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 Electrolitos y Gases Arteriales RAPIDPOINT SIEMENS
NO. IDENTIFICACIÓN RISARH	I1706-206
REFERENCIAS DEL DISPOSITIVO MEDICO	RAPIDPOINT 500, versión de software 2.4, seriales específicos.
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 Inc. Siemens Healthcare Diagnostics Manufacturing Ltd
DESCRIPCION DEL PROBLEMA	El fabricante establece que la información demográfica del paciente (apellido, nombre, sexo, fecha de nacimiento) puede ser mal asignada, cuando el campo ID del paciente se deja en blanco en múltiples muestras y se inicia una recuperación de la información del paciente, conllevando a que se presenten eventos adversos sobre los pacientes por confusión en la identificación de resultados.
FUENTE	ANEXO
FECHA DE NOTIFICACION	02 de Junio 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

[High Priority] - A28546 : Siemens—RAPIDPoint Blood Gas Analyzers: Patient Demographic Information May Be Misassigned When the Patient ID Field Is Left Blank

Medical Device Ongoing Action

Published: Thursday, May 25, 2017

UMDNS Terms:

- Analyzers, Laboratory, Blood Gas [18617]

Product Identifier:
RAPIDPoint 500 Blood Gas Analyzers *[Capital Equipment]*
Software Version V2.4; Siemens Material Nos.: 10492730, 10696857, 10697306; Serial Nos.: 30762, 30779, 30784, 30819, 30841, 30842, 30844, 30846, 30904, 30905, 30906, 30907, 31006, 31771, 31772, 32356, 32470, 33198, 33201, 33232, 33370, 33438, 33459, 33573, 33640, 33643, 33863, 33865, 33968, 33986, 33997, 33998, 33999, 34000, 34082, 34083, 34291, 34427, 34438, 34442, 34444, 34627, 35002, 35009, 35053, 35055, 35195, 35393, 35395, 35462, 35688, 35690, 35692, 35693, 35703, 35705, 35922, 36003, 36005, 36006, 36007, 36008, 36113, 36116, 36284, 37243, 37261, 37275, 37292, 37295, 37296, 37563, 38110, 38138, 38306, 38815, 39301, 39303, 39459, 39597, 39672, 39688, 39689, 39690, 39691, 39692, 39693, 39694, 39695, 39698, 39699, 39700, 39701, 39702, 39703, 40403, 40405, 40406, 40407, 40408, 40409, 40410, 40411, 40412, 40413, 40421, 40422, 40427, 40436, 40437, 40448, 40451, 40456, 40460, 40461, 40464, 40466, 40467, 40468, 40469, 40470, 40471, 40473, 40477, 40489, 40501, 40502, 40503, 40508, 40509, 40510, 40512, 40561, 40562, 40565, 40568, 40576, 40580, 40582, 40583, 40594, 40596, 40612, 40616, 40624, 40625, 40642, 40643, 40644, 40647, 40648, 40666, 40669, 40677, 40678, 40679, 40748, 40806, 313388

Geographic Regions: (Impact in additional regions has not been identified or ruled out at the time of this posting), Australia, Bangladesh, Chile, Colombia, France, Germany, Hong Kong, India, Ireland, Japan, Latvia, Mexico, Spain, Switzerland, Thailand, Uruguay, U.S.

Manufacturer(s): Siemens Healthcare40 Liberty Blvd, Malvern, PA 19355-9998, United States

Suggested Distribution: Clinical/Biomedical Engineering, Clinical Laboratory/Pathology, Diagnostic Imaging

Problem:
In an April 2017 Urgent Field Safety Notice letter posted by the German Federal Institute for Drugs and Medical Devices (BfArM), Siemens states that patient demographic information (Last Name, First Name, Gender, or Date of Birth) may be misassigned when the Patient ID field is left blank on multiple patient samples and a recall of the patient information is initiated. Siemens also states that an example of a scenario in which this error may occur is the following:

- Patient sample number 1 is run with a blank Patient ID field and demographics are assigned (Last Name, First Name, Gender, or DOB).
- Patient sample number 2 is run with a blank Patient ID field and different demographics are assigned (Last Name, First Name, Gender, or DOB).
- An attempt is made to recall patient sample number 1 results, but sample noumber 2 demographics are displayed, not sample number 1 demographics (results are for patient sample number 1).

Siemens further states that RAPIDPoint 400/405 or RAPIDLab blood gas analyzers are not affected by this problem. Siemens also states that falsely abnormal test results may occur, potentially necessitating additional diagnostic testing and treatment; patients with abnormal test results may be incorrectly identified as having normal test results. FDA's Center for Devices and Radiological Health (CDRH) states that Siemens initiated a correction by Urgent Field Safety Notice letter on April 10, 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 April 2017 Urgent Field Safety Notice letter and Field Correction Effectiveness Check form from Siemens. Maintain the Patient ID field as enabled and a required Patient Demographic entry on affected systems. To confirm that the Patient ID field is set as a required field on affected systems, verify that a black triangle appears next to the Patient ID field. The black triangle indicates that data is required in that field. If the Patient ID field is not set as required, reset it by following the steps below:

- Access Setup>Sample>Patient Demographics (you may need to login for setup access, depending on security settings).
- If the Patient ID option is unselected, first touch the Patient ID button to select it.
- To the left of the Patient ID button is another button (triangular shaped) that indicates whether a field is required. Touch this button to select the triangle.
- Exit the Setup screens by pressing the "=>" (Continue) buttons until the Status screen is displayed.

Siemens states that it is developing a software update to address this problem and that it will provide additional information when it becomes available. Complete the Field Correction Effectiveness Check form, and return it to Siemens using the instructions on the form. Review the letter with your medical director. Notify all relevant personnel at your facility of the information in the letter, forward a copy of the letter to any facility to which you have further distributed affected product, and retain a copy of the letter with your records.

For Further Information:
Siemens
Website: Click here

References:

- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall RAPIDPoint 500 blood gas analyzer [online]. 2017 May 5 [cited 2017 May 23]. Available from Internet: Click here .
- Germany. Federal Institute for Drugs and Medical Devices. Urgent field safety notice for RAPIDPoint 500 ROW by Siemens Healthcare Diagnostics Inc. Tarrytown [online]. 2017 May 5 [cited 2017 May 23]. Available from Internet: Click here .

Comments:

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- 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 May 23. BfArM (Germany). 03770/17 Download
- 2017 May 23. BfArM (Germany). April 2017 Siemens letter posted by Bfarm, POC 17-008.A.OUS (includes reply form) Download
- 2017 May 23. FDA CDRH Database. Class II. Z-2040-2017 Download