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	Equipo SPECT – CT
NO. IDENTIFICACIÓN RISARH	I1408-341
REFERENCIAS DEL DISPOSITIVO MEDICO	Symbia Intevo y Symbia T
REGISTRO SANITARIO	2008EBC-0002090
INDICACIONES Y USO ESTABLECIDOS	Sistema de adquisición de imágenes que realiza un estudio mediante la fusión de tomografía computarizada e imagenologia nuclear.
NOMBRE DEL FABRICANTE	Siemens A.G.
DESCRIPCION DEL PROBLEMA	El fabricante informa que el aislador de goma en el interior del conjunto del montaje del motor de rotación se puede degradar y romper causando pérdida de apoyo para el motor de giro y posible ruptura de la correa de transmisión ocasionando a su vez el daño de las cubiertas frontales del gantry, lo que puede conllevar a que se presenten potencialmente eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	25 de Agosto 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

A22871 - High Priority Medical Device Alert

Medical Device Ongoing Action

Updated: August 14, 2014

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

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

Geographic Regions:
- Worldwide

Siemens—Symbia Intevo and Symbia T SPECT/CT Systems: Rubber Isolator May Break and Cause Loss of Support for Rotate Motor

Product Identifier:
Symbia Single Photon Computed Tomography/Computed Tomography (SPECT/CT) Systems: (1) Intevo, (2) T *[Capital Equipment]*

Manufacturer:
- Siemens Medical Solutions USA Inc685 East Middlefield Rd, Mountain View, CA 94043-7393, United States

Problem: In a Customer Safety Advisory Notice letter submitted by ECRI Institute member hospitals, Siemens states that the rubber isolator inside the rotate motor mounting assembly of the above systems may degrade and break, potentially causing loss of support for the rotate motor. Siemens also states that this problem may lead to a rupture in the drive belt, potentially damaging the gantry covers and making contact with the patient. Siemens further states that it has received no reports of injury related to this problem.

Action Needed:
Identify any affected systems in your inventory. If you have affected systems, verify that you have received the Customer Safety Advisory Notice letter from Siemens. Siemens states that you may continue to use the above systems; however, if you observe abnormal noise or vibration, discontinue use of the system and notify your local service representative. Your Siemens local service engineer will contact your facility to arrange for mounting plate replacement. Retain a copy of the letter in the system's instructions for use. Forward a copy of the letter to any facility to which you have further distributed affected product, and notify Siemens of the transfer.

For Further Information:
Siemens
America
Tel.: (800) 888-7436
Europe, Middle East, and Africa
Tel.: 49 (9131) 9404000
Asia and Australia
Tel.: 86 (21) 38112121
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 11. Member Hospital. Siemens letter submitted by an ECRI Institute member hospital.
- 2014 Aug 12. Manufacturer. The manufacturer confirmed the information in the source material.
- 2014 Aug 13. BfArM (Germany). 4594/14
- 2014 Aug 13. BfArM (Germany).