# 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** | Monitor Cardiaco Insertable REVEAL LINQ MEDTRONIC |
| **NO. IDENTIFICACIÓN RISARH** | I1612-585 |
| **REFERENCIAS DEL DISPOSITIVO MEDICO** | LNQ11 |
| **REGISTRO SANITARIO** | 2014DM-0011606 |
| **INDICACIONES Y USO ESTABLECIDOS** | El monitor cardíaco insertable REVEAL LINQ de MEDTRONIC es un dispositivo programable que monitoriza de forma continua el ECG y otros parámetros fisiológicos del paciente. El dispositivo registra datos cardíacos en respuesta a la activación del paciente y a las arritmias que se hayan detectado de forma automática. Está indicado en los casos siguientes: Pacientes con síndromes clínicos o situaciones con mayor riesgo de arritmias cardíacas. Pacientes que experimentan síntomas transitorios que pueden sugerir una arritmia cardíaca. |
| **NOMBRE DEL FABRICANTE** | Medtronic, Inc.<br>Medtronic Europe S. A.R.L |
| **DESCRIPCION DEL PROBLEMA** | El fabricante afirma que ha identificado un problema con la sensibilidad de un algoritmo utilizado en los (ICMS), que pueden desencadenar prematuramente la alerta de tiempo de reemplazo (RRT) en algunos dispositivos. A partir del 12 de febrero de 2016, MEDTRONIC afirma que ha observado una tasa de ocurrencia del 0,45% de los dispositivos que experimentan este problema, conllevando a que se presenten posibles eventos adversos serios sobre el paciente. |
| **FUENTE** | ANEXO 1 |
| **FECHA DE NOTIFICACION** | 16 de Diciembre de 2016 |

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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

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## DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

**ANEXO 1**



**[Normal Priority ] - A25906 03 : *Medtronic—Model LNQ11 Reveal LINQ Insertable Cardiac Monitors: Manufacturer Releases Software Update for MyCareLink Monitors [Update]**
**Medical Device Ongoing Action**

**Published:** Thursday, December 15, 2016

**UMDNS Terms:**

- Monitors, Physiologic, Electrocardiography, Telemetric [13988]

**Product Identifier:**
Model LNQ11 Reveal LINQ Insertable Cardiac Monitors (ICMs) *[Consumable]*

**Geographic Regions:** Worldwide except Canada

**Manufacturer(s):** Medtronic Inc Cardiac Rhythm Heart Failure (CRHF) Div8200 Coral Sea St NE, Mounds View, MN 55112, United States

**Suggested Distribution:** Cardiology/Cardiac Catheterization Laboratory, OR/Surgery, Information Technology, Materials Management

**Summary:**
This Alert provides additional information based on a November 2016 Update to Medical Device Correction letter submitted by an ECRI Institute member hospital regarding Alert Accession Nos. A25906 , A25906 01 , and A25906 02 . Medtronic states that functionality to allow patients the ability to receive the software update via their MyCareLink patient monitor is now available. New information is provided in the Actions Needed field.

**Problem:**
[March 10, 2016]
In a February 2016 Urgent Field Safety Notice letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) and the German Federal Institute for Drugs and Medical Devices (BfArM), Medtronic states that it has identified a problem with the sensitivity of an algorithm used in the above ICMs that may prematurely trigger the recommended replacement time (RRT) alert in some devices. As of February 12, 2016, Medtronic states that it has observed an occurrence rate of 0.45% of devices experiencing this problem. Battery capacity is not affected and the device will continue to support data collection and manual data transmissions. As stated in the product labeling, the typical device will experience an average of 3 years longevity (refer to the device labelling for the corresponding use conditions). Medtronic further states that as part of the normal behavior of the device, 30 days after RRT status is reached, the devices will display an end of service (EOS) status at which time the device disables automatic wireless alerts and transmissions. Thereafter, patients will still be able to send remote manual transmissions for clinics to receive alerts and stored device data. Because of the design of the RRT algorithm, devices are not susceptible to this problem until 200 days (6.5 months) post-implant. Medtronic states that as of February 12, 2016, the earliest reported occurrence of RRT is 7.3 months post-implant, with median implant to RRT duration of 16.5 months.

**Action Needed:**
Identify any patients who have been implanted with affected product. If you have affected patients, verify that you have received the November 2016 Urgent Medical Device Correction letter from Medtronic. During the course of their normal monitoring and follow-up care, patients' devices can receive the software update via a programmer interrogation or home monitor manual transmission. Once the update has been installed on patients' MyCareLink monitor, the monitor itself will automatically apply the update to their Reveal LINQ ICM during a subsequent manual transmission. If your patient's Reveal LINQ ICM is at RRT/EOS, instruct the patient to complete the following actions to receive the update as quickly as possible:
(1) Unplug the MyCareLink patient monitor from the wall outlet, wait 10 seconds, and then plug it back in.
(2) Leave your MyCareLink patient monitor plugged in and untouched for 24 hours to allow software updates to be successfully installed.
(3) After 24 hours have elapsed, complete a manual transmission using your MyCareLink patient monitor.
Patients who are not actively monitored using a MyCareLink monitor or are using an analog adaptor to connect to the CareLink network will need to come into the clinic for interrogation by a programmer that has previously been loaded with the RRT software update.

**For Further Information:**
Medtronic Diagnostic patient or technical services department
Tel.: (800) 929-4043
Website: Click here

**References:**


- Great Britain. Medicines and Healthcare Product Regulatory Agency. Medtronic: Reveal LINQ™ insertable cardiac monitor [online]. London: Department of Health; 2016 Feb 29 [cited 2016 Mar 4]. (Field safety notice; reference no. 2016/002/023/292/027). Available from Internet: Click here .
- Germany. Federal Institute for Drugs and Medical Devices. Urgent field safety notice for Reveal LINQ insertable cardiac monitor (ICM) Model LNQ11, Medtronic [online]. 2016 Mar 1 [cited 2016 Mar 4]. 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):**

- 2016 Dec 15. Member Hospital. Medtronic letter submitted by ECRI Institute member hospital Download
- 2016 Dec 15. Member Hospital. May 2016 Medtronic letter submitted by ECRI Institute member hospitals Download
- 2016 Dec 15. Member Hospital. Manufacturer confirmed information