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	Máquina de Anestesia GE
NO. IDENTIFICACIÓN RISARH	I1611-521
REFERENCIAS DEL DISPOSITIVO MEDICO	AVANCE, AVANCE CS^2 y AMINGO
REGISTRO SANITARIO	2008EBC-0001418
INDICACIONES Y USO ESTABLECIDOS	Sistema de administración de anestesia.
NOMBRE DEL FABRICANTE	GE Medical Systems China Co, Ltd Datex - Ohmeda Inc.
DESCRIPCION DEL PROBLEMA	El fabricante informa que los dispositivos anteriores pueden experimentar un mal funcionamiento si la bandeja opcional de almacenamiento inferior (número de parte: PIC01-1009-3260-000), se cierra de una forma anormal y con exceso de fuerza, esto podría resultar potencialmente en una pérdida de la ventilación del paciente e hipoxia, conllevando a que se presenten potenciales eventos adversos sobre el paciente.
FUENTE	Anexo 1
FECHA DE NOTIFICACION	21 de Noviembre de 2016

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

ANEXO 1

[High Priority] - A27566 : GE— Avance and Amingo Anesthesia Devices with Large Tray Insert Accessory: May Transition to System Malfunction State If Storage Drawer Is Closed Forcefully

Medical Device Ongoing Action

Published: Monday, November 14, 2016

UMDNS Terms:

- Anesthesia Units [10134]

Product Identifier:
Anesthesia Devices with Large Tray Insert Accessory: (1) Amingo, (2) Avance, (3) Avance CS2 *[Capital Equipment]*
Large Tray Insert Part No. 1009-3260-000

Geographic Regions: Worldwide

Manufacturer(s): GE Healthcare9900 Innovation Dr, Wauwatosa, WI 53226, United States

Suggested Distribution: Anesthesia, Clinical/Biomedical Engineering, OR/Surgery, Pulmonology/Respiratory Therapy

Problem:
In a November 3, 2016, Urgent Medical Device Correction letter submitted by ECRI Institute member hospitals, GE states that the above devices may transition to a system malfunction state if the lower storage drawer containing the optional large tray insert accessory is closed with an abnormally high amount of force, potentially resulting in a loss of patient ventilation and hypoxia if the system malfunction is left unresolved. GE also states that the above devices will operate as follows in the system malfunction state:

- Alternative oxygen flow will automatically activate within a few seconds.
- High-priority audio and visual alarms will activate.
- Instructions to set the oxygen flow and manually ventilate the patient will display.
- Anesthetic agent will continue to be delivered at the existing vaporizer setting.

GE further 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 November 3, 2016, Urgent Medical Device Correction letter from GE. Remove the optional large tray insert accessory if it is installed. You can continue using affected devices once the large tray insert accessory is removed. GE recommends destroying all tray insert accessories. You may choose to return the tray insert to GE. To return the tray insert to GE, e-mail a request to Avance_Drawer.Insert_RMA@ge.com .
For Further Information:
GE
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):

- 2016 Nov 10. Member Hospital. GE Reference No. 34079 Download
- 2016 Nov 14. Manufacturer. The manufacturer confirmed the information provided in the source material.