

CLINICAL SUMMARY

AirLife Open™ Test Data Overview – AirLife Open vs. Simple Mask and Partial Rebreather Mask

DATA OVERVIEW

Testing was conducted by our research and development team. It was set up to simulate realistic clinical use situations for several oxygen delivery masks. The products tested were AirLife Open™, AirLife® simple mask, and AirLife partial rebreather. The traditional O₂ delivery devices (simple mask, rebreather mask) do not have size options like the AirLife Open, so the one adult size was used vs. medium and large in the open mask options. The simulation measured the tracheal concentration of FiO₂ over the indicated O₂ flow rate ranges and patient populations using an anatomical head model and servo-controlled test lung. The outcome shows the following:

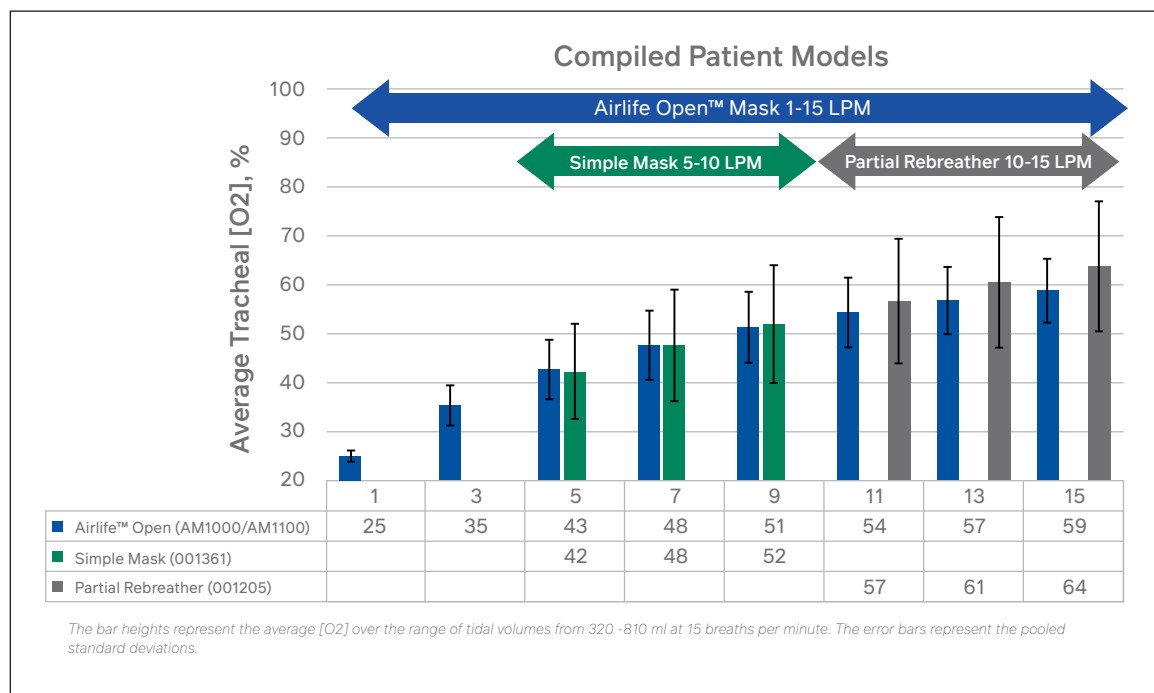


Figure 1. AirLife™ Open vs. Simple Mask and Partial Rebreather is clinically comparable in efficacy in patient simulation testing.

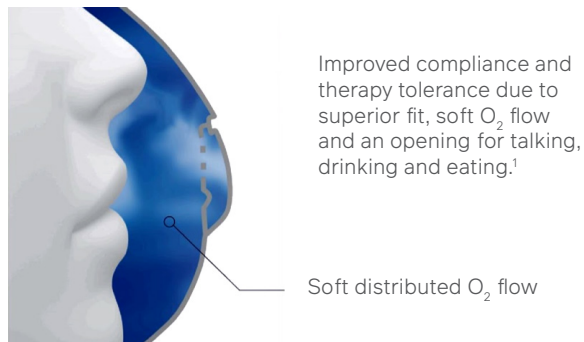
CONCLUSION

- The Airlife Open delivers equivalent average tracheal [O₂] as simple oxygen masks, with less variation
- The Airlife Open delivers comparable average tracheal [O₂] as the partial rebreather masks with less variation
- Only the open oxygen mask products can cover the full 1-15LPM range of O₂ delivery settings
- Masks were placed normally over the anatomically-correct head models to simulate clinical practice. No tapes or sealants were used to seal between the mask and facial surface.



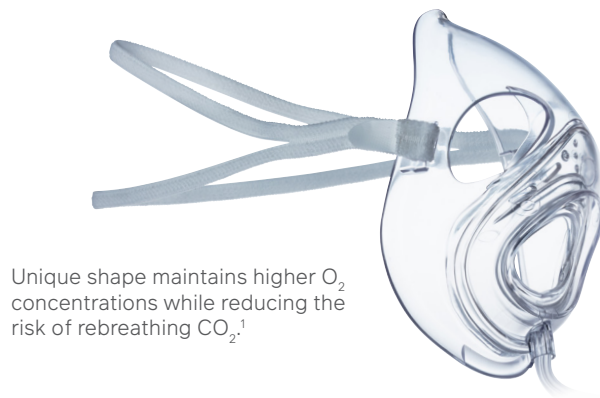
TESTING OVERVIEW

ITEM	DESCRIPTION
AirLife Open	M (AM-1000), L (AM-1100)
Simple Mask	Adult (001361)
Partial Rebreather	Adult (001205)



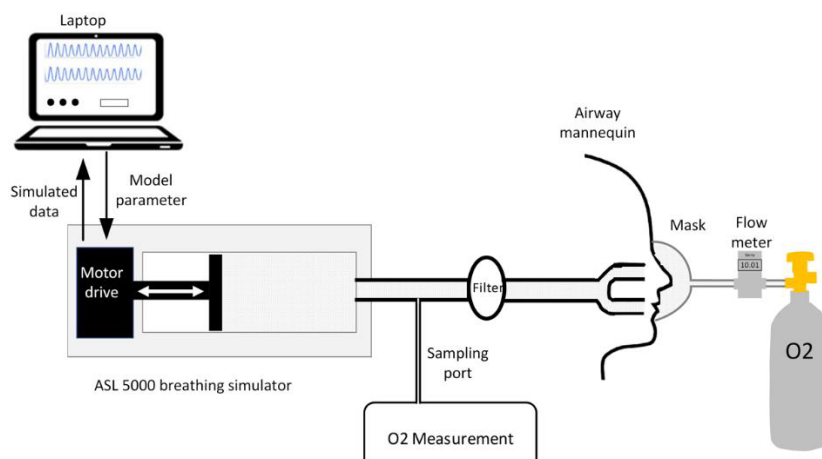
WHY CHOOSE AIRLIFE OPEN™ OXYGEN MASK?

- Can be used from 1-15 LPM and flush
- May improve workflow:
 - Can replace multiple O₂ delivery devices with one
 - Staff require training on less devices
- Can create storage and supply room efficiencies
- Helps improve compliance



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 O₂ 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 Vyair. CFD Analysis of Open O₂ Mask Rib Structure Efficacy 45 R4680.