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Note: Always consult the latest User Manual of Broncoflex devices.

1. Broncoflex User Manual ref. 1003012
2. Screeni User Manual ref. 30030511
3. Easy BAL Clip User Manual ref. 41040406

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Manufactured by: Axess Vision Technology, S.A.S.

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Technical Datasheet

BRONCOFLEX™

Single-use Bronchoscopy.
Everything you need. Nothing you don't.

tsc-life.com

BRONCOFLEX™

Description	Broncoflex™ is a single-use video-bronchoscope which is part of a system made up of the endoscope (Broncoflex) and its reusable high-definition display system (Screeni™). Two different bronchoscopes are available: • Broncoflex 5.6/2.8 (Vortex) • Broncoflex 3.9/1.4 (Agile) Combined with: • Screeni™ • Easy BAL Clip™
Intended Use	This video-bronchoscope is intended to provide an optical display of the pulmonary tract using a monitor (Screeni) and to be used with endotherapy accessories and instruments. The pulmonary tract includes the organs, tissues and subsystems represented by the nasal passages, trachea and bronchial tree beyond the primary bronchi. The video-bronchoscope is inserted via the oral or nasal route. Broncoflex should not be used for any purpose other than that described herein.
Indications for Use	This video-bronchoscope is designed for use exclusively in a hospital environment. Broncoflex can only be used on adult patients. **Endotherapy accessories and instruments** The effective length of an endoscopic instrument should be at least 30 cm greater than the effective length of the endoscope.

Name	Minimum compatible endotracheal tube size	Minimum compatible dual lumen endo-bronchial tube size	Maximum size of endotherapy instruments
Broncoflex 5.6/2.8 (Vortex)	6.0mm	≥ 41 Fr.	2.6mm
Broncoflex 3.9/1.4 (Agile)	5.0mm	≥ 35 Fr.	1.2mm

Name, Part Numbers and Dimensions

Name	Part Number/REF	External diameter of insertion tube	Working channel inner diameter
Broncoflex 5.6/2.8 (Vortex)	10030001	5.6mm	2.8mm
Broncoflex 3.9/1.4 (Agile)	20030001	3.9mm	1.4mm
Screeni	30030001	NA	NA
Easy BAL Clip	41010000	NA	NA

Single-Use Broncoflex Sizes

Broncoflex 5.6/2.8 (Vortex)

Description	Specification	
Part Number/REF	10030001	
Tube guard color	Orange	
Weight	127g (0.28lb)	
Optics	Field of vision direction	0°
	Field of vision	87.5°
	Field depth	5-50mm
	Image resolution (pixels)	400x400
	Lighting system	2 LEDs
Insertion tube	High/low deflection angle	200°/200°
	Minimum OD	5.4mm
	Maximum OD	5.6mm
	Working length	605mm
Working channel	Internal diameter	2.8mm
Sterilization Method	Ethylene Oxide (EO) Sterilization	
Instrument Compatibility	Endotracheal tube (internal diameter)	6mm
	Double-lumen tube (internal diameter)	41Fr
GMDN Code	60963	
GTIN-14 Code	03664977110031 (x5 devices) 03664977010034 (x1 device)	
FDA Device class	II	

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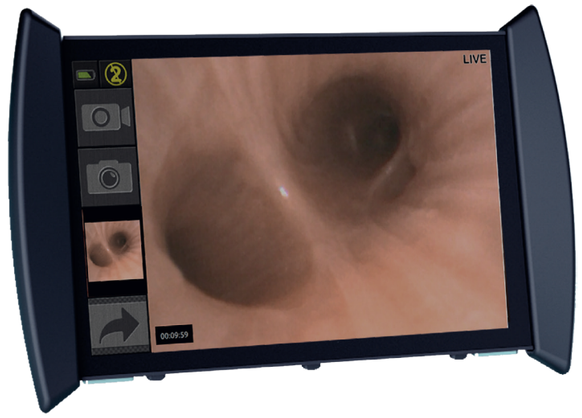
Broncoflex 3.9/1.4 (Agile)

Description	Specification	
Part Number/REF	20030001	
Tube guard color	Grey	
Weight	124g (0.27lb)	
Optics	Field of vision direction	0°
	Field of vision	87.5°
	Field depth	5-50mm
	Image resolution (pixels)	400x400
	Lighting system	2 LEDs
Insertion tube	High/low deflection angle	220°/220°
	Minimum outer diameter	3.6mm
	Maximum outer diameter	3.9mm
	Working length	605mm
Working channel	Internal diameter	1.4mm
Sterilization Method	Ethylene Oxide (EO)	
Instrument Compatibility	Endotracheal tube (internal diameter)	5mm
	Double-lumen tube (internal diameter)	35Fr
GMDN Code	60963	
GTIN-14 Code	03664977120030 (x5 devices) 03664977020033 (x1 device)	
FDA Device class	II	



Screeni

Description	Specification	
Part Number/REF	30030001	
Electrical	Power supply	Power requirement: 100-240V AC / 50-60Hz / 0.6A Power output: 15V DC / 2A
	Protection type against electrocution	Class 2
	Battery type	Lithium-Ion Battery
	Autonomy	3h
Touch screen	Screen size	10.1in
	Maximum resolution	1280x800
Miscellaneous	Protection Rating	IP 30
	Dimensions (L x H x D)	300 x 200 x 110mm
	Weight	1.8kg (3.96lb)
	Accessories supplied	Charger, mounting bracket, HDMI cable and medical-grade power supply (including UK-US-AU-EU adaptors)
	Physical memory size	16Gb
	Input connections	USB Type A
	Output connections	Ethernet (SN SCR30), HDMI (SN SCR31)
GMDN Code	56654	
GTIN-14 Code	03664977030032 (x1 device)	
FDA Device class	II	

Easy BAL Clip

Description	Specification
Part Number/REF	41010000
Material	ABS-PC
Length	90mm
Width	75mm
Height	30mm
Weight	15.5g (0.034lb)
GMDN	62137
GTIN-14 Code	03664977000042
FDA Device class	I

Safety Properties

- DEHP free.
- Does not contain latex or latex components.
- Biocompatible according to ISO 10993-1 for the intended use.

Packaging

Broncoflex

Each single-use device has a sterile barrier made of a Tyvek® pouch with a protective blister inside.

Broncoflex devices are packaged in carton boxes of 5 products.
Each Broncoflex carton includes a label indicating sterilization by EO.
Carton packaging box, dimensions 38.58 x 4.33 x 5.12in.
Weight 3.38lb.
User Manual, carton box and unit labelling/carton box labelling are included.

Regulatory Information

FDA 510(k) clearance, Regulatory Class II.
Electrical Safety Certified Body Certificate by UL.
CE mark.
For applicable standards please refer to the User Manual.

Recommended Storage Conditions

Broncoflex devices must be stored in their original unopened packaging, in a clean, dry and dark place. The storage conditions to ensure optimum product shelf life are normal temperature and pressure conditions, i.e. 20 °C and 1.013 bar.

	Parameters	Minimum	Maximum
Transport and storage conditions	Temperature	-10 °C (14 °F)	+60 °C (140 °F)
	Relative air humidity (no condensation)	10%	90%
	Atmospheric pressure	80kPa	109kPa
Conditions of use	Temperature	+ 10 °C (50 °F)	+ 40 °C (104 °F)
	Relative air humidity (no condensation)	30%	85%
	Altitude and atmospheric pressure	2000m – 80kPa ~ 109kPa	

Cleaning and Disinfecting Screeni

According to the User Manual.

Waste disposal

According to hospital practice and/or local legislation.

Manufacturer

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