

INTERNATIONAL
STANDARD

ISO
7376-3

First edition
1996-12-15

Laryngoscopic fittings —

Part 3:

Fibre-illuminated re-usable rigid laryngoscopes

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Éléments de laryngoscopes —

Partie 3: Laryngoscopes à fibres optiques rigides, réutilisables

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INTERNATIONAL

ISO



Reference number
ISO 7376-3:1996(E)

Foreword

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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.

International Standard ISO 7376-3 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

ISO 7376 consists of the following parts, under the general title *Laryngoscopic fittings*:

- Part 1: *Conventional hook-on type handle-blade fittings*
- Part 2: *Miniature electric lamps — Screw threads and sockets for conventional blades*
- Part 3: *Fibre-illuminated re-usable rigid laryngoscopes*

Annexes A and B of this part of ISO 7376 are for information only.

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Introduction

In clinical anaesthesia and resuscitation, a variety of laryngoscopes are widely used for direct laryngoscopy. Because there is a clinical need for a variety of blade forms, they are usually manufactured as detachable blade and handle units.

There are two basic types of rigid laryngoscopes: those in which the light source is in the blade with a power source in the handle and those in which the light source is in the handle with a rod or optical fibres being used to transmit light to the blade. The former type is specified in ISO 7376-1 and ISO 7376-2 while this part of ISO 7376 specifies two designs of the latter type.

The aim of this part of ISO 7376 is to promote ready interchangeability, within each of the two specified designs, between blades and handles of the hook-on type made by different manufacturers.

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Laryngoscopic fittings —

Part 3:

Fibre-illuminated re-usable rigid laryngoscopes

1 Scope

This part of ISO 7376 specifies basic dimensions and performance requirements for two designs of hook-on type re-usable rigid laryngoscopes, in which light from a source in the handle is transmitted to the blade by means of an illuminating rod or illuminating fibres. Requirements are also specified for colour-coding the blades and handles of each of the two designs to facilitate recognition of compatible blades and handles, and to differentiate fibre-illuminated rigid laryngoscopes from those covered in ISO 7376-1.

No attempt has been made in this part of ISO 7376 to standardize either the blade form or handle design except for the connection point between the two.

Laryngoscope blades and handles intended for single use, flexible laryngoscopes and those intended for specialist types of surgery are outside the scope of this part of ISO 7376.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 7376. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 7376 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 7376-1:1994, *Laryngoscopic fittings — Part 1: Conventional hook-on type handle-blade fittings.*

ISO 7376-2:—¹⁾, *Laryngoscopic fittings — Part 2: Miniature electric lamps — Screw threads and sockets for conventional blades.*

3 Definitions

For the purposes of this part of ISO 7376, the following definitions apply.

3.1 fibre-illuminated blade: Rigid component shaped to provide a direct view of the larynx, and which incorporates optical fibres to transmit light from a source in the handle. [ISO 4135:1995]

3.2 fibre-illuminated handle: Component held in the hand during use, which incorporates the light source and connection for the blade. [ISO 4135:1995]

3.3 contact: Components of the fittings which come together to make an electrical circuit and thus energize the light source when the blade and handle are engaged in the operating position. [ISO 4135:1995]

3.4 engagement: Mechanical attachment of the blade and handle so that the blade remains securely coupled to the handle in all positions.

3.5 operating position: Position of the engaged blade and handle when the rigid laryngoscope is ready for use.

1) To be published. (Revision of ISO 7376-2:1984)

3.6 locking mechanism: Mechanism that retains the blade in the operating position.

3.7 to illuminate: To project a beam of light upon the larynx.

4 Dimensions and performance

4.1 Test method

The requirements specified in 4.3 to 4.5 shall be determined with the blade attached to an appropriate test handle for the colour system being tested.

4.2 Handle fittings

The dimensions for handle fittings shall be in accordance with figure 1 or 2, as appropriate to the handle hook-on system used.

4.3 Blade fittings

Fibre-illuminated blade fittings shall not engage with handle fittings of non-fibre-illuminated rigid laryngoscopes specified in ISO 7376-1.

4.4 Engagement and disengagement

4.4.1 A detachable fibre-illuminated blade that engages with a handle having fittings as specified in 4.2 shall lock and illuminate when in the operating position.

4.4.2 When engaged, the blade shall be retained on the handle when the handle is held in any position.

4.4.3 When an engagement force between 10 N and 45 N is applied along the force axis shown in figure 3, the blade shall engage with the handle. When engaged, the clearance between the side of the handle slot and the blade shall not exceed 0,28 mm.

4.4.4 When a disengagement force between 10 N and 45 N is applied along the force axis shown in figure 3, the blade shall disengage from the handle.

4.5 Locking and unlocking of engaged blades

4.5.1 When a torque between 0,35 N·m and 1,35 N·m is applied to the blade, it shall lock into the operating position (see figure 4).

4.5.2 When a torque between 0,25 N·m and 1,35 N·m is applied to the blade, it shall unlock from the operating position (see figure 4).

4.6 Lamps

The lamps shall be incompatible with sockets specified in ISO 7376-2.

NOTE 1 Lamps used in fibre-illuminated systems tend to generate heat sufficient to burn human tissue. Such lamps should not be used in conventional blades specified in ISO 7376-1 because their exposed position facilitates contact with adjacent tissue.

5 Identification of compatible systems

5.1 Handles

5.1.1 Handles shall be colour-coded by means of a circumferential band, coloured as specified in 6.1 (see also annex A).

5.1.2 The width of the band shall be 5 mm \pm 2 mm.

5.1.3 The band shall be located between the hook-on fitting and the mid-point of the handle.

5.1.4 The handle shall be marked as specified in 6.2.

5.2 Blades

5.2.1 Blade assemblies shall be colour-coded (see also annex A) by means of a mark or marks on the heel of the blade or lightguide as shown in figure 5. The mark shall be clearly visible when the laryngoscope is in the operating position. The area of the mark shall be not less than 10 mm².

5.2.2 The blade shall be marked as specified in 6.2.

5.2.3 If the fibre-illuminated component is detachable, it shall be colour-coded as specified in 6.1 and 5.2.1.

6 Marking

6.1 Colour marking

The colour markings for handles and blades should be resistant to recommended methods of cleaning and disinfection.

For examples of suggested codes for identifying colours, see annex A.

6.1.1 Marks on handles whose fittings are dimensioned in accordance with figure 1 and on blades that engage with them shall be green.

6.1.2 Marks on handles whose fittings are dimensioned in accordance with figure 2 and on blades that engage with them shall be blue.

6.2 Blades and handles

6.2.1 Blades and handles shall be marked with the following:

- a) the name and/or trademark of the manufacturer and/or supplier; this marking shall be not less than 10 mm²;
- b) the country of origin;
- c) either "stainless" or "s/s", if made of stainless steel.

6.2.2 Blade assemblies shall be marked with the size and type, the size being expressed in numerals and the type in letters, e.g.

MAC 3

6.3 Removable fibre-illuminating components

To facilitate re-assembly, removable fibre-illuminating components shall be marked with their type and size, in accordance with 6.2.2.

7 Information to be supplied by manufacturer

The manufacturer shall provide, in the package in which the laryngoscope is supplied, instructions for cleaning and disinfection of blades, handles and any removable components.

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Dimensions in millimetres

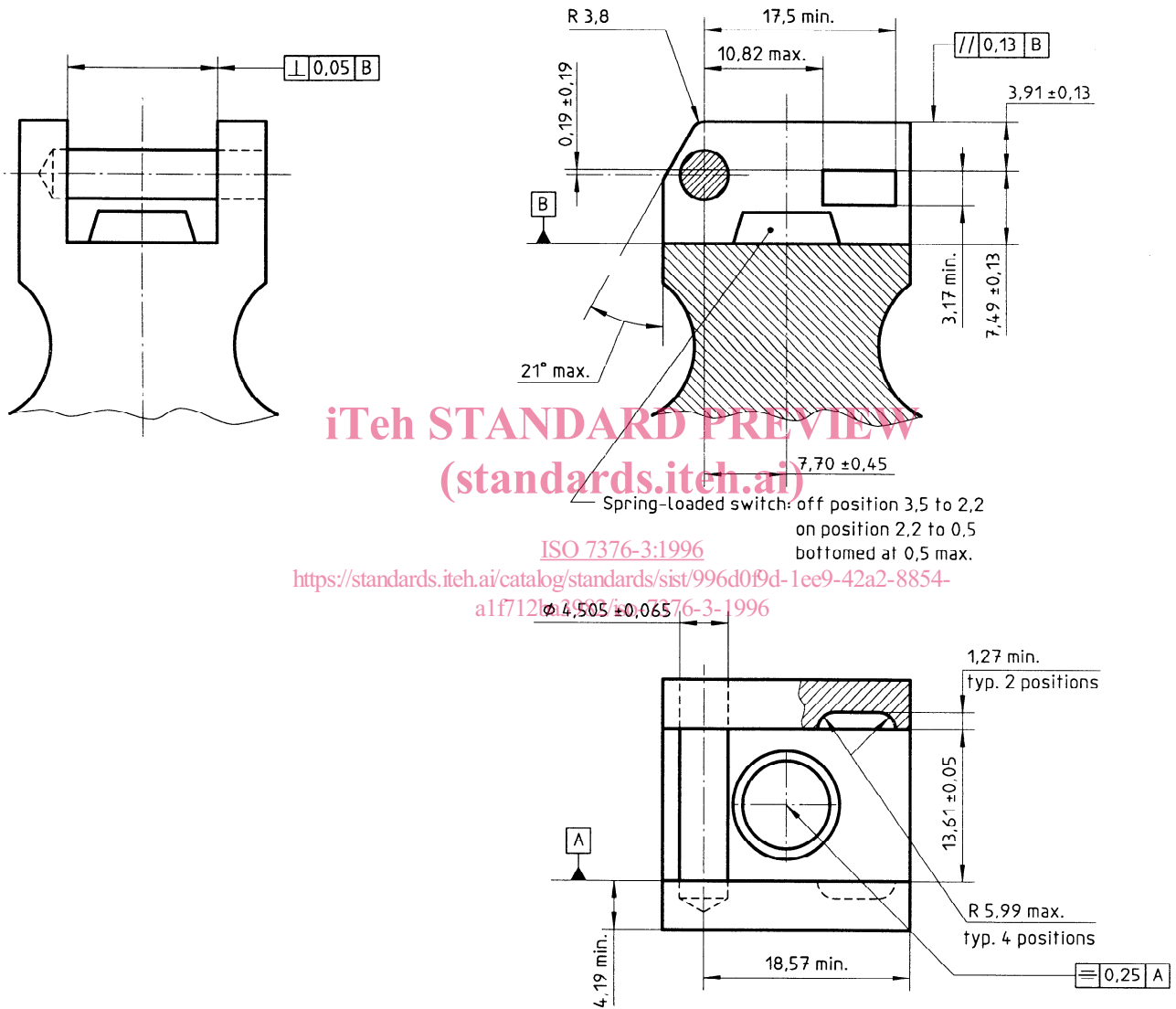
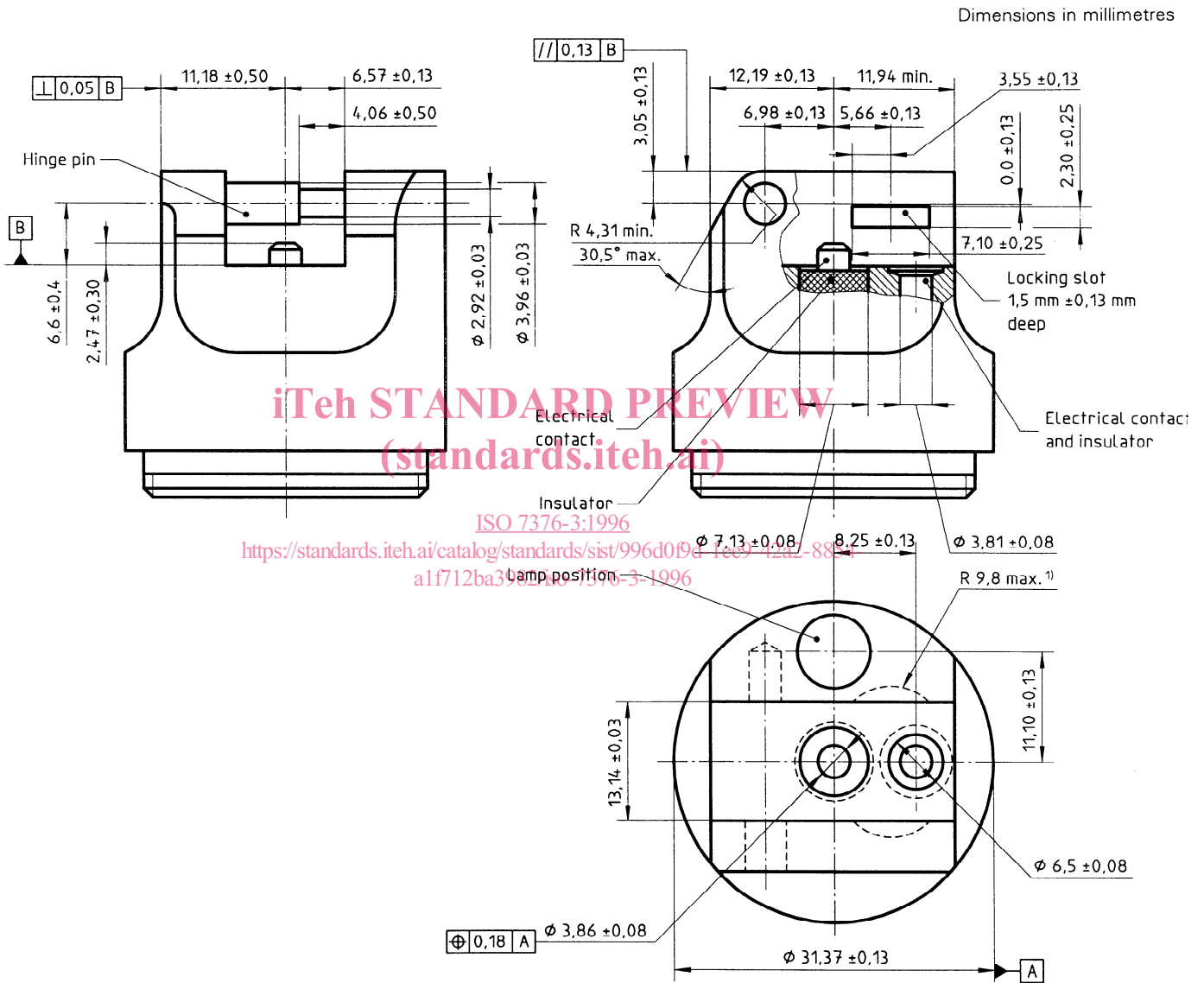


Figure 1 — Handle hook-on configuration of green system



1) Shape of slot to suit.

Figure 2 — Handle hook-on configuration of blue system