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Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices

Dispositifs médicaux implantables actifs — Compatibilité électromagnétique — Protocoles d'essai EMC pour pacemakers cardiaques implantables, défibrillateurs implantables et dispositifs de resynchronisation cardiaque

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14117 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

ISO 14117 is based on ANSI/AAMI PC69:2007. The relationship between the documents is addressed in A.2.4.

Introduction

The number and the types of electromagnetic (EM) emitters to which patients with active implantable cardiovascular devices are exposed in their day-to-day activities have proliferated over the past two decades. This trend is expected to continue. The interaction between these emitters and active implantable cardiovascular devices (pacemakers and implantable cardioverter defibrillators, or ICDs) is an ongoing concern of patients, industry and regulators, given the potential life-sustaining nature of these devices. The risks associated with such interactions include device inhibition or delivery of inappropriate therapy that, in the worst case, could result in serious injury or patient death.

In recent years, other active implantable cardiovascular devices have emerged, most notably devices that perform the function of improving cardiac output by optimizing ventricular synchrony, in addition to performing pacemaker or ICD function.

Although these devices can deliver an additional therapy with respect to pacemakers and ICD devices, most of their requirements concerning EM compatibility are similar so that, in most cases, the concepts that apply to pacemakers also apply to CRT-P devices, and the appropriate way to test a CRT-P device is similar to the way pacemakers are tested. Similarly, the concepts that apply to ICD devices mostly apply to CRT-D devices as well, so the appropriate way to test a CRT-D device is similar to the way ICD devices are tested.

Standard test methodologies allow manufacturers to evaluate the EM compatibility performance of a product and demonstrate that the product achieves an appropriate level of EM compatibility in uncontrolled EM environments that patients may encounter.

It is important that manufacturers of transmitters and any other equipment that produces EM fields (intentional or unintentional) understand that such equipment may interfere with the proper operation of active implantable cardiovascular devices.

It is important to understand that these interactions may occur despite the conformance of the device to this International Standard and the conformance of emitters to the relevant human exposure safety standards and pertinent regulatory emission requirements, e.g. those of the U.S. Federal Communications Commission (FCC).

Compliance with biological safety guidelines does not necessarily guarantee EM compatibility with active implantable cardiovascular devices. In some cases, the reasonably achievable EM immunity performance for these devices falls below these biological safety limits.

The potential for emitter equipment to interfere with active implantable cardiovascular devices is complex and depends on the following factors:

— frequency content of the emitter,

— modulation format,

— power of the signal,

— proximity to the patient,

— coupling factors, and

— duration of exposure.

Devices within the scope of this International Standard are life-sustaining and are designed to sense low-level physiological signals (as low as 0,1 mV) that have frequency content up to several hundred Hertz. For patient safety and comfort, these devices are small, offer many therapeutic features, and have a long battery life. These highly desired features, combined with the intrinsic functionality, limit the size and number of components and thus place practical constraints on the capability to control electromagnetic interference (EMI).

An emitter with a fundamental carrier frequency up to several hundred Hertz has the potential to be sensed directly by the pacemaker or ICD. Also, higher-frequency carriers that are modulated up to several hundred Hertz and that have sufficient proximity and power may be sensed by the pacemaker or ICD.

Additional details regarding this issue can be found in Annex M.

This International Standard addresses the EM compatibility of pacemakers and ICDs up to 3 000 MHz and is divided in several sections.

a) 0 Hz ≤ f < 450 MHz

In the lower-frequency bands (<450 MHz), there are many EM emitters, such as broadcast radio and television, and a number of new technologies or novel applications of established technologies that may increase the likelihood of interaction between the emitters and patients' pacemakers and ICDs. A few examples:

— electronic article surveillance (EAS) systems;

— access control systems (radio-frequency identification, or RFID);

— new wireless service in the ultra-high-frequency and very-high-frequency bands;

— magnetic levitation rail systems;

— radio-frequency (RF) medical procedures, such as high-frequency surgery and ablation therapy;

— metal detectors;

— magnetic resonance imaging; and

— experimental use of transponders for traffic control.

b) 450 MHz ≤ f < 3 000 MHz

These are the frequencies, f, that are typically associated with personal hand-held communication devices (e.g. wireless telephones and two-way radios).

Two decades ago, relatively few pacemaker patients used hand-held transmitters or were exposed to EM fields from portable transmitters. Hand-held, frequency-modulated transceivers for business, public safety, and amateur radio communications represented the predominant applications. However, the environment has changed rapidly during the past 15 years, with wireless phone systems becoming increasingly common as this technology matured and received widespread public acceptance. Thus, it is becoming increasingly likely that a large portion of the pacemaker and ICD patient population will be exposed to EM fields from portable wireless phone transmitters operated either by themselves or by others. Also, it should be expected that the wireless technology revolution will continue to evolve new applications using increasingly higher microwave frequencies.

Most electronic equipment, including external medical devices, has been designed for compatibility with relatively low-amplitude EM conditions. Recognizing the wide range of EM environments that patients could encounter, implantable devices have been designed to tolerate much higher-amplitude EM conditions than most other electronic products. However, in some instances, even this enhanced immunity is not sufficient to achieve compatibility with the complex electric and magnetic fields generated by low-power emitters located within a few centimetres of the implantable device. Studies in the mid-1990s demonstrated that some models of pacemakers and ICDs had insufficient immunity to allow unrestricted use when in close proximity to some hand-held emitters (e.g. wireless telephones and two-way radios). Although operating restrictions can help prevent EM interaction with implantable devices, this approach is not viewed as an optimum long-term solution. Rather, improved EM compatibility is the preferred method for meeting patient expectations for using wireless services with minimal operating restrictions.

Some technological factors are contributing to the expanding variety of emitters to which patients may now be exposed:

— smaller wireless phones,

— the introduction of digital technology, and

— peak transmitter power.

Wireless phone size has now been reduced sufficiently so that it is possible for patients to carry a phone that is communicating or in standby mode in a breast pocket immediately adjacent to a pectorally implanted device.

Since 1994, reported studies have indicated that interference effects in pacemakers are more severe from digital phones than from analog phones. As of September 2010, there were more than 5 billion digital subscriptions worldwide.

The various wireless phone standards allow for a range of power levels and modulation schemes. Most digital wireless phones are capable of producing greater peak transmitted power than analog phones are capable of producing. Those factors contribute to greater potential interactions with pacemakers and ICDs.

For frequencies of 450 MHz $\leq f \leq$ 3 000 MHz, this International Standard specifies testing at 120 mW net power into a dipole antenna to simulate a hand-held wireless transmitter 15 cm from the implant. An optional characterization test is described that uses higher power levels to simulate a hand-held wireless transmitter placed much closer to the implant. Claims that the manufacturer may wish to make on the basis of the results of the optional characterization are to be negotiated between the manufacturer and the appropriate regulatory authorities.

c) $f \geq$ 3,000 MHz

This International Standard does not require testing of devices above 3 GHz. The upper-frequency limit chosen for this International Standard reflects consideration of the following factors:

1) the types of radiators of frequencies above 3 GHz,

2) the increased device protection afforded by the attenuation of the enclosure and body tissue at microwave frequencies,

3) the expected performance of EMI control features that typically are implemented to meet the lower-frequency requirements of this International Standard, and

4) the reduced sensitivity of circuits at microwave frequencies.

Additional details can be found in Clause 5.

In conclusion, it is reasonable to expect that patients with pacemakers and ICDs will be exposed to increasingly complex EM environments. Also, the rapid evolution of new technologies and their acceptance by patients will lead to growing expectations for unrestricted use. In view of the changing EM environment and customer expectations, manufacturers will need to evaluate their product designs to assess compatibility with the complex fields, broad range of frequencies, and variety of modulation schemes associated with existing and future applications.