INTERNATIONAL STANDARD

ISO 14708-6

Second edition
2019-09

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 conçus pour traiter la tachyarythmie (y compris les défibrillateurs implantables)

Reference number
ISO 14708-6:2019(E)

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

Published in Switzerland

Contents

Page

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).

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 (see www.iso.org/patents).

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 14708-6 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 14708-6:2010), 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/defibrillation as shown in ISO 14117:2019, Annex N;

— inclusion of new temporary exposure criteria in 17.1 for outer surface temperatures exceeding 39 °C;

— revision of atmospheric pressure test requirements in Clause 25 to align with requirements of ISO 14708-2;

— replacement of detailed requirements in Clause 27 by reference to ISO 14117.

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 *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 *electrode*s 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 *electrode*s (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 *ICD*s also apply to *CRT-D* devices, and the appropriate way to test a *CRT-D* device is similar to the way *ICD*s 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 generator*s, 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.

In this document, terms printed in italic 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 italic letters unless the concept thus qualified is also defined.

Information is also provided in Annex A that explains the relationship between ISO/TR 14283, *Implants for surgery — Essential principles of safety and performance*, ISO 14708-1 and this document.

Notes on this document are provided in Annex B for information.

Annex C 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-D*s 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 lead*s or *epicardial lead*s. At the time of this edition, the authors recognized the emergence of technologies that do not use *endocardial* or *epicardial lead*s 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 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 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 14708-2:2019, *Implants for surgery — Active implantable medical devices — Part 2: Cardiac pacemakers*

IEC/TR 60878:2015, *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/

3.1
adaptor
special connector used between an otherwise incompatible *implantable pulse generator* and a lead

[SOURCE: ISO 14708-2:2019, 3.2]

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
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 14708-2:2019, 3.4, modified – "active implantable medical device" substituted for "*pacemaker*", NOTE 1 to entry added]

3.4
sensitivity
minimum signal required to control consistently the function of the *implantable pulse generator*

[SOURCE: ISO 14708-2:2019, 3.8]

3.5
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 14708-2:2019, 3.9]

3.6
endocardial lead
lead with an *electrode* designed to make contact with the endocardium, or inner surface of the heart

[SOURCE: ISO 14708-2:2019, 3.12]

3.7
epicardial lead
lead with an *electrode* designed to make contact with the epicardium, or outer surface of the heart

[SOURCE: ISO 14708-2:2019, 3.13]

3.8
transvenous
approach to the heart through the venous system

[SOURCE: ISO 14708-2:2019, 3.14]

3.9
insertion diameter
<lead>minimum bore of a rigid cylindrical tube into which the lead (not including the connector) can be inserted

[SOURCE: ISO 14708-2:2019, 3.15]

3.10
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.

[SOURCE: ISO 14708-2:2019, 3.16].

3.11
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 14708-2:2019, 3.17]

3.12
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 14708-2:2019, 3.18]

3.13
pulse
electrical output of an *implantable pulse generator* other than *CD pulse* intended to stimulate the myocardium

[SOURCE: ISO 14708-2:2019, 3.20, modified – added "other than *CD pulse*".]

3.14
pulse amplitude
amplitude of the *pulse*

[SOURCE: ISO 14708-2:2019, 3.21]

3.15
pulse duration
duration of the *pulse*

[SOURCE: ISO 14708-2:2019, 3.22]

3.16
pulse interval
interval between equivalent points of two consecutive *pulses*

[SOURCE: ISO 14708-2:2019, 3.23]

3.17
automatic sensitivity control
automatic adjustment of the *sensitivity* in response to available physiological signals

3.18
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 14708-2:2019, 3.35]

3.19
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: 2019, 3.36]

3.20
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 14708-2:2019, 3.38, modified – deleted "to prolong basic bradyarrhythmia pacing"]

3.21
power source indicator
means of indicating the electrical status of the power source during the *implantable pulse generator's* service life

[SOURCE: ISO 14708-2:2019, 3.39]

3.22
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*

[SOURCE: ISO 14708-2:2019, 3.40]

3.23
antitachycardia pacing
ATP
cardiac pacing sequences intended to terminate re-entry tachycardias

3.24
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)

3.25
cardioversion
termination of atrial tachyarrhythmia or ventricular tachycardia by *pulse(s)* synchronized to cardiac events

3.26
cardioversion/defibrillation pulse
CD pulse
high-energy monophasic, biphasic, or multiphasic *pulse* intended to restore normal rhythm by shocking the heart

3.27
capacitor formation
any charge to maximum-programmed energy that dissipates off the capacitors (is not dumped) for at least 10 min

3.28
cardioversion/defibrillation lead
CD lead
lead used to conduct a *CD pulse* from the *implantable pulse generator* to the heart

3.29
charge time
the time required to charge the high-voltage capacitors to a specified *CD pulse energy*

3.30
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 6.1.4

3.31
defibrillation
termination of fibrillation

3.32
ICD output voltage
peak voltage of the *cardioversion/defibrillation pulses*, measured according to 6.1.3

3.33
terminal
electrically separate conductive device connection

3.34
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

3.35
accessory
article which, while not being a device, is 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

[SOURCE: ISO 14708-2:2019, 3.1]

3.36
pacemaker
active implantable medical device intended to treat bradyarrhythmias, comprising an *implantable pulse generator* and lead(s)

[SOURCE: ISO 14708-2:2019, 3.3]

4 Symbols and abbreviated terms

The text in Clause 4 of ISO 14708-1:2014 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

5.1 General requirements for non-implantable parts

The text in 5.1 of ISO 14708-1:2014 applies.

5.2 General requirements for software

The text in 5.2 of ISO 14708-1:2014 applies.

5.3 Usability of non-implantable parts

The text in 5.3 of ISO 14708-1:2014 applies.

5.4 Data security and protection from harm caused by unauthorized information tampering

The text in 5.4 of ISO 14708-1:2014 applies.

5.5 General requirements for risk management

The text in 5.5 of ISO 14708-1:2014 applies.

5.6 Misconnection of parts of the active implantable medical device

The text in 5.6 of ISO 14708-1:2014 applies.

6 Measurement of *implantable pulse generator* and lead characteristics

6.1 Measurement of *implantable pulse generator* characteristics

6.1.1 General considerations

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.

6.1.2 Measurement of the bradyarrhythmia characteristics

Measurement of the bradyarrhythmia and cardiac resynchronization characteristics of the *implantable pulse generator* shall be performed using the appropriate methods specified in 6.1 of ISO 14708-2:2019. The characteristics shall be measured with the tachyarrhythmia therapies inactivated.

6.1.3 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.

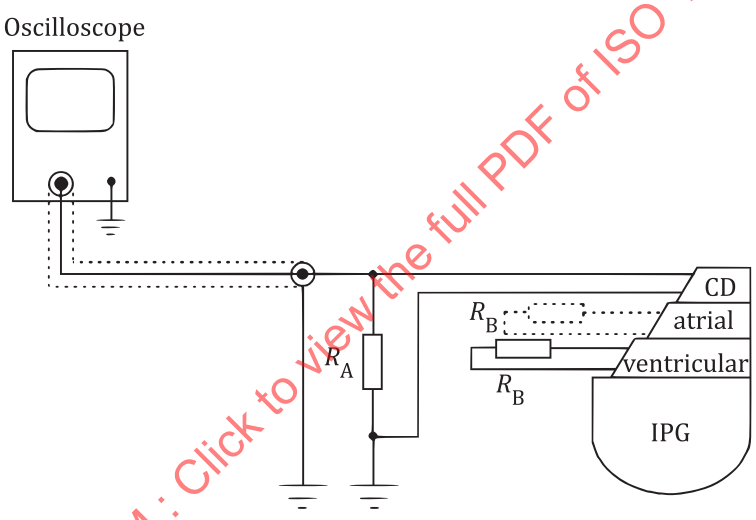


Figure 1 — Measurement of *CD pulse* characteristics

The *implantable pulse generator* shall be connected to the oscilloscope as shown in Figure 1. *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 1 and Figure 2).

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)].

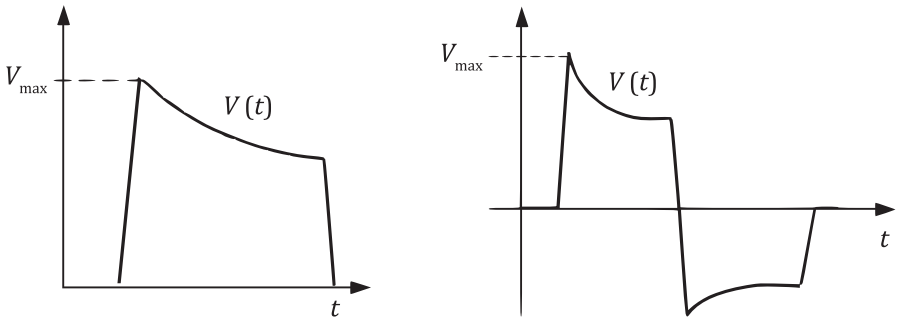


Figure 2 — Measurement of *ICD output voltage*

6.1.4 Measurement of delivered *CD pulse* energy

NOTE This clause does not apply to *ATP only devices*.

Procedure: Use the oscilloscope and measurement set-up specified in 6.1.3.

The oscilloscope shall be adjusted to display one *CD pulse*. The *implantable pulse generator* shall be programmed to deliver the maximum *CD pulse energy* setting.

The *CD pulse* shall be determined by recording the voltage waveform $V_{(t)}$ (see Figure 2) across the resistor R_A (see Figure 1). The *delivered CD pulse energy*, *W*, shall be calculated by applying the formula:

$$W = \int_0^{Tp} \frac{V^2(t)}{R_A} dt$$

where

T_p = duration (all phases) of the *CD pulse*;

$V_{(t)}$ = instantaneous voltage;

R_A = 50 Ω.

For devices with more than two output *terminals*, the *delivered CD pulse energy* (*W*) shall be determined by the sum of the energies delivered from each *terminal*, as measured by the manufacturer's disclosed method.

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

The result shall be expressed in joules (J) and shall be within the tolerance of disclosed data [see 28.8.2 d) 2)].

6.1.5 Measurement of the antitachyarrhythmia pacing *pulse amplitude*

The low-voltage antitachyarrhythmia pacing *pulse amplitude* of an *implantable pulse generator* shall be measured with the device set in the as-shipped mode or as recommended by the manufacturer using the procedure in 6.1.2 of ISO 14708-2:2019 [see 28.8.2 d) 3)].

6.1.6 Measurement of the sensitivity of an implantable pulse generator with automatic sensitivity control

The lowest (most sensitive) *sensing threshold* for both positive and negative polarities shall be measured using a method as specified by the manufacturer [see 28.8.2 d) 4)].

6.1.7 Charge time

NOTE This clause does not apply to *ATP only devices.*

The values of typical *charge times* (when the capacitors are fully formed) for maximum *CD pulse energy* shall be disclosed at *BOS* and at *RRT*, as a minimum [see 28.8.2 d) 5)].

6.1.8 *Capacitor formation* (capacitor maintenance)

NOTE This clause does not apply to *ATP only devices*.

If applicable the manufacturer shall provide instructions for periodic *capacitor formation* to be performed at least in connection with patient follow-up sessions, unless the *implantable pulse generator* provides a feature of fully automatic *capacitor formation*.

6.2 Measurement of the electrical characteristic of a sensing/pacing lead

The values of the electrical characteristics of any sensing/pacing lead of the *implantable cardioverter defibrillator* measured in accordance with the appropriate method specified in 6.2 of ISO 14708-2 shall be within the range of values stated by the manufacturer in the accompanying documentation (see 28.8.3).

7 General arrangement of the packaging

7.1 The text in 7.1 of ISO 14708-1:2014 applies.

7.2 The text in 7.2 of ISO 14708-1:2014 applies.

7.3 The *implantable pulse generator* shall be shipped with the *antitachycardia pacing* and/or *cardioversion* and/or *defibrillation* inactivated.

Compliance is checked by inspection.

NOTE When *cardioversion* and/or *defibrillation* are inactivated the *implantable pulse generator* is not capable of delivering any *CD pulse(s)*.

8 General markings for active implantable medical devices

8.1 The text in 8.1 of ISO 14708-1:2014 applies.

8.2 The text in 8.2 of ISO 14708-1:2014 applies.

9 Markings on the sales packaging

9.1 The text in 9.1 of ISO 14708-1:2014 applies.

9.2 The text in 9.2 of ISO 14708-1:2014 applies.

9.3 The text in 9.3 of ISO 14708-1:2014 applies.

9.4 The text in 9.4 of ISO 14708-1:2014 applies.

9.4.1 The sales packaging containing an *implantable pulse generator* shall bear a list of the tachyarrhythmia therapies available.

Instead of using words to describe the tachyarrhythmia therapies, the mode codes in Annex C may be used.

Compliance is checked by inspection.

9.4.2 The sales packaging containing an *implantable pulse generator* shall bear a statement that the tachyarrhythmia therapies of the *implantable pulse generator*, as shipped, are inactive.

NOTE 1 See 7.3 for the shipping requirements for *antitachycardia pacing*, *cardioversion* and *defibrillation*.

NOTE 2 For *ATP only devices*, the *CD terminal*s part of the requirement is not applicable.

Compliance is checked by inspection.

9.4.3 If applicable, the sales packaging containing an *implantable pulse generator* shall bear a description of the most comprehensive bradyarrhythmia pacing mode available and, if different, the pacing mode as shipped.

NOTE The pacing mode as shipped is meant to be the pacing mode of the device available when first removed from its packaging if the device is shipped in a ready-to-implant state, or the mode first available upon activation without any additional programming.

Instead of describing the bradyarrhythmia pacing mode in words, the mode codes defined in Annex C of ISO 14708-2:2019 may be used in the markings and accompanying documentation to designate the bradyarrhythmia pacing mode of the *implantable pulse generator*.

Compliance is checked by inspection.

9.4.4 The sales packaging containing a lead shall bear the following information necessary to appropriately prescribe the lead:

a) Identifying information as applicable: e.g. epicardial or endocardial; straight or shaped; unipolar, bipolar or multipolar; drug eluting; passive or active fixation; recommended anatomical placement.

b) Physical dimensions, including:

   1) the length (in centimetres);

   2) for a *transvenous lead*, the *insertion diameter* (in millimetres) and the size of the corresponding introducer (in French gauge);

   3) connector geometry shall be provided by a reference by symbols or markings defined in published standards or, if different, the bore depths and diameters in millimetres.

Compliance is checked by inspection.

9.5 The text in 9.5 of ISO 14708-1:2014 applies.

9.6 The text in 9.6 of ISO 14708-1:2014 applies.

9.7 The text in 9.7 of ISO 14708-1:2014 applies.

9.8 The text in 9.8 of ISO 14708-1:2014 applies.

9.9 If the intended use of an implantable part of an active implantable medical device enclosed within the sales packaging requires that it be connected to other devices or *accessories* not included in the package, the sales packaging shall identify the connector type (pace/sense, *cardioversion/defibrillation*, etc.), the configuration (unipolar, bipolar, etc.), and the connector geometry (lengths and diameters in millimetres or reference to published standards).

Compliance is checked by inspection.

9.10 The text in 9.10 of ISO 14708-1:2014 applies.

9.11 The text in 9.11 of ISO 14708-1:2014 applies.

9.12 The text in 9.12 of ISO 14708-1:2014 applies.

9.13 The text in 9.13 of ISO 14708-1:2014 applies.

9.14 The text in 9.14 of ISO 14708-1:2014 applies.

9.15 The sales packaging containing an *implantable pulse generator* shall be marked with the symbol for "dangerous voltage" (symbol 5036 in IEC TR 60878:2015).

NOTE This clause does not apply to *ATP only devices*.

Compliance is checked by inspection.

10 Construction of the sales packaging

10.1 The text in 10.1 of ISO 14708-1:2014 applies.

10.2 The text in 10.2 of ISO 14708-1:2014 applies.

10.3 The text in 10.3 of ISO 14708-1:2014 applies.

NOTE Removable stickers, which provide supplementary information exceeding the information specified in Clause 9, need not to be subjected to the test specified in 10.3

10.4 The text in 10.4 of ISO 14708-1:2014 applies.

11 Markings on the sterile pack

11.1 The text in 11.1 of ISO 14708-1:2014 applies.

11.2 The text in 11.2 of ISO 14708-1:2014 applies.

11.3 The text in 11.3 of ISO 14708-1:2014 applies.

11.4 The text in 11.4 of ISO 14708-1:2014 applies.

11.5 The text in 11.5 of ISO 14708-1:2014 applies.

11.6 The text in 11.6 of ISO 14708-1:2014 applies.

11.7 The text in 11.7 of ISO 14708-1:2014 applies.

11.8 The text in 11.8 of ISO 14708-1:2014 applies.

11.9 The text in 11.9 of ISO 14708-1:2014 applies.

11.10 The sterile pack containing an *implantable pulse generator* shall bear a list of the tachyarrhythmia therapies available.

Instead of using words to describe the tachyarrhythmia therapies, the mode codes in Annex C may be used.

Compliance is checked by inspection.

11.11 The sterile pack containing an *implantable pulse generator* shall bear a statement that the tachyarrhythmia therapies of the *implantable pulse generator,* as shipped, are inactive.

NOTE 1 See 7.3 for the shipping requirements for *antitachycardia pacing*, *cardioversion* and *defibrillation*.

NOTE 2 For *ATP only devices*, the *CD terminal*s part of the requirement is not applicable.

Compliance is checked by inspection.

11.12 If applicable, the sterile pack containing an *implantable pulse generator* shall bear a description of the most comprehensive bradyarrhythmia pacing mode available and, if different, the mode as shipped.

NOTE The pacing mode as shipped is meant to be the pacing mode of the device available when first removed from its packaging if the device is shipped in a ready-to-implant state, or the mode first available upon activation without any additional programming.

Instead of describing the bradyarrhythmia pacing mode in words, the mode codes defined in Annex C of ISO 14708-2:2019 may be used in the markings and accompanying documentation to designate the bradyarrhythmia pacing mode of the *implantable pulse generator*.

Compliance is checked by inspection.

11.13 The sterile pack containing an *implantable pulse generator* shall be marked with the symbol for "dangerous voltage" (symbol 5036 in IEC TR 60878:2015).

NOTE This clause does not apply to *ATP only devices*.

Compliance is checked by inspection.

11.14 The sterile pack containing a lead shall bear the following information necessary to appropriately prescribe the lead:

a) Identifying information as applicable: e.g. epicardial or endocardial; straight or shaped; unipolar, bipolar or multipolar; drug eluting; passive or active fixation; recommended anatomical placement.

b) Physical dimensions, including:

   1) the length (in centimetres);

   2) for a *transvenous lead*, the *insertion diameter* (in millimetres) and the size of the corresponding introducer (in French gauge);

   3) connector geometry shall be provided by a reference by symbols or markings defined in published standards or, if different, the bore depths and diameters in millimetres.

NOTE Examples of standards providing connector geometries, symbols, or markings include ISO 5841-3, ISO 11318, ISO 27185, and ISO 27186.

Compliance is checked by inspection.

12 Construction of the non-reusable pack

12.1 The text in 12.1 of ISO 14708-1:2014 applies.

12.2 The text in 12.2 of ISO 14708-1:2014 applies.

12.3 The text in 12.3 of ISO 14708-1:2014 applies.

13 Markings on the active implantable medical device

13.1 The text in 13.1 of ISO 14708-1:2014 does not apply.

13.1.1 Each *implantable pulse generator* shall legibly and indelibly bear the name or trade name of the manufacturer, the model designator and, optionally, the family name of the device, the *serial number*, and the following particulars, as applicable.

If there is more than one input/output connector, then each connector shall be identified by a marking [see 28.8.2 a)].

Compliance is checked by inspection.

13.1.2 Each lead and, if practicable and appropriate, each *adaptor* shall be permanently and visibly marked with an identification of the manufacturer, the *model designation*, and the *serial number* or when appropriate the batch number.

The *model designation* may be incorporated into the batch or *serial number*.

Compliance is checked by inspection.

13.2 The text in 13.2 of ISO 14708-1:2014 applies.

13.3 *Implantable pulse generators* shall incorporate a code by which the device and the manufacturer can be unequivocally identified particularly with regard to the *model designation.* It shall be possible to read this code, when necessary, without the need for a surgical operation, using equipment generally available to the physician.

The markings identifying the manufacturer and the *model designation* of the *implantable pulse generator* may be in the form of radio-opaque figures or letters.

Compliance is checked by a procedure defined by the manufacturer in the accompanying documentation (see 28.6 of ISO 14708-1).

13.4 The text in 13.4 of ISO 14708-1:2014 applies.

14 Protection from unintended biological effects being caused by the active implantable medical device

14.1 The text in 14.1 of ISO 14708-1:2014 applies.

14.2 The text in 14.2 of ISO 14708-1:2014 applies.

14.3 The text in 14.3 of ISO 14708-1:2014 applies.

14.4 The text in 14.4 of ISO 14708-1:2014 applies.

15 Protection from harm to the patient or user caused by external physical features of the active implantable medical device

15.1 The text in 15.1 of ISO 14708-1:2014 applies.

15.2 The text in15.2 of ISO 14708-1:2014 applies.

16 Protection from harm to the patient caused by electricity

16.1 The text in 16.1 of ISO 14708-1:2014 applies.

16.2 ISO 14708-1 specifies a maximum current density at any *electrode* of no more than 0,75 μA/mm^2. This limitation applies to the combination of any net direct current allowed at the pace/sense *terminal*s and the *electrode* area of the lead conductor attached to such *terminal*. Because the construction of the leads (and therefore lead *electrode* area) is out of the control of the *implantable pulse generator* manufacturer, the intent of the ISO 14708-1 limit is met here by limiting the net direct current under the assumption that the *electrode* area is sufficiently large so as not to exceed the specified current density.

Except for its intended function, an *implantable pulse generator* when in use shall be electrically neutral. No direct current of more than 1 μA shall occur in any of the current pathways of the *CD lead terminal*s and the case and no more than 0,1 μA in the current pathways of any other *terminal*.

NOTE 1 For case *terminals*, the minimum *electrode* area required to achieve the maximum current density specified in ISO 14708-1 is approximately 1,5 mm^2, and for any other *terminal*, the area is approximately 0,15 mm^2. The typical *electrode* area of pace/sense leads in use today is in the range of 2 mm^2 to 10 mm^2, and 200 mm^2 to 600 mm^2 for *defibrillation electrodes*.

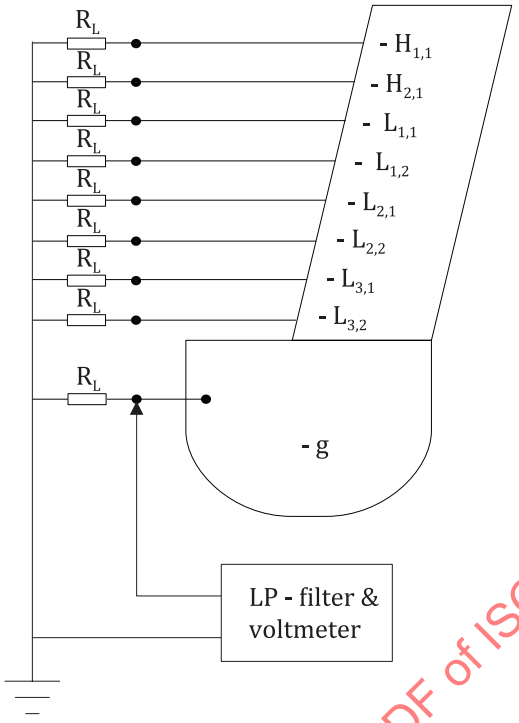
NOTE 2 It is assumed for the purposes of this clause that leads from any other manufacturer can be attached to the *implantable pulse generator* as a result of the use of common lead connector standards (e.g. ISO 5841-3, ISO 11318, or ISO 27186).

CAUTION — Ensure that the high-voltage capacitors are discharged. 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.

NOTE 3 For *ATP only devices*, the CD *terminal*s part of the requirement is not applicable.

Test: use a d.c. voltmeter, having a resolution of at least 2 μV, fed through a low-pass filter with a time constant (τ) of at least 10 s.

NOTE 4 As an example this low-pass filter (LP-filter) can be implemented by a fourth order low-pass RC filter with the elements built from 100 kΩ resistors and 10 μF metalized polyester capacitors. When using this type of filter, a d.c. voltmeter with an input resistance ≥40 MΩ will minimize measurement error.



Key

$H_{1,1}$	high voltage *electrode* of DF-1 connector, RV coil
$H_{2,1}$	high voltage *electrode* of DF-1 connector, SVC coil
$L_{1,1}$	low voltage *electrode* of IS-1 connector, RV lead tip
$L_{1,2}$	low voltage *electrode* of IS-1 connector, RV lead ring
$L_{2,1}$	low voltage *electrode* of IS-1 connector, RA lead tip
$L_{2,2}$	low voltage *electrode* of IS-1 connector, RA lead ring
$L_{3,1}$	low voltage *electrode* of IS-1 connector, LV lead tip
$L_{3,2}$	low voltage *electrode* of IS-1 connector, LV lead ring
g	case *terminal*
MD	measuring device
R_L	load resistor

NOTE 5 Figure 3 employs a nomenclature developed for modern *pacemaker* and *CRT-D* devices having more than two channels of pacing / sensing / defibrillation. ISO 14117:2019, Annex N provides additional details of the nomenclature.

Figure 3 — Example test set-up for measurement of electrical neutrality of a *CRT-D* device

The tachyarrhythmia therapy functions of the *implantable pulse generator* shall be inactive during the test, and, if applicable, the high-voltage capacitors shall be discharged. If the therapeutic function of the *implantable pulse generator* includes bradyarrhythmia pacing, the *implantable pulse generator* shall be set to the nominal settings recommended by the manufacturer (i.e. factory recommended settings) and the *pulse amplitude* and *pulse duration* shall be programmed to the highest available settings.

Each electrically conductive part of the *implantable pulse generator* in contact with body tissue when the device is implanted shall be identified and connected to a common bus through load resistors R_L of 500 Ω ± 1 % (see Figure 3). For devices with fewer *terminal*s than shown in Figure 3, the associated resistors R_L are not used.

Measure the average direct voltage across each of the load resistors (see Figure 3). Steady state conditions shall be reached before the measurement is made.

The measurement of the individual *terminal* currents may be made with a plurality of measuring devices.

Compliance is confirmed if the absolute value of the potential across each resistor R_L is less than 0,5 mV for any *CD lead terminal* and the *IPG*-case, and less than 50 µV for any other conductive pathway unless the manufacturer demonstrates that higher leakage current is justified for a particular condition subject to the maximum limit stated in 16.2 of ISO 14708-1.

16.3 The text in 16.3 of ISO 14708-1:2014 does not apply.

16.4 Except for the intended bradyarrhythmia pacing functions, the a.c. leakage current (r.m.s.) delivered through each lead shall not create an unacceptable hazard of fibrillation during charging of the capacitors in the *implantable pulse generator*.

CAUTION — The following test can produce high-voltage shocks. 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.

NOTE 1 This clause does not apply to *ATP only devices*.

Test: Use a true r.m.s. voltmeter, 1 Hz - 1 MHz, sampling period ≤1 s, input impedance ≥1 MΩ, fed via band pass filter (BP-filter) defined by Figure 4, with C_s = 15 µF ± 5 %, R_p = 1 kΩ ± 1 %, R_s = 10 kΩ ± 1 %, and C_p = 0,015 µF ± 5 %. (All resistors shall be low-inductance types.)

Any bradyarrhythmia pacing output available from the *implantable pulse generator* shall be suppressed during the test.

Each electrically conductive part of the *implantable pulse generator* in contact with body tissue when the device is implanted shall be identified and connected to a common bus through separate 100 Ω ± 1 % resistors R_L as shown in Figure 5. (All resistors R_L shall be 25 W low-inductance types.)

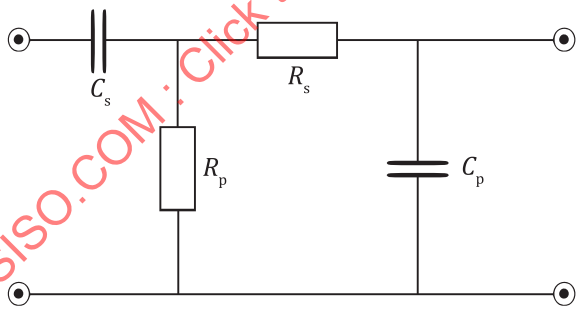
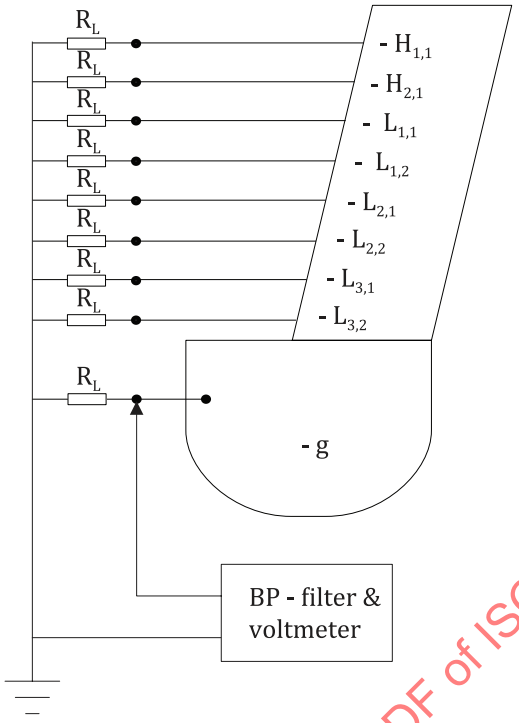


Figure 4 — Band pass filter for a.c. leakage current measurement



Key

$H_{1,1}$ high voltage *electrode* of DF-1 connector, RV coil
$H_{2,1}$ high voltage *electrode* of DF-1 connector, SVC coil
$L_{1,1}$ low voltage *electrode* of IS-1 connector, RV lead tip
$L_{1,2}$ low voltage *electrode* of IS-1 connector, RV lead ring
$L_{2,1}$ low voltage *electrode* of IS-1 connector, RA lead tip
$L_{2,2}$ low voltage *electrode* of IS-1 connector, RA lead ring
$L_{3,1}$ low voltage *electrode* of IS-1 connector, LV lead tip
$L_{3,2}$ low voltage *electrode* of IS-1 connector, LV lead ring
g case *terminal*
MD measuring device
R_L load resistor

NOTE 2 Figure 5 employs a nomenclature developed for modern *pacemaker* and *CRT-D* devices having more than two channels of pacing / sensing / defibrillation. ISO 14117:2019, Annex N provides additional details of the nomenclature.

Figure 5 — Example test set-up for measurement of a.c. leakage current of a *CRT-D* device

Measure the r.m.s. voltage across each resistor R_L (see Figure 5) while the output capacitors in the *implantable pulse generator* are charged to deliver the maximum energy *CD pulse*. For devices with fewer *terminals* than shown in Figure 5, the associated resistors R_L are not used.

Compliance is confirmed if the r.m.s. value across each resistor R_L is no more than 1 mV r.m.s. during each charging cycle.

16.5 The direct current from an *implantable pulse generator* with charged high-voltage capacitors shall not create an unacceptable hazard of fibrillation.

CAUTION — The following test can produce high-voltage shocks. 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.

NOTE This clause does not apply to *ATP only devices*.

Test: Use a d.c. voltmeter, input impedance ≥1 MΩ, which has demonstrated overall measurement accuracy of better than ±10 %.

The test shall be performed with the *implantable pulse generator* at a temperature of 37 °C ± 2 °C and any bradyarrhythmia pacing output available from the *implantable pulse generator* shall be suppressed.

Each electrically conductive part of the *implantable pulse generator* in contact with body tissue when the device is implanted shall be identified and connected to a common bus through separate 100 Ω ± 1 % resistors, R_L. (All resistors R_L shall be 25 W low inductance types.)

The *implantable pulse generator* shall be caused to charge ready to deliver a maximum energy *defibrillation pulse*. With the *implantable pulse generator* held in the charged state, measure the direct current through each resistor R_L in turn.

Compliance is confirmed if the voltage measured across each R_L is less than 10 mV for any *CD lead terminal* and the *IPG*-case, and less than 1 mV for any other conductive pathway.

17 Protection from harm to the patient caused by heat

17.1 Protection from harm to the patient caused by heat

In the absence of external influence, an implantable part of the implant system shall comply with at least one of the following conditions (a, b or c) when implanted, and when in normal operation.

NOTE 1 The single-fault condition for temperature rise is covered by the requirement in ISO 14708-1:2014, 19.3.

NOTE 2 Examples of external influences include exposure to external recharging fields, MRI, electrosurgery, external defibrillation, ultrasound, and electromagnetic fields.

a) no outer surface greater than 39 °C; or

b) no tissue receives a CEM43 thermal dose >2; or

c) manufacturer's evidence that a higher temperature rise is justified for a particular application.

The CEM43 dose value is calculated using Formula (1):

$$\mathrm{CEM43} = \sum_{i=1}^{n} t_i \cdot R^{(43-T_i)} \tag{1}$$

where

t_i is the i-th time interval in minutes;

T_i is the average temperature of the tissue in degrees Centigrade during the interval t_i;

R is 0,25 for $T < 43$ °C and 0,5 for $T \geq 43$ °C;

n is the number of samples taken during the heating duration.

This formula is valid for temperatures between 39 °C and 57 °C.

Compliance is checked by inspection of a design analysis provided by the manufacturer, supported by the manufacturer's calculations and data from test studies as appropriate.

17.2 Active implantable medical device intended to supply heat

The text in 17.2 of ISO 14708-1:2014 applies.

18 Protection from ionizing radiation released or emitted from the active implantable medical device

18.1 The text in 18.1 of ISO 14708-1:2014 applies.

18.2 The text in 18.2 of ISO 14708-1:2014 applies.

18.3 The text in 18.3 of ISO 14708-1:2014 applies.

19 Protection from unintended effects caused by the device

19.1 The text in 19.1 of ISO 14708-1:2014 applies.

19.2 If the implantable part of an active implantable medical device contains one or more power sources, such as batteries, the active implantable medical device shall provide advanced warning when depletion of any single power source will significantly limit the future availability of therapeutic functions, e.g. bradyarrhythmia pacing, *ATP*, post shock pacing.

The *prolonged service period* in normal use shall be at least three months under the most severe of the following conditions that is applicable:

1) The *implantable pulse generator* monitoring (no pacing) and delivering 6 maximum energy *CD pulses* into a 50 Ω ± 1 % load. The *CD pulses* shall be spaced uniformly over the three month period and the last *CD pulses* being delivered at the end of the period; or

2) the *implantable pulse generator* pacing 100 % with the manufacturer's nominal conditions and delivering 3 maximum energy *CD pulses* into a 50 Ω ± 1 % load. The *CD pulses* shall be spaced uniformly over the three-month period and the last *CD pulses* being delivered at the end of the period.

NOTE For *ATP only devices*, the *CD terminals* part of the requirement is not applicable.

The manufacturer shall provide suitable measures, instructions and/or tools to the physicians on the appropriate follow-up period so that *RRT* (or the status within *PSP*) will be reliably detected.

In some European countries the national cardiology societies have follow-up guidelines based on state of the art of medical practice that should be taken into consideration.

Compliance is checked by assessment of the design analysis provided by the manufacturer, supported by the manufacturer's calculations and data from test studies, as appropriate.

19.3 The text in 19.3 of ISO 14708-1:2014 applies.

19.4 The text in 19.4 of ISO 14708-1:2014 applies.

19.5 The text in 19.5 of ISO 14708-1:2014 applies.

19.6 The text in 19.6 of ISO 14708-1:2014 applies.

19.7 The *implantable pulse generator* shall be designed so that the implantable defibrillator *output voltage* shall not permanently affect the device, provided the warning about hazardous positioning of *electrodes* in 28.11.2 is respected.

CAUTION — The following test employs 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.

NOTE 1 This clause does not apply to *ATP only devices*.

Test: the *implantable pulse generator* shall be connected to deliver *CD pulses* to a voltage divider network of low inductance, 5 % tolerance resistors of 12,5 Ω (R_{L1}) and 25 Ω (R_{L2}) as shown in Figure 6. If the *implantable pulse generator* has more than two defibrillator output *terminals*, all positive *terminals* shall be connected to CD(+) and all negative *terminals* shall be connected to CD(-).

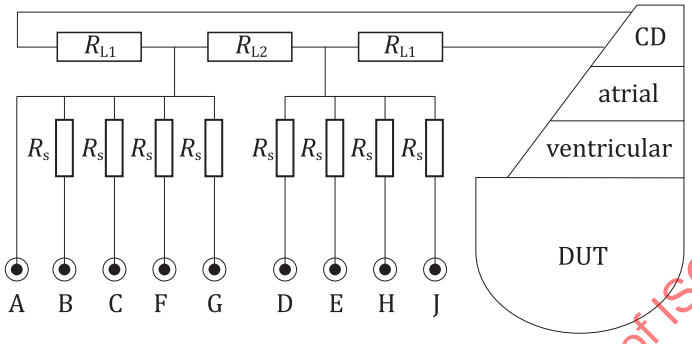


Figure 6 — Example test set-up for checking internal *defibrillation* protection in a *CRT-D* device

The *implantable pulse generator* shall be programmed to deliver maximum energy *CD pulses*. The potential divider is tapped to feed test point A directly and to feed test points B-E through separate 250 Ω ± 5 % resistors (R_s) (see Figure 6).

Two maximum energy *CD pulses* are delivered at each of eight configurations defined by Table 1.

NOTE 2 For single channel devices, configurations 3, 4, 5 and 6 are not applicable. The connection sequence is only applicable to the available *terminals*.

NOTE 3 If the *implantable pulse generator* case is a *CD terminal*, then configurations 7 and 8 are not applicable.

Table 1 — Connection sequence

Config#	A	B	C	F	G	D	E	H	J
1		V_{ring}	A_{ring}	LV2	LV4	V_{tip}	A_{tip}	LV_{tip1}	LV3
2		V_{tip}	A_{tip}	LV_{tip1}	LV3	V_{ring}	A_{ring}	LV2	LV4
3		A_{tip}	A_{ring}	LV_{tip1}	LV2	V_{tip}	V_{ring}	LV3	LV4
4		V_{tip}	V_{ring}	LV3	LV4	A_{tip}	A_{ring}	LV_{tip1}	LV2
5		V_{ring}	A_{tip}	LV2	LV3	V_{tip}	A_{ring}	LV_{tip1}	LV4
6		V_{tip}	A_{ring}	LV_{tip1}	LV4	V_{ring}	A_{tip}	LV2	LV3
7	all P/S[1]					Case			
8	Case					all P/S[1]			

[1] All P/S = all pacing/sensing *terminals* connected together through separate 250 Ω ± 5 % resistors.

Compliance is confirmed, if after all applicable test cases have been completed the *implantable pulse generator* functions as prior to the test without further adjustment.

20 Protection of the device from damage caused by external defibrillators

20.1 Testing and compliance shall be in accordance with ISO 14117.

20.2 Testing and compliance shall be in accordance with ISO 14117.

21 Protection of the device from changes caused by high-power electrical fields applied directly to the patient

21.1 The text in 21.1 of ISO 14708-1:2014 applies.

21.2 Testing and compliance shall be in accordance with ISO 14117.

22 Protection of the active implantable medical device from changes caused by miscellaneous medical treatments

22.1 The text in 22.1 of ISO 14708-1:2014 applies.

22.2 The text in 22.2 of ISO 14708-1:2014 applies.

23 Protection of the active implantable medical device from mechanical forces

23.1 The text in 23.1 of ISO 14708-1:2014 applies.

23.2 The text in 23.2 of ISO 14708-1:2014 applies.

Compliance is confirmed if, after completing the test procedure, the values for the *implantable pulse generator* listed in 28.8.2 d) and e) conform with the values stated in the manufacturer's original specification.

23.3 Implantable leads shall withstand the tensile forces that might occur after implantation, without fracture of any conductors or joints or breaching of any functional electrical insulation.

CAUTION — The following test employs 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.

Test: use a preconditioning bath of approximately 9 g/l saline at 37 °C ± 5 °C, a tensile load tester, a resistance meter, a test bath of 9 g/l saline at 37 °C ± 5 °C with a reference electrode plate having a noble metal surface with a minimum area of 500 mm^2, a leakage current tester, capable of applying 2 000 V and supplying a current of at least 2 mA, and a 200 µF ± 10 % capacitor (C_1) rated for use at 1 000 V.

Specimens intended for test shall be in the condition as normally shipped to the customer.

Specimens shall be totally immersed in the preconditioning bath for a minimum of 10 d. Immediately prior to testing, the lead shall be rinsed in distilled or deionized water, then wiped free of surface water. The test specimen(s) shall be placed in the test bath within 30 min of removal from the preconditioning bath.

The lead shall be fitted in the tensile tester, clamped at the metallic surface of the lead connector pin and at the appropriate point on the distal end of the lead. The distance between the clamping points shall be measured.

The lead shall be subjected to a tensile load, limited to a value causing 20 % elongation, otherwise increased to at least 5 N. The tensile load shall be sustained for a at least 1 min then relieved.

The tensile load application shall be repeated for each combination of tip distal end and lead connector pin. This may be accomplished by using multiple leads as the test sample.

The electrical continuity of each conduction path shall be verified by measuring the d.c. resistance.

The insulation integrity of each lead shall be verified by immersing the outer covering, other than within 20 mm of an *electrode* or *terminal*, in the test bath, not less than 50 mm nor more than 200 mm from the reference electrode plate. The lead shall be immersed in the test bath for a minimum of 1 h before proceeding.

CAUTION — Ensure that the *electrodes* and *terminals* are electrically isolated from the saline bath during this procedure.

The test voltage shall attain the full value within 0,1 s to 5 s. The test voltage shall be maintained at full value for at least 15 s before being lowered to zero.

Insulation between each electrical conductor carrying a *CD pulse* and every other conductor, and between each conductor carrying a *CD pulse* and the reference electrode, shall be subjected to a 2 000 V ± 50 V d.c. test voltage. Insulation between each electrical conductor used for pacing and/or sensing and every other conductor not previously exposed to the 2 000 V test voltage, and between each pace/sense conductor and the reference electrode, shall then be subjected to a 100 V ± 5 V d.c. test voltage.

The electrical continuity of each lead carrying a *CD pulse* shall be verified by passing current *pulses* through the electrical conductors.

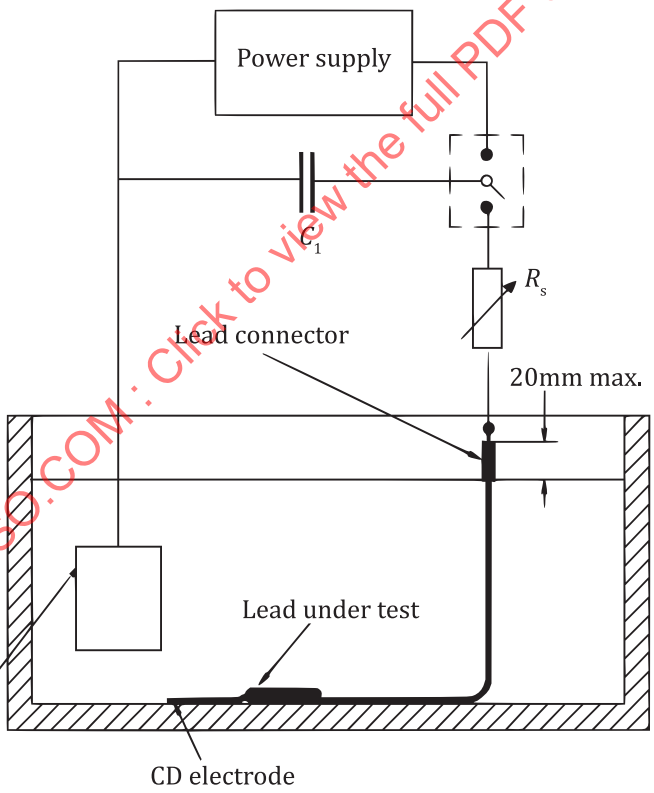


Figure 7 — Conductor current integrity test fixture

The lead, other than within 20 mm of the exposed *terminal*, shall be immersed in the test bath (see Figure 7).

CAUTION — Care must be taken when connecting to the *terminal* of the lead to assure that high currents will not cause damage. A set-screw is recommended for connection to the *terminal*.

Each lead conductor intended to carry a *CD pulse* shall be subjected to ten current *pulses*, each sustained for a minimum of 25 ms, produced by discharging the capacitor from 1 000 V ± 50 V. There shall be a

minimum of 10 s between current *pulses*. If total discharge circuit resistance is less than 20 Ω, a series resistor R_S may be used to increase total system resistance to a maximum of 25 Ω.

Compliance is confirmed if:

— the leakage current measured between each conductor and the reference electrode and between any two conductors that have an exposed conductive surface intended for contact with tissue does not exceed 2 mA during the voltage application;

— the lead exhibits no permanent functional damage, nor permanent elongation in excess of 5 % unless the lead is intended by the manufacturer to accommodate a longer permanent elongation;

— after performing the complete procedure, the d.c. resistance of the lead is within the manufacturer's specification.

23.4 The text in 23.4 of ISO 14708-1:2014 applies.

23.5 Implantable leads shall withstand the flexural stresses that might occur after implantation without fracture of any conductor.

Procedure: Two tests shall be performed. Test 1 shall be applied to all uniform lead segments. Test 2 shall be applied to the segment of the lead where the lead joins the connector body.

The test samples, whether in the form of complete leads or lead body segments, shall be preconditioned the same way as fully assembled and shipped product. The tests shall be performed in dry conditions and at room temperature.

Test 1: Use a special holding fixture (see Figure 8). The inside bore of the fixture shall be no greater than 110 % of the diameter of the lead segment under test. At the lower end of the fixture, the inside surface shall be formed into a bell mouth having a radius such that when the test segment conforms to the contour of the fixture the centre-line of the test segment forms a 6 mm ± 0,1 mm centre-line bending radius (see Figure 8).

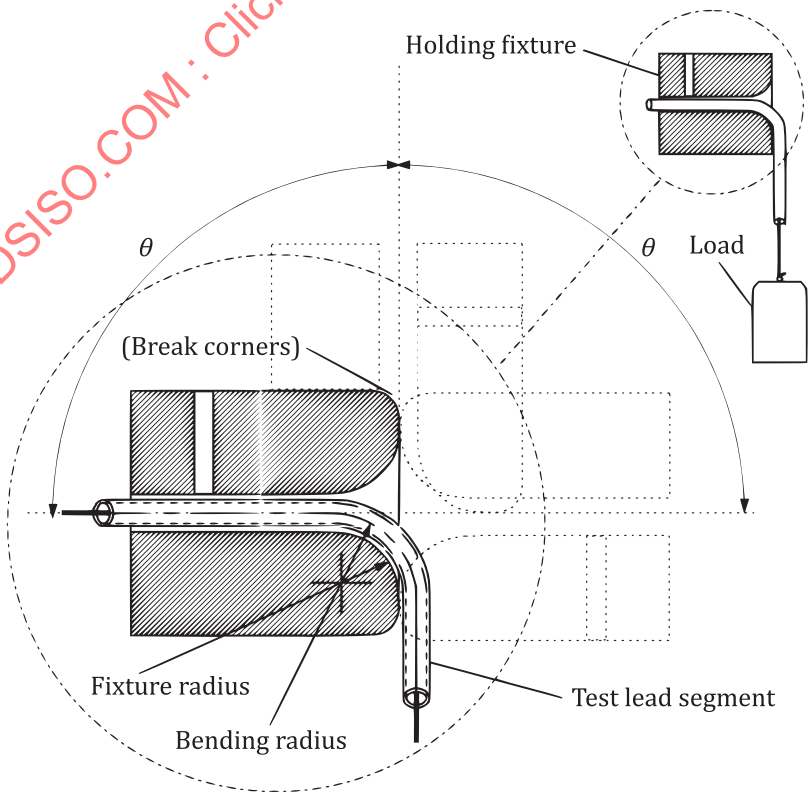


Figure 8 — Conductor flex test fixture

The fixture shall be mounted in a machine that can oscillate the fixture from the vertical and forces the test segment to flex in the bell mouth of the fixture. The lead test segment shall be mounted to hang vertically under gravity in the holding fixture, oriented in the worst-case test condition when the test segment allows multiple orientations.

A load sufficient to assure that the centre-line of the test segment conforms to the bending radius shall be attached to the lower end of a thin, flexible line (cord) strung through the test segment, or, for lead bodies with no accessible lumen, applied directly to the test segment, so that it conforms to the bending radius.

The fixture shall be oscillated through an angle $\theta = 90° \begin{smallmatrix} 0 \\ -5 \end{smallmatrix}$ each side of vertical at a rate of approximately 2 Hz for a minimum of 47 000 cycles.

NOTE Adjust the centre of rotation between the test fixture and the centre-line of the test lead segment so as to minimize vibration.

Compliance is confirmed if the measured resistance of each conduction path is within the manufacturer's specifications (adjusted for the length of the lead segment under test), and each conductor is functionally intact as per the manufacturer's performance specification.

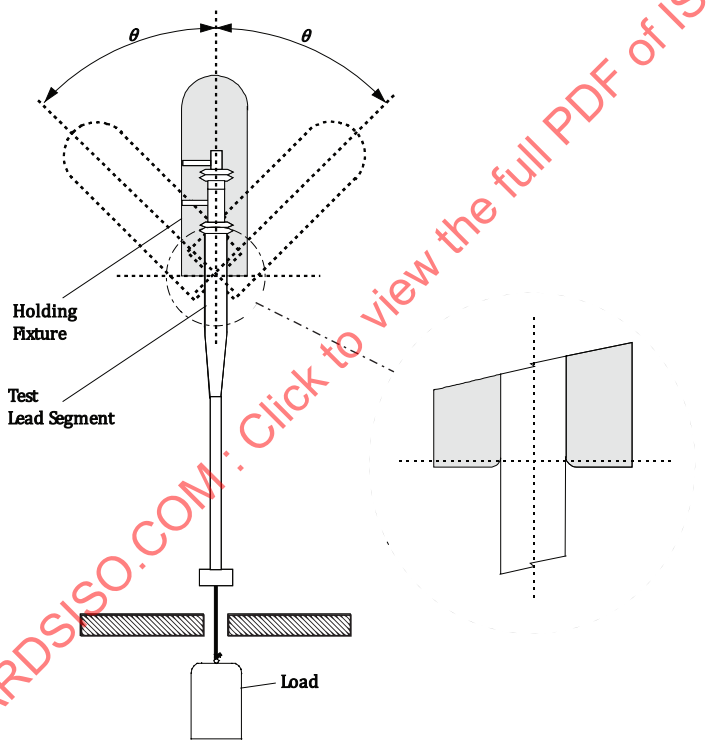


Figure 9 — Connector flex test fixture

Test 2: Use a special holding fixture (see Figure 9) similar in form to the intended *pulse* generator connector header. The holding fixture shall be made of rigid material, with the corners that might come in contact with the lead connector rounded to a maximum radius of 0,5 mm. The cavity depth shall be set at the minimum allowed in the applicable standard, or as specified by the manufacturer's connector specification if other connector systems are used. Except for the cavity depth and rounding, the test cavity dimensions shall be as specified in Figure 2 of ISO 5841-3:2013 (IS-1), Figure 4 of ISO 11318:2002 (DF-1), or Figure 4 of ISO 27186:2010 (IS4/DF4), or in accordance with the manufacturer's specifications if another connector system is used.

The holding fixture shall be mounted in a machine that can rotate the fixture ±45º from the vertical (see Figure 9). The centre of rotation shall be in the plane where the rounded corners of the holding fixture begin. The holding fixture shall allow the lead connector and attached lead segment to hang vertically

under gravity. The lead connector shall be fitted into the holding fixture, oriented in the worst-case test condition, and retained by the set-screw mechanisms.

A load shall be attached to the lead segment 10 cm ± 0,5 cm from the centre of rotation of the holding fixture. The load attachment mechanism shall ensure that there shall be no relative motion between the conductor and the tubing at the point of attachment. The load (including the attachment mechanism) shall be 100 g ± 5 g.

The holding fixture shall then be oscillated through an angle $\theta = 45° \pm 2°$ each side of vertical at a rate of approximately 2 Hz for a minimum of 82 000 cycles.

The test shall be repeated for each unique connector lead body assembly.

Compliance is confirmed if the measured resistance of each conduction path is within the manufacturer's specifications (adjusted for the length of the lead segment under test), and each conductor is functionally intact as per the manufacturer's performance specification.

23.6 Implantable connectors, intended for use by physicians to join *implantable pulse generator*s and leads, shall be identified as to type. The retention force provided by the implantable connector shall be greater than or equal to 7,5 N. The manufacturer shall declare [see 28.4 of ISO 14708-1, 28.8.2 h) and 28.8.3 e)] the intended performance as implanted, determined according to the following test.

NOTE The procedure is applicable only to connector systems without set-screws and/or lead connectors not compatible with set-screws.

Test procedure: The implantable connector pair shall be mated in accordance with the manufacturer's instructions and immersed in a saline bath, approximately 9 g/l at 37 ºC ± 5 ºC, for a minimum of 10 d.

After removal from the saline bath, the connector pair shall be subjected to successive straight pulls of 7,5 ± 0,5 N, and 10 ± 0,5 N each for not less than 10 s.

The maximum force that does not result in disconnection shall be recorded as the test result.

Compliance is checked by assessment of the test results provided by the manufacturer (see also 28.4 of ISO 14708-1).

23.7 The text in 23.7 of ISO 14708-1:2014 applies except for "Compliance is checked by a functional test" in the last paragraph.

Compliance is confirmed if, after completing the test procedure, the *implantable pulse generator*'s characteristics listed in 28.8.2 d) and e) conform with the values stated in the manufacturer's original specification.

24 Protection of the active implantable medical device from damage caused by electrostatic discharge

24.1 The text in 24.1 of ISO:14708-1:2014 applies.

24.2 The text in 24.2 of ISO:14708-1:2014 applies.

25 Protection of the active implantable medical device from damage caused by atmospheric pressure changes

25.1 Implantable parts of an active implantable medical device shall be constructed to withstand the changes of pressure which can occur during transit or normal conditions of use.

Test procedure: The test shall be conducted in saline solution with leads (approximately 9 g/l) at room temperature. The *pulse* generator will be exposed to the following:

— Low pressure: 50 kPa for 25 cycles with a minimum 3 min dwell time and ramp-up and ramp-down times of maximum 3 min each.

— High pressure: minimum 304 kPa for 40 cycles with a minimum 2 min dwell time and ramp-up and ramp-down times of maximum 2 min each.

NOTE The pressure values above are absolute values.

Compliance is confirmed if the *pulse* generator provides uninterrupted pacing during exposure. After exposure, the *pulse* generator shall function as prior to the test without adjustment. Permanent deformation of the implantable device is acceptable as long as it does not affect operation of the device, patient comfort, or safety (for example, deformation that resulted in sharp edges would not be acceptable).

25.2 The text in 25.2 of ISO 14708-1:2014 applies.

26 Protection of the active implantable medical device from damage caused by temperature changes

26.1 The text in 26.1 of ISO 14708-1:2014 applies.

26.2 The text in 26.2 of ISO 14708-1:2014 applies.

27 Protection of the active implantable medical device from electromagnetic non-ionizing radiation

27.1 Testing and compliance shall be in accordance with ISO 14117.

27.2 Testing and compliance shall be in accordance with ISO 14117.

28 Accompanying documentation

28.1 The accompanying documentation shall include the name and address of the manufacturer, the address being the postal address and telephone number.

Compliance is checked by inspection.

28.2 The text in 28.2 of ISO 14708-1:2014 applies.

28.3 The text in 28.3 of ISO 14708-1:2014 applies.

28.4 The text in 28.4 of ISO 14708-1:2014 applies.

28.5 The text in 28.5 of ISO 14708-1:2014 applies.

28.6 The text in 28.6 of ISO 14708-1:2014 applies.

28.7 The text in 28.7 of ISO 14708-1:2014 applies.

28.8 The text in 28.8 of ISO 14708-1:2014 applies.

28.8.1 The accompanying documentation shall include a description of the device, including the following information, as appropriate.

a) For *implantable pulse generator*s:

   1) an explanation of the tachyarrhythmia therapies;

   2) a description of other functions (e.g. bradyarrhythmia pacing features).

   Instead of using words to describe the tachyarrhythmia therapies, the mode codes in Annex C may be used in the markings and accompanying documentation.

   Instead of describing the bradyarrhythmia pacing mode in words, the mode codes defined in Annex C of ISO 14708-2:2019 may be used in the markings and accompanying documentation to designate the bradyarrhythmia pacing mode of the *implantable pulse generator*.

b) For leads:

   1) the configuration (unipolar, etc.);

   2) other characteristics (e.g. drug dispensing means).

c) For *adaptors*:

   — the configuration (unipolar, etc.).

Compliance is checked by inspection.

28.8.2 The device specifications and characteristics for an *implantable pulse generator* shall include the following information, as appropriate.

a) The connector configuration (unipolar, bipolar or other) and the geometry and/or dimensions of the receiving connector and locking mechanism. Any marking used to identify a connector shall be explained (see 13.1.1).

b) The physical characteristics, including:

   1) the mass of the *implantable pulse generator* (in g);

   2) the principal dimensions (in mm);

   3) the volume of the *implantable pulse generator* (in cm^3);

   4) a general description of the materials, including coatings, which will come into contact with human tissue.

c) If an *electrode* is an integral part of the *implantable pulse generator*, then the *electrode* material and surface area (in cm^2).

d) The electrical characteristics, nominal as shipped (including ranges and tolerances), at 37 °C ± 2 °C and 50 Ω ± 1 % load, (unless otherwise stated), including as applicable:

   1) the available energy settings for the *CD pulse*s;

2) for each type of *CD pulse* (e.g. monophasic, biphasic, etc.), the *delivered CD pulse energy* and peak *ICD output voltage* for the maximum energy setting, minimum energy setting and the energy setting closest to maximum plus minimum divided by 2 (mean value);

NOTE 1 See 6.1.4 for the method of measuring *delivered CD pulse energy* and 6.1.3 for the method of measuring *ICD output voltage*.

3) the maximum and minimum *pulse amplitude*s while providing *antitachycardia pacing*, measured for each programmable amplitude with the *pulse duration* and *pulse interval* programmed to the available settings closest to 0,5 ms and 300 ms respectively (see 6.1.5);

NOTE 2 See 6.1.1 of ISO 14708-2:2019 for the method of measuring *pulse amplitude* using load resistors of 500 Ω ± 1 %.

4) if equipped with an *automatic sensitivity control*, the lowest (most sensitive) *sensing threshold* for both positive and negative polarities and the *sensitivity* test signal waveform used (see 6.1.6);

5) the typical *charge time* (when capacitors are fully formed) for maximum energy setting of the *ICD pulse* at *BOS* and *RRT*, as a minimum.

NOTE 3 Requirements 1) and 2) above do not apply to *ATP only devices*.

e) If applicable, the *implantable pulse generator* specifications shall include the electrical characteristics (including ranges and tolerances), nominal as shipped, for all applicable bradyarrhythmia pacing parameters as required in 28.8.2 d) of ISO 14708-2.

NOTE 4 See Clause 6 of ISO 14708-2:2019 for the methods of measuring these parameters.

f) Recommended methods for determining that the *implantable pulse generator* is functioning properly after implantation.

g) Any recommendation regarding the use of lead(s) (see also ISO 14708-1, 28.4).

Compliance is checked by inspection.

28.8.3 The device specification and characteristics for a lead shall include the following information, as appropriate.

a) A general description of the materials used for the conductor, connector pin and insulation, and the shape, materials, and configuration of the *electrode(s)*.

b) A statement advising whether the lead contains a medicinal substance as an integral component, giving the identity of the medicinal substance.

c) The physical dimensions, including (nominal values):

1) the length (in cm);

2) the geometric surface area of *electrode(s)* (in mm^2);

3) the *insertion diameter* of *transvenous lead* (except for connector end) (in mm) and the size of the corresponding introducer (in French gauge);

4) the distance(s) between *electrode*s (bipolar or multipolar *endocardial leads*) (in mm);

5) the maximum depth of penetration into the tissue, if applicable (in mm);

6) the connector geometry (lengths and diameters) (in mm), including any designations or markings defined in the applicable connector standards;

d) The electrical characteristics of the lead (see 6.2), including:

1) the *lead pacing impedance* (in Ω);

e) Any recommendations regarding use with *implantable pulse generators* (see also ISO 14708-1, 28.4).

Compliance is checked by inspection.

28.8.4 The accompanying documentation for an *implantable pulse generator* shall include information (for example, by diagram) on all *pulse* waveforms.

Compliance is checked by inspection.

28.8.5 The device specification and characteristics for an *adaptor* shall include the following information, as appropriate.

a) A general description of the materials used for the conductor, connector pin and insulation.

b) The compatible *implantable pulse generator*s and leads (in particular, see 23.6) and the compatibility with proprietary locking mechanisms of leads and *implantable pulse generator*s.

c) The physical dimensions (nominal values) including geometry, lengths, and diameters (in mm), including any designations or markings defined in the applicable connector standards.

Compliance is checked by inspection.

28.8.6 The device specification and characteristics for *accessories* shall include a general description of the materials used if they are intended to remain in contact with body tissues.

Compliance is checked by inspection.

28.9 The text in 28.9 of ISO 14708-1:2014 applies.

28.9.1 The accompanying documentation for an *implantable cardioverter defibrillator* shall include a description of all recommended lead configurations.

Compliance is checked by inspection.

28.9.2 The accompanying documentation for an *implantable cardioverter defibrillator* shall clearly indicate which connections on the *implantable pulse generator* and leads are intended for cardioversion/*defibrillation* and which connections are intended for sensing and pacing.

NOTE For *ATP only devices*, the *CD terminal*s part of the requirement is not applicable.

Compliance is checked by inspection.

28.10 The text in 28.10 of ISO 14708-1:2014 applies.

28.11 The text in 28.11 of ISO 14708-1:2014 applies.

28.11.1 The accompanying documentation for an *implantable cardioverter defibrillator* shall include a warning regarding the adverse effects of high-voltage shocks during handling and implantation. The accompanying documentation shall describe how accidents with high-voltage shocks can be avoided during handling and implantation.

Compliance is checked by inspection.

28.11.2 The accompanying documentation for an *implantable cardioverter defibrillator* shall include a warning if there are hazards to the patient or the device due to positioning (i.e. shorting) of *electrodes*.

Compliance is checked by inspection.

28.12 The text in 28.12 of ISO 14708-1:2014 applies.

28.13 The accompanying documentation for an *implantable pulse generator* shall include a warning to inactivate tachyarrhythmia therapies during surgical procedures, in particular when high-frequency surgery or diathermy is used.

Compliance is checked by inspection.

28.14 The text in 28.14 of ISO 14708-1:2014 applies.

28.15 The text in 28.15 of ISO 14708-1:2014 applies.

28.16 The text in 28.16 of ISO 14708-1:2014 applies.

28.17 The text in 28.17 of ISO 14708-1:2014 applies.

28.18 The text in 28.18 of ISO 14708-1:2014 applies.

28.19 *ATP only devices* shall comply with ISO 14708-2:2019, 28.19.

NOTE 1 The replacement and the additional 28.19.1 and 28.19.2 do not apply to *ATP only devices*.

The accompanying documentation for an *implantable pulse generator* shall include information (for example, by graphs) on the average estimated longevity of the device in years as a function of the total number of maximum energy *CD pulses* delivered. The total number of maximum energy *CD pulses* delivered is spaced uniformly over the estimated life of the *implantable pulse generator*.

The estimated longevity shall be calculated under the following conditions, as applicable:

1) the *implantable pulse generator* is monitoring (no pacing) and delivering the maximum energy *CD pulses* into a 50 Ω ± 1 % load;

2) if applicable, the *implantable pulse generator* is pacing 100 % at the manufacturer's specified settings into a 500 Ω ± 5 % load and delivering the maximum energy *CD pulses* into a 50 Ω ± 1 % load.

If applicable, any energy used to reform the output capacitors shall be deducted from the total energy available when determining estimated longevity.

Compliance is checked by inspection.

28.19.1 The accompanying documentation for an *implantable pulse generator* shall state the *prolonged service period*, expressed in months, and the estimated number of maximum energy *CD pulses* available between *recommended replacement time* and *end of service*. When preparing these estimates, the manufacturer shall assume that the *implantable pulse generator* is delivering one maximum energy *CD pulse* every 15 d into a 50 Ω ± 1 % load.

Compliance is checked by inspection.

28.19.2 The accompanying documentation for an *implantable pulse generator* shall include the electrical characteristics after the *recommended replacement time*. The electrical characteristics shall be

measured at 37 °C ± 2 °C with the *CD lead* terminals connected to 50 Ω ± 1 % load(s) and the other *terminals* connected to 500 Ω ± 5 % load(s).

Compliance is checked by inspection.

28.20 The text in 28.20 of ISO 14708-1:2014 applies.

28.21 The text in 28.21 of ISO 14708-1:2014 applies.

28.22 The text in 28.22 of ISO 14708-1:2014 applies.

28.23 The text in 28.23 of ISO 14708-1:2014 applies.

28.24 The text in 28.24 of ISO 14708-1:2014 applies.

28.25 The text in 28.25 of ISO 14708-1:2014 applies.

28.26 The text in 28.26 of ISO 14708-1:2014 applies.

28.27 The text in 28.27 of ISO 14708-1:2014 applies.

28.28 The text in 28.28 of ISO 14708-1:2014 applies.

28.29 The text in 28.29 of ISO 14708-1:2014 applies.

28.30 The text in 28.30 of ISO 14708-1:2014 applies.

Annex A
(informative)

Relationship between the fundamental principles in ISO/TR 14283 and the clauses of this document

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
5 Essential principles		
5.1.1 Implants must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training, and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which can be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	(This principle is fundamental to all aspects of an active implantable medical device addressed by ISO 14708.) 5.3 Requires usability engineering process be applied to non-implantable parts of the active implantable medical device 5.5 Requires parts of an ISO 14971-compliant risk management process to be applied	* retained
5.1.2 The solutions adopted by the manufacturer for the design and manufacture of the implants must conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer must control the risks so that the residual risk associated with each hazard is judged acceptable. The manufacturer must apply the following principles in the priority order listed: — identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse; — eliminate risks as far as reasonably practicable through inherently safe design and manufacture; — reduce as far as reasonably practicable the remaining risks by taking adequate protection measures, including alarms; and — inform users of any residual risks.	(This principle is fundamental to all aspects of an active implantable medical device addressed by ISO 14708. This approach is particularly applicable to the requirements in Clauses 14, 19, and 21.) 5.4 Requires the manufacturer to provide information security when communication with the implantable part is through wireless communication channels 5.5 Requires parts of an ISO 14971-compliant risk management process to be applied	* retained
5.1.3 Implants must achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.	(This principle is fundamental to all aspects of an active implantable medical device addressed by ISO 14708.)	* retained

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
5.1.4 The characteristics and performances referred to in 5.1.1, 5.1.2 and 5.1.3 must not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the implant, as indicated by the manufacturer, when the implant is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.	19.2 Requires power source depletion indicator.	* replacement
	19.3 Defines methodology to ensure single fault conditions are not a HAZARD.	* retained
	23.1 Defines drop test for NON-IMPLANTABLE PARTS.	* retained
	23.2 Defines vibration test for patient carried parts.	* retained additional text
	23.3 Sets test of tensile strength (LEADS, etc.).	* replacement
	23.4 Requires strain relief (LEADS, etc.).	* retained
	23.5 Requires fatigue resistance (LEADS, etc.).	* replacement
	23.6 Requires connections to be reliable.	* replacement
	26.1 Requires protection from heat from powered NON IMPLANTABLE parts	* retained
	28.4 Requires disclosure of maximum proven connector retention strength.	* retained
	28.23 Requires warning against patient entry into hazardous environments.	* retained
5.1.5 Implants must be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected by transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.	7.2 Requires sterile pack to be protected by sales packaging.	* retained
	10.1 Requires packaging to be durable.	* retained
	10.2 Requires packaging to be protected against the effects of humidity.	* retained
	10.3 Requires markings on the sales package to be indelible.	* additional note
	10.4 Requires accompanying documentation to be physically associated with the device	* retained
	12.3 Requires markings on the sterile pack to be indelible.	* retained
	26.2 Requires device to be protected against the effect of temperature changes.	* retained
5.1.6 All known and foreseeable risks, and any undesirable effects, must be minimised and be acceptable when weighed against the benefits of the intended performance of implants during normal conditions of use.	19.3 Defines methodology to ensure single fault conditions are not a HAZARD.	* retained
	19.4 Requires investigation of unintended effects caused by the device.	* retained

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
5.2 Specific principles regarding design and construction		
5.2.1 Chemical, physical and biological properties		
5.2.1 The implants must be designed and manufactured in such a way as to ensure the characteristics and performance referred to in 5.1. Particular attention must be paid to: — the choice of materials used, particularly as regards toxicity and where applicable flammability, — the compatibility between the materials used and biological tissues, cells, and body fluids taking account of the intended purpose of the device, — the choice of materials used, reflecting, where appropriate, matters such as hardness, wear and fatigue strength.	14.3 Requires investigation of biocompatibility.	* retained
5.2.2 The implants must be designed, manufactured and packaged in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the implants and to patients, taking account of the intended purpose of the implant. Particular attention must be paid to tissues exposed and to the duration and frequency of exposure.	14.2 Defines test for particulate contamination	* retained
	14.3 Requires investigation of biocompatibility.	* retained
5.2.3 The implants must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the implants are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	19.5 Demonstrate compatibility with medicinal substances	* retained
5.2.4 The implants must be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that can leach or leak from the implant. Special attention must be given to substances which are carcinogenic, mutagenic or toxic to reproduction.	25.1 Requires implanted parts to withstand pressure changes	* replacement
5.2.5 The implants must be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the implant taking into account the implant and the nature of the environment in which it is intended to be used.	25.1 Requires implanted parts to withstand pressure changes	* replacement

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
5.2.6 The implants must be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by insufficient cleanliness of the implant. Risks posed by insufficient cleanliness include risks posed by bacterial endotoxins, pyrogens and particulate contaminates.	14.1 Requires device to be supplied sterile	* retained
5.3 Infection and microbial contamination		
5.3.1 The implants and manufacturing processes must be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design must: — allow easy handling, and, where necessary: — reduce as far as reasonably practicable and appropriate any microbial leakage from the implant and/or microbial exposure during use, — prevent microbial contamination of the implant, by the patient, user or other person.	14.1 Requires device to be supplied sterile	* retained
5.3.2 Implants labelled as having a special microbiological state must be designed, manufactured and packaged to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.	7.1 Requires device to be supplied in non-reusable pack.	* retained
	7.2 Requires sterile pack to be protected by sales packaging.	* retained
	10.1 Requires packaging to be durable.	* retained
	10.2 Requires packaging to be proof against the effects of humidity.	* retained
	11.7 Requires contents of sterile pack to be declared or visible.	* retained
	11.9 Requires the sterile pack to be marked with the instructions for opening it.	* retained
	12.1 Applies ISO 11607 to the reusable pack.	* retained
	12.2 Shall be apparent if sterile pack has been opened.	* retained
	14.1 Requires device to be supplied sterile.	* retained
5.3.2 Implants labelled as having a special microbiological state must be designed, manufactured and packaged to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.	(Not applicable because 14.1 requires that implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE be provided sterile.)	—

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
5.3.3 Implants delivered in a sterile state must be designed, manufactured and packaged in a non-reusable pack, and/or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.	7.1 Requires device to be supplied in non-reusable pack	* retained
	7.2 Requires sterile pack to be protected by sales packaging	* retained
	10.1 Requires packaging to be durable	* retained
	10.2 Requires packaging to be proof against the effects of humidity	* retained
	11.7 Requires contents of sterile pack to be declared or visible	* retained
	11.9 Requires the sterile pack to be marked with the instructions for opening it	* retained
	12.1 Applies ISO 11607-1 to the reusable pack	* retained
	12.2 Shall be apparent if sterile pack has been opened	* retained
	14.1 Requires device to be supplied sterile	* retained
5.3.4 Implants labelled either as sterile or as having a special microbiological state must have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.	—	—
5.3.5 Implants intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.	14.1 Requires device to be supplied sterile.	* retained
	14.2 Defines test for particulate contamination	* replacement
5.3.6 Packaging systems for non-sterile implants must maintain the integrity and cleanliness of the product and if the implants are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	(Not applicable because subclause requires that implantable parts of an active implantable medical device be provided sterile.)	—
5.3.7 The labelling of the implant must distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.	(Not applicable because subclause requires that implantable parts of an active implantable medical device be provided sterile.)	—
5.4 Implants incorporating a substance considered to be a medicinal product/drug		
5.4.1 This subclause is not intended to provide guidance on “combination products” as a whole since definitions have yet to be harmonized and practice varies between different jurisdictions.		

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
5.4.2 Where an implant incorporates, as an integral part, a substance which, if used separately, might be considered to be a medicinal product/drug as defined in the relevant legislation that applies within that jurisdiction and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and performance of the implant as a whole must be verified, as well as the safety, quality and efficacy of the substance in the specific application.	14.4 Requirement for quality and safety of incorporated medicinal substances.	* retained
5.5 Implants incorporating materials of biological origin		
5.5.1 This subclause is not intended to provide guidance on "combination products" as a whole since definitions have yet to be harmonized and practice varies between different jurisdictions.		
5.5.2 In some jurisdictions implants incorporating tissues, cells and substances of animal origin might be considered medical devices. In this case, such tissues, cells and substances should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. National regulations might require that the manufacturer and/or the Regulatory Authority retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents (e.g. such as prions) must be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.	(Not applicable to ACTIVE IMPLANTABLE MEDICAL DEVICES)	—
5.5.3 In some jurisdictions implants incorporating human tissues, cells and substances might be considered medical devices. In this case, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin must be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents must be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.	(Not applicable to ACTIVE IMPLANTABLE MEDICAL DEVICES.)	—

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
5.5.4 In some jurisdictions implants incorporating cells and substances of microbial origin might be considered medical devices. In this case, processing, preservation, testing and handling of cells and substances must be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents must be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.	(Not applicable to ACTIVE IMPLANTABLE MEDICAL DEVICES.)	—
5.6 Environmental properties		
5.6.1 If the implant is intended for use in combination with other devices or equipment the whole combination, including the connection system must be safe and must not impair the specified performance of the implants. Any restrictions on use applying to such combinations must be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer or mechanical coupling, must be designed and constructed in such a way as to minimize all possible risks from incorrect connection.	9.9 Requires implantable connectors to be identified on sales pack.	* replacement
	11.8 Requires implantable connectors to be identified on sterile pack.	* retained
	23.6 Requires connector retention force to be specified.	* replacement
	28.4 Requires disclosure of maximum proven connector retention strength.	* retained
	28.5 Requires provision of information on accessories that might be required to facilitate the intended use of the device.	* retained
5.6.2 Implants must be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate:		
5.6.2.1 The risk of injury to the patient, user or other persons in connection with their physical and ergonomic features;	15.1 Sets requirement for surfaces of NON-IMPLANTABLE PARTS.	* retained
	15.2 Requires implantable parts to have appropriate physical form.	* retained
5.6.2.2 The risk of use error due to the ergonomic features, human factors and the environment in which the implant is intended to be used;	5.3 Requires USABILITY ENGINEERING PROCESS be applied to non-implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE	* retained
	5.5 Requires parts of an ISO 14971-compliant risk management process to be applied	* retained

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
5.6.2.3 Risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature or variations in pressure and acceleration;	23.1 Defines drop test for NON-IMPLANTABLE PARTS.	* retained
	23.2 Defines vibration test for patient carried parts.	* retained replacement compliance text
	24.1 Defines electrostatic discharge test for NON-IMPLANTABLE PARTS.	* retained
	25.1 Requires implanted parts to be proof against pressure changes.	* replacement
	26.2 Requires implantable devices to be undamaged by extremes of temperature in transit.	* retained
	27.1 Defines requirement for electromagnetic immunity.	* replacement
5.6.2.4 The risks associated with the use of the implant when it comes into contact with materials, liquids, and gases to which it is exposed during normal conditions of use;	19.3 Requires a design analysis and defines the methodology for the analysis	* retained
5.6.2.5 The risk associated with the possible negative interaction between software and the environment within which it operates and interacts;	19.3 Requires a design analysis and defines the methodology for the analysis	* retained
5.6.2.6 The risks of accidental penetration of substances into the implant;	19.3 Requires a design analysis and defines the methodology for the analysis	* retained
5.6.2.7 The risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;	20.1 Requires defibrillation protection of external ECG leads.	* replacement
	20.2 Defines test to prove defibrillation protection of implanted device.	* replacement
	21 Requires protection against diathermy, etc.	* retained 21.2 replacement
	22 Requires protection against diagnostic ultrasound.	* retained
	28.12 Requirement for warning notices.	* retained
	28.13 Requires warning about monitoring device in case of diathermy etc.	* replacement
	28.14 Requires warning not to expose device to therapeutic levels of ultrasound.	* retained
	28.15 Requires warning about the effect of therapeutic irradiation on implanted devices.	* retained

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
5.6.2.8 Risks arising where maintenance or calibration are not possible, including from: — ageing of materials used, — loss of accuracy of any measuring or control mechanism, — excessive increase of leakage currents, — excess heat generated by the implant.	17.1 Requires investigation of local heating caused by faulty implanted device	* replacement
	17.2 Requires that supply heat be investigated	* retained
	19.1 Requires a design analysis.	* retained
	19.2 Requires power source depletion indicator.	* replacement
5.6.3 Implants must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to implants whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.	5 Applies IEC 60601-1 to the NON-IMPLANTABLE PARTS of the active implantable medical device.	* retained
5.6.4 Implants must be designed and manufactured in such a way that adjustment, calibration, and maintenance, where such is necessary to achieve the performances intended, can be done safely.	17.1 Requires investigation of local heating caused by the implanted device in normal operation or in any single component failure	* replacement
	19.1 Requires a design analysis	* retained
	19.2 Requires power source depletion indicator	* replacement
5.6.5 Implants must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.	28.29 Requires information on proper disposal of the device	* retained
5.7 Implants with a diagnostic or measuring function		
5.7.1 Diagnostic implants and implants with a measuring function, must be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for the intended purpose of the implant, based on appropriate scientific and technical methods. The limits of accuracy must be indicated by the manufacturer.	5.1 Applies IEC 60601–1 to the non-implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE that are connected to or equipped with an electrical power source	* retained
5.7.2 Any measurement, monitoring or display scale used in association with an implant must be designed in line with ergonomic principles, taking account of the intended purpose of the implant.	5.1 Applies IEC 60601–1 to the non-implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE that are connected to or equipped with an electrical power source	* retained
5.7.3 Wherever possible values expressed numerically must be in commonly accepted, standardised units, and understood by the users of the implant.	5.1 Applies IEC 60601–1 to the non-implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE that are connected to or equipped with an electrical power source	* retained

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
5.8 Protection against radiation		
5.8.1 General Implants must be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation must be reduced as far as reasonably practicable and appropriate, compatible with the intended purpose, while not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	(See more particular requirements below)	—
5.8.2 Intended radiation Where implants are designed to emit hazardous, or potentially hazardous, levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such implants must be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.	(Not applicable to active implantable medical devices)	—
5.8.3 Unintended radiation Implants must be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as reasonably practicable and appropriate.	9.1 Requires markings warning of any radioactive substances	* replacement
	18.1 Requirement for sealed sources	* retained
	18.2 Requires justification of radiation dose on patient	* retained
	18.3 Requires radiation dose as low as is possible	* retained
	28.2 Requires information to be provided about radioactive substances	* retained
5.8.4 Ionizing radiation	(Not applicable to active implantable medical devices)	—
5.8.4.1 Implants intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where reasonably practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.	—	—
5.8.4.2 Implants emitting ionizing radiation intended for diagnostic radiology must be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose while minimising radiation exposure of the patient and user.	—	—

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
5.8.4.3 Implants emitting ionizing radiation, intended for therapeutic radiology must be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.	—	—
5.9 Implants that incorporate software		
5.9.1 Implants incorporating electronic programmable systems, including software must be designed to ensure repeatability, reliability and performance according to the intended use. In the event of a single fault condition, appropriate means must be adopted to eliminate or reduce as far as reasonably practicable and appropriate consequent risks.	5.2 Requires implants to be designed according to software life cycle process activities compliant with IEC 62304:2006 and validated	* retained
	19.3 Requires a design analysis and defines the methodology for the analysis	* retained
5.9.2 For implants which incorporate software, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, verification and validation.	5.2 Requires implants to be designed according to software life cycle process activities compliant with IEC 62304:2006 and validated	* retained
5.10 Active implants and devices connected to them		
5.10.1 For active implants, in the event of a single fault condition, appropriate means must be adopted to eliminate or reduce as far as reasonably practicable and appropriate consequent risks.	19.3 Defines methodology to ensure single fault conditions are not a hazard	* retained
5.10.2 Implants where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.	19.2 Requires power source depletion indicator	* replacement
5.10.3 Implants where the safety of the patients depends on an external power supply must include an electronic alarm system to signal any power failure by way of an external device used in association with the implant.	5.1 Applies IEC 60601–1 to the non-implantable parts of the active implantable medical device that are connected to or equipped with an electrical power source	* retained
5.10.4 Implants intended to monitor one or more clinical parameters of a patient must be equipped with appropriate electronic alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health by way of an external device used in association with the implant.	5.1 Applies IEC 60601–1 to the non-implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE that are connected to or equipped with an electrical power source	* retained
5.10.5 Implants must be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the usual environment.	27.1 Defines requirement for electromagnetic immunity	* replacement
5.10.6 Implants must be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.	27.1 Defines requirement for electromagnetic immunity	* replacement

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
5.10.7 Implants must be designed and manufactured in such a way as to avoid, as far as reasonably practicable, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the implant and in the event of a single fault condition in the implant, provided the implant is installed and maintained as indicated by the manufacturer.	5.1 Applies IEC 60601–1 to the non-implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE that are connected to or equipped with an electrical power source	* retained
	16.1 Sets safety limits for leakage currents from non-implantable parts	* retained
5.11 Protection against mechanical risks		
5.11.1 Implants must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.	5 Applies IEC 60601-1 to the non-implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE.	* retained
5.11.2 Implants must be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the implants, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device	* retained
5.11.3 Implants must be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device	* retained
5.11.4 Implants must be designed and manufactured in such a way as to reduce to the lowest practicable level, the risk of error when certain parts within the implant are intended to be connected or reconnected before or during use.	5.3 Requires usability engineering process be applied to non-implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE	* retained
5.11.5 Implant (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal conditions of use.	17.1 Defines requirement for protection from heat	* replacement
5.11.6 Implant packaging must be designed and manufactured in such a way as to reduce abrasion between packaging and implant to the lowest practicable level.	10.1 Specifies packaging construction	* retained
15.12 Protection against the risks posed to the patient by energy supplies or substances		
5.12.1 Implants for supplying the patient with energy or substances must be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	19.3 Requires a design analysis and defines the methodology for the analysis.	* retained
	5.1 Applies IEC 60601–1 to the non-implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE that are connected to or equipped with an electrical power source	* retained

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
5.12.2 Implants must be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Implants must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.	5.1 Applies IEC 60601–1 to the non-implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE that are connected to or equipped with an electrical power source	* retained
5.12.3 The function of the controls and indicators must be clearly specified on the implants or associated devices. Where an implant or associated device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user.	13.4 Specifies on-device markings	* retained
5.13 Label and Instruction for Use		
5.13.1 General principles		
This subclause describes the general principles that apply equally to all implants. The primary purpose of labelling is to identify the implant and its manufacturer and communicate safety and performance related information to the user, professional or other person, as appropriate. Such information can appear on the implant itself, on packaging or as instructions for use. The following principles are recommended.		
The medium, format, content, legibility, and location of the label and instructions for use must be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use must be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.	4 Allows use of symbols, abbreviations, and identification colours	* retained additional note
The information required on the label, might be provided on the implant itself. If this is not practicable or appropriate, some or all of the information can appear on the packaging for each unit, and/or on the packaging of multiple implants.	12.3 Requirement that any markings shall be indelible	* retained
	13.2 Requires implantable parts to be marked with sufficient information to allow for positive identification at the time of implantation	* retained
Where the manufacturer supplies multiple implants to a single user and/or location, it might be sufficient to provide only a single copy of the instructions for use. In these circumstances, the manufacturer must provide further copies upon request.	—	—
Instructions for use might not be needed or might be abbreviated for implants if they can be used safely and as intended by the manufacturer without any such instructions for use.	—	—
Labels must be provided in a human-readable format but can be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.	—	—

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
Instructions for use can be provided to the user either in paper or non-paper format (e.g. electronic). They can be supplied by various means either with the implant or separate from it. Examples of other means are information downloaded from the manufacturer's website using the internet, and machine-readable sources. The means chosen must be appropriate for, and accessible to, the anticipated user population.	10.4 Requires accompanying documentation to be physically associated with the device	* retained
Where instructions for use are provided on a medium other than paper, the manufacturer must ensure the user has information on how to: 1) view the instructions for use; 2) access the correct version of the instructions for use; and 3) obtain a paper version of the instructions for use.	—	—
Residual risks which are required to be communicated to the user and/or other person must be included as limitations, contraindications, precautions or warnings in the labelling.	8.1 Requires warnings to be prominent	* retained
The use of internationally recognized symbols must be encouraged provided that implant safety is not compromised by a lack of understanding on the part of the user. Where the meaning of the symbol is not obvious to the implant user, e.g. for a newly introduced symbol, an explanation must be provided within the instructions for use.	4. Allows use of symbols, abbreviations and identification colours	* retained additional note
Country-specific requirements for the content of the labelling must be kept to the minimum and, where they currently exist, eliminated as the opportunity arises.	—	—
Where national legislation, such as customs statutes, trade agreements and the like, include requirements for additional documentation to accompany the implant, there might be an inconsistency between the additional documentation and the content of implant labelling described in this document. An example is a customs requirement to indicate the "country of origin" of the implant which does not necessarily align with the address of the manufacturer indicated in the labelling according to 5.13.2 c) or 5.13.3 b) of this document.	—	—
Provided that safe and correct use of the implant is ensured, a regulatory authority might authorize labelling to be in one or more language(s) other than its national language(s).	—	—
5.13.2 Content of the label		
The label must contain the following particulars which can appear on the implant itself, or on the packaging of each unit, or on the packaging of multiple devices.		

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
a) The name or trade name of the implant.	11.1 Requires identification of MANUFACTURER on STERILE PACK	* retained
b) The details strictly necessary for a user to identify the implant and its use.	9.3 Requires description of device and model designation on the SALES PACK	* retained
	9.4 Requires MARKING with characteristics sufficient to identify device	* retained 9.4.1 through 9.4.4 additional subclause
	9.8 Requires SALES PACK to bear information about accessories provided	* retained
	9.10 Requires supplementary description, if 9.3 and 9.4 are inadequate to declare purpose	* retained
	11.6 Requires description of device and mode designation on the STERILE PACK	* retained
	11.7 Requires identification of contents of STERILE PACK	* retained
c) The name and address of the manufacturer in a format that is recognizable and allows the location of the manufacturer to be established.	9.2 Requires name and address of MANUFACTURER on the sales pack	* retained
d) For imported implants, the name and postal address of the authorized representative, or importer or distributor established within the importing country/jurisdiction might be required. This information can be added by the authorized representative, importer, or distributor within the country of import, rather than be provided by the manufacturer, in which case, the additional label must not obscure any of the manufacturer's labels.	9.2 Requires name and address of MANUFACTURER on the sales pack	* retained
e) Where appropriate, an indication that the implant contains or incorporates a medicinal or biological substance, e.g. bone cement containing an antibiotic for use in orthopaedics.	28.7 Requires information about medicinal products which the device is designed to administer	* retained
	28.28 Requires an indication that the device contains medicinal substance derived from human blood or human plasma	* retained
f) The batch code/lot number or the serial number of the implant preceded by the word LOT or SERIAL NUMBER or an equivalent symbol, as appropriate, to allow post-market action to be taken if there is a need to trace or recall the implant.	9.3 Requires batch code or serial number on the SALES PACK	* retained
	11.6 Requires batch code or serial number on the STERILE PACK	* retained

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
g) An unambiguous indication of the date until when the implant can be used safely, expressed at least as the year and month (e.g. on implants supplied sterile), where this is relevant.	9.7 Requires MARKING of a "USE-BEFORE" date	* retained
	11.5 Requires MARKING of a "use-by" date	* retained
h) Where there is no indication of the date until when it can be used safely, the year of manufacture. This year of manufacture can be included as part of the batch or serial number, provided the date is clearly identifiable.	9.7 Requires MARKING and defines format	* retained
	11.4 Requires MARKING and defines format	* retained
i) An indication of any special storage and/or handling condition that applies.	9.11 Requires MARKING and defines format	* retained
j) If the implant is supplied sterile, an indication of its sterile state and, where appropriate, the sterilization method.	11.2 Requires method of sterilization to be marked	* retained
k) Warnings or precautions to be taken that need to be brought to the immediate attention of the user of the implant as relevant, and to any other person where appropriate (e.g. "THIS IMPLANT CONTAINS LATEX"). This information can be kept to a minimum in which case more detailed information must appear in the instructions for use.	8.1 Requires warnings to be prominent	* retained
	28.12 Requirement for warning notices	* retained
l) If the implant is intended for single use, an indication of that fact.	28.18 Requires and defines warning notice about reuse of the device	* retained
n) If the implant is intended for premarket clinical investigation only, an indication of that fact.	9.13 Requires MARKING of special purpose.	* retained
	11.3 Requires MARKING of special purpose.	* retained
o) If the implant is intended for non-clinical research, teaching or testing purposes only, an indication of that fact.	9.13 Requires MARKING of special purpose.	* retained
	11.3 Requires MARKING of special purpose.	* retained
p) If the implant is intended for presentation or demonstration purposes only, an indication of that fact.	9.13 Requires MARKING of special purpose.	* retained
	11.3 Requires MARKING of special purpose.	* retained
5.13.3 Content of the instructions for use		
The instructions for use must contain the following particulars: a) The name or trade name of the implant.	28.1 Requires name and address of manufacturer	* replacement —
b) The name and address of the manufacturer in a format that is recognizable and allows the location of the manufacturer to be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance.	28.1 Requires name and address of manufacturer	* replacement
c) The implant's intended use/purpose including the intended user (e.g. professional), as appropriate.	28.8 Requires information describing the intended use.	*additional subclauses

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
d) The performance of the implant intended by the manufacturer.	28.8 Requires information describing the intended use.	* additional subclauses
e) Where the manufacturer has included clinical investigations as part of premarket conformity assessment to demonstrate conformity to Essential Principles, a summary of the investigation, outcome data and clinical safety information, or a reference as to where such information can be accessed.	19.4 Requires investigation of unintended effects caused by the device	* retained
f) Any residual risks, contraindications and any expected and foreseeable side effects, including information to be conveyed to the patient in this regard.	28.12 Requires warning notices on hazards arising from interaction	*retained
g) Specifications the user requires to use the implant appropriately, e.g. if the implant has a measuring function, the degree of accuracy claimed for it.	5.1 Applies IEC 60601–1 to the non-implantable parts of the active implantable medical device	* retained
h) If the implant contains, or incorporates, a medicinal substance and/or material of biological origin, identification of that substance or material, as appropriate.	28.7 Requires information about medicinal products which the device is designed to administer.	* retained
	28.28 Requires an indication that the device contains medicinal substance derived from human blood or human plasma	* retained
i) Details of any required preparatory treatment or handling of the implant before it is ready for use (e.g. checking, cleaning, disinfection, drying, packaging, sterilization, final assembly, calibration, etc.). NOTE 1 The principle in i) is in addition to information given in the previous edition of this document, and in addition to information given in Global Harmonization Task Force guidance documents.	(Not applicable to active implantable medical devices)	—
j) Any requirements for special facilities, or special training, or particular qualifications of the implant user and/or third parties.	(Not applicable to active implantable medical devices)	—

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
k) The information needed to verify whether the implant is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant: — details of the nature, and frequency, of preventative and regular maintenance, and of any preparatory cleaning or disinfection; — identification of any consumable components and how to replace them; — information on any necessary calibration to ensure that the implant operates properly and safely during its intended life span; — methods of eliminating the risks encountered by persons involved in installing, calibrating or servicing the implants.	(Not applicable to active implantable medical devices)	—
l) An indication of any special storage and/or handling condition that applies.	7.2 Requires sterile pack to be protected by sales packaging	* retained
	10.1 Requires packaging to be durable	* retained
	10.2 Requires packaging to be protected against the effects of humidity	* retained
	10.3 Requires markings on sales packaging to be indelible	* retained with additional note
	10.4 Requires accompanying documentation to be physically associated with the device	* retained
	12.3 Requires markings on sales packaging to be indelible	* retained
	26.2 Requires device to be protected against the effect of temperature changes	* retained
m) If the implant is supplied sterile, instructions in the event of the sterile packaging being damaged before use.	28.17 Requires instructions on dealing with the contents if the sterile pack has been opened or damaged.	* retained
n) If the implant is supplied non-sterile, the appropriate instructions for sterilization. NOTE 2 Further information is provided in ISO 17664.	(Not applicable because 14.1 requires that active implantable medical device be provided sterile.)	—

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
o) If the implant is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization. Information must be provided to identify when the implant must no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses.	(Not applicable to active implantable medical devices)	—
p) For implants intended for use together with other implants, medical devices and/or general purpose equipment: — information to identify such implants, medical devices or equipment, in order to obtain a safe combination and/or; — information on any known restrictions to combinations of implants, medical devices and equipment. NOTE 3 Medical devices and equipment intended for use together with the implant include both those designed and manufactured by the implant manufacturer (for example, associated instruments) and those designed and manufactured by others (for example, general purpose equipment).	28.4 Requires information on connector specifications, assembly instructions, and connector performance.	* retained
	28.5 Requires provision of information on accessories that might be required to facilitate the intended use of the device	* retained
	28.9 Requires information to allow selection of device, accessories and related devices	* additional subclauses
q) If the implant emits hazardous, or potentially hazardous levels of radiation for medical purposes: — detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation; — the means of protecting the patient, user, or third party from unintended radiation during use of the implant;	9.1 Requires markings warning of any radioactive substances	* retained
	28.2 Requires information to be provided about radioactive substances	* retained

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
r) Information that allows the user and/or patient to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the implant. This information must cover, where appropriate: — warnings, precautions and/or measures to be taken in the event of malfunction of the implant, or malfunction of devices used in association with the implant, or changes in implant performance that can affect safety; — warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature; — warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the implant during specific diagnostic investigations, evaluations, therapeutic treatment or use (e.g. electromagnetic interference emitted by the implant affecting other equipment); — if the implant administers medicinal or biological products, any limitations or incompatibility in the choice of substances to be delivered; — warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the implant as an integral part of the implant; — precautions related to materials incorporated into the implant that are carcinogenic, mutagenic or toxic, or could result in sensitization or allergic reaction of the patient or user.	28.22 Requires warnings on precautions to avoid adverse environments	* retained
	28.12 Requires warning regarding known hazards by reciprocal interference.	* retained
	14.3 Requires investigation of biocompatibility.	* retained

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-6 and aspects coverd
s) Warnings or precautions to be taken related to the disposal of the implant, its accessories and the consumables used with it, if any. This information must cover, where appropriate: — infection or microbial hazards (e.g. explants, needles or surgical equipment contaminated with potentially infectious substances of human origin); — environmental hazards (e.g. batteries or materials that emit potentially hazardous levels of radiation); — physical hazards (e.g. from sharps).	28.29 Requires instructions for proper removal and disposal.	* retained
t) Date of issue or latest revision of the instructions for use and, where appropriate, an identification number.	28.25 Requires the date of issue or an indication of last revision.	* retained
5.14 Clinical evaluation		
5.14.1 For all implants, the demonstration of conformity with essential principles must include a clinical evaluation. The clinical evaluation must review clinical data in the form of any: — clinical investigation reports, — literature reports/reviews, and — clinical experience. to establish that a favourable benefit-risk ratio exists for the implant.	19.4 Requires investigation of unintended effects caused by the device	* retained
5.14.2 Clinical investigations on human subjects must be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results. In addition, some countries might have specific regulatory requirements for pre-study protocol review or informed consent.	19.4 Requires that any clinical investigations are conducted according to ISO 14155	* retained

Annex B
(informative)

Notes on ISO 14708-6

B.1 General

This document attempts to quantify the fundamental principles of ISO/TR 14283 related to *implantable cardioverter defibrillators* and the functions of active implantable medical devices intended to treat tachyarrhythmia. In many clauses, the standard does this by detailing a particular aspect of the essential requirement and specifying an assessment procedure or test. A compliance requirement then allows the particular device under examination to be deemed to meet the aspect of the essential requirement.

This document supplements or modifies ISO 14708-1, referred to in this document as ISO 14708-1. ISO 14708-1 should not be applied alone to the devices covered by this document. The requirements of this document take priority over those of ISO 14708-1.

For some hazards, this document prescribes specific requirements along with compliance measures (e.g. a.c. and d.c. leakage current levels) which, if met, satisfy an aspect of the fundamental principles of ISO/TR 14283. For other risks, this document requires potential hazards to be assessed, identified, and mitigated using a similar procedure to that described in ISO 14971. Compliance is then determined by review of documentation provided by the manufacturer.

In developing this document, it is recognized that there are cases, particularly where accelerated fatigue testing is involved, where a variety of test methods produce equivalent results. In those cases, the test methods presented in the standard are viewed as "referee tests". The manufacturer may use an alternative test method provided it can be demonstrated that the alternative is equivalent to that in the standard. In a dispute, the method specified in this document is to be used.

In some cases, no laboratory test of limited duration can provide adequate assurance of the characteristics of a particular design or assurance of its performance after several years' implantation. The device manufacturer should then be required to prepare documented studies for expert review.

B.2 Notes on specific clauses and subclauses

The following, more detailed, notes on some of the provisions of this document are provided as an aid to understanding. This annex is directed toward those who are familiar with the construction and use of *implantable cardioverter defibrillators* (and implantable *antitachycardia pacing* devices) but have not themselves participated in drafting this document. The notes in this annex carry the numbers of the relevant clauses in the standard; therefore, the numbering in this annex is not consecutive.

[1] The *implantable cardioverter defibrillator* (*ICD*) market and the technology used in the products are still developing and changing rapidly. In drafting this document, the it has been tried to ensure that the requirements specified will not become obsolete, or become unnecessary limitations, as the therapy and the technology develop. For these reasons, this document does not include requirements for:

— arrhythmia detection,

— *antitachycardia pacing*,

— duration of high-voltage *pulses*.

The fundamental principles of ISO/TR 14283 were used as guidelines when drafting requirements for this document.