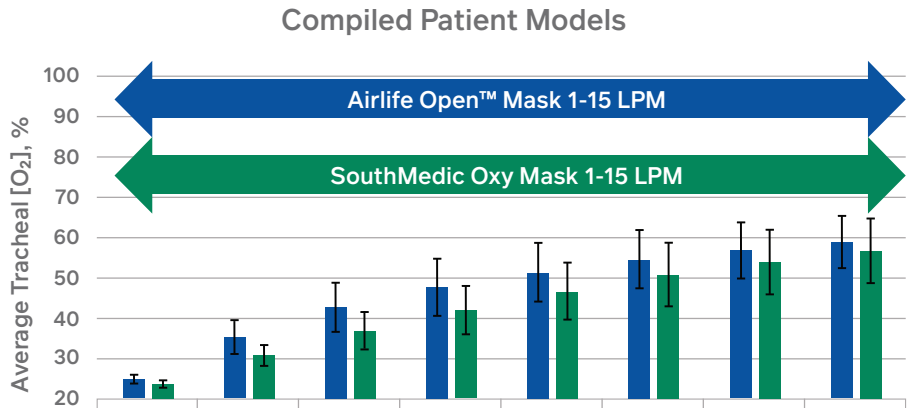
CLINICAL SUMMARY

AirLife Open™ Test Data Overview – AirLife Open vs. SouthMedic OxyMask™

DATA OVERVIEW

Testing was conducted by our research and development team. It was set up to simulate realistic clinical use situations for two open oxygen delivery masks. The products tested were AirLife™ Open and SouthMedic OxyMask™. The simulation measured the tracheal concentration of FiO_2 over the indicated O_2 flow rate ranges and patient simulations using an anatomical head model and servo-controlled test lung. The outcome shows the following:



	1	3	5	7	9	11	13	15
Airlife™ Open (AM1000/AM1100)	25	35	43	48	51	54	57	59
SouthMedic (OM1125-8/OP1125-8)	24	31	37	42	47	51	54	57

The bar heights represent the average [O2] over the range of tidal volumes from 320 -810 ml at 15 breaths per minute. The error bars represent the pooled standard deviations.

Figure 1. AirLife™ Open vs. SouthMedic OxyMask is clinically comparable in efficacy in patient simulation testing

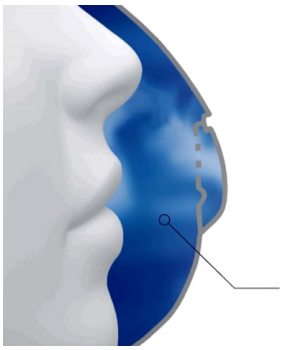
CONCLUSION

- The Airlife Open delivers better average tracheal (O_2) when compared to SouthMedic OxyMask at any given oxygen flow rate
- The AirLife Open oxygen mask products can cover the full 1-15 LPM range of O_2 delivery settings
- During testing masks were not sealed to the models to prevent leaks to simulate more realistic clinical practice

AirLife®

TESTING OVERVIEW

ITEM	DESCRIPTION
AirLife Open	M (AM-1000), L (AM-1100)
SouthMedic Oxymask	M (OM1125-8), Plus (OP1125-8)

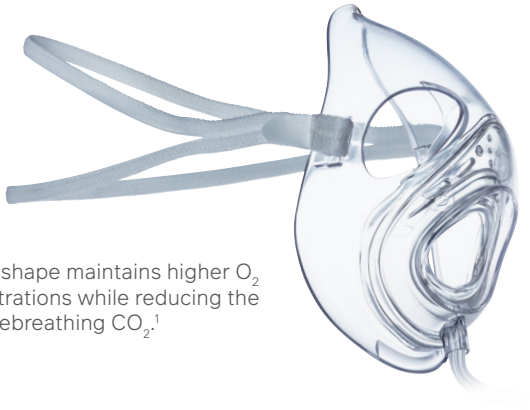


Improved compliance and therapy tolerance due to superior fit, soft O_2 flow and an opening for talking, drinking and eating.[1]

Soft distributed O_2 flow

WHY CHOOSE AIRLIFE OPEN™ OXYGEN MASK?

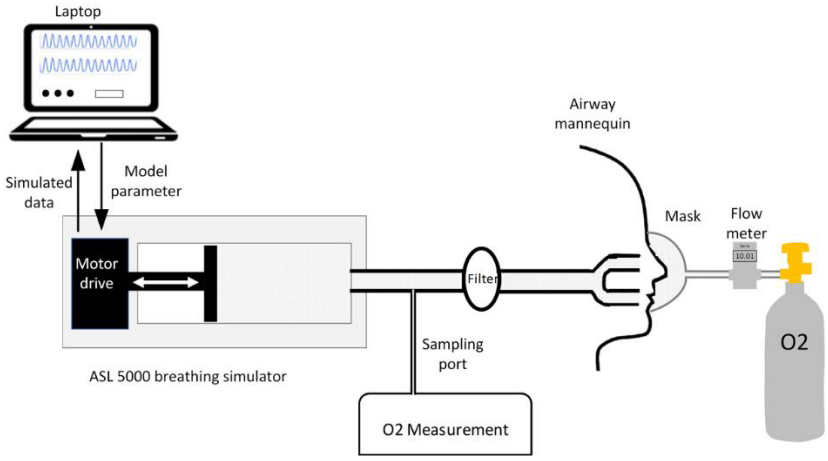
- Can be used from 1-15 LPM and flush
- May improve workflow:
  - Can replace multiple O_2 delivery devices with one
  - Staff require training on less devices
- Can create storage and supply room efficiencies
- Helps improve compliance



Unique shape maintains higher O_2 concentrations while reducing the risk of rebreathing CO_2.[1]

TEST METHOD

- All tests were conducted using the same end-use simulation apparatus with customized head models and an active servo test lung (ASL500, IngMar)
- Head models are based on anthropometric data and made with soft, pliable silicone, including oral and nasal structures and proportional flow paths
- An Oxigraf analyzer was used to measure O_2 concentrations in the simulated trachea and averaged over the test period for comparison
- Set on assumption that tracheal oxygen concentration correlates most closely to patient oxygenation
- Wide array of breathing patterns were derived with clinical input to cover normal/ typical breathing patterns and COPD breathing patterns
- Each product was tested 9 times and placed on the head model using the included strap to simulate realistic clinical use of the masks
- **No sealing materials or tapes were used to seal the mask surfaces to the head model to ensure real case simulation**



1. *Data on file at Vyaire. CFD Analysis of Open O_2 Mask Rib Structure Efficacy 45 R4680.*

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