

ISO 14117:2019-09 (E)

Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implant able cardioverter defibrillators and cardiac resynchronization devices

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms, definitions, symbols and abbreviated terms	1
3.1	Terms and definitions	1
3.2	Acronyms and abbreviations	3
4	Test requirements for the frequency band 0 Hz – 3 000 MHz	4
4.1	General requirements for all devices	4
4.2	Induced lead current	5
4.2.1	General requirements	5
4.2.2	Pacemakers and CRT-P devices	5
4.2.3	ICDs and CRT-D devices	9
4.3	Protection from persisting malfunction attributable to ambient electromagnetic fields	12
4.3.1	General requirements	12
4.3.2	Pacemaker and CRT-P devices	12
4.3.3	ICDs and CRT-D devices	17
4.4	Protection from malfunction caused by temporary exposure to CW sources	23
4.4.1	Pacemaker and CRT-P device' response to temporary continuous wave sources in the frequency range 16,6 Hz to 167 kHz	23
4.4.2	ICDs and CRT-D devices	25
4.5	Protection from sensing EMI as cardiac signals	26
4.5.1	General requirements	26
4.5.2	Protection from sensing EMI as cardiac signals in the frequency range of 16,6 Hz to 150 kHz	27
4.5.3	Protection from sensing EMI as cardiac signals in the frequency range of 150 kHz to 10 MHz	30
4.5.4	Protection from sensing EMI as cardiac signals in the frequency range of 10 MHz to 385 MHz	33
4.6	Protection from static magnetic fields of flux density up to 1 mT	35
4.6.1	General requirements	35
4.6.2	Pacemakers and CRT-P devices	35
4.6.3	ICDs and CRT-D devices	36
4.7	Protection from static magnetic fields of flux density up to 50 mT	37
4.7.1	General requirements	37
4.7.2	Pacemakers and CRT-P devices	37
4.7.3	ICDs and CRT-D devices	37
4.8	Protection from AC magnetic field exposure in the range of 1 kHz to 140 kHz	37
4.8.1	General requirements	37
4.8.2	Pacemakers and CRT-P devices	37
4.8.3	ICDs and CRT-D devices	38
4.9	Test requirements for the frequency range of 385 MHz – 3 000 MHz	38
4.9.1	General requirements	38
4.9.2	Test setup	39

4.9.3	Test procedure	40
4.9.4	Performance criteria	42
4.10	Transient exposure to stationary low-frequency electromagnetic field sources in the frequency range 16,6 Hz to 167 kHz	43
5	Testing above frequency of 3 000 MHz	43
6	Protection of devices from EM fields encountered in a therapeutic environment	43
6.1	Protection of the device from damage caused by high-frequency surgical exposure	43
6.1.1	General requirements	43
6.1.2	Pacemakers and CRT-P devices	44
6.1.3	ICDs and CRT-D devices	44
6.2	Protection of the device from damage caused by external defibrillators	45
6.2.1	General requirements	45
6.2.2	Pacemakers and CRT-P devices	45
6.2.3	ICDs and CRT-D devices	48
7	Additional accompanying documentation	49
7.1	Disclosure of permanently programmable sensitivity settings	49
7.2	Descriptions of reversion modes	49
7.3	Known potential hazardous behaviour	49
7.4	Minimum separation distance from hand-held transmitters	49
Annex A (informative)	Rationale	50
Annex B (informative)	Rationale for test frequency ranges	63
Annex C (informative)	Code for describing modes of implantable generators	64
Annex D (normative)	Interface circuits	66
Annex E (informative)	Selection of capacitor Cx	71
Annex F (normative)	Calibration of the injection network (Figure D.5)	74
Annex G (normative)	Torso simulator	76
Annex H (normative)	Dipole antennas	80
Annex I (normative)	Pacemaker/ICD programming settings	82
Annex J (normative)	Simulated cardiac signal	84
Annex K (normative)	Calculation of net power into dipole antenna	85
Annex L (informative)	Loop area calculations	90
Annex M (informative)	Correlation between levels of test voltages used in this document and strengths of radiated fields	96
Annex N (informative)	Connections to DUTs having ports with more than two electrode connections	104
Annex O (informative)	Example method for evaluation of transient and permanent malfunction of a CIED due to temporary exposure to low frequency (<167 kHz) electromagnetic fields	127
Bibliography	132