eversense® XL

Continuous Glucose Monitoring System

Quick Reference Guide

Your Eversense XL CGM System includes a sensor inserted in your upper arm, a smart transmitter worn over the sensor, and a mobile device app to display your glucose readings. Schedule the insertion and removal of your sensor with your health care provider.

Refer to the Eversense XL CGM User Guide for more detailed information.

Indications for Use

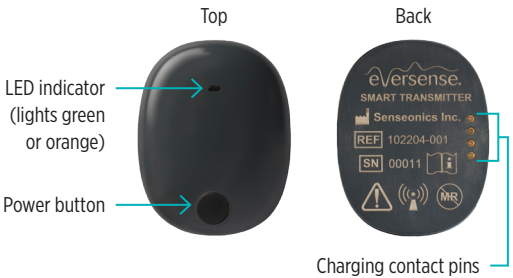
The Eversense XL CGM System is intended for continually measuring interstitial glucose levels in adults (18 years and older) with diabetes for the operating life of the sensor. The system is intended to:

- Aid in the management of diabetes.
- 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).
- 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 indicated for use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices.

Contraindications

- 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. The sensor is MR conditional. For more information on the sensor, see MRI Safety Information in the Eversense XL 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 XL 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 vibe 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.

To ensure continuous glucose readings:

- Charge the smart transmitter battery daily (15 minutes to fully charge) using a wall outlet.
- Position the smart transmitter over the sensor so that either the power button symbol or the LED points downward. Tap the **Menu** icon (☰) and then **Placement Guide** on the app to confirm communication is established between the sensor and the smart transmitter. Refer to the **Placement Guide** when attaching your smart transmitter to ensure there is some connection between the sensor and smart transmitter.
- Pay attention to the on-body vibe alerts on your smart transmitter. Alert messages will appear on the app whenever an alert is activated.

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

Warnings

- The Eversense CGM System has not been tested using insertion sites other than the upper arm.
- 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 metre.
- Always test your glucose with your blood glucose metre before making a treatment decision.
- 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 (electromagnetic interference) 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.
- Tetracyclines may falsely lower sensor glucose readings. Always test your glucose with your blood glucose meter if you are taking tetracyclines.
- 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 professional. For additional Eversense product questions and troubleshooting issues, please see the back cover to find 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.
- DO NOT insert your infusion set 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 health care provider's instructions for care after the sensor insertion or removal. Contact your health care provider if any of the following events occur:
  – You have pain, redness, or swelling at the incision site(s) later than 5 days after the sensor insertion or removal.

Cautions

- DO NOT wear the smart transmitter during medical x-rays or computed tomography (CT) scans. To avoid interference with results, remove the smart transmitter before undergoing medical x-ray or CT scans. Make sure your health care provider knows about your smart transmitter.
- The smart transmitter is intended to be single-patient use only. DO NOT exchange smart transmitters with another person or with another sensor. Each smart transmitter can be linked to only one sensor at a time.
- 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.
- The following medical therapies or procedures may cause permanent damage to the sensor particularly if used in close proximity to the device:
  - **Lithotripsy** - The use of lithotripsy is not recommended for people who have an inserted sensor because the effects are unknown.
  - **Diathermy** – DO NOT use diathermy on people who have an inserted sensor. Energy from the diathermy can transfer through the sensor and cause tissue damage in the insertion area.
  - **Electrocautery** – The use of electrocautery near the inserted sensor may damage the device. DO NOT use electrocautery near the sensor.
- Steroid use – It has not been determined whether the risks usually associated with injectable dexamethasone acetate apply to the use of this dexamethasone acetate elution ring, a highly localized, controlled-release device. The dexamethasone acetate ring could cause other adverse events not listed or previously seen.

Cautions (continued)

- If the sensor, insertion site or smart transmitter feels warm, remove the smart transmitter immediately and contact your health care provider for further advice. A warm sensor could mean there is an infection or a sensor malfunction and should be removed.
- Remove the smart transmitter from your arm before charging the smart transmitter battery. Failure to remove the smart transmitter while it is charging could result in electrical shock.
- DO NOT attempt to use the Eversense XL 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.
- Use only the AC power adapter and USB cable provided with the smart transmitter when charging the smart transmitter battery. Use of another power supply could damage the smart transmitter, not allowing glucose readings to be received properly, and could result in voiding your warranty.
- If you have any concerns about allergic reaction to silicones, contact your health care provider prior to use. Discard the adhesive patch after 24 hours of use.
- The Eversense NOW Remote Monitoring App does not replace the monitoring regimen as directed by your healthcare professional.
- The Eversense XL 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).

Eversense XL App

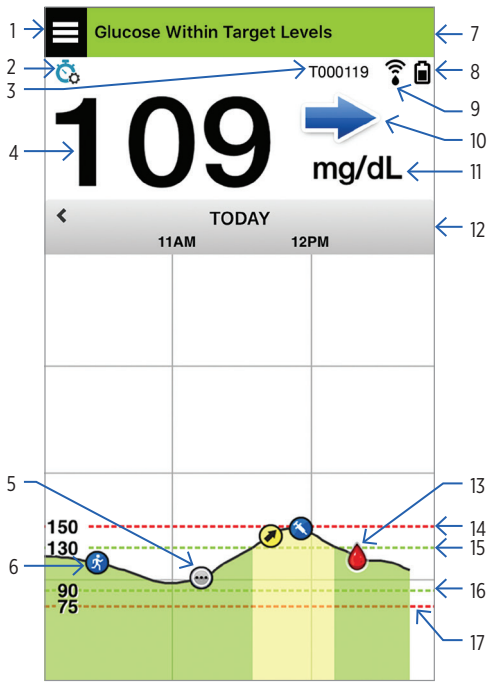
The smart transmitter communicates wirelessly with the app to display glucose data, trends, graphs and alerts. The app also stores glucose value history and statistics.

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
- Alert History
- Event Log
- Reports
- Share My Data
- Placement Guide
- Connect
- Settings
- About

1– Menu icon
2– Temp Profile icon
3– Transmitter ID
4– Current glucose reading
5– Multiple events mark
6– Event mark (exercise)
7– Status bar
8– Transmitter battery power
9– Transmitter connection to sensor
10–Trend arrow
11– Unit of measurement
12–Date and time
13–Calibration mark
14–High glucose alert level (Top red dashed line)
15–High glucose target level (Top green dashed line)
16–Low glucose target level (Bottom green dashed line)
17– Low glucose alert level (Bottom red dashed line)



Calibration

To help ensure accurate glucose readings, you must routinely calibrate your CGM System with a fingerstick test from a blood glucose metre. Your CGM System automatically notifies you when it's time to calibrate:

- 24 hours after inserting your sensor, you must complete 4 fingerstick calibration tests spaced 2 to 12 hours apart.
- Every day thereafter you must complete 2 fingerstick calibration tests per day, spaced 10 to 14 hours apart.

Set your daily calibration schedule by tapping **Menu** > **Settings** > **Daily Calibration**.

How to calibrate:

- Do a fingerstick test with a blood glucose metre. Always follow the metre manufacturer's instructions, including washing hands with warm water, and drying prior to testing.
- Enter the fingerstick reading into the app within 10 minutes of testing, ensuring reading and time are correct.
- Calibrate only when glucose is NOT changing rapidly (e.g., before meals, before dosing insulin).
- The smart transmitter must be worn 5 minutes before and 15 minutes after the test for a successful completion of the calibration.

Alerts

- BOTH your mobile device and smart transmitter provide alerts to notify you when your CGM readings have reached certain target settings or if your CGM System requires attention.
- Review and confirm alerts on your mobile device.
- You can set high/low glucose alerts or target settings by tapping **Menu** > **Settings** > **Glucose**.
- See the User Guide for a complete listing of alerts on your app.

Getting Started Steps

Steps 1 and 2 take you up to the point of sensor insertion. Schedule an appointment with your health care provider to have the sensor inserted. After insertion, you will need to wait 24 hours to perform the first set of calibrations and start receiving glucose readings on your app.

To get started you need:

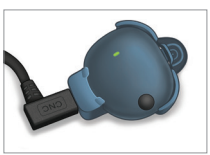
- A compatible mobile device (like your smartphone)
  - For a list of compatible devices, visit https://global.eversensediabetes.com/compatibility.
- Wireless internet connection
- Eversense XL Smart Transmitter

Charging the Smart Transmitter

After you receive your smart transmitter it must be fully charged before pairing with the app.

- Plug the standard end of the USB cable into the adapter on the USB port.
- Plug the micro end of the USB cable into the charging cradle on the USB port.
- Line up the four gold pins on the bottom of the smart transmitter with the four gold pins on the charging cradle.

Once fully charged (about 15 minutes), a small green light appears on the top side of the smart transmitter. Remove the USB cable from the charging cradle after it is fully charged.



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.

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 Eversense power adapter or USB cable is damaged or lost, contact Customer Support for a replacement to ensure safe operation of the device.

Step 1. Download and Install the App

1. Select the mobile device you want to display your glucose readings. Make sure the date and time are correct and Bluetooth is enabled.

2. From your mobile device, download the mobile Eversense XL App from the Apple® App Store℠ or on Google Play™.

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

   The Eversense XL app icon is displayed on your mobile device.

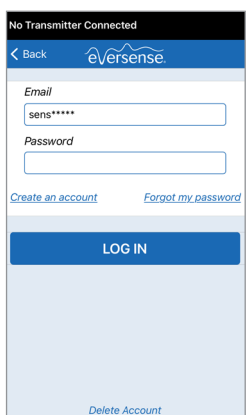
Note: You will be prompted to create an account, and then register that account to have your app data synced with the cloud (web) version.

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

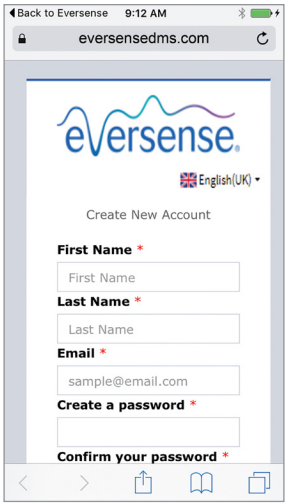
1. Launch the app by tapping the Eversense XL icon. The **END USER LICENSE AGREEMENT** appears.

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

3. Create and register an account with an Email and Password.



4. Enter your account information and tap **Register.**



5. On the **WELCOME** screen, choose one of two options depending on whether you have your smart transmitter:

I have a Smart Transmitter

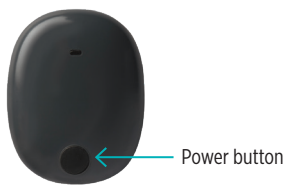
I do not have a Smart Transmitter

Before receiving your smart transmitter you may begin familiarizing yourself with the app before completing these next steps.

If you have received your smart transmitter you may proceed with pairing your smart transmitter to the app.

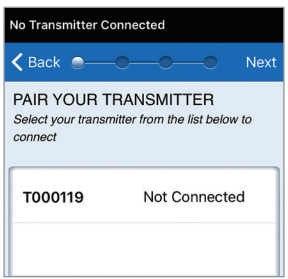
Note: On Android operating systems you may be prompted to acknowledge and enable location or Bluetooth services in order to pair your smart transmitter with your mobile device and receive alerts from the Eversense XL CGM system.

6. With the smart transmitter turned on, and when the **PAIR YOUR TRANSMITTER** screen appears, set your smart transmitter to "Discoverable Mode" by pressing the power button on your smart transmitter three times. The LED light on your smart transmitter will blink green and orange.



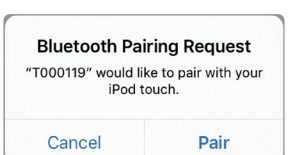
7. On the **PAIR YOUR TRANSMITTER** screen the smart transmitter serial number detected by the app is listed as "Not Connected".

Tap **Not Connected** to begin the pairing process.



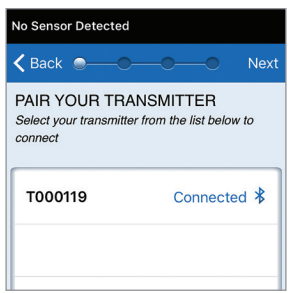
8. A **Bluetooth Pairing Request** pop-up appears.

Tap **Pair** to confirm the pairing.



9. The app displays "Connected" next to your smart transmitter serial number once the pairing is complete. The smart transmitter will provide intermittent vibrations until the smart transmitter is linked with the inserted sensor.

Tap **Next**.



10. The **DAILY CALIBRATION** screen appears where you set your twice-daily calibration reminder times. Tap **Morning** and then **Evening** to change either time.

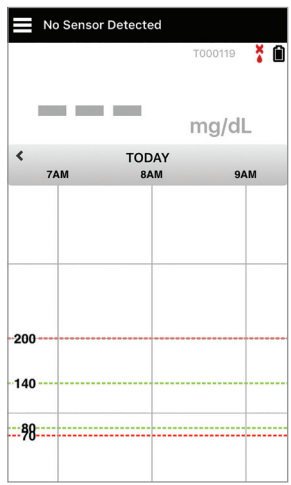
Tap **Next** when done.

11. **The UNIT OF MEASUREMENT screen appears to indicate the standard unit of measurement used for calculating and displaying glucose readings in your region. DO NOT change the unit of measurement until you consult with your health care provider.**

Tap **Finish** to keep the unit of measure and continue.

12. **Next, the MY GLUCOSE main screen appears. This screen will not have any glucose data to display until your sensor has been inserted and you have started calibrating the system.**

As a reminder, the smart transmitter will provide intermittent vibrations until the smart transmitter is linked with the inserted sensor. To turn off the smart transmitter until you have it linked with the sensor, press and hold the power button for about 5 seconds.



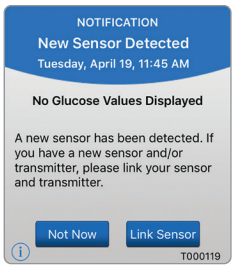
Inserting and Linking the Sensor

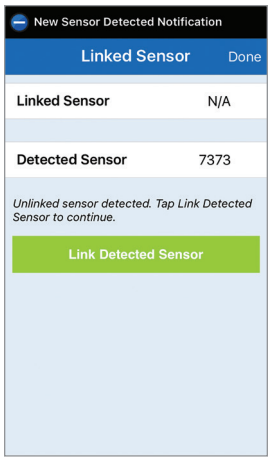
Work with your health care provider to schedule your sensor insertion. Once the sensor has been inserted, your sensor will need to be linked to your smart transmitter.

Note: Your mobile device needs an internet connection in order to be linked to the sensor.

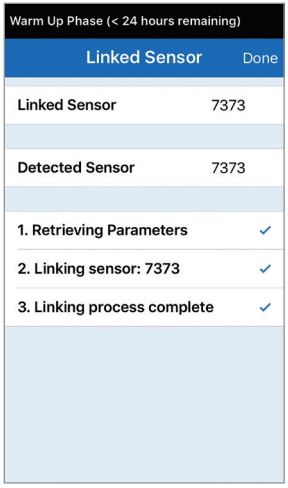
1. **Position the smart transmitter directly over the inserted sensor until the smart transmitter stops vibrating and the New Sensor Detected message appears on the app.**

2. **Tap Link Sensor and then Link Detected Sensor.**





3. **When the smart transmitter and sensor are successfully linked, the LINKED SENSOR screen displays the sensor ID number.**



Important 24-hour Warm-Up Phase:

- The sensor requires 24 hours to stabilise in your body before the smart transmitter will calculate glucose values.
- You do not need to secure the smart transmitter over the sensor during the 24-hour Warm-Up Phase.
- If you decide to secure the smart transmitter over the sensor now, a **WARM-UP PHASE STATUS** screen appears and provides you with a 24-hour countdown until your first calibration.
- You can access the app during this 24-hour Warm-Up Phase to include entering events such as a blood glucose reading, insulin and carb intake.
- Glucose readings will begin to appear on screen after successfully completing the 2nd calibration.

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Dimensions	
Trim: 6.75" w x 5.8" h	Bleed: 0.125"
Folded (*Include folded dimensions if applicable*):	

Colors: 4/color
Spot (*Name PMS colors if applicable*): N/A

Paper Weight:
Cover: 65# Gloss Cover
Text: 60# Gloss Text