# Safe magnetic resonance imaging scanning of patients with cardiac rhythm devices: A role for computer modeling

Bruce L. Wilkoff, MD, FHRS,[*] Timothy Albert, MD, FACC,[†] Mariya Lazebnik, PhD,[‡] Sung-Min Park, PhD,[‡] Jonathan Edmonson,[‡] Ben Herberg,[‡] John Golnitz,[‡] Sandy Wixon,[‡] Joel Peltier,[‡] Hyun Yoon, PhD,[‡] Sarah Willey, MPH,[‡] Yair Safriel, MD[§]

*From the [*]Cleveland Clinic, Cleveland, Ohio, [†]Salinas Valley Memorial Hospital, Salinas, California, [‡]Medtronic Inc., Mounds View, Minnesota and [§]Pharmascan, Wilmington, Delaware.*

**BACKGROUND** Although there are several hazards for patients with implanted pacemakers and defibrillators in the magnetic resonance imaging (MRI) environment, evaluation of lead electrode heating is the most complex because of the many influencing variables: patient size, anatomy, body composition, patient position in the bore, scan sequence (radiofrequency power level), lead routing, and lead design. Although clinical studies are an important step in demonstrating efficacy, demonstrating safety through clinical trials alone is not practical because of this complexity.

**OBJECTIVE** The purpose of this study was to develop a comprehensive modeling framework to predict the probability of pacing capture threshold (PCT) change due to lead electrode heating in the MRI environment and thus provide a robust safety evaluation.

**METHODS** The lead heating risk was assessed via PCT change because this parameter is the most clinically relevant measure of lead heating. The probability for PCT change was obtained by combining the prediction for power at the electrode–tissue interface obtained via simulations with a prediction for PCT change as a function of radiofrequency power obtained via an *in vivo* canine study.

**RESULTS** The human modeling framework predicted that the probability of a 0.5-V PCT change due to an MRI scan for the Medtronic CapSureFix MRI SureScan model 5086 MRI leads is $<1/70{,}000$ for chest scans and $<1/10{,}000{,}000$ for either head scans or lower torso scans.

**CONCLUSION** The framework efficiently models millions of combinations, delivering a robust evaluation of the lead electrode heating hazard. This modeling approach provides a comprehensive safety evaluation that is impossible to achieve using phantom testing, animal studies, or clinical trials alone.

**KEYWORDS** 5086 MRI lead; Computer modeling; Hazards; Lead electrode heating; MR conditional; Magnetic resonance imaging; SureScan

**ABBREVIATIONS** **AAMI** = Association for the Advancement of Medical Instrumentation; **ISO** = International Organization for Standardization; **MRI** = magnetic resonance imaging; **PCT** = pacing capture threshold; **RF** = radiofrequency



## Introduction

Regarded by many as the gold standard for soft tissue imaging, magnetic resonance imaging (MRI) has become the imaging modality of choice for neurologic, soft tissue, tumors, and musculoskeletal disorders.[1] The prevalence of common comorbidities increases rapidly for individuals older than 65 years, resulting in an increasing likelihood of benefiting from MRI.[2–4] For example, pacemaker patients, who on average are 75 years of age,[5,6] have a 70% chance of developing an indication for an MRI scan over the expected life of the implanted device.[7] MRI scans have been considered contraindicated for pacemaker patients since the development of MRI more than 30 years ago. MR Conditional pacing and defibrillator systems represent a technological breakthrough in the medical device industry, addressing a compelling market need with significant patient benefit.

Drs. Wilkoff, Albert, and Safriel are consultants to Medtronic. Dr. Lazebnik, Dr. Park, J. Edmonson, B. Herberg, J. Golnitz, S. Wixon, J. Peltier, Dr. Yoon, and S. Willey are employees of Medtronic. **Address reprint requests and correspondence:** Dr. Bruce L. Wilkoff, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University, 9500 Euclid Ave, Desk J2-2, Cleveland, OH 44195. E-mail address: wilkofb@ccf.org.

## MRI system: Source of hazards

MRI scanners deliver pulsed radiofrequency (RF) and switched gradient magnetic fields in the presence of a powerful static magnetic field to create an image of the body. Together, the three powerful fields (static, RF, and switched gradient) create a hostile environment for an implantable pacing or defibrillation system.[8] However, with proper design and evaluation methods, it is possible to mitigate the hazards and produce a system that will allow patients to be safely scanned.

Hazards for patients with implanted pacemakers and defibrillators undergoing MRI scans fit into several categories: (1) arrhythmias initiated by MRI-induced cardiac stimulation, (2) RF-induced tissue heating near the lead electrodes causing tissue damage, (3) temporary or permanent device malfunction that results in inappropriate therapy, and (4) device and/or lead dislodgement, caused by interaction between the static and fast switching gradient magnetic field and ferrous materials.

## Rationale for computer modeling

The lead electrode heating complexity is due to a combination of multiple clinical variables, including patient size, anatomy, body composition, patient position in the bore, scan sequence (RF power level), lead routing, and lead design. This leads to a significant variation in lead electrode heating. Figure 1 shows lead electrode heating variation due to patient size (three different human body models), patient position in the bore (shown along the x-axis), and lead routing in the body (four different lead routings are shown using different color lines). Figure 1 illustrates the extreme variation in lead electrode heating due to these variables: (1) there is at least a 10× difference between the highest- and lowest-heating lead routings within a specific human body model; (2) the highest- and lowest-heating lead routings are different for different human body models (e.g., compare the lead routing marked with a black line); and (3) the peak heating is different for different size human body models.

Computer-aided modeling is a practical and efficient method for exploring millions of variable combinations in a holistic manner. Computer modeling also allows for analysis of parameter extremes, outside the bounds of normal clinical practice, which allows further assessment of safety margin and the sensitivity of influencing variables. The accuracy of modeling results is dependent on the ability to simulate and predict real use scenarios. The objective of this study was to develop a robust modeling framework to predict risk of lead electrode heating in the MRI environment and thus provide a robust safety evaluation for new and existing products.

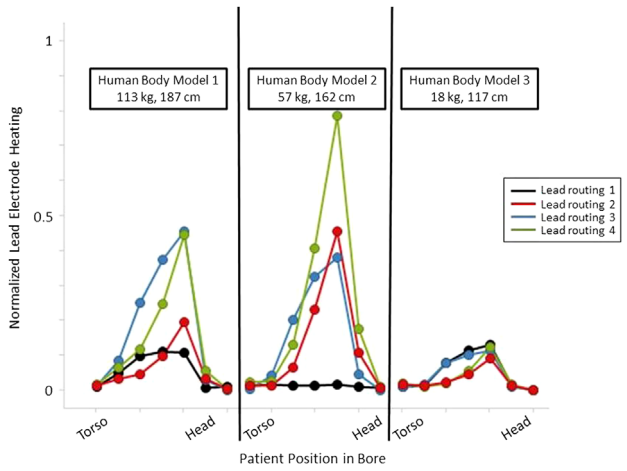


**Figure 1** Lead electrode heating variation due to patient size (three different human body models), patient position in the bore (shown along the x-axis), and lead routing in the body (four different lead routings shown using different color lines). For each patient, the left point corresponds to lower torso scans and the right point corresponds to head scans.

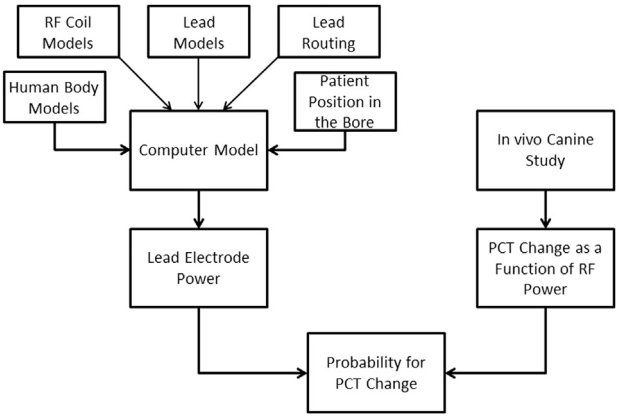


**Figure 2** Strategy for evaluating the probability for pacing capture threshold (PCT) change as a result of magnetic resonance imaging (MRI) scans. Lead electrode heating is quantified via a computer model with a number of inputs: human body models (which account for variation in patient size, anatomy, and body composition), patient position in the bore, radiofrequency (RF) coil models, lead routings, and lead-specific electrical models (which account for variation in lead design). The physiologic effect of the heating is measured in an *in vivo* canine study. The final output of the model is the probability of PCT change due to an MRI scan.

## MRI lead electrode model overview

The modeling framework consists of two major parts: (1) the RF power at the electrode–tissue interface is simulated using models of human bodies, RF coils, leads, and lead routings; and (2) the effect of RF power on pacing capture threshold (PCT) is evaluated *in vivo* via a canine study. PCT is the minimum voltage required to pace, or capture, the heart. The results of these two steps are combined to develop a statistical prediction of PCT change during an MRI scan. A block diagram of the strategy is shown in Figure 2. Note that this approach does not rely on *in vivo* temperature rise measurements because the relationship between the change in PCT and RF power is directly obtained.

PCT was chosen as the basis of the lead electrode heating evaluation strategy because the change in PCT is directly caused by tissue heating near the lead electrode. In addition, it is the most sensitive parameter for monitoring changes in the electrode–tissue interface and is the parameter of most significance with respect to pacing therapy delivery.

Models of human bodies, RF coils, leads, and lead routings are simulated in order to calculate the coupled RF power. In addition, an *in vivo* canine study is performed to measure PCT change as a function of RF power delivered directly to the cardiac lead. These two components are combined in order to calculate the probability of MRI-induced PCT change.

## Methods

As discussed in the Introduction, the modeling framework consists of two parts: (1) the simulations that predict lead