Sensor Smart Transmitter Mobile App

eversense E3®

User Guide

A guide for using the Eversense E3
Continuous Glucose Monitoring System

Continuous Glucose Monitoring System

Eversense E3 Trademark

Contents

Glossary

Alert An alert warns you that a situation needs your attention and that you should respond/take appropriate action.

Blood Glucose Meter A commercially available device used to measure glucose using a blood sample from a fingerstick.

Bluetooth® A brand name for a wireless networking technology that uses short wave radio frequencies (RF) to connect mobile devices and other wireless electronic devices.

Calibration Blood glucose reading from a fingerstick sample entered in the Eversense App to check the accuracy of the system. With the Eversense E3 System, there are two phases: Initialization Phase during which 4 fingerstick tests are required, and the Daily Calibration Phase, during which a fingerstick test is required once or twice daily.

CGM Continuous Glucose Monitoring. Continuously monitoring your glucose levels from interstitial fluid every few minutes.

Contraindication A condition or circumstance in which a person should not use the device.

CT Computed Tomography

Do Not Disturb Mode (DND in the Eversense App) When enabled, the mobile app will stop displaying non-critical alerts, and the smart transmitter will stop providing vibratory notifications for non-critical alerts. Critical alerts will still be provided. Many mobile devices have a separate Do Not Disturb Mode. Consult the manufacturer's instructions for more information.

Electromagnetic Interference A strong field of energy generated by electrical or magnetic devices.

EULA End User License Agreement

Eversense App Software program that is installed on a mobile device and is used to display CGM glucose data sent from the smart transmitter.

Eversense DMS A web-based application compatible with the Eversense App where your glucose data is stored and can be viewed.

Eversense NOW A remote monitoring mobile application that allows you to share your glucose data with other people.

FAQ Frequently Asked Questions

Health Care Provider A physician, physician assistant, and/or nurse practitioner who has successfully completed the Eversense E3 CGM Insertion and Removal Training Program and has read and understood the Eversense E3 CGM Sensor Insertion and Removal Instructions.

"HI" Reading Indicates a sensor glucose reading is > 400 mg/dL.

Hyperglycemia An episode of high blood glucose.

Hypoglycemia An episode of low blood glucose.

Interstitial Fluid (ISF) The fluid between cells in the body. The Eversense E3 CGM measures glucose from an interstitial fluid sample, versus glucose in a blood sample obtained from a fingerstick.

Jailbroken Device A device (iPhone or iPod) that has been modified to remove the controls and limits set by the original manufacturer.

LED Light Emitting Diode

Linked Sensor A sensor that is connected to a smart transmitter.

"LO" Reading Indicates sensor glucose reading is < 40 mg/dL.

Mobile Device A handheld device built on a mobile operating system that runs the Eversense App and communicates with the smart transmitter.

mg/dL Milligrams per deciliter, a unit of measure that shows the concentration of a substance in a specific amount of fluid. In some countries, including the United States, glucose test results are reported as mg/dL, indicating how much glucose is in the blood when using a blood glucose meter, or how much glucose is in the interstitial fluid when using some CGM systems, like the Eversense E3 CGM System.

mmol/L Millimoles per liter, a unit of measure that shows the concentration of a substance in a specific amount of fluid. In many countries, glucose test results are reported as mmol/L, indicating how much glucose is in the blood when using a blood glucose meter, or how much glucose is in the interstitial fluid when using some CGM systems, like the Eversense E3 CGM System.

MRI Magnetic Resonance Imaging

MR Conditional An item with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields.

Rate of Change/Trend Arrows Indicators of direction and speed of change of your glucose levels.

Remote Monitoring An optional feature that allows you to invite others to view your CGM data using Eversense NOW, a separate mobile app they download to a compatible mobile device.

Sensor A device inserted subcutaneously for continually measuring interstitial fluid glucose levels.

Snooze Setting Used to set how often an alert repeats.

Subcutaneous Located beneath the skin.

Smart Transmitter A reusable device worn externally over the inserted sensor that powers the sensor and sends glucose information to the mobile device for display in the Eversense App.

Warm-Up Phase The period the sensor requires to adjust after the sensor has been inserted and before calibrations.

I. Introduction

This section reviews how to use this guide and describes your new Eversense E3 CGM System, including its components and intended purpose.

Congratulations on having Eversense E3 CGM technology to assist you in managing your diabetes. Your Eversense E3 CGM System is intended to continually measure glucose levels for up to 180 days after your sensor is inserted. Glucose information collected by the system is automatically sent to your mobile device. You must contact your health care provider (physician, physician assistant, and/or nurse practitioner) to schedule the insertion and removal of your sensor.

Help and Support

Please review this User Guide with your health care provider. For additional Eversense E3 product questions and troubleshooting issues, contact Customer Support toll free in the US at 844-SENSE4U (844-736-7348).

For additional information on getting started with Eversense E3, watch the training videos and view training resources at www.eversensediabetes.com/resources. To check for the most recent version of this user guide, visit www.eversensediabetes.com.

Eversense E3 CGM System Components

The System includes 1) a small sensor inserted subcutaneously by a health care provider, 2) a removable smart transmitter worn over the sensor, and 3) a mobile app to display the glucose readings.

Eversense E3 Sensor

The sensor is inserted under the skin (upper arm) and measures glucose in interstitial fluid for up to 180 days. These glucose levels are then calculated by the smart transmitter and sent to the app. Sensors provided with the Eversense E3 CGM System include the sacrificial boronic acid (SBA) design modification.

Sensor

Eversense E3 Smart Transmitter

The removable smart transmitter is worn externally over the sensor and powers the sensor. It wirelessly sends glucose data (via Bluetooth) to the mobile device app. The smart transmitter also provides on-body vibe alerts based on the glucose settings you choose. It has a rechargeable battery and is reusable for up to one year.

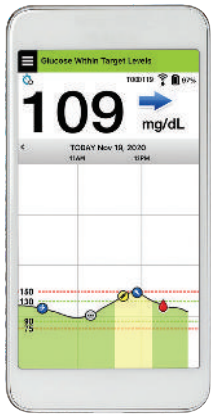
Smart Transmitter

Eversense App

The Eversense App is a software application that runs on a mobile device (e.g., smartphone or tablet) and displays glucose data in a variety of ways. It also provides alerts based on the glucose settings you choose.

The Eversense App screens layouts will vary based on your mobile device's model and/or operating system. Throughout this User Guide, we have included some examples of these differences.

Make sure your mobile device is using the latest operating system that is listed as compatible on our website at www.eversensediabetes.com/compatibility.



iOS

Android

IMPORTANT: In order to use the Eversense E3 CGM System, you must have an understanding of downloading and using mobile apps on your handheld device. Data from the Eversense E3 Smart Transmitter is sent wirelessly via Bluetooth. Carefully read the instructions in this User Guide for downloading and installing the Eversense Mobile App, and for pairing your mobile device with the smart transmitter. If there is anything you do not understand in this User Guide, please consult your health care provider. For product questions, contact Senseonics Customer Support.

Disposable adhesive patches for daily use are also included as part of the system, and will be provided to you by your health care provider after your sensor has been inserted. The patch has an acrylic adhesive side that attaches to the back of the smart transmitter, and a silicone adhesive side that attaches to the skin.

Eversense E3 System Overview

A separate blood glucose monitoring system (not provided by Senseonics) is required for calibrating the CGM System, and to make treatment decisions under certain conditions. See Understanding Treatment Decisions with CGM. When used properly, these components work together to help ensure you get continuous glucose monitoring for up to 180 days.

To ensure you receive continuous glucose readings and other information, follow these daily use tips:

- ✓ Wear your smart transmitter all the time except when charging.
- ✓ The smart transmitter is water-resistant to a depth of 1 meter (3.2 feet) for 30 minutes. Exposing the smart transmitter to conditions beyond this will result in damage and void your warranty.
- ✓ Make sure your smart transmitter has enough battery power at all times.
- ✓ Perform two blood glucose meter calibration tests each day when prompted.
- ✓ Pay attention to alerts and notifications you receive from your smart transmitter and mobile device.
- ✓ Replace the adhesive patch on your smart transmitter daily.
- ✓ You can remove the smart transmitter from the upper arm at any time, except during calibration. Remember that no data are collected when the smart transmitter is not communicating with the sensor. When you place the smart transmitter back on the sensor site, it will take up to 10 minutes for sensor communication to re-start and for glucose readings to appear in the app.
- ✓ When the smart transmitter and mobile device are not within range of each other, any data gathered by the smart transmitter is stored and sent to the app when the mobile device and smart transmitter are back within range.
- ✓ It is safe for you to wear your sensor and smart transmitter when you go through metal detectors at airports. While flying, the smart transmitter performs similarly to any other Bluetooth device. Be sure to follow the specific safety guidelines mandated by the airline.

Some of the features of the Eversense E3 CGM System:

- Wireless communication with the sensor, smart transmitter and app.
- Long-term sensor wear in the upper arm for up to 180 days.
- Alerts when pre-set Low or High Glucose Alert levels (hypoglycemia or hyperglycemia) are reached.
- Predictive Alerts let you know ***before*** reaching pre-set Low or High Glucose Alert levels.
- Use of mobile device (e.g., smartphone) to display glucose readings.
- On-body vibe alerts with the smart transmitter even when mobile device is not nearby.
- Provides readings within 40 - 400 mg/dL range every 5 minutes.
- Trend arrows that show whether your glucose values are rising or falling and how fast.
- Graphs and statistics that show your glucose results in easy-to-understand formats.
- Removable and rechargeable smart transmitter.
- Event entry capabilities (like meals, exercise and insulin).
- Stores glucose data in the app and on the smart transmitter.
- Provides remote monitoring capability to others using the Eversense NOW Mobile App.

System Requirements

- The Eversense E3 CGM System.
- A compatible smartphone for Android or Apple iPhone® or iPod® or iPad® that has Bluetooth Smart (or Bluetooth Low Energy). The Eversense App also works with the Apple Watch®.
- For a list of compatible devices and operating systems, please go to www.eversensediabetes.com.
- The Eversense App downloaded to your mobile device from the Apple App Store or on Google Play™.

End User License Agreement and Privacy Policy

Use of the Eversense App is subject to the terms and conditions of the most current Eversense End User License Agreement and Eversense Privacy Policy. These documents are updated from time to time and are posted at www.eversensediabetes.com.

Jailbroken Devices

DO NOT use the Eversense Apps on jailbroken iPhones or iPods. Jailbroken devices do not provide an acceptable level of security for the user and are not approved for use by Senseonics.

Broken Screen or Button

If the screen of your mobile device is broken, or the buttons do not work, then you may not be able to use your Eversense E3 System and you may miss low or high glucose events.

Device Modifications

DO NOT modify the Eversense E3 CGM System for use with products, accessories, or peripheral equipment not furnished or approved in writing by Senseonics. Unauthorized modifications void your transmitter warranty and may impact system performance.

Indications for Use

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

The system is intended to:

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

The system is a prescription device. Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns and trends seen over time.

The system is intended for single patient use.

MRI Safety Information

Non-clinical testing has demonstrated the Eversense E3 Sensor is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5T or 3.0T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode).

Under the scan conditions defined above, non-clinical testing results indicate the Sensor is expected to produce a maximum temperature rise of less than 5.4 °C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 2.83 inches (72 mm) from the Eversense E3 Sensor when imaged with a gradient echo pulse sequence and a 3T MR system.

The Eversense E3 Smart Transmitter is MR Unsafe and MUST BE REMOVED before undergoing an MRI procedure. Before you undergo an MRI procedure, tell the MRI staff that you have an Eversense E3 Sensor and Smart Transmitter.

Contraindications

The smart transmitter is incompatible with magnetic resonance imaging (MRI) procedures. The smart transmitter is MR Unsafe and MUST BE REMOVED before undergoing an MRI (magnetic resonance imaging) procedure. For information on the sensor, please see MRI Safety Information.

The system is contraindicated in people for whom dexamethasone or dexamethasone acetate may be contraindicated.

Mannitol or sorbitol, when administered intravenously, or as a component of an irrigation solution or peritoneal dialysis solution, may increase blood mannitol or sorbitol concentrations and cause falsely elevated readings of your sensor glucose results. Sorbitol is used in some artificial sweeteners, and concentration levels from typical dietary intake do not impact sensor glucose results.

What is Included in this Kit

This Eversense E3 Smart Transmitter Kit contains the following:

Eversense E3 Smart Transmitter

Power Supply
(USB cable and AC power adapter)

Also included in this package is this User Guide, Quick Reference Guide, Next Steps sheet, and a wallet card (not shown).

How to Use this User Guide

This guide describes how to use your CGM System. Read the entire guide before using the system.

- Any **warnings** or **precautions** are highlighted in a box.
- User tips are preceded by the ✓ symbol.

2. Benefits and Risks

This section describes the benefits, expectations and risks associated with using the Eversense E3 CGM System.

Continuous glucose monitoring aids in the management of diabetes and glucose control, which can improve your quality of life. Best results are achieved when you are fully informed about the risks and benefits, insertion procedure, follow-up requirements, and self-care responsibilities. You should not have the sensor inserted if you cannot properly operate the CGM System.

The 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. Glucose levels in ISF lag behind glucose levels in blood by several minutes.

IMPORTANT: If your symptoms do not match the glucose alerts and readings from the Eversense E3 CGM System, a fingerstick blood glucose check with a home blood glucose meter should be performed prior to making treatment decisions.

Failure to use the Eversense E3 CGM System in accordance with the instructions for use may result in you missing a hypoglycemic or hyperglycemic glucose event, which may result in injury.

The sensor has a silicone ring that contains a small amount of an anti-inflammatory drug (dexamethasone acetate). It has not been determined whether the risks associated with injectable dexamethasone acetate apply to the dexamethasone acetate elution ring inside the sensor. The elution ring releases a small amount of dexamethasone acetate when the sensor comes in contact with body fluids and serves to minimize the body's inflammatory response to the inserted sensor. Dexamethasone acetate in the ring may also cause other adverse events not previously seen with the injectable form. For a listing of potentially adverse effects related to dexamethasone acetate, contact your health care provider.

Unauthorized modifications of the equipment, improperly accessing information within it or "jailbreaking" your system, and taking any other unauthorized actions may cause the CGM system to malfunction and may put you at risk. Unauthorized modification of the equipment is not permitted and voids your warranty.

Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

Risks and Side Effects

The glucose alerts and notifications will not audibly notify you when the sound on the mobile device is turned off. If the system cannot display a glucose value, it also cannot provide glucose alerts. If you are unable to feel the vibration of the smart transmitter you may not notice the alerts. You may need medical attention in the event that you have high or low glucose and are unaware of it.

IMPORTANT: If you do not test your glucose with a blood glucose meter when your symptoms are not consistent with the sensor glucose readings, you may miss a high or low glucose event.

Treatment decisions should be made based on a review of the following: a sensor glucose value, trend arrow, recent glucose trend graph, and system alerts/notifications. You should not make a treatment decision unless you have considered all this information.

Be sure you talk with your health care provider about insulin action, so you understand how its impact on your glucose may factor into your treatment decisions.

The sensor is inserted by making a small incision and placing it under the skin. This process may cause infection, pain or skin irritation. Additionally, the adhesive may cause a reaction or skin irritation. Dizziness, fainting and nausea were reported in small numbers during clinical studies, as were instances of the sensor breaking or not being removed on first attempt. Any medical issue related to the procedure or use of the device should be reported to your health care provider.

Warnings

- The Eversense E3 CGM System has not been tested using insertion sites other than the upper arm.
- If at any time your symptoms are not consistent with the sensor glucose readings, you should test your glucose with a blood glucose meter.
- 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.
- If your smart transmitter is damaged or cracked, DO NOT use, as this could create an electrical safety hazard or malfunction, and could result in electrical shock.
- Close contact with direct EMI may interfere with the smart transmitter's ability to send data to your mobile device. Move away from the source of EMI and check that your mobile device is connected to your smart transmitter.
- Antibiotics of the tetracycline class may falsely lower sensor glucose readings. You should not rely on sensor glucose readings while taking tetracyclines.
- The bandage should remain covering the incision for 48 hours as this is a standard of care to allow formation of a water-tight seal to help protect against infection. Until it has healed, always cover the insertion site with a sterile bandage before placing the smart transmitter adhesive over the sensor. Failure to do so could result in infection at the insertion site.
- Please review this User Guide with your health care provider. For additional Eversense E3 product questions and troubleshooting issues, contact Customer Support toll free in the US at 844-SENSE4U (844-736-7348).
- Always calibrate the system using only a fingerstick blood sample. DO NOT use an alternative site (such as forearm or palm) blood glucose reading to calibrate the system.

Warnings (continued)

- DO NOT insert your infusion set or inject insulin within 4 in (10.16 cm) of the sensor site. If the insulin delivery site is within 4 in (10.16 cm) of the sensor site, it may interfere with sensor glucose readings and can cause inaccurate glucose readings.
- Always follow your health care provider's instructions for care after the sensor insertion or removal. Contact your health care provider if any of the following events occur:
  - You have pain, redness, or swelling at the incision site(s) later than 5 days after the sensor insertion or removal, or if the incision has not healed within 5 to 7 days.
- If your sensor glucose is very low (below 40 mg/dL) or very high (above 400 mg/dL), you should perform a fingerstick blood glucose test prior to making a treatment decision.
- The Eversense E3 CGM System requires calibration in order to provide accurate readings. You should not use CGM readings to make treatment decisions unless you have followed the instructions for daily calibration.
- The Eversense E3 CGM System will not provide readings during the 24 hour Warm-Up Phase and until a second calibration is successful during the Initialization Phase. During this time, you should monitor your glucose using a home blood glucose monitor.
- Certain conditions and alerts will prevent glucose data from being displayed. During these times, you should use a home blood glucose monitor to make treatment decisions. You should carefully read the *Alerts and Notifications* section of their *Eversense E3 CGM System User Guide* to understand these conditions.
- The glucose alerts and notifications will not audibly notify you when the sound on your mobile device is turned off. If the system cannot display a glucose value, it also cannot provide glucose alerts. If you are unable to feel the vibration of the smart transmitter you may not notice the alerts.
- When the smart transmitter is not worn over the sensor, such as during charging, the Eversense E3 CGM System will not provide alerts and notifications on the mobile device or through vibration alerts from the smart transmitter.

Precautions

- DO NOT exchange smart transmitters with another person. Each smart transmitter can be linked to only one sensor at a time. The system is to be used by one person in the home environment.
- The following medical therapies or procedures may cause permanent damage to the sensor particularly if used in close proximity to the device:
  - **Lithotripsy –** The use of lithotripsy is not recommended for people who have an inserted sensor because the effects are unknown.
  - **Diathermy –** DO NOT use diathermy on people who have an inserted sensor. Energy from the diathermy can transfer through the sensor and cause tissue damage in the insertion area.
  - **Electrocautery –** The use of electrocautery near the inserted sensor may damage the device. DO NOT use electrocautery near the sensor.
- Steroid use – It has not been determined whether the risks usually associated with injectable dexamethasone acetate apply to the use of this dexamethasone acetate elution ring, a highly localized, controlled-release device. The dexamethasone acetate ring could cause other adverse events not listed or previously seen.
- DO NOT wear the smart transmitter during medical x-rays or computed tomography (CT) scans. To avoid interference with results, remove the smart transmitter before undergoing medical x-ray or CT scans. Make sure your health care provider knows about your smart transmitter.
- The sensor and smart transmitter should be linked the day of insertion. Failure to link the sensor and smart transmitter could result in a delay in receiving glucose readings.
- If the sensor, insertion site or smart transmitter feels warm, remove the smart transmitter immediately and contact your health care provider for further advice. A warm sensor could mean there is an infection or a sensor malfunction.
- DO NOT attempt to use the Eversense App while operating a motor vehicle.
- You should not receive massage therapy near the inserted sensor site. Massage therapy near the sensor site could cause discomfort or skin irritation.

Precautions (continued)

- Use only the AC power adapter and USB cable provided with the smart transmitter when charging the smart transmitter battery. Use of another power supply could damage the smart transmitter, not allowing glucose readings to be received properly, and could result in voiding your warranty.
- Never stick any object other than the charging cable into the USB port of the transmitter. Doing so may damage the transmitter and void your warranty.
- If you have any concerns about allergic reaction to adhesive products containing silicone, contact your health care provider prior to use. Discard the Eversense adhesive patch after each use of up to 24 hours.
- DO NOT change the unit of measurement unless you have discussed it with your health care provider. Using the incorrect unit of measure could result in missing a high or low glucose event.
- Entering incorrect blood glucose values for calibration can result in inaccurate sensor glucose readings, which may result in you missing a high or low glucose event.
- Follow your health care provider's recommendation for setting your glucose alerts. Incorrectly setting your glucose alerts can result in you missing a high or low glucose event.
- Pay attention to the glucose alerts the system provides. Failure to appropriately respond to an alert might result in you missing a high or low glucose event.
- The Eversense NOW Remote Monitoring App does not replace the monitoring regimen as directed by your health care provider.
- The Eversense E3 CGM System has not been tested in the following populations: women who are pregnant or nursing, people under the age of 18, critically ill or hospitalized patients, people receiving immunosuppressant therapy, chemotherapy or anti-coagulant therapy, those with another active implantable device, e.g., an implantable defibrillator (passive implants are allowed, e.g., cardiac stents), those with known allergies to or using systemic glucocorticoids (excluding topical, optical or nasal, but including inhaled). The system's accuracy hasn't been tested in these populations, and sensor glucose readings may be inaccurate, resulting in missing a severe low or high glucose event.
- The Apple Watch is a secondary display of Eversense E3 CGM data and should not be used in place of the primary Eversense E3 CGM display.

3. Getting Started

This section describes the initial start-up steps required before you can begin using your new Eversense E3 CGM System on a daily basis. You may perform these steps before your health care provider inserts the sensor.

To get started you need:

- Your mobile device to download the Eversense App.
- Wireless internet connection.
- The Eversense E3 Smart Transmitter box that includes your smart transmitter and power supply.

Note: If you have not received your Smart Transmitter box, skip to instructions on downloading and installing the Eversense App to your mobile device later in this section.

You may complete the following start-up steps before your sensor is inserted so that you can familiarize yourself with the system.

2 easy start-up steps:

1. Download the Eversense App to your mobile device.
2. Set up the app – Create an Account, Pairing and Settings.

After you receive your smart transmitter it must be charged for at least 15 minutes or until the LED blinks green before pairing with the app.

Note: Your smart transmitter is set to "sleep" status for shipping. When you charge the smart transmitter for the first time, the status changes to active.

Your smart transmitter comes with a 12 month warranty. The system will alert you when the transmitter warranty exceeds 365 days.

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Charge your Smart Transmitter

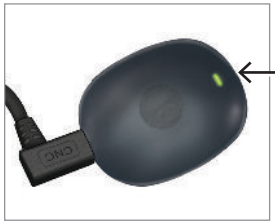
It is important to charge the smart transmitter battery daily to ensure data is collected from the sensor and sent to the app. The smart transmitter does not collect information from the sensor or send it to the app while charging. You may also charge your smart transmitter by connecting the USB cable to a computer USB port instead of the AC power adapter. Using a computer may take longer to fully charge the smart transmitter battery.

Precaution: Use only the AC power adapter and USB cable provided with the smart transmitter when charging the smart transmitter battery. Use of another power supply could damage the smart transmitter, not allowing glucose readings to be received properly, and could result in voiding your warranty.

1. **Plug the standard end of the USB cable into the adapter on the wall plug.**

2. **Plug the micro end of the USB cable into the USB port of the smart transmitter.**

3. **Plug the adapter into an AC power outlet.**
   - Once fully charged, a small green LED light appears on the top front of the smart transmitter (above the power button).
   - Disconnect the USB cable from the smart transmitter after it is charged for at least 15 minutes and the LED flashes green.



Battery Indicator

The smart transmitter battery power can be checked using the app, or on the smart transmitter itself.

With the app:

- Tap **Menu** > **About** > **My Transmitter**. Scroll down to the Battery Level line that indicates amount of battery power left.

  Or

- Check the battery icon and percentage on the upper right corner on the **MY GLUCOSE** screen. A red battery icon indicates the smart transmitter battery is empty.

With the smart transmitter:

- With the smart transmitter ON, tap the soft-touch button in the center of the smart transmitter once. The LED will blink green once if the battery has at least 10% power. A fully charged battery with this transmitter will last approximately 5 days. Charging for 15 minutes each day will ensure the transmitter has at least 10% (~24 hours) of power. See the following chart for more information on the LED indicators. For more information on using the smart transmitter's soft-touch feature, see *Daily Transmitter Wear*.

LED battery status indicators during smart transmitter charging:

LED Status	Battery Status	Action
Glowing orange when connected to the USB cable	Less than 10% charged	Charge for at least 15 minutes or until the LED flashes green before disconnecting from power supply.
Flashing green when connected to the USB cable	About 24 hours or 10% charged	Use or continue charging until LED is solid green.
Solid green when connected to the USB cable	100% charged	Ready to use.

Step 1. Download and Install the App

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The app is designed to work with the smart transmitter to automatically receive and display sensor glucose data.

1. Select the mobile device you would like to use to display your glucose readings. In most cases, this would be a smartphone.

2. Download the free Eversense App from the Apple App Store or on Google Play.

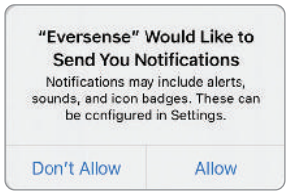
The prompts to install the app will vary between iOS and Android operating systems.

Eversense App Icon

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

3. On the install screen, tap Install application and follow the installation instructions.

After 1 - 2 minutes, check your mobile device display for the Eversense App icon (as shown to the left).



Note: Make sure to Allow Notifications from the Eversense App to receive alerts and notifications to your mobile device.

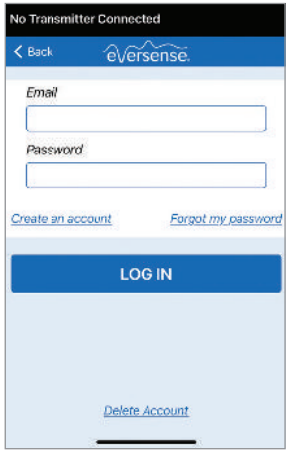
IMPORTANT: Make sure that you have a wireless internet connection, the date and time are correct on your mobile device, and that Bluetooth is turned ON before continuing.

Step 2. Set up the App – Account Creation, Pairing and Settings

Once the app is downloaded, connect the app and smart transmitter by pairing the smart transmitter with your mobile device.

1. **Launch the app by tapping the Eversense App icon on your mobile device. The END USER LICENSE AGREEMENT will appear.**
   - Review the Agreement and tap **Accept** to agree to the terms of the License Agreement.

2. **After you accept the Agreement, you will be prompted to create and register an account with an Email and Password.**
   - You must register an account before you are able to log in. Tap **Create an Account**.



Note: If you already have an account and you forget your password, you can reset it via the app. If you forget your email associated with your account, go to **Main Menu** > **About** > **My Account**.

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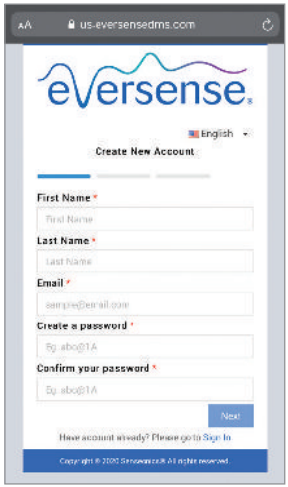
3. **Enter your account information and then tap Submit.**

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

   - Tap **Done** to return to the Eversense LOGIN screen.

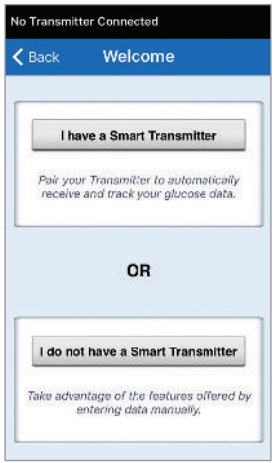


Note: If you have not received the confirmation email with the link to complete your registration within a few minutes, check your spam folder.

4. **Enter your email address and password and tap LOG IN. You will see a confirmation screen. Tap OK.**

Note: The password is case sensitive.

5. When you complete registration and log in, a **WELCOME** screen appears.



6. Choose one of the two options depending on whether you already have your smart transmitter or not:

I have a Smart Transmitter

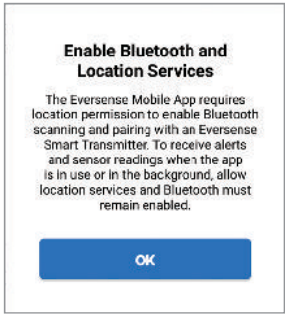
or

I do not have a Smart Transmitter

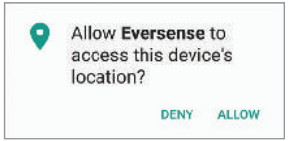
(skip to step 12).

Android users must enable location services.

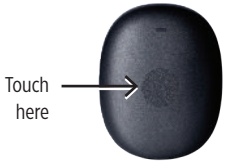
- Tap **OK** to confirm location services permission for the Bluetooth connection is required.



- Then tap **Allow** to ensure you receive alerts when the app is in use or in the background.

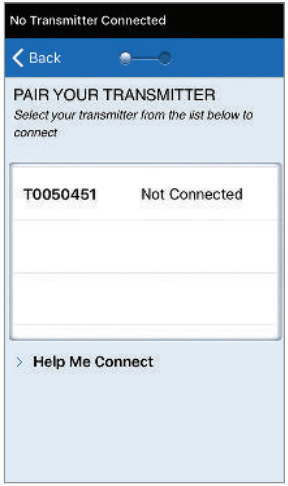


7. **With the smart transmitter turned on, and when the PAIR YOUR TRANSMITTER screen appears on your mobile device, activate pairing mode for the mobile device to find the smart transmitter:**
   - Touch the smart transmitter's soft-touch power button three times. Make sure your smart transmitter is not plugged into the power supply.
   - The LED will blink blue to indicate the smart transmitter is in pairing mode.



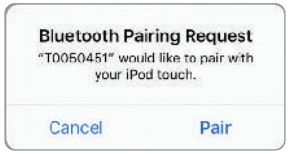
Note: If you tap the soft-touch power button on the smart transmitter and no LED appears, touch and hold in the center of the transmitter for about 3 seconds to turn it on.

8. **On the PAIR YOUR TRANSMITTER screen, the smart transmitter ID detected by the app is listed as "Not Connected". (Your smart transmitter ID matches the serial number found on the back of the smart transmitter.)**
   - Tap **Not Connected** to begin pairing process.

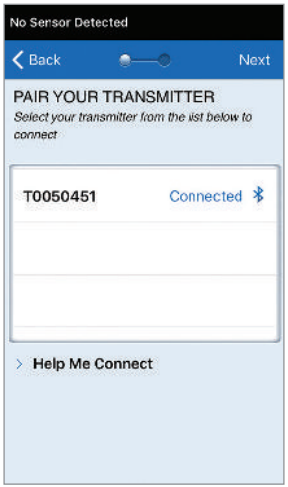


9. **A BLUETOOTH PAIRING REQUEST pop-up screen appears.**
   - Tap **Pair** to complete the pairing process.

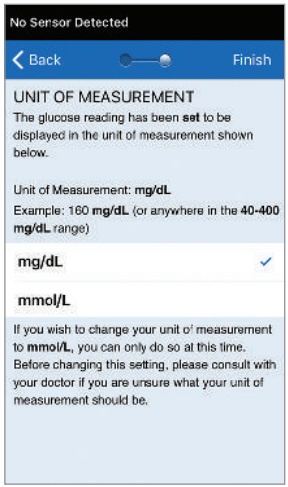
Note: The smart transmitter can only be paired with one mobile device at a time.



10. "Connected" appears next to the smart transmitter ID once the pairing is complete. The smart transmitter will provide intermittent vibrations and the button will flash orange until the smart transmitter is linked with the inserted sensor (see *Inserting and Linking the Sensor*).
    - Tap **Next**.

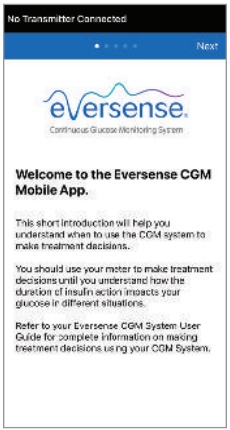


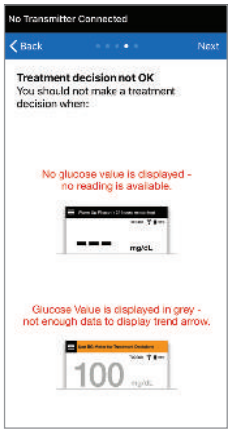
11. The **UNIT OF MEASUREMENT** screen appears and indicates the standard unit of measurement for your region. Your glucose readings will always be displayed in this unit of measurement.
    - When the unit of measurement is confirmed, tap **Finish**.

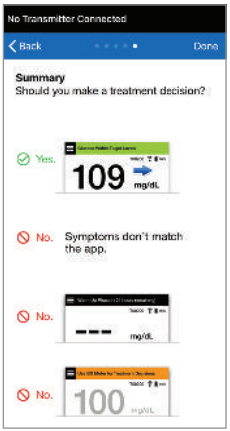


Precaution: DO NOT change the unit of measurement unless you have discussed it with your health care provider.

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







13. **Next, the MY GLUCOSE screen appears. The screen will not have any glucose data to display at this time.**

Once the sensor is inserted by your health care provider and the 24-hour Warm-Up Phase is completed, you can begin calibration. If you have not yet had your sensor inserted, you can review this User Guide to become familiar with the app and its features.

Smart Transmitter Connection Icons

When the icon is a grey blood drop with an X, no smart transmitter is detected. You will see this icon before you pair your smart transmitter to your mobile app and any time the BLE connection between the smart transmitter and your mobile app is interrupted.

When the icon is a red blood drop with an X, no sensor is detected. You will see this icon before you link a sensor to your transmitter and any time a linked sensor cannot be detected by the transmitter.

When the icon is a grey or black blood drop with bars on top, the NFC connection between the sensor and smart transmitter has been established.

The bars indicate the strength of the connection. Signal strength information is also displayed in **Main Menu** > **Placement Guide** in the Eversense App.

Reminder: You cannot link to a sensor until your transmitter is paired with the Eversense App.

4. Linking the Sensor

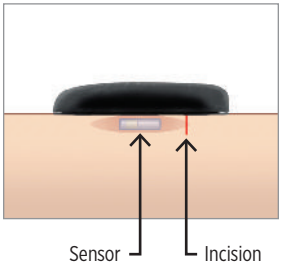
This section describes how to link the sensor and smart transmitter for the first time after your health care provider has inserted the sensor. Only your health care provider can insert the sensor. See "About the Sensor" to learn more.

Once your health care provider has inserted your sensor, the smart transmitter and the sensor must be linked in order to start the **24 hour** Warm-Up Phase. Your smart transmitter can only be linked to one sensor at a time. There is no need to wear the smart transmitter during the Warm-Up Phase.

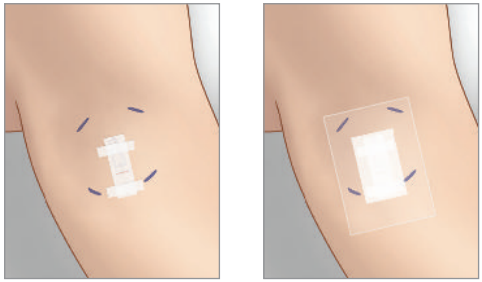
IMPORTANT: Please read this entire section before linking your sensor.

You can link your sensor to the smart transmitter any time after the sensor is inserted and the smart transmitter is paired with the Eversense App. To link the sensor, your mobile device must be connected to the internet and your transmitter must be charged, turned on, and paired with your mobile device.

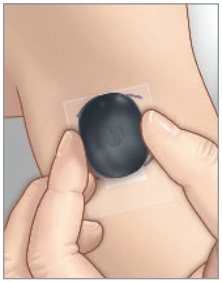
The incision site is closed using Steri Strips and an adhesive bandage, such as Tegaderm is placed over the top. It's important to understand how the smart transmitter should be positioned over the sensor to ensure linking can be completed. The smart transmitter should be centered over the sensor as shown.



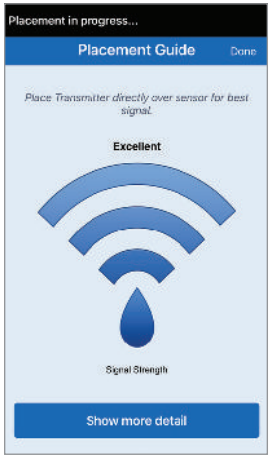
When you first link the sensor, with the Tegaderm bandage over the insertion site, the incision is likely in the center of the Tegaderm. This means the sensor is likely above the center of the Tegaderm.



The first time you link the sensor, do not use an Eversense adhesive patch on the smart transmitter. When positioning the smart transmitter over the sensor, it should be slightly above the center of the Tegaderm patch.



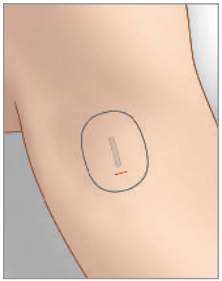
1. **Make sure your smart transmitter is turned ON (see *Using the Smart Transmitter*) and that your mobile device has access to the internet.**
   - Position the smart transmitter directly over the inserted sensor until the **Placement Guide** in the app shows some connection and keep in position without applying pressure. The Placement Guide page is located in **Menu** > **Placement Guide**.

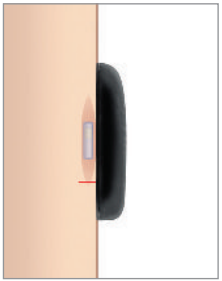


2. **Navigate away from the Placement Guide page to the Main Menu screen once you have confirmed there is a signal.**

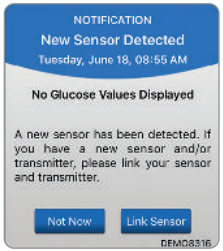
4

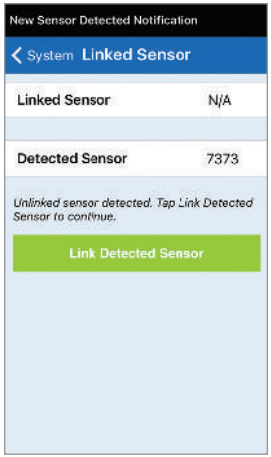
Note: The connection between the sensor and the smart transmitter is sensitive to the orientation of the transmitter. If the smart transmitter is directly over the sensor and the Placement Guide indicates there is no connection, try rotating the smart transmitter slightly to the left or right so transmitter is centered over the sensor vertically.





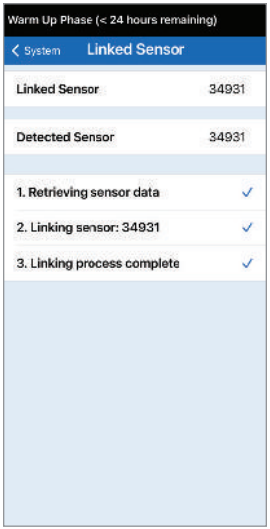
3. To link the smart transmitter and sensor, tap **Link Sensor** on either the **New Sensor Detected** pop-up screen or by tapping **Menu** > **Settings** > **System**> **Linked Sensor** and then tap **Link Detected Sensor**.

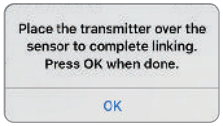




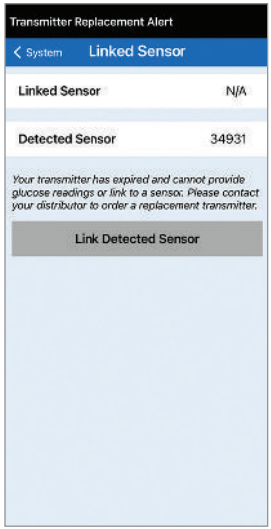
Note: It may take up to 5 minutes for the New Sensor Detected notification to be displayed.

4. **The linking process will begin. Each step will show a check mark when finished. It may take up to 10 minutes for the process to complete. DO NOT remove the smart transmitter from your insertion site until the third check mark is displayed.**



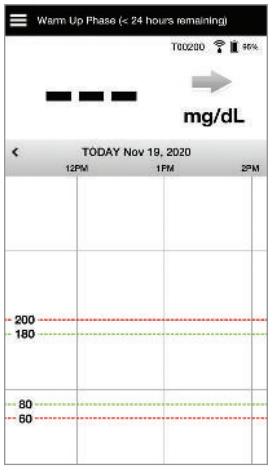


If the smart transmitter is removed from the sensor site, the system will display a notification.



If your smart transmitter has expired, it cannot be linked to a sensor.

After the sensor is linked, you can remove the smart transmitter, connect it to the cable and leave it charging for the next 24 hours. See the section, Using the Smart Transmitter, to learn about using your system after the Warm-Up Phase.



4

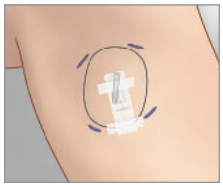
Precaution: The sensor and smart transmitter should be linked the day of the sensor insertion. Failure to link the sensor and smart transmitter could result in a delay in receiving glucose readings.

Note: The sensor requires a 24-hour Warm-Up Phase to stabilize in your body before glucose values will be collected by the smart transmitter. During the Warm-Up Phase, you do not need to wear the smart transmitter. If you decide to wear the smart transmitter over the sensor during this time, you will receive a message on the app indicating the Warm-Up Phase is in progress. Once the Warm-Up Phase is complete, turn ON the smart transmitter and place it over the sensor with the Eversense adhesive patch. The system will prompt you to calibrate using the app.

Warning: The Eversense E3 CGM System will not provide readings during the 24 hour Warm-Up Phase and until a second calibration is successful during the Initialization Phase. During this time, you should monitor your glucose using a home blood glucose monitor.

IMPORTANT: After the **24 hour** Warm-Up Phase, if your smart transmitter is not turned on and worn over the sensor, the system cannot provide glucose readings after the Warm-Up Phase.

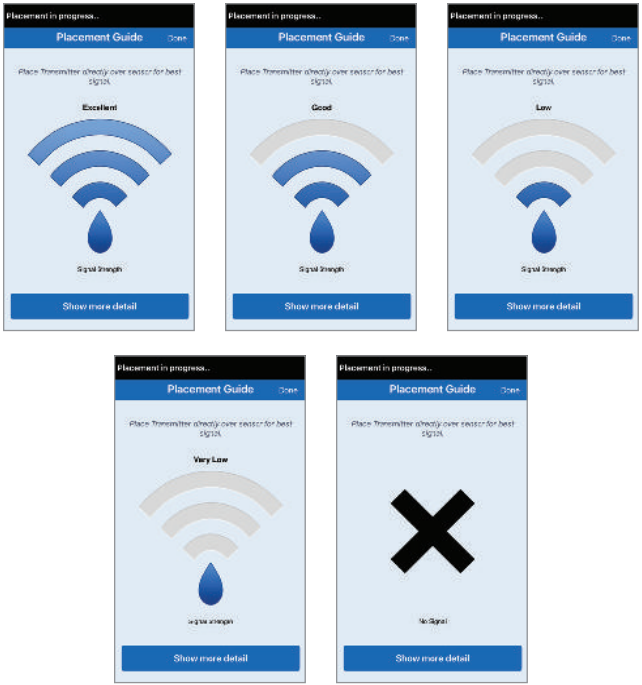
✓ **Tip:** Your sensor may not be precisely perpendicular to the incision. If you find it difficult to get a Good or Excellent signal in the Placement Guide, DO NOT apply pressure. Do try slightly rotating the smart transmitter over the sensor. Wait about 1 second for the Placement Guide to refresh between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



Placement Guide – Main Screen

Below are the various signal strength levels that may be displayed.

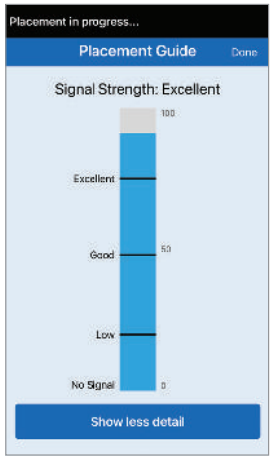
✓ **Tip:** You do not need Excellent signal strength in order to link the sensor or use your system.



Placement Guide – Show More Detail Screen

Tapping Show More Detail displays a higher resolution signal strength indicator.

- This may assist you in properly positioning the transmitter over the sensor.



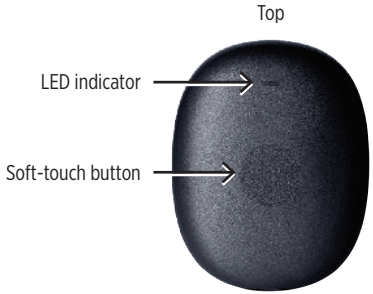
5. Daily Transmitter Wear

This section describes the many features of the smart transmitter and how to get uninterrupted and continuous monitoring of your glucose levels.

Once the Warm-Up Phase has ended, the Initialization Phase begins, and you're ready to start wearing the smart transmitter. For the first few days, you'll wear the smart transmitter over the Tegaderm™ bandage. Always start with a transmitter that has been charged for at least 15 minutes. Your smart transmitter communicates with both the sensor and the app to provide CGM information.

Your Eversense E3 Smart Transmitter does the following:

- Powers the sensor.
- Calculates and stores glucose data.
- Provides on-body vibe alerts when you have reached the glucose alert levels you set.
- Sends glucose data to the app via Bluetooth.
- Can be recharged using the USB port in the transmitter and the charging cable.
- Uses USB port with charging cable to download data to compatible external applications.
- Multi-color LED to indicate various system conditions.
- Communicates with mobile device.
- Can be powered ON or OFF.



Daily Use

To receive continuous glucose readings and information, keep the following in mind when using your smart transmitter:

- ✓ Wear your smart transmitter at all times except when charging.
- ✓ The smart transmitter is water-resistant to a depth of 3.2 feet (1 meter) for 30 minutes. Exposing the smart transmitter to conditions beyond this will result in damage and void your warranty.
- ✓ Make sure your smart transmitter has enough battery power at all times.
- ✓ Perform a blood glucose meter calibration test when prompted.
- ✓ Pay attention to alerts and notifications you receive from your smart transmitter and mobile device.
- ✓ Replace the adhesive patch on a daily basis.
- ✓ You can remove the smart transmitter from the upper arm at any time, except during calibration. Remember that no data are collected when the smart transmitter is not communicating with the sensor. When you place the smart transmitter back on the sensor site, it can take up to 10 minutes for sensor communication to re-start and for glucose readings to appear in the app.
- ✓ When the smart transmitter and mobile device are not within range of each other, any data gathered by the smart transmitter is stored and sent to the app when the mobile device and smart transmitter are back within range.
- ✓ It is safe for you to wear your sensor and smart transmitter when you go through metal detectors at airports. While flying, the smart transmitter performs similarly to any other Bluetooth device. Be sure to follow the specific safety guidelines mandated by the airline.
- ✓ Until the smart transmitter has received the first glucose value after positioning over the sensor, the status bar on the mobile app will display Collecting Data. You may also see this status bar just after charging the smart transmitter.

Warning: If your smart transmitter is damaged or cracked, DO NOT use, as this could create an electrical safety hazard or malfunction, and could result in electrical shock.

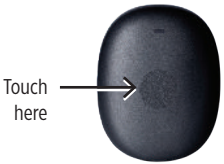
Using the Smart Transmitter

This smart transmitter has a soft-touch button. To operate the smart transmitter, you either touch and hold, or tap your finger on the soft-touch button. The touch is similar to how you would touch an app icon on your smartphone to open an app. The smart transmitter provides information about system status by vibration and by LED lights.

5

1. **To turn on the smart transmitter, touch and hold your finger on the soft-touch button for about 3 seconds.**
   - You will feel a quick vibe, and the LED will blink once, indicating the power is ON.
   - At any time, you can tap the soft-touch button to see if it is ON. If you feel a quick vibe and the LED appears, the smart transmitter is ON.

2. **To turn the smart transmitter OFF, touch and hold your finger on the soft-touch button for about 5 seconds – the LED will turn on.**
   - You will feel a quick vibe, and the LED will turn off, indicating the power is OFF.



If your smart transmitter is turned off or the battery is completely empty, there will be no vibration or LED response when you tap the soft-touch button. Plug the smart transmitter into the USB cable and charge it for a few minutes.

Note: You must touch the button directly with your finger – it cannot detect a touch through clothing.

LED Status Indicators during smart transmitter use:

LED Status	Status	Action
Blinking blue when power button is tapped 3 times in 5 seconds	Pairing mode	Pair smart transmitter with mobile device.
Does not blink when power button is tapped	Smart transmitter off	Touch and hold in the center of the transmitter for 3 seconds to turn on.
Blinks green (once) when power button is tapped	At least 10% or ~24 hours battery power remaining	No immediate action required.
Blinks orange (once) when power button is tapped	Low battery, less than 10% (~24 hours) battery power remaining	Charge battery soon.
LED is orange for one minute	An alert has been triggered	Check the app on your mobile device to understand the alert.
Blinks orange	Transmitter and sensor communication interrupted or not yet linked	Position transmitter over sensor site. If prompted, link sensor.

Smart Transmitter Care and Maintenance

- Keep the smart transmitter clean (free of visible dirt) and protected when not in use. Wipe the outside with a cloth between uses to keep clean.
- Contact Customer Support for a replacement transmitter if you receive a Battery Error Alert.
- Never stick any object other than the charging cable into the USB port of the transmitter. Doing so may damage the transmitter and void your warranty.
- If the USB port appears to be obstructed, contact Customer Support for a replacement.
- Charge the smart transmitter whenever the battery power is low.
- Use only the power supply supplied with your system to charge the smart transmitter battery. Using a power supply other than one provided by Senseonics may void your smart transmitter warranty. DO NOT use the power supply if it is damaged in any way.
- To clean your smart transmitter, wipe it down with a water dampened cloth; dispose of the cloth according to your local regulations.
- Dispose of the smart transmitter and all other system components according to local regulations.

Secure the Smart Transmitter over Inserted Sensor

The smart transmitter must be secured on the skin directly over the sensor with the disposable adhesive patch. Each adhesive patch is designed to be replaced daily and has an adhesive side that attaches to the back of the smart transmitter and a silicone adhesive side that attaches to the skin. Both the skin and smart transmitter surfaces should be clean and dry to secure the adhesive surfaces of the patch. During the first few days after insertion, you will wear the smart transmitter over the Tegaderm bandage. Leave the Tegaderm bandage in place for as long as your health care provider instructs.

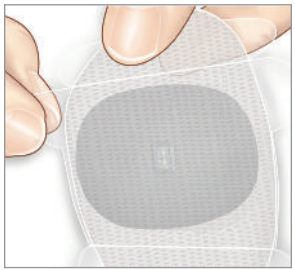
Note: You will receive adhesive patches from your health care provider.

Precaution: If you have any concerns about allergic reaction to silicones, contact your health care provider prior to use. Discard the patch after 24 hours of use.

1. **Peel off the paper backing with the Eversense E3 Smart Transmitter outline on it. Try not to touch the sticky portion of the adhesive in the center.**

2. **Align the smart transmitter over the sticky side (center) of patch and press firmly to secure.**
   - The smart transmitter should be placed so that its sides face the wings of the patch (as shown).

3. **Remove the larger clear backing and position the smart transmitter directly over the sensor.**
   - For the optimal signal strength, the smart transmitter must be placed directly over the sensor. Signal strength can also be improved by rotating the smart transmitter over the sensor such that the sensor is centered vertically under the smart transmitter.



You may wear the smart transmitter over the Tegaderm with the Eversense adhesive patch after the 24 hour Warm-Up Phase is complete.

4. **Check the connection between the smart transmitter and the sensor.**
   - Tap **Menu** > **Placement Guide**.
   - Refer to the **Placement Guide** when attaching your smart transmitter to ensure there is some connection between the sensor and smart transmitter.

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

5. **Press the adhesive patch firmly on skin surface over the sensor. DO NOT use excessive pressure for the first several days after insertion.**
   - The smart transmitter should be positioned so that the patch wings lay horizontally on the arm.

6. **Use the tab to pull off the remaining clear liner.**
   - Smooth the adhesive onto the skin. Make sure the patch is flat on the skin surface.

6. Calibrating the System

This section describes the calibration procedure and schedule of your Eversense E3 CGM System.

Warning: DO NOT use alternative test sites such as your forearm when entering BG values for calibration.

To ensure best performance, routine calibration is required using fingerstick readings from a blood glucose meter. Any commercially available meter may be used for calibration. Once your sensor has been inserted and linked to your smart transmitter, the system begins a 24-hour Warm-Up Phase. No calibration is required during this phase.

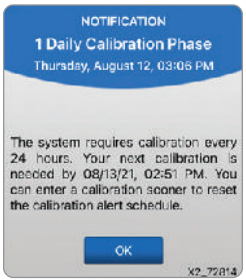
There are three calibration phases:

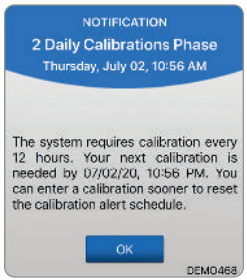
Initialization Phase – After the 24-hour Warm-Up Phase, you must complete 4 fingerstick calibration tests, spaced 2 to 12 hours apart.

2 Daily Calibrations Phase – After the Initialization Phase, you must complete a fingerstick calibration test every 12 hours for at least 21 days.

1 Daily Calibration Phase – The system will detect if 1 or 2 daily calibrations are needed and will alert you. In the 1 Daily Calibration Phase, you must complete a fingerstick calibration test every 24 hours.

After the first 21 days, the system will notify you if 1 or 2 daily calibrations are needed.





Warning: **In the 2 Daily Calibrations Phase, the Eversense E3 CGM System requires calibration every 12 hours in order to provide accurate readings. In the 1 Daily Calibration Phase, the Eversense E3 CGM System requires calibration every 24 hours. You should not use CGM readings to make treatment decisions unless you have followed the instructions for daily calibration.**

Routine calibration is critically important to ensuring the best performance of the Eversense E3 CGM System. The following tips can help you improve your calibration measurements:

Tips for ensuring good calibration:

- ✓ Calibrate at times when glucose is NOT changing rapidly (e.g., before meals, before dosing insulin).
- ✓ Calibrate when you know you will not be removing the smart transmitter during the next 15 minutes.
- ✓ Wash your hands with warm, soapy water and dry thoroughly before taking a blood glucose meter reading. It is very important to have clean, dry hands when you test your blood glucose.
- ✓ Always follow the blood glucose meter manufacturer's instructions to get accurate blood glucose readings for calibration.
- ✓ Be sure the code on test strip vial matches the code on your blood glucose meter (if coding is required).

Calibration will *NOT* be complete or results *NOT* accepted if:

- ✘ Blood glucose meter reading is less than 40 mg/dL.
- ✘ Blood glucose meter reading is greater than 400 mg/dL.
- ✘ Blood glucose meter reading was taken more than 10 minutes before entering the result in the Eversense App.
- ✘ Sensor glucose reading is significantly different than the blood glucose meter reading.
- ✘ Your smart transmitter was removed or could not collect sensor glucose data during the 15 minutes after you entered your calibration value.

Calibration Phases

A. Initialization Phase (after 24-hour Warm-Up Phase)

During this phase, 4 fingerstick blood glucose meter tests are required.

- The 4 calibration tests must be spaced 2 to 12 hours apart, and all 4 tests must be completed within a 36 hour period. After 8 hours without a calibration entry, no glucose data will be displayed.
  - 1st calibration = 24 hours after sensor is linked.
  - 2nd calibration = 2 to 12 hours after 1st successful calibration.
  - 3rd calibration = 2 to 12 hours after 2nd successful calibration.
  - 4th calibration = 2 to 12 hours after 3rd successful calibration.
- Glucose readings will start displaying in the app a few minutes after the 2nd calibration is successfully completed.

IMPORTANT: If your smart transmitter is not turned on and paired with the Eversense App and sensor, the system is not able to prompt you to calibrate.

Re-Entering Initialization Phase

The following will cause the system to re-enter Initialization Phase.

- Not completing a calibration test within a 12-hour period during the Initialization Phase.
- Not completing all 4 calibration tests within 36 hours during the Initialization Phase.
- Not completing required calibration entries during the Daily Calibration Phase.
  - 1 calibration every 12 hours during the first 21 days of wear, and anytime the system is in 2 Daily Calibrations Phase
  - 1 calibration every 24 hours when the system is in 1 Daily Calibration Phase
- When the last several blood glucose meter measurements are significantly different than the sensor glucose values.
- If the smart transmitter is out of battery power for more than 16 hours.
- When you receive a Sensor Check Alert.
- Six hours after you receive a Sensor Suspend Alert.

B. Daily Calibration Phases

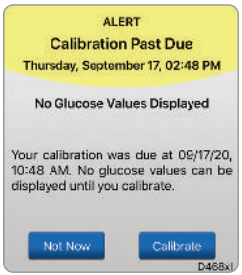
There are two daily calibration phases.

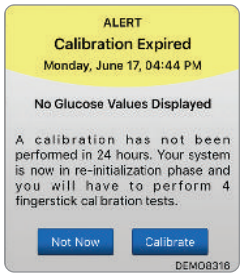
The 2 Daily Calibrations Phase requires a blood glucose fingertsick test every 12 hours. Daily Calibration Phase begins after successful completion of the Initialization Phase.

- 12 hours after your last successful calibration, the system prompts you to calibrate.
- You may optionally enter calibrations more frequently. Daily calibration entries must be spaced at least one hour apart.
- If you do not calibrate within 16 hours, you will receive a Calibration Past Due Alert and no glucose values will be displayed until a calibration value is entered. After 24 hours without a calibration value entered, you will receive a Calibration Expired Alert and the system returns to Initialization Phase.

The 1 Daily Calibration Phase requires a blood glucose fingerstick test every 24 hours.

- 24 hours after your last successful calibration, the system prompts you to calibrate.
- You may optionally enter calibrations more frequently. Daily calibration entries must be spaced at least one hour apart.
- If you do not calibrate within 28 hours, you will receive a Calibration Past Due Alert and no glucose values will be displayed until a calibration value is entered. After 40 hours without a calibration value entered, you will receive a Calibration Expired Alert and the system returns to Initialization Phase.





Warning: Certain conditions and alerts will prevent glucose data from being displayed. During these times, you should use a home blood glucose monitor to make treatment decisions. You should carefully read the *Alerts and Notifications* section of this *User Guide* to understand these conditions.

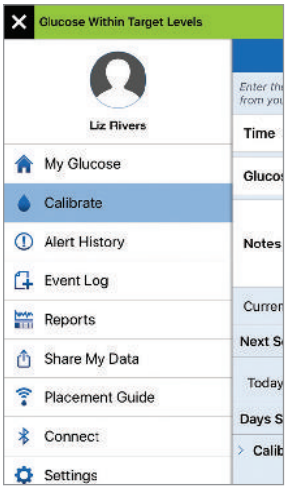
Note: If a calibration entry is very different from the system's sensor glucose value, you will be prompted with a Calibrate Now Notification about an hour later. A Calibrate Now Alert will display 11 to 12 hours later, regardless of which Daily Calibration phase the system is in. In this situation, if you do not calibrate within 16 hours, no glucose values will be displayed. After 24 hours with no calibration, the system returns to Initialization Phase.

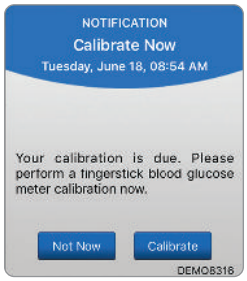
How To Calibrate

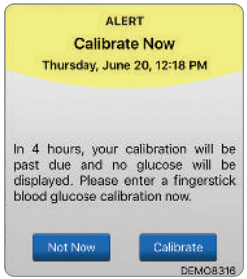
Warning: **Always calibrate the system using only a fingerstick blood sample. DO NOT use an alternative site (such as forearm or palm) blood glucose reading to calibrate the system.**

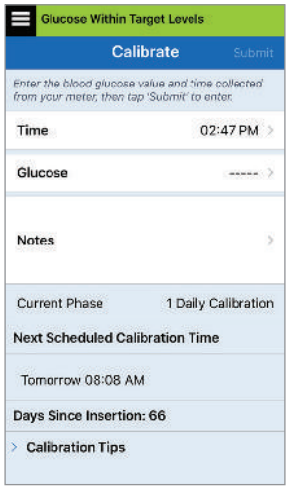
Note: You can enter additional calibration readings as long as each calibration is at least one hour apart.

1. **You can enter the calibration value by tapping Calibrate from the main menu or from the Calibrate Now Notification or Alert.**

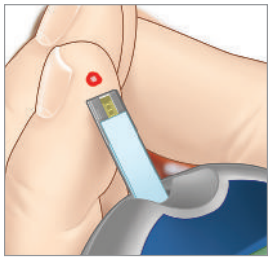




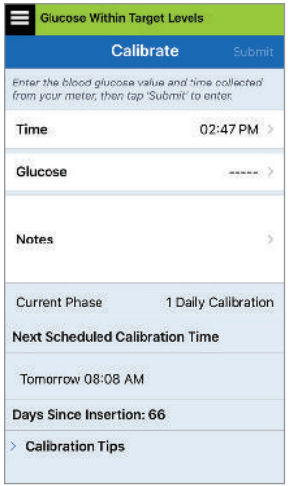


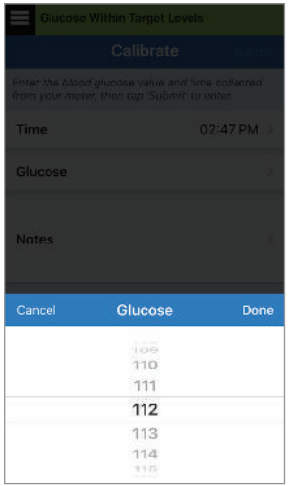


2. **Obtain a fingerstick reading from your blood glucose meter.**



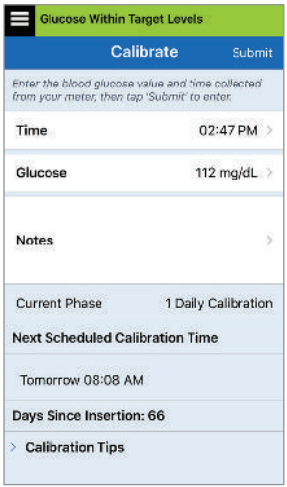
3. **Tap Glucose and enter the value from your fingerstick blood glucose test.**
   - Tap **Done**.
   - Tap **Notes** to enter any notes.
   - Tap **Done**.



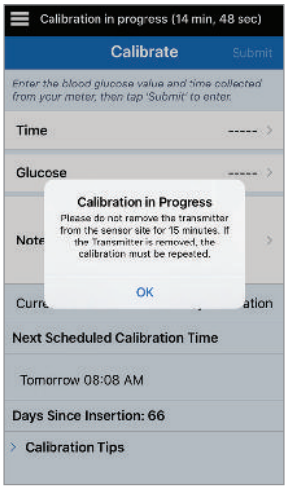


Note: You cannot enter a calibration value that is older than 10 minutes.

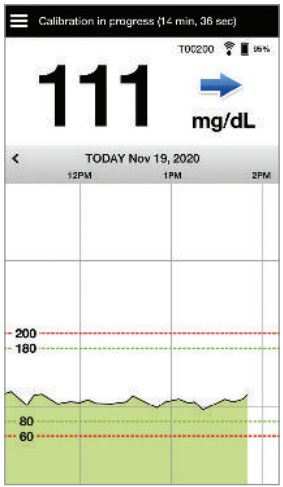
4. The **CALIBRATE** screen now shows the time and glucose reading you entered. If not correct, repeat steps 3.
   - When correct, tap **Submit**.



5. The **CALIBRATION IN PROGRESS** screen appears.
   - Tap **OK**.



6. The **MY GLUCOSE** screen appears with a red blood drop icon to identify your fingerstick calibration.

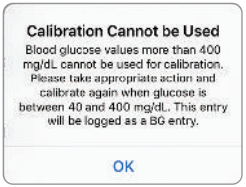


IMPORTANT: The smart transmitter should not be removed from over the sensor for at least 5 minutes before the test to 15 minutes after the test while calibration is in progress. The Status Bar at the top of the screen lets you know when calibration will be complete. If the smart transmitter is removed before the calibration is complete, you will be prompted to calibrate again.

Note: There may be conditions when your calibration result is NOT accepted.

Calibration will *NOT* be accepted if:

- ✕ Blood glucose meter reading is less than 40 mg/dL.
- ✕ Blood glucose meter reading is greater than 400 mg/dL.



- ✕ Your smart transmitter was removed or could not collect sensor glucose data during the 15 minutes after you entered your calibration value.

The calibration icon colors indicate the status of your calibration entry. See table below.

Status		Description
	**Calibration in Progress**	Displayed during the ~15 minutes after you have entered a calibration value. Do not remove your transmitter during this time. The icon will turn either red, black or blue when calibration is no longer in progress.
	**Calibration Accepted**	Displayed after the ~15 minute calibration period if the calibration entry is accepted.
	**Calibration Incomplete**	Displayed if the transmitter is removed from over the sensor during the ~15 minute calibration period. A new calibration entry will be required.
	**Calibration Cannot be Used**	Displayed if the calibration value entered is less than 40 mg/dL or more than 400 mg/dL. The entered value is stored as a manual blood glucose entry. Calibrate again when your blood glucose value is between 40 and 400 mg/dL.
	**Blood Glucose Event Entry**	Displayed when a manual BG value is entered via the Event Log.

7. Using the App

This section describes the Eversense App including the main screen, trend graph, trend arrows, and the menu screen.

The app communicates with the smart transmitter to receive and then display glucose data, trends, graphs and alerts. The app also stores your glucose history with up to 90 days of stored data.

Note: When you log out of the Eversense App, your smart transmitter will not send glucose data to the app until you log back in.

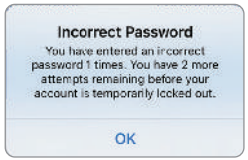
On the **MY GLUCOSE** screen, you have easy access to:

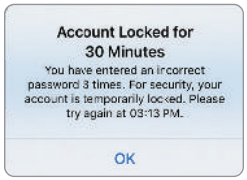
- Real-time sensor glucose measurements.
- Rate and direction of your changing glucose levels.
- Graphical trends of your glucose levels.
- Alerts (hypoglycemia or hyperglycemia).
- Events such as meals, exercise, and medications.

Note: A wireless internet connection is required to download or update the Eversense App.

Eversense Account Management

For security purposes if you enter an incorrect password three consecutive times in the mobile app, your account will be locked for 30 minutes. During this time, you will not have access to your CGM data on the mobile app.





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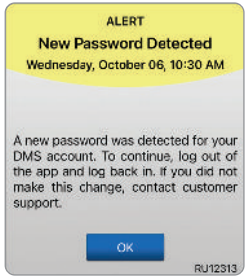
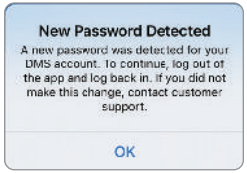
Precaution: If you cannot access your CGM data, you should monitor your glucose using a home blood glucose monitor.

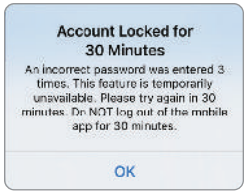
The Eversense Mobile App will periodically check to confirm your log in information has not been changed via your Eversense DMS account.

If you change your Eversense account password from your DMS log in screen or the DMS Change Password page, you must log out of the Eversense Mobile App and log back in using the new password. If the passwords do not match, the Eversense Mobile App will notify you and indicate that some features are not available, including not being able to sync your data to your DMS account, not being able to add Eversense NOW users to your Circle, and not being able to make changes to your profile picture.





If you enter an incorrect password three times on your DMS log in page, some mobile app features may be unavailable for 30 minutes, including no data syncing to your DMS account, no Eversense NOW users can be added to your Circle, and no changes to your profile picture can be made. You should not log out of the mobile app during this time.



Check Your Mobile Device Settings

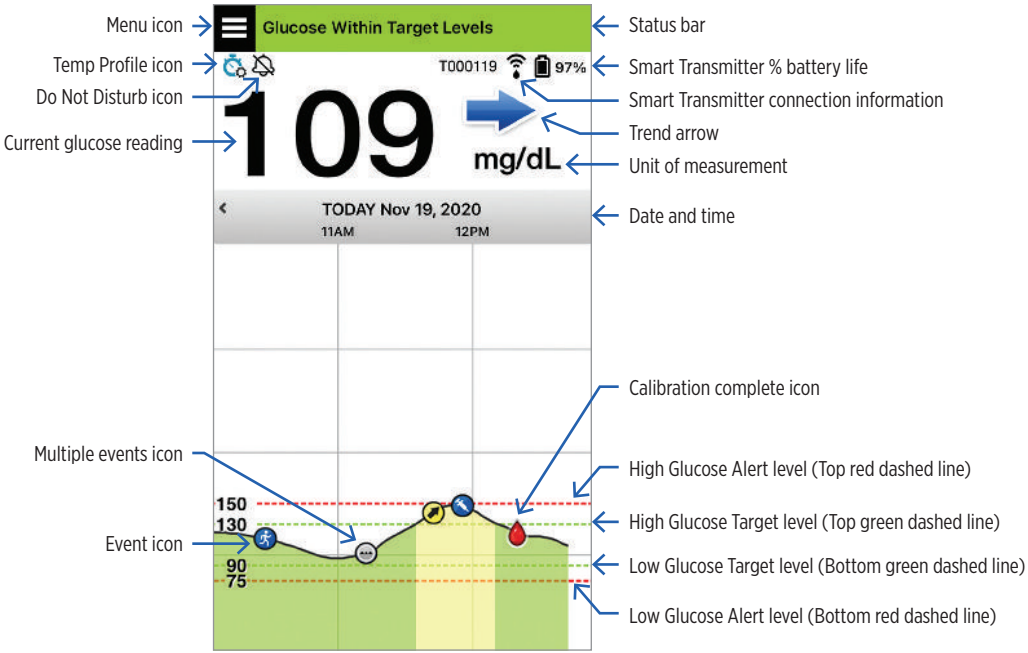
You will need a mobile device (such as your smartphone) to use the Eversense E3 CGM System. It is very important that your mobile device is set up properly to ensure accurate display of your glucose data in the app. Follow the manufacturer's instructions for your mobile device to set up the following:

- Time and date.
- Bluetooth turned ON (enabled).
- Notifications turned on.
- Battery is charged.
- Geographic zone.
- Language.
- Mobile device sound should not be on vibrate.
- Do Not Disturb should be OFF, some apps and settings such as Driving Mode may automatically enable Do Not Disturb. Please refer to your mobile device instructions for more information.
- If you have your mobile device set to Do Not Disturb, you will not hear any notifications from the Eversense App.*

*** For iOS 12 and above, and Android 6 and above, you can allow the Eversense Low Glucose and Out of Range Low Glucose Alerts to override your phone sound settings. See *Sound Settings* for more information.**

Get To Know the “My Glucose” Screen

The **MY GLUCOSE** screen is the main display screen for the app. It displays a variety of data, including sensor glucose readings, direction and rate of change arrow, trend graph, events, calibrations, alerts and notifications.



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.

Note:

- You can view a snapshot of Eversense information on your iOS or Android devices. For information on managing widgets, consult your mobile device user guide.
- You can view the **MY GLUCOSE** screen in landscape orientation to access short cut buttons to view the last 7, 14, 30 or 90 days and you can email this view with a single tap.

Status bar	Provides important information about your current glucose and system status.
Smart Transmitter ID	This is the smart transmitter you are now using. You can change the name by tapping **Settings** > **System**.
Current glucose reading	Current real-time glucose level. This is updated every 5 minutes.
Date and time	Current date and time. You can scroll left or right to see different dates and times.
Smart Transmitter % battery life	Indicates battery power left in the smart transmitter with both an icon and percentage.
Smart Transmitter connection	Indicates the strength of your smart transmitter connection with the sensor or with the mobile device.
Trend arrow	Shows the direction your glucose levels are moving.
Unit of measurement	This is the unit of measurement used to display all glucose data.
High/Low Glucose *alert* level	The levels set for the high and low glucose alerts.
High/Low Glucose *target* level	The levels set for the high and low glucose targets (target range).