



CLASS 1 RECALL: PHYSIO CONTROL, INC. LIFEPAK CR PLUS AUTOMATED EXTERNAL DEFIBRILLATORS (AEDS)

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 distributed from May 20, 2004 through December 4, 2007. Two hundred forty-nine (249) devices are affected.

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 visit the following website at www.physio-control-notices.com/config for more information or to enter the serial numbers of their devices to determine if they are affected by this action. Customers may also call Physio-Control Technical Support at 1-800-442-1142, option 5, between 6:00 a.m. and 4:00 p.m. (Pacific Time).

FDA District: Seattle

FDA Comment: Physio Control began calling their customers on August 28, 2008 and:

- described the problem of the covered and invisible shock button, and the inability to provide shock to adults who may be having a heart attack.

- informed their customers that their AEDs would be replaced immediately.
- sent a follow-up letter that was FAXed or emailed the same day stating that the customers should immediately perform **one** of the following actions:
 - Remove the affected AEDs from service **or**
 - Remove and discard the shock button cover (a diagram showing what to do was enclosed).

The company completed notifying its customers on September 2, 2008

Healthcare professionals and consumers may report any problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by FAX.

- **Online** : www.fda.gov/MedWatch/report.htm
- **Regular Mail** : use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm
Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- **FAX**: 1-800-FDA-0178

Updated September 16, 2008



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phone 518.474.6746
fax 518.474.3240
email fire@dos.state.ny.us

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