



## The Florida ESRD Network

### *Class 1 Recall: Physio Control, Inc. LifePak CR Plus Automated External Defibrillators (AEDs)*



**The FDA Safety Information and Adverse Event Reporting Program**

Physio Control, Inc., issued a recall on August 28, 2008 of LifePak CR Plus Automated External Defibrillators (AED), used by emergency or medical personnel to treat adults in cardiopulmonary arrest.

**Product:** LifePak CR Plus Automated External Defibrillator  
Product Number: 3200731-003 and 3200731-027  
This device was manufactured from May 20, 2004 through August 11, 2007 and was distributed from May 20, 2004 through December 4, 2007.

**Reason for Recall:** The product was recalled because the AED instructs the responder, by voice prompts, to press the shock button, which is covered and not visible, therefore the responder is not able to provide therapy (shock).

**Use:** These devices are used by emergency or medical personnel, or by others, who have taken the appropriate training to use this AED. The devices are intended to treat adults in cardiopulmonary arrest (heart attack). They analyze an unconscious patient's heart rhythm and automatically deliver an electrical shock to the heart if needed to restore normal heart rhythm.

**Recalling Firm:** Physio Control, Inc. 11811 Willows Rd NE Redmond, Washington 98052-2003

**Public Contact:** Customers with questions may call Physio Control, Inc. at 1-425-867-4000, extension 4644.

**The AED device should be removed from service or the manufacturer-provided diagram should be consulted to remove and discard the shock button cover.**

The 2008 MedWatch Safety Summary, including a link to the manufacturer's Recall Notice regarding this issue are located at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#LifePakCR>.

*Thank you to ESRD Network 14 for information shared for use in this fax blast.*

The Florida ESRD Network (Network 7) is providing this fax blast as a technical assistance activity for the Florida renal community.

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