3 CGM System has three types of Calibration Phases: the Initialization Phase, 2 Daily Calibrations Phase and 1 Daily Calibration Phase. Initialization Phase begins 24 hours after sensor insertion and requires 4 fingerstick blood glucose tests for calibration. The system will notify you if 1 or 2 calibrations per day are needed.

Alerts and Notifications

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

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

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

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

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

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

Q: What are rate of change alerts?

A: Rate of Change Alerts notify you when your glucose level is falling or rising faster than the setting you entered in **Settings** > **Glucose**.

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

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

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

Q: What are predictive alerts?

A: Predictive Alerts notify you in advance of an event that is likely to occur if current trends continue. Predictive Alerts use High and Low Glucose Alert levels you set to determine when the Predictive Alerts occur. You can set the alerts to notify you at 10, 20, or 30 minutes in advance of when the CGM System anticipates you reaching the alert levels you set. Your smart transmitter will vibrate, and your app will sound an alert and display a message on the **MY GLUCOSE** screen to notify you of a predicted high or low glucose. If your symptoms do not match the sensor glucose value, or what the alerts indicate, you should immediately perform a fingerstick blood glucose test before making a treatment decision.

Q: What are rate of change alerts?

A: Rate of Change Alerts notify you when your glucose level is falling or rising faster than the setting you entered in **Settings** > **Glucose**.

Q: Why am I unable to see notifications when the app is in the background?

A: Refer to your mobile device instructions to enable the notifications in the background.

Q: What happens to the notifications if my app is disconnected from my smart transmitter?

A: If the app is disconnected from your smart transmitter, but you have been wearing your smart transmitter over your sensor, the alerts received during that time will be sent to the app once it is reconnected and synced with the smart transmitter.

Q: How can I sort the notifications on the ALERT HISTORY screen?

A: The **ALERT HISTORY** screen has a sort filter at the top. You can sort based on the severity levels (yellow and blue), and alert type. Tap the desired sort filter icon.

Q: How do I silence glucose alerts?

A: Glucose Alerts can be silenced by confirming the alert on your mobile device and taking the appropriate action if necessary.

Glucose Readings

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

A: The Eversense E3 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), and for some people, during the first several days after insertion due to inflammation that may result from the insertion procedure. On average, glucose levels in ISF lag behind glucose levels in blood by several minutes. Until you are aware of what these differences are, confirm sensor readings with a fingerstick blood glucose check. Also, if your symptoms do not match the sensor glucose readings, you should confirm with a fingerstick blood glucose check.

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

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

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

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

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

Making Treatment Decisions

Q: What information should be considered before I make a treatment decision?

A: Before making a treatment decision, you should take into account the sensor glucose value, the trend graph, the trend arrow and any alerts from the Eversense E3 CGM System. If no trend arrow is displayed, the system does not have enough data to display direction and rate of change. You should not make a treatment decision based solely on the sensor glucose value.

Q: Why is my glucose value grey?

A: When the system does not have enough data to provide a trend arrow, the sensor glucose value may be displayed in grey. You should not make a treatment decision based solely on the sensor glucose value.

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

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

- When it is time to calibrate.
- 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.

Trend Arrows

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

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

Q: My trend arrow is missing.

A: The CGM System uses the **last 20 minutes of continuous glucose data** for calculating and displaying the trend arrow. When there are not enough sensor values available for the calculation, the arrow is not displayed. You should not make treatment decisions unless you see a glucose value, a trend arrow, and consider recent trends and alerts.

App

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

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

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

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

Q: How will my app be updated?

A: Follow the process of keeping your mobile app up to date via the Apple App Store or the Google Play Store.

Q: What devices are compatible with the Eversense App?

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

Q: Can I delete my Eversense account?

A: If you delete your account, it is permanent, and you will no longer have access to your CGM data on the Eversense Mobile App, or in your Eversense DMS account. If you are using the Eversense NOW Mobile app, you will no longer be able to remotely view Eversense CGM data. You cannot use the same email address to create a new account. To initiate account deletion, tap Delete Account on the log in page.

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

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

Q: What is the Do Not Disturb option?

A: When Do Not Disturb is enabled in the Eversense App Settings, the mobile app will stop displaying non-critical alerts. The smart transmitter will also stop providing vibratory alerts for non-critical alerts. Critical alerts will still be provided by the smart transmitter and the mobile app.

Note that the Do Not Disturb feature on your smartphone overrides the Do Not Disturb option in the app. So if the Do Not Disturb feature on your smartphone is turned on, you will not receive the alerts on the smart transmitter or in the app. However with certain phone operating systems you can enable Low Glucose Alerts to override your phone sound setting. See Sound Settings for more information. Be aware that some apps may automatically enable Do Not Disturb on your phone.

Q: Why does my status bar say "syncing"?

A: "Syncing" will appear in the status bar when the app on your mobile device is connecting to your smart transmitter.

Q: My Glucose Settings and Temp Profile Settings are grayed out and I cannot adjust them.

A: Your app must be paired to a smart transmitter to be able to adjust your Glucose and Temp Profile settings.

Q: Can I edit a manual BG entry event?

A: Manual BG entries and calibration entries cannot be edited.

Q: If I hide an event, can I restore later?

A: Event entries that have been hidden cannot be restored.

Q: What repeat intervals can i set for High and Low Glucose?

A: For High Glucose, the repeat interval can be 15 to 180 minutes, in 15-minute increments. For Low Glucose, the repeat interval can be 5 to 30 minutes in 5-minute increments.

Sensor

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

A: The Eversense E3 CGM System was only tested in the upper arm during clinical studies, and the sensor should not be inserted in other locations.

Q: When do I need to replace my sensor?

A: Your sensor lasts up to 180 days. You will receive periodic notices (60, 30, 14, 7, 3, and 1 day prior) to remind you when the sensor needs to be replaced. Contact your health care provider to schedule a sensor replacement.

Q: Can I extend the life of the sensor?

A: The sensor will no longer provide glucose readings after its wear time has expired.

Q: Where can I find the sensor serial number?

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

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

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

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

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

Q: Why do I see a "New Sensor Detected" notification?

A: This message appears when your smart transmitter detects a new sensor so you may link the smart transmitter and sensor. The smart transmitter can only be linked to one sensor at a time. If you see a **New Sensor Detected** message and you already have a sensor inserted and linked to your smart transmitter, tap **Not Now**. If unsure, contact Customer Support for more information.

Q: Why did my CGM System re-enter Initialization Phase?

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

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

- A new transmitter has been linked to your existing sensor. For example, if you have replaced your existing transmitter.
- If you were instructed by Customer Support to re-link your sensor.

Q: Is it okay for an MRI technician to wear the Eversense E3 CGM System?

A: Yes, MRI technicians can wear the Eversense E3 CGM System. However, for people undergoing an MRI with a static magnetic field of 1.5T or 3.0T, the sensor can stay in place under the skin, but the smart transmitter must be removed and left outside the room. See MRI Safety Information for more details.

Events

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

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

Sync

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

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

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

Shortcuts

Q: Is there a way to select a date to view on the MY GLUCOSE screen, instead of scrolling backwards?

A: Yes, tap the **"**Today**"** bar right above the graph. A pop-up will appear for you to select the desired date to be displayed on the graph.

Q: If I'm viewing a date/time in the past on the MY GLUCOSE screen, is there a short cut back to the current date and time?

A: Yes, tap the glucose value/trend arrow to return to the current date/time on the **MY GLUCOSE** screen.

Q: Is there a shortcut to the ALERT HISTORY screen?

A: If your smart transmitter is connected to the app, you can tap the status bar at the top of the screen to display the **ALERT HISTORY** screen.

Q: Is there a shortcut to the CONNECT screen?

A: If your smart transmitter is disconnected from the app, when you tap the status bar at the top of the screen, the **CONNECT** screen is displayed.

Q: Is there a shortcut to enter an event, like meals or exercise?

A: From the **MY GLUCOSE** screen, tap on the graph to display the **EVENT ENTRY** screen.

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19. Device Performance

This section lists Device Performance Characteristics.

Clinical Study Performance

The safety and effectiveness of the Eversense E3 CGM System has been evaluated in the PROMISE clinical study conducted in the U.S. The data collected was analyzed using a new algorithm, SW 604. A modified sensor design, referred to in this document as the E3 sensor, was evaluated in the PROMISE study. Compared to the Primary sensor (which was the original sensor used in the PROMISE study), the E3 sensor had a modified hydrogel formulation (sacrificial boronic acid, SBA) intended to extend the in vivo functional life of the sensor. The formulation change was not intended to affect the primary mechanism of action of the sensor (glucose binding or fluorescence). Data from both sensors is included in the Device Performance section. Accuracy assessments were made at various points during the study and subjects were asked to report any adverse events throughout the study. The Safety section reflects all subjects (n=181) from the study. Sensors provided with the Eversense E3 CGM System include the SBA design modification.

PROMISE Study

The PROMISE study was a multi-site, prospective, non-randomized pivotal clinical study. One hundred eighty-one (181) adults (18 years and older) with type 1 or type 2 diabetes participated in the study across 8 sites in the U.S. Ninety six (96) subjects had two sensors inserted, one in each arm. Forty three (43) of the secondary sensors were SBA sensors. Participants interacted with the system to calibrate and address notifications not related to glucose data. All diabetes care decisions were based on blood glucose values and clinical standard of care. Accuracy was measured during day-long clinic visits. These visits occurred on Days 1, 7 or 14, 22, 30, 60, 90, 120, 150, and 180. At each visit, sensor accuracy was evaluated relative to a standard laboratory analyzer known as the YSI. Glucose readings were compared at the same moment in time between the reference analyzer and the continuous device. A safety follow-up visit occurred ten days after the sensor was removed.

Table 1 – Accuracy to YSI in PROMISE*

YSI Glucose Range (mg/dL)		Total Number of Paired CGM and YSI Values	Percent of CGM System Readings Within				MARD
			Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	
Primary Sensor	Overall	49,613	85.6	92.9	98.0	99.3	9.1%
E3 Sensor	Overall	12,034	87.3	93.9	98.6	99.6	8.5%

*Glucose values between 40 and 400 mg/dL.

Accuracy to YSI in PROMISE Study

Accuracy was measured by comparing the CGM glucose values to YSI blood glucose values. For blood glucose values less than or equal to 80 mg/dL, the mean absolute difference between the two results was calculated. For values greater than 80 mg/dL, the mean absolute relative difference was calculated.

Primary Sensor

Table 2a – Primary Sensor Accuracy to YSI in PROMISE Study

YSI Glucose Range (mg/dL)	Number of Paired CGM-YSI	Mean Absolute Relative Difference (%)
Overall	49,613	9.1
< 40*	20	16.1
40 - 60*	2,281	9.4
61 - 80*	5,270	8.8
81 - 180	19,001	9.0
181 - 300	14,578	7.7
301 - 350	6,862	7.1
351 - 400	1,510	8.0
> 400	91	13.4

*For YSI ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).

E3 Sensor

Table 2b – E3 Sensor Accuracy to YSI in PROMISE Study

YSI Glucose Range (mg/dL)	Number of Paired CGM-YSI	Mean Absolute Relative Difference (%)
Overall	12,034	8.5
< 40*	0	--
40 - 60*	592	7.5
61 - 80*	1,221	7.7
81 - 180	5,067	8.6
181 - 300	3,300	7.4
301 - 350	1,457	6.9
351 - 400	372	6.4
> 400	25	9.5

*For YSI ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).

Performance was also measured by calculating the percentage of sensor glucose readings within 15 mg/dL or 15% of the YSI reference. These tables show the percent agreement at multiple levels, at different glucose ranges, and at different days during the sensor wear. Results in the glucose ranges of 80 mg/dL or less reflect the percentage of values within mg/dL, and results in the glucose ranges over 80 mg/dL reflect the percentage within reference. As an example, CGM glucose values between 40 and 60 mg/dL were within 15 mg/dL of the reference value 87.9% and 91.6% of the time for the primary and E3 sensors, respectively.

Primary Sensor

Table 3a – Primary Sensor Percentage of Readings in Agreement Overall in the PROMISE Study

CGM System Glucose Range (mg/dL)	Paired CGM and YSI Reference	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent > 40/40% of Reference
Overall	49,613	85.6	92.9	98.0	99.3	0.7
40 - 60	2,205	87.9	94.6	98.5	99.2	0.8
61 - 80	4,623	89.2	95.2	99.3	99.9	0.1
81 - 180	19,566	81.5	90.1	97.1	99.0	1.0
181 - 300	15,654	86.5	93.9	98.4	99.4	0.6
301 - 350	5,676	93.7	97.4	99.0	99.5	0.5
351 - 400	1,889	84.6	93.3	98.4	99.3	0.7

E3 Sensor

Table 3b – E3 Sensor Percentage of Readings in Agreement Overall in the PROMISE Study

CGM System Glucose Range (mg/dL)	Paired CGM and YSI Reference	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent > 40/40% of Reference
Overall	12,034	87.3	93.9	98.6	99.6	0.4
40 - 60	574	91.6	96.5	98.6	99.3	0.7
61 - 80	1,178	89.7	93.8	98.9	99.8	0.2
81 - 180	5,078	85.1	93.2	98.5	99.6	0.4
181 - 300	3,493	87.0	93.7	98.4	99.6	0.4
301 - 350	1,191	93.3	96.8	99.2	99.6	0.4
351 - 400	520	87.3	93.8	98.7	99.6	0.4

Performance was evaluated at various points during the study. Tables 4a and 4b show both overall and point-in-time results on various days during sensor wear.

Primary Sensor

Table 4a – Primary Sensor Accuracy over Time in the PROMISE Study

Day Number	Number of Paired CGM-YSI	Mean Absolute Relative Difference (%)	Percent of CGM System Readings Within			
			Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference
Overall	49,613	9.1	85.6	92.9	98.0	99.3
Day 1	5,584	11.0	80.0	89.0	96.5	98.3
Day 7	2,724	9.6	83.1	91.3	98.2	99.3
Day 30	6,488	8.4	88.4	94.8	98.7	99.6
Day 60	6,345	7.7	90.5	95.8	99.1	99.8
Day 90	6,039	8.2	88.7	94.4	98.4	99.6
Day 120	5,173	9.2	85.5	93.3	98.3	99.5
Day 150	4,227	9.6	85.5	92.7	97.9	99.1
Day 180	4,517	10.4	81.0	89.6	96.2	98.3

E3 Sensor

Table 4b – E3 Sensor Accuracy over Time in the PROMISE Study

Day Number	Number of Paired CGM-YSI	Mean Absolute Relative Difference (%)	Percent of CGM System Readings Within			
			Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference
Overall	12,034	8.5	87.3	93.9	98.6	99.6
Day 1	1,203	11.2	78.6	87.4	96.5	99.3
Day 7	792	10.0	81.9	88.0	94.7	98.5
Day 30	1,523	8.2	85.8	93.4	98.2	99.3
Day 60	1,365	8.6	87.9	94.2	98.6	99.8
Day 90	1,418	7.0	93.1	97.1	99.8	99.9
Day 120	1,195	8.4	89.2	96.1	99.6	99.9
Day 150	1,285	8.8	84.0	91.9	99.5	99.9
Day 180	1,413	7.4	93.1	98.0	99.3	99.7

Alert Performance

The tables in this section show an alert performance assessment. The Confirmed Event Detection Rate shows the percentage of time the CGM System confirmed the reference value by presenting an alert within a 15 minute window of a reference value beyond the alert setting threshold. The Missed Detection Rate shows the percentage of time the CGM System did not present an alert within a 15 minute window of a reference value beyond the alert setting threshold. The True Alert Rate shows the percentage of time the alert from the CGM system was confirmed by a reference value within a 15 minute window of the alert being presented. The False Alert Rate shows the percentage of time the alert from the CGM system was not confirmed by a reference value within a 15 minute window of the alert being presented.

Primary Sensor

Table 5a – Primary Sensor High and Low Glucose Alert Performance (Threshold and Predictive) in the PROMISE Study

Alert Setting (mg/dL)		Confirmed Event Detection Rate	Missed Detection Rate	True Alert Rate	False Alert Rate
Low Alert	60	87%	13%	68%	32%
	70	93%	7%	87%	13%
	80	96%	4%	90%	10%
	90	97%	3%	90%	10%
High Alert	120	99%	1%	96%	4%
	140	99%	1%	95%	5%
	180	99%	1%	94%	6%
	200	98%	2%	93%	7%
	220	98%	2%	92%	8%
	240	98%	2%	92%	8%
	300	92%	8%	87%	13%

E3 Sensor

Table 5b – E3 Sensor High and Low Glucose Alert Performance (Threshold and Predictive) in the PROMISE Study

Alert Setting (mg/dL)		Confirmed Event Detection Rate	Missed Detection Rate	True Alert Rate	False Alert Rate
Low Alert	60	90%	10%	73%	27%
	70	94%	6%	84%	16%
	80	97%	3%	87%	13%
	90	98%	2%	89%	11%
High Alert	120	99%	1%	96%	4%
	140	99%	1%	95%	5%
	180	99%	1%	93%	7%
	200	99%	1%	93%	7%
	220	98%	2%	92%	8%
	240	98%	2%	91%	9%
	300	92%	8%	87%	13%

Rate of Change Trend Agreement

The shaded areas in Tables 6a and 6b show agreement between the CGM glucose trends and the YSI reference trends while glucose is trending at different rates (mg/dL per minute). As an example, when glucose is trending at a rate of between -1 and 1 mg/dL/minute, CGM glucose trends are in agreement with the reference trends 90% of the time for both the primary sensor and the E3 sensor.

Primary Sensor

Table 6a – Primary Sensor Rate of Change Trend Agreement in the PROMISE Study

CGM Trend (mg/dL/min)	Reference Rate of Change (mg/dL/min) Percent of Matched Pairs in Each Reference Trend Range for Each CGM ROC Range					
	< -2	[-2, -1)	[-1, 1]	(1, 2]	> 2	Total
< -2	17%	41%	41%	1%	0%	756
[-2, -1)	3%	31%	66%	1%	0%	2,963
[-1, 1]	0%	4%	90%	5%	1%	35,777
(1, 2]	0%	1%	52%	37%	10%	3,263
> 2	0%	0%	28%	38%	33%	1,635
						44,394

E3 Sensor

Table 6b – E3 Sensor Rate of Change Trend Agreement in the PROMISE Study

CGM Trend (mg/dL/min)	Reference Rate of Change (mg/dL/min) Percent of Matched Pairs in Each Reference Trend Range for Each CGM ROC Range					
	< -2	[-2, -1)	[-1, 1]	(1, 2]	> 2	Total
< -2	24%	35%	41%	0%	0%	163
[-2, -1)	4%	36%	59%	0%	0%	824
[-1, 1]	0%	4%	90%	5%	1%	8,716
(1, 2]	0%	1%	46%	42%	11%	896
> 2	0%	0%	24%	40%	35%	336
						10,935

Calibration Stability Agreement

Tables 7a and 7b compare the percentage of sensor glucose values to the YSI reference at various time points after a calibration entry. As an example, in tables 7a and 7b, 84.5% of the primary sensor values and 89.7% of the E3 sensor values were within 15 mg/dL (for reference readings of 80 mg/dL or less), and within 15% (for reference readings over 80 mg/dL) of the reference value 8 to 10 hours after a calibration entry.

Primary Sensor

Table 7a – Primary Sensor Calibration Stability Agreement in the PROMISE Study

Time from Calibration	Number of Paired CGM-YSI	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent > 40/40% of Reference
(0, 2) Hours	10,303	87.4	94.2	98.4	99.4	0.6
[2, 4) Hours	8,824	85.8	92.8	98.1	99.3	0.7
[4, 6) Hours	6,955	86.8	93.5	98.2	99.3	0.7
[6, 8) Hours	5,318	85.0	92.5	97.8	99.2	0.8
[8, 10) Hours	4,161	84.5	92.5	98.4	99.5	0.5
[10, 12) Hours	4,164	83.7	90.8	97.6	99.2	0.8
[12, 14) Hours	2,269	82.9	92.0	97.6	99.1	0.9
[14, 16) Hours	1,441	83.3	91.1	96.5	98.0	2.0
[16, 18) Hours	1,297	87.7	94.4	97.6	99.2	0.8
[18, 20) Hours	1,242	87.2	94.4	98.8	99.8	0.2
[20, 22) Hours	1,443	84.2	92.9	97.9	99.4	0.6
[22, 24) Hours	1,682	83.2	92.4	97.7	99.0	1.0
[24, 26) Hours	509	82.3	91.4	97.4	98.2	1.8
[26, 28) Hours	5	60.0	100.0	100.0	100.0	0.0

E3 Sensor

Table 7b – E3 Sensor Calibration Stability Agreement in the PROMISE Study

Time from Calibration	Number of Paired CGM-YSI	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent > 40/40% of Reference
(0, 2) Hours	2,638	88.8	94.1	98.7	99.9	0.1
[2, 4) Hours	1,905	87.2	94.4	98.5	99.5	0.5
[4, 6) Hours	1,404	85.3	93.3	98.1	99.3	0.7
[6, 8) Hours	1,043	83.0	91.5	97.7	99.6	0.4
[8, 10) Hours	1,041	89.7	93.9	98.8	99.6	0.4
[10, 12) Hours	1,091	87.8	94.1	97.7	99.5	0.5
[12, 14) Hours	590	85.8	93.4	99.0	99.3	0.7
[14, 16) Hours	440	82.7	91.8	100.0	100.0	0.0
[16, 18) Hours	379	87.6	93.9	99.5	100.0	0.0
[18, 20) Hours	370	90.0	97.0	98.4	99.7	0.3
[20, 22) Hours	436	88.3	94.5	99.5	99.8	0.2
[22, 24) Hours	522	89.7	96.2	99.4	99.8	0.2
[24, 26) Hours	168	93.5	98.2	99.4	100.0	0.0
[26, 28) Hours	7	100.0	100.0	100.0	100.0	0.0

Sensor Life

Sensor life measured the percentage of sensors being able to function through the intended 180 day duration. In the PROMISE study, 90% of E3 sensors functioned through the 180 day period. Mean number of days was 175. Of the primary sensors, 65% functioned through the 180 day period.

Safety

The PROMISE study lasted for 180 days, and the number of related adverse events was recorded. The system was well tolerated in the study. During the study's 31,373 sensor wear days, there were no unanticipated adverse events. Fifty-nine adverse events were reported in 37 participants. None of the adverse events resulted in hospitalization.

Table 8 – Adverse Events (All Subjects, n = 181)

Event Type	Number of Events	Number of Subjects (% of Subjects)
	59	37 (20.4)
Skin irritation, adhesive patch location or insertion site (including erythema, pruritus, rash, contact dermatitis, seroma)	16	11 (6.1)
Skin atrophy	4	4 (2.2)
Hypopigmentation	4	3 (1.7)
Infection (procedure related)	2	2 (1.1)
Infection (not procedure related)	1	1 (0.6)
Bruising	19	11 (6.1)
Bleeding	3	3 (1.7)
Pain	7	6 (3.3)
Arm Numbness	1	1 (0.6)
Tremor	1	1 (0.6)
Adhesive Skin Closure Strips did not hold	1	1 (0.6)

20. Technical Specifications

Sensor

Characteristic	Description
Dimensions	Length: 18.3 mm Diameter: 3.5 mm
Materials	Homopolymer polymethylmethacrylate (PMMA), Hydroxyethylmethacrylate (HEMA) based Hydrogel, Platinum, Silicone, Dexamethasone Acetate, epoxy 301-2
Glucose Range	40 - 400 mg/dL
Sensor Life	Up to 180 days
Calibration	Commercially available self-monitoring blood glucose meter
Calibration Range	40 - 400 mg/dL
Sterilization	Sterile by Ethylene Oxide

Smart Transmitter

Characteristic	Description
Dimensions	Length: 37.8 mm Width: 48.0 mm Thickness: 9.1 mm
Materials	Body: polycarbonate
Weight	13.4 g
Power Supply	Rechargeable lithium polymer batteries (not replaceable)
Operational Conditions	5 - 40 °C (41 - 104 °F)
Operational Life	12 months
Storage Conditions	0 - 35 °C (32 - 95 °F)
Moisture Protection	IP67: submerged up to 1 meter of water for up to 30 minutes
Protection Against Electrical Shock	Type BF applied part
Charge time using AC adapter	A fully charged battery with this transmitter will last approximately 5 days. Charging for 15 minutes each day will ensure the transmitter always has at least 10% or ~24 hours of power.
Communication Distance	Between app and smart transmitter is up to 24.9 feet Wireless communication to the app will not function well when communicating through water. The range will decrease if you are in a bathtub, water bed, pool, etc.
Cabin Pressure	700 hPa to 1060 hPa
Relative Humidity Range (non-condensing)	15% to 90%
Altitude	10,000 ft

Power Supply and Charger

Characteristic	Description
Class	II
Input	AC Input, 100-240Vac, 50/60Hx, 0.3-0.15A
DC Output	5V DC, 1A (5.0 watts)

USB Cable* for Charging and Downloading

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

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

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

Transmitter Electromagnetic Immunity Specifications

Immunity Test	Immunity Test	Transmitter Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 15 kV Air	± 8 kV Contact ± 15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power Frequency (110VAC/60Hz, 230VAC/50 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

The Eversense E3 CGM System is intended to be used in the electromagnetic environment detailed in the table below. Users of the System should ensure it is used according to these specifications.

System Electromagnetic Immunity Specifications

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

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Eversense E3 CGM System is used exceeds the applicable RF compliance level above, the Eversense E3 CGM System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Eversense E3 CGM System.

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

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Eversense E3 CGM Mobile System is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the System should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	The Eversense E3 CGM System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Eversense E3 CGM System is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

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

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

Symbols on the Eversense CGM Mobile App

Symbol	Explanation
	**Glucose Alert** Appears when the glucose is above the high glucose alert range and below the low glucose alert range. The icon appears in the **ALERT HISTORY** screen.
	**Predicted Low or Rate Falling Alert** Indicates a Rate Falling or Predicted Low Alert occurred. The icon appears in the **ALERT HISTORY** screen and on the home screen trend line.
	**Predicted High or Rate Rising Alert** Indicates a Rate Rising or Predicted High Alert occurred. The icon appears in the **ALERT HISTORY** screen and on the home screen trend line.
	**Empty Battery Alert** Appears when the smart transmitter battery is empty.
	**Low Battery Alert** Appears when the smart transmitter battery is less than 10% charged.
	**Smart Transmitter/Sensor Alert** The icon appears in the **ALERT HISTORY** screen.
	**Smart Transmitter/Sensor Notifications** Appears when there are notifications related to the smart transmitter or sensor.
	**Calibration Alert** Appears when there are calibration-related alerts.
	**Calibration Notification** Appears in **ALERT HISTORY** when there are calibration-related notifications. The icon also appears on the My Glucose trend line and Event Log when a manual BG entry is logged.

Symbols on the Eversense CGM Mobile App (continued)

Symbol	Explanation
	**Calibration Accepted** Appears on the glucose trend line and **EVENT LOG** when a calibration is entered and accepted.
	**Calibration in Progress** Appears on the glucose trend line and the Event Log during the ~15 minutes while a calibration is in progress. The icon will turn either red, black or blue when calibration is no longer in progress.
	**Calibration Incomplete** Appears on the glucose trend line and the Event log when not enough data is not collected to complete the calibration. For example, when the transmitter is removed from over the sensor during the ~15 minute calibration period.
	**Calibration Cannot be Used** Appears on the glucose trend line and the Event Log when a calibration has been entered that cannot be used. For example, the value entered is less than 40 mg/dL or more than 400 mg/dL. In this case, the calibration value is stored as a manual BG entry.
	**System Connection Successful** Appears when the smart transmitter is connected to the smartphone and the sensor is linked to the smart transmitter. The bars indicate the strength of the connection.
	**Transmitter and Sensor Connection** Appears before a transmitter is linked to a sensor and when the connection between a transmitter and sensor is interrupted.
	**Transmitter and Mobile App Connection** Appears when the BLE connection between the transmitter and mobile app is interrupted.

Symbols on the Eversense CGM Mobile App (continued)

Symbol	Explanation
	**Multiple Alerts (more than one alert or event)** Appears when there are two or more alerts or events in a short interval.
	**Event Icons** Appear on the glucose trend line and in the **EVENT LOG** after an event is entered. The events that can be entered are:  Glucose  Insulin  Exercise  Meals  Health
	**Temp Profile** Appears when the Temp Profile is active.
	**Do Not Disturb (DND)** Appears when the DND setting is active.
	**Battery Power Icons** Indicates approximate battery power remaining.  No battery power remaining  Full battery power remaining

Symbols on Packaging and Devices

Symbol	Explanation
	Consult accompanying documents
	Caution, consult accompanying documents
	Use by
	Manufacturer
	Date of manufacture
	Storage temperature limits
	Lot number
	Universal Serial Bus (USB)
	Part number

Symbol	Explanation
	Serial number
	Type BF Applied Part
	Non-ionizing electromagnetic radiation
	Not made with natural rubber latex
FCC ID	FCC ID is assigned to all devices subject to certification
	Non-sterile
	Magnetic Resonance Imaging (MRI) procedures are contraindicated for the smart transmitter
	No known hazards for leaving the sensor inserted in use with MR with a static magnetic field of 1.5T or 3.0T

Symbols on Packaging and Devices (continued)

Symbol	Explanation
	European Union WEEE Directive 2012/19/EU
	Single use only
	Do not re-sterilize
	Do not use if package is damaged
STERILE EO	Sterilized using Ethylene Oxide
STERILE EO	Single sterile barrier: Sterilized using Ethylene Oxide
Rx only	U.S. (Federal) law restricts the sale of the Eversense E3 CGM System to sale by or on the order of a physician
	Follow instructions for use

Symbol	Explanation
	Single patient, multiple use
	Distributor

Eversense E3 Smart Transmitter Limited Warranty

1. Coverage and duration of limited warranty.

Senseonics, Incorporated ("Senseonics") warrants to the original patient end user ("you") of the Eversense E3 Smart Transmitter (the "Smart Transmitter") that the Smart Transmitter shall be free from defects in material and workmanship under normal use for a period of one year (365 days) commencing on the date that you first received the Smart Transmitter from your health care provider ("Limited Warranty Period"). This warranty gives you specific legal rights, and you may also have other rights which vary from jurisdiction to jurisdiction. This limited warranty is made on the condition that you provide Senseonics with written notice of any defects in material and/or workmanship immediately upon discovery, and provided that Senseonics determines that your claim is due to defects in original material and/or workmanship. If Senseonics provides you with a replacement Smart Transmitter pursuant to the terms of this limited warranty, any remaining warranty on the original Smart Transmitter will transfer to the replacement Smart Transmitter, the warranty period for the replacement Smart Transmitter shall end on the one year anniversary of the date that you first received the Smart Transmitter from your health care provider, and this warranty will be void with respect to the original Smart Transmitter.

2. Exclusions to the limited warranty.

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

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

3. Senseonics' obligations under the limited warranty.

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

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

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

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About Bluetooth®

Bluetooth® is a type of wireless (RF) communication. Mobile devices like smartphones use Bluetooth® technology as do many other devices. Your smart transmitter uses Bluetooth® Smart to pair with the mobile device and to send results to the app.

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FCC Information

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

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

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

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

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

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

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

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