



NSAI
Standards

Irish Standard

I.S. EN 60601-2-50:2009&A11:2011&A1:2016

Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment

I.S. EN 60601-2-50:2009&A11:2011&A1:2016

Incorporating amendments/corrigenda/National Annexes issued since publication:

EN 60601-2-50:2009/A11:2011

EN 60601-2-50:2009/A1:2016

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

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National Foreword

I.S. EN 60601-2-50:2009&A11:2011&A1:2016 is the adopted Irish version of the European Document EN 60601-2-50:2009, Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment

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

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EUROPEAN STANDARD

EN 60601-2-50:2009/A1

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 2016

ICS 11.040.60

English Version

**Medical electrical equipment - Part 2-50: Particular requirements
for the basic safety and essential performance of infant
phototherapy equipment
(IEC 60601-2-50:2009/A1:2016)**

Appareils électromédicaux - Partie 2-50: Exigences particulières
pour la sécurité de base et les performances essentielles des
appareils de photothérapie pour nouveau-nés
(IEC 60601-2-50:2009/A1:2016)

Medizinische elektrische Geräte - Teil 2-50: Besondere
Festlegungen für die Sicherheit einschließlich der wesentlichen
Leistungsmerkmale von Säuglings-Phototherapiegeräten
(IEC 60601-2-50:2009/A1:2016)

This amendment A1 modifies the European Standard EN 60601-2-50:2009; it was approved by CENELEC on 2016-06-03. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 amendment 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 60601-2-50:2009/A1:2016

European foreword

The text of document 62D/1327/FDIS, future IEC 60601-2-50:2009/A1, prepared by SC 62D "Electromedical equipment", of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-50:2009/A1:2016.

The following dates are fixed:

- latest date by which the document has to be implemented at (dop) 2017-06-16
national level by publication of an identical national
standard or by endorsement
- latest date by which the national standards conflicting with (dow) 2019-12-16
the document have to be withdrawn

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

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).

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 60601-2-50:2009/A11:2011.

Endorsement notice

The text of the International Standard IEC 60601-2-50:2009/A1:2016 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 60601-2-50:2009, replace the existing reference to ISO 3743-1 by the following:

IEC 61672-1 NOTE Harmonized as EN 61672-1.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>In Annex ZA of EN 60601-2-50:2009, replace the existing reference to IEC 60601-1-2:2007 as follows:</i>				
IEC 60601-1-2	-	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60601-2-50/A11

October 2011

ICS 11.040.60

English version

**Medical electrical equipment -
Part 2-50: Particular requirements for the basic safety and essential
performance of infant phototherapy equipment**

Appareils électromédicaux -
Partie 2-50: Exigences particulières pour
la sécurité de base et les performances
essentielles des appareils de
photothérapie pour nouveau-nés

Medizinische elektrische Geräte -
Teil 2-50: Besondere Festlegungen für die
Sicherheit einschließlich der wesentlichen
Leistungsmerkmale von Säuglings-
Phototherapiegeräten

This amendment A11 modifies the European Standard EN 60601-2-50:2009; it was approved by CENELEC on 2011-10-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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.

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

CENELEC

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Foreword

This document (EN 60601-2-50:2009/A11:2011) has been prepared by CLC/TC 62 "Electrical equipment in medical practice".

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) 2012-10-01
- latest date by which the national standards conflicting with this document have to be withdrawn (dow) 2014-10-01

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

Replace Annex ZZ of EN 60601-2-50:2009 by:

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC except as follows:

- Essential Requirement 6a
- Essential Requirement 7.1
- Essential Requirement 7.4
- Essential Requirement 7.5 paragraph 2 & 3
- Essential Requirement 13.6 (q)

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60601-2-50

May 2009

ICS 11.040.60

Supersedes EN 60601-2-50:2002

English version

**Medical electrical equipment -
Part 2-50: Particular requirements
for the basic safety and essential performance
of infant phototherapy equipment
(IEC 60601-2-50:2009)**

Appareils électromédicaux -
Partie 2-50: Exigences particulières
pour la sécurité de base
et les performances essentielles
des appareils de photothérapie
pour nouveau-nés
(CEI 60601-2-50:2009)

Medizinische elektrische Geräte -
Teil 2-50: Besondere Festlegungen
für die Sicherheit einschließlich
der wesentlichen Leistungsmerkmale
von Säuglings-Phototherapiegeräten
(IEC 60601-2-50:2009)

This European Standard was approved by CENELEC on 2009-05-01. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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

CENELEC

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

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

Foreword

The text of document 62D/736A/FDIS, future edition 2 of IEC 60601-2-50, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-50 on 2009-05-01.

This European Standard supersedes EN 60601-2-50:2002.

Specific technical changes from EN 60601-2-50:2002 include:

- requiring graphical representation of the spectral irradiance in the instructions for use (this was previously optional; see 201.7.9.2.5 b));
- requirements for support and mounting brackets for ACCESSORIES (see 201.9.8.101);
- requiring restoration of any preset values upon interruption and restoration of the power supply, if applicable (see 201.11.8); and
- corrections to the first four exposure limits (ELs) listed in Table AA.1.

Minor changes from EN 60601-2-50:2002 include replacing the figure containing the eye protection symbol with a reference to this same symbol in IEC 60878 (see 201.7.2.101), defining an INFANT (see 201.3.202) and clarifying the titles for subclauses 201.5.4.102 and 201.5.4.103.

The main purpose, however, is to provide consistency with the general standard EN 60601-1:2006. This EN 60601-2-50:2009 further provides consistency with the four other particular standards related to pediatric equipment for which the committee is responsible.

The following dates were fixed:

- latest date by which the EN has to be implemented
at national level by publication of an identical
national standard or by endorsement (dop) 2010-02-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2012-05-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-50:2009 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60335-2-27	NOTE Harmonized as EN 60335-2-27:1997 (not modified).
IEC 60601-2-19	NOTE Harmonized as EN 60601-2-19:2009 (not modified).
IEC 60601-2-21	NOTE Harmonized as EN 60601-2-21:2009 (not modified).
ISO 3743-1	NOTE Harmonized as EN ISO 3743-1:1995 (not modified).

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Annex ZA of EN 60601-1:2006 applies, except as follows:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Replace the reference to IEC 60601-1-2 by:</i>				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007

Annex ZZ (informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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IEC 60601-2-50

Edition 2.0 2009-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Medical electrical equipment –
Part 2-50: Particular requirements for the basic safety and essential performance
of infant phototherapy equipment**

**Appareils électromédicaux –
Partie 2-50: Exigences particulières pour la sécurité de base et les performances
essentielles des appareils de photothérapie pour nouveau-nés**



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- Service Clients: www.iec.ch/webstore/custserv/custserv_entry-f.htm

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IEC 60601-2-50

Edition 2.0 2009-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Medical electrical equipment –
Part 2-50: Particular requirements for the basic safety and essential performance
of infant phototherapy equipment**

**Appareils électromédicaux –
Partie 2-50: Exigences particulières pour la sécurité de base et les performances
essentiels des appareils de photothérapie pour nouveau-nés**

INTERNATIONAL
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COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-2-50 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 2000. This edition constitutes a technical revision.

Specific technical changes from the previous edition of this particular standard include:

- requiring graphical representation of the spectral irradiance in the instructions for use (this was previously optional; see 201.7.9.2.5 b));
- requirements for support and mounting brackets for ACCESSORIES (see 201.9.8.101);
- requiring restoration of any preset values upon interruption and restoration of the power supply, if applicable (see 201.11.8); and
- corrections to the first four exposure limits (ELs) listed in Table AA.1.

Minor changes from the previous edition of this particular standard include replacing the figure containing the eye protection symbol with a reference to this same symbol in IEC 60878 (see 201.7.2.101), defining an INFANT (see 201.3.202) and clarifying the titles for subclauses 201.5.4.102 and 201.5.4.103.

The main purpose of this new edition, however, is to provide consistency with the third edition of the general standard. This edition further provides consistency with the four other particular standards related to pediatric equipment for which the committee is responsible.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/736A/FDIS	62D/765/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

The contents of the corrigendum of August 2010 have been included in this copy.

INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of INFANT PHOTOTHERAPY EQUIPMENT.

This particular standard amends and supplements IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

The requirements are followed by specifications for the relevant tests.

A general guidance and rationale for the requirements of this particular standard are given in Annex AA.

It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of this particular standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment

201.1 Scope, object and related standards

Clause 1 of the general standard¹⁾ applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of INFANT PHOTOTHERAPY EQUIPMENT, as defined in 201.3.203 of this standard, also referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This particular standard specifies safety requirements for INFANT PHOTOTHERAPY EQUIPMENT, but alternate methods of compliance with a specific clause by demonstrating equivalent safety will not be judged as non-compliant if the MANUFACTURER has demonstrated in his RISK MANAGEMENT FILE that the RISK presented by the HAZARD has been found to be of an acceptable level when weighed against the benefit of treatment from the device.

This particular standard does not apply to:

- devices supplying heat via BLANKETS, PADS or MATTRESSES in medical use, for information see IEC 80601-2-35;
- INFANT INCUBATORS; for information see IEC 60601-2-19;
- INFANT TRANSPORT INCUBATORS; for information, see IEC 60601-2-20;
- INFANT RADIANT WARMERS; for information see IEC 60601-2-21.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for INFANT PHOTOTHERAPY EQUIPMENT (as defined in 201.3.203), which reduce the safety HAZARDS to PATIENTS and OPERATORS as much as possible and to specify tests for demonstrating compliance with these requirements.

¹⁾ The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

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