EXPERT REVIEWS

Radiofrequency identification and medical devices: the regulatory framework on electromagnetic compatibility. Part I: medical devices

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Radiofrequency identification (RFID) technology has acheived significant success and has penetrated into various areas of healthcare. Several RFID-based applications are used in various modalities with the ultimate aim of improving patient care. When a wireless technology is used in a healthcare environment, attention must be paid to the potential risks deriving from its use; one of the most important being electromagnetic interference with medical devices. In this paper, the regulatory framework concerning the electromagnetic compatibility between RFID and medical devices is analyzed to understand whether and how the application of the current standards allows for the effective control of the risks of electromagnetic interference.

Keywords: electromagnetic • interferencemedical device • radiofrequency identification

Radiofrequency identification (RFID) is a technology that uses electromagnetic coupling in the radiofrequency (RF) portion of the electromagnetic spectrum to uniquely identify an object, animal or person. An RFID system consists of a reader (an antenna that acts as the transceiver) and a transponder (the tag). The antenna uses RF waves to transmit a signal that activates the transponder. When activated, the tag transmits data back to the antenna. RFID readers can be either fixed (e.g., a doorway) or portable handheld devices. Tags can be active or passive, that is, with or without an intrinsic power source, respectively.

Healthcare is one of the areas that benefits from RFID [1–6]. Numerous applications are improving patient care by tracking medical devices, drugs, patients and so on [7–12]. However, albeit the advantages, there is one important potential risk: electromagnetic interference with medical devices [13–18], because RFID systems emit electromagnetic waves.

In this paper, the regulatory framework concerning this issue is discussed: standards regarding the electromagnetic immunity of medical devices and the electromagnetic compatibility (EMC) of RFID systems. Specifically, whether and how the application of these standards addresses all the potential risks associated with electromagnetic interference of RFID with medical devices is analyzed.

RFID regulations

RFID operates in unlicensed frequency bands, sometimes referred to as industrial, scientific and medical (ISM), but the exact frequencies that constitute ISM may vary depending on the regulations in force in different countries. Typical RFID frequency bands are reported in Table 1, together with their related maximum transmission power.

RFID systems operating at frequencies up to 13.56 MHz use the inductive coupling of a magnetic field between reader and tag. The reader creates an alternating magnetic field and this induces an electric current in the tag's antenna, which is used to power the integrated circuit and obtain the information (passive tag

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Table 1. Frequency ranges and associated maximum allowed field strengths/emitted powers for radiofrequency identification technology.

Frequency ranges	Maximum field strengths/emitted powers
125 and 134.5 kHz	~64 dBμA/m at 10 m
13.56 MHz	42–60 dBμA/m at 10 m
865–956 MHz	2W
2.45 GHz	2 W, 4 W (USA, Canada)
5.8 GHz	2 W, 4 W (USA,Canada)

technology) or to trigger the tag response (active tag technology). This information is communicated back to the reader by varying the load on the antenna's coil, which changes the current drawn on the reader's communication coil. RFID systems operating at higher frequencies (from 800 MHz) use electromagnetic power. The reader sends radio waves that are reflected back by the tag's antenna. During the process, the tag encodes the signal to be reflected with its information using a modulation (i.e., shifting the amplitude or phase of the waves returned).

The most important parameter for electromagnetic interference of an RFID system with a medical device is the power emitted by the reader, whose limit depends not only on the RFID operating frequency, but also on local (e.g., national or federal) regulations. Indeed, since RFID systems are intentional radiators of radio waves, they are controlled under local radio laws and regulations.

In Europe, radio and telecommunication equipment are regulated by the European Radio and Telecommunications Terminal Equipment Directive. The main objective of this Directive is to establish a regulatory framework for placing on the market, free movement of and putting into service the radio equipment and telecommunications terminal equipment in the territory of the EU. The applications, frequency bands and power levels relating to the use of short-range devices, such as RFID systems, are defined in the recommendation CEPT REC 70-03 of the European Conference of Postal and Telecommunications Administrations. The European Telecommunications Standards Institute (ETSI) has developed harmonized standards for many short-range devices. RFID electromagnetic compatibility (EMC) is regulated by three ETSI standards that cover the frequency range from 9 kHz to 40 GHz [19–21].

In the USA, RFID systems, as devices that transmit RF energy, are subject to Federal Communications Commission (FCC) regulation. FCC rules are located in Title 47 of the Code of Federal Regulations. Part 15 of Title 47 concerns RF devices and covers the regulations under which an intentional, unintentional or incidental radiator can be operated, as well as the technical specifications, administrative requirements and other conditions relating to the marketing of these devices. The FCC rules pertinent to RFID concern RF emissions limits, power restrictions and the use of certain frequencies.

Table 1 shows the maximum allowed field strengths/transmission powers for RFID systems. The limits are referred to the regulations in force in the USA and Europe. Power limits are similar in both regions for some frequency ranges; when limits differ, it is clearly indicated in the table.

Medical device regulations

In the EU, medical devices are regulated by the European Community directives that define the 'essential requirements' assuring health and safety protection; the goods must meet these specifications to be placed on the market. The European standards bodies have the task of drawing up the technical specifications to meet the essential requirements of the directives. Compliance with these technical specifications, referred to as 'harmonized standards,' will provide presumption of conformity with the essential requirements. There are three directives for medical devices [22–24]: the Active Implantable Medical Devices Directive (AIMD) – 90/385/EEC; the Medical Devices Directive (MDD) – 93/42/EEC; and the *In Vitro* Diagnostic Devices Directive (IVD) – 98/79/EC. In the following sections, the MDD is being referred to.

Electromagnetic immunity is an essential requirement for medical devices. MDD clearly states that "devices must be designed and manufactured in such a way as to remove or minimize as far as is possible … risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration; the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given."

In the USA, medical devices are regulated under the Federal Food Drug & Cosmetic Act (FD&C Act) Part 800–1299 by the US FDA Center for Devices and Radiological Health (CDRH). Medical devices are classified on the basis of their risk: class I, general controls are required; class II, special controls are required; and class III, asks for a pre market approval and implies more controls [101].

As far as EMC is concerned, the FDA is becoming increasingly concerned about the EMC aspects of medical devices. The FDA inspectors are requiring assurance from manufacturers that they have addressed EMC concerns during the design process, and that the device will operate properly in its intended electromagnetic environment [102].

The standards that are recognized in Europe and the USA are usually accepted in many other countries, where CE-marked or the FDA-approved products are considered to meet quality and performance criteria to be put into service in these countries.

Regulation of electromagnetic immunity of medical devices

Definition

Electromagnetic immunity of medical devices is defined as their ability to perform without degradation in the presence of an electromagnetic disturbance. A list of degradations in performance of a medical devices is reported in Box 1.

International standards

In Europe, the harmonized standard (EN 60601-1-2: Medical electrical equipment – Part 1: general requirements for safety. 2. Collateral standard: EMC – requirements and tests) covers the topics relevant to EMC [25]. In the USA, the FDA refers to reviewers' guidelines to assure that medical devices are properly designed to be immune to electromagnetic interference. The document "Guide to Inspections of Electromagnetic Compatibility Aspects of Medical Devices Quality Systems" encourages manufacturers to use International Electrotechnical Commission (IEC) 60601-1-2 as the EMC standard. As a result, in most cases, IEC 60601-1-2 has effectively become the unofficial, *de facto*, EMC standard that has to be met for medical equipment.

Since the harmonized standard EN 60601-1-2 does not substantially differ from IEC 60601-1-2, in the following sections IEC/EN 60601-1-2 will be referred to as the standard concerning the EMC of medical devices.

Relevant points

The most important issues established by the up-to-date revision of this standard (IEC/EN 60601-1-2: third edition) regard: the minimum immunity level and the assessment of the actual levels of immunity of medical device by the manufacturer; the declaration of the manufacturer about the electromagnetic immunity level to be included in the accompanying documents of the medical device; and the shared responsibility between manufacturers, responsible organizations and operators to ensure that medical devices are used in a compatible electromagnetic environment where the medical device performs as intended.

The declared levels of electromagnetic immunity are established on the basis of appropriate tests to be performed on the device, according to those specified by the standard. The minimum levels of immunity of medical devices specified by the standard differ between life-support and non-life-support medical devices (Table 2). The immunity levels declared by the manufacturer may be equal or higher than the minimum ones specified by the standards. Actually, immunity levels may be lower than minimum levels, provided there is sufficient technical justification and the manufacturer discloses such lower levels in the declaration to be included in the documents accompanying the medical device.

The declaration about the electromagnetic immunity of the medical device – to be included in the accompanying documents – will feature information about the electromagnetic environment where the medical device works as intended, defining the recommended separation distances between the medical device and portable/mobile RF communication equipment.

The recommended separation distances for both life support and non-life support medical devices are given in Tables 3 & 4. These tables must be completed in accordance with the indicated formulas, with the immunity level of the device and the maximum output power of the portable RF transmitter.

The IEC 60601-1-2 standard is meant for medical device manufactures, but the standard clearly recognizes that manufacturers, responsible organizations and operators (i.e., healthcare facilities and associated staff) share the responsibility to ensure that medical devices are designed and operated as intended, that is, they are used in a compatible electromagnetic environment according to the manufacturer's information.

Box 1. List of degradations in performance of a medical device.

- Component failures
- Changes in programmable parameters
- Reset to factory defaults
- Change of operating mode
- False alarms
- Cessation or interruption of any intended operation, even if accompanied by an alarm
- Initiation of any unintended operation, even if accompanied by an alarm
- Error of a displayed numerical value sufficiently large to affect diagnosis, treatment or monitoring
- Artifact or distortion in an image that would interfere with diagnosis, treatment or monitoring
- Failure of automatic diagnosis or treatment, even if accompanied by an alarm

RFID & medical devices

When handheld RFID readers are brought into a hospital setting, they must be regarded as portable RF communication equipment. Thus, in order to provide the electromagnetic environment where the performance of the medical device would be expected to be normal, a separation distance between the RFID system and the medical devices must be assured. In other words, electromagnetic interference can be prevented if the RFID reader is far enough away from the medical devices. How far depends on the level of electromagnetic immunity of the medical device, and on the emitted power and operating frequency of the RFID reader, according to the formulas in the IEC/EN 60601-1-2:2007 standard (Tables 3 & 4). Considering the minimum level of immunity of a life support medical device (10 V_{RMS} from 150 kHz and 80 MHz, and 10 V/m from 80 MHz to 2.5 GHz), the minimum separation distance (in cm) between RFID reader and medical devices is reported in Table 5, for the typical RFID operating frequencies and emitted powers (Table 1).

In Table 5, some columns are empty as the standard does not take portable RF equipment operating at frequencies below 150 kHz or above 2.5 GHz into account, although RFID

Table 2. Minimum immunity levels according to standard International Electrotechnical Commission 60601-1-2.

Frequency range	Immunity level	
	Life support device	*Non-life support device*
Conducted radiofrequency (150 kHz to 80 MHz)	10 V_{RMS}	3 V_{RMS}
Radiated radiofrequency (80 MHz to 2.5 GHz)	10 V/m	3 V/m

Table 3. Guidance tables reported in standard International Electrotechnical Commission 60601-1-2.

P = rated maximum output power of the transmitter (W)	Recommended separation distance between portable and mobile RF communications equipment and the life support medical device		
	150 kHz to 80 MHz, $D = 12\sqrt{P/V}$	80–800 MHz, $D = 12\sqrt{P/E}$	800 MHz to 2.5 GHz, $D = 23\sqrt{P/E}$
0.01			
0.1			
1			
10			
100			

Guidance tables for the computation of the recommended separation distance between portable and mobile RF communications equipment and the life support medical device, according to the immunity level of the device and to the power and operating frequency of the portable RF equipment.
D: Distance in meters; E: Medical device immunity level in V/m for the frequency range 80 MHz to 2.5 GHz; P: Rated maximum output power of the transmitter in watts; RF: Radiofrequency; V: Medical device immunity level in V_{RMS} for the frequency range 150 kHz to 80 MHz.

systems (as well as other wireless systems) operating in these frequency bands are, or will be soon, used in healthcare facilities. At 13.56 MHz, there is a misalignment between standard IEC/EN 60601-1-2 and RFID regulations concerning the expression of the transmission power of the portable RF equipment. In RFID regulations, the power limit is expressed in terms of the maximum magnetic field generated by the antenna at a distance of 10 m (in A/m), while in standard IEC/EN 60601-1-2, the power limit is expressed as the antenna's effective radiated power (in W).

Table 4. Guidance tables reported in standard International Electrotechnical Commission 60601-1-2.

P (W)	Recommended separation distance between portable and mobile RF communications equipment and the non-life support medical device		
	150 kHz to 80 MHz, $D = 3.5\sqrt{P/V}$	80–800 MHz, $D = 3.5\sqrt{P/E}$	800 MHz to 2.5 GHz, $D = 7\sqrt{P/E}$
0.01			
0.1			
1			
10			
100			

The guidance tables for the computation of the recommended separation distance between portable and mobile RF communications equipment and the non-life support medical device, according to the immunity level of the device and to the power and operating frequency of the portable RF equipment.
D: Distance in meters; E: Medical device immunity level in V/m for the frequency range 80 MHz to 2.5 GHz; P: Rated maximum output power of the transmitter in watts; RF: Radiofrequency; V: Medical device immunity level in V_{RMS} for the frequency range 150 kHz to 80 MHz.

Since at these frequencies, the relationship between the magnetic field generated by the antenna and the effective radiated power depends on the physical characteristics of the antenna, and requires electromagnetic expertise, the computation of the recommended separation distance from a RFID system operating at 13.56 MHz is neither straightforward nor general. The table indicates that, for RFID operating at higher frequencies, having power limits as high as 2 and 4 W, this distance becomes greater than 3 m.

As for fixed RFID readers (e.g., doorway- or wall-mounted), the standard does not indicate recommended separation distances. In any case, a similar approach could be followed in those situations where medical devices are moved close to RFID readers.

Despite these regulatory issues regarding the electromagnetic environment where medical devices perform without degradation, most of the examples in the literature promote applications of RFID in healthcare settings without considering the safety of RFID technology within the healthcare environment [2–6], or where the IEC/EN 60601-1-2 recommended separation distance of portable transmitters is not dealt with [13,17]. Commonly, even in healthcare applications, RFID powers and frequencies are chosen only on the basis of the desired RFID system performances [8,9,11,12].

Expert commentary & five-year view

As a matter of fact, the electromagnetic environment in healthcare has changed significantly over the last decade. Portable RF transmitters are now essential to the delivery of healthcare and are often used closer to medical electrical equipment than the immunity test levels of the current standard would allow. Experimental evidence [13,16,17] suggests that electromagnetic interference only occurs at shorter distances than those allowed by the standard [13,16,17], indicating that such recommended distances are very conservative and that there could be margin for a revision. To reflect the electromagnetic environment in modern healthcare, it is desirable that new standards are proposed, which specify close-distance RF immunity tests, extend the frequency range below 150 kHz and above 2.5 GHz, and re-align RFID regulations and medical device standards with respect to RFID transmission power.

According to standard IEC/EN 60601-1-2, to assure the electromagnetic environment where the medical device performs as intended, portable RFID transmitters may not be used in the proximity of the medical device (except those emitting less than few mW). The medical device manufacturer provides the recommended separation distances, at least for RFIDs operating at 800 MHz and 2.4 GHz. The responsible healthcare organization must assure that these separation distances are respected, that is, there is an adequate electromagnetic environment.

As detailed in the previous paragraph, RFID technology operates in frequency ranges not fully and/or properly covered by current medical device standards, so there are no regulatory tools to assess and control the risk of electromagnetic interference.

Given that the use of RFID systems is becoming essential to the efficient provision of healthcare, it is desirable that new standards are proposed, which specify close-distance RF

Table 5. Minimum recommended separation distances between portable radiofrequency identification equipment and a life support medical device.

Rated maximum output power of transmitter (W)	Recommended separation distances between portable and mobile RF communications equipment and the medical device (cm)				
	Sistemi RFID				
	125 kHz/134.5 kHz	*13.56 MHz*	*865–956 MHz*	*2.45 GHz*	*5.8 GHz*
0.01			23	23	
0.1			73	73	
0.2			103	103	
0.5			163	163	
1			230	230	
2			325	325	
4 (USA, Canada)			–	460 (USA, Canada)	

The medical device having the minimum level of immunity according to standard International Electrotechnical Commission (IEC)/EN 60601-1-2. Frequency ranges 125 kHz, 134.5 kHz and 5.8 GHz are not contemplated in the standard. At 13.56 MHz, there is a misalignment between standard IEC/EN 60601-1-2 and the standard on RFID in the way in which the portable equipment transmission power is expressed.
RF: Radiofrequency; RFID: Radiofrequency identification.

immunity tests, extend the frequency range below 150 kHz and above 2.5 GHz, and realign RFID regulations and medical device standards with respect to RFID transmission power. Given the experimental evidences of medical device malfunctions in the LF bands, the range below 150 kHz deserves particular attention [17,18].

Ad hoc testing for a specific RFID system in a given healthcare environment is a possible way of assessing the risk of electromagnetic interference, at least in those frequency ranges not covered by the IEC/EN 60601-1-2 standard. Such tests can be conducted according to the ANSI AAMI C63.18 standard, developed for responsible organizations to help obtain additional information on the potential risk of electromagnetic interference [26].

Other identification systems based on electromagnetic fields are entering the market (e.g., RuBee protocol and near field communication). Their EMC with medical devices should be addressed, taking into account the kinds of field generated, which are those used by RFID technology (magnetic, electric, electromagnetic). Thus, for them, most of the issues discussed in this paper are still valid.

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Key issues

- The introduction of radiofrequency identification (RFID) technology in healthcare environments requires accurate evaluation of the potential risks of interference with medical devices.
- The harmonized standard in Europe and the *de facto* standard in the USA for electromagnetic compatibility of medical devices is the International Electrotechnical Commission (IEC)/EN 60601-1-2.
- The IEC/EN 60601-1-2 does not cover all the frequencies used by RFID readers: radiofrequency fields at frequencies lower than 150 kHz and higher than 2.5 GHz are not covered.
- At 13.56 MHz RFID, field strength and medical device immunity levels are expressed – in their relative standards – by diverse physical quantities (A/m vs V), so that the assessment of the risk of interference as well as the definition of a safety separation distance are not straightforward.
- In the range of 80 MHz to 2.5 GHz, to assure the electromagnetic environment where the medical device performs as intended, a safety distance between portable RFID transmitters and medical devices must be respected.
- Given the modern electromagnetic environment in healthcare, it is desirable that new standards are proposed, which specify close-distance radiofrequency immunity tests, extend the frequency range below 150 kHz and above 2.5 GHz, and realign RFID regulations and medical device standards with respect to RFID transmission power.

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