INTERNATIONAL STANDARD

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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.

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

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)*

In this International Standard, the following print types are used:

— Requirements and definitions: roman type.

— *Test specifications: italic type.*

— Informative material appearing outside of tables, such as notes, examples and references: smaller type. Normative text of tables is also in a smaller type.

— TERMS DEFINED IN CLAUSE 3 OF ISO 14708-1, IN THIS PART OF ISO 14708 OR AS NOTED: SMALL CAPITALS

In referring to the structure of this standard, the term

— “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

— “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this collateral standard are by number only.

In this International Standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

— “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Introduction

This part of ISO 14708 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 may 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 may 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 may 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 may be adjusted non-invasively by means of an electronic device, known as a programmer.

This part of ISO 14708 is relevant to all parts of ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat tachyarrhythmia other than pacing functions to control bradyarrhythmia. Typical examples are IMPLANTABLE PULSE GENERATORS, LEADS, ADAPTORS, ACCESSORIES, programmers and the related software (bradyarrhythmia pacing functions are dealt with in ISO 14708-2).

The requirements of this part of ISO 14708 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 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.

Annex D describes a coding system that may be used to designate tachyarrhythmia therapy modes. Annex E defines the tissue equivalent interface circuits and low-pass filter required for some compliance tests. Annex F describes a method for selecting the filter capacitor used in the tissue equivalent interface circuits defined by Annex E. Annex G defines the method of calibrating the injection network defined by Annex E. All annexes except Annex E and Annex G 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 part of ISO 14708 specifies requirements that are applicable to IMPLANTABLE CARDIOVERTER DEFIBRILLATORS 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 part of ISO 14708 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 part of ISO 14708 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 part of ISO 14708 shall apply.

Any aspect of an ACTIVE IMPLANTABLE MEDICAL DEVICE intended to treat bradyarrhythmias is covered by ISO 14708-2.

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 The terminology used in this European Standard is intended to be consistent with the terminology of Directive 90/385/EEC.

NOTE 3 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.

NOTE 4 Particular requirements for congestive heart failure devices are under consideration. These types of devices are not covered by this part of ISO 14708.

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.

This clause of ISO 14708-1 applies except as follows:

Additional references:

ISO 5841-3 + corr. 1, *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, *Cardiac defibrillators — Connector assembly DF-1 for implantable defibrillators — Dimensions and test requirements*

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*

ISO 14708-2, *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 60068-2-27, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

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*

IEC 60878, *Graphical symbols for electrical equipment in medical practice*

ANSI/AAMI/ISO PC69, *Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators*

3 Terms and definitions

This clause of ISO 14708-1 applies except as follows:

Additional definitions:

3.3.1
adaptor
special connector used between an otherwise incompatible IMPLANTABLE PULSE GENERATOR and a LEAD

3.3.2
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

3.3.3
implantable pulse generator (IPG)
part of the ACTIVE IMPLANTABLE MEDICAL DEVICE, including the power supply and electronic circuit that produces an electrical output

NOTE For purposes of this part of ISO 14708, the term IMPLANTABLE PULSE GENERATOR describes any ACTIVE IMPLANTABLE MEDICAL DEVICE that incorporates functions intended to treat tachyarrhythmias.

3.3.4
sensitivity (sensing threshold)
minimum signal required to consistently control the function of the IMPLANTABLE PULSE GENERATOR

[see 6.1.5]

3.3.5
sensor
special part of an IMPLANTABLE PULSE GENERATOR that is designed to detect signals for the purpose of RATE MODULATION or other control purposes

3.5.1
electrode
electrically conducting part (usually the termination of a LEAD), which is designed to form an interface with body tissue or body fluid

3.5.2
endocardial lead
LEAD with an ELECTRODE designed to make a contact with the endocardium, or inner surface of the heart

3.5.3
epicardial lead
LEAD with an ELECTRODE designed to make a contact with the epicardium, or outer surface of the heart

3.5.4
transvenous
approach to the heart through the venous system

3.5.5
insertion diameter (of a lead)
minimum bore of a rigid cylindrical tube into which the LEAD (not including the connector) may be inserted

3.5.6
lead conductor resistance
R_c
ohmic resistance between the ELECTRODE and the corresponding LEAD connector TERMINAL

[see 6.2.1 of ISO 14708-2]

3.5.7
lead pacing impedance
Z_p
impedance that is formed by the ratio of a voltage PULSE to the resulting current [see 6.2.2 of ISO 14708-2]. The impedance is composed of the ELECTRODE/tissue interface and the LEAD CONDUCTOR RESISTANCE

3.5.8
lead sensing impedance
Z_s
source impedance of a LEAD as seen by an IMPLANTABLE PULSE GENERATOR

[see 6.2.3 of ISO 14708-2]

3.9.1
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

3.9.2
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

3.20.1
beat
ordered spontaneous activity of the heart

3.20.2
pulse
electrical output of an IMPLANTABLE PULSE GENERATOR other than CD PULSE [see 3.3.5] intended to stimulate the myocardium

3.20.3
pulse amplitude
amplitude of the PULSE measured according to the procedure in 6.1.1 of ISO 14708-2

3.20.4
pulse duration
duration of the PULSE, measured between two reference points specified in this part of ISO 14708

[see 6.1.1 of ISO 14708-2]

3.20.5
pulse interval
interval between equivalent points of two consecutive PULSES

[see 6.1.1 of ISO 14708-2]

3.20.6
basic pulse interval
PULSE INTERVAL in absence of sensed cardiac or other electrical influence

3.20.7
automatic sensitivity control
automatic adjustment of the SENSITIVITY in response to available physiological signals

3.21.1
beginning of service; BOS
when an individual IMPLANTABLE PULSE GENERATOR is first released by the manufacturer as fit for being placed on the market

3.21.2
end of service; EOS
when the PROLONGED SERVICE PERIOD has elapsed and no further pacing function is specified nor can be expected

3.21.3
prolonged service period; PSP
period beyond the RECOMMENDED REPLACEMENT TIME during which the IMPLANTABLE PULSE GENERATOR continues to function as specified by the manufacturer

[ISO 14708-2, 3.20.4, modified]

3.21.4
power source indicator
means of indicating the electrical status of the power source during the IMPLANTABLE PULSE GENERATOR'S service life

3.21.5
recommended replacement time; RRT
when the POWER SOURCE INDICATOR reaches the value set by the manufacturer of the IMPLANTABLE PULSE GENERATOR for its recommended replacement. This indicates entry into the PROLONGED SERVICE PERIOD

3.21.6
use-before date
date after which the manufacturer recommends that the ACTIVE IMPLANTABLE MEDICAL DEVICE should not be implanted

3.22.1
antitachycardia pacing; ATP
cardiac pacing sequences intended to terminate re-entry tachycardias

3.22.2
arrhythmia detection interval
interval below which the IMPLANTABLE PULSE GENERATOR will classify a rhythm as a tachyarrhythmia

3.22.3
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)

3.22.4
cardioversion
termination of atrial tachyarrhythmia or ventricular tachycardia by PULSE(S) synchronized to cardiac events

3.22.5
cardioversion/defibrillation pulse (CD pulse)
high-energy monophasic, biphasic, or multiphasic PULSE intended to restore normal rhythm by shocking the heart

3.22.6
capacitor formation
any charge to maximum-programmed energy that dissipates off the capacitors (is not dumped) for at least 10 min

3.22.7
cardioversion/defibrillation lead (CD lead)
LEAD used to conduct a CD PULSE from the IMPLANTABLE PULSE GENERATOR to the heart

3.22.8
charge time
the time required to charge the high-voltage capacitors to a specified CD PULSE ENERGY

3.22.9
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

3.22.10
defibrillation
termination of fibrillation

3.22.11
ICD output voltage
peak voltage of the CARDIOVERSION/DEFIBRILLATION PULSE(S), measured according to 6.1.2

3.22.12
terminal
electrically separate conductive device connection

4 Symbols and abbreviated terms (optional)

This clause of ISO 14708-1 applies.

5 General requirements for non-implantable parts

This clause of ISO 14708-1 applies.

6 (Vacant)

Replacement:

6 Measurement of implantable pulse generator and lead characteristics

6.1 Measurement of IMPLANTABLE PULSE GENERATOR characteristics

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 may employ the use of high voltage. Failure to use safe laboratory practices may 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 ºC ± 2 ºC.

The overall measurement accuracy for each test shall be within the limits ± 5 %.

6.1.1 Measurement of the bradyarrhythmia characteristics

Measurement of the bradyarrhythmia characteristics of the IMPLANTABLE PULSE GENERATOR shall be performed using the appropriate methods specified in 6.1 of ISO 14708-2. The bradyarrhythmia 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.

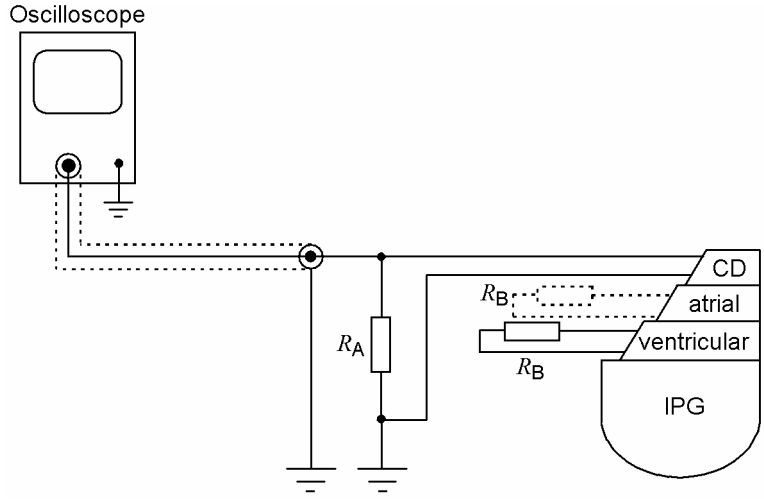

Figure 101 — Measurement of CD PULSE characteristics

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)].

The results shall be expressed in volts (V) and shall be within the tolerance of disclosed data [see 28.8.2 d) 2)].

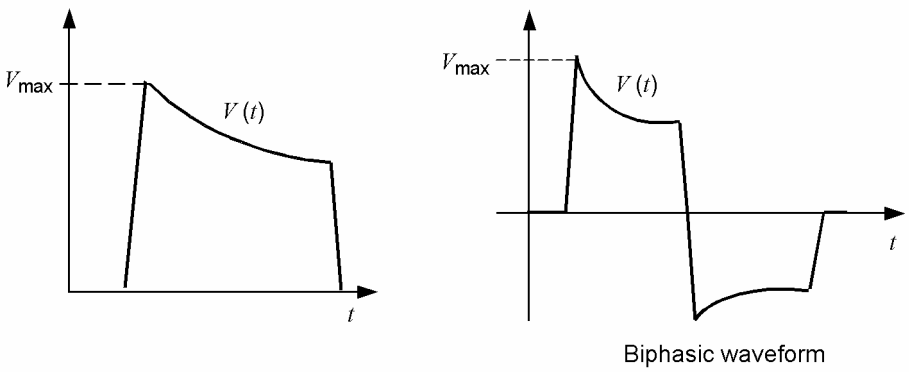

Figure 102 — Measurement of ICD OUTPUT VOLTAGE