BS EN 50527-1:2016

BSI Standards Publication

Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices

Part 1: General

bsi.

National foreword

This British Standard is the UK implementation of EN 50527-1:2016. It supersedes BS EN 50527-1:2010 which will be withdrawn on 4 July 2019.

The UK participation in its preparation was entrusted to Technical Committee GEL/106, Human exposure to low frequency and high frequency electromagnetic radiation.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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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

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
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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- latest date by which the national standards conflicting with this document have to be withdrawn (dow) 2019-07-04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).

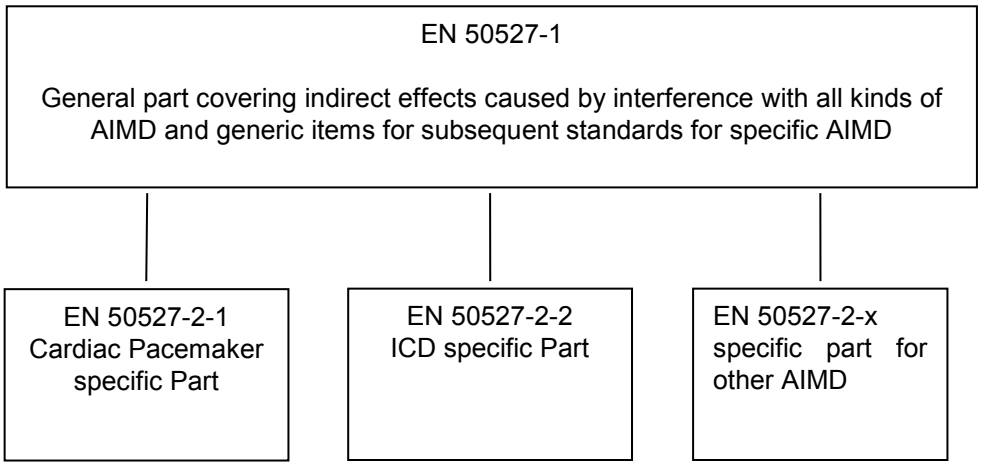

Figure 1 — Structure of the EN 50527 family of standards

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.

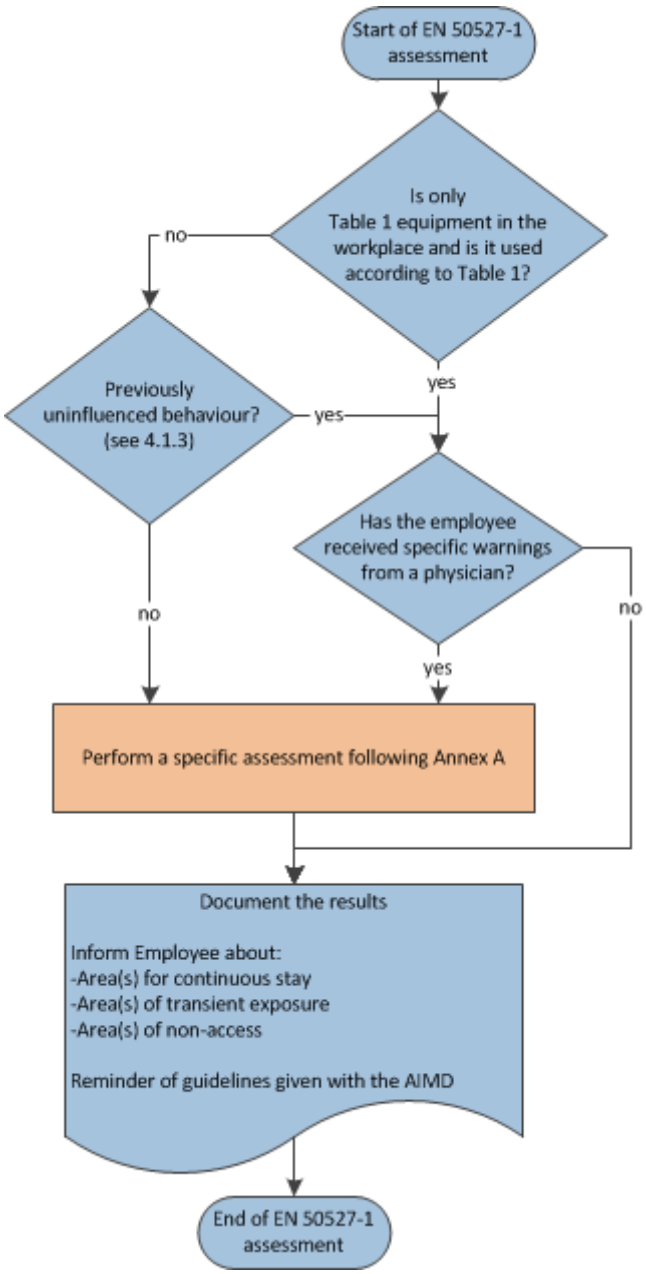

Figure 2 — Risk assessment process

4.2 Documentation and information for the AIMD-Employee

The risk assessment shall be documented and the result be communicated to the AIMD-Employee. This documentation shall follow national regulations. In the absence of national requirements for the documentation, forms for documenting the risk assessment are suggested in Annex B.

Where applicable, the AIMD-Employee shall be informed about:

- areas for continuous stay,
- areas of transient exposure,
- areas of non-access.

It is recommended to remind the AIMD-Employee that guidelines were provided with the AIMD, that they were provided by a responsible physician, and that they still apply in the workplace.

4.3 Maintaining the risk assessment

The result of the risk assessment procedures shall be kept up to date. A procedure shall be established to ensure that the employer is informed about any changes of the risk situation.

Such a change of the risk situation occurs:

- when the AIMD-Employee receives a new AIMD,
- when the clinical situation of the AIMD-Employee changes,
- where the settings of the AIMD-Employee's AIMD have been changed,
- when the workplace exposure changes in ways not already accounted for in the present assessment.

If the AIMD-Employee reports symptoms that may be related to the exposure in the workplace, the risk assessment shall be updated.

5 Equipment at workplaces

5.1 General approach

This section describes equipment present at the workplace which is identified as not causing interference with AIMD. No further assessment is needed if only such equipment is present at the workplace. Other equipment not listed in this section may cause interference with AIMD and a more detailed assessment is needed, nevertheless the result of the assessment may be that no risk for the AIMD-Employee is identified.

The basis for the immunity limits set for AIMDs in their product standards is derived from the Reference Levels from Council Recommendation 1999/519/EC without any time averaging being included. Table 1 reflects these immunity requirements and therefore may be different from the limit values and action values of Directive 2013/35/EU.

Static magnetic fields with flux density of $B > 1$ mT, at the region occupied by the AIMD, may cause influenced behaviour of the implanted AIMD. This 1 mT limit also applies for "quasi static" magnetic fields in the frequency range from 0 Hz to 1 Hz. In addition AIMD product standards also include protection mechanisms for exposure above the reference levels of Council Recommendation 1999/519/EC. These mechanisms allow interference levels above this basis but only under some circumstances and not for all types of AIMD. Transient exposure in the order of seconds under those circumstances may be permitted provided the AIMD-Employee has not received warnings against this from their responsible physician.

Except from some specific cases the electric and magnetic field levels decrease with increasing distance from any piece of equipment. This is discussed in detail in D.3 and the decrease amount depends on the size of the source, the type of field and the distance itself. This allows the identification of interference distances for some equipment, outside of which an AIMD-Employee can work normally. Similarly, if portable equipment is kept at a distance greater than the interference distance, from the AIMD or attached leads, the AIMD-Employee can work normally.

The AIMD-Employee should not work inside the interference distance unless a specific risk assessment has been made for that situation. It may be possible for the AIMD-Employee to pass by equipment closer than the interference distance in conditions of transient exposure. In any case of doubt further guidance may be obtained from device or emitter manufacturers, the responsible physician or by the use of the appropriate device specific standard.

Table 1 may be amended or replaced in vertical standards for the specific needs of different AIMDs.

5.2 Equipment with recommendations restricting use

5.2.1 General recommendations

In all cases where recommendations restricting use of workplace equipment are given with the AIMD, they should be identified and taken into account as part of the risk assessment. Where these recommendations cannot be taken into account at the workplace, a specific risk assessment following Annex A is required. Such recommendations are normally in the form of a minimum separation distance between the equipment and the AIMD. Those recommendations are given in the patients manual the AIMD-Employee receives from the implanting institution or by the suppliers of the specific equipment in the workplace.

5.2.2 Compliant workplaces and exceptions

Table 1 — Compliant workplaces and equipment with exceptions

Designation of workplace	Examples of equipment	Exceptions and remarks
All places	**Lighting equipment**	**Excluding specialized lighting for industrial purposes where the energy is deployed by microwave or radio frequency fields.**
All places	**Computer and IT equipment**	**Provided that such equipment does not contain radio transmission equipment such as RadioLANs, Bluetooth or Mobile Telephony. If such items are included in the equipment,see 5.2.1.** **Hard disks (other than solid state harddiscs) of portable computers and external harddisks should be treated as equipment producing static magnetic fields and be used only with minimum distance of 15 cm between the hard disk and the AIMD.**
All places	**Computer, tablets and ITE equipment *including* wireless communication**	**See 5.2.1.** **Hard disks (other than solid state harddiscs) of portable computers and external harddisks should be treated as equipment producing static magnetic fields and be used only with minimum distance of 15 cm between the hard disk and the AIMD.**
All places	**Office equipment**	**Excluding tape erasers.**
All places	**Mobile phones, smart phones and cordless phones**	**See 5.2.1 As example for pacemakers and defibrillators the interference distance between source and AIMD is 15 cm for peak powers up to 2 W.**
All places	**Two-way radios**	**See 5.2.1.**
All places	**Base stations for DECT cordless phones and WLAN (e.g. Wi-Fi)**	**See 5.2.1 As example for pacemakers and defibrillators the interference distance between source and AIMD is 15 cm for peak powers up to 2 W.**
All places	**Non - wireless communication equipment and networks**	

Designation of workplace	Examples of equipment	Exceptions and remarks
All places	**Electric hand-held and transportable tools**	**Areas containing such equipment are deemed to comply without further assessment.** **If the AIMD-Employee operates the tools see 5.2.1.**
All places	**Portable heating tools (e.g. glue guns, heat guns)**	**Areas containing such equipment are deemed to comply without further assessment.** **If the AIMD-Employee operates the tools see 5.2.1.**
All places	**Small battery chargers for household use**	**Large chargers (for professional use) require further assessment.** **For chargers using inductive coupling or proximity coupling further information from the manufacturer is needed.**
All places	**Electric operated garden appliances**	**Areas containing such equipment are deemed to comply without further assessment.** **If the AIMD-Employee operates the tools see 5.2.1.**
All places	**Audio and video equipment**	**If the equipment uses wireless transmission see 5.2.1.** **External harddisks (other than solid state harddiscs) should be treated as equipment producing static magnetic fields and be used only with minimum distance of 15 cm between the hard disk and the AIMD.** **Loudspeakers and earphones should be considered equipment producing static magnetic fields.**
All places	**Portable battery powered equipment not including radio frequency transmitters**	
All places	**Electrical room heating equipment**	**In general no restrictions. For workers very close to large industrial heating systems further information from the manufacturer is required.**
All places	**All non-electrical equipment**	**Some non-electrical equipment may include high static magnetic fields (for example permanent magnets). In this case see 5.2.1.**
All places	**All equipment producing static magnetic fields**	**Equipment capable of producing static magnetic flux density of B > 1 mT, at the region occupied by the AIMD, may cause influenced behaviour of the implanted AIMD. This 1 mT peak limit also applies for "quasi static" magnetic fields in the frequency range from 0 Hz up to a few Hz.**

Designation of workplace	Examples of equipment	Exceptions and remarks
All places	**Electricity supply networks in the workplace and electricity distribution and transmission circuits passing through or over the workplace. The magnetic and electric field exposure are considered separately.** **For magnetic field exposures the following are compliant:** • **any electrical installation with a phase current rating of 100 A or less;** • **any individual circuit within an installation, with a phase current rating of 100 A or less;** • **any circuit where the conductors are close together and having a net current of 100 A or less;** • **all components of the networks satisfying the criteria above are covered, (including the wiring, switchgear, transformers etc.);** • **any overhead bare conductors in substations of any voltage.** **For electric fields exposures the following are compliant:** • **any underground or insulated cable circuit, rated at any voltage;** • **any overhead uninsulated conductor rated at a voltage up to 110 kV;** • **any overhead line up to 150 kV above the workplace;** • **any overhead line at any voltage passing over the workplace building where the workplace is indoors.**	**The criteria given in the middle column here for demonstrating that fields are low enough to avoid interfering with AIMDs are based on demonstrating that the exposures are lower than the reference levels given in the Council Recommendation 1999/519/EC of EMF exposures for the general public. It states that for magnetic fields all overhead lines satisfy this criterion but for electric fields only lines with a rated voltage up to 150 kV satisfy it. However for an overhead line whose voltage is greater than 150 kV the electric field will usually, but not always, be lower than the public reference level.** **Clause C.2 gives more information about this, and as a result a risk assessment for a workplace with an overhead line passing over is not required if any of the following apply:** • **if measurements in the workplace have shown that the general public electric field reference level is not exceeded;** • **if computations of the electric field in the workplace from the overhead line (e.g. provided by the operator of the line) have shown that general public electric field reference level is not exceeded;** • **if no part of the line where it passes over the workplace has a clearance to ground that is less than 16 m (291 kV to 420 kV lines), 11 m (226 kV to 290 kV lines), 9 m (151 kV to 225 kV lines) or any height (0 kV to 150 kV lines).** • **where the workplace is indoors.** **This applies where an AIMD-Employee is at ground level (standing or sitting, etc), and not where the employee is above the ground.** **In the electricity supply industry some work places may be very close to electricity supply equipment, in which case the field may exceed the Council Recommendation general public reference levels. The risk assessment for an AIMD-Employee needs to consider the levels fields that could be encountered by the employee and the sensitivity to interference of the particular AIMD implanted taking account of its type, its sensitivity**

Designation of workplace	Examples of equipment	Exceptions and remarks
		settings and whether the leads are bipolar or unipolar. **Areas where the field exceeds these levels may involve only "transient exposures" (see D.4.6) in which case they may be permitted for the AIMD.**
All places	**Instrumentation, measurement, automation and control equipment**	**Provided that such equipment does not contain radio transmission equipment such as Radio-LANs, Bluetooth or mobile telephony. If such items are included in the equipment see 5.2.1.**
All places	**Household appliances**	**Inductive heating equipment is excluded.** **Professional appliances like cookers, laundry machines, microwave ovens, etc. used in restaurants, shops, etc. are included.** **For household appliances containing radio transmission equipment (e.g. Radio-LANs, Bluetooth and mobile telephony) follow recommendations restricting use received with the AIMD or go to Annex A.**
All places	**Battery driven transmitters**	**Follow recommendations restricting use received with the AIMD or go to Annex A.**
All places	**Base stations antennas**	**Keep outside the interference distance as described in the assessment following Annex A.** **If an interference distance is specified by a competent authority this shall be used.**
Medical workplaces	**All medical equipment not using electromagnetic field emitters for therapeutic or diagnostic purposes**	**If medical workplaces include static or time varying magnetic or electric fields, then operational precautions may be necessary. For equipment used at medical workplaces listed elsewhere in this table look at the appropriate section.**
Workplaces open to the general public (as covered by Article 4.6 of Directive 2013/35/EU)	**Places open to the public and in compliance with the exposure limits given in the European Council Recommendation 1999/519/EC are deemed to comply without further assessment provided that the compliance was made against the derived reference levels.**	**It is possible, under certain circumstances, to exceed the reference levels and still comply with the Recommendation basic restrictions. Such circumstances are usually in localized areas, close to EMF emitting equipment, so transient exposure in those areas may be permitted. In case of doubt further guidance may be obtained from device or emitter manufacturers, medical advisors or by the use of the appropriate device specific standard.**

Designation of workplace	Examples of equipment	Exceptions and remarks
All places	**CE marked equipment placed on the European market in compliance with the Council Recommendation 1999/519/EC as required by the relevant directives in particular in compliance with their related harmonized standards listed in the Official Journal of the European Union.**	**Some equipment placed on the European market may also be compliant with the Council Recommendation 1999/519/EC although they have not received the CE marking, for example if it is part of an installation.** **Areas containing such equipment are deemed to comply without further assessment provided that the compliance was made against the derived reference levels.** **It is possible, under certain circumstances, to exceed the reference levels and still comply with the Recommendation basic restrictions. Such circumstances are usually in localized areas, close to the CE marked equipment, so transient exposure in those areas may be permitted. In case of doubt further guidance may be obtained from device or emitter manufacturers, the responsible physician or by the use of the appropriate device specific standard.**

6 Special cases

Exposure situations caused by

- movement through external fields in places open to the general public,
- moving field sources emitting field levels up to the General Public reference levels

do not add to the fields generated by the mobile workplace in a relevant way and are not considered in the risk assessment.

NOTE In case of movement through static magnetic fields the magnet mode of a pacemaker, if present, might be triggered; see EN 50527–2–1.

7 AIMD-Employees with more than one AIMD

For AIMD-Employees bearing more than one AIMD a risk assessment is conducted separately for each AIMD and the recommendations shall be made based on the most restrictive result.

8 Documentation

The result of the risk assessment shall be documented following national regulations.

In the absence of national documentation requirements, examples of forms documenting the assessment may be found in Annex B.

Annex A
(normative)

Specific risk assessment

A.1 General

This annex provides a method for the specific assessment of AIMD-Employees where there is no particular standard. If there is a standard for a specific AIMD in the EN 50527-2-x series, then the provisions given in that standard take precedence over the methods in this annex.

The risk assessment should involve input from:

— employer and if applicable his occupational health and safety experts and/or occupational physician,

— AIMD-Employee and his responsible physician,

— experts (technical and medical), e.g. manufacturer of the AIMD.

If specific warnings are given, they as well as the “general warnings” are additional restrictions valid independently of all other assessment results.

Clauses A.2 and A.3 are alternative methods and only one of them needs to be performed.

A.2 Non-clinical approach

A.2.1 Assessment of the exposure situation

The maximum continuous and transient field strength at the workplace shall be known or determined. Information about peak field strength, modulation, etc. shall be collected. Plain R.M.S. measurement results are not sufficient for non-sinusoidal field sources. Weighted peak measurements may need additional considerations on the peak values.

The determination may be done by one or more of the following options:

- measurement;
- calculation;
- information provided by the supplier of the equipment.

Measurements shall follow an appropriate standard such as EN 50413 or applicable product or measurement standard.

In the absence of a specific warning an assessment following Subclauses A.2.2 to A.2.4 is not necessary, when the General public reference levels (without time averaging) are not exceeded.

A.2.2 Assessment of the AIMD immunity

The immunity to continuous and transient field exposure of the specific implanted AIMD under investigation shall be known or determined. The determination may be done by using information provided by the supplier of the AIMD and the responsible physician or by using the results of competent services or persons.

A.2.3 Assessment of the compatibility

The exposure situation is a function of the distance from the field emitting source or equipment. In most cases as the distance increases, the exposure decreases.

NOTE For further information see D.3.

Thus the assessment of compatibility is a spatial comparison of the given immunity of the AIMD with the local field strength.

If in all areas the immunity is above the exposure then interference can be excluded. Therefore the AIMD-Employee can work at this workplace.

If areas are identified where the exposure is above the immunity an assessment of risk shall be performed.

A.2.4 Assessment of the risk of incompatibility

For doing the assessment of risk the clinical relevance of the interference shall be obtained. Examples of possible AIMD responses to interference that could be used for this are given in D.8.

In areas where the exposure is above the AIMD immunity (A.2.2), the responsible physician shall determine, whether these electromagnetic interference effects on the AIMD are clinically significant for either short or long term exposure;

- If not clinically significant for long term exposure, the AIMD-Employee can access this area and work there.
- If clinically acceptable for short periods (transient exposure), but not for longer periods, the AIMD-Employee can transit through the area but not remain or work there.
- If not clinically acceptable, then the AIMD-Employee shall not be allowed to enter these areas.

A.3 Clinical approach

The clinical approach could be used to assess the risk for the AIMD-Employee. The AIMD-Employee is exposed under clinical supervision for a significant duration in the workplace to the foreseeable exposure situations or in a laboratory simulating the workplace exposure situation. The behaviour of the AIMD is then checked by the the responsible physician or under his responsibility by e.g. telemetry during and after the exposure.

The AIMD-Employee may be exposed to the foreseeable exposure levels investigating occurance or absence of interference with the AIMD (non-provocative test) or may be exposed and the exposure level raised until interference with the AIMD is observed (provocative test).

It should be considered that this approach may not identify a safety margin unless a provocative test is undertaken.

Details of such clinical investigation cannot be standardized but the responsibility and the required depth of investigation shall be determined with the responsible physician and the physician supervising the tests.

A.4 Documentation of the specific assessment

All documentation shall follow national legal requirements. The following topics shall be documented additional to the documentation following Clause 8:

- the exposure situation at the workplace (A.2.1);
- the AIMD immunity (A.2.2);
- the result of the compatibility assessment (A.2.3);
- result of the risk assessment (A.2.4);
- result of the clinical approach (A.3).

All relevant documents used during the assessment shall be added to the documentation file so as to permit consultation at a later stage.

In the absence of national documentation requirements, examples of forms documenting the assessment are found in Annex B.

Annex B
(informative)

Documenting the risk assessment

B.1 Introduction

This annex offers forms that help to document the risk assessment process. They may be used in case national regulation does not require other means of documentation.

The first form given in B.2 may be used in cases:

- where all workplace equipment is identified in Table 1 and is used according to the exceptions and remarks specified there, and
- the employee has not received specific warnings (see 4.1.4) from a responsible physician.

In cases where workplace equipment not identified in Table 1 or not used according to the exceptions and remarks specified there but the AIMD-Employee has worked at the same workplace experiencing all possible exposure situations and no indications of interference have shown, the assessment following the path “previously uninfluenced behaviour (see 4.1.3)” may be documented using the form given in B.3.

If neither of these two assessment routes is followed and a detailed risk assessment following the non-clinical approach specified in A.2 is performed, the form given in B.4 may be used. The information suggested in this form would only provide an overview, and further documentation might be needed in a measurement report. The full contents of such a report is not within the scope of this annex but the essential information i.e. the measurement results and the uncertainty, are pointed to in the form.

Where clinical tests have been done following Clause A.3, a standardized form for documentation is not feasible. The documentation shall represent the justification of the responsible physician for decision taking.

B.2 Workplace compliance documentation form

B.2.1 General

In the absence of national documentation requirements at least the following should be documented:

- Name and address of the company.
- Date of assessment.
- Assessment group (name and profession of participants taking part in the assessment).
- Address or location of the workplace (i.e. of different company locations, room number…).
- Short description of workplace and equipment.

B.2.2 Assessment

	Yes	No
Question 1: Is all equipment at the workplace listed in Table 1 (Clause 6) and used according to the remarks and exceptions given?	❑	❑
Question 2: Is equipment producing large fields (e.g. mid or high-voltage power transformers and their cabling, transmitters) very close to the workplace?	❑	❑
Question 3: Has the employee received specific warnings from a responsible physician?	❑	❑
Question 4: Can all equipment at the workplace be operated according to the general warnings given?	❑	❑
Question 5: Has the employee been instructed about the general warnings all bearers of this kind of AIMD receive?	❑	❑
Question 6: Is the employer aware of the general warnings all bearers of this kind of AIMD receive?	❑	❑

B.2.3 Conclusion

Is one or more of the shaded tick boxes ticked in Question 1 to 4?

If no, Workplace is compliant and the AIMD-Employee can work there ❑

If yes, a specific risk assessment following Annex A has to be performed before

the AIMD-Employee can continue ❑

If one or more of the shaded tick boxes in Question 5 to 6 is ticked then further education and training is necessary and should be carried out and documented.

Date of conclusion ……..……..

Date, when the conclusion has to be confirmed ……..

Signatures of assessment group

B.3 Previously uninfluenced behaviour

B.3.1 General information

In the absence of national documentation requirements at least the following should be documented:

- Name and address of the company.
- Date of assessment.
- Assessment group (name of participants taking part in the assessment).
- Address or location of the workplace (i.e. of different company locations, room number, …).
- Short description of workplace and equipment.
- Description of the equipment not identified in Table 1 or of the conditions of use of equipment identified in Table 1 but not used according to the exceptions and remarks with relevant EMF emission parameters.
- Description as to how long the AIMD-Employee has worked under these conditions and whether during this time all foreseeable exposure situations have occurred.
- Decision as to how long the assessment remains valid and when it needs to be maintained.

B.3.2 Assessment

	Yes	No
Question 1: Has the employee been exposed to all foreseeable exposure situations?	❑	❑
Question 2: Has the employee received the AIMD at least 12 months ago so that he has been exposed to all variations of exposure resulting fromseasonal influence? **How long ago:……?**	❑	❑
Question 3: Has the employee ever reported any anomaly that was felt to be related to the AIMD at the workplace?	❑	❑
Question 4: Has the employee received specific warnings from a responsible physician?	❑	❑
Question 5: Can all equipment at the workplace be operated according to the general warnings given?	❑	❑
Question 6: If the employee's AIMD is capable of producing clinically significant outcomes in the presence of interference, has the clinical indication for the AIMD been changed in the last 12 months?	❑	❑
Question 7: Is the employer aware of the general warnings all bearers of this kind of AIMD receive?	❑	❑
Question 8: Is the employee aware of the general warnings all bearers of this kind of AIMD receive?	❑	❑

B.3.3 Conclusion

Is one or more of the shaded tick boxes in questions 1 to 5 ticked?

If no, it can be assumed that the residual risk is acceptable as long as:

- no new equipment is brought into the workplace,
- no changes to the AIMD configuration are made
- no changes in the therapy indication are given.

❑

If yes, an assessment following Annex A has to be performed before the AIMD-Employee can continue working there. ❑

If the answer to question 6 is yes, the responsible physician must be involved in the assessment.

If one or more of the shaded tick boxes in Question 7 to 8 is ticked then further education and training is necessary and should be carried out and documented.

Date of conclusion ……..……..

Date, when the conclusion has to be maintained ……..……..

Signatures of assessment group

B.4 Documenting the detailed risk assessment

B.4.1 General information

In the absence of national documentation requirements at least the following should be documented:

- Name and address of the company.
- Date of assessment.
- Assessment group (names of participants taking part in the assessment).
- Address or location of the workplace (i.e. different company locations, room number, etc.).

B.4.2 Assessment

- Detailed description of workplace/equipment (type, manufacturer, etc.).
- Detailed description of working conditions (Working process and time of exposure, equipment settings, location of worker to equipment, e.g. with drawing, etc.).
- Standards related to the equipment (List of used standards _____).

B.4.3 Exposure situation (see A.2.1)

o Reference to the report of calculation and/or measurement of exposure, including any uncertainty if known (containing type of measurement equipment, calculation program, measurement condition, e.g. with drawings).

A summary of locations around the workplace where the AIMD-Employee is expected to be, indicating which locations exceed the reference levels of Council Recommendation 1999/519/EC.

a) **The AIMD immunity:**

1) source of information for AIMD immunity;

2) AIMD immunity for the relevant frequencies present at the workplace;

b) **Compatibility assessment:**

1) describe areas (including toilets, rest rooms, etc.) and pathways where the immunity level is above the field levels present at the workplace;

2) describe areas and pathways where the immunity level is below the field levels present at the workplace;

c) **Assessment of the risk:**

1) assessment of the clinical relevance;

2) assessment of transient exposure.

B.4.4 Compliance demonstration

o Definition of unrestricted areas and pathways

o Definition of areas and pathways for transient exposure

o Definition of areas and pathways for non entry

Date of conclusion ……..

Date, when the conclusion has to be confirmed ……..

Signatures of assessment group

Annex C
(informative)

Specific electromagnetic environments

C.1 Railways

Magnetic, electric and electromagnetic fields arise from the operation of railway systems.

For the examples of Austrian “ÖBB”, Swiss “SBB” and German “Deutsche Bahn AG”, in the workplaces in AC and Diesel driven railway systems including high speed trains open to the general public, the reference levels of Council Recommendation 1999/519/EC are not exceeded, at today's state of science and technology.

C.2 Workplace power transmission and distribution

C.2.1 General

Exposures to the general public arise from the electricity transmission and distribution systems, comprising overhead lines and underground cables. The electricity supply in Europe operates at 50 Hz and at this frequency electric and magnetic fields are measured and considered separately. Magnetic fields are a consequence of the current transmitted along overhead lines or cables and electric fields are a consequence of the voltage on them. There is no electric field from underground cables.

C.2.2 Field levels in public exposure situations

In the “normal environment” (see EN 45502-2-1 and EN 45502-2-2), that is nearly everywhere accessible to the general public, the electric and magnetic fields are typically lower than the reference levels (5,0 kV/m and 100 µT at 50 Hz) of the Council Recommendation 1999/519/EC, which applies to “areas where members of the public spend significant time”. However according to the Council Recommendation (see Clause 6), in some such areas, fields may exceed the reference levels provided the basic restrictions are not exceeded, and they are permitted to be higher elsewhere.

The electric fields from an overhead line generally increase with the voltage rating of the line. For lines whose rated voltage is up to 150 kV the electric field exposure to people is always lower than the reference level. The value of electric fields depends on the clearance between the conductors and ground. The electric field will be less than the reference level if no part of the line, where it passes over the workplace, has a clearance to ground that is less than 16 m (for 291 kV to 420 kV lines), 11 m (for lines of 226 kV to 290 kV), 9 m (for lines of 151 kV to 225 kV) or any height (for lines up to 150 kV).

The conductors sag down between two pylons such that their height exceeds these minimum heights over most of all spans. The only places where the field might exceed the reference level are therefore either side of the lowest point on the lowest spans of the higher-voltage overhead lines.

The maximum magnetic field beneath an overhead line, whatever the voltage, will usually be less than 40 µT and will only very occasionally reach 45 µT, less than the reference level. Higher fields of up to about 125 µT may be theoretically possible for full loading on high voltage power lines with the conductors closest to the ground.

Similarly the maximum electric fields are usually less than 3 kV/m. and occasionally may be as much as 6 kV/m to 9 kV/m, depending on the detailed design parameters of the overhead line, and with the conductors closest to the ground. Higher fields of 13 kV/m represent a theoretical worst-case scenario.

Representative field levels are summarized in Table C.1. The theoretical maximums are included as an aid to future AIMD design and test standards, to ensure minimum interference in future from 50 Hz fields in the environment.

Table C.1 — Summary of maximum field values beneath high-voltage overhead lines at 1 m above ground

	Electric field kV/m rms	**Magnetic field** µT rms
Typical	≤ 3,0	≤ 40
Occasional	6,0 to 9,0	45
Theoretical worst-case (if measured at 2m above ground)	13	125

Underground cables do not produce electric field exposures, and the magnetic fields are low for the lower-voltage distribution cables. However where separated phases are used (sometimes at 110 kV, and above) it is possible for magnetic fields to significantly exceed the reference level particularly close to the ground.

C.2.3 Sensitivity of AIMDs to 50 Hz fields

AIMD devices are manufactured and tested in accordance with parts of the EN 45502 series (for example EN 45502-2-1 for pacemakers and EN 45502-2-2 for defibrillators) where the tests are designed to ensure they will offer reasonable immunity to electromagnetic interference. The main interference occurs where there are leads connecting the device to the body. Pacemakers and defibrillators are the most common, and have leads connecting the device to the heart. Similarly brain stimulators have leads connecting the device to the brain.

Voltages are induced in the leads in different ways for each of electric fields and magnetic fields, and the magnitude of the voltage induced depends on the type of lead used (e.g. unipolar or bipolar) and its key dimensions, where bipolar leads are much less sensitive to interference than unipolar leads. The criterion for assessing fields used in this general horizontal standard (using the public reference levels in the Council Recommendation) is based conservatively on the sensitivity to interference of pacemakers with unipolar leads. Most, but not all, other types of AIMD are less sensitive to interference. AIMD which have bipolar leads (defibrillators and most pacemakers) will be less sensitive and those that do not have leads at all (or have very short leads) will not be susceptible to this type of interference, and other forms of interference affecting the device directly are unlikely to be problematic until much higher levels of field.

Details of sensitivity for individual types of AIMD are given in the specific AIMD standards associated with this general horizontal standard.

C.2.4 Risk assessment in occupational situations

In occupational situations there is the possibility that the electric or magnetic field exceeds the reference level for the general public given in Council Recommendation 1999/519/EC. Knowledge of the type of AIMD, its sensitivity setting and whether the leads are unipolar or bipolar can be taken into account in any risk assessment, by referring to the relevant specific AIMD standard.

Areas where the field exceeds the public reference levels (5,0 kV/m and 100 µT at 50 Hz) of the Council Recommendation 1999/519/EC may involve only transient exposure in which case they may be acceptable for AIMD.

C.3 Broadcasting

In the vicinity of broadcast transmitting antennas where the general public has access, the field levels would almost always be below the general public reference level. In some countries (e.g. Germany) the general public reference levels are maintained in areas around broadcasting stations where the general public can have access.

Annex D
(informative)

Theoretical considerations

D.1 Introduction

This annex provides very general information for people unfamiliar with electromagnetic fields, their interference with the human body or with implantable devices. More extensive information may be found e.g. in EN 45502-1.

D.2 Brief summary of exposure limits for persons without implant

Any electromagnetic field induces currents inside the body tissue. This secondary effect may cause nerve stimulation, cell membrane damage and heating. The induced current density should be limited to avoid clinically relevant effects.

At low frequencies (below 100 kHz) nerve stimulation takes place at lower exposure levels than relevant heating effects. The stimulation effects decrease with frequency. At high frequencies (above 10 MHz) unacceptable heating occurs at lower levels than nerve stimulation. In the frequency range 100 kHz to 10 MHz both effects are to be observed.

Nerve stimulation starts immediately, therefore the threshold for short pulses is not significantly higher than for continuous wave exposure. Below 100 kHz the instantaneous value of fields (peak) should be limited.

Heat is accumulative and any short pulse adds with its power integral only. Therefore the threshold for short pulses is much higher than for continuous wave exposure. Above 10 MHz the mean value (r.m.s.) should be limited. The maximum acceptable peak value is set to 32 times the r.m.s. limit of field strength or 1 000 times the r.m.s. limit of power flux density.

The electromagnetic immunity of AIMDs depends rather on peak than on r.m.s. values. Therefore there is no direct comparability at frequencies above 10 MHz between exposure limits for persons without implants and those with AIMD.

At low frequencies (below 100 kHz) the human body is nearly transparent for magnetic fields; this means that the magnetic field inside the body tissue has the same level as the outer magnetic field. Since the body tissue is conductive, the inner magnetic fields induce eddy currents in the tissue. The induced currents increase with frequency and thus the opposing magnetic field increases too. Therefore the body tissue distorts the magnetic field inside the human body at higher frequencies (above 100 kHz) and the magnetic field is attenuated inside the tissue.

At low frequencies (below 100 kHz) the human body shields the electric field, because the tissue is conductive and dielectric, this means that the electric field inside the human body is much smaller than the outer field. The electric field influences displacement currents inside the body, which increase with frequency. Because of the finite conductivity of body tissue the electric shielding effect decreases with frequency.

Starting at about 5 MHz the body tissue can be characterized rather as an attenuator for electromagnetic fields than as an electrically shielding and magnetically transparent object.

The human body can act as a resonator in case one of its main extensions equals half of the wavelength of the electromagnetic field. For a big person raising its arms straight up the height is about 2,5 m and corresponds to about 60 MHz resonance frequencies. In case this person stands barefoot on a conductive ground, the virtual length of the resonator is doubled and the resonance frequency is about 30 MHz. This is the lowest resonance frequency for humans. Smaller persons and children start with higher resonance frequencies. The resonance frequency of the body depends upon its orientation and its relevant extension with respect to the electric field vector. The highest body resonance frequency occurs when the electric field vector is perpendicular to the back. Since attenuation of body tissue increases with frequency, the intensity

of resonance effects decrease in parallel. At frequencies above about 400 MHz no resonances can be observed.

At frequencies above 2 GHz the attenuation from the body tissue is strong enough to concentrate the effects on the surface of the body. Above 10 GHz only the skin and the tissue directly beneath it is involved.

The exposure limits for humans without AIMD reflect all these effects. In the frequency range from 10 MHz to 400 MHz (covering all body resonances) the reference levels are minimal.

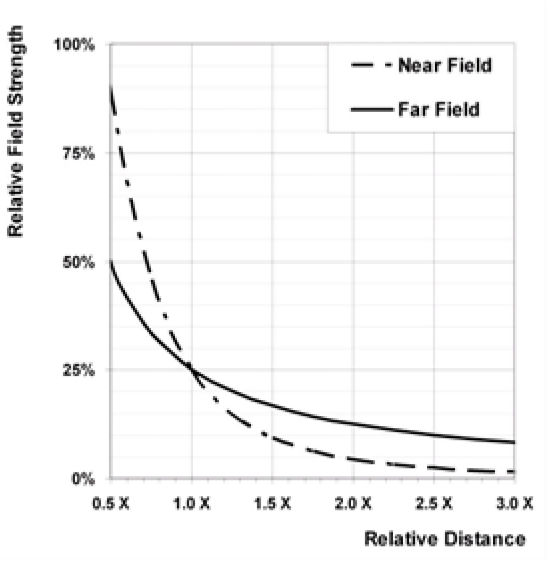

Figure D.1 — Field strength – Distance ratio

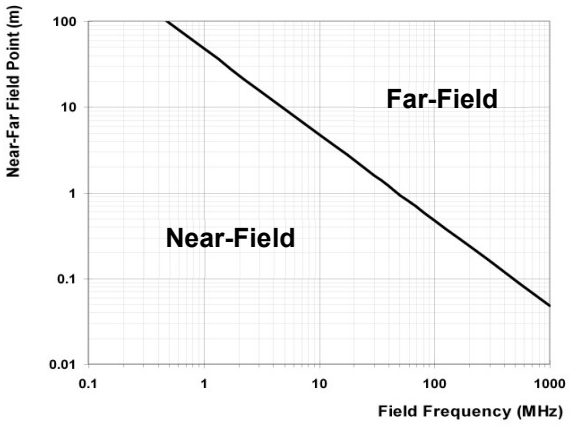

Figure D.2 — Near field – far field transition for sources smaller than half wavelength in size

D.3 General considerations about electromagnetic fields

Electromagnetic fields can be different in frequency and intensity. One common consideration which is particularly important for exposure assessment is that in most cases the intensity reduces as the distance from the emitting source becomes greater. The intensity reduction with distance depends on whether the exposure is in the near-field or the far-field, relative to the source. All fields have both near and far field effects and there is a distance from the source at which the effects change from near to far field.

The point at which the near field effect becomes far-field effect is related to the frequency of the field and can also depend on the size of the source in relation to the emitted frequency. As a good guideline, Figure D.2 can be used. Because the transition between near and far field is not precise, if the distance is near to the borderline, assume a far-field reduction with distance to be conservative.

In the near-field the field intensity is usually proportional to the inverse cube of the distance (doubling the distance from the source gives one eighth of the field strength). In the far-field the intensity is proportional to

the inverse of the distance (doubling the distance from the source gives half the field strength) as shown in Figure D.1. At lower frequencies the reduction with distance can be quite dramatic so increasing the exposure distance by moving the source or by moving the workplace by a relatively small amount can create a significant improvement to the an assessed risk situation.

NOTE This is a simplified model. Technically, the field intensity depends on the geometry of the source (electric field predominant or magnetic field predominant). An electric field predominant source (e.g. straight wire antenna) will have an E field proportional to $1/r^3$, and H field proportional to $1/r^2$. For a magnetic field predominant source (e.g. loop antenna), the H field is proportional to $1/r^3$ and the E field is proportional to $1/r^2$.

D.4 General considerations about AIMDs

D.4.1 General

AIMDs have different configurations depending on the device type and the type of medical condition being treated. Some AIMDs have leads implanted which connect the device onto the human body. These leads can be used to sense the status of the body or to stimulate activity in the body (or both). Other AIMDs fulfil their function without needing a lead to make an electrical connection to the body. In addition some AIMDs use radio or inductive coupling either for communication to and from programming/diagnostics peripherals or as part of the devices normal operation (cochlear implants for example).

The effects from electromagnetic fields differ for the different types of AIMD and for the different connections and coupling methods. It is possible for a single AIMD to have both sensing leads and stimulating leads (a defibrillator for example) or combine leads with inductive coupling (a cochlear implant for example). In cases where there are multiple connectivity methods, the effect of the electromagnetic field can be assessed independently for each type of lead and/or each type of coupling.

D.4.2 Devices with sensing leads

An external electromagnetic field can cause voltages and/or currents to be generated in the lead. This can cause an electrical signal to be induced at the sensing terminals of the AIMD. Under normal circumstances, if the fields are below the reference levels then the voltage is low enough that there are no electromagnetic interference effects. For higher fields the voltage can cause electromagnetic interference effects but often this is not clinically significant (see also D.7) and transient exposure can be permitted.

D.4.3 Devices with stimulating leads

An external electromagnetic field can cause voltages and/or currents to be generated in the lead. This can cause an electrical signal to be induced at the terminals of the AIMD. Under most conditions this is not a problem, unless the fields are high enough to generate voltages sufficient to damage the AIMD stimulation outputs. There is also a possibility with higher fields, that induced voltages and currents at the tip of the lead might act similarly to the device stimulus. Often this is not clinically significant (see also D.7) and transient exposure can be permitted.

D.4.4 Devices without leads

Any effect from electromagnetic field on these devices would be directly onto the circuits inside the case of the device. Such devices are generally much more immune than those with sensing leads so it is likely that there will be no problems with working except in the presence of very high fields. General tests on AIMDs ensure that there is no damage to the device at low frequencies from fields below 150 A/m. Many devices may be OK at higher fields than this.

D.4.5 Devices using RF or inductive coupling

When external electromagnetic fields operate at similar frequencies to those used for the AIMD device coupling, there can be an electromagnetic interference effects to the AIMD system. In such cases it may be possible to turn off the AIMD (if operation is not clinically essential) or the electromagnetic interference effects may not be clinically relevant (a sound in the ear from a hearing implant for example). In such cases transitory exposure and sometimes long term exposure can be possible.

D.4.6 Considerations for minimizing transient exposure

When transient exposure is possible there are some considerations to reduce the exposure, taking into account the field characteristics in D.1. In a region of transient exposure, the AIMD-Employee should move through the region at normal pace and should not go too close or lean on the source of the fields. If the source is mobile then the AIMD-Employee should try to keep the source away from the body.

In such cases there is normally some general advice on how to pass by or how to operate portable equipment (recommended distances, “don’t linger don’t lean”, etc.).

In cases where the AIMD-Employee is in a moving carriage or vehicle, then fields external to the carriage/vehicle are transitory and usually of lesser electromagnetic interference effects than internal fields. No special precautions are necessary.

D.5 Description of electromagnetic interference effects

The exposure of persons without implant to electromagnetic fields is restricted because these fields enter into the human body and induce currents inside the body tissue. The currents may stimulate nerves, damage cell membranes or heat up body tissue. Health aspects of persons without implant are not covered in this standard. Nevertheless to some degree it is necessary to understand the physical background for the derived exposure limits, which are summarized in D.1.

In case the person has an implant with conductive parts, the effects of the exposure to the body tissue may be intensified: the implant may heat up itself and thus the tissue contacting it (e.g. implanted leads in MRI) or may distort the field causing increased current densities in the surrounding body tissue. Non-active medical implants are not covered by this standard and therefore these effects are not addressed in this standard separately. In case these effects are relevant for a specific AIMD too, this will be handled in the according standard specific tor this type of AIMD.

In case of an active medical implant the function of the AIMD may be influenced additionally. This is the main concern of this standard. The physical background of functional interference to AIMDs is described in D.6.

Whether an AIMD response causes any harm to the patient depends upon the kind of this AIMD response, its duration and upon the instantaneously desired therapy for the patient. Clinical relevance of induced AIMD response is addressed in D.8.

The assessment of exposure of persons with AIMDs can be split into two steps:

– in a first step the technical possibility of induction of AIMD response is determined. If induction of AIMD response can be excluded at the workplace, assessment is complete and no further assessment is necessary; this first step is explained in D.6;

– if induction of AIMD response cannot be excluded in the first step the clinical relevance of it is evaluated in a second step.

D.6 Model to assess the possibility of induction of AIMD response

The assessment of the possibility of induction of AIMD response follows the physical path of the electromagnetic interference as shown in Figure D.3:

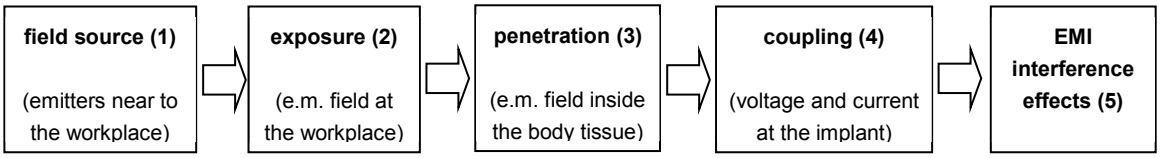

Figure D.3 — Entire model to assess the possibility of induction of AIMD response

This model only allows predicting whether any induction of AIMD response can be excluded. It allows neither to forecast whether an AIMD response really will take place during work nor to predict the clinical relevance of an AIMD response if it will happen at all.

The first two boxes (field source and exposure) are characteristics of the workplace, thus the employer can assess these without identifying the AIMD-Employee working on this place. In some cases it will be easier to join these two boxes and immediately determine the field at the workplace. In other cases, especially if all emitters are well known, it may be easier to estimate the exposure by summing up their fields.

The third and fourth boxes are individual and depend upon the AIMD-Employee. The third box depends primarily upon the body shape of the employee and the forth box upon the shape of the implanted device (including its leads if applicable). In some cases, especially when the AIMD is connected to leads, it will be easier to join these two boxes and directly address the transformation from outer electromagnetic field to voltages and currents induced on the implant.

The last box (5) only depends upon the characteristic of the AIMD with regard to its programmed settings. Especially for AIMDs not connected to implanted leads, the immunity of the AIMD is defined by field thresholds, thus the fourth box (coupling) will be unnecessary in this case.

In many practical cases, especially if the exposure is expected to be far below the influencing threshold, the model can be simplified as shown in Figure D.4:

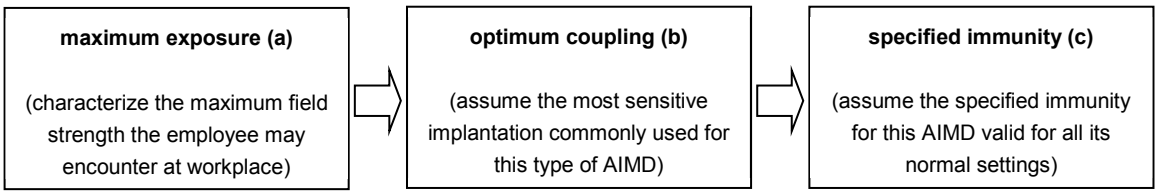

Figure D.4 — Simplified model to assess the possibility of AIMD response in special cases

This simplified model neglects the individual characteristics of the body of the AIMD-Employee, the individual implantation of the AIMD and its individually programmed settings. Instead this simplified model assumes the most critical body characteristics, which maximize the field inside the body. Additionally it assumes the most critical implantation and the most critical settings of the AIMD within good clinical practice, which minimize interference threshold. Thus this model simulates the most sensitive interference situation realistically foreseeable.

If the result even with this worst case scenario is that the exposure is below the interference threshold, then interference can be excluded for every AIMD-Employee independently from its individual situation.

If this worst case scenario shows that the exposure is above the interference threshold, then electromagnetic interference effects cannot be excluded in general for all AIMD-Employees. This does nevertheless not imply that electromagnetic interference effects will occur to any real AIMD-Employee unless it matches to all of these worst case assumptions. In consequence the occurrence of electromagnetic interference effects cannot be predicted and the simplified method is not suitable to assess the risk. In this case the simplification fails and more detailed assessment is necessary.

D.7 Possibility of induced AIMD response

In most real situations it is not possible to predict, whether electromagnetic interference will affect the AIMD during work, since it is hard to foresee all situations the AIMD-Employee will go through. On the other hand it is possible to predict, whether electromagnetic interference may affect the AIMD. In consequence the decision is always:

- electromagnetic interference effects can be excluded completely, if the exposure is below interference level,

- electromagnetic interference effects may occur, if the exposure is above interference threshold.

In case the simplified method allows excluding electromagnetic interference effects, the assessment is done. Otherwise the worst case assumptions should be replaced as much as possible by real data of the AIMD-Employee and the AIMD in its actual settings.

In case the real data lead to the result, that the exposure is below the interference threshold, AIMD response can be excluded for this particular AIMD-Employee.

Otherwise uninfluenced function of the AIMD cannot be ensured and the AIMD-Employee shall not work at this workplace.

D.8 Possible AIMD responses to interference

When an AIMD-Employee is exposed to electromagnetic interference, the AIMD may exhibit one or more adverse responses. Some examples are offered below:

a) pacemakers:

   1) missed pacing beats / stop pacing (pacemaker inhibition);

   2) stop sensing and revert to asynchronous pacing;

   3) high pacing rate (tracking of the EMI signal by dual chamber devices);

   4) current induced into the lead system that can trigger an arrhythmia;

   5) activation of the magnetic switch;

   6) hazardous heating of the lead tip;

   7) damage of integrated circuits;

b) implantable cardioverter defibrillators:

   1) missed pacing beats / stop pacing (inhibition of pacemaker functionality, if feature is available);

   2) stop sensing and revert to asynchronous pacing (if feature is available);

   3) high pacing rate (tracking of the EMI signal by dual chamber devices);

   4) current induced into the lead system that can trigger an arrhythmia;

   5) activation of the magnetic switch;

   6) inappropriate delivery of high voltage therapy;

   7) hazardous heating of the lead tip;

   8) damage of integrated circuits;

c) cochlear implants:

   1) temporary distortion or loss of audible signals;

   2) artifacts added to audible signals causing degraded intelligibility;

d) neurostimulators:

   1) inappropriate signal (perceived as very painful) to the spinal cord or other area that is being stimulated;

   2) hazardous heating of the lead tip;

   3) damage of the integrated circuits;

e) implantable drug infusion systems:

1) drug Infusion System includes a catheter, therefore the probability of induced currents is greatly reduced;

2) under- or over-infusion due to strong magnetic fields;

3) damage of the integrated circuits.

However, not all these responses will have clinical significance for the patient. The potential for the patient to be affected by the device response is dependent on several factors, such as (but not limited to):

- duration of exposure;
- proximity to the patient;
- position of the patient;
- patient characteristics: pacemaker dependency, susceptibility to asynchronous pacing, susceptibility to high pacing rate.

Bibliography

The latest amendments of the directives mentioned below and as published in the Official Journal will be used.

[1] EN 45502-2-1, *Active implantable medical devices — Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)*

[2] EN 45502-2-2, *Active implantable medical devices — Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)*

[3] EN 45502-2-3, *Active implantable medical devices — Part 2-3: Particular requirements for cochlear and auditory brainstem implant systems*

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

[5] EN 50499, *Procedure for the assessment of the exposure of workers to electromagnetic fields*

[6] EN 50500, *Measurement procedures of magnetic field levels generated by electronic and electrical apparatus in the railway environment with respect to human exposure*

[7] 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*

[8] 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*

[9] ISO 14708-3, *Implants for surgery — Active implantable medical devices — Part 3: Implantable neurostimulators*

[10] ISO 14708-4, *Implants for surgery — Active implantable medical devices — Part 4: Implantable infusion pumps*

[11] 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

[12] 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

[13] 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)

[14] Directive 2013/35/EU of the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) and repealing Directive 2004/40/EC

[15] 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

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