INTERNATIONAL STANDARD

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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 — Primary ignition, penetration, flame spread and secondary ignition

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 — Inflammation principale, pénétration et inflammation secondaire

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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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 9, *Electro-optical systems*.

This second edition cancels and replaces ISO 11810-1:2005 and ISO 11810-2:2007 which have been technically revised.

Introduction

Some laser applications in medicine can 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 surgical 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 can have other risks but they can 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 International Standard 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 can 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 might need to be tested.

CO_2 lasers can induce the most challenging conditions of all medical lasers. Ignition/flammability tests and penetration tests can reveal more challenging laser wavelengths as well as modes of laser delivery, for example Q-switching in the nanosecond range. The 20 W CO_2 laser (continuous wave) has been selected as the laser for this International Standard.

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 patient-protective cover should be tested at the wavelengths for which it is intended to be used. If tested using other wavelengths, it is necessary to explicitly state the power settings and modes of delivery.

The results from this International Standard should not be applied to other wavelengths and temporal formats.

The performance of laser-resistant surgical drapes or other patient-protective covers can 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 — Primary ignition, penetration, flame spread and secondary ignition

CAUTION — This test method can involve hazardous materials, operations and equipment. This International Standard 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 International Standard to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

1 Scope

This International Standard 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 International Standard 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 International Standard to serve as a general fire safety specification, and as such, this International Standard does not cover other sources of ignition.

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

The test procedure can be used to assess the laser induced flammability properties of non-laser-resistant items

NOTE Users of products tested by this method are cautioned that the laser resistance of a surgical drape and/or patient-protective cover will be wavelength sensitive and that a surgical drape and/or patient-protective cover are better tested at the wavelength for which it is intended to be used. If tested using other wavelengths, it is necessary to explicitly state the power settings and modes of delivery.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11145, *Optics and photonics — 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*

ISO 80000-4, *Quantities and units — Part 4: Mechanics*

IEC 60825-1, *Safety of laser products — Part 1: Equipment classification and requirements*

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
beam diameter
d_{95}
diameter of an aperture in a plane perpendicular to the beam axis which contains 95 % of the total beam power

3.6
beam cross-sectional area
A_{95}
smallest area containing 95 % of the total beam power

Note 1 to entry: Adapted from ISO 11145:2006, 3.2.1.

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.

3.8
damage
any change, other than combustion, which can affect the safety of the patient or efficacy of the product due to increasing the risk of ignition

EXAMPLE Local heating, melting, creation of holes, pyrolysis.

3.9
flammable
subject to ignition and flaming combustion

3.10
ignition
creation of combustion induced by the delivery of power

3.11
laser resistance
measure of the ability of a material to withstand laser power without ignition or damage

3.12
melting behaviour
softening of a material under the influence of heat (including shrinking, dripping and burning of molten material, etc.)

3.13
patient-protective cover
material, other than a surgical drape, intended to protect a patient

3.14
penetration resistance
ability of a material to prevent the passage of laser energy

3.15
product
finished medical device (surgical drape or other patient-protective cover) that can be composed of one or more homogeneous materials (samples)

3.16
reusable product
product intended to be laundered and re-sterilized for multiple use

3.17
secondary ignition
ignition of a specimen by an underlying material caused to burn by a laser beam transmitted through the specimen

3.18
single use
product intended to be used once and then discarded

3.19
surgical drape
material intended to be draped over a patient during surgery

3.20
thermal resistance
ability of a material to resist conduction of heat

4 Principle

WARNING — This test method can result in a rocket-like fire involving the surgical drape. 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 of up to 98 % ± 2 % oxygen.

5 Significance and use of the test

5.1 This International Standard describes a uniform and repeatable test method for measuring the primary ignition, penetration, flame spread and secondary ignition of surgical drapes and other patient-protective covers. Variables involved in laser ignition have been fixed in order to establish a basis for comparison. This test method can be used to compare differing types and designs.

5.2 A large number and range of variables is involved in ignition of surgical drapes. A change in one variable can affect the outcome of the test. Caution should be exercised, since the direct applicability of the results of this test method to the clinical situation has not been fully established.

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

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

5.5 Many manufacturers of laser-resistant surgical drapes recommend using isotonic saline or water to moisten the material. In case of water-proof surgical drapes, the underlying material cannot be moistened and so can have the original burning behaviour.

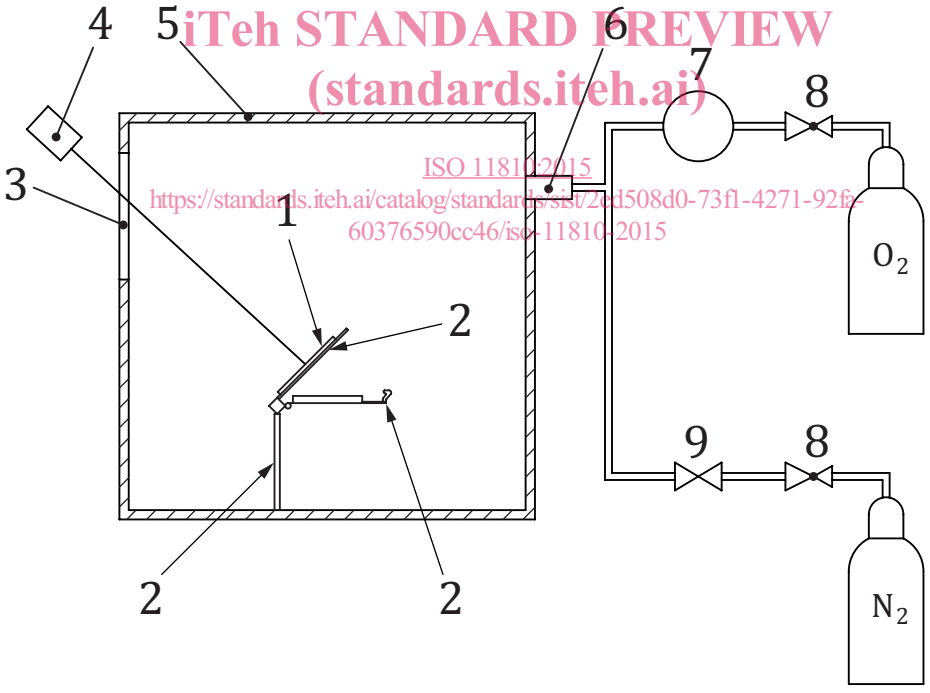
NOTE 1 This method can be applied to study the effect of changing the test conditions, but this is outside the scope of this International Standard.

NOTE 2 Use of beam cross-sectional shape, other than circular, or mode of laser power delivery, other than continuous wave, can affect the ignition characteristics.

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 Figure 1).



Key

1 specimen
2 specimen holder (see Figures 2, 3 and 4 for more detail)
3 opening for laser access
4 laser
5 containment box (lateral view)
6 flashback arrestor
7 oxygen flow meter and controller
8 pressure regulator with inlet and outlet gauges
9 quick-action inert gas valve

Figure 1 — Typical test apparatus (schematic)

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 have the following characteristics:

a) it is rectangular in shape and measures approximately 46 cm × 46 cm × 46 cm;

b) it is fire-proof and easily cleaned of soot and residue from burned specimens;

c) it allows the mounting of the specimen at an angle such that by gravity the underlying material is removed spontaneously;

d) it allows access to the specimen;

e) it allows direct access of the laser beam to the specimen;

f) it allows 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) it exhausts the gas and any products of combustion to a safe area;

h) it allows cleaning of the box, and cleaning of the covers and/or windows themselves;

i) it is capable of maintaining an environment of 98 % ± 2 % oxygen around the specimen;

j) it can be rapidly flooded with nitrogen or another gas to extinguish any fire inside the box;

k) the internal surfaces are non-reflective to protect the specimen from reflections;

l) 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.

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 (see Figure 2) shall consist of three metal plates (of stainless steel or equivalent, approximately 2 mm thick). The specimen shall be clamped between the top two plates (top frame and mount). The connection between these two plates shall be stable and may be achieved by clamps or screws. The plates shall be slotted and loosely pinned for alignment. The third plate (bottom frame) is to allow for the attachment of the cotton gauze. The construction of the fixture shall ensure that when testing for secondary ignition the specimen is in direct contact with the cotton gauze and is not squeezed out of its attachment between the top frame and the mount. The bottom frame is connected to the mount by a hinge.

Top frame, mount and bottom frame have openings of 40 mm by 100 mm (size of exposed specimen) to ensure access of the laser beam and to avoid cooling of the specimen due to heat conduction of the mount. The outer dimensions of these plates should not be smaller than 70 mm by 170 mm.

When testing for secondary ignition, the separation mechanism shall be white mercerized cotton thread having a linear density of 45 g/1 000 m to 50 g/1 000 m. The white mercerized cotton thread is used to keep the lower and upper two frames together. To avoid direct laser induced ignition of the white mercerized cotton thread, it shall be placed 30 mm above the laser spot on the specimen's surface, normal to the fastest burning direction. Ignition of the cotton gauze will burn off the white mercerized