INTERNATIONAL STANDARD

ISO 5841-2

Third 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 concernant 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

This third edition cancels and replaces the second edition (ISO 5841-2:2000), which has been technically revised.

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

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

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

Introduction

ISO 14708-2:2012, 28.19 requires the clinician's manual to document the projected service life using defined settings. 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 projected 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.

Programmed settings and differing or changing patient therapy needs might also result in a device having more or less than the projected service life as defined by ISO 14708-2. In addition, clinical management and implant technique can have a significant impact on long term performance of lead and pulse generators. These variables are reflected in the product performance report data.

These factors underscore the value of maintaining an accurate and discriminating view of clinical performance of a population of devices within the scope of this part of ISO 5841, so as to aid patient management. In order to do this, it is necessary to collect implant and explant information as allowed by local law. Physicians and clinicians are encouraged to report their complaints and return associated explanted devices to the device manufacturers to support the accuracy of product performance reports.

It is recognized that certain devices are marketed in geographies where device implant and explant data are not available due to patient privacy laws. This situation requires manufacturers to apply alternative methods to calculate survival probability.

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 can give cumulative clinical-experience information based on a variety of assumptions and statistical techniques. This part of ISO 5841 provides a method for categorizing devices, requirements for the statistical techniques (see Annex A) that shall be used to obtain the most benefit from the data and a statement of the rationale (see Annex B) 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 cardiac pulse generators or leads, intended for long-term implantation, hereinafter referred to as devices. Devices to be reported has to be market approved in one or more geographies. 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. It also provides normative requirements for statistical calculations, 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 B gives the rationale for this part of ISO 5841.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14708-2:2012, *Implants for surgery — Active implantable medical devices — Part 2: Cardiac pacemakers*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14708-2 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 might 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
complaint
any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution[15]