SLOVENSKI STANDARD
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Safety of implantable cardiac pacemakers

Safety of implantable cardiac pacemakers

Sicherheit implantierbarer Herzschrittmacher

Sécurité des stimulateurs cardiaques implantables

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English version

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: Rue Bréderode 2, B-1000 Brussels

Brief history

The European Standard 50 061 was prepared by TC 62 of CENELEC; it was submitted to the CENELEC members for formal vote and acceptance as a European Standard (EN) by CENELEC.

Technical text

The text of the European Standard 50 061 was approved by all CENELEC members with the exception of Austria and Norway on 1 March 1988.

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CENELEC

Safety of implantable cardiac pacemakers

0 Introduction

This standard was prepared by a working group of CENELEC/TC 62 "Electroradiological and Electromedical Equipment". In preparing this standard for cardiac pacemakers, the working group was faced with a variety of problems.

Pacemakers which are used nowadays differ considerably in their mode of operation and longevity. These medical devices are also subject to frequent and rapid technical development. Because of this, the standard cannot state all the necessary requirements for pacemakers. In addition, a standard for pacemakers which specifies certain constructional requirements would hamper future medical and technical development.

Thus, when stipulating safety requirements for pacemakers, the working group set as its objectives:

* to improve communication between manufacturers and users, as well as among the users themselves, by providing appropriate terminology and documentation, which would lead to easier comparability of different pacemaker makes and models;
* to increase the protection of patients against hazards caused by malfunction or by exogenous influences.

It is not the purpose of this standard to specify the level of quality and reliability of individual products because the working group acknowledged the central role of clinical experience in setting required levels of reliability and performance.

NOTE. This standard covers besides others the mechanical safety and among the electrical hazards the safety during defibrillation. It does not cover safety aspects of electro-magnetic compatibility and high frequency electro-surgery. These aspects are under consideration at the present time.

1 Scope and field of application

This standard specifies safety and other requirements exclusively for all types of wholly implantable cardiac PACEMAKERS.

This standard also establishes basic terminology and definitions and includes requirements for the marking of PACEMAKERS and their packaging. In addition, minimum requirements are specified for the ability of PACEMAKERS to withstand environmental stress conditions. Appropriate test methods are given. This standard specifies the requirements for the reliable operation of PACEMAKERS only insofar as they affect safety.

It does not cover the antitachyarrythmia and defibrillation functions of PACEMAKERS, nor PACEMAKERS operated by isotopic cells.

2 Terminology

The following terms given in this Clause have been established to encourage common usage. Sub-clause **2.4** presents the terminology particular to the modes of PULSE GENERATORS and uses the coding system described in annex A.

2.1 A-V interval (atrio-ventricular interval)
The delay between an atrial PULSE or the sensing of an atrial depolarization and the subsequent ventricular PULSE or the sensing of a ventricular depolarization.

2.2 V-A interval (ventricular-atrial interval)
The delay between a ventricular PULSE or the sensing of a ventricular depolarization and the subsequent atrial PULSE or the sensing of an atrial depolarization.

2.3 Blanking period
Period during which a sensing function of a PULSE GENERATOR is disabled.

2.4 Modes of pulse generators
The definitions that follow describe the mode of operation of PULSE GENERATORS. A system of coding modes is described in annex A.

2.4.1 Atrial asynchronous mode (AOO)
Mode in which an atrial PULSE is provided independent of the activity of the heart. Ventricular functions and atrial sensing are disabled or absent.

2.4.2 Atrial inhibited mode (AAI)
Mode where if during the ESCAPE INTERVAL the atrial sensing function detects a BEAT, then the PULSE GENERATOR suppresses atrial pacing. If the sensed atrial BEAT occurs after the ESCAPE INTERVAL, then the PULSE GENERATOR provides atrial pacing at the BASIC RATE. Ventricular functions are disabled or absent.

2.4.3 Atrial triggered mode (AAT)
Mode where if during the ESCAPE INTERVAL the atrial sensing function detects a BEAT, then an atrial PULSE is produced in synchrony with the atrial BEAT (provided that the MAXIMUM TRACKING RATE is not exceeded). If the sensed atrial BEAT occurs after the ESCAPE INTERVAL, then the PULSE GENERATOR provides atrial pacing at the BASIC RATE. Ventricular functions are disabled or absent.

2.4.4 A-V sequential, asynchronous mode (DOO)
Mode in which the PULSE GENERATOR provides atrial pacing at the BASIC RATE. At the specified A-V interval after each atrial PULSE, a ventricular PULSE is provided independent of the activity of the heart. Atrial and ventricular sensing functions are disabled or absent.

2.4.5 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 a spontaneous ventricular BEAT is not sensed during the specified A-V interval after each atrial PULSE, a ventricular PULSE is provided.

2.4.6 A-V sequential, ventricular synchronized (triggered) mode (DVT)
Mode in which the PULSE GENERATOR provides atrial pacing at the BASIC RATE. After each atrial PULSE, during a period equal to the set A-V interval, a ventricular PULSE is provided in synchrony with a spontaneous ventricular BEAT. If no ventricular BEAT is sensed in that period, then a ventricular PULSE is immediately provided. The atrial sensing function is disabled or absent.

2.4.7 A-V sequential mode, with sensing and pacing in both chambers

The following four modes can be distinguished:

2.4.7.1 Inhibition in both channels (DDI)

Mode in which a spontaneous atrial BEAT interrupts the PULSE GENERATOR's V-A interval and starts an A-V interval without release of an atrial PULSE. A spontaneous ventricular BEAT interrupts either an A-V or V-A interval and starts a new V-A interval without release of a ventricular PULSE.

2.4.7.2 Triggering in the atrial channel and inhibition in the ventricular channel (DDD)

Mode in which a spontaneous atrial BEAT interrupts the PULSE GENERATOR's V-A interval and starts an A-V interval with release of an atrial output. A spontaneous ventricular BEAT interrupts either an A-V or V-A interval and starts a new V-A interval without release of a ventricular PULSE.

2.4.7.3 Inhibition in the atrial channel and triggering in the ventricular channel (DDD)

Mode in which a spontaneous atrial BEAT interrupts the PULSE GENERATOR's V-A interval and starts an A-V interval without release of an atrial PULSE. A spontaneous ventricular BEAT interrupts the A-V interval and starts a new V-A interval with release of a ventricular PULSE.

2.4.7.4 Triggering in both channels (DDT)

Mode in which a spontaneous atrial BEAT interrupts the PULSE GENERATOR's V-A interval and starts an A-V interval with release of an atrial PULSE. A spontaneous ventricular BEAT interrupts that A-V interval and starts a new interval with release of a ventricular PULSE.

NOTE. If the A-V interval cannot be interrupted by a ventricular BEAT with a release of a ventricular PULSE as consequence, the system is said to be "committed".

2.4.8 Ventricular asynchronous mode (VOO)

Mode in which a ventricular PULSE is provided at the BASIC RATE, independent of the activity of the heart. Atrial functions and ventricular sensing are disabled or absent.

2.4.9 Ventricular inhibited mode (VVI)

Mode where if the ventricular sensing function detects a BEAT interval shorter than the ESCAPE INTERVAL, then the PULSE GENERATOR suppresses ventricular pacing. If the sensed ventricular BEAT interval exceeds the ESCAPE INTERVAL, then the PULSE generator provides ventricular pacing at the BASIC RATE. Atrial functions are disabled or absent.

2.4.10 Atrial synchronized mode (VAT)

Mode in which, when a spontaneous atrial BEAT is sensed, the set A-V interval commences and a ventricular PULSE is provided at the end of that interval. If the sensed atrial BEAT interval exceeds the ESCAPE INTERVAL, then the PULSE GENERATOR provides ventricular pacing at the BASIC RATE. Ventricular sensing and atrial pacing functions are disabled or absent.

2.4.11 Atrial synchronized, ventricular inhibited mode (VDD)

Mode in which both ventricular and atrial sensing are provided. The set A-V interval commences when a spontaneous atrial BEAT is sensed and a ventricular PULSE is provided at the end of that interval. If either the sensed atrial or ventricular BEAT intervals exceed the ESCAPE INTERVAL, then the PULSE GENERATOR provides ventricular pacing at the BASIC RATE. Atrial pacing is disabled or absent.

2.4.12 Ventricular triggered mode (VVT)

Mode where if the sensed ventricular BEAT interval is shorter than the ESCAPE INTERVAL, then a ventricular PULSE is provided synchronously with the spontaneous ventricular BEAT. If the sensed ventricular BEAT interval exceeds the ESCAPE INTERVAL, then ventricular pacing is provided at the BASIC RATE. Atrial functions are disabled or absent.

NOTE. This terminology may be amended if the codes for PULSE GENERATORS are revised (see annex A).

3 Definitions

For the purposes of this standard the definitions given in clause **3** apply. Terms used throughout this standard which have been defined in clause **3** are printed in CAPITALS.

3.1 ADAPTOR

Special connector used between an otherwise incompatible PULSE GENERATOR and a LEAD.

3.2 BASIC PULSE INTERVAL

The PULSE INTERVAL in absence of sensed cardiac or other electrical influence.

3.3 BASIC RATE

The PULSE RATE of a PULSE GENERATOR, either atrial or ventricular, unmodified by sensed cardiac or other electrical influence.

3.4 BATTERY DEPLETION INDICATOR

Means of indicating the quantity of electricity that has been drawn from a battery during the PULSE GENERATOR's service life.

3.5 BEAT

Ordered spontaneous activity of the heart.

3.6 BEGINNING OF LIFE (BOL)

Time when an individual PULSE GENERATOR is first released by the manufacturer as fit for sale.

3.7 DUAL-CHAMBER

Relating both to the atrium and ventricle.

3.8 ELECTRODE

Electrically conducting part (usually the termination of a LEAD) which is designed to form an interface with body tissue or body fluid.

3.9 END OF LIFE (EOL)

Time at which the BATTERY DEPLETION INDICATOR reaches the value set by the manufacturer of the PULSE GENERATOR for its elective replacement.

3.10 ESCAPE INTERVAL
Time between the sensing of a spontaneous BEAT and the succeeding non-triggered PULSE of a PULSE GENERATOR.

3.11 HYSTERESIS
Characteristic of a 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.

3.12 INPUT IMPEDANCE
For PULSE GENERATORS the electrical impedance presented at its input terminals to the test signal defined by figure C3 and taken as equal to that presented to a sensed BEAT.

3.13 INSERTION DIAMETER
The minimum bore of a rigid cylindrical tube into which a LEAD may be inserted.

3.14 LEAD
Means of electrically connecting a PULSE GENERATOR to the ELECTRODE(S).

3.14.1 BIPOLAR LEAD
LEAD with two independent ELECTRODES.

3.14.2 ENDOCARDIAL LEAD
LEAD with an ELECTRODE designed to make a contact with the endocardium, or inner surface of the heart.

3.14.3 EPICARDIAL LEAD
LEAD with an ELECTRODE designed to make a contact with the epicardium, or outer surface of the heart.

3.14.4 UNIPOLAR LEAD
LEAD with one ELECTRODE.

3.15 MARKING
Any display of written, printed or graphic matter appearing on or affixed to a device or appearing upon a PACKAGE containing a device.

3.16 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.

3.17 NOMINAL PULSE GENERATOR SERVICE LIFE
An 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, but ignoring the possibility of any cause of failure other than that due to BATTERY DEPLETION.

3.18 PACEMAKER
Device for stimulating the heart comprising a PULSE GENERATOR and LEAD(S).

3.19 PACKAGE
Any container or wrapping material in which a device is wholly or partly contained, placed or packed.

3.19.1 SHIPPING PACKAGE
PACKAGE in which a PULSE GENERATOR, LEAD or accessory or any combination of these may be supplied and which is designed to protect the STORAGE PACKAGE during transportation.

3.19.2 STERILIZED PACKAGE
PACKAGE in which a PULSE GENERATOR, LEAD or accessory or any combination of these has been STERILIZED.

3.19.3 STORAGE PACKAGE
PACKAGE containing the STERILIZED PACKAGE designed by the manufacturer to protect the content during storage at the implanting centre.

3.20 PULSE
Monophasic electrical output of a PULSE GENERATOR intended to stimulate the myocardium.

3.20.1 INTERFERENCE PULSE RATE
Rate with which the PULSE GENERATOR responds when it senses electrical activity, other than that from the myocardium, that it recognizes as interference.

NOTE. The INTERFERENCE PULSE RATE is pre-set.

3.20.2 PULSE AMPLITUDE
Magnitude of the PULSE.

3.20.3 PULSE DURATION
Duration of the PULSE, measured between the reference points specified in this Standard (see annex C).

3.20.4 PULSE GENERATOR
That part of the PACEMAKER that produces a periodic electrical output, including the power supply and electronic circuit.

3.20.5 PULSE INTERVAL
Time interval between identical points of two consecutive PULSES.

3.20.6 PULSE RATE
The number of PULSES per minute.

3.20.7 TEST PULSE RATE
PULSE RATE of a PULSE GENERATOR when directly influenced by a testing device.

3.21 REFRACTORY PERIOD
Period during which a PULSE GENERATOR will not respond other than to an input signal of a specified type.

3.22 SENSITIVITY (SENSING THRESHOLD)
The minimum signal required to control consistently the function of the PULSE GENERATOR (see figure C3, annex C).

3.23 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.

3.24 STERILE
The condition of a product, free of living organisms, that has been STERILIZED and maintained in the state of sterility by suitable protection (for example, by packaging).

3.25 STERILIZED
Subjected to a recognized sterilization process.

3.26 TRACKING RATE, MAXIMUM
Maximum PULSE RATE at which the PULSE GENERATOR will respond on a 1:1 basis to a triggering signal.

3.27 TRANSVENOUS
Approach to the heart through the venous system.

3.28 USE-BEFORE-DATE
Date after which the manufacturer recommends that the PULSE GENERATOR should not be implanted.

4 PACKAGES and MARKINGS

4.1 PACKAGES, Classification

PACKAGES shall be classified as:

* SHIPPING PACKAGE (optional),
* STORAGE PACKAGE,
* STERILIZED PACKAGE.

4.2 MARKINGS, General requirements

NOTE 1. See annex B for optional symbols for use in expressing information so as to reduce the need for expressions in multiple languages.

NOTE 2. Instead of using a description in words, the mode codes defined in annex A may be used in the MARKINGS and accompanying documents to designate the mode of the PULSE GENERATOR.

4.2.1 Each PACKAGE shall have legible MARKINGS which shall not adversely affect the contents. The MARKING shall be of materials that will maintain legibility during normal handling.

4.2.2 The MARKINGS on the STERILIZED PACKAGE shall include instructions for unpacking the contents so as to prevent physical damage and maintain sterility.

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

4.3 SHIPPING PACKAGE

4.3.1 *Contents of the SHIPPING PACKAGE*

The SHIPPING PACKAGE shall contain the STORAGE PACKAGE(S).

4.3.2 *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.

4.4 STORAGE PACKAGE

4.4.1 *Contents of the STORAGE PACKAGE*

The STORAGE PACKAGE shall contain the STERILIZED PACKAGE(S).

NOTE. The accompanying documents may be within each STORAGE PACKAGE, or may be supplied separately with each PACEMAKER, LEAD or PULSE GENERATOR.

4.4.2 *STORAGE PACKAGE MARKINGS*

The STORAGE PACKAGE MARKINGS shall include the following information:

a) the name of the manufacturer or his recognized trade mark, with his postal address;

b) the contents of the STERILIZED PACKAGE(S), namely PULSE GENERATOR (MODEL DESIGNATION, SERIAL NUMBER) and/or LEAD (MODEL DESIGNATION, SERIAL NUMBER), and/or ADAPTOR;

c) the most comprehensive pacing mode available and the mode as shipped (see Sub-clause **4.2** Note 2);

d) the PULSE GENERATOR's non-programmable parameters (nominal and as shipped) at 37 ± 2 °C with 500 Ω ± 5 % load, including as applicable:

1) BASIC RATE (in reciprocal minutes);
2) PULSE AMPLITUDE (in volts or milliamperes);
3) PULSE DURATION (in milliseconds);
4) SENSITIVITY (in millivolts);

e) a statement that the PACKAGE contains a STERILIZED PACKAGE;

f) the USE-BEFORE-DATE, expressed in accordance with Sub-clause **4.2.3**;

g) any recommendations regarding storage and handling;

h) the connector configuration (unipolar, bipolar or other).

NOTE. If applicable, a space shall be provided for the agent to write his name, postal address and telephone number.

4.4.3 Any warnings shall be prominently displayed.

4.5 STERILIZED PACKAGE

4.5.1 The STERILIZED PACKAGE shall be designed so that once it has been opened, this shall be readily apparent. If the STERILIZED PACKAGE has been re-sealed, it shall still be apparent that the STERILIZED PACKAGE has been previously opened.

4.5.2 *Contents of the STERILIZED PACKAGE*
The PULSE GENERATOR, LEAD and necessary accessories/ADAPTORS (either separately or in combination) shall be supplied in the STERILIZED PACKAGE. It shall be capable of maintaining the contents STERILE during shipping and under conditions of normal storage and handling and allow the contents to be presented for use in an aseptic manner.

4.5.3 *STERILIZED PACKAGE MARKINGS*
The STERILIZED PACKAGE MARKINGS shall include the following information, as applicable:

a) the name of the manufacturer or his recognized trade mark;

b) the contents of the STERILIZED PACKAGE, namely PULSE GENERATOR (MODEL DESIGNATION, SERIAL NUMBER) and/or LEAD (MODEL DESIGNATION, SERIAL NUMBER) and/or ADAPTOR (MODEL DESIGNATION);

c) the PULSE GENERATOR's non-programmable characteristics (nominal and as shipped) at 37 ± 2 °C and 500 Ω ± 5 % load, including as applicable:

1) BASIC RATE (in reciprocal minutes);
2) TEST PULSE RATE (in reciprocal minutes);
3) PULSE AMPLITUDE (in volts or milliamperes);

4) PULSE DURATION (in milliseconds);

5) SENSITIVITY (in millivolts);

d) the most comprehensive pacing mode available and the mode as shipped (see Sub-clause **4.2**, Note 2);

e) a statement that the PACKAGE and its contents have been STERILIZED;

f) the USE-BEFORE-DATE, expressed in accordance with Sub-clause **4.2.3**;

g) the connector configuration (unipolar, bipolar or multipolar);

h) instructions for opening.

4.5.4 Any warning notices shall be prominently displayed.

4.6 PULSE GENERATORS, LEADS and ADAPTORS

4.6.1 *PULSE GENERATOR MARKINGS*

The MARKINGS on the PULSE GENERATOR shall be permanent, legible and give the following information:

a) name of the manufacturer and place of manufacture;

b) most comprehensive pacing mode available, see Sub-clause **4.2**, Note 2;

c) MODEL DESIGNATION;

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

4.6.2 *Non-invasive identification of PULSE GENERATOR*

The non-invasive identification of PULSE GENERATOR 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 that the clinician can identify it non-invasively with the aid of the appropriate code information.

NOTE. The identification shall indicate, at least, the manufacturer and the particular MODEL DESIGNATION 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 Accompanying documents

5.1 General

Accompanying documentation shall include the following:

* manual for the clinician,
* registration form,
* patient's identification card,
* explantation form,
* individual technical sheet.

5.2 Manual for the clinician

The manual shall give the information as indicated in Sub-clauses **5.2.1** to **5.2.5** about the PACEMAKER. If only a PULSE GENERATOR is supplied, Sub-clauses **5.2.4** and **5.2.5** may be omitted. If only a LEAD is supplied, Sub-clauses **5.2.3** and **5.2.5** may be omitted.

5.2.1 *Manufacturer's details*

Name, postal address and telephone number of manufacturer.

5.2.2 *Handling instructions*

Recommendations and instructions shall be provided regarding the opening of the STERILIZED PACKAGE, handling procedures and storage conditions.

5.2.3 *PULSE GENERATOR details*

NOTE 1. If the PULSE GENERATOR is programmable then the range or set of values rather than the actual value shall be given and the programmer shall be specified.

NOTE 2. If the programmable features change in the range 20 °C to 43 °C, it shall be stated.

The following information and details shall be provided, as applicable:

a) the MODEL DESIGNATION and name;

b) a general description, explanation of function, available modes, and a description of each heart/PULSE GENERATOR interaction for each mode (see Sub-clause **4.2**, Note 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 of the PULSE GENERATOR (in grams);

2) principal dimensions (in millimetres);

3) volume of the PULSE GENERATOR (in cubic centimetres);

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

f) if an ELECTRODE is an integral part of the PULSE GENERATOR, then the ELECTRODE material, its surface area (in square centimetres) and shape;

g) suitable programmers;

h) electrical characteristics (including tolerances), nominal as shipped, at 37 ± 2 °C and 500 Ω ± 5 % load (unless otherwise stated), including as applicable:

1) ranges of BASIC RATE, TEST PULSE RATE and INTERFERENCE PULSE RATE and the equivalent PULSE INTERVALS (and ESCAPE INTERVALS) (in reciprocal minutes and milliseconds);

2) any expected change in BASIC RATE during an initial, stated time period;

3) PULSE shape (for example, by diagram) with the points which define the PULSE AMPLITUDE and PULSE DURATION identified;

4) PULSE AMPLITUDE (in volts or milliamperes);

5) PULSE DURATION (in milliseconds);

6) INPUT IMPEDANCE (in ohms);

7) SENSITIVITY range for both positive and negative polarities, together with a description of the waveform used;

8) REFRACTORY PERIODS, pacing and sensing (in milliseconds);

9) A-V intervals, pacing and sensing (in milliseconds);

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

11) PULSE RATE limit (runaway protection) including tolerances;

NOTE. See Clause **10** for the methods of measuring these parameters.

i) information correlating the BATTERY DEPLETION INDICATOR with the PULSE GENERATOR characteristics (measured at a temperature of 37 ± 2 °C and 500 Ω ± 5 %) and modes, including as applicable:

1) BASIC 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.

NOTE. Changes of characteristics that can be used as BATTERY DEPLETION INDICATOR(S) in accordance with Clause 7 shall be identified.

j) characteristics of the battery, including:

1) its manufacturer, model, type, number and arrangement of cells;

2) estimated residual capacity at END OF LIFE (EOL);

3) effective battery voltage when reaching END OF LIFE (EOL).

k) current consumption of the PULSE GENERATOR under BEGINNING OF LIFE (BOL) conditions and standard programming both when pacing and when inhibited.

NOTE. With DUAL-CHAMBER systems, values shall be provided both in one and two channel operation.

l) information (for example, by graphs) shall be provided which shows the typical variation of the following PACEMAKER characteristics with temperature in the range 20 to 43 °C, as applicable:

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).

m) information for non-invasive identification of the PULSE GENERATOR (see Sub-clause **4.6.2**);

(n) recommendations regarding the choice of suitable LEAD(S) and information on compatible ADAPTORS;

o) specific implantation considerations regarding the attachment of the LEAD(S);

p) recommended methods for determining that the implanted PACEMAKER is functioning properly;

q) warnings regarding the effects of therapeutic energy sources (for example external cardioversion, diathermy, cautery or other sources);

r) recommendations about the methods of disposal of the PULSE GENERATOR after explant;

s) the NOMINAL PULSE GENERATOR SERVICE LIFE (under specified conditions).

5.2.4 *LEAD*

The following information and details shall be provided, as applicable:

a) the configuration (UNIPOLAR etc), MODEL DESIGNATION and the name;

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

c) physical dimensions, including:

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 (BIPOLAR or multipolar ENDOCARDIAL LEADS) (in millimetres);

5) maximum depth of penetration, for EPICARDIAL LEADS (in millimetres);

6) connector geometry (lengths and diameters) (in millimetres);

d) the resistance of conductors (in ohms);

e) any recommendations regarding use with PULSE GENERATORS;

f) handling instructions, to avoid damage to the LEAD.

5.2.5 *ADAPTOR*

The following information and details shall be provided, as applicable:

a) the configuration (unipolar or other), MODEL DESIGNATION and the name;

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

c) compatible PULSE GENERATORS and LEADS.

5.3 Registration form

A registration form shall be provided in duplicate, with one part marked "For return to the manufacturer". This form shall have space for recording at least the following patient and implantation information:

a) patient identification code, sex, age and pacing indication;

b) the PULSE GENERATOR manufacturer, MODEL DESIGNATION and SERIAL NUMBER;

c) the pacing mode selected (see annex A);

d) the date on which the PULSE GENERATOR was implanted, and LEAD implantation date(s), expressed in accordance with Sub-clause **4.2.3**;

e) the LEAD configuration(s) (unipolar or other), MODEL DESIGNATION(S) and SERIAL NUMBER(S);