SLOVENSKI STANDARD
oSIST prEN 50527-2-2:2017

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Postopek ocenjevanja izpostavljenosti delavcev z aktivnimi medicinskimi vsadki elektromagnetnim poljem - 2-2. del: Specifično ocenjevanje delavcev z kardioverter-defibrilatorjem (ICD)

Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices - Part 2-2: Specific assessment for workers with cardioverter defibrillators (ICDs)

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

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11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
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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 2-2: Specific assessment for workers with cardioverter defibrillators (ICDs)

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

To be completed

This draft European Standard is submitted to CENELEC members for enquiry.
Deadline for CENELEC: 2017-10-20.

It has been drawn up by CLC/TC 106X.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CENELEC in three official versions (English, French, German).
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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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European foreword

This document (prEN 50527-2-2:2017) has been prepared by CLC/TC 106X “Electromagnetic fields in the human environment”.

This document is currently submitted to the Enquiry.

The following dates are proposed:

• latest date by which the existence of this document has to be announced at national level	(doa)	dor + 6 months
• latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	dor + 12 months
• latest date by which the national standards conflicting with this document have to be withdrawn	(dow)	dor + 36 months (to be confirmed or modified when voting)

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

1 Scope

This draft European Standard provides the procedure for the specific assessment required in EN 50527-1:2016, Annex A, for workers with implanted cardioverter defibrillators (ICDs) and Cardiac Resynchronization Therapy devices with associated defibrillation functions (CRT-D). Only devices of this type equipped with leads implanted transvenously are considered. It offers different approaches for doing the risk assessment.

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.

NOTE 2 The risks to patients due to interference with pacing functions associated with CRT-D devices are assessed using EN 50527–2-1.

The purpose of the specific assessment is to determine the risk for workers with implanted ICDs and CRT-Ds 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 3 This standard does not address risks 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 devices within the scope of this Particular Standard is expected to occur when the exposure limits are not exceeded.

NOTE 4 The rationale for limiting the observation range to 3 GHz can be found in ISO 14117:2012, Clause 5.

NOTE 5 Further information concerning the functions of Pacemakers, CRT-D, and ICD devices can be found in Ellenbogen and Kaszala, 2014.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 45502-2-2:2008, *Active implantable medical devices — Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)*

EN 50413, *Basic standard on measurement and calculation procedures for human exposure to electric, magnetic and electromagnetic fields (0 Hz – 300 GHz)*

EN 50527-1:2016, *Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices — Part 1: General*

EN ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice (ISO 14155)*

ISO 14117:2012, *Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 50527-1:2016 and the following apply.

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

Note 1 to entry: For the purposes of this Particular Standard, the term IMPLANTABLE PULSE GENERATOR describes any ACTIVE IMPLANTABLE MEDICAL DEVICE that incorporates functions intended to treat tachyarrhythmias.

3.2
implantable cardioverter defibrillator (ICD)
ACTIVE IMPLANTABLE MEDICAL DEVICE comprising an IMPLANTABLE PULSE GENERATOR and LEAD(S) that is intended to detect and correct tachycardias and fibrillation by application of CARDIOVERSION/-DEFIBRILLATION PULSE(S) to the heart

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 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 Particular Standard, the term AIMD-Employee refers to the patient whose implant is of type ICD or CRT-D.

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
implantable cardiac resynchronization therapy/defibrillator device
CRT-D
active implantable medical device intended to detect and correct tachycardias and fibrillation by application of cardioversion/defibrillation pulses to the heart, and to provide improved ventricular activation to optimize cardiac output

3.8
anti-tachycardia pacing
ATP
therapy function associated with CRT-D devices consisting of pacing pulses delivered to the heart to interrupt a tachyarrhythmia episode and restore normal sinus rhythm

3.9
EM phantom
physical model containing tissue-equivalent material used to simulate the body in an experimental dose measurement (from World Health Organization)

Note 1 to entry: EM phantoms are sometimes also referred to as torso simulator or phantom.

3.10
uninfluenced behaviour
conditions for uninfluenced behaviour are provided in EN 50527-1:2016, 4.1.3

3.11
device
<in the context of this standard> either the implanted ICD or CRT-D device

4 Specific assessment

4.1 Description of the assessment process

4.1.1 General

The risk assessment is based on the approach that, according to EN 45502-2-2 and ISO 14117, ICDs and CRT-Ds are expected to work uninfluenced as long as the General Public Reference levels of Council Recommendation 1999/519/EC are not exceeded (except for static magnetic fields and for pulsed high frequency electromagnetic fields) (see also F.7).

The EMC requirements within EN 45502–2-2 have been incorporated with updates into ISO 14117 and their use is recommended here.

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 severe (clinically significant) interaction.

A specific risk assessment for the AIMD-Employee is required when there is history of influenced behaviour or one of the following three conditions is fulfilled:

a) there is equipment present in the workplace that is neither included in, nor used in accordance with Table A.1;

b) all equipment at the workplace is listed in Table A.1 (see Annex A) and is used accordingly, but the AIMD-Employee has received warning(s) from the responsible physician that their device might be susceptible to electromagnetic interference (EMI), thereby increasing the risk at the workplace. There are two types of warnings that can be given:

   1) patient-specific warnings provided by the responsible physician to the AIMD-Employee due to settings in effect that can cause changes in device behaviour in the presence of electromagnetic fields (EMF) that are below the reference levels; or

   2) general warnings supplied by the device manufacturer in accompanying documentation about recognized behaviour changes of the device when it is subjected to EMF generated by specific types of equipment;

c) there is equipment present in the workplace that is neither included in, nor used in accordance with Table A.1 and for which the AIMD-Employee does have a history of uninfluenced behaviour while in its presence, but the AIMD-Employee has received a specific warning as described above.

In order to minimize the burden placed on the employer and AIMD-Employee, the assessment should begin with the investigation steps shown in Figure 1. The steps to be taken are based upon whether the specific assessment is the result of an equipment issue or a patient warning issue.

When only condition a) exists, then 4.1.2 shall apply. When only condition b) exists, then 4.1.3 shall apply. When condition c) exists, then both 4.1.2 and 4.1.3 shall apply.

When a device is tested according to EN 45502–2-2, the manufacturer is required to provide a warning to the implanting physician in the accompanying technical information as to any sensitivity settings available in the device that if used, afford the device with a reduced immunity to certain types of EMI. A specific warning would only be given to the patient receiving the implant if they were discharged with one of these settings in effect, or if at follow-up, a change to one of these settings was made for clinical reasons.

For equipment included in and used per Table A.1					Legend	
History		Influenced Behaviour	Un-influenced Behaviour	No History available	1	Further risk assessment is not necessary
Warning from responsible Physician ?	Yes	2	3	2	2	Specific risk assessment for the AIMD-Employee is required
	No	2	1	1	3	further risk assessment unnecessary if responsible physician has confirmed that this history is sufficient to exclude clinically significant interaction
For Equipment not included in or not used per Table A.1						
Specific risk assessment for the AIMD-Employee is required						

Figure 1 — Overview of the assessment process

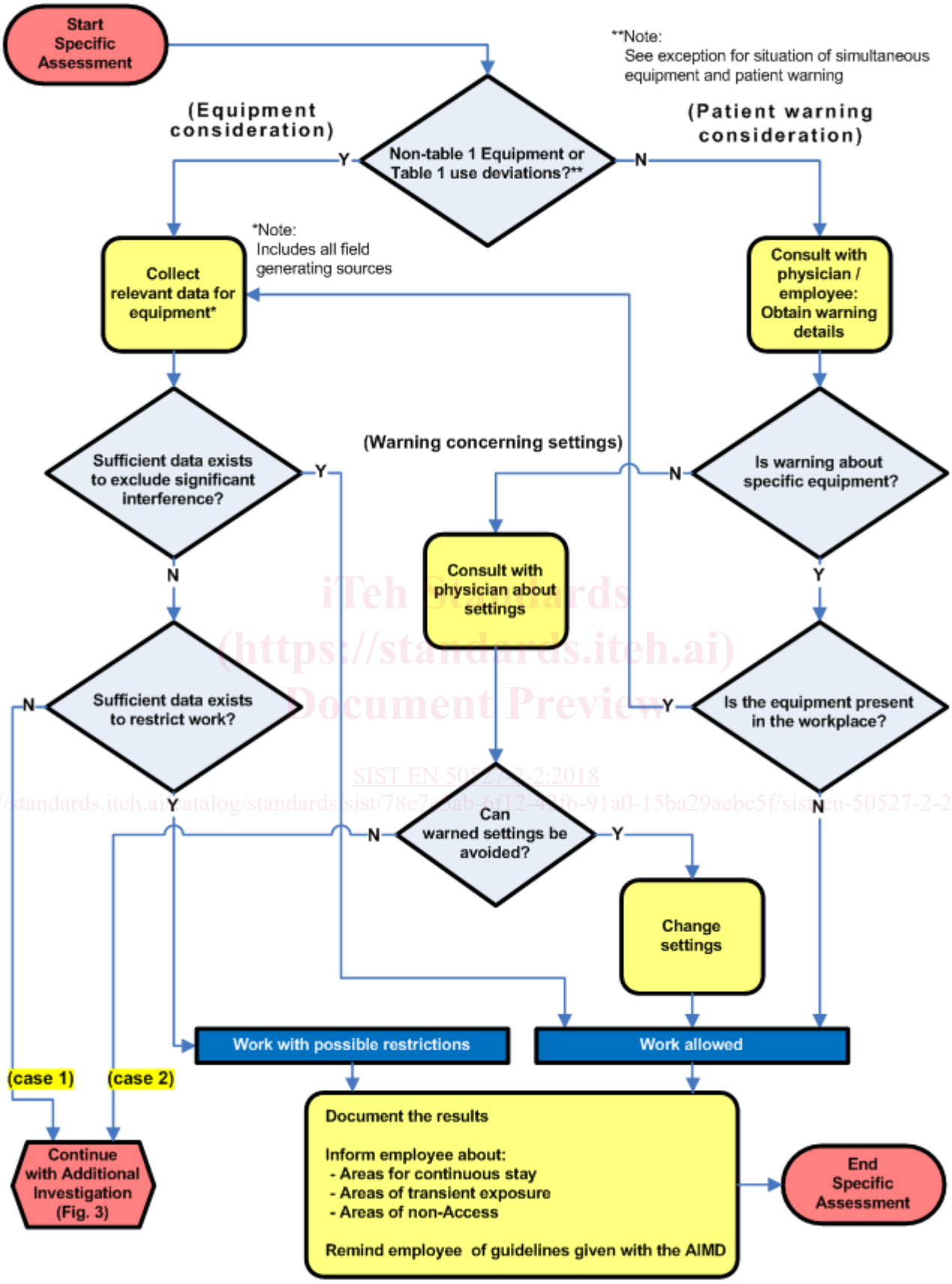

Figure 2 — Specific assessment process

4.1.2 Equipment consideration

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 clinically significant interference with the device 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, additional investigation, hereafter referred to as "Case 1", is required as specified in 4.1.4.

The intent of this clause is to find and utilize information that might already exist and that allows the assessment to be completed without further, more costly 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 EMI effects with implanted devices.

4.1.3 Patient warning consideration

The responsible physician and AIMD-Employee shall be consulted to determine the type of and details for any EMI warnings applicable to the device.

If the warning is about behaviour of the device due to interference from particular types of equipment (see 4.1.1 b) 2)) then it shall first be determined whether that equipment is actually present in the workplace:

- if the equipment is not present, the AIMD-Employee is allowed to work without restrictions and the specific assessment can be completed and documented as required in Clause 5.

- if the equipment subject to the warning is present, the steps given in 4.1.2 shall be taken.

If the warning is due to the applied settings of the device that might cause reduced immunity (see 4.1.1 b) 1)) to EMI that is at or below the reference levels, the responsible physician shall be consulted to determine whether the settings can be changed to avoid settings that are associated with the warning, thereby restoring standard immunity levels:

- if it is determined that such a change of settings can be made, the AIMD-Employee shall be advised to arrange, through consultation with the responsible physician, for these changes of settings to be made prior to returning to work. When the change of setting has been completed, the AIMD-Employee is allowed to work without restrictions. The results shall be documented as required in Clause 5 and the assessment is concluded;

- if the settings cannot be changed, then additional investigation, hereafter referred to as "Case 2" is required as discussed in 4.1.4.

4.1.4 Cases for additional investigation

When the investigation steps shown in Figure 2 have been followed but fail to mitigate or to dismiss risk to the AIMD-Employee from the effects of workplace EMI, then an additional investigation shall be performed as shown in Figure 3 and described in 4.1.5. The goal of the investigation is to determine the likelihood of a clinically significant response of the device to the EMI at the workplace that is the result of the following.

a) **Case 1**: Equipment is used at the workplace that is:

   1) neither listed in, nor used in accordance with, Table A.1, and for which there is no information available that allows a pre-determination of safe or restricted work for the AIMD-Employee, or

2) capable of emitting fields that can induce device lead voltages exceeding the immunity levels established by conformity with the device product standard, EN 45502-2-2,

3) known by the device manufacturer to potentially cause interference with the device and there is no applicable safe use guideline available from other sources.