

Portable Multimedia Players and Implantable Pacemakers and Defibrillators

SUMMARY

Boston Scientific CRM has performed testing to identify potential interactions that may occur between portable multimedia players and implantable pacemakers and defibrillators. Testing suggests that multimedia players will not interfere with the operation of the implanted device; however, precautions should be taken with respect to other components of the player.

To prevent unwanted telemetry interference in a clinic, hospital, or at home using a LATITUDE Wandless Communicator, multimedia players should be turned Off or placed at least 30 cm (12 in) away from the wand.

CRM PRODUCTS REFERENCED

All Boston Scientific ICD, CRT-D, CRT-P, and Pacing Systems.

The following are trademarks of Cardiac Pacemakers Inc., a Boston Scientific company: ZOOM, LATITUDE, and ZIP Wandless Telemetry

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

CRT-D: Cardiac Resynchronization Therapy Defibrillator

CRT-P: Cardiac Resynchronization Therapy Pacemaker

ICD: Implantable Cardioverter Defibrillator

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Portable multimedia players are small electronic devices that can store and play back digital media (Figure 1). These devices include components such as the base unit (player), headphones (including earbuds), and sometimes an integrated cellular phone. Each of these components generates electromagnetic fields that must be evaluated for potential electromagnetic interference (EMI).



Figure 1. Examples of portable multimedia players.

Testing for Potential EMI

EMI occurs when the electromagnetic field of one electronic device interferes with the intended operation of another electronic device. Some electronic devices encountered on a daily basis generate electromagnetic signals that can interfere with an implanted pacemaker or defibrillator. Interference and its effects are typically temporary and can be eliminated if the patient increases the distance between themselves and the source of EMI.

Because portable multimedia players are commonly used or carried in a breast/shirt pocket or on an armband, they are in close proximity to a pacemaker or defibrillator typically implanted in the chest/torso region. Boston Scientific tested various players¹ and accessory components to determine if they could be a source of EMI to an implanted pacemaker or defibrillator:

- Certain brands/models of **headphones**, including **earbuds**, used with multimedia players contain strong magnets in the earpiece. As described in the pacemaker and defibrillator instructions for use, exposure to strong magnetic fields >10 Gauss (1 mTesla) may alter implanted device function. Because some headphones or earbuds contain magnets with magnetic fields of >10 Gauss, patients should not carry headphones or earbuds in their shirt/breast pocket within 15 cm (6 in) of the implanted device.
- **Cellular phones** may cause an implanted device to sense and misinterpret the electromagnetic signals as a rapid heart signal, as described in the pacemaker and defibrillator instructions for use. Therefore, patients should not carry multimedia players with an integrated cellular phone in their breast/shirt pocket or on a belt within 15 cm (6 in) of the implanted device, or within 30 cm (12 in) of the implanted device if the phone transmits more than 3 Watts.
- Testing of the **multimedia player** itself was performed to simulate an environment outside the hospital or clinic as well as an environment specific to a device-programmer communication session inside a hospital or clinic. **NOTE: For this testing, cellular phone functionality was disabled.**

Away from the hospital or clinic: At no time during testing did the player impede the ability of the pacemaker or defibrillator to sense or deliver pacing and/or shock therapy, regardless of the distance between the player and the implanted device.

At the hospital or clinic, specific to an interrogation session between the implanted device and ZOOM® LATITUDE® programmer:

- Radio frequency (RF) telemetry session:² No interference of any kind was observed when the player was turned On and operating within 5 cm (2 in) of the defibrillator.
- Wandless telemetry session: When the player was turned On and placed at least 30 cm (12 in) away from the programmer's telemetry wand during an interrogation session, telemetry interference was not observed. When the player was turned On and placed within 5 cm (2 in) of the wand, telemetry interference was observed on the programmer; however, this interference did not affect pacemaker or defibrillator function (pacing, sensing and defibrillation). At no time during testing was partial programming observed; programming was either completely successful, or no changes were made.

NOTE: The Food & Drug Administration's Office of Science and Engineering Laboratories (OSEL) conducted a study to determine if the Apple iPod portable music player could interfere with pacemaker function. The OSEL concluded that the Apple iPod players tested could not interfere with implanted pacemakers based on the field levels generated by the players tested. Boston Scientific tests its pacemakers for compliance with the Industry Standard AAMI PC-69 which includes testing at levels greater than the levels generated by the portable music players evaluated and reported in the OSEL study.³

Evaluation of the LATITUDE[®] Patient Management System

The LATITUDE Patient Management system uses either the Wanded Communicator or the Communicator with ZIP[™] Wandless Telemetry (RF telemetry) to communicate with compatible Boston Scientific defibrillators. Evaluation suggests that during an interrogation session between the Communicator and the implanted device:

- RF telemetry used by the Communicator with ZIP Wandless Telemetry to interrogate defibrillators is not susceptible to the telemetry interference described above.
- Wanded telemetry used by the Wanded Communicator to interrogate defibrillators may be susceptible to the telemetry interference described above when an operating portable multimedia player is within 5 cm (2 in) of the Communicator wand during interrogation.

Testing Summary

While testing suggests that the portable multimedia player itself should not interfere with the function of an implanted pacemaker or defibrillator, many multimedia players contain components and accessories (e.g., cellular phone and headphones) that may be sources of EMI.

Frequently Asked Questions

Can the patient carry their portable multimedia player on an armband (Figure 2)? Yes. Patients may carry their portable multimedia player on an armband, as Boston Scientific's testing shows that the player should not interfere with the operation of their implanted pacemaker or defibrillator.

Should the patient carry the portable multimedia player or earbuds in their breast/shirt pocket?

No. While the multimedia player itself should not interfere with the operation of the implanted device, the integrated cell phone or headphones/earbuds may be sources of EMI, and should not be stored within 15 cm (6 in) of the implanted device (e.g., in their breast/shirt pocket).

Should the patient listen to the multimedia player while their implanted device is being interrogated by a ZOOM LATITUDE programmer or a LATITUDE Communicator? No.

Patients should not listen to their multimedia player during an interrogation session. Portable multimedia players should be turned Off or placed at least 30 cm (12 in) away from the telemetry wand during the telemetry session. Telemetry interference can occur during a wanded telemetry session using the ZOOM LATITUDE programmer or LATITUDE Wanded Communicator.

Additional Information

For additional information on how pacemakers and defibrillators respond to magnets, cellular phones or other potential sources EMI, please contact CRM Technical Services or refer to the following resources on Boston Scientific's web site:

- Physician Instructions for Use web page⁴—includes product "System Guides"
- **A Closer Look** web page⁵—includes educational articles such as *Cellular Phones and Implantable Devices*
- Living with Your Implanted Device web page⁶—includes general information on EMI, common items that may cause EMI, and general precautions for patients



Figure 2. Functioning portable multimedia player attached to armband.

¹Portable multimedia players tested: Apple iPod (third generation #A1040 and fifth generation # A1136), Apple iPod Nano #A1236, Apple iPod Mini #1051, Apple iPhone #A1203; Creative Zen V; and Motorola MOTO Q.

² RF telemetry in Boston Scientific defibrillators and programmers operate in a higher frequency band, outside of the frequency range of spurious noise generated by the multimedia player function of the products evaluated. The multi-media/music player peak emissions were centered near 250 kHz (wanded telemetry range) and extended up to 30 MHz. These peak emissions are well below the range of RF telemetry operation (869-928 MHz).

³OSEL FY2007 Annual Report page. U.S. FDA Web site. Available at <http://www.fda.gov/cdrh/osel/annualreports/fy2007/#a>. Accessed on February 18, 2009.

⁴Instructions for Use manuals website path: bostonscientific.com > Cardiac Rhythm Management > Physician Instructions for Use

⁵**A Closer Look** article website path: bostonscientific.com > Product Performance Resource Center > A Closer Look Articles > EMI

⁶Living with Your Implanted Device website path: bostonscientific.com > Cardiac Rhythm Management > Living with Your Implanted Device