

This is a preview of "ISO 14708-7:2013". [Click here to purchase the full version from the ANSI store.](#)

First edition
2013-01-15

Implants for surgery — Active implantable medical devices —

Part 7: Particular requirements for cochlear implant systems

*Implants chirurgicaux — Dispositifs médicaux implantables actifs —
Partie 7: Exigences particulières pour les systèmes d'implant cochléaire*



Reference number
ISO 14708-7:2013(E)

© ISO 2013

This is a preview of "ISO 14708-7:2013". Click here to purchase the full version from the ANSI store.



COPYRIGHT PROTECTED DOCUMENT

© ISO 2013

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

This is a preview of "ISO 14708-7:2013". Click here to purchase the full version from the ANSI store.

Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Symbols and abbreviations	3
5 General requirements for non-implantable parts	3
6 Inspection and measurement	4
6.1 Measurement of output signal characteristics	4
6.2 Measurement of the output SIGNAL amplitude and pulse width	4
6.3 Impedance measurement accuracy	4
7 General arrangement of the packaging	5
8 General markings for active implantable medical devices	5
9 Markings on the SALES PACKAGING	5
10 Construction of the SALES PACKAGING	6
11 Markings on the sterile pack	6
12 Construction of the non-reusable pack	6
13 Markings on the active implantable medical device	7
14 Protection from unintentional biological effects being caused by the active implantable medical device	7
15 Protection from harm to the patient or user caused by external physical features of the active implantable medical device	8
16 Protection from harm to the patient caused by electricity	8
17 Protection from harm to the patient caused by heat	8
18 Protection from ionizing radiation released or emitted from the active implantable medical device	8
19 Protection from unintended effects caused by the device	9
20 Protection of the device from damage caused by external defibrillators	9
21 Protection of the device from changes caused by high power electrical fields applied directly to the patient	10
22 Protection of the active implantable medical device from changes caused by miscellaneous medical treatments	10
23 Protection of the active implantable medical device from mechanical forces	13
24 Protection of the active implantable medical device from damage caused by electrostatic discharge	18
25 Protection of the active implantable medical device from damage caused by atmospheric pressure changes	18
26 Protection of the active implantable medical device from damage caused by temperature changes	18
27 Protection of the active implantable medical device from electromagnetic non-ionising radiation	19
28 Accompanying documentation	21

This is a preview of "ISO 14708-7:2013". [Click here to purchase the full version from the ANSI store.](#)

Annex AA (informative) Relationship between the fundamental principles in ISO/TR 14283 and the clauses of this part of ISO 14708	24
Annex BB (informative) Relationship between the clauses of this part of ISO 14708 and the fundamental principles listed in Annex A.....	37
Annex CC (informative) Notes on EN 45502-2-3 (basis for this part of ISO 14708)	39
Annex DD (informative) Notes on theoretical modelling to demonstrate compliance with Clause 27	47
Annex EE (informative) Notes on EMI measurements to demonstrate compliance with Clause 2749	49
Bibliography	53

This is a preview of "ISO 14708-7:2013". [Click here to purchase the full version from the ANSI store.](#)

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 14708-7 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)*
- *Part 7: Particular requirements for cochlear implant systems*

Introduction

This International Standard specifies particular requirements for ACTIVE IMPLANTABLE MEDICAL DEVICES used to treat hearing impairment via electrical stimulation (for example cochlear implant systems or auditory brainstem implant systems), to provide basic assurance of safety for both patients and users.

A COCHLEAR IMPLANT SYSTEM or AUDITORY BRAINSTEM IMPLANT SYSTEM is an ACTIVE IMPLANTABLE MEDICAL DEVICE comprising implantable and NON-IMPLANTABLE PARTS (external parts). The power source may be externally derived or from an internal battery. The IMPLANT SYSTEM is designed to restore hearing via electrical stimulation of the auditory pathways. Externally or internally processed acoustic information is converted to electrical stimulation signals which are delivered via one or more electrodes. The working parameters of the device may be adjusted via a non-implantable accessory.

This International Standard is relevant to all parts of IMPLANT SYSTEMS, including accessories.

The requirements of this International Standard 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*.

Figures or tables that are additional to those of Part 1 are numbered starting from 101; additional annexes are lettered AA, BB, etc.

In this part of ISO 14708, terms printed in small capital letters are used as defined in Clause 3. Where a defined term is used as a qualifier in another term, it is not printed in small capital letters unless the concept thus qualified is also defined.