Eversense® E3

CGM Sensor Insertion and Removal Instructions

IMPORTANT:

- Only health care providers (physicians, physician assistants, and/or nurse practitioners) who have successfully completed the Eversense E3 CGM Insertion and Removal Training Program and have read and understood the Eversense E3 CGM Sensor Insertion and Removal Instructions may perform the insertion and removal procedure on patients. Contact Customer Support (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 (8am to 12am Eastern US time) will be returned as soon as possible. For a list of certified providers, contact Customer Support.
- 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 health care provider immediately.
- Store the sensor kit refrigerated at the labeled temperature range.
- Review the Eversense E3 CGM System User Guide to help facilitate your patient's understanding of their new Eversense E3 CGM System and determining their personalized glucose settings.

I. Overview of the Eversense E3 Continuous Glucose Monitoring (CGM) System

Congratulations on having Eversense E3 CGM technology to assist your patients in managing their diabetes. The Eversense E3 CGM System is for people with diabetes to continually measure glucose levels for up to 180 days from the time of sensor insertion.

Some of the features of the Eversense E3 CGM System:

- Wireless communication with the sensor, smart transmitter and app.
- Long-term sensor wear in the upper arm for up to 180 days.
- Alerts when pre-set Low or High Glucose Alert levels (hypoglycemia or hyperglycemia) are passed.
- 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 vibe alerts with the smart transmitter even when mobile device is not nearby.
- Provides readings within 40-400 mg/dL (2.2-22.2 mmol/L) 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 E3 CGM System Components

The System includes:

1) a small sensor inserted subcutaneously by a health care provider,

2) a removable smart transmitter worn over the sensor, and

3) a mobile app to display the glucose readings.

Eversense E3 Sensor

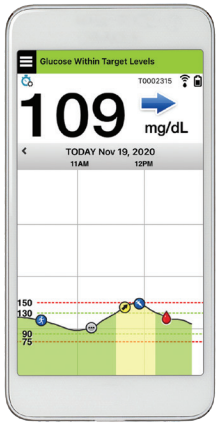
The sensor is inserted under the skin (upper arm) and measures glucose in interstitial fluid for up to 180 days. These glucose levels are then calculated by the smart transmitter and sent to the app. Sensors provided with the Eversense E3 CGM System include the sacrificial boronic acid (SBA) design modification.

The Eversense E3 Sensor lasts up to 180 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 Kit, is listed in *Section 4*.

Sensor

Smart Transmitter



Eversense App

Note: Not actual size

Eversense E3 Smart Transmitter

The removable smart transmitter is worn externally over the sensor and powers the sensor. It wirelessly sends glucose data (via Bluetooth) to the mobile app. The smart transmitter also provides on-body vibe alerts based on the pre-set glucose level settings. It has a rechargeable battery that is reusable for up to one year. Adhesive patches are shipped to the health care provider along with the Eversense Sensor Kit, and 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.

2. Benefits and Risks

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), and for some people, during the first several days after insertion due to inflammation that may result from the insertion procedure. Glucose levels in ISF lag behind glucose levels in blood by several minutes.

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

Failure to use the Eversense E3 CGM System in accordance with the instructions for use may result in missing a hypoglycemic or hyperglycemic glucose event, which may result in injury. In the *Eversense E3 CGM System User Guide* provided in the smart transmitter kit box for patients, the section titled *Understanding Treatment Decisions with CGM* provides instructions for patients.

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

The system is intended to:

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

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

The system is intended for single patient use.

MRI Safety Information

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

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

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

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

Contraindications

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

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

Mannitol or sorbitol, when administered intravenously, or as a component of an irrigation solution or peritoneal dialysis solution, may increase blood mannitol or sorbitol concentrations and cause falsely elevated readings of the patient's 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. Medical attention may be needed in the event that he/she has high or low glucose and is unaware of it.

IMPORTANT: If the patient does not check their glucose with a blood glucose meter when symptoms are not consistent with the sensor glucose readings, he/she may miss a high or low glucose event.

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

Patients should understand insulin action, and factor in its impact on glucose prior to making a treatment decision.

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

Warnings

- **The Eversense E3 CGM System has not been tested using insertion sites other than the upper arm.**
- **Before making treatment decisions, patients should take into account the sensor glucose value, the trend graph, the trend arrow and any alerts from the Eversense E3 CGM System. If no trend arrow is displayed, the system does not have enough data to display direction and rate of change. Treatment decisions should not be based solely on the sensor glucose value.**
- **If at any time a patient's 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.**
- **Antibiotics of the tetracycline class may falsely lower sensor glucose readings. Patients should not rely on sensor glucose readings while taking tetracyclines.**
- **The bandage should remain covering the incision for 48 hours as this is a standard of care to allow formation of a water-tight seal to help protect against infection. Until it has healed, patients should 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.**
- **Insulin should not be injected and infusion sets for insulin pumps should not be inserted within 4 in (10.16 cm) of the sensor site. If the insulin delivery site is within 4 in (10.16 cm) of the sensor site, it may interfere with sensor glucose readings and can cause inaccurate glucose readings.**
- **Patient should always follow health care provider's instructions for care after the sensor insertion or removal. Patients should contact their health care provider if any of the following events occur:**
  - **Pain, redness, or swelling at the incision site(s) later than 5 days after the sensor insertion or removal, or if the incision has not healed within 5 to 7 days.**

Warnings (continued)

- If sensor glucose is very low (below 40 mg/dL) or very high (above 400 mg/dL), the patient should perform a fingerstick blood glucose test prior to making a treatment decision.
- The Eversense E3 CGM System requires calibration in order to provide accurate readings. The patient should not use CGM readings to make treatment decisions unless he/she has followed the instructions for daily calibration.
- The Eversense E3 CGM System will not provide readings during the 24 hour Warm Up Phase and until a second calibration is successful during the Initialization Phase. During this time, the patient should monitor their glucose using a home blood glucose monitor.
- Certain conditions and alerts will prevent glucose data from being displayed. During these times, the patient should use a home blood glucose monitor to make treatment decisions. The patient should carefully read the *Alerts and Notifications* section of their *Eversense E3 CGM System User Guide* to understand these conditions.
- The glucose alerts and notifications will not audibly notify the patient when the sound on the mobile device is turned off. If the system cannot display a glucose value, it also cannot provide glucose alerts. If the patient is unable to feel the vibration of the smart transmitter he/she may not notice the alerts.
- When the smart transmitter is not worn over the sensor, such as during charging, the Eversense E3 CGM System will not provide alerts and notifications on the mobile device or via vibration alerts from the smart transmitter.
- If you are allergic to any of the materials used in the sensor or smart transmitter that are listed in the *Technical Specifications* of this User Guide, DO NOT use the Eversense CGM System.

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 system is to be used by a single patient in the home environment.
- The following medical therapies or procedures have not been tested with the Eversense E3 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, the smart transmitter should be removed before undergoing medical x-ray or CT scans.
- 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 health care provider for further advice. A warm sensor could mean there is an infection or a sensor malfunction.
- 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.

Precautions (continued)

- 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, create the risk of fire and could result in voiding the warranty. If the Eversense AC power adapter or USB cable is damaged or lost, he/she should contact Customer Support for a replacement to ensure safe operation of the device.
- If the patient has any concerns about allergic reaction to adhesive products containing silicone, he/she should contact the health care provider prior to use. The Eversense adhesive patch should be discarded after each use of up to 24 hours.
- Patients should not change the unit of measurement unless they have discussed it with their health care provider. Using the incorrect unit of measure could result in missing a high or low glucose event.
- Entering incorrect blood glucose values for calibration can result in inaccurate sensor glucose readings, which may result in 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 NOW Remote Monitoring App does not replace the monitoring regimen as directed by the health care provider.
- The Eversense E3 CGM System has not been tested in the following populations: women who are pregnant or nursing, people under the age of 18, critically ill or hospitalized patients, people receiving immunosuppressant therapy, chemotherapy or anti-coagulant therapy, those with another active implantable device, e.g., an implantable defibrillator (passive implants are allowed, e.g., cardiac stents), those with known allergies to or using systemic glucocorticoids (excluding topical, optical or nasal, but including inhaled). The system's accuracy hasn't been tested in these populations, and sensor glucose readings may be inaccurate, resulting in missing a severe low or high glucose event.

3. Eversense E3 CGM System Candidates and Pre-Insertion Activities

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 under certain conditions. See *Understanding Treatment Decisions with CGM* in the *Eversense E3 User Guide*.
- Have hypoglycemic unawareness/frequent hypoglycemia.
- With their hemoglobin A1c (HbA1c) over target, or with excess glycemic variability – requiring HbA1c lowering without increased hypoglycemia.

Eversense E3 CGM System Candidates

- Must have a compatible Android or IOS device, be familiar with its functionality and have internet connectivity. For a list of compatible devices, visit www.eversensediabetes.com.
- Willing to enter a calibration blood glucose (BG) into the app when prompted.
- Discuss appropriate placement of sensor insertion and smart transmitter wear.
- No known contraindication to dexamethasone acetate.
- Is not receiving mannitol or sorbitol, administered intravenously, or as a component of an irrigation solution or peritoneal dialysis solution, as this may increase blood mannitol or sorbitol concentrations and cause falsely elevated readings of sensor glucose results. Sorbitol is used in some artificial sweeteners, and concentration levels from typical dietary intake do not impact sensor glucose results.
- Is not pregnant or under the age of 18.

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 www.eversensediabetes.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 health care provider recommendations.
- Instruct patients to bring smart transmitter and mobile device to clinic if it was shipped to patient’s home.

* 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.

4. Eversense E3 CGM System Kit

The Eversense E3 CGM System Kit comes in four packages: 1) Sensor Kit, 2) Insertion Tools Kit, 3) Smart Transmitter Kit, and the 4) Adhesive Kit.

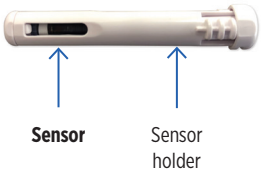
IMPORTANT: The Sensor Kit and Insertion Tools Kit contain components that are packaged sterile. Both kits are designed for single patient-use only. DO NOT re-use, re-process or re-sterilize the sensor, blunt dissector, or insertion tool.

Items Not Included: Other procedure instruments, tools and equipment are not included and must be provided by the clinic. To download the latest version of the Eversense Insertion and Removal Instructions, please visit: www.eversensediabetes.com/HCPUserGuides.

1. Eversense E3 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).

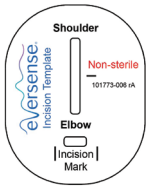
IMPORTANT: Store the sensor kit refrigerated at the labeled temperature range.

2. Eversense Insertion Tools Kit

(Incision Template , Blunt Dissector, Insertion Tool, and Tray)

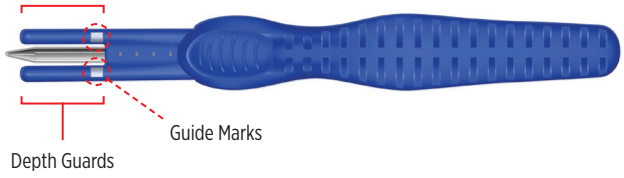
The **Incision Template** is used to guide and mark the incision area on the skin surface by aligning the marking template to the marked outer edges of the smart transmitter when placed in a comfortable position.

Incision Point Marking Template



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.

Blunt Dissector



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.

Insertion Tool

3. Eversense E3 Smart Transmitter Kit

(Smart Transmitter, Power Supply, User Guide, and 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 E3 CGM System.

4. Eversense E3 Adhesive Patches Kit

(180 patches)

The **Adhesive Patch** 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. The health care provider gives these to the patient when they leave the office.

5. Product Handling

The sensor kit, 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. Sensors should be inserted before the "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 kit refrigerated at the labeled temperature range.
- Dispose of product packaging in accordance with clinic, administrative and/or local government policy.

6. Suggested Equipment

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 (health care provider 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, health care provider-preferred size
- 1 10 mL sterile saline filled syringe (for insertion only)
- 1 Sterile surgical clamp 10-16 cm

7. Insertion Procedure

Before inserting the sensor, confirm that the patient:

- Does not have allergies to the antiseptic and local anesthetic to be used during insertion.

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

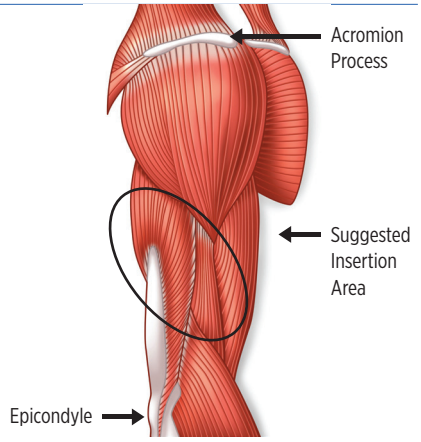
A. Prep the Insertion Area

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. 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.

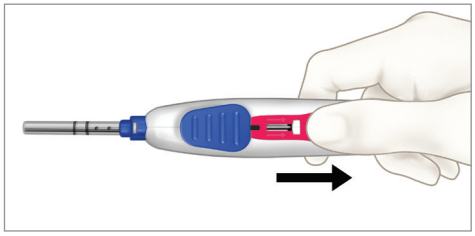


2. **Once the position for the smart transmitter is selected, mark the corners on the skin.**
3. **Using the non-sterile incision template, align the template inside the marked lines and mark the skin for the incision using the incision template's slots.**
4. **Position the patient in a reclined position 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

1. **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 Kit and place in the sterile procedure field created for the procedure.**

   Note that the inner tray of the Sensor Insertion Kit is sterile and can be placed within the sterile procedure field.



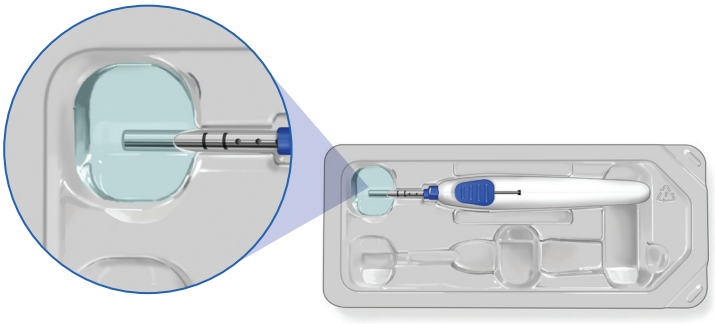
2. **Remove the insertion tool from the inner tray and remove its red locking tab by sliding it toward the back of the tool.**

   Ensure the blue slide stays in the forward position.

3. **Snap the tool back into its position in the tray.**

4. **Wet the cannula by filling the preformed well with enough sterile saline (0.9% sterile saline for injection) to completely cover the cannula (approximately 10 mL).**

5. **Remove the sensor holder from the sensor pouch and place in the sterile field.**



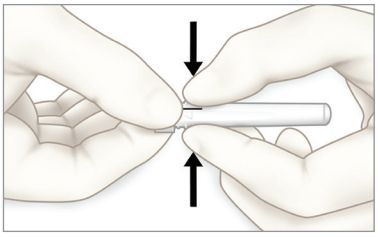
Cautions

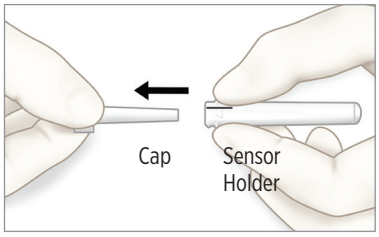
- **The sensor and sensor holder are sterile in the unopened, undamaged, sterile package. The sensor should not be used if the sterile package has been opened or damaged.**
- **DO NOT insert a sensor if it has been dropped from a height of 30 cm or more.**
- **Use only the insertion tools provided in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

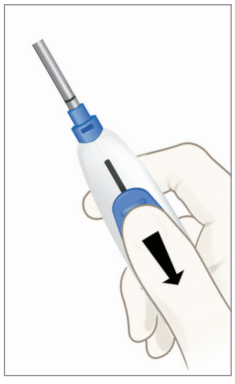
   Discard the cap.

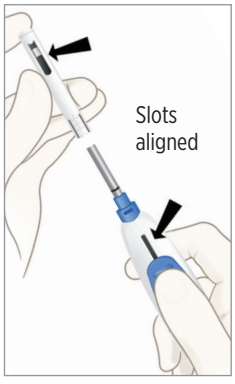




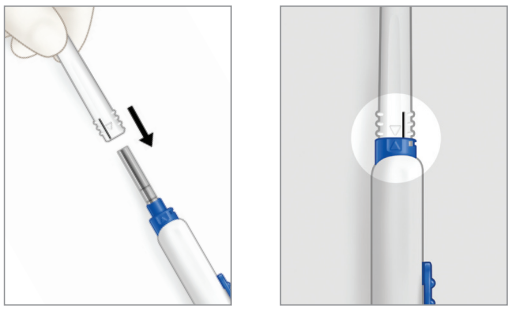
2. **Remove the insertion tool from the tray and retract the blue slide.**

   With the cannula pointed up, 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.





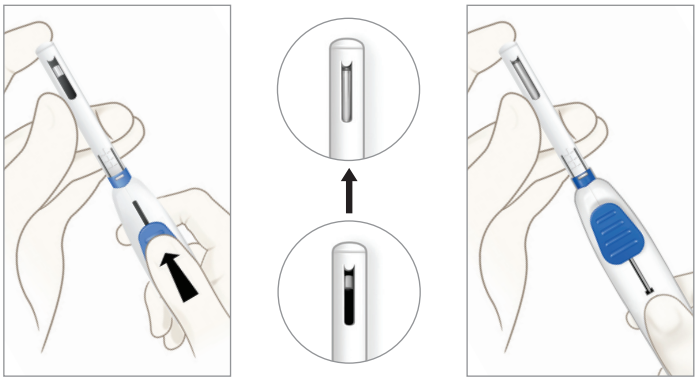
3. **With the blue slide retracted, slide the sensor holder over the cannula so that the two triangles are touching at the tip and snap into place.**



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

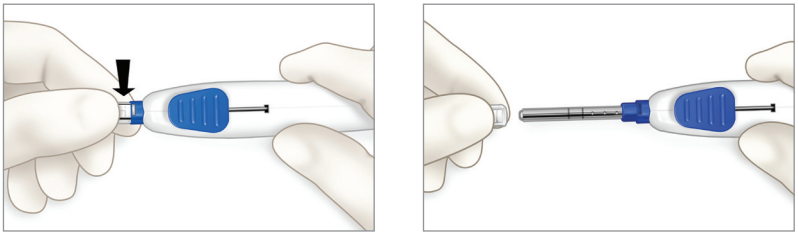
   This action secures the sensor inside the cannula. The cannula, not the sensor, is now visible through the slot in the sensor holder.

   DO NOT RETRACT the thumb slide at this step.



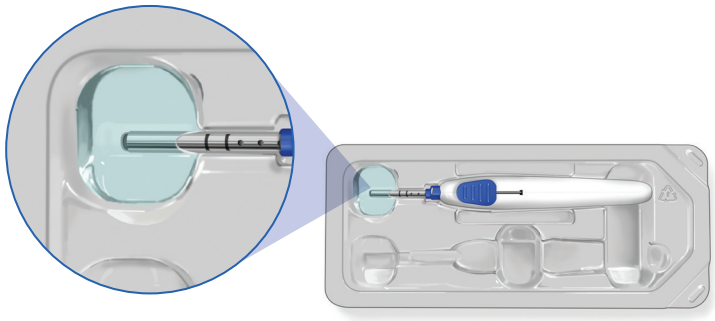
5. **Depress the ridged portion of the sensor holder to remove it from the insertion tool.**

   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. To ensure proper hydration, fully submerge the cannula 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 chlorhexidine 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 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).

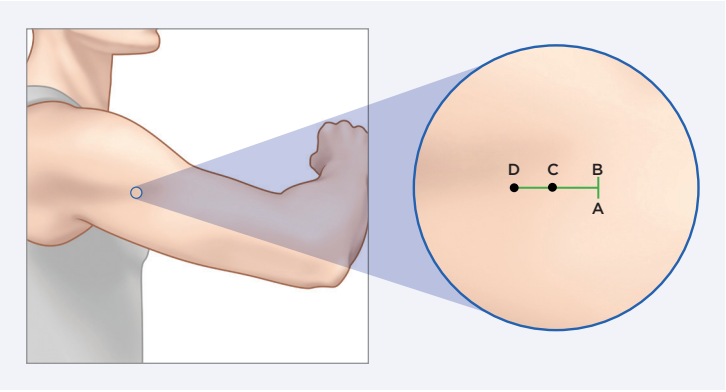


Figure 1

E. Make Incision and Subcutaneous Pocket

1. **Once the insertion area is sufficiently anesthetized, make an approximately 5 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 mm.

2. **Remove the blunt dissector from the tray and introduce the blunt dissector at approximately a 45 degree entry angle at the midline 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.**

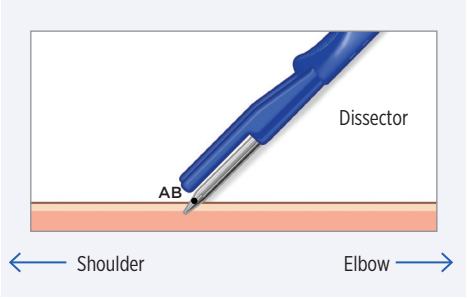
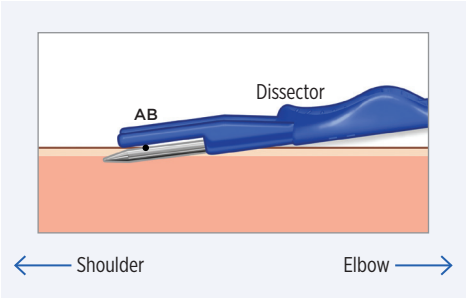


Figure 2

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.**



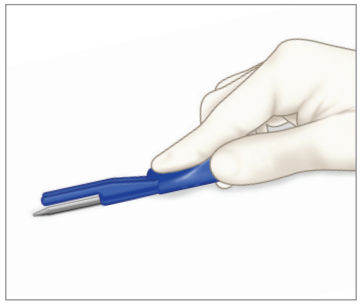


Figure 3

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.

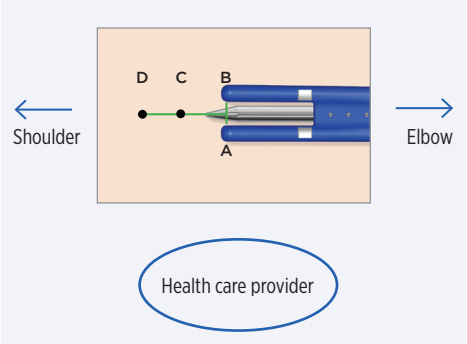


Figure 4

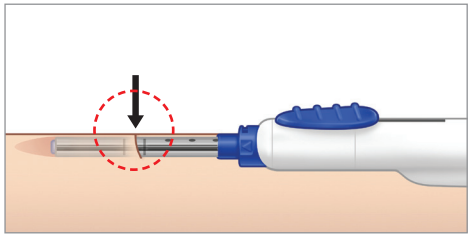
Note:

- Pinching and tenting the skin can aid in forming a small space in the skin for insertion.
- Slight rotation of the blunt dissector along the axis of the tool while advancing may be 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 insert the sensor, it should be level in the pocket, which will facilitate communication between the sensor and the smart transmitter.

F. Sensor Placement and Wound 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.**

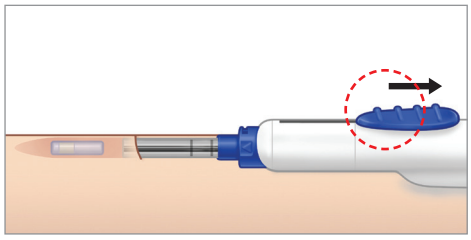


3. **Advance the tool until the incision line is between the first and second marked lines on the cannula.**

   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 without tension.**

G. Insertion Tool and Blunt Dissector Disposal

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

H. Connecting the Eversense E3 CGM System

Note: Pairing the transmitter and mobile device, and linking the sensor and transmitter may be performed by the patient at home.

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.

Refer to the *Eversense E3 CGM System User Guide, Linking the Sensor* for additional information.

8. Post-Insertion Patient CGM Start-Up

Your patients may need assistance in getting started with the Eversense E3 CGM System. Refer to the *User Guide* and *Quick Reference Guide* that is included in the smart transmitter kit 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 has been turned off to avoid vibrations, patients 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 E3 User Guide* to help facilitate your patient's understanding of their new Eversense E3 CGM System and determining their personalized glucose settings.

9. Sensor Removal Procedure

A. Locate the Sensor

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

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

1. **Push down on the skin over the expected location of the proximal end of the sensor to stabilize it.**

2. **Create approximately a 5-6 mm incision through the dermis at the location determined in A2 of this section.**

D. Remove the Sensor

1. **Carefully dissect the subcutaneous tissue until the end of the sensor distal to the incision can be grasped by a small surgical clamp (such as 10-16 cm). Spreading of the tissue through the incision using the small clamp both parallel and perpendicular to the incision may be required to enable visualization and grasping of the sensor with the small clamp.**

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 small clamp to grasp the distal end of the sensor and remove it from the pocket. Rotation of the sensor with the clamp 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

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 without tension.**

F. Sensor Disposal

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

10. Potential Complications

The insertion and removal of the Eversense E3 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

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.

– Slight rotation of the blunt dissector along the axis of the tool may 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 2-3 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 small clamp/or other desired instrument as required. Gently rotate the small clamp with the secured sensor to release any small fibrous tissue encapsulation.

II. Device Performance

This section lists Device Performance Characteristics.

Clinical Study Performance

The safety and effectiveness of the Eversense E3 CGM System has been evaluated in the PROMISE clinical study conducted in the U.S. The data collected was analyzed using a new algorithm, SW 604. A modified sensor design, referred to in this document as the E3 sensor, was evaluated in the PROMISE study. Compared to the Primary sensor (which was the original sensor used in the PROMISE study), the E3 sensor had a modified hydrogel formulation (sacrificial boronic acid, SBA) intended to extend the in vivo functional life of the sensor. The formulation change was not intended to affect the primary mechanism of action of the sensor (glucose binding or fluorescence). Data from both sensors is included in the Device Performance section. Accuracy assessments were made at various points during the study and subjects were asked to report any adverse events throughout the study. The Safety section reflects all subjects (n=181) from the study. Sensors provided with the Eversense E3 CGM System include the SBA design modification.

PROMISE Study

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

Table 1 – Accuracy to YSI in PROMISE*

YSI Glucose Range (mg/dL)		Total Number of Paired CGM and YSI Values	Percent of CGM System Readings Within				MARD
			Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	
Primary Sensor	Overall	49,613	85.6	92.9	98.0	99.3	9.1%
E3 Sensor	Overall	12,034	87.3	93.9	98.6	99.6	8.5%

*Glucose values between 40 and 400 mg/dL.

Accuracy to YSI in PROMISE Study

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

Primary Sensor

Table 2a – Primary Sensor Accuracy to YSI in PROMISE Study

YSI Glucose Range (mg/dL)	Number of Paired CGM-YSI	Mean Absolute Relative Difference (%)
Overall	49,613	9.1
< 40*	20	16.1
40 - 60*	2,281	9.4
61 - 80*	5,270	8.8
81 - 180	19,001	9.0
181 - 300	14,578	7.7
301 - 350	6,862	7.1
351 - 400	1,510	8.0
> 400	91	13.4

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

E3 Sensor

Table 2b – E3 Sensor Accuracy to YSI in PROMISE Study

YSI Glucose Range (mg/dL)	Number of Paired CGM-YSI	Mean Absolute Relative Difference (%)
Overall	12,034	8.5
< 40*	0	--
40 - 60*	592	7.5
61 - 80*	1,221	7.7
81 - 180	5,067	8.6
181 - 300	3,300	7.4
301 - 350	1,457	6.9
351 - 400	372	6.4
> 400	25	9.5

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

Performance was also measured by calculating the percentage of sensor glucose readings within 15 mg/dL or 15% of the YSI reference. These tables show the percent agreement at multiple levels, at different glucose ranges, and at different days during the sensor wear. Results in the glucose ranges of 80 mg/dL or less reflect the percentage of values within mg/dL, and results in the glucose ranges over 80 mg/dL reflect the percentage within reference. As an example, CGM glucose values between 40 and 60 mg/dL were within 15 mg/dL of the reference value 87.9% and 91.6% of the time for the primary and E3 sensors, respectively.

Primary Sensor

Table 3a – Primary Sensor Percentage of Readings in Agreement Overall in the PROMISE Study

CGM System Glucose Range (mg/dL)	Paired CGM and YSI Reference	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent > 40/40% of Reference
Overall	49,613	85.6	92.9	98.0	99.3	0.7
40 - 60	2,205	87.9	94.6	98.5	99.2	0.8
61 - 80	4,623	89.2	95.2	99.3	99.9	0.1
81 - 180	19,566	81.5	90.1	97.1	99.0	1.0
181 - 300	15,654	86.5	93.9	98.4	99.4	0.6
301 - 350	5,676	93.7	97.4	99.0	99.5	0.5
351 - 400	1,889	84.6	93.3	98.4	99.3	0.7

E3 Sensor

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

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

Performance was evaluated at various points during the study. Tables 4a and 4b show both overall and point-in-time results on various days during sensor wear.

Primary Sensor

Table 4a – Primary Sensor Accuracy over Time in the PROMISE Study

Day Number	Number of Paired CGM-YSI	Mean Absolute Relative Difference (%)	Percent of CGM System Readings Within			
			Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference
Overall	49,613	9.1	85.6	92.9	98.0	99.3
Day 1	5,584	11.0	80.0	89.0	96.5	98.3
Day 7	2,724	9.6	83.1	91.3	98.2	99.3
Day 30	6,488	8.4	88.4	94.8	98.7	99.6
Day 60	6,345	7.7	90.5	95.8	99.1	99.8
Day 90	6,039	8.2	88.7	94.4	98.4	99.6
Day 120	5,173	9.2	85.5	93.3	98.3	99.5
Day 150	4,227	9.6	85.5	92.7	97.9	99.1
Day 180	4,517	10.4	81.0	89.6	96.2	98.3

E3 Sensor

Table 4b – E3 Sensor Accuracy over Time in the PROMISE Study

Day Number	Number of Paired CGM-YSI	Mean Absolute Relative Difference (%)	Percent of CGM System Readings Within			
			Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference
Overall	12,034	8.5	87.3	93.9	98.6	99.6
Day 1	1,203	11.2	78.6	87.4	96.5	99.3
Day 7	792	10.0	81.9	88.0	94.7	98.5
Day 30	1,523	8.2	85.8	93.4	98.2	99.3
Day 60	1,365	8.6	87.9	94.2	98.6	99.8
Day 90	1,418	7.0	93.1	97.1	99.8	99.9
Day 120	1,195	8.4	89.2	96.1	99.6	99.9
Day 150	1,285	8.8	84.0	91.9	99.5	99.9
Day 180	1,413	7.4	93.1	98.0	99.3	99.7

Alert Performance

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

Primary Sensor

Table 5a – Primary Sensor High and Low Glucose Alert Performance (Threshold and Predictive) in the PROMISE Study

Alert Setting (mg/dL)		Confirmed Event Detection Rate	Missed Detection Rate	True Alert Rate	False Alert Rate
Low Alert	60	87%	13%	68%	32%
	70	93%	7%	87%	13%
	80	96%	4%	90%	10%
	90	97%	3%	90%	10%
High Alert	120	99%	1%	96%	4%
	140	99%	1%	95%	5%
	180	99%	1%	94%	6%
	200	98%	2%	93%	7%
	220	98%	2%	92%	8%
	240	98%	2%	92%	8%
	300	92%	8%	87%	13%

E3 Sensor

Table 5b – E3 Sensor High and Low Glucose Alert Performance (Threshold and Predictive) in the PROMISE Study

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

Rate of Change Trend Agreement

The shaded areas in Tables 6a and 6b show agreement between the CGM glucose trends and the YSI reference trends while glucose is trending at different rates (mg/dL per minute). As an example, when glucose is trending at a rate of between -1 and 1 mg/dL/minute, CGM glucose trends are in agreement with the reference trends 90% of the time for both the primary sensor and the E3 sensor.

Primary Sensor

Table 6a – Primary Sensor Rate of Change Trend Agreement in the PROMISE Study

CGM Trend (mg/dL/min)	Reference Rate of Change (mg/dL/min) Percent of Matched Pairs in Each Reference Trend Range for Each CGM ROC Range					
	< -2	[-2, -1)	[-1, 1]	(1, 2]	> 2	Total
< -2	17%	41%	41%	1%	0%	756
[-2, -1)	3%	31%	66%	1%	0%	2,963
[-1, 1]	0%	4%	90%	5%	1%	35,777
(1, 2]	0%	1%	52%	37%	10%	3,263
> 2	0%	0%	28%	38%	33%	1,635
						44,394

E3 Sensor

Table 6b – E3 Sensor Rate of Change Trend Agreement in the PROMISE Study

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

Calibration Stability Agreement

Tables 7a and 7b compare the percentage of sensor glucose values to the YSI reference at various time points after a calibration entry. As an example, in tables 7a and 7b, 84.5% of the primary sensor values and 89.7% of the E3 sensor values were within 15 mg/dL (for reference readings of 80 mg/dL or less), and within 15% (for reference readings over 80 mg/dL) of the reference value 8 to 10 hours after a calibration entry.

Primary Sensor

Table 7a – Primary Sensor Calibration Stability Agreement in the PROMISE Study

Time from Calibration	Number of Paired CGM-YSI	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent > 40/40% of Reference
(0, 2) Hours	10,303	87.4	94.2	98.4	99.4	0.6
[2, 4) Hours	8,824	85.8	92.8	98.1	99.3	0.7
[4, 6) Hours	6,955	86.8	93.5	98.2	99.3	0.7
[6, 8) Hours	5,318	85.0	92.5	97.8	99.2	0.8
[8, 10) Hours	4,161	84.5	92.5	98.4	99.5	0.5
[10, 12) Hours	4,164	83.7	90.8	97.6	99.2	0.8
[12, 14) Hours	2,269	82.9	92.0	97.6	99.1	0.9
[14, 16) Hours	1,441	83.3	91.1	96.5	98.0	2.0
[16, 18) Hours	1,297	87.7	94.4	97.6	99.2	0.8
[18, 20) Hours	1,242	87.2	94.4	98.8	99.8	0.2
[20, 22) Hours	1,443	84.2	92.9	97.9	99.4	0.6
[22, 24) Hours	1,682	83.2	92.4	97.7	99.0	1.0
[24, 26) Hours	509	82.3	91.4	97.4	98.2	1.8
[26, 28) Hours	5	60.0	100.0	100.0	100.0	0.0

E3 Sensor

Table 7b – E3 Sensor Calibration Stability Agreement in the PROMISE Study

Time from Calibration	Number of Paired CGM-YSI	Percent of CGM System Readings Within				
		Percent 15/15% of Reference	Percent 20/20% of Reference	Percent 30/30% of Reference	Percent 40/40% of Reference	Percent > 40/40% of Reference
(0, 2) Hours	2,638	88.8	94.1	98.7	99.9	0.1
[2, 4) Hours	1,905	87.2	94.4	98.5	99.5	0.5
[4, 6) Hours	1,404	85.3	93.3	98.1	99.3	0.7
[6, 8) Hours	1,043	83.0	91.5	97.7	99.6	0.4
[8, 10) Hours	1,041	89.7	93.9	98.8	99.6	0.4
[10, 12) Hours	1,091	87.8	94.1	97.7	99.5	0.5
[12, 14) Hours	590	85.8	93.4	99.0	99.3	0.7
[14, 16) Hours	440	82.7	91.8	100.0	100.0	0.0
[16, 18) Hours	379	87.6	93.9	99.5	100.0	0.0
[18, 20) Hours	370	90.0	97.0	98.4	99.7	0.3
[20, 22) Hours	436	88.3	94.5	99.5	99.8	0.2
[22, 24) Hours	522	89.7	96.2	99.4	99.8	0.2
[24, 26) Hours	168	93.5	98.2	99.4	100.0	0.0
[26, 28) Hours	7	100.0	100.0	100.0	100.0	0.0

Sensor Life

Sensor life measured the percentage of sensors being able to function through the intended 180 day duration. In the PROMISE study, 90% of E3 sensors functioned through the 180 day period. Mean number of days was 175. Of the primary sensors, 65% functioned through the 180 day period.

Safety

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

Table 8 – Adverse Events (All Subjects, n = 181)

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

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, 50/60Hx, 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.

Symbols on Packaging and Device

Symbol	Explanation
	Consult accompanying documents
	Consult electronic instructions for use
	Caution, consult accompanying documents
	Use by
	Manufacturer
	Date of manufacture
	Storage temperature limits
	Lot number
	Part number
	Serial number
	Type BF Applied Part
	Non-ionizing electromagnetic radiation
	Not made with natural rubber latex
	Universal Serial Bus (USB)
FCC ID	FCC ID is assigned to all devices subject to certification

Symbol	Explanation
	Magnetic Resonance Imaging (MRI) procedures are contraindicated for the smart transmitter
	No known hazards for leaving the sensor inserted in use with MR with a static magnetic field of 1.5T or 3.0T
	European Union WEEE Directive 2012/19/EU
	Single use only
	Do not re-sterilize
	Do not use if package is damaged
	Sterilized using Ethylene Oxide
	Single sterile barrier: Sterilized using Ethylene Oxide
	Non-sterile
	U.S. (Federal) law restricts the sale of the Eversense E3 CGM System to sale by or on the order of a physician
	Follow instructions for use
	Distributor
	Single patient, multiple use
	Importer

Manufactured by:
Senseonics, Inc.
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Germantown, MD 20876-7005 USA
www.eversensediabetes.com

Distributed by:
Ascensia Diabetes Care US, Inc.
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www.ascensia.com/eversense

Patents: www.senseonics.com/products/patents

℞ only

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Date: 6/22/2023	
File name: LBL-4008-01-201 Rev A_Eversense E3 Insertion Tools Kit PI_EN_8.5x11_R1_eIFU	
Job description: Eversense E3 CGM Sensor Insertion and Removal Instructions	
Project Manager: Tom Paradiso	**Art Director:** Ivy Tsang

Dimensions	
Trim: 8.5 (w) x 11 (h) in	Bleed: 0.125 in
Folded (*Include folded dimensions if applicable*):	

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