INTERNATIONAL STANDARD

ISO 11810-2

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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 2: 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 —

Partie 2: Inflammation secondaire

Reference number
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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 11810-2 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 9, *Electro-optical systems*.

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*

For the purposes of this part of ISO 11810 the CEN annex regarding fulfilment of European Council Directives will be removed at publication stage.

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, inflammability, 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, etc., this test method addresses only the laser ignition source. A surgical drape or other patient protective cover that claims to be laser-resistant must be tested according to this part of ISO 11810.

CO_2 lasers may provide the most challenging conditions of all medical lasers. Ignition/inflammability 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 CO_2 laser (continuous wave) has been selected as the laser to be used for this part of ISO 11810. For laser-induced secondary ignition of drapes and/or patient protective covers, the risk is dependent on spot size at a given power setting. In addition, areas within a given product may vary in material composition or design. Depending on the claims being made by the manufacturer or end-user requirements, all areas within the product may need to be tested.

This part of ISO 11810 applies to secondary ignition and is provided with information additional to ISO 11810-1 for testing and reporting test results. The purpose of secondary ignition is to simulate a situation where a surgical drape or other protective cover is placed over another material. A piece of cotton gauze is used to simulate this other material. This part of ISO 11810 determines whether ignition of the cotton gauze will ignite the surgical drape and/or patient protective cover and whether the surgical drape and/or patient protective cover will continue to burn once the burning cotton has been removed. The afterflame of the surgical drape and/or protective cover is also determined.

The performance of laser resistant surgical drapes or other patient covers may be degraded 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 2: Secondary ignition

1 Scope

This part of ISO 11810 is applicable to disposable and re-usable, as well as woven and non-woven materials used as surgical drapes and/or 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/or 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. This part of ISO 11810 is limited to testing the secondary ignition of materials that are rated I1 or I2 from ISO 11810-1.

All materials reflect portions of the beam and it is necessary for the user to decide whether specular reflection may be a hazard. This measurement, however, is not covered in this part of ISO 11810.

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

The 20 W CO_2 laser (continuous wave) has been selected as the laser to be used for this part of ISO 11810.

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, the power settings and modes of delivery need to be explicitly stated.

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, *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 11810-1, *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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11145, ISO 11810-1 and the following apply.

3.1
secondary ignition
ignition of a test sample by an underlying material caused to burn by a laser beam transmitted through the sample

4 Test methods

4.1 General conditions

The suggested testing sequence is shown in Figure 1.

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 Re-usable products

Re-usable 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 as determined by the manufacturer.

4.1.1.3 Specimens

The samples are 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, five specimens shall be tested.

4.1.1.5 Conditioning

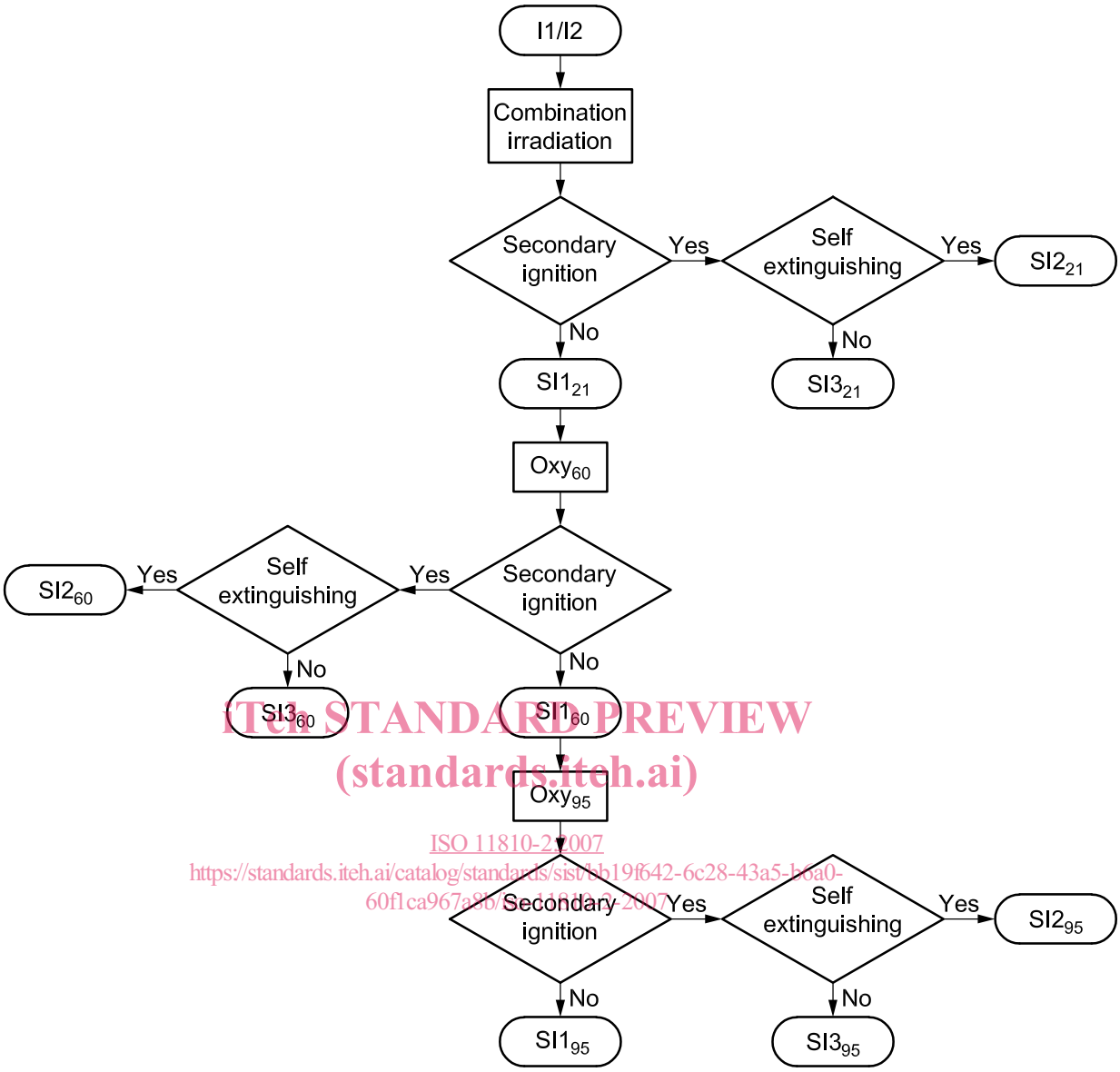
All materials (specimens, cotton gauze, and white mercerized cotton thread) shall be conditioned for 24 h at 20 °C ± 2 °C and 65 % ± 2 % relative humidity. Materials requiring special treatment or preparation shall be conditioned according to the manufacturer's instructions for use. Any special treatment or preparation shall be stated when reporting results.

NOTE These conditions have been chosen in accordance with 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 draught-resistant ventilated chamber, specimen holder, specimen rack, laser energy source and associated parts (see Figures 2 and 3).



Key

I1, I2	Ignition classification according to ISO 11810-1
SI1	Secondary ignition class 1
SI2	Secondary ignition class 2
SI3	Secondary ignition class 3
Indices	21, 60, 95: Amount of oxygen in percent
Oxy	Oxygen

Figure 1 — Suggested testing sequence for secondary ignition testing