

## ADRES

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[www.physio-control.nl](http://www.physio-control.nl)

March 2013

**URGENT FIELD SAFETY NOTICE**  
**LIFEPAK CR® Plus and LIFEPAK EXPRESS® AEDs**  
**FSCA - FA260**

Dear Customer,

Physio-Control, Inc. is notifying you of a potential issue with your LIFEPAK CR Plus or LIFEPAK EXPRESS AEDs that may cause internal battery depletion earlier than expected. The purpose of this communication is to remind you of the necessary maintenance activities you need to routinely perform, make you aware of the potential issue, and provide you with instructions on what to do now.

**What issues have been reported?**

The LIFEPAK CR Plus and LIFEPAK EXPRESS AEDs are battery powered devices and rely upon battery power to operate and deliver therapy. The CHARGE-PAK™ replaceable battery charger is designed to be replaced approximately every two years. In some rare situations, the CHARGE-PAK replaceable battery charger has not lasted two years because of an internal electrical failure that leads to early internal battery depletion. The likelihood of this failure is extremely remote, occurring at an overall rate of ~0.09% of devices in this population over the last 7 years, including one event in 2008 that was associated with a patient death.


The readiness display on your AED will continue to accurately communicate both the device and battery status, even in the event it is affected by this issue.




Routine and consistent monitoring of your device readiness per the Operating Instructions continues to be the most critical ownership responsibility you have to ensure your device is ready when needed.

**Am I affected by this issue?**

Our records indicate LIFEPAK CR Plus or LIFEPAK EXPRESS AED devices with the potential to experience an early internal battery depletion issue have been distributed to your facility. The enclosed list provides the affected serial numbers that we track to your facility.

**What should I do?**

1. Check the readiness of your LIFEPAK® AED immediately by looking at the readiness display:
  - If the **OK** symbol is visible your AED requires no action at this time. Continue to monitor routinely per the Operating Instructions.
  - If the **OK** symbol is not visible, and the CHARGE-PAK symbol () is visible, it is now time to replace the CHARGE-PAK. **If your current CHARGE-PAK has been installed for less than 2 years, your device may be affected by the electrical problem described above.** Contact Physio-Control Technical Support and we will work with you to determine next steps.

- If the **OK** symbol is not visible, and either the ATTENTION () or WRENCH () symbols are present, your device requires immediate attention to ensure its readiness. Contact Physio-Control Technical Support immediately to determine next steps.
2. Leave your device in service and continue to monitor the status of your AED routinely per the Operating Instructions on pages 5-2 through 5-5 and replace the CHARGE-PAK prior to expiration or as soon as the **OK** symbol is gone and the CHARGE-PAK symbol () becomes visible in the readiness display.

**What is Physio-Control going to do with my returned device?**

In the event your device is returned to Physio-Control for assessment, we will analyse it to determine if it is affected by the early internal battery depletion issue. If it is verified to be affected, you will be provided with a permanent replacement device.

**What if I don't have the LIFEPAK CR Plus or LIFEPAK EXPRESS AEDs any longer?**

If you no longer own the LIFEPAK AEDs listed, please contact Physio-Control Technical Support as soon as possible to ensure accurate updating of your account.

**Transmission of this Field Safety Notice:**

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

Please maintain awareness of the potential that your device could be affected by this issue and routinely monitor the readiness of both the device and the battery per the Operating Instructions as long as you own the device.

If you have any questions regarding this notification, please contact our Technical Support at <email address>, or call <phone number> Monday to Friday from <opening hours>.

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

Sincerely,

  
 Director, Quality & Regulatory Affairs EMEA  
 Physio-Control Operations Netherlands B.V.