

Australian Standard™

Laryngoscopic fittings

**Part 1: Conventional hook-on type
handle blade fitting**

This Australian Standard was prepared by Committee HE-019, Anaesthetic and breathing equipment. It was approved on behalf of the Council of Standards Australia on 26 June 2002 and published on 28 June 2002.

The following are represented on Committee HE-019:

Australasian Society of Anaesthesia Technicians
Australian Chamber of Commerce and Industry
Australian College of Operating Room Nurses
Australian Industry Group
Australian Society of Anaesthetists
Australian and New Zealand College of Anaesthetists
Australian and New Zealand Intensive Care Society
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This Standard was issued in draft form for comment as DR 02167.

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Part 1: Conventional hook-on type handle blade fittings

First published as AS ISO 7376.1—2002.

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Published by Standards Australia International Ltd
GPO Box 5420, Sydney, NSW 2001, Australia

ISBN 0 7337 4689 6

PREFACE

This Standard has been developed to assist in the process of implementation of the Australian Medical Device legislation.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/New Zealand Standard, through the Joint Standards Australia/Standards New Zealand Committee HE-019 on Anaesthetic and breathing equipment.

This Standard is identical with and has been reproduced from ISO 7376-1:1994, *Laryngoscopic fittings — Part 1: Conventional hook-on type handle blade fittings*.

The objective of this Standard is to specify requirements for laryngoscopes and critical dimensions for the junction of any handle and any blade of a hook-on type laryngoscope to allow engagement, lamp illumination and disengagement through multiple cycles.

As this Standard is reproduced from an international Standard, the following applies:

- (a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.
- (b) In the source text 'this International Standard' should read 'this Australian Standard'.
- (c) A full point substitutes for a comma when referring to a decimal marker.

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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AUSTRALIAN STANDARD

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.