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.

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.

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

<table>
<thead>
<tr>
<th>ITU Designation</th>
<th>LF</th>
<th>HF</th>
<th>UHF</th>
<th>Microwave</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>30 kHz</td>
<td>300 kHz</td>
<td>3000 kHz</td>
<td>30 MHz</td>
</tr>
<tr>
<td>Range</td>
<td>125–134 kHz</td>
<td>13.56 MHz</td>
<td>860-930 MHz</td>
<td>2.4 GHz</td>
</tr>
<tr>
<td>Read Range</td>
<td>0 to 1.5 ft*</td>
<td>0 to 3 ft*</td>
<td>10-20 ft*</td>
<td>0-30 ft*</td>
</tr>
<tr>
<td>Used for:</td>
<td>Access control</td>
<td>Animal tracking</td>
<td>Product Authorization</td>
<td>Smart cards</td>
</tr>
<tr>
<td>Pros</td>
<td>Works well around water and metal objects</td>
<td>Low cost of tags</td>
<td>Long-read range</td>
<td>Base of EPC Standard</td>
</tr>
<tr>
<td>Cons</td>
<td>Slow</td>
<td>Short read range</td>
<td>Can't penetrate metal</td>
<td>Can't penetrate metal</td>
</tr>
</tbody>
</table>

**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. 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 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

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Device Family</th>
<th>Separation Distance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pacemakers</td>
<td><strong>PULSAR MAX®</strong>, <strong>PULSAR MAX® II</strong>, <strong>DISCOVERY®</strong>, <strong>DISCOVERY® II</strong>, <strong>MERIDIEN®</strong></td>
<td>60 cm (2 ft)</td>
</tr>
<tr>
<td></td>
<td><strong>INSIGNIA®</strong>, <strong>ALTRUA™</strong></td>
<td>40 cm (1.5 ft)</td>
</tr>
<tr>
<td>Defibrillators</td>
<td>All ICD, CRT-D, and S-ICD Device Families</td>
<td>15 cm (6 in)</td>
</tr>
</tbody>
</table>

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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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.

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