

Cardiac pacemakers —

Part 2: Method for reporting the clinical performance of populations of pulse generators

[ISO title: Implants for surgery — Cardiac pacemakers —
Part 2: Reporting of the clinical performance of populations of
pulse generators]

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- Biological Engineering Society
- British Cardiac Society
- British Pacing Group
- British Surgical Trades Association Incorporated
- Cardiothoracic Institute
- Department of Health and Social Security
- Institution of Electrical Engineers
- Ministry of Defence
- Royal College of Physicians of London

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National foreword

This Part of BS 6902 has been prepared under the direction of the Health Care Standards Committee. It is identical with ISO 5841-2:1986 *“Implants for surgery — Cardiac pacemakers — Part 2: Reporting of the clinical performance of populations of pulse generators”*, published by the International Organization for Standardization (ISO).

BS 6902 is intended to cover the various aspects of cardiac pacemakers including pulse generators and connecting devices. It is being published in a number of Parts which, at the time of publication of this Part, are in preparation.

It is assumed in the drafting of this British Standard that it will be used and applied by those who are appropriately qualified and experienced.

Terminology and conventions. The text of the International Standard has been approved as suitable for publication as a British Standard without deviation. Some terminology and certain conventions are not identical with those used in British Standards; attention is drawn especially to the following.

The comma has been used as a decimal marker. In British Standards it is current practice to use a full point on the baseline as the decimal marker.

Wherever the words “International Standard” and “this part of ISO 5841” appear, referring to this standard, they should be read as “British Standard” and “this Part of BS 6902” respectively.

Cross-reference. There is at present no British Standard corresponding to ISO 5841-1. The Technical Committee has reviewed the definitions given in the current edition of ISO 5841-1, to which reference is made in clause 3 of this Part of BS 6902, and has decided that they are acceptable for use in conjunction with this standard. It is intended to implement the revision of ISO 5841-1, which is in preparation, as BS 6902-1.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 16, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

0 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 pacemaker components and assemblies have resulted in actual service life different from the nominal service life. Defined production groups of pulse generators 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 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. 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 pacemakers, not the clinical reasons for their use. It is realized that reasons for use can be a guide in the design of future products.

At present, reporting parties 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 pacemakers, 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 pulse generator the performance of which has changed, either expectedly or unexpectedly, is sometimes left implanted due to other medical considerations. Instances exist where the performance of an implanted pulse generator has changed to stable but out-of-specification performance which 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 which meet all longevity claims and cease functioning due to normal power source depletion.

1 Scope and field of application

This part of ISO 5841 specifies requirements for reports on the clinical performance in humans of population samples of pulse generators. It includes general requirements for all reports and supplementary requirements for reports on recent experience and cumulative experience, including specific statistical expressions based on an adaptation of actuarial analysis.

Annex A provides requirements for categorizing pulse generators. Annex B provides guidelines for statistics, including a discussion on 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 Reference

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

3 Definitions

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

3.1 advisory notification

in respect of a device, any action taken to inform the clinicians concerned by a manufacturer who has become aware that the pulse generator may fail to conform to any claims made relating to effectiveness, benefits, performance characteristics or safety

3.2 clinical performance period

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

3.3 damaged

term used to describe a device the characteristics of which have changed outside the limits stated by the manufacturer due to some external agency

3.4 dysfunction

term used to describe a device having some characteristic outside the limits recommended by the manufacturer for clinical use, except changes due to the expected battery condition

**3.5
follow-up centre**

a medical centre, hospital, clinic or individual responsible for the care of a patient after the implantation of a pacemaker

**3.6
in service**

term used to describe a device that is functioning in such a manner as to provide potential medical benefits to the patient although the pulse generator may be out of specification (see 3.10)

**3.7
in specification**

term used to describe a device having characteristics within the limits recommended by the manufacturer for clinical use

**3.8
medical reasons**

reasons unrelated to the pulse generator or its operation (e.g. infection, extrusion, high threshold, etc.)

**3.9
out of service**

term used to describe a device not providing a medical benefit to the patient. The pulse generator is not necessarily out of specification (see 3.10) or explanted

**3.10
out of specification**

term used to describe a device having one or more characteristics outside the limits recommended by the manufacturer for clinical use

**3.11
population sample**

a group of pulse generators designated for the purpose of reporting performance experience that it assumed to be representative of the population

**3.12
production group**

a particular population sample of pulse generators designated by the manufacturer on the basis of, 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 expected performance of the pulse generator

**3.14
recommended replacement condition**

condition in which the pulse generator has exhibited the maximum allowable changes in the battery condition indicators stated by the manufacturer

**3.15
registered explant**

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

**3.16
registered implant**

an implanted pulse generator 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**

an individual or organization publishing clinical pacemaker data or the analysis thereof

4 General requirements (see also Annex C)

4.1 The report shall indicate the sources of the data and the methods used to collect them.

4.2 The report shall specify the sample size and how the population and population sample are defined.

4.3 The criteria for including and excluding data shall be given.

4.4 The time period over which the data were acquired shall be given.

4.5 The units of time of the data shall be given.

4.6 Each report shall explain the presentation of the information and any methods of analysis used to calculate numerical expressions of performance. It shall be stated in the report that it has been prepared in accordance with this part of ISO 5841.

4.7 The report shall explain methods used to adjust for any sources of bias known to be present (see Annex B).

4.8 Any generalizations or inferences from data shall be qualified as to assumptions, limitations and associated confidence levels.

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

4.10 The report shall state the basis for adjusting registered implant months to compensate for unreported morality and unreported explants.

4.11 Pulse generators shall be assigned the appropriate category in accordance with Annex A.

NOTES ON CLAUSE 4

1 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.

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

5 Reporting of recent clinical performance of implanted pulse generators for patient management

5.1 A report of this type shall comply with the qualifications and limitations given in **5.2** to **5.5**. (See also Annex C.)

5.2 The basis of the report on a specific registered implant shall be the clinical performance of that production group to which it belongs.

5.3 The clinical performance period shall fall completely within a specified 12 calendar month period. The date of the report shall be within six months of the end of the specified period.

5.4 For the production group and clinical performance period, the report shall compare the number of registered implant months with the number of pulse generators categorized, in accordance with Annex A, as being out of specification (including sub-categories). As a minimum, monthly survival rate and population sample size shall be given.

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

5.5 The manufacturer of the pulse generator shall provide a report on the production group at least once a year for as long as there are devices known to be in service. This report shall be made available to the implanting and follow-up centres at their request.

6 Reporting of cumulative experience with implanted pulse generators

6.1 A report of this type shall comply with the qualifications and limitations given in **6.2** to **6.5**. (See also Annex C.)

6.2 For a given population sample, the report shall compare the total number of registered implant months with the total number of pulse generators categorized, in accordance with Annex A, as being out of specification (including sub-categories). 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.

6.3 The report shall state that it is based on cumulative analysis and, as such, may not reflect changes in recent implant performance nor reflect differences in performance between production groups.

6.4 The report shall direct attention to recent experience reports suitable for patient management purposes.

6.5 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. This report shall be made available to the implanting and follow-up centres at their request.