



## CGM Sensor Insertion and Removal Instructions

### IMPORTANT:

- Only physicians who have successfully completed the Eversense CGM Insertion and Removal Training Program and have read and understood the Eversense CGM Sensor Insertion and Removal Instructions may perform the insertion and removal procedure on patients. Contact Senseonics (in the US toll free at 844-SENSE4U (844-736-7348)) if training has yet to be conducted or if you experience any difficulty or issues with the insertion or removal procedure. Calls received after business hours (9am to 8pm Eastern US time) will be returned within two business days. Outside the US, call your local distributor or visit [www.eversenseddiabetes.com](http://www.eversenseddiabetes.com) to locate your local distributor.
- All symptoms of infection (e.g., increased temperature, inflammation, redness, pain, tenderness, warmth, swelling or purulence) at the insertion or removal area should be reported. If any of the above occurs, please advise patients to contact their physician immediately.
- Store the sensor pack refrigerated at the labeled temperature range.



# I. Overview of the Eversense Continuous Glucose Monitoring (CGM) System

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Congratulations on having the latest diabetes technology to assist your patients in managing their diabetes. The Eversense CGM System is for people with diabetes to continually measure glucose levels for up to 90 days from the time of sensor insertion.

Some of the features of the Eversense CGM System:

- Wireless communication with the sensor, smart transmitter and app.
- Long-term sensor wear in the upper arm for up to 90 days.
- Alerts when pre-set Low or High Glucose Alert levels (hypoglycemia or hyperglycemia) are reached.
- Predictive alerts to alert the patient before reaching pre-set Low or High Glucose Alert levels.
- Use of mobile device (e.g., smartphone) to display glucose readings.
- On-body vibrate alerts with the smart transmitter even when mobile device is not nearby.
- Provides readings within 2.2-22.2 mmol/L (40-400 mg/dL) range every 5 minutes.
- Trend arrows that show whether glucose values are rising or falling and how fast.
- Graphs and statistics that show 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.

## Eversense CGM System Components

The System includes:

- 1) a small sensor inserted subcutaneously by a doctor,
- 2) a removable smart transmitter worn over the sensor, and
- 3) a mobile app to display the glucose readings.

### Eversense Sensor

The sensor is inserted under the skin (upper arm) and measures glucose in interstitial fluid for up to 90 days. These glucose levels are then calculated by the smart transmitter and sent to the app.

The Eversense Sensor lasts up to 90 days. The sensor has a silicone ring that contains a small amount of dexamethasone acetate, an anti-inflammatory steroid drug. The dexamethasone acetate minimizes inflammatory responses, very similar to common medical devices, such as pacemakers.

Specially designed sensor insertion tools are provided for subcutaneous insertion of the sensor. Other equipment necessary for the procedure, but not included in the Eversense Insertion Tool Pack, is listed in *Section 4*.

### Eversense 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 vibrate alerts based on the pre-set glucose level settings. It has a rechargeable battery and is reusable for up to one year. Adhesive patches included with the Eversense Insertion Tools Pack are provided for the patient to replace daily.

### Eversense App

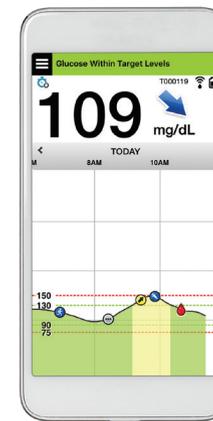
The Eversense App is a software application that runs on a mobile device (e.g., smartphone) and displays glucose data in a variety of ways. It also provides alerts based on the pre-set glucose level settings.



Sensor



Smart Transmitter



Eversense App

**Note:** Not actual size

## 2. Benefits and Risks

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Continuous glucose monitoring aids in the management of diabetes and glucose control, which can improve your patient's quality of life. Best results are achieved when the user is fully informed about the risks and benefits, insertion procedure, follow-up requirements, and self-care responsibilities. Patients should not have the sensor inserted if they 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). Glucose levels in ISF lag behind glucose levels in blood by several minutes.

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

### Indications for Use

The Eversense CGM System is indicated for continually measuring glucose levels in adults (18 years or older) with diabetes for the operating life of the sensor.

The system is intended to:

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

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

The system is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices.

## Contraindications

The sensor and smart transmitter are incompatible with magnetic resonance imaging (MRI) procedures. DO NOT undergo an MRI procedure while the sensor is inserted or when wearing the smart transmitter. Should an MRI be required, please contact your physician to arrange for sensor removal before the procedure.

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

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

## Risks and Side Effects

The glucose alerts and notifications will not audibly notify the user when the sound on their mobile device is turned off. If the system cannot display a glucose value, it also cannot provide glucose alerts. If the patient is unable to feel the vibration of the smart transmitter he/she may not notice the alerts. The system's calculated glucose can be slightly different from a blood glucose meter. This may cause an alert to activate at a different time than they would have if the system's values always matched the blood glucose meter values. If the patient does not take frequent blood glucose measurements and misses an alert, he/she may not be aware of high or low glucose levels. Medical attention may be needed in the event that he/she has high or low glucose and is unaware of it. If the patient does not test their glucose with a blood glucose meter when symptoms of a low or high blood glucose level appear OR when symptoms are not consistent with the sensor glucose readings, he/she may miss a high or low glucose event. If a patient does not always test glucose with a blood glucose meter before making a treatment decision, he/she may inadvertently cause a high or low blood glucose value because actual glucose values can be slightly different than the system's displayed values.

The sensor is inserted by making a small incision and placing it under the skin. This process may cause infection, pain or skin irritation. Additionally, the adhesive may cause a reaction or skin irritation.

## Warnings

- The Eversense CGM System has not been tested using insertion sites other than the upper arm.
- Patients should always test glucose with a blood glucose meter before making a treatment decision. Using the sensor glucose value to make a treatment decision could result in a high or low blood glucose.
- If at any time there are symptoms of a low or high glucose level OR if patient symptoms are not consistent with the sensor glucose readings, patients should test glucose levels with a blood glucose meter.
- Patients should not use a smart transmitter if it is damaged or cracked as this could result in electrical shock.
- Patients should avoid close contact with electromagnetic interference (EMI) while wearing the 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.
- The system should only be calibrated using a fingerstick blood sample. Alternative sites (such as forearm or palm) should not be used to calibrate the system.
- Infusion sets for insulin pumps should not be inserted 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.

## Precautions

- The sensor and sensor holder are sterile in the unopened, undamaged, sterile package. The sensor should not be used if the sterile package has been opened or damaged.
- A sensor should not be inserted if it has been dropped from a height greater than 30 cm.
- Use only the insertion tools provided in the insertion tool kit to insert the sensor. Other insertion tools may damage the sensor.
- Instruct patients to notify airport security personnel of the presence of the device when going through the security system.
- Patients should NOT exchange smart transmitters with another person. Each smart transmitter can be linked to only one sensor at a time.
- The following medical therapies or procedures have not been tested with the Eversense Sensor and 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.
- Patients should 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 physician 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.
- **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.
- If the sensor, insertion site or smart transmitter feels warm, the patient should remove the smart transmitter immediately and contact his/her physician for further advice. A warm sensor could mean there is an infection or a sensor malfunction.

## Precautions (continued)

- Patients should remove the smart transmitter from the body before charging the smart transmitter battery. Failure to remove the smart transmitter while it is charging could result in electrical shock.
- Patients should NOT attempt to use the Eversense App while operating a motor vehicle.
- Patients should not receive massage therapy near the inserted sensor site. Massage therapy near the sensor site could cause discomfort or skin irritation.
- Patients should 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 the warranty.
- If the patient has any concerns about allergic reaction to adhesive products containing silicone, he/she should contact the physician prior to use. The Eversense adhesive patch should be discarded after 24 hours of use.
- Patients should not change the unit of measurement unless they have discussed it with their physician. 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 the user missing a high or low glucose event.
- Patients should follow their health care provider's recommendation for setting their glucose alerts. Incorrectly setting the glucose alerts can result in the user missing a high or low glucose event.
- Patients should pay attention to the glucose alerts the system provides. Failure to appropriately respond to an alert might result in the user missing a high or low glucose event.
- The Eversense CGM System has not been tested in the following populations: women who are pregnant or nursing, people under the age of 18, critically ill or hospitalized patients, people receiving immunosuppressant therapy, chemotherapy or anti-coagulant therapy, those with another active implantable device, e.g., an implantable defibrillator (passive implants are allowed, e.g., cardiac stents), those with known allergies to or using systemic glucocorticoids (excluding topical, optical or nasal, but including inhaled).

## 3. Eversense CGM System Candidates and Pre-Insertion Activities

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### Candidate Selection

Per ACE/AACE guidelines\*, potential candidates for CGM include those patients:

- Taking insulin to treat their T1 or T2 diabetes, and motivated to optimize their blood glucose management with the addition of new glucose monitoring technology.
- Able to follow device labeling and use their blood glucose meter results to make treatment decisions.
- Have hypoglycemic unawareness/frequent hypoglycemia.
- With their hemoglobin A1c (HbA1c) over target, or with excess glycemic variability – requiring HbA1c lowering without increased hypoglycemia.

### Eversense CGM System Candidates

- Must have a compatible Android or IOS device, be familiar with its functionality and have WiFi connectivity. For a list of compatible devices, visit [eversenseddiabetes.com](https://eversenseddiabetes.com).
- Not planning on having an MRI in the next 90 days.
- Willing to enter a calibration blood glucose (BG) into the app twice a day.
- Discuss appropriate placement of sensor insertion and smart transmitter wear.
- No known contraindication to dexamethasone acetate.

- Does not take high, chronic doses of aspirin (over 2 g/day) or IV Mannitol.
- Is not pregnant or under the age of 18.

\* Blevins T, Bode B, Garg S, Grunberger G, Hirsch I, Jovanovic L, et al. Statement by the American Association of Clinical Endocrinologists Consensus Panel on Continuous Glucose Monitoring. *Endocrine Practice*, 2010; 16(5): A.

### **Pre-Insertion Training Activities for Patient**

- Download Eversense App to compatible mobile device (requirements are listed in User Guide) and become familiar with functionality.
- Discuss the importance of setting the correct “Unit of Measure” in the Eversense App.
- Go to [eversensediabates.com](http://eversensediabates.com) – view insertion animation video, download Quick Reference Guide (QRG) and/or User Guide for review.

### **To pair Smart Transmitter with Compatible Mobile Device**

- Confirm the patient has downloaded the Eversense CGM App from the App Store or Google Play store.
- Charge smart transmitter for 15 minutes
- Pair smart transmitter to mobile device.
- Set system preferences according to doctor recommendations.
- Instruct patients to bring smart transmitter and mobile device to clinic if it was shipped to patient’s home.

## 4. Eversense CGM System Kit

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The Eversense CGM System Kit comes in three packages: 1) Sensor Pack, 2) Insertion Tools Pack, and the 3) Smart Transmitter Pack.

**IMPORTANT:** The Sensor Pack and Insertion Tools Pack contain components that are packaged sterile. Both packs are designed for single patient-use only. DO NOT re-use, re-process or re-sterilize the sensor, blunt dissector, or insertion tool.

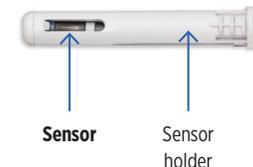
**Items Not Included:** Other procedure instruments, tools and equipment are not included and must be provided by the clinic.

### 1. Eversense Sensor Pack (Sensor in holder)

The **Sensor** is shipped sterile inside a protective holder for safe handling purposes. You will need to transfer the sensor to the insertion tool before use. The pouch that holds the sensor is not sterile.

The sensor is approximately 3.5 mm x 18.3 mm and is subcutaneously inserted using the insertion tool. The sensor has a silicone ring that contains an anti-inflammatory steroid drug (dexamethasone acetate). Upon exposure to body fluids the dexamethasone acetate is eluted from the ring in the area near the sensor. The dexamethasone acetate minimizes inflammatory responses, very similar to some already available medical devices (e.g., pacemaker leads).

**IMPORTANT:** Store the sensor pack refrigerated at the labeled temperature range.



## 2. Eversense Insertion Tools Pack

(Incision Template , Blunt Dissector, Insertion Tool, Tray, Adhesive Patches, and Insertion/Removal Instructions)

The **Incision Template** is used to guide and mark the incision area on the skin surface by aligning the marking template to the marked outer edges of the smart transmitter when placed in a comfortable position.

The **Blunt Dissector** is used to create the subcutaneous pocket for insertion of the sensor. This tool has two depth guards to help prevent the pocket from being made too deep in the skin. The depth guards have guide marks to assist in determining the length of the subcutaneous pocket for placing the sensor.

The **Insertion Tool** is used to insert the sensor inside the subcutaneous pocket created with the blunt dissector. It has two guide marks on the cannula to assist in proper placement.

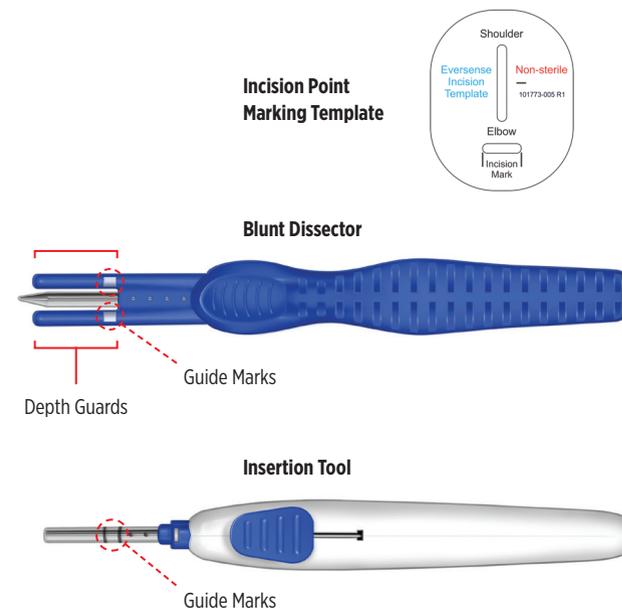
The **Adhesive Patch** (90 patches in pack) has an adhesive side that attaches to the back of the smart transmitter and a silicone adhesive side that attaches to the skin intended to be changed daily.

## 3. Eversense Smart Transmitter Pack

(Smart Transmitter, Power Supply, User Guide, Quick Reference Guide)

The **Smart Transmitter** is the reusable and rechargeable device worn externally over the sensor. The smart transmitter wirelessly powers the sensor. Use only the **Power Supply** included in this kit to charge the smart transmitter.

The **User Guide** and **Quick Reference Guide** are designed for the patient to learn about their Eversense CGM System.



## 5. Product Handling

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The sensor package, blunt dissector, and insertion tool have been sterilized by the method indicated on the package labels.

Inspect the condition of the sterile package before opening and using the contents.

- DO NOT use the contents if the package is broken or torn, or if contamination is suspected because of a defective sterile package seal.
- DO NOT re-sterilize the sensor or the components by any sterilization method.
- DO NOT use the product if the labeled “Use By” date has passed.

### **Handling and Storage**

- Handle the sensor and all other components with care, using appropriate aseptic technique.
- DO NOT open any of the sterile packages until ready for use.
- Keep sharp instruments away from the kit components.
- DO NOT use the sensor or any kit component if it has been dropped on a hard surface from a height of more than 30 cm.
- Store the sensor package refrigerated at the labeled temperature range.
- Dispose of product packaging in accordance with clinic, administrative and/or local government policy.

## 6. Suggested Equipment

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**Items Not Included:** Other procedure instruments, tools and equipment are not included in insertion tool kit and must be provided by the clinic. Please see list of suggested equipment below.

***Materials (or equivalent) suggested for sensor insertion/removal:***

- Chlorhexidine OR Betadine solution
- 2-3 Sterile Gauze Pads
- 1 Disposable Sterile Scalpel (e.g., Disposable Sterile Scalpel, #15)
- 1 Sterile Syringe and Needle (for lidocaine injection)
- Steri-Strip Adhesive Skin Closure and/or available sutures (physician preference)
- 1 sterile scissors (e.g., disposable) to cut steri strips
- 1 Sterile Towel Drape
- 1 Sterile Drape with aperture approximately 22 in x 25 in
- 2 Tegaderm™ + Pad Film Dressing
- 1 Lidocaine HCL without epinephrine (1-2 mL)
- 1 Surgical skin marker
- 3 Sterile, non-latex surgical gloves, physician-preferred size
- 1 10 mL sterile saline filled syringe (for insertion only)
- 1 Sterile Hemostat (for removal only)

# 7. Insertion Procedure

Before inserting the sensor, confirm that the patient:

- Does not plan to have an MRI within 90 days after sensor insertion.
- Does not have allergies to the antiseptic and local anesthetic to be used during insertion.

**Note:** The procedure below assumes a right handed physician with the patient facing (left arm insertion) or looking away from (right arm insertion) the physician. The dimensions indicated in the instructions are approximate to give a conceptual context of the insertion.

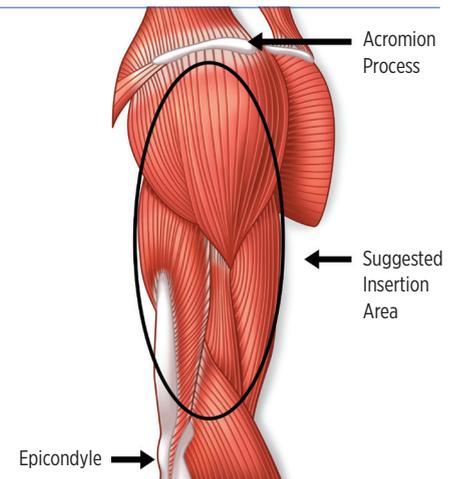
## A. Prep the Insertion Area

1. With the subject seated on the procedure table, position the smart transmitter on the patient's arm to select the insertion location for the sensor. It is recommended to alternate arms for subsequent insertion sites.

Suggested insertion location is approximately at the midway point between the acromion process and the lateral epicondyle.

Things to consider when choosing insertion location:

- It must be comfortable for the user to wear 24/7 for 90 days. Place the smart transmitter on the intended site and confirm that the patient is comfortable with the placement.
- Not too lateral such that patient cannot easily apply adhesive patch.
- Avoid area with loose skin such as back of arm.
- Avoid areas with scar tissue, tattoo, nevus, or apparent or noticeable blood vessels that could be incised.



2. Once the position for the smart transmitter is selected, mark the corners on the skin.
3. Using the non-sterile incision template, align the template inside the marked lines and mark the skin for the incision using the incision template's slot.
4. Position the patient in a reclined position preferably on their side, with the elbow flexed up to 90 degrees and the palm resting on the chest or abdomen.

## B. Open the Sensor Pack and Insertion Tools Pack

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Over the prepared sterile field, remove the sensor holder from the Sensor pouch and remove the sterile inner tray with tools from the Insertion Tools Pack and place in the sterile procedure field created for the procedure. Note that the inner tray of the Sensor Insertion Package is sterile and can be placed within the sterile procedure field.

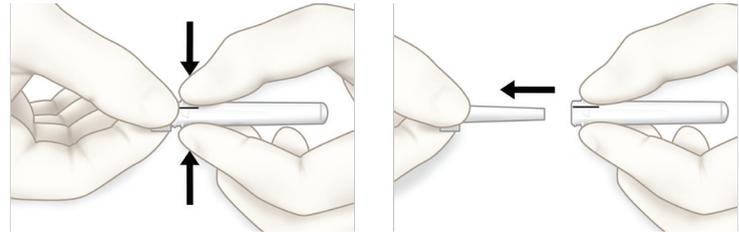
### Precautions

- The sensor and sensor holder are sterile in the unopened, undamaged, sterile package. The sensor should not be used if the sterile package has been opened or damaged.
- DO NOT insert a sensor if it has been dropped from a height of 30 cm or more.
- Use only the insertion tools provided in the insertion tool kit to insert the sensor. Other insertion tools may damage the sensor.

## C. Prepare the Sensor

1. Remove the cap from the end of the sensor holder by pressing the ridged portion and pulling the cap.

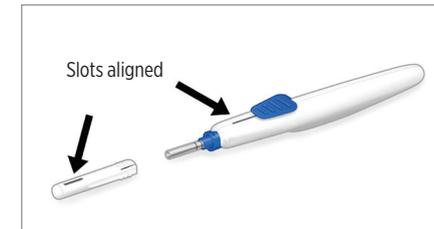
Discard the cap.



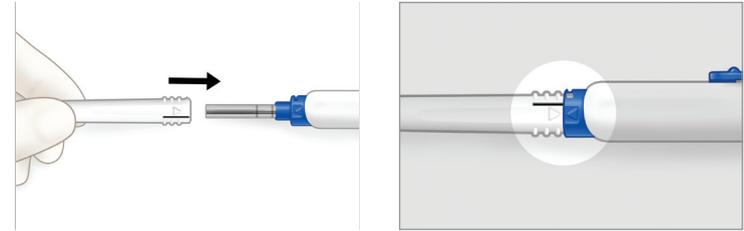
2. Align the insertion tool cannula and sensor holder.

Ensure that the blue thumb slide is still in the retracted position.

Align the slot of the sensor holder with the exposed slot of the thumb slide and the triangle on the side of the sensor holder with the triangle on the insertion tool.



**3. Slide the sensor holder over the insertion tool cannula so that the two triangles are touching at the tip.**



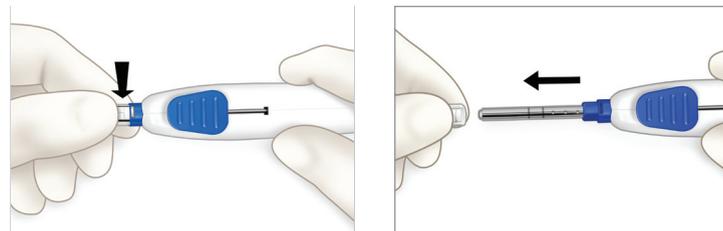
**4. Depress the blue thumb slide down to unlock and advance it all the way forward until it stops.**

This action secures the sensor inside the cannula. The cannula is now visible through the slot in the sensor holder.  
DO NOT RETRACT the thumb slide at this step.



**5. Depress the ridged portion of the sensor holder to remove it from the insertion tool.**

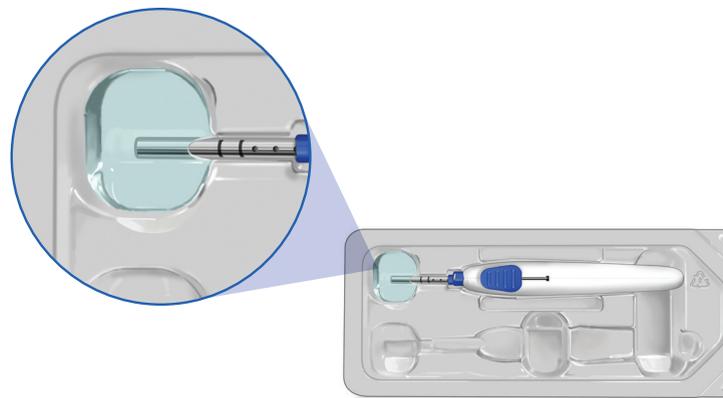
Discard the sensor holder. You should see the tip of the sensor at the end of the insertion tool.



**6. Place the insertion tool back in its original placement in the tray.**

The insertion tool will snap into position in the insertion kit inner tray and the tip of the cannula with the sensor will be positioned in the preformed well in the tray.

**7. Wet the cannula and sensor by filling the preformed well with enough sterile saline (0.95 sterile saline for injection) to completely cover the cannula and sensor (approximately 10 mL). To ensure proper hydration, submerge the tip in the well for a few minutes (approximately 5 minutes).**



## D. Clean and Anesthetize the Insertion Area

1. If not done previously, position the patient in a reclined position, preferably on their side, with the elbow flexed up to 90 degrees and the palm resting on the chest or abdomen.
2. Clean and disinfect the insertion area.  
Apply disinfectant chlorhexadine to marked area. Cover the arm with sterile drape so opening is around incision site.
3. Anesthetize the insertion area as appropriate.  
Local anesthesia (approximately 2 mL of Lidocaine) should be injected approximately 5-8 mm along the planned incision (along AB) and approximately 30 mm perpendicular to the planned incision (along CD) which is the planned track of the blunt dissector tool. (Figure 1).

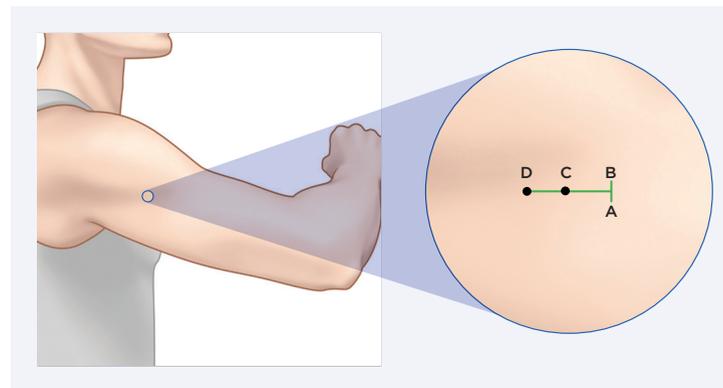


Figure 1

## E. Make Incision and Subcutaneous Pocket

1. Once the insertion area is sufficiently anesthetized, make an approximately 5-8 mm incision at the insertion location such that you will be able to create an appropriately sized subcutaneous pocket approximately 3-5 mm below the skin surface.

Start incision at point B (Figure 1) and go towards point A, until the incision is approximately 5-8 mm.

2. Remove the blunt dissector from the tray and introduce the blunt dissector at approximately a 45 degree entry angle at the midpoint between A and B (Figures 1 & 2) so that the tip and tapered portion of the blunt dissector are under the skin, and until the depth guards are touching the skin.

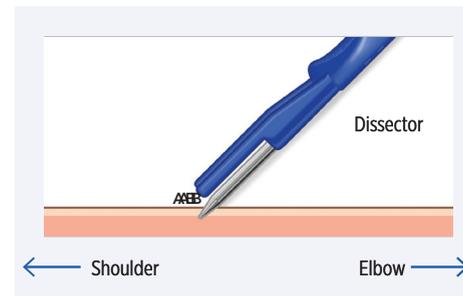


Figure 2

3. With the tips of the depth guards on the skin and the blunt dissector at the subcutaneous space, lower the angle of skin entry to approximately 5-10 degrees (Figure 3) taking care to ensure that the fingers are not under the metal rod or plastic portions of the tool which would cause a steeper angle.

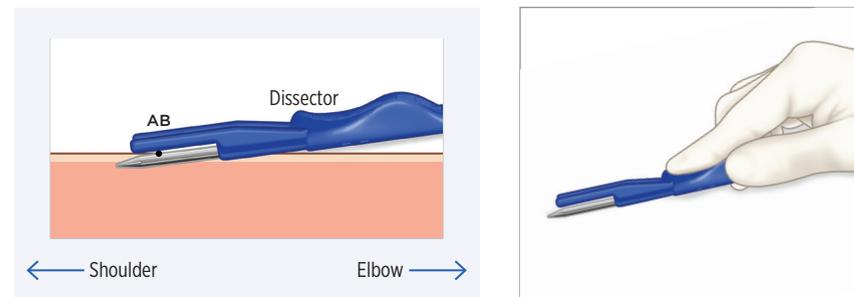


Figure 3

4. Move the blunt dissector toward the shoulder, while maintaining the metallic and plastic parts of the tool in close contact with the skin to ensure the smallest possible angle of the pocket with respect to the skin (Figure 3).

Continue advancing the tool until the incision between A and B is within the white guide marks on the depth guards (Approximately 25-30 mm) (Figure 4). Completely retract the blunt dissector and set aside.

**Note:**

- Pinching and tenting the skin can aid in forming a small space in the skin for insertion.
- Rotating the blunt dissector (+/- 45 degrees) along the axis of the tool is also helpful.
- DO NOT create a pocket more than 3-5 mm below the skin. If the sensor is placed too deep, it may be difficult to communicate with the smart transmitter or to later remove.
- It is important to ensure that the subcutaneous pocket is parallel to and along the same axis as the humerus bone. When you place the sensor, it should be level in the pocket, which will facilitate communication between the sensor and the smart transmitter.

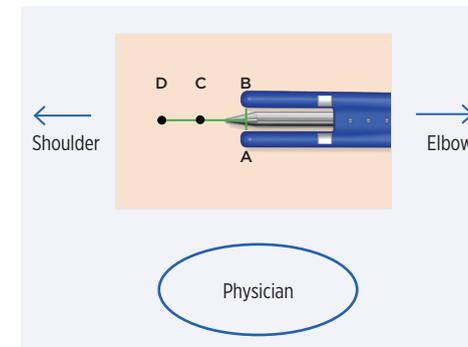
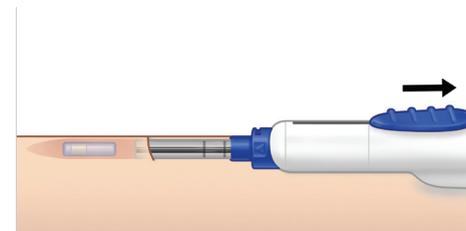
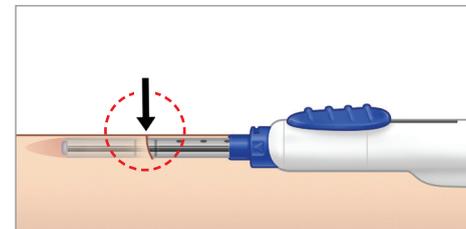


Figure 4

## F. Sensor Placement and Incision Closure

1. Using approximately a 45 degree entry angle, place the tip of the insertion tool into the incision opening such that the tip of the cannula is beneath the incision.
2. Similar to steps E3 & E4, lower the entry angle to about 5-10 degrees and advance toward the shoulder following the pocket created by the blunt dissector.
3. Advance the tool until the incision line is between the first and second marked lines on the cannula.  
If necessary, re-use the blunt dissector or widen the incision if excessive force is encountered. DO NOT force the insertion tool into the incision site.
4. Pushing down on the back of the thumb slide to unlock it, retract the thumb slide to deploy the sensor into the pocket.  
The slide locks into place when it has reached the end point. DO NOT re-advance the thumb slide.
5. Lightly palpate the insertion area to confirm that the sensor is in place; remove the insertion tool from the incision.
6. Close and dress the incision in the appropriate manner using adhesive skin closure (e.g., Steri-Strip™) or suture and dressing, making sure the two sides of the incision are closed together.



## G. Insertion Tool and Blunt Dissector Disposal

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Dispose of used insertion tool and blunt dissector in accordance with clinic, administrative and/or local government policy.

## H. Connecting the Eversense CGM System

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1. Confirm the patient's mobile device has been paired with the Eversense App and has an internet connection.
2. Link the sensor to the smart transmitter.
  - a. Place the smart transmitter directly over the bandage.
  - b. On the Eversense App, use the Placement Guide screen to confirm there is a signal.
  - c. Navigate away from the Placement Guide page once you have confirmed there is a signal.

**Note:** It may take up to 5 minutes to receive the notification for "New Sensor Detected". DO NOT remove the smart transmitter from over the insertion site until the linking process is complete. You may use the Eversense adhesive to place the smart transmitter over the bandage of the insertion site.

Refer to the *Eversense CGM System User Guide, Inserting and Linking the Sensor* for additional information.

## 8. Post-Insertion Patient CGM Start-Up

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Your patients may need assistance in getting started with the Eversense CGM System. Refer to the User Guide and Quick Reference Guide that is included in the smart transmitter pack for information on getting the smart transmitter and mobile device ready for use.

This includes:

- Charging the smart transmitter.
- Downloading the Eversense App to their mobile device.
- Personalizing the patient's glucose settings.
- Pairing (connecting) the smart transmitter and app.
- Linking the smart transmitter with the sensor after the sensor is inserted.

### **Note:**

- All but the linking step can be completed before the sensor is inserted.
- Patients do not need to secure the smart transmitter over the sensor during the first 24 hours after insertion. After the sensor is linked to the smart transmitter, the sensor requires 24 hours to stabilize in the body before glucose values can be calculated by the smart transmitter.
- If the smart transmitter is secured over the sensor within the first 24 hours after insertion, the patient will receive a message indicating a Warm-Up Phase status of the system and will provide the patient with a 24-hour countdown.
- If the smart transmitter is not secured over the sensor and turned off to avoid vibrations, patient must remember to turn smart transmitter back on at the 24th hour. It will take about 5 minutes after the smart transmitter is placed over the sensor for the first calibration prompt to be displayed. After calibration is completed, the smart transmitter should not be removed for 15 minutes.
- Glucose readings will appear on screen after successfully completing the 2nd calibration.

Review the Eversense User Guide to help facilitate your patient's understanding of their new Eversense CGM System and determining their personalized glucose settings.

## 9. Sensor Removal Procedure

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### A. Locate the Sensor

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1. Using the initial incision point as a guide, palpate and locate the sensor to determine an appropriate incision location. For reference, mark both ends of the sensor if possible to palpate.

**Note:** If the sensor cannot be located by palpating, the smart transmitter may be used to aid in locating the sensor. To use the smart transmitter to locate the sensor, open the Placement Guide page in the App. Move the smart transmitter around the sensor insertion area until the screen displays the greatest signal strength. Mark the edges of the smart transmitter at this location and use the incision template to determine the proper incision location.

2. Mark the incision point on the skin.

If the site of the original incision is within 3-5 mm of the distal tip of the sensor, removal can be accessed through the same location.

### B. Prep the Removal Area

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1. Position the patient in a reclined position, preferably on their side, with the elbow flexed up to 90 degrees and the palm resting on the chest or abdomen.
2. Clean and disinfect the insertion area.  
Prepare the insertion site and surrounding area, using aseptic technique.
3. Anesthetize the insertion area as appropriate for the patient similar to step D3 in section 7.

## C. Incision and Pocket Opening

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1. Push down on the skin over the expected location of the proximal end of the sensor to stabilize it.
2. Create approximately a 5-8 mm incision through the dermis at the location determined in A1.

## D. Remove the Sensor

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1. Carefully dissect the subcutaneous tissue until the end of the sensor distal to the incision can be grasped by a small hemostat (such as a 10-15 cm hemostat). Spreading of the tissue through the incision using the hemostat both parallel and perpendicular to the incision may be required to enable visualization and grasping of the sensor with the hemostat.
2. Put gentle pressure on the proximal end of the sensor through the skin to help stabilize and facilitate grasping the distal end of the sensor. Use a hemostat to grasp the distal end of the sensor and remove it from the pocket. Rotation of the sensor with the hemostat may aide in freeing the sensor from any attached tissue.
3. If the sensor is encapsulated, further dissection may be necessary to grasp and remove the sensor.

## E. Close and dress the incision in the appropriate manner

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1. Close and dress the incision in the appropriate manner using adhesive skin closure (e.g., Steri-Strip™) or suture, making sure the two sides of the incision are closed together.

## F. Sensor Disposal

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1. Dispose of sensor according to your area's local regulations.

# 10. Potential Complications

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The insertion and removal of the Eversense Sensor is a minor procedure and requires aseptic technique to minimize the possibility of infection. Please review this document for complete training.

## A. During Insertion Process

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### 1. Unable to insert blunt dissector through incision

**a. Incision may be too small**

Increase incision size by 2-3 mm and re-insert the blunt dissector.

**b. Refer to tips for proper insertion technique in this document**

- Pinching or tenting the skin can aid in forming a small pocket for the insertion.
- Rotating the blunt dissector (+/- 45 degrees) along the axis of the tool can be helpful.
- DO NOT create a pocket more than 3-5 mm below surface of skin.

### 2. Unable to advance the insertion tool into the subcutaneous pocket

**a. Ensure the insertion tool is below the incision when advancing into subcutaneous pocket**

**b. Incision size may be too small**

Increase incision size by 3-5 mm with scalpel and re-insert the insertion tool.

### 3. Unable to locate the subcutaneous pocket with the insertion tool when inserting the sensor

Re-insert the blunt dissector into incision to ensure subcutaneous pocket is adequate.

### 4. Subject experiences pain during the procedure

Administer additional local anesthetic as required.

### 5. Excessive bleeding after incision is made

Apply pressure until bleeding subsides.

## B. During Removal Process

---

### 1. Unable to palpate/locate the sensor

Use the Placement Guide on the app and the smart transmitter to find the sensor. Once the location of the sensor is made with the Placement Guide, mark the position of the smart transmitter on the skin and use the incision template to mark the point of incision. In some cases, an ultrasound may be required to locate the proper point of the incision.

### 2. Excessive bleeding after the sensor is removed

Apply pressure and, if necessary, use sutures to close incision in place of Steri-Strips™.

### 3. Subject experiences pain during the procedure

Administer additional local anesthetic as required.

### 4. Tissue encapsulation prevents sensor from moving

Dissect encapsulation by spreading the tissue using the hemostats/or other desired instrument as required. Gently rotate sensor during removal to break free from tissue encapsulation.

## II. Device Performance

*This section lists Device Performance Characteristics.*

### Clinical Study Performance

The performance of the Eversense CGM System was evaluated in a multi-site, non-randomized pivotal clinical study. Adult subjects (18 years and older) with diabetes were enrolled at 8 sites in the U.S. Each had a sensor inserted in the upper arm to collect glucose data but not be displayed to the subject. Some subjects had a sensor inserted into each arm for clinical data collection. Subjects interacted with the system to calibrate and address notifications not related to glucose data. Accuracy assessments were made at various points during the study, and subjects were asked to report any adverse events throughout the study. The Mean Absolute Relative Difference (MARD) measured throughout the 90 days was 8.5% for values between 40 and 400 mg/dL (2.2 to 22.2 mmol/L).

### System Performance Compared to Reference (YSI) System

The tables that follow show the percentage of CGM system glucose values that fall within an absolute or percentage range of the YSI reference values. Data are presented separately for reference values  $\leq 80$  mg/dL and  $> 80$  mg/dL.

YSI Glucose Range (mg/dL)	Number of Paired Eversense CGM and YSI Reference Values	Percent of System Readings Within			
		15 mg/dL of Reference	20 mg/dL of Reference	30 mg/dL of Reference	40 mg/dL of Reference
$\leq 80$	1,654	85.9	92.8	98.0	99.3

YSI Glucose Reference Range (mg/dL)	Number of Paired Eversense CGM and YSI Reference Values	Percent of System Readings Within			
		15% of Reference	20% of Reference	30% of Reference	40% of Reference
$> 80$	14,099	86.9	94.5	98.7	99.6

## Clarke Error Grid Analysis

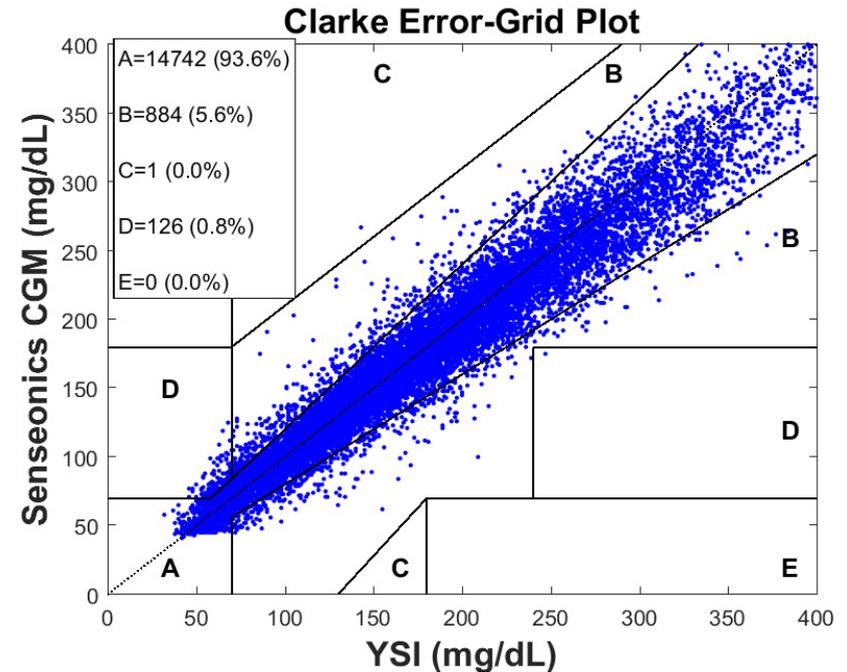
The Clarke Error Grid Analysis (EGA) is one of the standards for quantifying the accuracy of CGM systems. Clarke EGA measures accuracy by comparing subject glucose values taken from their CGM system to reference values taken in a lab.

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

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

## Clarke Error Grid Scatterplot

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



### Clarke Error Grid Accuracy by Glucose Level

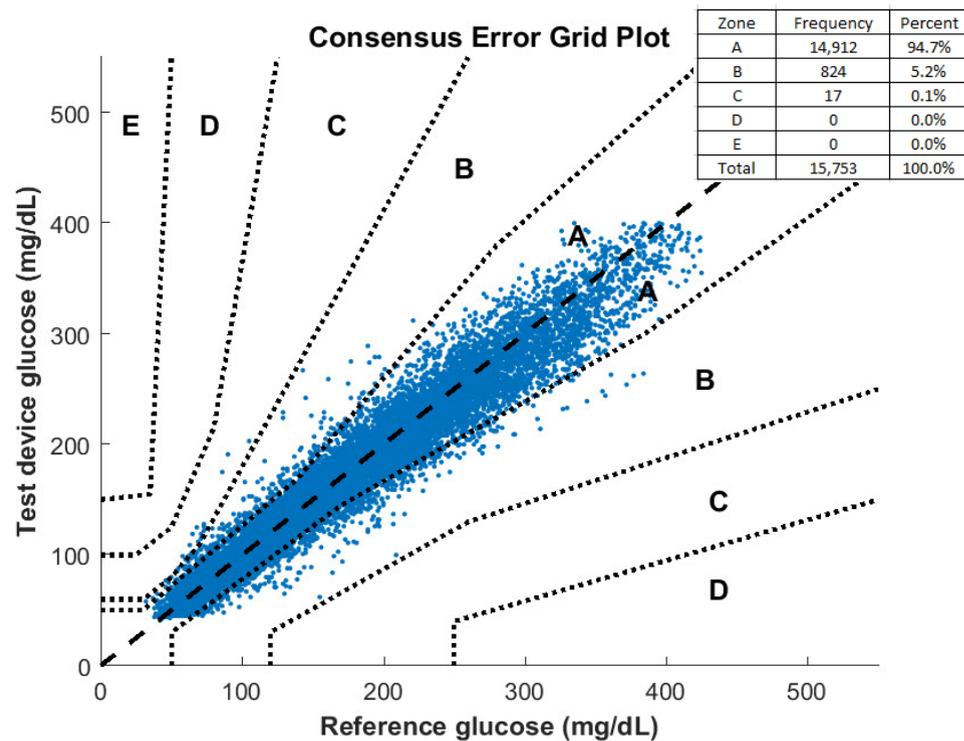
Reference Glucose Range (mg/dL)	Number of Paired System – Reference Readings	N / % by Zone				
		A (95% CI)	B	C	D	E
≤ 70	1,072	942 / 87.9% (85.8 - 89.8%)	5 / 0.5%	0 / 0.0%	125 / 11.7%	0 / 0.0%
71 - 180	8,122	7,494 / 92.3% (91.7 - 92.8%)	627 / 7.7%	1 / 0.0%	0 / 0.0%	0 / 0.0%
> 180	6,559	6,306 / 96.1% (95.6 - 96.6%)	252 / 3.8%	0 / 0.0%	1 / 0.0%	0 / 0.0%
Overall	15,753	14,742 / 93.6% (93.2 - 94.0)	884 / 5.6%	1 / 0.0%	126 / 0.8%	0 / 0.0%

Overall, 93.6% of Eversense CGM readings fell within zone A. This indicates CGM readings were in close agreement with reference values for the great majority of readings.

## Consensus (Parkes) Error Grid Analysis

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

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



### Consensus Error Grid Accuracy by Glucose Level

Zone	Frequency	Percent
A	14,912	94.7%
B	824	5.2%
C	17	0.1%
D	0	0.0%
E	0	0.0%
Total	15,753	100.0%

Overall, 94.7% of CGM readings fell within zone A. This indicates CGM readings were in close agreement with reference values for the great majority of readings.

## Calibration Performance

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

Time from Calibration	Number of Paired Senseonics CGM and Reference	Percent of System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent Greater than 40/40% of Reference
0 - 2 Hours	4,347	85.0	92.2	97.8	99.3	0.7
2 - 4 Hours	2,800	87.5	94.8	98.9	99.7	0.3
4 - 6 Hours	2,396	85.5	93.8	98.5	99.7	0.3
6 - 8 Hours	2,115	87.6	95.6	99.1	99.6	0.4
8 - 10 Hours	2,019	87.8	95.9	99.3	100.0	0.0
10 - 12 Hours	1,815	88.9	95.8	98.8	99.6	0.4

Overall, the CGM accuracy is consistent in all time periods after calibration.

## Sensor Life

Sensor life measured the percentage of sensors being able to function through the intended 90 day duration. Overall, the analysis estimated that 91% of sensors remained functioning through 90 days.

## Safety

The number of related adverse events was recorded over the 90 day study period. The Eversense CGM System was extremely well tolerated in the study. During the study's 9,773 sensor wear days, there were no unanticipated adverse events. Fourteen adverse events were reported in 7 subjects, including one serious adverse event related to the removal procedure. There were no infections. Mild irritation, pain and redness at the insertion sensor site were observed at a low rate of occurrence. None of the adverse events resulted in hospitalization.

## 12. Technical Specifications

Sensor	Description
Length	18.3 mm
Diameter	3.5 mm
Materials	Homopolymer polymethylmethacrylate (PMMA), Hydroxyethylmethacrylate (HEMA) based Hydrogel, Platinum, Silicone, Dexamethasone Acetate, epoxy 301-2
Storage Temp	Between 36° F (2° C) and 46° F (8° C)
Sterilization	Sterile by Ethylene Oxide

Blunt Dissector	Description
Materials	Acrylonitrile butadiene styrene (ABS), Stainless Steel
Storage Temp	Between 50° F (10° C) and 86° F (30° C)
Sterilization	Sterile by Ethylene Oxide

Insertion Tool	Description
Materials	Acrylonitrile butadiene styrene (ABS) and Polytetrafluoroethylene (PTFE); Cyanoacrylate adhesive and Stainless Steel
Storage Temp	Between 50° F (10° C) and 86° F (30° C)
Sterilization	Sterile by Ethylene Oxide

Sensor Holder	Description
Materials	Acrylonitrile butadiene styrene (ABS) and Polytetrafluoroethylene (PTFE)

Power Supply and Charger	Description
Class	II
Input	AC Input, 100-240Vac, 50/60Hz, 0.3-0.15A
DC Output	5V DC, 1A (5.0 watts)
Moisture Protection	IP22

USB Cable* for Charging and Downloading	Description
Input/Output	5V DC, 1A
Type	USB-A to USB micro-B
Length	36 inches (91 cm)

\*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.

System component	Part Number
Eversense Smart Transmitter Kit	FG-3300-01-001
Charging Cable	FG-6100-00-301
Charging Adapter	FG-6201-91-301
Charging Cradle	FG-6600-00-301
Eversense Adhesive Patches, White, 30 Pack	FG-6402-01-300
Eversense Adhesive Patches, Clear, 30 Pack	FG-6401-01-300
Eversense Quick Reference Guide	LBL-1603-01-001 (mg/dL)
Eversense CGM User Guide	LBL-1602-01-001 (mg/dL)
Eversense Data Management Software Application	FG-5700-01-300
Eversense Mobile Application iOS	FG-5500-01-300
Eversense Mobile Application Android	FG-5600-01-300
Eversense Sensor Kit	FG-4200-00-301
Eversense Insertion Tools Kit	FG-5211-01-201

## Symbols on Packaging and Device

Symbol	Explanation
	Consult accompanying documents
	Caution, consult accompanying documents
	Use by
	Manufacturer
	Authorized representative in the European Community
	Date of manufacture
	Storage temperature limits

Symbol	Explanation
	Lot number
	Marking certifies that the device meets the European Council Directive 90/385/EEC
	Part number
	Serial number
	Type BF Applied Part
	Non-ionizing electromagnetic radiation
	Not made with natural rubber latex

Symbol	Explanation
	Universal Serial Bus (USB)
<b>FCC ID</b>	FCC ID is assigned to all devices subject to certification
	Magnetic Resonance Imaging (MRI) procedures are contraindicated for this device.
	European Union WEEE Directive 2012/19/EU
	Single use only
	Do not re-sterilize

Symbol	Explanation
	Do not use if package is damaged
<b>TERILE   EO</b>	Sterilized using Ethylene Oxide
	Non-sterile
<b>Rx only</b>	U.S. (Federal) law restricts the sale of the Eversense CGM System to sale by or on the order of a physician







Manufactured and Distributed by:  
20451 Seneca Meadows Parkway • Germantown, MD 20876-7005 USA  
Phone: 844.SENSE4U (844.736.7348) • 301.515.7260  
[www.eversenseddiabetes.com](http://www.eversenseddiabetes.com)



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