

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	Equipo PACS SIEMENS.
NO. IDENTIFICACIÓN RISARH	I1502-60
REFERENCIAS DEL DISPOSITIVO MEDICO	SYNGO.PLAZA
REGISTRO SANITARIO	2010DM-0005218
INDICACIONES Y USO ESTABLECIDOS	Almacenamiento, recuperación, distribución y procesamiento de imágenes diagnósticas.
NOMBRE DEL FABRICANTE	Siemens AG Siemens Medical Solutions Usa, Inc.
DESCRIPCION DEL PROBLEMA	El fabricante afirma que en caso de fallo del sistema (por ejemplo, pantalla azul o corte de energía), las imágenes no se graban en el disco duro, lo cual, potencialmente resulta en inconsistencias en la base de datos ocasionando su pérdida, conllevando a que se presenten posibles eventos adversos sobre los pacientes
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	09 de Febrero 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

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[High Priority] - A23772 : Siemens—syngo.plaza Picture Archiving and Communication Systems: Data May Not Be Saved in Case of System Crash Medical Device Ongoing Action

UMDNS Terms:

- Information Systems, Picture Archiving and Communication, Radiology [16247]

Product Identifier:

syngo.plaza Picture Archiving and Communication Systems (PACS) [Capital Equipment]
Model Nos.: 10592457, 10863171, 10863172, 10863173; Serial Nos.: 100025, 100029, 100031, 100033, 100084, 100132, 100133, 100135, 100139, 100139, 100140, 100146, 100170, 100174, 100177, 100181, 100185, 100186, 100188, 100197, 100198, 100198, 100198, 100199, 100203, 100206, 100207, 100212, 100213, 100215, 100221, 100226, 100228, 100230, 100232, 100233, 100245, 100247, 100253, 100256, 100257, 100258, 100262, 100301, 100306, 100314, 100539, 100544, 200211, 200308
50 units distributed

Geographic Regions: Worldwide

Manufacturer(s): Siemens AG Wittelsbacherplatz 2, Muenchen, D-80333, Germany

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

Problem: FDA's Center for Devices and Radiological Health (CDRH) states that in case of system crash (e.g., blue screen, power outage), images may not be written to the hard disk, potentially resulting in inconsistencies in the database or data getting lost. FDA's CDRH also states that the manufacturer initiated a product correction by Safety Advisory Notice letter dated January 13, 2015.

Action Needed:

Identify any affected product in your inventory. If you have affected product, verify that you have received the January 13, 2015, Safety Advisory Notice letter from Siemens. Siemens recommends that you check patient data in the event of a system crash.

For Further Information:

Siemens
Tel.: (610) 219-6300
Website: [Click here](#)

References:

- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall syngo.plaza [online]. 2015 Jan 28 [cited 2015 Jan 30]. 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 Jan 30. FDA CDRH Database. Class II. Z-1027-2015 [Download](#)
- 2015 Feb 3. Manufacturer. The manufacturer confirmed the information in the source material.

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