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## **Bedömning av exponering av arbetstagare med aktiva implanterbara medicintekniska produkter för elektriska och magnetiska fält – Del 2-1: Särskild bedömning beträffande arbetstagare med pacemaker**

*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*

Som svensk standard gäller europastandarden EN 50527-2-1:2016. Den svenska standarden innehåller den officiella engelska språkversionen av EN 50527-2-1:2016.

### **Nationellt förord**

Tidigare fastställd svensk standard SS-EN 50527-2-1, utgåva 1, 2011, gäller ej fr o m 2019-07-04.

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Denna standard är fastställd av SEK Svensk Elstandard, som också kan lämna upplysningar om **sakinnehållet** i standarden.  
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English Version

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

Procédure pour l'évaluation de l'exposition des travailleurs  
porteurs de dispositifs médicaux implantables actifs aux  
champs électromagnétiques - Partie 2-1: Spécification  
d'évaluation pour les travailleurs avec un simulateur  
cardiaque

Verfahren zur Beurteilung der Exposition von  
Arbeitnehmern mit aktiven implantierbaren medizinischen  
Geräten (AIMD) gegenüber elektromagnetischen Feldern -  
Teil 2-1: Besondere Beurteilung für Arbeitnehmer mit  
Herzschrittmachern

This European Standard was approved by CENELEC on 2016-07-04. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the 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

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

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## European foreword

This document (EN 50527-2-1:2016) 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 (dop) 2017-07-04  
at national level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with (dow) 2019-07-04  
this document have to be withdrawn

This document supersedes EN 50527-2-1:2011.

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<sup>1)</sup>*.

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1) Currently at drafting stage.

## **1 Scope**

This European Standard provides the procedure for the specific assessment required in EN 50527-1:2016, Annex A, for workers with implanted pacemakers. It offers different approaches for doing the risk assessment. The most suitable one will be used. If the worker has other Active Implantable Medical Devices (AIMDs) implanted additionally, they need to be assessed separately.

The purpose of the specific assessment is to determine the risk for workers with implanted pacemakers arising from exposure to electromagnetic fields at the workplace. The assessment includes the likelihood of clinically significant effects and takes account of both transient and long-term exposure within specific areas of the workplace.

NOTE 1 This standard does not address risks from contact currents.

The techniques described in the different approaches may also be used for the assessment of publicly accessible areas.

The frequency range to be observed is from 0 Hz to 3 GHz. Above 3 GHz no interference with the pacemaker occurs when the exposure limits are not exceeded.

NOTE 2 The rationale for limiting the observation range to 3 GHz can be found in ISO 14117:2012, Clause 5.

## **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 45502-2-1:2003<sup>2)</sup>, *Active implantable medical devices — Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)*

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

EN 50527-1:2016, *Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices — Part 1: General*

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2) The EMC requirements within EN 45502-2-1 have been incorporated with updates into ISO 14117 and their use is recommended here.