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	Gammacámaras PHILIPS
NO. IDENTIFICACIÓN RISARH	I1504-146
REFERENCIAS DEL DISPOSITIVO MEDICO	BRIGHTVIEW, BRIGHTVIEW X y BRIGHTVIEW XCT
REGISTRO SANITARIO	2008DM-0001422
INDICACIONES Y USO ESTABLECIDOS	Sistema de diagnostico clínico por medicina nuclear diseñados para producir imágenes diagnosticas a partir de la detección de radiación que es suministrada previamente al paciente a través de un radiofármaco o trazador radioactivo mezclado con un fármaco de vía metabólica conocida.
NOMBRE DEL FABRICANTE	Philips Medical Systems (Cleveland) Inc. Philips Nuclear Medicine Inc
DESCRIPCION DEL PROBLEMA	El fabricante afirma que los detectores en los dispositivos médicos referenciados pueden entrar en contacto con el suelo mientras es nuevamente posicionado entre las exploraciones cuando el sistema está en el modo de movimiento preprogramado ocasionando daños en el equipo, conllevando a que se presenten potencialmente eventos adversos sobre los pacientes o usuarios.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	16 de Abril 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

ANEXO 1

[Normal Priority] - S0273 : Philips—BrightView Gamma Cameras: Detectors May Be Damaged by Hitting the Floor during Repositioning [ECRI Institute User Experience Network]

Medical Device Special Report

Published: Monday, March 30, 2015

UMDNS Terms:

- Scanning Systems, Gamma Camera, Single Photon Emission Tomography [18444]
- Scanning Systems, Computed Tomography/Single Photon Computed Tomography [24013]

Product Identifier: Single Photon Emission Computed Tomography (SPECT) Gamma Cameras: (1) Brightview, (2) Brightview X, (3) Brightview XCT *[Capital Equipment]*

Geographic Regions: Worldwide

Manufacturer(s): Philips Healthcare North America3000 Minuteman Rd, Andover, MA 01810-1099, United States

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

Problem:

1. The detectors on the above gamma camera systems may come into contact with the floor while being repositioned between scans when the system is in the preprogrammed motion mode.
2. This problem may result in serious damage to the gamma camera.

ECRI Institute Recommendations:

In addition to the manufacturer's instructions and the existing hospital's procedures, ECRI Institute recommends the following:

Nuclear Medicine Technologists/Operators:

1. Ensure that the detectors are raised to the isocenter of the gantry before repositioning the detectors for the next study.
2. Observe the camera during repositioning while staying within reach of the emergency stop switch. Activate the emergency stop switch if contact with the floor or any other objects is likely.
3. Report any incidents of the detector contacting the floor to ECRI Institute and the manufacturer.

Manufacturer Perspectives

Philips has confirmed that they have replicated the problem and have not taken corrective action at this time.

ECRI Institute Perspectives

ECRI Institute believes gamma cameras should be designed to prevent the detector from hitting the floor during automatically controlled motion.

Background:

1. A member hospital reported that while repositioning the detectors on a Philips BrightView gamma camera using the preprogrammed motion (PPM) mode, one of the detectors collided with the floor.
2. The camera had just completed a pediatric standing study, for which the detectors were positioned below the isocenter of the system and close to the floor.
3. The detectors were being repositioned in preparation for the next patient, while there was no patient in the scan room.
4. The PPM mode was used to complete all the repositioning steps.
5. The detector came into contact with the floor and was damaged.