

**URGENT MEDICAL DEVICE CORRECTION – ACTION REQUIRED**  
**LIFEPAK<sup>®</sup> CR Plus AED and LIFEPAK<sup>®</sup> EXPRESS AED**

**PHYSIO  
CONTROL**

Physio-Control Operations Netherlands B.V. | Lifesaving starts here.™

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**URGENT – Please bring this letter to the immediate attention of the person(s) responsible for maintaining/monitoring your Automated External Defibrillators (AED's).**

August 2016

Dear Customer,

This communication is intended to provide you with critical information regarding the readiness of your **LIFEPAK CR Plus** and/or **LIFEPAK EXPRESS** Automatic External Defibrillator(s). Physio-Control is conducting a **Field Correction** for certain serial of the LIFEPAK CR Plus and LIFEPAK EXPRESS AED's. The attached Confirmation Sheet includes the list of affected units by serial number that are in your possession, and are impacted by this Field Correction. If the serial number is not numbers listed on the Confirmation Sheet it is not impacted by this Field Correction and no additional actions are necessary for that device.

**Description of the Issue**

Physio-Control has become aware of an issue whereby the **LIFEPAK CR Plus AED or LIFEPAK EXPRESS AED** may fail to initiate voice prompts when the ON/OFF button is pressed and the lid is opened due to an internal component (reed switch) that can intermittently become fixed in the closed position. A defibrillator in this condition will fail to deliver a shock, with the potential result that therapy is not delivered and a patient is not resuscitated. All reports received from customers have been noted during initial set up and testing of the device. To date, there have been no patient related events.

**Physio-Control's Planned Actions**

Physio-Control is contacting customers with **LIFEPAK CR Plus and LIFEPAK EXPRESS AED's** that contain the affected reed switch assembly. A device correction including replacement of reed switch component will be arranged for all affected devices.

**Requested Customer Actions**

Enclosed with this notice is a Confirmation Sheet that provides a list of affected serial numbers that our records indicate have been distributed to your facility. Please follow the instructions on the Confirmation Sheet that outline specific actions to take for the serial numbers listed. Physio-Control will contact you to arrange component replacement for all affected serial numbers.

**Important Reminders**

The **LIFEPAK CR Plus AED's and LIFEPAK EXPRESS AED's** have a readiness indicator that provides the user with information about the device. If you have a routine check process, please continue this process. If you have not established a routine check process, please refer to section 5 of the Operating Instructions for recommended actions. If you have any questions regarding this notification, please call Physio-Control at 0808 258 0094, 9:00 to 17:00, Monday – Friday.

Sincerely,  
PHYSIO-CONTROL, INC.



Rod Rylands  
Vice President, Quality