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URGENT MEDICAL DEVICE CORRECTION

Potential for Suspension of Dynamic Sensing Algorithm

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

29 October 2025 | 20:39 PDT

Attention: Risk Management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

Dear Health Care Professional:

In the above identified devices, there is a potential for delayed time to high-voltage (HV) therapy should a rare sequence of events occur. Through 2 October 2025, six (6) events (delay of 2-17 seconds) were observed among 4,900 implanted devices worldwide (~0.12%). Five of the six events experienced this behavior during a controlled defibrillation 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. A device software update to fully correct this behavior will be available for download into implanted devices pending regulatory approvals.

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 a software update in manufacturing. Devices manufactured with this update are not susceptible to this delay (see Appendix B). In previously distributed devices, the availability of the software update will be communicated upon regulatory approval.

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:

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.**
- Continue managing patients per standard practice. Note that professional societies recommend use of remote monitoring to enhance patient follow-up.
- Contact your local Medtronic representative if the behavior described in this letter is suspected.

CUSTOMER ACTIONS:

- **Please complete the enclosed Confirmation Form, following the review of this letter, and return the completed form to your local Medtronic representative to confirm receipt of this notification.**
- 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. Per your facility's standard medical device complaint procedures, report to Medtronic any adverse reactions or quality problems if the quality issue described above has been observed.

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 local Medtronic Representative.

Sincerely,

Signed by:
Siak Wah Yew
Signer Name: Siak Wah Yew
Signing Reason: I approve this document
Signing Time: 29 October 2025 | 20:38 PDT
99B5834721984194B5948835E56FD5D9

Quality and Regulatory Affairs Lead
Malaysia

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.

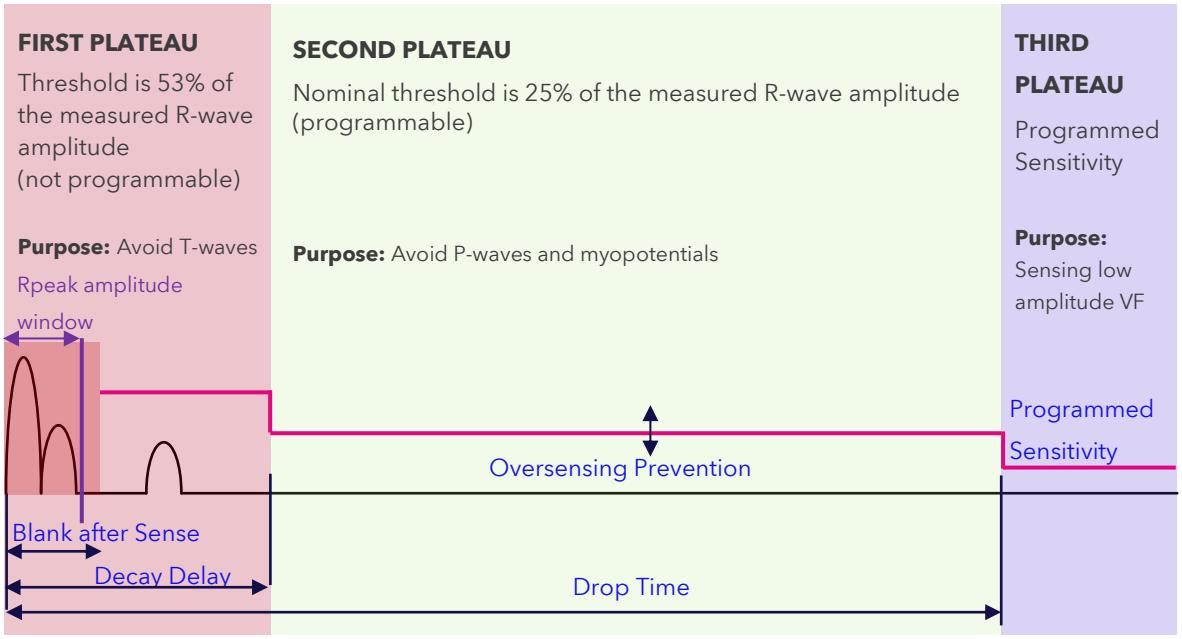

Figure 1- Operation of Sensing Thresholds – The first plateau duration ("Decay Delay") is nominally 360 ms, the second plateau duration ("Drop Time") is nominally 1500 ms, and the third plateau lasts until another sensed beat. R-wave amplitude measurements take place during "Rpeak amplitude window" shown 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.

Appendix B

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

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Customer Confirmation Form

URGENT MEDICAL DEVICE CORRECTION

Potential for Suspension of Dynamic Sensing Algorithm

Aurora EV-ICD™ (DVEA3E4), Clinical EV-ICD (DVEX3E4)

For completion by Medtronic Customers Only - Please complete all fields below and return all pages immediately.

<table>
<tr><th colspan="2">Customer Contact Details</th><th>Medtronic Contact Details</th></tr>
<tr><td colspan="2" rowspan="2">Distributor / Hospital / Clinic / Physician / Patient name:</td><td>Name:</td></tr>
<tr><td>Mobile no:</td></tr>
<tr><td colspan="2">Address:</td><td rowspan="2">Email:</td></tr>
<tr><td>Phone no:</td><td>Email:</td></tr>
</table>

I have read and understand the Urgent Medical Device Correction Notification Letter, dated 29 October 2025 | 20:39 PDT **from Medtronic regarding Potential for Suspension of Dynamic Sensing Algorithm Aurora EV-ICD (DVEA3E4), Clinical EV-ICD (DVEX3E4) and have followed the instructions as outlined in the Notification Letter.**

Please complete and sign the form as instructed below. If you are submitting the form on behalf of multiple accounts, please ensure that all relevant accounts are clearly listed. Return the completed form to your local Medtronic representative.

Name (print): _____ Signature: _____ Date: dd Mmm yyyy

For questions, contact your local Medtronic Representative.

Note: The addressee may continue to receive reminders of this notice until a response is received.