

CONSOLIDATED VERSION

VERSION CONSOLIDÉE



**Medical electrical equipment –
Part 2-41: Particular requirements for the basic safety and essential performance
of surgical luminaires and luminaires for diagnosis**

**Appareils électromédicaux –
Partie 2-41: Exigences particulières pour la sécurité de base et les performances
essentielles des éclairages chirurgicaux et des éclairages de diagnostic**

<https://standards.iteh.ai/standards/iec/ics/3781-8358-4d8c-8c7e-b23f44b86d90/iec-60601-2-41-2009>



THIS PUBLICATION IS COPYRIGHT PROTECTED
Copyright © 2013 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 la CEI ou du Comité national de la CEI du pays du demandeur.
Si vous avez des questions sur le copyright de la CEI ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de la CEI 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.

Useful links:

IEC publications search - www.iec.ch/searchpub

The advanced search enables you 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 on-line and also once a month by email.

Electropedia - www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing more than 30 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary (IEV) on-line.

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 la CEI

La Commission Electrotechnique Internationale (CEI) 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 CEI

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

Liens utiles:

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

La recherche avancée vous permet de trouver des publications CEI 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.

Just Published CEI - webstore.iec.ch/justpublished

Restez informé sur les nouvelles publications de la CEI. 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 au monde de termes électroniques et électriques. Il contient plus de 30 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans les langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (VEI) en ligne.

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 2-41: Particular requirements for the basic safety and essential performance
of surgical luminaires and luminaires for diagnosis**

**Appareils électromédicaux –
Partie 2-41: Exigences particulières pour la sécurité de base et les performances
essentielle des éclairages chirurgicaux et des éclairages de diagnostic**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.20; 11.040.55; 11.040.99

ISBN 978-2-8322-1184-7

**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.**

Withdrawn

iTech Standards
(<https://standards.iteh.ai>)
Document Preview

[IEC 60601-2-41:2009](https://standards.iteh.ai/standards/iec/adc3781-8358-4d8c-8c7e-b23f44b86d90/iec-60601-2-41-2009)

<https://standards.iteh.ai/standards/iec/adc3781-8358-4d8c-8c7e-b23f44b86d90/iec-60601-2-41-2009>

REDLINE VERSION

VERSION REDLINE



**Medical electrical equipment –
Part 2-41: Particular requirements for the basic safety and essential performance
of surgical luminaires and luminaires for diagnosis**

**Appareils électromédicaux –
Partie 2-41: Exigences particulières pour la sécurité de base et les performances
essentielles des éclairages chirurgicaux et des éclairages de diagnostic**

<https://standards.iteh.ai/en/standards/iec/60601-2-41-2009>

CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
INTRODUCTION TO THE AMENDMENT	7
201.1 Scope, object and related standards.....	8
201.2 Normative references	9
201.3 Terms and definitions	10
201.4 General requirements	14
201.5 General requirements for testing of ME EQUIPMENT.....	14
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	14
201.7 ME EQUIPMENT identification, marking and documents.....	15
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	16
201.9 Protection against mechanical hazards of ME EQUIPMENT and ME SYSTEMS	16
201.10 Protection against unwanted and excessive radiation HAZARDS.....	20
201.11 Protection against excessive temperatures and other HAZARDS.....	20
201.12 Accuracy of controls and instruments and protection against hazardous outputs.....	21
201.13 HAZARDOUS SITUATIONS and fault conditions.....	34
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	34
201.15 Construction of ME EQUIPMENT.....	34
201.16 ME SYSTEMS	34
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	34
Annex AA (informative) Guidance and rationale for particular clauses and subclauses.....	36
Bibliography.....	39
Index of defined terms	40
Figure 201.101 – Example of power supplies for SURGICAL LUMINAIRES.....	11
Figure 201.102 – DETACHABLE HANDLE attachment and detachment tests.....	17
Figure 201.103 – Test for ease of motion.....	19
Figure 201.104 – Light distribution.....	23
Figure 201.105 – CENTRAL ILLUMINANCE measurement.....	25
Figure 201.106 – Measurements of LIGHT FIELD DIAMETER and diameter at 50 % of CENTRAL ILLUMINANCE	25
Figure 201.107 – Illuminance measurement with one mask.....	26
Figure 201.108 – Illuminance measurement with two masks	26
Figure 201.109 – Illuminance measurement with four different positions of the two masks.....	27
Figure 201.110 – Tube for illuminance measurement.....	28
Figure 201.111 – Detail of the inner surface of the tube (example)	28
Figure 201.112 – Illuminance measurement at the bottom of a cavity, with one mask	29
Figure 201.113 – Illuminance measurement at the bottom of a cavity, with two masks	30
Figure 201.114 – Illuminance measurement at the bottom of a cavity, with four different positions of the two masks.....	31
Figure 201.115 – Measurement of DEPTH OF ILLUMINATION	32

Figure AA.1 – Changeover cycle to an emergency backup system	38
Table 201.101 – Classification of SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS.....	13
Table 201.102 – Distributed ESSENTIAL PERFORMANCE requirements	13
Table 201.103 – Allowable maximum temperatures for ME EQUIPMENT parts that are likely to be touched.....	20

Withdrawing

iTech Standards
(<https://standards.iteh.ai>)
Document Preview

IEC 60601-2-41:2009
<https://standards.iteh.ai/cou/standards/iec/acs/3781-8358-4d8c-8c7e-b23f44b86d90/iec-60601-2-41-2009>

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis**

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, 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 nearly 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.

This Consolidated version of IEC 60601-2-41 bears the edition number 2.1. It consists of the second edition (2009) [documents 62D/773/FDIS and 62D/787/RVD] and its amendment 1 (2013) [documents 62D/1081/FDIS and 62D/1097/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 and deletions are displayed in red, with deletions being struck through. A separate Final version with all changes accepted is available in this publication.

This publication has been prepared for user convenience.

International standard IEC 60601-2-41 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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 publication using a colour printer.

INTRODUCTION

This particular standard concerns the basic safety and essential performance of SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS.

It amends and supplements IEC 60601-1 (third Edition 2005), hereinafter referred to as the general standard.

The requirements of this particular standard take priority over those of the general standard, entitled "Medical electrical equipment Part 1: General requirements for basic safety and essential performance.

Withdrawing

iTech Standards
(<https://standards.iteh.ai>)
Document Preview

[IEC 60601-2-41:2009](https://standards.iteh.ai/standards/iec/acc/3781-8358-4d8c-8c7e-b23f44b86d90/iec-60601-2-41-2009)

<https://standards.iteh.ai/standards/iec/acc/3781-8358-4d8c-8c7e-b23f44b86d90/iec-60601-2-41-2009>

INTRODUCTION TO THE AMENDMENT

The purpose of this amendment is to address comments received during the process of harmonizing the standard in Europe, update defined terms, improve terminology usage and expand the rationale for the Scope in Annex AA to take these changes into account.

Withdrawing

iTech Standards
(<https://standards.iteh.ai>)
Document Preview

<https://standards.iteh.ai/coutry/standards/iec/acs3781-8358-4d8c-8c7e-b23f44b86d90/iec-60601-2-41-2009>

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis

201.1 Scope, object and related standards

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

201.1.1 *Scope

Replacement:

This particular standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of SURGICAL LUMINAIRES AND LUMINAIRES FOR DIAGNOSIS, hereafter referred to as ME EQUIPMENT.

This particular standard does not apply to

- headlights;
- endoscopes, laparoscopes and their light sources, which are covered by IEC 60601-2-18;
- luminaires used in dentistry, which are covered by ISO 9680;
- luminaires for general purposes, which are covered by IEC 60598-2-1 and IEC 60598-2-4;
- luminaires dedicated to therapeutic purposes;
- special purpose lights with different conditions of use such as UV lights for dermatological diagnosis, slit lamps for ophthalmology, lights for surgical microscopes and lights for surgical navigation systems;
- lights connected to surgical instruments;
- luminaires of an emergency lighting, which are covered by IEC 60598-2-22.

NOTE See also 4.2 of the general standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS as defined in 201.3.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

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

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

Clause 2 of the general standard applies except as follows:

Addition:

IEC 60417, *Graphical symbols for use on equipment*

IEC 60598-2-9, *Luminaires – Part 2: Particular requirements. Section Nine: Photo and film luminaires (non-professional)*

ISO 11664-1, *Colorimetry – Part 1: CIE standard colorimetric observers*

CIE 13.3, *Method of Measuring and Specifying Colour Rendering Properties of Light Sources*

CIE 15, *Colorimetry*

CIE 69, *Methods of characterizing illuminance meters and luminance meters: Performance, characteristics and specifications*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:~~2005~~, apply, except as follows:

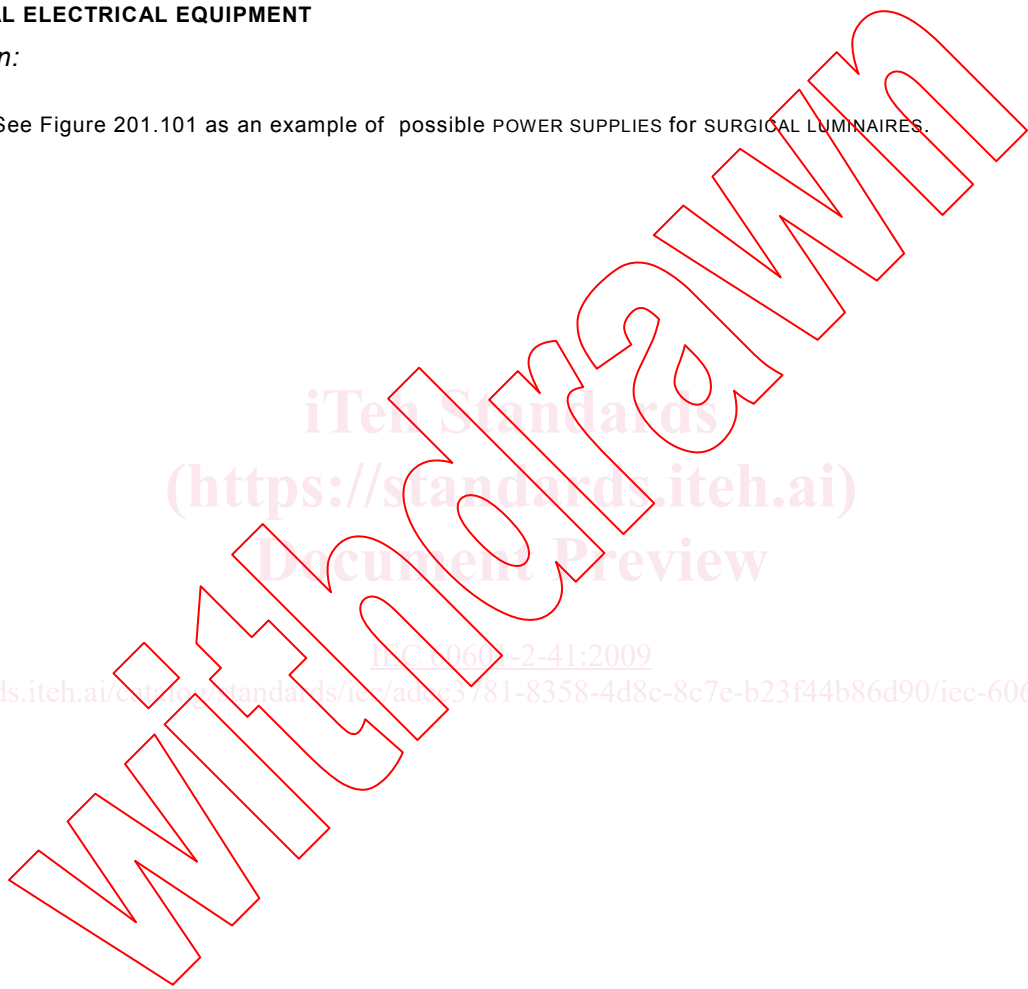
NOTE An index of defined terms is found beginning on page ~~39~~ 40.

201.3.63

MEDICAL ELECTRICAL EQUIPMENT

Addition:

NOTE See Figure 201.101 as an example of possible POWER SUPPLIES for SURGICAL LUMINAIRES.



iTech Standards
(<https://standards.iteh.ai>)
Document Preview

<https://standards.iteh.ai/cou/standards/iec/acc/3781-8358-4d8c-8c7e-b23f44b86d90/iec-60601-2-41-2009>