

ISO 14708-7:2019-12 (E)

Implants for surgery - Active implantable medical devices - Part 7: Particular requirements for cochlear and auditory brainstem 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
5.1	General requirements for non-implantable parts	3
5.2	General requirements for software	3
5.3	Usability of non-implantable parts	3
5.4	Data security and protection from harm caused by unauthorized information tampering 3	
5.5	General requirements for risk management	3
5.6	Misconnection of parts of the active implantable medical device	3
5.7	Protection against external electrical hazards for fully implantable systems	3
6	Inspection and measurement	4
6.1	General	4
6.2	Measurement of output signal characteristics	4
6.3	Measurement of the output signal amplitude and pulse width	4
6.4	Impedance measurement accuracy	4
6.5	Inductive link characterization	4
6.6	Sound processor battery testing	4
7	General arrangement of the packaging	4
8	General markings for active implantable medical devices	4
9	Markings on the sales packaging	4
10	Construction of the sales packaging	5
11	Markings on the sterile pack	5
12	Construction of the non-reusable pack	5
13	Markings on the active implantable medical device	5
14	Protection from unintentional biological effects being caused by the active implantable medical device	6
15	Protection from harm to the patient or user caused by external physical features of the active implantable medical device	6
16	Protection from harm to the patient caused by electricity	6

17	Protection from harm to the patient caused by heat	7
18	Protection from ionizing radiation released or emitted from the active implantable medical device	8
19	Protection from unintended effects caused by the device	8
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	9
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	18
24	Protection of the active implantable medical device from damage caused by electrostatic discharge	22
25	Protection of the active implantable medical device from damage caused by atmospheric pressure changes	22
26	Protection of the active implantable medical device from damage caused by temperature changes	23
27	Protection of the active implantable medical device from electromagnetic non- ionising radiation	23
27.1	Protection from static magnetic fields	23
27.2	Radiated magnetic field test for frequencies 16,6 Hz to 27 MHz	23
27.3	Radiated electric field test for frequencies 10 MHz to 2,7 GHz	25
27.4	General test configuration and setup	25
27.4.1	Test configuration and setup	25
27.4.2	Operating functions, modes and settings	26
27.4.3	Patient physiological simulation	26
27.5	Acceptance Criteria	26
28	Accompanying documentation	27
Annex A (informative) General guidance and rationale		31
Annex B (informative) Relationship between the fundamental principles in ISO/TR 14283 and the clauses of this document		42
Annex C (informative) Notes on EN 45502-2-3 (basis for this document)		61
Annex D (informative) Notes on EMI measurements to demonstrate compliance with Clause 27		62
Bibliography		66