



February 9, 2010

MEMORANDUM #2010-01

FROM: Saginaw Valley Medical Control Authority
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OFFICE OF THE MEDICAL DIRECTOR
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SUBJECT: Physio-Control Advisory on Aftermarket Pads

Our office recently received an advisory letter from Physio-Control regarding the use of aftermarket pads with LIFEPAK monitors/AEDs.

Physio-Control has had a recent increase of reports where therapy (defibrillation) was delayed when agencies were using other manufacturers' electrodes. In these cases, the display on the LIFEPAK would read "Leads Off" or "Connect Electrodes" causing a delay in treatment. The problem in many cases appears to be an issue with the connector/adaptor.

In August 2009, SKINTACT[®] Multifunction Defib Electrodes were recalled by Leohard-Lang. The pads were noted to have issues with the connector when used with the LIFEPAK.

Although Physio-Control does not prevent any agency from using aftermarket electrodes; it is important to understand that they do not test these products themselves and therefore cannot attest to their proper function.

For all agencies within the SVMCA: If you have any of the recalled aftermarket pads, please return them to the manufacturer for replacement. For those using aftermarket pads with your monitor/AED (PadPro, etc.), you can continue to use them but check your connections on you next inspection and ensure the monitor detects their presence. If you experience a failure of any sort during the inspection or on a call, please contact our office and Physio-Control immediately.

We have attached the Physio-Control advisory to this memo.



Physio-Control, Inc.
11811 Willows Road NE, P.O. Box 97006, Redmond, WA 98073
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Dear Customer:

We would like to alert you to an issue that involves the use of therapy electrodes sold by other manufacturers for use with Physio-Control LIFEPAK® defibrillators. Our Complaints Handling department has reported an increasing number of customer complaints involving the use of non-Physio-Control therapy electrodes and other accessories.

Physio-Control is driven by our commitment to quality and affording our customers the assurance that the products and accessories we offer provide a complete system from a medical, operational and legal standpoint. It is important to understand that our devices have not been tested for use with other manufacturers' therapy electrodes, so we cannot confirm the reliability, safety or effectiveness of these therapy electrodes for use with our LIFEPAK products.

We have had several reported cases in which therapy was delayed when customers were using other manufacturers' therapy electrodes with Physio-Control LIFEPAK products. In these cases the device continually displayed a "Leads Off" or "Connect Electrodes" message during use. Subsequent evaluation found no failures with the Physio-Control LIFEPAK devices.

In August of 2009, Leonhard-Lang issued a recall of their electrodes (SKINTACT® Multifunction Defib Electrodes) stating that the electrodes they manufacture for use with Physio-Control devices posed a potential patient risk. According to the recall letter, "it was found that some of the connectors do not easily slip into the sockets of the defibrillator or an extension cord of the defibrillator". The letter states, "although we have inspected the connectors for their fit with original Physio-Control equipment, we cannot rule out that some of the connectors, which do not insert into the sockets, have slipped through our inspection".

If you experience problems with your Physio-Control LIFEPAK devices when using therapy electrodes manufactured by another company, please do the following:

- Report the issue to your Physio-Control Sales or Service representative.
- Retain the therapy electrodes that were used, along with packaging, as these will be needed as part of any investigation.

In summary, only those electrodes labeled as Physio-Control products are recommended for use with LIFEPAK defibrillator/monitors and automated external defibrillators (AEDs). You can obtain Physio-Control Accessories by calling 800-442-1142, visiting the Physio-Control web store at <http://store.physio-control.com> or by contacting your authorized reseller.

Sincerely,

PHYSIO-CONTROL, INC.

Paula Lank
VP, Clinical and Regulatory Affairs

