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Urgent Field Safety Notice

Potential for Suspension of Dynamic Sensing Algorithm

Aurora EV-ICD™ (DVEA3E4) UDI: 00763000368463, Clinical EV-ICD (DVEX3E4) <00763000217891

Device update via CareLink™ SmartSync™ Device manager available

October 2025

Medtronic Reference: FA1511
EU Manufacturer Single Registration Number (SRN): US-MF-000019977

Dear Health Care Professional:

In a subset of the above identified devices, there is a potential for delayed time to high-voltage therapy should a rare sequence of events occur. **A device update via CareLink™ SmartSync™ Device manager is available to eliminate this potential delay**. Through 2 October 2025, six (6) events (delay of 2-17 seconds) were observed among approximately 4,900 implanted devices worldwide (0.12%). Five of the six events experienced this behavior during a controlled defibrillation threshold test. While not observed clinically, a delay in HV therapy may impact defibrillation efficacy. There have been **zero** reports of permanent harm or death due to this behavior.

The root cause of this behavior is related to the EV-ICD dynamic sensing algorithm becoming static if a charge-end occurs while the device is processing a sensed event. This will set the sensitivity to 53% of the prior R-wave amplitude. A subsequent R-wave amplitude that exceeds the static 53% level will restore automatic sensitivity operation and allow R-wave synchronization for therapy delivery. See Appendix A for additional details.

Medtronic has implemented manufacturing changes, and devices manufactured with this update are not susceptible to this delay. In previously distributed devices, a device interrogation with the CareLink™ SmartSync™ Aurora EV-ICD™ application (D00U025) on CareLink SmartSync Device Managers will resolve the potential for this behavior (see Appendix B).

Medtronic records indicate one or more devices noted in the model numbers above are on your shelf or implanted at your facility, as identified in the enclosed Detail Report. The report includes devices identified through 2 October 2025; however, identified devices may extend beyond the report refresh date. Individual devices susceptible to this behavior can be identified via search/look-up on the Medtronic Product Performance Report Website (http://productperformance.medtronic.com).

PATIENT MANAGEMENT RECOMMENDATIONS FOR PREVIOUSLY DISTRIBUTED DEVICES:

Medtronic acknowledges that each patient requires unique clinical considerations. Based on internal investigation and consultation with our Independent Physician Quality Panel, Medtronic provides the following guidance:

- **Prophylactic device replacement is NOT recommended.**
- Schedule an **in-clinic SmartSync interrogation** to receive the software update, with the intent for all patients to receive the update within **the next 3-6 months**.

For patients remotely followed via CareLink, your Medtronic representative can provide a report to assist with identifying patients

that require this in-person update. You may contact your local representative to obtain an updated copy of the report at any time.

CUSTOMER ACTIONS:

- Ensure your SmartSync application is updated to include the Aurora EV-ICD Application. Contact your Medtronic representative if assistance is needed.
- Please forward this notice to everyone within your organization who needs to be aware and to locations where these devices could be followed if they are outside of your organization.

Medtronic has notified all applicable regulatory agencies about this matter.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have questions regarding this communication, please contact your Medtronic Representative.

Sincerely,

Local / OU Manager

Appendix A

Technical Details

The Aurora EV-ICD dynamic sensing algorithm is unique due to the implant location within the substernal space. Figure 1 below illustrates how the device sets sensitivity beat-by-beat based on R-wave measurement of the rectified and filtered EGM.

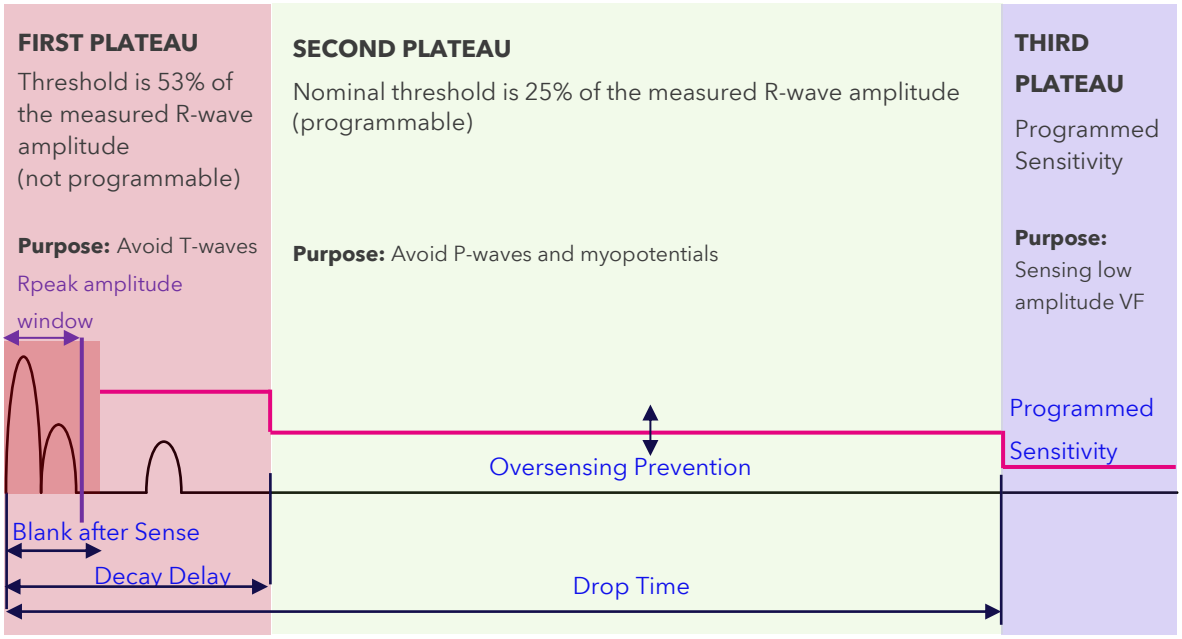

Figure 1- Operation of Sensing Thresholds – The first plateau duration ("Decay Delay") is nominally 360 ms, the second plateau duration ("Drop Time") is nominally 1500 ms, and the third plateau lasts until another sensed beat. R-wave amplitude measurements take place during "R peak amplitude window" shown above, nominally 128.75 ms (not programmable).

The dynamic sensing algorithm may become suspended at the first plateau if the following sequence of events occurs:

1. Charge-end occurs within 128.75ms of the prior sensed beat, thus interrupting the in-progress R-wave measurement- ***suspension of the dynamic sensing algorithm occurs and the sensitivity plateau becomes static at 53%.***
2. The sensitivity plateau will remain at 53% until a subsequent **R-wave amplitude exceeds this value.** In the case of a significant drop in R-wave amplitudes, delay in HV therapy delivery can occur.

While not observed clinically, a delay in HV therapy may impact defibrillation efficacy and result in harm related to failure to terminate an arrhythmia.

This behavior **applies only to non-committed shocks.** This includes cardioversion (CV) therapies in the ventricular tachycardia (VT), fast ventricular tachycardia (FVT) zones, and the first shock in the ventricular fibrillation (VF) zone.

A Medtronic white paper, *Suspension of the Dynamic Sensing Algorithm: Determining the Potential Occurrence, Duration, and Patient Impacts of Delays to Therapy,* with additional technical details is available from your Medtronic representative if desired.

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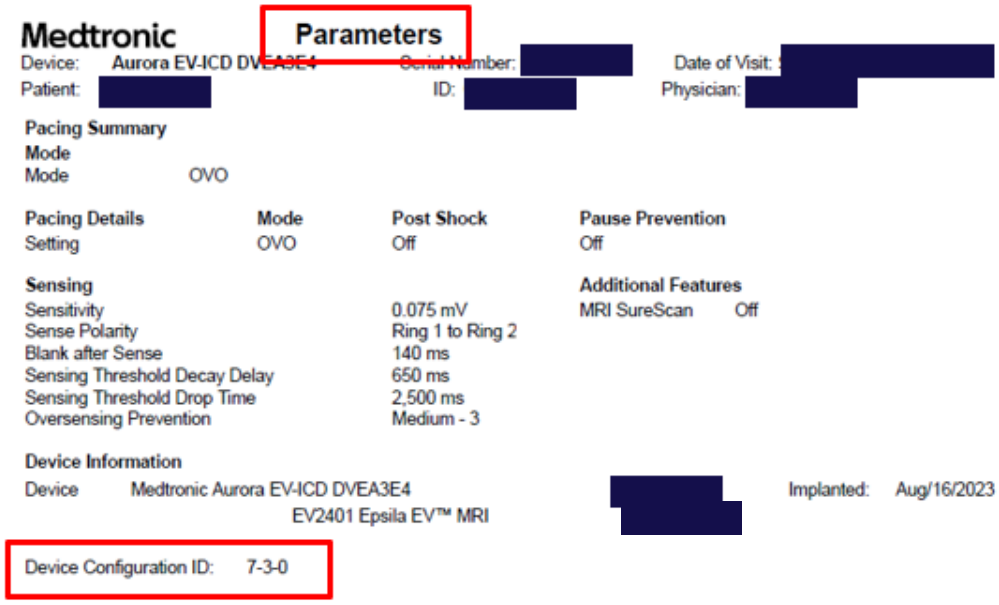
Appendix B

To identify if a patient's device has successfully received the update, view the displayed Configuration ID and confirm the first number in the sequence as indicated below:

- Clinical device (DVEX3E4) configuration ID is 6-1-0 or greater
- Aurora EV-ICD (DVEA3E4) is 7-3-0 or greater

The Device Configuration ID can be found under the "Device Information" section of the SmartSync Parameters Report, or for CareLink patients, under the *Transmission Details* page by selecting <More Reports > 'Parameters.' The Configuration ID is also included on the CareLink patient report that is available upon request. Note that devices that have successfully received the update will not be removed from the serial number lookup on the Medtronic Product Performance Report Website and will remain listed as in scope, therefore checking the configuration ID is required.



Medtronic **Parameters**

Device: Aurora EV-ICD DVEA3E4 Serial Number: [redacted] Date of Visit: [redacted]
Patient: [redacted] ID: [redacted] Physician: [redacted]

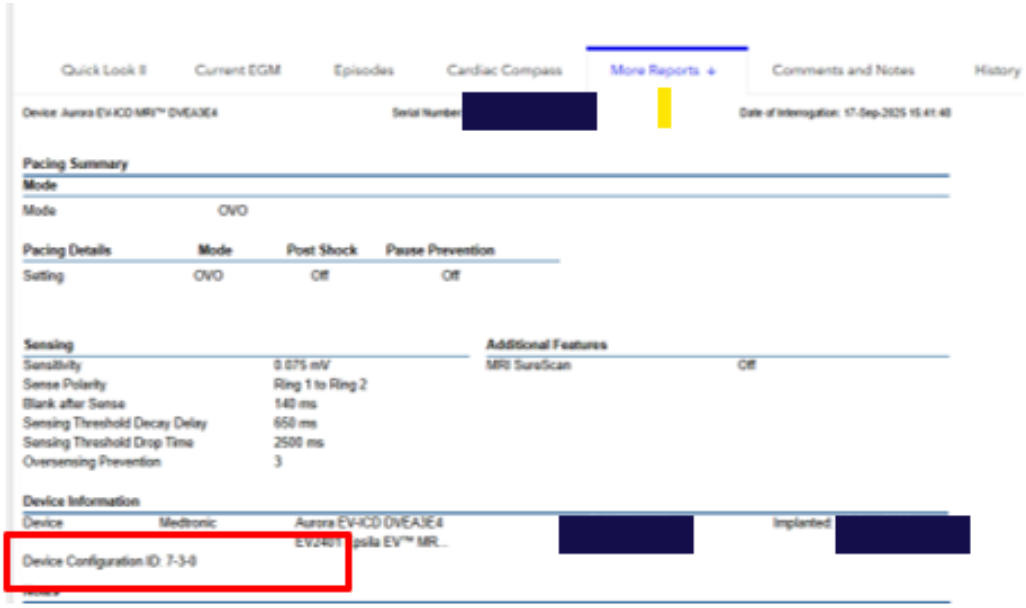
Pacing Summary
Mode
Mode OVO

Pacing Details	Mode	Post Shock	Pause Prevention
Setting	OVO	Off	Off

Sensing		Additional Features	
Sensitivity	0.075 mV	MRI SureScan	Off
Sense Polarity	Ring 1 to Ring 2		
Blank after Sense	140 ms		
Sensing Threshold Decay Delay	650 ms		
Sensing Threshold Drop Time	2,500 ms		
Oversensing Prevention	Medium - 3		

Device Information
Device Medtronic Aurora EV-ICD DVEA3E4 [redacted] Implanted: Aug/16/2023
EV2401 Epsila EV™ MRI

Device Configuration ID: 7-3-0



Quick Look II | Current EGM | Episodes | Cardiac Compass | More Reports | Comments and Notes | History

Device: Aurora EV-ICD MRI™ DVEA3E4 Serial Number: [redacted] Date of Interrogation: 17-Sep-2025 15:41:40

Pacing Summary
Mode
Mode OVO

Pacing Details	Mode	Post Shock	Pause Prevention
Setting	OVO	Off	Off

Sensing		Additional Features	
Sensitivity	0.075 mV	MRI SureScan	Off
Sense Polarity	Ring 1 to Ring 2		
Blank after Sense	140 ms		
Sensing Threshold Decay Delay	650 ms		
Sensing Threshold Drop Time	2500 ms		
Oversensing Prevention	3		

Device Information
Device Medtronic Aurora EV-ICD DVEA3E4 [redacted] Implanted [redacted]
EV2401 Epsila EV™ MR...

Device Configuration ID: 7-3-0

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To identify if a device on your shelf was manufactured with the update, look for version 02 or higher listed underneath the barcode: