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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).

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

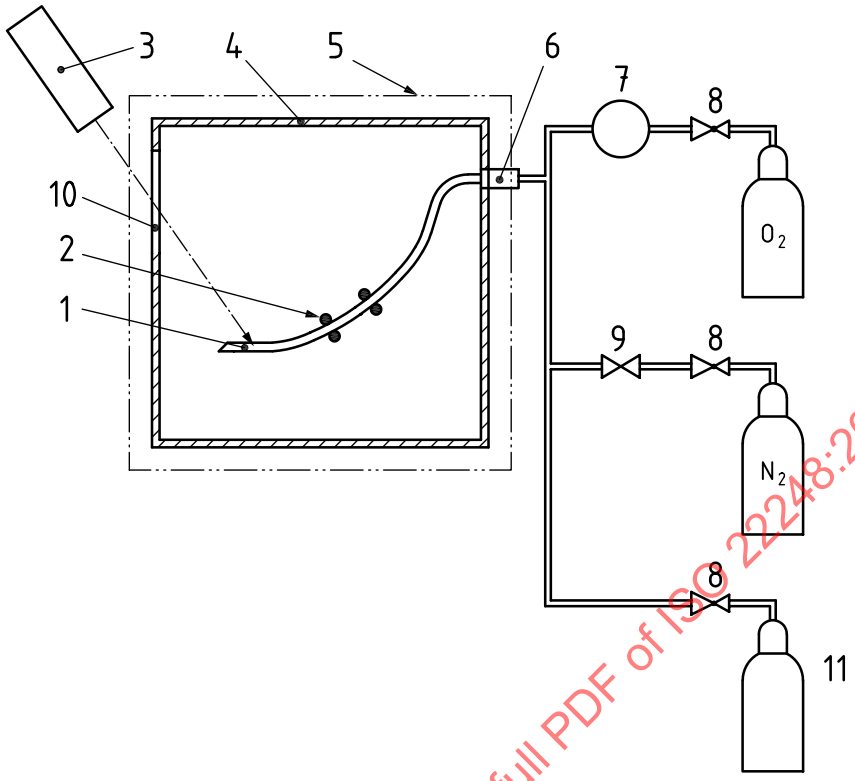
5.4 Since an oxygen-enriched atmosphere is often present in the clinical situation, either intentionally or unintentionally, the test is performed under ambient air conditions and an environment of 60 % ± 2% and 98 % ± 2 % oxygen, respectively.

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

6 Apparatus

6.1 General

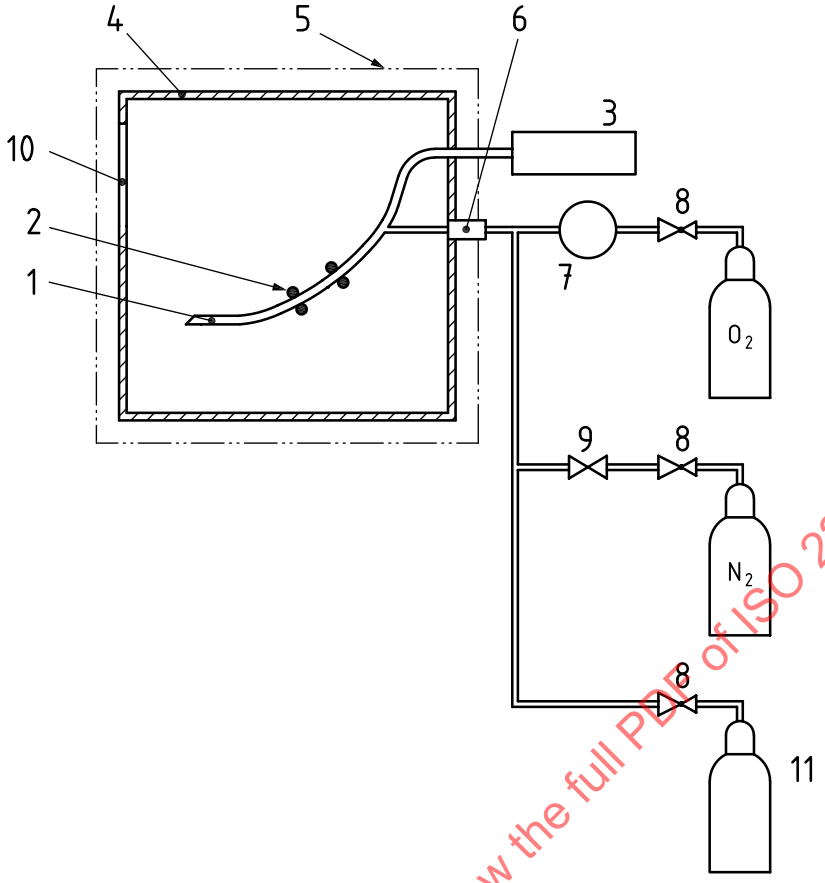
The test apparatus shall consist of a draught-resistant ventilated containment box, specimen holder, specimen rack, laser energy source and associated parts (see Figures 1 and 2).



Key

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

Figure 1 — Apparatus for irradiation ignition testing



Key

1	medical beam delivery system	6	flashback arrestor
2	medical beam delivery system support using two clamps	7	oxygen flow meter and controller
3	laser source for transmission	8	pressure regulator with inlet and outlet gauges
4	containment box (lateral view)	9	quick-action inert gas valve
5	enclosure cover (may be multi-piece)	10	opening for laser access
		11	liquid for cooling / cleaning

Figure 2 — Apparatus for transmission ignition testing

6.2 Containment box

The containment box controls the environment around the specimen while allowing the laser beam to be directed onto the specimen.

The containment box shall

a) be rectangular in shape and have dimensions of approximately 46 cm × 46 cm × 46 cm,

b) be fire-proof and easily cleaned of soot and residue from burned specimens,

c) allow the mounting of the test specimen for the irradiation of the specimen (Figure 1) and transmitted irradiation (Figure 2),

d) allow access to the specimen,

e) allow direct access of the laser beam to the specimen (Figure 1),

f) allow observation with video cameras on the top and on all sides of the box; a minimum of three video cameras (one camera positioned above the containment box and two cameras positioned at two of the sides of the containment box) is needed for recording purposes,

g) exhaust the gas and any products of combustion to a safe area,

h) allow cleaning of the box, and cleaning of the covers and/or windows themselves,

i) be capable of maintaining an environment of 60 % ± 2% and 98 % ± 2% respectively oxygen around the specimen,

j) allow to be rapidly flooded with nitrogen or another gas to extinguish any fire inside the box, and

k) have internal surfaces that are non-reflective to protect the specimen from reflections.

Other configurations may be used, as long as the requirements of the test method as defined herein are not affected.

6.3 Specimen holder

The specimen holder shall consist of suitable material and construction which allows the passage of the medical beam delivery system. The specimen shall be positioned within the specimen holder in such a way that the end of the fibre, specifically the connection between fibre and end piece, is a minimum of 3 cm away from the specimen holder.

6.4 Lasers and beam delivery systems

WARNING — Surgical lasers emit radiation of sufficient power to damage living tissue or ignite fires directly or by reflection of radiation. In addition to other precautions, test personnel should be trained in the use of lasers and take proper safety measures based on the type of laser being used. These precautions should include laser-safety eyewear, protective clothing and controlled access to the test area.

6.4.1 Various laser types emitting radiation of wavelengths in the ultraviolet, visible and infrared ranges are used during surgery. Any of these lasers that meets the requirements listed in this test procedure is suitable for use in this test.

6.4.2 The laser radiation shall be applied with the same optical quality as is typically used for a surgical procedure. The system shall provide an appropriate beam diameter, d_{95}, at the surface of the specimen measured in accordance with ISO 13694.

6.5 Power meter

6.5.1 For measuring the power of the laser radiation, power meters which provide a suitable measurement range and an uncertainty of less than 5 % shall be used.

6.5.2 The power of radiation transmitted by these systems shall be verified as accurate as ±10 %. This can be accomplished by use of an external power meter or internal calibration systems.

6.6 Gas supply system

6.6.1 The gas supply system shall provide oxygen to the medical beam delivery system at a controllable flow rate. Also, the system shall be capable of rapidly flooding the containment box with nitrogen or other inert gas or stopping oxygen flow, or both, to extinguish any burning material. An oxygen flow meter and controller and a quick-action inert gas valve shall be part of this system (see Figure 1). The nitrogen or inert gas supplied shall be at a higher pressure and allow a flow rate of at least an order of magnitude greater than that of the oxygen supplied to the medical beam delivery system.

6.6.2 Other arrangements, such as an oxygen flood valve for rapidly purging the containment box or an inert gas flooding system for rapid extinguishment of burning material, may be used as long as the requirements of the test method as defined herein are not affected.

6.6.3 Oxygen analyser, any device that can measure the concentration of gaseous oxygen with a repeatability of at least 1 % of full scale and a calibrated accuracy of at least 1 % of full scale is satisfactory. The oxygen sensor shall be positioned so as to minimize the chance of its ignition by any fire in the containment box.

6.6.4 Cooling systems, if the manufacturer does not provide specific requirements for any cooling or cleaning gases/solutions, the test shall be done without such a system because these gases or solutions can alter the resistance or extinguish nascent fires. If the manufacturer provides specific requirements, the according instructions shall be followed.

6.7 Environment

6.7.1 Ambient air conditions

The tests under ambient air conditions shall be performed at room temperature of 20 °C ± 3 °C and 20 % ± 2 % relative humidity.

6.7.2 Oxygen enriched atmospheres

The tests under oxygen-enriched atmosphere shall be performed at oxygen concentrations of 60 % ± 2 % and 98 % ± 2 %.

The oxygen concentration within the containment box shall be established at the desired ratio by proportional mixing of nitrogen and oxygen by suitable means.

6.8 Smoke evacuation device

WARNING — Combustion of most materials produces toxic gases such as carbon monoxide, hydrogen chloride and hydrogen cyanide. Also, the smoke produced in such fires contains hazardous particles of carbon, silica, unburned matter and other materials.

6.9.1 A device shall be attached to the containment box to safely remove smoke resulting from a burning specimen but shall be designed to eliminate the chance of drawing fire into the exhaust system. Placing the containment box in a fume hood that exhausts to a safe location satisfies this requirement.

6.9.2 The smoke evacuation device shall not interfere with maintaining the oxygen environment within the containment box. For example, the flow of a fume hood shall not create draughts that would enter or pull gas from the opening for laser access. The smoke evacuation shall not be activated until after the initiation of combustion.

7 Reagents and materials

7.1 Oxygen, 98 % ± 2 % (volume fraction) pure.

7.2 Nitrogen or **other gas** (i.e. non-oxidizing, non-flammable), 98 % ± 2 % (volume fraction) pure.

7.3 Absorber materials as phantoms.

7.3.1 Sterile wood mouth spatula, EAN-code 4049500304924 for pre blackening.

7.3.2 Agar E406, as carrier substance for:

7.3.2.1 Intralipid, 20% as liquid diffuser.

7.3.2.2 Eosin-methylene blue solution, according to MAY-GRÜNWALD[1)] for specific absorption in visible wavelength range (VIS).

7.3.2.3 ICG indocyanine green, for specific absorption in near infrared wavelength range (NIR).

8 Preparation of test specimens

8.1 Sampling

The test specimen shall be any material, device or system used as medical beam delivery system.

8.1.1 Single use products

Single use products shall be obtained directly from the packaging in which the products are sold.

8.1.2 Reusable products

Reusable products shall be tested new and after reprocessing to the point when their rating changes. Reprocessing shall include cleaning, decontaminating and, if necessary, sterilization in accordance with the manufacturer's recommendations. The point at which the product rating degrades shall be the maximum allowed number of uses.

8.2 Five test specimens shall be used.

8.3 Materials requiring special treatment or preparation shall be conditioned according to the manufacturer's instructions for use. Any special treatment or preparation shall be stated when reporting results.

8.4 The test specimens shall be free from any extraneous materials, as such materials can significantly alter the laser ignition.

EXAMPLE Char, ash, soot, blood, mucous, lubricants and other materials, beside the absorber materials described in 7.3.

8.5 Specimens shall be conditioned for 24 h at 20 °C ± 3 °C and 20 % ± 2 % relative humidity.

9 Preparation of apparatus

9.1 Ensure that the containment box is clean (i.e. free of contaminants) by visual inspection.

NOTE Contamination can interfere with the performance of the test or evaluation of the results.

9.2 Ensure that the laser is in working order, that its operation is understood, and that personal protection is in place.

9.3 Ensure that there is adequate oxygen for the test and nitrogen or other gas for extinguishing any resulting fire.

1) MAY-GRÜNWALD coloration is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

9.4 Have other means of fire extinguishment (e.g. a carbon dioxide fire extinguisher) at hand. Water is not recommended, as it will not extinguish some materials burning in oxygen and, if used, will cause considerable soiling of the containment box and will interfere with interpretation of the results of laser interaction with the specimen. Water is not recommended for use on a fire involving energized electrical equipment.

10 Test methods

10.1 General conditions

10.1.1 Perform the test at 20 °C ± 3 °C.

10.1.2 Insert the specimen in the containment box. Connect the gas supply systems to the apparatus.

10.1.3 Ensure that the opening for laser access is as small as possible, in order to maintain the oxygen-enriched atmosphere but still allow laser access to the specimen.

10.1.4 Ensure that the gas flush is working properly.

10.1.5 Ensure that the smoke evacuation system is working properly and will not affect the gas concentration in the containment box during the test.

10.1.6 Flow oxygen into the containment box at a rate and time period sufficient to establish an environment of 60 % ± 2 % and 98 % ± 2 % oxygen, respectively. This oxygen level shall be verified by use of an oxygen analyser (6.6.3) measuring the environment.

10.2 Testing during laser irradiation

10.2.1 Principle

Position the laser so that

— the laser beam is perpendicular to the surface of the test specimen (see Figure 1);

— the beam diameter, d_{95}, measured in accordance with ISO 13694, shall be the smallest diameter of the medical beam delivery system (e.g. fibre core diameter or diameter of the hollow waveguide) at the surface of the test specimen (the beam cross-sectional area, A_{95}, is a critical dimension).

Lateral motion of the laser spot shall be minimized by some form of stabilization.

10.2.2 Verify that the following standardized test parameters are correct during performance of the test:

a) exact positioning of the laser beam;

b) The sequence of testing shall be: (21 ± 2) % O_2 (ambient air), (60 ± 2) % O O_2 then at least (98 ± 2) % O_2. Refer to Figure 3 regarding the procedure;

c) temperature (20 ± 3) °C;

d) the smallest diameter of the medical beam delivery system d_{95};

e) mode of laser operation shall match the specification given by the manufacturer of the specimen.

10.2.3 Starting with 10 % of the maximum power specified manufacturer's of the specimen, apply the laser beam to the test specimen for a specified duration of 1 s up to 10 s maximum, using the mode

of laser operation specified by the specimens manufacturer. Stop the laser beam if direct ignition, or damage occurs. These data shall be reported in addition to data collected at 10 s.

10.2.4 Increase the laser power in reasonable steps. Repeat the application of the laser beam for each new power level or until ignition or damage occurs as described in 10.2.3. This shall necessitate the use of a new specimen. Once the maximum power setting has been determined, verify the maximum power setting by beginning the testing procedure with the five specimens.

10.3 Testing during laser transmission

10.3.1 Principle

Connect the medical beam delivery system with the laser source according to the manufacturer's instructions. Position the medical beam delivery system end according to the intended use of the system (see also Figure 2).

10.3.2 Check the following standardized test parameters for each specimen:

10.3.2.1 Kind of applicator:

a) bare fibre:
   1) blank;
   2) shaped fibre;
   3) end cap;
b) combined delivery system:
   1) internally marked fibre;
   2) connected end piece;

10.3.2.2 Kind of cooling:

a) no cooling;
b) integrated cooling system;
c) external cooling system;
d) gas or liquid cooling.

10.3.2.3 Kind of application modus:

a) non-contact device;
b) contact device

10.3.2.4 Kind of intended tissue reaction:

a) cutting;
b) coagulation;
c) non thermal irradiation.

10.3.3 Starting with 10 % of the maximum manufacturer's specified power, apply the laser beam to the test specimen, for a specified duration of 1 s up to 10 s maximum, using the mode of laser operation specified by the specimens manufacturer. Stop the laser beam if transmission-ignition, or damage occurs. These data shall be reported in addition to data collected at 10 s.

10.3.4 Increase the laser power in reasonable steps. Repeat the application of the laser beam for each new power level or until ignition or damage occurs as described in 10.3.3. This shall necessitate the use of a new specimen. Once the maximum power setting has been determined, verify the maximum power setting by beginning the testing procedure with the five specimens.

10.3.5 Testing during laser beam transmission.

10.3.5.1 Clean fresh prepared fibre end or applicator in non-contact mode with and without cooling.

10.3.5.2 Clean fresh prepared fibre end or applicator in contact to wood spatula with and without cooling.

10.3.5.3 Clean fresh prepared fibre end or applicator in contact with intralipid solution.

10.3.5.4 Clean fresh prepared fibre end or applicator in contact with agar with eosin-methylene blue solution according MAY-GRÜNWALD[2)] for specific absorption in VIS and ICG indocyanine green for specific absorption in NIR.

10.3.6 Cooling systems.

10.3.6.1 Without cooling/cleaning.

If the manufacturer has not given specific requirement for any cooling or cleaning gases/liquids, start without such a system.

10.3.6.2 With Cooling or cleaning system.

If the manufacturer has given specific requirements for cooling, start with testing according to the manufacturers' instruction. If no ignition/destruction appears, repeat the same procedure without cooling. In case that under these condition ignition and/or destruction happens the manufacturer shall be given a warning that use without cooling or cleaning is not recommended.

10.3.6.3 Any test specimen that experiences ignition as defined in 3.10 is considered to have laser resistance up to the maximum power at which the ignition did not occur under the specified test conditions.

10.3.6.4 Any damage (see 3.8) to the test specimen (e.g. melting) shall be described in the test report, together with the laser settings that caused such change(s).

11 Classification

11.1 General

11.1.1 If all specimens belong to the same class, the tested product belongs to this class.

2) MAY-GRÜNWALD coloration is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

11.1.2 If two or more of the five specimens belong to a higher (less safe) class, then the tested product shall be assigned to that class.

11.1.3 If one of the specimens belongs to the higher (less safe) class, a new test series with five new specimens shall be performed. If one or more specimens of the new series belong to the higher (less safe) class, the tested product shall be assigned to that class.

11.2 Irradiation ignition testing (I)

For irradiation ignition testing (see Figure 3) each specimen shall be graded/classified with the symbol (I) followed by a number that describes the result of the test and a subscript which indicates the used oxygen concentration (see also Table 1).

— Class I1 indicates that the product did not ignite with the oxygen concentrations of 21 % ± 2 % (ambient), 60 % ± 2 % and/or at 98 % ± 2 %.

EXAMPLES $I1_{21}$, $I1_{60}$ and $I1_{98}$ where $I1_{98}$ is the best rating.

— Class I2 ignites and self-extinguishes after stopping the laser with the oxygen concentrations of 21 % ± 2 % (ambient), 60 % ± 2 % and/or at 98 % ± 2 %.

EXAMPLES $I2_{21}$, $I2_{60}$ and $I2_{98}$.

— Class I3 ignites and did not self-extinguish after stopping the laser with the oxygen concentrations of 21 % ± 2 % (ambient), 60 % ± 2 % and/or at 98 % ± 2 %; ignition time > 4s

EXAMPLES $I3_{21}$, $I3_{60}$ and $I3_{98}$.

— Class I4 ignites and did not self-extinguish after stopping the laser with the oxygen concentrations of 21 % ± 2 % (ambient), 60 % ± 2 % and/or at 98 % ± 2 %; ignition time ≤ 4s

EXAMPLES $I4_{21}$, $I4_{60}$ and $I4_{98}$.

Table 1 — Classification system for irradiation ignition testing (I)

Class	Ignite	Ignition time	Self-extinguish
I1	No		
I2	Yes		Yes
I3	Yes	>4 s	No
I4	Yes	≤4 s	No

11.3 Transmission ignition and destruction testing (T/D)

11.3.1 Transmission ignition testing (T)

For transmission ignition testing (see Figure 3) each specimen shall be graded/classified with the symbol (T) followed by a number that describes the result of the test and a subscript that indicates the used oxygen concentration (see also Table 2).

— Class T1 indicates that the product did not ignite with the oxygen concentrations of 21 % ± 2 % (ambient), 60 % ± 2 % and/or at 98 % ± 2 %.

EXAMPLES $T1_{21}$, $T1_{60}$ and $T1_{98}$ where $T1_{98}$ is the best rating.

— Class T2 ignites and self-extinguishes after stopping the laser with the oxygen concentrations of 21 % ± 2 % (ambient), 60 % ± 2 % and/or at 98 % ± 2 %.

EXAMPLES $T2_{21}$, $T2_{60}$ and $T2_{98}$.

— Class T3 ignites and did not self-extinguish after stopping the laser with the oxygen concentrations of 21 % ± 2 % (ambient), 60 % ± 2 % and/or at 98 % ± 2 %; ignition time > 4s;

EXAMPLES $T3_{21}$, $T3_{60}$ and $T3_{98}$.

— Class T4 ignites and did not self-extinguish after stopping the laser with oxygen concentrations of 21 % ± 2 % (ambient), 60 % ± 2 % and/or at 98 % ± 2 %; ignition time ≤ 4s

EXAMPLES $T4_{21}$, $T4_{60}$ and $T4_{98}$.

Table 2 — Classification system for Transmission ignition testing (T)

Class	Ignite	Ignition time	Self-extinguish
T1	No		
T2	Yes		Yes
T3	Yes	>4 s	No
T4	Yes	≤4 s	No

11.3.2 Transmission destruction testing (D)

If during transmission testing, destruction of the specimen occurs (see Figure 4), each specimen shall be graded/classified with the symbol (D) followed by a number that describes the result of the test and a subscript that indicates the used oxygen concentration (see also Table 3).

- Class D1 indicates that the product did not destruct with the oxygen concentrations of 21 % ± 2 % (ambient), 60 % ± 2 % and/or at 98 % ± 2 %.

  EXAMPLES $D1_{21}$, $D1_{60}$ and $D1_{98}$ where $D1_{98}$ is the best rating.

- Class D2 destructs but does not break and lose any parts with the oxygen concentrations of 21 % ± 2 % (ambient), 60 % ± 2 % and/or at 98 % ± 2 %.

  EXAMPLES $D2_{21}$, $D2_{60}$ and $D2_{98}$.

- Class D3 destructs and lost parts with the oxygen concentrations of 21 % ± 2 % (ambient), 60 % ± 2 % and/or at 98 % ± 2 %; ignition time > 4s;

  EXAMPLES $D3_{21}$, $D3_{60}$ and $D3_{98}$.

Table 3 — Classification system for applicator destruction testing (D)

Class	Destruction
D1	No
D2	Yes, but no loss of parts
D3	Yes, with loss of parts