

Step-by-Step Instructions To Apply and Wear Your Cardea SOLO ECG Sensor

INTRODUCTION

This guide tells you how to apply and start your Cardea SOLO ECG Sensor. Please read the **“All About Cardea SOLO™”** patient information pamphlet included in this kit. **SAVE** these instructions for removing and returning your Sensor at the end of the wear period.

Watch the Cardea SOLO Sensor Application Video:
www.cardiacinsightinc.com/patients
or scan the QR Code



Ready To Apply Your Cardea SOLO? Let's GO!

You Will Need:

- ☐ Marker or ball point pen
- ☐ Loose, comfortable top that allows easy access to your upper left chest
- ☐ Razor or electric shaver if needed for chest hair removal

Ask someone else in your household to help you apply Cardea SOLO as needed.

SKIN PREPARATION



Your skin must be clean, dry and free of any oils, lotions, powders or hair. This is very important.

SHAVE all chest hair on your upper left chest, see Figure 1.

TIP: Wet and/or electric shaving can help reduce the chance of skin irritation.

CAUTION: Do not place Sensor over open wound.



Figure 1.

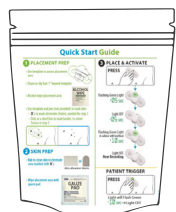
Shave ALL body hair in this area

OPEN CARDEA SOLO SENSOR POUCH AND REVIEW CONTENTS

Wash hands and dry thoroughly. Open the Cardea SOLO pouch and review its contents. Once the pouch is opened, apply the Sensor right away to keep adhesive tacky.

SAVE the Cardea SOLO Pouch for Sensor return after your wear period is complete.

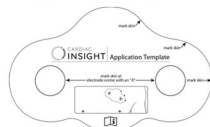
Cardea SOLO
Sensor Pouch



Cardea SOLO™
ECG Sensor



Application
Template



Patient
Diary



Skin Prep Materials



Alcohol
pad



Abrasive
sponge



Abrasive
paper

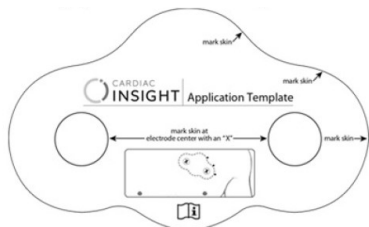


Gauze
pad

PLACING THE CARDEA SOLO SENSOR

Use the provided **Application Template** shown below to locate the correct placement area on your **LEFT CHEST**.

Application Template

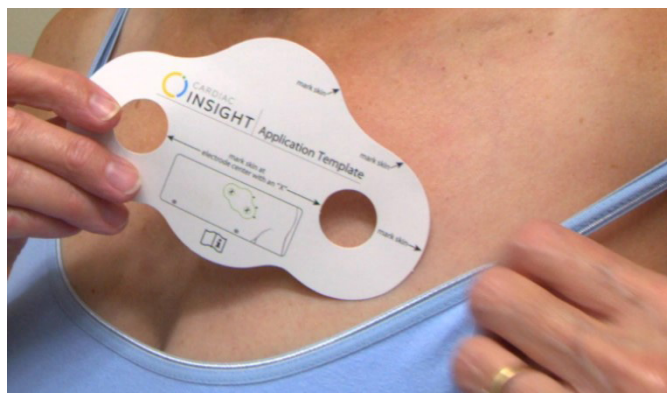


Stand in front of a mirror to determine the correct placement.



Or, have another person assist you.

- 1 Place the **Application Template** two fingers below your clavicle bone, and above your LEFT breast. The template can be placed on a slight diagonal with the right side higher, or straight across. This is the Cardea SOLO placement area.



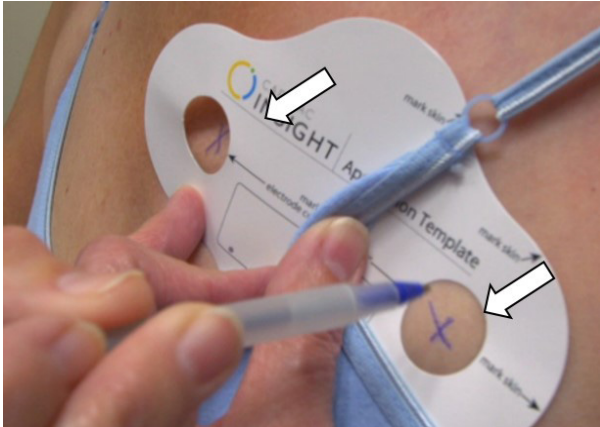
TIP: Avoid placing the Application Template too low on your left breast tissue or into your armpit. If needed, place closer towards the breastbone and slightly higher.

- 2 Use the **Alcohol Pad** to wipe clean an area slightly larger than the Cardea SOLO placement area. Let skin dry for 30 seconds.

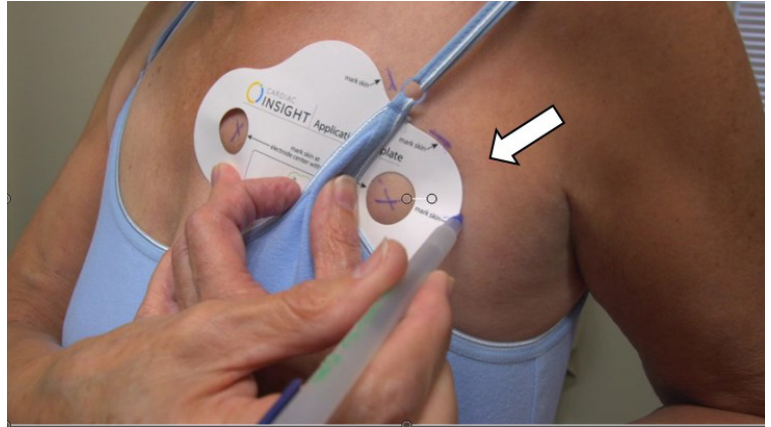


- 3 Place the paper **Application Template** two fingers below your LEFT clavicle.

4 Use a pen or marker to mark these areas on your skin:



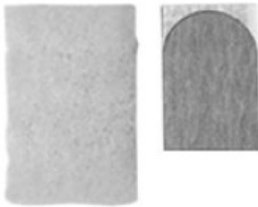
A. With the Application Template in place, draw an **X** in each of the two holes.



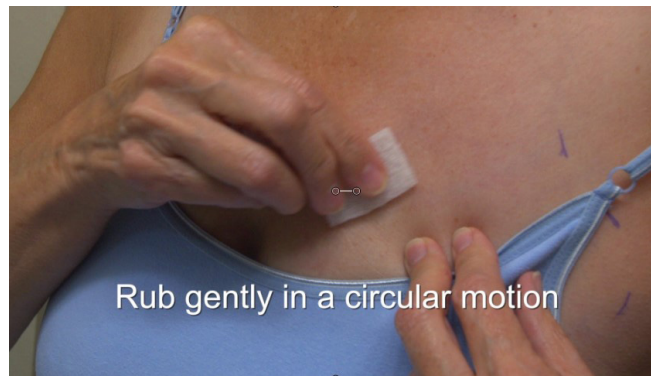
B. Mark **dots or short lines** along the outside border of the template. These dots will guide your Sensor application. You may also trace around the entire Application Template.

CLEANING AND PREPPING YOUR SKIN

- 1 Choose **one** of the two **Skin Abrasion Pads** and **over each of the two X's**, rub skin gently in a circular motion. You may feel your skin sting a little but this should go away.



Skin abrasion pads



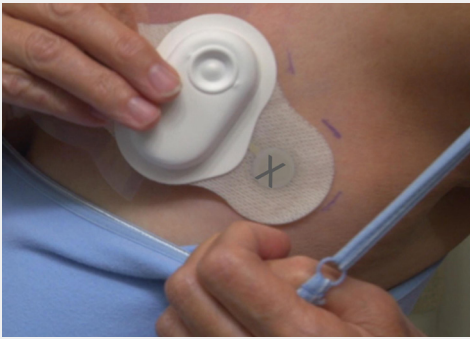
TIP: Use only the Sponge-Type Abrasion Pad if you are taking a blood thinner or if your skin is sensitive.

- 2 Briskly wipe the Cardea SOLO placement area **three times** with the dry sterile **Gauze Sponge** To remove the dead skin cells and debris.



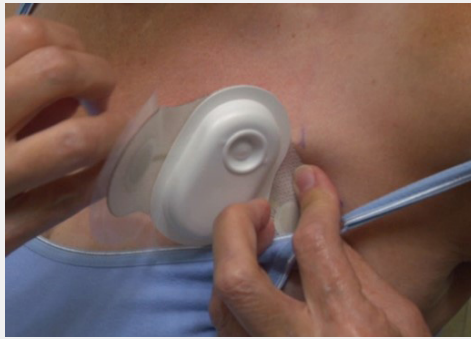
TIP: Do not skip this step.

APPLYING CARDEA SOLO



- 1** Remove the clear plastic liner from the **LEFT** side of the SOLO Sensor. Take care not to wrinkle or fold the outer adhesive border when removing the liner.

Align the **LEFT** sticky side onto your **LEFT** chest – be sure the **gray circular electrode** aligns over the **X** on the **lower left** of your chest.



- 2** Remove the **RIGHT** plastic liner, then place the **gray circular electrode** over the right X and stick Cardea SOLO on completely.



- 3** Make sure **Cardea SOLO** is firmly attached, lying smooth and flat across your chest.

Firmly press down and smooth out the SOLO Sensor against skin again, including the top, bottom, middle and all around the sides.

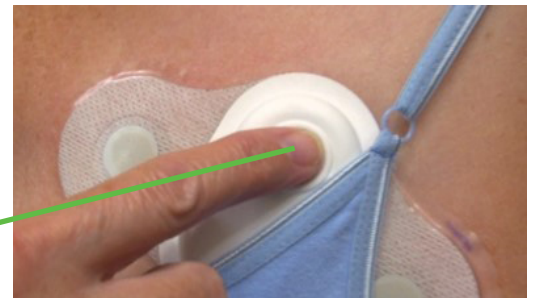
STARTING CARDEA SOLO

Stand in front of a mirror in a slightly darkened room to easily see the activation light sequence. You can also ask a household member to assist you.

Stay still for 30 – 60 seconds while doing these next steps:

- 1** Press the Cardea SOLO's round Start Button once to turn on Cardea SOLO.

Start Button



- 2** **WATCH AND VERIFY YOU SEE THE START-UP LIGHT SEQUENCE BELOW:**

First: A **Green Light** will Flash for *about* 5 seconds.

Second: This Green Light will turn OFF for another 5 seconds.

Third: The **Green Light** starts **Flashing again in the same rhythm of your heartbeat** for about 10 seconds.

Fourth: The **Green Light** will then turn **OFF** completely, indicating that it has started correctly.



- 3** When the Green Light turns completely OFF, write your **START DATE** and **START TIME** on the Cardea SOLO Pouch label. Include your *usual* Bedtime and Wake Time, your Date of Birth (DOB) and other information requested.

Your healthcare provider needs the exact Cardea SOLO Start Date and Start Time for accurate ECG Analysis. It is very important to write this down right away.



Did your Cardea SOLO Start? If you did not see the start-up light sequence as expected, or if you see a **RED** light, the Cardea SOLO Sensor is not making good contact with your skin.

Press down again over and around the entire SOLO sensor and the surrounding adhesive. Wait a few minutes and repeat the button sequence above. If the green light still does not flash in time to your heartbeat and then turn off, contact your Healthcare Provider for next steps.

That's it! Cardea SOLO is recording your heart's electrical activity and you can go about your day.

USING THE SYMPTOM MARKER BUTTON

The same button used to start Cardea SOLO is also the symptom Marker Button.

- 1** If you experience any symptoms, or as directed by your Healthcare Provider, calmly approach and press your Cardea SOLO Symptom Marker Button **ONCE** if you have symptoms to indicate that you felt something.
- 2** A Green Light, synchronized to your heartbeat, will flash for about 10 seconds after the button is pressed and then turn off.
- 3** Be still for about a minute after pressing the Marker Button.




IMPORTANT: Cardea SOLO does not wirelessly monitor or transmit your heart rhythm to your healthcare provider. Contact your healthcare provider with any questions, concerns, or to report changes in your condition. If you are experiencing a medical emergency, dial 911 or your local emergency number.

USING THE PATIENT DIARY

After you press the symptom Marker Button, and whenever you have symptoms write the date, time, your activity and symptoms experienced in your Patient Diary. See the example below.

Patient Diary

CARDIAC INSIGHT	Patient Diary
Patient ID: <u>Polly Patient</u>	
Sensor ID: _____ <small>(Filled in by Clinician upon Sensor return)</small>	
Clinician Contact: <u>My Provider or Practice Name</u>	
<small>While wearing the Sensor keep an accurate diary of your activities when you feel symptoms. Give your diary to the clinician when your Sensor is removed.</small>	

Date: <u>Mar 15, 2020</u>	Time: <u>10:14 AM</u>
Duration (min): <u>About 10 seconds</u>	Button pressed? <input checked="" type="radio"/> Yes / No
Symptoms: <u>Thumping heartbeats</u>	
<u>Could not catch my breath</u>	
Activity: <u>Sitting watching TV</u>	

TIP: If you feel fine and don't have any symptoms, you do not need to press the Marker Button or write in your Patient Diary unless otherwise directed by your Healthcare Provider.

HOW TO CARE FOR YOUR CARDEA SOLO WHILE YOU ARE WEARING IT

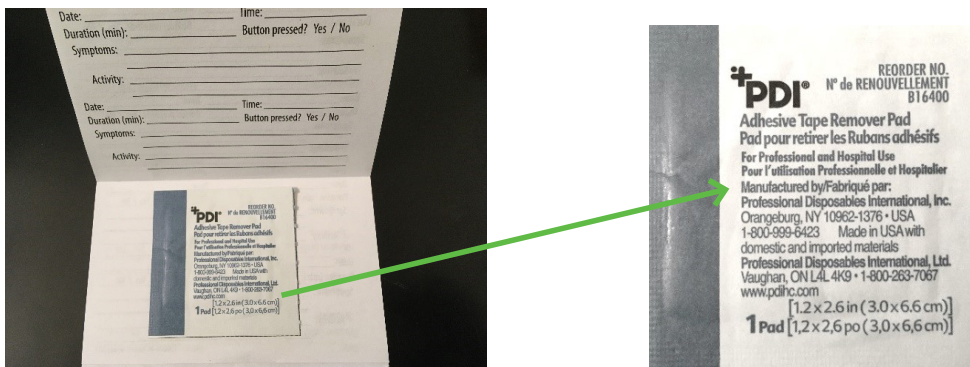
Cardea SOLO is water-resistant but NOT waterproof. You can indirectly shower and do moderate exercise.

- a. Keep showers BRIEF and AVOID any direct water spray or stream on the SOLO Sensor.
- b. Do not swim or take a tub bath or immerse the SOLO Sensor. No hot tubs! No saunas!
- c. If your Cardea SOLO becomes damp, gently press over it with a dry towel.
- d. AVOID activities that will cause excessive sweating.
- e. Contact your Healthcare Provider if you have any questions, experience intense itching, skin redness or irritation suggesting an allergic reaction.

REMOVING CARDEA SOLO

Remove the SOLO Sensor on the date and at the exact time as instructed by your Healthcare Provider. If you are unsure of the timing, contact your Healthcare Provider.

- 1 Wash hands thoroughly.
- 2 Dry hands and have your Instruction Guide available.
- 3 Remove the Adhesive Remover Pad attached to your Patient Diary. See Figure 2.



TIP: You can also use petroleum jelly (Vaseline®) or baby oil.

- 4 Use the Adhesive Remover Pad to wipe around the edges of the SOLO Sensor. Gently lift and slowly peel the SOLO Sensor from your skin. Hold your skin down with your opposite hand to avoid skin injury.
- 5 Cleanse skin with mild soap and water to remove any remaining adhesive.
- 6 It is normal to have slight redness and odor on your skin after removal. It should disappear after a few days. If redness with itchiness continues or gets worse, or if you have any concerns about your skin's appearance or condition, contact your Healthcare Provider.



RETURNING THE CARDEA SOLO SENSOR TO YOUR HEALTHCARE PROVIDER

- 1
- After removing the SOLO Sensor, fold the two wings together under the middle. See Figure 3.
- 2
- Insert your folded SOLO Sensor back in its original zipper Pouch and re-seal.
- 3
- Place both the Pouch and your Patient Diary in the postage-paid mailer that is addressed to your Healthcare Provider.

IMPORTANT: After removal, return Cardea SOLO to your Healthcare Provider as soon as possible for ECG analysis.



Figure 3.

TROUBLESHOOTING



PROBLEM	SOLUTION
Light sequence does not occur as expected at start of monitoring period.	<p>Your Cardea SOLO must detect your heartbeat signal for ECG recording to start. There must be NO RED LIGHT displayed at any time.</p> <ol style="list-style-type: none">1. Make sure your Cardea SOLO is lying flat on your chest without wrinkles or folds. Press down firmly and smooth all parts of Cardea SOLO against your skin.2. Press the Start button again. If it is working, the Cardea SOLO light will flash green in time with your heartbeat for a short time and then stop.3. If there is no light, or a Red light after you try to press down the Cardea SOLO to your skin, please contact your healthcare provider for instructions.
Cardea SOLO is coming off my skin before the end of my recording period.	<ol style="list-style-type: none">1. Apply firm but gentle pressure to the area that is peeling. Smooth down Cardea SOLO on the skin with a warm hand. If Cardea SOLO becomes damp, use a dry cloth and gently pat dry over the Sensor and surrounding skin..2. If this does not work, contact your Healthcare Provider for instructions.
I lost my Cardea SOLO or it isn't working properly.	<p>If your Cardea SOLO gets lost, damaged or isn't working, please contact your Healthcare Provider for instructions.</p>

THANK YOU for reading and following the instructions in this Guide. Contact your Healthcare Provider directly if you need assistance or have questions.

CONTRAINDICATIONS

1. Patients with known allergic reaction or hypersensitivity to adhesives or hydrogels or family history of adhesive skin allergies.
2. Patients with potentially life-threatening arrhythmias, or who require inpatient monitoring or immediate analysis of their ECG.
3. Patients with an implantable pacemaker in use. Paced beats may interfere with the analysis of the ECG and cause misclassification of beats and rhythms.
4. Do not use the Sensor in combination with external cardiac defibrillators or high frequency surgical equipment near strong magnetic fields or devices such as MRI.
5. Do not use the Sensor on patients who do not have the competency to wear the Sensor for the prescribed monitoring period.

Rxonly **CAUTION:** Federal (USA) law restricts the sale of this device to or on the order of a licensed physician.

ENVIRONMENTAL SPECIFICATIONS

Transport Environment - Sensor

Temperature: -10° C to 50° C (14° F to 122° F)

Humidity: 10% to 95% (non-condensing)

Pressure: 500 hPa to 1060 hPa

Storage Environment (Recommended) - Sensor

Temperature: 5° C to 50° C (41° F to 122° F)

Humidity: 10% to 95% (non-condensing)

Pressure: 500 hPa to 1060 hPa

Operating Environment - Sensor

Temperature: 5° C to 45° C (41° F to 113° F)

Humidity: 10% to 95%

Pressure: 500 hPa to 1060 hPa

Ingress of Solids and Liquids: IEC 60529 Ed. 2.1:2001, IP27 (protected against intrusion from fingers and small objects, and from the effects of temporary immersion in water)

PRECAUTIONS










1. The Sensor should be removed prior to external defibrillation or an MRI scan.
2. Patients with sensitive skin conditions should use the Sensor with caution. The Sensor may cause mild discomfort, skin irritation, redness, itching, rash or contact dermatitis in some individuals. The device should be removed if any pain or discomfort occurs. This may be facilitated through the use of an adhesive removal agent such as the wipe included with the Patient Diary. If skin irritation or redness persists after the device has been removed the patient should consult their health care provider.
3. Excessive sweating may limit wear duration. Avoid situations that may cause excessive sweating.
4. The Sensor electrodes should not contact other conductive equipment or electric ground prior to wear.
5. The Sensor is intended for single patient use.
6. The Sensor should not be applied to an open wound or to broken, damaged or irritated skin.
7. The Sensor is water resistant, but not waterproof. No swimming or immersion bathing.
8. Showering while wearing the Sensor is permitted. However, instruct the patient to keep total shower time brief and to avoid a continuous, direct water spray over the Sensor.
9. No modification of the Sensor beyond access to the Electronics Module is allowed. Modification may lead to inaccuracies in reported data or complete loss of data.
10. Replace the Sensor if it peels off completely; do not reapply (it is meant for one-time use).
11. Do not use the Sensor if it or its immediate packaging appears damaged or if it is not activated within 15 minutes of application.
12. No creams or lotions should be applied in the application area immediately prior to use of the Sensor.
13. Store the Sensor at controlled room temperature.
14. The Sensor is not intended for infants or pediatric patients. Safety and effectiveness of the Sensor on pediatric patients has not been established.










CAUTION: If the Sensor is removed from its pouch, the useful life of the ECG electrode hydrogel becomes limited (use within 15 min). Take care to remove the Sensor from its pouch during the same session as patient attachment.

CAUTION: If the Sensor is activated and it does not detect an ECG signal (e.g., activated when not attached to a patient), it will return to its as-shipped state to conserve battery.

CAUTION: To avoid contacting the Sensor electrodes with unintended conductive surfaces, leave the release liner in place until placement on the patient's skin.

SYMBOLS AND MEANING

Symbol	Meaning
	Manufacturer. ISO 15223-1:2012, Symbol 5.1.1
	Use by date. This symbol is accompanied by a date YYYY-MM-DD to indicate the device should not be used after the date shown. ISO 15223-1:2012, Symbol 5.1.4
	Batch or lot code. This symbol is accompanied by identifier of manufacturing lot. ISO 15223-1:2012, Symbol 5.1.5
	Catalog number. ISO 15223-1:2012, Symbol 5.1.6
	Serial Number. ISO 15223-1:2012, Symbol 5.1.7
	Do not use if package is damaged. ISO 15223-1:2012, Symbol 5.2.8
	Temperature limits. Indicates the temperature limits to which the device can be safely exposed. ISO 15223-1:2012, Symbol 5.3.7
	Humidity limitation. Indicates the range of humidity to which the device can be safely exposed. ISO 15223-1:2012, Symbol 5.3.8
	Do not re-use. Indicates a medical device that is intended for one use. ISO 15223-1:2012, Symbol 5.4.2

Symbol	Meaning
	Consult instructions for use. ISO 15223-1:2012, Symbol 5.4.3
	Caution, consult accompanying documents for cautionary information. ISO 15223-1:2012, Symbol 5.4.4
	Type BF Applied Part.
	Global Trade Identification Number
	Protected against the effects of temporary immersion in water.
	CAUTION: Federal (USA) law restricts the sale of this device to or on the order of a licensed physician.
	This product contains no natural rubber latex
	MR Unsafe ASTM F2503-13
	Do not incinerate