Purpose:

The purpose of this evaluation is to determine selected performance characteristics of the TopOx single-use oxygen mask. The disposable mask features an attached bottle/bag fixture that stores a volume of delivered continuous flow oxygen (CFO) during the user's exhalation phase. Application of the mask is intended to provide greater FiO_2% than standard CFO by allowing the user to inhale both the stored oxygen and inspiratory CFO. This evaluation compared FiO_2% in application of the TopOx with and without the oxygen storage bottle attached in various test conditions. In addition, the effect of mask application on $ETCO_2$% was measured as well as any inspiratory restrictions placed on the user due to their tidal volume exhausting the storage volume of the bottle/bag.

Equipment:

Units Under Test (UUT):

TopOx Single-Use Oxygen Mask – TopOx Ltd, Gloucester, UK

Additional Equipment:

Series 1101 Breathing Simulator- Hans Rudolph, Inc.

Oxygen Analyzer, Model 570A- Servomex

BTC-II Miniature Diaphragm Pump- Hargraves Technology Corp.

Model 4140 Mass Flowmeter- TSI, Inc.

Mannequin Head

Modified with 22mm adapter placed in oro-nasal area

Model 7100 CO_2SMO $ETCO_2/SpO_2$ Monitor- Novametrix Medical Systems

100% O_2; 100% CO_2- Airgas Puritan Bennett

Corr-a-Flex 22mm tubing- Hudson RCI

Test Procedures:

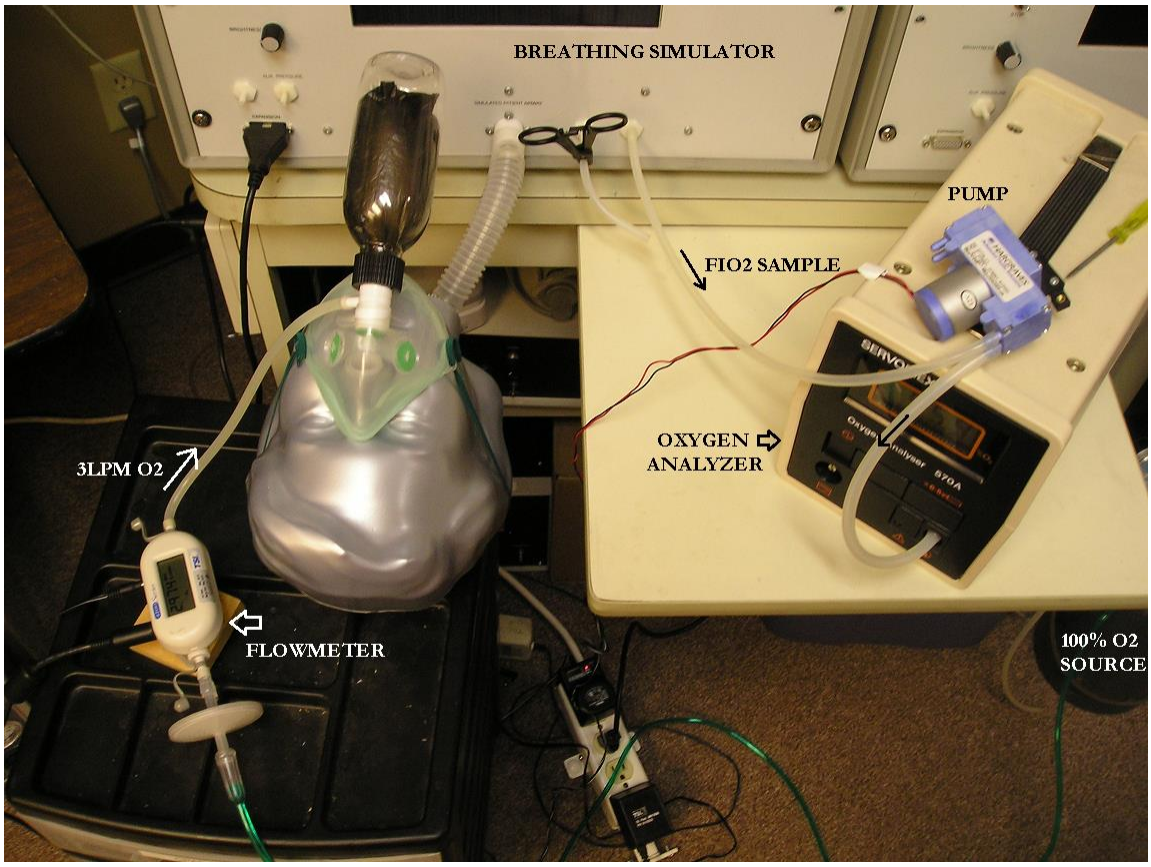
Prior to testing, the TopOx mask was inspected for any product deficiencies or damage; no issues were found.

Using Annex F of the ISO 17510-2 (2007): "Sleep apnoea breathing therapy—Part 2: Masks and application accessories" standard as reference for test setup of a simulated patient, a length of 22mm diameter Corr-a-Flex was cut to measure 140mL volume and used to connect the breathing simulator connection port to the 22mm adapter on the mannequin head.

The TopOx mask was placed on the mannequin head with the headgear securing the mask to the mannequin face. No attempt was made to ensure there was no unintentional leak other than adjusting the fit of the mask to best fit the face.

The Servomex oxygen analyzer was calibrated with room air (20.9%) and 100% oxygen. The $ETCO_2$ monitor was calibrated using the unit's self-calibration feature.

Setup and Procedures for FiO_2 Test



Silicone tubing was used to connect the breathing simulator sampling port to the pump inlet port, and also to connect the pump outlet port to the Servomex oxygen analyzer. The pump takes gas samples from the lung and directs them to the oxygen analyzer at a rate of approximately 0.725 LPM.

Standard 25' oxygen tubing was used to connect the 100% O_2 gas source (a cylinder fitted with a low flow regulator) to the flowmeter. Silicone tubing was used to connect the flowmeter to the oxygen inlet port of the mask. Oxygen delivery was regulated to 3 LPM continuous flow (+/- 0.050 LPM), and verified by observing the reading on the flowmeter, adjusting the regulator as necessary.

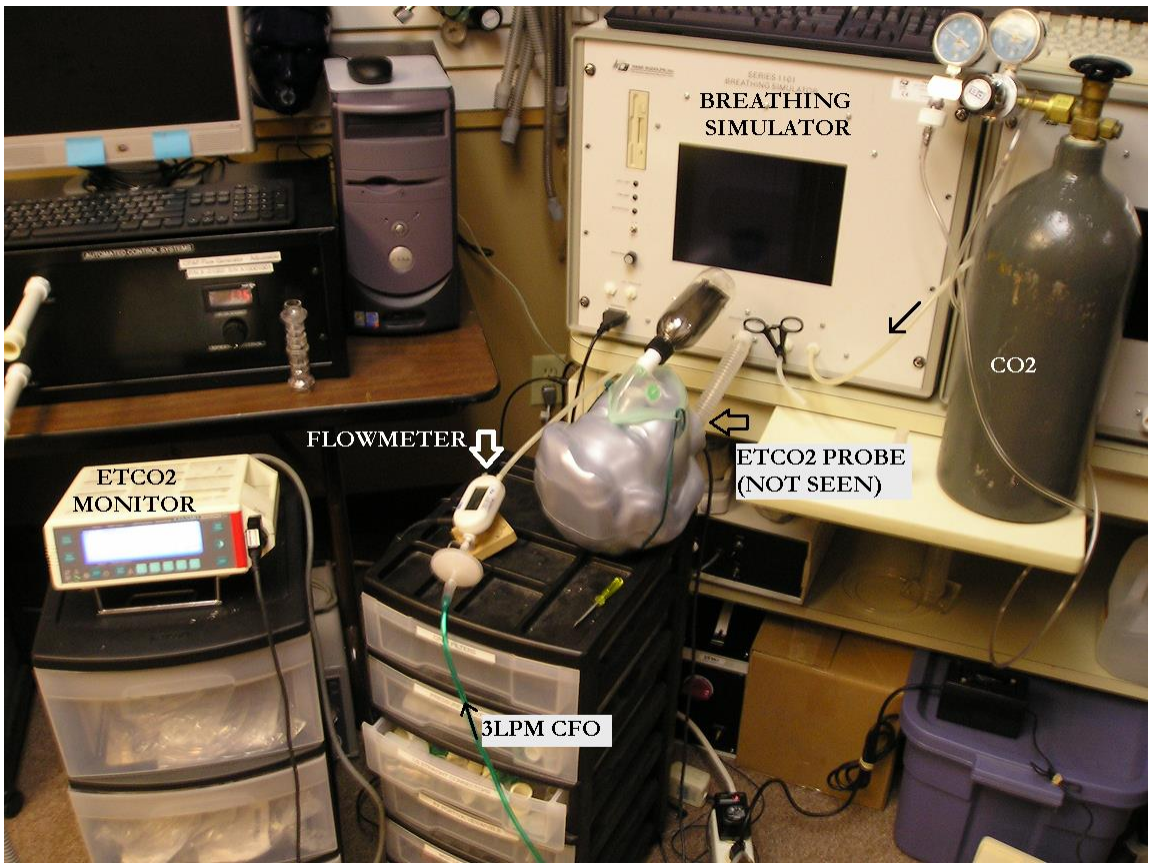
Three patient conditions were separately tested. Breathing simulator settings are shown below:

	Breathing Simulator Settings					
	Test 1		**Test 2**		**Test 3**	
Resistance	5		5		5	**Resistance**
Compliance	80		80		80	**Compliance**
Breath Rate	15		30		40	**Breath Rate**
Amplitude	29.5		34		34.5	**Amplitude**
Effort Slope	3		3		3	**Effort Slope**
% Inhale	34		50		50	**% Inhale**
	15 BPM		**30 BPM**		**40 BPM**	
	500 Vt		**400 Vt**		**300 Vt**	

For a given test and with the simulator actively breathing, the TopOx was applied and 3 LPM CFO was delivered to the mask. Readings from the Servomex oxygen analyzer were observed until the displayed reading stabilized, at which time the value was recorded.

Following the above tests, each scenario was retested without the TopOx storage bag/bottle attached to the mask.

Setup and Procedures for $ETCO_2$ Test



Test setup for $ETCO_2$ was identical to the FiO_2 test, with two exceptions: The oxygen analyzer and pump were replaced by a CO_2 gas source and regulator, and an $ETCO_2$ monitor was added to the setup. The CO_2 regulator was connected to the simulator gas sample port via silicone tubing. The $ETCO_2$ monitor probe was placed between the Corr-a-Flex tubing and the 22mm adapter on the mannequin head (the probe cannot be seen in the image above, as it is inside the hollow mannequin head).

The breathing simulator was set to run a sinusoidal-type wave pattern at 15bpm with a tidal volume of ~500mL and an I:E ratio of 1:2. With the TopOx mask removed from the mannequin head, gas flow from the CO_2 tank was initiated and $ETCO_2$ values were monitored on the capnograph. CO_2 gas flow was adjusted until a ~5 % baseline $ETCO_2$ was achieved. This setup was allowed to run for five minutes to ensure baseline $ETCO_2$ was stable, at which time baseline $ETCO_2$ was recorded.

The TopOx mask was then reapplied to the mannequin head, and the oxygen regulator was adjusted to deliver 3LPM CFO. $ETCO_2$ values were monitored on the capnograph. Five minutes were allowed to pass to ensure $ETCO_2$ was stable, at which time $ETCO_2$ was recorded.

Additional Observational Information

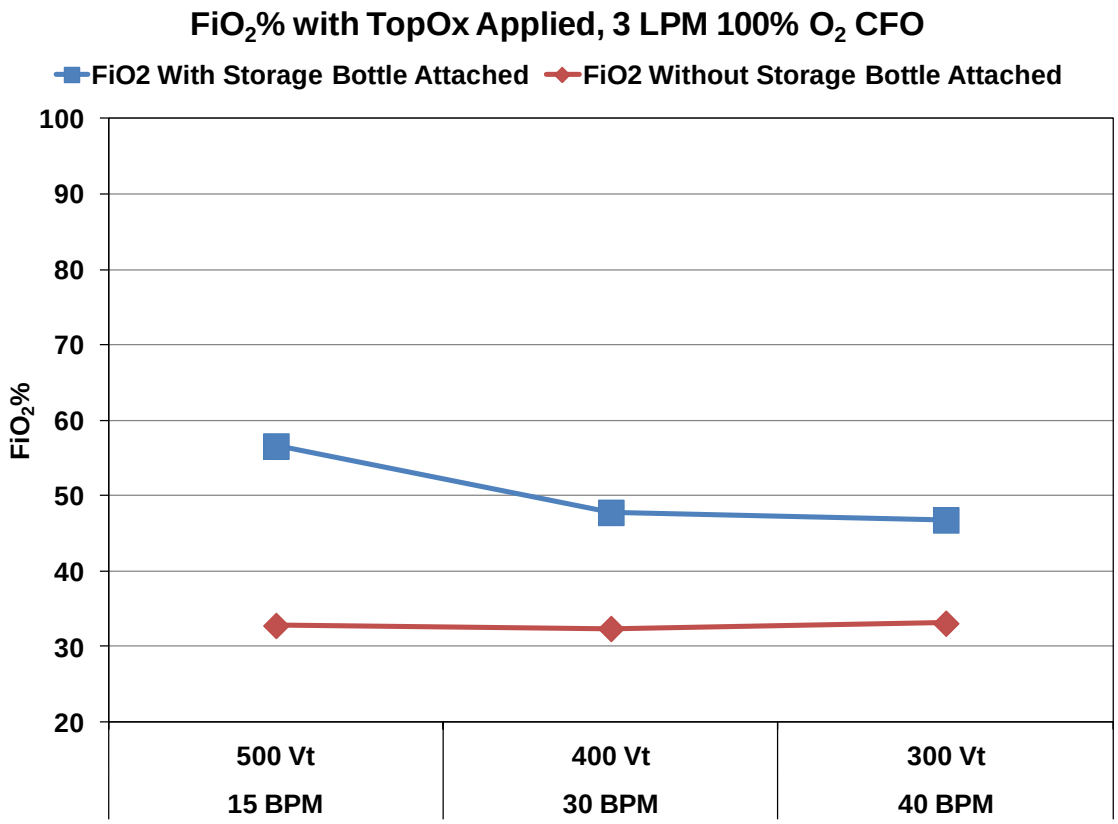
Using the test setup described for the FiO_2 test at 15BPM and 30 BPM, the simulator's Amplitude setting was adjusted upward (this increases tidal volume) until it was noted that the oxygen storage bag of the TopOx was fully collapsed due to the vacuum caused during inhalation. The on-screen graphics of the breathing simulator were monitored to note if there was any added resistance due to the collapse of the bag (identifiable by a sudden reduction or ceasing of flow in the patient flow curve and/or an increase in peak-to-peak airway pressures).

Using the test setup described for the FiO_2 tests, substituting a simulated nose fitted with a Hudson 1104 nasal cannula for the TopOx mask/dummy head fixture, oxygen flow was adjusted through the system so that FiO_2 values matched that recorded from each tested condition with the TopOx mask at 3 LPM CFO. The O_2 flow reported on the flowmeter was recorded to note the liter flow equivalency to the TopOx FiO_2 results.

Results and Observations:

FiO_2 Tests

	TopOx FiO_2% at 3LPM CFO			
	Test 1	**Test 2**	**Test 3**	
w/ storage	56.6	47.8	46.8	**w/ storage**
w/o storage	32.8	32.4	33.1	**w/o storage**
	15 BPM	**30 BPM**	**40 BPM**	
	500 Vt	**400 Vt**	**300 Vt**	



$ETCO_2$ Test

		CO2 Rebreathing		
		Baseline ETCO2%	Mask ETCO2%	% Increase
TopOx	3LPM CFO	5.0	6.4	28

Application of the mask in the setup increased $ETCO_2$% from 5.0% baseline to 6.4% (a 28% increase), which is above the limit set by the ISO 17510-2 standard for CPAP masks with pressure applied (20% or less), but is much less than the "fault condition" limit of 60%, where no pressure is applied. While there was an increase in $ETCO_2$% due in part to a lack of flushing of the deadspace during exhalation, the one way valves around the mask force volume to be exhaled outside the mask and the mask appears to have enough venting capability that CO_2 is not successively retained.

Liter Flow Equivalency

Liter flow equivalency (continuous flow O_2) needed to achieve the FiO_2 values recorded with the TopOx mask at 3 LPM were as follows:

	Liter Flow Equivalency			
	Test 1	Test 2	Test 3	
FiO_2%	56.6	47.8	46.8	FiO_2%
TopOx	3.0 LPM	3.0 LPM	3.0 LPM	TopOx
CFO	8.9 LPM	7.5 LPM	6.9 LPM	CFO
	15 BPM	30 BPM	40 BPM	
	500 Vt	400 Vt	300 Vt	

Discussion/Conclusions:

Application of the TopOx mask/bottle with 3 LPM CFO resulted in significantly greater FiO_2s than FiO_2s seen with standard 3 LPM CFO. These results indicate that the storage bottle attachment does retain a volume of delivered O_2 during exhalation and that some or all of this volume is inhaled on the subsequent breath, supplementing the 3 LPM CFO that is delivered during inhalation..

Application of a mask to a patient's face adds a certain amount of deadspace to the oro-nasal profile. Since some exhaled air remains in the area between the mask and the patient's face, applying masks with limited venting (especially without PAP pressure applied) can lead to CO_2 rebreathing and/or an increase in $ETCO_2$. The ISO 17510-2 mask standard specifically outlines what is acceptable in terms of changes in $ETCO_2$ due to a mask being applied. Hence it was determined to utilize the test protocol outlined in the standard to note if application of the TopOx led to an increase in $ETCO_2$ and/or rebreathed CO_2. Results showed that ETCO2 did increase when the mask was applied, largely due to the deadspace added to the oro-nasal area. However, this increase was well within the acceptable range described in the single-fault condition tests of the standard, where positive pressures are absent from the mask, as is the case when the TopOx is applied.

Application of the TopOx mask significantly reduced the liter flow requirements to achieve specific FiO_2s in the tested conditions, suggesting significant oxygen conservation benefits when using the TopOx mask versus standard CFO.

Exceeding the volume capacity of the O_2 storage bag on inspiration did not significantly affect the breathing pattern at 15 or 30 BPM. There was some resistance/work of breathing when breathing in deeply with large tidal volumes (>750mL), noted by a peak-to-peak increase of about 2 cmH_2O in the pressure profile, and visual inspection during inhalation identified the mask being slightly drawn in to the mannequin head, but the looseness of the one way flappers and mask fit essentially allowed enough flow to pass through the mask to the lung without causing the flow pattern to be significantly altered or abruptly halted. If the mask were to be held forcefully to the face and/or the one-way valves blocked, then the possibility of additional resistance/work of breathing exists.

It is understood that the TopOx mask tested for this evaluation was in prototype stage, so any modifications to the product going forward may impact device performance and the results presented here should not be considered applicable to any device revisions.

All testing, data analysis and initial report generation completed from May 23—June 5, 2013. Evaluation of liter flow equivalency and RevA report completed July 2-3, 2013.

Signed:

Ryan Diesem, Research Manager