

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	Sistema de Navegación EP-CARTO BIOSENSE
NO. IDENTIFICACIÓN RISARH	I1804-273
REFERENCIAS DEL DISPOSITIVO MEDICO	CARTO 3, Versión de software 4
REGISTRO SANITARIO	2017DM-0000863-R1
INDICACIONES Y USO ESTABLECIDOS	El sistema CARTO-XP está diseñado para generar mapas electrofisiológicos cardíacos en tercera dimensión a través de catéteres y provee información sustancial sobre la actividad eléctrica del corazón.
NOMBRE DEL FABRICANTE	Biosense Webster, Inc Biosense Webster, Ltd
DESCRIPCION DEL PROBLEMA	El fabricante informa que ha lanzado una nueva versión de software (versión 6) que, además de nuevas funcionalidades, también incluirá parches del sistema operativo (SO) y actualizaciones de firmas de antivirus para cerrar vulnerabilidades en los sistemas operativos de versiones anteriores, conllevando a minimizar potenciales ataques informáticos y la presentación de posibles eventos adversos sobre los pacientes.
FUENTE	Anexo
FECHA DE NOTIFICACION	30 de abril 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.

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

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[High Priority] - A30393 : Biosense Webster—CARTO 3 Navigation Systems: Manufacturer Issues Software Update to Address Operating System Vulnerability Medical Device Ongoing Action

Published: Wednesday, April 25, 2018

UMDNS Terms:

- Stereotactic Systems, Image-Guided, Cardiac Mapping/Ablation [18607]
- Software, Stereotactic System, Image-Guided Cardiac Mapping/Ablation [26973]

Product Identifier:
[Capital Equipment]

Product	Biosense Webster Inc Model	Version	Manufacture Date
Navigation Systems	CARTO 3	4	< Apr 2018

Geographic Regions: Worldwide

Manufacturer(s): Biosense Webster Inc 3333 Diamond Canyon Rd, Diamond Bar, CA 91765, United States

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Emergency/Outpatient Services, OR/Surgery, Information Technology

Problem: In a letter submitted by an ECRI Institute member hospital, Biosense Webster states that it has released a new software version (version 6) that, in addition to new functionalities, will also include operating system (OS) patches and antivirus signature updates to close known vulnerabilities in the OSs of the above systems. Biosense Webster also states that if the affected system is networked, the network interface of the above systems is sufficiently restricted by a software firewall to provide customers reasonable assurance that the system will not be exploited remotely or by malware/ransomware. If an attacker has persistent physical access to the above systems, the attacker could exploit system-level vulnerabilities, accessing information stored in the device, affecting device integrity, or denying device availability. Additionally, an attacker with persistent physical access may also be able to access other systems in the facility network if the above systems are networked. Biosense Webster further states that these vulnerabilities cannot be exploited remotely. Even if the above system is networked, its network interface is restricted by a software firewall. These vulnerabilities require physical access to the CARTO 3 V4 system to exploit.

Action Needed:

Identify any affected systems in your inventory. If you have affected systems, verify that you have reviewed the Biosense Webster advisory. The firm will contact your facility to arrange to apply the software update as it receives regulatory clearance for software version 6. For a list of vulnerabilities that will be patched, [click here](#).

For more information:

Biosense Webster
Website: [Click here](#)

References:

- Johnson & Johnson. Security Advisories: Product security notification for Biosense Webster CARTO® 3 [online]. 2018 Apr 9 [cited 2018 Apr 13]. 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 Apr 13. Member Hospital. Biosense Webster letter submitted by an ECRI Institute member hospital. [Download](#)
- 2018 Apr 24. Manufacturer. The manufacturer confirmed the information in the source material.