State of New Hampshire
Department of Safety

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CLINICAL BULLETIN

Bulletin #	Title			Date Issued
44	Incorrect Artwork on Packaging on Infant Defibrillation Pads			January 9, 2018
Superseded	**Released By**	**Approved By**	**Source**	
	Vicki Blanchard, NRP	Jim Suozzi, DO	FDA	

Defibrillation Electrodes for Lifepak AEDs by Physio-Control: Class I Recall - Incorrect Placement Instructions for Infants Depicted on Artwork

Includes electrodes for LIFEPAK EXPRESS AED, LIFEPAK CR Plus AED, LIFEPAK 1000 defibrillator, or LIFEPAK 500 Biphasic AED with a pink connector

[Posted 12/19/2017]

AUDIENCE: Risk Manager, Critical Care Medicine, Emergency Medicine

ISSUE: Physio-Control Inc. is recalling infant/child defibrillation electrodes because the artwork on the pads within the packaging shows incorrect placement instructions for infants. There is no issue with the performance or function of the defibrillation electrodes. However, incorrect placement of the electrodes on an infant may result in failure to deliver an effective shock to an infant in cardiac arrest. A delay in therapy could result in serious injury and/or death.

- Model/Item Numbers: 11101-000016 and 11101-000017
- Lot codes: 713609, 717912, 713904, 718033, 715008, 719323, 45932237, 46042286, 45979590, 46050960, 45979954, 46052545, 46007867, 46061770, 46023185, 46063054, 46023823, 46078012
- Manufacturing Dates: April 27, 2017 to August 10, 2017
- Distribution Dates: May 30, 2017 to September 4, 2017

BACKGROUND: Automatic external defibrillators (AEDs) are used to deliver lifesaving electrical shocks to people with sudden cardiac arrest, a medical condition in which the heart suddenly and unexpectedly stops beating. Defibrillation electrodes are connected to the AED to help the device analyze a patient's heart rhythm and deliver an electrical shock to restore normal heart rhythm when needed. The primary users of AEDs are first responders and hospital health care providers.

RECOMMENDATION: On October 27, 2017, Physio-Control Inc. issued a Voluntary Field Action to provide customers with correct electrode placement instructions to be included with the AEDs until they receive their corrected 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, customers may consider the use of adult defibrillation electrodes based on American Heart Association and European Resuscitation Council 2015 Guidelines until they receive their replacement set of infant/child defibrillation electrodes.