Critical Review

A Review and Analysis of Managing Commonly Seen Implanted Devices for Patients Undergoing Radiation Therapy

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Abstract

Purpose: This review article aims to consolidate information regarding existing and emerging implanted devices used in patients undergoing radiation therapy and to categorize levels of attention needed for each device, including which devices require monitoring throughout treatment.

Methods and Materials: Based on the collective information from scholar searches, manufacturers' technical reports, and institutional experiences in the past years, commonly present devices in patients with cancer are compiled. This work summarizes cardiac pacemaker, implanted cardiac defibrillator, hepatic pump, intrathecal pain pump, neurostimulator, shunt, loop recorder, and mediport. Three different classifications of implanted devices can be made based on the potential effect of radiation: life-dependent, nonlife-dependent but with adverse effects if overdosed, and devices without electronic circuits. Implanted devices that contain electronic circuits that would be life-dependent or have adverse effects if overdosed, include cardiac pacemakers, implanted cardiac defibrillators, programmable hepatic pumps, pain pumps, neurostimulators, and loop recorders.

Results: Dose exposure to these devices need to be calculated or measured in vivo, especially for cardiac implanted devices, and they should be minimized to assure continued healthy functioning. Treatment planning techniques should be chosen to reduce entry, exit and internal scatter dose. Lower energy photon beams should be used to decrease potential neutron contamination. Implanted devices without electronic circuits are less of a concern. If a patient is life-dependent on the implanted device, it is not recommended to treat the patient with proton therapy. **Conclusions:** This study reviewed the management of patients with commonly seen implanted devices and summarized a workflow for identifying and planning when a patient has implanted devices. Classifications of implanted devices could help clinicians make proper decisions in regard to patients with specific implanted devices. Lastly, the management of such devices in the era of the pandemic is also discussed in this review article.

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Introduction

The use of implanted devices has increased progressively in the 30 years since the first implantable cardioverter-defibrillator (ICD) was released commercially in the United States. Pacemakers and ICDs are among the top 5 most frequently implanted medical devices beside artificial hips, breast implants, and spine screws/rods/discs in the United States.¹ As the number of patients with implanted devices (IDs) increases, radiation therapy clinics are seeing proportionally more patients with IDs, including those who have concurrent chemoradiation.^{2,3} Devices most commonly encountered in patients with cancer include cardiac pacemakers, ICDs, intrahepatic pumps, pain pumps, neurostimulators, shunts, loop recorders, and mediports.⁴⁻¹³

Clinicians typically take counsel from the patient's cardiologist, electrophysiologist, or manufacturer of the ID before radiation treatment (RT) to create strategies unique to each patient for instrument monitoring and validating appropriate device functions. However, the effects of therapeutic radiation on IDs are often difficult to predict. A variety of factors may influence the effect of radiation therapy on ID, including ID type, proximity to the radiation beam, the dose being delivered to the device, energy of the radiation beam, the type of device, and delivery technique; does it function as a conduit or does it have circuitry with programing and memory (complementary metal oxide semiconductors [CMOS]).^{5,8,9} Electronic devices can be damaged by various levels of high energy ionizing radiation. It has been observed that doses from RT induce malfunctions, including abnormal changes in pulse repletion frequency when implantable electronic devices are exposed to radiation. Therefore, it is important to identify, document, and account for the expected dose exposure during the treatment planning and beam delivery processes. It is essential to approximate the expected radiation dosage to the IDs.¹⁴⁻¹⁶

Widely adopted guidelines from the 1990s, published in the British Journal of Radiology and by the American Association of Physicists in Medicine (AAPM), do not include some of the newer implanted devices in recent decades.^{16,17} The newly published AAPM TG-203 Report¹⁸ focuses mainly on the management of implantable cardiac pacemakers and defibrillators (cardiac implantable electronic devices [CIEDs]), but also provides some guidance on the management of patients with other implantable devices. Conversely, a report from the Dutch Society of Radiation therapy and Oncology¹⁹ emphasizes the patients' perspective and the practical aspects of the safe management of patients with CIEDs. The AAPM TG-203¹⁸ categorized CIEDs patients based on the CIED cumulative dose, pacing dependency and neutrons present into low, medium, and high-risk. The Dutch Society of Radiation therapy and Oncology report¹⁹ categorized CIED patients based only on the cumulative dose and patient dependency. This work assumes the adoption of such risk categorizations in practice.

Based on the searches in literature databases such as PubMed/ScienceDirect, this article represents the first addressing a variety of IDs commonly seen in patients undergoing RT, consolidating their corresponding dosimetric tolerances, and addressing adaptive management during Coronavirus disease 2019 pandemic in a single resource. This work aims to provide a general review of existing and newly emerging IDs and recommends planning considerations for each one.

Management of Commonly Seen Implanted Devices in RT Patients

We have compiled and reviewed management guidelines for IDs from different manufacturers and the range of dose tolerances of their devices. The most frequently seen IDs in patients undergoing RT are shown in Fig. 1. These include cardiac pacemakers (Medtronic, St. Jude Medical, Guidant/ Boston Scientific), ICDs (Medtronic, St. Jude Medical, Guidant/Boston Scientific), intrahepatic pumps (Johnson & Johnson, Medtronic), intrathecal pain pumps (Medtronic, Flowonix Medical), neurostimulators (Medtronic, St. Jude Medical, Guidant/Boston Scientific, LivaNova), cardiac loop recorders (Medtronic, St. Jude Medical), cerebral shunts (Aesculap, Medtronic, Sophysa), and mediports (Aesculap, AngioDynamics, Bard Medical).

Description of implanted devices

A cardiac pacemaker is usually placed in the chest or abdomen to help control abnormal heart rhythms. Some new leadless pacemakers are directly implanted into the right ventricular heart muscle. The pacemaker uses electrical pulses to prompt the heart to beat at a specified rate.^{8,9,18,19} An ICD is implantable in the subcutaneous tissues of the chest or abdomen. ICD performs cardioversion, defibrillation, and pacing of the heart, and corrects most life-threatening cardiac arrhythmias.^{8,9,18,19} Both pacemaker and defibrillator can be used in cardiac resynchronization therapy. A hepatic arterial infusion pump is a small, programmable device implanted in the abdominal cavity that is designed to deliver chemotherapy at a constant rate directly to the liver. This method allows for high doses of chemotherapy to be delivered to the liver with protection of the surrounding normal tissues. The pump is sensitive to heat, for example, the medication would flow faster if the surrounding temperature increases.²⁰ An intrathecal pump directly delivers medications into the space between the spinal cord and the protective sheath surrounding the spinal cord. Radiation could cause alarm and failure of the pump due to electronic circuit damage or battery depletion.^{4,13} An implantable neurostimulation device modulates the nervous system's activity, usually through electromagnetic approaches. Similar to CIEDs, the neurostimulator also

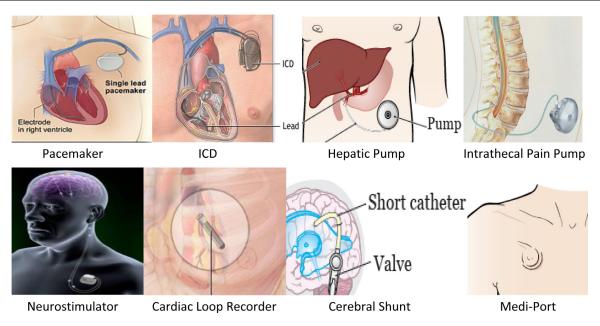


Fig. 1 Commonly seen implanted devices in Radiation Oncology. Reprinted Permissions from National Institutes of Health, ^{23,24} Memorial Sloan Kettering Cancer Center, ²⁰⁻²² Mayo Clinic, ²⁵ St. Jude Medical, ²⁶ and Dove Medical Press.²⁷

has a pulse generator component, which can be potentially damaged by radiation. $^{10\text{-}12}$ A loop recorder records and remotely reports heart rhythm continuously or, on-demand, for up to 3 years. It is a small device inserted just beneath the skin of the chest to capture the electrical signals of the heart. Alike CIEDs, the loop recorder also has CMOS electronic circuitry that could have radiation-induced effects.⁵ A cerebral shunt is commonly used to treat hydrocephalus, the swelling of the brain due to excess buildup of cerebrospinal fluid. They are catheters that redirect the fluid from the ventricles typically into the heart or abdomen where it can be absorbed.²¹ A mediport is a small, implantable reservoir that allows chemotherapy medications to be delivered through the port.²² Both cerebral shunt and mediport do not have an electronic circuitry component in them. A tubeless insulin pump is a newer device, which is programmed to cover basic insulin needs by regularly delivering small amounts of shortacting insulin or extra amounts at mealtimes as needed. We will not discuss more on this device in this article as it is attached externally to the patient; however, it is advised that patients remove these devices for radiation therapy delivery.

A leadless pacemaker serves the same function as a traditional pacemaker, but without the lead. Instead, the leadless pacemaker is transvenously placed into the myocardium at the right ventricle. The dose limit and effect stay the same as a traditional pacemaker.²⁸ The intramuscular cardiac positioning of the device makes monitoring its exposure more challenging and less likely to be repositioning. Often, as can be seen in Fig. 2 in a clinical case at the authors' institution, a leadless pacemaker placed into the right ventricle can be very close to the irradiated volume for a patient with left-breast cancer. Unlike a traditional pacemaker which can be moved to a distal location if necessary, the treatment plan has to be carefully designed to minimize doses to the leadless pacemaker. In any case, the simulation scan should include the level of the device so a dose estimation can be calculated as an in vivo measurement is impossible (Fig. 2).

Categorizing the implanted devices

Usually, IDs are identified during the initial radiation oncology consultation in the patient's self-reporting questionnaire or the nursing review. When an ID is reported, a copy of both sides of the patient's device identification card is obtained and stored in the patient's electronic medical record if available. Three different classifications of implanted devices can be made based on the effect of radiation: life-dependent, nonlife-dependent but with adverse effects if overdosed (adverse), and devices without electronic circuits (without circuits). We classify each category based on their potential malfunctions due to radiation and the effects to the patient in case of malfunctions.

Factors affecting implanted devices

Multiple studies^{18,19,29,30} report on factors determining the effect of therapeutic radiation on implanted devices. These factors include device type, proximity to radiation field, radiation energy and modality, radiation beam orientation, dose rate, cumulative dose, shielding, patient anatomy and physiology, frequency of radiation treatment, and any concurrent therapy or diagnosis. Some

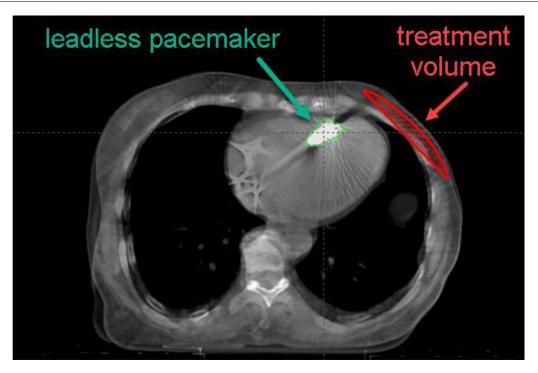


Fig. 2 A fused image of planning computed tomography and cone-beam computed tomography on the leadless pacemaker (green) implanted in the interventricular septum near the intended treatment volume (red) for a left-breast patient.

clinical studies provided clinical perspectives on the effects of ionizing radiation.^{16,17,31,32} Zaremba et al³³ reported that CIED malfunctions were seen in ~ 3% of RT courses, and typically consisted of transient software disturbances and only rarely presented permanent damage to the device. Ahmed et al³⁴ reported a case of full-dose chemoradiotherapy to lung cancer where an ICD was located within the irradiating field. As the patient was not ICD-dependent; he was treated with the ICD in its original location with a mean dose of 29.3 Gy to the device, much higher than the recommended limit. This patient successfully went through the entire RT course without experiencing or reporting cardiac symptoms.

Owing to the variability of the many factors, it is accepted that there is not a single safe radiation dosage to a given family of devices. Similar to the ALARA ("as low as reasonably achievable") principle for personnel exposure management, effort should be made to minimize dose to the IDs, through the shielding of the device if possible, or the optimal designing of the treatment plan. The absorbed dose to be received by the device should be calculated. Practically, a dose limit would still be useful. Some clinical studies provide a recommended maximum total dose of 2 Gy to the implanted device.¹⁶⁻ ^{18,33} A recent review article showed that the strongest predictive factors of CIED malfunction are higher radiation doses and higher beam energy given the concern for neutron production.³⁵ Most device manufacturers provide their own recommendations on dose tolerances depending on the device/model. The AAPM TG-203 provides

patient risk categories also based on cumulative dose (<2 Gy, 2-5 Gy, >5 Gy) to the CIED and pacing independent versus pacing dependent.¹⁸ All manufacturers recommend relocating the device generator outside the radiation field; however, relocation may not be required for devices receiving a cumulative dose <5 Gy.³⁵ Some vendors such as St. Jude Medical/Boston Scientific will not guarantee zero risk of malfunctions at any dose level.³⁵ A recent study also reported that adverse clinical events can occur in any group of risk and no dose-dependency was observed on the CIED malfunction.³⁶ Another study confirmed that lung stereotactic ablative radiation therapy is safe for CIEDs when the dose is kept <2 Gy and beam energy is <10 MV, regardless of the pacing-dependency and the CIED type.³⁷ A retrospective study found that all single-event upset malfunctions occurred in the setting of neutron production, with 21% for neutron-producing RT (ie, 15 MV or 18 MV) and 0% for non-neutron-producing RT (ie, electrons, Gamma Knife, or 6 MV).³⁸

Dose limits of implanted devices and in vivo measurement

Table 1 lists the commonly used implanted devices and their functions, categories, and recommended dose limits. Previous studies have revealed that higher energy radiation (ie, >10 MV) will cause more IDs to experience electric malfunction^{14-19,31-35,37-39}; as a result,

Implanted device	Clinical use	Susceptible component	Category	Dose limit	Historical malfunctions reported	References
Pacemaker	Control heartbeat	CMOS RAM Battery	Life-dependent	2-5 Gy	Transient damage Permanent damage EC damage Parameter reset Signal interference Battery depletion	8,9,18,19, 33,38,46
ICD	Sends electrical signals to the heart	CMOS RAM Battery	Life-dependent	0.5-2 Gy	Transient damage Permanent damage Pacing pulse change Pacing frequency change Sensing threshold change Lead impedance change Loss of telemetry capability Loss of signal/data Battery depletion	8,14,18,19, 33,38,39
Programmable hepatic pump	Gives continual chemo- therapy to the liver	EC, Battery	Adverse	10 Gy*	NA	20
Intrathecal pain pump	Gives continual pain medication to spine	EC, Battery	Adverse	28.5 Gy	EC damage Battery depletion Pump alarm	4,13
Neurostimulator	Sends electrical signals to the brain and spine	Implantable pulse generator	Adverse	5 Gy	NA	10,11,12
Loop recorder	Monitors heart rhythm	CMOS Battery	Adverse	$5 \mathrm{Gy}^{\dagger}$	NA	5,39
Mediport	Vein access point for chemotherapy, IV, etc	NA	Without circuits	NA	NA	22
Cerebral shunt	Drains excess CSF from brain	NA	Without circuits	NA	NA	21

 Table 1
 Commonly seen implanted devices and their uses, categories, dose limits, historic malfunction

Abbreviations: CMOS = complementary metal oxide semiconductors; CSF = cerebrospinal fluid; EC = electronic circuit; IV = intravenous; NA = not applicable.

* Private communication from the manufacturer, Medtronic, Minneapolis, MN, October 23, 2019.

† A conversation needed with the cardiologist on the fidelity of the information retrievable after radiation.

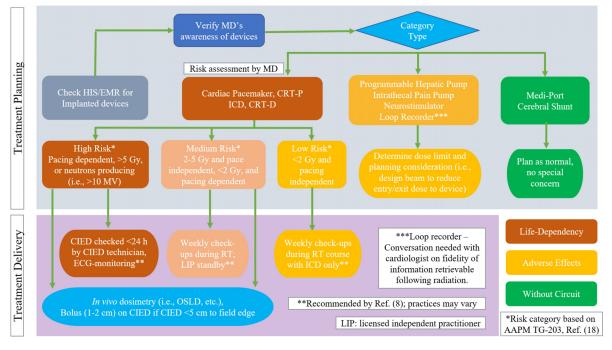


Fig. 3 A sample workflow to handle implanted devices.

devices with electronic circuits should be treated with low energy (ie, <10 MV photons) only.⁴⁰ Because both severity and risk of failure of devices from dose rate effects are mild and low,⁴¹ the AAPM TG-203 recommends a dose rate of <0.2 Gy/min as guidance. A recent study investigated the effects of x-ray dose rates of 4 to 24 Gy/min on CIED function and found that a dose rate >8 Gy/min would cause a temporary malfunction due to interference.⁴² It had been recommended that in lowrisk patients with the presence of an ICD and mediumrisk patients with CIED, a weekly device check during the RT is recommended.⁸ In high-risk patients, device evaluation within 24 hours after each fraction is needed. Given the potential device malfunction, a close collaboration among cardiologist, radiation oncologist, and physicist is necessary to minimize the risk to patients.⁸ Any in vivo dosimetry system (eg, optically stimulated luminescence dosimeter [OSLD], thermoluminescent dosimeter [TLD], diodes, etc) may be used on the first day of treatment to measure the daily or fractional dose the device receives, and calculate the cumulative dose expected over the course of treatment. The use of different in vivo dosimeters for out-of-field measurements requires knowing the detector sensitivity as a function of off-axis distance; an out-of-field calibration for the detector in use is recommended¹⁴ in addition to other considerations and requirements about out-of-field dosimetry at CIED depths.^{18,43} Depending on the spatial distance between the radiation field edges and the most proximal part of the ID, different approaches can be used to reduce radiation exposure to the IDs.

Treatment planning of patients with implanted devices

A systematic policy in identifying ID-bearing patients should be integrated with early treatment planning procedures. A possible workflow is illustrated in Fig. 3. Electronic device presence should be documented in a patient's electronic medical record or the health care information system, where dosimetrists should check for information regarding devices and act accordingly throughout treatment planning. This will help dosimetrists recognize newly emerging devices and avoid damaging them, thereby preventing adverse effects.

During the treatment planning process, implanted devices should be contoured as a structure to be optimized for a lower dose. For patient setup verification, imaging fields should be angled to minimize exposure to the devices, and if necessary, the collimator for pretreatment kV imaging should be adjusted to block the direct entrance of x-rays for the same consideration. If the device sits within 5 cm proximal to the field edge, a bolus (1-2 cm thickness) on the top of the device for the entire course of treatment minimizes scatter and leakage because the photon spectra outside the treatment fields are in the kV range.^{14,44} Chan et al reported that placement of bolus on the top of the ICD would reduce the dose to the device by 34% to 58% depending on the distance from the edge of the field.¹⁴ Treatment planning techniques such as coplanar beam arrangement can also reduce entry and exit through the device. Lower energy photon beams <10 MV should be used to eliminate neutron contamination that could reset the read-only memory state of the device.45

Patients undergoing proton therapy

Patients with CIED may be treated with proton therapy; however, the risk should be evaluated together with the patient's cardiologist before treatment start. Gomez et al reported that 23.6% of patients with CIEDs receiving proton therapy were for thoracic tumors from March 2009 to July 2012 and 20% of the patients experienced CIED resets.⁴⁵ There was also a report that CIED reset can occur despite not being detected by electrocardiogram monitoring; instead, it was uncovered by posttreatment programmer analysis.⁴⁶ Modern CIEDs have CMOS which can tolerate doses of more than 2 $Gy^{47,48}$; however, the proton machine design has an effect on the CIED due to the overall physical environment around the patient. The pencil beam scanning system snout creates a relatively strong magnetic field around the patient, which may induce CIED malfunction.¹⁷ Therefore, each patient needs to be considered individually and recognition of the patient's dependence on the CIED identified. If the patient is pacing-dependent, it is usually not recommended to treat them with proton therapy,45,46,49 especially in standalone centers with limited resources. Likewise, for the pacing independent patient, risks should be evaluated before delivering proton therapy. For low-risk patients whose accumulative dose from proton therapy plan on CIED < 2 Gy, the patient will be instructed to report any symptoms of cardiac nature. For medium-risk patients, a cardiology expert should be present during the treatment and check the CIED function before and after the treatment.⁸ High-risk patients should be monitored during every fraction and the pacemaker should be checked before and after treatment by CIED technician. The patient should be further checked by CIED technician after the proton therapy at a frequency of 1, 3, and 6 months.⁸ If possible, the dose should be measured with a phantom for the proton therapy plan, and the patient should have an in vivo measurement (eg, OSLD, TLD, diodes, etc) during the treatment.⁵⁰ In summary, because the modality has a higher risk of generating secondary neutron contamination and complex electromagnetic interference, a detailed plan should be created to include a multidisciplinary treating team, cardiologist, and CIED technician before the patient receives proton therapy. Patients with implanted cardiac loop recorders can be treated with both photon and proton therapy but the device would preferentially not be in the direct radiation beam. Loop recorders have a reported tolerance of 5 Gy before corrupting. Even with lower dose exposures, it is very possible that the arrhythmia detection will be harmed at least during the time of radiation therapy delivery. It is also possible that detection after completion of RT delivery will also be corrupted and this needs to be discussed with the patient's cardiologist.⁵

Patients with Non-CIED IDs

The management of patients with other programmable implanted devices such as hepatic pump,²⁰ intrathecal pain pump,^{4,13} and neurostimulators¹⁰⁻¹² should be comparable to that of CIED patients due to having electronic circuitry, battery, or pulse generator. Similarly, these devices carry dose limits to avoid radiation-induced failure of the device. A programmable hepatic pump has a dose tolerance being 10 Gy as per the manufacturer and the medication would flow faster when the body temperature rises.²⁰ Similarly, a programmable intrathecal pain pump might malfunction if cumulative doses were above 28.5 Gy as reported in one case.¹³ Any patient with an infusion pump undergoing radiation therapy should be alerted for possible pump's alarm sounding during treatment. Pump functionality assessment should be conducted after radiation treatment.⁴ Neurostimulator typically consists of an implantable pulse generator, electrode array, and insulating wiring connecting the electrodes to the generator. A dose limit of 5 Gy was recommended, and the pulse generator should be kept away at least 1 cm from the radiation field edge.¹⁰ All of them also require a multidisciplinary approach before radiation therapy delivery. On the other hand, mediport,²² and cerebral shunt²¹ are without electronic circuitry, and they are less of a concern in terms of dose tolerances. However, during radiation therapy care must be taken to prevent potential infection and obstruction of the devices. In addition, most implanted devices use CMOS technology to produce integrated circuits that are sensitive to radiation. Nowadays the majority of devices equipped with improved CMOS circuitry (more radioresistant) such as thin CMOS gates (<1.5 μ m), those devices would tolerate a higher cumulative dose and dose rate (ie, 10 Gy and 0.2 Gy/min).^{18,19,51,52} However, because the susceptibility of an implanted device is very dependent on the underlying integrated circuit technology, which varies among different subsystems and models, whether to go beyond the common practice guideline (2 Gy) should be personalized. Future studies can be built on the findings of existing reports and perform risk-based analysis, and thereby recommend refining workflows on clinical management of patients with such emerging devices.

Management of RT patients with implanted devices in a pandemic

There have recently been many publications on the oncologic care of patients in the setting of the new Coronavirus disease 2019 pandemic.^{53,54} The primary focus of these reports is the protection of the patients and the health care staff from possible exposure to the virus from an unrecognized carrier. In the entire network of the authors' institution,

we have implemented strategies to minimize the patient time in the department, contact between patients and staff, and to reduce the number of visits a patient will need to make into the cancer clinic. There are certain patient care interventions that require extended time with the patient or may require a physician or medical physics staff presence in the patient care environment. One such situation is the management of a patient with a CIED. As required, a conversation needs to be had with the patient's electrophysiologist or cardiologist to determine whether the device has been interrogated in the past 6 months and is in working order as well as the degree of the patient's dependence on the device. This will help guide the indications for midtreatment device interrogation and safe patient handling.^{55,56} Similarly, every effort should be made to design RT fields that avoid the IDs and a plan which uses <10 MV photons to minimize the risk of any neutron production and scatter.^{38-40,57}

The AAPM TG-203 guideline¹⁸ helps reduce the duration of direct patient interaction by offering a classification of low-, medium-, and high-risk patients based primarily on the distance of the treatment field from the device, as well as energy used and pacing dependency. This strategy was well used during the pandemic when attempting to shorten time with patients and to only take actual dose measurements with OSLDs or TLDs on the patient for situations in which the radiation field edge was in close proximity to the CIED. For treatment fields positioned further away from the devices, the dose to the device can be estimated by medical physicists if the site has been included in the simulation scan. As the placement of cardiac leads to monitor a patient during their first fraction requires working near the head of the patient, it is important that the patient and the health care worker both wear protective masks. We suggest in addition to these measures, that cardiac monitoring of the patient is completed remotely to the machine if possible, to minimize the crowding of health care professionals at the treatment console. One should try to use video-streaming devices to project the rhythm strip from the room to the licensed independent practitioner assigned to monitor the patient while treatment is delivered. This practice permits the practitioner to be located at some distance from the rest of the treatment team. To view the strip reliably, this also requires that the gain be increased as much as possible on the electrocardiogram display so the tracing can be accurately monitored. Post radiation treatment management remains the same with the patient returning to their electrophysiologist shortly after completing radiation to have the device retested and confirm continued proper functioning.

Conclusions

This study provides an easily accessible reference to practical dose limits for IDs for radiation oncology staff, the uses for these devices, and manufacturers were identified. The radiation dose tolerances to the devices were collected and they can differ among varying models and manufacturers. We summarized a workflow for identifying and planning when a patient has IDs included cardiac pacemaker, ICD, hepatic pump, pain pump, neurostimulator, shunt, loop recorder, and mediport. Classifications of implanted devices into 3 categories—life-dependent, nonlife-dependent but with adverse effects if overdosed, devices without electronic circuits—could help clinicians make a proper decision to a radiation therapy patient with specific implanted devices.

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