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# Implants for surgery — Active implantable medical devices —

## Part 3: Implantable neurostimulators

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



Reference number  
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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](http://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](http://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 voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, SC 6, *Active implants*.

This second edition cancels and replaces the first edition (ISO 14708-3:2008), which has been technically revised.

A list of all parts in the ISO 14708 series can be found on the ISO website.

## Introduction

This document 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 14708-1:2014, hereinafter referred to as ISO 14708-1.

The requirements of this document 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 devices 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 document is intended to apply to these neurostimulator types regardless of therapy.

This document is relevant to all parts and accessories of implantable neurostimulators, including programmers, 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.

Not included in the scope of this document are non-implantable medical devices, such as external neurostimulators and RF-coupled neurostimulators, even though such devices might have implantable parts, because they are covered under the IEC 60601-1 series of standards.

Within this document, 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 document.

“Addition”: the text of this document 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 document.

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

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.