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Management of radiotherapy patients with implanted cardiac pacemakers and defibrillators: A Report of the AAPM TG-203[†]

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Managing radiotherapy patients with implanted cardiac devices (implantable cardiac pacemakers and implantable cardioverter-defibrillators) has been a great practical and procedural challenge in radiation oncology practice. Since the publication of the AAPM TG-34 in 1994, large bodies of literature and case reports have been published about different kinds of radiation effects on modern technology implantable cardiac devices and patient management before, during, and after radiotherapy. This task group report provides the framework that analyzes the potential failure modes of these devices and lays out the methodology for patient management in a comprehensive and concise way, in every step of the entire radiotherapy process. © 2019 American Association of Physicists in Medicine [<https://doi.org/10.1002/mp.13838>]

Key words: cardiac implantable electronic devices (CIED), device malfunction, implantable cardiac pacemakers (ICP), implantable cardioverter-defibrillators (ICD), patient management, radiation damage

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1. PURPOSE

The objective of this report was to review published literature evaluate all possible effects of therapeutic radiations on cardiac implantable electronic devices (CIEDs), provide methods to clinically assess the dose levels, provide an estimate of the risks for the various radiation modalities associate lethal and nonlethal types of device failures, recommend methods to manage patients with such devices, as well as to develop recommendations in order to minimize the damage to the devices during radiotherapy (RT) procedures.

2. INTRODUCTION

The American Association of Physicists in Medicine (AAPM) Task Group 34 (TG-34) provided a set of guidelines

on the management of cancer patients with implanted cardiac pacemakers receiving RT.¹ The report provided valuable information on the effects of radiation on implantable pacemakers and suggested a protocol to manage such patients. One of the main recommendations of TG-34 was that treatment planning results should yield no more than 2 Gy to any part of the pacemaker. While TG-34 presented valuable recommendations when the report was published in 1994, the recommendations then dealt with pacemakers only and were based on older device technology, and older delivery methods.

In a contemporary setting, management is further complicated as it is common to encounter implantable cardiac pacemakers (ICPs) as well as implantable cardioverter-defibrillators (ICDs), collectively referred to as CIEDs, to indicate that they require a source of electrical power for their function. For these modern devices, numerous investigations^{2–14} have dealt with their functionality during RT treatments, including the effects of dose, dose-rate, and secondary neutrons to these devices from conformal RT, intensity-modulated RT, and proton beam therapy. Some research has even dealt with the effects of imaging procedures on ICPs and ICDs.^{14–16} However, in spite of the availability of TG-34 and other published research,^{2–16} major discrepancies still exist among manufacturer recommendations and clinic policies regarding patient management and safety guidance.⁵ Furthermore, some of this information, particularly on malfunction limits and mechanisms, is somewhat confusing and often contradictory. For example, some devices have suffered deleterious effects⁴ at a dose of 0.15 Gy at a dose-rate of only 0.2 Gy/min, while others exhibited dose tolerance above 20 Gy. There has been a reported pacemaker software failure at 0.11 Gy of scattered dose, which the authors attributed to electromagnetic interference (EMI) effects during RT.¹⁷ Although it should be noted that it is impossible to isolate EMI effects from other radiation effects, so many such errors have unknown origin. Mouton *et al.*,⁴ reported changes in CIED output for an 18 MV beam at total doses of as little as 0.15 Gy, concluding changes are more likely due to a single-event upset (SEU) induced by photoneutrons^{10,18} rather than from a high dose-rate. Assessment of malfunctions in these devices, and corresponding management in clinical situations, are clearly complicated by malfunctions attributed to a range of possible mechanisms.

The challenges posed by the lack of consistent information were made clear by the work of Solan *et al.*,⁵ who, in 2004, published a survey of clinical practice patterns among 75 radiation oncology departments in the United States and Canada for management of CIED patients during RT. It was found that only 31% of radiation facilities limit the total allowable dose exposure to the device, whereas 20% of facilities strictly follow TG-34 guidelines; only 15% have a management policy; 37% of the clinics consult a cardiologist; and 33% contact the CIEDs manufacturer for advice. A mere 35% monitor the patient during treatment and only 20% of the clinics perform *in vivo* dose measurements regularly. Similar inconsistent or insufficient practices were observed by Lester *et al.*¹⁹ based on a survey across the United Kingdom, and by Soejima *et al.*,²⁰

in a survey of centers in Japan. Gossman *et al.*,²¹ in a retrospective physicians' survey on treatment approach, delivery and follow-up for management of RT patients with CIEDs, concluded that most radiation oncologists were unfamiliar with the recommended standard of practice by the AAPM, and the involvement of the medical physicist (MP) with patient management, finding both to be insufficient. The absence of, and need for, clearly defined and up-to-date set of guidelines with a uniform approach to the management of these patients is apparent.

Even after 20 or so years following the publication of TG-34, not all centers adhere to its recommendations. As shown by Solan *et al.*, in 2004⁵ and by Soejima *et al.*,²⁰ radiation oncologists failed to communicate radiation safety concerns with implanting physicians, even though in most instances those concerns have resulted in device explantation. Education and scientific awareness appears to be markedly unexploited.

In 2017, the Heart Rhythm Society (HRS) published their expert consensus statement on cardiac devices. While the focus of this report was on MRI interactions with CIEDs, this report also discussed management of RT patients (Section 7 in that report).²² In their report, HRS focused on avoiding the use of neutron-producing beams (e.g., photons of $E > 10$ MV or protons), and considered a 5 Gy dose threshold, but were ultimately unable to make a recommendation concerning cumulative dose risks. While the HRS report provides some framework for patient management, it does not offer detailed recommendations on the management of these patients, nor does it provide guidance on dose assessment to CIEDs, both of which are key components of the current task group report. In addition, HRS guidelines did not provide clear recommendations on several issues, including how to manage the patient if there is a discrepancy between a 5 Gy society-based dose threshold and manufacturer's recommended dose threshold. Therefore, while guidelines are typically consistent between this task group report and the HRS report (a notable exception being the inclusion of 2 and 5 Gy cumulative dose thresholds for CIEDs), there are substantial differences in the focus of the reports.

It is the intent of TG-203 to provide more up-to-date formal guidance as well as an initial mechanism for wider communication between professionals in the radiotherapy community and in the field of cardiac rhythm management. Furthermore, the complementary information of the 2017 HRS expert consensus and TG-203 will be beneficial for the users of new MRI-linac RT technologies.²³ Finally, it should be noted that the successful treatment of patients implanted with CIEDs requires a cooperative effort involving not only the expertise of the MP but also the close involvement of the radiation oncologist, cardiologist, radiation therapist, nurse, and electrophysiologist.

3. ICP AND ICD DEVICES

3.A. Design and function

Implantable cardiac pacemakers are devices designed to maintain cardiac rhythm and are usually implanted

subcutaneously in the chest or in the abdomen. In general, the device is positioned overlying the pectoral muscles, although occasionally implanted in the abdominal wall. ICPs sense continuously and pace when intervals exceed the programmed limits. During pacing, they emit electrical pulses to prompt the normal rate while during sensing they monitor the heart's natural activity. ICDs function similar to ICPs except that they use a capacitor to deliver a high-voltage shock to the heart when needed. ICPs are generally prescribed for the prevention of bradycardia, cardiac arrest, and more recently in the treatment of congestive heart disease. ICDs are implanted to treat symptomatic ventricular tachycardia (VT) and fibrillation or to prevent sudden cardiac death in high-risk cardiac patients. Both devices consist of a battery-powered pulse generator with encased electronics that is connected to pacing leads that serve both to monitor the cardiac functions and to deliver treatment (Fig. 1). The primary manufacturers of CIEDs in the United States are Medtronic, Inc. (Minneapolis, MN, USA), Boston Scientific (Boston, MA, USA), and St. Jude Medical (St. Paul, MN, USA). A list of major device manufacturers is presented in Table I.

Both ICPs and ICDs have undergone substantial improvements in function since the publication of TG-34 in 1994, with more complex therapies, better diagnostics, an increase in the number of the heart's chambers that are sensed and controlled, smaller sizes, and reduced power consumption. Although the concurrent implant of pacers and defibrillators was common in the early 1990s, this practice has been largely abandoned due to the increased sophistication of the implantable defibrillator.

Modern CIEDs utilize complementary metal oxide semiconductor (CMOS) technology in very-large-scale integrated circuits to provide these increased capabilities. The advantages of CMOS technology are high noise immunity, greater reliability, and lower power consumption. However, these advantages might come at the cost of higher susceptibility to radiation effects. The CMOS technology available in the early 1990s was generally more susceptible to permanent damage from ionizing radiation than the previously encountered bipolar transistor technology.^{1,24} Several cases have been reported of their failure both *in vivo*^{25–29} and *in vitro*.^{30–34} Modern devices require as many as 50,000,000 CMOS transistors compared to less than 1,000 in the most advanced 1994 bipolar designs. This increased circuit complexity and ultra-low-power consumption are largely responsible for the continued sensitivity to ionizing radiation, rather than the integrated circuit technology itself.

The ICP produces a small electrical stimulus that is sufficient to begin a heartbeat by depolarizing the small portion of the myocardium immediately adjacent to the pacing electrode. The RF transducer provides an RF signal for interrogating the device. The ICP is most often adjusted to sense the heart's intrinsic rhythm and only discharges pulses when a beat is missed, referred to as "demand pacing". Pacing electrodes may be implanted to sense or control the right atrium, right ventricle, or left ventricle depending on the patient's disease status and lifestyle requirements. The ICP is either a

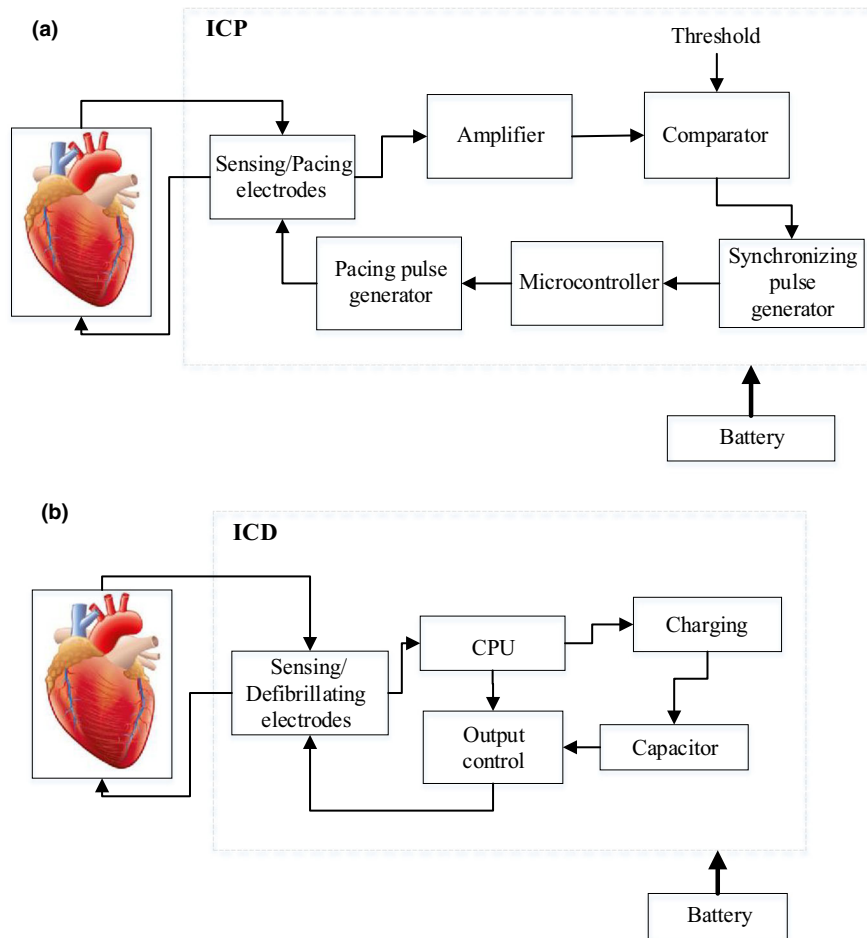


FIG. 1. Schematic representation of an implantable cardiac pacemaker (a) and implantable cardioverter-defibrillator (b) showing the typical subsystems.

TABLE I. Manufacturers of implanted cardiac pacemakers and cardiac defibrillators.

Manufacturer	Location	Web Address Technical Support Contact
Biotronik Biomedical	Berlin, Germany	http://biotronik.com
Boston Scientific (including the Cardiac Pacemakers and Guidant brands)	Boston, Massachusetts, USA	http://www.bostonscientific.com +1-888-272-1001
CCC Medical	Montevideo, Uruguay	http://www.ccc.com.uy
Medico S.p.A	Rubano, Italy	http://www.medicoweb.com
Medtronic, Inc. (including the Vitatron brand)	Minneapolis, Minnesota, USA	http://www.medtronic.com (800) 328-2518 (US) or +1-763-514-4000 (worldwide)
Shree Pacetronix	Pithampur, Dist. Dhar, India	http://www.pacetrnix.com
Sorin Group (including the ELA Medical brand)	Milano, Italy	http://www.sorin.com
St. Jude Medical	St. Paul, Minnesota, USA	http://sjm.com 800-328-9634 (US) or +1-651-756-3301 (worldwide)
Baikal Medical, CardioElectronica, Elestim-Cardio	Moscow, Russia,	http://www.elestim-cardio.ru

single-chamber device sensing and controlling either the right atrium or right ventricle, or a dual-chamber device sensing and controlling both of these chambers. An ICD includes

functions equally as sophisticated as those found in an ICP and adds the capability to sense the onset of a tachycardia or ventricular fibrillation (VF). The ICD also delivers a higher

voltage pulse to halt such episodes. A typical pacing output is a short duration pulse of 1–5 V and yields output energy of a few tenths of micro-joules. In contrast, the ICD output ranges from a high-speed series of slightly higher voltage pulses to a more than a 700-V shock, delivering between 2 and 35 J through its auxiliary defibrillation electrodes.

Cardiac implantable electronic devices add an output and lead to pace the left ventricle in order to restore a more physiological timing between right and left heart depolarization. Almost all CIEDs implanted today will include a non-rechargeable power source, an ultra-low-power microcomputer, storage memory, RF communication, specialty power supply, and interface circuitry as shown in Fig. 1. Many devices also include sensors for activity, respiration, temperature, and other factors that can be used to adjust patient therapy. These functions are subject to different interactions with ionizing radiation leading to potentially different and often confusing clinical outcomes.

Complicating matters from a management standpoint, patients may be dependent on their CIED for pacing, or not. However, for CIEDs, pacing dependency is not always clearly defined. A commonly used clinical definition of when pacing is dependent is when patients have an inadequate or absent intrinsic heart rhythm, which turns symptomatic in case of a (sudden) failure of the CIED's pacing function. Symptoms can vary, but may include acute syncope, heart failure, arrhythmia, and can lead to death.^{35–37} The incidence of pacing dependency is roughly 10%. Patients with an ICD can also be pacing dependent. The cardiologist in consultation with the radiation oncologist can categorize the pacing dependency of the patient into one of three classes. Class 1: patients who display bradycardia-related symptoms that may result in an emergent situation or who have a history of these symptoms in the absence of device pacing (highly dependent). Class 2: patients who are asymptomatic even with an intrinsic ventricular rate of less than 30 beats per minute (intermediately dependent). Class 3: patients with an intrinsic ventricular rate in excess of 30 beats per minute and who

have never experienced an emergent situation related to bradycardia (nondependent). In clinical practice, it is difficult to distinguish between the three classes.^{35–38} In RT practice, it is the cardiologist's realm to state the patient's device dependence for the appropriate management during RT.²²

3.B. Sensitivities and potential failures

A number of theoretical mechanisms causing malfunction in these devices from ionizing irradiation have been proposed. One of the principal failure pathways results from an aberrant accumulation of charge or current flow within the irradiated semiconductor material that can induce malfunction. The basic radiation problem is illustrated in Fig. 2 where a CMOS device with normal operation is shown [Fig. 2(a)] in contrast with one experiencing effects from irradiation [Fig. 2(b)]. During normal operation, the gate is isolated from the channel between the source and the drain by a thin layer of silicon dioxide (SiO₂). The application of the appropriate gate voltage induces the formation of a conduction channel between the source and the drain so that current flows when the device is turned ON. Ionizing radiation produces excess electron-hole pairs in both the silicon and the SiO₂ insulator. When the radiation ceases, the excess pairs in the silicon continue to rapidly recombine, whereas in the oxide layer the electrons flow toward the metal or semiconductor determined by the bias polarity. Then, the holes that escape initial recombination in the valence band are relatively immobile and remain near their point of generation. This buildup results in the trapping of trapped positive charges in the gate oxide [Fig. 2(b)], inducing a negative shift in the threshold voltage needed to be applied to turn the device ON. With a large enough voltage shift the device cannot be turned OFF, even with a zero applied voltage, where the device then fails. The buildup of charge can cause several aberrant behaviors.² A detail description of the mechanism of the induced aberrant behaviors, transient effects in CIEDs^{2,33,39–42} and their dose-rate⁴ dependence can be found in literature.

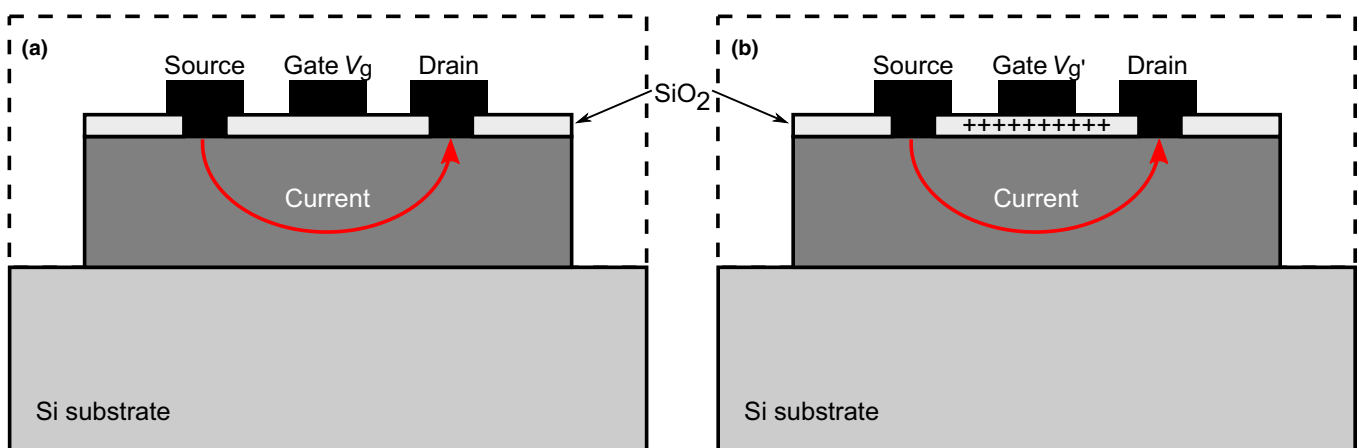


FIG. 2. Schematic diagram of complementary metal oxide semiconductor device illustrating radiation-induced charge, which modifies the threshold voltage. (a) shows the normal operation with current flow for a gate voltage, V_g . (b) shows the buildup of the radiation-induced charge in the SiO₂ layer causing a shift in the threshold voltage, V_g' for current flow.

Another mechanism for malfunction is the SEU, due to high linear energy (photon energies >10 MV) transfer (LET) ionizing radiation.^{10,12,29,43} Specifically, the small amount of charge stored in the random access memory (RAM) of the device is sensitive to high LET radiation damage, because the electronic state of that RAM (i.e., 0 or 1) can be changed by local charge deposition (a high LET is required to deposit sufficient local charge). These consequences are based on a single-event occurrence and are therefore stochastic in nature, with the probability of these events increasing with increasing flux of high LET particles.¹¹ This effect is not relevant for the low LET megavoltage electron and photon energies used in RT with LETs less than 0.5 keV/ μm . However, neutrons produced during high-energy photon (energies >10 MV) or proton treatments have sufficiently high LET (1 to 80 keV/ μm)⁴⁴ to induce this effect.

The device failures described above can manifest clinically in many different ways. These can be broadly described as: not pacing as required by the heart, pacing erratically or inappropriately, complete loss of function, or inappropriate delivery of shocks. These can be further subdivided, as was done by Mouton *et al.*,⁴ as listed below:

1. Missing pulse at the start of irradiation, which is a reversible failure that should have little patient impact,
2. Compatible amplitude modification in which the signal amplitude changes by less than 10%, considered generally as a transient effect that is due to the engineered safety margin in pulse amplitude and should have little clinical consequence,
3. Compatible decreased rate resulting in arrhythmia with average frequency decrease without interruptions longer than 10 s, which may induce lipothymia (light headed/fainting),
4. Compatible accelerated rate resulting in a reversible arrhythmia with a moderate increase in the average frequency,
5. Signal deformation producing permanent defects such as shape distortions of impulses, which may induce incompatible signal changes preventing cardiac stimulation,
6. Amplitude change greater than 10% is considered to be potentially lethal for patients with a low margin of voltage threshold for cardiac stimulation,
7. Silences longer than 10 s resulting in an incompatible arrhythmia, which is considered to be potentially lethal,
8. Permanent silence in which there is no detectable signal and no recovery of the signal.

A short summary of the most relevant malfunction modes of CIEDs during RT can also be found in the 2017 HRS consensus report.²²

4. CONDITIONS IN CLINICAL USE THAT CAN INDUCE MALFUNCTIONS

The malfunctions described above in Section 3.B. arise from one of five clinical conditions.

4.A. Cumulative dose effects

A high cumulative dose can lead to permanent damage to the device. This is historically the most commonly cited interaction between a CIED and therapeutic radiation.^{1,2,6} The CIED circuitry is degraded in proportion to the accumulated dose often resulting in decreased output amplitude, increased current drain, and erroneous or failed sensor operation, including the heartbeat sensing functions. While some of this degradation may be obvious externally or through the device's telemetry data, there are cases where, for example, with increased current drain, that may not be obvious and can lead to sudden failure immediately or within a few months following therapy.⁴⁵ Such risks make proper assessment and management particularly important, including consideration given to any previous patient radiotherapy. Threshold dose levels that produce damage depend on the manufacturer and model of the device.⁷ It has been shown by various studies that for some new devices, there is no safe radiation dose to avoid all important failures, and some CIEDs have shown failures at 2 Gy or less.^{4,5,46}

Mouton *et al.*,⁴ directly irradiated a sample of 96 pacemakers *in vitro* and showed most failures at cumulative doses of 2 Gy or higher. While the risk of such damage is not stochastic (low doses are not reported to cause damage), individual devices do show a wide variability in their sensitivity to dose failure, making establishment of fixed cumulative dose thresholds challenging. However, it is apparent from the four studies that evaluated direct irradiation of CIEDs that 3 out of 49 devices (6%) malfunctioned at a dose ≤ 5 Gy, and 12 out of 38 devices (32%) malfunctioned at a dose ≤ 50 Gy.^{6,47–49} Clearly, there is some risk associated with moderate-to-high doses to CIEDs that requires attentive management.

Cumulative dose to CIEDs is most often associated with scattered photons and electrons. For cases of high-energy photon or proton therapy, the cumulative dose added from neutrons can be considered. It is unclear if a radiation weighting factor is appropriate for CIEDs, and if so, what the value would be. However, if biologically based radiation weighting factors are used, the dose equivalent will still generally be much lower than 2 Sv for both photon and proton therapy.^{50,51} Therefore, cumulative dose estimates can rely on assessment of the photon dose only for high-energy photon therapy. For proton therapy, cumulative dose issues are not generally a concern unless the device is within the primary proton field.

High cumulative doses have been associated with the following clinical effects in ICPs: (a) changes in pacing pulse (amplitude or pulse deviation changes $>25\%$ and complete loss of signal which may prevent heart stimulation), (b) sensing threshold changes $>25\%$, (c) loss of telemetry capability (temporary or permanent) preventing inspection or adjustment of the device settings, (d) pacing frequency changes $>10\%$ before or after irradiation or device inhibition, (e) complete loss of signal, and (f) miscellaneous effects such as battery depletion and lead impedance changes.^{9,12,46,48,52,53} Fewer investigational reports are available for ICDs

comparatively. ICDs are suspected to be more sensitive to radiation than ICPs, due to their more complex circuitry.⁵⁴ In addition to the failures observed in the ICPs, the existing studies on different ICDs report on sensing threshold changes (as first malfunction), shock, energy deviation >25%, VT, and even VF that might cause a shock.⁴⁹

4.B. Neutron-induced upsets

Neutron-induced upsets in memory or logic circuits can occur. High-LET radiation can change stored values in memory through the SEU mechanism. This may cause changes in the microprocessor circuitry (e.g., resets) without any physical damage to the device (“soft errors”), but may also cause an abnormal high-current state in a device causing loss of functionality (“latch up”).^{10,11,18,55,56} However, even for soft errors where there is no damage to the CIED, it is possible that the upset may not be functionally recoverable *in vivo*, requiring the device to be explanted (2 out of 15 upset events were unrecoverable in the data from Grant *et al.*⁵⁷). Most often, soft errors manifest as a reset of the device or the loss of stored diagnostic data and can be recovered. In some devices, the reset may cause a reversion to default parameters requiring intervention using a pacemaker programmer to restore proper function. In very rare cases, the reset may be delayed for hours or even weeks following the therapy. It is essential that the device manufacturer be consulted for recommendations specific to the implanted device model if neutron presence is anticipated.

Single-event upsets are only associated with high-LET radiation, predominantly neutrons produced during RT delivery. The threshold for this type of interaction in CMOS devices was measured to be about 0.6 keV/ μm . This is above the LET of therapeutic photons and electrons.⁵⁸ However, it is well below the LET of fast neutrons, which have an LET peak around 10 keV/ μm and a maximum value of greater than 100 keV/ μm . The relationship between LET and a latch-up event is complicated. Soft errors are most commonly associated with thermal neutrons, while latch-up events are most commonly associated with fast neutrons or protons (10s of MeV).

The risk of a SEU error is stochastic in nature, characterized by a constant probability of failure per unit flux of high-LET particles. Consequently, any high-LET radiation exposure to the device is associated with some risk of device failure. As such, it is equally probable that the event will occur at the beginning of treatment as at any later time during therapy (some devices have been described by the manufacturer as contraindicated for RT due to this risk). Over the course of neutron-producing therapy (15 and 18 MV photon or proton therapy), the risk of device malfunction has been found to be between 12% and 29% per course of treatment.^{29,43,57} It is preferred to avoid use of protons, and limit photon use to energies less than (or equal to) 10 MV in order to reduce such risks.^{10,29}

It is important to note that a device can undergo substantial neutron interactions, even if it is not in close proximity to

the treatment site, since secondary neutrons scatter throughout the treatment vault. The risk can only be well mitigated by employing treatments that avoid neutron contamination produced in therapies at energies at or below 10 MV. If this is not possible, the risk of reset errors can be reduced by reducing the beam energy, which in turn reduces neutron contamination. Higher treatment energies have higher neutron fluences and therefore will have higher rates of reset errors. The flux at 18 MV is approximately 300 million times greater than the background neutron flux from cosmic radiation ($\sim 13 \text{ n}^0/\text{cm}^2 \text{ hr}$). This flux drops by a factor of 2 at 15 MV, and by a further factor of 10 at 10 MV. Siemens and Elekta machines both produce less than half the neutrons as compared to Varian accelerators.^{59–62} Beyond considerations of the nominal energy used, most treatment parameters (field size, distance from the field edge, and SSD) have only minor influences on the fluence.^{61,63}

While there is some neutron production from 10-MV beams (and even at lower energies), the neutron flux increases dramatically above 10 MV. Therefore, in this report, and consistent with the recommendations from other reports,^{22,57} 10-MV photon beams are considered to be *not* neutron producing in the context of risk management for patients with CIEDs.

Electron therapy produces few neutrons, even at high energy. A 20-MeV electron beam produces fewer neutrons than a 10 MV x-ray beam (per MU)^{64,65} so electron beams can be considered non-neutron producing. In contrast, proton and heavy ion therapy generate an abundance of neutrons.^{50,51,66} For proton therapy, scanning beam procedures will produce less neutrons than passively scattered therapies, and low-energy treatments will produce less neutrons than high-energy treatments, but all proton and ion therapies should be considered neutron producing.⁶⁷

Attempts to perform neutron dosimetry are not recommended, because stochastic effects are very challenging. Rather, RT procedures should be conducted with low photon energy (≤ 10 MV) or electron beams to avoid neutron contamination. If neutron contamination is unavoidable, the neutron flux should be minimized if possible by using the lowest reasonable treatment energy. Patients should then be managed as described later in this report (Section 8.E).

4.C. Dose-rate effects

Dose-rate effects can induce transient interference during irradiation. In some circuits, particularly those associated with cardiac rhythm sensing, reference voltages and physiologic sensors are subject to interference from high dose-rate (Gy/min) x-rays incident on the device’s circuits. Additionally, the device can become confused with periodic x-rays signals and interpret them as cardiac signals. This interference, which has also been described during CT imaging, is frequently mistaken for EMI effects. No permanent damage is caused, unless the accumulated dose is also high, but the device may sense inappropriately leading to inappropriate

ICD shocks, improper or nonexistent pacing output, resets, or other effects.¹³

The severity of failure from dose-rate effects is generally mild, being primarily transient and manifesting as noise while the radiation beam is on. The risk of this failure mode is also relatively low. In a study involving 249 courses of RT, there were only 3 recorded noise events, corresponding to a 1.2% risk per course of radiotherapy.⁵⁷ While the frequency and severity of this failure mode is much less than the previous two, care should nevertheless be exercised to minimize the risk of patient harm when the device is exposed to a high dose-rate, even if it does not result in a high total dose.⁴

Although the vast majority of dose-rate effects tend to be both transient and manageable, this may not always be the case. Important failures due to dose-rate effects can include: (a) amplitude changes of electrical signal >10%, (b) silence in electrical signal >10 s, and (c) permanent silence (no signal). These failures may be potentially lethal for a pacemaker-dependent patient.⁴⁶ Also of concern is that the risk of these effects in clinical devices is not well documented. Mouton *et al.*,⁴ is the only study to date to examine dose-rate dependency. While they concluded that the most important failure probability (70% of irradiated pacemakers) is observed for 8 Gy/min, whereas no pacemakers failed at a dose-rate lower than or equal to 0.2 Gy/min, these devices already had a high cumulative dose (6.2 Gy) before the dose-rate was increased to 8 Gy/min. Consequently, dose-rate effects cannot be isolated from cumulative dose effects in these data. This study also found one irradiated pacemaker that exhibited an important defect at a dose-rate of 0.2 Gy/min, with a cumulative dose of only 0.15 Gy. However, this study used 18-MV photons, so it is highly probable that the observed effect at the low dose-rate was actually due to SEU from neutrons. Clearly, dose-rate effects have not been well separated from cumulative dose and SEU effects in the literature, and have also often been erroneously described as EMI effects. Therefore, dose-rate issues are highly uncertain. Matters are further complicated, because the relationship between risk of failure and dose-rate is not simple or even monotonic. There can be complex interplay between the dose-rate, the frequency of dose pulses, and the sensing band of a CIED. It is not known which time-scale is most relevant for dose-rate effects: dose per linear accelerator (LINAC) pulse (elevated in flattening filter free “FFF” beams), dose per second (elevated for higher nominal dose-rates), dose per minute (elevated in volumetric modulated radiation therapy “VMAT”), or dose per fraction (elevated in stereotactic body radiation therapy “SBRT” or stereotactic radiosurgery “SRS”).⁶⁸

In an effort to provide some guidance on this issue, there have been several recommendations to maintain a dose-rate of 0.2 Gy/min or less.^{4,5,7,10,46} Some manufacturers recommend dose-rates <0.01 Gy/min however, as this dose-rate has not been found to increase the risk of device error. A 0.01 Gy/min dose-rate (or higher) could be exceeded in clinical practice if the device is within 5 cm from the field edge (for conventional therapy).⁶⁹ For intensity-modulated radiation therapy (IMRT), slightly more caution may be warranted.

IMRT delivery yields higher leakage radiation doses and dose-rates. Although IMRT treatments are also typically slower, the risk depends on whether the relevant dose-rate is of the level dose/s or dose/min, which is not well known with dynamic delivery. However, there is no published evidence currently available that suggests that the slightly different dose-rates (e.g., from IMRT/VMAT, SBRT, or even specifically using FFF beams for therapy) result in an elevated risk to CIEDs. Given that the bulk of experience is based on conventional dose-rates, increased monitoring (pre- and post-treatment) may be necessary when hypofractionation is used, in agreement with the 2017 HRS expert consensus.²² Especially, if the patient would benefit from a different dose-rate offered by IMRT/VMAT, SBRT, or FFF beams, such an approach is almost certainly appropriate given the low risk from dose-rate effects and the limited data⁷⁰ indicating an elevated risk.

Dose-rate considerations are a potentially greater concern for imaging procedures. For short-duration imaging procedures, high dose-rates may still be acceptable provided they do not occur for a long period of time (>3 s). Such long periods can be insufficient time for transient effects to manifest clinically. The kV planar images only last a short time and therefore are unlikely to confuse the CIED. MV portal images or simulation CT scans will not only exceed the 0.01 Gy/min dose-rate but they are also typically delivered very quickly (less than few seconds), and are therefore well tolerated. However, CBCTs deliver >0.01 Gy/min dose-rate over a relatively long period of time. If the device is within the field of view (or even within 1–2 cm of the field of view), it may receive high dose-rates for a long time with a risk of missensing. Similar concerns exist for extended-duration CT scans, such as 4DCT procedures. A mechanism that has been recently documented⁷¹ occurs with CT scanners. CT scanners typically rotate at approximately twice per second, resulting in maximum dose to the device with a period of approximately 120 pulses per minute. This signal can be misinterpreted as a physiological heart rate and trigger a device response. In general, LINACs deliver pulses in a mode much more rapidly than that of CT, making it less prone to be confused for a cardiac signal.

In summary, if the dose-rate to the device is below 0.01 Gy/min (e.g., it is outside 5 cm of the edge of the treatment field, or 2 cm in the longitudinal direction of a CBCT or 4DCT FOV), published research to date concludes there is little risk to the patient. However, if the dose-rate is above this, further management is warranted as described in Section 8.E.

4.D. Magnetic fields effects

The effects of MR imaging procedures on CIEDs vary and are thoroughly described in the HRS 2017 report.²² They depend on several factors including the device type, how the device is programmed, the static magnetic field strength, and the imaging conditions. Strong MRI magnetic fields may cause the following effects:

1. Lead tip heating — radiofrequency currents can be induced in the pacing lead resulting in damage to tissue near the electrode,
2. Unintended stimulation — radiofrequency currents from MRI can cause pulsed energy to be emitted from the lead tip, potentially causing stimulation to tissue and unintended pacing,
3. Mechanical movement — the static and time-varying magnetic fields can induce mechanical forces causing the device to move (force and torque),
4. Radiofrequency interference — radiofrequency energy during the MRI procedure can be coupled into the circuitry producing transient interference with sensitive circuits such as the sensing amplifier,
5. Undesired artifacts — imaging of normal tissues and target volumes may exhibit degraded resolution.

4.E. Electromagnetic interference (EMI)

Induced effects from EMI may result in sensing the field as myocardial potential resulting in the inhibition of the output.² Other potential malfunctions may include: (a) shut-off of the reed switch (electrical switch operated by applied magnetic fields sensor susceptible to EMI) that would result in fixed pacing rate, (b) triggering of output, or (c) isolated serious permanent disruption of function and inappropriate reprogramming.² EMI effects have not been well documented in the literature, and in particular have not been well isolated from other malfunction mechanisms. Even so, the sensitivity of CIED devices to EMI has been reported to be minimal and of transient nature, existing only while the interference is present.^{46,52} Electromagnetic noise around modern LINACs is minimal. There is little concern with transient effects, when present, for CIEDs.⁶ Possible reprogramming of an ICD has been reported, as a poorly understood interaction with the LINAC or the radiation beam itself.^{9,10,52,53} In today's RT practice, other sources of EMI for CIEDs remain uninvestigated for some electromagnetic image guidance systems, respiratory gating technologies, and more recently developed treatment modalities.

5. MALFUNCTION RISK ASSOCIATED WITH CLINICAL PROCEDURES

The following sections discuss the potential source of malfunction for the various imaging and therapeutic procedures used in RT.

5.A. Imaging

5.A.1. kV Imaging for treatment planning and localization

Several recent studies have shown a small risk to CIEDs from CT irradiation.^{13,14} The most common effect observed was oversensing.^{13,14} Over-sensing in ICPs may result in an inappropriate inhibition of pacing output, with the additional

complication of possibly triggering unnecessary tachyarrhythmia therapy in ICDs.²² Based on these studies, the effects were transient and were only observed during direct irradiation of the CIED generator. Effects were not observed when the leads were irradiated.^{13,14,72} Transient effects that last only a short period of time, such as over the course of a traditional CT scan, do not generally last long enough to induce clinically relevant effects. However, Hayes *et al.*,⁷³ suggested that clinically significant inhibition could result from pauses in excess of 3 s for patients that are dependent on their CIED. As such, brief CT examinations are safe for patients with a CIED. Caution may be warranted when performing prolonged scans such as perfusion imaging or 4DCT to manage risk to the device. However, CT irradiation of a CIED has not shown to be a clinically significant problem.⁷⁴ For positron emission tomography with 2-deoxy-2-[fluorine-18] fluoro-D-glucose integrated with CT (18F-FDG PET/CT) scans, patients with a CIED can safely undergo the PET scan. However, patients should inform the technologist about the presence of the CIED at the time of the scan. Imaging a CIED may result in an uptake of FDG around it, potentially increasing the risk of false positive or false negative readings by the radiologist.

In addition to oversensing, the cumulative dose delivered to the device can be considered. For a multislice adult chest CT, typical CT doses range from 0.03–0.05 Gy,^{75,76} while the dose from a 4DCT scan is approximately eight times greater.⁷⁷ Still, even these doses are small for individual scans. Image guidance procedures also tend to yield low doses. If intensive imaging is used regularly, cumulative doses (particularly in combination with the dose from the therapeutic procedure) may become relatively high. Elekta X-Ray Volume Imaging (XVI; Elekta, Crawley, UK) and Varian On-Board Imaging (OBI; Varian, Palo Alto, CA, USA) systems yield a dose of typically 0.001–0.003 Gy per radiographic image. These procedures are short in duration, so there is little risk from dose-rate effects. However, fluoroscopic dose-rates of 0.0108 Gy/min are possible with the Elekta kV-CBCT.⁷⁸ Fluoroscopic imaging times range from 30 s to 5 min, with imaging doses exceeding 0.1 Gy for a 5 min fluoroscopic study.⁷⁹ Similarly, for the Varian CBCT system, cumulative doses can easily be 0.09 Gy and typically take 1 min to deliver.⁸⁰ A compilation of local and effective doses from kV-CBCT for the surface and center of the head and chest are provided in Task Group 75.^{81,82} While the cumulative dose will often be small, the dose-rates may be high and therefore of concern when coupled with the relatively long duration of many of these procedures. Assessing the risk to radiation is challenging, because of the unclear relationship between dose-rate and CIED effects. However, the reported “over-sensing” effect, where the CT scan signal is mistaken for a cardiac signal, would clearly not be possible for fluoroscopic or CBCT procedures. It is for this reason that fluoroscopic or CBCT project to be relatively safe procedures comparatively. The scientific community would clearly benefit from improved understanding of this issue.

5.A.2. MV imaging for treatment localization

There are three major modes of MV imaging: portal imaging, MV-CBCT (Siemens, Erlangen, Germany), and Tomotherapy helical MVCT (Accuray, Sunnyvale, CA, USA).

Each imaging session using port films produces a dose between 0.01 and 0.05 Gy.⁸¹ Typical exposures during a single MV-CBCT image acquisition range from 0.02 to 0.15 Gy (although lower doses are becoming more achievable⁸³), and with the dose close to being uniformly distributed.⁸⁴ One advantage of using MV-CBCT beams is that they can be modeled in a treatment planning system and the dose can therefore be accounted for in the treatment plan.^{85–87} The tomotherapy imaging system produces helical MVCTs resulting in maximum imaging doses of 0.01–0.02 Gy.⁸⁸

Dose-rates associated with MV imaging should be considered similar to those from kV imaging. Port films are short, with transient effects almost certainly not clinically relevant. Longer MV CT scans may yield a high dose-rate for an extended period of time. The risks associated with such conditions are not well studied. However, the lack of data indicating a problem suggests such procedures are relatively safe. Cumulative doses from MV imaging procedures should be considered in the management of patients with CIED devices as they may accumulate substantially over the course of treatment. Of particular note is that imaging fields tend to be somewhat larger than the treatment fields. This can result in the delivery of the full imaging dose to the CIED device. Treatment planners should be encouraged to consult with the radiation oncologist to confirm if smaller setup fields could be used to minimize the dose to the CIED.

5.A.3. MR imaging

Performing MRI scanning for patients with a CIED has been an issue of extensive debate.^{89–91} Historic guidelines for safe MRI scanning strongly discourage MR examination of CIED patients, except in case of urgent need, as documented by the American Heart Association.⁹² However, in the past few years, a number of studies have shown that MRI can be done safely on patients with an ICP or ICD,^{90,91,93} culminating in a report largely focusing on this topic by the Heart Rhythm Society.²² This report highlighted that with approximately 1500 MRI scans involving MR-conditional devices (i.e., those for which an MR environment does not pose a known hazard) only one serious adverse event occurred. Even over the course of hundreds of MRI scans of CIEDs that were not MR conditional, the risk of CIED malfunction was not significantly elevated (low) compared to CIEDs that were not exposed to magnetic fields. There were nevertheless many reported instances of CIED malfunctions associated with magnetic fields (particularly resets and transient effects). This report recommends that a protocol for performing MRI safely on patients with CIEDs be implemented based on a well-established multi-disciplinary procedure. Particularly for nonconditional devices, while MRI scanning may not be avoidable, it should be done with caution as there may be abandoned leads still present.

5.B. Therapy

5.B.1. kV therapy treatment units

During kV therapy, devices near the treatment fields will receive dose from collimator scatter, head leakage, and internal scatter. Dose levels outside the treatment field from these procedures are less well documented than for MV treatments, which may necessitate in vivo dose estimates. Otherwise, concerns associated with kV therapy are similar to those from MV therapy described below.

5.B.2. Brachytherapy

Similar to kV therapy, dose levels distant to brachytherapy sources are not well documented and may require in vivo dose estimates. While the dose to the device has been measured to be low from clinical procedures including coronary artery brachytherapy,⁹⁴ the dose may also exceed 1 Gy.⁹⁵ For example, the Mammosite® (Hologic, Inc., Marlborough, MA, USA) system can deliver 1 Gy at 15 cm from the source (for a prescription dose of 34 Gy), although Croshaw et al., reported a maximum dose of 1.03 Gy from a balloon breast applicator with an average distance to device of 9.1 cm from three patients (with no adverse event).⁹⁶ Optimization flexibility may allow for dose reduction during multilumen treatment for partial breast irradiation.⁹⁷

A recent study⁹⁸ made use of a simple method of estimating the maximal dose to the implanted CIED from an HDR spherical breast applicator surface. Based on Table II, one can evaluate the expected maximal dose to a CIED prior to treatment. For a CIED at close proximity to the breast applicator, a more sophisticated plan optimization and dose evaluation is likely appropriate. It was shown that the iodine contrast medium in the balloon reduced the dose to the device up to 9%.⁹⁹ In the absence of a CIED and other inhomogeneities, the agreement between this study and the previous one⁹⁸ was within 2%.

The accuracy of dose calculation to the CIED is complicated by the high effective atomic number of the device leading to increased dose deposition as compared to water. For

TABLE II. Estimated maximal dose (D_d) to the device for typical distances from a spherical breast applicator’s surface. (Table reproduced from Kim et al.⁹⁸).

Balloon Vol. (cc)	35	50	70	90	110	125
Balloon Diam. (cm)	4.06	4.58	5.12	5.56	5.94	6.20
1 Gy	15.6	16.9	18.2	19.3	20.2	20.8
2 Gy	10.5	11.3	12.1	12.8	13.4	13.8
3 Gy	8.2	8.8	9.4	10.0	10.4	10.7
4 Gy	6.8	7.3	7.8	8.2	8.6	8.9
5 Gy	5.9	6.3	6.7	7.1	7.4	7.6

Estimated dose to the device at distance, d from a spherical applicator is given by: $D_d = D_p \cdot \left(\frac{R_{\text{balloon}} + 1}{R_{\text{balloon}} + d} \right)^2$, where D_p is 3.4 Gy at 1 cm from applicator surface and R_{balloon} is the balloon radius (cm).

example, for balloon-to-device distances of 5–10 cm, Monte Carlo calculations have found that the dose is elevated by a factor of approximately 2.4 as compared to typical measurements or clinical calculations.⁹⁹ However, as detailed in Section 4.B, given the substantial uncertainties associated with this correction, there is ambiguity concerning the beam quality on which manufacturer-recommended dose tolerances have been based. That research recommended using standard measurements or calculation techniques to determine dose, with additional corrections for the effective-Z of the CIED not recommended. Similarly, intraoperative RT is another modality available that has been reviewed in a case report where a low cumulative dose did not induce any effects.¹⁰⁰

5.B.3. MV photon and electron Beams

Cardiac implantable electronic devices should not be in the direct radiation field of therapy beams if possible, because of the possibility of loss of function by the device. This may be particularly important for ICDs which have shown interference as soon as they were placed inside the radiation field.⁷⁷

Various studies on direct and indirect irradiation of CIEDs have been performed with a wide range of results both on the type and severity of malfunctions, and on the minimum absorbed dose to the device that caused that malfunction. Tables III and IV summarize recent *in vitro* and *in vivo* ICP and ICD studies, respectively.^{46,52} Additionally, the Heart Rhythm Society has published a consensus statement on the management of CIEDs based on all types of malfunctions caused by all known sources with complete set of

recommendations and extensive literature of all the reported cases of interaction of radiation with cardiac implantable devices.²² Special consideration is warranted for relatively new treatment modalities.

Photon therapy treatment (out-of-field doses): The radiation dose outside of the treatment field decreases approximately exponentially with increasing distance from the treatment field edge.¹⁰¹ At 10 cm from the field edge, the radiation dose is approximately 1% of the target dose. Dose outside the treatment field increases with field size, but is generally independent of energy. Patient scatter contributions to the out-of-field dose are reduced for IMRT in contrast to conventional therapy, because of a reduced treatment volume. However, head leakage contributions are elevated in proportion to the modulation of the beams. Overall, the impact of IMRT on the total dose to the CIED is highly dependent on the specific treatment plan parameters and relative location of the device to the treatment field edge.^{102–105} A separate consideration for stray radiation outside the treatment field is that the out-of-field dose near the surface is elevated relative to dose below the surface, by as much as a factor of 5.^{105,106} This elevated dose is maximal at the surface, and decreases until a depth of d_{max} , beyond which the dose is relatively constant.^{69,103,105,106} CIED devices are typically located from 1 to 3 cm below the skin.

In addition to the photon leakage and scatter contributions, high-energy treatments (>10 MV) also generate neutrons. These neutrons are produced in the head of the accelerator,^{50,104,107} and subject the patient to a broad and

TABLE III. CIEDs *in vitro* studies in recent literature.

Author	Year	Device (ICP or ICD)	Outcome
Souliman ⁴²	1994	18 ICPs (dual- and single-chamber models, various manufacturers)	11 ICPs failed with no recovery, first complete failure at accumulated dose of 16.8 Gy
Mouton ⁴	2002	96 ICPs (various manufacturers and models)	66% amplitude change >10%, 50% permanent silence, 48% slowed down rate, 41% silence longer than 10 s. 30% accelerated rate, 27% missing impulses at start of irradiation, 23% signal compatible modification, 17% shape deformation. NB. 5% of all pacemakers were concerned with multiple short silences, which are considered to be harmful.
Hurkmans ⁴⁸	2005	19 ICPs (4 manufacturers)	All ICPs showed a point of failure at or above 90 Gy, except of one at 20 Gy; 5 of 19 ICPs showed a battery replacement warning. Loss of output was the most commonly observed point of failure. ICPs showed a large variation in their sensitivity to radiation.
Hurkmans ⁶	2005	11 ICDs (4 manufacturers)	First malfunction observed at 0.5 Gy. Sensing threshold changes were often seen as first malfunction. 4 ICDs failed ≤ 2.5 Gy, 4 ICDs showed VT or VF, which would have resulted in delivery of a shock. No significant changes in pulse amplitude or pulse frequency were observed. No telemetry problems recorded.
Uiterwaal ⁴⁹	2006	11 ICDs	Interference detection observed for all ICDs irradiated in the treatment field, noted from the first radiation fraction. 4 ICDs showed VF or VT detection.
Kapa ¹²³	2008	12 ICDs (3 manufacturers)	No malfunctions observed.
Hashimoto ¹²⁸	2012	4 ICDs (same manufacturer)	Proton beam with secondary neutrons-29 Soft Error (SEU) were noted, 1 event/15 Gy approx.
Hashii ¹⁰⁸	2013	8 ICDs (2 models same manufacturer)	10- and 18-MV photon beams, no hard errors observed, soft error more frequently observed at 18 MV.
Zaremba ³⁴	2013	10 ICPs and 2 ICDs (various manufacturers)	6 and 18 MV to 150 Gy (2 Gy fraction) dose. 6-MV group: One ICP malfunction; 18-MV group: 14 ICP malfunctions at lower dose. <u>No</u> ICD malfunctions were noted at <u>any</u> dose level.

TABLE IV. CIED *in vivo* studies in recent literature

Author	Year	Tumor site (Device)	Prescribed dose (Beam Energy)	Dose to device	Outcome
Tsekos ¹²²	2000	Neuro endocrine CA of the arm (ICP)	50.4 Gy (6-MV photons)	>50 Gy (not specified) <u>device in field</u>	Magnetic frequency began to decrease, no failure observed.
Nibhanupudy ¹¹⁵	2001	Lt breast (ICP)	50.4 Gy (breast)/50 Gy SCF (6-MV photons)	1.8 Gy	No malfunction.
Riley ¹⁶⁶	2004	NSCLC (ICP)	63 Gy GTV/59.85Gy PTV (6-MV photons)	<5 Gy	No malfunction.
John ¹¹⁶	2004	Lt breast (ICD)	50 Gy (6-MV photons — possibly)	Partial exposure to generator, full exposure to leads	Battery depletion, shock impedance >125Ω, indicating shock coil failure, possibly due to leads.
Thomas ¹¹³	2004	Bronchial CA (ICD)	56 Gy (18-MV photons)	Unable to ascertain	Electrical reset detected 9 days after event.
Mitra ¹⁷⁹	2006	NSCLC (ICP)	40 Gy (6-MV photons — possibly)	0.73 Gy (estimated from TPS)	No malfunction.
Sepe ¹¹⁷	2007	Larynx CA (ICD)	60 Gy tumor/ 50 Gy lymph nodes (6-MV photons)	2.5 Gy	No malfunction.
Nemec ¹¹⁴	2007	Lung (ICD)	59.4Gy (6-MV photons — possibly)	Unable to report	Patient collapsed on 3 rd fx and required CPR. ICD suggestive of RAM damage but no evidence.
Munshi ¹¹⁹	2008	Lt Breast (ICP)	50.4 Gy (10-MV photons)	4.3 Gy	No malfunction.
Oshiro ⁹	2008	Liver and Lung (ICP)	33–77 GyE (Protons)	Zero computed dose to the generator by protons.	Minor changes in heart rate in 2 out of 8 patients noted, due to changes in pulse rate and pattern.
Kapa ¹²³	2008	Various sites (ICP & ICD)	30–70 Gy (ICP) 18–54 Gy (ICD) (6-MV photons)	Unreported	No malfunction.
Lau ¹¹⁸	2008	Pelvis irradiation (ICD)	74 Gy (23-MV photons)	<0.1 Gy	Electrical reset potentially by secondary neutrons.
Ng ¹⁸⁰	2008	Esophagus, Prostate	45 Gy/72 Gy	Unreported	Power-on reset/pulse width change noted.
Gelblum ¹⁰	2009	33 patients treated at various sites including prostate (ICD)	0.6–81 Gy (6/15-MV photons)	0.01–2.9 Gy	Reprogramming of device in one case. Photon beams <10 MV was recommended
Tondato ⁵²	2009	Thyroid, Nose, Lung (ICP)	28–63 Gy (6-MV photons — possibly)	Unreported	Most cases had minor parameter changes (over/under sensing). Some were more serious that required re-programming.
Wadasadawala ¹⁶⁵	2011	Various sites (ICP)	45–70 Gy (6-MV photons)	0.06–60 Gy	No malfunction after 5 months of median follow-up.
Ferrara ⁶⁸	2010	37 patients with ICPs and 8 with ICDs	8–79.2 Gy (6- and 18-MV photons, electrons)	0.3–5.6 Gy	No malfunctions reported.
Soejima ²⁰	2011	Prospective survey: 60 patients with ICPs and 2 with ICDs	20–74 Gy (6/15-MV photons, Cyberknife, IMRT)	0.48–2.1 Gy (6 patients >2 Gy reported)	No malfunction for >2 Gy reported, 1 ICP prostate IMRT 15 MV memory initialized.
Makkar ¹⁸¹ Prisciandaro ⁷⁰	2012/2015	69 patients devices placed 1.5–10 cm from treatment field (ICPs and ICDs)	4–77.7 Gy (electrons, photons, IMRT, SRS, SBRT)	ICP: 5 Gy (max); ICD: 1.7 Gy (max) Mean dose: <2 Gy to all devices	Soft Errors in two ICD patients irradiated with 16 MV.
Elders ²⁹	2013	15 patient treated in various sites (ICD)	Doses ranged from 16–70 Gy depending on the site (6/10/18-MV photons)	<1 Gy in most cases.	Soft Errors noted in 29% of treatments with higher energy beams-secondary neutrons suspected as reason.
Gomez ^{43,182}	2013	42 patients treated in various sites (ICPs and ICDs)	Median prescribed dose 74 GyE (protons)	Median estimated: 0.8-Gyproton 346-mSv neutron	2 ICDs reset, 2 ICPs reset
Grant ⁵⁷	2015	215 patients treated in various sites (ICPs&ICDs)	Dose ranged by site. Primarily 6 and 18 MV.	Median 0.50 Gy; range: 0–30.2 Gy	15 SEU events (attributed to neutrons), 2 unrecoverable.3 transient noise events.

GTV: gross tumor volume; PTV: planning target volume; SCF: supraclavicular field; NSCLC: nonsmall cell lung CA; TPS: treatment planning system; GyE: gray equivalents; VF: ventricular fibrillation; VT: ventricular tachycardia.

relatively uniform bath of neutrons that may affect the device.¹⁰⁸ Neutron fluence and absorbed dose (inside and outside the treatment field) increases with nominal x-ray energy, and varies with accelerator manufacturer (being highest for Varian LINACs).^{59,62} Neutron absorbed dose changes minimally with field size^{62,107} or distance from the field edge,¹⁰⁵ but does decrease rapidly with depth.^{50,109} It is important to note that if shielding is desired, high-Z materials provide little protection against neutrons. Instead, hydrogenous materials are required for attenuation.¹¹⁰ Since electronic devices can show substantial sensitivity to high-LET radiation,¹¹¹ any neutron contribution should be carefully considered.

IMRT: The vast majority of studies in the literature have not specified the treatment delivery technique^{10,68,112–114} or have merely used 2D or 3D techniques.^{17,115–119} One institution¹²⁰ looked at 24 patients with CIEDs treated for localized prostate cancer using IMRT. All devices were interrogated prior to treatment delivery and one week after treatment completion. It was determined that six ICPs suffered from an interference. Each device reset to the manufacturer's default settings. In addition, two ICPs permanently remained in the default settings. Although no mention of beam energy was made in the study,¹²⁰ 18 MV beam is suspected. One additional reference used 6-MV IMRT for thyroid carcinoma metastatic to the right cardiac atrium and ventricle of an ICP-dependent patient with the leads in the treatment field. For this research, no effects to the devices were noted.¹²¹ In another study that included IMRT, two partial reset events were identified, but concluded to be related to the high photon energy (16 MV) used.⁷⁰ In order to obtain a better understanding of this sensitivity, authors who publish case reports of CIED malfunctions in the future should provide more details on the irradiation technique and conditions than have been reported in the past. Furthermore, an *in vitro* study of sensitivity of CIEDs to scatter dose from any sort of dynamically modulated delivery is of future interest.

Stereotactic Body RT (SBRT): Stereotactic body RT is a unique modality, because of the potential for long treatments and high dose-rates (e.g., FFF beams). However, the cumulative dose to the device will typically be smaller than for filtered beams. Given the high dose per fraction, length of the treatment session, number of treatment beams, high dose-rates, and beam-on-time for SBRT, caution should be exercised when treating patients with CIEDs. The treatment planner should avoid using beam directions that pass through the device. Planning and delivery parameters should be carefully inspected in terms of the number and energy of the beams, beam directions, dose-rate, MU per fraction, MU/control-point for VMAT, beam-on-time, and treatment time, as this may affect the dose received by the CIED. Due to these special considerations, such patients should be managed as discussed below in Section 8.

Although direct irradiation of the CIEDs should be avoided in clinical SBRT practice, it is important to

emphasize that malfunctions can also occur by scattered radiation outside the treatment field.^{118,122,123}

Electron therapy treatment (out-of-field doses): Electron RT also results in dose outside the treatment field.^{124,125} Although, the dose is often much lower than that from x-ray therapy. Elekta and Siemens accelerators in particular can have higher scattered doses than from x-ray therapy than for Varian LINACs.^{65,125} Out-of-field radiation is electrons, and therefore not very penetrative, so the dose is predominantly limited to the patient surface on which the electron beam is incident (i.e., for an anterior electron field, the anterior patient surface receives the bulk of the out-of-field dose). However, CIEDs are superficially implanted, and the out-of-field electron dose has been measured to be as high as 3% of the given dose at d_{max} , extending at this level to beyond 30 cm from the field edge.¹²⁶ The cumulative doses for superficial locations in the patient could potentially reach as much as 2 Gy. The cumulative out-of-field dose from electron therapy should therefore be assessed if the CIED is on the same local surface of the patient as aimed at by the treatment field, and up to 30 cm from the treatment field edge.

Neutron production with electron beams is less than that from a 10 MV x-ray beam.^{64,65} While high-energy electron beams may be problematic for the most sensitive of electronic systems, electron beams can broadly be considered to be “non-neutron producing”.

5.B.4. Neutron and proton/particle beams

Neutron therapy treatment: High LET particles produce densely ionizing tracks that are more effective in causing damage than low LET radiation, and a high cumulative dose is not required.¹² Koivunoro *et al.*,⁵³ showed that epidermal neutrons in boron neutron capture therapy (BNCT) produced severe malfunctions in ICPs at doses between 1 and 2 Gy. It is often recommended not to treat CIED patients with neutron therapy. Even outside the treatment field, there will be an abundance of high-LET neutrons that could adversely affect the CIED.

Proton and heavy ion therapy treatment: These modalities also produce an abundance of secondary neutrons. However, high-energy photons and passively scattered protons have 1–2 orders of magnitude higher neutron production (depending on distance from field border) than scanned protons and scanned carbon beams¹²⁷ (see Fig. 3). An experimental study on the influence of proton and charged particle beams on CIEDs placed outside the irradiation field showed that the frequency of power-on reset (SER) errors observed was twice as high for ICDs in the proton beam irradiation than in carbon-ion beam irradiation.¹²⁸

For passive scattering systems, neutrons are generated in the treatment head, beam modulators, scattering devices, and patient-specific apertures or compensators, and are the

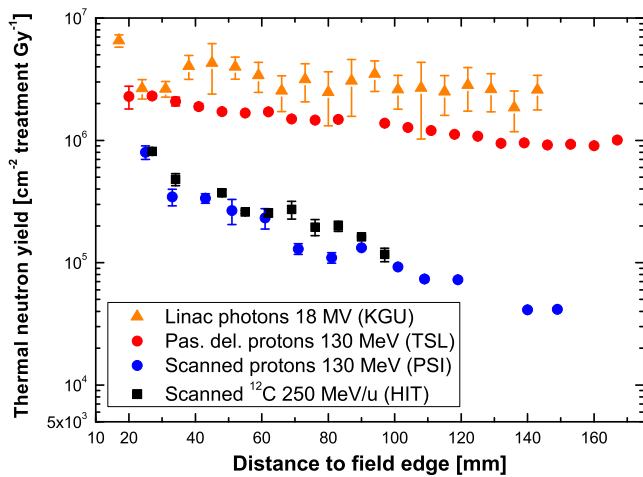


FIG. 3. Fluence of secondary thermal neutrons for all radiation types and delivery techniques in the depth of maximum dose (31 mm for 18 MV photons and 125 mm for charged particles) during the irradiation of the water phantom with a $5 \text{ cm} \times 5 \text{ cm}$ field. (Reprinted from Kaderka *et al.* with permission).¹²⁷

dominant contribution to the total dose in the region downstream of the Bragg peak and at distances greater than 10–15 cm from the field edge.¹²⁹ The field defining aperture dominates as a secondary neutron production source due to its proximity to the patient, making the neutron dose dependent on the ratio of the field size to the aperture opening.⁶⁶ Out-of-field patient neutron doses increase with beam range/energy and treatment volume.^{66,130} Active/modulated scanning systems do not require scattering devices in the treatment head or patient apertures. Consequently, the secondary neutron production in the treatment head is reduced leaving the majority of neutrons generated by the patient's body.^{66,129,131} Although scanning systems have a smaller out-of-field equivalent dose compared to passive scattering systems by a factor of 40 in the superficial region, this factor decreases at deeper depths.¹²⁹

Based on device interrogation, minor ICP malfunctions such as changes in pulse rate and pulse patterns were noticed in 2 out of 8 patients (all patients were device dependent more than 80% of the time).⁹ Therefore, electrocardiographic monitoring was recommended for all patients with an ICP during proton beam therapy.⁹ A more recent phantom study on four ICDs, outside the treatment field of a passive scattering proton irradiation,¹²⁸ found:

1. The gamma ray dose was approximately 0.00011–0.00045 Gy per Gy of protons, with a ratio of gamma ray dose at central axis of 5% of the total secondary dose (unimportant effect on the ICDs),
2. The major contribution of secondary out-of-field dose was due to neutrons with 0.0027 per Gy of protons for the ICDs and 0.0013–0.0089 Gy per proton Gy, for the phantom,
3. There was 1 SEU per 15 Gy and 1 power-on reset error per 50 Gy and,
4. The timing in occurrence for soft and hard errors was unpredictable and random.

6. DOSE ASSESSMENT CONSIDERATIONS

The dose (and dose-rate) delivered to the CIED is of particular importance in managing patients with implanted devices. The dose to the device can be crudely estimated from literature such as TG-36⁶⁹ or TG-158.¹³² If the device receives a dose that is concerning (i.e., $>2 \text{ Gy}$), further evaluation is warranted prior to treatment. In general, if the device is further than 10 cm from the photon treatment field edge, the dose will not exceed 2 Gy. However, if it is within 10 cm, a more rigorous determination of the dose is appropriate (e.g., a measurement or calculation, see Section 6.C). The precision of any dose assessment should be sufficient to ensure that the patient is properly categorized and therefore properly managed.

There are several dose assessment considerations that merit attention.

6.A. Where to assess dose

While some areas of the device are less sensitive than others, these may not be obvious and will vary between different devices. Furthermore, it is not possible to determine how the device is seated in various patients. Therefore, the most prudent and reasonable approach is to assess (at least) the maximum dose to any point in the device. Of note, CIED leads (“heart wires”) will not be damaged by clinically relevant doses^{72,121} (for electronically passive leads where mechanical damage would be the greatest risk). Such leads do not need to be considered as part of the CIED, since they are highly resistant to therapy doses. However, ongoing research is investigating electronically active leads (which are metal wires emanating from a CIED that contain additional electronic components at the distal end for monitoring the performance of the device) that could be damaged by radiation. It is not known whether they should be considered as part of the CIED. The most practical option is therefore to include them until this issue is better understood.

6.B. Medium specification

Careful understanding is required when using the phrase, “dose to the CIED”. Dose measurements (and many calculations) are typically reported as dose-to-water or muscle and as such, dose reporting is almost always specified to one of these media. Yet, neither are present in electronic devices. The predominant mechanism for device damage is the buildup of trapped charge in the device's insulating layers leading to shifts in transistor operating parameters. Correspondingly, a dose to SiO_2 is more relevant than dose to tissue. (Unfortunately, even this is insufficient and even more complicated. While a dose to silicon predicts the rate of free charge generation, the final amount of trapped charge is also dependent on the radiation energy and circuit operating conditions.) Consistent with the higher effective atomic number of SiO_2 , interaction cross sections are higher than in tissue,

particularly for low-energy photons (<0.1 MeV). Thus, the traditional “dose” (as in dose-to-water) will be an underestimation of the dose to the device, particularly outside the treatment field where the spectrum is softer.¹³³ Although not directly quantified, SiO₂ would be expected (based on similar known use of Al₂O₃) to overrespond relative to tissue by ~20–30% outside of a 6-MV treatment field,¹³⁴ and potentially by more than a factor of 3 for kV energies.^{135,136} Ultimately, accurately calculated tissue dose serves as a good estimate of dose to the device inside the megavoltage treatment field, but is an increasingly poor estimate out of the beam or in kV environments. This task group does not recommend accounting for it. We recommend to report measured doses per their normal clinical calibration, where no additional corrections need to be applied, even to the treatment planning system (TPS) calculations. This recommendation was based on: (a) the overresponse of SiO₂ in clinical situations not being well established, (b) the relationship between dose to SiO₂ and consequences of its use not being straight forward, (c) dose tolerances promulgated by the manufacturers are often based on beams of unknown energy, but may include low-energy beams (in which there would be no overresponse relative to the conditions in which the dose limit was established), (d) a potential 20–30% dose error is believed to be within the acceptable uncertainty of dose determination to the device outside the RT field and, (e) all published data on the radiation effects on these devices are reported in dose-to-water or tissue already. However, for imaging intensive IGRT procedures this estimate more seriously underestimates the dose (potentially by a factor of 3 or more). The terminology of “dose to the CIED”, as used in this report and in history, should be understood to typically refer to “dose-to-water” or to something similar at the location of the device, rather than truly as dose to the device.

6.C. Dose assessment

6.C.1. Calculation

A convenient option for assessing the dose to the CIED if it is near (or in) the treatment field is to use the treatment planning system. Particularly close to the treatment field, the TPS is likely the most accurate way to assess dose. This is because steep dose gradients make measurements very challenging. Treatment planning systems can readily estimate the maximum dose to the device. Caution must be used still, because treatment planning systems routinely underestimate the dose outside of the treatment field.^{137–139} Even for a simple conventional field,¹³⁷ the treatment planning system typically underestimates the actual delivered dose. This calculation error can be 40–125% at 4–11 cm from the field edge. The treatment planning system is useful if the CIED is within 3 cm of the treatment field edge (or within the 5% isodose line for an IMRT plan) where reasonable dose calculations are achievable. Beyond 3 cm from the treatment field, the TPS should not be used as a method of assessing dose to the device.

Calculation options exist for CIED devices located more than 3 cm from the edge of the treatment field. For example, AAPM TG-36⁶⁹ or Peridose¹⁴⁰ are accurate within approximately 30% (underestimating)^{140–142} on average. However, these systems are limited to conventional fields and do not incorporate IMRT treatments. Monte Carlo models have also been developed that are capable of calculating the dose outside of the treatment field with good accuracy for arbitrary treatments and geometries.^{103,105,143} Nevertheless, development of such models is demanding and requires extensive coding and validation.^{103,144}

Neutron contamination is not included in any commercial treatment planning system, nor is it handled by TG-36⁶⁹ or Peridose.¹⁴⁰ For neutrons, the cumulative dose is generally unimportant. Only the presence or absence of neutrons has been reported to matter.

6.C.2. Measurement

Generally, beyond 3 cm from the treatment field a measurement is the most appropriate way of determining the dose to the CIED. The maximum dose to the CIED should be measured, corresponding to the point of the device that is closest to the treatment field and most superficial. Dosimeters with high sensitivity are recommended. Dose measurements are less accurate outside the treatment field, because of greater uncertainties in the characteristics of the radiation field. Two major considerations are justified when considering radiation field characteristics: energy and depth of treatment.

Energy: For measurements outside the treatment field, a substantial portion of the dose comes from low-energy scatter radiation. The energy spectrum of a 6-MV photon beam averages only 200–400 keV outside the treatment field, vs. 1.5 MeV inside.^{133,145} This will result in an overresponse of many dosimeters in terms of determining dose to tissue for out-of-field measurements.¹⁴⁶ Although the relevant comparison may better be described as dose to SiO₂, as discussed in Section 6.B., it is recommended to report dose-to-water when possible. Therefore, dosimeters with a relatively flat energy response or well-known corrections are ideal. The energy response is particularly important for patients treated with orthovoltage energies or treatments involving IGRT, as the overresponse of common dosimeters can exceed a factor of 3 at kV energies.^{135,136} Barring a flat energy response or well-documented correction factors, dosimeters can be calibrated against an ion chamber in an out-of-field geometry. Ion chambers show little energy dependence in this energy range with simple correction.¹³³ Calibration should be done at 1 cm depth and at 5 cm or more from the field border. Dosimeter results should then be related to their readings under standard reference open field (10 cm × 10 cm) calibration conditions.

Depth: The depth of the CIED requires attention for patient-specific measurements. Outside of the primary field, the dose is highly elevated (by a factor of 2–5) at the surface and there is a build-down effect until a depth of d_{max} is reached.^{103,106} Therefore, bolus should be used over the

detectors to provide buildup to match the depth of the CIED. Devices are typically implanted at a minimum depth of 0.5 cm, but are often placed deeper in the muscle under layers of body fat. If the device is superficially implanted, or the depth is unknown, dosimeters on the patient's surface should be placed at a depth of 0.5 cm. If the device is implanted at a known depth, the measurement should be made at that depth (up to the beam's nominal d_{max}). Although a depth of 1 cm is a practical solution, it mitigates the bulk of this build-down effect.

Several detectors suitable for CIED dosimetry are discussed below.

Ion Chambers can be used in phantom to assess the dose, and typically have only small corrections. A major exception is the use of microchambers with high-Z electrodes that can show dramatic overresponse to low-energy photon beams.¹⁴⁷ Caution must also be used for *in vivo* measurements, because of the necessary high voltage.

Thermoluminescent dosimeters (TLD) are well suited for the measurement of dose to CIEDs. TLD use is detailed in the upcoming TG-191 report,¹⁴⁸ including special considerations for out-of-field applications. Although most out-of-field considerations are minor, the soft out-of-field photon spectrum causes an overresponse of less than 10%. Correction factors are available when soft beams are considered.¹³³ Caution must be used with the standard LiF TLD-100 at high x-ray energies (>10 MV). This dosimeter overresponds to thermal neutrons. While in-field measurements are reliable, measurements outside the treatment field can be in error by more than a factor of 10.¹⁴¹ For out-of-field dosimetry in high-energy photon beams, the TLD-700 is recommended for use. It has a very low thermal neutron cross section,¹⁴⁹ but will accurately measure only photon doses.

Optically Stimulated Luminescent Dosimeters (OSLDs) are expected to be detailed in an upcoming AAPM TG-191 report. OSLDs are reasonably well suited to measurement of the dose to CIEDs as they can be read-out 10 min following irradiation and with little loss of signal. As they have a relatively high effective atomic number, OSLDs can overrespond to the soft spectrum outside of the treatment field by more than 25%. Correction factors are also available for these detector types.¹³⁴ Similarly, OSLDs overrespond in the kV range by a factor of 3 or more.^{135,136} Their overresponse to kV radiation can be accounted for by a calibration at the approximate kV energy. While OSLDs have shown some angular dependence, this effect is on the order of a few percent for most situations relevant to clinical therapeutic RT,¹⁵⁰ and is therefore considered irrelevant for CIED dosimetry.

Diodes have the required sensitivity, but overrespond to lower energy scatter radiation. The magnitude of this overresponse varies between devices, but can be 70% or more at just 1 cm outside the treatment field.¹⁴⁵ Other corrections may also be appropriate, such as dependence on angular orientation, temperature, and dose-rate, etc. These effects are typically small. For example, dose-rate dependence can approach 10%.¹⁵¹ The variety and culmination of these correction factors can be a challenge for out-of-field dosimetry,

although if the device is well characterized this dosimeter may readily provide sufficiently accurate dose measurements.

Metal oxide semiconductor field-effect transistors (MOSFETs) can provide an immediate dose measurement, and have properties similar to diodes regarding energy, temperature, angular dependence, and dose-rate dependence. However, their sensitivity is limited to about 0.10 Gy. The MOSFET also has a finite lifetime of about 10 Gy accumulated dose. In addition, these detectors are more expensive than other *in vivo* dosimeters. Special consideration may also be required in an IGRT environment, as MOSFETs can overrespond by a factor of ~3 to kV photons.¹⁵²

Film can also provide a dose measurement to the CIED. Film can be cut to provide a two-dimensional estimate of the CIED dose. However, since the out-of-field radiation spectrum has a number of lower energy photons and since film has a relatively higher atomic number, radiographic film will have a substantial over-response. In contrast, radiochromic film will provide a more accurate estimate of the CIED dose, because its atomic number is closer to water.¹⁵³

Table V provides a summary of characteristics of commonly used detectors used for megavoltage *in vivo* dosimetric measurements. While we have ample options for dosimeter usage, dosimeters continue to be developed. For example, scintillators have minimal energy dependence and may be well suited to dosimetry for CIED devices.^{154,155}

Neutron dosimetry is particularly challenging and requires specialized equipment and expertise as detailed in the TG-158 report.¹³² Therefore, neutron dosimetry is not recommended unless both equipment and expertise exist. When neutron production is unavoidable, it should be minimized by using the lowest suitable treatment energy. Furthermore, the patient should be monitored in the High-Risk category (see Table VI).

6.C.3. Typical out-of-field doses

Out-of-field dose estimates are presented in TG-158¹³² for a range of treatment modalities. In the context of a 2 Gy threshold, the following general observations can be made. For conventional photon therapy, and a 50–60 Gy tumor dose, the dose to the CIED will be less than 2 Gy for most scenarios if the device is more than 5 cm from the field edge. For IMRT treatments, the dose could exceed 2 Gy if the device is within ~7 cm from the field edge. This distance may be slightly smaller for FFF beams^{156,157} or VMAT techniques,¹⁵⁸ but likely only minimally. This distance may also be slightly smaller for SRS/SBRT modalities¹⁵⁷ (in part due to lower target doses), although noncoplanar beams may increase the dose to the device. Therefore, as a simple rule of thumb, for external beam x-ray therapy, if the device is within 10 cm of the field edge (or within 10 cm of the 50% isodose line for an IMRT treatment), the dose to the device should be determined (e.g., *in vivo* measurement if the device is between 3 and 10 cm from the field edge, or for IMRT, a TPS calculation if the device is within 3 cm of the field edge or 5% isodose line should be specifically performed). If the

TABLE V. Summary of characteristics of commonly used detectors used for megavoltage *in vivo* dosimetric measurements.¹⁸³ While any detector listed may be able to achieve the necessary precision, the dual requirements of high sensitivity and relative energy independence for out-of-field measurements lend preference to TLDs and OSLDs.

Characteristic	Diode	MOSFET	TLD	OSLD	Film	
					Radiographic	Radiochromic
Dose	0	+	0	0	+	+
Accumulated dose	+	+	+	++	Not applicable	Not applicable
Dose-rate	+	+	0	0	0	0
Energy	+	+	+	+	++	+
SSD	+	+	0	0	0	0
Field size	+	+	0	0	+	0
Linearity	0	0	+	+	+	+
Reproducibility	0 (<1%)	+ (<2%)	+ (<2%)	+ (<2%)	+ (<2%)	+ (<3%)
Orientation	+	+	0	0	0	+
Temperature	+	+	0	0	0	+
Readout delay	0	0	++	+	+	++
Correction factors	++	++	+	+	+	+
Estimated dose uncertainty (1SD)	±3%	±5%	±3%	±3%	±3%	±3%
Main advantages	Reproducibility, Immediate readout	Immediate reading, minor fading	No cables, reused after annealing, few corrections	No cables, readout 10 min post irradiation, reused after optical bleaching	2 D dose, resolution, reread, permanent record, various shapes	2 D dose, resolution, reread, permanent record, various shapes, light insensitive
Main disadvantages	Cumbersome calibration, many corrections, cable	Limited lifetime, high cost	Labor intensive, TLD equipment	Short lifetime, dependence on accumulated dose, OSLD equipment	Light sensitive, processing equipment and maintenance, scanning equipment	Scanning equipment, strict readout protocol

0, No concern; +, Minor concern; ++, Serious concern.

Assumes calibrations at a particular energy.

Orientation plays a role in readout.

For measurements within the radiation field where their response has been well characterized. Values based on the authors' experience and publications on in-field measurements (Mijnheer et al. 2013).¹⁸³ As discussed in the section on out-of-field measurements, the uncertainties would be increased. The reader is referred to TG-158¹³² for a discussion on detector uncertainties for out-of-field measurements.

Assumes a well-maintained processor.

TABLE VI. Patient risk categories: cumulative dose to the CIED and pacing independent versus pacing-dependent. The patient's risk is not equal to the risk of a CIED defect. Higher cumulative doses can be used if the manufacturer recommended dose tolerances are above the dose thresholds presented here. Neutrons are considered present when protons or photons with energy >10 MV are used.

Patient	Dose region and risk category			Neutrons present
	<2 Gy	2–5 Gy	>5 Gy	
Pacing independent	Low risk	Medium risk	High risk	High risk
Pacing dependent	Medium risk	Medium risk	High risk	High risk

device is entirely more than 10 cm from the field edge or 10 cm outside of the 50% isodose cloud for IMRT treatments, a dose assessment is not necessary unless noncoplanar/vertex beams are used, as in the case for a Cyberknife treatment. If noncoplanar beams are used, dose verification

should be considered even at CIED distances beyond 10 cm from the treatment field edge.

Treatments in proton therapy will typically have less than 2 Gy of neutron dose. Neutron dose measurements are not recommended, because of the challenges in dosimetry and the variability of data in the literature. Rather, these patients should be monitored in the High-Risk category on the basis of the risk for a single-particle SEU.

7. RECOMMENDED DOSE THRESHOLDS

From the preceding sections, it is evident that issues related to the device, beam energy, and dose play an important role in determining the chance of device malfunction that can arise during RT. It is also evident that there is limited information available to define a quantitative dose-effect relationship within a narrow confidence interval. The only dose threshold available otherwise is a zero dose threshold. The absence of any dose given yields no effects on the CIED. Above this threshold, there is an increasing chance of a

device malfunction. There are no published data showing any detrimental radiation effects in these devices at doses less than 0.5 Gy in photon beams with energies 10 MV or lower.

The type of device malfunction, being transient, reversible, or irreversible, is not predictable when considering only the cumulative dose received by the device, the dose-rate, or the presence of high-LET radiation. Permanent damage to the device has been repeatedly documented from high cumulative doses or the presence of high-LET radiation. The risk of these different outcomes is important when trying to decide what type of precautions should be taken to minimize a possible device malfunction and what type of action is needed, should such an event occur. Furthermore, patient-related factors should also be taken into account. A patient who is not pacing-dependent might require less monitoring compared to a patient who is pacing dependent. Similarly, the indication for RT is also important. The small risk of a device failure is likely acceptable for a patient referred for RT, because of an acute paraplegia risk. Finally, the available cardiology infrastructure and knowledge will influence how patient management can be established in a specific institution.

To summarize, these are the factors that are considered in the proposed recommendation:

1. CIED type, model, and whether it contains active leads,
2. Presence of neutrons or other high-LET radiation, which might cause SEUs,
3. Cumulative dose, which might lead to permanent failures,
4. Patient's pacing dependency,
5. Dose-rate at the location of the CIED, which might lead to mostly transient oversensing effects or reset type events,
6. Radiation therapy treatment intent (curative/palliative).

Weighting these considerations is not a mathematical exercise. This report's aim was to define an optimally safe and

practical procedure that can be implemented on a large scale. As such, it is important to prioritize the recommendations based on clinical relevance. The patient's pacing dependency mainly determines the immediate impact of the CIED malfunction on the patient, whereas the cumulative dose and the presence of high-LET radiation produces the most abundant (and often severe) malfunctions. These aspects are combined to derive patient risk categorizations for levels of Low Risk, Medium Risk, and High Risk (see Table VI).

The *relative importance of different dosimetric factors* (cumulative dose, presence of high-LET neutrons, and dose-rate) is very complex and will vary by device type, clinical practice, and specific treatment conditions. A large-scale review of 249 courses of RT in CIED patients sheds some light on this in clinical practice as it included courses that delivered >2 Gy to the device, and courses that included neutron-producing radiation (usually 18 MV photons). Grant et al.⁵⁷ observed 18 event malfunctions, including 15 SEUs (2 of which were permanent malfunctions) and 3 transient (and asymptomatic) noise events. The risk of SEU based on cumulative dose and neutron-producing RT is shown in Fig. 4, illustrating the risk of failure in clinical practice overwhelmingly due to neutrons. Research shows that neutron-producing therapy is more clinically common than having the device receive a high cumulative dose. In the study by Grant et al.,⁵⁷ 71 out of 249 patients (29% of cases) were treated with neutron-producing therapy. In contrast, cumulative doses greater than 2 Gy were seen in 47 cases (19%), and greater than 5 Gy was seen in only 4 cases (2%). Of the cases treated with neutron-producing therapy, 21% had a risk of SEU device malfunction during the course of therapy. None of the devices that received a high cumulative dose suffered any observed effects. These limited data were the justification by the HRS 2017 report²² that prevented them from recommending a cumulative dose threshold or monitoring strategy for high cumulative doses. In an *ex vivo* setting, four studies evaluated direct irradiation of CIEDs and reported that 6% of

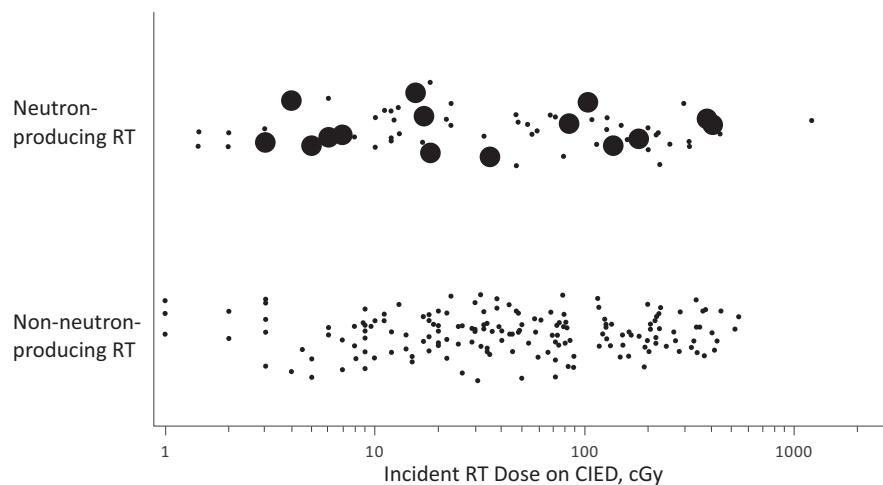


FIG. 4. Incident RT dose received by the CIED, grouped by the neutron-producing capability of the RT. Neutron-producing RT included 15-MV and 18-MV photon beams; non-neutron-producing RT included 6 MV, 10 MV, Co-60, and electron beams. Large dots identify courses in which a SEU took place. Note that dose is plotted on a logarithmic axis. Reproduced from Grant et al.⁵⁷

devices malfunctioned at a dose ≤ 5 Gy with 32% malfunctioning at a dose ≤ 50 Gy.^{6,47–49} At high CIED doses, particularly above 5 Gy, the risk of device malfunction is apparent and comparable to the risk associated with neutron-producing therapies. Therefore, it is reasonable that in cases of high cumulative dose, the CIED should be monitored in a comparable manner as in cases of neutron-producing therapy.

In the study by Grant *et al.*,⁵⁷ there were also 3 noise events observed out of the 249 courses of radiotherapy which occurred in 2 out of 215 patients. All of these events were observed with less than 0.5 Gy delivered to the device and attributed to dose-rate effects.

Use of secondary neutron-producing radiation is one of the more important considerations when categorizing risk to the device. Given the very high rate of failures in neutron-producing beams, patients treated with any neutron-producing beams should be considered as High-Risk. As for cumulative dose, there are limited data (see Tables III and IV) that support modification of the 2 Gy dose threshold originally proposed by the AAPM TG-34¹ to define risk categories. Therefore, we have also adopted this dose level for Low-Risk patients, unless the device vendor recommends a higher dose threshold that should then be followed. While modern technology reprogrammable CIEDs that incorporate advanced CMOS circuitry have reported an increase in radiation sensitivity,^{7,46,52} other investigators argue against the modern CIEDs' increased sensitivity to radiation.⁵⁴ There is currently no definitive evidence that new technology CIEDs are more or less sensitive to radiation than the older bipolar semiconductor technology ones⁵⁴ or that ICDs are more or less sensitive to radiation than ICPs.⁴³ Only a minority of the patients are pacing dependent. It then follows that only a minimum level of monitoring should be provided for the majority of patients.

There was not consensus among the task group members to either adapt the treatment, revise the position the CIED, or have ECG-monitoring for all patients who were expected to receive CIED doses of more than 2 Gy. Such measures would only be warranted for patients receiving a higher CIED dose. The HRS 2017 expert consensus report²² has a very useful discussion on device repositioning, highlighting the important risk associated with moving the device, ultimately recommending against moving the device for Low-Risk scenarios (i.e., cumulative doses below 5 Gy). Thus, a second upper dose threshold of 5 Gy is introduced by this report, which would only apply to a small subset of patients, above which more intensive monitoring is warranted. These dual thresholds make the guideline easier to implement and better aligned with clinical practice. The dose threshold of 5 Gy²² is more stringent than the 10 Gy threshold recommended by the new Dutch and Italian practice guidelines.^{159,160} This threshold was chosen, because the number of patients that will fall in the category of 5 Gy or higher was deemed manageable (see Table VI). Additionally, there are very few reports of CIED malfunctions at doses less than 5 Gy (see Tables III and IV). Some vendors (e.g., Medtronic¹⁶¹) recommend dose threshold of 5 Gy to their devices

already.¹⁵⁹ In addition, the introduction of our 2–5 Gy dose level does not duplicate the 5 Gy value discussed in the 2017 HRS expert consensus report.²² We explicitly recommend determining the dose delivered to the device as well as a management strategy for both device dependent and independent patients (see next section). Another reason for introducing the intermediate dose level is that there is limited data available from only a finite number of vendors that “allow” 5 Gy to the CIED. There are vendors that recommend 3–5 Gy dose thresholds, with others still recommending < 2 Gy (e.g., Biotronik). If the cumulative dose is estimated to be 5 Gy or more, adaptation of the treatment plan can be considered. Even at these high doses, the risk and consequence of device failure are likely smaller than the risk from suboptimal radiotherapy.

8. PATIENT MANAGEMENT AND RECOMMENDATIONS

Key aspects of the patient management workflow are presented in Fig. 5 for consideration and guidance.

8.A. Staff and department requirements

Prior to treating patients with CIEDs, the RT department should develop a treatment management plan in cooperation with the cardiology department or cardiologist's office. A treatment management plan may involve numerous people in different capacities, with clear role definitions and communication pathways. A sample workflow, including the suggested roles and responsibilities of each individual, is provided in Fig. 6. At least one radiation oncologist, one qualified MP, and one nurse knowledgeable on the function of CIEDs need to be involved to ensure the correct and safe management of patients about to undergo RT. Assistance from a cardiologist or CIED technician is necessary to provide ad hoc consultation. Radiation therapists should receive specialty training for the management of CIED patients from the qualified MP. The RT department should consider opportunities to have appropriate personnel available for monitoring these patients. The institution should develop specific guidelines for the management of radiotherapy patients with a CIED as well as be able to recognize and assist with CIED-related problems as they arise. The RT department is responsible for training the therapists as well as ensuring the availability of specialty equipment (Table VII). At a minimum, the training should include understanding the purpose of the device, what visual and audio monitoring is required, what typical problems a patient might exhibit during treatment, and who to notify if the patient exhibits any of these problems. When an ICD patient is scheduled to undergo RT, a device expert from cardiology or the device clinic should be consulted as to whether switching the ICD anti-tachycardia therapy OFF is appropriate. This can be accomplished with a heavy magnet or by a properly trained device technician who can program this function OFF and ON at each fraction. A standalone RT center without a cardiology department should consider coordinating with the device vendor to have a technical

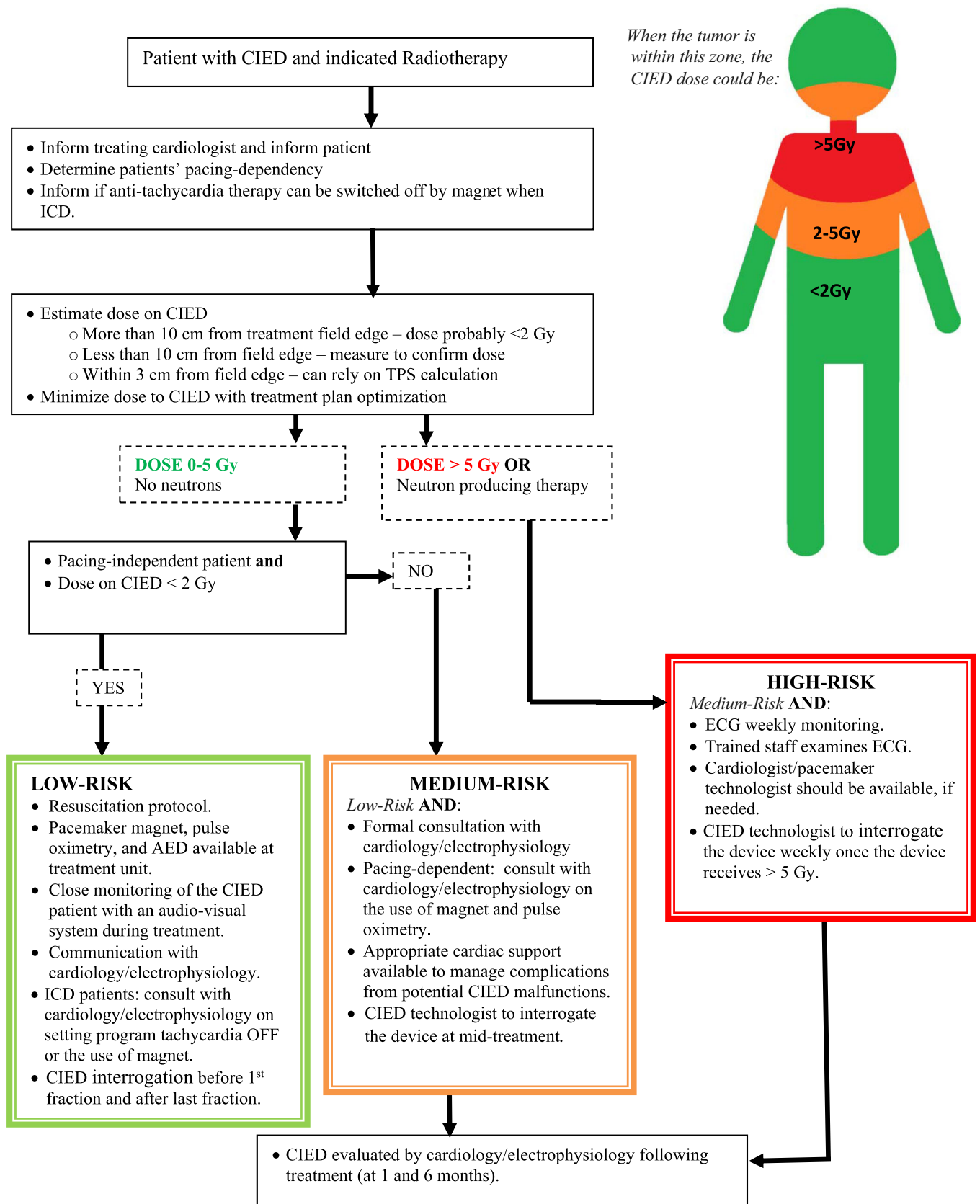


Fig. 5. Flowchart or recommended guidelines, definition of patient Risk Categories (adapted and modified from Hurkmans et al.¹⁵⁹).

representative available at the time of treatment. A referral to a cardiology clinic might be warranted in selected cases if reprogramming of the device is preferred.

It is imperative to identify patients with CIEDs as early in their RT treatment process as possible. To identify these patients, clinics should ensure that all patients that may undergo RT be asked during their initial consultation whether they have

any implanted electronic devices. In addition, clinics should institute written policies for handling such patients, including consultation with the cardiology department or cardiology care provider to obtain information on the device and determine the patient's pacing dependency. These policies should include the necessary workflow for patients, clearly indicate who is responsible for each step of the process, and be periodically reviewed

Management of Patients with CIED Suggested Medical Staff Responsibilities

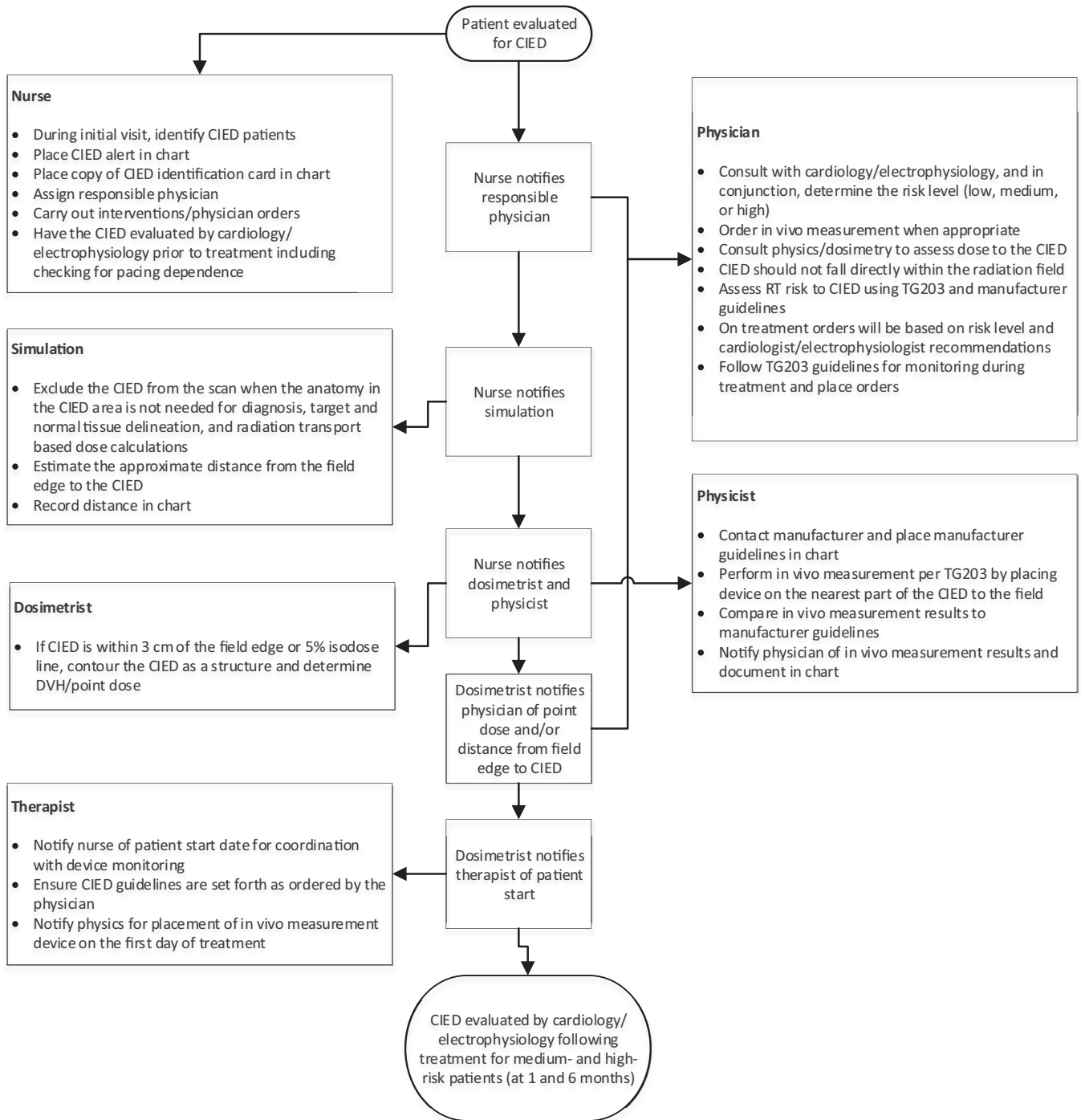


Fig. 6. Flowchart of responsibilities for management of patients with CIEDs.

TABLE VII. Staff and departmental requirements.

	Low Risk (<2 Gy)	Medium Risk (2–5 Gy)	High Risk (>5 Gy or neutrons)
Department	<ul style="list-style-type: none"> Resuscitation protocol. Pacemaker magnet, pulse oximetry, and AED available at treatment unit. Close monitoring of the CIED patient with an audio-visual system during treatment. Communication with cardiology/electrophysiology ICD patients: consult with cardiology/electrophysiology on setting program tachycardia OFF or the use of magnet. 	<p><i>Low-Risk</i> requirements AND</p> <ul style="list-style-type: none"> Formal consultation with cardiology/electrophysiology. Pacing dependent: consult with cardiology/electrophysiology on the use of magnet and pulse oximetry. Appropriate cardiac support available to manage complications from potential CIED malfunctions. 	<p><i>Medium-Risk</i> requirements AND</p> <ul style="list-style-type: none"> ECG monitoring weekly.
Staff	<ul style="list-style-type: none"> CIED interrogation before the first and after the last treatment fractions. Radiation oncologist and MP available with sufficient knowledge in the management of patients with a CIED. Radiation therapists/technologists should be experienced in the management of CIED patients receiving radiation treatment. 	<p><i>Low-Risk</i> requirements AND</p> <ul style="list-style-type: none"> CIED technologist to interrogate the device at mid-treatment. 	<p><i>Medium-Risk</i> requirements AND</p> <ul style="list-style-type: none"> Trained staff examines ECG. Cardiologist/pacemaker technologist should be available, if needed. CIED technologist to interrogate the device weekly once the device receives >5 Gy.

MP: Medical Physicist.

The use of a magnet over an ICD will temporarily inhibit defibrillation therapy while it is applied. Prior to its use cardiology/electrophysiology should be consulted. Cardiology may require monitoring the patient during treatment in case defibrillation is required.

Since the use of a magnet causes the pacemaker to pace asynchronously, cardiology/electrophysiology should be consulted. Note that the magnet will cause the ICD to ignore any sensed activity and is therefore asynchronous to any intrinsic patient heart rhythm.

and updated as new information concerning the CIEDs become available. An example workflow diagram and example checklist is provided in Fig. 5 and Table VIII, respectively, for managing patients with CIEDs. It is prudent for a facility to include a section regarding potential malfunction of CIEDs due to radiation in their patient consent form.

Once patients are identified as having a CIED, their baseline cardiac function, CIED function, and battery life expectancy should be evaluated. It is advised to schedule a device interrogation with the cardiology department prior to the patient's first treatment, and preferably, prior to their treatment planning simulation if such a check has not been performed within the preceding 3 months.^{7,159} During the patient's cardiac consultation, the following information should be documented: CIED make, model, whether the device contains active leads, date of implantation, patient's device dependency, position of the device, purpose for the device, patient-specific device settings, and what intervention the device should deliver.¹⁶² The decision on whether a magnet should be used over the device during irradiation should also be considered in consultation with the cardiology department and be documented.

8.B. Measures before treatment

Prior to simulation, an MP should be consulted to evaluate the possible effects of RT on the CIED. This evaluation should consider all possible failure mechanisms. Treatment options should be considered that minimize risk to the device while not increasing morbidity to the patient. The MP should

advise the radiation oncologist should take caution in selecting the imaging modality, imaging aperture size needed, as well as the beam modality, beam energy, beam dose-rate, and other treatment planning parameters for the particular patient.

The patient risk category needs to be known as soon as possible in the RT process (Table VI) as it will determine what monitoring is appropriate. Full categorization of the patient should be discussed before simulation, and should be confirmed before the first fraction. Cumulative dose to the CIED can be estimated in advance numerically (e.g., TG-158¹³²), but measurements should occur before the first fraction. It is important to realize that the accuracy of the calculation or measurement only needs to be sufficient to determine in which risk category the patient will fall. If unknown, conservative estimates should be used and the patient should be categorized in the highest risk category that might be applicable for that case.

The manufacturer should be consulted when establishing the dose and dose-rate tolerance of the CIED if possible. The recommended dose thresholds in this report are intended to provide realistic management options, especially if manufacturer thresholds are unreasonable or non-existent. If the manufacturer states a 0 Gy limit, we recommend using the guidelines in this report. If the manufacturer specifies a dose tolerance above 2 Gy, the manufacturer tolerance can be used. The manufacturer should make available any available information about radiation and management of cardiac patients. Solan et al.,⁵ have compiled a table of information regarding recommendations from primary manufacturers, for the management of patients with CIEDs during RT.

TABLE VIII. RT patient management check list.

Patient Information _____		
Date: _____		
1. Initial Consultation		
a. CIED alert added to patient’s chart	_____	
b. Copy of CIED card made and filed in patient’s chart	_____	
c. Appointment with Cardiac Electrophysiology (EP) scheduled if needed	_____	
d. Determine from cardiologist whether magnet is required	_____	
2. Simulation stage		
a. Patient was evaluated to verify dependence on device	_____	
b. Verify CIED alert added to patient’s chart	_____	
c. Verify treatment planning directive completed by physician	_____	
d. Note added to planning directive to only use photons ≤ 10 MV and avoid physical wedges where possible	_____	
e. Contact vendor for dose threshold recommendations	_____	
3. Planning stage		
a. Verify only ≤ 10 MV photons used for treatment	_____	
b. Estimate dose/fraction and cumulative dose	_____	
c. Verify proximity of treatment fields to device	_____	
i. If edge of field > 10 cm, then no further action necessary.		
ii. If edge of field < 10 cm, then continue with checklist.		
d. If necessary, add note to patient’s chart to place <i>in vivo</i> dosimeter on fraction #1 _____		
e. Verify/adjust imaging fields do not irradiate device.	_____	
i. If device is in imaging field, use kV imaging where possible.		
ii. If fields adjusted, add note in chart to indicate appropriate field size for imaging.		
4. First day of treatment delivery		
a. Place <i>in vivo</i> dosimeter on CIED at closest approach to treatment field area _____		
b. Verify imaging field does not irradiate CIED	_____	
c. Read dosimeter and generate summary of reading for physician	_____	
5. Dose to CIED		
<2 Gy (Low-Risk)	2-5 Gy (Medium-Risk)	>5 Gy or neutrons (High-Risk)
<ul style="list-style-type: none"> • Resuscitation protocol. • Pacemaker magnet, pulse oximetry, and AED available at treatment unit. • Close monitoring of the CIED patient with an audio-visual system during treatment. • Communication with cardiology/electrophysiology • ICD patients: consult with cardiology/electrophysiology on setting program tachycardia OFF or the use of magnet. • CIED interrogation before 1st fraction and after last fraction. 	<p><i>Low-Risk</i> requirements <i>AND</i></p> <ul style="list-style-type: none"> • Formal consultation with cardiology/electrophysiology. • Pacing-dependent: consult with cardiology/electrophysiology on the use of magnet and pulse oximetry. • Appropriate cardiac support available to manage complications from potential CIED malfunctions. • CIED technologist to interrogate the device at mid-treatment. 	<p><i>Medium-Risk</i> requirements <i>AND</i></p> <ul style="list-style-type: none"> • ECG weekly monitoring. • Trained staff examines ECG. • Cardiologist/pacemaker technologist should be available, if needed. • CIED technologist to interrogate the device weekly once the device receives > 5 Gy.

The radiation oncologist should consult with and inform the treating cardiologist about the indications for RT and, determine if the patient is pacing dependent or not. The radiation oncologist should inform the patient about the small risks involved and request the patient to report all cardiologic symptoms encountered during his/her course of RT.

8.C. Simulation

Brief CT examinations have been found to be safe for patients with CIEDs. The study by Hussein *et al.*⁷⁴ showed no strong evidence of clinical significant risks associated with direct CT irradiation of CIEDs. However, precautions may need to be taken for scans that will directly irradiate the device for longer than 3 s (e.g., 4DCT scans or perfusion imaging). For dynamic scans appropriate precautions may include avoiding the CIED during the CT examination or turning off the device for nondependent CIED patients when possible. Therefore, we recommend the following:

1. To minimize risk, direct CT irradiation of CIEDs should be avoided when readily possible (i.e., it should be excluded from the scan extent when the anatomy in that area is not necessary for diagnosis, target, and normal tissue delineation, radiation transport, etc.). Technologists may want to verify the location of the device with low-dose CT localization images prior to selecting the limits of the full length scan.^{15,71}
2. CT imaging with techniques that involve helical scan with pitch >1 are preferred (to prevent long periods of direct irradiation of the device).
3. If it is not possible to avoid prolonged (>3 s) direct irradiation of the device, the simulation team should carefully observe the patient for possible transient effects of the device.
4. With the introduction of magnetic resonance (MR) simulators in RT departments and the availability of MR conditional and compatible cardiac devices, such as the Medtronic Revo MRI SureScan pacing system, it is imperative to verify the CIED compatibility prior to simulating the patient. In particular, one should contact the device manufacturer to ensure the device compatibility with the magnetic field strength used during the MR simulation for planning.^{163,164} The HRS 2017 expert consensus report,²² which focuses on CIED management in MRI environments, provides many detailed suggestions that support and supplement these comments.

8.D. Treatment planning

Cardiac implantable electronic devices are composed of, and can be contoured into, many different sections.¹⁶⁵ The electronically sensitive component of the device is the body. Dosimetric assessment should be based on the maximum

dose to the part of the CIED body closest to the radiation field. Absorbed dose to the pacemaker should be evaluated by an MP and documented.^{2,6,165}

The CIED should not be placed in the direct radiation field if possible.^{1,6,165} If placement within the field is unavoidable, the physicist, radiation oncologist, and the cardiology department should engage in a consultation. The patient should be associated with the High-Risk category. However, the quality of the treatment plan should not generally be compromised for the sake of sparing the device (i.e., to minimize the relatively small risk of malfunction), because in almost all cases controlling the disease will be more important than reducing the comparatively low risk of device failure. The ultimate justification and decision may depend on the purpose of the treatment (whether curative or palliative). Regardless, the dose and risk to the device can often be minimized through appropriate treatment planning strategies, such as the use of an appropriate beam energy, gantry angles, and modality.^{2,8,166} The use of non-coplanar beams,¹⁶⁶ electron beams,⁷ and specific targeting of the tumor (e.g., using partial breast irradiation instead of whole breast irradiation)¹¹⁹ have all been used to minimize dose to the CIED. For machine-specific treatment modalities, like Cyberknife delivery, the advantage of selectively blocked entry and exit of the beams through the device areas can be employed. Consideration should be given to the possibility of repositioning (revise) the device while leads are left in place. This may be deemed an appropriate course of action, particularly if the patient has a low cardiac output and is pace dependent. However, it is not generally recommended because the potential complications, such as infections to the patient,^{159,167} are typically more serious than the possible risk of a device malfunction. Temporary explanation may also be an option made available by the cardiologist. The 2017 HRS expert consensus report states explicitly that moving the device is inappropriate if the device receives less than 5 Gy.²² If the device is within a primary field, multiple treatment beams and/or intensity modulation segments can be utilized to block the device generator¹⁶⁸ using the multileaf collimator.⁶⁸ Although the target will not be completely covered in each segment or in the field of each beam angle, this approach is intended to minimize the dose to the CIED while covering the target within other segments or angles.

Treatment planning systems are optimized for the estimation of dose to patients. To resolve high-Z components, the Hounsfield unit (HU) calibration can be enabled with an extended range HU calibration curve.¹⁶⁹ The extended HU range should be used for in-field or near-field dosimetry. For out-of-field dosimetry, it is recommended to calculate the dose from the TPS using the normal HU range of $-1,000$ to $+1,000$ (e.g., air-to-bone), as the complexities of medium specification (D_w vs. D_m) and dose escalation from low-energy scattered x-rays have not been well documented. As treatment planning system accuracy becomes unacceptably poor, even for this type of assessment beyond 3 cm from the field edge, they should not be used to assess dose beyond this distance.¹³⁷

To keep the dose to the device as low as possible, it is advisable to also keep it out of portal images or the CBCT range, if clinically reasonable.

Placing lead shielding over the device to decrease the scatter radiation (mostly head scatter) to it has been reported in literature.²² Lead shielding on the patient would not shield internally scattered radiation, nor would it meaningfully attenuate the photons leaking through the accelerator head (only a thin piece of lead could be placed on a patient). Lead shielding does reduce the superficial dose associated with electron emanating from the accelerator head. These electrons produce an elevated superficial dose (from the patient's surface to a depth of the photon beam d_{max}). The lead shielding would block these electrons, thereby reducing the superficial dose. However, this shielding is only relevant for beams that are incident on the shielded surface of the patient (i.e., an anterior shield would have no impact on a posterior or even a lateral beam). As such, for multifield treatments, the impact of such shielding is minimal and would rarely be worth applying. Also of note, as the dose is elevated only down to d_{max} , 1–1.5 cm of bolus would shield equally as well as a piece of lead. With bolus material lighter in weight than lead, a bolus would likely be better tolerated better by the patient.

Based on the published research indicating CIED susceptibility to damage and interference under various radiations and energies, the following are recommended:

1. Determine if the patient had prior irradiation proximal to the device area.
2. Nominal x-ray energies lower than (or equal to) 10 MV should be used to avoid neutron production.^{55,56} If high photon energies (>10 MV) cannot be avoided, then the patient should be managed within the High-Risk category.
3. Irradiation with proton or neutron beams should be avoided to avoid neutron production. If used, the patient should be managed within the High-Risk category.
4. Lower dose-rates are preferred (see Section 4.C).
5. Cumulative dose should be kept at <5 Gy level for CIEDs (i.e., Low- to Medium-Risk categories), when possible.
6. The recommended dose thresholds of 2 and 5 Gy in this report are intended to be practical thresholds, particularly when manufacturers provide unreasonable thresholds. If the manufacturer states a 0 Gy limit, for example, we recommend using the guidelines in this report. If the manufacturer specifies a dose tolerance above 2 Gy, that manufacturer tolerance can be used.
7. Treatment planning should include selection of the appropriate beam angles to increase the distance and shielding of the CIED.⁴⁶
8. Whenever feasible, the generator for the device should be kept at least 5 cm from the collimated field edge (including imaging fields) to limit the dose to the device.⁴⁶

9. The use of external lead shielding is not recommended for treatment.

Prior to implementing the treatment plan, it is strongly recommended that a thorough review of the techniques used in planning process, the settings of the accelerator (e.g., MU/min rate), and the calculated doses to target structures and the implantable device, be conducted by the MP. Where necessary, out-of-field dosimetry should be estimated and/or measured for further consideration.

8.E. Measures during treatment

The main points of managing a patient with CIED during RT treatment are discussed below.

1. If the CIED is more than 10 cm from the edge of the radiation treatment area, *in vivo* dosimetry is not necessary to estimate the cumulative dose to the device (which will be less than 2 Gy) unless noncoplanar beams are used or there is some other condition that could unexpectedly elevate the dose to the CIED.
2. If the CIED generator is between 3 and 10 cm from edge of radiation treatment area, an *in vivo* dosimeter should be placed over the device and covered with bolus (typically ≥ 0.5 cm) to measure dose from the first treatment fraction. From the measurement, the estimated cumulative dose to the CIED should be calculated and presented to the radiation oncologist. If the cumulative dose exceeds 2 Gy, treatment planning modifications can be considered or the patient should be managed according to the Medium-Risk category. If the dose is >5 Gy, the patient should be managed under the High-Risk category.
3. If the nearest edge of the CIED generator is closer than 3 cm from edge of radiation treatment area (or within the 5% isodose line), the treatment planning system should be used to estimate the maximum dose to the CIED. If the cumulative dose exceeds 2 Gy, treatment planning modifications can be considered or the patient should be managed according to the Medium-Risk category. If the dose is >5 Gy, the patient should be managed under the High-Risk category.
4. The patient, their family, and personnel working with patient should be asked (by the physician or nurse) to report any transient or prolonged cardiac symptoms.¹⁶⁵
5. For patients with ICDs, consult with cardiology staff on the need to deactivate antitachycardia therapy temporarily during treatment sessions. Deactivation can be accomplished by placing a magnet over the ICD to inhibit tachycardia therapy, or through programming to inhibit therapy. If the ICD is programmed to inhibit, then therapy must be re-enabled following each session. A magnet will only inhibit therapy while it is in place.^{10,46,159}
6. For an ICP, the magnet causes the device to pace at a constant rate, where it cannot be affected by the radiation conditions.

7. If the device is deactivated, careful patient and heart rhythm monitoring is needed. If an intracardiac electrogram does not show aberrations or morphology that would trigger antitachycardia therapy during the first fraction, then it may be concluded that the risk of an inappropriate response to delivered therapy in subsequent fractions is minimal as long as the therapy does not change. In this case, refraining from deactivating the antitachycardia function during subsequent fractions may be considered. Careful monitoring of the device by a trained staff member or the vendor representative is recommended.¹⁵⁹

Once RT begins, patient monitoring and device interrogation should be conducted according to the patient risk category described below. Interrogation can be performed by interfacing the device with appropriate heart rhythm equipment. This can be performed by trained personnel in a physician's office, over the phone, or with self-check devices operated by the patient or a family member.^{10,162} The essential information obtained during interrogation is the battery life, device status, and if and when the device was activated since last interrogation.¹⁶² The reader is also referred to the 2017 HRS expert consensus report²² for further information on device interrogation.

8.E.1. Low-Risk management

Patients should be carefully visually and audibly monitored during each fraction. For some patients with a CIED, the cardiologist may recommend using a magnet over the device which will cause an ICP to pace at a constant rate, but will turn off an ICD. A CIED should be interrogated by a trained professional before the first fraction to establish a baseline, as well as at the completion of RT treatment.

8.E.2. Medium-risk management

Patients should be visually and audibly monitored during each fraction. A crash cart with external defibrillator should be at hand during all sessions. A person appropriately trained should be available within 10 min to help the patient in the event of a CIED malfunction. If the patient is device dependent, a cardiac specialist should be notified and be on-call for all treatment fractions (available within 10 min) to address an emergent cardiac episode that may arise.^{46,159,165} A CIED should be interrogated before the first fraction for a baseline and then at mid-treatment and at the completion of the course of RT by a trained professional.¹⁵⁹

8.E.3. High-risk management

Patient monitoring identically as for the Medium-Risk management case, plus the CIED should be interrogated after each weekly treatment.¹⁶⁵ ECG monitoring should be conducted weekly, with the device checked within 24 h of the treatment by a trained professional. When a patient is at

High-Risk, because of cumulative dose (dose >5 Gy), weekly monitoring is recommended only after the device has received 5 Gy (i.e., weekly monitoring need only begin once the device receives 5 Gy). High-Risk cases associated with neutron production are at risk for all fractions and therefore High-Risk monitoring is necessary from the first fraction onward.

Depending on the risk categories of patient management, attention should also be paid to the following during and after the course of treatment:

1. If a CIED malfunction is detected during the course of RT, appropriate steps need to be taken. The patient, treating radiation oncologist, cardiologist, and responsible MP should be notified. If possible, the malfunction should be resolved (e.g., having a trained professional reprogram the device). Depending on the severity of the malfunction, it must be decided how the treatment should continue and if extra monitoring is warranted, while considering the patient's pacing dependency and number of treatment fractions remaining.
2. For Medium and High-Risk categories at the completion of RT, the device should be evaluated by a trained cardiology professional to determine whether it may need to be reprogrammed or replaced. The patient should continue to be monitored following RT at 1 and 6 months after the last RT fraction to assess possible late radiation-induced effects such as device malfunctions, functional changes, and increased sensitivity to EMI.

When treating a patient with a CIED, emergency response equipment should be readily available in case medical intervention is required (see Table VII). At a minimum, for Medium- and High-Risk category patients, this equipment should include:^{6,46,165}

1. Crash cart – including CPR devices
2. Cardiac monitoring device, that is, ECG
3. Pacemaker magnet, pulse oximetry, and automated external defibrillator
4. Temporary transcutaneous pacing with staff trained in its use.

This equipment should be maintained by either the department of radiation oncology or cardiology. If the department or clinic does not have a crash cart and/or an Advanced Cardiac Life support-trained staff member, the clinic should have an emergency response plan in place. Following the requirements in Table VII, besides the departmental equipment requirements, the necessary staffing requirements should also be met. This includes having both a radiation oncologist and an MP with sufficient technical knowledge involved in the dose management of a CIED. If a Medium or High-Risk category patient is treated, a trained cardiology professional should be available within 10 min.

For a patient with CIED that needs RT in an emergency setting, the risk from disease complications far exceeds the potential risk to CIED from RT. The staff should document the location of the device via photos and, in the case the device was in close proximity to the treatment field, to ensure the device was contained within the CT scan so that dose to the device is reconstructed. If the device is not in field, the patient should be able to receive a few fractions of treatment without nearing the dose thresholds and associated risk categories recommended in this report. A more detailed treatment and management plan should be produced using the recommendations in this report and in consultation with the cardiologist following the initial treatment.

8.F. Documentation and record keeping

During weekly chart rounds meetings, it should be known and announced whether a patient has a CIED. It should already be written in the patient's medical file. In case this is not known prior to consultation, the patient should be asked during the first visit to the RT facility. The patient (or patient's legal representative) consent should be obtained in which that person is educated and notified about the potential adverse effects of RT on CIEDs and that an ICD might be deactivated during RT.^{19,170}

A copy of the patient's device card should be obtained and the device manufacturer should be contacted to discuss the radiation-related issues of that device. Results of the first device interrogation should be made available to the radiation oncologist and incorporated in the patient's file. In addition, it should also be noted if the patient is pacing dependent or not, whether a magnet should be used to turn off antitachycardia therapy, and an estimate of the cumulative dose to the device. The preliminary decision to opt for device revision/explant or adaptation the RT plan, should be known before proceeding with radiation treatment delivery. This information should also be made available through the cardiology department.

It is the responsibility of the MP to calculate and measure the CIED dose for the treatment plan and note this information in the medical record. All *in vivo* or phantom measurements performed need to be included in the patient's file. The management strategy selected for the patient should be documented.

After RT, documentation that the cardiologist was advised to interrogate the device at 1 and 6 month post-RT to verify its functionality should be included in the patient's medical records.

9. MANAGEMENT OF PATIENTS WITH OTHER IMPLANTABLE DEVICES

In addition to CIEDs, there are a number of other implantable medical devices that may be seen in patients receiving RT. For example, implantable loop monitors (ILMs) are not CIEDs, but are used for cardiac diagnostics and cardiac resynchronization. These are USB-sized devices implanted under the skin to provide a continuous ECG recording of the patient's heart rhythm. Other devices include cochlear

implants,¹⁷¹ epidural pumps, nerve stimulators, and insulin pumps. There are already a handful of case reports documenting radiation tolerance and failure. For example, cochlear implants have been shown to tolerate doses up to 80 Gy.^{172–175} A case report showed a Programmable Intrathecal (IT) drug delivery device receiving a dose of approximately 10 Gy from direct irradiation that did not experience any adverse effects.¹⁷⁶ However, there is also a case report of failure of an epidural pain pump that received 28.5 Gy.¹⁷⁷

A recent study of radiation effects (6 and 18 MV beams) on a specific manufacturer's vagus nerve stimulators (VNS) models revealed that while some models exhibited no malfunctions, others showed an apparent loss of stimulation output immediately after irradiation. The effects were dependent on beam energy and location of the device relative to the irradiation field. Cumulative dose effects were also noted (49–58 Gy of tolerance dose for some models).¹⁷⁸

However, in general, the published studies are limited in assisting with clinical management of any of these specific devices. To manage such a case, we encourage the radiation oncologist to communicate with the appropriate specialty clinic that manages the implanted device.

In general, for implanted electronic devices, specific guidance from the device manufacturer should be obtained, if available, during the planning phase of treatment. The treating physician must balance coverage of the target volume with dose delivered to the device. It is recommended that direct irradiation of the device be avoided whenever possible. The device should be tested before the start of treatment and periodically throughout treatment. Other steps may be possible as well, for example, for VNS devices, it may be possible for the generator to be programmed "off" prior to treatment, and can then be reprogrammed by the electrophysiologist after the treatment to resume stimulation to the patient's settings. Whatever the device may be, if it does fail, the dose delivered and treatment conditions (energy, dose-rate, etc.) should be documented. This information should be provided to the manufacturer. It should also be presented to the community at large (e.g., a case report), so that a status review of affects published in literature can be made possible at a later date.

In conclusion, all implantable medical devices are based on CMOS technology and have been since the late 1980s. The majority of newer medical devices entering the market are based on improved CMOS circuitry which are believed to be more radiation resistant. As manufacturers integrate this newer CMOS technology into their products, it is expected that their radiation tolerance will improve. However, it would be prudent for the MP not to simply accept that they are more radiation tolerant, but consult with the manufacturer regarding their recommended radiation dose tolerance and consider implementing the guidelines discussed in this report.

10. SUMMARY AND CONCLUSIONS

Management of RT patients with a CIED is essential. Safe medical practice requires that the risk to patients be reduced as much as possible. This includes minimizing the risk

associated with CIED malfunctions. It is to this end that our task group has devised recommendations for the management of patients from simulation to postirradiation follow-up with a special emphasis on reducing potential damage to CIEDs. It is essential that this risk of CIED malfunction be weighed against other medical risks the patient may be subjected to. Such risks may include infection associated with moving/explanting the device, or even the risk of treatment failure associated with compromising the radiotherapy treatment. In principle, it is unreasonable to compromise the quality of radiotherapy and increase the risk of recurrence for the sake of reducing the risk to a CIED (which is comparatively low). Rather, the risk to the patient should be minimized by ensuring they have optimal care, including (a) minimizing risk to the CIED to the extent reasonable, and (b) appropriate monitoring of the CIED, so that device malfunctions are identified and can be resolved. This section summarizes some of the important recommendations of the task group. For further details on each recommendation, the relevant section is listed in the parentheses at the end of each bullet.

1. Management of patients should be based on device risk levels shown in Table VI (Section 7).
2. CT irradiation of CIED for longer than 3 s should be avoided, whenever possible (Section 8.C).
3. CIED compatibility with MRI should be verified prior to MR simulation, and protocols for safe MRI scanning should be developed and implemented (Sections 5.A.3 and 8.C)
4. If >10 MV photon, proton, or neutron beams are used, the patient should be managed in the High-Risk category (Section 4.B).
5. Lower dose-rates are preferred (Section 4.C).
6. The generator for the device should be kept at least 5 cm from the collimated field edge if possible, including imaging fields, by selection of the appropriate beam angles that increase the distance between the field edge and the CIED (Section 8.D).
7. Perform *in vivo* dosimetry for the first fraction if the device is <10 cm from treatment area. The treatment planning system should be used in lieu of a measurement if the device is within 3 cm (laterally) of the field edge or 5% isodose line for IMRT (Sections 6.C.3 and 8.E).
8. Lead should not be used for shielding CIED during treatment (Section 8.D).
9. Cumulative dose should be kept at <5 Gy level for CIEDs (i.e., Low- to Medium-Risk categories), as much as possible or below the manufacturer's recommended dose threshold if higher (Sections 4.A. and 7).
10. Patients should be monitored with specified frequencies and techniques (Section 8.E)

The creation of a management program for RT patients with CIED is a difficult task. This task group provides a risk-based approach for patient management along with the description of many of the issues, which must be considered

before, during, and after treatment. Critical recommendations of this task group is that neutron-producing treatments be avoided, and that the cumulative dose to the CIED should be kept below 2 and 5 Gy as much as possible for pacing-dependent and pacing-independent patients, respectively. As CIEDs and RT technologies evolve, the management of patients with CIEDs should also evolve. Imaging and treatment delivery machine evolution may enable a more safe utilization of techniques when a CIED remains implanted. This task group concludes that the appropriate implementation of the recommendations provided in this report will offer clinics the needed tools to develop a safer and effective treatment management program for patients with CIEDs.

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