

# ISO/TS 10974:2018-04 (E)

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

---

<b>Contents</b>		<b>Page</b>
Foreword .....		vii
Introduction .....		viii
1	Scope .....	1
2	Normative references .....	1
3	Terms and definitions .....	1
4	Symbols and abbreviated terms .....	6
5	General requirements for non-implantable parts .....	6
6	Requirements for particular AIMDs .....	6
7	General considerations for application of the tests of this document .....	6
7.1	Compliance criteria .....	6
7.2	Use of tiers .....	7
7.3	Test reports .....	7
7.3.1	General .....	7
7.3.2	Description of the AIMD under test .....	7
7.3.3	Test methods and results .....	7
8	Protection from harm to the patient caused by RF-induced heating .....	8
8.1	Introduction .....	8
8.2	Outline of the Stage 1 four-tier approach .....	8
8.3	Measurement system prerequisites for all tiers .....	10
8.3.1	RF field source .....	10
8.3.2	Tissue simulating phantom .....	10
8.3.3	Definition of power deposition .....	12
8.3.4	Measurement system validation .....	12
8.4	Determination of RF-induced power deposition in a tissue simulating medium .....	12
8.4.1	General .....	12
8.4.2	Determine location of hot spots around the AIMD .....	13
8.4.3	Determination of spatial (3D) distribution of power deposition for each hot spot .....	13
8.4.4	Determine the final power deposition .....	14
8.5	Proximity effect of electrodes from multiple leads .....	16
8.6	Modelling prerequisites for Tier 2, Tier 3, and Tier 4 .....	17
8.7	Tier selection for RF-induced power deposition .....	17
8.7.1	General .....	17
8.7.2	Tier 1 .....	17
8.7.3	Tier 2 .....	18
8.7.4	Tier 3 .....	19
8.7.5	Tier 4 .....	20
8.8	In vitro model validation .....	21
8.9	Overall uncertainty analysis .....	23
8.10	In vivo analysis of power deposition .....	24
8.11	RF-induced heating assessment flow chart .....	24
9	Protection from harm to the patient caused by gradient-induced device heating .....	27

9.1	Introduction .....	27
9.2	Testing considerations .....	28
9.2.1	General .....	28
9.2.2	Determination of $ dB/dt $ rms exposure limits .....	29
9.2.3	Determination of test duration .....	29
9.3	Test requirements .....	29
9.3.1	General .....	29
9.3.2	In vitro test phantom or other suitable container .....	30
9.3.3	Gelled solution .....	30
9.3.4	Temperature survey to determine orientation and hot spots .....	30
9.3.5	Minimum temperature instrumentation .....	31
9.3.6	Definition of dB/dt test waveform .....	31
9.3.7	Characterization of applied dB/dt .....	32
9.4	Lab testing using simulated MR gradient field .....	32
9.5	MR scanner testing .....	32
9.6	Analysis of gradient heating test .....	33
10	Protection from harm to the patient caused by gradient-induced vibration .....	33
10.1	Introduction .....	33
10.2	Overview of tiers .....	34
10.3	MR environmental conditions .....	35
10.3.1	General .....	35
10.3.2	Determination of maximum clinical dB/dt .....	35
10.3.3	Determination of clinical B0 .....	35
10.3.4	Determination of clinical dB/dt $\times$ B0 .....	35
10.3.5	Test frequencies .....	35
10.3.6	Test duration .....	36
10.3.7	Test temperature .....	37
10.4	General test procedure .....	37
10.4.1	Measurement of gradient field and determination of AIMD location .....	37
10.4.2	AIMD/test unit setup .....	37
10.5	Method 1 -- MR scanner .....	38
10.6	Method 2 -- Shaker table .....	39
10.6.1	General .....	39
10.6.2	Determine scanner input .....	39
10.6.3	AIMD vibration response .....	39
10.6.4	Determine shaker table amplitude (dB/dt scaling) .....	40
10.6.5	Perform vibration exposure using a shaker table .....	40
11	Protection from harm to the patient caused by B0-induced force .....	41
12	Protection from harm to the patient caused by B0-induced torque .....	41
13	Protection from harm to the patient caused by gradient-induced extrinsic electric potential .....	41
13.1	Introduction .....	41
13.2	General requirements .....	42
13.3	Gradient pulse leakage test .....	46
13.3.1	General .....	46
13.3.2	Test equipment .....	46
13.3.3	Test signal .....	46
13.3.4	Tier 1 -- Combined gradient-induced charge measurement test procedure .....	48
13.3.5	Tier 2 -- Separate transient gradient-induced charge and steady-state current measurement test procedure .....	51
13.4	Gradient rectification test .....	53
13.4.1	General .....	53
13.4.2	Test equipment .....	53
13.4.3	Test signal .....	53
13.4.4	Gradient-induced rectification measurement test procedure .....	54
13.5	Gradient pulse distortion of AIMD output test .....	56
13.5.1	General .....	56

13.5.2	Test equipment .....	56
13.5.3	Test signal .....	56
13.5.4	Gradient-induced AIMD output distortion test procedure .....	56
14	Protection from harm to the patient caused by B0-induced malfunction .....	58
14.1	Introduction .....	58
14.2	Static field testing .....	59
14.2.1	B0 general requirements for static field testing .....	59
14.2.2	B0 field generation .....	60
14.2.3	Test conditions .....	60
14.3	Test procedures .....	60
14.3.1	General .....	60
14.3.2	Class 0 test procedure .....	60
14.3.3	Class 1 test procedure .....	60
14.3.4	Class 2 test procedure .....	61
15	Protection from harm to the patient caused by RF-induced malfunction and RF rectification .....	61
15.1	Introduction .....	61
15.2	General requirements .....	61
15.3	Mechanisms for RF interaction with an AIMD .....	61
15.4	Selecting radiated vs injected test methods .....	63
15.4.1	General .....	63
15.4.2	AIMD type designation for test method selection .....	63
15.4.3	RF antenna type designation for test method selection .....	65
15.4.4	RF EMC tier selection .....	65
15.4.5	RF test conditions .....	65
15.4.6	B0 considerations .....	68
15.5	Injected immunity test .....	68
15.5.1	General .....	68
15.5.2	Determination of peak and rms injected levels for Tier 1 and Tier 2 -- AIMD with short electrical length .....	69
15.5.3	Determination of peak and rms injected levels for Tier 3 and Tier 4 .....	69
15.5.4	Injected immunity test procedure .....	71
15.5.5	RF phase test conditions .....	71
15.5.6	AIMD monitoring during the test .....	72
15.6	Radiated immunity test .....	72
15.6.1	General .....	72
15.6.2	Determining the RF radiated field level .....	72
15.6.3	Radiated test procedure .....	72
15.6.4	AIMD monitoring during the test .....	73
15.7	Test equipment .....	73
15.7.1	Generating the RF electric field for radiated testing (AIMD with short electrical length) .....	73
15.7.2	Phantom and tissue simulating medium for radiated testing .....	73
15.7.3	AIMD monitoring apparatus .....	73
15.7.4	RF level measuring device .....	74
15.7.5	RF injection network .....	74
15.8	Determining the peak RF injected level using a radiated test .....	75
16	Protection from harm to the patient caused by gradient-induced malfunction .....	76
16.1	Introduction .....	76
16.2	General requirements .....	76
16.3	Selecting radiated and injected test methods .....	77
16.4	Radiated immunity test .....	78
16.4.1	General .....	78
16.4.2	Test equipment .....	78
16.4.3	Radiated test signal .....	79
16.4.4	Test procedure .....	81
16.5	Injected immunity test .....	82
16.5.1	General .....	82
16.5.2	Test equipment .....	82
16.5.3	Injected test signal .....	82

16.5.4	Test procedure .....	84
16.5.5	AIMD test configuration .....	86
17	Combinedfieldstest .....	93
17.1	Introduction .....	93
17.2	Test setup .....	94
17.3	AIMD fixation .....	96
17.4	Test procedure .....	97
17.4.1	General .....	97
17.4.2	Before MR exposure .....	97
17.4.3	During MR exposure .....	97
17.4.4	After MR exposure .....	97
17.5	Test equipment .....	97
17.5.1	Field generation .....	97
17.5.2	Phantom and tissue simulating medium .....	97
17.5.3	AIMD monitoring apparatus .....	98
18	Markings and accompanying documentation .....	98
18.1	Definitions .....	98
18.2	Applicability of labelling requirements .....	98
18.3	Labelling requirements .....	98
Annex A (normative) Pulsed gradient exposure for Clause 10, Clause 13, and Clause 16 .....		100
Annex B (informative) Derivation of lead length factor for injected voltage test levels for Clause 13 and Clause 16 .....		112
Annex C (informative) Tier 1 high tangential E-field trough liner resonator .....		121
Annex D (informative) Supporting information and rationale for gradient-induced device heating .		128
Annex E (informative) Example RF injection network .....		133
Annex F (informative) Supporting information and rationale for MR-induced vibration .....		135
Annex G (informative) Gradient vibration patent declaration form .....		139
Annex H (informative) Assessment of dielectric and thermal parameters .....		141
Annex I (informative) RF exposure system validation method .....		146
Annex J (informative) MR scanner RF transmit coil .....		156
Annex K (informative) Current distribution on the AIMD as a function of the phase distribution of the incident field .....		158
Annex L (informative) Tissue simulating medium formulations .....		161
Annex M (informative) Generation of incident fields .....		165
Annex N (informative) Dielectric and thermal tissue properties .....		180
Annex O (informative) Gradient field injected testing -- AIMD electrode tissue impedance determination method .....		184
Annex P (informative) Estimation of conservative B <sub>1</sub> and 10 g averaged E-field values for Tier 1 for RF- induced heating and RF malfunction .....		189
Annex Q (informative) AIMD configuration .....		197
Annex R (informative) Electrically excitable tissue stimulation, terms and definitions .....		198

<b>Annex S (informative) Combined field test .....</b>	<b>200</b>
<b>Annex T (informative) General methods for modelling dB/dt levels in MR gradient coils .....</b>	<b>206</b>
<b>Bibliography .....</b>	<b>212</b>