SLOVENSKI STANDARD
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Laringoskopi za trahealno intubacijo - Posebne zahteve

Laryngoscopes for tracheal intubation - Particular requirements

Laryngoskope für Trachealintubation - Besondere Anforderungen

Laryngoscopes pour intubation trachéale - Prescriptions particulieres

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English version

Laryngoscopes for tracheal intubation - Particular requirements

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Laryngoskope für Trachealintubation - Besondere Anforderungen

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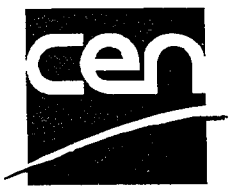

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COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 1998, and conflicting national standards shall be withdrawn at the latest by June 1998.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

This European Standard is based on ISO 7376-1:1994 "Laryngoscopic fittings - Part 1: Conventional hook-on type handle-blade fittings", ISO 7376-2:1984 "Laryngoscopic fittings - Part 2: Miniature electric lamps - screw threads and sockets" and ISO 7376-3:1996 "Laryngoscopic fittings - Part 3: Fibre-illuminated re-usable rigid laryngoscopes, prepared by TC 121 of the International Organization for Standardization (ISO). However, the requirements for different systems given in ISO 7376-3 are not included.

Annexes A and B are normative and form part of this European Standard. Annexes C, D, E and ZA are for information only.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard gives requirements for laryngoscopes for tracheal intubation, hereinafter referred to as laryngoscopes, during anaesthesia, intensive care, emergency care and similar procedures.

Laryngoscopes are manufactured in several forms, including single-piece handle and blade construction, and detachable blade and handle. In the latter case the light source to illuminate the larynx during use is either a lamp attached to the blade or a lamp in the handle with a light guide in the blade.

The form and dimensions of blades for laryngoscopes are selected by the user on the basis of clinical judgement and are not covered by this standard. A conventional system of indicating the size and form of blades is given in annex B.

Annex C gives rationales for some of the clauses of this standard, which are identified in the text by the inclusion of 'R' after the clause number.

1 R Scope

This standard specifies general requirements for laryngoscopes and critical dimensions for the handle and lamp of hook-on type laryngoscopes.

This standard does not apply to :

a) the blade form or handle design except for general requirements and the interchangeability aspects of the connection between the blade and the handle;

b) the measurement and specification of the lamp illumination intensity;

c) flexible laryngoscopes, or laryngoscopes designed for surgery;

d) laryngoscopes powered from mains electricity supply;

e) laryngoscopes connected by light-transmitting cables to external light sources;

f) custom-made devices.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 556 : 1994	Sterilization of medical devices - Requirements for medical devices to be labelled "STERILE"
EN 868-1	Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods
EN 980	Graphical symbols for use in the labelling of medical devices
EN 30993-1	Biological evaluation of medical devices - Part 1: Guidance on selection of tests (ISO 10993-1:1992 + Technical Corrigendum1:1992)
ISO 5864	ISO inch screw threads - Allowances and tolerances
ISO 7376-3	Laryngoscopic fittings - Part 3: Fibre-illuminated re-usable rigid laryngoscopes

3 Definitions

For the purposes of this standard the following definitions apply.

3.1 blade: Part of laryngoscope that is inserted into the mouth of a patient and is intended to permit direct vision of the larynx.

3.2 detachable blade: Blade that can be separated from a handle by the user.

3.3 hook-on fittings: Fittings that connect a detachable blade to its appropriate handle and that incorporate electrical contacts or optical fibre connection points.

NOTE : The fitting on the blade is a hook and that on the handle is a pin that acts as a hinge.

3.4 conventional blade: Detachable blade incorporating a lamp positioned to provide direct illumination of the larynx during use and having electrical connections in the hook-on fittings to the handle (see figure 1).

NOTE : The lamp can either be mounted near the tip of the blade or be installed near the handle end of the blade and provided with a light guide to transmit light to illuminate the area of the larynx.

3.5 fibre-illuminated blade: Rigid component shaped to provide a direct view of the larynx, and which incorporates optical fibres to transmit light from a source in the handle
[EN ISO 4135 : 1996]

3.6 single-piece laryngoscope: Laryngoscope constructed with the blade and handle made in one piece.

3.7 engagement: Mechanical attachment of the blade and handle such that the blade remains coupled to the handle in all positions.

3.8 operating position: Position of the engaged blade and handle when the laryngoscope is ready for use.

3.9 locking mechanism: Mechanism that retains the blade in the operating position.

3.10 lamp: Electric filament bulb intended to provide illumination during laryngoscopy [EN ISO 4135 : 1996].

3.11 lamp shell: Metallic outer housing of the lamp which provides electrical contact and mechanical engagement of the lamp by means of a male screw thread.

3.12 socket: Component with a female screw thread attached to a laryngoscope blade and intended to provide electrical contact and mechanical engagement with a lamp [EN ISO 4135 : 1996].

3.13 handle: Component held in the hand during use, one end forming the connection for the blade [EN ISO 4135 : 1996]

4 General requirements

4.1 Design

Except for single-piece laryngoscopes, the lamp shall light when the blade and handle are placed in the operating position (see figure 3). Single-piece laryngoscopes shall have a switch to control power to the lamp which latches in both on and off positions and is marked accordingly.

4.2 Materials for laryngoscope blades and single-piece laryngoscopes

Materials shall be non-toxic and compatible under transient use with skin, mucosa in the pharyngeal area and related body fluids, in accordance with EN 30993-1.

4.3 Environmental requirements

Laryngoscopes and their components shall be capable of meeting the requirements of clauses 5, 6, 10 and 11 after being exposed for 14 days in their storage and/or transport packaging in environmental conditions not outside the following ranges:

a) ambient temperature range of -40 °C to +70 °C;

b) relative humidity range of 10 % to 95 % non-condensing;

c) atmospheric pressure range of 50 kPa to 106 kPa.

Batteries are to be removed from handles during this exposure.

4.4 R Internal electrical power source

If the handle is intended for use with re-chargeable cells, a current limiting device shall be incorporated to prevent more than 3× normal current flowing in a single fault condition.

NOTE: Power outputs from some re-chargeable cells can fall rapidly as the remaining capacity decreases. This can result in a very rapid failure of illumination during use. The use of re-chargeable cells is therefore not recommended.

5 Performance requirements

5.1 Hook-on blade and handle fittings

Detachable hook-on blade and handle combinations that engage shall lock and illuminate when in the operating position, and shall stay illuminated in any orientation.

5.2 Handle fittings

5.2.1 *Handle dimensions*

The hook-on fitting forming part of the handle for use with a conventional blade shall conform to the dimensions of figure 4. The measurements shall be taken from the datum plane L, datum plane M and the hinge pin centre-line.

5.2.2 *Electrical contact - conventional system*

Electrical contacts forming parts of the hook-on fittings of the handle and a conventional blade shall ensure that the lamp lights when the blade is placed in the operating position. Test by inspection.

The electrical contact forming part of the hook-on fitting of a conventional blade of a laryngoscope shall be rigid and the electrical contact forming part of the hook-on fitting of the handle shall be either flexible or spring-loaded.

NOTE: The return electrical circuit is through unspecified parts of the hook-on joint.

5.2.3 *Electrical contact - fibre-illuminated system*

Electrical contacts forming part of the electrical circuit in the handle of a fibre-illuminated system shall ensure that the lamp lights when the blade is placed in the operating position. Test by inspection.

5.3 Blade fittings

5.3.1 A conventional blade shall not engage with a handle made in accordance with the green fibre-illuminated system as specified in ISO 7376-3.

5.3.2 A blade that engages a handle made in accordance with the green fibre-illuminated system as specified in ISO 7376-3 shall not engage with a handle of a conventional system.

5.3.3 Conventional blade hook-on fittings shall engage with any conventional handle hook-on fittings as specified in **5.2.1** and **5.2.2**, and figure 4. When engaged, clearance between handle slot and blade shall not exceed 0,28 mm.

NOTE: Typical blade hook-on fittings are shown in figure 1.

5.4 Engagement

The force required to engage a blade on to any handle hinge pin dimensioned in figure 4 shall be between 10 N and 45 N (see figure 2). The engaged blade shall be free to rotate about the pin under gravity.

5.5 Operating position

5.5.1 *Locking*

A torque between 0,35 N·m and 1, 35 N·m applied to the blade in engagement with any handle made using any combination of dimensions within the tolerances given in figure 4, shall lock the joint into the operating position (see figure 3).

5.5.2 *Unlocking*

A torque between 0,25 N·m and 1,35 N·m applied to the blade in the operating position in any handle made using any combination of dimensions within the tolerances given in figure 4, shall unlock the joint into engagement (see figure 3).

5.6 Disengagement

When the blade is engaged with any handle hinge pin dimensioned in figure 4, a disengagement force between 10 N and 45 N shall disengage the hook-on fitting of the blade from the pin.

6 Lamps for conventional blades

6.1 Lamp shell and base contacts

6.1.1 Lamps for use on conventional blades shall have a single central contact with electrical return through the lamp shell. The dimensions of the contact shall comply with figure 5 and table 1.

6.1.2 The exterior of the lamp shell shall be designed to facilitate insertion and removal of the lamp from the socket.

6.1.3 The central contact shall withstand the application of an axial force of 1 N when tested in accordance with annex A.1, without becoming displaced by more than 0,2 mm.

6.1.4 A seal shall be provided as part of the lamp that prevents the ingress of substances into the lamp socket and resists unscrewing of the lamp (see figure 5 and table 1).

6.1.5 Components of contacts shall be made of corrosion-resistant materials to ensure durability and continuity in the circuit between the socket and the lamp.

6.2 Screw thread for lamp

6.2.1 The screw thread of the lamp shell for small lamps shall have the nominal size and designation of $^1/_8$-72 UN-3A, in accordance with table 1, and shall be designed in accordance with ISO 5864.

6.2.2 The screw thread of the lamp shell for large lamps shall have the nominal size and designation of N°8-32 UNC-2A in accordance with table 1, and shall be designed in accordance with ISO 5864.

6.3 R Lamp and blade temperature

Lamp and blade parts that may in normal use have any contact with the patient shall not attain a temperature more than 50 °C when tested in accordance with annex A.2.

The duty cycle for testing purposes shall be (2 ± 0,1) min "on" and (10 ± 0,5) min "off" (see annex A.2).