INTERNATIONAL STANDARD

ISO 14708-2

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Implants for surgery — Active implantable medical devices —

Part 2:
Cardiac pacemakers

Implants chirurgicaux — Dispositifs médicaux implantables actifs —

Partie 2: Stimulateurs cardiaques

Reference number
ISO 14708-2:2012(E)

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Foreword

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

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14708-2 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

This second edition cancels and replaces the first edition (ISO 14708-2:2005), which has been technically revised.

ISO 14708 consists of the following parts, under the general title *Implants for surgery — Active implantable medical devices*:

— *Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

— *Part 2: Cardiac pacemakers*

— *Part 3: Implantable neurostimulators*

— *Part 4: Implantable infusion pumps*

— *Part 5: Circulatory support devices*

— *Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)*

The following parts are under preparation:

— *Part 7: Particular requirements for cochlear implant systems*

Introduction

This part of ISO 14708 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.

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 may be adjusted non-invasively by an electronic device, known as a programmer.

This part of ISO 14708 is relevant to all parts of implantable PACEMAKERS, including all accessories. Typical examples are IMPLANTABLE PULSE GENERATORS, LEADS, ADAPTORS, programmers and the related software.

The requirements of this part of ISO 14708 supplement or modify those of ISO 14708-1, referred to as the General Standard. The requirements of this part of ISO 14708 take priority over those of ISO 14708-1.

Figures or tables that are additional to those of ISO 14708-1 are numbered starting from 101; additional annexes are lettered AA, BB, etc.

Although both this part of ISO 14708 and the Directive 90/385/EEC deal with the same products, the structure and purpose of the two documents are different. Annex AA correlates the requirements of the Directive with the subclauses of ISO 14708-1 and this part of ISO 14708. Annex BB provides reference in the other direction, from this part of ISO 14708 to the Directive. Annex CC is a rationale providing further explanation of the subclauses of this part of ISO 14708.

Annex DD describes a coding system that may be used to designate bradyarrhythmia pacing modes. Annex EE provides optional symbols that may be used to reduce the need for translation of MARKINGS and information in the accompanying documentation in multiple languages. Annex FF 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 FF are informative.

Implants for surgery — Active implantable medical devices —

Part 2: Cardiac pacemakers

1 Scope

This part of ISO 14708 specifies requirements that are applicable to those ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat bradyarrhythmias.

The tests that are specified in this part of ISO 14708 are type tests, and are to be carried out on samples of a device to show compliance.

This part of ISO 14708 is also applicable to some non-implantable parts and ACCESSORIES of the devices (see NOTE 1).

The 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 may in fact be a single device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of these parts are required to be either partially or totally implantable, but there is a need to specify some requirements of non-implantable parts and accessories if they could affect the safety or performance of the implantable device.

NOTE 2 In this part of ISO 14708, terms printed in SMALL CAPITAL LETTERS are used as defined in Clause 3. Where a defined term is used as a qualifier in another term, it is not printed in small capital letters unless the concept thus qualified is also defined.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5841-3:2000, *Implants for surgery — Cardiac pacemakers — Part 3: Low-profile connectors (IS-1) for implantable pacemakers*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 11318:2002, *Cardiac defibrillators — Connector assembly DF-1 for implantable defibrillators — Dimensions and test requirements*

ISO 14117, *Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices*

ISO 14708-1:2000, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

IEC 60068-2-47, *Environmental testing — Part 2-47: Test — Mounting of specimens for vibration, impact and similar dynamic tests*

IEC 60068-2-64, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

3 Terms and definitions

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

3.1
accessory
article which, while not being a device, is intended specifically by its 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 active 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

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

3.7
input impedance
Z_{in}
⟨implantable pulse generator⟩ electrical impedance presented at an input terminal, measured according to the procedure in 6.1.4 and taken as equal to that presented to a sensed beat

3.8
sensitivity
sensing threshold
minimum signal required to control consistently the function of the IMPLANTABLE PULSE GENERATOR

NOTE See 6.1.3.

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) may be inserted

3.16
lead conductor resistance
R_c
ohmic resistance between the ELECTRODE and the corresponding lead connector terminal

3.17
lead pacing impedance
Z_p
impedance that is formed by the ratio of a voltage PULSE to the resulting current

NOTE 1 The impedance is composed of the ELECTRODE/tissue interface and the LEAD CONDUCTOR RESISTANCE.

3.18
lead sensing impedance
Z_s
source impedance of a LEAD as seen by an IMPLANTABLE PULSE GENERATOR

3.19
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

3.20
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

3.21
beat
ordered spontaneous or paced activity of the heart

3.22
pulse
electrical output of an IMPLANTABLE PULSE GENERATOR intended to stimulate the myocardium

3.23
pulse amplitude
amplitude of the PULSE measured according to the procedure in 6.1.2

3.24
pulse duration
duration of the PULSE measured according to the procedure in 6.1.2

3.25
pulse interval
interval between equivalent points of two consecutive PULSES

NOTE See 6.1.2.

3.26
basic pulse interval
PULSE INTERVAL in absence of sensed cardiac or other electrical influence

3.27
pulse rate
number of PULSES per minute

NOTE See 6.1.2.

3.28
basic rate
PULSE RATE of an IMPLANTABLE PULSE GENERATOR, either atrial or ventricular, unmodified by sensed cardiac or other electrical influence

3.29
atrioventricular interval
AV interval
delay between an atrial PULSE or the sensing of an atrial depolarization and the subsequent ventricular PULSE or the sensing of a ventricular depolarization

NOTE See 6.1.8.

3.30
escape interval
time elapsing between the sensing of a spontaneous BEAT and the succeeding non-triggered PULSE of an IMPLANTABLE PULSE GENERATOR

NOTE See 6.1.5.

3.31
hysteresis
characteristic of an IMPLANTABLE PULSE GENERATOR defined by the difference between the ESCAPE INTERVAL and the BASIC PULSE INTERVAL

NOTE The ESCAPE INTERVAL is normally longer than the BASIC PULSE INTERVAL; this is “positive” hysteresis.

3.32
interference pulse rate
PULSE RATE with which the IMPLANTABLE PULSE GENERATOR responds when it senses electrical activity that it recognizes as interference

3.33
maximum tracking rate
maximum PULSE RATE at which the IMPLANTABLE PULSE GENERATOR will respond on a 1:1 basis to a triggering signal

3.34
rate modulation
altering of the PULSE interval as a function of a control parameter other than a sensed BEAT

3.35
refractory period of the device
period of time during which atrial or ventricular pacemaker timing is unaffected by sensed spontaneous depolarizations, although sensing is not completely disabled

3.36
test pulse interval
PULSE INTERVAL of an IMPLANTABLE PULSE GENERATOR when directly influenced by a testing device

3.37
test pulse rate
PULSE RATE of an IMPLANTABLE PULSE GENERATOR when directly influenced by a testing device

3.38
beginning of service
BOS
time at which an individual IMPLANTABLE PULSE GENERATOR is first released by the manufacturer as fit for placing on the market

3.39
end of service
EOS
time at which the PROLONGED SERVICE PERIOD has elapsed and no further pacing function is specified nor can be expected

3.40
projected service life
period from the implantation of the IMPLANTABLE PULSE GENERATOR to the RECOMMENDED REPLACEMENT TIME under defined conditions

3.41
prolonged service period
PSP
period during which the IMPLANTABLE PULSE GENERATOR continues to function as defined by the manufacturer to prolong basic bradyarrhythmia pacing beyond the RECOMMENDED REPLACEMENT TIME

3.42
power source indicator
means of indicating the electrical status of the power source during the implantable pulse generator's service life

3.42
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 This indicates entry into the PROLONGED SERVICE PERIOD.

3.44
stoichïometric capacity
capacity as defined by the active materials contents in the power source

3.45
use-before date
date after which the manufacturer recommends that the ACTIVE IMPLANTABLE MEDICAL DEVICE should not be placed in a patient

3.46
usable capacity
portion of the STOICHÏOMETRIC CAPACITY of the power source that can be utilized by the IMPLANTABLE PULSE GENERATOR UNTIL END OF SERVICE is reached

4 Symbols and abbreviated terms

This clause of the General Standard applies.

Additional NOTE.

NOTE See informative Annex EE for optional symbols for use in expressing information so as to reduce the need for multiple languages on packaging and in manuals.

5 General requirements for non-implantable parts

This clause of the General Standard applies.

6 Measurements of implantable pulse generator and lead characteristics

6.1 Measurement of implantable pulse generator characteristics

6.1.1 General considerations

This subclause addresses only the acuity of the measurement system. The accuracy tolerances described below are not intended to reflect performance of the implantable pulse generator under test. 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].

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.

The overall measurement accuracy for each test shall be within the limits given in Table 101.

Table 101 — Overall measurement accuracy limits

Measurement	Accuracy
PULSE AMPLITUDE (6.1.2)	± 5 %
EFFECTIVE PACING CAPACITANCE (6.1.2)	± 15 %
PULSE DURATION (6.1.2)	± 5 % or ± 20 μs, whichever is greater
PULSE INTERVAL/TEST PULSE INTERVAL (6.1.2)	± 1 ms
PULSE RATE/TEST PULSE RATE (6.1.2)	± 2 %
SENSITIVITY (6.1.3)	± 10 % or ± 20 μV, whichever is greater
INPUT IMPEDANCE (6.1.4)	± 25 %
ESCAPE INTERVAL (6.1.5)	± 10 ms
REFRACTORY PERIOD (6.1.6, 6.1.7, and 6.1.9)	± 10 ms
AV INTERVAL (6.1.8 and 6.1.10)	± 5 ms

NOTE Manufacturers have the option of testing to tighter accuracy limits.

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

6.1.2 Measurement of pulse amplitude, pulse duration, pulse interval, pulse rate, and effective pacing capacitance

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 101. The oscilloscope shall be adjusted to display one pulse in full.

The PULSE DURATION (D) shall be measured between 10 % of the leading edge amplitude (10 % A_{max}) and 90 % of the trailing edge amplitude (see Figure FF.101).

The PULSE AMPLITUDE (A) shall be measured as peak pulse amplitude (A_{max}) between the baseline and the voltage sample taken at maximum amplitude (see Figure FF.102). Another voltage sample, V_s, is taken after t_2 = 0,3 ms to calculate effective pacing capacitance. For measurement of effective pacing capacitance, the pace duration is programmed to 0,3 ms.

The EFFECTIVE PACING CAPACITANCE (C) shall be calculated using the measured voltage samples A_{max} and A_s (see Figure FF.102), according to the equation:

$$C = -(t_2 - t_1) / R_L * 1/ \ln[A_s/A_{max}]$$

where ln designates the natural logarithm.

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.

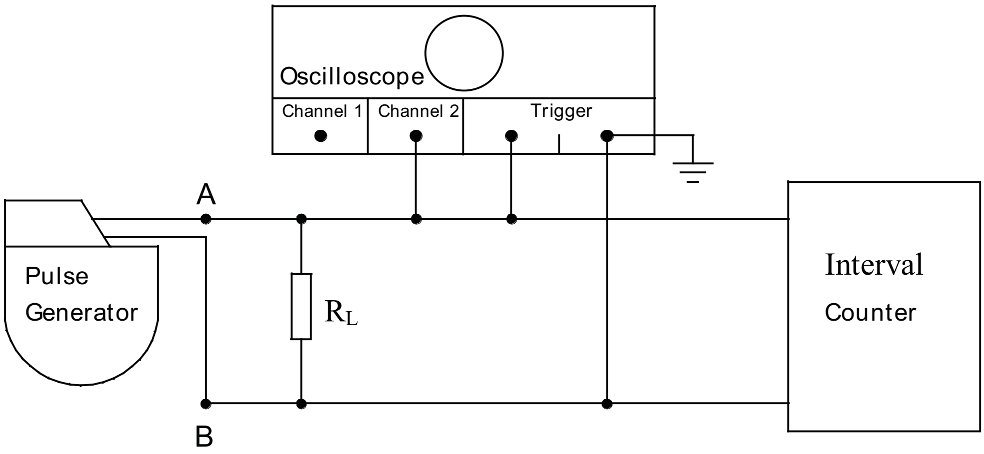


Figure 101 — Measurement of pulse amplitude, pulse duration, pulse interval, pulse rate, leading edge fall time, and effective pacing capacitance

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, except for the measurement of the EFFECTIVE PACING CAPACITANCE.

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});

— EFFECTIVE PACING CAPACITANCE: microFarad (µF).

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 (sensing threshold) (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 FF.103.

The IMPLANTABLE PULSE GENERATOR shall be connected to a 500 Ω ± 1 % load resistor (R_L) and the test equipment as shown in Figure 102. 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 200.

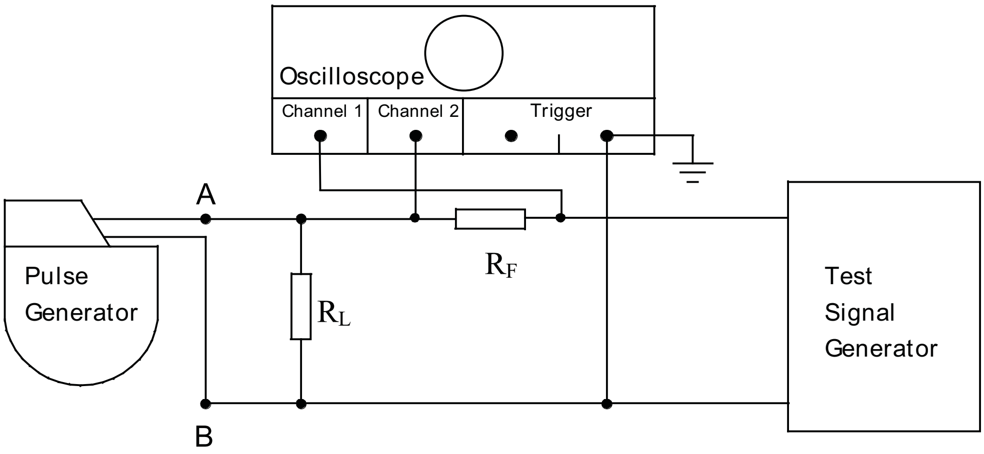


Figure 102 — Sensitivity measurement

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})

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 FF.103.

The IMPLANTABLE PULSE GENERATOR shall be connected to 500 Ω ± 1 % load resistors (R_L) and the test equipment as shown in Figure 103. Apply test signals of either polarity from the test signal generator through series feed resistors R_1 (potentiometer) and R_F (fixed value) to point A. Potentiometer R_1 shall be chosen to have a maximum resistance greater than, but of the same order of magnitude as, the expected input impedance of the implantable pulse generator (e.g. 10 kΩ, 100 kΩ, etc.). R_F shall be 100 kΩ ± 1 %. 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 pulse generator. The test signal amplitude (A_T) shall be adjusted to zero, and the oscilloscope shall be adjusted to display several PULSES.

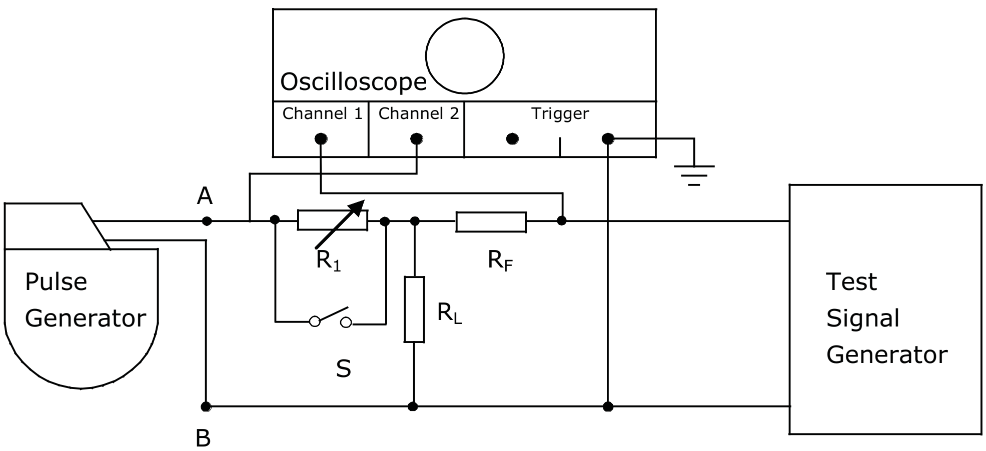


Figure 103 — Input impedance measurement

The switch, S, shall be closed, bypassing variable resistor (potentiometer) R_1, and the test signal amplitude adjusted from zero up to that value at which the implantable pulse generator consistently either just inhibits or triggers, whichever is appropriate.

The test signal amplitude shall be measured and designated V_1.

Increase the test signal amplitude to twice the value of V_1.

The switch, S, shall be opened and the variable resistor (potentiometer) R_1 shall be adjusted until the implantable pulse generator again just consistently either inhibits or triggers, as before.

The value of the variable resistor (potentiometer) R_1 shall be measured and designated Z.

The INPUT IMPEDANCE, Z_{in}, of the implantable pulse generator shall be calculated according to the equation:

$$Z_{in} = \frac{R_S * Z}{R_S - Z}$$

Where R_S is the channel 2 input impedance of the oscilloscope.

The result shall be expressed in kilo-ohms (kΩ).

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 104. Apply the test signal generator through a 100 kΩ ± 1 % feed resistor (R_F) to point A.

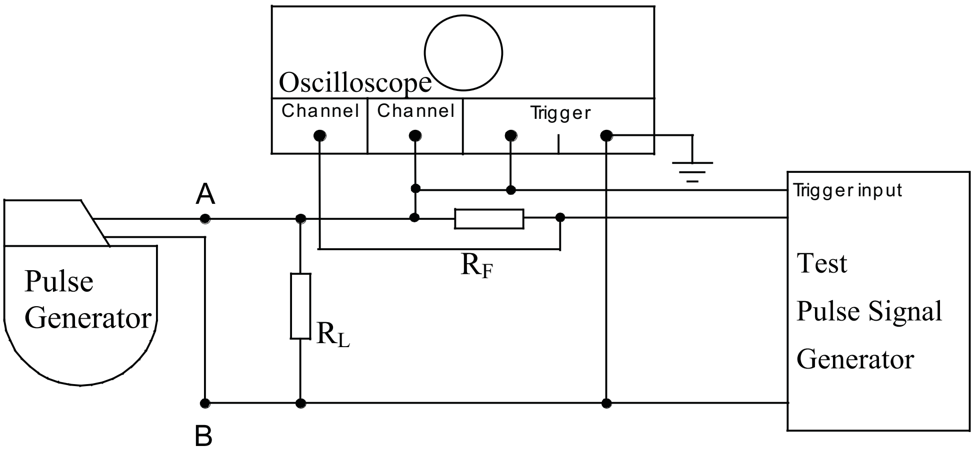


Figure 104 — Escape interval measurement

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 105 is obtained (the test signals and the PULSES both appear as lines).

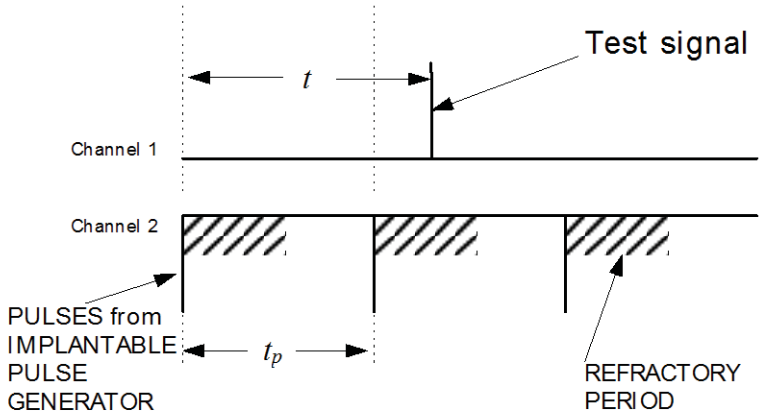


Figure 105 — Initial oscilloscope display, when measuring the escape interval

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 106. If a triggered (synchronous) implantable pulse generator is being tested, then the display will be similar to that shown in Figure 107.

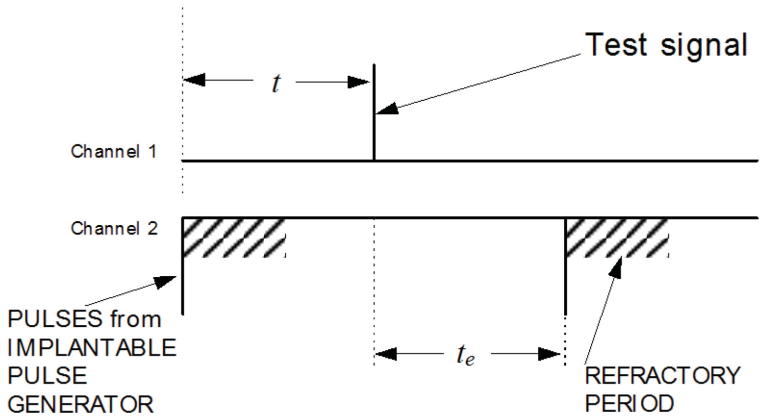


Figure 106 — Measurement of escape interval (t_e) in inhibited mode

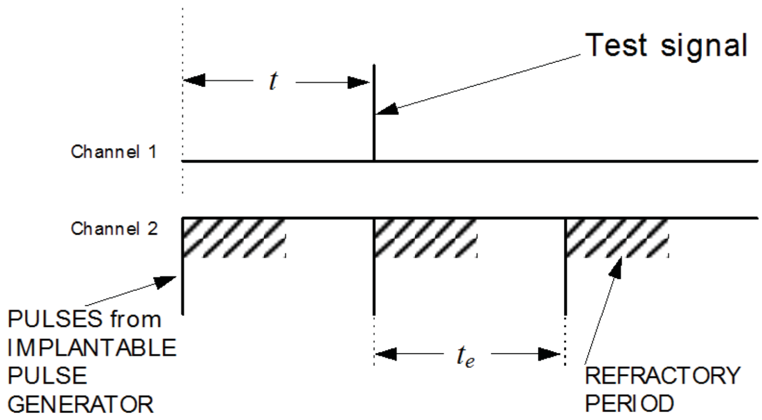


Figure 107 — Measurement of escape interval (t_e) in triggered (synchronized) mode

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 108. Apply the test signal through the series feed resistor (R_F) to point A. R_F shall be 100 kΩ ± 1 %.

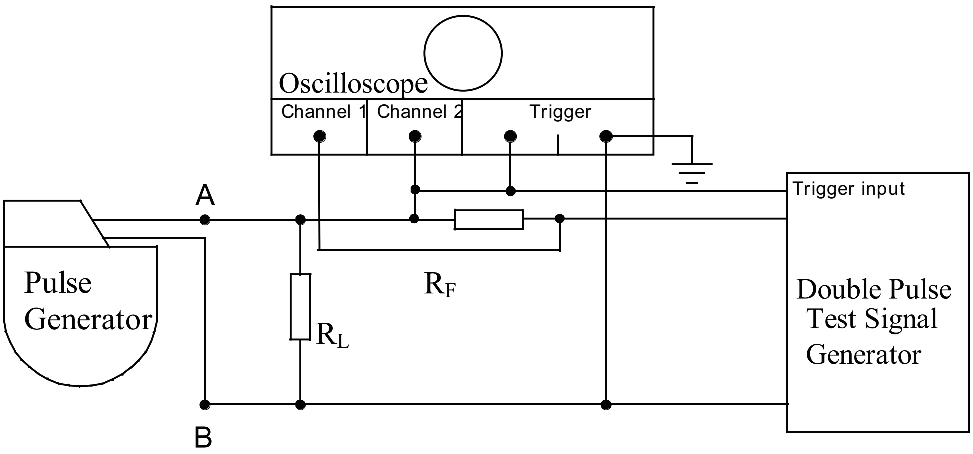


Figure 108 — Refractory period measurement

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 109).

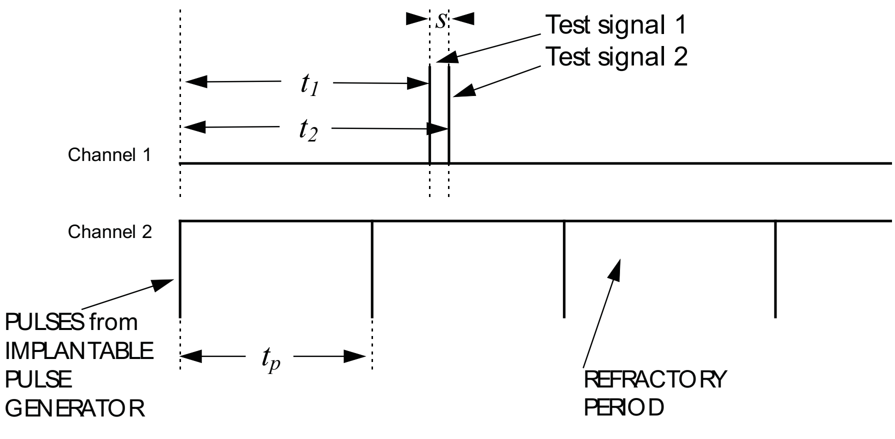


Figure 109 — Initial oscilloscope displays when measuring sensing and pacing refractory period

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 110. Then, keeping t_1 constant, t_2 shall be increased until the test signal 2 in Figure 110 is delayed as shown in Figure 111. The second pulse in Figure 111 is displaced from test signal 2 by the ESCAPE INTERVAL (t_e).

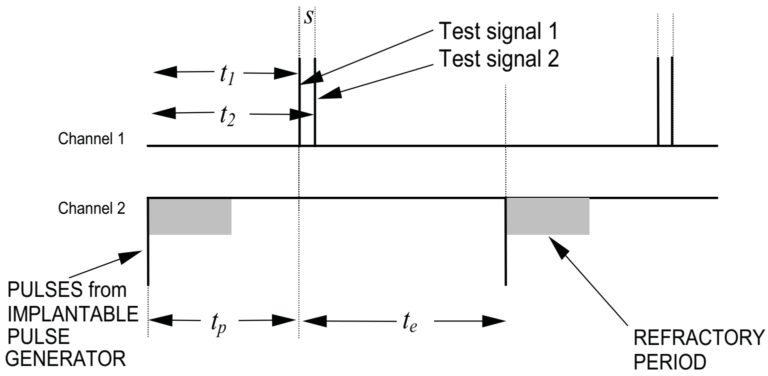


Figure 110 — Measurement of sensing refractory period in inhibited mode – A

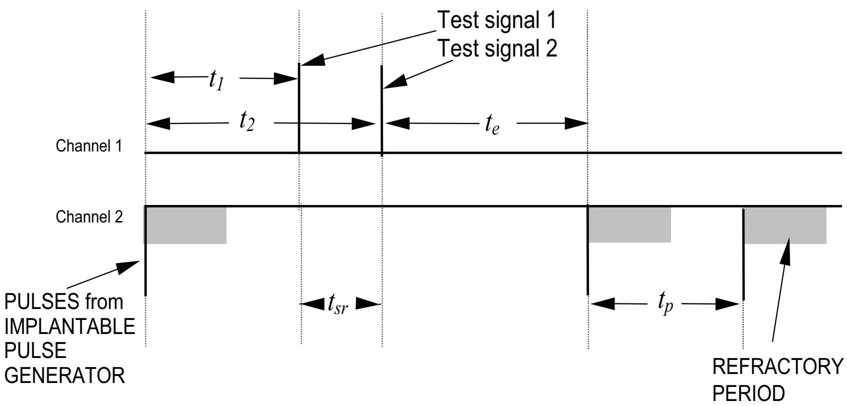


Figure 111 — Measurement of sensing refractory period in inhibited mode – B

In the case of a triggered implantable pulse generator, sensing test signal 1 triggers the implantable pulse generator (see Figure 112). Then, keeping t_1 constant, t_2 shall be increased until the third PULSE in Figure 112 occurs simultaneously with test signal 2, as shown in Figure 113.

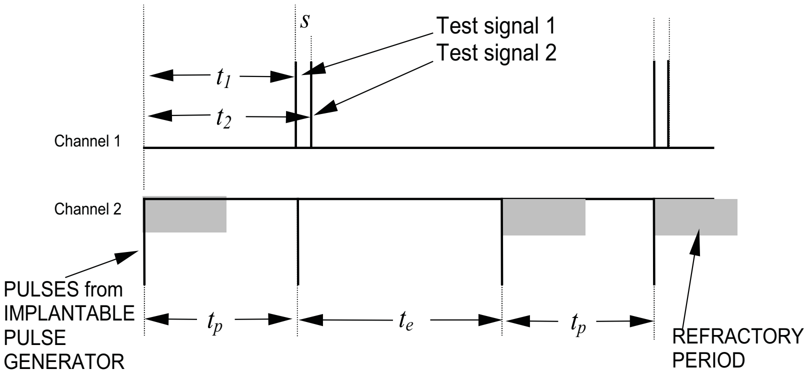


Figure 112 — Measurement of sensing refractory period in triggered (synchronous) mode – A

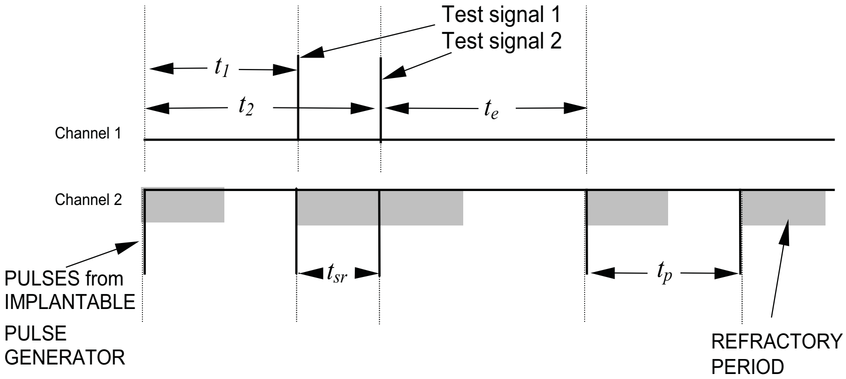


Figure 113 — Measurement of sensing refractory period in triggered (synchronous) mode – B

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 6.1.4 and Figure 104.

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 105 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 107 is displaced to the right (see Figure 114). The third pulse will be displaced from the test signal by the ESCAPE INTERVAL (t_e).

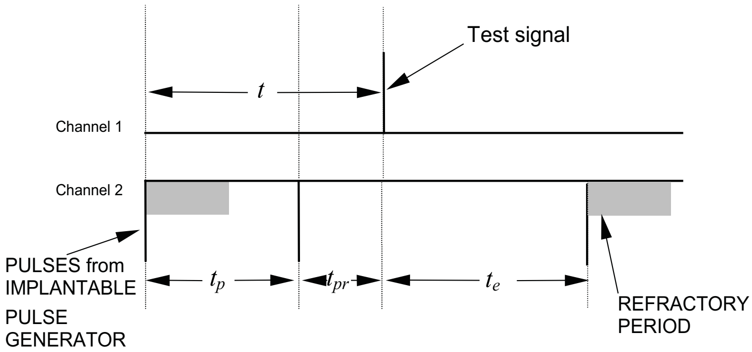


Figure 114 — Measurement of pacing refractory period in inhibited mode

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 115 is obtained (the pulses appear as lines).

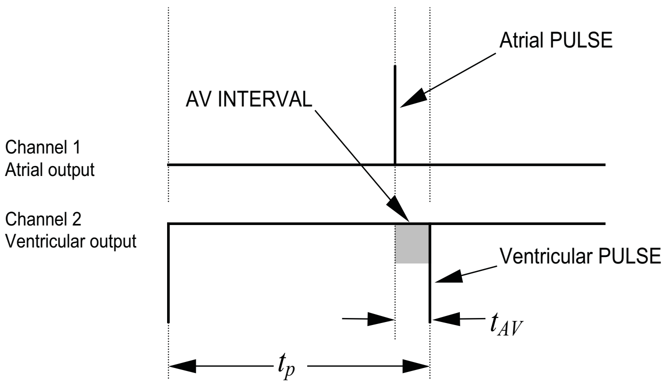


Figure 115 — Oscilloscope display when measuring AV interval

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 116. 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.

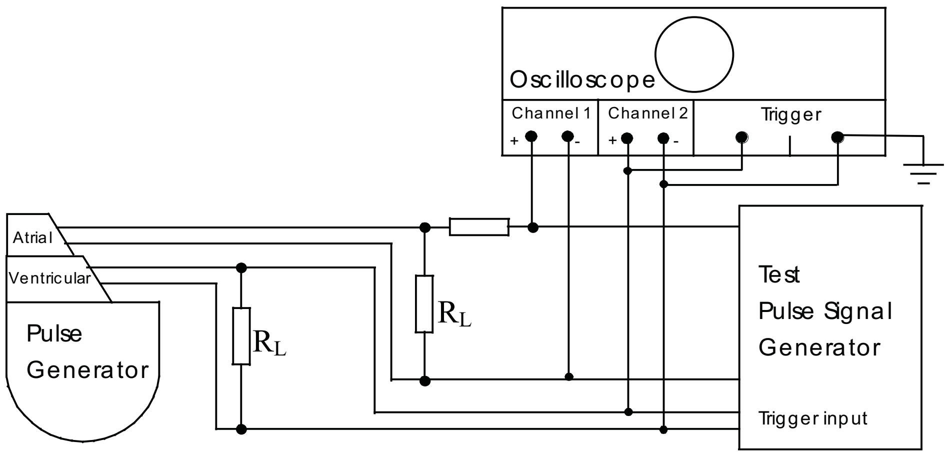


Figure 116 — Post-ventricular atrial refractory period (PVARP) measurement

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 117 is obtained.

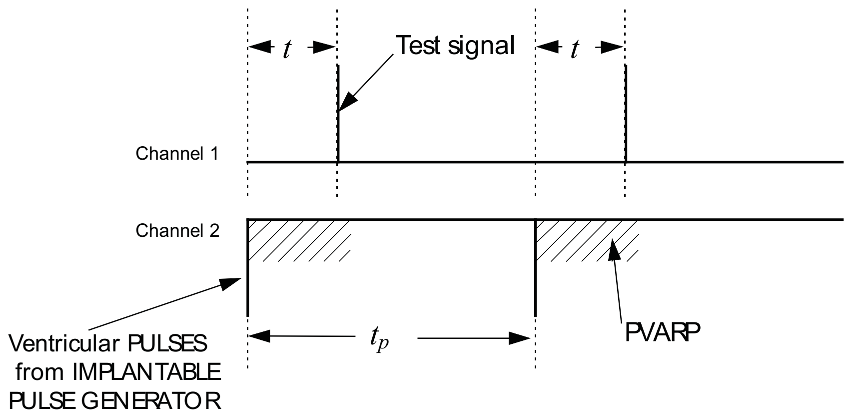


Figure 117 — Initial oscilloscope display when measuring PVARP

The delay t shall be slowly increased until the second pulse depicted in Figure 117 is displaced to the left (see Figure 118).

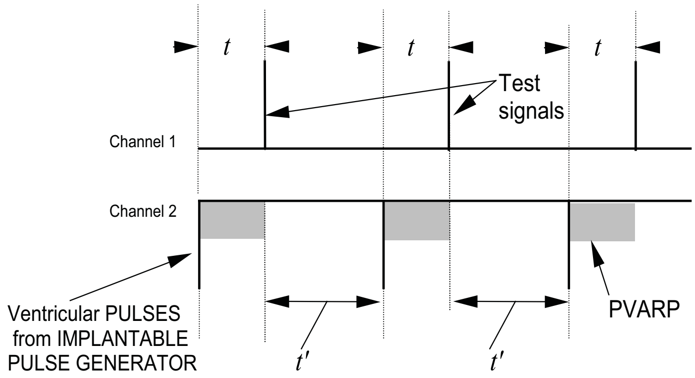


Figure 118 — Oscilloscope display when measuring PVARP

NOTE The interval between the test signal and the following ventricular pulse t' may 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 FF.103.

The IMPLANTABLE PULSE GENERATOR shall be connected to 500 Ω ± 1 % load resistors (R_L) and the test equipment as shown in Figure 119. 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 120 is obtained. (The test signals and pulses appear as lines.)

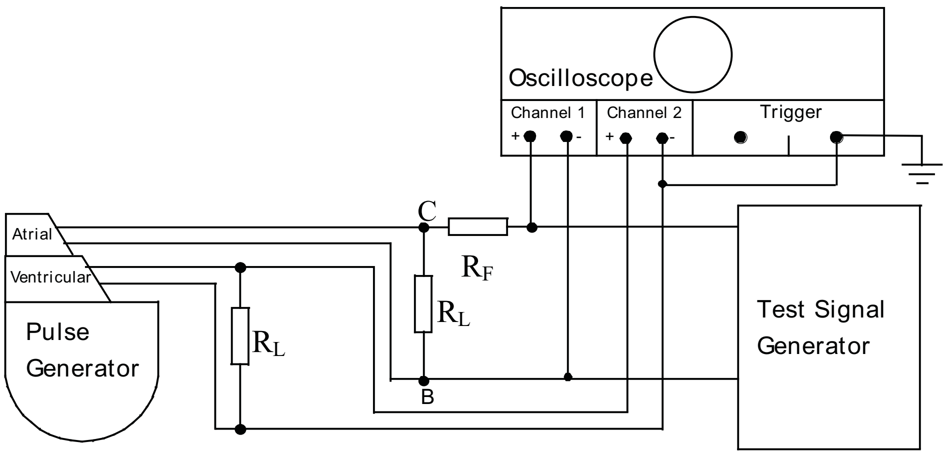


Figure 119 — AV interval after sensing measurement

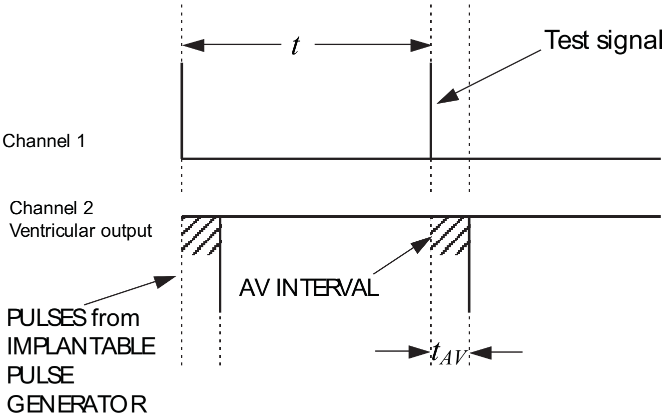


Figure 120 — Oscilloscope display when measuring the AV interval after sensing

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)

The values of the lead pacing impedance (Z_p) measured in accordance with the method described in this subclause shall be within the range of values stated in the accompanying documentation (see 28.8).

The effects caused by the conductivity across the electrode myocardial interface shall be simulated where required 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.

The overall measurement accuracy shall be within ±5 %. This requirement addresses the acuity of the measurement system. The accuracy tolerance is not intended to reflect the performance of the lead under test.

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 0,8d. The separation between the plates shall be 1,2d. 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 121.

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.

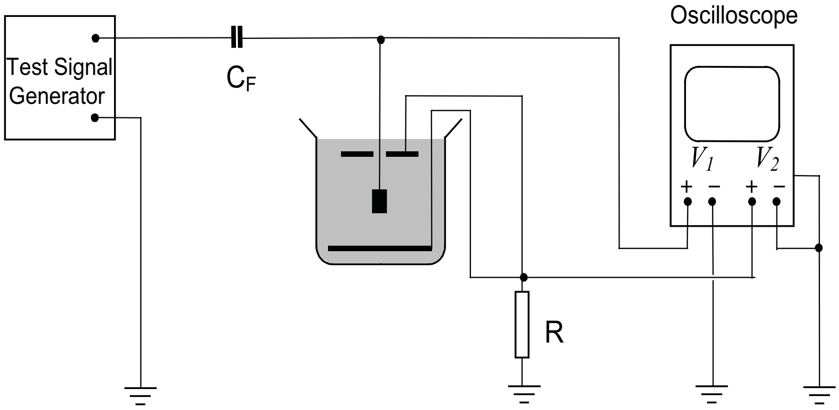


Figure 121 — Determination of the lead pacing impedance of a unipolar lead

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 122.

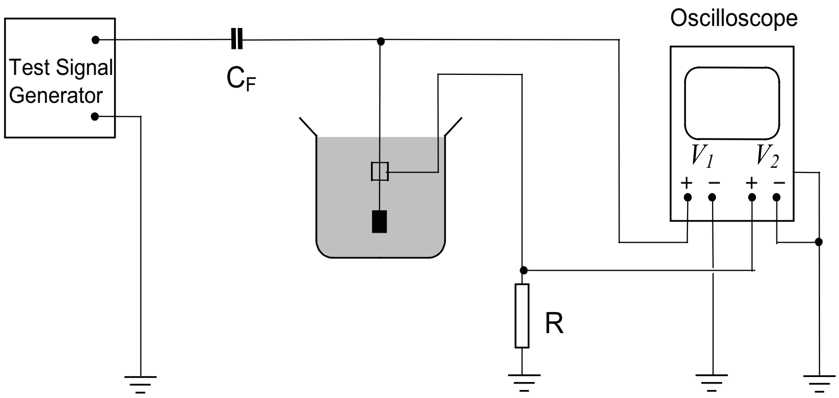


Figure 122 — Determination of the lead pacing impedance of a bipolar lead

Set the signal generator to provide negative pulses, 65 ± 5 per minute, amplitude 4 V ± 0,1 V and duration 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 See Figure 121 and Figure 122 for definitions of V_1 and V_2.

The result shall be expressed in ohms (Ω).

7 General arrangement of the packaging

This clause of the General Standard applies.

8 General markings for active implantable medical devices

This clause of the General Standard applies.

9 Markings on the sales packaging

This clause of the General Standard applies except as follows.

9.4

Additional note and subclauses

NOTE Instead of using a description in words, the mode codes defined in Annex DD 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
- as shipped, if different.

b) In case of a rate adaptive device, a statement that the implantable pulse generator is rate responsive, the most comprehensive rate adaptive mode if this is not described by a) above, and the type of sensor used for control.

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) the REFRACTORY PERIOD (in milliseconds);
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 by symbols or markings defined in published standards or, if different, the bore depths and diameters in millimetres.

g) Any additional information and relevant characteristics necessary to identify the IMPLANTABLE PULSE GENERATOR (e.g. MODE SWITCHING).

Compliance shall be confirmed by inspection.

9.4.2 The SALES PACKAGING containing a LEAD shall bear the following information:

a) Type of lead (atrial/ventricular/coronary sinus, epicardial/endocardial, straight/preshaped, unipolar/bipolar, etc.).

b) Anchoring mechanism (passive, screw-in, etc.)

c) Physical dimensions, including:

1) the length (in centimetres);

2) for a transvenous lead, the INSERTION DIAMETER (in millimetres) and the size of the appropriate introducer (in French);

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

d) Any additional information and relevant characteristics necessary to identify the LEAD (STEROID ELUTING, LOW POLARIZATION, etc.).

Compliance shall be confirmed by inspection.

9.7

Replacement:

The SALES PACKAGING containing an IMPLANTABLE PULSE GENERATOR, LEAD, ADAPTOR, or other sterile part shall bear the USE-BEFORE DATE presented in the sequence: year, month, and, if appropriate, day; and expressed as numerals as specified in ISO 8601.

Compliance shall be confirmed by inspection.

10 Construction of the sales packaging

This clause of the General Standard applies except as follows.

10.3

Additional note:

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.

11 Markings on the sterile pack

This clause of the General Standard applies except as follows:

Additional subclauses:

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 a rate adaptive device, 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) the maximum tracking rate (in reciprocal minutes);

   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 or uncoated.

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

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

h) Type of sensor if rate response is present.

Compliance shall be confirmed by inspection.

11.11 The STERILE PACK containing a LEAD shall bear the following information:

a) Type of lead (atrial/ventricular/coronary sinus, epicardial/endocardial, straight/preshaped, unipolar/bipolar, etc.).

b) Physical dimensions, including:

   1) the length (in centimetres);

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

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

c) Anchoring mechanism (passive, screw-in, etc.).

d) Any additional information and relevant characteristics necessary to identify the lead (steroid eluting, low polarization, etc.).

Compliance shall be confirmed by inspection.

12 Construction of the non-reusable pack

This clause of the General Standard applies.

13 Markings on the active implantable medical device

This clause of the General Standard applies except as follows:

13.1

Delete and replace with additional subclauses:

13.1.1 Each implantable pulse generator shall be permanently marked with the name or trademark of the manufacturer, the model designation of the device, the serial number, and the following particulars, as applicable.

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

   1) two-chamber implantable pulse generators:

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

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

   2) three- or four-chamber implantable pulse generators:

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

      — the left atrial terminal shall be marked with the symbolic designation “LA”,

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

      — the right atrial terminal shall be marked with the symbolic designation “RA”;

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

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

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

Compliance shall be confirmed 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.

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

Compliance shall be confirmed by inspection.

13.3

Replacement:

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.

NOTE 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 14708-1:2000, 28.6).

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

This clause of the General Standard applies except as follows:

14.2

Replacement:

When the ACTIVE IMPLANTABLE MEDICAL DEVICE is used as intended by the manufacturer, parts of the device intended to be in contact with body fluids shall not cause any unacceptable release of particulate matter.

Test: The ACTIVE IMPLANTABLE MEDICAL DEVICE shall be removed aseptically from the NON-REUSABLE PACK. The implantable part shall be immersed in a bath of saline solution, approximately 9 g/l and suitable for injection, in a neutral glass container. The volume of the saline, in millilitres, shall be 5 ± 0,5 times the numerical value of the surface area of the implantable part expressed in cm^2. The container shall be covered with a glass lid and maintained at 37 °C ± 2 °C for between 8 h and 18 h, the bath being agitated throughout the period. A reference sample of similar volume shall be prepared from the same batch of saline, maintained and agitated in a similar way to the specimen. A sample of liquid from the specimen bath and from the reference bath shall be compared using apparatus suitable for measuring particle size, such as apparatus operating on the light blockage principal [see method 2.9.19 of the European Pharmacopoeia, 3rd edition, 1977, (Council of Europe)].

Compliance shall be confirmed if the excess average count of particles from the specimen compared to the reference sample does not exceed 100 particles per millilitre greater than 5,0 µm and does not exceed 5 particles per millilitre greater than 25 µm.

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

This clause of the General Standard applies.

16 Protection from harm to the patient caused by electricity

This clause of the General Standard applies except as follows:

16.2

Replacement:

Except for its intended function, an IMPLANTABLE PULSE GENERATOR, when in use, shall be electrically neutral. No d.c. leakage 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.

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 As an example, this low-pass filter (LP-filter) can be implemented by a four-element low-pass RC filter with the elements built from 100 kΩ resistors and 10 µF metalized polypropylene capacitors. Then the input resistance of the d.c. voltmeter should be ≥ 40 MΩ.

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 125).

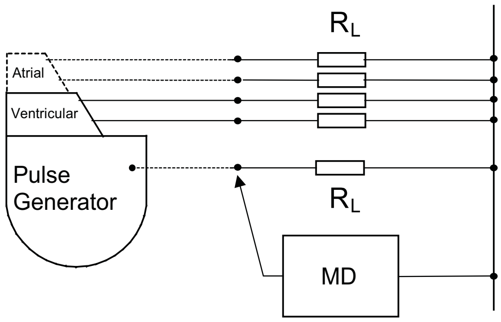


Figure 125 — Test set-up for measurement of electrical neutrality

Measure the average direct voltage across each load resistor with the measuring device. Steady-state conditions shall be reached before the measurement is made.

Compliance shall be 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.

16.3

Not applicable

Additional subclause:

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

This clause of the General Standard applies except as follows:

17.1

No outer surface of an implantable part of the active implantable medical device shall be greater than 2 °C above the normal surrounding body temperature of 37 °C. Temperature increases from 2 °C up to 4 °C are allowed for not more than 30 min when implanted, and when the ACTIVE IMPLANTABLE MEDICAL DEVICE is in normal operation.

For other implanted parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE, the General Standard applies.

NOTE The single-fault condition for temperature rise is covered by the requirement in ISO 14708-1:2000, 19.3.

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

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

This clause of the General Standard applies.

19 Protection from unintended effects caused by the device

This clause of the General Standard applies except as follows.

19.2

Replacement and additional subclauses.

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 102 — 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 102.

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

19.2.1 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 103.

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 103 — 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 $\Omega \pm 1$ %
Sensor(s) status	ON
Data storage or other diagnostic functions, if applicable to the pacing mode	ON

Compliance shall be confirmed by an assessment of the manufacturer's documentation.

19.2.2 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 19.2.1) 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 shall be confirmed by an assessment of the manufacturer's documentation.

20 Protection of the device from damage caused by external defibrillators

Replacement:

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

This clause of the General Standard applies except as follows:

21.2

Replacement:

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

This clause of the General Standard applies.

23 Protection of the active implantable medical device from mechanical forces

This clause of the General Standard applies except as follows.

23.2

Replacement:

The IMPLANTABLE PULSE GENERATOR shall be constructed to withstand the mechanical forces that may occur during normal conditions of use, including the time prior to implant.

Test: The implantable pulse generator, mounted in accordance with the requirements and guidance given in IEC 60068-2-47, shall withstand a random vibration test in accordance with IEC 60068-2-64, Test Fh, under the following conditions:

a) frequency range: 5 Hz to 500 Hz;

b) acceleration spectral density: 0,7 $(m/s^2)^2$/Hz;

c) shape of acceleration spectral density curve: flat horizontal, 5 Hz to 500 Hz;

d) duration of testing: 30 min in each of three mutually perpendicular axes.

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

Replacement:

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.

NOTE 1 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.

NOTE 2 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 shall be 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.

23.5

Replacement:

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 127). 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 127).

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.

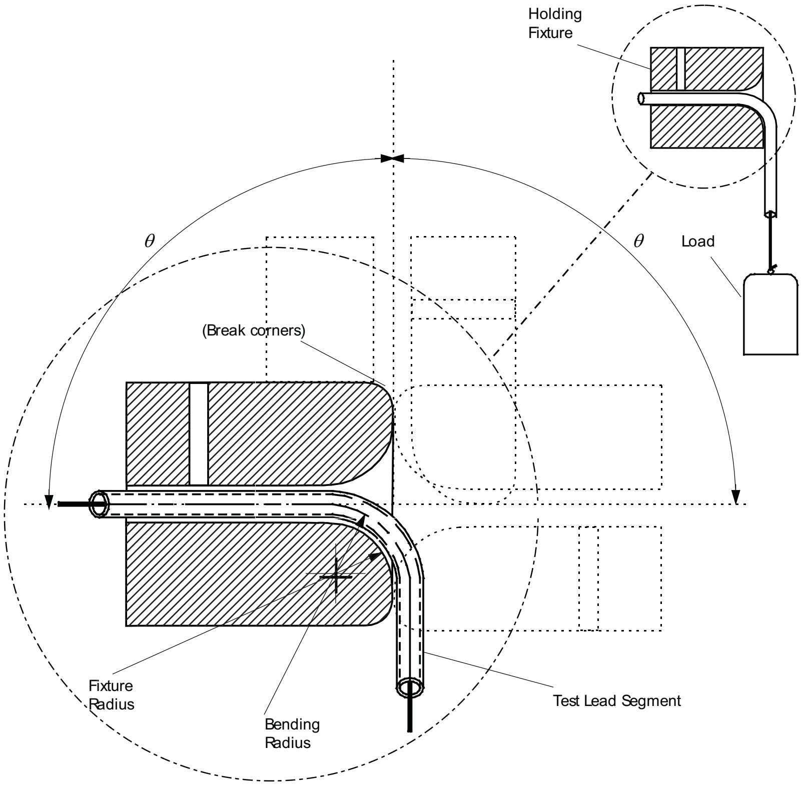


Figure 127 — Conductor flex test fixture

The fixture shall be oscillated through an angle $\theta = 90°\ ^{0}_{-5}$ 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 shall be 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 128) similar in form to the intended pulse generator connector header. The holding fixture shall be made of rigid material, with the corners that may 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 5841-3:2000 (IS-1), or Figure 4 of ISO 11318:2002 (DF-1), or in accordance with the manufacturer's specifications if another connector system is used.

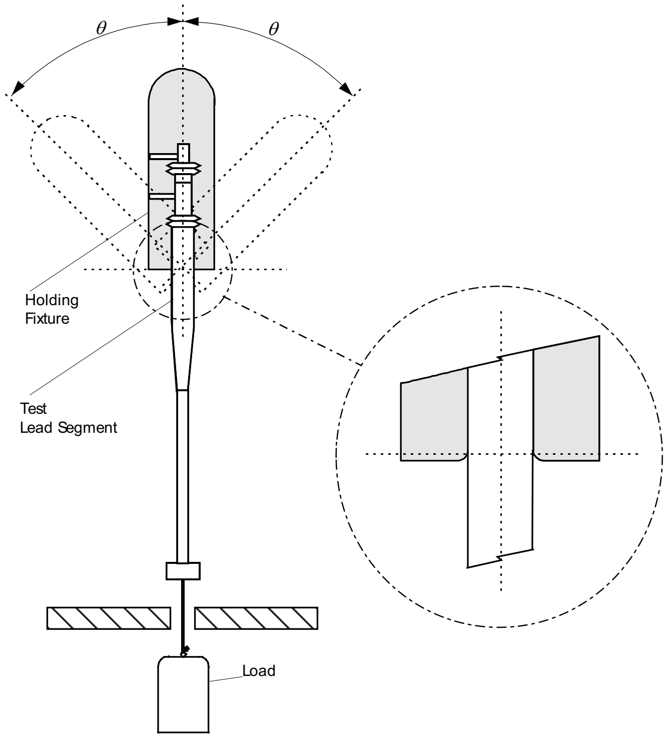


Figure 128 — Connector flex test fixture

The holding fixture shall be mounted in a machine that can rotate the fixture 45° ± 2° from the vertical (see Figure 128). 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 shall be 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

Replacement:

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 (see 28.4).

Addition subclause:

23.7 The implantable pulse generator shall be constructed so that minor shocks caused by manhandling during the implant procedure do not damage the device.

Test: The IMPLANTABLE PULSE GENERATOR shall withstand the mechanical shock test in accordance with IEC 60068-2-27, Test Ea, under the following conditions.

a) Shock shape: half sine or haversine.

b) Severity: peak acceleration: 5 000 m/s^2 (500 g).

c) Duration of shock: 1 ms.

d) Direction and number of shocks: one shock in each direction along three mutually perpendicular axes (total of six shocks).

Compliance shall be 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

This clause of the General Standard applies.

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

Replacement:

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

Test procedure: The test shall be conducted in saline solution with leads (50 Ω·cm resistivity) 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 shall be 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).

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

This clause of the General Standard applies.

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

Replacement:

Testing and compliance shall be in accordance with ISO 14117.

28 Accompanying documentation

This clause of the General Standard applies except as follows.

28.1

Replacement:

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 shall be confirmed by inspection.

28.8

Additional subclauses:

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;

NOTE Instead of using a description in words, the mode codes defined in Annex DD 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. elution of steroid, etc.).

c) For ADAPTORS:

   1) the configuration (unipolar, etc.).

Compliance shall be confirmed 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 FF.101 and Figure FF.102);

   3) the PULSE AMPLITUDE (in volts or milliamperes);

   4) the PULSE DURATION (in milliseconds);

   5) the INPUT IMPEDANCE (in kilo-ohms);

   6) the SENSITIVITY range for both positive and negative polarities, together with a description of the waveform used (see Figure FF.103);

   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 14708-1:2000, 28.4).

Compliance shall be confirmed 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 appropriate introducer (in French);

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 14708-1:2000, 28.4).

Compliance shall be confirmed 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 shall be confirmed 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 shall be confirmed by inspection.

28.19

Replacement:

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 19.2.2).

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 19.2.1).

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.

NOTE Changes of characteristics that can be used as POWER SOURCE INDICATOR(S) in accordance with 19.2 should be identified.

e) The standardized PROLONGED SERVICE PERIOD (see 19.2), and the conditions under which the prolonged service period is derived. Also include mean PSP values at the manufacturer's default device settings.

Compliance shall be confirmed by inspection.

Annex AA
(informative)

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

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–2 AND ASPECTS COVERED
3 General principles		
3.1 The implants should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will 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 may 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.	8.1 Requires warnings to be prominent.	* retained
3.2 The solutions adopted by the manufacturer for the design and construction of the implants should conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order: (a) eliminate or reduce risks as far as possible (inherently safe design and construction); (b) where appropriate take adequate protection measures including alarms, if necessary, in relation to risks that cannot be eliminated; (c) inform users of the residual risks due to any shortcomings of the protection measures adopted.	(This principle is fundamental to all aspects of an active implantable medical device addressed by this International Standard. This approach is particularly applicable to the requirements in Clauses 14, 19 and 21.)	* retained
3.3 The implants should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in 3.1 [of ISO/TR 14283], as specified by the manufacturer.	10.4 Requires accompanying documentation to be physically associated with the device.	* retained 6.1 Measurement of implantable pulse generator characteristics 6.2 Measurement of the electrical parameters of the lead

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–2 AND ASPECTS COVERED
3.4 The characteristics and performances referred to in 3.1, 3.2 and 3.3 [of ISO/TR 14283] should not be adversely affected to such a degree that the clinical conditions and safety of the patients 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.	19.2 Requires power source depletion indicator.	19.2 replacement 19.2.1 projected service life 19.2.2 usable capacity
	19.3 Defines methodology to ensure single-fault conditions are not a hazard.	* retained * retained
	23.1 Defines drop test for non-implantable parts.	
	23.2 Defines vibration test for patient-carried parts.	23.2 test changed
	23.3 Sets test of tensile strength (leads, etc.).	23.3 specific test given
	23.4 Requires strain relief (leads, etc.).	* retained
	23.5 Requires fatigue resistance (leads, etc.).	23.5 specific test given
	23.6 Requires connections to be reliable.	23.6 test changed
	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
3.5 The implants should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage 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
	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
3.6 Any undesirable side-effect should constitute an acceptable risk when weighed against the performances intended.	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

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–2 AND ASPECTS COVERED
4 Specific principles regarding design and construction		
4.1 Chemical, physical and biological properties 4.1.1 The implants should be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Clause 3 on "General principles". Particular attention should be paid to:		
4.1.1 (a) the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,	14.3 Requires investigation of biocompatibility.	* retained
4.1.1 (b) the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the implant.	14.3 Requires investigation of biocompatibility.	* retained
4.1.2. The implants should be designed, manufactured and packed 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 the patients, taking account of the intended purpose of the product. Particular attention should be paid to the tissues exposed and to the duration and frequency of exposure.	14.2 Defines test for particulate contamination. 14.3 Requires investigation of biocompatibility.	* retained * retained
4.1.3 The implants should 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 should 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 Demonstrates compatibility with medicinal substances	* not applicable to pacemakers
4.1.4 Where an implant incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in 2.7 [of ISO/TR 14283] and which is liable to act upon the body with an action ancillary to that of the implant, the safety, quality and usefulness of the substance should be verified, taking account of the intended purpose of the implant.	14.4 Specifies requirements for quality and safety of incorporated medicinal substances.	* not applicable to pacemakers
4.1.5 The implants should be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the implant.	25 Requires implanted parts to withstand pressure changes.	* retained
4.1.6 Implants should be designed and manufactured in such a way as to reduce, as much as possible, the risks posed by the unintentional ingress of substances into the implant taking into account the implant and the nature of the environment in which it is intended to be used.	25 Requires implanted parts to withstand pressure changes.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–2 AND ASPECTS COVERED
4.1.7 Implants should be designed and manufactured in such a way as to minimize the risks to the patient or user by the systems, including software.	19.3 Requires a design analysis and defines the methodology for the analysis.	* retained
4.2 Infection and microbial contamination		
4.2.1 The implants and manufacturing processes should be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design should allow easy handling and, where necessary, minimize contamination of the implant by the patient or vice versa during use.	14.1 Requires device to be supplied sterile.	* retained
4.2.2 Tissues of animal origin should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Information on the geographical origin of the animals should be retained by the manufacturer. Processing, reservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal security. In particular, safety with regard to viruses and other transferable agents should be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	(Not applicable to active implantable medical devices)	* Idem[1]
4.2.3 Implants delivered in a sterile state should be designed, manufactured and packed in protective packaging which provides a microbial barrier to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions stipulated by the manufacturer, until the protective packaging is damaged or opened.	7.1 Requires device to be supplied in non-reusable packs.	* 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 humidity-proof.	* retained
	11.7 Requires contents of sterile pack to be declared or visible.	* retained
	11.9 Requires sterile pack to be marked with the instructions for opening it.	* retained
	12.1 Applies ISO 11607 (all parts) 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
4.2.4 Implants delivered in a sterile state should have been manufactured and sterilized by an appropriate, validated method.	14.1 Confirmed if device sterilized by a validated process.	* retained
4.2.5 Implants intended to be sterilized should 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

[1] The same as previously given or mentioned.

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–2 AND ASPECTS COVERED
4.2.6 Packaging systems for non-sterile implants should keep the product without deterioration at the level of cleanliness stipulated and, if the implants are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should 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.)	* Idem
4.2.7 The packaging and/or label of the implant should distinguish between identical or similar products sold in both sterile and non-sterile conditions.	(Not applicable because subclause requires that implantable parts of an active implantable medical device be provided sterile.)	* Idem
4.3 Construction and environmental properties		
4.3.1 If the implant is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performances of the devices. Any restrictions on use should be indicated on the label or in the instructions for use.	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.	* test changed
	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
4.3.2 Implants should be designed and manufactured in such a way as to remove or minimize as far as possible:		
4.3.2 (a) the risk of injury, in connection with their physical features, including the volume/ pressure ratio, dimensional and where appropriate ergonomic features,	15.1 Sets requirement for surfaces of non-implantable parts.	* retained
	15.2 Requires implantable parts to have appropriate physical form.	* retained
4.3.2 (b) the risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, 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.	* test changed
	24 Defines electrostatic discharge test for non-implantable parts.	* retained
	25 Requires implanted parts to be proof against pressure changes.	* retained
	26.2 Requires implantable devices to be undamaged by extremes of temperature in transit.	* retained
	27 Defines requirement for electromagnetic immunity.	* 27.1 replacement

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–2 AND ASPECTS COVERED
4.3.2 (c) the risks of reciprocal interference with other devices (such as defibrillators or high-frequency surgical equipment) normally used in the investigations or for the treatment given,	20.1 Requires defibrillation protection of external ECG leads.	* retained
	20.2 Defines test to prove defibrillation protection of implanted device.	* retained
	21 Requires protection against diathermy, etc.	* added test
	22 Requires protection against diagnostic ultrasound.	* retained
	28.12 Requirement for warning notices.	* retained
	28.13 Requires warning about monitoring devices 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
4.3.2 (d) the risks which may arise where maintenance and calibration are impossible, including (if applicable): - excessive increase of leakage currents, - ageing of the materials used, - excess heat generated by the implant, - decreased accuracy of any measuring or control mechanism.	17 Requires investigation of local heating caused by faulty implanted device.	* retained
	19.1 Requires a design analysis.	* retained
	19.2 Requires a power source depletion indicator.	* additional requirements
4.3.3 Implants should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal conditions and fault conditions. By risks during “normal conditions and fault conditions” are meant those risks which have been determined by a risk analysis. Particular attention should be paid to implants whose intended use includes exposure to flammable substances or to substances which could cause combustion.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* retained
4.4 Implants with a measuring function		
4.4.1 Implants with a measuring function should be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the implant. The limits of accuracy should be indicated by the manufacturer.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* retained
4.4.1.1 The measurements, monitoring and display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the implant.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* retained
4.4.1.2 When an implant or its accessories bear instructions required for the operation of the implant or indicate operating or adjustment parameters, by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	13.4 Requirement about visual indicators.	* retained
	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–2 AND ASPECTS COVERED
4.4.2 The measurements made by implants with a measuring function should be expressed in units conforming to the provisions of the ISO 31 series.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* retained
4.5 Protection against radiation		
4.5.1 General Implants should be designed and manufactured in such a way that exposure of patients, users and other persons to radiation be reduced as far as possible compatible with the intended purpose, while not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	(See more particular requirements below)	
4.5.2 Intended radiation	(Not applicable to active implantable medical devices)	
4.5.2.1 Where implants are designed to emit hazardous levels of radiation necessary for a specific medical purpose, the benefit of which is considered to outweigh the risks inherent in the emission, the implants should be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.		
4.5.2.2 Where implants are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.		
4.5.3 Unintended radiation Implants should 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 possible.	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
4.5.4 Instructions The operating instructions for implants emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in use.	(Not applicable to active implantable medical devices)	* Idem
4.6 Ionizing radiation	(Not applicable to active implantable medical devices)	* Idem
4.6.1 Implants intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled, taking into account the intended use.		

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–2 AND ASPECTS COVERED
4.6.2 Implants emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose while minimizing radiation exposure of the patient and user. 4.6.3 Implants emitting ionizing radiation intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose.		
4.7 Principles for implants connected to, or equipped with, an energy source		
4.7.1 Implants incorporating electronic programmable systems should be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of risks (of the system) as determined by a risk analysis for the particular device/system, appropriate means should be adopted to eliminate or reduce as far as possible their risk.	19.3 Requires a design analysis and defines the methodology for the analysis.	* retained
4.7.2 Implants where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.	19.2 Requires a power source depletion indicator.	* 19.2 replacement * 19.2.1 projected service life * 19.2.2 usable capacity
4.7.3 Implants should bear – if practical and appropriate – a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of implant); it should be possible to read this code, if necessary, without the need for a surgical operation.	13.3 Requirement stated and expanded. 28.6 Requires an explanation of the code to be provided with the device.	* retained * retained
4.7.4 For implants where the safety of the patients depends on an external power supply, the external power supply should include an alarm system to signal any power failure.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* retained
4.7.5 External devices intended to monitor one or more clinical parameters from an implant should be equipped with appropriate alarm systems to alert the user to situations which could lead to death or severe deterioration of the patient's state of health.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* retained
4.7.6 Protection against electrical risks		
4.7.6.1 Implants should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal conditions and fault conditions, provided the implants are installed correctly. By risks during "normal conditions and fault conditions" are meant those risks which have been determined by a risk analysis for the particular device(s).	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device. 16.1 Sets safety limits for leakage currents from non-implantable parts.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–2 AND ASPECTS COVERED
4.7.6.2 Active implants should be designed and manufactured in such a way as to minimize the risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices.	16.2 Sets safety limits for leakage currents from implantable parts.	* requirement replaced
	16.3 Requires testing of electrical insulation (leads, etc.).	* not applicable
	17 Requires investigation of local heating caused by implanted device.	* 16.4 additional requirement
	26.1 Requires protection from heat from powered non-implantable parts.	* retained
4.7.7 Protection against mechanical risks		
4.7.7.1 Implants should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* retained
4.7.7.2 Implants should be designed and manufactured in such a way as to minimize the risks arising from vibration generated by the implants, taking account of technical progress and of the means available for limiting vibration, 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
4.7.7.3 Implants should be designed and manufactured in such a way as to minimize 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
4.7.7.4 Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* retained
4.7.8 Protection against the risks posed to the patient by energy supplies or substances		
4.7.8.1 Implants should be designed and constructed in such a way that the proper functioning of the programming and control systems, including software, do not jeopardize the safety of the patient and of the user, taking account of the intended use.	19.3 Requires a design analysis and defines the methodology for the analysis.	* retained
4.7.8.2 Implants designed to supply energy or administer medicinal substances should be designed and constructed in such a way that the flow rate can be set and maintained accurately enough to minimize the risk to the patient.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* retained
4.7.8.3 Implants designed to administer medicinal products should incorporate suitable means to prevent and/or indicate any inadequacies in the flow rate that could pose a danger.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–2 AND ASPECTS COVERED
4.7.8.4 Implants designed to supply energy or administer medicinal substances should be designed and constructed so that suitable means are incorporated to minimize the risk of accidental release of dangerous levels of energy or the medicinal substance.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* retained
4.8 Information supplied by the manufacturer		
4.8.1 Each implant should be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the implant safely should be set out on the implant itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information should be set out in the leaflet supplied with one or more implants. Instructions for use should be included in the packaging for every implant.	10.4 Requires accompanying documentation to be physically associated with the device.	* retained
	12.3 Requirement that any markings be indelible.	* retained
4.8.2 Where appropriate, this information should take the form of symbols. Any symbol or identification colour used should conform to International Standards. Where no standards exist, the symbols should be described in the documentation supplied with the implant.	4. Allows use of symbols, abbreviations and identification colours.	* retained and additional note
4.8.3 The label should bear the following particulars:	5 Invokes the labelling requirements of IEC 60601-1 for non-implantable parts.	* retained
4.8.3 (a) the name or trade name and address of the manufacturer;	9.2 Requires name and address of manufacturer on the sales pack.	* retained
	11.1 Requires identification of manufacturer on sterile pack.	* retained
4.8.3 (b) the details strictly necessary for the user to identify the implant and the contents of the packaging;	9.3 Requires description of device and model designation on sales pack.	* retained
	9.4 Requires marking with characteristics sufficient to identify device.	* additional requirements
	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

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–2 AND ASPECTS COVERED
4.8.3 (c) where appropriate, an indication that the contents of the packaging are sterile (e.g. “STERILE”);	9.5 Requires statement that the package has been sterilized.	* retained
	11.2 Requires declaration that the package and its contents have been sterilized.	* retained
	11.3 Requires display of the “sterile” symbol	* retained
4.8.3 (d) where appropriate, the batch code or the serial number, preceded by an appropriate identification (e.g. “LOT” or “SN” respectively);	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
4.8.3 (e) where appropriate, an indication of the date by which the implant should be used;	9.7 Requires marking of a “use-before date”.	* additional requirements
	11.5 Requires marking of a “use-before date”.	* retained
4.8.3 (f) an indication that the implant is for single use;	28.18 Requires and defines warning notice about reuse of the device.	* retained
4.8.3 (g) where appropriate, any indication of special purpose (e.g. “custom-made device” or “exclusively for clinical investigations”);	9.12 Requires marking of special purpose.	* retained
	11.10 Requires marking of special purpose.	* additional requirements
4.8.3 (h) any special storage and/or handling conditions;	9.11 Requires marking with information on any exceptional environmental or handling constraints.	* retained
4.8.3 (i) any special operating instructions;	(For implantable parts of an active implantable medical device, all operating instructions are provided in the accompanying documentation.)	
4.8.3 (j) any warnings or precautions to be taken;	(In the general case, warnings and precautions except for those dealing with special handling conditions [see 4.8.2 (h)] should be described in the accompanying documentation instead of on the label.)	
4.8.3 (k) for active implants, month and year of manufacture;	9.6 Requires marking and defines format.	* retained
	11.4 Requires marking and defines format.	* retained
4.8.3 (l) if applicable, method of sterilization.	11.2 Requires method of sterilization to be marked.	* retained
4.8.4 If the intended purpose of the implant is not obvious to the user, the manufacturer should clearly state it on the label and in the instructions for use.	9.10 Requires supplementary description if 9.3 and 9.4 are inadequate to declare purpose.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–2 AND ASPECTS COVERED
4.8.5 Wherever reasonable and practicable, the implants and detachable components should be identified, where appropriate in terms of serial numbers or batches, to allow all appropriate actions to be taken following the discovery of any potential risk posed by the implants and detachable components.	8.2 Requires implanted parts to be traceable.	* retained
	13.1 Requires identification of manufacturer, model, etc. on device.	* replaced
	13.2 Requires that if different power sources might have been used, the actual source used shall be identified.	* retained
4.8.6 Where appropriate, the instructions for use should contain the following particulars:		
4.8.6 (a) the details referred to in 4.8.3, with the exception of (d), (e) and (k);	28.1 Requires name and address of manufacturer.	* replaced
	28.3 Requires description of the device.	* retained
	28.16 Requires statement that implantable parts of a device have been sterilized.	* retained
	28.18 Requires and defines warning notice about reuse of the device.	* retained
	28.21 Requires marking with information on any exceptional handling constraints.	* retained
4.8.6 (b) the performances referred to in 3.3 [of ISO/TR 14283] and any undesirable side-effects;	28.8 Requires information to be provided about the intended use and characteristics, and about possible side effects.	* additional requirements
4.8.6 (c) if the implant should be used with, or connected to, other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct implants or equipment to be used in order to obtain a safe combination;	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
	28.9 Requires information to allow selection of device, accessories and related devices.	* retained
4.8.6 (d) all the information needed to verify whether the implant is properly used and can operate correctly and safely, plus, where appropriate, information allowing the lifetime of the energy source to be established;	28.10 Requires definitive instructions for use to be provided.	* retained
4.8.6 (e) where appropriate, information to avoid specified risks in connection with implantation of the implant;	28.11 Requires that information be provided on avoiding hazards during implantation.	* retained
4.8.6 (f) information regarding the risks of reciprocal interference posed by the presence of the implant during specific investigations or treatment;	28.12 Requires warning notices on hazards arising from interaction.	* retained
4.8.6 (g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;	28.17 Requires precautions for dealing with opened or damaged sterile pack.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–2 AND ASPECTS COVERED
4.8.6 (h) where implants are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization should be such that, if correctly followed, the implant will still comply with the principles in Clause 3 [of ISO/TR 14283];	28.17 Requires instructions for sterilizing accessories that are provided non-sterile.	* retained
4.8.6 (i) details of any further treatment or handling needed before the implant can be used (sterilization, final assembly, etc.);	(Not applicable because subclause requires that active implantable medical devices be provided sterile.)	* Idem
4.8.6 (j) in the case of implants emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation. The instructions for use should also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:	(Not applicable to active implantable medical devices.)	* Idem
4.8.6 (k) precautions to be taken in the event of changes in the performance of the implant;	28.19 Requires information allowing the lifetime of the energy source to be estimated.	* detailed requirement provided
	28.20 Requires information on precautions to be taken to prevent adverse effects from changes in device performance.	* retained
4.8.6 (l) precautions to be taken as regards exposure to, in reasonably foreseeable environmental conditions, e.g. to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;	28.22 Requires warnings on precautions to avoid adverse environments.	* retained
4.8.6 (m) adequate information regarding the medicinal product or products which the implant in question is designed to administer, including any limitations in the choice of substances to be delivered;	28.7 Requires information about medicinal products which the device is designed to administer.	* retained
4.8.6 (n) precautions to be taken against any special, unusual risks related to the disposal of the implant;	28.24 Requires information on proper disposal of the device.	* retained
4.8.6 (o) medicinal products incorporated into the implant as an integral part in accordance with 4.1.4 [of ISO/TR 14283];	28.8 Requires information to be provided about the intended use and characteristics, and about possible side effects.	* additional requirements
4.8.6 (p) degree of accuracy claimed for implants with a measuring function.	5 Applies 6.8 of IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–2 AND ASPECTS COVERED
4.9 Clinical evaluation Where conformity with the fundamental principles for implants should be based on clinical data, as in 3.6 [of ISO/TR 14283], such data should be established by either:		
4.9 (a) a compilation of the relevant scientific literature currently available on the purpose intended by the manufacturer, or	19.4 Requires investigation of unintended effects caused by the device.	* retained
4.9 (b) the results of all the clinical investigations carried out in a way that protects the human subjects and ensures the scientific conduct of the investigation.	19.4 Requires investigation of unintended effects caused by the device.	* retained

Annex BB
(informative)

Relationship between the clauses of ISO 14708-1 and the fundamental principles in Annex A

Clause/Subclause	Relevant fundamental principle
4	4.8.2
5	4.4.1, 4.4.1.1, 4.4.1.2, 4.4.2, 4.7.4, 4.7.5, 4.7.7.1, 4.7.7.2, 4.7.7.3, 4.7.7.4, 4.7.8.2, 4.7.8.3, 4.7.8.4, 4.8.3 and 4.8.6.(p)
7.1	4.2.3
7.2	3.5 and 4.2.3
8.1	3.1
8.2	4.8.5
9.1	4.5.3
9.2	4.8.3 (a)
9.3	4.8.3 (b) and 4.8.3 (d)
9.4	4.8.3 (b)
9.5	4.8.3 (c)
9.6	4.8.3 (k)
9.7	4.8.3 (e)
9.8	4.8.3 (b)
9.9	4.3.1
9.10	4.8.3 (b) and 4.8.4
9.11	4.8.3 (h)
9.12	4.8.3 (g)
10.1	3.5 and 4.2.3
10.2	3.5 and 4.2.3
10.3	3.5
10.4	3.3 and 4.8.1
11.1	4.8.3 (a)
11.2	4.8.3 (c) and 4.8.3 (l)
11.3	4.8.3 (c)
11.4	4.8.3 (k)
11.5	4.8.3 (e)

Clause/Subclause	Relevant fundamental principle
11.6	4.8.3 (b) and 4.8.3 (d)
11.7	4.8.3 (b) and 4.2.3
11.8	4.3.1
11.9	4.2.3
11.10	4.8.3 (g)
12.1	4.2.3
12.2	4.2.3
12.3	3.5
13.1	4.8.5
13.2	4.8.5
13.3	4.7.3
13.4	4.4.1.2
14.1	4.2.1, 4.2.3, 4.2.4 and 4.2.5
14.2	4.1.2 and 4.2.5
14.3	4.1.1 (a), 4.1.1 (b) and 4.1.2
14.4	4.1.4
15.1	4.3.2 (a)
15.2	4.3.2 (a)
16.1	4.7.6.1
16.2	4.7.6.2
16.3	4.7.6.2
17	4.7.6.2 and 4.3.2 (d)
18.1	4.5.3
18.2	4.5.3
18.3	4.5.3
19.1	4.3.2 (d)
19.2	3.4, 4.3.2 (d) and 4.7.2

Annex CC
(informative)

Rationale

CC.1 General

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

For some hazards, this part of ISO 14708 prescribes specific requirements along with compliance measures (e.g. d.c. leakage current levels). For other risks, this part of ISO 14708 requires potential hazards to be assessed and identified, using a similar procedure to that described in ISO 14971. Compliance is then determined by a review of the documentation provided by the manufacturer.

During the development of this part of ISO 14708, it was recognized that there are cases, particularly where accelerated fatigue testing is involved, where a variety of test methods produce equivalent results. In those cases, the test method presented in this part of ISO 14708 is viewed as “a reference test”. The manufacturer may use an alternative test method provided it can be demonstrated that the alternative is equivalent to the method described in this part of ISO 14708. In case of dispute, the method specified in this part of ISO 14708 is to be used.

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

CC.2 Notes on specific subclauses

The following, more detailed, notes on some of the provisions of this part of ISO 14708 are provided as an aid to understanding. This annex is directed toward those who are familiar with the construction and use of pacemakers but have not themselves participated in drafting this part of ISO 14708. The notes in this annex carry the numbers of the relevant clauses in this part of ISO 14708; therefore, the numbering in this annex is not consecutive.

[6] The procedures are specified for devices only at 37 °C ± 2 °C. As established designs are not temperature-sensitive within such a temperature range, this is believed sufficient to validate an implantable pulse generator at thermal equilibrium after implantation.

[6.1.2] The upper value of the load resistor was increased to 2 kΩ since several newer lead models have pacing impedances greater than 1 000 Ω.

The proposed test method has the following advantages: a) it simplifies labelling of parameter values and tolerances for programmers' screens and technical manuals; b) it is independent of pacing load and programmed settings (except when the parameter value depends on the programmed setting by design, e.g. effective pacing capacitance may vary with the programmed amplitude setting); c) it is more intuitively meaningful to the user: labelling effective pacing capacitance gives the user information on how much the pacing pulse amplitude will droop.

[6.1.4] This procedure changes the existing procedure of ISO 5841-1:1989, B.4.2, which has been found to give very inaccurate and poorly reproducible results if the value of resistor R_1 is not in the same order of magnitude as the input impedance, because it then requires division by small numbers. Additionally, noise in the detector input circuitry and external noise makes measurements poorly reproducible.

[6.2] The physiologic solution (normal or isotonic saline solution) is 9 g/l = 0,9 g/dl. The measurement of the lead pacing impedance is done in a 1/10 dilution of the physiologic solution, i.e. 0,9 g/l, which approximates the electrode myocardial interface.

The measurement x is the shortest distance between the distal extremities of the electrodes under test, measured along the surface of the lead (see Figure CC.101).

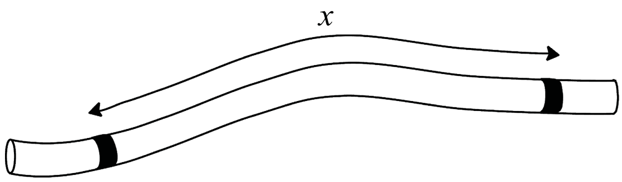


Figure CC.101 — Measurement of x

[9] The information required differs from that required by EN 50061 because of the developments in pacing technology since that document was prepared.

Key information required on the sales packaging is intended to uniquely identify the enclosed device and prevent unnecessary inspection of the device compromising the protection provided by the packaging before the time for implantation.

Additional information is provided for the convenience of the handler/implanting physician, but the scope of this data is limited by the restricted space available on the surface of the packaging and the need to display other data and warnings in a prominent manner, so that persons handling the sales package do not miss seeing them. Legal requirements specifying the language used to provide information further limit the space on any package intended for rapid international distribution.

Other necessary information is provided in the accompanying documentation, included in every sales package.

[11] Similar considerations apply here as for [9] above, except that the space for information on the sterile pack is even more limited than the space on the sales package.

[13.1.2] Leads and adaptors are usually very small devices with little space for identifying marks. Therefore, the required information may be abbreviated using techniques such as a recognized logo to identify the manufacturer and incorporation of the model designation into the serial number.

[13.3] For pacemakers, the power source is located in the implantable pulse generator. This is the part of the system that is to be identifiable using non-invasive procedures. At the present time, the procedure for non-invasively identifying the implantable pulse generator utilizes X-ray equipment, as this equipment is generally available to physicians. Device-specific equipment, such as a programmer, is not considered to be acceptable. However, once the unit is identified, a programmer can be used to obtain the serial number, or other identifying information, from which the date of manufacture can be determined, possibly by contacting the manufacturer.

[14.2] As well as the specific requirement that an implant be sterile, the implant should not introduce unnecessary loose particulate matter ("sterile dirt"). The method of compliance assessment is specified so that meaningful quantitative limits can be set for assessing the results of the test. The manufacturer may choose a recognized measurement technique based on the apparatus that is readily available.

The number of particles is related to the surface of the device and not its volume. For example, an empty bag (large surface but negligible volume) may present an excessive particle count when soaked in a bath based on the volume of the empty bag. The same bag, when filled, may pass the test even though the total particle count is the same. The same holds true for devices covered by this part of ISO 14708, especially leads that typically have a large surface area but have a small volume. For implantable pulse generators, this approach would specify a bath that is of the same order of magnitude as the volume approach in the General Standard.

The test limits are based on a standard test for particulate contamination in large-volume parenteral injections given in the European Pharmacopoeia.

[16.2] Sustained (long term) direct currents from implanted ELECTRODES may cause tissue damage or ELECTRODE corrosion. The direct current measurement should include the contribution, if any, resulting from sustained therapeutic functions such as bradycardia pacing.

The d.c. leakage current test uses load resistors that simulate the impedance seen by the pulse generator once implanted. The acceptance limits for the pacing/sensing TERMINALS are 0,1 µA maximum and remain unchanged from the first edition of this part of ISO 14708. For the CASE, the acceptance limits are higher by a factor of 10, i.e. 1,0 µA, due to the much larger surface area of the CASE connection.

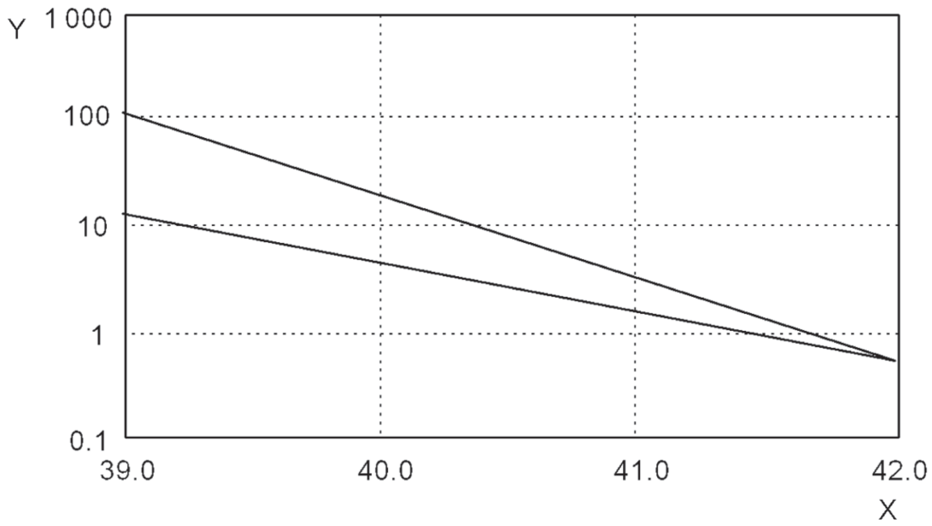
[16.3] The dielectric strength test for lead insulation is replaced by the compliance test in 23.3 that checks the integrity of the insulation following a conditioning soak in saline and application of tensile force to the lead.

[17.1] When considering the effect of temperature rise on tissue, the duration of the exposure to elevated temperature should be taken into account. It has been well established in burn literature that tissue damage should be evaluated as a function of exposure time[8][9][10][11]. Tissue SENSITIVITY is usually assessed by plotting the time to an "isoeffect" versus temperature. An "isoeffect" is any identifiable and repeatable level of detriment to the tissue. Although absolute SENSITIVITY can vary widely among tissue types, the slopes of isoeffect plots are consistent. Specifically, below 42 °C, for each 1 °C decrement in temperature, the time to reach an equivalent level of detriment is 4 to 6 times longer. This relationship has been demonstrated by many investigators, using both human and rodent tissue[12].

Most ICDs are implanted in adipose and skeletal muscle tissue. Martinez *et al*. conducted a thermosensitivity study of such tissues in normal porcine tissue[13]. (Henriques established porcine tissue as an accepted model for human tissue.) A total of 102 sites on 15 pigs were exposed to steady, elevated temperatures between 40 °C and 50 °C for 30 min. Acute and chronic damage levels were assessed from biopsies taken 24 h and 1 month post-treatment, respectively. Damage levels were graded by two independent observers who were unaware of the corresponding treatment. They found that there was no identifiable acute or chronic damage when the exposure temperature was 42 °C or less.

The results of this study may be used to determine a safe time-temperature relationship for MEDICAL DEVICES adjacent to adipose and/or skeletal muscle tissue. Such a relationship, shown in Figure CC.102, was obtained using the isoeffect rule outlined above. For example, since 42 °C was determined as safe for 30 min, then 41 °C should be safe for at least 4 times longer, or 2 h, and 40 °C should be safe for 8 h, etc.

It is emphasized that the specified device surface temperatures are as measured *in vivo* during operation, and not in air. Also, careful attention should be paid to the uncertainty in temperature measurements as this may affect the appropriate exposure time.



Key

X temperature (°C)

Y exposure time (h)

Figure CC.102 — Safe exposure times for adipose/skeletal muscle tissue at various temperatures

In more recent publications a 43 °C threshold for damage has been corroborated by numerous investigators. Interestingly, it has also been found that most of the damage caused to muscle and adipose tissue between 43 °C and 45 °C (30 min) is reversible. Above 45 °C, tissue necrosis appears, resulting in irreversible tissue injury (Martinez *et al.*, as referenced in GM Hahn, Hyperthermia and Cancer, Plenum Press, NY, 1982)[29].

From the studied literature, it may be safe to conclude that localized chronic tissue heating by an ACTIVE IMPLANTABLE MEDICAL DEVICE should be limited to temperatures of and below 41 °C in order not to affect normal tissue function. It seems reasonable, however, that tissue temperatures of up to 42 °C would be well tolerated during acute applications, and would not cause detrimental chronic effects.

A relatively recent publication[21] reported that temperatures ranging between 43 °C and 46 °C were measured in tissue adjacent to the motor and gear pump of the Cleveland Clinic-Nimbus total artificial heart. The tissues reaching these temperatures belong to the lung and muscle tissue within the chest. At these temperatures, according to the same paper, acute HARM should not be caused, but detrimental chronic effects may appear.

The authors supported these conclusions by referencing the following results from previous studies:

a) At and below 42 °C, polymorphonuclear (PMN) phagocytic function is maintained within normal ranges. At and above 44 °C, however, PMN function is irreversibly damaged, especially when the time of exposure exceeds 30 min. (J. Utoh *et al.*, The Effects of Heat on Human and Calf Polymorphonuclear Cells (PMN), *J. Invest. Surg.*, 3, p. 303, 1990[23]).

b) Angiogenesis was elicited in the myocardium of mongrel dogs by applying localized heat resulting in tissue temperatures of and above 43 °C. Angiogenesis, evidenced by neocapillarity and increased fibroblastic activity occurred at distances of up to 2 mm from the surface of the probe heaters for chronic exposures of 7 days to 31 days (J.C. Norman *et al.,* Heat-Induced Myocardial Angiogenesis, I, *Trans. ASAIO*, 17, pp. 213-218, 1971[25]).

c) Experiments carried out on T-lymphocytes (R. Hershkovits *et al.*, Heat-Stressed CD4+ T Lymphocytes: Differential Modulations of Adhesiveness to Extracellular Matrix Glycoproteins, Proliferative Responses and Tumour Necrosis Factor-+ Secretion, *Immunology*, 79, pp. 241-247, 1993[26]) suggest that heat stress at 41 °C (1 h) could suppress immune cell function and reactivity at local sites of elevated temperature due to loss of T-cell adhesion to the extracellular matrix. However, these same studies have demonstrated that heat stress at these temperatures augments T-cell proliferation and tumor-necrosis factor-+ secretion, indicating that heat stress at 41 °C itself does not suppress the overall immune function of T-cells. In any case, the effects of heat stress on T-cell adhesion and proliferation were completely reversible within 60 h of exposure.

d) Human red blood cells have shown significant changes in osmotic fragility and surface morphology at temperatures of 48 °C and above (J. Utoh *et al.*, Comparative Study of Heat Effects on Human and Calf Erythrocytes (RBC), *J. Invest. Surg,*, 3, p. 308, 1990[24]).

Another paper regarding the Cleveland Clinic-Nimbus artificial heart (H. Harasaki *et al.*, Progress in Cleveland Clinic-Nimbus Total Artificial Heart Development, *ASAIO Journal*, 40, pp. 494-498, 1994[27]) reported that tissues surrounding the artificial heart, including the tissue capsule, lung and pericardium, showed localized hyperemia and vascular engorgement for temperatures above the targeted range of 42 °C to 43 °C.

Research in the fields of whole-body hyperthermia and hyperthermia-enhanced radiotherapy has also yielded relevant information. In his Ph.D. dissertation, Prionas (S.D. Prionas, Thermal SENSITIVITY and Thermotolerance of Normal Mammalian Tissues, Ph.D. Dissertation, Stanford University, 1984[28]) stated:

"Most mammalian cells are readily inactivated at temperatures of 41 °C or higher. Under standard conditions (pH 7,4 and adequate nutrients and oxygen), the shape of the survival curves obtained when cells are exposed to elevated temperatures for varying lengths of time depends upon the temperature of exposure. Above 43 °C such curves resemble survival curves obtained from cells exposed to ionizing radiations: when the logarithm of the surviving fraction is plotted against time of exposure, the curves exhibit a shoulder, followed by a linear segment. The width of the shoulder as well as the slope of the linear part of the curve depend on the temperature. At higher temperatures the shoulder is smaller and the slope steeper. Below 43 °C the curves are more complex, with resistant tails developing as the duration of heating is increased."

The experiments carried out by Dr. Prionas demonstrate minimal thermal SENSITIVITY of adipose tissue and skeletal muscle for temperatures under 43 °C (<1 % of maximal tissue damage). However, damage increases dramatically at temperatures above 43 °C. The heat doses required to induce 50 % of maximal damage (30 min Single-Dose ED50) to skeletal muscle and adipose tissue are reported to be (45,1 ± 0,5) °C and (44,8 ± 0,5) °C respectively.

The 43 °C threshold for damage has been corroborated by numerous other investigators. Interestingly, it has also been found that most of the damage caused to muscle and adipose tissue between 43 °C and 45 °C (30 min) is reversible. Above 45 °C, tissue necrosis appears, resulting in irreversible tissue injury (Martinez *et al.,* as referenced in GM Hahn, Hyperthermia and Cancer, Plenum Press, NY, 1982[29]).

From the studied literature, it may be safe to conclude that localized CHRONIC tissue heating by an ACTIVE IMPLANTABLE MEDICAL DEVICE should be limited to temperatures of and below 41 °C in order not to affect normal tissue function. It seems reasonable, however, that tissue temperatures of up to 42 °C would be well tolerated during acute applications, and would not cause detrimental chronic effects.

A PACEMAKER may experience fault conditions, which result in a temperature rise exceeding the 4 °C limit. Examples include an internal short in the battery or any fault condition that results in a fault current that is less than the peak operating current of the device. ISO 14708-1:2000, 19.3, requires that the manufacturer assess the probable HARM being caused by each single-fault condition and to document the HAZARD CONTROL implemented to ensure that the failure does not cause an UNACCEPTABLE HAZARD. Therefore, it was deemed appropriate to eliminate the temperature rise requirement in a fault condition.

[21.2] This subclause provides some immunity from hf electrical currents arising from surgical diathermy. The test frequency of 500 kHz was selected as typical of the majority of electro-surgical equipment, and the peak-to-peak amplitude of 20 V of the burst-test signal was selected based on results of work by Dr. W. Irnich *et al*.[19]. (This indicates that thermal equilibrium can be maintained for induced voltages up to about 5 V rms (14 V pp) during electro-surgery, raising the temperature from 37 °C to 43 °C at the electrode to heart tissue interface.) Induced voltages above this value can cause thermal damage to the heart tissue, eventually resulting in a pacing threshold increase and/or necessitating replacement of the lead. The selected amplitude of 20 V pp to test the protection of the device therefore constitutes a reasonable compromise well above the tolerable level of 14 V_{pp} with respect to the protection of the patient. The test signal amplitude of 20 V_{pp} is consistent with the corresponding test of DIN VDE 0750-9[31].

During the test the device should ideally be programmed to provide asynchronous stimulation at a rate of greater than 60 pulses/min. This ensures, with the specified duration and duty cycle of test signal, that stimulation pulses are emitted by the device under test while the implantable pulse generator under test is subject to the test-signal burst.

The compliance check requires reactivation of the implantable pulse generator to restore full function (after being set for asynchronous stimulation during the test).

The requirement does not provide complete protection since the voltages picked up during exposure to surgical diathermy are very dependent upon the distances between the diathermy electrodes and any conductive part of the implantable pulse generator or its leads, and the surgeon may not be aware of the positioning of such parts.

[23.2] This subclause is intended to establish minimum requirements for the durability of implantable pulse generators with respect to mechanical robustness.

The replacement text is based on a new part of the standard IEC 60068-2-64.

The test severity is determined by the test conditions a) to d). The range of test frequencies is based on experience with the sinusoidal sweep method which has been in common use for a number of years within the industry.

The value for the acceleration spectral density was also derived from the sinusoidal sweep method in EN 50061:1988, 8.1.1. That test specifies a peak acceleration of 26 m/s^2. This translates into an rms value of 1,77 g. An acceleration spectral density of 0,7 $(m/s^2)^2/Hz$ translates into an rms value of 1,86 g. This last calculation is an approximation that may vary slightly depending on the equipment used to generate the random vibration. However, the level of stress on the implantable pulse generator is comparable to the level in the method in EN 50061.

In general, a short duration test will produce low-confidence level results. The duration value for this test is the midpoint of the recommended values in IEC 60068-2-64, 5.5. It should provide for reasonable confidence in the reproducibility of the results while providing a test method whose overall time to complete is also reasonable.

Protection of the device during delivery and storage is provided by appropriate design of the packaging, which is evaluated with respect to vibration in 10.1.

[23.3 to 23.5] The tests required by 23.3 to 23.5 are intended to establish minimum requirements for the durability of implantable leads with respect to commonly known mechanical failure modes. There are some lead failure modes for which standardized tests cannot yet be established, since a consensus has not been reached about either the mechanisms of failure or valid test methods. It is the responsibility of the lead manufacturer to define a complete set of lead reliability requirements for a particular design.

[23.3] The lead is soaked to allow for the influence of body fluids on the physical properties of the lead. It is important that the lead does not dry out during the tensile test. After the tensile testing, the lead is soaked to allow saline to penetrate any damage regions resulting from the test. During the insulation integrity test, the exposed conductive surfaces should be kept completely isolated from the saline bath to ensure safety for the test personnel.

The manufacturer should determine the distal point on the lead where the fracture or permanent deformation of any conductor or joint, or breaching or separation of the insulation, would affect the intended function of the lead. By clamping at this point and at the lead connector pin, it is possible to evaluate the composite strength of the lead. Visual inspection of the lead at each stage of the procedure is strongly recommended to detect possible functional damage.

Different parts of the lead may be exposed to varied levels of tensile force. The compliance check requires a 5 N wet pull force. Leads that meet the composite wet pull requirement of 5 N are believed to have sufficient overall mechanical integrity because some clinically used leads that do not meet this criteria for the portion of the lead in the vascular system have demonstrated acceptable field performance.

When implanted, the maximum possible elongation is not likely to exceed 20 %. The fatigue life of the lead is not likely to be compromised if the lead is permanently elongated less than 5 %. This has been commonly accepted as a reasonable acceptance criterion for a long period of time.

The d.c. resistance measurement is checking for gross fractures of conductors or separation of joints.

The 2 mA limit is derived from the requirement for a minimum electrical impedance of 50 KΩ between conductive elements that appears in 4.1.2.2 of ISO 5841-3:2000 (IS-1). The 0,1 s to 5 s time for the 100 V ± 5 V d.c. test voltage to be ramped up was chosen to prevent voltage overshoot beyond the upper limit of 105 V d.c.

[23.5] During the development of this second edition of this part of ISO 14708, comments were received requesting the development of lead fatigue test methods that would demonstrate performance against known acceptable behaviour. At this time, no changes have been made to the tests in this clause, since development of more comprehensive lead tests is currently being considered by the AAMI PC85 Leads Test Task Force. At such time as those tests have been agreed upon, they will be considered for adoption within, or be referenced by, a future revision of this part of ISO 14708.

The tests contained in 23.5.1 and 23.5.2 are intended to establish minimum requirements for the flexural durability of implantable leads. In accordance with this approach, a conductor or connector is to withstand a minimum of 47 000 and 82 000 cycles respectively, without failure.

For all conductor and connector design geometries and materials, it is recommended that a margin of safety be established with respect to these minimum requirements. It is left up to each manufacturer to determine the appropriate sample size, data analysis technique and margin of safety, as well as to demonstrate with confidence that the minimum cycle requirements can be achieved.

The tests are intended to accelerate the fatigue of the conductor and not the insulation, therefore the pass/fail criterion looks for conformity of the conductor. Although test methods designed to accelerate fatigue of conductors can introduce test artefact damage to insulation, fatigue failures of known insulation materials *in vivo* are generally not experienced in the absence of biodegradation mechanisms. The types of insulation damage seen in these accelerated fatigue tests are not necessarily representative of the insulation damage seen after implantation.

[Test 1] The bell mouth test was designed with the following conditions in mind: variations in human anatomy, ranges of motion, implant sites, and loading conditions.

The fixture radius is dependent on the diameter of the lead segment under test [fixture radius = centre-line bending radius (6,00 mm ± 0,10 mm) minus half the maximum segment outside diameter].

Loading conditions were determined by evaluating coil designs and by observing the morphology of the fracture surface. Each type of fracture surface will produce a characteristic fracture signature or morphology. The fracture sites of both the *in vitro* and *in vivo* samples from the bell mouth test were compared and determined to exhibit the same morphology.

Although the exact conditions are impossible to determine, it is believed that loading by torsional shear or bending in the bell mouth flex test causes similar loading conditions to those experienced by *in vivo* failures. This is supported by studies, by light microscopy, scanning electron microscopy, and analytical stress analysis of the various types of slant and flat fractures found both in tested and explanted leads.

Figure CC.103 specifies a reference test coil based on a bipolar lead, with established field performance that utilizes the reference test coil as the inner conductor coil. Based on a study of chronic implants and return product analysis, this lead has been found to achieve a nominal survival rate from fracture of the inner coils of 99,3 % at 60 months.

Weibull distribution analysis of the reference test coil fractures predicts a minimum population value of 46 476 that supports the observed minimum of 47 908 cycles. The specification minimum is proposed to be set at the sample minimum, rounded down to the nearest 1 000 cycles (47 000). The specification minimum is set at the Weibull t_0 value, rounded up to the nearest 1 000 cycles (47 000).

Weibull distribution analysis was conducted on 224 samples of the reference test coil tested using the procedure in 23.5. The reference test coil was tested in both a lead-body and bare-coil configuration. Although the standard test is designed to test lead-body configurations, a majority of the population was tested in a bare-coil configuration. Bare-coil configurations have been shown to give a slightly different average flex life value than co-axial lead-body configurations due to structural interactions that are seen in lead bodies. The use of the bare-coil configuration was used to help remove any discrepancies created when validating a manufacturer's test set-up. The Weibull analysis predicts a B_{50} value of 127 685 and a minimum, t_0, of 46 476 that supports the observed minimum of 47 908 cycles.

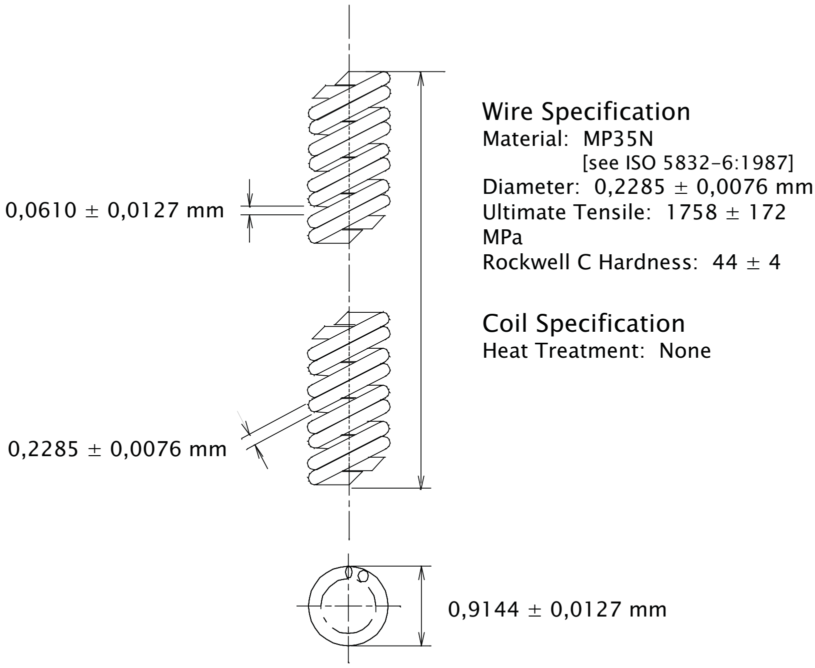


Figure CC.103 — Reference test coil

By using the same centre-bend radius, the same strain conditions will be applied for every different conductor diameter. This approach was chosen because it is consistent with typical strain analysis techniques and with existing LEAD flex test databases.

The accelerated flex testing described in this part of ISO 14708 purposely imposes higher strain on the lead that results in a shorter fatigue life of the test specimens than is expected to occur in implanted leads. However, changing the frequency and/or radii may or may not change the morphology of the fracture site of the *in vitro* tests. Regardless, the altered test would need to be verified with field data and evaluations to determine whether failure modes of the test specimens are representative of the field.

Therefore, the current bell mouth test is appropriate for assessing the relative flex fatigue characteristics of various lead designs utilising MP35N. For conductors that are not constructed from MP35N or do not have a coil geometry, it is the responsibility of the lead manufacturer to either justify using the 47 000 cycle acceptance criteria (with the bell mouth test method) or identify alternative, appropriate test requirements.

It was recognized that there were several alternative test methods (e.g. spin test) that were appropriate to evaluate the flex characteristics of leads. Alternative flex test methods may be compared to the bell mouth test by using the reference test coil as a reference.

[Test 2] The connector flex test is designed to accelerate the fatigue of the conductive path in the vicinity of the connector and not to test the insulation, therefore the pass/fail criterion looks for conformity of the conductive path. Although test methods designed to accelerate fatigue of conductors can introduce test artefact damage to insulation, fatigue failures of known insulation materials *in vivo* are generally not experienced in the absence of biodegradation mechanisms. The types of insulation damage seen in these accelerated fatigue tests are not necessarily representative of the insulation damage seen in the body.

The orientation of the connector in the fixture will make a difference if the connector is non-symmetrical, i.e. has a label imbedded in the connector sleeve. To accommodate this, it is required that the lead connector be placed in a “worst-case” orientation.

A minimum cavity depth is required to simulate the worst-case *in vivo* situation where a vulnerable point of strain concentration exists outside the connector cavity. By bending the test sample ± 45 for 82 000 cycles, the test creates more severe strain at the connector than is expected *in vivo*. A 100 g weight is attached to the tests segment to force the test sample to conform to the required angular displacement without providing a significant tensile load.

The specification minimum of 82 000 cycles was established from industry testing of different connectors. This minimum is based on a DF-1 connector design that has acceptable field performance. Weibull distribution analysis of this connector predicts a minimum population value, t_0, of 81 697 cycles. The specification minimum is set to a value rounded up to the nearest 1 000 cycles.

[23.6] Field experience and design analysis have shown that connector systems that utilize set-screws bearing on lead connector metal pins mated according to the manufacturer's specifications will meet this requirement and will not prove a clinical risk. Therefore, the test is unnecessary for these systems.

No torque is applied in the test because the implantable pulse generator/lead implanted subcutaneously cannot introduce significant torque on the connector interface since the length of the lead body in this area will deform sufficiently to dissipate any rotational effects.

[25] Pressure variations applied to the outside of the body are directly transmitted to the device since they are implanted in soft tissue composed primarily of incompressible water. Repeated exposure to various activities and medical treatments (skin/scuba diving, hiking, skiing or driving to high altitude, air travel, and exposure to hyperbaric chamber medical treatments) exerts different pressures on the device shields, which may result in device shield deformation. Changes in pressure may also cause distortion of the connector, seals and leads, which may affect the functioning of the device. Potential exposure to various pressures may be experienced as a result of:

— hyperbaric chamber medical treatment mostly to 3 ATA (equivalent to 20 m of sea water);

— hyperoxia therapy 3 ATA (equivalent to 20 m of sea water);

— commercial aircraft pressurized to an equivalent altitude of 2 438 m (8 000 ft), equivalent to 10,9 psia;

— travel to high altitude representing multiple climbing trips to altitudes ranging from 4 267 m to 8 850 m (14 00 ft to 29 035 ft) [there are several mountain summits at 4 267 m (14 000 ft) and above accessible by automobiles];

— loss of cabin pressure in commercial aircraft at an altitude of 12 192 m (40 000 ft), approximately 2,7 psia;

— multiple skin dives to depths of 10 m (33 ft), equivalent to 2 ATA;

— multiple scuba diving to a depth of 20 m (66 ft) (initial dive certification depth for scuba, deeper for advance certifications, 3 ATA).

[27] This clause makes reference to ISO 14117 which addresses specific EMC requirements for implantable pacemakers and ICDs. The rationale in A.1 and Annex M of ISO 14117 provide the appropriate information.

Annex DD
(informative)

Code for describing modes of implantable pulse generators

DD.1 General

This annex recommends a code to be used for marking the IMPLANTABLE PULSE GENERATOR to designate its primary intended use. Multiple programmable or universal implantable pulse generators are covered in this code scheme.

DD.2 The code

The code is presented as a sequence of five letters. Table DD.101 gives an outline of the basic concept of the code.

Table DD.101 — Basic mode code scheme

Position	I	II	III	IV	V
Category	Chamber(s) paced	Chamber(s) sensed	Response to sensing	Rate modulation	Multisite pacing
	O=None	O=None	O=None	O=None	O=None
	A=Atrium	A=Atrium	T=Triggered	R=Rate modulating	A=Atrium
	V=Ventricle	V=Ventricle	I=Inhibited		V=Ventricle
	D=Dual(A+V)	D=Dual(A+V)	D=Dual(T+I)		D=Dual (A+V)
Manufacturer's designation only	S=Single (A or V)	S=Single (A or V)			
Source: The Revised NASPE/BPEG Generic Pacemaker Code for Antibradycardia, Adaptive-Rate and Multisite Pacing, PACE February 2002, Vol. 25, No. 2: pp. 260-264[21].					

The significance of the position of the code letter is as follows:

First letter: The paced chamber is identified by “V” for ventricle, “A” for atrium, “D” for dual (i.e. both atrium and ventricle), or “S” for single chamber (either atrium or ventricle).

Second letter: The sensed chamber is identified by either “V” for ventricle, “A” for atrium. An “O” indicates that the implantable pulse generator has no sensing function. “D” indicates dual (i.e. both ventricle and atrium), and “S” indicates single chamber (either atrium or ventricle).

Third letter: The mode of response is either “I” for inhibited (i.e. an implantable pulse generator whose output is inhibited by a sensed signal), or “T” for triggered (i.e. an implantable pulse generator whose output is triggered by a sensed signal); “O” is used if the implantable pulse generator has no sensing functions, and “D” is used for a implantable pulse generator that can be inhibited and triggered.

Fourth letter: The fourth letter is used only to indicate the presence “R” or absence “O” of an adaptive-rate mechanism (rate modulation).

Fifth letter: This letter is used to indicate whether multisite pacing is present in “O”, none of the cardiac chambers, “A”, one or both of the atria, “V”, one or both of the ventricles, or “D”, any combination of A or V as just described.

Examples of the code, as commonly used, are given in Table DD.102.

Table DD.102 — Examples of mode code

Code	Explanation of code used
AAI	Atrial inhibited
AAT	Atrial triggered
AOO	Atrial asynchronous
DDD	A-V sequential Atrial/Ventricular inhibited, triggered
DOO	A-V sequential asynchronous
DVI	A-V sequential ventricular inhibited
DVT	A-V sequential ventricular synchronized
VAT	Atrial synchronized
VDD	Atrial synchronized ventricular inhibited
VOO	Ventricular asynchronous
VVI	Ventricular inhibited without RATE MODULATION
VVT	Ventricular triggered
SSI	Single-chamber pace/sense, inhibited
DDDR	A-V sequential Atrial/Ventricular inhibited, triggered with RATE MODULATION
VVIR	Ventricular triggered with RATE MODULATION

DD.3 Modes of implantable pulse generators

DD.3.1 The definitions that follow describe the mode of operation of implantable pulse generators. A system of coding modes is described in DD.2.

DD.3.2 Standby mode (OOO): Mode with no interaction between the PACEMAKER and the heart.

DD.3.3 Atrial asynchronous mode (AOO): Mode in which an atrial pulse is provided independently of the activity of the heart. Ventricular functions and atrial sensing are disabled or absent.

DD.3.4 Atrial inhibited mode (AAI): Mode where, if during the ESCAPE INTERVAL, the atrial sensing function detects a BEAT, then the implantable pulse generator suppresses atrial pacing. If the sensed atrial beat occurs after the ESCAPE INTERVAL, then the implantable pulse generator provides atrial pacing at the BASIC RATE. Ventricular functions are disabled or absent.

DD.3.5 Atrial triggered mode (AAT): Mode where, if during the ESCAPE INTERVAL, the atrial sensing function detects a BEAT, then an atrial pulse is produced in synchrony with the atrial beat (provided that the MAXIMUM TRACKING RATE is not exceeded). If the sensed atrial beat occurs after the ESCAPE INTERVAL, then the implantable pulse generator provides atrial pacing at the BASIC RATE. Ventricular functions are disabled or absent.

DD.3.6 A-V sequential, asynchronous mode (DOO): Mode in which the implantable pulse generator provides atrial pacing at the BASIC RATE. At the specified AV INTERVAL after each atrial pulse, a ventricular pulse is provided independently of the activity of the heart. Atrial and ventricular sensing functions are disabled or absent.

DD.3.7 A-V sequential mode with ventricular sense (inhibition) (DVI): Mode in which the atrial sensing function is disabled or absent, and the implantable pulse generator provides atrial pacing at the BASIC RATE. If a spontaneous ventricular beat is not sensed during the specified AV INTERVAL after each atrial pulse, a ventricular pulse is provided.

DD.3.8 A-V sequential, ventricular synchronized (triggered) mode (DVT): Mode in which the implantable pulse generator provides atrial pacing at the basic rate. After each atrial pulse, during a period equal to the set AV INTERVAL, a ventricular pulse is provided in synchrony with a spontaneous ventricular beat. If no ventricular beat is sensed in that period, then a ventricular pulse is immediately provided. The atrial sensing function is disabled or absent.

DD.3.9 For A-V sequential mode, with sensing and pacing in both chambers, the following four modes can be distinguished:

— Inhibition in both channels (DDI): Mode in which a spontaneous atrial beat interrupts the implantable pulse generator's VA interval and starts an AV INTERVAL without release of an atrial pulse. A spontaneous ventricular beat interrupts either an AV or VA interval and starts a new VA interval without release of a ventricular pulse.

— Triggering in the atrial channel and inhibition in the ventricular channel (DDD): Mode in which a spontaneous atrial beat interrupts the implantable pulse generator's VA interval and starts an AV INTERVAL with release of an atrial output. A spontaneous ventricular beat interrupts either an AV or VA interval and starts a new VA interval without release of a ventricular pulse.

— Inhibition in the atrial channel and triggering in the ventricular channel (DDD): Mode in which a spontaneous atrial beat interrupts the implantable pulse generator's VA interval and starts an AV INTERVAL without release of an atrial pulse. A spontaneous ventricular beat interrupts that AV INTERVAL and starts a new VA interval with release of a ventricular pulse.

— Triggering in both channels (DDT): Mode in which a spontaneous atrial beat interrupts the implantable pulse generator's VA interval and starts an AV INTERVAL with release of an atrial pulse. A spontaneous ventricular beat interrupts that AV INTERVAL and starts a new interval with release of a ventricular pulse.

NOTE If the AV INTERVAL cannot be interrupted by a ventricular beat with a release of a ventricular pulse as consequence, the system is said to be “committed”.

DD.3.10 Ventricular asynchronous mode (VOO): Mode in which a ventricular pulse is provided at the BASIC RATE, independent of the activity of the heart. Atrial functions and ventricular sensing are disabled or absent.

DD.3.11 Ventricular inhibited mode (VVI): Mode where, if the ventricular sensing function detects a beat interval shorter than the ESCAPE INTERVAL, then the implantable pulse generator suppresses ventricular pacing. If the sensed ventricular beat interval exceeds the ESCAPE INTERVAL, then the implantable pulse generator provides ventricular pacing at the BASIC RATE. Atrial functions are disabled or absent.

DD.3.12 Atrial synchronized mode (VAT): Mode in which, when a spontaneous atrial beat is sensed, the set AV INTERVAL commences and a ventricular pulse is provided at the end of that interval. If the sensed atrial beat interval exceeds the ESCAPE INTERVAL, then the implantable pulse generator provides ventricular pacing at the BASIC RATE. Ventricular sensing and atrial pacing functions are disabled or absent.

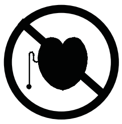
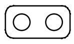
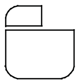
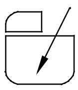
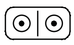
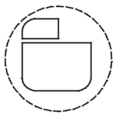
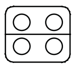
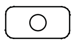
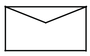
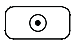
DD.3.13 Atrial synchronized, ventricular inhibited mode (VDD): Mode in which both ventricular and atrial sensing are provided. The set AV INTERVAL commences when a spontaneous atrial BEAT is sensed and a ventricular pulse is provided at the end of that interval. If either the sensed atrial or ventricular beat intervals exceed the ESCAPE INTERVAL, then the implantable pulse generators provide ventricular pacing at the BASIC RATE. Atrial pacing is disabled or absent.

DD.3.14 Ventricular triggered mode (VVT): Mode where, if the sensed ventricular beat interval is shorter than the ESCAPE INTERVAL, then a ventricular pulse is provided synchronously with the spontaneous ventricular beat. If the sensed ventricular beat interval exceeds the ESCAPE INTERVAL, then ventricular pacing is provided at the BASIC RATE. Atrial functions are disabled or absent.

Annex EE
(informative)

Symbols

Table EE.101 — Conventional symbols

Symbol	Title	Symbol	Title
	Prohibitive sign CARDIAC PACEMAKER Defibrillators		Single chamber connector - BIPOLAR (bifocal)
	IMPLANTABLE PULSE GENERATOR - not programmable		Dual chamber connector - UNIPOLAR
	IMPLANTABLE PULSE GENERATOR - programmable		Dual chamber connector - BIPOLAR (coaxial connector)
	IMPLANTABLE PULSE GENERATOR - with telecommunication		Dual chamber connector - BIPOLAR (bifocal)
	Single chamber connector - UNIPOLAR		Documentation inside
	Single chamber connector - BIPOLAR (coaxial connector)		

Annex FF
(normative)

Pulse forms

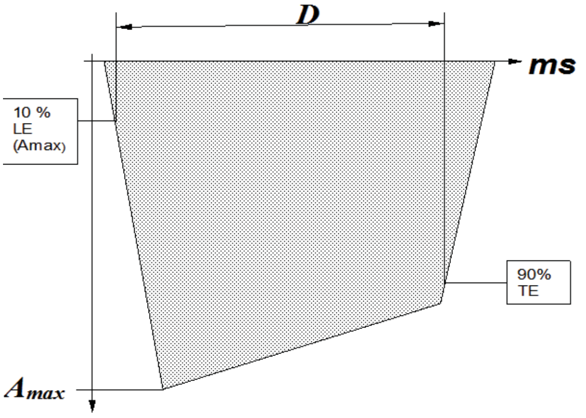


Figure FF.101 — Measurement of pulse duration

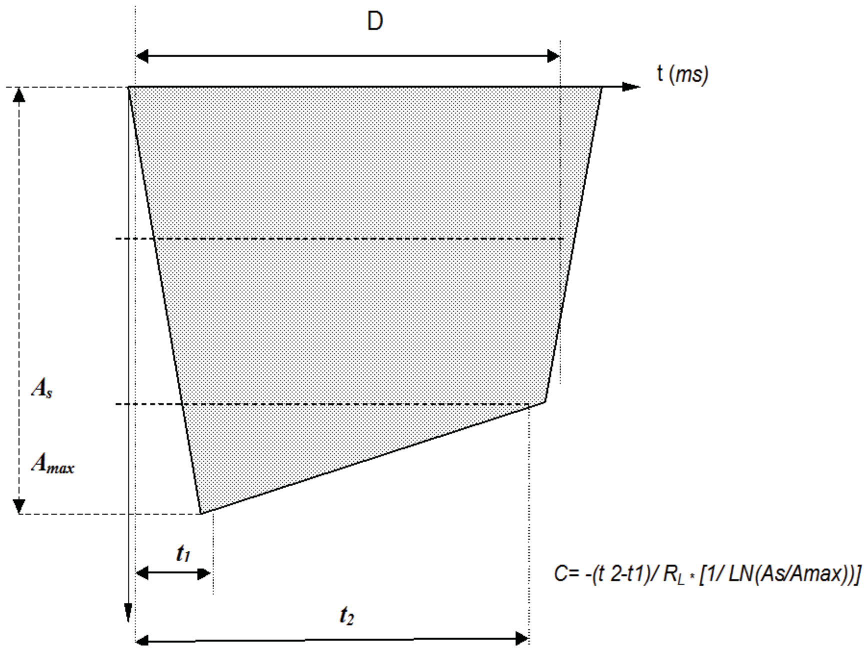
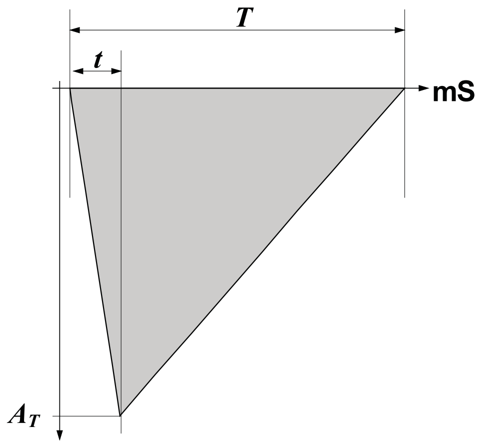


Figure FF.102 — Measurement of pulse amplitude and effective pacing capacitance (voltage sample A_{max} is taken at time t_1 and voltage sample A_s at time t_2 = 0,3 ms)



t = 2 ms ± 0,2 ms

T = 15 ms ± 1 ms

Source impedance: ≤1 kΩ

NOTE The signal may be either positive or negative.

Figure FF.103 — Form of signal from a test signal generator used for the exact determination of sensitivity (sensing threshold)

Bibliography

[1] ISO 31 (all parts), *Quantities and units*[2]

[2] ISO 5841-1:1989, *Cardiac pacemakers — Part 1: Implantable pacemakers*[3]

[3] ISO 11607 (all parts), *Packaging for terminally sterilized medical devices*

[4] ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

[5] ISO/TR 14283, *Implants for surgery — Fundamental principles*

[6] ISO 14708-6, *Implants for surgery — Active implantable medical devices — Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)*

[7] ISO 14971, *Medical devices — Application of risk management to medical devices*

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2 Withdrawn.

3 Withdrawn and replaced by this part of ISO 14708.

4 Superseded by EN 45502-2-1 and EN 45502-2-2.

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