URGENT MEDICAL DEVICE RECALL
Infant/Child Reduced Energy Defibrillation Electrodes

PHYSIO CONTROL

ADDRESS
35 Great St. Helen's
London EC3A 6AP
United Kingdom

www.physio-control.co.uk

December 2017

Please bring this letter to the immediate attention of the person(s) responsible for maintaining/monitoring your LIFEPAK® automated external defibrillators (AED).

Dear Valued Customer,

The purpose of this letter is to advise you that Physio-Control is voluntarily recalling specific production lots of Infant/Child Reduced Energy Defibrillation Electrodes (defibrillation electrodes) produced by Cardinal Health. Approximately 14,200 electrodes have been affected.

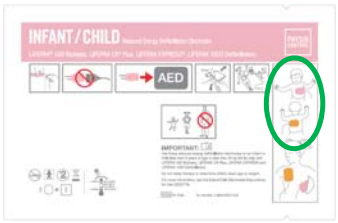
The defibrillation electrodes are used only with LIFEPAK EXPRESS® AED, LIFEPAK CR® Plus AED, LIFEPAK®1000 defibrillator, or LIFEPAK 500 Biphasic AEDs with a pink connector. There have been no customer complaints reported for this issue.

Description of Issue

The artwork on the defibrillation electrodes, as manufactured by Cardinal Health, does not meet Physio-Control's specifications, and 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. **The artwork on the electrode packaging shows the correct electrode placement for an infant.**

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

Correct Electrode Package Label



Correct Artwork on Electrode

Incorrect Artwork on Electrode

Required Customer Actions:

Upon receipt of this notification, post a copy of the enclosed Correct Electrode and Packaging Labeling with each of your AEDs, which shows the correct placement of the electrodes.

As an alternative, if you decide not to use the affected electrodes and you do not have a spare set of infant/child electrodes, based on American Heart Association (AHA) and European Resuscitation Council (ERC) 2015 Guidelines[1,2], your Medical Director may consider the use of adult electrodes until you receive your replacement set of infant/child electrodes.

[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.

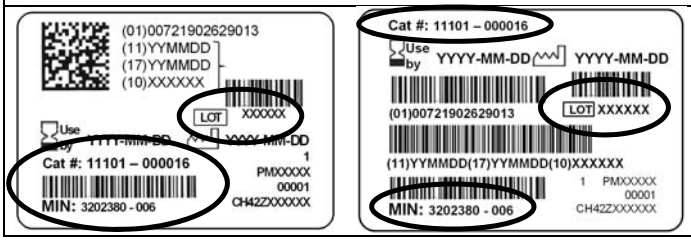
[2] Ian K. Maconochie, Robert Bingham et al. European Resuscitation Council Guidelines for Resuscitation 2015 Section 6. Pediatric life support. Resuscitation 95 (2015) 223–248. Resuscitation 95 (2015) 223–248: p235.

Physio-Control's Planned Actions

Physio-Control will provide replacement products for all unused affected electrodes. Following are the affected lots:

Description	Catalog #	MIN #	Lot Number	
Electrode	11101-000016	3202380-006	713609	717912
			713904	718033
			715008	719323
Electrode Starter Kits	11101-000017	3202784-009	45932237	46042286
			45979590	46050960
			45979954	46052545
			46007867	46061770
			46023185	46063054
			46023823	46078012

Confirm the quantity of the affected lot numbers listed above in your inventory. You may identify the Catalog and Lot Number by looking at the labels on the outside of the electrode pouch, electrode box, or electrode starter kit box following the information below.

Electrode Pouch and Box Labeling	Electrode Starter Kit Box Labeling
	

We apologize for this inconvenience. Please contact your local Physio-Control distributor to arrange for replacement of your unused electrodes and if you have any questions about this Product Recall.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies.

Sincerely,

Kathryn E. Janecke

Kathryn E. Janecke
Senior Director, Quality
Physio-Control, Inc.