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

**Part 1:
Primary ignition and penetration**

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

Partie 1: Allumage primaire et pénétration



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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 2.

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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11810-1 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 9, *Electro-optical systems*.

This first edition cancels and replaces ISO 11810:2002, which has been technically revised.

ISO 11810 consists of the following parts, under the general title *Lasers and laser-related equipment — Test method and classification for the laser resistance of surgical drapes and/or patient protective covers*:

- *Part 1: Primary ignition and penetration*
- *Part 2: Secondary ignition*

Introduction

Some laser applications in medicine may require laser-resistant surgical drapes or other patient protective covers. Surgical drapes 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 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. fibre optic illumination systems, electro-surgical units, hot wire cauteries), this test method addresses only the laser ignition source. This part of ISO 11810 is intended for use in testing a surgical drape or other patient protective cover that claims to be laser-resistant. In addition, areas within this product may vary in material composition or design. Depending on the claims being made by the manufacturer or end-user requirements, all areas for which laser resistance is claimed may need to be tested.

CO₂ lasers may provide the most challenging conditions of all medical lasers. 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. The 20 W CO₂ laser (continuous wave) has been selected as the laser for this part of ISO 11810.

Users of this test method are cautioned that the laser resistance of a surgical drape or other patient protective cover will be wavelength sensitive and that a surgical drape or other protective cover should be tested at the wavelengths for which it is intended to be used. If tested using other wavelengths, the power settings and modes of delivery need to be explicitly stated.

The results from this part of ISO 11810 should not be applied to other wavelengths and temporal formats.

The performance of laser-resistant surgical drapes or other patient protective covers may be changed when used in combination rather than individually.

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

Part 1: Primary ignition and penetration

1 Scope

This part of ISO 11810 is applicable 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.

The purpose of this part of ISO 11810 is to provide a standardized method for testing and classifying surgical drapes and other patient protective covers with respect to laser-induced hazards. An appropriate classification system is given. It is not the purpose of this part of ISO 11810 to serve as a general fire safety specification, and as such, this part of ISO 11810 does not cover other sources of ignition. It also does not 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 part of ISO 11810.

2 Normative references

The following referenced documents are indispensable for the application 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 11145:2001, *Optics and optical instruments — Lasers and laser-related equipment — Vocabulary and symbols*

ISO 11146-1, *Lasers and laser-related equipment — Test methods for laser beam widths, divergence angles and beam propagation ratios — Part 1: Stigmatic and simple astigmatic beams*

3 Terms and definitions

For the purposes of this document, 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 the ignition source has been removed
- 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
- 3.5
combustion**
any continuing burning process that occurs on the test sample
- 3.6
flammable**
subject to ignition and flaming combustion
- 3.7
ignition**
initiation of combustion
- 3.8
melting behaviour**
softening of a material under the influence of heat (including shrinking, dripping and burning of molten material, etc.)
- 3.9
patient protective cover**
material, other than a surgical drape, intended to protect a patient
- 3.10
penetration resistance**
ability of a material to prevent the passage of laser energy
- 3.11
product**
finished medical device (drape or other patient cover) that may be composed of one or more homogeneous materials (samples)
- 3.12
reusable product**
product intended to be laundered and re-sterilized for multiple use
- 3.13
single use**
product intended to be used once and then discarded
- 3.14
surgical drape**
material intended to be draped over a patient during surgery
- 3.15
thermal resistance**
ability of a material to resist conduction of heat

4 Test methods

4.1 General conditions

The suggested testing sequence for ignition is shown in Figure 1. The suggested testing sequence for penetration is shown in Figure 2.

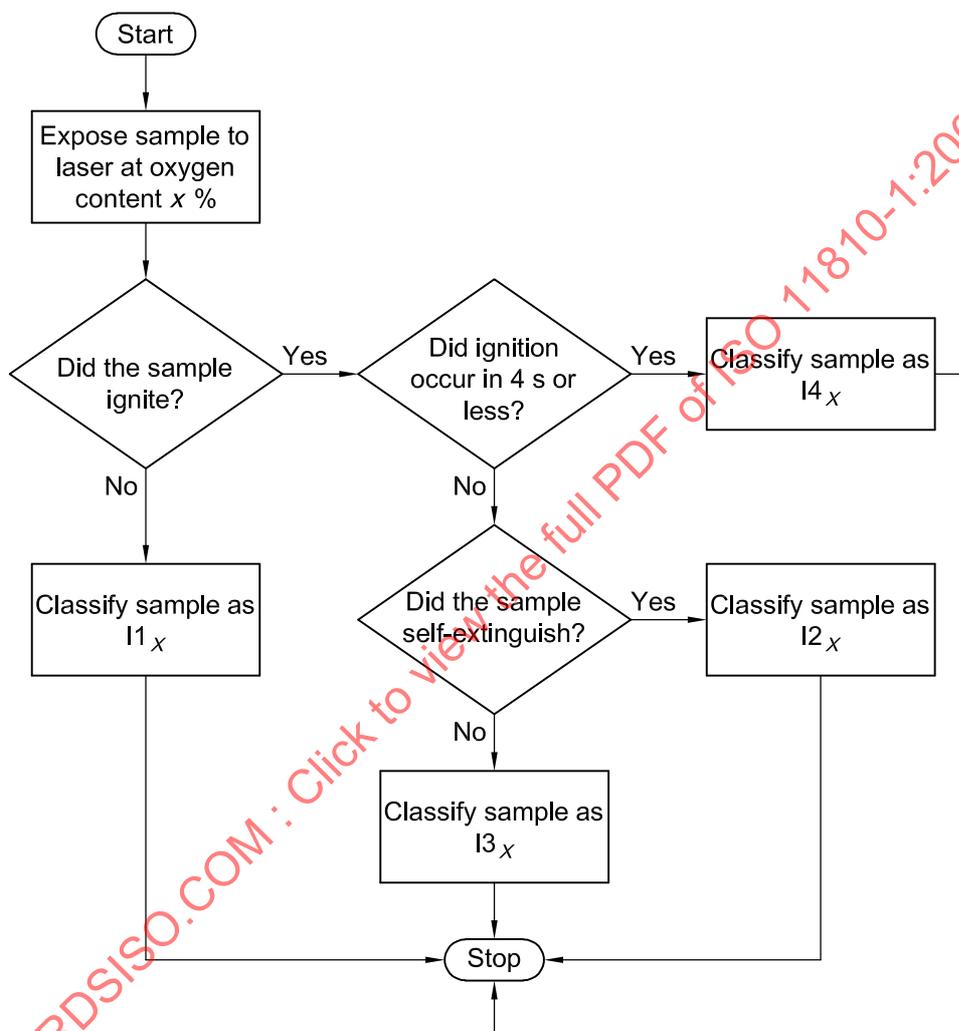


Figure 1 — Suggested testing sequence for ignition

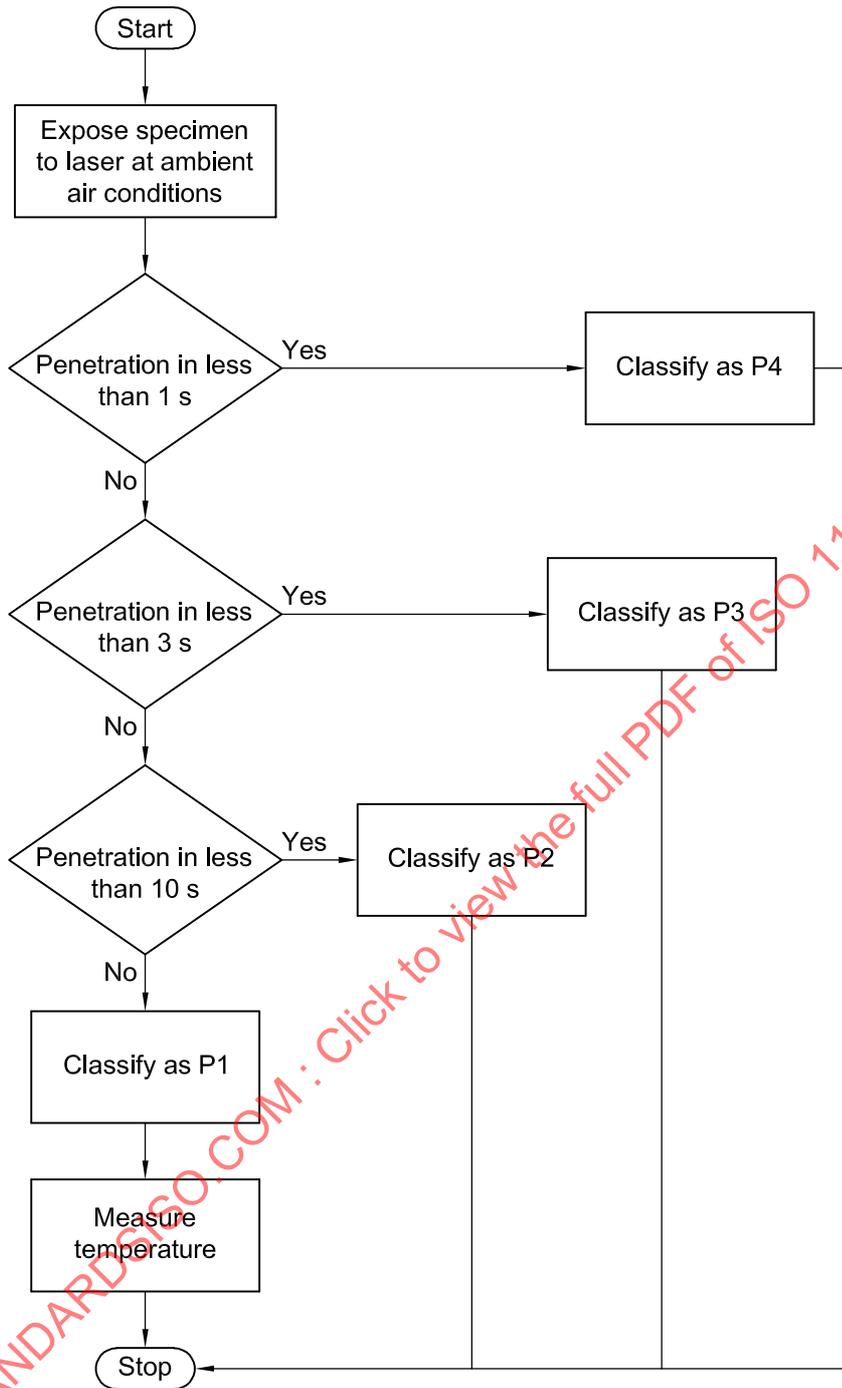


Figure 2 — Suggested testing sequence for penetration

4.1.1 Sampling

4.1.1.1 Single-use products

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

4.1.1.2 Reusable products

Reusable products shall be tested new and after reprocessing to the point when 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 sample is cut into specimens of at least 150 mm in length by at least 50 mm in width, with the faster burning direction (as determined by preliminary testing) in the long direction.

4.1.1.4 Quantities

For each parameter to be measured, 5 specimens shall be tested.

4.1.1.5 Conditioning

Specimens shall be conditioned for 24 h at $20\text{ °C} \pm 2\text{ °C}$ and $65\% \pm 2\%$ 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.

NOTE These conditions have been chosen according to ISO 139:2005 to ensure standard test results and simulate operating room conditions.

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 3 and 4).

4.1.2.2 Test chamber

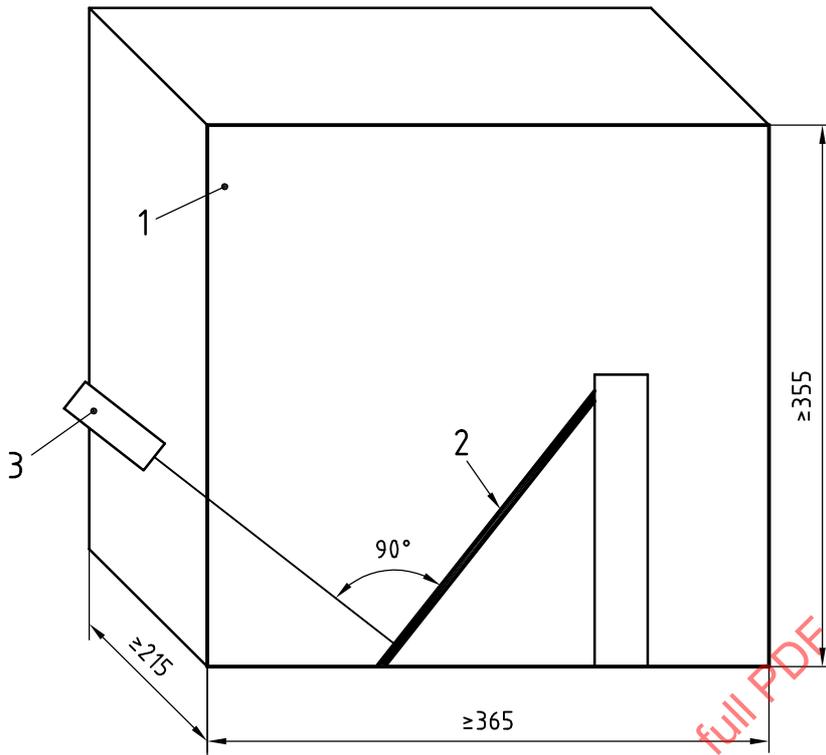
The test chamber shall be constructed of a corrosion-resistant and laser and fireproof material. It shall be a box with minimum dimensions of 365 mm length by 215 mm depth by 355 mm height with ventilation openings at the top and a door at one side. At least one side of the chamber shall have a glass window for observation during testing. One side of the chamber shall have a hole for the laser transmission system. 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 shall provide support to mount the specimen at a 45° angle to the bottom of the chamber. Measures shall be taken to ensure that no dangerous radiation leaves the chamber. A piece of clean filter paper shall be positioned on the floor of the test chamber directly beneath the test specimen for detection of dropped particles capable of igniting other materials.

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 might not provide accurate results.

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 shall be fixed between the two plates which are held together with spring clamps mounted along the sides of the plates. The plates shall be slotted and loosely pinned for alignment. The size of the exposed specimen shall be 40 mm × 100 mm. Figure 4 shows an example of a specimen holder.

Dimensions in millimetres

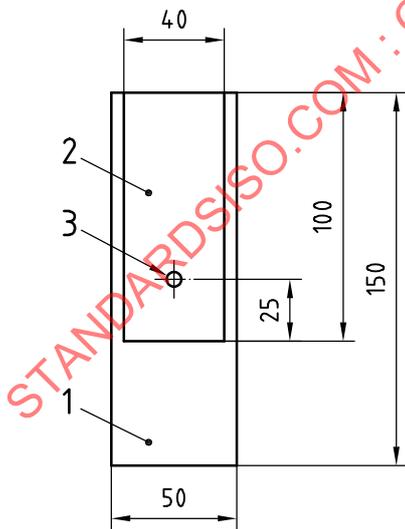


Key

- 1 test chamber
- 2 specimen holder
- 3 laser

Figure 3 — Test chamber

Dimensions in millimetres



Key

- 1 frame
- 2 specimen
- 3 aiming spot (25 mm from the bottom edge)

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

Figure 4 — Example of a specimen holder

4.1.2.4 Laser system

A continuous wave (CW) CO₂ laser with a minimum power of 20 W at the specimen shall be used for all measurements. The spot diameter (in accordance with ISO 11145 and ISO 11146-1) d_{95} shall be 2 mm for laser induced ignition measurements and 1 mm for the penetration resistance measurement.

4.1.2.5 Power measurement

For measuring the power of the laser radiation and for determining the penetration resistance, power meters which provide a measuring range from less than 10 mW to greater than 20 W shall be used. A response time of $\leq 0,25$ s shall be used for the penetration resistance measurements. Testing shall be done at the power density required for the test.

4.1.2.6 Environment

4.1.2.6.1 Ambient air conditions

The tests under ambient air conditions shall be performed at room temperature of $20\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ and $65\% \pm 2\%$ relative humidity.

4.1.2.6.2 Oxygen-enriched atmospheres

The tests under oxygen-enriched atmosphere shall be performed at oxygen concentrations of

- a) $60\% \pm 2\%$, and
- b) at least 95 %.

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 testing for ignition and penetration shall be done on separate groups of 5 specimens.

NOTE The risk of penetration increases with increasing power. At a given power setting, a small spot induces the highest risk. For laser induced ignition of drapes, the risk increases with increasing spot diameter at a given power setting.

The sequence of testing shall be 21 % O₂ (ambient air), ($60\% \pm 2\%$) O₂ then at least 95 % O₂. Refer to Figures 1 and 2 for the testing protocol.

4.2.1 Specimen preparation

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

4.2.2 Laser-induced ignition

4.2.2.1 For ambient air testing, place the specimen, the specimen holder and rack at a 45° orientation. Close the chamber door. Record the temperature and relative humidity of the chamber.

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

- a) $60\% \pm 2\%$, or
- b) at least 95 %

oxygen in the testing chamber. Verify the oxygen concentration by use of an oxygen analyser and appropriate sampling techniques. Record the temperature and relative humidity of the chamber.

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, 25 mm from the bottom edge.

4.2.2.4 Expose the specimen to the laser energy until ignition occurs or a maximum of 10 s.

4.2.2.5 Classify the tested specimen as I1, I2, I3, or I4 (see 5.1). Report whether during or after the laser irradiation there is “afterflame” or “afterglow” or particles or droplets fall from the specimen. When all specimens have been tested at the given condition, classify the sample as outlined in 5.3.

4.2.3 Penetration resistance

4.2.3.1 Place the specimen in the vertical position and outside of the chamber on an appropriate optical bench system. Verify normal ambient air composition at 20 °C ± 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. The exposure time has to 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 specimen, it should be at least 5 cm from the specimen.

NOTE The value of 10 mW is the skin MPE for a 1 mm diameter 10,6 µm beam at 0,33 s.

4.2.3.4 Classify the tested specimens as P1, P2, P3 or P4 (see 5.2). Report, whether during or after the laser irradiation there was “afterflame” or “afterglow” or flaming.

4.2.3.5 When all specimens have been tested at the given condition, classify the sample as outlined in 5.3.

4.2.3.6 Thermal response of P1 Class materials shall be done on all 5 specimens. A material that absorbs laser radiation will heat up. The temperature on the backside of the material opposite to the irradiated surface needs to be measured. Using a laser exposure duration of 10 s at 20 W and at 1 mm spot diameter, monitor the temperature of the back surface with an appropriate device such as a thermographic camera or with a device which contacts the surface of the material, e.g. liquid crystal tape. The maximum detected temperature shall be noted in addition to the class.

5 Classification

5.1 Laser induced ignition (I)

5.1.1 Every specimen shall be graded according to the following classification system.

Table 1 — Classification system for ignition

Class	Ignite	Time	Self-extinguish
I1	No	—	—
I2	Yes	—	Yes
I3	Yes	> 4 s	No
I4	Yes	≤ 4 s	No