# **OxyMask**<sup>™</sup>

# Empower Best Practice. Safer Care. Exceptional Experience.



# **Clinical Evidence Summary**

### **Executive Summary**

OxyMask is a solution for safer, more efficient oxygen delivery. It is an all-in-one replacement for other oxygen delivery modalities, such as the venturi mask and non-rebreather mask. The unique OxyMask technology helps enhance patient experience, increase efficiency, and reduce costs.

## **Introduction: Enhance Patient Experience**

In an ever-competitive healthcare market, patient experience is at the forefront of advances in healthcare. Patients treated with oxygen therapy may feel they are trapped or helpless.¹ Patient-centered solutions are increasingly recommended in policy and research.² OxyMask brings patient-centered care to fruition through its design and dependability.

### Patient-centered design

OxyMask utilizes a light-weight, open design that:

- Sits lightly on the face
- Allows unrestricted communication
- · Allows for oral medication delivery
- · May reduce the feeling of claustrophobia

### Dependability

OxyMask is clinically proven to deliver more oxygen at lower flow rates compared to traditional delivery methods.<sup>3</sup> Additionally, laboratory testing suggests that OxyMask reduces the risk of carbon dioxide rebreathing when compared to non-rebreather masks.<sup>4,5</sup>



# OxyMask Delivers Oxygen More Efficiently Than a Venturi Mask<sup>3</sup>

Beecroft JM, Hanly PJ. Comparison of the OxyMask and Venturi mask in the delivery of supplemental oxygen: Pilot study in oxygen-dependent patients. Can Respir J. 2006;13(5):247-252.

### Objective

Measure the efficiency and safety of OxyMask compared to a venturi mask in delivering oxygen to patients with chronic hypoxemia.

### Methods

This was a randomized controlled trial with a cross-over design, where patients were treated with both the OxyMask and the venturi mask in a randomized order. The following variables were measured:

- · Baseline SaO,
- SaO, during treatment
- · Inspired/Expired oxygen and carbon dioxide

### Results

OxyMask was associated with favorable patient outcomes:

- OxyMask maintained clinically desirable SaO<sub>2</sub> at a lower oxygen flow rate (Figure 1)
  - Flow rate used with OxyMask was significantly lower (P < 0.001)</li>
- Furthermore, OxyMask delivered more inspired oxygen than the venturi mask (P < 0.005)

## Average SaO, and Flow Rate by Mask Type

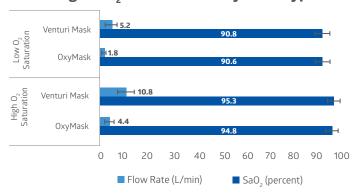


Figure 1: OxyMask maintained clinically desirable SaO<sub>2</sub> at a lower oxygen flow rate

### Conclusion

OxyMask maintained clinically desirable SaO<sub>2</sub> levels for all patients. **Patients inspired more oxygen at lower flow rates while using OxyMask, making it a dependable and costefficient choice.** 

### OxyMask May Reduce the Risk of Carbon Dioxide Rebreathing Compared to a Non-Rebreather Mask<sup>4</sup>

Lamb K, Piper D. Southmedic OxyMaskTM compared with the Hudson RCI® Non-Rebreather Mask™: Safety and performance comparison. Can J Resp Ther. 2016;52(1):13-15.

### Objective

Measure carbon dioxide rebreathing that may occur with OxyMask compared to a non-rebreather mask.

### Methods

This was a laboratory study where a respiratory model was used to compare OxyMask to a non-rebreather mask. Oxygen and carbon dioxide concentrations were analyzed using an  $O_2/CO_2$  analyzer. The following variables were measured:

- · Inspired oxygen
- · End tidal carbon dioxide
- Inspired carbon dioxide

### Results

OxyMask was associated with favorable results:

- OxyMask delivered more or similar amounts of oxygen (P < 0.001)</li>
- More CO<sub>2</sub> is cleared immediately after breathing with OxyMask (P < 0.001)</li>
- Less CO<sub>2</sub> was inspired when OxyMask was used (P < 0.001)</li>

	OxyMask*	Non-Rebreather Mask*
Reduction in CO <sub>2</sub> from mask interface after exhalation (percent)	83.1 ± 6.85%	63.8 ± 13.52%
Inhaled CO2 (FiCO <sub>2</sub> )	2.2 ± 0.5%	3.0 ± 1.1%

<sup>\*</sup>Results presented as mean ± one standard deviation

#### Conclusion

**OxyMask was associated with conditions that reduce CO<sub>2</sub> rebreathing.** Though this was a laboratory study and may not fully capture the complexities of human respiration, reducing CO<sub>2</sub> rebreathing may promote patient safety and well-being.

# **Introduction: Increase Caregiver Efficiency**

Nurses, respiratory therapists, and other clinicians are tasked with difficult workloads, made up of patients of varying acuity who depend on their care. OxyMask provides an all-in-one solution that simplifies oxygen therapy, saving time and freeing capacity for different tasks. Furthermore, OxyMask may reduce risks associated with mask changing errors.

### All-in-one solution

OxyMask is a single mask that can be used at various flow rates and oxygen titrations. OxyMask is a viable replacement for simple masks, venturi masks, partial non-rebreather masks, and non-rebreather masks.<sup>6</sup> It may also replace a nasal cannula as patient acuity improves. A single mask change takes approximately 10 minutes<sup>7</sup>; OxyMask eliminates the need for device changes which may save time and costs.

### Reduce risk

Traditional oxygen delivery devices are designed for specific flow rates and oxygen titrations, so any error in device or oxygen setting can introduce risk to patients. One study found that nearly 30% of patients received oxygen therapy outside their medically indicated target range.<sup>8</sup>

OxyMask may enhance patient safety through simplification of practice. In a large retrospective study, transitioning to the OxyMask reduced the annual number of mask changing errors to zero.9 Minimizing mask changing errors helps ensure that patients receive oxygen within the prescribed range.

# OxyMask is an All-In-One Replacement for Other Mask Types<sup>6</sup>

Paul JE, Hangan H. The OxyMask™ development and performance in healthy volunteers. Medical Devices: Evidence and Research. 2009;2(1):9-17.

### Objective

Measure the efficacy of OxyMask at providing adequate oxygen to patients under a variety of flow rates.

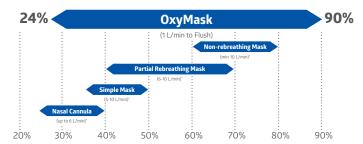
#### Methods

This was a prospective observational study where healthy volunteers used OxyMask at escalating oxygen flow rates. Fraction of inspired oxygen ( $FiO_2$ ) was the main clinical endpoint.

#### Results

OxyMask was effective at supplying a wide range of FiO<sub>2</sub> values at various flow rates:

- 25% FiO<sub>2</sub> at 1.5 L/min
- 90% FiO<sub>2</sub> at 15 L/min
- FiO<sub>2</sub> can be adjusted to between 25% and 90% by changing the flow rate



\*Flow rates and FiO<sub>2</sub> values of other devices were sourced from the 2002 AARC Clinical Practice Guideline<sup>10</sup>

### Conclusion

OxyMask effectively delivered a wide range of  ${\rm FiO_2}$  values through simple adjustments to the flow rate. OxyMask is an allin-one replacement for other mask types, which could save time and reduce trips to the supply room. Furthermore, using only one mask to meet a patient's needs may reduce the risk of mask changing errors.

# **Introduction: Maximize efficiency. Reduce costs.**

OxyMask $^{\text{TM}}$  may reduce overall oxygen therapy costs. OxyMask maintains appropriate  $\text{FiO}_2$  levels at lower flow rates than traditional oxygen delivery devices. Additionally, its all-in-one design may reduce storing and shipping costs by condensing several masks into one. One institution in the Midwest reported significant cost savings through increased storage efficiency and caregiver time-savings.

## OxyMask May Reduce Overall Oxygen Costs<sup>9</sup>

DeJuilio PA, Jenkins MB. Evaluation of safety and cost of an open-design oxygen mask in a large community hospital. Respiratory Care. 2018;63(4):412-416.

### Objective

Reduce safety events and oxygen costs through adoption of the OxyMask oxygen mask.

## Setting

395 bed acute-care, full-service tertiary hospital.

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### Methods

Cost data were retrospectively reviewed for one year before and after adoption of OxyMask. The following cost-related variables were collected and analyzed:

- · Patient days
- Bulk oxygen used, oxygen cost per patient day
- Total number of oxygen masks used, oxygen mask cost per patient day

Results	Pre-OxyMask	During OxyMask	Percent Change
Patient days	74,734	99,428	33%
Bulk O2 used (ft3)	13,036,686	12,072,610	-7.4%
O2 cost/patient day*	\$1.14	\$0.82	-28.1%
Number of oxygen devices used	3,848	5,512	43.2%
Mask cost/patient day*	\$0.05	\$0.13	185.6%
Total cost/patient day*	\$1.19	\$0.95	-19.9%

<sup>\*</sup>Cost presented in 2016 US Dollars.

### Conclusion

Though the cost of oxygen masks increased, the overall oxygenrelated costs significantly decreased. **This hospital reduced their oxygen-related costs by nearly 20%, saving \$23,487 annually.** 

### References

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- 5. Mani M, Maghur H. Evaluation of the capnographic monitoring and oxygen delivery functions of three variable oxygen delivery masks. Anesthesia. 2010;65:97-98.
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