

TECHNICAL  
REPORT

**ISO**  
**TR 11991**

First edition  
1995-07-15

---

---

**Guidance on airway management during  
laser surgery of upper airway**

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

*Guide pour assurer la ventilation au cours d'opérations par laser des voies  
respiratoires supérieures*

ISO/TR 11991:1995

<https://standards.iteh.ai/catalog/standards/sist/ae98d2e3-7975-417f-9ec4-79627e63d604/iso-tr-11991-1995>



Reference number  
ISO/TR 11991:1995(E)

## Contents

	Page
1 Scope .....	1
2 References .....	1
3 Terminology .....	2
4 Ideal properties of tracheal tubes for use with lasers.....	3
4.1 Materials.....	3
4.2 Design.....	3
4.3 Packaging and labelling.....	4
5 Description of current practices which reduce the risk of airway fire.....	4
5.1 Non-intubation techniques.....	4
5.2 Intubation techniques .....	5
5.3 Management of airway fires.....	10

## Tables

1 Combustion properties of conventional tracheal tube materials.....	11
2 Primary emergency management following recognition of airway fire ...	11
3 Secondary emergency management following recognition of an airway fire .....	12

## Annex

A Bibliography .....	13
----------------------	----

© ISO 1995

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Organization for Standardization  
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

## 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 main task of technical committees is to prepare International Standards, but in exceptional circumstances a technical committee may propose the publication of a Technical Report of one of the following types:

- type 1, when the required support cannot be obtained for the publication of an International Standard, despite repeated efforts;
- type 2, when the subject is still under technical development or where for any other reason there is the future but not immediate possibility of an agreement on an International Standard;
- type 3, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example).

Technical Reports of types 1 and 2 are subject to review within three years of publication, to decide whether they can be transformed into International Standards. Technical Reports of type 3 do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful.

ISO/TR 11991, which is a Technical Report of type 3, was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This document is being issued as a type 3 Technical Report to summarize current methods for airway management during laser surgery of the upper airway to minimize the risk of fire. (See the Introduction.)

## Introduction

This guide provides information for clinicians for appropriate selection of airway devices for operations on the upper airway, including the larynx, in which a laser is used. It also provides information for the appropriate selection of intubation and non-intubation techniques. Tracheal tubes are commonly used in patients during general anaesthesia for such operations. These tubes provide effective control of ventilation and oxygenation, protect the airway from aspiration (if cuffed), and allow monitoring of ventilation through capnography and spirometry. A laser is a source of intense light energy which can provide an ignition source, so that a fire is a risk in the operative field. Risk of fire is particularly enhanced in oxidant ( $O_2$  or  $N_2O$ ) enriched atmospheres. Tracheal tubes assist ventilation and patient monitoring but may be ignited by the laser in these circumstances.

In these procedures, the clinician must be aware of the risk of fire. Fire requires three elements: an ignition source, a combustible material, and an oxygen source. These three are sometimes referred to as "the fire triangle". During laser surgery on the upper airway, all three elements are often present. The laser is an intense light energy which can provide a source of ignition. Tracheal tubes when present are usually made of combustible material. Finally, most patients are treated in an oxidant-enriched atmosphere. Care to minimize these three elements is essential to avoid a fire during laser surgery of the upper airway.

Of the numerous methods available for airway management during laser operations on the upper airway, each has its own risks and advantages. This guide summarizes the current methods and the applications, advantages, and disadvantages of each. The guide serves to assist the anaesthetist and surgeon in their joint decision regarding selection of the most appropriate method to oxygenate and ventilate the patient during laser surgery involving the upper airway. This guide does not recommend any one method of airway management. The test data included in Table 1 of this guide are based upon continuous beam  $CO_2$  Lasers. While this data may not be directly applicable to other wavelengths or beam modes (such as super pulse), the basic principles still apply. Decisions regarding practice methods can only be made by the clinicians caring for the patient, having knowledge of the clinical circumstances, available expertise, and technology, e.g. the properties of the specific laser wavelength planned for the surgery.

Other complications of laser surgery not involving airway management may be found in ANSI Z136.1 (1), and ANSI Z136.3 (2), CAN/CSA Z386 M91 (3).

# Guidance on airway management during laser surgery of upper airway

## iTeh STANDARD PREVIEW (standards.iteh.ai)

### 1 Scope

At present there is no way to avoid completely the risk of an airway fire when a laser is used in the airway. This guide is intended to help minimize this risk by listing a) those characteristics of a tracheal tube that make it most suitable for laser airway operations, recognizing that it may not be possible in practice to produce a device combining such characteristics; b) several standard practices that reduce the risk of airway fire during laser operations on the airway; c) recommendations for emergency management should an airway fire occur.

This guide represents current knowledge at the time of publication and is subject to review. This guide does not address management of the patient with a tracheostomy. This guide is also intended to assist related groups, such as laser safety committees.

### 2 References

ISO 5361-1:1988, *Tracheal tubes — Part 1: General requirements.*

ISO 5361-2:1993, *Tracheal tubes — Part 2: Oro-tracheal and naso-tracheal tubes of Magill type (plain and cuffed).*

ISO 5361-5:1984, *Tracheal tubes — Part 5: Requirements and methods of test for cuffs and tubes.*

ISO 7228:1993, *Tracheal tube connectors.*

ISO 10993-1:—<sup>1)</sup>, *Biological evaluation of medical devices — Part 1: Evaluation and testing.*

---

1) To be published. (Revision of ISO 10993-1:1992)

### 3 Terminology

For the purpose of this technical report, the following definitions apply.

**3.1 anatomical airway** : Natural pathways through which respired gases pass in either direction between the atmosphere and the alveoli.

**3.2 combustion** : Rapid oxidation to produce heat and light.

**3.3  $F_I O_2$**  : The fractional concentration of oxygen in inspired gas.

**3.4 flammability** : The ability to sustain combustion.

**3.5 ignitability** : The ability to initiate combustion.

**3.6 intubation** : Placement of a tracheal tube into the trachea.

**3.7 laser platform** : A surgical handpiece made of a non-combustible material with a non-reflective surface. The end of the device is placed behind the target tissue as a backstop for the laser.

**3.8 laser plume** : Gaseous and particulate by-products of combustion and/or pyrolysis produced by the effect of laser energy upon a target.

**3.9 oxidant enriched atmosphere** : Any atmosphere that contains oxidants ( $O_2$ ,  $N_2O$ ) in total concentration greater than 25% of volume at ambient pressure.

**3.10 oxygen index of flammability** : The minimum concentration of  $O_2$  in  $N_2$  necessary to support a candle-like flame for a given substance.

**3.11 pledget (cottonoid)** : A compress, usually of gauze or absorbent cotton.

**3.12 power density (irradiance)** : The power delivered by a laser beam per unit area of irradiated surface (spot size), expressed as watts per square centimetre.

**3.13 pyrolysis** : Transformation of a compound into one or more other substances by heat alone (without oxidation).

**3.14 specular reflectance** : The characteristics of a material to reflect light in such a way that the angle of reflection is equal to the angle of incidence, such as the reflectance from a mirror.

**3.15 thermal conductivity** : Time rate of heat flow through unit area, per unit temperature gradient, in the direction perpendicular to the area.

**3.16 upper anatomical airway (the upper airway)** : The airway above the laryngotracheal junction.

## 4 Ideal properties of tracheal tubes for use with lasers

### 4.1 Materials

The materials used for the manufacture of the part of the tracheal tube intended to lie in the upper airway should have the following characteristics:

#### 4.1.1 Ignitability

Materials should be resistant to ignition by a laser beam in the presence of 100 % O<sub>2</sub>.

#### 4.1.2 Flammability

Materials should not maintain combustion in 100 % O<sub>2</sub>.

#### 4.1.3 Specular reflectance

Materials should have no specular reflectance so as to avoid injury to non-targeted tissue.

#### 4.1.4 Heat transfer

Materials should minimize heat transfer that may damage adjacent tissue.

#### 4.1.5 Products of pyrolysis and combustion

The products of pyrolysis and combustion should satisfy appropriate biological safety test as specified in ISO 10993-1.

### 4.2 Design

#### 4.2.1 General

Tubes should comply with the requirements specified in ISO 5361-1, ISO 5361-2, ISO 5361-5 and ISO 7228.

#### 4.2.2 Integrity

In the event of tube ignition, integrity of the tube and attached components should be maintained so that they can be immediately removed intact.

#### 4.2.3 Transparency

The material used for the manufacture of the tracheal tube should be sufficiently optically transparent or translucent to enable condensation of airway vapour and evidence of combustion to be seen within its lumen.

#### 4.2.4 Cuff inflation

The tracheal tube cuff should be capable of being inflated with liquid and rapidly deflated under normal conditions of use.

#### 4.2.5 The cuff and inflation system

The cuff and inflation system, if exposed, should be laser resistant.

### 4.3 Packaging and labelling

4.3.1 The tracheal tube and attached components should be preassembled and individually packaged.

4.3.2 The tube should be intended and labelled for single use.

## 5 Description of current practices which reduce the risk of airway fire

At present there is no way to completely avoid the risk of an airway fire when a laser is used in the airway. The following are descriptions of current practices that reduce the risk of airway fire. Accompanying each practice is a discussion of its advantages and disadvantages. No significance should be attributed to the order in which these practices are presented.

### 5.1 Non-intubation techniques

ISO/TR 11991:1995

<https://standards.iteh.ai/catalog/standards/sist/ae98d2e3-7975-417f-9ec4-79627e63d604/iso-tr-11991-1995>

These methods of ventilation do not use a tracheal tube.

#### 5.1.1 Spontaneous breathing techniques

With the patient breathing spontaneously, gas with or without supplemental oxygen and/or potent inhalation anaesthetic is insufflated into the operating laryngoscope, bronchoscope, a metal hook, or a catheter (4). The anaesthetic may be supplemented with intravenous agents and/or regional anaesthesia to the airway.

*Advantages* : There is no tracheal tube in the airway so that the risk of fire is reduced. The method also provides excellent visibility of the surgical field and avoids potential trauma to the airway that use of a tracheal tube might cause.

*Disadvantages* : Hypoventilation is a risk which may go undetected since capnography is difficult and inaccurate, and spirometry cannot be used. Pulmonary aspiration of gastric contents and/or laser plume can also occur. Ventilation cannot be assisted or controlled. Depth of anaesthesia may fluctuate so that patient movement can occur. Insufflation techniques make scavenging anaesthetic gases difficult. The risk of fire is increased if a flammable catheter is used as the insufflation device.



### 5.1.2 Apnoeic techniques

The patient is ventilated through a mask, tracheal tube, or bronchoscope, using oxygen-enriched gas, with or without potent inhalation anaesthetic. During ventilation, the laser is not used. Ventilation is then temporarily discontinued and the mask or tracheal tube is removed. During apnoea, laser resection is performed. After a period of time, laser resection is stopped and ventilation is resumed. Periods of ventilation alternate with laser resection/apnoea in this manner.

*Advantages* : There is no tracheal tube in the airway so that the risk of fire is reduced. The method also provides excellent visibility of the surgical field and avoids potential trauma to the airway that use of a tracheal tube might cause.

*Disadvantages* : Hypoventilation is a risk which may go undetected since capnography and spirometry are not applicable during apnoea. Pulmonary aspiration of gastric contents and/or laser plume may occur. There is a potential for airway trauma from repeated instrumentation.

### 5.1.3 Jet ventilation technique

A metal needle or similar device is mounted either in the operating laryngoscope or placed below the site of operation and attached to a jet injector. A high-velocity jet of O<sub>2</sub>, air/O<sub>2</sub>, N<sub>2</sub>O/O<sub>2</sub>, or He/O<sub>2</sub> mixture is directed into the airway lumen either above or below the glottis by the surgeon. The lungs are ventilated with jet gas and entrained room air (5).

*Advantages* : There is no tracheal tube in the airway so that the risk of fire is reduced. The method also provides excellent visibility of the surgical field and avoids potential trauma to the airway that use of a tracheal tube might cause.

*Disadvantages* : Hypoventilation can be a problem with this technique due to the following: obstructive airway lesions, decreased pulmonary compliance (e.g. bronchospasm, obesity, or chronic obstructive pulmonary disease), and/or inability of the surgeon to direct the jet optimally. Spirometry is not possible and capnography is difficult and inaccurate with this method so that hypoventilation may be undetected. The inspired O<sub>2</sub> concentration cannot be controlled or monitored. Pulmonary aspiration of gastric contents, surgical debris (which may include bacteria and/or malignant cells) and laser plume, as well as inadvertent laser burn to the trachea, are risks since no tracheal tube is present. Misdirection of the jet may cause soft tissue injury, gastric distention, or barotrauma including pneumothorax and pneumomediastinum. It is difficult to administer volatile anaesthetics with this technique.

## 5.2 Intubation techniques

With all intubation techniques, ventilation can be monitored and controlled, and both inhalation and intravenous anaesthetic agents can be administered.

### 5.2.1 Unprotected conventional tracheal tubes

Unprotected conventional tracheal tubes may be manufactured from polyvinyl chloride (PVC), red rubber, silicone, or polyurethane, all of which readily ignite and maintain combustion in the presence of oxidant-enriched atmospheres. In the event of a fire, the tube integrity will be compromised and allow components to be retained within the tracheobronchial tree. Unprotected conventional tracheal tubes can produce products of combustion which are toxic to tissue (6). The use of unprotected conventional tracheal tubes is inappropriate, and strongly discouraged.

### 5.2.2 Protected conventional tracheal tubes

Conventional tracheal tubes manufactured of PVC, red rubber, polyurethane, and silicone may be protected by the clinician, by wrapping with metallic tape, sponge material with metal film backing, or other materials to shield the flammable material from laser contact.

*Advantages* : Metallic wrapping may prevent the laser beam from igniting the tube yet still allow use of a conventional tracheal tube. A metallic-backed sponge material has been designed specifically for use with conventional tracheal tubes in airway laser operations. When wet, the sponge material absorbs laser energy. Textured metallic backings are intended to diffuse laser beam reflections.

*Disadvantages* : Metallic tapes may reflect the laser on to non-targeted tissues. The user must apply the tape smoothly and continuously so as to prevent rough edges which may abrade the mucosa, or gaps which expose the tube to the laser beam. Spiral wrapped coverings may cause the tube to kink. The metal-backed sponge preparation adds considerable thickness to the tube; the sponge must be kept wet to avoid thermal injury, fire, and tissue abrasion. If the tape or wrap is dislodged it may occlude the airway. Tubes cannot be wrapped at or below the cuff, and so this area remains exposed and vulnerable to laser energy with this technique. Metallic wrapping has no advantage when the site of operation is distal to the tube and/or the laser beam is delivered through the lumen of the tube. It is not possible to maintain sterility when tubes are prepared in this manner.

Not all metallic tapes can protect all types of tubes from all types of lasers at every power setting (7, 8, 9). The adhesive backing or surface coating of some tapes can be ignited by laser beams. Presently available metallic tapes have not been specifically designed for medical use. Therefore laser protection of tracheal tubes, other than that specified in certain products, is the responsibility of the user and not the manufacturer of the product.

### 5.2.3 Ready-to-use, laser-resistant tubes

These products are designed for use during laser surgery of the upper airway. Tubes with flammable components can ignite if manufacturers' warnings, precautions, and directions for use are not followed. An additional advantage of the tubes over tubes wrapped by the clinician is that the tube is pre-assembled and checked by the manufacturer.

#### 5.2.3.1 Aluminium corrugated tracheal tube with silicone covering and self-inflating foam sponge cuff

The tube is intended for use with carbon dioxide (CO<sub>2</sub>) lasers.

*Advantages* : Atraumatic external surface with a nonflammable inner surface. The cuff tends to maintain a seal despite penetration by the laser.

*Disadvantages* : Flammable external surface and cuff, requiring that saline be added to the cuff to decrease the risk of ignition. It may be difficult or impossible to deflate the cuff if the cuff or inflation tube is damaged.

#### 5.2.3.2 Airtight stainless steel corrugated spiral tracheal tube with PVC Murphy eye tip and double cuffs

A plain (uncuffed) version is available in the smaller diameters. This item is intended for use with CO<sub>2</sub> or potassium titanyl phosphate (KTP) lasers.

<https://standards.iteh.ai/catalog/standards/sist/ae98d2e3-7975-417f9ec4-79627e63d604/iso-tr-11991-1995>

*Advantages* : Metal components are essentially nonflammable. The tube maintains its shape well during intubation, and is kink resistant. A proximal fluid filled cuff serves as a shield for the distal tracheal tube.

*Disadvantages*: Although metal may reflect the laser onto non-targeted tissues and result in damage, the matt finish and convexity of the spiral reduces this potential. Metal tubes are thick-walled and may transfer heat to adjacent tissue and other material. The cuffed model contains materials that are flammable and therefore requires that saline be added to decrease the risk of ignition. The double cuff requires more time to inflate and deflate than a single cuff.

#### 5.2.3.3 Silicone tubes covered with aluminium-filled silicone layer

This product is no longer manufactured.

This tube is intended for use with the CO<sub>2</sub> laser.

*Disadvantages* : Can be ignited by lasers in the presence of room air and is difficult to extinguish once ignited.