INFORME DE SEGURIDAD

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 un Informe de Seguridad asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Desfibriladores NIHON KOHDEN
NO. IDENTIFICACIÓN RISARH	I1612-572
REFERENCIAS DEL DISPOSITIVO MEDICO	AED-2100K
REGISTRO SANITARIO	2008EBC-0002632
INDICACIONES Y USO ESTABLECIDOS	Diseñado para usar en la resucitación cardiaca a los pacientes en el momento de sufrir paros cardiacos.
NOMBRE DEL FABRICANTE	Nihon Kohden Corporation
DESCRIPCION DEL PROBLEMA	El fabricante indica que la energía en los desfibriladores (AED) mencionados pueden no apagarse, después de completar la prueba de autodiagnóstico diario, lo que podría dar como resultado que la batería se descargue en un día. Si ocurre este problema, el indicador de estado permanece encendido (rojo), pero no hay sonido de alarma generada y la desfibrilación puede no estar disponible cuando sea necesario debido a un agotamiento de batería conllevando a que se presenten posibles eventos adversos serios sobre el paciente.
FUENTE	Anexo 1
FECHA DE NOTIFICACION	14 de Diciembre de 2016

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 1

[High Priority] - A27550 : NIHON KOHDEN—cardiolife AED-2100K Automated External Defibrillators: Battery May Become Depleted Prematurely after Post-Self-Test Shutdown Failure
Medical Device Ongoing Action

Published: Wednesday, December 7, 2016

UMDNS Terms:

- Defibrillators, External, Automated [17116]

Product Identifier:
cardiolife AED-2100K Automated External Defibrillators (AEDs) *[Capital Equipment]*

Geographic Regions: Asia, Central America, Europe, Middle East, South America

Manufacturer(s): Nihon Kohden Europe GmbHRaiffeisenstrasse 10, D-61191 Rosbach vor der Hoehe, Germany

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Nursing, Information Technology, Home Care, EMS/Transport

Problem:
In a December 2016 Important Field Safety Notice letter posted by the German Federal Institute for Drugs and Medical Devices (BfArM), NIHON KOHDEN states that the power on the above AEDs may not turn off after completion of the daily internal self-test, potentially resulting in the battery becoming discharged within one day. NIHON KOHDEN also states that if this problem occurs, the status indicator remains lit (red) but no alarm sound is generated and defibrillation may not be available when required because of a depleted battery.

Action Needed:
Identify any affected AEDs in your inventory. If you have affected AEDs, verify that you have received the December 2016 Important Field Safety Notice letter, receipt of Field Safety Notice form, and Return Delivery Sheet from NIHON KOHDEN. Notify all relevant personnel at your facility of the information in the Important Field Safety Notice letter. Complete the receipt of the Field Safety Notice form, and return it to NIHON KOHDEN using the information in the letter. Upon receipt of the form, a NIHON KOHDEN representative will contact your facility to arrange to pick up affected AEDs. Complete the Return Delivery Sheet, and return it, along with affected product, to NIHON KOHDEN. NIHON KOHDEN will update the software to version 02-02.
For Further Information:
NIHON KOHDEN technical department
Tel.: 49 (6003) 827160
E-mail: NKE-SERVICE2@nke.de
Website: Click here

References:

- Germany. Federal Institute for Drugs and Medical Devices. Urgent field safety notice for automated external defibrillators cardiolife AED-2100K, NIHON KOHDEN EUROPE GmbH [online]. 2016 Nov 8 [cited 2016 Nov 28]. Available from Internet: 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):

- 2016 Nov 28. BfArM (Germany). 09428/16 Download
- 2016 Nov 28. BfArM (Germany). Nihon Kohden Reference No. AED-2100K/2016/1 Download
- 2016 Dec 7. Manufacturer. The manufacturer confirmed the information in the source material.