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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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Contents

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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 3.

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.

International Standard ISO 11990 was prepared by ISO/TC 172, *Optics and Optical Instruments*, Subcommittee SC 9, *Electrooptical systems*.

This International Standard is based on ASTM F29.01.10.

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 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 should be used to measure and describe the properties of materials, products or assemblies in response to heat and flame under controlled laboratory conditions and should 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 of the factors which are pertinent to an assessment of the hazard of a particular end use.

NOTE 1 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 2 This test method may involve hazardous materials, operations, and equipment. This International Standard does not purport to address all of 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 reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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 International Standard, the following terms and definitions apply.

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

3.2
burning
chemical process of oxidation with the liberation of heat

3.3
combustion
any continuing burning process that occurs in or on the test specimen

EXAMPLES Flame, smoldering, rapid evolution of smoke.

3.4
ignition
creation of propagated combustion induced by the application of energy, usually heat

3.5
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.

3.6
blemish
any apparent physical change to the shaft of the tracheal tube, other than damage or combustion

EXAMPLES Discoloration, surface pitting, minor deformation.

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

3.8
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)

[ISO 11145]

3.9
beam cross-sectional area
A_{95}
smallest area containing 95 % of the total beam power (energy)

[ISO 11145]

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. This fire can produce high heat, intense light and toxic gases.

5 Significance and use of the test

5.1 This International Standard 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 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 a 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 [1] (see Bibliography).

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 International Standard (see [2] to [5] in the Bibliography).

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 unit (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 96 % oxygen around the tracheal tube;

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

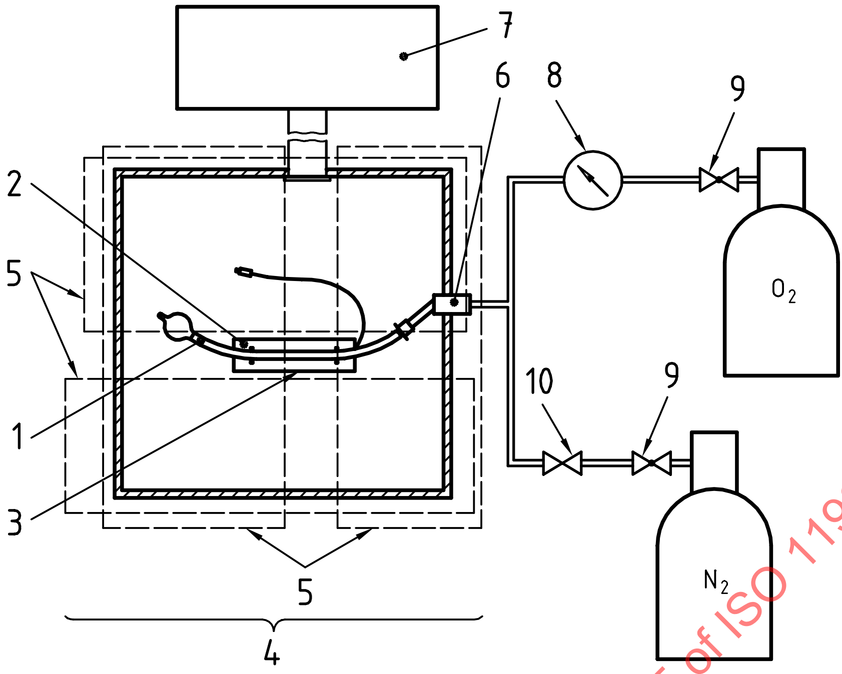
e) is fireproof and easily cleaned of soot and residue from burned tracheal tubes;

f) is a rectangular parallelepiped approximately 46 cm × 46 cm × 15 cm;

g) has transparent, non-flammable enclosure covers that are positioned on top of the box to allow visibility of and access to the test unit 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 unit. The covers shall be easily removable for access to the test unit, 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.

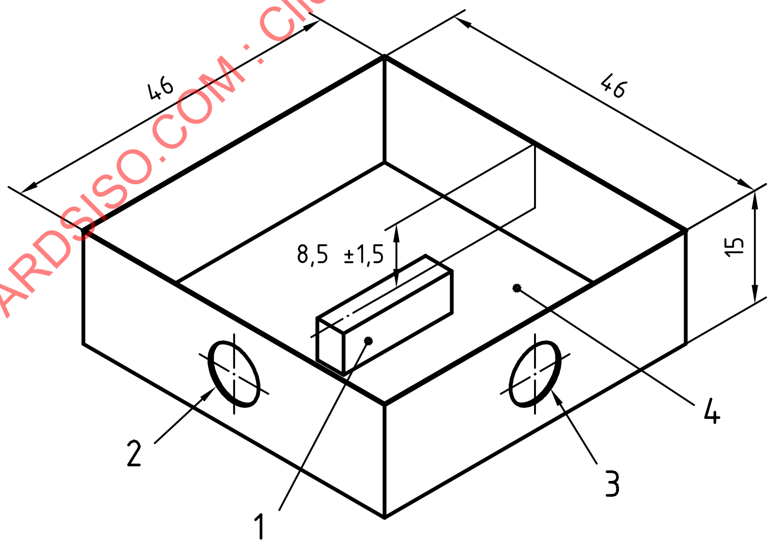


Key

1 Test specimen
2 Specimen holder
3 Opening for laser access (38 cm² max.)
4 Test enclosure (top view)
5 Enclosure covers
6 Flashback arrestor
7 Smoke evacuator
8 Oxygen flow meter and controller
9 Pressure regulator with supply and output gauges
10 Toggle valve

Figure 1 — Typical testing apparatus schematic

Dimensions in centimetres



Key

1 Test specimen holder (located roughly in middle of containment box)
2 Gas inlet
3 Smoke evacuation port
4 Bottom of box

All tolerances are ± 6 cm except as noted. Gas inlet and smoke evacuation ports shall be sufficiently large to allow for appropriate plumbing access. Commonly available electrical pull boxes with knock-outs may be used.

Figure 2 — Containment box

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

6.3 Smoke evacuation

WARNING — Combustion of most materials used in tracheal tubes produces toxic gases such as carbon monoxide, hydrogen chloride and hydrogen cyanide. Also, the smoke produced in such fires contains hazardous particles of carbon, silica, unburned matter and other materials.

6.3.1 A device to safely remove smoke resulting from any burning tube should be attached to the containment box so as 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 the opening for laser access. A smoke evacuator, if used, should not be activated until after the initiation of combustion.

6.4 Lasers and delivery systems

WARNING — Surgical lasers emit sufficient power to damage living tissue or ignite fires directly or by reflection of power. In addition to other precautions, test personnel should be trained in the use of lasers and take proper safety measures based on the type of laser being used. These precautions should include laser-safety eyewear, protective clothing, and controlled access to the test area.

6.4.1 Various laser types emitting wavelengths in the visible and infrared ranges are used during ENT (Ear Nose Throat) surgery. Any of these lasers which is used in the free-beam mode and meets the other requirements listed here is suitable for use in this test.

6.4.2 The laser emission shall be applied using the specific focussing/handling system supplied by the manufacturer. These devices allow the laser power of known and controllable size to be directed onto an area of treatment without physical contact. The system shall provide a beam diameter d_{95} of 0,5 mm ± 10 %.

6.4.3 Bare fibres, contact tips, contact fibres, or other devices that convert some laser power into heat and are used in physical contact with tissue are not covered by this test method. Heat affects materials differently than does laser power and is inconsistent with this test method.

CAUTION — Cooling or clearing gases shall not be used. Cooling or clearing gases are used by some lasers to maintain the quality of the delivery system. It is understood that the flow of these gases may alter the measured laser resistance, e.g. by extinguishing nascent fire.

6.4.4 The power transmitted by these systems should be verified as accurate to ± 10 %. This can be accomplished by use of an external power meter or internal calibration systems.

6.5 Oxygen analyzer

6.5.1 Any device that can measure the concentration of gaseous oxygen with a repeatability of at least 1 % of full scale and an accuracy of at least 1 % of full scale is sufficient.

6.5.2 The oxygen sensor should be positioned to minimize the chance of its ignition by any resulting fire in the containment box.

7 Reagents and materials

7.1 Oxygen, typically 99 % (volume fraction) pure, shall be used.

7.2 Nitrogen or other inert gas (i.e. non-oxidizing, nonflammable), typically 99 % (volume fraction) pure, shall be used.

8 Preparation of test units

8.1 The test units shall be any material, device or system used as a tracheal tube, with whatever modifications used to protect the tracheal tube from laser power.

8.2 Five test units shall be used, each with 6,0 mm inside diameter.

8.3 Each test unit shall be prepared according to the manufacturer's instruction for use. Some devices may require special preparation, e.g. wetting of tube, filling cuff with saline, insufflation of inert gas, as part of the laser protection.

8.4 Test units shall be free from extraneous materials such as blood, mucous, lubricants, char, ash or soot, as such materials can significantly alter the laser resistance of the tracheal tube.

8.5 The test units and apparatus shall be equilibrated to 20 °C ± 3 °C prior to the start of testing. This is done to standardize the test conditions rather than to simulate a clinical condition. The ignitability and flammability of most materials do not significantly change between room temperature and body temperature. Some polymers do change their oxygen takeup, and therefore their flammability, with temperature.

8.6 The test units shall not be preconditioned in an oxygen-enriched atmosphere. It shall be recognized that some materials, for example polymers, absorb oxygen and may have reduced laser-resistance if exposed to oxygen for long periods.

9 Preparation of apparatus

9.1 Ensure that the containment box is clean, i.e., free of visible, gross contaminants and debris which may interfere with the performance of the test or evaluation of the results. The enclosure covers shall be clean enough to allow test personnel to view laser interaction with the test unit. The containment box shall not contaminate the test unit with any visible material.

9.2 Ensure there is adequate gas for the test and means are provided to extinguish any resulting fire.

9.3 Ensure that the laser is in working order, that its operation is understood, and that personnel protection is in place.

9.4 Have other methods of fire extinguishment, e.g. carbon dioxide fire extinguisher, at hand. Water is not advised, as it will not extinguish some materials burning in oxygen and, if used, will cause considerable soiling of the containment box and will interfere with interpretation of the results of laser interaction with the test unit. Water is also hazardous for use on fire involving energized electrical equipment.

10 Test procedure

10.1 Perform the test at 20 °C ± 3 °C.

10.2 Insert the test unit into the containment box. Connect the gas supply system to the test unit.

10.3 Place the enclosure covers on the top of the containment box, as shown in Figure 1. Ensure that the opening for laser access is not larger than 38 cm^2 and allows laser access to the shaft of the test unit. Also, ensure that the test unit is visible through the enclosure covers.

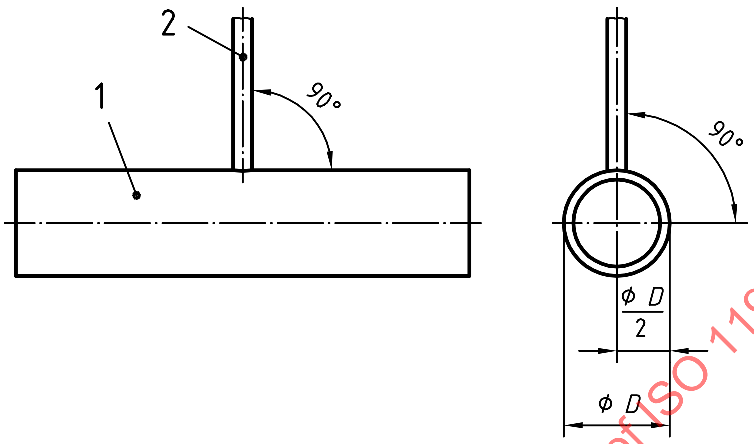
10.4 Determine that the inert gas flush is working properly to extinguish any fire resulting from the test.

10.5 Determine that the smoke evacuation system is working properly and does not affect the gas environment of the containment box during the test.

10.6 Flow oxygen into the containment box at a rate and time period sufficient to establish an environment of (98 ± 2) % oxygen. This oxygen level shall be verified by use of an oxygen analyzer (see 6.5) measuring the environment at the location of test unit.

10.7 Establish an oxygen flowrate of 1 l/min through the tracheal tube.

10.8 Position the laser so that the laser beam is perpendicular to the surface of the shaft of the test unit (see Figure 3). Also, position the laser so that the diameter of the beam incident on the surface of the test unit is 0,5 mm ± 10 %, as the beam cross-sectional area (A_{95}) is a critical dimension. Confirm beam diameter in accordance with ISO 11146. Lateral motion of the laser spot shall be minimized by some form of stabilization.



Key

1 Test shaft

2 Laser beam

Figure 3 — Laser beam firing angle

10.9 Verify that the following standardized test parameters are correct during performance of the test:

a) inside diameter of test unit: 6,0 mm;

b) oxygen concentration: (98 ± 2) %;

c) oxygen flowrate: 1 l/min;

d) laser beam diameter d_{95}: 0,5 mm ± 10 %;

e) mode of laser application: continuous.

10.10 Starting with a recommended 2 W, apply the laser beam to the test unit for a specified duration of 1 s to 10 s, using the continuous mode of laser emission. Stop laser emission upon any evidence of tracheal tube burning or difficulty with the test apparatus.

These data shall be reported in addition to data collected at 10 s.

10.11 Increase the laser power by the minimum increment available with the type of laser being used, but not less than 2 W. Repeat the application of the laser power at a cool, clean, undamaged area on the test unit for each new power level. This can be accomplished by starting the test at the patient end of the shaft and proceeding toward the machine end.

10.12 Continue testing by increasing the power until burning occurs or the test unit becomes damaged. If burning occurs, extinguish the fire with the nitrogen or inert gas system.

11 Interpretation of results

11.1 Any test unit that experiences burning or damage, as defined in 3.2 and 3.5, is considered to have laser resistance up to the maximum power at which the burning or damage did not occur under the specified test conditions.