SUMMARY

Radiofrequency identification (RFID) is a wireless technology that may potentially cause clinically significant events for patients. This article discusses different types of RFID technology and precautions for patients exposed to Electromagnetic Interference (EMI) from these devices.

Products Referenced

All referenced Boston Scientific pacemakers, ICDs, CRT-Ds, CRT-Ps, and S-ICDs

For comprehensive information on device operation, reference the full instructions for use found at: **www.bostonscientific-elabeling.com**.

CAUTION: Law restricts this device to sale by or on the order of a physician. Indications, contraindications, precautions and warnings can be found with product labeling supplied with each device. Products referenced herein may not be approved in all geographies.Information is for the use in countries with applicable Health Authority product registrations.

All graphics produced by Boston Scientific Corporation, unless otherwise noted.

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

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Radiofrequency Identification and Implantable Pacemakers and Defibrillators

What is RFID?

Radiofrequency identification (RFID) is a wireless technology used to identify RFID tags mounted on objects or carried by/embedded in people or animals. Data stored in the RFID tag is read by RFID readers, wireless devices that contain one or more RF antennas. These antennas 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. Examples of RFID applications in public and occupational settings are provided in Figure 2.

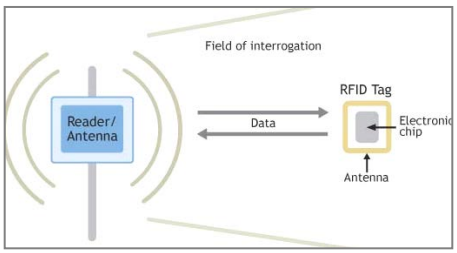

Figure 1. Example of RFID system operation.[1]

Figure 2. Examples of RFID Applications

Retail Tracking
(e.g., theft prevention, library book check-out, and pharmaceutical tracking)

Anti-theft RFID reader.[a]

Handheld RFID reader (inventory mgmt.[b])

Payment Processing
(e.g, toll booths and mass transit ticketing)

RFID toll collection.[c]

RFID subway ticketing [d]

Access Management
(e.g., buildings, parking lots, marinas, and international travel)

RFID access to community.[e]

Passport card RFID reader.[f]

RFID marina access control.[g]

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 (Table 1). 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.

ITU Designation Frequency	LF 30 kHz 300 kHz	HF 3000 kHz 30 MHz	UHF 300 MHz	Microwave 3000 MHz 30 GHz 300 GHz
Range	125–134 kHz	13.56 MHz	860-930 MHz	2.4 GHz
Read Range	0 to 1.5 ft*	0 to 3 ft*	10-20 ft*	0-30 ft*
Used for:	Access control Animal tracking Product Authorization	Smart cards Clothing ID Library books	Electronic tolls Animal tracking Pallet/carton tracking	Airline baggage Electronic tolls Fleet vehicle ID
Pros	Works well around water and metal objects	Low cost of tags Penetrates water	Long-read range Base of EPC Standard	Long-range read Fastest read rates High data transfer rate
Cons	Slow Short read range	Can't penetrate metal	Can't penetrate metal Can't penetrate water	Can't penetrate metal Can't penetrate water

Table 1. Examples of RFID applications in various frequency bands.

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.[2] The study was developed with support of the Association for the Advancement of Medical Instrumentation Cardiac Rhythm Management Devices Electromagnetic Compatibility Task Force and investigated in-vitro (simulated) interaction between RFID readers[3] and implantable pacemakers and defibrillators.

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

- 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 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. The data in Table 2 reflects currently marketed Boston Scientific implantable devices based on testing evidence obtained after the completion of the referenced study.

Separation Distances Suggested for Patients Implanted with Boston Scientific Devices		
Device Type	**Device Family**	**Separation Distance**
Pacemakers	PULSAR MAX®, PULSAR MAX® II, DISCOVERY®, DISCOVERY®II, MERIDIEN®	60 cm (2 ft)
	INSIGNIA® , ALTRUA™	40 cm (1.5 ft)
	CONTAK RENEWAL® TR/TR2, ADVANTIO™, INGENIO™, VITALIO™, FORMIO™, INVIVE™, INTUA™, INLIVEN™, ALTRUA™ 2, ESSENTIO™, PROPONENT™, ACCOLADE™, VALITUDE™ , VISIONIST™	15 cm (6 in)
Defibrillators	All ICD, CRT-D, and S-ICD Device Families	15 cm (6 in)

Table 2. Suggested separation distance between RFID source (transmit antenna) and implanted device.

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's evidence suggests that maintaining the Table 2 separation distances (measured between an RFID reader and an implanted Boston Scientific cardiac pacemaker or defibrillator) should minimize the likelihood of encountering interaction. This expectation is based on the study's sample size and test methodology. 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. Interaction is 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 our website, www.bostonscientific.com, and searching "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 ANSI/AAMI/ISO 14117:2012 (formerly AAMI PC-69) standard includes an informative *Annex M* that provides manufacturers of electromagnetic emitters with information about the level of immunity to be expected from active implantable pacemakers and defibrillators.

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

[2] Current Issue 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. Accessed July 26, 2017.

[3] 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.

a http://www.rfid-library.com/e_rf06.htmlhttp://www.rfid-library.com/e_rf06.html. Accessed September 29, 2009.
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e http://www.archiexpo.com/prod/vingcard/rfid-reader-for-access-control-10481-34254.html. Accessed July 26, 2017.
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