INTERNATIONAL STANDARD

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Optics and optical instruments — Lasers and laser-related equipment — Test method for the laser-resistance of surgical drapes and/or patient-protective covers

Optique et instruments d'optique — Lasers et équipements associés aux lasers — Méthode d'essai de la résistance au laser des draps chirurgicaux et/ou des couvertures de protection des patients

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11810 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments,* Subcommittee SC 9, *Electro-optical systems.*

Introduction

Only a small number of laser applications in medicine require laser-resistant surgical drapes and/or other patient-protective covers. Surgical drapes and/or other patient-protective covers are necessary when a sterile procedure is performed and the surrounding area needs to be protected from liquids, secretions and inadvertent laser radiation. While conventional surgical drapes and/or other patient-protective covers are not necessarily laser-resistant, specifically designed drapes offer the possibility of laser-resistance.

Laser-induced risks include ignition, flammability, melting, penetration, thermal transfer and reflectivity. Textile and non-woven drape materials may have other risks, but they may provide a laser barrier. While there are many potential ignition devices present in the operating room, e.g. fiberoptic illumination systems, electrosurgical units, hot wire cauteries, etc., this test method addresses only the laser ignition source. While it may not be necessary for all materials used in combination with laser equipment to possess laser-resistance, a surgical drape or other patient-protective cover that claims to be laser-resistant must be tested according to this International Standard. CO_2 lasers may provide the most challenging conditions of all medical lasers, but this is not certain. Ignition/flammability tests, and penetration tests may disclose more challenging laser wavelengths, as well as modes of laser delivery, for example Q-switching in the nanosecond range. Nevertheless, the 20 W CO_2 laser (continuous wave) has been selected as the default laser for this International Standard. The structure of this International Standard is sufficiently general so that it can be performed using other wavelengths, power settings and modes of delivery. When a CO_2 laser is used in testing under this International Standard, in no case should it have a power level less than 20 W. Users of this test method are cautioned that the laser-resistance of a surgical drape and/or other patient-protective cover will be wavelength sensitive and that a surgical drape and/or other patient-protective cover shall be tested at the wavelength for which it is intended. If used, those other wavelengths, power settings and modes of delivery need to be explicitly stated.

Optics and optical instruments — Lasers and laser-related equipment — Test method for the laser-resistance of surgical drapes and/or patient-protective covers

1 Scope

This International Standard specifies a standardized method for testing and classifying surgical drapes and other patient-protective covers with respect to laser-induced hazards. It applies to disposable and reusable, as well as woven and non-woven materials used as surgical drapes and other patient-protective covers which claim to be laser-resistant. An appropriate classification system is given.

It is not the purpose of this International Standard to serve as a general fire safety specification and, as such, it does not cover other sources of ignition nor does it cover the issue of laser-induced secondary ignition.

All materials reflect portions of the beam and it is necessary for the user to decide whether specular reflectance may be a hazard. This measurement, however, is not covered in this International Standard.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 139:1973, *Textiles — Standard atmospheres for conditioning and testing*

ISO 11145:2001, *Optics and optical instruments — Lasers and laser-related equipment — Vocabulary and symbols*

ISO 11146:1999, *Lasers and laser-related equipment — Test methods for laser beam parameters — Beam widths, divergence angle and beam propagation factor*

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply.

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

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

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

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 removal of the ignition source

3.5
disposable
product intended for use on a single occasion

3.6
flammable
subject to ignition and flaming combustion

3.7
ignition
initiation of combustion

3.8
melting behaviour
phenomena accompanying the softening of a material under the influence of heat

EXAMPLE Shrinking, dripping and burning of molten material.

3.9
patient-protective cover
material, other than a surgical drape, intended to protect a patient from laser radiation

3.10
penetration resistance
ability of a material to prevent the passage of laser energy

3.11
reflectance
characteristic of a material whereby laser energy is returned from the surface of the material

NOTE The reflectance is defined as the ratio of the reflected power to the incident power.

3.12
reusable
product intended to be laundered and resterilized for multiple use

3.13
surgical drape
material intended to be draped over a patient during surgery

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

4 Test method

4.1 General conditions

The suggested testing sequence is given in Figure 1.

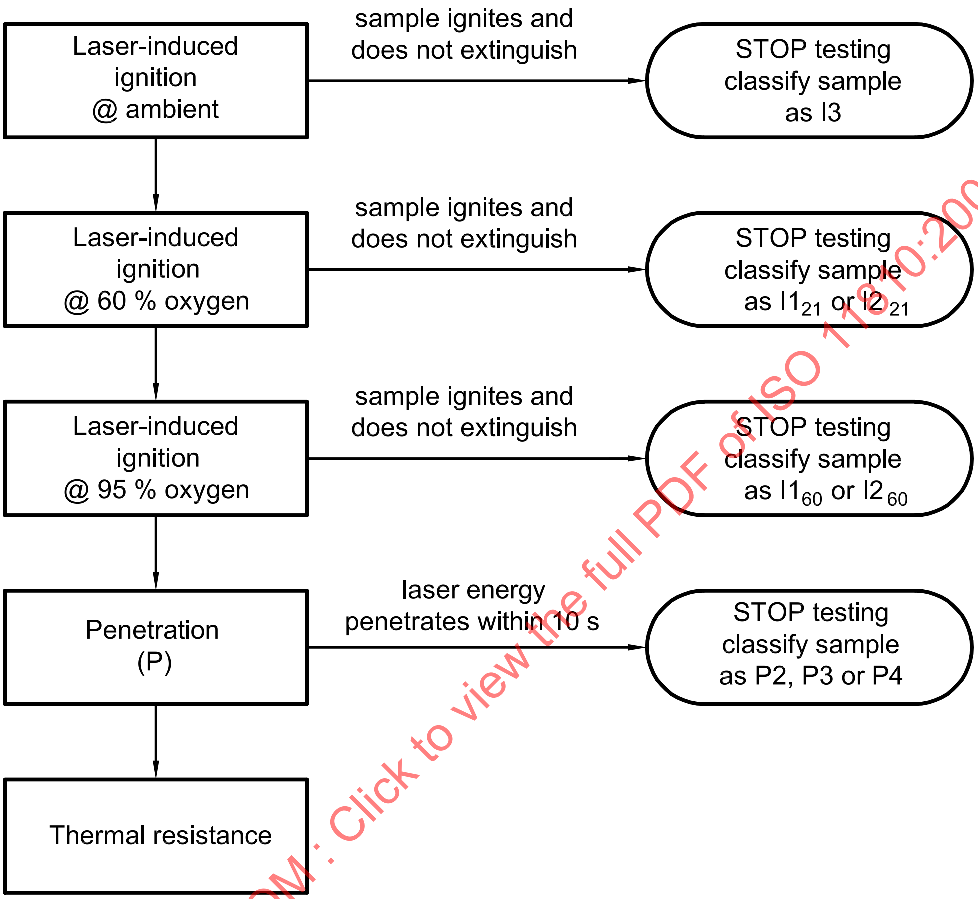


Figure 1 — Suggested testing sequence

4.1.1 Sampling

4.1.1.1 Disposable products

Samples of disposable products shall be obtained directly from the packing in which the products are sold.

4.1.1.2 Reusable products

Samples of reusable products shall be tested new and after reprocessing to the point where their rating changes. Reprocessing shall include laundering, 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.

4.1.1.3 Specimens

The samples are cut into pieces of at least 150 mm in length by at least 50 mm in width, with the faster burning direction lengthways, as determined by preliminary testing.

4.1.1.4 Quantities

For each parameter to be measured, five specimens shall be tested.

4.1.1.5 Conditioning

Specimens should normally be conditioned for 24 h at (20 ± 2) °C and (65 ± 2) % relative humidity. 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.

4.1.2 Test equipment

4.1.2.1 General

The test apparatus shall consist of a draft-resistant ventilated chamber (required for the laser-induced flammability tests, optional for other parameters), specimen holder, specimen rack, laser energy source and associated parts (see Figures 2 and 3).

4.1.2.2 Test chamber

The test chamber shall be constructed of a corrosion-resistant and laser- and fireproof material. It shall be a box with minimum dimensions of 365 mm length by 215 mm depth by 355 mm height with ventilation openings at the top and a door at one side. At least one side of the chamber shall have a glass window for observation during testing. One side of the chamber shall have a hole for the laser transmission system. At the opposite side there shall be the capability to mount a power meter. The test chamber shall be connected with the gas supply system in such a way that homogeneous ventilation of the chamber is achieved. A specimen rack provides support to mount the samples at a 45° angle to the bottom of the chamber. Measures shall be taken to ensure that no dangerous radiation leaves the chamber. The flowrate of the gas mixture shall be sufficient to produce one exchange of the test chamber volume every 30 s. A sample of filter paper shall be positioned directly beneath the test specimen for detection of dropped particles capable of igniting other materials.

4.1.2.3 Specimen holder

The specimen holder shall consist of two U-shaped metal plates of appropriate size (material: stainless steel or equivalent, approximately 2 mm thick). The specimen is fixed between the two plates, which are held together with spring clamps mounted along the sides of the plates. The plates are slotted and loosely pinned for alignment. The size of the exposed sample is 40 mm × 150 mm. Figure 3 shows an example of a specimen holder.

NOTE The mass of oxygen available to support combustion of the mass of fuel is important for the proper conduct of the laser-induced flammability tests. Large test chambers may not provide accurate results.

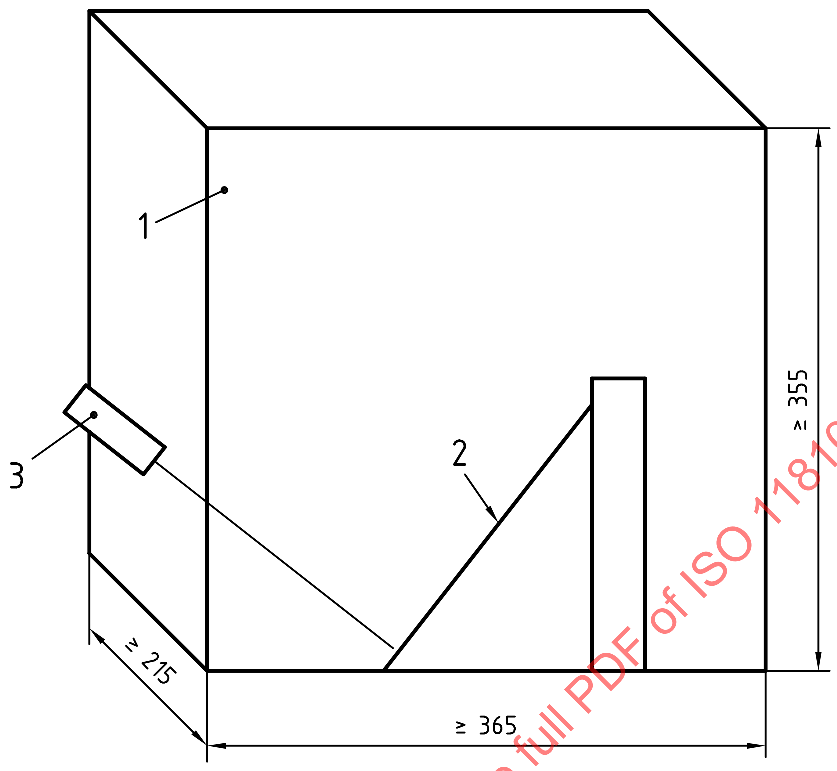
4.1.2.4 Laser system and power measurement

A continuous wave (CW) CO_2 laser with a minimum power of 20 W at the sample shall be used for all measurements. The spot diameter, d_{95}, in accordance with ISO 11145 and ISO 11146, shall be 2 mm for laser-induced ignition measurements or 1 mm for the penetration resistance measurement.

NOTE Since laser beam profile and mode structure can change as the power increases, testing the spot diameter with a pinhole may be more reliable than with a beam profile meter. Most profile monitors do not function at high power and small spot sizes.

For measuring the power of the laser radiation and for determining the penetration resistance, power meters which provide a measuring range from < 10 mW to > 20 W shall be used. A response time of < 1 s shall be used. Testing shall be done at the power density required for the test.

Dimensions in millimetres

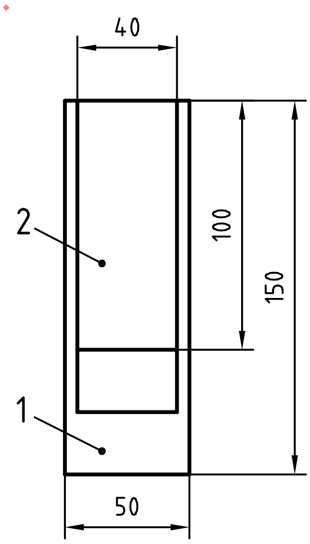


Key

1 Test chamber
2 Specimen holder
3 Laser source

Figure 2 — Test chamber

Dimensions in millimetres



Key

1 Frame
2 Test specimen

NOTE Two frame sections should hold the material securely along both upright edges using clips or other means.

Figure 3 — Example of a specimen holder

4.1.2.5 Environment

4.1.2.5.1 Ambient air conditions

The tests under ambient air conditions shall be performed at (20 ± 2) °C room temperature and (65 ± 2) % relative humidity in accordance with ISO 139.

4.1.2.5.2 Oxygen-enriched atmospheres

The tests under oxygen-enriched atmosphere shall be performed at oxygen concentrations of (60 ± 2) % and at least 95 % at the above room conditions. The oxygen concentration within the test chamber shall be established at the desired level by proportional mixing of nitrogen and oxygen by suitable means.

4.2 Testing procedure

The risk of penetration increases with increasing power density. This means that, at a given power setting, a small spot induces the highest risk. For laser-induced ignition of drapes, the risk increases with spot size at a given power setting. For example, the same power spot may penetrate without burning, whereas a larger spot might cause ignition.

The sequence of testing is ambient air, 60 % O_2 ± 2 %, then at least 95 % O_2. Refer to Figure 1 for the testing protocol.

4.2.1 Specimen preparation

Each specimen, after conditioning (see 4.1.1.5), is attached in the frame. A composite material shall be tested as it is intended to be used.

4.2.2 Laser-induced ignition

NOTE Testing the laser-induced ignition of drapes is not comparable to testing the laser-induced flammability of tracheal tubes. The major risk in an airway fire results from perforation of the tracheal tube by the laser and ignition of the inner wall of the tube in a high oxygen concentration. The risk for penetration increases with increasing power density. This means that, at a given power setting, a small spot induces the highest risk. In contrast, the laser-induced flammability of drapes increases with increasing spot size at a given power setting. For example, the same power density with a small spot may penetrate without burning, whereas a larger spot might cause ignition.

4.2.2.1 For ambient air testing, place the specimen in the specimen holder and rack at a 45° orientation. Close the chamber door.

4.2.2.2 For testing in enriched oxygen atmospheres, place the specimen in the specimen holder and rack at a 45° orientation. Close the chamber door, and flow oxygen and nitrogen at a rate and time period sufficient to establish an environment of (60 ± 2) % and/or at least 95 % oxygen in the testing chamber. Verify the oxygen concentration by use of an oxygen analyser and appropriate sampling techniques.

4.2.2.3 Aim the laser beam spot normal to the specimen. Position the centre of the 2 mm spot at the centre of the specimen.

4.2.2.4 Expose the specimen to the laser energy for 10 s.

4.2.2.5 Classify the tested specimen as I1, I2, or I3 (see 5.3). Report if, during or after the laser irradiation, there is afterflame or afterglow, or if particles or droplets fall from the specimen. When all specimens have been tested at the given condition, classify the material as outlined in clause 5.

4.2.3 Penetration resistance

4.2.3.1 Place the specimens in the vertical position and outside the chamber on an appropriate optical bench system.

Verify normal ambient air composition at (20 ± 2) °C and (65 ± 2) % relative humidity.

4.2.3.2 Adjust the spot diameter on the specimen surface to be 1 mm. Adjust the laser beam to hit the specimen normally.

NOTE This is to achieve a definite spot diameter and an even distribution of the incident beam power.

4.2.3.3 Expose the specimen to 20 W for 10 s or until the power meter behind the specimen detects 10 mW. This exposure time shall be measured

Care should be taken to shutter the laser beam as soon as possible after 10 mW penetration to protect the laser power meter.

In order to ensure that the power meter does not measure the temperature increase of the sample, it should be at least 5 cm from the sample.

4.2.3.4 Classify the tested specimen as P1, P2, P3 or P4 (see 5.3). Report if, during or after the laser irradiation, there was afterflame or afterglow or flaming.

4.2.3.5 When all the specimens have been tested under the given conditions, classify the material as outlined in 5.3.

4.2.3.6 Note the thermal response of P1 class materials. A material that absorbs laser radiation will heat up. The temperature on the underside of the material opposite to the irradiated surface needs to be measured. After a laser exposure duration of 10 s at 20 W and at 1 mm spot size, switch off the laser beam and measure the temperature with an appropriate temperature measurement device that contacts the sample surface, e.g. liquid crystal tape. The detected temperature shall be noted in addition to the class.

5 Classification

5.1 Laser-induced ignition

Every specimen shall be graded according to the following classification system:

— I1 material did not ignite;

— I2 material did ignite but extinguished itself;

— I3 material did ignite and did not extinguished itself.

5.1.1 Oxygen-enriched atmosphere

A suffix shall be added to class I1 to indicate that the product did not ignite under oxygen concentrations of (60 ± 2) % and/or 95 %, for example, $I1_{60}$ and $I1_{95}$ (ambient is indicated by $I1_{21}$). $I1_{95}$ is the best rating.

5.2 Resistance to laser penetration (P)

Every specimen shall be graded according to the classification given in Table 1.

Table 1 — Classification of laser penetration

Class	Classification requirements 10 mW power will be reached in a time period
P1	> 10 s
P2	< 10 s but > 3 s
P3	< 3 s but > 1 s
P4	< 1 s

5.3 Classification prescription

5.3.1 If all the specimens belong to the same class, the tested material belongs to this class.

5.3.2 If two or more of the five specimens belong to a class with a higher number, then the tested material shall be assigned to the class with a higher number.

5.3.3 If one of the specimens belongs to the class with a higher number, a new test series with five new samples shall be performed. If one or more specimens of the new series belong to the class with a higher number, the tested material shall be assigned to the class with a higher number.

6 Additional requirements

A product which claims to be a laser-resistant surgical drape or other patient-protective cover shall meet the following requirements:

a) there shall be no deterioration of laser-resistance after reuse and sterilization according to the instructions of the manufacturer;

b) there shall be no dangerous overheating in case of absorption of the laser radiation;

c) there shall be instructions for use.

The user of the product shall be cautioned by the manufacturer that the performance of laser-resistant surgical drapes and other patient-protective covers may be degraded when used in combination rather than individually.

7 Test report

The test report shall contain the following information:

a) reference to this International Standard;

b) date of the test;

c) power and wavelength of the laser;

d) laser mode (continuous, pulsed); if other than continuous, pulse duration and energy per pulse;

e) method of determining power and spot diameters;