



only



Read Usage
Instructions



Latex-Free



Single Use
Only



Medical
Device

Indications for Use

The Adhesive Overlay is an adhesive for use in conjunction with the VitalPatch device. This is an optional accessory that may be used when the VitalPatch device does not adhere for the full monitoring session period. Other adhesives or overlays not specifically made for the VitalPatch device are not recommended and could void the warranty of the VitalPatch device when used. Follow the instructions below when applying and removing the Adhesive Overlay.

Warnings and Precautions

The adhesives in this product may cause adverse skin reactions. Healthcare providers should advise patients to seek medical attention if either of the following occurs:

- A severe adverse event.
- An allergic reaction persisting beyond 2-3 days.

If discomfort or irritation occurs, the adhesive overlay should be removed

Overview

Figures 1, 2, and 3 provide an overview of the adhesive overlay application sites, positioning, and final appearance. Detailed instructions on how to apply the overlay are in the next section.

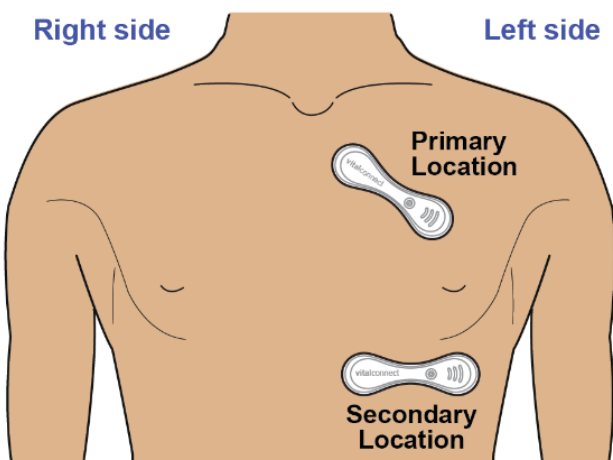


Figure 1: VitalPatch and Adhesive Overlay Application Sites

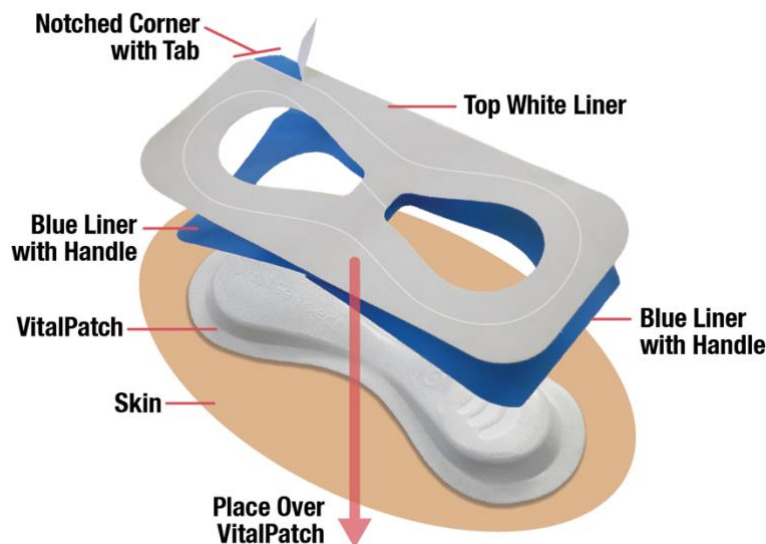


Figure 2: Adhesive overlay being positioned over the VitalPatch

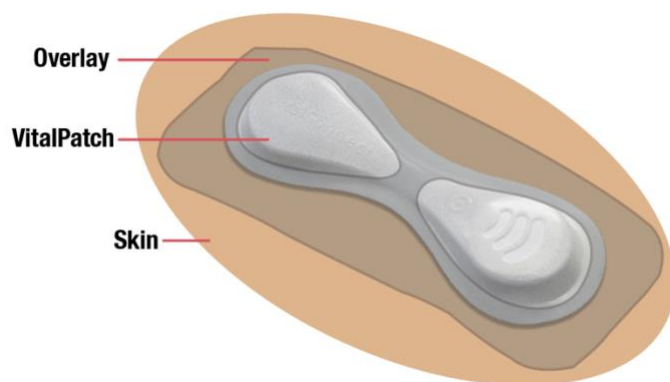
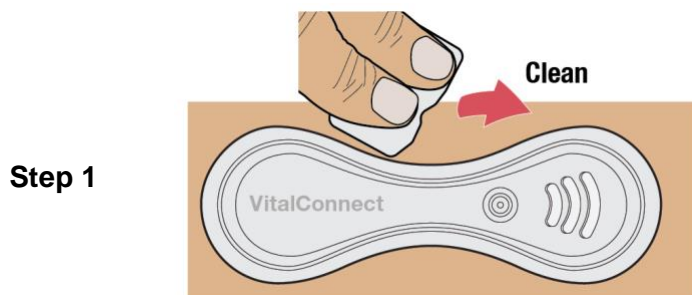


Figure 3: Final appearance after the adhesive overlay application

Instructions for Applying the Adhesive Overlay

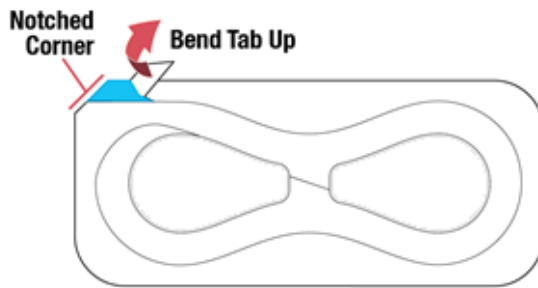
Instructional Video: <https://vitalconnect.com/docs/overlay-video.html>

Note that looking in a mirror can be helpful in doing the following steps.



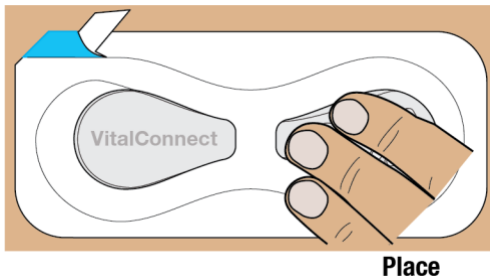
- For people with dense chest hair, it is advised to trim the chest hair before application of the VitalPatch and the adhesive overlay.
- **Clean** the skin around the VitalPatch device with an alcohol prep-pad. **Avoid touching VitalPatch with the pad.**
- Allow the skin to dry.

Step 2



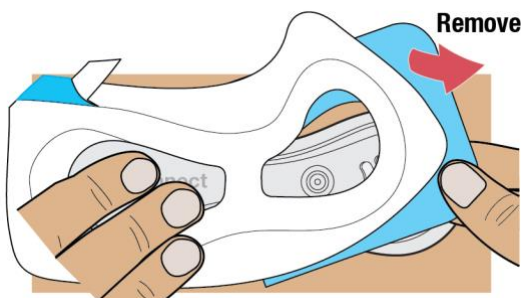
- Before applying the adhesive overlay, find the **notched corner**.
- **Bend the tab up** approximately half an inch to match image. This creates a bent tab that will help you remove the white top liner later.

Step 3



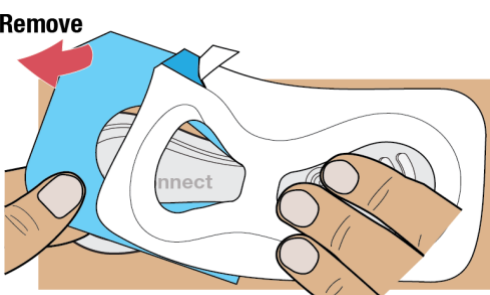
- **Place** the adhesive overlay over the VitalPatch such that the white liner is facing up away from the skin.
- Align the two cutouts of the adhesive overlay with the raised portions of the VitalPatch.

Step 4



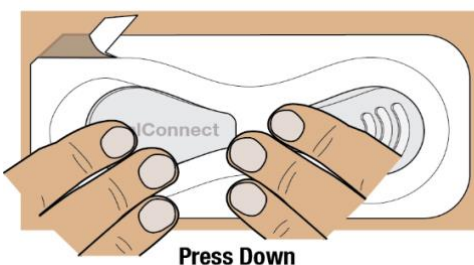
- Once the adhesive overlay is in position; with one hand hold one end of the adhesive overlay firmly in place.
- With the other hand find and grab onto the blue liner.
- Slowly peel away and **remove** the blue liner as shown in the image.
- Then press the adhesive overlay to adhere it to the skin and VitalPatch.

Step 5



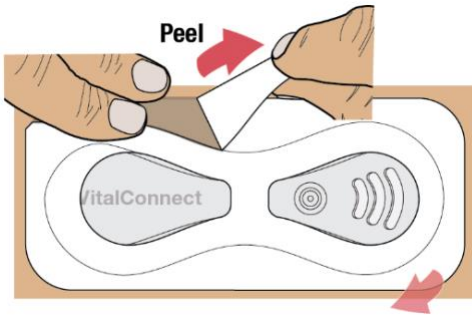
- Repeat Step 4 for the remaining blue liner.

Step 6



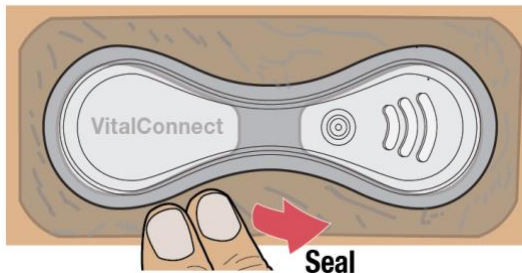
- **Press down** the adhesive overlay to adhere it to the skin and VitalPatch.

Step 7



- **Peel** off the top white liner starting with the bent tab.
- Press the overlay against the skin and VitalPatch with your other hand as you continue to remove the whole white liner.

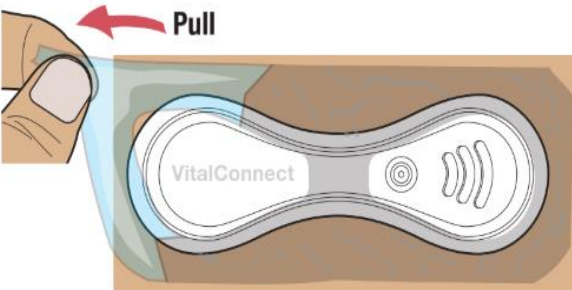
Step 8



- Press down on the adhesive overlay to **seal** all the edges against the skin and VitalPatch.

Removal of the Adhesive Overlay and the VitalPatch

Step 1



- When removing the adhesive overlay and the VitalPatch:
 - Grasp a corner of the overlay and **pull** it off the skin by stretching it horizontally to help release it from the skin.
 - Continue peeling off the adhesive overlay and the VitalPatch.
- If the VitalPatch does not come off with the overlay, remove the VitalPatch by peeling it from one end.

Health care professionals and care providers may contact VitalConnect with questions regarding this product. Patients who have questions should contact their care provider.

Adverse Event Reporting

Adverse events and/or potential patient injury complications that are reasonably associated with the use of the VitalPatch Adhesive Overlay should be reported, as follows:

Region	Where to Report
USA	1. VitalConnect, Inc. 2. Users and patients can report to FDA at: https://www.accessdata.fda.gov/scripts/medwatch/
EU	1. VitalConnect, Inc. 2. The Competent Authority of the Member State in which the user and/or patient is established

Contact Information

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