

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE

**Medical electrical equipment –  
Part 2-75: Particular requirements for the basic safety and essential performance  
of photodynamic therapy and photodynamic diagnosis equipment**

**Appareils électromédicaux –  
Partie 2-75: Exigences particulières pour la sécurité de base et les performances  
essentielle des appareils de thérapie photodynamique et de diagnostic  
photodynamique**



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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

## MEDICAL ELECTRICAL EQUIPMENT –

**Part 2-75: Particular requirements for the basic safety  
and essential performance of photodynamic therapy  
and photodynamic diagnosis equipment**

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International Standard IEC 60601-2-75 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62D/1477/FDIS	62D/1490/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 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 Clause 7 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;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “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.

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- withdrawn,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

## MEDICAL ELECTRICAL EQUIPMENT –

### Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment

#### 201.1 Scope, object and related standards

Clause 1 of the general standard<sup>1</sup> applies, except as follows:

##### 201.1.1 Scope

*Replacement:*

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS 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.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This document applies to PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT used for compensation or alleviation of disease, injury or disability.

In the case of combined equipment (e.g. equipment additionally provided with a function or an APPLIED PART for the target area) such equipment shall also comply with any particular standard specifying safety requirements for the additional function.

This particular standard does not apply to:

- light therapy equipment intended for use in photothermal ablation, coagulation, and hyperthermia;
- low-level laser therapy equipment not intended for use with a PHOTOSENSITIZER;
- illumination equipment intended for use in observation, monitoring, and diagnosis, not intended for use with a PHOTOSENSITIZER.

<sup>1</sup> The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*