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Optics and optical instruments — Lasers and laser-related equipment — Determination of laser resistance of tracheal tube shafts

Optique et instruments d'optique — Lasers et équipements associés aux lasers — Détermination de la résistance au laser des 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 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 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 9, *Electro-optical systems*.

This second edition cancels and replaces the first edition (ISO 11990:1999), Clause 12 of which has been technically revised.

Introduction

Surgery in the airway in which a laser is used brings together an oxygen-enriched atmosphere, fuel and high energy that can combine to create a fire. In the early to middle 1980s, the increasing use of such lasers was followed by airway fires and the subsequent 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 lead to the development of the test method described in this International Standard, in order to assist the clinician in determining which tracheal tube shaft is most laser-resistant for a defined set of conditions.

Optics and optical instruments — Lasers and laser-related equipment — Determination of laser resistance of tracheal tube shafts

1 Scope

This International Standard specifies a method of testing the continuous wave (cw) laser resistance of the shaft of a tracheal tube. Other components of the system, such as the inflation system and cuff, are outside the scope of this International Standard.

The specified test method shall be used to measure and describe the properties of materials, products or assemblies in response to heat and flame under controlled laboratory conditions and shall not be used to describe or appraise the fire hazard or fire risk of materials, products, or assemblies under actual fire conditions. However, results of this test may be used as elements of a fire risk assessment which takes into account all the factors which are pertinent to an assessment of the hazard of a particular end use. Caution should be observed in interpreting these results, since the direct applicability of the result of this test method to the clinical situation has not been fully established.

NOTE This test method may involve hazardous materials, operations, and equipment. This International Standard does not purport to address all the safety problems associated with its use. 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 11146:1999, *Lasers and laser-related equipment — Test methods for laser beam parameters — Beam widths, divergence angle and beam propagation factor*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
laser resistance
measure of the ability of a material to withstand laser power without combustion or damage

3.2
combustion
any continuing burning process that occurs in or on the test specimen caused by chemical process of oxidation with the liberation of heat

EXAMPLES Flame, smoldering, rapid evolution of smoke.

3.3
ignition
creation of combustion induced by the delivery of energy

3.4
damage
any change, other than combustion, which may affect the safety of the patient or efficacy of the shaft of the tracheal tube

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

3.5
blemish
any apparent physical change to the shaft of the tracheal tube, other than damage or combustion

EXAMPLES Discoloration, surface pitting, minor deformation.

3.6
shaft
portion of the tracheal tube between the cuff and the machine end of the tube

3.7
beam diameter
d_{95}
diameter of an aperture in a plane perpendicular to the beam axis which contains 95 % of the total beam power (energy)

NOTE Adapted from ISO 11145:2001.

3.8
beam cross-sectional area
A_{95}
smallest area containing 95 % of the total beam power (energy)

NOTE Adapted from ISO 11145:2001.

4 Principle

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.

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

5 Significance and use of the test

5.1 This document describes a uniform and repeatable measurement of 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 measurement 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 laser ignition of a tracheal tube. A change in one variable may 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.

5.3 Since it is conceivable that an oxygen-enriched atmosphere may be encountered in the clinical situation, either intentionally or unintentionally, the test is performed in an environment of (98 ± 2) % oxygen.

5.4 A flowrate of 1 litre/min in a 6,0 mm inner diameter tube was chosen as the best conditions for tube ignition and establishment of a fire based on studies detailed in [11].

5.5 Opportunities for development: variations of this method can be applied to study the effect of changing the test conditions, but are outside the scope of this test method. For example, variation of the breathing-gas flowrate or different breathing-gas mixtures may affect the laser resistance of the tracheal tube. Use of beam cross-sectional areas other than circular or modes of laser power delivery other than continuous, e.g. pulsed, superpulsed, Q-switched, ultrapulsed, may alter the tracheal tube's ignition characteristics. Also, tubes of different diameter will have laser resistances different from that defined in this document (see [6] to [12]).

6 Apparatus

6.1 Gas supply system

6.1.1 The gas supply system shall provide oxygen to the tracheal tube at a controllable flowrate. Also, the system shall be capable of rapidly flooding the containment box with nitrogen or other inert gas and/or stopping oxygen flow, or both, to extinguish any burning material. An oxygen flow control and flow meter and a quick-action inert gas valve should be part of this system (see Figure 1). The nitrogen or inert gas supplied should be at a higher pressure and allow a flowrate 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 made as long as the requirements of the test method as defined herein are not affected.

6.2 Containment box

6.2.1 The containment box is a means to control the environment around the test specimen while allowing access for the laser delivery system to the test specimen (see Figure 2).

6.2.2 The typical containment box shall have the following characteristics:

a) allows direct access of the laser power to the entire length of the tracheal tube shaft;

b) supports the shaft of the tracheal tube 7 cm to 10 cm below the opening for laser access, as shown in Figure 2;

c) maintains an environment of at least (98 ± 2) % oxygen around the tracheal tube;

d) exhausts the gas flowing through the tube and any products of combustion to a safe area;

e) is fireproof and easily cleaned of soot and residue from burned tracheal tubes;

f) is a rectangular parallelepiped approximately 46 cm $\times$ 46 cm $\times$ 15 cm;

g) has transparent, non-flammable enclosure covers that are positioned on top of the non-flammable (in 98 % $O_2 \pm 2$ %) box to allow visibility of and access to the test specimen while maintaining the test environment. The covers shall be able to define an opening of 38 cm^2 to allow laser access to the test specimen. The covers shall be easily removable for access to the test specimen, cleaning of the box and cleaning of the covers themselves;

h) can be rapidly flooded with nitrogen or other inert gas to extinguish any fire inside the box;

i) the top shall be covered with appropriate filter media to protect from reflections.

6.2.3 Other configurations may be used, as long as the requirements of the test method as defined herein are not affected.

6.3 Smoke evacuation

6.3.1 A device to safely remove smoke resulting from any burning tube should be attached to the containment box to minimize the chance of drawing fire into the exhaust system. Alternatively, the containment box may be placed in a fume hood that exhausts out-of-doors.

6.3.2 The smoke evacuation device shall not interfere with maintaining the oxygen environment within the containment box. For example, the flow of a fume hood should not create drafts that would enter or pull gas from