
**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

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.

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.

CO₂ 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 CO₂ 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 $60\% \pm 2\%$ and $98\% \pm 2\%$ 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.

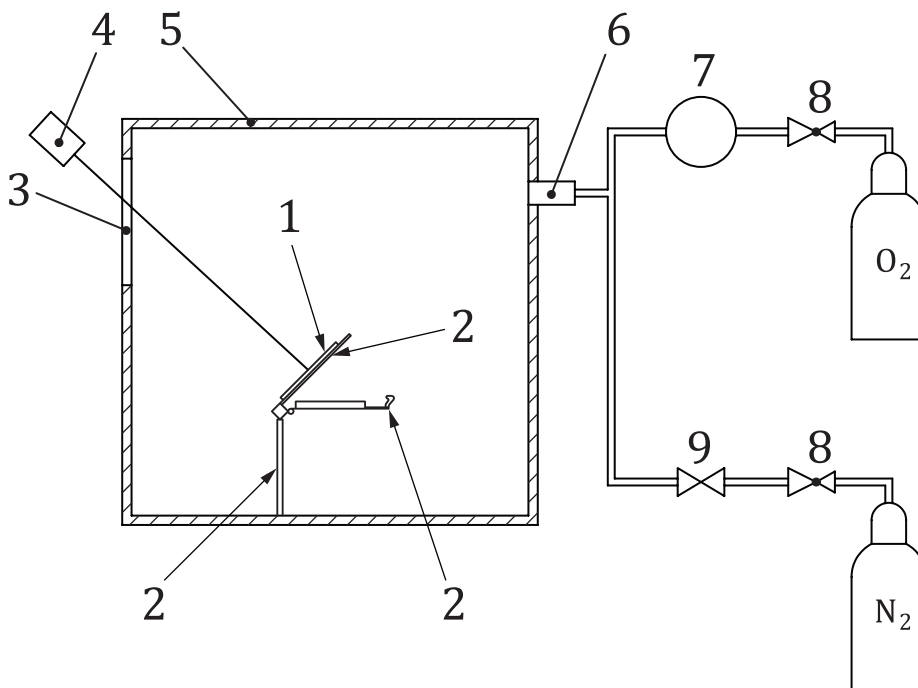
NOTE 1 This method can be applied to study the effect of changing the test conditions, but this is outside the scope of this International Standard.

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

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.

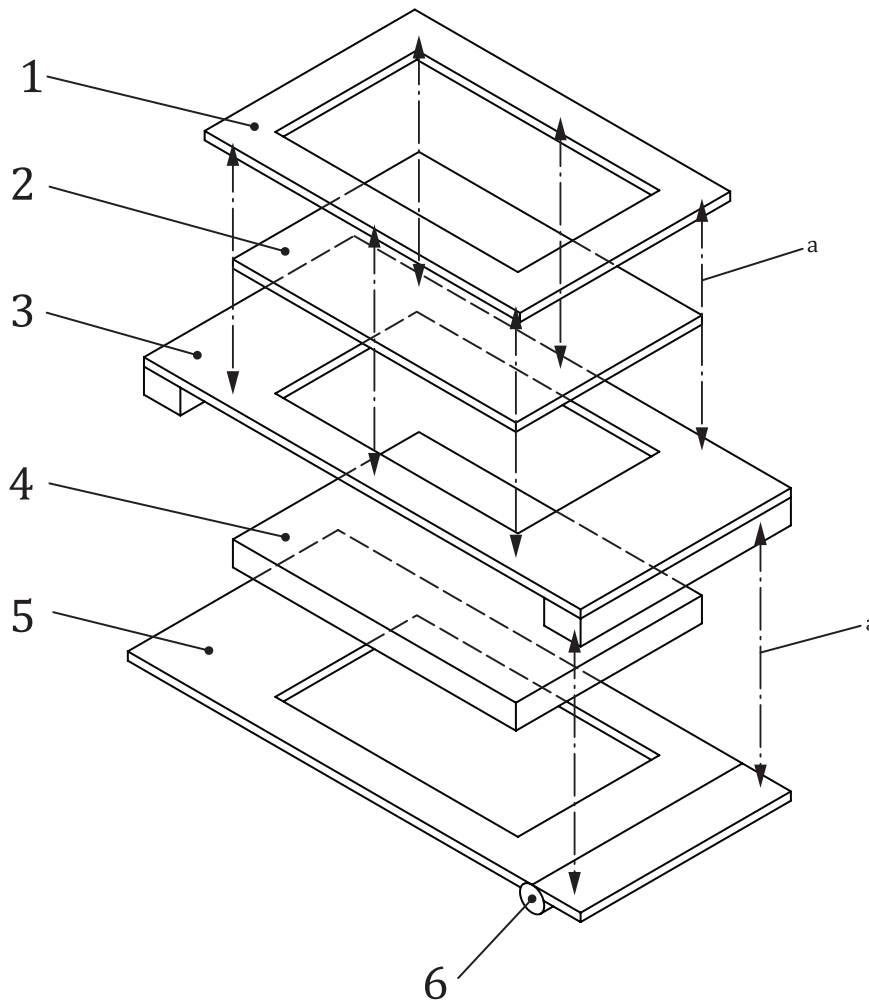
When testing for secondary ignition, the separation mechanism shall be white mercerized cotton thread having a linear density of 45 g/1 000 m to 50 g/1 000 m. The white mercerized cotton thread is used to keep the lower and upper two frames together. To avoid direct laser induced ignition of the white 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

cotton thread and thus separate the cotton gauze from the specimen without involving the reaction of a person. [Figure 3](#) illustrates the specimen holder, showing the use of the white mercerized cotton thread.

NOTE 1 White mercerized cotton thread having linear density of 45 g/1 000 m to 50 g/1 000 m is used as marker thread in ISO 6941.

NOTE 2 Manufacturers are usually familiar with the unit “Tex” for the linear density of textiles, including mercerized thread (e.g. ISO 1144, ISO 2947). The unit “Tex” is a non-SI (International System of Units) unit. In accordance with ISO 80000-4, the SI unit “g/1 000 m” is used in place of the non-SI unit “Tex”.

NOTE 3 White mercerized cotton thread of approximately 30 cm length is used; a loop is made in one end of the white mercerized cotton thread; the other end is pulled through this loop, resulting in a large ring; this ring is placed around the frames; the end of the white mercerized cotton thread is pulled to fasten it. This end is attached.

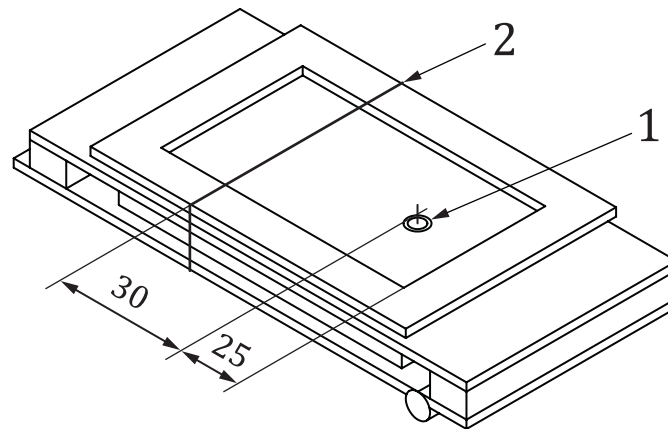


Key

- | | |
|----------------------------------------------------------|---------------------------|
| 1 top frame | 5 bottom frame |
| 2 specimen | 6 hinge |
| 3 mount | a Elements are connected. |
| 4 cotton gauze (used in secondary ignition testing only) | |

Figure 2 — Example of a specimen holder

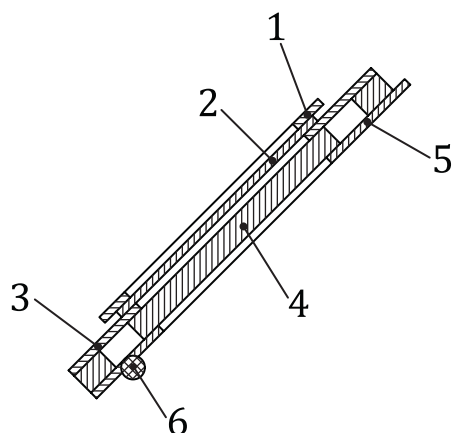
Dimensions in millimetres

**Key**

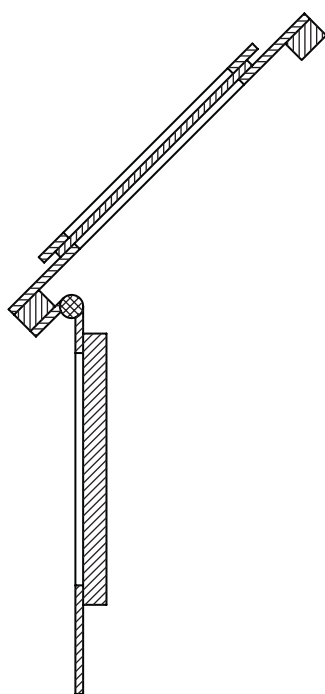
- 1 laser spot
- 2 white mercerized cotton thread

Figure 3 — Specimen holder, illustrating position of laser spot and white mercerized cotton thread

[Figure 4](#) illustrates the operation of the specimen holder. As shown in [Figure 4 a](#)), the specimen holder shall be set up at a 45° orientation to the vertical axis with the hinge on the lower side. After ignition of the specimen, there will be burn off of the white mercerized cotton thread which will cause the bottom frame with the cotton gauze to swing down and separate from the specimen [see [Figure 4 b](#))].



a) Start of experiment



b) Gravity causes cotton gauze and bottom frame to swing down and thus separates them from the specimen

Key

- | | | | |
|---|-----------|---|--------------------------------------------------------|
| 1 | top frame | 4 | cotton gauze (used in secondary ignition testing only) |
| 2 | specimen | 5 | bottom frame |
| 3 | mount | 6 | hinge |

Figure 4 — Specimen holder in operation

6.4 Laser system

6.4.1 Laser

A continuous wave (CW) CO₂ laser with a minimum power of 20 W at the specimen shall be used for all measurements. The beam 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.

WARNING — Surgical lasers emit radiation of sufficient power to damage living tissue or ignite fires directly or by reflection of radiation. In addition to other precautions, test personnel should be trained in the use of lasers and take proper safety measures based on the type of laser being used. These precautions should include laser-safety eyewear and controlled access to the test area.

6.4.2 Power meter

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 performed at the power density required for the test.

The power of radiation transmitted by these systems should be verified as being accurate to ± 10 %. This can be accomplished by the use of an external power meter or internal calibration systems.

6.5 Gas supply system

6.5.1 The gas supply system shall be capable of rapidly flooding the containment box with nitrogen or other gas or stopping oxygen flow, or both, to extinguish any burning material. The containment box shall be connected with the gas supply system in such a way that homogeneous ventilation of the box is achieved. An oxygen flow meter and controller shall be part of this system. Alternatively, direct measure of % oxygen is permissible (see [Figure 1](#)).

6.5.2 Other arrangements, such as an oxygen flood valve for rapidly purging the containment box or a gas flooding system for rapid extinguishment of burning material, may be used as long as the requirements of the test method as defined herein are not affected.

6.5.3 As an oxygen analyser, any device that can measure the concentration of gaseous oxygen with a repeatability of at least 1 % of full scale and a calibrated accuracy of at least 1 % of full scale is satisfactory. The oxygen sensor shall be positioned so as to minimize the chance of its ignition by any fire in the containment box.

6.6 Environment

6.6.1 Ambient air conditions

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

6.6.2 Oxygen enriched atmospheres

The tests under oxygen-enriched atmosphere shall be performed at oxygen concentrations of $60\% \pm 2\%$ and $98\% \pm 2\%$.

The oxygen concentration within the containment box shall be established at the desired level by proportional mixing of nitrogen and oxygen by suitable means.

6.7 Smoke evacuation device

WARNING — Combustion of most materials produces toxic gases such as carbon monoxide, hydrogen chloride and hydrogen cyanide. Also, the smoke produced in such fires contains hazardous particles of carbon, silica, unburned matter and other materials.

6.7.1 A device shall be attached to the containment box to safely remove smoke resulting from a burning specimen but shall be designed to eliminate the chance of drawing fire into the exhaust system. Placing the containment box in a fume hood that exhausts to a safe location satisfies this requirement.

6.7.2 The smoke evacuation device shall not interfere with maintaining the oxygen environment within the containment box. For example, the flow of a fume hood shall not create draughts that would enter or pull gas from the opening for laser access. The smoke evacuation shall not be activated until after the initiation of combustion.

7 Reagents and materials

7.1 Oxygen, 98 % ± 2 % (volume fraction) pure.

7.2 Nitrogen or other gas (i.e. non-oxidizing, non-flammable), 98 % ± 2 % (volume fraction) pure.

8 Preparation of specimens

8.1 Sampling

8.1.1 Single use products

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

8.1.2 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.

8.2 Specimens

The product to be tested 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 longer direction.

8.3 Quantities

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

8.4 Conditioning

Specimens shall be conditioned for 24 h at 20 °C ± 2 °C and 20 % ± 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.

9 Preparation of apparatus

9.1 Ensure that the containment box is clean (i.e. free of contaminants).

NOTE Contamination can interfere with the performance of the test or evaluation of the results.

9.2 Ensure that the laser is in working order, that its operation is understood, and that personnel protection is in place.

9.3 Ensure that there is adequate oxygen for the test and nitrogen or other gas for extinguishing any resulting fire.

9.4 Have other means of fire extinguishment (e.g. a carbon dioxide fire extinguisher) at hand. Water is not recommended, as it will not extinguish some materials burning in oxygen and, if used, will cause considerable soiling of the containment box and will interfere with interpretation of the results of laser interaction with the specimen. Water is not recommended for use on a fire involving energized electrical equipment.

10 Test methods

10.1 General conditions

10.1.1 Perform the test at $20\text{ °C} \pm 3\text{ °C}$.

10.1.2 Insert the specimen in the containment box. Connect the gas supply systems to the apparatus.

10.1.3 Ensure that the opening for laser access is as small as possible, in order to maintain the oxygen-enriched atmosphere but still allow laser access to the specimen.

10.1.4 Ensure that the gas flush is working properly.

10.1.5 Ensure that the smoke evacuation system is working properly and will not affect the gas concentration in the containment box during the test.

10.1.6 Flow oxygen into the containment box at a rate and time period sufficient to establish an environment of $60\% \pm 2\%$ and $98\% \pm 2\%$ oxygen, respectively. This oxygen level shall be verified by use of an oxygen analyser (6.5.3) measuring the environment.

10.2 Primary ignition and penetration

10.2.1 Principle

[Figure 5](#) shows a flowchart of the procedure for primary ignition testing. [Figure 6](#) shows a flowchart of the procedure for penetration testing.

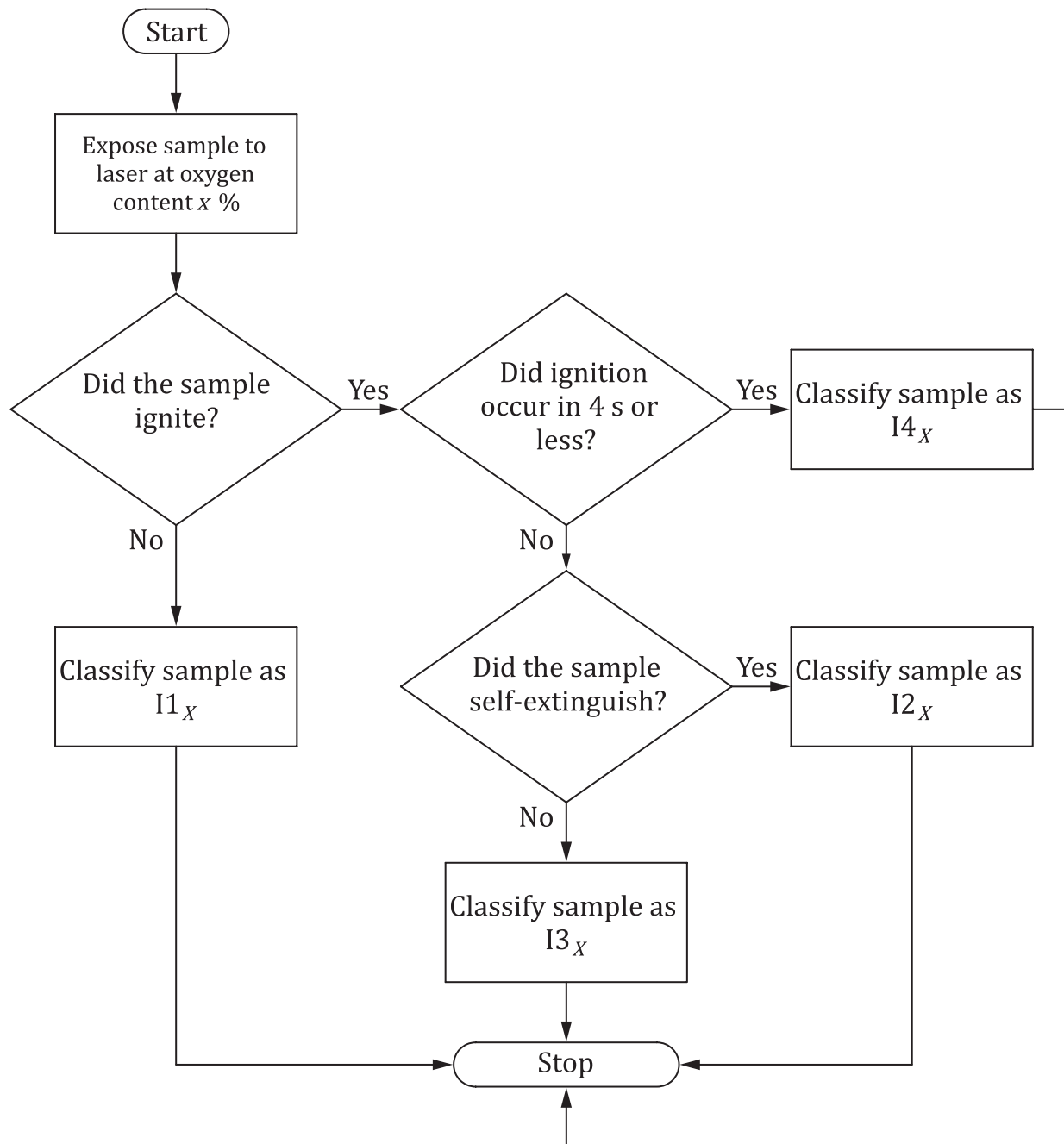


Figure 5 — Flowchart of procedure for primary ignition testing

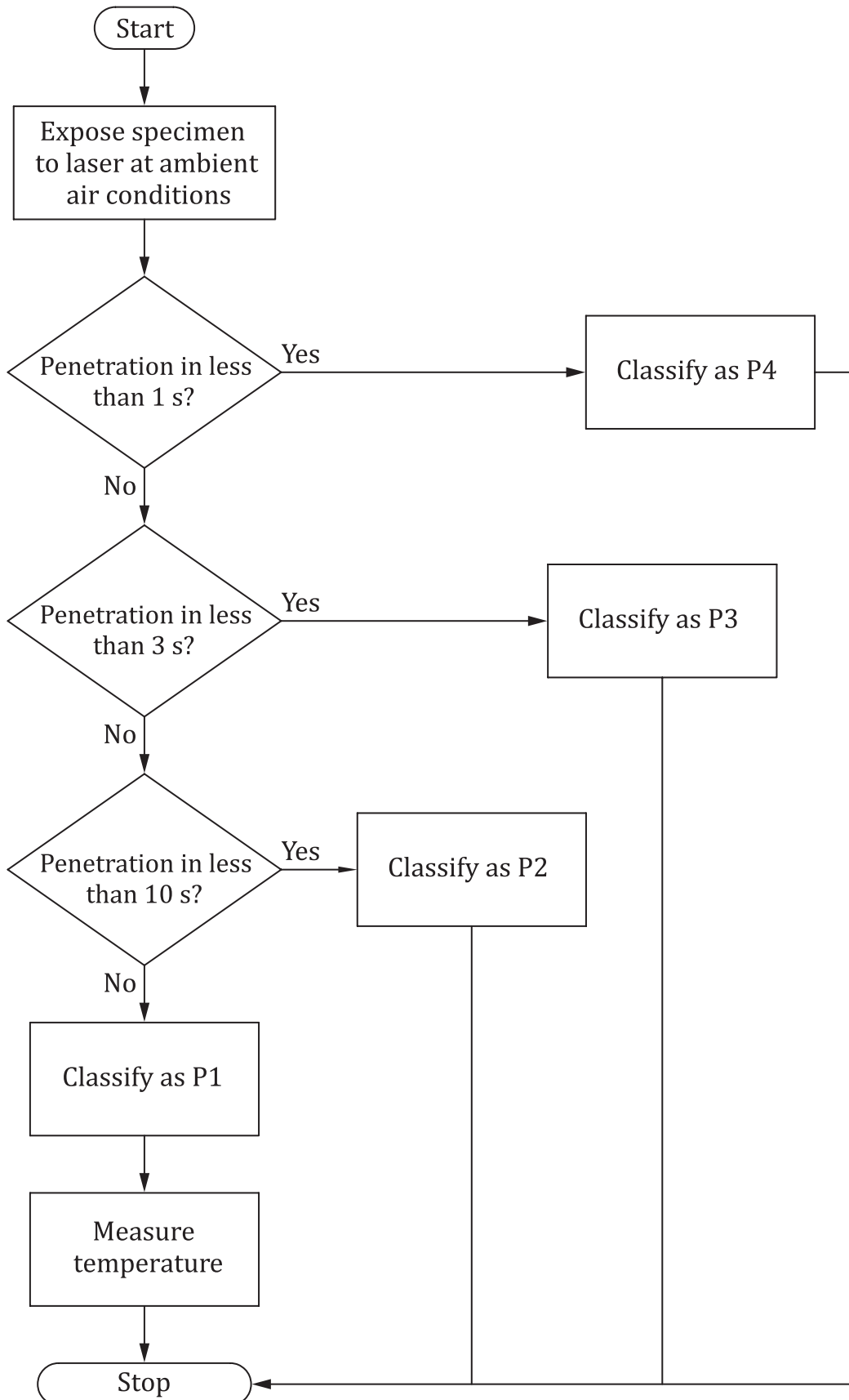


Figure 6 — Flowchart of procedure for penetration testing

10.2.2 Testing procedure

10.2.2.1 General

The testing for primary ignition and penetration shall be performed on separate groups of five 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 surgical drapes, the risk increases with increasing spot diameter at a given power setting.

The sequence of testing shall be: 21 % O₂ (ambient air), (60 % ± 2 %) O₂ then at least (98 ± 2) % O₂. Refer to [Figures 5](#) and [6](#) for the flowchart of procedure.

10.2.2.2 Specimen preparation

Each specimen, after conditioning (see [8.4](#)), shall be attached in the frame. A composite material shall be tested as it is intended to be used.

10.2.2.3 Laser-induced ignition

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

10.2.2.3.2 For testing in enriched oxygen atmospheres, place the specimen in the specimen holder and rack at a 45° orientation. Close the containment box door and flow oxygen and nitrogen at a rate and time period sufficient to establish an environment of 60 % ± 2 % and 98 % ± 2 % oxygen in the testing containment box. Verify the oxygen concentration by use of an oxygen analyser and appropriate sampling techniques. Record the temperature and relative humidity of the containment box.

10.2.2.3.3 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.

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

10.2.2.3.5 Classify the tested specimen as **I1**, **I2**, **I3**, or **I4** (see [11.2](#)). 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 tested product as outlined in [11.1](#).

10.2.2.4 Penetration resistance

10.2.2.4.1 Place the specimen in the specimen holder. Verify normal ambient air composition at 20 °C ± 2 °C and 20 % ± 2 % relative humidity.

10.2.2.4.2 Adjust the spot diameter on the specimen surface to be 1 mm. Adjust the laser beam to hit the specimen normally, thereby ensuring a symmetric distribution of the incident beam power.

10.2.2.4.3 Expose the specimen to 20 W for 10 s or until the power meter behind the specimen detects a power density above skin maximum permissible exposure (MPE) according to IEC 60825-1. Record the exposure time.

In order to ensure that the power meter does not measure the temperature increase of the specimen, it should be at least 5 cm apart from the specimen.

10.2.2.4.4 Classify the tested specimens as **P1**, **P2**, **P3** or **P4** (see [11.3](#)). Report, whether during or after the laser irradiation there was “afterflame” or “afterglow” or flaming.

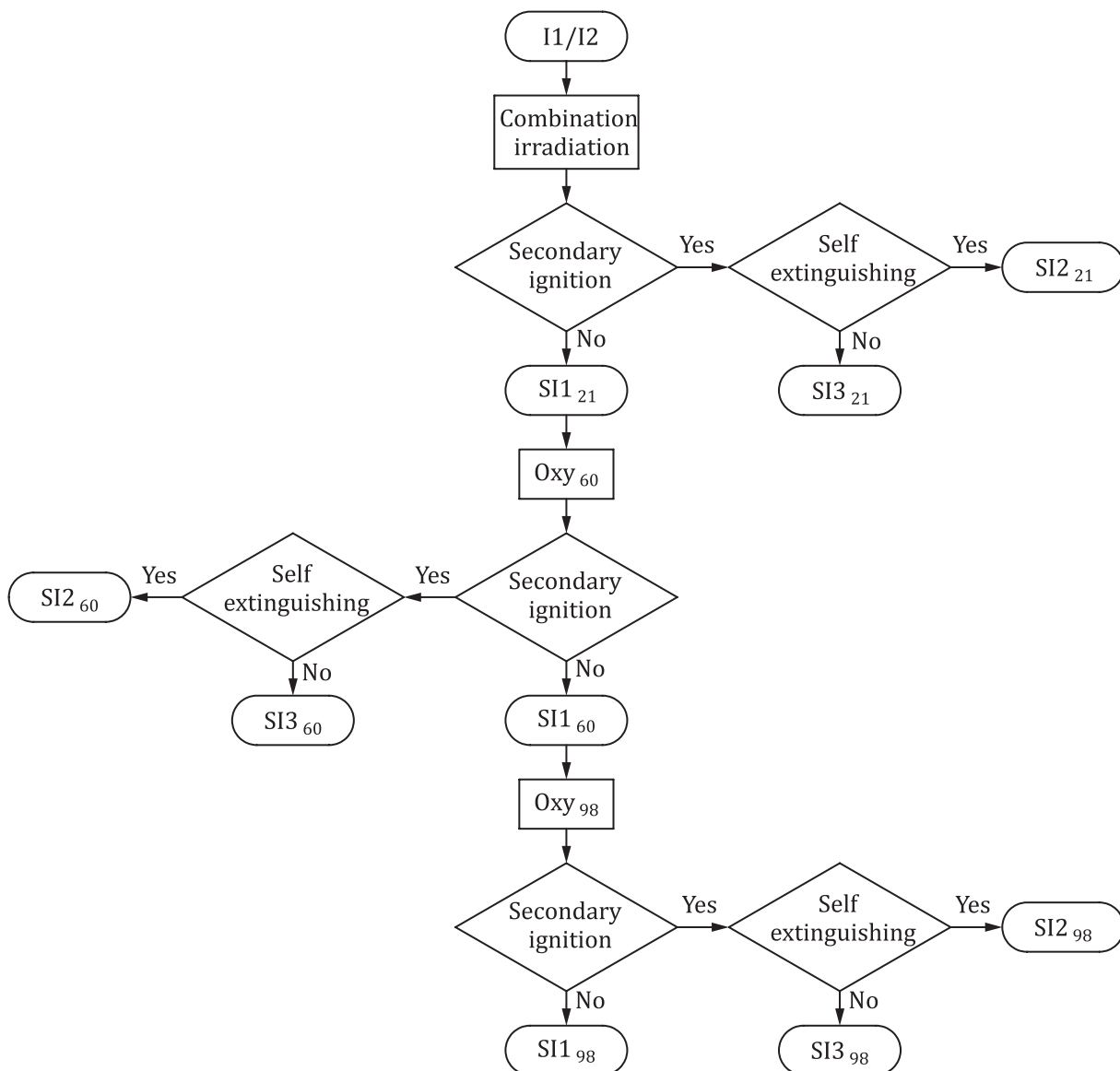
10.2.2.4.5 When all specimens have been tested at the given condition, classify the product as outlined in [11.1](#).

10.2.2.4.6 Thermal response of **P1** Class materials shall be performed on all five 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.

10.3 Secondary ignition

10.3.1 Principle

The flowchart of procedure for secondary ignition testing is shown in [Figure 7](#).



Key

I1, I2 Ignition classification according to ISO 11810

SI1 Secondary ignition class 1

SI2 Secondary ignition class 2

SI3 Secondary ignition class 3

Indices 21, 60, 98: Amount of oxygen in percent

Oxy Oxygen

Figure 7 — Flowchart of procedure for secondary ignition testing

10.3.2 Testing procedure

10.3.2.1 Sequence of testing

The sequence of testing shall be: 21 % O₂ (ambient air), 60 % O₂ ± 2 %, then at 98 % ± 2 % O₂. Refer to [Figure 7](#) for the testing protocol.

10.3.2.2 Specimen preparation

Each specimen, after conditioning (see [8.4](#)), shall be attached in the frame. A composite material shall be tested as it is intended to be used.

10.3.2.3 Laser-induced secondary ignition

10.3.2.3.1 Those materials which are classified as either **I1** or **I2** when tested in accordance with [10.2](#) shall be subject to laser-induced secondary ignition testing.

10.3.2.3.2 Laser ignition of cotton gauze type 17 is used as the primary ignition source to examine secondary subsequent ignition.

NOTE Type 17 cotton gauze (*Tela gossypii absorbens*) is described in EN 14079.

10.3.2.3.3 Prefolded cotton gauze 100 mm in length by 100 mm in width, 12 ply to 16 ply, shall be used. The cotton gauze is fixed between the bottom frame and the mount of the specimen holder. The specimens are fixed between the mount and the top frame of the specimen holder, above the cotton gauze. Ensure that the specimen is in contact with the cotton gauze. The rack holder shall be fixed high enough above the containment box base to ensure that when the white mercerized cotton thread burns off, the bottom frame plus cotton gauze falls into a vertical position. This will ensure that the burning cotton gauze falls far enough below the specimen so that no further direct burning of the specimen by the cotton gauze occurs.

10.3.2.3.4 For ambient air testing, place the specimen and cotton gauze in the specimen holder and rack at 45° orientation. Close the containment box door. Record the temperature and relative humidity of the containment box.

10.3.2.3.5 For testing in an oxygen-enriched atmosphere, place the specimen and cotton gauze in the specimen holder and rack at 45° orientation. Close the containment box door and allow oxygen and nitrogen to flow at a rate and time period sufficient to establish an environment of 60 % ± 2 % and 98 % ± 2 % oxygen in the containment box. Verify the oxygen concentration by use of an oxygen analyser and appropriate sampling techniques. Record the temperature and the relative humidity of the containment box.

10.3.2.3.6 Aim the laser beam normal to the specimen and cotton gauze combination (see [Figure 2](#)). Position the centre of the 2 mm spot at the centre of the specimen and cotton gauze combination, 25 mm from the bottom edge (see [Figure 3](#)). Expose the specimen and cotton gauze combination to the laser energy for a maximum of 10 s or until burn off of the white mercerized cotton thread.

10.3.2.3.7 Observe the burning behaviour of the specimen and cotton gauze combination and record the results in the test report.

10.3.2.3.8 Measure and record the afterflame and afterglow time according to [10.2.2.3](#).

10.3.2.3.9 Classify the tested specimen as **SI1**, **SI2** or **SI3** (see [11.4](#)). According to the manufacturer's preference, the testing procedure may be stopped at a lower classification level (e.g. stop at **SI1₂₁** and not test at higher oxygen concentration). When all specimens have been tested, classify the product as outlined in [11.1](#).

11 Classification

11.1 General

11.1.1 Every specimen shall be classified according to [11.2](#) (laser-induced primary ignition), [11.3](#) (laser-resistance to penetration) and [11.4](#) (laser-induced secondary ignition), as applicable.

11.1.2 If all specimens belong to the same class, the tested product belongs to this class.

11.1.3 If two or more of the five specimens belong to a higher (less safe) class, then the tested product shall be assigned to that class.

11.1.4 If one of the specimens belongs to the higher (less safe) class, a new test series with five new specimens shall be performed. If one or more specimens of the new series belong to the higher (less safe) class, the tested product shall be assigned to that class.

11.2 Laser-induced primary ignition (I)

Every specimen shall be graded according to the classification system given in [Table 1](#).

Table 1 — Classification system for primary ignition

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

A subscript × × shall be added to each class corresponding to the oxygen concentration at which the specimen did not ignite.

EXAMPLES I1₆₀ and I1₉₈ (ambient is indicated by I1₂₁).

11.3 Resistance to laser penetration (P)

Every specimen shall be graded according to the classification system given in [Table 2](#).

Table 2 — Classification system for penetration

Class	Time <i>t</i> to reach 10 mW
P1	$t \geq 10$ s
P2	$3 \text{ s} \leq t < 10 \text{ s}$
P3	$1 \text{ s} \leq t < 3 \text{ s}$
P4	$t < 1 \text{ s}$

11.4 Laser-induced secondary ignition (SI)

Every specimen shall be graded according to the classification system in [Table 3](#).

Table 3 — Classification system for secondary ignition

Class	Ignite	Self-extinguish
SI1	No	—
SI2	Yes	Yes
SI3	Yes	No

A subscript $\times \times$ shall be added to class **SI1** to indicate that the product did not ignite under oxygen concentrations of 21 % (ambient), 60 % \pm 2 % and/or at 98 % \pm 2 %.

EXAMPLES **SI1**₂₁, **SI1**₆₀ and **SI1**₉₈ where **SI1**₉₈ is the best rating.

Similarly, a subscript $\times \times$, is added to classes **SI2** (ignites and self-extinguishes) and **SI3** (ignites and did not self-extinguish) to denote oxygen concentrations at which testing occurred.

12 Test report

The test report shall contain the following information:

- a) reference to this International Standard, i.e. ISO 11810;
- b) product identification (manufacturer, product name or code and batch number);
- c) person performing test with signature;
- d) time and date of the test;
- e) test environment (temperature and relative humidity);
- f) test laser parameters and method of determining;
- g) description of the tested material (including colour, number of times reprocessed and method of reprocessing, if re-usable material);
- h) conditioning atmosphere used for all test materials (specimens, white mercerized cotton thread, cotton gauze);
- i) time elapsed between conditioning and completion of the test;
- j) class (**I**, **P** and **SI**) to which the tested material is assigned;
- k) for P1 materials, the maximum temperature on the back side of the specimen after irradiating the front side with 20 W for 10 s;
- l) for ignition testing (**I** and **SI**), the following characteristics:
 - 1) the afterflame time and the afterglow time in seconds;
 - 2) the maximum burned or damaged length;
 - 3) whether or not a hole or melted area developed in the specimen;
 - 4) whether any particles or drippings fell from the specimen to the filter paper on the floor of the containment box;
 - 5) whether the filter paper on the floor of the containment box below the specimen was ignited [see 6.2, l)];
 - 6) description of observed burning behaviour of specimen.

Bibliography

- [1] ISO 139, *Textiles — Standard atmospheres for conditioning and testing*
- [2] ISO 1144, *Textiles — Universal system for designating linear density (Tex System)*
- [3] ISO 2947, *Textiles — Integrated conversion table for replacing traditional yarn numbers by rounded values in the Tex System*
- [4] ISO 4880, *Burning behaviour of textiles and textile products — Vocabulary*
- [5] ISO 6940, *Textile fabrics — Burning behaviour — Determination of ease of ignition of vertically oriented specimens*
- [6] ISO 6941, *Textile fabrics — Burning behaviour — Measurement of flame spread properties of vertically oriented specimens*
- [7] ISO 9773, *Plastics — Determination of burning behaviour of thin flexible vertical specimens in contact with a small-flame ignition source*
- [8] IEC 60601-2-22, *Medical electrical equipment — Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment*
- [9] EN 13795, *Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment — General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels*
- [10] EN 14079, *Non-active medical devices — Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze*

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