Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices - Part 2-3: Specific assessment for workers with implantable neurostimulators

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 50527-2-3:2021 sisaldab Euroopa standardi EN 50527-2-3:2021 ingliskeelset teksti.	This Estonian standard EVS-EN 50527-2-3:2021 consists of the English text of the European standard EN 50527-2-3:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 29.10.2021.	Date of Availability of the European standard is 29.10.2021.
Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.40, 17.240

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 50527-2-3

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English Version

Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices - Part 2-3: Specific assessment for workers with implantable neurostimulators

Procédure pour l'évaluation de l'exposition des travailleurs porteurs de dispositifs médicaux implantables actifs aux champs électromagnétiques - Partie 2-3 : Evaluation spécifique aux travailleurs porteurs de neurostimulateurs implantés

Verfahren zur Beurteilung der Exposition von Arbeitnehmern mit aktiven implantierbaren medizinischen Geräten gegenüber elektromagnetischen Feldern - Teil 2-3: Besondere Beurteilung für Arbeitnehmer mit implantierbaren Neurostimulatoren

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

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European foreword

This document (EN 50527-2-3:2021) 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 at national level by publication of an identical national standard or by endorsement	(dop)	2022-08-09
• latest date by which the national standards conflicting with this document have to be withdrawn	(dow)	2024-08-09

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a Standardization Request given to CENELEC by the European Commission and the European Free Trade Association.

Any feedback and questions on this document should be directed to the users’ national committee. A complete listing of these bodies can be found on the CENELEC website.

1 Scope

This document provides the procedure for the specific assessment required in EN 50527-1:2016, Annex A, for workers with implanted neurostimulator systems (NS), specifically of the type used for spinal cord stimulation (SCS).

It is recognized that implantable neurostimulators have been developed for a wide variety of clinical applications, however the SCS devices within the scope of this document represent the largest segment of the implantable neurostimulator applications thus far.

NOTE 1 If the worker has other Active Implantable Medical Devices (AIMDs) implanted additionally, they are assessed separately according to EN 50527-1 or other particular standards within the EN 50527 series.

The purpose of the specific assessment is to determine the risk for workers with implanted SCS devices arising from exposure to electromagnetic fields (EMF) at the workplace. The assessment includes the likelihood of clinically significant effects.

NOTE 2 This document does not address risks from contact currents, or the effects upon any associated non-implantable devices (e.g. Patient Programmers).

The techniques described in the different approaches can 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 devices within the scope of this document is expected to occur.

NOTE 3 The rationale for limiting the observation range to 3 GHz can be found in ISO 14708-3 [1].

NOTE 4 Further information concerning the functions of neurostimulator systems can be found at https://www.aans.org/Patients/Neurosurgical-Conditions-and-Treatments/Spinal-Cord-Stimulation.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 50527-1:2016, *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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at https://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

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

3.2
neurostimulator system
NS
active implantable medical device comprising an implantable pulse generator and therapy delivering electrodes usually part of implanted electrical leads that are intended to deliver therapy to a patient by electrically stimulating certain nerve structures, along with an associated external patient programming device