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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	I1801-63
REFERENCIAS DEL DISPOSITIVO MEDICO	9100C, AELITE, seriales específicos.
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. Carefusion Finland 320 Oy
DESCRIPCION DEL PROBLEMA	El fabricante informa que ha detectado que la comunicación entre la tarjeta de control y la tarjeta del monitor puede perderse durante el uso, lo que podría impedir al médico ajustar los parámetros de ventilación en la pantalla, también indica que el sistema continuará ventilando al paciente y monitoreando los parámetros con alarmas de audio disponibles durante estas fallas, los modos de ventilación mecánica y manual permanecen disponibles, lo anterior podría conllevar a que se presenten eventos adversos serios sobre los pacientes.
FUENTE	ANEXO
FECHA DE NOTIFICACION	29 de enero de 2018

RECOMENDACIÓN:

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con su proveedor quien determinara las acciones que se llevaran a cabo.

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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] - A29858 : GE—9100c and Aelite Anesthesia Systems: Loss of Communication between Control Sample Board and Display Monitor Board May Occur
Medical Device Ongoing Action

Published: Wednesday, January 24, 2018

UMDNS Terms:

- Anesthesia Systems [35373]

Product Identifier:
[Capital Equipment]

Product	GE Healthcare Model	Serial No.
Anesthesia Systems	9100c, Aelite	ME12070224, ME13115243, ME13125285, ME14010049, ME14020124, ME14020129, ME14040279, ME14080563, ME14090666, ME14100745, ME14100750, ME15030182, ME15040203, ME15050311, ME15060371, ME15090550, ME15090588, ME15100627, ME15120776, ME15120779, ME15120780, ME16075183, ME16075207, ME16075221, ME16085262, ME16085274, ME16095350, ME16095359, ME16105383, ME16115503, ME16115547, ME17025061, ME17025062, ME17025063, ME17025064, ME17025065, ME17025066, ME17025067, ME17025068, ME17025069, ME17025070, ME17025071, ME17025072, ME17025073, ME17025074, ME17025075, ME17025076, ME17025077, ME17025078, ME17025079, ME17025080, ME17025081, ME17025082, ME17025083, ME17025084, ME17025085, ME17025086, ME17025087, ME17025088, ME17025089, ME17025090, ME17025091, ME17025155, ME17025156, ME17025157, ME17025158, ME17025159, ME17025160, ME17025161, ME17025162, ME17025163, ME17025164, ME17025165, ME17025166, ME17025167, ME17025168, ME17030169, ME17030191, ME17030208, ME17030209, ME17035170, ME17035171, ME17035172, ME17035173, ME17035174, ME17035175, ME17035176, ME17035177, ME17035178, ME17035179, ME17035180, ME17035181, ME17035182, ME17035248, ME17035249, ME17035250, ME17035251, ME17035252, ME17035253, ME17035254, ME17035255, ME17035256, ME17035257, ME17035258, ME17035259, ME17035260, ME17035261, ME17035262, ME17045263, ME17045264, ME17045265, ME17045266, ME17045267, ME17045268, ME17045269, ME17045270, ME17045271, ME17045272, ME17045273, ME17045274, ME17045275, ME17045276, ME17045277, ME17045278, ME17055341, ME17055342, ME17055343, ME17055344, ME17055345, ME17055346, ME17055347, ME17055348, ME17055349, ME17055350, ME17055351, ME17055352, ME17055353, ME17055354, ME17055355, ME17055356, ME17055357, ME17055358, ME17055359, ME17055360, ME17055361, ME17055362, ME17055363, ME17055364, ME17055365, ME17055366, ME17055367, ME17055368, ME17055369, ME17060370, ME17060371, ME17075434, ME17080467, ME17080472, ME17080473, ME17080474, ME17085435, ME17085436, ME17085437, ME17085438, ME17085439, ME17085440, ME17085441, ME17085442, ME17085443, ME17085444, ME17085445, ME17085446, ME17085447, ME17085448, ME17085449, ME17085450, ME17085451, ME17085452, ME17085453, ME17085454, ME17085455, ME17085456, ME17085457, ME17085458, ME17085459, ME17085460, ME17095527, ME17095528, ME17095529, ME17095530, ME17095531, ME17095532, ME17095533, ME17095534, ME17095535, ME17095536, ME17095537, ME17095538, ME17095539, ME17100540, ME17105541, ME17105542, ME17105543, ME17105544, ME17105545, ME17105546, ME17105547, ME17105548, ME17105549, ME17105550, ME17105551, ME17105552, ME17105553, ME17105554, ME17105555, ME17105556, ME17105557, ME16125633, ME17010012, ME17010013, ME17010014, ME17015001, ME17015002, ME17015003, ME17015004, ME17015005, ME17015006, ME17015007, ME17015008, ME17015009, ME17015010,

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Geographic Regions: Worldwide

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

Suggested Distribution: Anesthesia, Clinical/Biomedical Engineering, OR/Surgery

Problem:
In an Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), GE states that the communication between the above systems' control sample board and display monitor board may be lost during use, potentially preventing the clinician from adjusting the ventilation parameters on the display and causing reversible, non-life-threatening changes in clinical status if the clinician is unable to change these settings. GE also states that the system will continue to ventilate the patient and monitor parameters with audio alarms available during these failures. Mechanical and manual ventilation modes remain available in this scenario. GE further states that it has received no reports of injuries 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 Urgent Field Safety Notice letter from GE. You can continue to use affected systems. If you observe a display malfunction before use on a patient, cycle the power of the system to resolve the problem. If you observe a display malfunction during use, select bag mode using the bag to vent switch. At any time, the clinician can use a self-inflating bag to ventilate the patient and/or switch to another anesthesia device. A GE representative will contact your facility to arrange to correct this problem.
For Further Information:
GE U.K. service center
Tel.: 44 (8457) 333999
E-mail: uk.customerserviceoffice@ge.com
For regulatory inquiries:
Paul Mardle, GE regulatory affairs manager
Tel.: 44 (1494) 498169
E-mail: paul.mardle@ge.com
Website: Click here

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. GE Medical Systems: 9100c/Aelite [online]. London: Department of Health; 2018 Jan 15 [cited 2018 Jan 16]. (Field safety notice; reference no. 2018/001/010/000/012). 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 .

Source(s):

- 2018 Jan 16. MHRA FSN. 2018/001/010/000/012 Download
- 2018 Jan 16. MHRA FSN. GE Reference No. 34089 Download
- 2018 Jan 16. Manufacturer. The manufacturer confirmed the information provided in the source material.