

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

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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

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Comité Européen de Normalisation Electrotechnique  
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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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- latest date by which the national standards conflicting with this document have to be withdrawn (dow) 2024-08-09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