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Implants for surgery - Active implantable medical devices - Part 2: Cardiac pacemakers (ISO/DIS 14708-2:2018)

Implants chirurgicaux - Dispositifs médicaux implantables actifs - Partie 2: Stimulateurs cardiaques (ISO/DIS 14708-2:2018)

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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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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

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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. 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.

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.

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

NOTE The attention of Member Bodies is drawn to the fact that equipment MANUFACTURERS and testing organizations might need a transitional period following publication of a new, amended, or revised ISO publication in which to make products in accordance with the new requirements and to equip them for conducting new or revised tests. It is the recommendation of the committee that the content of this publication not be adopted for mandatory implementation nationally earlier than three years from the date of publication.

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 devices, 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 part of ISO 14708 supplement or modify those of ISO 14708-1, referred to as the General Standard. The requirements of this document 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 document 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 document. Annex BB provides reference in the other direction, from this document to the Directive. Annex CC is a rationale providing further explanation of the subclauses of this document.

Annex DD describes a coding system that may be used to designate bradyarrhythmia pacing modes. Annex EE 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 EE are informative.

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 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 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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 8601:2004, *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:—[1], *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*

3 Terms and definitions

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

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

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

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

3.101
accessories
articles which, while not being a device, are intended specifically by the MANUFACTURER to be used together with a device in accordance with the use of the device intended by the device MANUFACTURER

3.102
adaptor
special connector used between an otherwise incompatible active IMPLANTABLE PULSE GENERATOR and a LEAD

3.103
pacemaker
ACTIVE IMPLANTABLE MEDICAL DEVICE intended to treat bradyarrhythmias, comprising an IMPLANTABLE PULSE GENERATOR and LEAD(S)

3.104
implantable pulse generator
part of the PACEMAKER, including the power supply and electronic circuit that produces an electrical output

3.105
sensor
part of a PACEMAKER that is designed to detect signals for the purpose of RATE MODULATION or other control purposes

[1] In development.

3.106
dual-chamber
condition of relating both to the atrium and ventricle

3.107
implantable cardiac resynchronization therapy pacing device
CRT-P
ACTIVE IMPLANTABLE MEDICAL DEVICE intended to provide improved ventricular activation to optimize cardiac output, comprising an IMPLANTABLE PULSE GENERATOR and LEADS

[SOURCE: ISO 14117:201x, 3.3, modified – PULSE GENERATOR substituted for "DUT"]

3.108
sensitivity
minimum signal required to control consistently the function of the IMPLANTABLE PULSE GENERATOR

3.109
electrode
electrically conducting part (usually the termination of a LEAD), which is designed to form an interface with body tissue or body fluid

3.110
bipolar lead
LEAD with two ELECTRODES, electrically isolated from each other

3.111
unipolar lead
LEAD with one ELECTRODE

3.112
endocardial lead
LEAD with an ELECTRODE designed to make contact with the endocardium, or inner surface of the heart

3.113
epicardial lead
LEAD with an ELECTRODE designed to make contact with the epicardium, or outer surface of the heart

3.114
transvenous
approach to the heart through the venous system

3.115
insertion diameter
⟨LEAD⟩ minimum bore of a rigid cylindrical tube into which the LEAD (not including the connector) can be inserted

3.117
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.

3.119
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

3.120
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

3.121
beat
ordered spontaneous or paced activity of the heart

3.122
pulse
electrical output of an IMPLANTABLE PULSE GENERATOR intended to stimulate the myocardium

3.123
pulse amplitude
amplitude of the PULSE

Note 1 to entry: The PULSE AMPLITUDE is measured according to the procedure in 6.1.2

3.124
pulse duration
duration of the PULSE

Note 1 to entry: The PULSE DURATION is measured according to the procedure in 6.1.2

3.125
pulse interval
interval between equivalent points of two consecutive PULSES

Note 1 to entry: The PULSE INTERVAL is measured according to the procedure in 6.1.2

3.126
basic pulse interval
PULSE INTERVAL in absence of sensed cardiac or other electrical influence

3.127
pulse rate
number of PULSES per minute

Note 1 to entry: The PULSE RATE is measured according to the procedure in 6.1.2

3.128
basic rate
PULSE RATE of an IMPLANTABLE PULSE GENERATOR, either atrial or ventricular, unmodified by sensed cardiac or other electrical influence

3.129
atrioventricular interval
AV interval
delay between an atrial PULSE or the sensing of an atrial depolarization and the subsequent ventricular PULSE or the sensing of a ventricular depolarization

Note 1 to entry: The AV INTERVAL is measured according to the procedure in 6.1.8

3.130
escape interval
time elapsing between the sensing of a spontaneous BEAT and the succeeding non-triggered PULSE of an IMPLANTABLE PULSE GENERATOR

Note 1 to entry: The ESCAPE INTERVAL is measured according to the procedure in 6.1.5

3.131
hysteresis
characteristic of an IMPLANTABLE PULSE GENERATOR defined by the difference between the ESCAPE INTERVAL and the BASIC PULSE INTERVAL

Note 1 to entry: The ESCAPE INTERVAL is normally longer than the BASIC PULSE INTERVAL; this is "positive" HYSTERESIS.

3.132
interference pulse rate
PULSE RATE with which the IMPLANTABLE PULSE GENERATOR responds when it senses electrical activity that it recognizes as interference

3.133
maximum tracking rate
maximum PULSE RATE at which the IMPLANTABLE PULSE GENERATOR will respond on a 1:1 basis to a triggering signal

3.134
rate modulation
altering of the PULSE INTERVAL as a function of a control parameter other than a sensed BEAT

3.135
refractory period
period of time during which atrial or ventricular PACEMAKER timing is unaffected by sensed spontaneous depolarizations, although sensing is not completely disabled

3.136
test pulse interval
PULSE INTERVAL of an IMPLANTABLE PULSE GENERATOR when directly influenced by a testing device

3.137
test pulse rate
PULSE RATE of an IMPLANTABLE PULSE GENERATOR when directly influenced by a testing device

3.138
beginning of service
BOS
time at which an individual IMPLANTABLE PULSE GENERATOR is first released by the MANUFACTURER as fit for being placed on the market

3.139
end of service
EOS
time at which the PROLONGED SERVICE PERIOD has elapsed and no further pacing function is specified nor can be expected

3.140
projected service life
period from the implantation of the IMPLANTABLE PULSE GENERATOR to the RECOMMENDED REPLACEMENT TIME under defined conditions

3.141
prolonged service period
PSP
period beyond the RECOMMENDED REPLACEMENT TIME during which the IMPLANTABLE PULSE GENERATOR continues to function as specified by the MANUFACTURER to prolong basic bradyarrhythmia pacing

3.142
power source indicator
means of indicating the electrical status of the power source during the IMPLANTABLE PULSE GENERATOR's service life

3.143
recommended replacement time
RRT
time at which the POWER SOURCE INDICATOR reaches the value set by the MANUFACTURER of the IMPLANTABLE PULSE GENERATOR for its recommended replacement

Note 1 to entry: This indicates entry into the PROLONGED SERVICE PERIOD.

3.144
stoichïometric capacity
capacity as defined by the active materials contents in the power source

348 **3.145**
349 **usable capacity**
350 portion of the STOICHIOMETRIC CAPACITY of the power source that can be utilized by the IMPLANTABLE PULSE
351 GENERATOR until END OF SERVICE is reached

352 # 4 Symbols and abbreviated terms

353 *This clause of the General Standard applies.*

354 Additional NOTE.

355 NOTE See ISO 27185 for symbols to use when expressing information so as to reduce the need for multiple
356 languages on packaging and in manuals.

357 # 5 General requirements for non-implantable parts

358 *This clause of the General Standard applies.*

359 # 6 Measurements of IMPLANTABLE PULSE GENERATOR and LEAD characteristics

360 ## 6.1 Measurement of IMPLANTABLE PULSE GENERATOR characteristics

361 ### 6.1.1 General considerations

362 The MANUFACTURER shall ensure that measurement equipment accuracy is sufficient to support the
363 stated tolerances for the parameters being measured within this clause and stated by the MANUFACTURER
364 in the accompanying documentation [see 28.8].

365 The values of the IMPLANTABLE PULSE GENERATOR characteristics measured in accordance with the
366 methods described in this clause shall be within the range of values stated by the MANUFACTURER in the
367 accompanying documentation [see 28.8].

368 The procedures shall be performed with the IMPLANTABLE PULSE GENERATOR at a temperature of
369 37 °C ± 2 °C, connected to a load of 500 Ω ± 1 % and set to the nominal settings recommended by the
370 MANUFACTURER (the factory recommended settings), unless otherwise stated.

371 If the IMPLANTABLE PULSE GENERATOR has multichannel functionality, each channel's characteristics shall
372 be determined separately. For simplicity, all the measurement procedures provided show bipolar
373 IMPLANTABLE PULSE GENERATORS. For unipolar IMPLANTABLE PULSE GENERATORS, the case is properly
374 incorporated in the set-up as the indifferent terminal.

375 In this document, the term “oscilloscope” may also be interpreted as including data acquisition systems
376 capable of performing similar measurements.

377 ### 6.1.2 Measurement of PULSE AMPLITUDE, PULSE DURATION, PULSE INTERVAL, and PULSE RATE

378 *Procedure:* Use an interval counter and an oscilloscope.

379 The IMPLANTABLE PULSE GENERATOR shall be connected to a 500 Ω ± 1 % load resistor (R_L), and the test
380 equipment as shown in Figure 101. The oscilloscope shall be adjusted to display one PULSE in full.

