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	Equipos para Resonancia Magnética GENERAL ELECTRIC
NO. IDENTIFICACIÓN RISARH	I1806-387
REFERENCIAS DEL DISPOSITIVO MEDICO	SIGNA
REGISTRO SANITARIO	2017EBC-0001028-R1
INDICACIONES Y USO ESTABLECIDOS	Utiliza una técnica de diagnóstico por imágenes que emplea las propiedades magnéticas de los núcleos atómicos de la materia (tejidos, órganos, huesos, etc). Esta señal que reflejan los átomos es captada y traducida en imágenes muy precisas, las cuales revelan un sin número de situaciones anatómicas normales y anormales, que un profesional experimentado puede interpretar para el diagnóstico de diversas patologías.
NOMBRE DEL FABRICANTE	GE Medical Systems, Llc. GE Healthcare Japan Corporation GE Medical Systems Llc GE Healthcare (Tianjin) Company Limited
DESCRIPCION DEL PROBLEMA	El fabricante informa que la última versión del software pueden no haberse reinstalado en los sistemas anteriores en algunos sitios después de que se realizaron actividades de servicio que requerían software para ser recargado, si las anteriores versiones inválidas del software MR Apps Disk Software Build y Service Pack Build se cargan en el sistema, las imágenes pueden voltearse a la izquierda / derecha y/o pueden producirse discrepancias en los datos del paciente, la anterior situación podría conllevar a que se presenten potenciales eventos adversos sobre los pacientes.
FUENTE	ANEXO
FECHA DE NOTIFICACION	15 de junio de 2018

INFORME DE SEGURIDAD
DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

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

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

ANEXO

[High Priority] - A30821 : GE— Various MRI Systems with Certain Software Configurations: Latest On-Site Software Version May Not Have Been Reinstalled after Service Activities Were Performed
Medical Device Ongoing Action

Published: Thursday, June 14, 2018

UMDNS Terms:

- Scanning Systems, Magnetic Resonance Imaging [16260]

Product Identifier:
[Capital Equipment]

Product	GE Healthcare Model	MR Apps Disk Software Build No.	Service Pack No.	Service Pack Build No.
Magnetic Resonance Imaging (MRI) Software	1.5T Signa HDx, 1.5T Signa HDxt, 3.0T Signa HDx, 3.0T Signa HDxt, Excite, Signa	11.1_M4_0818.a	Service Pack 1, Service Pack 2, Service Pack 3, Service Pack 4	No Service Packs, 11.1_M4_0818.a.PA, 11.1_M4_0818.a.PB,

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

Excite 3T, Signa Excite HD 1.5T, Signa Excite HD 3.0T, Signa HDi, Signa Infinity, Signa Infinity with Excite Technology, Signa Vibrant, TwinSpeed			11.1_M4_0818.a.PC, 11.1_M4_0818.a.PD, 11.1_M4_0818.a.PE, 11.1_M4_0818.a.PF, 11.1_M4_0818.a.PG, 11.1_M4_0818.a.PH, 11.1_M4_0818.a.PJ, 11.1_M4_0818.a.PK, 11.1_M4_0818.a.PL, 11.1_M4_0818.a.PM, 11.1_M4_0818.a.PN, 11.1_M4_0818.a.PO, 11.1_M4_0818.a.PP
1.5T Signa HDx, 1.5T Signa HDxt, 3.0T Signa HDx, 3.0T Signa HDxt, Excite, Signa Excite 3T, Signa Excite HD 1.5T, Signa Excite HD 3.0T, Signa HDi, Signa Infinity, Signa Infinity with Excite Technology, Signa Vibrant, TwinSpeed	12.0_M5, 12.0_M5A	N/A	N/A
1.5T Signa HDx, 1.5T Signa HDxt, 3.0T Signa HDx, 3.0T Signa HDxt, Excite, Signa Excite 3T, Signa Excite HD 1.5T, Signa Excite HD 3.0T, Signa HDi, Signa Infinity, Signa Infinity with Excite Technology, Signa Vibrant, TwinSpeed	12.0_M5B_0846.d	Service Pack 1	12.0_M5B_0846.d.PA, 12.0_M5B_0846.d.PB, 12.0_M5B_0846.d.PC, 12.0_M5B_0846.d.PD, 12.0_M5B_0846.d.PE
1.5T Signa HDx, 1.5T Signa HDxt, 3.0T Signa HDx, 3.0T Signa HDxt, Excite, Signa Excite 3T, Signa Excite HD 1.5T, Signa Excite HD 3.0T, Signa HDi, Signa Infinity, Signa Infinity with Excite Technology, Signa Vibrant, TwinSpeed	15.0_M4_0910.a	Service Pack 1, Service Pack 2, Service Pack 3, Service Pack 4	No Service Packs, 15.0_M4_0910.a.PA, 15.0_M4_0910.a.PB, 15.0_M4_0910.a.PC, 15.0_M4_0910.a.PD, 15.0_M4_0910.a.PE, 15.0_M4_0910.a.PF, 15.0_M4_0910.a.PG, 15.0_M4_0910.a.PH, 15.0_M4_0910.a.PI
1.5T Signa HDx, 1.5T Signa HDxt, 3.0T Signa HDx, 3.0T Signa HDxt, Excite, Signa Excite 3T, Signa Excite HD 1.5T, Signa Excite HD 3.0T, Signa HDi, Signa Infinity, Signa Infinity with Excite Technology, Signa Vibrant, TwinSpeed	15.0_M4A_0947.a	Service Pack 1, Service Pack 2, Service Pack 3	No Service Packs, 15.0_M4A_0947.a.PA, 15.0_M4A_0947.a.PB, 15.0_M4A_0947.a.PC, 15.0_M4A_0947.a.PD, 15.0_M4A_0947.a.PE, 15.0_M4A_0947.a.PF, 15.0_M4A_0947.a.PG, 15.0_M4A_0947.a.PH, 15.0_M4A_0947.a.PI
1.5T Signa HDx, 1.5T Signa HDxt, 3.0T Signa HDx, 3.0T Signa HDxt, Excite, Signa Excite 3T, Signa Excite HD 1.5T, Signa Excite HD 3.0T, Signa HDi, Signa Infinity, Signa Infinity with Excite Technology, Signa Vibrant, TwinSpeed	15.0_M4B_1034.a	Service Pack 1, Service Pack 2, Service Pack 3	No service packs, 15.0_M4B_1034.a.PA, 15.0_M4B_1034.a.PB, 15.0_M4B_1034.a.PC
1.5T Signa HDx, 1.5T Signa HDxt, 3.0T Signa HDx, 3.0T Signa HDxt, Excite, Signa Excite 3T, Signa Excite HD 1.5T, Signa Excite HD 3.0T, Signa HDi, Signa Infinity, Signa Infinity with Excite Technology, Signa Vibrant, TwinSpeed	HD16.0_V01_1108.b	N/A	No Service Packs
1.5T Signa HDx, 1.5T Signa HDxt, 3.0T Signa HDx, 3.0T Signa HDxt, Excite, Signa Excite 3T, Signa Excite HD 1.5T, Signa Excite HD 3.0T, Signa HDi, Signa Infinity, Signa Infinity with Excite Technology, Signa Vibrant, TwinSpeed	HD16.0_V02_1131.a	N/A	No Service Packs

Geographic Regions: Worldwide

Manufacturer(s): GE Healthcare 3200 N. Grandview Blvd., Waukesha, WI 53188, United States

INFORME DE SEGURIDAD
DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

Suggested Distribution: Clinical/Biomedical Engineering, Diagnostic Imaging, Information Technology

Problem:
In a June 7, 2018, Urgent Medical Device Correction letter submitted by ECRI Institute member hospitals, GE states that the latest on-site software version may not have been reinstalled on the above systems at some sites after service activities were performed that required software to be reloaded. If the above invalid software MR Apps Disk Software Build and Service Pack Build combinations are loaded on the system, the images can be flipped left/right and/or patient data mismatch may occur. GE also states that it has received no reports of patient injury as a result of this problem.

Action Needed:
Identify any affected systems in your inventory. The configurations listed in Table 1 in the letter are valid and not affected by this problem. To confirm the current software version of your system, complete the following steps:

1. Click on the tools icon located on the top-left of the screen.
2. Click on the Service Browser button.
3. The MR Service Desktop browser will launch (may take one minute to launch).
4. Look at the Release Information on the screen, and compare both MrpApps Build Number and the Service Pack Build number on the screen to the product information above and Table 1 in the letter . If your system has both the MR Apps Build and Service Pack Build number as listed in a row of Table 1, your system is not affected by the problem. If your system's Apps Build and Service Pack Build number match any row listed above, your system is affected by the problem.

If you have affected systems, verify that you have received the June 7, 2018, Urgent Medical Device Correction letter from GE. If your system has invalid software, contact a GE service representative. GE will inspect affected systems to ensure that the correct software version is installed. GE will check systems remotely (online) where possible and will visit your site if a remote check is not possible. GE Healthcare will advise you after your software version has been inspected and inform you if any correction is needed. If a correction is needed, a service representative will contact your facility to arrange for this correction.

For Further Information:
GE service department
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):

- 2018 Jun 12. Member Hospital. GEHC Ref# 60936 Download
- 2018 Jun 14. Manufacturer. The manufacturer confirmed the information provided in the source material.