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- ii) affects other national standard(s)
- iii) requires additional national guidance or information

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Full document details: 22/30450431 DC

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



76/696/CD

COMMITTEE DRAFT (CD)

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DATE OF CIRCULATION:
2021-12-24

CLOSING DATE FOR COMMENTS:
2022-02-18

SUPERSEDES DOCUMENTS:

IEC TC 76 : OPTICAL RADIATION SAFETY AND LASER EQUIPMENT	
SECRETARIAT: United States of America	SECRETARY: Mr William Ertle
OF INTEREST TO THE FOLLOWING COMMITTEES: SC 62A	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.
FUNCTIONS CONCERNED: ☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY	

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Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

FOREWORD

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- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-57 has been prepared by IEC technical committee TC 76: Optical radiation safety and laser equipment

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

FDIS	Report on voting

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 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;

– “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 date¹ 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.

¹ The National Committees are requested to note that for this publication the stability date is [..]

INTRODUCTION

This particular standard amends and supplements IEC 60601-1:2005+AMD1:2012+AMD2:2020 *Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance*.

This edition of the standard constitutes a major review of the previous edition and covers the recent development of LS EQUIPMENT. It now includes the Risk Group 1C, which is defined in IEC 62471-1. LS EQUIPMENT of RG 1C incorporates technical means which inhibit emission into free space when the APPLICATOR is not in good contact with the target tissue.

It now excludes LS EQUIPMENT of RG 1 and RG 2 as these are assumed to represent no hazard. It now includes LS EQUIPMENT of Risk Group 1C which is defined in IEC 62471-1, but only where the embedded LS EQUIPMENT is of RG3. LS EQUIPMENT of RG 1C incorporates technical means which inhibit emission into free space when the applicator is not in GOOD CONTACT with the target tissue.

This edition of the standard clarifies its relation to the concept of Risk Groups (RGs), as introduced in IEC 62471-1. The information about classification and rules for the determination of Risk Groups is now linked to IEC 62471-1.

[Note to NCs: The next edition of IEC 62471-1 is still under work by JTC5. We anticipate that the next edition will contain the definition of the new RG 1C]

Although this particular standard was applicable to LS EQUIPMENT containing UV sources, more emphasis was given to UV applications of the equipment than in the previous edition.

This edition of the standard now excludes LS EQUIPMENT which is intended to be used on animals.

The requirements of this particular standard should be taken as the minimum to comply with, in order to achieve a reasonable level of safety and reliability during operation and application of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.

An asterisk (*) notes clauses for which there is rationale comment in annex AA. It is considered that knowledge of the reasons for these requirements will facilitate the proper application of this particular standard and be of use in any revision that may be necessitated by changes in clinical practice or as a result of developments in technology.

MEDICAL ELECTRICAL EQUIPMENT

Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

201.1 Scope, object and related standards

Clause 1 of the general standard²⁾ applies, except as follows:

201.1.1 *Scope

Replacement:

This particular Standard applies to BASIC SAFETY and ESSENTIAL PERFORMANCE of equipment incorporating one or more sources of OPTICAL RADIATION in the wavelength range 200 nm to 3 000 nm, with the exception of laser radiation, and intended to create photobiological effects in humans for therapeutic, diagnostic, monitoring, or cosmetic/aesthetic applications; hereafter referred to as light source equipment (LS EQUIPMENT).

[WG's note to NCs: This document now includes UV medical equipment. It was felt that UV equipment such as 308 nm excimer systems, which are applied to treat psoriasis and vitiligo, is assumed to be covered by the IEC 60601 series including this document. However, some experts argue that medical UV equipment is already sufficiently covered by other standards and there would be no need for IEC 60601-2-57 to deal with medical UV equipment. In this document, UV equipment requires safety information (see 201.7.9.2.101.2), labelling (see Table 201.104) and a risk assessment regarding stray optical radiation (see 201.10.105 and Annex AA). NCs please comment.]

This particular standard applies to LS EQUIPMENT of Risk Group 1C (but only where the embedded source of OPTICAL RADIATION is of RG3), and of Risk Group 3.

Note: Classification rules for Risk Groups, see 201.6.1.102

This particular standard does not apply to equipment for sun tanning such as sunlamp products, for ophthalmic instruments, for lighting purposes in medical/cosmetic environments, for photography/video, for equipment which produces non-visual effects such as circadian entrainment or for infant phototherapy and infant radiant warmers. This particular standard does not apply to sterilisation equipment.

This particular standard does not apply to equipment which is intended to be used on animals only.

This particular standard does not apply to home-use appliances. It does not apply to home light therapy equipment, such as equipment which is intended to be used in the HOME HEALTHCARE ENVIRONMENT and is typically used by a LAY OPERATOR.

Note: Home-use appliances are covered by IEC 60335-2-113:2016. Appliances for skin exposure to OPTICAL RADIATION, such as sunlamp products are covered by IEC 60335-2-27. Home light therapy equipment providing light therapy by means of eye-mediated photobiological effects, which can be visual or non-visual, and skin-mediated photobiological effects, possible applications including pain relief, psoriasis treatment, and treatment of winter depression (SAD), is covered by IEC 60601-2-83:2019. See Bibliography.

²⁾ 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*.

226 Note: Safety requirements in this particular standard are intended to address only HAZARDS to the eye and superficial
227 tissues including skin or mucosa. As OPTICAL RADIATION does not penetrate more than a few mm in tissue, HAZARDS
228 to underlying tissues are not considered.

229 **201.1.2 Object**

230 *Replacement:*

231 The objects of this particular standard are:

- 232 – to establish the risk from OPTICAL RADIATION, specify basic safety and essential performance
233 requirements for LS EQUIPMENT;
- 234 – to specify requirements for the MANUFACTURER to supply information and establish
235 procedures so that proper precautions can be adopted;
- 236 – to provide warning to individuals of risks associated with accessible OPTICAL RADIATION from
237 LS EQUIPMENT through signs, labels and instructions;
- 238 – to reduce the possibility of adverse effects and injuries by minimizing unnecessary
239 accessible OPTICAL RADIATION; to provide means of improved control of the HAZARDS related
240 to OPTICAL RADIATION through engineering controls;
- 241 – to specify requirements for protection against other HAZARDS resulting from the operation
242 and use of LS EQUIPMENT.

243

244 **201.1.3 Collateral standards**

245 *Addition:*

246 This particular standard refers to the applicable collateral standards that are listed in Clause 2
247 of the general standard and in clause 201.2 of this particular standard.

248 All published collateral standards in the IEC 60601 series apply as published.

249 **201.1.4 Particular standards**

250 *Replacement:*

251 In the IEC 60601 series, particular standards may modify, replace or delete requirements
252 contained in the general standard and collateral standards as appropriate for the particular
253 ME EQUIPMENT under consideration, and may add other basic safety and essential performance
254 requirements.

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

256 For brevity, IEC 60601-1 is referred to in this particular standard as the general standard.
257 Collateral standards are referred to by their document number.

258 The numbering of clauses and subclauses of this particular standard corresponds to that of the
259 general standard with the prefix "201" (e.g. 201.1 in this particular standard addresses the
260 content of Clause 1 of the general standard) or applicable collateral standard with the prefix
261 "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this
262 particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard,
263 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral
264 standard, etc.). The changes to the text of the general standard are specified by the use of the
265 following words:

266 "Replacement" means that the clause or subclause of the general standard or applicable
267 collateral standard is replaced completely by the text of this particular standard.