INTERNATIONAL STANDARD

ISO 11990-1

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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

Reference number
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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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.

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]

3.2
beam diameter
d_{95}
diameter of an aperture in a plane perpendicular to the beam axis which contains 95 % of the total beam power

NOTE Adapted from ISO 11145.

[ISO 11990-2:2010]

3.3
combustion
any continuing burning process that occurs in or on the test specimen caused by a chemical process of oxidation with the liberation of heat

EXAMPLES Flame, smouldering, rapid evolution of smoke.

[ISO 11990-2:2010]

3.4
damage
any change, other than combustion, which may affect the safety of the patient or efficacy of the tracheal tube due to increasing the risk of ignition

EXAMPLES Local heating, melting, creation of holes, pyrolysis.

[ISO 11990-2:2010]

3.5
ignition
creation of combustion induced by the delivery of power

[ISO 11990-2:2010]

3.6
laser resistance
measure of the ability of a material to withstand laser power without ignition or damage

[ISO 11990-2:2010]

3.7
shaft
portion of the tracheal tube between the cuff and the machine end of the tube

4 Principle

WARNING — This test method can result in a rocket-like fire involving the tracheal tube. Such a fire can produce intense heat and light and toxic gases.

To simulate worst-case conditions, the shaft of a tracheal tube is exposed to laser power of known characteristics while in an environment of (98 ± 2) % oxygen.

5 Significance and use of the test

5.1 This part of ISO 11990 describes a uniform and repeatable test method for measuring the laser resistance of the shaft of a tracheal tube. Most of the variables involved in laser ignition of a tracheal tube have been fixed in order to establish a basis for comparison. This test method for measuring can be used to compare tracheal tubes having differing types and designs of laser protection.

5.2 A large number and range of variables are involved in ignition of a tracheal tube. A change in one variable can affect the outcome of the test. Caution should be observed, since the direct applicability of the results of this test method to the clinical situation has not been fully established.

NOTE This method can be applied to study the effect of changing the test conditions, but this is outside the scope of this part of ISO 11990. For example, variation of the breathing-gas flow rate or different breathing-gas mixtures might affect the laser resistance of the shaft of a tracheal tube.

5.3 Since an oxygen-enriched atmosphere is often present in the clinical situation, either intentionally or unintentionally, the test is performed in an environment of (98 ± 2) % oxygen.

5.4 A flow rate of 1 l/min of oxygen in a 6,0 mm inner diameter tube was chosen as the most appropriate conditions for shaft ignition and establishment of a fire, based on the work cited in Reference [8].

5.5 The preparation of the shaft of the test specimen shall be in accordance with the manufacturer's instructions for use.

5.6 Use of beam cross-sectional shape other than circular, or mode of laser power delivery other than continuous wave can affect the shaft ignition characteristics. Also, shafts of different construction have different laser resistances (see References [8] to [14]).

6 Apparatus

6.1 Gas supply system

6.1.1 The gas supply system shall provide oxygen to the tracheal tube at a controllable flow rate. Also, the system shall be capable of rapidly flooding the containment box with nitrogen or other inert gas or stopping oxygen flow, or both, to extinguish any burning material. An oxygen flow meter and controller and a quick-action inert gas valve shall be part of this system (see Figure 1). The nitrogen or inert gas supplied shall be at a higher pressure and allow a flow rate of at least an order of magnitude greater than that of the oxygen supplied to the tracheal tube.

6.1.2 Other arrangements, such as an oxygen flood valve for rapidly purging the containment box or an inert gas flooding system for rapid extinguishment of burning material, may be used as long as the requirements of the test method as defined herein are not affected.