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	I1804-223
REFERENCIAS DEL DISPOSITIVO MEDICO	INFINITY Acute Care (IACS), INFINITY M540, Versión de Software VG7.0
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 presentar fallos en la toma de lecturas de NIBP cuando se cambian entre las diferentes categorías de paciente disponibles, conduciendo a mayores presiones y tiempos de aplicación más extensos, o cuando se validan límites de alarma con el modo temporizador activado, reiniciando el equipo o colocándolo en modo falla, lo anterior podría conllevar a que se presenten eventos adversos sobre los pacientes.
FUENTE	Anexo
FECHA DE NOTIFICACION	13 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] - A30167 : Draeger— Infinity Acute Care Systems and Standalone Infinity M540 Patient Monitors: May Exhibit Various Software-Related Problems
Medical Device Ongoing Action

Published: Wednesday, March 21, 2018
Last Updated: Thursday, March 22, 2018

UMDNS Terms:

- Monitors, Physiologic, Multipurpose, Telemetric [13987]
- Software, Physiologic Monitoring, Blood Pressure [26711]
- Monitors, Physiologic, Multipurpose, Bedside [20170]

Product Identifier:
[Capital Equipment]

Product	Draeger Medical Systems Inc. Model	Software Version
Patient Monitors	Infinity Acute Care System (IACS)	VG7.0
	Standalone Infinity M540	VG7.0

Geographic Regions: Australia, Columbia, France, Germany, Italy, U.K.

Manufacturer(s): Draeger Medical Systems Inc.3135 Quarry Rd, Telford, PA 18969, United States

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

Problem:
In a March 2018 Important Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Draeger states that the above monitors may exhibit the following problems:

1. When the operator changes a patient category, and then a non-invasive blood pressure (NIBP) measurement is taken, the NIBP inflation limits that are applied may not correlate to the patient category chosen. For example, if the operator switches the patient category from "Adult" to "Pediatric," the "Adult" inflation limits will be applied, instead of the desired "Pediatric" setting. The visual indicator on the screen will correspond to the desired selection. This may lead to higher pressure and longer application times in neonatal and pediatric patients.
2. When the alarm validation timer is turned on, and the NIBP measurements are taken, the Infinity M540 patient monitor may reboot whenever the NIBP measurement violates the set alarm limit. If the reboot occurs three times in 10 minutes or less, the Infinity M540 patient monitor may go into fail-state, potentially resulting in a resetting to factory defaults, losing patient settings and stored patient data. When the M540 patient monitor enters a fail-state, a continuous tone is annunciated from the device. If the M540 patient monitor is connected to the Central Station, the Central Station will annunciate a medium alarm tone, along with an "Offline" message.

Action Needed:
Identify any affected systems in your inventory. If you have affected systems, verify that you have received the March 2018 Important Safety Notice letter and Customer Response Form from Draeger. To avoid the described problems, Draeger recommends the following:

- If you are using the system with neonate or pediatric patient mode, Draeger will downgrade your systems to the previous software version.
- If you are using the system with Adult patient mode only, you may choose to:
  - Downgrade your system to the previous software version or;
  - Continue to use the VG7.0 software version. If you choose this option, your Draeger service representative will schedule a visit to label all systems indicating that the systems are not for use in Neonate or Pediatric patient mode and will set the Alarm Validation setting to Off.

Draeger will release software version VG7.0.1 to correct these problems. When the upgraded software version is available, your Draeger representative will schedule a visit to upgrade all affected systems. Notify all relevant personnel at your facility of the information in the Important Safety Notice letter. Complete the Customer Response Form, and return it to Draeger using the information on the form.

For Further Information:
Draeger
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Drager: Infinity Acute Care System (M540) [online]. London: Department of Health; 2018 Mar 12 [cited 2018 Mar 12]. (Field safety notice; reference no. 2018/003/007/478/029). 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 .

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Source(s):

- 2018 Mar 12. MHRA FSN. 2018/003/007/478/029 Download
- 2018 Mar 12. MHRA FSN. (includes reply form) Download
- 2018 Mar 21. Manufacturer. The manufacturer confirmed the information in the source material.