

Evaluation of Current Literature to Determine the Potential Effects of Radio Frequency Identification on Technology Used in Diabetes Care

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Abstract

This article examines recently published studies exploring the impact of radio frequency identification (RFID) systems on the technology involved in patient care. The conclusions will be extrapolated to include insulin delivery devices. Background material will also be presented to support examination of the variables involved in electromagnetic fields and potential interference from these RFID systems.

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Introduction

The use of radio frequency identification (RFID) techniques is pervasive throughout both the clinical setting and the commercial world. Applications vary widely from tracking sponges during surgery to locker rentals at amusement parks. Creative applications continue to emerge encouraged by falling RFID tag costs. With this in mind, it is difficult to predict the possible and probable exposure of all kinds of medical technology to the electromagnetic fields generated by these systems. Instead, an evaluation of the impact of RFID on the technology that currently exists or may be designed in the future must include an understanding of recent testing results. In addition, one must have a solid comprehension of the relationships among interference, distance, and RFID system frequency to evaluate potential device performance impact.

Radio frequency identification systems fundamentally contain two parts: a tag and a two-way device—a reader/antenna. The reader/antenna sends out a signal at a specific frequency. The tag has a tiny antenna that can pick up this signal and use it to power circuitry that will generate a reflected signal. The reflected signal is picked up by the antenna reader, which can interpret data in the tag-generated signal. This allows identification of the unique signature associated with the tag. The tags themselves can be active (battery powered), passive (use the energy of the antenna), or some combination of active and passive and are often placed on devices, people, and pets.

The area of potential interference relates to the electromagnetic energy emitted from the antenna when

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Abbreviations: (EMF) electromagnetic fields, (EMI) electromagnetic interference, (ICD) implantable cardiac defibrillator, (RFID) radio frequency identification

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it is broadcasting. This magnetic field can potentially interfere with the functioning of electronics of almost any kind, that is, the small electronic components and wires that make up a device do not perform as intended or in a functional, predictable way. Some interference can also occur as signals are transmitted wirelessly between components (perhaps through skin and tissue). However, because signals generally have a reserved, specific frequency, not shared with other devices, this second type of signal interference is not a primary concern with RFID systems.

In addition, it is important to note that the tags themselves do not produce enough electromagnetic energy to have an impact on the function of electronics. The electromagnetic fields are generated in varying strength from the antennas. The antennas needed for the two different types of tags do vary in their power intensity. Passive tag antennas generally produce higher power electromagnetic fields than active tag antennas.

Recent studies provide some clues to the understanding of the impact of antenna electromagnetic power on the technology used in patient care. Unfortunately, a complete, thorough investigation is hampered in two ways. First, no study will mirror all real-world applications, situations, and configurations. Second, only a few studies have been published. However, careful consideration of the tests performed previously and an understanding of the underlying physics can lead to general conclusions for specific applications.

Essentially, there are two concerns for insulin delivery devices. First, is the device in the presence of a significant electromagnetic field? Several variables impact the strength of an electromagnetic field, including antenna power, frequency, and distance from the source. Second, is that electromagnetic field impacting the performance of the electronics inside the device? Actual, observed performance alterations can vary widely.

Electromagnetic Interference (EMI) and Distance

The relationship between distance and electromagnetic field strength is both nonlinear and critical to an evaluation of the impact of RFID antennas on electronic performance. A graphical representation of the relationship is shown in **Figure 1**. Upon first inspection, one can see that a very strong electromagnetic field is present when the distance between the antenna and the device is small. In addition, this distance is related to the wavelength of

the source. The wavelength can be determined using the equation

$$\text{Wavelength (in meters)} = \frac{3 \times 10^8 \text{ meters/second}}{\text{Frequency of the antenna in hertz}}$$

Using this equation and examination of the shape of the function, important junctures in the graph can be used to demarcate field strength variations and its potential impact on technology. First, there is a point on the graph where the field strength is approximately zero. This distance can be identified for various types of antennas:

- Lowest frequencies antennas (125 kHz)—5.8 meters
- High-frequency antennas (2.4 GHz)—0.91 meters

One can conclude that beyond these distances, there is negligible magnetic field strength and negligible likelihood of interference in the performance of electronic devices.

Second, there is a section of the graph where field strength is consistently at its highest. This distance can be identified for various types of antennas:

- Lowest frequencies antennas (125 kHz)—less than 24.4 cm
- High-frequency antennas (2.4 GHz)—less than 1.3 cm

One can conclude that there would be a high probability of intense electromagnetic field strength and possible interference if a medical device and an antenna were together within these distances.

Field strength is related not only to distance from the antenna but also to antenna power. Active tag readers are commonly milliwatts in strength, and passive tag readers are in the order of 2–4 watts.

Guidelines from American National Standards Institute

Annex C of Standard C63.18 provides recommendations for the mitigation of electromagnetic interference.¹ Lengthy and detailed, these guidelines can be filtered for general suggestions, which guide RFID/medical device interactions. In addition, it also can form the foundation for policies and implementation strategies for engineers and clinicians. One could summarize the information to draw the following conclusion: medical equipment should have a level of inherent electromagnetic immunity so that a minimum distance of 3.3 meters from the antenna should ensure interference-free device performance. A complete table of immunity ratings and antenna powers is within the standard, Table C.1. Many other recommendations are available in this standard.

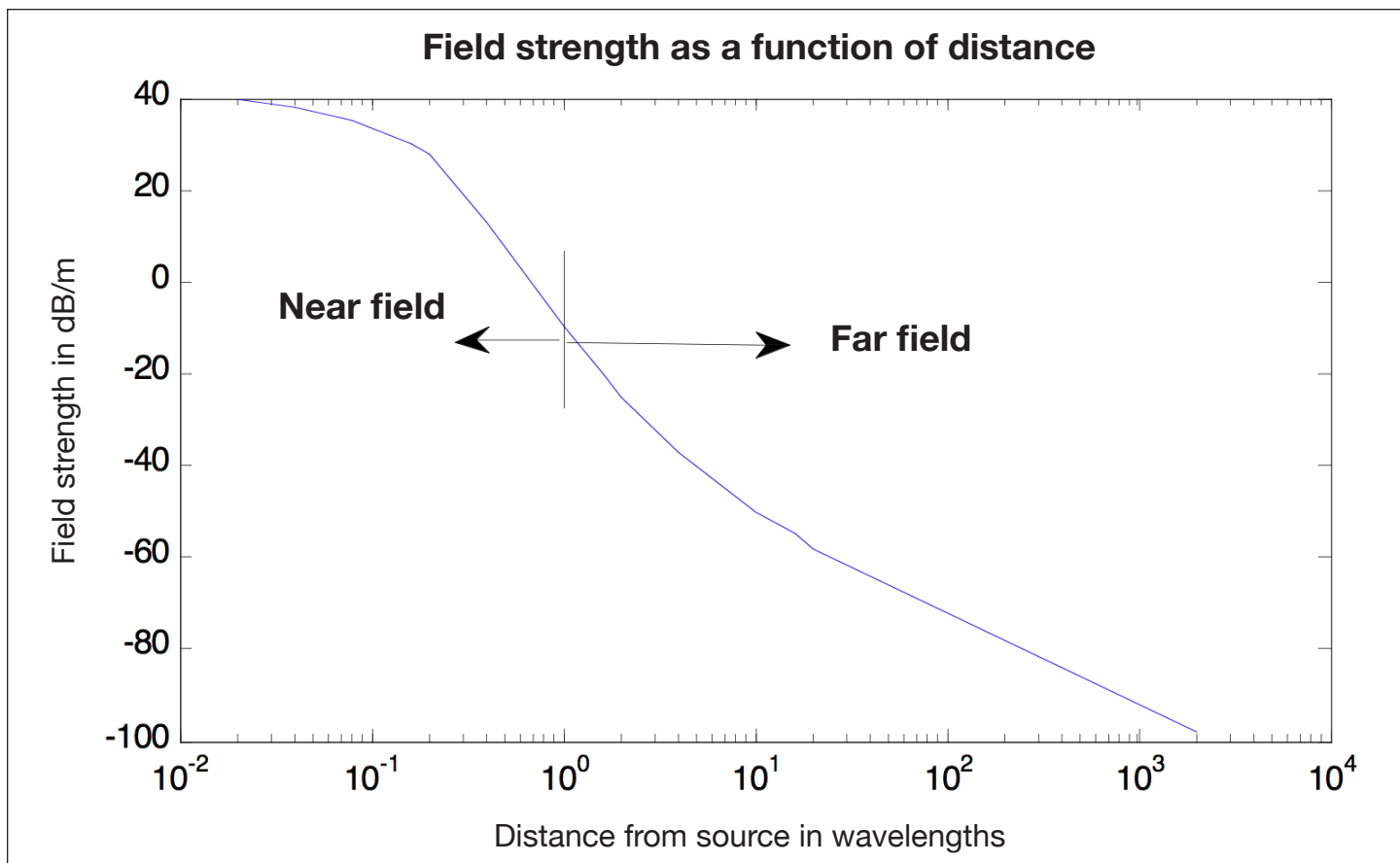


Figure 1. Relationship between electromagnetic field strength and distance.

Common Applications of RFID in the Clinical Setting

As fast as articles can be written and studies can be performed, manufacturers are developing new applications for RFID in the clinical setting. However, a few examples of common applications can be useful in the evaluation of potential electromagnetic interference.

- Infant security systems—many hospitals use RFID to assist in the tracking of neonates in the nursery. Antenna/readers are hidden in the ceiling, and tags are placed on the limbs of patients. These systems employ technology to ensure that tag security cannot be circumvented.
- Asset tracking—high-volume devices, for example, infusion pumps, are tracked using a variety of tag types and antenna placements.
- Sponge counting in surgical cases—sponges labeled with small passive tags are tracked using handheld readers.

In these common scenarios the physical proximity between medical devices and reader/antennas is typically greater than 30 cm. In some cases (infant security), readers/antennas *must* be placed in locations that ensure significant separation from medical equipment in order for the system to function as designed. Essentially, the benefits of RFID include the ability to detect a tag at a distance, no longer needing a line of sight (bar code technology) or human intervention (staff to read an affixed identification code).

Electromagnetic Shielding

While potentially strong electromagnetic fields from RFID antenna/readers are a recent concern, strong EMI from electromagnets has been present in the clinical setting for many years. For example, medical equipment has operated around magnetic resonance imaging devices. Devices are designed carefully using shielding techniques to minimize the impact of electromagnetic fields on operational electronics. Shielding that prevents the passage of electromagnetic waves can be used to limit RFID component interference if necessary.

Methods

A search for published works related specifically to the electromagnetic impact of RFID components to health care technologies yielded few results. In fact, only three studies could be found.

Several Food and Drug Administration engineers and cardiologists performed a study in 2006 that appears in print in the *International Journal of Radio Frequency Identification Technology and Applications* in November 2007.² This study examined the impact of three different antenna frequencies on pacemakers and implantable cardiac defibrillators (ICD). The behavior of the devices was observed during exposure to the electromagnetic fields present from the antennas at an initial distance of 1 meter from the human torso simulator. The antenna was moved toward the torso and the behavior of the defibrillator or ICD was observed. Eighty-three percent of the pacemakers had impacted performance when exposed to electromagnetic fields of a low-frequency antenna (134 kHz). Fifteen percent of the devices showed performance alterations at 13.56 MHz, and 6% of the pacemakers had performance alterations when exposed to the higher frequency antenna (915 MHz). Similar results were reported for the implantable defibrillators tested, 71% were impacted by the low-frequency antenna, and no defibrillators were impacted by the higher frequency antenna. For both devices, distances were at about 50–60 cm when performance alterations occurred. These results are predictable based on the knowledge that, for similar distances, lower frequency antennas have higher electromagnetic field strength compared with higher frequency antennas. This higher strength EMI impacts the devices adversely.

A comprehensive study appeared in the *Journal of the American Medical Association* in June 2008.³ Researchers in The Netherlands tested 17 categories of medical devices in the fields of two antennas: a low-frequency active tag antenna and a higher frequency passive tag antenna. Large amounts of data were generated. In this testing design, interference (in several severity levels) was noted at a wide variety of distances but many as close as 0.1 cm. In general, interference incidents had a median distance of 30 cm. This study showed that, under certain conditions, alteration of medical device performance could be induced based on the close proximity of the antenna to the device. The tiny distances between the antennas and the devices verified that electromagnetic interference is possible, with potentially serious compromised performance. This study caused quite a

stir when the paper was summarized and publicized by the *Associated Press*. Newspapers across the country ran headlines that included dire warnings: “RFID Can Kill You.” It is, however, vital to view this study as a large set of data that simply shows that strong electromagnetic fields can cause device performance problems.

Results of a March 2008 study appeared in *Biomedical Instrumentation and Technology* in December 2008.⁴ This study examined a clinical setting scenario that included a general patient care room and five commonly used types of monitors and devices. The physical layout for testing was selected to reflect real-use applications of RFID in the patient care area. This study examined the effect of passive antennas (two types, near field and far field) at distances that both approximated common-use scenarios. In 1600 tests, no performance alterations were noted. The minimum testing distance was 30.5 cm. It is likely that this paper reached different conclusions than data from The Netherlands mainly because of the different testing distances between device and antenna used in gathering data.

Finally, a brief overview of comprehensive testing that took place at the Georgia Tech Research Institute was presented in a 2008 paper in the *Journal of Diabetes Science and Technology*.⁵ In it, Herkert described the many investigations that examined electromagnetic interference from a variety of sources. While no data are presented (due to the proprietary nature of the work), one important observation is reported: “...nearly all responses observed in the test center in production devices have been temporary in nature, i.e., upon removal of the exposure fields, the devices return to their preexposure as-designed operational states.” This information can assist scientists in identifying, understanding, and troubleshooting electromagnetic interference.

Discussion

These conflicting studies took different approaches to the examination of EMI on medical devices with differing results. Unfortunately, the number of variables limits the direct comparison of one study to another, as well as the application to the clinical setting. All three studies confirm that EMI from RFID systems will impact the performance of electronics under some conditions.

Electromagnetic interference will occur in situations where the antenna (tag reader) is in close proximity to the device. Both data and underlying physical principles validate this premise. Therefore, studies show that

insulin delivery systems and other electronics should not be located near RFID antennas. Fortunately, one of the guiding principles expanding RFID use is the ability to track tagged items at a distance. For example, neonate tracking systems in nurseries draw great benefit from antennas locating infants over a distance. Often antennas are concealed in the ceiling—ensuring a known distance between the antenna and electronic devices. The benefit of these system configurations is forced minimum distances between patient and antenna, severely restricting the probability of the patient getting “too close” to a possible EMI source.

The reader may conclude that this dearth of research and testing on RFID systems with medical technology should spawn a grand, comprehensive study. However, it is important to realize that it is unlikely that an experimental design could include all the relative physical locations of both a medical device, such as insulin pumps, and all types of RFID antennas. In addition, notation of interference in one study will not ensure flawed performance in all cases; conversely, a lack of performance errors will not guarantee flawless performance in similar situations.

To gain additional insight applicable to implanted insulin delivery devices, one can examine the history of EMI and implanted cardiac medical devices. Patients with implanted pacemakers and defibrillators are surrounded by electromagnetic field-generated sources, such as motors. Cardiac patients are educated on the dangers of EMI,⁶ and widespread malfunctions have not been reported. Careful awareness and patient education decrease the likelihood of adverse interactions.

Conclusion

To evaluate the potential of interference and possible device performance alterations due to RFID components, three general, overarching factors must be examined. These factors include device proximity to RFID antenna, the frequency of the system in use, and the power of the antenna (related directly to active or passive tag applications). Antennas generate electromagnetic fields. In addition, it is a principle of physics that the behavior of electronic components can be impacted by these magnetic fields. The potential for unplanned and unacceptable performance requires users of RFID systems and medical devices to be cautious around the antennas of RFID systems. Understanding the conditions when electromagnetic interference can occur is critical as RFID systems applications expand as fast as human

imagination. Clinicians and users of the technology that support patient care must identify potentially hazardous situations and work to avoid the conditions that can cause device faults.

References:

1. Institute of Electrical and Electronics Engineers. American national standard recommended practice for on-site ad hoc test method for estimating radiated electromagnetic immunity of medical devices to specific radio-frequency transmitters (Standard C63.18). Piscataway, NJ: IEEE; 1997.
2. Seidman SJ, Ruggera PS, Brockman RG, Lewis BM, Shein MJ. Electromagnetic compatibility of pacemakers and implantable cardiac defibrillators exposed to RFID readers. *Int J Radio Freq Ident Technol Appl*. 2007;1(3):237-46.
3. Van der Togt R, van Lieshout EJ, Hensbroek R, Beinat E, Binnekade JM, Bakker PJ. Electromagnetic interference from radio frequency identification inducing potentially hazardous incidents in critical care medical equipment. *JAMA*. 2008;299(24):2884-90.
4. Christe B, Cooney E, Maggioli G, Doty D, Frye R, Short J. Testing potential interference with RFID usage in the patient care environment. *Biomed Instrum Technol*. 2008;42(6):479-84.
5. Herkert R. Electromagnetic environmental effects testing of medical devices including those used for the treatment of diabetes. *J Diabetes Sci Technol*. 2008;2(5):809-13.
6. Questions about electromagnetic interference (EMI): living with your ICD [brochure on the Internet]. Minneapolis: Medtronic, Inc; c1998. Available from: http://www.medtronic.com/rhythms/downloads/icd_en199300962cEN.pdf