S
ince 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 depen-
dent 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 indica-
tor.” In this specific instance, the charge circuit timeout
occurred because of a glitch in the software. Three events
occurred almost simultaneously, exposing the software pro-
gramming 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 explana-
tion of the sequence of events leading to the battery measure-
ment 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 dis-
charges 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 observa-
tions displayed an “end of service” alert along with a
notification that 39 shocks had been delivered. Review of the
endocardial electrogams 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 reimplanted. 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
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.

**Acknowledgments**

The authors thank Pung-Pung Huang and Andrew Yu of Medtronic for their assistance in the acquisition of technical data pertaining to this report.

**Disclosures**

None.

**References**

Charge Circuit Timeout: A Sequence of Events Leading to Failure of an Implantable Cardioverter-Defibrillator to Deliver Therapy
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Circ Arrhythm Electrophysiol. 2011;4:e33-e35
doi: 10.1161/CIRCEP.111.962092
Circulation: Arrhythmia and Electrophysiology is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 1941-3149. Online ISSN: 1941-3084

The online version of this article, along with updated information and services, is located on the World Wide Web at:
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