

## 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:

<b>NOMBRE DEL DISPOSITIVO MÉDICO</b>	Monitor de Paciente CARESCAPE
<b>NO. IDENTIFICACIÓN RISARH</b>	I1410-393
<b>REFERENCIAS DEL DISPOSITIVO MEDICO</b>	B450, B650 y B850
<b>REGISTRO SANITARIO</b>	2008EBC-0001978
<b>INDICACIONES Y USO ESTABLECIDOS</b>	Monitorizar parámetros clínicos a pacientes hospitalizados
<b>NOMBRE DEL FABRICANTE</b>	GE Medical Systems Technologies Co Ltd GE Healthcare Finland Oy
<b>DESCRIPCION DEL PROBLEMA</b>	El fabricante informa que si el modulo PDM (Patient Data Module) se desconecta rápidamente y se vuelve a conectar (en un tiempo menor a 10 segundos), los parámetros de la señal de ECG mostraran valores inferiores a la verdadera condición clínica del paciente, igualmente se podría ver afectada la forma de onda de la respiración, saturación y presión arterial invasiva, conllevando a que se presenten potencialmente eventos adversos sobre el paciente.
<b>FUENTE</b>	ANEXO 1
<b>FECHA DE NOTIFICACION</b>	03 de Octubre de 2014

### 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](mailto:tecnovigilancia@invima.gov.co)

**ANEXO 1**

www.ecri.org • Printed from Health Devices Alerts on Friday, October 03, 2014 Page 1

**A23081 - Critical Priority Medical Device Alert**

**Medical Device  
Ongoing Action**

Updated: September 30, 2014

**UMDNS Terms:**  
• Monitors, Bedside, Physiologic [20170]

**Suggested Distribution:**

- Clinical/Biomedical Engineering
- Critical Care
- Emergency/Outpatient Services
- Home Care
- Information Technology
- Nursing
- OR/Surgery

**Geographic Regions:**

- Worldwide

**GE—CARESCAPE B450, B650, and B850 Monitors: ECG May Exhibit Performance Problems following Patient Data Module Disconnect/Reconnect Cycle**

**Product Identifier:**  
Patient Data Modules (PDMs) used with the following CARESCAPE Monitors: (1) B450, (2) B650, (3) B850 [Capital Equipment]  
PDM Software Version: 2.2 and below

**Manufacturer:**  
• GE Healthcare USA9900 Innovation Dr, Wauwatosa, WI 53226, United States

**Problem:**  
In a September 18, 2014, Urgent Medical Device Correction letter submitted by ECRI Institute member hospitals, GE states that if the PDM is quickly disconnected and reconnected (a less than 10 sec cycle) from the above monitors following "Patient Discharge" or during active monitoring, the electrocardiogram (ECG) waveform and its associated waveform parameters may be incorrectly analyzed. GE states that if the problem occurs, the monitors will display ECG heart rate parameter data, the ECG waveform, and other ECG parameter measurements at values that are less than the actual patient's physiologic condition and that because of the abnormal data analysis, alarms for serious conditions may not be appropriately triggered. GE also states that the problem may affect heart rate, ECG ST segment analysis, 12-lead ECG analysis, ECG, SpO<sub>2</sub>, respiration, and invasive blood pressure waveforms both locally and at CIC; additionally, data displayed at CIC may display data drop out. GE further states that neither bedside nor CIC can reliably represent the parameters being measured and that the problem does not exist if PDM is used only with Transport Pro or Solar monitors.

**Action Needed:**

Identify any affected product in your inventory. If you have affected product, verify that you have received the September 18, 2014, Urgent Medical Device Correction letter from GE. GE recommends that you wait a minimum of 10 sec after physically disconnecting the PDM from the above monitors before reconnecting the PDM. If you observe that the ECG heart rate value appears to be half of the patient's physiologic condition or the patient waveforms (ECG, SpO<sub>2</sub>, invasive blood pressure, or impedance respiration) appear to show every other pulse, perform the following instructions to correct the parameter and alarm problems:

(1) Physically disconnect the PDM E-port cable or undock the PDM from the host monitor.

(2) Wait a minimum of 10 sec, then reconnect or re-dock the PDM.

When the PDM reestablishes communication with the monitor, the parameters and alarms will operate as expected. GE will contact your facility to arrange to correct affected monitors at no charge.

**For Further Information:**

GE Healthcare technical support

Tel.: (800) 558-7044

Website: [Click here](#)

**Comment:**

- 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):**

- 2014 Sep 26. Member Hospital. GE letter submitted by ECRI Institute member hospitals; Reference No. 36107
- 2014 Sep 30. Manufacturer. Manufacturer confirmed the information provided in