

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:

NOMBRE DEL DISPOSITIVO MÉDICO	Sistema de Rayos X SAMSUNG
NO. IDENTIFICACIÓN RISARH	I1805-322
REFERENCIAS DEL DISPOSITIVO MEDICO	GC80
REGISTRO SANITARIO	2015EBC-0013644
INDICACIONES Y USO ESTABLECIDOS	Sistemas de alto rendimiento, diseñados para ofrecer imágenes digitales de alta calidad y desempeño con fines diagnósticos; mediante rayos X.
NOMBRE DEL FABRICANTE	Samsung Electronics Co., Ltd
DESCRIPCION DEL PROBLEMA	El fabricante ha detectado que en los equipos referenciados, si el usuario no cierra completamente la bandeja del detector en la mesa o soporte, el sistema anterior conmuta a modo portátil o multi portátil y el control de exposición automática (AEC) se apaga, en caso de realizar una exposición esta puede efectuarse con parámetros diferentes a los programados por el usuario. Además, si el sistema se reinicia después de un <i>error 4596</i> (un error de comunicación entre el controlador del actuador de columna y el módulo de control de la mesa), la THU puede tocarse con la mesa si el usuario usa la función de posición automática, o con el paciente en caso de tenerlo posicionado sobre la mesa, esta situación podría conllevar a que se presenten retrasos en la atención y posibles eventos adversos sobre los pacientes.
FUENTE	ANEXO
FECHA DE NOTIFICACION	25 de mayo de 2018

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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

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ANEXO

www.ecri.org . Printed from *Health Devices Alerts* on Friday, May 25, 2018 Page 1

[High Priority] - A30652 : Samsung—Model GC80 Digital X-Ray Systems: Exposure May Be Irradiated Differently than Intended and/or Tube Head Unit May Bump Into The Table If Auto Position Function Is Used under Specific Errors
Medical Device Ongoing Action

Published: Thursday, May 24, 2018
Last Updated: Friday, May 25, 2018

UMDNS Terms:

- Radiographic Systems, Digital [18430]

Product Identifier:
 [Capital Equipment]

Product	Samsung Electronics America Inc Model
Digital X-Ray Systems	GC80

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

Manufacturer(s): Samsung Electronics America Inc 85 Challenger Rd, Ridgefield, NJ 07660, United States

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

Problem:

In a May 8, 2018, Urgent Field Safety Notice letter posted by the German Federal Institute for Drugs and Medical Devices (BfArM), Samsung states that the following may occur during use of the above digital x-ray systems:

- (Problem 1) If the user does not completely close the detector tray in the table or stand, the above system turns into portable or multi-portable mode and auto exposure control (AEC) turns off. At this time, the screen of the workstation and the screen of tube head unit (THU) show the portable mode on or the multi portable mode on and AEC off. However, if the user makes an exposure without checking it, the exposure may be irradiated differently than the user intended and the user may get an unintended image. Image retake may be required.
- (Problem 2) When the system is rebooted after a 4596 error (a communication error between the column actuator controller and the table control module), the THU may bump into the table if the user uses the auto position function. The THU may bump into a patient if there is a patient on the table.

Action Needed:

Identify any affected systems in your inventory. If you have affected product, verify that you have received the May 8, 2018, Urgent Field Safety Notice letter and FSN Acknowledgment Form from Samsung. The firm recommends the following actions:

- (Problem 1) Carefully close the detector tray, and check that the detector tray is completely closed. Check the screen of the workstation or the THU screen before making an exposure, and be sure to check the receptor, AEC mode, and the exposure condition. (For a screenshot of the display, see the [letter](#).) If the detector you intend is not set, select a detector to be used.
- (Problem 2) When rebooting the system after a 4596 error, use the auto-position function with no patient on the table.

Samsung is developing a software update that will include the following three improvements:

- (1) Exposure is not carried out unless the detector tray is completely closed or completely opened and the irradiation unperformable icon is displayed on the workstation or THU screen as indicated by an icon on the display. If the user selects the irradiation unperformable icon, the user can determine the cause.
- (2) The user must confirm which detector is to be used by clicking on the check box to allow an exposure when two or more detectors are available in portable mode.
- (3) THU does not move to the point of making contact with a patient under the circumstances of this problem.

A Samsung service engineer will contact your facility when the software update is ready to be implemented.

Complete the FSN Acknowledgment Form, and return it to Samsung by e-mail at eu.vigilance@samsung.com or hnevigilance@samsung.com. Inform all relevant personnel at your facility of the information in the letter, and 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 Samsung XGEO GC80 DR-System by Samsung Electronics Co., Ltd. [online]. 2018 May 16 [cited 2018 May 22]. 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):

- 2018 May 22, BfArM (Germany). 05194/18 [Download](#)
- 2018 May 22, BfArM (Germany). Samsung Reference No. FSN- GC80_180427-1 (includes reply form) [Download](#)
- 2018 May 24, Manufacturer. The manufacturer confirmed the information in the source material.

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