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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

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 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.

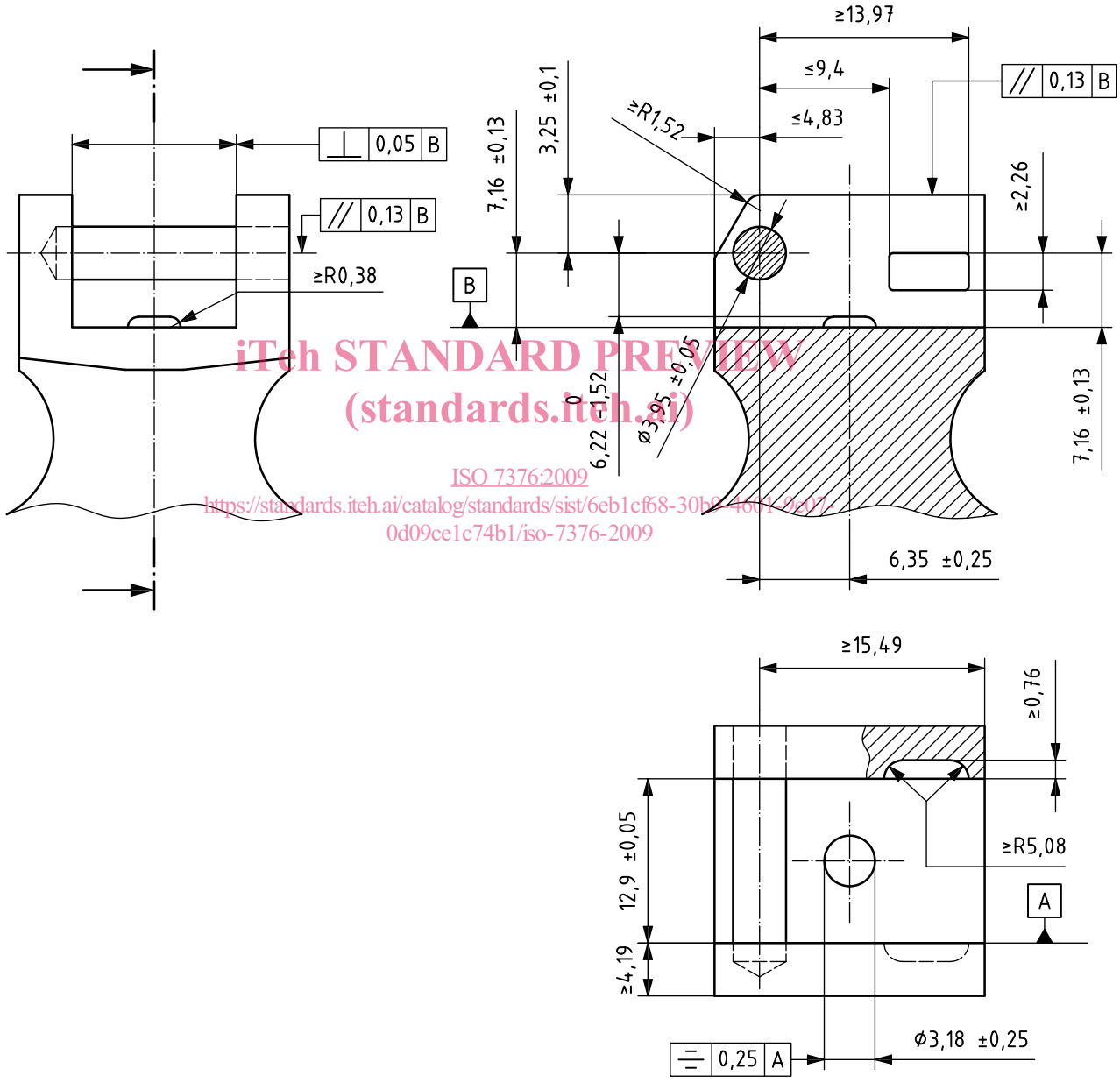
5.4.2.2 The electrical contact of a conventional blade shall be rigid. The electrical contact of a handle that can accept a conventional blade shall be either flexible or spring-loaded.

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.

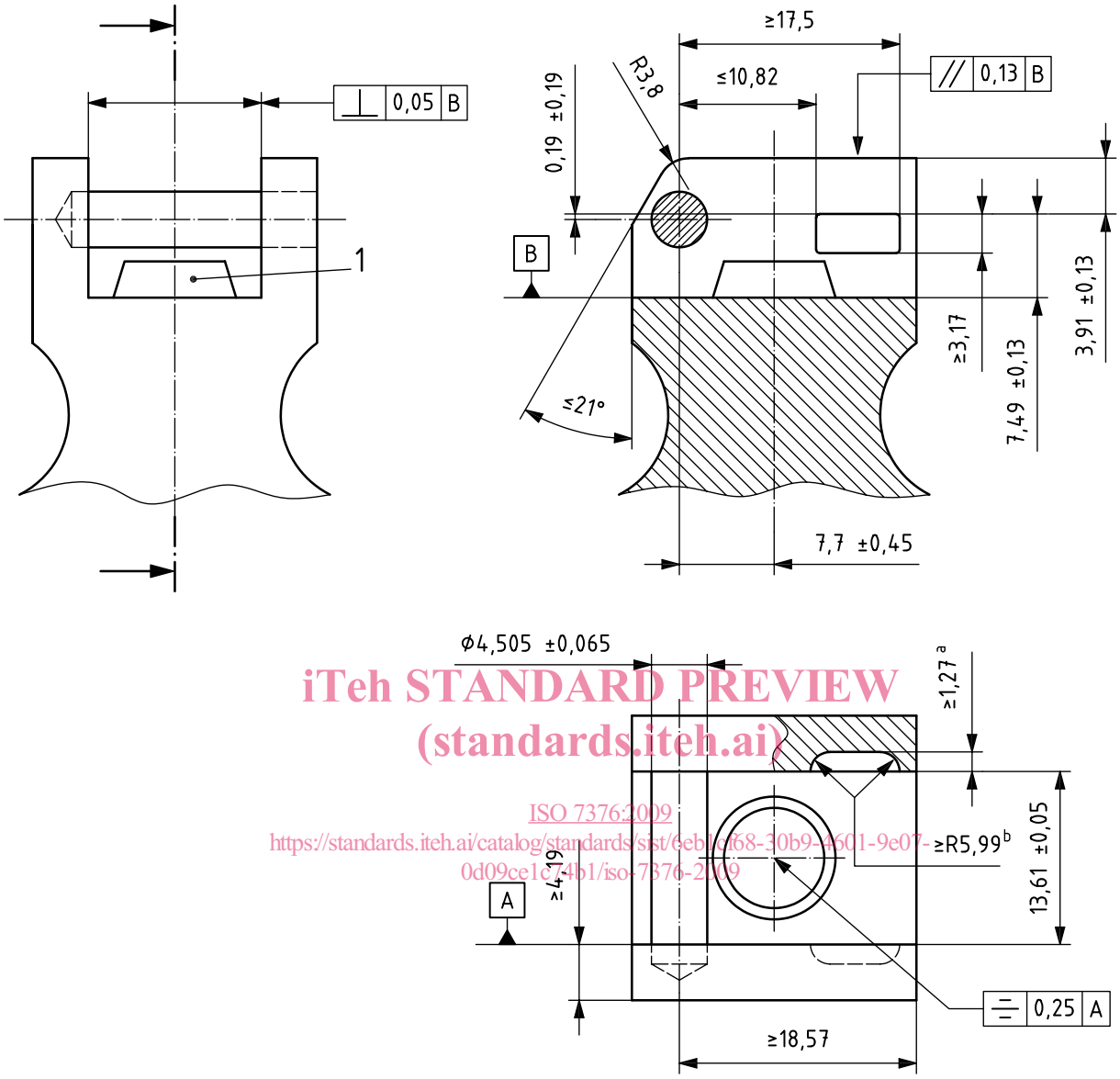
Dimensions in millimetres



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.