SLOVENSKI STANDARD
SIST EN 50527-2-3:2022

01-januar-2022

Postopek ocenjevanja izpostavljenosti delavcev z aktivnimi medicinskimi vsadki elektromagnetnim poljem - 2-3. del: Specifično ocenjevanje delavcev z vsadljivimi nevrostimulatorji

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

Ta slovenski standard je istoveten z: **EN 50527-2-3:2021**

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
17.240	Merjenje sevanja	Radiation measurements

SIST EN 50527-2-3:2022 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 50527-2-3

October 2021

ICS 17.240; 11.040.40

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• latest date by which the national standards conflicting with this document have to be withdrawn	(dow)	2024-08-09

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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

3.3
electrode
electrically conducting part (usually the termination of a lead) which is designed to form an interface with body tissue or body fluid

3.4
bipolar lead
lead with at least two electrodes that are electrically isolated from each other

3.5
AIMD-Employee
worker with an active implantable medical device

Note 1 to entry: For the purposes of this document, the term AIMD-Employee refers to the patient whose implant consists of a neurostimulator system of the type intended for spinal cord stimulation.

3.6
assessment team
team consisting of:

— employer and if applicable, his occupational health and safety experts and/or occupational physician;

— AIMD-Employee and his responsible physician;

— (technical and medical) experts as necessary, e.g. manufacturer of the device

3.7
unipolar stimulation
stimulation using a single electrode with reference to the outer shell of the implantable pulse generator

3.8
single lead bipolar stimulation
stimulation using two or more adjacent electrodes of a single lead structure

Note 1 to entry: Leads for use with SCS devices typically have a minimum of 8 electrodes.

3.9
two lead bipolar stimulation
stimulation using two or more electrodes located on two separate leads that are implanted in close proximity to one another

3.10
device
<in the context of this document> implanted spinal cord stimulator

3.11
electromagnetic field
EMF
<in the context of this document> alternating electric field, alternating magnetic field, or radio wave between 1 Hz and 3 GHz whether continuous, pulsed, or modulated in space or time

3.12
spinal cord stimulator
SCS
neurostimulator system designed specifically for stimulation of the human spinal cord to treat chronic pain by electrically stimulating the spinal cord but not the Dorsal Root Ganglion (DRG)

3.13
General Public Reference Level
GPRL
measurable level of electric or magnetic field strength given in Council Recommendation 1999/519/EC for the general public environment, exposure to which is not considered harmful for persons not bearing an active implant

3.14
nerve stimulation ratio
NSR
ratio of the electric field at the spinal cord induced by external electromagnetic fields, to the electric field level below which the AIMD-Employee is not expected to perceive nervous system stimulation

3.15
tissue damage ratio
TDR
ratio of the electrode current induced by external electromagnetic fields, to the current for a given electrode area below which the AIMD-Employee is not expected to undergo any damage to the tissues surrounding the implanted electrode

4 Specific assessment

4.1 Overview of specific assessments

4.1.1 Relation to OH&S Management Systems

Nonionizing radiation is a hazard to the health of workers. Whether this hazard constitutes a risk is determined in the process of hazard identification and risk assessment (e.g. ISO 45001:2018, 6.1.2 [2], and OHSAS 18001, 4.3.1 [3]). Assessing this hazard on all workplaces should be integrated into the organization's process of risk assessment for occupational safety and health. In that process, the general aspects for AIMD-Employees shall be considered, regardless if an AIMD-Employee is actually present at that workplace. The organization has to plan and foresee the repetition of the hazard evaluation and risk assessment at a definite interval. If there is a change of the work-system at the workplace (i.e. new machinery, new installations producing EMF, or a change in the configuration of the implant) the risk assessment according to this document shall be repeated.

4.1.2 Description of the assessment process

Spinal Cord Stimulation (SCS) is generally used for chronic pain reduction. The stimulation does not provide therapy in direct relation to AIMD-Employee safety, so changes to therapy, or turning therapy off, does not pose a specific risk to the AIMD-Employee. It is noted that an AIMD-Employee can also receive therapy changes which can appear as a "shock" or "jolt" due to abrupt movements such as coughing and laughing as well as from postural changes such as standing up from seating, or vice versa. These are not significant direct risk situations to the AIMD-Employee, but there can be indirect implications due to the nature of the occupation or positioning. Such indirect risks might include for example, dropping a tool, losing balance, unintended exposure to dangerous situations, etc. A workplace risk assessment needs to consider a balance of the benefits of continued employment, and the possible effects assessed in this document, both direct and indirect, due to the nature of the employment.

The risks to an AIMD-Employee resulting from exposure to EMF in the workplace include the categories of effects upon the implanted device, as well as the possibility of clinically significant effects upon the AIMD-Employee as further described below:

— The implanted SCS can itself be influenced in a way that leads to temporary or permanent loss of therapy, or delivery of a corrupted form of therapy that might not meet the needs of the patient such that they might be unable to carry out their employee functions. ISO 14708-3 [1] is the product standard that addresses the risks of malfunction and damage to the SCS NS when exposed to EMF. The working group has deemed the risks to the AIMD-Employee related to malfunction and device damage to be acceptable, and they are therefore not assessed by this document. See C.2 for additional rationale.

— The AIMD-Employee might experience unintended effects upon their nervous system due to nerve stimulation arising from induced currents in their implanted lead system resulting from exposure to external EMF. These effects can include unpleasant sensations, up to and including “shocking” and “jolting”,

— The induced currents might be of sufficient magnitude to cause tissue damage. This risk would occur at higher exposure levels and where the EMF frequencies are high enough that they would not be perceived by the AIMD-Employee.

To address these risks, this document describes a multi-phase risk assessment as summarized in Figure 1.

— Exclusion from further assessment based upon a consideration of prior history

— Exclusion from further assessment based upon a survey of the equipment in the workplace

— Exclusion from further assessment if the AIMD-Employee has a SCS with a mode of operation that the AIMD-Employee can activate that temporarily prevents current flow in the stimulation leads (and thereby discontinues therapy delivery) while at the workplace. Reliance on this exclusion would be dependent upon the ability of the AIMD-Employee to tolerate the lack of therapy while still carrying out their assigned work tasks. See also C.2.7.

— Assessment of the likelihood that the induced current arising from the EMF environment of the workplace will exceed the stimulation threshold (i.e. limit of perceived stimulation) for the spinal cord portion of the human nervous system.

— Assessment of the likelihood that the induced current arising from the EMF environment of the workplace could cause damage to the tissues of the spinal cord. This risk is present when the characteristics of the induced currents are such that they are not perceived by the AIMD-Employee yet are of sufficient magnitude to result in a level of deposited power as to cause tissue damage as a result of tissue heating. The underlying approach is first to allow work without restriction if it can be determined that no unintended nerve stimulation and no tissue damage would occur,

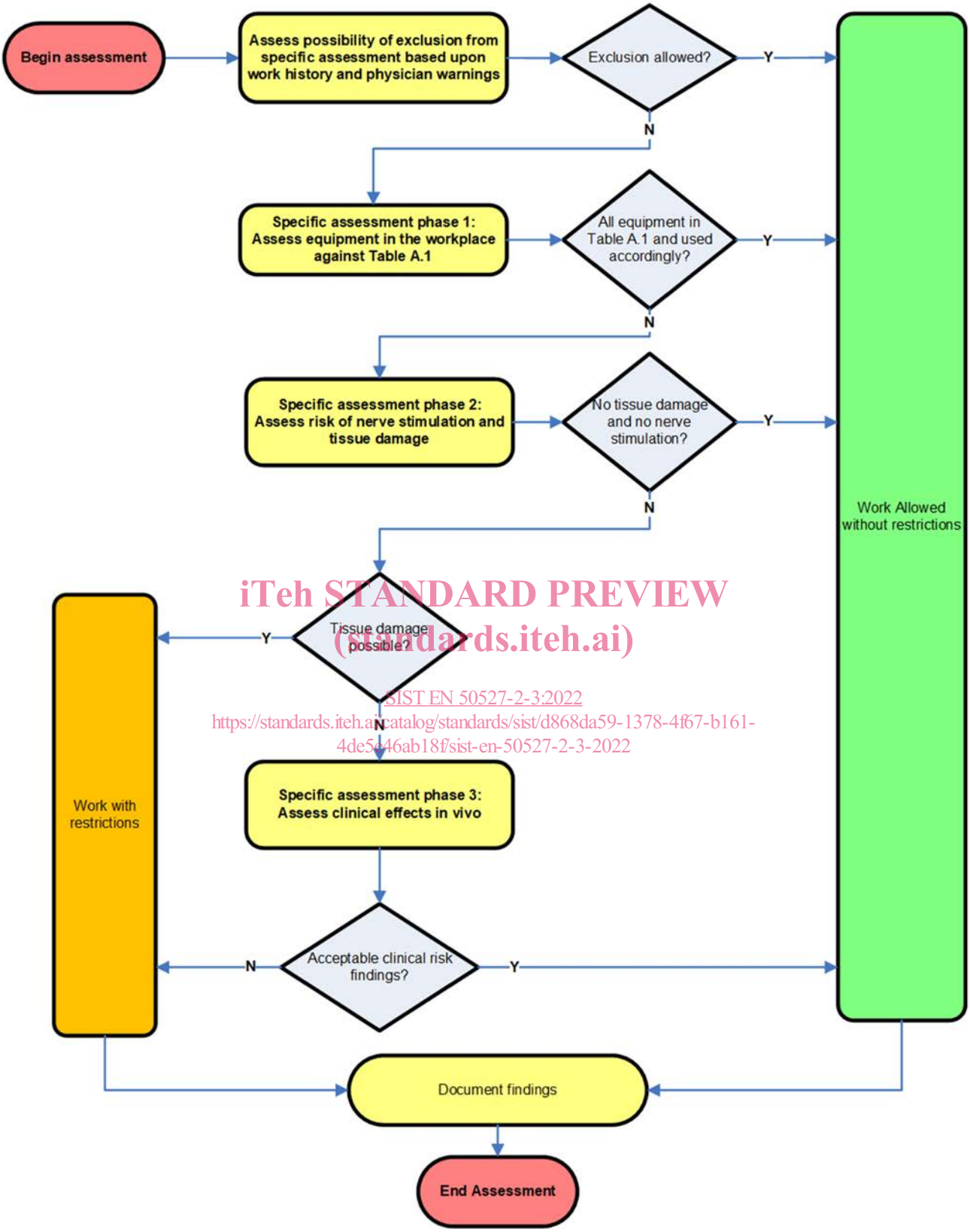

Figure 1 — Overview of the assessment process

4.2 Specific assessment phase 0: Exclusion based on history and physician warnings

Further risk assessment is not necessary if a history of uninfluenced behaviour at the workplace exists and a responsible physician has confirmed that this history is sufficient to exclude clinically significant interaction. The conditions for uninfluenced behaviour are provided in EN 50527-1:2016.

When a SCS NS is tested according to ISO 14708-3, the manufacturer is required to provide in the accompanying documents “warnings or precautions to be taken to prevent adverse effects to the patient due to hazards associated with electromagnetic disturbances”. These are generic warnings for the specific model of SCS and intended to instruct the patient about risks they might encounter in their daily lives. They are not specific to a particular patient’s implant scenario, in that SCS devices such as those covered by this document do not contain sensing functions, and therefore no associated sensitivity settings that a physician might adjust that would affect the immunity to electromagnetic interference.

Figure 2 summarizes the situations where further risk assessment is unnecessary, and where further assessment (beginning with 4.3) is required. To apply these exclusions, the assessment team first needs to list all equipment used by the AIMD-Employee in the workplace, and then compare that list to Table A.1 in Annex A. The team should consider how the equipment is used by the AIMD-Employee, as well as what history (if it exists) relative to interaction between the equipment and the AIMD-Employee’s SCS.

For equipment included in and used according to Table A.1:				
Warnings		**History**		
		Un-Influenced Behaviour	Influenced Behaviour	No History available
Warning from responsible physician or given in patient instructions for use?	No	1	3	1
	Yes	2	3	3
For equipment not included in or not used according to Table A.1, further risk assessment according to 4.3 is required				

Legend	
1	Further risk assessment unnecessary-proceed to Clause 5
2	Further risk assessment is not required if responsible physician has confirmed that this history is sufficient to exclude clinically significant interaction-proceed to Clause 5, otherwise to 4.3.
3	Further risk assessment according to 4.3 is required

Figure 2 — Summary of assessment exclusion criteria

4.3 Specific assessment phase 1: Consideration of equipment and SCS therapy type

This phase of the assessment is undertaken when the exclusions described in 4.2 cannot be applied. This is the case when there is a history of influenced behaviour or one of the following three conditions exists:

a) there is equipment present in the workplace that is not included in Table A.1;

b) there is equipment present in the workplace that is not used in accordance with Table A.1;

c) all equipment at the workplace is listed in Table A.1 and is used accordingly, but the AIMD-Employee has received warning(s) from the responsible physician (or listed in their Patient Instructions for Use) that their device might be susceptible to EMF associated with one or more of these workplace equipment items.

Figure 3 depicts phase 1 of the specific assessment. The steps to be taken are based upon a consideration of equipment in the workplace and consultation with the responsible physician and / or the Patient Instructions for Use.

Information relevant to the equipment or other field generating sources under consideration shall be collected to answer sufficiently the following two questions:

— can it be determined that the clinically significant effects described in 4.1.2 will not occur as a result of expected exposure to the equipment under consideration? If so, no further assessment is required, and documentation of the result can proceed, as required in Clause 5;

— can it be determined that the AIMD-Employee can return to the workplace only with restrictions placed on the work tasks or areas of access? If so, no further assessment is required, and documentation of the work restrictions can proceed as required in Clause 5.

When neither of these questions can be answered positively, the assessment continues to phase 2a according to 4.4.

The intent of this subclause is to find and utilize information that might already exist and that allows the assessment to be completed without further, costlier and time-consuming effort. It is recommended that experts who are likely to have such information be contacted. Examples of such experts are the device manufacturer, equipment manufacturer, employer's technical department, consultants, or others skilled in EMF effects with implanted devices.