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)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Annexes

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.

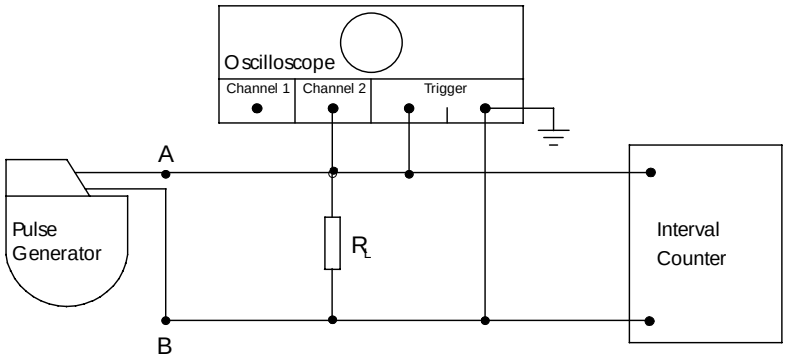

Figure 101 - Measurement of pulse amplitude, pulse duration, pulse interval and pulse rate

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.

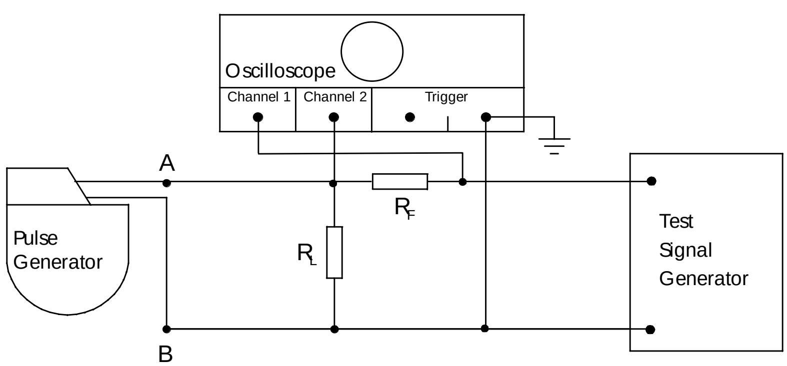

Figure 102 - Sensitivity measurement

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.

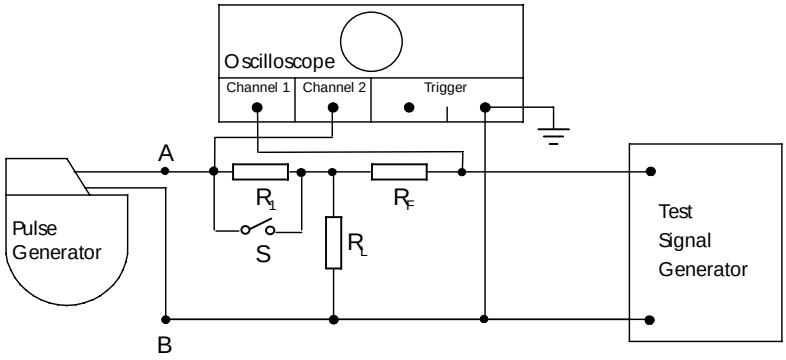

Figure 103 - Input impedance measurement

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 %.

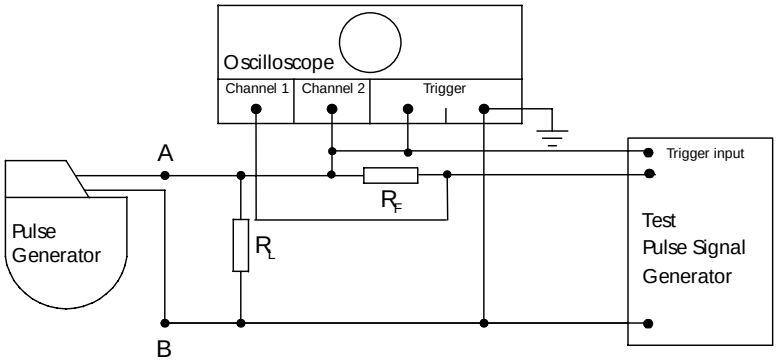

Figure 104 - Escape interval measurement

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.)

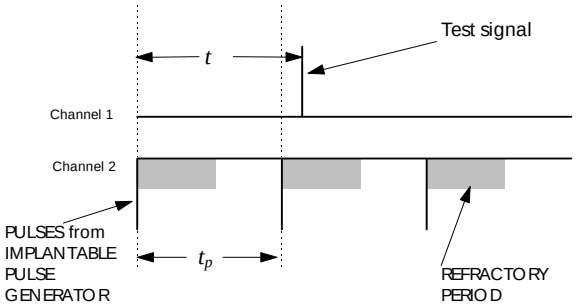

Figure 105 - Initial oscilloscope display, when measuring the ESCAPE INTERVAL

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.