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	Desfibrilador HEARTSTRAR XL
NO. IDENTIFICACIÓN RISARH	I1401-33
REFERENCIAS DEL DISPOSITIVO MEDICO	861290
REGISTRO SANITARIO	2009EBC-0005096
INDICACIONES Y USO ESTABLECIDOS	Indicado para reanimación cardiaca y monitorización del paciente.
NOMBRE DEL FABRICANTE	Philips Medical Systems
DESCRIPCION DEL PROBLEMA	Se manifestó por parte del fabricante que se pueden presentar demoras en los tiempos de carga de las baterías, sin que ello necesariamente conlleve a posibles eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	24 de Enero de 2014

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

A21737 - Normal Priority Medical Device Alert

Medical Device Ongoing Action
Updated: January 23, 2014
UMDNS Terms:
- Defibrillator/Pacemakers, External [17882]
- Defibrillators, External, Manual [11134]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Critical Care
- Emergency/Outpatient Services
- Cardiology/Cardiac Catheterization Laboratory
- EMS/Transport
- Nursing
- OR/Surgery

Geographic Regions:
- Worldwide

Philips—Model 861290 HeartStart XL+ Monitor/Defibrillators: Manufacturer Updates Instructions for Use

Product Identifier:
Model 861290 HeartStart XL+ Monitor/Defibrillators *[Capital Equipment]*
Manufacturer:
- Philips Healthcare North America3000 Minuteman Rd, Andover, MA 01810-1099, United States

Problem:
In an Instructions for Use Addendum letter, Philips states a change has been made to the battery charging temperature specification in the instructions for use (IFU) (Part No. 453564434511) for the above monitor/defibrillators. The battery may take slightly longer to charge to 100% at 35°C (95°F) than specified in the IFU. Philips states that the system can operate with a partially charged battery and there is no patient risk associated with a longer battery charge time.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the Instructions for Use Addendum letter from Philips. Keep a copy of the addendum with your IFU.
For Further Information:
Philips
Website: Click here

Comment:
- 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):
- 2014 Jan 22. Manufacturer.