

Electromagnetic immunity of medical devices: the European regulatory framework

Giovanni Calcagnini, Federica Censi and Pietro Bartolini

Dipartimento di Tecnologie e Salute, Istituto Superiore di Sanità, Rome, Italy

Summary. In this paper, the international standards and the European Regulation on medical devices are discussed, with attention to the collateral standards and the particular standards concerning the electromagnetic compatibility and immunity of medical devices. In addition, recommended guidelines to be used by health care organizations to assess the immunity of medical devices to radiated electromagnetic fields from portable radio frequency transmitters are indicated and discussed. As far as electromagnetic immunity of active implantable devices are concerned, the difference between United States and European Union (EU) regulatory frameworks is presented (standard ANSI/AAMI PC69:2000 for US and EN45502-1 framework in EU). Finally, some considerations on how to address the risk assessment of workers with implanted devices are discussed.

Key words: medical devices, equipment and supplies, directives, reference standards, electromagnetic compatibility.

Riassunto (*Immunità elettromagnetica dei dispositivi medici: il quadro di riferimento normativo europeo*). In questo lavoro vengono discussi gli standard internazionali e la regolamentazione europea sui dispositivi medici, con particolare attenzione agli standard collaterali e particolari riguardanti la compatibilità e l'immunità elettromagnetica dei dispositivi medici. Inoltre, sono indicate e discusse le linee guida per le organizzazioni ospedaliere al fine di valutare l'immunità dei dispositivi medici ai campi elettromagnetici irradiati da trasmettitori portatili a radio frequenze. Per quanto riguarda l'immunità elettromagnetica dispositivi medici impiantabili attivi, si riporta la differenza tra il quadro normativo in vigore in Europa e negli Stati Uniti (standard ANSI/AAMI PC69:2000 per gli USA e EN45502-1 nella Comunità Europea). Infine sono riportate alcune considerazioni su come affrontare la determinazione del rischio di lavoratori con dispositivi impiantabili.

Parole chiave: dispositivi medici, apparecchiature e forniture, direttive, standard di riferimento, compatibilità elettromagnetica.

INTRODUCTION

Medical devices are regulated by the EC directives, which define the "essential requirements", e.g., protection of health and safety that goods must meet when they are placed on the market. The European standards bodies have the task of drawing up the corresponding technical specifications meeting the essential requirements of the directives, compliance with which will provide a presumption of conformity with the essential requirements. Such specifications are referred to as "harmonised standards". There are three directives for medical devices [1-3]: the active implantable medical device (AIMD) directive - 90/385/EEC; the medical device directive (MDD) - 93/42/EEC; the *in vitro* diagnostic device directive (IVD) - 98/79/EC [1-3].

In particular, electromagnetic immunity is an essential requirements for both not implantable and implantable medical devices, as it is clearly stated in the EC directives: "*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".

Problems with electromagnetic compatibility (EMC) of medical devices have been known for some time in hospitals. Research groups, manufacturers, and governmental and non-governmental agencies have reported incidents related to electromagnetic interference (EMI) to medical devices. Some of them had life-threatening consequences, others could have had, others can be considered just a nuisance. From 1979 to 1993 the Food and Drug Administration received more than one hundred reports related to EMI. These reports prompted the need for an increased attention to medical device EMC by users, manufacturers, and standard organizations.

There are several motivations behind the increasing researches and efforts in this field:

- deaths and severe injuries have occurred due to EMI on life-supporting medical devices;
- the ambient electromagnetic environment continues to intensify (e.g.; mobile phones, wireless local area networks, paging system);
- use of higher carrier frequencies the medical devices have not been tested for;
- increase in electronic sensors, actuators, and microprocessors based medical devices (e.g., ventilators and infusion pumps);
- increased number of patients with electrical active implanted devices (pacemaker and cardioverters/defibrillators);
- widespread of new EM sources such as anti-theft systems and metal detectors, due to the increased need for security in public areas and buildings.

Most of the reported incidents before 1993 involved EMI originated from sources such as electro-surgical units, other medical devices and power line interferences. In the report of Silberberg, 3% of the reports involved mobile phones and 6% hand-held transceivers [4]. It should be observed that in 1993 the usage of mobile phones was much less prevalent than today.

The large number of different medical devices, the peculiarity of some of them (e.g., implantable vs non-implantable or diagnostic vs therapeutic), and the gravity of the potential consequences in case of EMI make difficult to regulate this matter in a unique way. The wide number of potential sources of interference and their associated mechanism (e.g., conducted vs radiated) make the problem even more complex. These differences are also reflected in the international standards on EMC for medical devices. According to these standards, three groups of devices may be considered:

- electrical active implantable devices (e.g., pacemakers, implanted defibrillators, nerve stimulators);
- life-support devices (e.g., ventilators, external defibrillators, electro-surgical units, infusion pumps, monitors);
- non life-support devices (e.g., ECG, EEG, ultrasound scanner, MRI, CT-SCAN).

The topic of MRI between mobile phones and pacemakers (PM) and implantable defibrillators (ICD) has raised much interest among physicians since 1995, when several research data were reported on the adverse effects of electromagnetic fields

(EMF) radiated from mobile phones on implantable PM [5-12]. Later on, studies were extended to ICD [13] and to the mechanisms involved and the solution to be adopted [14, 15]. More recently, other sources of interference such as electronic surveillance systems and metal detectors have been investigated [16].

In the following the international standards and the European Regulation on medical devices and implantable devices will be discussed (*Table 1* and *Table 2*). At international level, such standards are issued by the International Electrotechnical Commission (IEC) and/or by the the European Committee for Electrotechnical Standardization (CENELEC).

The IEC is the international standards and conformity assessment body for all fields of electrotechnology, including electromagnetic compatibility and immunity. Each National Committee of the IEC handles the participation of experts from its country. Norms and standards issued by the International Electrotechnical Commission are easily recognized by the prefix IEC followed by a number indicating the particular field.

In the European Union (EU), CENELEC is proposed to issue harmonized standards. These standards are named using the EN prefix, followed by a number indicating the particular field.

To avoid duplication of efforts, speed up standards preparation and ensure the best use of the resources available and particularly of experts' time, a joint working agreement exists between IEC and CENELEC (Dresden Agreement, 1996), covering nearly 30 IEC National Committees. If the results of parallel voting are positive in both the IEC and CENELEC, the IEC will publish the international standard, while the CENELEC Technical Board will ratify the European standard. In this case the standard will bear both IEC and EN prefixes.

The typical structure of IEC/EN standards comprehends a "parent" standard which establishes the "default" set of requirements in the particular field. There are 2 types of "sibling" standards related to the "parent": the "collateral standards" and the "particular standards".

A collateral standard contains requirements that are an addition to the parent. Collaterals are referred to as "dash-one" standards and are numbered IEC/EN AABBB-1-X. Collateral standards cover topics

Table 1 | International standards and European directives related to electromagnetic compatibility and immunity of non-implantable medical devices

MDD 93/42: Medical device directive	European Union directive
IEC EN 60601-1-2 Medical electrical equipment. Part 1: General requirements for safety 2. Collateral standard: electromagnetic compatibility - requirements and tests	Harmonized standard
EN ISO 14971:2004 Application of risk management to medical devices [27]	Harmonized standard
ANSI C63.18-1997 Recommended practice for an on-site, ad hoc test method for estimating radiated electromagnetic immunity of medical devices to specific radiofrequency transmitters	Guidelines

Table 2 | *International standards and European directives related to electromagnetic compatibility and immunity of implantable medical devices*

AIMD 90/385 Active implantable medical device directive	European Union directive
DIRECTIVE 2004/40/EC Minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)	European Union directive
Council recommendation 1999/519/EC of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz) [28]	Recommendation
EN 45502-1:1997 CEN/CLC/JWG AIMD Active implantable medical devices. Part 1: General requirements for safety, marking and information to be provided by the manufacturer	Harmonized standard
EN 45502-2-1:2003 CEN/CLC/JWG AIMD Active implantable medical devices. Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers) 6060 90/385/EEC	Harmonized standard
prEN 45502-2-2:2006 CEN/CLC/JWG AIMD Active implantable medical devices. Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators) 5020 90/385/EEC	Harmonized standard
prEN 45502-2-3:2006 CEN/CLC/JWG AIMD Active implantable medical devices. Part 2-3: Particular requirements for cochlear implant systems 4020 90/385/EEC	Harmonized standard
ANSI/AAMI PC69:2000 Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators	Guideline
EN ISO 14971:2004 Application of risk management to medical devices	Harmonized standard

applicable to all equipments. They may be published separately due to the unique nature of the topic, like EMC, or may simply be an issue that was not considered or not complete when the parent was last revised. As the parent is revised, existing collaterals are occasionally absorbed into the parent.

The “particular” standard contains requirements that are exceptions to both the parent and the collateral standards. Particular standards are written for specific types of devices. Particulars are referred to as “dash-two” standards and are numbered IEC/EN AABBB-2-X.

THE IEC EN 60601 MEDICAL ELECTRICAL EQUIPMENT SAFETY STANDARDS: PARENTS, COLLATERALS AND PARTICULARS

The IEC EN 60601-1: Medical electrical equipment. Part 1: general requirements for safety [17] (parent standard) establishes general safety requirements for all aspects of medical devices from light boxes to beds to high-end diagnostic equipment like ultrasound or magnetic resonance (MR). It includes test requirements, documentation, protection from electrical hazards, protection from mechanical hazards, protection against excessive or unwanted radiation, protection against temperature, fire prevention, ingress of liquids, disinfection, biocompatibility etc. At present there are 8 collateral standards including medical systems, programmable systems, EMC, alarms etc. As the parent is revised, existing collaterals are occasionally absorbed into the parent (IEC EN 60601-1, *Figure 1*).

The topics relevant to EMC are covered in the collateral standard IEC EN 60601-1-2: Medical electrical equipment. Part 1: general requirements for safety - 2. Collateral standard: electromagnetic compatibility - Requirements and tests [18].

Within the IEC EN 60601 framework, particular standards are written for specific types of devices such as X-ray, MR, computed tomography (CT) and the like. Particulars are referred to as “dash-two” standards and are numbered IEC 60601-2-X. At present, there are more than 50 particular standards. Particular standards identify changes to the parent standards and any applicable collateral standard, which are unique to that particular technology. In the case of EMC, a particular standard may increase the required immunity.

EMC FOR MEDICAL ELECTRICAL DEVICES: IEC EN 60601-1-2

Several standards worldwide pertain to the permissible levels of electromagnetic power that can be radiated by a medical device and to the level of immunity from EMI a device must demonstrate. As for electrical medical devices, the most comprehensive one is the IEC EN 60601-1-2. Medical electrical equipment. Part 1: general requirements for safety - collateral standard: electromagnetic compatibility - requirements and tests. The IEC EN 60601-1-2 is a collateral standard of the major safety standard for medical electrical equipment (IEC EN 60601-1, *Figure 1*).

As mentioned above, as far as the EMC immunity level are concerned, the up-to-date revision of the

IEC EN 60601-1-2:2003 distinguishes between life-support and non life-support medical device. In addition, EMC of active implantable devices is regulated by different norms (*e.g.*, ANSI PC69 in the US [19] and EN 45502-1 [20], in the EU).

The IEC EN 60601-1-2 standard specifies test limits for emissions, immunity, electrostatic discharge (ESD), radiated radio frequency (RF) EMF bursts, and surges. As for radiated RF EMF, the first version of this collateral standard required a minimum immunity of 3 V/m, over a frequency range of 26 MHz to 1 GHz. This standard has been updated (2nd edition, 2001). This second edition expands RF immunity requirements in three areas. First, the highest frequencies used are increased from 1.0 to 2.5 GHz. The second important change is the modulation of the signal to which the equipment is exposed: the first edition required the signal be amplitude modulated at 1000 Hz, while the second edition requires equipment that controls or monitors physiological parameters (*e.g.*, heart rate) be tested with signals modulated at 2 Hz (closer to the frequencies of such biological parameters). Equipment that does not fall into this category is tested at a modulation frequency of 1000 Hz. The first edition did not specify the modulation level; however, the new standard sets it at 80%. Finally, life-support equipment, such as ventilators or infusion pumps, must now be tested for immunity to RF at a field strength of 10 V/m; all other equipment is still tested at 3 V/m.

Compliance with the requirements of the norms is confirmed if the device performs as intended, irrespective of the interfering signals. For those devices involving measurements of low level physiological signals, compliance level can be lower than the IEC EN 60601-1-2 test level. If this is the case, the manufacturer is required to disclose (in the instructions for use) the levels at which the device meets the performance requirements of this standard and to specify the electromagnetic characteristics of the environment in which the device will perform as intended.

In addition the norm provides formulas to calculate the recommended separation distance from portable and mobile RF communications equipment, given the compliance level of the equipment and the rated maximum output power of RF transmitter. *Table 3* summarizes the RF requirements: conducted RF, radiated RF, compliance levels and separation distances (calculated assuming far-field conditions).

Testing the immunity of medical devices as described in the EN 60601-1-2 requires specialized facilities, extensive knowledge on electromagnetics and expensive instrumentation (*e.g.*, anechoic chambers). The test set-up for radiated fields is described in the EN 61000-4-3. It requires the following types of equipment: anechoic chamber, EMI filters, RF signal generators, power amplifiers, and transmitting and monitoring antennas.

This kind of testing is generally performed by the device manufacturers or by specialized companies. In

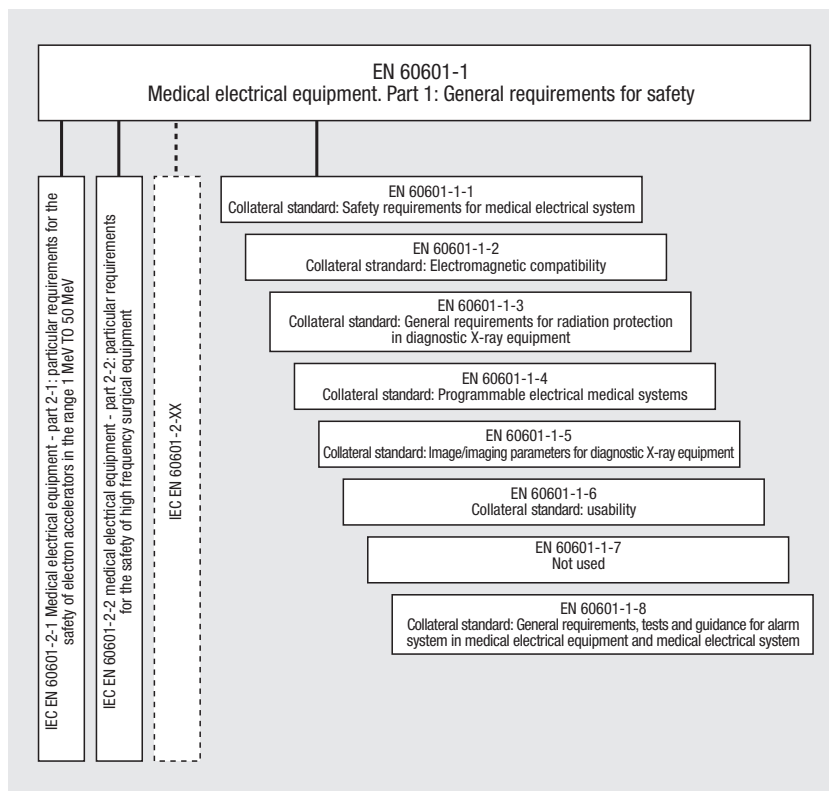


Fig. 1 | The IEC-EN 60601 medical electrical equipment safety standards: parents, collaterals and particulars.

Table 3 | Life-supporting and not life-supporting devices: immunity tests and levels, in accordance with the IEC EN 60601-1-2:2003

Immunity test	Life-supporting device			Not life-supporting device		
	IEC EN 60601-1-2 test level	Compliance level	Recommended separation distance	IEC EN 60601-1-2 test level	Compliance level	Recommended separation distance
Conducted RF (150 kHz – 80 MHz)	3 V (rms) (outside ISM band)	V_1 (V)	$d = \frac{3.5}{V_1} \sqrt{P}$	3 V (rms)	V_3 (V)	$d = \frac{3.5}{V_3} \sqrt{P}$
	10 V (rms) (inside ISM band)	V_2 (V)	$d = \frac{12}{V_2} \sqrt{P}$			
Radiated RF (80 MHz – 2.5 GHz)	10 V/m	E_1 (V/m)	$d = \frac{12}{E_1} \sqrt{P}$	3 V/m	E_2 (V/m)	$d = \frac{3.5}{E_2} \sqrt{P}$
			80 MHz-800 MHz			80 MHz-800 MHz
			$d = \frac{23}{E_1} \sqrt{P}$ 800 MHz-2.5GHz			$d = \frac{7}{E_2} \sqrt{P}$ 800 MHz-2.5GHz

ISM: industrial, scientific and medical bands.

addition it is worth noting that, in the evaluation of EM immunity, devices are exposed to far-fields: such testing may thus not be representative of particular EM interference as those arising from mobile emitters at close distances (near field). In the far-field (distance greater than several wavelengths of the transmitter carrier frequency) and for typical antennas, the field strength varies proportional to the inverse of the distance from the transmitter (*Figure 2*). Note that for distances lower than 1 meter, field strength can exceed the immunity level indicated by the norm. In addition, the typical exposure from mobile emitters hardly matches the conditions of far-field.

The above considerations are the basis for the developments of guidelines and standards for electromagnetic immunity of medical devices, to be used by health care organizations. An example of such guidelines is the America National Standard Institute

(ANSI) publication entitled *Recommended practice for an on-site, ad hoc test method for estimating radiated electromagnetic immunity of medical devices to specific radio-frequency transmitters* (C63.18) [21].

GUIDELINES FOR AD HOC TESTING IN HEALTH FACILITIES: ANSI C63.18-1997

The ANSI C63.18-1997 [21] recommended practice was developed in response to a need expressed by clinical and biomedical engineers for a technical guide to aid them in assessing the immunity of medical devices to radiated EMF from portable RF transmitters. The test modality suggested in this document differs from that described in the IEC EN 60601-1-2. If anechoic chamber is not available, medical devices can be tested in a proper dimensioned clear area. RF transmitters can be selected among commercial

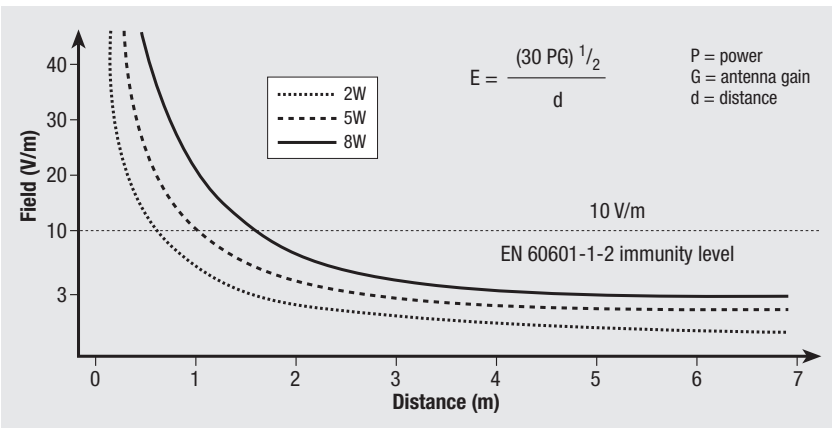


Fig. 2 | Electric field (E [V/m]) as a function of distance (d [m]) generated by an antenna having gain $G = 1.64$, with emitting power P [W] of 2 W, 5 W and 8 W (according to the reported formula). The IEC EN 60601-1-2 immunity level for life supporting equipments of 10 V/m is also indicated (gray line).

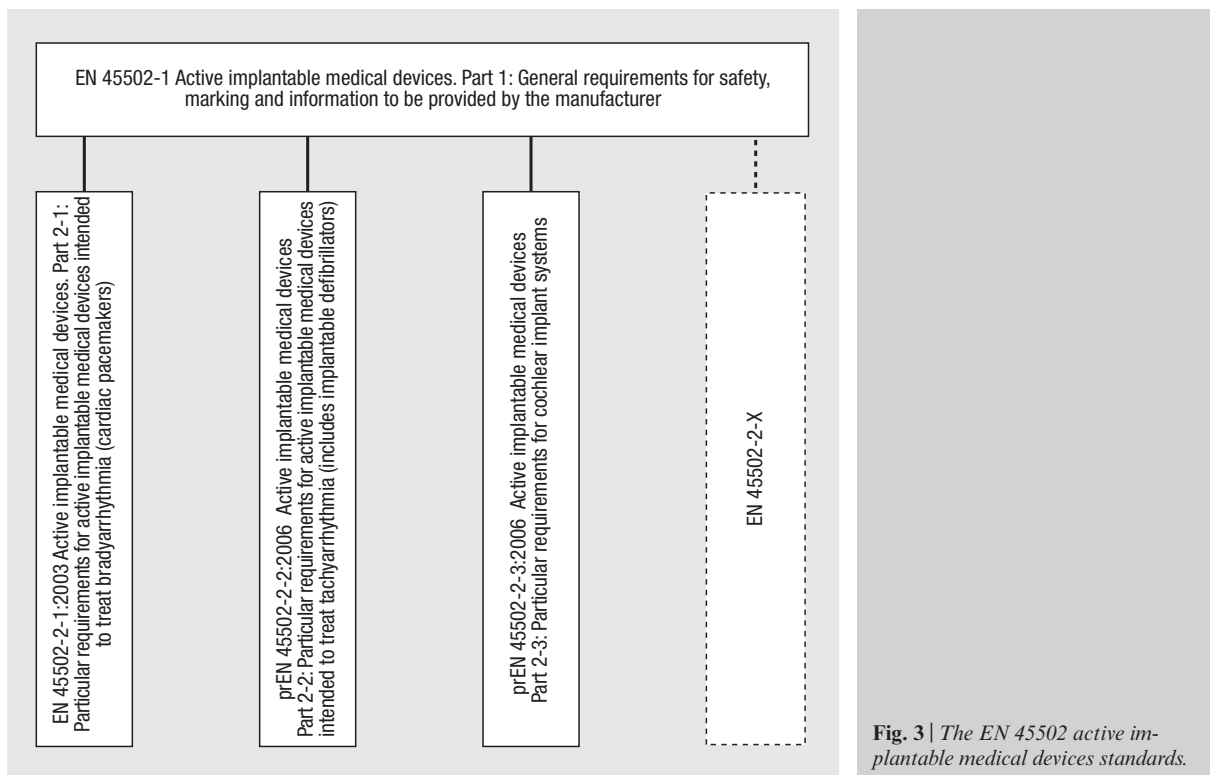


Fig. 3 | The EN 45502 active implantable medical devices standards.

equipment used in the health facilities. Care should be paid to set the transmitters to their maximum output power.

Tests are carried out during normal operation of the transmitter (e.g., making and receiving calls) located at an initial distance which would expose the medical device to fields strengths of approximately 3 to 7 V/m. During the test transmitter is moved progressively closer to the medical device up to a minimum recommended test distance, which would expose the medical device to no more than approximately 22 V/m.

As a matter of fact, this guideline complements the 60601-1-2 by exploring EM immunity of medical devices at distances shorter than the recommended separation distance indicated by the 60601-1-2. As far as mobile transmitters are concerned, this approach accounts for the actual situation of RF transmitters frequently used in the vicinity of medical devices. It should be also noted that this standard was designed assuming an immunity level of 3 V/m, thus not taking into account the higher immunity level recommended for the life-supporting medical devices, which was introduced after ANSI C63.18 publication.

STANDARDS ON ELECTROMAGNETIC COMPATIBILITY OF IMPLANTABLE DEVICES

The standards addressing the electromagnetic immunity of active implantable devices differs between US and EC.

In the US, active implantable device should comply with the ANSI/AAMI PC69:2000 [19], while in the EU active implantable devices should comply with the EN45502-1 [20], and its particular device-specific norms: EN45502-2-1 (for pacemakers) [22], prEN 45502-2-2:2006 (for defibrillators) [23], prEN 45502-2-3:2006 (for cochlear implants) [24] (Figure 3). For frequency higher than 450 MHz, these vertical standards partially adopt the testing procedures of the ANSI/AAMI PC69:2000.

The EN 45502 family cover several topics related to the safety of active implantable devices, besides the electromagnetic compatibility. As far as this field is concerned, assessment of EMC includes tests on both conducted and radiated fields.

The tests of the European standards for implantable pacemakers and defibrillators EM immunity are summarised in Table 4. Compliance is achieved if the device at all times functions in its set mode irrespective of the application of the EM signal. For frequency up to 1 kHz, however, compliance is achieved even if there are sensitivity settings causing malfunctioning, provide that an appropriate warning is given in the accompanying documentation.

Immunity to radiated field requires compulsory testing up to 40 mW, and voluntary testing up to 8 W. The specified test requirement of a 40 mW emitted power ensures compatibility of implanted cardiac devices with handheld wireless and personal communication services phones when the transmitter is maintained a minimum of 15 cm from the implanted device, and it is consistent with the

Table 4 | *Implanted active cardiac devices: EMC tests with modulated electromagnetic fields. In accordance with EN45502-2-1:2005 and prEN45502-2-2:2006*

Frequency (carrier)	Test	Type of signal	Amplitude	
16.6 Hz – 150 kHz	Conducted	Square wave amplitude modulation	2 mV 2 mV*($f/1\text{kHz}$) ² 6 mV*/1kHz	for 16.6 Hz ≤ f ≤ 1 kHz for 1 kHz ≤ f ≤ 3 kHz for 3 kHz ≤ f ≤ 150 kHz
150 kHz – 10 MHz	Conducted	Sinusoidal amplitude modulation at 130 Hz	6 mV*/1kHz 1V 1V*/1MHz	for 150 kHz ≤ f ≤ 167 kHz for 167 kHz ≤ f ≤ 1 MHz for 1 MHz ≤ f ≤ 20 MHz
10 MHz – 450 MHz	Conducted	Sinusoidal amplitude modulation at 130 Hz	10 V	
450 MHz – 3 GHz	Radiated	AAMI PC69 (amplitude modulation)	40 mW*	

*voluntary testing at 8W in the frequency range 450 MHz ≤ f < 1000 MHz, and at 2W in the frequency range 1000 MHz ≤ f ≤ 3000 MHz.

device labelling and patient guidance adopted by the producers. The voluntary testing level of 8 W are intended to ensure compatibility of implanted cardiac devices with handheld wireless phones that are operated without restrictions near the implantable device. In this standard, the test for the radiated fields can be skipped if the PM is equipped with a feed-through filter with an attenuation of at least 30 dB. The rationale behind this clause is that for PM it is known that this solution is effective for radiated EMI in this band.

Protection from exposure to weak and strong static magnetic fields and to varying magnetic fields which patients may encounter in the general public environment is addressed according to the test reported in Table 5. A major difference between the electromagnetic and the magnetic tests concerns the mechanism of coupling with the device: the major influence of EMF is through induced voltages and currents in the leads; magnetic fields could cause malfunctions due to direct effects on the internal circuitry of the device.

Scope of the 45502 family of standards is to standardize the testing procedures to be used by the manufacturers and notified bodies to assess the compliance to the applicable essential requirements. The essential requirements on EM immunity of implantable devices guarantees a high level of safety in several conditions, although, in a number of specific exposure conditions, interferences due to external EMF

may occur. For example, the working environment is a typical condition which may require appropriate precautions and protective measures, as described in the next paragraph.

PROTECTION OF WORKERS BEARING ACTIVE IMPLANTABLE DEVICE

The European Directive 2004/40/EC deals with the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (EMF) [25].

The 2004/40/EC Directive sets exposure limits and action values which provide a high level of protection as regards the established health effects that may result from exposure to EMF. These limits come from the maximum occupational exposure limits of the ICNIRP guidelines [26], and are based on direct effects of EMF exposure to the human body. For the low frequency range the induced current density in the nervous system is the limiting factor whereas in the higher frequency area tissue heating by absorption has to be limited. Thus, adherence with these limits may not necessarily avoid interference problems with, or effects on the functioning of, implanted medical devices such as metallic prostheses, cardiac PM and defibrillators, cochlear implants and other implants; interference problems especially with PM may occur at levels below the action values. Therefore appropriate precautions and protec-

Table 5 | *Implanted active cardiac devices: EMC tests with static and time-variable magnetic fields, in accordance with EN 45502-2-1:2005 and prEN 45502-2-2:2006*

Frequency	Type of signal	Amplitude		Compliance if:
DC	Constant	1 mT		Unaffected
DC	Constant	10 mT		Recovery within 5 s
1 kHz – 140 kHz	Sinusoidal	150 A/m 150 A/m*100 kHz/ f	for 1 kHz ≤ f ≤ 100 kHz for 100 kHz ≤ f ≤ 140 kHz	Unaffected

tive measures are needed. The occupational exposure directive 2004/40/EC in article 4.5 obliges the employer to investigate during the risk assessment process also indirect effects like interference with medical electronic equipment and devices (including cardiac PM and other implanted devices). To help the employer to carry out the risk assessment for workers with implanted devices, CENELEC gave mandate to technical committees to prepare harmonized standard to produce standardised simple mechanisms for assessing possible risks to implanted workers exposed to EMF.

CONCLUSIONS

Up to date the collateral standard IEC EN 60601-1-2 on EMC is the International standard to which the medical device manufacturers (eventually through specialized companies) should refer to provide the presumption of conformity with the essential requirement on EMC.

The ANSI C63.18-1997 recommended practice is instead a technical guide to be used by health care

organizations to assess the immunity of medical devices to radiated EMF from portable RF transmitters.

The standards addressing the EM immunity of active implantable devices differs between US and EC. In the US, active implantable device should comply with the ANSI/AAMI PC69:2000, while in the EU active implantable devices should comply with the EN 45502-1, and its particular device-specific norms: EN 45502-2-1 (for PM), prEN45502-2-2:2006 (for defibrillators), prEN45502-2-3:2006 (for cochlear implants). For some frequencies (higher than 450 MHz), these particular standards partially adopt the testing procedures of the ANSI/AAMI PC69:2000. Particular attention should be paid for the risk assessment of workers with implanted devices, for which the CENELEC set technical committees to prepare standardised simple rules for assessing possible risks.

Submitted on invitation.

Accepted on 24 January 2007.

References

1. Council of the European Communities. *Council Directive of 14 June 1993, 93/42/EEC. Medical Device*. Bruxelles.
2. Council of the European Communities. Council Directive of 20 June 1990, 90/385/EEC. Active implantable medical devices. *Official Journal of the European Community* L189, 20/07/1990.
3. Council of the European Communities. Council Directive of 27 October 1998 on in vitro diagnostic medical devices, 98/79/EEC. *Official Journal of the European Community* L169, 12/07/1993.
4. Silberberg JL. Performance degradation of electronic medical devices due to electromagnetic interferences. *Compliance Engineering* 1993;25:39.
5. Barbaro V, Bartolini P, Donato A, Militello C, Altamura G, Ammirati F, Santini M. Do European GSM mobile cellular phones pose a potential risk to pacemaker patients? *Pacing Clin Electrophysiol* 1995;18:1218-24.
6. Carillo R, Saunkeah B, Pickels M, Trad E, Wyatt C, Williams D. Preliminary observation on cellular telephones and pacemakers. *Pacing Clin Electrophysiol* 1995;18:863.
7. Hayes DL. Wireless phones and pacemaker interaction. *Pacing Clin Electrophysiol* 1996;19:1405-6.
8. Irnich W, Batz L, Muller R, et al. Electromagnetic interference of pacemakers by mobile phones. *Pacing Clin Electrophysiol* 1996;19:1431-46.
9. Nowak B, Rosocha S, Zellerhoff C, Liebrich A, Himmrich E, Voigtlander T, Meyer J. Is there a risk for interaction between mobile phones and single lead VDD pacemakers? *Pacing Clin Electrophysiol* 1996;19:1447-50.
10. Sparks PB, Mond HG, Joyner KH, Wood MP. The safety of digital mobile cellular telephones with minute ventilation rate adaptive pacemakers. *Pacing Clin Electrophysiol* 1996;19:1451-5.
11. Wilke A, Grimm W, Funck R, Maisch B. Influence of D-net (European GSM-standard) cellular phones on pacemaker function in 50 patients with permanent pacemakers. *Pacing Clin Electrophysiol* 1996;19:1456-8.
12. Ruggera PS, Witters DM, Bassen HI. *In vitro* testing of pacemakers for digital cellular phone electromagnetic interference. *Biomed Instrum Technol* 1997;31:358-71.
13. Barbaro V, Bartolini P, Bellocchi F, Caruso F, Donato A, Gabrielli D, Militello C, Montenero AS, Zecchi P. Electromagnetic interference of digital and analog cellular telephones with implantable cardioverter defibrillators: *in vitro* and *in vivo* studies. *Pacing Clin Electrophysiol*. 1999;22(4 Pt 1):626-34.
14. Carillo R, Williams D, Traad E, Schor J. Electromagnetic filters impede adverse interference of pacemakers by digital cellular telephones. *J Am Coll Cardiol* 1996;27:901-22.
15. Stevenson R. Design and application of broadband ceramic feedthrough capacitor EMI filters to cardiac pacemakers and implantable defibrillators. In: *Proceedings Annual International Conference IEEE Engineering in Medicine and Biology Society*. Chicago, USA: 30 October-2 November 1997. p. 2558-62.
16. Kolb C, Schmieder S, Lehmann G, Zrenner B, Karch MR, Plewan A, Schmitt C. Do airport metal detectors interfere with implantable pacemakers or cardioverter-defibrillators? *J Am Coll Cardiol* 2003;41:2054-9.
17. International Electrotechnical Commission. IEC EN 60601-1. *Medical electrical equipment. Part 1: General requirements for basic safety and essential performance*. Geneva: IEC; 2006.
18. International Electrotechnical Commission. IEC EN 60601-1-2. *Medical electrical equipment. Part 1: General requirements for safety. 2. Collateral standard: electromagnetic compatibility: Requirements and tests*. Geneva: IEC; 2003.
19. ANSI/AAMI PC69. *American active implantable medical devices – Electromagnetic compatibility – EMC test protocols for implantable cardiac pacemaker and implantable cardioverter defibrillators*. Washington, DC: National Standard Institute / Association for the Advancement of Medical Instrumentation; 2000.
20. CEN/CLC/JWG AIMD EN 45502-1. *Active implantable medical devices. Part 1: General requirements for safety, marking and information to be provided by the manufacturer*. Bruxelles: Comité Européen de Normalisation Electrotechnique (CENELEC); 1997.

21. Standard C63.18. *Recommended practice for an on-site, ad hoc test method for estimating radiated electromagnetic immunity of medical devices to specific radiofrequency transmitters*. Washington, DC: American National Standard Institute; 1999.
22. CEN/CLC/JWG AIMD EN 45502-2-1. *Active implantable medical devices. Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)*. Bruxelles: Comité Européen de Normalisation Electrotechnique (CENELEC); 2003.
23. CEN/CLC/JWG AIMD prEN 45502-2-2. *Active implantable medical devices. Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)*. Bruxelles: Comité Européen de Normalisation Electrotechnique (CENELEC); 2006.
24. CEN/CLC/JWG AIMD prEN 45502-2-3. *Active implantable medical devices. Part 2-3: Particular requirements for cochlear implant systems*. Bruxelles: Comité Européen de Normalisation Electrotechnique (CENELEC); 2006.
25. Council of the European Communities. Council Directive of Directive 2004/40/EC of the European Parliament and of the Council of 29 April 2004 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields). (18th individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC. *Official Journal of the European Union* L159; 30/04/2004.
26. International Commission on Non-Ionizing Radiation Protection. Guidelines for limiting exposure to time-varying electric, magnetic, and electromagnetic fields (up to 300 GHz). *Health Physics* 1998;74:494-522.
27. EN ISO 14971. *Application of risk management to medical devices*. Bruxelles: Comité Européen de Normalisation Electrotechnique (CENELEC); 2004.
28. European Council. Council Recommendation 1999/519/EC of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz). *Official Journal of the European Community* L199, 30/07/1999.