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	I1501-16
REFERENCIAS DEL DISPOSITIVO MEDICO	Modelo RAPIDLAB 1245, RAPIDLAB 1265, RAPIDPOINT 405 y RAPIDPOINT 500, 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 Manufacturing Ltd. Siemens Healthcare Diagnostics Inc.
DESCRIPCION DEL PROBLEMA	El fabricante afirma que el valor resultante del parámetro de bilirrubina neonatal (nBili) puede verse afectado bajo condiciones específicas de funcionamiento del equipo, conllevando a que se presenten posibles eventos adversos sobre los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	13 de Enero 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] - A23643 : Siemens—Various RAPIDPoint and RAPIDLab Analyzers: Neonatal Bilirubin Results May Be Higher or Lower than Expected

Medical Device Ongoing Action

UMDNS Terms:

- Analyzers, Laboratory, Blood Gas/pH [15709]
- Analyzers, Point-of-Care, Whole Blood, Gas/pH [18510]

Product Identifier:

Blood Gas Analyzers:	Siemens Material Nos.:
RAPIDLab 1245	10321844, 10337179, 10491393
RAPIDLab 1265	10321852, 10335524, 10491395
RAPIDPoint 405	10310464, 10314817, 10317193, 10318999, 10320055, 10322347, 10328278, 10328302, 10336784
RAPIDPoint 500	10492730, 10696855, 10696857, 10697306

[Capital Equipment]

Geographic Regions: Albania, Algeria, Argentina, Australia, Bahrain, Belarus, Bosnia & Herzegovina, Botswana, Brazil, Brunei, Canada, Chile, China, Colombia, Egypt, Georgia, Hong Kong, Indonesia, Israel, India, Iraq, Ivory Coast, Japan, Kazakhstan, Kuwait, Lebanon, Lesotho, Macedonia, Malaysia, Mexico, New Caledonia, New Zealand, Peru, Qatar, Russia, Saudi Arabia, Serbia, Singapore, South Africa, South Korea, Taiwan, Thailand, United Arab Emirates, U.S., Vatican City, Venezuela, Vietnam

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

Suggested Distribution: Clinical/Biomedical Engineering, Clinical Laboratory/Pathology, Point-of-Care Coordination

Problem:
In a December 2014 Urgent Field Safety Notice letter submitted by an ECRI Institute member hospital, Siemens states that the neonatal bilirubin (nBili) parameter may have increased variability when the nBili concentration is > 12 mg/dL (205 µmol/L) and the total hemoglobin (tHb) concentration exceeds the upper reportable range of > 25 g/dL (15.5 mmol/L) on the above systems. Siemens also states that the analyzer may report an nBili result that is higher or lower than expected. The nBili parameter is dependent on tHb. For nBili to be accurately measured, the tHb channel must be in calibration and have no associated error codes. Refer to the table in the letter to see how the analyzer reports these scenarios. Siemens also reminds customers of the information stated in the neonatal bilirubin interference section of the Operator's Guide. As with all diagnostic tests, do not base a definitive diagnosis on the results of a single test. A physician should make a diagnosis after all clinical and laboratory findings are evaluated. On whole blood, the total analyical error may be higher than the fixed limits of +/- 20%. The measured total analytical error includes many sources of error such as day-to-day variation, instrument-to-instrument differences, and variability in the reference for method used for comparison. Siemens states that this problem is limited to a potential delay in hyperbilirubinemia detection while the result is being confirmed by biochemical means if the result is lower than expected. There is negligible risk to health if a higher than expected result is obtained since phototherapy would already be initiated and exchange therapy would require confirmation by biochemical testing in the laboratory.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the December 2014 Urgent Field Safety Notice letter and Field Correction Effectiveness Check Form from Siemens. If your analyzer reports high and out of range ("----- ") tHb results and an nBili result is reported, do not use the nBili result reported from the analyzers. Review this letter with your medical director. Complete the Field Correction Effectiveness Check Form, and return it to Siemens using the instructions on the form. 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 Jan 2. Member Hospital. Siemens letter submitted by an ECRI Institute member hospital. 32258 Rev A Download
- 2015 Jan 5. Manufacturer. The manufacturer confirmed the information in the source material.