INTERNATIONAL STANDARD

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Implants for surgery — Cardiac pacemakers —

Part 2: Reporting of clinical performance of populations of pulse generators or leads

Implants chirurgicaux — Stimulateurs cardiaques —
Partie 2: Établissement d'un rapport sur le fonctionnement clinique de populations de générateurs d'impulsions ou de fils-électrodes

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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 3.

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 part of ISO 5841 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 5841-2 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants*.

This second edition cancels and replaces the first edition (ISO 5841-2:1986), which has been technically revised.

ISO 5841 consists of the following parts, under the general title *Implants for surgery — Cardiac pacemakers*:

— *Part 1: Implantable pacemakers*

— *Part 2: Reporting of clinical performance of populations of pulse generators or leads*

— *Part 3: Low-profile connectors (IS-1) for implantable pacemakers*

Annex A forms a normative part of this part of ISO 5841. Annexes B and C are for information only.

Introduction

ISO 5841-1 requires the clinician's manual to contain a statement of nominal pulse-generator service life. Expectations of available power-source energy are not always fulfilled, and changes in pulse-generator components and assemblies have resulted in an actual service life which is different from the nominal service life. Defined production groups of pulse generators or leads have required closer follow-up or replacement due to changes in performance exhibited in clinical use.

This experience shows the value of maintaining an accurate and discriminating view of clinical performance of a population of pulse generators or leads, referred to in this document as devices, so as to aid patient management. In order to do this, it is necessary to collect implant and explant information. ISO 5841-1 specifies the content of forms to report implant and explant information for pulse generators.

The primary purpose of this part of ISO 5841 is to describe the reporting responsibilities in sharing clinical performance information for patient management. When clinical performance reports discriminate by production group and focus on recent experience, they are of value in patient management.

This part of ISO 5841 concerns the clinical performance of devices, not the clinical reasons for their use. It is realized that reasons for use can be a guide in the design of future products.

Reporting parties may give cumulative clinical-experience information based on a variety of assumptions and statistical techniques. This part of ISO 5841 gives, in annexes, a method for categorizing devices, guidelines to the statistical techniques that should be used to obtain the most benefit from the data and a statement of the rationale for this part of ISO 5841.

Clinicians have emphasized that a device whose performance has changed, either expectedly or unexpectedly, is sometimes left implanted due to other medical considerations. Instances exist where the performance of a device has changed to stable but out-of-specification performance that is considered safe and effective by the attending clinician. This is an important reason why the term "failure" is avoided throughout the classification.

"Failure" is not sufficiently specific to express the significance of a change in performance. In addition, "failure" implies a negative connotation for pulse generators that meet all longevity claims and cease functioning due to normal power-source depletion.

Implants for surgery — Cardiac pacemakers —

Part 2:
Reporting of clinical performance of populations of pulse generators or leads

1 Scope

This part of ISO 5841 specifies requirements for reports on the clinical performance in humans of population samples of pulse generators or leads, intended for long-term implantation as cardiac pacemakers, hereinafter referred to as devices. It includes general requirements for all reports and supplementary requirements for reports on cumulative experience with devices and estimates of future clinical performance for devices, when appropriate.

Annex A provides requirements for categorizing devices. Annex B provides guidelines for statistics, including a discussion of application of the results obtained. As with other statistical methods, the benefit of the analytical methods in this part of ISO 5841 is limited by the size of population under consideration. Annex C gives the rationale for this part of ISO 5841.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this part of ISO 5841. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 5841 are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 5841-1, *Implants for surgery — Cardiac pacemakers — Part 1: Implantable pacemakers.*

3 Terms and definitions

For the purposes of this part of ISO 5841, the terms and definitions given in ISO 5841-1 and the following apply.

3.1
advisory notification
<of a device> any action taken to inform the clinicians concerned by a manufacturer who has become aware that a device may fail to conform to any claims made relating to effectiveness, benefits, performance characteristics or safety

3.2
clinical performance period
calendar period, defined by the reporting party, during which the clinical performance of a specific population sample of devices is assessed

3.3
damaged, adj
<of a device> having characteristics which have changed outside the limits stated by the manufacturer, due to some external agency

3.4
dysfunctional, adj
<of a device> having some characteristic outside the limits specified in the technical manual, except changes to the characteristics of a pulse generator due to expected battery depletion

3.5
follow-up centre
medical centre, hospital, clinic or individual responsible for the care of a patient after the implantation of a device

3.6
in service
<of a device> functioning in such a manner as to provide potential medical benefits to the patient

NOTE This term can apply to a device that may be out of specification (see 3.10).

3.7
in specification
<of a device> having characteristics within the limits recommended by the manufacturer for clinical use

3.8
medical reasons
reasons unrelated to the device or its operation

EXAMPLES Infection, extrusion, indication for an alternative medical device (e.g. the replacement of a single-chamber pacemaker in a patient with pacemaker syndrome with a dual-chamber pacemaker), etc.

3.9
out of service
<of a device> not providing a medical benefit to the patient

NOTE A device thus described is not necessarily out of specification (see 3.10) or explanted.

3.10
out of specification
<of a device> having one or more characteristics outside the limits established by the manufacturer for clinical use

3.11
population sample
group of devices designated for the purpose of reporting performance experience that is assumed to be representative of the population

3.12
production group
population sample of devices designated by the manufacturer on the basis of a particular parameter

EXAMPLE Such a parameter may be, for example, time or place of manufacture or a change in the manufacturing process or components.

3.13
prophylactic explantation
explantation for reasons based on the anticipated performance of the device or other medical reasons

3.14
recommended replacement condition
condition in which the device exhibits characteristic(s) identified by the manufacturer as signalling that the device should be taken out of service

EXAMPLE A pulse generator that exhibits the maximum allowable changes in the battery-condition indicators stated by the manufacturer is in a condition where replacement is recommended.

3.15
registered explant
registered implant for which the date of explantation is known by the reporting party

3.16
registered implant
implanted device for which the date of implantation is known by the reporting party

3.17
registered implant month
one month of operation by a registered implant

3.18
reporting party
individual or organization publishing clinical pacemaker data or the analysis thereof

4 General requirements

A report on the clinical performance that conforms to this part of ISO 5841 shall contain the following information:

a) model designation(s) of the devices covered by the report;

b) sources of the data and the methods used to collect them;

c) sample size and how the population and population sample are defined;

d) criteria for including and excluding data;

e) time period over which the data were acquired;

f) units of time of the data;

g) category assigned to the device, in accordance with annex A;

h) explanation of methods used to adjust for any sources of bias known to be present (see annex B);

i) statement of the basis for adjusting registered implant months to compensate for unreported mortality and unreported explants.

Each report shall explain the presentation of the information and any methods of analysis used to calculate numerical expressions of performance. Any generalizations or inferences from data shall be qualified as to assumptions, limitations and associated confidence levels.

Devices referred to in an advisory notification shall be identified by means of the serial numbers of the devices.

If the results are segregated by production group, the report shall explain the basis on which the production groups are established.

It shall be stated in the report that it has been prepared in accordance with this part of ISO 5841.

It is recommended that supplementary information be included in the report, for instance lower confidence limits (see annex B).

NOTE Reports applicable to any number of production groups or population samples may be included in one document. However, they should be arranged in an easily distinguishable manner.

5 Reporting cumulative experience with devices

In addition to the requirements in clause 4, a report of this type shall comply with the qualifications and limitations given in this clause. (See also annex C.)

For a given population sample, the report shall compare the total number of registered implant months with the total number of devices categorized, in accordance with annex A, as being out of specification (including subcategories). As a minimum, the cumulative survival probability for the population sample and population sample size shall be given.

NOTE Examples of data sets and analyses are given in annex B.

The manufacturer shall provide a report on each model at least once a year for as long as there are devices known to be in service or for a period equal to 1,25 times the manufacturer's predicted lifetime of the device, measured from the time of the last unit implanted, whichever is shorter. This report shall be made available to the implanting and follow-up centres and regulatory authorities at their request.

6 Reporting estimated future clinical performance for devices

In addition to the requirements in clause 4, reports of this type shall comply with the qualifications and limitations given in this clause.

From time to time, a manufacturer may wish to estimate the future clinical performance of a particular device. Such estimates of future clinical performance shall be developed by extrapolating the cumulative survival data (see B.2.3).

The report shall explain the method used to smooth and extrapolate the cumulative survival probability.

The report shall state that the analysis assumes that each patient will survive through the period covered by the report, and that the device will not be removed for any reason other than a device-related complication.

Annex A
(normative)

Categorization of devices

The device shall be assigned the appropriate category in accordance with the following criteria and according to the evidence available to the reporting party. Figure A.1 is intended to illustrate these criteria.

A device shall be classified in that category that best describes its status after implant, use being made of the best information available. The reporting party should detail the composition of the categories A, B, C, D and L, with special attention given to distinguishing units in categories C_1 and C_2.

NOTE A device that is not implanted because it is damaged is not included in this categorization.

A general category shall be assigned to the device, in accordance with the following criteria:

— Category A: Device that is in service and, as far as can be verified, in specification.

— Category B: Device removed from service for reasons not related to the functioning of the device.

— Category C: Device that is out of specification.

  — Subcategory C_1: Device is out of specification because it has become dysfunctional.

  — Subcategory C_2: Device is out of specification because it has reached the point in its service life at which the manufacturer recommends its replacement.

— Category D: Patient has died. However, the death, as far as can be verified, is unrelated to the functioning of the device.

— Category L: Device is lost to follow-up.