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STN	**Chirurgické implantáty Aktívne implantovateľné zdravotnícke pomôcky Časť 2: Kardiostimulátory (ISO 14708-2: 2019)**	**STN EN ISO 14708-2** 85 3001

Implants for surgery - Active implantable medical devices - Part 2: Cardiac pacemakers (ISO 14708-2:2019)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

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English version

Implants for surgery - Active implantable medical devices - Part 2: Cardiac pacemakers (ISO 14708-2:2019)

Implants chirurgicaux - Dispositifs médicaux implantables actifs - Partie 2: Stimulateurs cardiaques (ISO 14708-2:2019)

Chirurgische Implantate - Aktive implantierbare medizinische Geräte - Teil 2: Herzschrittmacher (ISO 14708-2:2019)

This European Standard was approved by CEN on 6 July 2022.

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European foreword

This document (EN ISO 14708-2:2022) 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of an identical text or by endorsement, at the latest by January 2023, and conflicting national standards shall be withdrawn at the latest by January 2023.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.

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Endorsement notice

The text of ISO 14708-2:2019 has been approved by CEN-CENELEC as EN ISO 14708-2:2022 without any modification.

INTERNATIONAL STANDARD

ISO 14708-2

Third edition
2019-09

Implants for surgery — Active implantable medical devices —

Part 2: Cardiac pacemakers

Implants chirurgicaux — Dispositifs médicaux implantables actifs — Partie 2: Stimulateurs cardiaques

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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).

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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 14708-2 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

This third edition cancels and replaces the second edition (ISO 14708-2:2012), 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 as shown in ISO 14117:2019, Annex N;

— revision of the method for measurement of *pulse amplitude* and *pulse duration* in 6.1.2;

— removal of measurement requirements for input impedance in 6.1.4;

— inclusion of new temporary exposure criteria in 17.1 for outer surface temperatures exceeding 39 °C. 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 those active implantable medical devices intended to treat bradyarrhythmias (*pacemakers*), to provide basic assurance of safety to both patients and users.

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* functions.

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

An implantable cardiac *pacemaker* is essentially a powered electronic device within a sealed, encapsulating enclosure (an *implantable pulse generator*). The device can stimulate heart *beats* by generating electrical impulses which are transmitted to the heart along implanted, insulated conductors with *electrodes* (leads). The *pacemaker* can be adjusted non-invasively by an electronic device, known as a programmer.

This document is relevant to all parts of implantable *pacemakers*, including all *accessories*. Typical examples are *implantable pulse generators*, leads, *adaptors*, programmers and the related software.

The requirements of this document supplement or modify those of ISO 14708-1. The requirements of this document take priority over those of ISO 14708-1.

Although both this document and the Directive 90/385/EEC deal with the same products, the structure and purpose of the two documents are different. Annex A correlates the requirements of the Directive with the subclauses of ISO 14708-1 and this document. Annex B is a rationale providing further explanation of the subclauses of this document.

Annex C describes a coding system that may be used to designate bradyarrhythmia pacing modes. Annex D defines reference points for measurements of *pulse amplitude* and *pulse duration*, and the form of test signal used to determine *sensitivity*.

All annexes except Annex D are informative.

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

INTERNATIONAL STANDARD **ISO 14708-2:2019(E)**

Implants for surgery — Active implantable medical devices —

Part 2: Cardiac pacemakers

1 Scope

This document specifies requirements that are applicable to those active implantable medical devices intended to treat bradyarrhythmias and devices that provide therapies for cardiac resynchronization.

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

This document was designed for bradyarrhythmia *pulse* generators used with *endocardial leads* or *epicardial leads*. At the time of this edition, the authors recognized the emergence of leadless technologies 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 electrical characteristics of the *implantable pulse generator* or lead are determined either by the appropriate method detailed in this particular standard or by any other method demonstrated to have an accuracy equal to, or better than, the method specified. In case of dispute, the method detailed in this particular standard applies.

Any features of an active implantable medical device intended to treat tachyarrhythmias are covered by ISO 14708-6.

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, implantable cardioverter defibrillators and cardiac resynchronization devices, Second Edition*

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 27186:2010, *Active implantable medical devices — Four-pole connector system for implantable cardiac rhythm management devices — Dimensional and test requirements*