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	IMPAX – PACS Y RIS AGFA
NO. IDENTIFICACIÓN RISARH	I1402-92
REFERENCIAS DEL DISPOSITIVO MEDICO	IMPAX RIS QDoc Software versión 5.8 y posteriores
REGISTRO SANITARIO	INVIMA 2012DM-0009238
INDICACIONES Y USO ESTABLECIDOS	El sistema IMPAX RIS (radiology information system) gestiona de forma electrónica todas las tareas de radiología, desde el principio hasta el final, incluyendo solicitud y programación de exámenes, creación de protocolos, registro de pacientes, establecimiento de listas de trabajo, elaboración de informes médicos, transcripción, business intelligence y distribución de resultados.
NOMBRE DEL FABRICANTE	AFGA Healthcare NV
DESCRIPCION DEL PROBLEMA	El fabricante informa que el software podría visualizar e imprimir el nombre de un paciente sobre un estudio que no corresponde, este error afirma se encuentra relacionado con la impresión en cola de Microsoft Word, conllevando a que se presenten potencialmente eventos adversos sobre el paciente.
FUENTE	Anexo
FECHA DE NOTIFICACION	25 de Febrero 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

ANEXO

A21790 - High Priority Medical Device Alert

Medical Device Ongoing Action

Updated: February 12, 2014

UMDNS Terms:
- Information Systems, Data Management, Radiology [17175]
- Software, Information System, Data Management [26857]

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

Geographic Regions:
- CA (U.S.)
- FL (U.S.)
- GA (U.S.)
- ME (U.S.)
- OH (U.S.)
- OR (U.S.)
- SC (U.S.)
- SD (U.S.)
- TX (U.S.)
- Argentina
- Australia
- Belgium
- Brazil
- Canada
- Chile
- Colombia
- Ecuador
- Finland
- France
- Greece
- Iceland
- India
- Ireland
- Jordan
- Kuwait
- Lebanon
- Luxembourg
- Mexico
- Namibia
- The Netherlands
- New Zealand
- Norway
- Oman
- Paraguay
- Peru
- Russian
- Saudi Arabia
- South Africa
- Spain
- Sweden
- United Arab Emirates
- U.K.

Agfa—IMPAX RIS QDoc Software: May Print Incorrect Patient Name on Patient Reports

Product Identifier:
IMPAX RIS QDoc Software [Capital Equipment]
Software Versions: 5.8 and above
14 units distributed

Manufacturer:
- Agfa HealthCare (US)10 S Academy St, Greenville, SC 29601, United States

Problem: FDA's Center for Devices and Radiological Health (CDRH) states that the above software may display and print the incorrect patient name on the patient report. Agfa states that a code investigation has determined that the Agfa software cannot create this specific error because it prints in a consecutive manner and that the problem is related to Microsoft Word background printing. FDA's CDRH also states that the manufacturer initiated a product correction by Urgent Field Safety Notice letter on January 8, 2014. The manufacturer states that this action is complete in Canada.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the Urgent Field Safety Notice letter and reply form from Agfa. Agfa states that turning off Microsoft Word background printing will solve this problem. Disable the Microsoft Word background printing function using the instructions in the letter. Agfa states that a service representative will check each affected site. Complete the reply form, and return it to Agfa by fax or by e-mail using the information in the form.

For Further Information:
Agfa
Website: Click here

References:
- United States. Food and Drug Administration. Medical device recalls: Class 2 recall—IMPAX RIS QDOC 5.8 and higher [online]. 2014 Feb 3 [cited 2014 Feb 10]. Available from Internet: 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 Feb 10. FDA CDRH Database. Class II. Z-0919-2014
- 2014 Feb 12. Manufacturer. Manufacturer confirmed information