Elektrilised meditsiiniseadmed. Osa 2-41: Erinõuded kirurgiliste lampide ja diagnoosilampide ohutusele

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 60601-2-41:2002 sisaldab Euroopa standardi EN 60601-2-41:2000 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-41:2002 consists of the English text of the European standard EN 60601-2-41:2000.
Standard on kinnitatud Eesti Standardikeskuse 18.12.2002 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 18.12.2002 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 14.06.2000.	Date of Availability of the European standard text 14.06.2000.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.30, 11.040.55, 11.040.99

electrical medical e, instructions, medicine, operating requirements, protection against electric, safety, safety devices, safety engineering, safety requirements, specification (approval), specifications, surgery, surgical equipment, surgical instruments, testing

EUROPEAN STANDARD **EN 60601-2-41**

NORME EUROPÉENNE

EUROPÄISCHE NORM June 2000

ICS 11.040.30; 11.040.55; 11.040.99

English version

Medical electrical equipment
Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
(IEC 60601-2-41:2000)

Appareils électromédicaux
Partie 2-41: Règles particulières de sécurité pour les éclairages chirurgicaux et les éclairages de diagnostic
(CEI 60601-2-41:2000)

Medizinische elektrische Geräte
Teil 2-41: Besondere Festlegungen für die Sicherheit von Operationsleuchten und Untersuchungsleuchten
(IEC 60601-2-41:2000)

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Ref. No. EN 60601-2-41:2000 E

Foreword

The text of document 62D/344/FDIS, future edition 1 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 was approved by CENELEC as EN 60601-2-41 on 2000-04-01.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2001-01-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2003-04-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative and annexes AA and ZB are informative.
Annexes ZA and ZB have been added by CENELEC.

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Endorsement notice

The text of the International Standard IEC 60601-2-41:2000 was approved by CENELEC as a European Standard without any modification.

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Annex ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60417	Series	Graphical symbols for use on equipment	EN 60417	Series
IEC 60598-2-9	1987	Luminaires Part 2: Particular requirements Section 9: Photo and film luminaires (non-professional)	EN 60598-2-9	1989
IEC 60695-1-1	1995	Fire hazard testing Part 1: Guidance for assessing fire hazard of electrotechnical products Section 1: General guidance	EN 60695-1-1[1)]	1995
ISO/CIE 10527	1991	CIE standard colorimetric observers	-	-
CIE 13.3	1995	Method of measuring and specifying colour rendering of light sources	-	-
CIE 15.2	1986	Colorimetry	-	-
CIE 69	1987	Methods of characterizing illuminance meters and luminance meters: Performance, characteristics and specifications	-	-

1) EN 60695-1-1 is replaced by EN 60695-1-1:2000, which is based on IEC 60695-1-1:1999.

Annex ZB (informative)

Other international publications with the references of the relevant European publications

Publication	Year	Title	EN/HD	Year
IEC 60364-7-710	[2]	Electrical installations of buildings Part 7: Requirements for special installations or locations -- Section 710: Medical locations and associated areas	-	-
IEC 60598-1 (mod)	1996	Luminaires Part 1: General requirements and tests	EN 60598-1	1997
IEC 60598-2-1	1979	Part 2: Particular requirements Section 1: Fixed general purpose luminaires	EN 60598-2-1[3]	1989
IEC 60598-2-4	1997	Part 2: Particular requirements Section 4: Portable general purpose luminaires	EN 60598-2-4	1997
IEC 60598-2-22 (mod)	1997	Part 2-22: Particular requirements - Luminaires for emergency lighting	EN 60598-2-22 + corr. February	1998 1999
IEC 60598-2-25 + corr. September	1994 1994	Part 2: Particular requirements Section 25: Luminaires for use in clinical areas of hospitals and health care buildings	EN 60598-2-25	1994
IEC 60601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July	1990 1994
A1	1991		A1 + corr. July	1993 1994
A2 + corr. June	1995 1995		A2 A13	1995 1996
IEC 60601-2-18	1996	Part 2: Particular requirements for the safety of endoscopic equipment	EN 60601-2-18	1996
ISO 9680 + corr. 1	1993 1995	Dental operating light	EN ISO 9680	1996

2) To be published.

3) EN 60598-2-1 includes A1:1987 to IEC 60598-2-1.

INTERNATIONAL STANDARD

IEC 60601-2-41

First edition
2000-02

Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-41:
Règles particulières de sécurité pour les éclairages chirurgicaux et les éclairages de diagnostic

Reference number
IEC 60601-2-41:2000(E)

Numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series.

Consolidated publications

Consolidated versions of some IEC publications including amendments are available. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

Validity of this publication

The technical content of IEC publications is kept under constant review by the IEC, thus ensuring that the content reflects current technology.

Information relating to the date of the reconfirmation of the publication is available in the IEC catalogue.

Information on the subjects under consideration and work in progress undertaken by the technical committee which has prepared this publication, as well as the list of publications issued, is to be found at the following IEC sources:

- **IEC web site***
- **Catalogue of IEC publications**
  Published yearly with regular updates
  (On-line catalogue)*
- **IEC Bulletin**
  Available both at the IEC web site* and as a printed periodical

Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams.*

* See web site address on title page.

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE R

For price, see current catalogue

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The 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 the 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 National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

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

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

FDIS	Report on voting
62D/344/FDIS	62D/352/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

Annex AA is for information only.

In this Particular Standard the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type;
– notes, explanations, advice, introductions, general statements, exceptions and references: in smaller type;
– *test specifications: in italic type;*
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD IEC 60601-1 OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that this publication remains valid until 2005.

At this date, in accordance with the committee's decision, the publication will be

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

A bilingual version of this standard may be issued at a later date.

INTRODUCTION

This Particular Standard concerns the safety of SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS. It amends and supplements IEC 60601-1 (second edition 1988), 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 safety."*

A "Guidance and rationale" for the requirements of this Particular Standard is included in annex AA.

It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this Standard.

An asterisk (*) inserted before a clause or subclause number indicates that some explanatory notes are given in annex AA at the end of this Particular Standard.

MEDICAL ELECTRICAL EQUIPMENT –

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

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows.

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

This Particular Standard details the requirements to be applied to SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS as defined in 2.101 to 2.105, hereinafter referred to as EQUIPMENT.

This 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 of an emergency lighting, which are covered by IEC 60598-2-22.

NOTE Luminaires used in clinical areas of hospitals other than those defined in 2.101 to 2.105 are covered by IEC 60598-2-25.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of SURGICAL LUMINAIRES and LUMINAIRES FOR DIAGNOSIS.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 60601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety*, as amended by its amendment 1 (1991) and its amendment 2 (1995).

For brevity, IEC 60601-1 is referred to in this Particular Standard either as the General Standard or as the General Requirement(s).

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. 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 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.

“Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

“Modification” means that the clause or subclause of the General Standard is modified as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc. and additional items aa), bb), etc.

The term “this Standard” is used to make reference to the General Standard and this Particular Standard taken together.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification; where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Additional definitions:

2.101
MAJOR SURGICAL LUMINAIRE
Single luminaire in the PATIENT environment which is FAIL SAFE and provides an adequate CENTRAL ILLUMINANCE to illuminate locally the body of the PATIENT. It is intended to support the treatment and diagnosis, and to be used in operating rooms. See table 101

2.102
MINOR SURGICAL LUMINAIRE (treatment luminaire)
Single luminaire in the PATIENT environment which provides an adequate CENTRAL ILLUMINANCE to illuminate the body of the PATIENT locally. It is intended to be used in operating rooms for diagnosis and treatment which can be interrupted without any hazard for the PATIENT in case of failure of the light. See table 101

2.103
LUMINAIRE FOR DIAGNOSIS
Luminaire to illuminate the body of the PATIENT locally in order to support diagnosis or treatment which could be interrupted without any hazard for the PATIENT in case of failure of the light. It is not intended to be used in operating rooms. See table 101