

eversense 365

Continuous Glucose Monitoring System

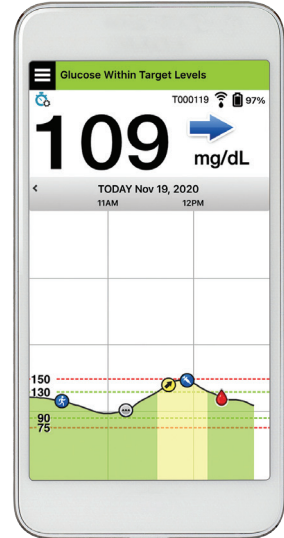
Quick Reference Guide



Sensor



Smart Transmitter



App

To access additional reference materials, go to: www.eversenseddiabetes.com

Refer to the *Eversense 365 CGM System User Guide* for more detailed information.

Indications for Use

The Eversense 365 Continuous Glucose Monitoring (CGM) System is indicated for continually measuring glucose levels for up to 1 year in people (18 years or older) with diabetes. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions.

The system is intended to:

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

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 Eversense 365 CGM System is also intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems. The Eversense 365 CGM System can be used alone or in conjunction with these digitally connected medical devices for the purpose of managing diabetes.

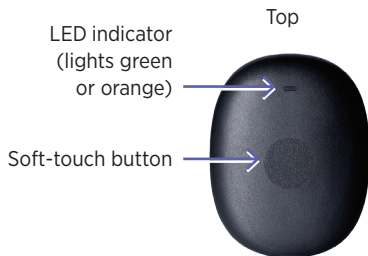
The system is intended for single patient use and requires a prescription.

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. The smart transmitter is MR Unsafe and **MUST BE REMOVED** before undergoing an MRI (magnetic resonance imaging) procedure. The sensor is MR Conditional. For more information on the sensor, see *MRI Safety Information* in the *Eversense 365 CGM System User Guide*.
- Mannitol or sorbitol, when administered intravenously, or as a component of an irrigation solution or peritoneal dialysis solution, may increase blood mannitol or sorbitol concentrations and cause falsely elevated readings of your sensor glucose results. Sorbitol is used in some artificial sweeteners, and concentration levels from typical dietary intake do not impact sensor glucose results.

Eversense 365 Smart Transmitter

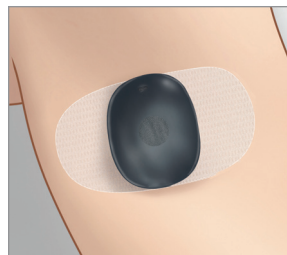
Your rechargeable smart transmitter powers the sensor, calculates glucose readings, and stores and sends data to the app. It also provides on-body vibrate alerts. The smart transmitter is secured to your skin with a disposable adhesive patch that is changed daily.



Wearing the Smart Transmitter

- Replace the adhesive patch on your smart transmitter daily.
- The smart transmitter can be removed and reapplied to the skin at any time.

Note: Your smart transmitter is water resistant (IP67) to a depth of 1 meter (3.2 feet) for up to 30 minutes.



Turn the Smart Transmitter ON and OFF

To turn the smart transmitter ON, touch and hold the soft-touch button for about three seconds.

To turn the smart transmitter OFF, touch and hold the soft-touch button for about five seconds.

To see if your smart transmitter is ON, tap the soft-touch button once. If the LED appears, the smart transmitter is ON. If no LED appears, the smart transmitter is OFF.

LED Battery Status Indicators during smart transmitter charging:

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

LED Status Indicators during smart transmitter use:

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

Getting Started Steps

Charging the Smart Transmitter

Before you begin, you need:

- A compatible mobile device.
For supported smart devices and operating systems, go to www.eversenseddiabetes.com/compatibility.
- Wireless internet connection.
- Fully charged Eversense 365 Smart Transmitter.

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



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

Once charged for about 15 minutes, a small green light blinks on the top side of the smart transmitter. The blinking green light means the transmitter has about 24 hours of life. Remove the USB cable from the smart transmitter.



IMPORTANT: Use only the AC power adapter and USB cable provided with the smart transmitter when charging the smart transmitter battery, and never stick any object other than the charging cable into the USB port of the transmitter. Use of another power supply could damage the smart transmitter, not allowing glucose readings to be received properly, create the risk of fire, and could result in voiding your warranty. If your power adapter or USB cable is damaged or lost, contact Customer Support for a replacement to ensure safe operation of the device.

Downloading the Eversense 365 App and Pairing the Smart Transmitter

Download and Install the App

1. Download the free app from the **Apple App Store** or on **Google Play**.

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

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

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

After 1 - 2 minutes, check your mobile device display for the Eversense 365 App icon.



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

Note: When prompted, review and tap **Accept** to agree to the terms of the License Agreement. A LOG IN screen appears.

Launch the App by Tapping the Eversense 365 Icon



1. Tap **Create an account** to create your Eversense account.

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

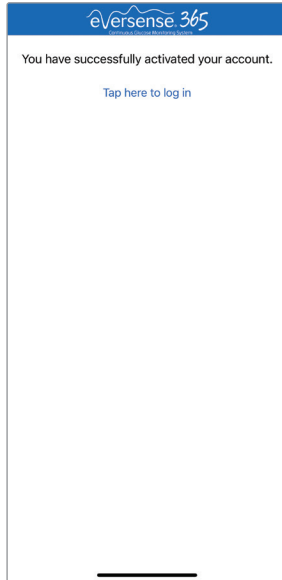
- To activate your Eversense account, click the link in the email sent from **donotreply@eversensed diabetes.com**.

Note: If you have not received the confirmation email with the link to activate your account within a few minutes, check your spam folder. After clicking the link in the email, the app will display that the account was successfully activated.

- Tap **Back** to login to continue.

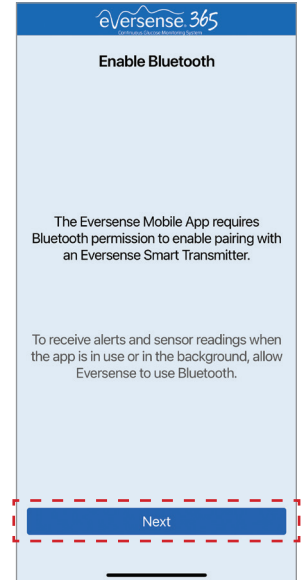
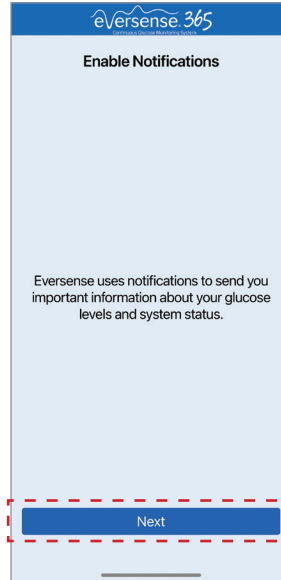
3. The app will open. Tap the link to log in.

- Enter your email address and password and tap **LOG IN**.



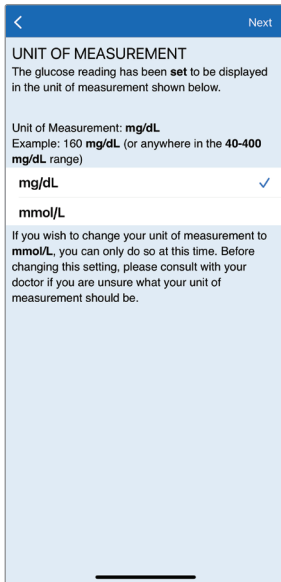
4. The app will ask you to enable notifications and Bluetooth.

- Tap **NEXT** to continue.

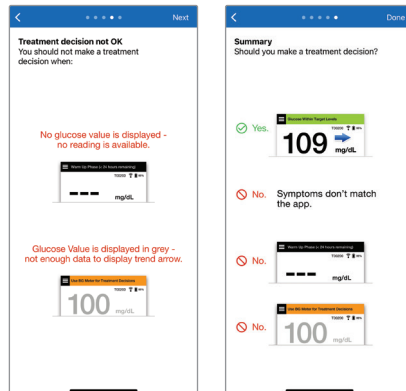
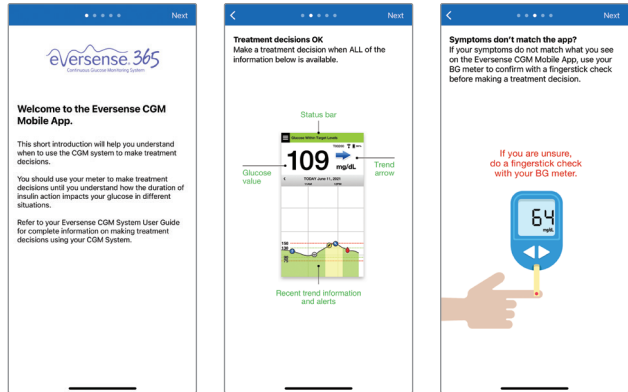


5. The unit of measurement is used for calculating and displaying your glucose readings. **DO NOT** change the unit of measurement until you consult with your health care provider.

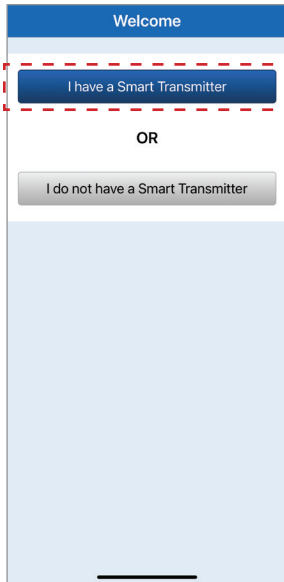
- Tap **Next** to continue.



6. Tap through the introduction screens that provide information about when to make treatment decisions.



7. Select **I have a Smart Transmitter** and you will begin System Setup to pair the smart transmitter to your mobile device.



System Setup

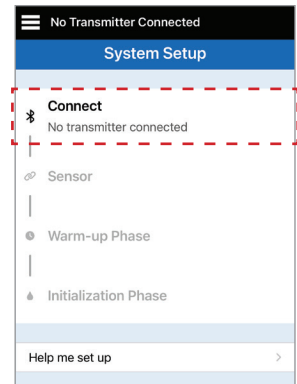
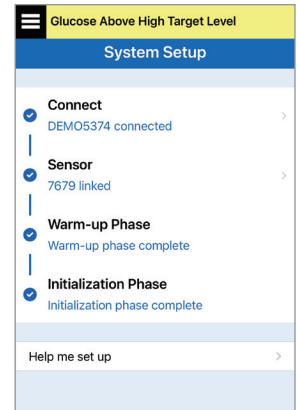
System Setup Menu

The System Setup Menu will be your guide for setting up your system. Check marks will be displayed after completing each step.

- **Connect:** Pair your smart transmitter to the mobile device.
- **Link sensor:** Link your inserted sensor with the smart transmitter.
- **Warm-up Phase:** The 24-hour period after the sensor is linked with the smart transmitter.
- **Initialization Phase:** Enter 4 calibrations 2 to 12 hours apart.

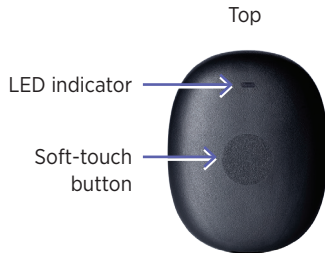
Connect

On the System Setup Menu, tap **Connect** to pair your transmitter.

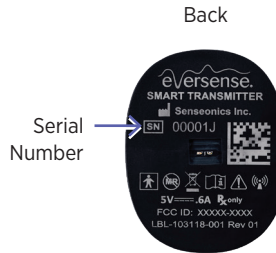


1. With the smart transmitter turned on, tap the button three times to start pairing mode:

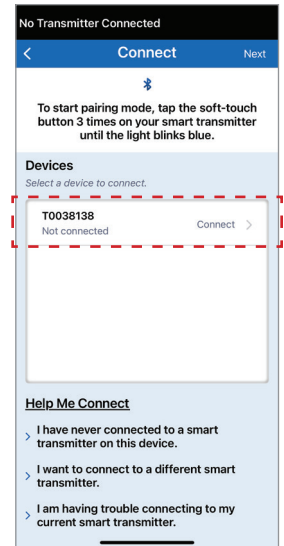
The LED will blink blue to indicate the smart transmitter is in pairing mode.



2. On the **Connect** screen, tap your smart transmitter serial number. (Your smart transmitter serial number can be found on the back of the smart transmitter.)



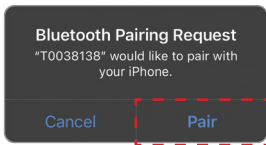
Note: Your mobile device must be connected to the internet in order to pair with the smart transmitter. Internet is only required at pairing.



3. A **Bluetooth Pairing Request** pop-up screen appears.

- Tap **Pair**.

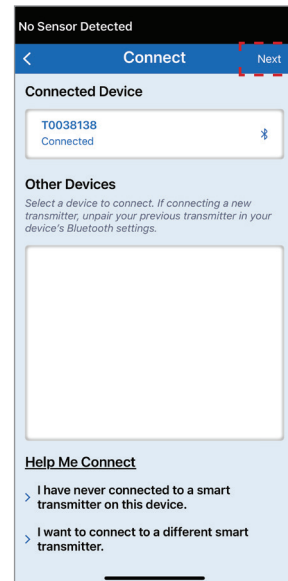
Note: The smart transmitter can only be paired with one mobile device at a time.



Note: If the transmitter detects software that appears to be invalid trying to communicate with the transmitter over BLE, device pairing will be prevented.

4. The smart transmitter serial number and **Connected** will be displayed under **Connected Devices** once the pairing is complete. The smart transmitter will provide intermittent vibrations until the smart transmitter is linked with the inserted sensor.

- Tap **Next**.



Linking the Sensor and Smart Transmitter

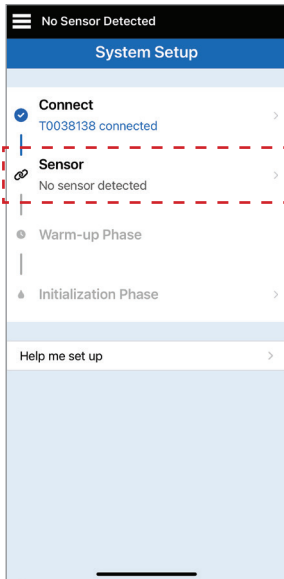
Once the sensor has been inserted by your health care provider and you have paired your transmitter and the app, your sensor needs to be linked to your smart transmitter. This will start the 24 hour Warm-Up Phase. There is no need to wear the smart transmitter during the Warm-Up Phase. To link the sensor, your mobile device must be connected to the internet and your transmitter must be charged, turned on, and paired with your mobile device.

When you first link the sensor, with the Tegaderm™ bandage over the insertion site, the incision is likely in the center of the Tegaderm. This means the sensor is likely above the center of the Tegaderm. The first time you link the sensor, do not use an adhesive patch on the smart transmitter. When positioning the smart transmitter over the sensor, it should be slightly above the center of the Tegaderm patch.

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

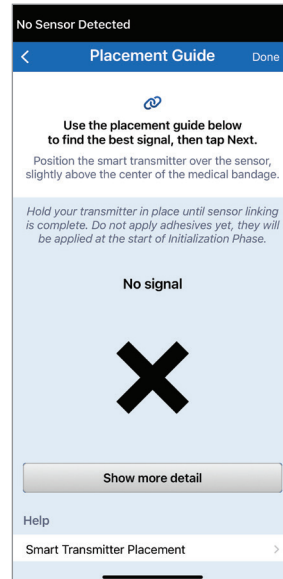
For details on linking the sensor, please review *Linking the Sensor* in the *Eversense 365 CGM System User Guide*.

Tap **Link sensor** to display the Placement Guide.



Place Smart Transmitter over Sensor

1. Make sure your smart transmitter is turned ON 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.

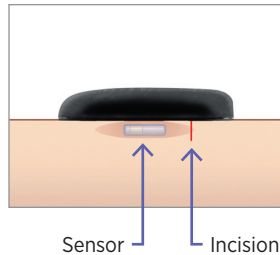
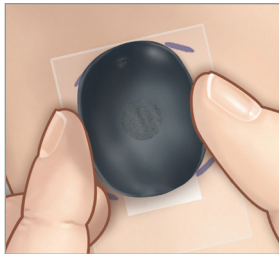


2. Using any visible smart transmitter corner marks as a guide, gently place your smart transmitter toward the top half of the bandage.

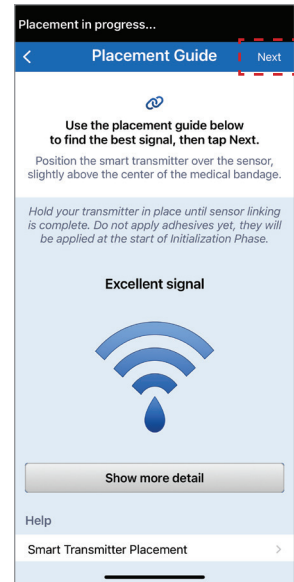
Watch the placement guide for signal strength – this may take several seconds.

To get the best signal, gently lift and move the smart transmitter as needed until the placement guide shows 2-3 bars (good to excellent).

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



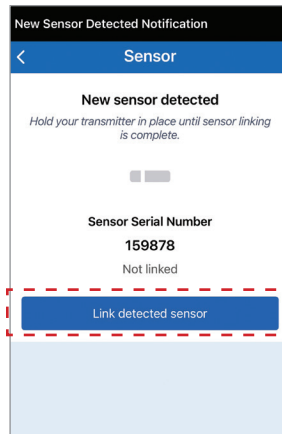
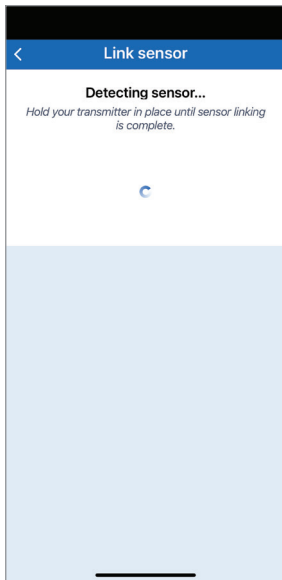
3. Tap Next.



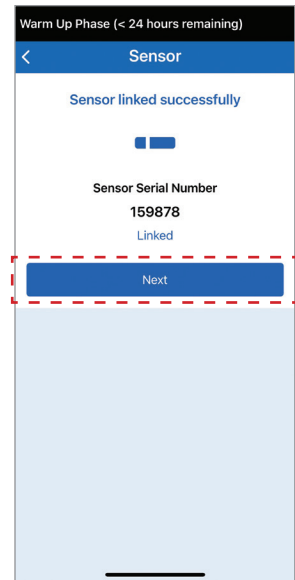
Link Detected Sensor

After establishing the signal using the Placement Guide, you can now link the sensor.

1. The app will display **Detecting sensor**. During this time, continue to hold your transmitter in place.
2. When the **New sensor detected** screen is displayed, tap **Link detected sensor**.
3. Tap **Next**.



The linking process will begin. DO NOT remove the smart transmitter from your insertion site until the progress bar is completed and **Sensor linked successfully** is displayed.

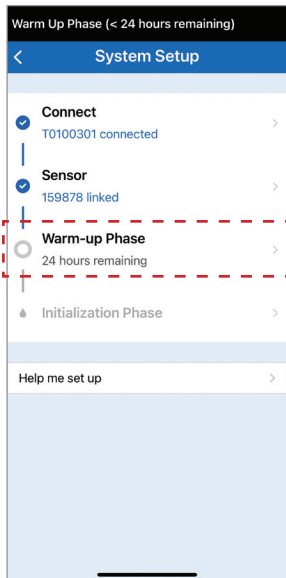


Warm-Up Phase

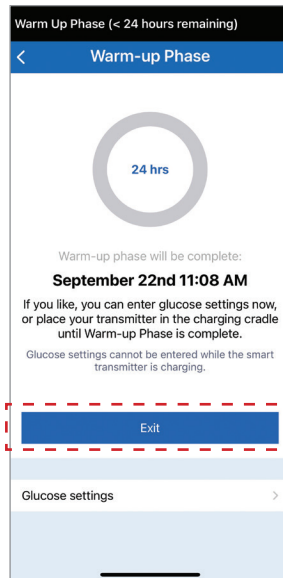
The sensor requires a 24-hour Warm-Up Phase to stabilize in your body before glucose values will be collected by the smart transmitter. **During the Warm-Up Phase, you do not need to wear the smart transmitter.** Once the Warm-Up Phase is complete, you will receive a notification to let you know that you can continue with the next step in your system setup. At that time, you can turn ON the smart transmitter and place it over the sensor with the adhesive patch. The system will prompt you to calibrate using the app.

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

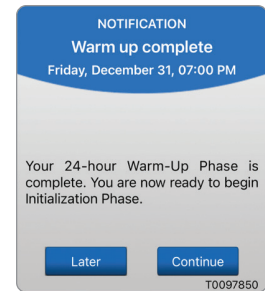
In the System Setup Menu, tap **Warm-up Phase** to see details about Warm-up Phase duration.



- Tap **Exit** to go to the Home Screen.
or
- Tap **Glucose settings** to set your target and alert settings.



Once the 24-hour Warm-Up Phase is complete, the app will notify you to begin Initialization Phase.

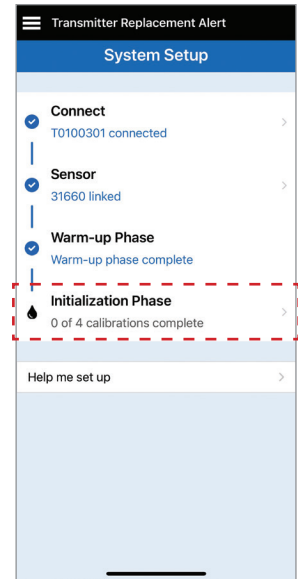


Initialization Phase

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

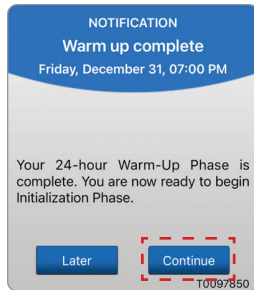
- The 4 calibration tests must be spaced 2 to 12 hours apart, and all 4 tests must be completed within a 36 hour period. After 8 hours without a calibration entry, no glucose data will be displayed.
- Glucose readings will start displaying in the app a few minutes after the 2nd calibration is successfully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

IMPORTANT: Your smart transmitter must be turned on and paired with the app and linked to your sensor in order to calibrate.



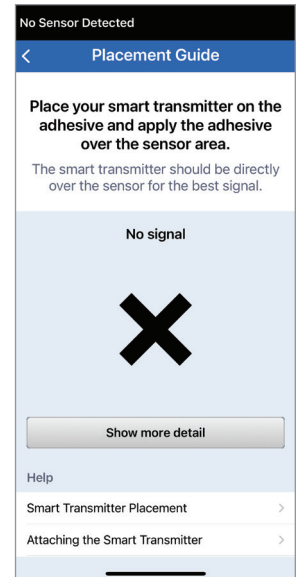
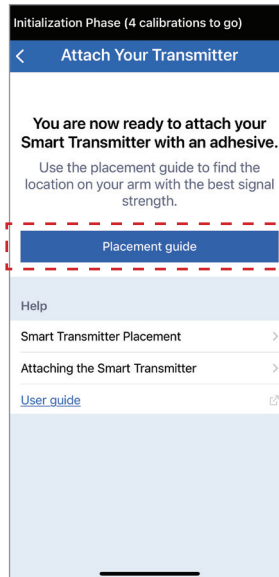
Once the Warm-Up Phase has ended, the Initialization Phase begins, and you're ready to start wearing the smart transmitter. For the first few days, you'll wear the smart transmitter over the Tegaderm™ bandage. Always start with a freshly charged smart transmitter.

1. On the Warm-Up Complete notification, tap **Continue** to begin the Initialization Phase.



2. Tap on **Placement Guide**.

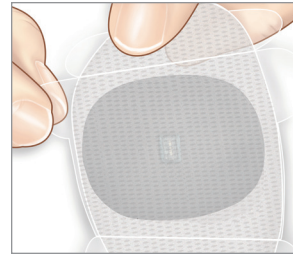
Until the transmitter is secured over the sensor and a signal is established, the **Placement Guide** screen will show **No signal**.



3. Peel off the paper backing of the adhesive patch with the Eversense logo on it and place the smart transmitter in the center.



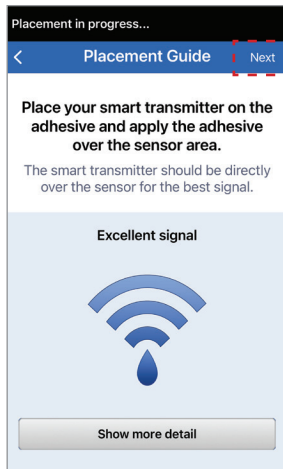
4. Remove the larger clear backing and position the smart transmitter directly over the sensor.



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

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

6. Tap **Next** once the signal strength is established.



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

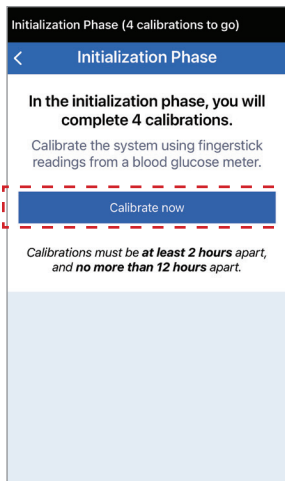


8. Use the tab to pull off the remaining clear liner.



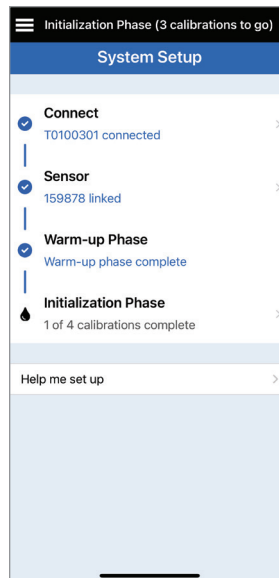
Note: For more information on using the Placement Guide, review *Placement Guide - Show More Detail Screen* in the *Linking the Sensor* section of the *Eversense 365 CGM System User Guide*.

9. Tap **Calibrate now**. Enter your blood glucose reading from your meter. See *Calibrating the System* for more details on entering calibrations.



Note: You will receive calibration prompts during initialization, each 2 hours after the previously completed calibration. You can complete all 4 calibrations in as quickly as 6 hours. All 4 calibrations must be completed within 36 hours. You can record the times below as a reference.

Once Initialization Phase has concluded your System Setup is complete.



Calibration Tips:

- Wash and dry hands thoroughly.
- Avoid calibrating when glucose may be changing rapidly (such as after meals, after taking insulin, or during/after exercise).
- Always use an actual blood glucose value, and enter calibration within 10 minutes.
- Keep smart transmitter in place over the sensor 5 minutes before and 15 minutes after each calibration.

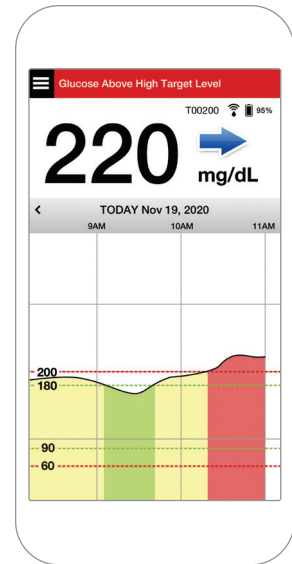
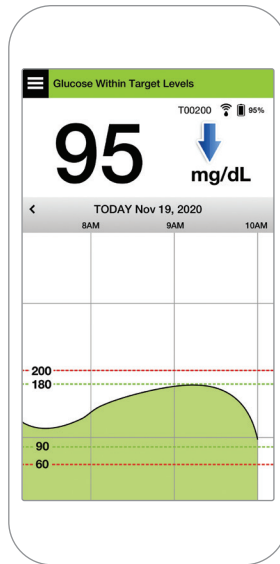
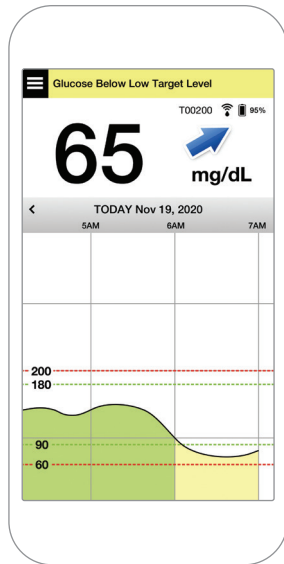
Daily Use

Once the Initialization Phase has passed, the system requires one calibration each day for the first 13 days. After 13 days, the system will prompt you for calibration once a week. Please see *Calibrating the System* in the *Eversense 365 CGM System User Guide* for more information.

Making Treatment Decisions

To make a treatment decision, you should consider:

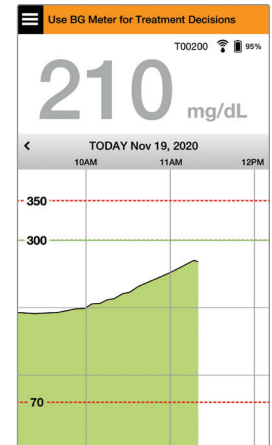
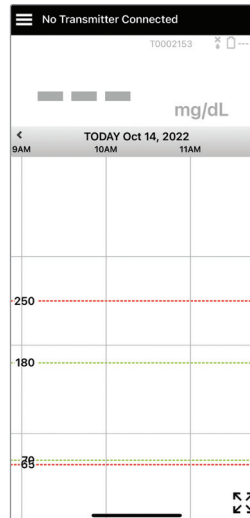
- Status bar information
- Current sensor glucose value – the current glucose value should be displayed in black
- Trend arrow – a trend arrow should be displayed
- Recent trend information and alerts



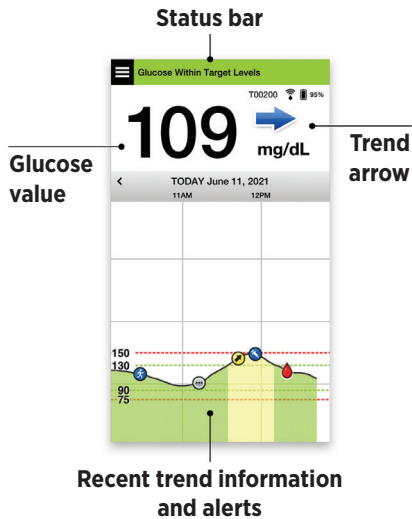
When to NOT make a treatment decision:

- 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 app on your smartphone to make treatment decisions. Do not utilize a secondary display like the Apple Watch or Eversense NOW.



Use all available CGM information



When to use your blood glucose meter

Do not make a treatment decision if:

- Your symptoms do not match your sensor glucose value.
- No glucose data or trend arrow is displayed.
- **“Use BG Meter for Treatment Decisions”** appears on the status bar of your **My Glucose home screen**.
- You are currently taking a medication of the tetracycline class.








⊘ No. Symptoms don't match the app.



Additional resource: *Eversense 365 CGM System User Guide: Using the App.*

Your Diabetes Management

Understand your trend arrows – this can help you make more informed diabetes management decisions.

	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.
	Rapidly rising glucose levels, rising at a rate between 2.0 mg/dL and 3.0 mg/dL per minute.
	Rapidly falling glucose levels, falling at a rate between 2.0 mg/dL and 3.0 mg/dL per minute.
	Very rapidly rising glucose levels, rising at a rate more than 3.0 mg/dL per minute.
	Very rapidly falling glucose levels, falling at a rate more than 3.0 mg/dL per minute.






Understanding Sensor Glucose versus Blood Glucose

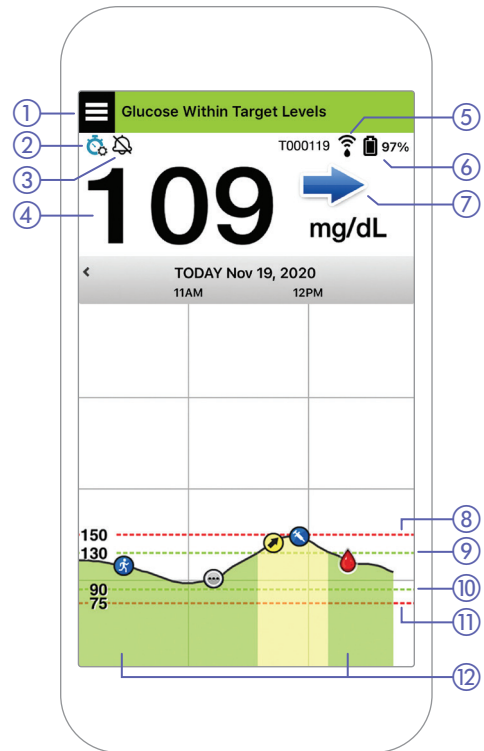
- Your sensor measures glucose in the fluid in your skin tissue – called interstitial fluid. Your blood glucose (BG) meter measures glucose in the blood.
- The glucose level in interstitial fluid and blood are usually close. Calibrating your system properly is the best way to ensure they are as close as possible.
- Differences between glucose levels in the interstitial fluid and the blood are especially evident during times of rapid change in blood glucose (after eating, dosing insulin or exercising), and for some people, during the first several days after insertion due to inflammation that may result from the insertion procedure.
- Typically, the difference you see is the sensor glucose level "lags behind" the blood glucose level by several minutes.

Using the App

The **MY GLUCOSE** screen will display your glucose data once your sensor has been inserted and you have started calibrating the system.

- ① **Menu icon** (see next page)
- ② Temp Profile icon
- ③ Do Not Disturb icon
- ④ Current glucose reading
- ⑤ Transmitter connection to sensor and/or app
- ⑥ Transmitter % battery life
- ⑦ Trend arrow
- ⑧ High glucose alert level - - - -
- ⑨ High glucose target level - - - -
- ⑩ Low glucose target level - - - -
- ⑪ Low glucose alert level - - - -
- ⑫ Event Log icon

- | | |
|--|---|
|  Exercise |  Insulin |
|  Multiple Event |  Calibration |
|  Predicted High Glucose Alert | |



Menu Icon

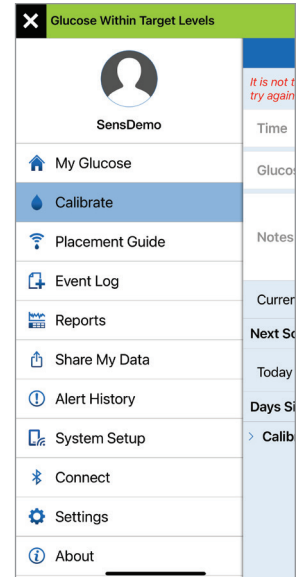
Tap the **MENU** icon (☰) on the top left of any screen to navigate to any of the available menu options:



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

Alerts

- BOTH your mobile device and smart transmitter provide alerts to notify you when your CGM readings have reached certain alert settings or if your CGM System requires attention.
- See the *Eversense 365 CGM System User Guide* for a complete listing of alerts on your app.

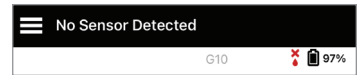
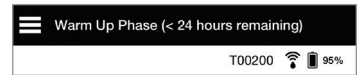


Main Menu

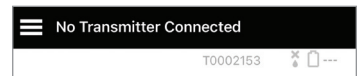
App Status Bar

- **Warm-up Phase** – applies after linking the smart transmitter and sensor for the first time.
- **No Sensor Detected** – will appear any time you remove the smart transmitter from over your sensor.
- **No Transmitter Connected** – will appear if the smart transmitter is turned off, being charged, or out of range of your mobile device.
- **Use BG Meter for Treatment Decisions** – will appear when you should take a confirmatory fingerstick check before making a treatment decision.

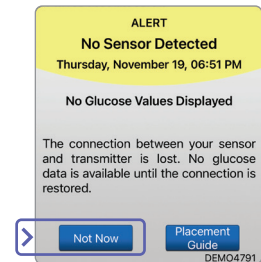
Tip: A **“No Sensor Detected”** alert may pop-up in your app. This will happen if your smart transmitter is powered on, but not on your arm. Clear the alert by tapping **Not Now**.



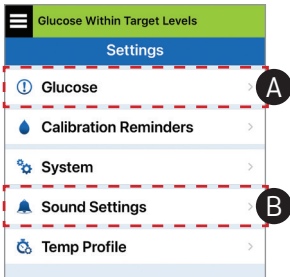
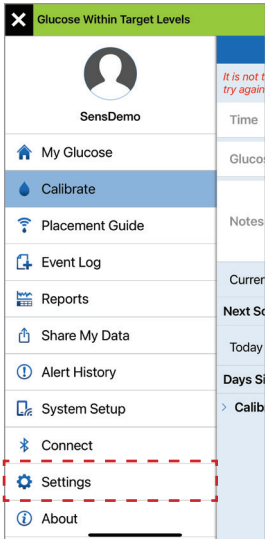
Transmitter powered on
but not over the sensor



Transmitter powered off



Personalized Settings

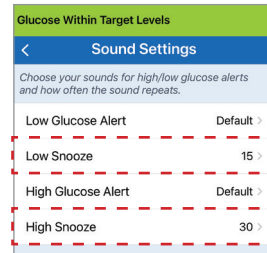


A Set glucose targets and glucose alerts



Tip: If you are new to CGM, wait to set predictive or rate-of-change alerts until you are accustomed to wearing your system.

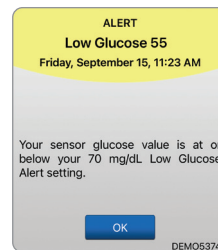
B Set how often alerts repeat (snooze)



Your alerts sounds are also customizable. See the *Eversense 365 CGM System User Guide Section 8*.

Alerts and Notifications – See, Hear, Feel

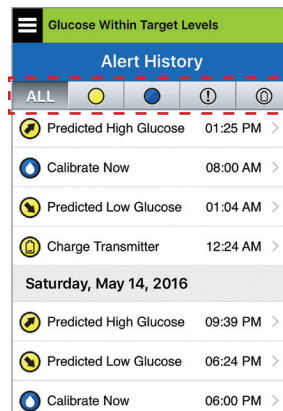
Alerts and notifications	Smart transmitter vibration pattern
Alerts when no glucose values can be displayed and when the transmitter battery is empty	3 long vives
Alerts related to Low Glucose and Out-of-Range Low Glucose	3 short vives x 3
Alerts related to Predictive Low Glucose	3 short vives
Alerts related to High Glucose	1 long vibe then 2 short vives
Alerts related to low transmitter battery	3 quick vives then 1 long vibe x 2
Alerts related to less critical issues, or notifications	1 short vibe



See *Alert Descriptions* in the *Eversense 365 CGM System User Guide* for more information.

To access alert history:
Menu > Alert History

- Alerts are sortable.



Accessing your DMS Account

You are always logged into your account through the app, but to get full access to all your data just go to: <https://us.eversensedms.com/> and enter your log-in information.

Remember your log-in information is the same as what you used when you created your Eversense account.

Note: To share your Eversense data with your health care provider, ask them for their Eversense Clinic ID number. See the *Eversense 365 CGM System User Guide* for more information on sharing data with your health care provider via the app.

Notes

Contact Information

- Contact your health care provider if you have a medical question or concerns about your diabetes treatment plan.
- Contact Customer Care if you have technical questions about the system.

Eversense Customer Care:

1-844-SENSE4U (736-7348)

Support@eversensediabete.com

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