

# The Heart Rhythm Society (HRS)/American Society of Anesthesiologists (ASA) Expert Consensus Statement on the Perioperative Management of Patients with Implantable Defibrillators, Pacemakers and Arrhythmia Monitors: Facilities and Patient Management

*This document was developed as a joint project with the American Society of Anesthesiologists (ASA), and in collaboration with the American Heart Association (AHA), and the Society of Thoracic Surgeons (STS)*

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**ABBREVIATIONS** ICD = Implantable cardioverter defibrillator; EMI = Electromagnetic interference; CIED = Cardiovascular implantable electronic device; RF = Radio frequency; ECT = Electroconvulsive therapy; TUNA = Transurethral needle ablation; TURP = Transurethral resection of the prostate; TENS = Transcutaneous electrical nerve stimulation; CRT-P = Cardiac resynchronization therapy pacemaker; CRT-D = Cardiac resynchronization therapy defibrillator; CIED team = The physician, nurse, and technicians who care for the patient's CIED; Perioperative team = The anesthesiologist, surgeon, and/or other physicians and nurses associated with the procedure and the preparation for that procedure (Heart Rhythm 2011;8:1114-1152)

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## Preamble

The purpose of this document is to provide an expert consensus on the management of patients with cardiovascular implantable electronic devices (CIEDs) during and after surgical or medical procedures. This writing group, appointed by the Heart Rhythm Society and the American Society of Anesthesiologists (ASA), is a representative group of experts in pacemaker and defibrillator management. Each of the authors is an expert in the management of CIEDs in the setting of medical procedures that might interfere with their function. The writing group consists of eight cardiac electrophysiologists, four anesthesiologists, one cardiothoracic surgeon, and one allied health professional. This statement represents the consensus of the writing committee based on a review of the literature, their own experience in treating patients, and input from a reference group. In generating its consensus, the committee reviewed a large body of literature that consists mainly of case reports and small series of cases. There are no randomized controlled trials and very few case series to rely upon; therefore, many of the recommendations are based upon the extensive experience of the writing group. Consequently, there has been no assignment of levels of evidence. [Appendix 2](#) summarizes the literature. This document is intended to provide guidance to health care professionals who care for patients with CIEDs. It is especially intended to give CIED professionals guidance in the provision of an appropriate prescription for the perioperative care of patients with CIEDs.

**Consensus document:** The document represents the consensus of the writing committee, which was developed as described above. In writing a “consensus” document, it is recognized that consensus does not mean that there was complete agreement among all writing group members. The expert panel identified those aspects of perioperative management of CIEDs for which a true “consensus” could be achieved. Surveys of the entire writing group were used to identify these areas of consensus. For the purposes of this document, they defined a consensus as 85% or greater agreement by the authors of this document.

**Appropriate use of this document:** When using or considering the guidance given in this document, it is important to remember that there are no absolutes with regard to many

clinical situations. The ultimate judgment regarding care of a particular patient must be made by the health care provider and patient in light of all the circumstances presented by that patient, the management options available, as well as the relative risks and benefits. This document focuses on the management of patients with CIEDs who are undergoing medical procedures. The writing committee focused specifically on perioperative management of the CIED and explicitly excluded issues concerning magnetic resonance imaging because of the evolving technology in that area. Further, they did not address the wider arena of the assessment of the perioperative clinical risk of these patients, many of whom have medical conditions that remarkably increase their surgical risk.

## 2. Introduction

The perioperative period for patients with pacemakers and defibrillators poses unique challenges to ensure a high degree of patient safety. Rapid changes in CIED technology, expanding use of potential sources of electromagnetic interference (EMI) and confusing recommendations based upon limited data have highlighted the need for a review of the known risks and a statement of recommendation. For example, in the past, there was great concern for phantom reprogramming, which is unintended random reprogramming due to EMI.<sup>1</sup> With current complex digital transmission of programming signals, this is clearly no longer a concern. Nonetheless, advice can be found in the literature and in online websites that is contradictory and leaves the physician without the information to make safe decisions for the physician's patients. Until recently, the website of at least one CIED manufacturer suggested that every electro-surgical procedure required that all CIEDs needed to be reprogrammed to an inactive mode. This approach is outside of standard of care and highlights the need for a consistent statement.

### 2.1. Methods

We selected a group of experts to review all of the available information and create recommendations. To assist us, we also invited a reference group of engineers and regulatory staff from various manufacturers of CIEDs and electro-surgical units to provide engineering and regulatory guidance to the writing group. See [Appendix 2](#). On October 23, 2009, we convened a meeting of this reference group and the writing committee; we greatly appreciate their thoughtful and knowledgeable input.

In this document, we provide our evaluation of the potential problems that can occur in these patients in the perioperative setting, and recommendations for the appropriate preoperative evaluation, the management of the CIED during the procedure and the postoperative care of the patient with a CIED who has undergone certain medical procedures.

In the past, a reasonable "one size fits all" recommendation could have been made about patients with CIEDs having surgery. Both defibrillators and pacemakers could have

the effects of electrosurgery ameliorated by a magnet. The approach of placing a magnet without analyzing the patient's situation is no longer acceptable given the complexity of both the CIEDs and patients who have these devices implanted. For example, patients may be pacemaker dependent and pace via their defibrillator. That defibrillator may or may not be programmable to an asynchronous mode. The magnet response of some defibrillators can be made non-functional by programming. There are rate responsive sensors that can affect monitoring equipment and cause untoward heart rate changes in the operating room. There are also pacemakers that act more like defibrillators. [Table 1](#) displays our general areas of consensus.

### 2.2. Primary recommended approach

Our primary recommendation is that the best prescription for the perioperative care of a patient with a CIED will be realized when that patient's CIED team is asked for advice and that advice is effectively communicated to the procedural team. To accomplish this, there must be adequate information provided to the CIED team regarding the nature of the planned procedure and potential risks for the patient with a CIED. It is our strong consensus that physicians without experience in CIED management will have a difficult time navigating through the morass of technological differences and recommendations. Therefore, we strongly recommend that the patient's CIED team (or another available CIED team) give the operative team recommendations for the perioperative management of the CIED.

The writing committee affirms that most patients will not need a de novo preoperative evaluation by the CIED management team because in most cases, the information necessary to give such a recommendation will reside in the records of the CIED clinic. In the absence of the availability of a recommendation from the patient's own CIED team, the next best approach is to have an available CIED team evaluate that patient and provide a recommendation and the

**Table 1** General principles of CIED management

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- The perioperative management of CIEDs must be individualized to the patient, the type of CIED and the procedure being performed. A single recommendation for all CIED patients is not appropriate
  - A CIED team is defined as the physicians and physician extenders who monitor the CIED function of the patient
  - The surgical or procedural team should communicate with the CIED team to identify the type of procedure and likely risk of EMI
  - The CIED team should communicate with the procedure team to deliver a prescription for the perioperative management of patients with CIEDs.
  - For most patients, the prescription can be made from a review of the records of the CIED clinic. A small percentage of patients may require consultation from CIED specialists if the information is not available.
  - It is inappropriate to have industry employed allied health professionals independently develop this prescription
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**Table 2** Problems that can occur during medical procedures

- Bipolar electrosurgery does not cause EMI unless it is applied directly to a CIED
- EMI from monopolar electrosurgery is the most common problem incurred during surgical procedures
  - Pacemakers may have oversensing and be inhibited when exposed to EMI
  - ICDs and pacemakers with antitachycardia function may be inhibited or may falsely detect arrhythmias when exposed to EMI
  - Device reset occurs infrequently with electrosurgery
  - Electrosurgery applied below the umbilicus is much less likely to cause PM or ICD interference than when applied above the umbilicus
  - Pulse generator damage from electrosurgery can occur, but is uncommon
  - Impedance based rate responsive systems may go to upper rate behavior with electrosurgery exposure
  - Risk mitigation strategies can be effective
  - Keeping the current path away from CIED diminishes the potential for adverse interaction with the CIED
  - Using bipolar electrosurgery whenever possible
  - Minimizing the length of monopolar electrosurgery bursts to 5 seconds or less
- Lead tissue interface damage from external current is considered an unlikely risk
- Cardioversion can cause reset of the CIED
- RF ablation can cause all of the interactions that monopolar electrosurgery can cause but may have a more significant risk profile due to the prolonged exposure to current
- Therapeutic radiation is the most likely source of EMI to result in CIED reset
- ECT has rarely been reported to cause EMI during the stimulus, but the more common problem with EMI may be the extreme sinus tachycardia that occurs with the seizure, prompting a need to review tachycardia therapy zones in ICDs
- GI procedures that use electrosurgery may result in interference
- TENS units can result in EMI

necessary communication with the operative team. However, it is not appropriate for the perioperative evaluation and prescription to be determined and delivered by an industry-employed allied professional (IEAP).<sup>2</sup> We strongly support the prior Heart Rhythm Society (HRS) recommendations that representative members of the CIED manufacturers cannot be placed in a position of medical responsibility to provide independent prescriptive recommendations or independent postoperative CIED care. That is well beyond their scope of practice.<sup>2</sup> That is not to say that an IEAP cannot assist with the technical part of that evaluation as long as the IEAP is under the supervision of a physician experienced in CIED management.

A CIED team is a heterogeneous group that cares for patients with CIEDs. It may be led by one or more electrophysiologists or, in some centers, it may be led by a cardiologist, anesthesiologist or surgeon with expertise in CIED management.

### 3. Identification of problems specific to patients with CIEDs during medical procedures

**3.1.** Table 2 summarizes the problems that can occur in CIED patients in the perioperative/periprocedural period.

#### 3.2. EMI and CIEDs

EMI causing malfunction of pacemakers and defibrillators is well-described.<sup>3</sup> The perioperative period is particularly problematic as patients are exposed to a number of energy sources and machinery that may generate EMI and interact with a CIED, ranging from transient effects such as pacing inhibition, inappropriate tracking of electrical noise, damage at the lead-tissue interface, pulse generator damage, and the induction of an electrical reset mode. EMI can also

interfere with rate responsive algorithms and can rarely cause pulse generator damage. The significance and extent of abnormal behavior seen in CIEDs when exposed to EMI depends on the strength, duration, and particular type of interference. The clinical impact of EMI on the patient depends upon clinical indications for their CIED, the patient's intrinsic rate and rhythm, the pacing mode, as well as the functioning of protective circuitry engineered to filter out extraneous electrical currents, and manufacturer-specific algorithms designed to minimize adverse clinical effects.

##### 3.2.1. Electrosurgical energy

Electrosurgery involves the application of focused radio frequency electrical current to produce tissue desiccation, cutting or coagulation. Electrical current can be delivered in bipolar or monopolar configurations, and with a variety of power waveforms to produce these tissue effects. For bipolar electrosurgery (e.g. ophthalmic and microsurgery) there appears to be minimal chance for an adverse CIED interaction.<sup>4,5</sup> Bipolar electrosurgery is used far less commonly than monopolar electrosurgery because, unlike monopolar electrosurgery, bipolar electrosurgery is useful only for coagulation and not dissection. Bipolar surgery involves the use of electrical forceps where each limb is an electrode. Monopolar electrosurgery is utilized for most surgical procedures. In monopolar electrosurgery, electrical current is applied via a small active electrode "pen or stylus" to the operative site, and then flows through the patient's body to a large surface area return electrode. Monopolar electrosurgery is the most common source of EMI and CIED interaction in the operating room. These interactions include inhibition, triggering unneeded tachyarrhythmia therapy, and

more serious ones such as causing electrical reset of the pulse generator. When appropriate precautions are taken, these serious reactions are infrequent.

While there have been many older reports of various untoward responses to EMI, including failure to pace, system malfunction and even inappropriate life-threatening reprogramming resulting in uncontrolled pacing activity,<sup>6-16</sup> most recent reports suggest little effect on CIED function.<sup>17</sup> Advances made in lead and generator design and in EMI resistance, as well as the development of newer surgical tools<sup>18,19</sup> have made these events, including reset, much less common in modern-day systems.

Those possible interactions of CIED with EMI can be grouped by effects on oversensing of the electrosurgery energy, initiation of noise-reversion mode, initiation of electrical reset mode, permanent damage to or failure of the CIED pulse generator, and damage to the lead-myocardial interface causing an increase of pacing thresholds.<sup>11</sup> The latter two interactions are exceedingly rare unless the energy is applied directly to the pulse generator or system electrode. Experience has shown that if the distance from the electrosurgery current path to the pulse generator and leads is greater than 6 inches, damage to or interaction with the pulse generator is unlikely.<sup>20</sup> Each of these possible interactions is discussed separately.

### 3.3. Oversensing

By far, the most frequent CIED interaction with EMI is oversensing. The result of oversensing on the pacing function of a CIED is inappropriate inhibition of pacing output. As discussed below, continuous ventricular sensing of EMI may rarely initiate temporary "noise reversion mode"<sup>21</sup> see below for details. Oversensing by an ICD has the additional problem of false detection of a tachyarrhythmia, possibly leading to inappropriate CIED therapy.

The consequences of oversensing are determined by a number of patient- and device-related factors, such as the duration of exposure to the radiofrequency current, the path of the current and the patient's underlying rhythm. Implantable defibrillators require a certain duration of continuous high-rate sensing (typically several seconds or more) to fulfill arrhythmia detection criteria. Therefore, short bursts of electrosurgery that are punctuated by several-second pauses in electrosurgery application are less likely to result in false tachyarrhythmia detection than in long continuous applications. For a patient with a robust underlying rhythm, pacing inhibition may be inconsequential; while a pacemaker-dependent patient may experience a hemodynamically unstable underlying rhythm with prolonged pacing inhibition, short electrosurgical bursts limited to 4 to 5 seconds are unlikely to result in significant hemodynamic compromise for the majority of patients. Therefore, in many instances, an approach that limits electrosurgery usage to short bursts may be a safer approach to patient-CIED management than either reprogramming the CIED or placement of a magnet over the pulse generator.

Functional pacemaker dependence can also influence hemodynamic stability in the operating room and should be considered in some patients with cardiac resynchronization devices (CRT). Most CRT patients are not pacemaker dependent, and they will not experience hemodynamic difficulties if biventricular pacing is interrupted. However, a few CRT patients do suffer acute decompensation of their congestive heart failure when CRT is inhibited for long periods of time because of reversion to a dyssynchronous electrical activation of the heart. This is the type of information that could only be provided by the CIED team managing the patient, where a comprehensive understanding of the patient, their particular CIED and the surgical environment will be considered when offering prescriptive recommendations.

Oversensing in ICDs results in inhibition of pacing and can result in the delivery of inappropriate ICD therapy. This is undesirable and avoidable. Both inappropriate antitachycardia pacing (ATP) therapy and inappropriate asynchronous ICD shocks can occur. Either of these can induce sustained ventricular arrhythmias. Despite these concerns, inappropriate ICD shock delivery to a patient under anesthesia will likely cause no adverse consequence other than, ICD shock-induced skeletal muscle contraction if the patient is not under anesthesia induced paralysis, although depending on the level of intraoperative paralysis, an ICD shock-induced skeletal muscle contraction could cause an undesired sudden movement of the patient.

While one is usually concerned about oversensing on the ventricular lead, it also commonly occurs on the atrial lead, which can lead to tracking at the upper rate limit or mode switching.<sup>21,22</sup> In general, mode switching is unlikely to compromise the patient's safety but could be a source of confusion for the surgical team if they are unaware of the occurrence.

### 3.4. Rate responsive algorithms and EMI

CIED operation can also be influenced by electrosurgery in ways that are highly specific to the model and manufacturer. For example, a CIED that uses a minute-ventilation sensor for rate response can be caused to operate at the upper limit. This occurs because the impedance measurement is miscalculated due to the current from the electrosurgery. Also in some CIEDs, the magnetic switch can be activated by electrosurgery, causing rapid pacing.

### 3.5. Reset

Device reset mode occurs infrequently, and is more commonly caused by therapeutic ionizing radiation rather than EMI.<sup>23,24</sup> Resetting of pacemakers has been rarely reported after exposure to electrosurgery.<sup>25</sup> This reset mode is a type of safety backup in case of catastrophic failure. There is consensus that the two most common precipitants of this are (1) corruption of the memory in the circuitry which is usually caused by therapeutic radiation and rarely caused by ambient radiation, and (2) a surge of energy coursing through the pulse generator that simulates the initial con-

nection of the power source at the time of manufacture. This is one of the purposes of this reset mode. In the reset mode, pacing and antitachycardia therapy parameters are unique to each manufacturer and are summarized in [Appendix 4A](#) and [4B](#). These settings are not necessarily optimal for any given patient, but neither are they likely to be unsafe for the patient. The CIED programmer is required to restore programming from reset mode back to the original pacing and arrhythmia detection/therapy parameters. If reset mode is detected, we recommend contacting the technical support service of the manufacturer, since recommendations for actions vary greatly.

Some newer Boston Scientific ICDs have Safety Core, and it is planned for future pacemakers. Safety Core is a back-up mode intended for major hardware failures that provides high-voltage therapy with a simple unipolar VVI pacing. If Safety Core occurs while the ICD Tachy Mode is OFF, the device returns to Monitor+Therapy. If there are additional high voltage faults while the device is in Safety Core, the Tachy Mode will be set to 'Tachy Therapy Not Available'. This situation has not been reported, but could for instance, occur with multiple direct exposures to therapeutic radiation. If this were to occur, the device can be returned to Monitor+Therapy by toggling Tachy Mode OFF then back to Monitor+Therapy. Tachy Mode programmability is the only programming available while in Safety Core. The pulse generator must then be replaced. This reversion to Safety Core has been rarely reported to occur during electrosurgery.

### 3.6. Pulse generator damage

CIEDs are rigorously engineered for protection from electrical energy sources such as electrosurgery, which are routinely encountered in the operating room. However, it is possible to cause failure or permanent damage to a CIED from application of electrosurgery either in immediate close proximity or directly to the pulse generator. In older-model pacemakers (with voltage-controlled oscillators), failure was more likely to occur near or at the battery end-of-life.<sup>26,27</sup> Devices with these types of oscillators are no longer manufactured, and it is unlikely that any patients currently still have one of these types of devices. Application of monopolar electrosurgery close to the pulse generator or electrodes may cause current entry with damage to the pulse generator, and should be avoided. ICDs may be somewhat more resistant to the effects of electrosurgery; however, electrical energy can still enter the pulse generator through any breach of lead insulation or through corruption of the sealing rings with conductive fluid bridge to the lead connector. Therefore, surgeries close to the CIED (such as breast, shoulder, head and neck, pulse generator replacement, or carotid procedures) should be done with bipolar rather than monopolar electrosurgery whenever that is possible. Also, strategic positioning of the electrosurgery return electrode such that the predicted current path avoids the CIED coupled with working at a lower electrosurgery power setting may reduce exposure of the CIED to the

effects of electrosurgical energy. An example is that if a patient is having surgery on the ipsilateral hand, the return electrode should be on the ipsilateral arm.

### 3.7. Lead tissue interface damage

Electrosurgical collateral damage to the lead-myocardial interface is possible, although generally thought to occur rarely with current-generation CIEDs. Monopolar electrosurgery pathways that cross or come close to a pulse generator can produce enough voltage to activate the Zener diodes and create a unipolar current path of least resistance from the pulse generator case to a pacing electrode in contact with myocardium, and then on to the return electrode. This has been rarely reported to result in damage to the tissue at that electrode surface, resulting in an increase in pacing threshold or loss of capture or induction of arrhythmias.<sup>28</sup>

### 3.8. Risk mitigation

Oversensing is the adverse interaction most likely to occur when a CIED is exposed to EMI. The anatomical site of electrosurgery application, the duration of electrosurgery application, and the position of the return electrode determine the risk of oversensing. The risk is greatest if the current path crosses the CIED and/or leads. The risk is less when the presumed current path is kept at least 6 inches away from the CIED. For example, if surgery is being done on the ipsilateral arm to the CIED, the return electrode should be placed on the same arm as opposed to placing it on the flank and exposing the CIED to all of the electrosurgical energy.

Experience has demonstrated, and literature suggests, that in a CIED implanted in the usual upper chest position, oversensing problems are unlikely for operative procedures where the application of electrosurgery will be inferior to the umbilicus and the return electrode is placed on the lower body (thigh or gluteal area).<sup>29</sup> The use of monopolar electrosurgery involving the upper abdomen, chest, arms, head and neck pose more of a risk for oversensing and damage to the CIED system.<sup>30,31</sup>

Understanding the likelihood of oversensing (either pacing inhibition or false arrhythmia detection) can assist the CIED professional in the development of reasonable recommendations. For example, if monopolar electrosurgery is applied below the umbilicus, inhibition of pacing is unlikely. The writing group feels that it is generally best to make a pacemaker asynchronous only if significant inhibition is observed, even if the patient is pacemaker dependent. Similarly, oversensing in an ICD patient is unlikely when monopolar electrosurgery is applied below the umbilicus.

Prophylactic magnet application in ICDs is an approach the committee recommends as an alternative to no intervention for procedures below the umbilicus. Some operators may be more comfortable with this approach. Magnet application will suspend arrhythmia detection and protect the patient from inappropriate EMI sensing,

which would be interpreted incorrectly by the device as an arrhythmia. The CIED team should have informed the surgical team ahead of time to the surgical team whether the patients' particular device has the magnet function programmed "on" as in a few devices this is a feature that can be programmed to "off" (see Appendix 5A and 5B). In that circumstance, the device would NOT respond to a magnet placed over the device and arrhythmia detection would NOT be suspended.

While in general, reprogramming and magnet application are options that can be considered, these approaches may simply be unnecessary for surgical procedures utilizing monopolar electrosurgery below the umbilicus, and as with any intervention, these actions should not be undertaken without a thoughtful consideration of their value. An example where reprogramming would be needed is a patient with an ICD who is pacemaker dependent and their ICD is capable of programming to asynchronous pacing. In this scenario, prolonged inhibition of pacing could not be mitigated with magnet use as an ICD will not revert to asynchronous pacing with magnet application.

This risk for pacing inhibition or false tachyarrhythmia detection is considered by the committee to be so low for surgical procedures performed on the lower extremities that neither re-programming nor magnet application is considered mandatory regardless of PM or ICD and regardless of pacemaker dependency. While this recommendation is not based upon randomized trials, it is based on extensive personal experiences of the committee and some descriptive literature.<sup>29,32</sup>

In all cases, having a magnet immediately available is critical in cases where re-programming is not chosen. When ICDs are deactivated (detections turned off or therapies turned off), patients should be monitored continuously for possible spontaneous or surgical stress-induced ventricular arrhythmia. Equipment for urgent cardioversion or defibrillation as well as emergent pacing must be immediately available.

These examples illustrate the need for the CIED team and the surgical team to communicate effectively regarding the type of procedure, the potential for EMI and the potential for patient harm. Only in this manner can the best perioperative plan be designed for the patient.<sup>32</sup>

### 3.9. Special situations

#### 3.9.1. Cardioversion

External cardioversion was associated with transient dysfunction of older CIEDs, particularly those that used unipolar leads. Individual reports noted transient loss of capture and electrical reset, particularly when using an anterior-lateral electrode position.<sup>33,34</sup> The mechanism for threshold changes at the tissue-electrode interface is poorly understood, although, tissue edema or microcauterization from exposure to high voltages have been suggested. With the widespread use of bipolar leads and incorporation of sophisticated circuitry, abnormal function of CIEDs during cardioversion is now rarely observed.<sup>34-37</sup> In a recent clinical

study of 44 patients with various types of CIEDs, no CIED malfunction was observed during cardioversion using an anterior-posterior electrode positioned with >8 cm between the anterior electrode and the CIED. The pads were placed in the anterior-posterior position. No clinically important problems such as loss of capture or undersensing, were identified during interrogations 1 hour and 1 week after cardioversion although a transient decrease in battery impedance and voltage was identified at 1 hour.<sup>36</sup> Although it has not been evaluated in a randomized trial, an anterior-posterior electrode position, with the anterior pad placed away from the pulse generator, has the theoretical advantage of creating an electrical field that is more likely to be perpendicular to the orientation of intracardiac ventricular lead electrodes. Rare reports exist that noted adverse interactions of cardioversion and CIEDs when using the anterolateral electrode position.<sup>34</sup> In a case-series of three patients, high pacing thresholds developed several hours to one day after the cardioversion, requiring lead revision.<sup>35</sup> After aortic unclamping in cardiac surgery, defibrillation energies of 10 to 30 Joules may be applied directly to the ventricles. In the experience of several committee members, occasionally, this has been associated with pulse generator reset.

#### 3.9.2. Catheter ablation for cardiac arrhythmias

Intraoperative and catheter-based ablation of rhythm disorders in patients with CIEDs involves radiofrequency or alternative energy sources. Although uncommon, radiofrequency energy delivery near CIEDs may result in various adverse consequences including electrical reset, reprogramming, oversensing, inappropriate inhibition, and undersensing.<sup>38,39</sup> Rarely, myocardial thermal lesions may occur at the tip of pacemaker and ICD leads from transmitted radiofrequency energy. Likewise, pulse generator reset is occasionally seen with cardiac RF ablation. With ICDs, inappropriate arrhythmia detection may also occur.<sup>39</sup> Newer energy sources include microwave energy. While several studies have shown that household microwave energy has no significant impact on pacemakers and ICDs secondary to adequate shielding from microwave energy in modern microwave ovens,<sup>39,40</sup> no specific studies or recommendations are available in terms of microwave ablation, whether the energy is delivered to the epicardium or endocardium. The effect of direct-current energy in close proximity to a CIED may certainly cause pulse generator malfunction.<sup>16,41</sup>

#### 3.9.3. Diagnostic radiation

Diagnostic radiation generally does not have any significant adverse effect on CIEDs, although rare instances of adverse oversensing and electrical reset have been reported. However, with the newest generation of multislice computed tomography machines that use higher radiation doses, transient effects on CIEDs due to oversensing have been reported with both maximal and standard doses used during computed tomography scanning.<sup>42,43</sup> Oversensing have been reported when the beam was directed over the generator for an abnormally delayed exposure. Similarly, in an in

vitro study, transient oversensing was observed infrequently.<sup>42</sup> Partial electrical reset was also uncommonly seen.<sup>42</sup>

#### 3.9.4. Therapeutic radiation

While diagnostic radiography rarely interferes with CIED function, therapeutic radiation can have several potential damaging effects on CIED function, especially when the beam is directed onto the pulse generator.<sup>44-46</sup> Modern CIEDs utilize metal oxide semiconductors (CMOS) in the integrated circuitry. These circuits may be more readily damaged by lower levels of radiation than were older devices that were designed with discrete components. When the semiconductors are exposed to ionizing radiation, damage occurs to the silicon and the silicon oxide insulators within the semiconductor.<sup>47</sup> The mechanism of failure is unpredictable, since any part of the semiconductor can be damaged. Sudden output failure or runaway pacing has been reported<sup>23,24</sup> in older devices and remains at least a theoretical concern with present CIEDs.<sup>48</sup> Reports in the literature include damage from radiation doses as low as 10 Gy, while safe operation has been reported with accumulated doses of 30 to 150 Gy.<sup>48</sup> Therefore, direct radiation of pacemakers and ICDs should be strictly avoided and accumulated doses should generally not be allowed to exceed 5 Gy.

Severe malfunctions have been reported in ICDs when the pulse generators were exposed to photon radiation.<sup>49</sup> Both the detection and charge times for shock delivery increased with accumulated radiation dose, and charge time dramatically increased at less than 50 Gy delivered when compared to a charge time of ICDs implanted at the same time.<sup>49</sup> In another study, similar results were obtained with 9 MV photon radiation.<sup>50</sup> Eight of 17 pacemakers in one study failed before 50 Gy, while four of six exposed to electron radiation failed before 70 Gy.

For all cases, shielding options should be discussed with the radiation oncologist and physicist responsible for treating the patient. For all therapeutic radiation, there should be sophisticated modeling of the radiation that will be absorbed by the pulse generator. Each CIED manufacturer has recommended tolerances for each pulse generator. If the modeling suggests that there will be an exposure that is at or near the tolerance of that specific pulse generator, repositioning of the generator to another site may be required. Risks and benefits of relocation will vary depending upon the patient, radiation therapy plan, and the degree of pacing dependence. When a pulse generator is to be moved, some physicians will extract the system and others will use lead extenders and move the pulse generator with a plan to put the pulse generator back in its original location after the therapy is completed.

Electrical reset may occur as a result of scatter neutron exposure during conventional radiotherapy, and the probability of scatter neutrons increases as the photon beam energy increases. Importantly, the use of conventional x-ray shielding during radiotherapy does not protect the pulse

generator from the effects of the scattered neutrons. If the photon beam energy exceeds 10 MV, evaluation of CIED function immediately after each radiotherapy treatment might be necessary. Electrical reset requires reprogramming of device parameters. Electron beam therapy has not been reported to cause electrical reset of presently used CIEDs.

#### 3.9.5. Electroconvulsive therapy

In electroconvulsive therapy (ECT), an electric current is delivered to the brain, triggering a brief seizure. This has been associated with abnormal CIED function.<sup>51</sup> There are several small case reports spanning both older and modern day devices that illustrate the effects of ECT on pacemaker and ICD function. Despite the high amount of current used in these procedures, no report demonstrated CIED malfunction or reversion to a backup safety mode.<sup>51-53</sup> The noise reversion mode may also be triggered. An additional concern is myopotential oversensing from the resulting seizure activity. Although transient, this can be a significant issue in pacemaker-dependent patients, especially those with unipolar lead configurations. Another clinical concern is the potential for marked sinus tachycardia, which could cause an inappropriate shock by an ICD.

There are no reports of direct damage to CIED circuitry as a result of the electric current, although inhibition of pacing is certainly possible. The duration of the electrical stimuli is typically quite brief (1 to 2 seconds). Thus, hemodynamically significant inhibition of pacing is unlikely. Similarly, with standard programming on ICDs, inappropriate shocks from this brief electrical therapy are also unlikely. If a prolonged stimulus is used, then there is some potential for bradycardia or inappropriate ICD shocks. Pacemaker-dependent patients should not have devices programmed with unipolar sensing and should have their devices be made asynchronous. When magnet responses is programmed ON in the appropriate device, placing a magnet over the pacemaker rather than actual interrogation and reprogramming is reasonable. The physician needs to know the ICD tachycardia detection rate and should have a magnet handy in case the sinus rate gets near that rate. Pretreatment with short-acting beta-adrenergic blockers might also be considered in such patients.

#### 3.9.6. Transurethral needle ablation (TUNA)

TUNA is a therapeutic procedure for patients with benign prostatic hypertrophy. Radiofrequency energy is used to ablate prostatic tissue. Effects on CIEDs have been rarely described.

#### 3.9.7. Transurethral resection of the prostate (TURP)

Electrosurgery or RF energy may be used during transurethral prostatic resection. Placement of the patient return electrode on the buttock or thigh minimizes the effects on the CIED. Damage to the pulse generator is unlikely, and magnet application over the pacemaker in patients who are pacemaker dependent can be considered, although oversensing is also unlikely to occur.<sup>32,54</sup> In addition to placing the patient return electrode on a leg, limiting applications of



TURP-related electrosurgery to 1 to 2 seconds every 10 seconds can reduce the risk of inhibition in individuals who are pacemaker dependent and avoid ICD inappropriate detections as it does in all applications of monopolar RF energy.

### 3.9.8. Gastroenterology procedures

**3.9.8.1. Colonoscopy or gastroscopy.** There is no evidence of gastroscopy or colonoscopy interfering with cardiac pacemakers or defibrillators unless electrosurgery is used. If electrosurgery is planned, EMI should be anticipated and the recommendation should be the same as for surgical procedures using monopolar electrosurgery above the umbilicus. In one study of 92 patients undergoing gastroscopy with electrosurgery, there were no serious effects and oversensing was infrequently seen.<sup>55</sup> Inappropriate delivery of antitachycardia therapy has been reported<sup>11,13,20</sup> when detection was not inactivated. Therefore, it is recommended that reprogramming of an ICD to inactivate tachyarrhythmia detection be performed prior to procedures where electrosurgery is to be used. Alternatively, a magnet could be used if the magnet can be secured over the pulse generator. Inhibition of sensing using a magnet is reasonable if the magnet can be secured. In the situation of pacemakers and pacemaker-dependent patients, short electrosurgical bursts may be a reasonable approach without the need to reprogram the pacemaker or place a magnet. A magnet should, however be available should prolonged periods of inhibition occur.

When possible, a bipolar electrosurgery system should be used, and if monopolar electrosurgery is used, regardless of the type of endoscopy, the patient return electrode should be placed lower in the chest or over the abdomen to avoid a current pathway pattern near the CIED and leads.

**3.9.8.2. Capsule endoscopy.** Capsule endoscopy uses a digital camera encased in a capsule with light-emitting diodes, a battery, and a transmitter. Radiofrequency transmission of the data occurs when the capsule emits short bursts of radiofrequency energy, approximately 2 per second for an 8-hour diagnostic period. CIED malfunction has not been reported, and there is no report of radiofrequency emissions from commonly used capsules (M2A) causing cardiac device malfunction. In spite of this, current recommendations discourage the use of capsule video endoscopy in patients with CIEDs because of a theoretical risk for device-device interference. Whereas it seems more likely that the pacemaker will inhibit capsule video recording,<sup>56</sup> case reports have demonstrated no effect of the capsule video on pacemaker activity or an increased risk for backup safety mode reversion.<sup>57-59</sup>

Because capsule endoscopy has not yet been reported causing interference to a pacemaker or ICD and theoretical interactions are likely mild, The writing committee recommends no specific interventions on the pacemaker or defibrillator. However, we do note that the manufacturer of this

device states that its use is contraindicated in patients with pacemakers and ICDs.

### 3.9.9. Tissue expanders

Devices called tissue expanders are used by plastic surgeons to prepare for reconstructive breast surgery. They sometimes incorporate magnets to direct a needle used to fill the expander with fluid. These magnets are often close enough to a CIED that magnetic switch activation can occur. This causes pacemakers to pace asynchronously and caused ICDs to ignore detection of tachycardias. Therefore tissue expanders that employ magnets should not be used in patients with pacemakers or defibrillators.<sup>60</sup> These patients should receive tissue expanders without magnetic aiming guides.

### 3.9.10. TENS and spinal cord stimulators

TENS can interfere with pacemaker and ICD function. Adverse responses include inhibition of pacing (or triggering noise reversion mode) and inappropriate ICD therapy due to misinterpreted electrical noise. The transcutaneous impulses could also be misinterpreted as inappropriate supraventricular arrhythmia in atrial tachycardia devices.

In one study, no malfunction was noted in 51 patients with 20 older CIEDs being evaluated.<sup>61</sup> Anecdotal reports of malfunction, however, exist with older and newer CIEDs.<sup>62</sup> Inappropriate tracking in DDD or VDD programmed devices may occur, but are likely uncommon with no reports in the literature.

In general, TENS is not recommended in pacemaker-dependent patients. It is conceivable that an exception can be made when (1) the TENS is an exceptionally important therapy for that particular patient, (2) robust testing has been performed and safety is confirmed and the therapy is used intermittently. The initial testing required includes live monitoring with TENS activated followed by intermittent Holter monitoring while the patient is using the TENS, to look for pacemaker inhibition. If a TENS unit is to be used, the pacemaker should be programmed as follows: sensing polarity set to bipolar; impedance-based sensors such as minute ventilation should be off. The TENS unit should not use the burst mode. The electrodes should be further away from the CIED but close to each other and in a horizontal (rather than vertical) orientation. High-frequency stimulation (more than 30 Hz) should be maintained at all times. TENS units should be avoided in the thoracic cervical shoulder, upper lumbar, and chest areas due to the proximity of the ICD or PM and lead system. Testing can be performed by turning detections on and therapies off to see if ICD detections can be left on, using maximum TENS output and maximum (i.e., lowest value) ICD sensitivity settings.

These recommendations generally extend to spinal cord stimulators as well. There are a few reports that have suggested that, with proper precautions, bipolar neurostimulators can be used safely with CIEDs.<sup>63-69</sup> Individual testing is recommended to be certain there is no evidence of pace-

maker inhibition or false arrhythmia detections. We feel that it might be necessary to demonstrate that spinal cord stimulation during ventricular fibrillation (VF) does not cause problems with sensing.

### 3.9.11. Radiofrequency identification devices (RFID)

Auto identification technologies including (RFID) are increasingly used as a means to decrease cost and improve patient safety particularly in the operating room.<sup>70</sup> Wireless technology used in this specific setting has documented potential for interference with other complex electronic devices, including monitoring equipment and cardiac devices.<sup>71,72</sup> Electromagnetic interference is dependent on distance and frequency of the RF source, occurring more significantly at lower frequencies (in vitro interaction 50% to 70% with 134 kHz vs. no interaction with 915 MHz) and at closer distances peaking with direct contact.<sup>73</sup> Evidence for exact effects on pacemakers and defibrillators is minimal with standard autoidentification systems (those using their own power supply or an external field to operate).<sup>72</sup> It seems prudent to avoid placing identification tags close to the pulse generator. It is important to emphasize that the Food and Drug Administration has received no incident reports of CIED electromagnetic interference associated with any RFID system.<sup>73</sup>

### 3.9.12. Other wireless technology

Medical equipment may involve wireless technology. These include radiofrequency identification systems, wireless telemetry systems, and flow pumps that communicate with monitoring systems and blood chemical analysis systems. Several studies have evaluated interaction of global communications systems (GSM) with CIEDs and found interference when the wireless device is closer than 10 cm to the CIED pocket.<sup>74,75</sup>

It appears that the extent of external interference is independent of the sensing configuration (unipolar vs bipolar) and the type of signal. Cellular phone interactions with ICDs are well described and can be easily mitigated by keeping the energy source away from the pulse generator.<sup>75,76</sup> The extent of interference is dependent on the carrier frequency used for data transmission by the respective device.<sup>77,78</sup> As new communications systems are developed, they will require testing for interference with pacemakers and defibrillators.

### 3.9.13. Electromyelograms (EMGs) and nerve conduction testing

Few studies are published regarding the effects of nerve conduction studies and EMGs on CIED function. The amount of current used in these studies is very small and unlikely to affect CIED behavior. Although a theoretical concern exists if they are performed near the CIED generator, there are currently no reports on CIEDs reverting to a backup safety mode or unanticipated device malfunction.<sup>79,80</sup>

### 3.9.14. Lithotripsy

Extracorporeal shockwave lithotripsy has been described to induce inappropriate sensing and suppression of pacing. Case reports<sup>81</sup> have described occurrences of backup safety mode reversion in pacemakers after these procedures, but these events remain extremely rare. Experiences with ICDs have also been reported and have shown no reports of backup safety mode reversion.<sup>82,83</sup> A recent review article has suggested practice guidelines on the proper management of CIEDs based on current practices and modern-day device technologies.<sup>84</sup> This includes continuous telemetry, having a CIED team available, terminating lithotripsy for arrhythmias, using a magnet only if inhibition occurs and interrogation in the case of complications. Overall, the risk to the CIED system is low.

### 3.9.15. Iontophoresis

Transdermal drug delivery via iontophoresis relies on delivering a small amount of DC current in a localized fashion. There are no reports of this technology in altering CIED functionality.

### 3.9.16. Photodynamic therapy

These technologies utilize light and therefore do not generate electromagnetic interference that would affect CIED function. There are no reports of this technology in altering CIED functionality.

### 3.9.17. Dental procedures

There is a single report of interference between dental tools and CIEDs.<sup>85</sup> When carefully reviewed, the interference demonstrated was interference with telemetry, not device function.<sup>86</sup>

## 3.10. CIED responses to electrical interference

### 3.10.1. Magnet response

Magnet application is often used in the perioperative period to change the behavior of CIEDs. Appendix 5A and 5B displays the nature of the magnet response for currently implanted CIEDs. It is recognized that magnet features may change as manufacturers release new devices and that CIED teams will need to apprise themselves continually of these differences. A simple doughnut magnet (typically 90 Gauss) is the standard magnet used for inhibiting tachyarrhythmia detection in CIEDs. A magnet will not render the pacemaker function in an ICD asynchronous. This magnet should be in the room with any patient undergoing a procedure that involves the potential for EMI. A magnet applied to a pacemaker will avoid inhibition by initiating asynchronous pacing, as well as gain control of inappropriate tracking or rate response operation with the device in the operating room.<sup>87</sup> However, there are exceptions when CIED magnet functions are programmed differently by virtue of manufacturer, and device function is either transiently or completely unaffected by magnet application. It is important for the CIED team to notify the surgical team if this is the case.

**3.10.1.1. Pacemakers.** For pacemakers, the magnet generally causes asynchronous pacing by closing a magnetic switch. Older pulse generators used a mechanical reed

switch, while newer generators either employ a Hall sensor or giant magneto resistive (GMR) sensor, neither of which have moving parts and are therefore more robust. The pulse-generator-specific magnet behavior (i.e., magnet pacing rate and whether the device responds with unique characteristics to placement of a magnet) should be known to the operating room staff to ensure appropriate application of the magnet. Some antitachycardia pacing devices (e.g. Medtronic AT500) do *not* convert to an asynchronous pacing mode in the presence of a magnet; however, atrial antitachycardia pacing is suspended. It is important to realize that in some cases an unnecessary and inappropriate use of a magnet can be associated with significant untoward hemodynamic effects; for example, because the magnet rate may compete with the patient's own heart rate resulting in competing rhythms. Or due, for example in a dual chamber pacemaker, to a magnet determined A-V delay which may be shorter than the patients' intrinsic AV conduction resulting in undesirable ventricular pacing. Rarely, asynchronous pacing in a patient with a competing intrinsic rhythm can also potentially induce an atrial or ventricular arrhythmia. Many current pacemakers have an autocapture algorithm, at least in the ventricular chamber and often also the atrial chamber. When these functions are operating, the programmed device amplitude output may be re-set above the autocapture threshold. Placing the magnet over a pacemaker will alter the pacing amplitude in several manufacture's devices while in others it will continue to pace at the last programmed output. With BIOTRONIK, Boston Scientific and Medtronic pacemakers, placing a magnet will not alter the programmed amplitude (which will be the last autocapture determined output if that feature is enabled). In St. Jude and ELA/Sorin pacemakers, magnet placement temporarily changes the output to a higher output setting (See [Appendix 5A](#)).

**3.10.1.2. Implantable cardioverter-defibrillators (ICDs).** For implantable cardioverter defibrillators (ICDs), tachycardia detections can be disabled by magnet application without having an effect on pacing mode or rate (see [Appendix 5B](#)). Some Boston Scientific (Guidant) ICDs may be permanently deactivated by magnet application, necessitating reprogramming of the pulse generator prior to the patient being removed from a cardiac monitor.<sup>88</sup> In most CIEDs, however, arrhythmia detection will be automatically re-enabled when the magnetic field is removed. An important feature unique to ICDs is that magnet response will not affect ICD antibradycardia pacing functions. Permanent reprogramming can also be used in lieu of a magnet to suspend ICD arrhythmia detection. However, resumption of therapy to treat spontaneously occurring ventricular tachycardia (VT) or VF will not occur unless the CIED is reprogrammed.

### 3.10.2. Noise response to EMI

If high-frequency signals of sufficient strength are continuously sensed in the ventricular refractory period, noise reversion may occur during which time the CIED paces asynchronously and tachyarrhythmia therapy is suspended.<sup>89</sup> The noise

reversion mode is a manufacturer-specific algorithm to minimize the impact of electromagnetic interference. Automatic exit from noise response mode occurs once the noise is no longer present.<sup>90</sup> Since noise response algorithms are designed to respond to continuous uninterrupted noise, the noise reversion algorithm may not provide adequate protection to the pacemaker-dependent patient. This is because most EMI encountered in the operating room environment is sporadic, and therefore it is more likely that transient inhibition of pacing or inappropriate pacing at the programmed upper rate limit will be observed despite a noise reversion algorithm. Consequently, one should not rely on the noise reversion mode alone to handle EMI sources such as monopolar electrosurgery.

## 4. Preoperative evaluation of a patient with a CIED

Timely, thorough preoperative evaluation is essential for the safe perioperative management of patients with CIEDs and should include a multidisciplinary and systematic approach. The preoperative evaluation presents an opportunity for mutual understanding between the CIED team (cardiologist, cardiac electrophysiologist, device clinic nurses and staff) and the perioperative team (anesthesiologist, surgeon, perioperative assessment team). We assert that the most effective prescription for the perioperative care of a patient with a CIED will be obtained from the team that monitors that patient and device combined with an understanding of the procedure to be performed and risk for EMI. The general principles of the preoperative evaluation are enumerated in [Table 3](#).

### 4.1. Preoperative/preanesthesia assessment by the perioperative team

During the preoperative evaluation of a CIED patient, several elements of the history need to be obtained before customizing a perioperative management plan. History and physical examination will determine the presence of a CIED. The perioperative management team should consult the CIED managing team for recommendations regarding perioperative device management. This is true whether the patient is having the surgical procedure in the same institution where he/she received their CIED care as well as if the two sites are remote from each other. The consultation request should provide the elements in [Table 4](#) to the CIED physician/team to obtain informative and personalized recommendations. These data will allow the CIED team to gauge the risk of the planned procedure and provide recommendations to the procedure team to help mitigate those risks.

The patient should be queried to identify the CIED team that cares for them. If this is not available, then data regarding the make and model of the CIED can be obtained from a wallet-sized card that is given to the patient following implantation. If the patient cannot provide information and the CIED management physician is unavailable or unknown, an identifier is located on the generator and can be viewed on a chest radiograph. This will allow for the identification of the pulse generator. The patient registration

**Table 3** Preoperative recommendations

- The Procedure team must advise the CIED team about the nature of the planned procedure.
- The CIED team will provide guidance in the form of a prescription to the procedure team for the management of the CIED.
- General principles guiding this prescription include the acknowledgement that:
  - Inactivation of ICD detection is *not* a universal requirement for all procedures.
  - Rendering PMs asynchronous in pacemaker-dependent patients is *not* a universal requirement of all procedures.
  - Pacemakers that need to be protected from inhibition may be made asynchronous by programming or by placement of a magnet applied over the pulse generator, provided the pulse generator is accessible.
  - ICD arrhythmia detection can be suspended by placement of a magnet over the pulse generator, provided the pulse generator is accessible.
  - A magnet placed over an ICD generator will not render pacemaker function in an ICD asynchronous.
  - Inactivation of ICD detection is recommended for all procedures using monopolar electrosurgery or RF ablation above the umbilicus.
  - Rendering a PM asynchronous in a PM-dependent patient is preferable for most procedures above the umbilicus.
  - In pacemaker patients, no reprogramming is usually needed if the electrosurgery is applied below the level of the umbilicus.
- All patients with pacemakers undergoing elective surgery should have had a device check as part of routine care within the past 12 months that identifies the required elements specified below.
- All patients with ICDs undergoing elective surgery should have had a device check as part of routine care within the past 6 months that identifies the required elements specified in Table 4.

department of each of the major manufacturers can be queried by telephone to see if they have a record of the patient's most recent implant.

It should be acknowledged that the CIED management team will provide advice about the pacemaker or defibrillator system but will often not be the same health care team that provides for the patient's usual cardiac clinical care and therefore the perioperative cardiac risk assessment. If upon review of the patient's CIED interrogation and review of the medical record and or in-person evaluation, the CIED management team identifies new or worsened arrhythmias or new clinical symptoms, then there should be collaboration with the patient's clinical management team for further assessment as needed.

#### 4.2. Preoperative assessment by the CIED management team

The critical data that the CIED team needs to identify and provide to the procedural team include the indication for the CIED implant, the CIED model, programming, battery longevity, leads types and functionality (Table 5). In most cases, patients with CIEDs have regular CIED evaluations as part of their routine care, and the CIED team will be able to use the information in the patient's records to generate the perioperative prescription. The HRS/European Heart Rhythm Association (EHRA) expert consensus statement on the monitoring of CIEDs, recommends that the minimum frequency for monitoring pacemakers is every 3 to 12 months, and every 3-6 months for ICDs and CRT-Ds either by in-person or remote evaluation.<sup>91</sup> All patients with pacemakers undergoing elective surgery should have a device check as part of routine care within the past 12 months that identifies the required elements specified below. All patients with ICDs or any CRT device (Cardiac Resynchronization Therapy Defibrillator (CRT-D), Cardiac Resynchronization Therapy (CRT-P)) undergoing elective surgery should have had a device evaluation as a part of routine care within the past 6 months that identifies the required elements specified

below. If the perioperative management team identifies a patient who has not been seen in the appropriate time frame, a consultation with the patient's CIED team or an available CIED team should occur prior to the anticipated procedure. These 6- and 12-month guidelines are intended for stable patients without intervening medical problems that might adversely affect the function of the CIED. The CIED team may want to shorten these times if the patient has problems such as unstable heart failure, active ischemia or the like, or modify for their own institutions.

The suggested elements of that communication are listed in table 5. These elements can be addressed in a pre-formatted document completed by a member of the CIED managing provider team. A copy of the most recent interrogation may be helpful for some operative teams with special expertise in pacing. *The date of the most recent CIED evaluation* should be supplied to verify that a pacemaker was evaluated within 12 months and an ICD or CRT device within 6 months.<sup>91</sup> Since ICD patients tend to be more ill and changes in their status are more

**Table 4** Essential elements of the information given to the CIED physician

- Type of procedure
- Anatomic location of surgical procedure
- Patient position during the procedure
- Will monopolar electrosurgery be used? (if so, anatomic location of EMI delivery)
- Will other sources of EMI likely be present?
- Will cardioversion or defibrillation be used?
- Surgical venue (operating room, procedure suite, etc)
- Anticipated postprocedural arrangements (anticipated discharge to home <23 hours, inpatient admission to critical care bed, telemetry bed)
- Unusual circumstances: cardiothoracic or chest wall surgical procedure that could impair/damage or encroach upon the CIED leads, anticipated large blood loss, operation in close proximity to CIED

**Table 5** Essential elements of the preoperative CIED evaluation to be provided to the operative team

- 
- Date of last device interrogation
  - Type of device—pacemaker, ICD, CRT-D, CRT-P, ILR, implantable hemodynamic monitor
  - Manufacturer and model
  - Indication for device:
    - Pacemaker: e.g., sick sinus syndrome, AV block, syncope
    - ICD: primary or secondary prevention
    - Cardiac resynchronization therapy
  - Battery longevity documented as >3 months
  - Are any of the leads less than 3 months old?
  - Programming
    - Pacing mode and programmed lower rate
    - ICD therapy
      - Lowest heart rate for shock delivery
      - Lowest heart rate for ATP delivery
    - Rate-responsive sensor type, if programmed on
  - Is the patient pacemaker dependent, and what is the underlying rhythm and heart rate if it can be determined?
  - What is the response of this device to magnet placement?
    - Magnet pacing rate for a PM
    - Pacing amplitude response to magnet function
    - Will ICD detections resume automatically with removal of the magnet? Does this device allow for magnet application function to be disabled? If so, document programming of patient's device for this feature
  - Any alert status on CIED generator or lead
  - Last pacing threshold—document adequate safety margin with the date of that threshold
- 

likely, the checks (including pacing threshold checks) are recommended at a higher frequency. This date is requested to verify the timeliness of the data for the planned procedure.

The *type of device* should be identified: pacemaker (single or dual chamber), ICD (single or dual chamber), CRT-P or CRT-D, implantable loop recorders (ILR), or an implantable hemodynamic monitor. The manufacturer and generator model need to be noted.

It is important that the procedure team knows the *indication for the CIED implant*. For example, common indications for pacemakers include sinus node dysfunction, AV block, or syncope. Common indications for ICDs include primary or secondary prevention (for a history of known ventricular tachyarrhythmias either before or after ICD implantation). Some patients have indications for both pacing and arrhythmia therapies. CRT devices are placed to improve heart failure symptoms, but often these patients also have a standard indication for a defibrillator or pacemaker.

The *battery longevity* should be noted and determined if it is adequate for the perioperative period. The estimated battery longevity ideally should be at least 3 months. If it is not, there may be an increased sensitivity for pulse generator damage from EMI. Also, the CIED team needs to take into account the expected postoperative course. For example, if there is an expectation of a prolonged period of radiation and or chemotherapy after surgery, and the pulse generator has limited expected longevity, one might con-

sider recommending that the pulse generator be replaced before surgery.

The *programmed pacing mode* should be documented (e.g., VVI, VVIR, DDD, DDDR). This is important because some modern modes use atrial pacing only until a beat is dropped (AAI → DDD), whereupon they switch to dual chamber-pacing, termed in one manufacture's device as "MVP" mode (managed ventricular pacing). Without knowledge of these kinds of programming, pacemaker malfunction may be misdiagnosed. Seemingly innocent, pseudo-malfunctions could delay surgery, cause inappropriate therapy, or generate needless communications with CIED management personnel. For ICDs and antitachycardia enabled pacemakers, it is important to document the *lowest heart rate for which the CIED will deliver therapy*, either antitachycardia pacing or shocks.

It should be noted if the CIED is programmed for rate-responsive pacing and the untoward responses that the particular sensor might create in the procedure room. For example, an impedance (minute ventilation) sensor may exhibit faster than expected pacing rates when the patient is ventilated, either mechanically or with a bag and mask. Artifacts from these sensors may also be detected on telemetry monitoring systems. External respiratory impedance monitors may stimulate the minute ventilation sensor to increase paced rate. Thus, consideration could be given to disabling these sensors for the perioperative period. Likewise, activity-based sensors may accelerate the heart rate with moving the patient or with prepping of the skin.

It is important to know if the patient is *pacemaker dependent*. Pacemaker dependence may be absolute or functional. Note that patients who are not usually pacemaker dependent may become pacemaker dependent intraoperatively (e.g., with sedation, direct or indirect vagal stimulation, certain high potency opiates, other anesthetics or other pharmacologic agents).<sup>92</sup> The *underlying cardiac rhythm*, if any, should be determined. This may be done by temporarily programming the CIED to the VVI mode at 40 beats per minute, or by completely inhibiting pacing.

It should be noted whether any of the leads are new (<3 months old). Leads implanted within the last 3 months are at greatest risk for dislodgement during cardiac surgery, central line placement, or manipulation of intracardiac catheters.

The *magnet response* of the CIED should be documented (Appendix 5A and 5B). In most pacemakers, a magnet will lead to asynchronous pacing at a rate that varies with each manufacturer. In most ICDs, a magnet will lead to suspension of tachyarrhythmia detection with inhibition of tachycardia therapies but will not affect the pacing mode. Magnet application may reprogram some Boston Scientific devices to permanently disable tachyarrhythmia detection after 30 seconds of application. There are also some pacemakers where magnet application does not result in asynchronous pacing if the "magnet response" parameter had been reprogrammed.

If there is an *advisory* on the lead or pulse generator, this should be relayed to the operative team if it has any impact on the risks of the perioperative management. For example, it may be useful to warn the operative team about a threatened lead failure that might cause oversensing. However, the majority of advisory situations would not be expected to interfere with the safety of the patient undergoing a surgery/procedure with exposure to EMI.

Adequate *pacing safety margin* needs to be ensured for each lead. The usual recommendation is that the stimulus output be 2 to 3 times pacing threshold or at least 3 times the threshold pulse width, although with LV pacing less than a two fold amplitude or pulse width safety margin is often programmed. Many current CIEDs perform automatic threshold testing and adjust the stimulus output at a safety margin which could be less than 2-fold the threshold. This feature is available in some newer pacemakers and ICDs. This automatic threshold determined output setting may be acceptable for the surgical procedure; however, consideration may be given to temporally increasing the stimulation outputs during the operative period. It is important to note that real-time autocapture algorithms may reduce the safety margin below our recommendations. Placing a magnet or reprogramming a *pacemaker* to asynchronous, suspends the autocapture feature from operating during that time. Should loss of capture be observed, a programmer would be needed to set the outputs at an higher amplitude. An advantage however, to using a magnet over the pacemaker rather than reprogramming is that upon removal of the magnet, most manufacturers' current devices (BIOTRONIK, Boston Scientific, ELA/Sorin, St. Jude Medical) will immediately perform an autothreshold test and/or beat-to-beat surveillance for loss of capture. Thus, any loss of capture would likely be quickly mitigated with a higher pacing output delivered from the device. While Medtronic pacemakers will perform autothreshold checks only at the scheduled intervals, the nominal safety margins are always set two times the autothreshold, minimizing the chance of loss of capture.

### 4.3. CIED prescription for perioperative device management

A product of the preoperative CIED assessment is a recommended prescription for device management in the perioperative period. A qualified physician or allied health professional, operating under the supervision of a qualified physician, should recommend a prescription for management of the CIED device during the planned surgery/procedure when EMI will likely be present. If the CIED team professional is unable to complete a prescription due to missing elements, then the patient may need to be seen prior to the scheduled procedure. This prescription should not be derived by an industry-employed allied health professional. Some clinicians may choose to reprogram the pacing mode or deactivate the sensor at this time. These elements can be

addressed in a preformatted document completed by the CIED managing provider.

Elements of the device prescription should include any recommendations for programming required for the procedure, including if this can be performed prior to the day of surgery or if it must be performed on the day of surgery. The recommendations should include reprogramming of the pacing mode, inactivation of tachyarrhythmia detection (ICDs) or potential inactivation of minute ventilation rate sensors. Additionally, recommendations should be given about whether, for elective procedures, a magnet could be used, and the appropriate method to *use the magnet* (see Intraoperative Management section for discussion of intraoperative magnet use, and Appendix 5A and 5B), recommendation for the follow-up assessment and reprogramming needed after surgery, and the timing of postoperative CIED evaluation (e.g., prior to removal from rhythm monitoring, one month, routine follow-up, see *postoperative CIED evaluation*).

### 4.4. Protocol for cases of emergency procedures

It is expected that some patients with CIEDs will present for urgent or emergent surgery. Some hospitals will have 24 hour per day coverage by a CIED professional. Most hospitals will not have this luxury. In these cases, it may be necessary to proceed with surgery without obtaining all of the information that is described above. This is clearly a suboptimal solution and should only be used in an urgent or emergent situation. See Table 6.

The first step is to identify the type of device. This is critical, and patients may not always know whether they have an ICD or a pacemaker. We recommend first getting either the medical records or the registration card from the patient. If a card is available, the physician may need to call the company to clarify the device type. As a backup, the chest radiograph can be examined. Defibrillators that have transvenous leads all have radiodense coils at least in the right ventricle (single coil lead), and many have an addition coil that will be noted either in the atrium or high superior vena cava/innominate vein location (dual coil or separate superior vena cava lead). Pacemakers do not have those coils. See Figure 1. (PA radiographs of an ICD and pacemaker).

#### 4.4.1. Pacemakers: emergency protocol

For pacemakers, determine if the patient is pacing by obtaining a 12-lead electrocardiogram or rhythm strip documentation. If pacemaker spikes are noted in front of all or most P wave and/or QRS complexes, the assumption for the purpose of an emergent surgery is that the patient is pacemaker dependent. If there is no evidence of pacing, proceed with the surgery but have a magnet in the room in case there is the development of bradycardia or tachycardia. If during the procedure a bradycardia or tachycardia occurs, apply the magnet by securing it over the CIED generator. If, on the other hand, the preoperative evaluation shows that the patient is pacing, then more attention needs to be paid to assuring continued pacing. There are several options for patients who demonstrate pacing on the electrocardiogram.

**Table 6** Approach to emergent/urgent procedures**Identify the type of device**

- ICD, pacemaker, CRT-ICD, or CRT-pacemaker. Options for help in identification are:
  - Evaluate the medical record
  - Examine the patient registration card
  - Telephone the company to clarify device type
  - Examine the chest radiograph

**Determine if the patient is pacing**

- Obtain a 12-lead electrocardiogram or rhythm strip documentation
- If there are pacemaker spikes in front of all or most P wave and/or QRS complexes, assume pacemaker dependency
  - **Pacemaker dependent?#**
    - **Yes:** pacemaker (not ICD) → Use short electrosurgical bursts, place magnet over device for procedures above umbilicus or extensive electrosurgery, have magnet immediately available for procedures below umbilicus
      - Monitor patient with plethysmography or arterial line
      - Transcutaneous pacing and defibrillation pads placed anterior/posterior
      - Evaluate the pacemaker before leaving a cardiac-monitored environment
    - **Yes:** ICD or CRT-D\* → Place magnet over device to suspend tachyarrhythmia detection, use short electrosurgical bursts†
      - Monitor patient with plethysmography or arterial line
      - Transcutaneous pacing and defibrillation pads placed anterior/posterior
      - Evaluate the ICD before leaving a cardiac-monitored environment
    - **No:** pacemaker (not ICD) → Have magnet immediately available
      - Monitor patient with plethysmography or arterial line
      - Transcutaneous pacing and defibrillation pads placed anterior/posterior
      - Evaluate the pacemaker before leaving a cardiac-monitored environment
    - **No:** ICD or CRT-D → Place magnet over device to suspend tachyarrhythmia detection, use short electrosurgery bursts‡
      - Monitor patient with plethysmography or arterial line
      - Transcutaneous pacing and defibrillation pads placed anterior/posterior
      - Evaluate the ICD before leaving a cardiac-monitored environment

**Contact CIED team**

- A member of the CIED team should be contacted as soon as feasible
  - Provide preoperative recommendations for CIED management if time allows
  - Contact manufacturer representative to assist in interrogation of device pre- and/or post-operative (under the direction of a physician knowledgeable in CIED function and programming)
  - Perform or review postoperative interrogation

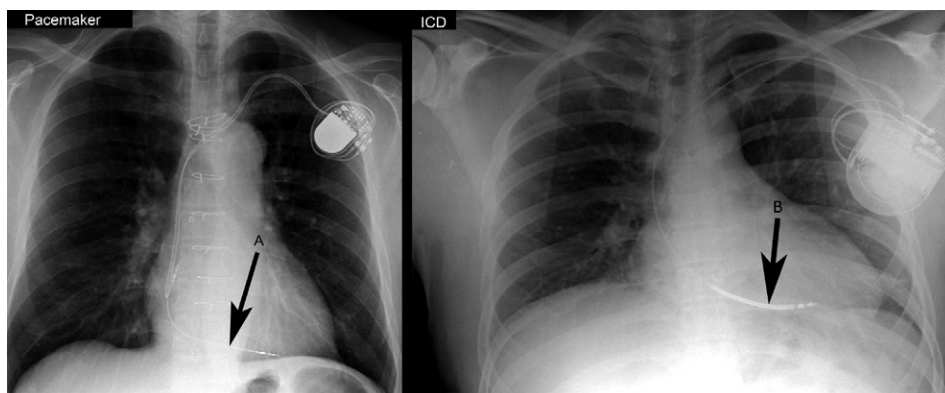
\*A magnet placed over an ICD (or CRT-ICD) will not result in asynchronous pacemaker ICD function. This can only be accomplished by reprogramming of ICDs (or CRT-ICDs) capable of this feature (majority of newer devices implanted).

†Long electrosurgery application (>5 seconds and/or frequent close spaced bursts) may result in pacemaker inhibition, causing hemodynamic risk in a pacemaker-dependent patient. Long electrosurgery application in close proximity to the device generator may rarely result in power on reset or Safety Core™ programming (Appendix 4 for the pacemaker and ICD parameters associated with these features).

#Pacemaker dependency is defined as absence of a life-sustaining rhythm without the pacing system.

If the anticipated use of electrosurgery can be limited to short bursts, it may be reasonable to have a magnet handy should long periods of pacemaker inhibition be observed. On the other hand if the surgical procedure will either use extensive periods

of electrosurgery and/or the position of the patient would preclude being able to rapidly place a magnet over the pulse generator, we recommend that the operative team place the magnet over the pulse generator. For surgical sites of lower



**Figure 1** PA radiographs of a patient with a pacemaker (left) and ICD (right) are shown. **Arrow A** shows the right ventricular lead of the pacemaker which does not have a radiodense coil. **Arrow B** shows the right ventricular lead of the ICD.

**Table 7** Recommendations for the intraoperative monitoring of patients with CIEDs

- External defibrillation equipment is required in the OR and immediately available for all patients with pacemakers or ICDs having surgical and sedation procedures or procedures where EMI may occur
- All patients with ICDs deactivated should be on a cardiac monitor and during surgery should have immediate availability of defibrillation
- Some patients may need to have pads placed prophylactically during surgery (e.g. high-risk patients and patients in whom pad placement will be difficult due to surgical site)
- All patients with pacemakers or ICDs require plethysmographic or arterial pressure monitoring for all surgical and sedation procedures
- Use an ECG monitor with a pacing mode set to recognize pacing stimuli
- PMs may be made asynchronous as needed with either a magnet application or reprogramming, provided that the pulse generator is accessible
- ICD detection may be suspended by either magnet application as needed or reprogramming, provided that the pulse generator is accessible
- During the placement of central lines using the Seldinger technique from the upper body, caution should be exercised to avoid causing false detections and/or shorting the RV coil to the SVC coil
- Because of interactions with monitoring, ventilation, and other impedance monitoring operative devices, inactivating minute ventilation sensors can be considered
- Keep a magnet immediately available for all patients with a CIED who are undergoing a procedure that may involve EMI

risk, below the umbilicus, we recommend having a magnet immediately available in case there is inhibition of the pacemaker. All pacemaker-dependent CIED patients should be monitored by plethysmography or by an arterial line and with transcutaneous pacing pads placed in the anterior/posterior position. All of these patients should have their pacemaker system evaluated prior to leaving the monitored environment. That is, the pacemaker system should be evaluated in the recovery room or the patient should be on a cardiac monitor until that interrogation is accomplished.

#### 4.4.2. Defibrillators: emergency protocol

For ICDs, a magnet should be placed over the pulse generator. Exceptions might be a surgical procedure on the lower extremities where the chance of false detection is very low. All patients should be protected with the placement of transcutaneous patches for both emergent defibrillation and emergent transcutaneous pacing. It is important to determine if the patient is pacing. It is important to remember that a magnet placed over an ICD generator will not protect the patient from EMI pacing inhibition. Consequently, the patient must be monitored closely for bradycardia and if observed, short electrosurgical bursts (less than 5 seconds) are recommended to minimize the inhibition. The only way to render a patient with an ICD to asynchronous pacing is to reprogram the ICD, as a magnet renders a defibrillator unable to treat tachyarrhythmias, but it does not change the pacing mode. Older ICDs may not have the capability to reprogram pacing into an asynchronous pacing mode.

A member of the CIED team can be contacted to provide further recommendations or to reprogram the ICD as soon as possible if the procedure can be delayed, or even provide that programming once the procedure has begun if EMI pacing inhibition is frequent and the patient safety is compromised. It will be helpful to try to define the manufacturer of the device. If it is known that there is a CIED but the type simply cannot be determined due to the urgency of the situation (such as ruptured aneurysm or trauma), the surgi-

cal team should apply a magnet and pacing/defibrillation pads to protect the patient. All patients having urgent or emergent surgery procedures following this protocol should have their CIED system evaluated prior to leaving the monitored environment either in the recovery room or prior to removing the patient from cardiac monitoring.

## 5. Intraoperative monitoring and considerations

The goal of intraoperative monitoring is to provide a safe environment for the patient with a CIED undergoing a surgical, interventional or diagnostic procedure where interference from EMI is likely to be present. This includes both assuring rhythm stability and protection of the CIED from damage related to the EMI, therefore providing patient safety. See Table 7.

To accomplish this goal requires knowledge of the potential risks to the patient and the CIED, appropriate preparation of the patient and the CIED, monitoring of the patient's rhythm throughout the procedure and emergency preparedness. All operative team members should be aware that a CIED is in place, should review the preoperative assessment and the prescription provided by the CIED team managing the patient and should review the surgical and/or procedural equipment for potential CIED interaction.

### 5.1. Intraoperative monitoring

Monitoring should be performed with techniques appropriate to the patient's underlying medical condition and the extent of the surgery as well as monitoring of the patient's rhythm throughout the procedure regardless of whether they are receiving general or regional anesthesia, sedation, or monitored anesthesia care. Intraoperative monitoring includes continuous electrocardiography as well as monitoring of the peripheral pulse (e.g., palpation of the pulse, auscultation of heart sounds, monitoring of a tracing of intra-arterial pressure, ultrasound peripheral pulse monitoring, pulse plethysmography or oximetry).<sup>93</sup> Important inter-



actions may occur between the heart rate monitoring system and the CIED. The anesthesiologist should be aware of potential limitations of electrocardiographic monitoring.

## 5.2. Interactions with OR monitoring equipment

There may be difficulties in the identification of the paced complex on the monitoring equipment. The pulse generator output may not be visible as spikes in displayed leads due to typical low voltage outputs of bipolar pacing or due to a low amplitude signal on the selected ECG lead. Also, modern digital monitors filter high-frequency signals (between 1,000 to 2,000 Hz) that include pacemaker spikes (the pacemaker signal is at about 2000 Hz), unless options accentuating display of pacing spikes are enabled in the monitor setup. It is important to recognize that this accentuation scheme occasionally goes awry and marks artifact as pacing spikes. Multiple vectors improve the likelihood of detecting changes in the paced ECG. Because of these difficulties, it is vital that there be monitoring of the peripheral pulse, whether by contour display pulse oximetry, arterial waveforms, or other appropriate methods, confirming adequate pulse and prevents confusion with ECG artifacts. This will avoid the misinterpretation of a noncaptured pacing stimulus for a QRS complex.

The heart rate counting may be inaccurate, most often falsely reporting a higher electrocardiographic heart rate by double counting the pacemaker spike and the QRS complex. Regardless of the situation, responding to erroneous heart rates could result in inappropriate use of anesthetic or chronotropic medications. Conversely, rhythms such as atrial fibrillation may include nonperfused QRS complexes with undercounting of heart rate by pulse oximetry. For these reasons, all monitoring equipment used on patients with a CIED should include an electrocardiographic monitor and a plethysmographic pulse measurement and display.

When CIED rate-responsive sensors are not inactivated either by reprogramming or use of a magnet, the operative team needs to be aware that the paced heart rate could increase due to normal function of the sensor. It is important to know what type of rate sensor is used in the patient's CIED. Most CIEDs use activity sensors that measure vibration or pressure on the generator. Therefore, movement of the patient onto the surgical table, pressure placed over the device or motion of the ipsilateral arm may result in a paced heart rate that could increase up to a maximum rate defined by the programming of the upper sensor rate in the device. Minute ventilation sensors use the measurement of thoracic impedance. Current emitted by the CIED to measure changes in thoracic impedance can be detected by monitoring equipment and appear to be rapid pacing without capture. Also, electrosurgery may interfere with this measurement and cause pacing at the upper sensor rate. BIOTRONIK pacemakers have a rate algorithm based upon measurement of right ventricle (RV) lead tip impedance changes with cardiac contraction. Interference with monitoring equipment has not been reported.

Occasionally, problems have been noted with monitors that measure electroencephalographic activity as an index of sedation depth. These may sometimes report erroneous activity in the setting of CIED pacing. Unless dealt with appropriately by filtering, the new electrical signal of the CIED may be assumed biological in origin.

## 5.3. Other intraoperative considerations

### 5.3.1. Central venous access

When considering central venous access, caution should be used as a guide wire enters the heart in a patient with an active ICD. Contact between wire and sensing electrodes can trigger antitachycardia therapy. A worse scenario exists if there is a defibrillator discharge and the guide wire has shorted the proximal coil to the distal coil. Arrhythmias triggered by the guide wire might also activate antitachycardia therapy. Caution is also advised when leads have been recently inserted (within 3 months) because of an increased chance for dislodgement of the lead. In general, if the guide wire does not enter the ventricle, there will be no problems.

### 5.3.2. Magnet vs. reprogramming

There are many situations where either a pacemaker needs to be made asynchronous or a defibrillator needs to have its tachycardia detection disabled. These tasks can be accomplished either by placing a magnet over the defibrillator or by reprogramming the CIED to the desired mode. There are advantages to each. The principal advantage of reprogramming is that the operative team need not be concerned with keeping the magnet in the correct location. The principal disadvantage of reprogramming is that the changes that are made with the programmer are not readily reversible. For example, if a patient develops sinus tachycardia or an arrhythmia during the procedure, asynchronous pacing may have deleterious effects and the ICD cannot be allowed to respond. In order to remedy this situation, a programmer will need to be brought back to the procedure room along with a competent operator in order to remedy the situation. Likewise, there is the risk of human error and failure to re-enable tachycardia therapies after the procedure is completed, leaving the patient unprotected should ventricular arrhythmias occur. This was demonstrated by the report from Boston Scientific of their first 67,410 remote follow-up patients in which the most common "red alert" was that VF detections and therapies were off.<sup>94</sup>

It is imperative that the patient be continuously monitored after reprogramming has occurred. That is, it is not acceptable for a patient's ICD to be deactivated in the preoperative holding without continuous cardiac monitoring during transport into and then again out of the surgical or procedural area. It is essential to remember that patients with ICDs are considered to be at risk for serious ventricular arrhythmias and carry these risks into the perioperative environment. Without continuous cardiac monitoring, the temporary deactivation of device therapy could result in delay in recognition and treatment of spontaneous ventric-

**Table 8** Specific procedures and writing committee recommendations on postoperative CIED evaluation

| Procedure                             | Recommendation   |
|---------------------------------------|--|
| <b>Monopolar electrosurgery</b>       | CIED evaluated# within 1 month from procedure unless Table 9 criteria are fulfilled  |
| <b>External cardioversion</b>         | CIED evaluated# prior to discharge or transfer from cardiac telemetry  |
| <b>Radiofrequency ablation</b>        | CIED evaluated# prior to discharge or transfer from cardiac telemetry  |
| <b>Electroconvulsive therapy</b>      | CIED evaluated# within 1 month from procedure unless fulfilling Table 9 criteria   |
| <b>Nerve conduction studies (EMG)</b> | No additional CIED evaluation beyond routine   |
| <b>Ocular procedures</b>              | No additional CIED evaluation beyond routine   |
| <b>Therapeutic radiation</b>          | CIED evaluated prior to discharge or transfer from cardiac telemetry; remote monitoring optimal; some instances may indicate interrogation after each treatment (see text) |
| <b>TUNA/TURP</b>                      | No additional CIED evaluation beyond routine   |
| <b>Hysteroscopic ablation</b>         | No additional CIED evaluation beyond routine   |
| <b>Lithotripsy</b>                    | CIED evaluated# within 1 month from procedure unless fulfilling Table 9 criteria   |
| <b>Endoscopy</b>                      | No additional CIED evaluation beyond routine   |
| <b>Iontophoresis</b>                  | No additional CIED evaluation beyond routine   |
| <b>Photodynamic therapy</b>           | No additional CIED evaluation beyond routine   |
| <b>Xray/CT scans/mammography</b>      | No additional CIED evaluation beyond routine   |

#This evaluation is intended to reveal electrical reset. Therefore, an interrogation alone is needed. This can be accomplished in person or by remote telemetry.

ular tachyarrhythmias, which would otherwise have been promptly corrected by the device. Likewise, it is imperative that patients whose ICDs have been rendered inactive by reprogramming be “tagged” in an effective manner so that they cannot be discharged with an inactive ICD.

The principal advantage of the magnet is that it can be quickly removed. For example, if a patient suffers ventricular tachycardia or ventricular fibrillation, during a hemodynamically stressful procedure, the magnet can be removed and the tachyarrhythmia will be treated. Otherwise, that situation might require removal of the drapes and external cardioversion, with the attendant sterility breach issues. Likewise, if a patient who is being paced asynchronously using a magnet develops a competing rhythm, the magnet can be removed expeditiously. There are certainly situations where stable magnet localization cannot be ensured, as is the case in a prone patient. If the perioperative plan involves the use of a magnet to change pacing mode or rate, then the magnet behavior (and magnet-determined heart rate) should be verified prior to the start of the procedure. The CIED team should also note whether the pacing output will function at an autcapture-determined output should a magnet be used (Appendix 5A).

Magnet application may be straightforward or problematic depending on the patient body position and habitus. The pulse generator may have built-in tools to help (Appendix 5B). Boston Scientific ICDs will emit a beeping tone synchronous with the QRS complex when the magnet is positioned to close the internal magnetic switch<sup>87</sup> and suspend arrhythmia detection. Loss of beeping tone indicates absence of the magnet effect. (In Boston Scientific [Guidant] PRIZM series ICDs, R-synchronous beeping followed by a continuous tone indicates a permanent inactivation of device detection, which can be reactivated with a repeat magnet application.) Medtronic devices will emit a continuous 20 to 30 second tone when a magnet closes the switch, even momentarily. Given that the tone ultimately stops despite appropriate positioning of the magnet over

the device, there is no ongoing audible indication of continued magnet contact. Neither, BIOTRONIK, ELA Sorin, or St. Jude ICDs provide audible tones or any other feedback to indicate adequate magnet position.

Even if preoperative reprogramming or prophylactic magnet application is not felt to be needed for a particular case, it is imperative that a magnet be immediately available in case the pacemaker patient has difficulties with EMI-induced bradycardia or inappropriate rate response. Likewise, a magnet should be available in the case of an unexpected inappropriate shock from an ICD.

### 5.3.3. Radiofrequency ablation (RFA) will be used

RFA amounts to the application of electrosurgery in a continuous fashion for minutes at a time. This has a high chance of causing inhibition of pacing and likewise a high chance that the noise reversion mode will be effective. Asynchronous pacing is indicated in a pacemaker-dependent patient when RFA is performed above the umbilicus. Preemptive temporary transvenous pacing is not necessary, but can be considered or available. If RFA is below the umbilicus, asynchronous pacing is indicated only if inhibition is noted. As in patients with ICDs who are exposed to monopolar electrosurgery, tachycardia detection should be disabled either by reprogramming or by magnet application. A possible exception might be considered for RFA on a leg with a return pad on the same leg. As with other EMI sources, when possible, the current RFA path should be directed away from the CIED. Similarly, the RFA path axis should be perpendicular to the CIED axis.

### 5.4. Proper use of electrosurgery

There have been reports of threshold rise after electrosurgery where older, nonisolated earth-grounded electrosurgical RF generators were used. Stray RF currents entering a pacing lead can also induce ventricular fibrillation.<sup>95</sup> In the earth-grounded electrosurgical systems, failure of the return electrode connection resulted in shunting of current to al-

ternative RF ground sites, including the pacing electrode, with resulting threshold increase or loss of capture.<sup>96</sup> Optimal “grounding” of the electrosurgical system involves the use of a split foil return electrode, which allows for detection of proper application to the patient.<sup>3</sup> As has been previously discussed, the current from the electrosurgery system can be effectively managed by placing the return electrode in a position that directs the current away from the CIED. For example, if surgery is planned on the ipsilateral shoulder, the return electrode should be placed on the ipsilateral arm.

## 6. Intraoperative evaluation of CIEDs

### 6.1. Effect of intraoperative procedures on postoperative functionality of CIEDs

The rationale for postoperative interrogation of devices rests primarily on 1) assuring that the device has not entered a backup safety mode, 2) functionality was not impaired and, 3) restoring preprocedural programming settings if changes were made prior to the procedure. The timing of postoperative assessment depends upon whether EMI exposure was present, the type of CIED, the type of procedure performed and whether preoperative reprogramming was performed. The recommendations for postoperative evaluation are listed in Table 8. The source of EMI and the degree to which it may alter CIED functionality is a result of both the amount of EMI energy delivered as well as the procedure performed. Patients who will require CIED evaluation prior to patient discharge or transfer from a cardiac telemetry environment include (1) those whose devices were reprogrammed prior to the procedure that left the device nonfunctional such as disabling tachycardia detection in an ICD, (2) those undergoing hemodynamically embarrassing surgeries such as cardiac surgery or significant vascular surgery (e.g., abdominal aortic aneurysmal repair), (3) those who experienced significant intraoperative events including cardiac arrest requiring temporary pacing or cardiopulmonary resuscitation and tachyarrhythmias requiring external electrical cardioversion, (4) those who are exposed to certain types of procedures that emit EMI with a greater probability of affecting device function and (5) those with logistical limitations that would prevent reliable device evaluation within one month from their procedure. Those patients have a significant risk of entering the reset mode and may have some risk of changes in CIED function. See Table 9.

In all other situations, there is little or no risk of a change in CIED function and there is only a small risk of entering reset mode. In these patients it is reasonable to have the CIED interrogated no more than one month from the time of the procedure (see Table 8). An in-office evaluation is not necessary and the evaluation may be performed with remote CIED evaluation technologies. This one-month time was empirically chosen and is intended to be a maximum interval. It may be altered in specific situations by the physicians involved.

**Table 9** Indications for the interrogation of CIEDs prior to patient discharge or transfer from a cardiac telemetry environment

- Patients with CIEDs reprogrammed prior to the procedure that left the device nonfunctional such as disabling tachycardia detection in an ICD.
- Patients with CIEDs who underwent hemodynamically challenging surgeries such as cardiac surgery or significant vascular surgery (e.g., abdominal aortic aneurysmal repair).\*
- Patients with CIEDs who experienced significant intraoperative events including cardiac arrest requiring temporary pacing or cardiopulmonary resuscitation and those who required external electrical cardioversion.\*
- Emergent surgery where the site of EMI exposure was above the umbilicus
- Cardio-thoracic surgery
- Patients with CIEDs who underwent certain types of procedures (Table 8) that emit EMI with a greater probability of affecting device function.
- Patients with CIEDs who have logistical limitations that would prevent reliable device evaluation within one month from their procedure.\*

CIED = Cardiac implantable electrical device.

\*The general purpose of this interrogation is to assure that reset did not occur. In these cases a full evaluation including threshold evaluations is suggested.

### 6.2. Specific considerations for various EMI sources

#### 6.2.1. Electrosurgery

As discussed above, the application of electrosurgery to a patient with a CIED can result in various untoward events. The writing committee recommends that all pacemakers, ICDs and cardiac resynchronization devices be interrogated after procedures involving monopolar electrosurgery at the appropriate time. In cases where the CIED is recommended to be evaluated prior to discharge or transfer from a cardiac telemetry environment (see Table 9), this should be performed by a trained individual well-versed in device interrogations and programming. For all other cases, CIED evaluation can be performed after discharge or transfer from a cardiac telemetry environment but should be performed within one month from the time of procedure either remotely or through an in-office evaluation.

#### 6.2.2. Cardioversion

High-voltage cardiac defibrillation can introduce a large amount of current to CIEDs and rarely either result in permanent damage or reversion to a backup safety mode. However, as discussed in the introduction, when an anterior/posterior patch position is used and the pads are positioned away from the pulse generator, this risk appears to be quite low with present CIEDs. Because of the risk, although uncommon with current-day CIED pulse generators of backup mode, we recommend that all patients undergoing cardioversion have their CIED interrogated prior to leaving the monitored environment. Unplanned, emergent cardioversion may carry a greater risk as pad positions may not be ideal.

### 6.2.3. Radiofrequency ablation

All pacemakers, ICDs and cardiac resynchronization devices must be interrogated immediately after radiofrequency energy delivery prior to patient discharge or transfer from a cardiac telemetry setting. Exceptions might be when RFA is used on the legs.

### 6.2.4. Diagnostic radiation

Because of the unlikely occurrence of adverse effects on CIEDs, no additional interrogation of the CIED beyond that performed as part of routine follow up is required.

### 6.2.5. Therapeutic radiation

The application of external beam ionizing radiation represents one of the greatest risks for reversion to a safety mode or CIED malfunction. Although in most cases every effort is made to focus the beam away from the device, scatter particles including neutrons and protons (regardless of the location of the beam) can cause the CIED to enter a backup safety mode. These instances can pose a risk for inappropriate ICD shocks (given lower rate cut offs) and loss of cardiac resynchronization pacing until the device has been reprogrammed to its original settings. It is often the case that patients undergoing therapeutic radiation receive several cycles of treatment over the course of weeks. Theoretically, each application of radiation can render the device into a backup safety mode, thereby requiring frequent evaluation of the device. Given these issues, the writing committee recommends that all individuals anticipating therapeutic radiation be enrolled in a remote monitoring system if possible. In certain high-risk cases such as direct beam to the chest or high-energy photon irradiation, CIEDs should be evaluated within 24 hours of each treatment. In other patients, a regular enhanced evaluation may be appropriate, such as a weekly evaluation. This can be accomplished by remote monitoring if available or if this is not available, the physician can consider programming the pacing rate to a higher rate (i.e., 80 beats per minute) and having the radiation therapy staff check the heart rate after each treatment. If the rate has changed to the reset mode rate (which must be identified prior to the treatments beginning), then the patient needs to come to the device clinic for interrogation. If neither of these approaches is possible, it is necessary to have the device interrogated immediately after each treatment prior to discharge or transfer from a cardiac telemetry setting.

### 6.2.6. Electroconvulsive therapy

As described in Section 3.9.5, rare case reports have described adverse effects of ECT on pacemaker and ICD function. It is reasonable to recommend that pacemakers, ICDs and cardiac resynchronization devices be interrogated within one month from the application of ECT.

### 6.2.7. TUNA/TURP

TUNA and TURP utilizes radiofrequency energy and electrosurgery in the management of prostatic disease. Although there are earlier reports of TURP inhibiting pacemaker

activity,<sup>97,98</sup> there are no reports of these effects on modern-day systems, and additional periprocedural device interrogation is not required.

### 6.2.8. Gastroenterological procedures

Electromagnetic interference encountered from gastric and colorectal endoscopic procedures include sources from monopolar electrosurgery and wireless telemetry from capsule video endoscopy. Current recommendations discourage the use of capsule video endoscopy. Given this, the additional periprocedural device interrogations are not required. If monopolar electrosurgery is used, the committee recommends evaluating the CIED within one month.

### 6.2.9. Nerve conduction studies and electromyography (EMG)

The writing committee does not recommend additional periprocedural device interrogation beyond what is routinely recommended for standard CIED management.

### 6.2.10. Ocular procedures

Ocular procedures usually involve the use of bipolar electrosurgery. Therefore, the likelihood of altering CIED functionality is very low. The writing committee does not recommend that interrogation is needed unless monopolar electrosurgery is used. If it is employed, then the committee recommends interrogation within one month from the ocular procedure. Often, concern is voiced by the ophthalmologic surgeons that an ICD shock would be dangerous to the patient due to concerns of instrument movement and trauma to the eye in that setting. We would suggest that a patient who has an ICD is at risk for ventricular arrhythmias and the greater risk is the development of VT or VF and not receiving appropriate ICD therapy. The occurrence of VT or VF in an unmonitored patient with a deactivated ICD not only would result in unexpected patient motion, but potentially sudden cardiac death.

### 6.2.11. Hysteroscopic ablation

These procedures have been introduced as an alternative to hysterectomy for endometrial disorders and involve the use of several sources of energy including laser photovaporization, electrosurgery (loop or rollerball techniques), radiofrequency energy and hot saline thermoablation. There are no reports on the effects of these therapies in altering CIED function.<sup>99</sup> Given this, the writing committee does not recommend additional periprocedural device interrogation beyond what is routinely recommended for standard CIED management.

### 6.2.12. Lithotripsy

In light of current practices and technological advances in modern-day CIEDs, the writing committee recommends that all pacemakers, ICD and cardiac resynchronization devices be evaluated within 1 month from the time of the procedure.

### 6.2.13. Iontophoresis

The writing committee does not recommend additional periprocedural device interrogations beyond what is routinely recommended for standard CIED management.

### 6.2.14. Photodynamic therapy

The writing committee does not recommend additional periprocedural device interrogations beyond what is routinely recommended for standard CIED management.

## 7. Future needs

In this document, we have provided recommendations that are based upon the available literature and input from experts in the field: both health care providers and engineer representatives from the companies that manufacture these devices. The limitations to our recommendations are the nature of the literature available, which are chiefly case reports or small patient series, and the changing technology. Without robust scientific data collected prospectively, the approach to these patients will continue to be based largely upon personal experience.

We would be well served to have better scientific evaluation of the real risks of EMI, radiation and the like. Future CIEDs are likely to provide better protection from EMI, however unless other forms of electrosurgery are developed that have a lower risk of EMI inference with CIEDs, it is unlikely that concern for interactive risks will lessen. We would envision that this will take rigorous bench evaluations as well as large clinical evaluations, likely in the form of a prospective registry to evaluate the effects of EMI. Regarding the risk of therapeutic radiation, there is a critical need for long-term data collection on radiation-exposed devices, with the outcome data coupled to the radiation modeling, as typically done.

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**Appendix 1** Author disclosures

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|----------------------------------|--|--|--|---|------------------------------------|---|
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| <b>Alan Cheng, MD</b>            | Boston Scientific<br>Medtronic<br>St. Jude Medical   |  | Biosense Webster*<br>Boston Scientific   | None  | None                               | None                                    |
| <b>Mina K. Chung, MD</b>         | National Institutes of Health<br>University of Texas, Health Science Center                              | None                                       | BIOTRONIK*<br>Boston Scientific*<br>Medtronic*<br>National Institutes of Health*<br>Reliant Pharma/<br>GlaxoSmithKline*<br>St. Jude Medical* | BIOTRONIK*<br>Boston Scientific*<br>Medtronic*<br>St. Jude Medical* | None                               | National Institutes of Health* – salary |
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\*Significant: The relationship is considered to be "significant" if (1) the person receives \$10,000 or more during any 12-month period or 5% or more of the person's gross income; or (2) the person owns 5% or more of the voting stock or share of the entity or owns \$10,000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.



**Appendix 2** Summary of studies published in the literature describing interactions between CIEDs and medical equipment

| Author   | Type | Patient #  | CIED type                | Findings  |
|--|------|--|--------------------------|---|
| <b>Electrosurgery</b>  |      |  |                          |   |
| Hoyt RH, Johnson WB, Lieserowitz A. Monopolar electrosurgery interactions with the implantable defibrillator. <i>Heart Rhythm</i> 2010;7:S246.   | Ab   | 171  | ICD                      | Detection if EMI observed in 45/96 patients undergoing generator change and 9/22 patients undergoing surgery above the diaphragm. No EMI noted in 53 surgeries performed below the diaphragm.   |
| Goel AK, Korotkin S, Walsh D, Bess M, Frawley S. Monomorphic ventricular tachycardia caused by electrocautery during pacemaker generator change in a patient with normal left ventricular function. <i>Pacing Clin Electrophysiol</i> 2009;32:957-978.   | CR   | 1 (generator change)                                 | PM                       | Monomorphic ventricular tachycardia induced by electrosurgery delivered at the surface of the generator.  |
| Cheng A, Nazarian S, Spragg DD, Bilchick K, Tandri H, Mark L, Halperin H, Calkins H, Berger RD, Henrikson CA. Effects of surgical and endoscopic electrocautery on modern-day permanent pacemaker and implantable cardioverter defibrillator systems. <i>Pacing Clin Electrophysiol</i> 2008;31:344-350. | CS   | 92 patients undergoing noncardiac surgery/ endoscopy | ICD: 38, CRT: 19, PM: 35 | All devices programmed to active detection and for ICDs, therapies programmed "off." All devices withstood periprocedural EMI exposure without malfunction or changes in programming. Minor changes in lead parameters were noted. Three device systems demonstrated brief atrial mode switching episodes, one of which was likely secondary to inappropriate sensing of atrial noise. Two pacemaker devices demonstrated inappropriate sensing of ventricular noise, both of which occurred when the application of electrosurgery was within close proximity to the pacemaker generator (<8 cm). In one pacemaker that was approaching ERI, electrical reset was observed. No ventricular sensed events were noted in any ICD system. |
| Porres JM, Laviñeta E, Reviejo C, Brugada J. Application of a clinical magnet over implantable cardioverter defibrillators: is it safe and useful? <i>Pacing Clin Electrophysiol</i> 2008;31:1641-1644.  | CR   | 1 (CABG)   | ICD                      | Magnet used during the procedure. After surgery, ICD battery indicator gave "end-of-life" message. Oversensing also noted on postprocedure evaluation.  |
| Pili-Fluory S, Farah E, Samain E, Schauvliege F. Perioperative outcome of pacemaker patients undergoing noncardiac surgery. <i>Eur J Anesthesiol</i> 2007;25:514-516.  | Le   | 65 surgeries or interventional procedures            | PM                       | No specific preoperative programming changes made. No major dysfunction of the pacemaker device occurred in the perioperative period.   |
| Lo R, Mitrache A, Quan W, Cohen T. Electrocautery induced ventricular tachycardia and fibrillation during device implantation and explantation. <i>J Invasive Cardiol</i> 2007;19:12-15.   | CS   | 4 (implant)  | ICD: 3, PM: 1            | Retrospective single center analysis identified 4 patients (out of 4,698 total procedures) with ventricular arrhythmias induced by electrosurgery applied near the generator surface.   |
| Bales JG, Colon J, Ramadhyani U, LeDoux E, Bennett JT. Electrocautery-induced asystole in a scoliosis patient with a pacemaker. <i>J Pediatr Orthop B</i> 2007;16:19-22.   | CR   | 1 (spine surgery)                                    | PM                       | No preprocedure programming or magnet use. EMI sensing and inhibition observed during surgery.  |
| Epstein AE. Troubleshooting of implantable cardioverter-defibrillators. In: Ellenbogen KA, Kay GN. <i>Clinical Cardiac Pacing, Defibrillation, and Resynchronization Therapy</i> , 3 <sup>rd</sup> Ed. Philadelphia, PA: Saunders/Elsevier, 2007.  | BC   | 1 (skin cancer at the ear lobe)                      | ICD                      | EMI recorded during electrosurgery. No details on preprocedure programming provided.  |

## Appendix 2 Continued

| Author  | Type | Patient #                                   | CIED type        | Findings   |
|---|------|---|------------------|--|
| Matzke TJ, Christenson LJ, Christenson SD, Atanashova N, Otley CC. Pacemakers and implantable cardiac defibrillators in dermatologic surgery. <i>Dermatol Surg</i> 2006;32:1155–1162.   | CS   | 186   | PM: 173; ICD: 13 | ICDs deactivated prior to surgery. For pacemaker-dependent patients pacemaker programmed to the V00 pacing mode. Otherwise precautions such as use of bipolar forceps and short electrocautery bursts were used. No complications were observed. |
| Lee D, Sharp VJ, Konety BR. Use of bipolar power source for transurethral resection of bladder tumor in patient with implanted pacemaker. <i>Urology</i> 2005;66:194.   | CR   | 1 (TURP)                                    | ICD              | Bipolar electrocautery performed safely without deactivation of the ICD.   |
| Fiek M, Dorwarth U, Durchlaub I, Janko S, Von Bary C, Steinbeck G, Hoffmann E. Application of radiofrequency energy in surgical and interventional procedures: are there interactions with ICDs? <i>Pacing Clin Electrophysiol</i> 2004;27:293–298. | CS   | 45 surgeries or interventional procedures   | ICD              | Variety of surgeries (33) and interventional procedures (12). ICD programmed to active detection but therapies “off.” No oversensing, reprogramming or damage identified.  |
| Pinski SL, Trohman RG. Interference in implanted cardiac defibrillators: part II. <i>PACE</i> 2002;25:1496–1509.  | Re   | 1   | ICD              | Example of EMI due to electrocautery. No details about surgery or preprocedure programming provided.   |
| El Gamal HM, Dufresne RG, Saddler K. Electrocautery, pacemakers, and ICDs: a survey of precautions and complications experienced by cutaneous surgeons. <i>Dermatol Surg</i> 2001;27:385–390.   | S    | NA  | ICD/PM           | Survey of 166 physicians performing Mohs procedure. Incidence of ICD/PM “complication” 0.8 cases/100 years of surgical experience. No problems associated with use of bipolar forceps.   |
| Wong DT, Middleton W. Electrocautery-induced tachycardia in a rate-responsive pacemaker. <i>Anesthesiology</i> 2001;94:710–711.   | CR   | 1 (TURP)                                    | PM               | No preprocedure programming or perioperative magnet use. Pacing at the sensor driven upper rate due to activation of the minute ventilation sensor.  |
| Ahern TS, Luckett C, Ehrlich S, Pena EA. Use of bipolar electrocautery in patients with implantable cardioverter defibrillators: no reason to inactivate detection or therapies (abstract). <i>PACE</i> 1999;22:776.                                | A    | 25 ICD implant, 15 other surgeries          | ICD              | ICD programmed to active detection. “Oversaturation” noted in 80% of acute implants and “similarly” observed in the 15 surgical procedures. No oversensing noted.  |
| Peters RW, Gold MR. Reversible prolonged pacemaker failure due to electrocautery. <i>J Interv Card Electrophysiol</i> 1998;2:343–344.   | CR   | 1 (carotid endarterectomy)                  | PM               | Device programmed to V00. During electrocautery prolonged loss of capture due to conversion to “power-on reset mode.”  |
| Casavant D, Haffajee C, Stevens S, Pacetti P. Aborted implantable cardioverter defibrillator shock during facial surgery. <i>Pacing Clin Electrophysiol</i> 1998;21:1325–1326.  | CR   | 1 (facial surgery)                          | ICD              | Aborted ICD therapy during electrocautery.   |
| Nercessian OA, Wu H, Nazarian D, Mahmud F. Intraoperative pacemaker dysfunction caused by the use of electrocautery during a total hip arthroplasty. <i>J Arthroplasty</i> 1998;13:599–602.   | CR   | 1 (hip replacement)                         | PM               | No preprocedure programming or magnet use. EMI sensing and inhibition observed during surgery.   |
| Kellow NH. Pacemaker failure during transurethral resection of the prostate. <i>Anesthesia</i> 1993;48:136–138.   | CR   | 1 (transurethral resection of the prostate) | PM               | Presurgical programming to the VVI pacing mode. During electrocautery intermittent failure to capture (relatively high thresholds [between 2.5 and 5.0 Volts] prior to surgery). After surgery increase in ventricular threshold to 8.0 Volts.   |
| Mangar D, Atlas GM, Kane PB. Electrocautery induced pacemaker malfunction during surgery. <i>Can J Anesth</i> 1991;38:616–618.  | CR   | 1 (cardiac surgery)                         | PM               | Older CR of a PM programmed to V00 pacemaker mode prior to surgery but asystole due to circuitry and battery failure.  |

**Appendix 2** Continued

| Author  | Type | Patient #                        | CIED type               | Findings   |
|---|------|----------------------------------|-------------------------|--|
| Heller LI. Surgical electrocautery and the runaway pacemaker syndrome. <i>PACE</i> 1990;13:1084–1085.   | CR   | 1 (arteriovenous graft revision) | PM                      | No preprocedure programming. With electrocautery ventricular pacing at 140 bpm with intermittent capture observed. Evaluation of the explanted device found that abnormal function precipitated by electrocautery was due to PM at end-of-life.                                |
| Godin JF, Petitot JC. Pacemaker failures due to electrocautery and external electric shock. <i>PACE</i> 1989;12:1011.   | Le   | 2                                | PM                      | Pacemaker failure after direct contact with electrocautery and cardioversion (STIMAREC report).  |
| Lamas GA, Antman EM, Gold JP, Braunwald NS, Collins JJ. Pacemaker backup-mode reversion and injury during cardiac surgery. <i>Ann Thorac Surg</i> 1986;41:155–157.  | CS   | 5 (cardiac surgery)              | PM                      | Despite presurgical programming to the VOO pacing mode, during surgery backup-mode reversion, loss of telemetry and sensing changes observed.  |
| Levine PA, Balady GJ, Lazar HL, Belott PH, Roberts AJ. Electrocautery and pacemakers: management of the paced patient subject to electrocautery. <i>Ann Thorac Surg</i> 1986;41:313–317.  | CS   | 3 (CABG, lung)                   | PM                      | Ventricular fibrillation, reversion to back-up mode, and loss of capture described in three separate patients.   |
| Batra YK, Bali IM. Effect of coagulating and cutting current on a demand pacemaker during transurethral resection of the prostate: a case report. <i>Can Anesth Soc J</i> 1978;25:65–66.  | CR   | 1                                | PM                      | EMI sensing during electrocautery in the cutting mode.   |
| Smith BS, Wise WS. Pacemaker malfunction from urethral electrocautery. <i>JAMA</i> 1971;218:256.  | CR   | 1                                | PM                      | Ground failure in the electrocautery unit may have led to pacemaker malfunction.   |
| <b>Cardioversion</b>  |      |                                  |                         |  |
| Manegold JC, Israel CW, Ehrlich JR, Duray G, Pajitnev D, Wegener FT, Hohnloser SH. External cardioversion of atrial fibrillation in patients with implanted pacemaker or cardioverter-defibrillator systems: a randomized comparison of monophasic and biphasic shock energy application. <i>Eur Heart J</i> 2007;28:1731–1738. | CS   | 44                               | PM: 29; ICD: 12; CRT: 3 | No preprocedure programming. No evidence for device or lead malfunction in any patient at interrogation 1 hour and 1 week after cardioversion.   |
| Waller C, Callies F, Langenfeld H. Adverse effects of direct current cardioversion on cardiac pacemakers and electrodes: is external cardioversion contraindicated in patients with permanent pacing systems? <i>Europace</i> 2004;6:165–168.   | CS   | 3                                | PM                      | After AP transthoracic shock elevated thresholds developed over the next one day to five weeks requiring lead revision in three cases.   |
| Das G, Staffanson DB. Selective dysfunction of ventricular electrode-endocardial junction following DC cardioversion in a patient with a dual chamber pacemaker. <i>Pacing Clin Electrophysiol</i> 1997;20:364–365.   | CR   | 1                                | PM                      | AP transthoracic shock caused elevated thresholds in the ventricular lead.   |
| Snow JS, Kalenderian D, Colasacco JA, Jadonath RL, Goldner BG, Cohen TJ. Implanted devices and electromagnetic interference: case presentations and review. <i>J Invasive Cardiol</i> 1995;7:25–32.   | CS   | 3                                | PM                      | Transient loss of capture, loss of telemetry, and conversion to back-up mode.  |
| Altamura G, Bianconi L, Lo Bianco F, Toscano S, Ammirati F, Pandozi C, Castro A, Cardinale M, Mennuni M, Santini M. Transthoracic DC shock may represent a serious hazard in pacemaker dependent patients. <i>PACE</i> 1995;18:194–198.   | CS   | 36                               | PM                      | AP transthoracic shock in patients with unipolar devices. Transient loss of capture in 50% (range 5 seconds to 30 minutes). In a selected group of patients ventricular pacing threshold increased six-fold at 3 minutes with gradual recovery to baseline values at 24 hours. |

## Appendix 2 Continued

| Author   | Type | Patient #                | CIED type       | Findings   |
|--|------|--------------------------|-----------------|--|
| Levine PA, Barold SS, Fletcher RD, Talbot P. Adverse acute and chronic effects of electrical defibrillation and cardioversion on implanted unipolar cardiac pacing systems. <i>J Am Coll Cardiol</i> 1983;1:1413–1422.   | CS   | 7                        | PM              | Transient loss of capture in 6 patients for 2 seconds to 3 minutes after cardioversion or defibrillation (anterior anterior pad position in four, pad position not documented in three). In one patient permanent loss of capture due to circuitry damage.   |
| <b>Cardiac RF ablation</b>   |      |                          |                 |  |
| Kolb C, Luik A, Hessling G, Zrenner B. Magnetic catheter navigation system interference with a dual-chamber pacemaker. <i>J Cardiovasc Electrophysiol</i> 2007;18:892–893.   | CR   | 1                        | PM              | Partial electrical reset after ablation using magnetic catheter navigation.  |
| Lakkireddy D, Patel D, Ryschon K, Bhateja R, Bhakru M, Thal S, Verma A, Wazni O, Kilicaslan F, Kondur A, Prasad S, Cummings J, Belden W, Burkhardt D, Saliba W, Schweikert R, Bhargava M, Chung M, Wilkoff B, Tchou P, Natale A. Safety and efficacy of radiofrequency energy catheter ablation of atrial fibrillation in patients with pacemakers and implantable cardiac defibrillators. <i>Heart Rhythm</i> 2005;2:1309–1316. | CS   | 86                       | PM, ICD         | No changes in the sensing and pacing thresholds, impedance of atrial and ventricular leads, or defibrillator coil impedance after AF ablation were observed. 2 recently implanted leads (<6 mo) were dislodged during the procedure.   |
| Burke MC, Kopp DE, Alberts M, Patel A, Lin AC, Kall JG, Arruda M, Mazeika P, Wilber DJ. Effect of radiofrequency current on previously implanted pacemaker and defibrillator ventricular lead systems. <i>J Electrocardiol</i> 2001;34 Suppl:143–148.  | CS   | 59 (His bundle ablation) | PM: 46; ICD: 13 | A progressive rise in pacing threshold required lead revision in 2/13 patients with ICD leads (15%) and 2/46 patients with pacing leads (4%).  |
| Sadoul N, Blankoff I, de Chillou C, Beurrier D, Messier M, Bizeau O, Magnin I, Dodinot B, Aliot E. Effects of radiofrequency catheter ablation on patients with permanent pacemakers. <i>J Interv Card Electrophysiol</i> 1997;1:227–233.  | CS   | 38                       | PM              | A variety of effects including transient inhibition, noise mode with return to normal function, and electrical reset observed in 53% of patients. Increased ventricular threshold in one patient due to erosion of the ventricular insulation at a site that was near the ablation catheter (after lead extraction). |
| Ellenbogen KA, Wood MA, Stamber BS. Acute effects of radiofrequency ablation of atrial arrhythmias on implanted permanent pacing systems. <i>PACE</i> 1996;19:1287–1295.   | CS   | 35                       | PM              | No EMI sensing in 40% of patients and normal noise response in an additional 46% of patients during ablation. Rare cases of reset with no significant changes in sensing or pacing parameters after the ablation procedure.  |
| Pfeiffer D, Tebbenjohanns J, Schumacher B, Jung W, Luderitz B. Pacemaker function during radiofrequency ablation. <i>PACE</i> 1995;18:1037–1044.   | CS   | 25                       | PM              | Noise response (32%) and transient failure to capture (16%) observed. 24/25 patients had unipolar leads. No specific preprocedure programming.   |
| Chang AC, McAreavey D, Tripodi D, Fananapazir L. Radiofrequency catheter atrioventricular node ablation in patients with permanent cardiac pacing systems. <i>PACE</i> 1994;17:65–69.  | CS   | 27                       | PM              | Prior to ablation PMs programmed to the VVI pacing mode. EMI sensing with pacing inhibition noted in one patient and asynchronous pacing in another. No change in pacing thresholds detected.  |
| Chin MC, Rosenqvist M, Lee MA, Griffin JC, Langberg JJ. The effect of radiofrequency catheter ablation on permanent pacemakers: an experimental study. <i>Pacing Clin Electrophysiol</i> 1990;13:23–29.  | EX   | 19                       | PM              | During radiofrequency ablation 1 cm away from the lead, inhibition due to EMI was observed in 12/19 PPMs and abnormal heart rates were observed in five and one exhibited runaway pacemaker.   |

## Appendix 2 Continued

| Author  | Type | Patient #                        | CIED type      | Findings  |
|---|------|----------------------------------|----------------|---|
| Vanerio G, Maloney J, Rashidi R, McCowan R, Castle L, Morant V, Wilkoff B, Simmons T. The effects of percutaneous catheter ablation on preexisting permanent pacemakers. <i>PACE</i> 1990;13:1637-1645.   | CS   | 23                               | PM             | During DC ablation, abnormalities identified in 52% of patients including transient loss of capture, undersensing and oversensing, loss of telemetry, and abnormal magnet response. Four patients developed symptoms subsequent evaluation of the explanted device demonstrated circuitry damage. |
| <b>LVAD</b>   |      |                                  |                |   |
| Bakhtiary F, Therapidis P, Scherer M, Dzemali O, Moritz A, Kleine P. Electromagnetic interaction between an axial left ventricular assist device and an implantable cardioverter defibrillator. <i>J Thorac Cardiovasc Surg</i> 2008;136:1380-1381.                 | CR   | 1                                | ICD            | Ipsilateral LVAD prevented ICD telemetry. Issue resolved by placing the ICD in the right upper chest.   |
| Matthews JC, Betley D, Morady F, Pelosi F. Adverse interaction between a left ventricular assist device and an implantable cardioverter defibrillator. <i>J Cardiovasc Electrophysiol</i> 2007; 18:1107-1108.   | CR   | 1                                | ICD            | Telemetry impossible. Managed by using a different manufacturer.  |
| Mehta R, Love CJ, Sai-Sudhaker C, Hasan AK, Chan D. A device-device interaction between a Thoratec Heartmate II left ventricular assist device and a St. Jude Atlas (V-193) implantable cardioverter defibrillator. <i>J Cardiovasc Electrophysiol</i> 2007;18:E27. | Le   | 1                                | ICD            | Loss of telemetry due to similar frequencies used by the ICD and the pulse width modulator of the LVAD. Managed by using a newer-generation ICD from the same manufacturer.   |
| <b>Harmonic scalpel</b>   |      |                                  |                |   |
| Nandalan SP, Vanner RG. Use of the harmonic scalpel in a patient with a permanent pacemaker. <i>Anaesthesia</i> 2004;59: 621.   | CR   | 1 (laparoscopic cholecystectomy) | PM             | Left in VVIR pacing mode but sensitivity reduced for the procedure. No interference observed.   |
| Ozeren M, Doğan OV, Düzgün C, Yücel E. Use of an ultrasonic scalpel in the open-heart reoperation of a patient with pacemaker. <i>Eur J Cardiothorac Surg</i> 2002;21:761-762.  | CR   | 1 (aortic valve replacement)     | PM             | No preprocedure programming and no interaction observed.  |
| Strate T, Bloechle C, Broering D, Schuchert A, Izbicki JR, Rogiers X Hemostasis with the ultrasonically activated scalpel. Effective substitute for electrocautery in surgical patients with pacemakers. <i>Surg Endosc</i> 1999;13:727.                            | CR   | 1 (laparoscopic cholecystectomy) | PM             | No interference observed. No preprocedure programming.  |
| Epstein MR, Mayer JE, Duncan BW. Use of an ultrasonic scalpel as an alternative to electrocautery in patients with pacemakers. <i>Ann Thorac Surg</i> 1998;65:1802-1804.  | CS   | 4                                | PM             | No interference observed. No preprocedure programming.  |
| <b>Other surgery</b>  |      |                                  |                |   |
| Engelhardt L, Grobe J, Birnbaum J, Volk T. Inhibition of a pacemaker during nerve stimulation for regional anesthesia. <i>Anesthesia</i> 2007;62:1071-1074.   | CR   | 1                                | PM             | Peripheral nerve stimulator used for regional anesthesia led to transient inhibition of a pacemaker due to EMI oversensing.   |
| Rasmussen MJ, Rea RF, Tri JL, Larson TR, Hayes DL. Use of a transurethral microwave thermotherapeutic device with permanent pacemakers and implantable defibrillators. <i>Mayo Clin Proc</i> 2001;76:601-603.   | EX   | 21                               | PM: 13, ICD: 8 | With in vitro testing, no interaction between PM or ICD and a transurethral microwave device were observed.   |

## Appendix 2 Continued

| Author  | Type | Patient # | CIED type    | Findings   |
|---|------|-----------|--------------|--|
| Samain E, Marty J, Souron V, Rosencher N, Eyrolle L. Intraoperative pacemaker malfunction during a shoulder arthroscopy. <i>Anesthesiology</i> 2000;93:306–307.                                     | Le   | 1         | PM           | Loss of capture due to direct lead position/generator change during the shoulder operation.  |
| <i>Extracardiac RF</i>  |      |           |              |  |
| Skonieczki BD, Wells C, Wasser EP, Dupuy DE. Radiofrequency and microwave tumor ablations in patients with cardiac devices: is it safe? <i>Eur J Radiol</i> 2010 (in press).                        | CS   | 19        | 15 PM, 4 ICD | During percutaneous RF/microwave ablation EMI sensing with inhibition observed in one patient and reset in another patient.        |
| Donohoo JH, Anderson MT, Mayo-Smith WW. Pacemaker reprogramming after radiofrequency ablation of a lung neoplasm. <i>AJR Am J Roentgenol</i> 2007;189:890–892                                       | CR   | 1         | CRT          | Device programmed to the VOO pacing mode in preparation for radiofrequency ablation. Partial electrical reset after the procedure. |
| Sun DA, Martin L, Honet CR. Percutaneous radiofrequency trigeminal rhizotomy in a patient with an implanted cardiac pacemaker. <i>Anesth Analg</i> 2004;99:1585–1586.                               | CR   | 1         | PM           | No EMI sensing observed.   |
| Tong NY, Ru HJ, Ling HY, Cheung YC, Meng LW, Chung PC. Extracardiac radiofrequency ablation interferes with pacemaker function but does not damage the device. <i>Anesthesiology</i> 2004;100:1041. | Le   | 1         | PM           | Pacing due to atrial tracking of EMI.  |
| Hayes DL, Charboneau JW, Lewis BD, Asirvatham SJ, Dupuy DE, Lexvold NY. Radiofrequency treatment of hepatic neoplasms in patients with permanent pacemakers. <i>Mayo Clin Proc</i> 2001;76:950–952. | CS   | 2         | PM           | Intrahepatic radiofrequency ablation performed safely without interference.  |
| <i>ECG monitoring</i>   |      |           |              |  |
| Hu R, Cowie DA. Pacemaker-driven tachycardia induced by electrocardiograph monitoring in the recovery room. <i>Anaesth Intensive Care</i> 2006;34:266–268.  | CR   | 1         | PM           | Rate adaptive pacing due to interaction between the ECG monitoring equipment and the minute ventilation sensor/algorithm.          |
| Houtman S, Rinia M, Kalkman C. Monitor-induced tachycardia in a patient with a rate-responsive pacemaker. <i>Anaesthesia</i> 2006;61:399–401.   | CR   | 1         | PM           | Rate adaptive pacing due to interaction between the ECG monitoring equipment and the minute ventilation sensor/algorithm.          |
| Lau W, Corcoran SJ, Mond HG. Pacemaker tachycardia in a minute ventilation rate-adaptive pacemaker induced by electrocardiographic monitoring. <i>Pacing Clin Electrophysiol</i> 2006;29:438–440.   | CR   | 1         | PM           | Rate adaptive pacing due to interaction between the ECG monitoring equipment and the minute ventilation sensor/algorithm.          |
| Wilkinson DA, Popham P, Morgan D. Pacemaker interference from cardiac monitors revisited. <i>Anaesth Intensive Care</i> 2004;32:842–843.  | Le   | 1         | PM           | Rate adaptive pacing due to interaction between the ECG monitoring equipment and the minute ventilation sensor/algorithm.          |
| Southorn PA, Kamath GS, Vasdev GM, Hayes DL. Monitoring equipment induced tachycardia in patients with minute ventilation rate-responsive pacemakers. <i>Br J Anaesth</i> 2000;84:508–509.          | CS   | 2         | PM           | Rate adaptive pacing due to interaction between the ECG monitoring equipment and the minute ventilation sensor/algorithm.          |

Appendix 2 Continued

| Author   | Type  | Patient # | CIED type      | Findings  |
|--|-------|-----------|----------------|---|
| <b>Electroconvulsive therapy</b>   |       |           |                |   |
| MacPherson RD, Loo CK, Barrett N. Electroconvulsive therapy in patients with cardiac pacemakers. <i>Anaesth Intensive Care</i> 2006;34:470–474.  | CS    | 10        | PM             | No abnormal function with PM.   |
| Giltay EJ, Kho KH, Keijzer LT, Leijenaar M, van Schaick HW, Blansjaar BA. Electroconvulsive therapy (ECT) in a patient with a dual-chamber sensing, VDDR pacemaker. <i>J ECT</i> 2005; 21:35–38.   | CR    | 1         |                | Oversensing in a VDD (floating atrial system).  |
| Dolenc TJ, Barnes RD, Hayes DL, Rasmussen KG. Electroconvulsive therapy in patients with cardiac pacemakers and implantable cardioverter defibrillators. <i>Pacing Clin Electrophysiol</i> 2004;27:1257–1263.  | CS    | 29        | PM: 26; ICD: 3 | Magnet available for pacemakers but not routinely used. ICDs programmed to therapies off. No ECT interactions noted. One episode of supraventricular tachycardia not related to device. |
| Lapid MI, Rummans TA, Hofmann VE, Olney BA. ECT and automatic internal cardioverter-defibrillator. <i>J ECT</i> 2001;17: 146–148.  | CR    | 1         | ICD            | Deactivated and reactivated prior to each therapy with no observed interaction.   |
| Abiuso P, Dunkelmann R, Proper M. Electroconvulsive therapy in patients with pacemakers. <i>JAMA</i> 1978;240:2459–2460.   | CR    | 1         | PM             | ECT performed with magnet application with no abnormal pacemaker function.  |
| Youmans CR, Bourianoff G, Allensworth DC, Martin W, Derrick JR. Cardiovascular alterations during electroconvulsive therapy in patients with cardiac pacemakers. <i>South Med J</i> 1972;65:361–365.   | EX/CR | 5 dogs/1  | PM             | No abnormal function during ECT therapy.  |
| <b>Gastroenterology/capsule endoscopy</b>  |       |           |                |   |
| Elias G, Toubia N. Safety of capsule endoscopy in the setting of implanted cardiac defibrillators: a brief report. <i>Am J Gastroenterol</i> 2009;104:1856–1857.   | Le    | 4         | ICD            | ICD therapies were not switched off and no inappropriate intervention or malfunction of any kind was recorded from the device at the end of the procedure.                              |
| Bandorski D, Irnich W, Brück M, Beyer N, Kramer W, Jakobs R. Capsule endoscopy and cardiac pacemakers: investigation for possible interference. <i>Endoscopy</i> 2008;40:36–39.  | EX    | 21        | PM             | No interference identified between the two devices.   |
| Dirks MH, Costea F, Seidman EG. Successful videocapsule endoscopy in patients with an abdominal cardiac pacemaker. <i>Endoscopy</i> 2008;40:73–75.   | CS    | 5         | PM             | Safe procedure without interference, although a brief inactivation of the capsule was noted when the capsule and pacemaker were physically close to each other.                         |
| Guertin D, Faheem O, Ling T, Pelletier G, McComas D, Yarlagadda RK, Clyne C, Kluger J. Electromagnetic interference (EMI) and arrhythmic events in ICD patients undergoing gastrointestinal procedures. <i>Pacing Clin Electrophysiol</i> 2007;30:734–739. | CS    | 41        | ICD            | No EMI or arrhythmic events triggered during endoscopic procedure in patients with pectorally implanted transvenous ICDs.   |
| Pelargonio G, Dello Russo A, Pace M, Casella M, Lecca G, Riccioni ME, Bellocci F. Use of video capsule endoscopy in a patient with an implantable cardiac defibrillator. <i>Europace</i> 2006;8:1062–1063.   | CR    | 1         | ICD            | No interaction between video capsule endoscopy and the ICD.   |
| Payeras G, Piqueras J, Moreno VJ, Cabrera A, Menéndez D, Jiménez R. Effects of capsule endoscopy on cardiac pacemakers. <i>Endoscopy</i> 2005;37:1181–1185.  | CS    | 20        | PM             | No interference was observed.   |

## Appendix 2 Continued

| Author  | Type  | Patient #                      | CIED type      | Findings   |
|---|-------|--------------------------------|----------------|--|
| Leighton JA, Srivathsan K, Carey EJ, Sharma VK, Heigh RI, Post JK, Erickson PJ, Robinson SR, Bazzell JL, Fleischer DE. Safety of wireless capsule endoscopy in patients with implantable cardiac defibrillators. <i>Am J Gastroenterol</i> 2005; 100:1728–1731. | CS    | 5                              | ICD            | No arrhythmia or other adverse cardiac events were noted during capsule transmission. No interference by the ICD on the capsule endoscopy video images was seen.   |
| Dubner S, Dubner Y, Gallino S, Spallone L, Zagalsky D, Rubio H, Zimmerman J, Goldin E. Electromagnetic interference with implantable cardiac pacemakers by video capsule. <i>Gastrointest Endosc</i> 2005;61:250–254.   | EX    | 100                            | PM             | A test capsule broadcasting at the same frequency as the video capsule was used. In 4 of 100 patients, the potential for interference identified.  |
| Leighton JA, Sharma VK, Srivathsan K, Heigh RI, McWane TL, Post JK, Robinson SR, Bazzell JL, Fleischer DE. Safety of capsule endoscopy in patients with pacemakers. <i>Gastrointest Endosc</i> 2004;59:567–569.   | CS    | 5                              | PM             | Capsule endoscopy appears to be safe in patients with cardiac pacemakers and does not appear to be associated with any significant adverse cardiac event. Pacemakers do not interfere with capsule imaging   |
| Guyomar Y, Vandeville L, Heuls S, Coviaux F, Graux P, Cornaert P, Filoche B. Interference between pacemaker and video capsule endoscopy. <i>Pacing Clin Electrophysiol</i> 2004;27:1329–1330.   | CR    | 1                              |                | VOO pacemaker-no capsule interference.   |
| Ito S, Shibata H, Okahisa T, Okamura S, Wada S, Yano M, Saijyo T, Honda H, Hayashi H, Shimizu I. Endoscopic therapy using monopolar and bipolar snare with a high-frequency current in patients with a pacemaker. <i>Endoscopy</i> 1994;26:270.                 | Le    | 5                              | PM             | Devices reprogrammed to minimize interaction.  |
| <b>Lithotripsy</b>  |       |                                |                |  |
| Küfer R, Thamasett S, Volkmer B, Hautmann RE, Gschwend JE. <i>J Endourology</i> 2001;15:479–484.  | EX    | 2                              | ICD            | ICDs tested within the focus of the lithotripter with a range of strengths. No damage noted. Post-shock pacing inhibition noted due to sensing observed in one case.   |
| Chung MK, Stroom SB, Ching E, Grooms M, Mowrey KA, Wilkoff BL. Effects of extracorporeal shock with lithotripsy on tiered therapy implantable cardioverter-defibrillators. <i>PACE</i> 1999; 22:738–742.  | EX/CS | <i>In Vitro: 4; in Vivo: 2</i> | ICD            | Loose setscrew with in vitro testing. Reset in one ICD during in vivo evaluation.  |
| <b>Diagnostic Radiation (CT)</b>  |       |                                |                |  |
| McCullough CH, Zhang J, Primak AN, Clement WJ, Buysman JR. Effects of CT irradiation on implantable cardiac rhythm management devices. <i>Radiology</i> 2007;243:766–774.   | EX    | 21                             | PM: 13, ICD: 8 | Oversensing was observed in 20 of 21 devices at maximum doses and in 17 of 20 devices at typical doses. Oversensing most often manifested as inhibition, although it occasionally manifested as tracking or safety pacing. Two devices inhibited for more than 4 seconds in spiral mode at clinical dose levels. Oversensing was transient and ceased as soon as the device stopped moving through the x-ray beam or the beam was turned off. The partial electrical reset (PER) safety feature was activated in two models, InSync 8040 and Thera DR. With the exception of PER, programming was not altered. Effects occurred only if the x-ray beam passed directly over the generator. |



**Appendix 2** Continued

| Author  | Type  | Patient #                         | CIED type             | Findings  |
|---|-------|-----------------------------------|-----------------------|---|
| Yamaji S, Imai S, Saito F, Yagi H, Kushiro T, Uchiyama T. Does high-power computed tomography scanning equipment affect the operation of pacemakers? <i>Circ J</i> 2006;70:190–197.   | EX    | 11                                | PM                    | Transient oversensing in 6 of 11 pacemakers when the beam was directly over the generator.  |
| <b>Therapeutic radiation</b>  |       |                                   |                       |   |
| Zweng A, Schuster R, Hawlicek R, Weber HS. Life-threatening pacemaker dysfunction associated with therapeutic radiation: a case report. <i>Angiology</i> 2009;60:509–512.   | CR    | 1                                 | PM                    | Runaway pacemaker (ventricular pacing to 180 bpm) after an estimated dose of 0.11 Gy.   |
| Kapa S, Fong L, Blackwell CR, Herman MG, Schomberg PJ, Hayes DL. Effects of scatter radiation on ICD and CRT function. <i>Pacing Clin Electrophysiol</i> 2008;31:727–732.   | EX/CS | ICD & CRT-D (12 & 8), 13 patients | PM: 7; ICD: 4; CRT: 1 | There was no evidence of reset or malfunction during or after radiation. Also, no episodes of device reset, inappropriate sensing or therapy, or changes in programmed parameters were found in their review of patients undergoing radiotherapy.   |
| Oshiro Y, Sugahara S, Noma M, Sato M, Sakakibara Y, Sakae T, Hayashi Y, Nakayama H, Tsuboi K, Fukumitsu N, Kanemoto A, Hashimoto T, Tokuuye K. Proton beam therapy interference with implanted cardiac pacemakers. <i>Int J Radiat Oncol Biol Phys</i> 2008;72:723–727. | EX/CS | 8                                 | PM                    | Proton beam therapy was not associated with any changes.  |
| Hurkmans CW, Scheepers E, Springorum BG, Uiterwaal H. Influence of radiotherapy on the latest generation of implantable cardioverter-defibrillators. <i>Int J Radiat Oncol Biol Phys</i> 2005;63:282–289.   | EX    | 11                                | ICD                   | 11 ICD models directly exposed to radiotherapy with sensing interference in all 11. Complete loss of function in 4 between 0.5 Gy and 1.5 Gy.   |
| Hurkmans CW, Scheepers E, Springorum BG, Uiterwaal H. Influence of radiotherapy on the latest generation of pacemakers. <i>Radiother Oncol</i> 2005;76:93–98.   | EX    | 19                                | PM                    | Seven pacemakers lost output at 120 Gy. Eight pacemakers showed inhibition during irradiation in the direct beam. Five pacemakers did not show any malfunction at all. Most malfunctions were observed at dose levels exceeding 20 Gy. Electrical reset observed.   |
| Thomas D, Becker R, Katus HA, Schoels W, Karle CA. Radiation therapy-induced electrical reset of an implantable cardioverter defibrillator device located outside the irradiation field. <i>J Electrocardiol</i> 2004;37:73–74.   | CR    | 1                                 | ICD                   |   |
| Mouton J, Haug R, Bridier A, Dodinot B. Influence of high-energy photon beam irradiation on pacemaker operation. <i>Phys Med Biol</i> 2002;47:2879–2893.  | EX    | 96                                | PM                    | The authors felt that warnings provided by manufacturers about the maximum tolerable cumulative radiation doses for safe operation of irradiated pacemakers (5 Gy), even reduced to 2 Gy, are not reliable. The spread of cumulative doses inducing failures was large with one failure noted at 0.15 Gy, while ten pacemakers withstood more than 140 Gy of cumulative dose. |
| Rodriguez F, Filimonov A, Henning A, Coughlin C, Greenberg M. Radiation-induced effects in multiprogrammable pacemakers and implantable defibrillators. <i>PACE</i> 1991;14: 2143–2153.   | EX    | 27                                | PM: 23; ICD: 4        | 8/17 pacemakers exposed to photon radiation failed before delivery of 50 Gy and 4/6 pacemakers exposed to electron radiation failed before 70 Gy. For ICDs an increase in charging time associated with cumulative radiation dose was identified.   |
| Brooks C, Mutter M. Pacemaker failure associated with radiation. <i>Am J Emerg Med</i> 1988;6:591–593.  | CR    | 1                                 | PM                    | Pacing at the upper rate limit after receiving radiation.   |
| Katzenberg CA, Marcus FI, Heusinkveld RS, Mammana RB. Pacemaker failure due to radiation therapy. <i>PACE</i> 1982;5: 156–159.  | CR    | 1                                 | PM                    | After a dose of 3,000-3,600 rads intermittent atrial pacing (320 bpm) and ventricular pacing (104 bpm) with loss of ventricular sensing developed.  |

## Appendix 2 Continued

| Author  | Type | Patient # | CIED type | Findings   |
|---|------|-----------|-----------|--|
| Adamec R, Haefliger JM, Killisch JP, Niederer J, Jaquet P. Damaging effect of therapeutic radiation on programmable pacemakers. <i>PACE</i> 1982;5:146–150.   | EX   | 25        | PM        | Increased sensitivity to radiation noted with more sophisticated programmable PMs.   |
| <b><i>Transcutaneous electronic nerve stimulation (TENS); neuromuscular electrical stimulation (NMES)</i></b>   |      |           |           |  |
| Holmgren C, Carlsson T, Mannheimer C, Edvardsson N. Risk of interference from transcutaneous electrical nerve stimulation on the sensing function of implantable defibrillators. <i>Pacing Clin Electrophysiol</i> 2008;31:151–158.   | CS   | 30        | ICD       | TENS at different power levels led to intermittent oversensing in both the maxillary (47%) and hip (17%) regions.  |
| Kowalski M, Huizar JF, Kaszala K, Wood MA. Problems with implantable cardiac device therapy. <i>Cardiol Clin</i> 2008;26:441–458.   | Re   | 1         | ICD       | No details but EMI from a TENS unit was detected by an ICD.  |
| Epstein AE. Troubleshooting of implantable cardioverter-defibrillators. In: Ellenbogen KA, Kay GN. <i>Clinical Cardiac Pacing, Defibrillation, and Resynchronization Therapy</i> , 3 <sup>rd</sup> Ed. Philadelphia, PA: Saunders/Elsevier, 2007.   | BC   | 1         | ICD       | EMI recorded during TENS.  |
| Siu CW, Tse HF, Lau CP. Inappropriate implantable cardioverter defibrillator shock from a transcutaneous muscle stimulation device therapy. <i>J Interv Card Electrophysiol</i> 2005;13:73–75.  | CR   | 1         | ICD       | Inappropriate shock due to TENS electrodes placed in the mid-back. No testing was performed.   |
| Crevenna R, Wolzt M, Fialka-Moser V, Keilani M, Nuhr M, Paternostro-Sluga T, Pacher R, Mayr W, Quittan M. Long-term transcutaneous neuromuscular electrical stimulation in patients with bipolar sensing implantable cardioverter defibrillators: a pilot safety study. <i>Artif Organs</i> 2004;28:99–102. | CS   | 6         | ICD       | During long-term therapy with neuromuscular electrical stimulation, no adverse events were observed. ICD function after the stimulation period revealed no abnormalities in any patient. |
| Pyatt JR, Trenbath D, Chester M, Connelly DT. The simultaneous use of a biventricular implantable cardioverter defibrillator (ICD) and transcutaneous electrical nerve stimulation (TENS) unit: implications for device interaction. <i>Europace</i> 2003;5:91–93.  | CR   | 1         | CRT-D     | Oversensing with inhibition and development of symptoms despite prior testing.   |
| Curwin JH, Coyne RF, Winters SL. Inappropriate defibrillator (ICD) shocks caused by transcutaneous electronic nerve stimulation (TENS) units. <i>Pacing Clin Electrophysiol</i> 1999;22:692–693.  | Le   | 1         | ICD       | Inappropriate shock after reorientation of TENS electrodes without testing.  |
| Philbin DM, Marieb MA, Aithal KH, Schoenfeld MH. Inappropriate shocks delivered by an ICD as a result of sensed potentials from a transcutaneous electronic nerve stimulation unit. <i>Pacing Clin Electrophysiol</i> 1998;21:2010–2011.  | CR   | 1         | ICD       | Inappropriate shock due to oversensing.  |
| Glotzer TV, Gordon M, Sparta M. Electromagnetic interference from a muscle stimulation device causing discharge of an implantable cardioverter defibrillator: epicardial and endocardial bipolar sensing circuits are compared. <i>PACE</i> 1998;21:1996–1998.  | CS   | 2         | ICD       | TENS associated with inappropriate shock with an ICD that used epicardial leads with no evidence of oversensing in another patient with an ICD using endocardial leads.                  |

| Author  | Type  | Patient # | CIED type       | Findings   |
|---|-------|-----------|-----------------|--|
| Vlay SC. Electromagnetic interference and ICD discharge related to chiropractic treatment. <i>Pacing Clin Electrophysiol</i> 1998;21:2009.  | CR    | 1         | ICD             | TENS in the sacral region led to ICD discharge.  |
| Chen D, Philip M, Phillip PA, Monga TN. Cardiac pacemaker inhibition by transcutaneous electrical nerve stimulation. <i>Arch Phys Med Rehabil</i> 1990;71:27–30.  | CS    | 2         | PM              | Despite initial testing with the TENS unit (posterior thigh in one patient and neck and right shoulder in the other), transient inhibition noted on subsequent ECG monitoring managed by decreasing the sensitivity.   |
| Rasmussen MJ, Hayes DL, Vliestra RE, Thorsteinsson G. Can transcutaneous electrical nerve stimulation be safely used in patients with permanent pacemakers? <i>Mayo Clin Proc</i> 1988; 63:443–445.   | CS    | 51        | PM              | TENS studies at four anatomic sites (lumbar region, cervical spine, left leg, and lower arm on the ipsilateral side of the PM) performed in 51 patients. No evidence of interference or inhibition was observed.   |
| <b>Nerve conduction study</b>   |       |           |                 |  |
| Schoeck AP, Mellion ML, Gilchrist JM, Christian FV. Safety of nerve conduction studies in patients with implanted cardiac devices. <i>Muscle Nerve</i> 2007;35:521–524.   | CS    | 15        | PM: 10, ICD: 5  | No interaction with peroneal nerve and median nerve evaluation.  |
| <b>Dental</b>   |       |           |                 |  |
| Brand HS, Entjes ML, Nieuw Amerongen AV, van der Hoeff EV, Schrama TA. Interference of electrical dental equipment with implantable cardioverter-defibrillators. <i>Br Dent J</i> 2007; 203:577–579.  | EX    | 3         | ICD             | One ultrasonic bath cleaner interfered with two of the ICDs. Otherwise no interactions seen with a large number of different pieces of dental equipment.   |
| Roedig JJ, Shah J, Elayi CS, Miller CS. Interference of cardiac pacemaker and implantable cardioverter-defibrillator activity during electronic dental device use. <i>JADA</i> 2010;141:521–526.  | EX    | none      | ICD and PM      | Some dental equipment interfered with CIED telemetry.  |
| <b>Hyperbaric conditions</b>  |       |           |                 |  |
| Lafay V, Trigano JA, Gardette B, Micoli C, Carre F. Effects of hyperbaric exposures on cardiac pacemakers. <i>Br J Sports Med</i> 2008;42:212–216.  | EX    | 20        | PM              | No dysfunction to 60 meters underwater, but generator case deformation noted.  |
| Trigano A, Lafay V, Blandeau O, Levy S, Gardette B, Micoli C. Activity-based rate-adaptive pacemakers under hyperbaric conditions. <i>J Interv Card Electrophysiol</i> 2006;15:179–183.   | EX    | 16        | PM              | Pacemakers with accelerometers showed no abnormal function at 30 and 60 meters underwater, although generator case distortion was noted at 60 meters underwater.   |
| <b>Wireless technology</b>  |       |           |                 |  |
| Seidman SJ, Brockman R, Lewis BM, Guag J, Shein MJ, Clement WJ, Kippola J, Digby D, Barber C, Huntwork D. In vitro tests reveal sample radiofrequency identification readers inducing clinically significant electromagnetic interference to implantable pacemakers and implantable cardioverter-defibrillators. <i>Heart Rhythm</i> 2010;7:99–107. | EX    | 34        | ICD: 19; PM: 15 | During exposure with a radiofrequency identification reader, interaction was observed for 6% of all pacemaker tests (maximum distance 22.5 cm) and 1% of all ICD tests (maximum distance 7.5 cm). For both PMs and ICDs, no reactions were observed during exposure to ultra-high frequency or continuous-wave readers. PMs and ICDs were most susceptible to modulated low frequency readers. |
| Bassen HI, Moore HJ, Ruggera PS. Cellular phone interference testing of implantable cardiac defibrillators in vitro. <i>Pacing Clin Electrophysiol</i> 1998;21:1709–1715.   | EX    | 3         | ICD             | EMI noted on the ICD when the phone was within 2.3 to 5.8 cm of the ICD.   |
| Fetter JG, Ivans V, Benditt DG, Collins J. Digital cellular telephone interaction with implantable cardioverter-defibrillators. <i>J Am Coll Cardiol</i> 1998;31:623–628.   | EX/CS | 41        | ICD             | None of the ICDs tested in 41 patients were affected by oversensing of the EMI field of the cellular telephones during the in vivo study. Therefore, the binomial upper 95% confidence limit for the failure rate of 0% is 7%.   |

## Appendix 2 Continued

| Author   | Type | Patient # | CIED type | Findings  |
|--|------|-----------|-----------|---|
| Altamura G, Toscano S, Gentilucci G, Ammirati F, Castro A, Pandozi C, et al. Influence of digital and analogue cellular telephones on implanted pacemakers. <i>Eur Heart J</i> 1997;18:1632–1641.              | CS   | 43        | PM        | In 141 patients, EMI sensed by the PM was observed in 18% to 22% of cases particularly during the ringing phase and when the telephone was placed directly over the pocket.   |
| Hayes DL, Wang PJ, Reynolds DW, Estes M, III, Griffith JL, Steffens RA, Carlo GL, Findlay GK, Johnson CM. Interference with cardiac pacemakers by cellular telephones. <i>N Engl J Med</i> 1997;336:1473–1479. | CS   | 980       | PM        | The incidence of any type of interference was 20% in the 5,533 tests, and the incidence of symptoms was 7.2%. The incidence of clinically significant interference was 6.6%   |
| Naegeli B, Osswald S, Deola M, Burkart F. Intermittent pacemaker dysfunction caused by digital mobile telephones. <i>J Am Coll Cardiol</i> 1996;27:1471–1477.  | CS   | 39        | PM        | EMI detected in 18% of patients usually when the telephone was near the PM (<10 cm) or if the PM was programmed to maximal sensitivity or the unipolar sensing mode.  |
| Irnich W, Batz L, Muller R, Tobisch R. Electromagnetic interference of pacemakers by mobile phones. <i>PACE</i> 1996;19:1431–1446.   | EX   | 231       | PM        | Pacemakers tested in a saline bath using three communications systems that use different frequencies available in Germany. Incidence of EMI ranged from 0–34% with a higher likelihood of interaction with lower frequencies. |

EX = Experimental study; CR = Case report; CS = Case series; A = Abstract; Le = Letter; S = Survey; BC = Example given in a book chapter; Re = Example given in a review; ICD = Implantable cardiac defibrillator; PM = Pacemaker; CRT = Cardiac resynchronization therapy; EMI = Electromagnetic interference; CABG = Coronary artery bypass grafting; STIMAREC = stimulation cardiaque de la Société française de cardiologie et de l'Association européenne de stimulo-vigilance; bpm = BPM = Beats per minute; ERI = Elective replacement interval.

**Appendix 3** Reference group

| Name             | Company                 | Field       |
|------------------|-------------------------|-------------|
| Jon Brumbaugh    | BIOTRONIK, Inc.         | Regulatory  |
| Steve Chang      | BIOTRONIK, Inc.         | Engineering |
| Arjun Sharma, MD | Boston Scientific Corp. | Clinical    |
| Michael Flanagan | Boston Scientific Corp. | Engineering |
| Jeff Eggleston   | Covidien                | Engineering |
| Andy Frye        | Medtronic, Inc.         | Clinical    |
| Jay Wilcox       | Medtronic, Inc.         | Engineering |
| Stacey Wessman   | Medtronic, Inc.         | Regulatory  |
| Mark Carlson, MD | St. Jude Medical Corp.  | Clinical    |
| Larry Selznick   | St. Jude Medical Corp.  | Engineering |
| James Gerrity    | Sorin Medical           | Engineering |

**Appendix 4A** Programmed parameters for pacemakers during power-on reset mode

| Manufacturer       | Pacing mode  | Pacing output   | Pacing polarity | Sensitivity | Magnet response |
|--------------------|--------------|-----------------|-----------------|-------------|-----------------|
| BIOTRONIK          | VVI 70 bpm   | 4.8 V @ 1.0 ms  | Unipolar        | 2.5 mV      | Yes             |
| Boston Scientific† | VVI 65 bpm   | 5.0 V @ 1.0 ms  | Bipolar         | 1.5 mV      | No              |
| Medtronic          | VVI 65 bpm   | 5.0 V @ 0.4 ms  | Bipolar         | 2.8 mV      | Yes             |
| St. Jude Medical   | VVI 67.5 bpm | 4.0 V @ 0.6 ms* | Unipolar        | 2.0 mV      | No              |
| ELA-Sorin          | VVI 70 bpm   | 5.0 V @ 0.5 ms  | Unipolar        | 2.2 mV      | No              |

\*Accent/Anthem and Frontier II models deliver 5 V @ 0.6 ms.

†Boston Scientific CRT-P devices differ in pacing output (5 V @ 0.5 ms) and pacing polarity (right ventricle lead is unipolar and left ventricle lead paces from left ventricle tip to pulse generator).

bpm = beats per minute; V = volts; ms = milliseconds; mV = millivolts; magnet = device will/will not pace asynchronously in response to a magnet during safety mode/reset mode.

**Appendix 4B** Programmed parameters for implantable cardioverter defibrillators during power on reset mode

| Manufacturer      | Rate cutoff | Detection criteria | Sensitivity | Energy    | Pacing mode  | Pacing output   |
|-------------------|-------------|--------------------|-------------|-----------|--------------|-----------------|
| Biotronik         | 150 bpm     | 8/12               | 0.8 mV      | 40 J × 8  | VVI 70 bpm   | 7.5 V @ 1.5 ms* |
| Boston Scientific | 165 bpm     | 8/10               | 0.25 mV     | 41 J × 5  | VVI 72.5 bpm | 5.0 V @ 1.0 ms  |
| Medtronic         | 188 bpm     | 18/24              | 0.3 mV      | 35 J × 6  | VVI 65 bpm   | 6.0 V @ 1.5 ms  |
| St. Jude Medical† | 146 bpm     | 12                 | 0.3 mV      | 36 J × 6‡ | VVI 60 bpm   | 5.0 V @ 0.5 ms  |
| ELA-Sorin         | 190 bpm     | 6/8                | 0.4 mV      | 42 J × 4§ | VVI 60 bpm   | 5.0 V @ 0.35 ms |

All devices will respond to magnet application by temporarily disabling tachyarrhythmic detection. Pacing polarity for all devices is bipolar with the exception of Boston Scientific, which paces in a unipolar configuration. Energy values listed for Medtronic and St. Jude represent energy delivered. The remaining represent energy charged.

\*In CRT devices, left ventricle lead output is 4.8 V @ 0.5 ms.

†The Current and Promote family of devices revert to an AutoSense sensitivity setting, pace at VVI 67.5 bpm with pacing outputs of 5.0 V @ 0.6 ms.

‡The Epic and Epic II family of devices deliver 30 J × 6.

§Ovatio family of devices: 34 J × 4.

bpm = beats per minute; V = volts; ms = milliseconds; mV = millivolts; magnet = device will/will not pace asynchronously in response to a magnet during safety mode/reset mode.

**Appendix 5A** Pacemaker magnet response

| Manufacturer      | Magnet response at beginning of life (BOL)  | Magnet response at elective replacement indicator (ERI)*   | Is magnet response programmable?†  | Audible tones with magnet placement? |
|-------------------|---|--|--|--------------------------------------|
| BIOTRONIK         | <ol style="list-style-type: none"> <li>Pacing mode depends on programming: <ul style="list-style-type: none"> <li>—ASYNC - Asynchronous pacing (D00 or V00) @ 90 bpm</li> <li>—SYNC - Programmed pacing mode at programmed rate (not asynchronous)</li> <li>—AUTO - V00 @ 90 bpm for 1st 10 beats then programmed pacing mode at programmed rate</li> </ul> </li> <li>Suspends rate response in all modes§</li> <li>Pacing amplitudes remain unchanged‡</li> </ol>  | Pacing mode depends on programming: <ul style="list-style-type: none"> <li>—ASYNC - V00 @ 80 bpm</li> <li>—SYNC - VDD or VVI @ programmed rate minus 11%</li> <li>—AUTO - V00 @ 80 bpm for 1st 10 beats then VDD or VVI @ programmed rate minus 11%</li> </ul> | Yes§   | None                                 |
| Boston Scientific | <ol style="list-style-type: none"> <li>Asynchronous pacing at 100 bpm (D00 or V00) <ul style="list-style-type: none"> <li>—Note, pulse width on 3<sup>rd</sup> pulse reduced by 50% in order to check threshold safety margin</li> </ul> </li> <li>Suspends rate response</li> <li>Pacing amplitudes remain unchanged‡</li> </ol>   | D00 or V00 85 bpm <ul style="list-style-type: none"> <li>—Nearer to ERI will pace at 90 bpm</li> <li>—Magnet pacing amplitude between ERI and EOL is 2× last threshold and at least between 3.5 and 5 V</li> </ul>   | Yes <ul style="list-style-type: none"> <li>—If magnet response programmed to “EGM”, device will not result in asynchronous pacing when magnet is placed over the pacemaker</li> <li>—To activate magnet response, the feature must be programmed back to “ON”</li> </ul>   | None                                 |
| ELA/Sorin         | <ol style="list-style-type: none"> <li>Asynchronous pacing at 96 bpm (D00 with max AV delay or V00)</li> <li>Suspends rate response</li> <li>Pacing amplitudes go to 5 V and 0.5 ms unless programmed higher‡ <ul style="list-style-type: none"> <li>—Note, 8 asynchronous beats after magnet removal; first 6 at magnet rate at programmed output with AV Delay at 95 ms and last 2 beats at base rate, programmed output, and Max AV Delay</li> </ul> </li> </ol> | Gradual decrease to D00 or V00 @ 80 bpm  | No   | None                                 |
| Medtronic         | <ol style="list-style-type: none"> <li>Asynchronous pacing at 85 bpm (D00 or V00)</li> <li>Suspends rate response</li> <li>Pacing amplitudes remain unchanged‡ <ul style="list-style-type: none"> <li>—Note, first 3 beats with magnet application are at 100 bpm with reduction of pulse width on 3<sup>rd</sup> pulse reduced by 25% in order to check threshold safety margin</li> </ul> </li> </ol>   | V00 @ 65 bpm#  | No   | None                                 |
| St. Jude Medical  | <ol style="list-style-type: none"> <li>Asynchronous pacing at 100 bpm or 98.6 bpm (V00 or D00) depending on the model** <ul style="list-style-type: none"> <li>—Magnet rate will gradually decline throughout the life of the device.</li> </ul> </li> <li>Suspends rate response</li> <li>Pacing amplitudes vary by model‡</li> </ol>  | V00 at <85 bpm or 86.3 bpm, depending on the model¶ <ul style="list-style-type: none"> <li>—Magnet pacing amplitude between ERI and EOL is 2× last threshold when AutoCapture enabled</li> </ul>   | Yes <ul style="list-style-type: none"> <li>—If magnet response is programmed to “OFF” device will not result in magnet pacing rate</li> <li>—If magnet response is programmed to “Event Snapshots + Battery Test” device will trigger an event snapshot and then pace at the magnet rate</li> <li>—To activate magnet response, the feature must be programmed back to “Battery Test” (On)</li> <li>—VARIO enabled devices will initiate a magnet rate followed by a threshold test**</li> </ul> | None                                 |

**Appendix 5A** Continued**Pacemaker models included in Table 5A:****BIOTRONIK:**

Evia, Estella, Effecta, Cylos, Protos, Philos II, Philos, Axios, Actros, Actros+, Stratos (model numbers 359529, 359533, 359524, 359531, 371205, 371202, 371199, 371207, 371200, 377848, 377851, 349806, 349799, 349811, 122300, 122302, 343175, 341826, 341824, 331443, 331446, 331447, 331598, 331599, 331445, 122544, 338845, 338851, 122311, 122314, 122312, 122445, 122315, 122316, 121894, 121961, 121890, 121896, 338202, 338200)

**Boston Scientific:**

PULSAR, PULSAR MAX/II, DISCOVERY/II, MERIDIAN/II, INSIGNIA (Entra/Plus/Ultra), ALTRUA (20/40/60) (1170/1172/1174/1176/1180/1184/1270/1272/1274/1276/1280/1284, 1190/1194/1195/1198/1290/1291/1294/1295/1296/1297/1298, S201/S401/S601/S202/S203/S204/S205/S208S402/S403/S404//S602/S603/S605/S606)

**ELA/Sorin:**

Reply DR, SR and Esprit DR, SR; Symphony (2550, 2250); Rhapsody (2530, 2510, 2410, 2210, 2130); Talent (233, 133, 213, 113); Brio (222, 212, 112); Chorus RM (7034, 7134); Chorus (6234, 6244, 6034, 6043, 6001); and Opus RM and G (4624, 4534, 3001, 4034, 2001)

**Medtronic:**

Adapta, Versa and Sensia: (ADDR01/03/06, ADDR51, ADDR11, ADD01, ADVDD01, ADSR01/03/06, VEDR01, SEDR01, SEDR11, SED01, SESR01, SES01, REDR01, RED01, RESR01, RES01, REVDD01, SW010); EnPulse: (E1DR01, E1DR03, E1DR06, E1DR21, E2D01, E2D03, E2DR01, E2DR03, E2DR06, E2DR21, E2DR31, E2DR33, E2SR01, E2SR03, E2SR06, E2VDD01) Kappa and Sigma: (KD700, KD701, KD703, KD706, KD901, KD903, KD906, KDR401, KDR403, KDR600, KDR601, KDR603, KDR606, KDR651, KDR653, KDR656, KDR700, KDR700V, KDR701, KDR701V, KDR703, KDR703V, KDR706, KDR706V, KDR720, KDR721, KDR730, KDR731, KDR733, KDR801, KDR803, KDR806, KDR901, KDR903, KDR906, KDR921, KDR931, KDR933, KSR401, KSR403, KSR700, KSR701, KSR703, KSR706, KSR901, KSR903, KSR906, KVDD700, KVDD701, KVDD901, SD203, SD303, SDR203, SDR303, SDR306, SS103, SS106, SS203, SS303, SSR203, SSR303, SSR306, SVDD303, SVVI103) EnRhythm Model Pacemaker: P1501DR, Syncra CRT-P: Model C2TR01 Consulta CRT-P: Model C4TR01, Revo MRI SureScan: Model RVDR01

**St. Jude Medical:**

Microny/Microny, Regency, Accent, Accent RF, Nuance, Nuance RF, Anthem, Anthem RF (2525T, 2535K, 2425T, PM1110-PM1214, PM2110-PM2214, PM3110-PM3214) Affinity, Affirmity, Integrity, Entity, Verity ADx, Integrity ADx, Identity, Identity ADx, Fidelity, Victory, Zephyr, Emprise, Frontier, Frontier II]: (5130-5142, 5226-5348, 5056, 5156-5180, 5356-5388, 5610-5628, 5810-5828, 5430-5432i, 5456-5480)

\*EOL Magnet pacing rates vary between manufacturers but are generally lower than the ERI pacing rates.

†Whether or not a pacemaker will respond to a magnet placed over the generator by reverting to asynchronous pacing at a set magnet determined pacing rate, is programmable in some manufacturer's devices (BIOTRONIK, Boston Scientific, and St. Jude Medical). While rarely used, the purpose of a programmable magnet feature is to allow patient activated rhythm recordings using the magnet placed over the device. When in this mode, the pacemaker will not respond to a magnet by changing to asynchronous pacing. The exception to this is with the St. Jude Medical "Affinity, Integrity, Entity" models which have a "Snapshot + Battery mode" which, if programmed, allows rhythm recording but preserved magnet response function. It can be confirmed that the magnet response is "ON" by placing the magnet over the pacemaker and noting the change to asynchronous pacing at the manufacturer determined pacing rate. Medtronic and ELA/Sorin pacemakers do not have a programmable magnet function, that is, a magnet placed over those devices will always result in a magnet determined pacing rate in an asynchronous mode.

‡Pacing amplitude during magnet application:

*BIOTRONIK, Boston Scientific and Medtronic* pacemakers: will be the last programmed amplitude. If this is the auto-threshold determined output, the amplitude may be < than  $2 \times$  safety margin (depending upon the safety margin programmed for auto-threshold testing).

*St. Jude Medical* pacemakers will pace at an amplitude of 4.5V @ $\geq 0.5$  ms if AutoCapture is programmed on in the Microny, Microny II, Regency, Verity ADx, Integrity ADx, Identity, Identity ADx, Fidelity, Affinity, Affirmity, Entity, Integrity, Victory/Zephyr (5.0V). For the *St. Jude Medical* Emprise, Accent, Accent RF, Nuance, and Nuance RF series, the magnet amplitude will be the last capture threshold +1V @ $\geq 0.5$  ms when Auto Capture is programmed on. *ELA/Sorin* pacemakers pace at 5.0 V at 0.5 mv with magnet application over the device.

§BIOTRONIK Actros and Actros+ pacemakers programmed to ASYNC mode pace at the magnet rate for 10 cycles, then revert to pacing at the programmed mode and base rate. SYNC magnet response mode in BIOTRONIK pacemakers is rarely programmed as it provides no overview of the battery status and there is no change in pacing rates with magnet application. It is typically only used when the physician wants to store patient triggered EGM events. Magnet application does not inhibit rate response in the BIOTRONIK "Evia" models, but does inhibit rate response in all previous models.

#For the Medtronic Kappa 400 series only: Extended Threshold Margin Test ("Extended TMT"): Three beats at 100 ppm, then drops pulse width by 25% then two beats at programmed output, then pulse width drops by 50%, and then two beats at programmed output, then PW drop at 75.

\*\*St. Jude Medical pacemakers which have a BOL magnet pacing rate of 100 bpm/ERI < 85 bpm are: Microny, Microny II, Regency, Accent, Accent RF, Nuance, Nuance RF, Anthem, Anthem RF. St. Jude Medical pacemakers with a magnet pacing rate of 98.6 bpm/ERI < 86.3 bpm are: Affinity, Affirmity, Integrity, Entity, Verity ADx, Integrity ADx, Identity, Identity ADx, Fidelity, Victory, Zephyr, Emprise, Frontier, Frontier II.

¶Vario is a programmable option in the St. Jude Medical Microny, Microny II, Regency pacemakers only. If this feature is programmed on, threshold testing will be performed with the application of a magnet. It consists of 32 asynchronous pacing pulses, the first 16 are the battery test phase (BOL-ERI rate), the second 16 are the capture test phase. In this phase, the device decrements the voltage from 4.5 V to 0.0 V (in 0.3 V increments) at 120 ppm. Upon completion of this phase, the device returns to the battery indicated rate.

**Appendix 5B** ICD magnet response (includes CRT-ICD)

| Manufacturer      | Magnet effect on tachyarrhythmia detection/therapy* | Magnet effect on pacing**  | Is magnet response programmable?  | Are tones audible with placement of magnet?  |
|-------------------|---|--|---|--|
| BIOTRONIK         | Suspends†   | None   | No  | None   |
| Boston Scientific | Suspends  | None   | Yes‡<br>PRIZM/2/HE:<br>There are 3 programmable options:<br>1. Enable Magnet Use ON/OFF<br>2. Change Tachy Mode with Magnet ON/OFF<br>3. Patient Triggered EGM ON/OFF.<br>VITALITY/2/DS/EL/HE; RENEWAL/3/HE; CONFIENT/LIVIAN; CONGNIS/TELIGEN:<br>There are 2 programmable options:<br>1. Enable Magnet Use ON/OFF<br>2. Patient Triggered EGM ON/OFF | Yes<br>R-wave synchronous beeping tones indicates that the device has detected a magnet and that tachycardia therapy is currently disabled.  |
| ELA/Sorin         | Suspends  | Magnet rate changes but continues in DDD mode (demand). Paces at 96 bpm at BOL gradual decline to 80 bpm at ERI• | No  | None   |
| Medtronic         | Suspends  | None   | No  | Yes<br>All devices have an audible tone for up to 30 sec. with magnet applied correctly over the device. A steady tone indicates normal magnet placement. Tones may be difficult to hear. Beeping or oscillating tones indicate an Alert condition—notify ICD care provider. |
| St. Jude Medical  | Suspends  | None   | Yes<br>Two programmable options:<br>1. Magnet response is nominally programmed to “Normal” (on)<br>2. “Ignore” (off)  | None   |

**ICD models included in Table 5B:**

**BIOTRONIK:**

Lumax 5 series, Lumax 3 series, Kronos, Lumos, Xelos, Lexos, Belos, Tachos (360342, 360347, 355262, 355263, 347406, 360344, 360345, 360348, 360340, 360341, 360346, 355270, 355271, 355266, 355267, 353219, 353220, 350822, 347000, 347001, 346998, 346999, 342873, 342874, 338170, 338171, 122499, 335572)

**Boston Scientific:**

PRIZM/2/HE (1850, 1855, 1851, 1856, 1852, 1857, 1853, 1858, 1860, 1861); VITALITY/2/DS/EL/HE (1870, 1871, 1872, A135, A155, T165, TT177, T125, T135, T127); RENEWAL/3/HE (H210, H215, H217, H219, H135, H170, H175, H177, H179); CONFIENT, LIVIAN (E030, H220, H225, H227, H229); CONGNIS/TELIGEN (E102, E110, N118, N119)



**Appendix 5B** Continued**ELA/Sorin:**

Paradym (8770, 8750, 8550, 8250); Ovatio (6750, 6550, 6250); Alto II (627, 624, 625); Alto (617, 615, 614); Defender IV (612); and Defender II (9201)

**Medtronic:**

Concerto II, Virtuoso II, Maximo II (D314TRG, D334TRG, D314DRG, D334DRG, D314VRG, D334VRG, D224VRC, D274VRC, D284VRC, D274DRG, D284DRG, D224TRK, D274TRK, D284TRK); Concerto Virtuoso Model (C154DWK, D154AWG, D154VWC); EnTrust (D153ATG, D153DRG, D153VRC); Gem II, Gem III model (7273, 7229, 7275, 7276, 7231); InSync (7272, 7289, 7295, 7277, 7303, 7304, 7299); Intrinsic 7288, 7287; Marquis (7230, 7230CX, 7230B, 7230E, 7274), Maximo (7232, 7232B, 7232CX, 7232E, 7278); Secura (D224DRG, D224VRC); Consulta (D224TRK, D234TRK); Protecta/Protecta XT (D314TRG, D334TRG); Protecta/Protecta XT (D334DRG, D314DRG); Protecta/Protecta XTVR (D334VRG and D314VRG)

**St. Jude Medical:**

Photon (V-230, V-194, V-232), Atlas (V-199, V-240, V-242), Atlas+ (V-243, V-193, V-193C, V-340, V-341, V-343, V-344), Atlas II (V-168, V-265, V-365), Atlas II+ (V-268, V-366, V-367), Epic (V-197, V-233, V-235, V-337, V-338, V-352), Epic+ (V-196[T], V-236, V-239[T]), Epic II (V-158, V-255, V-355), Epic II+ (V-258, V-356, V-357), Convert (V-191), Convert+ (V-195), Current (1107-30, 1107-36, 1207-30, 1207-36, 2107-30, 2107-36, 2207-30, 2207-36), Current Accel (CD1215-30, CD1215-36, CD2215-30, CD2215-36), Promote (3107-30, 3107-36, 3109-30, 3109-36, 3207-30, 3207-36, 3213-36), Promote Accel (CD3215-30, CD3215-36) Current+ (CD1211-36[Q], CD2211-36[Q]), Promote+ (CD3211-36[Q]), Promote Q (CD3221-36), Fortify (CD1231-40[Q], CD2231-40[Q]), Unify (CD3231-40[Q]), AnalyST (CD1217-30, CD1217-36, CD1219-30, CD1219-36, CD2217-30, CD2217-36, CD2219-30, CD2219-36)

\*Removal of magnet immediately restores tachyarrhythmia detection.

\*\*Magnets placed over ICDs will not result in asynchronous pacing.

†Lumax series: a magnet placed continuously over the device will disable therapy for a maximum time of 8 hours, at which point therapy will be reactivated. To inhibit ICD therapy for longer than 8 hours, the device must be reprogrammed to inactivate therapy permanently until restored by reprogramming.

‡Boston Scientific magnet programmable options:

1. "Enable Magnet Use" is nominally programmed ON but can be programmed OFF with a programmer.
2. PRIZM series only: "Change Tachy Mode with Magnet" is nominally OFF but can be programmed ON by a clinician. When this feature is programmed to ON, the Tachy Mode can be permanently programmed OFF with a continuous application of a magnet for more than 30 seconds. When this has occurred the device will emit a continuous tone, indicating that the magnet can be removed and the Tachy Mode will remain OFF. Reapplying the magnet continuously for 30 seconds will reactivate Tachy therapy. The device will begin to emit R-wave synchronous beeping tones again, indicating that when the magnet is removed the Tachy Mode will remain in Monitor + Therapy (DETECTION AND THERAPY ON).
3. "Patient Triggered EGM" is nominally OFF but can be programmed ON by a clinician. When OFF, the device will respond appropriately to magnet application by suspending Tachy therapy. If programmed to ON, then the device will NOT suspend Tachy therapy. The feature is intended for patients who are symptomatic from unknown causes. This feature allows the patient to apply a magnet over their device while symptomatic to capture the episode. When this feature is ON the device will respond to a magnet by storing an EGM rather than by inhibiting Tachy therapy. Therefore, in the Boston Scientific ICDS, if no tones are heard from the device following magnet application "Enable Magnet Use" was likely programmed to OFF or the "Patient Triggered EGM" feature has been programmed to ON.

•A magnet rate occurs with the ELA/Sorin ICDs, but it is in DDD mode not D00, i.e, the magnet does not render pacing asynchronous. Therefore pacing output could still be inhibited with sensed electrocautery or other sources of EMI.