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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 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.

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*

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

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 11145:2006.

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

EXAMPLE Flame, smouldering, rapid evolution of smoke.

3.4
cuff
inflatable balloon permanently attached around the tracheal tube near the patient end to provide an effective seal between the tube and the trachea

[ISO 5361:1999, definition 3.3]

3.5
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

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

3.6
ignition
creation of combustion induced by the delivery of power

3.7
laser resistance
measure of the ability of a material to withstand laser power without ignition or damage

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 cuff of a tracheal tube is exposed to laser power of known characteristics 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 cuff 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 cuff. 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 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 cuff ignition and establishment of a fire based on studies detailed in the work of Sidebotham, Wolf *et al.* [8].

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

5.6 The majority of manufacturers of laser-resistance cuffs recommend using isotonic saline or water to fill the cuff. For preliminary testing of leakage of the cuff, filling with air is recommended by most manufacturers. This can cause an air bubble, which, in a typical position of the patient during surgery, is not on the top of the filled cuff, but at the area where the cuff and shaft meet. The test report shall include whether a bubble occurs and, if so, report if the bubble fills out the space between the cuff and the underlying shaft material, and whether the shaft material in the cuff region is laser-resistant or not.

NOTE 1 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 cuff of a tracheal tube.

NOTE 2 Use of beam cross-sectional shape, other than circular, or mode of laser power delivery, other than continuous wave, may affect the cuff ignition characteristics. Also, cuffs of different construction have different laser resistances.

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.