INTERNATIONAL STANDARD

ISO 5841-1

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Cardiac pacemakers —

Part 1 :
Implantable pacemakers

Stimulateurs cardiaques —
Partie 1 : Stimulateurs cardiaques implantables

Reference number
ISO 5841-1 : 1989 (E)

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.

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.

International Standard ISO 5841-1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

This second edition cancels and replaces the first edition (ISO 5841-1 : 1985), of which it constitutes a technical revision.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

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Cardiac pacemakers —

Part 1 : Implantable pacemakers

0 Introduction

0.1 This is the first of several parts of an International Standard covering cardiac pacemakers; ISO 5841-2 deals with the reporting of the clinical performance of populations of pulse generators.

During the development work, which has been jointly carried out by ISO and IEC working groups, this part of ISO 5841 was used as the basis for harmonizing regulatory requirements being considered in several European countries under the auspices of the European Economic Community. The harmonization effort has, in turn, contributed important improvements, most notably in environmental and electrical hazard testing.

0.2 The International Standards which cover the general category of electro-medical equipment are not applicable to pacemakers, which are therapeutic, implantable battery-powered devices. The implantable pacemaker presents concerns different from safety in the patient environment, generally considered to be external to the patient, which is the focus of general electro-medical equipment standards.

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

0.3 Basically, pacemakers treat cardiac arrhythmias. Such arrhythmias reduce cardiac output and may lead to confusion, dizziness, loss of consciousness and death. The implantable pacemaker is an effective treatment which has restored hundreds of thousands of patients to full lives.

The objective of pacing is to restore cardiac rhythm and output appropriate to the patient's physiological needs. As patients present unique and changing arrhythmias due to a variety of causes, a broad range of approaches to treatment is required. In response to this need, a large variety of pacemakers has been developed. More recently, pacemakers have been used which can be changed in operating mode and characteristics to match patient need at implant and subsequently as her/his needs change.

Implantable pacemakers are evolving from devices which were limited in reliability, longevity and in their benefits to patients into devices there are employing new technologies to optimize patient benefit. These improvements are accompanied by improved longevity and reliability of the device. Patient risks have markedly decreased as a result of reduced need for surgical reintervention.

Standards for pacemakers require attention to information which will aid in selecting and applying these devices. Standardization work must also acknowledge the central role of clinical experience in evaluating pacemaker designs and the central role of consistent manufacturing practices in ensuring the quality, reliability and biocompatibility of each pacemaker produced. The ability to determine how a pacemaker will perform in a specific patient based on the testing of a device to a set of technical criteria is limited.

Some tests and requirements are still under consideration, pending resolution of technical issues.

1 Scope and field of application

1.1 This part of ISO 5841 establishes basic terminology and definitions, and specifies requirements for marking implantable cardiac pacemakers and their packaging.

Minimum requirements for the ability of pacemaker pulse generators to withstand environmental stress conditions are also specified along with appropriate test methods.

Annex A explains the coding system for identifying the mode of operation of pulse generators. Test methods to assess the basic electrical parameters for conformance with claims are included in annex B; annex C describes the estimation and expression of the nominal service life of a pulse generator; annex D provides an example of a technical information sheet; annex E provides a rationale for certain of the provisions of this part of ISO 5841 and annex F provides optional symbols to be used in place of written words.

1.2 This part of ISO 5841 applies to all types of wholly implantable cardiac pacemakers; it does not cover anti-tachyarrythmia and defibrillation functions of pacemakers, nor pacemakers powered by isotopic cells (nuclear-powered pacemakers).

2 References

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

ISO 5841-2, *Implants for surgery — Cardiac pacemakers — Part 2 : Reporting of the clinical performance of populations of pulse generators.*

IEC Publication 68-2-6, *Basic environmental testing procedures — Part 2 : Tests — Test Fc and guidance : Vibration (sinusoidal).*

IEC Publication 68-2-27, *Basic environmental testing procedures — Part 2 : Tests — Test Ea : Shock.*

3 Definitions

3.1 Basic definitions

The following definitions have been established in order to encourage common usage worldwide.

Subclause 3.1.4 presents the terminology particular to the modes of pulse generators, and uses the coding system described in annex A.

3.1.1 atrial blanking at ventricular pace : Interruption of atrial sensing during the ventricular pulse.

3.1.1.1 atrio-ventricular (A-V) 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.

3.1.1.2 ventricular-atrial (V-A) interval : Delay between a ventricular pulse or the sensing of a ventricular depolarization and the subsequent atrial pulse or the sensing of an atrial depolarization.

3.1.2 battery depletion indicator : Means of indicating the quantity of electricity that has been drawn from a battery during the pulse generator's service life.

3.1.3 blanking period : Period during which a sensing function of a pulse generator is disabled.

3.1.4 Modes of pulse generators (see 3.2.24)

NOTE — The three-letter code given for each term is explained in annex A.

3.1.4.1 atrial asynchronous mode (AOO) : Mode in which the ventricular and the atrial sensing are disabled; atrial pacing is provided independent of the activity of the heart.

3.1.4.2 atrial inhibited mode (AAI) : Mode in which the ventricular functions are disabled or absent. If an atrial beat is sensed during the escape interval, then the pulse generator suppresses atrial pacing. If no atrial beat is sensed during the escape interval, then the pulse generator provides atrial pacing at the basic rate.

3.1.4.3 atrial triggered mode (AAT) : Mode in which the ventricular functions are disabled or absent. If an atrial beat is sensed during the escape interval, then an atrial pulse is provided immediately in synchrony with the atrial beat. If no atrial beat is sensed during the escape interval, then the pulse generator provides atrial pacing at the basic rate.

3.1.4.4 A-V sequential mode, asynchronous (DOO) : Mode in which the atrial and ventricular sensing functions are disabled or absent; the pulse generator provides atrial pacing at the basic rate. At the end of the specified A-V interval after each atrial pulse, a ventricular pulse is provided independent of the activity of the heart.

3.1.4.5 A-V sequential mode with ventricular sense (inhibition) (DVI) : Mode in which the atrial sensing function is disabled or absent and the pulse generator provides atrial pacing at the basic rate if no ventricular beat is sensed before the end of the escape interval. If no ventricular beat is sensed during the specified A-V interval, a ventricular pulse is provided at the end of the A-V interval. If at any time a ventricular beat is sensed, it starts a new V-A interval.

3.1.4.6 A-V sequential mode, ventricular synchronized (triggered) (DVT) : Mode in which the atrial sensing function is disabled or absent and the pulse generator provides atrial pacing at the basic rate if no ventricular beat is sensed before the end of the escape interval. If no ventricular beat is sensed during the specified A-V interval, a ventricular pulse is provided at the end of the A-V interval. If at any time a ventricular beat is sensed, a ventricular pulse is provided immediately and starts a new V-A interval.

3.1.4.7 A-V sequential mode with sensing and pacing in both chambers (universal) (DDI, DDD) : If neither an atrial nor a ventricular beat is sensed, the pulse generator provides both atrial and ventricular pulses at the basic rate. The following two modes are used :

DDI : Mode in which an atrial beat interrupts the pulse generator's atrial escape interval without release of an atrial pulse; a ventricular beat interrupts the ventricular escape interval and starts a new ventricular escape interval without release of a ventricular pulse.

DDD : Mode in which an atrial beat interrupts the pulse generator's V-A interval and starts an A-V interval without release of an atrial pulse. Then, if no ventricular beat is sensed during that A-V interval a ventricular pulse is provided at the end of the A-V interval unless the maximum tracking rate is exceeded. If a ventricular beat is sensed at any time, it starts a new V-A interval without release of a ventricular pulse. If the A-V interval cannot be interrupted by a ventricular beat, with as a consequence release of a ventricular pulse, the system is said to be "committed".

3.1.4.8 ventricular asynchronous (VOO) : Mode in which the atrial functions and ventricular sensing are disabled. A ventricular pulse is provided at the basic rate independent of the activity of the heart.

3.1.4.9 ventricular inhibited (VVI) : Mode in which the atrial functions are disabled or absent. If the ventricular sensing function detects a beat interval shorter than the escape interval, then the pulse generator suppresses ventricular pacing. If no ventricular beat is sensed during the escape interval, then the pulse generator provides ventricular pacing at the basic rate.

3.1.4.10 atrial synchronized (VAT) : Mode in which the ventricular sensing and atrial pacing functions are disabled or absent. The set A-V interval commences when an atrial beat is sensed and a ventricular pulse is provided at the end of that interval unless the maximum tracking rate is exceeded. If no atrial beat is sensed during the escape interval, then the pulse generator provides ventricular pacing at the basic rate.

3.1.4.11 atrial synchronized, ventricular inhibited (VDD) : Mode in which both atrial and ventricular sensing are provided but atrial pacing is disabled or absent. The set A-V interval commences when an atrial beat is sensed. If no ventricular beat is sensed during the A-V interval, a ventricular pulse is provided at the end of the A-V interval unless the maximum tracking rate is exceeded. If neither an atrial nor a ventricular beat is sensed during the the escape interval, then the pulse generator provides ventricular pacing at the basic rate. If at any time a ventricular beat is sensed, it starts a new V-A interval.

3.1.4.12 ventricular triggered (VVT) : Mode in which the atrial functions are disabled or absent. If a ventricular beat is sensed during the escape interval, then a ventricular pulse is provided immediately in synchrony with the ventricular beat. If no ventricular beat is sensed during the escape interval then ventricular pacing is provided at the basic rate.

3.1.4.13 beat : Ordered spontaneous activity of the heart.

3.2 Definitions for this part of ISO 5841

For the purposes of this part of ISO 5841 only, the following definitions apply.

3.2.1 adaptor : Special connector used between an otherwise incompatible pulse generator and lead.

3.2.2 basic pulse interval : Pulse interval unmodified by sensed cardiac or other electrical influence.

3.2.3 basic rate : Pulse rate of a pulse generator, either atrial or ventricular unmodified by sensed cardiac or other electrical influence.

3.2.4 electrode : Electrically-conducting part (usually the termination of a lead) which is designed to form an interface with body tissue.

3.2.5 escape interval : Time between a sensed beat or a pulse and the succeeding non-triggered pulse of a pulse generator.

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

3.2.7 bipolar (multipolar) lead : Lead with two (or more) independent electrodes.

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

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

3.2.10 hysteresis : Characteristic of a pulse generator defined by the difference between the escape interval after a sensed beat and the basic pulse interval.

NOTE — The escape interval is normally longer than the basic pulse interval, and this is referred to as "positive" hysteresis.

3.2.11 unipolar lead : Lead with one electrode.

3.2.12 marking : Any display of written, printed or graphical item(s) appearing on or affixed to a device or appearing upon a package containing a device.

3.2.13 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.

3.2.14 nominal pulse generator service life : Estimate of the expected implant lifetime 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 disregarding the possibility of any cause of failure other than that due to battery depletion.

3.2.15 pacemaker : Device for stimulating the heart comprising a pulse generator and lead(s).

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

3.2.17 shipping package : Package in which a pulse generator, lead or accessory or any combination thereof may be supplied in order to protect the storage package during transportation and which is so designed.

3.2.18 sterilized package : Package in which a pulse generator, lead/accessory or combination thereof has been subjected to a recognized sterilization process.

3.2.19 storage package : Package which is designed by the manufacturer to protect the contents during storage at the implanting centre.

3.2.20 pulse: Monophastic electrical output of a pulse generator intended to stimulate the myocardium.

3.2.21 dual chamber (ADJ): Relating to both atrium and ventricle.

3.2.22 transvenous : Term used to describe an approach to the heart through the venous system.

3.2.23 pulse amplitude : Magnitude of the pulse, expressed in volts or milliamperes.

3.2.24 pulse duration : Duration of the pulse measured between reference points specified in this part of ISO 5841 (see annex B).

3.2.25 pulse generator : That part of the pacemaker that produces a periodic electrical pulse and which includes the power supply and electronic circuit.

3.2.26 pulse interval : Time interval between identical points of two consecutive pulses, expressed in milliseconds.

3.2.27 pulse rate : Number of pulses per minute, expressed in reciprocal minutes.

3.2.28 interference pulse rate : Pulse rate with which the pulse generator responds when it senses electrical activity other than that from the myocardium and which is recognized as interference.

NOTE — The interference pulse rate is pre-set.

3.2.29 test pulse rate : Pulse rate of a pulse generator when directly influenced by a test device.

3.2.30 refractory period : Period during which a pulse generator will not respond other than to an input signal of a specified type.

3.2.31 sensitivity : Minimum signal, expressed in millivolts, required to control consistently the function of the pulse generator.

3.2.32 serial number : Unique combination of letters and/or numbers, selected by the manufacturer, to distinguish a device from other devices with the same model designation.

3.2.33 sterile : Condition of a product free of living organisms; that has been sterilized and maintained in the state of sterility by suitable protection (e.g. packaging).

3.2.34 sterilized: Subjected to a recognized sterilization process.

3.2.35 use-before date : Date after which the manufacturer recommends the pulse generator should not be implanted.

3.2.36 input impedance: For a pulse generator the electrical impedance presented at its terminals to the test signal defined in B.1.4, annex B and taken as equal to that presented to a sensed beat.

3.2.37 insertion diameter: Minimum bore of a rigid cylindrical tube into which the lead can be inserted.

4 Packages, markings and accompanying documentation (see rationale statement in annex E)

4.1 Packages and markings

4.1.1 Packages

Packages shall be classified as

a) shipping packages (optional);

b) storage packages;

c) sterilized packages.

4.1.2 Package markings in general

Each package shall have legible markings that do not adversely affect the contents. The markings shall be of material that will maintain legibility during normal handling of the package.

NOTE — Instead of using a description in words, the mode codes defined in 3.1.4 and annex A may be used in markings and accompanying documents to designate the mode of a pulse generator.

Any dates shall be presented in the sequence: year-month-day, expressed in numerals, as specified in ISO 2014.

4.2 Shipping packages

4.2.1 Contents of shipping packages

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

4.2.2 Shipping package markings

The shipping package markings shall include the following information :

a) the name of the manufacturer with his postal address and, if different from the manufacturer, the name of the agent or distributor with his postal address;

b) essential warnings concerning handling and storage during shipment.

4.3 Storage packages

4.3.1 Storage package markings

Any warnings shall be prominently displayed. The storage package markings shall include the following information :

a) the manufacturer's name or recognized trademark and the postal address of the manufacturer;

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

c) the contents of the sterilized package(s), i.e. pulse generator (mode as shipped, model designation, serial number) and/or lead (type, model designation, serial number), and/or adaptor;

d) the most comprehensive pacing mode(s) available and the pacing mode as shipped;

e) the pulse generator's non-programmable parameters (nominal as shipped) at 37 °C ± 2 °C with 500 Ω ± 5 % load, as follows :

1) basic pulse rate, in pulses per minute,

2) pulse amplitude, in volts or milliamperes,

3) pulse duration, in milliseconds,

4) sensitivity, in millivolts;

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

g) the use-before date (see 4.1.2);

h) recommendations regarding storage and handling;

i) the connector configuration (unipolar or bipolar or other multipolar).

4.3.2 Contents of storage packages

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

NOTE — The accompanying documents (see 4.4) may either by supplied within each storage package or be supplied separately with each pacemaker, lead or pulse generator.

4.4 Accompanying documents

The documentation accompanying the pacemaker (i.e. pulse generator, lead or adapter) shall be the following :

a) the manual for the clinician (see 4.4.1);

b) the registration form (see 4.4.2);

c) the patient's identification form (see 4.4.3);

d) the explantation form (see 4.4.4);

e) the individual technical information sheet (see 4.4.5).

4.4.1 Manual for clinician

4.4.1.1 The manual shall give the following information concerning the pulse generator or lead or adapter :

a) the name, postal address and telephone number of the manufacturer;

b) handling instructions, including

1) instructions for opening the sterilized package,

2) recommendations regarding handling, including storage, conditions;

c) information on the pulse generator, if supplied, as specified in 4.4.1.2;

d) information on the lead(s), if supplied, as specified in 4.4.1.3;

e) information on the adaptor(s), if supplied, as specified in 4.4.1.4.

4.4.1.2 If a pulse generator is supplied, the following information shall be included in the manual [see 4.4.10 c)] :

a) model designation and name, if applicable;

b) a general description, explanation of function available, and a description of each heart/pulse generator interaction for each available pacing mode (see note in 4.1.2);

c) the name of the power source manufacturer, and his model designation for the battery used;

d) the connector configuration (unipolar, bipolar or other) and the geometry and/or dimensions of the receiving connector;

e) the physical characteristics, including :

1) mass, in grams,

2) principal dimensions, in millimetres,

3) volume, in millilitres;

4) general description of the materials which will come into contact with human tissue;

f) if the electrode is an integral part of the pulse generator, the material of the electrode and its surface area (in square centimetres) and shape;

g) the suitable programmes and any warnings regarding the likelihood of hazardous effects if used with programmers other than those specified by the manufacturer;

h) the electrical characteristics (including tolerances where appropriate) at 37 °C ± 2 °C and 500 Ω ± 5 % load, unless otherwise stated, as follows :

1) ranges of basic, test, escape and interference pulse rates and equivalent pulse intervals (if applicable),

2) the acceptable change in basic pulse rate during an initial stated time period (if applicable),

3) the pulse shape (for example, by means of a diagram) with the points which define the pulse output amplitude and duration identified,

4) pulse amplitude,

5) pulse duration,

6) the input impedance (if applicable),

7) the sensitivity range for both positive and negative polarity, together with a description of the waveform used,

8) the refractory period (pacing and sensing) and A-V interval (if applicable),

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

10) values/ranges of programmable parameters stated with specified programmers,

11) the settings produced with the emergency function of each programmer (if applicable),

12) the rate limit (runaway protection), in pulses per minute;

NOTE — See annex B for methods of determining these characteristics.

i) information correlating the battery depletion indicator with the pulse generator characteristics (measured at a temperature of 37 °C ± 2 °C with 500 Ω ± 5 %) and its modes, including as applicable:

1) basic pulse rate and basic pulse interval, in reciprocal minutes and in milliseconds,

2) test pulse rate and test pulse interval, in reciprocal minutes and in milliseconds,

3) pulse duration(s) in milliseconds,

4) pulse amplitude(s), in volts or milliamperes,

5) sensitivity, in millivolts,

6) mode change;

Also changes of characteristics that can be used as battery depletion indicator(s) in accordance with annex C shall be identified.

j) information (for example, diagrammatic or by graphs) to show the typical variation of the following pacemaker characteristics with temperature over the range from 20 °C to 43 °C;

1) basic rate or basic pulse interval, in reciprocal minutes or in milliseconds,

2) test pulse rate or test pulse interval, in reciprocal minutes or in milliseconds,

3) pulse duration in milliseconds,

4) pulse amplitude, in volts or milliamperes,

5) sensitivity, in millivolts;

k) information on non-invasive identification (see 4.6.2);

l) the connector type and recommendations regarding the 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;

o) warnings regarding the effects of therapeutic energy sources (e.g. external cardioversion, diathermy, cautery or similar sources);

p) recommendations for the disposal of pulse generators after explant;

q) the nominal pulse generator service life under stated conditions (see annex C);

r) if applicable a statement to the effect that longevity experience data is available (see ISO 5841-2).

4.4.1.3 If a lead is supplied, the following information shall be included under item d) specified in 4.4.1.1 :

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

b) a general description, including conductor, connector pin, conductor/insulation materials, and shape and material and configuration of electrodes;

c) physical dimensions (including tolerances if applicable), as follows :

1) length, in centimetres,

2) geometric surface area of electrode(s), in square millimetres,

3) insertion diameter of transvenous lead (except for connector end), in millimetres,

4) distance(s) between electrodes, for bipolar or multipolar endocardial leads, in millimetres,

5) maximum depth of penetration, for epicardial leads,

6) connector geometry (length and diameter), in millimetres;

d) resistance of each conductor, in ohms;

e) any recommendations regarding use with pulse generators;

f) specific implantation considerations regarding attachment of leads;

g) handling instructions to avoid damage to the lead.

4.4.1.4 If an adaptor is supplied, the following information shall be included under item e) specified in 4.4.1.1 :

a) the configuration (unipolar, bipolar, multipolar) model designation and name, if applicable;

b) a general description of the materials used for the conductor, connector pin and insulation and the shape, materials and configuration of the electrodes;

c) the compatibility with pulse generators and leads.

4.4.2 Registration form

A registration form shall be provided in duplicate with one part marked "FOR RETURN TO MANUFACTURER". The form shall have space for recording at least the following patient and implantation information :

a) identification of the patient's sex, age and pacing indication;

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

c) the pacing mode selected;

d) the date on which the pulse generator was implanted (expressed in accordance with ISO 2014);

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

f) the name, postal address and telephone number of the implanting centre and the name of the clinician responsible;

g) the address(es) of the clinician/hospital.

4.4.3 Patient's identification card

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

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

b) the name, address and telephone number of the implanting centre where the pacemaker was implanted;

c) the name of the clinician responsible for the patient's care;

d) the name of the pacemaker manufacturer or agent;

e) dates of implantation of pulse generator and leads;

f) the model designation and serial number;

g) the selected pacing mode (specific) and most comprehensive pacing mode;

h) the selected pulse generator rates (basic/test pulse rate) and pulse duration;

i) the type of lead(s), model designation(s) and serial number(s) and name of manufacturer.

4.4.4 Explantation form for pulse generators

An explantation form with space for recording basic information shall be provided. The form should be at least in duplicate, with one part marked "FOR RETURN TO MANUFACTURER". The following basic data shall be included :

a) patient data;

b) the name of the implanting centre;

c) the name and address of the clinician responsible for explantation;

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

e) the reason for explantation of pulse generator — apparent change in pulse generator characteristics, prophylactic replacement (optional replacement), other reasons.

4.4.5 Individual technical information sheet

An individual technical information sheet shall be supplied by the manufacturer with each pulse generator. The technical information sheet shall provide at least the following :

a) the manufacturer's name or trademark, and postal address;

b) the pacing modes available (see annex A);

c) the type or model designation;

d) the serial number;

e) the use-before date (expressed in accordance with ISO 2014);

f) the sterilization method;

g) the sterilization date (expressed in accordance with ISO 2014);

h) pulse generator functions, measured at 37 °C ± 2 °C with 500 Ω ± 5 % load (at factory setting), as follows :

1) basic pulse rate, in pulses per minute, and basic pulse interval, in milliseconds,

2) test pulse rate, in pulses per minute, and test pulse interval, in milliseconds,

3) pulse amplitude(s), in volts or milliamperes,

4) pulse duration(s), in milliseconds,

5) sensitivity(ies), in millivolts,

6) pacing mode, as shipped,

7) whether programmable or non-programmable,

8) refractory period after a pacing pulse, in milliseconds;

i) rate limit at factory setting, in pulses per minute;

j) the connector configuration;

k) battery depletion indicators;

l) identification of the characteristics which are programmable.

NOTE — An example of the format for a technical sheet is given in annex D.

4.5 Sterilized packages

4.5.1 Contents of sterilized packages

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 shipment 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 shall be designed so that once it has been opened, this shall be readily apparent. If the package has been re-sealed, it shall still be apparent that the package has been previously opened.

4.5.2 Sterilized package markings

The sterilized package markings shall include the following information :

a) the manufacturer's name or recognized trade-mark, and plant location;

b) the contents of the sterilized package, i.e. pulse generator (model designation, serial number) and/or lead (type, model designation, serial number), and/or adaptor (model designation);

c) the pulse generator's non-programmable characteristics (nominal as shipped), measured at 37 °C ± 2 °C with 500 Ω ± 5 % load, as follows :

1) basic rate, in pulses per minute,

2) test pulse rate, in pulses per minute,

3) pulse amplitude, in volts or milliamperes,

4) sensitivity, in millivolts,

5) pulse duration, in milliseconds;

d) the most comprehensive pacing mode available and the pacing mode as shipped;

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

f) the use-before date (expressed in accordance with ISO 2014);

g) any warnings shall be prominently displayed;

h) instructions for opening so as to prevent physical damage and to maintain sterility;

i) the connector configuration (unipolar, bipolar or multipolar.

4.6 Pulse generators, leads and adaptors

4.6.1 Pulse generator markings

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

a) the name and location of the manufacturer;

b) the most comprehensive pacing mode available;

c) the model designation;

d) the serial number, preceded by either "SERIAL NUMBER" or "SN".

4.6.2 Non-invasive identification of pulse generators

The non-invasive identification of pulse generators shall be by the use of radio-opaque letters, numbers and/or symbols in the form of a code specific to the individual pulse generator. The identification shall be incorporated into the pulse generator so the clinician can identify it non-invasively with the aid of the appropriate code information.

The identification shall indicate, at least, the manufacturer and the particular model of the pulse generator.

4.6.3 Markings on leads and adaptors

Each lead and, if possible, each adaptor shall be permanently and visibly marked with an identification of the manufacturer and with a serial number.

5 Protection against environmental stress

(see rationale statement in annex E)

5.1 Vibration test

5.1.1 Requirements

When tested in accordance with 5.2.2, the following characteristics of the pulse generator shall be in accordance with those specified in accordance with 4.4.3 h) 1—6.