

ISO 14708-7:2013-01 (E)

Implants for surgery - Active implantable medical devices - Part 7: Particular requirements for cochlear implant systems

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 salespackaging	5
10	Construction of the salespackaging	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
	Annex AA (informative) Relationship between the fundamental principles in ISO/TR 14283 and fundamental principles listed in Annex A	37
	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 27.4.9 Bibliography	53