U.S. FOOD & DRUG ADMINISTRATION

MedWatch - The FDA Safety Information and Adverse Event Reporting Program

Infant/Child Reduced Energy Defibrillation Electrodes by Cardinal Health: Voluntary Field Action - Incorrect Artwork on Packaging

Electrodes used only with LIFEPAK EXPRESS AED, LIFEPAK CR Plus AED, LIFEPAK 1000 defibrillator, or LIFEPAK 500 Biphasic AED with a pink connector

AUDIENCE: Risk Manager, Emergency Medicine

ISSUE: Physio-Control announced it is launching a voluntary field action for specific production lots of Infant/Child Reduced Energy Defibrillation Electrodes (defibrillation electrodes) produced by Cardinal Health. The company is notifying customers of an issue with the artwork on the defibrillation electrodes, as manufactured by Cardinal Health, which shows incorrect electrode placement for an infant. There is no issue with the performance or function of the defibrillation electrodes; this is limited to incorrect artwork on the defibrillation electrodes within the packaging.

If the user incorrectly places the defibrillation electrodes, it may result in ineffective energy delivery to the patient and serious injury or death.

BACKGROUND: The defibrillation electrodes are used only with LIFEPAK EXPRESS AED, LIFEPAK CR Plus AED, LIFEPAK 1000 defibrillator, or LIFEPAK 500 Biphasic AED with a pink connector. Adult defibrillation electrodes are not impacted. Approximately 14,200 electrodes have been affected.

RECOMMENDATION: Affected customers will be notified by letter. The company is contacting customers to notify them of the issue, and to provide customers with correct electrode placement instructions to be included with the AEDs until they receive their corrected defibrillation electrodes. Physio-Control will provide replacement products for all unused affected defibrillation electrodes.

As an alternative, if customers decide not to use the affected defibrillation electrodes and they do not have a spare set of infant/child defibrillation electrodes, based on American Heart Association (AHA) and European Resuscitation Council (ERC) 2015 Guidelines, customers may consider the use of adult defibrillation electrodes until they receive their replacement set of infant/child defibrillation electrodes.

Information is available at: https://www.physio-control.com/ProductNotices.aspx. Customers with questions regarding this notification should contact Physio-Control by calling 1-866-231-1220, 6:00 a.m. to 4:00 p.m. (Pacific) Monday – Friday, or by email to rsrecalls@physio-control.com or fax to 1-866-448-9567

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch Safety Alert, including a link to the press release, at:
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm583874.htm