

Active implantable medical devices —

Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)

The European Standard EN 45502-2-1:2003 has the status of a
British Standard

ICS 11.040.40

National foreword

This British Standard is the official English language version of EN 45502-2-1:2003. It supersedes BS 6902-1:1990 and BS 6902-1:Supplement No. 1:1996 which are withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/150, Implants for surgery, to Subcommittee CH/150/6, Active implants, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the *BSI Catalogue* under the section entitled “International Standards Correspondence Index”, or by using the “Search” facility of the *BSI Electronic Catalogue* or of British Standards Online.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 20 January 2004

Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 95 and a back cover.

The BSI copyright notice displayed in this document indicates when the document was last issued.

Amendments issued since publication

Amd. No.	Date	Comments

© BSI 20 January 2004

ISBN 0 580 43280 7

Active implantable medical devices
Part 2-1: Particular requirements for active implantable
medical devices intended to treat bradyarrhythmia
(cardiac pacemakers)

Dispositifs médicaux implantables actifs
Partie 2-1: Règles particulières
pour les dispositifs médicaux implantables
actifs destinés à traiter la bradyarythmie
(stimulateurs cardiaques)

Aktive implantierbare medizinische Geräte
Teil 2-1: Besondere Festlegungen
für aktive implantierbare medizinische
Geräte zur Behandlung
von Bradyarrhythmie
(Herzschrittmacher)

This European Standard was approved by CEN and CENELEC on 2003-09-01. CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Lithuania, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and United Kingdom.

CEN/CENELEC

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

This European Standard has been prepared by the CEN/CENELEC Joint Working Group on Active Implantable Medical Devices (CEN/CLC JWG AIMD). Members of the Joint Working Group were nominated by one of the member bodies of either CEN or CENELEC.

The text of the draft was submitted to the formal vote and was approved by CEN and CENELEC as EN 45502-2-1 on 2003-09-01.

This European Standard, together with EN 45502-2-2, supersedes EN 50061:1988 + A1:1995 + A1:1995/corrigendum Oct. 1995.

The following dates were fixed:

- latest date by which the EN has to be implemented (dop) 2004-09-01
at national level by publication of an identical national
standard or by endorsement
- latest date by which the national standards (dow) 2005-09-01
conflicting with the EN have to be withdrawn

This European Standard has been prepared under mandates given to CEN and CENELEC by the Commission of the European Communities and the European Free Trade Association, and supports essential requirements of Directive 90/385/EEC.

Contents

	Page
Introduction	7
1 Scope	8
2 Normative references	8
3 Definitions	9
4 Symbols and abbreviations (optional).....	13
5 General requirements for non-implantable parts	13
6 Measurement of implantable pulse generator and lead characteristics	13
7 General arrangement of the packaging	28
8 General markings for active implantable medical devices.....	28
9 Markings on the sales packaging	28
10 Construction of the sales packaging.....	29
11 Markings on the sterile pack	29
12 Construction of the non-reusable pack	30
13 Markings on the active implantable medical device.....	31
14 Protection from unintentional biological effects being caused by the active implantable medical device	32
15 Protection from harm to the patient or user caused by external physical features of the active implantable medical device	32
16 Protection from harm to the patient caused by electricity	32
17 Protection from harm to the patient caused by heat	33
18 Protection from ionizing radiation released or emitted from the active implantable medical device.....	33
19 Protection from unintended effects caused by the device	34
20 Protection of the device from damage caused by external defibrillators	35
21 Protection of the device from changes caused by high power electrical fields applied directly to the patient.....	35
22 Protection of the active implantable medical device from changes caused by miscellaneous medical treatments	35
23 Protection of the active implantable medical device from mechanical forces.	36
24 Protection of the active implantable medical device from damage caused by electrostatic discharge	40
25 Protection of the active implantable medical device from damage caused by atmospheric pressure changes	40
26 Protection of the active implantable medical device from damage caused by temperature changes.	40

27	Protection of the active implantable medical device from electromagnetic non-ionizing radiation.	40
28	Accompanying documentation.....	56
Annex AA (informative)	Table of cross-references from 90/385/EEC to EN 45502-2-1	61
Annex BB (informative)	Relationship between the clauses of EN 45502-2-1 and the essential requirements of 90/385/EEC listed in Annex AA	72
Annex CC (informative)	Notes on EN 45502-2-1	74
Annex DD (informative)	Code for describing modes of implantable pulse generators.....	84
Annex EE (informative)	Symbols	88
Annex FF (normative)	Pulse forms.....	89
Annex GG (normative)	Interface circuits	90
Annex HH (informative)	Selection of capacitor C_x	93
Annex II (normative)	Calibration of the injection network, Figure GG.104	94

Figures

Figure 101 - Measurement of pulse amplitude, pulse duration, pulse interval and pulse rate	15
Figure 102 - Sensitivity measurement	16
Figure 103 - Input impedance measurement	16
Figure 104 - Escape interval measurement.....	17
Figure 105 - Initial oscilloscope display, when measuring the escape interval.....	18
Figure 106 - Measurement of escape interval (t_e) in inhibited mode	18
Figure 107 - Measurements of escape interval (t_e) in triggered (synchronised) mode.....	18
Figure 108 - Refractory period measurement.....	19
Figure 109 - Initial oscilloscope display when measuring sensing and pacing refractory period.....	19
Figure 110 - Measurement of sensing refractory period in inhibited mode - A.....	20
Figure 111 - Measurement of sensing refractory period in Inhibited mode - B.....	20
Figure 112 - Measurement of sensing refractory period in triggered (synchronous) mode - A	20
Figure 113 - Measurement of sensing refractory period in triggered (synchronous) mode - B	21
Figure 114 - Measurement of pacing refractory period in inhibited mode	21
Figure 115 - Oscilloscope display when measuring AV interval	22
Figure 116 - Post ventricular atrial refractory period (PVARP) measurement.....	23
Figure 117 - Initial oscilloscope display when measuring PVARP	23
Figure 118 - Oscilloscope display when measuring PVARP	23
Figure 119 - AV INTERVAL after sensing measurement	24
Figure 120 - Oscilloscope display when measuring the AV interval after sensing	24

Figure 121 - Determination of the lead pacing impedance of a unipolar lead	25
Figure 122 - Determination of the lead pacing impedance of a bipolar lead	26
Figure 123 - Determination of the lead sensing impedance of a unipolar lead	27
Figure 124 - Determination of the lead sensing impedance of a bipolar lead	27
Figure 125 - Test set-up for measurement of electrical neutrality	33
Figure 126 - Test set-up for proof protection from high frequency currents caused by surgical equipment	35
Figure 127 - Conductor flex test fixture	38
Figure 128 - Connector flex test fixture	39
Figure 129 - Test signal 2	42
Figure 130 - Test set-up for measurement of induced current flow	42
Figure 131 - Connection to a single channel unipolar pulse generator	43
Figure 132 - Connection to a multichannel unipolar pulse generator	43
Figure 133 - Common mode connection to single channel bipolar pulse generator	43
Figure 134 - Differential mode connection to single channel bipolar pulse generator	43
Figure 135 - Common mode connection to multichannel bipolar pulse generator	44
Figure 136 - Differential mode connection to multichannel bipolar pulse generator	44
Figure 137 - Test set-up to check for induced malfunction	45
Figure 138 - Connection to a single channel unipolar pulse generator	45
Figure 139 - Connection to a multichannel unipolar pulse generator	46
Figure 140 - Common mode connection to a single channel bipolar pulse generator	46
Figure 141 - Differential mode connection to a single channel bipolar pulse generator	46
Figure 142 - Common mode connection to a multi channel bipolar pulse generator	47
Figure 143 - Differential mode connection to a multi channel bipolar pulse generator	47
Figure 144 - Test set-up to characterise performance while subject to interference	48
Figure 145 - Test signal for frequencies in the range 16,6 Hz - 150 kHz	49
Figure 146 - Test signal for frequencies 150 kHz - 450 MHz	51
Figure 147 – Test set-up to check for malfunction at high frequency	52
Figure 148 - Connection to a unipolar pulse generator	52
Figure 149 - Connection to a bipolar pulse generator	53
Figure 150 - Test set-up for magnetostatic measurements	54
Figure 151 - Loop configuration for varying magnetic field test	55
Figure CC.101 - Measurement of x	74
Figure CC.102 - Reference test coil	78
Figure FF.101 - Measurement of pulse duration	89

Figure FF.102 - Measurement of pulse amplitude.....	89
Figure FF.103 - Form of signal from a test signal generator used for the exact determination of sensitivity (sensing threshold).....	89
Figure GG.101 - Tissue equivalent interface circuit for current measurements.....	90
Figure GG.102 - Tissue equivalent interface circuit to check for malfunction	90
Figure GG.103 - Low pass filter used to attenuate the 500 kHz component of the test signal	91
Figure GG.104 - Injection network.....	91
Figure HH.101 - Test to check for spurious low frequency noise and to determine the value of C_X	93

Tables

Table 101 - Overall measurement accuracy limits	14
Table 102 - Overall measurement accuracy limits	25
Table 103 - Settings for determining the projected service life.....	34
Table 104 - Spurious injection current limits.....	44
Table 105 - Peak to peak amplitudes V_{pp} in the range 16,6 Hz to 150 kHz	50
Table 106 - Peak to peak amplitudes V_{pp} in the range 150 kHz to 10 MHz	51
Table 107 - Sinusoidally modulated magnetic field strengths	55
Table AA.1	61
Table BB.1	72
Table DD.101 - Basic mode code scheme.....	84
Table DD.102 - Examples of mode code	85
Table EE.101 - Conventional symbols.....	88
Table GG.101 - Component values for Figure GG.101.....	92
Table GG.102 - Component values for Figure GG.102.....	92
Table GG.103 - Component values for Figure GG.103.....	92
Table GG.104 - Component values for Figure GG.104.....	92
Table II.101 – Calibration signal amplitude.....	95

Introduction

This Part 2-1 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 2-1 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 2-1 supplement or modify those of EN 45502-1:1997, *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 2-1 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 AA, BB, etc.

Although both this Part 2-1 and the Directive 90/385/EEC deal with the same products, the structure and purpose of the two documents are different. Annex AA of this Part 2-1 correlates the requirements of the Directive with the subclauses of EN 45502-1:1997 and this Part 2-1. Annex BB provides reference in the other direction, from this European Standard to the Directive. Annex CC is a rationale providing further explanation of the subclauses of this Part 2-1.

Annex DD describes a coding system that may be used to designate bradyarrhythmia pacing modes. Annex EE provides optional symbols that may be used to reduce the need for translation of MARKINGS and information in the accompanying documentation in multiple languages. Annex FF defines reference points for measurements of PULSE AMPLITUDE and PULSE DURATION, and the form of test signal used to determine SENSITIVITY. Annex GG defines the tissue equivalent interface circuits, signal injection network and low pass filter required for some compliance tests. Annex HH describes a method for selecting the filter capacitor used in the tissue equivalent interface circuits defined by Annex GG. Annex II defines the method of calibrating the injection network defined by Annex GG.

All annexes except Annex FF, GG and II are informative.

1 Scope

This Part 2-1 specifies requirements that are applicable to those ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat bradyarrhythmias.

The tests that are specified in EN 45502 are type tests, and are to be carried out on samples of a device to show compliance.

This Part 2-1 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 2-1 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 2-1 shall apply.

Any features of an ACTIVE IMPLANTABLE MEDICAL DEVICE intended to treat tachyarrhythmias are covered by EN 45502-2-2.

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 European Standard is intended to be consistent with the terminology of Directive 90/385/EEC.

NOTE 3 In this European 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:

EN 28601:1992	Data elements and interchange formats – Information interchange – Representation of dates and times (ISO 8601:1988 + technical corrigendum 1:1991)
EN 45502-1:1997	Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
EN 45502-2-2 ¹⁾	Active implantable medical devices – Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)
EN 60068-2-27:1993	Basic environmental testing procedures – Part 2: Tests – Test Ea and guidance: Shock (IEC 60068-2-27:1987)

¹⁾ At draft stage.

EN 60068–2–47:1999	Environmental testing – Part 2-47: Test methods – Mounting of components, equipment and other articles for vibration, impact and similar dynamic tests (IEC 60068-2-47:1999)
EN 60068–2–64:1994	Environmental testing – Part 2: Test methods – Test Fh: Vibration, broad-band random (digital control) and guidance (IEC 60068-2-64:1993 + corr. Oct. 1993)
ISO 5841-3:1992	Low profile connectors (IS1) for implantable pacemakers
ISO 11318:1993	Cardiac defibrillators – Connector assembly DF-1 for implantable defibrillators – Dimensions and test requirements
ANSI/AAMI PC69-2000	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 2-1, 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 2-1 [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 recognises 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**stoichiometric 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 STOICHIOMETRIC 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 EE 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 (Vacant)

Delete and replace as follows:

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 $37\text{ °C} \pm 2\text{ °C}$, connected to a load of $500\ \Omega \pm 1\%$ 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)	$\pm 5 \%$
PULSE DURATION (6.1.1)	$\pm 5 \%$
PULSE INTERVAL/TEST PULSE INTERVAL (6.1.1)	$\pm 0,2 \%$
PULSE RATE/TEST PULSE RATE (6.1.1)	$\pm 0,5 \%$
SENSITIVITY (6.1.2)	$\pm 10 \%$
INPUT IMPEDANCE (6.1.3) if $< 1 \text{ M}\Omega$	$\pm 10 \%$
ESCAPE INTERVAL (6.1.4)	$\pm 10 \%$
REFRACTORY PERIOD (6.1.5, 6.1.6, and 6.1.8)	$\pm 10 \%$
AV INTERVAL (6.1.7 and 6.1.9)	$\pm 5 \%$
NOTE Information about INPUT IMPEDANCE is always required. However above $1 \text{ M}\Omega$, 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 $500 \Omega \pm 1 \%$ 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 FF.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.

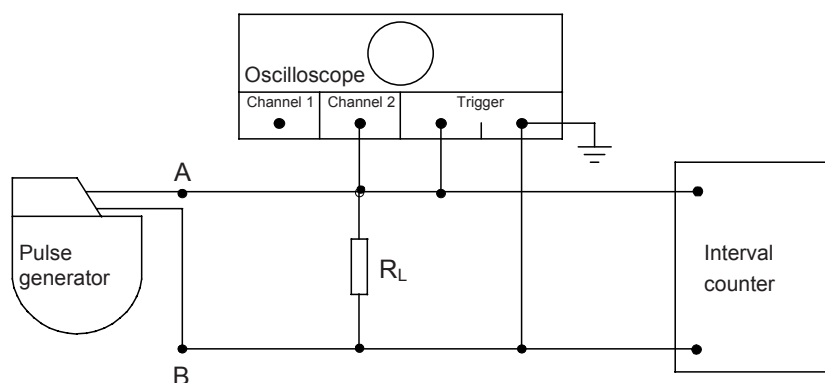


Figure 101 - Measurement of PULSE AMPLITUDE, PULSE DURATION, PULSE INTERVAL and PULSE RATE

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 $240 \Omega \pm 1 \%$ and $1 \text{ k}\Omega \pm 1 \%$ 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 $1 \text{ M}\Omega$, and a test signal generator, output impedance $\leq 1 \text{ k}\Omega$, that provides a signal in the form defined by Figure FF.103.

The IMPLANTABLE PULSE GENERATOR shall be connected to a $500 \Omega \pm 1 \%$ 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 $100 \text{ k}\Omega \pm 1 \%$ 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.

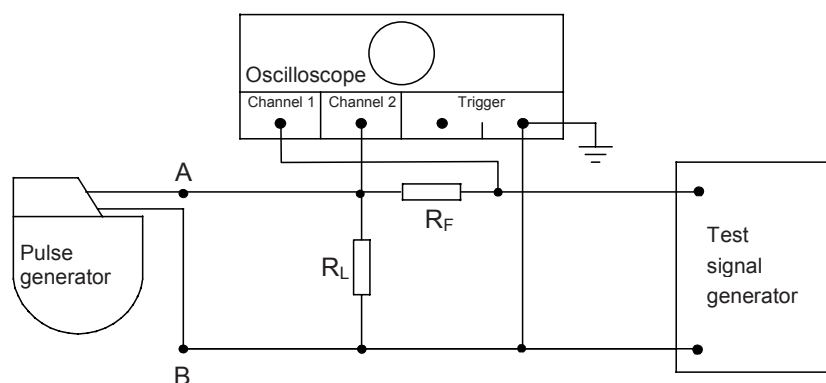


Figure 102 - Sensitivity measurement

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 $1 \text{ M}\Omega$, and a test signal generator, output impedance $\leq 1 \text{ k}\Omega$, that provides a signal in the form defined by Figure FF.103.

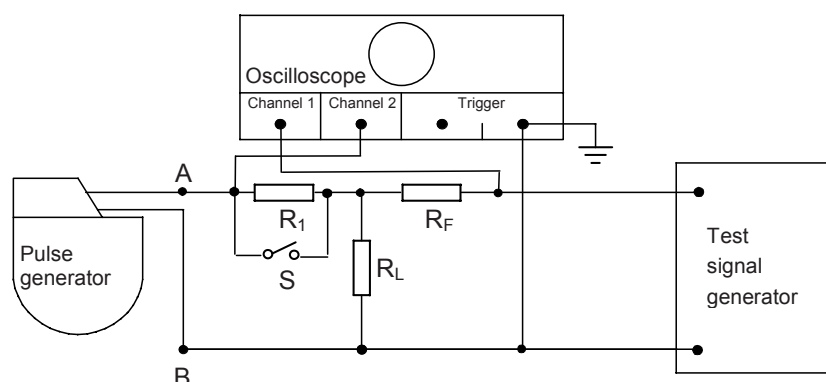


Figure 103 - Input impedance measurement

The IMPLANTABLE PULSE GENERATOR shall be connected to $500 \Omega \pm 1 \%$ 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. $10 \text{ k}\Omega$, $100 \text{ k}\Omega$ etc.), and R_1 shall be known to within $\pm 1 \%$. R_F shall be $100 \text{ k}\Omega \pm 1 \%$. 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 (k Ω).

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 $500 \Omega \pm 1 \%$ 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 $100 \text{ k}\Omega \pm 1 \%$.

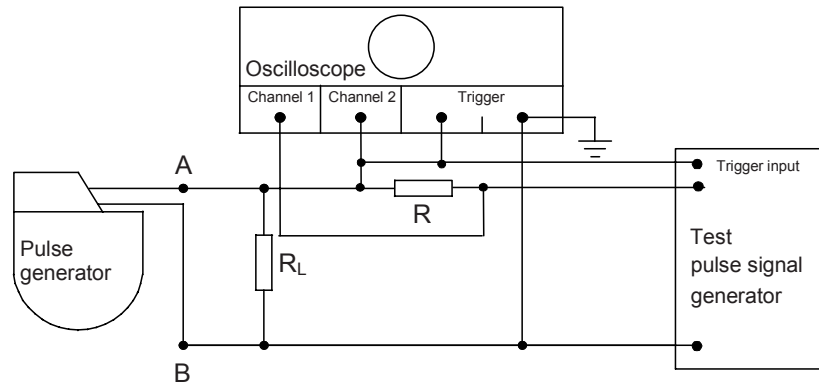


Figure 104 - ESCAPE INTERVAL measurement

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.)

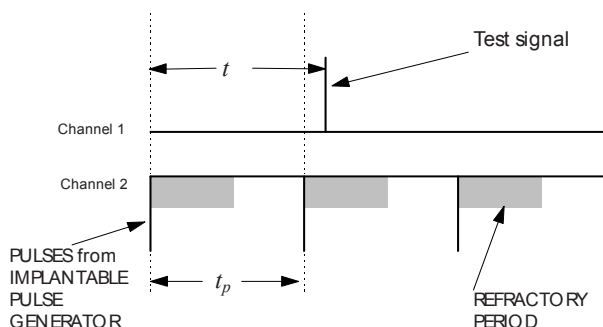


Figure 105 - Initial oscilloscope display, when measuring the ESCAPE INTERVAL

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.

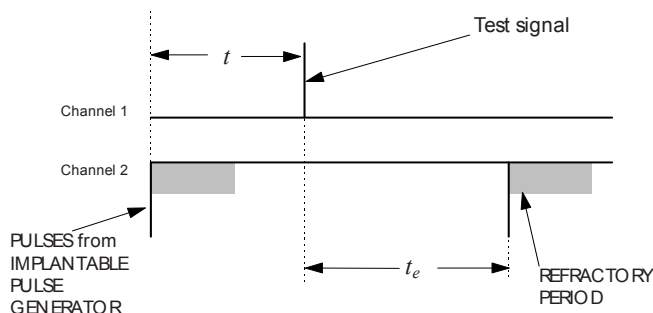


Figure 106 - Measurement of ESCAPE INTERVAL (t_e) in inhibited mode

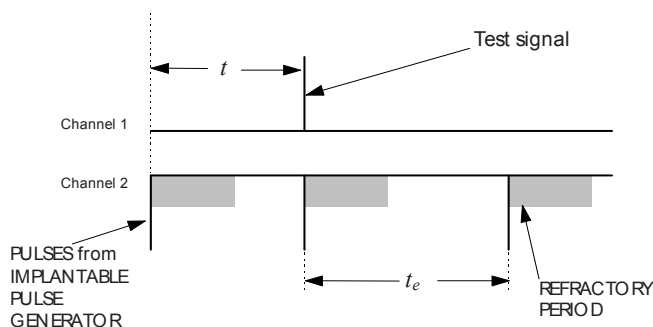


Figure 107 - Measurements of ESCAPE INTERVAL (t_e) in triggered (synchronised) mode

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 $500\ \Omega \pm 1\%$ 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 $100\ \text{k}\Omega \pm 1\%$.

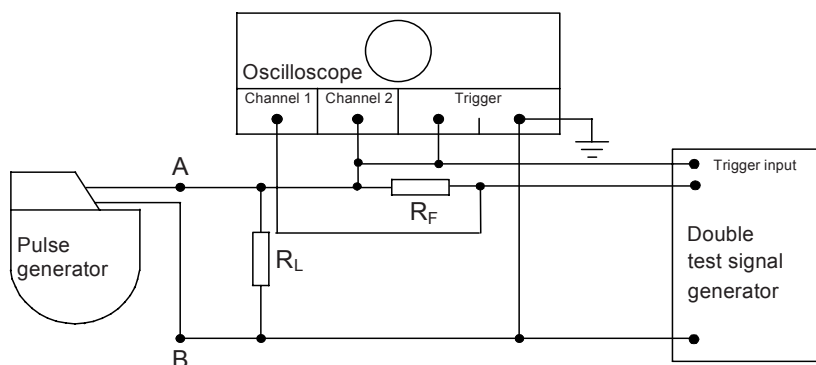


Figure 108 - REFRACTORY PERIOD measurement

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].

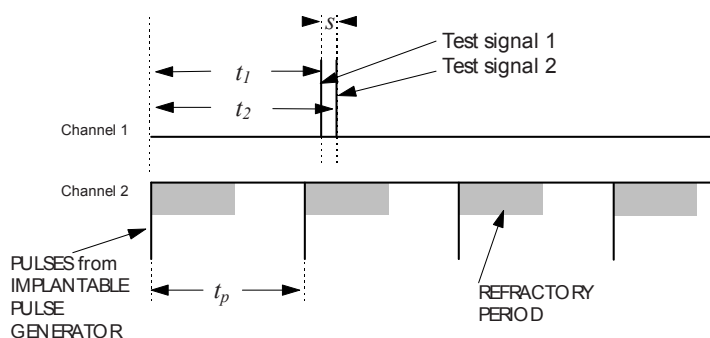


Figure 109 - Initial oscilloscope display when measuring sensing and pacing REFRACTORY PERIOD

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).

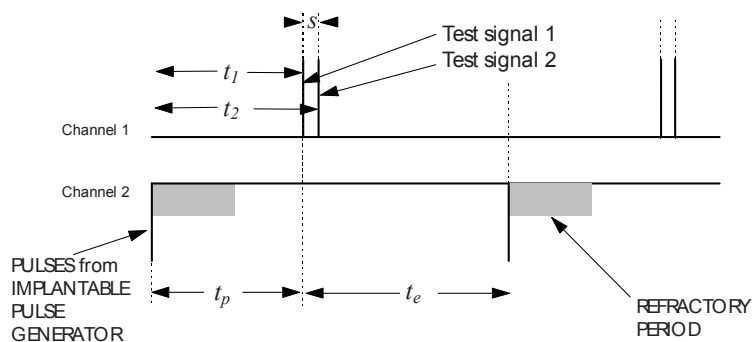


Figure 110 - Measurement of sensing REFRACTORY PERIOD in inhibited mode - A

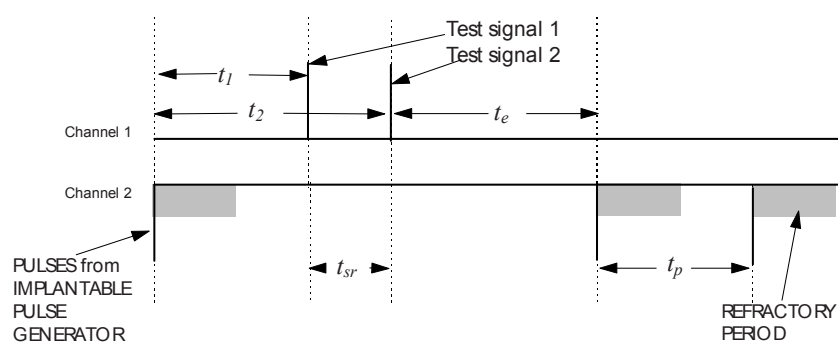


Figure 111 - Measurement of sensing REFRACTORY PERIOD in Inhibited mode - B

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.

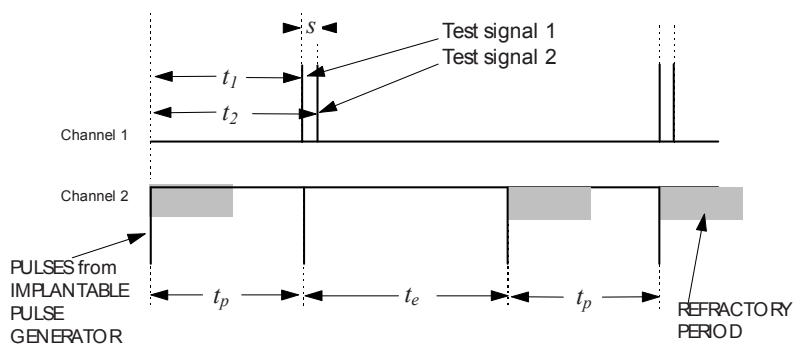


Figure 112 - Measurement of sensing REFRACTORY PERIOD in triggered (synchronous) mode - A

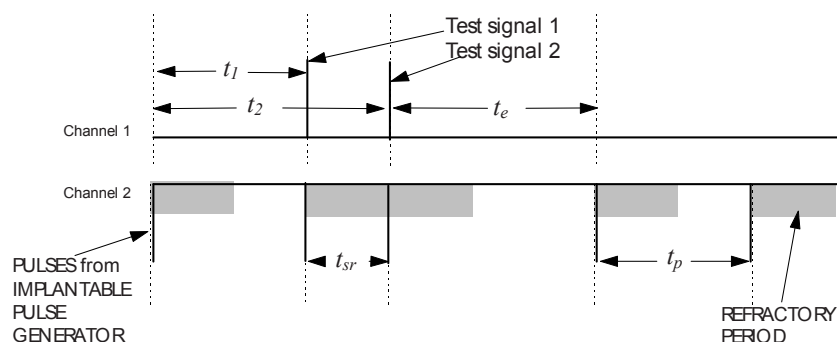


Figure 113 - Measurement of sensing REFRACTORY PERIOD in triggered (synchronous) mode - B

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).

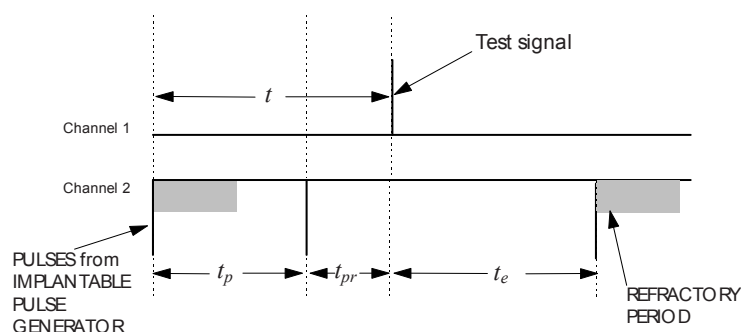


Figure 114 - Measurement of pacing REFRACTORY PERIOD in inhibited mode

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 $500\ \Omega \pm 1\%$ 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).

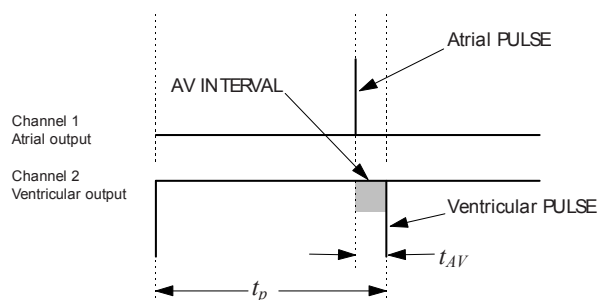


Figure 115 - Oscilloscope display when measuring AV INTERVAL

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 $500\ \Omega \pm 1\%$ 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 $100\ \text{k}\Omega \pm 1\%$. 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.

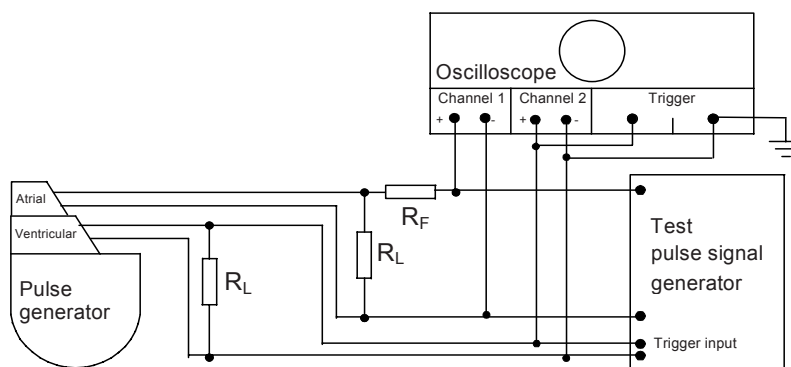


Figure 116 - Post ventricular atrial REFRACTORY PERIOD (PVARP) measurement

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.

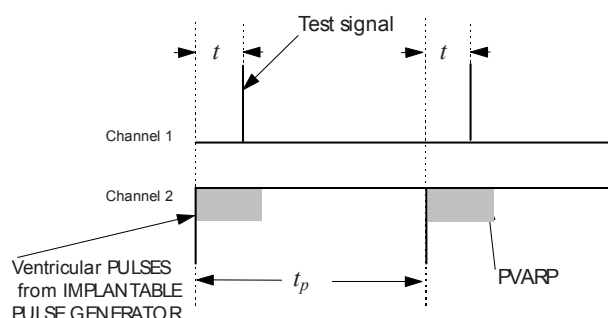
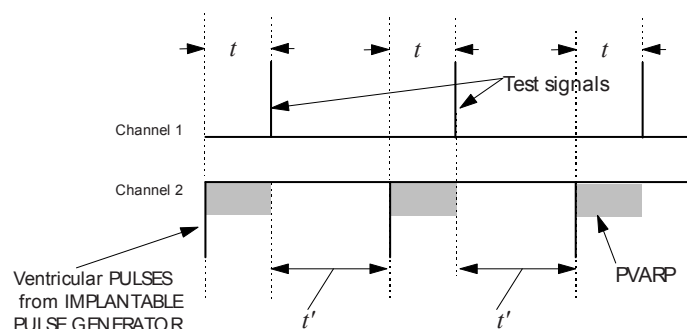


Figure 117 - Initial oscilloscope display when measuring PVARP

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 FF.103.

The IMPLANTABLE PULSE GENERATOR shall be connected to $500\ \Omega \pm 1\%$ 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 $100\ \text{k}\Omega \pm 1\%$ feed resistor (R_F) to point C.

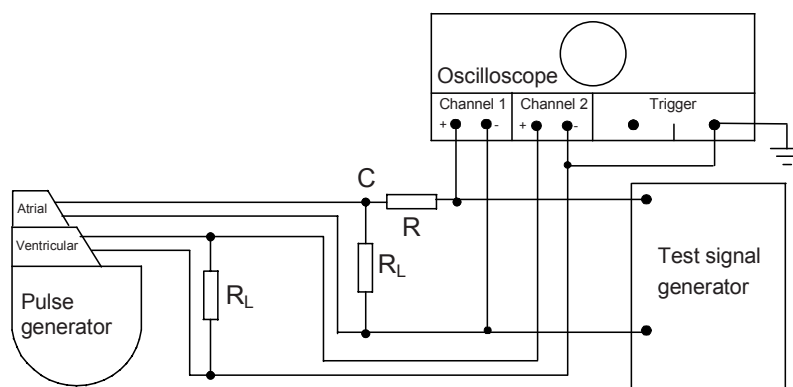


Figure 119 - AV INTERVAL after sensing measurement

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.)

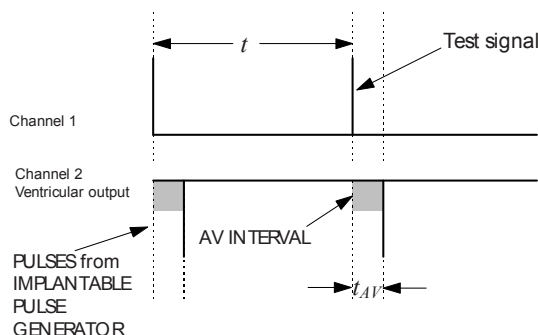


Figure 120 - Oscilloscope display when measuring the AV INTERVAL after sensing

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 $\pm$ 10 %, which represents 1/10 concentration of the isotonic saline solution, maintained at a temperature of 37 °C $\pm$ 2 °C.

The input impedance of the oscilloscope used for testing shall be nominally 1 M Ω .

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)	$\pm$ 5 %
LEAD PACING IMPEDANCE (6.2.2)	$\pm$ 15 %
LEAD SENSING IMPEDANCE (6.2.3)	$\pm$ 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 $\geq$ 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 $\pm$ 5 % μ F series film capacitor (C_F) to the LEAD, the metal plates and the oscilloscope as shown in Figure 121.

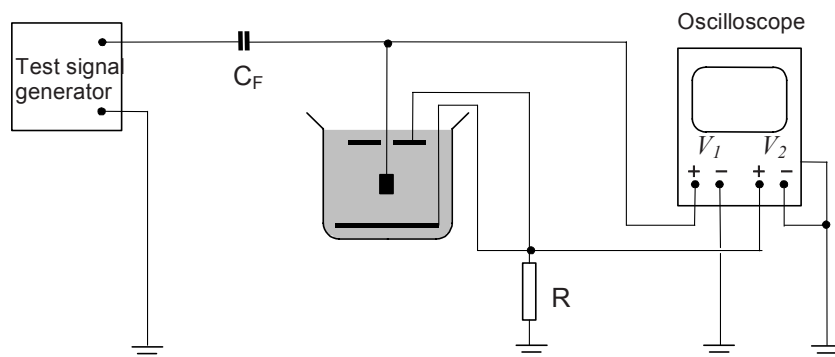


Figure 121 - Determination of the LEAD PACING IMPEDANCE of a UNIPOLAR LEAD

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 $33 \pm 5 \text{ } \mu\text{F}$ series film capacitor (C_F) to the LEAD and oscilloscope as shown in Figure 122.

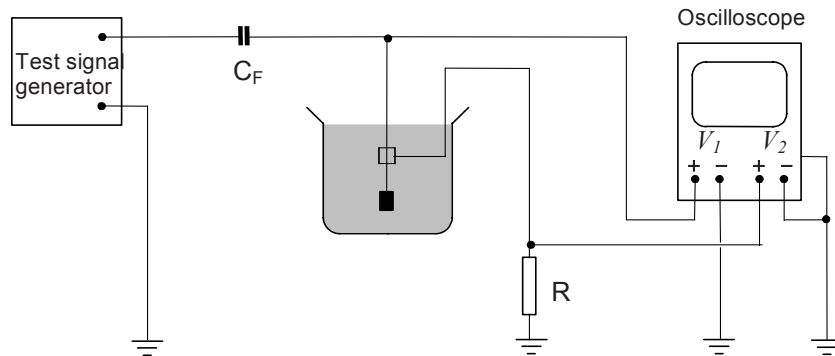


Figure 122 - Determination of the LEAD PACING IMPEDANCE of a BIPOLAR LEAD

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

The lead current shall be determined by measuring the voltage drop across the $10 \text{ } \Omega \pm 2 \text{ } \%$ 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 $\leq 1 \text{ k}\Omega$, which provides a signal in the form defined by Figure FF.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 $\geq x + 25 \text{ mm}$, where x is the linear separation (measured along the LEAD) of the distal extremities of the sensing ELECTRODES under test, with the restriction $d \leq 50 \text{ mm}$. 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 $500\ \Omega \pm 1\%$ resistor (R_F) and $33 \pm 5\%$ 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).

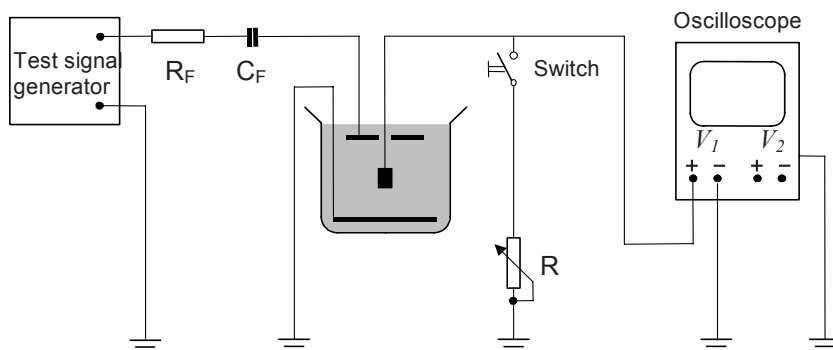


Figure 123 - Determination of the LEAD SENSING IMPEDANCE of a UNIPOLAR LEAD

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 $500\ \Omega \pm 1\%$ resistor (R_F) and $33 \pm 5\%$ 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 $10\ \text{mV} \pm 0,2\ \text{mV}$, 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 $5\ \text{mV} \pm 0,1\ \text{mV}$.

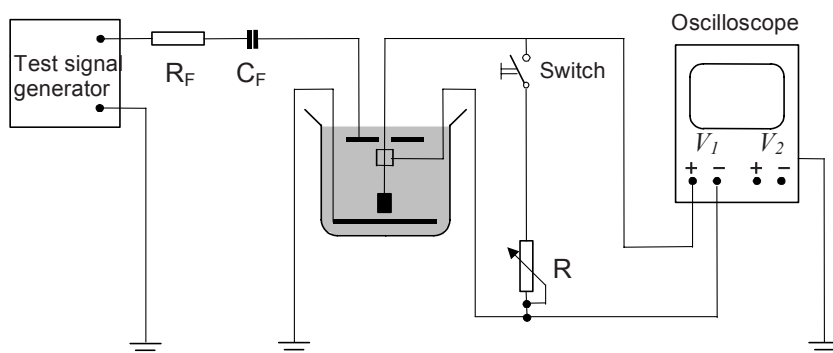


Figure 124 - Determination of the LEAD SENSING IMPEDANCE of a BIPOLAR LEAD

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 DD may be used in the MARKINGS and accompanying documentation to designate the bradyarrhythmia pacing mode of the IMPLANTABLE PULSE GENERATOR.

9.4.1 The SALES PACKAGING containing an IMPLANTABLE PULSE GENERATOR shall bear the following information:

- 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 $37\text{ °C} \pm 2\text{ °C}$ and $500\ \Omega \pm 1\%$ 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.