

CONSOLIDATED VERSION

VERSION CONSOLIDÉE



**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**



THIS PUBLICATION IS COPYRIGHT PROTECTED
Copyright © 2016 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'IEC ou du Comité national de l'IEC du pays du demandeur. Si vous avez des questions sur le copyright de l'IEC ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de l'IEC de votre pays de résidence.

IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

IEC Catalogue - webstore.iec.ch/catalogue

The stand-alone application for consulting the entire bibliographical information on IEC International Standards, Technical Specifications, Technical Reports and other documents. Available for PC, Mac OS, Android Tablets and iPad.

IEC publications search - www.iec.ch/searchpub

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and also once a month by email.

Electropedia - www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing 20 000 terms and definitions in English and French, with equivalent terms in 15 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary

65 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: csc@iec.ch.

A propos de l'IEC

La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC

Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Catalogue IEC - webstore.iec.ch/catalogue

Application autonome pour consulter tous les renseignements bibliographiques sur les Normes internationales, Spécifications techniques, Rapports techniques et autres documents de l'IEC. Disponible pour PC, Mac OS, tablettes Android et iPad.

Recherche de publications IEC - www.iec.ch/searchpub

La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études,...). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished

Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et aussi une fois par mois par email.

Electropedia - www.electropedia.org

Le premier dictionnaire en ligne de termes électroniques et électriques. Il contient 20 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans 15 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

Glossaire IEC - std.iec.ch/glossary

65 000 entrées terminologiques électrotechniques, en anglais et en français, extraites des articles Termes et Définitions des publications IEC parues depuis 2002. Plus certaines entrées antérieures extraites des publications des CE 37, 77, 86 et CISPR de l'IEC.

Service Clients - webstore.iec.ch/csc

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: csc@iec.ch.

CONSOLIDATED VERSION

VERSION CONSOLIDÉE



**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**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.60

ISBN 978-2-8322-3380-1

**Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.**

Currently in preview, click buy full version

REDLINE VERSION

VERSION REDLINE



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

CONTENTS

FOREWORD.....	3
INTRODUCTION.....	6
201.1 Scope, object and related standards	7
201.2 Normative references	9
201.3 Terms and definitions	9
201.4 General requirements	10
201.5 General requirements for testing of ME EQUIPMENT.....	11
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	11
201.7 ME EQUIPMENT identification, marking and documents.....	11
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	14
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	14
201.10 Protection against unwanted and excessive radiation HAZARDS	15
201.11 Protection against excessive temperatures and other HAZARDS	16
201.12 Accuracy of controls and instruments and protection against hazardous outputs.....	16
201.13 HAZARDOUS SITUATIONS and fault conditions.....	19
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	19
201.15 Construction of ME EQUIPMENT.....	19
201.16 ME SYSTEMS	20
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	20
202 Electromagnetic compatibility	20
Annexes	20
Annex AA (informative) Particular guidance and rationale	21
Bibliography	26
Index of defined terms used in this particular standard	28
Figure 201.101 – Example of a measuring grid.....	17
Figure 201.102 – Layout of weight test devices	19
Table 201.101 – List of symbols, abbreviations and acronyms	10
Table AA.1 – Ionizing radiation exposure limits and spectral weighting function.....	24

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.
- 2) The formal decisions or agreements of IEC on technical matters express, as far as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with an IEC Publication.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative References cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 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.

DISCLAIMER

This Consolidated version is not an official IEC Standard and has been prepared for user convenience. Only the current versions of the standard and its amendment(s) are to be considered the official documents.

This Consolidated version of IEC 60601-2-50 bears the edition number 2.1. It consists of the second edition (2009-03) [documents 62D/736A/FDIS and 62D/765/RVD], its corrigendum 1 (2010-08) and its amendment 1 (2016-04) [documents 62D/1327/FDIS and 62D/1348/RVD]. The technical content is identical to the base edition and its amendment.

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

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.

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 the base publication and its amendment will remain unchanged until the stability 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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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*.