

<b>STN</b>	<b>Postup na hodnotenie expozície elektromagnetickým poliam pre pracovníkov používajúcich aktívne implantovateľné zdravotnícke pomôcky. Časť 2-1: Špecifické hodnotenie pre pracovníkov s kardiostimulátormi.</b>	<b>STN EN 50527-2-1</b>  36 7938
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Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices - Part 2-1: Specific assessment for workers with cardiac pacemakers

Táto norma obsahuje anglickú verziu európskej normy.  
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 03/17

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Podľa zákona č. 264/1999 Z. z. o technických požiadavkách na výrobky a o posudzovaní zhody a o zmene a doplnení niektorých zákonov v znení neskorších predpisov sa slovenská technická norma a časti slovenskej technickej normy môžu rozmnožovať alebo rozširovať len so súhlasom slovenského národného normalizačného orgánu.



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English Version

**Procedure for the assessment of the exposure to  
electromagnetic fields of workers bearing active implantable  
medical devices - Part 2-1: Specific assessment for workers with  
cardiac pacemakers**

Procédure pour l'évaluation de l'exposition des travailleurs  
porteurs de dispositifs médicaux implantables actifs aux  
champs électromagnétiques - Partie 2-1: Spécification  
d'évaluation pour les travailleurs avec un simulateur  
cardiaque

Verfahren zur Beurteilung der Exposition von  
Arbeitnehmern mit aktiven implantierbaren medizinischen  
Geräten (AIMD) gegenüber elektromagnetischen Feldern -  
Teil 2-1: Besondere Beurteilung für Arbeitnehmer mit  
Herzschrittmachern

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European Committee for Electrotechnical Standardization  
Comité Européen de Normalisation Electrotechnique  
Europäisches Komitee für Elektrotechnische Normung

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

# Contents

Page

European foreword.....	5
<b>1 Scope.....</b>	<b>6</b>
<b>2 Normative references.....</b>	<b>6</b>
<b>3 Terms and definitions.....</b>	<b>6</b>
<b>4 Specific assessment.....</b>	<b>8</b>
4.1 Description of the assessment process.....	8
4.1.1 General.....	8
4.1.2 Equipment consideration.....	11
4.1.3 Patient warning consideration.....	11
4.1.4 Cases for additional investigation.....	11
4.1.5 Choice of investigative method.....	14
4.2 Clinical investigation.....	15
4.3 Non-clinical investigation.....	15
4.3.1 General.....	15
4.3.2 Non-clinical investigation by <i>in vitro</i> testing.....	16
4.3.3 Non-clinical investigation by comparative study.....	17
<b>5 Documentation.....</b>	<b>20</b>
<b>Annex A (normative) Pacemaker specific replacement of EN 50527-1:2016, Table 1.....</b>	<b>21</b>
<b>Annex B (informative) Clinical investigation methods.....</b>	<b>27</b>
B.1 External ECG monitoring.....	27
B.2 Assessment of pacemaker compatibility using stored data and diagnostic features.....	27
B.3 Real time event monitoring by telemetry.....	27
<b>Annex C (informative) <i>in vitro</i> testing/measurements.....</b>	<b>29</b>
C.1 Introduction.....	29
C.2 EM phantom.....	29
C.2.1 General.....	29
C.2.2 EM phantom design.....	29
C.3 Basic procedure for cardiac pacemaker <i>in vitro</i> testing.....	30
C.4 References.....	31
C.5 Literature.....	32
<b>Annex D (informative) Modelling.....</b>	<b>33</b>
D.1 General.....	33
D.2 Analytical techniques.....	33
D.3 Numerical techniques.....	33
D.4 Field modelling or calculations.....	33
D.5 Modelling the human body and implant.....	34
D.6 References.....	34
<b>Annex E (informative) Derived worst case conversions for frequencies below 450 MHz.....</b>	<b>35</b>
E.1 Introduction.....	35
E.2 Functionality of implanted pacemaker leads.....	35
E.3 Conversion based on known field strength.....	36
E.3.1 General.....	36
E.3.2 Low frequency range (below 5 MHz).....	36
E.3.3 Pure magnetic field (16 Hz to 5 MHz).....	37
E.3.4 Pure electric field (16 Hz to 150 kHz).....	39
E.3.5 Field with electric component (16 Hz to 150 kHz).....	42
E.3.6 Field with electric and magnetic component (150 kHz to 5 MHz).....	43
E.3.7 Range between low and high frequency ranges (5 MHz to 30 MHz).....	44

E.3.8	High frequency range (above 30 MHz).....	44
E.4	Conversion based on known compliance with basic restrictions.....	46
E.4.1	General .....	46
E.4.2	Short survey on the direct effects of human exposure (induced current density) .....	46
E.4.3	Short survey on induced voltages on an implanted lead.....	48
E.4.4	A simple model to analyse the possible voltages at pacemaker terminations generated from induced current density equivalent the basic restrictions of Council Recommendation 1999/519/EC.....	48
E.5	References .....	50
<b>Annex F</b>	<b>(informative) Interference from power-frequency magnetic and electric fields from transmission, distribution and use of electricity .....</b>	<b>52</b>
F.1	Sensitivity of pacemakers to interference.....	52
F.2	Immunity requirements .....	52
F.3	Voltage induced in the leads by magnetic fields .....	53
F.4	Voltage induced in the leads by electric fields.....	54
F.5	Values of 50 Hz magnetic and electric field that may cause interference .....	56
F.6	Factors that affect the immunity from interference .....	57
F.6.1	Reasons for improved immunity .....	57
F.6.2	Adjustment for pacemaker sensitivity .....	58
F.7	Application to exposure situations .....	59
F.7.1	Public exposures.....	59
F.7.2	Beneath high voltage power lines.....	59
F.7.3	Occupational settings.....	60
F.7.4	Temporary exposure above the interference levels .....	61
F.8	References .....	61
<b>Annex G</b>	<b>(informative) Determination of the pacemaker immunity and guidelines provided by pacemaker manufacturers – Determination method.....</b>	<b>62</b>
G.1	Introduction .....	62
G.2	EMC and pacemakers – General guidelines .....	62
G.3	Induced voltages, fields and zones .....	65
G.3.1	Induced voltage test levels .....	65
G.3.2	Magnetic field amplitudes producing test limits .....	65
G.3.3	Induced voltage zones.....	67
G.3.4	Magnetic field zones .....	67
G.4	References .....	68
G.5	Literature.....	69
<b>Bibliography</b>	.....	<b>70</b>

## Figures

<b>Figure 1</b>	<b>— Overview of the assessment process.....</b>	<b>9</b>
<b>Figure 2</b>	<b>— Pacemaker specific assessment process .....</b>	<b>10</b>
<b>Figure 3</b>	<b>— Additional investigation process .....</b>	<b>13</b>
<b>Figure 4</b>	<b>— Comparison process .....</b>	<b>18</b>
<b>Figure C.1</b>	<b>— Example of <i>in vitro</i> procedure for EM interference at low frequency using planar electrodes, bipolar lead and ECG and data recording .....</b>	<b>31</b>
<b>Figure E.1</b>	<b>— Typical implantations of cardiac pacemakers (abdominal implantation with prolonged lead is used in clinical environment only).....</b>	<b>36</b>
<b>Figure E.2</b>	<b>— Effective induction area of an open wire loop inside a conductive medium .....</b>	<b>37</b>
<b>Figure E.3</b>	<b>— Schematic representation of bipolar pickup of interference in an infinitely extended homogeneous conducting medium .....</b>	<b>39</b>
<b>Figure E.4</b>	<b>— Induced voltage on the implanted lead in a pure <i>E</i> field .....</b>	<b>41</b>
<b>Figure E.5</b>	<b>— Schematic graphs of the same voltage on the lead for different layouts.....</b>	<b>43</b>
<b>Figure E.6</b>	<b>— Eddy-current inside a conductive medium induced by varying magnetic flux .....</b>	<b>47</b>

Figure E.7 — Voltage induced on a lead inside conductive body tissue .....	48
Figure E.8 — Voltages on an implanted lead.....	50
Figure F.1 — How the immunity ratio affects magnetic field that may result in interference .....	58
Figure F.2 — How the immunity ratio affects electric field that may result in interference .....	59
Figure G.1 — Induced voltage test levels .....	65
Figure G.2 — Magnetic field amplitudes, for frequencies below 5 000 kHz, producing test limits in unipolar configurations .....	66
Figure G.3 — Induced voltage zones for unipolar configurations .....	67
Figure G.4 — Magnetic field zones, for frequencies below 5 000 kHz and for unipolar configurations .....	68

## Tables

Table A.1 — Compliant workplaces and equipment with exceptions .....	21
Table F.1 — Amplitude of the immunity test signal applied .....	53
Table F.2 — Values of 50 Hz electric and magnetic field (r.m.s.) that might, under unfavourable circumstances, cause interference in a pacemaker.....	56
Table F.3 — Summary of typical maximum field values beneath high-voltage overhead lines at 1 m above ground .....	60

## European foreword

This document (EN 50527-2-1:2016) has been prepared by CLC/TC 106X "Electromagnetic fields in the human environment".

The following dates are fixed:

- latest date by which this document has to be implemented (dop) 2017-07-04  
at national level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with (dow) 2019-07-04  
this document have to be withdrawn

This document supersedes EN 50527-2-1:2011.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

EN 50527 is currently composed with the following parts:

- EN 50527-1, *Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices — Part 1: General*;
- EN 50527-2-1, *Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices — Part 2-1: Specific assessment for workers with cardiac pacemakers*;
- prEN 50527-2-2, *Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices — Part 2-2: Specific assessment for workers with implantable cardioverter defibrillators*<sup>1)</sup>.

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1) Currently at drafting stage.

## 1 Scope

This European Standard provides the procedure for the specific assessment required in EN 50527-1:2016, Annex A, for workers with implanted pacemakers. It offers different approaches for doing the risk assessment. The most suitable one will be used. If the worker has other Active Implantable Medical Devices (AIMDs) implanted additionally, they need to be assessed separately.

The purpose of the specific assessment is to determine the risk for workers with implanted pacemakers arising from exposure to electromagnetic fields at the workplace. The assessment includes the likelihood of clinically significant effects and takes account of both transient and long-term exposure within specific areas of the workplace.

NOTE 1 This standard does not address risks from contact currents.

The techniques described in the different approaches may also be used for the assessment of publicly accessible areas.

The frequency range to be observed is from 0 Hz to 3 GHz. Above 3 GHz no interference with the pacemaker occurs when the exposure limits are not exceeded.

NOTE 2 The rationale for limiting the observation range to 3 GHz can be found in ISO 14117:2012, Clause 5.

## 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 45502-2-1:2003<sup>2)</sup>, *Active implantable medical devices — Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)*

EN 50413, *Basic standard on measurement and calculation procedures for human exposure to electric, magnetic and electromagnetic fields (0 Hz - 300 GHz)*

EN 50527-1:2016, *Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices — Part 1: General*

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**

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2) The EMC requirements within EN 45502–2-1 have been incorporated with updates into ISO 14117 and their use is recommended here.