



The Florida ESRD Network

Class I Recall: Physio-Control Inc., LIFEPAK CR Plus Automated External Defibrillators (AEDs)

Product: Only the Physio-Control LIFEPAK CR PLUS AEDs with the serial numbers below are affected by this recall. The serial number is located on the underside of the device.

Serial Numbers

37026963, 37026983, 37026984, 37026997, 37027002, 37027008, 37027039, 37027040, 37027049, 37027053, 37027063, 37027065, 37027066, 37027070, 37027071, 37027073, 37027075, 37027090, 37027099, 37027105, 37027122, 37027197, 37027529, 37027569, 37031393, 37037850, 37037893, 37037986, 37038002, 37038211, 37038365, 37135986, 37154526, 37154638

The AEDs were manufactured and distributed from July 9, 2008 through August 19, 2008.

Use: This device is used by emergency or medical personnel, by others who have completed CPR AED training courses, or the public at large. It is intended to treat patients in cardiac arrest. The device analyzes an unconscious patient's heart rhythm and instructs the user to press a button that delivers an electrical shock to the heart to restore a normal heart rhythm.

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

Reason for Recall: An extremely humid environment may cause the LIFEPAK CR Plus AED to improperly analyze the rhythm correctly and may cause the device to delay or fail to delivery therapy.

Public Contact: Physio-Control Customer Care
1-800-442-1142, 6 AM through 4 PM Pacific Time

FDA Comments: Physio-Control called their customers from August 18-19, 2009 with a follow-up email message on August 20, 2009. The company sent replacements on August 19, 2009.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious injury or death.

Read the MedWatch 2009 Safety summary, including a link to the Class 1 recall notice at: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm182496.htm>

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