



# Management of Patients with Cardiac Implantable Electronic Devices during Radiotherapy

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## SUMMARY

In recent years, the number of cancer patients with cardiac implantable electronic devices (CIEDs) undergoing radiotherapy has been increasing with prolonged life expectancy and the aging population. Ionizing radiation, electromagnetic interference, and scattered radiation can cause permanent damages or temporary malfunctions on such devices. Appropriate management of patients with CIEDs undergoing radiotherapy is more challenging due to recent developments in radiation therapy techniques, image guidance methods, and device technology. The effects of radiation on devices depend on the model of the cardiac devices, clinical condition, and pacing dependency of the patient, cumulative dose to device and the treatment parameters such as beam energy, beam modality, total dose, dose rate, scattered radiation, radiotherapy fields, and imaging modality. A close collaboration among the radiation oncologist, medical physicist, patients' cardiologist, device technologist, radiation therapist, and nurse is crucial before, during, and after the radiotherapy sessions. Clinical guidelines and consensus of experts have been published regarding the management of patients with devices undergoing radiotherapy. We reviewed these guidelines and the literature on this issue and present recommendations for safer and more successful radiotherapy of patients with cardiac implanted electronic devices.

**Keywords:** Implantable cardiac pacemakers; implantable cardioverter-defibrillators; patient management; radiotherapy.

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## Introduction

At present, the leading cause of death globally is cardiovascular disease followed by cancer.[1] Incidences of cardiovascular diseases and cancers have increased with prolonged life expectancy and the aging population.[1,2] Recent publications have reported that the frequency of patients with cardiac implantable electronic devices (CIEDs), including implantable cardiac pacemakers (PMs) or implantable cardioverter-defibrillators (ICDs), increases with age and is higher in older (>65 years) people.[3] This indicates more cancer patients with CIEDs will require radiotherapy.[4]

Radiotherapy is one of the main treatments modality and approximately 70% of cancer patients require radiotherapy at some point during the course of their treatment.[5] However, the management of patients with CIEDs requiring radiotherapy is challenging since various malfunctions or failures have been reported with direct or indirect irradiation of PMs and ICDs.[6-9] Radiation-induced damage to the device has been observed in approximately 3% of patients with CIEDs. Even, radiotherapy at low doses may cause device failure with potentially life-threatening consequences. [10,11] In 1994, the American Association of Physicians in Medicine (AAPM) published a guideline regarding

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the management of patients with PMs undergoing radiotherapy.[12] However, the studies mentioned in the AAPM Task Group-34 encompass older PM types. In addition to advances in device technology, there have been significant developments in radiation therapy techniques and image guidance methods since then. Although various clinical guidelines or expert consensus statements have been published by several scientific associations or societies regarding the management of patients with CIEDs during radiotherapy, there are some discrepancies among them.[6,8,13-16] In 2019, a report of the AAPM TG-203 has been published.[17] TG-203 analyzed the potential failure modes of devices and presented recommendations about the management of patients with both PMs and ICDs. This report suggested close collaboration between the cardiologist, radiation oncologist, medical physicist, radiation therapist, nurse, and electrophysiologist during the treatment of the patients with CIEDs.

We reviewed these guidelines and the literature on this issue and present recommendations for safer and more successful radiotherapy of patients with cardiac implanted electronic devices.

### **Radiation Effects on CIEDs**

CIEDs 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 the treatment.[17] Recently, CIEDs technologies have changed significantly. Today, complementary metal-oxide semiconductors (CMOSs) are used in new generation modern cardiac electronic devices. Thus, devices have become smaller, less energy consuming, and safer, but are supposed to be more sensitive to ionizing radiation.[6,8,9] Radiotherapy can cause device malfunctions through ionizing radiation, electromagnetic interference, and scattered radiation.[7,17-19] Ionizing radiation can alter current flow and the threshold voltage by affecting CMOS in the device. High-energy photon (>10 MV) treatments generate neutrons that may interact with the boron element present in the dielectric layers of CMOS components. This boron-neutron interactions produce charged particles and cause electrical current impairments. Furthermore, high neutron fluences may cause reset errors and loss of functionality. Electromagnetic interference is the sensing the electromagnetic noise around linear accelerator as myocardial potential during radiotherapy. This effect may cause inappropriate reprogramming, inhibition, or triggering of

output. Scattered radiation arises from the deflection of particles or photons arising from either the head of the linear accelerator or from within the patient. Changes within the device parameters as a result of scattered radiation are observed even the cardiac device is outside the radiotherapy field. In the literature, various functional impairments have been reported such as altered sensing (over/under sensing), stimulation (frequency or amplitude), changes in anti-tachyarrhythmia therapy settings and shock energy in ICDs, premature battery depletion, impairment of programmed settings, deletion of patient records, loss of telemetry capability, and lead impedance changes.[6,7,15,17,20] These types of radiation-induced damages to the device can be transient or permanent. Errors in hardware cause permanent damage while software errors generally cause transient damage.[16]

### **Radiotherapy in the Presence of CIEDs**

It is important to identify patients with PMs/ICDs when they are referred to the radiation oncology clinic. Then, radiation oncologist should decide whether radiotherapy is needed or radiotherapy is the only treatment option for the patient. If there are alternative treatment options for the patient rather than radiotherapy, these options should be discussed in the multidisciplinary tumor board. If the radiotherapy is given to patient, all safety procedures should be implemented before the radiotherapy, during the planning and radiotherapy, and after the radiotherapy by following a specific algorithm.[6-8,13,15-17]

Magnetic resonance imaging (MRI)-guided radiotherapy is a new technology with a limited data on this issue. The effects of diagnostic MRI scans on CIEDs are known. TG-203 and the Heart Rhythm Society expert consensus guidelines describe these effects in details and provide useful recommendations for performing MRI on patients with CIEDs.[15,21] Hence, the management of patients with CIEDs undergoing MRI-guided radiotherapy has not been evaluated in this review.

### **Evaluation Before Radiotherapy**

A detailed cardiac history should be obtained from the patient and questioned whether or not the patient had received prior radiotherapy to a localization close to the CIED. Radiation oncologists should contact the patient's cardiologist, inform about the radiotherapy procedure, and request a consultation. Information on CIED type, model, serial number, type of the leads,

device implanted date, baseline cardiac function, the purpose for the device, and the location of the implant should be obtained during the consultation. The cardiologist should evaluate the patient to verify dependence on device.[15,17] For patients with ICD, it is also advised to learn whether it is appropriate to temporarily deactivate anti-tachycardia therapy during simulation and radiotherapy. Recommendations of the cardiologist about monitoring of the patient with pulse oximetry, ECG, etc., during and after the radiotherapy should be considered. Besides, the device manufacturer or the technician should be contacted to check the PM/ICD before the start of radiotherapy. All these information should be documented and recorded in the patient's file.

Before the simulation and the radiotherapy, the radiation oncologist should evaluate the patient and plan all the processes with a medical physicist to estimate the cumulative dose to the CIED. Then, the risk category of the patient should be defined according to AAPM TG-203 recommendation (Table 1). During radiotherapy, the appropriate safety precautions and monitoring should be taken according to risk categories.[17] The patient should be informed about all the process and the precautions to be taken. In addition to this, potential malfunction of PM/ICD, complications, and risks that may occur during and after the radiotherapy should be discussed with the patient and a written informed consent form should be obtained before the treatment.

Each clinic should have a protocol on the management of patients with CIEDs during computerized tomography (CT) simulation, radiotherapy planning, treatment, and follow-up. There should be a radiation oncologist, a medical physicist, and a nurse who are trained and competent in the management of patients with CIEDs. The radiation therapist should receive training for the management of the patient with CIED. There should be appropriate personnel who monitor the patient, notify and assist the CIED-related prob-

lems, and know the usage of special equipment and emergency intervention when needed. Before, during, and after the radiotherapy, a close multidisciplinary collaboration involving the patient's cardiologist, and the device technologist is crucial.

### Simulation with CT

The treatment file should include the information that the patient has a PM/ICD and the information of contact persons in case of emergencies such as the patient's relatives, the device technologist, and the cardiologist. The radiation therapist should be informed about the patient with CIED and notified about the appropriate monitoring of the device and the patient. It is recommended that CIED should be excluded from the scan extent during the CT imaging if that area is not needed for target volume or normal tissue delineation and dose calculations. A helical scan with pitch more than 1 should be preferred for CT imaging. There may be a risk of missensing if the device is exposed to irradiation for longer than 3 s such as in 4DCT procedure. To prevent or mitigate inappropriate shock delivery as a result of accidental sensing of electromagnetic interference, this can be temporarily deactivated before simulation through programming function off or using a heavy magnet according to cardiologist's suggestions. In this situation, the device technologist should be ready at the planning CT monitor room and reprogram after the scanning. During overstimulation, the patient usually feels faint and weak even though it is generally temporary. If the patient has these symptoms during the CT imaging, the patient should be warned to inform the radiation oncologist or therapist. Furthermore, the patient whose device is deactivated should be carefully monitored during CT simulation by fully trained and competent health professionals.[6-8,11,13,17]

### Radiotherapy Planning

The chance of device malfunction during radiotherapy depends on the treatment parameters such as beam energy, beam modality, total dose, dose rate, scattered radiation, radiotherapy fields, and imaging modality. Hence, it is essential to consider these factors during planning.

Contouring of the body of the CIED, which is an electronically sensitive component of the device, as a structure is recommended if it is within 3 cm of the treatment field edge or 5% isodose.[17] There is no

**Table 1** Patient risk categories (AAPM TG-203)

Received radiation dose	Patient	
	Not pacing dependent	Pacing dependent
<2 Gy	Low risk	Medium risk
2–5 Gy	Medium risk	Medium risk
>5 Gy	High risk	High risk
Neutrons present	High risk	High risk

clear information about the sensitivity of leads.[22] Recently, there are ongoing researches especially on electronically active leads that may be more sensitive to radiation doses. The radiation oncologist should be informed whether the device contains active leads or not before the planning. Hence, it is suggested to include them, assess the doses delivered to the CIED, and monitor the patient and the device performance throughout the treatment. Direct radiation beams that pass through the CIED should be avoided if possible and also it is suggested to be at least 3 cm distance from the treatment field. Furthermore, it is suggested to not to use physical wedges, if possible.[6-8]

Due to the high risk of device failure with high LET radiation exposure, low photon energy  $\leq 10$  MV should be preferred during planning.[8,14,16,17] Patients, who need to be treated with high photon energies ( $>10$  MV), should be managed in the high-risk category. For electrons, neutron exposure at high energy must be kept in mind (5% at 15 MeV, 20% at 25 MeV).[16] Furthermore, care should be taken about the cumulative out-of-field dose within 30 cm from the electron field edge since CIEDs are implanted superficially.[17]

It has been reported that the dose rate is responsible for mostly reset type events or transient oversensing effects. Some guidelines recommend to use dose rate of  $<0.2$  Gy/min or less for treatment.[9,18] However, TG-203 and some manufacturers stated that there is a slight risk to the patient with a dose rate of  $<0.01$  Gy/min to the device if it is outside 5 cm of the edge of the treatment field.[17] Although there are a limited data, more caution during planning and radiotherapy is warranted when treating patients with stereotactic body radiotherapy using flattening filter-free beams.[15,16,23] Medical physicists should carefully check the MU per fraction, dose rate, number and the directions of beams, and beam-on time.[17]

Brachytherapy applications are considered safe while their lower energy spectrum and the rapid dose fall-off. Until now, radiation-induced device failure with an adverse event during brachytherapy applications has not been reported in the literature.[6] However, special consideration should be given during high-dose rate brachytherapy for partial breast irradiation.[24]

Some studies have shown that the risk of CIEDs malfunction increases as the cumulative radiation dose to the device increases. To take proper precautions during radiotherapy and prevent device failure; the cumulative radiotherapy dose to the CIEDs should be estimated beforehand and the dose contribution from imaging (image-guided radiotherapy) should also be considered

for this calculation. However, there is no recommended safe radiation dose to avoid all malfunctions.[7,8] It is advised to keep the maximum dose to any point in the CIED body as low as possible during treatment plan optimization. It is better to keep the cumulative dose to the CIEDs below 2 Gy for pacing-dependent patients and 5 Gy for pacing-independent patients.[17] ICDs are thought to be more sensitive to radiotherapy damage at lower doses than PMs and dose  $<0.5-1$  Gy is recommended for ICDs in some studies.[7,10,11,25,26] Furthermore, device manufacturers recommend different threshold dose levels. Hence, the manufacturers' instructions or comments specific to the CIEDs model should be ascertained, especially when higher than 10 MV photon energy is used.[9,16,18] If the manufacturer recommends a dose threshold 0 Gy which is unreasonable, tolerance doses of AAPM-203 can be used. If the stated limit is above 2 Gy, the manufacturer's recommended tolerance dose can be used.[17]

AAPM TG-203 report recommended a categorization of patients into low-, medium-, and high-risk groups according to the cumulative radiation dose delivered to the CIEDs, the patients' pacing dependency, beam energy, and modality of radiotherapy.[17] If the patient is categorized in the high-risk group, the radiation oncologist should liaise with medical physics to decrease the total dose to the device with different treatment planning strategies. If the risk is too high or if the device remains in the radiation beam, other radiotherapy techniques such as electron beam therapy, brachytherapy can be considered, or alternative treatment options such as chemotherapy, surgery can be discussed in the multidisciplinary tumor board. If radiotherapy is the only treatment choice and the CIED is in the field of radiotherapy, relocation of CIED out of the field should be discussed with the cardiologist, especially in pace dependent patients with low cardiac output.[17,18] This decision should be made individually, considering the potential complications due to relocation and the risks of malfunction during radiotherapy without relocation.[8]

### During Radiotherapy

Image-guided radiotherapy (IGRT) techniques are relatively safe for patients with CIEDs. Oversensing is the most commonly reported effect. High cumulative dose delivered to the CIEDs from the therapeutic procedure and the intensive imaging may increase this risk. Hence, IGRT techniques (kV-CBCT, MV-CBCT, MVCT, por-

tal imaging, fluoroscopic imaging...), imaging limits, and the number of images that will be used during radiotherapy should be defined beforehand. If the CIED is not within the radiotherapy field, it is suggested to use smaller set-up fields to minimize the dose to the device. If CIED has to be within the imaging field, kV imaging should be preferred, where possible. The radiotherapy technician should be informed about the patient's situation and imaging procedures before the treatment.[16,17]

Medical physicists should be present during the first radiotherapy fraction. The treatment planning system can accurately estimate the maximum dose to the CIED; if the CIED is within the first 3 cm from the treatment field edge (within the 5% isodose line) or within the treatment area. If the CIED is located between 3 and 10 cm from the treatment field edge, *in vivo* dosimetric measurements are recommended on the 1<sup>st</sup> day of the treatment. Detectors such as thermoluminescent dosimeters, diodes, optically stimulated luminescent dosimeters, and metal oxide semiconductor field-effect transistors can be used for CIED dosimetry.[17] If the CIED is located further than 10 cm from the treatment field edge, the estimated dose to the CIED is probably <2 Gy. Dose verification is not necessary unless non-coplanar beams are used. All the measurements or calculations should be documented in the patient's file.

Patients are categorized into low-, medium-, or high-risk groups according to the cumulative radiation dose to device, beam energy, modality of radiotherapy, and pace dependency of the patient. Appropriate precautions for radiotherapy according to the patient's risk category are described below.[16,17]

### Low-risk Management

The radiation oncologist, medical physicist, and an experienced nurse who have knowledge and experience in the management of patients with CIEDs should be available during radiotherapy. An emergency support system should be prepared. The radiation therapist should be informed about the patient and trained on the management of patients with CIEDs. Continuous audio-visual monitoring of the patient with CIED is needed during each fraction of radiotherapy. There should be a close communication with the cardiologist and the device technologist. In some cases, cardiologists may suggest temporary deactivation of anti-tachycardia therapy through programming or by placing a heavy magnet over the device. These patients should be closely monitored according to cardiologists' suggestions by competent health professional. The device

technologist should be present in the treatment monitor room and reprogram the device after the scanning. Any changes in the patient's clinical status or device parameters should be documented. The device interrogation is needed before the first fraction of radiotherapy and after the completion of radiotherapy.

### Medium-risk Management

In addition to low-risk requirements; an emergency protocol should be prepared for cardiopulmonary resuscitation. ECG, pulse oximetry, external defibrillator, and a PM magnet should be available at the treatment unit with the necessary equipment to manage complications for potential device malfunctions. Especially during the treatment of pacing-dependent patients, there should be a doctor who recognizes the CIED malfunction and related complications (e.g., asystole and ventricular tachycardia) and intervenes immediately. Otherwise, the reanimation team or a cardiologist and device technologist should be close to a distance of 10 min to reach the department. Furthermore, the necessity of temporary external pacing is consulted to a cardiologist. The device should be interrogated at the beginning, middle, and end of the treatment. The frequency of performing function checks can be increased according to cardiologist's suggestions.

### High-risk Management

In addition to the low- and medium-risk group requirements, the cardiologist and the device technologist must be present at each radiotherapy fraction. Regular telemetric checks of the CIED have to be performed by a trained professional within 24 h after each radiotherapy fraction. Furthermore, the CIED should be interrogated once a week during radiotherapy. Weekly monitoring of the patient with ECG which is examined by trained staff is recommended. If any malfunction is detected in the CIED, the risk of continuing radiotherapy should be evaluated with cardiologist, radiation oncologist, and medical physicist. If treatment continues, extra patient monitoring and precautions related to this situation should be discussed and provided.

### After Radiotherapy

After radiotherapy is completed, the device should be controlled for telemetric functions and reprogrammed if the pre-treatment settings are changed. Routine follow-up of the patient and the evaluation of the CIED are recommended by cardiologist and CIED technol-

ogist at 1 and 6 months after the radiotherapy for possible late damage. All patients with CIEDs should be warned about the potential risk of malfunction and trained to be aware of the clinical symptoms of CIEDs failure such as irregular cardiac rhythm, dizziness, and syncope. In this case, the patient should contact with his/her cardiologist.

## Conclusion

The incidence of patients with CIEDs undergoing radiotherapy is increasing. It has been shown that radiotherapy even at low doses can cause malfunction on device with potentially life-threatening consequences. Hence, all radiotherapy centers should have strategies for the safe radiotherapy to patients with CIEDs. To manage patients with CIEDs, the risk group of the patients should be identified according to the cumulative dose to the CIEDs, beam energy, modality of radiotherapy, and the patients' pacing dependency. The appropriate precautions according to risk stratification should be taken during the planning and radiotherapy. Furthermore, treatment parameters such as beam energy, beam modality, total dose, dose rate, scattered radiation, radiotherapy fields, and imaging modality should be considered during planning to prevent device malfunction. Close collaboration and communication between the radiation oncologist, medical physicists, radiation therapist, nurse, patient's cardiologist, and device technologist is essential before, during, and after the radiotherapy. Continuous advances in both radiotherapy and the CIEDs technologies may lead to changes in recommendations regarding the management of patients with CIEDs.

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