BRITISH STANDARD

BS EN ISO
7376:2009

Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation (ISO 7376:2003)

ICS 11.040.10; 11.040.55

BSI
British Standards

National foreword

This British Standard is the UK implementation of EN ISO 7376:2009. It is identical to ISO 7376:2003. It supersedes BS EN ISO 7376:2003 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121/5, Lung ventilators, tracheal tubes and related equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Anästhesie- und Beatmungsgeräte - Laryngoskope für Trachealintubation (ISO 7376:2003)

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Foreword

The text of ISO 7376:2003 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 7376:2009 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of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 7376:2003.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

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

Endorsement notice

The text of ISO 7376:2003 has been approved by CEN as a EN ISO 7376:2009 without any modification.

Annex ZA
(Informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 ± Correspondence between this European Standard and EU Directives

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.1	1 (first paragraph), 2, 12.9	
4.2.1	1 (first paragraph), 2, 7.1, 7.3	
4.2.2	1 (first paragraph), 2, 9.2	As per CEN
4.2.3	1 (first paragraph), 2, 7.1, 7.3, 9.2	
4.2.4	1 (first paragraph), 2	
4.3	4, 5, 7.1, 7.2, 8.6, 9.2,	
4.3.a	4, 5, 7.2	
4.3.b	4, 5, 7.2	
4.3.c	4, 5, 7.2	
4.4	2, 12.7.4, 12.8.2	
5.1	1 (first paragraph), 2, 3, 9.2	
5.2.1.1	3, 9.2	
5.2.1.2	3, 9.2	
5.2.2.1	3, 12.7.4	
5.2.2.2	3, 12.7.4	
5.2.2.3	3, 12.7.4	
5.2.2.4	3, 12.7.4	
5.2.3	3, 12.7.4	
5.3.1	2, 3	
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5.3.3	2, 3	
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5.5.2	3, 12.7.1	

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6.1.5	3, 12.7.4	
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6.2.2	2	
7.1	2	
7.2	2, 3, 12.7.4	
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8.1.2	2, 3, 12.7.1	
8.1.3	3, 12.7.4	
8.1.4	7.1	
8.2.1	2, 12.7.1	
8.2.2	2, 12.7.1	
9.1	1 (first paragraph), 8.1, 13.6(h)	
9.2	2, 8.1, 13.6(h)	
10.1	13.1, 13.3(a), 13.6(a)	
10.2	13.1, 13.3(a)	
-	1 (first paragraph and 2nd paragraph, 1st dash)	This relevant Essential Requirement is not addressed in this European Standard
-	1 (first paragraph and 2nd paragraph, 2nd dash)	This relevant Essential Requirement is not addressed in this European Standard
-	6a)	This relevant Essential Requirement is not addressed in this European Standard
-	7.1 (3rd dash)	This part of this Essential Requirement is not addressed in this European Standard
10.2	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
10.3 a	13.1, 13.3(b)	
10.3 b	13.1, 13.3(b)	
10.3 c	2, 3	
10.3 d	2, 3, 12.9, 13.3(b)	
10.3 e	2, 13.2	

10.4	2, 13.5	
10.5	2, 13.2	
10.6 a	13.3(d), 13.5	
10.6 b	3, 8.3, 8.4, 8.7, 13.3 (c)	
10.6 c	8.3, 8.7, 13.1, 13.3(f)	
10.6 c)	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard
-	13.6 (h)(3rd paragraph)	This relevant Essential Requirement is not addressed in this European Standard
-	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard
11	2, 13.1, 13.2, 13.3(i, j, k), 13.6(b)	
11 a)	13.6(d)	
11 b)	3, 8.1, 13.3(m), 13.6(h, i)	
11 c)	2, 6, 13.6(h)	
11 d)	13.6(g, i)	
11 e)	12.2, 12.6(d)	
11 f)	3, 12.2, 12.3	
11 g)	7.5	
11 h)	2, 13.3(j, k), 13.4, 13.6(h)	
11 i)	4, 9.2, 13.6(f)	
11 j)	4, 5, 13.3(c, f), 13.6(d, h)	
11 k)	4, 13.6(d)	
11 l)	2, 6, 12.7.5	
A	1 (first paragraph),2,7.1, 12.7.1	
B	13.1	
C		
Annex ZB		Bibliography

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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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.

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 7376 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This first edition of ISO 7376 cancels and replaces ISO 7376-1:1994, ISO 7376-2:1997 and ISO 7376-3:1996, which have been technically revised.

Introduction

This International 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 a blade or a lamp in the handle with a light guide in the blade.

The forms and dimensions of blades for laryngoscopes are selected by the operator on the basis of clinical judgement and are not covered by this International Standard. Annex A describes a test method for security of lamp contact. A conventional marking system for indicating the size and form of blades is given in Annex B. Annex C of this International Standard gives rationales for some of the clauses which are identified by the inclusion of an asterisk (*) after the clause number.

INTERNATIONAL STANDARD ISO 7376:2003(E)

Anaesthetic and respiratory equipment – Laryngoscopes for tracheal intubation

1 Scope

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

It is applicable only to instruments with an electrical power source for illuminating the larynx, since electrical safety requirements may be more stringent for instruments connected to mains or external power packs.

This International Standard is not applicable to surgical instruments known by the same generic name.

This International 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.

NOTE Instruments connected by light guides to an external light source may be subject to other International Standards for endoscopes.

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 5864, *ISO inch screw threads ± Allowances and tolerances*

ISO 10993-1:2003, *Biological evaluation of medical devices ± Part 1: Evaluation and testing*

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
blade
rigid laryngoscope component shaped to provide a view of the larynx

3.2
detachable blade
blade that can be separated from a handle by the operator

3.3
hook-on fitting
fitting that connects a detachable blade to its appropriate handle and that incorporates an electrical contact or optical fibre connection point

3.4
conventional blade
detachable blade incorporating a lamp, positioned to provide direct illumination of the larynx during use, and having an electrical connection to the handle in the hook-on fitting

See Figure 1.

3.5
fibre-illuminated blade
blade incorporating optical fibres to transmit light from a source to illuminate the larynx

[ISO 4135:2001]

3.6
single-piece laryngoscope
laryngoscope constructed with a handle and non-detachable blade

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
electrical filament bulb intended to provide illumination during laryngoscopy

3.11
lamp base
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

3.13
handle
component held in the hand during use, one end forming the connection for the blade

3.14
contact
metallic part of the hook-on fitting which meets to make an electrical circuit between the handle and the lamp

4 General requirements

4.1 Design

Except for a single-piece laryngoscope, the lamp shall light when the blade and handle are placed in the operating position. A single-piece laryngoscope shall have a switch which latches in both the on and off positions to control power to the lamp, and is marked accordingly.

4.2 Materials for laryngoscope blades and single-piece laryngoscopes

4.2.1 Materials shall satisfy appropriate biological safety testing, as specified in ISO 10993-1.

4.2.2 Laryngoscope blades and handles shall be free of sharp edges, burs and other features which can cause trauma to the patient.

4.2.3 Materials shall be resistant to transient exposure to oxygen and to the gases and vapours used in anaesthetic procedures.

4.2.4 Materials shall be of a finish to minimize glare and reflections from the blade surface.

4.3 Environmental requirements

Laryngoscope systems without batteries shall be capable of meeting the requirements of Clauses 5, 6, 7, 8,10 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.

4.4 * Internal electrical power source

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

5 Performance requirements

5.1 Blade and handle hook-on fittings

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

5.2 Handle fittings

5.2.1 Handle dimensions

5.2.1.1 The hook-on fitting forming part of the handle for use with a conventional blade shall conform to the dimensions of Figure 1.

5.2.1.2 The hook-on fitting forming part of the handle for use with a fibre-illuminated blade shall conform to the dimensions of Figure 2.

Dimensions in millimetres

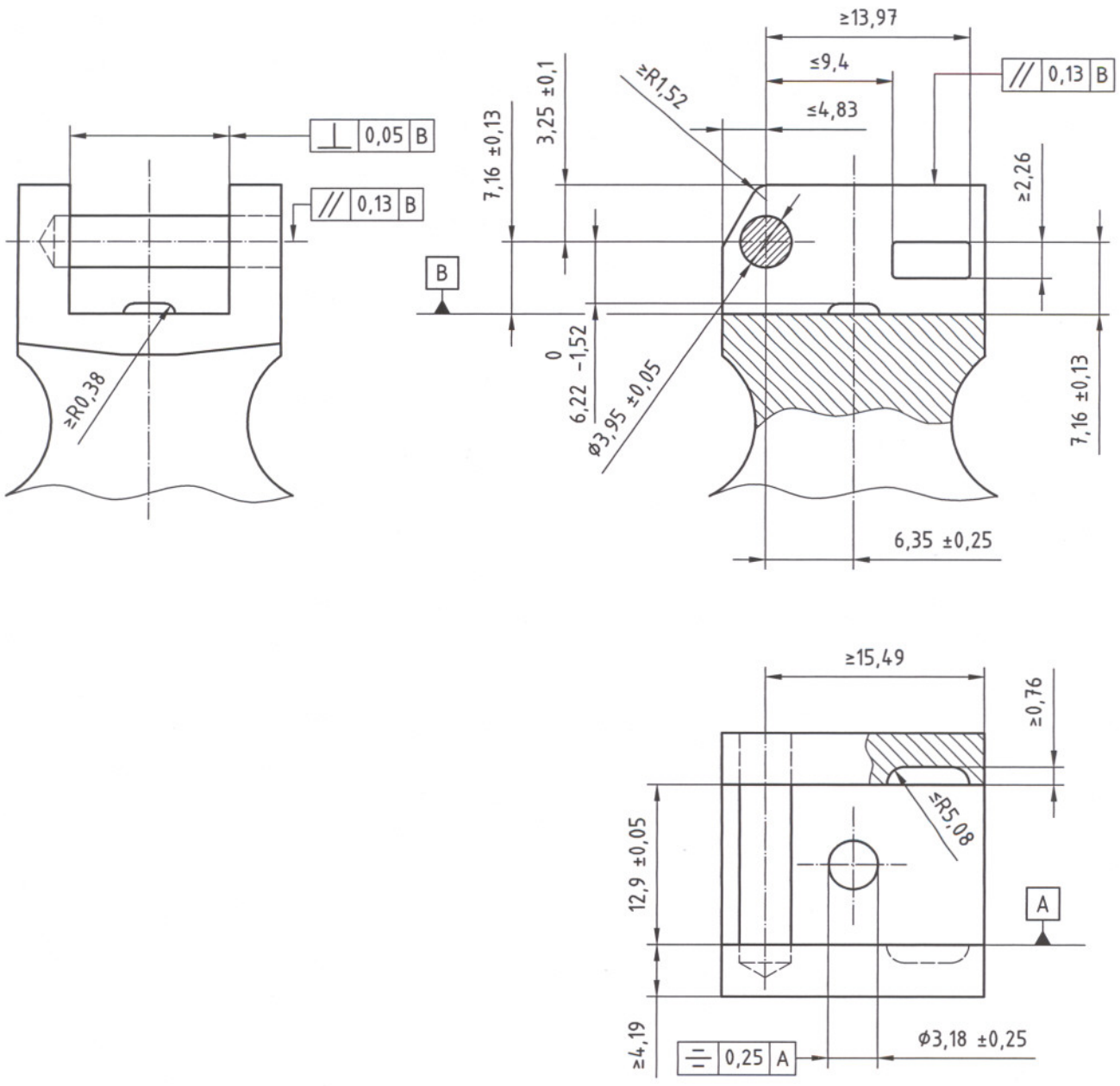
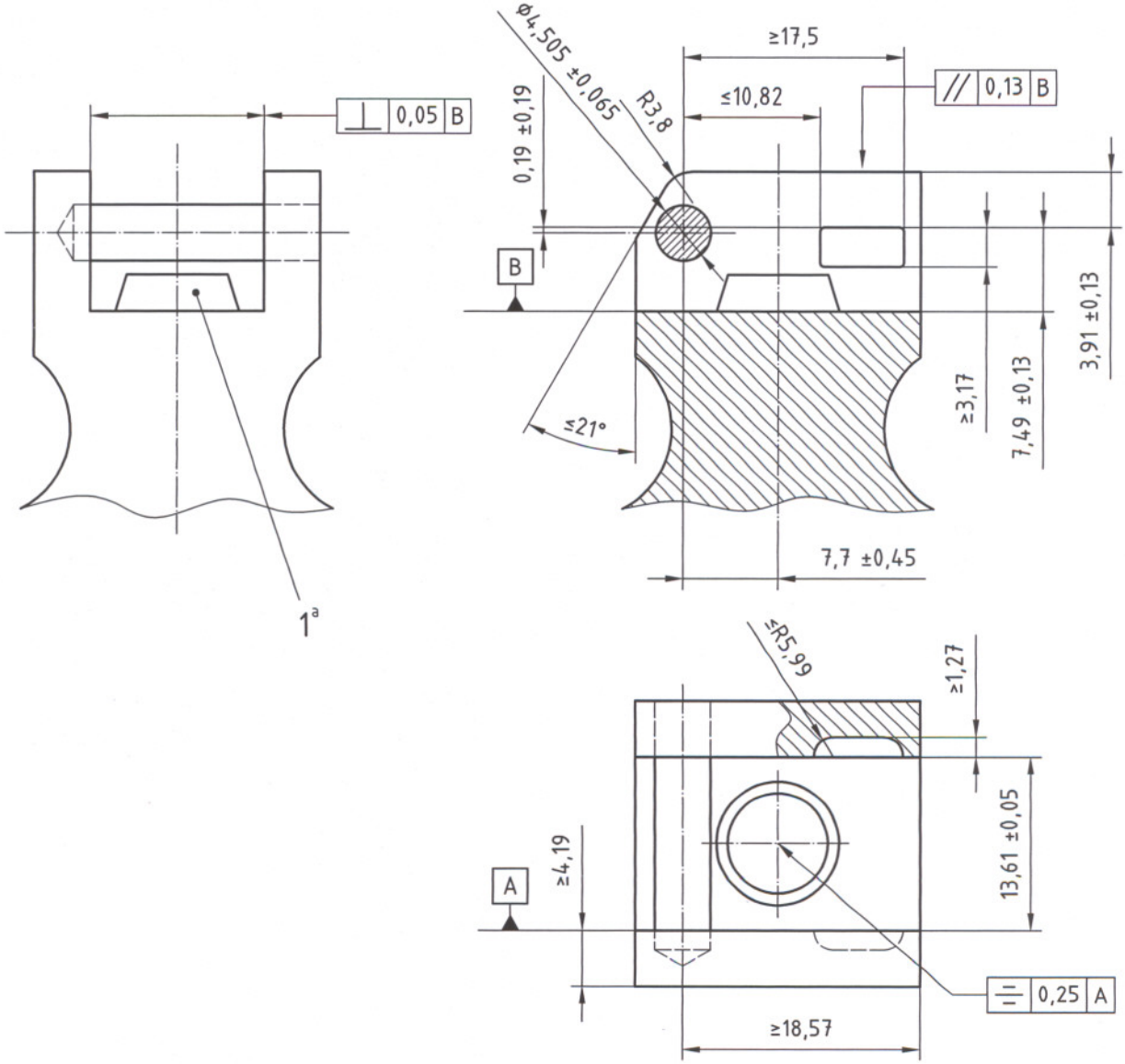


Figure 1 – Handle hook-on fitting of conventional system

Dimensions in millimetres



Key

1 spring-loaded switch

NOTE Drawing not to scale.

a Off-position height 3,5 mm to 2,2 mm; on-position height 2,2 mm to 0,5 mm; bottomed at ⩽ 0,5 mm.

Figure 2 – Handle hook-on configuration of fibre-illuminated system

5.2.2 Electrical contact ± Conventional system

5.2.2.1 The electrical contact which forms part of the hook-on fitting of the handle for use with a conventional blade shall ensure that the lamp lights when the blade is placed in the operating position. Test by inspection.

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

5.2.2.3 Electrical continuity of the contact for the small lamp is ensured when the sealing washer is compressed by (35 ± 10) % during installation.

5.2.2.4 Electrical continuity of the contact for the large lamp is ensured when either the sealing washer is compressed by (15 ± 5) % or the O-seal is compressed by (65 ± 5) % during installation.

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

5.2.3 Electrical contact ± Fibre-illuminated system

Electrical contacts which form 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 a fibre-illuminated system, as specified in 5.2.1.2.

5.3.2 A blade that engages a handle made in accordance with the fibre-illuminated system, as specified in 5.2.1.2, shall not engage with a handle of a conventional system, as specified in 5.2.1.1 and Figure 1. When engaged, the clearance between the handle slot and the handle blade shall not exceed 0,28 mm.

5.3.3 Conventional blade hook-on fittings shall engage with any conventional handle hook-on fittings, as specified in 5.2.1.1, 5.2.2 and Figure 1. When engaged, the clearance between the handle slot and the handle blade shall not exceed 0,28 mm.

NOTE Typical blade hook-on fittings are shown in Figure 3.

5.4 Engagement

The force required to engage a blade onto any handle hinge pin dimensioned as in Figure 1 or Figure 2 shall be between 10 N and 45 N (see Figure 4). The engaged blade shall be free to rotate about the pin under gravity.

5.5 Operating position

5.5.1 Locking

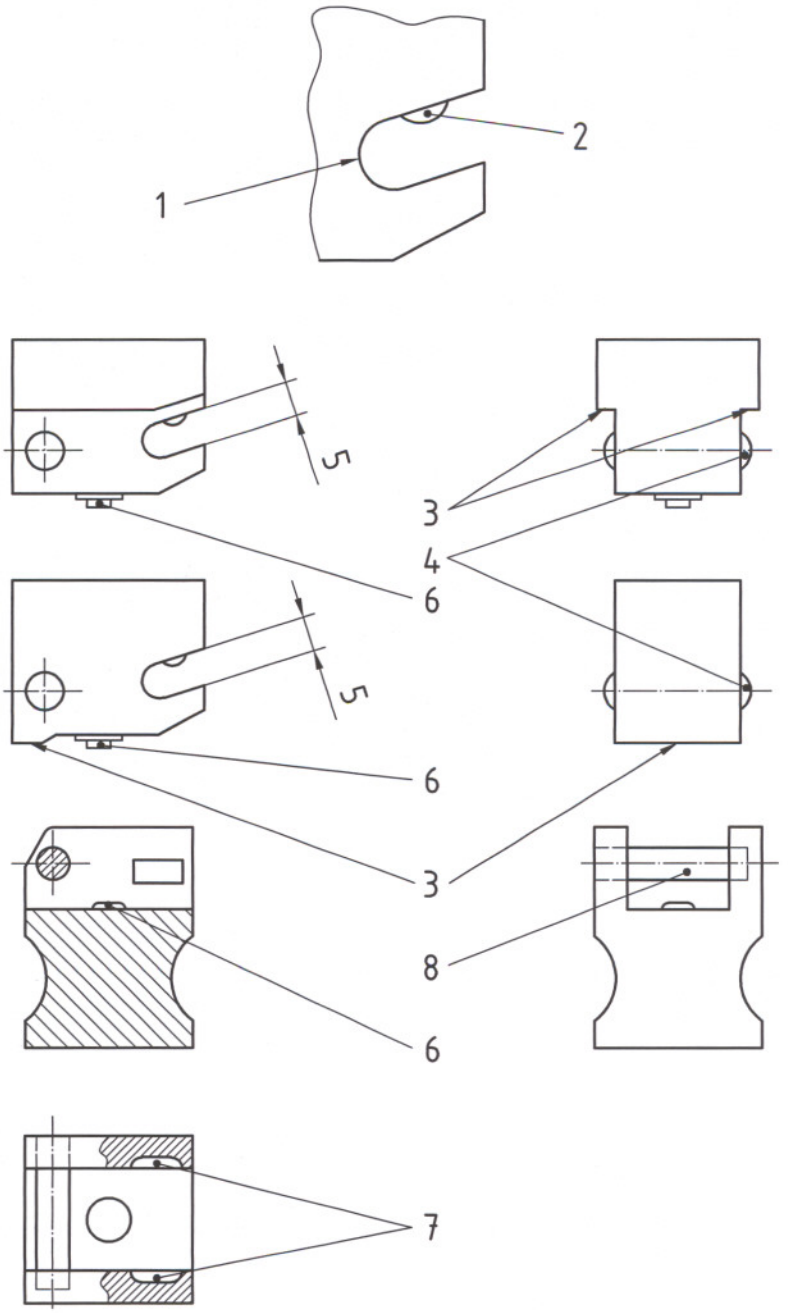
When a torque between 0,35 N·m and 1,35 N·m is applied to the blade, it shall lock into the operating position.

5.5.2 Unlocking

When a torque between 0,25 N·m and 1,35 N·m is applied to the blade, it shall unlock from the operating position.

5.6 Disengagement

When a disengagement force between 10 N and 45 N is applied along the force axis shown in Figure 4, the blade shall disengage from the handle.

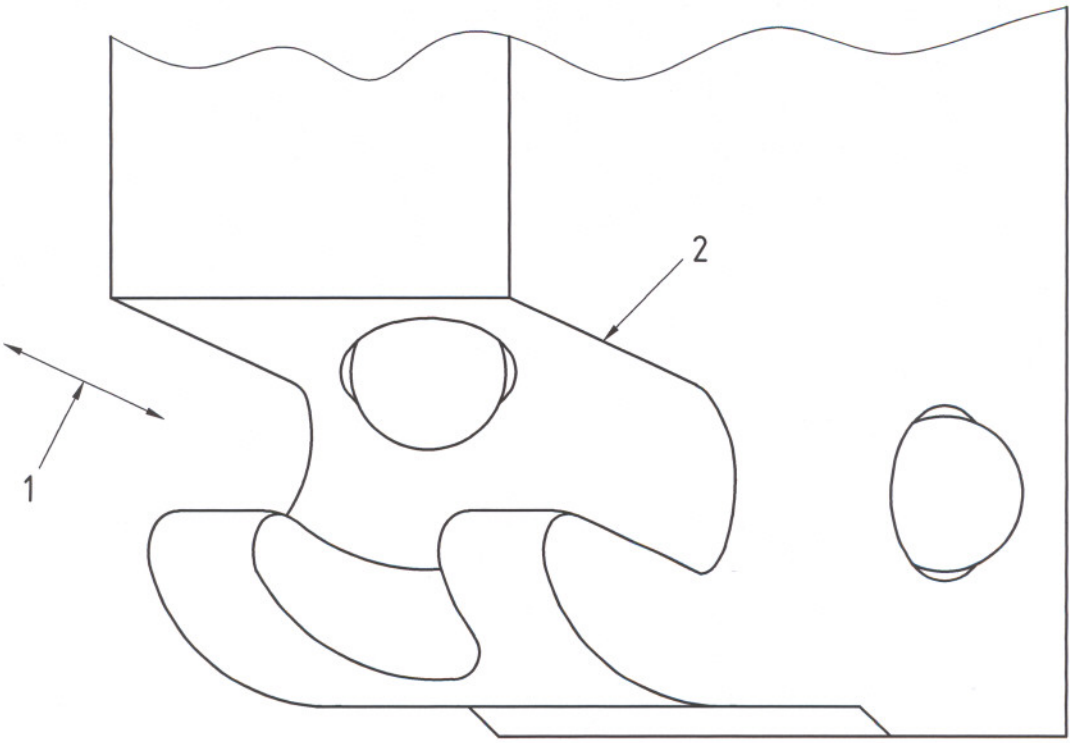


Key

1	end portion of hinge slot (shape not specified)	5	hinge slot
2	retainer (shape not specified)	6	electrical contact (conventional)
3	seating surfaces	7	locking slots (detent)
4	locking surfaces (shape not specified)	8	hinge pin

NOTE Drawing not to scale.

Figure 3 – Typical blade and handle hook-on fitting configurations of conventional systems



Key

1 force axis parallel to slot

2 hinge slot

NOTE Drawing not to scale.

Figure 4 – Force axis for engagement/disengagement

6 Lamp for conventional blade

6.1 Lamp and lamp base contact

6.1.1 A lamp for use on a conventional blade shall have a central contact with electrical return through the amp base. The dimensions of the contact shall comply with Figure 5 and Table 1.

6.1.2 The exterior of the lamp base 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 displacing by more than 0,2 mm.

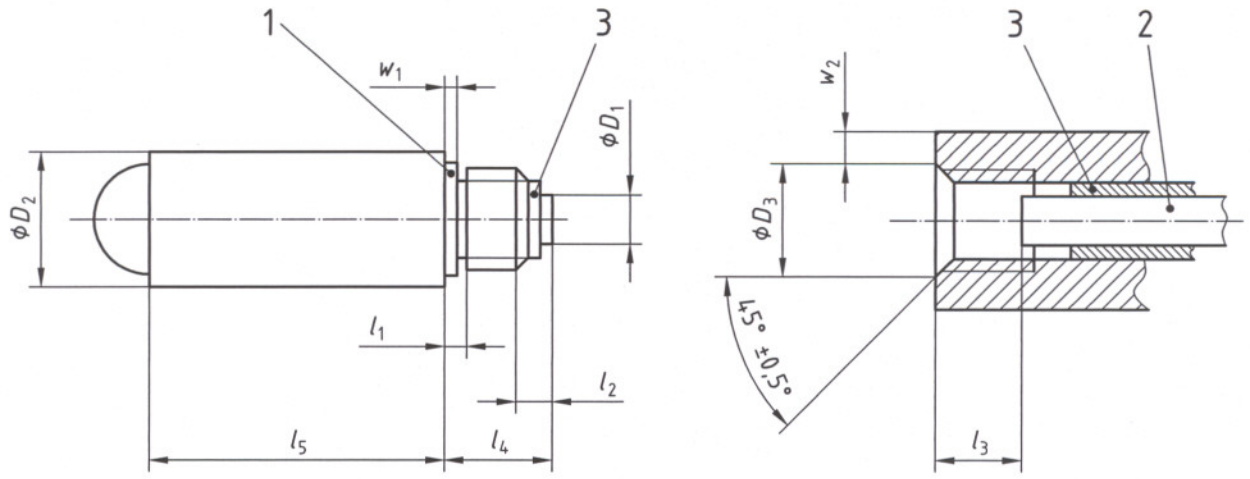
6.1.4 The lamp shall be provided with a seal that prevents the ingress of substances into the lamp socket and resists unscrewing of the lamp (see Figure 5 and Table 1).

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 threads for lamps

6.2.1 The screw thread of the lamp base for small lamps shall have nominal size in accordance with Table 1, and shall be designated 1/8-72 UN-3A, in accordance with ISO 5864.

6.2.2 The screw thread of the lamp base for large lamps shall have nominal size in accordance with Table 1, and shall be designated No. 8-32 UNC-2A, in accordance with ISO 5864.



a) Lamp **b) Socket**

Key

1 sealing washer/O-seal
2 centre contact
3 insulator

NOTE Drawing not to scale.

l_2 distance to the start of the full thread.

l_3 depth of the electrical contact in the socket prior to lamp insertion.

w_2 minimum width of the flat sealing face.

D_3 outside diameter of the socket thread chamfer.

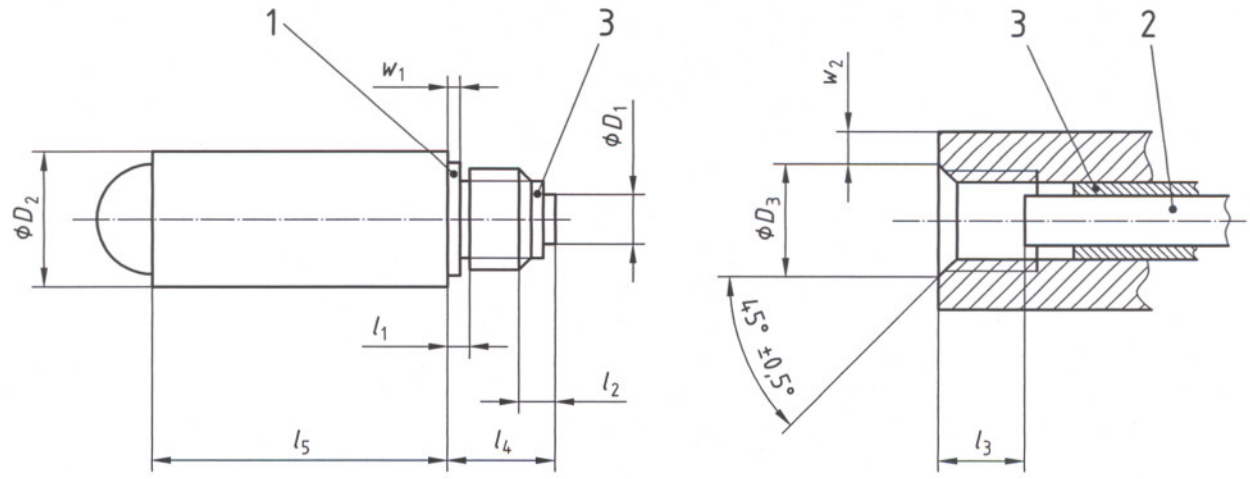
Figure 5 – Lamp and socket dimensions for use with conventional blades

Table 1 – Dimensions for lamps and sockets for use with conventional blades

Dimensions in millimetres

Size designation	l_1	l_2[a]	l_3[b]	l_4	l_5	Sealing washer w_1	O-seal w_1	w_2[c]	D_1	D_2	D_3[d]
1/8-72 UN small	0,8 ± 0,2	1,00 ± 0,25	2,6 ± 0,4	4,0 ± 0,3	11,5 ± 2,5	0,5 ± 0,1		0,2	1,4 ± 0,4	4,3 ± 0,2	3,7 ± 0,2
No. 8-32 UNC large	0,9 ± 0,2	1,20 ± 0,25	3,5 ± 0,4	4,9 ± 0,3	12,0 ± 2,5	0,5 ± 0,1	∅ 0,90 ± 0,05	0,2	2,0 ± 0,5	5,5 ± 0,5	4,6 ± 0,2

[a] l_2 distance to the start of the full thread.
[b] l_3 depth of the electrical contact in the socket prior to lamp insertion.
[c] w_2 minimum width of the flat sealing face.
[d] D_3 is the outside diameter of the socket thread chamfer.



a) Lamp **b) Socket**

Key

1 sealing washer/O-seal
2 centre contact
3 insulator

NOTE Drawing not to scale.

l_2 distance to the start of the full thread.

l_3 depth of the electrical contact in the socket prior to lamp insertion.

w_2 minimum width of the flat sealing face.

D_3 outside diameter of the socket thread chamfer.

Figure 5 – Lamp and socket dimensions for use with conventional blades

Table 1 – Dimensions for lamps and sockets for use with conventional blades

Dimensions in millimetres

Size designation	l_1	l_2[a]	l_3[b]	l_4	l_5	Sealing washer w_1	O-seal w_1	w_2[c]	D_1	D_2	D_3[d]
1/8-72 UN small	0,8 ± 0,2	1,00 ± 0,25	2,6 ± 0,4	4,0 ± 0,3	11,5 ± 2,5	0,5 ± 0,1		0,2	1,4 ± 0,4	4,3 ± 0,2	3,7 ± 0,2
No. 8-32 UNC large	0,9 ± 0,2	1,20 ± 0,25	3,5 ± 0,4	4,9 ± 0,3	12,0 ± 2,5	0,5 ± 0,1	∅ 0,90 ± 0,05	0,2	2,0 ± 0,5	5,5 ± 0,5	4,6 ± 0,2

[a] l_2 distance to the start of the full thread.
[b] l_3 depth of the electrical contact in the socket prior to lamp insertion.
[c] w_2 minimum width of the flat sealing face.
[d] D_3 is the outside diameter of the socket thread chamfer.

7 Lamps for fibre-illuminated laryngoscopes

7.1 * Lamps for a fibre-illuminated laryngoscopes shall not be compatible with the sockets described in Clause 8.

7.2 Components of lamp electrical contact shall be made of corrosion-resistant materials to ensure durability and continuity between the socket and the lamp.

8 Sockets for conventional blades

8.1 Dimensions and centre contact

8.1.1 Screw threads for sockets shall be in accordance with Figure 5 and Table 1.

8.1.2 * Electrical contact shall cease and the lamp shall be extinguished at least 1,5 turns prior to mechanical disengagement of the threaded joint. Test by inspection.

8.1.3 The centre contact of the socket shall have a mechanism for maintaining electrical contact with the lamp, e.g. a spring.

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

8.2 Internal screw threads

8.2.1 * The internal screw thread of the socket for small lamps shall have the nominal size and designation of 1/8 – 72 UN-3B, in accordance with ISO 5864.

8.2.2 The internal screw thread of the socket for large lamps shall have the nominal size and designation of No. 8 – 32 UNC-2B, in accordance with ISO 5864.

9 Cleaning, disinfection and sterilization

9.1 Laryngoscopes or components not intended for single use shall be suitable for cleaning, disinfection and/or sterilization by methods described in the accompanying documents.

9.2 Those devices suspected of being exposed to Creutzfeld-Jacob Disease or variants should not be reprocessed under any conditions.

10 Marking and labelling

10.1 Marking and labelling of unit packs and of shelf- or multi-packs and information to be supplied by the manufacturer in accompanying documents should comply with EN 1041.

10.2 Blades and handles shall be marked with the name and/or trademark of the manufacturer and/or supplier. The area occupied by the name and/or trademark shall each be not less than 10 mm^2.

10.3 Blades shall be marked with the following:

a) size expressed in numerals (see Annex B);

b) type expressed in letters (see Annex B);

c) "stainless" or "s/s" if made from stainless steel;

d) material designation or recycling code;

e) the colour Pantone 355C[1)], if fibre-optic.

10.4 To facilitate reassembly, a removable fibre-illuminated component shall be marked with its size and type, as described in 10.3 a) and 10.3 b).

10.5 A fibre-optic illuminated handle shall be marked with the colour Pantone 355C. This requirement may also be met by the use of appropriate symbols from ISO 7000 or EN 980.

10.6 If applicable, the immediate packaging shall be marked with:

a) the lot number or date of manufacture;

b) the word "Sterile", if appropriate;

c) the words "For single use", if appropriate.

11 Accompanying documents

In the package in which the laryngoscopes are supplied, the manufacturer shall provide the following documentation in addition to the requirements of 10.4:

a) specifications for batteries, and instructions for their fitting;

b) instructions for the cleaning, disinfection and sterilization of blades, handles and removable components for laryngoscopes supplied non-sterile. This shall include a warning that batteries shall be removed prior to chemical or heat processing;

c) *a warning that current cleaning, disinfection and/or sterilization techniques will not inactivate prions, e.g. new variants of Creutzfeld-Jacob disease (CJD).

d) instructions for action in the event of damage to the sterile packaging or laryngoscopes supplied sterile, and appropriate methods of resterilization or disposal;

e) *instructions to check the condition of the internal electrical power source by switching on the lamp before commmencing a clinical procedure;

f) a warning that the power outputs from some rechargeable cells can fall rapidly during use, resulting in the rapid failure of illumination;

g) information concerning the precautions required when disposing of used or defective batteries;

h) a statement that "only trained personnel shall use a laryngoscope for intubation";

i) information regarding the suitability of the laryngoscope for use in intense magnetic fields, e.g. magnetic resonance imaging;

j) a statement on any limitation on the life of the laryngoscope, if it is intended for single use;

k) instructions for routine servicing of the laryngoscope and for checking its condition prior to use, including specifications of any replacement components;

l) *a warning that lamps in an exposed position may generate heat sufficient to burn human tissue, if left illuminated.

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1) Pantone 355C is the trade name of a product supplied by Pantone Inc., 590 Commerce Boulevard, Carlstadt, NJ, USA This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

Annex A
(normative)

Test method for security of lamp contact

A.1 Principle

The lamp base is securely fixed and a load is applied to the contact to test if it becomes displaced.

A.2 Procedure

A.2.1 Thread the fixture to receive the lamp thread, so that the contact and the end of the lamp base are left exposed for loading and measurement.

A.2.2 Precondition the test piece and apparatus in accordance with IEC 60601-1:1988, 4.8. Follow any manufacturer's instructions prior to testing.

A.2.3 Screw the lamp securely in to the threaded fixture and measure, to ± 0,01 mm, the projection of the contact from the lamp base.

A.2.4 Apply a steady force of 1 N for 1 min to the contact, and measure the projection of the contact from the lamp base under load.

A.3 Expression of results

Record whether or not the measurement of projection taken in A.2.4 is more than 0,2 mm smaller than the measurement of projection taken in A.2.3.

Annex B
(normative)

Blade markings

B.1 Blade pattern abbreviation

If one of the following patterns of laryngoscope blade is used for identification, the abbreviation shall be as follows:

— Macintosh MAC;

— Miller MIL;

— Robertshaw RSHAW;

— Wisconsin WIS.

B.2 Blade size marking

The appropriate size marking is required on laryngoscope blades to guide the operator in choosing the appropriate size laryngoscope for the patient. The marking shall be chosen from Table B.1.

Table B.1 – Size markings for laryngoscopes

Marking	Intended laryngoscope use
000	Small premature infant
00	Premature infant
0	Neonate
1	Small child
2	Child
3	Adult
4	Large adult
5	Extra large adult

Annex C
(informative)

Rationale

C.1 Clause 4 General requirements

The high current capacity of some types of battery, particularly those which are interchangeable, can result in excessive operating temperatures under a single fault condition, e.g. short circuit. Such batteries can also produce sparks with sufficient energy to ignite flammable anaesthetic gases, and the user should be made aware of this hazard. Current-limiting devices should be incorporated if required.

C.2 Subclause 7.1

Higher-powered lamps, which are used to make good the losses of light in fibre-light guides, operate at higher temperatures and may be hazardous if they can be fitted where they might make tissue contact. Consequently their compatibility with sockets described in Clause 8 is prohibited.

C.3 Subclause 8.1.2

Cases have occurred of a lamp unscrewing from a laryngoscope and entering the patient's airway. This requirement ensures that warning is given of a loose lamp by its being extinguished before detachment can occur.

C.4 Subclause 8.2

The use of inch-series threads has been common practice for many years and manufacturers see no problem in continuing to supply them. Conversion to metric standard threads (e.g. M4 and M3) has been shown to greatly increase the risk of disengagement during use if such lamps are used in existing instruments, resulting in serious danger to the patient. It is considered that the merits of metrication are insufficient to outweigh these hazards to the patient and the use of existing inch-series threads has been continued.

C.5 Clause 11, item c)

Some countries may have national guidelines or regulations regarding the use of laryngoscopes in certain patients and/or procedures.

C.6 Subclause 11, item e)

Instruction manuals should make the user aware of the need to check the condition of the internal electrical power source before each use by checking the illumination provided.

C.7 Subclause 11, item l)

Attention is drawn to the requirement in IEC 60601-1 that the temperature of equipment parts which may, in normal use, have a brief contact with a patient shall not exceed 50 °C. This can be applicable to lamps in conventional laryngoscopes unless other protective means are provided.

Bibliography

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

[2] ISO 7000, *Graphical symbols for use on equipment – Index and synopsis*

[3] ISO/IEC TR 10000-1, *Information technology – Framework and taxonomy of International Standardized Profiles – Part 1: General principles and documentation framework*

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

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

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