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 de Paciente GE
NO. IDENTIFICACIÓN RISARH	I1806-382
REFERENCIAS DEL DISPOSITIVO MEDICO	B650 con conexión LAN
REGISTRO SANITARIO	2008EBC-0001978
INDICACIONES Y USO ESTABLECIDOS	Monitorizar parámetros clínicos a pacientes hospitalizados.
NOMBRE DEL FABRICANTE	Ge Medical Systems Technologies Co Ltd Carefusion Finland 320 Oy Ge Healthcare Finland Oy
DESCRIPCION DEL PROBLEMA	El fabricante informa que cuando más de uno de los equipos referenciados están conectados a la misma red y ocurre una sobrecarga de red durante un tiempo prolongado, los monitores pueden reiniciarse simultáneamente, el reinicio del monitor no se completará hasta que se haya corregido el problema de la red, durante el ciclo de reinicio automático, el sistema mostrará una pantalla de reinicio en el monitor de cabecera, los monitores proporcionarán un tono audible prolongado durante el reinicio, y la estación central de monitoreo mostrará un mensaje de "Sin comunicación", después de que se complete el reinicio, los monitores vuelven automáticamente a la monitorización normal, la anterior situación podría conllevar a que se presenten potenciales eventos adversos serios sobre los pacientes.
FUENTE	ANEXO
FECHA DE NOTIFICACION	13 de junio 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

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

ANEXO

[High Priority] - A30726 : GE—CARESCAPE Monitor B650: May Restart Because of a Network Overload Situation Caused by Network Misconfiguration
Medical Device Ongoing Action

Published: Monday, June 4, 2018

UMDNS Terms:

- Monitors, Physiologic, Multipurpose, Bedside [20170]

Product Identifier:
[Capital Equipment]

Product	GE Healthcare Model
Patient Monitors with Hardwired (LAN) Connections	CARESCAPE B650

Geographic Regions: Worldwide

Manufacturer(s): GE Healthcare3000 N. Grandview Blvd., Waukesha, WI 53188, United States

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

Problem:
In a May 25, 2018, Urgent Medical Device Correction letter submitted by ECRI Institute member hospitals, GE states that when more than one of the above CARESCAPE B650 monitors are connected to the same network and a network overload occurs for a prolonged time, the monitors may simultaneously restart as designed. The monitor restart will not be completed until the network problem has been corrected. GE also states that loss of overall monitoring for a prolonged time may lead to a delay in detection of permanent or irreversible impairment or life-threatening changes in the condition of the patient. GE further states that, during the automatic restart cycle, the system will display a restart screen on the bedside monitor, the monitors will provide an extended audible tone during the restart, and the CARESCAPE Central Station will display a No Communication "NO COMM" message. After the restart completes, the monitors automatically return to normal monitoring, including availability of trends and data collected previously, and regain network connection to central monitoring. The CARESCAPE Central Station will also have the capability to provide historical data and trends. GE states that when the CARESCAPE 650 network is configured and connected appropriately, a network overload situation should not occur. GE also states that it has received no reports of injury as a result of this problem.

Action Needed:
Identify any affected systems in your inventory. If you have affected systems, verify that you have received the May 25, 2018, Urgent Medical Device Correction letter (all customer with affected systems) and Customer Response Form (U.S. customers only) from GE. If a prolonged network overload occurs and affected monitors on the network do not resume normal functionality in approximately 90 seconds, perform the following actions:

1. Temporarily switch the monitor from central monitoring to local-only (bedside) monitoring, which can be done by completing the following:
    1. Disconnect the LAN cables from the IX/MC ports on the backside of the monitor (see Figure 1 in the letter). The monitor will now be in local-only mode.
    2. Keep the patient under close observation and continuous surveillance at the local (bedside) monitor.
    3. Disconnect the LAN cables from the monitor (see Figure 1 in the letter).
2. Contact your facility's IT department or other appropriate personnel in your facility responsible for the patient monitoring network, and provide them with the Network Configuration Instructions Summary for Hospital IT section of the letter (Appendix A).
3. After the network problem has been resolved, switch the monitor back to central monitoring by reconnecting the LAN cables to the IX/MC ports.
4. Verify that the monitoring state and alarm function is correct.

If a transient network overload occurs in which the affected monitors on the network restart within approximately 90 seconds (i.e., all functionality resumes and the monitor reconnects to the network automatically), proceed with step 2 above to check network functionality. If your network is not maintained by GE, ensure that the network in your facility meets the network configuration requirements described in Appendix A of the letter . U.S. customers should complete the Customer Response Form, and return it to GE using the instructions on the form. If requested, GE will provide your facility with revised network installation and user instructions documentation. U.S. customers should report adverse events or product quality problems relating to the use of affected product to FDA 's MedWatch Adverse Event Reporting program by telephone at (800) 332-1088; by fax at (800) 332-0178; by mail (using postage-paid FDA Form 3500, available here) at Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787; or online at the MedWatch website .
For Further Information:
GE healthcare service department
Tel.: (800) 437-1171
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 May 31. Member Hospital. GE Reference No. 36127-US (includes reply form) Download