

---

---

**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*



**PDF disclaimer**

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

STANDARDSISO.COM : Click to view the full PDF of ISO 11810-2:2007



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2007

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

**Contents**

Page

Foreword.....	iv
Introduction .....	v
1 Scope .....	1
2 Normative references .....	1
3 Terms and definitions.....	2
4 Test methods.....	2
4.1 General conditions .....	2
4.1.1 Sampling.....	2
4.1.2 Test equipment .....	2
4.2 Testing procedure.....	8
4.2.1 Sequence of testing.....	8
4.2.2 Specimen preparation .....	8
4.2.3 Laser-induced secondary ignition .....	8
5 Classification.....	9
5.1 Laser-induced secondary ignition of test material .....	9
5.2 Classification definition .....	9
6 Test Report .....	10
Bibliography .....	11

STANDARDSISO.COM : Click to view the full PDF of ISO 11810-2:2007

## 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<sub>2</sub> 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<sub>2</sub> 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.

[STANDARDSISO.COM](http://STANDARDSISO.COM) : Click to view the full PDF of ISO 11810-2:2007

# 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<sub>2</sub> 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

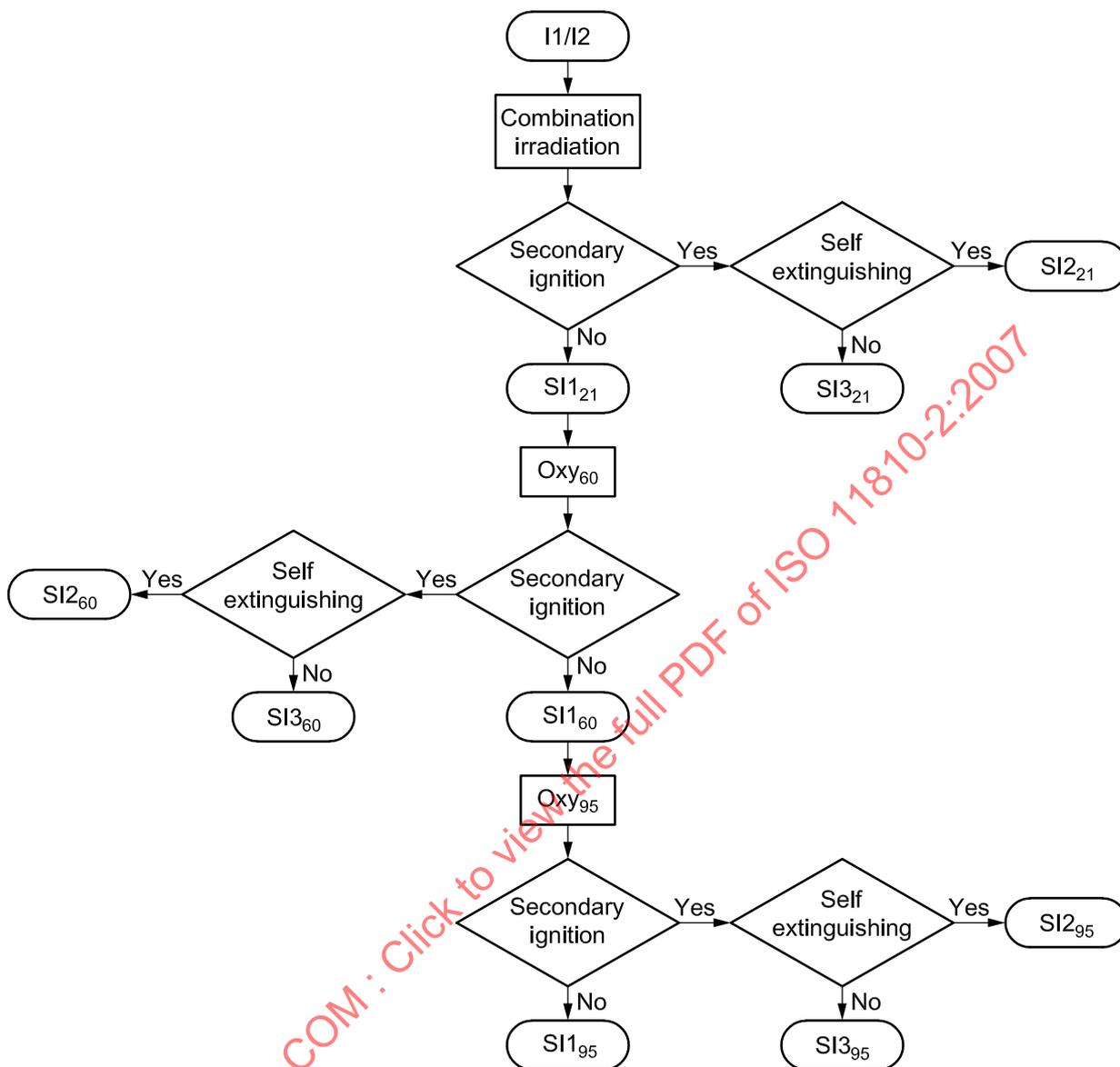
All materials (specimens, cotton gauze, and white mercerized cotton thread) shall be conditioned for 24 h at  $20\text{ °C} \pm 2\text{ °C}$  and  $65\% \pm 2\%$  relative humidity. Materials requiring special treatment or preparation shall be conditioned according to the manufacturer's instructions 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).

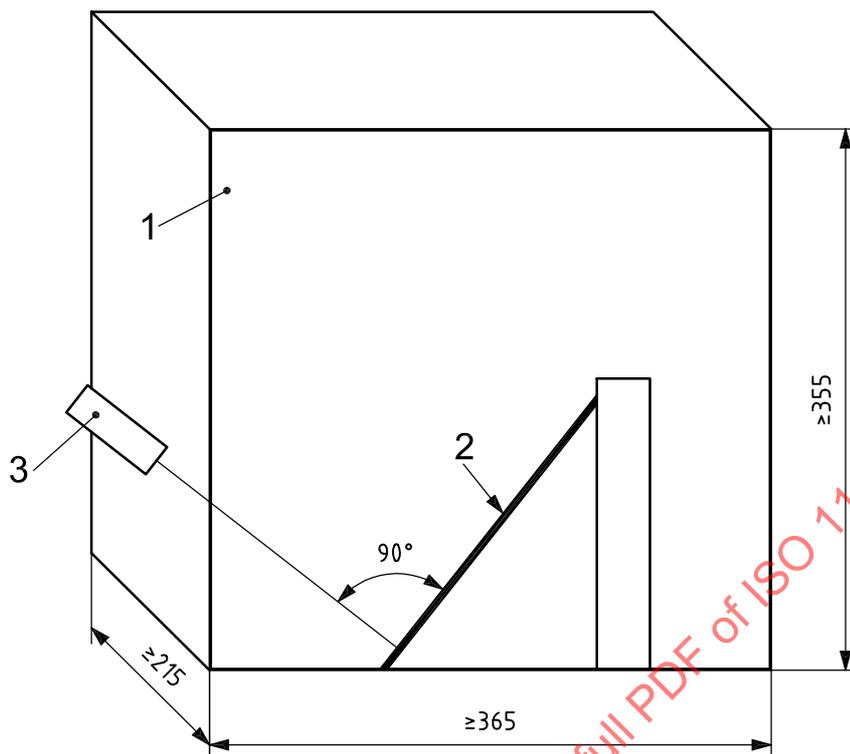


**Key**

- 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**

Dimensions in millimetres

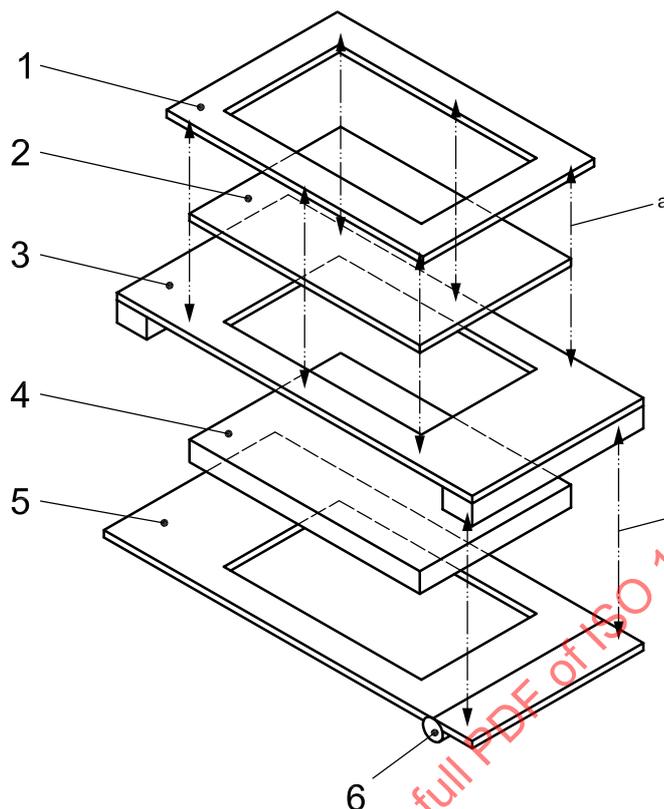


**Key**

- 1 test chamber
- 2 specimen holder
- 3 laser

**Figure 2 — Test chamber**

STANDARDSISO.COM : Click to view the full PDF of ISO 11810-2:2007

**Key**

1	top frame	4	cotton gauze
2	sample	5	bottom frame
3	mount	6	hinge

a Elements are connected.

**Figure 3 — Example of a specimen holder**

**4.1.2.2 Test chamber**

The test chamber shall be constructed of a corrosion-resistant and laser and fireproof material. It shall be a box with minimum dimensions of 365 mm length by 215 mm depth by 355 mm height with ventilation openings at the top and a door at one side. At least one side of the chamber shall have a glass window for observation during testing. One side of the chamber shall have a hole for the laser transmission system. The test chamber shall be connected to the gas supply system in such a way that homogeneous ventilation of the chamber is achieved. A specimen rack shall provide support to mount the specimen holder at a 45° angle to the bottom of the chamber. Measures shall be taken to ensure that no dangerous radiation emanates from the chamber.

**NOTE** The mass of oxygen available to support combustion of the mass of fuel is important for the proper conduct of the laser-induced inflammability tests. Large test chambers might not provide accurate results.

**4.1.2.3 Specimen holder**

The specimen holder (see Figure 3) 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 has to be stable and may be achieved by clamps or screws. The plates shall be slotted and loosely pinned for alignment. In contrast to the fixture used in ISO 11810-1, the third plate (bottom frame) is to allow for the attachment of the cotton gauze. The construction of the fixture shall guarantee that 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.

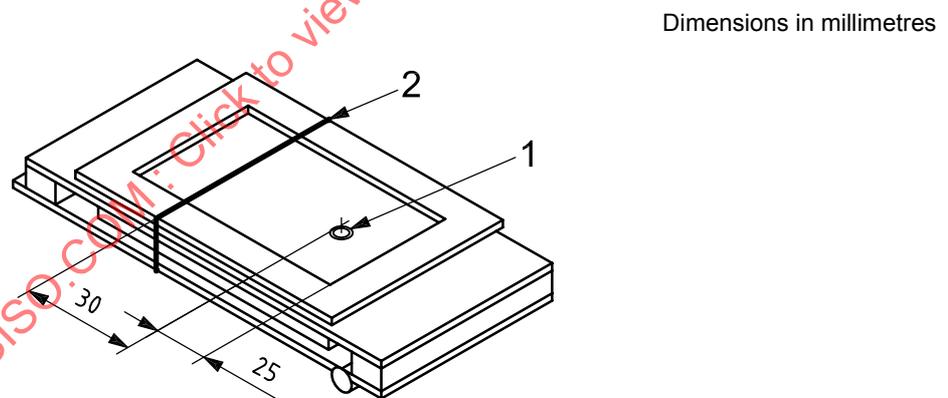
The separation mechanism shall be white mercerized cotton thread having a linear density of 45 g/1 000 m to 50 g/1 000 m. The white mercerized cotton thread is used to keep the lower and upper two frames together. To avoid direct laser induced ignition of the white mercerized cotton thread, it shall 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 4 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 may be 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.

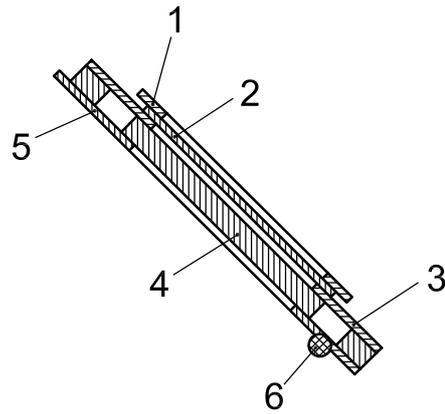
Figure 5 illustrates the operation of the specimen holder. As shown in Figure 5, a), the specimen holder shall be set up at a 45° orientation to the vertical axis with the hinge on the lower side. After ignition of the specimen, there will be burn off of the white mercerized cotton thread which will allow the cotton gauze to separate from the specimen [Figure 5, b)].



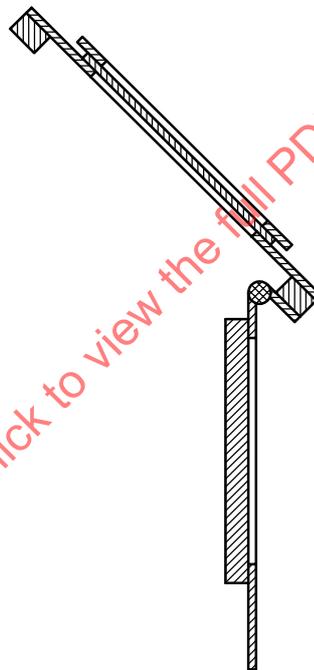
**Key**

- 1 laser spot
- 2 white mercerized cotton thread

**Figure 4 — Specimen holder, illustrating position of laser spot and white mercerized cotton thread**



a) Start of experiment



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

**Key**

- |             |                |
|-------------|----------------|
| 1 top frame | 4 cotton gauze |
| 2 sample    | 5 bottom frame |
| 3 mount     | 6 hinge        |

**Figure 5 — Specimen holder in operation**

#### 4.1.2.4 Laser system

A continuous wave (CW) CO<sub>2</sub> laser with a minimum power of 20 W at the specimen shall be used for all measurements. The spot diameter (in accordance with ISO 11145 and ISO 11146-1)  $d_{95}$  shall be 2 mm for the laser-induced secondary ignition measurements. An appropriate power meter shall be used for measuring the laser radiation.

#### 4.1.2.5 Environment

##### 4.1.2.5.1 Ambient air conditions

The tests under ambient air conditions shall be performed at room temperature of 20° C ± 2° C and 65 % ± 2 % relative humidity.

##### 4.1.2.5.2 Oxygen-enriched atmospheres

The tests under oxygen-enriched atmosphere shall be performed at oxygen concentrations of

- a) 60 % ± 2 % and
- b) at least 95 %.

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

## 4.2 Testing procedure

### 4.2.1 Sequence of testing

The sequence of testing shall be 21 % O<sub>2</sub> (ambient air), 60 % O<sub>2</sub> ± 2 %, then at least 95 % O<sub>2</sub>. Refer to Figure 1 for the testing protocol.

### 4.2.2 Specimen preparation

Each specimen, after conditioning (see 4.1.1.5), shall be attached in the frame. A composite material shall be tested as it is intended to be used.

### 4.2.3 Laser-induced secondary ignition

4.2.3.1 Those materials which are classified as either I1 or I2 when tested in accordance with ISO 11810-1, shall be subject to laser-induced secondary ignition testing.

4.2.3.2 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 14079:2003.

4.2.3.3 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 test specimens are fixed between the mount and the top frame of the specimen holder, above the cotton gauze. Assure that the specimen is in contact with the cotton gauze. The rack holder shall be fixed high enough above the chamber 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.

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