SLOVENSKI STANDARD
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Postopek ocenjevanja izpostavljenosti delavcev z aktivnimi medicinskimi vsadki elektromagnetnim poljem - 1. del: Splošno

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

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

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

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11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
13.100	Varnost pri delu. Industrijska higiena	Occupational safety. Industrial hygiene
13.280	Varstvo pred sevanjem	Radiation protection

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EUROPEAN STANDARD
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English Version

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

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- latest date by which the national standards conflicting with this document have to be withdrawn (dow) 2019-07-04

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).

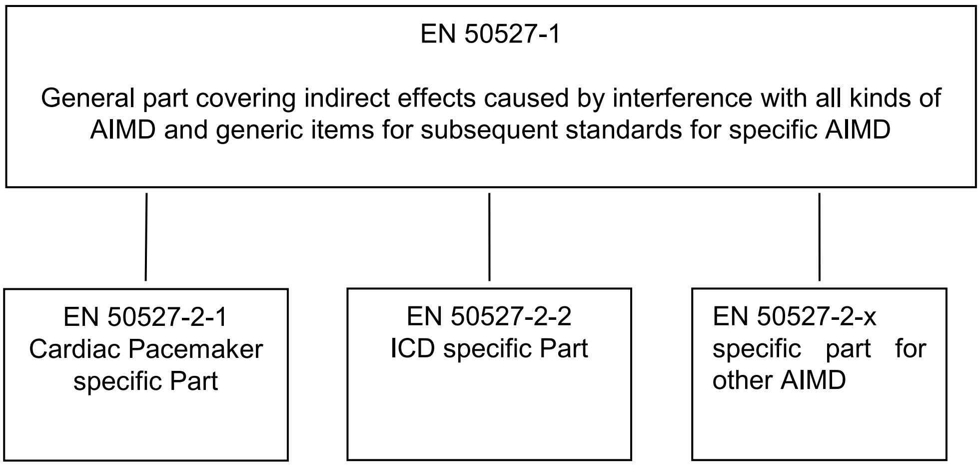

Figure 1 — Structure of the EN 50527 family of standards

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*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
AIMD-Employee
employee bearing one or more AIMDs

3.2
interference distance
distance identified for a piece of equipment, outside of which distance an AIMD-Employee can work normally

Note 1 to entry: This is also used in the same way to identify the closest distance an item of portable equipment can be, while the AIMD-Employee can work normally. At closer distances the AIMD-Employee may still be allowed to work normally, but this requires a specific assessment for that situation; or transient exposure may be possible provided no warnings against this have been received by the AIMD-Employee.

Note 2 to entry: Sometimes this distance is quoted as a "safety distance" but it should not be confused with the safety distances identified for general EMF exposure of all employees in the workplace. At these general EMF safety distances the fields may be high enough to cause response changes or other effects to an AIMD.

3.3

medical device
instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

[SOURCE: Directive 2007/47/EC]

3.4
active medical device
medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity

[SOURCE: Directive 90/385/EEC]

3.5
active implantable medical device
AIMD
active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

[SOURCE: Directive 90/385/EEC]

3.6
responsible physician
physician responsible for the implantation and/or follow up monitoring of the AIMD

3.7
transient exposure
exposure to electromagnetic fields in the order of seconds which:

- is not continuous; i.e. comes to an end or reduces to non-influential levels;
- does not damage the AIMD;
- only leads to acceptable response of the AIMD based on the advice from the responsible physician (for example by general guidance or by a specific warning) and/or described in the documentation accompanying the AIMD

Note 1 to entry: Such exposure may be caused by the electromagnetic field being temporary or by the exposed person moving within, or through, an electromagnetic field.

3.8
workplace
location where workers have access as part of their duties or during their breaks and all pathways that need to be used to reach these

4 Risk assessment

4.1 Risk assessment procedure

4.1.1 Introduction

The Occupational Health and Safety Framework Directive 89/391/EEC requires in Article 15 about Risk groups:

"*Particularly sensitive risk groups must be protected against the dangers which specifically affect them.*"

The interference of EMF with an implanted AIMD is identified as being an indirect effect causing particular risk within the scope of Article 4.5 of Directive 2013/35/EU.

Figure 2 gives a schematic overview of the risk assessment process.

For some types of workplaces the EMF risk assessment is covered by a specific workplace standard. If such a standard is used for risk assessment then the presentation of the result should normally be done in accordance with that standard.

Special considerations are often needed when it comes to the assessment of work that takes place outside the employer's premises. It is generally advised that the employer trains AIMD-Employees to be aware of particular risks that they might encounter during their work. This could be, for example, in situations where craftsmen like bricklayers, plumbers and carpenters do maintenance work on chimneys, rooftops, etc. where radio transmission or other transmitting antennas could be installed.

AIMD-Employees should be instructed on how to deal with such equipment in a safe manner. Generally this means that AIMD-Employees are informed about the interference distances or zones of such equipment. If the safety information is not provided in a sign at the site, it can be requested from the owner of the

equipment. However, it is the employer's responsibility that AIMD-employees have the right information on every workplace that they visit.

4.1.2 Workplace equipment

The risk assessment is based on the approach that AIMDs are expected to function as described in their product standards as long as the General Public Reference levels of Council Recommendation 1999/519/EC (except for static magnetic fields) are not exceeded [Directive 2007/47/EC] [1] [2] [3] and where no specific warnings have been issued to the AIMD-Employee.

NOTE 1 Such specific warnings are rarely required. Examples include combinations of unipolar sensing in conjunction with the most sensitive settings available.

This risk assessment therefore checks both for fields present at the workplace that exceed these levels and for AIMD-Employees that are subject to lower immunity of their AIMD due to clinical reasons.

The risk assessment continues by checking the equipment present at the workplace. Equipment listed in Table 1 may be assumed to produce fields that do not exceed the General Public reference levels of Council Recommendation 1999/519/EC. If there is equipment present that is not listed in Table 1 or is not used as specified in the remarks in Table 1 it needs to be assumed that the electric, magnetic or electromagnetic field levels may be too high to ensure uninfluenced behaviour of the AIMD. In this case a specific assessment following Annex A shall be performed.

If all equipment at the workplace is listed in Table 1 and is used as specified in the remarks in Table 1 it is necessary to find out whether the AIMD-Employee has received specific warnings from the responsible physician. Such specific warnings are based on the fact that the immunity of the implant under the condition of implantation and parameter setting is not compatible with General Public reference levels.

If the AIMD-Employee is being exposed to static magnetic fields of flux density > 1mT, some types of AIMD such as pacemakers, ICDs, neurostimulator etc may respond to the field by switching to a clinically acceptable behaviour for short exposure. It is not advisable, however, to have the worker exposed to such fields for long periods of time (i.e. over several seconds) as it may result in unacceptable responses or changes in intended performance of the AIMD. This 1mT limit also applies for "quasi static" magnetic fields in the frequency range from 0 Hz to 1 Hz (or up to a few Hz).

NOTE 2 Such magnetic fields may occur in industries using DC applications (e.g. electrolysis) or may be caused by equipment using permanent magnets like e.g. loud speakers or ear phones.

NOTE 3 Directive 2013/35/EU states an action level of 0,5 mT for static magnetic fields reasoned by interference of pacemakers.

4.1.3 Previously uninfluenced behaviour

The assessment effort can be reduced by checking whether or not the AIMD-Employee has worked within the current role without experiencing clinically significant effects even though not all equipment present at the workplace is listed in Table 1.

If this is so, proportionate to the risk, it can be assumed that the residual risk is acceptable as long as:

- the AIMD-Employee has experienced all reasonably foreseeable exposure situations and they have been in their position for a period of at least 12 months,
- no new equipment is brought into the workplace,
- no changes to the AIMD configuration have been made during the last 12 months,
- no changes in the therapy indication are given.

If previously uninfluenced behaviour is concluded, it should be considered that this approach does not provide any safety margin. Therefore this approach might be suitable only if tolerable interference (e.g. acoustic sound in a cochlear implant) is expected. If clinically significant interaction might be possible (e.g. delivery of an inappropriate therapy of an implanted defibrillator) this approach is not recommended.

The period of 12 months is chosen:

- to make sure that at least one follow up clinical visit with the responsible physician has taken place,
- to ensure that all seasonal changes of workplace electromagnetic environment have been accounted for.

Documentation of the result and AIMD-Employee's information shall be performed as described in 5.2.

4.1.4 Specific warnings

All AIMD-Employees receive from their responsible physician general warnings to avoid situations in which risk of interference may occur such as for example mobile phones should not be used closer than a specified distance from the AIMD and not to use motor-operated equipment immediately adjacent to the implantation site. Such warnings are not considered specific warnings but nevertheless needs to be followed. Specific warnings are instructions given by the responsible physician caused by the configuration of the AIMD, its settings or clinical conditions of the patient which are more stringent than the warnings every AIMD-Employee receives, including any warning in the manual that the AIMD-Employee receives. Specific warnings originate from EN 45502-1:2015, 28.22.

When an AIMD-Employee has received such specific warnings a specific assessment following Annex A shall be performed. If not, documentation of the result and AIMD-Employees information shall be performed as described in 5.2.