

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	Sistema CARDIOMEMS TM HF – ST JUDE MEDICAL
NO. IDENTIFICACIÓN RISARH	I1610-410
REFERENCIAS DEL DISPOSITIVO MEDICO	CM3000, CM1000 y CM1010
REGISTRO SANITARIO	2015DM-0013476
INDICACIONES Y USO ESTABLECIDOS	El sistema CARDIOMEMS HF está indicado para medir y monitorizar de forma inalámbrica la presión de la arteria pulmonar en pacientes con insuficiencia cardiaca NYHA (NEW YORK HEART ASSOCIATION) clase III que han sido hospitalizados por insuficiencia cardiaca durante el año anterior. Los datos hemodinámicos permiten a los médicos tratar la insuficiencia cardiaca y reducir las hospitalizaciones por esta afección. El medico puede utilizar el sistema CARDIOMEMS HF en el hospital o la consulta para realizar mediciones de presión arterial pulmonar y analizarlas. El paciente puede utilizar el sistema CARDIOMEMS HF en su casa para realizar y enviar mediciones hemodinámicas y de presión arterial pulmonar de forma inalámbrica a una base de datos segura para su análisis y evaluación por parte del médico.
NOMBRE DEL FABRICANTE	St Jude Medical Inc
DESCRIPCION DEL PROBLEMA	El fabricante afirma que ha detectado que si el usuario apaga incorrectamente el sistema estos pueden mostrar una incapacidad para encender nuevamente, conllevando a que se presenten retrasos y posibles eventos adversos sobre los pacientes.
FUENTE	Anexo
FECHA DE NOTIFICACION	04 de Octubre 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

ANEXO

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[Normal Priority] - A27316 : St. Jude Medical—CardioMEMS Patient and Hospital Electronic Systems: Manufacturer Reinforces IFU for Proper System Shutdown Medical Device Ongoing Action

Published: Wednesday, September 28, 2016
Last Updated: Thursday, September 29, 2016

UMDNS Terms:

- Monitoring Systems, Physiologic [12636]
- Monitoring Systems, Physiologic, Pulmonary Artery Pressure/Heart Rate, Telemetric, Implantable Sensor [34408]

Product Identifier:

CardioMEMS Electronic Systems:	Model Nos.:
Hospital with Software Versions 1.6.7-r3 and below	CM3000
Patient with GSM (Cell) Modem	CM1000
Patient with Landline Modem	CM1010

[Consumable]

Geographic Regions: Worldwide

Manufacturer(s): St Jude Medical Inc 387 Technology Circle NW, Suite 500, Atlanta, GA 30313, United States

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Critical Care, Information Technology, Home Care, Materials Management

Problem:

In a September 15, 2016, Important Upgrade Availability Notice letter submitted by an ECRI Institute member hospital, St. Jude Medical states that if the user improperly shuts down the above systems, the systems may exhibit an inability to power on (start). St. Jude Medical also states that this problem poses no risk to health because a call to St. Jude Medical will result in a replacement unit being sent and it does not affect implants or patient therapy. St. Jude Medical further states that this problem has been reported for approximately 1% of distributed systems to date. St. Jude Medical states that no patient safety concern is associated with this problem and that the notification is reinforcing the existing instructions for use (IFU).

Action Needed:

Identify any affected systems in your inventory and any patients using affected systems. If you have affected systems and/or patients, verify that you have received the September 15, 2016, Important Upgrade Availability Notice letter from St. Jude Medical. St. Jude Medical recommends that, during use, you allow the system to complete the shutdown sequence before removing power from the system. St. Jude Medical states that it will provide a power cord clip to users of affected systems and that the clip secures the power cord to the power supply and reduces the potential for unintended power-downs. No action is required to receive the power cord clip. Once you receive the clip, install it on affected systems using the instructions provided with the clip. St. Jude Medical will contact your facility to arrange to install a software update that will reduce the potential for this problem to occur. If an affected system is unable to start, contact the St. Jude Medical remote care technical support department by telephone using the information below to arrange for system return and replacement. St. Jude Medical states that affected patients will receive a similar notice and that no action is required from clinicians on behalf of patients associated with this notice.

For Further Information:

St. Jude Medical local representative or St. Jude Medical remote care technical support department

Tel.: (877) 696-3754

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):

- 2016 Sep 27. Member Hospital. St. Jude Medical letter submitted by an ECRI Institute member hospital [Download](#)
- 2016 Sep 27. Manufacturer. St. Jude Medical confirmed the information provided in the source material.

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