BS EN ISO 11990-2:2014

BSI Standards Publication

Lasers and laser-related equipment — Determination of laser resistance of tracheal tubes

Part 2: Tracheal tube cuffs

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National foreword

This British Standard is the UK implementation of EN ISO 11990-2:2014. It is identical to ISO 11990-2:2010. It supersedes BS EN ISO 11990-2:2010 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CPW/172, Optics and Photonics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

ISBN 978 0 580 88583 9

ICS 11.040.10; 31.260

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2014.

Amendments issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11990-2

October 2014

ICS 11.040.10; 31.260

Supersedes EN ISO 11990-2:2010

English Version

Lasers and laser-related equipment - Determination of laser resistance of tracheal tubes - Part 2: Tracheal tube cuffs (ISO 11990-2:2010)

Lasers et équipements associés aux lasers - Détermination de la résistance au laser des tubes trachéaux - Partie 2: Ballonnet de tubes trachéaux (ISO 11990-2:2010)

Laser und Laseranlagen - Bestimmung der Laserresistenz von Trachealtuben - Teil 2: Trachealtubusmanschetten (ISO 11990-2:2010)

This European Standard was approved by CEN on 22 October 2014.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

The text of ISO 11990-2:2010 has been prepared by Technical Committee ISO/TC 172 “Optics and photonics” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11990-2:2014 by Technical Committee CEN/TC 123 “Lasers and photonics” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2015, and conflicting national standards shall be withdrawn at the latest by April 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 11990-2:2010.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11990-2:2010 has been approved by CEN as EN ISO 11990-2:2014 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC (Medical Devices)

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on Medical Devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

NOTE When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on Medical Devices

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
This entire standard	7.1 (first indent only)	This standard is intended to provide a test method that will allow an evaluation of the risk of ignition associated with the use of a tracheal tube and lasers during ear, nose and throat surgery as part of the risk assessment as set out in these essential requirements.
This entire standard	7.3	
This entire standard	9.3	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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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.

INTERNATIONAL STANDARD **ISO 11990-2:2010(E)**

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.

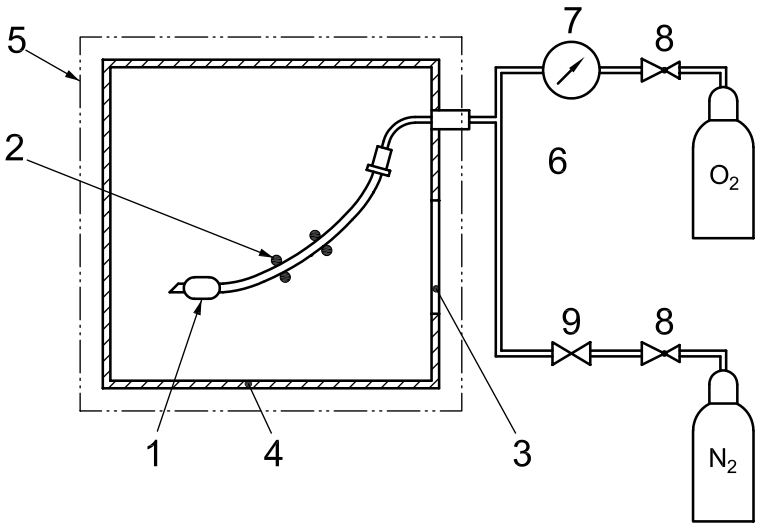
NOTE 2 Use of beam cross-sectional shape, other than circular, or mode of laser power delivery, other than continuous wave, may affect the cuff ignition characteristics. Also, cuffs of different construction have different laser resistances.

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.



Key

1 test tracheal tube
2 tracheal tube support using two clamps
3 opening for laser access
4 containment box (lateral view)
5 enclosure cover (may be 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 test specimen while allowing the laser beam to be directed on to the test specimen.

6.2.2 The containment box shall have the following characteristics:

a) it allows direct access of the laser beam to the cuff and to the point at which the cuff connects to the tracheal tube shaft;

b) it maintains an environment of 98 % ± 2 % oxygen around the tracheal tube;

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

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

e) it is rectangular in shape and measures approximately 46 cm × 46 cm × 46 cm;

f) it 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;

g) while maintaining the test environment in a 98 % ± 2 % oxygen, it has openings, closed with transparent, non-flammable covers, or windows, to allow:

   1) 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;

   2) access to the test specimen;

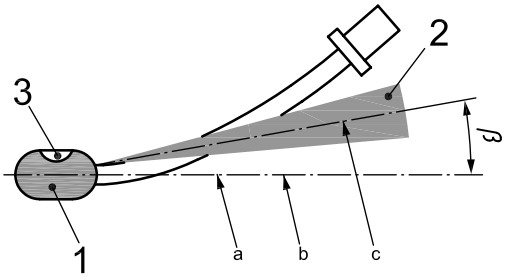
   3) cleaning of the box, and cleaning of the covers and/or windows themselves.

The opening to allow laser access to the test specimen shall 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 α and β). A door, or at least one cover or window, shall allow access to the test specimen;

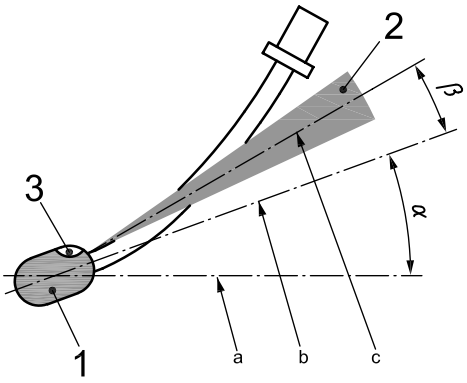
h) It can be rapidly flooded with nitrogen or another inert gas to extinguish any fire inside the box;

i) the top is covered with appropriate filter media to protect the sample and the interior of the box from reflections.

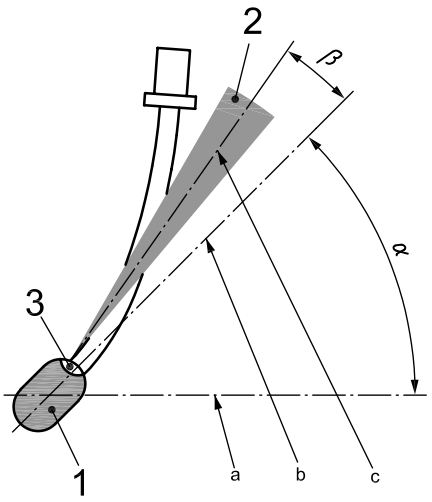
6.2.3 Other configurations may be used, as long as the requirements of the test method as defined herein are not affected.



a) horizontal alignment: α **between** 0° and 5°; $\beta = 10°$



b) tilted alignment: α **between** 15° and 20°; $\beta = 10°$



c) tilted alignment: α **between** 40° and 45°; $\beta = 10°$
(laser beam impacting at the air bubble)

Key

1 cuff of the test specimen
2 laser beam
3 air bubble
α angle between horizontal line and the cuff symmetry axis
β angle between cuff symmetry axis and the optical axis of laser beam

a Horizontal line.
b Cuff symmetry axis.
c Optical axis of laser beam.

Figure 2 — Alignment of test specimen and angle of impact of the laser beam on the cuff

6.3 Smoke evacuation device

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 shall be attached to the containment box to safely remove smoke resulting from a burning tracheal tube but shall be designed to minimize the chance of drawing fire into the exhaust system. Placing the containment box in a fume hood that exhausts to a safe location satisfies this requirement.

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 draughts that would enter or pull gas from the opening for laser access. The smoke evacuation should not be activated until after the initiation of combustion.

6.4 Lasers and delivery systems

WARNING — Surgical lasers emit radiation of sufficient power to damage living tissue or ignite fires directly or by reflection of radiation. 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 radiation of wavelengths in the visible and infrared ranges are used during ENT (ear, nose and throat) surgery. Any of these lasers that meet the requirements listed in this test procedure is suitable for use in this test.

6.4.2 The continuous wave laser radiation shall be applied with the same optical quality as is typically used for a surgical procedure. The system shall provide a beam diameter, d_{95}, of 0,5 mm $\pm$ 10 % at the surface of the test specimen in accordance with ISO 11146-1. The laser radiation shall be applied at a 10° angle (denoted as β in Figure 2) to the cuff symmetry axis and shall hit the cuff in the connection area between the cuff and the shaft. The tracheal tube cuff shall be tested at three orientations as indicated in Figure 2, such that the angle α has the following values:

a) between 0° and 5°;

b) between 15° and 20°;

c) between 40° and 45°.

NOTE 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 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. The flow of these gases can alter the measured laser resistance, e.g. by extinguishing nascent fire.

6.4.3 The power of radiation transmitted by these systems shall be verified as accurate to $\pm$10 %. This can be accomplished by use of an external power meter or internal calibration systems.

6.5 Oxygen analyser

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

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

7 Reagents and materials

7.1 **Oxygen**, 98 % ± 2 % (volume fraction) pure.

7.2 **Nitrogen** or **other inert gas** (i.e. non-oxidizing, non-flammable), 98 % ± 2 % (volume fraction) pure.

8 Preparation of test specimens

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

8.2 Five test specimens shall be used.

8.3 Each test specimen shall be prepared according to the manufacturer's instruction for use. Some devices may require special preparation (e.g. wetting of the tube, filling the cuff with isotonic saline or water, insufflation with inert gas). Measure the outer diameter of the filled cuff.

8.4 The test specimens shall be free from any extraneous materials, as such materials can significantly alter the laser resistance of the tracheal tube.

EXAMPLES Char, ash, soot, blood, mucous, lubricants and other materials.

8.5 The test specimen and apparatus shall be equilibrated at 20 °C ± 3 °C in an oxygen-enriched 98 % ± 2 % atmosphere for 10 min prior to the start of testing.

NOTE 1 This is done to standardize the test conditions rather than to simulate the clinical condition. The ignitability and flammability of most materials do not significantly change between room temperature and body temperature. However, some polymers change their oxygen absorption, and therefore their flammability, with temperature.

NOTE 2 Some materials, such as polymers, absorb oxygen and might have diminished laser resistance if exposed to oxygen for long periods of time.

9 Preparation of apparatus

9.1 Ensure that the containment box is clean (i.e. free of contaminants). The enclosure cover should be clear and clean enough to allow test personnel to view laser interaction with the test specimen by observation with video cameras.

NOTE Contamination may interfere with the performance of the test or evaluation of the results.

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

9.3 Ensure that there is adequate oxygen for the test and nitrogen or other gas for extinguishing any resulting fire.

9.4 Have other means of fire extinguishment (e.g. a carbon dioxide fire extinguisher) at hand. Water is not recommended, 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 specimen. Water is not recommended for use on a fire involving energized electrical equipment.

10 Test procedure

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

10.2 Insert the test specimen in the containment box. Connect the gas supply systems to the apparatus.

10.3 Place the enclosure cover on the top of the containment box, as shown in Figure 1. Ensure that the opening for laser access is as small as possible, in order to maintain the oxygen-enriched atmosphere but still allow laser access to the cuff of the test specimen. Also, ensure that the test specimen is visible through the enclosure cover.

10.4 Ensure that the inert gas flush is working properly.

10.5 Ensure that the smoke evacuation system is working properly and will not affect the gas concentration in 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 analyser (6.5) measuring the environment.

10.7 Establish an oxygen flow rate of 1 l/min through the test specimen.

10.8 Position the laser so that the laser beam is applied at a 10° angle (denoted as β in Figure 2) to the cuff symmetry axis and is focused on the connecting area between the cuff and the shaft. Also, position the laser so that the beam diameter, d_{95}, at the surface of the test specimen, is 0,5 mm ± 10 %, because the beam cross-section area, A_{95}, is a critical dimension. Confirm that the beam diameter is measured in accordance with ISO 11146-1. Lateral motion of the laser spot shall be minimized by some form of stabilization. Testing shall be performed at the following three angles (denoted as α in Figure 2) of the cuff symmetry axis to the horizontal:

— between 0° and 5°;

— between 15° and 20°;

— between 40° and 45°.

10.9 Verify that the following standardized test parameters are correct during performance of the test for each of the three specified angles (denoted as α in Figure 2):

a) exact positioning of the laser beam relative to the connecting area between the cuff and the shaft;

b) oxygen concentration: 98 % ± 2 %;

c) temperature 20 °C ± 3 °C;

d) oxygen flow rate: 1 l/min;

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

f) mode of laser operation: continuous wave.

10.10 Starting with a power of 2 W, apply the laser beam to the test specimen, for a specified duration of 1 s up to 10 s maximum, using the continuous wave mode of laser operation. Stop the laser beam if ignition, or damage (i.e. melting, perforation, leakage, etc.), occurs or if there is difficulty with the test apparatus. These data shall be reported in addition to data collected at 10 s.

10.11 Increase the laser power in reasonable steps. Repeat the application of the laser beam for each new power level or until ignition or damage occurs as described in 10.10. This shall necessitate the use of a new specimen or, if the construction of the cuff-shaft area is identical over the whole circumference, the rotation of

the specimen to determine the maximum power setting at which ignition or damage did not occur. Once the maximum power setting has been determined, verify the maximum power setting by beginning the testing procedure with the five specimens in accordance with 8.2.

11 Interpretation of results

11.1 Any test specimen that experiences ignition, as defined in 3.6, is considered to have a laser resistance up to the maximum power at which the ignition did not occur under the specified test condition.

11.2 Any damage (see 3.5) to the test specimen (e.g. melting, creation of holes) shall be described in the test report, together with the laser settings that caused such change(s).

12 Test report

The test report shall include the following information for each test specimen:

a) laser type, nominal wavelength and delivery system used;

b) laser power duration in seconds;

c) maximum power of the laser in watts;

d) outside diameter of the filled cuff of the test specimen in millimetres;

e) manufacturer of tracheal tube and identifying data, material of the cuff and preparation (filled with isotonic saline or water, wetted outside);

f) if any air bubble occurs, location of the bubble inside the cuff and whether the bubble fills out the space between the cuff and the underlying shaft material;

g) if the shaft material in the cuff region is laser-resistant or not;

h) a description of any ignition or damage;

i) power at which ignition or damage of the cuff occurred, in watts;

j) maximum power that did not cause ignition or damage of the cuff, in watts;

k) angle α where ignition or damage of the cuff occurred;

l) location where ignition or damage of the cuff occurred;

m) physical description (colour, size) of the flame or damage produced;

n) statement that the test has been performed in accordance with this part of ISO 11990;

o) date and time of test;

p) name and address of the test organization;

q) name and signature of the individual performing the test;

r) graphical report of results showing power against laser exposure duration;

s) report of results.

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