International Standard 5841/1

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Implants for surgery — Cardiac pacemakers — Part 1 : Implantable ventricular pacemakers

Implants chirurgicaux — Stimulateurs cardiaques — Partie 1 : Stimulateurs ventriculaires implantables

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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. Every 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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

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Contents

Implants for surgery — Cardiac pacemakers — Part 1 : Implantable ventricular pacemakers

0 Introduction

This part of ISO 5841 is the first of several parts of an International Standard envisaged to cover cardiac pacemakers. It describes implantable ventricular pacemakers, the largest section of pacemakers currently in use. Subsequent parts of ISO 5841 will deal with other types of pacemaker and other aspects of cardiac pacing.

Although an electro-medical device, an implantable pacemaker should nevertheless be considered separately from standards which cover electro-medical equipment in general. Whereas the focus of general electro-medical equipment standards is on safety in the patient environment, which is usually considered external to the patient, the implantable pacemaker has different concerns.

It is acknowledged that specific clinical situations may demand the use of pacemakers which do not meet all the requirements of ISO 5841.

The many kinds of cardiac pacemakers differ in the various ways in which they maintain and control cardiac activity under diverse circumstances. The simplest kind of pacemaker stimulates the ventricle independently of cardiac activity; others monitor ventricular activity and stimulate the ventricles as and when required; other more complex pacemakers depend on monitoring and/or stimulating the ventricle and/or the atrium. Some implantable pacemakers operate at preset values of rate, amplitude and duration. Others may have one or more characteristics adjustable and/or mode of operation changed non-invasively by means of an external adjustment device. Those pacemakers which require long-term attachment of an external controller over the implanted pacemaker are deemed to be only partially implantable. Those which require the presence of an external device only to adjust characteristics or mode are deemed wholly implantable. Thus the possible ways in which cardiac pacing can be achieved are as numerous and complex as are the kinds of pacemakers available.

Annex A does not form part of this International Standard. Annexes B and C are integral parts of this International Standard. Annex D gives a rationale for some of the provisions of this International Standard.

The bibliography in clause 6 gives the principal documents on which this part of ISO 5841 is based.

1 Scope and field of application

1.1 This part of ISO 5841 specifies requirements for the marking and packaging of implantable ventricular pacemakers and for the documentation to accompany them.

1.2 This part of ISO 5841 applies exclusively to wholly implantable cardiac pacemakers, either of the preset or the adjustable type, and is confined to those aspects of pacemakers which are concerned only with stimulation of the ventricle (asynchronous pacing) and with sensing and stimulation of the ventricle (ventricular inhibited or ventricular triggered pacing).

2 Reference

ISO 2014, *Writing of calendar dates in all-numeric form.*

3 Definitions

For the purpose of this part of ISO 5841 the following definitions apply.

3.1 adaptor : Specialized connector used between an otherwise incompatible pulse generator and lead.

3.2 electrode : Electrically conductive element (usually a termination of a lead) which interfaces with body tissue.

3.3 hysteresis : The characteristic of a pulse generator in which the escape pulse interval (rate) is longer (slower) than the basic pulse interval (rate).

3.4 lead : Means of electrically connecting a pulse generator to the heart.

3.5 lead, bipolar : Lead with two electrically isolated electrodes.

3.6 lead, endocardial : Lead with an electrode designed to contact the endocardium or inner surface of the heart.

3.7 lead, epicardial : Lead with an electrode designed to contact the epicardium or outer surface of the heart.

3.8 lead, myocardial : Lead with an electrode(s) designed to be inserted into the myocardium.

3.9 lead, unipolar : Lead with one electrode.

3.10 leading edge : Initial portion of the pulse from zero to its peak amplitude.

3.11 marking : Any display of written, printed or graphic matter appearing on or affixed to a device or appearing on a package containing a device.

3.12 model designation : Name or group of letters and/or numbers designated by a manufacturer, distinguishing by function or type one device from another device.

3.13 nominal pulse generator service life : An estimate of the expected implant life-time of a given model of pulse generator, taking into account the usable battery capacity, which enables the pulse generator performance characteristics to remain within defined limits under specified conditions, and ignoring the possibility of any cause of failure other than that due to battery discharge.

3.14 pacemaker (pacer) : Device for stimulating the heart comprising a pulse generator and lead or leads.

3.15 package : Any container or wrapping material in which a device is wholly or partly contained, placed or packed.

3.16 package, shipping : Package in which the pulse generator, lead, accessory or combination thereof is supplied and which is not intended to be a storage package.

3.17 package, sterilized : Package in which a pulse generator, lead, accessory or combination thereof has been through a sterilization process.

3.18 package, storage : Package in which a pulse generator, lead, adaptor or combination thereof is intended by the manufacturer to be stored at the implanting centre.

3.19 pervenous : Indirect approach to the heart through the venous system.

3.20 pulse amplitude, measured : Amplitude value measured by the manufacturer prior to shipment.

3.21 pulse duration, measured : Pulse duration measured by the manufacturer prior to shipment.

3.22 pulse rate(s), measured : Pulse rate(s) measured by the manufacturer prior to shipment.

3.23 pulse generator : Portion of the pacemaker that produces a periodic electrical pulse and includes the power supply and electronic circuit.

3.24 pulse generator, asynchronous : Pulse generator in which the pulse rate is independent of the activity of the heart.

3.25 pulse generator, ventricular inhibited : Ventricular stimulating pulse generator which is intended to suppress its output in response to natural ventricular activity, and produces an output at its basic pulse rate in the absence of natural ventricular activity.

3.26 pulse generator, ventricular triggered : Ventricular stimulating pulse generator which is intended to deliver its output synchronously with the natural ventricular activity, and at its basic pulse rate in the absence of natural ventricular activity.

3.27 pulse interval : Time interval between selected identical points on the pulses of two consecutive pulse generator output pulses expressed in milliseconds.

3.28 pulse interval, basic (basic pulse period) : The pulse interval free from modifying cardiac or other electromagnetic influence.

3.29 pulse interval, escape : Time interval between the sensing of a spontaneous beat and the succeeding nontriggered output pulse of a pulse generator free from modifying cardiac activity or other electromagnetic influences.

3.30 pulse rate : The number of pulses per minute (abbreviated as ppm).

3.31 pulse rate, basic : Pulse rate free from modifying cardiac activity or other electromagnetic influence.

3.32 pulse rate, test : Pulse rate of a pulse generator when under the influence of a testing device.

3.33 pulse rate, interference : Pulse rate of a pulse generator when an electromagnetic field is recognized as interference.

3.34 refractory period : Period during which a pulse generator is unresponsive to an input signal of specified amplitude.

3.35 sensitivity (sensing threshold) : Measure in millivolts of the minimum signal required to control consistently the pulse generator function.

3.36 sensitivity, measured : Sensitivity measured by the manufacturer prior to shipment.

3.37 serial number : Unique combination of letters or numbers, or both, selected by the manufacturer to identify any part of a pacemaker.

3.38 use-before date : Date specified by the manufacturer after which the pulse generator should not be implanted.

4 Packages, markings and accompanying documentation

NOTE — The type codes given in annex A are acceptable as type designations in marking and accompanying documents in lieu of a description in words.

4.1 Packages and markings

4.1.1 Packages

Packages shall be classified as :

a) shipping packages.

b) storage packages.

c) sterilized packages.

4.1.2 General requirements for package markings

Each package shall have readily readable markings which shall be of material that will maintain legibility during normal handling and not adversely affect the contents. The storage and sterilized package shall have instructions for the proper unpacking of the contents so as to prevent physical damage and maintain sterility.

4.2 Shipping package

4.2.1 Markings

The following information shall be included in shipping package markings :

a) identification of the contents;

b) manufacturer (and agent/distributor, if different from manufacturer) information, with complete address;

c) warnings concerning handling and storage during shipment.

4.2.2 Contents

The shipping package shall contain the storage package(s).

4.3 Storage package

4.3.1 Markings

The following information specific to the contents shall be included :

a) manufacturer's name or trademark and location;

b) space for the agent's name, address and telephone number;

c) contents of the sterilized package(s), viz : pulse generator (type, model designation, serial number) or lead (type, model designation, serial number) or pulse generator and pacing lead, together with a list of any accessories;

d) pulse generator characteristics at 37 ± 2 °C with 510 Ω ± 2 % load :

1) measured basic pulse rate (pulses per minute);

2) measured test pulse rate, if applicable (pulses per minute);

3) measured pulse amplitude (volts or milliamperes);

4) measured pulse duration (milliseconds);

5) measured sensitivity, if applicable (millivolts).

In the case of adjustable pulse generators, the parameters shall refer to the generator as shipped.

The values of all other parameters upon which all of the above are dependent shall be given.

e) a statement as to which of the characteristics are adjustable;

f) a statement to the effect that contents of the package have been through a sterilization process;

g) use-before date, expressed in accordance with ISO 2014;

h) recommendations regarding storage and handling;

j) any warnings which shall be prominently displayed.

4.3.2 Contents

The storage package shall contain accompanying documentation and sterilized package(s).

4.4 Accompanying documentation

4.4.1 Manual for the clinician

The manual shall give information as indicated in 4.4.1.1 to 4.4.1.5 about the pulse generator and/or lead. If a pulse generator only is supplied, 4.4.1.4 may be omitted. If a lead only is supplied, 4.4.1.3 may be omitted.

4.4.1.1 Supplier's details

The name, address, and telephone number of the manufacturer (or responsible agent) shall be provided.

4.4.1.2 Handling instructions

Instructions shall be provided for opening the sterilized package. Recommendations shall be provided regarding handling and storage conditions.

4.4.1.3 Pulse generator

The following details shall be provided :

a) type and model designation (and name, if applicable);

b) general description and explanation of function;

c) type of power source;

d) physical characteristics :

1) mass (grams);

2) principal dimensions (millimetres);

3) volume (cubic centimetres).

e) material, surface area (square centimetres) and form of the electrode which is an integral part of the pulse generator (if applicable);

f) electrical characteristics at 37 ± 2 °C and 510 Ω ± 2 % load unless otherwise stated (including tolerance, where applicable) as follows :

1) ranges of basic, test, escape and interference pulse rates (pulses per minute) and equivalent pulse intervals (milliseconds) (if applicable);

2) acceptable change in basic pulse rate during an initial stated time period;

3) pulse shape; a diagram of a typical output pulse shape; the points which define the output pulse amplitude and duration shall be identified;

4) pulse amplitude [range (s)] (volts or milliamperes);

5) pulse duration (range and stability) (milliseconds);

6) input impedance, if applicable (ohms);

7) sensitivity range (in millivolts) for both positive and negative polarity, if applicable; a description of the waveform used shall be included;

8) refractory period (in milliseconds) (pacing and sensing), if applicable;

9) operational characteristics when subjected to environmental electric, electromagnetic and magnetic fields;

g) information shall be provided which correlates power source depletion (that is, the state of power source discharge) with the pulse generator characteristics which are listed below. This information should be representative of the pulse generators and should be given for the temperature 37 ± 2 °C and 510 Ω ± 2 % (curves may be used) :

1) basic pulse rate (pulses per minute);

2) test pulse rate (if applicable) (pulses per minute);

3) pulse duration (milliseconds);

4) pulse amplitude (volts or milliamperes);

5) sensitivity (if applicable) (millivolts).

It shall state which of the changes in characteristics can be used as power source depletion indicators and shall state the maximum changes which should be allowed to take place before consideration be given to explanting a generator;

h) the typical variation of the following pulse generator characteristics with temperature over the range 20 to 43 °C shall be provided (a curve may be used) :

1) basic pulse rate (pulses per minute);

2) pulse duration (milliseconds);

3) pulse amplitude (volts or milliamperes);

4) sensitivity (if applicable) (millivolts);

5) input impedance (if applicable) (ohms).

j) information on non-invasive identification;

k) recommendations regarding choice of suitable lead and information on some compatible adaptors;

m) specific implantation considerations regarding attachment of leads;

n) recommended methods for determining that the implanted pacemaker is functioning properly;

p) warnings regarding therapeutic energy sources, for example, external cardioversion, diathermy, cautery or other sources;

q) information regarding registration (see 4.4.2);

r) recommendations regarding resterilization including warnings concerning unsuitable methods of resterilization;

s) recommendations for disposal of pulse generators;

t) nominal pulse generator service life in accordance with annex C;

u) the address from which longevity experience data can be obtained, if applicable.

4.4.1.4 Lead

The following details shall be provided :

a) type, model designation (and name, if applicable);

b) general description including conductor(s), conductor insulation materials, and shape and material of electrode(s);

c) physical dimensions (including applicable tolerances) :

1) length (including the connector) (centimetres);

2) surface area of electrode(s) (square millimetres);

3) maximum diameter of pervenous lead (except for connector end) (millimetres);

4) distance between electrodes (bipolar endocardial lead) (millimetres);

5) maximum depth of electrode penetration, if applicable (millimetres);

6) connector size (millimetres).

d) resistance of each conductor (ohms) measured at a temperature of 23 ± 2 °C using a test current of 10 ± 5 mA;

e) recommendations regarding use with pulse generators;

f) recommendations regarding resterilization including warnings concerning unsuitable methods of resterilization;

g) specific implantation considerations regarding attachment of leads;

h) handling precautions to avoid damage to the lead.

4.4.1.5 Adaptor (if applicable)

The following details shall be provided :

a) type, model designation (and name, if applicable);

b) general description including conductor and conductor materials;

c) compatibility with pulse generators and leads.

4.4.2 Registration form

A registration form for recording basic patient and implantation information shall be provided. The registration form should be in duplicate with one part marked "For return to the manufacturer".

Space shall be provided on the form for the following information :

a) patient data (required for patient identification card);

b) type of pulse generator, model designation and serial number;

c) date on which pulse generator was implanted, in accordance with ISO 2014;

d) type of pacing lead(s), model designation(s) and serial number(s) and implantation date, in accordance with ISO 2014;

e) telephone number(s) of clinician/hospital to contact;

f) clinician/hospital address.

4.4.3 Patient's identification card

The manufacturer shall supply to the implanting centre an identification card. Space shall be provided on the card for at least the following information, where applicable :

a) patient's name, address, telephone number and identification code suitable for computer data processing;

b) name, address and telephone number of hospital where pacemaker was implanted;

c) name, address and telephone number of clinician responsible for patient's care;

d) name, address and telephone number of pacemaker manufacturer or agent;

e) dates of implantation, in accordance with ISO 2014, of pulse generator and leads;

f) type of pulse generator, model designation and serial number;

g) measured generator rates (basic pulse rate, test and escape pulse rates), if applicable;

h) type of lead(s), model designation(s) and serial number(s).

4.4.4 Explantation form

An explantation form shall be provided. The form should be in duplicate, with one part marked "For return to the manufacturer". Separate forms may be provided for pulse generator and leads. The form should request the following :

a) patient data :

1) patient's name/identification code;

2) patient's address;

3) name and address of hospital;

4) name and address of clinician responsible for patient care;

b) data on pulse generators and leads :

1) manufacturer, type, model designation, serial number and dates of implantation and explantation of removed pulse generator;

2) reason for replacement of pulse generator : i.e.; apparent change in pulse generator characteristics, prophylactic replacement (elective replacement), other reason;

3) data on leads : manufacturer, type, model designation, serial number and date of implantation and explantation of removed lead;

4) reason for replacement of lead : i.e.; apparent change in lead structure, exit block, high threshold, displacement of lead, infection, extrusion, other reason;

5) evidence : (electrocardiographic, electronic, etc.) which shows the pacemaker performance prior to its removal (if applicable).

4.5 Sterilized package

4.5.1 Sterilized package marking

The sterilized package marking shall include the following :

a) contents of the sterilized package, viz : pulse generator (type, model designation, serial number) or lead (type, model designation, serial number) or pulse generator and pacing lead, together with a list of any accessories;

b) pulse generator characteristics at 37 ± 2 °C and 510 Ω ± 2 % load :

1) measured basic pulse rate (pulses per minute);

2) measured test pulse rate, if applicable (pulses per minute);

3) measured pulse amplitude (volts or milliamperes);

4) measured pulse duration (milliseconds);

5) measured sensitivity (millivolts).

In the case of adjustable pulse generators, the characteristics shall refer to the generator as shipped.

c) a statement as to which of the characteristics are adjustable;

d) a statement to the effect that the package and its contents have been subjected to a sterilization process;

e) use-before date, in accordance with ISO 2014;

f) any warnings which shall be prominently displayed;

g) instructions for opening.

4.5.2 Sterilized package contents

The pulse generator, lead and necessary accessories/adaptors (either separately or in combination) shall be supplied in a sterilized package capable of maintaining the sterility of the product during shipping and under conditions of normal storage and handling and to allow the contents to be presented for use in an aseptic manner. The sterilized package should not be resealable.

4.6 Pulse generators, leads and adaptors

4.6.1 Pulse generator markings

The markings on a pulse generator shall be permanent, readily readable and give the following information :

a) name and location of manufacturer;

b) type;

c) model designation;

d) serial number, which shall be preceded by one of the following : serial number, serial, serial no., ser. no., SN;

e) an appropriate designation if the pulse generator has characteristics which are not generally available from the manufacturer.

4.6.2 Non-invasive identification of pulse generators

The method of identification shall be a code consisting of radiopaque letters, numbers, and/or symbols incorporated into the pulse generator to allow a clinician to identify the pulse generator non-invasively, with appropriate code information.

The identifiable information shall indicate at least the manufacturer and the model of the particular pulse generator, allowing subsequent identification of the pulse generator performance characteristics.

4.6.3 Markings on leads and adaptors

Each lead or adaptor shall be permanently and visibly marked for identification of serial number and manufacturer. The manufacturer shall supply a publicly available code by which its leads (and adaptors) shall be identified.

5 Method of test for pulse generators

The values of the characteristics of pulse generators that are to be stated in accordance with the requirements of clause 4 shall be determined by any suitable methods. In case of dispute, the methods given in annex B shall be the referee methods.

6 Bibliography

[1] PARSONNET, VICTOR; FURMAN, SEYMOUR and SMYTH, NICHOLAS. *Implantable cardiac pacemakers status report and resource guideline.* Report of Inter-Society Commission for Heart Disease Resources. Circulation volume L, Oct. 1974.

[2] Pacemaker Standard : *Labeling requirements, performance requirements and terminology for implantable artificial cardiac pacemakers.* FDA Contract no. 223-74-5083, Association for the Advancement of Medical Instrumentation, Aug. 1975.

Annex A

Code for type of pulse generator

(This annex does not form part of the standard.)

A.1 This annex provides a code which may be used in marking and accompanying documentation to designate the primary intended use of a pulse generator as the acceptable alternative to a description in words. The code cannot be fully applied to complex pulse generators.

A.2 Table 1 gives an outline of the basic concept of the code.

Table 1 — Basic code scheme

First letter	Second letter	Third letter
Chamber paced	Chamber sensed	Mode of response

A.3 In the code the following abbreviations shall be used :

V = Ventricle
A = Atrium
D = Double chamber
I = Inhibited
T = Triggered
O = Not applicable

A.4 The code letter significance is explained below :

First letter : The paced chamber is identified by V for ventricle, A for atrium or D for double (i.e. both atrium and ventricle).

Second letter : The sensed chamber is identified by either V for ventricle or A for atrium. O indicates that the pulse generator has no sensing function. D indicates sensing of both chambers.

Third letter : The mode of response is either :

I for inhibited, (i.e. a pulse generator whose output is blocked by a sensed signal), or

T for triggered, (i.e. a pulse generator whose output is triggered by a sensed signal).

O is used if the pulse generator has no sensing function.

D for both inhibited and triggered.

A.5 Examples of code application are given in table 2.

Table 2 — Code application

Type of pulse generator	Explanation of code used
VOO	Ventricular pacing : no sensing function.
AOO	Atrial pacing : no sensing function.
DOO	Double-chamber pacing : no sensing function.
VVI	Ventricular pacing and sensing, inhibited mode.
VVT	Ventricular pacing and sensing, triggered mode.
AAI	Atrial pacing and sensing, inhibited mode.
AAT	Atrial pacing and sensing, triggered mode.
VAT	Ventricular pacing, atrial sensing, triggered mode.
DVI	Double-chamber pacing, ventricular sensing, inhibited mode.