URGENT MEDICAL DEVICE RECALL
Physio-Control QUIK-COMBO® pacing/defibrillation/ECG electrodes with EDGE System™ technology and REDI-PAK® preconnect system

Physio-Control, Inc. | Lifesaving starts here.™

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November 6, 2015

Attention: Risk Management Director and Materials Management

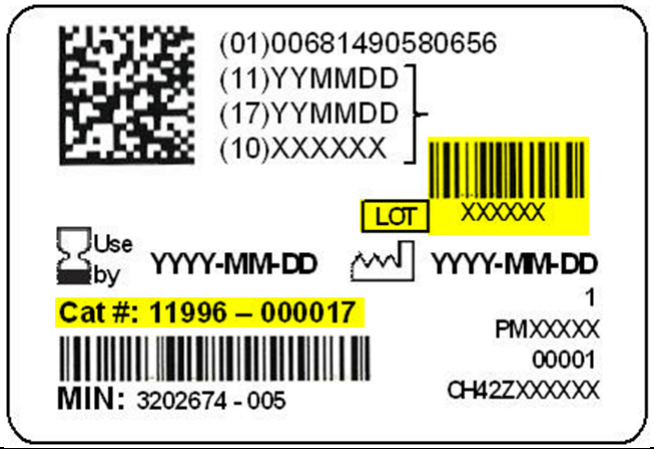
Dear Valued Customer,

The purpose of this letter is to advise you that Physio-Control's supplier of QUIK-COMBO adult, pacing/defibrillation/ECG Electrodes with Edge System technology and REDI-PAK preconnect system is voluntarily recalling specific production lots. The defibrillation electrodes are used in conjunction with certain Physio-Control LIFEPAK® products. This voluntary recall is being conducted due to a low-level potential for damage to the wire insulation during the manufacturing process of these specific lots. No complaints for this issue have been reported from customers. The use of products with this condition may result in a potentially increased risk for reduced or no patient therapy, arcing of current, sparking, and patient and/or clinician burns. **No patient injuries have been reported related to this damaged wire insulation issue.**

On behalf of our supplier, Physio-Control, Inc. is requesting that customers quarantine any remaining stock of the items/lots detailed below. Unused products from the affected item codes and lots should be returned as described in the **Required Actions** section below. Accompanying this letter, we are providing replacement product for all affected electrodes shipped to your facility.

Catalog #	MIN #	Description	Lot Number
11996-000017	3202674-005	ADULT-EDGE Electrode with QUIK-COMBO Connector and REDI-PAK Preconnect	516907
			519815
			519816

Required Actions:

1.	PLEASE QUARANTINE AND DISCONTINUE USE IMMEDIATELY OF THE AFFECTED LOT NUMBERS LISTED ABOVE AND DESCRIBED IN THE ATTACHED CONFIRMATION SHEET.
2.	**How to distinguish affected product by Catalog Number and Lot Number** 
3.	Complete the attached confirmation sheet and return all unused inventory of the affected lot codes to Physio-Control.

This action is being taken with the knowledge of the FDA and other regulatory authorities. We request you report any quality problems experienced with the use of this product to the FDA and Physio-Control:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or
- Call FDA 1-800-FDA-1088
- Email Physio-Control Technical Support at: LIFEPAKsupport@physio-control.com

We apologize for this inconvenience. Should you have any questions about this Product Recall, please contact us at 1-800-442-1142, option 2, 6:00 A.M. to 4:00 P.M. (Pacific), Monday – Friday.

Sincerely,

Rod J. Rylands
Vice President, Quality
PHYSIO-CONTROL, INC.