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 de Inmunoanálisis SIEMENS
NO. IDENTIFICACIÓN RISARH	I1806-393
REFERENCIAS DEL DISPOSITIVO MEDICO	CENTAUR XPT, versión de software 1.3
REGISTRO SANITARIO	2015DM-0013041
INDICACIONES Y USO ESTABLECIDOS	El ADVIA CENTAUR XPT SYSTEM es un instrumento analizador automatizado 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 los grupos de ensayos incluyen los de fertilidad, función tiroidea, oncología, cardiovascular, anemia, determinación de fármacos terapéuticos, enfermedades infecciosas, alergia, función adrenal y metabólica. Es en sistema automatizado que reporta los valores de las pruebas y comunica los resultados de clínicos del paciente. Sistema XPT es de alta eficiencia y rendimiento para pruebas especializadas y de rutina en el laboratorio clínico.
NOMBRE DEL FABRICANTE	Siemens Healthcare Diagnostics Inc. Siemens Healthcare Diagnostics Manufacturing Ltd
DESCRIPCION DEL PROBLEMA	El fabricante informa que la versión del software referenciada puede no resolver completamente el estado del sistema desconocido, comunicación LAS y errores "no primarios", la anterior situación podría conllevar a que se presenten retrasos en el procesamiento de las muestras y potenciales eventos adversos sobre los pacientes.
FUENTE	ANEXO
FECHA DE NOTIFICACION	18 de junio de 2018

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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

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ANEXO

[Normal Priority] - A28085 01 : Siemens—ADVIA Centaur XPT Systems: Software Problems May Cause Delay in Testing [Update]
Medical Device Ongoing Action

Published: Tuesday, June 12, 2018

UMDNS Terms:

- Analyzers, Laboratory, Clinical Chemistry/Immunoassay [20821]
- Software, Laboratory Analysis, Immunoassay [26805]
- Software, Laboratory Analysis, Clinical Chemistry [26802]

Product Identifier:
[Capital Equipment]

Product	Siemens Healthcare Model	Material No.	Software Version
Clinical Chemistry/Immunoassay Analyzers	ADVIA Centaur XPT	10711433	V1.3

Geographic Regions: (Impact in specific regions has not be identified or ruled out at the time of this posting), Worldwide

Manufacturer(s): Siemens Healthcare 40 Liberty Blvd, Malvern, PA, 19335, United States

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

Summary:
Update Reason: The above software version may not resolve the System Status Unknown, LAS Communication, and "No Primary" Errors. This Alert provides new information based on a May 2018 Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) regarding Alert A28085 . New information is provided in the Product Identifier, Problem, and Action Needed fields.
Problem:
In a May 2018 Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Siemens states that, although you may have received the Software Version 1.3 Release Notes (SMN 11313041 Rev 01), the above software version does not fully resolve the System Status Unknown, LAS Communication, and "No Primary" Errors, described in Alert A28085 . The problems not resolved include the following:

1. The system may display an "Unknown status" if a software error occurs because of reagent bar-code processing, missing wash packs for mitigations, sample processing if the aHAVM assay is ordered, a problem during the daily cleaning or rinse operation, and/or software processing errors.
2. Tubes received from the laboratory automation system (LAS) may not be processed under certain conditions.
3. A "No Primary" error may be generated and tests may be aborted in certain scenarios.

For details on each problem and the circumstances under which they may occur, see Table 2 in the letter . The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify any affected systems in your inventory. If you have affected systems, verify that you have received the May 2018 Urgent Field Safety Notice Follow Up Information letter and Field Correction Effectiveness Check form from Siemens. Siemens states that these problems will be corrected in future software versions. In the meantime, perform the following actions to address the problems, respectively:

1. Ensure that all wash mitigation packs are loaded in the system before starting sample processing to ensure that all samples will be processed successfully. If "Unknown Status" is displayed, shut down and restart the system before restarting sample processing. When disabling a test, remove the test from the QC Scheduler before disabling the test from the test definition screen and running the QC sample. Ensure that there is enough reagent volume on board the system before starting sample processing. Avoid having numerous reagent lots that are depleted and/or expired onboard the system. For additional recommendations from Siemens regarding restarting the system, see the letter .
2. Optimize the delivery of tubes so that a steady stream of tubes arrives at the system to be processed to prevent sampling from stopping because of sporadic tube arrival.
3. To minimize interruption of test processing and "no primary" errors, adhere to the following procedures:
   - When running tests that may require auto-repeats with auto-dilutions, ensure that the packs have sufficient reagent volume so that they do not go low or deplete while running.
   - If a "No Primary" flag is received on a test, it will need to be reordered.

Review the letter with your medical director. 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. Retain a copy of the letter with your records. Siemens does not recommend a laboratory lookback of previously generated results because of these problems. Complete the Field Effectiveness Check form, and return it to Siemens using the instructions on the form.
For further Information:
Siemens customer care center
Tel.: (312) 275-7795
Website: Click here

References:
United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall ADVIA Centaur XPT system [online]. 2017 Feb 23 [cited 2017 Apr 3]. Available from Internet: Click here .

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Great Britain:

- Medicines and Healthcare Regulatory Agency. Siemens: ADVIA Centaur XPT [online]. London: Department of Health; 2017 Feb 13 [cited 2017 Apr 6]. (Field Safety Notice; reference no. 2017/002/007/601/003). Available from Internet: Click here .
- Medicines and Healthcare Regulatory Agency. Siemens: ADVIA Centaur XPT [online]. London: Department of Health; 2018 May 31 [cited 2018 Jun 8]. (Field Safety Notice; reference no. 2017/002/007/601/003). 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):

- 2018 Jun 8. MHRA FSN. 2017/002/007/601/003 Download
- 2018 Jun 8. MHRA FSN. (includes reply form) Download