AS/NZS ISO 11990: 2002
ISO 11990:1999

Australian/New Zealand Standard™

Optics and optical instruments—Lasers and laser-related equipment—Determination of laser resistance of tracheal tube shafts

Standards Australia

STANDARDS NEW ZEALAND
Paerewa Aotearoa

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 26 June 2002 and on behalf of the Council of Standards New Zealand on 20 June 2002. It was published on 28 June 2002.

The following are represented on Committee HE-003:

Australasian College of Physical Scientists and Engineers In Medicine
Australasian Society for Ultrasound in Medicine
Australian Chamber of Commerce and Industry
Australian Dental Association
Australian Institute of Radiography
Australian Radiation Protection and Nuclear Safety Agency
Australian Society of Anaesthetists
Australian and New Zealand College of Anaesthetists
Canterbury District Health Board
College of Biomedical Engineering
Institution of Engineers Australia
Commonwealth Department of Health and Ageing
Department of Defence (Australia)
Health Industry Suppliers Association of New Zealand
Masterton Hospital
Medical Industry Association of Australia Inc
Ministry of Economic Development (New Zealand)
Royal Australasian College of Physicians
Royal Australasian College of Surgeons
The Royal Australian and New Zealand College of Radiologists

Keeping Standards up-to-date

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about joint Australian/New Zealand Standards can be found by visiting the Standards Australia web site at www.standards.com.au or Standards New Zealand web site at www.standards.co.nz and looking up the relevant Standard in the on-line catalogue.

Alternatively, both organizations publish an annual printed Catalogue with full details of all current Standards. For more frequent listings or notification of revisions, amendments and withdrawals, Standards Australia and Standards New Zealand offer a number of update options. For information about these services, users should contact their respective national Standards organization.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia International or Standards New Zealand at the address shown on the back cover.

This Standard was issued in draft form for comment as DR 02153.

Australian/New Zealand Standard™

Optics and optical instruments—Lasers and laser-related equipment—Determination of laser resistance of tracheal tube shafts

First published as AS/NZS ISO 11990:2002.

Jointly published by Standards Australia International Ltd, GPO Box 5420, Sydney, NSW 2001 and Standards New Zealand, Private Bag 2439, Wellington 6020

ISBN 0 7337 4677 2

PREFACE

This Joint Australian/ New Zealand Standard has been developed to assist in the process of implementation of the Australian Medical Device legislation.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as a Joint Australian/New Zealand Standard, through the Joint Standards Australia/Standards New Zealand Committee HE-003 on Medical Electrical Equipment.

This Standard is identical with and has been reproduced from ISO 11990:1999, *Optics and optical instruments — Lasers and laser-related equipment — Determination of laser resistance of tracheal tube shafts.*

The objective of this Standard is to specify a method of testing the laser resistance of the shaft of a tracheal tube.

As this Standard is reproduced from an international Standard, the following applies:

(a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

(b) In the source text ‘this International Standard' should read ‘this Australian/New Zealand Standard’.

(c) A full point substitutes for a comma when referring to a decimal marker.

CONTENTS

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.

AUSTRALIAN/NEW ZEALAND STANDARD

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