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 STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 50527-2-1:2011 sisaldab Euroopa standardi EN 50527-2-1:2011 ingliskeelset teksti.	This Estonian standard EVS-EN 50527-2-1:2011 consists of the English text of the European standard EN 50527-2-1:2011.
Standard on kinnitatud Eesti Standardikeskuse 30.06.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.06.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 27.05.2011.	Date of Availability of the European standard text 27.05.2011.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.40, 17.240

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 50527-2-1

May 2011

ICS 11.040.40; 17.240

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 2011-05-02. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 50527-2-1:2011 E

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.

Contents

Figures

Tables

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 bradyarrythmia (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