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.*

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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.

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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

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.

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2 Normative references

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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

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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

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EXAMPLE Shrinking, dripping and burning of molten material.

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

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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

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4 Test method

4.1 General conditions

The suggested testing sequence is given in Figure 1.

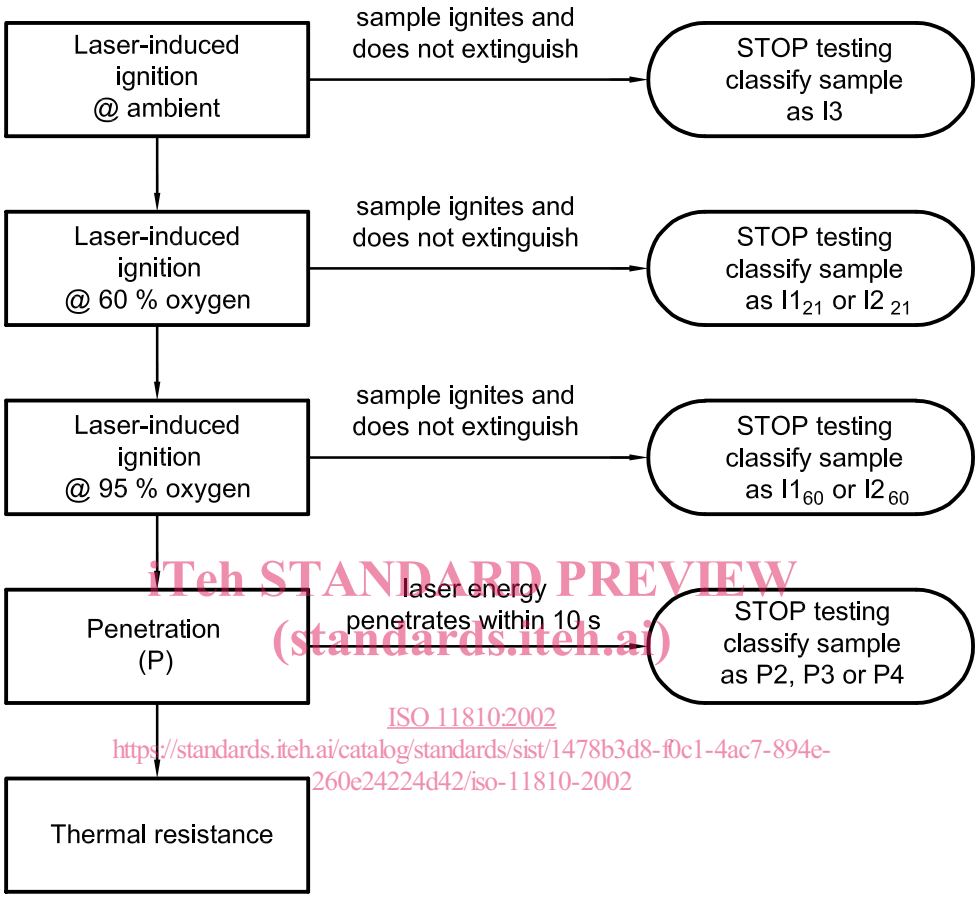

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Figure 1 — Suggested testing sequence

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.

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