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	Ecógrafos GENERAL ELECTRIC
NO. IDENTIFICACIÓN RISARH	I1704-126
REFERENCIAS DEL DISPOSITIVO MEDICO	VIVID E80, E90, E95, S60, S70, S60N y S70N, con versiones de software específicas.
REGISTRO SANITARIO	2007DM-0000953
INDICACIONES Y USO ESTABLECIDOS	Obtener, procesar y ofrecer imágenes internas del cuerpo y ayudar al diagnóstico de posibles patologías o lesiones, guiar para procedimientos bajo ultrasonido como toma de biopsias y obtener imágenes del feto durante el embarazo con fines diagnósticos.
NOMBRE DEL FABRICANTE	GE Medical Systems Israel - Functional Imaging GE Ultrasound Israel GE Vingmed Ultrasound A/S GE Medical Systems China Co, Ltd. GE Ultrasound Korea Co, Ltd. GE Medical Systems Technologies Co Ltd Wipro GE Healthcare Private Ltd. GE Medical Systems Ultrasound & Primary Care Diagnostics Llc GE Healthcare Japan Corporation GE Healthcare Austria Gmbh & Co Og
DESCRIPCION DEL PROBLEMA	El fabricante indica que el usuario puede seleccionar de forma incorrecta a un paciente en los dispositivos referenciados cuando el tiempo de respuesta de búsqueda de lista de trabajo DICOM es lento, lo cual podría conllevar a que se presenten diagnósticos erróneos y potencialmente eventos adversos sobre los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	03 de Abril de 2017

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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 1

[High Priority] - A28218 : GE— Vivid Ultrasound Systems: User May Select Incorrect Patient if DICOM Worklist Search Response Time Is Slow

Medical Device Ongoing Action

Published: Thursday, March 16, 2017
Last Updated: Monday, April 3, 2017

UMDNS Terms:

- Scanning Systems, Ultrasonic, General-Purpose [15976]
- Scanning Systems, Ultrasonic, Cardiac [17422]
- Scanning Systems, Ultrasonic, Vascular [15957]

Product Identifier:

Vivid Ultrasound Systems:	Software Versions:
E80, E90, E95	201, revision 54.0, 61.0
S60, S70	201, revision 55.0, 63.0
S60N, S70N	201, revision 63.0

[Capital Equipment]

Geographic Regions: Worldwide

Manufacturer(s): GE Healthcare9900 Innovation Dr, Wauwatosa, WI 53226, United States

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Diagnostic Imaging, Information Technology

Problem:
In a March 10, 2017, Urgent Medical Device Correction letter submitted by an ECRI Institute member hospital, GE states that the user may incorrectly select a patient in the above systems when the DICOM Worklist search response time is slow, potentially leading to misdiagnosis if the user does not recognize that images from the intended patient are stored under the incorrect patient after the exam. GE also states that it has received no reports of injuries as a result of this problem.

Action Needed:
Identify any affected systems in your inventory. If you have affected systems, verify that you have received the March 10, 2017, Urgent Medical Device Correction letter from GE. To reduce the likelihood of this problem occurring, reduce the size of the DICOM Worklist search by setting the "max results" to 75 in the Worklist dataflow config dialog and/or configuring the DICOM Worklist server to automatically delete "Scheduled Procedure Steps" that have been performed on the ultrasound scanner. If the latter option is not available on your DICOM Worklist server, manually clear all "Scheduled Procedure Steps" that have been performed from the DICOM Worklist on a regular basis. Consult your facility's IT department for assistance with this option. After selecting a patient in the DICOM Modality Worklist, always review and confirm that the patient demographics shown on the ultrasound scanner screen during the exam are from the intended patient. If the incorrect and/or intended patient already exist in the patient archive, a Patient Match dialog will display to inform the user about a patient information inconsistency. A GE representative will contact your facility to arrange for a correction at no cost.

For Further Information:
GE
Tel.: (800) 437-1171
Website: 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 Mar 16. Member Hospital. GE Reference No. 76164, 76168 Download
- 2017 Mar 16. Manufacturer. The manufacturer confirmed the information provided in the source material.
- 2017 Apr 3. MHRA FSN. 2017/003/029/701/009; 2017/003/029/701/017 Download
- 2017 Apr 3. MHRA FSN. GE Reference No. 76164, 76168 Download