SLOVENSKI STANDARD
SIST EN IEC 60601-2-41:2022

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Nadomešča:
SIST EN 60601-2-41:2010
SIST EN 60601-2-41:2010/A1:2015
SIST EN 60601-2-41:2010/A11:2012

Medicinska električna oprema - 2-41. del: Posebne zahteve za osnovno varnost in bistvene lastnosti kirurških in diagnostičnih svetilk (IEC 60601-2-41:2021)

Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2021)

Medizinische elektrische Geräte - Teil 2-41: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Operationsleuchten und Untersuchungsleuchten (IEC 60601-2-41:2021)

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 60601-2-41:2021)

Ta slovenski standard je istoveten z: **EN IEC 60601-2-41:2021**

ICS:

11.040.30	Operacijski instrumenti in materiali	Surgical instruments and materials
11.040.55	Diagnostična oprema	Diagnostic equipment
29.140.40	Svetila	Luminaires

SIST EN IEC 60601-2-41:2022 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60101-2-41

December 2021

ICS 11.040.20; 11.040.55; 11.040.99

Supersedes EN 60601-2-41:2009 and all of its amendments and corrigenda (if any)

English Version

Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2021)

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This European Standard was approved by CENELEC on 2021-10-08. 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, 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: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 62D/1859/FDIS, future edition 3 of IEC 60601-2-41, 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 IEC 60101-2-41:2021.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2022–07–08
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024–10–08

This document supersedes EN 60601-2-41:2009 and all of its amendments and corrigenda (if any).

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

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 60601-2-41:2021 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 60364-7-710:2002	NOTE Harmonized as HD 60364-7-710:2012 (modified)
IEC 60598-1	NOTE Harmonized as EN IEC 60598-1
IEC 60598-2-1	NOTE Harmonized as EN IEC 60598-2-1
IEC 60598-2-4	NOTE Harmonized as EN 60598-2-4
IEC 60598-2-22	NOTE Harmonized as EN 60598-2-22
IEC 60598-2-25	NOTE Harmonized as EN 60598-2-25
IEC 60601-1-10	NOTE Harmonized as EN 60601-1-10
IEC 60601-2-18	NOTE Harmonized as EN 60601-2-18
IEC 60601-2-50	NOTE Harmonized as EN IEC 60601-2-50
ISO 9680	NOTE Harmonized as EN ISO 9680

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1 Where 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.

The Annex ZA of EN 60601-1:2006 and EN 60601-1:2006/A1:2013 apply with the following changes:

Publication	Year	Title	EN/HD	Year
Add the following references:				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
IEC 62471 (mod)	2006	Photobiological safety of lamps and lamp systems	EN 62471	2008
ISO/CIE 11664-1	-	Colorimetry - Part 1: CIE standard colorimetric observers	EN ISO/CIE 11664-1	-
ISO/CIE 19476	2014	Characterization of the performance of illuminance meters and luminance meters	-	-
ANSI C78.377	2017	Specifications for the Chromaticity of Solid-State Lighting (SSL) Products	-	-
CIE 13.3	1995	Method of measurement and specifying colour rendering properties of light sources	-	-
CIE 15	2018	Colorimetry	-	-

Publication	Year	Title	EN/HD	Year
Replace the following references:				
IEC 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529	1991
-	-		+ corrigendum May	1993
+ A1	1999		+ A1	2000
+ A2	2013		+ A2	2013

IEC 60601-1-2	2014	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
IEC 60601-1-6	2010	Medical electrical equipment - Part 1–6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010

IEC 60601-2-41

Edition 3.0 2021-09

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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, 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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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.

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

An annex in this publication contains an embedded Microsoft Excel file intended to help in organizing data and calculating exposures associated with photobiological HAZARDS. This file is intended to be used as a complement and does not form an integral part of the publication.

This third edition cancels and replaces the second edition published in 2009 and Amendment 1:2013. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) revised the statement of essential performance;
b) added exposure limits, test conditions, calculation methods and safety warnings related to photobiological hazards;
c) removed the terms “MINOR SURGICAL LUMINAIRES” and “MAJOR SURGICAL LUMINAIRES”;

d) added definitions of MAXIMUM ILLUMINANCE DISTANCE and REFERENCE DISTANCE and allowed MANUFACTURERS to measure some performance characteristics at the REFERENCE DISTANCE that they specify;

e) replaced the region of acceptable chromaticity in (x,y) colour space with a requirement for $D_{u,v}$;

f) added a requirement for acceptable drift of the lighthead when attached to the suspension system;

g) added a requirement for fluid ingress protection;

h) revised Table 201.101 of IEC 60601-2-41:2009 and IEC 60601-2-41:2009/AMD1:2013 and moved it to Annex BB;

i) specified a new device for measuring SHADOW DILUTION in a simulated cavity;

j) specified test conditions for luminaires equipped with distance sensors.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
62D/1859/FDIS	62D/1879/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

In this document, 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 document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– "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 document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific publication. At this date, the document will be

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

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

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 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, hereinafter referred to as the "general standard".

The requirements of this particular standard take priority over those of the general standard.

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 part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS, hereafter 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.

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 light sources intended solely for decontamination of air and surfaces, UV lights for dermatological diagnosis, slit lamps for ophthalmology, lights for surgical microscopes and lights for surgical navigation systems;
- lights connected to surgical instruments, such as luminous retractors;
- luminaires for emergency lighting, which are covered by IEC 60598-2-22.

NOTE See also 4.2 of the general standard.

SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS are medical devices and not general lighting equipment.

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.

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[1] The general standard is IEC 60601-1 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-3, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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.

For brevity, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are 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 document 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 IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard and applicable collateral standards are specified using 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, since definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document 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 document" is used to refer to the general standard, any applicable collateral standards and this particular standard taken together.