

## CLINICAL UPDATE CARDIOLOGY

# Are My CONMED ECG Electrodes “Hypoallergenic”?

What you should know about the FDA’s stance on using the term Hypoallergenic

1. The term hypoallergenic is used in the cosmetic industry and some medical device manufacturers have also adopted the term.
2. There are no federal standards or definitions that govern the use of the term “hypoallergenic.” The term can mean whatever a particular company wants it to mean. Manufacturers of cosmetics labeled as hypoallergenic are not required to submit substantiation of their hypoallergenicity claims to FDA.<sup>1</sup>
3. In the market, the term Hypoallergenic is sometimes also used to indicate that the product is Latex Free. CONMED ECG electrodes are not made with natural rubber latex.
4. Other ECG manufacturers may claim their products are Hypoallergenic, which typically refers to ECG electrodes that do not use medical grade adhesive as the adhesive that comes into contact with patients’ skin. Instead, an all gel backing consisting of a conductive adhesive hydrogel is used.
5. Since this term is not defined by the FDA, CONMED does not use such language to describe our ECG products. CONMED does offer such products that have an all gel backing that comes into contact with patient skin. The absence of medical grade adhesive makes the product ideal for patients who have sensitive or more fragile skin.
6. CONMED refers to these ECG electrodes as Repositionable electrodes, as they are designed to be easily repositioned while maintaining acceptable adhesion and have all hydrogel adhesive backing.
7. CONMED also has a full line of pediatric electrodes with all hydrogel adhesive backing as well.

Learn more by speaking with your local territory manager or visiting [www.CONMED.com/patientcare](http://www.CONMED.com/patientcare)

<sup>1</sup> [FDA.gov/cosmetics/cosmetics-labeling-claims/hypoallergenic-cosmetics](http://FDA.gov/cosmetics/cosmetics-labeling-claims/hypoallergenic-cosmetics)

### Softrace® Small

2320 and 2320C Series

### Softrace® Medium

2330 and 2330C Series

### Softrace® Large

2350 and 2350C Series

