

## 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:

<b>NOMBRE DEL DISPOSITIVO MÉDICO</b>	Equipo PET - CT Siemens
<b>NO. IDENTIFICACIÓN RISARH</b>	I1501-9
<b>REFERENCIAS DEL DISPOSITIVO MEDICO</b>	Modelo BIOGRAPH mCT y BIOGRAPH mCT Flow, seriales 11002, 11005, 11006, 11008, 11042, 11021 y 1003, versiones VG50A.
<b>REGISTRO SANITARIO</b>	2008EBC-0002089
<b>INDICACIONES Y USO ESTABLECIDOS</b>	Diseñado para oncología de cuerpo completo, neurología y exámenes de cardiología. Su uso debe ser realizado para determinar diversas funciones metabólicas (moleculares) y fisiológicas del cuerpo humano y permite visualizar estructuras anatómicas tras convertir patrones de rayos x en imagenes visibles por computador.
<b>NOMBRE DEL FABRICANTE</b>	Siemens Medical Solutions Usa, Inc.
<b>DESCRIPCION DEL PROBLEMA</b>	El fabricante afirma que la pantalla puede congelarse en el transcurso del procedimiento sin mostrar ningún mensaje de error para alertar al operador, conllevando a que se presenten posibles eventos adversos sobre los pacientes.
<b>FUENTE</b>	ANEXO 1
<b>FECHA DE NOTIFICACION</b>	02 de Enero 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](mailto:tecnovigilancia@invima.gov.co)

## ANEXO 1

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### [High Priority ] - A23466 : Siemens—Biograph mCT and mCT Flow PET/CT Systems: System Display May Freeze Medical Device Ongoing Action

#### UMDNS Terms:

- Scanning Systems, Computed Tomography/Positron Emission Tomography [20161]

#### Product Identifier:

Biograph Positron Emission Tomography (PET)/Computed Tomography (CT) Systems:

	Siemens Material Nos.:	Serial Nos.:
(1) mCT Flow 40-4R	(1) 10529159	(1) 11002
(2) mCT Flow Edge-4R	(2) 10528955	(2) 11002, 11005, 11006, 11008
(3) mCT S(40)-4R	(3) 10248671	(3) 11042
(4) mCT S(64)-4R	(4) 10248672	(4) 11021
(5) mCT X-4R	(5) 10248670	(5) 1003

[Capital Equipment]  
Software Version VG50A

**Geographic Regions:** (Impact in specific regions has not been ruled out or identified at the time of this posting), Worldwide

**Manufacturer(s):** Siemens Healthcare Diagnostics Inc 511 Benedict Ave, Tarrytown, NY 10591, United States

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

#### Problem:

In a Customer Safety Advisory Notice letter posted by the German Federal Institute for Drugs and Medical Devices (BfArM), Siemens states that the above system display may freeze during CT interventional procedures. Siemens also states that the user interface may lock-up when performing an adaptive 3D interventional procedure when the "auto save last displayed images as key images" is enabled. Normal interaction with the system may not be possible, and no error messages will be displayed to alert the end user so the end-user and/or interventionist may not know that the system has stopped interacting and continue with the interventional procedure. This problem may increase the risk of injury to the patient because the display no longer updates with important information, such as the current biopsy needle position. Siemens states that it has received no reports of injury related to this problem. FDA's Center for Devices and Radiological Health (CDRH) states that the manufacturer initiated a product correction by certified mail on November 13, 2014. The manufacturer has not confirmed the information provided in the source material.

#### Action Needed:

Identify any affected product in your inventory. If you have affected product, verify that you have received the Customer Safety Advisory Notice letter from Siemens. Siemens states that it will correct this problem in a software update. Until the software update is available, Siemens recommends the following workaround:

- Ensure that the system is in an idle state.
  - From the main menu on the syngo Acquisition Workplace, select Options->Configuration.
  - Double click on the intervention icon (refer to the image in the [letter](#)).
  - Within the Intervention Configuration window, select "storage" and deactivate the option "auto save last displayed images as key images."
  - Select "OK".
  - When performing an adaptive 3D interventional procedure, the end-user or interventionist can still manually save the key images by "right-clicking" in the background of the images and selecting "save all selected images as key images."
- Retain a copy of the letter in your operator's manual, and notify all relevant personnel at your facility of the information in the letter. Forward a copy of the letter to any facility to which you have further distributed affected product, and inform Siemens of the transfer.

#### For Further Information:

Siemens  
America  
Tel.: (800) 888-7436  
Europe, Middle East, and Africa  
Tel.: 49 (9131) 9404000  
Asia and Australia  
Tel.: 86 (21) 38112121  
Website: [Click here](#)

#### References:

Germany: Federal Institute for Drugs and Medical Devices. Safety notice for the Biograph mCT-and Biograph mCT Flow systems, running VG50A equipped with the Adaptive 3D Intervention option, Siemens Medical Solutions USA, Inc. [online]. 2014 Dec 3 [cited 2014 Dec 19]. Available from Internet: [Click here](#).

United States:

- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Biograph mCT Flow Edge4R. [online]. 2014 Dec 16 [cited 2014 Dec 19]. Available from Internet: [Click here](#).
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Biograph mCT Flow 404R. [online]. 2014 Dec 16 [cited 2014 Dec 19]. Available from Internet: [Click here](#).
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Biograph mCT X4R. [online]. 2014 Dec 16 [cited 2014 Dec 19]. Available from Internet: [Click here](#).
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Biograph mCT S(64) 4R. [online]. 2014 Dec 16 [cited 2014 Dec 19]. Available from Internet: [Click here](#).
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Biograph mCT S(40) 4R. [online]. 2014 Dec 16 [cited 2014 Dec 19]. Available from Internet: [Click here](#).

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Dec 16 [cited 2014 Dec 19]. 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):**

- 2014 Dec 19. BfArM (Germany). 7789/14 [Download](#)
- 2014 Dec 19. BfArM (Germany). [Download](#)
- 2014 Dec 19. FDA CDRH Database. Class II. Z-0807/0811-2015 [Download](#)