# INTERNATIONAL STANDARD

ISO 11990-2

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# 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

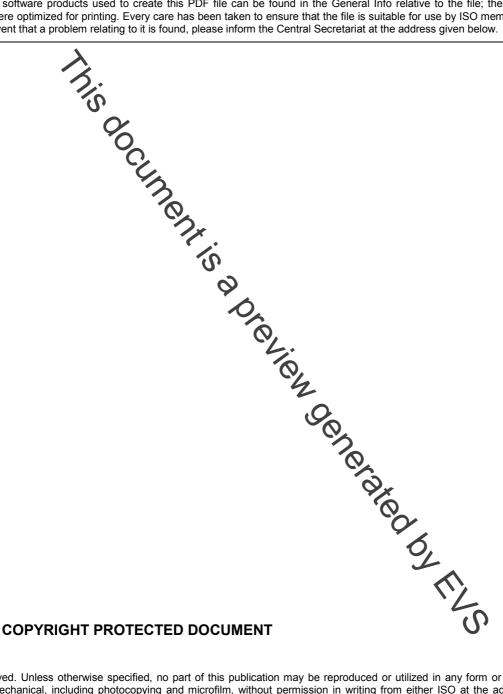


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### **Foreword**

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 Maison 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 control tees 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 applying 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.

review denerated by this 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 bacheal 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 fost likely to be contacted by the laser beam, even when used according to the manufacturer's instructions. Climbal experience has shown that not only perforation of the part of the shaft below the cuff has happened, broads 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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# Lasers and laser-related equipment — Determination of laser resistance of tracheal tubes —

# Part 2:

# Tracheal tabe 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 fame 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 the propriate 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

#### 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

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