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	Unidad de Inmunoanálisis CENTAUR
NO. IDENTIFICACIÓN RISARH	I1410-430
REFERENCIAS DEL DISPOSITIVO MEDICO	CENTAUR y CENTAUR XP
REGISTRO SANITARIO	2008DM-0002712
INDICACIONES Y USO ESTABLECIDOS	Este equipo es un analizador automático para pruebas de inmunoanálisis por quimioluminiscencia directa de acceso aleatorio continuo. Utiliza muestras de orina, suero o plasma para ensayos de diagnóstico in-vitro (IVD) de hormonas, drogas, cardiovascular, oncología y anemia. Es un sistema automatizado que reporta los valores de las pruebas y comunica los resultados clínicos del paciente.
NOMBRE DEL FABRICANTE	Siemens Healthcare Diagnostics Inc Siemens Helathcare Diagnostics Manufacturing Limited Siemens Healthcare Diagnostics Mfg Ltd Stratec Biomedical Switzerland Ag
DESCRIPCION DEL PROBLEMA	El fabricante afirma que el estrés mecánico puede causar el agrietamiento de la tubería para los depósitos superiores, resultando en un goteo menor de líquido en el depósito y en la bandeja de goteo, activando las alarmas de detección de nivel y provocando que el procesamiento de las muestras puedan no tener el volumen correcto de fluido dispensado de ácido o base para la reacción, conllevando a que potencialmente se presentes retrasos en la obtención de los resultados.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	24 de octubre 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

A23163 01 - High Priority Medical Device Alert

Medical Device Ongoing Action

Updated: October 17, 2014

UMDNS Terms:
- Analyzers, Laboratory, Immunoassay, Chemiluminescent [17916]

Suggested Distribution:
- Clinical/Biomedical Engineering
- Clinical Laboratory/Pathology

Geographic Regions:
- Worldwide

Siemens—ADVIA Centaur Immunoassay Systems: Fluid Reservoir Tubing May Be Cracked

Product Identifier:
Fluid Reservoir Connector Tubing used with the following ADVIA Systems: (1) Centaur, (2) Centaur XP *[Consumable, Capital Equipment]*

Fluid Reservoir Connector Tubing:	Siemens Material Nos.:
Bulk Fluid Reserve Assembly (Acid & Base)	10282187, 10483525
Wash 1 Reservoir Connector	10364516, 10483526

Manufacturer:
- Siemens Healthcare Diagnostics Inc 511 Benedict Ave, Tarrytown, NY 10591, United States

Summary: This Alert provides additional information based on manufacturer correspondence regarding Alert Accession No. A23163. Additional information is provided in the Geographic Regions field (see bolded region).

Problem:
[October 15, 2014]
In an October 9, 2014, Urgent Medical Device Correction letter submitted by an ECRI Institute member hospital, Siemens states that mechanical stress may cause the tubing for the above reservoirs to become cracked, potentially resulting in a minor drip of fluid onto the reservoir and into the drip tray underneath the reservoirs and causing the reservoir to empty faster than the system expects. If fluid in the reservoir is empty, samples being processed may not have the correct volume of acid or base fluid dispensed for the reaction. Once these fluids are depleted, the system will detect it, flag all subsequent results with a signal error flag if the Wash 1 fluid becomes low and stop processing samples. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
The following actions are those listed in Alert Accession No. A23163. Identify any affected product in your inventory. If you have affected product, verify that you have received the October 9, 2014, Urgent Medical Device Correction letter and Field Correction Effectiveness Check Form from Siemens. Siemens is not recommending a review of previously reported results due to the extremely low occurrence rate. Replace the bulk bottle for all fluids immediately when the yellow warning appears to mitigate the possibility of improper fluid dispenses. Refer to the ADVIA Centaur or ADVIA Centaur XP operator's guide for bottle replacement procedures. Proper personal protective equipment (PPE) must be worn when coming in contact with any fluids leaked from the system. Siemens recommends that you examine your systems to see if there is any fluid in the reservoir drip tray (refer to Figure 1 in the letter). If fluid is present, contact your Siemens customer care center or your local Siemens technical support representative to schedule a visit. A Siemens service engineer will examine the tubing on the next service visit and replace the tubing if necessary. Review this letter with your medical director. Complete the Field Correction Effectiveness Check Form, and return it to Siemens using the instructions on the form. If you have received complaints of illness or adverse events associated with affected products, immediately contact Siemens customer care center or your local Siemens technical support representative. Retain a copy of the letter with your laboratory records, and forward a copy of the letter to any facility to which you have further distributed affected product.

For Further Information:
Siemens customer care center
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.

Source(s):

- 2014 Oct 15. Member Hospital. Siemens letter submitted by an ECRI Institute member hospital.
- 2014 Oct 16. Manufacturer. The manufacturer confirmed the information in the source material.