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Implants for surgery — Active implantable medical devices —

Part 2: Cardiac pacemakers

Implants chirurgicaux — Dispositifs médicaux implantables actifs —

Partie 2: Stimulateurs cardiaques

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Foreword

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

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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

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

The main changes compared to the previous edition are as follows:

— addition of requirements for congestive heart failure devices;

— introduction of nomenclature for devices having more than two channels of pacing / sensing as shown in ISO 14117:2019, Annex N;

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

— removal of measurement requirements for input impedance in 6.1.4;

— inclusion of new temporary exposure criteria in 17.1 for outer surface temperatures exceeding 39 °C. Other changes include updates to selected definitions and incorporation of new measurement equipment accuracy requirements.

A list of all parts in the ISO 14708 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document specifies particular requirements for those active implantable medical devices intended to treat bradyarrhythmias (*pacemakers*), to provide basic assurance of safety to both patients and users.

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

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

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

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

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

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

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

All annexes except Annex D are informative.

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

Implants for surgery — Active implantable medical devices —

Part 2: Cardiac pacemakers

1 Scope

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

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

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

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

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

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

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

NOTE 2 In this document, terms printed in italics are used as defined in Clause 3. Where a defined term is used as a qualifier in another term, it is not printed in italics unless the concept thus qualified is also defined.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5841-3:2013, *Implants for surgery — Cardiac pacemakers — Part 3: Low-profile connectors (IS-1) for implantable pacemakers*

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

ISO 14117:2019, *Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices, Second Edition*

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

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

3 Terms and definitions

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

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

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

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

3.1
accessory
article which, while not being a device, is intended specifically by the manufacturer to be used together with a device in accordance with the use of the device intended by the device manufacturer

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

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

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

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

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

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

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

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

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

3.11
unipolar lead
lead with one *electrode*

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

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

3.14
transvenous
approach to the heart through the venous system

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

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

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

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

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

3.19
beat
ordered spontaneous or paced activity of the heart

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

3.21
pulse amplitude
amplitude of the *pulse*

3.22
pulse duration
duration of the *pulse*

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

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

3.25
pulse rate
number of *pulses* per minute

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

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

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

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

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

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

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

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

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

3.35
beginning of service
BOS
time at which an individual *implantable pulse generator* is first released by the manufacturer as fit for being placed on the market

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

3.36
end of service
EOS
time at which the *prolonged service period* has elapsed and no further pacing function is specified nor can be expected

[SOURCE: ISO 14708-1:2014, 3.7, modified – existing definition entirely replaced]

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

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

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

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

3.40
recommended replacement time
RRT
time at which the *power source indicator* reaches the value set by the manufacturer of the *implantable pulse generator* for its recommended replacement

Note 1 to entry: This indicates entry into the *prolonged service period.*

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

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

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

3.43
terminal
electrically separate conductive device connection

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

4 Symbols and abbreviated terms

The text in Clause 4 of ISO 14708-1:2014 applies.

NOTE See ISO 27185 for symbols to use when expressing information so as to reduce the need for multiple languages on packaging and in manuals.

5 General requirements for non-implantable parts

5.1 General requirements for non-implantable parts

The text in 5.1 of ISO 14708-1:2014 applies.

5.2 General requirements for software

The text in 5.2 of ISO 14708-1:2014 applies.

5.3 Usability of non-implantable parts

The text in 5.3 of ISO 14708-1:2014 applies.

5.4 Data security and protection from harm caused by unauthorized information tampering

The text in 5.4 of ISO 14708-1:2014 applies.

5.5 General requirements for risk management

The text in 5.5 of ISO 14708-1:2014 applies.

5.6 Misconnection of parts of the active implantable medical device

The text in 5.6 of ISO 14708-1:2014 applies.

6 Measurements of *implantable pulse generator* and lead characteristics

6.1 Measurement of *implantable pulse generator* characteristics

6.1.1 General considerations

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

The values of the *implantable pulse generator* characteristics measured in accordance with the methods described in this clause shall be within the range of values stated by the manufacturer in the accompanying documentation (see 28.8.2).

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

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

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

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

Procedure: Use an interval counter and an oscilloscope.

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

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

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

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

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

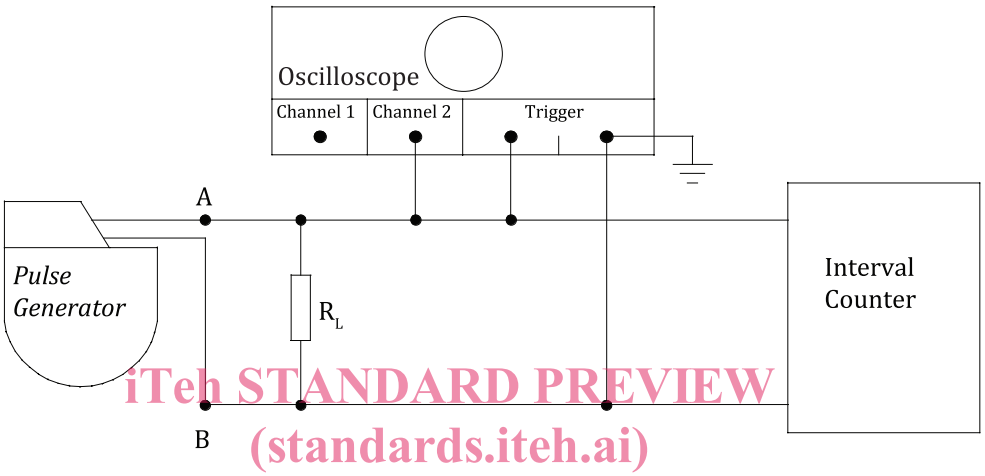

Figure 1 — Measurement of pulse amplitude, pulse duration, pulse interval, and pulse rate

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

The results shall be expressed in the following units:

— *Pulse duration*: milliseconds (ms);

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

— *Pulse interval*: milliseconds (ms);

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

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

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

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

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

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

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

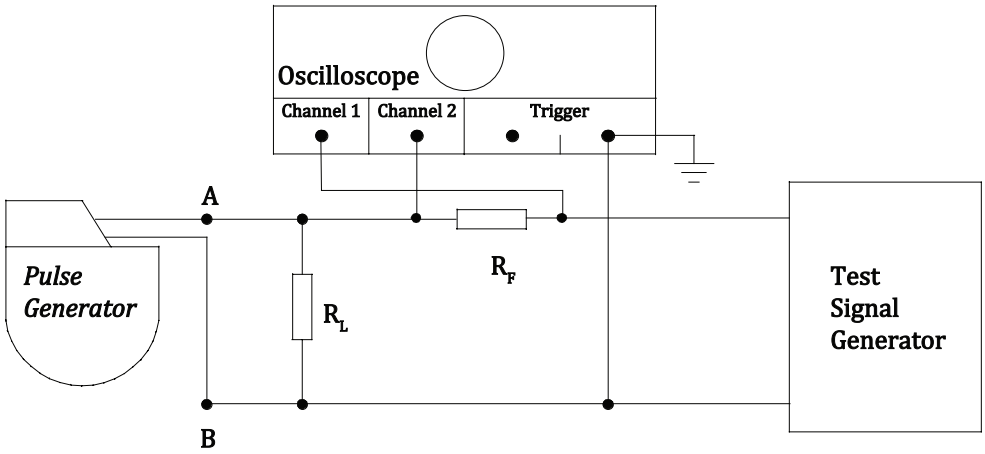

Figure 2 — *Sensitivity* measurement

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

The results shall be expressed in millivolts (mV).

6.1.4 Measurement of input impedance (Z_{in})

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

6.1.5 Measurement of *escape interval* (t_e)

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

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

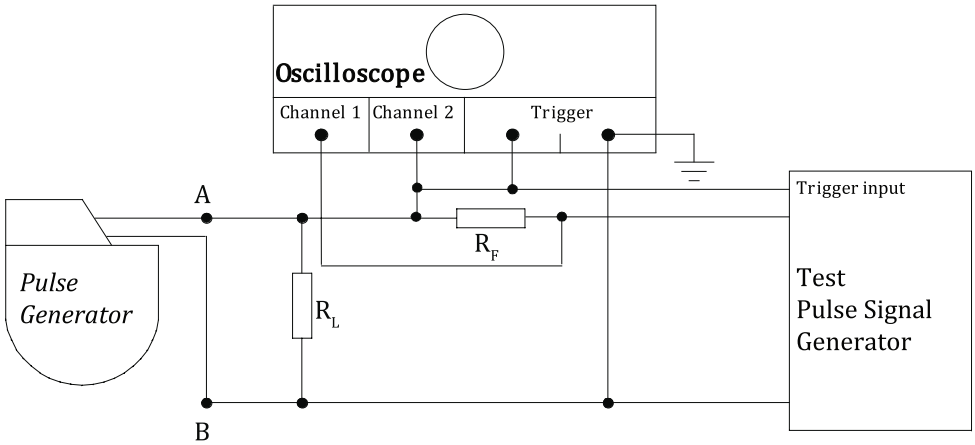

Figure 3 — *Escape interval* measurement

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

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

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

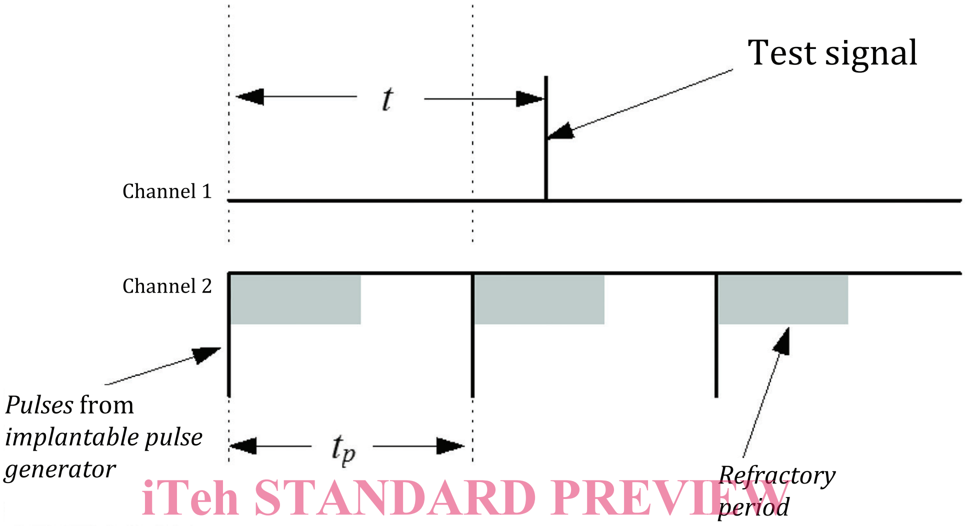

Figure 4 — Initial oscilloscope display, when measuring the *escape interval*

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

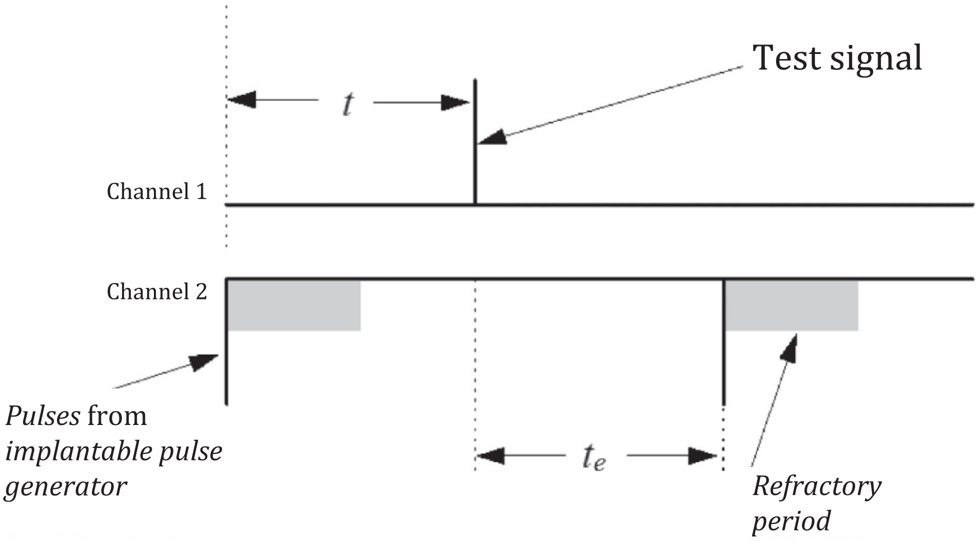

Figure 5 — Measurement of *escape interval* (t_e) in inhibited mode

