SVENSK STANDARD SS-EN 50527-1

| Fastställd | Utgåva | Sida | Ansvarig kommitté |
|---|---|---|---|
| 2010-08-23 | 1 | 1 (1+39) | SEK TK 106 |



# Bedömning av exponering av arbetstagare med aktiva implanterbara medicintekniska produkter för elektriska och magnetiska fält – Del 1: Allmänt

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

Som svensk standard gäller europastandarden EN 50527-1:2010. Den svenska standarden innehåller den officiella engelska språkversionen av EN 50527-1:2010.

ICS 11.040.40; 13.100; 13.280

Denna standard är fastställd av SEK Svensk Elstandard,
som också kan lämna upplysningar om **sakinnehållet** i standarden.
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## *Standarder underlättar utvecklingen och höjer elsäkerheten*

Det finns många fördelar med att ha gemensamma tekniska regler för bl a säkerhet, prestanda, dokumentation, utförande och skötsel av elprodukter, elanläggningar och metoder. Genom att utforma sådana standarder blir säkerhetskraven tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

## *SEK är Sveriges röst i standardiseringsarbetet inom elområdet*

SEK Svensk Elstandard svarar för standardiseringen inom elområdet i Sverige och samordnar svensk medverkan i internationell och europeisk standardisering. SEK är en ideell organisation med frivilligt deltagande från svenska myndigheter, företag och organisationer som vill medverka till och påverka utformningen av tekniska regler inom elektrotekniken.

SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

## *Stora delar av arbetet sker internationellt*

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

## *Var med och påverka!*

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN 50527-1

April 2010

ICS 11.040.40; 13.100; 13.280

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



CENELEC

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

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Ref. No. EN 50527-1:2010 E

SEK Svensk Elstandard

## 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).

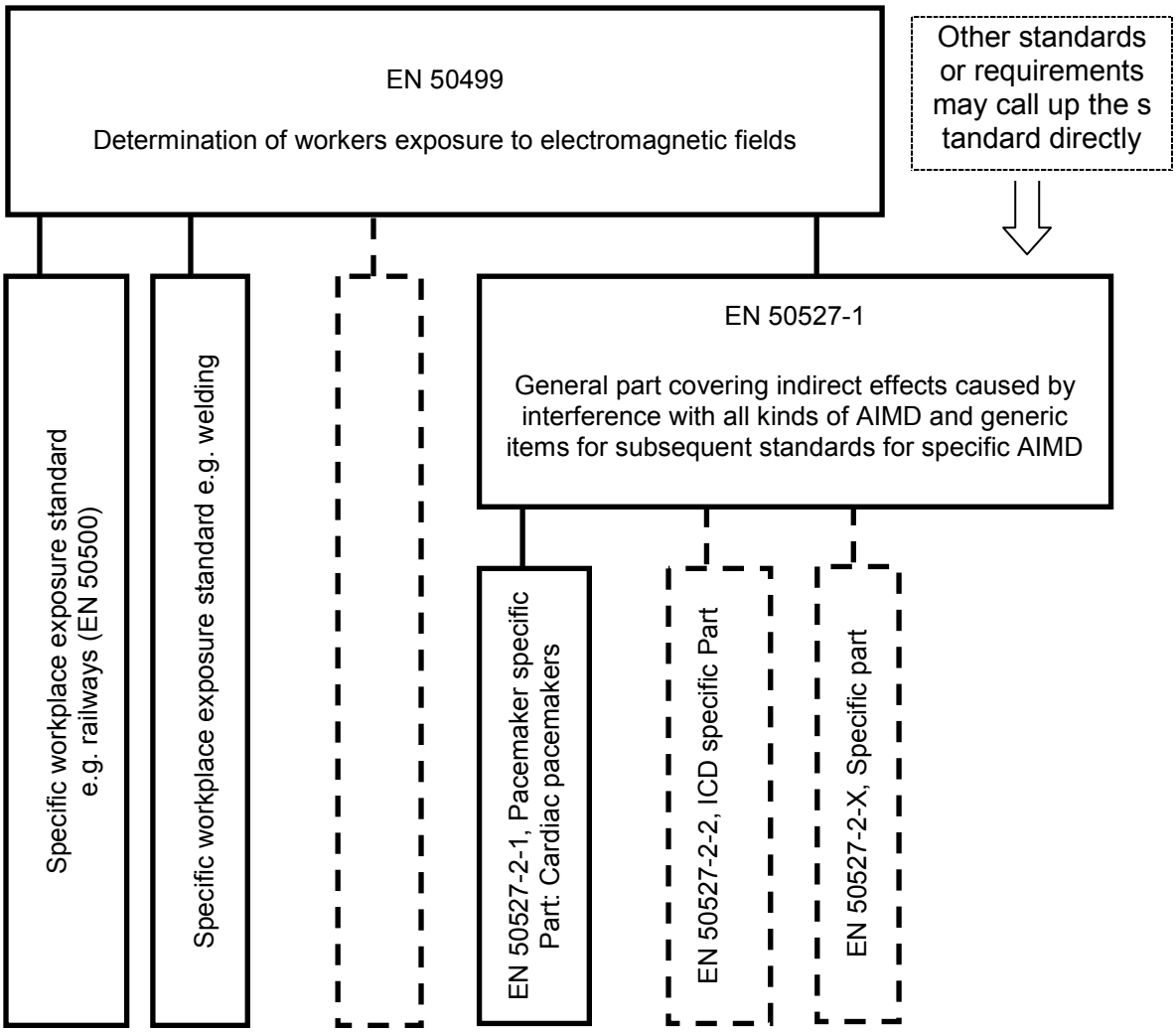


**Figure 1 – Relationship of standards**

## 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*

[redacted]