

Portable Multimedia Players and Implantable Device Systems

SUMMARY

Boston Scientific CRM has performed testing to identify potential interactions that may occur between portable multimedia players and implantable pacemakers, CRT-Ps, ICDs, and CRT-Ds (referred to herein as pacemakers and defibrillators). Testing suggests that the players will not interfere with the operation of an implanted pacemaker or defibrillator. To prevent wanted telemetry interference in a clinic, hospital, or at home using a Wanded Communicator, portable multimedia players should be turned Off or placed at least 30 cm (12 in) away from the programming wand.

Multimedia players with integrated cell phone function require additional considerations relative to potential interference with implanted devices.

ICD: Implantable Cardioverter
Defibrillator

CRT-D: Cardiac Resynchronization
Therapy Defibrillator

CRT-P: Cardiac Resynchronization
Therapy Pacemaker

CRM PRODUCTS REFERENCED*

All ICD, CRT-D, CRT-P and pacing systems,
ZOOM® LATITUDE® Programmer, and
LATITUDE® Patient Management System

*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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Electromagnetic Interference

Electromagnetic interference (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.

Portable Multimedia Players

Portable multimedia players are small electronic devices that can store and play back digital media such as music and/or video recordings (e.g., Apple iPod). Some multimedia players also function as a cellular phone (e.g., MOTOROLA Moto Q or Apple iPhone). Like all electronic devices, these consumer devices generate electromagnetic fields.

Boston Scientific has performed testing to determine if various portable multimedia players¹ could be a source of EMI to implanted devices. Testing was performed to simulate an environment outside the hospital or clinic and an environment specific to a device-programmer communication session inside a hospital or clinic.

NOTE: If the portable multimedia player included an integrated cellular phone, phone functionality was disabled (turned Off) for this testing. Refer to product literature or the **A Closer Look** entitled “Cellular Phones and Implantable Devices” for testing results and recommendations regarding potential cellular phone interference.²

Test results for an environment away from the hospital or clinic

At no time during this testing did an operating multimedia 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.

If the cellular phone is turned Off, testing for this environment indicated that a patient could carry an operating multimedia player in close proximity to their implanted pacemaker or defibrillator (e.g., in a shirt pocket or on an arm-band), and the player should not interfere with the operation of their implanted device.

Test results for a device-programmer communication session inside a clinic or hospital RF communication session

No interference of any kind was observed when the portable multimedia player was turned On and operating within 5 cm (2 in) to a defibrillator during an RF telemetry session. RF telemetry in Boston Scientific’s defibrillators and ZOOM® LATITUDE® programmers operate in a higher frequency band, outside of the frequency range of spurious noise generated by the portable multimedia player function of the products evaluated.³

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

²Boston Scientific pacemakers and defibrillators comply with ANSI/AAMI PC69 standards, which are based on the use of a typical cellular phone held 15 cm (6 in) from the implanted device. Test requirements were for the frequency range of 450 MHz to 3,000 MHz. Source: ANSI/AAMI PC69:2007. *Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators.*

³The 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).

Wanded communication session

When the multimedia player was turned On and placed at least 30 cm (12 in) away from the ZOOM LATITUDE programmer's telemetry wand during a communication session, telemetry interference was not observed.

When the multimedia player was turned On and placed within 5 cm (2 in) of the wand during a communication session, telemetry interference was observed; however, under no circumstances were pacemaker and defibrillator functions (pacing, sensing and defibrillation) affected. During telemetry interference, noise signals and extra electrogram markers occasionally appeared on both the programmer display and the printed real-time electrograms. In the presence of significant interference, programming could not be completed. When there was a disruption of the telemetry link, the programmer displayed an "Out-of-range/Telemetry Noise" pop-up message. Interrogation and/or programming activities were either lengthened or prevented during telemetry link disruption. At no time during testing, was partial programming observed; programming was either completely successful, or no changes were made.

Evaluation of the LATITUDE® Patient Management system

The LATITUDE Patient Management system uses either the Wanded Communicator or the Communicator with ZIP™ Wandless Telemetry to communicate remotely with compatible Boston Scientific defibrillators so that data can be collected and transferred to a central database.

Evaluation of the Communicator with ZIP™ Wandless Telemetry suggests that it is not susceptible to telemetry interference described above. Evaluation of the Wanded Communicator may be susceptible to telemetry interference when an operating portable multimedia player is within 5 cm (2 in) to the Communicator wand during interrogation.

Summary

The Testing Boston Scientific CRM conducted suggests that:

For portable multimedia players without a built-in cellular phone:

- Patients may carry the player in close proximity to their implanted device (e.g., in a shirt pocket or on an arm band), and the player should not interfere with the operation of their implanted device.
- Telemetry interference should not occur during RF telemetry sessions, even if the player is operating in close proximity to the implanted device during the RF telemetry session.
- Telemetry interference can occur during wanded telemetry sessions; therefore, in the clinic, hospital, or at home using a Wanded Communicator, portable multimedia players should be turned Off or placed at least 30 cm (12 in) away from the programming wand during the telemetry session.

For portable multimedia players with a built-in cellular phone:

- If the cellular phone is turned Off, patients may carry the player in close proximity to their implanted device (e.g., in a shirt pocket or on an arm band), and the player should not interfere with the operation of their implanted device.
- If the cellular phone is turned On, it can be a source of EMI to the implanted device. Refer to product literature, the **A Closer Look** entitled *Cellular Phones and Implantable Devices*, or CRM Technical Services for testing results and recommendations regarding potential cellular phone interference.
- Telemetry interference can occur during wanded telemetry sessions; therefore, in the clinic, hospital, or at home using a Wanded Communicator, portable multimedia players should be turned Off or placed at least 30 cm (12 in) away from the programming wand during the telemetry session.