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STN	**Postup posudzovania expozície pracovníkov s aktívnymi implantovateľnými zdravotníckymi pomôckami elektromagnetickým poliam Časť 2-3: Špecifické hodnotenie pre pracovníkov s implantovateľnými neurostimulátormi**	**STN EN 50527-2-3** 36 7938

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

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• latest date by which the national standards conflicting with this document have to be withdrawn	(dow)	2024-08-09

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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*