

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	Incubadora Abierta y Cerrada GE
NO. IDENTIFICACIÓN RISARH	I1806-385
REFERENCIAS DEL DISPOSITIVO MEDICO	GIRAFFE, PANDA, fabricadas antes del 30 de septiembre de 2017
REGISTRO SANITARIO	2008EBC-0002105 2008EBC-0002081
INDICACIONES Y USO ESTABLECIDOS	Proporcionar al bebe la regulación térmica a través de un calefactor.
NOMBRE DEL FABRICANTE	Wipro GE Healthcare Pvt. Ltd Ohmeda Medical GE Klinik Sistemier Tic A.S
DESCRIPCION DEL PROBLEMA	El fabricante informa que la corrosión / oxidación de la tapa plateada de los fusibles de los equipos referenciados puede ocurrir con el tiempo, lo que puede ocasionar un contacto insuficiente y la disminución de la conducción de corriente entre la superficie de la tapa y el portafusibles de la tarjeta de alimentación, la anterior situación podría conllevar a que se presenten potenciales eventos adversos sobre los pacientes.
FUENTE	ANEXO
FECHA DE NOTIFICACION	14 de junio de 2018

RECOMENDACIÓN:

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

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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

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[Normal Priority] - A30751 : GE—Giraffe and Panda Infant Warmers: Fuse Silver End Cap May Exhibit Corrosion/Oxidation over Time; Manufacturer Provides Power Board Replacement Fuses Medical Device Ongoing Action

Published: Thursday, June 7, 2018

UMDNS Terms:

- Incubators, Infant [12113]

Product Identifier:
[Capital Equipment]

Product	GE Healthcare Model	Manufacture Date
Infant Warmers	Giraffe, Panda	< 2017 Sep 30

Geographic Regions: Worldwide

Manufacturer(s): GE Healthcare 3000 N. Grandview Blvd., Waukesha, WI 53188, United States

Suggested Distribution: Clinical/Biomedical Engineering, Nursery, Nursing, NICU

Problem:

In a February 2018 Field Modification Instruction letter submitted by an ECRI Institute member hospital, GE states that corrosion/oxidation of the silver end cap of the fuses of the above warmers may occur over time, potentially resulting in non-typical (high) contact resistance between the cap surface and the fuse holder. GE also states that it is providing a different type of fuse (F7 and F8 fuses) with an end cap made of gold, which will mitigate corrosion.

Action Needed:

Identify any affected systems in your inventory. If you have affected systems, verify that you have received the February 2018 Field Modification Instruction letter, Power Board Fuse Replacement Instructions (part number 2108779-001), and power board replacement kit (part number 2108726-001), which includes four "SMD 2A Fuses, Socketed Lead-Free Nano2 Very Fast Acting Subminiature" (part number 2104203-001). The fuse replacement kits will be distributed starting May 2018; worldwide distribution is anticipated to be completed July 2018. GE states that if the display and heating unit in your warmer(s) are working correctly, you may continue to use the existing silver-capped F7 and F8 fuses. If a black display or heat output loss occurs on your warmer(s), biomedical or authorized personnel must replace the existing silver-capped fuses with the supplied gold-capped fuses by following the directions in the [Giraffe and Panda Warmers FMI No. 32058 Power Board Fuse Replacement Instructions](#). Note that there are four fuses (two sets of two) supplied with the kit. Use only two fuses; the additional two fuses are supplied in case the fuses are lost during unpacking or fixing.

For Further Information:

GE technical support department

Brazil

Tel.: (0800) 165799

Australia

Tel.: (1300) 722229

Canada/U.S.

Tel.: (800) 345-2700

Korea

Tel.: 02 (1544) 4564

China

Tel.: (8621) 38777888 or (800) 810-8188

EGM/Europe

Tel.: 358 (10) 39411

Germany

Tel.: (0800) 4343258

Latin America

Tel. (954) 744-5600

India

Tel.: (800) 425-7255

Southeastern Asia

Tel.: 65 (6277) 3444

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):

- 2018 Jun 4. Member Hospital. GE FMI No. 32058 [Download](#)
- 2018 Jun 4. Member Hospital. Giraffe and Panda Warmers FMI No. 32058 Power Board Fuse Replacement Instructions [Download](#)
- 2018 Jun 7. Manufacturer. The manufacturer confirmed the information provided in the source material.