

Sensor Smart Transmitter Mobile App

eversense® E3

User Guide

A guide for using the Eversense E3
Continuous Glucose Monitoring System



Eversense E3 Trademark

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Contents

Glossary 6

I. Introduction 9

Help and Support 9
Eversense E3 CGM System Components 10
System Requirements 13
End User Licence Agreement and Privacy Policy 13
Jailbroken Devices 14
Broken Screen or Button 14
Device Modifications 14
Indications for Use 14
MRI Safety Information 15
Contraindications 16
What is Included in this Package 16
How to Use this User Guide 16

2. Benefits and Risks 17

Risks and Side Effects 19
Warnings 20
Cautions 22

3. Getting Started 24

Charge your Smart Transmitter 25
Step 1. Download and Install the App 27
Step 2. Set up the App – Account Creation, Pairing and Settings 28
Smart Transmitter Connection Icons 35

4. Linking the Sensor 36

5. Daily Transmitter Wear 42

Daily Use 43
Secure the Smart Transmitter over Inserted Sensor 44
Turn the Smart Transmitter ON and OFF 47
Smart Transmitter Care and Maintenance 48
Battery Indicator 48
LED Status Indicators 49

6. Calibrating the System 50

Calibration Phases 52
How To Calibrate 55

7. Using the App 59

Eversense Account Management 60
Check Your Mobile Device Settings 61
Get To Know the “My Glucose” Screen 62

Trend Arrows 65
Understanding Treatment Decisions with CGM 66
Discuss with Your Healthcare Provider 68
Making Treatment Decisions with Eversense E3 70
Eversense E3 Trend Arrows and Treatment Decisions 72
What Would You Do 74
Trend Graph 78
Menu Options 79

8. Customising your Settings... 80
Setting Glucose Alert Levels 82
Setting Glucose Target Levels 84
Setting Predictive Alerts 86
Setting Rate of Change Alerts 88
Setting Daily Calibration Reminders 90
Setting System Information 91
Re-linking a Sensor 92
Setting Sounds 94
Low Glucose Override Setting 95
Transmitter Disconnect Setting 101
Setting Temporary Profile 104

9. Alert Descriptions..... 107
Alert History 109
Alert Descriptions and Actions 111

10. Event Log..... 137
Glucose 139
Meals 140
Insulin 141
Health 142
Exercise 143

11. Reports..... 144
Weekly Modal Summary 145
Glucose Pie Chart 146
Glucose Statistics 146

12. Sharing Data..... 147
Eversense Data Management Software (DMS) Program 147
Share My Data 147
Sync 148
My Circle 149
Application Sharing 150

13. Product and General Information on the App..... 151
Profile Picture 152
Logging out 154

14. Viewing Eversense E3 Data on the Apple Watch..... 155

Alerts and Notifications Displayed on the Apple Watch 158

15. My Circle 178

Remote Monitoring with Eversense E3 CGM System and Eversense NOW App 178

16. About the Sensor 184

Insertion Steps 185
Removal Steps 186

17. Travel 187

18. Troubleshooting 188

Smart Transmitter 188
Smart Transmitter Battery and Charging 190
Connection with Smart Transmitter 191
Calibration 194
Alerts and Notifications 196
Glucose Readings 198
Making Treatment Decisions 199
Trend Arrows 200
App 200
Sensor 202
Events 204
Sync 204
Shortcuts 205

19. Device Performance 206

Clinical Study Performance 206
Eversense E3 Accuracy to YSI in PROMISE Study 208
Sensor Life 218
Safety 219

20. Technical Specifications 220

Sensor 220
Smart Transmitter 221
Power Supply and Charger 222
USB Cable* for Charging and Downloading 222
Electrical and Safety Standards 223
Symbols on the Eversense CGM Mobile App 226
Symbols on Packaging and Devices 229
Eversense E3 Smart Transmitter Limited Warranty 232

21. Eversense DMS 235

Introduction 235
Getting Started 236
Reports 251
Settings 269
Transmitter 273

Data Share 281
Help 283

22. Eversense NOW..... 285

Remote Monitoring with Eversense CGM System and Eversense NOW App 285
Using the Eversense NOW App 288
Joining an Eversense Circle 290
Main Menu 296
Viewing CGM Data 298

Legal Notices..... 305

Apple Legal Notice 305
Google Legal Notice 305
About Bluetooth® 305
Bluetooth® Trademark 305
FCC Information 306
Radio Equipment Directive 306

Index..... 307

Glossary

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

AutoSync When this feature is turned on in the Eversense mobile app, your glucose data and settings will automatically be synced to the Eversense DMS every two hours.

Blood Glucose The glucose value obtained from a finger-stick test.

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: Initialisation 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 Licence 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 Client Application A desktop application that allows Eversense users to upload the data on their smart transmitter to the Data Management System using a USB cable.

Eversense Data Management System (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

Healthcare Provider A qualified healthcare professional who has successfully completed the Eversense E3 CGM Insertion and Removal Training Programme 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.

Hyperglycaemia An episode of high blood glucose.

Hypoglycaemia 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 decilitre, 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 litre, 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.

Sensor Glucose The glucose value obtained from the Eversense Sensor.

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 healthcare provider to schedule the insertion and removal of your sensor.

Help and Support

Please review this User Guide with your healthcare provider. For additional Eversense E3 product questions and troubleshooting issues, contact Customer Support toll free in the US at 844-SENSE4U (844-736-7348). Outside the US, call your local distributor or visit **https://global.eversensediabetes.com** to locate your local distributor. To check for the most recent version of this User Guide, visit **https://global.eversensediabetes.com.**

Eversense E3 CGM System Components

The System includes 1) a small sensor inserted subcutaneously by a healthcare 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.



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.



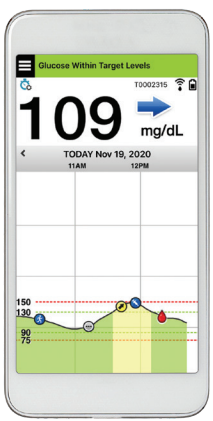
Smart Transmitter

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 screen 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 https://global.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 contact your local distributor.

Disposable adhesive patches for daily use are also included as part of the system and will be provided to you by your healthcare 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 metre (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 is 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 (hypoglycaemia or hyperglycaemia) 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 **https://global.eversensediabetes.com/compatibility**.
- The Eversense App downloaded to your mobile device from the Apple App Store or on Google Play™.

End User Licence Agreement and Privacy Policy

Use of the Eversense App is subject to the terms and conditions of the most current Eversense End User Licence Agreement and Eversense Privacy Policy. These documents are updated from time to time and are posted at **https://global.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. Unauthorised 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 (hypoglycaemia) and high blood glucose (hyperglycaemia).
- Aid in the management of diabetes.

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

A patient with this device can be safely scanned in a horizontal, closed bore MR scanner meeting the following conditions:

- Static magnetic field of 1.5 T or 3.0 T.
- Maximum spatial field gradient of 1900 gauss/cm (≤ 19 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode) for 15 minutes of continuous scanning, or SAR of 2 W/kg for 30 minutes of continuous scanning.

Under the scan conditions defined above, non-clinical testing results indicate the Eversense E3 Sensor is expected to produce a maximum temperature rise of less than 5.4°C.

In non-clinical testing, the image artifact caused by the device extends approximately 72 mm (2.83 inches) from the Eversense E3 Sensor when imaged with a gradient echo pulse sequence and a 3 T MR system.

The Eversense E3 Sensor has not been tested in MR systems that do not meet the conditions above. Exposing the Eversense E3 Sensor to MRI conditions which are outside of the conditions outlined above can cause potential complications such as device migration, heating and tissue damage or erosion through the skin.

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, and consult with the healthcare provider who inserted your sensor.

For the most updated version of the Eversense E3 CGM System labelling, visit **https://global.eversensediabetes.com**. You will receive an International Implant Card from your healthcare provider with each sensor insertion. Keep this card in your wallet as a reference.

Contraindications

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

The smart transmitter is incompatible with magnetic resonance imaging (MRI) procedures. Patients should not undergo an MRI procedure when wearing the smart transmitter. For information on the sensor, please see *MRI Safety Information*.

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 Package

This Eversense E3 Smart Transmitter Kit contains the following:



Eversense E3 Smart Transmitter



Charging Cradle



Power Supply
(Your Smart Transmitter kit will include a wall plug appropriate for use in your local region.)

Also included in this package is this *User Guide* and a *Quick Reference Guide*.

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 **cautions** 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. Additional safety information is available at https://ec.europa.eu/tools/eudamed (European database on medical devices – EUDAMED) in the Eversense E3 CGM System Summary of Safety and Performance (SSCP), or upon request to Customer Support. The SSCP is linked to the Eversense E3 CGM system component Basic UDI-DI numbers that are listed on the back cover of this Instruction Manual.

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 hypoglycaemic or hyperglycaemic 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 minimise 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 healthcare provider.

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

Any serious incident that has occurred relating to use of the device should be reported to the manufacturer and the competent authority of your Member State.

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. The system's calculated glucose can be slightly different from your blood glucose meter. This may cause an alert to activate at a different time than it would have if the system's values always matched the blood glucose meter values.

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 healthcare 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. The implantation may cause infection, pain, skin irritation, bruising, skin discolouration or atrophy. 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. Additionally, the adhesive may cause a reaction or skin irritation. Any medical issue related to the procedure or use of the device should be reported to your healthcare provider. The sensor will require an additional removal procedure at the end of sensor life.

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 healthcare provider. For additional Eversense E3 product questions and troubleshooting issues, contact Customer Support toll free in the US at 844-SENSE4U (844-736-7348). Outside the US, call your local distributor or visit **https://global.eversensediabetes.com** to locate your local distributor.
- 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 10.16 cm (4 in) of the sensor site. If the insulin delivery site is within 10.16 cm (4 in) of the sensor site, it may interfere with sensor glucose readings and can cause inaccurate glucose readings.
- Always follow your healthcare provider's instructions for care after the sensor insertion or removal. Contact your healthcare 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 Initialisation 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.
- If you are allergic to any of the materials used in the sensor or smart transmitter that are listed in the Technical Specifications of this user guide, DO NOT use the Eversense CGM System.

Cautions

- 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 localised, 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 healthcare 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 healthcare 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.

Cautions (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, create the risk of fire, and could result in voiding your warranty. If your Eversense AC power adapter or USB cable is damaged or lost, contact Customer Support for a replacement to ensure safe operation of the device.
- If you have any concerns about allergic reaction to adhesive products containing silicone, contact your healthcare 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 healthcare 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 healthcare 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 healthcare 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 hospitalised 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 healthcare 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 familiarise 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 fully charged 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.

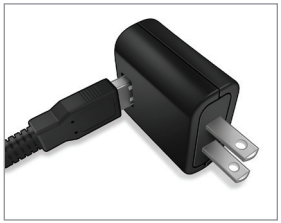
Your smart transmitter comes with a 12-month warranty. The system will alert you when the transmitter warranty exceeds 365 days.

Charge your Smart Transmitter

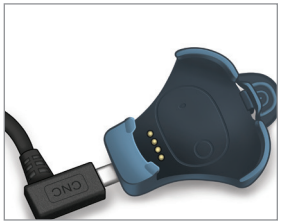
It is important to charge the smart transmitter battery daily to ensure data is collected from the sensor and sent to the app. The smart transmitter does not collect information from the sensor or send it to the app while charging. You may also charge your smart transmitter by connecting the USB cable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

Caution: 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, create the risk of fire, and could result in voiding your warranty. If your Eversense AC power adapter or USB cable is damaged or lost, contact Customer Support for a replacement to ensure safe operation of the device.

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

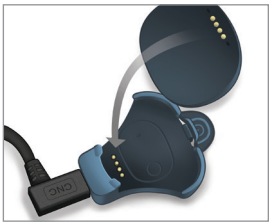


2. **Plug the micro end of the USB cable into the charging cradle on the USB port.**



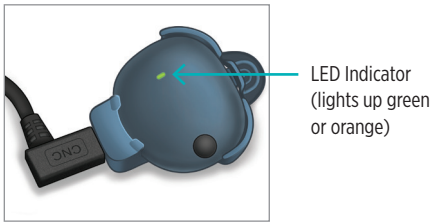
3. Line up the four gold pins on the bottom of the smart transmitter with the four gold pins on the charging cradle.

- Slide the smart transmitter into place in the charging cradle.
- Once positioned, push down on the smart transmitter until it snaps into place.



4. 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 power supply from the smart transmitter after it is fully charged.
- To release the smart transmitter from the charging cradle, pull back on the tab and lift the smart transmitter out of the cradle.



Step 1. Download and Install the App

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.

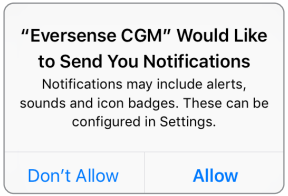


Eversense App Icon

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.

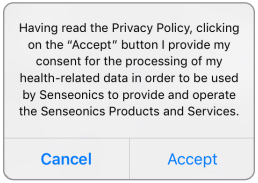
IMPORTANT: Make sure that you have a wireless internet connection, the date and time are correct on your mobile device, and that Bluetooth is turned ON before continuing.

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

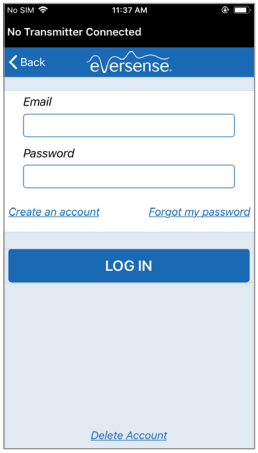
Once the app is downloaded, connect the app and smart transmitter by pairing the smart transmitter with your mobile device.

1. **Launch the app by tapping the Eversense App icon on your mobile device. The full version of the END USER LICENCE AGREEMENT is displayed.**
   - Review and tap **Accept**.



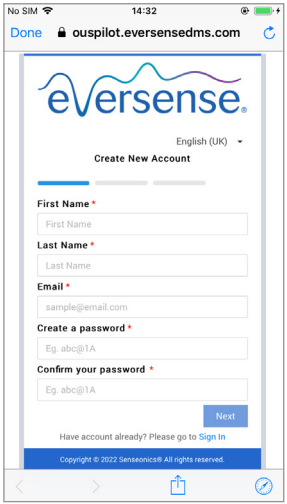


2. **After you accept the Agreement, you will be prompted to create and register an account with an Email and Password.**
   - You must register an account before you are able to log in. Tap **Create an Account**.



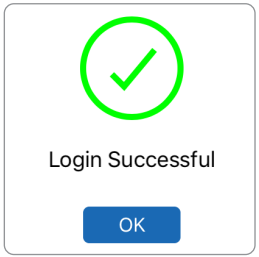
Note: If you already have an account and you forget your password, you can reset it via the app. If you forget your email associated with your account, go to **Main Menu** > **About** > **My Account**.

3. **Enter your account information and then tap Submit.**
   - Tap Done to return to the Eversense LOGIN screen.

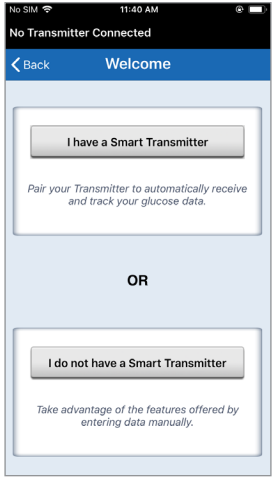


4. **Enter your email address and password and tap LOG IN. You will see a confirmation screen. Tap OK.**

   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

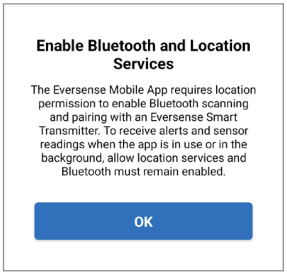
or

I do not have a Smart Transmitter

(skip to step 12).

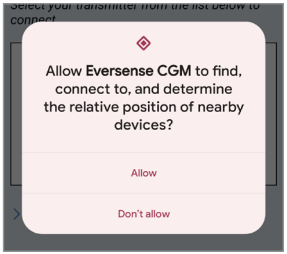
Android users must enable location services.

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

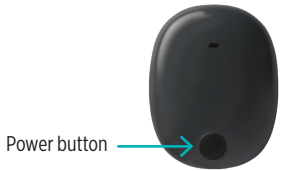


- Then tap **Allow** to ensure you receive alerts when the app is in use or in the background.

Note: Android OS 12 and above may see a different permission request pop up.

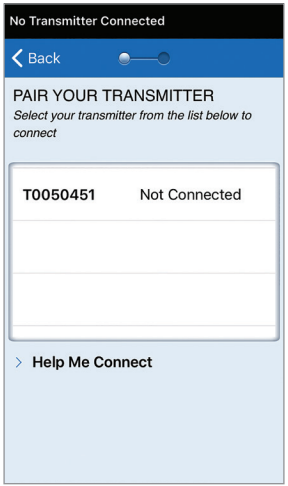


7. **With the smart transmitter turned on, and when the PAIR YOUR TRANSMITTER screen appears on your mobile device, set your smart transmitter to "Discoverable" mode for the mobile device to find the smart transmitter:**
   - Press the smart transmitter power button three times. Make sure your smart transmitter is not plugged into the power supply.
   - The LED will flash green and orange to indicate the smart transmitter is in Discoverable mode.



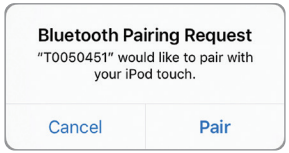
Note: If you press the power button on the smart transmitter and no LED appears, press and hold the power button for about 5 seconds to turn it on.

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.

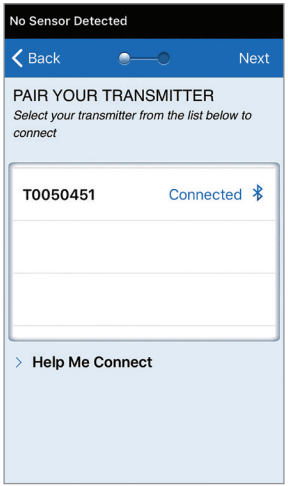


9. **A BLUETOOTH PAIRING REQUEST pop-up screen appears.**
   - Tap **Pair** to complete the pairing process.

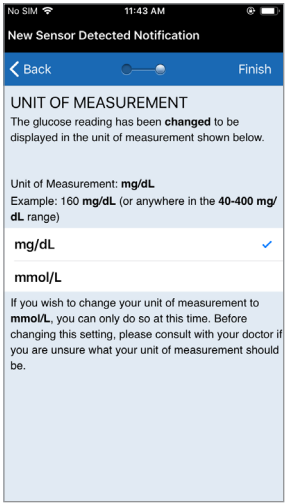
Note: The smart transmitter can only be paired with one mobile device at a time.



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

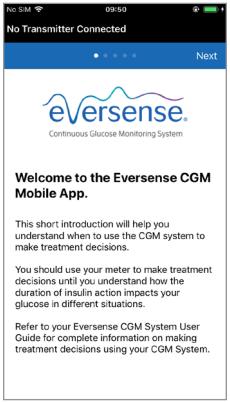


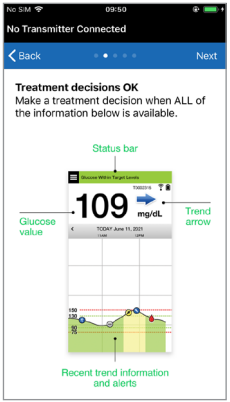
11. The **UNIT OF MEASUREMENT** screen appears and indicates the standard unit of measurement for your region. Your glucose readings will always be displayed in this unit of measurement.
    - When the unit of measurement is confirmed, tap **Finish**.

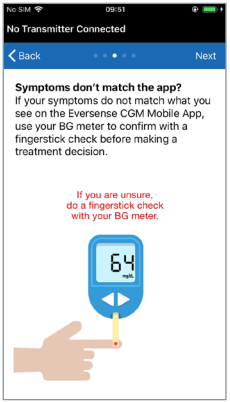


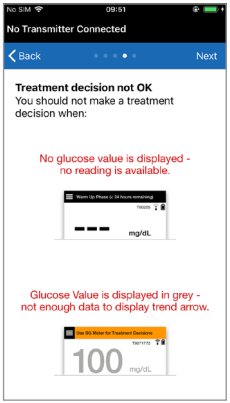
Caution: DO NOT change the unit of measurement unless you have discussed it with your healthcare provider.

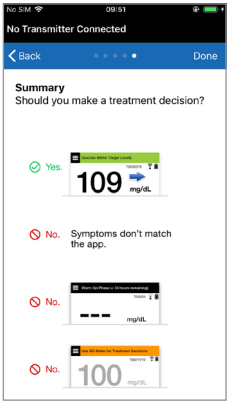
12. Tap through the introduction screens that provide information about when to make treatment decisions with the Eversense E3 CGM System.



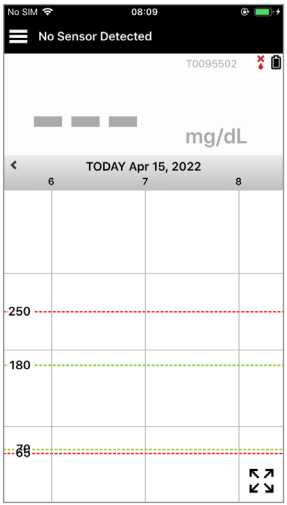








13. Next, the **MY GLUCOSE** screen appears. The screen will not have any glucose data to display at this time.



Once the sensor is inserted by your healthcare 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

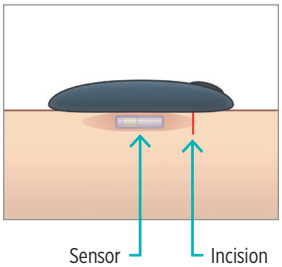
This section describes how to link the sensor and smart transmitter for the first time after your healthcare provider has inserted the sensor. Only your GP can insert the sensor. See "About the Sensor" to learn more.

Once your healthcare 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.

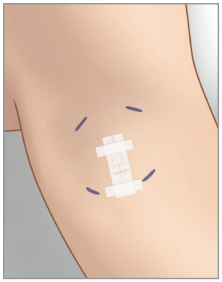
You can link your sensor to the smart transmitter any time after the sensor is inserted and the smart transmitter is paired with the Eversense App. To link the sensor, your mobile device must be connected to the internet and your transmitter must be charged, turned on, and paired with your mobile device.

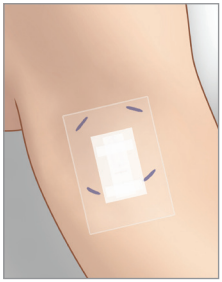
The incision site is closed using Steri Strips and an adhesive bandage, such as Tegaderm is placed over the top. It is important to understand how the smart transmitter should be positioned over the sensor to ensure linking can be completed. The smart transmitter should be centred over the sensor as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



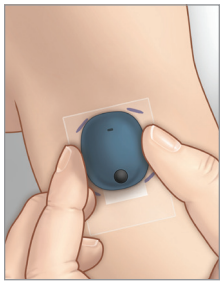
IMPORTANT: Your healthcare provider will complete an Implant Card at the time of your insertion. Please keep this card in your wallet and replace it when you receive a new card with your next insertion.

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

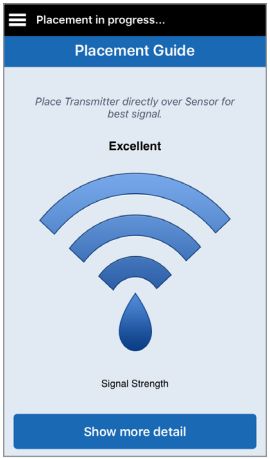




The first time you link the sensor, do not use an Eversense adhesive patch on the smart transmitter. When positioning the smart transmitter over the sensor, it should be slightly above the centre of the Tegaderm patch.

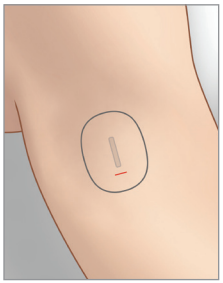


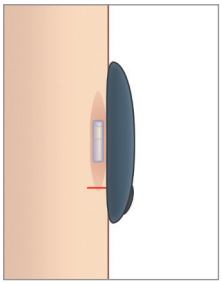
1. **Make sure your smart transmitter is turned ON (see *Using the Smart Transmitter*) and that your mobile device has access to the internet.**
   - Position the smart transmitter directly over the inserted sensor until the **Placement Guide** in the app shows some connection and keep in position without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



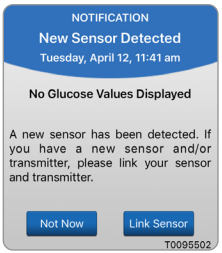
2. **Navigate away from the Placement Guide page to the Main Menu screen once you have confirmed that there is a signal.**

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 centred over the sensor vertically.

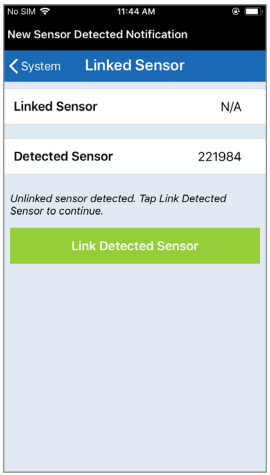




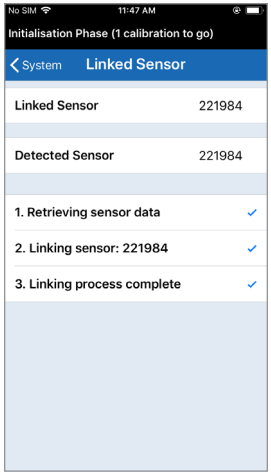
3. **To link the smart transmitter and sensor, tap Link Sensor on either the New Sensor Detected pop-up screen or by tapping Menu > Settings > System > Linked Sensor and then tap Link Detected Sensor.**

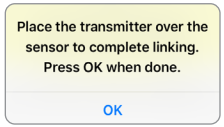


Note: It may take up to 5 minutes for the New Sensor Detected notification to be displayed.

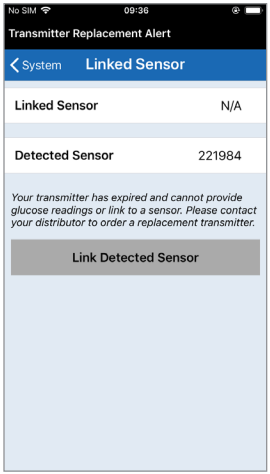


4. The linking process will begin. Each step will show a check mark when finished. It may take up to 10 minutes for the process to complete. DO NOT remove the smart transmitter from your insertion site until the third check mark is displayed.



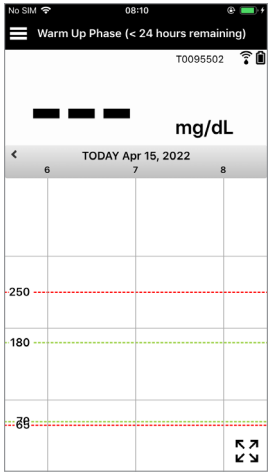


If the smart transmitter is removed from the sensor site, the system will display a notification.



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

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



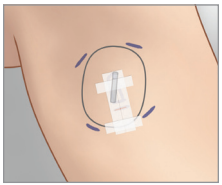
Caution: The sensor and smart transmitter should be linked the day of the sensor insertion. Failure to link the sensor and smart transmitter could result in a delay in receiving glucose readings.

Note: The sensor requires a 24-hour Warm-Up Phase to stabilise 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 Initialisation 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.

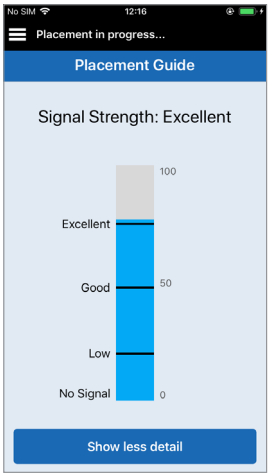
✓**Tip:** You do not need Excellent signal strength in order to link the sensor or use your system.



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.



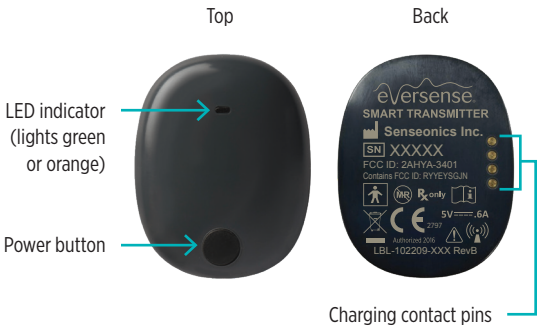
5. Daily Transmitter Wear

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 Initialisation Phase begins, and you're ready to start wearing the smart transmitter. For the first few days, you'll wear the smart transmitter over the Tegaderm™ bandage. Always start with a freshly charged smart transmitter. 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 charging cradle.
- Uses USB port on charging cradle to download data to compatible external applications.
- Multi-colour LED to indicate various modes of the smart transmitter.
- 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 1 metre (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 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 is 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 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.

Secure the Smart Transmitter over Inserted Sensor

5

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 healthcare provider instructs. Discard used adhesive patches in accordance with your local regulations.

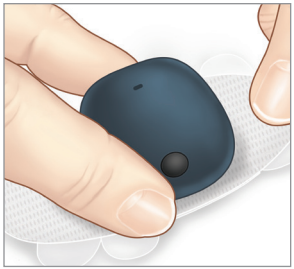
Note: You will receive adhesive patches from your healthcare provider. Adhesive patches are provided in both white and clear material. The white adhesives are perforated, allowing for moisture to be wicked away. The clear adhesives allow for use on the occasions you may want more discretion.

Caution: If you have any concerns about allergic reaction to silicones, contact your healthcare 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 centre.**

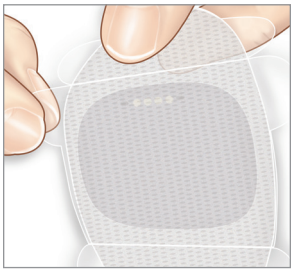


2. **Align the smart transmitter over the sticky side (centre) of patch and press firmly to secure.**
   - The smart transmitter should be placed so that its sides face the wings of the patch (as shown).



3. Remove the larger clear backing and position the smart transmitter directly over the sensor.

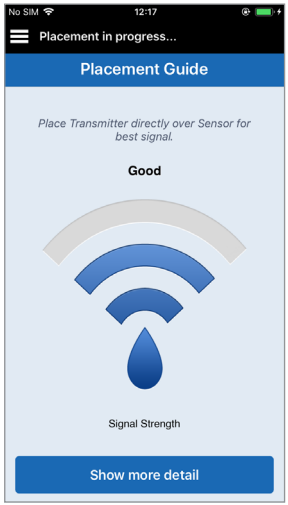
- For the optimal signal strength, the smart transmitter must be placed directly over the sensor. Signal strength can also be improved by rotating the smart transmitter over the sensor such that the sensor is centred vertically under the smart transmitter.



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

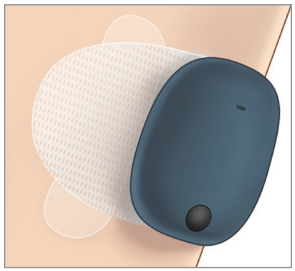
4. Check the connection between the smart transmitter and the sensor.

- 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.

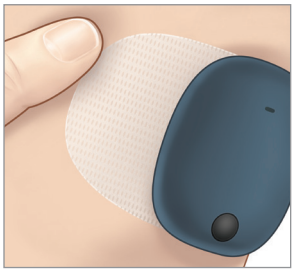


Note: To see more information about signal strength and transmitter positioning, see *Placement Guide – Show More Detail Screen* in the *Linking the Sensor* section.

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.

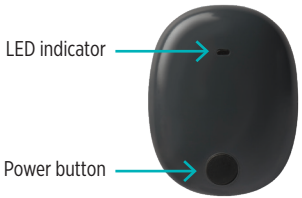


Turn the Smart Transmitter ON and OFF

The smart transmitter has a power button to turn the device on and off. The power button and two light emitting diodes (LED) lights are also used to indicate the remaining battery power.

1. **To turn the smart transmitter ON, press and hold the power button for about five seconds.**
   - The smart transmitter will vibrate once.
   - Release the power button and the LED will flashes once indicating the power is ON.

   At any time, you can press the power button once to see if the smart transmitter is ON. If the LED appears, the smart transmitter is ON. If no LED appears, the smart transmitter is OFF.



2. **To turn the smart transmitter OFF, press and hold the power button for about five seconds.**
   - The smart transmitter will vibrate once.
   - Release the power button and an orange light will flash once, indicating the power is OFF.

Smart Transmitter Care and Maintenance

- Keep the smart transmitter and charging cradle 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.
- 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.

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 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, press and release the power button. The LED will flash green once if the battery has at least 10% power. It is recommended to always charge the smart transmitter for a full 15 minutes using a wall outlet to ensure a full charge. See the next page for more information on the LED indicators

LED Status Indicators

The smart transmitter communicates several different statuses based upon the colour of the LED.

- **During smart transmitter use:**

LED Status	Status	Action
Alternating green and orange when power button is pressed 3 times in 5 seconds	Discoverable mode	Pair smart transmitter with mobile device
Does not flash when power button is pressed	Smart transmitter off	Hold down power button for 5 seconds to turn on
Flashes green (once) when power button is pressed	10%-90% battery power	No immediate action required
Flashes orange (once) when power button is pressed	Low battery, less than 10% 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

- **During smart transmitter charging:**

LED Status	Battery Status	Action
Solid or flashing orange when connected to the USB cable	0%-65% charged	Charge for 15 minutes before disconnecting from power supply
Solid green when connected to the USB cable	65%-100% charged	Charge for 15 minutes before disconnecting from power supply

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.

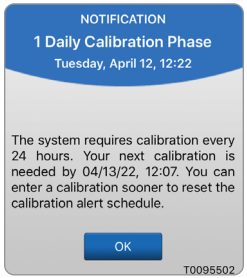
There are three calibration phases:

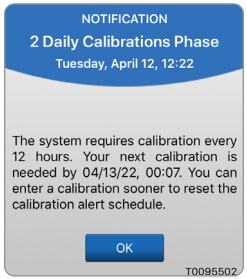
Initialisation Phase – After the 24-hour Warm-Up Phase, you must complete 4 fingerstick calibration tests, spaced 2 to 12 hours apart.

2 Daily Calibrations Phase – After the Initialisation 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 the 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. Initialisation 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 Initialisation Phase

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

- Not completing a calibration test within a 12-hour period during the Initialisation Phase.
- Not completing all 4 calibration tests within 36 hours during the Initialisation 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

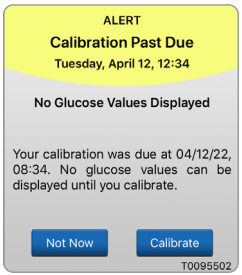
There are two daily calibration phases.

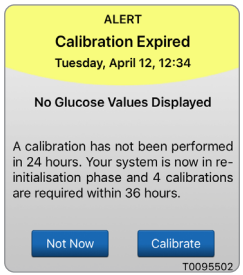
The 2 Daily Calibrations Phase requires a blood glucose meter test every 12 hours. Daily Calibration Phase begins after successful completion of the Initialisation Phase.

- 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 Initialisation 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 Initialisation 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.

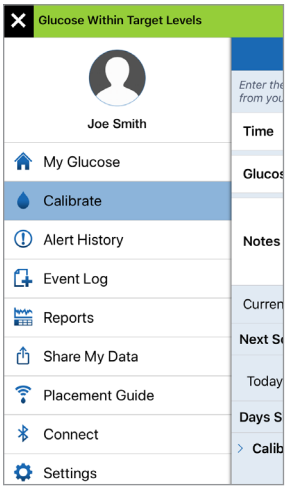
Note: If a calibration entry is very different from the system's sensor glucose value, you will be prompted with a Calibrate Now Notification about an hour later. A Calibrate Now Alert will display 11 to 12 hours later, regardless of which Daily Calibration phase the system is in. In this situation,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

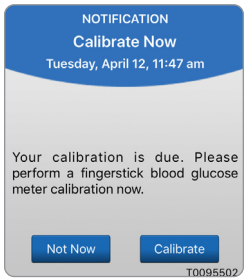
How To Calibrate

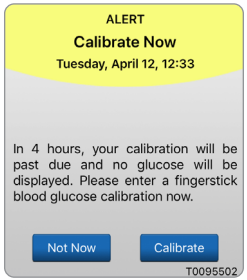
Warning: Always calibrate the system using only a fingerstick blood sample. DO NOT use an alternative site (such as forearm or palm) blood glucose reading to calibrate the system.

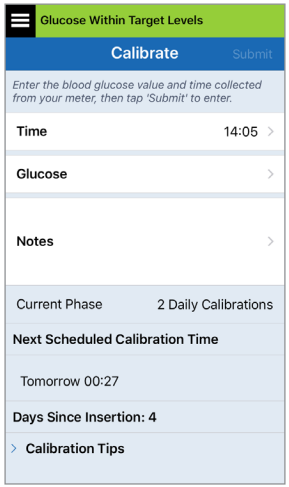
Note: You can enter additional calibration readings as long as each calibration is at least one hour apart.

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

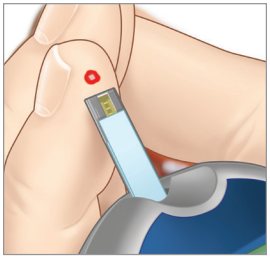




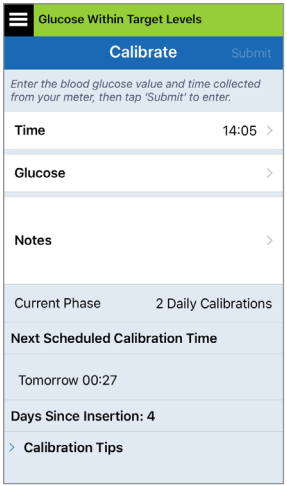


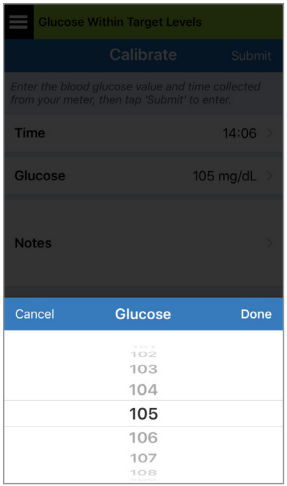


2. Obtain a fingerstick reading from your blood glucose meter.



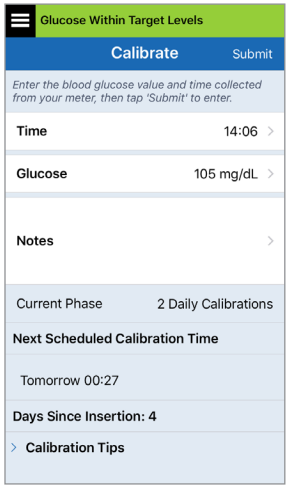
3. Tap **Glucose** and enter the value from your fingerstick blood glucose test.
   - Tap **Done**.
   - Tap **Notes** to enter any notes.
   - Tap **Done**.



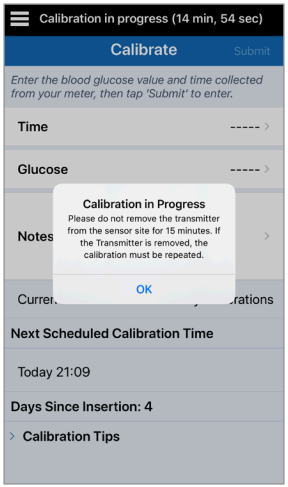


Note: You cannot enter a calibration value that is older than 10 minutes.

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 grey blood drop icon to identify your fingerstick calibration is in progress.

   The blood drop will turn red when the calibration value is accepted.

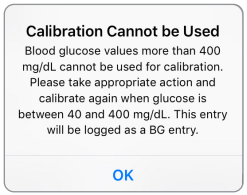


IMPORTANT: The smart transmitter should not be removed from over the sensor for at least 5 minutes before the test to 15 minutes after the test while calibration is in progress. The Status Bar at the top of the screen lets you know when calibration will be complete. If the smart transmitter is removed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

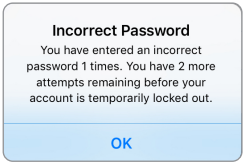
On the **MY GLUCOSE** screen, you have easy access to:

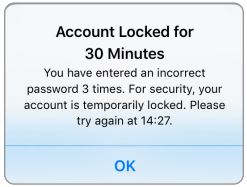
- Real-time sensor glucose measurements.
- Rate and direction of your changing glucose levels.
- Graphical trends of your glucose levels.
- Alerts (hypoglycaemia or hyperglycaemia).
- Events such as meals, exercise, and medications.

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.

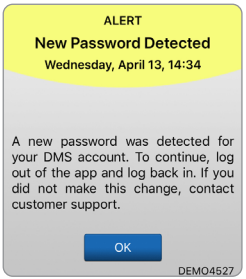


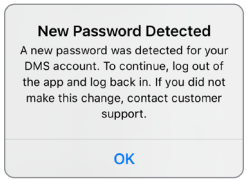


Caution: If you cannot access your CGM data, you should monitor your glucose using a home blood glucose monitor.

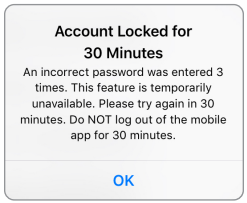
The Eversense Mobile App will periodically check to confirm your log in information has not been changed via your Eversense DMS account.

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

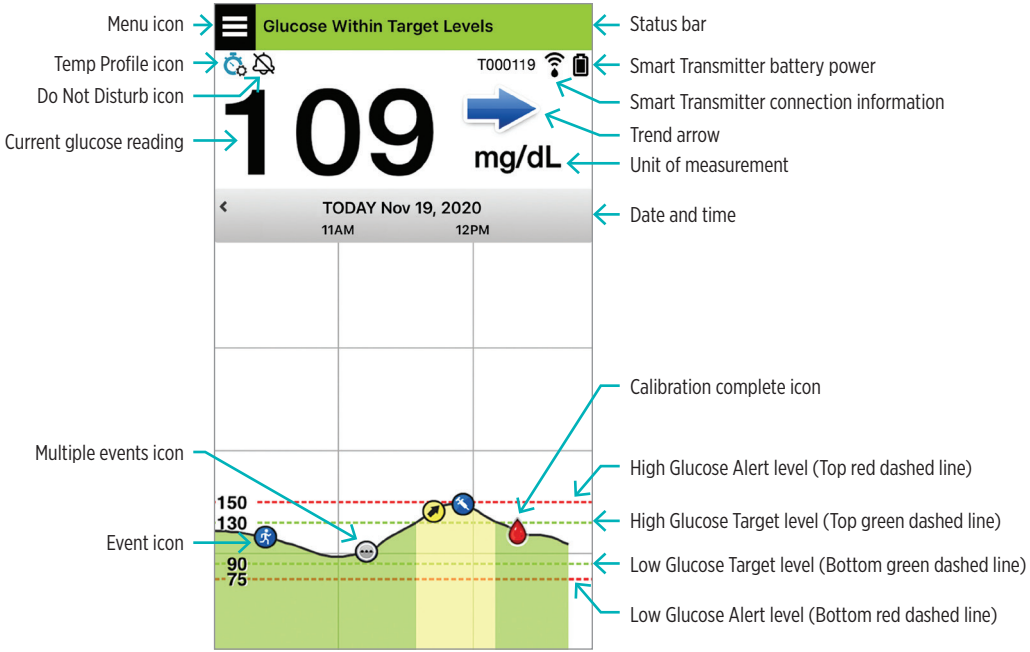
You will need a mobile device (such as your smartphone) to use the Eversense E3 CGM System. It is very important that your mobile device is set up properly to ensure accurate display of your glucose data in the app. Follow the manufacturer's instructions for your mobile device to set up the following:

- 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. The Eversense Widget is not available on all operating systems.
- 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 power	Indicates battery power left in the smart transmitter.
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).

Multiple events icon	Indicates multiple events have occurred at the same time.
Event icon	Indicates manually entered events (e.g., exercise). See *Logging Events* for more information.
Calibration icons	Indicates calibration entry status.
Glucose trend graph	Glucose levels over time. You can scroll back and forth to see trends or zoom in to display as few as 3 hours of data, or zoom out to see up to 3 days.
Menu	Provides easy navigation to various sections of the Eversense App: My Glucose Calibrate Alert History Event Log Reports Share My Data Placement Guide Connect Settings About

Trend Arrows

There are 5 different trend arrows that show the current direction of your glucose levels, and how fast they are changing.

	Gradually rising or falling glucose levels, falling or rising at a rate between 0.0 mg/dL and 1.0 mg/dL per minute.
	Moderately rising glucose level, rising at a rate between 1.0 mg/dL and 2.0 mg/dL per minute.
	Moderately falling glucose levels, falling at a rate between 1.0 mg/dL and 2.0 mg/dL per minute.
	Very rapidly rising glucose levels, rising at a rate more than 2.0 mg/dL per minute.
	Very rapidly falling glucose levels, falling at a rate more than 2.0 mg/dL per minute.

The app uses the **last 20 minutes of continuous glucose data** for calculating glucose trends.

When there are not enough sensor values available to calculate a trend arrow, it is not displayed and the glucose value is grey instead of black.

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.

Understanding Treatment Decisions with CGM

Read the entire Eversense E3 CGM System User Guide and be sure you are familiar with when you should and should not make treatment decisions based on your CGM information. Before you begin using Eversense E3 to make treatment decisions, talk with your healthcare provider about understanding how food, insulin, medications, stress, and exercise impact your glucose.

IMPORTANT:

- If your symptoms do not match the sensor glucose information displayed, or the app is not displaying both a number and a trend arrow, then use your BG meter to make treatment decisions.
- Use your blood glucose meter to make treatment decisions until you understand how Eversense E3 works for you. It may take days, weeks, or even months for you to be comfortable using your CGM data to make treatment decisions.

Take your time and follow your healthcare provider's recommendation for when to use Eversense E3 instead of your BG meter.

Sensor Glucose and Blood Glucose

Sensor glucose is measured in the interstitial fluid, not in blood. Because of this, sensor glucose values may lag behind blood glucose values. For example, when your CGM trend arrow shows rapidly falling glucose, your blood glucose may be lower than the number shown; or when your CGM trend arrow shows a rapid rise, your blood glucose may be higher than the number shown. These examples are more likely when your glucose is changing rapidly, such as after a meal, after dosing insulin, or during and after exercise. Stress, illness, and even some medications you take can also impact your glucose. Sometimes the right treatment decision is to wait and check your CGM data frequently before taking action.

Early Wear Time

During the 24-hour Warm up Phase, glucose values are not displayed. Also, during early wear time as your insertion site heals, your sensor glucose values may not match your blood glucose values as closely as they will when healing is complete. Use your BG meter to make treatment decisions during the Warm up Phase and until you are confident with your CGM values. Always remember, if the way you feel does not match the glucose value and trend arrow, use your BG meter.

Bluetooth Communication

The smart transmitter communicates wirelessly with your mobile device via Bluetooth to display your glucose reading. If the connection between your smart transmitter and your mobile device is interrupted, you will not see a glucose value or a trend arrow. Use your BG meter to make treatment decisions if your smart transmitter is not communicating with your mobile device.

On-body Vibe Alert

Your smart transmitter provides vibratory alerts when you have passed the glucose alert levels you set. However, do not use on-body vibe alerts to make treatment decisions. When you receive an on-body vibe alert, check your glucose reading and trend arrow on your Eversense App.

Remote Monitoring with Eversense NOW

Treatment decisions must not be made based on CGM information displayed on the Eversense NOW Remote Monitoring Mobile App. Remote monitoring relies on data being sent from your mobile device through the Eversense cloud and then to the Eversense NOW app. Interruptions in any of these connections will delay data being displayed in Eversense NOW. Only the CGM information sent directly from the smart transmitter to your mobile device can be used to make treatment decisions.

Discuss with Your Healthcare Provider

Meals

Different types of meals and foods can impact your glucose levels and trend arrows in different ways, as can conditions such as delayed gastric emptying. Some foods will raise your glucose more rapidly than others. Before using CGM data to make treatment decisions, discuss with your healthcare provider about how to manage insulin dosing for different types of food, and how to accurately calculate carbohydrates.

Insulin

Insulin does not instantly impact your glucose. For example, depending on the brand of rapid-acting insulin used, onset of action can be from 5 to 15 minutes, peak effect in 1-2 hours and duration of action of 4-6 hours. Be sure to understand when you can expect the insulin you take to start lowering your glucose, when its maximum effectiveness is, and how long it lasts in your body continuing to lower your glucose. Working with your healthcare provider to understand the onset, peak, and duration of your insulin action will help you avoid stacking insulin. Stacking insulin is when you take a dose of insulin while a previous dose is still working at lowering your glucose. Hypoglycaemia, sometimes severe, can result. Rather than reacting and taking insulin based on a high CGM value, be sure to consider whether insulin from your most recent dose is still actively lowering your glucose.

Exercise

Even relatively mild exercise, if it is not part of your normal routine, may cause your glucose to change more rapidly than usual. If your symptoms do not match your CGM value, or if your CGM value and trend arrow are not what you expect, use your BG meter to make treatment decisions. Some people experience delayed-onset hypoglycaemia hours after exercise. You should follow your healthcare provider's recommendation on dosing insulin following exercise to avoid low glucose.

Illness & Stress

When you are ill or stressed, your glucose is impacted, and this may be a consideration for making treatment decisions. Keep in mind that stress is not always negative. You could find your glucose levels changing while headed on holiday or going to a fun social event. Your healthcare provider can help you create a plan for treatment decisions when you are sick or in stressful situations.

Medications

Understand how the medications you take impact your glucose. Some diabetes medications work to decrease your glucose, and some medications, like steroids, may increase your glucose levels. With Eversense E3, medications of the Tetracycline class may falsely lower glucose and you should not rely on CGM readings when taking drugs in this class. Talk with your healthcare provider about the medications you take and what to consider about them when making treatment decisions.

Eversense E3 Glucose Alerts

Your healthcare provider will help you determine the target range and glucose alert levels that are right for you. Pay careful attention to your Eversense E3 glucose alerts – you may need to make a treatment decision. When you receive an Out of Range Glucose Alert, the sensor glucose value is below 40 mg/dL with LO displayed instead of a number, or above 400 mg/dL with HI displayed instead of a number. Ask your healthcare provider about how treating very low and very high glucose may be different from the way you otherwise treat, and always use your BG meter to make a treatment decision when LO or HI is displayed.

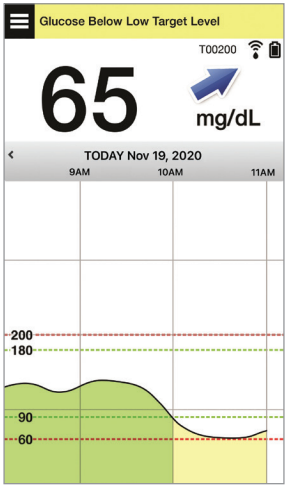
Look Ahead

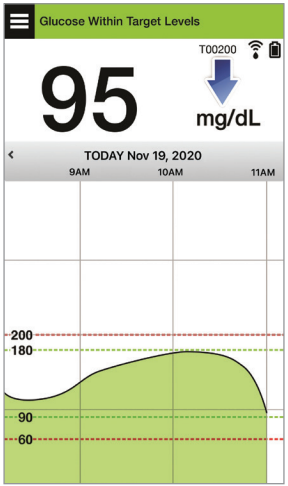
Carefully consider the time of day when making CGM treatment decisions, just like you do when using your BG meter. For example, if your glucose is high and rising just before bedtime, adjust your insulin dose according to your healthcare provider's recommendation. Also think about how to treat if you are planning to exercise or will be sitting in a meeting all day. Your healthcare provider may recommend adjusting your treatment decision based on what is about to happen in order to avoid high or low glucose.

Making Treatment Decisions with Eversense E3

To make a treatment decision, you should consider:

- Status bar information.
- Current sensor glucose value – the current glucose value should be displayed in black.
- Trend arrow – a trend arrow should be displayed.
- Recent trend information and alerts.

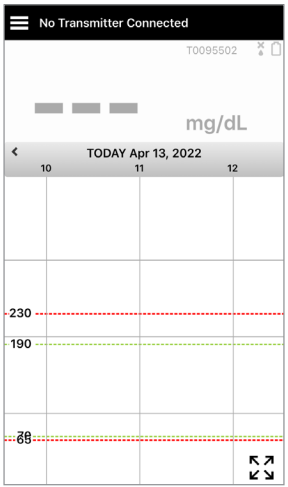


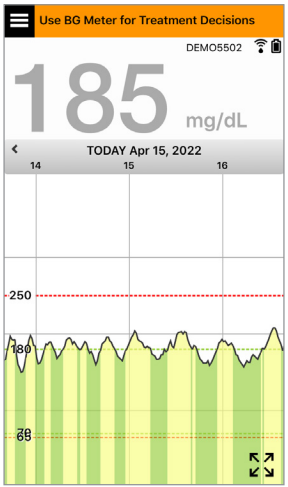




When to NOT make a treatment decision:

- No glucose value is displayed.
- No trend arrow is displayed.
- Your symptoms do not match the glucose information displayed.
- The current sensor glucose value is displayed in grey.
- The status bar is displayed in orange.
- You are taking medications of the tetracycline class.





Note: Always refer to the glucose information on your Eversense CGM App on your smartphone to make treatment decisions. Do not use a secondary display like the Apple Watch or Eversense NOW.

Eversense E3 Trend Arrows and Treatment Decisions

Eversense E3 trend arrows show the direction and rate of change of your glucose to give you an idea of where your glucose is headed. Talk with your healthcare provider about using trend arrows to help you make treatment decisions. Generally, if the arrow is going down, you may consider taking less insulin, and if the trend arrow is going up, you may take more. Be careful not to take too much insulin in a short time, as that could result in low glucose from stacking insulin. The Eversense E3 arrows are listed below, along with how you may use them when considering treatment. Talk with your healthcare provider about making adjustments to treatment based on trend arrows. **Never make a treatment decision using CGM if there is no arrow displayed.**

Eversense E3 Trend Arrow		What it Indicates	Low Glucose	High Glucose	Glucose in Range
No trend arrow		Not enough data to calculate glucose trend direction or rate of change.	**Do a fingerstick blood glucose check with your BG meter before making a treatment decision, even if your glucose is in range.**		
	Glucose is falling at a rapid rate (> 2.0 mg/dL/ minute).	Your glucose could drop 30 mg/dL **or more** within 15 minutes.	Treat with carbs and consider if you recently have finished exercising or if you may have taken too much insulin.	If you've recently taken insulin or are about to exercise, wait and check your CGM value and trend arrow frequently before making a treatment decision.	Treat with carbs and consider if you recently have finished exercising or if you may have taken too much insulin.
	Glucose is falling at a moderate rate (between 1.0 and 2.0 mg/ dL/minute).	Your glucose could drop between 15 and 30 mg/dL within 15 minutes.			

Eversense E3 Trend Arrow		What it Indicates	Low Glucose	High Glucose	Glucose in Range
	Glucose is rising at a rapid rate (> 2.0 mg/dL/ minute).	Your glucose could rise 30 mg/dL **or more** within 15 minutes.	If you've recently taken insulin or are about to exercise, wait and check your CGM value and trend arrow frequently before making a treatment decision.	If you've recently taken insulin or are about to exercise, wait and check your CGM value and trend arrow frequently. If you have not recently taken insulin, and are not about to exercise, consider adjusting insulin correction dose up.	If you've recently taken insulin or are about to exercise, wait and check your CGM value and trend arrow frequently before making a treatment decision. If you have not recently taken insulin or finished exercise, consider adjusting insulin correction dose up.
	Glucose is rising at a moderate rate (between 1.0 and 2.0 mg/ dL/minute).	Your glucose could rise between 15 and 30 mg/dL within 15 minutes.			
	Glucose is changing gradually (1.0 mg/dL/ minute or less).	Your glucose could rise or fall up to 15 mg/dL within 15 minutes.	Consider treating with carbs. If you've recently taken insulin, check your CGM value and trend arrow frequently.	If you've recently taken insulin or are about to exercise, wait and check your CGM value and trend arrow frequently. If you have not recently taken insulin, consider adjusting insulin correction dose up.	No treatment, but if you've recently taken insulin or are about to exercise, check your CGM value and trend arrow frequently.

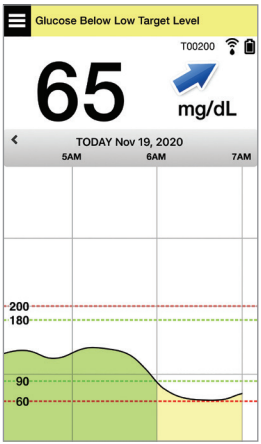
What Would You Do

This section provides examples of some situations you may encounter. It's important to consider what has happened and what is about to happen when making treatment decisions with CGM. Review these examples carefully, and think about what you would consider before making a treatment decision. If you're not sure, always check your BG with a fingerstick before making a treatment decision.

Glucose below target at 65, but rising moderately. Your glucose could reach 120 within 30 minutes.

It's 7 am, and you're about to eat breakfast, and you drank a small glass of orange juice when you first woke up.

- Should you consider taking a little less insulin than you usually would for your meal?
- Should you take the amount of insulin you typically would for this breakfast, and keep an eye on your glucose value, the arrow and how you feel?



It's 9 am, and you dosed insulin for your breakfast about 2 hours ago.

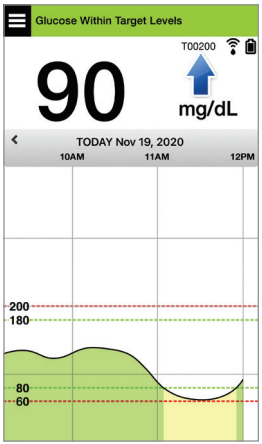
- Should you wait and keep an eye on your glucose value and the arrow before making a treatment decision?
- Should you consider taking carbs to treat the low now?



Glucose in target at 90, but rising rapidly. Your glucose could reach 180 or higher within 45 minutes.

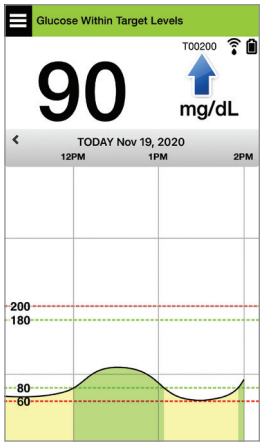
It's noon, and you're about to have lunch.

- What might be causing this rise in glucose?
- Should you consider taking more insulin than you usually would for your meal?
- What does your healthcare provider recommend for adjusting your insulin in this situation?



It's 2 pm, and you dosed insulin to cover your lunch, plus a little extra because of the rapidly rising arrow, about 90 minutes ago.

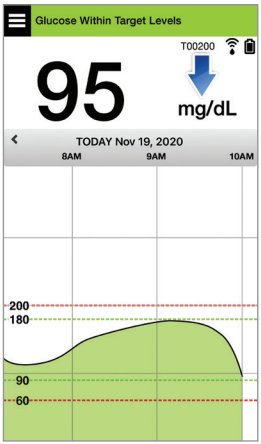
- Since it's only been 90 minutes since you dosed insulin, should you wait and keep an eye on your glucose number and trend arrows?
- How long does your healthcare provider recommend you wait between insulin doses to help prevent stacking insulin?



Glucose in target at 95, but falling rapidly. Your glucose could reach 65 or lower within 15 minutes.

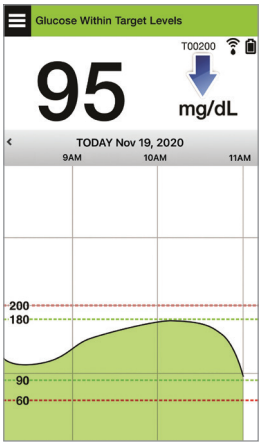
You're about to start your workout.

- What might be causing this rapid drop in glucose?
- Consider a snack to prevent a low glucose event.
- Consider postponing your workout until your trend and glucose are more steady. Keep a close eye on your glucose number, trend arrow and how you feel.



You've just finished your workout.

- How does your healthcare provider recommend you prevent low glucose after a workout?
- Consider a snack to prevent a low glucose event.
- Keep a close eye on your glucose number and trend arrow, and how you feel.



Glucose above high alert level at 220, and changing gradually. Your glucose could drop to 190 or rise to 250 within 30 minutes.

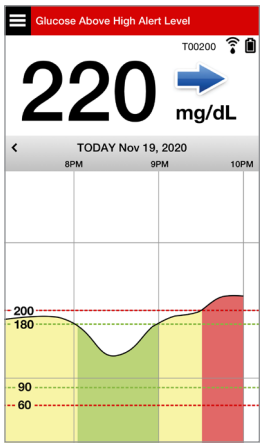
It's 7 pm, and you're about to eat dinner. It's been 6 hours since you dosed insulin for lunch.

- What might be causing this high glucose so long after your last meal?
- Are you having a stressful day; are you not feeling well?
- Should you consider taking more insulin or eating fewer carbs than you typically would for this meal?



It's 10 pm, and you're about to go to bed. It's been two and a half hours since you last dosed insulin.

- What might be causing this high glucose?
- How long does it usually take for the insulin you use to finish lowering your glucose?
- What bedtime glucose value is recommended by your healthcare provider?
- How do you typically treat for a high glucose at bedtime?



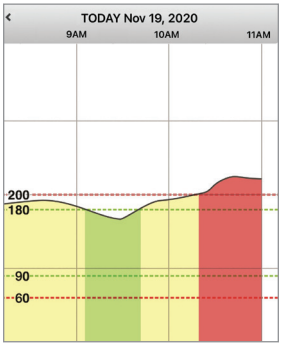
Remember, if you are not sure, always do a fingerstick check with your blood glucose meter before making a treatment decision.

Trend Graph

The trend graph is used to review and analyse historical data and trends in your glucose values over time. It also displays marks for events you have manually logged in the app (e.g., calibration tests and exercise).

There are several ways you can use the trend graph:

- Quickly review how well you are doing when compared to the glucose targets and alert levels you set. The red dashed lines indicate your High and Low Glucose Alert levels, and the green dashed lines indicate your high and low glucose target levels (your target range).
- Shaded areas of the graph are colour coded as follows depending on the glucose settings you enter:
  - Glucose values that are ***outside of your glucose alert levels*** will be red.
  - Glucose values that are ***within your glucose target levels*** will be green.
  - Glucose values that are ***between your glucose target and alert levels*** will be yellow.
- Press and hold any point in the line graph to view a specific glucose reading for that point in time.
- Tap any of the marks on the app screen to get more information about the event or alert.
- Pinch in and out on the screen to display different day/time ranges on the trend graph. You can zoom in and out to display as few as 3 hours or up to 3 days of information.



- To view trend graph data for a different date, tap the date on the screen and enter the desired date.
- You can view the trend graph in either portrait or landscape mode. In landscape mode, there are shortcut buttons to see 7, 14, 30 and 90 day views.

Note: All of your glucose data will be stored in the app as long as you have memory available on your mobile device.

Menu Options

The Menu icon ( ) appears at the top left corner of all app screens and provides easy navigation to other app features. The following menu items are available:

Menu Options		Description
	My Glucose	Main app screen that displays current CGM reading, direction and rate of change, trend graph, events and alerts.
	Calibrate	Enter fingerstick blood glucose calibration values.
	Alert History	Review past alerts and notifications. See *Alert Descriptions* for more information.
	Event Log	Enter information about activities such as blood glucose values, meals, insulin, health and exercise. See *Event Log* for more information.
	Reports	Review a variety of reports about your CGM data. See *Reports* for more information.
	Share My Data	Allow others to view your glucose data through the Eversense NOW Mobile App.
	Placement Guide	Check the communication between the smart transmitter and sensor. Use this screen whenever you are attaching the smart transmitter to be sure communication is established.
	Connect	Establish or check the connection between the smart transmitter and mobile device. A Bluetooth connection is required to send data to the app.
	Settings	Customise settings such as glucose target levels, alert levels, sounds, and temporary profile. See *Customising your Settings* for more information.
	About	View information about your CGM System, including sensor and smart transmitter ID numbers. Change or delete your profile picture and log out of the app.

8. Customising your Settings

This section describes how to customise settings in your Eversense E3 CGM System.

Areas where you can customise app settings include:

- **Glucose –** glucose levels and change rates that will trigger an alert.
- **Calibration Reminders –** optionally set calibration reminder times.
- **System –** identifies or lets you enter personalised information about your system.
- **Sound Settings –** change the sounds for some glucose alerts, set snooze times and Do Not Disturb.
- **Temp Profile –** set a temporary glucose profile.

Glucose Levels

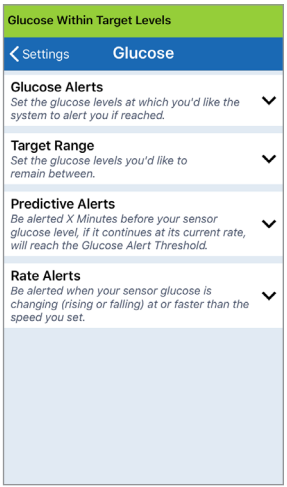
The Eversense E3 CGM System is designed to provide alerts on your smart transmitter and mobile device when your glucose level has reached the alert levels you set. You will decide the settings for your glucose alerts, targets, and rates of change based on input from your healthcare provider.

Warning: The Low and High Glucose Alerts are designed to assist you in managing your diabetes and should not be exclusively used to detect hypoglycaemia or hyperglycaemia. The alerts should always be used in conjunction with other indications of glycaemic state such as your glucose level, trend, line graph etc.

IMPORTANT:

- **Low and High Glucose Alerts are different from your Low and High Glucose Targets.**
  - Low and High Glucose Alerts notify you on your mobile device and smart transmitter when you have reached a certain low or high value.
  - Glucose Targets are used in the reports and line graphs to show how your glucose levels have been performing compared to the targets you set. You will not receive an alert when you have reached your Glucose Target levels.
  - Predictive Low and High Glucose alerts notify you on your mobile device and smart transmitter when your glucose is likely to reach the Low and High Glucose Alert levels you have set.

On the **Glucose Settings** screen, tap the "carat symbols" ⌄ to expand and collapse the settings options.



Setting Glucose Alert Levels

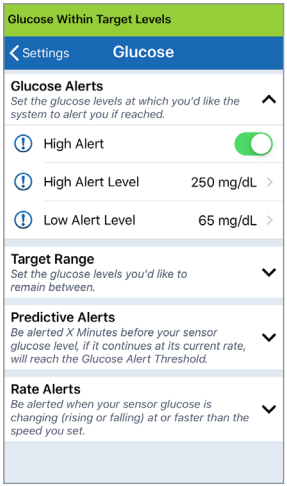
Your Eversense E3 CGM System will alert you when your glucose levels are outside the alert settings you choose. When you have passed your low and high glucose alert levels, the smart transmitter vibrates, and the mobile app gives an audible alert as well as displays a message on the screen.

Default setting	Low: 65 mg/dL High: 250 mg/dL You can change these alert levels based on what you and your GP agree are the right levels for you. Your Low Glucose Alert cannot be set above your Low Glucose Target, and your High Glucose Alert cannot be set below your High Glucose Target.
Allowable setting	Low: 60-115 mg/dL High: 125-350 mg/dL
On/Off setting	Low Glucose Alert setting is Always ON High Glucose Alert setting can be turned ON and OFF. No High Glucose alerts will display or vibe on the smart transmitter if this feature is turned off.
Notes	Audio notification and visual alerts on your mobile device and smart transmitter on-body vibe alerts.

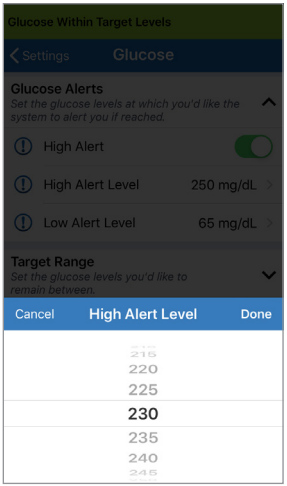
IMPORTANT:

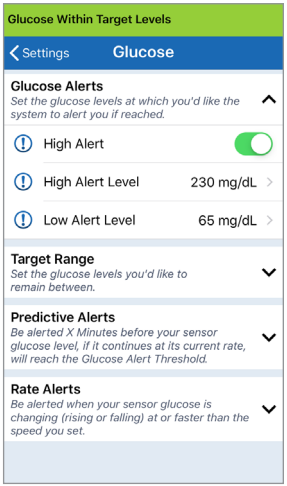
- The Low and High Glucose Alert levels you set are the same levels used to provide Predictive Alerts. See this section, *Setting Predictive Alerts*.
- For iOS 12 and above, and Android 6 and above, you can allow the Eversense Low Glucose and Out of Range Low Glucose Alerts to override your phone sound settings. See *Sound Settings* for more information.

1. Tap **Menu** > **Settings** > **Glucose** to display the **GLUCOSE SETTINGS** screen.



2. Under **Glucose Alert Levels**, tap **High Alert** and select the appropriate High Glucose Alert level.
   - Tap **Done** when complete.
   - Repeat step to make your **Low Alert** selection.



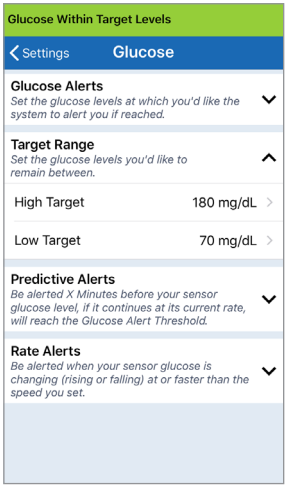


Setting Glucose Target Levels

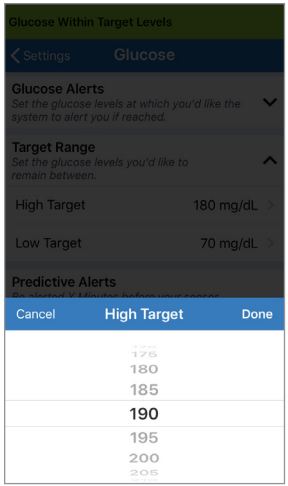
Glucose Targets are the low and high levels of the range you are aiming for throughout the day. These settings are used in the app to indicate when glucose values are in your target range.

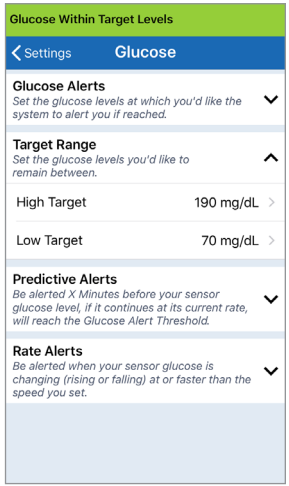
Default setting	Low: 70 mg/dL High: 180 mg/dL You can change this target range based on what you and your GP agree are the right target levels for you.
Allowable setting	Low: 65-120 mg/dL High: 120-345 mg/dL
On/Off setting	Always ON (cannot be turned OFF)
Notes	Used in graphs and charts on the app to show time spent in target range.

1. Tap **Menu** > **Settings** > **Glucose** to display the **GLUCOSE SETTINGS** screen.



2. Under **Glucose Target Levels**, tap **High Target** and select the appropriate High Glucose Target level.
   - Tap **Done** when complete.
   - Repeat step to make your **Low Target** selection.





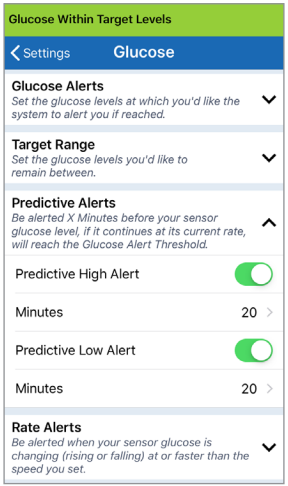
Setting Predictive Alerts

Predictive Alerts let you know in advance that a high or low glucose event is likely to occur if current trends continue.

Predictive Alerts use the Low and High Glucose alert levels previously set to provide an “early” warning. You set the early warning time (10, 20, or 30 minutes) to alert you in advance of reaching your alert levels, based on current glucose trends. When you have reached the early warning time, the smart transmitter vibrates, and the mobile app gives an audible alert as well as displays a message on the screen.

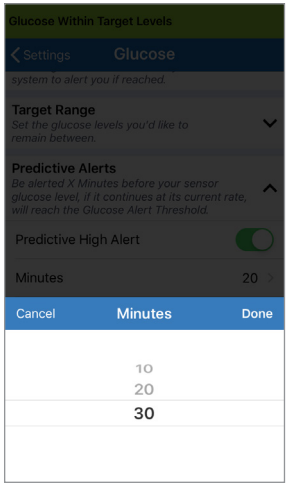
Default setting	OFF
Allowable setting	10, 20, or 30 minutes prior
On/Off setting	You can turn these alerts ON and OFF. No predictive alerts will occur until this feature is turned ON. The default is 20 minutes.
Notes	Audio notification and visual alerts on your mobile device and smart transmitter on-body vibe alerts.

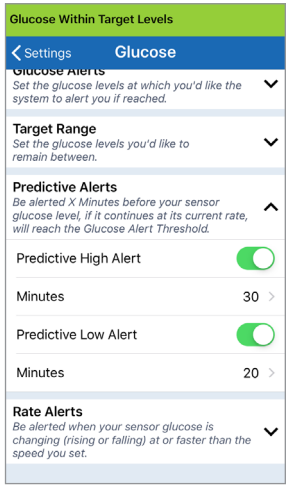
1. To turn this feature ON, tap **Menu** > **Settings** > **Glucose** to display the **GLUCOSE SETTINGS** screen.



2. Next to **the High and Low Predictive Alerts**, slide the **OFF** button to **ON.**

3. Tap **Minutes** to select the amount of advance warning
   - Tap **Done** when complete.



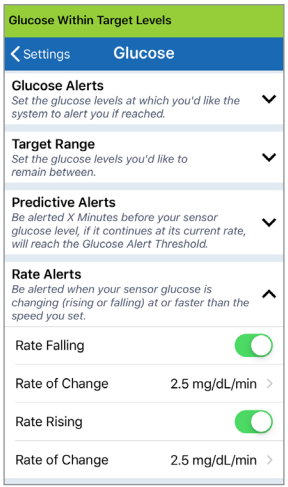


Setting Rate of Change Alerts

The Rate of Change Alerts let you know when your glucose level is falling or rising faster than the Rate Alert setting you choose.

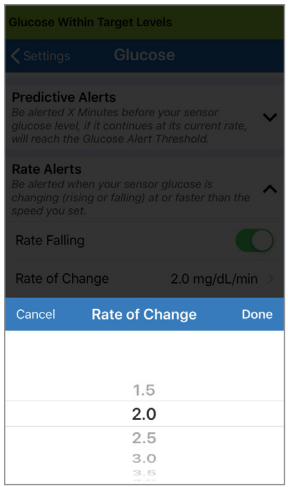
Default setting	OFF
Allowable setting	1.5-5 mg/dL per minute
On/Off setting	You can turn these alerts ON and OFF. No rate of change alerts will occur until this feature is turned ON.
Notes	Audio notification and visual alerts on your mobile device and transmitter vibration alerts.

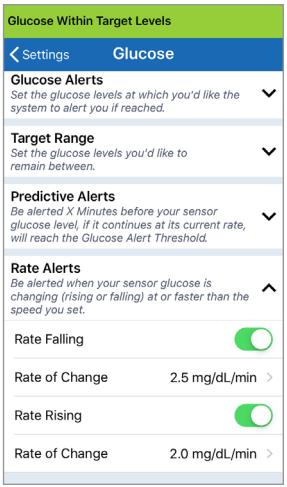
1. To turn this feature ON, tap **Menu** > **Settings** > **Glucose** to display the **GLUCOSE SETTINGS** screen.



2. Next to **Rate Alerts**, slide the **OFF** button to **ON**.

3. Tap **Rate of Change** to select the rate.
   - Tap **Done** when complete.





Setting Daily Calibration Reminders

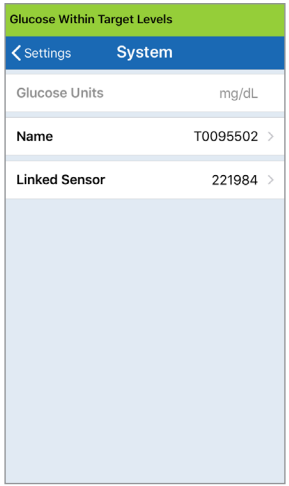
You can optionally set calibration reminders at times most convenient for you. You will still receive the system generated calibration notifications and alerts.

Default setting	OFF
Allowable setting	Time of Day in increments of 1 minute
On/Off setting	You can turn this feature ON or OFF. No reminders will display unless this feature is turned ON.
Notes	You can set one or two daily reminders. Audio notification and visual alerts on your phone screen only – no transmitter vibrations. If you delete the mobile app and re-install, these reminders must be reset. These reminders are not stored in Alert History. If you pair a new transmitter with the existing app, the settings will remain intact. See *Do Not Disturb on Eversense App and Mobile Devices* for more information.

Setting System Information

The **SYSTEM** screen lets you view and edit other settings in your Eversense E3 CGM System.

1. Tap **Menu** > **Settings** > **System** to display the **SYSTEMS** screen.



2. On the **SYSTEMS** screen, you can tap each of the following to set:

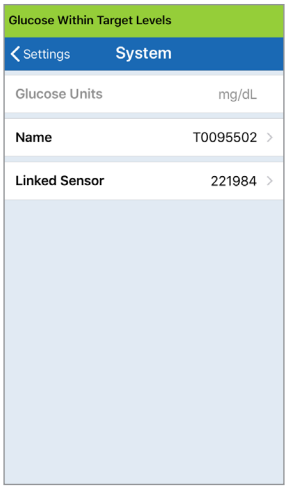
- **Glucose Units.** The unit of measurement for your glucose readings. The App must be reinstalled to edit this setting.
- **Name.** The serial number of your smart transmitter. You can also tap on the serial number displayed here and give your smart transmitter a custom name.
- **Linked Sensor.** The serial number of the sensor currently linked with the smart transmitter. Tap this feature to access the ability to link or re-link a sensor.

Re-linking a Sensor

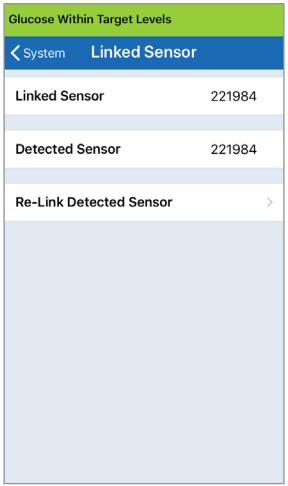
IMPORTANT: Do not re-link your sensor unless instructed by customer support. Re-linking the sensor returns the system to Initialisation Phase, requiring 4 blood glucose fingerstick calibrations within 36 hours.

1. Confirm with Customer Support that you should re-link your sensor.

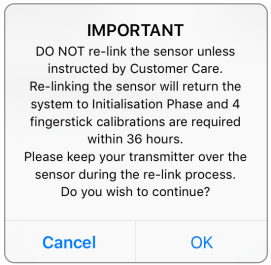
2. Tap **Linked Sensor**.



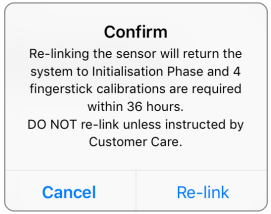
3. Tap **Re-link detected sensor**.



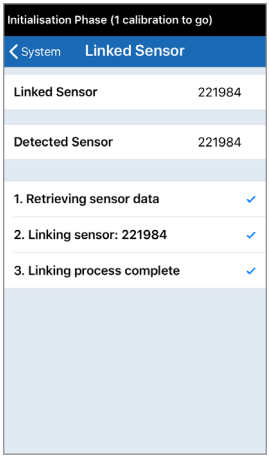
4. Tap **Cancel** or **OK** to continue.

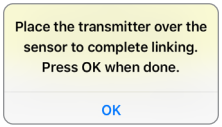


5. Tap **Cancel** or **Re-link**.

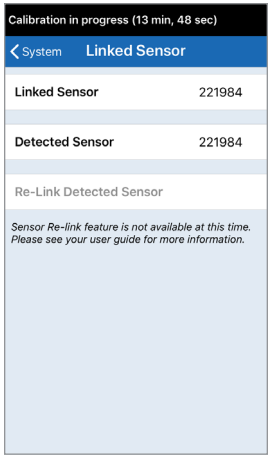


6. The linking process will begin. Each step will show a check mark when finished. It may take up to 10 minutes for the process to complete. DO NOT remove the smart transmitter from your insertion site until the third check mark is displayed.





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



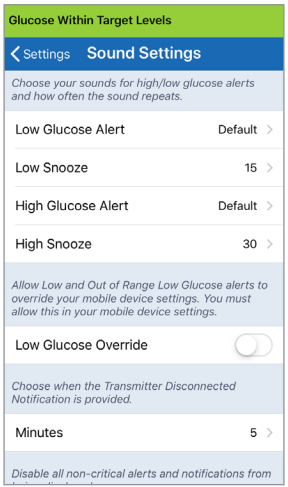
Note: The re-link button will not be available under the following conditions:

- Your transmitter battery needs to be charged or is empty.
- While calibration is in progress.
- Before a sensor has been linked.
- Certain sensor replacement alerts.
- If any of the below alerts are active:
  - Transmitter End of Life
  - System Time Error
  - Sensor Suspend

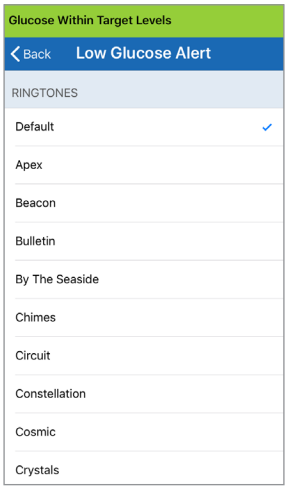
Setting Sounds

The **SOUND SETTINGS** screen displays the alert sound settings for Low Glucose and High Glucose. This screen also allows you to enter a snooze setting for the alerts listed, and the option to have Low and Out of Range Low Glucose Alerts to override your phone sound settings (iOS 12 and above, and Android 6 and above).

1. **Tap Menu > Settings > Sound Settings to display the SOUND SETTINGS screen.**



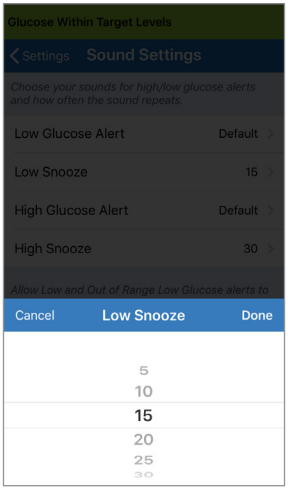
2. **Tap each alert to select the alert sound. Tap Back to get back to the SOUND SETTINGS screen.**



IMPORTANT: Be sure the sound on your mobile device is turned on. If you turn the sound on your mobile device off, you will not hear any sounds from the app.

By setting the snooze alert, you can set how often an alert repeats after you have received a Low Glucose and High Glucose alert.

3. **Tap each snooze alert to set how often the alert repeats.**
   - Tap **Done** when complete.

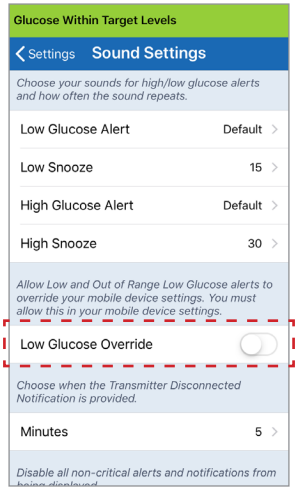


Low Glucose Override Setting

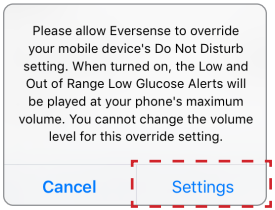
If your mobile device is running iOS 12 and above or Android 6 and above, you can optionally allow Eversense Low and Out of Range Low Glucose alerts to always override your mobile device sound settings. When turned on, the Low and Out of Range Low Glucose alerts will be played at your phone's maximum volume. You cannot change the volume level for this override setting. This allows you to still receive Low and Out of Range Low Glucose alerts on your phone, even if your phone's Silent Mode is on, or Do Not Disturb is on. You must allow this in your mobile device settings.

iOS Devices

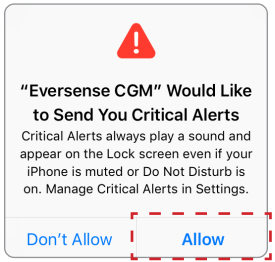
1. Tap the button to turn on the override.



2. Tap **Settings**.

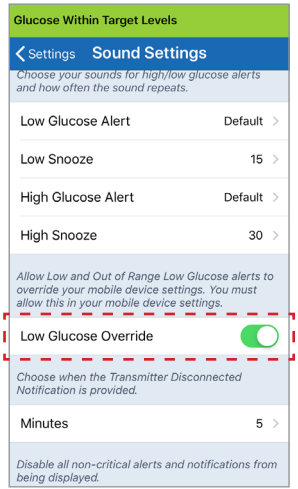


3. Tap **Allow**.



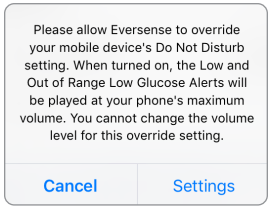
4. The switch for Low Glucose Override can now be turned on.

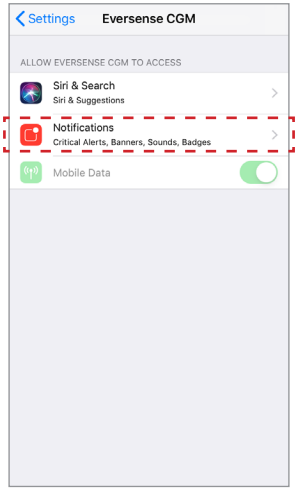
Your system will now alert you of Low and Out of Range Low Glucose alerts at maximum volume even if your Apple device's Silent/Vibration Mode is on, or Do Not Disturb is on.

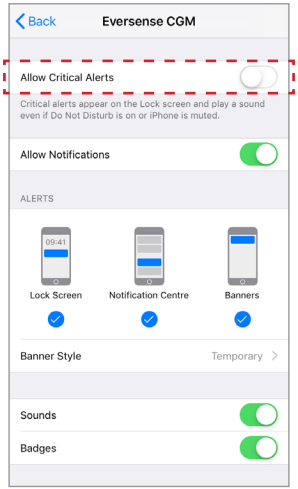


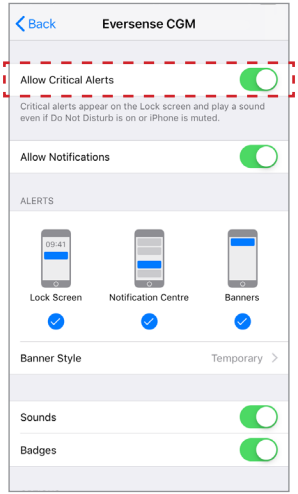
Note: This feature works similar to apps with an alarm clock feature that will always sound regardless of your phone sound settings.

Note: If you tap **Don't Allow** in Step 3, you cannot turn on the Low Glucose Override setting. To turn this setting on at another time, when you tap **Settings** from Step 2, the Eversense settings in your mobile device settings page will be displayed. Tap **Notifications > Allow Critical Alerts**. Then you can turn on the switch for Low Glucose Override in the Eversense App.





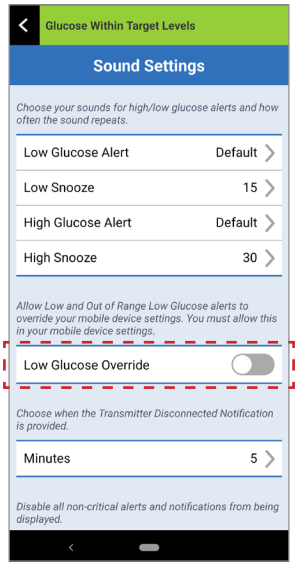




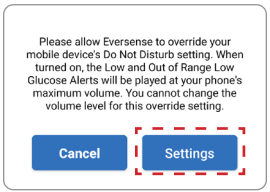
Android Devices

For devices with Android 6 and above:

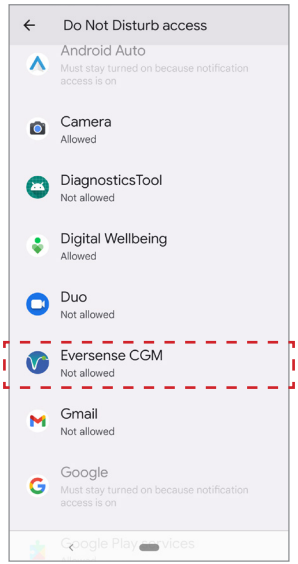
1. Tap the button to turn on the override.



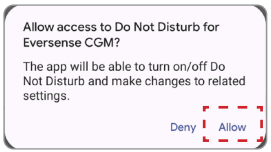
2. Tap **Settings**.



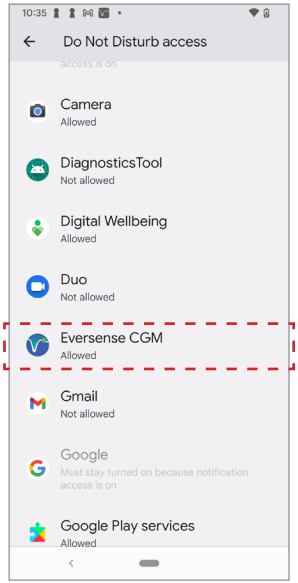
3. Tap on Eversense from the Do Not Disturb access page.



4. Tap **Allow**.

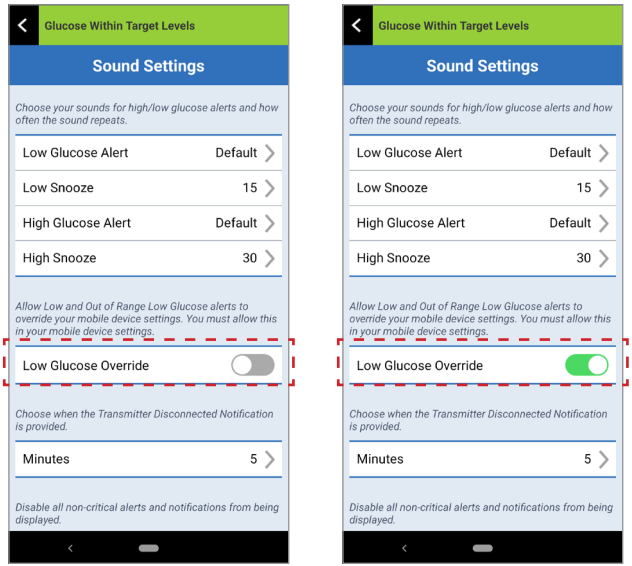


5. Tap the button next to Eversense to allow Eversense to override the Do Not Disturb settings.



6. Return to the Eversense CGM mobile app.

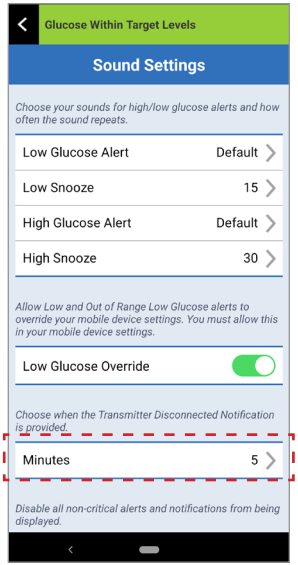
7. Tap on the Low Glucose Override switch to sound the Low and Out of Range Low Glucose alerts at maximum volume even if your device's Silent Mode, Vibration Mode, or Do Not Disturb is on.



Note: This feature works similar to apps with an alarm clock feature that will always sound regardless of your phone sound settings.

Transmitter Disconnect Setting

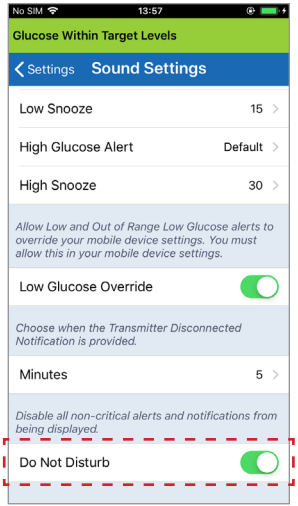
There may be times when the Bluetooth connection between your smart transmitter and mobile device is interrupted. This may be due to the devices being out of range, smart transmitter battery empty, or the Bluetooth feature is turned off in your phone settings. You can customise how long before the system notifies you of a communication interruption. You can set the time to alert you 5 to 30 minutes after a connection is lost. When there is no communication between the smart transmitter and the app, you will only receive vibratory alerts from the smart transmitter. See next section regarding Do Not Disturb mode.



The **SOUND SETTINGS** screen also allows you to enable and disable the Do Not Disturb mode.

- **Do Not Disturb.** Places the app and smart transmitter in a "Do Not Disturb" mode.
- **OFF** – ALL notifications – alerts and notifications – regardless of critical nature will be provided by the smart transmitter and app.
- **ON** – ONLY critical alerts will be provided by the app and smart transmitter's on-body vibe alerts.

Note: When you enable Do Not Disturb mode on your mobile device you will not receive any alerts or notifications from the Eversense App. The DND icon will appear on the Home Screen. For a list of alerts, please see *Alert Descriptions*.



Do Not Disturb on Eversense App and Mobile Devices

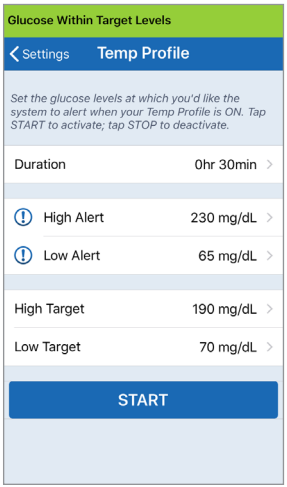
	Eversense App DND off; Mobile device DND off	Eversense App DND on; Mobile device DND off	Eversense App DND off; Mobile device DND on	Eversense App DND on; Mobile device DND on
Transmitter Vibration (Non-Critical Alerts and Notifications)	Yes	No	Yes	No
Eversense App Display, Phone Sound and Phone Vibration (Non-Critical Alerts and Notifications)	Yes	No	No	No
Transmitter Vibration (Critical Alerts)	Yes	Yes	Yes	Yes
Eversense App Display, Phone Sound and Phone Vibration (Critical Alerts)	Yes	Yes	No	No
Calibration Reminders (Phone notification)	Yes	Yes	No	No
Low Glucose Alert (Override turned ON)	Yes	Yes	Yes	Yes

IMPORTANT: Certain phone operating systems allow you to enable Low Glucose Alerts to override your phone sound setting. See *Sound Settings* for more information.

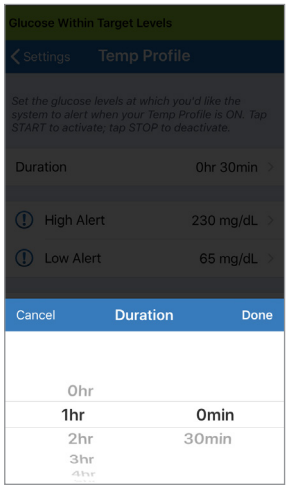
Setting Temporary Profile

During activities or conditions outside your normal routine, you may wish to temporarily use glucose settings that are different from the standard glucose settings you have entered. The **TEMP PROFILE** screen allows you to temporarily change glucose target and alert settings for the duration you choose. When the Temp Profile duration is over, the standard glucose settings you entered in **Settings** > **Glucose** will automatically resume.

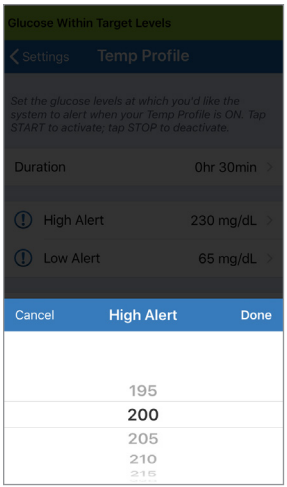
1. Tap **Menu** > **Settings** > **Temp Profile** to display the **TEMP PROFILE** screen.

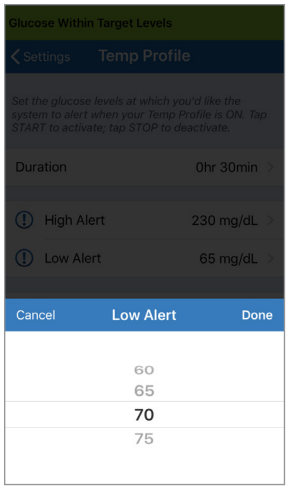


2. Select the duration. You can set a Temp Profile for up to 36 hours in 30 minute increments.



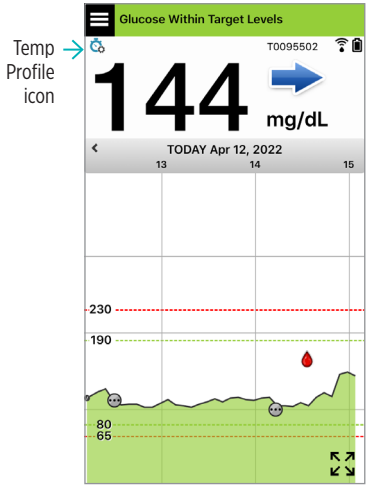
3. Set the High and Low Alerts and High and Low Target levels desired. Tap **START**.





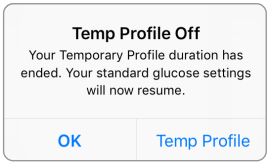
The Temp Profile selections cannot be changed when the duration has been started.

While a Temp Profile is active, the Temp Profile icon will be displayed on the **MY GLUCOSE** screen.

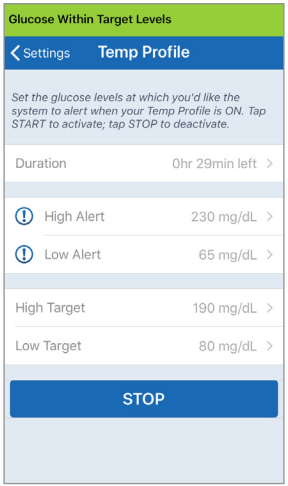


8

When the Temp Profile duration is finished, the app displays a notice and the Temp Profile icon is no longer displayed on the **MY GLUCOSE** screen.



To end the Temp Profile earlier than the time you set, go to **Settings** > **Temp Profile** and tap **STOP**.



9. Alert Descriptions

This section describes the various alerts and notification messages you may see on the Eversense App screens and actions you may need to take.

Your CGM System provides you with alerts and notifications related to glucose readings and system status on both your smart transmitter and mobile device. The smart transmitter provides on-body vibe alerts when an alert level has been reached. The mobile device app sounds an alert and displays messages on the **MY GLUCOSE** screen. The table below describes the vibration patterns on the smart transmitter and the indicators on your app.

Alerts and Notifications	Smart Transmitter Vibration Pattern	App Alert Indicators
Alerts where no glucose values can be displayed Requires immediate and appropriate action.	3 long vibes	**MESSAGE APPEARS IN YELLOW**
Low Glucose Alert Requires immediate and appropriate action.	3 short vibes x 3	**MESSAGE APPEARS IN YELLOW**
Alerts related to Predictive Low and Out-of-Range Low Glucose Requires immediate and appropriate action.	3 short vibrations	**MESSAGE APPEARS IN YELLOW**
Alerts related to High Glucose High Glucose Alert, Predictive High, and Out-of-Range High. Requires immediate and appropriate action.	1 long vibe then 2 short vibes	**MESSAGE APPEARS IN YELLOW**

Alerts and Notifications	Smart Transmitter Vibration Pattern	App Alert Indicators
Alerts related to less critical issues Requires some action but may not be as critical in nature. See following section for examples.	1 short vibe	**MESSAGE APPEARS IN YELLOW**
Charge Smart Transmitter Alert Your smart transmitter is running low on battery and should be charged.	3 quick vibes then 1 long vibe x 2	**MESSAGE APPEARS IN YELLOW**
Notifications Requires some action but not critical in nature. See following section for examples.	1 short vibe	**MESSAGE APPEARS IN BLUE**

Alert History

The **ALERT HISTORY** screen lists alerts and notifications you have received.

The following icons are used to indicate the severity level of messages.


Alerts

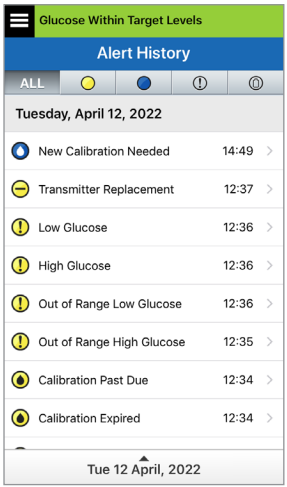

Notifications


Glucose-related alerts


Battery Alerts

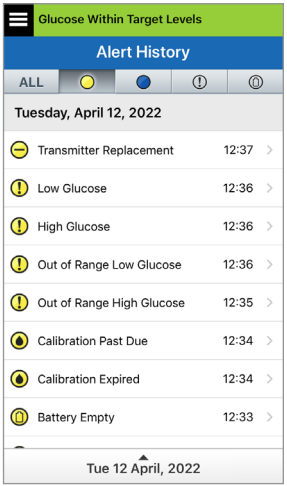
Note: When you receive 2 or more alerts that have not been acknowledged, the app will display an option to **Dismiss All**. This can happen when your mobile device has been out of range of your smart transmitter and then re-syncs. You can review each alert in **Alert History**.

1. Tap **Menu > Alert History**.
   - The **ALERT HISTORY** screen will list ALL alerts and notifications for that day.
   - Tap on any message to get more information.



Example of ALL

2. **You can choose to include only certain messages (alerts and notifications, etc.) for review by tapping selected alert icons.**
   - Tap **ALL**, then tap icons on top of the screen to select only the types of alerts you want displayed.
   - Tap **Menu** when done.



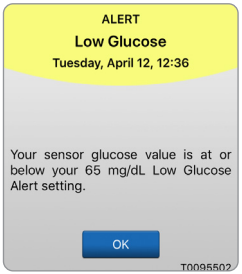
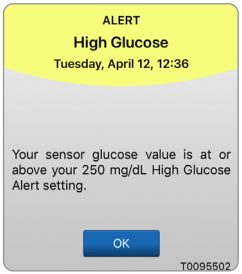
Example of alerts only

Alert Descriptions and Actions

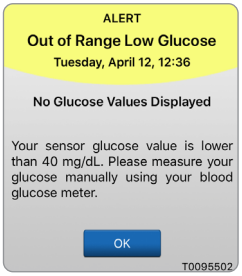
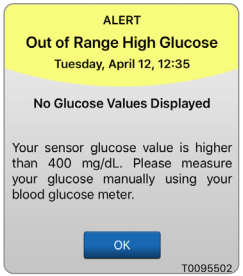
The following table lists the alerts and notifications you may receive on the Eversense App.

IMPORTANT: Alerts marked with a * cannot be turned off in the app or in the smart transmitter using the DND in the app settings.

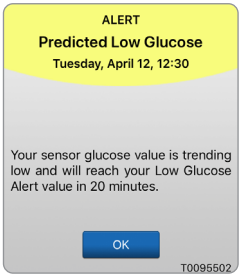
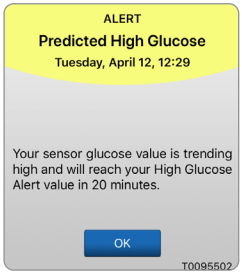
Alerts

App Display		
Description	**Low Glucose*** Appears at the interval you enter in sound settings when your sensor glucose reading is at or below the low glucose alert level you set. The default repeat interval is 15 minutes.	**High Glucose** Appears at the interval you enter in sound settings when your sensor glucose reading is at or above the high glucose alert level you set. The default repeat interval is 30 minutes.
Actions	Pay close attention to your glucose values, symptoms, and trends. If your symptoms do not match the sensor glucose value, confirm your glucose value with a blood glucose meter before making a treatment decision.	Pay close attention to your glucose values, symptoms, and trends. If your symptoms do not match the sensor glucose value, confirm your glucose value with a blood glucose meter before making a treatment decision.

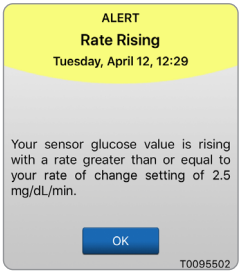
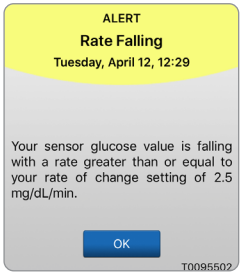
Alerts

App Display		
Description	**Out of Range Low Glucose*** Appears when your glucose reading is lower than 40 mg/dL. No glucose readings can be displayed (only **LO** is displayed on the **MY GLUCOSE** screen).	**Out of Range High Glucose*** Appears when your glucose value is higher than 400 mg/dL. No glucose readings can be displayed (only **HI** is displayed on the **MY GLUCOSE** screen).
Actions	Confirm your glucose value with a blood glucose meter test before making a treatment decision. Once the sensor glucose value is at or higher than 40 mg/dL, glucose readings will resume on the display.	Confirm your glucose value with a blood glucose meter test before making a treatment decision. Once the sensor glucose value is at or lower than 400 mg/dL, glucose readings will resume on the display.

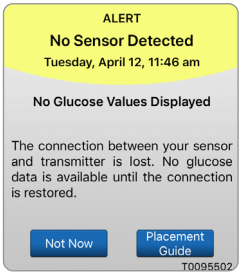
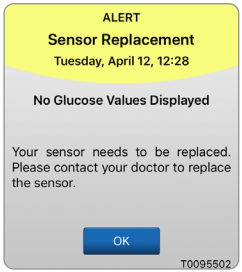
Alerts

App Display		
Description	**Predicted Low Glucose** Appears every 60 minutes when your glucose values are trending low and will reach your Low Glucose Alert level within the time you entered in Settings.	**Predicted High Glucose** Appears every 60 minutes when your glucose values are trending high and will reach your High Glucose Alert level within the time you entered in Settings.
Actions	Pay close attention to your glucose values, symptoms, and trends. If your symptoms are different than the sensor glucose values or what the alert indicates, confirm your glucose value with a blood glucose meter test before making a treatment decision.	Pay close attention to your glucose values, symptoms, and trends. If your symptoms are different than the sensor glucose values or what the alert indicates, confirm your glucose value with a blood glucose meter test before making a treatment decision.

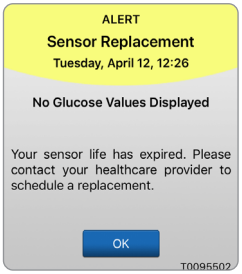
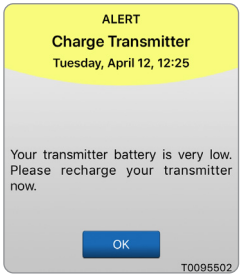
Alerts

App Display		
Description	**Rate Rising** Appears every 60 minutes when your glucose value is rising at a rate equal to or faster than the rate of change you entered in Settings.	**Rate Falling** Appears every 60 minutes when your glucose values are falling at a rate equal to or faster than the rate of change you entered in Settings.
Actions	Pay close attention to your glucose values, symptoms and trends. If your symptoms are different than the sensor glucose values or what the alert indicates, confirm your glucose value with a blood glucose meter test before making a treatment decision.	Pay close attention to your glucose values, symptoms, and trends. If your symptoms are different than the sensor glucose values or what the alert indicates, confirm your glucose value with a blood glucose meter test before making a treatment decision.

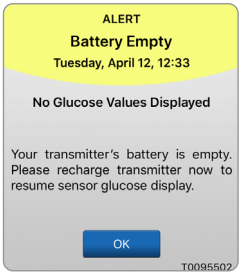
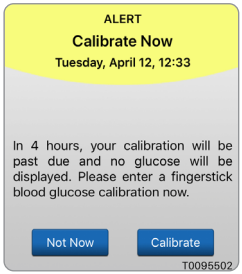
Alerts

App Display		
Description	**No Sensor Detected*** Appears when the connection between your sensor and transmitter is lost. No glucose data is available until the connection is restored.	**Sensor Replacement*** Appears once when system self-checks detect the sensor is no longer able to provide glucose values. No glucose readings can be displayed until the sensor is replaced.
Actions	Using the Placement Guide for reference, place the smart transmitter over the sensor until it shows that there is a connection.	Contact your GP to have your sensor replaced.

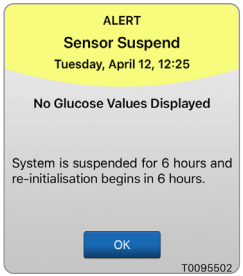
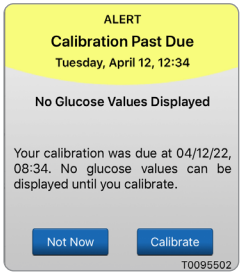
Alerts

App Display		
Description	**Sensor Replacement*** Appears once when your sensor life has expired. No glucose readings can be displayed until the sensor is replaced.	**Charge Smart Transmitter*** Appears when the smart transmitter battery power is very low and you need to charge your battery very soon.
Actions	Contact your GP to have your sensor replaced.	Charge your smart transmitter as soon as possible.

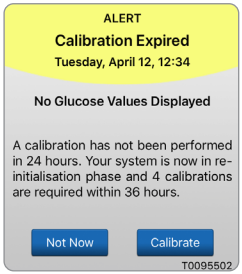
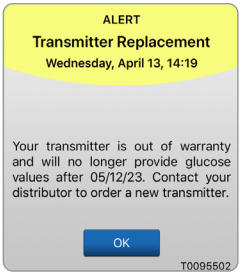
Alerts

App Display		
Description	**Battery Empty*** Appears once when your smart transmitter battery is empty and needs to be charged. No glucose readings can be displayed until the smart transmitter is charged.	**Calibrate Now** Appears to alert you that your calibration is due. If you do not calibrate within 4 hours, glucose values will no longer be displayed.
Actions	Charge the smart transmitter immediately. Remove the smart transmitter from your body before connecting it to the power supply.	Tap **Calibrate** to enter a calibration value.

Alerts

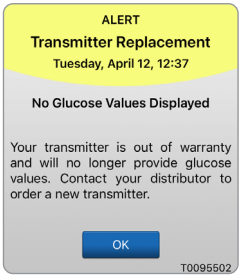
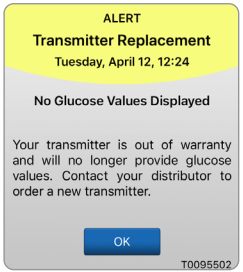
App Display		
Description	**Sensor Suspend** Appears when the system's internal checks detect a need to restart the Initialisation Phase for additional calibrations. No glucose readings can be displayed until after the second successful calibration.	**Calibration Past Due** Appears when your system is past due for calibration (16 hours in 2 Daily Calibrations Phase and 28 hours in 1 Daily Calibration Phase). No glucose readings can be displayed until calibration is performed.
Actions	Re-initialisation of the system begins in 6 hours. Glucose values will be displayed a few minutes after the second successful calibration during the Initialisation Phase.	Perform a fingerstick calibration in order to resume displaying glucose values.

Alerts

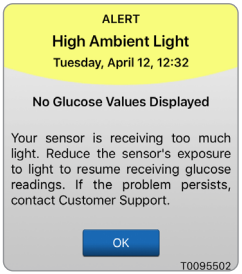
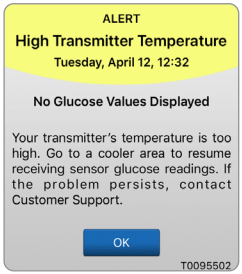
App Display		
Description	**Calibration Expired** Appears when a calibration has not been performed in 24 hours while in 2 Daily Calibrations Phase, or has not been performed within 40 hours while in 1 Daily Calibration Phase. The system returns to the Initialisation Phase. No glucose readings are displayed until calibration is performed.	**Transmitter End of Life Day 366*** Appears once every 7 days when your transmitter has been in use for 365 days and your transmitter is out of warranty. After 395 days of use, your transmitter will no longer provide glucose readings.
Actions	In the Initialisation Phase, you must perform 4 fingerstick calibration tests spaced 2-12 hours apart. Display of glucose readings will resume after the 2nd successful fingerstick calibration test.	Contact your distributor to order a new transmitter.

Note: In either Daily Calibration Phase, if a calibration entry is very different from the system's sensor glucose value, you will be prompted to calibrate again. If you do not calibrate within 16 hours, no glucose values will be displayed, and after 24 hours with no calibration, the system returns to Initialisation Phase.

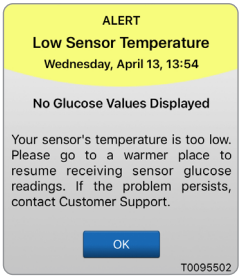
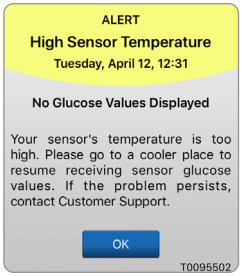
Alerts

App Display		
Description	**Transmitter End of Life Day 395*** Appears once your transmitter has been out of warranty for 30 days. Glucose readings cannot be displayed after the date of this alert until you replace your transmitter.	**Transmitter End of Life Day 396*** Appears once your transmitter has been in use for 395 days of use. Glucose readings cannot be displayed until you replace your transmitter. If your transmitter has reached its end of life it cannot be linked to a sensor.
Actions	Contact your distributor to order a new transmitter.	Contact your distributor to order a new transmitter.

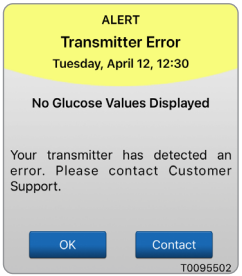
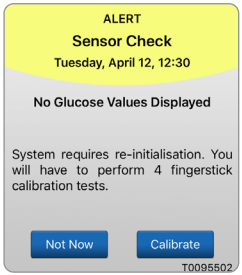
Alerts

App Display		
Description	**High Ambient Light** Appears every 60 minutes when your sensor is receiving too much ambient light, affecting its ability to communicate with the smart transmitter. No glucose readings can be displayed until ambient light is reduced.	**High Smart Transmitter Temperature*** Appears every 20 minutes when your smart transmitter temperature is too high. No glucose readings are displayed until the smart transmitter temperature is within normal operating conditions.
Actions	Reduce ambient light by doing one or more of the following: • Move to an area where there is less light exposure. • Place a dark material over the smart transmitter. • Wear the smart transmitter under clothing.	Reduce the smart transmitter temperature by moving to a cooler environment. Once the smart transmitter temperature is below 42 °C (108 °F), it will resume displaying glucose values. You may temporarily remove the smart transmitter to cool it down. Once the smart transmitter is back to a lower temperature, be sure to replace it over the sensor.

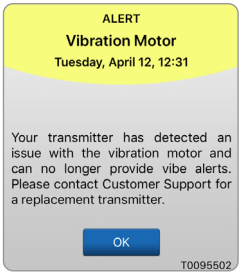
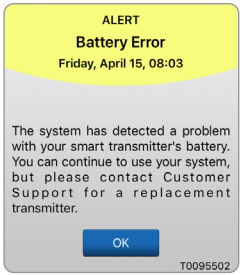
Alerts

App Display		
Description	**Low Sensor Temperature*** Appears every 20 minutes when the sensor temperature is too low. No glucose readings are displayed until the sensor temperature is within normal operating conditions.	**High Sensor Temperature*** Appears every 20 minutes when the sensor temperature is too high. No glucose readings are displayed until the sensor temperature is within normal operating conditions.
Actions	Go to a warmer environment to increase the sensor temperature. Keep your smart transmitter turned on so you will start receiving glucose values when the sensor temperature is between 26-40°C (81-104°F).	Go to a cooler environment to reduce the sensor temperature. Briefly remove the smart transmitter while the sensor temperature cools to between 26-40°C (81-104°F). Then put the smart transmitter back on to start receiving glucose values again from the sensor.

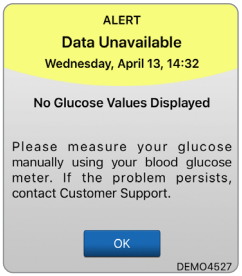
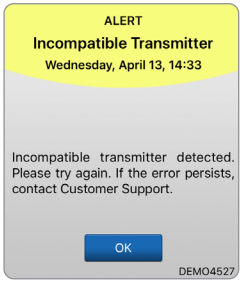
Alerts

App Display		
Description	**Smart Transmitter Error*** Appears when the system's internal checks detect a smart transmitter error. No glucose readings are displayed until the error is corrected.	**Sensor Check** Appears once when the system's internal checks detect instability with the sensor which requires a return to calibration Initialisation Phase. No glucose readings can be displayed until the second successful calibration has been entered.
Actions	Follow the steps shown in the Troubleshooting section to reset your smart transmitter. If you are unable to complete the reset, contact Customer Support.	In the Initialisation Phase, you must perform 4 fingerstick calibration tests spaced 2-12 hours apart. Display of glucose readings will resume after the 2nd successful fingerstick calibration test.

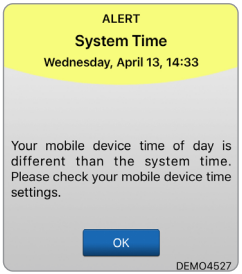
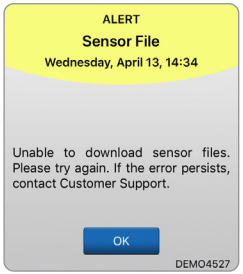
Alerts

App Display		
Description	**Vibration Motor*** Appears every 60 minutes when the vibration motor on your smart transmitter can no longer provide on-body vibe alerts. You will continue to get glucose readings up to 72 hours after receiving the alert message. After 72 hours, you will receive a Transmitter Error Alert every 20 minutes until you replace the smart transmitter.	**Battery Error*** Appears when the system's internal checks detect an error with your smart transmitter battery. Glucose readings will continue to be displayed, but your smart transmitter will need to be replaced.
Actions	Contact Customer Support to have your smart transmitter replaced immediately.	Contact your distributor to order a new transmitter.

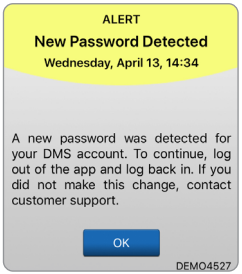
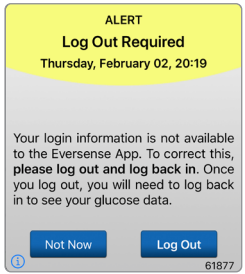
Alerts

App Display		
Description	**Data Unavailable** Appears when the system's internal checks detect a system error. No glucose readings are displayed until the error is corrected.	**Incompatible Transmitter Detected*** Appears during linking when the system detects the transmitter is incompatible with the sensor.
Actions	Plug the charging cradle with cable into a wall outlet or USB port. Put the smart transmitter into the cradle and remove it. If the condition persists, follow the steps shown in the *Troubleshooting* section to reset your smart transmitter. If you are unable to complete the reset, contact Customer Support.	Try linking again. If the error is displayed on the second attempt, contact Customer Support.

Alerts

App Display		
Description	**System Time Error** Appears when your system detects a discrepancy in time between your mobile device clock and the system clock.	**Sensor File Error*** Appears when the system detects a problem during linking.
Actions	Set your mobile device clock to your current local time. If the issue persists, contact Customer Support.	Try linking again. If the error is displayed on the second attempt, contact Customer Support.

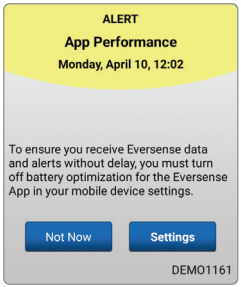
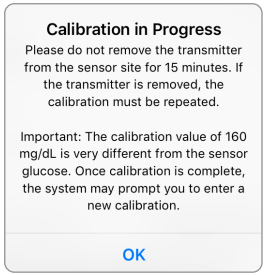
Alerts

App Display		
Description	**New Password Detected** Appears once when the system detects the password was changed via your Eversense DMS account.	**Log Out Required** Appears every 24 hours for iOS users when the system detects that your Eversense credentials are not available via the iOS keychain feature.
Actions	Log out of the mobile app and log back in with the new password.	Log out of the mobile app and log back in with your existing username and password.

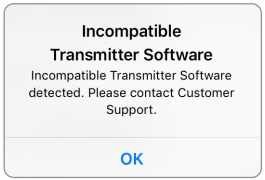
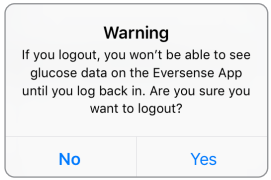
Alert Descriptions and Actions (continued)

Alerts

9

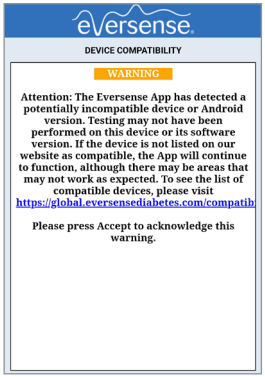
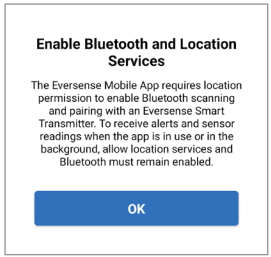
App Display		
Description	**App Performance*** Appears every day for Android operating systems when the system detects frequent app crashes or interruptions in Bluetooth communication due to the Eversense App being included in battery optimisation settings.	**Calibration In Progress** Appears when your calibration value is significantly different from your sensor glucose value.
Actions	Go to your phone's battery optimisation settings and turn off for the Eversense App to ensure Eversense alerts are not delayed.	Do not remove your transmitter for 15 minutes. Re-calibrate when prompted.

Alerts

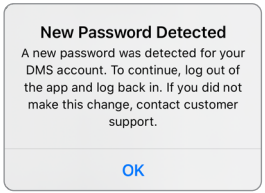
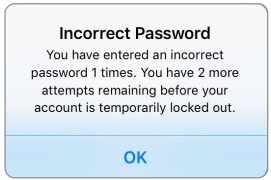
App Display		
Description	**Incompatible Transmitter Software** Appears when the software in your smart transmitter is incompatible with the Eversense CGM Mobile App version on your mobile device.	**Log Out Warning** Appears when you attempt to log out of the mobile app. If you log out, you will not be able to view glucose data in the Eversense mobile app.
Actions	Contact Customer Support.	Remain logged in to the mobile app to continue viewing your glucose data. If you log out, you must log back in with your username and password to continue using the app.

Alert Descriptions and Actions (continued)

Alerts

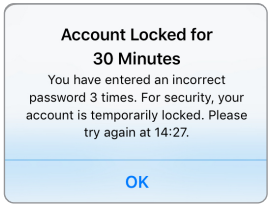
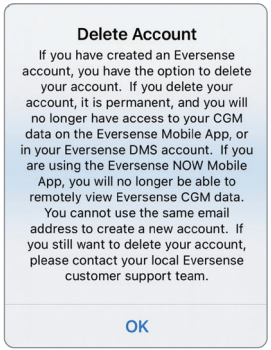
App Display		
Description	**Incompatible Device/Operating System** Appears when an incompatible device/operating system is being used with the app.	**Enable Bluetooth and Location Services** **For Android only.** Explains the use of location services is required to enable Bluetooth connection and to receive alerts.
Actions	For a list of compatible devices/operating systems visit **https://global.eversensediabetes.com**.	Tap **OK** to acknowledge.

Alerts

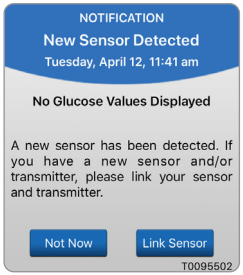
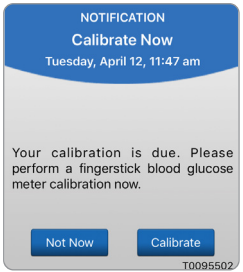
App Display		
Description	**New Password Detected** Appears once when the system detects the password was changed via your Eversense DMS account.	**Incorrect Password** Appears when the system detects one or two incorrect passwords have been entered consecutively via your mobile app.
Actions	Log out of the mobile app and log back in with the new password.	Use the correct password to log in to the mobile app.

Alert Descriptions and Actions (continued)

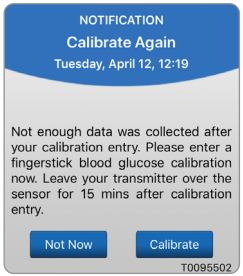
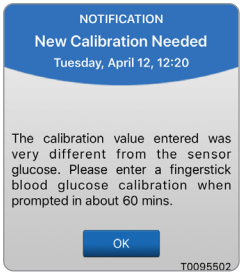
Alerts

App Display		
Description	**Account Locked** Appears after three incorrect passwords have been entered consecutively via your mobile app.	**Delete Account** Appears when Delete Account is tapped on the log in page.
Actions	Wait 30 minutes. Log in with correct password or reset your password.	Contact Customer Support if you wish to proceed.

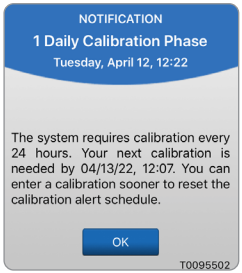
Notifications

App Display		
Description	**New Sensor Detected** Appears when the smart transmitter detects a new sensor. The inserted sensor and the smart transmitter must be linked to begin communication.	**Calibrate Now** Appears when it is time for you to calibrate when the system is in Initialisation Phase or after a calibration has been entered that is very different from the sensor glucose.
Actions	Tap **Link Sensor** to complete the linking process and begin the 24-hour Warm-Up Phase. You do not need to wear your smart transmitter over the sensor until the Warm-Up Phase is complete.	Do a fingerstick blood glucose test and enter the reading as your calibration value. DO NOT use an alternative site (such as forearm) to obtain your blood glucose reading.

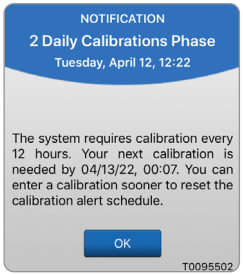
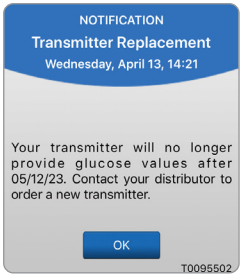
Notifications

App Display		
Description	**Calibrate Again** Appears when not enough data has been collected during calibration.	**New Calibration Needed** Appears if the calibration value entered is very different from the sensor glucose value. After about 1 hour, you will receive a Calibrate Now notification.
Actions	Tap **Calibrate** to enter a new calibration value.	Enter a new calibration value when prompted.

Notifications

App Display		
Description	**Sensor Replacement** Appears 60, 30, 14, 7, 3, and 1 day before your sensor has completed its wear period as a reminder to replace your sensor.	**1 Daily Calibration** Appears once when the system requires calibration once every 24 hours.
Actions	Contact your GP to schedule the removal and replacement of your sensor.	Enter a new calibration value when prompted.

Notifications

App Display		
Description	**2 Daily Calibrations** Appears once when the system requires calibration twice a day.	**Transmitter End of Life Day 330** Appears once 35 days before your transmitter warranty expires.
Actions	Enter a new calibration value when prompted.	Contact your distributor to order a new transmitter.

10. Event Log

This section describes how to review and log events to help better track glucose patterns.

The Eversense E3 CGM System allows you to log and track events in addition to continually monitoring glucose levels. You can manually enter events that will appear on the trend graph and glucose reports to help you find patterns in your glucose profile.

Types of Events:

- Glucose
- Meals
- Insulin
- Health
- Exercise

Note: You can also access the **ADD EVENT** screen directly from the **MY GLUCOSE** screen with a single tap anywhere on the graph area.

View Events

You can view past events entered from the **EVENT LOG** screen.

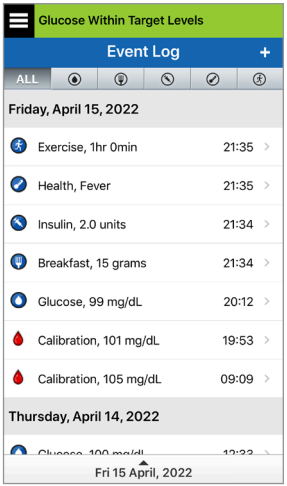
1. **Tap Menu > Event Log.**

   The **EVENT LOG** screen will appear.

2. **All your entered events will be listed.**

   You can also select specific event types to view by tapping a selected event type.

   - Tap **ALL**, then tap icons on top of the screen to select only the types of events you want displayed.



Log Specific Events

Glucose

Enter and track blood glucose meter tests (test results other than calibrations).

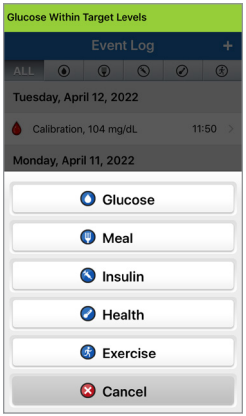
1. Tap **Menu** > **Event Log**.

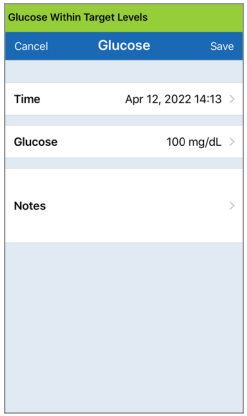
2. Add an event using the event icon "**+**" > **Glucose**.

3. Tap **Time** to enter the correct date and time.
   Tap **Done**.

4. Tap **Glucose** to enter the correct blood glucose value.
   Tap **Done**.

   Note: You can enter a BG value between 20 and 600 mg/dL. Entries < 20 mg/dL will be converted to 20, and entries above 600 mg/dL will be converted to 600 for calculation and display purposes.

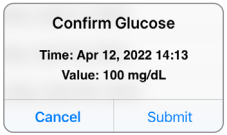




5. Tap **Save**.

6. On the Confirm Glucose pop-up box, tap **Submit** to confirm the glucose event and return to the **EVENT LOG** screen, or tap **Cancel** to exit without saving changes or to edit the information before saving.

   Note: Glucose Events do not replace calibration measurements. You will still have to enter calibration readings.



iOS



Android

Meals

Enter the type of meal, date and time and carbohydrate count.

1. Tap **Menu** > **Event Log**.

2. Add an event using the event icon "**+**" > **Meals**.

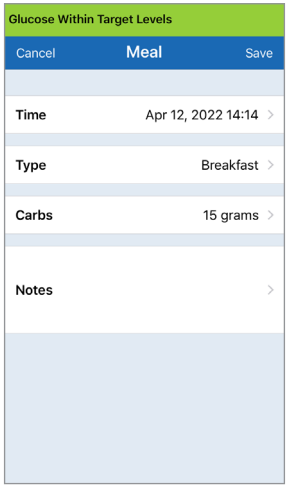
3. Tap **Time** to enter the correct date and time.
   Tap **Done**.

4. Tap **Type** to enter the type of meal.
   Tap **Done**.

5. Tap **Carbs** to enter correct number of carbohydrates.
   Tap **Done**.

6. Tap **Notes** to enter any notes.
   Tap **Done**.

7. Tap **Save** to save entry and return to **EVENT LOG** screen.
   Tap **Cancel** to exit without saving changes.



Insulin

Enter the units of insulin according to Time and Insulin type.

1. Tap **Menu** > **Event Log**.

2. Add an event using the event icon "**+**" > **Insulin**.

3. Tap **Time** to enter the correct date and time.
   Tap **Done**.

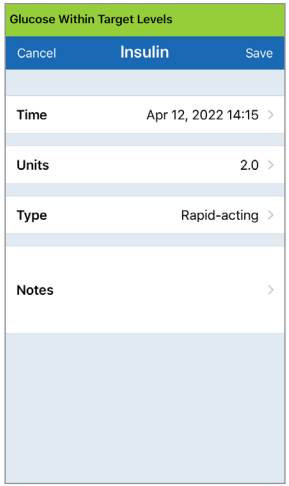
4. Tap **Units** to enter the correct number of Units.
   Tap **Done**.

   Note: The maximum insulin units that can be entered is 200U.

5. Tap **Type** to enter the correct Type of Insulin.
   Tap **Done**.

6. Tap **Notes** to enter any notes.
   Tap **Done**.

7. Tap **Save** to save entry and return to **EVENT LOG** screen.
   Tap **Cancel** to exit without saving changes.



Health

Enter the type of health condition, severity, and date and time.

1. Tap **Menu** > **Event Log**.

2. Add an event using the event icon "**+**" > **Health**.

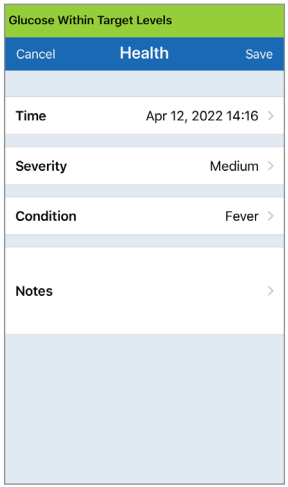
3. Tap **Time** to enter the correct date and time.
   Tap **Done**.

4. Tap **Severity** to enter Low, Medium or High.
   Tap **Done**.

5. Tap **Condition** to enter the health condition.
   Tap **Done**.

6. Tap **Notes** to enter any notes.
   Tap **Done**.

7. Tap **Save** to save entry and return to **EVENT LOG** screen.
   Tap **Cancel** to exit without saving changes.



Exercise

Enter exercise type, duration, and intensity.

1. Tap **Menu** > **Event Log**.

2. Add an event using the event icon "**+**" > **Exercise**.

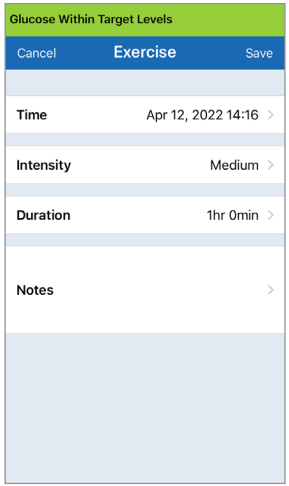
3. Tap **Time** to enter the correct date and time.
   Tap **Done**.

4. Tap **Intensity** to enter Low, Medium or High.
   Tap **Done**.

5. Tap **Duration** to enter the duration.
   Tap **Done**.

6. Tap **Notes** to enter any notes.
   Tap **Done**.

7. Tap **Save** to save entry and return to **EVENT LOG** screen.
   Tap **Cancel** to exit without saving changes.



II. Reports

This section describes the different glucose reports available for a summary of your glucose profile. You may choose specific dates or select pre-selected time ranges.

Types of reports

- Weekly Modal Summary.
- Glucose Pie Chart.
- Glucose Statistics.

Note: Be sure to set the mobile device date and time correctly. The accuracy of the graphs and reports depends upon the date and time being correct.

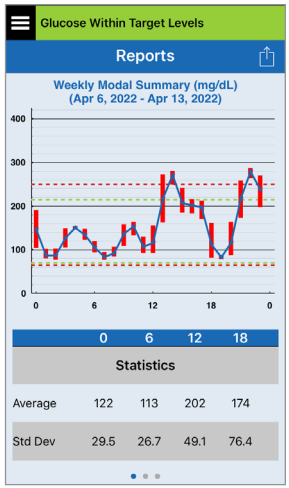
To view the glucose reports tap **Menu** > **Reports** and swipe to move across the three different reports. You can also email each report as a pdf file by tapping the email icon in the top right hand corner.

Weekly Modal Summary

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

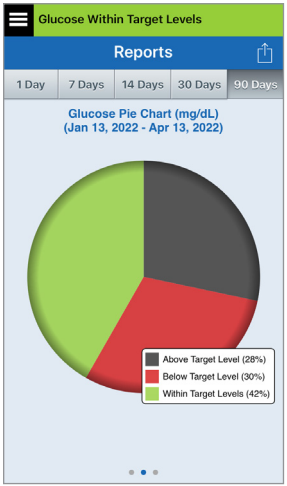
- The **blue line** is the average of the last seven days of your readings in an hour time block.
- The **red bars** show the highest and lowest actual readings in the same hour time block.
- The **red horizontal dotted lines** are your pre-set High and Low Glucose Alert levels.
- The **green horizontal 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 6-hour time slots.

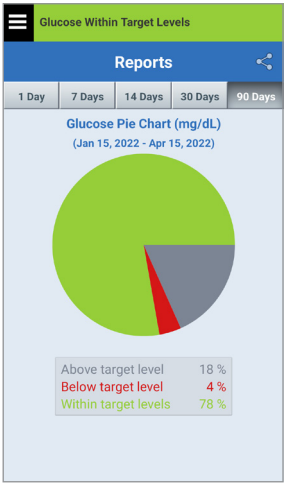


Glucose Pie Chart

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.



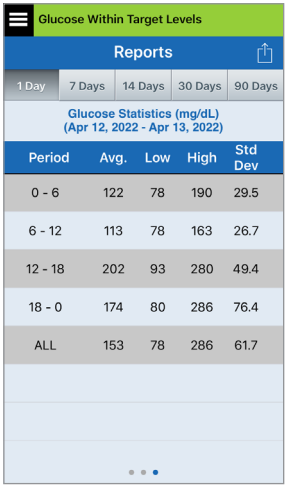
iOS



Android

Glucose Statistics

This report shows your average, low and high glucose readings, along with standard deviation within 6-hour time periods. You can choose the last 1, 7, 14, 30 or 90 days.



Period	Avg.	Low	High	Std Dev
0 - 6	122	78	190	29.5
6 - 12	113	78	163	26.7
12 - 18	202	93	280	49.4
18 - 0	174	80	286	76.4
ALL	153	78	286	61.7

12. Sharing Data

You can share data in multiple ways with Eversense.

Eversense Data Management Software (DMS) Program

The Eversense DMS Program is a web-based application that enables patients, caregivers, and healthcare professionals to view and analyse glucose data that has been transmitted from the Eversense E3 Smart Transmitter or the Eversense CGM System Mobile App.

This programme is offered at no cost to users of the Eversense E3 CGM System. To learn about the Eversense DMS Programme, go to: **https://global.eversensediabetes.com**. When you create and register your account during the installation of the Eversense CGM Mobile App, an Eversense DMS account is automatically created for you. The *Eversense NOW* section has more information on how to remotely view glucose data from the Eversense E3 CGM System.

IMPORTANT: EVERSENSE E3 DATA MANAGEMENT SYSTEM DOES NOT PROVIDE MEDICAL ADVICE. CHANGES TO YOUR TREATMENT PLAN SHOULD ONLY BE MADE BY YOUR HEALTHCARE TEAM.

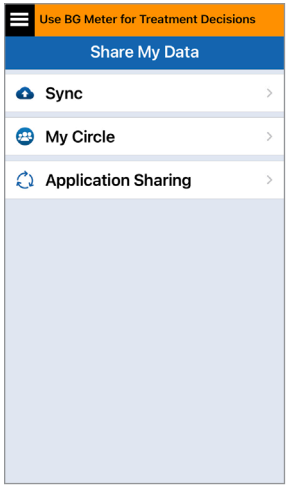
Share My Data

The Share My Data feature in the Eversense CGM System Mobile App allows you to manually sync data to your Eversense DMS account, invite friends and family to remotely view your CGM data via the Eversense NOW Mobile App, and to connect with other compatible health applications.

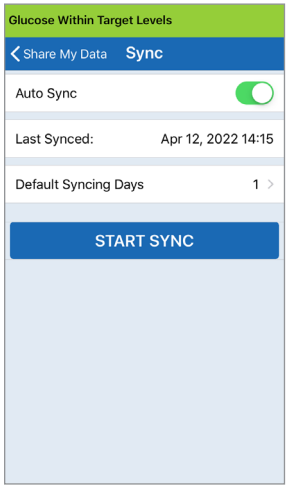
Sync

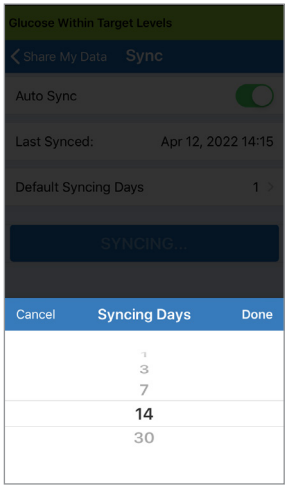
As long as you have an internet connection, Auto Sync is turned on, and you are logged into the app, your glucose readings sync to your Eversense DMS account about every 5 minutes. You can turn off Auto Sync.

To turn off Auto Sync, tap **Sync** on the **SHARE MY DATA** screen. Tap the **Auto Sync** button to off.



To manually sync your data, tap the **START SYNC** button. Data for the number of days set as your default will be synced. You can set the Default Syncing Days to 1, 3, 7, 14 or 30 days.

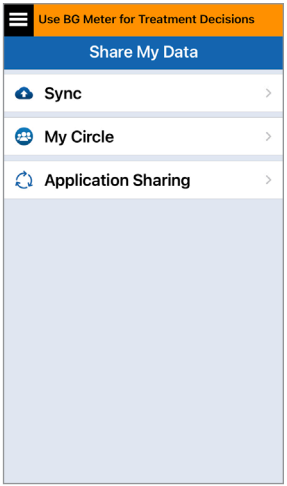




IMPORTANT: If you turn off Auto Sync, your data will not be sent to anyone using the Eversense NOW App to remotely monitor your glucose data, and your historical glucose data will not be stored in your DMS account.

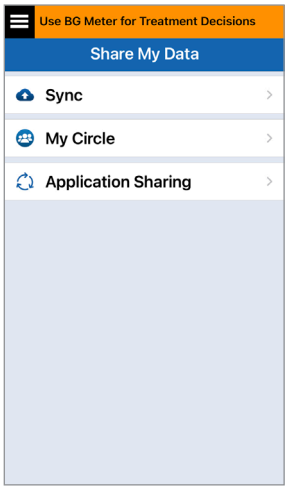
My Circle

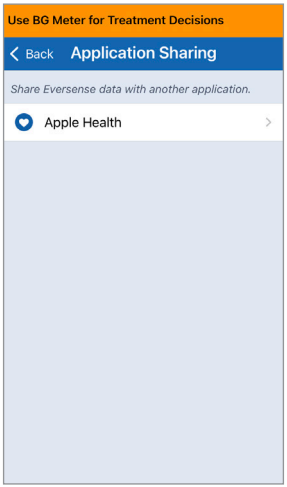
My Circle is an optional feature that allows you to activate remote monitoring of your Eversense E3 CGM data. For more information on this feature, see *My Circle - Remote Monitoring*.

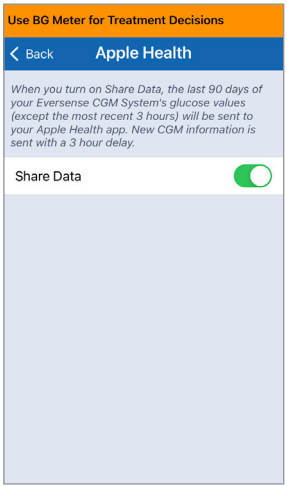


Application Sharing

Application Sharing is an optional feature that allows you to share certain Eversense data with another compatible health application. Tap the application and turn on **Share Data**. You may need to also allow sharing via the health application.





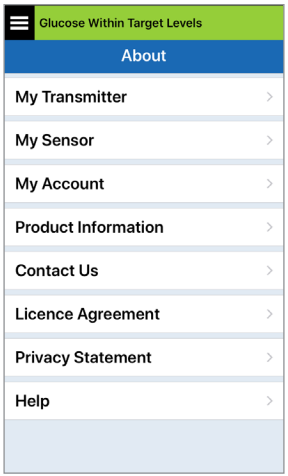


13. Product and General Information on the App

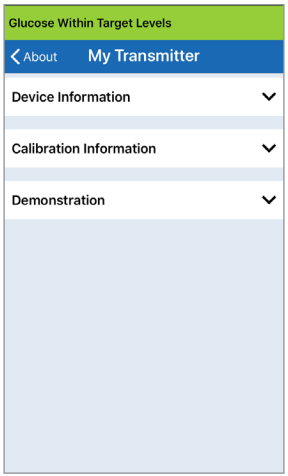
This section describes the information available from the About section of the Main Menu.

You can view product information about your smart transmitter, your sensor and your Eversense CGM Mobile App.

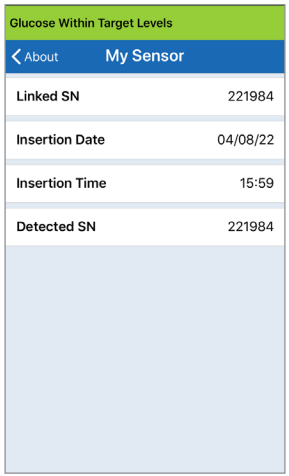
1. Tap **Menu** > **About** and then tap **My Transmitter**, **My Sensor** or **Product Information**.



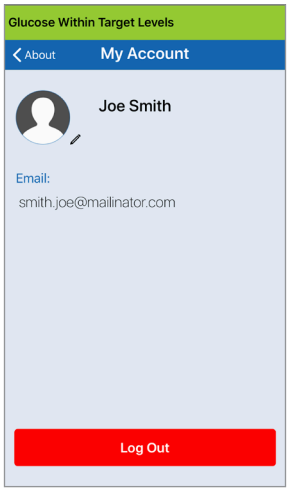
On the **My Transmitter** screen, you can find information that includes the serial number, calibration information and battery level. You can also demonstrate the vibration feature of the smart transmitter.



On the **My Sensor** screen, you can view the sensor serial number and insertion details.



On the **My Account** screen, you can edit your profile picture, view the email address used to create your Eversense account, and log out of the Eversense App.

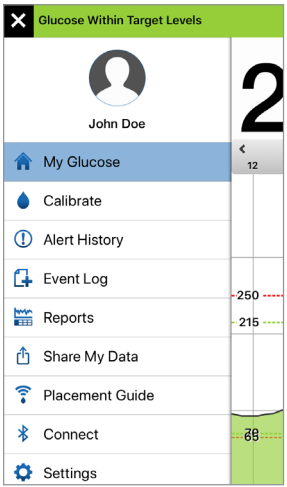


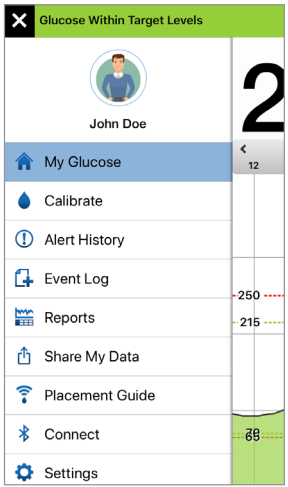
Profile Picture

You can update the profile picture in your Eversense account, which will be displayed in your Eversense Mobile App and in your Eversense DMS account.

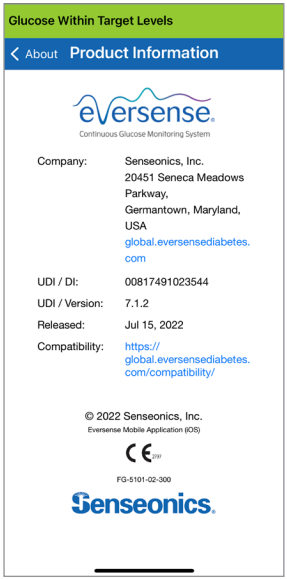
- Go to **About** > **My Account** and tap on the picture. You can also tap on the picture from the main menu.
- Follow the prompt to either update or delete the image. You can either take a new photo or choose an existing photo that is saved on your device.
- The photo you select will be displayed on the **Main Menu** screen.

Note: You can also change your profile picture from your Eversense DMS account. See the *Eversense DMS* section for more information.



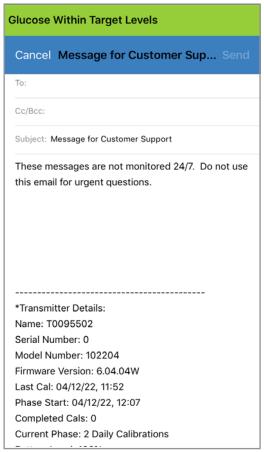


On the **Product Information** screen, you can view information about the mobile app software version and Senseonics, Inc., the manufacturer of the Eversense E3 CGM System.



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

- Tap **Contact Us** to send an email to your local customer support team.



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

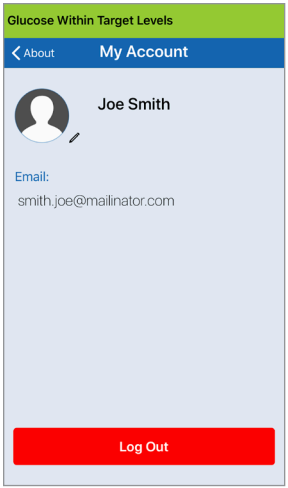
To read the End User Licence Agreement and the Privacy Policy, tap either option.

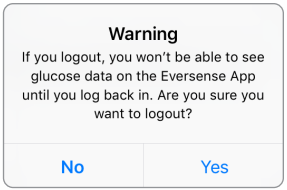


To find your local distributor on our website, tap **Help**.

Logging out

To log out of your Eversense account, tap **My Account** > **Log Out**.





13

IMPORTANT: If you log out, no glucose data will be displayed on the app until you log back in using the email and password you entered when you set up your account.

14. Viewing Eversense E3 Data on the Apple Watch

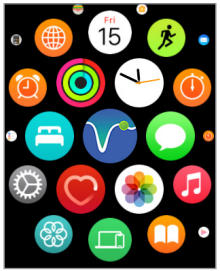
You can view a snapshot of your Eversense E3 CGM data on your Apple Watch. Once you've downloaded and installed the Eversense CGM Mobile App on your mobile device, follow the Apple Watch instructions for adding the app to your watch.

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.

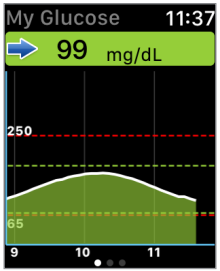
Any problems with mobile devices, wireless internet, data connection, the Eversense Data Management System (DMS), the CGM user's smart transmitter out of range of their mobile device, or charging their smart transmitter may cause data transfer to be delayed or not to be displayed.

If at any time you have symptoms of a low or high blood glucose level OR if 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.

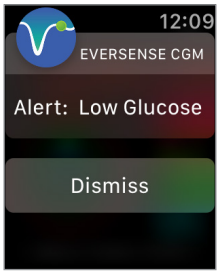
To access additional app features, tap the **Eversense** icon on your watch **HOME** screen to open the app.



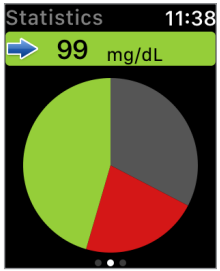
The **My Glucose** screen shows your current glucose with trend arrow, and a trend graph of your last three hours of CGM data.



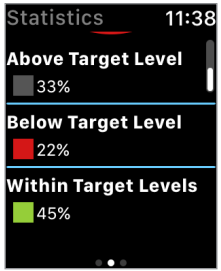
You can also access the **MY GLUCOSE** screen if you turn on notifications from Eversense E3 in your Apple Watch settings. When you receive a notification, you can also tap on the message to see the **MY GLUCOSE** screen.



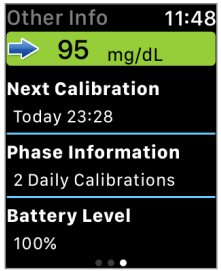
Swipe left to the next screen showing a pie chart of your total time within and outside your target range for the past 24 hours.



Swipe up to display the same data shown as percentages.



Swipe left to the next screen showing your current glucose with trend arrow, your next calibration time, the current system calibration phase, and battery level of your smart transmitter.

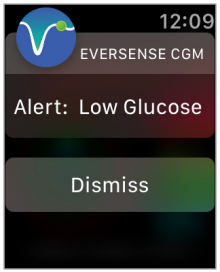
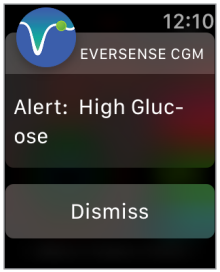


Alerts and Notifications Displayed on the Apple Watch

The Apple Watch is a secondary display to the Eversense CGM Mobile App. Any alerts or notifications received on the Apple Watch should be confirmed on the Eversense CGM Mobile App before any action is taken.

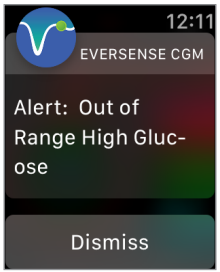
If you dismiss an alert on the watch, the alert display will disappear from the phone lock screen. Once the mobile app is opened, the alert will be displayed with all of its information.

The following table lists the alerts and notifications you may receive on the Apple Watch from the Eversense App. Some alerts and notifications are affected by the sound settings in the mobile app, and the Do Not Disturb function in the mobile app. See *Setting Sounds* and *Alert Descriptions and Actions* for more information.

Apple Watch Display		
Description	**Low Glucose** Appears at the interval you enter in sound settings when your sensor glucose reading is at or below the low glucose alert level you set.	**High Glucose** Appears at the interval you enter in sound settings when your sensor glucose reading is at or above the high glucose alert level you set.
Actions	**Confirm the alert on your Eversense CGM Mobile App.** Pay close attention to your glucose values, symptoms, and trends. If your symptoms do not match the sensor glucose value, confirm your glucose value with a blood glucose meter before making a treatment decision.	**Confirm the alert on your Eversense CGM Mobile App.** Pay close attention to your glucose values, symptoms, and trends. If your symptoms do not match the sensor glucose value, confirm your glucose value with a blood glucose meter before making a treatment decision.

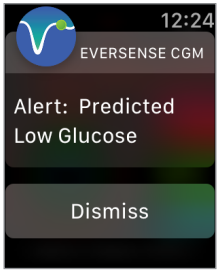
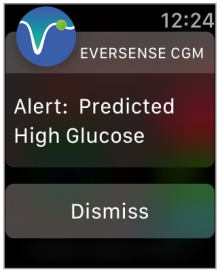
Alerts and Notifications Displayed on the Apple Watch (continued)

Alerts

Apple Watch Display		
Description	**Out of Range Low Glucose** Appears when your glucose reading is lower than 40 mg/dL. No glucose readings can be displayed.	**Out of Range High Glucose** Appears when your glucose value is higher than 400 mg/dL. No glucose readings can be displayed.
Actions	**Confirm the alert on your Eversense CGM Mobile App.** Measure your glucose manually by using your blood glucose meter. Always confirm your glucose value with a blood glucose meter before making a treatment decision. Once the sensor glucose value is at or higher than 40 mg/dL, glucose readings will resume on the display.	**Confirm the alert on your Eversense CGM Mobile App.** Measure your glucose manually by using your blood glucose meter. Always confirm your glucose value with a blood glucose meter before making a treatment decision. Once the sensor glucose value is at or lower than 400 mg/dL, glucose readings will resume on the display.

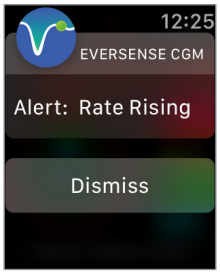
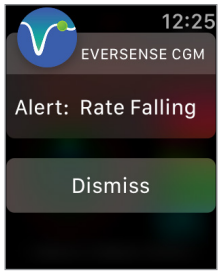
Alerts and Notifications Displayed on the Apple Watch (continued)

Alerts

Apple Watch Display		
Description	**Predicted Low Glucose** Appears every 60 minutes when your glucose values are trending low and will reach your Low Glucose Alert level within the time you entered in Settings.	**Predicted High Glucose** Appears every 60 minutes when your glucose values are trending high and will reach your High Glucose Alert level within the time you entered in Settings.
Actions	**Confirm the alert on your Eversense CGM Mobile App.** Pay close attention to your glucose values, symptoms, and trends. If symptoms do not match the sensor glucose value, confirm your glucose value with a blood glucose meter before making a treatment decision.	**Confirm the alert on your Eversense CGM Mobile App.** Pay close attention to your glucose values, symptoms, and trends. If symptoms do not match the sensor glucose value, confirm your glucose value with a blood glucose meter before making a treatment decision.

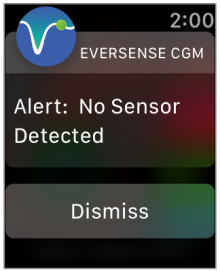
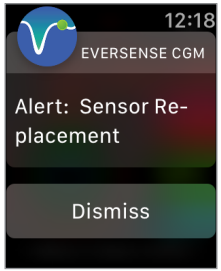
Alerts and Notifications Displayed on the Apple Watch (continued)

Alerts

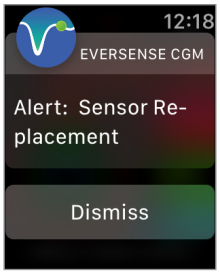
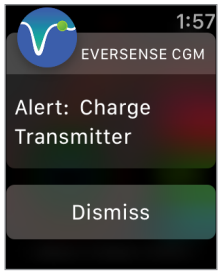
Apple Watch Display		
Description	**Rate Rising** Appears every 60 minutes when your glucose value is rising at a rate equal to or faster than the rate of change you entered in Settings.	**Rate Falling** Appears every 60 minutes when your glucose values are falling at a rate equal to or faster than the rate of change you entered in Settings.
Actions	**Confirm the alert on your Eversense CGM Mobile App.** Pay close attention to your glucose values, symptoms, and trends. If symptoms do not match the sensor glucose value, confirm your glucose value with a blood glucose meter before making a treatment decision.	**Confirm the alert on your Eversense CGM Mobile App.** Pay close attention to your glucose values, symptoms, and trends. If symptoms do not match the sensor glucose value, confirm your glucose value with a blood glucose meter before making a treatment decision.

Alerts and Notifications Displayed on the Apple Watch (continued)

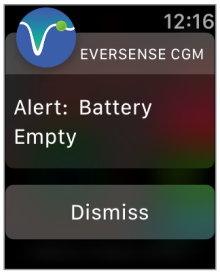
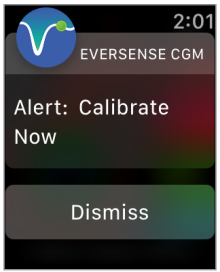
Alerts

Apple Watch Display		
Description	**No Sensor Detected** Appears when the connection between your sensor and transmitter is lost. No glucose data is available until the connection is restored.	**Sensor Replacement** Appears once when system self-checks detect the sensor is no longer able to provide glucose values.
Actions	**Confirm the alert on your Eversense CGM Mobile App.** Using the Placement Guide for reference, place the smart transmitter over the sensor until it shows that there is a connection.	**Confirm the alert on your Eversense CGM Mobile App.** Contact your GP to have your sensor replaced.

Alerts

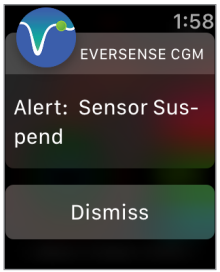
Apple Watch Display		
Description	**Sensor Replacement** Appears once when your sensor life has expired. No glucose readings can be displayed until the sensor is replaced.	**Charge Transmitter** Appears when the smart transmitter battery power is very low and you need to charge your battery very soon.
Actions	**Confirm the alert on your Eversense CGM Mobile App.** Contact your GP to have your sensor replaced.	**Confirm the alert on your Eversense CGM Mobile App.** Charge your smart transmitter as soon as possible.

Alerts

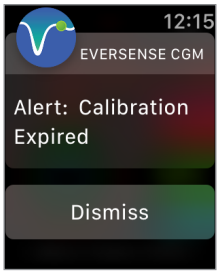
Apple Watch Display		
Description	**Battery Empty** Appears once when your smart transmitter battery is empty and needs to be charged. No glucose readings can be displayed until the smart transmitter is charged.	**Calibrate Now** Appears to alert you that your calibration is due. If you do not calibrate within 4 hours, glucose values will no longer be displayed.
Actions	**Confirm the alert on your Eversense CGM Mobile App.** Charge the smart transmitter immediately. Remove the smart transmitter from your body before connecting it to the power supply.	**Confirm the alert on your Eversense CGM Mobile App.** Tap **Calibrate** on your mobile device to enter a calibration value.

Alerts and Notifications Displayed on the Apple Watch (continued)

Alerts

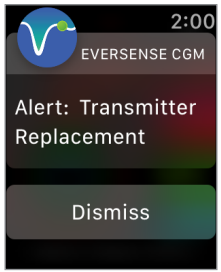
Apple Watch Display		
Description	**Sensor Suspend** Appears when the system's internal checks detect a need to restart the Initialisation Phase for additional calibrations. Glucose values will be displayed a few minutes after the second successful calibration during the Initialisation Phase.	**Calibration Past Due** Appears when your system is past due for calibration. No glucose readings can be displayed until calibration is entered in the Eversense CGM Mobile App.
Actions	**Confirm the alert on your Eversense CGM Mobile App.** Re-initialisation of the system begins in 6 hours.	**Confirm the alert on your Eversense CGM Mobile App.** Perform a fingerstick calibration in order to resume displaying glucose values.

Alerts

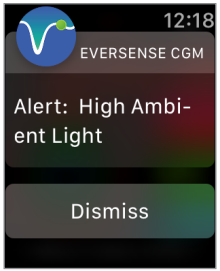
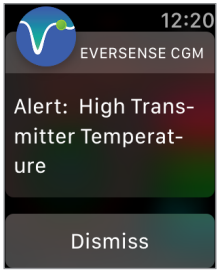
Apple Watch Display		
Description	**Calibration Expired** Appears when a calibration has not been performed in 24 hours. The system returns to the Initialisation Phase. No glucose readings can be displayed until calibration is entered in the Eversense CGM Mobile App.	**Transmitter End of Life 366** Appears once your transmitter has been in use for 365 days and your transmitter is out of warranty. After 395 days of use, your transmitter will no longer provide glucose readings.
Actions	**Confirm the alert on your Eversense CGM Mobile App.** In the Initialisation Phase, you must perform 4 fingerstick calibrations spaced 2-12 hours apart. Display of glucose readings will resume after the 2nd successful fingerstick calibration.	**Confirm the alert on your Eversense CGM Mobile App.** Contact your distributor to order a new transmitter.

Alerts and Notifications Displayed on the Apple Watch (continued)

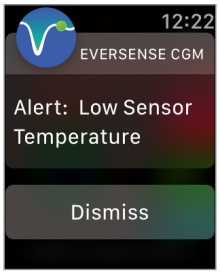
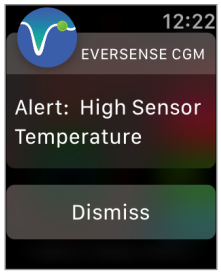
Alerts

Apple Watch Display		
Description	**Transmitter End of Life 395** Appears once your transmitter has been out of warranty for 30 days. Glucose readings cannot be displayed after the date of this alert until you replace your transmitter.	**Transmitter End of Life 396** Appears once your transmitter has been in use for 395 days of use. Glucose readings cannot be displayed until you replace your transmitter
Actions	**Confirm the alert on your Eversense CGM Mobile App.** Contact your distributor to order a new transmitter.	**Confirm the alert on your Eversense CGM Mobile App.** Contact your distributor to order a new transmitter.

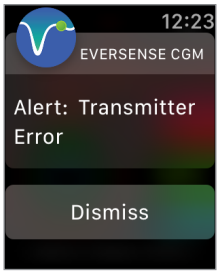
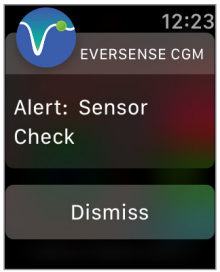
Alerts

Apple Watch Display		
Description	**High Ambient Light** Appears every 60 minutes when your sensor is receiving too much ambient light, affecting its ability to communicate with the smart transmitter. No glucose readings can be displayed until ambient light is reduced.	**High Transmitter Temperature** Appears every 20 minutes when your smart transmitter temperature is too high. No glucose readings are displayed until the smart transmitter temperature is within normal operating conditions.
Actions	**Confirm the alert on your Eversense CGM Mobile App.** Reduce ambient light by doing one or more of the following: • Move to an area where there is less light exposure. • Place a dark material over the smart transmitter. • Wear the smart transmitter under clothing.	**Confirm the alert on your Eversense CGM Mobile App.** Reduce the smart transmitter temperature by moving to a cooler environment. Once the smart transmitter temperature is below 42 °C (108 °F), it will resume displaying glucose values. You may temporarily remove the smart transmitter to cool it down. Once the smart transmitter is back to a lower temperature, be sure to replace it over the sensor.

Alerts

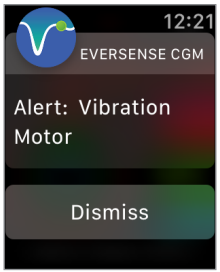
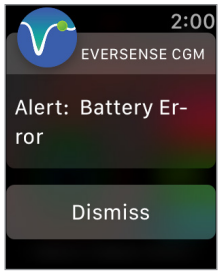
Apple Watch Display		
Description	**Low Sensor Temperature** Appears every 20 minutes when the sensor temperature is too low. No glucose readings are displayed until the sensor temperature is within normal operating conditions.	**High Sensor Temperature** Appears every 20 minutes when the sensor temperature is too high. No glucose readings are displayed until the sensor temperature is within normal operating conditions.
Actions	**Confirm the alert on your Eversense CGM Mobile App.** Go to a warmer environment to increase the sensor temperature. Keep your smart transmitter turned on so you will start receiving glucose values when the sensor temperature is between 26-40°C (81-104°F).	**Confirm the alert on your Eversense CGM Mobile App.** Go to a cooler environment to reduce the sensor temperature. Briefly remove the smart transmitter while the sensor temperature cools to between 26-40°C (81-104°F). Then put the smart transmitter back on to start receiving glucose values again from the sensor.

Alerts

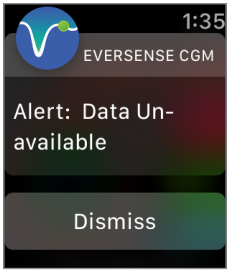
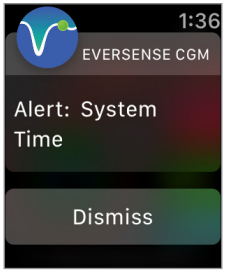
Apple Watch Display		
Description	**Smart Transmitter Error** Appears when the system's internal checks detect a smart transmitter error. No glucose readings are displayed until the error is corrected.	**Sensor Check** Appears once when the system's internal checks detect instability with the sensor which requires a return to calibration Initialisation Phase.
Actions	**Confirm the alert on your Eversense CGM Mobile App.** Follow the steps shown in the *Troubleshooting* section to reset your smart transmitter. If you are unable to complete the reset, contact Customer Support.	**Confirm the alert on your Eversense CGM Mobile App.** In the Initialisation Phase, you must perform 4 fingerstick calibrations spaced 2-12 hours apart. Display of glucose readings will resume after the 2nd successful fingerstick calibration.

Alerts and Notifications Displayed on the Apple Watch (continued)

Alerts

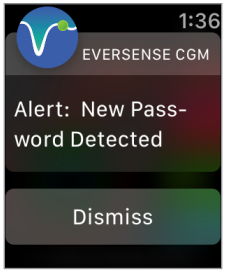
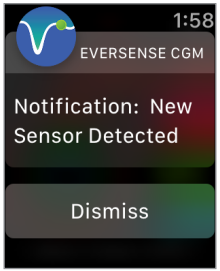
Apple Watch Display		
Description	**Vibration Motor** Appears every 60 minutes when the vibration motor on your smart transmitter can no longer provide on-body vibe alerts. You will continue to get glucose readings up to 72 hours after receiving the alert message. After 72 hours, you will receive a Transmitter Error Alert every 20 minutes until you replace the smart transmitter.	**Battery Error** Appears when the system's internal checks detect an error with your smart transmitter battery. Glucose readings will continue to be displayed, but your smart transmitter will need to be replaced.
Actions	**Confirm the alert on your Eversense CGM Mobile App.** Contact Customer Support to have your smart transmitter replaced immediately.	**Confirm the alert on your Eversense CGM Mobile App.** Contact your distributor to order a new transmitter.

Alerts

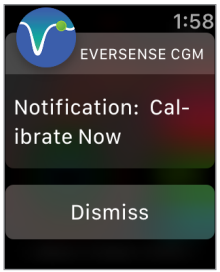
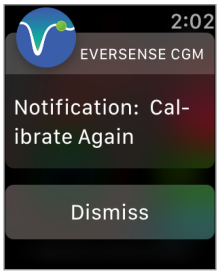
Apple Watch Display		
Description	**Data Unavailable** Appears when the system's internal checks detect a system error. No glucose readings are displayed until the error is corrected.	**System Time Error** Appears when your system detects a discrepancy in time between your mobile device clock and the system clock.
Actions	**Confirm the alert on your Eversense CGM Mobile App.** Plug the charging cradle with cable into a wall outlet or USB port. Put the smart transmitter into the cradle and remove it. If the condition persists, follow the steps shown in the *Troubleshooting* section to reset your smart transmitter. If you are unable to complete the reset, contact Customer Support	**Confirm the alert on your Eversense CGM Mobile App.** Set your mobile device clock to your current local time. If the issue persists, contact Customer Support.

Alerts and Notifications Displayed on the Apple Watch (continued)

Alerts

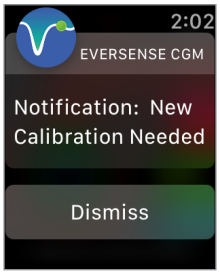
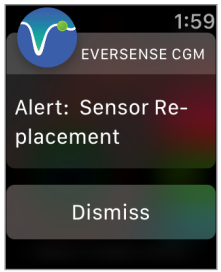
Apple Watch Display		
Description	**New Password Detected** Appears once when the system detects the password was changed via your Eversense DMS account.	**New Sensor Detected** Appears when the smart transmitter detects a new sensor. The inserted sensor and the smart transmitter must be linked to begin communication.
Actions	**Confirm the alert on your Eversense CGM Mobile App.** Log out of the mobile app and log back in with the new password.	**Confirm the alert on your Eversense CGM Mobile App.** In your mobile app, tap **Link Sensor** to complete the linking process and begin the 24-hour Warm-Up Phase. You do not need to wear your smart transmitter over the sensor until the Warm-Up Phase is complete.

Notifications

Apple Watch Display		
Description	**Calibrate Now** Appears when it is time for you to calibrate when the system is in Initialisation Phase or after a calibration has been entered that is very different from the sensor glucose.	**Calibrate Again** Appears when not enough data has been collected during calibration.
Actions	**Confirm the alert on your Eversense CGM Mobile App.** Do a fingerstick blood glucose test and enter the reading as your calibration value. DO NOT use an alternative site (such as forearm) to obtain your blood glucose reading.	**Confirm the alert on your Eversense CGM Mobile App.** Tap **Calibrate** on your mobile device to enter a new calibration value.

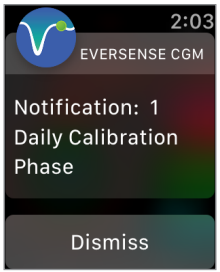
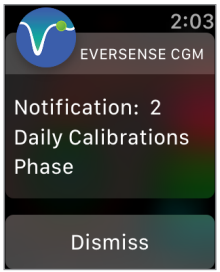
Alerts and Notifications Displayed on the Apple Watch (continued)

Notifications

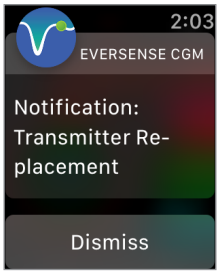
Apple Watch Display		
Description	**New Calibration Needed** Appears if the calibration value entered is very different from the sensor glucose value. After 60 minutes, you will receive a Calibrate Now notification.	**Sensor Replacement** Appears 60, 30, 14, 7, 3, and 1 day before your sensor has completed its wear period as a reminder to replace your sensor.
Actions	**Confirm the alert on your Eversense CGM Mobile App.** Enter a new calibration value when prompted.	**Confirm the alert on your Eversense CGM Mobile App.** Contact your GP to schedule the removal and replacement of your sensor.

Alerts and Notifications Displayed on the Apple Watch (continued)

Notifications

Apple Watch Display		
Description	**1 Daily Calibration** Appears once when the system requires calibration once every 24 hours.	**2 Daily Calibrations** Appears once when the system requires calibration twice a day.
Actions	**Confirm the alert on your Eversense CGM Mobile App.** Enter a new calibration value when prompted.	**Confirm the alert on your Eversense CGM Mobile App.** Enter a new calibration value when prompted.

Notifications

Apple Watch Display	
Description	**Transmitter End of Life Day 330** Appears once 35 days before your transmitter warranty expires.
Actions	**Confirm the alert on your Eversense CGM Mobile App.** Contact your distributor to order a new transmitter.

15. My Circle

Remote Monitoring with Eversense E3 CGM System and Eversense NOW App

The Eversense CGM App includes an optional remote monitoring feature. The Eversense CGM App interacts with the Eversense NOW Remote Glucose Monitoring App to allow other people to view your data.

Risks

There may be times when glucose data cannot be sent to the Eversense NOW App. If a member of your Circle is not receiving glucose data from your Eversense E3 CGM System, they cannot assist you in the event of a high or low glucose value. The secondary display and notifications on the Eversense NOW Mobile App are not a replacement for the primary display on your Eversense CGM System Mobile App.

Members of your Circle may not always have a connection to support data transfer such as internet/wifi or 3G/4G/LTE. If you or a member of your Circle does not have an internet connection, your glucose data will not be available for viewing on a secondary display. Any problems with mobile devices, wireless internet, data connection, the Eversense Data Management System (DMS) System, having your smart transmitter out of range of your mobile device, or charging your smart transmitter may prevent data from being displayed to members of your Circle. You should not rely on people remotely monitoring your glucose data to assist you in the event of a high or low glucose event.

The remote monitoring feature provides a secondary display of notifications and data to those in your Circle. It is not a real-time remote monitoring system.

Benefits

The Eversense E3 CGM System used with the Eversense NOW Remote Monitoring App may provide CGM users with additional confidence, knowing that others can also view their CGM data.

Warnings

- Glucose information displayed on the Eversense NOW App should not be used to make treatment decisions. Always use blood glucose values from your meter to make treatment decisions. Using a sensor glucose value to make a treatment decision could result in a high or low blood glucose. The Eversense NOW App is a secondary display of Eversense E3 CGM data and should not be used in place of the primary Eversense E3 CGM display.
- You should not rely on those who are remotely monitoring your glucose to notify you about high or low glucose events.

Cautions

- The Eversense NOW Mobile App does not replace the monitoring regimen as directed by your healthcare provider.
- If you do not have Auto Sync (the feature that enables data to automatically be sent to the Eversense NOW App) turned on, you cannot share data with those in your Circle and they will not see high or low glucose trends and events.
- If you and the members of your Circle do not have an internet connection, or the mobile device has shut down due to a low or empty battery, your Eversense E3 CGM data cannot be displayed on the Eversense NOW App.
- If the members of your Circle turn off the sounds on their mobile device, they will not receive audible alerts about your CGM data on their Eversense NOW App.
- If you set your status to offline with any of the members of your Circle, they will not receive any of your CGM data on their Eversense NOW App. DO NOT set your status to offline if you want members of your Circle to see your CGM data.
- The Eversense NOW App does not communicate directly with the Eversense E3 Sensor and/or with the Eversense E3 Smart Transmitter.
- The Eversense NOW App cannot change the settings on the Eversense CGM App.

Cautions (continued)

- **If the Eversense NOW user does not allow notifications from the Eversense NOW App, they will not receive glucose related alerts from you.**
- **If you have your mobile device set to Do Not Disturb, you will not hear any notifications from the Eversense NOW App.**

Through the **MY CIRCLE** screen on your Eversense CGM Mobile App, you can invite up to five people to view your data. When you invite someone to join your Circle, an invitation will be sent to the email address you entered. Once the invitation is accepted, and the Eversense NOW App is downloaded, members of your Circle can view your recent glucose data, events and alerts.

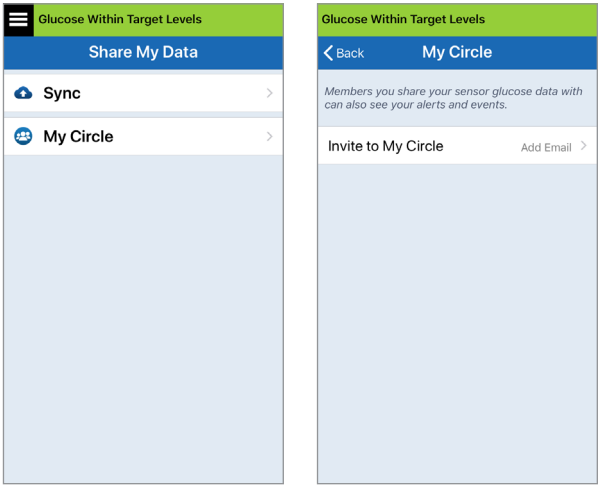
IMPORTANT: Members of your Circle who do not have the Eversense NOW App will not be able to see your data.

As long as your Eversense CGM System App and the Eversense NOW App have an internet connection, your glucose data is synced to the Eversense NOW App approximately every 5 minutes. Calibration values may take longer to sync to the Eversense NOW App.

If you have turned off Auto Sync, your glucose data will NOT be available on the Eversense NOW Remote Monitoring App.

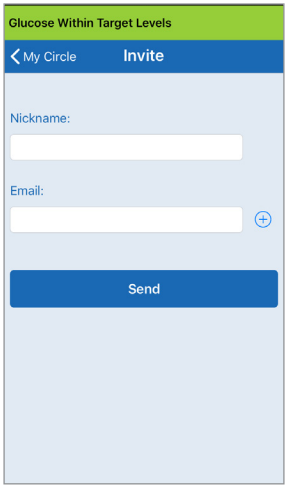
1. From the Main Menu, tap **Share My Data** > **My Circle** to display the **MY CIRCLE** screen.

2. To invite a new member to view your glucose data, tap **Invite to My Circle**.



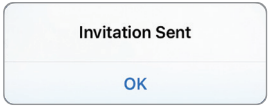
3. **Enter the email for the person you would like to invite to your Circle, and tap Send when complete.**

Note: You can tap the "**+**" next to the email field to select an email address from your Contact list.

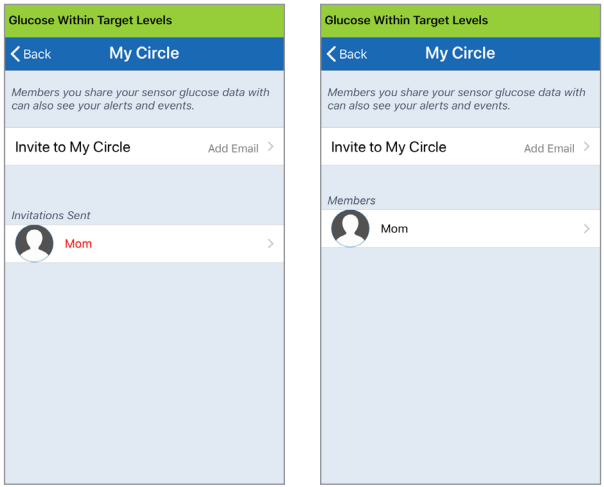


Tip: Nicknames are optional, and are used to help you easily manage your Circle Members. If you choose not to give a nickname to a Circle Member, their email address will show in place of a nickname.

4. **An Invitation Sent screen appears. Tap OK.**



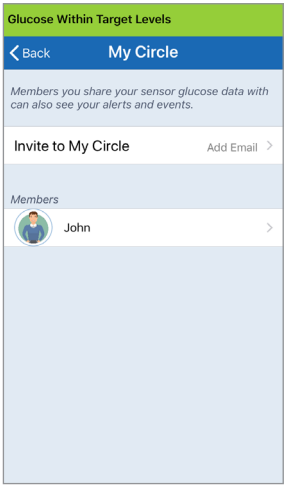
When the invitation has been accepted, the member's name will appear in your Members List on the **MY CIRCLE** screen in your app.



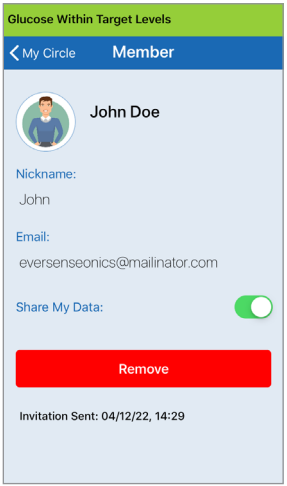
Note: Profile pictures of those remotely viewing your glucose data are set up in the DMS account by the account owner. You cannot change profile pictures of those you have invited to your Circle.

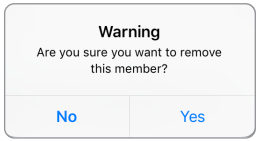
Remove a Member from Your Circle

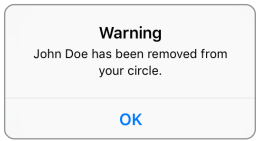
1. To remove a member or an invitation, tap the person's name in the Members List or the Invitations Sent List on the **MY CIRCLE** screen.



2. Tap **Remove** to remove the member from your circle. Tap **Yes** when prompted.





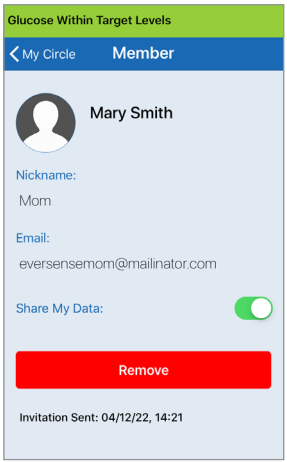


The member you remove will be notified on their Eversense NOW App if they have already accepted.

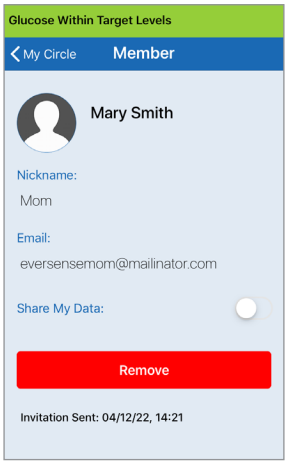
Temporarily Stop Sharing Data

There may be times when you wish to temporarily stop sharing data with a member, but not remove them from your Circle.

1. **Tap the member's name in the My Circle list to open the MEMBER screen.**



2. **Tap the Share My Data button to turn on/off data share with this member.**



IMPORTANT: If you have disabled the Share My Data feature for a member, that member will not see any of your Eversense E3 CGM System glucose data, alerts or event history. Members will see your status as Offline on their Eversense NOW App when you have disabled the Share my Data feature. It can take up to 10 minutes for the change to display on the Eversense NOW user's app.

Note: The Eversense NOW user can also remove you from their app. It can take up to 2 hours for these changes to display on your Eversense CGM App.

For more information about the Eversense NOW App, refer to the *Eversense NOW* section.

16. About the Sensor

This section describes the Eversense E3 Sensor and how it is inserted by your healthcare provider.

The Eversense E3 Sensor is a miniaturised 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 180 days.



Eversense E3 Sensor

The sensor is encased in a biocompatible material and utilises 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 3.5 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 minimises inflammatory responses, very similar to common medical devices, such as pacemakers.

Insertion Steps

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

Insertion site:

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

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

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

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

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

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

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

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

Removal Steps

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

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

Step 2: **Incision –** a small (less than 1 centimetre) 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 Steri-Strips™ (sutures may be used depending on provider's preference).

17. Travel

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

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

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

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

18. Troubleshooting

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

Smart Transmitter

Q: How do I turn my smart transmitter OFF?

A: 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.

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

Q: My smart transmitter will not vibrate. Why?

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

- Check that the smart transmitter is paired to your mobile device.
- Check that the **Do Not Disturb** is disabled by tapping **Menu** > **Settings** > **Sound Settings.**

- Check that your smart transmitter has enough battery power and charge if necessary.

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

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

A: Repeated removal and replacement may reduce adhesion strength.

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

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

Q: How do I customise 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 approximately 24 to 36 hours.

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 or when the battery is empty.

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

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

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

A: There are three ways to check battery status:

1. 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 top 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: On the About > My Transmitter page, the battery level shows 65% and then drops to 35%. Why is that?

A: The rate battery levels discharge varies widely based on use; the same battery model in two devices will not discharge at the same rate. This is why we show battery level indicators on this screen in large increments: 100%, 65%, 35%, 10% and 0%. Our testing shows that the “Low Battery” alert is triggered consistently at the point the smart transmitter still has approximately 2 hours of power left (at about the 10% indicator level). It is important to charge your battery when you receive the “Low Battery” alert.

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 flashes green and orange, tap the smart transmitter ID on the **CONNECT** screen. The app will then begin the searching process.
   - Your smart transmitter ID is the same as the serial number listed on the back of the smart transmitter.
4. When the app finds your smart transmitter, a **BLUETOOTH PAIRING REQUEST** pop-up screen appears.
5. Tap **Pair** to confirm the pairing.
6. The app will display **Connected** next to the smart transmitter ID once the pairing is completed.

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

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

- Make sure 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. Place the smart transmitter into the charging cradle and connect the USB cable. 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 power button (for approx. 14 seconds) on the smart transmitter while connected to the USB. Release the power button.
3. The LED will start flashing in about two seconds indicating the smart transmitter is going through a self-test sequence. The LED will flash in various colours. Once the self test is complete, the smart transmitter will vibrate and a steady green or orange LED will stay on.
4. If the self-test does not complete, repeat steps 1 through 3.
5. If step 3 is successfully completed, the smart transmitter is now ready for use.
6. Disconnect the smart transmitter from the USB cable and proceed with pairing. Once paired, the system will be in the Initialisation Phase. If you are unable to complete the reset, contact Customer Support.

Q: Can other people connect to my smart transmitter?

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

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

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

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

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

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

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

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

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

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

Calibration

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

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

Q: Why was my calibration rejected?

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

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

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

Q: Why am I unable to calibrate?

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

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

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

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

Q: What are the different types of calibration phases?

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

Alerts and Notifications

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

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

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

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

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

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

Q: What are rate of change alerts?

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

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

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

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

Q: What are predictive alerts?

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

Q: What are rate of change alerts?

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

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

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

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

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

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

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

Q: How do I silence glucose alerts?

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

Glucose Readings

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

A: The Eversense E3 CGM System measures glucose in interstitial fluid (ISF) between the body's cells. Physiologic differences between ISF and blood from a fingerstick may result in differences in glucose measurements. These differences are especially evident during times of rapid change in blood glucose (e.g., after eating, dosing insulin, or exercising), and for some people, during the first several days after insertion due to inflammation that may result from the insertion procedure. On average, glucose levels in ISF lag behind glucose levels in blood by several minutes. Until you are aware of what these differences are, confirm sensor readings with a fingerstick blood glucose check. Also, if your symptoms do not match the sensor glucose readings, you should confirm with a fingerstick blood glucose check.

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

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

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

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

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

Making Treatment Decisions

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

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

Q: Why is my glucose value grey?

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

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

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

- When it is time to calibrate.
- No glucose value is displayed.
- No trend arrow is displayed.
- Your symptoms do not match the glucose information displayed.
- The current sensor glucose value is displayed in grey.
- The status bar is displayed in orange.
- You are taking medications of the tetracycline class.

Trend Arrows

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

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

Q: My trend arrow is missing.

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

App

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

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

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

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

Q: How will my app be updated?

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

Q: What devices are compatible with the Eversense App?

A: Visit **https://global.eversensediabetes.com/compatibility** 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: Can I delete my Eversense account?

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

Q: What is the Do Not Disturb option?

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

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

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

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

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

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

Q: Can I edit a manual BG entry event?

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

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

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

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

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

Sensor

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

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

Q: When do I need to replace my sensor?

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

Q: Can I extend the life of the sensor?

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

Q: Where can I find the sensor serial number?

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

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

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

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

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

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

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

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

A: You will re-enter Initialisation 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 reinitialise to your mobile device.
- A new transmitter has been linked to your existing sensor. For example, if you have replaced your existing transmitter.
- If you were instructed by Customer Support to re-link your sensor.

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

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

Events

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

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

Sync

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

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

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

Shortcuts

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

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

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

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

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

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

Q: Is there a shortcut to the CONNECT screen?

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

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

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

19. Device Performance

This section lists Device Performance Characteristics.

Clinical Study Performance

The safety and effectiveness of the Eversense E3 CGM System has been evaluated in the PROMISE clinical study conducted in the U.S. The data included in this Device Performance section is based on the data collected during the PROMISE study with new algorithm (SW604) and minor design modification in the Sensor (E3 Sensor). Accuracy assessments were made at various points during the study and subjects were asked to report any adverse events throughout the study. The Safety section reflects all subjects (n=181) from the study.

PROMISE Study

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

Table 1 – Accuracy to YSI in PROMISE*

Total Number of Paired CGM and YSI Values	Percent of CGM System Readings Within				MARD
	Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	
12,034	87.3	93.9	98.6	99.6	8.5%

*Glucose values between 40 and 400 mg/dL.

Eversense E3 Accuracy to YSI in PROMISE Study

Accuracy was measured by comparing the Eversense E3 sensor glucose values to YSI blood glucose values. For blood glucose values less than or equal to 80 mg/dL, the mean absolute difference between the two results was calculated. For values greater than 80 mg/dL, the mean absolute relative difference was calculated.

Table 2 – Accuracy to YSI in PROMISE Study

YSI Glucose Ranges (mg/dL)	Number of Paired CGM-YSI	Mean Absolute Relative Difference (%)
Overall	12,034	8.5
< 40*	0	--
40 - 60*	592	7.5
61 - 80*	1,221	7.7
81 - 180	5,067	8.6
181 - 300	3,300	7.4
301 - 350	1,457	6.9
351 - 400	375	6.4
> 400	25	9.5

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

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

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

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

Table 4 – Eversense E3 System Accuracy by Day

Day	Mean Absolute Relative Difference (%)	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent > 40/40% of Reference
Day 1	11.2	78.6	87.4	96.5	99.3	0.7
Day 7	10.0	81.9	88.0	94.7	98.5	1.5
Day 14	7.4	87.4	95.0	99.0	100.0	0.0
Day 22	8.4	88.9	95.7	99.2	99.9	0.1
Day 30	8.2	85.8	93.4	98.2	99.3	0.7
Day 60	8.6	87.9	94.2	98.6	99.8	0.2
Day 90	7.0	93.1	97.1	99.8	99.9	0.1
Day 120	8.4	89.2	96.1	99.6	99.9	0.1
Day 150	8.8	84.0	91.9	99.5	99.9	0.1
Day 180	7.4	93.1	98.0	99.3	99.7	0.3

Eversense E3 Alert Performance

The tables in this section show an alert performance assessment. The Confirmed Event Detection Rate shows the percentage of time the Eversense E3 CGM System confirmed the reference value by presenting an alert within a 15 minute window of a reference value beyond the alert setting threshold. The Missed Detection Rate shows the percentage of time the Eversense E3 CGM System did not present an alert within a 15 minute window of a reference value beyond the alert setting threshold. The True Alert Rate shows the percentage of time the alert from the CGM system was confirmed by a reference value within a 15 minute window of the alert being presented. The False Alert Rate shows the percentage of time the alert from the CGM system was not confirmed by a reference value within a 15 minute window of the alert being presented.

The table below shows an assessment of the ability of the Eversense E3 CGM System to detect high and low glucose levels, and assess true positive alerts vs false positive alerts. These are shown as a percentage of alerts provided compared to the YSI reference values at various thresholds.

Table 5 – Eversense E3 High and Low Glucose Alert Performance (Threshold Only) in the PROMISE Study

Alert Setting (mg/dL)		Confirmed Event Detection Rate	Missed Detection Rate	True Alert Rate	False Alert Rate
Low Alert	60	76%	24%	82%	18%
	70	89%	11%	90%	10%
	80	93%	7%	92%	8%
	90	96%	4%	93%	7%
High Alert	120	99%	1%	97%	3%
	140	99%	1%	96%	4%
	180	98%	2%	95%	5%
	200	97%	3%	95%	5%
	220	97%	3%	95%	5%
	240	97%	3%	94%	6%
	300	88%	12%	90%	10%

The table below shows an assessment of the ability of the Eversense E3 CGM System to detect high, low, and predictive high and low alerts, and assess true positive alerts vs false positive alerts. These are shown as a percentage of alerts provided compared to the YSI reference values at various thresholds.

Table 6 – Eversense E3 High, Low, and Predictive Alert Performance (Threshold and Predictive) in the PROMISE Study

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

Eversense E3 Rate of Change Trend Agreement

The shaded area in the table below shows agreement between the Eversense E3 glucose trends and the YSI reference trends while glucose is trending at different rates (mg/dL per minute). As an example, when glucose is trending at a rate of between -1 and 1 mg/dL/minute, Eversense E3 glucose trends are in agreement with the reference trends 90% of the time.

Table 7 – Eversense E3 Rate of Change Trend Agreement in the PROMISE Study

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

Eversense E3 Concurrence with YSI Values

The shaded area in the tables below show what percentage of YSI reference values were in the same range as the sensor glucose values. As an example, when sensor glucose is between 81 and 120 mg/dL, YSI reference values are in the same range 76% of the time.

Table 8 – Concurrence with YSI Range All Days in the PROMISE Study

CGM (mg/dL)	Number of Paired CGM-YSI	Percent of Matched Pairs in Each YSI Glucose Range for Each CGM Glucose Range YSI (mg/dL)										
		< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400
40 - 60	574	0%	62%	36%	1%	0%	0%	0%	0%	0%	0%	0%
61 - 80	1,178	0%	19%	66%	15%	0%	0%	0%	0%	0%	0%	0%
81 - 120	2,066	0%	0%	11%	76%	12%	0%	0%	0%	0%	0%	0%
121 - 160	2,067	0%	0%	0%	14%	71%	14%	0%	0%	0%	0%	0%
161 - 200	1,648	0%	0%	0%	0%	21%	66%	13%	0%	0%	0%	0%
201 - 250	1,437	0%	0%	0%	0%	1%	15%	68%	15%	1%	0%	0%
251 - 300	1,353	0%	0%	0%	0%	0%	1%	17%	56%	25%	1%	0%
301 - 350	1,191	0%	0%	0%	0%	0%	0%	1%	17%	70%	12%	0%
351 - 400	520	0%	0%	0%	0%	0%	0%	0%	3%	51%	42%	5%
> 400	155	0%	0%	0%	0%	0%	0%	0%	1%	21%	52%	26%

Table 9 – Concurrence with YSI Range Day 1 in the PROMISE Study

CGM (mg/dL)	Number of Paired CGM-YSI	Percent of Matched Pairs in Each YSI Glucose Range for Each CGM Glucose Range YSI (mg/dL)										
		< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400
40 - 60	120	0%	51%	45%	3%	1%	0%	0%	0%	0%	0%	0%
61 - 80	146	0%	10%	54%	36%	0%	0%	0%	0%	0%	0%	0%
81 - 120	271	0%	0%	5%	70%	25%	0%	0%	0%	0%	0%	0%
121 - 160	202	0%	0%	0%	14%	62%	21%	3%	0%	0%	0%	0%
161 - 200	124	0%	0%	0%	0%	33%	51%	16%	0%	0%	0%	0%
201 - 250	75	0%	0%	0%	0%	4%	19%	51%	27%	0%	0%	0%
251 - 300	121	0%	0%	0%	0%	0%	1%	24%	57%	18%	0%	0%
301 - 350	86	0%	0%	0%	0%	0%	0%	3%	33%	64%	0%	0%
351 - 400	58	0%	0%	0%	0%	0%	0%	0%	7%	84%	9%	0%
> 400	25	0%	0%	0%	0%	0%	0%	0%	4%	48%	48%	0%

Calibration Stability Agreement

The table below compares the percentage of sensor glucose values to the YSI reference at various time points after a calibration entry. As an example, in the table below, 89.7% of the Eversense E3 values were within 15 mg/dL (for reference readings of 80 mg/dL or less), and within 15% (for reference readings over 80 mg/dL) of the reference value 8 to 10 hours after a calibration entry.

Table 10 – Eversense E3 Calibration Stability Agreement in the PROMISE Study

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

Table 10 – Eversense E3 Calibration Stability Agreement in the PROMISE Study (continued)

Time from Calibration	Number of Paired CGM-YSI	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent > 40/40% of Reference
[20, 22) Hours	436	88.3	94.5	99.5	99.8	0.2
[22, 24) Hours	522	89.7	96.2	99.4	99.8	0.2
[24, 26) Hours	168	93.5	98.2	99.4	100.0	0.0
[26, 28) Hours	7	100.0	100.0	100.0	100.0	0.0

Sensor Life

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

Percentage of Sensors that lasted 60, 120 and 180 days

Days	Sensor Life
60	98%
120	98%
180	90%

Average # of Days
175

Safety

The PROMISE study lasted for 180 days, and the number of related adverse events was recorded. The Eversense E3 CGM System was well tolerated in the study. During the study's 31,373 sensor wear days, there were no unanticipated adverse events. Fifty-nine adverse events were reported in 37 participants. None of the adverse events resulted in hospitalisation.

Table 11 – Adverse Events (All Subjects, n = 181)

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

20. Technical Specifications

Sensor

Characteristic	Description
Dimensions	Length: 18.3 mm Diameter: 3.5 mm
Materials	Homopolymer polymethylmethacrylate (PMMA) - 86 mg, Hydroxyethylmethacrylate (HEMA) based Hydrogel containing glucose indicator - 2.0 mg, Platinum - 0.012 mg, Silicone - 4.1 mg, Dexamethasone Acetate - 1.7 mg, epoxy 301-2 - 0.62 mg
Glucose Range	40-400 mg/dL
Sensor Life	Up to 180 days
Calibration	Commercially available self-monitoring blood glucose meter
Calibration Range	40-400 mg/dL
Sterilisation	Sterile by Ethylene Oxide

Smart Transmitter

Characteristic	Description
Dimensions	Length: 48.0 mm Width: 37.6 mm Thickness: 8.8 mm
Materials	Body: polycarbonate
Weight	11.3 g
Power Supply	Rechargeable lithium polymer batteries (not replaceable)
Operational Conditions	5-40°C (41-104°F)
Operational Life	12 months
Storage Conditions	0-35°C (32-95°F)
Moisture Protection	IP67: submerged in up to 1 metre of water for up to 30 minutes
Protection Against Electrical Shock	Type BF applied part
Charge time using AC adapter	15 minutes to fully charge
Communication Distance	Between app and smart transmitter is up to 24.9 feet Wireless communication to the app will not function well when communicating through water. The range will decrease if you are in a bath, water bed, pool, etc.
Cabin Pressure	700 hPa to 1060 hPa
Relative Humidity Range (non-condensing)	15% to 90%
Altitude	10,000 ft

Power Supply and Charger

Characteristic	Description
Class	II
Input	AC Input, 100-240 Vac, 50/60 Hx, 0.3-0.15 A
DC Output	5 V DC, 1 A (5.0 watts)
Moisture Protection (charging cradle)	IP22

USB Cable* for Charging and Downloading

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

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

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

Transmitter Electromagnetic Immunity Specifications

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

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

System Electromagnetic Immunity Specifications

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

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

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

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

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

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

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

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

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

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

Symbols on the Eversense CGM Mobile App

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

Symbols on the Eversense CGM Mobile App (continued)

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

Symbols on the Eversense CGM Mobile App (continued)

Symbol	Explanation
	**Event Icons** Appear on the glucose trend line and in the **EVENT LOG** after an event is entered. The events that can be entered are:  Glucose  Insulin  Exercise  Meals  Health
	**Temp Profile** Appears when the Temp Profile is active.
	**Do Not Disturb (DND)** Appears when the DND setting is active.

Symbols on Packaging and Devices

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

Symbol	Explanation
	Part number
	Serial number
	Type BF Applied Part
	Non-ionising electromagnetic radiation
	Not made with natural rubber latex
FCC ID	FCC ID is assigned to all devices subject to certification
	Non-sterile
	Magnetic Resonance Imaging (MRI) procedures are contraindicated for the smart transmitter

Symbols on Packaging and Devices (continued)

Symbol	Explanation
	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 radio frequency fields. Please refer to the *MRI Safety Information* section for complete information.
	European Union WEEE Directive 2012/19/EU
	Single use only
	Do not re-sterilise
	Do not use if package is damaged

Symbol	Explanation
	Sterilised using Ethylene Oxide
	Single sterile barrier: Sterilised using Ethylene Oxide
	U.S. (Federal) law restricts the sale of the Eversense E3 CGM System to sale by or on the order of a doctor
	Follow instructions for use
	Marking certifies that the device meets Medical Device Regulation 2017/745
	Medical Device (Note: On the implant card, this indicates the device name)
	Unique Device Identifier
	Date of insertion

Symbols on Packaging and Devices (continued)

Symbol	Explanation
	Implanting healthcare centre or doctor
	Patient identification (name)
	Patient information website
	Importer
	Authorised representative in the European Community
	Single patient multiple use
	Contains a medicinal substance

Symbol	Explanation
	Recycling information
	Distributor

Eversense E3 Smart Transmitter Limited Warranty

1. Coverage and duration of limited warranty.

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

2. Exclusions to the limited warranty.

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

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

3. Senseonics' obligations under the limited warranty.

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

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

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

THE LIMITED WARRANTY OF SENSEONICS DESCRIBED ABOVE IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, STATUTORY OR OTHERWISE, AND SENSEONICS EXPRESSLY EXCLUDES AND DISCLAIMS ALL SUCH OTHER WARRANTIES, INCLUDING WITHOUT LIMITATION, ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, SATISFACTORY QUALITY, NON-INTERFERENCE, ACCURACY OF INFORMATIONAL CONTENT, OR ARISING FROM A COURSE OF DEALING, LAW, USAGE, OR TRADE PRACTICE. EXCEPT TO THE EXTENT PROHIBITED BY APPLICABLE LAW, SENSEONICS SHALL NOT BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, ARISING IN ANY WAY OUT OF THE SALE, USE, MISUSE OR INABILITY TO USE THE SMART TRANSMITTERS OR ANY SENSEONICS EVERSENSE E3 SYSTEM. THIS LIMITATION SHALL APPLY EVEN IF SENSEONICS OR ITS AGENT HAS BEEN ADVISED OF SUCH DAMAGES AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF THIS LIMITED REMEDY.

THIS LIMITED WARRANTY SHALL NOT EXTEND TO ANYONE OTHER THAN YOU, THE ORIGINAL END USER OF THIS PRODUCT AND IT STATES YOUR EXCLUSIVE REMEDY. IF ANY PORTION OF THIS LIMITED WARRANTY IS ILLEGAL OR UNENFORCEABLE BY REASON OF ANY LAW, TO THE EXTENT THAT SENSEONICS MAY NOT, AS A MATTER OF APPLICABLE LAW, DISCLAIM ANY IMPLIED WARRANTY OR LIMIT ITS LIABILITIES, THE SCOPE AND DURATION OF SUCH WARRANTY AND THE EXTENT OF LIABILITY OF SENSEONICS SHALL BE THE MINIMUM PERMITTED UNDER SUCH APPLICABLE LAW.

21. Eversense DMS

Introduction

Intended Use

The Eversense Data Management System (DMS) is intended for use as an accessory to compatible Eversense CGM products. It is a web based application that may be used to view, analyse, and store glucose information from your Eversense CGM System.

For a list of compatible devices and operating systems, please go to **https://global.eversensediabetes.com/compatibility**.

IMPORTANT: EVERSENSE DATA MANAGEMENT SYSTEM DOES NOT PROVIDE MEDICAL ADVICE. DO NOT MAKE TREATMENT DECISIONS WITHOUT CONSULTING WITH YOUR HEALTHCARE TEAM.

End User Licence Agreement and Privacy Policy

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

Help and Support

If you don't understand something in this *Eversense DMS* section, contact Customer Support toll-free in the US at 844-SENSE4U (844-736-7348). Outside of the US, call your local distributor or visit: **global.eversensediabetes.com** to locate your local distributor. To access the latest version of the Eversense DMS Instructions for use, please visit: **https://global.eversensediabetes.com/patient-education/eversense-user-guides**.

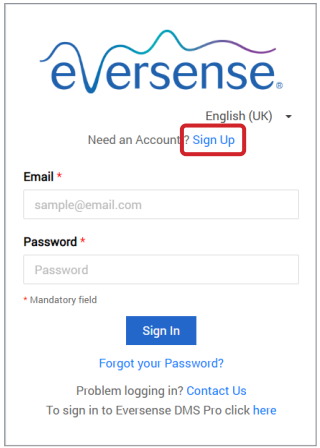
Getting Started

The Eversense DMS is an internet browser-based application (web app) that enables you to automatically upload your Eversense mobile app data from your compatible smart device to the internet for ongoing storage and review.

The desktop software enables your computer to communicate directly with the web app. You can also upload your data directly from the smart transmitter to your Eversense DMS Account via cable connection by downloading and installing the Eversense Client desktop software directly onto your computer.

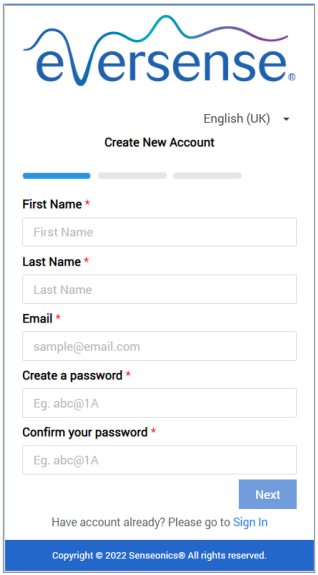
Create New Account

Before you can begin using Eversense DMS, you will need to register as a user.



If you have already created an account in the Eversense mobile app, you do not need to register a new account.

1. Go to **global.eversensedms.com**
2. Click **"Sign Up"**
3. Enter the requested information
4. Click **"Submit"**



Note: You will be prompted to set a secret question for added security after you log in for the first time. Your registered email and password can now be used as your login for your Eversense DMS account and for all other Eversense products.

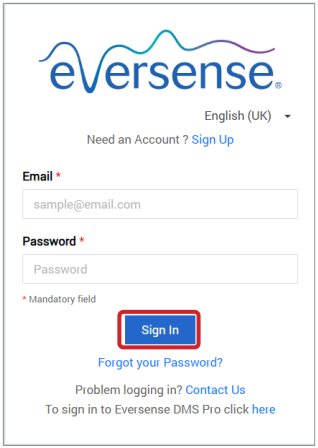
Sign In

Each time you access Eversense DMS you will need to sign in.

1. Go to **global.eversensedms.com**
2. On the Sign In page, enter your Email and Password
3. Click "**Sign In**"

IMPORTANT: If you make more than three unsuccessful attempts to sign in, your Eversense DMS account will be locked for 30 minutes.

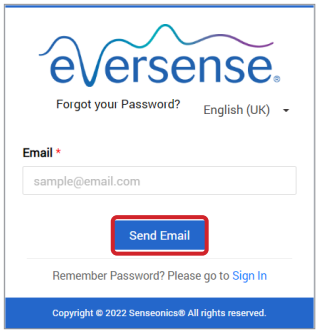
Note: If you are inactive on the DMS site for up to an hour, you will receive a pop-up instructing you to select "**Continue**" if you want to remain logged in.

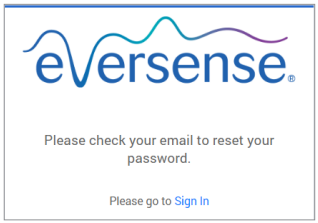


Forgot Your Password

If you have forgotten your sign in password, you can easily create a new password.

1. Click **"Forgot your password"** on the Sign In page
2. Enter your email when prompted
3. Click **"Send Mail"**

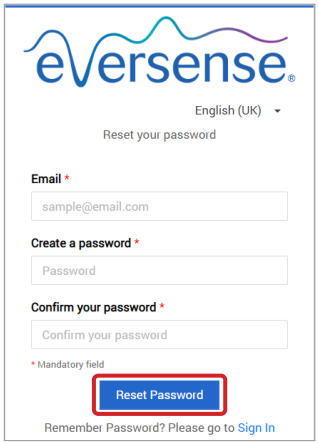


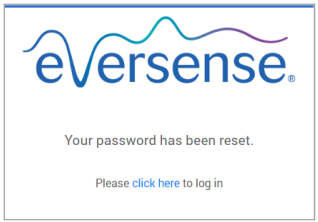


A message will display to let you know an email has been sent to you with instructions for resetting your password.

4. Open the email and click the website link

   You will be directed to a web page to create and confirm a new password.
5. Click **"Reset Password"**



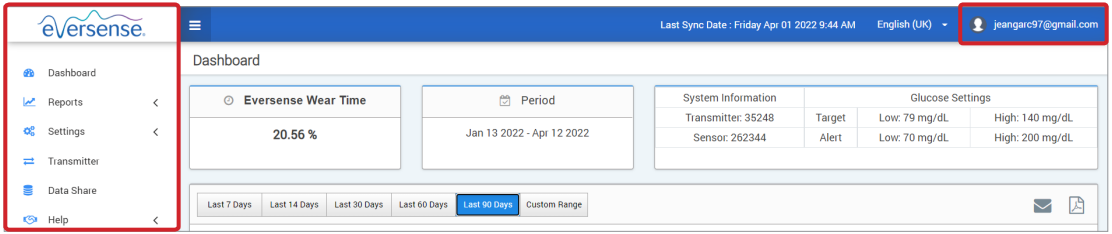


*A message will appear, confirming your password has been reset. Select the "**click here**" link to return to the Sign In page.*

Your Profile and the Navigation Menu

Upon successful sign in, the Dashboard with AGP will be displayed.

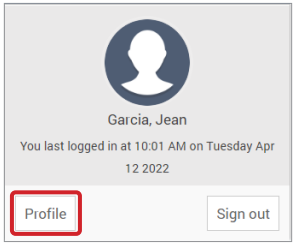
- On the top right of the page you can access your **Profile** information.
- On the top left side of the page you will see a **Navigation Menu**.



Profile

Located at the top right of the Dashboard, this feature allows you to change your name or password, edit your user profile, or sign out of the Eversense DMS software.

If you want to change your login password, you can easily re-set a new password.

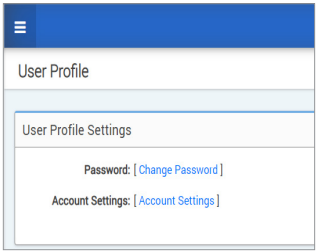


1. **Click your username**

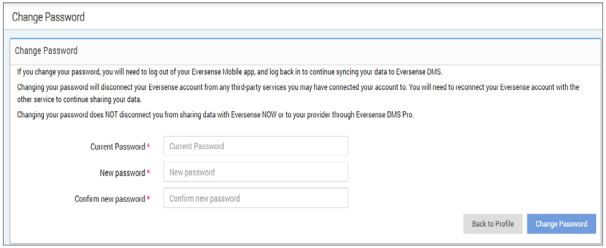
   A drop-down will appear displaying your profile picture, your most recent log in, and options to view/edit your profile or sign out.

2. **Click "Profile" to access User Profile Settings**

3. **Click "Change Password" to display and change your current password**



4. **Enter your Current Password**
5. **Enter and confirm your new password**
6. **Click "Change Password" to save your changes**

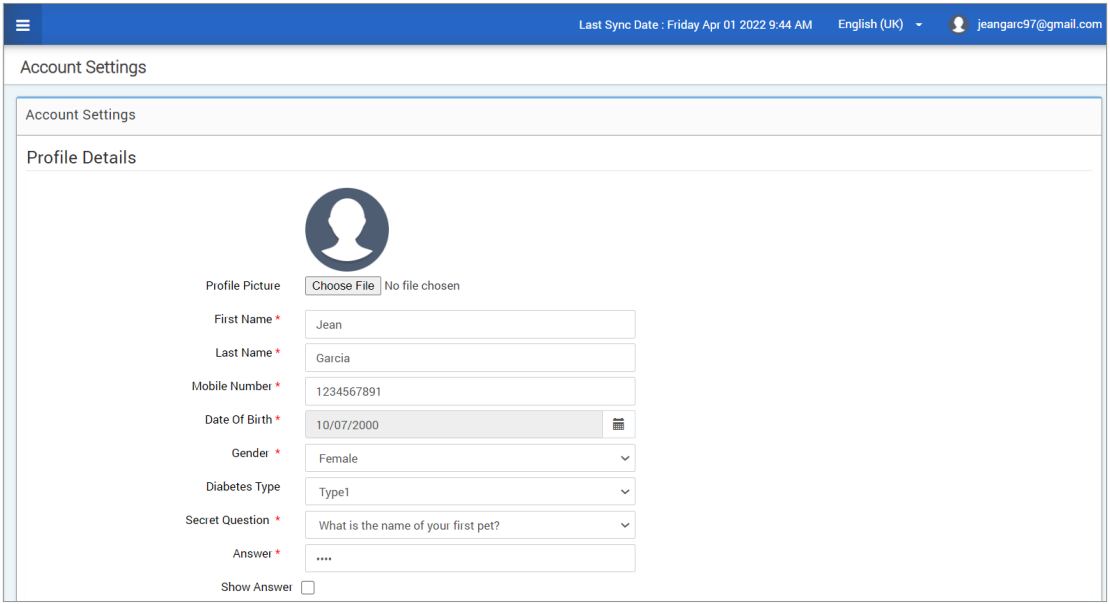


To adjust your personal account information:

1. Click "Account Settings"

2. Enter the information you will be changing

You can change your profile picture by pressing the **Choose File** button, and choosing a picture from your computer's files. The profile picture will be changed for all compatible Eversense products.



3. Click "Save" to save your changes

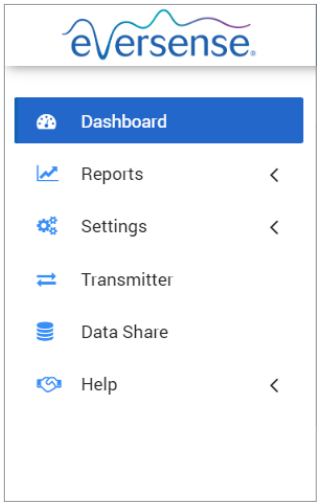
The User Profile Settings page will appear again. To return to the Dashboard, click "**Dashboard**" at the top left on the navigation panel.

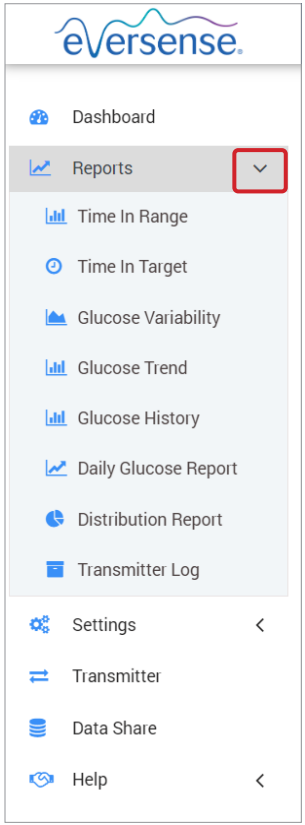
Navigation Menu

At the top left-hand side of the AGP Dashboard is the navigation menu. You can open and close the navigation menu by clicking ≡. Click any button on the menu to navigate to that selection.

Note: You can also select your preferred language by clicking the language.

You can click on the ⌄ icon to expand the selection in the navigation menu.





Menu Selections	Features
Dashboard	Return to the Dashboard
Reports	Display, print, and share reports • Time In Target • Time In Range • Glucose Variability • Glucose Trend • Glucose History • Daily Glucose Report • Distribution Report • Transmitter Log
Settings	Eversense DMS Settings • Glucose • Report Summary
Transmitter	Download Client Application
Data Share	Link DMS account to DMS Pro
Help	• About • Contact • Deactivate Account • Release Notes

Setting Date Range

At the top of the Dashboard, you will find your options for predefined date ranges, as well as the option to set your own custom date range. This will impact which data is used for analyses and how they are displayed throughout the AGP Dashboard and all of the Reports.

To adjust your date range settings:

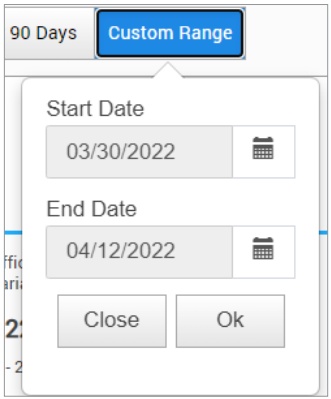
1. **If you would like to view a set of data that is not within one of the predefined date ranges, click the button labelled "Custom Range" to display a drop-down calendar**

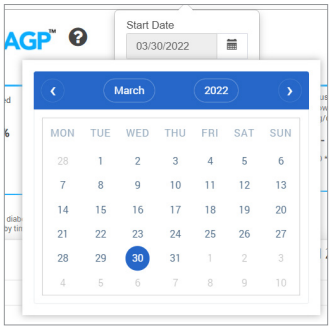


This will display a pop-up that allows you to select your Custom Date Range.

Note: Data accessible through DMS goes as far back as one year.

2. **Select the desired report *Start Date***
3. **Select the desired report *End Date***
4. **Click "Ok" when complete**





Eversense DMS Dashboard with AGP

The Eversense DMS Dashboard is the default page that you will see each time you log into DMS. This page contains your Eversense Wear Time, Captur AGP reports, and your System Information.

Eversense Wear Time

Eversense Wear Time is the percentage of time the smart transmitter was worn, over the date range you selected. 100% is 23.5 hours of daily smart transmitter wear time. The percentage does not include times in which the glucose is not displayed. For example: the beginning of Initialisation Phase or when an alert is activated that prevents glucose from being displayed.

Eversense Wear Time
21.3 %

System Information: Located at the top of the AGP Dashboard is the System Information section.

This section shows your:

- Transmitter Serial Number
- Sensor Serial Number
- Glucose settings: Glucose settings can be changed in the DMS as well as through your Eversense mobile app (see *Settings* for more information).

System Information	Glucose Settings		
Transmitter: 35248	Target	Low: 79 mg/dL	High: 140 mg/dL
Sensor: 262344	Alert	Low: 70 mg/dL	High: 200 mg/dL

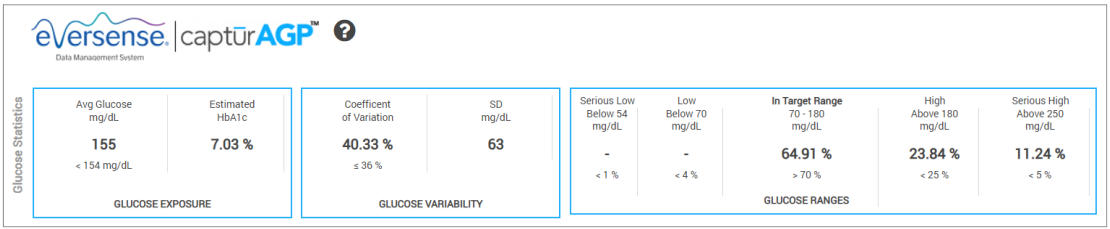
Captur AGP in Eversense DMS

The Eversense DMS Dashboard's primary report is the Captur AGP (Ambulatory Glucose Profile) report. The AGP report displays glucose data within 3 sections of their report.



Glucose Statistics: Metrics about your glucose data

- Avg. Glucose (mean): All glucose values added together, divided by number of readings
- Estimated HbA1c: Calculated from the AGP glucose values; may differ from a lab A1c due to different time periods
- Glucose Ranges: Ideally, glucose values are in target range
  - Low/Very low: Goal – no very low or low values; reducing lows make you feel better
  - High/Very High: Goal – no very high or high values; reducing highs will make your A1c lower over time
- SD (Standard Deviation): How much variation is in your data set; ideally a low number
- CV (Coefficient of Variation): How far values are from the average; ideally a low number

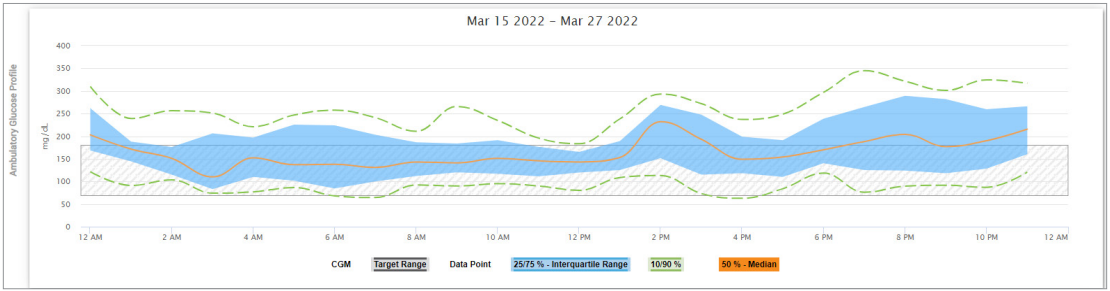


Glucose Profile: **Daily glucose profiles are combined to make a one day (24-hour) picture. Ideally, lines stay within the grey shaded area (target range). Lines may not go all the way across, since you may not test every hour of the day.**

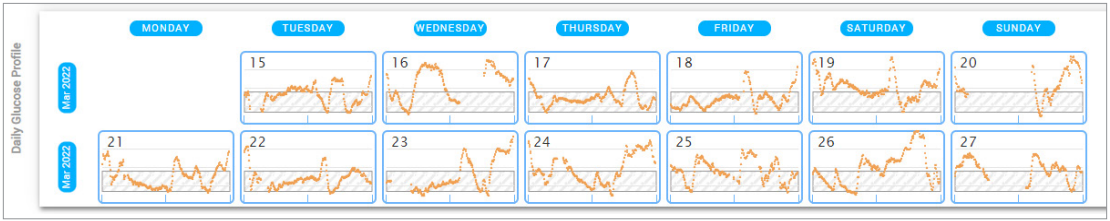
Orange: Median (middle) line where half of the glucose values are above and half are below; ideally, the orange line is mostly flat and inside the grey shaded area

Blue: Area between blue lines shows 50% of the glucose values; ideally, space between is narrow

Green: 10% of values are above (90% top line) and 10% are below (10% bottom line); ideally, the closer the green lines are to the grey shaded area, the better



Daily Glucose Profiles: Each box is a single day's glucose pattern. It will only display if your date range is set at 14 days or less.



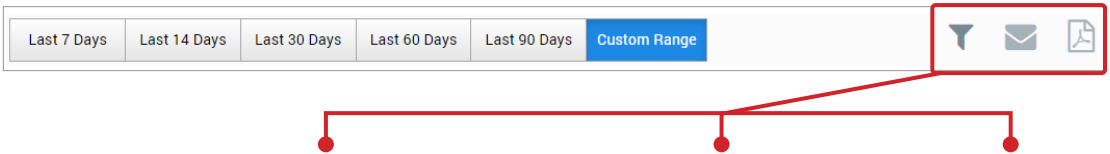
Reports

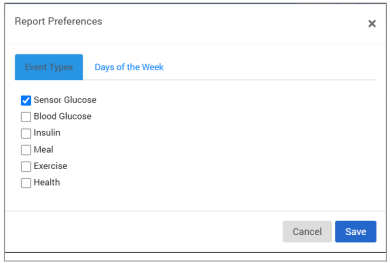
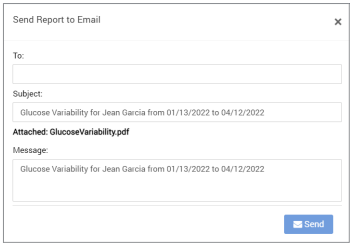
A key feature of the Eversense DMS Application is the ability to generate, print, and share detailed reports about your glucose history. Reports provide various ways to organise and visualise your glucose readings from moment to moment, day to day, or over the course of several weeks or months.

Note: If you select a report and no data is displayed, check that glucose data has been previously uploaded for the selected date range. If data is still not displayed, contact customer support.

Filter, Print, or Email what is displayed in the reports

On the top right of report pages are options for changing report preferences, printing the report, and emailing the report.



Click			
To	**Change Report Filters**	**Email Report**	**Save Report as PDF**
How	Make selections for choosing which event types, days of the week, and other options will appear in reports, when applicable. This filter is not available for the AGP, Time in Range by Time of Day, or Time in Target reports. 	Follow pop-up window prompts for emailing a printer-friendly report to a designated recipient. 	Click the icon to convert your report into a PDF that allows you to print the report at home.

Time in Target

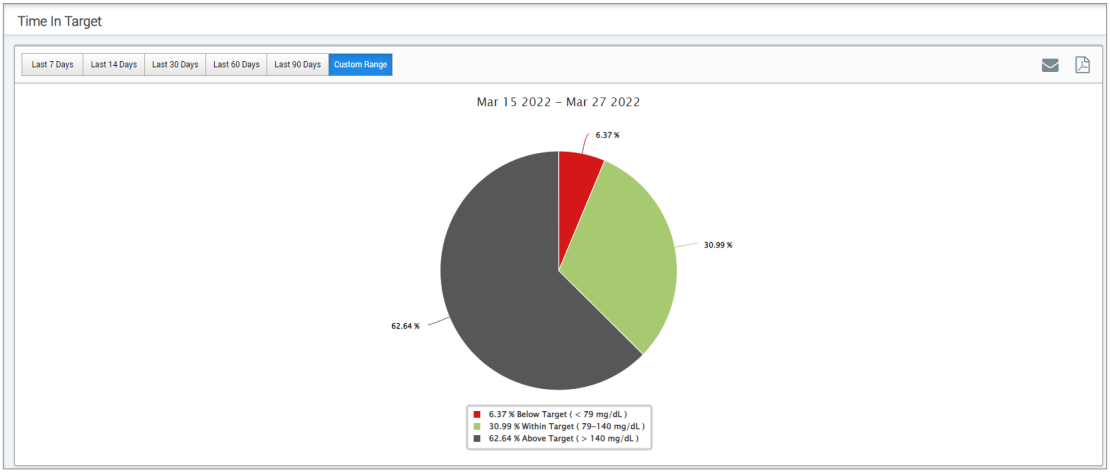
The Time in Target report shows a pie chart that analyses the percentage of time your glucose is below, within, or above the target range you set in your Glucose Settings.

Viewing the report:

The green wedge represents the percentage of time you spent within your target range.

The grey wedge represents the percentage of time you spent above your target range.

The red wedge represents the percentage of time you spent below your target range.



Time in Range

Time in Range by Time of Day

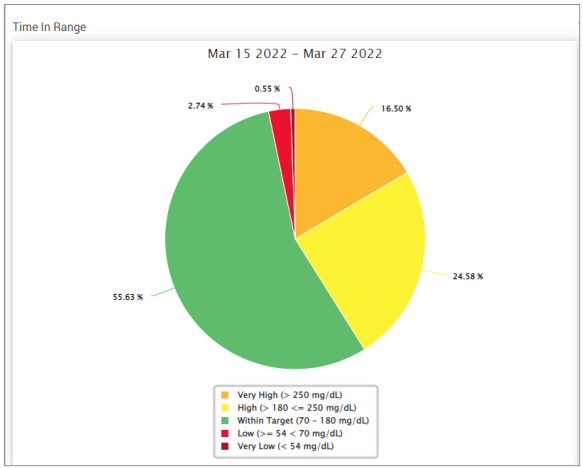
The Time in Range by Time of Day report shows a set of bar charts that analyse the percentage of time your glucose is within preset glucose ranges.

- Very Low: < 54 mg/dL
- Low: 54-70 mg/dL
- Within Range: 70-180 mg/dL
- High: 180-250 mg/dL
- Very High: > 250 mg/dL

There are two sections of this report:

Time in Range

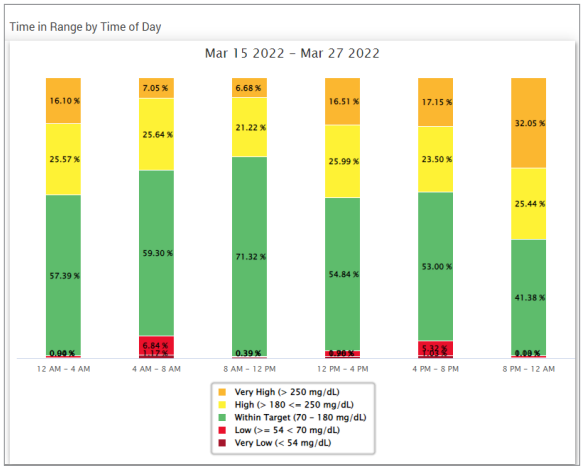
This displays your overall percentage of time spent in the preset glucose ranges, based on the date range you have selected.



Time in Range by Time of Day

This section of the report breaks out the overall Time in Range chart into various segmented times of day. You can view your data in segments of 4 hours, 6 hours, or 8 hours. This is adjusted by selecting an option in the top right of the report.

Each segment shows a percentage of time your glucose was within those same segments of Very Low, Low, Within Range, High, and Very High.



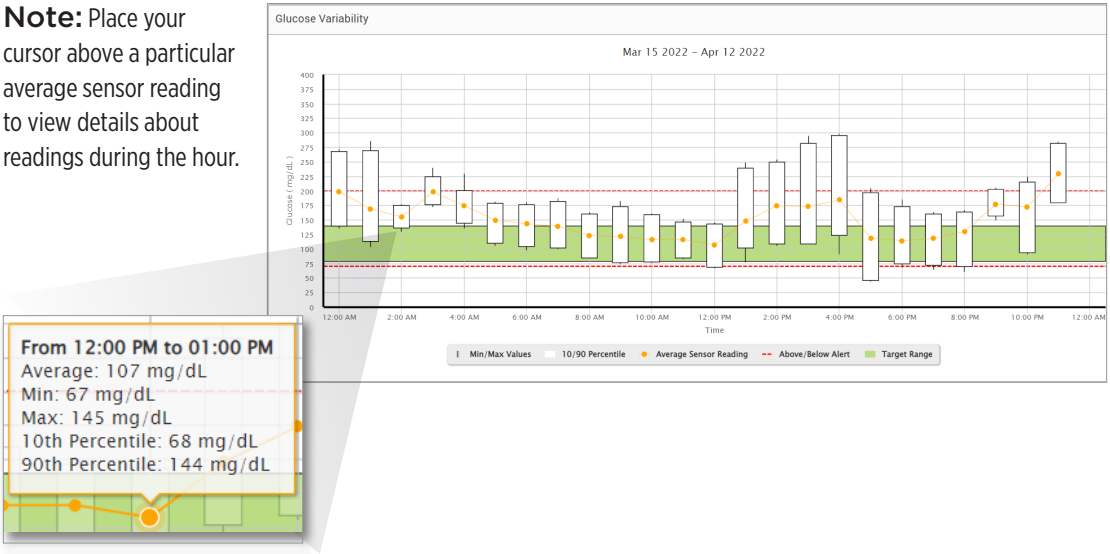
Glucose Variability Report

The Glucose Variability Report displays information in two ways:

The Trend Graph:

- Displays summary glucose readings over a 24-hour period.
- Includes multiple days of data overlaid on the same graph.
- Shows the maximum, minimum, and average glucose reading for every hour.
- Provides a visual snapshot of variations in your daily glucose levels.

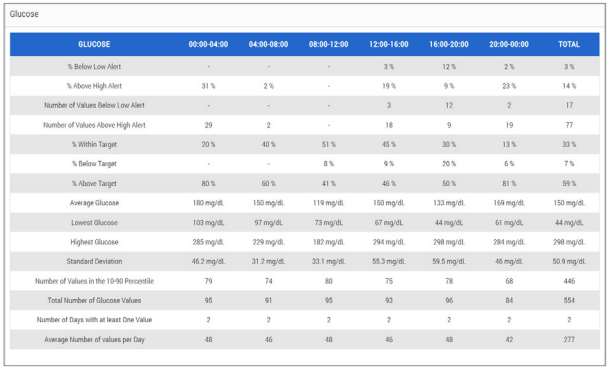
Note: Place your cursor above a particular average sensor reading to view details about readings during the hour.



The Table:

- Organises glucose data by 4-hour time period.
- Provides a detailed statistical analysis for each period.
- Includes the percentage of readings that are within, above, and below the glucose target range.
- Provides a breakdown of insulin usage and carbs entered for those same time periods.

Note: If you are having trouble displaying the report, try limiting your date range. Unusually large amounts of data may not allow the report to function.



Glucose

GLUCOSE	00:00-04:00	04:00-08:00	08:00-12:00	12:00-16:00	16:00-20:00	20:00-00:00	TOTAL
% Below Low Alert	-	-	-	3 %	12 %	2 %	3 %
% Above High Alert	31 %	2 %	-	19 %	9 %	23 %	14 %
Number of Values Below Low Alert	-	-	-	3	12	2	17
Number of Values Above High Alert	29	2	-	18	9	19	77
% Within Target	20 %	40 %	51 %	45 %	30 %	13 %	33 %
% Below Target	-	-	8 %	9 %	20 %	6 %	7 %
% Above Target	80 %	60 %	41 %	46 %	50 %	81 %	59 %
Average Glucose	180 mg/dL	150 mg/dL	119 mg/dL	150 mg/dL	133 mg/dL	169 mg/dL	150 mg/dL
Lowest Glucose	103 mg/dL	97 mg/dL	73 mg/dL	67 mg/dL	44 mg/dL	61 mg/dL	44 mg/dL
Highest Glucose	285 mg/dL	229 mg/dL	182 mg/dL	294 mg/dL	298 mg/dL	284 mg/dL	298 mg/dL
Standard Deviation	46.2 mg/dL	31.2 mg/dL	33.1 mg/dL	55.3 mg/dL	59.5 mg/dL	46 mg/dL	50.9 mg/dL
Number of Values in the 10-90 Percentile	79	74	80	75	78	68	446
Total Number of Glucose Values	95	91	95	93	96	84	554
Number of Days with at least One Value	2	2	2	2	2	2	2
Average Number of values per Day	48	46	48	46	48	42	277

Running the report

1. Select **Reports > Glucose Variability**

   The displayed date range will be the last week of data entered or uploaded.

2. **Select the date range**

   Note: To change the date range for the report, follow the previous *Setting Date Range instructions* in the *Dashboard* section of this user guide.

Glucose Trend Report

The Glucose Trend Report:

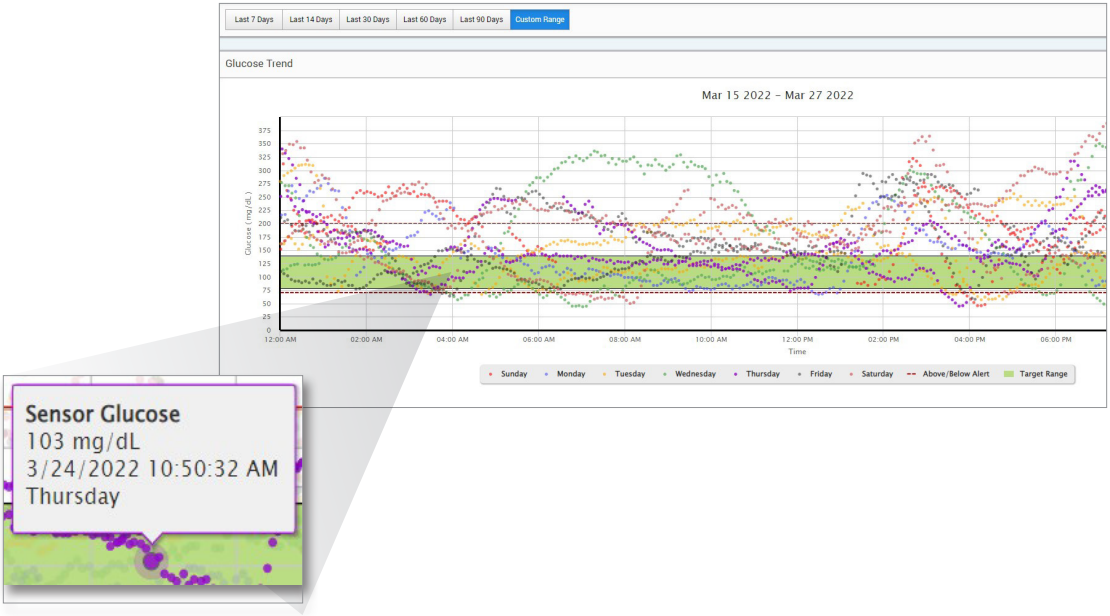
- Displays individual glucose readings over a 24-hour period.
- Displays multiple days of data overlaid on the same graph.
- Provides an easy way to identify variability among the days of the week.

Running the report

1. Select **Reports > Glucose Trend**
2. Select the date range

Viewing the report

Data points in the report are colour-coded with each day of the week displayed in a different colour. You can use the report filter to choose the day/s you want to display on the graph.



Note: Place your cursor above a particular sensor glucose reading to view details about that reading.

Glucose History Report

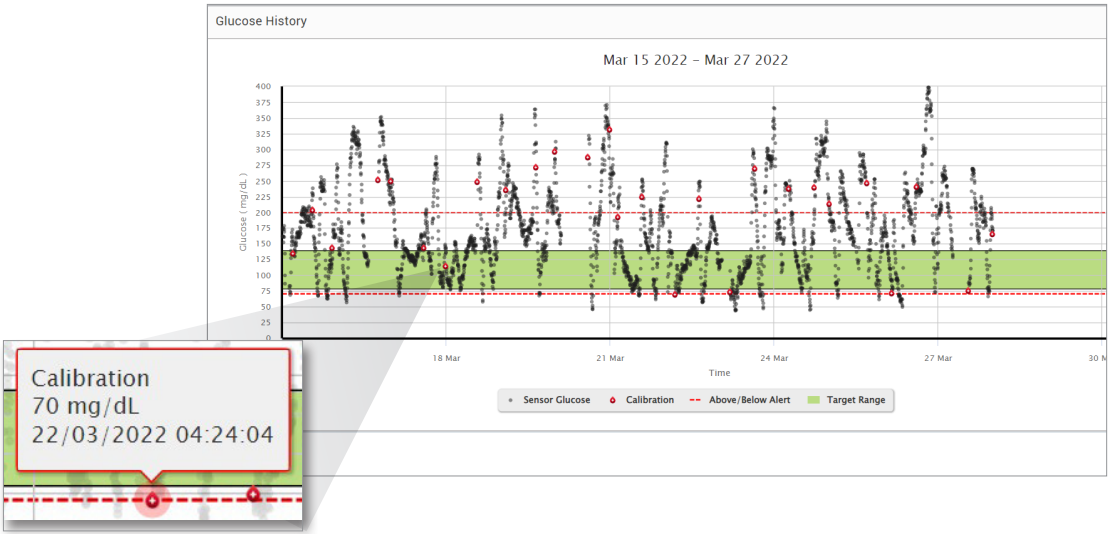
The Glucose History Report displays historical CGM and manually entered data in the form of a trend graph. The Glucose History Report provides an efficient way to track sensor glucose readings and calibrations.

Running the report

1. Select **Reports > Glucose History Report**
2. Select the date range

Viewing the report

Each data point is a sensor glucose reading. The events that were logged in the mobile app are displayed in the report at the time they were logged. If you select a date range of more than 30 days, events such as meals, insulin, etc. are not displayed.



Note: Place your cursor above a particular sensor glucose reading to view details about that reading. You may also place your cursor above an event icon to view details about that event.

Daily Glucose Report

The daily glucose report displays glucose readings over a 24-hour period for multiple days in a sequence.

The Daily Glucose Report:

- Has a fixed glucose target range of 70-180 mg/dL.
- Shows high and low glucose alert levels (red lines) that you have set in your CGM system.
- Shows key statistics for each day based upon glucose target and alert settings.
- Includes an option to display event icons on the trend graph, and to expand a table of events for each day.

Running the report

1. Select **Reports > Daily Glucose Reports**
2. **Select the date range**

Viewing the report

The Daily Glucose Report displays multiple days in sequence for the date range selected, and provides a way to identify glucose patterns across multiple days. Statistics for each day appear to the right of the trend graph and are based on the standard glucose target range of 70-180 mg/dL and the high and glucose alert levels set by you. To review additional CGM information for each day (alerts, calibrations, events you entered into the CGM app), you can turn on the display of event icons on the trend graph and expand the event table beneath the trend graph to display more information. When expanded, the event table lists information in 4-hour increments aligned with the 4-hour segments in the trend graph.



Note: When multiple events are recorded in a single cell in the events table, hovering over the cell will display more information.

Glucose Distribution Report

The Glucose Distribution Report:

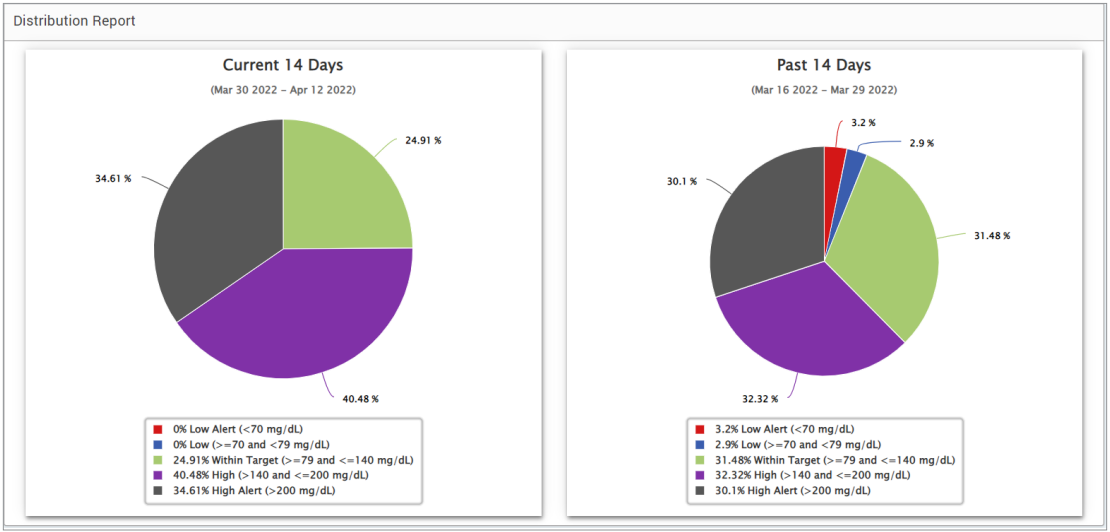
- Organises your glucose data according to your glucose targets and alert ranges and displays the data in pie chart format.
- Displays separate pie charts for the current and previous periods.
- Target ranges are set under Glucose Settings.
- Provides a visual check for the number of readings within target during the predefined range selected and a change over time.

Running the report

1. Select **Reports > Glucose Distribution Report**
2. **Select the date range**

Viewing the report

The Glucose Distribution Report will display two pie charts based on the predefined date range you select. It will show the current and previous set of data for the date range selected. This data allows you to see a comparison of current to past changes in your management.



Transmitter Log Report

The Transmitter Log Report provides a comprehensive data review over the selected date range.

The Transmitter Log Report displays three separate tables:

- **Blood Glucose:** This displays a list view of all manually entered blood glucose and related events in chronological order.
- **Event Entries:** This displays patient events entered through the Eversense Mobile App.
- **Sensor Glucose:** This displays glucose values picked up by the sensor.

Running the report

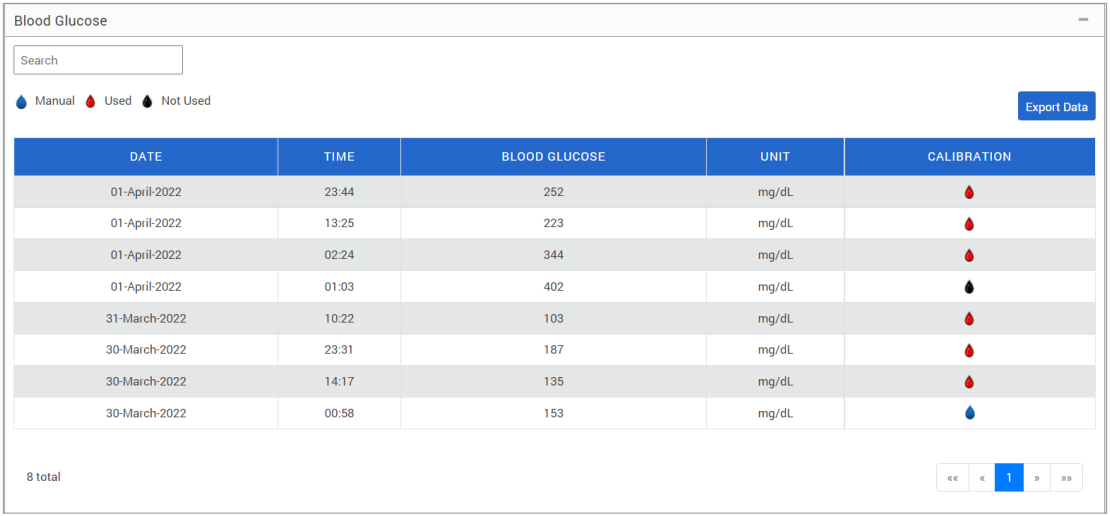
1. Select **Reports > Transmitter Log**
2. Select the date range

Viewing the report

Events are displayed with information regarding Date, Time, and:

- **Blood Glucose:** Glucose Value, Unit, Calibration
- **Event Entries:** Event Type, Event Sub Type, Value
- **Sensor Glucose:** Glucose Value, Unit, Sensor ID

Events can be sorted in ascending or descending order by clicking the column header. The number of records is indicated at the bottom of each log.



A symbol under the "**Calibration**" column of the Blood Glucose table will indicate whether a glucose value was Used for calibration, Not Used, or Manual.

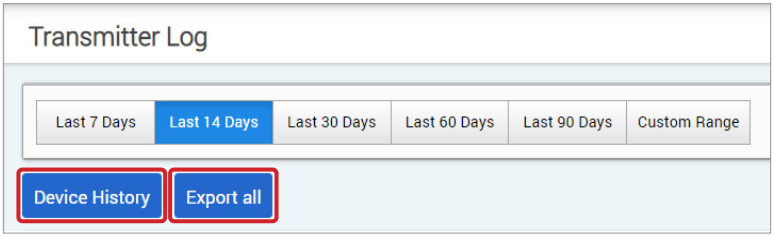
- **Used:** A blood glucose value that you entered as a calibration and is accepted by the system.
- **Not used:** A calibration that you enter that is over 400 mg/dL or below 40 mg/dL.
- **Manual:** A blood glucose event not entered as a calibration.

Selecting "**Device History**" will show when the sensor was inserted, as well as the calibration start date.

Exporting Data

From the Transmitter Log Report page, you can also export data in a .xlsx format.

1. Select **Reports > Transmitter Log**
2. **Select "Export all" at the top of the page to export all of the Transmitter Log data as an .xlsx (Excel Spreadsheet)**



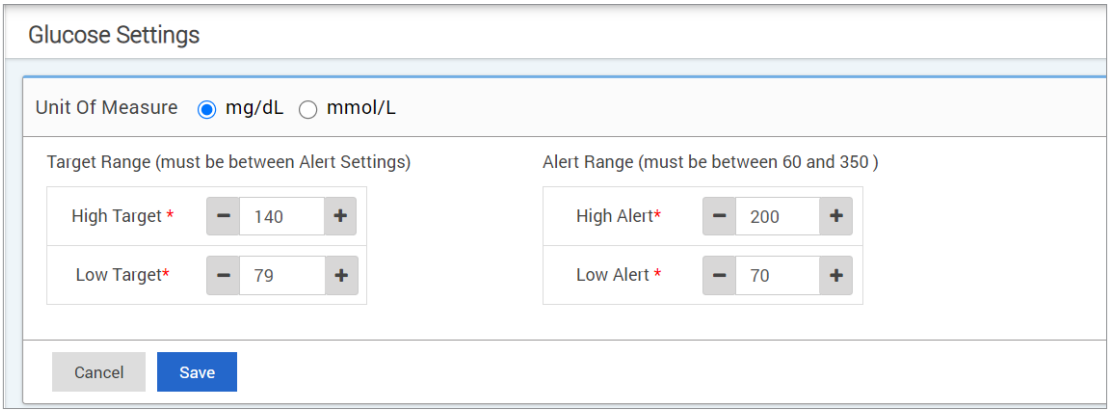
Settings

Glucose

Glucose settings allow you to customise your glucose target and alert levels. This setting impacts how glucose and other event data are organised and displayed in reports. When you wirelessly sync your data via the Share My Data feature on the mobile app, the glucose settings you have saved on the app will also be synced to your DMS account.

Note:

- Glucose settings DO NOT get synced when data is uploaded from the smart transmitter via the USB Cable with the Eversense Client Application.
- Changing the settings in the DMS will NOT change the settings you have entered on the Eversense mobile app. You can only change the settings for your Eversense CGM System directly on the Eversense CGM mobile app.



To change the settings in your Eversense DMS account, follow the steps below:

1. Select **Settings > Glucose**
2. **Click the mg/dL or mmol/L button below the Units Of Measure to select the desired unit of measure for displaying glucose data**

   If you change the unit of measure, the glucose range and alert range values will change accordingly.
3. **Click the -/+ buttons to the right of the High Target and Low Target to display and adjust the high and low limits of your glucose Target Range**
4. **Repeat for the glucose Alert Range**
5. **When you have finished making changes, click "Save" to save your changes**

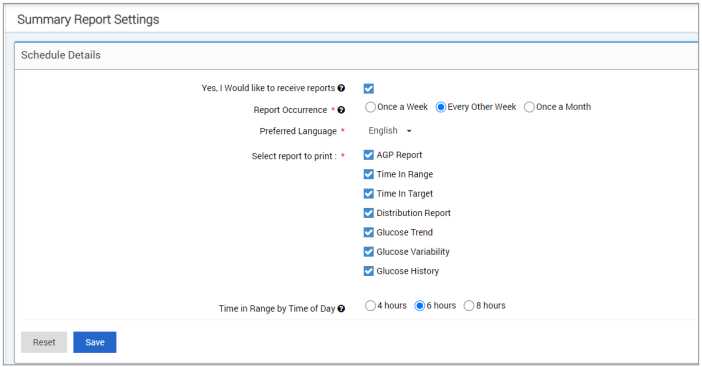
Note: Eversense DMS settings do not affect the Eversense CGM System settings and only impact how the data is organised and displayed on the Eversense DMS display.

Report Summary

Report Summary settings allow you to set up a regularly scheduled automated report to be emailed to you. You can select how often you will receive the reports, and which reports you want to receive.

Note:

- You will receive the reports as PDFs attached to the email.
- The email will be sent to the email address used to create your Eversense account.



To change the settings in your Eversense DMS account, follow the steps below:

1. Select **Settings > Report Summary**
2. **Click the box next to "Yes, I would like to receive reports" so that a check mark is displayed**
3. **Choose how often you want to receive the report to your email**
   - **Once a week:** You will receive the report every Sunday. The reports will display the data that your Eversense CGM System calculated during the previous week.
   - **Every Other Week:** You will receive the report every other Sunday. The reports will display the data that your Eversense CGM System calculated during the previous 2 weeks.
   - **Once a Month:** You will receive the report every first day of the month. The reports will display the data that your Eversense CGM System calculated during the previous month.

4. **Select which language you would like the reports to be displayed in**

5. **Select which reports you would like to receive**

Note:

- The reports will be sent as a PDF attachment in the email you will receive.
- If you select the Time in Range report, you will also need to select the Time of Day setting as well. For more information on the Time in Range by Time of Day report, see *Reports*.

6. **Click "Save"**

   Once this setting is saved, you will receive your first email on the first day of the next cycle. If you select Once a Week or Every Other Week, you will receive your first report on the next upcoming Sunday. If you select Once a Month, you will receive your first report on the first day of the following month.

To stop receiving the Report Summary emails:

1. Select **Settings > Report Summary**

2. **Click the box next to "Yes, I would like to receive reports" so that there is no check mark displayed in the box**

3. **Click "Save" at the bottom of the page**

Note: If you did not sync any data to your Eversense account from your Eversense CGM system for one whole report period, you will receive an email notification letting you know that you will not receive any more emails until data is synced to your account again.

Transmitter

Upload Device Data

Your CGM data can be uploaded to your DMS account wirelessly or by using the USB cable that came with your Eversense CGM System:

1. **If you have Auto Sync turned on in the Eversense mobile app, your CGM data will be automatically uploaded every 5 minutes to your DMS account.**

   Tip: A wireless internet connection from your mobile device is required to sync your data via the Eversense mobile app.

   Note: You may manually upload data by going to Share My Data in the Eversense mobile app and tapping Start Sync to wirelessly upload your CGM data to your DMS account.

2. **You can also upload smart transmitter data via the USB cable provided with the Eversense CGM System. In order to upload the smart transmitter data using the USB cable, you must first download and install the Eversense Client Application.**

   Note: During the upload process, your smart transmitter will not be collecting data from the sensor.

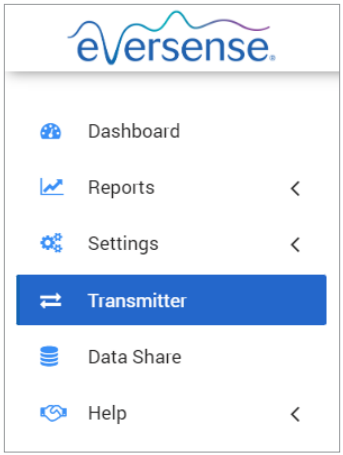
To download and install the Eversense Client Application:

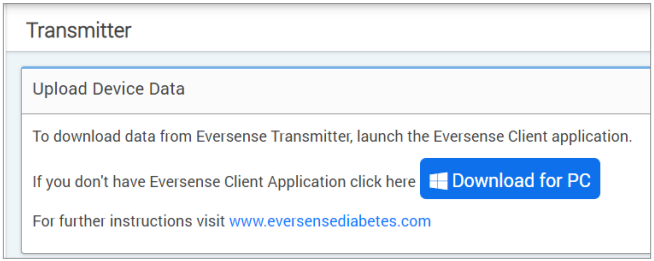
1. Select **Transmitter** from the navigation menu

2. Click **Download for PC** or **Download for Mac**

   The appropriate button will display depending on the computer system you are using.

   Note: Upon successful download, you may see a warning from your browser that says the installation software is not commonly downloaded and could be dangerous. Eversense DMS **does not** contain malware or computer viruses that might harm your computer.





To download the Eversense Client Application for PC Users:

1. Run the installation software

You may also click "**Save**" to save the software on your desktop and install it at a later time. When you run the software, follow the prompts from the InstallShield Wizard.

For Chrome users:



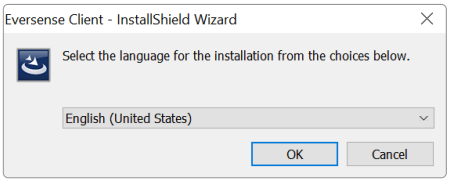
For Internet Explorer and other browser users:



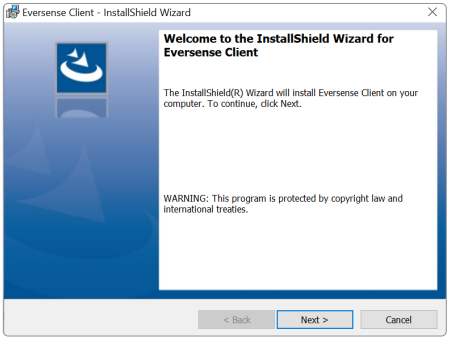
Note: The Eversense Client Application is downloaded directly from Eversense DMS. A pop-up may be displayed that asks if you want to install this application because it is not downloaded from the Microsoft store. Please click "**Run Anyway**" to continue the installation.

2. Click through the default options to install the software

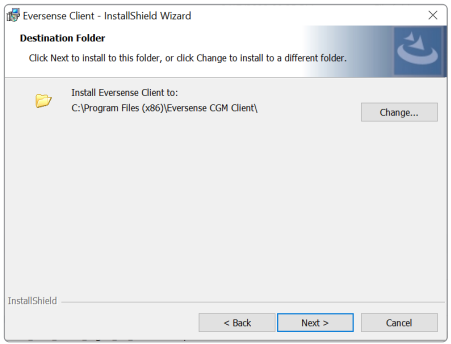
a.



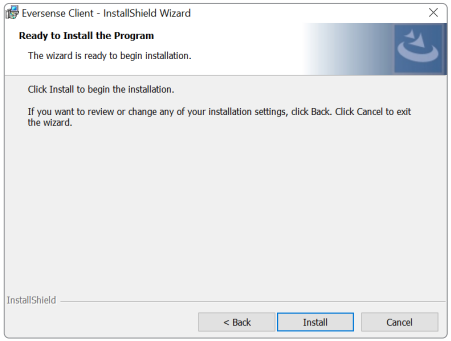
b.



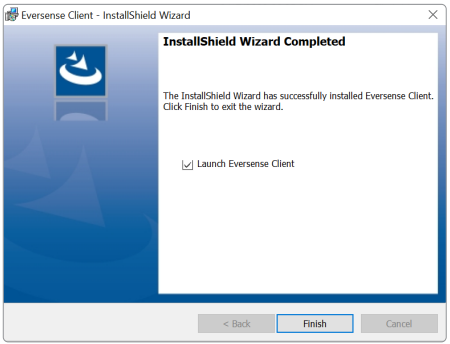
c.



d.



e.


Eversense Client - InstallShield Wizard
InstallShield Wizard Completed
The InstallShield Wizard has successfully installed Eversense Client. Click Finish to exit the wizard.
Launch Eversense Client
< Back
Finish
Cancel

To download the Eversense Client Application for Mac Users:

1. Run the installation software
2. Drag and drop the Eversense Client icon into the application folder on the screen



3. Open The Eversense Client Application in your Mac's Applications folder.



IMPORTANT: THE EVERSENSE CLIENT APPLICATION IS DOWNLOADED DIRECTLY FROM EVERSENSE DMS. WHEN YOU GO TO OPEN THE APPLICATION, YOU MAY GET A POP-UP THAT APPLE CANNOT OPEN THIS APPLICATION. THE EVERSENSE CLIENT APPLICATION DOES NOT CONTAIN ANY MALWARE.

To open the application, you will need to:

1. Go to **System Preferences > Security and Privacy**
2. Click on **"Open Anyway"** next to **"Eversense Client was blocked from use because it is not from an identified developer"**
3. Click **"Open"** on the next pop-up

To upload smart transmitter data to your DMS account:

1. Launch the Eversense Client Application by opening the **Start menu** > **All Programs** > open **Eversense** folder > open **Eversense Client** folder > Click the icon

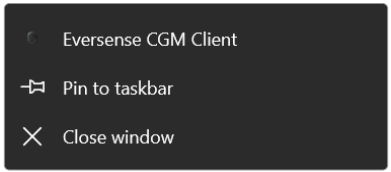


2. Click on **"Upload My Transmitter Data"** then enter the email you used to create your account and password

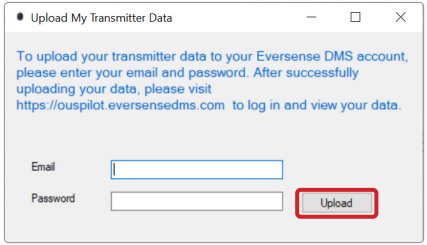
Connect your smart transmitter to your computer using the USB cable.

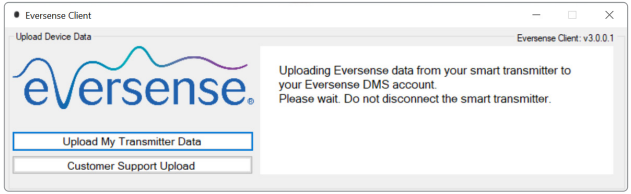


Tip: For PC users to quickly launch the program using Windows operating systems, right click on the **Eversense Client icon** and pin it to the **Taskbar** or **Start** Menu.

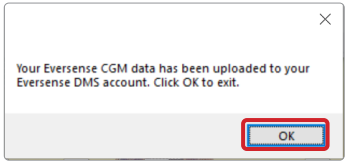


3. When prompted, click "**Upload**" to start uploading your smart transmitter data to your account

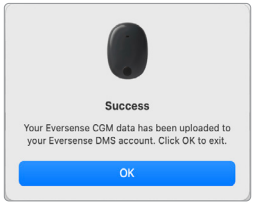




4. Click "**OK**" to continue



(PC)



(Mac)

Note: When contacting Customer Support for technical assistance, you may be asked to upload the diagnostic log. This will be used to send a diagnostic log file from your smart transmitter to Customer Support. This function will only be used for advanced troubleshooting with the assistance of customer support.



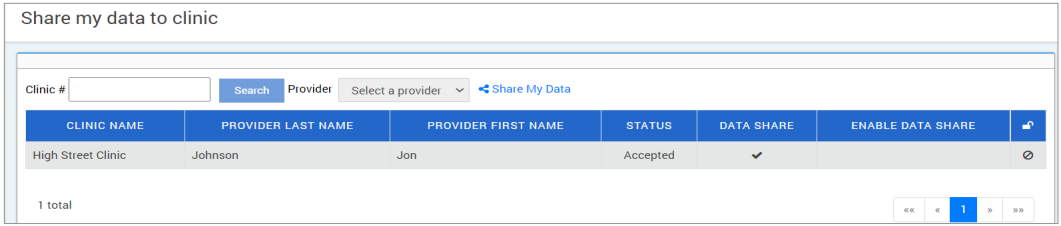
Data Share

DMS Pro

You can connect your Eversense DMS account to your physician's Eversense DMS Pro account to view and analyse your DMS reports.

Inviting your clinic

To link your Eversense DMS account to your clinic's Eversense DMS Pro account:



1. **Type in your clinic's Eversense DMS Pro clinic number and press the ENTER button on your keyboard.**

Note: Contact your clinic if you do not know your clinic's Eversense DMS Pro number.

2. **Select your provider from the Provider drop-down list.**

3. **Click "Share My Data"**

   The Clinic Name, Provider Name, Status, and Data Share will be displayed. The status will display **Pending** until your clinic accepts your invitation.

   Once your clinic accepts your invitation, **Pending** will change to **Accepted**, and the ✖ will change to ✔ in the Data Share column.

   Your provider will now be able to view your data from their Eversense DMS Pro account.

Invitation from your clinic

Your clinic may invite you to share your data with their Eversense DMS Pro account.

You will receive an email from **DMS.Feedback@senseonics.com**.

Click the link in the email to share your reports.

Once you click the link, your account will be added to your clinic's Eversense DMS Pro account.

Removing your clinic

To remove access to your data from a clinic, click the  at the end of their row. You can remove access for a clinic that you have invited but has not accepted yet, or a clinic who already has access to view your data.

To allow them to view your data, you will need to click  to give them access to your data.

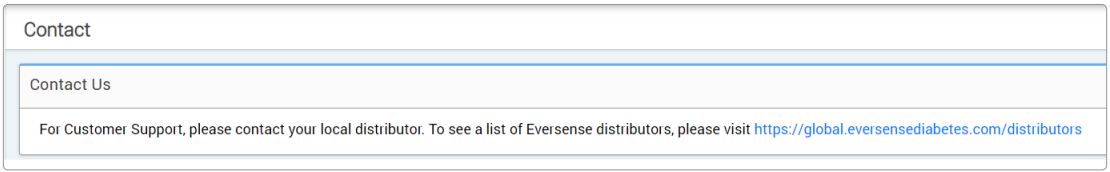
Help

About

This page shows the most up-to-date versions of the Eversense DMS and Eversense Client Application.

Contact Us

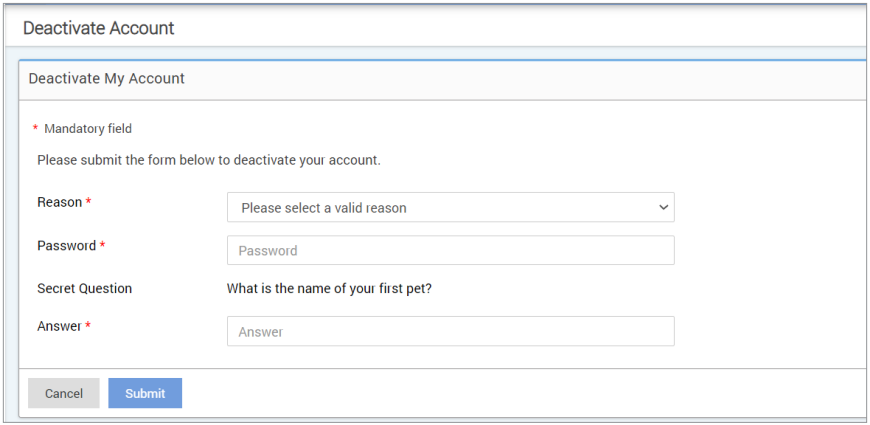
Customer Support contact information.



IMPORTANT: For questions about your Eversense CGM System, contact your local distributor. In the U.S. call 844-SENSE4U (844-736-7348).

Deactivate My Account

IMPORTANT: Deactivating your Eversense DMS account will deactivate your account for ALL Eversense products.



Release Notes

Provides an overview of recent updates to the Eversense DMS software.

Note: When there is an update to the Eversense DMS software, a banner across the top of the site will be displayed. Click on the banner to view the list of updates.

22. Eversense NOW

Remote Monitoring with Eversense CGM System and Eversense NOW App

The Eversense CGM App includes an optional remote monitoring feature. This feature allows Eversense CGM data to be viewed on a secondary display via the Eversense NOW mobile app.

Intended Use

The Eversense NOW App is intended to be used as a secondary display to view glucose data and alerts from Eversense CGM users.

Contraindications

Follow clinic and other institution guidelines for using your mobile device in the presence of MRIs, CT scans and other procedure equipment.

Risks

There may be times when glucose data cannot be sent to the Eversense NOW App. If you are not receiving glucose data from the Eversense CGM user, you cannot assist them in the event of a high or low glucose value. The remote monitoring feature provides a secondary display of data. It is not a real-time remote monitoring system.

Eversense CGM users may not always have a connection to support data transfer such as internet/wifi or 3G/4G/LTE. If you do not or the Eversense CGM user does not have an internet connection, their glucose data will not be available for you to view. Any problems with mobile devices, wireless Internet, data connection, the Eversense Data Management System (DMS), the CGM user's smart transmitter out of range of their mobile device, or charging their smart transmitter may cause data not to be displayed. The Eversense user should not rely on you monitoring their glucose data to assist them in the event of a high or low glucose event. Additional safety information is available at **https://ec.europa.eu/tools/eudamed**.

Benefits

The Eversense CGM System used with the Eversense NOW Remote Monitoring App may provide CGM users with additional confidence, knowing that others can also view their CGM data.

Warnings:

- **Glucose information displayed on the Eversense NOW App should not be used to make treatment decisions. The Eversense NOW App is a secondary display of Eversense CGM data and should not be used in place of the primary Eversense CGM display. Eversense CGM users should always use blood glucose values from their meter to make treatment decisions. Using a sensor glucose value to make a treatment decision could result in a high or low blood glucose.**
- **Eversense CGM users should not rely on those who are remotely monitoring the glucose readings to notify them about high or low glucose events.**

Cautions:

- The Eversense NOW Remote mobile app does not replace the monitoring regimen as directed by a healthcare provider.
- If an Eversense CGM user does not have Auto Sync (the feature that enables data to automatically be sent to your Eversense NOW App) turned on, you may not see high or low glucose trends and events.
- If you and the Eversense CGM users do not have an internet connection, or the CGM user's mobile device has shut down due to a low or empty battery, their Eversense CGM data cannot be displayed on the Eversense NOW App.
- If you turn off the sounds on your mobile device, you will not receive audible alerts about the CGM data you are remotely monitoring on your Eversense NOW App.
- If a CGM user sets their status to Offline, you will not receive any of their CGM data on your Eversense NOW App.
- The Eversense NOW App does not communicate directly with the Eversense Sensor and/or with the Eversense Smart Transmitter.
- The Eversense NOW App cannot change the settings on the Eversense CGM App.
- If you do not allow notifications from the Eversense NOW App, you will not receive glucose-related alerts from Eversense CGM users.
- If you have your mobile device set to Do Not Disturb, you will not hear any notifications from the Eversense NOW App.

Using the Eversense NOW App

This User Guide instructs how to use the Eversense NOW App for remote glucose monitoring of Eversense CGM System users.

Thank you for downloading the Eversense NOW mobile app. Eversense NOW allows you to remotely monitor glucose data from Eversense CGM System users.

Caution: **The Eversense NOW Remote Monitoring App does not replace the primary display on the Eversense CGM System App, or the monitoring regimen as directed by a healthcare provider.**

System Requirements

- The Eversense NOW App downloaded to your mobile device from the Apple® App Store.
- A compatible Android device or Apple® iPhone® or iPod® or iPad®.
- For a list of compatible devices and operating systems, please go to **http://global.eversensediabetes.com/compatibility**.

Note: A wireless internet connection is required to download the app and to receive remote glucose values for display on your Eversense NOW App. If the Eversense CGM user has turned off Auto Sync, no glucose values will be displayed on your Eversense NOW App.

End User Licence Agreement and Privacy Policy

Use of the Eversense NOW App is subject to the terms and conditions of the most current Eversense NOW End User Licence Agreement and Eversense NOW App Privacy Policy. These documents are updated periodically, and are posted at **global.eversensediabetes.com**.

Jailbroken Devices

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

Help and Support

If you do not understand something in this section, contact Customer Support (toll-free in the US) at 844-SENSE4U (844-736-7348). Outside of the US, call your local distributor or visit: **global.eversensediabetes.com** to locate your local distributor. To access the latest version of the Eversense NOW Instructions for use, please visit: **https://global.eversensediabetes.com/patient-education/eversense-user-guides.**

Joining an Eversense Circle

The Eversense Circle refers to the group of people able to remotely monitor the glucose data and glucose-related alerts of an Eversense CGM user. To join the Circle, you will need to accept the email invitation you receive from the Eversense CGM user, create an account on the Eversense DMS website and download the Eversense NOW mobile app.

The Eversense DMS Program is a web-based application that is compatible with the Eversense CGM System to display historical glucose data and reports to help identify glucose trends as an aid to diabetes management. The Eversense DMS Program also allows you to create an account so you can remotely view glucose data using your Eversense NOW App. You cannot remotely view glucose data through the Eversense DMS program. To learn more about the Eversense DMS Program, go to **www.eversensediabetes.com**.

Accepting an Invitation to Join an Eversense Circle

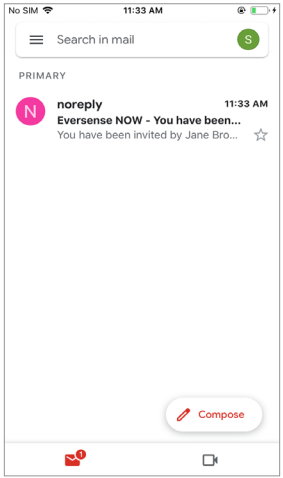
An Eversense Circle is the group of people an Eversense CGM user has invited to view their glucose data and alerts remotely.

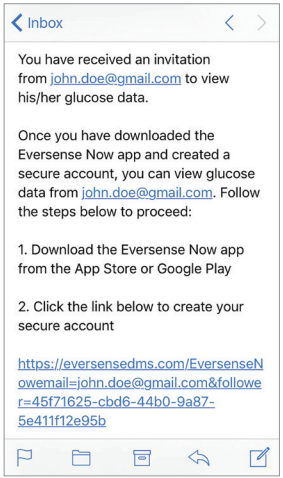
1. **You will receive an email invitation, "Request to view glucose data", to join an Eversense CGM user's Circle.**

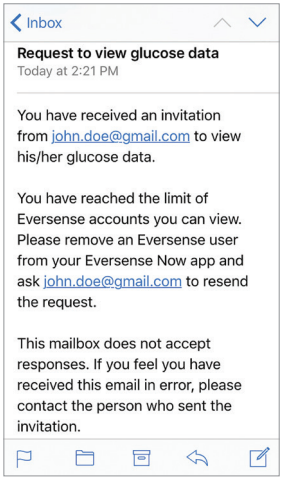
Note: If you are expecting an invitation and do not see it in your Inbox, check your Spam or Junk folders.

2. **Click the link in the email.**

3. **Log in to your Eversense account.**







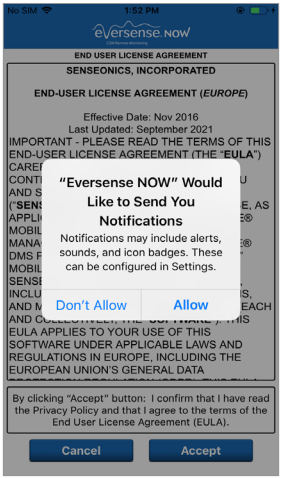
Note: The Eversense NOW App lets you join a maximum of 10 Eversense Circles. If you are invited to join an 11th Circle you will receive an email asking you to remove yourself from an existing Circle before being added to a new one.

Download the Eversense NOW App

1. Go to the Apple App Store and search for "**Eversense NOW**".
2. Tap the **Eversense NOW** icon, download and install the app to your smart device.
3. When prompted, tap "**Allow**" in order to receive glucose-related alerts from the Eversense CGM users on your list.

Caution: If you do not allow notifications from the Eversense NOW App, you will not receive glucose-related alerts from Eversense CGM users.







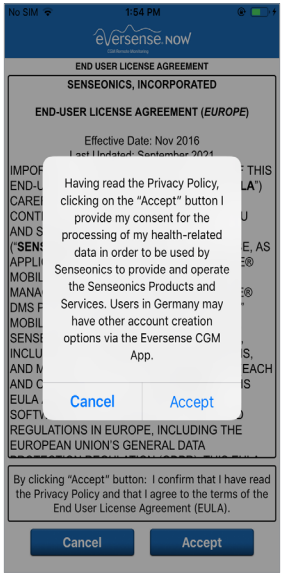
4. The full version of the END USER LICENCE AGREEMENT is displayed. Review and Accept. An overview of the End User Licence Agreement is then displayed.
   - Confirm and tap **Accept**.

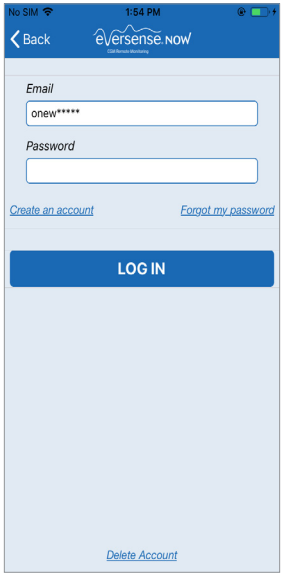
5. Create an Eversense account to log in to the app.

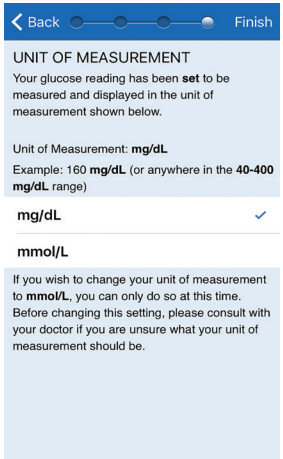
Note: If you already have an Eversense account, you do not have to create a new one to use Eversense NOW. Click the link in the email invitation and sign into your existing Eversense account. When you refresh the Home Page in your Eversense NOW App, you will see the name of the CGM user whose invitation you accepted. If you want to delete an account that you have already created, contact Customer Support.

Note: 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 remotely monitor Eversense CGM users' data.

6. Choose the unit of measure. The unit of measure you choose will apply to all of the Eversense CGM users whose data you can view. You cannot change the unit of measure once the app is installed.







To Remove an Eversense CGM User from your List

Removing an Eversense CGM user from your list means you will no longer be able to remotely monitor their glucose data. To add a user back to your list, contact the Eversense CGM user to send you a new invitation.

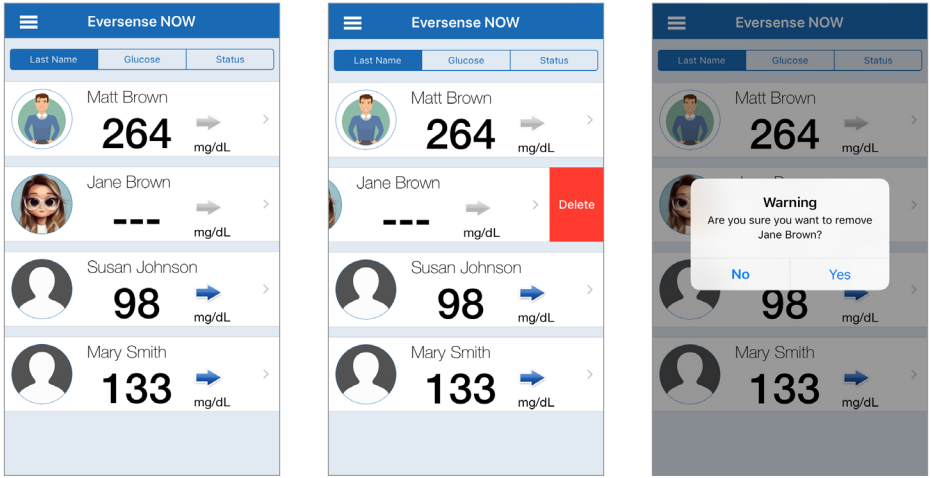
1. **Swipe the Eversense CGM System user's name on the Home Page to the left.**

2. **Tap "Delete".**

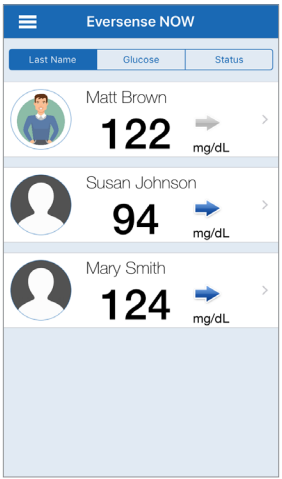
   A warning will ask you to confirm you want to remove the Eversense CGM user.

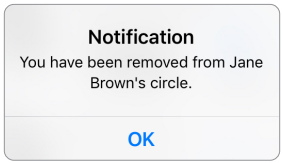
3. **Tap "Yes" to permanently remove this person from your list.**

   The Home Page will no longer show the user in your list.



Note: It can take up to 2 hours for the Eversense CGM user to see that you are no longer in their Circle on their Eversense CGM App.



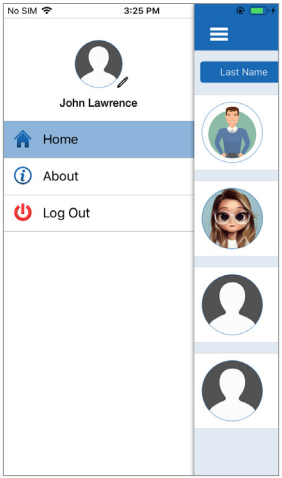


Note: An Eversense CGM user may also remove you from their Circle. If this happens, this notification will appear.

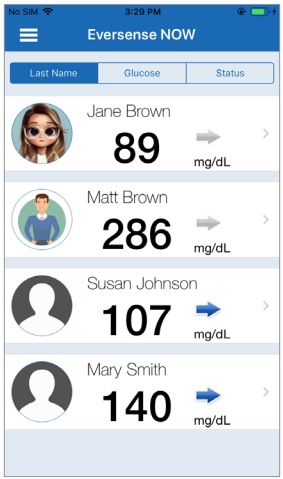
Main Menu

Main Menu displays access to the Eversense NOW Home page, About page, and the log out page.

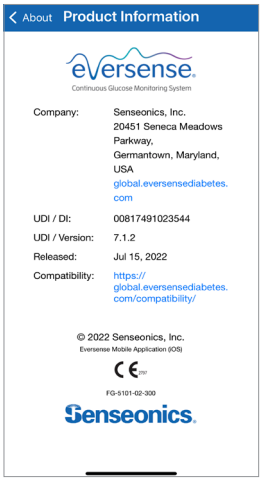
From the Main Menu, you can access the Home page to see the Eversense CGM users on your list, review information about the Eversense NOW App on the About page, log out of the app, or add a profile picture.



To access the Main Menu, tap the 3 bars icon in the top left of the screen.

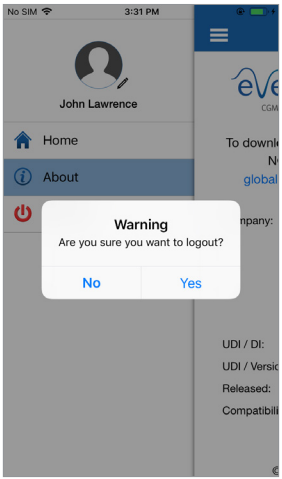


Home



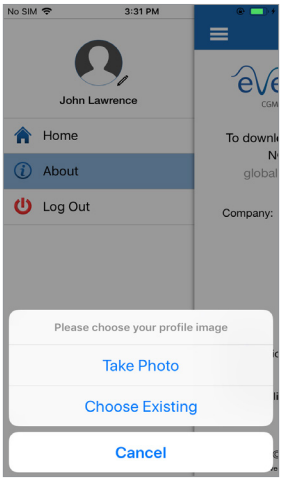
About

Eversense NOW will ask you to confirm before logging out. If you log out of the app, you will need to enter your username and password to re-open the app.



Log Out

You can add your profile picture by tapping on the profile photo in the Main Menu of the Eversense NOW App. Follow the prompts to take or add a picture that is saved on your mobile device. The profile picture you add will also be displayed on the CGM user's app next to your name.



Profile Pictures

Viewing CGM Data

The Home Page displays the list of people whose CGM data you can view remotely, along with their most recent CGM value, and a trend arrow indicating direction and rate of change.

The list is sorted by Last Name as the default option. You can sort the list by Last Name, Glucose Value, or Status by clicking the desired tab at the top of the page.

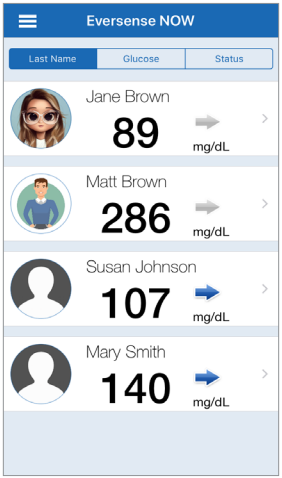
Eversense NOW Home Page

To Refresh the Home Page:

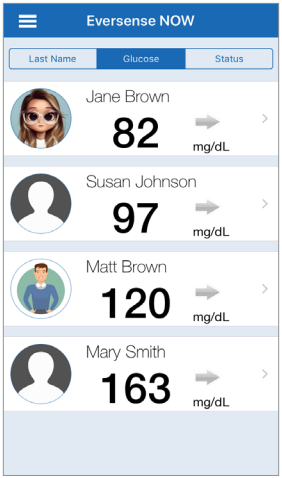
1. Open the **Home Page**.
2. Swipe down from inside the Home Page ***(if using an iOS device, when you swipe from the very top of the screen, it opens your iOS widgets instead of refreshing the Home Page).***

   Glucose data from the CGM user is automatically refreshed on your Eversense NOW App about every 5 minutes when you and the CGM user have an internet connection.

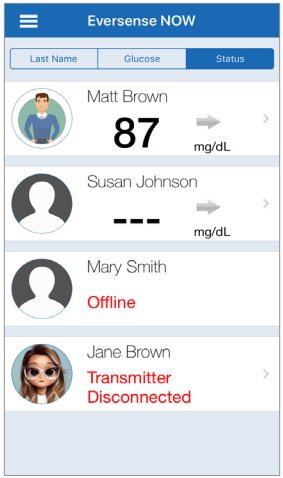
Caution: **If the Eversense CGM user has turned off Auto Sync, no glucose data will be automatically sent to your Eversense NOW App.**



Home Page sorted by Last Name



Home Page sorted by Glucose Value



Home Page sorted by Status

Trend Arrows

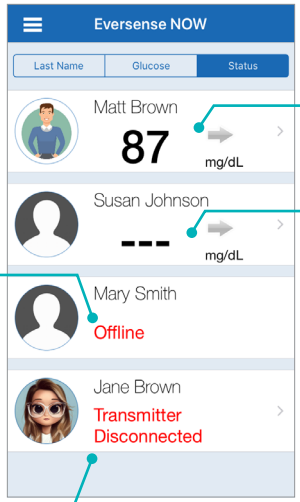
Next to the Eversense CGM user's name you will see a trend arrow. The trend arrow shows the current direction the glucose is going and how fast the glucose trend is changing.

The app uses the **last 20 minutes of continuous glucose data** for calculating glucose trends. When there are not enough sensor values available to calculate a trend arrow, it is not displayed and the glucose value is grey instead of black.

	Gradually rising or falling glucose levels, falling or rising at a rate between 0.0 mg/dL and 1.0 mg/dL per minute.
	Moderately rising glucose level, rising at a rate between 1.0 mg/dL and 2.0 mg/dL per minute.
	Moderately falling glucose levels, falling at a rate between 1.0 mg/dL and 2.0 mg/dL per minute.
	Very rapidly rising glucose levels, rising at a rate more than 2.0 mg/dL per minute.
	Very rapidly falling glucose levels, falling at a rate more than 2.0 mg/dL per minute.

Status

There are four different status conditions you may see next to an Eversense CGM System user's name.



Most recent glucose reading

The user is actively receiving glucose data.

"---"

The user's smart transmitter is connected but is not currently receiving glucose data or there is not enough glucose data to display a value.

This may be due to:

- The CGM system is in Warm-Up Phase.
- The CGM user is in Initialisation Phase and has not yet received their first glucose reading.
- The user has received an alert that prevents glucose data from being displayed.

"Offline"

The user has temporarily turned off data sharing with you. (It can take up to 10 minutes for this status update to be displayed on your Eversense NOW App.)

"Transmitter Disconnected"

There is no connection between the smart transmitter and the Eversense CGM App. This may be due to:

- The smart transmitter battery needs to be recharged or is being charged.
- The Bluetooth connection, internet connection, or mobile device may be off.
- The smart transmitter is out of range or turned off.
- The CGM user has turned off Auto Sync.

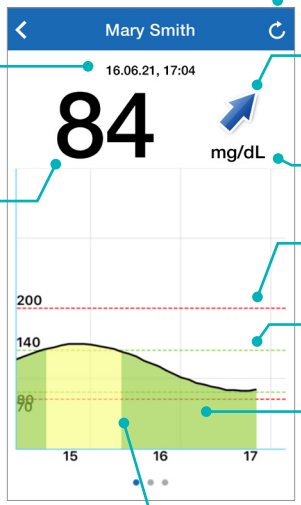
Trend Graph

To see more detailed glucose information about a CGM user, tap any Eversense CGM System user 's name on the Home Page. The first screen shows a trend graph of the user's sensor glucose values for the past three hours. A trend arrow indicates the direction the current glucose is moving and how fast the glucose trend is changing.

To refresh the screen, tap the refresh icon.

Date and Time*
Date and time of the displayed glucose reading.

Glucose reading
Glucose level from last sync.



Refresh
Loads the most recently synced glucose data.

Trend Arrow
The direction the user's glucose is moving and how fast (gradually, moderately, or rapidly rising or falling).

Unit of Measure
The unit of measure used to display all glucose data.

Red dashed lines
The High and Low Alert settings the user has entered.

Green dashed lines
The High and Low Target range the user has set.

Green area under the trend line
Indicates the user's glucose values were within the Target range set.

Yellow area under the trend line
Indicates the user's glucose values were outside the Target range that was set but inside the Alert range that was set.

Red area under the trend line
Indicates the user's glucose values were outside the Alert range that was set.

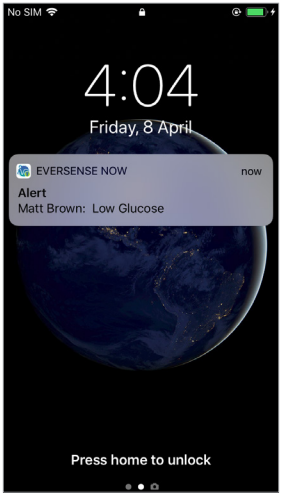
** If you do not receive a new glucose reading within 5 minutes of the most recent glucose value the date and time text will turn red.*

Eversense NOW Alerts

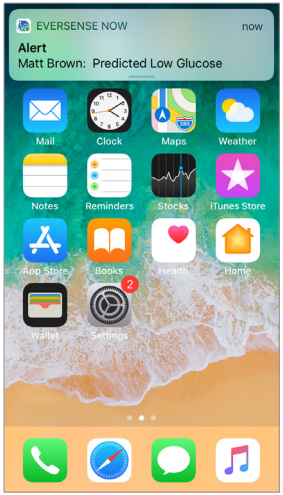
When an Eversense CGM user receives a glucose-related alert, members of their Circle will also receive the alert from their Eversense NOW App. These alerts will appear in one of four ways: on your lock screen, as a notification at the top of your screen, as an in-app pop-up, or on an Apple Watch.

Warning: Glucose information displayed on the Eversense NOW App should not be used to make treatment decisions. The Eversense NOW App is a secondary display of Eversense CGM data and should not be used in place of the primary Eversense CGM display.

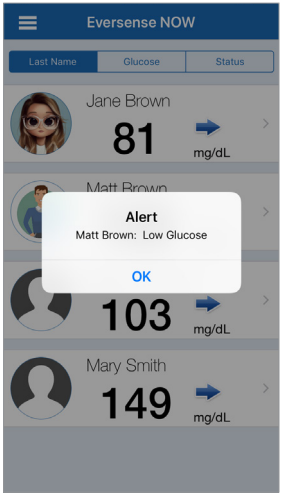
Note: Notification mirroring must be enabled in your Apple Watch notifications settings for Eversense NOW in order to receive glucose alerts on your Apple Watch.



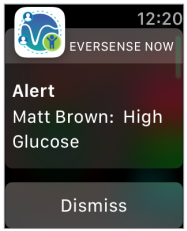
Alert: lock screen



Alert: notification



Alert: in-app pop-up



Alert: on Apple Watch

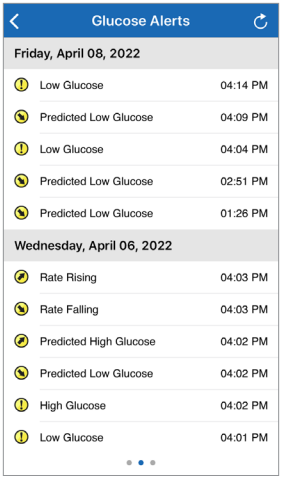
Alert History

To view the Eversense CGM System user's Glucose Alert History, swipe your screen to the left from the trend graph.

The **Alert History** screen will list the last 20 glucose-related alerts that the user received in their Eversense CGM App.

These alerts monitor events such as the rising or falling of glucose rates as well as low or high glucose values (hypoglycaemia or hyperglycaemia).

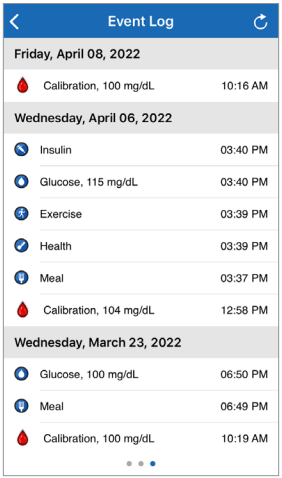
Note: You will only receive predicted high and low glucose alerts if the Eversense CGM user has predictive alerts enabled.



Event Log

To view the Eversense CGM System user's Event Log, swipe the screen to the left from the Alert History.

The **Event Log** lists the 20 most recent events logged by the CGM user. The Event Log shows information entered by the Eversense CGM user such as calibrations, meals, exercise, blood glucose values, insulin levels, health, and exercise. If the user has not entered any Events this log will be empty.



Legal Notices

Apple Legal Notice

"Made for iPod touch", "Made for iPhone" and "Made for iPad" mean that an electronic accessory has been designed to connect specifically to iPod touch, iPhone or iPad, respectively, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards. Please note that the use of this accessory with iPod touch, iPhone or iPad may affect wireless performance.

Apple, iPad, iPhone, iPod, and iPod touch are trademarks of Apple Inc., registered in the U.S. and other countries.

Google Legal Notice

The "Android" name, the Android logo, and Google Play are trademarks of Google Inc.

About Bluetooth®

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

Bluetooth® Trademark

The Bluetooth® word mark and logos are owned by the Bluetooth® SIG, Inc. and any use of such marks by Senseonics, Inc. is under licence.

FCC Information

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

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

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

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

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

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

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

Radio Equipment Directive

Senseonics, Inc. declares the radio equipment type Eversense E3 Smart Transmitter is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: **https://global.eversensediabetes.com/declarationofconformity**.

Index

Adhesive patch.....44, 46
Alerts.....79, 82, 86, 88, 94, 107, 108, 109, 111
Alerts and Notifications, Apple Watch.....158
App, about.....11, 79
App, download.....27
App, launch.....28
App, log out.....154
App, product information...151, 153
App, using.....59
Battery, charging.....25
Battery power, indicator.....48
Bluetooth.....79, 305
Bluetooth, restart.....191
Button on smart transmitter.....31, 42, 47
Calibration, Daily Phase.....50, 53
Calibration, Initiation Phase..50, 52
Calibration, procedure...50, 55, 79
Charging cradle.....16
Data Management System (DMS).....147
Discoverable mode.....31, 191, 193
Do Not Disturb mode.....102
Events.....79, 137
Eversense DMS.....147, 235
Eversense NOW.....285
FCC Information.....306
LED indicator.....26, 42, 47, 49
Link, smart transmitter with sensor.....36
Menu.....79
Mobile device.....27, 61
Mobile device, Apple Watch.....155
MRI, Magnetic Resonance Imaging.....15, 16
My Circle.....149, 178
MY GLUCOSE screen.....34, 59, 62, 79
Notifications.....108, 133, 174
Pairing, smart transmitter and mobile device.....28, 31, 191
Placement guide, signal strength.....45, 79
Power adapter.....26
Reports.....79, 144
Reset smart transmitter....123, 192
Restart Bluetooth.....191
RF, radio frequency communication.....305
Sensor.....184
Sensor, about.....10, 184, 187
Sensor, insertion and removal..185, 186
Settings, app.....28, 79, 80, 91
Share My Data.....147
Smart transmitter, about.....10, 16
Smart transmitter, attaching.....44
Smart transmitter, maintenance.....48
Smart transmitter, on/off.....47
Smart transmitter, reset....123, 192
Smart transmitter, using.....42, 43
Snooze setting.....94
Symbols, alerts, notifications..226, 227, 228
Symbols, packaging and device.....229, 230, 231
System components.....10
Target levels.....84
Temp Profile.....104
Travel.....187
Trend arrows.....65
Trend graph.....78
Troubleshooting, FAQs.....188
Unit of measurement.....32
USB, cable.....25
USB, port.....25
Wireless.....24, 59, 305

Notes

Basic UDI/DI:
- Eversense E3 Smart Transmitter Kit: 081749102FG3500T8
- Eversense E3 Adhesive Patches Kit: 081749102FG6400TQ
- Eversense Charging Cradle: 081749102FG6501TX
- Eversense Mobile App iOS: 081749102FG5101T4
- Eversense Mobile App Android: 081749102FG5301TE
- Eversense DMS: 081749102FG5200T7
- Eversense NOW Mobile App iOS: 081749102FG5400TH
- Eversense NOW Mobile App Android: 081749102FG5401TK

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Folded (*Include folded dimensions if applicable*):	

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

Paper Weight:
Cover: 65# Gloss Cover
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