INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

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 Hematología ADVIA - SIEMENS
NO. IDENTIFICACIÓN RISARH	I1704-128
REFERENCIAS DEL DISPOSITIVO MEDICO	ADVIA 560, versiones de software 1.4.2133 y 1.4.2333
REGISTRO SANITARIO	2015DM-0013266
INDICACIONES Y USO ESTABLECIDOS	El ADVIA 560 Y 360 HEMATOLOGY SYSTEM es un sistema de hematología completamente automatizado, de alta calidad para la utilización en el diagnóstico in vitro en laboratorios clínicos. El sistema utiliza el método de impedancia para la medición de las concentraciones de leucocitos (WBC), eritrocitos (RBC) y plaquetas (PLT). La concentración de hemoglobina (HGB) de los glóbulos rojos se mide mediante refracción fotométrica. El sistema brinda una medición diferencial de la fórmula leucocitaria de 5 partes de WBC (LYM%, MON%, NEU%, EOS%, BAS%) mediante una tecnología de citometría de flujo óptica basada en láser. El ADVIA 560 y el ADVIA 360 HEMATOLOGY SYSTEM identifican pacientes con parámetros hematológicos dentro y fuera de los rangos de referencia establecidos. El sistema puede procesar hasta 100 ?l de sangre completa anticoagulada, de manera automática para hematología.
NOMBRE DEL FABRICANTE	Diatron Mi Plc Siemens Healthcare Diagnostics Inc
DESCRIPCION DEL PROBLEMA	El fabricante informa que los dispositivos médicos referenciados pueden obtener múltiples registros discordantes para la misma ID de la muestra, lo que puede dar lugar a una interpretación errónea de los datos completos, valores de recuento sanguíneo, seguimiento inapropiado y / o retraso en las pruebas, conllevando a que se presenten eventos adversos sobre los pacientes.
FUENTE	ANEXO 1

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FECHA DE NOTIFICACION 03 de Abril de 2017

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

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

ANEXO 1

[High Priority] - A27513 : Siemens—ADVIA 560 Hematology Systems: May Obtain Multiple Discordant Records for the Same Sample ID
Medical Device Ongoing Action

Published: Thursday, March 23, 2017
Last Updated: Friday, March 24, 2017

UMDNS Terms:

- Analyzers, Laboratory, Hematology, Cell Counting, Semiautomated [17742]

Product Identifier:
ADVIA 560 Hematology Systems *[Capital Equipment]*
Siemens Material No. (SMN) 11170842; Software Versions: 1.4.2133, 1.4.2333

Geographic Regions: Algeria, Angola, Australia, Belgium, Brazil, Canada, Chile, Colombia, Croatia, Czech Republic, Egypt, France, Germany, Greece, India, Italy, Japan, Kenya, Malaysia, Mexico, Myanmar, The Netherlands, Norway, Pakistan, Portugal, Puerto Rico, Saudi Arabia, Slovenia, Spain, Switzerland, Turkey, Uganda, U.K., U.S., Vietnam

Manufacturer(s): Siemens Healthcare Diagnostics Inc511 Benedict Ave, Tarrytown, NY 10591, United States

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

Summary:
In October and December 2016 Urgent Field Safety Notice letters posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Siemens states that the above systems may obtain multiple discordant records for the same sample ID, potentially leading to misinterpretation of complete blood count values, inappropriate follow-up, and/or a delay in testing or follow-up. Siemens also states that the database should contain only 1 record of a sample ID number for any given time and date. Siemens further states that multiple results may be manually or automatically sent to the laboratory information system (LIS), printed, or displayed on the results report screen as a result of this problem. Siemens states that this problem will cause 1 of the following messages to display with a red "X":

- Rbc data missing
- Baso data missing
- Differential data missing
- Hgb data missing
- Wbc data missing
- Some raw data file are missing

FDA's Center for Devices and Radiological Health (CDRH) states that the manufacturer initiated a correction by Urgent Medical Device Correction letter dated October 21, 2016, in the U.S.

Problem:
Identify any affected systems in your inventory. If you have affected systems, verify that you have received the October and/or December 2016 letters and Field Correction Effectiveness Check form from Siemens. Complete the Field Correction Effectiveness Check form, and return it to Siemens using the instructions on the form. Your Siemens customer service engineer will contact your facility to arrange for the installation of software version 1.4.2378, which corrects this problem. Siemens states that it is necessary to review results generated with affected systems. If you receive multiple results for 1 sample ID, contact your Siemens local technical support representative to report the problem. If any of the above messages display, do not release the results without checking the database screen on the system. To view the database, tap the database icon at the top of the home screen. If any of the above messages display, complete the following steps:

1. Acknowledge the error by hitting the "OK" button in the dialog box. The message must be cleared before samples are manually processed. If you are running the samples with autoloader, the instrument will continue to process the samples even if the dialog box appears.
2. Check the database for sample IDs run at the time of the error and discard all of those sample results.
3. Discard all sample results associated with multiple records in the database, LIS, and printed records screen.
4. Restart the system before continuing to process samples.
5. Verify the results by reassaying samples if any sample ID has multiple records.

Retain a copy of the Urgent Field Safety Notice letter with your records, review the letter with your medical director, and forward a copy of the letter to any facility to which you have further distributed affected product.

For Further Information:
Siemens U.S. customer care center
Tel.: (312) 275-7795
Siemens U.K. Helpdesk
Tel.: 44 (845) 6001955
E-mail: haematology.healthcare@siemens.com
Website: Click here

References:
Great Britain:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Siemens Healthcare: ADVIA 560 hematology system [online]. London: Department of Health; 2016 Nov 1 [cited 2016 Mar 22]. (Field safety notice; reference no. 2016/010/024/601/006). Available from Internet: Click here .
- Great Britain. Medicines and Healthcare Products Regulatory Agency. Siemens: ADVIA 560 hematology system [online]. London: Department of Health; 2017 Feb 13 [cited 2017 Mar 22]. (Field safety notice; reference no. 2016/010/024/601/006). Available from Internet: Click here .

United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall ADVIA 560 hematology systems [online]. 2016 Dec 8 [cited 2017 Mar 22]. Available from Internet: 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):

- 2017 Mar 22. FDA CDRH Database. Class II. Z-0723-2017 Download
- 2017 Mar 22. MHRA FSN. 2016/010/024/601/006 Download
- 2017 Mar 22. MHRA FSN. Siemens Reference No. HI17-02.A.OUS (includes reply form) Download
- 2017 Mar 22. MHRA FSN. 2016/010/024/601/006 Download
- 2017 Mar 22. MHRA FSN. HI17-02.B.OUS (includes reply form) Download
- 2017 Mar 24. Manufacturer. The manufacturer confirmed the information provided in the source material.