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# Lasers and laser-related equipment — Determination of laser resistance of tracheal tube shaft and tracheal tube cuffs

*Lasers et équipements associés aux lasers — Détermination de la résistance au laser des axe et 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.



This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 9, *Laser and electro-optical systems*.

This third edition of ISO 11990 cancels and replaces ISO 11990-1:2011 and ISO 11990-2:2010 which have undergone a revision in order to adjust the two documents to each other thereby eliminating redundancies and unintended discrepancies.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

# 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. This led to the development of a test method, described in this document, 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 this document 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 tube shaft and tracheal tube cuffs

## 1 Scope

This document specifies a method of testing the continuous wave (cw) laser resistance of the shaft of a tracheal tube and the cuff regions including the inflation system of tracheal tubes designed to resist ignition by a laser.

NOTE 1 When interpreting these results, the attention of the user is drawn to the fact that the direct applicability of the results of this test method to the clinical situation has not been fully established.

NOTE 2 The attention of the users of products tested by this method is drawn to the fact that the laser will be wavelength sensitive and tested at the wavelength for which it is intended to be used. If tested using other wavelengths, explicitly state the power settings and modes of delivery.

**CAUTION — This test method can involve hazardous materials, operations and equipment. This document 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 document to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.**



## 2 Normative references



The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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*

ISO 11810, *Lasers and laser-related equipment — Test method and classification for the laser resistance of surgical drapes and/or patient protective covers — Primary ignition, penetration, flame spread and secondary ignition*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

ISO 5361:2016, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors*

ISO 11145:2016, *Optics and photonics — Lasers and laser-related equipment — Vocabulary and symbols*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11810, ISO/IEC Guide 99 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

**3.1**
**beam diameter**
$d_{95}$
smallest diameter of a circular aperture in a plane perpendicular to the beam axis that contains 95 % of the total beam power (energy)

[SOURCE: ISO 11145:2016, 3.3.1, modified — The value of contained total beam power has been set to 95 %, and the note to entry has been removed.]

**3.2**
**beam cross-sectional area**
$A_{95}$
smallest completely filled area containing 95 % of the total beam power (energy)

[SOURCE: ISO 11145:2016, 3.2.1, modified — The value of contained total beam power has been set to 95 %, and the note to entry has been removed.]

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

EXAMPLE Flame, smouldering, rapid evolution of smoke.

[SOURCE: ISO 11810:2015, 3.7]



**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

[SOURCE: ISO 5361:2016, 3.4]



**3.5**
**damage**
any change, other than combustion, which can 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.

[SOURCE: ISO 11810:2015, 3.8, modified — "product" has been replaced with "tracheal tube".]

**3.6**
**flammable**
subject to ignition and flaming combustion

[SOURCE: ISO 11810:2015, 3.9]

**3.7**
**ignition**
creation of combustion induced by the delivery of power

[SOURCE: ISO 11810:2015, 3.10]

**3.8**
**laser resistance**
measure of the ability of a material to withstand laser power without ignition or damage

[SOURCE: ISO 11810:2015, 3.11]

**3.9**
**melting behaviour**
softening of a material under the influence of heat (including shrinking, dripping and burning of molten material, etc.)

[SOURCE: ISO 11810:2015, 3.12]

**3.10**
**penetration resistance**
ability of a material to prevent the passage of laser energy

[SOURCE: ISO 11810:2015, 3.14]

**3.11**
**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 material is exposed to laser power of known characteristics in an environment of up to 98 % ± 2 % oxygen.



## 5 Significance and use of the test

**5.1** This document describes a uniform and repeatable test method for measuring the laser resistance of the shaft and 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 the 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 1 This method can be applied to study the effect of changing the test conditions, but this is outside the scope of this document. For example, variation of the breathing-gas flow rate or different breathing-gas mixtures might affect the laser resistance of the shaft and cuff 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 condition for shaft and cuff ignition and establishment of a fire, based on the work cited in Reference [5].

**5.5** The preparation of the 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 and cuff ignition characteristics. Also, shafts and cuff of different construction have different laser resistances (see References [5] to [12]).

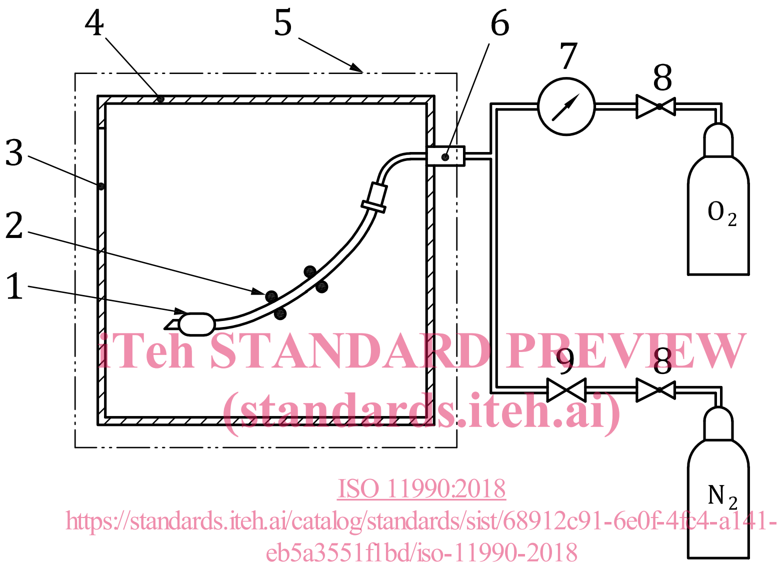
**5.7** The majority of manufacturers of laser-resistant cuffs recommend using isotonic saline or water to fill the cuff. For preliminary testing of leakage of the cuff, filling with air is recommended by most manufacturers. This can cause an air bubble, which, in a typical position of the patient during 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 2 This method can be applied to study the effect of changing the test conditions, but this is outside the scope of this document.

# 6 Apparatus

## 6.1 General

**6.1.1** The test apparatus shall consist of a draught-resistant ventilated containment box, specimen holder, specimen rack, laser energy source and associated parts (see Figure 1).






**Key**

1 test specimen
2 specimen holder using two clamps
3 opening for laser access
4 containment box (lateral view)
5 enclosure cover (maybe multi-piece)
6 flashback arrestor
7 oxygen flow meter and controller
8 pressure regulator with inlet and outlet gauges
9 quick-action inert gas valve

**Figure 1 — Typical testing apparatus (schematic)**

## 6.2 Containment box

**6.2.1** The containment box controls the environment around the specimen while allowing the laser beam to be directed onto the specimen.

**6.2.2** The containment box shall have the following characteristics:

a) rectangular in shape and measures approximately 46 cm × 46 cm × 46 cm;

b) fire-proof and easily cleaned of soot and residue from burned specimens;

c) an opening, or at least one cover or window, to allow access to the test specimen;

d) allow direct access of the laser beam to the specimen;

e) allow observation with video cameras on the top and on all sides of the box; a minimum of three video cameras (one camera positioned above the containment box and two cameras positioned at two of the sides of the containment box) is needed for recording purposes;

f) exhaust the gas and any products of combustion to a safe area;

g) allow cleaning of the box, and cleaning of the covers and/or windows themselves;

h) maintaining an environment of 98 % ± 2 % oxygen around the specimen;

i) it can be rapidly flooded with nitrogen or another gas to extinguish any fire inside the box;

j) the internal surfaces are non-reflective to protect the specimen 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 Specimen holder

The specimen holder shall allow laser access to the test specimen to be able to allow for different angles of positioning of the tracheal tube and an angle of the laser beam to the tracheal tube cuff. Figure 2 shows these angles (denoted as $\alpha$ and $\beta$) which allows the mounting of the test specimen at an angle such that an air bubble, if present, inside the cuff is directed to the connecting area between the cuff and the tube shaft.

