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Third edition
2019-09

Implants for surgery — Active implantable medical devices —

Part 2: Cardiac pacemakers

Implants chirurgicaux — Dispositifs médicaux implantables actifs —

Partie 2: Stimulateurs cardiaques

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (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 14708-2 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

This third edition cancels and replaces the second edition (ISO 14708-2:2012), which has been technically revised.

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 as shown in ISO 14117:2019, Annex N;

— revision of the method for measurement of *pulse amplitude* and *pulse duration* in 6.1.2;

— removal of measurement requirements for input impedance in 6.1.4;

— inclusion of new temporary exposure criteria in 17.1 for outer surface temperatures exceeding 39 °C. 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 those active implantable medical devices intended to treat bradyarrhythmias (*pacemakers*), to provide basic assurance of safety to both patients and users.

In recent years, other active implantable cardiovascular devices have emerged, most notably devices that perform the function of improving cardiac output by optimizing ventricular synchrony, in addition to performing *pacemaker* functions.

Although these devices can deliver an additional therapy with respect to *pacemakers*, most of their requirements are similar so that, in most cases, the concepts that apply to *pacemakers* also apply to *CRT-P* device, and the appropriate way to test a *CRT-P* device is similar to the way *pacemakers* are tested.

An implantable cardiac *pacemaker* is essentially a powered electronic device within a sealed, encapsulating enclosure (an *implantable pulse generator*). The device can stimulate heart *beats* by generating electrical impulses which are transmitted to the heart along implanted, insulated conductors with *electrodes* (leads). The *pacemaker* can be adjusted non-invasively by an electronic device, known as a programmer.

This document is relevant to all parts of implantable *pacemakers*, including all *accessories*. Typical examples are *implantable pulse generators*, leads, *adaptors*, programmers and the related software.

The requirements of this document supplement or modify those of ISO 14708-1. The requirements of this document take priority over those of ISO 14708-1.

Although both this document and the Directive 90/385/EEC deal with the same products, the structure and purpose of the two documents are different. Annex A correlates the requirements of the Directive with the subclauses of ISO 14708-1 and this document. Annex B is a rationale providing further explanation of the subclauses of this document.

Annex C describes a coding system that may be used to designate bradyarrhythmia pacing modes. Annex D defines reference points for measurements of *pulse amplitude* and *pulse duration*, and the form of test signal used to determine *sensitivity*.

All annexes except Annex D are informative.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

Implants for surgery — Active implantable medical devices —

Part 2: Cardiac pacemakers

1 Scope

This document specifies requirements that are applicable to those active implantable medical devices intended to treat bradyarrhythmias and devices that provide therapies for cardiac resynchronization.

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

This document was designed for bradyarrhythmia *pulse* generators used with *endocardial leads* or *epicardial leads*. At the time of this edition, the authors recognized the emergence of leadless technologies for which adaptations of this part will be required. Such adaptations are left to the discretion of manufacturers incorporating these technologies.

This document is also applicable to some non-implantable parts and *accessories* of the devices (see Note 1).

The electrical characteristics of the *implantable pulse generator* or lead are determined either by the appropriate method detailed in this particular standard or by any other method demonstrated to have an accuracy equal to, or better than, the method specified. In case of dispute, the method detailed in this particular standard applies.

Any features of an active implantable medical device intended to treat tachyarrhythmias are covered by ISO 14708-6.

NOTE 1 The device that is commonly referred to as an active implantable medical device can in fact be a single device, a combination of devices, or a combination of a device or devices and one or more *accessories*. Not all of these parts are required to be either partially or totally implantable, but there is a need to specify some requirements of non-implantable parts and *accessories* if they could affect the safety or performance of the implantable device.

NOTE 2 In this document, terms printed in 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, implantable cardioverter defibrillators and cardiac resynchronization devices, Second Edition*

ISO 14708-1:2014, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

ISO 27186:2010, *Active implantable medical devices — Four-pole connector system for implantable cardiac rhythm management devices — Dimensional and test requirements*

3 Terms and definitions

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

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

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

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

3.1
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

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

3.3
pacemaker
active implantable medical device intended to treat bradyarrhythmias, comprising an *implantable pulse generator* and lead(s)

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

3.5
sensor
part of a *pacemaker* that is designed to detect signals for the purpose of *rate modulation* or other control purposes

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

3.7
implantable cardiac resynchronization therapy pacing device
CRT-P
active implantable medical device intended to provide improved ventricular activation to optimize cardiac output, comprising an *implantable pulse generator* and leads

3.8
sensitivity
minimum signal required to control consistently the function of the *implantable pulse generator*

3.9
electrode
electrically conducting part (usually the termination of a lead), which is designed to form an interface with body tissue or body fluid

3.10
bipolar lead
lead with two *electrodes*, electrically isolated from each other

3.11
unipolar lead
lead with one *electrode*

3.12
endocardial lead
lead with an *electrode* designed to make contact with the endocardium, or inner surface of the heart

3.13
epicardial lead
lead with an *electrode* designed to make contact with the epicardium, or outer surface of the heart

3.14
transvenous
approach to the heart through the venous system

3.15
insertion diameter
<lead> minimum bore of a rigid cylindrical tube into which the lead (not including the connector) can be inserted

3.16
lead pacing impedance
Z_p
impedance that is formed by the ratio of a voltage *pulse* to the resulting current

Note 1 to entry: The impedance is composed of the *electrode* to tissue interface and the lead impedance.

3.17
model designation
name and/or a combination of letters and numbers used by a manufacturer to distinguish, by function or type, one device from another

3.18
serial number
unique combination of letters and/or numbers, selected by the manufacturer, intended to distinguish a device from other devices with the same *model designation*

3.19
beat
ordered spontaneous or paced activity of the heart

3.20
pulse
electrical output of an *implantable pulse generator* intended to stimulate the myocardium

3.21
pulse amplitude
amplitude of the *pulse*

3.22
pulse duration
duration of the *pulse*

3.23
pulse interval
interval between equivalent points of two consecutive *pulses*

3.24
basic pulse interval
pulse interval in absence of sensed cardiac or other electrical influence

3.25
pulse rate
number of *pulses* per minute

3.26
basic rate
pulse rate of an *implantable pulse generator*, either atrial or ventricular, unmodified by sensed cardiac or other electrical influence

3.27
AV interval
atrioventricular interval
delay between an atrial *pulse* or the sensing of an atrial depolarization and the subsequent ventricular *pulse* or the sensing of a ventricular depolarization

3.28
escape interval
time elapsing between the sensing of a spontaneous *beat* and the succeeding non-triggered *pulse* of an *implantable pulse generator*

3.29
interference pulse rate
pulse rate with which the *implantable pulse generator* responds when it senses electrical activity that it recognizes as interference

3.30
maximum tracking rate
maximum *pulse rate* at which the *implantable pulse generator* will respond on a 1:1 basis to a triggering signal

3.31
rate modulation
altering of the *pulse interval* as a function of a control parameter other than a sensed *beat*

3.32
refractory period
period of time during which atrial or ventricular *pacemaker* timing is unaffected by sensed spontaneous depolarizations, although sensing is not completely disabled

3.33
test pulse interval
pulse interval of an *implantable pulse generator* when directly influenced by a testing device

3.34
test pulse rate
pulse rate of an *implantable pulse generator* when directly influenced by a testing device

3.35
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 14708-1:2014, 3.4, modified – “time” substituted for “point”]

3.36
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 14708-1:2014, 3.7, modified – existing definition entirely replaced]

3.37
projected service life
period from the implantation of the *implantable pulse generator* to the *recommended replacement time* under defined conditions

3.38
prolonged service period
PSP
period beyond the *recommended replacement time* during which the *implantable pulse generator* continues to function as specified by the manufacturer to prolong basic bradyarrhythmia pacing

[SOURCE: ISO 14708-1:2014, 3.23, modified – existing definition entirely replaced]

3.39
power source indicator
means of indicating the electrical status of the power source during the *implantable pulse generator*'s service life

3.40
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 14708-1:2014, 3.25, modified – "time" substituted for "point" and "*implantable pulse generator*" substituted for "active implantable medical device"]

3.41
stoichiometric capacity
capacity as defined by the active materials contents in the power source

3.42
usable capacity
portion of the *stoichiometric capacity* of the power source that can be utilized by the *implantable pulse generator* until *end of service* is reached

3.43
terminal
electrically separate conductive device connection

[SOURCE: ISO 14708-6:2019, 3.39]

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 Measurements 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 *implantable pulse generator* characteristics 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).

The procedures shall be performed with the *implantable pulse generator* at a temperature of 37 °C ± 2 °C, connected to a load of 500 Ω ± 1 % and set to the nominal settings recommended by the manufacturer (the factory recommended settings), unless otherwise stated.

If the *implantable pulse generator* has multichannel functionality, each channel's characteristics shall be determined separately. For simplicity, all the measurement procedures provided show bipolar *implantable pulse generators*. For unipolar *implantable pulse generators*, the case is properly incorporated in the set-up as the indifferent *terminal*.

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

6.1.2 Measurement of *pulse amplitude*, *pulse duration*, *pulse interval*, and *pulse rate*

Procedure: Use an interval counter and an oscilloscope.

The *implantable pulse generator* shall be connected to a 500 Ω ± 1 % load resistor (R_L), and the test equipment as shown in Figure 1. The oscilloscope shall be adjusted to display one *pulse* in full.

The *pulse duration* (*D*) shall be measured between the points on the *pulse* equal to one-third of the peak *pulse amplitude* (A_{max}) (see Figure D.1).

The *pulse amplitude* (*A*) shall be calculated from the time integral over current or voltage, as appropriate, divided by the *pulse duration* (see Figure D.2).

The *pulse interval* (t_p) shall be recorded from the display on the interval counter when set to trigger on the leading edge of each *pulse*.

The *pulse rate* shall be calculated from the mean interval over at least 20 *pulses*.

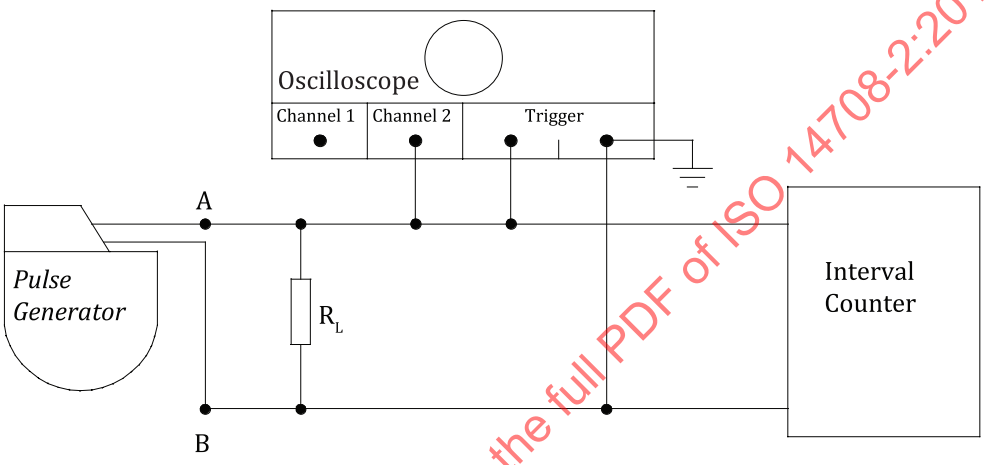


Figure 1 — Measurement of pulse amplitude, pulse duration, pulse interval, and pulse rate

The procedures shall be repeated with load resistors R_L of 240 Ω ± 1 % and 2 kΩ ± 1 % to determine any change in the values as functions of load resistance.

The results shall be expressed in the following units:

— *Pulse duration*: milliseconds (ms);

— *Pulse amplitude*: volts or milliamperes (V or mA);

— *Pulse interval*: milliseconds (ms);

— *Pulse rate*: reciprocal minutes (min^{-1}).

Whenever the result is recorded, the operating settings of the *implantable pulse generator* (programmed *pulse rate*, etc.) shall also be noted.

6.1.3 Measurement of *sensitivity* (e_{pos} and e_{neg})

Procedure: Use an oscilloscope, nominal input impedance ≥1 MΩ, and a test signal generator, output impedance ≤1 kΩ, which provides a signal in the form defined by Figure D.3.

The *implantable pulse generator* shall be connected to a 500 Ω ± 1 % load resistor (R_L) and the test equipment as shown in Figure 2. Apply positive polarity test signals from the test signal generator through a 100 kΩ ± 1 % feed resistor (R_F) to point A. Adjust the pulse interval of the test signal generator so that it is at least 50 ms less than the *basic pulse interval* of the implantable generator. The test signal amplitude (A_T) shall be adjusted to zero, and the oscilloscope shall be adjusted to display several *pulses*.

The test signal amplitude shall be slowly increased until either: for an inhibited-mode *implantable pulse generator*, the *pulse* shall be consistently suppressed; or, for a triggered-mode *implantable pulse generator*, the *pulse* always occurs synchronously with the test signal.

The test signal amplitude shall then be measured. The positive *sensitivity*, designated e_{pos}, shall be calculated by dividing the measured test signal voltage by 201.

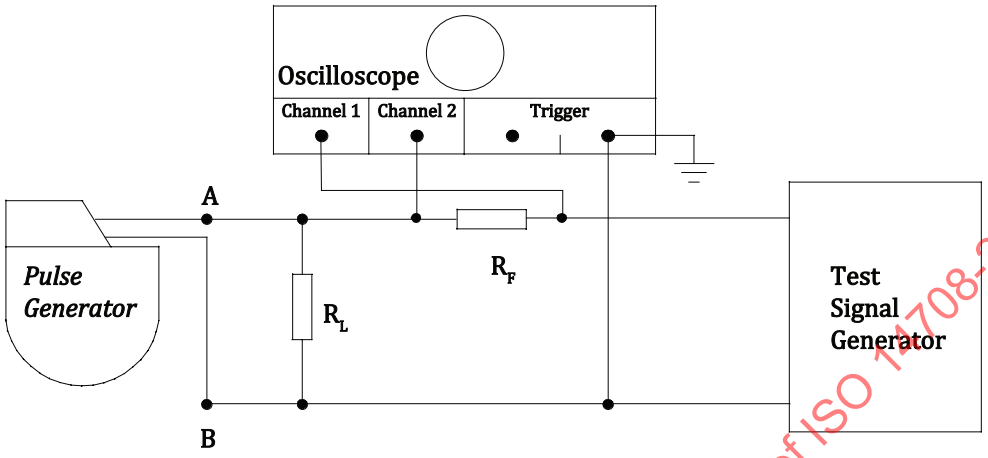


Figure 2 — *Sensitivity* measurement

The procedure shall be repeated with negative polarity test signals applied at point A and the negative *sensitivity* designated e_{neg} shall be similarly calculated.

The results shall be expressed in millivolts (mV).

6.1.4 Measurement of input impedance (Z_{in})

The text in 6.1.4 of ISO 14708-2:2012 no longer applies in this document.

6.1.5 Measurement of *escape interval* (t_e)

Procedure: Use an oscilloscope and a triggerable pulse test signal generator.

The *implantable pulse generator* shall be connected to a 500 Ω ± 1 % load resistor (R_L) and the test equipment as shown in Figure 3. Apply the test signal generator through a 100 kΩ ± 1 % feed resistor (R_F) to point A.

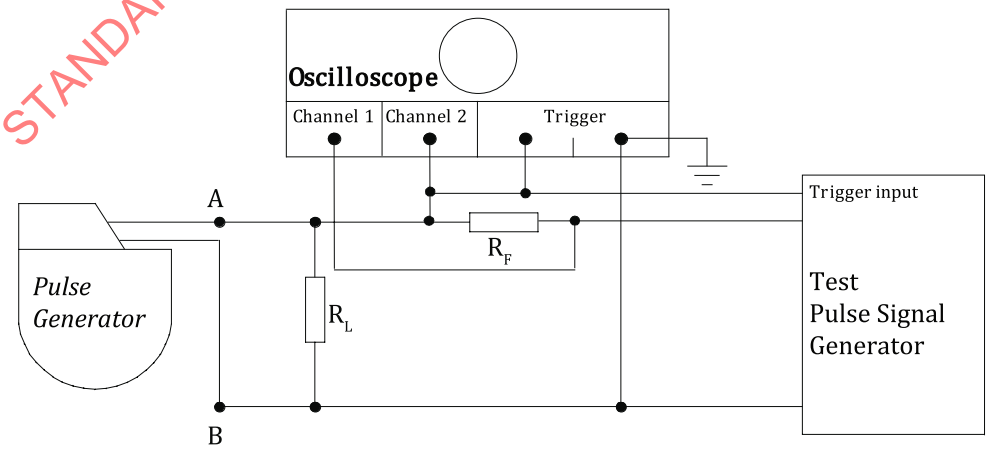


Figure 3 — *Escape interval* measurement

The test signal generator shall be adjusted until the amplitude of the test signal is approximately twice the value of the positive *sensitivity* e_{pos} as determined according to 6.1.3.

The test signal generator shall be adjusted to provide a single pulse with delay, *t*, between being triggered and generating the pulse, where *t* is between 5 % and 10 % greater than the *basic pulse interval* (t_p) of the *implantable pulse generator*.

The oscilloscope shall be adjusted so that a display similar to that shown in Figure 4 is obtained (the test signals and the *pulses* both appear as lines).

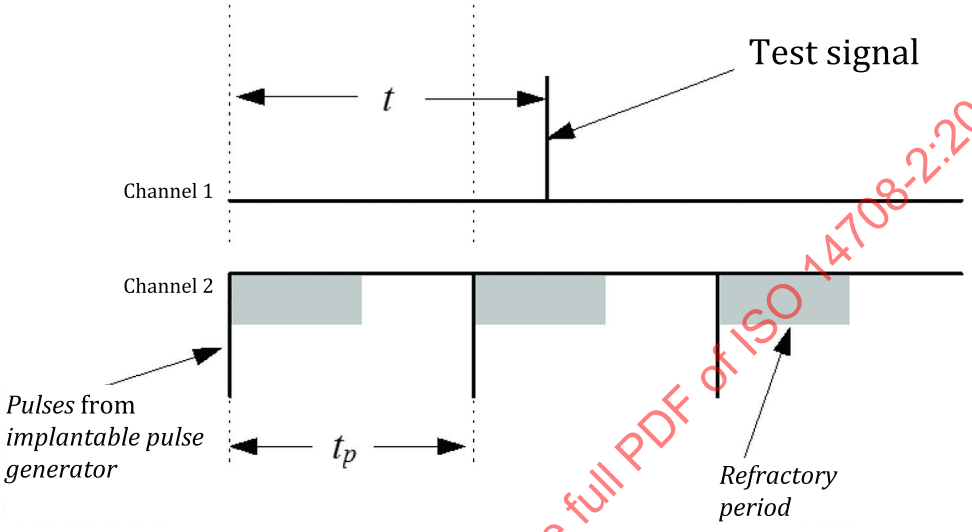


Figure 4 — Initial oscilloscope display, when measuring the *escape interval*

The test signal delay, *t*, shall be reduced until the test signal no longer falls in the *implantable pulse generator*'s *refractory period*. If an inhibited type of *implantable pulse generator* is being tested, the oscilloscope display is then similar to that shown in Figure 5. If a triggered (synchronous) *implantable pulse generator* is being tested, then the display will be similar to that shown in Figure 6.

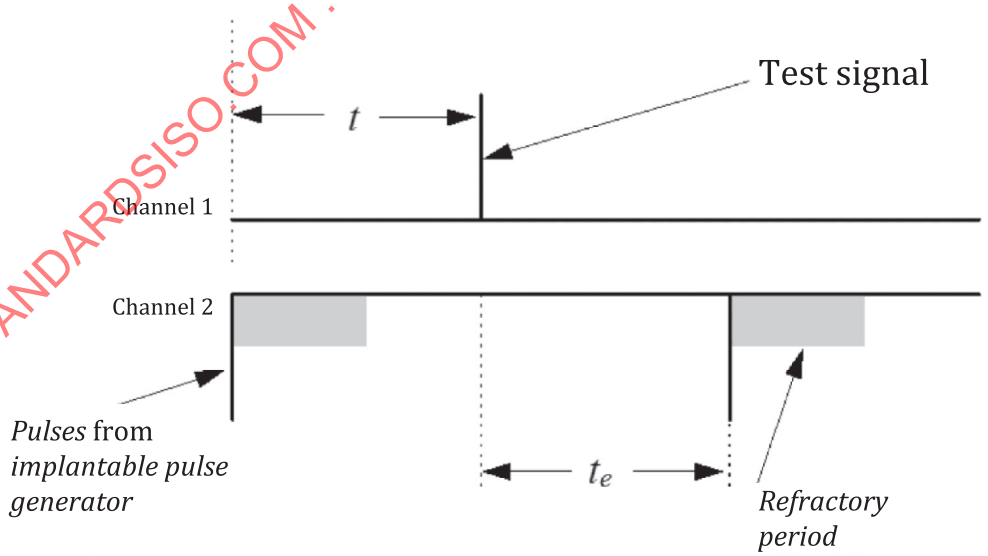


Figure 5 — Measurement of *escape interval* (t_e) in inhibited mode

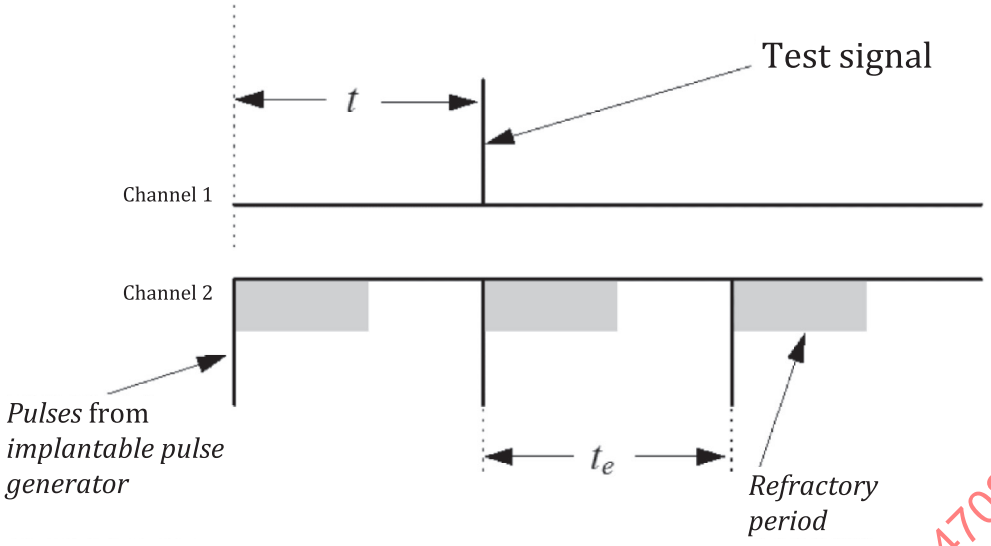


Figure 6 — Measurement of escape *interval* (t_e) in triggered (synchronized) mode

Measure the time between the test signal (or the output that is triggered by the test signal) and the next output *pulse*. This is the *escape interval* (t_e).

The result shall be expressed in milliseconds (ms).

6.1.6 Measurement of sensing *refractory period* (t_{sr})

Procedure: Use an oscilloscope and a triggerable double pulse test signal generator.

The *implantable pulse generator* shall be connected to a 500 Ω ± 1 % load resistor (R_L) and the test equipment as shown in Figure 7. Apply the test signal through the series feed resistor (R_F) to point A. R_F shall be 100 kΩ ± 1 %.

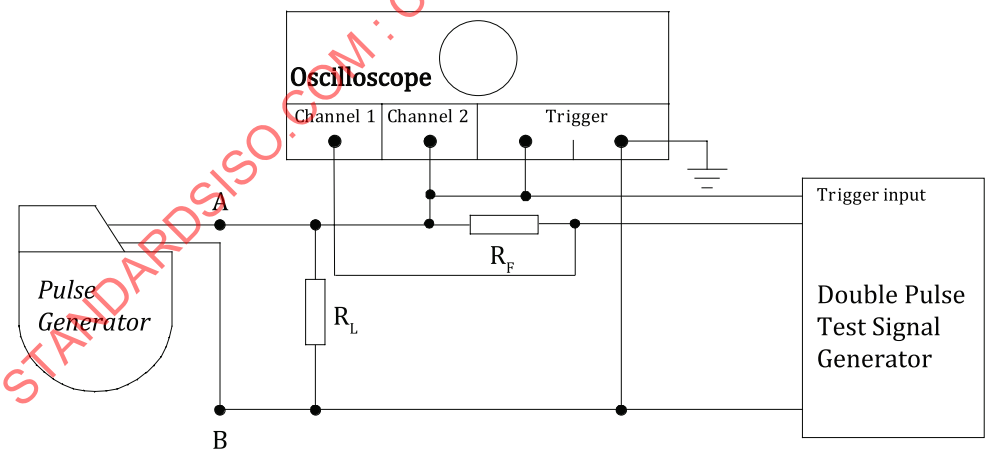


Figure 7 — *Refractory period* measurement

The test signal generator shall be adjusted until the amplitude of the test signal is approximately twice the value of positive *sensitivity* e_{pos} as determined in 6.1.3.

The test signal generator shall be adjusted to provide a delay, t_1, between being triggered and generating the test signal, where t_1 is between 5 % and 10 % greater than the *basic pulse interval* of the *implantable pulse generator*.

The test signal generator shall be set so that the test signal is in the form of a double-pulse with a small separation, *s*, between the leading edges of the two components of the test signal (see Figure 8).

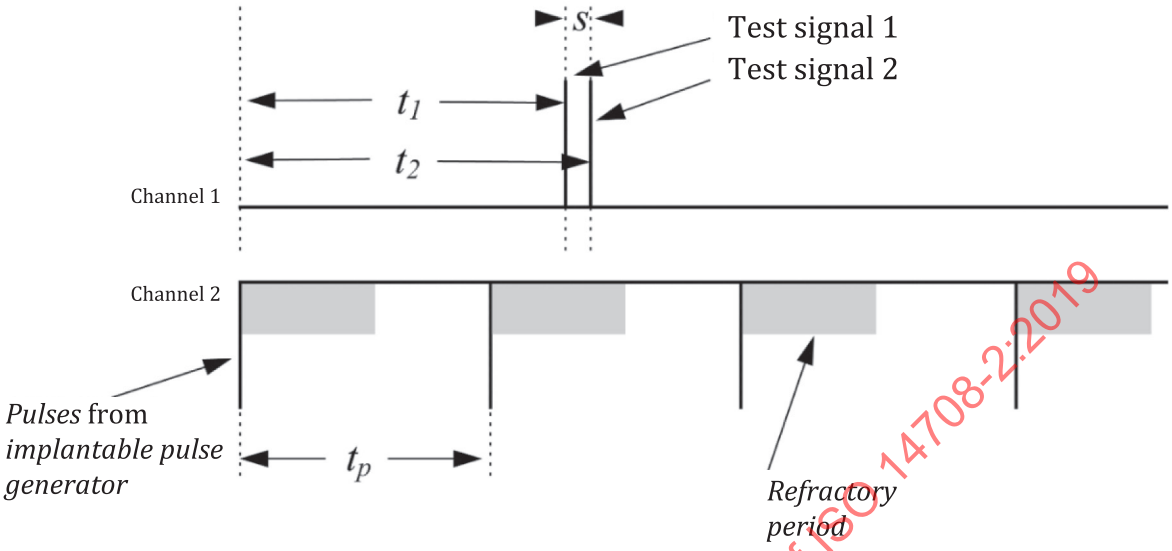


Figure 8 — Initial oscilloscope displays when measuring sensing and pacing *refractory period*

The delay (t_1) of the test signal shall be reduced (keeping *s* constant) until the *implantable pulse generator* senses the test signal 1.

Then, in the case of an inhibited *implantable pulse generator*, test signal 1 causes inhibition of one *pulse* from the *implantable pulse generator* as shown in Figure 9. Then, keeping t_1 constant, t_2 shall be increased until the test signal 2 in Figure 9 is delayed as shown in Figure 10. The second *pulse* in Figure 10 is displaced from test signal 2 by the *escape interval* (t_e).

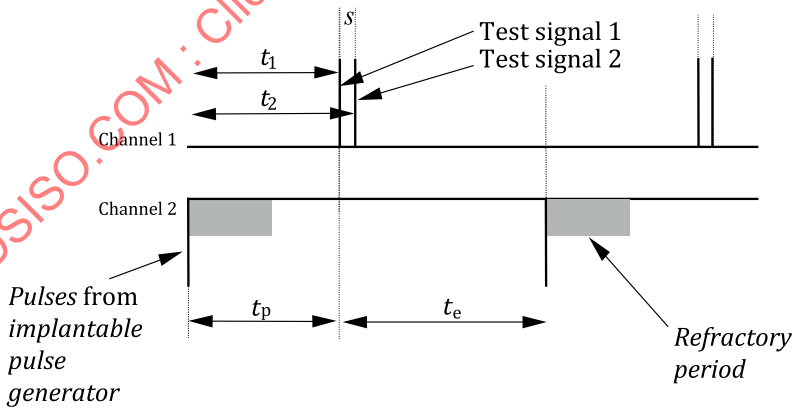


Figure 9 — Measurement of sensing *refractory period* in inhibited mode – A

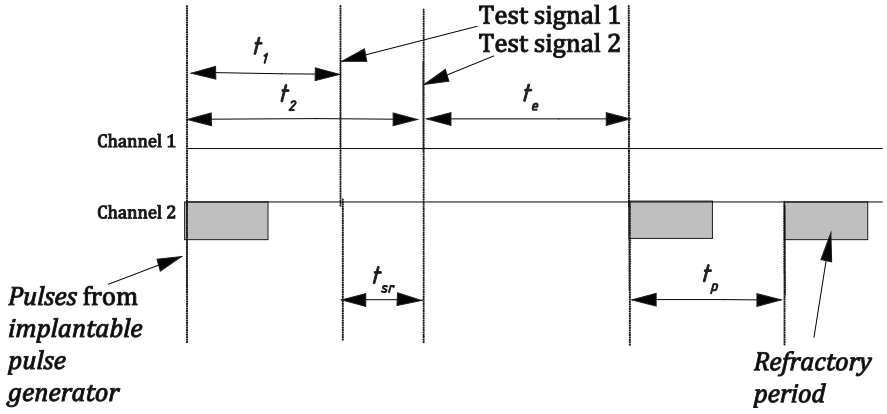


Figure 10 — Measurement of sensing *refractory period* in inhibited mode – B

In the case of a triggered *implantable pulse generator*, sensing test signal 1 triggers the *implantable pulse generator* (see Figure 11). Then, keeping t_1 constant, t_2 shall be increased until the third *pulse* in Figure 11 occurs simultaneously with test signal 2, as shown in Figure 12.

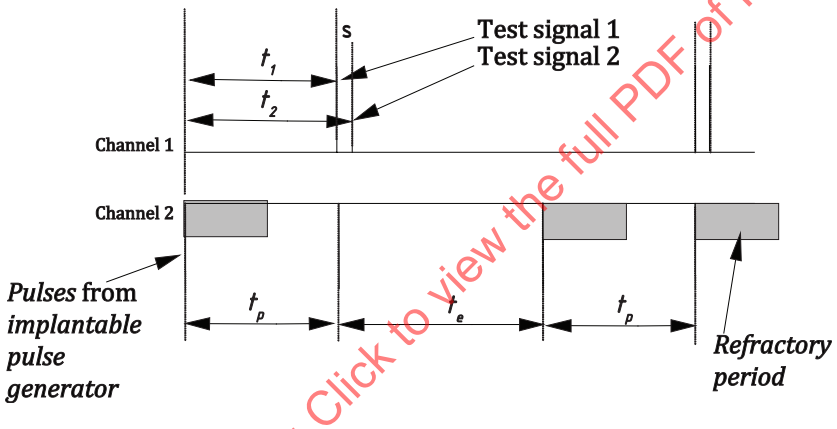


Figure 11 — Measurement of sensing *refractory period* in triggered (synchronous) mode – A

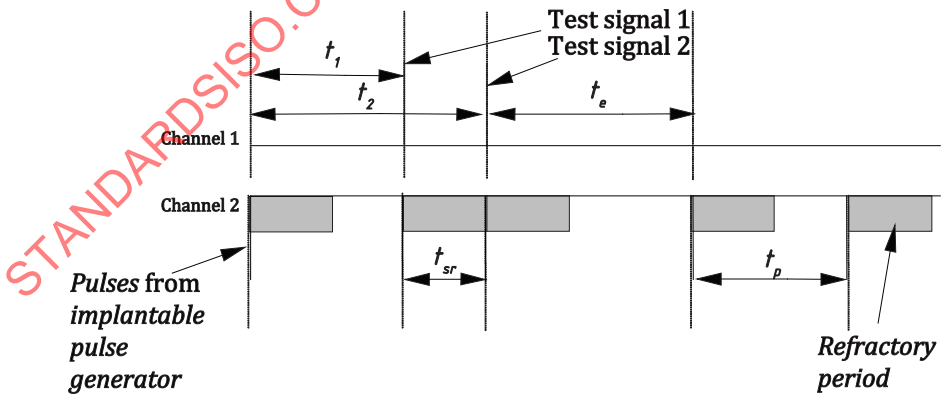


Figure 12 — Measurement of sensing *refractory period* in triggered (synchronous) mode – B

The interval, $t_2 - t_1$, shall be measured. This interval corresponds to the sensing *refractory period* (t_{sr}).

The result shall be expressed in milliseconds (ms).

6.1.7 Measurement of pacing *refractory period* (t_{pr}) (applicable only to inhibited *implantable pulse generators*)

Procedure: Use the equipment and connections required by 6.1.5 and Figure 3.

The test signal generator shall be adjusted until the amplitude of the test signal is approximately twice the value of positive *sensitivity* e_{pos} as determined according to 6.1.3.

The test signal generator shall be adjusted to provide a delayed test pulse, the delay t between triggering and generating the test signal between 5 % and 10 % greater than the *basic pulse interval* (t_p) of the *implantable pulse generator*.

The oscilloscope shall be adjusted so that a display similar to that shown in Figure 4 is obtained (the test signals and the *pulses* both appear as lines).

The delay t shall be slowly increased until the third *pulse* depicted in Figure 6 is displaced to the right (see Figure 13). The third *pulse* will be displaced from the test signal by the *escape interval* (t_e).

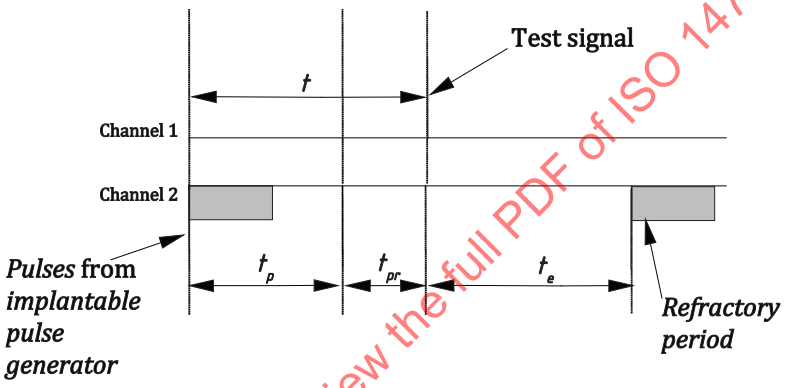


Figure 13 — Measurement of pacing *refractory period* in inhibited mode

The interval between the second *pulse* and the test signal shall be measured. This corresponds to the pacing *refractory period* (t_{pr}).

The result shall be expressed in milliseconds (ms).

6.1.8 Measurement of AV interval (applicable only to dual-chamber implantable pulse generators)

Procedure: Use a dual-trace oscilloscope.

The *dual-chamber implantable pulse generator* shall be connected to 500 Ω ± 1 % load resistors (R_L) and to the oscilloscope. Set the *implantable pulse generator* for *dual-chamber* pacing.

The oscilloscope shall be adjusted so that a display similar to that depicted in Figure 14 is obtained (the *pulses* appear as lines).

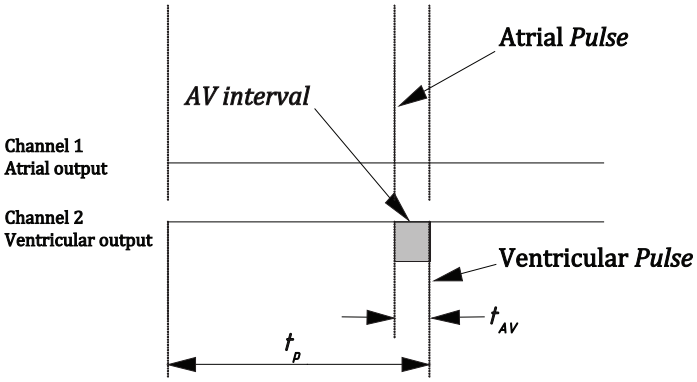


Figure 14 — Oscilloscope display when measuring *AV interval*

The interval between the atrial *pulse* and the succeeding ventricular *pulse* shall be measured. This interval is designated the *AV interval* (t_{AV}).

The result shall be expressed in milliseconds (ms).

6.1.9 Measurement of the post-ventricular atrial *refractory period* (PVARP) (applicable only to *implantable pulse generators* with atrial sensing and ventricular pacing)

Procedure: Use an oscilloscope and a triggerable double-pulse test signal generator.

The *implantable pulse generator* shall be connected to 500 Ω ± 1 % load resistors (R_L) and the test equipment as shown in Figure 15. Set the *implantable pulse generator* to an atrial-tracking mode. Apply the test signal through a series of feed resistors (R_F) to the atrial *terminal* of the *implantable pulse generator*. R_F shall be 100 kΩ ± 1 %. The test signal generator shall be set to trigger on the output of the ventricular output of the *implantable pulse generator*.

The test signal generator shall be adjusted until the amplitude of the test pulse is approximately twice the positive *sensitivity* e_{pos} as determined in 6.1.3.

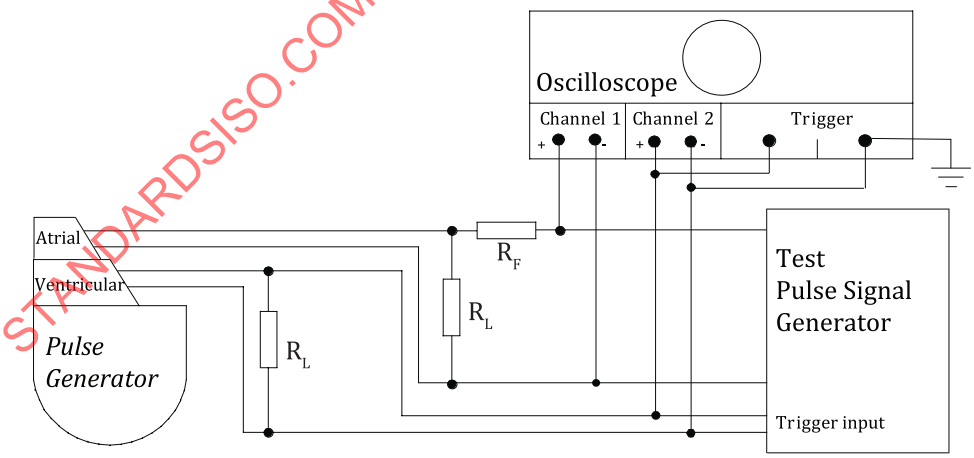


Figure 15 — Post-ventricular atrial *refractory period* (PVARP) measurement

The test signal generator shall be adjusted to provide a delay *t* between triggering and generating the test signal, where *t* is slightly less than the expected post-ventricular atrial *refractory period*. The oscilloscope shall be adjusted so that a display similar to that depicted in Figure 16 is obtained.

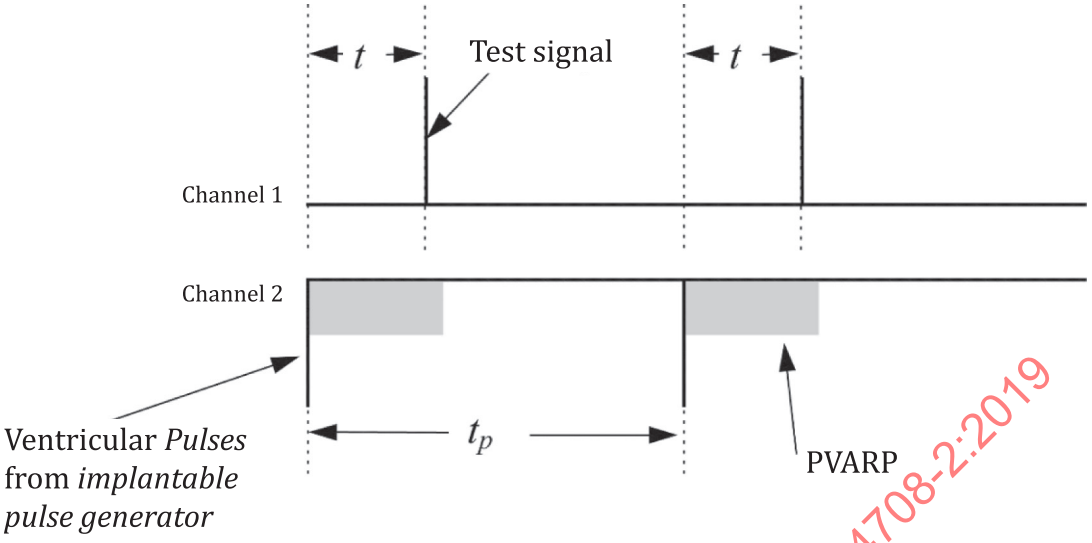


Figure 16 — Initial oscilloscope display when measuring PVARP

The delay *t* shall be slowly increased until the second *pulse* depicted in Figure 17 is displaced to the left (see Figure 17).

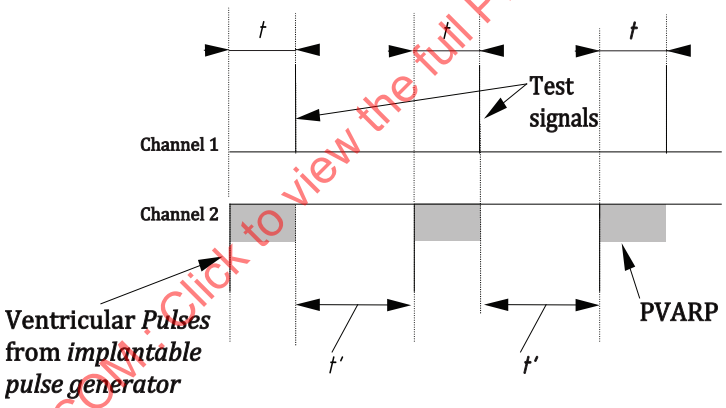


Figure 17 — Oscilloscope display when measuring PVARP

NOTE The interval between the test signal and the following ventricular *pulse* t' can be longer than the *AV interval* if the *maximum tracking rate* interval is longer than the sum of the *AV interval* and the PVARP.

Measure t, which then corresponds to the post-ventricular atrial *refractory period* (PVARP).

The result shall be expressed in milliseconds (ms).

6.1.10 Measurement of the atrial-ventricular (AV) interval after sensing (applicable only to *implantable pulse generators* with atrial sensing and ventricular pacing)

Procedure: Use an oscilloscope and a test signal generator, output impedance not greater than 1 kΩ, which provides a signal in the form defined by Figure D.3.

The *implantable pulse generator* shall be connected to 500 Ω ± 1 % load resistors (R_L) and the test equipment as shown in Figure 18. Set the *implantable pulse generator* to an atrial-tracking mode. Apply positive polarity test signals from the test signal generator through a series of feed resistors (R_F) to point C. R_F shall be 100 kΩ ± 1 %.

Adjust the repetition rate of the test signal generator so that it is at least 50 ms shorter than the *basic pulse interval* of the *implantable pulse generator*. The oscilloscope shall be adjusted so that a display similar to that depicted in Figure 19 is obtained. (The test signals and *pulses* appear as lines.)

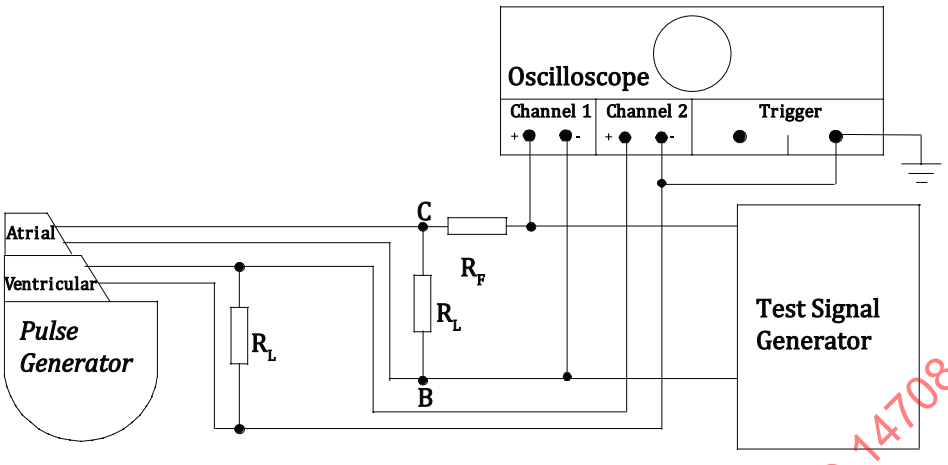


Figure 18 — *AV interval* after sensing measurement

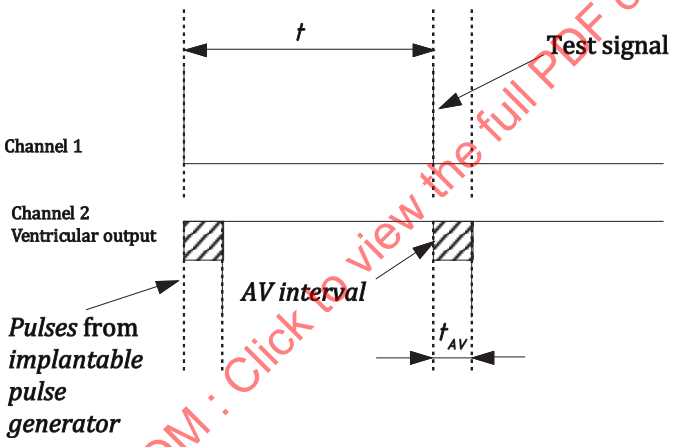


Figure 19 — Oscilloscope display when measuring the *AV interval* after sensing

The interval between the test signal and the succeeding ventricular *pulse* shall be measured. This corresponds to the *AV interval* after sensing (t_{AV}).

The results shall be expressed in milliseconds (ms).

6.2 Measurement of the *lead pacing impedance* (Z_p)

6.2.1 Measurement equipment accuracy

The manufacturer shall ensure that measurement equipment accuracy is sufficient to support the stated tolerances for the parameter being measured within this clause and stated by the manufacturer in the accompanying documentation (see 28.8).

6.2.2 Methods of measuring *lead pacing impedance*

Lead pacing impedance (Z_p) may be measured in one of two ways:

— by direct measurement from in vivo studies, or

— using the in vitro test method specified in 6.2.3.

NOTE Direct measurement in vivo of *lead pacing impedance* is the preferred method, based upon experience of manufacturers and physicians. The results are more clinically relevant.

For leads constructed to be compatible with connector cavities specified by ISO 27186, the pacing impedance for all applicable *electrode* combinations available for pacing shall be measured from in vivo studies.

The measured values of (Z_p) shall be within the range of values stated in the accompanying documentation (see 28.8).

6.2.3 In vitro method for measurement of *lead pacing impedance*

When a manufacturer chooses to report *lead pacing impedance* using the in vitro approach, the following test method shall be used.

The effects caused by the conductivity across the *electrode* myocardial interface shall be simulated by a test body comprising a beaker filled with a saline solution of 0,9 g/l ± 10 %, which represents a 1/10 concentration of the isotonic saline solution, maintained at a temperature of 37 °C ± 2 °C.

The input impedance of the oscilloscope used for testing shall be nominally ≥1 MΩ.

Procedure: Use the test body, an oscilloscope and a test signal generator, output impedance 50 Ω.

For a unipolar lead: The indifferent *electrode* of the pacing system shall be simulated by two metal plates of titanium immersed in the test body. The diameter *d* of the lower plate shall be ≥50 mm. The diameter of the upper plate shall be 0,8*d*. The separation between the plates shall be 1,2*d*. Holes cut into the upper plate shall not reduce its surface area by more than 10 %.

The lead shall be inserted into the test body so that the *electrode* tip is approximately in the centre of the beaker. The test signal generator shall be connected through a 33 µF ± 5 % series film capacitor (C_F) to the lead, the metal plates and the oscilloscope as shown in Figure 20.

Non-conductive stand-offs or spacers may be added at the circumference of the beaker, if they are kept a minimum distance of 15 mm from the *electrode* under test and they do not reduce the total cross-sectional conductive area between plates by more than 10 %. A non-conductive stiffener may be used as required, either internally or externally, to control *electrode* placement of the lead.

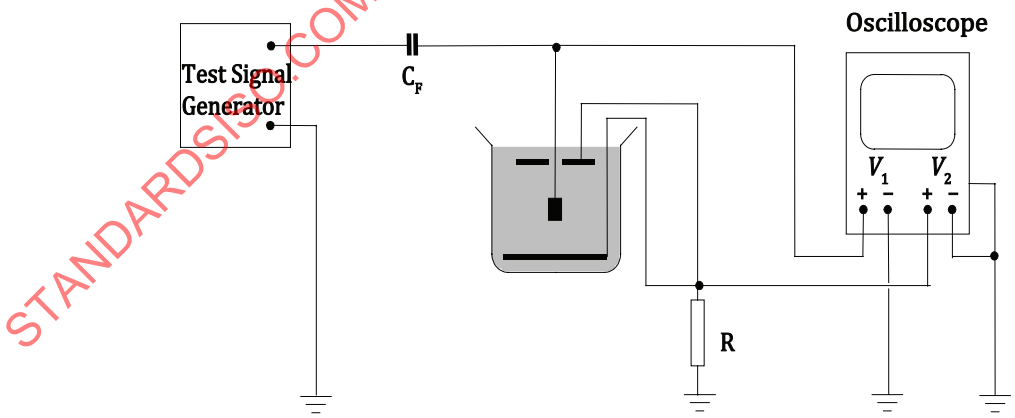


Figure 20 — Determination of the *lead pacing impedance* of a *unipolar lead*

For a bipolar lead*:* The lead shall be inserted into the test body so that the *electrodes* are at least 10 mm from any fluid boundary. The test signal generator shall be connected through a 33 µF ± 5 % series film capacitor (C_F) to the lead, the metal plates and the oscilloscope as shown in Figure 21.

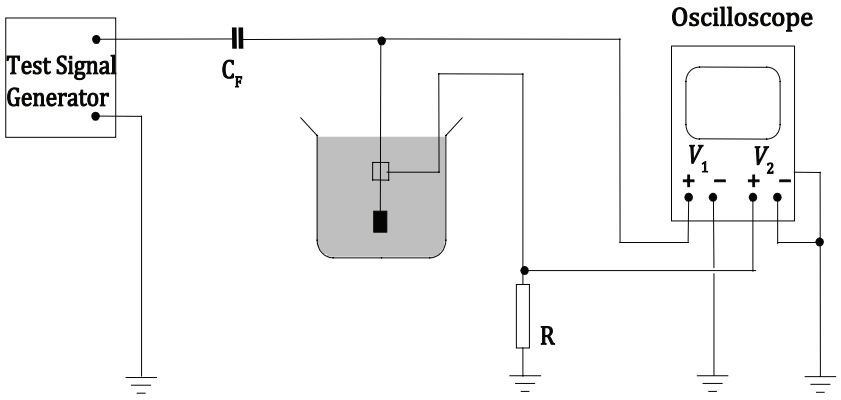


Figure 21 — Determination of the *lead pacing impedance* of a *bipolar lead*

Set the signal generator to provide negative pulses, 65 ± 5 per minute, amplitude 4 V ± 0,1 V and duration (T_p) of 0,5 ms ± 0,05 ms.

The lead current shall be determined by measuring the voltage drop across the 10 Ω ± 2 % resistor. The *lead pacing impedance* (Z_p) shall be calculated, using the mean values of voltage and current, by applying the formula:

$$Z_p = R * \frac{\int_0^{T_p} V_1 - V_2 dt}{\int_0^{T_p} V_2 dt}$$

NOTE 1 See Figure 20 and Figure 21 for definitions of V_1 and V_2.

NOTE 2 It is common practice to evaluate the above formula using the measurement functions of a digital oscilloscope.

The result shall be expressed in ohms (Ω).

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.

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.

Instead of using a description in words, the mode codes defined in Annex C may be used in the markings and accompanying documentation to designate the bradyarrhythmia pacing mode of the *implantable pulse generator*.

9.4.1 The sales packaging containing an *implantable pulse generator* shall bear the following information, as applicable.

a) The most comprehensive pacing mode available and, if different, the pacing mode as shipped.

NOTE 1 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.

b) If the device has a rate-adaptive mode, a statement that the *implantable pulse generator* is rate-adaptive, the most comprehensive rate-adaptive mode if this is not described by a) above, and the type of *sensor*(*s*) used for control (e.g. activity, minute ventilation, etc.).

c) The sensing, pacing configuration (bipolar, unipolar or automatically adjusted) as shipped.

d) The *implantable pulse generator* characteristics, measured at 37 °C ± 2 °C and 500 Ω ± 1 % load, for each input/output *terminal* as applicable:

1) the *basic rate* (in reciprocal minutes);

2) the *pulse amplitude* (in volts or milliamperes);

3) the *pulse duration* (in milliseconds);

4) the *sensitivity* (in millivolts);

5) [this indent deleted]

6) the *AV interval*, if applicable (in milliseconds).

It shall be specified if any of the above are not programmable.

e) A statement that the *implantable pulse generator* is coated, if applicable.

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

NOTE 2 Examples of standards providing connector geometries, symbols, or markings include ISO 5841-3, ISO 11318, ISO 27185, and ISO 27186.

g) Any additional information and relevant characteristics necessary to identify the *implantable pulse generator*.

Compliance is checked by inspection.

9.4.2 The sales packaging containing a lead shall bear 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 using 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 The text in 9.9 of ISO 14708-1:2014 applies.

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.

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 the following information:

a) The most comprehensive pacing mode available and the pacing mode as shipped (see note in 9.4).

b) If the device has a rate-adaptive mode, a statement that *rate modulation* is "ON" or "OFF".

c) The sensing, pacing configuration (bipolar, unipolar, automatically adjusted) as shipped.

d) The *implantable pulse generator* as-shipped characteristics, measured at 37 °C ± 2 °C and 500 Ω ± 1 % load, for each input/output *terminal* as applicable:

   1) the *basic rate* (in reciprocal minutes);

   2) [this indent deleted]

   3) the *pulse amplitude* (in volts or milliamperes);

   4) the *pulse duration* (in milliseconds);

   5) the *sensitivity* (in millivolts);

   6) the *AV interval*, if applicable (in milliseconds).

e) A statement that the *implantable pulse generator* is coated, if applicable.

f) Connector geometry shall be provided by a reference using 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.

g) Any additional information about special functions, which are active as shipped.

h) Type of *sensor* if rate response used for control (e.g. activity, minute ventilation, etc.).

Compliance is checked by inspection.

11.11 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 using 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.

a) If there is more than one input/output connector, then each connector shall be identified as follows:

   1) two-chamber *implantable pulse generators*:

      — the ventricular connector shall be marked with the symbolic designation “V”,

      — the atrial connector shall be marked with the symbolic designation “A”;

   2) three- chamber *implantable pulse generators*:

      — the left ventricular connector shall be marked with the symbolic designation “LV”,

      — the right ventricular connector shall be marked with the symbolic designation “RV”,

      — the right atrial connector shall be marked with the symbolic designation “A or RA”;

   3) a *sensor* connector shall be identified with the symbolic designation “S”, if present.

b) The most comprehensive pacing mode available as shipped (see Annex C).

If standardized connector types are used, these shall be marked with the appropriate symbol.

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 the batch number as appropriate.

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 manufacturer can be unequivocally identified. It shall be possible to read this code 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 radiopaque figures or letters.

Compliance is checked by a procedure defined by the manufacturer in the accompanying documentation (see ISO 14708-1:2014, 28.6).

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

14 Protection from unintentional 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 direct 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 *terminals* 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 case *terminals* 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).

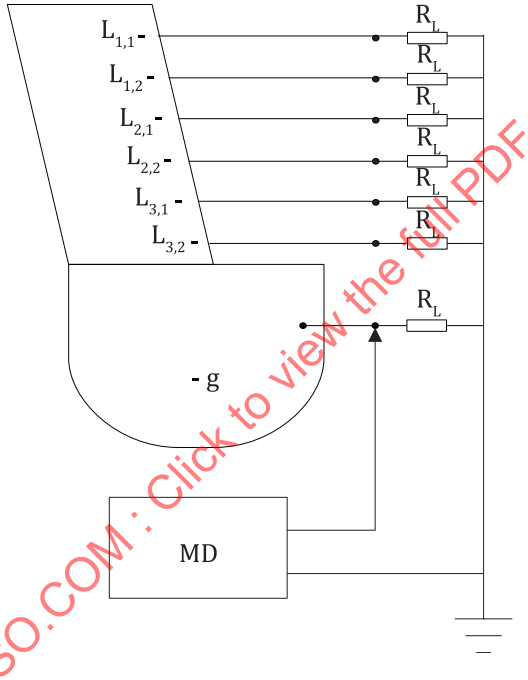
Test: Use a measuring device (MD) consisting of a d.c. voltmeter, with resolution better than 2 µV, fed through a low-pass filter with a time constant of at least 10 s.

NOTE 3 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 polypropylene capacitors. When using this type of filter, a d.c. voltmeter with an input resistance ≥40 MΩ will minimize measurement error.

The *implantable pulse generator* shall be set to the nominal settings recommended by the manufacturer (i.e. the "factory recommended settings") but with the *pulse amplitude* and *pulse duration* 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 500 Ω ± 1 % load resistors R_L (see Figure 22). For devices with fewer *terminals* than shown in Figure 22, the associated resistors R_L are not used.

NOTE 4 Figure 22 employs a nomenclature developed for modern *pacemaker* and *CRT-P* devices having more than two channels of pacing / sensing. ISO 14117:2019, Annex N provides additional details of the nomenclature.



Key

$L_{1,1}$	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

Figure 22 — Example test set-up for measurement of electrical neutrality of a *CRT-P* device

Measure the average direct voltage across each load resistor with the measuring device. 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 difference across the resistor R connected to the *pulse generator* case is less than 500 µV and less than 50 µV for any other conductive pathway, unless the manufacturer demonstrates that higher direct 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 The design of the *implantable pulse generator* shall include a feature to limit the *pulse rate* in the event of a fault within the device (runaway protection). The *pulse rate* limit shall be declared by the manufacturer in the accompanying documents [see 28.8.2 e)].

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, assuming the normal surrounding body temperature of 37 °C when implanted.

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):

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

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 The text in 19.2 of ISO 14708-1:2014 does not apply.

19.2.1 The *implantable pulse generator* shall provide at least one *power source indicator* to warn of the onset of *recommended replacement time*. The standardized *prolonged service period*, under the conditions specified below, shall be at least the minimum follow-up period of six months [see 28.19 e)].

Table 2 — Standardized *PSP* conditions

Function	*Dual-chamber* settings	Single-chamber settings
Pacing mode	DDD	VVI (SSI)
Pulse amplitude	*2,5 V*	*2,5 V*
Pulse duration	*0,4 ms*	*0,4 ms*
Basic rate	*60 min^{-1}*	*60 min^{-1}*
Percentage pacing	100 %	100 %
Pacing load	600 Ω ± 1 %	600 Ω ± 1 %
Sensor(s) status	OFF	OFF
Data storage or other diagnostic functions, if applicable to the pacing mode	OFF	OFF

NOTE 1 The *pulse* generators will not actively switch to standardized *PSP* conditions upon reaching RRT.

NOTE 2 If the manufacturer's settings do not allow turning off *sensors* and/or data storage, it is the manufacturer's responsibility to demonstrate compliance using the rest of the parameters in Table 2.

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

19.2.2 The *projected service life* shall be calculated for the maximum internal current drain conditions with the *implantable pulse generator* set as closely as possible to the values in Table 3.

The calculation shall be repeated with the *implantable pulse generator* set as closely as possible to twice the *pulse amplitude* selected for the first calculation.

Table 3 — Settings for determining the *projected service life*

Function	Setting
Pacing mode	Most comprehensive
Pulse amplitude (all channels)	2,5 V
Pulse duration	*0,4 ms*
Basic rate	*60 min^{-1}*
Percentage pacing	100 %
Pacing load	600 Ω ± 1 %
Sensor(s) status	ON

Table 3 *(continued)*

Function	Setting
Data storage or other diagnostic functions, if applicable to the pacing mode	ON

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

19.2.3 The *usable capacity* of the power source shall be calculated by adding the capacity that can be utilized until *recommended replacement time* with the *implantable pulse generator* operating under the conditions specified in 19.2.2 to the capacity that can be utilized during *prolonged service period* with the *implantable pulse generator* operating under the conditions specified by the manufacturer [see 28.19 e)].

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.

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 shall be confirmed if, after completing the test procedure, the values for the *implantable pulse generator* characteristics listed in 28.8.2 d) conform to 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.

Procedure: 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 approximately 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, and a leakage current tester, capable of applying 100 V and supplying a current of at least 2 mA.

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

Specimens shall be totally immersed in the preconditioning bath for a minimum of 10 days. Immediately prior to testing, the lead shall be rinsed in distilled or deionized water, and then wiped free of surface water.

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 at least 1 min, then relieved.

The tensile load application shall be repeated for each combination of distal end tip 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 20 mm of any exposed conductive surface, in the test bath. The test specimen(s) shall be placed in the test bath within 30 min of removal from the preconditioning bath and shall be immersed in the test bath for a minimum of 1 h before proceeding. The test specimen shall be positioned in the test bath so that the lead body is not less than 50 mm nor more than 200 mm from the reference electrode plate.

Care should be taken to ensure that the exposed conductive surfaces are electrically isolated from the saline bath during this procedure.

The insulation shall then be subjected to a 100 V ± 5 V d.c. test potential between each conductor and the reference *electrode* and between any two conductors that have an exposed conductive surface intended for contact with tissue. The test voltage shall attain the full value within 0,1 s to 5 s. The test potential shall be maintained at full value for at least 15 s before being lowered to zero.

Compliance is confirmed if:

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

b) the continuity measurements comply with the manufacturer's specifications;

c) 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 is ≤2 mA during the voltage application.

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 flexible 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 the fully assembled and shipped product. The tests shall be performed in dry conditions and at room temperature.

Test 1: Use special holding fixture (see Figure 23). 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 23).

The fixture shall be mounted in a machine that can oscillate the fixture $\theta = 90^{\circ}{}^{+0}_{-5}$ 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 ensure 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. For lead bodies with no accessible lumen, a minimal tensile load may be applied directly to the test segment, so that it conforms to the bending radius.

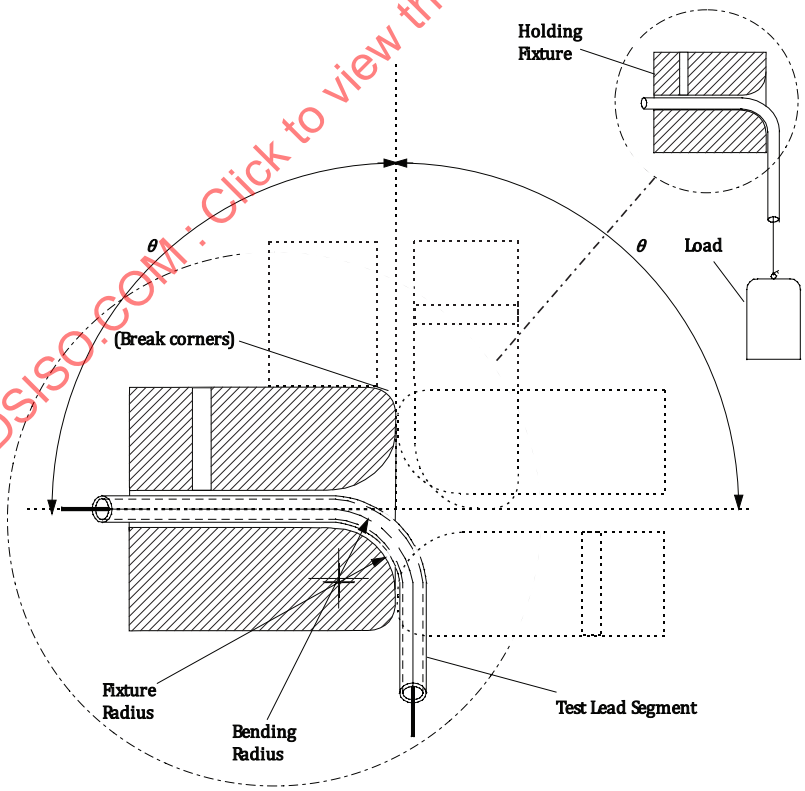


Figure 23 — Conductor flex test fixture

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.

The test shall be repeated for each unique uniform flexible part of the lead body.

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 specified in the manufacturer's performance specification.

Test 2: Use a special holding fixture (see Figure 24) 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 in accordance with 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), Figure 4 of ISO 27186:2010 (IS-4/DF-4), or in accordance with the manufacturer's specifications if another connector system is used.

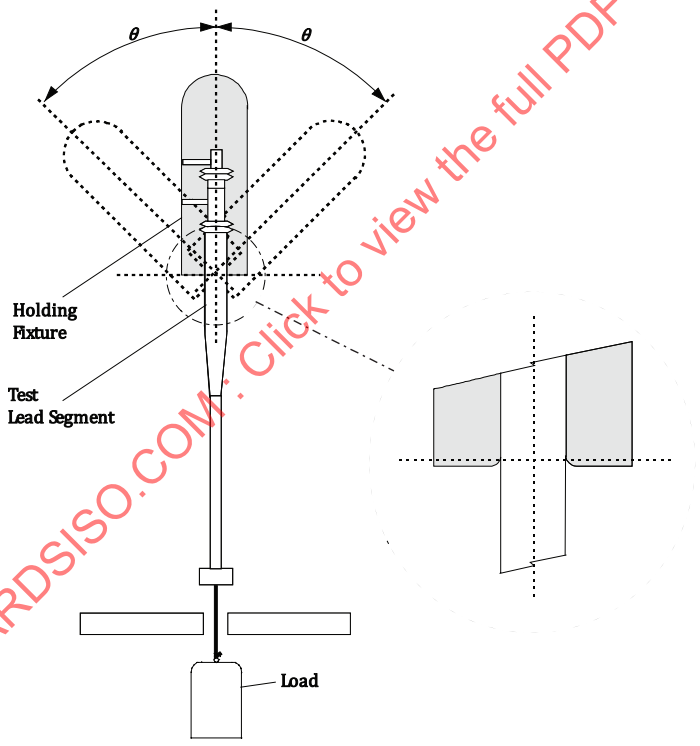


Figure 24 — Connector flex test fixture

The holding fixture shall be mounted in a machine that can rotate the fixture 45° ± 2° from the vertical (see Figure 24). 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 is 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 θ = 45° ± 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 joint in the lead body.

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 specified in the manufacturer's performance specification.

23.6 Implantable connectors, intended for use by physicians to join *implantable pulse generators* and leads, shall be identified as to type. The retention force provided by the implantable connector shall be greater than or equal to 5 N. The manufacturer shall declare (see 28.4) the intended performance as implanted, determined according to the following test.

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

Test: 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 °C ± 5 °C, for a minimum of 10 days.

After removal from the saline bath, the connector pair shall be subjected to successive straight pulls of 5 N ± 0,5 N, 7,5 N ± 0,5 N, and 10 N ± 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 values for the *implantable pulse generator*'s characteristics listed in 28.8.2 d) conform to 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 (approximately 9 g/l) with leads 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 contact details consisting of the postal address, telephone number and internet (www) address.

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 generators:

   1) general description, explanation of function, available pacing modes, and description of each available pacing mode;

Instead of using a description in words, the mode codes defined in Annex C may be used in the markings and accompanying documentation to designate the pacing mode of the implantable pulse generator.

2) description of other functions (e.g. mode switching, antitachycardia pacing features).

b) For leads:

1) type of lead (atrial/ventricular/coronary sinus, epicardial/endocardial, straight/preshaped, unipolar/bipolar, etc);

2) anchoring mechanism (passive, screw-in, etc.);

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

c) For adaptors:

1) 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, etc.), the geometry (bore depths and diameters in millimetres) of the receiving connector and the type of locking mechanism. References to applicable connector standards may be used in lieu of providing the dimensions of the receiving connector. Any markings used to identify connector *terminals* (see 13.1.1) and any symbol(s) or markings defined in the applicable connector standards shall be explained.

b) The physical characteristics, including:

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

2) the principal dimensions (in millimetres);

3) the volume of the *implantable pulse generator* (in cubic centimetres);

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 its surface area (in square centimetres).

d) The programmable parameters (see 6.1), nominal values and values as shipped (including ranges and tolerances), at 37 °C ± 2 °C and 500 Ω ± 1% load (unless otherwise stated), including as applicable:

1) ranges of *basic rate*, *test pulse rate*, and *interference pulse rate* and the equivalent *pulse intervals* (and *escape intervals*) (in reciprocal minutes and milliseconds);

2) the *pulse* shape (for example, by diagram) with the points which define the *pulse amplitude* and *pulse duration* identified (see Figure D.1 and Figure D.2);

3) the *pulse amplitude* (in volts or milliamperes);

4) the *pulse duration* (in milliseconds);

5) [this indent deleted]

6) the *sensitivity* range for both positive and negative polarities, together with a description of the waveform used (see Figure D.3);

7) the *refractory periods*, pacing, sensing, and, if applicable, PVARP (in milliseconds);

8) the *AV intervals*, pacing and sensing (in milliseconds);

9) the *maximum tracking rate* range (in reciprocal minutes).

e) Any non-programmable characteristics measured in 6.1, and the *pulse rate* limit (runaway protection) in reciprocal minutes (with tolerances), at 37 °C ± 2 °C and 500 Ω ± 1 % load (unless otherwise stated).

f) Recommended methods for determining that the implanted *pacemaker* is functioning properly.

g) Any recommendation regarding the use of lead(s) (see also ISO 14708-1:2014, 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(s), connector pin and insulation, and the shape, materials, and configuration of the *electrode(s).*

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

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

1) the length (in centimetres);

2) the geometric surface area of *electrode*(s) (in square millimetres);

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

4) the distance(s) between *electrodes* (bipolar or multipolar *endocardial leads*) (in millimetres);

5) the maximum depth of penetration of the fixation mechanism into the tissue, if applicable (in millimetres);

6) the connector geometry (lengths and diameters in millimetres), or a reference to published connector standards including any designations or markings;

7) the type of *sensor*, if applicable, with description and compatibility with the *implantable pulse generator*.

d) The *lead pacing impedance* (in ohms) (see 6.2).

e) Any recommendations regarding use with *implantable pulse generators* (see also ISO 14708-1:2014, 28.4).

Compliance is checked by inspection.

28.8.4 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 generators* and leads (in particular, see 23.6 and the compatibility with proprietary *implantable pulse generator* locking mechanisms).

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

Compliance is checked by inspection.

28.8.5 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.

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

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

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

28.13 The text in 28.13 of ISO 14708-1:2014 applies.

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. Also refer to 28.12.

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 The accompanying documentation for an *implantable pulse generator* shall include the following information, as appropriate, to allow the lifetime of the power source to be estimated.

a) The *usable capacity* of the power source (see 19.2.3).

b) Current consumption of the *implantable pulse generator,* both when pacing into 500 Ω ± 1 % loads and when inhibited, at *beginning of service* and set to the most comprehensive pacing mode available with other parameters programmed to the manufacturer's recommended settings.

c) The nominal *projected service life* of the *implantable pulse generator*, under specified conditions (see 19.2.2).

d) Information correlating the *power source indicator* with the *implantable pulse generator* characteristics (measured at a temperature of 37 °C ± 2 °C and 500 Ω ± 1%) and modes, including as applicable:

   1) the *basic rate* and *basic pulse interval* (in reciprocal minutes and in milliseconds);

   2) the *test pulse rate* and *test pulse interval* (in reciprocal minutes and in milliseconds);

   3) the *pulse duration(s)* (in milliseconds);

   4) the *pulse amplitude(s)* (in volts or milliamperes);

   5) the *sensitivity* (in millivolts);

   6) any pacing mode change.

   Changes of characteristics that can be used as *power source indicator(s)* in accordance with 19.2.1 should be identified.

e) The standardized *prolonged service period* (see 19.2.1), and the conditions under which the *prolonged service period* is derived. Also include mean *PSP* values at the manufacturer's default device settings.

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 14708-2 and aspects covered
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 14708-2 and aspects covered
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.	* retained 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
5.2 Specific principles regarding design and construction		
5.2.1 Chemical, physical and biological properties		

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-2 and aspects covered
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
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

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-2 and aspects covered
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 14708-2 and aspects covered
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	* retained
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.		
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

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-2 and aspects covered
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.)	—
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		

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-2 and aspects covered
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.	* retained
	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
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 additional 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

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-2 and aspects covered
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.	* 21.1 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.	* retained
	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 additional text
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

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-2 and aspects covered
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
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)	—

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-2 and aspects covered
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	* retained
	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.	—	—
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

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-2 and aspects covered
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
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

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-2 and aspects covered
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
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.		

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-2 and aspects covered
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.	—	—
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

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-2 and aspects covered
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:		
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 additional note and subclauses 9.4.1 through 9.4.4
	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

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-2 and aspects covered
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
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
	11.3 Requires MARKING of special purpose.	* retained

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-2 and aspects covered
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
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

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-2 and aspects covered
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)	
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

Essential principles	Clauses of ISO 14708-1	Clauses of ISO 14708-2 and aspects covered
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.)	
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	* retained
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 14708-2 and aspects covered
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 14708-2 and aspects covered
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