Third edition
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Implants for surgery — Cardiac pacemakers —

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

Implants chirurgicaux — Stimulateurs cardiaques —

Partie 3: Connecteurs à bas profil (IS-1) pour stimulateurs implantables

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Foreword

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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. www.iso.org/directives

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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 5841-3:2000), which has been technically revised. It also incorporates the Technical Corrigendum ISO 5841-3:2000/Cor 1:2003.

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

Introduction

The development of this part of ISO 5841 was prompted by the concern of clinicians over the variety of apparently similar but incompatible pacing leads of the low-profile in-line type. (Because the major diameter of such leads is 3,2 mm, these connectors were frequently referred to as “3,2 mm” leads.) The purpose of this part of ISO 5841 is to specify a standard connector assembly, IS-1, to allow leads and pulse generators from different manufacturers to be interchangeable. The safety, reliability and function of a particular connector part are the responsibility of the manufacturer.

Annex A gives a test method for lead connector impedance.

Annex B provides a rationale: it is recommended that this annex be read before using this part of ISO 5841 so that the user is informed about its limited objectives.