

March 28, 2016

To: Our Valued CONMED Customers

Re: Revised Labeling for PADPRO® Multifunction Electrodes

CONMED has been marketing multifunction electrodes for over thirteen years. During that time, the American Heart Association (AHA) has published several updates to their guidelines and recommendations pertaining to Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care (ECC. In an effort to maintain market consistency with AHA and keep pace with other defibrillator manufacturers, CONMED will be incorporating revised labeling on all of the PADPRO® products. The three fundamental labeling changes are:

- 1. Products currently labeled ADULT (with the exception of 2001-EPS), will now be labeled as ADULT/CHILD ≥ 10kg. (There is a statement on the pouch that addresses Child use in AED Mode (the patient weight in this instance becomes ≥ 25kg).
- 2. Products currently labeled PEDIATRIC (<100J/25kg), will now be labeled as INFANT < 10kg.
- 3. Products currently labeled MINI PEDIATRIC (<30J/7.5kg), will now be labeled as MINI INFANT < 3kg.

Please be aware that these changes are strictly labeling changes. The electrodes have NOT changed in terms of product design or functionality (for fit, form, or function). For ordering simplicity, the product codes have NOT changed either. The visual details of the artwork and labeling changes are defined in the three attachments. Each attachment shows the CURRENT product description, electrode artwork, and pouch labeling on the left. Information and images on the right represent the NEW product description, electrode artwork, and pouch labeling.

These changes will be rolling out over the course of the next few months. Effective immediately, CONMED is implementing the changes to the INFANT products. Next up, will be the changes to the ADULT/CHILD products as well as the MINI INFANT products. Keep in mind, because of current inventory levels and different production rates/demand, the changes (to each specific product) will appear in the field at different times. Please be sure to share this information with all pertinent individuals within your facility, so that all users of PADPRO® electrodes are well informed.

CONMED is proud to provide the most complete portfolio of multifunction electrode products in the industry (currently, fifty-six unique product codes). It is our mission to ensure that our products, as well as their labeling, meet the needs of our customers and remain consistent with industry guidelines and recommendations.

Your loyalty and continued business is extremely important to CONMED. If you or any of your colleagues have guestions or concerns regarding these labeling changes, please contact me or your local Cardiology Sales Representative.

Sincerely,

Frank J. Kopyt

Marketing Manager, Cardiology Products

CONMED Corporation (315) 624-3154

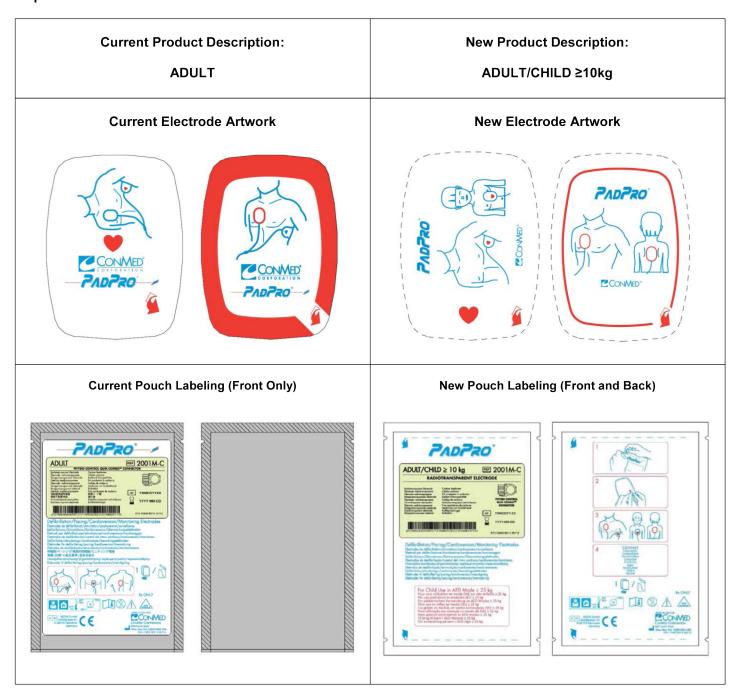
MCM2016107

Changes Affecting ADULT Electrodes

Product Codes Affected:

2516 series 2516 pre-connect series 2001 series 2001 pre-connect series 2001-C series 2502 sterile series

31 product codes



Note: Silver pouches (depicted by the grey background above) were used to identify adult radiotransparent electrodes (while white pouches were used to identify the radiotranslucent electrodes). As part of this labeling project, ALL products will be packaged in white pouches regardless. The text on the label will differentiate radiotransparent electrodes from radiotranslucent electrodes.

Changes Affecting PEDIATRIC Electrodes

Product Codes Affected:

2603

2603-PC

2603H

2603M

2603P

2603R

2603Z

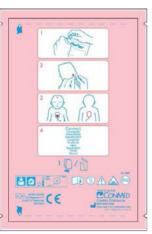
7 product codes

Current Product Description: PEDIATRIC Current Electrode Artwork New Electrode Artwork PADPRO PADPRO Current Pouch Labeling (Front Only) New Pouch Labeling (Front and Back)









Changes Affecting MINI PEDIATRIC Electrodes

Product Codes Affected:

2602 2602H 2602M 2602P 2602Z

5 product codes

