Medical Device Safety
Medical Device Recalls
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Heart Sync, Multi-function Defibrillation Electrodes Will Not Work with Philips FR3 and FRx AEDs

Recall Class: Class I

Date Recall Initiated: November 11, 2014

Devices:

All lot codes of the following AED electrodes distributed between October 26, 2011 and November 26, 2014

- Adult Radiotransparent Electrode
  - Catalog Number C100-PHILIPS
- Adult/Child Radiotransparent Electrode
  - Catalog Number C100AC-PHILIPS
- Adult Radiotransparent Electrode
  - Catalog Number T100LO-PHILIPS
- Radiotranslucent Electrode

- Catalog Number T100-PHILIPS

- Adult/Child Radiotranslucent Electrode
  - Catalog Number T100AC-PHILIPS

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
Heart Sync, Inc.
5643 Plymouth Road
Ann Arbor, Michigan 48105-9586

Reason for Recall:

Philips made changes to the connector design of their FR3 and FRx AEDs. Because of these changes, the Heart Sync 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 Heart Sync at 734-213-5530, 24 hours a day, 7 days a week or by email at Jahana@heartsync.net.

FDA District: Detroit District Office

More Information about this Recall:

On November 11, 2014, Heart Sync sent customers a Voluntary Field Safety Alert by email. On November 26, 2014, Heart Sync issued a Voluntary Device Correction via Press Release. Each communication included a description of the recalled product and indicated that the company was in the process of revising their labeling.

Heart Sync advised customers not to use the affected electrodes with Philips FR3 or FRx AEDs.

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
- Photos of Device Label
- Covidien, Medi-Trace Cadence and Kendall Defibrillation Electrodes – Electrodes will Not Work with Philips FR3 and FRx Automated External Defibrillators (AEDs)
- CONMED Corporation, PadPro and R2 Multi-Function Defibrillation Electrodes Will Not Work with Philips FR3 and FRx AEDs

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Contact FDA