

# 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:**

<b>NOMBRE DEL DISPOSITIVO MÉDICO</b>	Sistema Digital de Rayos X SAMSUNG
<b>NO. IDENTIFICACIÓN RISARH</b>	I1803-180
<b>REFERENCIAS DEL DISPOSITIVO MEDICO</b>	GC80
<b>REGISTRO SANITARIO</b>	2012EBC-0009015
<b>INDICACIONES Y USO ESTABLECIDOS</b>	Ha sido diseñado para capturar imágenes digitales mediante rayos x de varias partes del cuerpo, incluida la cabeza, el pecho, la columna vertebral, el abdomen, las articulaciones, las manos, los pies y otros órganos. No ha sido diseñado para realizar mamografías
<b>NOMBRE DEL FABRICANTE</b>	Samsung Electronics Co., Ltd
<b>DESCRIPCION DEL PROBLEMA</b>	El fabricante ha detectado una imagen obtenida con sobreexposición durante un examen de tórax utilizando el control de exposición automático (AEC), como resultado de un error inesperado de desconexión de la red entre la unidad de la cabeza del tubo (THU) y la estación de trabajo, lo anterior podría conllevar a que se presenten eventos adversos sobre los pacientes.
<b>FUENTE</b>	Anexo
<b>FECHA DE NOTIFICACION</b>	20 de marzo de 2018

### 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)

# INFORME DE SEGURIDAD

## DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

### ANEXO

www.ecri.org . Printed from *Health Devices Alerts* on Tuesday, March 20, 2018 Page 1

**[High Priority] - A28491 01 : Samsung—Model GC80 Digital X-Ray Systems: Generator Setting Error May Result from Network Connection Error between the Tube Head Unit and the Workstation**  
 Medical Device Ongoing Action

Published: Monday, March 12, 2018  
 Last Updated: Tuesday, March 13, 2018

**UMDNS Terms:**

- Radiographic Systems, Digital [18430]

**Product Identifier:**  
 [Capital Equipment]

Product	NeuroLogica Corp Sub Samsung Electronics America Inc Model	Accession No.
Digital X-Ray Imaging Systems	GC80	1310459

**Geographic Regions:** Africa, Asia, Australia, Europe, Middle East, South America, U.S.

**Manufacturer(s):** NeuroLogica Corp Sub Samsung Electronics America Inc 14 Electronics Ave, Danvers, MA 01923, United States

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

**Summary:** Update Reason: New accession number, U.S. distribution. This Alert provides additional information based on FDA Center for Devices and Radiological Health (CDRH) source material regarding [Alert A28491](#). Additional information is provided in the Product Identifier and the Geographic Regions fields.

**Problem:**

In an April 18, 2017, Urgent Field Safety Notice letter posted by the German Federal Institute for Drugs and Medical Devices (BfArM), Samsung states that it has received a report of an image obtained with overexposure during a thorax examination using the automatic exposure control (AEC) function as a result of an unexpected network disconnection error between the tube head unit (THU) and the workstation on the above systems.

**Action Needed:**

The following actions are those listed in [Alert A28491](#). Identify any affected systems in your inventory. Samsung states that the system label is located on the back of the system cabinet. If you have affected product, verify that you have received the April 18, 2017, Urgent Field Safety Notice letter and acknowledgment form from Samsung. The firm is developing a software update to prevent overexposure associated with this problem. If the receptor information is delivered to high-voltage generator (HVG) during the ready mode, an error message 1016 will occur. To close the error message, release ready mode (i.e., by releasing the exposure switch). Once the 1016 error message is closed, the current receptor information can be delivered to the HVG successfully. By default, the 1016 error message blocks irradiation of the system. Samsung further states that it will revise the user manual to include information about AEC backup time and the 1016 error message. Complete the acknowledgment form, and return it to Samsung by e-mail at [s\\_sur@samsung.com](mailto:s_sur@samsung.com) or [eu.vigilance@samsung.com](mailto:eu.vigilance@samsung.com). Forward a copy of the letter to any facility to which you have further distributed affected product.

**For Further Information:**

Samsung  
 Website: [Click here](#)

**References:**

- Germany. Federal Institute for Drugs and Medical Devices. Urgent field safety notice for GC80 by Samsung Electronics Co., Ltd. [online]. 2017 Apr 26 [cited 2017 May 2]. Available from Internet: [Click here](#).
- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 Device Recall GC80 digital xray imaging system [online] 2018 Mar 2 [cited 2018 Mar 6]. 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):**

- 2017 Jun 5. BfArM (Germany). 00721/17 [Download](#)
- 2017 Jun 5. BfArM (Germany). Samsung Reference No. FSN- GC80\_161221001 [Download](#)
- 2018 Mar 6. FDA CDRH Database. Class II. Z-0726-2018 [Download](#)
- 2018 Mar 12. Manufacturer. The manufacturer confirmed the information in the source material.