SLOVENSKI STANDARD
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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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13.100	Varnost pri delu. Industrijska higiena	Occupational safety. Industrial hygiene
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EUROPEAN STANDARD

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English version

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This European Standard was approved by CENELEC on 2010-02-01. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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CENELEC

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

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Foreword

This European Standard was prepared by the Technical Committee CENELEC TC 106X, Electromagnetic fields in the human environment. The text of the draft was submitted to the formal vote and was approved by CENELEC as EN 50527-1 on 2010-02-01.

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

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2011-02-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2013-02-01

This European Standard has been prepared under Mandate M/351 given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 2004/40/EC.

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 (2004/40/EC) 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 both directives 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 is the limiting factor whereas in the higher frequency area tissue heating by absorption has to be limited.

The occupational exposure directive 2004/40/EC in Article 4.5 additionally obliges the employer to investigate during the risk assessment process also 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).

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 introduces 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 may need 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.

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1 Scope

The scope of this European Standard is to provide a procedure in order 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 specifies how to perform a general risk assessment and to determine 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 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 must be taken to comply with the provisions of Directive 2004/40/EC. 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.

NOTE 3 The European Parliament and Council Directive 2004/40/EC 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 4 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.

NOTE 5 This standard is written under mandate M/351 and relates to the exposure limits as specified in the Directive 2004/40/EC which is intended to protect workers from risks to their health and safety arising or likely to arise from exposure to electromagnetic fields (0 Hz to 300 GHz) during their work. However, this and other directives may include additional measures for the protection of specific groups of workers and/or specific workplaces for which the employer is required to investigate other protective measures as a part of the overall risk assessment.

2 Relationship to other standards

This European Standard complements the workers exposure assessment standard EN 50499.

It provides the general methodology for doing the risk assessment for employees bearing an AIMD at the workplace.

AIMDs are regulated by Directive 90/385/EEC amended by Directive 2007/47/EC.

NOTE 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/PRF 14708-3), implantable infusion pumps (ISO/PRF 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).

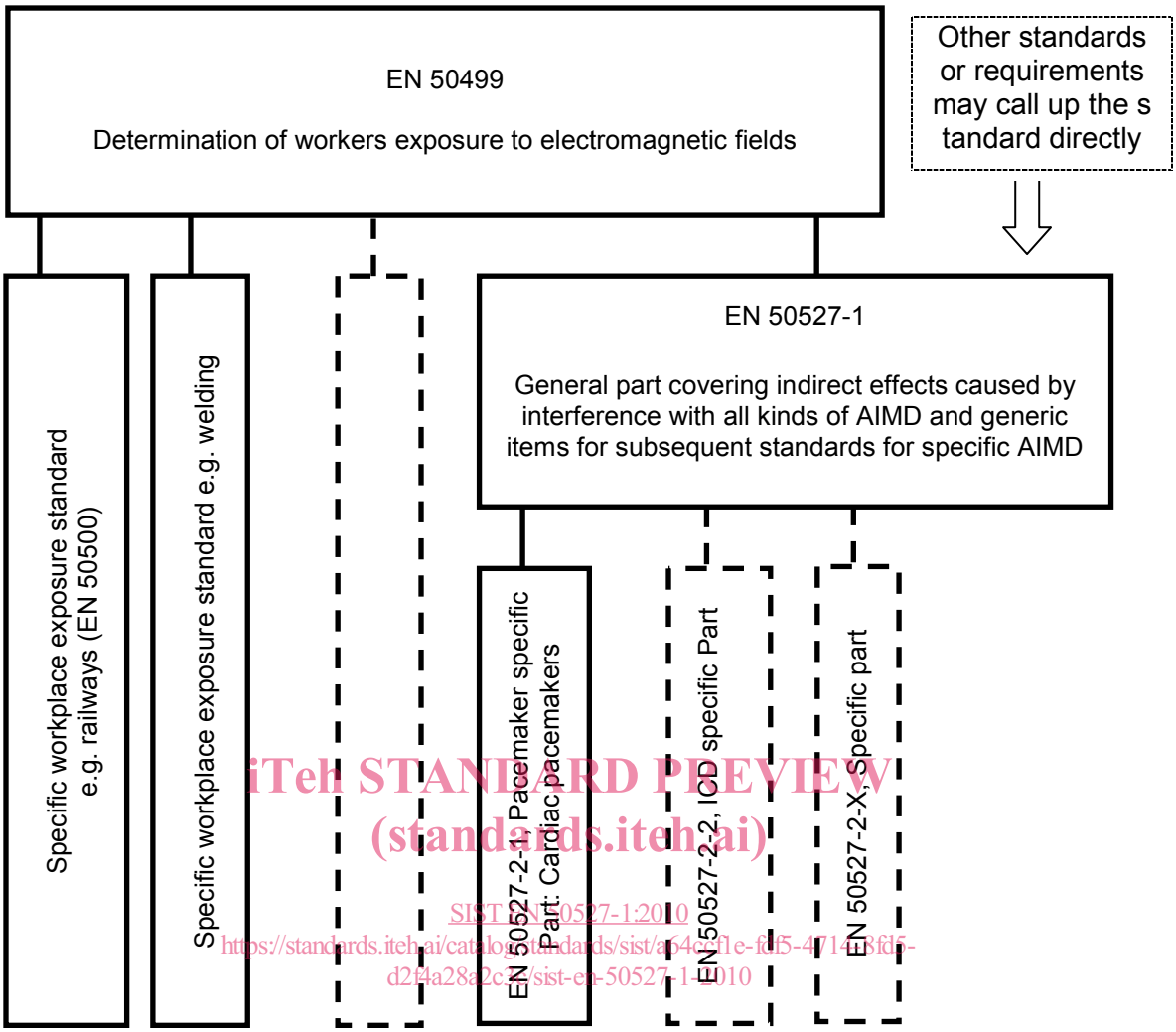

Figure 1 – Relationship of standards

3 References

3.1 Normative references

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

EN 50499:2008, *Procedure for the assessment of the exposure of workers to electromagnetic fields*

3.2 Regulatory references

Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, Official Journal L 183, 29/06/1989, p. 1 – 8

Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Official Journal L 189, 20/07/1990, p. 17–36

1999/519/EC: Council Recommendation of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz), Official Journal L 199, 30/07/1999, p. 59 - 70

Directive 2004/40/EC of the European Parliament and of the Council of 29 April 2004 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (18th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), Official Journal L 159, 30/04/2004, p. 1–26

Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market, Official Journal L 247, 21/09/2007, p. 21–55

4 Terms and definitions

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

4.1
AIMD-Employee
an employee bearing one or more AIMDs

4.2
interference distance
a distance identified for a piece of equipment, outside of which distance an AIMD-Employee can work normally. 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 warnings against this have not been received by the AIMD-Employee

NOTE 1 Sometimes this distance is quoted as a “safety distance” but it must 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.

4.3
medical device
means any 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

[from 2007/47/EC]

4.4
active medical device
any 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

[from 90/385/EEC]

4.5
active implantable medical device (AIMD)
any 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

[from 90/385/EEC]

4.6
responsible physician
physician responsible for the implantation and/or follow up monitoring of the AIMD

4.7
transient exposure
exposure to electromagnetic fields which

- is not continuous and coming to an end or reducing 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.

Such exposure may be caused by the electromagnetic field being temporary or by the exposed person moving within, or through, an electromagnetic field

4.8
workplace
location where workers have access as part of their duties or during their breaks and all pathways that have to be used to reach these

5 Risk assessment

5.1 Risk assessment procedure

5.1.1 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 implanted AIMD is identified as being an indirect effect causing particular risk within the scope of Article 4.5(d) of Directive 2004/40/EC.

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

NOTE 1 In case of doubt the relevant authorities in accordance with national law should be involved.

The first step in the risk assessment is the identification of AIMD-Employees. According to Article 13.2(f) of Directive 89/391/EEC the worker is obliged to co-operate with the employer to identify possible risks, like the possible interference of the AIMD with EMF at the workplace. The privacy of employees’ medical data may lead to situations in which the employer is not or not fully aware of which employees are AIMD-Employees and to what extent they have to be considered to be workers at particular risk.

NOTE 2 Quote from Directive 89/391/EEC, Article 13:

" 2. To this end, workers must in particular, in accordance with their training and the instructions given by their employer:

…

(f) cooperate, in accordance with national practice, with the employer and/or workers with specific responsibility for the safety and health of workers, for as long as may be necessary to enable the employer to ensure that the working environment and working conditions are safe and pose no risk to safety and health within their field of activity."

When no AIMD-Employees are identified the risk assessment following this standard ends. Document that no AIMD-Employee is present unless this has already been documented as part of the general EMF worker assessment.

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.

5.1.2 Workplace equipment

The risk assessment is based on the approach that AIMDs are expected to work uninfluenced as long as the General Public Reference levels of 1999/519/EC (except for static magnetic fields) are not exceeded [2007/47/EC] [2] [3] [4], where the AIMD has been implanted and programmed following good medical practice [9] [10]. 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. 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 must be assumed that the electric, magnetic or electromagnetic field levels may be too high to guarantee 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 worker 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 behavior 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). This 1mT limit also applies for "quasi static" magnetic fields in the frequency range from 0 to 1Hz (or up to a few Hz).

NOTE Such magnetic filelds may be 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.

5.1.3 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, it can proportionately be assumed that the residual risk is acceptable as long as

- the AIMD-Employee has experienced all reasonably foreseeable exposure situations,
- no new equipment is brought into the workplace,
- no changes to the AIMD configuration are made,
- no changes in the therapy indication are given.

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

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

5.1.4 Specific warnings

All AIMD-Employees receive from their AIMD physician general warnings to avoid situations in which risk of interference may occur such as for example mobile phones must 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 must nevertheless 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 is not covered by a harmonized standard or that the requirements of a harmonised standard are not fulfilled.

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