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	PACS – Sistema De Archivo, Administración y Transferencia de Imágenes Medicas
NO. IDENTIFICACIÓN RISARH	I1404-144
REFERENCIAS DEL DISPOSITIVO MEDICO	CENTRICITY PACS
REGISTRO SANITARIO	2010DM-0006391
INDICACIONES Y USO ESTABLECIDOS	Los PACS de GE-Healthcare están diseñados para el archivado digital de imágenes médicas y así como para su administración y transmisión a otras estaciones de computadores de visualización dedicadas o entre estas a través de una red informática. Los PACS igualmente permiten realizar consultas con especialistas en otras locaciones fuera de la institución vía web/internet para médicos autorizados, protegiendo la privacidad del paciente y la integridad de los datos. Entre las imágenes medicas que puede archivar y administrar los PACS figuran resultados imagenológicos de exámenes de: medicina nuclear, tomografía computarizada (CT), radiografía computarizada(RC), radiografía digital (RD), DEXA(DX), procedimientos especiales y radiografía intervencionista, ecografía, mamografía, entre otros exámenes igualmente permite el archivo y administración de datos en forma de onda, documentos y datos del paciente incluyendo todas las funciones que se necesitan para acceder y gestionar los estudios. Se anota que el sistema PACS no tiene contacto con el paciente ni controla ningún dispositivo del que dependa la vida. Solo constituye un soporte sobre el cual los médicos interpretan las imágenes e información que está siendo mostrada por pantalla o impresa mediante su intervención humana y profesional competente. Incluye un juego de herramientas de software que permiten hacer mediciones, añadir referencias cruzadas, ajustar las ventanas, sincronizar y re-posicionar las imágenes y verlas de manera dinámica. También es posible imprimir, copiar y enviar por correo electrónico las imágenes y estudios, incluso vía internet para usuarios clínicos autorizados
NOMBRE DEL FABRICANTE	GE Healthcare, Division de General Electric Company GE Healthcare.
DESCRIPCION DEL PROBLEMA	El fabricante informa que ha detectado un potencial fallo en el flujo de trabajo el cual puede presentar conflictos al realizar la apertura de varios estudios previos sobre las estaciones de trabajo y las imágenes son rechazadas a partir del estudio

	activo provocando así posibles perdida de datos, conllevando a que se presenten potencialmente eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	15 de Abril de 2014

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

A22126 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: April 9, 2014
UMDNS Terms:
- Workstations, Picture Archiving and Communication System [21968]

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

Geographic Regions:
- Worldwide

GE—Centricity PACS RA1000 Workstations: Previously Displayed Images May Be Rejected in a Reject Image Workflow

Product Identifier:
Centricity Picture Archiving and Communication Systems (PACS) RA1000 Workstations *[Capital Equipment]*
Software Versions: 3.2, 3.2.0.1, 3.2.0.2, 3.2.1, 3.2.2, 3.2.2.1, 3.2.2.2, 3.2.2.3, 3.2.6, 3.2 SP7, 3.2 SP8, 4.0, 4.0.1, 4.0 SP3

Manufacturer:
- GE Healthcare IT540 W Northwest Hwy, Barrington, IL 60010, United States

Problem:
In an April 3, 2014, Urgent Medical Device Correction letter submitted by ECRI Institute member hospitals, GE states that in a reject image workflow, in which multiple studies are simultaneously opened on the above workstations and images are rejected from the active displayed study, images from the previously displayed study may also be rejected. GE states that the problem can occur with a previously displayed study that remains open in the background under the following circumstances:

- If one or more, but not all, images in the exam were inadvertently rejected, the image count in the work modes palette identifies fewer images; however, all the images remain viewable.
- For newly acquired exams, if the entire exam was inadvertently rejected, the workstation will return a message stating "Unable to fetch this exam: No images in the exam." The images would then need to be resent to PACS from the modality.
- For historical exams, if the entire exam was inadvertently rejected, the workstation will return a message stating "Unable to fetch this exam: No images in the exam," and the exam is not available on the modality, a GE Healthcare service representative would need to be contacted to restore the exam on the database.

GE also states that there is a DelRejImg task in the above systems, that if enabled and running, in conjunction with the inadvertently rejected image problem, poses a potential patient safety hazard because of data loss. If the DelRejImg task runs, the inadvertently rejected images will be permanently deleted from the system and may result in a missed intervention or misdiagnosis. If you do not have the DelRejImg task running, there is no potential hazard since the inadvertently rejected images remain on the system. GE states that it has received no reports of patient injuries related to the above problems.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the April 3, 2014, Urgent Medical Device Correction letter from GE. A GE Healthcare service representative will contact your facility to arrange to correct affected systems at no cost. Until the software update is installed, GE recommends that you perform the following steps:
(1) Check to see if the DelRejImg task is active and running.
(a) Log into the CA Tool.
(b) From the Navigation menu, select "System Monitor."
(c) From the pull down menu, select "Dbase Maintenance."
(d) Scroll to the DelRejImj task (this list is alphabetical).
(e) Review the Task Status. Possible statuses are "IDLE" or "SUSPEND."
(f) If the task status is set to "SUSPEND," the task is not running.
(g) If the task is set to "IDLE," move to Step 2.
(2) Check the Minimum Rejected Image Deletion Time.
(a) From the Navigation menu, select "Sys. Configuration."
(b) From the pull down menu, select "Pacs Configuration."
(c) Scroll to "Minimum Rejected Image Deletion Time" (this list is alphabetical).
(d) Review the Value field.
(e) If the value field is a negative integer (such as the default setting of -1), the Delete Rejected Image process is NOT running and no patient safety hazard exists. If the

value field is a positive integer (such as 1 or higher), the Delete Rejected Image process is running and a potential patient safety hazard exists.
(3) A GE Healthcare service representative will remove the DelRejImg task from the task table in the Centricity PACS database. This will prevent the DelRejImg task from running and prevent any rejected images from being deleted. This feature is being removed entirely from the 3.2 release family of Centricity PACS and will be reinstated in a future 4.X workstation release of Centricity PACS.
(4) Perform the reject image workflow with only one patient study open at a time.

For Further Information:
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Tel.: 8008108188
Hong Kong
Tel.: 852-21006288
Website: Click here

Comment:

- 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):

- 2014 Apr 8. Member Hospital. GE letter submitted by ECRI Institute member hospital; Reference No. 85324
- 2014 Apr 9. Manufacturer. Manufacturer confirmed the information provided in the source material.