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# Implants for surgery — Active implantable medical devices —

## Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)

*Implants chirurgicaux — Dispositifs médicaux implantables actifs —*

*Partie 6: Exigences particulières pour les dispositifs médicaux implantables actifs destinés à traiter la tachyarythmie (y compris les défibrillateurs implantables)*

Reference number
ISO 14708-6:2010(E)

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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 14708-6 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*

— *Part 5: Circulatory support devices*

— *Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)*

In this International Standard, the following print types are used:

— Requirements and definitions: roman type.

— *Test specifications: italic type.*

— Informative material appearing outside of tables, such as notes, examples and references: smaller type. Normative text of tables is also in a smaller type.

— TERMS DEFINED IN CLAUSE 3 OF ISO 14708-1, IN THIS PART OF ISO 14708 OR AS NOTED: SMALL CAPITALS

In referring to the structure of this standard, the term

— “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

— “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this collateral standard are by number only.

In this International Standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

# Introduction

This part of ISO 14708 specifies particular requirements for IMPLANTABLE CARDIOVERTER DEFIBRILLATORS and the functions of ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat tachyarrhythmia, to provide basic assurance of safety for both patients and users.

An external defibrillator is a MEDICAL DEVICE used, in the emergency setting, to deliver a high-energy shock to the heart, by means of ELECTRODES applied to the external chest wall, in patients suffering ventricular fibrillation (a rapid, disorganized and potentially lethal heart rhythm abnormality), to restore normal heart action. External defibrillators may also be used, in emergency or elective settings, to terminate other ventricular or atrial tachyarrhythmias by delivery of a high-energy shock, synchronized to the intrinsic cardiac rhythm, a procedure known as CARDIOVERSION. In patients known to be at risk of such arrhythmias, due to the occurrence of previous episodes or the presence of specific predisposing cardiac conditions, an IMPLANTABLE CARDIOVERTER DEFIBRILLATOR may be implanted to perform similar functions. The implantable device, which is much smaller than an external defibrillator, is contained within a sealed, encapsulating enclosure. It generates high voltage PULSES from an enclosed, miniature, electrical battery. The PULSES are transmitted to the heart by means of implanted, insulated conductors with ELECTRODES (LEADS). The IMPLANTABLE CARDIOVERTER DEFIBRILLATOR may also incorporate other sensing and pacing functions, such as rate support for bradycardia and ANTITACHYCARDIA PACING (ATP) to terminate certain tachyarrhythmias without the need of a high-energy shock. The defibrillator may be adjusted non-invasively by means of an electronic device, known as a programmer.

This part of ISO 14708 is relevant to all parts of ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat tachyarrhythmia other than pacing functions to control bradyarrhythmia. Typical examples are IMPLANTABLE PULSE GENERATORS, LEADS, ADAPTORS, ACCESSORIES, programmers and the related software (bradyarrhythmia pacing functions are dealt with in ISO 14708-2).

The requirements of this part of ISO 14708 supplement or modify those of 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*, hereinafter referred to as ISO 14708-1. The requirements of this part of ISO 14708 take priority over those of ISO 14708-1.

Figures or tables that are additional to those of ISO 14708-1 are numbered starting from 101.

Annex D describes a coding system that may be used to designate tachyarrhythmia therapy modes. Annex E defines the tissue equivalent interface circuits and low-pass filter required for some compliance tests. Annex F describes a method for selecting the filter capacitor used in the tissue equivalent interface circuits defined by Annex E. Annex G defines the method of calibrating the injection network defined by Annex E. All annexes except Annex E and Annex G are informative.