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Standard Test Method for Determining Laser Resistance of the Shaft of Tracheal Tubes[1]

This standard is issued under the fixed designation F 1497; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

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. Various materials and devices have been used to minimize the chance of airway fire. This test method was developed to determine the laser resistance of a tracheal tube shaft for a defined set of conditions.

1. Scope

1.1 This test method covers a standard means of testing the laser resistance of the shaft of a tracheal tube.

1.2 This test method addresses the laser resistance of the shaft of the tracheal tube. Other components of the system, such as the inflation system and cuff, are outside the scope of this test method.

1.3 Caution should be observed since the direct applicability of the results of this test method to the clinical situation has not been fully established.

1.4 The values stated in SI units are to be regarded as the standard. The values given in parentheses are for information only.

1.5 *This 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 that takes into account all of the factors that are pertinent to an assessment of the fire hazard of a particular end use.*

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.* Specific precautionary statements are given in Notes 1-6.

2. Referenced Documents

2.1 *ASTM Standards:*

F 1242 Specification for Cuffed and Uncuffed Tracheal Tubes[2]

2.2 *ANSI Standards:*

ANSI Z136.1 American National Standard for the Safe Use of Lasers-1993[3]

ANSI Z136.3 American National Standard for the Safe Use of Lasers in Health Care Facilities-1996[3]

2.3 *CGA Standard:*

CGA G-4.3 Commodity Specification for Oxygen[4]

CGA G-10.1 Commodity Specification for Nitrogen[4]

3. Terminology

3.1 *Definitions:*

3.1.1 *blemish*—any apparent physical change to the shaft of the tracheal tube, other than damage or burning. Some examples of blemish are discoloration, surface pitting, and minor deformation.

3.1.2 *burning*—any continuing combustion process that occurs in or on the test specimen. Some signs of burning are flame, smoldering, and rapid evolution of smoke.

3.1.3 *damage*—any physical change (for example, local heating, melting, creation of holes, ashing without burning, pyrolysis), other than burning, that may affect the safety of the patient or efficacy of the shaft of the tracheal tube.

3.1.4 *laser resistance*—the relative ability of a material to withstand laser energy without burning or damage.

3.1.5 *power density*—the rate at which laser energy is delivered per unit area of irradiated surface, given in watts per square centimetre (W/cm^2).

3.1.6 *shaft*—the portion of the tracheal tube between the cuff and the machine end of the tube.

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[2] Discontinued; See 2001 *Annual Book of ASTM Standards*, Vol 13.01.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

[4] Available from Compressed Gas Association, 1235 Jefferson Davis Highway, Arlington, VA 22202.

4. Summary of Test Method

4.1 The shaft of a tracheal tube will be exposed to laser energy of known characteristics while in an environment of 98 ± 2 % oxygen.

NOTE 1—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

5.1 This test method determines 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 There are a large number and range of variables 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 flow rate of 1 L/min in a 6.0-mm inner diameter tube was chosen as the best condition for tube ignition and establishment of a fire.

5.5 *Opportunities for Development*—Variations of this test 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 respiratory gas flow rate or different breathing gas mixtures may affect the laser resistance of the tracheal tube. Use of modes of laser energy delivery other than continuous, (for example, pulsed, superpulse, q-switched, and ultrapulsed), may alter the tracheal tube's ignition characteristics. Also, tubes of different diameter will have laser resistance different from that defined in this test method.

6. Apparatus

6.1 *Gas Supply System*:

6.1.1 The gas supply system shall provide oxygen to the containment box 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. (See Fig. 1.) The nitrogen or inert gas supplied should be at a higher pressure and allow a flow at least an order of magnitude greater than the oxygen supplied to the containment box.

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 this test method 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 of the laser delivery system to the test unit (see Fig. 2).

6.2.2 The typical containment box will have the following characteristics:

6.2.2.1 Allows direct access of the laser energy to the entire length of the tracheal tube shaft, and

6.2.2.2 Supports the shaft of the tracheal tube 7 to 10 cm (3 to 4 in.) below the opening for laser access as shown in Fig. 1.

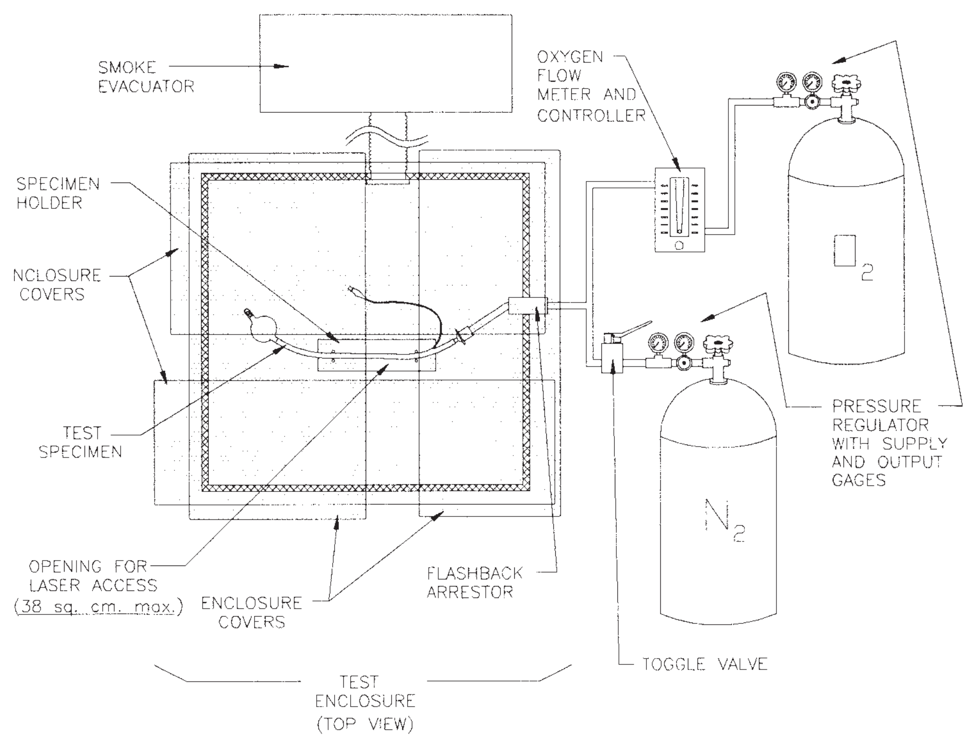
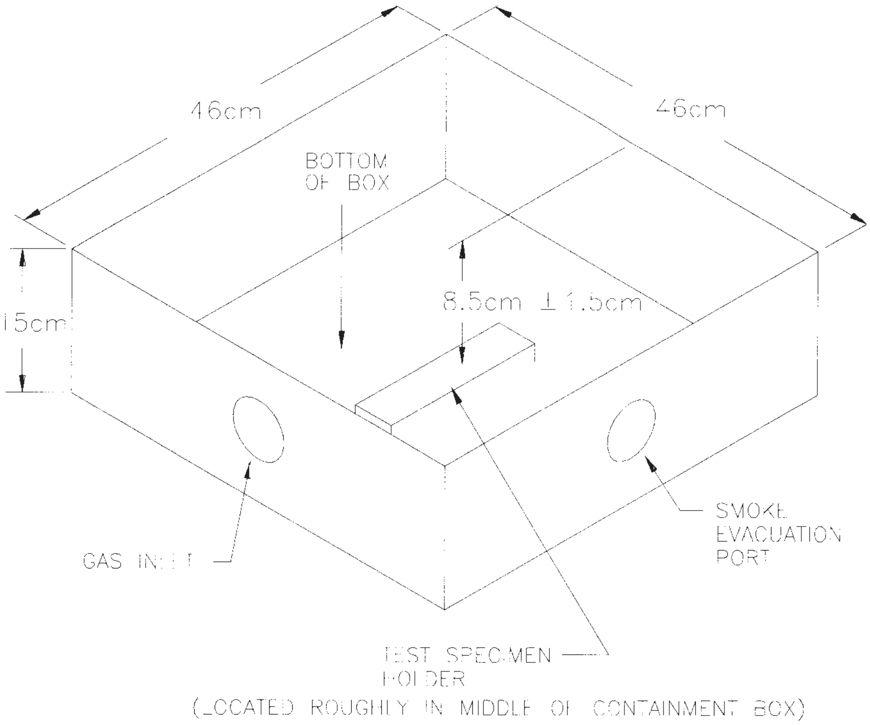


FIG. 1 Typical Testing Apparatus Schematic



Construction Notes:
1) All tolerances are ±6 cm except as noted.
2) Gas inlet and smoke evacuation ports are to be sufficiently large to allow for appropriate plumbing access.
3) Commonly available electrical pull boxes with knockouts may be used.
4) A fume hood which encloses the containment box may be used in the place of a smoke evacuator.
5) The containment box should be covered with glass during testing. An opening large enough for laser access should be present. The area of this opening is not to exceed 6 in.^{2}

FIG. 2 Containment Box Drawings

6.2.2.3 Maintains an environment of at least 96 % oxygen around the tracheal tube,

6.2.2.4 Exhausts the gas flowing through the tube and any products of combustion to a safe area,

6.2.2.5 Is fireproof and easily cleaned of soot and residue from burned tracheal tubes,

6.2.2.6 Is a rectangular parallel pipe approximately 46 by 46 by 15 cm (18 by 18 by 6 in.),

6.2.2.7 Has transparent, nonflammable 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 must be able to define an opening of no longer than 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, and

6.2.2.8 Can be rapidly flooded with nitrogen or other inert gas to extinguish any fire inside the box.

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

6.3 *Smoke Evacuation*:

NOTE 2—**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. Alternately, the containment box can be placed in a fume hood that exhausts out-of-doors.

6.3.2 This device must 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 ignition of a fire.

6.4 *Lasers*:

NOTE 3—**Warning:** Surgical lasers emit concentrated, coherent light energy of sufficient power to damage living tissue or ignite fires directly or by reflected energy.

NOTE 4—**Precaution:** In addition to other precautions, test personnel should be schooled 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. Refer to ANSI Z136.1-1993 and ANSI Z136.3-1996 for detailed guidelines for the safe use of lasers.

6.4.1 Lasers typically used during surgery shall be used. Some of these lasers are as follows:

6.4.1.1 *Carbon Dioxide Laser*, commonly known as CO^2 laser, that emits infrared light energy with a wavelength of 10 600 nm.

6.4.1.2 *Neodymium:Yttrium Aluminum Garnet Laser*, commonly known as Nd:YAG laser, that emits near-infrared light energy with a wavelength of 1064 nm.

6.4.1.3 *Frequency-Doubled Nd:YAG Laser*, that emits visible light energy with a wavelength of 532 nm. A particular design of this laser is known as the potassium titanyl phosphate laser or KTP laser.

6.4.1.4 Other types of lasers may be used as they become available, or become used for surgery, or both.

6.4.2 Other lasers, such as those used for aiming systems or industrial machining, that have capabilities (for example, 5 mW HeNe, 1000 W CO^2) outside those of typical surgical lasers, shall not be used for this test method.

6.4.3 *Laser Delivery Systems*:

6.4.3.1 The laser emission shall be by means of the typical systems used with the particular laser, that is, focusing lens or micromanipulator, in accordance with the manufacturer's instructions. These devices allow the laser energy of known and controllable size to be directed onto an area for treatment without physical contact. The system shall provide a spot size of 0.5-mm ± 10 % diameter.

NOTE 5—**Caution:** Cooling or clearing gases should be used at the minimum settings recommended by the laser manufacturer. 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, for example, by extinguishing nascent fire.

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

NOTE 6—**Caution:** The power transmitted by these systems should be verified as accurate. This can be accomplished by use of an external power meter or internal calibration systems. Fiber transmitted laser energy should be frequently checked, that is, at each new power level and after fiber cleaving, as the fiber ends are easily damaged by the testing performed in this procedure.

6.5 *Oxygen Analyzer*:

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

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 Produced by Air Liquefaction, U.S.P.*—Medical grade oxygen as defined by *United States Pharmacopoeia* and CGA G-4.3 typically at least 99 % pure oxygen.

7.2 *Nitrogen or Other Inert Gas (That Is, Non-Oxidizing, Nonflammable), such as Nitrogen Produced by Air Liquefaction, U.S.P.*—Medical grade nitrogen as defined by *United States Pharmacopoeia* and CGA G-10.1 typically at least 99 % pure nitrogen.

8. Test Units

8.1 The test units shall be any material, device, or system used as a tracheal tube, as generally defined in Specification F 1242, with whatever modifications used to protect the tracheal tube from laser energy.

8.2 Five test units shall be used for each time value tested each with 6.0-mm inside diameter.

9. Preparation of Apparatus

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

9.2 Ensure that the gas supply system has sufficient gases for the test and extinguishment of any 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, for example, 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 not recommended and is hazardous for use on fire involving energized electrical equipment.

10. Conditioning

10.1 Prepare each test unit in accordance with the manufacturer's instructions for use. Some devices may require special preparation, for example, wetting of the tracheal tube, filling cuff with saline, or insufflation of inert gas, as part of the laser protection.

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

10.3 The test units, all apparatus, and all gases shall be at 20 ± 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.

10.4 The test units shall not be preconditioned in an oxygen-enriched atmosphere. Some materials absorb oxygen and may have reduced laser resistance if exposed to oxygen for long periods.

11. Procedure

11.1 Perform the test at 20 ± 3°C.

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

11.3 Place the enclosure covers on top of the containment box as shown in Fig. 1. Ensure that the opening for laser access is not larger than 38 cm^2 (6 $in.^2$) and allows laser access to the shaft of the test unit. Also, ensure that the test unit is visible through the enclosure covers.

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

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

11.6 Flow oxygen at a rate and time period sufficient to establish an environment of 98 ($\pm$2 %) oxygen in the containment box. Verify this environment of 98 ($\pm$2 %) oxygen by use of an oxygen analyzer measuring at the location of the test unit.

11.7 Establish a flow of oxygen at 1 L/min through the tracheal tube.

11.8 Position the laser so that the emitted energy will be perpendicular to the surface of the shaft of the test unit proximal to the cuff (see Fig. 3). Also, position the laser so that the spot size of the emitted beam on the surface of the test unit is 0.5 mm $\pm$ 10 % in diameter. Avoid pre-focus or post-focus of the beam as the spot size of the beam is a critical dimension and uniform absorption of the laser energy depends on focusing of the beam. Lateral motion of the laser spot must be minimized by some form of stabilization, for example, laser handpiece probe tip resting on the test unit.

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

NOTE 7—These test data shall be reported in addition to data collected at 10 s.

11.10 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 energy at a cool, clean, undamaged area on the test unit for each new power. This can be accomplished by starting the test at one end of the shaft and proceeding toward the other end.

11.11 Continue testing by increasing the power density until burning occurs, or the maximum power of the laser is reached. If burning occurs, extinguish the fire with the nitrogen or inert gas system.

12. Interpretation of Results

12.1 Any test unit that experiences burning, as defined in 3.1.2 and 3.1.3 will be considered to have laser resistance up to the maximum power at which the burning did not occur under the specified test conditions.

12.2 Any damage or blemish occurring to the test unit other than burning (for example, melting, creation of holes) must be described in the test report, together with the laser settings which caused such change(s). These changes should be evaluated for their potential to harm the patient or operating-room personnel. For example, a tube that melts during the laser emission may become occluded and risk loss of the airway.

13. Report

13.1 Verify that the following standardized test parameters were correct during performance of the test:

13.1.1 Inside diameter of test unit = 6.0 mm,

13.1.2 Oxygen concentration = 98 ($\pm$2 %),

13.1.3 Oxygen flow rate = 1 L/min,

13.1.4 Laser spot size = 0.5 mm ($\pm$10 %), and

13.1.5 Mode of laser application = continuous.

13.2 Report the following information for each test unit:

13.2.1 Laser type and delivery system used,

13.2.2 Laser energy duration, in (seconds),

13.2.3 Maximum power of the laser, W,

13.2.4 Outside diameter of test unit, cm,

13.2.5 Length of the test unit, cm,

13.2.6 Power at which damage occurred, W,

13.2.7 Maximum power that did not cause damage, W,

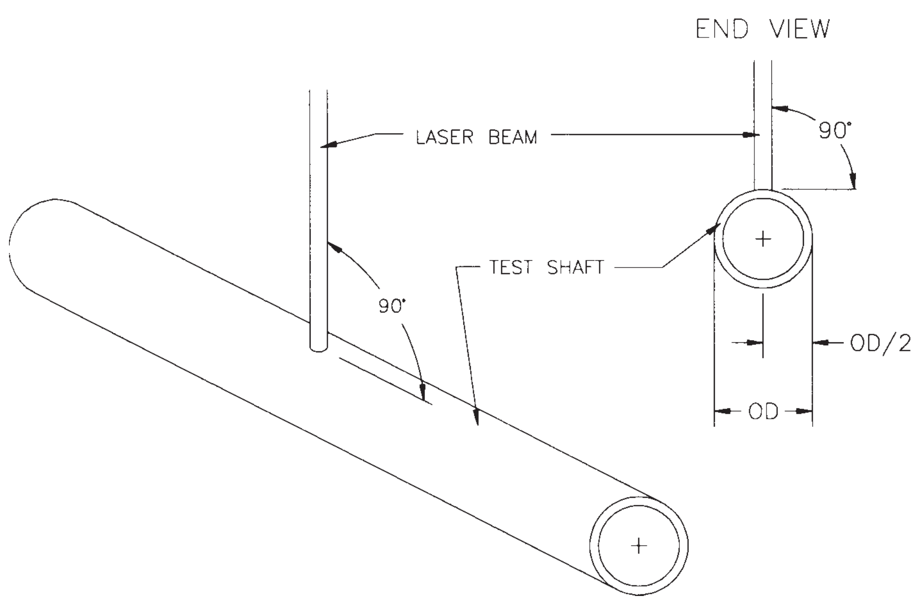


FIG. 3 Laser-Beam Firing-Angle Diagram

13.2.8 Power at which burning occurred, W,

13.2.9 Maximum power that did not cause burning, W,

13.2.10 Physical description of the flame produced (for example, color, size),

13.2.11 Physical description of smoke evolved (for example, color, amount),

13.2.12 Physical description of ash produced (for example, color, texture),

13.2.13 Physical description of damage produced, and

13.2.14 Physical description of any blemish occurring at the maximum power that did not cause burning or damage.

13.3 Report any other effect that could result in harm to the patient or operating-room personnel, for example, reflected laser energy.

14. Precision and Bias

14.1 *Precision*—The precision of the procedure in this test method for defining the laser resistance of the shaft of a tracheal tube is being evaluated. Preliminary intralaboratory results suggest that the laser resistance will be within ±4 W.

14.2 *Bias*—Since there is no accepted reference material suitable for defining the bias of the laser resistance of the shaft of a tracheal tube, bias has not been determined.

15. Keywords

15.1 burning; fire; laser; laser resistance; oxygen; power density; safety; tracheal tube