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STANDARD

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INTERNATIONALE

**60601-2-22**

Third edition  
Troisième édition  
2007-05

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**Medical electrical equipment –**

**Part 2-22:**

**Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment**

**Appareils électromédicaux –**

**Partie 2-22:**

**Règles particulières pour la sécurité de base et les performances essentielles des appareils chirurgicaux, esthétiques, thérapeutiques et de diagnostic à laser**



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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

**MEDICAL ELECTRICAL EQUIPMENT –****Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment**

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International standard IEC 60601-2-22 has been prepared by IEC subcommittee 76: Optical radiation safety and laser equipment.

This third edition cancels and replaces the second edition of IEC 60601-2-22, published in 1995. This edition constitutes a technical revision.

This third edition takes account of the recently published new editions of the General Standard IEC 60601-1 and Group safety publication IEC 60825-1. Additionally, it addresses technical and safety issues which have arisen in the time following the previous second edition.

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

|             |                  |
|-------------|------------------|
| FDIS        | Report on voting |
| 76/359/FDIS | 76/363/RVD       |

Full information on the voting for the approval of this particular 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 2.

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

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
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- “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

The committee has decided that the contents of this publication will remain unchanged until the maintenance result 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

This particular standard amends and supplements IEC 60601-1 (third edition, 2005: *Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance*).

This standard also refers to IEC 60825-1 (2007).

The requirements of this standard are the minimum that need to be complied with, in order to achieve a reasonable level of safety and reliability during operation and application of medical laser equipment.

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. Understanding of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revisions necessitated by changes in clinical practice or by developments in technology.

Withdrawn