

# Clinical Evidence

## Product Performance

ORIGINAL RESEARCH

### The OxyMask™ development and performance in healthy volunteers

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“(OxyMask) can provide a wide range of  $FiO_2$ , from 25% to 90%, while keeping its unique open design.”

#### Introduction

Oxygen was discovered and production occurred in 17...

“...the OxyMask was more efficient than the venturi mask in supplying oxygen to patients with chronic, stable respiratory disease.”

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OxyMask™ is a unique, open-style, oxygen mask that was originally the original mask was modified, using computational fluid dynamics numerical simulation to achieve the goal of allowing it to produce a wider range of  $FiO_2$ . This analysis was a comparison of the mask shell and the location for the oxygen diffuser.

OxyMask was attached to 10 healthy subjects and used to deliver escalating flow rates (2, 2.5, 3, 5, 10, 15, 20, 25 and 30 LPM) for 90 seconds at each level.  $FiO_2$  was recorded (averaged) from 5 consecutive measurements at each

5.4% at 1.5 LPM, 74.5% at 2.5 LPM, 74.5% at 3 LPM, 74.5% at 5 LPM, 74.5% at 10 LPM, 74.5% at 15 LPM, 74.5% at 20 LPM, 74.5% at 25 LPM, 74.5% at 30 LPM.

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“OxyMask device uses the mushroom/diffuser that by mixing and convection produces turbulent flow at any flow rate. Therefore the oxygen concentration levels coming out of the OxyMask device can be conveniently adjusted by controlling the flow rate.”

of cotton, or leather which was Bacteriostatic. That was systematically treated with supplemental oxygen who published “The therapeutic administration of oxygen in the modern era of oxygen therapy by founding a rational system of oxygen therapy during World War One (1914–1918) led to advancements in the treatment of phosgene gas poisoning. Dursk, nasal prongs, oxygen masks with a reservoir were developed.<sup>1</sup>

Oxygen masks and cannulae found their way into modern oxygen therapy and later in the application of these low flow devices were variable performance devices.  $FiO_2$  (fraction of inspired oxygen) that depended on the flow rate of the device were used. Specifically, since the delivered oxygen concentration is dependent on the patient's peak inspiratory flow rate (PIFR) the delivered oxygen is diluted by room air entrained from around the masks. These types of masks

