INTERNATIONAL STANDARD

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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.

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## 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*