INTERNATIONAL STANDARD

ISO 14708-2

Second edition
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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.

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 14708-2 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 14708-2:2005), which has been technically revised.

ISO 14708 consists of the following parts, under the general title *Implants for surgery — Active implantable medical devices*:

— *Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

— *Part 2: Cardiac pacemakers*

— *Part 3: Implantable neurostimulators*

— *Part 4: Implantable infusion pumps*

— *Part 5: Circulatory support devices*

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

The following parts are under preparation:

— *Part 7: Particular requirements for cochlear implant systems*

Introduction

This part of ISO 14708 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.

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 may be adjusted non-invasively by an electronic device, known as a programmer.

This part of ISO 14708 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 part of ISO 14708 supplement or modify those of ISO 14708-1, referred to as the General Standard. The requirements of this part of ISO 14708 take priority over those of ISO 14708-1.

Figures or tables that are additional to those of ISO 14708-1 are numbered starting from 101; additional annexes are lettered AA, BB, etc.

Although both this part of ISO 14708 and the Directive 90/385/EEC deal with the same products, the structure and purpose of the two documents are different. Annex AA correlates the requirements of the Directive with the subclauses of ISO 14708-1 and this part of ISO 14708. Annex BB provides reference in the other direction, from this part of ISO 14708 to the Directive. Annex CC is a rationale providing further explanation of the subclauses of this part of ISO 14708.

Annex DD describes a coding system that may be used to designate bradyarrhythmia pacing modes. Annex EE provides optional symbols that may be used to reduce the need for translation of MARKINGS and information in the accompanying documentation in multiple languages. Annex FF 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 FF are informative.

Implants for surgery — Active implantable medical devices —

Part 2:
Cardiac pacemakers

1 Scope

This part of ISO 14708 specifies requirements that are applicable to those ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat bradyarrhythmias.

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

This part of ISO 14708 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 may 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 part of ISO 14708, terms printed in SMALL CAPITAL 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 small capital letters unless the concept thus qualified is also defined.

2 Normative references

The following referenced documents are indispensable for the application 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 5841-3:2000, *Implants for surgery — Cardiac pacemakers — Part 3: Low-profile connectors (IS-1) for implantable pacemakers*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

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

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

ISO 14708-1:2000, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

IEC 60068-2-47, *Environmental testing — Part 2-47: Test — Mounting of specimens for vibration, impact and similar dynamic tests*

IEC 60068-2-64, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

3 Terms and definitions

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

3.1
accessory
article which, while not being a device, is intended specifically by its manufacturer to be used together with a device in accordance with the use of the device intended by the device manufacturer

3.2
adaptor
special connector used between an otherwise incompatible active implantable pulse generator and a lead

3.3
pacemaker
ACTIVE IMPLANTABLE MEDICAL DEVICE intended to treat bradyarrhythmias, comprising an IMPLANTABLE PULSE GENERATOR and LEAD(S)

3.4
implantable pulse generator
part of the PACEMAKER, including the power supply and electronic circuit that produces an electrical output

3.5
sensor
part of a pacemaker that is designed to detect signals for the purpose of RATE MODULATION

3.6
dual-chamber
condition of relating both to the atrium and ventricle

3.7
input impedance
Z_{in}
⟨implantable pulse generator⟩ electrical impedance presented at an input terminal, measured according to the procedure in 6.1.4 and taken as equal to that presented to a sensed beat

3.8
sensitivity
sensing threshold
minimum signal required to control consistently the function of the IMPLANTABLE PULSE GENERATOR

NOTE See 6.1.3.

