

SUMMARY

This article provides radiation oncologists, cardiologists, and electrophysiologists with information regarding administration of care to patients with implanted cardiac devices undergoing radiation treatment.

The article includes the following:

- Possible effects of radiation therapy on implanted devices
- Clinical recommendations and device programming mitigations
- Answers to frequently asked questions

Products Referenced

All BSC ICDs, CRT-Ds, CRT-Ps, and Pacing Systems, and the LATITUDE® Patient Management System

Products referenced herein may not be approved in all geographies. For comprehensive information on device operation, reference the full instructions for use found at: www.bostonscientific.com/cardiac-rhythm-resources/international-manuals.html.

CAUTION: Law restricts this device to sale by or on the order of a physician. Indications, contraindications, precautions and warnings can be found with product labeling.

All graphics produced by Boston Scientific Corporation, unless otherwise noted.

CRT-D: Cardiac Resynchronization Therapy Defibrillator
CRT-P: Cardiac Resynchronization Therapy Pacemaker
ICD: Implantable Cardioverter Defibrillator

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Therapeutic Radiation and Implantable Device Systems

Many sources of ionizing radiation are commonly used for the diagnosis and treatment of diseases. These sources vary significantly in their potential impact on an implanted cardiac device, such as a pacemaker or defibrillator. Several therapeutic radiation sources are capable of interfering with or damaging an implanted device, including those used for the treatment of cancer (i.e., radioactive cobalt, linear accelerators, radioactive seeds, and betatrons). Most diagnostic tools, such as radiography (X-ray) and fluoroscopy, have not been identified as sources of device interference or damage. The impact of ionizing radiation varies from one implanted device to another and may range from no change in function to a loss of pacing or defibrillation therapy.

If a physician chooses to administer radiation therapy to pacemaker, ICD, CRT-D or CRT-P patients, advance planning and extra precautions are required, as outlined in pacemaker and defibrillator product labeling. Prior to a course of therapeutic radiation treatment, radiation oncologists should consult with the patient's cardiologist or electrophysiologist to develop strategies specific to each patient for monitoring patient health and verifying appropriate device operation during and following radiation treatment sessions.

Factors Determining the Impact of Radiation Therapy on Implanted Device Systems

The impact of therapeutic radiation on implanted devices is difficult to predict. Multiple factors collectively determine the impact of radiation therapy on an implanted device. These factors include:

- Type of implanted device
- Proximity of the implanted device to the radiation beam
- Type and energy level of radiation beam
- Orientation of the beam to the implanted device
- Dose rate
- Total dose delivered over the life of the device
- Shielding of the implanted device
- Patient anatomy and physiology
- Frequency of radiation treatments
- Concurrent therapies and diagnostics

Due to this variability, it is not possible to specify a "safe" radiation dosage or guarantee proper device function following exposure to ionizing radiation.

Potential Impact of Therapeutic Radiation on Implanted Device Systems

Therapeutic radiation, including scatter particles can have a temporary negative effect on the implanted device's electrical components, such as the microprocessor or memory, resulting in temporary alteration of device function. Additionally, the cumulative effects of radiation in sufficient doses (total dose or dose rate) can result in permanent degradation of performance below device specifications.¹

Exposure to radiation may cause the device to experience one or more of the behaviors described in Table 1. The impact may be temporary or permanent.

Table 1. Potential Device Behaviors (temporary or permanent) Due to Radiation Exposure		
ICDs/ CRT-Ds	Pacemakers/ CRT-Ps	Potential Device Behaviors (temporary or permanent)
•	•	Altered device status (e.g., premature elective replacement indicator)
•	•	Altered pacing outputs (e.g., decreased pacing amplitude)
•	•	Inhibition of pacing—pacing therapy not provided when needed
•		Altered tachyarrhythmia outputs (e.g., shock energy)
•		Inhibition of tachyarrhythmia therapy—shock therapy not provided when needed
•		Inappropriate shocks—shock therapy provided when not needed
•	•	Complete loss of device function
•		Reversion to a safety mode*
•	•	Loss of remote monitoring with the LATITUDE [®] Patient Management System

*These modes (Safety Mode, Safety Core, or Reset Mode), collectively referred to as "Safety Mode" throughout this article, were designed to provide backup pacing and/or shock therapy in some situations when normal device function is not possible. Specific device behavior in these modes varies by device family. If activated, Reset and Safety Mode reload the microprocessor from protected backup memory. Safety Core utilizes independent backup circuitry in case the microprocessor itself is no longer functional. Use of Read Only Memory (ROM) makes this back-up mode less susceptible to radiation damage.

Device memory is the component most likely to be affected by therapeutic radiation (either direct beam or scatter particles). Boston Scientific CRM devices include periodic self-diagnostic memory checks to locate and correct many memory errors. If the degree of memory alteration is beyond the capability of self-correcting algorithms, devices may enter Safety Mode; this mode is designed to provide continuous patient protection by providing basic pacing and/or shock therapy. In other situations, the effects of radiation may cause sufficient damage that Safety Mode may not be available, resulting in loss of therapy. Multiple exposures to any source of ionizing radiation source over the life of the device further increases the likelihood of impacting device function.

Clinical Considerations

Advance planning

Prior to a course of therapeutic radiation treatment, radiation oncologists should consult with the patient's cardiologist or electrophysiologist to develop strategies specific to each patient. When developing a radiation treatment program for patients with implanted devices, the physician team should consider the best method for treating the patient's disease, as well as for protecting the patient's implanted device. Strategies for monitoring patient health and verifying appropriate device operation during and following radiation treatment sessions should be discussed. Additionally, discussion of current patient conditions, including disease state, type of implanted device, and tolerance to potential device function disruptions as previously described will help to optimize success of the radiation treatment program while reducing the potential impact to the implanted device and the patient.² The possibility and timing of device replacement should be considered during advance planning as device operation cannot be guaranteed following exposure to therapeutic radiation.

Emphasis should be placed on shielding within the radiation equipment and optimization of the treatment field, as well as focus, direction and energy level of the primary beam. An estimation of the absorbed dose to be received by the device may be calculated. No single total dose limit can be specified for a given device family due to the variations listed above; however, clinical studies provide some insight into the effects of ionizing radiation from the clinical perspective.^{2,3,4,5} Furthermore, some clinical studies do provide a recommended maximum total dose of 2 Gy to the implanted device.^{2,5}

Shielding

To reduce the probability of interaction with a primary beam or secondary radiation scatter, consider using all available shielding options, including both internal shielding on the radiation equipment as well as external shielding for the patient. Shielding within the head of the machine should be maximized, and the primary beam should not be aimed directly at the implanted device. If the beam cannot be moved, the physician team may consider other options as described in published studies, such as moving the device to a different location.^{2,5,6} The treatment field design should include maximum shielding regardless of the distance from the primary beam, thereby minimizing the potential effects of scatter particles on the device.⁵

Patient care during therapy session

The physician team should determine the most appropriate level of monitoring during treatment. Because each patient's medical condition and type of device is different, the cardiologist or electrophysiologist should provide patient-specific recommendations to promote safety. For example, a pacemaker-dependent patient may require continuous cardiac monitoring during every therapy session.²

Device programming considerations

Programming considerations are described in Table 2.

Table 2. Device Programming Considerations		
Products	Potential Interactions	Programming Considerations
ICDs & CRT-Ds	<ul style="list-style-type: none"> • Inhibition of pacing therapy • Inappropriate shock therapy • Inhibition of shock therapy 	<p>If inhibition of pacing is observed, a programmer can be used to initiate temporary asynchronous pacing (VOO/AOO/DOO).</p> <ul style="list-style-type: none"> ➤ Wandless telemetry: the wand must remain in place over the implanted device and the session should be monitored during asynchronous pacing. ➤ Wandless (RF ZIP™) telemetry: the telemetry session should be monitored. Switch to wandless telemetry if necessary. <p>Deactivate tachy therapy.</p> <ul style="list-style-type: none"> ➤ Program the device Tachy Mode to Electrocautery Protection Mode or to Off-Electrocautery, if available. In these modes, tachyarrhythmia detection and therapy features are deactivated, and the pacing mode switches to an asynchronous mode (VOO, AOO, or DOO). <p>or</p> <ul style="list-style-type: none"> ➤ Program the device Tachy Mode to Off, or place a magnet over the device to temporarily inhibit or deactivate tachy therapy.* The brady pacing mode remains as programmed. <p>NOTE: Re-activate the Tachy Mode (Monitor + Therapy) following the session</p>
Pacemakers & CRT-Ps	<ul style="list-style-type: none"> • Inhibition of pacing therapy 	<p>A magnet can be placed over the device to pace asynchronously at the magnet rate.</p> <p>or</p> <p>The device can be programmed to an asynchronous pacing mode (VOO, AOO, or DOO).</p>

NOTE: If any programming changes were made, the device should be reprogrammed back to the desired settings following the procedure.

NOTE: If using wandless telemetry during the session, the programmer should be located as far from the primary beam as possible.

*Use of a magnet depends on feature availability and device programming. For additional information, refer to the **A Closer Look** article on this topic.

Assessment of device function after therapy sessions

Boston Scientific recommends evaluation of device function following radiation treatment. The extent, timing and frequency of this evaluation relative to the radiation therapy regimen depend upon current patient health, and therefore should be determined by the attending cardiologist or electrophysiologist. A thorough post-therapy follow-up may include:

- Interrogation of the device with a programmer
- Review of clinical events and fault codes
- Review of the Arrhythmia Logbook, including stored electrograms (EGMs)
- Review of real-time EGMs
- Testing, in all chambers, the pacing threshold, intrinsic amplitude and lead impedance
- Manual capacitor re-formation (only for ICDs and CRT-Ds) †
- Programming any Brady setting in permanent Brady Parameters and then reprogramming it back to the desired value
- Programming the Tachy Mode to a new value and then reprogramming back to the desired value (only for ICDs and CRT-Ds)
- Performing a Save All to Disk (exercises additional memory locations)

If any abnormalities are observed during this evaluation, please contact Technical Services; the consultant may request that a Save All to Disk be submitted for analysis.

If any programming changes were made, the device should be reprogrammed back to the desired settings prior to allowing the patient to leave the clinic. **Re-activate the Tachy Mode (Monitor+Therapy) on ICDs and CRT-Ds.**

Patient health may dictate the timing of post-therapy device evaluation activities (for example, timely verification of appropriate pacing is important for a pacer-dependent patient). Many device diagnostics are performed automatically once per hour, so device evaluation should not be concluded until device diagnostics have been updated and reviewed — at least one hour after radiation exposure.

The effects of radiation exposure on the implanted device may remain undetected until sometime following exposure. For example, a malfunction due to radiation exposure may not be discovered until a previously unused device feature is activated several months after completion of a radiation treatment regimen. For this reason physicians should continue to monitor device function closely and use caution when programming a feature following radiation therapy.

†Longevity impact of manual capacitor reformations varies by device as described in product labeling, and ranges from 5 to 19 days per capacitor reform.

Frequently Asked Questions

Q1. Why doesn't Boston Scientific quote a radiation dosage level that would be considered "safe"?

A1. It is not possible to specify a safe radiation dosage or guarantee proper pulse generator function following exposure to ionizing radiation. Multiple factors collectively determine the impact of radiation therapy on an implanted pulse generator, including proximity of the pulse generator to the radiation beam, type and energy level of the radiation beam, dose rate, total dose delivered over the life of the pulse generator, and shielding of the pulse generator. The impact of ionizing radiation will also vary from one pulse generator to another and may range from no changes in function to a loss of pacing and defibrillation therapy.

It is theoretically possible to quote a dosage level that would result in permanent hardware circuitry damage. However, random alteration of device memory or electrical components by scatter particles (rather than permanent physical damage) is a more concerning issue in modern devices and is difficult to predict by dosage level.³ Precautions to reduce scatter (shielding, beam focus, energy level selection, treatment field design, etc.) may significantly reduce the probability of impact to device memory. Some devices are susceptible to other sources of radiation that do not originate as scatter. Specifically, thermal neutrons can be generated by linear accelerators and they can adversely affect device behavior.^{4,10} Since it is impossible to fully shield against ionizing radiation, devices will always be susceptible to some extent to the effects of ionizing radiation, regardless of the selected energy level or distance from the primary beam.

Q2. If you cannot quote a "safe" radiation dosage level, can you at least quote a "safe" distance from the primary beam?

A2. No.. Despite distance and shielding opportunities, the impact of radiation on the implanted device remains a possibility,² and full precautions should be taken under all circumstances, regardless of the distance from implant site to beam location. The likelihood of radiation particles disrupting device function is reduced very quickly as the distance between the implant site and the primary beam increases. Radiation for the treatment of prostate cancer, for example, is more likely to impact an abdominally-placed device than a device implanted in the pectoral region.

Q3. What should be done if the implanted device is positioned in the immediate area to be irradiated?

A3. Consultation with the patient's cardiologist or electrophysiologist is recommended. The physician team may consider moving the device to a different location prior to radiation sessions.^{5,6} However, a device may be subject to radiation damage at its new site as well. The physician team may prefer to alter the treatment design and maximize shielding, and then replace a damaged device only once, following completion of the radiation therapy regimen.

Q4. Are "self-check" diagnostics capable of detecting and correcting all modes of radiation-induced failure?

A4. No. As mentioned previously, many minor memory disruptions are found and corrected without any impact to device function. Major disruptions of memory are often identified by self-diagnostic checks, but may be beyond the scope of self-correcting algorithms. It is possible that temporary disruption of electrical components or permanent hardware failure could prevent detection and corrective action (such as memory repair or Safety Mode execution). In this case, diagnostics, therapy and/or telemetry may be non-functional. The location(s) and extent of the damaged components will determine the effect on device functionality.

Q5. Do all Boston Scientific/Guidant devices whose memory is affected revert to Safety Mode?

A5. No. There is also a possibility of permanent damage to the device, and the physician team must consider this possibility during treatment protocol design and post-therapy device assessment.

Q6. What should be done when a device is found in Safety Mode?

A6. While devices in Safety Mode may continue to provide basic pacing and/or shock therapy, these devices should be replaced if and when the physician deems it clinically appropriate for the patient. Limited programmability or complete loss of interrogation/programming and diagnostic features may lead a cardiologist or electrophysiologist to recommend device replacement if and when it is clinically appropriate for the patient. Until replacement, these devices should be monitored closely to verify therapy availability.

Q7. How can the LATITUDE Patient Management system be used to monitor patients undergoing therapeutic radiation?

A7. The LATITUDE Patient Management system can be a supplement to in-clinic evaluations. However, LATITUDE may not be able to alert for many of the possible device outcomes following radiation exposure. For example, LATITUDE may not be able to immediately alert for device conditions if RF ZIP telemetry and/or inductive telemetry are disabled as a result of radiation therapy. However, if the LATITUDE Communicator is unable to detect and interrogate an implanted device for 14 days, the LATITUDE System will generate a Data Collection Failure message which can result in a notification from LATITUDE Customer Support to the clinic. Additionally, LATITUDE cannot be used to command diagnostic functions, such as pacing threshold tests or lead impedance tests, nor can this patient monitoring system be used to program device modes, if needed. An in-clinic follow-up

with a programmer is required to perform these functions. It is important to note that the LATITUDE remote monitoring is currently not available in all geographies or for all products.

Q8. What if the device is damaged during the course of radiation treatment?

A8. If a device is damaged prior to completion of the therapy regime, the patient's cardiologist or electrophysiologist should consider all available options to determine the best course of action. For example, if the patient is pacemaker-dependent, immediate replacement of a device may be required, with special consideration given to location of the new implant (relative to the site of the primary beam). If the patient is not pacemaker-dependent, it may be acceptable to delay a device replacement until completion of all therapy sessions. Similarly, if an ICD or CRT-D is verified to be capable of delivering Safety Mode shock therapy following each treatment session, it may be possible to delay replacement of the device until completion of all therapy sessions.

Q9. Will warranty credit be provided for any device that must be replaced following radiation therapy?

A9. If the device must be replaced following radiation exposure and has not exceeded its defined warranty period, warranty credit will be applied in accordance with the regulations for the geography in which the device was sold. Warranty program requirements include replacement with another Boston Scientific product, as well as return of the device to Boston Scientific within the designated timeframe.

Q10. To what extent are Boston Scientific sales and clinical representatives trained to verify proper device function following radiation therapy?

A10. Boston Scientific field representatives are extremely knowledgeable about the characteristics of appropriate function of Boston Scientific implantable devices. They are often present at implant procedures and subsequent in-clinic follow-up sessions to provide information about device function. However, support from Boston Scientific representatives should occur only under the direction of the attending cardiologist or electrophysiologist, who remains the focal point for prescriptions related to treatment of the patient's specific medical conditions.

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² Last A. Radiotherapy in patients with cardiac pacemakers. *Br J Radiol*.1998;71:4-9.

³Kobayashi H, Shiraishi K, Tsuchiya H, et al. Soft Errors in SRAM Devices Induced by High Energy Neutrons, Thermal Neutrons and Alpha Particles. *Electron Devices Meeting, 2002. IEDM Digest, International*. 2002:337-340.

⁴ Wilkinson JD, Bounds C, Brown T, Gerbi BJ, Peltier J. Cancer-Radiotherapy Equipment as a Cause of Soft Errors in Electronic Equipment. *IEEE Transactions on Device and Materials Reliability*. 2005;5:449-451.

⁵Marbach JR, Sontag MR, VanDyk J, Wolbarst AB. Management of Radiation Oncology Patients with Implanted Cardiac Pacemakers. *American Association of Physicists in Medicine Report No. 45*. 1994:85-89.

⁶Solan A, Solan M, Bednarz G, Goodkin M. Treatment of patients with cardiac pacemakers and implantable cardioverter-defibrillators during radiotherapy. *Int J Radiat Oncol Biol Phys*. 2004;59:897-904.