ISO/TS 10974:2018-04 (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 Termsanddefinitions 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 × 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)Tier1hightangentialE-fieldtroughlineresonator 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 distributionoftheincidentfield 158

Annex L (informative) Tissue simulating medium formulations 161

Annex M (informative)Generationofincidentfields 165

Annex N (informative) Dielectric and thermal tissue properties 180

Annex O (informative)Gradientfieldinjectedtesting--AIMDelectrodetissueimpedance determination method 184

Annex P (informative) Estimation of conservative B1and10gaveragedE-fieldvaluesfor Tier 1 for RF-induced heating and RF malfunction 189

Annex Q (informative)AIMDconfiguration 197

Annex R (informative)Electricallyexcitabletissuestimulation,termsanddefinitions 198

Annex S (informative)Combinedfieldstest 200

Annex T (informative) General methods for modelling dB/dt levels in MR gradient coils 206

Bibliography 212