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	Analizador de química sanguínea ADVIA
NO. IDENTIFICACIÓN RISARH	I1402-59
REFERENCIAS DEL DISPOSITIVO MEDICO	ADVIA 1800 y 2400
REGISTRO SANITARIO	2008DM-0002852
INDICACIONES Y USO ESTABLECIDOS	Este equipo es un analizador automatizado para pruebas de química sanguínea por colorimetría, enzimáticas, punto final, cinéticas, ion selectivo para electrolitos de acceso aleatorio continuo. Utiliza muestras de orina, suero o plasma para ensayos de diagnóstico in vitro de enzimas, bioquímica, cardiovascular, oncología, anemia, electrolitos, etc. 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. Newport Medical
DESCRIPCION DEL PROBLEMA	Se manifestó por parte del fabricante que al momento de efectuar la calibración del equipo, el sistema puede fallar debido a un sesgo en el parámetro de cloruro, conllevando a que se presenten errores en los resultados del diagnóstico y potencialmente eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	10 de Febrero 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

A21652 - Normal Priority Medical Device Alert

Medical Device Ongoing Action
Updated: February 5, 2014
UMDNS Terms:
- Analyzers, Laboratory, Clinical Chemistry [15551]

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

Geographic Regions:
- Argentina
- Australia
- Austria
- Belarus
- Brazil
- Bulgaria
- Canada
- Colombia
- Cyprus
- Czech Republic
- Dominican Republic
- Egypt
- Finland
- France
- Germany
- Greece
- Hungary
- India
- Italy
- Kazakhstan
- Latvia
- Lebanon
- Lithuania
- Norway
- Peru
- Poland
- Portugal
- Romania
- Russia
- Serbia
- Slovakia
- South Africa
- South Korea
- Spain
- Sweden
- Turkey
- U.K.
- United Arab Emirates

Siemens—ADVIA 1800 and 2400 Chemistry Systems: Electrodes May Fail Prematurely during Calibration

Product Identifier:
ADVIA Chemistry Systems: (1) 1800, (2) 2400 *[Capital Equipment, Consumable]*
Firmware Version 2.23

Manufacturer:
- Siemens Healthcare Diagnostics Inc511 Benedict Ave, Tarrytown, NY 10591, United States

Problem:
In a January 2014 Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Siemens states that the above chemistry systems may fail prematurely during calibration because of a chloride bias parameter error. Siemens also states that the operator may receive an NG flag, potentially requiring immediate action.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the January 2014 Urgent Field Safety Notice letter and field correction effectiveness check form from Siemens. Your Siemens representative will contact you to arrange for firmware to be reverted back to version 2.22. Review the Urgent Field Safety Notice letter with your facility's laboratory medical director. Complete the field correction effectiveness check form, and return it to Siemens using the information provided on the form. Keep a copy of the Urgent Field Safety Notice letter with your laboratory records, and forward a copy of the letter to any facilities to which you have further distributed affected product.

For Further Information:
Siemens technical solutions center
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Siemens Healthcare Diagnostics. IVDs, clinical chemistry instrumentation. Chloride electrode/ISE firmware V2.23 [online]. London: Department of Health; 2014 Feb 3 [cited 2014 Feb 4]. (Field safety notice; reference no. 2014/001/023/601/011). Available from Internet: 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 Feb 4. MHRA FSN. 2014/001/023/601/011
- 2014 Feb 4. MHRA FSN.
- 10817232 (includes reply form)
- 2014 Feb 5. Manufacturer. The manufacturer confirmed the information provided in the source material.

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