

STN	Postup na hodnotenie expozície elektromagnetickým poliam pre pracovníkov používajúcich aktívne implantovateľné zdravotnícke pomôcky. Časť 1: Všeobecne.	STN EN 50527-1 36 7938
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Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices - Part 1: General

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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Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2017
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.

English Version

Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices - Part 1: General

Procédure pour l'évaluation de l'exposition des travailleurs
porteurs de dispositifs médicaux implantables actifs aux
champs électromagnétiques - Partie 1 : Généralités

Verfahren zur Beurteilung der Exposition von
Arbeitnehmern mit aktiven implantierbaren medizinischen
Geräten (AIMD) gegenüber elektromagnetischen Feldern -
Teil 1: Allgemeine Festlegungen

This European Standard was approved by CENELEC on 2016-07-04. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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

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Contents	Page
European foreword	4
1 Scope	6
2 Normative references	7
3 Terms and definitions	7
4 Risk assessment	8
4.1 Risk assessment procedure.....	8
4.1.1 Introduction.....	8
4.1.2 Workplace equipment.....	9
4.1.3 Previously uninfluenced behaviour.....	9
4.1.4 Specific warnings.....	10
4.2 Documentation and information for the AIMD-Employee.....	11
4.3 Maintaining the risk assessment.....	12
5 Equipment at workplaces	12
5.1 General approach.....	12
5.2 Equipment with recommendations restricting use.....	13
5.2.1 General recommendations.....	13
5.2.2 Compliant workplaces and exceptions.....	13
6 Special cases	17
7 AIMD-Employees with more than one AIMD	17
8 Documentation	17
Annex A (normative) Specific risk assessment	18
A.1 General.....	18
A.2 Non-clinical approach.....	18
A.2.1 Assessment of the exposure situation.....	18
A.2.2 Assessment of the AIMD immunity.....	18
A.2.3 Assessment of the compatibility.....	18
A.2.4 Assessment of the risk of incompatibility.....	19
A.3 Clinical approach.....	19
A.4 Documentation of the specific assessment.....	19
Annex B (informative) Documenting the risk assessment	20
B.1 Introduction.....	20
B.2 Workplace compliance documentation form.....	20
B.2.1 General.....	20
B.2.2 Assessment.....	21
B.2.3 Conclusion.....	21
B.3 Previously uninfluenced behaviour.....	22
B.3.1 General information.....	22
B.3.2 Assessment.....	22
B.3.3 Conclusion.....	23
B.4 Documenting the detailed risk assessment.....	23

B.4.1	General information	23
B.4.2	Assessment	23
B.4.3	Exposure situation (see A.2.1).....	24
B.4.4	Compliance demonstration	24
Annex C	(informative) Specific electromagnetic environments.....	25
C.1	Railways	25
C.2	Workplace power transmission and distribution.....	25
C.2.1	General	25
C.2.2	Field levels in public exposure situations.....	25
C.2.3	Sensitivity of AIMDs to 50 Hz fields	26
C.2.4	Risk assessment in occupational situations	26
C.3	Broadcasting	26
Annex D	(informative) Theoretical considerations	27
D.1	Introduction.....	27
D.2	Brief summary of exposure limits for persons without implant.....	27
D.3	General considerations about electromagnetic fields	28
D.4	General considerations about AIMDs	29
D.4.1	General	29
D.4.2	Devices with sensing leads.....	29
D.4.3	Devices with stimulating leads.....	29
D.4.4	Devices without leads	29
D.4.5	Devices using RF or inductive coupling.....	29
D.4.6	Considerations for minimizing transient exposure	30
D.5	Description of electromagnetic interference effects	30
D.6	Model to assess the possibility of induction of AIMD response	30
D.7	Possibility of induced AIMD response.....	31
D.8	Possible AIMD responses to interference	32
Bibliography	34
 Figures		
Figure 1	— Structure of the EN 50527 family of standards	6
Figure 2	— Risk assessment process	11
Figure D.1	— Field strength – Distance ratio.....	28
Figure D.2	— Near field – far field transition for sources smaller than half wavelength in size	28
Figure D.3	— Entire model to assess the possibility of induction of AIMD response	30
Figure D.4	— Simplified model to assess the possibility of AIMD response in special cases	31
 Tables		
Table 1	— Compliant workplaces and equipment with exceptions	13
Table C.1	— Summary of maximum field values beneath high-voltage overhead lines at 1 m above ground.....	26

European foreword

This document (EN 50527-1:2016) 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 50527-1:2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

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*¹⁾.

EN 50527-1:2016 includes the following significant technical changes with respect to EN 50527-1:2010:

- updates to recognize the Occupational Exposure Directive 2013/35/EU;
- inclusion of EN 50527-2-2 within the family of standards for AIMD-Employee assessment;
- former Clause 2 (Relationship to other standards) was removed, subsequent renumbering of all later clauses;
- update of normative references to the “state of the art”, including the removal of EN 50499;
- clarification of the defined term “transient exposure”;
- numerous editorial changes to improve readability and clarity;
- correction of minor technical issues related to the general and specific assessment procedures;
- update to the Bibliography.

1) Currently at drafting stage.

The human exposure to electromagnetic fields (EMF) is regulated at European level in a twofold way. For the general public, Council Recommendation 1999/519/EC stipulates maximum exposure limits based on the ICNIRP guidelines. Nevertheless, Article 153 of the European treaty grants the member states the right to set stricter limit values in their obligation to govern public health and safety.

For Occupational Exposure Directive 2013/35/EU as individual physical agents directive issued under the Occupational Health and Safety Framework Directive 89/391/EEC sets the minimum health and safety requirements based on the maximum occupational exposure limits of the ICNIRP guidelines.

Common to the European Recommendation and Directive limiting human exposure to EMF and to the ICNIRP guidelines is the fact that their limit values are based on direct effects of EMF exposure to the human body. For the low frequency range the induced current density in the nervous system or induced voltages across membranes are the limiting factors whereas in the higher frequency area tissue heating by absorption needs to be limited.

The Occupational Exposure Directive 2013/35/EU in Article 4.5 additionally obliges the employer to investigate during the risk assessment process indirect effects like interference with medical electronic equipment and devices (including cardiac pacemakers and other implanted devices).

Risks to the bearer may be caused by different effects:

- a conductive implant may directly cause an increase of current density in the body tissue surrounding the implant, or
- the behaviour of the device may be interfered with (for examples see D.8 in Annex D of this standard).

The possibility of interference to the device depends on the EMF exposure level and the electromagnetic performance of the device, its settings and the method of implantation. The clinical relevance of interference may depend on the duration of exposure.

The main objective of this standard is to describe how a risk assessment for an employee bearing one or more active implantable medical devices (AIMD-Employee) in electromagnetic fields may be performed. A first step consists of a simplified risk analysis, followed where necessary, by a more extensive risk assessment.

Directives 90/385/EEC and 2007/47/EC on medical devices requires that AIMDs are designed and manufactured in such a way as to remove or minimize as far as possible risks connected with reasonably foreseeable environmental conditions such as magnetic fields, external electromagnetic interference effects, and electrostatic discharge.

EN 50499 originally introduced a concept of identifying equipment not likely to cause exposure to EMF above the limit values. This standard follows this approach but some of the identified equipment for general purpose assessment needs further analysis for AIMD-Employee. For higher frequency exposures, human body tissue has a time constant with respect to heating effects and a high immunity to pulsating exposure, whereas the electronic circuitry of an implant may be interfered with even by short pulses.

1 Scope

This European Standard provides a procedure to assess the risk to workers bearing one or more active implantable medical devices from exposure to electric, magnetic and electromagnetic fields at a workplace. It describes how a general risk assessment should be performed and determines whether it is necessary to carry out a detailed risk assessment.

NOTE 1 This European Standard does not cover indirect effects caused by non active implants.

NOTE 2 The risk of human exposure to EMF considered is only due to malfunctioning of AIMD. Possibilities of AIMD contribution to the risk, e.g. local modification of the distribution of EMF produced by external source or production of own EMF, are covered by the respective product standards for the AIMD.

Based on specific workplace standards it can be determined whether preventive measures/actions need to be taken to comply with the provisions of Directive 2013/35/EU. The work situation covered is considered to be under normal working conditions including normal operation, maintenance, cleaning and other situations being part of the normal work.

The frequencies covered are from 0 Hz to 300 GHz.

The European Parliament and Council Directive 2013/35/EU will be transposed into national legislation in all the EU member countries. It is recommended that users of this standard consult the national legislation related to this transposition in order to identify the national regulations and requirements. These national regulations and requirements may have additional requirements that are not covered by this standard and take precedence.

NOTE 3 Performance requirements with respect to active implantable medical devices are excluded from the Scope of this standard. These are defined in the relevant particular standards for active implantable medical devices.

The risk assessment described in this standard is only required if an AIMD-Employee is present.

Active Implantable Medical Devices (AIMDs) are regulated by Directive 90/385/EEC and the amendments to it.

NOTE 4 Product standards EN 45502-1 and of the EN 45502-2-X series describe the product requirements for different kinds of AIMDs. Different kinds of AIMDs are e.g. pacemaker (EN 45502-2-1), implantable cardioverter defibrillators (EN 45502-2-2), cochlear implants (EN 45502-2-3), implantable neurostimulators (ISO 14708-3), implantable infusion pumps (ISO 14708-4).

In situations where the risk assessment following this standard does not lead to a conclusion, complementary provisions for the assessment of workers exposure for different kinds of AIMDs are given in particular standards for these specific AIMDs (see Figure 1).

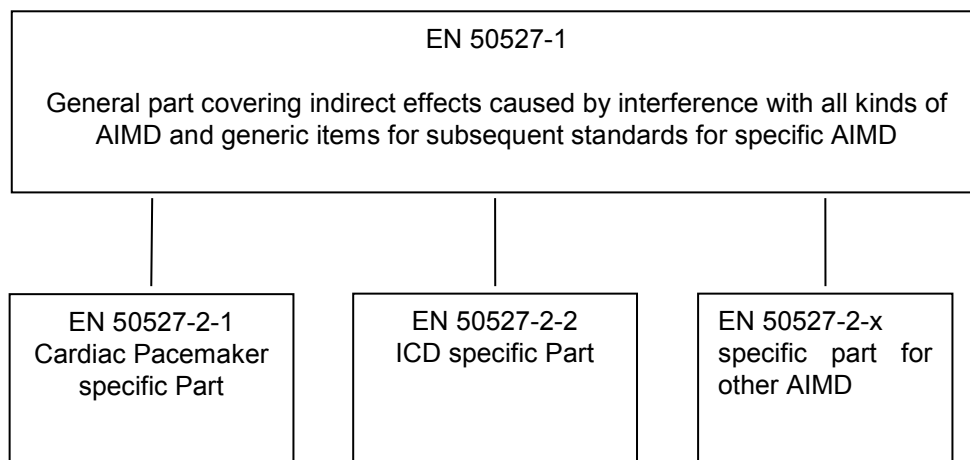


Figure 1 — Structure of the EN 50527 family of standards

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 45502-1:2015, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

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