

ISO 14708-5:2020-05 (E)

Implants for surgery - Active implantable medical devices - Part 5: Circulatory support devices

Contents

Page

Foreword	vi
Introduction	vii
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Symbols and abbreviations	5
5 General requirements for active implantable medical devices	5
5.1 General requirements for non-implantable parts	5
5.2 General requirements for software	5
5.3 Usability of non-implantable parts	5
5.4 Data security and protection from harm caused by unauthorized information tampering	6
5.5 General requirements for risk management	6
5.6 Misconnection of parts of the active implantable medical device	6
5.7 Wireless coexistence and wireless quality of service	6
6 Requirements for particular active implantable medical devices	6
6.1 Intended clinical use/indications	6
6.2 System description	6
6.2.1 General	6
6.2.2 System configuration	8
6.2.3 System performance and operating limits	8
6.3 Design analysis	8
6.3.1 General	8
6.3.2 Human factors analysis	8
6.4 Risk analysis	9
6.5 Human factors	10
6.6 In vitro design evaluation and system performance testing	10
6.6.1 Objective	10
6.6.2 System characterization	10
6.6.3 Subsystem component testing	13
6.7 Electromagnetic compatibility	17
6.8 Materials qualification	17
6.9 Biocompatibility	18
6.10 Dynamic haemolysis	18
6.11 Environmental testing	18
6.12 <i>In vivo</i> evaluation	18
6.12.1 Objective	18
6.12.2 Definition of success or failure	19
6.12.3 Test articles	19
6.12.4 Test system	19
6.12.5 Control	20
6.12.6 Test equipment	20
6.12.7 Preoperative animal care	20
6.12.8 Implant procedure	20
6.12.9 Special instructions for early termination	20
6.12.10 Postoperative care	21
6.12.11 Anticoagulation	21

6.12.12	Adverse events.....	21
6.12.13	System performance.....	21
6.12.14	Measurement of physiological parameters.....	21
6.12.15	Clinical pathology.....	21
6.12.16	Necropsy and device retrieval.....	21
6.12.17	Macroscopic examination.....	22
6.12.18	Histological examination.....	22
6.12.19	Explanted device analysis.....	22
6.12.20	Data analysis.....	22
6.13	Reliability.....	22
6.14	Clinical evaluation.....	23
7	General arrangement of the packaging.....	23
8	General <i>markings</i> for active implantable medical devices.....	24
9	Markings on the sales packaging.....	24
10	Construction of the <i>sales packaging</i>.....	24
11	Markings on the sterile pack.....	24
12	Construction of the non-reusable pack.....	25
13	Markings on the active implantable medical device.....	25
14	Protection from unintentional biological effects being caused by the active implantable medical device.....	25
15	Protection from harm to the patient or user caused by external physical features of the active implantable medical device.....	26
16	Protection from harm to the patient caused by electricity.....	26
17	Protection from harm to the patient caused by heat.....	26
17.1	Protection from harm to the patient caused by heat.....	26
17.2	Active implantable medical device intended to supply heat.....	26
18	Protection from ionizing radiation released or emitted from the active implantable medical device.....	26
19	Protection from unintended effects caused by the active implantable medical device.....	26
20	Protection of the active implantable medical device from damage caused by external defibrillators.....	27
21	Protection of the active implantable medical device from changes caused by electrical fields applied directly to the patient.....	27
22	Protection of the active implantable medical device from changes caused by miscellaneous medical treatments.....	27
23	Protection of the active implantable medical device from mechanical forces.....	28
24	Protection of the active implantable medical device from damage caused by electrostatic discharge.....	28
25	Protection of the active implantable medical device from damage caused by atmospheric pressure changes.....	28
26	Protection of the active implantable medical device from damage caused by temperature changes.....	28
27	Protection of the active implantable medical device from electromagnetic non-ionizing radiation.....	29
27.1	General.....	29
27.2	Test conditions.....	29
27.2.1	Acceptance criteria.....	29
27.2.2	Test configuration and setup.....	29
27.2.3	Operating functions, modes, and settings.....	30
27.2.4	Patient physiological simulation.....	30
27.2.5	Immunity test levels.....	30
27.3	Risk management file and test report file documentation.....	30
27.4	Protection from static magnetic fields of flux density up to 50 mT.....	31
27.5	Protection from AC magnetic fields in the range of 1 kHz to 140 kHz.....	31

27.6	Protection from proximity fields due to RF wireless communications equipment.....	32
28	Accompanying documentation	32
Annex A	(informative) Relationship between the fundamental principles in ISO/TR 14283 and the clauses of this document.....	36
Annex B	(informative) Rationale.....	55
Annex C	(informative) Pre-clinical <i>in vitro/in silico</i> evaluation.....	61
Annex D	(informative) Active implantable medical device hazards, associated failure modes, and evaluation methods.....	65
Bibliography	67