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	Monitores Infinity Acute Care System Workstation Critical DRAEGER
NO. IDENTIFICACIÓN RISARH	I1804-233
REFERENCIAS DEL DISPOSITIVO MEDICO	INFINITY Acute Care (IACS), INFINITY M540, Versión de Software VG2.0 a VG4.1 equipados con sensores de corriente principal MCable (M11.1) con numero de revisión 16
REGISTRO SANITARIO	2009EBC-0004116
INDICACIONES Y USO ESTABLECIDOS	Este equipo permite ventilar pacientes adultos y pediátricos. Permite seleccionar modos de ventilación mandatorios o modos de ventilación asistidos a la respiración espontánea y de monitorización de vías respiratorias, contando con pantallas de monitorización y control para sistema para cuidados agudos INFINITY lo cual se realiza a través del programa de software SMARTCARE diseñado especialmente para la automatización de medidas terapéuticas
NOMBRE DEL FABRICANTE	Draeger Medical Systems, Inc. Drägerwerk Ag & Co. Kgaa
DESCRIPCION DEL PROBLEMA	El fabricante ha detectado que los equipos referenciados pueden reiniciarse si el sensor ingresa a modo de precisión reducida, además si el reinicio ocurre tres veces en un tiempo de 10 minutos el equipo se colocara en modo falla, lo anterior podría conllevar a que se presenten eventos adversos sobre los pacientes.
FUENTE	Anexo
FECHA DE NOTIFICACION	16 de abril de 2018

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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

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ANEXO

[High Priority] - A30258 : Draeger—Infinity Acute Care Systems and Standalone Infinity M540 Patient Monitors: May Reboot and Enter Fail State if the Infinity MCable Mainstream CO2 Sensor Enters a Reduced Accuracy Mode
Medical Device Ongoing Action

Published: Wednesday, April 4, 2018
Last Updated: Monday, April 16, 2018

UMDNS Terms:

- Monitors, Physiologic, Multipurpose, Telemetric [13987]
- Physiologic Monitor Modules, Exhaled Carbon Dioxide [20776]

Product Identifier:
[Capital Equipment]

Product	Draeger Medical Systems Inc Model	Software Version	Revision No.
Patient Monitors	Standalone Infinity M540 Patient Monitors	VG2.2 to VG4.1	N/A
	Infinity Acute Care System (IACS)	VG2.2 to VG4.1	N/A
Sensors	Infinity MCable Mainstream CO2 (M11.1)	N/A	16

Geographic Regions: Worldwide

Manufacturer(s): Draeger Medical Systems Inc3135 Quarry Rd, Telford, PA 18969, United States

Suggested Distribution: Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Nursing, Information Technology

Problem:
In a March 19, 2018, Urgent Medical Device Recall letter submitted by an ECRI Institute member hospital, Draeger states that when the above patient monitors are used with and connected to the above sensors, the monitors may reboot if the sensor enters a reduced accuracy mode. Draeger also states that if the above monitors reboot three times within 10 minutes, they will enter a fail state, resulting in a resetting to factory defaults and loss of patient settings and stored patient data. Draeger further states that revision 16 sensors were introduced in mid-2017 and that use of revision 15 and below sensors will not cause this problem to occur. Additionally, Draeger states that it has received two reports of this problem occurring in the field; however, it has received no reports of adverse events associated with this problem.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the March 19, 2018, Urgent Medical Device Recall letter and Customer Reply Card from Draeger. Do not use revision 16 sensors with affected monitors. You may continue to use previous revisions of the CO_2 sensor. Draeger states that it is in the process of resolving this problem. If you choose to upgrade your system, a Draeger service representative will contact your facility to schedule a service visit to perform the upgrade when the updated software is available. Complete the Customer Reply Card, and return it to Draeger using the information on the card.
For Further Information:
Canada
Karina Torres, Draeger
Tel.: (905) 212-6530
U.S.
Michael Kelhart, Draeger
Tel.: (215) 660-2349
Draeger service techincal support department for the U.S. and Canada
Tel.: (800) 543-5047 (select option 4)
Outside U.S. and Canada
Local Draeger representative
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):

- 2018 Mar 26. Member Hospital. Draeger letter submitted by an ECRI Institute member hospital (includes reply form) Download
- 2018 Apr 4. Manufacturer. The manufacturer confirmed the information in the source material.
- 2018 Apr 16. Health Canada Recall Listings. Type I. RA-66412 Download