Irish Standard
I.S. EN ISO 11990:2018

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

I.S. EN ISO 11990:2018

Incorporating amendments/corrigenda/National Annexes issued since publication:

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National Foreword

I.S. EN ISO 11990:2018 is the adopted Irish version of the European Document EN 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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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 11990-2:2014

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.

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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 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: Rue de la Science 23, B-1040 Brussels

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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.

Annex ZA
(informative)

Relationship between this European standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request 'M/023 concerning the development of European standards related to medical devices' to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this European Standard	Remarks/Notes
7.1 (first indent only)	This entire standard	These Essential Requirements (ERs) are partly covered. This standard is intended to provide a test method that will allow an evaluation of the risk of ignition of the shaft and cuff of a tracheal tube associated with its use with lasers during ear, nose and throat surgery as part of the risk assessment as set out in these essential requirements.
7.3 (first part only)	This entire standard	
9.3	This entire standard	

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard 'within the meaning of Annex ZA', the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlations between undated normative references and dated EN and ISO standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	**ISO**
ISO 11146-1	EN ISO 11146-1:2005	ISO 11146-1:2005
ISO 11810	EN ISO 11810:2015	EN ISO 11810:2015
ISO/IEC Guide 99	—	ISO/IEC Guide 99:2007
ISO 5361:2016	EN ISO 5361:2016	ISO 5361:2016
ISO 11145:2016	EN ISO 11145:2016	ISO 11145:2016

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INTERNATIONAL STANDARD

ISO 11990

Third edition
2018-08

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

Lasers et équipements associés aux lasers — Détermination de la résistance au laser des axe et ballonnet de tubes trachéaux

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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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 9, *Laser and electro-optical systems*.

This third edition of ISO 11990 cancels and replaces ISO 11990-1:2011 and ISO 11990-2:2010 which have undergone a revision in order to adjust the two documents to each other thereby eliminating redundancies and unintended discrepancies.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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/