



## FDA Medical Device and Safety Recall

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### Physio-Control Inc. Recalls LIFEPAK 1000 Defibrillator Due to an Electrical Issue Which May Cause the Device to Shut Down Unexpectedly

*The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.*

#### Recalled Product:

- The LIFEPAK 1000 defibrillator
- Affected Product Part Numbers: 320371500XX
- Serial Numbers: There are 133,330 affected serial numbers. [Search Affected Devices](#)
- Distribution Dates: June 30, 2006 to December 23, 2016
- Manufacturing Dates: June 30, 2006 to December 20, 2016
- Devices Recalled in the U.S.: 50,046 nationwide

#### Device Use

The LIFEPAK 1000 Defibrillator is used to deliver lifesaving electrical shocks to people with sudden cardiac arrest, a medical condition in which the heart suddenly and unexpectedly stops beating. Defibrillation electrodes are attached to the patient and then connected to the defibrillator to help the device analyze a patient's heart rhythm and deliver an electrical shock to restore normal heart rhythm when needed. The LIFEPAK 1000 defibrillator is intended for use by medical professionals who are trained in CPR.



#### Reason for Recall

Physio-Control is recalling the LIFEPAK 1000 due to an electrical issue which may cause the device to shut down unexpectedly during patient treatment. Physio-Control has determined that wear and oxidation formation between the battery and device electrical contacts may cause power interruptions. This may prevent the device from delivering the electrical shock needed to revive a patient in cardiac arrest. A delay in delivering this therapy could result in serious patient injury such as permanent organ damage, brain injury, or death.

### **Who May be Affected**

- Health care providers and first responders using this defibrillator
- Patients who may need this defibrillation to restore normal heart rhythm

### **What to Do**

On January 13, 2017, Physio-Control sent an "Urgent Medical Device Correction" letter to all affected customers. The letter asked customers to:

- Review the safety notice and ensure appropriate staff is aware of the notice.
- Follow the instructions on the Confirmation Sheet for each device in possession as indicated by serial number listed. Promptly return the completed Confirmation Sheet to Physio-Control.
- Immediately remove and reinstall the battery from the LIFEPAK 1000 defibrillator. The removal and reinstallation of the battery will clean the contacts of oxidation and will restore power to the device.
- Implement a weekly schedule of battery removal and reinstallation for all LIFEPAK 1000 devices. Removing and reinstalling the battery on a weekly basis will help ensure the device is ready for use. It is also important to always carry a spare, fully charged battery.
- If the device powers off unexpectedly, either during inspection or during patient treatment, immediately remove and reinstall the existing battery to restore power to the device. If power is not restored, replace the battery with a spare battery and call Physio-Control immediately to arrange for servicing of the device.

Physio-Control anticipates contacting customers in May 2017, to schedule a hardware device correction for the LIFEPAK 1000 devices, which includes modifying the power control circuit board of the device and placing dielectric lubrication on the battery and device contacts.

### **Contact Information**

Health care professionals and consumers with questions are instructed to contact Physio Control at 1-866-231-1220 with any questions related to this recall.

### **Date Recall Initiated**

January 12, 2017

### **Additional Resources**

- [Physio-Control Urgent Medical Device Correction Notice](#)
- [Physio-Control Press Release](#)
- [Physio-Control Battery Inspection Checklist](#)

### **How do I report a problem?**

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#) either online, by regular mail or by FAX to 1-800-FDA-0178.

### **Full Release**

[https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm545569.htm?source=govdelivery&utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm545569.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery)

