SLOVENSKI STANDARD
SIST EN ISO 14708-6:2022

01-oktober-2022

Vsadki (implantati) za kirurgijo - Aktivni medicinski pripomočki za vsaditev - 6. del: Posebne zahteve za aktivne vsadljive medicinske pripomočke, namenjene za zdravljenje tahiaritmije (vključuje vsadljive defibrilatorje) (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) (ISO 14708-6:2019)

Chirurgische Implantate - Aktive implantierbare medizinische Geräte - Teil 6: Besondere Festlegungen für aktive implantierbare medizinische Produkte zur Behandlung von Tachyarrhythmie (einschließlich implantierbaren Defibrillatoren) (ISO 14708-6:2019)

Implants chirurgicaux - Dispositifs médicaux implantables actifs - Partie 6: Exigences particulières pour les dispositifs médicaux implantables actifs destinés à traiter la tachyarythmie (y compris les défibrillateurs implantables) (ISO 14708-6:2019)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14708-6

July 2022

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English version

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

Implants chirurgicaux - Dispositifs médicaux implantables actifs - Partie 6: Exigences particulières pour les dispositifs médicaux implantables actifs conçus pour traiter la tachyarythmie (y compris les défibrillateurs implantables) (ISO 14708-6:2019)

Chirurgische Implantate - Aktive implantierbare medizinische Geräte - Teil 6: Besondere Festlegungen für aktive implantierbare medizinische Produkte zur Behandlung von Tachyarrhythmie (einschließlich implantierbaren Defibrillatoren) (ISO 14708-6:2019)

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CEN-CENELEC Management Centre:
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European foreword

This document (EN ISO 14708-6:2022) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN-CENELEC/ JTC 16 “Active Implantable Medical Devices” the secretariat of which is held by DKE.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2023, and conflicting national standards shall be withdrawn at the latest by January 2023.

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

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN and CENELEC websites.

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Endorsement notice

The text of ISO 14708-6:2019 has been approved by CEN-CENELEC as EN ISO 14708-6:2022 without any modification.

INTERNATIONAL STANDARD

ISO 14708-6

Second edition
2019-09

Implants for surgery — Active implantable medical devices —

Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)

Implants chirurgicaux — Dispositifs médicaux implantables actifs —

Partie 6: Exigences particulières pour les dispositifs médicaux implantables actifs conçus pour traiter la tachyarythmie (y compris les défibrillateurs implantables)

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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).

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.

ISO 14708-6 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 14708-6:2010), which has been technically revised.

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

— addition of requirements for congestive heart failure devices;

— introduction of nomenclature for devices having more than two channels of pacing/sensing/defibrillation as shown in ISO 14117:2019, Annex N;

— inclusion of new temporary exposure criteria in 17.1 for outer surface temperatures exceeding 39 °C;

— revision of atmospheric pressure test requirements in Clause 25 to align with requirements of ISO 14708-2;

— replacement of detailed requirements in Clause 27 by reference to ISO 14117.

Other changes include updates to selected definitions and incorporation of new measurement equipment accuracy requirements.

A list of all parts in the ISO 14708 series can be found on the ISO website.

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

This document specifies particular requirements for *implantable cardioverter defibrillators* and the functions of active implantable medical devices intended to treat tachyarrhythmia, to provide basic assurance of safety for both patients and users.

An external defibrillator is a medical device used, in the emergency setting, to deliver a high-energy shock to the heart, by means of *electrode*s applied to the external chest wall, in patients suffering ventricular fibrillation (a rapid, disorganized and potentially lethal heart rhythm abnormality), to restore normal heart action. External defibrillators can also be used, in emergency or elective settings, to terminate other ventricular or atrial tachyarrhythmias by delivery of a high-energy shock, synchronized to the intrinsic cardiac rhythm, a procedure known as *cardioversion*. In patients known to be at risk of such arrhythmias, due to the occurrence of previous episodes or the presence of specific predisposing cardiac conditions, an *implantable cardioverter defibrillator* might be implanted to perform similar functions. The implantable device, which is much smaller than an external defibrillator, is contained within a sealed, encapsulating enclosure. It generates high voltage *pulses* from an enclosed, miniature, electrical battery. The *pulses* are transmitted to the heart by means of implanted, insulated conductors with *electrode*s (leads). The *implantable cardioverter defibrillator* can also incorporate other sensing and pacing functions, such as rate support for bradycardia and *antitachycardia pacing* (*ATP*) to terminate certain tachyarrhythmias without the need of a high-energy shock. The defibrillator can be adjusted non-invasively by means of an electronic device, known as a programmer.

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 *ICD* functions.

Although these devices can deliver an additional therapy with respect to *ICD* devices, most of their requirements are similar so that, in most cases, the concepts that apply to *ICD*s also apply to *CRT-D* devices, and the appropriate way to test a *CRT-D* device is similar to the way *ICD*s are tested.

This document is relevant to all parts of active implantable medical devices intended to treat tachyarrhythmia other than pacing functions to control bradyarrhythmia or provide cardiac resynchronization. Typical examples are *implantable pulse generators*, leads, *adaptors*, *accessories*, programmers and the related software (bradyarrhythmia and cardiac resynchronization pacing functions are dealt with in ISO 14708-2).

The requirements of this document supplement or modify those of ISO 14708-1, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*, hereinafter referred to as ISO 14708-1. The requirements of this document take priority over those of ISO 14708-1.

In this document, terms printed in italic letters are used as defined in Clause 3. Where a defined term is used as a qualifier in another term, it is not printed in italic letters unless the concept thus qualified is also defined.

Information is also provided in Annex A that explains the relationship between ISO/TR 14283, *Implants for surgery — Essential principles of safety and performance*, ISO 14708-1 and this document.

Notes on this document are provided in Annex B for information.

Annex C describes a coding system that may be used to designate tachyarrhythmia therapy modes. All annexes are informative.

Implants for surgery — Active implantable medical devices —

Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)

1 Scope

This document specifies requirements that are applicable to *implantable cardioverter defibrillators* and *CRT-D*s and the functions of active implantable medical devices intended to treat tachyarrhythmia.

The tests that are specified in ISO 14708 are type tests and are to be carried out on samples of a device to show compliance.

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

This document is also applicable to some non-implantable parts and *accessories* of the devices (see Note 1).

The characteristics of the *implantable pulse generator* or lead shall be determined by either the appropriate method detailed in this document or by any other method demonstrated to have accuracy equal to, or better than, the method specified. In the case of dispute, the method detailed in this document shall apply.

Any aspect of an active implantable medical device intended to treat bradyarrhythmias or cardiac resynchronization is covered by ISO 14708-2.

NOTE 1 The device that is commonly referred to as an active implantable medical device can in fact be a single device, a combination of devices, or a combination of a device or devices and one or more *accessories*. Not all of these parts are required to be either partially or totally implantable, but there is a need to specify some requirements of non-implantable parts and *accessories* if they could affect the safety or performance of the implantable device.

NOTE 2 In this document, terms printed in italics are used as defined in Clause 3. Where a defined term is used as a qualifier in another term, it is not printed in italics unless the concept thus qualified is also defined.

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 5841-3:2013, *Implants for surgery — Cardiac pacemakers — Part 3: Low-profile connectors (IS-1) for implantable pacemakers*

ISO 11318:2002, *Cardiac defibrillators — Connector assembly DF-1 for implantable defibrillators — Dimensions and test requirements*

ISO 14117:2019, *Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators*

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*

IEC/TR 60878:2015, *Graphical symbols for electrical equipment in medical practice*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14708-1 and the following apply.

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

— IEC Electropedia: available at http://www.electropedia.org/

3.1
adaptor
special connector used between an otherwise incompatible *implantable pulse generator* and a lead

[SOURCE: ISO 14708-2:2019, 3.2]

3.2
implantable cardioverter defibrillator
ICD
active implantable medical device comprising an *implantable pulse generator* and lead(s) that is intended to detect and correct tachycardias and fibrillation by application of *cardioversion/defibrillation pulse*(s) to the heart

3.3
implantable pulse generator
IPG
part of the active implantable medical device, including the power supply and electronic circuit that produces an electrical output

Note 1 to entry: For purposes of this document, the term *implantable pulse generator* describes any active implantable medical device that incorporates functions intended to treat tachyarrhythmias.

[SOURCE: ISO 14708-2:2019, 3.4, modified – "active implantable medical device" substituted for "*pacemaker*", NOTE 1 to entry added]

3.4
sensitivity
minimum signal required to control consistently the function of the *implantable pulse generator*

[SOURCE: ISO 14708-2:2019, 3.8]

3.5
electrode
electrically conducting part (usually the termination of a lead), which is designed to form an interface with body tissue or body fluid

[SOURCE: ISO 14708-2:2019, 3.9]

3.6
endocardial lead
lead with an *electrode* designed to make contact with the endocardium, or inner surface of the heart

[SOURCE: ISO 14708-2:2019, 3.12]

3.7
epicardial lead
lead with an *electrode* designed to make contact with the epicardium, or outer surface of the heart

[SOURCE: ISO 14708-2:2019, 3.13]

3.8
transvenous
approach to the heart through the venous system

[SOURCE: ISO 14708-2:2019, 3.14]

3.9
insertion diameter
<lead>minimum bore of a rigid cylindrical tube into which the lead (not including the connector) can be inserted

[SOURCE: ISO 14708-2:2019, 3.15]

3.10
lead pacing impedance
Z_p
impedance that is formed by the ratio of a voltage *pulse* to the resulting current

Note 1 to entry: The impedance is composed of the *electrode* to tissue interface and the lead impedance.

[SOURCE: ISO 14708-2:2019, 3.16].

3.11
model designation
name and/or a combination of letters and numbers used by a manufacturer to distinguish, by function or type, one device from another

[SOURCE: ISO 14708-2:2019, 3.17]

3.12
serial number
unique combination of letters and/or numbers, selected by the manufacturer, intended to distinguish a device from other devices with the same *model designation*

[SOURCE: ISO 14708-2:2019, 3.18]

3.13
pulse
electrical output of an *implantable pulse generator* other than *CD pulse* intended to stimulate the myocardium

[SOURCE: ISO 14708-2:2019, 3.20, modified – added "other than *CD pulse*".]

3.14
pulse amplitude
amplitude of the *pulse*

[SOURCE: ISO 14708-2:2019, 3.21]

3.15
pulse duration
duration of the *pulse*

[SOURCE: ISO 14708-2:2019, 3.22]