

Physio-Control Inc. Recalls Defibrillation Electrodes Due to Incorrect Placement Instructions for Infants Depicted on Artwork

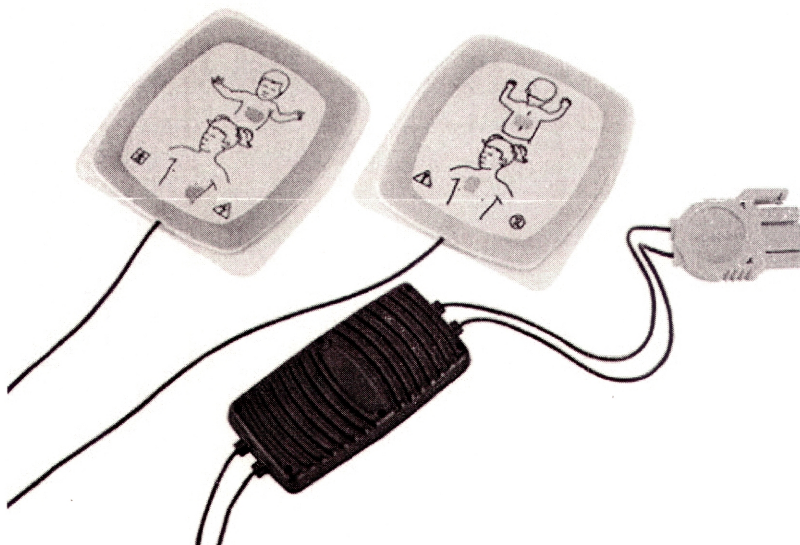
The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product(s):

- Defibrillation electrodes used on the LIFEPAK EXPRESS® AED, LIFEPAK CR® Plus AED, LIFEPAK® 1000 defibrillator, or LIFEPAK 500 Biphasic AED with a pink connector.
- Model/Item Numbers: 11101-000016 and 11101-000017
- Lot codes: 713609, 717912, 713904, 718033, 715008, 719323, 45932237, 46042286, 45979590, 46050960, 45979954, 46052545, 46007867, 46061770, 46023185, 46063054, 46023823, 46078012
- Manufacturing Dates: April 27, 2017 to August 10, 2017
- Distribution Dates: May 30, 2017 to September 4, 2017
- Devices Recalled in the U.S.: 7,973 units nationwide

Device Use

Automatic external defibrillators (AEDs) are 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 connected to the AED to help the device analyze a patient's heart rhythm and deliver an electrical shock to restore normal heart rhythm when needed. The primary users of AEDs are first responders and hospital health care providers.



Physio-Control Inc. Infant/Child Defibrillation Electrodes

Reason for Recall

Physio-Control Inc. is recalling infant/child defibrillation electrodes because the artwork on the pads within the packaging shows incorrect placement instructions for infants. There is no issue with the performance or function of the defibrillation electrodes. However, incorrect placement of the electrodes on an infant may result in failure to deliver an effective shock to an infant in cardiac arrest. A delay in therapy could result in serious injury and/or death.

Who May be Affected

- Infant patients who may need these defibrillation electrodes to restore normal heart rhythm.
- Health care providers and first responders using these defibrillation electrodes on infant patients.

What to Do

On October 27, 2017, Physio-Control Inc. issued a Voluntary Field Action to provide customers with correct electrode placement instructions to be included with the AEDs until they receive their corrected defibrillation electrodes. As an alternative, if customers decide not to use the affected defibrillation electrodes and they do not have a spare set of infant/child defibrillation electrodes, customers may consider the use of adult defibrillation electrodes based on American Heart Association and European Resuscitation Council 2015 Guidelines until they receive their replacement set of infant/child defibrillation electrodes.

Contact Information

Customers with questions regarding this notification, please contact Physio-Control by calling 1-866-231-1220, Monday – Friday, between 6:00 am to 4:00 pm (Pacific time), or by email to rsrecalls@physio-control.com or fax to 1-866-448-9567.

Date Recall Initiated

October 13, 2017

Additional Resources

- [Physio-Control Inc. Field Action Notice \(https://www.physio-control.com/uploadedFiles/Physio85/Contents/About Us/Newsroom/FA279 Infant Child Press Release.pdf\)](https://www.physio-control.com/uploadedFiles/Physio85/Contents/About Us/Newsroom/FA279 Infant Child Press Release.pdf)
- [FDA Press Release - Physio-Control Launches Voluntary Field Action \(/Safety/Recalls/ucm583529.htm\)](/Safety/Recalls/ucm583529.htm)

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 \(https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home\)](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) either online, by regular mail or by FAX to 1-800-FDA-0178.

More in Medical Device Recalls
[\(/MedicalDevices/Safety/ListofRecalls/default.htm\)](/MedicalDevices/Safety/ListofRecalls/default.htm)

2017 Medical Device Recalls [\(/MedicalDevices/Safety/ListofRecalls/ucm535289.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

2016 Medical Device Recalls [\(/MedicalDevices/Safety/ListofRecalls/ucm480134.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)