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16. Abstract

Pulse oxygen systems deliver a pulse or bolus of oxygen during inhalation through a nasal cannula or oro-nasal mask. The design and function of pulse oxygen systems contains elements of continuous flow and diluter demand oxygen delivery systems. Continuous flow and diluter demand systems are defined by Federal Aviation Administration (FAA) regulation; however, these regulations do not define requirements for the certification of pulse oxygen systems. To provide data for potential certification actions, a physiological performance evaluation of an electronically operated pulse oxygen system manufactured by the Mountain High Company (MH) and a mechanical system manufactured by the Precise Flight Company (PF) was conducted in the Civil Aerospace Medical Institute's research altitude chamber. Both the MH and PF systems were tested at 18,000 ft using nasal cannulas and oro-nasal masks for oxygen delivery and at 25,000 ft using only the oro-nasal masks as the delivery method. Sixteen subjects tested the MH system and 14 subjects tested the PF system. Pulse arterial oxygen saturation (SpO_2) was determined via pulse oximeter. Heart rate and subjective observations were also used to assess system performance. Based on performance requirements for diluter demand oxygen systems, maintenance of an equivalent to 5,000 ft altitude breathing ambient air was established as the primary test criterion. The MH systems met the 5,000 ft criterion in all test conditions The PF system did not meet test criterion with either the nasal cannula or either of the two oro-nasal masks provided for testing. In all cases subjects had to be reminded to breathe through their nose when using the nasal cannula. Results from this study indicate that pulse oxygen systems can be designed to meet oxygen delivery requirements; however, we recommend that the operator of these pieces of oxygen delivery equipment have a thorough understanding of the equipment used to ensure safe operation.

17. Key Words Hypoxia, Pulse Oxygen Delivery Systems, Altitude, General Aviation, Oxygen Saturation, Cannula, Oro-nasal Mask.	18. Distribution Statement Document is available to the public through the Defense Technical Information Center, Ft. Belvior, VA 22060; and the National Technical Information Service, Springfield, VA 22161

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Introduction

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. 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, a physiologic performance evaluation at altitudes up to 25,000 feet above Mean Sea Level (MSL) was required to support certification.

Background

To prevent the effects of hypoxia, Federal Aviation Regulations require supplemental oxygen aboard aircraft. For unpressurized aircraft, supplemental oxygen is required for each occupant at altitudes above 15,000 ft MSL. Pilots are required to use supplemental oxygen if a flight exceeds 30 min in the altitude range of 12,500 to 14,000 ft MSL or continuously if the flight is above 14,000 ft MSL [1].

In general aviation aircraft, either continuous flow or diluter demand oxygen systems are generally used to provide supplemental oxygen. In continuous flow systems, the use of a nasal cannula for oxygen delivery is allowed up to altitudes of 18,000 feet MSL, and oro-nasal masks are permitted up to 25,000 ft MSL. Diluter-demand oxygen systems use an oro-nasal mask for oxygen delivery. Diluter-demand or pressure-demand oxygen systems are required if the airplane is to be certificated for operation above 25,000 ft [2].

Basic specifications for flight crew continuous flow oxygen systems are provided in Title14 of the Code of Federal Regulations (CFR) Part 23, §23.1443, paragraphs (a)(2) or (a)(3) [3]. Paragraph (a)(3) states that for each crew member the minimum mass flow of oxygen must support a mean tracheal oxygen pressure of 149 mm. Hg. 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.

Other references and standards convert the basic regulatory requirements into measurements and procedures that are more adaptable to human testing. Federal Aviation Administration (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 which provides test procedures for human subjects at altitude [4, 5]. The NAS defines mask test procedures that use either end tidal gasses or arterial oxygen saturation as the measure of merit in determining the physiological effectiveness of the system. Society of Automotive Engineers (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 merit and specifies that 11 subjects should be tested at the maximum altitude requested for certification [6].

Advances in the areas of both pneumatic and electronic technologies may allow supplemental oxygen systems to be developed that deliver oxygen to the user more efficiently than previous continuous flow designs. These designs provide a bolus of oxygen during inspiration; thus, the operation of the pulse oxygen system is similar to diluter demand oxygen systems that deliver oxygen only during inspiration. Theoretically, by delivering oxygen only during inspiration, the pulse system conserves the aircraft oxygen supply when compared to a standard continuous-flow system. The pulse oxygen does not characteristically fit the continuous-flow requirements anticipated at the time the FAA regulations covering the topic were written; thus, the pulse systems must demonstrate that design meets safety requirements before they can be approved for use in aviation. Pulse, or bolus oxygen delivery, is commonly used for patients requiring oxygen for medical reasons [7], and portable oxygen systems using pulse-oxygen delivery schedules have been used in flight; however, permanently installed oxygen systems have not been certified.

The pulse oxygen systems provide supplemental oxygen on inspiratory demand; thus, the oxygen standard defined for flight crewmembers using demand oxygen systems was designated as the arterial oxygen saturation baseline. Per §23.1443 (b), demand-oxygen systems must provide a mean tracheal oxygen pressure of 122 mm. Hg. at altitudes up to 35,000 ft [3]. The USAF flight surgeons guide states that the tracheal oxygen pressure at 5,000 ft MSL is 123 mm. Hg.; thus, 5,000 ft was selected as a baseline altitude for comparison of system performance [8]. The null hypothesis for this study is stated as follows, “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.” Both systems were tested to a maximum altitude of 18,000 ft with a nasal cannula, and an oral-nasal mask was used for oxygen delivery from 18,000 ft to the maximum test altitude of 25,000 ft.

Methods and Materials

Test Items

To provide data relative to the performance of pulse oxygen systems, equipment manufactured by two companies - Mountain High E&S Company, Redmond, OR, (MH) and Precise Flight Inc., Bend, OR (PF) - were evaluated using a nasal catheter and an oro-nasal mask for oxygen delivery. Systems supplying oxygen via the nasal catheter were tested at a maximum of 18,000 ft MSL. The systems were tested to a maximum altitude of 25,000 ft MSL when an oro-nasal mask was used for oxygen delivery.

Mountain High

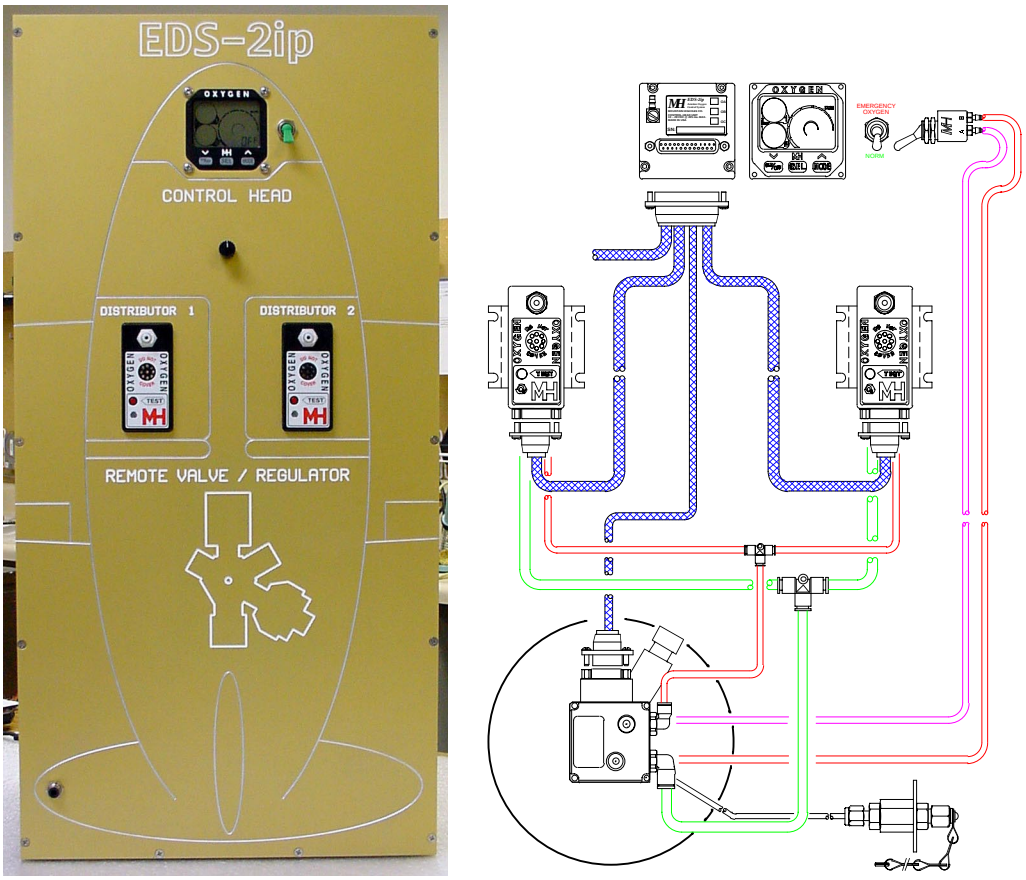


Figure 1. Display of the MH 2 person oxygen delivery system. Showing the master control unit (control head) and individual control units (distributors).

The Mountain High (MH) system (Designated EDS 2ip – two person system or EDS 4ip – four person system) consisted of a master control unit that can be used by the pilot to control and monitor oxygen delivery, cabin altitude and oxygen system pressures for himself and one to three other occupants (Figure 1). Either a nasal cannula or oro-nasal mask can be used for oxygen delivery to the occupants. Other than the number of occupants that 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) was the equivalent of the FAA required oxygen mass flow (14 CFR 23.1443) [3]. The individual control units can also be adjusted to set the altitude at which oxygen delivery is started. Additionally, the control units will provide a warning if the system is disconnected or the system does not sense a breath at least every 40s. The MH system was tested with a nasal cannula (Figure 2) and an oro-nasal mask manufactured by the Aerox Co., Limington, ME (Figure 3). The oro-nasal mask was provided in three sizes to allow appropriate fitting.

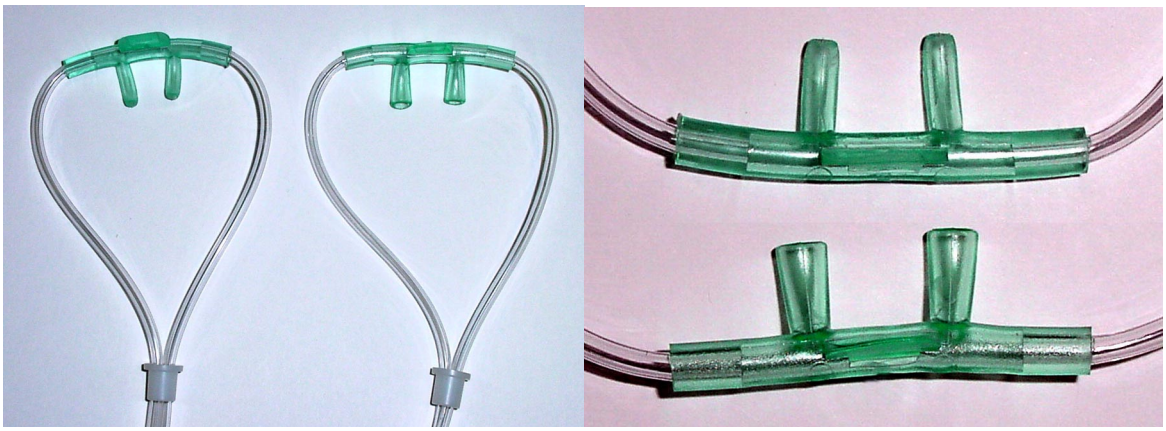
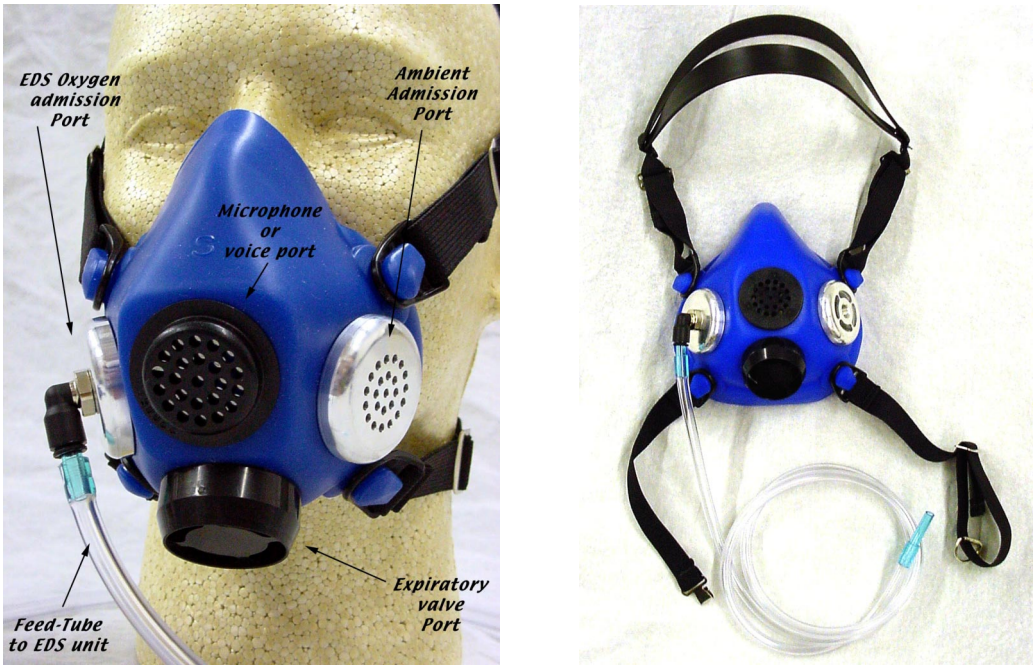


Figure 2. MH nasal single lumen cannula. Constructed of molded silicone tubing and is made to fit the face with a set of over-the-ear feed tubes and prongs to be inserted into the nose. The single combination oxygen delivery and inspiratory pressure sensing tube that feeds from the individual control unit is split at the back of the head to form the two over ear oxygen feed/pressure sensing lines. Wide flair-tip and normal type shown.

Figure 3. MH oro-nasal mask. The oxygen delivery pressure sensing line connects to the mask at the right cheek fitting. Mask features a voice transmitter (located at the nose of the mask) to propagate voice transmission through the mask and support use of a standard aircraft communication headset with boom-type microphone. A flapper-type exhalation valve is located at the lower center part of the mask, and an inhalation valve with flapper is located on the left cheek of the mask.



Precise Flight

The Precise Flight (PF) system, Precise Flow Oxygen Conserver, uses a mechanical regulator that provides oxygen to a single occupant via a dual lumen delivery tube (one lumen provides oxygen to a nasal cannula or oro-nasal mask, and the other lumen is the pressure sensing line that detects the start of inhalation). The PF system requires a regulator for each individual with each regulator receiving oxygen directly from the aircraft's supply (Figure 4). 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 was calculated by the manufacturer to exceed the oxygen mass flow requirements specified in §23.1443 [3]. The regulator can be used in two different modes. The first mode, called "Constant," functions as a continuous-flow system and provides a constant flow of oxygen at the appropriate rate for the altitude selected on the regulator. The second mode is called "Conserve" and uses the sensor to detect a pressure drop during inhalation by the pilot, signaling the regulator to provide a bolus of oxygen through the delivery line as required for the appropriate altitude. The PF system was operated using only the Conserve mode for this evaluation.

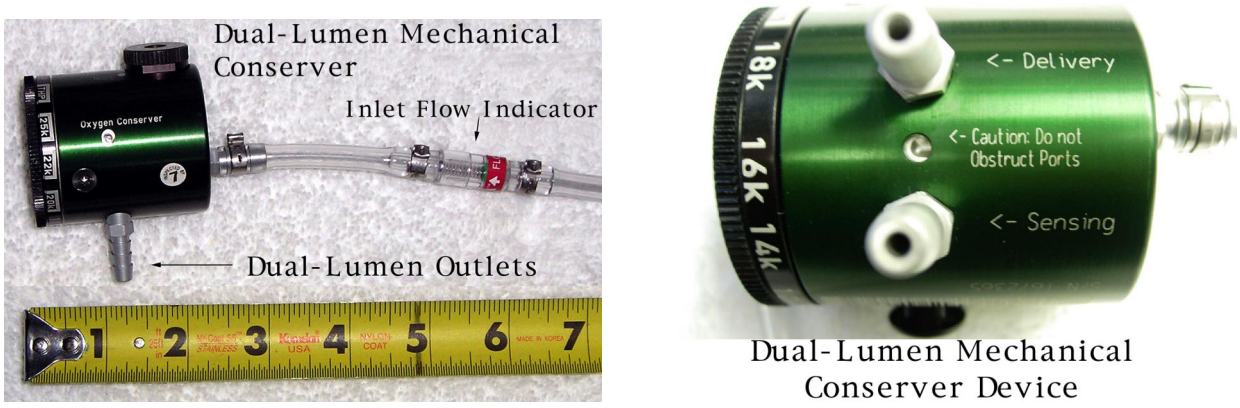


Figure 4. PF Precise Flow oxygen Conserver. Photo at the left shows the mode selector knob on the top of the regulator and the dial on the right end of the regulator that can be used to adjust the oxygen flow for the continuous flow mode. Photo at the right shows the connectors for the oxygen delivery line and pressure-sensor line. Oxygen inlet is at the right side of the regulator.

The PF system was tested with a dual lumen nasal cannula (Figure 5) and two different oxygen masks (PF designated as Standard and Deluxe). The standard mask (shown in Figure 6) was manufactured by the Hudson RCI Company, Temecula, CA. The Deluxe mask (Figure 7) used the same face form as the MH mask. The mask was designed with two inhalation/exhalation valves, a microphone, and the dual lumen sensing/oxygen delivery lines. The inhalation/exhalation valves have a simple open foam insert with no flappers; thus, they allow air to pass in and out of the mask, with the foam acting to minimally restrict flow in either direction.

Figure 5. Dual Lumen Cannula. One tube acts as the inspiration (pressure) sensing line and the other delivers oxygen to the nose piece.

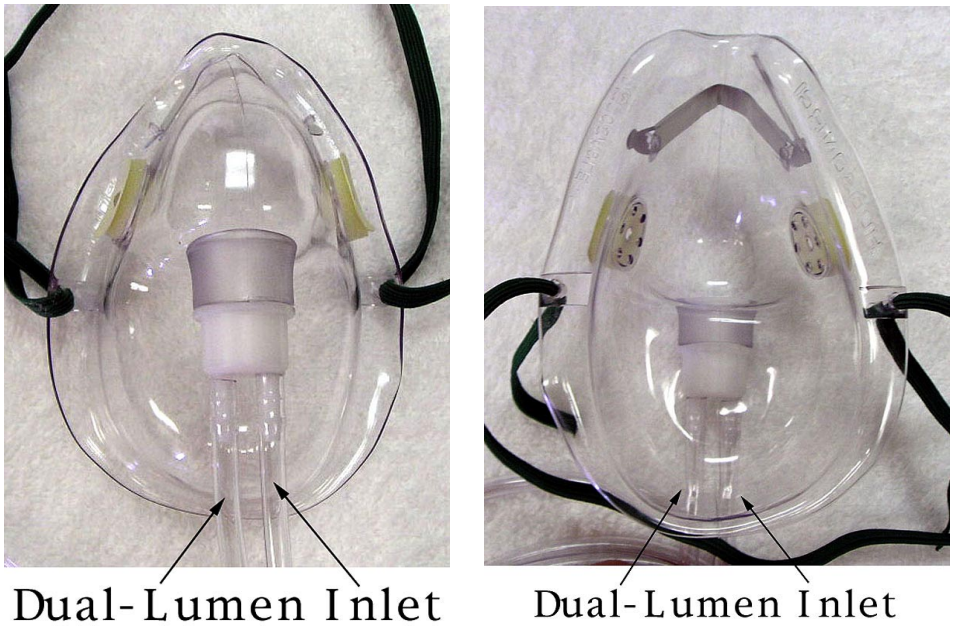


Figure 6. PF Standard Mask. The mask face form was manufactured from a clear soft vinyl. The mask has two flapper-type exhalation valves located the cheeks of the mask with the dual lumen oxygen-delivery and pressure-sensing line attaching to the mask in the front.

Figure 7. PF Deluxe Mask. Left photo shows the front of the mask with microphone connection at the nose of the mask, sensing/oxygen delivery line entering at the bottom of the mask and inhalation/exhalation valves at the side of the mask. Right photo shows the microphone center of the mask and the inside view of the inhalation/exhalation valves.

Subjects:

The research protocol was approved by the CAMI Institutional Review Board and sixteen subjects (10 male and 6 female) were tested with MH equipment and 14 subjects (8 male and 6 female) were used to evaluate the PF equipment (Table 1). These subject numbers met test validity requirements identified in (NAS-1179 and SAE Aerospace Standard AS8025) and statistical analysis requirements. All subjects were examined by the Civil Aerospace Medical Institute (CAMI) Occupational Health Division to ensure that they met medical standards equivalent to a FAA Class III FAA pilot's certificate. All subjects were non-smokers. After passing the medical examination, the subjects' medical data were reviewed by the medical monitor for final participation approval. In addition, the subjects completed an FAA physiological training program to ensure familiarity with the physiological effects of altitude. The subjects reviewed and signed the consent form. The subjects tested the PF and the MH oxygen systems separately during two altitude chamber exposures. The altitude chamber configuration allowed two subjects to be tested during each flight with both subjects testing the same manufacturer's equipment. Evaluation of both manufacturers' equipment required two altitude chamber exposures per subject with a minimum of 72 h between exposures.

Table 1. Subject demographics. Mean (X) and range for subjects height, weight, age and Body Mass index (BMI).

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

Test Procedures:

The flight profile shown in Figure 8 was used to evaluate the two pulse oxygen systems. The profile included an initial ear and sinus check ascent to 5,000 ft MSL, followed by a 30 min denitrogenation period at ground level (1270 ft MSL), with the subjects breathing 100% oxygen via a pressure-demand-type oxygen mask. The mask was removed prior the to the chamber ascent to 10,000 ft MSL. The subjects remained at 10,000 ft breathing ambient air until their arterial oxygen saturation remained relatively stable for 4 min. The subjects then donned a nasal cannula, and the chamber was ascended to 18,000 ft and the 4 min data-gathering period was conducted. Upon completion of the nasal cannula test at 18,000 ft, the subjects switched to the oro-nasal mask and completed a 4 min data collection period. If the subjects were using the MH system, the chamber altitude was increased to 25,000 ft for a data collection period at the peak altitude for the flight. When the PF system was evaluated, the subjects were tested using both the PF Standard and the PF Deluxe oro-nasal masks at the 18,000 and 25,000 ft altitudes.

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 movments of the test subject. Therefore,It is most advised that someone be available to asist if any equipment changes are made during testing.

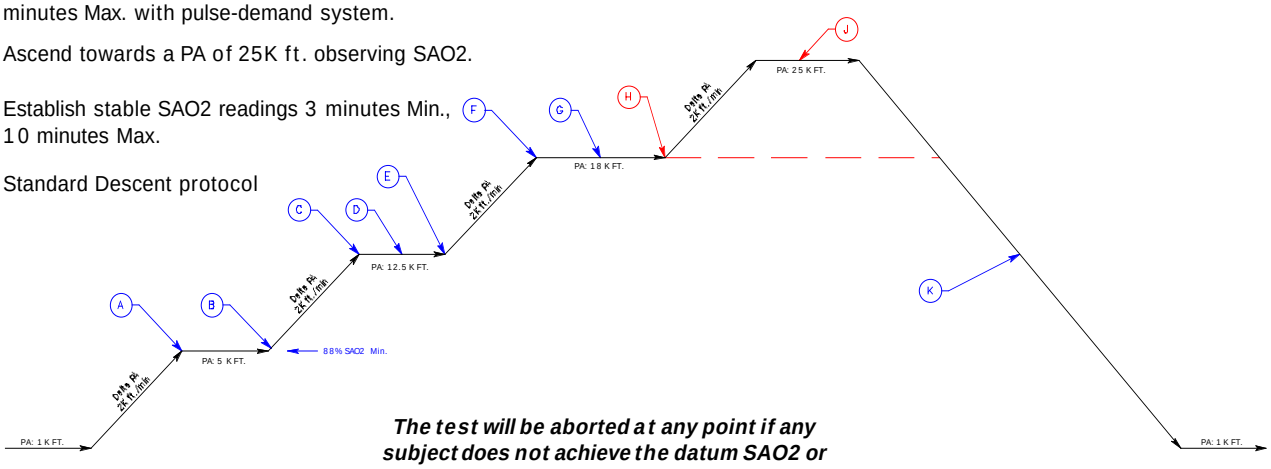


Figure 8. Altitude chamber profile used for evaluation of pulse oxygen systems. Profile included a 30 min denitrogenation period and reached a maximum altitude of 25,000 ft MSL.

From the maximum altitude of 25,000 ft, the chamber was 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 min or less, depending on the stability of the subject's pulse arterial oxygen saturation, SpO_2. From 14,000 ft, the chamber was descended to 12,500 ft and remained there for the 4-minute stable SpO_2. The chamber was then descended to 5,000 ft for the baseline arterial oxygen saturation data. Following the 5,000 ft stop, the chamber was 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 83 minutes.

Subject heart rate (HR), rhythm and SpO_2 were monitored continuously during the chamber exposure. HR and SpO_2 were electronically recorded using Labview 8.0 software (National Instruments Corporation, Austin, TX) during controlled data collection periods. Arterial oxygen saturation and HR data was collected via a digital Nelcor N-200 Pulse Oximeter, (Nelcor Puritan Bennett Div, Pleanston, CA). Subject heart rhythm was monitored via a SensorMedics ECG Mac-1.

Results

Subject SpO_2 was recorded every 15 s during each 4-min test period; thus, the principal measure of merit was a comparison of the subject's mean SpO_2 averaged for the 4-min test period at 5,000 ft MSL (breathing ambient air), with the subject's mean SpO_2 averaged for the 4-min test periods at 18,000 ft MSL (with nasal cannula) and at 18,000 and 25,000 ft MSL using the oro-nasal masks. Since each subject served as his/her own control and the comparative SpO_2 data were gathered on the same chamber flight for each test condition, a paired T test was used for statistical analysis (Tables 2 and 3). In consideration of the potential variability in SpO_2 measurements relative to hyperventilation and other physiological changes, the subject's SpO_2 at the 18,000 ft and 25,000 ft data collection points were compared only with the individual subject's 5,000 ft baseline SpO_2 for that specific flight. Monitoring of the subjects' heart and respiration rates found no objective evidence of tachycardia, tachypnea, or hyperventilation that would suggest respiratory alkalosis that could affect the accuracy of the oximetry [9]. Preliminary testing using the finger-tip pulse oximeter to measure SpO_2 did find inconsistent readings possibly related to chamber temperature. This inconsistency was alleviated by closely monitoring the chamber temperature, using a scalp probe in lieu of the finger-tip SpO_2 sensor, and taking extra care to monitor the subjects for any deviant readings. Subject heart rates and breathing rates were monitored to provide an indication of their status and to ensure that the subject was relaxed and breathing normally during data collection.

Table 2. Mountain High Test Results. Mean Spo_2 and Standard Deviation (SD) for each 4 min test period per subject at 5,000 ft (5K) breathing ambient air, 18,000 ft (18K) using nasal cannula and oro-nasal mask, and 25,000 ft (25K) using oro-nasal mask.

Subject	5K (+/- SD)	NC @ 18K (+/- SD)	Mask @ 18K (+/- SD)	Mask @ 25K (+/- SD)
718723	99.0 (0.9)	99.8 (0.4)	100.0 (0.0)	100.0 (0.0)
656527	97.8 (0.8)	96.0 (1.5)	98.1 (1.1)	99.2 (0.5)
504523	96.9 (0.7)	99.9 (0.3)	99.2 (0.4)	100.0 (0.0)
727727	96.8 (0.5)	99.2 (1.4)	100.0 (0.0)	99.6 (1.4)
702445	95.9 (1.1)	100.0 (0.0)	98.6 (0.4)	98.9 (0.1)
728192	97.3 (1.2)	99.0 (1.0)	99.9 (0.2)	100.0 (0.0)
714302	93.5 (1.3)	100.0 (0.0)	99.9 (0.3)	99.9 (0.3)
785626	95.6 (2.8)	99.0 (1.0)	98.2 (1.1)	98.0 (0.5)
264530	96.6 (1.4)	99.8 (0.4)	98.1 (1.0)	99.7 (0.4)
244324	97.8 (1.5)	100.0 (0.0)	100.0 (0.0)	100.0 (0.0)
711564	95.6 (0.6)	97.9 (1.0)	100.0 (0.0)	99.9 (0.3)
601868	98.5 (1.6)	99.8 (0.4)	99.3 (0.9)	99.7 (0.5)
927230	94.6 (3.1)	98.2 (0.6)	98.6 (0.4)	98.1 (1.4)
712112	96.9 (1.3)	96.9 (1.2)	98.5 (0.8)	98.0 (0.7)
697359	98.1 (0.8)	98.7 (0.4)	100.0 (0.0)	99.9 (0.3)
711844	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

Mountain High

Results from the 16 subjects who tested the MH system indicate that the electronic system performed well with either the nasal cannula or the oro-nasal mask. The MH system maintained the subject's SpO_2 at near-maximum saturation levels for all test conditions. Although the

differences were not large, the MH system maintained SpO_2 values in all subjects and all test conditions that were higher than the values measured at 5,000 ft; thus, the oxygen use conditions were significantly different. While the subjects were occasionally reminded to breathe through their nose when they were using the nasal cannula, no decreases in SpO_2 were observed to be directly related to mouth breathing.

Precise Flight

Data from 14 subjects were used to evaluate the PF system (Table 3). One male subject who participated in testing of the MH system was injured in an accident - not related to the research project - and was unable to test the PF system. A second male subject tested the PF system but did not establish a stable baseline SpO_2 at the 5,000-ft level, disallowing the use of his data. Results indicate that the PF system did not meet the 5,000 ft test criterion in any of the test conditions. In the 18,000 ft test using the nasal cannula, the SpO_2 for nine of the subjects was less than the 5,000 ft criterion. In the 18,000 ft test (Table 3), the PF system using the nasal cannula provided a mean SpO_2 of 94.1% while the mean SpO_2 at the 5,000 ft level with the subjects breathing ambient air was 95%. This difference was statistically significant ($p<.05$). The SpO_2 values for the PF system with Standard and Deluxe masks were significantly different at both test altitudes (18,000 ft and 25,000 ft) than the 5,000-ft criterion. At the 25,000-ft test level using the PF Standard mask, the SpO_2 values for 13 of the 14 test subjects were less than the 5,000 ft criterion. When using the deluxe mask, all 14 of the subjects had SpO_2 values that were less than the criterion.

Table 3. Precise Flight Test Results: Mean SpO_2 and Standard Deviation (SD) at 5,000 ft (5K) breathing ambient air, 18,000 ft (18K) using Nasal Cannula (NC), Standard and Deluxe oro-nasal masks, and 25,000 ft (25K) using Standard and Deluxe oro-nasal masks.

Subject	5K (+/- SD)	NC @ 18K (+/- SD)	Standard @ 18K (+/- SD)	Deluxe @ 18K +/- SD)	Standard @ 25K (+/- SD)	Deluxe @ 25K (+/- SD)
504523	93.0 (1.3)	95.3 (1.3)	86.4 (3.0)	86.9 (3.7)	84.3 (3.7)	85.1 (1.9)
702445	95.7 (0.9)	96.2 (0.7)	89.3 (3.4)	91.6 (1.7)	82.8 (5.0)	86.4 (2.4)
727727	89.4 (3.4)	86.2 (2.7)	86.8 (2.2)	87.6 (2.5)	78.7 (4.7)	84.0 (3.2)
927230	96.0 (1.7)	96.2 (1.7)	97.0 (1.7)	96.4 (1.5)	77.5 (3.1)	84.1 (5.3)
656527	98.1 (0.5)	94.1 (0.7)	78.8 (2.7)	86.0 (1.5)	81.6 (3.2)	80.3 (3.4)
244324	96.9 (1.4)	94.8 (4.7)	98.5 (0.7)	94.8 (1.3)	87.7 (5.6)	86.6 (2.3)
714302	94.3 (1.4)	91.6 (0.9)	90.2 (3.5)	90.4 (5.3)	79.6 (7.6)	86.0 (2.7)
718723	96.6 (0.9)	95.3 (1.4)	93.5 (3.9)	92.4 (1.5)	87.8 (4.2)	89.6 (3.6)
785626	99.6 (0.8)	100.0 (0.2)	99.8 (0.5)	99.7 (0.4)	95.8 (1.5)	96.7 (1.1)
697359	96.3 (2.9)	99.6 (0.5)	98.4 (0.8)	97.7 (1.0)	97.7 (0.8)	90.5 (3.6)
711564	92.5 (1.2)	87.6 (1.4)	89.4 (0.8)	85.9 (0.9)	72.6 (6.8)	81.3 (4.2)
601868	99.0 (1.3)	94.0 (1.9)	84.8 (3.1)	90.4 (2.5)	79.9 (5.0)	79.5 (3.5)
712112	98.6 (1.7)	96.3 (1.0)	96.7 (1.2)	96.8 (1.3)	92.7 (1.1)	94.1 (1.5)
264530	94.9 (1.4)	92.6 (1.3)	91.1 (1.1)	81.9 (3.3)	91.0 (1.3)	75.7 (18.7)
Mean of all Subjects	95.8 (1.5)	94.3 (1.5)	91.5 (2.1)	91.3 (2.0)	85.0 (3.8)	85.7 (4.1)
P(T<=t) two-tail		0.0457	0.0192	0.0024	0.00003	0.0000

Four subjects (two female and two male), using the PF Deluxe mask at 25,000 ft, were noted to have SpO_2 values consistently decreased during the 4-min test period reaching levels below 80% at the end of the test. They were placed on a military-style to demand oxygen system and recovered to normal oxygen levels. Also at the 25,000 ft level, two male subjects using the PF Deluxe masks and one male subject using the PF Standard mask were noted to have their SpO_2

levels fall below 80% at the end of the test period. They were able to bring their SpO_2 levels above 90% by switching the PF regulator from the "Conserve" mode to "Constant" flow mode. While none of the testing was terminated due to a hypoxic event, all subjects required close monitoring to ensure their full recovery.

Subjective Symptoms Questionnaire

All subjects were asked to complete a subjective questionnaire at the end of each flight to report hypoxia symptoms. The questionnaire asked the subjects to list any symptoms they had experienced at any time during the chamber flight. Following tests using the MH equipment, two male and three female subjects reported that they did not experience altitude related symptoms at any time during the flight. The remaining 11 subjects reported various symptoms. Symptoms most commonly reported by the male subjects were numbness, light headedness, dizziness, and tingling. The females' most commonly reported symptoms were cold flashes, sweating, and numbness. Following the PF test flights, two male subjects reported that they had experienced no symptoms. The most common symptoms reported by the remaining male subjects were fatigue, visual disturbances, and tingling. The female subjects testing the PF equipment most commonly reported symptoms were light headedness, fatigue, and tingling. No distinction could be made between the MH and PF systems relative to symptom severity; however, more symptoms were reported by subjects using the PF system than those using the MH system.

Discussion

The pulse oxygen systems tested were designed with the intention of providing adequate supplemental oxygen for pilots flying at altitudes up to 25,000 ft while minimizing the waste of oxygen that is inherent in continuous-flow systems. Recognition that continuous-flow oxygen systems are not efficient relative to oxygen use has been understood for years. Since the continuous-flow systems provide oxygen throughout the respiratory cycle, approximately 50% of the oxygen delivered is wasted.

Continuous-flow oxygen mask modifications were developed prior to World War II to make more efficient use of continuously supplied oxygen. Continuous-flow masks may incorporate a “rebreather bag” that directly connects to the oro-nasal mask and acts as a reservoir for oxygen supplied to the system during exhalation and collects the first portion of the exhaled air that generally has an elevated oxygen concentration. In this manner, some of the oxygen supplied during inspiration and some increased oxygen content expired air is collected and supplied to the user, potentially allowing for decreased continuous flow and conservation of the oxygen supply. A modification of this system involves placing a one-way valve in the bag that allows one-way passage of gas from the bag to the oro-nasal mask. This modification converts the mask from a rebreather system to a reservoir system that collects oxygen supplied to the bag during expiration and delivers this supply to the user during inspiration. Similar to the rebreather system, the reservoir system conserves oxygen [10].

The pulse oxygen delivery systems may provide the opportunity to use a simple continuous-flow oxygen mask and conserve aircraft oxygen supply without using the cumbersome rebreather or reservoir bags. To effectively supply adequate supplemental oxygen and conserve supply, the pulse system must deliver an adequate volume of oxygen during inspiration to meet physiological requirements. To accurately deliver a pulse of oxygen at the start of inspiration, the pulse system must sense the very slight pressure changes that occur in the nose (when a nasal cannula is used for oxygen delivery) or in the oro-nasal mask. Further, when correctly timed, the oxygen volume (flow rate and duration of flow) that is delivered during inspiration must be adequate. A failure in either the pulse trigger mechanism or inadequate pulse volume delivery could cause the user to become hypoxic at altitude. System trigger pressure or flow measurements were not taken during this study to determine why the PF equipment could not maintain adequate levels of oxygenation. Investigator's observations and subject comments suggest that delivery of the oxygen pulse was inconsistent and perhaps related to the pulse trigger mechanism. Perhaps simple adjustments or system modifications could correct the discrepancy. It was also recognized that the MH system occasionally failed to deliver an oxygen pulse on inspiration; however, the MH electronic system partially mitigates this problem by providing a warning if 40 seconds elapse between pulses.

Conclusions

The electronic MH oxygen system operating in the pulse delivery (conserve) mode provided sufficient oxygen to exceed the requirements of the 5,000-ft test criterion at the test altitudes of 18,000 ft using either a nasal cannula or an oro-nasal mask for oxygen delivery and at 25,000 ft using an oro-nasal mask. These results allow recommendation for use of the MH equipment at altitudes allowed by the CFR section 23.1443 in the oxygen conserving mode [3].

The PF equipment was tested at 18,000 ft using a nasal cannula and both oro-nasal masks for oxygen delivery, and at 25,000 ft using both oro-nasal masks for oxygen delivery. The PF system, using either the nasal cannula or the oro-nasal masks, did not maintain the subjects' SpO_2 levels at or above the 5,000-ft criterion. Results indicate that the PF pulse oxygen delivery system should not be used in the "Conserve" mode to provide supplemental oxygen at altitudes above 18,000 ft with either the nasal cannula, Standard or Deluxe oro-nasal masks.

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