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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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## Contents

Page

Foreword .....	iv
Introduction .....	v
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 General requirements</b> .....	<b>3</b>
4.1 Design .....	3
4.2 Materials for laryngoscope blades and single-piece laryngoscopes .....	3
4.3 Environmental requirements .....	3
4.4 * Internal electrical power source.....	3
<b>5 Performance requirements</b> .....	<b>3</b>
5.1 Blade and handle hook-on fittings .....	3
5.2 Handle fittings .....	3
5.3 Blade fittings .....	6
5.4 Engagement.....	6
5.5 Operating position.....	6
5.6 Disengagement .....	6
<b>6 Lamp for conventional blade</b> .....	<b>8</b>
6.1 Lamp and lamp base contact.....	8
6.2 Screw threads for lamps .....	8
<b>7 Lamps for fibre-illuminated laryngoscopes</b> .....	<b>10</b>
<b>8 Sockets for conventional blades</b> .....	<b>10</b>
8.1 Dimensions and centre contact.....	10
8.2 Internal screw threads .....	10
<b>9 Cleaning, disinfection and sterilization</b> .....	<b>10</b>
<b>10 Marking and labelling</b> .....	<b>10</b>
<b>11 Accompanying documents</b> .....	<b>11</b>
<b>Annex A (normative) Test method for security of lamp contact</b> .....	<b>12</b>
<b>Annex B (normative) Blade markings</b> .....	<b>13</b>
<b>Annex C (informative) Rationale</b> .....	<b>14</b>
<b>Bibliography</b> .....	<b>15</b>

## 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.

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## 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.

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# 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  $-40\text{ }^{\circ}\text{C}$  to  $+70\text{ }^{\circ}\text{C}$ ;
- 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  $3 \times$  normal current flowing in a single fault condition.

## 5 Performance requirements

### 5.1 Blade and handle hook-on fittings

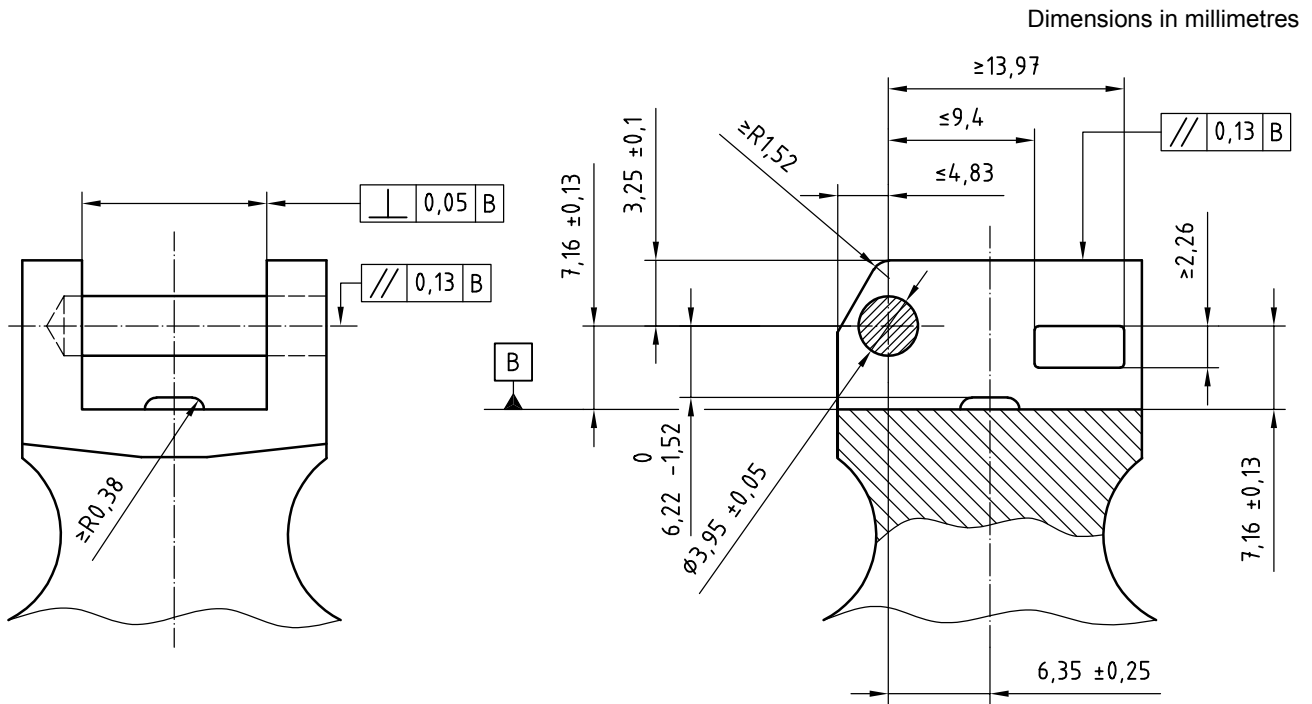
Detachable hook-on blade and handle combinations that engage shall lock and illuminate when in the operating position, and shall stay illuminated when the laryngoscope is held in any orientation.

### 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.



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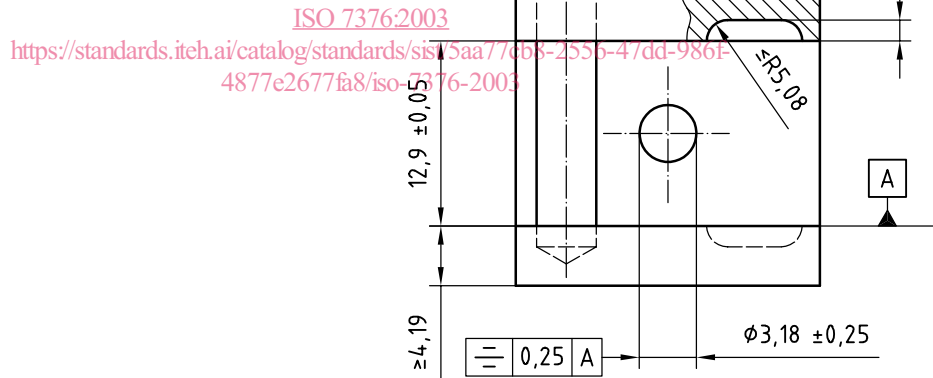
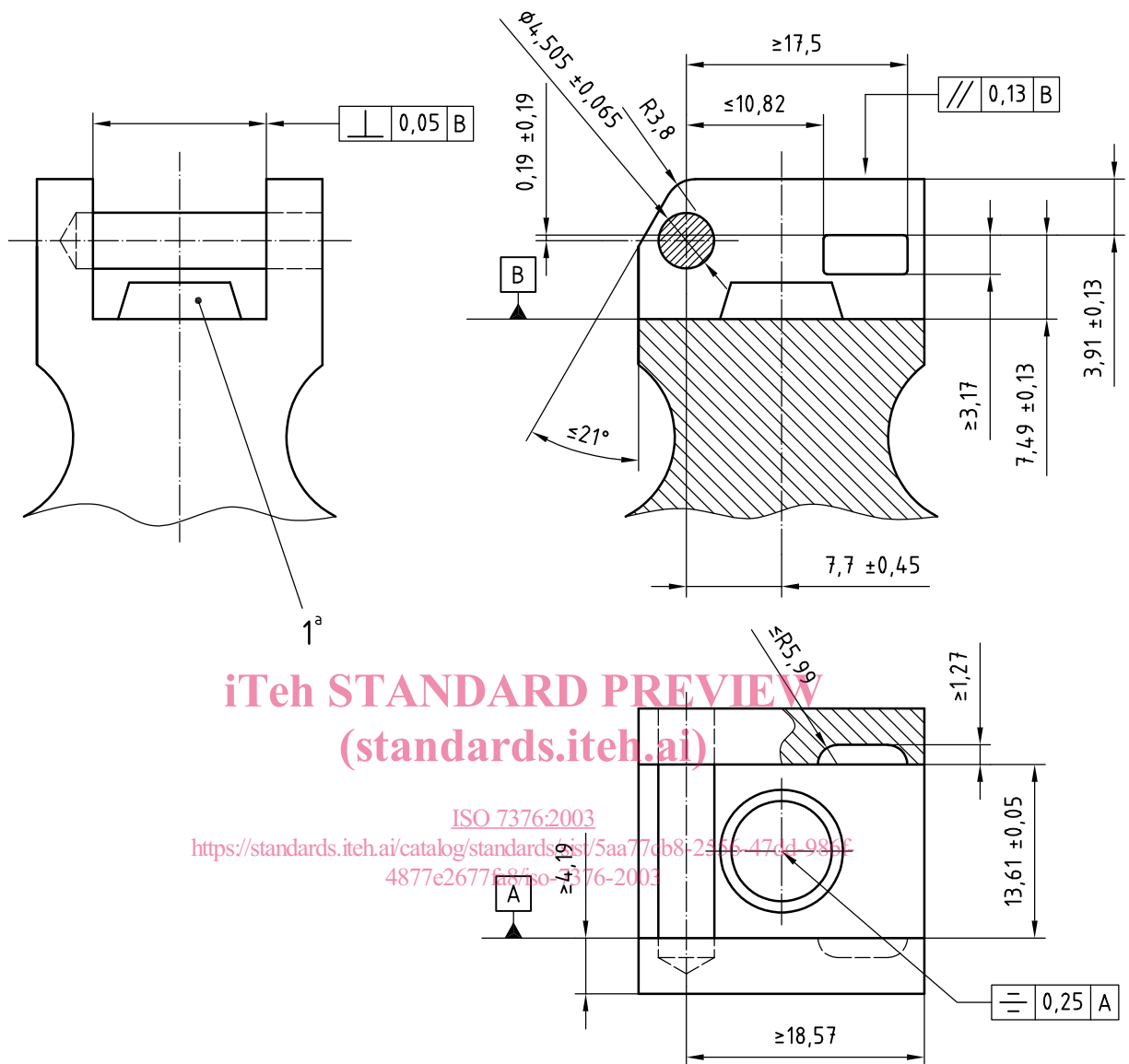


Figure 1 — Handle hook-on fitting of conventional system

Dimensions in millimetres



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**Key**

1 spring-loaded switch

NOTE Drawing not to scale.

<sup>a</sup> 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.