

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: Executive Summary

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)

George H. Crossley, MD, FHRS,¹ Jeanne E. Poole, MD, FHRS,² Marc A. Rozner, PhD, MD,^{3*} Samuel J. Asirvatham, MD, FHRS,⁴ Alan Cheng, MD,^{5†} Mina K. Chung, MD, FHRS,⁶ T. Bruce Ferguson, Jr., MD,^{7##} John D. Gallagher, MD,^{8*} Michael R. Gold, MD, PhD, FHRS,^{9#} Robert H. Hoyt, MD,¹⁰ Samuel Irefin, MD,^{11*} Fred M. Kusumoto, MD, FHRS,¹² Liza Prudente Moorman, MSN, ACNP, FHRS,¹³ Annemarie Thompson, MD^{14*}

From ¹St. Thomas Research Institute and University of Tennessee College of Medicine, Nashville, Tennessee, ²University of Washington, Seattle, Washington, ³University of Texas, Department of Anesthesiology and Perioperative Medicine, Houston, Texas, ⁴Mayo Clinic, Rochester, Minnesota, ⁵Johns Hopkins University School of Medicine, Baltimore, Maryland, ⁶Cleveland Clinic, Department of CV Medicine, Cleveland, Ohio, ⁷East Carolina Heart Institute, Department of Cardiovascular Sciences, Greenville, North Carolina, ⁸Dartmouth Medical School, Hanover, New Hampshire, ⁹Medical University of South Carolina, Charleston, South Carolina, ¹⁰Iowa Heart Center, West Des Moines, Iowa, ¹¹Cleveland Clinic, Department of Anesthesiology, Cleveland, Ohio, ¹²Mayo Clinic, Jacksonville, Florida, ¹³University of Virginia Health Systems, Charlottesville, Virginia, and ¹⁴Vanderbilt University Department of Anesthesiology, Nashville, Tennessee.

**Representing the American Society of Anesthesiologists.*

#Representing the American College of Cardiology Foundation.

†Representing the American Heart Association.

##Representing the Society of Thoracic Surgeons.

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 (HRS) 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 and reference groups are described in the main article. This statement represents the consensus of the writing committee. In generating its consensus, the committee reviewed a large body of literature, which 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

ABBREVIATIONS ASA = American Society of Anesthesiologists; ATP = antitachycardia pacing; CIED = cardiovascular implantable electronic device; CIED team = the physician, nurse, and technicians who care for the patient's CIED; CRT-D = cardiac resynchronization therapy defibrillator; CT = computed tomography; ECT = electroconvulsive therapy; EOL = end of life; ERI = elective replacement indicator; EMG = electromyography; EMI = electromagnetic interference; GI = gastrointestinal; HRS = Heart Rhythm Society; ICD = implantable cardioverter-defibrillator; IEAP = industry-employed allied professional; ILR = implantable loop recorder; J = joule; LV = left ventricle; perioperative team = the anesthesiologist, surgeon, and/or other

physicians and nurses associated with the procedure and the preparation for that procedure; PM = pacemaker; RF = radiofrequency; RFID = Radio frequency identification; TENS = transcutaneous electrical nerve stimulation; TUNA = transurethral needle ablation; TURP = transurethral resection of the prostate (Heart Rhythm 2011;8:e1-e18)

Endorsed by the Heart Rhythm Society, the American College of Cardiology Foundation and the American Heart Association. **Address reprint requests and correspondence:** Sonja Olson, Heart Rhythm Society, 1400K Street, NW, suite 500, Washington DC 20005. E-mail: solson@hrsonline.org.

writing group. Consequently, there has been no assignment of levels of evidence. The consensus 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. In preparing this Executive Summary, we have emphasized those aspects we believe best reflect the overall intent and content of the consensus document.

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 the consensus 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 magnet 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. Certain details have been removed from this executive summary. We recommend reading the entire article for a comprehensive review.

Introduction

The perioperative period poses unique challenges to assure a high degree of patient safety for patients with pacemakers and defibrillators. The potential problems that can occur in patients with a CIED in the perioperative setting are detailed. We provide recommendations for the appropriate preoperative evaluation, intraoperative management and postoperative care of the patient with a CIED undergoing medical procedures. Table 1 displays our general areas of consensus.

We strongly believe that the best perioperative care of a patient with a CIED will result from the CIED team providing a specific prescription for CIED management to the procedural team. Information regarding the nature of the planned proce-

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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cedure and potential risks for the patient with a CIED must be shared with the CIED team in order for this prescription to be formed. 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 own CIED team (or another available CIED team) give the operative team recommendations for the perioperative management of the CIED.

Most patients will not need a *de novo* preoperative evaluation by the CIED management team as generally the required information resides in the records of the CIED clinic. If this information is not accessible, the next best approach is to have an available CIED team evaluate that patient and provide a recommendation and the necessary communication to 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).¹ We strongly support the prior 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 post-operative CIED care. That is well beyond their scope of practice.¹ 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.

Problems unique to the CIED patient and electromagnetic interference risk during surgical or medical procedures

Electromagnetic interference

EMI causing malfunction of pacemakers and defibrillators is well-described² and is the most common problem occurring in patients with CIEDs. The perioperative period is particularly problematic as patients are exposed to a number

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

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 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.

The most common source of EMI is electrosurgical energy. The problems seen with electrocautery are summarized in [Table 2](#). Other sources of EMI are listed in [Appendix 2](#) and will not be discussed in this summary. The reader is referred to the main Consensus Document.

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.^{3,4} 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,^{5–15} most recent reports suggest little effect on CIED function.¹⁶ Advances made in lead and generator design, EMI resistance, as well as the development of newer surgical tools¹⁷ have made these events, including reset, much less common in modern day systems.

EMI–CIED interactions include oversensing, 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.¹⁰ 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.¹⁸ Each of these possible interactions is discussed separately.

Oversensing: By far, the most frequent CIED interaction with EMI is oversensing, which results in inappropriate inhibition of pacing output. Continuous ventricular sensing of EMI may rarely initiate temporary “noise reversion mode.”¹⁹ 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. 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 re-programming 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 therapy (CRT) devices. While most CRT patients who are not pacemaker dependent will not experience hemodynamic difficulties if biventricular pacing is interrupted, the possibility of acute heart failure decompensation should be considered if CRT is withheld for a prolonged time. 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, his/her 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 both undesirable and avoidable. Both inappropriate anti-tachycardia 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 skeletal muscle contraction if the patient is not paralyzed.

Rate responsive algorithms and EMI: Pacemaker rate-responsive algorithms may cause unwanted elevation of the heart rate during a procedure. These algorithms are specific to the particular CIED model and manufacturer. Minute-ventilation sensors are impedance based. Electrosurgical current sensed by the device could result in an inappropriate elevation of the heart rate. Also, in some CIEDs the magnetic switch can be activated by electrosurgery, causing rapid pacing.

Reset: Device reset mode occurs infrequently after exposure to electrosurgery, and is more commonly caused by therapeutic ionizing radiation rather than EMI.^{20,21} The purpose of a reset mode is to provide safety backup programming in case of catastrophic failure. The specific pacing and antitachycardia therapy parameters are unique to each manufacturer and are summarized in [Appendix 3](#). These settings are not necessarily optimal for any given patient, but neither are they likely to be unsafe for the patient. If reset has occurred, the CIED programmer will be required to restore programming to the original pacing and arrhythmia detection and therapy parameters. We recommend contacting the technical support service of the manufacturer for assistance.

Some newer Boston Scientific ICDs have Safety Core, and it is also planned for future pacemakers. Safety Core is a backup mode intended for major hardware failures, which provides high voltage therapy with unipolar VVI pacing. It is imperative that the CIED team understand the required response to address this issue should it occur. See [Appendix](#)

[3B](#) footnote and the Consensus Document for a full discussion.

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, current entry into the pulse generator with failure or permanent CIED damage could occur from application of electrosurgery either in immediate close proximity or directly to the pulse generator. 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 performed 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 setting a lower electrosurgery power, may reduce exposure of the CIED to the effects of electrosurgical energy.

Lead tissue interface damage: Electrosurgical collateral damage to the lead–myocardial interface is 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.²²

Electrosurgical risk mitigation

Oversensing is the adverse interaction most likely to occur when a CIED is exposed to electrosurgical 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).²³ 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.²⁴

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 provided the information ahead of time to the surgical team whether the patient's particular device has the magnet function programmed "on," as in a few devices this is a feature that can be programmed to "off" Appendix 4. 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 his/her ICD is capable of programming the pacemaker mode to asynchronous pacing. In this scenario, prolonged inhibition of pacing could not be mitigated with just the use of a magnet 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 pacemaker (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.^{23,25}

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.²⁵

CIED response to magnets: As noted above, magnet application is often used in the perioperative period to change the behavior of CIEDs. Appendix 4 display 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 to gain control of inappropriate tracking or rate response operation with the device in the operating room.²⁶ 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.

For pacemakers, the magnet generally causes asynchronous pacing by closing a magnetic switch. 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 anti-tachycardia 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 to, for example, in a dual chamber pacemaker, a magnet determined A-V delay that may be shorter than the patient's 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 (Appendix 4A).

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 acknowledgment 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 5.

*Maximum times intended for stable patients, which may need to be reduced for concurrent disease or modified for individual institutions.

For ICDs, tachycardia detections can be disabled by magnet application without having an effect on pacing mode or rate (Appendix 4B). Some Boston Scientific ICDs may be permanently deactivated by magnet application, necessitating reprogramming of the pulse generator prior to the patient being removed from a cardiac monitor.²⁷ In most CIEDs, however, arrhythmia detection will be automatically re-enabled when the magnetic field is removed. We emphasize again that an important feature unique to ICDs is that a magnet will not alter ICD 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 or ventricular fibrillation will not occur unless the CIED is reprogrammed to reactivate the tachyarrhythmia detection and therapies.

Noise reversion mode: The noise reversion mode is a manufacturer-specific algorithm to minimize the impact of con-

tinuously sensed EMI. Automatic exit from noise response mode occurs once the noise is no longer present.²⁸ One should not rely on the noise reversion mode alone to handle EMI sources such as monopolar electrosurgery as this mode may not adequately protect a pacemaker dependent patient.

Other sources of EMI

Appendix 2 summarizes other sources of EMI and recommended risk mitigation.

The preoperative evaluation

The preoperative evaluation is the cornerstone of patient safety for operative procedures. Our recommendation rests upon the clear and precise communication between the CIED team (cardiologist, cardiac electrophysiologist, device clinic nurses and staff) and the perioperative team (anesthesiologist, surgeon, perioperative assessment team). The general principles of these recommendations are found in Table 3.

During the preoperative evaluation of a CIED patient, the operative team must identify that the patient has a CIED and document where the patient receives his/her regular CIED care. Patients are provided a card at the time of their CIED implant, which notes the make, model and physician following their CIED. Other mechanisms to identify the CIED include the patient registration department of each of the major manufacturers and chest radiography.

Well in advance of the planned procedure, the perioperative management team should consult the patient's usual CIED team in order to communicate the nature of the planned procedure and EMI risk. This will allow the CIED team to develop a prescription for the perioperative device management. The critical elements to be communicated between the operative and the CIED teams are summarized in Tables 4 and 5.

Recommendation for use of a magnet versus reprogramming

The CIED team may recommend the use of a magnet rather than reprogramming the CIED. The benefit of using a mag-

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

net over reprogramming a CIED has been largely a matter of preference and convenience. However, the two approaches are not completely interchangeable and it is important for the health care team to understand why one approach may be preferable over the other.

A magnet placed over a pacemaker will always render the pacing mode asynchronous by interruption of the sensing function. A magnet placed over an ICD generator will suspend tachyarrhythmia detection but *not* change pacing to an asynchronous mode.

A magnet is an appropriate option for any patient who is pacemaker dependent where the risk of electrocautery causing significant pacemaker inhibition is high (in general, procedures above the umbilicus) and the magnet can be secured over the pacemaker generator. The issue for the CIED team is to consider whether the manufacturer-determined magnet rate is acceptable for the type of procedure being performed (Appendix 4). For many types of procedures, the EMI risk may be low enough that neither a magnet nor reprogramming will be recommended. Having a magnet handy in such cases would be appropriate should significant pacemaker inhibition occur.

In the case of a procedure with a high likelihood of EMI and a pacemaker dependent patient that has an ICD, the ICD must be reprogrammed to turn off tachyarrhythmia detections first and then to program the pacing mode asynchronous (note, some older ICD models may not have the option

Table 5 Essential elements of the pre-operative CIED evaluation to be provided to the operative team

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- 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 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
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Table 6 Cardiac monitoring interactions with CIEDs

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- Overcounting the heart rate due to counting pacemaker spikes and QRS complexes individually
 - Inability to identify pacemaker spikes with monitors employing high frequency filters
 - Falsely “marking” artifact as a pacemaker spike
 - Pacemaker initiated heart rate increase due to rate responsive pacemaker algorithms with inappropriate response by surgical team
 - Most rate sensors employ an accelerometer such that patient movement could increase the patient's paced rate if the sensor is not inactivated
 - Minute ventilation creates a unique situation where current emitted by the CIED to measure changes in thoracic impedance can be detected by monitoring equipment and appears to be rapid pacing without capture
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of asynchronous pacing). If a patient with an ICD is not pacemaker dependent, consideration may be given to using a magnet secured over the device.

The benefit of a magnet is that in the event of spontaneous ventricular tachycardia or ventricular fibrillation, the magnet can be removed and the device will detect and deliver tachyarrhythmia therapy within its programmed rate detection zones. Use of a magnet also avoids the risk to the patient of inadvertent failure of the team to re-activate tachyarrhythmia detections and therapies.²⁹ Manufacturers of some CIEDs provide variable audible tones to indicate appropriate magnet placement over their CIED generators²⁶ (Appendix 4).

Recommendations for radiofrequency ablation

If radiofrequency ablation (RFA) is to be used during the medical procedure, the CIED team will also need to provide specific recommendations. RFA amounts to the application of electrosurgery in a continuous fashion for minutes at a time. Given the high chance of pacing inhibition, the CIED team will recommend that the patient be protected with magnet placement or reprogramming. ICD patients should have tachycardia detection disabled by either reprogramming or 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.

Intraoperative monitoring and considerations

All patients with a CIED undergoing a procedure with a risk of EMI interaction require cardiac rhythm monitoring, regardless of the complexity of the procedure performed or the level of anesthesia used. Due to possible interactions between many of the cardiac rhythm monitoring units and CIEDs, heart rate monitoring must encompass the ability to identify the pulse, either by plethysmography, oximetry or intraarterial pressure monitoring.³⁰ Specific problems with cardiac monitoring and CIEDs are found in Table 6.

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.

Other requirements or concerns for patients with a CIED include:

- Defibrillation patches should be placed if the patient is at high risk for ventricular arrhythmias or with extensive surgical procedures.

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 10) 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 1 month from their procedure.*

*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.

- Emergency equipment should be easily accessible to the procedure area.
- The electrosurgical units must be properly grounded. Although adverse interactions with contemporary earth-grounded electrosurgical systems are uncommon,^{31,32} problems can occur if not grounded properly. Optimal “grounding” involves the use of a split foil return electrode, which allows for detection of proper application to the patient.² The return electrode should be placed such that the current is directed away from the CIED.

Table 8 Specific procedures and committee recommendations on postoperative CIED evaluation

Procedure	Recommendation
Monopolar Electrosurgery	CIED evaluated# within 1 month from procedure unless Table 7 criteria are fulfilled
External Cardioversion	CIED evaluated# prior to discharge or transfer from cardiac telemetry
Radiofrequency Ablation	CIED evaluated# prior to discharge or transfer from cardiac telemetry
Electroconvulsive Therapy	CIED evaluated# within 1 month from procedure unless Table 10 criteria are fulfilled
Nerve Conduction Studies (EMG)	No additional CIED evaluation beyond routine
Ocular Procedures	No additional CIED evaluation beyond routine
Therapeutic Radiation	CIED evaluated prior to discharge or transfer from cardiac telemetry; remote monitoring optimal; some instances may indicate interrogation after each treatment
TUNA/TURP	No additional CIED evaluation beyond routine
Hysteroscopic Ablation	No additional CIED evaluation beyond routine
Lithotripsy	CIED evaluated# within 1 month from procedure unless fulfilling Table 7 criteria
Endoscopy	No additional CIED evaluation beyond routine
Iontophoresis	No additional CIED evaluation beyond routine
Photodynamic Therapy	No additional CIED evaluation beyond routine
X-ray/CT Scans/Mammography	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.

Table 10 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 function. This can only be accomplished by re-programming 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 (see Appendix 3 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.

-When gaining central venous access, guidewires should be advanced carefully into the heart particularly if the CIED lead has been recently placed. Also, guidewires should not contact the sensing electrodes of an ICD lead as this could result in inappropriate sensing and possible ICD shock (if the ICD has not been deactivated).

Postoperative evaluation

The purpose for performing a post-procedural interrogation of a CIED is to assure that the device has not entered a backup safety mode and that functionality was not damaged. Patients who should have a post-procedure interrogation prior to leaving a cardiac monitored setting are those whose settings were re-programmed prior to the procedure, patients who had a major surgical procedure performed such as cardiac surgery or vascular surgery and any patient who was at risk for or experienced significant intraoperative events such as significant hemodynamic alterations, cardiac arrest, ventricular tachycardia, required temporary pacing, cardiopulmonary resuscitation or external electrical cardioversion. Patients exposed to EMI with a high probability of

affecting device function (therapeutic radiation) should also be checked with the frequency determined by the power of the radiation and the vicinity to the CIED. The recommended timing for post-procedural CIED evaluation is in Tables 8 and 9.

Protocol for cases of emergency procedures

Emergent procedures create a situation where there may not be adequate time to contact the patient's CIED team or gather the important CIED information.

The first step is to identify the type of device. The operative team should realize that neither patients nor their families are always clear on whether they have a pacemaker or ICD, much less the device manufacturer or model. Patients may use their ICD for pacing, including when pacemaker dependent. Obtaining appropriate medical records and the patient's CIED registration card should be accessed, if available. Other methods to identify a CIED type include contacting the device companies who can help to identify if a patient is in their database and, if so, the type of device and model and year of last generator placement. One pitfall

of this approach is that patients may have had a newer device implanted from another manufacturer. If a chest radiograph can be examined, the type of device (ICD vs pacemaker) can be determined and often the manufacturer's identification marking can be noted on the generator. A member of the CIED team should be contacted as soon as possible to provide further recommendations or to reprogram the ICD if time allows.

After identifying that the patient has a CIED, the next step is to determine whether the patient is pacemaker dependent. If pacemaker spikes are noted in front of all or most P wave or QRS complexes, the assumption for the purpose of an emergent surgery is that the patient is pacemaker dependent. If the procedure is likely to involve extensive monopolar electrocautery, placing a magnet over a pacemaker generator would be an appropriate solution. In the case of a pacemaker dependent patient using an ICD for his/her pacemaker function, a magnet placed over the ICD will not result in asynchronous pacing. This situation would require re-programming of the device to assure asynchronous pacing. If re-programming is not an option given the urgency of the need to perform the procedure, then careful attention to short cautery bursts (≤ 5 seconds) to minimize pacing inhibition or placement of a temporary transvenous pacemaker will be required.

For patients not identified to be pacemaker dependent or for lower risk procedures (below the umbilicus), a magnet should be available in the room in case there is the development of bradycardia, which once applied will result in asynchronous pacing (pacemakers only).

The emergent procedure for all patients with an ICD requires placing a magnet over the generator if the device cannot be re-programmed in order to suspend tachyarrhythmia detection. Exceptions might be a surgical procedure on the lower extremities where the chance of false detection is very low.

If the situation requires the need to rapidly take a critically ill patient for an emergent surgical procedure and time does not permit gathering CIED patient information, the surgical team should secure a magnet over an identified CIED, watching the cardiac rhythm to note pacemaker activity and observe for pacemaker inhibition. If the latter occurs, short bursts of electrocautery or temporary pacing are the only options.

All patients with a CIED undergoing an emergent procedure require placement of transcutaneous patches for both emergent defibrillation and emergent transcutaneous pacing (anterior/posterior pad placement). Cardiac monitoring should be with plethysmography or by an arterial line. In all cases of emergent surgery, the patient's CIED system must be evaluated prior to leaving the monitored environment either in the recovery room or prior to removing the patient from cardiac monitoring.

Summary

In this summary 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 refer health care providers to the main Consensus Document for a more detailed discussion of the perioperative management of the patient with a CIED. We cannot overemphasize that the best care provided to such patients will be achieved through a careful preoperative assessment of the patient. This assessment relies upon shared communication between the pivotal physicians involved in the patient's procedure. It is not acceptable for a patient to arrive in a pre-operative holding area and a "discovery" be made of a pacemaker or ICD. This scenario generally prompts an anxious call to a cardiology team member, who likely is not familiar with the patient but nevertheless must assure the patient's safety—while a surgical team is waiting to begin the procedure. A complete and thoughtful preoperative evaluation by the surgical and CIED team alike will minimize the risk for the CIED patient.

It is our sincere hope that the recommendations we have set forth will result in physicians initiating protocols for their own hospitals and databases to track performance outcomes.

We recognize the need for better scientific evaluation of patients with CIEDs who are exposed to EMI. The particular risk of therapeutic radiation is a growing concern. There is a critical need for long-term data collection on radiation-exposed devices, with the outcome data coupled to radiation modeling.

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. [Tables 7, 10, and Appendix 3A.](#)

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*Significant. A 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 Additional sources of EMI risk

Situation	Possible risk			Risk mitigation
	Rarely expected	Moderate	Likely	
External Cardioversion	<ul style="list-style-type: none"> —Reset —Transient dysfunction especially in older CIEDs^{33–36} —Threshold changes³⁴ 			—Anterior–posterior pad placement may help ^{33,35}
Catheter Ablation for Cardiac Arrhythmias	<ul style="list-style-type: none"> —Reset 	<ul style="list-style-type: none"> —Oversensing —Undersensing 	<ul style="list-style-type: none"> —Pacing inhibition^{37,38} —Inappropriate arrhythmia detection (ICDs)³⁸ 	<ul style="list-style-type: none"> —Avoid close contact with elements of the CIED Disable ICD detections
Diagnostic Radiation	<ul style="list-style-type: none"> —Oversensing has been reported with newer CT units^{39,40} 			—Risk currently considered too low for specific recommendations
Therapeutic Radiation		<ul style="list-style-type: none"> —Reset may occur due to beam scatter 	<ul style="list-style-type: none"> —Direct beam exposure can cause catastrophic failure of pulse generator^{23,24,41,42} 	<ul style="list-style-type: none"> —Radiation dose planning and shielding —May need to relocate the pulse generator
ECT	<ul style="list-style-type: none"> —Oversensing 	<ul style="list-style-type: none"> —Sinus tachycardia after seizures is common—could fall into ICD detection zone 		<ul style="list-style-type: none"> —In pacemaker dependent patients, can consider asynchronous programming —Know the ICD programming zones, re-program if necessary
TUNA	<ul style="list-style-type: none"> —Oversensing 			—If occurs: magnet application
TURP	<ul style="list-style-type: none"> —Oversensing 			—If occurs: limit duration of electrosurgery, magnet application
GI Procedures	<ul style="list-style-type: none"> —Oversensing if electrosurgery is used^{10,12,18} 			<ul style="list-style-type: none"> —If occurs: magnet application or reprogramming —If possible, use bipolar electrosurgery
Capsule Endoscopy	<ul style="list-style-type: none"> —No reported problems, but the units are FDA labeled with instruction not to use them in patients with pacemakers or defibrillators 			—No specific recommendations
Tissue Expanders		<ul style="list-style-type: none"> —If a magnetic needle port is included: can activate magnet mode (inhibit ICD detection, or asynchronous pacing)⁴³ 		Avoid the use of magnetic needle port device in patients with PMs and ICDs
TENS and Spinal Cord Stimulators			Oversensing	<ul style="list-style-type: none"> —Not recommended in pacemaker dependent patients —Must evaluate for safety with any PM or ICD patient prior to use
RFID		<ul style="list-style-type: none"> —Oversensing if close proximity 		—Avoid close proximity with CIED
EMG and Nerve Conduction Tests	<ul style="list-style-type: none"> —Theoretical concern exists if tests performed near the CIED generator; however, —No reports exist documenting reverting to backup safety mode or unanticipated device malfunction^{44,45} 			—No recommendation
Lithotripsy	<ul style="list-style-type: none"> —Reset⁴⁶ 			<ul style="list-style-type: none"> —Continuous telemetry —CIED team available —Terminate lithotripsy for arrhythmias —Use a magnet only if inhibition occurs —Interrogation of CIED after procedure in the case of any complications
Iontophoresis	<ul style="list-style-type: none"> —No reports of risk 			
Photodynamic Therapy	<ul style="list-style-type: none"> —No reports of risk 			
Dental Procedures	<ul style="list-style-type: none"> —No reports of risk unless electrocautery is used (refer to risk with electrocautery) 			

Appendix 3A 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 ventricular lead is unipolar and LV lead paces from LV tip to pulse generator).

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

Appendix 3B 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 (see below for discussion of Boston Scientific Safety Core). Energy values listed for Medtronic and St. Jude represent energy delivered. The remaining represent energy charged.

Safety Core is a Boston Scientific backup mode designed as a response to catastrophic failure as a result of significant EMI exposure. If this mode occurs while the ICD Tachy Mode is OFF, the device returns to Monitor+Therapy. If there are additional High Voltage faults detected while the device is in Safety Core, the Tachy Mode will be set to "Tachy Therapy Not Available." While not reported, Safety Core could 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. There have been rare reports of Safety Core occurring during electrosurgery.

*In CRT devices, LV lead output is 4.8 V @ 0.5 ms.

†The Current and Promote family of devices revert to a 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 device deliver 30 J × 6.

#Ovatio family of devices: 34 J × 4.

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

Appendix 4A 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"> Pacing mode depends on programming: <ul style="list-style-type: none"> —ASYNC - Asynchronous pacing (D00 or V00) @ 90 bpm —SYNC - Programmed pacing mode at programmed rate (not asynchronous) —AUTO - V00 @ 90 bpm for 1st 10 beats then programmed pacing mode at programmed rate Suspends rate response in all modes§ Pacing amplitudes remain unchanged‡ 	Pacing mode depends on programming: <ul style="list-style-type: none"> —ASYNC - V00 @ 80 bpm —SYNC - VDD or VVI @ programmed rate minus 11% —AUTO - V00 @ 80 bpm for 1st 10 beats then VDD or VVI @ programmed rate minus 11% 	Yes§	None
Boston Scientific	<ol style="list-style-type: none"> Asynchronous pacing at 100 bpm (D00 or V00) <ul style="list-style-type: none"> —Note, pulse width on 3rd pulse reduced by 50% in order to check threshold safety margin Suspends rate response Pacing amplitudes remain unchanged‡ 	D00 or V00 85 bpm <ul style="list-style-type: none"> —Nearer to ERI will pace at 90 bpm —Magnet pacing amplitude between ERI and EOL is 2× last threshold and at least between 3.5 and 5 V 	Yes <ul style="list-style-type: none"> —If magnet response programmed to “EGM,” device will not result in asynchronous pacing with magnet —To activate magnet response, the feature must be programmed back to “ON” 	None
ELA/Sorin	<ol style="list-style-type: none"> Asynchronous pacing at 96 bpm (D00 with Max AV Delay or V00) Suspends rate response Pacing amplitudes go to 5 V and 0.5 ms unless programmed higher‡ <ul style="list-style-type: none"> —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 	Gradual decrease to D00 or V00 @ 80 bpm	No	None
Medtronic	<ol style="list-style-type: none"> Asynchronous pacing at 85 bpm (D00 or V00) Suspends rate response Pacing amplitudes remain unchanged‡ <ul style="list-style-type: none"> —Note, first 3 beats with magnet application are at 100 bpm with reduction of pulse width on 3rd pulse reduced by 25% in order to check threshold safety margin 	V00 @ 65 bpm#	No	None
St. Jude Medical	<ol style="list-style-type: none"> Asynchronous pacing at 100 bpm or 98.6 bpm (V00 or D00) depending on the model** <ul style="list-style-type: none"> —Magnet rate will gradually decline throughout the life of the device Suspends rate response Pacing amplitudes vary by model‡ 	V00 at <85 bpm or 86.3 bpm, depending on the model¶ <ul style="list-style-type: none"> —Magnet pacing amplitude between ERI and EOL is 2× last threshold when AutoCapture enabled 	Yes <ul style="list-style-type: none"> —If magnet response is programmed to “OFF” device will not result in magnet pacing rate —If magnet response is programmed to “Event Snapshots + Battery Test” device will trigger an event snapshot and then pace at the magnet rate —To activate magnet response, the feature must be programmed back to “Battery Test” (On) —VARIO enabled devices will initiate a magnet rate followed by a threshold test** 	None

Pacemaker models included in Table 4A:

BIOTRONIK:

Evia, Cylos, Protos, Philos II, Philos, Axios, Actros, Actros+, Stratos (model numbers 359529, 359533, 359524, 359531, 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)

Appendix 4A Continued

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

St. Jude Medical:

Microny/MIchrony, 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 manufacturers' 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" that, 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 in the device. If this is the auto-threshold determined output, the amplitude may be $<2 \times$ safety margin (depending upon the safety margin programmed for auto-threshold testing).

St. Jude Medical pacemakers will pace at an amplitude of 4.5 V @ ≥ 0.5 ms if AutoCapture is programmed on in the Microny, Microny II, Verity Adx, Integrity Adx, Identity, Identity Adx, Fidelity, Affinity, Affirmity, Entity, Integrity, Affinity VDR, Affirmity VDR, Verity Adx VDR, Identity, and Adx VDR series. For the St. Jude Medical Victory, Zephyr, Emprise, Accent, Accent RF, Nuance, and Nuance RF series, the magnet amplitude will be the last capture threshold +1 V @ ≥ 0.5 ms when Auto Capture is programmed on.

ELA/Sorin pacemakers pace at 5.0 V @ 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 are 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 25% then two beats at programmed output, then pulse width drop at 50%, and then two beats at programmed output, then pulse width drop at 75%.

**St. Jude Medical pacemakers that have a magnet pacing rate of 100 bpm/ERI < 85 bpm are Microny/MIchrony, 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/MIchrony II pacemakers only. If this feature is programmed on, threshold testing will be performed with the application of a magnet. It consists of 31 asynchronous pacing pulses, the first 16 are the battery test phase (BOL-ERI rate), the second 15 are the capture test phase. In this phase, the device decrements the voltage from the programmed output to 0.0 V at 120 ppm. Upon completion of this phase, the device returns to the battery indicated rate.

Appendix 4B 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‡ PRIZM/2/HE: There are 3 programmable options: 1. Enable Magnet Use ON/OFF 2. Change Tachy Mode with Magnet ON/OFF 3. Patient Triggered EGM ON/OFF VITALITY/2/DS/EL/HE; RENEWAL/3/HE; CONFIENT/LIVIAN; CONGNIS/TELIGEN There are 2 programmable options: 1. Enable Magnet Use ON/OFF 2. Patient Triggered EGM ON/OFF	Yes 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 All devices have an audible tone for up to 30 seconds 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 Two programmable options: 1. Magnet response is nominally programmed to “Normal” (on) 2. “Ignore” (off)	None

ICD models included in Appendix 4B:

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)

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); Medtronic Secura Model (D224DRG, D224VRC); Medtronic Consulta (CRT-D:D224TRK, D234TRK)

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, 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)

Appendix Table 4B Continued

*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 DDO, i.e., the magnet does not render pacing asynchronous. Therefore pacing output could still be inhibited with sensed electrocautery or other sources of EMI.