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Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation

Matériel d'anesthésie et de réanimation respiratoire — Laryngoscopes pour intubation trachéale

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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 7376 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 7376:2003), which has been technically revised.

Introduction

This International Standard gives requirements for laryngoscopes in tracheal intubation, hereinafter referred to as laryngoscopes, during anaesthesia, intensive care, emergency care and similar procedures, including requirements for reusable and single-use laryngoscope blades and handles.

Laryngoscopes are manufactured in several forms and can, for example, be of single-piece handle and blade construction or have a detachable blade and handle. In the latter case, the light source for illuminating 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 minimum illumination from the laryngoscope is defined/disclosed.

The dimensions of laryngoscope blades are defined and disclosed to allow an informed decision by the operator to select the most appropriate instrument for intubation. Annexes A and B describe test methods. While Annexes C and D give blade markings and designs respectively, Annex E presents a rationale for certain subclauses in the main body of the document.

Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation

1 Scope

This International Standard gives general requirements for laryngoscopes used for intubation, and specifies critical dimensions for the handle and lamp of hook-on type laryngoscopes. It also addresses the interchangeability of blades and handles.

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

It is not applicable to surgical instruments known by the same generic name, nor is it applicable to

— flexible laryngoscopes or laryngoscopes designed for surgery,

— laryngoscopes powered from mains electricity supply,

— laryngoscopes connected by light-transmitting cables to external light sources, or

— video laryngoscopes designed to work with an external video system.

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

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, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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

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 direct view of the larynx

3.2
contact
metallic part of a hook-on fitting that completes an electrical circuit between the handle and lamp when a detachable blade and handle are placed in the operating position

3.3
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

NOTE See Figure 1.

3.4
detachable blade
blade that can be separated from a handle by the operator

3.5
engagement
mechanical attachment of the blade and handle such that the blade remains coupled to the handle in all positions

3.6
fibre-illuminated blade
blade incorporating optical fibres to transmit light from a source to illuminate the larynx

NOTE See Figure 2.

3.7
handle
component held in the hand during use, one end forming the connection to the blade

3.8
hook-on fitting
fitting on a laryngoscope handle that allows connection of a detachable blade to the handle and that incorporates an electrical contact or optical pathway

3.9
lamp
electrical filament bulb intended to provide illumination during laryngoscopy

3.10
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

3.11
locking mechanism
mechanism that retains the blade in the operating position

3.12
operating position
position of the engaged blade and handle when the laryngoscope is ready for use

3.13
single-piece laryngoscope
laryngoscope with a handle and non-detachable blade

3.14
socket
component with a female screw thread attached to a laryngoscope blade and intended to provide electrical contact and mechanical engagement with a lamp

4 General requirements

4.1 Design

4.1.1 Except for a single-piece laryngoscope, the lamp shall light when the blade and handle are placed in the operating position.

4.1.2 A single-piece laryngoscope shall have a switch that latches in both the ON and OFF positions to control power to the lamp, and that is marked accordingly.

4.2 Materials for laryngoscope blades and single-piece laryngoscopes

Materials shall satisfy appropriate biological safety testing, as specified in ISO 10993-1, i.e. external communicating, tissue/bone/dentin communicating, and of less than 24 hour duration.

4.3 Environmental requirements

4.3.1 A laryngoscope component, other than a battery, shall be capable of meeting the requirements of Clauses 5, 6, 7, 8, 10 and 11 after being exposed for 14 days in its storage and/or transport packaging in environmental conditions over the following ranges:

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

b) relative humidity up to 95 % non-condensing;

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

NOTE See Annex E for the rationale for inclusion of these requirements.

4.3.2 A laryngoscope component, other than a battery, shall be capable of functioning in its intended use after being exposed for 14 days in its storage and/or transport packaging in environmental conditions.

4.3.3 Compliance with 4.3.1 and 4.3.2 shall be checked by functional testing.

4.4 Internal electrical power source

If the handle is intended for use with rechargeable cells, a current-limiting device that prevents more than three times normal current flowing in a single fault condition shall be incorporated into the handle.

NOTE See Annex E for the rationale for inclusion of this requirement.

5 Performance requirements

5.1 Illumination

5.1.1 The manufacturer of the detachable laryngoscope blade shall specify the design of the handle to be used with the blade.

5.1.2 Except for a single-piece laryngoscope, the lamp shall light when the blade and handle are placed in the operating position.

5.1.3 When tested in accordance with Annex B, the illumination shall have the following characteristics.

a) The distance between the upper illumination edge and the blade tip on the screen shall be less than 3 mm.

b) The distance between the upper and lower illumination edges shall be greater than 30 mm but less than 80 mm.

c) The distance between the right edge and the centre of the blade tip shall be greater than 25 mm but less than 50 mm.

d) The distance between the left edge and the centre of the blade tip shall be greater than 25 mm but less than 50 mm.

5.1.4 When tested in accordance with B.2, illumination shall exceed 500 lx for at least 10 min. This requirement for the illumination test for reusable fibre-optic laryngoscopes shall be met after the number of cleaning and disinfection or sterilization cycles specified by the manufacturer have been performed and disclosed as per 9.2.

5.2 Blade strength and rigidity

5.2.1 When tested in accordance with B.2, the tip of the blade shall not move more than 10 mm and the illumination centre shall not move more than 10 mm.

5.2.2 When tested in accordance with B.2, the blade shall not break.

5.3 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.

Compliance with these requirements shall be checked by functional testing.

5.4 Handle fittings

5.4.1 Handle dimensions

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

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

5.4.2 Electrical contact — Conventional system

5.4.2.1 The electrical contact between a handle and conventional blade shall ensure that the lamp lights when the blade is placed in the operating position.

Compliance shall be checked by functional testing.

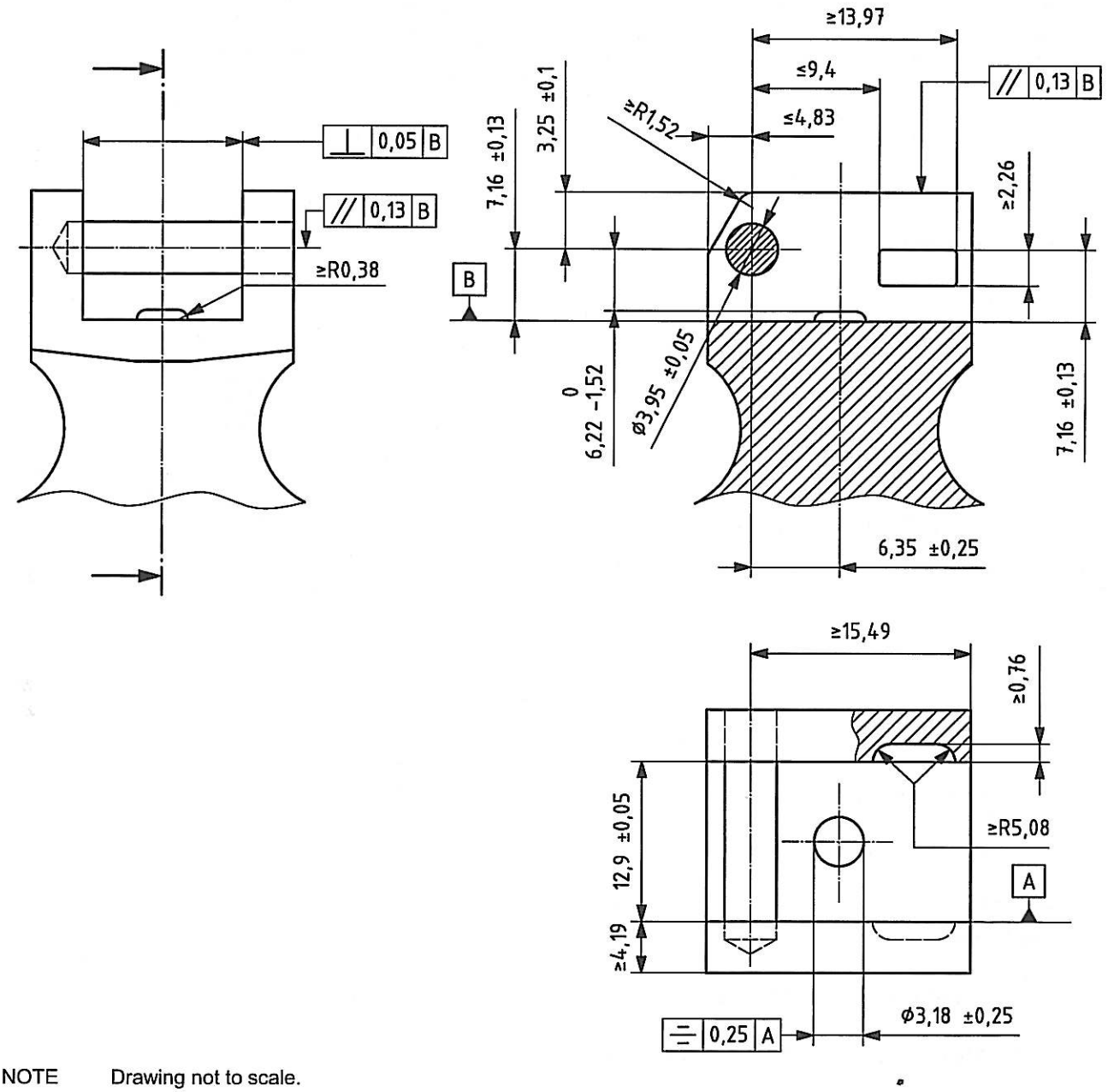
5.4.2.2 The electrical contact of a conventional blade shall be rigid. The electrical contact of a handle that can accept a conventional blade shall be either flexible or spring-loaded.

5.4.2.3 Electrical continuity of a contact for a small lamp shall be achieved when the sealing washer is compressed by (35 ± 10) % during installation.

5.4.2.4 Electrical continuity of a contact for the large lamp shall be achieved 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.

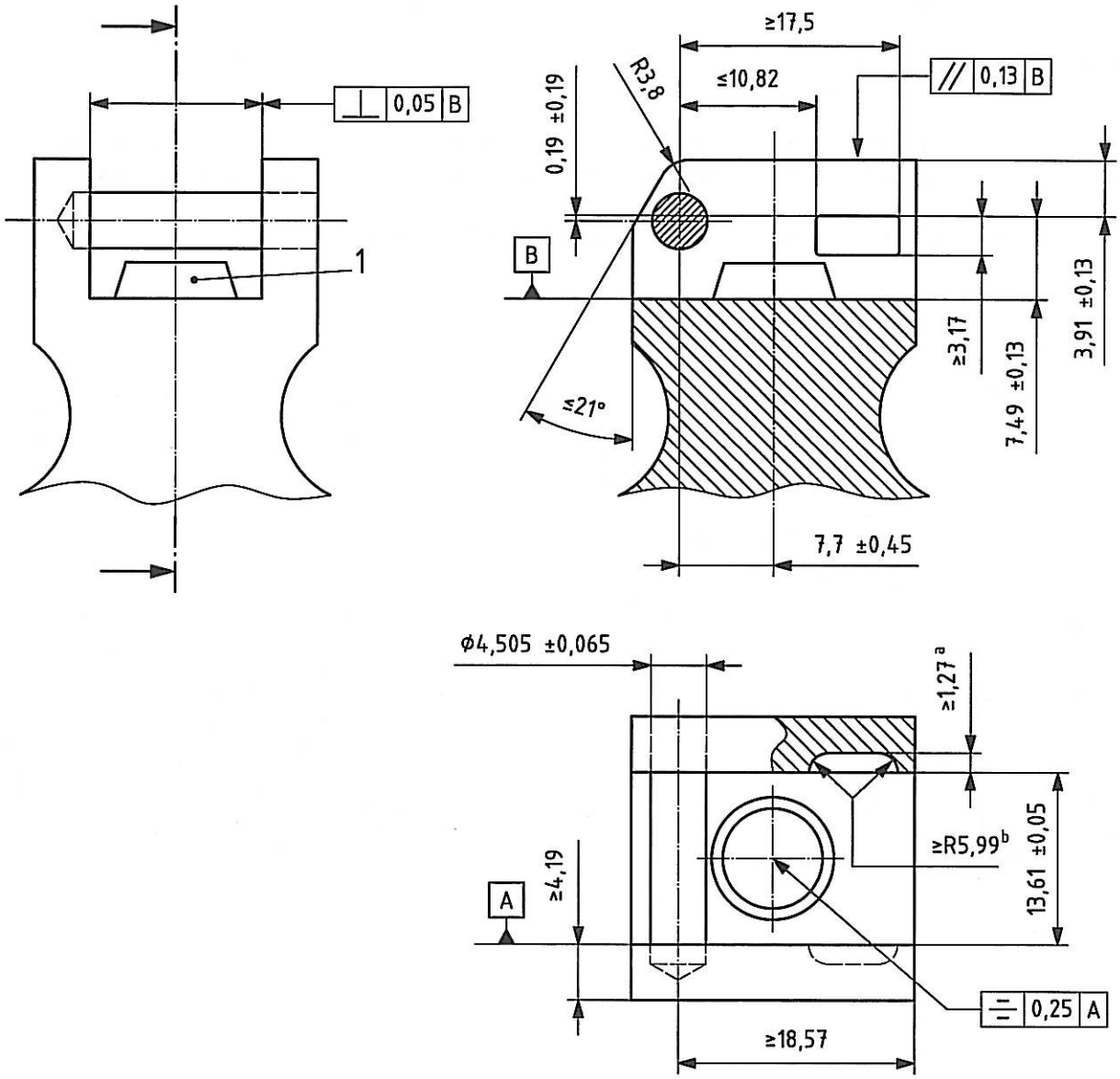
Dimensions in millimetres



NOTE Drawing not to scale.

Figure 1 — Handle hook-on fitting of conventional system

Dimensions in millimetres



Key

1 spring-loaded switch: OFF position, 3,5 to 2,2; ON position, 2,2 to 0,5; bottomed at ⩽ 0,5

NOTE Drawing not to scale.

a Two positions.

b Four positions.

Figure 2 — Handle hook-on configuration of green fibre-illuminated system

5.4.3 Electrical contact — Fibre-illuminated system

The electrical contact 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.

Compliance shall be checked by functional testing.

5.5 Blade fittings

5.5.1 A conventional blade shall not engage with a handle made in accordance with a fibre-illuminated system, as specified in 5.4.1.2 and as shown in Figure 2.

5.5.2 A blade that engages a handle made in accordance with the fibre-illuminated system, as specified in 5.4.1.2, shall not engage with a handle of a conventional system, as specified in 5.4.1.1 and as shown in Figure 1.

5.5.3 Conventional blade hook-on fittings shall engage with any conventional handle hook-on fittings, as specified in 5.4.1.1 and 5.4.2, and as shown in Figure 1.

5.5.4 When engaged, the clearance between the handle slot and the handle blade shall not exceed 0,28 mm.

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

5.6 Engagement

The force required to engage a blade onto any handle hinge pin dimensioned 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.

5.7 Operating position

5.7.1 Locking

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

Compliance shall be checked by functional testing.

5.7.2 Unlocking

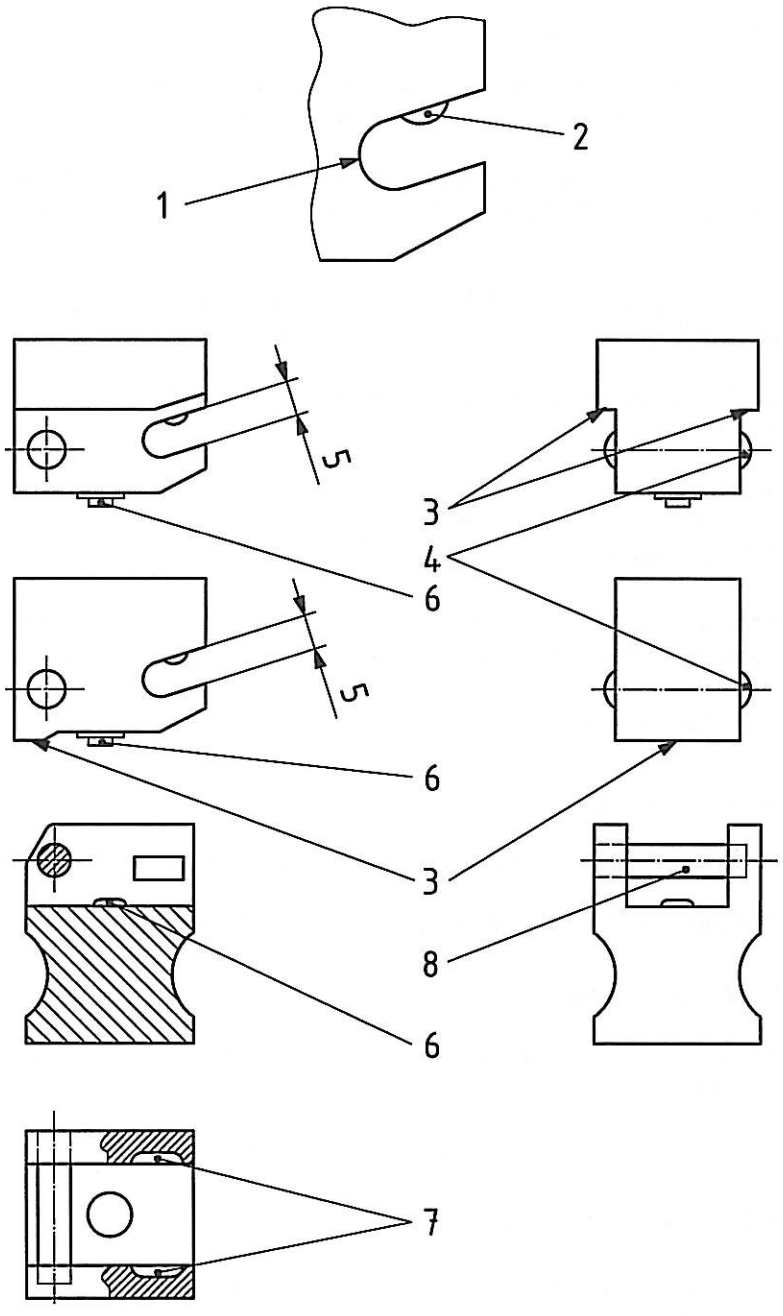
When a torque between 0,25 Nm and 1,35 Nm is applied to the blade, it shall unlock from the operating position.

Compliance shall be checked by functional testing.

5.8 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.

Compliance shall be checked by functional testing.

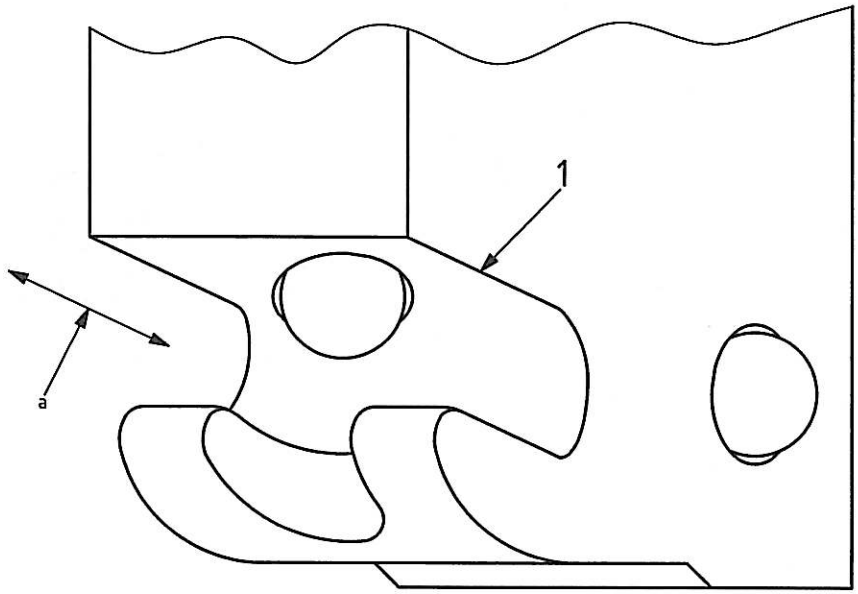


Key

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

NOTE Drawing not to scale.

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



Key

1 hinge slot

NOTE Drawing not to scale.

[a] Force axis parallel to slot.

Figure 4 — Force axis for engagement/disengagement

6 Lamp for conventional blade

6.1 Lamp and lamp base contact

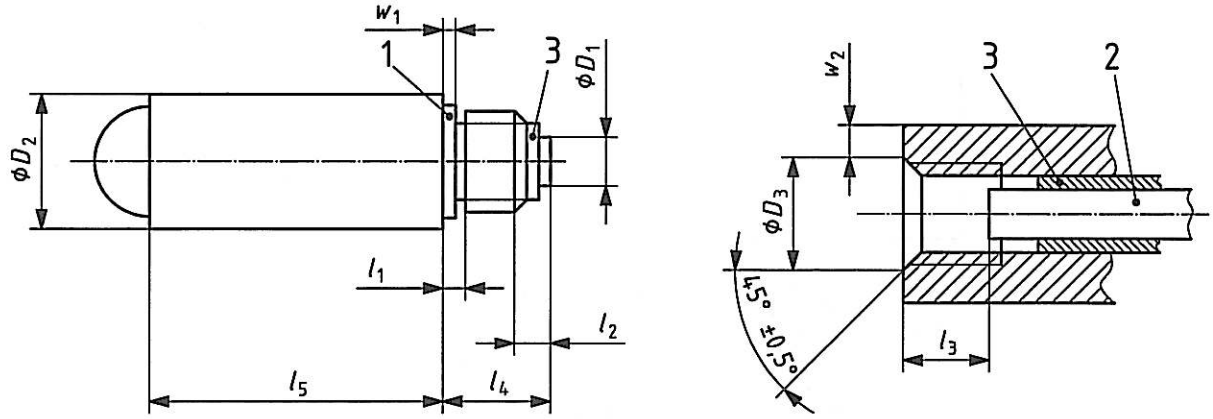
6.1.1 A lamp for use on a conventional blade shall have a central contact with electrical return through the lamp base. The dimensions of the contact shall comply with Figure 5 and Table 1.

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 without becoming displaced by more than 0,2 mm when tested in accordance with A.1.

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.



a) Lamp

b) Socket

Key

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

NOTE 1 Drawing not to scale.

NOTE 2 See Table 1 for dimensions.

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

Table 1 — Dimensions for lamps and sockets for use with conventional blades (see Figure 5)

Dimensions in millimetres

Size						Sealing washer	O-seal				
	l_1	l_2	l_3	l_4	l_5	w_1	w_1	w_2	$\varnothing_1$	$\varnothing_2$	$\varnothing_3$
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

The following definitions apply to this table, Figure 5, and to 6.1.1 and 6.1.4:

l_2 is the distance to the start of the full thread;

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

w_2 is the minimum width of the flat sealing face;

$\varnothing_3$ is the outside diameter of the socket thread chamfer.

6.2 Screw thread for lamps

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

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

7 Lamps for fibre-illuminated laryngoscopes

7.1 A lamp for a fibre-illuminated laryngoscope shall not be compatible with the socket specified in Clause 8.

NOTE See Annex E for the rationale for inclusion of this requirement.

7.2 The components of the 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 a socket 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.

NOTE See Annex E for the rationale behind inclusion of this requirement.

Compliance shall be checked by functional testing.

8.1.3 The centre contact of the socket shall have a mechanism for maintaining electrical contact with the lamp

EXAMPLE A spring.

Compliance shall be checked by functional testing.

8.1.4 The socket 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.

NOTE See Annex E for the rationale behind inclusion of this requirement.

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

SAFETY PRECAUTIONS — Those devices suspected of being exposed to Creutzfeldt-Jakob Disease (CJD) or variants shall not be reprocessed under any condition.

9.1 Laryngoscopes or components not intended for single use shall be suitable for cleaning, disinfection and/or sterilization.

9.2 The manufacturer of reusable laryngoscope components shall determine the number of cleaning and disinfection or sterilization cycles for which the laryngoscope or component is suitable.

NOTE See Annex E for the rationale behind inclusion of this requirement.

10 Marking and labelling

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

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

10.3 Blades shall be marked with the following:

— size expressed in numerals, in accordance with Annex C;

— "stainless" or "s/s", if made from stainless steel;

— material designation or recycling code;

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

— "single-use" or equivalent, if so intended, which shall be visible in the operating position.

10.4 To facilitate re-assembly, a removable fibre-illuminated component shall be marked with its size and type according to 10.2 and 10.3.

10.5 A fibre-optic illuminated handle shall be marked with the colour Pantone 355C [1)].

10.6 If applicable, the immediate packaging shall be marked with

— a lot number or date of manufacture,

— the length of the laryngoscope blade (from the base of the hook-on slot to the tip of the blade),

— the word "sterile", if appropriate, and

— the words "single use", if appropriate.

NOTE The requirements of this Clause could be met by the use of appropriate symbols given in ISO 7000.

11 Accompanying documents

As well as the markings specified in 10.3, the manufacturer shall provide in the package in which the laryngoscope is supplied:

a) instructions for use that are dated, as shall be any accompanying documents;

b) specifications of, and instructions for, fitting batteries, as appropriate;

c) the number and type of cleaning and disinfection or sterilization cycles for blades, handles and removable components for reusable laryngoscopes supplied non-sterile — which may include a warning that batteries should be removed prior to chemical or heat processing;

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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.

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

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

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

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

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

i) for single-use devices only, a warning giving information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be reused;

j) information on the suitability of the laryngoscope for use in intense magnetic fields, e.g. in magnetic resonance imaging (MRI);

k) a statement on any limitation on the life of the laryngoscope;

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

m) a warning that lamps, if left illuminated in an exposed position, could generate sufficient heat to burn human tissue;

n) information relating to handle and blade compatibility/interoperability.

NOTE See Annex E for the rationale behind inclusion of item m) above.

Annex A
(normative)

Test method for lamp contact security

A.1 Principle

The lamp base is securely fixed and a load is applied to the contact to ensure that it does not become displaced.

A.2 Apparatus

Fixture, threaded so as to receive the lamp thread, and so that the contact and the end of the lamp base is left exposed for loading and measurement.

A.3 Procedure

A.3.1 Precondition the test piece and apparatus in accordance with IEC 60601-1. Follow any manufacturer's instructions prior to testing.

A.3.2 Screw the lamp securely into the threaded fixture and measure the projection of the contact from the lamp base to ± 0,01 mm.

A.3.3 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.4 Expression of results

Record whether or not the measurement of projection taken as specified in A.3.3 decreased by more than 0,2 mm from the measurement of projection taken as specified in A.3.2.

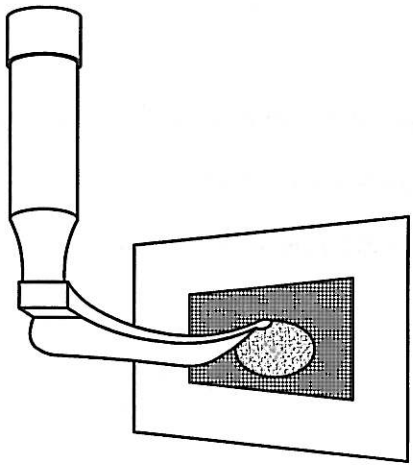
Annex B
(normative)

Test methods for strength, rigidity and illumination

B.1 Test method for Illumination in the resting position

Attach the blade to an appropriate handle and activate the light. In a darkened room, place a white translucent piece of paper 20 mm from the tip of the blade in a plane approximating the position of the vocal cords in relation to the blade, when the blade is in the operating position and normal to the line of sight. Mark the paper from the back with the position of 1) tip of the blade, 2) upper illuminated edge, 3) lower illuminated edge, 4) right illuminated edge, and 5) left illuminated edge.

NOTE The illuminated edge is where visible attenuation of illumination begins.



NOTE Illumination might not be uniform, i.e. oval or round.

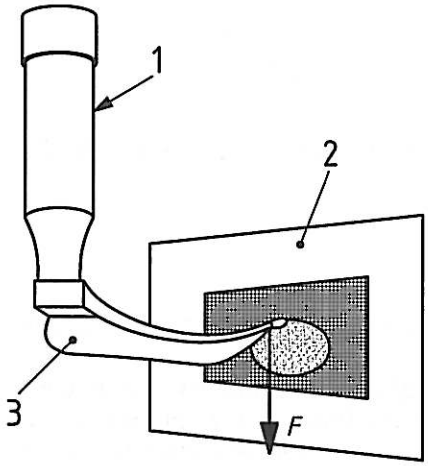
Figure B.1 — Illuminated edge

B.2 Test for appropriate strength and illumination under tension

Set up the test blade and handle according to B.1. Apply a 65 N force vertically downwards as illustrated in Figure B.2, not more than 10 mm from the tip of the blade. Realign the paper so that it is normal to the new line of sight.

The force shall not cause more than a 10 mm movement of the blade tip from the initial position. Furthermore, there shall be not more than a 12 mm shift of any luminal edge.

NOTE Consistent illumination of the laryngeal inlet, which is approximately 20 mm (in width) by 25 mm (anteroposteriorly), is essential for successful tracheal intubation.



Key

1 handle
2 screen
3 single-use blade
F force = 65 N

Figure B.2 — Illumination under tension

Repeat the test by applying a downward force of 150 N.

The integrity of the blade shall be checked by visual inspection.

Annex C
(informative)

Blade size markings

See Table C.1.

Table C.1 — Size markings for laryngoscope blades

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 D
(informative)

Laryngoscope blade designs

This annex presents an extract from Reference [6], with permission from the authors. ISO should not be held responsible for the conclusions of the authors.

"Laryngoscopes are used to view the larynx and adjacent structures, most commonly for the purpose of inserting a tube into the tracheobronchial tree. The wide range of available devices attests to the many diverse difficulties encountered in their use.

The blade is the component that is inserted into the mouth. When a blade is available in more than one size, the blades are numbered, with the number increasing with size. Table C.1 shows the appropriate size markings for laryngoscope sizes.

The blade is composed of several parts, including the base, heel, tongue, flange, web, tip and light source.

The base is the part that attaches to the handle. It has a slot for engaging the hinge pin of the handle. The end of the base is called the heel.

The tongue (spatula) is the main shaft. It serves to compress and manipulate the soft tissues (especially the tongue) and lower jaw. The long axis of the tongue may be straight or curved in part or all of its length.

Blades are commonly referred to as curved or straight, depending on the predominant shape of the tongue of the blade. In general, straight blades provide better visualization of the larynx than curved blades, while curved blades increase the ease of intubation. When a satisfactory view is obtained but intubation is difficult, use of a bougie may be helpful.

The flange projects off the side of the tongue and is connected to it by the web. It serves to guide instrumentation and deflect tissues out of the line of vision. The flange determines the cross-sectional shape of the blade. The vertical height of the cross-sectional shape of a blade is sometimes referred to as the "step".

The tip (beak) contacts either the epiglottis or the vallecula and directly or indirectly elevates the epiglottis. It is usually blunt and thickened to decrease trauma.

In most cases, use of a laryngoscope presents little or no difficulty to the experienced operator, and skill is of more importance than the type of blade employed. There are, however, situations in which a certain blade is particularly advantageous. This has led to the development of a number of blades: curved, straight, hybrid and others. A brief description of these blades follows.

Macintosh type blades

a) Macintosh blade

The Macintosh blade is one of the most popular blades. The tongue has a gentle curve that extends to the tip. In cross-section, the tongue, web, and flange form a reverse Z. Numerous modifications have been suggested. The No. 4 blade may be more useful than the No. 3 in normal and large-sized adults. The force, head extension and cervical spine movement is greater with the Macintosh blade than with the Miller blade.

b) Left-handed Macintosh blade

The left-handed (reversed) Macintosh blade has the flange on the opposite side from the standard Macintosh blade. This blade may be useful for abnormalities of the right side of the face or oropharynx, left-handed laryngoscopists, individuals with limited use of the left arm, intubating in the right lateral position, and positioning a tracheal tube directly on the left side of the mouth.

c) English Macintosh

The English Macintosh is similar to the conventional Macintosh except that the flange is curved and lower at the handle end. Two studies have found that this blade provided better results than other commonly used blades.

d) Polio blade

The polio blade is also a modification of the Macintosh. The blade is offset from the handle at an obtuse angle: to allow intubation of patients in iron lung respirators or body jackets; for use after the anesthesia screen is in place; for patients with obesity, breast hypertrophy, kyphosis with severe barrel chest deformity, a short neck, or restricted neck mobility. Disadvantages of this blade are that little force can be applied and control is minimal.

e) Improved vision Macintosh blade

The improved vision (IV) Macintosh blade is similar to the standard version except that the midportion of the tongue is concave.

f) Oxiport Macintosh (Mac/Port)

The Oxiport Macintosh blade is a Macintosh blade with a tube to deliver oxygen added.

g) Tull Macintosh

The Tull (suction) blade is a modified Macintosh that has a suction port near the tip. The suction channel extends next to the handle and has a finger-controlled valve so that suction can be controlled by the laryngoscopist.

h) Fink blade

The Fink blade is another modification of the Macintosh. The tongue is wider and has a sharper curve at the distal end. The height of the flange is reduced, especially at the proximal end. The light bulb is placed farther forward than on the conventional Macintosh blade.

i) Bizarri-Giuffrida blade

The Bizarri-Giuffrida blade (flangeless Macintosh) is a modified Macintosh on which the flange is removed, except for a small part that encases the light bulb. This was done to limit damage to the upper teeth. The blade is designed for patients with a limited mouth opening, prominent incisors, receding mandible, short thick neck, or anterior larynx.

j) ULP

The ULP (Upsher low profile) is a modified Macintosh blade with a low flange and a fairly straight proximal section which leads to a tip with a significant curve. This configuration is designed for insertion into a small mouth.

k) Upsher ULX Macintosh blade

The ULX blade has a little more curve than the standard Macintosh blade.

Miller blades

l) Miller blade

The Miller is one of the most popular blades. The tongue is straight with a slight upward curve near the tip. In cross-section the flange, web, and tongue form a C with the top fattened. Some versions of the blade have the lamp socket on the tongue, whereas others have it on the web. The lamp may be on either the right or left side of the blade. If the bulb is on the left side, the bulb is easier to change but can be covered by the tongue. Placing the bulb on the right side allows it to be protected by the flange. Several modifications have been described.

In comparing the Macintosh and Miller blades, it was found that force, head extension and cervical spine movement were less with the Miller.

m) Oxiport Miller blade

The Oxiport Miller (Miller/port, oxyscope) blade has a built-in tube that allows delivery of oxygen during intubation. It may also be used for suctioning. Insufflation of oxygen during intubation using this blade has been found to lessen oxygen desaturation in spontaneously breathing anesthetized patients.

n) Tull Miller blade

The Tull (suction) Miller blade is a standard Miller blade with a suction tube whose port ends near the tip of the blade. Near the handle is a finger-controlled port that allows control of suction.

o) Mathews blade

The Mathews blade is straight with a wide and flattened petalloid configuration tip. It is designed for difficult nasotracheal intubations.

Wisconsin blades

p) Wisconsin blade

Unlike the Miller blade, the Wisconsin blade's tongue has no curve. The flange is curved to form two-thirds of a circle in cross-section. The depth of the flange is small at the proximal end and wider in the distal portion.

q) Wis-Foregger blade

The Wis-Foregger is a modification of the Wisconsin blade with a straight tongue and a flange that expands slightly toward the distal end. The distal portion of the blade is wider and formed slightly to the right.

r) Wis-Hipple blade

The Wis-Hipple is also a modified Wisconsin blade. The tongue is straight, and the flange is large and circular. Compared with the Wisconsin blade, the flange is straighter and runs parallel to the tongue and the tip is wider. It is designed primarily for use in infants.

s) Schapira blade

The Schapira blade is a straight blade with a tip that curves upward. The vertical component is minimal. The blade is designed to facilitate intubation by cradling the tongue and pushing it to the left side of the mouth.

t) Alberts blade

The Alberts blade combines characteristics of the Miller and Wis-Hipple blades with a cut-away flange to increase visibility. There is a recess to facilitate insertion of a tracheal tube. The blade forms a 67° angle with the handle. It is used for pediatric patients.

u) Michaels blade

The Michaels blade differs from the Alberts blade only in that it forms a 93° angle with the handle.

v) Soper blade

The Soper blade combines the Z shape on the flange of the Macintosh blade with a straight blade. It has a slot built into the tip, which is intended to prevent the epiglottis from slipping off the blade.

w) Heine blade

The Heine blade is straight with a slight upward curve at the tip. The flat flange is curved away from the blade. It is useful for children with large tongues.

x) Snow blade

The Snow blade is a hybrid blade consisting of a Miller tongue and a Wis-Foregger flange. It is curved 2,54 cm (1 inch) from the tip.

y) Flagg blade

The Flagg blade has a straight tongue. The flange has a C shape that gradually decreases in size as it approaches the distal end.

z) Guedel blade

The Guedel blade is a straight blade on which the tongue is set at a 72° angle to the handle. The flange has the shape of a U on its side. The light is close to the tip, which has an uptilt of 10°.

aa) Bennett blade

The Bennett blade is a modification of the Guedel blade. It also forms an acute angle with the handle. The upper part of the flange has been omitted.

bb) Eversole blade

The Eversole blade has a straight tongue. The flange forms a C with the tongue and web near the proximal end. Midway to the tip, the upper flange tapers.

cc) Seward blade

The Seward blade has a straight tongue with a curve near the tip. It has a small reverse Z-shaped flange. The blade is useful for nasotracheal intubation because its shape allows a Magill forceps to be introduced with minimum loss of view. It is intended for use in children less than five years old.

dd) Phillips blade

The Phillips blade is straight with a low flange and a curved tip similar to a Miller blade. The light bulb is on the left side of the blade.

ee) Racz-Allen blade

The Racz-Allen blade is straight with a curved tip. The proximal portion of the blade flexes to relieve pressure on the teeth. The vertical portion is hinged and held in position by a spring. The spring allows lateral deflection of the vertical portion without occluding the view. Exposure is improved by tilting the handle of the laryngoscope to the left. The hinged portion is concave along its length. The tongue surface is rough and unpolished to reduce slippage.

ff) Robertshaw blade

The Robertshaw blade has a straight tongue with a gentle curve near the tip. It is designed to lift the epiglottis indirectly. The flange is extended to the left. The blade was designed for infants and children. It may be useful for nasotracheal intubation because it allows a Magill forceps to be introduced with a minimum loss of view.

gg) Oxford infant blade

The Oxford infant blade has a straight tongue that curves up slightly at the tip. It has a U shape at the proximal end with the bottom limb of the U decreasing toward the tip so that the distal part is open. It tapers from a maximum width at the proximal end to the tip. Although intended primarily for newborns, it can be used for children up to the age of four years.

hh) Bainton blade

The Bainton blade has a straight tongue. The distal 7 cm section is tubular so that it is protected from obstruction by edematous tissue, blood, secretions, intraoral masses, and scar tissue and has an intraluminal light source. The tip is beveled at a 60° angle to create an oval opening at the distal end of the tube. A tracheal tube of 8 mm or less can be inserted through the tubular lumen without significantly obstructing vision.

The Bainton blade is designed for patients with right-sided or circumferential pharyngeal lesions. The tubular portion can displace tissues circumferentially and thus overcome this problem.

A modified two-piece tubular pharyngolaryngoscope is also available. The two parts of the blade are held together by a screw during intubation. A tracheal tube is placed intraluminally into the glottis, then the two pieces are dismantled for removal from around the tube.

ii) Double-angle blade

The spatula of the double-angle (Choi) blade has two angulations, 20° and 30°, to improve lifting of the epiglottis. The spatula and tip form a wide, flat surface. The bulb is located on the left edge of the blade between the two curvatures. The flange has been eliminated. The blade may be especially useful for the patient with an anterior larynx. The absence of the flange leaves more room to pass the tracheal tube than with a straight blade.

jj) Blechman blade

The Blechman blade is a modification of the Macintosh-style blade, with the tip angled sharply to elevate the epiglottis. The flange has been removed near the handle end of the blade.

kk) Belscope blade

The Belscope blade is a straight blade bent forward 45° near its midpoint. The tip is beaded on the underside and the handle is offset. The blade is designed to be used like a straight blade, with the tip lifting the epiglottis. It is available in several lengths.

When a satisfactory view of the larynx cannot be obtained, a prism of transparent acrylic can be attached to the blade just proximal to the angle. Condensation of moisture on the prism can be prevented by applying an antifog preparation to the prism and/or warming it before use. Another measure to prevent

fogging is to direct a continuous flow of oxygen over the prism through a suction catheter taped to the blade. Because the image of the larynx is rotated, the user's head must be moved higher and further forward than when the prism is omitted.

Several studies have shown an improved view of the larynx can often be obtained with this blade compared to other blades. The Belscope provides a greater distance between the posterior end of the blade and the upper teeth, making it less likely to contribute to dental damage than other blades. This blade feels different from other blades so practice is necessary to acquire proficiency. Intubation may take longer and be less successful when the prism is used.

ll) Cranwall blade

The Cranwall blade has a curved tip like a Miller blade. There is a reduced flange to decrease the potential for damage to the upper teeth. It may be useful for an anaesthesia provider with limited use of the left arm.

mm) Whitehead blades

The Whitehead blade is a modification of the Wis-Foregger blade. The flange is reduced in height and open proximally and distally.

Flexible tip blades

There are a number of blades from different manufacturers that have a flexible tip that is controlled by a lever attached to the proximal end of the blade. When the lever is pushed toward the handle, the tip of the blade is flexed. These are available under various names: CLM (Corazzelli, London, and McCoy), McCoy, Flipper, Flex tip, levering laryngoscope blade, articulating laryngoscope blade. A pediatric version using a Seward-type blade and adult versions using Miller and Macintosh blades are available. The tip is less rounded than on the usual Macintosh blade. It may be helpful to use a narrow handle with these blades.

This laryngoscope may be helpful when a difficult intubation is encountered. It may be especially useful in patients with minimal neck movement. External laryngeal pressure may further improve the view. However, it will not always improve the view and may worsen it. Even if the blade does not improve the view of the larynx, it may improve the likelihood of successful intubation by elevating the epiglottis. In some patients in whom the view is satisfactory with the Macintosh blade, use of the McCoy may make the view worse.

Studies have shown that use of this blade results in significantly less force being applied and a reduction in the stress response compared to the Macintosh blade.

Failure of the McCoy blade has been reported. The connection of the lever mechanism was broken so the tip of the blade would not flex. Detachment of the hinged tip from the blade has been reported. Arytenoid dislocation has been reported with its use.

nn) Flexiblade

The Flexiblade is a stainless steel blade with six slots and seven windows on the flange. A control trigger causes the blade to change its shape from curved to nearly straight. Gentle squeezing of the trigger alters the curvature from 9° to 30°. The blade is inserted with the control trigger released. This permits the blade to be pulled back when encountering resistance from the tongue and mandible. The Flexibater adjustable laryngoscope is similar in shape to a Macintosh laryngoscope, but the distal tip changes its shape according to the pressure that is placed on the trigger.

The Flexiblade can be used for both routine and difficult intubations. In most cases the view improves when the blade is flexed. The Flexiblade has been reported to have broken after only five uses. Another problem involved incorrect assembly. The light bundle was on the wrong side of the blade and pointing away from the larynx. There have been reports of damage to the teeth and gums. A tongue laceration was also noted after an attempt at intubation with the incorrectly assembled blade.

oo) VitalView blade

The VitalView laryngoscope blade is a disposable plastic blade containing a fibre light. There was no significant difference in the view of the glottis or the success rate of tracheal intubation with the VitalView compared to a reusable metal blade.

pp) Henderson blades

Henderson blades are straight blades with an improved tip and light as well as a larger cross-sectional area. When used with the paraglossal technique a better view is obtained by optimizing control of the soft tissues and improving the line of sight.

qq) Cardiff blade

The Cardiff blade is designed for use in children from birth to adolescence. There is only one size. The blade is 10 cm long. The distal 4 cm is curved. Proximally the blade has a Z-section. The web and flange are attenuated distally so that the terminal 15 mm continues as a curved spatula, narrowing to 8 mm at the tip. It terminates with a thickened, transverse bead.

rr) Dorges blade

The Dorges laryngoscope blade combines features of both the Miller and Macintosh blades. Compared with the Macintosh, the flange has a lower height, and the curve of the blade is less. It is available in only one size and can be used in patients >10 kg. It has 10 kg and 20 kg markings on the blade. Studies have found that the Dorges did not perform any better than the standard Macintosh blade in easy or difficult intubation scenarios.

ss) Viewmax blade

The Viewmax laryngoscope has an optic side port on a standard Macintosh blade that refracts the image approximately 20° from the horizontal. This modification allows for a more anterior view from a position 1 cm behind the left tip of the blade while at the same time allowing the standard direct view.

tt) Truview blade

The Truview blade is a standard Macintosh blade that incorporates an unmagnified optic side (prism). Adult and pediatric sizes are available. The prism causes a 20° angle of refraction. It can be used as a straight or curved blade.

uu) Huffman prism and prism laryngoscope blade

The Huffman prism and prism laryngoscope blades are designed to provide an indirect view of the larynx in patients in whom direct exposure is difficult. The prism is a block of Plexiglas shaped to fit on the proximal end of a No. 3 Macintosh blade. It is fastened onto the blade with a steel clip. The ends are polished to produce optically flat surfaces. A refraction of 30° in the line of sight is provided, thereby bringing into view structures within a few millimetres of the tip of the blade. The image is right side up. It is necessary to warm the prism before use to prevent condensation.

The prism laryngoscope blade has the prism built into the blade. An additional 20° refraction from right to left is added, because the prism is to the left of the midline. The prism laryngoscope blade allows either conventional direct exposure of the larynx or indirect viewing through the prism."

Annex E
(informative)

Rationale for inclusion of certain requirements

Subclause 4.3.1

The laryngoscope components are expected to be exposed to the environmental extremes outlines in 4.3.1, since such extremes are often reached throughout the world in places where laryngoscopes are used and therefore users should expect to be able to use them without question. If a manufacturer claims a wider range of environmental tolerances, this claim has to be validated.

Although laryngoscopes are designed in a manner that allows them to be used in very dry conditions, no test is specified because it was felt that devices within the scope of this International Standard were unlikely to have their performance affected by very dry ambient conditions. It is expected that the manufacturer will perform a failure analysis to establish the possible effects of the lowest humidity specified.

Subclause 4.4

There have been incidents reported of battery short circuits, resulting in excessive heat generation within the laryngoscope handle. The high current capacity of some types of batteries, particularly those which are rechargeable, 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.

Subclause 7.1

High-powered lamps that are used to make good the losses of light in fibre-light guides operate at higher temperatures, and can be hazardous if they can be fitted where they might make tissue contact. Consequently, they are not compatible with the sockets described in Clause 8.

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.

Subclause 8.2.1

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 was considered that the merits of metrication were insufficient to outweigh this hazard to the patient and the use of existing inch-series threads has been continued.

Subclause 9.2

It is known that repeated sterilization cycles of laryngoscope blades degrade the light transmission of fibre-optic bundles and also other components of other light systems such as incandescent bulbs. Therefore, this International Standard requires the manufacturer to validate the performance of the device(s) after the number of specified sterilization cycles. See also Clause 11, item c).

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.

Clause 11, item m)

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

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