Second edition
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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

Reference number
ISO 5841-2:2000(E)

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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.