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	Equipos para Resonancia Magnética
NO. IDENTIFICACIÓN RISARH	I1405-187
REFERENCIAS DEL DISPOSITIVO MEDICO	Discovery MR450, Discovery MR750, Optima MR450w, Optima MR450w equipado con la opción GEM, Discovery MR750w, Discovery MR750w equipado con la opción GEM
REGISTRO SANITARIO	2007DM-0001028
INDICACIONES Y USO ESTABLECIDOS	Utiliza una técnica de diagnostico por imágenes que emplea las propiedades magnéticas de los núcleos atómicos de la materia (tejidos, órganos, huesos, etc.). Esta señal que reflejan los átomos es captada y traducida en imágenes muy precisas, las cuales revelan un sin número de situaciones anatómicas normales y anormales, que un profesional experimentado puede interpretar para el diagnostico de diversas patologías.
NOMBRE DEL FABRICANTE	GE Medical Systems, Llc. GE Medical Systems Information Technologies Gmbh GE Medical Systems, Llc (Dba Ge Healthcare) Xinaomdt Technology Co, Ltd GE Medical Systems Scs General Medical Merate Spa GE Healthcare GE Healthcare Do Brasil Comércio E Servicos Para Equipamentos Medico-Hospitalares Ltda GE Medical Systems Technologies Co Ltd .
DESCRIPCION DEL PROBLEMA	El fabricante afirma que la salida de los pacientes puede verse impedida o retrasada si el mecanismo del asa de liberación de movimientos se desalinea, conllevando a que se presenten posibles retrasos e incidentes adversos sobre los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	13 de Mayo 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

A22224 01 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: May 8, 2014
UMDNS Terms:
- Scanning Systems, Magnetic Resonance Imaging, Extremity [18109]
- Scanning Systems, Magnetic Resonance Imaging, Full-Body [18108]
- Scanning Systems, Magnetic Resonance Imaging, Mammographic [18110]
- Scanning Systems, Magnetic Resonance Imaging, Neurosurgical [18862]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Diagnostic Imaging

Geographic Regions:
- Worldwide

GE—Various Discovery and Optima Magnetic Resonance Imaging Systems: Malfunction of Cradle Release Handle and/or Cradle Release Block Mechanism May Delay Patient Release

Product Identifier:
Magnetic Resonance Imaging (MRI) Systems: (1) Discovery MR450, (2) Discovery MR750, (3) Discovery MR750w, (4) Discovery MR750w with GEM Option, (5) Optima MR450w, (6) Optima MR450w with GEM Option *[Capital Equipment]*
Manufacturer:
- GE Healthcare USA9900 Innovation Dr, Wauwatosa, WI 53226, United States

Summary: This Alert provides additional information based on manufacturer correspondence regarding Alert Accession No. A22224. Additional information is provided in the Geographic Regions field (see bolded region).
Problem:
[April 28, 2014]
In an April 18, 2014, Urgent Medical Device Correction letter submitted by ECRI Institute member hospitals, GE states that patient egress from the above systems may be delayed or impeded if the cradle release handle and/or cradle release block mechanism malfunctions or becomes misaligned. GE also states that it has received no reports of injury related to this problem.

Action Needed:
The following actions are those listed in Alert Accession No. A22224. Identify any affected systems in your inventory. If you have affected systems, verify that you have received the April 18, 2014, Urgent Medical Device Correction letter from GE. If you encounter difficulty moving the cradle out because the cradle release handle does not release properly or if the cradle movement is impeded, contact your GE Healthcare local service representative. A GE Healthcare service representative will contact your facility to arrange to inspect, and, if needed, repair the above systems at no cost. Until the systems have been inspected and repaired, the operator should assess patient positioning and ease of egress. Discontinue use of the system if cradle movement for egress is impeded.
For Further Information:
GE Healthcare
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 Apr 30. Member Hospital.
- GE letter submitted by ECRI Institute member hospitals; Reference No. 60863
- 2014 Apr 30. Manufacturer. Manufacturer confirmed information provided in the source material.