
**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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 14117:2012), which has been technically revised.

The main changes compared to the previous edition are as follows:

- new definitions added for *interference mode* and *transient exposure*;
- the breakpoint between injected voltage testing and radiated testing reduced from 450 MHz to 385 MHz to account for new wireless services;
- modification and clarification of 4.4, temporary exposure to CW sources;
- new 4.10 concerning *transient exposure* to low-frequency magnetic field sources;
- recognition of multiple electrode leads such as those with IS-4 and DF-4 connectors;
- new 7.4 explicitly requiring separation distance warning when applicable;
- elimination of the table of emitters and frequencies from Annex B;
- addition of new informative Annex N describing generic nomenclature for multi-port, multi-electrode systems;
- addition of new informative Annex O to provide a sample test method for evaluation of transient exposure;
- overall language clarifications, corrections to minor use issues from edition 1, and updated rationale.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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* functions.

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 might encounter.

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

It is important to understand that these interactions can occur despite the conformance of the device to this document 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.

See [Annex M](#) for rationale concerning the use of ICNIRP 1998 levels. See [Annex M](#) for rationale applicable to emitters above 10 MHz.

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.

An emitter with a fundamental carrier frequency up to 1 kHz has the potential to be sensed directly by the *pacemaker* or *ICD*. Also, higher-frequency carriers that have baseband modulation rates below 500 Hz and that have sufficient proximity and power might be sensed by the *pacemaker* or *ICD*.

Additional details regarding this issue can be found in [Annex M](#).

This document addresses the EM compatibility of *pacemakers* and *ICDs* up to 3 000 MHz and is divided in several subclauses.

a) $0 \text{ Hz} \leq f < 385 \text{ MHz}$

In the lower-frequency bands ($<385 \text{ MHz}$), there are many EM emitters, such as broadcast radio and television, and a number of new technologies or novel applications of established technologies that can 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 services 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;
- experimental use of transponders for traffic control;
- wireless charging systems for electric or hybrid vehicles.

b) $385 \text{ MHz} \leq f < 3\,000 \text{ MHz}$

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 might now be exposed:

- smaller wireless phones;