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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

Reference number
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Foreword

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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).

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The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related Equipment*.

This third edition cancels and replaces the second edition (ISO 14408:2005), which has been technically revised.

Major changes include an update on the normative references to ISO 11990-1, *Lasers and laser-related equipment — Determination of laser resistance of tracheal tubes — Part 1 Tracheal tube shaft* and ISO 11990-2, *Lasers and laser-related equipment — Determination of laser resistance of tracheal tubes — Part 2: Tracheal tube cuffs*.

The attention of Member Bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended, or revised ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

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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 11990-1 and ISO 11990-2 including a standard format for reporting results obtained when tested in accordance with ISO 11990-1 and ISO 11990-2. 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.

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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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7000[1)], *Graphical symbols for use on equipment — Registered symbols*

ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 11990-1, *Lasers and laser-related equipment — Determination of laser resistance of tracheal tubes — Part 1: Tracheal tube shaft*

ISO 11990-2, *Lasers and laser-related equipment — Determination of laser resistance of tracheal tubes — Part 2: Tracheal tube cuffs*

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

[SOURCE: 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

[SOURCE: ISO 4135:2001, modified]

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

Note 1 to entry: This includes devices sold preassembled or in kit form.

1) The graphical symbols in ISO 7000 are also available on line in the ISO web store. For more information, consult http://www.iso.org/iso/publications_and_e-products/databases.htm?= .

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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
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 ISO 15223-1.

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 shall resist deterioration by anaesthetic agents. The markings shall be durable and remain legible during use of the tube. If the

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tracheal tube is intended for reuse, the materials shall 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 manufacture or symbols 5.1.5 from ISO 15223-1:2012/ISO 7000-2492, 5.1.6 from ISO 15223-1:2012/ISO 7000-2493 or 5.1.7 from ISO 15223-1:2012/ISO 2498 or 5.1.3 from ISO 15223-1:2012/ISO 7000-2497;

g) the word “STERILE” or “NON-STERILE”, as appropriate or symbols 5.2.1 from ISO 15223-1:2012/ISO 7000-2499 (or as appropriate for sterilization method) or 5.2.7 from ISO 15223-1/ISO 7000-2609;

h) for tracheal tubes not intended for reuse, the words “SINGLE USE” or equivalent or symbol 5.4.2 from ISO 15223-1/ISO 7000;

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) or appropriate symbols in ISO 15223-1:2012, 5.3; or appropriate symbols in ISO 15223-1:2012, 5.3 or appropriate symbols in ISO 15223-1:2012, 5.3 symbol 5.1.4 from ISO 15223-1:2012/ISO 7000-2607;

k) 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.

l) an indication of the presence of natural rubber (latex), if present in the device with the word “LATEX”, or symbol 5.4.5 from ISO 15223-1:2012/ISO 7000-2725

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 and address of

   — the manufacturer or supplier, and

   — where the manufacturer does not have an address within the locale, an authorized representative within the locale

   to which the responsible organization can refer;

c) the product code or catalogue number;

d) the nominal outside diameter of the tube;

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e) the nominal inside diameter of the tube;

f) the batch number or symbol 5.1.5 from ISO 15223-1/ISO 7000;

g) the word(s) “STERILE” or “NON-STERILE”, as appropriate or symbols 5.2.1 from ISO 15223-1:2012/ISO 7000-2499 (or as appropriate for sterilization method) or 5.2.7 from ISO 15223-1/ISO 7000-2609;

h) for tracheal tubes not intended for reuse, the words “SINGLE USE” or equivalent or symbol 5.4.2 from ISO 15223-1/ISO 7000;

i) the “use by” date expressed as (YYYY-MM) or symbol 5.1.4 from ISO 15223-1:2012/ISO 7000-2607;

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); or

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.

5.1.3 The manufacturer shall indicate the presence of natural rubber (latex), if present in the device.

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 11990-1.

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 11990-1, a graphic presentation of the results shall be given. For cuffed tubes where a manufacturer believes that the laser resistance of the cuff to clinically relevant laser setting and wishing to convey this information to the user then the cuff shall be tested in accordance with ISO 11990-2 and a separate graphic presentation of the results shall be given. For cuffed tubes where the manufacturer does not believe that the laser resistance of the cuff to clinically relevant laser

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setting can be graphically shown, then as per 5.3 a description of damage to the cuff and effects on the cuff that may result from contact with lasers and which could result in harm to the patient or healthcare personnel shall be provided.

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 showing test results of the shaft shall be "Maximum power settings at which ignition of the shaft did not occur when tested using a spot size of 0,5 mm". The title of the graph showing test results of the cuff, if provided by the manufacturer, shall be "Maximum power settings at which damage to the cuff 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 tracheal tube shaft test results graph and if applicable the cuff test results 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 have not been tested;

b) a statement that the data obtained applies only to the cuff of the tracheal tube;

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

d) 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.

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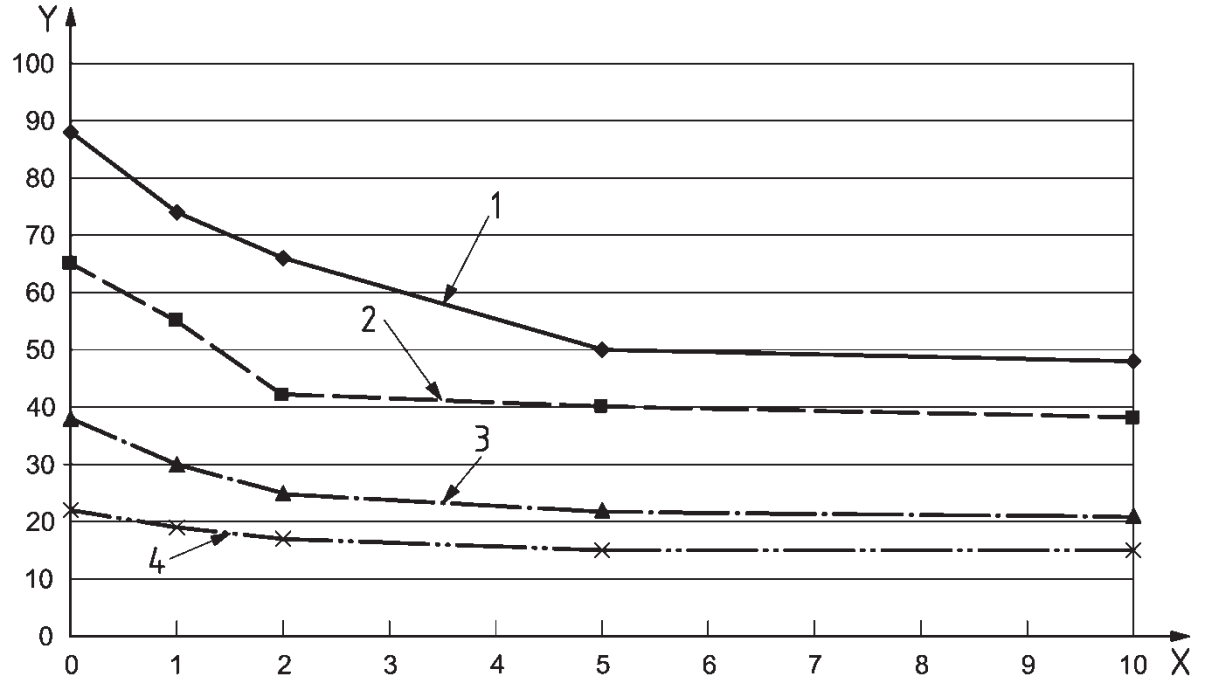

Key

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

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Bibliography

[1] ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

[2] ISO 5361, *Tracheal tubes*

[3] EN 1041, *Information supplied by the manufacturer with medical devices*

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