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 Electrolitos y Gases Arteriales SIEMENS
NO. IDENTIFICACIÓN RISARH	I1508-386
REFERENCIAS DEL DISPOSITIVO MEDICO	RAPIDPOINT 500
REGISTRO SANITARIO	2009DM-0004077
INDICACIONES Y USO ESTABLECIDOS	Los instrumentos RAPIDPOINT 400/405 son analizadores para pruebas de electrolitos y gases arteriales en la cabecera del paciente por electroquímica. Utiliza muestras de sangre arterial o capilar. Reporta los valores de PH, PCO2, PO2, HCO3- , CTCO2 ; CO-OXI, BE(ECF), O2SAT, O2CT, PO2(A-A), PO2(A/A), FO2HB, FMETHB Y FCOHB para gases sanguíneos y análisis de electrolitos Na+, K+, Ca++, Cl-, Li+, glucosa, lactato, HCT y HB. Es en sistema diseñado para pacientes críticos en cirugía, uci y urgencias que reporta los valores de las pruebas y comunica los resultados de clínicos del paciente. Los reactivos que se utilizan con los equipos RAPIDPOINT cuentan con respectivo registro sanitario.
NOMBRE DEL FABRICANTE	Siemens Healthcare Diagnostics Manufacturing Ltd Siemens Healthcare Diagnostics Inc.
DESCRIPCION DEL PROBLEMA	El fabricante afirma que cuando ambos puertos (serie y Ethernet) están configurados para transmitir datos, el flujo de datos de un puerto puede afectar el flujo de datos desde el otro puerto, conllevando a que se presenten potencialmente confusiones entre los resultados de análisis de las pruebas y en el diagnostico posterior.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	13 de Agosto 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

[High Priority] - A24806 : Siemens—RAPIDPoint 500 Blood Gas Analyzers: Data Errors May Occur

Medical Device Ongoing Action

Published: Monday, August 3, 2015
Last Updated: Monday, August 10, 2015

UMDNS Terms:

- Analyzers, Point-of-Care, Whole Blood, Gas/pH [18510]
- Analyzers, Point-of-Care, Whole Blood, Gas/pH/Electrolyte [18511]
- Analyzers, Point-of-Care, Whole Blood, Gas/pH/Electrolyte/Metabolite [18853]
- Analyzers, Point-of-Care, Whole Blood, Multianalyte [18509]

Product Identifier:
RAPIDPoint 500 Blood Gas Analyzers *[Capital Equipment]*
Siemens Material Nos.: 10492730, 10696855, 10696857, 10697306

Geographic Regions: Worldwide

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

Suggested Distribution: Clinical/Biomedical Engineering, Clinical Laboratory/Pathology, Pulmonology/Respiratory Therapy, Information Technology, Point-of-Care Coordination

Problem:
In a July 2015 Urgent Field Safety Notice letter submitted by an ECRI Institute member hospital, Siemens states when both ports (serial and Ethernet) are configured to transmit data, the data stream from one port may affect the data stream from the other port on the above analyzers. This problem may cause the message received by the laboratory information system (LIS) to include the following:

- Duplicate data,
- Missing data, or
- Data from a different patient (Siemens has not observed this scenario and the expected frequency is extremely unlikely).

Siemens states that this problem occurs only if the dual port LIS transmission feature is enabeled on the above systems. If this problem occurs, only one analyte has the potential to be affected (i.e., if a panel of analytes is ordered, only one could be affected). Siemens states that a duplicate or missing analyte is of no risk to health. Siemens also states that a transposed sodium, potassium, glucose, lactate, carboxyhemoglobin, methemoglobin, or neonatal bilirubin result may lead to a potential risk to health when the true value is critical.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the July 2015 Urgent Field Safety Notice letter and Field Correction Effectiveness Check Form from Siemens. Determine if your system is configured to use dual port LIS transmission. If your system is currently set up with dual LIS transmission enabled, one of the ports (either serial or Ethernet) must to be disabled. To disable the connections, refer to the instructions and figures in the letter . Complete the Field Correction Effectiveness Check form, and return it to Siemens using the instructions on the form. Siemens states that this problem will be resolved in the next software release. Keep a copy of the Urgent Field Safety Notice letter with your facility's laboratory records, 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

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 Jul 30. Member Hospital. Siemens letter submitted by an ECRI Institute member hospital. (includes reply form) Download
- 2015 Aug 3. Manufacturer. The manufacturer confirmed the information in the source material
- 2015 Aug 10. MHRA FSN. 2015/007/030/601/001 Download
- 2015 Aug 10. MHRA FSN. 33114 Rev A. (includes reply form) Download