



Hi-Ox™ High FiO₂ Oxygen Mask

FREQUENTLY ASKED QUESTIONS

What are the intended uses of the Hi-Ox?

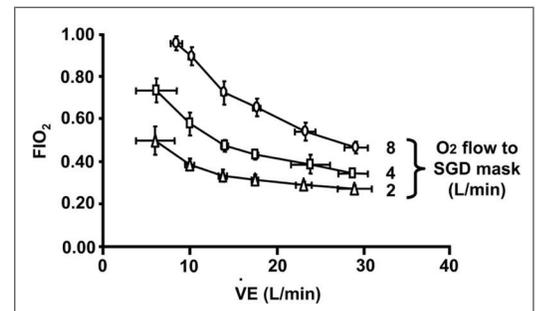
The Hi-Ox is intended for patients who either require high FiO₂'s or require high oxygen flow rates to deliver moderately high FiO₂'s. This may be of particular importance for patients in environments with limited oxygen supplies such as the home, EMS field use or unpiped areas of a hospital.

How much oxygen flow is required for the Hi-Ox?

The Hi-Ox typically can maintain FiO₂'s greater than 80 percent with flows of 8 LPM. In patients without respiratory failure, flows as low as 5-6 LPM can be adequate, while patients with severe respiratory distress may require higher flows of 10-12 LPM.

How does the FiO₂ delivery change with different oxygen flows and what are the effects of the patient's minute ventilation?

As long as the minute ventilation is below the set oxygen flow, the inspired oxygen should remain above 80%. As the minute ventilation increases above the set oxygen flow, more room air will be added at greater percentages of the inspired volume towards the end of the breath and this will reduce the efficiency of the Hi-Ox. The table below graphs the estimates of those relationships. There will also be some variable effect caused by the patient's breathing pattern itself.



What makes the Hi-Ox able to deliver these FiO₂'s at lower flows than other masks?

Exploring what causes inspired oxygen to be diluted by room air with existing masks, revealed that there were 2 entrainment sources. One was a limitation of the fit to the face and the other was the holes in the mask that patients exhaled through. On inspiration however, these holes provide a large source of dilution, particularly when the one-way valve between the inspired reservoir and the mask is of higher resistance than the holes. The design of the Hi-Ox mask removed the holes in the mask as well as included dual straps (one above and one below the ear) to get better sealing. Additionally, the mask is of slightly softer vinyl to form better to the face; the mask at the bridge of the nose was trimmed so that it wouldn't ride up the patient's forehead; and foam was placed in the inside of the bridge portion of the mask to get a better seal across the bridge.

The Hi-Ox has a 3-valve system that separates inspired oxygen coming from the reservoir bag from the exhalation path (See graphic explanation in the last question). This disposable mask has extremely low resistance valves (they will match

Caution: Federal Law restricts this device to sale by or on the order of a physician.



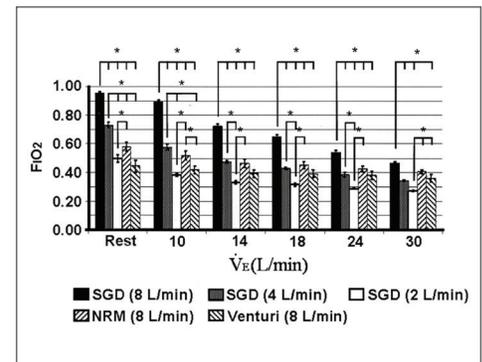
Read and follow instructions for use: www.twelfthmantec.com/instructions/



resistance performance of \$100 reusable valves) so that the inspiratory leaf will open at a lower pressure and with a lower resistance than most leaks around the mask. As long as the patient's minute ventilation is less than the flowmeter setting to the mask, the reservoir should meet any peak inspiratory flow (assuming that the tidal volume is less than the 0.75 liter reservoir plus the inflow during the inspiratory time). Beyond that, the mask takes advantage of the patient's anatomic deadspace to buffer high minute ventilation. The Hi-Ox has a third low resistance sequential dilution valve (slightly higher cracking pressure than the inspiratory/expiratory valves) that will open only once the reservoir bag is emptied, so that it sequentially adds room air at the end of the inspired breath. Because the last approximate 150 mL (assumed deadspace) of inspiration does not participate in gas exchange, the oxygen concentration of that gas in the airways is immaterial to the delivered FiO₂ to the alveoli.

How does the Hi-Ox compare to other oxygen delivery systems?

In peer reviewed publications, the Hi-Ox at 8 LPM, with its sequential gas dilution feature (SGD), out-performed non-rebreathing masks (NRBM) and Venturi masks (VM) with up to an absolute 37 percent higher FiO₂ than the NRBM and 51 percent higher than the VM. Even at 4 LPM, at modest minute ventilation levels, the Hi-Ox out-performed these other masks running at 8 LPM.¹



What is the resistance of the valves in the Hi-Ox?

The resistance of the Hi-Ox disposable valves is approximately 1 cmH₂O/L/s. This compares favorably to the Hans Rudolph permanent valves at 2.1 cmH₂O/L/s and the Hudson disposable mask valve of 2.44 cmH₂O/L/s.

What is the deadspace in the Hi-Ox Mask?

Although the physical deadspace of the large adult Hi-Ox is approximately 103 mL (varies by face size displacement), much of the space is below the chin and around the cheeks where this air does not participate in, or affect gas exchange. Studies of the functional deadspace of the Hi-Ox demonstrated that the effective deadspace is only around 45 mL and would not add significantly to rebreathing of carbon dioxide. The small adult mask has less deadspace as does the pediatric mask.

How many different Hi-Ox sizes are offered?

There are three different sizes of the Hi-Ox. There is a large and a small adult mask and a pediatric mask. The valve bodies for all three are the same size.

Don't high FiO₂'s cause atelectasis?

Although atelectasis has been associated with breathing 100 percent oxygen, the Hi-Ox doesn't deliver exactly 100% oxygen and slightly lower concentrations have been safely applied to patients without causing loss of lung volume. A study in postoperative patients in which they performed FRC measurements in patients receiving 30% oxygen versus 80% oxygen, they found no difference in the incidence of atelectasis.²

¹Slessarev M, et.al. Efficiency of oxygen administration: Sequential gas delivery versus "flow into a cone" methods. *Crit Care Med* 2006; 34:829–834

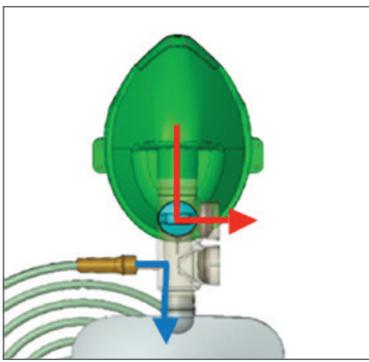
²Sessler DI, Akca O. Nonpharmacological Prevention of Surgical Wound Infections. *Clinical Infectious Diseases* 2002; 35:1397–404

Can the Hi-Ox be used for other gases such as Heliox?

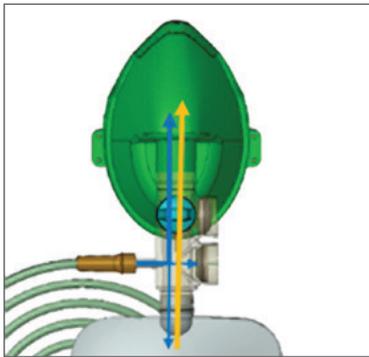
The Hi-Ox has not been specifically approved for the delivery of Heliox. However, because it is the most efficient mask for limiting dilution of the source gas supply, some clinicians have found it very effective for this application when compared with other masks.³

How Does the Hi-Ox Work?

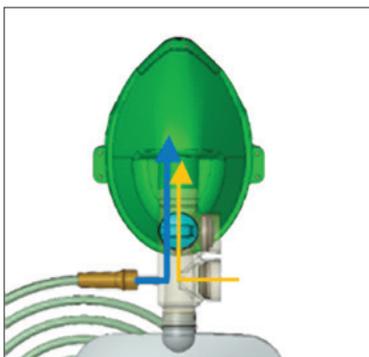
To maximize delivered inspired oxygen, exhalation holes in the mask which, also dilute inspired oxygen, were removed. The 3-valve system separates the reservoir bag inspired oxygen from the exhalation path to the room. The Hi-Ox's third dilution valve's slightly higher cracking pressure, opens only once the reservoir bag is emptied, so that room air is sequentially added at the end of the inspired breath. Taking advantage of the patient's approximate 150 mL anatomic deadspace, which does not participate in gas exchange, the oxygen concentration of that gas in the airways becomes immaterial to the delivered FiO_2 to the alveoli.



During exhalation, the patient's breath flows only out the exhalation valve. There are no holes in the mask for exhaled flow. During this time, the oxygen flow entering the Hi-Ox fills the inspiratory reservoir.



During the patient's inspiration, 100% oxygen entering the Hi-Ox flows up through the inspiratory valve to the facemask without the dilution from holes in conventional masks. The oxygen source also applies closing pressure against the dilution valve and fills the inspiratory reservoir.



If the patient's inspiratory demand exceeds the 0.75-liter reservoir (and the reservoir has emptied), the dilution valve will open and fill the patient's deadspace with room air. Filling non-gas exchange deadspace limits reductions in alveolar oxygen.

³ Roche-Campo, et. al. Delivery of helium-oxygen mixture during spontaneous breathing. *Intensive Care Med* 2011; 37:1787-92



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