
**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

iTeh STANDARD PREVIEW

*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 —*

ISO 11810-1:2005
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*

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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.

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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.

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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

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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.

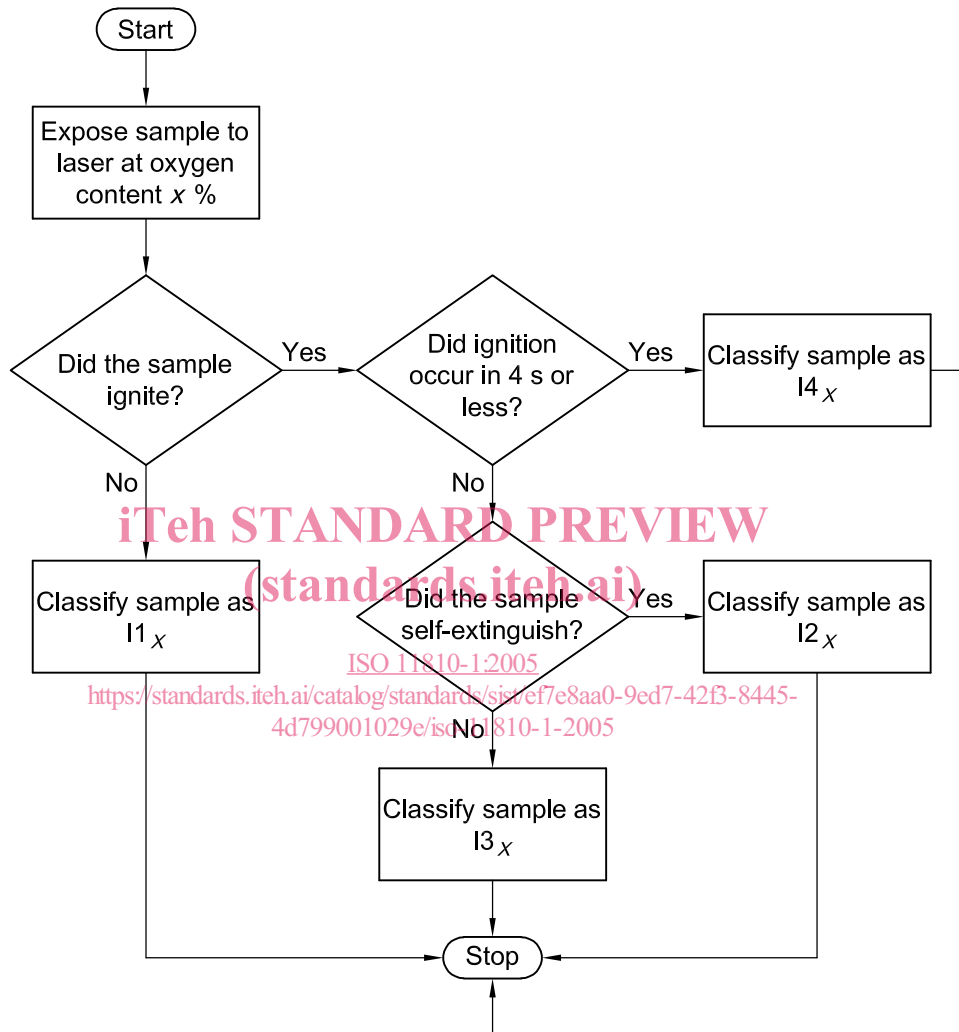


Figure 1 — Suggested testing sequence for ignition