INTERNATIONAL STANDARD

ISO 11990

Third edition
2018-08

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

Reference number
ISO 11990:2018(E)

© ISO 2018



COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

 © ISO 2018 – All rights reserved

Contents

Page

Foreword ..... **iv**
Introduction ..... **v**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
4 Principle **3**
5 Significance and use of the test **3**
6 Apparatus **4**
6.1 General 4
6.2 Containment box 4
6.3 Specimen holder 5
6.4 Lasers and delivery systems 7
6.5 Power meter 7
6.6 Gas supply system 7
6.7 Environment 7
6.7.1 Ambient air conditions 7
6.7.2 Oxygen enriched atmospheres 8
6.8 Smoke evacuation device 8
7 Reagents and materials **8**
8 Preparation of test specimens **8**
9 Preparation of apparatus **9**
10 Test methods **9**
10.1 General conditions 9
10.2 Shaft 9
10.3 Cuff 10
11 Interpretation of results **11**
12 Test report **11**
Bibliography **13**

© ISO 2018 – All rights reserved

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.

© ISO 2018 – All rights reserved

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.

© ISO 2018 – All rights reserved

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/

© ISO 2018 – All rights reserved