

ISO/TC 121/SC 2

Secretariat: ANSI

Voting begins on:
2020-03-30

Voting terminates on:
2020-05-25

Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation

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

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Reference number
ISO/FDIS 7376:2020(E)

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Published in Switzerland

Contents

Page

Foreword.....	iv
Introduction.....	v
1 *Scope	1
2 Normative references	1
3 *Terms and definitions	1
4 General requirements	2
5 Materials	2
6 Design requirements	2
6.1 General.....	2
6.2 *Environmental conditions.....	2
7 Performance requirements	3
7.1 <i>Handles</i>	3
7.1.1 *Electrical safety.....	3
7.1.2 Electrical <i>contact</i>	3
7.1.3 Dimensions.....	3
7.1.4 *Optical output.....	5
7.1.5 *Strength.....	5
7.2 Laryngoscope blades.....	5
7.2.1 Dimensions.....	5
7.2.2 *Rigidity.....	5
7.2.3 *Strength.....	5
7.2.4 *Illumination.....	6
7.2.5 Electrical interface.....	6
7.3 Hinged combinations.....	6
7.4 <i>Single-piece laryngoscopes</i>	7
8 Cleaning disinfection and sterilization	8
9 Information supplied by the manufacturer	8
9.1 General.....	8
9.2 Marking.....	8
9.3 Designated size for the intended patient demographic.....	8
9.4 Instructions for use.....	8
Annex A (informative) Rationale	10
Annex B (normative) Test method for illumination, strength and rigidity	12
Annex C (informative) Common terms for parts of a laryngoscope blade	15
Bibliography	16

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.

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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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](#).

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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 requirements given 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

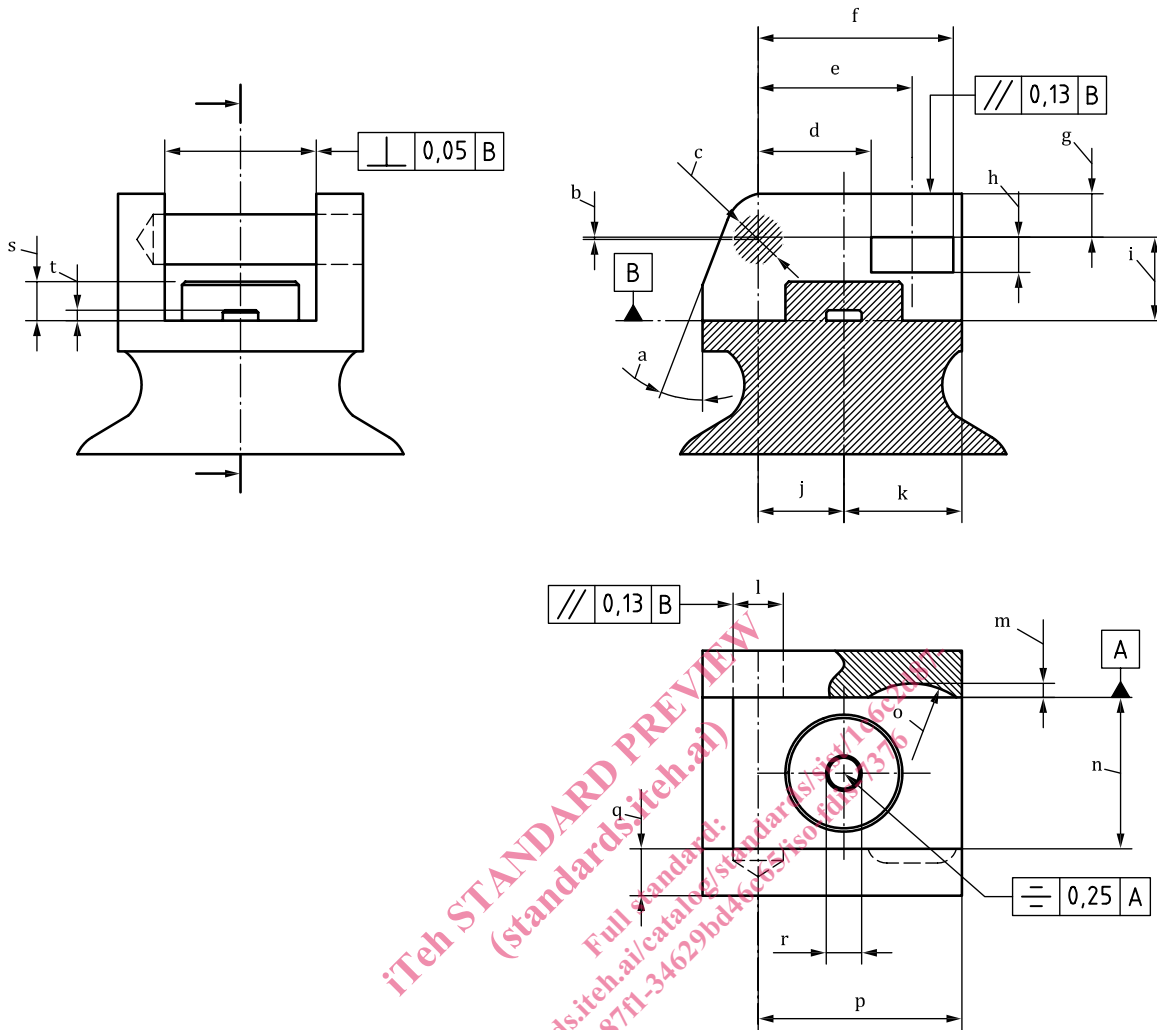
The electrical *contact* of a *handle* that can accept a *hook-on fitting, directly illuminating laryngoscope blade* shall be either flexible or spring-loaded.

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	Directly illuminating laryngoscope blades
	Dimension	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