

# CLINICAL EVIDENCE DOSSIER

Ambu® aScope™ 4 RhinoLaryngo



**Ambu**

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This document includes published studies on rhinolaryngoscope performance, sterility, cost-effectiveness, and COVID-19 implications. The studies support claims related to Ambu aScope 4 RhinoLaryngo single-use endoscopes.

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# PREFACE

Ambu aScope 4 RhinoLaryngo endoscope is a single-use rhinolaryngoscope that removes the risk of patient cross-contamination. aScope 4 RhinoLaryngo eliminates the need for complex reprocessing and ongoing repairs.

The design of aScope 4 RhinoLaryngo is based on the latest conventional rhinolaryngoscopes, and the familiar form and function deliver consistent performance.

This dossier provides an overview of the evidence related to aScope 4 RhinoLaryngo. A systematic literature search was conducted to obtain a balanced and impartial overview of the data. It comprises studies published from 2010 to 2023 related to performance, sterility, cost-effectiveness, organizational impact, and COVID-19 implications.

## A HISTORY OF BREAKTHROUGH IDEAS

Ambu has been bringing breakthrough healthcare solutions to life since 1937. Today, millions of patients and healthcare professionals worldwide depend on the efficiency, safety and performance of our single-use endoscopy, anesthesia, and patient monitoring diagnostics solutions. Our efforts have evolved from early innovations like the Ambu Bag™ resuscitator and the Ambu BlueSensor™ electrodes to our newest landmark solutions like aScope Broncho - the world's first single-use bronchoscope. Moreover, we continuously look to the future, with a commitment to deliver innovative, high-quality products. Ambu leads by example by offering eco-friendly product disposal, all while remaining cost-effective to the consumer.

Headquartered near Copenhagen, Denmark, Ambu employs approximately 4,200 people in Europe, North America, and Asia-Pacific.

For more information, please visit [www.SingleUseEndoscopy.com](http://www.SingleUseEndoscopy.com) or [www.AmbuUSA.com](http://www.AmbuUSA.com).

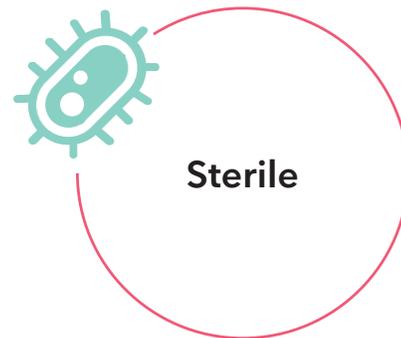
# SUMMARY OF EVIDENCE

Ambu entered the ENT (Ear, Nose, Throat) domain in 2019 by introducing the aScope 4 RhinoLaryngo portfolio. Our influence in the U.S. has surged due to the market shift towards single-use rhinolaryngoscopy. This evolution is driven by: the necessity to reduce expenses linked to reprocessing and repairing reusable endoscopes and eliminating the risk of device-related patient cross-contamination.

The purpose of this Clinical Dossier is to serve as a resource to describe the unparalleled value of the aScope 4 RhinoLaryngo. This comprehensive dossier presents a summary of device features such as performance, sterility, and cost-effectiveness.

## The studies included in this dossier demonstrate:

- The aScope 4 RhinoLaryngo can successfully replace reusable rhinolaryngoscopes for flexible ENT procedures.<sup>5</sup>
- aScope 4 RhinoLaryngo received high ratings from physicians in image quality, maneuverability, ergonomics, and overall impression.<sup>2</sup>
- Over one third of reusable nasopharyngoscope device failures involved contamination.<sup>4</sup>
- Even properly reprocessed reusable rhinolaryngoscopes cannot guarantee sterility and can lead to infection.<sup>3</sup>
- Single-use rhinolaryngoscopes have the potential to reduce the risk of COVID-19 transmission by eliminating reprocessing, an aerosol-generating procedure.<sup>8</sup>
- aScope 4 RhinoLaryngo is often the cost-effective option for facilities compared to reusable rhinolaryngoscopes.<sup>5,6</sup>



# SUPPORTING EVIDENCE-BASED PRACTICE WITH THE BEST AVAILABLE EVIDENCE

## HOW WERE THE STUDIES IN THIS DOSSIER SELECTED?

Two major scientific online databases, PubMed (MEDLINE) and Embase, were searched for all relevant articles up to January 2024. Articles published in English within the areas of infection control, performance and health economics were included.

This evidence dossier includes summaries of 7 published studies related to rhinolaryngoscopes.



This clinical evidence dossier is updated bi-annually and includes summaries of published, peer-reviewed studies related to bronchoscopes and bronchoscopy procedures. Stay up to date with the most recently published literature, abstracts and bronchoscopy-related data by scanning the QR code to visit our Supporting Evidence page at [ambuUSA.com/supporting-evidence/rhinolaryngo](https://ambuUSA.com/supporting-evidence/rhinolaryngo).



# **CLINICAL PERFORMANCE**

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# TAKEAWAY

The study found both resident users and patients rated single-use rhinolaryngoscopes higher across multiple characteristics measured.

# KEY FINDINGS

- Single-use rhinolaryngoscopes received higher overall ratings compared to reusables across each metric captured including: overall consult time (4.3 vs. 2.2,  $p < .001$ ), multiscope consults (4.4 vs. 3.1,  $p < .001$ ), patient communication (4.6 vs. 2.1,  $p < .001$ ), teaching opportunities (4.6 vs. 2.1,  $p < .001$ ) and overall ease of use (4.7 vs. 2.6,  $p < .001$ ).
- Residents rated single-use higher than reusable scopes after each consult in terms of ease of use (1.07 vs. 2.68,  $p < .001$ ) and visual clarity (1.27 vs. 1.89,  $p = .003$ ).
- Patients rated the single-use system higher for understanding of illness (3.9 vs. 3.1,  $p < .001$ ), and understanding of treatment rationale (3.9 vs. 3.1,  $p < .001$ ).

## Single-use versus Reusable Rhinolaryngoscopes for Inpatient Otorhinolaryngology Consults: Resident and Patient Experience

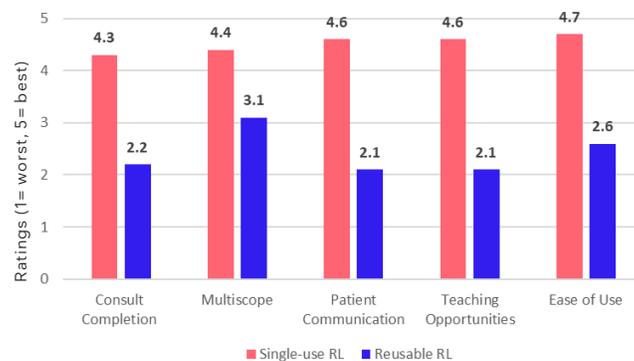
[Bowen et al., 2023](#)

### STUDY AIM

The goal of this study was to measure the overall impact of single-use rhinolaryngoscopes on the ENT consult experience from both the user and patient perspective.

### METHODS

- 18 residents were recruited to perform ENT consults with both single-use and reusable rhinolaryngoscope systems.
- Residents would alternate weeks utilizing one rhinolaryngoscope system.
- A five-question survey was administered across three assessment points over a 12-week study period, using a 5-point rating system to measure favorability.
- Both residents and patients completed surveys following each procedure to capture each consult experience, using a 4-point scale.
- Statistical analyses were performed to measure significant differences between responses.



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# TAKEAWAY

aScope 4 RhinoLaryngo can be a good alternative to conventional laryngoscopy systems.

# KEY FINDINGS

- The following scores were reported (1-very poor, 2-poor, 3-acceptable, 4-good, 5-very good):
  - Image quality:  $4.17 \pm 0.38$
  - Maneuverability:  $4.67 \pm 0.49$
  - Ergonomics of the handle:  $4.44 \pm 0.51$
  - Overall impression:  $4.33 \pm 0.49$
- Two thirds of examiners highlighted the ease of storing pictures and videos on the portable monitor.

## First experiences with a new flexible single-use rhinolaryngoscope with working channel - a preliminary study

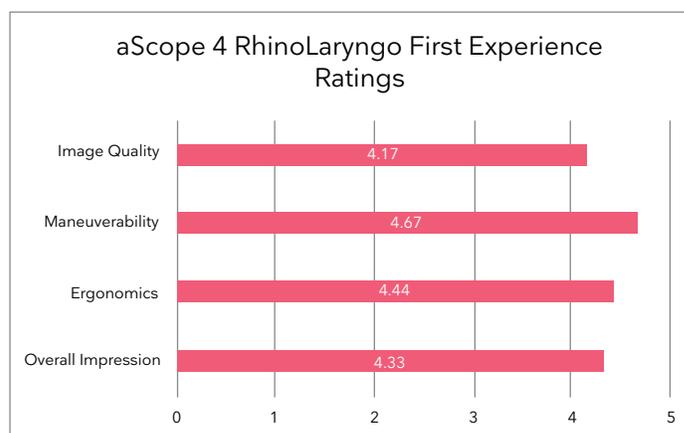
[Becker et al., 2019](#)

### STUDY AIM

To assess first impressions of flexible single-use rhinolaryngoscopes.

### METHODS

- Ten patients with an indication for a rhinolaryngoscopy were examined with the aScope 4 RhinoLaryngo Intervention by 6 different examiners in 18 procedures.
- After the procedure, examiners had to fill out a questionnaire concerning image quality, maneuverability, ergonomics of the handle, and overall impression of the system on a 5-point scale (1-very poor, 2-poor, 3-acceptable, 4-good, 5-very good).
- Examiners were given the opportunity to comment on the system.



# **CONTAMINATION AND INFECTIONS**

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# TAKEAWAY

Stricter protocols for cleaning the laryngoscope eyepiece, handle, and light cords are needed to minimize harmful organism growth after reprocessing.

# KEY FINDINGS

- Bacterial growth was identified on 7 of 20 (35%) collected samples.
- 60% of light cables, 17% of driver handles, and 50% of eyepieces were identified with positive bacterial cultures.
- Common bacterial isolates identified were:
  - *Corynebacterium*
  - Bacillus species
  - Gram-negative rod
  - *Staphylococcus*

## Microbiological Sampling of Common Otolaryngological Office Equipment: What Lessons Can We Learn?

[Bhatt et al., 2013](#)

### STUDY AIM

To analyze whether standard decontamination protocols are effective in cleaning integral components of common otolaryngological office equipment, including flexible fiberoptic laryngoscopes, detachable light cables, and otoscope handles.

### METHODS

- A random microbiological sampling of 6 flexible fiberoptic laryngoscopes including the eye piece and the driver handle, 3 light cables, and 5 otoscope handles was performed.
- All scopes underwent the clinic's cleaning protocol: debridement with an enzymatic sponge of the shaft and body, tap water rinse, and immersion of the shaft in Cidex (2.5% glutaraldehyde), followed by air drying.
- Samples were delivered within 1 hour of collection to the UC Irvine Medical Microbiology Laboratory, for culturing and incubation.



Contamination  
and infectionsNot open  
access

# TAKEAWAY

Although the rates of contamination were comparable across all endoscope categories, nasopharyngoscope contamination was less commonly associated with patient harm or death than bronchoscopes or duodenoscopes.

# KEY FINDINGS

- Nasopharyngoscope device failures were reported at an incidence of 0.64 cases per month. Bronchoscope, duodenoscope, and gastroscope failure were reported at incidences of 14.23, 28.08, and 4.34 cases per month, respectively.
- 34% of device failures involved contamination, which is comparable to the frequency observed for bronchoscopes (23.4%,  $p = 0.118$ ), duodenoscopes (29.2%,  $p = 0.493$ ), and gastroscopes (45.3%,  $p = 0.178$ ).
- Nasopharyngoscopes were significantly less associated with patient harm or death than bronchoscope (OR = 10.2) and duodenoscope (OR = 4.81) cases.

## A Manufacturer and User Facility Device Experience Analysis of Upper Aerodigestive Endoscopy Contamination: Is Flexible Laryngoscopy Different?

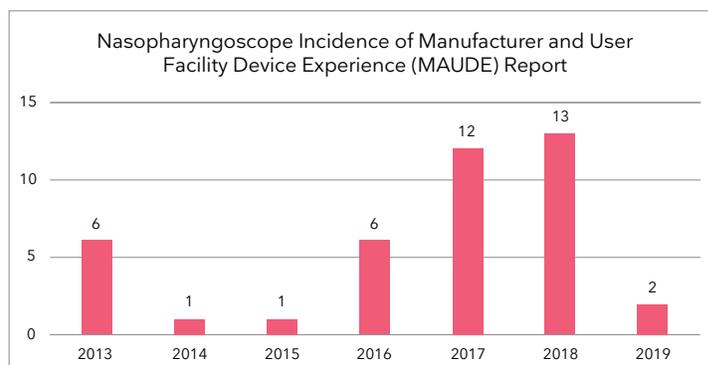
[Jiang et al., 2020](#)

### STUDY AIM

To quantify nasopharyngoscope microbial contamination relative to that of other endoscope categories and characterize the manufacturers, outcomes, and microbial profiles associated with these cases.

### METHODS

- Retrospective, cross-sectional study.
- 3,865 adverse events were collected from 2013 to 2019 using the US Food and Drug Administration Manufacturer and User Facility Device Experience database
- 3,027 reports were compiled after filtering.
- The fraction of total device failures associated with contamination was quantified for nasopharyngoscopes, bronchoscopes, duodenoscopes, and gastroscopes.
- Odds ratios of nasopharyngoscope contamination compared to that of bronchoscopes, duodenoscopes, or gastroscopes were calculated.



# **HEALTH ECONOMICS**

# TAKEAWAY

aScope 4 RhinoLaryngo provides a clinically comparable, and potentially cost-minimizing, alternative to the reusable rhinolaryngoscopes.

# KEY FINDINGS

- 3% of the investigators reported that they had to change to the reusable rhinolaryngoscope because of patient intolerance.
- 85% of investigators believed that the aScope 4 RhinoLaryngo could successfully replace the reusable rhinolaryngoscope.
- The cost of a procedure performed using the aScope 4 RhinoLaryngo was £105 (\$148.61) in both the outpatient and acute surgical assessment unit settings.
- The aScope 4 RhinoLaryngo was £4 (\$5.66) and £73 (\$103.32) cheaper per procedure than eyepiece rhinolaryngoscopes and video rhinolaryngoscopes, respectively.

## The single-use rhinolaryngoscope: an evaluation and cost comparison

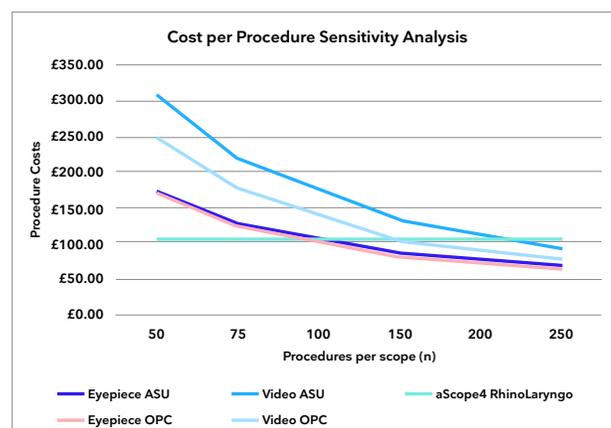
Mistry et al., 2020

### STUDY AIM

To determine whether the aScope 4 RhinoLaryngo is clinically and economically comparable to conventional reusable rhinolaryngoscopes within a tertiary otolaryngology center in the UK.

### METHODS

- Single-arm, non-blinded, prospective trial and cost-comparison at a tertiary otolaryngology center in the UK
- Investigators without previous single-use rhinolaryngoscope technology were trained prior to use.
- A Likert scale was used to quantify a range of parameters and provide an evaluation of the equipment, including image quality, advancing, navigation, overall perception, and ergonomics.
- Rhinolaryngoscopes were tracked and followed from the finalized procedure, through reprocessing, and until the start of a new procedure.



# TAKEAWAY

aScope 4 RhinoLaryngo may offer a cost-effective and highly favorable alternative to traditional reusable nasopharyngolaryngoscopes.

# KEY FINDINGS

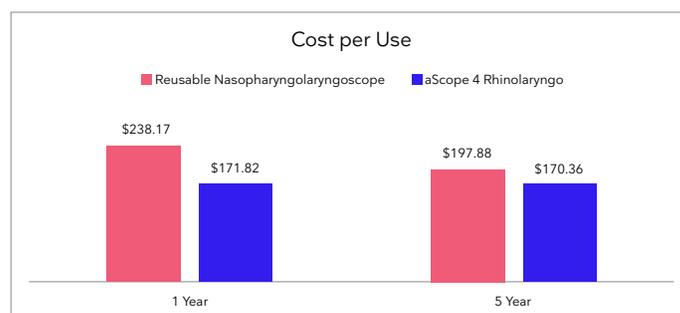
- The aScope 4 RhinoLaryngo reported better ratings than reusable nasopharyngolaryngoscopes in ergonomics (4.4 vs 4.3), setup (4.4 vs 3.5), convenience (4.6 vs 2.9), and overall score (4.4 vs 4.0).
- The reusable nasopharyngolaryngoscopes reported better ratings than aScope 4 RhinoLaryngo in imaging (3.8 vs 4.5) and maneuverability 4.3 vs 4.5).
- The aScope 4 RhinoLaryngo was found to cost \$171.82 and \$170.36 per use and the reusable nasopharyngolaryngoscope was found to cost \$238.17 and \$197.88 per use for a lifespan of 1 and 5 years, respectively.

## Reusable vs disposable nasopharyngolaryngoscopes: cost analysis and resident survey

Walczak et al., 2020

### STUDY AIM

To assess the quality of aScope 4 RhinoLaryngo through resident feedback at multiple academic institutions and provide a cost analysis of reusable and disposable nasopharyngolaryngoscopes at a single academic center.



### METHODS

- An online survey was distributed to residents at institutions throughout the United States that have implemented use of aScope 4 RhinoLaryngo.
- The survey collected demographic information and asked residents to rate aScope 4 RhinoLaryngo and other reusable nasopharyngolaryngoscopes using a 5-point Likert scale.
- A cost analysis was performed comparing reusable nasopharyngolaryngoscopes and aScope 4 RhinoLaryngo using information obtained at a single academic center.

# **SUSTAINABILITY**



# TAKEAWAY

Using one set of PPE per reprocessing, along with the materials for cleaning and disinfection, determines that RFBs have comparable or higher material and energy consumption, as well as higher emissions of CO<sub>2</sub> equivalents.

# KEY FINDINGS

- The materials used for the cleaning operations of the RFBs are a key factor affecting the assessed aspects: energy consumption and emission of CO<sub>2</sub> equivalent.
- Using one set of PPE per reprocessing, and the materials for cleaning and disinfection, determines that reusable scopes have comparable or higher material and energy consumption, as well as higher emissions of CO<sub>2</sub> equivalents.
- The three assessed parameters are highly dependent on the cleaning procedure and the use of PPE.

## Comparative Study on Environmental Impacts of Reusable and Single-Use Bronchoscopes

Sørensen et al., 2018

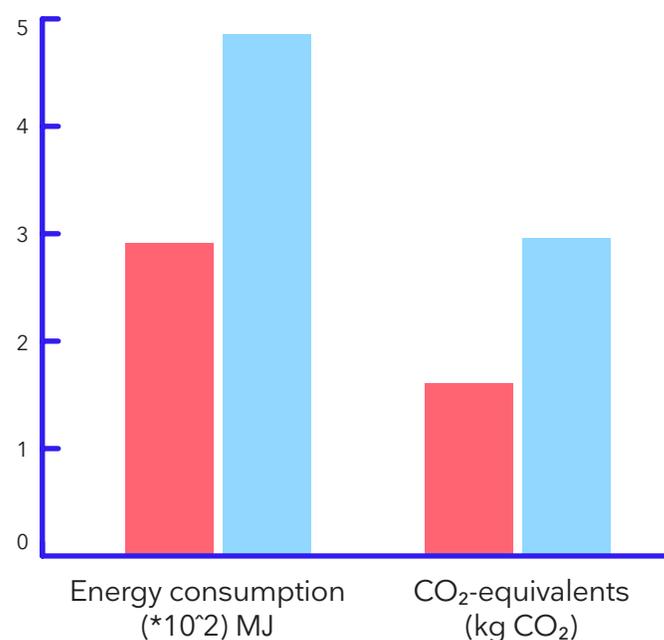
### STUDY AIM

This study aims to compare CO<sub>2</sub> equivalent emissions and energy consumption from a SFB (Ambu® aScope™ Broncho) with an RFB.

### METHODS

- The comparison is made using a simplified life-cycle-assessment methodology.
- The assessment compares: The use and disposal of one aScope Broncho with the cleaning and sterilization of one conventional RFB, including PPE.

### Resource consumption



■ aScope Broncho

■ RFB

\*MJ = mega joule

# **TECHNICAL SPECIFICATIONS**

# Ambu aScope 4 RhinoLaryngo

aScope 4 RhinoLaryngo is a sterile single-use rhinolaryngoscope that eliminates patient cross-contamination. aScope RhinoLaryngo eliminates the need for complex reprocessing and ongoing repair.

The design of aScope 4 RhinoLaryngo is based on the latest reusable rhinolaryngoscope, and the familiar form and function delivers consistent performance.

Whether you need high-quality imaging and easy connectivity options for the outpatient clinic or a portable grab-and-go solution for when you're called to a consult, Ambu aScope 4 RhinoLaryngo benefits you. It helps you perform procedures confidently, document them easily and streamline your workflow.

**Ambu aScope 4 RhinoLaryngo Intervention**



**Ambu aScope 4 RhinoLaryngo Slim**



## Innovative

aScope 4 RhinoLaryngo is about enhancing patient safety and workflow. It is always available and sterile straight from the pack. It helps you save time and work smarter by eliminating time-consuming steps required to use, maintain, and handle a reusable scope. It is the ideal solution for a wide range of rhinolaryngoscopic procedures.

## Simple set-up

The aScope 4 RhinoLaryngo solution consists of a single-use rhinolaryngoscope and aView™ 2 Advance Full-HD monitor unit. Remove aScope 4 RhinoLaryngo from its packaging, connect it to aView 2 Advance, and the system is ready. The system has an integrated rinsing function, and there is no need for an additional light source.

## Familiar control and design

The aScope 4 RhinoLaryngo Slim has control wheels designed to ensure precise angulation and locking of the endoscope bending section (Up: 130°, Down: 130°). It provides high-definition imaging with the 85°-degree field of view and 6-50 mm depth of field ensure optimal visibility. The small outer diameter (3.0 mm), precise tip motion, and high-bending angles help minimize patient discomfort during procedures allow you to easily maneuver the endoscope in the upper airway).

## KEY FEATURES

- Always ready and sterilely packed eliminating the risk of cross-contamination
- Improves workflow with no hassle of cleaning or repairs and reduces associated costs
- Performs consistently with compatible endoscopic accessories
- Offers cost transparency - one rhinolaryngoscope, one price. No long-term service contracts or leasing agreements
- Offers a cost-effective single-use solution
- Ergonomic design that ensures all-day comfort

# The Ambu aScope RhinoLaryngo Family



## Ambu aScope 4 RhinoLaryngo Slim

- Insertion cord diameter: 3.0 mm
- Distal end diameter: 3.5 mm
- Working length: 300 mm
- Bending capabilities: 130° up, 130° down



## Ambu aScope 4 RhinoLaryngo Intervention

- Insertion cord diameter: 5.0 mm
- Distal end diameter: 5.4 mm
- Channel average inner diameter: 2.2 mm
- Working Length: 350 mm
- Bending Capabilities: 130° up, 130° down



## Ambu aView 2 Advance Gen. 2

- 12.8" Full-HD touchscreen display
- 3 Hours of battery life
- Transfer patient imaging data to EMR with WIFI, USB or LAN
- HDMI or 3G-SDI (1080p @ 60Hz) digital video outputs

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For more information,  
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