

**Performance Evaluation of Pulse Oxygen Designs  
Designated for General Aviation use at  
Altitudes up to 25,000 feet above Sea Level**

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## **I. PURPOSE AND OBJECTIVES**

The purpose of this study was to identify the performance capabilities of pulse oxygen delivery systems that may be utilized in the general aviation flight environment. This study was requested by the FAA Northwest Mountain Region Aircraft Certification Region (ANM-100) to support equipment certification efforts. Current FAA regulations for general aviation oxygen equipment specify performance requirements for continuous flow oxygen systems (oxygen supplied continuously to an oral-nasal mask or nasal cannula at a specified flow rate), demand /diluter demand oxygen systems (100% oxygen or appropriately diluted oxygen supplied only during inhalation), and pressure demand oxygen systems (high altitude systems providing oxygen during inhalation at pressures greater than ambient). Pulse oxygen systems provide a flow of oxygen to a mask or nasal cannula only during the first phase of inhalation; thus, the function of the pulse system contains elements of both continuous flow and demand systems. Current regulations do not provide system performance or design standards that adequately define pulse oxygen systems; thus, the sponsor requested physiological evaluations at altitudes up to 25,000 ft.

## **II. DESCRIPTION OF THE STUDY**

### **Historical Background**

The amount of oxygen relative to the total amount of atmospheric gases remains constant at approximately 21.0% to altitudes of approximately 300,000 feet. Ascent to altitude results in a drop of the atmospheric pressure. Therefore, the partial pressure of oxygen available to the body decreases. Both cognitive and physical performance deficits are known to occur as a result of altitude exposures above 14,000 feet. To prevent the effects of hypoxia, Federal Aviation Regulations require supplemental oxygen aboard aircraft. For un-pressurized aircraft supplemental oxygen is required for each occupant at altitudes

above 15,000 feet Mean Sea Level (MSL). Pilots are required to use supplemental oxygen if a flight exceeds 30 minutes in the altitude range of 12,500 to 14,000 feet MSL or if the flight is above 14,000 feet MSL [1].

To provide the pilots and passengers with the ability to effectively function at altitude, a variety of supplemental oxygen equipment designs have been developed for use in the general aviation environment. Basically, the approach to providing supplemental oxygen to date can be categorized as continuous flow equipment that uses a nasal cannula or oro-nasal mask as a means of delivery to the user or diluter demand. In continuous flow systems, nasal cannula use is allowed up to altitudes of 18,000 feet MSL and oro-nasal masks are permitted up to an altitude of 25,000 feet MSL. Diluter demand oxygen equipment is required if the airplane is to be certificated for operation above 25,000 feet [2].

Basic specifications for flight crew continuous flow oxygen systems are provided in 14CFR 23.1443, paragraphs (a)(2) or (a)(3). Paragraph (a)(2) states that for each crew member the minimum mass flow of oxygen must support a mean tracheal oxygen pressure of 149 mmHg at a ventilatory rate of 15 l/min Body Temperature Pressure, Saturated (BTPS) and a maximum tidal volume of 700 cc. Paragraph (a)(2) provides an alternate certification method referencing a figure showing the required oxygen mass flow relative to aircraft cabin altitude. In general this figure shows an oxygen mass flow requirement of 1 l/min/10,000 ft cabin altitude such that at 10,000 ft cabin altitude the minimum mass flow of oxygen would be one l/min and at 25,000 ft, the minimum mass flow would be approximately 2.5 l/min. 14CFR 23.1443 paragraph (b) states that if diluter demand oxygen equipment is installed for use by crew members, the minimum mass oxygen flow may not be less than the flow required to maintain a mean tracheal oxygen pressure of 122 mmHg at altitudes up to 35,000 ft. For passenger oxygen systems, 14CFR23.1443 specifies that at altitudes from 10,000 ft to 18,000 ft, the system must maintain a mean tracheal oxygen pressure of 100 mmHg breathing 15 l/min BTPS with a tidal volume of 700 cc and at altitudes between 18,500 – 40,000 ft the passenger system must maintain a mean tracheal oxygen pressure of 83.8 mmHg breathing 30 l/min with a tidal volume of 1,100 cc [3].

Other references and standards convert the basic CFR requirements into measurements and procedures that are more adaptable to human testing. FAA Technical Standard Order TSO-C103 - Continuous Flow Oxygen Mask Assembly (For Non-transport Category Aircraft) - further defines certification test requirements and invokes National Aerospace Standard NAS 1179 – Oxygen Mask Assembly Passenger which provides test procedures for human subjects at altitude [4, 5]. NAS 1179 paragraph 4.1.8, defines mask testing that provides for the use of either end tidal gasses or arterial oxygen saturation as the measure

of merit in determining the physiological effectiveness of the mask. Specifically, NAS 1179 test procedures use the arterial oxygen saturation established by subjects breathing ambient air at 10,000 ft to be the equivalent of a mean tracheal oxygen pressure of 100 mmHg and the arterial oxygen saturation established by subjects breathing ambient air at 14,000 to be the equivalent of a mean tracheal oxygen pressure of 83.8 mmHg. SAE Aerospace Standard AS8025 also provides standard procedures for the certification testing of continuous flow oxygen equipment using arterial oxygen saturation as the principal measure of measure and specifies that 11 subjects should be tested at the maximum altitude requested for certification. Thus, to meet passenger requirements established in 14CFR23.1443, a comparison of the arterial oxygen saturations measures during mask use at altitude can be compared to a baseline arterial oxygen saturation values found at 10,000 and 14,000 ft [5].

Advances in the areas of both pneumatic and electronic technologies may allow supplemental oxygen systems to be developed that delivery oxygen to the user more efficiently than previous continuous flow designs. These designs provide a bolus of oxygen at the optimal time in the breathing cycle. Therefore, oxygen availability is theoretically the same physiologically as a diluter demand oxygen system but the total volume of oxygen utilized is reduced when compared to a continuous flow system. Additionally, the mask and nasal cannula used to deliver oxygen to the user is similar to continuous flow equipment. This approach does not characteristically fit the continuous flow requirements anticipated at the time the Federal Aviation Requirements covering the topic were written. Therefore, it must be demonstrated that the designs represent an equivalent level of safety for the user before they can be approved for use in aviation. Pulse or bolus oxygen delivery is commonly used in respiratory and other patients requiring oxygen for medical reasons [6] and portable oxygen systems using pulse oxygen delivery schedules have been certified by the FAA for use in flight; however permanently installed oxygen systems have not been certified.

ANM-100 requested that CAMI conduct altitude testing on two oxygen systems, an electronically controlled unit The Micro processor controlled system consists of a master control unit that can be used by the pilot to control and monitor oxygen delivery, cabin altitude, oxygen system pressures for the pilot and, depending upon the unit, from one to three other occupants using either cannula or masks. Other than the number of occupants who can be supplied with oxygen, the two person and the four person master control units function identically. The master control unit feeds oxygen via standard tubing to individual control units. The individual control unit feeds oxygen to the user via a combination delivery and sensing line. The individual control unit electronically senses delivery line pressure changes that indicate the start of inhalation and delivers a bolus of oxygen to coincide with the first phase of inhalation. The volume of oxygen delivered by

each bolus is adjustable up from a minimum standard that (according to the manufacturer) is the equivalent of the FAA required oxygen mass flow (14 CFR 23.1443). The individual control units can also be adjusted for the altitude at which oxygen breathing is started and provides warning if the system is disconnected or the system does not sense a breath at least every 40s [7].

The mechanically controlled system utilizes a mechanical regulator to provide oxygen to a single occupant via a dual lumen delivery tube (one lumen provides oxygen to a nasal cannula and the other lumen is the pressure sensing line that detects the start of inhalation). With the mechanically controlled system, one regulator is required for each individual. Each regulator receives oxygen directly from the ship's supply. The regulator senses the pressure change at the start of inhalation and starts delivery of oxygen to coincide with the inspiratory phase of respiration. The volume of oxygen delivered during inspiration is calculated by the manufacturer to exceed oxygen mass flow requirements specified in 14 CFR 23.1443 [8].

### **Hypothesis**

*Null Hypothesis:* The blood oxygen saturation maintained by the test systems at altitudes up to 25,000 ft. will not be significantly different from the blood oxygen saturations determined by subject breathing ambient air at 5,000 ft. MSL for crew members, 14,000 ft MSL for passenger systems used above 18,000 ft MSL and 10,000 ft MSL for passenger systems used below 18,000 ft MSL. The systems to be tested provide a pulse of oxygen on inspiratory demand; thus, the oxygen standard defined for flight crewmembers using a demand oxygen system will be used to establish the arterial oxygen saturation baseline. 14CFR 23.1443 (b) states that demand oxygen systems must provide a mean tracheal oxygen pressure of 122 mmHg at altitudes up to 35,000 ft. Per the USAF flight surgeons guide, the tracheal oxygen pressure at 5,000 ft MSL is 123 mmHg; thus, 5,000 ft. was selected as a baseline altitude for comparison of system performance for flight crewmembers. Both systems will be tested to a maximum altitude of 18,000 with a nasal cannula and oral-nasal mask used for oxygen delivery and a maximum of 25,000 ft with an oral-nasal mask used for oxygen delivery. For passenger use testing, subjects will breath ambient air at 10,000 ft. to establish an arterial oxygen saturation baseline for systems to be used at altitudes of 18,000 ft or lower and 14,000 ft breathing ambient air will be used to establish the baseline arterial oxygen saturation for systems that will be used above 18,000 ft.

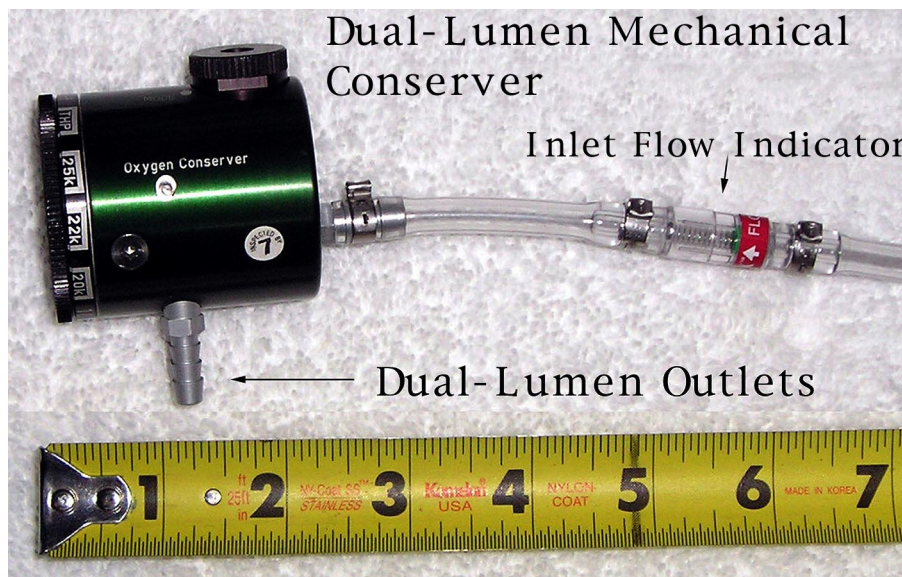
## METHODS:

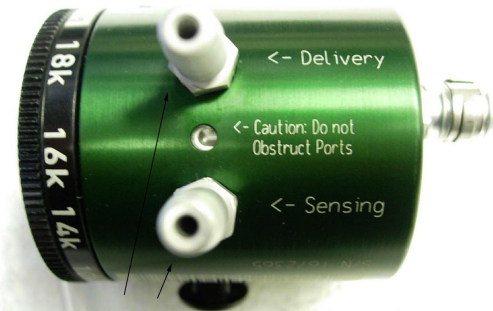
### Equipment and Facilities

The testing was conducted in the Civil Aerospace Medical Institute (CAMI) research hypobaric chamber and associated laboratories. Equipment utilized to monitor physiological responses of each subject during the testing included a 12 lead electrocardiogram (using only the limb leads) and a pulse oximeter for determination of blood oxygen saturation. The Civil Aerospace Medical Institute (CAMI) research personnel validated instrument accuracy, monitored subject performance and conducted data collection, analysis and reporting. CAMI Airman Education division personnel operated the hypobaric chamber and assisted in the oxygen equipment installation and operation. Representatives from the oxygen equipment manufacturer provided technical support in the installation and operation of their equipment that was tested. The CAMI research principal investigator exercised overall control and maintained primary responsibility for the conduct of the study including subject selection, subject briefing, instrumentation, data collection, analysis and reporting. A CAMI research division physician acted as the medical monitor for the project.

### Description of Experiment

This study was reviewed by the CAMI Institutional Review Board as risk protocol and approved by the Federal Air Surgeon. Two different oxygen systems and related equipment was tested under this protocol: A **mechanically** controlled pulse oxygen delivery system, tested in the pulse delivery mode, supplied oxygen via a nasal catheter, a clear mask and a blue mask. The blue mask was fitted with a microphone typically found on aviation headsets.





Dual-Lumen Mechanical Conservator Device



Dual-Lumen Inlet



Dual-Lumen Inlet



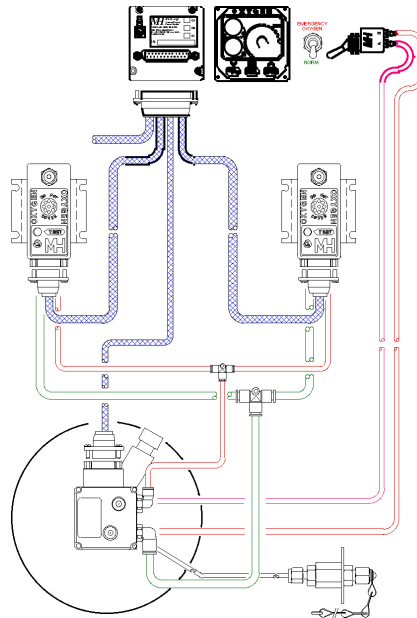
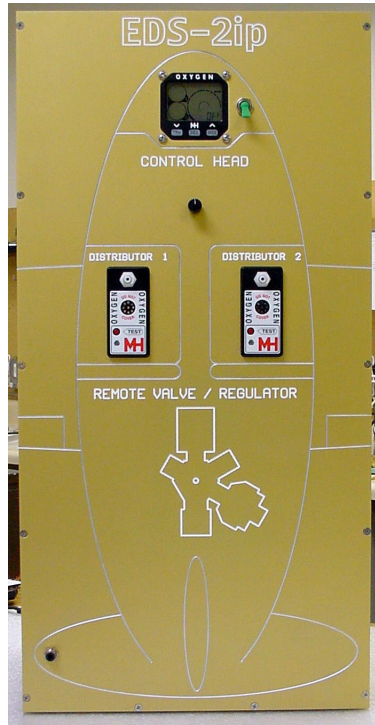
Dual-Lumen Inlet



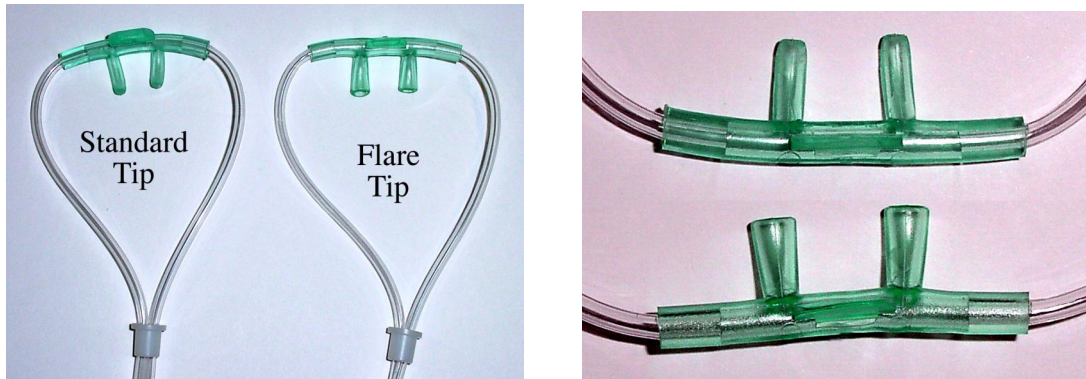
Dual-Lumen Inlet

Dual Lumen Cannula and Face masks for the mechanical version

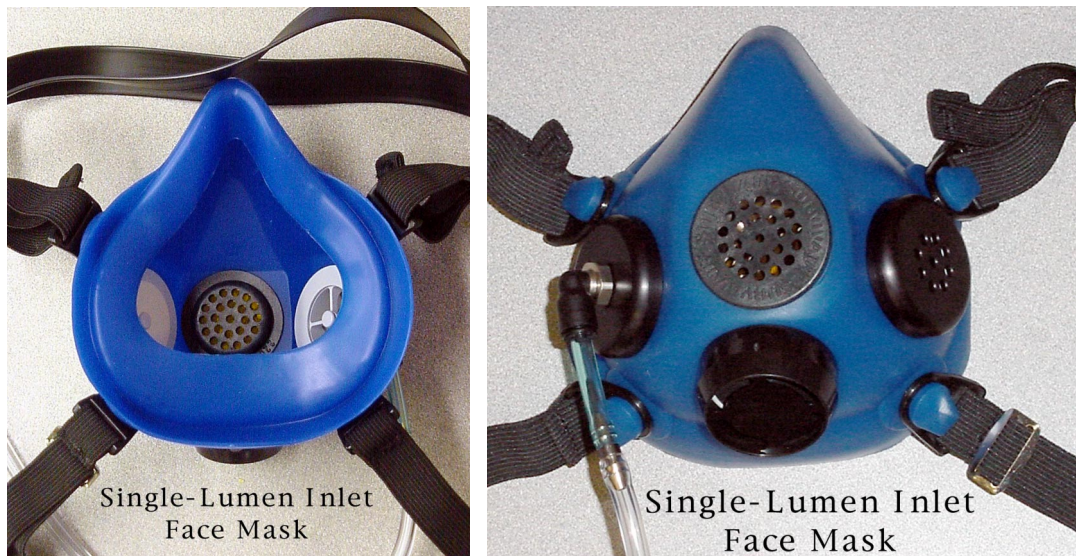
The **micro processor** controlled system supplied oxygen via a nasal catheter, and an oral-nasal mask. Systems supplying oxygen via the nasal catheter were tested at a maximum of 18,000 ft MSL and to a maximum altitude of 25,000 ft MSL using the various oral-nasal masks. Evaluation of the test systems required two altitude chamber “flights” per subject.



Microprocessor version in test-set fixture



Single lumen nasal cannula for the micro processor version



Single Lumen face mask for the micro processor version

The principal measure of merit will compare the subject's arterial oxygen saturation at 5,000 ft. MSL, 10,000 ft MSL and 14,000 ft. MSL (breathing ambient air) with the subject's arterial oxygen saturation using the test oxygen systems at 18,000 ft. MSL (with nasal cannula) and 25,000 ft MSL (Mask condition only).

### **Subjects:**

**Number of Subjects:** A total 16 subjects were recruited to complete the protocol to meet oxygen system performance standards (NAS-1179 and SAE Aerospace Standard AS8025) and statistical analysis requirements [5]. Experience in altitude research has shown that various events including illness (colds, upper respiratory tract infections, seasonal allergies) and personal issues (schedule conflicts, loss of interest), may cause subjects to be unable to complete the protocol; thus to ensure that at least 11 subjects do complete the protocol, a total of 20 subjects were recruited [9]. Both male and female subjects 18 to 30 years of age



were used in this study to test both oxygen systems. Statistical requirements for the number of subjects were determined using the UCLA statistics program, normal power requirements for a one sample, one sided, paired T test analysis. A reference study used arterial oxygen saturation to evaluate the performance of a portable oxygen system at altitudes up to 25,000 ft. This study showed arterial oxygen saturation with subjects breathing supplemental oxygen from a continuous flow oxygen system to be approximately 97% at 25,000 ft and the arterial oxygen saturation with subjects breathing a hypoxic gas mixture equivalent to 10,000 ft altitude to average 93.5%. The combined standard deviation for the referenced study was approximately 3%, which included an instrumentation accuracy range for the Nelcor N-200 pulse oximeter of 2% [9]. Using the referenced values with a desired significance level of .05% and a power level of .90, calculations showed the required number of subjects to be 10.081; thus, the use of 11 subjects can be expected to meet statistical requirements (Attachment 1).

**Table 1: Subject demographics**

Average (Range)	Number of Subjects	Age	Height	Weight	BMI
All	16	22 (19-25)	69 (61-74)	172 lbs (125-210 lbs)	25 (19.6-32.1)
Male	10	22 (19-25)	71 (67-74)	192 lbs (175-210)	27 (21.8-31.3)
Female	6	22 (19-24)	66 (61-74)	140 lbs (125-185)	22 (19.6-24.7)

**Subject Qualifications and Training:**

All subjects were required to meet the medical standards equivalent to a Class III FAA pilot certificate and did complete the FAA Physiological Training program. To assure consistent data collection, only non-smokers will be used as subjects. The CAMI Occupational Health Division conducted the medical examinations. After passing the medical examination, the subject's medical data were reviewed by the medical monitor for a final participation approval. One subject was disqualified because of the medications that he was required to take for pre-existing medical condition. Another subject was disqualified due to an abnormal EKG and did not complete the follow-up medical clearance in time to participate as a subject. A third participant required emergency abdominal surgery, unrelated to the study between scheduled test sessions and was therefore disqualified from completing the second "flight". The fourth subject dropped out because of scheduling conflicts.

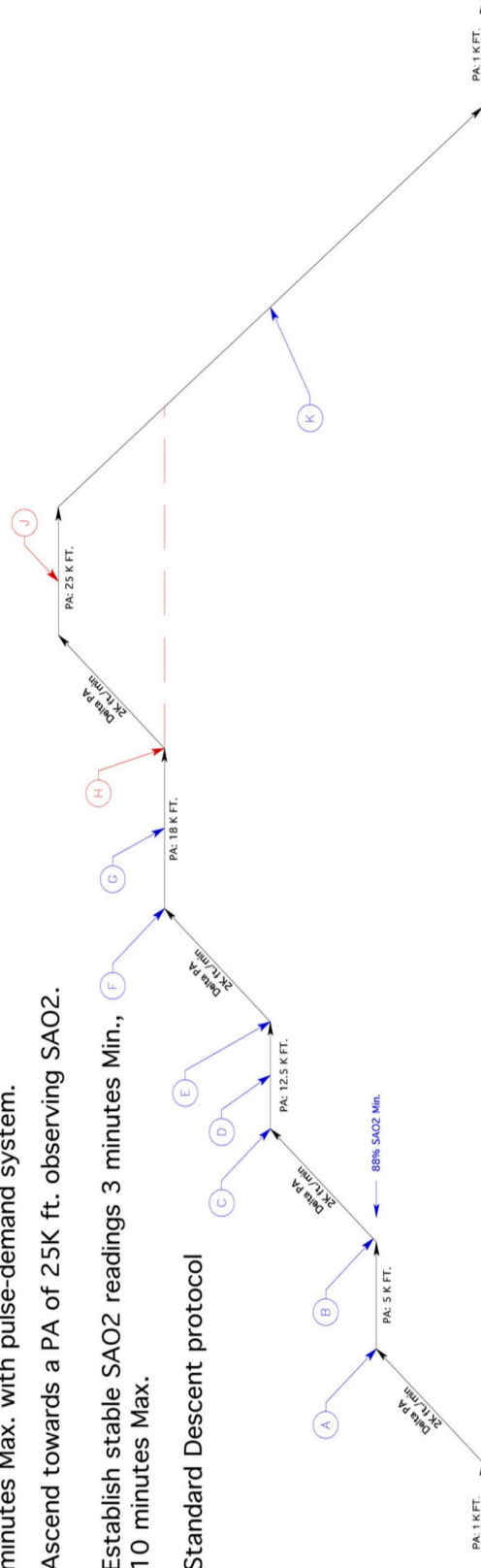
**Chamber Flight Profile Description:**

The chamber flight profile used in this study is graphically displayed in Figure 1. Both systems were tested following this flight profile. The profile included an initial ear and sinus check ascent to 5,000 ft MSL and return to ground level followed by the required 30 min. de-nitrogenation period at ground level pressure with the subjects breathing 100% oxygen via a pressure demand type oxygen mask. Two subjects were used as often as the scheduling permitted and the same oxygen systems were tested when possible, during each chamber flight. The subjects removed the aviator's breathing mask and started to ambient air prior to the chamber pressure being reduced to simulate an altitude of 10,000 ft MSL. The subject remained at this altitude breathing ambient air until the arterial oxygen saturation remained relatively stable for 4 minutes or a maximum time at 10,000 ft of 15 minutes. The subject will then don a nasal catheter and the chamber was ascended to 18,000 ft. The subjects remained at this altitude for a maximum of 10 min. or less if the subject's arterial oxygen saturation is stabilized for a 4 min. data collection period. Both micro processor controlled and the mechanically controlled systems were tested with nasal cannula and masks. The mechanically controlled system test flights included two different types masks with the nasal cannula. The micro processor controlled system had only a single mask that came in three sizes. Each subject was instructed to select a mask that fit them comfortably and was as air tight as possible. Alternately closing the intake port and inhaling and the closing the exhalation port and exhaling checked the air tightness of each mask. See next page.

- A: Establish SAO2 datum in 3 minutes min., 10 minutes Max.
- B: Don cannula with pulse-demand system and ascend towards a PA of 12.5K ft. observing SAO2.
- C: Establish stable SAO2 readings 3 minutes Min., 10 minutes Max. with pulse-demand system.
- D: Establish stable SAO2 readings in 3 minutes Min., 10 minutes Max. with pulse demand system. Change to constant-flow with cannula with flow meter @ 800 ml/minute and reestablish SAO2 readings in 3 minutes Min., 10 minutes Max.
- E: ReDon cannula with pulse-demand system and ascend towards a PA of 18K Ft. observing SAO2.
- F: Establish stable SAO2 readings 3 minutes Min., 10 minutes Max. with pulse-demand system.
- G: Change to face-mask and reestablish SAO2 readings in 3 minutes Min., 10 minutes Max. with pulse-demand system.
- H: Ascend towards a PA of 25K ft. observing SAO2.
- J: Establish stable SAO2 readings 3 minutes Min., 10 minutes Max.
- K: Standard Descent protocol

**Notes & Cautions**

SAO2 readings will be incorrect because of disturbances to the pulse oxymeter during movements of the test subject. Therefore, it is most advised that someone be available to assist if any equipment changes are made during testing.



*The test will be aborted at any point if any subject does not achieve the datum SAO2 or if any other medical problems occurs.*

When testing the each oxygen system, the subjects switched from the nasal cannula to the oro-nasal mask after sufficient oxygen saturation data was collected. For the flights where the mechanically controlled system was being tested, there were three equipment changes, nasal cannula to clear mask to blue mask. At the completion of the 18,000 ft. data collection period and the chamber ascended to 25,000 ft with the subject's wearing the oro-nasal mask. The subjects remained at 25,000 ft for a maximum of 10 minutes or less if the subject's oxygen saturation is stable for the 4-minute data collection period. For the mechanically controlled system test flights, the subject would switch from the blue mask back to the clear mask and data would be collected with the same requirements of a 4-minute stable arterial oxygen saturation data collection period. From the maximum altitude of 25,000 ft., the chamber descended to 14,000 ft and the subjects removed the supplemental oxygen supply and breathed ambient air. The chamber remained at this altitude for 10 minutes or less if a 4-minute stable arterial oxygen saturation period is established. From 14,000 ft, the chamber will descend to 12,500 ft. and remained there for the 4-minute stable arterial oxygen saturation. The chamber was then descended to 5,000 ft. for the baseline arterial oxygen saturation data. Following the 5,000 ft stop, the chamber descended to ground level. A 3,000-ft/min ascent and descent rate was maintained for all chamber flights. The total exposure times above ground level, not including the ear and sinus check were approximately 73 minutes. The subjects were not exposed to hypobaric conditions without a 72-hour break between exposures.

## **Data Collection**

### Procedures for Data Collection and Analysis:

All experimental variables will be collected using noninvasive transducers designed for human use. Electronic signals from the electrocardiograph (SensorMedics ECG Mac-1), and pulse oximeter (Nelcor N-200, Nellcor Puritan Bennett Division, 4280 Hacienda Drive, Pleasanton, CA 94588 USA) were monitored in real time using a digital computer and an accompanying data acquisition board. The cardiac data obtained during the testing sessions did not demonstrate any dysrhythmia. None of the chamber flights were terminated by the principal investigator or by the chamber inside observer in response to any observed abnormal physiological response. The Nelcor N-200 Pulse Oximeter was self-calibrating. The disposable probes were calibrated and encoded at the time of manufacture. This information was read by the N-200 at boot-up and calibrates the pulse oximeter at this time. The accuracy of the analog data output is  $\pm 20$  mvolts at 0 volts and  $\pm 0.5\%$  of full scale.

### **Statistical Analysis**

Statistical Analysis was initially preformed utilizing Excel spreadsheet software, which was also used to organize the data for exporting to S-Plus for additional analysis.

### **Results**

The standard altitude equivalent of 5,000 feet was selected to test the equipment for use by pilots.

### Micro processor controlled system

The micro processor controlled system was tested on 16 subjects with all pieces of equipment provided by the manufacturer at all appropriate altitudes per protocol. The table below the mean SpO<sub>2</sub> of all the subjects at the baseline altitude of 5,000 feet and the test altitudes of 18,000 feet and 25,000 feet with the standard deviation for each subject. The Mean of all the subjects and the standard deviation is along the bottom. All pieces of the micro processor controlled equipment supplied sufficient oxygen to exceed the 5,000-foot baseline requirement.

**Table 2: Micro processor controlled Test results – SpO<sub>2</sub> means across subjects**

Subject	5K	+/- SD	NC @ 18K	+/- SD	Blue @ 18K	+/- SD	Blue @ 25K	+/- SD
730718723	99.0	0.9	99.8	0.4	100.0	0.0	100.0	0.0
730656527	97.8	0.8	96.0	1.5	98.1	1.1	99.2	0.5
751504523	96.9	0.7	99.9	0.3	99.2	0.4	100.0	0.0
730727727	96.8	0.5	99.2	1.4	100.0	0.0	99.6	1.4
731702445	95.9	1.1	100.0	0.0	98.6	0.4	98.9	0.1
730728192	97.3	1.2	99.0	1.0	99.9	0.2	100.0	0.0
730714302	93.5	1.3	100.0	0.0	99.9	0.3	99.9	0.3
774785626	95.6	2.8	99.0	1.0	98.2	1.1	98.0	0.5
730264530	96.6	1.4	99.8	0.4	98.1	1.0	99.7	0.4
731244324	97.8	1.5	100.0	0.0	100.0	0.0	100.0	0.0
730711564	95.6	0.6	97.9	1.0	100.0	0.0	99.9	0.3
731601868	98.5	1.6	99.8	0.4	99.3	0.9	99.7	0.5
760927230	94.6	3.1	98.2	0.6	98.6	0.4	98.1	1.4
730712112	96.9	1.3	96.9	1.2	98.5	0.8	98.0	0.7
730697359	98.1	0.8	98.7	0.4	100.0	0.0	99.9	0.3
730711844	95.2	1.8	97.3	1.5	98.7	0.8	97.8	1.4
Mean of all Subjects	96.6	1.3	98.8	0.7	99.2	0.5	99.3	0.5
P(T<=t) two-tail			0.0003		0.0000		0.0000	

### **Conclusions**

The micro processor controlled system demonstrated that the nasal cannula and the oro-nasal mask, at the test altitudes of 18,000 feet and the oro-nasal mask at the test altitude of 25,000 feet, were able to deliver sufficient oxygen to exceed the requirements of the 5,000-foot standard set forth in the AIR-505 ( $p < 0.05$  all conditions). These results allow recommendation for use of the micro processor controlled equipment at altitudes allowed by the FAR 23.1443 in the oxygen conserving mode [3].

### **Attachments**

Report of Medical History (from the 8500-8 form / Class 3 medical)

Individual's Consent to Voluntary Participation in a Research Project

Graphs of equipment at test altitudes (average of all subjects for each piece of oxygen

equipment tested) Screen shots of SpO<sub>2</sub> and altitude readings from Lab View Recordings

**Reference:**

1. *Title 14 CFR 91.211*, in *Part 91 GENERAL OPERATING AND FLIGHT RULES*. 2005.
2. *Title 14 CFR 23.1441*, in *Part 23 AIRWORTHINESS STANDARDS: NORMAL, UTILITY, ACROBATIC, AND COMMUTER CATEGORY AIRPLANES*. 1993.
3. *Title 14 CFR 23.1443*, in *Part 23 AIRWORTHINESS STANDARDS: NORMAL, UTILITY, ACROBATIC, AND COMMUTER CATEGORY AIRPLANES*. 1993.
4. *FAA Technical Standard Order TSO-C103, Continuous Flow Oxygen Mask Assembly (for non-transport category aircraft)*. 1984, Department of Transportation FAA: Washington D.C.
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8. Removed
9. Garner, R., *Performance of a portable Oxygen Breathing System at 25,000 feet Altitude*. DOT/FAA, 1998 (AM-98/27): p. 11.