CONMED Corporation, PadPro and R2 Multi-Function Defibrillation Electrodes Will Not Work with Philips FR3 and FRx AEDs

Recall Class: Class I

Date Recall Initiated: November 6, 2014

Devices:

All lot codes of the following AED electrodes distributed between March 1, 2012 – October 29, 2014.

- Adult Radiotransparent Electrode
  - Catalog Number: 2001H, 2001H-C, 2001H-PC, 2516H, 2516H-PC
- Pediatric Radiotranslucent Electrode
  - Catalog Number: 2603H
- Mini Pediatric Radiotranslucent Electrode
  - Catalog Number: 2602H
- Pediatric R2 Multifunction Electrode
  - Catalog Number: 3115-1750
- R2 Multifunction Electrode
  - Catalog Number: 3115-1751

NOTE: These electrodes will work with other Philips AEDs that accept plug style connectors.

Use: Electrodes are connected to an automatic external defibrillator (AED), which analyzes the heart rhythm in cardiac arrest patients and delivers an electrical shock to restore normal heart rhythm. The primary users of AEDs are first responders and hospital health care providers.

Recalling Firm

CONMED Corporation
525 French Road
Utica, NY 13502-5994

Reason for Recall:
Philips made changes to the connector design of their FR3 and FRx AEDs. Because of these changes, the CONMED electrodes will no longer work with these AEDs.

The FRx AED requires electrode pads be connected to the device before it is used. The AED will make a continuous alarm chirp to alert the user that the correct pads are not connected.

The FR3 does not require electrode pads to be pre-connected. Users will not know that the pads do not work until they try to use the AED. This may result in a delay in delivering the electrical therapy needed to revive a patient.

Delay in therapy could result in serious injury or death.

Public Contact:
If you have questions about this recall, you can contact CONMED at 727-399-5276, Monday – Friday, 8 am- 5 pm ET, or by email at multifunctionelectrodes@conmed.com.

FDA District: New York District Office

More Information about this Recall:
On November 6, 2014, CONMED sent customers an Urgent Device Correction letter. The letter alerted customers of the issue and indicated that the company was in the process of revising their labeling.

The Urgent Device Correction advised customers:

- Not to use the affected electrodes with Philips FR3 or FRx AEDs
- Review the use of CONMED defibrillation electrodes in their facility to assure that CONMED electrodes are not placed for use with Philips FR3 or FRx AED's.
- Distributors should notify their customers of the issue.
- Product does not need to be returned.

Philips FR3 and FRx AEDs should only be used with the Philips brand electrodes listed in the device manual.

About Class I Recalls
Class I recalls are the most serious type of recall. They involve situations when it is likely that use of these devices will cause serious health problems or death.

Health care professionals and consumers can report bad reactions or quality

problems they had using the device to MedWatch: The FDA Safety Information and Adverse Event Reporting Program either online, by regular mail or by FAX.

Additional Resources:

- Firm Press Release
- Covidien, Medi-Trace Cadence and Kendall Defibrillation Electrodes – Electrodes will Not Work with Philips FR3 and FRx Automated External Defibrillators (AEDs)

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

Contact FDA