# A Closer Look

Product Education at a glance



## **Dental Equipment and Implantable** Pacemakers and Defibrillators

#### **SUMMARY**

This article provides an analysis of potential interactions between Boston Scientific implantable pacemakers and defibrillators and equipment used during dental procedures.

- Some manufacturers of dental equipment may contraindicate product use with patients implanted with a pacemaker or defibrillator.
- Boston Scientific has not evaluated for potential electromagnetic interference (EMI) between its devices and dental equipment. However, the results of product specification analysis are provided herein.
- > Patients should consult the physician who monitors their device to discuss any concerns they might have concerning the potential for interference.
  - ICD: Implantable Cardioverter Defibrillator
- CRT-D: Cardiac Resynchronization Therapy Defibrillator
- CRT-P: Cardiac Resynchronization Therapy Pacemaker AAMI: Association for the
- Advancement of Medical Instrumentation
- ANSI: American National Standards Institute

CRM PRODUCTS REFERENCED\* All Boston Scientific pacemakers, ICDs, CRT-Ds, & CRT-Ps

\*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. 1.800.CARDIAC (227.3422) Tech.Services@bsci.com

**Technical Services – Europe** +32 2 416 7222 eurtechservice@bsci.com

LATITUDE Clinician Support 1.800.CARDIAC (227.3422) latitude@bsci.com

**Patient Services** 1.866.484.3268 - U.S. and Canada 001.651.582.4000 - International

Common dental procedures often involve the use of electrical equipment that may come into close proximity to an implanted pacemaker or defibrillator. While Boston Scientific CRM devices have protection mechanisms to recognize and filter most environmental noise, the large variety of electrical equipment available makes it impossible to test all equipment for potential interference with cardiac devices. Boston Scientific has not directly tested the effects of dental equipment on its implanted cardiac devices, but has carefully examined product specifications relative to the standards to which its products were developed.

#### **Potential Interactions**

There is a possibility that exposure to some dental equipment may temporarily affect the function of an implanted pacemaker or defibrillator. Electromagnetic interference (EMI) may occur when the electromagnetic field from one electronic device interferes with the operation of another electronic device. These electromagnetic signals have the potential to mimic the electrical activity of the heart, or be interpreted by the implanted pacemaker or defibrillator as electrical noise. Possible device responses to EMI include:

- Inhibition of pacing pacing therapy not provided when needed
- Asynchronous pacing pacing therapy provided at a fixed rate regardless of the heart's need for therapy
- Inappropriate shocks shock therapy provided when not needed

### **General Dental Procedures and Equipment**

The following information may be helpful when using line-powered equipment (plugged into an electrical outlet-see Table 1).

- Consider keeping equipment power sources and cables as far as possible from the implanted device and lead system to help minimize EMI. Avoid draping the equipment cables over the device implant site.
- Consider adjusting dental equipment to the lowest clinically acceptable energy setting. However, minimizing the equipment's energy setting will not necessarily prevent EMI with the implanted pacemaker or defibrillator.
- · If a pacemaker or defibrillator patient experiences symptoms such as lightheadedness, increased heart rate, a defibrillation shock, or hears beeping tones from their device, moving away from the source of interference or turning it Off will usually allow the device to return to its normal mode of operation.
- Some manufacturers of dental equipment may contraindicate product use in patients implanted with a pacemaker or defibrillator.
- Patients should consult with the physician who monitors their device to discuss any concerns they might have regarding the potential for interference. Boston Scientific cannot assure the safe and effective operation of its implantable device with all possible types of dental equipment when used in combination.

If more information can be provided to CRM Technical Services specific to dental equipment used (brand, model, operating frequency and amplitude), our engineering staff may be able to provide additional insight into the potential for interference.

Dental Equipment	Equipment Function & Potential Interactions
Drills and cleaning equipment	Most dental drills and cleaning equipment should not affect cardiac device function.
Dental X-rays	Most diagnostic tools using ionizing radiation, such as radiography (X-ray), have not been identified as sources of device interference or damage. Dental X-rays should not affect pacemaker or defibrillator function.
Ultrasonic dental scalers	<ul> <li>Ultrasonic dental scalers use fast vibrations to clean teeth through one of two energy conversion technologies:<sup>2</sup></li> <li>Magnetorestrictive—uses a pulsing magnetic field applied to a metal "stack" that flexes to move tip in an elliptical pattern.</li> <li>Piezoelectric—uses pulsing voltage applied to ceramic crystals to move the tip in a reciprocating pattern.</li> <li>Boston Scientific devices comply with the AAMI PC69 standard,<sup>3</sup> which in general suggests Boston Scientific devices should not be affected by interference from peak magnetic field intensities less than 20 A/m (0.25 Gauss) between 10 to 100 kHz. A recent independent study conducted to investigate the potential for EMI between dental equipment and defibrillators identified no interference from the piezoelectric dental scaler tested.<sup>4</sup></li> <li>Though Boston Scientific analysis indicates that device interference due to ultrasonic dental scaler use is unlikely, testing for potential EMI between our devices and ultrasonic dental scalers has not been conducted, and we cannot quarantee</li> </ul>
	compatibility between the two technologies. While Boston Scientific has not identified any ultrasonic dental scalers that interfere with our implanted devices, caution should be exercised.
Apex locators	Apex locators are used by dentists to determine the length of the root canal space. Recent independent studies conducted to investigate the potential for EMI between dental equipment and pacemakers and/or defibrillators identified no interference from the apex locators tested. <sup>5,6</sup> Though Boston Scientific analysis indicates that device interference due to apex locator use is unlikely, Boston Scientific
	has not conducted testing for potential EMI between its devices and apex locators, and cannot guarantee compatibility between the two technologies. While Boston Scientific has not identified any apex locators that interfere with our implanted devices, caution should be exercised.
Dental chairs with magnetic headrests	<ul> <li>Some dental chairs contain magnets located in the headrest. If the pacemaker or defibrillator is programmed <i>not</i> to respond to a magnet, patients may sit in these chairs. If the implanted device is programmed to respond to a magnet and:</li> <li>The magnet power is <u>less than</u> 10 Gauss (1mTesla)—patients may sit in these chairs.</li> <li>The magnet power is <u>greater than</u> or equal to 10 Gauss (1mTesla)—patients should <i>not</i> sit in these chairs as device function/programming may be affected.</li> </ul>
Electrocautery	Electrocautery may temporarily affect the function of an implanted pacemaker or defibrillator. During electrocautery use, Boston Scientific defibrillators can be temporarily deactivated and a pacemaker can be programmed to pace asynchronously. The physician who monitors the patient's implantable device should be contacted to discuss the use of electrocautery and the potential impact of these programming options. Reference device Instructions for Use manuals or the <b>A Closer Look</b> article, <i>Electrocautery and Implantable Device Systems</i> for further instructions / precautions when using electrocautery during dental procedures. This information is available through CRM Technical Services or on Boston Scientific's website. <sup>7</sup>
<sup>1</sup> Boston Scientific has not directly tested the effects of dental equipment on its implanted cardiac devices, but has carefully examined product specifications relative to the standards to which its products were developed.	

Table 1. Boston Scientific Analysis<sup>1</sup> of Dental Equipment and Potential Interactions with Implantable Pacemakers and Defibrillators

standards to which its products were developed. <sup>2</sup>The Free Dictionary by Farlex web page. Available at <u>http://medical-dictionary.thefreedictionary.com/ultrasonic,+magnetostrictive+scaler</u>. Accessed on October 24, 2008. <sup>3</sup>ANSI/AAMI PC69:2007. Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable

cardioverter defibillators, pp 76-80. <sup>4</sup>Brand, HS, Entjes, ML, Nieuw Amerongen, AV, van der Hoeff, EV, Schrama, TAM. Interference of electrical dental equipment with Implantable Cardioverter-defibrillators.

Brand, HS, Entjes, ML, Nieuw Amerongen, AV, van der Hoeff, EV, Schrama, TAM. Interference of electrical dental equipment with Implantable Cardioverter-deribriliators British Dental Journal. 2007; 203:577-579.

<sup>5</sup>Garofalo, RR, Ede, EE, Dorn, SO, Kuttler, S. Effect of Electronic Apex Locators on Cardiac Pacemaker Function. *Journal of Endodontics*. 2002; 28:831-833. <sup>6</sup>Wilson, BL, Broberk, C, Baumgartner, JC, Harris, C, Kron, J. Safety of Electronic Apex Locators and Pulp Testers in Patients with Implanted Cardiac Pacemakers or Cardioverter/Defibrillators. *Journal of Endodontics*. 2006; 32: 847-582.

<sup>7</sup>A Closer Look article, *Electrocautery and Implantable Device Systems* website path: bostonscientific.com > Product Performance Resource Center > A Closer Look Articles > EMI (left side bar). Instructions for Use manuals website path: bostonscientific.com > Cardiac Rhythm Management > Physician Instructions for Use.