ALERTA

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con una Alerta asociada a:

NOMBRE DEL DISPOSITIVO MÉDICO	Desfibrilador PHYSIO CONTROL
NO. IDENTIFICACIÓN RISARH	A1712-578
REFERENCIAS DEL DISPOSITIVO MEDICO	LIFEPAK 20E, seriales específicos.
REGISTRO SANITARIO	2012EBC-0008670
INDICACIONES Y USO ESTABLECIDOS	Proporciona estimulación al corazón para el tratamiento automático de arritmias ventriculares que ponen en peligro la vida del paciente y cuando exhiben síntomas de paro cardiaco repentino.
NOMBRE DEL FABRICANTE	Physio Control, Inc
DESCRIPCION DEL PROBLEMA	El fabricante ha detectado fallas relacionadas con la energía ya que el usuario prepara el dispositivo para su descarga inicial o durante su uso dentro del primero año de distribución, las fallas pueden incluir encendido y apagado inesperados, bloqueo del dispositivo o falla al encender o apagar, dichas fallas son el resultado de un residuo del proceso de fabricación ubicado debajo de un componente montado en el ensamblaje de la placa de circuito impreso de alimentación (PCBA), cualquiera de estas fallas podría provocar la falla en la entrega de la terapia al paciente y lesiones graves o la muerte, conllevando a que se presenten potencialmente eventos adversos serios sobre los pacientes.
FUENTE	ANEXO
FECHA DE NOTIFICACION	29 de diciembre de 2017

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RECOMENDACIÓN:

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con su proveedor quien determinara las acciones que se llevaran a cabo.

Es importante mantener un estado de alerta, realizando un seguimiento permanente a los productos que se fabrican y/o comercializan en el país, divulgando la información de seguridad respectiva entre los profesionales de la salud que realizan uso de estos recursos tecnológicos.

Para mayor información comuníquese al teléfono 2948700 extensión 3880 en Bogotá, ó al correo electrónico tecnovigilancia@invima.gov.co

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ANEXO

[Critical Priority] - A29772 : Physio-Control—LIFEPAK 20e Defibrillator/Monitors: May Exhibit Power-Related Failures
Medical Device Ongoing Action

Published: Monday, December 11, 2017
Last Updated: Thursday, December 14, 2017

UMDNS Terms:

- Defibrillator/Pacemakers, External [17882]

Product Identifier:

LIFEPAK 20e Defibrillator/Monitors *[Capital Equipment]*

For affected serial numbers, see the letter sent to your facility.

Units manufactured between September 2016 and June 2017

Geographic Regions: Worldwide

Manufacturer(s): Physio-Control Inc11811 Willows Rd NE, Redmond, WA 98052, United States

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, OR/Surgery, Risk Management/Continuous Quality Improvement, Home Care, EMS/Transport

Problem:
In a December 2017 Urgent Medical Device Correction letter submitted by an ECRI Institute member hospital, Physio-Control states that it has received reports of the above devices exhibiting power-related failures as the user prepared the device for initial deployment or during use within the first year of distribution. The failures may include unexpected power on and power off, device lockup, or failure to power on or off. Any of these failures could result in a failure to deliver therapy to the patient and serious injury or death. Physio-Control also states that the failures are the result of a manufacturing process residue located beneath a component mounted on the power printed circuit board assembly (PCBA). Physio-Control has received 37 reports related to this problem; however, the firm has received no reports of adverse events related to the problem.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the December 2017 Urgent Medical Device Correction letter and Confirmation Sheet from Physio-Control. A Physio-Control representative will contact your facility to arrange for a device correction that will include replacement of the power PCBA. Completethe Confirmation Sheet, and return it to Physio-Control using the instructionson the form.
For Further Information:
Physio-Control
Tel.: (866) 231-1220, 6 a.m. to 4 p.m. Pacific time, Monday through Friday
Website: Click here

Comments:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our HDA Format Guide .

Source(s):

- 2017 Dec 8. Member Hospital. Physio-Control letter submitted by ECRI Institute member hospital Download
- 2017 Dec 14. Manufacturer. Manufacturer confirmed information