

SLOVENSKI STANDARD SIST EN ISO 11810-1:2005

01-junij-2005

BUXca Yý U. SIST EN ISO 11810:2003

Laserji in z laserji povezana oprema - Preskusna metoda in klasifikacija za ugotavljanje odpornosti proti laserju za kirurške zastirke in/ali za varovalna pokrivala za paciente – 1. del: Primarno zgorevanje in prodiranje (ISO 11810-1:2005)

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 (ISO 11810-1:2005)

SIST EN ISO 11810-1:2005

Laser und Laseranlagen - Prüfverfahren und Einstufung zur Laserresistenz von Operationstüchern und/oder anderen Abdeckungen zum Schutz des Patienten - Teil 1: Primäre Entzündung und Laserdurchstrahlung (ISO 11810-1:2005)

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 1: Allumage primaire et pénétration (ISO 11810-1:2005)

Ta slovenski standard je istoveten z: EN ISO 11810-1:2005

ICS:

11.140 Oprema bolnišnic Hospital equipment
 13.340.99 Druga varovalna oprema Other protective equipment
 31.260 Optoelektronika, laserska oprema equipment

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EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

EN ISO 11810-1

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Supersedes EN ISO 11810:2002

English version

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 (ISO 11810-1:2005)

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This European Standard was approved by CEN on 7 February 2005.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official

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Management Centre: rue de Stassart, 36 B-1050 Brussels

EN ISO 11810-1:2005 (E)

Foreword

This document (EN ISO 11810-1:2005) has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" in collaboration with Technical Committee CEN/TC 123 "Lasers and photonics", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2005, and conflicting national standards shall be withdrawn at the latest by August 2005.

This document supersedes EN ISO 11810:2002.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 11810-1:2005 has been approved by CEN as EN ISO 11810-1:2005 without any modifications.

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INTERNATIONAL STANDARD

ISO 11810-1

First edition 2005-02-15

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 iTeh STANDARD PREVIEW

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 1: Allumage primaire et pénétration https://standards.iteh.a/catalog/standards/sist/61ade9/c-9618-420d-a335

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ISO 11810-1:2005(E)

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 11810-1 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 9, *Electro-optical systems*.

This first edition cancels and replaces ISO 11810:2002, which has been technically revised.

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 8c6464bfc46c/sist-en-iso-11810-1-2005
- Part 2: Secondary ignition

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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, 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. fibre optic illumination systems, electrosurgical units, hot wire cauteries), this test method addresses only the laser ignition source. This part of ISO 11810 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 may 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 may need to be tested.

 ${
m CO_2}$ lasers may provide the most challenging conditions of all medical lasers. 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. The 20 W ${
m CO_2}$ laser (continuous wave) has been selected as the laser for this part of ${
m ISO_41810:TANDARD\ PREVIEW}$

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 protective cover should be tested at the wavelengths 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. ISO 11810-1:2005

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

The performance of laser-resistant surgical drapes or other patient protective covers may be changed when used in combination rather than individually.

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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 1:

Primary ignition and penetration

1 Scope

This part of ISO 11810 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 part of ISO 11810 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 part of ISO 11810 to serve as a general fire safety specification, and as such, this part of ISO 11810 does not cover other sources of ignition. It also does not cover the issue of laser-induced secondary ignition. **standards.iteh.ai**)

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 part of ISO 11810.

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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 11145:2001, Optics and optical instruments — 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

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