Original Date: May 11, 2023; Updated: December 15, 2023

Canadian Heart Rhythm Society Device Committee

RE: Potential for Intermittent Reduced-Energy or No-Energy High Voltage therapy in a subset of Medtronic Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)

Cobalt XT/Cobalt/Crome ICDs and CRT-Ds
A subset of: Visia AF/Visia AF MRI/Evera/Evera MRI/Primo MRI ICDs
A subset of: Claria MRI/Amplia MRI/Compia MRI/Viva/Brava CRT-Ds

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Nature of the Advisory:

Medtronic has identified an issue with devices manufactured with a glassed feedthrough component in their high voltage headers, a design feature introduced from July 2017 onwards. In certain devices, moisture ingress can cause a separation of the insulation layers around this component creating an unintended current pathway during high voltage (HV) therapy.

When an unintended current pathway is detected during HV therapy, the Short Circuit Protection (SCP) feature may trigger. SCP is a safety feature designed to truncate energy delivery and protect the device during a shock. The defibrillation waveform is truncated early resulting in reduced or no energy delivery (~0-12J). This behavior can be intermittent; both full-energy and reduced-energy HV therapies within the same episode have been observed. Latent onset of this behavior is also anticipated, as gradual moisture ingress and insulation separation is more likely to be observed in older implanted devices.

Potential harms related to reduced- or no-energy HV therapy include failure to terminate an arrhythmia, which could lead to death, as well as complications associated with device replacement and/or unnecessary lead replacement if the problem is erroneously attributed to a lead failure.

Scope of the problem:

Through April 10, 2023, Medtronic has identified 27 devices out of approximately 816,000 devices with glassed feedthroughs that experienced a reduced- or no-energy HV therapy (0.003% of distributed devices). Of these, 26 were in devices with an AX>B (can to coil) delivered pathway. There have been no deaths due to this issue reported to date.

There is increased risk for a reduced- or no-energy HV therapy when all the following are met:

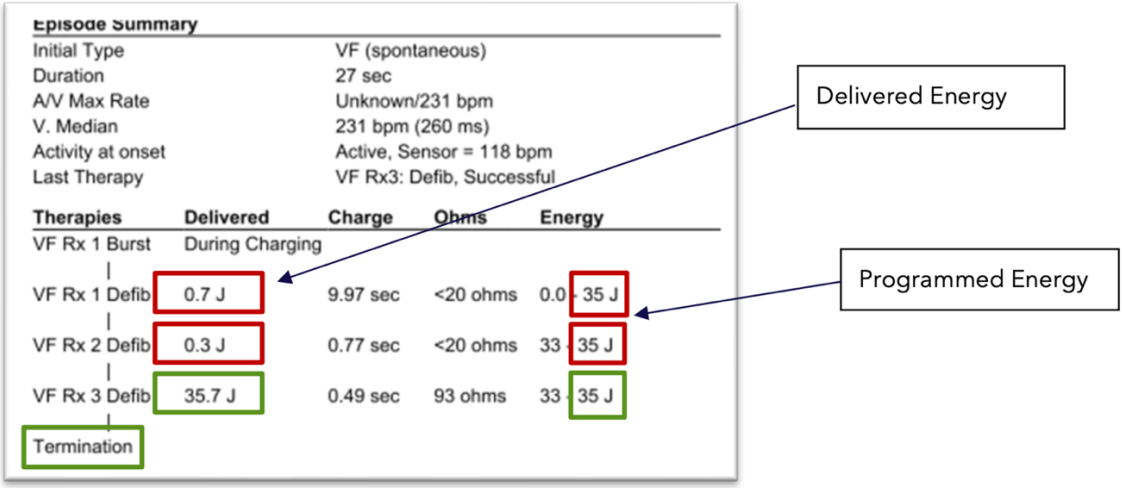
1. Programmed shock configuration of AX>B (can to coil)
2. The device has a glassed feedthrough (manufactured after July 2017).
3. There is significant separation of the layers of insulation materials in the feedthrough components of the device header.
4. An unintended current pathway forms by insulation separation, capable of conducting high levels of current during HV therapy.

How to identify the problem:

For Cobalt/Crome ICD and CRT-D devices: When an SCP event has occurred, the device will issue an RV Defibrillation Lead Impedance CareAlert. A CareAlert will occur simultaneous with HV therapy delivery and will specifically report "RV Defib Lead Impedance 0 Ω" with the same time stamp as the therapy delivery. The alert condition is displayed in the CareAlert Events log (Data >> CareAlert Events). The Quick Look Observations will also display "Alert: RV defib lead impedance warning on MMM/DD/YYYY." SCP events are not reflected in the long-term lead impedance trends.

Following an SCP event in devices with both the SVC Coil and Active Can enabled, the device will turn off the SVC coil. If the SCP event is caused by a lead integrity issue involving the SVC coil, turning off the SVC coil can allow any subsequent shocks to be delivered using the RV Coil -to- Active Can vector. The programmed therapy parameters will indicate the SVC Coil has been automatically disabled. The SVC coil will remain off until it is turned back on by the clinician.

For Evera/Visia AF/Primo/Mirro ICDs and Viva/Brava/Claria/Amplia/Compia CRT-D devices: If an SCP event has occurred, the Episode Text may indicate that a lower energy was delivered and a <20 ohm impedance value. Note: there is currently no available SCP alert in this family of devices.



Response of the CHRS Device Committee:

- As part of this formal advisory, we recommend that patients be notified about this issue.
- **UPDATED:** Prophylactic replacement is not recommended but *may be considered in rare cases for patients with a history of ineffective HV therapy in the B>AX configuration and after careful considerations of the risks of the procedure.*
- All affected devices should be reprogramed as follows:
    - **All HV therapies should be programmed to maximum output (36J or 40 J)**
    - **Shock configuration should be B>AX (coil to can) pathway in all therapy zones**
        - Programming all high voltage delivery pathways to B>AX will minimize the effect of an unintended current pathway in the device header (e.g., glassed feedthrough), thereby minimizing the potential for an SCP event. This programming reduces the potential for a reduced- or no-energy HV therapy to baseline historical performance (0.002% at five (5) years and 0.005% at nine (9) years).
- Patients should be followed in-person or via remote monitoring at their usual follow-up schedule.
    - Reprogramming can occur at the next scheduled follow-up interval for primary prevention implants.
    - Consider prioritizing secondary prevention patients or patients with previous appropriate therapies in for early follow-up and reprogramming to the B>AX (coil to can) pathway.

- Patients should be enrolled on the CareLink™ system where possible.
    - While this recommendation applies to all patients with CIEDs, it is especially important in this advisory patient group.
- Device alert tones should be demonstrated to patients at each in-person follow-up
    - Patients should be instructed to notify their follow-up device clinic as soon as possible if they hear the alert tone.
    - The device should be interrogated or a CareLink™ transmission initiated within **72 hours** after an alert tone.
- Consider enabling the device audible alert and/or CareAlert for "Number of Shocks Delivered in an Episode," with "N = 1."
    - Turning this alert "ON" may help ensure the patient and/or clinic is made aware when a HV therapy is delivered by the device.
- **Instruct patients to contact the clinic if they receive HV therapy or hear an audible tone coming from their device.**
    - Verify delivered energy is consistent with programmed energy in the Episode Summary.
- **Contact Medtronic Tech Services (1-800-929-4043) or your local representative in the Event of:**
    - Reduced- or no-energy HV therapy is displayed in Episode Text (regardless of programmed pathway)
    - A persistent drop of approximately 50% in RA, RV, and LV pacing lead impedance measurements as this may be an indication of increased potential for a future reduced- or no-energy therapy.
- The CHRS device committee may update these recommendations should more data become available or if there are delays in approval of the software update.

December 15, 2023 - Update

For patients with existing devices subject to the advisory the above response of the device committee has not changed, except in the case of patients with a history of ineffective HV therapy in the B>AX configuration. While prophylactic replacement is not recommended, *it may be considered in rare cases where no programming options are available and after careful considerations of the risks of the procedure.*

For patients where a new implant of a device subject to advisory is being contemplated, it is the recommendation of the CHRS Device committee that the following occur as part of the consent process:

1. Patients must be informed of nature of the advisory **prior to device implantation**.
2. Patients must be informed of the risks associated with implantation of an advisory device (as outlined above).
3. Patients must be offered an alternate device not subject to advisory.
4. Patients must be informed of the risks associated with implantation of an alternate device (e.g. lack of MRI conditionality in the case of mixed vendor systems at time of generator replacement).

CHRS Device Committee

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