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 Termsanddefinitions 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 Protectionofthedevicefromdamagecausedbyexternaldefibrillators 9

21 Protectionofthedevicefromchangescausedbyhighpowerelectricalfields 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