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Lasers and laser-related equipment — Test methods for laser-induced damage threshold — Classification of medical beam delivery systems

Lasers et équipements associés aux lasers — Méthodes d'essai du seuil d'endommagement provoqué par laser — Classification des systèmes de transmission de faisceau médical

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 9, *Laser and electro-optical systems*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Fire in an operating room is the most dangerous situation for patient and staff. Besides electrosurgical devices and endoscopic light sources, even surgical lasers can be ignition sources for drapes, gowns and tracheal tubes. This risk was identified very early and several ISO standards for laser proof materials have been published. The medical beam delivery system itself, however, was out of focus. Due to the increasing market on the one hand and necessity for cost reduction in health care on the other hand fibres have come into the market with a risk of self-ignition of the core or cladding material. Furthermore with reinvention of fibre-applicator-systems for contact application or integrated diffusor systems they have an increased risk for self-ignition due to high absorption. This document elaborates reproducible test parameters for medical beam delivery systems.

Lasers and laser-related equipment — Test methods for laser-induced damage threshold — Classification of medical beam delivery systems

1 Scope

This document specifies a method of testing the laser-induced ignition and damage of medical beam delivery systems to allow checking of suitable products according to the classification system.

NOTE 1 Take care when interpreting these results, since the direct applicability of the results of this test method to the clinical situation has not been fully established.

NOTE 2 Users of products tested by this method are cautioned that the laser will be wavelength sensitive and tested at the wavelength for which it is intended to be used. If tested using other wavelengths, the power settings and modes of beam delivery need to be explicitly stated.

CAUTION — This test method can involve hazardous materials, operations and equipment. This document provides advice on minimizing some of the risks associated with its use but does not purport to address all such risks. It is the responsibility of the user of this document to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13694, *Optics and photonics — Lasers and laser-related equipment — Test methods for laser beam power (energy) density distribution*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99 and the following apply.

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
afterflame
persistence of flaming of a material, under specified test conditions, after the ignition source has been removed

[SOURCE: ISO 11810:2015, 3.1]

3.2
afterflame time
length of time for which a material continues to flame, under specified test conditions, after the ignition source has been removed

[SOURCE: ISO 11810:2015, 3.2]

3.3
afterglow
persistence of glowing of a material, under specified test conditions, after cessation of flaming or, if no flaming occurs, after the ignition source has been removed

[SOURCE: ISO 11810:2015, 3.3]

3.4
afterglow time
time during which a material continues to glow, under specified test conditions, after cessation of flaming or, if no flaming occurs, after the ignition source has been removed

[SOURCE: ISO 11810:2015, 3.4]

3.5
beam diameter
d_{95}
diameter of a circular aperture in a plane perpendicular to the beam axis that contains 95 % of the total beam power (energy)

[SOURCE: ISO 11145:2018, 3.3.1, modified — Value of contained total beam power set to 95 % and Note 1 to entry removed.]

3.6
beam cross-sectional area
A_{95}
smallest completely filled area containing 95 % of the total beam power (energy)

[SOURCE: ISO 11145:2018, 3.6.1, modified — Value of contained total beam power set to 95 % and Note 1 to entry removed.]

3.7
combustion
any continuing burning process that occurs in or on the specimen caused by a chemical process of oxidation with the liberation of heat

EXAMPLE Flame, smouldering, rapid evolution of smoke.

[SOURCE: ISO 11810:2015, 3.7]

3.8
destruction
damage of the system during laser radiation transmission due to absorption rather than ignition (crumbling, melting, disconnecting, breaking) with or without loss of parts of the system

3.9
flammable
subject to ignition and flaming combustion

[SOURCE: ISO 11810:2015, 3.9]

3.10
ignition
creation of combustion induced by the beam delivery of laser power

[SOURCE: ISO 11810:2015, 3.10, modified — "laser" was included before "power"]

3.10.1
irradiation ignition
ignition of a specimen by laser irradiation of the specimen from outside

3.10.2
transmission ignition
ignition of a specimen by a laser beam transmission through the specimen

3.11
laser resistance
measure of the ability of a material to withstand laser power without ignition or damage

[SOURCE: ISO 11810:2015, 3.11]

3.12
medical beam delivery system
product intended to transmit the laser beam from the source to the treatment site directly or by the use of additional applicators

EXAMPLE Articulated arms, hollow waveguides, optical fibres.

Note 1 to entry: Directly means direct application either with bare fibres, shaped fibres or internal marked fibres.

3.12.1
applicator
attachment to the medical beam delivery system at the treatment site

EXAMPLE Focussing handpiece, micromanipulators, scanners, endoscopes, shaped tips like sapphire tips, ceramic/metal tips, radial tips, focussing lenses or diffusor tips.

3.13
melting behaviour
softening of a material under the influence of heat (including shrinking, dripping and burning of molten material, etc.)

[SOURCE: ISO 11810:2015, 3.12]

3.14
thermal resistance
ability of a material to resist conduction of heat

[SOURCE: ISO 11810:2015, 3.20]

3.15
product
finished medical device (samples)

3.16
reusable product
product intended to be prepared and re-sterilized for multiple use

[SOURCE: ISO 11810:2015, 3.16]

3.17
single use
product intended to be used once and then discarded

[SOURCE: ISO 11810:2015, 3.18]

4 Principle

WARNING — This test method can result in a rocket-like fire. Such a fire can produce intense heat and light and toxic gases.

To simulate worst-case conditions, the material is exposed to laser power of known characteristics in an environment up to 98 % ± 2 % oxygen.

5 Significance and use of the test

5.1 A medical beam delivery system is intended to transmit the laser beam from the source to the treatment area. This can be articulated arms, hollow waveguides or optical fibres. It can deliver the radiation to the target by connected applicators like focussing handpiece, micromanipulators, scanners or endoscopes or fix mounted applicators as shaped tips like sapphire tips, ceramic/metal tips, radial tips, focussing lenses or diffusor tips. Another technical solution is the direct application either with bare fibres, shaped fibres or internal marked fibres.

5.2 This document describes a uniform and repeatable test method for measuring the laser-induced ignition, flame spread and damage of medical beam delivery systems. Variables involved in laser ignition have been fixed in order to establish a basis for comparison. This test method can be used to compare different types and designs.

5.3 A large number and range of variables are involved in ignition. A change in one variable can affect the outcome of the test. Caution should be observed, since the direct applicability of the results of this test method to the clinical situation has not been fully established.

NOTE This method can be applied to study the effect of changing the test conditions, but this is outside the scope of this document. For example, variation of the breathing-gas flow rate or different breathing-gas mixtures might affect the laser ignition.

5.4 Since an oxygen-enriched atmosphere is often present in the clinical situation, either intentionally or unintentionally, the test is performed under ambient air conditions and an environment of 60 % ± 2% and 98 % ± 2 % oxygen, respectively.

5.5 The preparation of the specimen shall be in accordance with the manufacturer's instructions for use.

6 Apparatus

6.1 General

The test apparatus shall consist of a draught-resistant ventilated containment box, specimen holder, specimen rack, laser energy source and associated parts (see Figures 1 and 2).