Class I Medical Device Recall: Physio-Control Inc., LIFEPAK 20 and LIFEPAK 20e External Defibrillator and Monitors

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: May 27, 2010

Product(s): LIFEPAK 20 and LIFEPAK 20e External Defibrillator/Monitors

Physio-Control notification and instructions to search for affected devices by serial number.
[1]

The serial number is located on the underside of the device and contains only numbers.

Approximately 42,943 devices were distributed worldwide between September 16, 2002 and September 27, 2007. These devices were manufactured from July 31, 2002 to September 19, 2007.

Use: The LIFEPAK 20 and LIFEPAK 20e defibrillator/monitor is designed for use by trained medical personnel in hospitals and clinic settings to monitor patient heart rhythms and to treat patients experiencing cardiac arrest.

Recalling Firm:

Physio-Control, Inc.

11811 Willows Road NE

Redmond, Washington 98052-2003

Reason for Recall: A failure on the power supply assembly can result in either "No DC power" or "No DC or AC power". A failure of DC (battery) power can result in the inability to deliver defibrillation therapy if the device will not turn on using DC (battery) power and no AC (line) power is available.

Public Contact: Physio-Control Technical Support at rs.sealifepaksupport-usa@medtronic.com [2] or call 1-800-442-1142, Monday Ã¢?" Friday between 6:00 A.M. and 4:00 P.M. (Pacific Time).

FDA District: Seattle

FDA Comments: The firm began mailing notification letters to affected customers on May 26, 2010. All affected power supplies will be updated. Customers are advised to keep the defibrillators in service and follow recommended daily Operator Checklist steps while service updates are scheduled.

Class 1 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 adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to the FDAÃ¢??s MedWatch Adverse Event Reporting program either online, by regular mail or by FAX.

Useful Links:

- LIFEPAK 20 and LIFEPAK 20e daily Operator Checklist [3]
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program [4]

SOURCE [5]

Source URL (retrieved on *02/01/2015 - 12:40am*):
http://www.mdtmag.com/news/2010/07/class-i-medical-device-recall-physio-control-inc-lifepak-20-and-lifepak-20e-external-defibrillator-and-monitors

Links:
[1] http://www.physio-control-notices.com/notice_home.aspx?pid=95
[2] mailto://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/rs.sealifepaksupport-usa@medtronic.com
[3] http://www.physio-control-notices.com/(S(fnmiysq5bi1tkcmwnfmmgy55))/resources.aspx?pid=95
[4] http://www.fda.gov/Safety/MedWatch/default.htm
[5] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm217933.htm