TECHNICAL PAPER

One Mask™ FiO_2 Bench Testing

Abstract

This study was to evaluate oxygen delivery and flow rate requirements of a new oxygen mask available through Amsino International, Inc. The vast majority of oxygen delivery systems via a mask type system require changing masks as oxygen requirements change. The OneMask avoids the requirement of changing masks for all ranges of FiO_2. This study was designed to identify the ranges for oxygen flow rates as a correlate of inspired oxygen concentration (FiO_2). Its findings were submitted to the FDA for Class II registration.

Materials and Methods

Ten healthy volunteers (age range 27 to 62, Male 5 Female 5) were studied at the Kindred Hospital in Las Vegas, Nevada by John Leyva, Director of Respiratory, Radiology, and Lab Dept's. Equipment used in this evaluation included the following: MaxTec O_2 analyzer (MaxTec, Salt Lake City, Utah)

The OneMask was altered slightly to allow for monitoring of the pCO_2 and FiO_2. The mask was altered in the following way: a small slit was formed one half way between the top of the mask and the first curve as it courses the adapter. The slit allowed for air tight positioning of the transducers so that there was no air leakage or air entrainment from the mask-transducer interface.

Flow rates that were reviewed were 2 liters per minute, 4 liters per minute, 6 liters per minute, 8 liters per minute, 10 liter per minute and 15 liters per minute. FiO_2 values were recorded.

Sample #	LPM	ANALYZED FiO_2	LPM	ANALYZED FiO_2	LPM	ANALYZED FiO_2
1	2L	30%	4L	49%	6L	70%
2	2L	28%	4L	50%	6L	73%
3	2L	30%	4L	48%	6L	72%
4	2L	32%	4L	48%	6L	72%
5	2L	33%	4L	49%	6L	70%
6	2L	30%	4L	53%	6L	71%
7	2L	31%	4L	52%	6L	75%
8	2L	30%	4L	49%	6L	72%
9	2L	31%	4L	52%	6L	70%
10	2L	32%	4L	50%	6L	71%
	Average	**0.307**	Average	**0.500**	Average	**0.716**
	Z test	**0.327807115**	Z test	**0.185013856**	Z test	**0.42056592**
	Median	**31%**	Median	**50%**	Median	**72%**

One Mask™ FiO_2 Bench Testing

Sample #	LPM	ANALYZED FiO_2	LPM	ANALYZED FiO_2	LPM	ANALYZED FiO_2
1	8L	85%	10L	92%	15L	98%
2	8L	86%	10L	95%	15L	99%
3	8L	83%	10L	93%	15L	99%
4	8L	80%	10L	91%	15L	97%
5	8L	82%	10L	92%	15L	99%
6	8L	79%	10L	89%	15L	96%
7	8L	86%	10L	94%	15L	98%
8	8L	83%	10L	92%	15L	97%
9	8L	81%	10L	90%	15L	98%
10	8L	82%	10L	93%	15L	99%
	Average	**0.827**	Average	**0.921**	Average	**0.980**
	Z test	**0.396327405**	Z test	**0.429962127**	Z test	**0.5**
	Median	**83%**	Median	**92%**	Median	**98%**

Conclusions

The results indicate a linear relationship between flow rates and inspired oxygen concentration. There was statistically significant FiO_2 values in regards to accuracy at each flow rate and inspired oxygen. ***Inspired oxygen concentrations with any oxygen mask are in the clinical setting variable and depends on patient's own respiratory rate and tidal volume and that reliance on FiO_2 is not appropriate; the appropriate endpoint effect is the oxygen saturation of the patient. Standard of care requires documentation of efficacy either with pulse oximetry or arterial blood gas analysis.*** For this reason we have extrapolated approximate FiO_2 values for the flow rates not measured in this bench testing (flow rate of 3 and 5 liters per minute). Our recommended flow rates for FiO_2 ranges are as follows:

Liter Flow Rate	Approximate FiO_2 Value
2L	28-33 %
3L	34-47 %
4L	48-53 %
5L	54-69 %
6L	70-75 %
8L	76-86 %
10L	87-95 %
>15L	95-99 %

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