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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 50527-2-1:2011. Den svenska standarden innehåller den officiella engelska språkversionen av EN 50527-2-1:2011.

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**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

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## CENELEC

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

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## Foreword

This European Standard was prepared by the Technical Committee CENELEC TC 106X, Electromagnetic fields in the human environment.

The text of the draft was submitted to the formal vote and was approved by CENELEC as EN 50527-2-1 on 2011-05-02.

The following dates were fixed:

- latest date by which the EN has to be implemented  
at national level by publication of an identical  
national standard or by endorsement (dop) 2012-05-02
- latest date by which the national standards conflicting  
with the EN have to be withdrawn (dow) 2014-05-02

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

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## 1 Scope

This European Standard provides the procedure for the specific assessment required in Annex A of EN 50527-1:2010 for workers with implanted pacemakers. It offers different approaches for doing the risk assessment. The most suitable one shall be used. If the worker has other AIMDs implanted additionally, they have 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 to workers bearing a pacemaker 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 Clause 5 of ANSI/AAMI PC69:2007.

## 2 References

### 2.1 Normative references

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

EN 50527-1:2010, Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices – Part 1: General

EN 45502-2-1:2003, Active implantable medical devices – Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)

EN 62226-3-1:2007, Exposure to electric or magnetic fields in the low and intermediate frequency range – Methods for calculating the current density and internal electric field induced in the human body – Part 3-1: Exposure to electric fields – Analytical and 2D numerical models (IEC 62226-3-1:2007)