Computed Tomography (CT) Scanning and Implantable Pacemakers and Defibrillators

SUMMARY
This article provides information for medical personnel regarding care of patients with implanted cardiac vices who may also undergo a Computed Tomography (CT) scanning procedure, including:

- Possible effects of CT scan on implanted devices
- Clinical recommendations and device programming mitigations to reduce the potential risk

Prior to using diagnostic CT scans, the patient's cardiologist or electrophysiologist should be consulted to develop a strategy specific to each patient for monitoring health and verifying appropriate device operation both during and following the CT procedure.

FDA United States Food and Drug Administration
ICD: Implantable Cardioverter Defibrillator
CRT-D: Cardiac Resynchronization Therapy Defibrillator
CRT-P: Cardiac Resynchronization Therapy Pacemaker

CRM PRODUCTS REFERENCED*
All BSC ICDs, CRT-Ds, CRT-Ps, and Pacing Systems

*Products referenced herein may not be approved in all geographies. For comprehensive information on device operation, reference the appropriate product labeling.

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Historically, most diagnostic radiation tools, such as radiography (X-ray), fluoroscopy, and CT scanners have not been identified as sources that would interfere with or damage Boston Scientific Cardiac Rhythm Management (CRM) implantable devices. However, newer CT imaging equipment may employ a higher radiation dose rate and total dose per session than older equipment. For this reason, special consideration should be given to patients with an implanted pacemaker, ICD, CRT-D, or CRT-P who require CT scanning.

U.S. FDA Public Health Notification[1]

On July 14, 2008 the U.S. FDA issued a public health notification regarding potential interactions/malfunctions of implanted devices during CT scanning procedures. The FDA has received reports from physicians linking CT scanning equipment to temporary interference with implantable pacemaker function, including temporary inhibition of pacing therapy. Boston Scientific CRM is in the process of evaluating the potential for interference between modern CT equipment and implanted pacemakers and defibrillators. Upon completion of our evaluation, the test results will be made available.

Factors Determining the Impact of CT Scanning on Implanted Devices

Multiple factors may operate individually and collectively to determine the impact of CT scanning on an implanted cardiac device. These factors include:

- Type of implanted device (brand/model)
- Type of CT scanning equipment (brand/model)
- Proximity and orientation of the beam relative to the implanted device
- Energy level, delivery rate, and duration
- Total radiation dose
- Patient anatomy and physiology
- Concurrent therapies and diagnostics

Due to these variables, it is not possible to identify universally "safe" conditions that guarantee proper device function during and following exposure to CT scans. However, the risk of impact on the device and patient can be minimized by taking into consideration all of these factors when developing a CT scanning protocol for a patient with an implanted cardiac device.

Potential Impact of CT Scanning on Implanted Devices

Both the FDA[1] and a recent study[2] reported inhibition of pacing therapy associated with CT scanning of pacemakers and defibrillators (non-Boston Scientific). When inhibition occurred, it was temporary, and normal device function resumed when the patient was moved away from the CT scanner. No permanent device damage was reported in either article.

Prior to conducting a CT scan, Boston Scientific CRM suggests that physicians consider the possibility of encountering one or more of the device behaviors described in Table 1. If these behaviors occur, they will likely be temporary, and normal device function should resume when the patient is moved away from the CT scanner or when the scanner is off.

Table 1. Potential Temporary Implantable Device Behaviors Associated with CT Exposure

ICDs/ CRT-Ds	Pacemakers/ CRT-Ps	Potential temporary device behaviors
■	■	Inhibition of pacing—pacing therapy not provided when needed
■		Inappropriate shocks—shock therapy provided when not needed
■		Inhibition of tachyarrhythmia therapy—shock therapy not provided when needed

Clinical Recommendations

Advance planning

Prior to a CT scan, the patient's cardiologist or electrophysiologist should be consulted to develop a strategy specific to the patient for monitoring health and device operation both during and following the procedure. Discussion of current patient conditions, including cardiac disease state, type of implanted device, and tolerance to potential device behaviors described in Table 1, will help to optimize success of the CT scan while reducing potential impact to the implanted device or the patient.

FDA recommends[1]:

- Before beginning a CT scan, use "scout views" to determine if implanted medical devices are present and if so, their location relative to the programmed scan range.
- Select scanner energy levels at the minimum necessary for an adequate scan.
- Maximize the distance between the beam and the implanted device and avoid placing the device directly into the beam, whenever possible.

Additionally, a recent study by McCollough et al states that the primary consideration for a patient with an implanted cardiac device preparing for a CT scan is to determine if the device will enter the X-ray beam.[2]

Device programming considerations

Certain programming considerations may reduce the likelihood of interference during the CT scan, as described in Table 2.

Table 2. Device Programming Mitigations

Products	Potential interactions	Programming mitigations
ICDs & CRT-Ds	▪ Inhibition of pacing therapy ▪ Inappropriate shock therapy ▪ Inhibition of shock therapy	Deactivate tachy therapy. ➢ Program the device Tachy Mode to Electrocautery Protection Mode or to Off-Electrocautery, if available. In this mode, tachyarrhythmia detection and therapy features are deactivated, and the pacing mode switches to an asynchronous mode (VOO, AOO, or DOO), or ➢ Program the device Tachy Mode to Off to temporarily inhibit or deactivate tachy therapy. The brady pacing mode remains as programmed.
Pacemakers & CRT-Ps	▪ Inhibition of pacing therapy	Program the device to an asynchronous pacing mode (VOO, AOO, or DOO).
NOTE: If any programming changes were made in preparation for CT scanning, the device should be reprogrammed back to the desired settings following the CT procedure. Re-activate the Tachy Mode (Monitor + Therapy) on ICDs and CRT-Ds.		

Patient care during therapy session

The physician team should determine the most appropriate level of monitoring during CT scanning. The FDA suggests that attending staff should be ready to take emergency measures to treat adverse reactions if they occur.[1] For example, a pacemaker-dependent patient may require continuous cardiac monitoring and/or intervention during a CT scan.

Assessment of device function after CT scan

Boston Scientific CRM generally recommends evaluation of device function following any procedure that may involve device interference. The extent, timing, and frequency of this evaluation relative to the tests conducted are dependent upon current patient health, and therefore should be determined by the attending cardiologist or electrophysiologist.

If any programming changes were made, the device should be reprogrammed back to the desired settings following the CT procedure. **Reactivate the Tachy Mode (Monitor + Therapy) on ICDs and CRT-Ds.**

To report interactions between CT scanners and implantable devices or any abnormalities observed during post-CT scan evaluation, please contact CRM Technical Services.

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[1] Food and Drug Administration. David G. Schultz, MD. FDA Preliminary Public Health Notification: Possible Malfunction of Electronic Medical Devices Caused by Computed Tomography (CT) Scanning. Rockville, Md: National Press Office; July 14, 2008.

[2] McCollough CH, Zhang J, Primak AN, Clement WJ, Buysman JR. Effects of CT Irradiation on Implantable Cardiac Rhythm Management Devices; *Radiology. 2007;* 243:3.