
**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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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Contents

	Page
Foreword.....	iv
Introduction.....	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Principle	4
5 Significance and use of the test	4
6 Apparatus	4
6.1 General.....	4
6.2 Containment box.....	6
6.3 Specimen holder.....	7
6.4 Lasers and beam delivery systems.....	7
6.5 Power meter.....	7
6.6 Gas supply system.....	7
6.7 Environment.....	8
6.7.1 Ambient air conditions.....	8
6.7.2 Oxygen enriched atmospheres.....	8
6.8 Smoke evacuation device.....	8
7 Reagents and materials	8
8 Preparation of test specimens	9
9 Preparation of apparatus	9
10 Test methods	10
10.1 General conditions.....	10
10.2 Testing during laser irradiation.....	10
10.3 Testing during laser transmission.....	11
11 Classification	12
11.1 General.....	12
11.2 Irradiation ignition testing (I).....	13
11.3 Transmission ignition and destruction testing (T/D).....	13
11.3.1 Transmission ignition testing (T).....	13
11.3.2 Transmission destruction testing (D).....	14
12 Test report	16
Bibliography	18

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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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.

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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.

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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.]

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**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 % \pm 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.

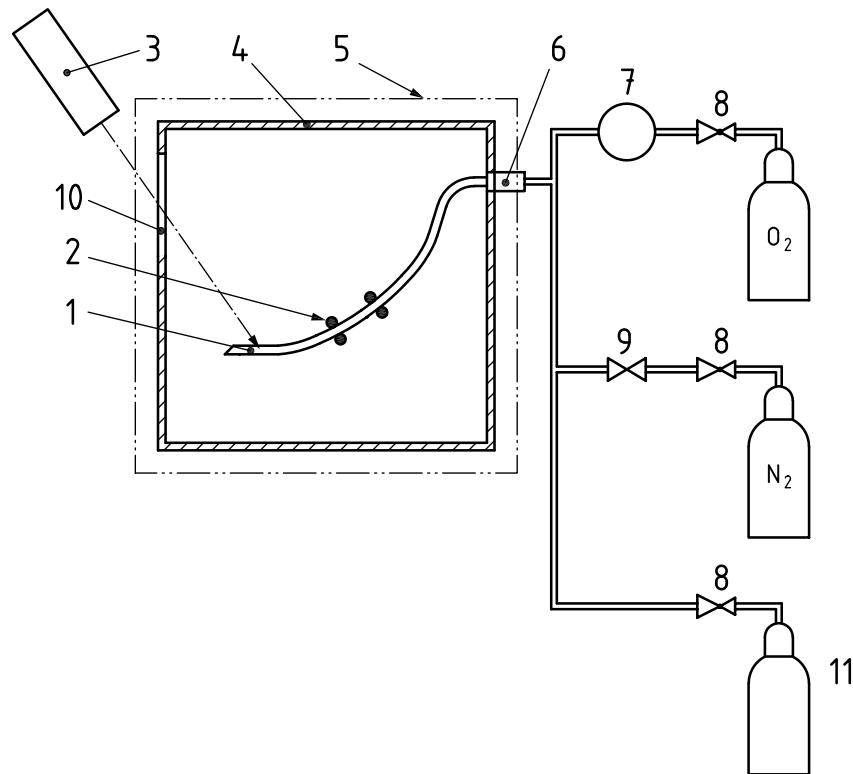
5.4 Since an oxygen-enriched atmosphere is often present in the clinical situation, either intentionally or unintentionally, the test is performed under ambient air conditions and an environment of 60 % \pm 2% and 98 % \pm 2 % oxygen, respectively.

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](#)).



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Key

- | | | | | |
|---|---|---|----|---|
| 1 | medical beam delivery system | (standards.iteh.ai) | 6 | flashback arrestor |
| 2 | medical beam delivery system support using two clamps | | 7 | oxygen flow meter and controller |
| 3 | laser source for irradiation | ISO 22248:2020 | 8 | pressure regulator with inlet and outlet gauges |
| 4 | containment box (lateral view) | 9856-448ac4e9d99/iso-22248-9020 | 9 | quick-action inert gas valve |
| 5 | enclosure cover (may be multi-piece) | | 10 | opening for laser access |
| | | | 11 | liquid for cooling/cleaning |

Figure 1 — Apparatus for irradiation ignition testing