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 para diagnostico SIEMENS
NO. IDENTIFICACIÓN RISARH	I1401-24
REFERENCIAS DEL DISPOSITIVO MEDICO	ACUSON SC2000
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.
DESCRIPCION DEL PROBLEMA	Se manifestó por parte del fabricante que se puede presentar una falla de conexión en la columna del modulo de interfaz de usuario del dispositivo médico antes mencionado, conllevando a que se presenten potencialmente eventos adversos sobre el paciente u operario.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	22 de Enero de 2014

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

ANEXO 1

A21627 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: January 27, 2014
UMDNS Terms:
- Scanning Systems, Ultrasonic, Cardiac [17422]

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

Geographic Regions:
- Albania
- Australia
- Austria
- Bangladesh
- Belgium
- Bosnia and Herzegovina
- Brazil
- Brunei
- Canada
- China
- Colombia
- Denmark
- Ecuador
- Egypt
- Finland
- France
- Germany
- Iceland
- India
- Israel
- Italy
- Japan
- Kuwait
- Malaysia
- Mauritius
- Mexico
- The Netherlands
- Norway
- Oman
- The Philippines
- Poland
- Portugal
- Qatar
- Romania
- Russia
- San Marino
- Saudi Arabia
- Singapore
- Slovakia
- South Africa
- South Korea
- Spain
- Sweden
- Switzerland
- Taiwan
- Thailand
- Turkey

Siemens—ACUSON SC2000 Ultrasound Systems: Interface Module Connection May Be Loose

Product Identifier:
ACUSON SC2000 Ultrasound Systems *[Capital Equipment]*
Serial Nos.: 401100 and below

Manufacturer:
- Siemens Medical Solutions USA Inc1230 Shorebird Way, Mountain View, CA 94043-7393, United States

Summary: On January 16, 2014, the manufacturer confirmed the information in the source material, and provided additional Geographic Regions (bolded above).

Problem:
In a Customer Safety Advisory Notification letter submitted by an ECRI Institute member hospital, Siemens states that the connection of the user interface module to the column on the above systems may become loose, potentially resulting in the entire module falling off the system. If this occurs, the module may injure anyone close to the system.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the Customer Safety Advisory Notification letter from Siemens. If you observe looseness in the attachment of the user interface module to the column of the system, immediately discontinue use of your system and contact your Siemens service representative for repair. A Siemens service engineer will contact your facility to arrange for product repair. Notify all relevant personnel at your facility of the information in the letter.

For Further Information:
Siemens
Website: Click here

Comment:
- 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.

- U.K.
- United Arab Emirates
- U.S.
- Venezuela
- Yemen

Source(s):

- 2014 Jan 9. Member Hospital. Siemens letter submitted by an ECRI Institute member hospital.
- 2014 Jan 16. Manufacturer. The manufacturer confirmed the information in the source material.
- 2014 Jan 27. FDA CDRH Database. Class II. Z-0824/0825-2014
- 2014 Jan 27. MHRA FSN. 2014/001/022/601/002
- 2014 Jan 27. MHRA FSN.