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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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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 7376:2009), which has been technically revised.

The main changes compared to the previous edition are as follows:

— the layout has changed to align with ISO 18190:2016;

— removal of the requirements for filament *luminaires*, which are now almost entirely replaced by LED *luminaires*;

— additional requirement to prevent current surges from batteries with a rated voltage exceeding 3,6 V;

— test methods have been rationalized;

— each requirement is now followed by a conformance requirement;

— the strength requirement has been extended to *handles*;

— environmental conditions during transport, storage and normal use are now referenced to IEC 60601-1-12.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Laryngoscopes are manufactured in several forms. There are, for example, *single-piece laryngoscopes*, *non-user-detachable hinged laryngoscope blades*, or detachable hinged laryngoscope blades and *handles*. In the latter case, the light source for illuminating the larynx during use is either a *luminaire* fixed in the laryngoscope blade or a *luminaire* in the *handle* with a light guide in the laryngoscope blade. The minimum light output from the laryngoscope is specified.

Laryngoscope blades are defined and marked by size designation (see Table 2), suitable for the patient demographic for which they are designed and ranges from small, premature infants to extra-large adults. Because there are so many variations, the length of laryngoscope blade is disclosed on the packaging to allow an informed decision by the operator to select the most appropriate instrument for intubation. Annex B describes test methods for illumination, rigidity and strength.

Throughout this document the following print types are used:

— Requirements and definitions: roman type;

— *Conformance tests: italic type*;

— Informative material appearing outside of tables, such as notes, examples and references: smaller type. The Normative text of tables is also in smaller type;

— *Terms defined in Clause 3: italics*.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation

1 *Scope

This document, which is device-specific, specifies requirements for laryngoscopes with non-flexible blades, with internal battery-operated power sources, used for illuminating the larynx during intubation. It also specifies critical dimensions for those *handles* and laryngoscope blades with interchangeable *hook-on fittings*.

It is not applicable to the following:

— flexible laryngoscopes;

— laryngoscopes designed for surgery;

— laryngoscopes powered from mains electricity supply;

— laryngoscopes connected by light-transmitting cables to external light sources;

— video laryngoscopes designed to work with an external, integral or attached video system.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 4135, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 18190:2016, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

IEC 60601-1-12:2014, *Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment*

3 *Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, ISO 18190 and the following apply:

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
contact
metallic part that provides the electrical connection between a hinged laryngoscope blade and *handle* (3.4)

3.2
directly illuminating laryngoscope blade
laryngoscope blade incorporating a *luminaire* (3.8)

3.3
engagement
mechanical attachment of the laryngoscope blade and *handle* (3.4) such that the blade remains coupled to the *handle* in all positions

3.4
handle
component held in the hand during use

3.5
hook-on fitting
mechanical connection between a *handle* (3.4) and a user-detachable laryngoscope blade

3.6
light-guide illuminated laryngoscope blade
laryngoscope blade that transmits light from a source in the *handle* (3.4)

3.7
locking mechanism
mechanism that retains the laryngoscope blade in the operating position

3.8
luminaire
light source

3.9
non-user-detachable hinged laryngoscope blade
folding laryngoscope blade that cannot be separated from a *handle* (3.4) by the operator

3.10
single-piece laryngoscope
handle (3.4) with a fixed laryngoscope blade

4 General requirements

The applicable requirements of ISO 18190:2016, Clause 4 shall apply.

5 Materials

The applicable requirements of ISO 18190:2016, Clause 5 shall apply.

6 Design requirements

6.1 General

The applicable requirements of ISO 18190:2016, Clause 6 shall apply.

6.2 *Environmental conditions

Laryngoscopes shall remain operational when subjected to the environmental conditions specified in IEC 60601-1-12:2014, 4.1.

7 Performance requirements

7.1 *Handles*

7.1.1 *Electrical safety

Handles with a rated voltage exceeding 3,8 V and designed for use with *hook-on fitting, directly illuminating laryngoscope blades*, shall incorporate a means of preventing the electrical current from exceeding 800 mW peak (measured over a period of 100 ms) and from exceeding 400 mW continuous during normal use and single fault conditions.

NOTE 1 For a *handle* rated at 6 V, these are equivalent to current limits of 133 mA and 67 mA respectively.

NOTE 2 The return electrical circuit is through unspecified parts of the *hook-on fitting*.

Check conformance by inspection of the technical file.

7.1.2 Electrical *contact*

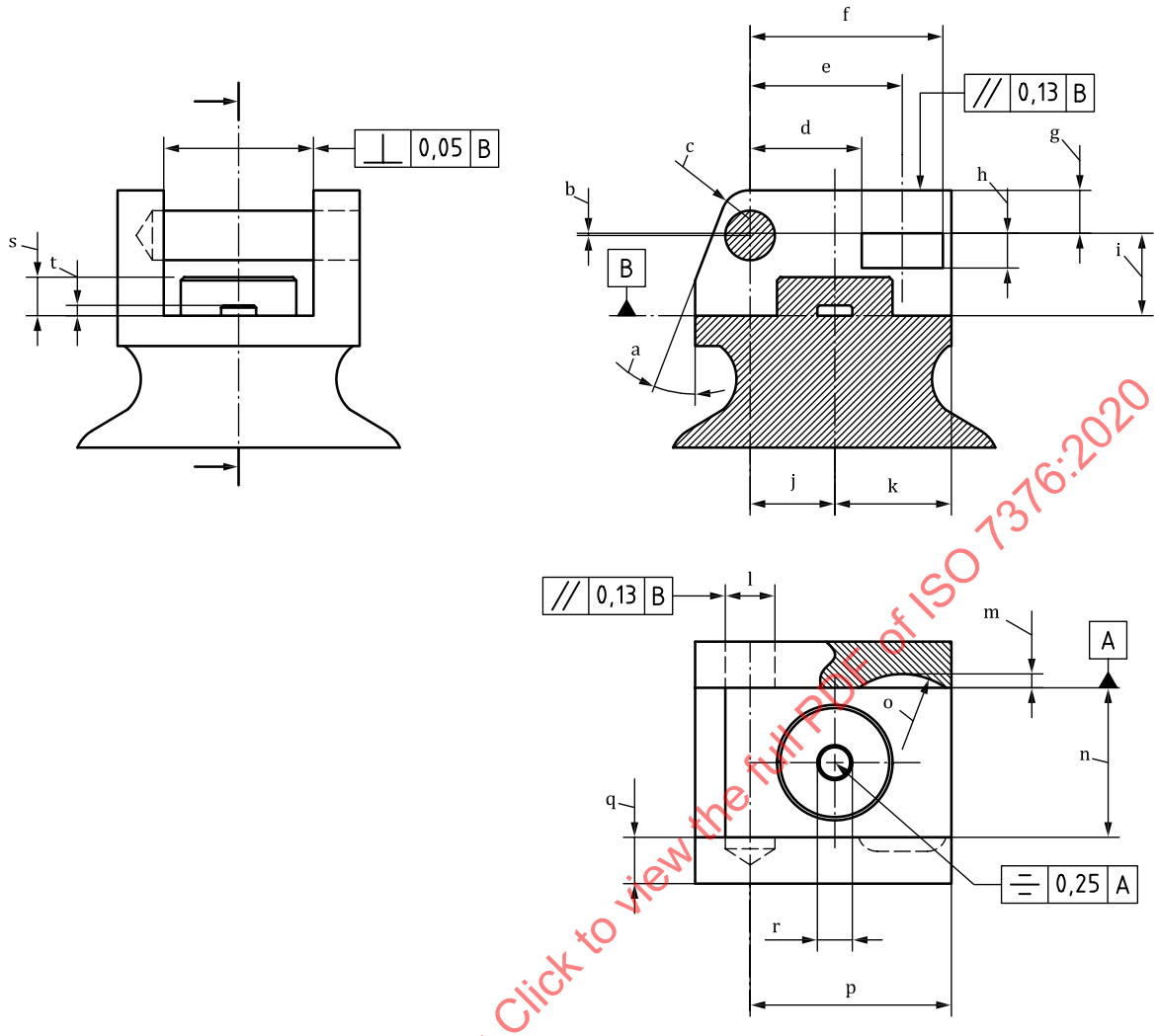
The electrical *contact* of a *handle* that can accept a *hook-on fitting, directly illuminating laryngoscope blade* shall be either flexible or spring-loaded.

Check conformance by functional testing.

7.1.3 Dimensions

Handles for use with *hook-on fitting, directly illuminating laryngoscope blades* and *hook-on fitting, light-guide illuminated laryngoscope blades* shall conform to the dimensions given in Figure 1, and Table 1.

Check conformance by functional testing.



NOTE Drawing not to scale.

Figure 1 — Dimensions of *handle hook-on fitting* for *directly illuminating laryngoscope blades* and *light-guide illuminated laryngoscope blades*

Table 1 — Dimensions of *handle hook-on fitting* for *directly illuminating laryngoscope blades* and *light-guide illuminated laryngoscope blades*

Reference	*Light-guide illuminating laryngoscope blades* Dimension	*Directly illuminating laryngoscope blades* Dimension
a	≤21°	N/A
b	0,200 ± 0,150	0 ± 0,150
c	(R3,800)	≥R1,520
d	≤10,820	≤9,400
e	(14, 175)	(11,685)
f	≥17,530	≥13,970
g	3,910 ± 0,1	3,250 ± 0,100
h	≥3,170	≥2,260

[a] Two positions.

Dimensions in mm unless otherwise indicated

Table 1 *(continued)*

Reference	***Light-guide illuminating laryngoscope blades*** Dimension	***Directly illuminating laryngoscope blades*** Dimension
i	7,490 ± 0,130	7,160 ± 0,130
j	7,700 ± 0,450	6,350 ± 0,250
k	(10,870)	(9,140)
l	4,505 ± 0,065	3,950 ± 0,050
m	≥1,270[a]	≥0,760[a]
n	13,610 ± 0,050	12,900 ± 0,050
o	≥R6,000	R6 ± 0,1 ≥R5,080
p	≥18,570	≥15,490
q	≥4,200	≥4,200
r	N/A	3,180 ± 0,250
s	3,500 – 2,200 "Out" 2,200 – 0,500 "On"	N/A
t	N/A	0,940 + 1,650, –0,130

[a] Two positions.

Dimensions in mm unless otherwise indicated

7.1.4 *Optical output

The optical output of *handles* designed for use with *hook-on fitting*, *light-guide illuminated laryngoscope blades* shall be >5 lumen.

Check conformance by the test method given in Annex B.

7.1.5 *Strength

When subjected to a tensile force of 150 N the *handle,* or parts thereof, shall not break.

Check conformance by the test method given in Annex B.

7.2 *Laryngoscope blades*

7.2.1 Dimensions

Hook-on fitting, *directly illuminating laryngoscope blades* or *light-guide illuminated laryngoscope blades* (as shown in Figure 3) shall be compatible with the *handle hook-on fitting* shown in Figure 1.

7.2.2 *Rigidity

When subjected to a tensile force of 65 N the illumination centre shall not move by more than 10 mm.

Check conformance by the test method given in Annex B.

7.2.3 *Strength

When subjected to a tensile force of 150 N the laryngoscope blade shall not break.

Check conformance by the test method given in Annex B.

7.2.4 *Illumination

The illumination shall meet the following requirements when measured (20 ± 0,1) mm from the tip of the laryngoscope blade:

a) widest dilatation between left and right illumination edges;

b) widest dilatation between upper and lower illumination edges;

c) tip of laryngoscope blade to lower illumination edge;

d) maximum illuminance >10 min. See Figure B.1.

Check conformance by the test method given in Annex B.

7.2.5 Electrical interface

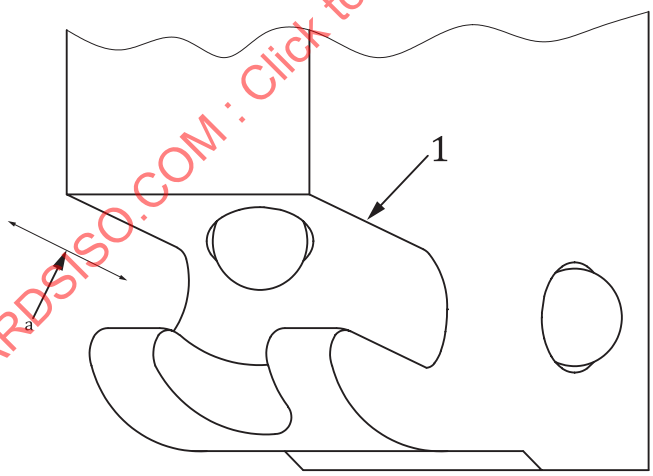
The electrical *contact* between a *hook-on fitting*, *directly illuminating laryngoscope blade* and a *handle* shall not be broken when a 150 N load is applied to the tip of the laryngoscope blade as shown in Figure B.3.

Check conformance by functional testing

7.3 *Hinged combinations*

7.3.1 The force required for *engagement* of a *hook-on fitting* laryngoscope blade to a *handle* hinge pin shall be between (10 and 45) N in the direction shown in Figure 2. When engaged the laryngoscope blade shall be free to rotate about the pin under its own weight.

Check conformance by functional testing.



Key

1 hinge slot

[a] Force axis parallel to slot.

NOTE Drawing not to scale.

Figure 2 — Axis for *engagement*/disengagement force

7.3.2 *Hook-on fitting* and hinged laryngoscope blade and *handle* combinations shall

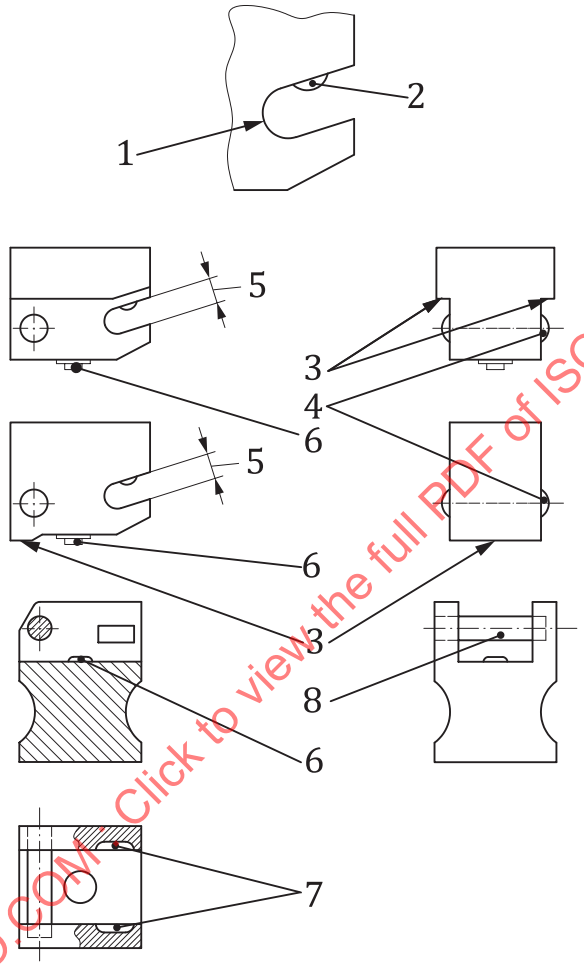
a) lock in the operating position when a torque between (0,35 and 1,35) Nm is applied to the laryngoscope blade,

b) illuminate, and

c) remain illuminated when the laryngoscope is held in any orientation.

Check conformance by functional testing.

NOTE Typical *hook-on fittings* for *directly illuminating laryngoscope blades* and *handles* are shown in Figure 3.



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*
7 locking slot (detent)
8 hinge pin

Figure 3 — Typical *hook-on fitting* configurations for *directly illuminating laryngoscope* or *light-guide illuminated laryngoscope blades* and *handles*

7.4 *Single-piece laryngoscopes*

Single-piece laryngoscopes shall be provided with a means to control the power to the *luminaire*.

Check conformance by inspection and functional testing.

8 Cleaning, disinfection and sterilization

Laryngoscope blades and *handles* not intended for single use shall be suitable for cleaning, disinfection and/or sterilization.

9 Information supplied by the manufacturer

9.1 General

The appropriate requirements of ISO 18190:2016, Clause 9 shall apply.

9.2 Marking

9.2.1 Laryngoscope blades shall be marked with the following:

a) the designated size expressed in numerals, in accordance with Table 2;

b) material designation or recycling code;

c) their size and type, if they have removable fibre-illuminated components;

d) if appropriate, “single-use” or equivalent, which shall be visible from the operating position.

NOTE An appropriate symbol can be used e.g. ISO 7000-1051[1].

9.2.2 Packaging shall be marked with the designated size and type of laryngoscope blade in accordance with Table 2.

9.3 Designated size for the intended patient demographic

Table 2 — Designated sizes

Designated size	Intended patient demographic
000	Small premature infant
00	Premature infant
0	Neonate
1	Small child
2	Child
3	Adult
4	Large adult
5	Extra-large adult

9.4 Instructions for use

The instructions for use shall include the following:

a) specifications of and instructions for fitting batteries;

b) *if appropriate, a warning that batteries should be removed prior to cleaning and disinfection or sterilization;

c) for single-use laryngoscopes, the maximum storage lifetime;

d) instructions to check the condition of the battery by activating the *luminaire* before use;

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

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

g) a warning to the effect that only trained personnel or those undergoing training shall use a laryngoscope for intubation;

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

i) information relating to *handle* and laryngoscope blade compatibility/interoperability.

Annex A
(informative)

Rationale

Clause 1 — Scope

Battery powered laryngoscopes are classified as electromedical equipment as defined in IEC 60601-1[5], the general safety standard for medical electrical equipment, however as this document excludes mains powered laryngoscopes, the requirements of IEC 60601-1[5] are less prescriptive. The interchangeability of laryngoscope blades and *handles* is addressed by specifying the dimensions and tolerances of the *hook-on fittings* for *handles* and laryngoscope blades.

Clause 3 — Terms and definitions

	Directly illuminating laryngoscope blade	***Light-guide illuminated laryngoscope blade***	***Non-user-detachable hinged laryngoscope blade***	***Single-piece laryngoscope***
engagement	Yes	Yes	No	No
Hinged laryngoscope blade *hook-on fittings*	Yes	Yes	Yes	No
locking mechanism	Yes	Yes	Yes	N/A
operating position	Yes	Yes	Yes	Always
Interface	Electrical	Optical	Not defined	Not defined

Subclause 6.2 — Environmental conditions

The laryngoscope components are expected to be exposed to the environmental extremes outlined in IEC 60601-1-12 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 should be validated.

Subclause 7.1.1 — Electrical safety

There have been incidents reported of battery short circuits within the laryngoscope *handle* resulting in excessive heat generation. The high current capacity of some types of batteries, particularly those which are rechargeable, can result in excessive operating temperatures. Such batteries can also produce sparks with sufficient energy to ignite flammable anaesthetic gases and the user should be made aware of this hazard.

There have also been incidents reported in which a laryngoscope blade with a 3 V filament bulb has been used with a *handle* intended for a laryngoscope blade with a 6 V LED light source, and the bulb has shattered as a result of overload current. There are also concerns (but no case reports) that a filament bulb might exceed the safe temperature for patient contact when used with an incorrectly rated voltage source.

Including a requirement for a current limiting device in the *handle* for a conventional laryngoscope with a rated voltage significantly greater than 3 V will prevent both types of incident. The worst-case scenario is that the lamp will not illuminate, and this should be detected when the device is tested prior to use.

Subclause 7.1.4 — Optical output

A *handle* light output of 5 lumen provides an approximate illuminance of 500 lux at the tip of the laryngoscope blade for all sorts of laryngoscope blades (e.g., reusable, disposable, fibre-optic, light-guide).

Subclauses 7.1.5, 7.2.2 and 7.2.3 — Rigidity and Strength

Laryngoscope blades and *handles* are subjected to tensile forces when used under normal conditions and even higher tensile forces during difficult intubations. Laryngoscope blades and *handles* should therefore be able to cope with these forces and not flex so that the illumination of the larynx is affected or, worse still, the blade or *handle* breaks.

Subclause 7.2.4 — Illumination

Consistent illumination of the laryngeal inlet which is approximately 20 mm (in width) by 25 mm (antero-posteriorly) is essential for successful tracheal intubation.

Subclause 9.4 b) — Instructions for removal of batteries

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

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.

Annex B
(normative)

Test method for illumination, strength and rigidity

B.1 Principle

The illumination is tested without the laryngoscope blade being under load prior to the tests for strength and rigidity which introduce a tensile load near the tip of the laryngoscope blade while the *handle* is securely held. Rigidity is confirmed by measuring the difference between the illuminated area at rest and when under load. Strength is confirmed by the laryngoscope blade and parts of the *handle* not breaking.

B.2 Test apparatus

a) Laryngoscope blade and *handle* under test;

b) Means of securing the *handle*;

c) Means of applying tensile loads of 65 N and 150 N;

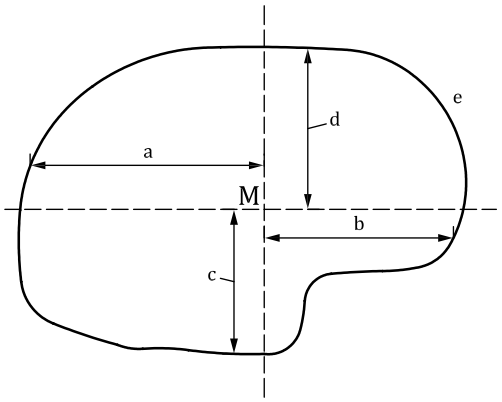
d) Translucent sheet of white paper or means of measuring illuminance distribution;

e) Means of measuring illuminance (e.g. lux meter);

f) Means of measuring luminous flux (e.g. integrating sphere).

B.3 Procedure

a) Attach the laryngoscope blade to an appropriate *handle*, secure and activate the light. In a darkened room, place the detector of the measurement device (20 ± 0,1) mm from the tip of the laryngoscope blade in a plane approximating the position of the vocal cords in relation to the laryngoscope blade, when the laryngoscope blade is in the operating position and normal to the line of sight and measure the maximum illuminance.



Key	Description	
a + b	widest dilatation between left and right illumination edges	(50 to 100) mm
c + d	widest dilatation between upper and lower illumination edges	(30 to 80) mm
e	tip of laryngoscope blade/lower illumination edge	<3 mm

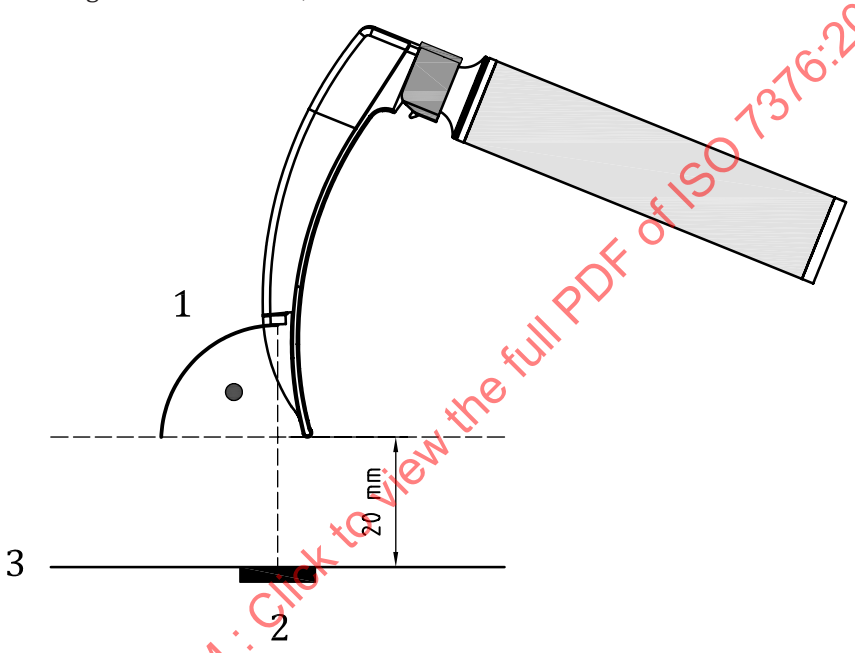
Key	Description	
M	maximum illuminance for >10 min	>500 lux

Figure B.1 — Illuminated area and maximum illuminance

b) Either measure the illuminance distribution or place a white translucent piece of paper (20 ± 0,1) mm from the tip to determine the size of the illuminated area. See Figure B.2.

NOTE 1 The illumination edges are defined by the d_{10} value. This is the checkpoint at which the value is only 10 % of the maximal illuminance.

NOTE 2 Illumination might not be uniform, i.e. oval or round.



Key

1 laryngoscope (light output perpendicular to 2 and 3)
2 detector (e.g. luxmeter)
3 piece of paper

Figure B.2 — Maximum Illuminance and illuminated edges

c) Apply a 65 N perpendicular tensile force vertically down from the tip of the laryngoscope blade as illustrated in Figure B.3. and check that there is <10 mm movement of the laryngoscope blade tip from the initial position.