INTERNATIONAL STANDARD

ISO 14708-2

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Implants for surgery — Active implantable medical devices —

Part 2: Cardiac pacemakers

Implants chirurgicaux — Dispositifs médicaux implantables actifs —

Partie 2: Stimulateurs cardiaques

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Foreword

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

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

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

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

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

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

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

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

— *Part 2: Cardiac pacemakers*

— *Part 3: Implantable neurostimulators*

— *Part 4: Implantable infusion pumps*

— *Part 5: Circulatory support devices*

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

The following parts are under preparation:

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

Introduction

This part of ISO 14708 specifies particular requirements for those ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat bradyarrhythmias (PACEMAKERS), to provide basic assurance of safety to both patients and users.

An implantable cardiac PACEMAKER is essentially a powered electronic device within a sealed, encapsulating enclosure (an IMPLANTABLE PULSE GENERATOR). The device can stimulate heart beats by generating electrical impulses which are transmitted to the heart along implanted, insulated conductors with ELECTRODES (LEADS). The PACEMAKER may be adjusted non-invasively by an electronic device, known as a programmer.

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

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

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

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

Annex DD describes a coding system that may be used to designate bradyarrhythmia pacing modes. Annex EE provides optional symbols that may be used to reduce the need for translation of MARKINGS and information in the accompanying documentation in multiple languages. Annex FF defines reference points for measurements of PULSE AMPLITUDE and PULSE DURATION, and the form of test signal used to determine SENSITIVITY.

All annexes except Annex FF are informative.

Implants for surgery — Active implantable medical devices —

Part 2: Cardiac pacemakers

1 Scope

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

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

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

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

Any features of an ACTIVE IMPLANTABLE MEDICAL DEVICE intended to treat tachyarrhythmias are covered by ISO 14708-6.

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

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

2 Normative references

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

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

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

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

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

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

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

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

3 Terms and definitions

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

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

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

3.3
pacemaker
ACTIVE IMPLANTABLE MEDICAL DEVICE intended to treat bradyarrhythmias, comprising an IMPLANTABLE PULSE GENERATOR and LEAD(S)

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

3.5
sensor
part of a pacemaker that is designed to detect signals for the purpose of RATE MODULATION

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

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

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

NOTE See 6.1.3.

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

3.10
bipolar lead
LEAD with two ELECTRODES, electrically isolated from each other

3.11
unipolar lead
LEAD with one ELECTRODE

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

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

3.14
transvenous
approach to the heart through the venous system

3.15
insertion diameter
〈LEAD〉 minimum bore of a rigid cylindrical tube into which the LEAD (not including the connector) may be inserted

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

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

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

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

3.19
model designation
name and/or a combination of letters and numbers used by a manufacturer to distinguish, by function or type, one device from another

3.20
serial number
unique combination of letters and/or numbers, selected by the manufacturer, intended to distinguish a device from other devices with the same MODEL DESIGNATION

3.21
beat
ordered spontaneous or paced activity of the heart

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

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

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

3.25
pulse interval
interval between equivalent points of two consecutive PULSES

NOTE See 6.1.2.

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

3.27
pulse rate
number of PULSES per minute

NOTE See 6.1.2.

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

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

NOTE See 6.1.8.

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

NOTE See 6.1.5.

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

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

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

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

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

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

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

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

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

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

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

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

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

3.42
recommended replacement time
RRT
time at which the POWER SOURCE INDICATOR reaches the value set by the manufacturer of the IMPLANTABLE PULSE GENERATOR for its recommended replacement

NOTE This indicates entry into the PROLONGED SERVICE PERIOD.

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

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

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

4 Symbols and abbreviated terms

This clause of the General Standard applies.

Additional NOTE.

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

5 General requirements for non-implantable parts

This clause of the General Standard applies.

6 Measurements of implantable pulse generator and lead characteristics

6.1 Measurement of implantable pulse generator characteristics

6.1.1 General considerations

This subclause addresses only the acuity of the measurement system. The accuracy tolerances described below are not intended to reflect performance of the implantable pulse generator under test. The values of the implantable pulse generator characteristics measured in accordance with the methods described in this clause shall be within the range of values stated by the manufacturer in the accompanying documentation [see 28.8].

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

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

Table 101 — Overall measurement accuracy limits

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

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

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

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

Procedure: Use an interval counter and an oscilloscope.

The IMPLANTABLE PULSE GENERATOR shall be connected to a 500 Ω ± 1 % load resistor (R_L), and the test equipment as shown in Figure 101. The oscilloscope shall be adjusted to display one pulse in full.

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

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

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

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

where ln designates the natural logarithm.

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

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

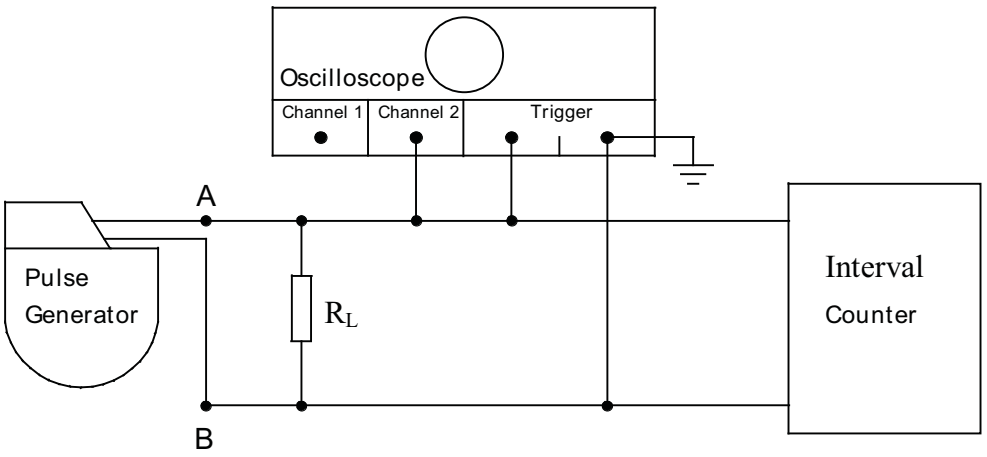

Figure 101 — Measurement of pulse amplitude, pulse duration, pulse interval, pulse rate, leading edge fall time, and effective pacing capacitance

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

The results shall be expressed in the following units:

— PULSE DURATION: milliseconds (ms);

— PULSE AMPLITUDE: volts or milliamperes (V or mA);

— PULSE INTERVAL: milliseconds (ms);

— PULSE RATE: reciprocal minutes (min^{-1});

— EFFECTIVE PACING CAPACITANCE: microFarad (μF).

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

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

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

The IMPLANTABLE PULSE GENERATOR shall be connected to a 500 Ω ± 1 % load resistor (R_L) and the test equipment as shown in Figure 102. Apply positive polarity test signals from the test signal generator through a 100 kΩ ± 1 % feed resistor (R_F) to point A. Adjust the pulse interval of the test signal generator so that it is at least 50 ms less than the basic pulse interval of the implantable generator. The test signal amplitude (A_T) shall be adjusted to zero, and the oscilloscope shall be adjusted to display several PULSES.

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

The test signal amplitude shall then be measured. The positive sensitivity, designated e_{pos}, shall be calculated by dividing the measured test signal voltage by 200.

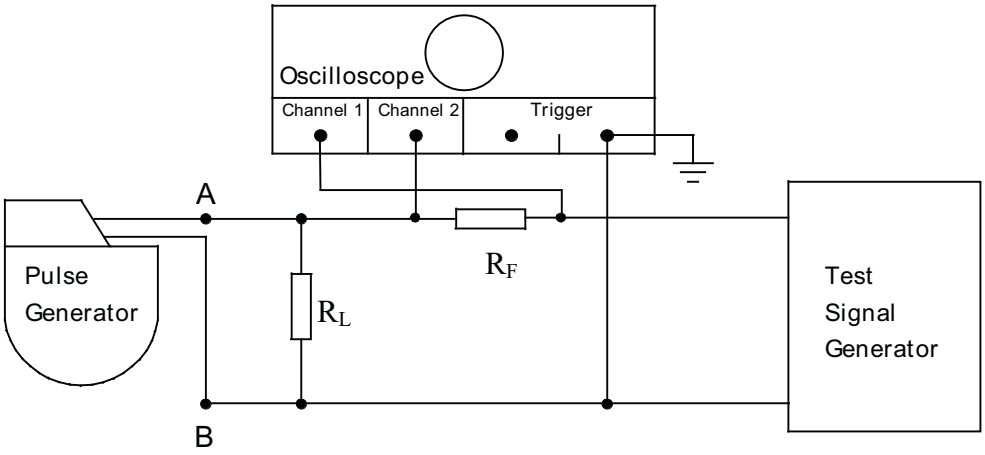

Figure 102 — Sensitivity measurement

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

The results shall be expressed in millivolts (mV).

6.1.4 Measurement of input impedance (Z_{in})

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

The IMPLANTABLE PULSE GENERATOR shall be connected to 500 Ω ± 1 % load resistors (R_L) and the test equipment as shown in Figure 103. Apply test signals of either polarity from the test signal generator through series feed resistors R_1 (potentiometer) and R_F (fixed value) to point A. Potentiometer R_1 shall be chosen to have a maximum resistance greater than, but of the same order of magnitude as, the expected input impedance of the implantable pulse generator (e.g. 10 kΩ, 100 kΩ, etc.). R_F shall be 100 kΩ ± 1 %. Adjust the pulse interval of the test signal generator so that it is at least 50 ms less than the basic pulse interval of the implantable pulse generator. The test signal amplitude (A_T) shall be adjusted to zero, and the oscilloscope shall be adjusted to display several PULSES.

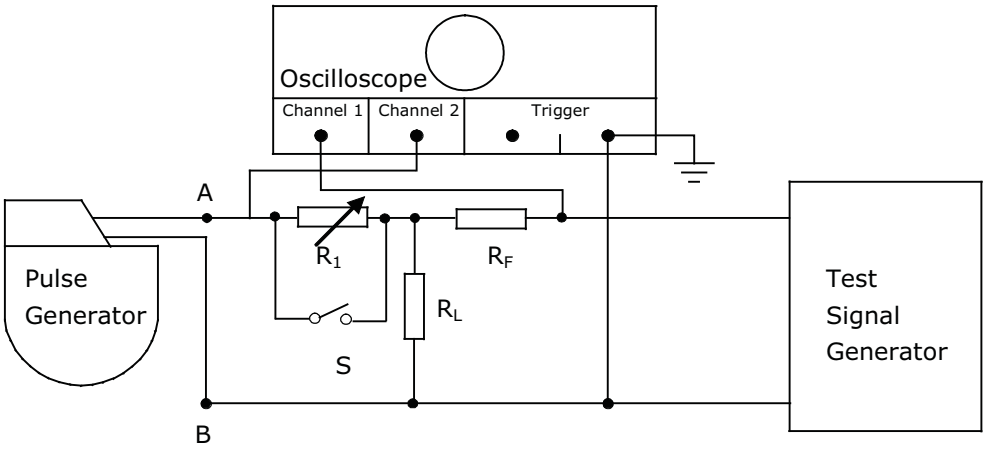

Figure 103 — Input impedance measurement

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