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 Ultrasonido SIEMENS
NO. IDENTIFICACIÓN RISARH	I1804-258
REFERENCIAS DEL DISPOSITIVO MEDICO	ACUSON SC2000 con Electrocardiograma, Versión de software VB20A, VB20B, VBV20C
REGISTRO SANITARIO	2008DM-0001867
INDICACIONES Y USO ESTABLECIDOS	Sistema de ultrasonido para aplicaciones de: abdomen, intraoperatorio, obstetricia y ginecología, pelvis, mama, ortopedia, urología, pequeñas partes, transcraneal, musculo esquelético, vascular, vascular periférico, cardiología, intracardiaca y transesofagia para pacientes neonatales, pediátricos y adultos.
NOMBRE DEL FABRICANTE	Siemens Medical Solutions Usa, Inc. Esaote S.P.A. Siemens Ltd. Seoul Siemens Ltd. Seoul
DESCRIPCION DEL PROBLEMA	El fabricante ha detectado que los dispositivos referenciados pueden presentar interferencias electromagnética causando deformación de la señal de ECG mientras se usa equipos electroquirúrgicos, también afirma que el ECG podría arrasar y provocar retrasos del sistema de hasta 20 segundos cuando los usuarios intentan capturar o modificar parámetros de imágenes (como la profundidad), lo anterior podría conllevar a que se presenten retrasos en los procedimientos y eventos adversos sobre los pacientes.
FUENTE	Anexo
FECHA DE NOTIFICACION	23 de abril 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

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

ANEXO

[High Priority] - A30181 : Siemens—ACUSON SC2000 Ultrasound Systems: Electromagnetic Interference May Cause Electrocardiogram (ECG) Signal to Flatline
Medical Device Ongoing Action

Published: Monday, April 16, 2018
Last Updated: Thursday, April 19, 2018

UMDNS Terms:

- Scanning Systems, Ultrasonic, Cardiac [17422]

Product Identifier:
[Capital Equipment]

Product	Siemens Healthcare Model	Software Version
Ultrasound Systems with Electrocardiogram (ECG) Hardware and Auxiliary (AUX IN/OUT) Cables	ACUSON SC2000	VB20A, VB20B, VB20C

Geographic Regions: (Impact in additional regions has not been identified or ruled out at the time of this posting). Argentina, Australia, Austria, Belgium, Bosnia-Herzegovina, Colombia, Croatia, Denmark, France, Germany, India, Ireland, Israel, Italy, Japan, Mexico, New Zealand, Philippines, Poland, Republic of Korea, Romania, Singapore, Slovakia, Spain, Sweden, Taiwan, Thailand, Turkey, United Arab Emirates, U.K., U.S., Vietnam

Manufacturer(s): Siemens Healthcare 40 Liberty Blvd, Malvern, PA, 19335, United States

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Diagnostic Imaging

Problem: In a Customer Safety Advisory Notification letter posted by the German Federal Institute for Drugs and Medical Devices (BfArM) and the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Siemens states that electromagnetic interference may occur in the above systems and cause the ECG signal to flatline while using electrosurgical equipment. The loss of communication with the physio module results in the loss of the ECG signal with no notification to the user. Siemens also states that the ECG could flatline and cause system delays up to 20 seconds when users attempt to clip capture or modify imaging parameters (such as depth). Siemens further states that it has received no reports of patient injuries as a result of this problem. FDA's Center for Devices and Radiological Health (CDRH) states that Siemens initiated a correction by undated letters by e-mail and certified mail on March 5, 2018. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify any affected systems in your inventory. If you have affected systems, verify that you have received the Customer Safety Advisory Notification letter from Siemens. If the ECG trace disappears or flatlines, perform the following steps to disable the ECG trace and exit the physio mode on affected systems:

1. Press F13 (Physio) on the keyboard.
2. Press the scroll wheel to select the appropriate ECG or AUXtrace option and then press the "Off" soft key.
3. Press F13 (Physio) again to exit the Physio menu.

Siemens states that after performing the above steps, the ultrasound system will use time-based captures instead of beat captures. Siemens also states that affected systems may need to be rebooted to reset the ECG trace; however, this problem may occur again if electrosurgical equipment is used. Siemens will provide a hardware update for affected product. Contact the Siemens customer care department to schedule a replacement if you have affected systems. Inform all relevant personnel of the information in the letter, and provide a copy of the letter to any facility to which you have distributed affected product.
For further Information:
Siemens
Website: Click here

References:

- Germany. Federal Institute for Drugs and Medical Devices. Urgent field safety notice for ACUSON SC2000 by Siemens Medical Solutions USA, Inc., ultrasound division [online]. 2018 Mar 12 [cited 2018 Apr 9]. Available from Internet: Click here .
- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall ACUSON SC2000 ultrasound system [online]. 2018 Mar 26 [cited 2018 Apr 12]. Available from Internet: Click here .
- Great Britain. Medicines and Healthcare Product Regulatory Agency. Siemens Medical Solutions (Siemens Healthineers): Acuson SC2000 ultrasound system [online]. London: Department of Health; 2018 Apr 9 [cited 2018 Apr 12]. (Field safety notice; reference no. 2018/004/003/601/009). 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 Apr 9. BfArM (Germany). Reference No. 02861/18 Download
- 2018 Apr 9. BfArM (Germany). Siemens letter posted by BfArM Download
- 2018 Apr 9. FDA Enforcement Report. Class II. Z-1200-2018
- 2018 Apr 16. FDA CDRH Database. Z-1200-2018 Download