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Since the advent of the implantable cardioverter-defibrillator (ICD) for primary prevention of sudden cardiac death, much attention has been given to the possibility of ICD or lead hardware failures resulting in inappropriate ICD function. Less attention has been given to the potential for software programming errors resulting in inappropriate device behavior. We report a case of a software programming error that led to a premature “end of service” alert that triggered a “lock-up” of the device antitachycardia therapies.

Typically, the capacitor charge time for the Medtronic Secura ICD in anticipation of a full energy shock is about 7.7 to 9.2 seconds, depending on how close the device is to the elective replacement time and other factors.1 A charge circuit timeout indicates that at least 1 charging period exceeded 30 seconds. When 3 consecutive charging periods each exceed 30 seconds, the ICD charge circuit becomes inactive, and all automatic therapy functions and manual system tests become disabled except for emergency VVI pacing, all for the purpose of conserving battery voltage for pacemaker dependent patients when the generator reaches end of service.1 An alert is displayed to indicate that the time allotted to reach the programmed output energy (30 seconds) has been exceeded. A charge circuit timeout usually occurs when the battery voltage is depleted below the “elective replacement indicator.” In this specific instance, the charge circuit timeout occurred because of a glitch in the software. Three events occurred almost simultaneously, exposing the software programming error.2 These events occurred during an episode of tachycardia in the brief time span between the end of charging the capacitors and redetection/confirmation before delivery of a shock. The 3 events are:

1. The high-voltage capacitors reach the programmed energy resulting in a charge end.
2. A battery voltage measurement is in progress at charge end. (These measurements are not displayed.)
3. Therapy is aborted (Figure 1).

If these 3 discrete events occur almost simultaneously, a lock-up of battery voltage measurements occurs. Because battery voltage can no longer be assessed during device charging, the device will continue to charge past 30 seconds and a charge circuit timeout occurs. (Because a full explanation of the sequence of events leading to the battery measurement lock-up would reveal Medtronic proprietary data, the vendor would not release further details leading up to the battery lock-up.) Once the charge circuit timeout is declared and 2 subsequent device charges exceed 30 seconds, the high-voltage capacitors will no longer charge and shocks will no longer be delivered as a safety algorithm to conserve battery voltage for back-up bradycardic pacing.

Case Report, Device Interrogation, and Firmware Analysis

A 68-year-old woman with a medical history of coronary artery disease, ischemic cardiomyopathy, aortic stenosis, mitral regurgitation, and aortic and mitral valve replacements underwent implantation of a Medtronic dual-chamber ICD (Secura DR, RA lead Medtronic 4026 to 52, RV lead Sprint Quattro) in February 2010 for primary prevention of sudden cardiac death. She was discharged to a nursing facility but was readmitted 3 weeks later to Long Island Jewish Medical Center for heart failure symptoms and multiple ICD discharges delivered in rapid succession. Review of the patient’s stored ECG revealed atrial fibrillation with a rapid ventricular response.

On interrogation of the device, the Quick Look observations displayed an “end of service” alert along with a notification that 39 shocks had been delivered. Review of the endocardial electrograms revealed that all shocks had been delivered for atrial fibrillation with rapid ventricular response (see Figure 2). Also noted during Episode 44 (see Figure 2) was that just after the charge end, the tachycardia slowed and therapy was aborted. The ICD was explanted and a new generator was reimplemented. The event was reported to the US Food and Drug Administration’s (FDA) Centers for Device and Radiological Health Branch in compliance with the Safe Medical Devices Act.

Analysis of the ICD by the Medtronic Returned Product Analysis Laboratory revealed that 3 critical events had...
occurred almost simultaneously, exposing the software programming algorithm glitch that resulted in the battery lock-up. As of April 2010, Medtronic confirmed 4 additional case reports of battery lock-up of approximately 144,000 devices implanted worldwide. Similar software is used in several Medtronic ICD models (Consulta CRT-D, Secura DR/VR, Concerto II CRT-D, Virtuoso II DR/VR, Maximo II CRT-D, and Maximo II DR/VR models).

A corrective software patch was approved by the FDA in May 2010. The patch is automatically downloaded to a patient’s device during an in-clinic interrogation. Without the software correction, the manufacturer estimated the rate of occurrence of this specific sequence of events in the ambulatory setting to be 1 in 27,000 (0.000037 events) devices per year. There have been no reported deaths caused by failure of any ICD to deliver therapy as a result of charge circuit timeout. However, it is possible that a death could have occurred from this malfunction that went undetected or unreported.

Discussion

Software programming errors resulting in pacemaker or ICD failure have not received significant attention. To our knowledge, the characteristics of clinical events caused by a charge circuit timeout have not been reported in the literature. Although the overall reliability and efficacy of device therapy remain high, as ICD technology increases in complexity, so does the potential for malfunction and difficulty in patient treatment. A study of pacemaker and ICD advisories demonstrated that the number and rate of pacemakers and ICD devices affected by advisory has increased since 1995. Device malfunctions are not always caused by hardware component failure but may be due to software errors. In one

Figure 1. Sequence of events leading to battery voltage lock-up. During a ventricular tachycardia (VT) episode, the capacitors charge and periodic voltage measurements take place. Shortly after the end of charging and during a battery measure, therapy is aborted. These 3 events lead to a battery voltage lock-up. VF indicates ventricular fibrillation.

Figure 2. Electrograms show atrial fibrillation with a rapid ventricular response inappropriately detected as ventricular tachycardia. However, the ventricular response slows enough and therapy is aborted. Not shown in the figure but critical to causing the battery lock-up is that a battery voltage measurement occurred between the charge end and first subsequent sensed event (see Figure 1). These 3 events occurring almost simultaneously (charge end, battery voltage measurement, and aborted therapy) caused the battery lock-up and led to a charge circuit timeout. FVT indicates fast ventricular tachycardia zone; ATP, antitachycardia pacing; A/V bpm, atrial and ventricular rate in beats per minute; Max V, maximum ventricular rate in beats per minute (no measurement); EGM, electrogram recorded; Atip to Aring, atrial electrogram recording between atrial tip electrode and atrial ring electrode; RVtip to RVring, right ventricular electrogram recording between right ventricular tip electrode and right ventricular ring electrode; A-A (ms), atrial cycle length in milliseconds. Markers: AS indicates atrial sense; AR, atrial refractory; AB, atrial blanking; CE, charge end; TF, cycle length of ventricular electrograms in the fast VT zone; VS, usually ventricular rate below the ventricular tachycardia zone; V-V (ms), ventricular cycle length in milliseconds; FVT/H11001 SVT, dual tachycardia (ventricular tachycardia in fast ventricular tachycardia zone and supraventricular tachycardia), although the true rhythm is atrial fibrillation with rapid ventricular response; FVT Rx 2 CV, device redetected what it considers fast ventricular tachycardia and is preparing to deliver second cardioversion. Red arrow indicates time at which 3 events occurred almost simultaneously: (1) charge end; (2) therapy aborted; (3) not shown, battery voltage measurement.
study, firmware (defined as integral device software) malfunctions accounted for only 1.5% of reported ICD malfunctions, whereas hardware accounted for 85% of such malfunctions. In our case, the interaction between 3 features that were intended to optimize battery charge time (battery voltage measurement) and to mediate normal device operation (abort therapy, charge end processing) resulted in a lock-up of device firmware and rendered the ICD ineffective in delivering therapy for tachyarrhythmias.

Most software problems may be corrected without replacing the pulse generator through the use of downloadable software updates. In this case, the software update prevents the battery measurement lock-up when the charge ends; abort therapy and battery measurement occur almost simultaneously, preventing a charge circuit timeout from occurring as the result of the battery measurement lock-up. However, once a battery measurement lock-up and 3 charge circuit timeouts occur, the device will be set to its end-of-service operational state: the condition cannot be cleared by the software update, and the device must be replaced. It should be noted that for our patient, more aggressive medical treatment of the atrial arrhythmia with higher doses of β-blocker as well as adjustment of the rate cut-off and supraventricular tachycardia–ventricular tachycardia discriminators may have prevented the succession of 39 shocks for atrial fibrillation and prevented the series of events that led to the battery lock-up.

This case raises the issue of systematic testing of devices before market release. In the past, the FDA has mandated more rigorous testing for potential hardware problems. Perhaps in the future, new devices and their detection algorithm software should be challenged more rigorously by a series of electrogram simulations such as those obtained from this patient’s device.

Finally, this case highlights the importance of clinicians or hospitals reporting device malfunction or failure to the FDA directly, independently, and in addition to the vendor’s report. The Medical Product Safety Network (MedSun) is an adverse event reporting program launched in 2002 by the US FDA’s Center for Devices and Radiological Health. The primary goal for MedSun is to work collaboratively with the clinical community to identify, understand, and solve problems with the use of medical devices.

The infrequency of the event reported in our case required aggregation of data from many sites. Early reporting to the vendor and FDA resulted in rapid recognition of the pattern of device failure and corrective action.

Conclusion
Our case highlights the possibility that a software programming error may result in device malfunction and end of service alert, and it illustrates the importance of an expeditious action by the US FDA and manufacturer to find the root cause and to implement a successful corrective action.

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Disclosures
None.

References
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