

Radiofrequency Identification and Implantable Pacemakers and Defibrillators

SUMMARY

The U.S. Food and Drug Administration conducted a study to evaluate the electromagnetic compatibility between certain types of radiofrequency identification (RFID) systems and implantable cardiac pacemakers and defibrillators.

The study authors reported that although they believe the study did not reveal an urgent public health risk, they were concerned that the continued proliferation of RFID technology without taking implantable pacemaker and ICD electromagnetic compatibility into consideration could potentially cause clinically significant events for patients. Additionally, the authors believe that further testing is warranted.

CRM PRODUCTS REFERENCED

All Boston Scientific pacemakers, ICDs, CRT-Ds, and CRT-Ps
The following are trademarks of Cardiac Pacemakers Inc., a Boston Scientific company: INSIGNIA and ALTRUA.

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

CRM CONTACT INFORMATION

United States
www.bostonscientific.com
Technical Services – U.S.
LATITUDE Clinician Support – U.S.
 1.800.CARDIAC (227.3422)
 +1.651.582.4000
 tech.services@bsci.com
 latitude@bsci.com
Patient Services
 1.866.484.3268

International
www.bostonscientific-international.com
Technical Services – Europe
 +32 2 416 7222
 eurtechservice@bsci.com
International LATITUDE Customer Support
www.latitude.bostonscientific-international.com
 latitude.international@bsci.com

What is RFID?

Radiofrequency identification (RFID) is a wireless technology used to identify RFID tags mounted on objects or carried by (or embedded in) people or animals. Data stored in the RFID tag is read by wireless devices, called RFID readers. The RFID reader contains one or more RF antennas that emit RF signals within a specified range. When an RFID tag enters the reader's RF signal field, information stored in the tag is captured by the reader (Figure 1). Each RFID tag relies on the reader to transmit information contained in the tag. Table 1 provides examples of RFID applications in public and occupational settings.

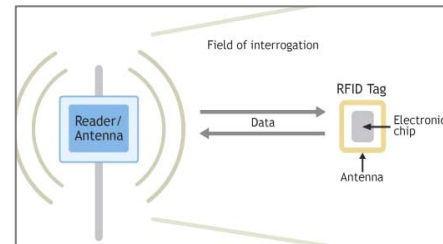


Figure 1. Example of RFID system operation.¹

Table 1. Examples of RFID Applications

| Retail Tracking | Payment Processing |
|--|--|
| (examples include theft prevention, library book check-out, and pharmaceutical tracking) <div style="display: flex; justify-content: space-around;">   </div> <p>Anti-theft RFID reader.^a Handheld RFID reader used for inventory management.^b</p> | (examples include toll booths and mass transit ticketing) <div style="display: flex; justify-content: space-around;">   </div> <p>RFID toll collection.^c RFID ticketing for subways.^d</p> |
| Access Management | |
| (examples include access for buildings, parking lots, marinas and international travel) | |
| <div style="display: flex; justify-content: space-around;">    </div> <p>RFID access to community.^e Passport card RFID reader.^f RFID marina access control.^g</p> | |
| <p><small>a http://www.rfid-library.com/e_rf06.htmlhttp://www.rfid-library.com/e_rf06.html. Accessed September 29, 2009.</small> b http://www.gaorfid.com/index.php?main_page=index&cPath=97. Accessed September 29, 2009. c http://www.phalsan.com/toll-collection-system. Accessed September 29, 2009. d http://embeddedsystemnews.com/seoul-subway-uses-rfid-technology-from-stmicroelectronics-for-ticketing-in-mass-transportation.html. Accessed September 29, 2009. e http://www.archiexpo.com/prod/vingcard/rfid-reader-for-access-control-10481-34254.html. Accessed September 29, 2009. f http://www.economist.com/sciencetechnology/displaystory.cfm?story_id=14066895. Accessed September 29, 2009. g http://www.maritimetrackingsystems.org.uk/id2.html. Accessed September 29, 2009.</p> | |

Electromagnetic Interference

Electromagnetic interference (EMI) occurs when electromagnetic waves from one electronic device interfere with and cause an undesired response in another electronic device. When an electronic device interferes with the intended operation of an implanted pacemaker or defibrillator, the effects of the EMI are usually temporary and can typically be eliminated by moving away from the noise source.

Like most electronic devices, RFID systems generate electromagnetic waves, which can vary in amplitude and frequency. The operating frequency chosen for a specific RFID system often depends on its application (Figure 2). Some RFID readers may potentially produce electromagnetic fields of sufficient amplitude and/or frequency to interact with an implanted cardiac device. Whether or not an RFID reader will interfere with an implanted pacemaker or defibrillator depends on a number of technical parameters (e.g., frequency, power, pulse repetition rate, pulse width, modulation, distance/location/orientation), most of which are unknown to device patients in the vicinity of these systems.

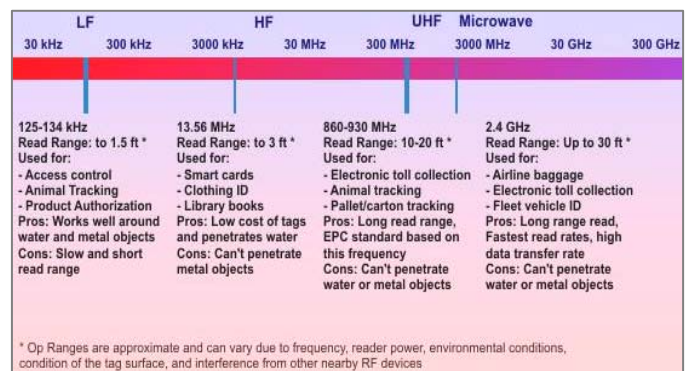


Figure 2. Examples of RFID applications in various frequency bands.²

Evaluation of RFID

The Food and Drug Administration Center for Device and Radiological Health evaluated electromagnetic compatibility between RFID systems and implantable cardiac pacemakers and defibrillators.³ The study was developed with support of the Association for the Advancement of Medical Instrumentation (AAMI) Cardiac Rhythm Management Devices Electromagnetic Compatibility Task Force and investigated in-vitro (simulated) interaction between RFID readers⁴ and implantable pacemakers and defibrillators.

Thirty implantable cardiac devices from various manufacturers and thirteen RFID readers were tested. The RFID readers used in this study operated in three commonly used frequency bands—low frequency (LF), high frequency (HF), and ultra high frequency (UHF). Potential interactions were classified as:

- Class I: Temporary ventricular inhibition ≥ 3 seconds, any permanent change in programmed settings, or inappropriate tachycardia therapy
- Class II: Temporary ventricular inhibition for > 2 seconds, but < 3 seconds
- Class III: Inappropriate pacing, atrial inhibition, ventricular inhibition for ≤ 2 seconds, noise reversion mode, and all other types of device reactions not in Class I or Class II

Interactions were not observed in the UHF band, while Class I and III interactions were observed in both the LF and HF bands, with interactions being most prevalent at LF. The separation distances where interactions occurred in the study ranged from 2.5 to 60 cm. For Boston Scientific devices, Class I interactions ranged from 2.5 to 40 cm for pacemakers and from 2.5 to 7.5 cm for ICDs, CRT-Ds and CRT-Ps. Table 2 lists suggested separation distances for patients implanted with a Boston Scientific cardiac device:

| Device Type | Separation Distance |
|--------------------------|--|
| Pacemakers | INSIGNIA [®] and ALTRUA [®] : 40 cm (1.5 ft) All other Boston Scientific pacemakers: 60 cm (2 ft) |
| ICDs, CRT-Ds, and CRT-Ps | 15 cm (6 in) |

IMPORTANT NOTES:

- The study authors cited many study limitations including programmable device sensitivity, lead configurations, RFID reader antenna orientation relative to the implant, and in-vitro as opposed to in-vivo testing. For this reason, test results may not be predictive of the actual clinical experience of a patient with an implanted pacemaker or defibrillator. It is possible that an individual patient may not encounter any interference at distances closer than those shown above; similarly, the above distances cannot be guaranteed as safe for all patients in all situations.
- The authors reported that although they believe the study did not reveal an urgent public health risk, they were concerned that the continued proliferation of RFID technology without considering implantable pacemaker and ICD electromagnetic compatibility could potentially cause clinically significant events for patients. Additionally, the authors believe that further testing is warranted.

Precautions for Patients in the Presence of EMI

Although implanted cardiac pacemakers and defibrillators are designed to function normally around most appliances and equipment, patients and their cardiologists should be aware that RFID readers may be a potential source of EMI and could have temporary effects on implanted cardiac devices. Because the presence of RFID systems may not always be apparent in public and occupational settings, patients who feel symptomatic (e.g., light-headed, fast heart rate) should move away from nearby electrical equipment (or the identifiable RFID system), and call their physician to report the episode.

Boston Scientific believes that based on the study's sample size and test methodology, and recognizing its limitations, maintaining the suggested separation distances described in Table 1 between an RFID reader and an implanted Boston Scientific cardiac pacemaker or defibrillator should minimize the likelihood of encountering interaction. As always, it is best to maintain the furthest distance possible from a suspected source of EMI.

Frequently Asked Questions

Q1. What is the potential for RFID to interact with an implanted device?

A1. Unlikely, unless the patient is in close proximity to an RFID reader. See Table 2 for suggested separation distances.

Q2. Is RFID utilized in bar code readers?

A2. No. Bar code readers use visible light to perform their designed function and are not a source of EMI to implantable pacemakers or defibrillators.

Q3. Should patients be concerned with RFID tags?

A3. To date, RFID tags have not been identified as sources of EMI to implanted cardiac devices.

Q4. Who should patients talk to regarding potential EMI and their implanted device?

A4. Patients should talk to their physician if they have any questions specific to their implanted device, including EMI-related topics.

Q5. Is there information available to patients regarding other potential sources of EMI to their implanted device?

A5. Boston Scientific's Living with Your Implanted Device web page includes an overview of some common items that create EMI. The page can be accessed by going to www.bostonscientific.com > Cardiac Rhythm Management > Living with Your Implanted Device.

Q6. Are there industry standards that reduce the likelihood of EMI to implantable devices?

A6. While medical device standards are intended to address device susceptibility to EMI, they cannot encompass every piece of technology. Therefore, there may be a need to review and/or test a specific or new piece of technology to understand if there are potential interactions. While individual technologies meet their respective standards, this does not guarantee compatibility when the two are brought together. The AAMI PC-69 standard includes an informative Annex M (2007 Edition) that provides manufacturers of electromagnetic emitters with information about the level of immunity to be expected from active implantable pacemakers and defibrillators.

¹ How does it work? web page. Trevis Consulting web site. Available at http://www.trevis-consulting.com/index_uk.php?page=page2 Accessed September 23, 2009.

² Passive RFID Frequency web page. Acquisition Community Connection web site. Available at <https://acc.dau.mil/CommunityBrowser.aspx?id=143395> Accessed September 23, 2009.

³ Articles in Press web page. Heart *Rhythm* Journal web site. In Vitro Tests Reveal Sample Radio Frequency Identification Readers Inducing Clinically Significant Electromagnetic Interference to Implantable Pacemakers and Implantable Cardioverter Defibrillators. Full-text PDF available for registered users. Abstract available at [http://www.heartrhythmjournal.com/article/S1547-5271\(09\)01146-1/abstract](http://www.heartrhythmjournal.com/article/S1547-5271(09)01146-1/abstract). Accessed October 13, 2009.

⁴ RFID readers from passive tag systems were used in the study, as their readers are generally known to emit stronger electromagnetic fields than those from active tag systems.