

FINAL DRAFT International **Standard**

ISO/FDIS 7376-2

Anaesthetic and respiratory equipment —

Part 2:

Video laryngoscopes

Équipement anesthésique et respiratoire — 1/812110 2110 S Partie 2: Vidéolaryngoscopes Document Preview

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ISO/TC 121/SC 2

Secretariat: ANSI

Voting begins on: 2025-05-28

Voting terminates on: 2025-07-23

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Website: www.iso.org
Published in Switzerland

ISO/FDIS 7376-2:2025(en)

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This document was prepared by Technical ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airway devices and related equipment*.

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Introduction

This document provides the essential performance and safety requirements for *video laryngoscopes*. *Video laryngoscopes* are tools used to facilitate endotracheal intubation. A rigid *video laryngoscope* holds and shapes the anatomical structures providing access to the trachea, not dependent on a line of sight. *Video laryngoscopes* are designed to provide a view of the larynx and entrance into the trachea.

Video laryngoscopes have been developed to provide the user with a view of the larynx via a camera and an image display unit. The use of video laryngoscopes is increasing in clinical practice and they have become an important tool for tracheal intubation. Video laryngoscopes are particularly useful for difficult intubations and for reducing the risk of oesophageal intubation. There is a wide variety of video laryngoscope designs and basic performance criteria need to be established to enhance patient safety.

The *video laryngoscope* incorporates a light source and miniature camera to view the larynx during the procedure of laryngoscopy. The image is displayed on a screen. Common use environments of *video laryngoscopes* include: operating rooms, emergency rooms, intensive care units, and in the pre-hospital setting. Typical users include: health care providers who intubate such as anaesthesiologists, respiratory therapists, emergency response physicians, intensive care unit physicians, paramedics, certified nurse anaesthetists and anaesthesia assistants.

This document is intended to provide a device specific standard focused on *video laryngoscopes*. *Video laryngoscopes* have evolved from direct laryngoscopes but, in contrast to direct laryngoscopes providing a direct view, *video laryngoscopes* provide an indirect view of the larynx made visible on an image display. *Video laryngoscopes* utilize digital imaging technology and can require less force to visualize the larynx compared to direct laryngoscopy.

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