

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE



**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**

**Appareils électromédicaux –  
Partie 2-57: Exigences particulières pour la sécurité de base et les performances  
essentiels des appareils à source de lumière non-laser prévus pour des  
utilisations thérapeutiques, de diagnostic, de surveillance et de  
cosmétique/esthétique**



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## CONTENTS

FOREWORD.....	4
INTRODUCTION.....	7
201.1 Scope, object and related standards.....	8
201.2 Normative references .....	10
201.3 Terms and definitions .....	10
201.4 General requirements.....	13
201.5 General requirements for testing ME EQUIPMENT.....	13
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	13
201.7 ME EQUIPMENT identification, marking and documents.....	15
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	19
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	20
201.10 Protection against unwanted and excessive radiation HAZARDS.....	20
201.11 Protection against excessive temperatures and other HAZARDS.....	21
201.12 Accuracy of controls and instruments and protection against hazardous outputs .....	21
201.13 HAZARDOUS SITUATIONS and fault conditions.....	22
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) .....	23
201.15 Construction of ME EQUIPMENT.....	23
201.16 ME SYSTEMS.....	23
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	23
Annexes .....	23
Annex AA (informative) Particular guidance and rationale .....	24
Annex BB (informative) Exposure limit values .....	26
Annex CC (informative) Protective eyewear for LS EQUIPMENT .....	30
Annex DD (informative) Summary of MANUFACTURER'S requirements .....	31
Annex EE (informative) Symbols on marking.....	32
Bibliography.....	33
Index of defined terms used in this particular standard.....	34
Figure 201.101 – Example of explanatory label for a device with multiple HAZARD spectral regions .....	18
Figure 201.102 – Warning label – HAZARD symbol.....	19
Table 201.101 – EMISSION LIMITS for risk groups of LS EQUIPMENT .....	14
Table 201.102 – Risk group time base criteria for classification of LS EQUIPMENT .....	15
Table 201.103 – Applicable ANGLE OF ACCEPTANCE for the assessment of accessible emission from LS EQUIPMENT .....	15
Table 201.104 – Requirements for labelling of LS EQUIPMENT according to risk group classification.....	17
Table BB.1 – EXPOSURE LIMIT values for non-coherent OPTICAL RADIATION .....	26
Table BB.2 – $S(\lambda)$ [dimensionless], 200 nm to 400 nm .....	28
Table BB.3 – $B(\lambda)$ , $R(\lambda)$ [dimensionless], 300 nm to 1 400 nm .....	29

Table DD.1 – Summary of MANUFACTURER’S requirements..... 31  
Table EE.1 – Symbols, references and descriptions..... 32

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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

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

FDIS	Report on voting
76/438/FDIS	76/441/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.);
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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.

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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:

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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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## INTRODUCTION

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

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.

Withdrawing