Laserid ja laserseadmed. Trahheaaltorude laserikindluse määramine. Osa 2: Trahheaaltoru mansetid

Lasers and laser-related equipment - Determination of laser resistance of tracheal tubes - Part 2: Tracheal tube cuffs (ISO 11990-2:2011)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11990-2:2014 sisaldab Euroopa standardi EN ISO 11990-2:2014 inglisekeelset teksti.	This Estonian standard EVS-EN ISO 11990-2:2014 consists of the English text of the European standard EN ISO 11990-2:2014.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 29.10.2014.	Date of Availability of the European standard is 29.10.2014.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.10, 31.260

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11990-2

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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.

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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

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Ref. No. EN ISO 11990-2:2014 E

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.

Contents

Page

Foreword iv
Introduction v
1 Scope 1
2 Normative references 1
3 Terms and definitions 1
4 Principle 2
5 Significance and use of the test 2
6 Apparatus 3
6.1 Gas supply system 3
6.2 Containment box 4
6.3 Smoke evacuation device 7
6.4 Lasers and delivery systems 7
6.5 Oxygen analyser 7
7 Reagents and materials 8
8 Preparation of test specimens 8
9 Preparation of apparatus 8
10 Test procedure 9
11 Interpretation of results 10
12 Test report 10
Bibliography 11

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.