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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

EESTI STANDARDI EESSÕNA

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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

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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this document have to be withdrawn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*¹⁾.

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 45502-2-1:2003²⁾, *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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 50527-1:2016 and the following apply.

3.1

implantable pulse generator

IPG

part of the active implantable medical device, including the power supply and electronic circuit, that produces an electrical output

Note 1 to entry: For the purposes of EN 50527-2-1, the term implantable pulse generator describes any active implantable medical device that incorporates functions intended to treat cardiac arrhythmias.

3.2

pacemaker

active implantable medical device intended to treat bradyarrhythmias, comprising an implantable pulse generator with or without lead(s)

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