

Malfunction of an MRI-Conditional Pacemaker Following an MRI



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Introduction

Patients with cardiac implantable electronic devices were historically unable to undergo magnetic resonance imaging (MRI).¹ In 2011 the Food and Drug Administration approved the first MRI conditional pacemaker system, the Revo MRI SureScan (Medtronic, Mounds View, MN). As per manufacturer recommendations, the Revo and other MRI conditional systems should be interrogated immediately before the MRI scan to activate the “SureScan” setting and immediately after the scan to confirm appropriate device function and enable restoration of pre-MRI settings.² MRI conditional pacemakers are specifically designed to minimize the risk of malfunction in the MRI environment. We report a case of an MRI conditional pacemaker system that malfunctioned at the time of an MRI scan and required a premature generator change procedure.

Case Report

A 63-year-old man underwent implant of a Revo MRI RVDR01 dual-chamber pacemaker with model 5086 leads

Device: Revo MRI RVDR01 SW018 Software Version 1.0
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Initial Interrogation: Quick Look Page 4

Pacing (% of Time Since 16-Jan-1996)	
AS-VS	<0.1 %
AS-VP	90.3 %
AP-VS	<0.1 %
AP-VP	9.7 %
MVP	Off

OBSERVATIONS (1)

MRI SureScan On: 16-Jan-1996 MRI SureScan Off: 16-Jan-1996 Data was not collected during MRI SureScan.

Figure 2 Also from the initial interrogation of device. Note the date of SureScan on and off, 16-Jan-1996 (underlined in red), and the evidence of pacer dependence, with >99.9% ventricular pacing.

on May 11, 2011 at an outside hospital for complete heart block. He was admitted to our institution on February 25, 2015 for a noncardiac condition. When his pacemaker was interrogated on admission, the device reported “Date of Visit” as April 8, 1996 (08-Apr-1996). However, the reported date of implant of May 11, 2011 11-May-2011 remained correct (Figure 1). The OBSERVATIONS section reported “MRI SureScan On: 16-Jan-1996 MRI SureScan Off: 16-Jan-1996. Data was not collected during MRI SureScan” (Figure 2). By the device clock, this event was 83 days prior to admission. Device information, including battery and lead measurements, lead trends, histograms, and arrhythmia data, was reported between May 1994 and April 1996 (Figure 3). Sensing, battery and lead impedances, and capture thresholds were within normal limits, and fluoroscopy of the system did not show any abnormalities (Figure 4). Review of outside records revealed that the patient underwent a brain MRI in a 1.5 T scanner 83 days prior to admission (Figure 5). The MRI was performed as per the MRI SureScan guidelines provided by Medtronic with maximum spatial gradient of <20 T/m (2000 G/cm), maximum gradient slew rate performance per axis of <200 T/m/s, and head specific absorption rate <3.2 W/kg.² As the patient was pacemaker dependent and the stability of the device could not be guaranteed, Medtronic technical support recommended generator replacement. The patient underwent removal of his Revo pulse generator and implant of a Medtronic Advisa DR MRI SureScan A2DR01. He did well post generator change and had no further abnormalities noted with his pacing system.

The pacemaker pulse generator was returned to Medtronic for analysis. Destructive analysis revealed “There was no

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Date of Visit: 08-Apr-1996
Date of Implant: 11-May-2011
Date of Interrogation: 25-Feb-2015

Initial Interrogation: Quick Look Page 1

Device Status (Implanted: <u>11-May-2011</u>)	Measured on: <u>08-Apr-1996</u>
Battery Voltage (RRT=2.81 V)	2.99 V
Lead Impedance	Atrial (5086MR) 560 ohms RV (5086MR) 576 ohms
Programmed Amplitude/Pulse Width	2 V / 0.4 ms
Measured P/R Wave	2.2 mV
Programmed Sensitivity	0.3 mV

Parameter Summary

Mode	DDDR	Lower Rate	40 bpm	Paced AV	160 ms
Mode Selection	Off	Upper Track	150 bpm	Sensed AV	130 ms
Detection		Upper Sensor	150 bpm		
AT/AF	Monitor	Rates	Therapies		
VT	Off	>171 bpm	All Rx Off		

Figure 1 Initial interrogation of device. Note the “Date of visit” of 08-Apr-1996, underlined in red; the actual date of interrogation, 25-Feb-2015, handwritten above the device date and outlined in blue; and the correct date of implant, 11-May-2011, also outlined in blue.

KEYWORDS Pacemaker; MRI; MRI-conditional pacemaker; Malfunction (Heart Rhythm Case Reports 2017;3:148-150)

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KEY TEACHING POINTS

- All cardiac implantable electronic devices (CIEDs) merit complete evaluation following magnetic resonance imaging (MRI) scans, regardless of whether or not they have been labeled as MRI conditional.
- It is important to recognize abnormal device parameters in CIEDs following exposure to an MRI environment.
- It is important to understand the potential effects an MRI can have on CIEDs, even if they are labeled as MRI conditional.

evidence of a device malfunction that would account for the power-on resets (PORs). No hybrid-related anomalies were found. Generation of a POR during analysis was unsuccessful and the root cause as to the reported events was unable to be determined.”

Discussion

We present a pacemaker-dependent patient with a Medtronic Revo MR Conditional Pacemaker that suffered a POR with subsequent malfunction of the device clock after a 1.5 T brain MRI. Such abnormal device behavior following exposure to the MRI environment has not been observed among non-MRI conditional devices in greater than 5000 reported scans and calls into question the durability of MRI-conditional devices in the MRI environment.³⁻⁵

Although patients with “legacy devices” (ie, those not labeled “MRI conditional”) can be scanned safely on a

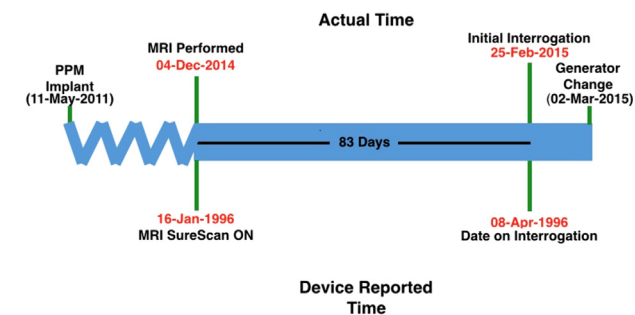


Figure 5 Timeline of events. The actual dates of device interrogation are on the top portion of the figure, and the device-reported dates are below. There are an identical 83 days between actual magnetic resonance imaging (MRI) scan and our interrogation and between the MRI SureScan activation/deactivation and our interrogation.

research basis under institutional review board–approved protocols, cardiac monitoring is required during the scan.⁶ A major impetus for the development of MRI-conditional devices was that the performance of legacy devices in the MRI setting was not established. Theoretical complications of scanning legacy devices can include heating of the lead, movement of the device, and software or hardware malfunction.⁷ Devices labeled as MRI conditional have presumably minimized the risk of these complications through reductions in ferrous content and have undergone extensive in vitro and in vivo testing prior to Food and Drug Administration approval.^{8,9} Nevertheless, concerns remain that these devices could be susceptible to the MRI environment and they have been branded as “MRI conditional” (rather than “MRI safe”). Additionally, MRI-conditional pulse generators are based on earlier platforms, their leads are more prone to dislodgment and perforation,^{10,11} and they are more expensive (in most settings) as compared with legacy devices.

We believe this is the first reported incidence of an MRI-conditional device that did not tolerate the MRI environment. Despite the implausible “Date of Visit” and reported device parameter dates, the accurate date of implant recorded by the device argues against a primary date entry error at the time of implantation. Furthermore, it should be noted that the antecedent brain MRI scan was performed within Medtronic guidelines for safe MRI exposure. Although we cannot definitively exclude exposure to alternative energy sources that may have affected device performance, the fact that the SureScan activation and the brain MRI were both 83 days

Device: **Revo MRI RVDR01** Date of Visit: **08-Apr-1996 15:02:20**
 SW018 Software Version 1.0
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Initial Interrogation: Rate Histograms Page 1

	Prior to Last Session <u>07-May-1994</u> to 16-Jan-1996 20 months	Since Last Session 16-Jan-1996 to 08-Apr-1996 84 days
% of Time		
AS-VS	< 0.1%	< 0.1%
AS-VP	81.4%	90.3%
AP-VS	< 0.1%	< 0.1%
AP-VP	18.6%	9.7%

Figure 3 Initial interrogation rate histograms. Note the “Prior to Last Session” information dating back to 07-May-1994 (underlined in red).

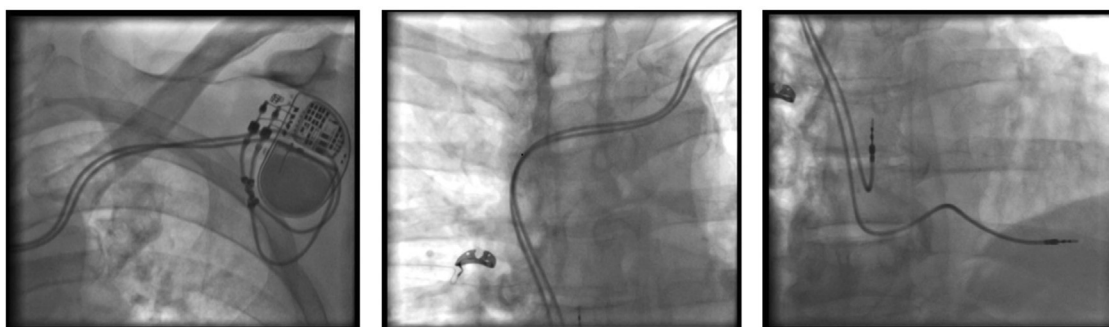


Figure 4 Fluoroscopy images of the device, showing an intact dual-chamber pacemaker system.

prior to interrogation strongly suggests the MRI was responsible for the abnormalities. Though the generator still appeared to function properly, the change of dates could not be clearly explained. In light of the patient's pacemaker dependency and recommendations from the device manufacturer, generator replacement was performed. Given the added expense and decreased functionality of MRI-conditional devices, the risks and benefits of using these devices should be carefully considered going forward.

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