

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 para Química Sanguínea e Inmunoanálisis
NO. IDENTIFICACIÓN RISARH	I1408-317
REFERENCIAS DEL DISPOSITIVO MÉDICO	DIMENSION EXL, referencia 200, LM y STM
REGISTRO SANITARIO	2008DM-0002953
INDICACIONES Y USO ESTABLECIDOS	Este equipo se utiliza en el análisis fotométrico y de inmunoensayos de múltiples test de química sanguínea, inmunología, drogas y electrolitos.
NOMBRE DEL FABRICANTE	Siemens Healthcare Diagnostics Inc Kimball Electronics Poland Sp.Z.O.O Siemens Healthcare Diagnostics Inc.
DESCRIPCIÓN DEL PROBLEMA	El fabricante informa que ha detectado que la bisagra de la tapa del contenedor de los reactivos puede desplazarse en los procedimientos de mantenimiento provocando que estos entren en contacto con el operador, lo que puede conllevar a que se presenten potencialmente eventos adversos sobre el operador o usuario.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	01 de Agosto 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

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A22748 - High Priority Medical Device Alert

Medical Device Ongoing Action

Updated: July 31, 2014

UMDNS Terms:

- Analyzers, Laboratory, Clinical Chemistry [15551]

Suggested Distribution:

- Clinical Laboratory/Pathology
- Clinical/Biomedical Engineering

Geographic Regions:

- Worldwide

Siemens—Dimension EXL Integrated Chemistry Systems: Reagent Lid Hinge May Shift Downward

Product Identifier:

Dimension EXL Integrated Chemistry Systems:	Siemens Material Nos. (U.S.):	Siemens Material Nos. (Outside U.S.):
200	10636929	10636928
LM	10486890	10472176
STM	10639337	10639338

[Capital Equipment]

Manufacturer:

- Siemens Healthcare Diagnostics Inc 511 Benedict Ave, Tarrytown, NY 10591, United States
- Siemens Healthcare 51 Valley Stream Pkwy, Malvern, PA 19355,

Problem: In a July 2014 Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Siemens states that the reagent lid hinge on the above systems may slowly shift downward during maintenance procedures, potentially coming into contact with the operator.

Action Needed:

Identify any affected product in your inventory. If you have affected product, verify that you have received the July 2014 Urgent Field Safety Notice letter and Field Correction Effectiveness Check Form from Siemens. Your Siemens customer service engineer will inspect and adjust the tension on the reagent lid hinges during every visit. If the hinges can no longer be properly adjusted, Siemens will replace them. If you observe the above problem, contact your Siemens local technical support representative. 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. Notify all relevant personnel at your facility of the information in the letter, 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](#)

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Siemens Healthcare Diagnostics Inc. IVDs, clinical chemistry instrumentation. Dimension EXL 200 / Dimension EXL LM/ Dimension EXL LM STM [online]. London: Department of Health; 2014 Jul 24 [cited 2014 Jul 25]. (Field safety notice; reference no. 2014/007/014/601/005). 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 Jul 25. MHRA FSN. 2014/007/016/601/005
- 2014 Jul 25. MHRA FSN. 14-46 (includes reply form)