



BROADCAST FAX/EMAIL ALERT

TO: Medical Directors, DON's Administrators
DATE: September 11, 2008
RE: Class 1 Recall: Physio Control, Inc. LifePak CR Plus Automated External Defibrillators (AEDs)
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The FDA Safety Information and Adverse Event Reporting Program

Physio Control, Inc., issued a recall of LifePak CR Plus Automated External Defibrillators (AED), used by emergency or medical personnel to treat adults in cardiopulmonary arrest. The product was recalled because the AED instructs the responder by voice prompts to press the shock button, which is not visible because it is covered, thereby making the responder unable to provide shock therapy.

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

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

Date Recall Initiated: August 28, 2008

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.

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

Reason for Recall: The AED instructs the responder, by voice prompts, to press the shock button. However, the shock button is covered and is not visible. Therefore, the responder is not able to provide therapy (shock).

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

For details on FDA Comments or to report problems with the use of this product please print the entire manufacturer's Recall Notice at the above web site.