Vibratory alert in a recalled implantable cardioverter-defibrillator: Is there something wrong with the device?

Matthew Ortman, MD

From the Cooper Medical School of Rowan University, Camden, New Jersey.

Introduction
Shock reduction algorithms reduce the incidence of inappropriate shocks, but add to the complexity of device management. It is incumbent upon implanting physicians to familiarize themselves with the principles of these company-specific algorithms, so that device alerts—which may be spurious—can be managed quickly and effectively.

Case report
A 56-year-old man with a longstanding, dilated cardiomyopathy came to the Emergency Department after noting a “buzzing” sensation from his implantable cardioverter-defibrillator (ICD). The device was a Unify Assura (St. Jude Medical, St. Paul, MN) that had been placed as a pulse generator replacement in February 2014. In October 2016, St. Jude Medical initiated a class I recall for certain models of the Fortify, Unify, and Assura ICDs due to an approximately 0.2% incidence of premature and potentially rapid battery depletion.

Interrogation confirmed normal battery longevity and lead parameters with the following programmed settings: DDDR 60–130 beats per minute (bpm) with a paced and sensed atrio-ventricular (AV) delay of 180 and 130 ms; LV → RV offset 20 ms; postventricular atrial refractory period (PVARP) 375 ms; ventricular tachycardia (VT) zone 187 bpm; and ventricular Blanking (PAVB) window, an example of functional ventricular undersensing. The device does not register the intrinsic QRS, so it delivers a ventricular pacing stimulus (#4) at the expiration of the sensor-adjusted AV interval. Up until now, every intrinsic atrial event has been ignored, every intrinsic ventricular event has been blanked, and all paced events—which fall into the effective refractory period of the atrial and ventricular myocardium—have resulted in physiologic non-capture. The device’s sensor-adjusted, lower rate limit dictates the paced atrial rate; hence, there is another sinus event (#5) and conducted QRS (#6) before the next paced atrial event (#7) restarts the cycle.

So why has the device triggered an alert for “nonsustained RV oversensing”? St. Jude’s SecureSense RV Lead Noise Discrimination algorithm seeks to prevent inappropriate therapy for noise by comparing the near-field electrogram (EGM) (“V Sense Amp”) and far-field EGM (“Discrimination”) in a rolling fashion. The algorithm triggers when 2 out of 3 near-field intervals are shorter than the longest programmed treatment interval, ie, the VT or VF zone. When 10 short R-R intervals on the near-field EGM (out of a running counter of 255 sinus cycles) fulfill this rate requirement and there is a discrepancy between the near- and far-field EGM, the ICD generates a “nonsustained RV oversensing” alert. The algorithm was designed to distinguish true ventricular arrhythmias from lead noise, but functional undersensing has been implicated in recent case reports.1,2

Discussion
On first glance, this seems to be a problem of undersensing. The underlying rhythm is sinus tachycardia with a PR inter-

val of ~200 ms, yet channel markers indicate the delivery of AV sequential biventricular pacing at the sensor indicated rate. If lead parameters are normal, why does the ICD seemingly pace asynchronously?

It is a simple matter of timing, highlighted and numbered for clarification in Figure 2.

There is a repeating pattern for the first 5 pacing cycles on the strip. The first event (#1) is a sinus event that falls into PVARP, an example of functional atrial undersensing. The conducted QRS that follows (#2) is nearly simultaneous with the next paced atrial event (#3) and therefore falls into the device’s nonprogrammable Post Atrial Ventricular Blanking (PAVB) window, an example of functional ventricular undersensing. The device does not register the intrinsic QRS, so it delivers a ventricular pacing stimulus (#4) at the expiration of the sensor-adjusted AV interval. Up until now, every intrinsic atrial event has been ignored, every intrinsic ventricular event has been blanked, and all paced events—which fall into the effective refractory period of the atrial and ventricular myocardium—have resulted in physiologic non-capture. The device’s sensor-adjusted, lower rate limit dictates the paced atrial rate; hence, there is another sinus event (#5) and conducted QRS (#6) before the next paced atrial event (#7) restarts the cycle.

From the Cooper Medical School of Rowan University, Camden, New Jersey.

KEYWORDS Noise detection algorithm; upper rate behavior; postventricular atrial refractory period; cross-chamber blanking; functional undersensing; physiologic non-capture (Heart Rhythm Case Reports 2017;3:319–322)

Address reprint requests and correspondence: Dr Matthew Ortman, Assistant Professor of Medicine, Cooper Medical School of Rowan University, Camden, NJ 08103. E-mail address: Ortman-Matthew@CooperHealth.edu.

2214-0271/© 2017 Heart Rhythm Society. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/). http://dx.doi.org/10.1016/j.hrcr.2017.03.008
In this example, the discrepancy between the near- and far-field EGM is a byproduct of the physiologic non-capture of ventricular paced events. For the first 5 pacing cycles, the near-field interval between the biventricular pacing stimulus (which fails to capture, as previously noted) and the intrinsic QRS ranges between 309 and 313 ms, fulfilling the rate criteria for the SecureSense algorithm. These short near-field intervals are unbinned events, denoted by a “prohibition” sign in Figures 2 and 3—that is, they do not count toward the running “tachy” counter (which triggers device therapy) because they deviate from the overall interval average, yet they still contribute to the rolling SecureSense counter itself. In contrast, the far-field Discrimination channel registers the true sinus rate, establishing the discrepancy between near- and far-field EGM that fulfills the second component of the SecureSense algorithm.

The sixth pacing cycle shows a slightly different pattern, highlighted and numbered for clarification in Figure 3. Due to a slight oscillation in the sinus rate, the sixth intrinsic QRS (#1) falls just beyond PAVB into the Ventricular Safety Standby (VSS) window, triggering the delivery of ventricular safety pacing (VSP) after a truncated AV interval of 117 ms. The subsequent near-field interval is longer in proportion to the prematurity of the VSP; hence, it falls outside the programmed VT zone, and the last intrinsic QRS on the strip registers as a “VS” event.

What is the fundamental issue? At 375 ms, the PVARP is unusually long, but the effective PVARP in this strip is actually nearly twice that because of the unusual confluence of

---

**KEY TEACHING POINTS**

- In October 2016, St. Jude Medical initiated a class I recall for certain models of the Fortify, Unify, and Assura implantable cardioverter-defibrillators (ICDs) due to an approximately 0.2% incidence of premature and potentially rapid battery depletion.
- St. Jude’s SecureSense RV Lead Noise Discrimination algorithm seeks to prevent inappropriate therapy for noise by comparing the near-field electrogram (EGM) (“V Sense Amp”) and far-field EGM (“Discrimination”) in a rolling fashion. The algorithm triggers when 2 out of 3 near-field intervals are shorter than the longest programmed treatment interval (ie, the ventricular tachycardia or ventricular fibrillation zone). When 10 short R-R intervals (out of a running counter of 255 sinus cycles) on the near-field EGM fulfill this rate requirement and there is a discrepancy between the near- and far-field EGM, the ICD generates a “nonsustained RV oversensing” alert.
- Functional undersensing, which may be a consequence of unusually long refractory periods, is one of several potential triggers for an inappropriate SecureSense alert.

---

Figure 1 The alert for nonsustained right ventricular oversensing. AP = atrial pacing; BP = biventricular pacing; SIR = sensor indicated rate.
Figure 2  The first half of the strip. There is a repeating pattern of functional undersensing and physiologic non-capture that generates short R-R intervals on the near-field electrogram, triggering the SecureSense RV Lead Noise Discrimination algorithm. The “prohibition” sign indicates unbinned events. See text for detailed explanation of numbered events.

Figure 3  The second half of the strip. QRS (#1) falls into the Ventricular Safety Standby (VSS) window, triggering the delivery of a ventricular safety pacing (VSP) stimulus. The subsequent R-R interval on the near-field electrogram falls outside the algorithm’s rate criteria for detection. The “prohibition” sign indicates unbinned events. See text for detailed explanation.
paced and sensed ventricular events. Factoring in the programmed AV delay of 180 ms, the total atrial refractory period encompasses almost 900 ms, essentially blinding the device to native atrial activity and thereby perpetuating the problem.

To rectify the issue, PVARP was reduced to 275 ms, based on the patient’s retrograde AV nodal conduction time of approximately 250 ms with VVI pacing. The patient (who thought that the vibratory alert was a sign of premature battery depletion) was reassured and discharged home.

Conclusion
In summary, this phenomenon is the consequence of cross-chamber blanking, an abnormally long PVARP, and St. Jude’s SecureSense algorithm. In a way, it is ironic that the issue—one of functional undersensing—only came to light as a consequence of the device’s oversensing algorithm. Regardless, it illustrates one of the many manifestations of upper rate behavior, and it is a reminder that apparent device malfunction can be often be corrected with reprogramming.

References
1. Mulpuru SK, Noheria A, Cha YM, Friedman PA. Nonsustained lead noise alert associated with repeating pattern of signals on the ventricular channel: is there true concern for lead malfunction? Heart Rhythm 2014;11:526–528.
2. Jackson N, Viswanathan K, Cameron D, Nair K. Implantable defibrillator timing windows: when coincidence can be confusing. Circ Arrhythm Electrophysiol 2016;9(3):e002876.