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Bedömning av exponering av arbetstagare med aktiva implanterbara medicintekniska produkter för elektriska och magnetiska fält – Del 2-2: Särskild bedömning för arbetstagare med implanterbar defibrillator (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)*

Som svensk standard gäller europastandarden EN 50527-2-2:2018. Den svenska standarden innehåller den officiella engelska språkversionen av EN 50527-2-2:2018.

ICS 11.040.40; 17.240.00

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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

Verfahren zur Beurteilung der Exposition von
Arbeitnehmern mit aktiven implantierbaren medizinischen
Geräten gegenüber elektromagnetischen Feldern - Teil 2-2:
Besondere Beurteilung für Arbeitnehmer mit Cardioverter-
Defibrillatoren (ICDs)

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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 50527-2-2:2018) 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) 2019-04-03
- latest date by which the national standards conflicting with this document have to be withdrawn (dow) 2021-04-03

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

1 Scope

This 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 (EMF) 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 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*