



MEMORANDUM

To: Facility Manager
From: Lisle Mukai, QI Coordinator
Subject: FDA Recall: LIFEPAK CR Plus Automated External Defibrillators
Date: September 16, 2009

FDA RECALL: LIFEPAK CR Plus Automated External Defibrillators (Physio-Control, Inc)

The Network is required to distribute information regarding recalls that potentially affect ESRD facilities and/or patients. The information below was posted on September 16, 2009.

The FDA notified healthcare professionals of a Class I recall of certain LIFEPAK CR Plus Automated External Defibrillators (AED) manufactured and distributed from July 9, 2008 through August 19, 2008. An extremely humid environment may cause the affected devices to improperly analyze the heart rhythm and may cause the device to delay or fail to deliver therapy.

Any adverse events or quality problems that may be related to the use of this product should be reported to the FDA's [MedWatch Adverse Event Reporting program online](#), by phone [1-800-332-1088], or by returning the postage-paid [FDA Form 3500](#) by mail or fax [1-800-FDA-0178].

A list of recalled product serial numbers is attached along with the company's contact information.

Please share this information as applicable within your organizations/practices.

Thank you for your time and attention to this important patient safety issue.

Cc: Steven Preston, Project Officer, CMS RO X

Mission Statement

To provide leadership and assistance to renal dialysis and transplant facilities in a manner that supports continuous improvement in patient care, outcomes, safety and satisfaction.



CLASS I RECALL

LIFEPAK CR Plus Automated External Defibrillators (Physio-Control, Inc)

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