

## 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 DE ULTRASONIDO SIEMENS
<b>NO. IDENTIFICACIÓN RISARH</b>	I1505-213
<b>REFERENCIAS DEL DISPOSITIVO MEDICO</b>	ACUSON SC2000
<b>REGISTRO SANITARIO</b>	2008DM-0001867
<b>INDICACIONES Y USO ESTABLECIDOS</b>	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 transeofagia para pacientes neonatales, pediátricos y adultos.
<b>NOMBRE DEL FABRICANTE</b>	Esaote S.P.A. Siemens Ltd. Seoul Siemens Medical Solutions Usa, Inc.
<b>DESCRIPCION DEL PROBLEMA</b>	El fabricante afirma que los equipos referenciados pueden ser incapaces de capturar una imagen o un videoclip durante una exploración de rutina, conllevando a que se presenten posibles eventos adversos sobre los pacientes o dificultades en el diagnostico.
<b>FUENTE</b>	Anexo 1
<b>FECHA DE NOTIFICACION</b>	20 de Mayo 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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### [Normal Priority] - A24339 : Siemens—ACUSON SC2000 Ultrasound Systems: May Be Unable to Capture Clip or Image during Routine Scan Medical Device Ongoing Action

Published: Tuesday, May 12, 2015

**UMDNS Terms:**

- Scanning Systems, Ultrasonic, Cardiac [17422]

**Product Identifier:**

ACUSON SC2000 Ultrasound Systems [Capital Equipment]  
Model No.: 10433816; Serial Nos.: 400023, 400083, 400084, 400092, 400126, 400139, 400168, 400223, 400225, 400230, 400236, 400265, 400270, 400308, 400318, 400404, 400458, 400459, 400460, 400461, 400462, 400463, 400466, 400467, 400470, 400479, 400484, 400485, 400493, 400519, 400577, 400589, 400615, 400617, 400634, 400650, 400663, 400664, 400665, 400674, 400678, 400679, 400680, 400687, 400689, 400691, 400693, 400708, 400717, 400740, 400743, 450122, 450123, 450143, 450151, 451021, 451024  
Software Versions: VA16C, VA16D, VA16E

**Geographic Regions:** (Impact in additional regions has not been identified or ruled out at the time of this posting). Angola, Armenia, Australia, Austria, Belgium, Bosnia and Herzegovina, Brazil, Brunei, Bulgaria, China, Colombia, Czech Republic, Finland, France, Germany, India, Japan, Kazakhstan, Kenya, Kuwait, Mauritius, Mexico, Norway, Oman, Poland, Romania, Russia, Saudi Arabia, Singapore, Slovakia, Spain, South Korea, Sweden, Switzerland, Taiwan, Thailand, Turkey, U.K., United Arab Emirates, U.S.

**Manufacturer(s):** Siemens Healthcare 51 Valley Stream Pkwy, Malvern, PA 19355, United States

**Suggested Distribution:** Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Obstetrics/Gynecology/Labor and Delivery, OR/Surgery, Diagnostic Imaging, Information Technology, Neurology, NICU

**Problem:**

FDA's Center for Devices and Radiological Health (CDRH) states that the above systems may be unable to capture a clip or image during a routine scan. FDA's CDRH also states that the manufacturer initiated a product correction by Customer Advisory Notice letter. 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 Advisory Notice letter from Siemens. Siemens will provide a software update to fix the above problem at no cost.

**For Further Information:**

Siemens  
Website: [Click here](#)

**References:**

- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall ACUSON SC2000 [online]. 2015 May 5 [cited 2015 May 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 [FDA Format Guide](#) .

**Source(s):**

- 2015 May 6. FDA CDRH Database. Class II. Z-1581-2015 [Download](#)

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