

URGENT FIELD SAFETY NOTICE
Physio-Control QUIK-COMBO® pacing/defibrillation/ECG electrodes
with EDGE System™ technology and
REDI-PAK® preconnect system



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

February XX, 2016

ADDRESS

11811 Willows Road NE
Redmond, WA 98052

PHONE

GENERAL
425 867 4000
TOLL-FREE
800 442 1142

www.physio-control.com

Attention: Risk Management Director and Materials Management

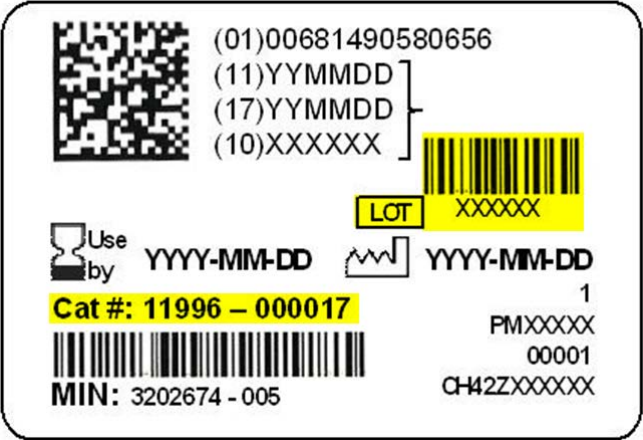
Dear Valued Customer,

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.

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 contact Physio-Control at {unique information to be filled in here for each country}, Monday – Friday to arrange for replacement of all unused inventory of the affected lot numbers.

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the electrodes have been transferred.

We apologize for this inconvenience. Should you have any questions about this Product Recall, please contact us at {unique information to be filled in here for each country}, Monday – Friday.\

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

Sincerely,

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