IEC 60601-2-41

Edition 2.1 2013-10

CONSOLIDATED VERSION

VERSION CONSOLIDÉE

colour inside

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

IEC 60601-2-41:2009+A1:2013

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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.
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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.

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 An0nex AA to take these changes into account.

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 standard[1)] 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.

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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.

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MEDICAL ELECTRICAL EQUIPMENT

Addition:

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