## SUMMARY

Electromagnetic Interference (EMI) is the disruption of normal operation of an electronic device when it is in the vicinity of an electromagnetic field created by another electronic device. Boston Scientific adheres to the Association for the Advancement of Medical Instrumentation (AAMI) standards for testing of implantable devices in the presence of EMI. Boston Scientific ICDs, CRT-Ds, CRT-Ps and pacing systems incorporate protection mechanisms (filters) for EMI encountered in public, home and occupational environments.


**Products Referenced**
All CRM ICDs, CRT-Ds, CRT-Ps, and Pacing Systems

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

CRT-D: Cardiac Resynchronization Therapy Defibrillator
CRT-P: Cardiac Resynchronization Therapy Pacemaker
ICD: Implantable Cardioverter Defibrillator
ATP: Anti-Tachycardia Pacing


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# Electromagnetic Interference (EMI) and Implanted Medical Devices

All electronic devices radiate energy in the form of electromagnetic radiation waves, which are the result of electrically and magnetically charged particles in motion. Electromagnetic waves vary in amplitude and frequency. Electromagnetic Interference (EMI) is the disruption of normal operation of an electronic device when it is in the vicinity of an electromagnetic field created by another electronic device.

## Potential impact of EMI on implantable device systems

Some electrical equipment has the potential to interfere with the proper function of an implanted device system. Electromagnetic waves of sufficient amplitude and/or frequency, generated within the proximity of the implanted device system, may have the potential to mimic the electrical activity of the heart and inhibit needed therapy or be interpreted by the device as electrical noise potentially resulting in delivery of unnecessary therapy. These types of EMI should be avoided if possible as they can impact device performance and could potentially lead to the following device responses:

| Device behavior | ICDs / CRT-Ds | Pacemakers/ CRT-Ps |
|---|---|---|
| Asynchronous pacing (pacing therapy provided independent of intrinsic cardiac activity) | ■ | ■ |
| Inhibition of pacing (pacing therapy not provided when needed) | ■ | ■ |
| Inhibition of tachyarrhythmia therapy (ATP/shock therapy not provided when needed) | ■ | |
| Inappropriate tachyarrhythmia therapy (ATP/shock therapy provided when not needed) | ■ | |
| Triggered ventricular pacing up to the Maximum Tracking Rate | ■ | ■ |
| Inability to communicate with the device | ■ | ■ |
| Induced ventricular arrhythmias and/or fibrillation | ■ | ■ |
| Electrical reset | ■ | ■ |

If the patient moves away from or turns off the source of EMI, the implanted device usually resumes its normal mode of operation. In rare instances, the impact to the device may be permanent such as memory corruption or reversion to Safety Mode operation.

## Precautions for Patients in the Presence of EMI

Patients in the presence of electronic equipment who feel light-headed, detect an increased heart rate, hear beeping tones from their device, or experience a defibrillation shock, should immediately move away from electronic equipment and call their physician to report the episode.

## Additional EMI information

See product labeling or refer to the following sources for additional EMI information:

· Device monitoring physician
· Boston Scientific CRM Technical Services
· Article: “What You Need to Know About Electromagnetic Interference (EMI)”
http://www.bostonscientific.com/templatedata/imports/HTML/CRM/patient/index.html