IEC 60601-2-75

Edition 1.0 2017-05

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 essentielles des appareils de thérapie photodynamique et de diagnostic photodynamique

IEC 60601-2-75:2017-05(en-fr)

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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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

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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.

The committee has decided that the contents of this 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.

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[1] 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.

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1 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*.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT [as defined in 201.3.214].

201.1.3 Collateral standards

Addition:

All collateral standards shall be treated as additional clauses to the general standard. Unless modified in the body of this document, all collateral standards apply to this particular standard.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x”, where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). 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 or applicable collateral 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 or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 27.

Clause 2 of the general standard applies, except as follows:

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60601-2-22:2007, *Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment*
IEC 60601-2-22:2007/AMD1:2012

IEC 60601-2-57:2011, *Medical electrical equipment – Part 2-57: Particular requirements for basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use*

IEC 60825-1:2014, *Safety of laser products – Part 1: Equipment classification and requirements*

IEC 62471:2006, *Photobiological safety of lamps and lamp systems*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 apply, except as follows:

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 28.

Addition:

201.3.201
BEAM DELIVERY SYSTEM
optical system which guides the OPTICAL RADIATION from its origin to the WORKING AREA

[SOURCE: IEC 60601-2-22:2007, 201.3.106, modified – “Laser radiation” has been replaced by "OPTICAL RADIATION".]

201.3.202
EXPOSURE DURATION
duration of a pulse, or series, or train of pulses or of continuous emission of OPTICAL RADIATION incident upon the human body

Note 1 to entry: For a single pulse, this is the duration between the half-peak power point of the leading edge and the corresponding point on the trailing edge. For a train of pulses (or subsections of a train of pulses), this is the duration between the first half-peak power point of the leading pulse and the last half-peak power point of the trailing pulse.

[SOURCE: IEC 60825-1:2014, 3.35, modified – “Laser radiation” has been replaced by "OPTICAL RADIATION".]

201.3.203
FLUENCE
quotient of the RADIANT ENERGY of all radiation incident on the outer surface of an infinitely small sphere centered at the given point by the areas of the diametrical cross-section of that sphere

$$H_{e,o} = \frac{dQ_{e,o}}{dA}$$

where

$dQ_{e,o}$ is the RADIANT ENERGY;

dA is the cross sectional area.

Note 1 to entry: SI unit: Joule per square meter (J/m^2)

[SOURCE: Photochem. Photobiol. 2007, 83 [2][2]: 425-432, 2007]

201.3.204
IRRADIANCE
quotient of the RADIANT FLUX incident on an element of the surface containing the point, by the area of that element

$$E = \frac{d\phi}{dA}$$

$d\emptyset$ is the RADIANT FLUX

dA is the area of the element.

Note 1 to entry: Symbol: E

Note 2 to entry: SI unit: watt per square meter (W/m^2).

[SOURCE: IEC 60825-1:2014, 3.43, modified – Addition of "containing the point", a key and a new Note to entry.]

201.3.205
LASER ENERGY
RADIANT ENERGY of the WORKING BEAM, incident on the WORKING AREA

[SOURCE: IEC 60601-2-22:2007, 201.3.111]

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2 Numbers in square brackets refer to the Bibliography.

201.3.206
LASER PRODUCT
any product or assembly of components which constitutes, incorporates or is intended to incorporate a laser or laser system

[SOURCE: IEC 60825-1:2014, 3.48]

201.3.207
LS EQUIPMENT
ME EQUIPMENT which incorporates one or more sources of OPTICAL RADIATION in the wavelength range 200 nm to 3 000 nm, with the exception of laser radiation, and which is intended to create non-visual photo-biological effects in humans or animals for therapeutic, diagnostic, monitoring, cosmetic/aesthetic or veterinary applications

[SOURCE: IEC 60601-2-57:2011, 201.3.208]

201.3.208
OPTICAL RADIATION
electromagnetic radiation with wavelengths between 100 nm and 1 mm

[SOURCE: IEC 60601-2-57:2011, 201.3.211]

201.3.209
OPTICAL RADIATION INDICATOR
visible means which indicates that the PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT makes all persons present in the area aware of the need to take precautions against hazardous OPTICAL RADIATION

201.3.210
OUTPUT
either radiant power or RADIANT ENERGY emitted by PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT

Note 1 to entry: OUTPUT defined in this document includes both the definitions LASER OUTPUT in IEC 60601-2-22:2007, 201.3.113 and LS EQUIPMENT OUTPUT in IEC 60601-2-57:2011, 201.3.209.

201.3.211
OUTPUT POWER
radiant power of the WORKING BEAM, incident on the WORKING AREA

[SOURCE: IEC 60601-2-22:2007, 201.3.114, modified – Replacement of the term "laser power" by "OUTPUT POWER".]

201.3.212
PHOTODYNAMIC DIAGNOSIS
diagnosis using a compound [PHOTOSENSITIZER] that, when exposed to specific wavelengths of light, causes a photonic emission which is targeted to enhance the contrast between diseased and healthy tissue, and which can be used to monitor the PHOTODYNAMIC THERAPY process

Note 1 to entry: PHOTODYNAMIC DIAGNOSIS is defined different from fluorescence contrast imaging (FCI). FCI is contrast enhancing technology not involving the use of a PHOTOSENSITIZER. Since this document addresses only equipment used in combination with a PHOTOSENSITIZER, FCI is outside of the scope of this document.

201.3.213
PHOTODYNAMIC THERAPY
therapy using a PHOTOSENSITIZER that, when exposed to specific wavelengths of light, causes a photochemical reaction which is targeted to lead to a therapeutic effect

201.3.214
PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT
ME EQUIPMENT intended to perform PHOTODYNAMIC THERAPY or provide PHOTODYNAMIC DIAGNOSIS using light-sensitive compounds in combination with devices producing specific wavelengths of light

201.3.215
PHOTOSENSITIZER
a compound that, when exposed to specific wavelengths of light, causes a photochemical reaction and photonic emission

201.3.216
PULSE DURATION
time increment measured between the half-peak power points at the leading and trailing edges of a pulse

[SOURCE: IEC 60825-1:2014, 3.69]

201.3.217
PULSE REPETITION RATE
number of pulses per second of a repetitively pulsed OPTICAL RADIATION

[SOURCE: ISO 11145:2016, 3.52, modified – Remplacement of "laser pulses" by "pulses", and "laser" by "OPTICAL RADIATION".]

201.3.218
RADIANT EXPOSURE
quotient of dQ_e, RADIANT ENERGY incident on an element of the surface containing the point over the given duration, by the area dA of that element

$$H_e = \frac{dQ_e}{dA}$$

where

dQ_e is the the RADIANT ENERGY;

dA is the cross sectional area.

Note 1 to entry: SI unit: Joule per square meter (J/m^2).

201.3.219
REACTIVE OXYGEN
oxygen molecules, ions or radicals that have an unpaired electron, thus rendering them extremely reactive

201.3.220
STAND-BY/READY
modes of operation when mains supply is connected and the mains switch activated, where the STAND-BY mode means that the OPTICAL RADIATION cannot be available even if the control switch is activated, and where the READY mode keeps the PHOTODYNAMIC THERAPY AND

PHOTODYNAMIC DIAGNOSIS EQUIPMENT enabled, so that it is capable of emitting OUTPUT when the control switch is activated

[SOURCE: IEC 60601-2-22:2007, 201.3.118, modified – "OPTICAL RADIATION" substituted for "laser" and "OUTPUT" substituted for "LASER OUTPUT".]

201.3.221
*** TARGET WAVELENGTH**
wavelength at which the PHOTOSENSITIZER causes a photochemical reaction or fluorescence

Note 1 to entry: The MANUFACTURER of the PHOTOSENSITIZER usually defines the TARGET WAVELENGTH and its allowed spectral width. For established PHOTOSENSITIZERS the TARGET WAVELENGTH and its allowed spectral width are usually also published in the literature.

Note 2 to entry: See also 201.12.1.101

201.3.222
WORKING AREA
area which is intended to be irradiated with OUTPUT

[SOURCE: IEC 60601-2-22:2007, 201.3.120, modified – "OUTPUT" substituted for "WORKING BEAM".]

201.4 General requirements

Clause 4 of the general standard applies.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

Addition:

MANUFACTURERS of LASER PRODUCTS shall comply with the classification and labelling requirements of IEC 60825-1:2014. When PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT uses a laser source, it is also a LASER PRODUCT in the understanding of IEC 60825-1:2014.

MANUFACTURERS of intense light products shall associate these devices with a RISK group according to IEC 62471:2006. LS EQUIPMENT for therapeutic or diagnostic purposes shall be associated with a RISK group according to IEC 60601-2-57:2011.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2.2 Identification

Additional subclause:

201.7.2.101 Additional items

If the PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT is LASER PRODUCT, IEC 60601-2-22:2007, 201.7.2.101 applies.

If the PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT is LS EQUIPMENT, IEC 60601-2-57:2011, 201.7.101 applies.

201.7.9.2 Instructions for use

201.7.9.2.1 * General

Addition:

The instructions for use shall give adequate instructions for proper operation, including clear warnings concerning the precautions necessary to avoid possible exposure to hazardous OPTICAL RADIATION.

The instructions for use shall identify the PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT by including, as applicable, the following:

- the PHOTOSENSITIZER(S) and their excitation wavelengths intended for use with the PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT,
- the BEAM DELIVERY SYSTEMS intended for use with the PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT.

NOTE 101 "As applicable" means that the requirement should be performed unless specific justification not to is provided.

NOTE 102 Refer to Annex AA.

201.7.9.2.2 Warning and safety notices

Addition:

The instructions for use shall include (as applicable):

- If the PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT is LASER PRODUCT, IEC 60601-2-22:2007, 201.7.9.2.101 shall be applied;
- If the PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT is LS EQUIPMENT, IEC 60601-2-57:2011, 201.7.9.2.101 shall be applied;
- the classification of the PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT as specified in IEC 60825-1:2014 or IEC 62471:2006;
- information and guidance for regular calibration of the OUTPUT and wavelength of the WORKING BEAM. The information shall include a specification for the measuring equipment, frequency of calibration and any clarification requirements concerning regular calibration of the OUTPUT and wavelength of the WORKING BEAM;
- a note, stating that PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT should be protected against unauthorized use;

  NOTE 101 For example by removal of a key or other similar security means.

- a specification for eye protection for the user and for the PATIENT including a specification for eye protection for the user and for the PATIENT which withstands a continuous irradiation.;

  NOTE 102 Appropriate eye protection for the PATIENT can be different from the eye protection for the USER, for example when the treated area is on the face or in the vicinity of the PATIENT's eye.

  NOTE 103 Refer to 8.4.5.2 of IEC TR 60825-14:2004.

- information on HAZARDS and RISKS associated with the combination of PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT and PHOTOSENSITIZERS;
- HAZARDOUS SITUATIONS resulting from the use of combination equipment;
- a warning to confirm the relationship between the irradiation parameters indicated by the PHOTOSENSITIZER and the parameter settings of the PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT;
- if applicable, a specification for skin protection;
- a note, stating that the PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT shall not be used if the INTENDED USE or the indication for use of the PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT do not coincide with the INTENDED USE or the indication for use of the PHOTOSENSITIZER.

  NOTE 104 "As applicable" means that the requirement should be performed unless specific justification not to is provided.

The user should consult the instructions for use and relevant prescription information of the PHOTOSENSITIZER regarding its INTENDED USE, indication, contraindications and side effects.

Additional subclause:

201.7.9.2.5.101 ME EQUIPMENT description

The instructions for use shall include:

- performance characteristic values including, but not limited to, wavelength, PULSE DURATION, PULSE REPETITION RATE, OUTPUT POWER or energy, WORKING AREA, exposure time and OUTPUT profile;
- maximum OUTPUT POWER or energy.

201.7.9.2.13 Maintenance

Addition:

The instructions for maintenance shall include clear warnings concerning precautions to avoid possible exposure to hazardous OPTICAL RADIATION.

Additional subclause:

201.7.9.2.101 ACCESSORIES, supplementary equipment and material

The instructions for use shall include:

- a description of the BEAM DELIVERY SYSTEMS connected to PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT including the following characteristics when connected:
  - OUTPUT,
  - WORKING AREA,
  - OUTPUT distribution,
  - targeting means for appropriate use,
  - calibration instruction;
- a description of specific eye protection for the PATIENT if different from the eye protection for the user;
- a description of specific endotracheal tubes if relevant for the INTENDED USE.