SLOVENSKI STANDARD
SIST EN 60601-2-41:2010/A1:2015

01-september-2015

Medicinska električna oprema - 2-41. del: Posebne zahteve za osnovno varnost in bistvene lastnosti kirurških in diagnostičnih svetilk - Dopolnilo A1

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

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

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

Ta slovenski standard je istoveten z: **EN 60601-2-41:2009/A1:2015**

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 60601-2-41:2010/A1:2015 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60601-2-41:2009/A1

May 2015

ICS 11.040.20; 11.040.55; 11.040.99

English Version

Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2009/A1:2013)

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)

Medizinische elektrische Geräte - Teil 2-41: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Operationsleuchten und Untersuchungsleuchten
(IEC 60601-2-41:2009/A1:2013)

This amendment A1 modifies the European Standard EN 60601-2-41:2009; it was approved by CENELEC on 2015-04-14. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 amendment 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 60601-2-41:2009/A1:2015 E

Foreword

The text of document 62D/1081/FDIS, future IEC 60601-2-41:2009/A1, 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 60601-2-41:2009/A1:2015.

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) 2016-01-14
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-04-14

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 60601-2-41:2009/A11:2011.

Endorsement notice

The text of the International Standard IEC 60601-2-41:2009/A1:2013 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 60601-2-41:2009, the following note has to be added for the standard indicated:

IEC 60601-2-50	NOTE	Harmonized as EN 60601-2-50:2009 (not modified).

IEC 60601-2-41

Edition 2.0 2013-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX E

ICS 11.040.20; 11.040.55; 11.040.99

ISBN 978-2-8322-1153-3

FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62D/1081/FDIS	62D/1097/RVD

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

The committee has decided that the contents of this amendment and the base publication 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.

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

---

201.1 Scope

Replace the existing footnote 1 by the following:

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

201.3 Terms and definitions

Replace the existing first sentence by the following:

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

Renumber existing terms and definitions 201.3.101 to 201.3.112 as 201.3.201 to 201.3.212.

201.3.202 (*previously 201.3.102)*
DEPTH OF ILLUMINATION

Replace the existing term by the following:

DEPTH OF ILLUMINATION ABOVE 60 %

Add the following new term and definition:

201.3.213
SINGLE SURGICAL LUMINAIRE
illumination device used for surgery that aims a light beam independently of other light beams

Table 201.101 Classification of SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS

Replace, in the second column of the row "FAIL SAFE", the existing reference to "201.3.103" by the new reference "201.3.203".

Add, after the existing row "SHADOW DILUTION, the following new row:

DEPTH OF ILLUMINATION ABOVE 60 %	201.12.1.102.1.1 d)	No requirement	Specified [e]	Specified [e]

Add, at the end of the table, the following new table footnote:

[e] Working range where the illuminance reaches at least 60 % of the central illuminance.

201.5.4 Other conditions

Replace, in item aa), the word "pre-aging" with "aging" three times.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Replace the existing second dashed item with the following:

– CENTRAL ILLUMINANCE E_c and the corresponding measurement distance and corresponding correlated colour temperature;

Replace the existing sixth dashed item with the following:

– correlated colour temperature and corresponding general colour rendering index R_a and the corresponding specific index R_9;

201.12.1.102.1.1 General requirements

*Replace, in item a), the defined term "*single SURGICAL LUMINAIRE*" with the same term entirely in small caps: "*SINGLE SURGICAL LUMINAIRE*".*

Replace, in point d), the existing text of the third and fourth paragraphs, ("The instructions for use … expressed as percentages)" by the following new text aligned with the left margin:

The information about LIGHT FIELD DIAMETER to be contained in the instructions for use according to 201.7.9.2.1 shall indicate the values of

– LIGHT FIELD DIAMETER d_{10};
– diameter d_{50} where the illuminance reaches 50 % of CENTRAL ILLUMINANCE.

The information about SHADOW DILUTION to be contained in the instructions for use according to 201.7.9.2.1 shall indicate the values of

– remaining illuminance when the beam is obstructed by one mask,
– remaining illuminance when the beam is obstructed by two masks,
– remaining illuminance at the bottom of a standardized tube (inside),
– remaining illuminance at the bottom of a standardized tube when the beam is obstructed by one mask,
– remaining illuminance at the bottom of a standardized tube when the beam is obstructed by two masks

All values of remaining illuminance are relative to CENTRAL ILLUMINANCE without obstruction by masks or tube and are expressed as percentages.

201.12.1.102.1.2 General conditions for tests

Replace, in the second sentence of the first paragraph, the reference to "4.5" of the general standard with "5.3".

Add, after the first paragraph, the following new paragraph:

Measurements should be performed after the light has been operated at highest intensity for at least one hour.

Add, after the existing fifth paragraph, the following new paragraph:

All tests shall be performed without any additional user-initiated adjustments (such as re-focussing).

Annex AA – Guidance and rationale for particular clauses and subclauses

Subclause 201.1.1 SCOPE

Add, after the last paragraph, the following new text:

Surgical luminaires are intended to produce a high illumination in the visible range (400 nm – 780 nm). They are not intended to produce invisible and potentially harmful UV radiation. However, in order not to lose too much of the visible blue light output, the cut-off filtering for UV may allow some output in the longest wavelength range of the UVA close to the visible blue boundary of 400 nm.

If measured with a radiometer that produces a flat wavelength response, a maximum unweighted UV irradiance of 10 W/m^2 in the range from 300 nm – 400 nm therefore is allowed.

Other IEC standards exist that also state maximum UV irradiance values. An example is IEC 60601-2-50 that allows for a maximum effective UV irradiance of 0,1 mW/m^2. This value is 5 orders of magnitude lower than the 10 W/m^2 listed in IEC 60601-2-41. The difference lies in the term effective irradiance. An effective UV irradiance or UV dose value indicates that a spectral weighting function (like, e.g. the ICNIRP combined action spectrum for skin and eyes) has been applied to the actual irradiance as measured by a radiometer with a flat spectral response.