BSI Standards Publication

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

National foreword

This British Standard is the UK implementation of ISO 14117:2019. It supersedes BS ISO 14117:2012, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/150/2, Cardiovascular implants.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Published by BSI Standards Limited 2019

ISBN 978 0 580 99091 5

ICS 11.040.40; 33.100.01

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 September 2019.

Amendments/corrigenda issued since publication

Date	Text affected

INTERNATIONAL ISO

Second edition
2019-09

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

Reference number
ISO 14117:2019(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword ... **v**

Introduction ... **vi**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms, definitions, symbols and abbreviated terms ... **1**
3.1 Terms and definitions ... 1
3.2 Acronyms and abbreviations ... 3

4 Test requirements for the frequency band 0 Hz ≤ *f* ≤ 3 000 MHz ... **4**
4.1 General requirements for all devices ... 4
4.2 Induced lead current ... 5
4.2.1 General requirements ... 5
4.2.2 ***Pacemakers*** and ***CRT-P*** devices ... 5
4.2.3 ***ICD***s and ***CRT-D*** devices ... 9
4.3 Protection from persisting malfunction attributable to ambient electromagnetic fields ... 12
4.3.1 General requirements ... 12
4.3.2 ***Pacemaker*** and ***CRT-P*** devices ... 12
4.3.3 ***ICD***s and ***CRT-D*** devices ... 17
4.4 Protection from malfunction caused by temporary exposure to CW sources ... 23
4.4.1 ***Pacemaker*** and ***CRT-P*** device' response to temporary continuous wave sources in the frequency range 16,6 Hz to 167 kHz ... 23
4.4.2 ***ICD***s and ***CRT-D*** devices ... 25
4.5 Protection from sensing EMI as cardiac signals ... 26
4.5.1 General requirements ... 26
4.5.2 Protection from sensing EMI as cardiac signals in the frequency range of 16,6 Hz to 150 kHz ... 27
4.5.3 Protection from sensing EMI as cardiac signals in the frequency range of 150 kHz to 10 MHz ... 30
4.5.4 Protection from sensing EMI as cardiac signals in the frequency range of 10 MHz to 385 MHz ... 33
4.6 Protection from static magnetic fields of flux density up to 1 mT ... 35
4.6.1 General requirements ... 35
4.6.2 ***Pacemakers*** and ***CRT-P*** devices ... 35
4.6.3 ***ICD***s and ***CRT-D*** devices ... 36
4.7 Protection from static magnetic fields of flux density up to 50 mT ... 37
4.7.1 General requirements ... 37
4.7.2 ***Pacemakers*** and ***CRT-P*** devices ... 37
4.7.3 ***ICD***s and ***CRT-D*** devices ... 37
4.8 Protection from AC magnetic field exposure in the range of 1 kHz to 140 kHz ... 37
4.8.1 General requirements ... 37
4.8.2 ***Pacemakers*** and ***CRT-P*** devices ... 37
4.8.3 ***ICD***s and ***CRT-D*** devices ... 38
4.9 Test requirements for the frequency range of 385 MHz ≤ *f* ≤ 3 000 MHz ... 38
4.9.1 General requirements ... 38
4.9.2 Test setup ... 39
4.9.3 Test procedure ... 40
4.9.4 Performance criteria ... 42
4.10 Transient exposure to stationary low-frequency electromagnetic field sources in the frequency range 16,6 Hz to 167 kHz ... 43

5 Testing above frequency of 3 000 MHz ... **43**

6 Protection of devices from EM fields encountered in a therapeutic environment ... **43**
6.1 Protection of the device from damage caused by high-frequency surgical exposure ... 43
6.1.1 General requirements ... 43

6.1.2 ***Pacemakers*** and ***CRT-P*** devices 44
6.1.3 ***ICD***s and ***CRT-D*** devices 44
6.2 Protection of the device from damage caused by external defibrillators 45
6.2.1 General requirements 45
6.2.2 ***Pacemakers*** and ***CRT-P*** devices 45
6.2.3 ***ICD***s and ***CRT-D*** devices 48

7 Additional accompanying documentation 49
7.1 Disclosure of permanently programmable sensitivity settings 49
7.2 Descriptions of reversion modes 49
7.3 Known potential hazardous behaviour 49
7.4 Minimum separation distance from hand-held transmitters 49

Annex A (informative) **Rationale 50**

Annex B (informative) **Rationale for test frequency ranges 63**

Annex C (informative) **Code for describing modes of implantable generators 64**

Annex D (normative) **Interface circuits 66**

Annex E (informative) **Selection of capacitor C_x 71**

Annex F (normative) **Calibration of the injection network (Figure D.5) 74**

Annex G (normative) **Torso simulator 76**

Annex H (normative) **Dipole antennas 80**

Annex I (normative) ***Pacemaker/ICD*** **programming settings 82**

Annex J (normative) **Simulated cardiac signal 84**

Annex K (normative) **Calculation of net power into dipole antenna 85**

Annex L (informative) **Loop area calculations 90**

Annex M (informative) **Correlation between levels of test voltages used in this document and strengths of radiated fields 96**

Annex N (informative) **Connections to DUTs having ports with more than two electrode connections 104**

Annex O (informative) **Example method for evaluation of transient and permanent malfunction of a CIED due to temporary exposure to low frequency (<167 kHz) electromagnetic fields 127**

Bibliography 132

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 (*pacemaker*s and *implantable cardioverter defibrillator*s, or *ICD*s) 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 *pacemaker*s and *ICD* devices, most of their requirements concerning EM compatibility are similar so that, in most cases, the concepts that apply to *pacemaker*s also apply to *CRT-P* devices, and the appropriate way to test a *CRT-P* device is similar to the way *pacemaker*s 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 *pacemaker*s and *ICD*s up to 3 000 MHz and is divided in several subclauses.

a) 0 Hz ≤ f < 385 MHz

In the lower-frequency bands (<385 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' *pacemaker*s and *ICD*s. 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 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 *pacemaker*s and *ICD*s 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;

— the introduction of digital technology;

— 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.

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 *pacemaker*s and *ICD*s.

For frequencies of 385 MHz ≤ f ≤ 3 000 MHz, this document 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.

c) f ≥ 3 000 MHz

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

— the types of radiators of frequencies above 3 GHz;

— the increased device protection afforded by the attenuation of the enclosure and body tissue at microwave frequencies;

— the expected performance of EMI control features that typically are implemented to meet the lower-frequency requirements of this document ; and

— 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 *pacemaker*s and *ICD*s 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.

Annex A provides the rationale for certain provisions of this document in order to provide useful background information for reviewing, applying, and revising this document. This rationale is directed toward individuals who are familiar with the subject of this document but have not participated in its drafting. Remarks made in this annex apply to the relevant clause, subclause, or annex in this document; the numbering therefore, might not be consecutive.

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

1 Scope

This document specifies test methodologies for the evaluation of the electromagnetic compatibility (EMC) of active implantable cardiovascular devices that provide one or more therapies for bradycardia, tachycardia and cardiac resynchronization in conjunction with transvenous lead systems.

NOTE This document was designed for pulse generators used with endocardial leads or epicardial leads. At the time of this edition, the authors recognized the emergence of technologies that do not use endocardial leads or epicardial leads for which adaptations of this part will be required. Such adaptations are left to the discretion of manufacturers incorporating these technologies.

It specifies performance limits of these devices, which are subject to interactions with EM emitters operating across the EM spectrum in the two following ranges:

— 0 Hz ≤ f < 385 MHz;

— 385 MHz ≤ f ≤ 3 000 MHz

This document also specifies requirements for the protection of these devices from EM fields encountered in a therapeutic environment and defines their required accompanying documentation, providing manufacturers of EM emitters with information about their expected level of immunity.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14708-1:2014, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

ISO 14708-2:2019, *Implants for surgery — Active implantable medical devices — Part 2: Cardiac pacemakers*

ISO 14708-6:2019, *Implants for surgery — Active implantable medical devices — Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)*

3 Terms, definitions, symbols and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14708-1:2014, ISO 14708-2:2019, ISO 14708-6:2019 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp