IEC 60601-2-75

Edition 1.0 2023-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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/AMD1:2023-01(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

AMENDMENT 1

FOREWORD

This amendment has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems.

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

Draft	Report on voting
62D/2006/FDIS	62D/2017/RVD

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

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

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- withdrawn,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

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

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INTRODUCTION to Amendment 1

At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the amendment projects within the IEC 60601-1 series. Those projects were all completed and the amendments published in 2020.

The full list of IEC SC 62D documents that will be amended or revised may be found within the IEC document 62D/1792/DC. The results and comments on the DC may be found within 62D/1808/INF. The review report for this amendment is 62D/1812/RR.

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201.1.1 Scope

Replace the existing footnote 1 with the following:

The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

201.1.4 Particular standards

Replace the first three paragraphs of this subclause with the following:

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

A requirement of a particular standard takes priority over the general standard and applicable collateral standards.

For brevity, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

201.2 Normative references

Replace the existing references to IEC 60601-1 and IEC 60601-2-22 and their amendments with the following new references:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-2-22:2019, *Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment*

201.3 Terms and definitions

Replace the existing first paragraph with the following:

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and the following definitions apply.

201.3.201
BEAM DELIVERY SYSTEM

*Replace, in the source, the reference "*IEC 60601-2-22:2007, 201.3.106" *with "*IEC 60601-2-22:2019, 201.3.205".

201.3.205
LASER ENERGY

Replace the existing definition and source with the following:

RADIANT ENERGY of the WORKING BEAM, incident on the WORKING AREA where the RADIANT ENERGY is the time integral of the radiant flux Φ over a given duration Δt

[SOURCE: IEC 60601-2-22:2019, 201.3.216, modified – Note 1 to entry deleted.]

201.3.207
LS EQUIPMENT

Replace the existing definition and source with the following:

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 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, modified – Deletion of the term "non-visual".]

201.3.210
OUTPUT

Replace the existing Note 1 to entry with the following:

Note 1 to entry: OUTPUT defined in this document includes both the definitions LASER OUTPUT in IEC 60601-2-22:2019, 201.3.216 and IEC 60601-2-22:2019, 201.3.218 and LS EQUIPMENT OUTPUT in IEC 60601-2-57:2011, 201.3.209.

201.3.211
OUTPUT POWER

Replace the existing definition and source with the following:

RADIANT POWER of the WORKING BEAM, incident on the WORKING AREA, where the RADIANT POWER is the power emitted, transferred, or received in the form of radiation

[SOURCE: IEC 60601-2-22:2019, 201.3.218, modified – Replacement of the term "laser power" with "OUTPUT POWER".]

201.3.215
PHOTOSENSITIZER

Replace the existing definition with the following:

compound which is used in conjunction with ME EQUIPMENT and which causes PHOTOTOXICITY in their combined clinical application

201.3.217
PULSE REPETITION RATE

*Replace, in the source, "*ISO 11145:2016, 3.52" *with "*ISO 11145:2018, 3.14.3".

201.3.218
RADIANT EXPOSURE

*Replace the existing term, definition and Note 1 to entry with "***(Void)***".*

201.3.220
STAND-BY/READY

*Replace the existing term, definition and source with "***(Void)***".*

201.3.222
WORKING AREA

*Replace, in the source, "*IEC 60601-2-22:2007, 201.3.120" *with "*IEC 60601-2-22:2019, 201.3.226".

Add the following new term and definition:

201.3.223
PHOTOTOXICITY
clinically relevant damage to living tissues arising from the photochemical action of compound used for medical diagnosis or therapy when combined with light delivered by the ME EQUIPMENT

Note 1 to entry: Relevant damage can be assessed by the rationale described in ICH Guideline S10 "Photosafety Evaluation of Pharmaceuticals", especially in Sections 4 and 5, in a way which is consistent with ICH Guideline Q9 "Quality Risk Management".

201.7.2.101 Additional items

*Replace, in the first paragraph of this subclause, "*IEC 60601-2-22:2007" *with "*IEC 60601-2-22:2019".

201.7.9.2.2 Warning and safety notices

*Replace, in the first dash of first paragraph, "*IEC 60601-2-22:2007" *with "*IEC 60601-2-22:2019".

201.7.9.2.5.101 ME EQUIPMENT description

Add, at the end of this subclause, the following NOTE:

NOTE Refer to Clause AA.2 subclauses 201.12.1.101 to 201.12.1.106 as specification of performance characteristics.

201.7.9.2.101 ACCESSORIES, supplementary equipment and material

*Replace, in the second dash of the first paragraph, "*WORKING AREA*" with "*working distance and related WORKING AREA*".*

*Replace, in the third dash of the first paragraph, "*OUTPUT distribution*" with "*OUTPUT profile*".*

Add, at the end of this subclause, the following NOTE:

NOTE Refer to Clause AA.2 subclauses 201.12.1.101 to 201.12.1.106 as specification of performance characteristics.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Replace, in the second existing paragraph, "IEC 60601-2-22:2007, IEC 60601-2-22:2007/AMD1:2012" *with* "IEC 60601-2-22:2019".

201.10.4 Lasers

Replace, in the third existing paragraph, "IEC 60601-2-22:2007 and IEC 60601-2-22:2007/AMD1:2012" *with* "IEC 60601-2-22:2019".

Replace, in the third existing paragraph, "201.10.4a) (remote interlock connector) and 201.10.4f) (target indicating device)" *with* "201.10.4.101a) (remote interlock connector) and 201.10.4.101f) (target indicating device)".

Replace, in Note 102, "IEC 60601-2-22:2007" *with* "IEC 60601-2-22:2019".

Replace, in the last paragraph of this subclause, "IEC 60601-2-22:2007 and IEC 60601-2-22:2007/AMD1:2012" *with* "IEC 60601-2-22:2019".

201.11 Protection against excessive temperatures and other HAZARDS

Replace, in the second existing paragraph, "IEC 60601-2-22:2007" *with* "IEC 60601-2-22:2019".

201.12.1.101 * Wavelength accuracy

Replace, in the seventh paragraph, "±3 nm" *with* "±5 nm".

Replace, in the seventh paragraph, "±10 nm" *with* "±20 nm".

201.12.1.103 * EXPOSURE DURATION CONTROL

Replace, in the fourth paragraph, "±20 %" *with* "±10 %".

201.12.1.104 * PULSE DURATION and PULSE REPETITION RATE ACCURACY

Replace, in the fourth paragraph, "±20 %" *with* "±10 %".

201.12.4.4.101 Light emergency stop

Replace, in the first paragraph of this subclause, "IEC 60601-2-22:2007, IEC 60601-2-22:2007" *with* "IEC 60601-2-22:2019".

201.13.1 Specific HAZARDOUS SITUATIONS

Replace the existing text after addition with the following:

The following HAZARDOUS SITUATIONS shall be taken into account for PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT regardless of its classification:

a) emission of excessive OUTPUT;

b) faulty release of the WORKING BEAM;

c) failure of the cutoff of the WORKING BEAM;

d) failure of the calibration process of the transmission of the BEAM DELIVERY SYSTEM for PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT devices which provides means to calibrate the actual OUTPUT of the device to the actual transmission of the BEAM DELIVERY SYSTEM;

NOTE Such failure can be the degradation of an integrating sphere due to staining; degradation of its measurement electronics; degradation of its calibration; degradation or staining of an insert into the integrating sphere which is frequently re-sterilized.

e) impairment of the sterility of the BEAM DELIVERY SYSTEM;

f) failure of integrity of calibrations due to memory failures, software HAZARDS of connected devices, or by incompetent service, including service by third parties.

201.14.6 RISK MANAGEMENT process

Replace, in the first paragraph, third paragraph and last paragraph of this subclause, "IEC 62304:2006" *with* "IEC 62304:2006 and IEC 62304:2006/AMD1:2015".

AA.1 General guidance

Replace, in the last paragraph of this subclause, "IEC 60601-2-22:2007" *with* "IEC 60601-2-22:2019".

AA.2 Rationale for particular clauses and subclauses

Table AA.1 – Characteristics relevant to parameters

*Replace, in the third column and second line of this table, "*Emitting wavelength*" with "*Emitting wavelength and spectral profile*".*

Please replace the existing last line of this table as follows:

OUTPUT profile	Depends on the targeted tissue, the non-targeted viable structure in its vicinity and on the mode of application, i.e. topical or interstitial.	Radiation characteristics associated with OUTPUT profile	Requirements for intended OUTPUT profile

Subclause 201.12.1.101 – WAVELENGTH ACCURACY

Replace, in the last paragraph of this subclause, "IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012" *with* "IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020".

Add, at the end of the existing text, the following new text:

Wavelength accuracy tolerance can be determined by the photoactivation performance of photosensitizer. Several reports showed wavelength dependency of photoactivation performance of photosensitizer *in vitro* or *in vivo* [15]. The result of this report can be in line with the status of wavelength accuracy tolerance of approved laser products for photodynamic therapy [16].

Subclause 201.12.1.102 – OUTPUT control

Replace, in this subclause, "ISO 11554:2006" *with* "ISO 11554:2017" (2 occurrences).

Subclause 201.12.1.103 – EXPOSURE DURATION control

Replace, in this subclause, "ISO 11554:2006" *with* "ISO 11554:2017".

Subclause 201.12.1.104 – PULSE DURATION and PULSE REPETITION RATE accuracy

*Replace, in this subclause, "*ISO 11554:2006" *with "*ISO 11554:2017" (2 occurrences).

Subclause 201.12.1.106 – OUTPUT profile accuracy

*Replace, in this subclause, "*ISO 13694:2015" *with "*ISO 13694:2018".

Subclause 201.12.1.107 – Targeting

*Replace, in the second paragraph of this subclause, "*IEC 60601-2-22:2007, 201.15.101" *with "*IEC 60601-2-22:2019, 201.10.4.101 f)".

Replace the first sentence of last paragraph with the following;

Other systems may be used as the targeting means for PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT including magnetic resonance imaging (MRI), computerized tomography (CT), ultrasound systems, neuro-navigation systems, planification systems for PHOTODYNAMIC THERAPY etc.

Subclause 201.13.2.101 – OPTICAL RADIATION HAZARDS

*Replace, in this subclause, "*IEC 60601-2-22:2007" *with "*IEC 60601-2-22:2019" (3 occurrences).

*Replace, in the first sentence, "*any OPTICAL RADIATION HAZARD in SINGLE FAULT CONDITIONS of up to 100 % for LASER PRODUCTS" *with "*any OPTICAL RADIATION HAZARD in SINGLE FAULT CONDITIONS of up to 50 % for LASER PRODUCTS".

BB.1 General

*Replace, in this subclause, "*IEC 60601-1:2005" *with "*IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020".

*Replace, in this subclause, "*IEC 60601-2-22:2007" *with "*IEC 60601-2-22:2019".

Replace, in this subclause, "ISO 14971:2007" *with "*ISO 14971:2019".

BB.3 RISK assessment guidance of PHOTODYNAMIC THERAPY AND PHOTODYNAMIC DIAGNOSIS EQUIPMENT

Replace, in the existing item d) of the third paragraph, "ISO 14971:2007" *with "*ISO 14971:2019".

Add, at the end of the existing text, the following text:

Assessment strategy for PHOTOTOXICITY potential may be referred to in ICH Guideline S10 "Photosafety Evaluation of Pharmaceuticals", especially in Sections 4 and 5[16].

Bibliography

Replace the existing reference [8] to "ISO 13694:2015" *with* "ISO 13694:2018".

Replace the existing reference [9] to "ISO 14971:2007" *with* "ISO 14971:2019".

Replace the existing reference [10] to "ISO 11554:2006" *with* "ISO 11554:2017".

Replace the existing reference [13] to "ISO 11145:2016" *with* "ISO 11145:2018".

Add, at the bottom of the existing reference [14], the following new amendment:

IEC 62304:2006/AMD1:2015

Add the following new references [15] to [18] as follows:

[15] E. M. Waterfield, M. E. Renke, C. B. Smits, M. D. Gervais, R. D. Bower, M. S. Stonefield, J. G. Levy, *Wavelength-dependent effects of benzoporphyrin derivative monoacid ring A in vivo and in vitro,* Photochemistry and Photobiology, 1994; Oct;60(4):383-7

[16] Y. Kawase, H. Iseki, *Parameter-finding studies of photodynamic therapy for approval in Japan and the USA,* Photodiagnosis and Photodynamic Therapy, 2013;10:434-45

[17] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH): ICH Harmonized Tripartite Guideline "Photosafety Evaluation of Pharmaceuticals" S10. Current Step 4 version, 13 November 2013

[18] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH): ICH Harmonized Tripartite Guideline "Quality Risk Management" Q9. Current Step 4 version, 9 November 2005