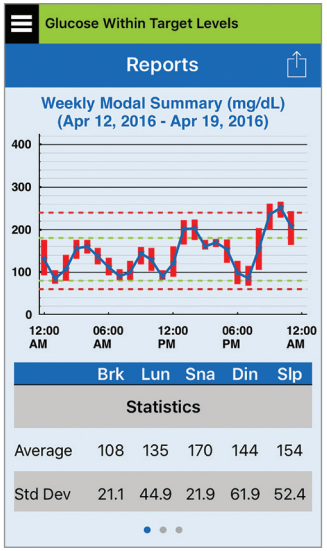
Weekly Modal Summary

This report shows your last seven days of glucose readings summarized in a 24-hour line graph format to help find patterns during the day.

- The **blue line** is the average of the last seven days of your readings in an hour time block.
- The **red bars** show the highest and lowest actual readings in the same hour time block.
- The **red horizontal dotted lines** are your pre-set High and Low Glucose Alert levels.
- The **green horizontal dotted lines** are your pre-set High and Low Glucose Target levels.

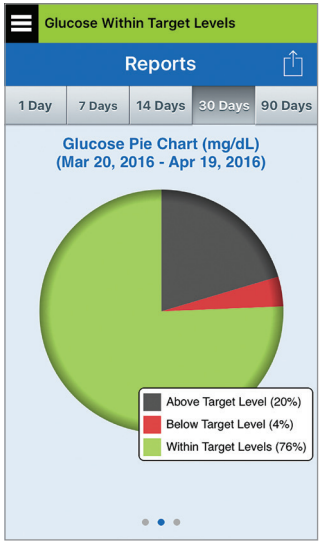
This report also provides summary statistics (average readings, standard deviation of readings), glucose target performance (percent within, above and below glucose target levels), and glucose reading highs and lows (percent of readings that fall within the low and high glucose target levels). The information is shown based on mealtime slots.

Note: To review or change the mealtime slots, please see *Setting Mealtimes Schedule*.



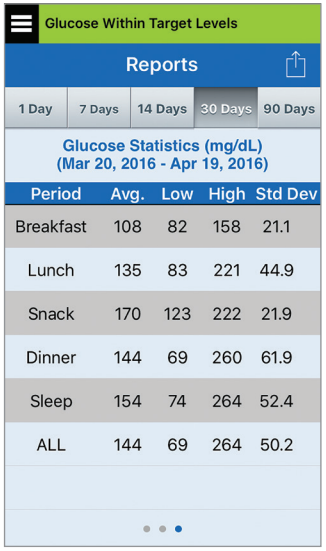
Glucose Pie Chart

This report shows in graphical format what percent of your readings within a given time period are within, below or above your Glucose Target levels. You can choose the last 1, 7, 14, 30 or 90 days.



Glucose Statistics

This report shows your average, low and high glucose readings, along with standard deviation within a mealtime slot period. You can choose the last 1, 7, 14, 30 or 90 days.



Period	Avg.	Low	High	Std Dev
Breakfast	108	82	158	21.1
Lunch	135	83	221	44.9
Snack	170	123	222	21.9
Dinner	144	69	260	61.9
Sleep	154	74	264	52.4
ALL	144	69	264	50.2

Eversense Data Management Software (DMS) Program

The Eversense DMS Program is a web-based application that enables patients, caregivers, and health care professionals to view and analyze glucose data that has been transmitted from the Eversense Smart Transmitter or application.

This program is offered at no cost to users of the Eversense CGM System. To learn about the Eversense DMS Program, go to www.eversensediabetes.com.

IMPORTANT: EVERSENSE DATA MANAGEMENT SYSTEM DOES NOT PROVIDE MEDICAL ADVICE. CHANGES TO YOUR TREATMENT PLAN SHOULD ONLY BE MADE BY YOUR HEALTH CARE TEAM.

Share My Data

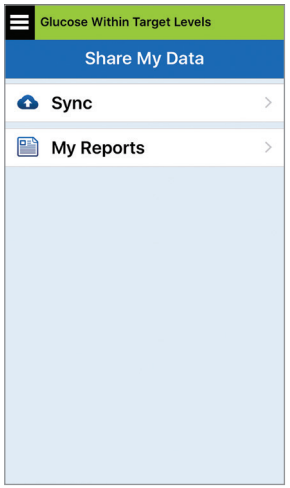
After authorizing your glucose readings to sync with the Eversense DMS, your results will auto sync every 2 hours as long as you stay logged into the app. You can choose to opt out of auto sync.

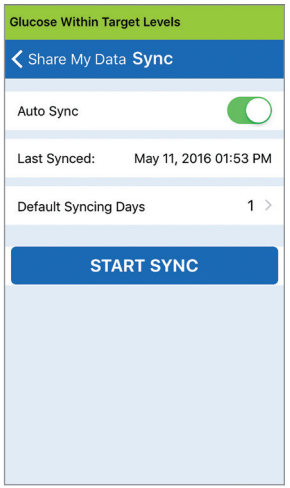
- Tap **Sync** on the **SHARE MY DATA** screen.
- Tap the Auto Sync button to off.

You may also choose to export your glucose readings in a CSV-file format.

Tap **Menu** > **Share My Data** > **My Reports**

- Select the number of days of your glucose readings you want to export then tap **Done**.
- Tap **Export**.
- Email the CSV-file format by tapping the email icon on the top right hand corner.



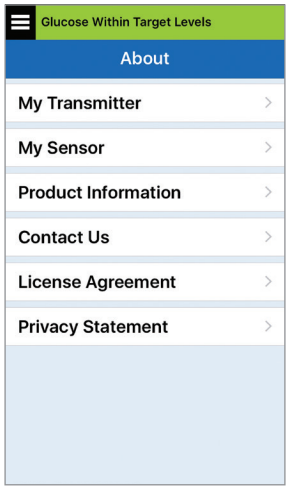


12. Product and General Information on the App

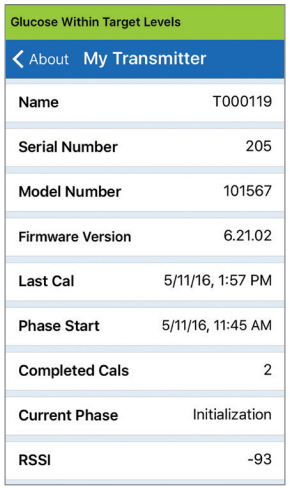
This section describes the information available from the About section of the Main Menu.

You can view product information about your smart transmitter, your sensor and your Eversense mobile app.

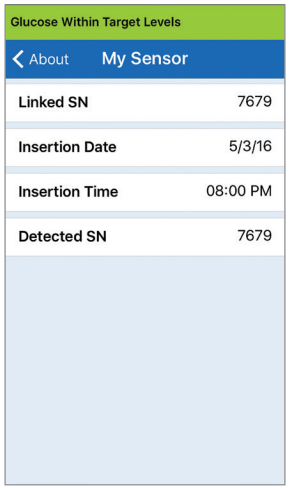
1. Tap **Menu > About** and then tap **My Transmitter, My Sensor** or **Product Information.**



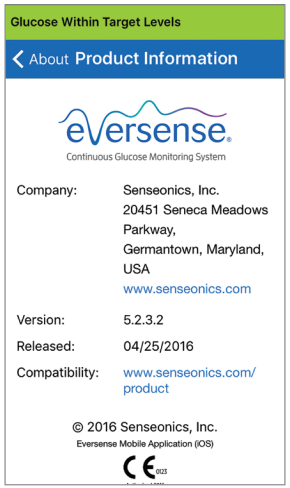
On the **MY TRANSMITTER** screen, you can find information that includes the serial number, calibration information and battery level.



On the **MY SENSOR** screen, you can view the sensor serial number and insertion details.

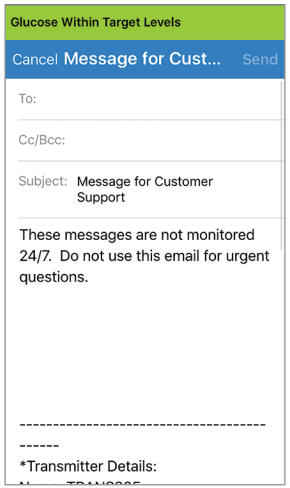


On the **PRODUCT INFORMATION** screen, you can view information about the mobile app software version and Senseonics, Inc., the manufacturer of the Eversense CGM System.



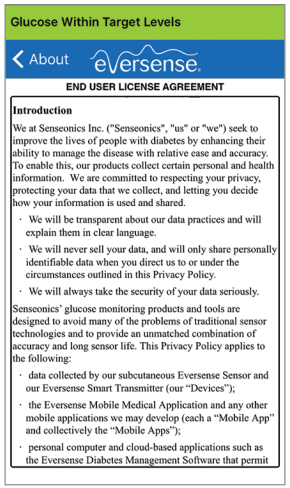
You can also send feedback or view the End User License Agreement and Privacy Policy from the About menu.

- Tap **Contact Us** to send an email to Senseonics, Inc.



IMPORTANT: This email is not monitored 24/7. **DO NOT** use this email for health-related or or any urgent issues.

To read the End User License Agreement and the Privacy Policy, tap either option.



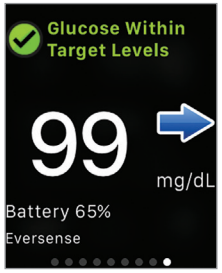
13. Viewing Eversense Data on the Apple Watch

You can view a snapshot of your Eversense CGM data on your Apple Watch. Once you've downloaded and installed the Eversense mobile app on your mobile device, follow the Apple Watch instructions for adding the app to your watch.

Glance View

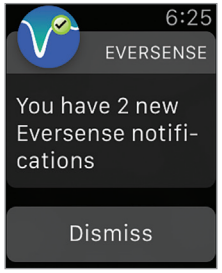
If you have already set the Eversense App on your mobile device to *Show in Glances* under the Apple Watch settings, simply swipe up on the watch **HOME** screen to display the Eversense App Glance View.

Status bar information, your current glucose value with trend arrow, and the battery life remaining in your smart transmitter appear.

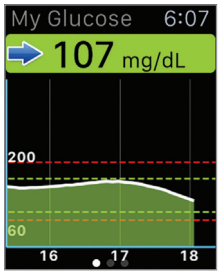


To access additional app features, tap the **Eversense** icon on your watch **HOME** screen to open the app.

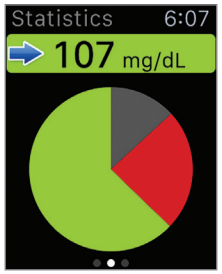
You can also access the **MY GLUCOSE** screen if you turn on notifications from Eversense in your Apple Watch settings. When you receive a notification, you can also tap on the message to see the **MY GLUCOSE** screen.



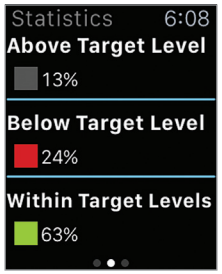
The **My Glucose** screen shows your current glucose with trend arrow, and a trend graph of your last three hours of CGM data.



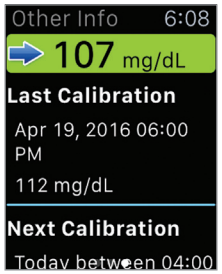
Swipe left to the next screen showing a pie chart of your total time within and outside your target range for the past 24 hours.



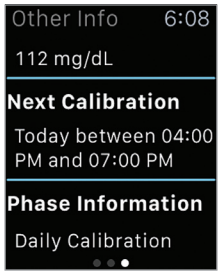
Swipe up to display the same data shown as percentages.



Swipe left to the next screen showing your current glucose with trend arrow, and the date, time and BG value for your last calibration.



Swipe up to display your next scheduled calibration time, and the current system calibration phase.



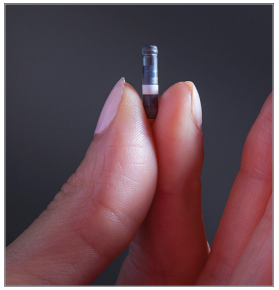
14. About the Sensor

This section describes the Eversense Sensor and how it is inserted by your physician.

The Eversense Sensor is a miniaturized fluorometer that uses fluorescent intensity to measure glucose in interstitial fluid. The sensor is implanted subcutaneously (under the skin) on the upper arm, leaving no part of the sensor protruding from the skin. The sensor remains in place and provides CGM measurements for up to 90 days.

The sensor is encased in a biocompatible material and utilizes a unique fluorescent, glucose indicating polymer. A light emitting diode embedded in the sensor excites the polymer, and the polymer then rapidly signals changes in glucose concentration via a change in light output. The measurement is then relayed to the smart transmitter. Measurements are completed automatically and require no action by the user.

The sensor is approximately 3.3 mm x 18.3 mm and has a silicone ring that contains a small amount of dexamethasone acetate, an anti-inflammatory steroid drug. The dexamethasone acetate minimizes inflammatory responses, very similar to common medical devices, such as pacemakers.



Eversense Sensor

Insertion Steps

Your physician 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 that is comfortable for you to wear the sensor and smart transmitter for the entire 90 day period. 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.

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 replacing 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 *Secure the Smart Transmitter over Inserted Sensor.*) 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 physician 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-stip (sutures may be used depending on provider's preference).

15. Travel

This section describes the safety issues when traveling with your Eversense 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 CGM System is safe for use on U.S. commercial airlines. The Eversense 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.

IMPORTANT: When traveling to different time zones, check your calibration reminder settings to ensure the times are convenient for you in the local time zone.

16. Troubleshooting

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

Smart Transmitter

Q: How do I turn my smart transmitter OFF?

A: Press and hold the smart transmitter power button for 5 seconds. Release the button when the smart transmitter begins to vibrate.

Q: How do I turn my smart transmitter ON?

A: Press and hold the smart transmitter power button for 5 seconds. Release the button when the smart transmitter begins to vibrate.

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.

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 connected to your mobile device.
- Check that the **Do Not Disturb** is disabled by tapping **Menu** > **Settings** > **System**.
- Check that your smart transmitter has enough battery power and charge if necessary.

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

Q: Can I use the same adhesive patch more than once a day?

A: The individual adhesive patch is intended to be used for a 24-hour period.

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.

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 about a day and half.

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

A: It takes approximately 15 minutes to fully charge a smart transmitter when plugged into a wall outlet.
It may take longer if charging via a computer USB port.

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

A: There are three ways to check battery status:

1. Tap **Menu** > **About** > **My Transmitter**. Scroll down to the Battery Level line that indicates amount of battery power left.
2. Check the battery symbol in the upper right corner on the **MY GLUCOSE** screen. A red battery icon indicates the smart transmitter battery is empty.
3. Power ON the smart transmitter. Press and release the smart transmitter power button. An orange LED on the smart transmitter indicates low battery. A green LED indicates the battery is at least 10% charged.

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.

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. Press the smart transmitter power button three times to get it into "Discoverable" mode.
3. When the smart transmitter blinks green and orange, tap the smart transmitter ID on the **PAIR YOUR TRANSMITTER** 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.
7. Tap **Next**.

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 the Bluetooth setting on your mobile device is ON and the smart transmitter's name or serial number appears on the device list.
- The condition may only be temporary. Tap **Menu** > **Connect**. If your smart transmitter name indicates **Disconnected**, tap the smart transmitter name to connect manually.
- Your smart transmitter and mobile device may be out of wireless range. Move your mobile device closer to the smart transmitter.
- Your smart transmitter may be turned off, out of battery power or is currently being charged. You may need to restart the Bluetooth (BLE) function on the smart transmitter by following the steps below.

1. Power off the smart transmitter – Press and hold the power button for 5 seconds and wait for the vibration to confirm it is powered off.
2. Wait 2 seconds and press the power button three times to restart BLE. **(Note: When doing a BLE restart, do not remove/forget the paired device via your mobile device's Bluetooth Settings.)**
3. Press the power button 3 times again to place the smart transmitter in discoverable mode and pair with your mobile device. Tap **Menu** > **Connect** to see if your smart transmitter is connected. If not connected, tap to select your smart transmitter from the list.

If these steps do not resolve the problem, you may need to go to the Bluetooth Settings feature on your mobile device and unpair or forget the smart transmitter and then press the smart transmitter power button 3 times to re-pair. If the problem still exists, you may need to reset your smart transmitter.

Q: How do I reset my smart transmitter?

A: Follow the steps below.

1. Connect the smart transmitter to the USB cable and adapter that came with your 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.)
2. Press and hold the smart transmitter's power button for about 10 seconds until it begins to vibrate. Do not release the power button until the vibration stops.
3. Once the vibration stops, release the power button. The orange LED should be on. Quickly (within about 2 seconds) unplug the smart transmitter from the USB cable. The LED should be off.
4. To verify the first part of the reset is complete, press the power button multiple times. The LED should not light up. If the LED lights up, repeat steps 1 through 4.
5. After 30 seconds, reconnect the transmitter to the USB cable. The smart transmitter will complete a series of self-tests that lasts about 90 seconds. During this time, the LED will blink green and orange. When the self-test is complete, the transmitter will vibrate and the LED (either green or orange) will stay on. If the self-test doesn't complete, repeat steps 1 through 5.
6. Disconnect the smart transmitter from the USB cable and proceed with pairing. Once paired, the system will be in the Initialization Phase. If you are unable to complete the reset, contact Customer Support.

Q: Can other people connect to my smart transmitter?

A: The Eversense 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 30 minutes 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 "Discoverable" (Pairing) mode?

A: Discoverable 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: The app may find other Bluetooth enabled devices in the vicinity. 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 unlink the old one and link the new one to my sensor?

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. Follow the steps in this User Guide for pairing the new smart transmitter with the app and linking it to your sensor.

Calibration

Q: Will doing more than 2 fingerstick calibrations per day affect the accuracy of the system?

A: The accuracy will not be negatively impacted if you do more than the required 2 calibrations per day.

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.
- When you cannot get sensor glucose readings.
- Any time you have reached your low or high glucose alert levels.
- Any time you have symptoms of low or high blood glucose.
- Any time your symptoms are not consistent with the sensor glucose readings.
- Prior to making treatment decisions, such as dosing insulin or consuming carbohydrates.

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 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.
- It is not time for your calibration.

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.
- The blood glucose reading entered is significantly different from the last sensor glucose reading.

If the calibration is rejected, you must re-calibrate. You may need to wait up to 60 minutes before re-calibrating.

Q: How do I change my scheduled morning and evening Daily Calibration times?

A: Tap **Menu** > **Settings** > **Daily Calibration**. Select the morning or evening time to change. Morning and evening times must be set a minimum of 10 hours apart and maximum of 14 hours apart.

Q: Can I calibrate earlier than my scheduled time?

A: You can calibrate up to 2 hours before the scheduled time. If you miss your scheduled time, the system will send an hourly calibration prompt. To view the next available calibration time, tap **Menu** > **Calibrate**. The next scheduled calibration time is displayed.

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 CGM System has two types of Calibration Phases, the Initialization Phase and the Daily Calibration Phase. Initialization Phase begins 24 hours after sensor insertion and requires 4 fingerstick blood glucose tests for calibration. The Daily Calibration Phase occurs after the Initialization Phase and requires 2 daily calibrations (morning and evening) for the life of the sensor.

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: 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.

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 physician. If you need to change your glucose alert settings, tap **Menu** > **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 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**. You should immediately perform a fingerstick blood glucose test to confirm your glucose value.

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. You should immediately perform a fingerstick blood glucose test to confirm your glucose value.

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.

Glucose Readings

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

A: The Eversense 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). On average, glucose levels in ISF lag behind glucose levels in blood by several minutes.

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.
- Sensor Suspend Alert.

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

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 gray instead of blue.

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 displayed in gray.

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: Visit www.eversensediabetes.com for instructions on updating the app software.

Q: What devices are compatible with the Eversense App?

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

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 smart transmitter will stop providing vibratory alerts for non-critical alerts. Critical alerts will still be provided via on-body vibe alerts. All alerts and notifications will continue to be provided on 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.

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.

Sensor

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

A: The Eversense CGM System was only tested in the upper arm during clinical studies.

Q: When do I need to replace my sensor?

A: Your sensor lasts up to 90 days. You will receive periodic notices (30, 14, 7, 3, 2, and 1 day prior) to remind you when the sensor needs to be replaced. Contact your physician to schedule a sensor replacement.

Q: Can I extend the 90 day life of the sensor?

A: The sensor will no longer provide glucose readings after 90 days of wear and must be replaced.

Q: Where can I find the sensor serial number?

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

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.

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.
- Your data is being uploaded to your Eversense DMS account.

17. Device Performance

This section lists Device Performance Characteristics.

Clinical Study Performance

The performance of the Eversense CGM System was evaluated in a multi-site, non-randomized clinical study. Adult (18 years and older) subjects with diabetes were enrolled at 7 different sites in 3 different countries. Each subject had 2 separate sensors inserted, one in each upper arm. One sensor was used to display glucose data on the subject's mobile device and the other sensor was used to collect glucose data but was not displayed to the subject. Forty-four (44) subjects were followed for 90 days following the insertion of the sensor. Accuracy assessments were made at various points during the study, and subjects were asked to report any adverse events throughout the study. The Mean Absolute Relative Difference (MARD) measured throughout the 90 days was 11.4% for glucose values over 75 mg/dL.

Overall System Performance Compared to YSI

The study demonstrated that 83.8% of overall CGM System readings were within ± 20% of YSI values, 93.9% were within ± 30% of YSI values, and 97.5% were within ± 40% of YSI values. The chart below provides a percentage breakdown by glucose range.

Difference between CGM System readings and YSI Measurements by Glucose Level

YSI Glucose Range (mg/dL)	Number of paired CGM-YSI Readings	Percent within 20% of YSI	Percent within 30% of YSI	Percent within 40% of YSI
≤ 70*	422	80.6%	93.4%	96.7%
71-180	6633	80.6%	92.2%	96.7%
> 180	3387	90.4%	97.3%	99.1%
Overall	10442	83.8%	93.9%	97.5%

*The absolute difference from the YSI reading is measured in mg/dL if the YSI reading is ≤ 70 mg/dL.

Although device measurement errors may have been present in either YSI or sensor readings, and interstitial values (sensor) are known to have time lags in responses to changing blood glucose levels compared to blood values (YSI), it was demonstrated that 80% or greater of differences were within 20%/20 mg/dL (20% for YSI values greater than 70 mg/dL, within 20 mg/dL for YSI values ≤ 70 mg/dL). The level of agreement increased to above 92% for differences within 30%/30 mg/dL and above 96% for differences within 40%/40 mg/dL.

Clarke Error Grid Analysis

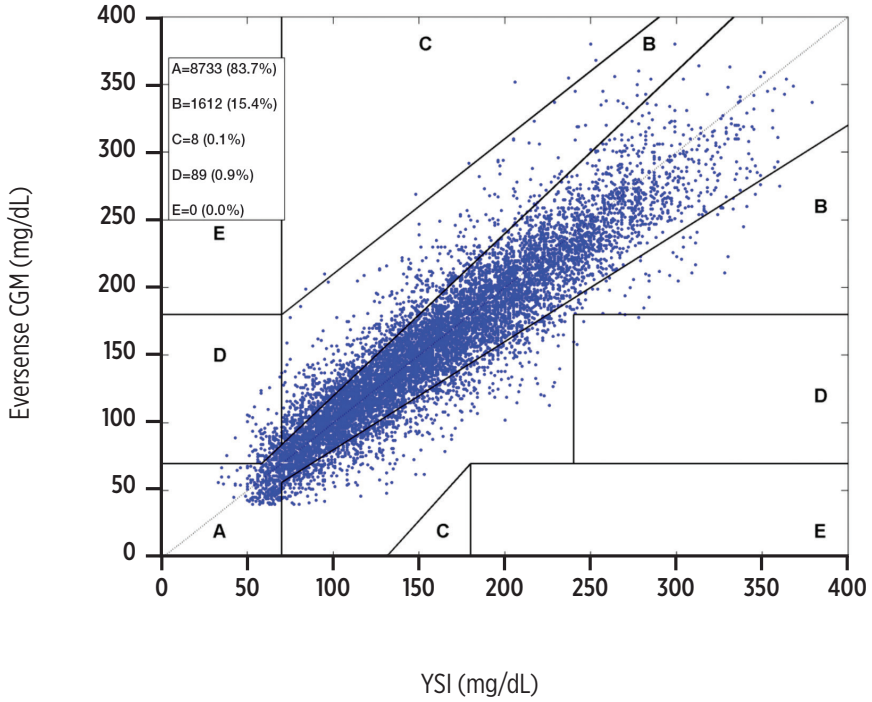
The Clarke Error Grid Analysis (EGA) is one of the standards for quantifying the accuracy of CGM systems. Clarke EGA measures accuracy by comparing subject glucose values taken from their CGM system to reference values taken in a lab.

Clarke EGA calculates accuracy by looking at the number and percentage of data points that fell into 5 "clinical risk" zones. Data is presented in both graph and chart formats.

- **Zone A** (no risk) contains CGM values that fell **within** ±20% of the reference values.
  - Zone A values are considered to be within the acceptable accuracy range of CGM systems.
- **Zone B** (no risk) contains CGM values that fell **outside** ±20% of the reference values.
  - Zone B values are not considered to be within the acceptable accuracy range, but their difference from the reference values would not lead a subject to making an inappropriate treatment decision.
- **Zone C** (low risk) contains CGM values that differed enough from the reference values that a subject might make an unnecessary treatment decision based on the CGM information.
- **Zone D** (medium risk) contains CGM values that were correctly identified as hypoglycemic or hyperglycemic by the reference system but not the CGM system.
  - Not correctly identifying a CGM value as hypoglycemic or hyperglycemic is a potentially dangerous situation.
- **Zone E** (high risk) contains CGM values that were incorrectly identified as hypoglycemic when the reference system correctly identified them as hyperglycemic (and vice versa).
  - Mistakenly identifying a CGM value as hypoglycemic when it is actually hyperglycemic (or vice versa) is a potentially dangerous situation.

Clarke Error Grid Scatterplot

Clarke Error Grid percentages were calculated by glucose range, and at certain "wear duration" points in the study.



Clarke Error Grid Accuracy by Glucose Level

YSI Glucose Range (mg/dL)	Number of paired CGM-YSI Readings	Clarke Score				
		A	B	C	D	E
≤70	422	77.2%	2.4%	0.0%	20.4%	0.0%
71-180	6633	80.6%	19.4%	0.0%	0.0%	0.0%
>180	3387	90.4%	9.4%	0.1%	0.1%	0.0%
Overall	10442	83.6%	15.4%	0.1%	0.9%	0.0%

Overall, 83.6% of CGM readings fell within zone A. This indicates CGM readings were in close agreement with reference values for the great majority of readings.

Clarke Error Grid Accuracy by Duration of Wear

Percent values are reported to single precision.

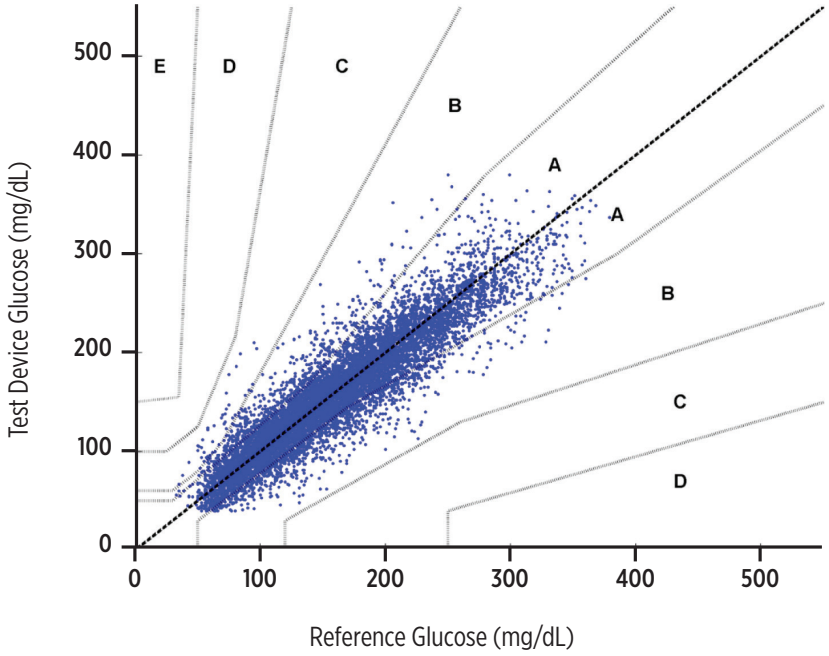
Period of Wear	Number of paired CGM-YSI Readings	Clarke Score				
		A	B	C	D	E
Days 1-30	6784	82.9%	16.0%	0.1%	1.1%	0.0%
Days 1-60	9529	83.5%	15.6%	0.1%	0.9%	0.0%
Days 1-90	10442	83.6%	15.4%	0.1%	0.9%	0.0%

Overall, 83.6% of CGM readings fell within zone A. This indicates CGM readings were in close agreement with reference values for the great majority of readings. Also, there were no real differences in zone A percentages as the duration of wear increased.

Consensus (Parkes) Error Grid Analysis

The Consensus Error Grid Analysis (CEG) is another standard for quantifying the accuracy of CGM systems. CEG is similar to the Clarke EGA in that it assigns the differences (errors) between the CGM system values and reference values to one of 5 “clinical risk” regions. But the CEG differs from the Clarke EGA in that the risk regions are continuous (A through E), whereas with the Clarke EGA they are not continuous (e.g., A is next to D).

CEG percentages were calculated for the total number of CGM readings.



Consensus Error Grid Accuracy by Glucose Level

Zone	Frequency	Percent
A	8922	85.4%
B	1481	14.2%
C	39	0.4%
D	0	0.0%
E	0	0.0%
Total	10442	100.0%

Overall, 85.4% of CGM readings fell within zone A. This indicates CGM readings were in close agreement with reference values for the great majority of readings.

17

Calibration Performance

Calibration performance looks at whether accuracy is affected by how much time has elapsed since the last system calibration with a blood glucose value.

CGM System Performance by Time Since Last Calibration

Time from Calibration	Number of paired CGM-YSI Readings	Percent within 20%	Percent within 30%	Percent within 40%
0-4 hrs	6043	83.1%	93.1%	97.0%
4-8 hrs	2479	85.0%	94.5%	97.7%
8-12 hrs	1663	83.6%	95.6%	98.6%
Total	10185	83.6%	93.8%	97.4%

Overall, there is no real difference in accuracy based on how long after the last blood glucose calibration the CGM readings were recorded.

Sensor Life

Sensor life measured how many days out of the intended 90-day duration period subjects were able to continue using the sensor to record CGM readings.

Overall, the analysis estimated that 87.5% of sensors remained functioning through 90 days.

Smart Transmitter Wear

Smart transmitter wear measured how many hours of the day subjects wore the smart transmitter. Overall, subjects wore their smart transmitters an average of 22.3 hours per day, with a median of 23.5 hours.

Safety

The number of adverse events were recorded over the first 90 days of the study period.

The CGM system was extremely well tolerated in the study. There were no serious adverse events reported that were related to use of the system or the insertion procedure. A total of 37 adverse events were reported in 26 subjects, all recorded as mild. Twelve (12) of these were related to the sensor insertion procedure. None of the adverse events resulted in hospitalization due to hypoglycemia, hyperglycemia, or ketoacidosis.

18. Technical Specifications

Sensor

Characteristic	Description
Dimensions	Length: 18.3 mm Diameter: 3.3 mm
Materials	Polymethylmethacrylate and Hydroxyethylmethacrylate (HEMA) Copolymer, and Polyethylene glycol diacrylate (PEGDA), Silicone, Dexamethasone acetate (NMT 1.0 mg), Platinum, epoxy 301-2
Glucose Range	40 - 400 mg/dL
Sensor Life	Up to 90 days
Calibration	Commercially available self-monitoring blood glucose meter
Calibration Range	40 - 400 mg/dL
Sterilization	Sterile by Ethylene Oxide
Altitude/Cabin Pressure	6561 to 9842 feet

Smart Transmitter

Characteristic	Description
Dimensions	Length: 3.9 cm Width: 4.2 cm Thickness: 1.4 cm
Materials	Body: polycarbonate
Operating Temperature	10 - 30 °C (50 - 86 °F)
Weight	22 g
Power Supply	Rechargeable lithium batteries (not replaceable)
Operational Conditions	5 - 40 °C (41 - 104 °F)
Operational Life	12 months
Storage Conditions	5 - 35 °C (41 - 95 °F)
Moisture Protection	IP22: dripping water when tilted up to 15 degrees
Protection Against Electrical Shock	Type BF applied part
Charge time using AC adapter	about 15 minutes
Communication Distance	Between app and smart transmitter is up to 24.9 feet

Electrical and Safety Standards

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	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 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	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Electrical and Safety Standards (continued)

The Eversense 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	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. **Recommended Separation Distance** d = 1.2 √P 150 kHz to 80 MHz d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with following symbol: 
Radiated RF IEC 61000-4-3	≥3 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 CGM System is used exceeds the applicable RF compliance level above, the Eversense 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 CGM System.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Eversense 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 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 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 as recommended in the next table, according to the maximum output power of the communications equipment. 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.

Electrical and Safety Standards (continued)

Minimum Recommended Distance Between Other RF Transmitters and the Eversense Smart Transmitter

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz d = 1.2 P½	80 MHz to 800 MHz d = 1.2 P½	800 MHz to 2.5 GHz d = 2.3 P½
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in feet can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture.

Note 1: At 80 MHz and 800 MHz, the separation distance for 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.

Symbols on the Eversense 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.
	**Falling Rate Alert** Appears when the glucose value is falling beyond a defined rate.
	**Rising Rate Alert** Appears when the glucose value is rising beyond a defined rate.
	**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.

Symbols on the Eversense Mobile App (continued)

Symbol	Explanation
	**Calibration Alert** Appears when there are calibration-related alerts.
	**Calibration Notification** Appears when there are calibration-related notifications.
	**Calibration Failure** Appears when the smart transmitter rejects the user-entered calibration value.
	**Connection Failure** Appears when the smart transmitter is disconnected from the smartphone or when the sensor is not linked to the smart transmitter.
	**Multiple alerts (more than one alert or event)** Appears when there are two or more alerts or events in a short interval.
	**Temp Profile** Appears when the Temp Profile is active.