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Standards

Irish Standard
I.S. EN ISO 11990-1:2011

Lasers and laser-related equipment - Determination of laser resistance of tracheal tubes - Part 1: Tracheal tube shaft (ISO 11990-1:2011)

I.S. EN ISO 11990-1:2011

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English Version

**Lasers and laser-related equipment - Determination of laser
resistance of tracheal tubes - Part 1: Tracheal tube shaft (ISO
11990-1:2011)**

Lasers et équipements associés aux lasers - Détermination
de la résistance au laser des tubes trachéaux - Partie 1:
Axe des tubes trachéaux (ISO 11990-1:2011)

Laser und Laseranlagen - Bestimmung der Laserresistenz
von Trachealtuben - Teil 1: Trachealtubusschaft (ISO
11990-1:2011)

This European Standard was approved by CEN on 31 July 2011.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



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Foreword

This document (EN ISO 11990-1:2011) 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of an identical text or by endorsement, at the latest by February 2012, and conflicting national standards shall be withdrawn at the latest by February 2012.

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

This document supersedes EN ISO 11990:2003.

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 relationship with EU Directive, 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 11990-1:2011 has been approved by CEN as a EN ISO 11990-1:2011 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC (Medical Devices Directive)

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC (Medical Devices Directive).

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the 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.

Table ZA — Correspondence between this European Standard and Directive 93/42/EEC (Medical Devices Directive)

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive ...	Qualifying remarks/Notes
This entire standard.	1, 2, 3, 7.1 (first indent only), 7.3, 9.3	This European Standard is intended to provide a test method that will allow an evaluation of the risk of ignition associated with the use of a tracheal tube and lasers during ear, nose and throat surgery as part of the risk assessment as set out in these essential requirements.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

I.S. EN ISO 11990-1:2011
**INTERNATIONAL
STANDARD**

**ISO
11990-1**

First edition
2011-08-01

**Lasers and laser-related equipment —
Determination of laser resistance of
tracheal tubes —**

**Part 1:
Tracheal tube shaft**

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

Partie 1: Axe des 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.

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 11990-1 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 9, *Electro-optical systems*.

This first edition of ISO 11990-1 cancels and replaces ISO 11990:2003, of which it constitutes a minor revision.

ISO 11990 consists of the following parts, under the general title *Lasers and laser-related equipment — Determination of laser resistance of tracheal tubes*:

- *Part 1: Tracheal tube shaft*
- *Part 2: Tracheal tube cuffs*

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.

In the early to mid-1980s, the increasing use of such lasers was followed by airway fires and, subsequently, the development of tracheal tubes designed specifically to be resistant to laser ignition and damage. Unfortunately, some of these tubes were not sufficiently resistant under operating room conditions, and airway fires continued to occur. These events led to the development of the test method described in this part of ISO 11990, in order to assist the clinician in determining which tracheal tube shaft is most laser-resistant for a defined set of conditions.

I.S. EN ISO 11990-1:2011

Lasers and laser-related equipment — Determination of laser resistance of tracheal tubes —

Part 1: Tracheal tube shaft

1 Scope

This part of ISO 11990 specifies a method of testing the continuous wave (cw) resistance of the shaft of a tracheal tube designed to resist ignition by a laser. It is not applicable to other components of the system, such as the inflation system and cuff, which are defined in ISO 11990-2 (see Note 1).

NOTE 1 ISO 11990-2 specifies the method for testing the laser resistance of the tracheal tube cuff.

This part of ISO 11990 can be used to measure and describe the properties of materials, products or assemblies in response to heat and flame under controlled laboratory conditions. It does not describe or appraise the fire hazard or fire risk of materials, products, or assemblies under actual clinical use conditions. However, the results of this test can be used as one element of a fire risk assessment which takes into account all factors pertinent to an assessment of the hazard of a particular end use.

NOTE 2 The direct applicability of the result of this test method to the clinical situation has not been fully established.

CAUTION — This test method can involve hazardous materials, operations, and equipment. This part of ISO 11990 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 part of ISO 11990 to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

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 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

beam cross-sectional area

A_{95}

smallest area containing 95 % of the total beam power

[ISO 11990-2:2010]

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