
Laserji in laserska oprema - Ugotavljanje odpornosti sapničnih (endotrahealnih) tubusov proti laserskemu žarku - 2. del: Sapnični (endotrahealni) tubusi (ISO 11990-2:2010)

Lasers and laser-related equipment - Determination of laser resistance of tracheal tubes - Part 2: Tracheal tube cuffs (ISO 11990-2:2010)

Laser und Laseranlagen - Bestimmung der Laserresistenz von Trachealtuben - Teil 2: Trachealtubusmanschetten (ISO 11990-2:2010)

Lasers et équipements associés aux lasers - Détermination de la résistance au laser des tubes trachéaux - Partie 2: Ballonnet de tubes trachéaux (ISO 11990-2:2010)

Ta slovenski standard je istoveten z: EN ISO 11990-2:2010

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11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
31.260	Optoelektronika, laserska oprema	Optoelectronics. Laser equipment

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 11990-2

July 2010

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English Version

**Lasers and laser-related equipment - Determination of laser
resistance of tracheal tubes - Part 2: Tracheal tube cuffs (ISO
11990-2:2010)**

Lasers et équipements associés aux lasers - Détermination
de la résistance au laser des tubes trachéaux - Partie 2:
Ballonnet de tubes trachéaux (ISO 11990-2:2010)

Laser und Laseranlagen - Bestimmung der Laserresistenz
von Trachealtuben - Teil 2: Trachealtubumanschetten
(ISO 11990-2:2010)

This European Standard was approved by CEN on 23 June 2010.

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Foreword

This document (EN ISO 11990-2:2010) 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of an identical text or by endorsement, at the latest by January 2011, and conflicting national standards shall be withdrawn at the latest by January 2011.

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 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.

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.

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The text of ISO 11990-2:2010 has been approved by CEN as a EN ISO 11990-2:2010 without any modification.

Annex ZA (informative)

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

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.

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.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
This entire standard	1, 2, 3, 7.1 (first indent only), 7.3, 9.3 <small>SIST EN ISO 11990-2:2010 https://standards.iteh.ai/catalog/standards/sist/6695e0ad-dca0-4076-a96f-b3a8becf1dd9/sist-en-iso-11990-2-2010</small>	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.

INTERNATIONAL STANDARD

ISO
11990-2

First edition
2010-07-15

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

Part 2: Tracheal tube cuffs

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*Lasers et équipements associés aux lasers — Détermination de la
résistance au laser des tubes trachéaux —
(standards.iteh.ai)
Partie 2: Ballonnet de tubes trachéaux*

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ISO 11990-2:2010(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 11990-2 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 9, *Electro-optical systems*.

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 shafts*

— *Part 2: Tracheal tube cuffs*

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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 may 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 ISO 11990-1, 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 ISO 11990-1 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.

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