
**Implants for surgery — Active
implantable medical devices —**

**Part 3:
Implantable neurostimulators**

*Implants chirurgicaux — Dispositifs médicaux implantables actifs —
Partie 3: Neurostimulateurs en implant*



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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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14708-3 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

ISO 14708 consists of the following parts, under the general title *Implants for surgery — Active implantable medical devices*:

- *Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*
- *Part 2: Cardiac pacemakers*
- *Part 3: Implantable neurostimulators*
- *Part 4: Implantable infusion pumps*

Introduction

This part of ISO 14708 specifies particular requirements for active implantable medical devices intended for electrical stimulation of the central or peripheral nervous system, to provide basic assurance of safety for both patients and users. It amends and supplements ISO 14708-1:2000, hereinafter referred to as ISO 14708-1.

The requirements of this part of ISO 14708 take priority over those of ISO 14708-1.

Devices that use electricity to stimulate the nervous system are commonly called neurostimulators. They produce controlled electrical pulses that are delivered through electrodes in contact with a specific target area. Whether or not a neurostimulator is totally or partially implantable, a lead or extension is usually required to convey stimulation pulses from a form of pulse generator to the electrodes, although newer forms of device might not utilize leads or extensions. An external programmer might be used to adjust device parameters.

Currently, several types of neurostimulators exist for treating the central or peripheral nervous system. This part of ISO 14708 is intended to apply to these neurostimulator types regardless of therapy. (See Clause 3 for device type definitions used throughout this part of ISO 14708.)

This part of ISO 14708 is relevant to all parts and accessories of implantable neurostimulators, including programmers, trial screeners, software, and technical manuals. Not all parts or accessories might be intended to be totally or partially implanted, but there is a need to specify some requirements of non-implantable parts and accessories if they could affect the safety or performance intended by the manufacturer.

Requirements for physiologic sensing functions of implantable neurostimulators are not included in this edition of this part of ISO 14708 but might be considered in future editions.

Within this part of ISO 14708 the following terms are used to amend and supplement ISO 14708-1:

“Replacement”: the clause of ISO 14708-1 is replaced completely by the text of this part of ISO 14708.

“Addition”: the text of this part of ISO 14708 is additional to the requirements of ISO 14708-1.

“Amendment”: the clause of ISO 14708-1 is amended as indicated by the text of this part ISO 14708.

“Not used”: the clause of ISO 14708-1 is not applied in this part ISO 14708.

Subclauses, figures, or tables that are additional to those of ISO 14708-1 are numbered starting from 101; additional annexes are lettered AA, BB, etc.

Implants for surgery — Active implantable medical devices —

Part 3: Implantable neurostimulators

1 Scope

This part of ISO 14708 is applicable to active implantable medical devices intended for electrical stimulation of the central or peripheral nervous system.

This part of ISO 14708 is also applicable to all non-implantable parts and accessories of the devices as defined in Clause 3.

The tests that are specified in this part of ISO 14708 are type tests intended to be carried out on a sample of a device to show compliance, and are not intended to be used for the routine testing of manufactured products.

NOTE This part of ISO 14708 is not intended to apply to non-implantable neurostimulation devices. However, it does apply to devices intended to be used as trial screeners because of their close affiliation with implantable neurostimulators.

2 Normative references

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

ISO 14708-1, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 61000-4-3:2002, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test*

ANSI/AAMI PC69:2000, *Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators*