INTERNATIONAL STANDARD

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

Tubes trachéaux destinés aux opérations laser — Exigences relatives au marquage et aux informations d'accompagnement

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Foreword

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

This second edition cancels and replaces the first edition (ISO 14408:1998), Clauses 4 and 5 and Figure 1 of which have been technically revised.

For the purposes of this International Standard, the CEN annex regarding fulfilment of European Council Directives has been removed.

Introduction

This International Standard is intended to provide requirements for marking, labelling and information supplied for tracheal tubes which are designed for resistance to ignition by a laser and which have been tested for laser resistance in accordance with ISO 11990 including a standard format for reporting results obtained when tested in accordance with ISO 11990. It is intended that, by limiting the requirements to disclosure of information determined in accordance with standard test methods, the manufacturer will be allowed maximum use of alternatives in design and materials.

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

1 Scope

This International Standard specifies marking, labelling and information to be supplied by the manufacturer for cuffed and uncuffed tracheal tubes and related materials designed to resist ignition by a laser.

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 11990, *Optics and optical instruments — Lasers and laser-related equipment — Determination of laser resistance of tracheal tube shafts*

3 Terms and definitions

For the purposes of this document, the following terms and 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 4135:2001]

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

NOTE Adapted from ISO 4135:2001.

3.3
laser-resistant tracheal tube
tracheal tube specifically designed by the manufacturer for use during laser surgery of the airway

NOTE This includes devices sold preassembled or in kit form.

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 of the airway

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

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

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

4.2.2 The following shall be permanently marked on or affixed to the tracheal tube or tracheal tube treatment:

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

b) the nominal inside diameter in millimetres 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 the cuff with saline or water before use”).

4.2.3 Additional marks may be provided (optional) to assist in positioning the tracheal tube within the trachea.

4.2.4 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 designated by the manufacturer as essential to the laser resistance of the tube (e.g. “saturate covering with saline solution”).

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

4.2.6 If any marks are applied to the laser-resistant area of the tracheal tube, the test to determine laser-resistance values required for the graph in 5.4 shall be carried out directly upon these markings.

4.2.7 All markings shall be of sufficient size and contrast to be legible.

4.2.8 All markings shall be non-toxic and tissue-compatible. Marking materials should resist deterioration by anaesthetic agents. The markings should be durable and remain legible during use of the tube. If the tracheal tube is intended for reuse, the materials should resist deterioration by the recommended agents and procedures used to clean and disinfect or sterilize the device.

4.3 Labelling of packs

The following information shall be on the laser-resistant tracheal tube or laser-resistant tracheal tube treatment 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 internal diameter in millimetres designated by the manufacturer for the tracheal tube;

f) the means to ensure traceability such as type, batch or serial number or year of manufacturer;

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

h) for tracheal tubes not intended for reuse, the words “SINGLE USE” or equivalent;

i) for cuffed tracheal tubes, the cuff resting diameter, expressed in millimetres;

j) any storage instructions, including a statement of known conditions of storage likely to result in rapid deterioration of the materials (e.g. high temperature, ultraviolet light or fluorescent lighting);

k) the “use by” date expressed as (YYYY-MM);

l) an instruction to refer to information describing laser resistance, including type(s) and nominal wavelength(s), considered by the manufacturer as appropriate for use and contraindications.

4.4 Labelling of shelf or multi-unit containers

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

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

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

c) the product code or catalogue number;

d) the nominal outside diameter of the tube;

e) the nominal inside diameter of the tube;

f) the batch number;

g) the word(s) “STERILE” or “NON-STERILE”, as appropriate;

h) for tracheal tubes not intended for reuse, the words “SINGLE USE” or equivalent;

i) the “use by” date expressed as (YYYY-MM);

j) the quantity of unit packages in the container;

k) any storage instructions, including a statement of known conditions of storage likely to result in rapid deterioration of the materials (e.g. ultraviolet light or fluorescent lighting);

l) an instruction to refer to information describing laser resistance, including type(s) and nominal wavelength(s) considered by the manufacturer as appropriate for use and contraindications.

5 Information to be supplied by the manufacturer

5.1 Instructions for preparation and use of laser-resistant tracheal tube and tracheal tube treatments

5.1.1 For laser-resistant tracheal tube treatments that require set-up and maintenance steps 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, recommended methods of cleaning and disinfection or sterilization shall be provided.

5.2 Indications for use

Information on type(s) of laser and nominal wavelength(s) considered by the manufacturer to be appropriate for use with the laser-resistant tracheal tube and information on contraindications shall be provided.

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 healthcare personnel shall be provided.

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

5.4 Graph showing test results for laser resistance

5.4.1 For each type of laser considered by the manufacturer to be appropriate for use with the tracheal tube as determined in accordance with ISO 11990, a graphic presentation of the results shall be given.

5.4.2 The graph shall take the form shown in Figure 1 and shall comply with 5.4.2.1 to 5.4.2.6.

5.4.2.1 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”.

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

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

5.4.2.4 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.

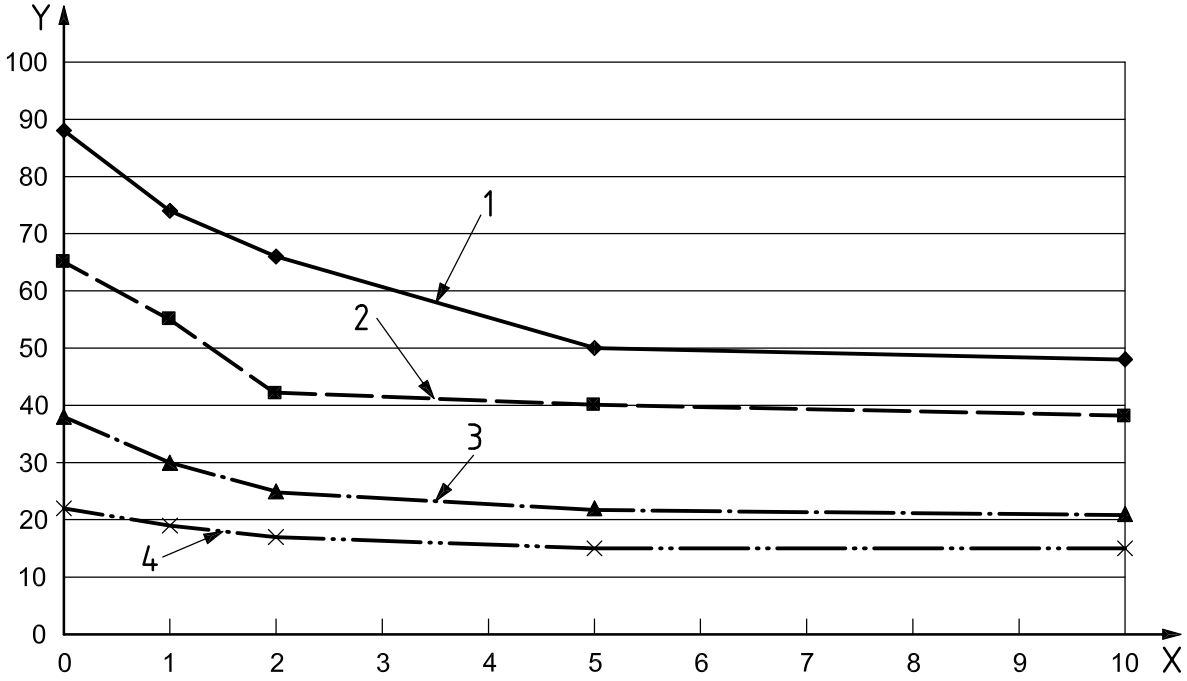
5.4.2.5 Power/duration curves shall be shown using straight lines between data points. Laser types and nominal wavelengths shall be identified for each curve.

5.4.2.6 The following statements shall appear in proximity to the graph, and they shall indicate that the statements apply to the data presented in the graph:

a) a statement that the data obtained apply only to the laser resistant portion of the tracheal tube shaft and that other components of the system, such as the inflation system and cuff, have not been tested;

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

c) 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.



Key

X laser energy duration, s

Y power, W

1 Nd:YAG laser (1,06 µm)

2 CO_2 laser (10,6 µm)

3 KTP laser (0,532 µm)

4 argon laser (0,5 µm)

Figure 1 — Example of graphic presentation of maximum power settings at which ignition did not occur when tested using a spot size of 0,5 mm