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	Sistemas De Rayos X Convencional Móvil PRACTIX 160 PHILIPS
NO. IDENTIFICACIÓN RISARH	I1503-110
REFERENCIAS DEL DISPOSITIVO MEDICO	PRACTIX 160
REGISTRO SANITARIO	2008EBC-0003048
INDICACIONES Y USO ESTABLECIDOS	Este equipo está indicado para la visualización y adquisición de imágenes de rayos X para diagnóstico.
NOMBRE DEL FABRICANTE	Philips Medical Systems Dmc Gmbh
DESCRIPCION DEL PROBLEMA	El fabricante afirma que cuando los sistemas anteriores se desconectan o cuando el brazo del tubo está ubicado en su posición de *Stand By* (generador de rayos x apagado), un pulso de radiación (50 kV, 2,5 µGy) se puede generar, potencialmente resultando en la exposición no intencional, esto ocurre solamente en sistemas que contienen un componente electrónico en particular en la placa controladora; el componente se utiliza sólo en un pequeño número de sistemas, conllevando a que se presenten potencialmente eventos adversos sobre los pacientes o usuarios.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	13 de Marzo de 2015

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

[High Priority] - A23996 : Philips—Practix Convenio Mobile X-Ray Systems: May Inadvertently Generate Radiation Pulse, Potentially Resulting in Unintentional Radiation Exposure

Medical Device Ongoing Action

Published: Wednesday, March 11, 2015

UMDNS Terms:

- Radiographic Units, Mobile [13272]

Product Identifier:
Practix Convenio Mobile X-Ray Systems *[Capital Equipment]*
Systems that have received part number 4512-133-60381 or 4512-133-60101 from service stock

Geographic Regions: Worldwide

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

Suggested Distribution: Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, OR/Surgery, Diagnostic Imaging

Problem: In a January 20, 2015, Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) and by the German Federal Institute for Drugs and Medical Devices (BfArM), Philips states that when the above systems are switched off or when the tube arm is parked into its designated parking position (x-ray generator switch off), a radiation pulse (50 kV, 2.5 µGy) may be generated, potentially resulting in unintended exposure. If a cassette is in the path of the radiation, artifacts may occur on the x-ray image. Philips states that this occurs only in systems containing a particular electronic component on the controller board; the component was only used on a small number of systems. Philips also states that the problem does not pose a health risk to patients, users, or bystanders.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the January 20, 2015, Urgent Field Safety Notice letter from Philips. Philips states that both shutters of the collimator should be completely closed before switching off the system and bringing the tube assembly to its parking position. A Philips service engineer will contact your facility to arrange an update to the controller board in affected systems.
For Further Information:
Philips customer care service centre
Tel.: (0870) 5329741
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Philips. Mobile x-ray Practix Convenio [online]. London: Department of Health; 2015 Mar 9 [cited 2015 Mar 10]. (Field safety notice; reference no. 2015/003/003/081/005). Available from Internet: Click here .
- Germany. Federal Institute for Drugs and Medical Devices. Corrective action for the Practix Convenio mobile x-ray system, Philips Medical Systems [online]. 2015 Mar 10 [cited 2015 Mar 10]. 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):

- 2015 Mar 10. MHRA FSN. 2015/003/003/081/005 Download
- 2015 Mar 10. MHRA FSN. FSN MA-FCO 70400058 Download
- 2015 Mar 10. BfArM (Germany). 0947/15 Download
- 2015 Mar 10. BfArM (Germany). FSN MA-FCO 70400058 Download
- 2015 Mar 10. Manufacturer. Manufacturer confirmed source documents