INFORME DE SEGURIDAD

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 un Informe de Seguridad asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Sistema de Rayos X Digital PHILIPS
NO. IDENTIFICACIÓN RISARH	I1706-253
REFERENCIAS DEL DISPOSITIVO MEDICO	DURADIAGNOST, serial 130006.
REGISTRO SANITARIO	2009EBC-0005021
INDICACIONES Y USO ESTABLECIDOS	Este equipo se utiliza para realizar exposiciones de rayos X digitales.
NOMBRE DEL FABRICANTE	Philips Medical Systems Dmc Gmbh Philips Healthcare (Suzhou) Co., Ltd Philips India Limited-India
DESCRIPCION DEL PROBLEMA	El fabricante establece que las juntas de soldadura de los soportes de transporte vertical del tubo en los equipos referenciados pueden agrietarse, en el caso que todas las uniones de soldadura se vean afectadas el soporte puede caer, conllevando a que se presenten posibles eventos adversos sobre pacientes y usuarios.
FUENTE	ANEXO
FECHA DE NOTIFICACION	27 de Junio 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

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ANEXO

[High Priority] - A28759 : Philips —DuraDiagnost X-Ray Systems: Welding Joints May Crack, Potentially Causing Tube Arm Assembly to Fall
Medical Device Ongoing Action

Published: Thursday, June 15, 2017

UMDNS Terms:

- Radiographic Systems, Digital [18430]

Product Identifier:
DuraDiagnost X-Ray Systems *[Capital Equipment]*

DuraDiagnost Releases:	Product Nos.:
1.0	712210
2.0	712211
3.0	712211

Serial Nos.: SN120001-SN120003, SN130001-SN130023, SN140001-SN140022, SN140024, SN140027, SN140030-SN140031, SN140033-SN140046, SN140048, SN140050-SN140068, SN150001-SN150004, SN150006, SN150008-SN150011
98 systems distributed

Geographic Regions: (Impact in additional regions has not been identified or ruled out at the time of this posting), Argentina, Australia, Australia, Burkina Faso, Chile, China, Colombia, Ecuador, Egypt, France, Germany, Hungary, Indonesia, Kazakhstan, Kuwait, Libya, Macedonia, Malaysia, Mayotte, Mexico, The Netherlands, Peru, Poland, Saudi Arabia, Slovenia, Spain, Switzerland, Turkey, United Arab Emirates, U.K., U.S., Uzbekistan

Manufacturer(s): Philips Healthcare 3000 Minuteman Rd, Andover, MA 01810, United States

Suggested Distribution: Clinical/Biomedical Engineering, Diagnostic Imaging

Problem: In a May 18, 2017, Urgent Field Safety Notice Medical Device Correction letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Philips states that the weld joints on the vertical carriage brackets of the tube stand of the above systems may crack. Philips also states that if all welding joints crack, the tube arm assembly may fall, potentially leading to serious injury or death of the patient or anyone in the vicinity. FDA's Center for Devices and Radiological Health (CDRH) states that the manufacturer initiated a recall by Urgent Field Safety Notice letter dated May 23, 2017. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify and discontinue use of any affected systems in your inventory. If you have affected systems, verify that you have received the May 18, 2017, Urgent Field Safety Notice Medical Device Correction letter from Philips. A Philips engineer will contact your facility to arrange for a free-of-charge inspection of the welding joints of tube stand vertical carriage brackets and, if necessary, install safety hooks to prevent this problem from occuring
For Further Information:
Outside U.K.
Philips
Tel.: (978) 659-3000
U.K.
Philips, customer service care center
Tel.: (0870) 5329741
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Philips: DuraDiagnost [online]. London: Department of Health; 2017 Jun 12 [cited 2017 Jun 13]. (Field safety notice; reference no. 2017/006/006/291/001). Available from Internet: Click here .
- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Philips DuraDiagnost (R1.0 product 712210, R2.0 product 712211, and R3.0 product 712211) [online]. 2017 Jun 9 [cited 2017 Jun 13]. Available from Internet: 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 Jun 13. FDA CDRH Database. Class II. Z-2322-2017 Download
- 2017 Jun 13. MHRA FSN. 2017/006/006/291/001 Download