

## 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:

<b>NOMBRE DEL DISPOSITIVO MÉDICO</b>	Termómetro para Medición de Temperatura Corporal
<b>NO. IDENTIFICACIÓN RISARH</b>	I1509-437
<b>REFERENCIAS DEL DISPOSITIVO MEDICO</b>	GENIUS 2
<b>REGISTRO SANITARIO</b>	2008DM-0002827
<b>INDICACIONES Y USO ESTABLECIDOS</b>	Comprende un termómetro de mano operado con batería atado a una estación de base. Mide la temperatura sintiendo las emisiones infrarrojas en la membrana timpánica en el canal del oído. Se miden temperaturas orales, rectales, centrales y axilares con base en la lectura timpánica. Indicado para el uso en pacientes en cuidados intensivos y medio para mediciones de la temperatura en la membrana timpánica.
<b>NOMBRE DEL FABRICANTE</b>	Covidien Medical Products (Shanghai) Manufacturing Llc. Covidien, Anteriormente Registrada Como Kendall A Division Of Tyco Healthcare Group Lp.
<b>DESCRIPCION DEL PROBLEMA</b>	El fabricante ha determinado que los termómetros pueden presentar fallos por el uso de desinfectantes incompatibles, la solución de limpieza puede afectar inadvertidamente las juntas del dispositivo, si el agente de limpieza es incompatible ciertos componentes que están expuestos a la solución se vuelven frágiles y se agrietan, lo que podría conllevar a que se presenten potencialmente error en las mediciones de temperatura del paciente.
<b>FUENTE</b>	ANEXO 1
<b>FECHA DE NOTIFICACION</b>	19 de Septiembre de 2015

### 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](mailto:tecnovigilancia@invima.gov.co)

## ANEXO 1

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### [Normal Priority ] - H0275 : Covidien/Medtronic—Genius 2 Ear Tympanic Thermometers: May Crack from Use of Incompatible Disinfectants [ECRI Exclusive Hazard Report]

Published: Thursday, September 10, 2015

#### UMDNS Terms:

- Thermometers, Electronic, Infrared, Ear [17887]

#### Product Identifier:

Genius 2 Tympanic Thermometers [*Capital Equipment*]

Geographic Regions: Worldwide

Manufacturer(s): Covidien (US)15 Hampshire St, Mansfield, MA 02048, United States

Suggested Distribution: Clinical/Biomedical Engineering, Emergency/Outpatient Services, Nursing, Pediatrics, Home Care, Internal Medicine, Central Sterilization Reprocessing

#### Problem:

1. Covidien Genius 2 tympanic thermometers are failing from the use of incompatible disinfectants.
2. When the housing of the Genius 2 is cleaned using disinfectant wipes, the cleaning solution may inadvertently collect in the seams of the device.
3. If the cleaning agent is incompatible with the Genius 2, certain components that are exposed to the solution will become brittle and crack. See Figure 1.

*Figure 1 Cracked Genius 2 tympanic thermometer*

#### Manufacturer's Corrective Action/Recommendations:

1. Covidien investigated 55 cleaning agents and found 22 to be incompatible with the Genius 2.
2. In September 2014, Covidien issued a notice to all of their customers with the results of these tests (See References for Genius 2 Thermometer—Recommended Cleaning Agents).
3. Covidien has also prepared the Genius 2 Thermometer Cleaning Guide which illustrates manufacturer recommended cleaning instructions.

#### ECRI Recommendations:

1. If a disinfectant cleaner is applied, confirm that it is one of the manufacturer's recommended cleaning agents.
2. As advised in the cleaning guide, do not soak the device with water or cleaning solution.
3. If the handset and base require cleaning, follow the manufacturer's recommended instructions and use warm water and mild detergent and allow 30 minutes of drying time before use.
4. In accordance with the user instructions, use a new disposable Genius 2 thermometer probe cover for each temperature reading.

#### Background:

- An ECRI Institute member hospital reports that after changing the thermometers' cleaning procedure, many thermometers developed cracks.
- CDC provides evidence-based recommendations on preferred methods for cleaning, disinfection and sterilization of patient-care medical devices in the "Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008."
- FDA provides nonbinding recommendations in the "Reprocessing Medical Devices in HealthCare Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff."
- Guidelines from CDC and FDA both use the Spaulding Classification scheme to describe the potential risk of infection of medical devices. According to Spaulding, devices are classified as either critical, semi-critical or non-critical devices.
- Tympanic thermometers are non-critical devices as they contact only intact skin.

#### References & Source Documents:

1. G2 Thermometer Cleaning Agent 2014 Customer Letter
2. G2 Thermometer Cleaning Guide

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3. CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. [Click here.](#)
4. FDA Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling – Guidance for Industry and Food and Drug Administration Staff. [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):**

- 2015 Sep 10. Manufacturer. Covidien letter [Download](#)
- 2015 Sep 10. Manufacturer. Cleaning Guide [Download](#)