



**NSAI**  
Standards

Irish Standard  
I.S. EN 50527-2-1:2016

Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices - Part 2-1: Specific assessment for workers with cardiac pacemakers

**I.S. EN 50527-2-1:2016**

*Incorporating amendments/corrigenda/National Annexes issued since publication:*

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation — recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

*This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):*

*NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.*

*This document is based on:*

EN 50527-2-1:2016

*Published:*

2016-12-02

*This document was published under the authority of the NSAI and comes into effect on:*

2016-12-20

ICS number:

11.040.40

17.240

NOTE: If blank see CEN/CENELEC cover page

NSAI  
1 Swift Square,  
Northwood, Santry  
Dublin 9

T +353 1 807 3800  
F +353 1 807 3838  
E standards@nsai.ie  
W NSAI.ie

Sales:  
T +353 1 857 6730  
F +353 1 857 6729  
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

## National Foreword

I.S. EN 50527-2-1:2016 is the adopted Irish version of the European Document EN 50527-2-1:2016, Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices - Part 2-1: Specific assessment for workers with cardiac pacemakers

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

**Compliance with this document does not of itself confer immunity from legal obligations.**

*In line with international standards practice the decimal point is shown as a comma (,) throughout this document.*

This page is intentionally left blank

EUROPEAN STANDARD

**EN 50527-2-1**

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 2016

ICS 11.040.40; 17.240

Supersedes EN 50527-2-1:2011

English Version

**Procedure for the assessment of the exposure to  
electromagnetic fields of workers bearing active implantable  
medical devices - Part 2-1: Specific assessment for workers with  
cardiac pacemakers**

Procédure pour l'évaluation de l'exposition des travailleurs  
porteurs de dispositifs médicaux implantables actifs aux  
champs électromagnétiques - Partie 2-1: Spécification  
d'évaluation pour les travailleurs avec un simulateur  
cardiaque

Verfahren zur Beurteilung der Exposition von  
Arbeitnehmern mit aktiven implantierbaren medizinischen  
Geräten (AIMD) gegenüber elektromagnetischen Feldern -  
Teil 2-1: Besondere Beurteilung für Arbeitnehmer mit  
Herzschrittmachern

This European Standard was approved by CENELEC on 2016-07-04. 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.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



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

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

## EN 50527-2-1:2016 (E)

<b>Contents</b>	Page
<b>European foreword</b> .....	<b>5</b>
<b>1 Scope</b> .....	<b>6</b>
<b>2 Normative references</b> .....	<b>6</b>
<b>3 Terms and definitions</b> .....	<b>6</b>
<b>4 Specific assessment</b> .....	<b>8</b>
4.1 Description of the assessment process.....	8
4.1.1 General.....	8
4.1.2 Equipment consideration.....	11
4.1.3 Patient warning consideration.....	11
4.1.4 Cases for additional investigation.....	11
4.1.5 Choice of investigative method.....	14
4.2 Clinical investigation.....	15
4.3 Non-clinical investigation.....	15
4.3.1 General.....	15
4.3.2 Non-clinical investigation by <i>in vitro</i> testing.....	16
4.3.3 Non-clinical investigation by comparative study.....	17
<b>5 Documentation</b> .....	<b>20</b>
<b>Annex A (normative) Pacemaker specific replacement of EN 50527-1:2016, Table 1</b> .....	<b>21</b>
<b>Annex B (informative) Clinical investigation methods</b> .....	<b>27</b>
B.1 External ECG monitoring.....	27
B.2 Assessment of pacemaker compatibility using stored data and diagnostic features.....	27
B.3 Real time event monitoring by telemetry.....	27
<b>Annex C (informative) <i>in vitro</i> testing/measurements</b> .....	<b>29</b>
C.1 Introduction.....	29
C.2 EM phantom.....	29
C.2.1 General.....	29
C.2.2 EM phantom design.....	29
C.3 Basic procedure for cardiac pacemaker <i>in vitro</i> testing.....	30
C.4 References.....	31
C.5 Literature.....	32
<b>Annex D (informative) Modelling</b> .....	<b>33</b>
D.1 General.....	33
D.2 Analytical techniques.....	33
D.3 Numerical techniques.....	33
D.4 Field modelling or calculations.....	33
D.5 Modelling the human body and implant.....	34
D.6 References.....	34
<b>Annex E (informative) Derived worst case conversions for frequencies below 450 MHz</b> .....	<b>35</b>
E.1 Introduction.....	35
E.2 Functionality of implanted pacemaker leads.....	35
E.3 Conversion based on known field strength.....	36
E.3.1 General.....	36
E.3.2 Low frequency range (below 5 MHz).....	36
E.3.3 Pure magnetic field (16 Hz to 5 MHz).....	37
E.3.4 Pure electric field (16 Hz to 150 kHz).....	39
E.3.5 Field with electric component (16 Hz to 150 kHz).....	42
E.3.6 Field with electric and magnetic component (150 kHz to 5 MHz).....	43
E.3.7 Range between low and high frequency ranges (5 MHz to 30 MHz).....	44

E.3.8	High frequency range (above 30 MHz).....	44
E.4	Conversion based on known compliance with basic restrictions.....	46
E.4.1	General .....	46
E.4.2	Short survey on the direct effects of human exposure (induced current density) .....	46
E.4.3	Short survey on induced voltages on an implanted lead.....	48
E.4.4	A simple model to analyse the possible voltages at pacemaker terminations generated from induced current density equivalent the basic restrictions of Council Recommendation 1999/519/EC.....	48
E.5	References .....	50
<b>Annex F</b>	<b>(informative) Interference from power-frequency magnetic and electric fields from transmission, distribution and use of electricity.....</b>	<b>52</b>
F.1	Sensitivity of pacemakers to interference.....	52
F.2	Immunity requirements .....	52
F.3	Voltage induced in the leads by magnetic fields .....	53
F.4	Voltage induced in the leads by electric fields.....	54
F.5	Values of 50 Hz magnetic and electric field that may cause interference.....	56
F.6	Factors that affect the immunity from interference .....	57
F.6.1	Reasons for improved immunity .....	57
F.6.2	Adjustment for pacemaker sensitivity .....	58
F.7	Application to exposure situations .....	59
F.7.1	Public exposures.....	59
F.7.2	Beneath high voltage power lines.....	59
F.7.3	Occupational settings.....	60
F.7.4	Temporary exposure above the interference levels .....	61
F.8	References .....	61
<b>Annex G</b>	<b>(informative) Determination of the pacemaker immunity and guidelines provided by pacemaker manufacturers – Determination method.....</b>	<b>62</b>
G.1	Introduction .....	62
G.2	EMC and pacemakers – General guidelines .....	62
G.3	Induced voltages, fields and zones .....	65
G.3.1	Induced voltage test levels .....	65
G.3.2	Magnetic field amplitudes producing test limits .....	65
G.3.3	Induced voltage zones.....	67
G.3.4	Magnetic field zones .....	67
G.4	References .....	68
G.5	Literature.....	69
<b>Bibliography</b>	.....	<b>70</b>

## Figures

<b>Figure 1</b>	<b>— Overview of the assessment process.....</b>	<b>9</b>
<b>Figure 2</b>	<b>— Pacemaker specific assessment process .....</b>	<b>10</b>
<b>Figure 3</b>	<b>— Additional investigation process .....</b>	<b>13</b>
<b>Figure 4</b>	<b>— Comparison process .....</b>	<b>18</b>
<b>Figure C.1</b>	<b>— Example of <i>in vitro</i> procedure for EM interference at low frequency using planar electrodes, bipolar lead and ECG and data recording.....</b>	<b>31</b>
<b>Figure E.1</b>	<b>— Typical implantations of cardiac pacemakers (abdominal implantation with prolonged lead is used in clinical environment only).....</b>	<b>36</b>
<b>Figure E.2</b>	<b>— Effective induction area of an open wire loop inside a conductive medium .....</b>	<b>37</b>
<b>Figure E.3</b>	<b>— Schematic representation of bipolar pickup of interference in an infinitely extended homogeneous conducting medium .....</b>	<b>39</b>
<b>Figure E.4</b>	<b>— Induced voltage on the implanted lead in a pure <i>E</i> field .....</b>	<b>41</b>
<b>Figure E.5</b>	<b>— Schematic graphs of the same voltage on the lead for different layouts.....</b>	<b>43</b>
<b>Figure E.6</b>	<b>— Eddy-current inside a conductive medium induced by varying magnetic flux .....</b>	<b>47</b>

**EN 50527-2-1:2016 (E)**

**Figure E.7 — Voltage induced on a lead inside conductive body tissue .....48**  
**Figure E.8 — Voltages on an implanted lead.....50**  
**Figure F.1 — How the immunity ratio affects magnetic field that may result in interference .....58**  
**Figure F.2 — How the immunity ratio affects electric field that may result in interference .....59**  
**Figure G.1 — Induced voltage test levels .....65**  
**Figure G.2 — Magnetic field amplitudes, for frequencies below 5 000 kHz, producing test limits in unipolar configurations .....66**  
**Figure G.3 — Induced voltage zones for unipolar configurations .....67**  
**Figure G.4 — Magnetic field zones, for frequencies below 5 000 kHz and for unipolar configurations .....68**

**Tables**

**Table A.1 — Compliant workplaces and equipment with exceptions .....21**  
**Table F.1 — Amplitude of the immunity test signal applied .....53**  
**Table F.2 — Values of 50 Hz electric and magnetic field (r.m.s.) that might, under unfavourable circumstances, cause interference in a pacemaker.....56**  
**Table F.3 — Summary of typical maximum field values beneath high-voltage overhead lines at 1 m above ground .....60**



## European foreword

This document (EN 50527-2-1:2016) 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 (dop) 2017-07-04  
at national level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with (dow) 2019-07-04  
this document have to be withdrawn

This document supersedes EN 50527-2-1:2011.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

EN 50527 is currently composed with the following parts:

- EN 50527-1, *Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices — Part 1: General*;
- EN 50527-2-1, *Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices — Part 2-1: Specific assessment for workers with cardiac pacemakers*;
- prEN 50527-2-2, *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 implantable cardioverter defibrillators*<sup>1)</sup>.

---

1) Currently at drafting stage.

## EN 50527-2-1:2016 (E)

### 1 Scope

This European Standard provides the procedure for the specific assessment required in EN 50527-1:2016, Annex A, for workers with implanted pacemakers. It offers different approaches for doing the risk assessment. The most suitable one will be used. If the worker has other Active Implantable Medical Devices (AIMDs) implanted additionally, they need to be assessed separately.

The purpose of the specific assessment is to determine the risk for workers with implanted pacemakers 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 1 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 pacemaker occurs when the exposure limits are not exceeded.

NOTE 2 The rationale for limiting the observation range to 3 GHz can be found in ISO 14117:2012, Clause 5.

### 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 45502-2-1:2003<sup>2)</sup>, *Active implantable medical devices — Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)*

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*

### 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 EN 50527-2-1, the term implantable pulse generator describes any active implantable medical device that incorporates functions intended to treat cardiac arrhythmias.

#### 3.2

##### **pacemaker**

active implantable medical device intended to treat bradyarrhythmias, comprising an implantable pulse generator with or without lead(s)

---

2) The EMC requirements within EN 45502-2-1 have been incorporated with updates into ISO 14117 and their use is recommended here.

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

- 
- [Looking for additional Standards? Visit Intertek Inform Infostore](#)
  - [Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation](#)
-