

PRODUCT LABEL REVISION

Monday, August 22, 2016

Dear Valued Life-Assist Customer,

Our supplier, Conmed Corporation has advised that they will be incorporating revised labeling on all PADPRO® Multifunction Electrodes in order to remain consistent with the American Heart Association guidelines and recommendations.

Please read the enclosed attachment and reference the affected Life-Assist stock item codes below.

It is important to note that these changes are strictly labeling revisions. The electrodes have NOT changed in terms of product design or functionality (for fit, form, or function).

Life-Assist will be updating our stock item codes once we receive product with revised labeling.

Old Life-Assist No.	New Life-Assist No.	Label Revision (see attached manufacturer letter for more details):	Product with Revised Labels Expected to start shipping:
EL2603H	EL3603H	Pediatric to Infant <10kg	Shipping Now (use new item number)
EL2603M	EL3603M	Pediatric to Infant <10kg	Shipping Now (use new item number)
EL2603Z	EL3603Z	Pediatric to Infant <10kg	Shipping Now (use new item number)
EL2001M	EL3001M	Adult to Adult/Child ≥10kg	Late October
EL2001MPC	EL3001MPC	Adult to Adult/Child ≥10kg	Late October
EL2001Z	EL3001Z	Adult to Adult/Child ≥10kg	Late October
EL2001ZPC	EL3001ZPC	Adult to Adult/Child ≥10kg	Late October

Please contact Life-Assist Customer Service 800-824-6016 or saleservice@life-assist.com with any questions.

We apologize for any inconvenience.





Cardiology & Critical Care Division

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 \geq 10kg**. (There is a statement on the pouch that addresses Child use in AED Mode (the patient weight in this instance becomes \geq 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 questions 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

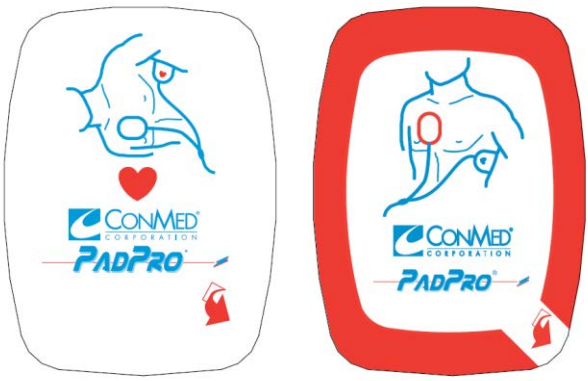
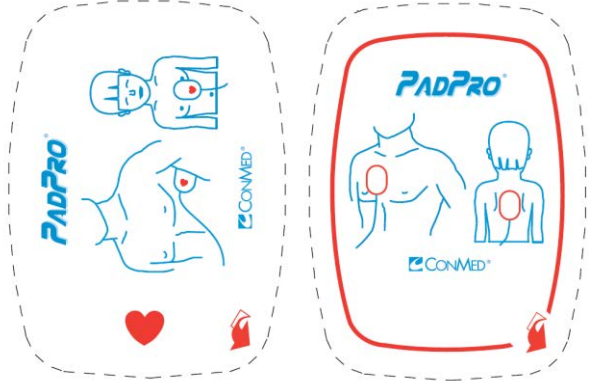
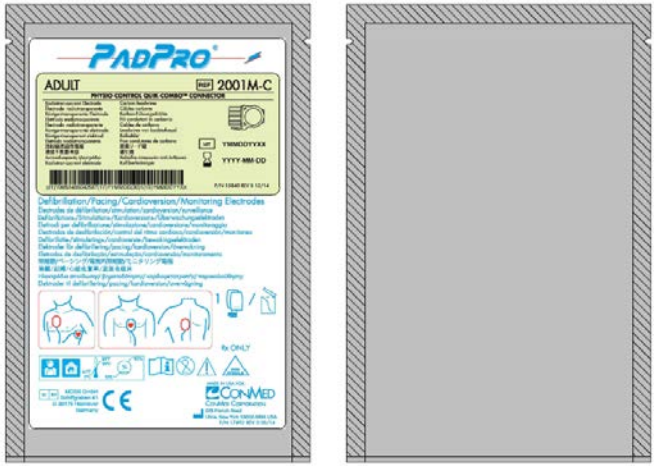
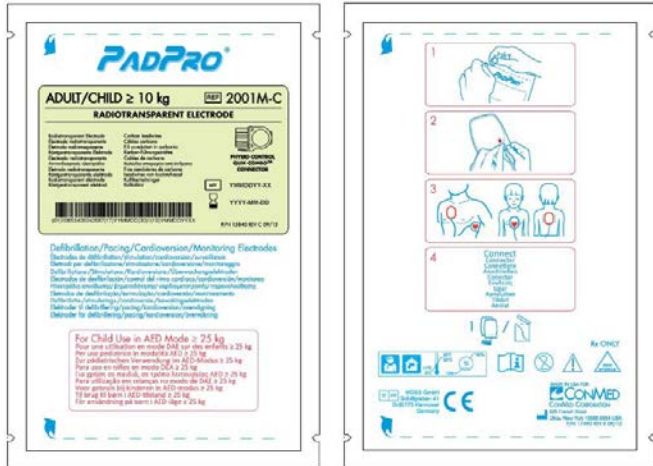
MCM2016107

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

Current Product Description: ADULT	New Product Description: ADULT/CHILD ≥10kg
Current Electrode Artwork 	New Electrode Artwork 
Current Pouch Labeling (Front Only) 	New Pouch Labeling (Front and Back) 

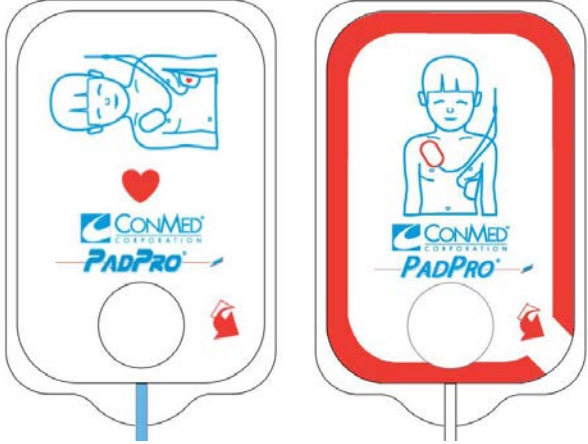
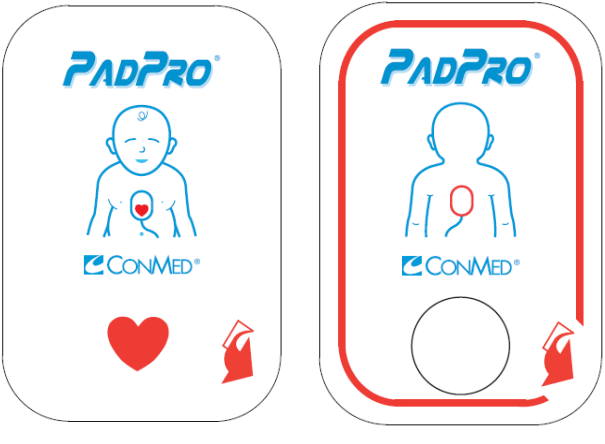

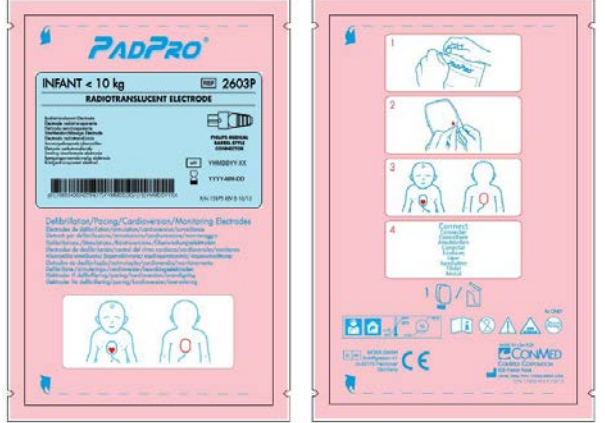
Note: Silver pouches (depicted by the grey background above) were used to identify adult radiotransparent electrodes (while white pouches were used to identify the radiotranslucent electrodes). As part of this labeling project, ALL products will be packaged in white pouches regardless. The text on the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

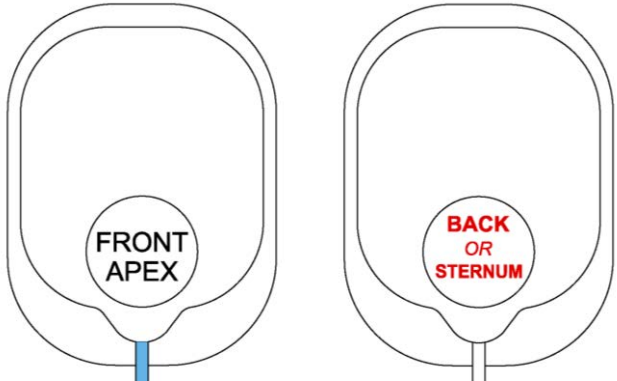
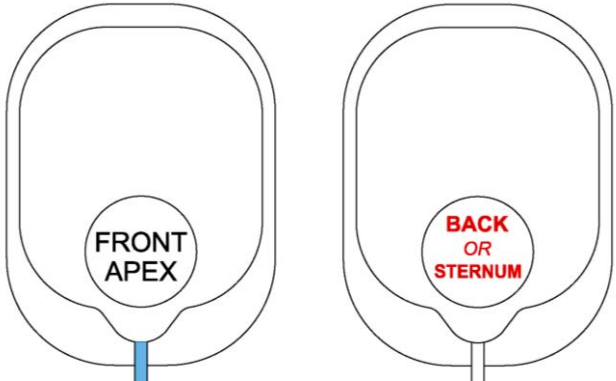
Current Product Description: PEDIATRIC	New Product Description: INFANT <10kg
Current Electrode Artwork	New Electrode Artwork
	
Current Pouch Labeling (Front Only)	New Pouch Labeling (Front and Back)
	

Changes Affecting MINI PEDIATRIC Electrodes

Product Codes Affected:

2602
2602H
2602M
2602P
2602Z

5 product codes

Current Product Description: MINI PEDIATRIC	New Product Description: MINI INFANT <3kg
Current Electrode Artwork	New Electrode Artwork
	 No Changes
Current Pouch Labeling (Front Only)	New Pouch Labeling (Front and Back)
