SLOVENSKI STANDARD
oSIST prEN ISO 14708-6:2018

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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/DIS 14708-6:2018)

Implants for surgery - Active implantable medical devices - Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) (ISO/DIS 14708-6:2018)

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/DIS 14708-6:2018)

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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 destinés à 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. 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. www.iso.org/patents

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

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 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 ELECTRODES 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 ELECTRODES (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 ICDs also apply to CRT-D devices, and the appropriate way to test a CRT-D device is similar to the way ICDs 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.

Figures or tables that are additional to those of ISO 14708-1 are numbered starting from 101.

Annex D 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-DS 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 or epicardial LEADS. At the time of this edition, the authors recognized the emergence of technologies that do not use ENDOCARDIAL or EPICARDIAL LEADS 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 might 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 The terminology used in this European Standard is intended to be consistent with the terminology of Directive 90/385/EEC.

NOTE 3 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.

NOTE 4 Particular requirements for congestive heart failure devices are under consideration. These types of devices are not covered by this document.

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 14117:2018, *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 14708-2:2018, *Implants for surgery — Active implantable medical devices — Part 2: Cardiac pacemakers*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60878, *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/

3.101
adaptor
special connector used between an otherwise incompatible IMPLANTABLE PULSE GENERATOR and a LEAD

[SOURCE: ISO 14708-2:2018, 3.102]

3.102
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

3.103
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 14708-2:2018, 3.104, modified – "ACTIVE IMPLANTABLE MEDICAL DEVICE" substituted for "PACEMAKER", NOTE 1 to entry added]

3.104
sensitivity
sensing threshold
minimum signal required to consistently control the function of the IMPLANTABLE PULSE GENERATOR

[SOURCE: ISO 14708-2:2018, 3.108]

3.106
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 14708-2:2018, 3.109]

3.107
endocardial lead
LEAD with an ELECTRODE designed to make a contact with the endocardium, or inner surface of the heart

[SOURCE: ISO 14708-2:2018, 3.112]

3.108
epicardial lead
LEAD with an ELECTRODE designed to make a contact with the epicardium, or outer surface of the heart

[SOURCE: ISO 14708-2:2018, 3.113]

3.109
transvenous
approach to the heart through the venous system

[SOURCE: ISO 14708-2:2018, 3.114]

3.110
insertion diameter
⟨lead⟩
minimum bore of a rigid cylindrical tube into which the LEAD (not including the connector) can be inserted

[SOURCE: ISO 14708-2:2018, 3.115]

3.112
lead pacing impedance
Z_p
impedance that is formed by the ratio of a voltage PULSE to the resulting current

[SOURCE: ISO 14708-2:2018, 3.117].

3.114
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 14708-2:2018, 3.119]

3.115
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 14708-2:2018, 3.120]

3.117
pulse
electrical output of an IMPLANTABLE PULSE GENERATOR other than CD PULSE intended to stimulate the myocardium

[SOURCE: ISO 14708-2:2018, 3.122, modified – added "other than CD PULSE".]

3.118
pulse amplitude
amplitude of the PULSE

[SOURCE: ISO 14708-2:2018, 3.123]

3.119
pulse duration
duration of the PULSE

[SOURCE: ISO 14708-2:2018, 3.124]

3.120
pulse interval
interval between equivalent points of two consecutive PULSES

[SOURCE: ISO 14708-2:2018, 3.125]

3.122
automatic sensitivity control
automatic adjustment of the SENSITIVITY in response to available physiological signals

3.123
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

[SOURCE: ISO 14708-2:2018, 3.138]

3.124
end of service
EOS
time at which the PROLONGED SERVICE PERIOD has elapsed and no further pacing function is specified nor can be expected

[SOURCE: ISO 14708-2: 2018, 3.139]

3.125
prolonged service period
PSP
period beyond the RECOMMENDED REPLACEMENT TIME during which the IMPLANTABLE PULSE GENERATOR continues to function as specified by the MANUFACTURER

[SOURCE: ISO 14708-2, 3.141, modified – deleted "to prolong basic Bradyarrhythmia pacing"]

3.126
power source indicator
means of indicating the electrical status of the power source during the IMPLANTABLE PULSE GENERATOR'S service life

[SOURCE: ISO 14708-2:2018, 3.142]

3.127
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.

[SOURCE: ISO 14708-2:2018, 3.143]

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

3.128
antitachycardia pacing
ATP
cardiac pacing sequences intended to terminate re-entry tachycardias

3.130
ATP only device
IMPLANTABLE PULSE GENERATOR capable of delivering rapid sequences of pacing PULSES to terminate ventricular (VT) and atrial (AT) tachycardia and atrial fibrillation (AF)

3.131
cardioversion
termination of atrial tachyarrhythmia or ventricular tachycardia by PULSE(S) synchronized to cardiac events

3.132
cardioversion/defibrillation pulse
CD pulse
high-energy monophasic, biphasic, or multiphasic PULSE intended to restore normal rhythm by shocking the heart

3.133
capacitor formation
any charge to maximum-programmed energy that dissipates off the capacitors (is not dumped) for at least 10 min

3.134
cardioversion/defibrillation lead
CD lead
LEAD used to conduct a CD PULSE from the IMPLANTABLE PULSE GENERATOR to the heart

3.135
charge time
the time required to charge the high-voltage capacitors to a specified CD PULSE ENERGY

3.136
delivered cardioversion/defibrillation pulse energy
delivered CD pulse energy
total energy delivered to a standard load (50 Ω) by all phases of a CD PULSE, measured according to 6.1.3

3.137
defibrillation
termination of fibrillation

3.138
ICD output voltage
peak voltage of the CARDIOVERSION/DEFIBRILLATION PULSES, measured according to 6.1.2

3.139
terminal
electrically separate conductive device connection

3.140
implantable cardiac resynchronization therapy/defibrillator device
CRT-D
ACTIVE IMPLANTABLE MEDICAL DEVICE intended to detect and correct tachycardias and fibrillation by application of CARDIOVERSION/DEFIBRILLATION PULSES to the heart, and to provide improved ventricular activation to optimize cardiac output, comprising an IMPLANTABLE PULSE GENERATOR and LEADS

4 Symbols and abbreviated terms

This clause of ISO 14708-1 applies.

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

5 General requirements for non-implantable parts

This clause of ISO 14708-1 applies.

6 Measurement of IMPLANTABLE PULSE GENERATOR and LEAD characteristics

6.1 Measurement of IMPLANTABLE PULSE GENERATOR characteristics

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

The values of the electrical characteristics for the IMPLANTABLE PULSE GENERATOR measured in accordance with the methods described in this clause shall be within the range of values stated by the MANUFACTURER in the accompanying documentation [see 28.8.2].

CAUTION The tests in this subclause can employ the use of high voltage. Failure to use safe laboratory practices can result in severe electrical shock, resulting in personal injury or death to

the persons handling the equipment or conducting the test. Also damage to electrical equipment is possible.

The measurements shall be made with the IMPLANTABLE PULSE GENERATOR at a temperature of 37 °C ± 2 °C.

6.1.1 Measurement of the bradyarrhythmia characteristics

Measurement of the bradyarrhythmia and cardiac resynhronization characteristics of the IMPLANTABLE PULSE GENERATOR shall be performed using the appropriate methods specified in 6.1 of ISO 14708-2. The characteristics shall be measured with the tachyarrhythmia therapies inactivated.

6.1.2 Measurement of ICD OUTPUT VOLTAGE

NOTE This clause does not apply to ATP ONLY DEVICES.

Procedure: use an oscilloscope, with input impedance of nominal 1 MΩ, ≤ 30 pF.

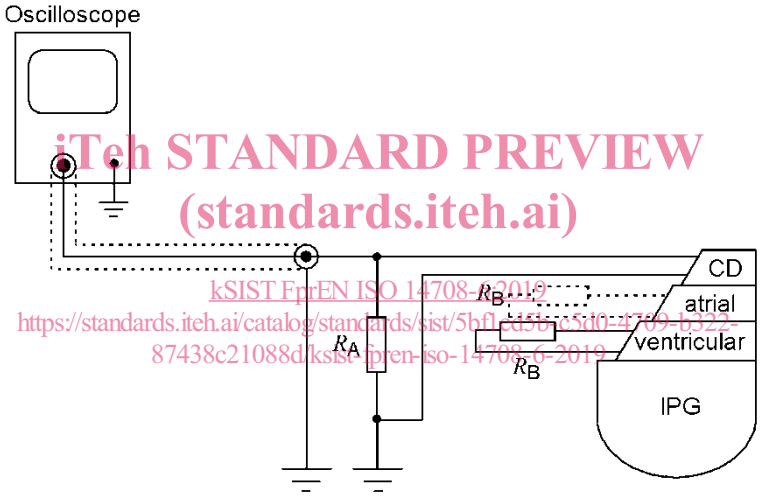

Figure 101 — Measurement of CD PULSE characteristics

The IMPLANTABLE PULSE GENERATOR shall be connected to the oscilloscope as shown in Figure 101. TERMINALS of the IMPLANTABLE PULSE GENERATOR intended to deliver a CD PULSE shall be connected to a low-inductance load of 50 Ω ± 1 % (R_A). Other inputs/outputs shall be connected to loads of 500 Ω ± 5 % (R_B). The oscilloscope shall be adjusted to display one phase of the CD PULSE.

The IMPLANTABLE PULSE GENERATOR shall be programmed to the maximum CD PULSE ENERGY setting.

The ICD OUTPUT VOLTAGE (V_{max}) shall be determined by recording the peak amplitude of the voltage across the resistor R_A [see Figure 101 and Figure 102].

The procedure shall be repeated for each type of CD PULSE (i.e. monophasic, biphasic waveform).

The entire procedure shall be repeated for the other required CD PULSE ENERGY settings [see 28.8.2 d) 2)].