INTERNATIONAL STANDARD

ISO 14408

First edition
1998-07-01

Tracheal tubes designed for laser surgery — Requirements for marking and accompanying information

Sondes trachéales destinées aux opérations au laser — Exigences relatives au marquage et aux informations d'accompagnement

Reference numbe
ISO 14408:1998(E)

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.

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.

International Standard ISO 14408 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment,* Subcommittee SC 2, *Tracheal tubes and other equipment.*

Annex A of this International Standard is for information only.

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet central@iso.ch
X.400 c=ch; a=400net; p=iso; o=isocs; s=central

Printed in Switzerland

Introduction

This International Standard is intended to provide a standard format for marking of tracheal tubes which are designed for laser surgery and which have been tested for laser resistance in accordance with ISO 11990. It is intended that by limiting the requirements to the disclosure of information relevant to safety and performance where appropriate, determined in accordance with standard test methods, a manufacturer will not be limited in his choice of design and materials.

Tracheal tubes designed for laser surgery — Requirements for marking and accompanying information

1 Scope

This International Standard specifies marking requirements and requirements for information to be supplied by the manufacturer of cuffed and uncuffed tracheal tubes and related materials designed for laser resistance.

2 Normative reference

The following standard contains provisions, which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of ISO and IEC maintain registers of currently valid European and International Standards.

ISO 11990: –[1)], *Optics and optical instruments — Lasers and laser-related equipment — Determination of laser resistance of tracheal tube shafts*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 tracheal tube
tube designed for insertion through the larynx into the trachea to convey gases and vapours to and from the trachea

[ISO 4135:1995]

3.2 cuff
inflatable balloon permanently attached around the tracheal tube near the patient end to provide an effective seal between the tube and the trachea

3.3 laser-resistant tracheal tube
tracheal tube specifically designated by the manufacturer for use during laser surgery

3.4 laser-resistant tracheal tube treatment
covering and/or surface treatment that adapts or modifies non-laser-resistant tracheal tubes for use in laser surgery

3.5 upper anatomical airway; upper airway
airway above the laryngotracheal junction

3.6 laser-resistant portion
that portion of the tracheal tube intended by the manufacturer to be laser-resistant

4 Marking and labelling

NOTE Marking of tracheal tubes, connectors, packages, inserts and information to be supplied by the manufacturer should comply with EN 1041.

---

1) To be published.

4.1 Use of symbols

The requirements given in 4.2, 4.3 and 4.4 may be met by the use of the appropriate symbols in accordance with ISO 7000 or EN 980.

4.2 Marking of tracheal tubes

4.2.1 The following shall be permanently marked on or affixed to any component of the tracheal tube:

a) the name and/or trademark of the manufacturer or supplier;

b) the nominal inside diameter designated by the manufacturer for the tracheal tube;

c) model identification, if necessary to distinguish between similar products from the same manufacturer;

d) for cuffed tracheal tubes, a reference to any preparation designated by the manufacturer as essential for protection of the cuff from ignition (e.g. "inflate cuff with saline or water before use").

4.2.2 Additional marks may be provided (optional) to assist in positioning the tracheal tube within the trachea. If the marks are applied to a laser-resistant area of the tube, the test to determine laser resistance values required for the graph in 5.4 shall be carried out directly upon these markings.

4.2.3 Any component of a laser-resistant tracheal tube treatment that is affixed to or protects the treatment covering or material until it is applied to the tracheal tube, shall be marked with a reference to any preparatory steps essential to the laser resistance of the tube (e.g. "saturate covering with saline solution").

4.2.4 If the laser-resistant portion is not obvious, this shall be marked.

4.3 Labelling of tracheal tube unit packs

The following information shall be labelled on the tracheal tube pack:

a) a description of contents, including wording to indicate that the tracheal tube is intended for use in laser surgery;

b) the name and/or trademark of the manufacturer or supplier;

c) the product code or catalogue number;

d) the largest outside diameter after preparations for use;

e) the nominal inside diameter designated by the manufacturer for the tracheal tube;

f) the batch number;

g) the word "STERILE" or "NON-STERILE", as appropriate;

h) for tracheal tubes not intended for re-use, the words "SINGLE USE" or equivalent;

i) any special storage instructions;

j) 'use by' date expressed as (YYY-MM).

4.4 Labelling of shelf or multi-unit containers

The following information shall be labelled on shelf or multi-unit containers:

a) the name and/or trademark of the manufacturer or supplier;

b) the product code or catalogue number;

c) the nominal outside diameter of the tube;

d) the nominal inside diameter designated by the manufacturer for the tube;

e) the descriptive name of the device (trademark, etc.);

f) the batch number;

g) the word "STERILE" if appropriate;

h) for tracheal tubes not intended for re-use, the words "SINGLE USE" or equivalent;

i) 'use by' date expressed as (YYY-MM);

j) quantity of unit packages in the container;

k) any special storage instructions.

5 Information to be supplied by the manufacturer

The following information shall be provided with each unit pack, e.g. as a package insert.

5.1 Instructions for preparation and use of the tracheal tube

5.1.1 For protective treatments that require setup and routine maintenance to achieve the stated laser resistance, explicit information shall be provided, including applicable precautionary statements.

5.1.2 Unless the tracheal tube is intended and marked as being for single use, instructions for cleaning and disinfection or sterilization.

5.2 Indications for use

Type of laser(s) and nominal wavelength considered by the manufacturer to be appropriate for use of the tube, and contraindications.

5.3 Warnings and precautions about the use of the tube

Descriptions of damage to tubes and effects on tubes that may result from contact with lasers and which could result in harm to the patient or operating room personnel.

These warnings shall include description of events (other than ignition) reported during testing for laser resistance in accordance with ISO 11990.

5.4 A graph giving laser resistance values and test results

For each type of laser considered by the manufacturer to be appropriate for use of the tube determined in accordance with ISO/DIS 11990.

The graph shall take the following form (see figure 1):

a) The title of the graph shall be "MAXIMUM POWER SETTINGS AT WHICH IGNITION DID NOT OCCUR WHEN TESTED USING A SPOT SIZE OF 0,5 mm".

b) Power shall be plotted versus duration onto linear axes.

   1) Power shall be plotted on the vertical axis from 0 to 100 W. Power levels greater than 100 W may be shown if warranted by test results.

   2) Duration shall be plotted on the horizontal axis from 0 to 10 s. The length of the horizontal axis at 10 s shall be (160 ± 10) % of the height of the vertical axis at 100 W.

c) Data shall be provided for durations of 1 s and 10 s. Additional data shall be included to limit the change from adjacent data points to no more than 20 % of the larger value or 2 W, whichever is greater. No data shall be included for durations less than 1 s or greater than 10 s.

d) Power/duration curves shall be shown using straight lines between data points. Laser types and nominal wavelengths shall be identified for each curve.

e) The following statements shall appear next to the graph, and they shall indicate that the statements apply to the data presented in the graph:

1) a statement that the applicability of the data is only to the laser resistant portion of the tracheal tube and that other components of the system, such as the inflation system and cuff are not tested;

2) a cautionary statement making clear that the clinical relevance of the tests has not been fully established.

3) a cautionary statement that laser resistance under surgical conditions may differ from the values given, due to the presence of water, blood or body fluids.

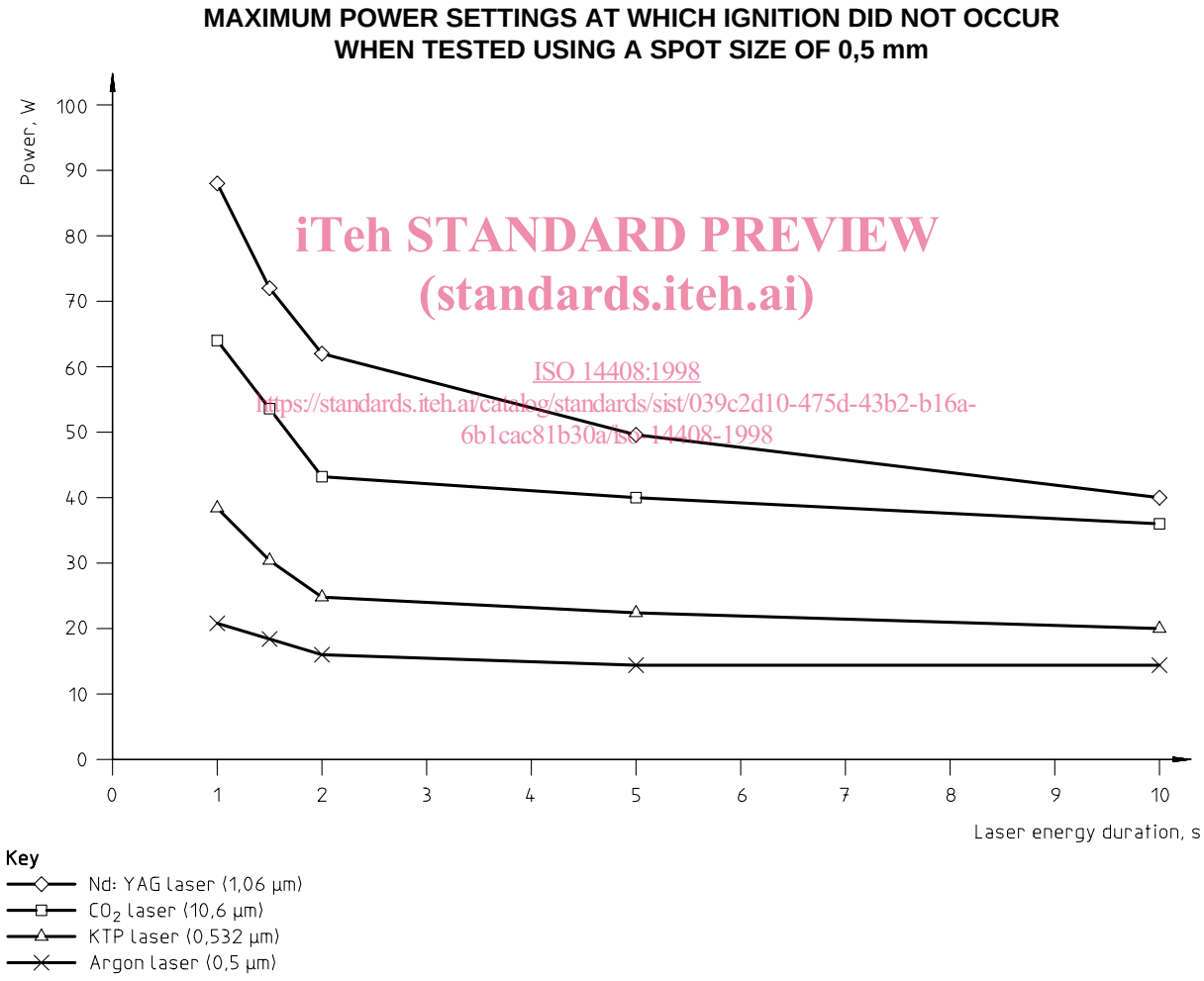

Figure 1 — Example of graphic presentation of laser results

Annex A
(informative)

Bibliography

[1] ISO 4135:1995, *Anaesthesiology — Vocabulary.*

[2] ISO 7000:1989, *Graphical symbols for use on equipment — Index and synopsis.*

[3] EN 980, *Terminology, symbols and information provided with medical devices — Graphical symbols for use in the labelling of medical devices.*

[4] EN 1041[2)], *Terminology, symbols and information provided with medical devices — Information supplied by the manufacturer with medical devices.*

2) To be published.