Electromagnetic Interference (EMI) and Implantable Device Systems

BACKGROUND INFORMATION
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.

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

CRM 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, reference the appropriate product labeling.

CRM CONTACT INFORMATION

Technical Services – U.S.
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Patient Services
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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. EMI may occur when electromagnetic waves from one electronic device interfere with and cause an undesired response in another electronic device.

Potential impact of EMI with CRM implantable device systems
Although most environments do not pose EMI risks, certain 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 or be interpreted by the device as electrical noise. These types of EMI should be avoided if possible as they can impact device performance and could potentially lead to the following temporary 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 (shock therapy not provided when needed)	■	
Inability to communicate with the device	■	■
Inappropriate shocks (shock therapy provided when not needed)	■	
Triggered ventricular pacing at Maximum Tracking Rate	■	■
Induced Ventricular Arrhythmias and/or fibrillation	■	■
Trigger the End-of-Life indicator	■	■
Electrical Reset	■	■

The impact to device function is typically temporary. If the patient moves away from or turns off the source of EMI, the implanted device 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.

Refer to the following sources for additional information regarding EMI:
- Physician monitoring patient's device
- Boston Scientific CRM Technical Services
- http://www.bostonscientific.com/templatedata/imports/HTML/CRM/patient/index.html