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	Tomógrafo Computarizado por Emisión de Fotones
NO. IDENTIFICACIÓN RISARH	I1409-360
REFERENCIAS DEL DISPOSITIVO MEDICO	E.CAM SINGLE
REGISTRO SANITARIO	2008EBC-0001900
INDICACIONES Y USO ESTABLECIDOS	Sistema de adquisición de imágenes que permite detectar o visualizar la distribución de la absorción de radionucleidos en el cuerpo u órgano, haciendo uso de las siguientes técnicas: tomografía planar, tomografía de cuerpo entero, imagenologia topográfica e imagenologia para isotopos con energías de hasta 588kev. Las cabezas de los detectores rotan fácilmente en numerosas posiciones para ofrecer estudios de propósito general, cardiología, oncología y neurología.
NOMBRE DEL FABRICANTE	Siemens Medical Solutions Usa, Inc. Siemens A.G. Orbotech Medical Denmark
DESCRIPCION DEL PROBLEMA	El fabricante informa que utilizando el equipo en conjunto con el sistema de manipulación de pacientes (PHS) se presento que la regresar a la posición inicial se retracto la paleta del PHS quedando atrapada la mano del paciente.
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

A22982 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: September 3, 2014
UMDNS Terms:
- Scanning Systems, Gamma Camera, Single Photon Emission Tomography [18444]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Diagnostic Imaging

Geographic Regions:
- Worldwide

Siemens—e.cam Single-Photon Emission Computed Tomography Patient Handling Systems: Patients May Be Injured during System Movement

Product Identifier:
e.cam Single-Photon Emission Computed Tomography (SPECT) Patient Handling Systems (PHS) [Capital Equipment]
Manufacturer:
- Siemens Medical Solutions USA Inc2501 N Barrington Rd, Hoffman Estates, IL 60192, United States

Problem: In an April 8, 2014, Customer Safety Advisory Notice letter submitted by an ECRI Institute member hospital, Siemens states that it has received one report of an incident in which a patient was reportedly grasping the integrated armrest of the above systems as the technician pulled the PHS pallet to the home position; during this movement, when the pallet was retracted, the patient's finger was caught between the moving and the stationary parts of the PHS and injured.
Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the April 8, 2014, Customer Safety Advisory Notice letter from Siemens. Siemens recommends that you monitor the patient at all times while he/she is on the system and during initiation of any system movement, as described in the device operator's manual and Patient Bed Safety Addendum of the operator's manual. Siemens also recommends that you observe the following general good practices:
- Never leave a patient unattended on the system.
- When moving a patient into or out of the gantry, make sure the patient's arms, fingers, hair, and loose items such as clothing are completely positioned on the PHS.
- When moving any components of the system, all areas should be checked to ensure that there are no obstacles in the path of motion.

Retain a copy of the letter in your device operator's manual, and notify all relevant personnel at your facility of the information in the letter. Forward a copy of the letter to any facility to which you have further distributed affected product, and inform Siemens of the new owner.
For Further Information:
Siemens
Tel.: (800) 888-7436, 7 am. to 8 p.m. Eastern time, Monday through Friday
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 Sep 3. Member Hospital. Siemens letter submitted by an ECRI Institute member hospital.
- 2014 Sep 3. Manufacturer. The manufacturer confirmed the information in the source material.