ALERTA

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con una Alerta asociada a:

NOMBRE DEL DISPOSITIVO MÉDICO	Equipo Hibrido PET-CT SIEMENS
NO. IDENTIFICACIÓN RISARH	A1703-108
REFERENCIAS DEL DISPOSITIVO MEDICO	mCT, mCT Flow.
REGISTRO SANITARIO	2008EBC-0002089
INDICACIONES Y USO ESTABLECIDOS	Diseñado para oncología de cuerpo completo, neurología y exámenes de cardiología. Su uso debe ser realizado para determinar diversas funciones metabólicas (moleculares) y fisiológicas del cuerpo humano y permite visualizar estructuras anatómicas tras convertir patrones de rayos X en imágenes visibles por computador.
NOMBRE DEL FABRICANTE	Siemens Medical Solutions Usa, Inc.
DESCRIPCION DEL PROBLEMA	El fabricante informa que ha detectado la posibilidad del aflojamiento o la caída de la ventana del láser de posicionamiento integrada a la carcasa exterior del equipo, lo cual podría conllevar a que se presenten potencialmente eventos adversos sobre los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	23 de Marzo de 2017

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

Instituto Nacional de Vigilancia de Medicamentos y Alimentos – INVIMA
Carrera 10 N.° 64/28
PBX: 2948700

Bogotá - Colombia
www.invima.gov.co

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DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

ANEXO 1

[High Priority] - A27894 : Siemens—Biograph mCT and mCT Flow PET/CT Systems: Light Marker Windows May Loosen and Expose Internal Components

Medical Device Ongoing Action

Published: Monday, March 6, 2017
Last Updated: Thursday, March 9, 2017

UMDNS Terms:

- Scanning Systems, Computed Tomography/Positron Emission Tomography [20161]

Product Identifier: Biograph Positron Emission Tomography (PET)/Computed Tomography (CT) Systems: (1) mCT, (2) mCT Flow *[Capital Equipment]*

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

Manufacturer(s): Siemens Healthcare810 Innovation Dr., Knoxville TN 37932-2562, United States

Suggested Distribution: Clinical Laboratory/Pathology, Diagnostic Imaging, Information Technology, Neurology

Problem: In a Customer Safety Advisory Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) and the German Federal Institute for Drugs and Medical Devices (BfArM), Siemens states that the light marker windows that are used for the positioning laser and integrated into the front cover of the above systems may become loose and fall out. Siemens also states that the gantry's electrical or rotating parts could be exposed and cause electric shock or harm if someone touches the exposed components. FDA's Center for Devices and Radiological Health (CDRH) states that Siemens initiated a recall by Customer Safety Advisory Notice letter on December 13, 2016. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify and discontinue use of any affected systems in your facility. If you have affected systems, verify that you have received the Customer Safety Advisory Notice letter from Siemens. Contact your Siemens local customer service engineer to correct affected systems. Keep the Safety Customer Advisory Notice letter with the Biograph Operator's manual. Notify all relevant personnel at your facility of the information in the Safety Customer Advisory Notice letter, forward a copy of the letter to any facility to which you have further distributed affected product, and notify Siemens of the transfer. U.S. customers should report adverse events or product quality problems relating to the use of affected product to FDA's MedWatch Adverse Event Reporting program by telephone at (800) 332-1088; by fax at (800) 332-0178; by mail (using postage-paid FDA Form 3500, available here) at Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787; or online at the MedWatch website .
For Further Information:
Siemens
Africa, Europe, Middle East
Tel.: 49 (9131) 9404000
Asia, Australia
Tel.: 86 (21) 38112121
U.S.
Tel.: (800) 888-7436
Website: Click here

References:

- Germany. Federal Institute for Drugs and Medical Devices. Urgent field safety notice for Biograph mCT and mCT FLow, Siemens Medical Solutions, Inc. [online]. 2016 Dec 22 [cited 2017 Mar 2]. Available from Internet: Click here .
- Great Britain. Medicines and Healthcare Products Regulatory Agency. Siemens. Biograph mCT and Biograph mCT Flow [online]. London: Department of Health; 2017 Jan 4 [cited 2017 Mar 2]. (Field safety notice; reference no. 2016/012/021/601/002). Available from Internet: here .
- United States. Food and Drug Administration. Center for Devices and Radiological Health. Medical Device Recalls. Recall Event ID: 76127. Siemens. 2017 Jan 10 [cited 2017 Mar 2]. Available from Internet: Click here .

Comments:

- 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):

- 2017 Feb 17. FDA CDRH Database. Class II. Z-0992/1002-2017 Download
- 2017 Feb 17. MHRA FSN. 2016/012/021/601/002 Download
- 2017 Feb 17. MHRA FSN. Siemens letter posted by MHRA, CAN 009-2016 Download
- 2017 Feb 17. BfArM (Germany). BfArM 11494/16 Download
- 2017 Mar 9. BfArM (Germany). Siemens letter posted by BfArM, CAN 009-2016 Download