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BSI Standards Publication

Medical electrical equipment

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

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National foreword

This British Standard is the UK implementation of EN IEC 60601-2-41:2021. It is identical to IEC 60601-2-41:2021. It supersedes BS EN 60601-2-41:2009+A1:2015, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/62/4, Electromedical equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Amendments/corrigenda issued since publication

Date	Text affected
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EUROPÄISCHE NORM

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)

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

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.

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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, 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

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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 60601-2-41:2021.

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

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(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:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Add the following references:</i>				
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	-	-

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

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		General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests		
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

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CONTENTS

FOREWORD.....	4
INTRODUCTION.....	7
201.1 Scope, object and related standards	8
201.2 Normative references	10
201.3 Terms and definitions.....	10
201.4 General requirements.....	15
201.5 General requirements for testing ME EQUIPMENT.....	15
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	16
201.7 ME EQUIPMENT identification, marking and documents.....	17
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	19
201.9 Protection against mechanical hazards of ME EQUIPMENT and ME SYSTEMS.....	19
201.10 * Protection against unwanted and excessive radiation HAZARDS	23
201.11 Protection against excessive temperatures and other HAZARDS.....	38
201.12 Accuracy of controls and instruments and protection against hazardous outputs.....	40
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT.....	41
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	41
201.15 Construction of ME EQUIPMENT	41
201.16 ME SYSTEMS	41
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	42
Annexes	43
Annex AA (informative) Particular guidance and rationale.....	44
Annex BB (informative) Requirements for SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS	50
Annex CC (informative) Technical information for conducting tests	52
Bibliography.....	58
Index of defined terms used in this particular standard.....	59
Figure 201.101 – Examples of providing power to a SURGICAL LUMINAIRE	11
Figure 201.102 – Examples of different distance and illuminance terms.....	14
Figure 201.103 – DETACHABLE HANDLE attachment and detachment tests	20
Figure 201.104 – Test for ease of motion.....	22
Figure 201.105 – Light distribution	25
Figure 201.106 – CENTRAL ILLUMINANCE measurement.....	26
Figure 201.107 – Measurements for determining LIGHT FIELD DIAMETERS d_{10} and d_{50}	26
Figure 201.108 – Illuminance measurement with one mask.....	27
Figure 201.109 – Illuminance measurement with two masks	28
Figure 201.110 – Illuminance measurement with four different positions of two masks.....	29
Figure 201.111 – Simulated cavity for illuminance measurements.....	30
Figure 201.112 – Illuminance measurement at the bottom of a simulated cavity, with one mask.....	30
Figure 201.113 – Illuminance measurement at the bottom of a simulated cavity, with two masks.....	31
Figure 201.114 – Illuminance measurement at the bottom of a simulated cavity, with four different positions of two masks	32

This is a preview of "BS EN IEC 60601-2-41...". [Click here to purchase the full version from the ANSI store.](#)

Figure 201.115 – Measurement of DEPTH OF ILLUMINATION	33
Figure 201.116 – Caution symbol for hot surface	39
Figure CC.1 – Location of the illuminance meter and mask on the luminaire	54
Figure CC.2 – Movement of the illuminance meter and mask on the luminaire	55
Figure CC.3 – Location of the spectrometer and mask on the luminaire	55
Figure CC.4 – Test conditions for measuring illuminance at 500 mm.....	56
Figure CC.5 – Test method for maintaining the measurement distance	56
Table 23 – Allowable maximum temperatures for ME EQUIPMENT parts that are likely to be touched.....	39
Table AA.1 – Summary of photobiological HAZARDS and exposure limits.....	45
Table BB.1 – Summary of requirements for SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS	50

This is a preview of "BS EN IEC 60601-2-41...". [Click here to purchase the full version from the ANSI store.](#)

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, 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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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";

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- 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 lighthouse 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.

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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.

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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.

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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

201.1 Scope, object and related standards

Clause 1 of the general standard¹ 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.

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.*