ICS 11.040.10, 31.260 SLOVENSKÁ TECHNICKÁ NORMA Apríl 2015

STN	**Lasery a laserové zariadenia. Určenie odolnosti tracheotomických rúrok proti laseru. Časť 2: Manžety tracheotomických rúrok (ISO 11990-2: 2010).**	**STN EN ISO 11990-2** 19 2017

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 03/15

Obsahuje: EN ISO 11990-2:2014, ISO 11990-2:2010

Oznámením tejto normy sa ruší
STN EN ISO 11990-2 (19 2017) z decembra 2010

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11990-2

October 2014

ICS 11.040.10; 31.260

Supersedes EN ISO 11990-2:2010

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: Trachealtubusmanschetten (ISO 11990-2:2010)

This European Standard was approved by CEN on 22 October 2014.

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.

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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 11990-2:2014 E

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Foreword

The text of ISO 11990-2:2010 has been prepared by Technical Committee ISO/TC 172 “Optics and photonics” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11990-2:2014 by 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 2015, and conflicting national standards shall be withdrawn at the latest by April 2015.

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 11990-2:2010.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11990-2:2010 has been approved by CEN as EN ISO 11990-2:2014 without any modification.

Annex ZA
(informative)

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

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 on Medical Devices.

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.

NOTE 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 on Medical Devices

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
This entire standard	7.1 (first indent only)	This 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.
This entire standard	7.3	
This entire standard	9.3	

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

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

Partie 2: Ballonnet de tubes trachéaux

Reference number
ISO 11990-2:2010(E)

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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 11990-2 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*

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.

INTERNATIONAL STANDARD **ISO 11990-2:2010(E)**

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

Part 2:
Tracheal tube cuffs

1 Scope

This part of ISO 11990 specifies a method of testing the continuous wave (cw) resistance of the cuff regions of tracheal tubes designed to resist ignition by a laser. Other components of the system, such as the inflation system and shaft (as defined in ISO 11990-1), are outside the scope of this part of ISO 11990.

NOTE 1 The method for testing the laser resistance of the tracheal tube shaft is in the scope of ISO 11990-1.

The specified test method 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 method may be used as an element of a fire risk assessment which takes into account all of the factors that are pertinent to an assessment of the hazard of a particular end use.

NOTE 2 Caution should be observed in interpreting these results, since the direct applicability of the results of this test method to the clinical situation has not been fully established.

NOTE 3 This test method might 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 test method to establish appropriate safety and health practices and 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*

