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 CENTAUR SIEMENS
NO. IDENTIFICACIÓN RISARH	I1705-188
REFERENCIAS DEL DISPOSITIVO MEDICO	ADVIA CENTAUR XPT SYSTEM, versiones de software V1.0.1, V1.0.2, V1.0.3, V1.1, V1.2
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 debido a múltiples problemas de software se podrían afectar la operación y flujo de trabajo de los dispositivos médicos referenciados, ocasionando tubos no procesados, mal funcionamiento del sistema LIS (*sistema de información*), también se puede generar algunos de los siguientes mensajes de error "*Unknown status*", "*No Primary*", lo anterior podría conducir a que se presenten errores y retrasos en el procesamiento de las muestras.
FUENTE	ANEXO
FECHA DE NOTIFICACION	31 de Mayo de 2017

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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

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

ANEXO

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

Published: Monday, May 15, 2017
Last Updated: Thursday, May 18, 2017

UMDNS Terms:

- Analyzers, Laboratory, Clinical Chemistry/Immunoassay [20821]

Product Identifier:
ADVIA Centaur XPT Systems *[Capital Equipment]*
System Siemens Material No. 10711433

Software Versions:	Bundles:	Software Siemens Material Nos.:
V1.0.1	1.0.912	10819704
V1.0.2	1.0.1086	11219806

V1.0.3	1.0.1108	11220781, 11219656
V1.1	1.1.243	11221979, 11222064
V1.2	1.2.223.0	11222258, 11223813

Geographic Regions: (Impact in additional regions may 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

Problem:
In a February 2, 2017, Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Siemens states that the above systems may have multiple software problems that could affect operation and workflow, potentially leading to delays in testing. The problems observed are 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. If a new test is added to an existing quality control (QC) profile, the new test is not added into all levels of the QC material that exist in the QC profile and the display will not show all control levels of the new test.
4. A "No Primary" error may be generated and tests may be aborted in certain scenarios.
5. The software may not operate according to the published laboratory information system (LIS) specification.

For details on each problem and the circumstances under which they may occur, see Table 2 in the letter . FDA's Center for Devices and Radiological Health (CDRH) states that the manufacturer initiated a correction by Urgent Medical Device Correction letter dated February 2, 2017. 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 February 2, 2017, Urgent Medical Device Correction letter and/or the February 2, 2017, Urgent Field Safety Notice 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 above 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, shutdown and restart the system before restarting sample processing. For additional recommendations from Siemens regarding restarting the system, see the letter .
2. Default test names must be used for the LIS Name in the Test Definition setup screen for the reagent status to be sent to the LAS. Your Siemens service personnel can check if this is set up correctly. 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 add a new test to an existing QC profile, delete all levels of the control material in the QC profile (using the "Remove Control" button) and recreate the entire QC profile again with all the tests, including the new one.
4. To minimize interruption of test processing and "no primary" errors, adhere to the following procedures:
   - Ensure that all reagents and bulk consumables are available before starting sample processing. If a "No Primary" flag is received on a test, resolve that condition before replenishing any bulk consumables.
   - When removing reagent packs causing the "immediate unload" command, do not request a "cancel unload." If a "cancel unload" is requested, the pack must be physically removed from the reagent compartment and the compartment door must be closed for the system to scan all the reagent packs and resume normal test processing. The pack can be reloaded after the reagent compartment scanning has completed.
   - 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.
5. Communicate the information regarding the changes in LIS specification stated in Table 2 of the letter to your LIS vendor and implement them. Siemens states that the CentraLink and syngo LIS interfaces are designed to work with this specification and do not need any changes.

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:

- 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 .
- 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 .

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 Apr 12. FDA CDRH Database. Class II. Z-1537-2017 Download
- 2017 Apr 26. MHRA FSN. Siemens Reference No. CSW17-02.A.OUS (includes reply form) Download
- 2017 Apr 26. MHRA FSN. 2017/002/007/601/003 Download