



Designation: F 1497 – 99a

Standard Test Method for Determining Laser Resistance of the Shaft of Tracheal Tubes¹

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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:

¹ This test method is under the jurisdiction of ASTM Committee F29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee F29.12 on Airways, Bronchoscopes, and Laryngoscopes.

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F 1242 Specification for Cuffed and Uncuffed Tracheal Tubes²

2.2 ANSI Standards:

ANSI Z136.1 American National Standard for the Safe Use of Lasers-1993³

ANSI Z136.3 American National Standard for the Safe Use of Lasers in Health Care Facilities-1996³

2.3 CGA Standard:

CGA G-4.3 Commodity Specification for Oxygen⁴

CGA G-10.1 Commodity Specification for Nitrogen⁴

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/cm²).

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

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 $98 \pm 2\%$ 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 $98 (\pm 2\%)$ 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.

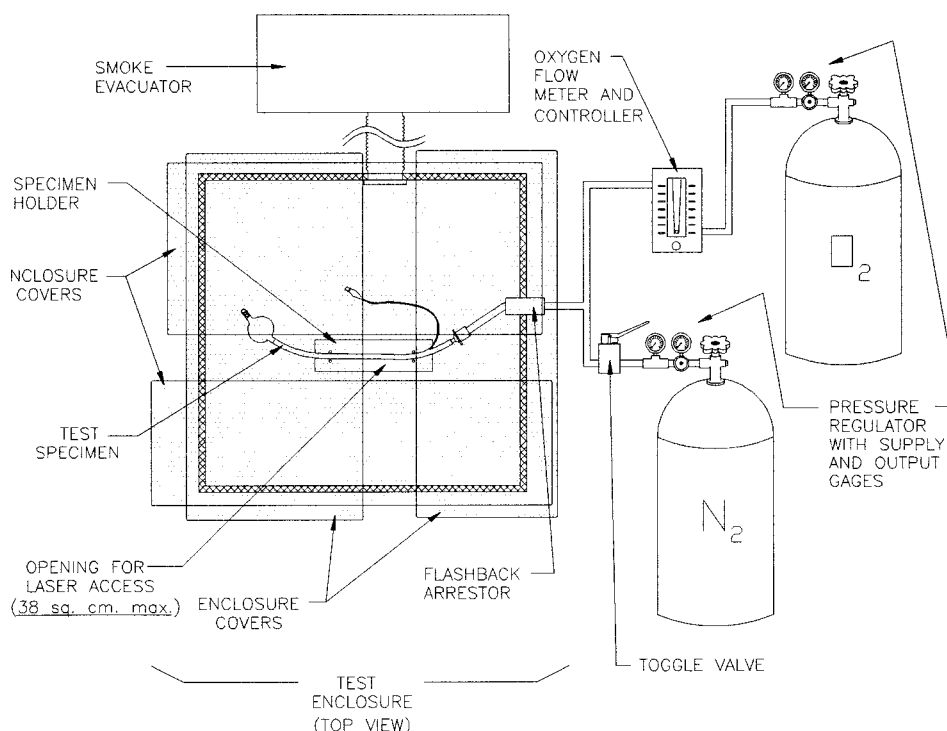


FIG. 1 Typical Testing Apparatus Schematic