

**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**

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

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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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Foreword

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

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- latest date by which the EN has to be implemented
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national standard or by endorsement (dop) 2012-05-02
- latest date by which the national standards conflicting
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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)

2.2 Regulatory references

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), Official Journal L 199, 30/07/1999, p. 59 – 70

2004/40/EC: Directive 2004/40/EC of the European Parliament and of the Council of 29 April 2004 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (18th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), Official Journal L 159, 30/07/2004, p. 1–26