

INTERNATIONAL STANDARD

AMENDMENT 1

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

AMENDMENT 1

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Amendment 1 to IEC 60601-2-22:2019 has been prepared by IEC technical committee 76: Optical radiation safety and laser equipment.

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

Draft	Report on voting
76/793/FDIS	76/796/RVD

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

The language used for the development of this Amendment is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications/.

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- reconfirmed,
- withdrawn, or
- revised.

INTRODUCTION to Amendment 1

The 4th Edition of IEC 60601-2-22 was published in 2019. This amendment is intended to align the standard to IEC 60601-1:2005/AMD2:2020.

Additionally, this amendment resolves minor ambiguities: refer to 201.1.3, 201.3.221, 201.7.9.2.101 b), 201.8.5, 201.10.4, 201.10.4.101 d), 201.10.4.103.

This amendment turns an informal note into a technical requirement. See 201.10.4.101 e) requiring that an aiming beam shall not take the function of the laser emission indicator.

201.1 Scope, object and related standards

Replace, in footnote 1 "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".

201.1.3 Collateral standards

Delete "and Clause 201.2 of this document."

201.1.4 Particular standards

Replace, in the first paragraph, the existing reference "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"

201.2 Normative references

Replace:

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

with:

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

201.3 Terms and definitions

Replace the existing heading with the following new heading:

Terminology and definitions

201.3.220

MPE

MAXIMUM PERMISSIBLE EXPOSURE

Add the following note to entry:

"Note 1 to entry: The MPE of the skin is given in IEC 60825-1:2014, Table A.5 and the MPE at the cornea is given in IEC 60825-1:2014, Table A.1 to Table A.4".

Replace the source as follows:

[SOURCE: IEC 60825-1:2014, 3.59, modified – The notes to entry have been deleted and a new Note 1 to entry has been added.]

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

Replace the existing heading with the following new heading:

Marking on the outside of ME EQUIPMENT or ME EQUIPMENT PARTS (see also Table C.1)

201.7.9.1 General

Replace the existing heading with the following new heading:

General (see also Table C.4)

201.7.9.2 Instructions for use

Replace the existing heading with the following new heading:

Instructions for use (see also Table C.5)