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	Gammacámara GE Medical
NO. IDENTIFICACIÓN RISARH	I1402-89
REFERENCIAS DEL DISPOSITIVO MEDICO	HELIX, INFINIA, INFINIA HAWKEYE, MILLENNIUM VG, VARICAM, VG HAWKEYE
REGISTRO SANITARIO	INVIMA 2008EBC-0002241
INDICACIONES Y USO ESTABLECIDOS	Equipo para diagnostico.
NOMBRE DEL FABRICANTE	GE Medical Systems Israel - Functional Imaging GE Medical Systems SCS
DESCRIPCION DEL PROBLEMA	Informa que el detector de movimiento radial del equipo biomédico puede llegar a contacto con el paciente por su movimiento involuntario durante su configuración o al termino del estudio, conllevando a que se presenten potencialmente eventos adversos sobre el paciente.
FUENTE	Anexo
FECHA DE NOTIFICACION	24 de Febrero 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

A21823 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: February 17, 2014

UMDNS Terms:
- Scanning Systems, Computed Tomography/Single Photon Computed Tomography [24013]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Diagnostic Imaging
- Nuclear Medicine

Geographic Regions:
- Worldwide

GE—Various Nuclear Medicine Systems: Unintended Detector Motion May Lead to Collision with Patient

Product Identifier:
Nuclear Medicine Systems: (1) Helix, (2) Infinia, (3) Infinia Hawkeye, (4) Millennium VG, (5) VariCam, (6) VG Hawkeye [Capital Equipment]
All configurations

Manufacturer:
- GE Healthcare USA9900 Innovation Dr, Wauwatosa, WI 53226, United States

Problem:
In February 7, 2014, Urgent Medical Device Correction letters submitted by ECRI Institute member hospitals, GE states that unintended radial detector motion on the above systems may lead to patient contact and pose a potentially life-threatening hazardous situation. GE states that unintended radial detector motion may occur during patient setup or at the end of a patient scan. In one incident, the failure mode occurred on a single system for a whole body scan, in which the detector moved to the home position and then slowly started drifting inward toward the patient. This generated both a visual and audio alert condition on both the console and the gantry. GE states that it has received no reports of injuries related to this problem.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the February 7, 2014, Urgent Medical Device Correction letter from GE. Monitor the patient and the system during the entire scan procedure to ensure that there is enough clearance between the patient and the detectors. If the detector comes into contact with the patient, press the "Detector Out" button on the remote control unit to reverse the motion of the detector. In case of unintended detector motion, press the "Emergency Off" button either at the console or on the gantry to stop this motion, and pull the patient release handle to extract the patient as directed in the user manual. GE states that using the pressure sensitive devices at the gantry may not stop the unintended detector motion. If you see "error #147 in axis 1," follow the user manual instructions and contact GE service. Inform all relevant personnel at your facility of the information in the Urgent Medical Device Correction letter.

For Further Information:
GE Healthcare local service representative
GE Healthcare call center
Tel.: (800) 437-1171 (U.S. and Canada) or (262) 896-2890 (Outside the U.S. and Canada)
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 Feb 14. Member Hospital. GE letter submitted by ECRI Institute member hospitals; reference no. 40856
- 2014 Feb 17. Member Hospital. GE letter submitted by ECRI Institute member hospital; reference no. 40856
- 2014 Feb 17. Manufacturer. Manufacturer confirmed the information provided in the source material.