Physio-Control Recalls LIFEPAK15 Monitor/Defibrillator Due to Risk of Device "Lockup" (Freezing)

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)

- Physio-Control, Inc. LIFEPAK15 Monitor/Defibrillator (LP15)
- Model: LIFEPAK 15 Monitor/Defibrillators with Printed Circuit Board Assembly (PCBA) part no. 3206834-011 or 3206834-012
- Serial/Lot Numbers: See "**Full List of Affected Devices**"
- Manufacturing Dates: March 21, 2013, to July 18, 2016
- Distribution Dates: March 21, 2013, to July 18, 2016
- Devices Recalled in the U.S.: 8,164

Device Use

Physio-Control's LIFEPAK 15 Monitor/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 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 15 monitor displays the patient's heart rhythm so the health care provider can study the heart's electrical activity.

The LIFEPAK 15 is designed to be used only by trained medical personnel during ground transport of a patient.

Reason for Recall

Physio-Control is recalling its LIFEPAK 15 Monitor/Defibrillator because the device may "lockup" (freeze) after a shock is delivered. When this occurs, the device's monitor display goes blank and there is no response from the keypad or the device although the device's LED lights remain on and indicates the device still has power.

Once the LIFEPAK 15 freezes, it cannot provide defibrillation therapy until the device is reset by restarting the device or removing and reinserting all connected power sources. The resulting delay in delivering a shock could and has resulted in serious patient injury including death.

Who May be Affected

- Hospitals, health care professionals, and first responders using Physio-Control's LIFEPAK15 Monitor/Defibrillator to deliver lifesaving defibrillation to patients
- Patients who may require defibrillation to restore normal heart rhythm

What to Do

On February 1, 2019, Physio-Control sent customers an "**Urgent Medical Device Safety Notice & Correction (http://www.strykeremergencycare.com/globalassets/product-notice-blocks/customer-letter/fa281-customer-letter-final-23jan2019.pdf/download)**" letter. The letter informed customers that Physio-Control will provide a firmware update in the affected devices to resolve this issue. The letter also instructed customers to:

- Continue to use their LIFEPAK 15 Monitor/Defibrillator according to the device's Operating Instructions until the firmware correction can be completed.
- Continue to perform the daily check as described in the Operator's Checklist, specifically, the QUIK-COMBO Therapy Cable Check as described in the *General Maintenance and Testing Section* (pages 10-4, and the LIFEPAK 15 Monitor/Defibrillator Operator's Checklist, number 7).
- Immediately follow the steps from the *General Troubleshooting Section* (page 10-18) of the LIFEPAK 15 Monitor/Defibrillator Operating Instructions if a device exhibits a lockup condition during patient use:
  - Press and hold the "ON" button for about 5 seconds until the LED turns off; then press the "ON" button to turn the device back on.
  - If the device does not turn off, remove both batteries and disconnect the device from the power adapter, if applicable; reinsert batteries and reconnect the power adapter, then press the "ON" button to turn the device back on.
  - Continue to perform cardiopulmonary resuscitation (CPR) while the above reset steps are followed.

Contact Information

Customers who have questions or need additional information regarding this recall should contact Stryker at 1-800-442-1142 (select option 7), from 6:00 AM - 4:00 PM, Monday through Friday (Pacific Time), or by emailing **rsfa281@stryker.com (mailto:rsfa281@stryker.com)** or faxing to 1-425-867-4948.

Date Recall Initiated

February 1, 2019

Full List of Affected Devices

- **Physio-Control, Inc. LIFEPAK15 Monitor/Defibrillator (LP15) (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=170355)**

Additional Resources

- **Stryker Urgent Medical Device Safety Notice & Correction: LIFEPAK15 Monitor/Defibrillator (February 1, 2019) (http://www.strykeremergencycare.com/globalassets/product-notice-blocks/customer-letter/fa281-customer-letter-final-23jan2019.pdf/download)**

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 (http://www.fda.gov/Safety/MedWatch/HowToReport/ucm2007306.htm)**. Health care professionals employed by facilities that are subject to **FDA's user facility reporting requirements (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)** should follow the reporting procedures established by their facilities.

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

2019 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm629347.htm)

2018 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm590900.htm)

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

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