

INTERNATIONAL STANDARD

NORME INTERNATIONALE



**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**



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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

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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";

- 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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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.

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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.