

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 Inmunoanálisis - SIEMENS
NO. IDENTIFICACIÓN RISARH	I1506-256
REFERENCIAS DEL DISPOSITIVO MEDICO	1000, 2000 y 2000Xpi concerniente a los portavasos e insertos de micromuestra numero de parte 10385360, 10385319 y 10385209.
REGISTRO SANITARIO	2008DM-0002621
INDICACIONES Y USO ESTABLECIDOS	Este equipo es un analizador automatizado para pruebas de inmunoanálisis por quimioluminiscencia de acceso aleatorio continuo. Utiliza muestras de orina, suero o plasma para ensayos de diagnóstico in-vitro (IVD). Reporta valores de las pruebas y comunica los resultados clínicos del paciente.
NOMBRE DEL FABRICANTE	Siemens Healthcare Diagnostics Productos Ltd. Siemens Healthcare Diagnostics Inc.
DESCRIPCION DEL PROBLEMA	El fabricante afirma que los portavasos e insertos de micromuestra referenciados pueden no cumplir con las especificaciones para detección de nivel de la muestra, produciendo mensajes de error o la no ejecución de la prueba, conllevando a que se presenten posibles eventos adversos sobre los pacientes o dificultades en el diagnostico.
FUENTE	Anexo 1
FECHA DE NOTIFICACION	16 de Junio 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

ANEXO 1

www.ecri.org . Printed from *Health Devices Alerts* on Thursday, June 18, 2015 Page 1

[High Priority] - A24534 : Siemens—Sample Cup Holders and Microsample Inserts Used With IMMULITE Systems: Sample Level Sense Errors May Occur Medical Device Ongoing Action

Published: Thursday, June 11, 2015

UMDNS Terms:

- Analyzers, Laboratory, Immunoassay, Chemiluminescent [17916]
- Analyzers, Laboratory, Immunoassay, Fluorimetric [16218]
- Analyzers, Laboratory, Immunoassay, Photometric, Enzyme (EIA) [16217]

Product Identifier:

Products used on
IMMULITE/IMMULI TE 1000 Systems:
Siemens Material Nos.: Lot Nos.:

Sample Cup Holder Sets (set of 1-50)	10385360	15, 16
Sample Cup Holder Sets (set of 51-100)	10385319	15, 16

Products used on
IMMULITE 2000/2000 Xpi Systems:
Siemens Material Nos.: Lot Nos.:

Microsample Inserts	10385209	18, 19, 20
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[Consumable, Capital Equipment]

Geographic Regions: Worldwide

Manufacturer(s): Siemens Healthcare Diagnostics Inc 511 Benedict Ave, Tarrytown, NY 10591, United States

Suggested Distribution: Clinical/Biomedical Engineering, Clinical Laboratory/Pathology, Materials Management

Problem: In a June 8, 2015, Customer Notification letter submitted by ECRI Institute member hospitals, Siemens states that the conductive material of the above sample cup holders and microsample inserts may not meet specifications for facilitating sample level sensing, potentially leading to sample level sense errors even if the required minimum sample volume is in the sample cup or tube. Siemens also states that when sample level sensing is compromised, the sample will not be pipetted, and any tests ordered for the sample will not be run. Siemens further states that error messages (see Table 2 of the [letter](#)) may occur if affected product contains insufficient samples. Siemens also states that there is no impact to health because the system will not generate test results if a level sense error occurs.

Action Needed:

Identify any affected product in your inventory. Siemens states that the lot numbers of the microsample inserts can only be tracked on the package and not on the microsample inserts. If you have affected product, verify that you have received the June 8, 2015, Customer Notification letter and Customer Notification Effectiveness Check form from Siemens. Consult the appropriate Operator's Guide for affected product for further information about required sample volumes. Siemens states that this issue is resolved with future lots. If the error messages seen in Table 2 of the [letter](#) occur, add additional sample to the sample cup or microsample tube. Siemens recommends that you order replacement cup holders and/or microsample inserts. Upon receipt of the replacement holders and/or inserts, discontinue use of and discard the sample cup holders from affected lots. If you observe an increase in errors identified in Table 2 of the [letter](#), contact your Siemens customer care center or your local Siemens technical support representative. Complete the Field Effectiveness Check Form, and return it to Siemens using the instructions on the form. Retain a copy of the letter for 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
Website: [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 [HDA Format Guide](#).

Source(s):

- 2015 Jun 10. Member Hospital. Siemens letter submitted by ECRI Institute member hospitals, IML-15-01.A. US (includes reply form) [Download](#)
- 2015 Jun 11. Manufacturer. Manufacturer confirmed information

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