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	Resonador Magnético
NO. IDENTIFICACIÓN RISARH	I1409-362
REFERENCIAS DEL DISPOSITIVO MEDICO	Ingenia, Intera, Achieva y Achieva dStream con versiones de software R5.1.7 y R5.1.8
REGISTRO SANITARIO	2008EBC-0001536
INDICACIONES Y USO ESTABLECIDOS	Permiten generar imágenes transversales en cualquier orientación de la estructura interna del paciente.
NOMBRE DEL FABRICANTE	Philips Healthcare (Suzhou) Co., Ltd Philips Medical Systems Nederland B.V.
DESCRIPCION DEL PROBLEMA	El fabricante afirma que los modelos del equipo en mención que cuenten con el software de aplicación MOBIVIEW pueden generar errores al fusionar imágenes coronal y sagital de forma invertida, lo que puede conllevar a un mal diagnóstico y posibles eventos adversos sobre los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	08 de Septiembre 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

ANEXO 1

A22960 - High Priority Medical Device Alert

Medical Device Ongoing Action

Updated: September 2, 2014

UMDNS Terms:
- Scanning Systems, Magnetic Resonance Imaging, Full-Body [18108]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Diagnostic Imaging
- Information Technology

Geographic Regions:
- (Impact in specific regions has not been identified or ruled out at the time of this posting)
- Worldwide

Philips—Achieva, Achieva dStream, Ingenia, and Intera Magnetic Resonance Systems: MobiView May Generate Images in Reverse Order

Product Identifier:
Magnetic Resonance (MR) Systems: (1) Achieva, (2) Achieva dStream (3) Ingenia, (4) Intera *[Capital Equipment]*
Software Versions: R5.1.7, R5.1.8

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

Problem: In a July 2014 Customer Information letter submitted by an ECRI Institute member hospital, Philips states that when scrolling through MobiView fused sagittal and coronal images on the above systems, the actual display order of the images on the screen may be reversed. This can occur in the MR console as well as on workstations and picture and archiving communication systems (PACS). Philips further states that the slice numbering of fused sagittal and coronal images is reversed compared to the unfused sagittal and coronal images. As a result, source image slice 1 becomes fused with image slice 9 in sagittal and coronal direction, and vice versa, but the slice numbering is correct In the transverse direction, as shown in the letter. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the July 2014 Customer Information letter from Philips. Philips states that to avoid confusion include the unfused images, transverse images, and anatomic landmarks when reading the examination and to export both unfused and fused images to the PACS and workstations. A software update will be installed that makes the slice numbering consistent for fused and unfused images.

For Further Information:
Philips technical support department
Tel.: (800) 722-9377
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 Aug 29. Member Hospital. CIL78100439