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Physio-Control Launches Voluntary Field Action for Specific Production Lots of Infant/Child Reduced Energy Defibrillation Electrodes Produced by Cardinal Health

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REDMOND, Wash.--(BUSINESS WIRE)--(Product Bulletin) Physio-Control announced today that the company 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.

Correct Electrode Package Label

Correct Artwork on Electrode

Incorrect Artwork on Electrode

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. There have been no customer complaints reported for this issue.

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,[1,2] customers may consider the use of adult defibrillation electrodes until they receive their replacement set of infant/child defibrillation electrodes.

Affected customers will be notified by letter. Information about this notice is available at: https://www.physio-control.com/ProductNotices.aspx. Customers with questions regarding this notification, please 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.

In addition to contacting Physio-Control, any potential quality problems or adverse reactions or events associated with the use of a Physio-Control product may be reported to the U.S. Food and Drug Administration's MedWatch Safety Information and Adverse Event Reporting Program online at www.fda.gov/MedWatch/report.htm, by phone 1-800-332-1088 or fax 1-800-FDA-0178.

About Physio-Control

Physio-Control is the world's leading provider of professional emergency medical response solutions that predict or intervene in life-threatening emergencies. The company's products include LIFEPAK® monitor/defibrillators and automated external defibrillators (AED), LUCAS® Chest Compression Systems, the LIFENET® System, HeartSine® AEDs and more. Learn more at www.physio-control.com, or connect on Facebook, LinkedIn or Twitter.

[1] Atkins D, Berger S, Duff J, et al. American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Care. *Circulation*. Part 11: Pediatric Basic Life Support and Cardiopulmonary Resuscitation Quality. 2015;132(18 suppl 2): pS525.

[2] Ian K. Maconochie, Robert Bingham et al. European Resuscitation Council Guidelines for Resuscitation 2015 Section 6. Pediatric life support. Resuscitation 95 (2015) 223–248: p235.

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