

ISO/TS 10974:2012-05 (E)

Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device

Contents		Page
Foreword		vii
Introduction		viii
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	Symbols and abbreviated terms	7
5	General requirements for non-implantable parts	7
6	Requirements for particular AIMDs	7
7	Protection of patients from potential hazards caused by interactions of the AIMD and MR scanners	8
8	Test signals	9
8.1	Gradient sequence of sequences	9
8.2	RF sequence of sequences	11
9	General considerations for application of the requirements of this Technical Specification	14
9.1	Compliance criteria	14
9.2	Monitoring equipment	14
9.3	Validation of models and test equipment	14
9.4	Uncertainty assessment	14
9.5	Test reports	14
10	Protection from harm to the patient caused by RF-induced heating	15
10.1	General	15
10.2	Outline of the four-tier approach	16
10.2.1	Tier 1	16
10.2.2	Tier 2	18
10.2.3	Tier 3	18
10.2.4	Tier 4	19
10.3	Determination of the induced electric and magnetic fields	20
10.3.1	Electromagnetic simulation	20
10.3.2	Relevant parameters	20
10.3.3	Assessment procedure	20
10.3.4	Uncertainty budget of incident field assessment	20
10.4	Validation of electromagnetic AIMD models	21
10.4.1	Validation procedure	21
10.4.2	Validation criteria	21
10.5	Generation of incident fields for Tier 1 to Tier 3 and minimal medium requirements	21
10.6	Measurement system requirements	22
10.6.1	Probe specification	22
10.6.2	Validation and characterization of the measurement system	22

10.7	Procedures and protocols for determination of the distribution and magnitude of the absorbed energy in the tissue equivalent material by SAR and T measurements	23
10.7.1	Determination of 3D relative distribution of local energy deposition	23
10.7.2	Measurement protocol for determination of maximum amplitude	24
10.8	Uncertainty assessment of energy deposition using SAR or temperature probes	27
10.9	Compliance criteria	28
10.10	Test report	28
11	Protection from harm to the patient caused by gradient-induced device heating	28
11.1	General	28
11.2	Testing considerations	29
11.2.1	General	29
11.2.2	Determination of clinical dB/dt exposure limits	29
11.2.3	Test duration	30
11.2.4	Data collection	30
11.3	Test requirements	31
11.3.1	General	31
11.3.2	In vitro, phantom or other suitable container	31
11.3.3	Gelled solution	31
11.3.4	Optical temperature probes	31
11.3.5	Temperature survey to determine worst-case orientation and hot spots	32
11.3.6	Minimum temperature instrumentation	32
11.3.7	Temperature data collection	32
11.3.8	Monitor applied dB/dt	32
11.3.9	Gradient field vector orientation relative to device	32
11.3.10	Monitoring AIMD for heating and malfunction	32
11.4	Lab testing using simulated MRI gradient field	33
11.4.1	Simulated field requirements	33
11.4.2	Pulse waveform RMS value	33
11.4.3	Gradient sequence of sequences	33
11.5	MR scanner testing	33
11.6	Analysis of gradient heating test	34
11.7	Uncertainty assessment	34
11.8	Test report	34
12	Protection from harm to the patient caused by gradient-induced vibration	35
12.1	General	35
12.2	General test considerations	36
12.2.1	Equipment	36
12.2.2	Determination of clinical dB/dt and B0 exposure limits	39
12.2.3	Test signals	39
12.3	Test method for the evaluation of AIMD functionality during exposure to gradient-induced vibration	39
12.3.1	General requirements	39
12.3.2	Conducting functional testing using a research scanner	40
12.3.3	Conducting functional testing using simulated fields	40
12.3.4	Conducting functional testing using a clinical scanner	40
12.3.5	Conducting functional testing using a shaker table or other vibration test equipment	40
12.4	Test method for the evaluation of patient discomfort during exposure to gradient-induced vibration	41
12.4.1	General requirements	41
12.4.2	Conducting patient discomfort testing using a research scanner	42
12.4.3	Conducting patient discomfort testing using simulated fields	42
12.4.4	Conducting patient discomfort testing using a clinical scanner	42
12.4.5	Conducting patient discomfort testing using a shaker table or other vibration test equipment	43
12.5	Test method for the evaluation of risk of tissue injury during exposure to gradient-induced vibration	43
12.5.1	General requirements	43
12.5.2	Conducting testing for the evaluation of risk of tissue injury using a research scanner	46
12.5.3	Conducting testing for the evaluation of risk of tissue injury using simulated fields	46
12.5.4	Conducting testing for the evaluation of risk of tissue injury using a clinical scanner	46

12.5.5	Conducting testing for the evaluation of risk of tissue injury using a shaker table or other vibration test equipment	46
12.6	Uncertainty assessment	47
12.7	Test report	47
13	Protection from harm to the patient caused by B0-induced force	47
14	Protection from harm to the patient caused by B0-induced torque	47
15	Protection from harm to the patient caused by image artefact	48
16	Protection from harm to the patient caused by gradient-induced extrinsic electric potential	48
16.1	General	48
16.2	Test procedure	48
16.3	Uncertainty assessment	49
16.4	Test report	49
17	Protection from harm to the patient caused by RF rectification	49
17.1	General	49
17.2	Test procedure	49
17.3	Uncertainty assessment	50
17.4	Test report	50
18	Protection from harm to the patient caused by B0-induced malfunction	50
18.1	General	50
18.2	Test procedure	50
18.3	Test equipment	50
18.3.1	Generating the B0 field	50
18.3.2	Phantom and tissue simulation medium	51
18.4	Uncertainty assessment	51
18.5	Test report	51
19	Protection from harm to the patient caused by RF-induced malfunction	51
19.1	Introduction of tiered approach	51
19.2	Injected immunity test	53
19.2.1	Using the tiers	53
19.2.2	Test procedure	55
19.2.3	Test equipment	55
19.2.4	Uncertainty assessment	55
19.2.5	Test report	55
19.3	Radiated immunity test	56
19.3.1	Using the tiers	56
19.3.2	Test procedure	56
19.3.3	Test equipment	56
19.3.4	Uncertainty assessment	57
19.4	Test report	57
20	Protection from harm to the patient caused by gradient-induced malfunction	57
20.1	Introduction of tiered approach	57
20.2	Injected immunity test	58
20.2.1	Tier 1	58
20.2.2	Tier 2	62
20.2.3	Tier 3	65
20.2.4	Test procedure	67
20.2.5	Test equipment	67
20.2.6	Uncertainty assessment	67
20.2.7	Test report	67
20.3	Radiated immunity test	67
20.3.1	Applicability	67
20.3.2	Tier 1	67
20.3.3	Tier 2	68

20.3.4	Test procedure	69
20.3.5	Test equipment	69
20.3.6	Uncertainty assessment	69
20.3.7	Test report	69
21	Combined fields test	69
22	Markings and accompanying documentation	70
Annex A (informative) Gradient vibration patent declaration form		72
Annex B (informative) Derivation of lead length factor for injected voltage test levels for gradient-induced malfunction		74
Annex C (informative) Basic MR physics		78
Annex D (informative) Gradient injection network		80
Annex E (informative) RF injection network		82
Annex F (informative) Estimation of the temperature rise in vivo from determined energy deposition		85
Annex G (informative) Methods of assessment of the temperature rise in vivo		88
Annex H (informative) Assessment of dielectric and thermal parameters		91
Annex I (normative) Measurement system validation		94
Annex J (informative) Example of coil systems		107
Annex K (informative) Current distribution on the AIMD as a function of the phase distribution of the incident field		108
Annex L (informative) Recipe and rationale for tissue simulating materials		111
Annex M (informative) Generation of incident fields		113
Annex N (informative) Dielectric parameters		117
Annex O (informative) Thermal and electrical properties of scar tissues		119
Annex P (informative) Estimation of conservative B1 and 10g averaged E-field values for Tier 1 for RF-induced heating and malfunction		120
Annex Q (informative) AIMD configurations		126
Annex R (normative) Uncertainty evaluation		127
Annex S (informative) Guidance on gradient field interactions and test methods for pacemakers ..		145
Annex T (informative) Characterization of lead port interface impedance for evaluating gradient-induced extrinsic electric potential effects		169
Annex U (informative) Method for in vitro measurement of gradient-induced E-field		173
Annex V (informative) Basic physics and interactions of gradient magnetic fields with AIMDs		184
Bibliography		197