

INTERNATIONAL
STANDARD

ISO
7376-1

Second edition
1994-12-01

Laryngoscopic fittings —

Part 1:

Conventional hook-on type handle-blade
fittings

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Éléments de laryngoscopes —

Partie 1. Système conventionnel manche/lame à enclenchement

INTERNATIONAL

ISO



Reference number
ISO 7376-1:1994(E)

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.

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 7376-1 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 7376-1:1984), of which it constitutes a technical revision.

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*

Annex A forms an integral part of this part of ISO 7376.

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International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

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 and sizes, 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 optical fibres being used to transmit light to the blade. The former type is specified in this part of ISO 7376 and ISO 7376-2, while the latter type is specified in ISO 7376-3.

The aim of ISO 7376 is to promote ready interchangeability between blades and handles of the hook-on type made by different manufacturers. The primary objective of this part of ISO 7376 is to ensure interchangeability concerning mechanical fit and electrical contact between the hook-on type of conventional laryngoscope handles and blades. This is achieved by specifying the critical dimensions of the handle hook-on fitting, combined with the use of two test pieces that affect interchangeability with the blades and by designating the minimum performance requirements. The secondary objective is to provide test procedures and values for performance.

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

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Laryngoscopic fittings —

Part 1:

Conventional hook-on type handle-blade fittings

1 Scope

This part of ISO 7376 specifies critical dimensions and considerations for the junction of any blade and any handle of a hook-on type laryngoscope to allow engagement, lamp illumination and disengagement through multiple cycles. An electrical lamp in the blade is supplied with energy from the handle.

This part of ISO 7376 does not cover

- a) the blade form or handle design other than the interchangeability aspects of the connection between the blade and the handle;
- b) the measurement and specification of the lamp illumination intensity;
- c) disposable or flexible laryngoscopes, or laryngoscopes designed for surgery;
- d) laryngoscopes without a lamp in the blade.

2 Definitions

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

2.1 conventional blade: Separate rigid component to provide direct vision of the larynx, incorporating a hook-on base and a lamp which has an electrical connection at the hook-on end of the blade.

2.2 contacts: 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.

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

2.4 handle: Component held in the hand of the operator during use, one end of which forms the hook-on connection for the blade.

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

2.6 locking slots: Components of the handle locking surfaces that accept the locking mechanism of the blade to resist blade displacement from the operating position.

2.7 operating position: Position of the engaged blade and handle when the instrument is ready for use.

3 Performance requirements

3.1 Test method

The requirements specified in 3.4 to 3.8 shall be determined with the blade attached to test piece 1 ("GO") specified in annex A.

3.2 Hook-on blade and handle fittings

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

3.3 Handle fittings

Dimensions and configurations not shown are at the discretion of the manufacturer but they should ensure safe operation.

3.3.1 Dimensions for handle fittings

3.3.1.1 The dimensions for handle fittings shall be in accordance with figure 1. All measurements shall be taken from datum plane A, datum plane B and the hinge-pin centreline.

3.3.1.2 The total clearance between the width of the handle hook-on fitting and the width of the blade hook-on fitting shall not exceed 0,3 mm.

3.3.2 Electrical contacts for handle fittings

The insulated central contact shall press against the central contact on the blade to maintain conductivity and ensure lamp illumination while in the operating position (see 3.9).

NOTE 1 Degradation of the electrical contacts is a common problem and it is recommended that electrical contacts are designed to resist deformation and corrosion.

3.4 Blade fittings

3.4.1 Blade hook-on fittings shall engage the handle hook-on fittings which comply with figure 1, and 3.3.1 and 3.9. Typical blade hook-on fittings are shown in figure 2.

3.4.2 The mechanical fit of the blade to the handle shall be tested by attaching the blade to test piece 1 ("GO") and test piece 2 ("NOT GO") as specified in annex A. The dimensions of the test pieces are given in table A.1 and figure A.1.

3.5 Engagement

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.

3.6 Blade retention

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

3.7 Operating position

3.7.1 Locking

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

3.7.2 Unlocking

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

3.8 Disengagement

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.

3.9 Hook-on handle-blade fittings and electrical contacts.

The lamp shall light when the blade is placed into the operating position.

4 Marking and labelling

4.1 Blades and handles shall be marked with the following:

- the name and/or trademark of the manufacturer and/or supplier, this symbol being not less than 10 mm²;
- the country of origin;
- either "stainless" or "s/s", if made of stainless steel.

4.2 Blades shall be marked with the size and type, the size being expressed in numerals and the type in letters, for example

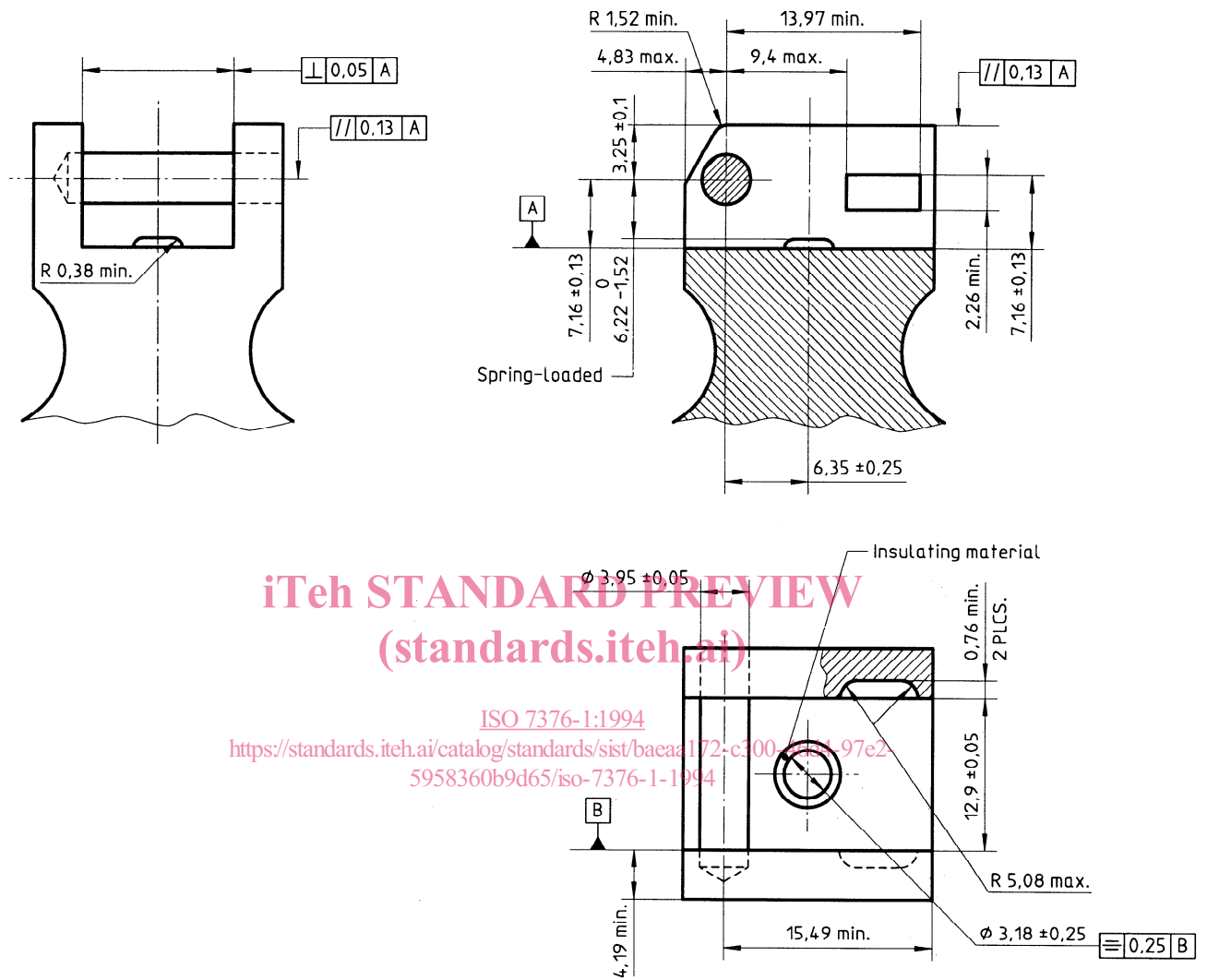
MAC 3

NOTE 2 Size and type of blades are not specified and may differ between manufacturers.

5 Information to be supplied by manufacturer

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

Dimensions in millimetres



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Figure 1 — Handle hook-on fitting of conventional system

Dimensions in millimetres

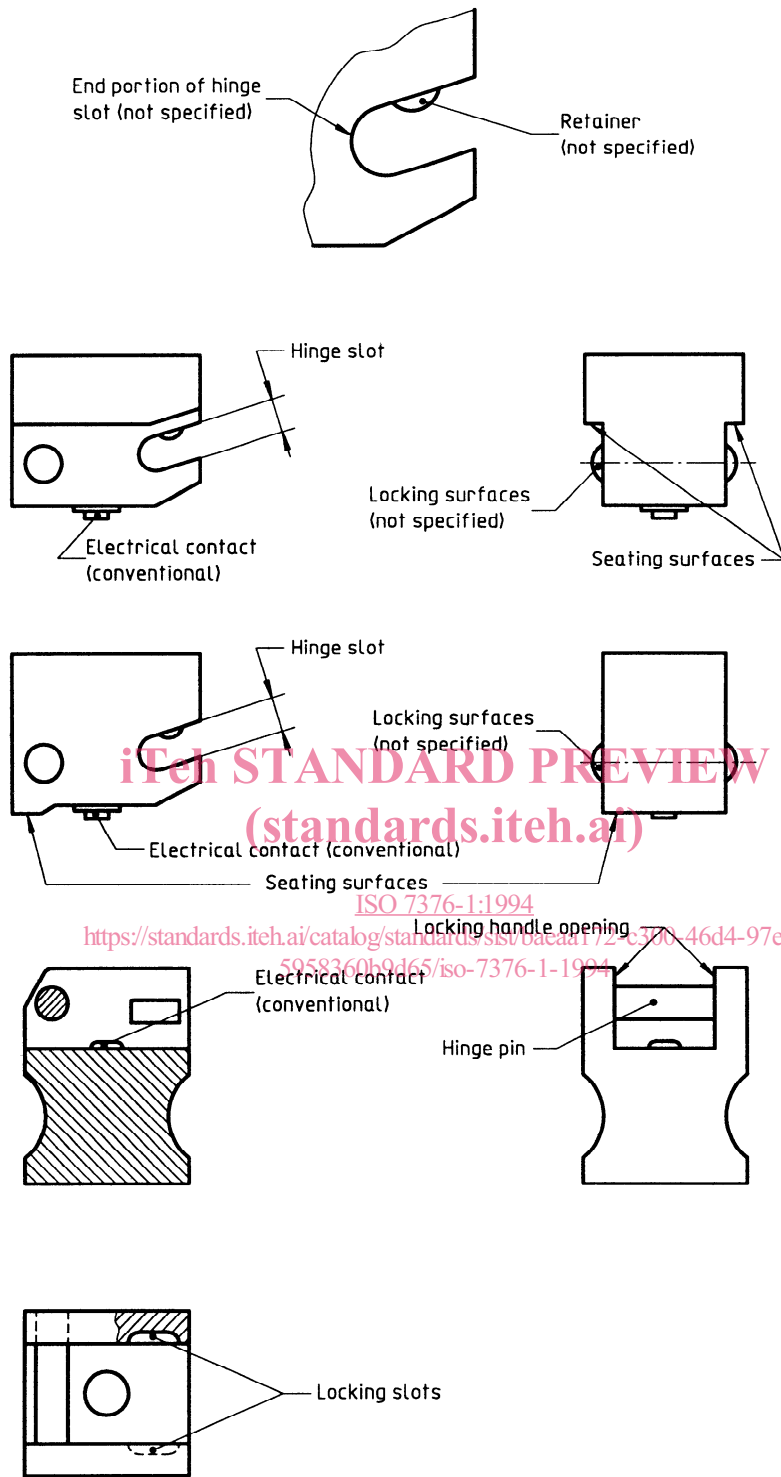


Figure 2 — Typical blade and handle hook-on fitting configurations of conventional system

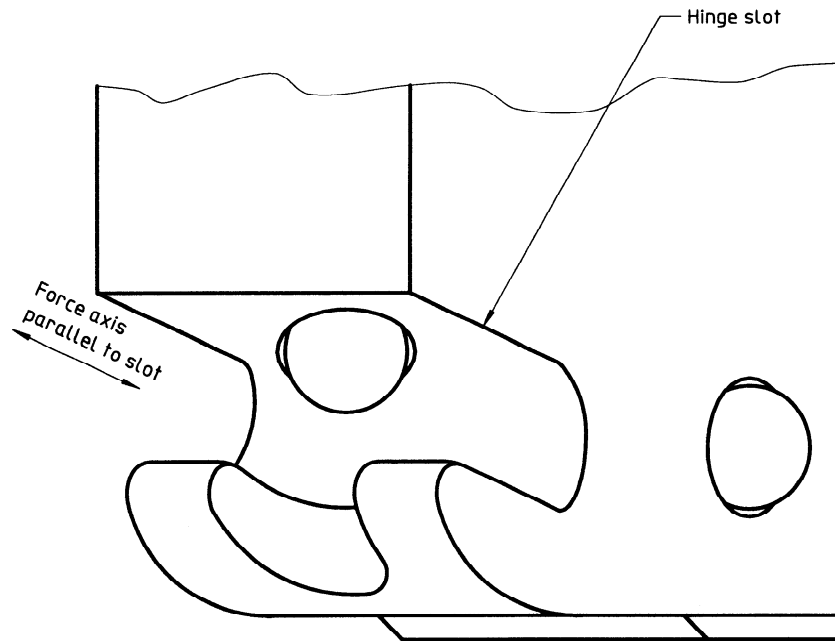


Figure 3 — Force axis for engagement/disengagement tests (see 3.5)

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