Medtronic

Urgent Field Safety Notice

For a subset of Viva™ Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and Evera™ Implantable Cardioverter Defibrillators (ICDs)

Patient Management Recommendations

12 August 2016

Medtronic reference: FA733

Dear Physician, Healthcare Professional,

Medtronic is writing to inform you about an issue with 78 Viva™ CRT-Ds and Evera™ ICDs that were manufactured with a specific subset of circuit components (see appendix A for a listing of affected devices). Devices in the affected population may experience rapid battery depletion due to a low resistance path developing within the circuit component. This is not related to a failure within the battery. Based on our records, an estimated 53 of these 78 devices remain active.

Development of a low resistance path in the circuit component in some cases has been reported to cause battery depletion in seven (7) days or less and may present clinically during a patient follow-up visit as:

- One or more electrical resets, which will display as an observation on the programmer
- No pacing or defibrillation therapy output
- No telemetry
- Programmer screen display of "SERIOUS DEVICE MEMORY FAILURE."

Patient audible alerts and CareAlerts™ may not reliably notify the patient or clinician, due to this issue.

Within these 78 devices there have been seven (7) confirmed failures (9%) through July 16, 2016. Medtronic modeling predicts an additional six (6) failures may occur in the remaining active population. Reported complications have included shortness of breath, pocket heating, low heart rate, and early device explant. No deaths have been reported related to this issue.

Medtronic records indicate you are following one or more patients with an affected device.

Patient Management Recommendations

We realise that each patient requires unique clinical consideration and we support your judgment in caring for your patients. After consultation with Medtronic's Independent Physician Quality Panel, Medtronic offers the following options for managing patients implanted with an affected device:

Advise patients to seek medical attention immediately if they experience symptoms (e.g. fainting or lightheadedness) or if the audible patient alert sounds.

For pacemaker-dependent patients or those at a higher risk of Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF):

- Physicians should consider device replacement.

For patients where the physician does not believe device explant is the best course of action, Medtronic offers these additional options:

- Program the audible alerts for "Low Battery Voltage RRT" to "On-High". It is possible that alerts may not sound if the battery is depleted. Therefore physicians should also consider one of the following:

Medtronic

- Provide a handheld magnet to patients to frequently check device status.
  - Requires one or more audible alerts be programmed ON.
  - Device operation may be monitored frequently (e.g., daily) by patients placing the magnet over the device for **1-2 seconds and then removing the magnet**. If the device is functional, a steady tone will sound for approximately 10 seconds. If no tone or an oscillating high/low tone is heard, advise patients to seek care immediately.

- Prescribe either a CareLink™ transmission be performed by the patient, or a maintenance transmission by the clinic, on a more frequent basis (e.g., weekly or daily) based on the unique patient considerations. The clinic should review these transmissions upon receipt.
  - If the transmission is unsuccessful the patient should be brought into the clinic for immediate follow-up as this may be an indication that the device battery has depleted to a level where it can no longer support telemetry.
  - Review transmissions for any signs of this issue (e.g., one or more electrical resets, or notification that a device alert has occurred).
  - Each transmission will decrease battery longevity by approximately one day.

Please share this notification with others in your organization as appropriate.

Medtronic has notified the Competent Authority of your country of this action.

We sincerely regret any difficulties this may cause you and your patients. Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients.

If you have any questions, please contact your Medtronic Representative.

Sincerely,

Mohamad El Khatib
Business Manager – CRHF KSA

Appendix A: List of 78 affected Viva™ Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and Evera™ Implantable Cardioverter Defibrillator (ICDs)

Medtronic

Appendix A: List of 78 affected Viva™ Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and Evera™ Implantable Cardioverter Defibrillator (ICDs)

Product Name	Models	Serial Numbers
Viva XT CRT-D	DTBA1D4 DTBA1D1	BLF203128H, BLF204746H BLE202888H, BLE202889H, BLE202890H, BLE202901H BLE202941H, BLE202947H, BLE202954H, BLE202958H BLE202961H, BLE202962H, BLE202964H, BLE202981H BLE202987H, BLE202989H, BLE202990H, BLE202991H BLE203019H, BLE203026H, BLE203027H, BLE203029H BLE203032H, BLE203046H, BLE203052H, BLE203073H
Viva S CRT-D	DTBB1D4 DTBB1D1	BLO202272H, BLN202206H
Evera XT DR ICD	DDBB1D4 DDBB1D1 DDBB2D4 DDBB2D1	BWC202738H, BWC202754H, BWB202998H, BWB203157H BWB203167H, BWB203173H, BWB203186H, BWE601558S BWE601571S, BWE601578S, BWE601579S, BWE601581S BWE601589S, BWE601591S, BWE601594S, BWE601600S BWE601605S, BWD602122S
Evera S DR ICD	DDBC3D1 DDBC3D4	BWG600597S, BWF600969S, BWF600970S, BWF600972S BWF600973S, BWF600975S, BWF600977S, BWF600978S BWF600979S, BWF600983S, BWF600984S, BWF600985S BWF600987S, BWF600989S, BWF600991S, BWF600992S BWF600996S, BWF601001S
Evera XT VR ICD	DVBB1D1 DVBB2D4	BWI201423H, BWI201436H, BWI201440H, BWI201451H BWI201454H, BWI201462H, BWI201473H, BWJ601102S BWJ601108S, BWJ601112S, BWJ601479S, BWJ601101S BWJ601103S, BWJ601106S