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

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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 It supersedes BS EN 50527-1:2010 which will be withdrawn on 4 July 2019.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.

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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

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

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

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

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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- latest date by which the national standards conflicting with this document have to be withdrawn (dow) 2019-07-04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).

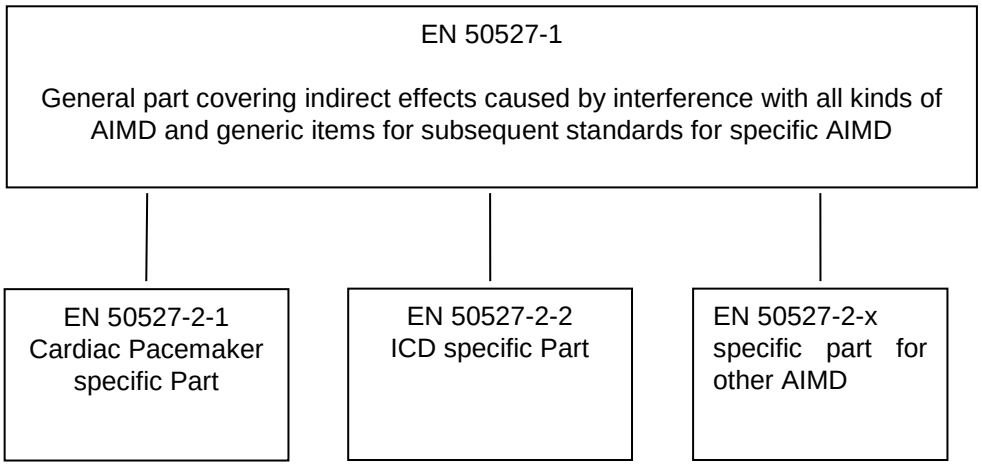

Figure 1 — Structure of the EN 50527 family of standards