SVENSK STANDARD
SS-EN ISO 11990:2018

Fastställd/Approved: 2018-10-23
Utgåva/Edition: 3
Språk/Language: engelska/English
ICS: 11.040.10; 31.260

SWEDISH STANDARDS INSTITUTE

Lasrar och lasertillbehör – Bestämning av resistensen hos trakealtuber och trakealkuffar (ISO 11990:2018)

Lasers and laser-related equipment – Determination of laser resistance of tracheal tube shaft and tracheal cuffs (ISO 11990:2018)

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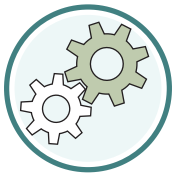

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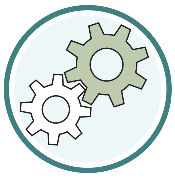

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Europastandarden EN ISO 11990:2018 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 11990:2018.

Denna standard ersätter SS-EN ISO 11990-1:2014, utgåva 2 och SS-EN ISO 11990-2:2014, utgåva 2

The European Standard EN ISO 11990:2018 has the status of a Swedish Standard. This document contains the official version of EN ISO 11990:2018.

This standard supersedes the SS-EN ISO 11990-1:2014, edition 2 and SS-EN ISO 11990-2:2014, edition 2

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS, who can also provide general information about Swedish and foreign standards.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11990

October 2018

ICS 31.260; 11.040.10

Supersedes EN ISO 11990-1:2014, EN ISO 11990-

English Version

Lasers and laser-related equipment - Determination of laser resistance of tracheal tube shaft and tracheal cuffs (ISO 11990:2018)

Lasers et équipements associés aux lasers - Détermination de la résistance au laser des axe et ballonnet de tubes trachéaux (ISO 11990:2018)

Laser und Laseranlagen - Bestimmung der Laserresistenz von Trachealtubusschaft und Trachealtubusmanschette (ISO 11990:2018)

This European Standard was approved by CEN on 5 August 2018.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 11990:2018: E

Contents

European foreword

This document (EN ISO 11990:2018) has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" 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 April 2019, and conflicting national standards shall be withdrawn at the latest by April 2019.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 11990-1:2014 and EN ISO 11990-2:2014.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZA, which is an integral part of this document.

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

Endorsement notice

The text of ISO 11990:2018 has been approved by CEN as EN ISO 11990:2018 without any modification.

Introduction

A fire in the airway is always a serious matter. In addition to local damage in the larynx, injury can occur to the lower airway and the parenchymal tissue in the lung. The products of combustion can be blown into the lungs.

Procedures performed in the airway, where a tracheal tube and a laser are used, bring together an oxygen-enriched atmosphere, a fuel and high power, the three ingredients necessary to create a fire. The likelihood that a laser beam will contact the tracheal tube during airway procedures is high. This led to the development of a test method, described in this document, to assist the clinician in determining which tracheal tube shaft was the most laser-resistant under a defined set of conditions.

Unfortunately, fires with tracheal tubes, whose shafts were laser-resistant according to this document have continued to occur. Investigations have shown that the cuff, and not the shaft, of the tracheal tube is the area of lowest laser resistance and most likely to be contacted by the laser beam, even when used according to the manufacturer's instructions. Clinical experience has shown that not only perforation of the part of the shaft below the cuff has happened, but also ignition of the outer surface of the cuff. This could then ignite other parts of the tracheal tube, such as the tip, which is normally unprotected.

Lasers and laser-related equipment — Determination of laser resistance of tracheal tube shaft and tracheal tube cuffs

1 Scope

This document specifies a method of testing the continuous wave (cw) laser resistance of the shaft of a tracheal tube and the cuff regions including the inflation system of tracheal tubes designed to resist ignition by a laser.

NOTE 1 When interpreting these results, the attention of the user is drawn to the fact that the direct applicability of the results of this test method to the clinical situation has not been fully established.

NOTE 2 The attention of the users of products tested by this method is drawn to the fact that the laser will be wavelength sensitive and tested at the wavelength for which it is intended to be used. If tested using other wavelengths, explicitly state the power settings and modes of delivery.

CAUTION — This test method can involve hazardous materials, operations and equipment. This document 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 document to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 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, *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*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

ISO 5361:2016, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors*

ISO 11145:2016, *Optics and photonics — Lasers and laser-related equipment — Vocabulary and symbols*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11810, ISO/IEC Guide 99 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
beam diameter
d_{95}
smallest diameter of a circular aperture in a plane perpendicular to the beam axis that contains 95 % of the total beam power (energy)

[SOURCE: ISO 11145:2016, 3.3.1, modified — The value of contained total beam power has been set to 95 %, and the note to entry has been removed.]

3.2
beam cross-sectional area
A_{95}
smallest completely filled area containing 95 % of the total beam power (energy)

[SOURCE: ISO 11145:2016, 3.2.1, modified — The value of contained total beam power has been set to 95 %, and the note to entry has been removed.]

3.3
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.

[SOURCE: ISO 11810:2015, 3.7]

3.4
cuff
inflatable balloon permanently attached around the tracheal tube near the patient end to provide an effective seal between the tube and the trachea

[SOURCE: ISO 5361:2016, 3.4]

3.5
damage
any change, other than combustion, which can affect the safety of the patient or efficacy of the tracheal tube due to increasing the risk of ignition

EXAMPLE Local heating, melting, creation of holes, pyrolysis.

[SOURCE: ISO 11810:2015, 3.8, modified — “product” has been replaced with “tracheal tube”.]

3.6
flammable
subject to ignition and flaming combustion

[SOURCE: ISO 11810:2015, 3.9]

3.7
ignition
creation of combustion induced by the delivery of power

[SOURCE: ISO 11810:2015, 3.10]

3.8
laser resistance
measure of the ability of a material to withstand laser power without ignition or damage

[SOURCE: ISO 11810:2015, 3.11]

3.9
melting behaviour
softening of a material under the influence of heat (including shrinking, dripping and burning of molten material, etc.)

[SOURCE: ISO 11810:2015, 3.12]

3.10
penetration resistance
ability of a material to prevent the passage of laser energy

[SOURCE: ISO 11810:2015, 3.14]

3.11
shaft
portion of the tracheal tube between the cuff and the machine end of the tube

4 Principle

WARNING — This test method can result in a rocket-like fire involving the tracheal tube. 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 document describes a uniform and repeatable test method for measuring the laser resistance of the shaft and the cuff of a tracheal tube. Most of the variables involved in laser ignition of a tracheal tube have been fixed in order to establish a basis for comparison. This test method for measuring can be used to compare tracheal tubes having differing types and designs of laser protection.

5.2 A large number and range of variables are involved in the ignition of a tracheal tube. A change in one variable can affect the outcome of the test. Caution should be observed, since the direct applicability of the results of this test method to the clinical situation has not been fully established.

NOTE 1 This method can be applied to study the effect of changing the test conditions, but this is outside the scope of this document. For example, variation of the breathing-gas flow rate or different breathing-gas mixtures might affect the laser resistance of the shaft and cuff of a tracheal tube.

5.3 Since an oxygen-enriched atmosphere is often present in the clinical situation, either intentionally or unintentionally, the test is performed in an environment of 98 % ± 2 % oxygen.

5.4 A flow rate of 1 l/min of oxygen in a 6,0 mm inner diameter tube was chosen as the most appropriate condition for shaft and cuff ignition and establishment of a fire, based on the work cited in Reference [5].

5.5 The preparation of the specimen shall be in accordance with the manufacturer's instructions for use.

5.6 Use of beam cross-sectional shape other than circular, or mode of laser power delivery other than continuous wave can affect the shaft and cuff ignition characteristics. Also, shafts and cuff of different construction have different laser resistances (see References [5] to [12]).

5.7 The majority of manufacturers of laser-resistant cuffs recommend using isotonic saline or water to fill the cuff. For preliminary testing of leakage of the cuff, filling with air is recommended by most manufacturers. This can cause an air bubble, which, in a typical position of the patient during surgery, is not on the top of the filled cuff, but at the area where the cuff and shaft meet. The test report shall