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Radiofrequency identification and medical devices: the regulatory framework on electromagnetic compatibility. Part II: active implantable medical devices

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The number and the types of electromagnetic emitters to which patients with active implantable medical devices (AIMD) are exposed to in their daily activities have proliferated over the last decade. Radiofrequency identification (RFID) is an example of wireless technology applied in many fields. The interaction between RFID emitters and AIMD is an important issue for patients, industry and regulators, because of the risks associated with such interactions. The different AIMDs refer to different standards that address the electromagnetic immunity issue in different ways. Indeed, different test setups, immunity levels and rationales are used to guarantee that AIMDs are immune to electromagnetic nonionizing radiation. In this article, the regulatory framework concerning electromagnetic compatibility between RFID systems and AIMDs is analyzed to understand whether and how the application of the current AIMD standards allows for the effective control of the possible risks associated with RFID technology.

Keywords: active implantable medical devices • electromagnetic interference • regulatory framework • RFID system

Active implantable medical devices (AIMDs) are active medical devices intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and are intended to remain after the procedure. Examples of AIMDs are implantable cardiac pacemakers (PMs), implantable defibrillators, implantable nerve stimulators, cochlear implants (CIs), implantable active drug administration devices and implantable active monitoring devices.

Such devices, because they are composed by electronic circuitry, are susceptible to electromagnetic interference (EMI), and despite the solutions adopted to minimize this phenomenon, there have been several reports of incidents caused by EMI to PMs and implantable cardioverter defibrillators (ICDs), the most common AIMDs [101]. Although no EMI incident reports of PM or ICD have been directly associated with radiofrequency identification (RFID) systems, recent research studies on PMs, ICDs and neurostimulators have shown that some reactions occur when certain RFID readers are brought to operate nearby these devices [1–4].

In Europe, electromagnetic compatibility is an essential requirement for AIMDs, as stated by the Active Implantable Medical Device Directive (90/385/EEC) [5]. According to this directive, compliance with the harmonized standard EN 45502-1 [6] and its particular device-specific norms (EN 45502-2-X) would give presumption of conformity to the prescriptions of the Directive. To date, these particular standards exist for PMs (EN 45502-2-1) [7], ICDs (EN 45502-2-2) [8] and CIs (EN 45502-2-3) [9]. The implantable neurostimulators (INs) do not have particular standards belonging to the EN 45502 family;

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for these kinds of AIMDs, there exists an international standard, the ISO 14708-3 [10]. Such a standard has the same structure as the family of harmonized norms 45502-2-X, and it is considered a reference norm for these kind of devices even in Europe. Paragraph 27 ('Protection of the AIMD from electromagnetic nonionizing radiation') of the previously mentioned norms is dedicated to the electromagnetic immunity of AIMDs.

In the USA, AIMDs are regulated by the norms belonging to the ISO 14708-X. As far as the electromagnetic immunity is concerned, according to the ISO 14708, PMs and ICDs should comply with the ANSI/AAMI PC69 [11]. Similarly, the standards EN 45502-2-1, EN 45502-2-2, EN 45502-2-3 and ISO 14708-3 often refer to the standard ANSI/AAMI PC69.

All of the above-mentioned standards for AIMD indicate immunity tests from 16.6 Hz (10 Hz for neurostimulators) to 3 GHz, thus covering the most used RFID operation frequencies. Immunity levels, test setups and rationales are different among the devices. Whether the immunity levels indicated in the standards take into account possible exposure to RFID transmitters is not straightforward, and will be analyzed in the following sections.

PMs & defibrillators

PMs are devices designed to treat bradyarrhythmia by stimulating heart beats by generating electrical impulses that are transmitted to the heart. ICDs are designed to monitor and treat life-threatening arrhythmias, including ventricular tachycardia and ventricular fibrillation.

It is thus clear how any potential malfunctions of these devices can pose serious risks to the life of the patient. With regard to the interferences caused by the exposure to electromagnetic fields generated by RFID systems, potential unwanted effects that the PMs and ICDs may experience are as follows:

- Induced currents from the lead into the heart, causing unwanted muscle stimulation, fibrillation or local heating;
- Induced voltages in the lead that damage the PM/ICD;
- Induced voltages in the lead that prevent the PM/ICD from correctly detecting and analyzing the intrinsic heart signal.

To ensure a reasonable immunity to such hazards, clause 27 of the standards EN 450502-2-1 and EN 450502-2-2 and paragraph 4 of the AAMI/ANSI PC69 address the following issues:

- Protection from persisting malfunctions of the device caused by ambient continuous wave (CW) electromagnetic fields;
- Protection from unacceptable transitions or operating modes of the device caused by ambient CW electromagnetic fields during the exposure to the electromagnetic field;
- Protection from transient changes in therapeutic behavior of the device caused by voltages induced in the implanted leads protection from persisting malfunction of the device caused by time-varying magnetic fields.

According to the standards in the frequency bands where the low frequency (LF), high frequency (HF) and ultra-high frequency (UHF) RFID systems operate, PM and ICD immunity is assessed by several tests. The immunity levels and the test setups depend on the frequency. Tests and levels of immunity are the same for PM and ICD, except for some differences: slightly different modulated signals used; different tissue interface circuits used for signal injection to the cardioversion/defibrillation terminals; some additional tests for ICD to be performed with signal levels higher than those indicated for PM.

Table 1 reports frequency ranges, test setups and immunity levels of the tests indicated by the standards; the first column indicates the number of the associated clause of the related standards. Table 2 reports the additional tests to be performed for ICD.

Immunity tests in the LF range (125 & 134 kHz)

In the frequency range of LF RFID, the PM and ICD must pass four types of test. In three tests, an interfering signal is applied directly to the device (conducted signal). In one test, the signal is radiated towards the device. The first test imposes a continuous sinusoidal signal applied to the device (the amplitude reported in Table 1). Compliance is confirmed if after application of this signal, the device functions as prior to the test. The signal frequency in this test can be freely chosen in the specified range, so a test at the exact RFID operating frequency can be performed. When calculated for the LF RFID frequencies, the values obtained were 6.25 V_{pp} (peak-to-peak) at 125 kHz and 6.7 V_{pp} at 134.5 kHz. The second test imposes the application of the same signal used in the first one, with an amplitude of 1 V_{pp}; in this case, the device has to continue to operate unperturbed or in a safe mode defined by the manufacturer during the application of the interference signal. In the third test, a pulse-modulated signal at various frequencies is applied to the PM. Compliance is confirmed if the PM functions unperturbed at all times. The carrier frequency in this test can be freely chosen in the specified range, so a test at the exact RFID operating frequency can be performed. The amplitude of the test signal is 0.750 V_{pp} (peak-to-peak) at 125 kHz and 0.804 V_{pp} at 134 kHz.

In the fourth test, the device is exposed to a time-varying magnetic field, and no malfunction persists after removal of the magnetic field. When calculated at the frequency of 125 and 134 kHz, the amplitude of the magnetic field is 120 and 112 A/m, respectively.

Immunity tests in the HF range (13.56 MHz)

In this range, a modulated signal is applied to the PM. For PMs, four carrier frequencies are imposed, and the closest to the HF RFID is 20 MHz. For ICD, the carrier frequencies have to be chosen at a minimum of six distinct, well-spaced frequencies per decade, beginning at 10 MHz and ending at 450 MHz; the frequency that most closely matches the one of the HF RFID emitters is thus 10 MHz. In both devices, the carrier is amplitude modulated to create bursts of 100 ms duration with a peak-to-peak amplitude of 10 V. Compliance is confirmed if the device functions unperturbed at all times.

Table 1. Frequency ranges, test setups and immunity levels of the tests indicated by the pacemaker/implantable cardioverter defibrillator standards.

Reference to standard	Frequency	Setup	RFID operating frequency	Immunity test level	
				Frequency range	*Level (V_{pp})*
4.3 AAMI/ANSI PC69 27.3 EN 45502-2-1 27.3 EN 45502-2-2	16.6 Hz to 140 kHz	Conducted signal through interface circuit Continuous signal	LF	16.6 Hz to 20 kHz 20–140 kHz	1 V_{pp} 1 V_{pp} (f/20 kHz)
4.4 AAMI/ANSI PC69 27.4 EN 45502-2-1 27.4 EN 45502-2-2	16.6 Hz to 167 kHz	Conducted signal through interface circuit Continuous signal	LF	16.6 Hz to 167 kHz	1 V_{pp}
4.5 AAMI/ANSI PC69 27.5.1 EN 45502-2-1	16.6 Hz to 150 kHz	Conducted signal through interface circuit	LF	16.6 Hz to 1 kHz 1–3 kHz	2 mV_{pp} 2 mV_{pp} $(f/1\ kHz)^2$
27.5.1 EN 45502-2-2		Modulated signal		3–150 kHz	6 mV_{pp} (f/1kHz)
4.8 AAMI/ANSI PC69 27.8 EN 45502-2-1 27.8 EN 45502-2-2	1–140 kHz	Exposure to time-varying magnetic field	LF	1–100 kHz 100–140 kHz	150 A_{RMS}/m 150 A_{RMS}/m 100 kHz/f
4.5.2 AAMI/ANSI PC69 27.5.2 EN 45502-2-1 27.5.2 EN 45502-2-2	150 kHz to 10 MHz	Conducted signal through interface circuit Modulated signal	–	150–167 kHz 167 kHz to 1 MHz 1–10 MHz	6 mV_{pp} (f/1 kHz) 1 V_{pp} 1V_{pp} (f/1 MHz)
4.5.3 AAMI/ANSI PC69 27.5.3 EN 45502-2-1 27.5.3 EN 45502-2-2	10–450 MHz	Conducted signal through injection network Modulated signal	HF	10–450 MHz	
4.5.4 AAMI/ANSI PC69 27.5.4 EN 45502-2-1 27.5.4 EN 45502-2-2	450 MHz to 3 GHz	Exposure to electromagnetic field radiated on a human trunk simulator Modulated signal	UHF	450 MHz to 3 GHz	

The first column indicates the number of the associated clause of the related standards.
HF: High frequency; LF: Low frequency; PP: Peak-to-peak; RFID: Radiofrequency identification transmitter; RMS: Root mean square; UHF: Ultra-high frequency.

Immunity tests in the UHF range (865 & 915 MHz)

In this range, a radiated test is performed using a dipole antenna (at 2.5 cm from the device) fed with a pulse-modulated signal with a net RF power of 120 mW (root mean square [RMS]). An additional test at 8 W (RMS) can be voluntarily performed for PM but must be performed for ICD. The carrier signal is a sinusoidal waveform at each of the following frequencies: 450, 600, 800, 825, 850, 875, 900, 930, 1610, 1850, 1910, 2450 and 3000 MHz. The signal is pulse modulated with the following characteristics: the carrier is gated on for 25 ms at 500 ms intervals. The gating rise and fall time should be <0.5 µs. The PM does not exhibit any deviation from its expected behavior during exposure to the RF field.

Neurostimulators

INs are implantable pulse generators designed to deliver electrical stimulation to nerves to treat a number of diseases such as chronic pain and neurological disturbances. To date, the European standards bodies have not drawn a device-specific norm for INs. The international standard ISO 14708:3-2008 can be taken as a reference to define the technical specifications for meeting the essential requirements of the directive. The protection from electromagnetic nonionizing radiation is assessed by performing immunity tests, during which the basic performances of the IN should not be affected. In particular, the following degradations are not allowed:

- Component failures;

Table 2. Additional tests for implantable cardioverter defibrillators.

Reference to standard	Frequency	Setup	RFID operating frequency	Immunity test level
27.3.2 EN 45502-2-1	10–450 MHz	Conducted signal through injection network Modulated signal	HF	14 V_{pp}
27.3.3 EN 45502-2-2	450 MHz to 3 GHz	Exposure to electromagnetic field radiated on a human trunk simulator	UHF	8 W_{RMS}

HF: High frequency; PP: Peak-to-peak; RFID: Radiofrequency identification transmitter; RMS: Root mean square; UHF: Ultra-high frequency.

- Changes in the programmable parameters setting;
- Reset to factory default;
- Change of operation mode;
- False alarms;
- Initiation of any unintended operation.

To assess the immunity of INs versus electromagnetic nonionizing radiation, the ISO standard defines three possible criteria that the device should comply to: criteria A, B and C. As illustrated in Table 3, each criterion identifies a different immunity condition. Basically, criterion B is less restrictive than criterion A and allows partial degradation of the device's performance during the tests. Criterion C allows the manufacturer to define his own immunity conditions, for which a specific risk assessment must be provided.

The standard ISO 14708-3 defines several immunity tests, in the range from 10 Hz to 3 GHz. Table 4 reports frequency ranges, test setups and immunity levels of the tests indicated by this standard; the first column indicates the number of the associated clause of the standard. For the frequencies used by RFID systems, all the tests define an exposure setup with the device submerged in a saline bath and exposed to a radiated field.

Immunity tests in the LF & HF range (125 kHz, 134 kHz & 13.56 MHz)

In this frequency range, the assessment of the IN is made by exposure of the device to continuous and pulsed magnetic fields. The device must be put into a saline bath. Frequencies of the applied test signal from 10 Hz to 30 MHz may be either swept or stepped. Thus, tests at the specific RFID operating frequencies in the LF and HF range can be performed. The levels of the magnetic field at which the device must be exposed vary depending on the frequency within the range, and are reported in the table. When calculated for the RFID operating frequencies the values obtained are as follows: 12.7 A/m at 125 kHz, 11.8 A/m at 134.5 kHz, 0.12 A/m at 13.56 MHz.

Table 3. Criteria used for implantable neurostimulators.

Criterion	Device operation during the test	Device operation after the test
A	Operates as intended No loss of function No unintentional responses	Operates as intended No loss of function No degradation of performance Conforms to device specifications
B	Allowed if no unacceptable risk Performance degradation Loss of function	Operates as intended No loss of function No degradation of performance Conforms to device specifications Lost functions are self-recoverable
C	Manufacturer defined	Manufacturer defined

Test signals corresponding to criterion A are applied as sinusoidal CW signals. In the same bands, the test signals corresponding to criterion B are applied as pulse-modulated signals. If performance degradation or unintentional responses occur for the pulse-modulated test signals but not for the CW signal, tests for the compliance with criterion A are repeated with the pulse-modulated signal.

INs that have more than one available electrode configuration for stimulation, such as bipolar or unipolar, are tested with the electrode configuration that is the most susceptible to EMI. For magnetic field tests, the electrode configuration that is normally the most susceptible is unipolar.

Immunity tests in the UHF range (865 & 915 MHz)

The assessment of the IN for the range of frequencies from 450 MHz to 3 GHz is made by exposure to radiated electromagnetic fields using test methods and equipment specified by ANSI/AAMI PC69:2000. PC69 was intended to be written for implantable cardiac devices; parts of the test setup and procedure do not apply for IN. In particular, the performance criterion A applies to evaluate the effect of the EMI. In addition, requirements related to signal injection and parameter programming, as used in PC69, are not applicable.

The IN radiated tests are performed using a dipole antenna fed with a pulse-modulated signal with a net RF power of 40 mW (RMS). An additional test at higher power, chosen at the manufacturer's discretion, can be voluntarily performed.

CIs

A CI is an implanted electronic hearing device, designed to produce useful hearing sensations to a person with severe-to-profound nerve deafness by electrically stimulating nerves inside the inner ear. The requirements in terms of exposure levels are defined for frequencies between 16.6 Hz and 3 GHz, according to two interference levels: requirement for uninfluenced function (lower level) and protection requirement (upper level). During the EMI tests, the compliance of the CI is confirmed if no permanent damage can be demonstrated after exposure at the upper level and if during exposure no currents larger than the maximum value of the output signal measured without any interfering signal are delivered to the tissue. In addition, it is verified that the function of the CI is not significantly influenced by external electromagnetic fields: to this aim, the device is configured to continuously produce between 25% ('threshold level') and 50% ('comfort level') of the maximum value of the output signal on at least two output electrodes. Compliance is confirmed if any output signal remains below 'comfort level' during exposure at the lower levels. During the exposure, the CI may occasionally drop out stimulation signals. In case the device completely stops stimulation prior to reaching the lower levels, the manufacturer declares the level at which this happens.

Table 4. Frequency ranges, test setups and immunity levels of the tests indicated by the implantable neurostimulator standards.

Reference to standard	Frequency	Setup	RFID operating frequency	Immunity test level		
				Frequency (kHz)	*Field strength H (A/m) RMS*	
					Criterion A	*Criterion B*
27.104 ISO – 14708-3	10 Hz to 30 MHz	Exposure of the device in saline bath to time-varying magnetic field Continuous and modulated signal	LF and HF	0.01–0.06 0.06–0.3 0.3–3.0 3.0–100 100–30000	795 47.7/f 47.7/f 15.9 1590/f	 159 159 15900/f
27.105 ISO – 14708-3	30–450 MHz	Exposure of the device in saline bath (in an anechoic chamber) to radiated electromagnetic field		16 V/m RMS 140 V/m RMS for 30 MHz, 50 MHz, 75 MHz, 150 MHz and 450 MHz		
27.106 ISO – 14708-3	450 MHz to 3 GHz	Exposure of the device in a human trunk simulator to radiated electromagnetic field Modulated signal	UHF	120 mWRMS		

The first column indicates the number of the associated clause of the related standards.
HF: High frequency; LF: Low frequency; RFID: Radiofrequency identification transmitter; RMS: Root mean square; UHF: Ultra-high frequency.

The standard EN 45502-2-3 prescribes that the immunity of the device to electromagnetic nonionizing radiation be tested with the device in a head simulator exposed to magnetic or electromagnetic fields. Table 5 reports frequency ranges, test setups and immunity levels of the tests indicated by the standard EN45502-2-3; the first column indicates the number of the associated clause of the standard. The norm specifically provides the exposure levels at which the implant must be tested, but leaves the manufacturer to choose the appropriate means to demonstrate compliance, either theoretical modeling or direct EMI measurements.

Immunity tests in the LF (125 & 134 kHz)

In the range from 16.6 Hz to 10 MHz, CIs must be put in a saline bath and exposed to magnetic fields with the frequencies and strengths reported in Table 4. The requirements are restricted to pure magnetic fields and to approximately two frequencies per decade, to reduce calculation time for exposure simulations of theoretical modeling or measuring time of EMI measurements. The frequencies used by LF RFID systems are not explicitly reported. The frequency that most closely matches those of RFID transmitters in the LF band is 166 kHz, for which an upper level of 110 A/m and a lower level of 7 A/m is defined.

Immunity tests in the HF & UHF range (13.56, 865 & 915 MHz)

In the range from 10 MHz to 3 GHz, CIs must be put in a saline bath and exposed to electromagnetic fields with the frequencies and strengths reported in Table 4. At a frequency >10 MHz, electric and magnetic components are both considered relevant. Since most exposures can be covered by far-field situations, only the electric field strength is specified. The requirements are restricted to fixed frequencies. The frequencies used by LF RFID systems are not explicitly reported. The closest ones are 10 MHz (for HF RFID) and 900 MHz (for UHF RFID). In particular, the immunity to RFID readers in the HF band assessed at 10 MHz indicates an upper level of the electric field strength of 200 V/m and a lower level of 40 V/m; in the UHF band at 900 MHz, the upper level of the electric field strength is 200 V/m and the lower level is 58 V/m. In both cases, the interference signal is a switched carrier, with a burst-on time of 400 µs and 10 ms for the upper and lower level, respectively. Interference signal at the upper level can be also be generated as a CW.

Discussion

The number and the types of electromagnetic emitters to which bearers with AIMD are exposed in their daily activities have proliferated over the last decade. This trend is expected to continue. The interaction between RFID emitters and AIMD is an important issue for patients, industry and regulators, because of the risks associated with such interactions. The potential for an RF emitting device to interfere with an AIMD depends on the following factors:

- Carrier frequency of the emitter;
- Carrier modulation;
- Emitted or radiated power;
- Proximity to the patient;
- Coupling factors (e.g., implant configuration and structure, emitting antenna specifications);

Table 5. Frequency ranges, test setups and immunity levels of the tests indicated by the cochlear implant standards.

Reference to standard	Frequency	Setup	RFID operating frequency	Immunity test level		
				Frequency	*Peak magnetic/electric† field strength*	
					Lower level	*Upper level*
27.3 EN 45502-2-3	16.6 Hz to 10 MHz	Exposure of the device in a head simulator to time-varying magnetic field Continuous and modulated signal	LF	16.6 Hz 50 Hz 1.66 kHz 5 kHz 16.6 kHz 50 kHz 166 kHz 500 kHz 1.66 MHz 5 MHz	340 A/m 110 A/m 7 A/m 7 A/m 7 A/m 7 A/m 7 A/m 4 A/m 2 A/m 0.15 A/m	480 A/m 1200 A/m 150 A/m 150 A/m 150 A/m 150 A/m 110 A/m 26 A/m 5.5 A/m 2.9 A/m
27.3 EN 45502-2-3	10 MHz to 3 GHz	Exposure of the device in a head simulator to radiated electromagnetic field (in TEM or GTEM cell) Modulated signal	HF and UHF	10 MHz 33 MHz 100 MHz 450 MHz 900 MHz 1800 MHz 2450 MHz	40 V/m 40 V/m 40 V/m 40 V/m 58 V/m 82 V/m 86 V/m	200 V/m 200 V/m 200 V/m 200 V/m 200 V/m 200 V/m 200 V/m

†The peak magnetic field strength is given for 16.6 Hz to 10 MHz and the peak electric field strength is given for 10 MHz to 3 GHz.
The first column indicates the number of the associated clause of the related standards.
GTEM: Gigahertz transversal electromagnetic; HF: High frequency; LF: Low frequency; RFID: Radiofrequency identification transmitter; TEM: Transversal electromagnetic; UHF: Ultra-high frequency.

- Duration of exposure;
- Programming parameters of the device.

While the impact of such factors have been systematically addressed for other consolidated RF sources (e.g., MRI [12,13], mobile phones [14,15] and power lines [16,17]), to date, similar data are not available for RFID transmitters.

LF & HF RFID bands

In the LF and HF bands, the comparison between the RFID regulations and the PM/ICD standards reveals a misalignment concerning the physical quantities used to express the exposure levels of the RFID and the PM immunity. 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 the PM/ICD standards the immunity is assessed as amplitude of a magnetic field incident on the device (in the LF range) and of a voltage signal directly applied to the PM (in the LF and HF range). Since the relationship between the magnetic field at 10 m from the antenna and the voltage inducted on the PM depends on several factors, the evaluation of the PM immunity requires electromagnetic expertise and a case-by-case analysis. Even when the limits for PM/ICD immunity are given in terms of A/m, they cannot be easily related to the value of the field at 10 m from the RFID reader, since the field in proximity to the antenna can widely vary as a function of its geometric characteristics (e.g., radius, shape, number of windings and materials).

The immunity test levels adopted in the standards described in the previous paragraphs are derived from the values of permitted human exposure to electromagnetic fields, as defined by a number of national and international guidelines and recommendations from bodies, such as International Commission on nonionizing Radiation Protection (ICNIRP), the European Commission, Comité Européen de Normalisation Électrotechnique (CENELEC), American National Standards Institute (ANSI), Institute of Electrical and Electronic Engineers (IEEE) and the International Electrotechnical Commission (IEC).

The transfer functions used to correlate the reference levels of public exposure to the voltage induced on PMs/ICDs are derived as a function of the frequency of the electromagnetic field. At low frequencies (below a few MHz) any lead and its return path (through the body for unipolar leads) form a closed conductive loop around which voltages are induced: the body has little screening effect on the fields and the induced voltage is proportional to the frequency. The induced voltage as a function of the field strength applied to the device can be fairly estimated by the Faraday–Neumann–Lenz induction law. As the frequency increases beyond this, body tissue starts to shield electromagnetic fields, and additionally the device leads act increasingly as dipole antennas. These effects are complex, and appropriate transfer functions are given in the German standard draft DIN VDE 0848 3-1:2003 Version 7.

Since the degree of interaction between the electromagnetic field and the implantable devices depends on several factors (antenna geometric factors, field modulation and polarization, implant material, positioning and configuration inside the

body) [12–17], immunity levels are increased by a safety factor. Accordingly, these levels are indented to prevent incompatibility with higher magnetic fields than the reference levels defined in the standards for public exposure.

IN and CI standards express the exposure levels for the immunity test in terms of magnetic field, as the limits imposed by RFID regulations for RFID emissions. Nevertheless, RFID regulations imposed restrictions in terms of the maximum magnetic field generated by the antenna at a distance of 10 m, while the device is exposed to magnetic fields generated in the vicinity of the antenna. The values of the magnetic field generated in the vicinity of an actual RFID reader antenna depend on several factors, and it is not straightforward to evaluate whether these values are considered in the exposure levels reported in the medical device standards. In addition, the standard for CIs indicates, at HF RFID, an exposure to an electromagnetic field and the exposure level is expressed in terms of peak electric field strength (V/m). Thus, also in this case, it is not straightforward to relate this exposure level to the limit imposed by RFID regulation on HF transmitters. In addition, the exposure levels are given only in terms of electric field amplitude, thus assuming a far-field wave propagation. On the other hand, the communication between RFID readers and the tag at 13.56 MHz is mainly based on inductive coupling mechanisms, in near-field conditions. Thus, the misalignment concerning the physical quantities used to express the exposure levels of the RFID and the electromagnetic immunity of AIMD, already highlighted for PMs and neurostimulators, is even more marked for CIs.

A schematic representation of the regulatory issues concerning the electromagnetic compatibility of PMs/ICDs, INs and CIs exposed to RFID transmitters operating in the HF band is reported in Figure 1.

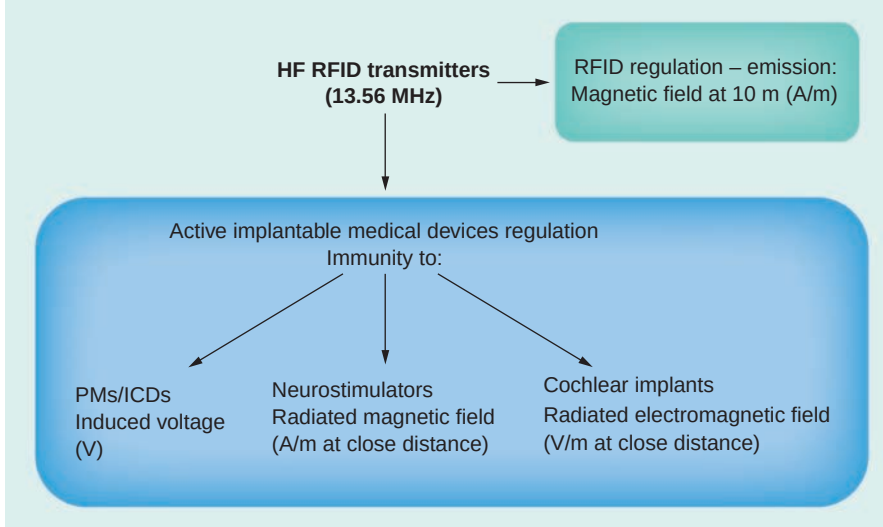

Figure 1. Regulatory issues for the electromagnetic compatibility of active implantable medical devices exposed to radiofrequency identification transmitters operating in the high frequency band.
HF: High frequency; ICD: Implantable cardioverter defibrillator; PM: Pacemaker; RFID: Radiofrequency identification.

UHF RFID bands

In the UHF band the immunity of, PMs and neurostimulators is regulated by the same tests (AAMI/ANSI PC69:2007). The maximum emitted power for RFID readers and the PM, ICD and IN immunity are all expressed in terms of watts. However, some considerations are still needed. The RF power of 120 mW used in AIMD standards is chosen to ensure the compatibility with RF transmitters, which operate at frequencies close to 900 MHz, with a maximum emitted power of 2 W, at approximately 15 cm, for typical antennas used in mobile phones and handheld transmitters. In principle, this safety distance could also apply for RFID transmitters since they operate at a similar power (maximum value allowed in Europe), but the authors of the standard itself acknowledge that the specific issue of RFID sources requires additional study and is to be a focus in future editions.

For CIs, the exposure level is expressed in terms of peak electric field strength (V/m). In this case, it is possible to relate this immunity to the electric field generated by a UHF RFID antenna. Assuming a far-field propagation, the following formula can be used:

$$E = \frac{\sqrt{30PG}}{d}$$

where P is the RF power, G is the antenna gain and d is the distance between the device and the antenna. For typical UHF RFID reader antenna, G is in the range from 3 to 5 dBi. If a CI is immune to 200 V/m (upper level of electric field exposure), no damage or harm for the patient occurs if it is kept at distance greater than a few centimeters from an RFID antenna emitting 2 W. Note that the assumption of far-field propagation might not be satisfied in many cases. Thus, the distance value provided by the formula may not be safe given that the field generated by the emitting antenna might not decrease as a function of the distance (near-field exposure).

Expert commentary & five-year view

The assessment of potential interference of RFID readers with AIMDs is more complicated than that of the other medical devices, since the peculiarity of AIMDs and of the mechanisms of interaction with an external electromagnetic field are reflected in device-specific testing setups and immunity levels. Indeed, different test setups, immunity levels and rationales are used to guarantee that AIMDs are immune to electromagnetic nonionizing radiation.

In accordance with EC Directive 385/90, standards cover fields of the order of magnitude likely to be encountered in the normal environment. In particular, the standards take into account the reference levels for electromagnetic fields reported in the European Recommendation 519 issued in 1999 (EC/519/99), under certain assumptions of field-to-voltage transfer functions. Reference levels represent the most lenient test of acceptability of general public exposure to fields according to EC 519/99. Magnetic fields more than 20-times higher than the reference levels may comply with the basic restrictions of EC 519/99, especially for localized sources of electromagnetic fields at low frequencies.

For INs, the criterion A levels in the LF and HF ranges closely track the ICNIRP general public reference level, except it is a factor of approximately 2.2-times higher. These factors can be used to account for pulsation margins. The B-line is used for additional assurance of protection from exposure above the A-line. It does not represent a particular general public environment, *per se*, but corresponds to IEEE C95.1 recommendations for maximum permissible human exposure. The safety margin provided by the B-line is ten-times over the A-line in the LF and HF bands. Potential sources at this level appear to be relatively few and proximity to the source is necessary to reach these levels. Therefore, general public exposure to magnetic fields represented by the B-line is considered to be possible, relatively infrequent and for short duration when occurring, and generally avoidable when sources are known. Operation of the implantable device under these exposure conditions is expected to be free from damage and unacceptable risk. However, the higher test levels indicated in the standard represent environments to which the general public might occasionally be exposed, are generally more avoidable, and when exposure does occur, it is generally for a shorter duration. Sources in this category include the higher powered electronic article surveillance gates and higher powered mobile communications equipment.

For CIs, the field strength for protection (upper level) and for uninfluenced function (lower level) requirements reflects the reference level of Recommendation 1999/519/EC. Even if correction factors are applied to take into account the localized exposure around the implant (local factor) and the pulse/modulated nature of the interfering signal (peak factor), locally increased or pulsed field strengths are covered only partially.

The AIMDs are very different from each other in terms of destination of use, therapy deliver and implant site. These differences explain the different test setups used in the particular standards. However, the rationales on which electromagnetic immunity tests are based on should be the same and should take into account all the possible sources of EMI.

It is worth noting that, to date, there is no standard that covers the exposure of AIMDs to therapeutic and diagnostic treatments, or to field levels that may occur in some occupational environments.

Financial & competing interests disclosure

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Key issues

- The wide diffusion of radiofrequency identification (RFID) transmitter technology and the increasing types and number of active implantable medical devices (AIMDs) prompt for a careful evaluation of potential AIMD malfunction due to electromagnetic interference.
- The peculiarity of AIMDs and of the mechanisms of interaction with an external electromagnetic field are reflected in device-specific testing setups and immunity levels indicated by the current standards.
- RFID field strength and AIMD immunity levels are expressed – in their relative standards – by diverse physical quantities, so that the assessment of the risk of interference as well as the definition of a safety separation distance are not straightforward.
- Alignment between RFID standards and AIMD standards is desirable, including the frequency band at 5.8 GHz.
- The electromagnetic fields used by RFID technology require the development of specific test setups for the evaluation of AIMD immunity.

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