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	Monitor de Signos Vitales DRAGER
NO. IDENTIFICACIÓN RISARH	I1704-137
REFERENCIAS DEL DISPOSITIVO MEDICO	Delta, Delta XL, Kappa con los siguientes módulos, Scio, Scio Four, Scio Four Oxi Plus, Scio Four Plus, versión de software VF10.0
REGISTRO SANITARIO	2008EBC-0002678 2008EBC-0002680
INDICACIONES Y USO ESTABLECIDOS	Utilizado en la vigilancia de pacientes a través de parámetros fisiológicos vitales.
NOMBRE DEL FABRICANTE	Draeger Medical Systems, Inc.
DESCRIPCION DEL PROBLEMA	El fabricante informa que los equipos biomédicos referenciados podrían no presentar alarmas a pesar de que el nivel medido en el módulo este por fuera de los rangos establecidos para los límites de alarma, las alarmas afectadas son: iO_2 > #, iO_2 < #, i[agent] > #, i[agent] < #, Inspired MAC High, etN_20 > 82%, lo cual podría conllevar a que se presenten eventos adversos sobre los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	12 de Abril de 2017

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 1

[High Priority] - A28314 : Draeger—Infinity Monitors Used with Scio Modules: May Not Generate Certain Alarms

Medical Device Ongoing Action

Published: Monday, April 3, 2017

UMDNS Terms:

- Monitors, Telemetric, Physiologic [13987]

Product Identifier:
Infinity Monitors: (1) Delta, (2) Delta XL, (3) Kappa used with the following Modules: (4) Scio, (5) Scio Four, (6) Scio Four Oxi Plus, (7) Scio Four Plus *[Capital Equipment]*
Software Version VF10.0

Geographic Regions: Worldwide

Manufacturer(s): Draeger Medical Deutschland GmbHMoislinger Allee 53-55, Luebeck, D-23558, Germany

Suggested Distribution: Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Nursing, OR/Surgery, Pulmonology/Respiratory Therapy, Information Technology, NICU

Problem: In a March 2017 Important Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Draeger states that the above monitors with software VF10.0 when combined with the referenced Scio modules will not generate the following alarms even though the level measured by the Scio module is outside of the set alarm limit: (# represents the set alarm limit): i02 > #, i02 < #, i[agent] > #, i[agent] < #, Inspired MAC High, etN20 > 82%. Draeger states that although the alarms are not generated, the parameter readings are not affected and will be displayed properly.

Action Needed:
Identify any affected product in your inventory. If you have any affected product, verify that you have received the March 2017 Important Safety Notice/Medical Device Recall letter and Reply and Order Card from Draeger. If you are using the above referenced Scio modules in your facility, do not combine them with Delta, Delta XL or Kappa monitors running software VF10.0 unless you can ensure adequate patient surveillance. A downgrade to software version VF9.1 is required as a short-term measure. If you have the above modules, contact Draeger using the attached Reply and Order card. Your Draeger sales and service representative will contact your facility to install the downgrade to VF9.1 at no charge. Inform all relevant personnel of the information in the Urgent Field Safety Notice letter. If you do not have any modules, no immediate action is required. Draeger is developing a new software version VF10.1. Once the VF10.1 Software is released, your Draeger sales and service representative will contact your facility to arrange to install the update to VF10.1 at no charge. Delta Family monitors that were downgraded because of this problem will also be upgraded to VF10.1 software.

For Further Information:
Draeger
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Draeger: Delta/Delta XL/Kappa [online]. London: Department of Health; 2017 Mar 27 [cited 2017 Mar 29]. (Field safety notice; reference no. 2017/003/021/291/007). 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 Mar 29. MHRA FSN. 2017/003/021/291/007 Download
- 2017 Mar 29. MHRA FSN. Download
- 2017 Mar 30. Manufacturer. Manufacturer confirmed source documents