INTERNATIONAL STANDARD

ISO 14708-2

First edition
2005-10-01

Implants for surgery — Active implantable medical devices —

Part 2: Cardiac pacemakers

Implants chirurgicaux — Dispositifs médicaux implantables actifs —

Partie 2: Stimulateurs cardiaques

Reference number
ISO 14708-2:2005(E)

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Published in Switzerland

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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 CEN and CENELEC (as EN 45502-2-1) and was adopted jointly by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*, and Technical Committee IEC/SC 62D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This first edition cancels and replaces ISO 5841-1:1989, 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*

The following parts are under preparation:

— *Part 3: Implantable neurostimulators*

— *Part 4: Implantable infusion pumps*

— *Part 5: Circulatory support devices*

Introduction

This Part 2 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 2 is relevant to all parts of implantable PACEMAKERS, including all accessories**.** Typical examples are IMPLANTABLE PULSE GENERATORS, LEADS, ADAPTORS, pro-grammers and the related software.

The requirements of this Part 2 supplement or modify those of ISO 14708-1*, Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and information to be provided by the manufacturer*, hereinafter referred to as Part 1. The requirements of this Part 2 take priority over those of Part 1*.*

Figures or tables that are additional to those of Part 1 are numbered starting from 101; additional annexes are lettered A, B, etc.

Although both this Part 2 and the European Directive 90/385/EEC deal with the same products, the structure and purpose of the two documents are different. Annex A of this Part 2 correlates the requirements of the Directive with the subclauses of ISO 14708-1 and this Part 2. Annex B provides reference in the other direction, from this ISO Standard to the Directive. Annex C is a rationale providing further explanation of the subclauses of this Part 2.

Annex D describes a coding system that may be used to designate bradyarrhythmia pacing modes. Annex E 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 F defines reference points for measurements of PULSE AMPLITUDE and PULSE DURATION, and the form of test signal used to determine SENSITIVITY. Annex G defines the tissue equivalent interface circuits, signal injection network and low pass filter required for some compliance tests. Annex H describes a method for selecting the filter capacitor used in the tissue equivalent interface circuits defined by Annex G. Annex I defines the method of calibrating the injection network defined by Annex G**.**

All annexes except Annex F, G and I are informative.

Implants for surgery — Active implantable medical devices —

Part 2:
Cardiac pacemakers

1 Scope

This Part 2 specifies requirements that are applicable to those ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat bradyarrhythmias.

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

This Part 2 is also applicable to some non-implantable parts and accessories of the devices (see Note 1).

The characteristics of the IMPLANTABLE PULSE GENERATOR or LEAD shall be determined by either the appropriate method detailed in this Part 2 or by any other method demonstrated to have an accuracy equal to, or better than, the method specified. In the case of dispute, the method detailed in this Part 2 shall apply.

Any features of an ACTIVE IMPLANTABLE MEDICAL DEVICE intended to treat tachyarrhythmias are covered by another ISO document under development.

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

NOTE 2 The terminology used in this International Standard is intended to be consistent with the terminology of Directive 90/385/EEC.

NOTE 3 In this International Standard, 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

This clause of Part 1 applies except as follows.

Additional references:

ISO 5841-3	Implants for surgery — Cardiac pacemakers — Part 3: Low profile connectors (IS-1) for implantable pacemekers
ISO 8601	Data elements and interchange formats — Information interchange — Representation of dates and times
ISO 11318	Cardiac defibrillators — Connector assembly DF-1 for implantable defibrillators — Dimensions and test requirements

ISO 14708-1	Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and information to be provided by the manufacturer
IEC 60068-2-27	Environmental testing — Part 2: Tests — Test Ea and guidance: Shock
IEC 60068-2-47	Environmental testing — Part 2-47: Test — Mounting of specimens for vibration, impact and similar dynamic tests
IEC 60068-2-64	Environmental testing — Part 2: Test methods — Test Fh: Vibration, broad-band random (digital control) and guidance
ANSI/AAMI PC69	Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators

3 Definitions

This clause of Part 1 applies.

Additional definitions:

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

NOTE For purposes of this Part 2, the term implantable pulse generator describes any ACTIVE IMPLANTABLE MEDICAL DEVICE that incorporates functions intended to treat bradyarrhythmias

3.3.2 pacemaker
ACTIVE IMPLANTABLE MEDICAL DEVICE intended to treat bradyarrhythmias, comprising an IMPLANTABLE PULSE GENERATOR and LEAD(S)

3.3.3 sensor
special part of a PACEMAKER that is designed to detect signals for the purpose of RATE MODULATION or other control purposes

3.3.4 terminal
electrically separate conductive device connection

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

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

3.3.7 pulse amplitude
the time integral over current or voltage, as appropriate, divided by the PULSE DURATION [see 6.1.1]

3.3.8 pulse duration
duration of the PULSE, measured between two reference points specified in Part 2 [see 6.1.1]

3.3.9 pulse interval
interval between equivalent points of two consecutive PULSES [see 6.1.1]

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

3.3.11 escape interval
time elapsing between the sensing of a spontaneous BEAT and the succeeding non-triggered PULSE of an IMPLANTABLE PULSE GENERATOR [see 6.1.4]

3.3.12 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.

3.3.13 AV interval; atrioventricular interval
delay between an atrial PULSE or the sensing of an atrial depolarisation and the subsequent ventricular PULSE or the sensing of a ventricular depolarisation [see 6.1.7]

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

3.3.15 pulse rate
number of PULSES per minute [see 6.1.1]

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

3.3.17 interference pulse rate
PULSE RATE with which the IMPLANTABLE PULSE GENERATOR responds when it senses electrical activity other than that from the myocardium that it recognizes as interference

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

3.3.19 rate modulation
altering of the PULSE RATE as a function of a control parameter other than a sensed BEAT

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

3.3.21 input impedance; Z_{in} (of an IMPLANTABLE PULSE GENERATOR)
electrical impedance presented at an input TERMINAL [see 6.1.3] and taken as equal to the electrical loading presented to a sensed BEAT

3.3.22 sensitivity; sensing threshold
minimum signal required to control consistently the function of the IMPLANTABLE PULSE GENERATOR [see 6.1.2]

3.3.23 refractory period
period during which an IMPLANTABLE PULSE GENERATOR will not respond to a BEAT [see 6.1.5 and 6.1.6]

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

3.5.2 unipolar lead
LEAD with one ELECTRODE

3.5.3 bipolar lead
LEAD with two ELECTRODES that are electrically isolated from each other

3.5.4 endocardial lead
LEAD with an ELECTRODE designed to make a contact with the endocardium, or inner surface of the heart. [cf. epicardial lead, a LEAD with an ELECTRODE designed to make a contact with the epicardium, or outer surface of the heart.]

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

3.5.6 lead conductor resistance, R_c
ohmic resistance between the ELECTRODE and the corresponding lead connector TERMINAL [see 6.2.1]

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

3.5.8 lead sensing impedance; Z_s
source impedance of a LEAD as seen by an IMPLANTABLE PULSE GENERATOR [see 6.2.3]

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

3.9.2 serial number
unique combination of letters and/or numbers, selected by the manufacturer, intended to distinguish a device from other devices with the same MODEL DESIGNATION

3.20.1 beginning of service (BOS)
when an individual IMPLANTABLE PULSE GENERATOR is first released by the manufacturer as fit for placing on the market

3.20.2 end of service (EOS)
when the PROLONGED SERVICE PERIOD has elapsed and performance to design specification cannot be assured

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

3.20.4 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

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

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

3.20.7 stoichïometric capacity
energy capacity as defined by the content of electro-chemically active materials in the power source

3.20.8 use-before date
date after which the manufacturer recommends that the IMPLANTABLE MEDICAL DEVICE should not be used

3.20.9 usable capacity
portion of the STOICHÈOMETRIC CAPACITY of the power source that can be utilised by the IMPLANTABLE PULSE GENERATOR until END OF SERVICE is reached

3.21.1 beat
ordered spontaneous activity of the heart

3.21.2 transvenous
approach to the heart through the venous system

3.21.3 dual-chamber
(adj.) relating both to the atrium and ventricle

4 Symbols and abbreviations (optional)

This clause of Part 1 applies. Additional note:

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

5 General requirements for non-implantable parts

This clause of Part 1 applies.

6 Measurement of IMPLANTABLE PULSE GENERATOR and LEAD characteristics

6.1 Measurement of IMPLANTABLE PULSE GENERATOR characteristics

The values of the electrical characteristics for the IMPLANTABLE PULSE GENERATOR measured in accordance with the methods described in this clause shall be within the range of values stated by the manufacturer in the accompanying documentation [see 28.8]

The procedures shall be performed with the IMPLANTABLE PULSE GENERATOR at a temperature of 37 ºC ± 2 ºC, 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 by Table 101.

Table 101 - Overall measurement accuracy limits

Measurement	Accuracy
PULSE AMPLITUDE (6.1.1)	± 5 %
PULSE DURATION (6.1.1)	±5 %
PULSE INTERVAL/TEST PULSE INTERVAL (6.1.1)	± 0,2 %
PULSE RATE/TEST PULSE RATE (6.1.1)	± 0,5 %
SENSITIVITY (6.1.2)	± 10 %
INPUT IMPEDANCE (6.1.3) if < 1 MΩ	± 10 %
ESCAPE INTERVAL (6.1.4)	± 10 %
REFRACTORY PERIOD (6.1.5, 6.1.6, and 6.1.8)	± 10 %
AV INTERVAL (6.1.7 and 6.1.9)	± 5 %
NOTE Information about INPUT IMPEDANCE is always required. However above 1 MΩ, the 10 % accuracy tolerance is relaxed because the INPUT IMPEDANCE will be much greater than the source impedance presented by the LEAD.	

If the IMPLANTABLE PULSE GENERATOR has DUAL-CHAMBER functions, the atrial and ventricular 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 setup as the indifferent TERMINAL

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

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 the points on the PULSE equal to one-third of the peak PULSE AMPLITUDE (A_{max}) [see Figure F.101].

The PULSE AMPLITUDE (*A*) shall be calculated from the time integral over current or voltage, as appropriate, divided by the PULSE DURATION [see Figure FF.102].

The PULSE RATE shall be calculated from the mean interval over at least 20 PULSES.

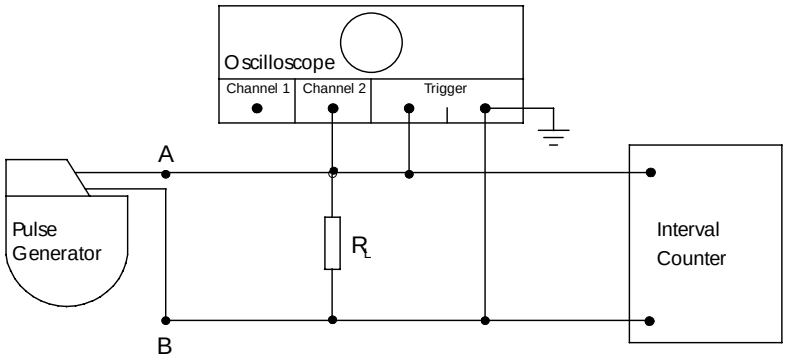


Figure 101 - Measurement of pulse amplitude, pulse duration, pulse interval and pulse rate

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

The results shall be expressed in the following units:

- PULSE DURATION: milliseconds (ms);
- PULSE AMPLITUDE: volts or milliamperes (V or mA);
- PULSE INTERVAL: milliseconds (ms);
- PULSE RATE: reciprocal minutes (min^{-1}). s

NOTE Whenever the result is recorded, the operating settings of the IMPLANTABLE PULSE GENERATOR (e.g., programmed pulse rate, etc.) shall also be noted.

6.1.2 *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, that provides a signal in the form defined by Figure F.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 to point A through a 100 kΩ ± 1 % feed resistor (R_F). 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 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 *(e_{pos})* shall be calculated by dividing the measured test signal voltage by 201.

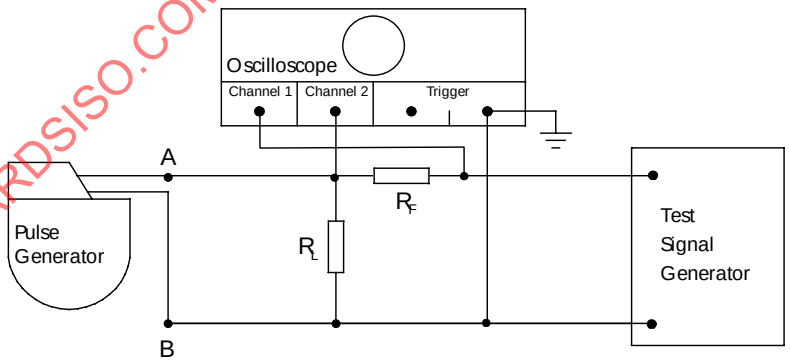


Figure 102 - Sensitivity measurement

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

6.1.3 *Measurement of input impedance (Z_{in})*

Procedure: Use an oscilloscope, nominal input impedance 1 MΩ, and a test signal generator, output impedance ≤ 1 kΩ, that provides a signal in the form defined by Figure F.103.

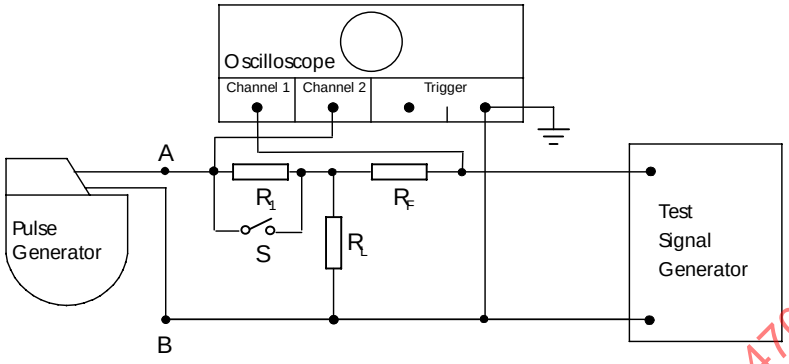


Figure 103 - Input impedance measurement

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 and R_F to point A. R_1 shall be chosen to have a resistance of the same order of magnitude as the expected INPUT IMPEDANCE of the IMPLANTABLE PULSE GENERATOR (e.g. 10 kΩ, 100 kΩ etc.), and R_1 shall be known to within ± 1 %. 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 shall be adjusted to zero, and the oscilloscope shall be adjusted to display several PULSES.

The switch, S, shall be closed, bypassing 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.

The switch, S, shall be opened and the test signal amplitude shall be re-adjusted until the IMPLANTABLE PULSE GENERATOR again just consistently either inhibits or triggers, as before.

The test signal amplitude shall be measured again and designated V_2.

The INPUT IMPEDANCE, Z_{in}, of the IMPLANTABLE PULSE GENERATOR shall be calculated according to the equations:

$$Z = \left[\frac{R_1 * V_1}{V_2 - V_1}\right] - 0{,}5$$

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

where R_S is the input impedance of channel 2 of the oscilloscope. The result shall be expressed in kilo-ohms (kΩ).

6.1.4 Measurement of ESCAPE INTERVAL *(t_e)*

Procedure: Use an oscilloscope and a triggerable test PULSE 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 through the series feed resistor (R_F) to point A. R_F shall be 100 kΩ ± 1 %.

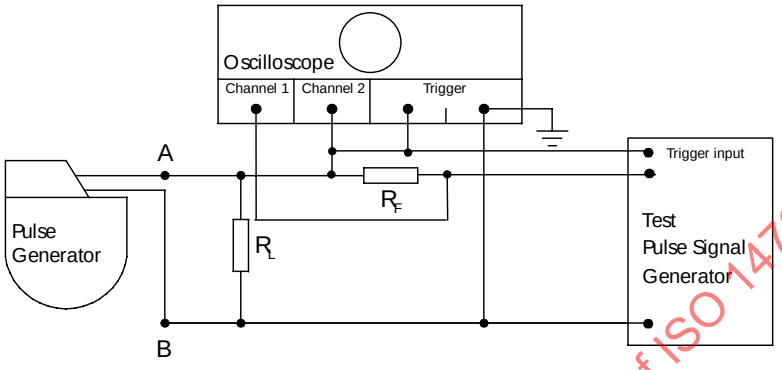


Figure 104 - Escape interval measurement

The test signal generator shall be adjusted until the amplitude of the test signal is approximately twice the positive SENSITIVITY as determined according to 6.1.2.

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.)

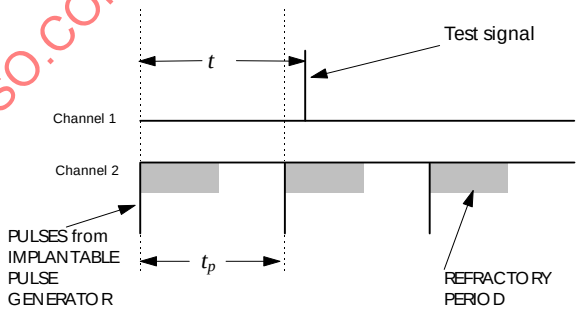


Figure 105 - Initial oscilloscope display, when measuring the ESCAPE INTERVAL

The 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, the display will be similar to that shown in Figure 107.

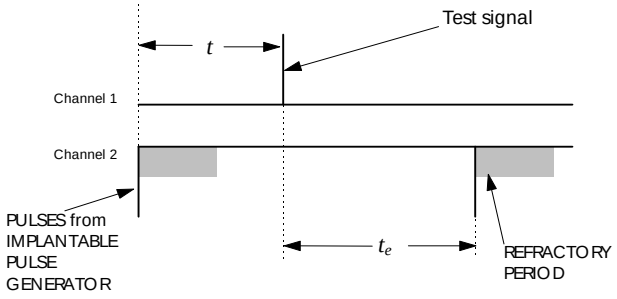


Figure 106 - Measurement of ESCAPE INTERVAL *(t_e)* in inhibited mode

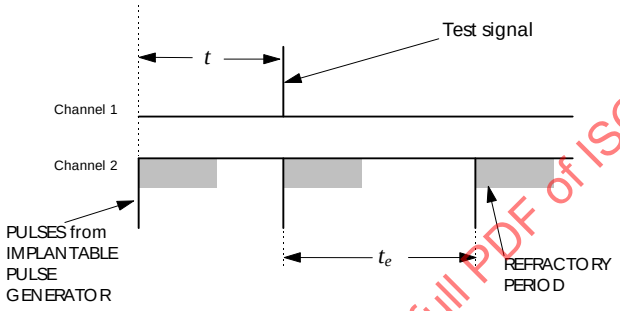


Figure 107 - Measurements of ESCAPE INTERVAL *(t_e)* in triggered (synchronised) mode

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).

6.1.5 *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 %.

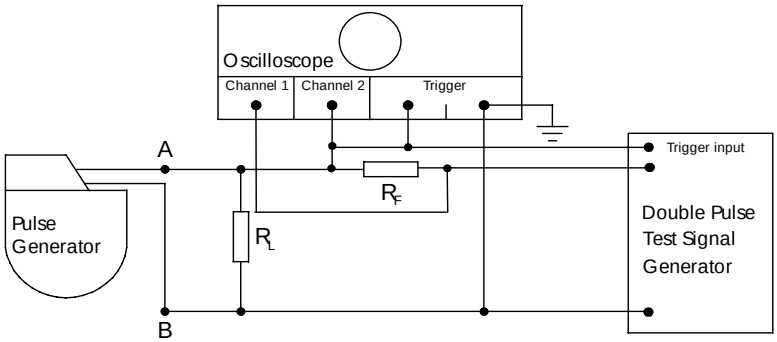


Figure 108 - Refractory period measurement

The test signal generator shall be adjusted until the amplitude of the test signal is approximately twice the positive

SENSITIVITY as determined in 6.1.2.

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].

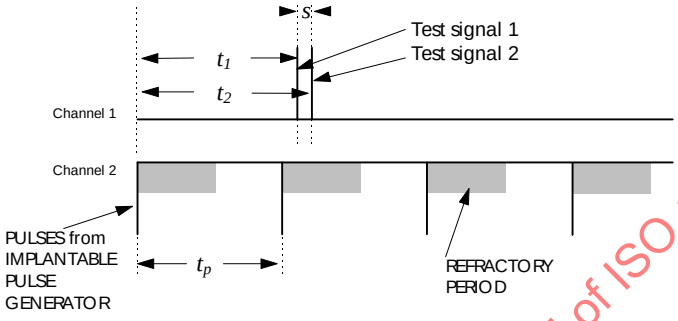


Figure 109 - Initial oscilloscope display when measuring sensing and pacing REFRACTORY PERIOD

The delay t_1 of the test signal shall be reduced (keeping *s* constant) until test signal 1 is sensed by the IMPLANTABLE PULSE GENERATOR.

Then, in the case of an inhibited IMPLANTABLE PULSE GENERATOR, test signal 1 causes inhibition of one PULSE from the IMPLANTABLE PULSE GENERATOR [see Figure 110]. Then keeping t_1 constant, t_2 shall be increased until 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).

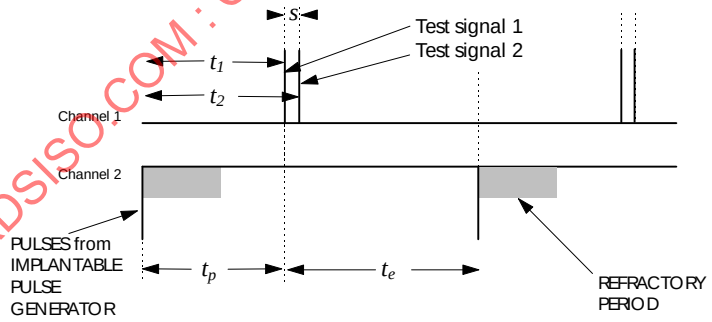


Figure 110 - Measurement of sensing refractory period in inhibited mode – A

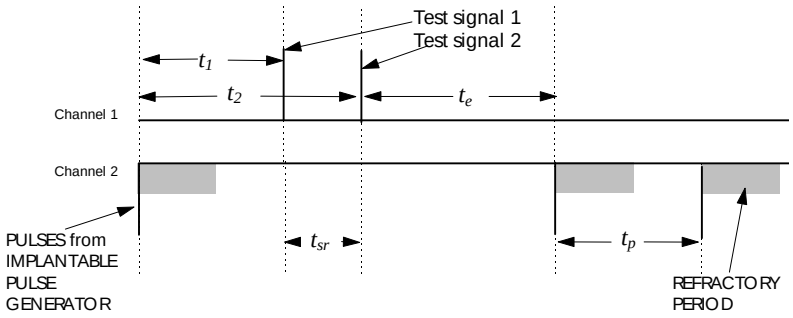


Figure 111 - Measurement of sensing REFRACTORY PERIOD in Inhibited mode – B

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.

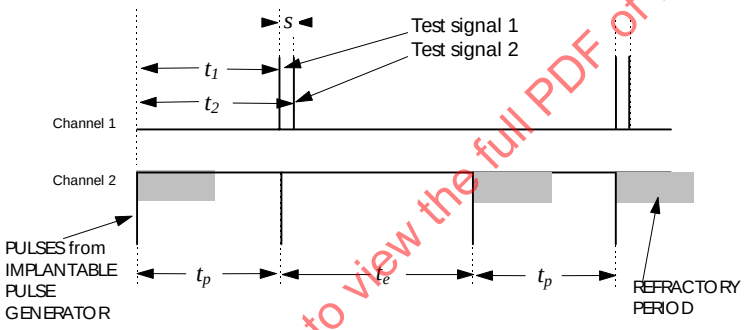


Figure 112 - Measurement of sensing refractory period in triggered (synchronous) mode – A

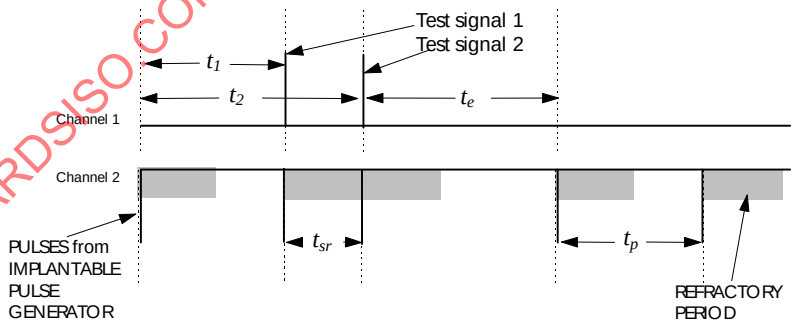


Figure 113 - Measurement of sensing REFRACTORY PERIOD in triggered (synchronous) mode – B

The interval t_2 -t_1 shall be measured. This corresponds to the sensing REFRACTORY PERIOD *(t_{sr})*.

The result shall be expressed in milliseconds (ms).

6.1.6 *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 positive SENSITIVITY as determined according to 6.1.2.

The test signal generator shall be adjusted to provide a delayed test PULSE, the delay *t* between being triggered and generating the test signal being 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).

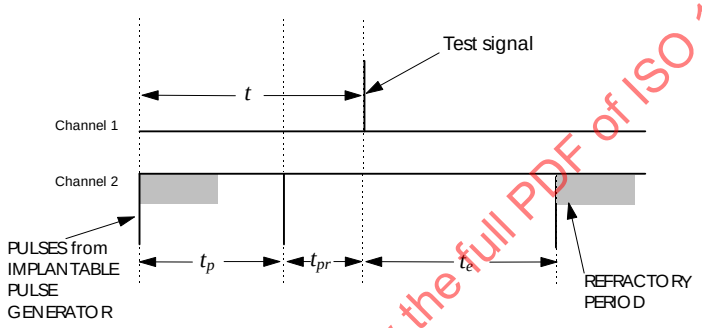


Figure 114 - Measurement of pacing REFRACTORY PERIOD in inhibited mode

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).

6.1.7 *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 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).

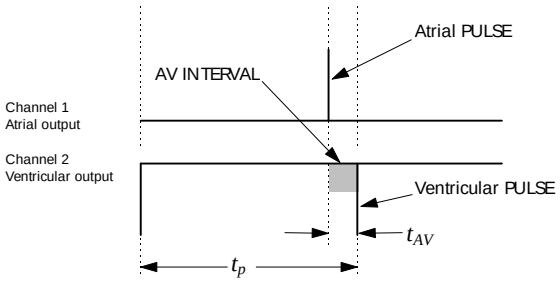


Figure 115 - Oscilloscope display when measuring AV interval

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

The result shall be expressed in milliseconds (ms).

6.1.8 *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 the series feed resistor (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 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 as determined in 6.1.2.

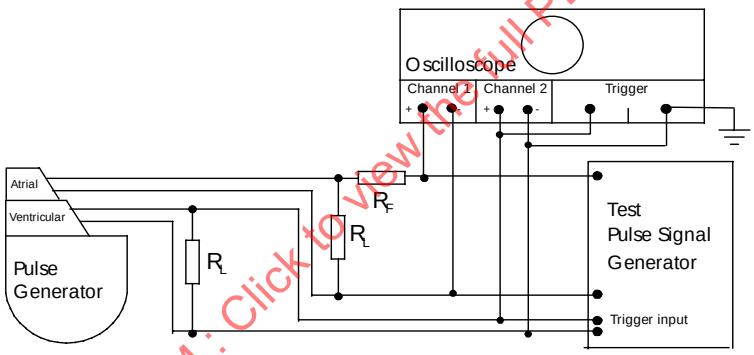


Figure 116 - Post ventricular atrial refractory period (PVARP) measurement

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.

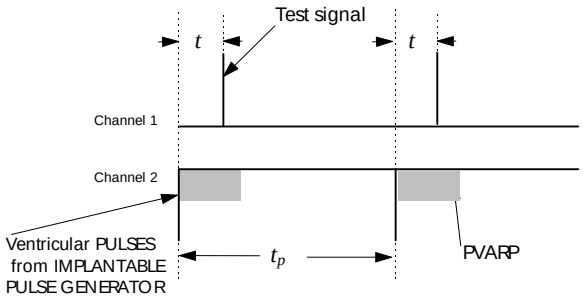
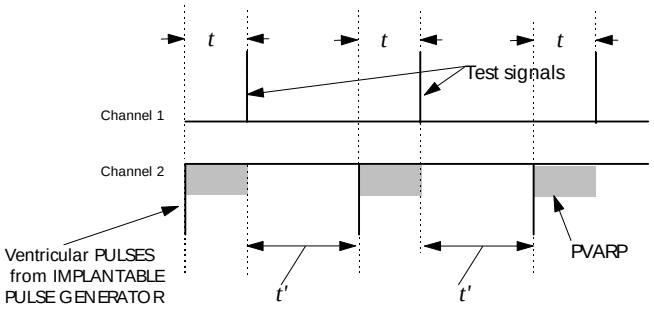


Figure 117 - Initial oscilloscope display when measuring PVARP

The delay t shall be slowly increased until the second PULSE depicted in Figure 117 is displaced to the left [see Figure

118].



NOTE The interval between the test pulse 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 AV INTERVAL and PVARP.

Figure 118 - Oscilloscope display when measuring PVARP

Measure t, which then corresponds to the post ventricular atrial REFRACTORY PERIOD (PVARP).

The result shall be expressed in milliseconds (ms).

6.1.9 *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 that provides a signal in the form defined by Figure F.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 100 kΩ ± 1 % feed resistor (R_F) to point C.

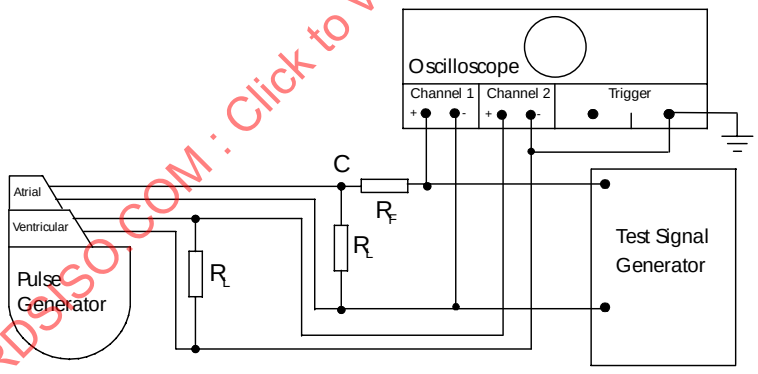


Figure 119 - AV interval after sensing measurement

Adjust the repetition interval t 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.)

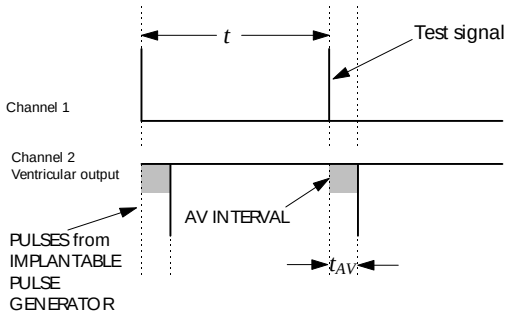


Figure 120 - Oscilloscope display when measuring the AV INTERVAL after sensing

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 electrical characteristics of a LEAD

The values of the electrical characteristics for the LEAD 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 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 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 for each test shall be within the limits given by Table 102.

Table 102 - Overall measurement accuracy limits

Measurement	Accuracy
LEAD CONDUCTOR RESISTANCE (6.2.1)	± 5 %
LEAD PACING IMPEDANCE (6.2.2)	± 15 %
LEAD SENSING IMPEDANCE (6.2.3)	± 15 %

6.2.1 *Measurement of the LEAD CONDUCTOR RESISTANCE (R_c)*

Procedure: The LEAD CONDUCTOR RESISTANCE (R_c) shall be measured by applying an ohm-meter between the lead connector TERMINAL and the ELECTRODE.

The results shall be expressed in ohms (Ω).

6.2.2 *Measurement of the LEAD PACING IMPEDANCE (Z_p)*

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

For a UNIPOLAR LEAD: The indifferent ELECTRODE of the pacing system shall be simulated by two metal plates of

titanium immersed in the test body. The diameter *(d)* of the lower plate shall be ≥ 50 mm. The diameter of the upper plate shall be 0,8 *d.* The separation between the plates shall be 1,2 *d*. Holes cut into the upper plate shall not reduce its surface area by more than 10 %.

The LEAD shall be inserted into the test body so that the electrode tip is approximately in the centre of the beaker. The test signal generator shall be connected through a 33 ± 5 % µF series film capacitor (C_F) to the LEAD, the metal plates and the oscilloscope as shown in Figure 121.

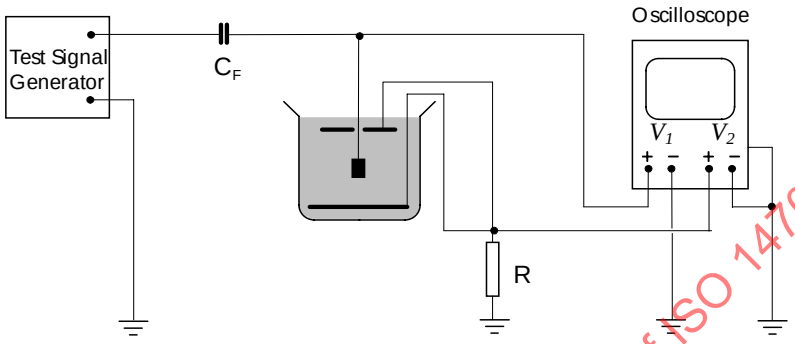


Figure 121 - Determination of the lead pacing impedance of a unipolar lead

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 the 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.

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 ± 5 % µF series film capacitor (C_F) to the LEAD and oscilloscope as shown in Figure 122.

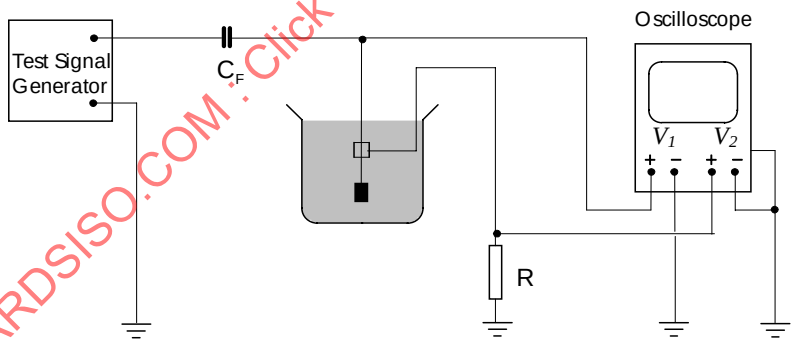


Figure 122 - Determination of the lead pacing impedance of a bipolar lead

Set the test signal generator to provide negative PULSES, 65 ± 5 per minute, amplitude 4 V ± 0,1 V and duration 0,5 ms ± 0,05 ms.

The lead current shall be determined by measuring the voltage drop across the 10 Ω ± 2 % resistor (R). 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).

6.2.3 *Measurement of the* LEAD SENSING IMPEDANCE *(Z_S)*

Procedure: Use the test body, an oscilloscope and a test signal generator, output impedance ≤ 1 kΩ, which provides a signal in the form defined by Figure F.103.

The test signal shall be injected from two feeding plates of titanium immersed in the test body. The diameter (*d*) of the lower feeding plate shall be ≥ *x* + 25 mm, where *x* is the linear separation (measured along the LEAD) of the distal extremities of the sensing ELECTRODES under test, with the restriction d ≤ 50 mm. The diameter of the upper feeding plate shall be 0,8 *d*. The separation between the feeding plates shall be 1,2 *d*. Holes cut into the upper feeding plate shall not reduce its surface area by more than 10 %.

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 the 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.

For a UNIPOLAR LEAD: 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 500 Ω ± 1 % resistor (R_F) and 33 ± 5 % µF series film capacitor (C_F) to the feeding plates, LEAD and oscilloscope as shown in Figure 123. The oscilloscope input shall be shunted with a switch and variable resistor (R).

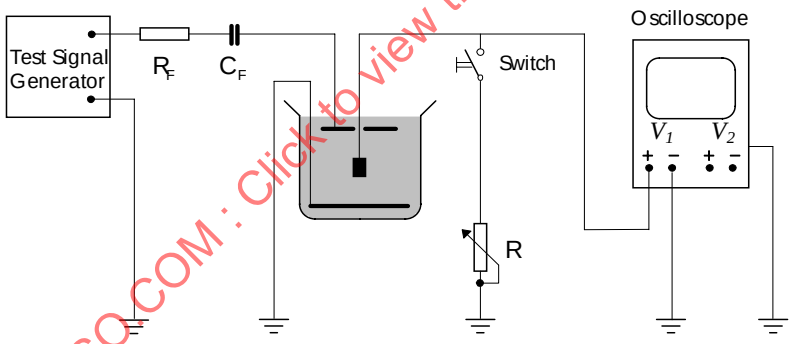


Figure 123 - Determination of the lead sensing impedance of a unipolar lead

For a BIPOLAR LEAD: The LEAD shall be inserted into the test body so that the ELECTRODES are equally separated from the feeding plates and any active ELECTRODE is at least 15 mm from any plate. The test signal generator shall be connected through a 500 Ω ± 1 % resistor (R_F) and 33 ± 5 % µF series film capacitor (C_F) to the feeding plates, LEAD and oscilloscope as shown in Figure 124. The oscilloscope input shall be shunted with a switch and variable resistor (R).

The switch shall be opened, and the test signal generator adjusted so that the peak voltage recorded on the oscilloscope is 10 mV ± 0,2 mV, the electrode tip sensing a negative polarity PULSE. Then the switch shall be closed and the resistor R adjusted until the amplitude of the leading edge portion of the signal measured by the oscilloscope is reduced to 5 mV ± 0,1 mV.

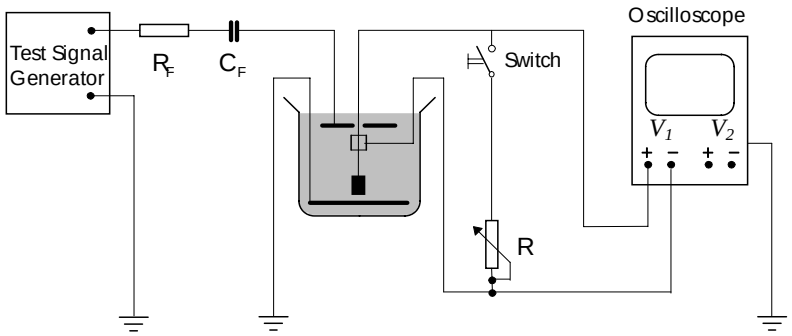


Figure 124 - Determination of the lead sensing impedance of a bipolar lead

Measure the resistance *R*. This then is equal to the LEAD SENSING IMPEDANCE (Z_s).

The result shall be expressed in ohms (Ω).

7 General arrangement of the packaging

This clause of Part 1 applies.

8 General markings for active implantable medical devices

This clause of Part 1 applies.

9 Markings on the sales packaging

This clause of Part 1 applies except as follows:

9.4

Additional note and subclauses:

NOTE Instead of using a description in words, the mode codes defined in Annex D 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:

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

b) If 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, automatically adjusted) as shipped.

d) The IMPLANTABLE PULSE GENERATOR's non-programmable 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).

e) A statement that the IMPLANTABLE PULSE GENERATOR is coated or uncoated.

f) The connector geometry (bore depths and diameters in millimetres), or provide a reference by symbols or MARKINGS defined in published connector standards.

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

Compliance shall be confirmed by inspection.

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

a) The configuration (UNIPOLAR LEAD, etc.).

b) The 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) the connector geometry (lengths and diameters in millimetres) or a reference by symbols or MARKINGS defined in published connector standards.

c) Any additional information and relevant characteristics necessary to identify the LEAD (e.g., anchoring mechanism). 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 Part 1 applies except as follows:

10.3

Additional note:

NOTE Removable stickers, which provide only 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 Part 1 applies. 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 devices, 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 characteristics as shipped, 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) The connector geometry, or provide a reference by symbols defined in published connector standards.

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

Compliance shall be confirmed by inspection.

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

a) The configuration (UNIPOLAR LEAD, etc.).

b) The 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) the connector geometry (lengths and diameters in millimetres) or a reference by symbols or MARKINGS defined in published connector standards.

Compliance shall be confirmed by inspection.

12 Construction of the non-reusable pack

This clause of Part 1 applies.

13 Markings on the active implantable medical device

This clause of Part 1 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) the ventricular TERMINAL shall be marked with a “V“;

2) the atrial TERMINAL shall be marked with an “A“;

3) a sensor TERMINAL shall be identified with an “S“, if present.

b) The most comprehensive pacing mode available (see Annex D).

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 device and the manufacturer can be unequivocally identified (particularly with regard to the MODEL DESIGNATION of the device and the year of manufacture). 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 radio-opaque figures or letters.

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

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

This clause of Part 1 applies except as follows:

14.2

Replacement:

When the ACTIVE IMPLANTABLE MEDICAL DEVICE is used as intended by the manufacturer, any part of the device intended to be in contact with body fluids shall cause no 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 measurement of 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 per ml greater than 5,0 µm and does not exceed 5 per ml 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 Part 1 applies.

16 Protection from harm to the patient caused by electricity

This clause of Part 1 applies except as follows:

16.2

Replacement:

Except for its intended function, an IMPLANTABLE PULSE GENERATOR shall be electrically neutral when in use. No d.c. leakage current of more than 0,1 µA shall occur in any of the current pathways.

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

NOTE This can be implemented by a four element low pass RC filter with the elements built from 1 MΩ resistors and 10 µF metalised polypropylene capacitors. Then the input resistance of the d.c. voltmeter should be ≥ 400 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].

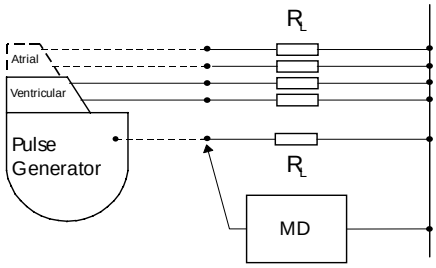


Figure 125 - Test set-up for measurement of electrical neutrality

Measure the average direct voltage across each load resistor with the measuring device, see Figure 125. Steady state conditions shall be reached before the measurement is made.

Compliance shall be confirmed if the absolute potential difference across each resistor R_L is less than 50 µV for any 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 (run-away protection). The PULSE rate limit shall be declared by the manufacturer in the accompanying documents [see 28.8.2 e)].

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

17 Protection from harm to the patient caused by heat

This clause of Part 1 applies.

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

This clause of Part 1 applies.

19 Protection from unintended effects caused by the device

This clause of Part 1 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 PROLONGED SERVICE PERIOD shall be determined under the conditions specified by the manufacturer but shall be at least three months [see28.19 e)].

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 consistent 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	0,5 ms
BASIC RATE	70 min^{-1}
Percent pacing	100 %
Pacing load	500 Ω ± 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 utilised until RECOMMENDED REPLACEMENT TIME (with the IMPLANTABLE PULSE GENERATOR operating under the conditions specified in 19.2.1) to the capacity that can be utilised 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

This clause of Part 1 applies.

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

This clause of Part 1 applies except as follows:

21.2

Replacement:

21.2 The IMPLANTABLE PULSE GENERATOR shall be designed so that stray, high frequency current from surgical equipment (surgical diathermy) flowing through the patient shall not permanently affect the device, provided the IMPLANTABLE PULSE GENERATOR does not lie directly in the path between cutting and return (HF earth) electrodes. [See also requirement for warning advice, 28.13.]

Test: Use a rf test signal generator, output impedance 50 Ω. The test signal frequency shall be 500 kHz and the open loop test signal amplitude 20 V_{pp}.

The IMPLANTABLE PULSE GENERATOR shall be set for asynchronous pacing at 60 beats min^{-1}. Each input or output TERMINAL shall be connected through individual 100 Ω resistors (R) to the active TERMINAL of the signal generator [see Figure 126]. The case of the IMPLANTABLE PULSE GENERATOR shall be connected directly to the other TERMINAL of the signal generator, unless the case is covered with an insulating material when the IMPLANTABLE PULSE GENERATOR's case shall be immersed in a bath of 9 g/l saline held in a metal container and the metal container shall be connected directly to the other TERMINAL of the signal generator.

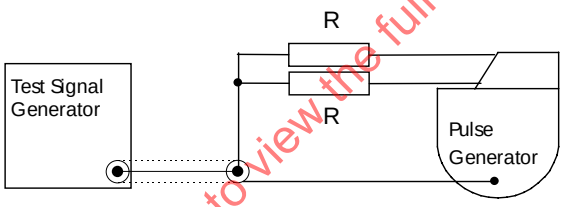


Figure 126 - Test set-up for proof protection from high frequency currents caused by surgical equipment

Apply the test signal in ten bursts each for a duration of 1 s, allowing a recovery period of 5 s between bursts.

Compliance shall be confirmed if after completing the test procedure and reactivating the IMPLANTABLE PULSE GENERATOR, the values for the IMPLANTABLE PULSE GENERATOR listed in 28.8.2 d) conform with the values stated in the manufacturer's original specification.

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

This clause of Part 1 applies.

23 Protection of the active implantable medical device from mechanical forces

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) test 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 with 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.

Test 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, 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 one minute then relieved.

The tensile load application shall be repeated for each combination of distal end tip and LEAD connector pin.

NOTE This may be accomplished by using multiple LEADS as the test sample.

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

The insulation integrity of each LEAD shall be verified by immersing the outer covering, other than within 20 mm of 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 one hour before proceeding. The test specimen(s) 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 Care must be taken to ensure that the exposed conductive surfaces are electrically isolated from the saline bath during this procedure.

The insulation shall be then 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 potential 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

- 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,
- the continuity measurements comply with the manufacturer's specifications,
- 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 each unique uniform flexible LEAD segment. Test 2 shall be applied to the segment of the LEAD where the LEAD joins the connector body.

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

Test 1: Use 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].

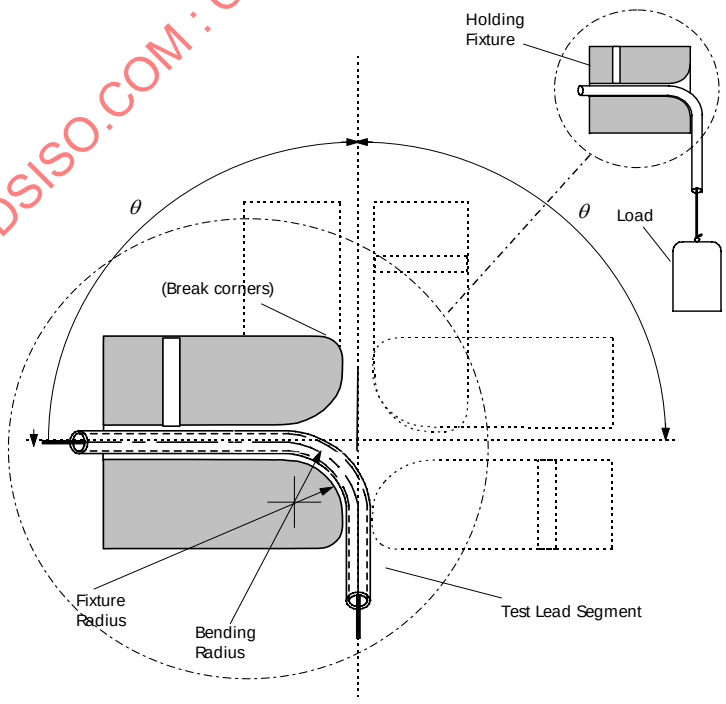


Figure 127 - Conductor flex test fixture

The fixture shall be mounted in a machine that can oscillate the fixture $\theta = 90° \, {}^{+0}_{-5^0}$ from the vertical and forces the test segment to flex in the bell mouth of the fixture. The lead test segment shall be mounted to hang vertically under gravity in the holding fixture, oriented in the worst case test condition when the test segment allows multiple orientations.

A load sufficient to assure that the centre line of the test segment conforms to the bending radius shall be attached to the lower end of a thin, flexible line (cord) strung through the test segment. 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.

The fixture shall be oscillated through an angle $\theta = 90° \, {}^{+0}_{-5^0}$ 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 minimise 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 per 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 to 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 per the manufacturer's connector specification if other connector systems are used. Except for the cavity depth and rounding, the test cavity dimensions shall be per Figure 2 of ISO 5841-3 (IS-1), or Figure 4 of ISO 11318 (DF-1), or per the manufacturer's specifications if another connector system is used.

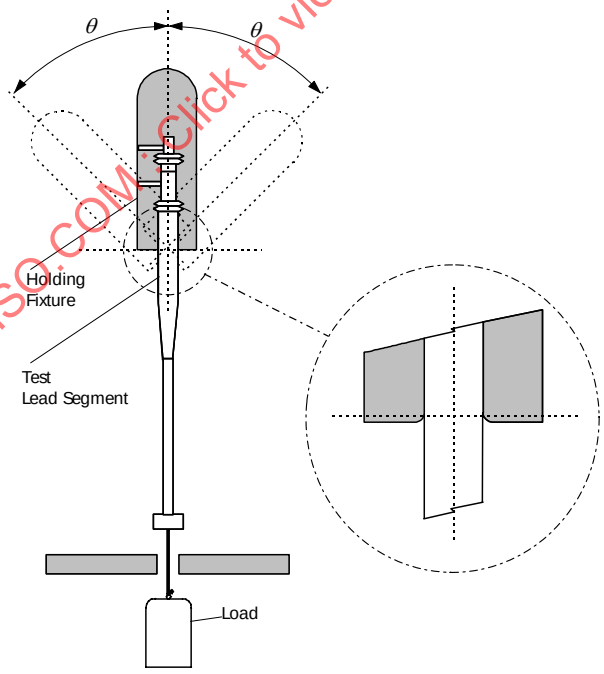


Figure 128 - Connector flex test fixture

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 shall be no relative motion between the conductor and the tubing at the point of attachment. The load (including the attachment mechanism) shall be 100 g ± 5 g.

The holding fixture shall be then oscillated θ = 45° ± 2° each side of vertical at a rate of approximately 2 Hz for a minimum of 82 000 cycles.

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 per 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].

Additional subclause:

23.7 The IMPLANTABLE PULSE GENERATOR shall be constructed so that minor shocks caused bymanhandling during the implant procedure do not damage the device.

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

a) shock shape: half sine or haversine;

b) 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 (a 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 with 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 Part 1 applies.

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

This clause of Part 1 applies.

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

This clause of Part 1 applies.

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

This clause of Part 1 applies except as follows:

27.1

Replacement:

Implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall not cause any HARM because of susceptibility to electrical influences due to external electromagnetic fields, whether through malfunction of the device, damage to the device, heating of the device, or by causing local increase of induced electrical current density within the patient.

Compliance shall be confirmed if after performing the appropriate procedures described in 27.2 to 27.8, the values of the characteristics listed in 28.8.2 d) when measured [see 6.1] are as stated by the manufacturer of the IMPLANTABLE PULSE GENERATOR.

All protection requirements shall be met for all settings of the IMPLANTABLE PULSE GENERATOR, except in 27.4 and 27.5.1 where the sensitivity settings the manufacturer specifies according to 28.22.1 shall be excluded.

NOTE This does not mean that all combinations of settings are tested but at least the setting to which the device is pre-set by the manufacturer should be tested completely.

27.2

Replacement:

27.2 The IMPLANTABLE PULSE GENERATOR shall be constructed so that ambient electromagnetic fields are unlikely to cause hazardous local increases of induced electrical current density within the patient.

NOTE The following test is intended to address the compatibility of the intracardiac signal sensing**.** Any additional physiological sensors may be turned off during testing unless otherwise specified**.** Tests for these additional sensors are under consideration.

Test equipment: Use the tissue equivalent interface circuit defined by Figure G.101; the low pass filter defined by Figure G.103; two oscilloscopes, input impedance nominal 1 MΩ; and test signal generators, output impedance 50 Ω.

NOTE Care must be taken that the test signal generator does not itself produce low frequency components [see Annex H].

Test signal: Two forms of test signal shall be used.

Test signal 1 shall be a sinusoidal signal of 1 V peak-to-peak amplitude. The frequency, shall be either swept over the range 16,6 Hz to 20 kHz at a rate of one decade per minute, or applied at a minimum of four distinct, well-spaced frequencies per decade between 16,6 Hz and 20 kHz with an evenly distributed dwell time of at least 60 s per decade. Test signal 2 shall be a sinusoidal carrier signal, frequency 500 kHz, with continuous amplitude modulation at 130 Hz (double sideband with carrier) [see Figure 129]. The maximum peak-to-peak voltage of the modulated signal shall be 2 V. The modulation index *(M)* shall be 95 percent, where:

$$M = \frac{V_{pp} - v}{V_{pp}} * 100$$

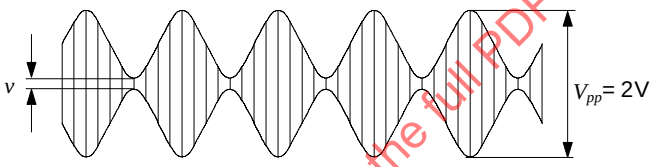


Figure 129 - Test signal 2

Test procedure: The test signal generator shall be connected through input C of the interface circuit as shown in Figure 130. The test signal shall be measured on the oscilloscope connected to monitoring point D.

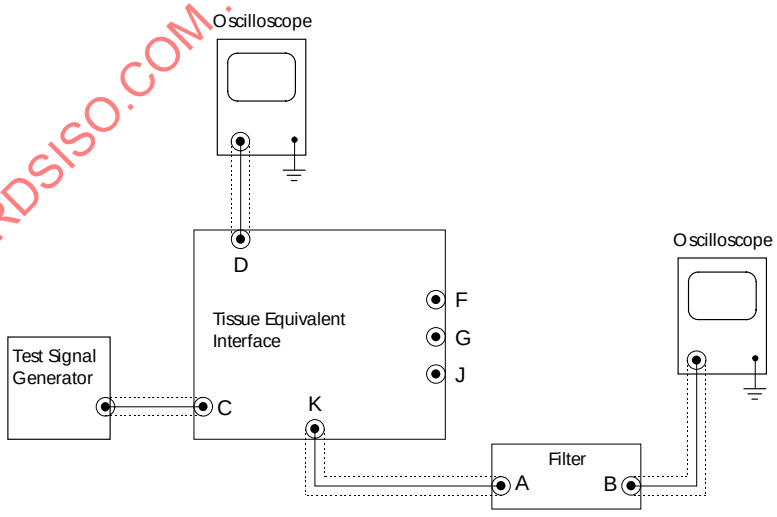


Figure 130 - Test set-up for measurement of induced current flow

The induced electrical current is measured by the oscilloscope connected to test point K through the low pass filter (see Figure G.103) as shown in Figure 103. When the test signal 1 is being used, the low-pass filter shall be switched to bypass mode.

The capacitor C_x of the interface circuit [see Figure G.101] shall be bypassed unless required to eliminate spurious low frequency signals produced by the interference signal generator [see Annex H].

NOTE It is not mandatory that a current measurement be made in the period from 10 ms preceding a stimulation PULSE to 150 ms after the stimulation PULSE.

The IMPLANTABLE PULSE GENERATOR shall be categorised into one or more of four groups as appropriate:

- single channel unipolar IMPLANTABLE PULSE GENERATORS shall be Group a);
- multichannel unipolar IMPLANTABLE PULSE GENERATORS shall be Group b);
- single channel bipolar IMPLANTABLE PULSE GENERATORS shall be Group c);
- multichannel bipolar IMPLANTABLE PULSE GENERATORS shall be Group d).

NOTE A bipolar channel should be tested in unipolar and/or bipolar mode according to the programmability of the device and should be changed where applicable.

Any TERMINAL of the IMPLANTABLE PULSE GENERATOR not being tested shall be connected to the channel under test through a resistor of value *R* between 10 kΩ and 100 kΩ as specified by the manufacturer.

Group a) The IMPLANTABLE PULSE GENERATOR shall be connected to the coupled outputs F and G of the tissue equivalent interface [as shown in Figure 131], with output J connected to the case.

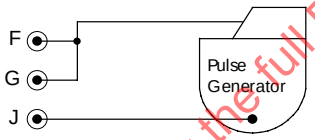


Figure 131 - Connection to a single channel unipolar pulse generator

Group b) Every input/output of the IMPLANTABLE PULSE GENERATOR shall be connected in turn to the coupled outputs F and G of the tissue equivalent interface [as shown in Figure 132], with output J connected to the case.

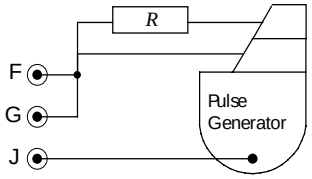


Figure 132 - Connection to a multichannel unipolar pulse generator

Group c) Common mode performance shall be tested with the IMPLANTABLE PULSE GENERATOR connected to the outputs F and G of the tissue equivalent interface [as shown in Figure 133], with output J connected to the case.

Differential mode performance shall be tested using the test signals reduced to one tenth amplitude. The IMPLANTABLE PULSE GENERATOR shall be connected between the coupled outputs F and G and the output J of the tissue equivalent interface [as shown in Figure 134].

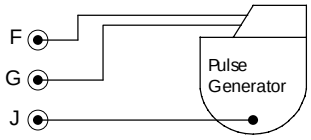


Figure 133 - Common mode connection to single channel bipolar pulse generator

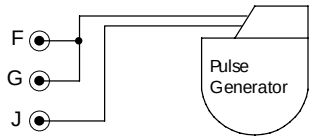


Figure 134 - Differential mode connection to single channel bipolar pulse generator

Group d) Common mode performance shall be tested by every input/output of the IMPLANTABLE PULSE GENERATOR being connected in turn to outputs F and G of the tissue equivalent interface [as shown in Figure 135], with output J connected to the case.

Differential mode performance shall be tested using the test signals reduced to one tenth amplitude. Every input/output of the IMPLANTABLE PULSE GENERATOR shall be connected in turn between the coupled outputs F and G and the output J of the tissue equivalent interface [as shown in Figure 136].

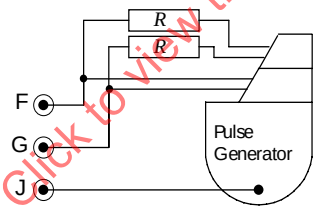


Figure 135 - Common mode connection to multichannel bipolar pulse generator

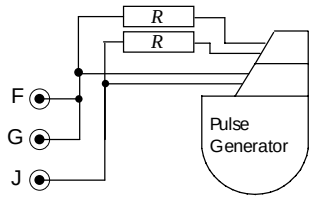


Figure 136 - Differential mode connection to multichannel bipolar pulse generator

The current (r.m.s) shall be determined by dividing the peak-to-peak voltage reading on the oscilloscope, connected to test point K by 232 Ω.

Compliance shall be confirmed if

- for test signal 1 the measured current is not greater than that specified in Table 104, and
- for test signal 2 the current at the modulating frequency of 130 Hz shall be not greater than 50 µA rms.

Table 104 - Spurious injection current limits

f	Current rms
20 Hz ≤ *f* ≤ 1 kHz	50 μA
1 kHz ≤ *f* ≤ 20 kHz	50 μA ∗ *f*⁄1kHz

Additional subclauses:

27.3 The IMPLANTABLE PULSE GENERATOR shall be constructed so that ambient continuous wave electromagnetic fields are unlikely to cause malfunction of the IMPLANTABLE PULSE GENERATOR that persists after the removal of the electromagnetic field.

NOTE The following test is intended to address the compatibility of the intracardiac signal sensing**.** Any additional physiological SENSORS may be turned off during testing unless otherwise specified**.** Tests for these additional SENSORS are under consideration.

Test equipment: Use the tissue equivalent interface circuit defined by Figure G.102; two oscilloscopes, input impedance nominal 1 MΩ; and a test signal generator, output impedance 50 Ω.

Test signal: The test signal shall be a continuous sinusoidal signal that shall be either, swept over the frequency range of 16,6 Hz to 140 kHz at a rate of one decade per minute, or, applied at a minimum of four distinct, well-spaced frequencies per decade between 16,6 Hz and 140 kHz with an evenly distributed dwell time of at least 60 s per decade. For frequencies, *f*, between 16,6 Hz and 20 kHz, the peak-to-peak amplitude, V_{pp}, shall be 1 V. For *f* between 20 kHz and 140 kHz, V_{pp} shall be 1 V increased by a factor *m*, where

$$m = \frac{f}{20\ kHz}$$

Test procedure: The test signal generator shall be connected through input C of the interface circuit as shown in Figure 137. The test signal shall be measured on the oscilloscope connected to monitoring point D. The operation of the IMPLANTABLE PULSE GENERATOR is recorded on the oscilloscope connected to monitoring point K.

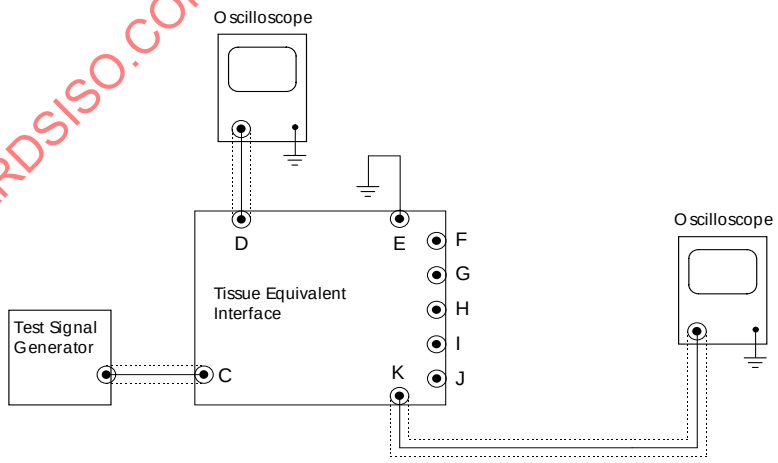


Figure 137 - Test set-up to check for induced malfunction

The IMPLANTABLE PULSE GENERATOR shall be categorised into one or more of four groups as appropriate:

- single channel unipolar IMPLANTABLE PULSE GENERATORS shall be Group a);
- multichannel unipolar IMPLANTABLE PULSE GENERATORS shall be Group b);
- single channel bipolar IMPLANTABLE PULSE GENERATORS shall be Group c);
- multichannel bipolar IMPLANTABLE PULSE GENERATORS shall be Group d).

NOTE A bipolar channel should be tested in unipolar and/or bipolar mode according to the programmability of the device and should be changed where applicable.

Group a) The IMPLANTABLE PULSE GENERATOR shall be connected to the coupled outputs H and I of the tissue equivalent interface [as shown in Figure 138], with output J connected to the case.

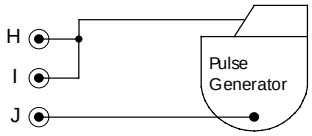


Figure 138 - Connection to a single channel unipolar pulse generator

Group b) Every input/output of the IMPLANTABLE PULSE GENERATOR shall be connected in parallel to the paired, coupled outputs F and G and H and I of the tissue equivalent interface [as shown in Figure 139], with output J connected to the case.

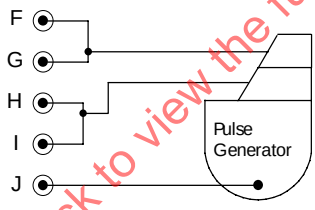


Figure 139 - Connection to a multichannel unipolar pulse generator

Group c) Common mode performance shall be tested with the IMPLANTABLE PULSE GENERATOR connected to the outputs H and I of the tissue equivalent interface [as shown in Figure 140], with output J connected to the case.

Differential mode performance shall be tested using test signal reduced to one tenth amplitude. The IMPLANTABLE PULSE GENERATOR shall be connected to the coupled outputs H and I and the output J of the tissue equivalent interface [as shown in Figure 141].

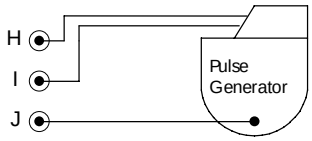


Figure 140 - Common mode connection to a single channel bipolar pulse generator

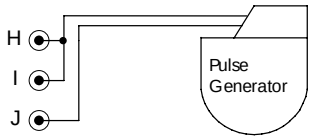


Figure 141 - Differential mode connection to a single channel bipolar pulse generator

Group d) Common mode performance shall be tested by every input/output of the IMPLANTABLE PULSE GENERATOR being connected to the outputs F, G, H and I of the tissue equivalent interface [as shown in Figure 142], with output J connected to the case.

Differential mode performance shall be tested using test signal reduced to one tenth amplitude.

Every input/output of the IMPLANTABLE PULSE GENERATOR shall be connected in turn between the coupled outputs H and I and the output J of the tissue equivalent interface [as shown in Figure 143]. Any TERMINAL of the IMPLANTABLE PULSE GENERATOR not being tested shall be connected to the equivalent TERMINAL of the channel under test through a resistor of value *R* between 10 kΩ and 100 kΩ.

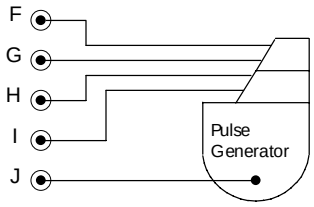


Figure 142 - Common mode connection to a multi channel bipolar pulse generator

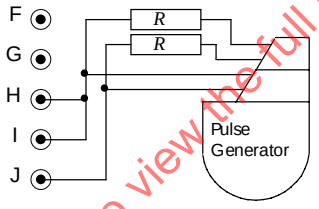


Figure 143 - Differential mode connection to a multi channel bipolar pulse generator

Compliance shall be confirmed if after application of the specified test signal, the IMPLANTABLE PULSE GENERATOR functions as prior to the test without further adjustment.

27.4 The IMPLANTABLE PULSE GENERATOR shall be constructed so that ambient continuous wave electromagnetic fields are unlikely to cause malfunction of the IMPLANTABLE PULSE GENERATOR during the exposure to the electromagnetic field.

NOTE The following test is intended to address the compatibility of the intracardiac signal sensing**.** Any additional physiological SENSORS may be turned off during testing unless otherwise specified**.** Tests for these additional SENSORS are under consideration.

Test equipment: Use the tissue equivalent interface circuit defined by Figure G.102; two oscilloscopes, input impedance nominal 1 MΩ; an inhibition signal generator, output impedance not greater than 1 kΩ which provides a simulated heart signal in the form defined by Figure F.103; and a test signal generator, output impedance 50 Ω.

Test signal: The test signal shall be a continuous sinusoidal signal applied at a minimum of four distinct, well-spaced frequencies per decade between 16,6 Hz to 167 kHz. At each selected frequency the test signal shall be slowly increased from zero to a maximum of 1 V peak-to-peak.

Test procedure: The test signal generator shall be connected through input C of the interface circuit as shown in Figure 144. The test signal shall be measured on the oscilloscope connected to monitoring point D of the interface circuit.

The operation of the IMPLANTABLE PULSE GENERATOR is recorded on the oscilloscope connected to monitoring point K.

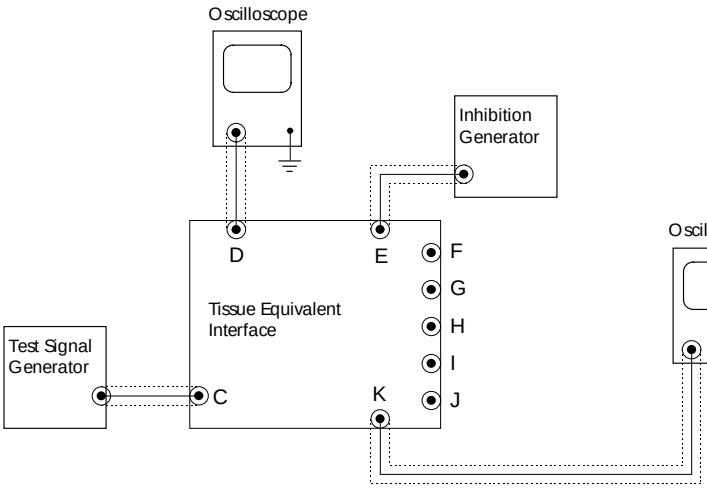


Figure 144 - Test set-up to characterise performance while subject to interference

The IMPLANTABLE PULSE GENERATOR shall be set to its highest sensitivity (most sensitive setting), unless the labelling of the IMPLANTABLE PULSE GENERATOR includes a clear warning that for given settings the IMPLANTABLE PULSE GENERATOR will be influenced by the test signal, in which case the IMPLANTABLE PULSE GENERATOR shall be set to its highest sensitivity for which the manufacturer claims compliance with this standard [see 28.22.1]. Other parameters shall be programmed to values that enable the person conducting the test to observe the point when the test signal is detected by the IMPLANTABLE PULSE GENERATOR.

The test shall be performed with the IMPLANTABLE PULSE GENERATOR in the pacing mode and in a synchronised mode when it is not possible to distinguish between uninfluenced mode and interference mode of operation.

The IMPLANTABLE PULSE GENERATOR shall be set in synchronised mode by a signal from the inhibition signal generator connected to test point E of the interface [as shown in Figure 144]. The amplitude shall be set at twice the value that just synchronises the IMPLANTABLE PULSE GENERATOR under test [see 6.1.2] and the interval shall be 800 ms or 90 % of the programmed BASIC PULSE INTERVAL as shipped, whichever is the shorter.

NOTE When the IMPLANTABLE PULSE GENERATOR is synchronised by the inhibition signal generator, this should be set without the test signal being applied.

Differential mode performance shall be tested using test signal reduced to one tenth amplitude.

The IMPLANTABLE PULSE GENERATOR shall be categorised into one of four groups as required by 27.3 and connected to the tissue equivalent interface according to Figure 138, Figure 139, Figure 140 and Figure 141, or Figure 142 and Figure 143, as applicable.

Compliance shall be confirmed if while the test conditions are varied as required, the IMPLANTABLE PULSE GENERATOR continues to operate as set or in its interference mode as characterised by the manufacturer.

If for some value of the test conditions, the IMPLANTABLE PULSE GENERATOR changes from its set mode to its interference mode, or vice versa, then no pause longer than twice the pre-set interval shall occur unless the change of mode is completed within a change by a factor of two in voltage of the test signal.

27.5 The IMPLANTABLE PULSE GENERATOR shall be constructed so that commonly encountered modulated electromagnetic fields are unlikely to change the therapeutic behaviour of the IMPLANTABLE PULSE GENERATOR.

NOTE The following test is intended to address the compatibility of the intracardiac signal sensing**.** Any additional physiological SENSORS may be turned off during testing unless otherwise specified**.** Tests for these additional SENSORS are under consideration.

The IMPLANTABLE PULSE GENERATOR shall be set to its most sensitive setting in both unipolar and bipolar modes for which the manufacturer claims compliance with this standard [see 28.22.1]. For frequencies above 1 kHz the least sensitive settings acceptable for compliance are 2,0 mV sensitivity in the unipolar sensing mode and 0,3 mV sensitivity in the bipolar sensing mode, or the SENSITIVITY as shipped, whichever is the more sensitive.

The tests shall be performed with the IMPLANTABLE PULSE GENERATOR in the pacing mode and in a synchronised mode when it is not possible to distinguish between uninfluenced mode and interference mode of operation. The IMPLANTABLE PULSE GENERATOR shall be set in synchronised mode by a signal from the inhibition signal generator. The amplitude shall be set at twice the value that just synchronises the IMPLANTABLE PULSE GENERATOR under test [see 6.1.2] and the interval shall be 800 ms or 90 % of the programmed BASIC PULSE INTERVAL as shipped, whichever is the shorter.

27.5.1 *Immunity from signals in the range 16,6 Hz - 150 kHz*

Test equipment: Use the tissue equivalent interface circuit defined by Figure G.102; two oscilloscopes, input impedance nominal 1 MΩ, < 30 pF, the oscilloscope to be connected to output D of the interface circuit having a bandwidth of at least 20 MHz; an inhibition signal generator, output impedance not greater than 1 kΩ, which provides a signal of the form defined by Figure F.103; and a test signal generator, output impedance of 50 Ω.

Test signal: The test signal shall be a modulated signal, carrier frequency, *f*, between 16,6 Hz and 150 kHz. The carrier shall be switched at zero amplitude 100 ms on, 600 ms off [see Figure 145]. The burst shall start and terminate at a zero crossings of the carrier and only complete carrier cycles shall be used.

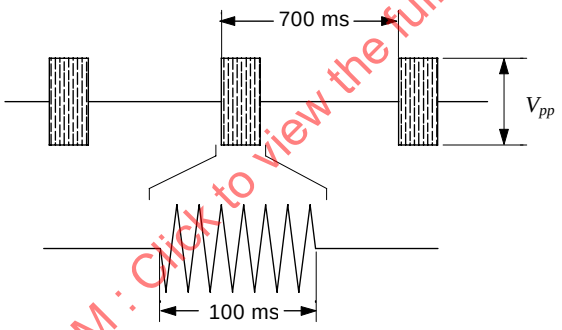


Figure 145 - Test signal for frequencies in the range 16,6 Hz - 150 kHz

The amplitude of the test signal (V_{pp}) is defined as the peak to peak amplitude of the open circuit voltage driving the IMPLANTABLE PULSE GENERATOR at the outputs of the tissue interface. The amplitude of the test signal, V_{pp}, shall be a function of the carrier frequency *f*, as defined by Table 105.

Table 105 - Peak to peak amplitudes V_{pp} in the range 16,6 Hz to 150 kHz

f	V_{pp}
20 Hz ≤ *f* ≤ 1 kHz	2 mV
1 kHz ≤ *f* ≤ 3 kHz	2 mV ∗ (*f* /1 kHz)^2
3 kHz ≤ *f* ≤ 150 kHz	6 mV ∗ *f* /1 kHz

Test procedure: The test signal generator shall be connected to the tissue equivalent interface circuit through input C as shown in Figure 144. The test signal shall be measured on the oscilloscope connected to monitoring point D. The operation of the IMPLANTABLE PULSE GENERATOR shall be recorded on the oscilloscope connected to monitoring point K.

The capacitor Cx of the interface circuit [see Figure G.102] shall be bypassed unless required to eliminate spurious

low frequency signals produced by the interference signal generator [see Annex H].

The modulated signal shall be applied at a minimum of four distinct, well-spaced frequencies per decade between 16,6 Hz and 150 kHz with an evenly distributed dwell time of at least 60 s per decade. (V_{pp} can be measured directly at connector D of the tissue interface.)

NOTE 1 Care must be taken that the interference generator does not itself produce low frequency components.

NOTE 2 When the IMPLANTABLE PULSE GENERATOR is synchronised by the inhibition signal generator, this should be set without the modulated test signal being applied.

If the IMPLANTABLE PULSE GENERATOR under test is a multi channel device, it shall be programmed to minimise the occurrence of possible cross-talk between channels.

Differential mode performance shall be tested using test signal reduced to one tenth amplitude. The IMPLANTABLE PULSE GENERATOR shall be categorised into one of four groups as required by 27.3 and connected to the tissue equivalent interface according to Figure 138, Figure 139, Figure 140 and Figure 141, or Figure 142 and Figure 143, as applicable.

Compliance shall be confirmed if the IMPLANTABLE PULSE GENERATOR at all times functions in its set mode irrespective of the application of the required modulated signal.

For those sensitivity settings of the IMPLANTABLE PULSE GENERATOR for frequencies up to 1kHz at which a change of pacing pattern occurs, compliance shall be confirmed if an appropriate warning is provided in the accompanying documentation [see 28.22.1].

27.5.2 *Immunity from signals in the range 150 kHz - 10 MHz*

Test equipment: Use the test equipment defined by 27.5.1

Test signal: The test signal shall be a modulated signal, carrier frequency, *f*, between 150 kHz and 10 MHz**.** The carrier shall be amplitude modulated with a 130 Hz sinusoidal wave to create modulation bursts of 100 ms duration. The burst to burst interval, *T*, shall be measured leading to leading edge [see Figure 146].

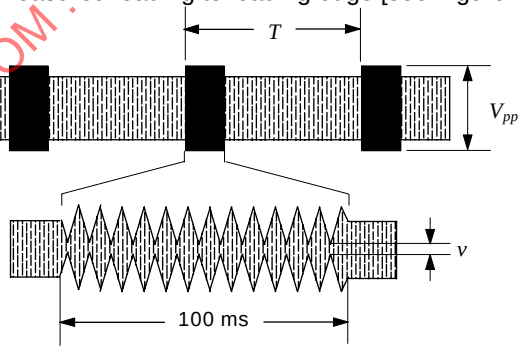


Figure 146 - Test signal for frequencies 150 kHz - 450 MHz

The modulation bursts shall start and terminate at zero crossings of the modulation signal (thus the envelope starts and terminates at a value of 100 %). The burst counts 13 complete modulation cycles. The modulation index shall *M* shall be 95 %, where:

$$M = \frac{V_{pp} - v}{V_{pp}} * 100$$

The burst to burst interval (T) of the test signal shall be set to 700 ms ± 50 ms.

The amplitude of the test signal (V_{pp}) is defined as the peak to peak amplitude of the open circuit voltage driving the IMPLANTABLE PULSE GENERATOR at the outputs of the tissue interface. The amplitude of the test signal, V_{pp}, shall be a function of the carrier frequency f, as defined by Table 106.

Table 106 - Peak to peak amplitudes V_{pp} in the range 150 kHz to 10 MHz

f	V_{pp}
150 kHz ≤ *f* ≤ 167 kHz	6 mV ∗ *f* /1 kHz
167 kHz ≤ *f* ≤ 1 MHz	1 V
1 MHz ≤ *f* ≤ 10 MHz	1 V ∗ *f* /1 MHz

Test procedure: The modulated signal shall be applied at a minimum of four distinct, well-spaced frequencies per decade between 150 kHz and 10 MHz with an evenly distributed dwell time of at least 60 s per decade. (V_{pp} can be measured directly at connector D of the tissue interface.) The test configuration and procedure shall be otherwise as required by 27.5.1.

Compliance shall be confirmed if the IMPLANTABLE PULSE GENERATOR at all times functions in its set mode irrespective of the application of the required modulated signal.

27.5.3 *Immunity from signals in the range 10 MHz - 450 MHz*

Test equipment: Use the tissue injection network defined by Figure G.104; an oscilloscope, #1, input impedance 50 Ω, accuracy of ± 10 % within a bandwidth of at least 450 MHz; an oscilloscope,#2, input impedance nominal 1 MΩ, an inhibition signal generator, output impedance not greater than 1 kΩ, which provides a signal of the form defined by Figure F.103; a test signal generator, output impedance 50 Ω.

Test procedure: The test signal generator shall be connected to the injection network through input C as shown in Figure 147. The test signal generator shall be adjusted so that the test signal amplitude measured on the oscilloscope #1 connected to monitoring point D (V_{osc}) when multiplied by the calibration factor for the injection network, determined according to the method of Annex I, is equal to the required test signal amplitude, V_{pp}.

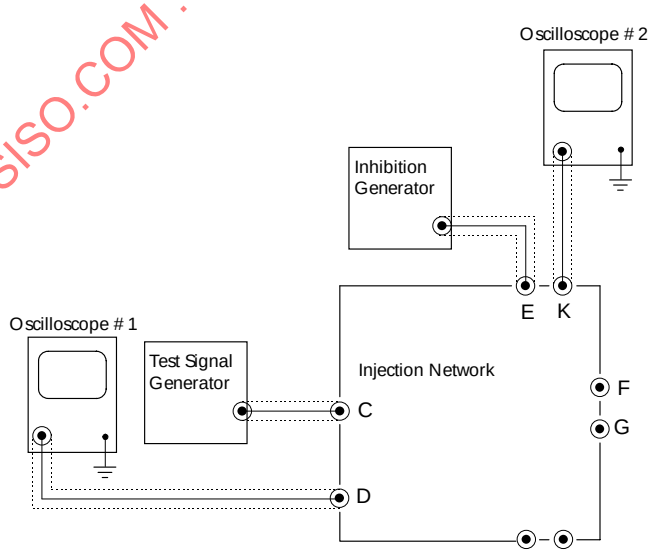


Figure 147 – Test set-up to check for malfunction at high frequency

NOTE The peak to peak amplitude of the test signal, V_{pp}, cannot be measured directly at any connector of the injection network during the test. Therefore it must be calculated from the voltage at connector D, V_{osc}, by applying the calibration factor, *m*, of Annex I.

Connections between outputs F and G and the IMPLANTABLE PULSE GENERATOR shall be by copper straps, width ≥ 5 mm, length ≤ 50 mm (not including the length of the standard connector pin inserted into the device header). Unused ports on the injection network shall be fitted with 50 Ω terminations.

Unipolar IMPLANTABLE PULSE GENERATORS shall be connected to output F of the injection network [as shown in Figure 148], with the outer braid of the co-axial feed connected to the case. Each channel of a multichannel device shall be tested in turn and any channel not under test shall be turned off and connected to a load of 500 Ω (R_L) [see Figure 148].

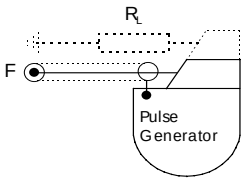


Figure 148 - Connection to a unipolar pulse generator

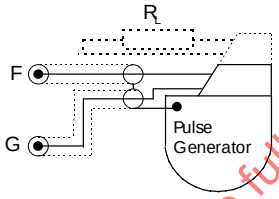


Figure 149 - Connection to a bipolar pulse generator

Bipolar IMPLANTABLE PULSE GENERATORS shall be connected to outputs F and G of the injection network [as shown in Figure 149], with the outer braid of the co-axial feeds connected to the case. Each channel of a multichannel device shall be tested in turn and any channel not under test shall be turned off and connected to a load of 500 Ω (R_L) [see Figure 149].

Compliance shall be confirmed if the IMPLANTABLE PULSE GENERATOR at all times functions in its set mode irrespective of the application of the required modulated signal.

27.5.4 *Immunity from signals in the range 450 MHz - 3 GHz*

Procedure: No test is required for IMPLANTABLE PULSE GENERATORS that provide a feed-thru filter at the case for all through-shield connections and the filters can be demonstrated to have an insertion loss of greater than 30 dB when measured with a 50 Ω source impedance OR in a balanced 50 Ω system at frequencies of 450, 600, 800, 825, 850, 875, 900, 930, 1 610, 1 850, 1 910, 2 450, and 3 000 MHz.

Test: The IMPLANTABLE PULSE GENERATOR shall be subjected to the required test procedure in Clause 6 of AAMI PC69.

Compliance shall be confirmed either

- by inspection of a design analysis of the feed-thru filters provided by the manufacturer, supported by data and calculations from test studies as appropriate, or
- the IMPLANTABLE PULSE GENERATOR complies with the applicable performance criteria in 6.5 of AAMI PC69 at each frequency tested.

27.6 The IMPLANTABLE PULSE GENERATOR shall not be affected by static magnetic fields of flux density of up to 1 mT.

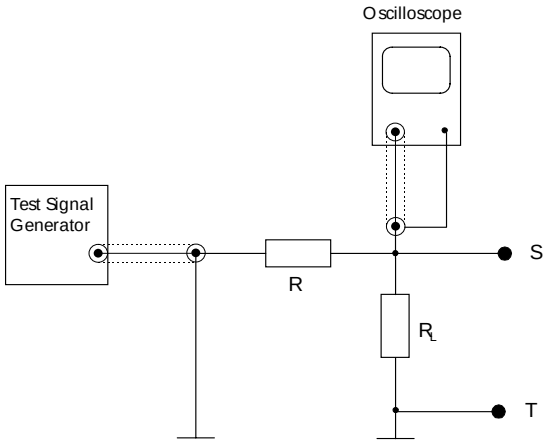


Figure 150 - Test set-up for magnetostatic measurements

Test equipment: Use a test signal generator which provides a signal in the form defined by Annex F, Figure F.103; an oscilloscope; 51 kΩ ± 1 % and 500 Ω ± 1 % resistors; and a field coil, capable of generating a uniform magnetic field with a flux density of up to 1 mT ± 0,1 mT in the region to be occupied by the IMPLANTABLE PULSE GENERATOR.

Test procedure: A 500 Ω ± 1 % load resistor (R_L) is connected between terminals S and T [see Figure 150], with the monitoring oscilloscope is connected to terminal S. The signal from the test signal generator shall be injected at terminal S through a 51 kΩ ± 1 % feed resistor (R).

For unipolar IMPLANTABLE PULSE GENERATORS, output S shall be connected to the TERMINAL of the channel under test and output T to the IMPLANTABLE PULSE GENERATOR case.

For bipolar IMPLANTABLE PULSE GENERATORS, outputs S and T shall be connected to the TERMINALS of the channel under test. Channels not under test shall be loaded with 500 Ω ±1 % resistors.

The IMPLANTABLE PULSE GENERATOR shall be set in synchronised mode by the signal from the test signal generator. The amplitude of the test signal shall be twice the amplitude that just synchronises the IMPLANTABLE PULSE GENERATOR under test [see 6.1.2].

The magnetic field shall be set to a flux density of 1 mT ± 0,1 mT in the region where the IMPLANTABLE PULSE GENERATOR will be placed.

While remaining connected to the test equipment, the IMPLANTABLE PULSE GENERATOR shall be placed within the coil, centred in its field, and aligned so that the most sensitive axis of the IMPLANTABLE PULSE GENERATOR is parallel to the axis of the coil. The magnetic field shall be maintained for at least one minute.

NOTE 1 Care should be given to avoid wire-loops.

NOTE 2 The field shall be measured in the absence of the IMPLANTABLE PULSE GENERATOR.

Compliance shall be confirmed if the IMPLANTABLE PULSE GENERATOR remains inhibited while the magnetic field is applied.

27.7 The IMPLANTABLE PULSE GENERATOR shall not remain functionally affected after exposure to stronger static magnetic fields of flux density of up to 10 mT.

Test equipment: Use a field coil, capable of generating a uniform magnetic field with a flux density of up to 10 mT ± 1 mT in the region to be occupied by the IMPLANTABLE PULSE GENERATOR.

Test procedure: The IMPLANTABLE PULSE GENERATOR shall be placed within a coil, centred in the field and aligned so that the most sensitive axis of the IMPLANTABLE PULSE GENERATOR is parallel to the axis of the coil.
The magnetic field flux density shall be set to strength of 1 mT. The field flux density shall be slowly increased to 10 mT and held at this level for at least 1 min. Then the magnetic field flux density shall be slowly reduced to zero.

NOTE If a uniform magnetic field of flux density of up to 10 mT ± 1 mT is not achievable in the region of the IMPLANTABLE PULSE GENERATOR the test may be repeated after repositioning the IMPLANTABLE PULSE GENERATOR. The test is repeated as many times as is necessary to ensure the entire device is exposed to the 10 mT field flux density.

Compliance shall be confirmed if within five seconds after the magnetic field is removed the IMPLANTABLE PULSE GENERATOR functions as prior to the test without adjustment.

27.8 The IMPLANTABLE PULSE GENERATOR shall be constructed so that ambient time-variable magnetic fields are unlikely to cause any malfunction of the IMPLANTABLE PULSE GENERATOR that persists after removal of the magnetic field.

Test equipment: Use a radiating coil, diameter ≥ 12 cm and exceeding the largest PULSE generator linear dimension by 50 %, and a calibration coil, diameter ≤ 4 cm. The radiating coil shall be energised by a signal generator.

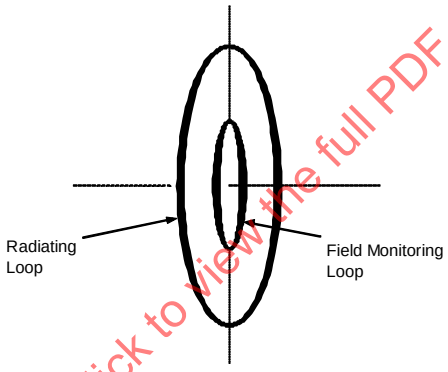


Figure 151 - Loop configuration for varying magnetic field test

Test field: The test magnetic field, H, shall be sinusoidally modulated at a frequency, *f*, as defined by Table 107.

Table 107 - Sinusoidally modulated magnetic field strengths

f	***H* rms (minimum)**
1 kHz ≤ *f* ≤ 100 kHz	150 A/m
100 kHz ≤ *f* ≤ 140 kHz	150 A/m *100 kHz/*f*

Test procedure: Using the calibration coil, determine the signal levels applied to the radiating coil that produce the magnetic field, H, in the centre of the radiating coil [see Figure 151]. Remove the calibration coil.

Place the centre of the IMPLANTABLE PULSE GENERATOR at the field intensity calibration point. Load the cardiac lead TERMINALS of the IMPLANTABLE PULSE GENERATOR LEAD interface as specified by the manufacturer using care to minimize loop areas of connections. Generate the required fields by either sweeping the test signal over the required frequency range at a maximum rate of one decade per minute or by applying the test signal at four distinct, well spaced frequencies per decade with an evenly distributed dwell time of at least 60 s per decade.

NOTE Observe care to slowly increase or decrease the field intensity when applying or removing the test signal.

Re-orientate the IMPLANTABLE PULSE GENERATOR so that a second orthogonal axis is aligned with the axis of the

radiating loop and again subject the IMPLANTABLE PULSE GENERATOR to the required fields**.** Then repeat again with the third orthogonal axis aligned with the axis of the radiating loop.

Compliance shall be confirmed if after application of the specified test signal, the IMPLANTABLE PULSE GENERATOR functions as prior to the test without further adjustment.

28 Accompanying documentation

This clause of Part 1 applies except as follows:

28.1

Replacement:

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

Compliance shall be confirmed by inspection.

28.8

Additional subclauses:

28.8.1 The description of the device shall include the following information, as appropriate:

a) For IMPLANTABLE PULSE GENERATORS:

   1) a general description, explanation of function, available pacing modes, and a description of the heart/IMPLANTABLE PULSE GENERATOR interaction for each bradyarrhythmia pacing mode;

      NOTE Instead of using a description in words, the mode codes defined in Annex D may be used in the MARKINGS and accompanying documentation to designate the pacing mode of the IMPLANTABLE PULSE GENERATOR.

   2) a description of other functions (e.g. antitachycardia pacing features, etc.).

b) For LEADS:

   1) the configuration (unipolar, etc.);

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

c) For ADAPTORS:

   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) For the connectors:

   1) The sensing, pacing configuration (bipolar, unipolar, other);

   2) The connector geometry (bore depths and diameters in millimetres), or a reference to published connector standards including any designations or markings;

   3) An explanation of any markings used to identify the connector on the IMPLANTABLE PULSE GENERATOR [see 13.1.1].

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 electrical characteristics [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 noted), 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 F.101 and Figure F.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 F.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 noted).

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

g) Any recommendation regarding the use of LEAD(S) [see also 28.4 of EN 45502-1].

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 a 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 a 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 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 electrical parameters of the LEAD [see 6.2], including:

   1) the LEAD CONDUCTOR RESISTANCE (in ohms);

   2) the LEAD PACING IMPEDANCE (in ohms); 3) the LEAD SENSING IMPEDANCE (in ohms).

e) Any recommendations regarding use with IMPLANTABLE PULSE GENERATORS [see also 28.4 of ISO 14708-1].

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) Characteristics of the power source(s), including:

   1) the manufacturer(s), model designations(s), type(s), and the number and arrangement of cells;

   2) the usable capacity of the power source [see 19.2.2];

   3) the estimated residual usable capacity at recommended replacement time.

b) Current consumption of the IMPLANTABLE PULSE GENERATOR, both when pacing into 500 Ω ± 1 % load(s) 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 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 PROLONGED SERVICE PERIOD, and the conditions under which the PROLONGED SERVICE PERIOD is derived.

Compliance shall be confirmed by inspection.

Additional subclauses:

28.22.1 If the IMPLANTABLE PULSE GENERATOR permits settings more sensitive than those warranted as complying with the tests defined in 27.5, the manufacturer shall provide a warning that these settings may cause the IMPLANTABLE PULSE GENERATOR to be more susceptible to electromagnetic interference, and that patients requiring such settings should be under medical direction.

Compliance shall be confirmed by inspection.

28.22.2 The accompanying documentation for a PACEMAKER shall include warnings about recognized hazardous behaviour, if any, of the IMPLANTABLE PULSE GENERATOR when subjected to environmental electric, electromagnetic and magnetic fields that are not covered by the tests in this Part 2. Additionally, the accompanying documentation shall include advice a clinician may consider providing to the patient on potential interactions with specific equipment, such as anti-theft devices, portable telephones, etc.

Compliance shall be confirmed by inspection.

Annex A
(informative)

Relationship between the fundamental principles in ISO/TR 14283 and the clauses of this 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 a active implantable medical device addressed by this standard. This approach is particularly applicable to the requirements in clauses 14, 19 and 21.)	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–2 AND ASPECTS COVERED
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 subclause 2.1 [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 IPG characteristics 6.2 Measurement of the electrical parameters of the lead
3.4 The characteristics and performances referred to in sub-clauses 3.1, 3.2 and 3.3 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
	23.1	Defines drop test for non-implantable parts.	* retained
	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

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–2 AND ASPECTS COVERED
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
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 of the “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

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–2 AND ASPECTS COVERED
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.	* retained
	14.3	Requires investigation of biocompatibility.	* 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	Demonstrate 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 medicinal product as defined in subclause 2.4 [of ISO/TR 14283] and which is liable to act upon the body with 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	Requirement 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

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–2 AND ASPECTS COVERED
4.1.6 Implants should be designed and manufactured in such a way as to reduce, as much as possible, 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
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, preservation, 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

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–2 AND ASPECTS COVERED
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 pack.	* retained
	7.2	Requires sterile pack to be protected by sales packaging.	* retained
	10.1	Requires packaging to be durable.	* retained
	10.2	Requires packaging to be proof against the effects of humidity.	* retained
	11.7	Requires contents of sterile pack to be declared or visible.	* retained
	11.9	Requires the sterile pack to be marked with the instructions for opening it.	* retained
	12.1	Applies ISO 11607 to the reusable pack.	* retained
	12.2	Shall be apparent if sterile pack has been opened.	* retained
	14.1	Requires device to be supplied sterile.	* retained
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
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

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–2 AND ASPECTS COVERED
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 condition.	(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 is 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

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–2 AND ASPECTS COVERED
4.3.2 (b) 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 * 27.2 test for induced currents * 27.3 test against malfunction * 27.4 test against background EMI * 27.5 test against environmental electromagnetic signals * 27.6 test against weak magnetic fields * 27.7 test against stronger magnetic fields * 27.8 test against time variable magnetic fields

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 device in case of diathermy etc.	* retained
	28.14	Requires warning not to expose device to therapeutic levels of ultrasound.	* retained
	28.15	Requires warning about the effect of therapeutic irradiation on implanted devices.	* retained
4.3.2 (d) risks which may arise where maintenance and calibration are impossible, including (if applicable): - excessive increase of leakage currents, - aging 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 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. With the 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 601–1 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 **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. 5 Applies IEC 60601–1 to the non-implantable parts of the active implantable medical device	* retained * retained
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, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	(See more particular requirements below)	

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–2 AND ASPECTS COVERED
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	9.1 Requires markings warning of any radioactive substances.	* retained
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.	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	(Not applicable to active implantable medical devices)	* Idem
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.		
4.6 **Ionizing radiation**	(Not applicable to active implantable medical devices)	* Idem

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–2 AND ASPECTS COVERED
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.			
4.6.2 Implants emitting ionizing 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 whilst 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 power source depletion indicator.	* 19.2 replacement * 19.2.1 projected service life * 19.2.2 usable capacity

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–2 AND ASPECTS COVERED
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.	* retained
	28.6	Requires an explanation of code to be provided with the device.	* retained
4.7.4 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 of 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. With the 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.	* retained
	16.1	Sets safety limits for leakage currents from non-implantable parts.	

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 * 16.4 additional requirement
	17	Requires investigation of local heating caused by implanted device.	* retained
	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

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–2 AND ASPECTS COVERED
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
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.	10.4	Requires accompanying documentation to be physically associated with the device.	* retained
	12.3	Requirement that any markings shall be indelible.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–2 AND ASPECTS COVERED
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 e every implant.			
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

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–2 AND ASPECTS COVERED
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 the 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
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

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–2 AND ASPECTS COVERED
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 take;	(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 sterilisation 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
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 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

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–2 AND ASPECTS COVERED
4.8.6 Where appropriate, the instructions for use should contain the following particulars:			
4.8.6 (a) the details referred to in clause 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 subclause 3.3 [of ISO/TR 14283] and any undesirable side-effects;	28.8	Requires information to be provided about 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 use 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

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–2 AND ASPECTS COVERED
4.8.6 (e) where appropriate, information to avoid specified risks in connection with implantation of the implant;	28.11 Requires information on avoiding hazards during implantation are provided.	* 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
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 (for example, sterilization, final assembly, etc.);	(Not applicable because subclause requires that active implantable medical device 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

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–2 AND ASPECTS COVERED
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 28.22.1 specific warnings about environmental electric and magnetic fields required 28.22.2 specific warning about sensitivity settings for which compliance with 27.4 is not claimed
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 sub-clause 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 clause 6.8 IEC 50601–1 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 clause 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 B
(informative)

Relationship between the clauses of this standard and the fundamental principles listed in Annex A

Subclause	Relevant fundamental principle	Subclause	Relevant fundamental principle
4	4.8.2	11.6	4.8.3 (b) and 4.8.3 (d)
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)	11.7	4.8.3 (b) and 4.2.3
7.1	4.2.3	11.8	4.3.1
7.2	3.5 and 4.2.3	11.9	4.2.3
8.1	3.1	11.10	4.8.3 (g)
8.2	4.8.5	12.1	4.2.3
9.1	4.5.3	12.2	4.2.3
9.2	4.8.3 (a)	12.3	3.5
9.3	4.8.3 (b) and 4.8.3 (d)	13.1	4.8.5
9.4	4.8.3 (b)	13.2	4.8.5
9.5	4.8.3 (c)	13.3	4.7.3
9.6	4.8.3 (k)	13.4	4.4.1.2
9.7	4.8.3 (e)	14.1	4.2.1, 4.2.3, 4.2.4 and 4.2.5
9.8	4.8.3 (b)	14.2	4.1.2 and 4.2.5
9.9	4.3.1	14.3	4.1.1 (a), 4.1.1 (b) and 4.1.2
9.10	4.8.3 (b) and 4.8.4	14.4	4.1.4
9.11	4.8.3 (h)	15.1	4.3.2 (a)
9.12	4.8.3 (g)	15.2	4.3.2 (a)
10.1	3.5 and 4.2.3	16.1	4.7.6.1
10.2	3.5 and 4.2.3	16.2	4.7.6.2
10.3	3.5	16.3	4.7.6.2
10.4	3.3 and 4.8.1	17	4.7.6.2 and 4.3.2 (d)
11.1	4.8.3 (a)	18.1	4.5.3
11.2	4.8.3 (c) and 4.8.3 (l)	18.2	4.5.3
11.3	4.8.3 (c)	18.3	4.5.3
11.4	4.8.3 (k)	19.1	4.3.2 (d)
11.5	4.8.3 (e)	19.2	3.4, 4.3.2 (d) and 4.7.2

Subclause	Relevant fundamental principle	Subclause	Relevant fundamental principle
19.3	3.4, 3.6, 4.1.7, 4.7.1 and 4.7.8.1	28.4	3.4, 4.3.1 and 4.8.6 (c)
19.4	3.6, 4.9 (a) and 4.9 (b)	28.5	4.3.1 and 4.8.6 (c)
19.5	4.1.3	28.6	4.7.3
20.1	4.3.2 (c)	28.7	4.8.6 (m)
20.2	4.3.2 (c)	28.8	4.8.6 (b) and 4.8.6 (o)
21	4.3.2 (c)	28.9	4.8.6 (c)
23.1	3.4 and 4.3.2 (b)	28.10	4.8.6 (d)
23.2	3.4 and 4.3.2 (b)	28.11	4.8.6 (e)
23.3	3.4	28.12	4.3.2 (c) and 4.8.6 (f)
23.4	3.4	28.13	4.3.2 (c)
23.5	3.4	28.14	4.3.2 (c)
23.6	3.4 and 4.3.1	28.15	4.3.2 (c)
24	4.3.2 (b)	28.16	4.8.6 (a) [3.8.3 (c)]
25	4.3.2 (b)	28.17	4.8.6 (g) and 4.8.6 (h)
26.1	3.4 and 4.7.6.2	28.18	4.8.6 (a) [4.8.3 (f)]
26.2	3.5 and 4.3.2 (b)	28.19	4.8.6 (k)
27	4.3.2 (b)	28.20	4.8.6 (k)
28.1	4.8.6 (a) [4.8.3 (a)]	28.21	4.8.6 (a) [4.8.3 (h)]
28.2	4.5.3	28.22	4.8.6 (l)
28.3	4.8.6 (a) [4.8.3 (b)]	28.23	3.4
		28.24	4.8.6 (n)

Annex C
(informative)

Notes on ISO 14708-2

C.1 General

In supporting the essential requirements of Directive 90/385/EEC as related to the ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat bradyarrhythmia, this Part 2 frequently details an aspect of the essential requirement and specifies an assessment procedure or test. A compliance requirement then allows the particular device under examination to be deemed to meet the aspect of the essential requirement.

For some HAZARDS, this standard prescribes specific requirements along with compliance measures (e.g., d.c. leakage current levels) which, if met, satisfy an aspect of the essential requirements of the Directive. For other risks, this standard requires potential HAZARDS to be assessed and identified, using a similar procedure to that described in EN 1441. Compliance is then determined by review of documentation provided by the manufacturer.

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.

C.2 Notes on specific clauses and subclauses

The following, more detailed, notes on some of the provisions of this standard 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 standard. The notes in this annex carry the numbers of the relevant clauses in this Part 2; therefore, the numbering in this annex is not consecutive.

[6] The procedures are specified for devices only at 37 ºC ± 2 ºC. 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.

[6.1.3] Changes the existing procedure of 10.4 of EN 50061:1988, 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 make measurements poorly reproducible.

The value of R_1 used in a particular test should be disclosed in a type test report.

[6.2.2] 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 C.101.

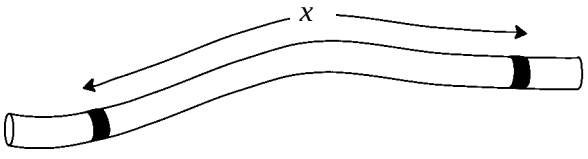


Figure C.101 - Measurement of x

[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. Non-programmable characteristics have to be disclosed as they restrict the range of application of the device.

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 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. Priority is given to describing the device as it comes out of the STERILE PACK.

[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 the incorporation of the MODEL DESIGNATION into the SERIAL NUMBER or, when appropriate, a batch number.

[13.3] For PACEMAKERS, the power source is located in the IMPLANTABLE PULSE GENERATOR. This is the part of the system that must be identifiable using non-invasive procedures. At the present time, the procedure for non invasively identifying the IMPLANTABLE PULSE GENERATOR must utilise 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 has been 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 recognised 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 standard, 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 Part 1.

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

[16.3] The dielectric strength test for LEAD insulation has been 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.

[21.2] 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[1] [This

[1] Ein Beitrag zur Sicherheit von Implantaten; W. Irnich et alia, ISBN 3-88 314-870-9, ISSN 0932- 3856 (Schriftenreihe der Bundesanstalt für Arbeitsschutz, Dortmund 1989)

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 ºC to 43 ºC at the ELECTRODE to heart tissue interface.] Induced voltages above this value can cause thermal damage to the heart tissue eventually resulting in pacing threshold increase and/or necessitating replacement of the LEAD. The selected amplitude of 20 V_{pp}, to test the protection of the device, constitutes therefore 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 Entwurf Juni 1985, DIN VDE 0750 Teil 9.

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 dependant 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] Intended to establish minimum requirements for the durability of IMPLANTABLE PULSE GENERATORS with respect to mechanical robustness.

The test specified in ISO 14708-1 has been replaced because the part of the standard defining the test has been withdrawn.

The replacement text is based on a new part of IEC 60068-2-64, Environmental testing — Part 2: Test methods — Test Fh: Vibration, broad-band random (digital control) and guidance.

The test severity is determined by the test conditions a) - d). The range of test frequencies is based on experience with the sinusoidal sweep method 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 8.1.1 of EN 50061**.** That test specifies a peak acceleration of 25 m/s^2 **.** This translates into an rms value of 1,77 g**.** An acceleration spectral density of 0,7 $(m/s^2)/Hz$ 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 5.5 of IEC 60068-2-64**.** 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 -23.5] The tests required by 23.3 through 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 standardised 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 must be kept completely isolated from the saline bath to ensure both a valid test and safety for the test personnel. The manufacturer must 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 effect 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 are believed to have sufficient overall mechanical integrity because some LEADS that have been used clinically and have demonstrated acceptable performance do not meet the required criteria for the portion of the LEAD in the vascular system. 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 %. 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 5841-3:1992 (IS-1). The 0,1 s to 5 s time for the 100 V ± 5 V d.c. test signal to be ramped up was chosen to prevent voltage overshoot beyond the upper limit of 105 V d.c.

[23.5] The tests 1 and 2 in 23.5 are intended to establish minimum requirements for the flexural durability of implantable LEADS. In accord with this approach, a conductor or connector must 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 to each manufacturer to determine the appropriate sample size, data analysis technique and margin of safety, as well as to demonstrate with confidence 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 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 after implantation.

[Test 1] The bell mouth test was designed bearing 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 one 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 produces 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 slant and flat fractures found both in tested and explanted LEADS.

Figure C.102 specifies a reference test coil of MP35N [ISO 5832-6] based on field experience with a BIPOLAR LEAD that used 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 percent at 60 months. Weibull distribution analysis of the reference test coilfractures 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 rest 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 manufacture'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.