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URGENT FIELD SAFETY NOTICE

Medtronic Cobalt XT™, Cobalt™ and Crome™ Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)

Potential for Intermittent-Reduced-Energy Shock Due To Short Circuit Protection Event

Recall

Cobalt XT Models	Cobalt Models	Crome Models
Cobalt XT VR: DVPA2D1, DVPA2D4 Cobalt XT DR: DDPA2D1, DDPA2D4 Cobalt XT HF: DTPA2D4, DTPA2D1 Cobalt XT HF Quad: DTPA2QQ, DTPA2Q1	Cobalt VR: DVPB3D1, DVPB3D4 Cobalt DR: DDPB3D1, DDPB3D4 Cobalt HF: DTPB2D4, DTPB2D1 Cobalt HF Quad: DTPB2QQ, DTPB2Q1	Crome VR: DVPC3D1, DVPC3D4 Crome DR: DDPC3D1, DDPC3D4 Crome HF: DTPC2D4, DTPC2D1 Crome HF Quad: DTPC2QQ, DTPC2Q1

June 2022

Medtronic reference: FA1225

EU Manufacturer Single Registration Number (SRN): US-MF-000019977

Dear Health Care Professional/Risk Manager,

Medtronic is notifying health care professionals of the potential for reduced shock energy (~79% of programmed energy) during high-voltage (HV) therapy for all Cobalt and Crome implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds). Through 03 June 2022, Medtronic has identified 27 devices (0.03% of devices distributed worldwide) that have experienced a reduced-energy shock, which is accompanied by a Short Circuit Protection (SCP) alert. Medtronic has not received any reports of permanent harm or death due to this issue. Medtronic has submitted a device software update to address this issue and anticipates it will be available for download into implanted devices beginning third/fourth quarter of calendar year 2022, pending regulatory approvals.

ISSUE SUMMARY:
(Refer to Additional Issue Details below for more information on this behavior)
Short Circuit Protection (SCP) alerts trigger during HV therapy during the first- or second-phase of the HV biphasic waveform delivery. This communication focuses on second-phase SCP events that are the result of a secondary, low-level current pathway detected in the HV circuitry.

- A second-phase SCP event **will deliver approximately 79%** of programmed energy as a monophasic waveform.
- **Defibrillation efficacy is reduced by ~1%** for this type of SCP event when HV therapy is programmed to 40J, considering cumulative success across the full series of shocks (Rx1 through Rx6).
  Based on analysis of peer-reviewed literature as well as CareLink data on shock efficacy from more than 279,000 episodes*, termination success rates for 32J (~79% of 40J), monophasic shocks versus 40J biphasic shocks are estimated in Table 1. Termination success may vary depending on individual patient risk factors and medication use.

TABLE 1

	Normal Operation (40J, Biphasic delivery)	Second-phase SCP (32J, Monophasic delivery)
Estimated First Shock Success* (in VF Zone)	89%	85%
Estimated Cumulative Success Shocks 1-6*	99%	98%

*Medtronic data on file; May 2022.

- While 0.03% has been observed to date, Medtronic projects 0.18%** of the ~80,000 distributed devices may experience a second-phase SCP within 24 months of service life, when considering the probability for these SCP events increases over time, and the likelihood a patient will need HV therapy during that time.
    - For the population of patients who received HV therapy, the observed rate was 0.77%. When projecting for this population, the chance of encountering a second-phase SCP event is ~5.0% at 24 months.

**The above projections are based on calculations without the planned device software update. Once installed, this update, in addition to the programming recommendations, will resolve occurrences of second-phase SCP events.

Potential harms related to a second-phase SCP event include failure to terminate the arrhythmia due to reduced-delivered-energy, a theoretical risk of proarrhythmia, and complications associated with device replacement, including unnecessary lead replacement due to misinterpretation of the SCP alert.

- **While not observed clinically**, Medtronic estimates the risk for proarrhythmia is 0.002% in the AX>B configuration, and improbable in the B>AX configuration (less than 0.00004%), with Active Can pathway enabled. These risks may be higher when Active Can is disabled.
- The overall risk for **patient mortality due to this issue is estimated to be 0.002%** at 24 months when combining the likelihood a patient will need therapy with the probability an arrhythmia fails to terminate after six sequences of 32J monophasic shocks.
    - Comparatively, the risk of **patient mortality due to complications associated with device replacement is 0.032% - 0.043%[1,2,3].**

PATIENT MANAGEMENT RECOMMENDATIONS AND CONSIDERATIONS:
(For additional details refer to Patient Management Step-By-Step Guidance below)
SCP events are evident to the patient and clinician. Devices will issue an audible tone, and for patients enrolled in CareLink, a wireless CareAlert, reporting *RV Defib lead impedance 0 ohms*.

Medtronic recognizes that each patient requires unique clinical considerations. In consultation with our Independent Physician Quality Panel (IPQP), Medtronic recommends:

- **Prophylactic device replacement is NOT recommended.**
- Remote monitoring with normal frequency of follow-up per clinic protocol, with patients' next follow-up scheduled in-clinic to allow for device reprogramming (if necessary):
    - **Programming all HV therapies to 40J with a B>AX pathway and Active Can/SVC Coil set with Active Can enabled across all therapy zones.**
- Contact your local Medtronic Field Representative if an *RV Defib Lead Impedance Alert* reporting zero (0) ohms is observed – as this is an indicator that an SCP event was detected during HV therapy.
    - Importantly, if the delivered energy during the episode is ~79% of the programmed energy AND the SCP alert indicates an RV Defib Lead impedance alert reporting exactly zero (0) ohms, this is an indication of a second-phase SCP event (as described in this letter) and not a lead issue.

[1] Tarakji KG, et al. Antibacterial Envelope to Prevent Cardiac Implantable Device Infection. The New England Journal of Medicine. 2019; 380(20):1895-1905.
[2] Medtronic Data on File. MDT2260884-CRHF CIED Infection Report; Agile: MDT2260884, Version 2.0, 11/02/2015.
[3] Birnie D, et al. Complications associated with defibrillation threshold testing: The Canadian experience. Heart Rhythm. 2008; 5(3):387-90.

- Consider device replacement only after observing and confirming the cause of an SCP event with a Medtronic representative, with the understanding a device has an ~81% probability of delivering subsequent reduced-energy shocks, and with the understanding an update for implanted devices is anticipated to be available beginning third quarter/fourth quarter of calendar year 2022.

  Note: The software update will require an additional in-clinic follow-up in order for it to be installed into a patient's device. The update will ensure the full shock energy is delivered in the presence of a secondary, low-level current pathway in the HV circuitry.
- After an SCP event, pacing, sensing, episode detection, and anti-tachycardia pacing (ATP) therapies are not impacted; additionally, HV charging, battery longevity and Bluetooth telemetry are not impacted.

Medtronic is requesting hospitals quarantine and return a subset of non-implanted Medtronic Cobalt™ and Crome™ implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds). An identified list (i.e. subset) of specific serial numbers may have a manufacturing non-conformance that can contribute to the potential for reduced shock energy during high-voltage therapy. The devices will undergo additional inspection to ensure conformance to manufacturing specifications.

Our records indicate your account has received sold or consigned Cobalt/Crome product from the specific subset of identified serial numbers in scope of this retrieval.

Risk Manager/Inventory Manager Actions:
Return unused product to Medtronic:

1. Identify and quarantine all unused, identified Cobalt and Crome devices in table 2 below.
2. Return all unused identified product in your inventory to Medtronic. Your local Medtronic Representative can assist you as necessary.
3. Please forward this notice to all those who need to be aware within your organization. Additionally, if any affected devices have been distributed to other organizations, please forward this notice to those entities.

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

We regret any difficulties this issue may cause you and your patients. We remain dedicated to ensuring the highest level of quality and will continue to monitor performance of our products to ensure we meet your needs and those of your patients. If you have any questions regarding this communication, please contact your Medtronic Field Representative.

Sincerely,
Medtronic (Switzerland) AG

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Additional Issue Details:

The potential for reduced shock energy is the result of a safety feature, Short Circuit Protection (SCP), that is designed to truncate delivered energy to protect the device when unexpected current is detected during high-voltage (HV) therapy. All Cobalt/Crome devices include the SCP feature. SCP events can trigger during delivery of the HV biphasic waveform in the presence of a lead insulation breach (typically first-phase SCP) or unexpected, additional current in the device HV circuit (typically second-phase SCP).

Analysis of returned devices has confirmed Cobalt/Crome devices can be sensitive to a non-destructive, secondary current pathway involving the HV circuitry. This secondary current does not permanently impair the device's internal circuitry or battery, but it can result in an electrical switch (that controls current flow during HV delivery) to remain intermittently active for longer than intended after delivery of the first phase of the biphasic waveform. When the secondary current flow through the active switch is detected, the SCP feature truncates delivery of the remaining HV energy. In Cobalt/Crome devices, an *RV Defib lead impedance* alert reporting zero (0) ohms will be displayed simultaneous with HV therapy delivery (see Appendix A for example images). Review of episode data from reported complaints confirms successful delivery of the first-phase energy, and that the second phase of the programmed energy is truncated. When a second-phase SCP event occurs, ~79% of the programmed output is delivered as a monophasic waveform.

Although not observed clinically, HV therapy programmed to the AX>B configuration, or any configuration with Active Can/SVC Coil set to "Can Off," creates the potential for residual current to flow back to the heart, theoretically resulting in proarrhythmia. Medtronic has confirmed the B>AX configuration (with Active Can On) mitigates the risk for proarrhythmia from this unintended current flow.

Additional analysis has confirmed the switch-mechanism can be intermittent, resulting in HV therapy sequences delivering both the intended full-energy biphasic waveform and/or a reduced-energy monophasic waveform within the same therapy episode. Therefore, programming a 40J output provides the best opportunity to deliver the highest shock energy if the device experiences a second-phase SCP event: in this case, a 32J monophasic waveform will be delivered.

Patient Management Step-by-Step Guidance:

Medtronic recognizes that each patient requires unique clinical considerations. In consultation with our Independent Physician Quality Panel (IPQP), Medtronic recommends normal frequency of follow-up per clinic protocol, with special attention taken if *an RV Defib Lead Impedance* Alert reporting zero (0) ohms is observed – as this is an indicator that an SCP event was detected during HV therapy. **Prophylactic device replacement is not recommended.**

FOR ALL COBALT/CROME PATIENTS

Patients should have their next regularly scheduled follow-up conducted in person to allow for device reprogramming (if necessary):

- Consider programming all HV therapy ***Energy*** to 40J and ***Pathway*** settings to B>AX and ***Active Can/SVC Coil set with Active Can enabled*** across all therapy zones.
    - If the *Get Nominals* feature is used, be aware that AX>B is set pending for Rx5 and Rx6 and should be reprogrammed B>AX.
    - If a patient requires *Active Can* be programmed Off, contact Medtronic Technical Services for further guidance.
- Ensure the *RV Defib Lead Impedance Out of Range* alert is enabled (this alert is shipped On with both Device Tone and Wireless CareAlert enabled).
    - Remind patients to contact the clinic if they hear an audible tone coming from their device.
    - Remind patients to keep their home monitor plugged in at all times, or their MyCareLink Heart™ smartphone app open and active in the background at all times.
- For patients in whom high DFT is suspected, consider DFT testing to ensure a 10J safety margin exists.
    - For manually delivered shocks, no episode data is stored, and no CareAlerts are triggered; Review *Last HV Therapy* values displayed on the Battery and Lead
    - Measurement screen (Data >>Battery and Lead Measurements) to determine if a reduced-energy shock was delivered. If a second-phase SCP occurs during DFT delivery, the device will display ~32J for a 40J programmed output.
    - Successful delivery of full-energy shocks during manual delivery does not guarantee future delivery of full-energy shocks for spontaneous arrhythmias.
- If an *RV Defib lead impedance* alert reporting 0 ohms is observed, this is evidence that an SCP event has occurred. Contact your local Medtronic Field Representative for confirmation on the source of the impedance alert.
    - A Save-Session file or a CareLink transmission file will be requested; Medtronic Technical Services can use stored device information to confirm whether the SCP event is due to a suspected lead issue, or due to unexpected current in the HV circuit.
    - If the delivered energy during the episode is ~79% of the programmed energy AND the SCP alert indicates an RV Defib Lead impedance alert reporting exactly zero (0) ohms, this is an indication of a second-phase SCP event (as described in this letter) and not a lead issue.
- After confirming the cause of the *RV Defib Lead Impedance* alert with Medtronic Technical Services:
    - Consider device replacement commensurate with the patient's underlying health and history, with the

understanding a device has an ~81% probability of delivering subsequent reduced-energy shocks, and with the understanding an update for implanted devices is anticipated to be available beginning third quarter/fourth quarter of calendar year 2022

- Note: The software update will require an additional in-clinic follow-up in order for it to be installed into a patient's device. The update will ensure the full shock energy is delivered in the presence of a secondary, low-level current pathway in the HV circuitry.
- After an SCP event, devices will continue to operate as programmed. Pacing, sensing, episode detection, and anti-tachycardia pacing (ATP) therapies are not impacted by a second-phase SCP event; additionally, HV charging, battery longevity and Bluetooth telemetry are not impacted.
- If the device remains implanted, ensure all HV therapy sequences, programmed parameter settings and SVC Coil pathway (where appropriate) are as desired following any lead and/or device replacement.

To ensure healthcare professionals have the information they need to support ongoing implants, Medtronic will provide periodic updates on observed and projected event rates on the Medtronic product performance website http://productperformance.medtronic.com .

Medtronic is updating the Cobalt and Crome Instructions for Use to be consistent with the information contained in this letter. Specifically the IFU update will add information regarding the Short Circuit Protection feature and the associated RV Defib lead impedance alert. Information will be shared via your local Medtronic representative when these updates receive regulatory approvals as applicable to the local region.

Table 2: Impacted Models and Serial Numbers

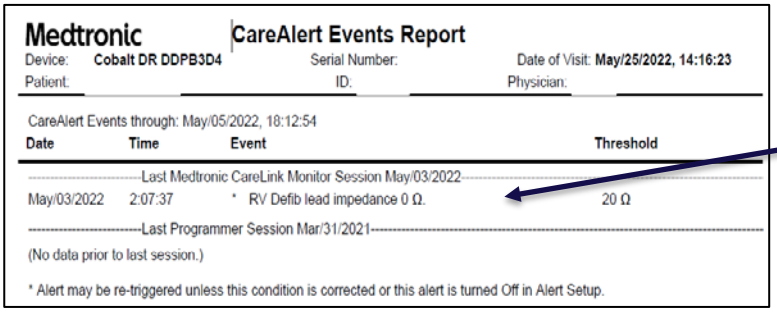
Model	Serial Number
DVPA2D1	RSC601582S
DVPA2D1	RSC601750S
DVPA2D4	RSD604316S
DDPA2D1	RSL601602S
DDPA2D1	RSL602022S
DDPA2D4	RSM607528S
DTPA2D4	RTG602596S

APPENDIX A

Potential for Intermittent Reduced-Energy Shock Due To Short Circuit Protection Event

Additional Information

When a Short Circuit Protection (SCP) event occurs, Cobalt/Crome devices will issue an *RV Defib lead impedance* alert reporting zero (0) ohms that occurs simultaneous with HV therapy delivery (see example images below). A fixed value of zero (0) ohms indicates that a short circuit was detected during HV therapy delivery.



Medtronic CareAlert Events Report

Device: Cobalt DR DDPB3D4 Serial Number: Date of Visit: May/25/2022, 14:16:23

Patient: ID: Physician:

CareAlert Events through: May/05/2022, 18:12:54

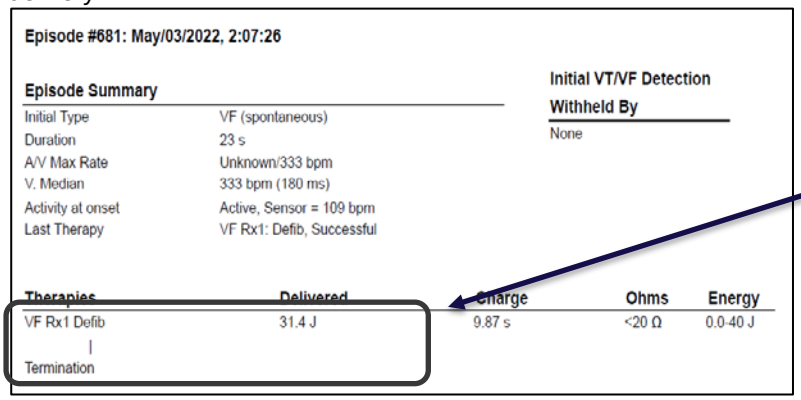
Date	Time	Event	Threshold
		Last Medtronic CareLink Monitor Session May/03/2022	
May/03/2022	2:07:37	* RV Defib lead impedance 0 Ω.	20 Ω
		Last Programmer Session Mar/31/2021	

(No data prior to last session.)

* Alert may be re-triggered unless this condition is corrected or this alert is turned Off in Alert Setup.

CareAlert Event list showing *RV Defib lead impedance* alert reporting 0 ohms, occurring simultaneous with Rx1 HV therapy delivery timestamp.

Example Images: CareAlert messaging and Episode Text when short circuit protection occurs during the second-phase of the HV waveform delivery.



Episode #681: May/03/2022, 2:07:26

Episode Summary

Initial Type	VF (spontaneous)
Duration	23 s
A/V Max Rate	Unknown/333 bpm
V. Median	333 bpm (180 ms)
Activity at onset	Active, Sensor = 109 bpm
Last Therapy	VF Rx1: Defib, Successful

Initial VT/VF Detection Withheld By

None

Therapies	Delivered	Charge	Ohms	Energy
VF Rx1 Defib	31.4 J	9.87 s	<20 Ω	0.0-40 J
Termination				

Episode Text example showing *Delivered* reduced shock energy for Rx1; 31.4J when programmed 40J *Energy*.

CUSTOMER ACKNOWLEDGEMENT FORM

FA1225: Cobalt Crome non-destructive SCP issue

Please complete this form and return to Medtronic (even if you do not have affected inventory)

June 2022

Customer Contact Details	**Medtronic Contact Details**
Hospital Name: **Account Number:**	**To:** [
Account Address: Street: Postal Code: City: Country: **Department:** Contact Person at Point of Collection: Opening Hours: **Name of person completing this form:**	**Address:**
Telephone:	**Telephone:**
Fax:	**Fax:**
E-mail:	**E-mail:**

Please list the details of unused affected product at your facility *

Item Code	**Invoice or Despatch Note (if available)**	**Lot # / Serial #**	**Quantity**	**Unit of measure (Each or Case)**

(*) If your inventory does not contain unused affected devices, please tick the box below

No affected inventory (Please tick): ☐

Information for the courier:

Number of parcels to collect: _____

Number of these parcels that weigh more than 45 KG: _____

By signing this form, I confirm that I have read and understand the Urgent Field Safety Notice from Medtronic regarding Cobalt Crome non-destructive SCP issue regarding FA1225 dated June 2022.

I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of the Cobalt Crome noted in this letter.

_____ _____ _____

Name (print) Signature Date

- Please fax or email this form back to Medtronic within 10 days using the contact details referenced at the top of this form.
- Customer Service will contact you directly to organise return of affected products and credit will be given for returned products.
- Please don't send the goods back before having received the return documentation.