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Performance of a Continuous Flow Passenger Oxygen Mask at an Altitude of 40,000 Feet

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16. Abstract

A redesigned continuous flow passenger oxygen mask was tested for its ability to deliver an adequate supply of oxygen at an altitude of 40,000 feet above sea level. Four male subjects participated in the study. Blood oxygen saturation (SaO_2) baseline levels for hypoxic exposure were established for each subject. Immediately prior to high altitude exposure, subjects prebreathed 100% oxygen for two hours through a pressure demand type mask. The hypobaric chamber was then decompressed to a simulated altitude of 35,000 feet. Subjects switched to the passenger oxygen mask. The initial oxygen flow rate to the passenger mask came from manufacturer production performance test data. Once heart and respiratory rates and SaO_2 level stabilized, chamber altitude was increased to 40,000 feet. Descent to ground level was performed in steps of 5,000 feet with SaO_2 levels being established for each altitude and recommended oxygen flow. Subjects remained at each test altitude for a minimum of three minutes or until SaO_2 levels stabilized. At no point during the testing did SaO_2 levels approach baseline levels for hypoxic exposure. This mask design would appear to offer protection from hypoxia resulting from altitude exposure up to 40,000 feet.

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PERFORMANCE OF A CONTINUOUS FLOW PASSENGER OXYGEN MASK AT AN ALTITUDE OF 40,000 FEET

INTRODUCTION

Continuous-flow, phase dilution type masks have been carried on aircraft for years to provide oxygen to passengers in the event of cabin decompression. These masks are designed to supply an adequate flow of oxygen to the passenger until safe flight altitudes are reached. Functionally, passenger oxygen masks must meet the performance specifications of Technical Standard Order (TSO) - C64a (1) before they are approved for use onboard aircraft. Currently, there are two TSO-C64a approved passenger masks in production: the Scott Aviation 289-601 series and the Puritan-Bennett 174080/81 series. Recently, Puritan-Bennett reengineered their version of the passenger mask to enhance production efficiency.

Even though the 174080/81 and the new mask designated the 174095 series mask are very similar in their physical design and performance on a breathing machine, the Los Angeles Aircraft Certification Office (ACO) requested that Puritan-Bennett obtain human subject testing data before considering the reengineered mask for certification. Puritan-Bennett requested, and the ACO representative agreed, that the testing be done at the FAA Civil Aeromedical Institute (CAMI) in Oklahoma City, OK, due to CAMI's previous experience in performing this type of testing (2, 3, 4, 5) and CAMI's capability of performing human subject testing at a simulated altitude of 40,000 feet above sea level.

The physical appearance of the 174095 series mask is similar to the previous design. In fact, the face cushions for the masks are the same. The primary differences in the 174095 mask and the 174080/81 mask include (1) a change in the way the diaphragms are mounted, (2) positioning of the reservoir bag, and (3) breathing port configuration. The 174080/81 mask uses a post mounted diaphragm. The 174095 diaphragms are installed with "pull tabs". The reservoir in the newer mask is a side mounted bag, whereas the reservoir bag of the 174080/81 is end- mounted. The ambient port spring is slightly stiffer in the new version of the mask. In addition, the ambient inhalation and exhalation port positions have been reversed in the new mask design. The purpose of these tests was to determine if the changes in mask design produced performance characteristics incompatible with TSO-C64a.

METHODS

Basically, the testing protocol followed the dictates of TSO - C64a (1) and Society of Automotive Engineers (SAE) Aerospace Standard (AS) 8025 (6) for passenger oxygen masks. However, changes were incorporated into the experimental design in an effort to reduce the risk of decompression sickness (DCS), while maintaining a sufficient performance challenge to the 174095 series mask. The following deviations from the basic test protocols were incorporated into this series of tests. Due to the similarities between the 174095 series mask and the previous design, the Certification Office felt that testing of only four individuals was acceptable for demonstrating mask performance capabilities. In an effort to minimize the risk of DCS, mask performance was not checked at an exercise induced ventilatory rate of 30 L/min BTPS and each subject was required to undergo a full two hour prebreathe on 100% oxygen before the altitude chamber flight to 40,000 feet. To facilitate scheduling of subjects and research resources, baseline blood oxygen saturation determinations under hypoxic conditions were made with the subject breathing hypoxic gas mixtures. All test protocols and consent forms were reviewed and approved by the CAMI Institutional Review Board (IRB) for human subject use.

Four males between 19 and 24 years of age served as research subjects. Their age, height and weight are listed in Table 1. Prior to participation, each individual was required to complete a health history questionnaire, given a Class II physical examination,

Subject	Age	Height (cm)	Weight (kg)
A	22	174	70.5
B	19	178	74.0
C	24	175	61.4
D	21	183	85.0
Average ± Std. Dev.	21.5 ± 2.5	178 ± 2	72.7 ± 6.5

Table 1. Physical characteristics of subjects involved in oxygen mask testing.

and went through a physiological training course presented by the CAMI Aeromedical Education Division. The potential hazards associated with high altitude exposure were thoroughly explained to the subjects before they signed informed consent forms agreeing to participate in the study. Each subject was taken to the CAMI Clinic for an additional physical evaluation after being exposed to the altitude of 40,000 feet. They were given a card with the phone numbers of the local hyperbaric treatment facility, the CAMI Clinic physician, and the investigator should delayed symptoms of altitude decompression sickness occur.

Blood oxygen saturation (SaO_2) level, as measured by a pulse oximetry, was the variable used to indicate whether the mask delivered sufficient oxygen flow to prevent or attenuate subject hypoxia. Baseline values for SaO_2 were established at least one week prior to mask testing for each subject. Gas mixtures containing 12% and 14% oxygen were used to establish baseline SaO_2 for a given hypoxic stimulus. SaO_2 while breathing the hypoxic gas mixtures was monitored for a period of at least five minutes and continued until steady state levels were observed for a minimum of two minutes (Table 2).

SaO_2 values were determined with the subject in a seated position at rest. Hypoxic gas mixtures were used to create approximate mean tracheal oxygen partial pressures of 85.6 (12% O_2) mmHg and 100 mmHg (14% O_2). These values were used in evaluating mask performance using the gas analysis method, in addition to the arterial blood oxygen saturation method of mask performance testing, as described in AS-8025. Gas analysis was also of interest because the data could be directly compared to earlier test data in which nitrogen analysis was the most readily available and technically reliable method of making estimations of tracheal or alveolar partial pressure of oxygen (7, 8, 20).

The flight protocol used for the oxygen mask tests is presented in Figure 1. Immediately prior to the chamber flight, each subject did a two hour prebreathe using 100% oxygen. Before mask testing began, an ear and sinus check was made at an equivalent altitude of 8,000 feet. The chamber was then decompressed to an altitude of 35,000 feet at a rate of approximately 3,000 ft/min (Figure 2). During this initial decompression, the subject wore a pressure demand type aviator's mask and breathed 100% oxygen. Upon

	Blood Oxygen Saturation (SaO_2) Levels (%)	
Subject	SaO_2 at F_iO_2 = 12%	SaO_2 at FIO_2 = 14%
A	76	89
B	75	88
C	78	85
D	81	88
Average ± Std. Dev.	78 ± 3	88 ± 2

Table 2. Changes in blood oxygen saturation as a result of breathing hypoxic gas mixtures of 12% and 14% oxygen.

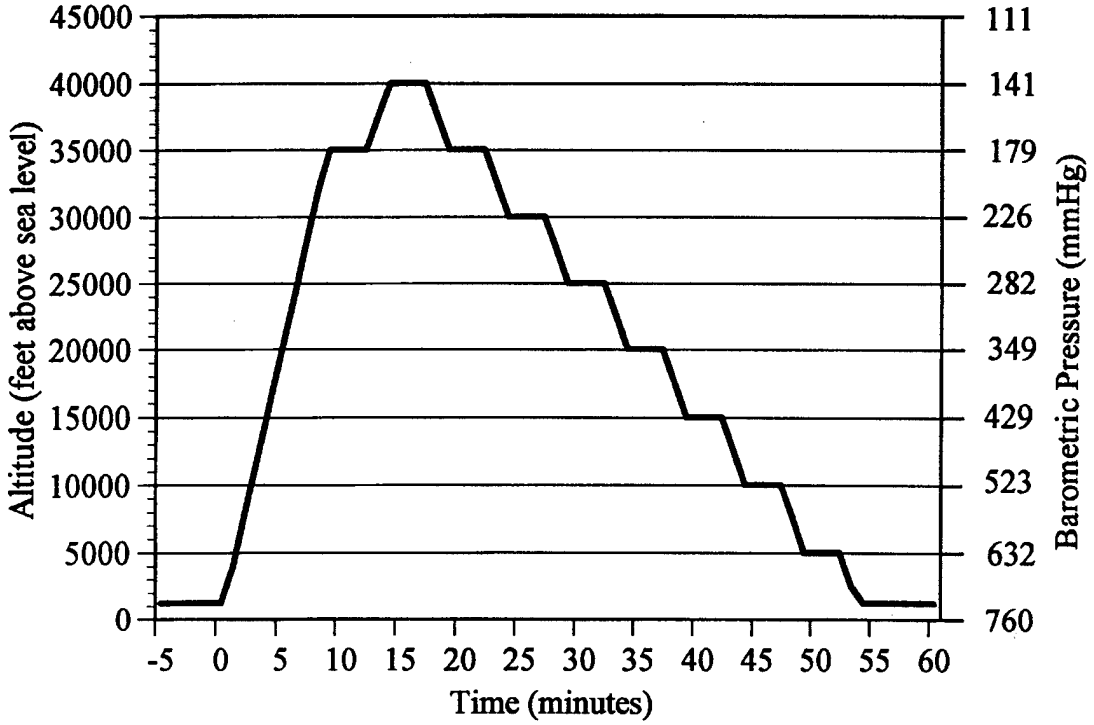

Figure 1. Under nominal test conditions, total altitude exposure was to be held under 60 minutes. Exposure to any given altitude was not to be less than 3 minutes and was not to exceed 10 minutes. Subjects performed a 2 hour oxygen prebreathe and an ear and sinus check at an altitude of 8,000 feet before the mask testing protocol was initiated. The ear and sinus check is not depicted in the above graph.

reaching a chamber altitude of 35,000 feet, ascent was stopped, and SaO_2 and heart rate checked. Once it was determined that the subject was physiologically stable and relatively comfortable, the subject switched to the continuous flow passenger oxygen mask. Oxygen flow to the test mask was set at a rate expected to maintain appropriate blood oxygen saturation levels at 40,000 feet. Before the chamber was further decompressed to 40,000 feet, SaO_2 levels were checked to ensure that the oxygen flow estimate was sufficient. Oxygen flow to the test mask was to be adjusted whenever necessary to maintain required blood oxygen saturation level. If stable SaO_2 levels were present during the third minute at a given altitude, a 5,000 foot decrement in altitude was initiated. During this descent, the oxygen flow to the test mask was adjusted to a rate that was predicted to provide adequate blood oxygen saturation for the upcoming altitude.

During the tests SaO_2 and heart rate were recorded using a Nelcor N-200 pulse oximeter. The oximeter sensor was placed on the forehead, immediately above the eyebrow, for all testing. Electrocardiograph data were monitored from chest lead V5 using a Bosch ECS 502 display system. The percentage of oxygen, nitrogen, and carbon dioxide present in the mask was measured by a Perkin Elmer MGA-1100 mass spectrometer. The mass spectrometer was equipped with four capillary inlets and selector switches, which allowed capillary internal diameter to be matched with air density at different altitudes. The capillaries were connected to a common manifold system that was mounted near the subject. A length of polyethylene tubing (PE 60) connected the manifold and mask cavity. The lightweight PE tubing did not add significant weight to the mask, or require major physical modifications of the mask. There was no indication that mask fit and operational characteristics had been changed by the addition of the gas sampling tube. Oxygen flow to the mask was manually controlled using a miniature needle valve. An oxygen mass flow meter (Kurz, Model 505-6-04-02) was placed in-line between the needle valve and a tank of aviator's

oxygen. Prior to testing, the flow meter was recalibrated and certified by Kurz Instruments to be within oxygen flow performance specifications consistent with National Institute of Standards and Technology specifications. Day-to-day checks of oxygen flow and corresponding voltage outputs from the mass flowmeter were made using Nilab Oxygen manometers. The analog signal from the mass flow meter was used to monitor oxygen flow to the mask. Analog outputs from pulse oximeter, mass spectrometer, and mass flow meter were connected to an analog to digital converter of a data acquisition and control system (National Instruments).

The problems associated with making accurate measurements of respiratory volumes and activity, while wearing a continuous flow passenger oxygen mask without compromising its design and/or performance, remain unsolved. The limitations and measurement errors associated with mask testing of this type have been previously described (3, 5). Through the years, it has been common practice to indirectly estimate the tracheal partial pressure of oxygen through measurement of the partial pressure of nitrogen (3, 5, 7, 19). In the present study, end tidal CO_2 ($P_{et}CO_2$) was used to identify the value used for the end tidal partial pressure of nitrogen ($P_{et}N_2$). The average mask partial pressure of N_2 during expiration was calculated from the N_2 signal. These values for nitrogen were then used to make alternative estimates of tracheal PO_2. Direct O_2 and CO_2 voltage signals from the mass spectrometer were used in estimating alveolar oxygen partial pressure (P_AO_2) using the following algebraic forms of the alveolar gas equation:

$$P_AO_2 = P_IO_2 - \frac{P_ACO_2}{R} + (P_ACO_2 * F_IO_2 * \frac{(1-R)}{R}) \quad (1)$$

and

$$P_AO_2 = F_IO_2 * (P_B - 47) - P_ACO_2 * (\frac{1 - F_IO_2 * (1-R)}{R}) \quad (2)$$

Equation 1 is currently the most commonly used form of the alveolar gas equation (9). Equation 2 is taken from the *Handbook of Respiratory Data in Aviation* (10). The respiratory exchange ratio (R) was assumed to be 0.85 for each subject. The values for O_2 and CO_2 used in the equations were identified using the following criteria. The highest observed PCO_2 marked the end of expiration and was used to represent end tidal and alveolar PCO_2. The partial pressure and fraction of inspired O_2 were calculated from a point in the respiratory cycle at which a maximal value in the O_2 signal coincided with a minimal N_2 value preceding the $P_{et}CO_2$ designation.

RESULTS

The primary objective of these experiments was to determine if oxygen flow provided by the series 174095 continuous flow oxygen mask was sufficient to prohibit a drop in SaO_2 below specific baseline limits. Oxygen flow to the mask during the last minute at each of the altitudes is presented in Figure 3. The average oxygen flow over the time course of the total altitude exposure is presented in Figure 4. The SaO_2 data are presented in Figure 5. Oxygen flow to the mask did not have to be increased at any altitude to prevent a drop in SaO_2 below baseline levels. As can be seen from comparing data from Figure 5 with the values presented in Table 1, SaO_2 values stayed well above baseline levels established by breathing hypoxic gas mixtures for each subject. SaO_2 levels were slightly reduced at altitudes of 40,000, 35,000, 15,000 and 10,000 feet, but these decreases are minimal. SaO_2 results are consistent with some of the previous mask testing reports (3, 4), but are slightly higher (~10-15%) than SaO_2 values in others (5, 20).

Figure 6 presents tracheal PO_2 estimates derived from both end tidal and average expiratory nitrogen values and estimates of P_AO_2(6). It did not matter whether the $P_{et}N_2$ value or the average N_2 value was used to estimate tracheal PO_2. Both approaches yielded approximately the same result. As expected, alveolar PO_2 estimates were less than the estimates for tracheal PO_2. The difference between tracheal and alveolar values seemed to be attenuated above, and augmented below, 25,000 feet. Equations used to estimate P_AO_2 also produced consistent results. SaO_2 data are compared to theoretical values corresponding to P_AO_2 estimates using the oxygen dissociation curve at pH

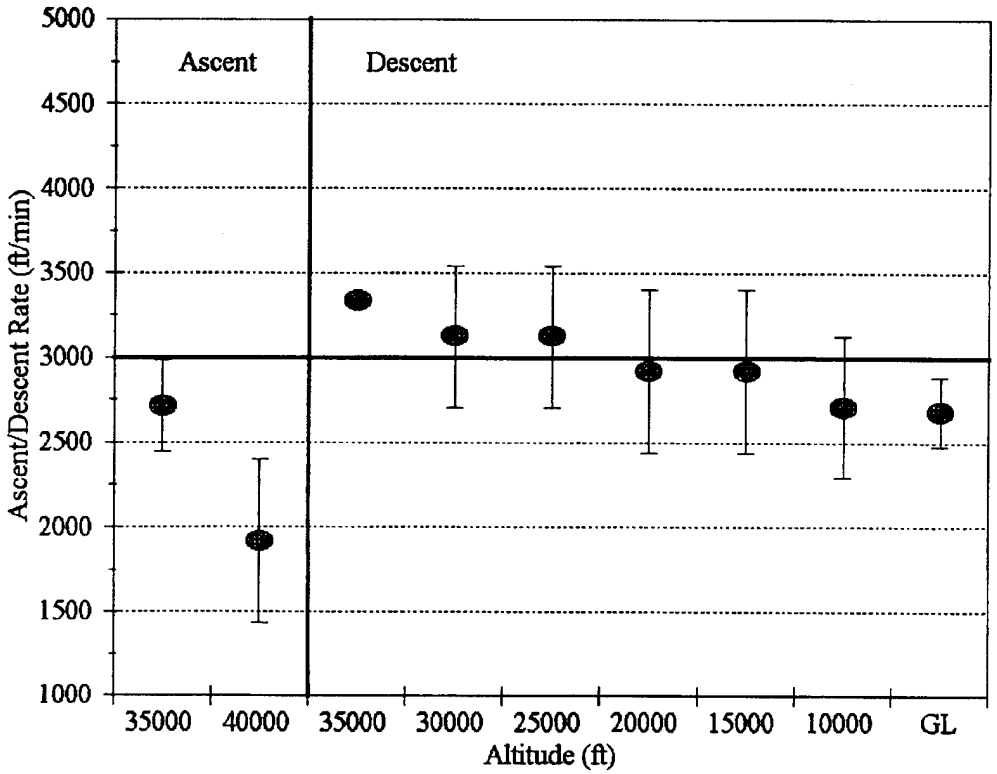

Figure 2. Ascent and descent rates were relatively consistent, except for the transition from 35,000 to 40,000 feet. This performance loss most likely reflects the impact of age on the chamber's capabilities.

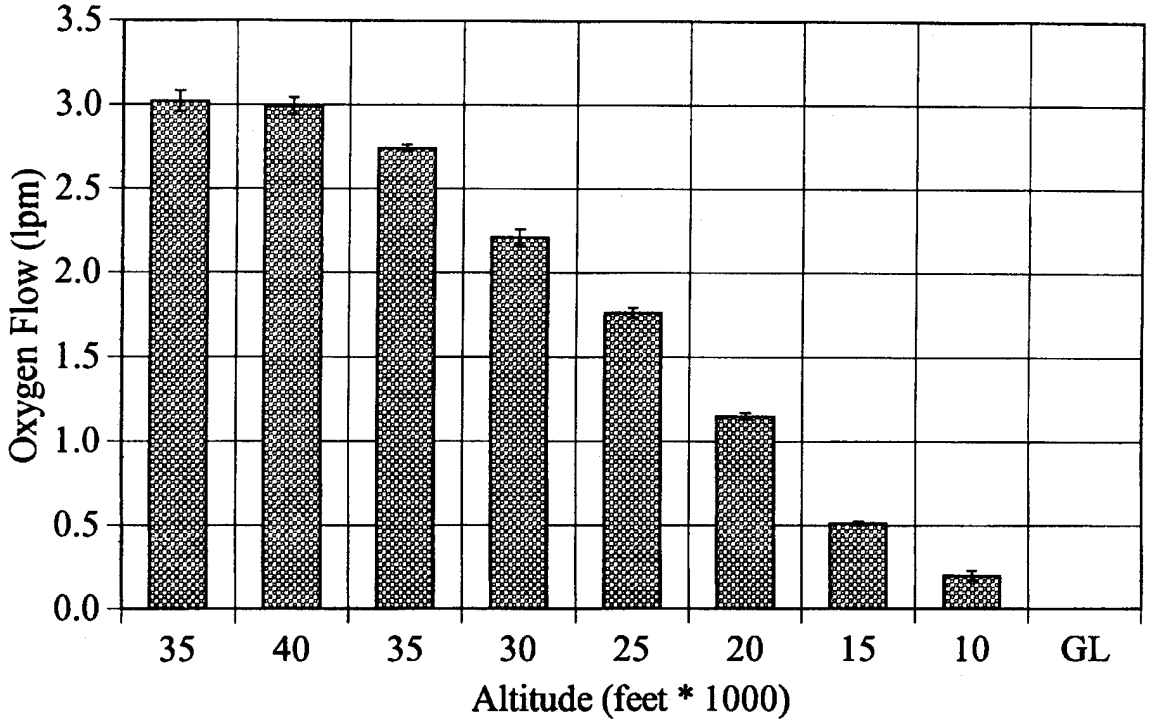

Figure 3. Oxygen flow to the mask during the last minute at each of the different test altitudes.

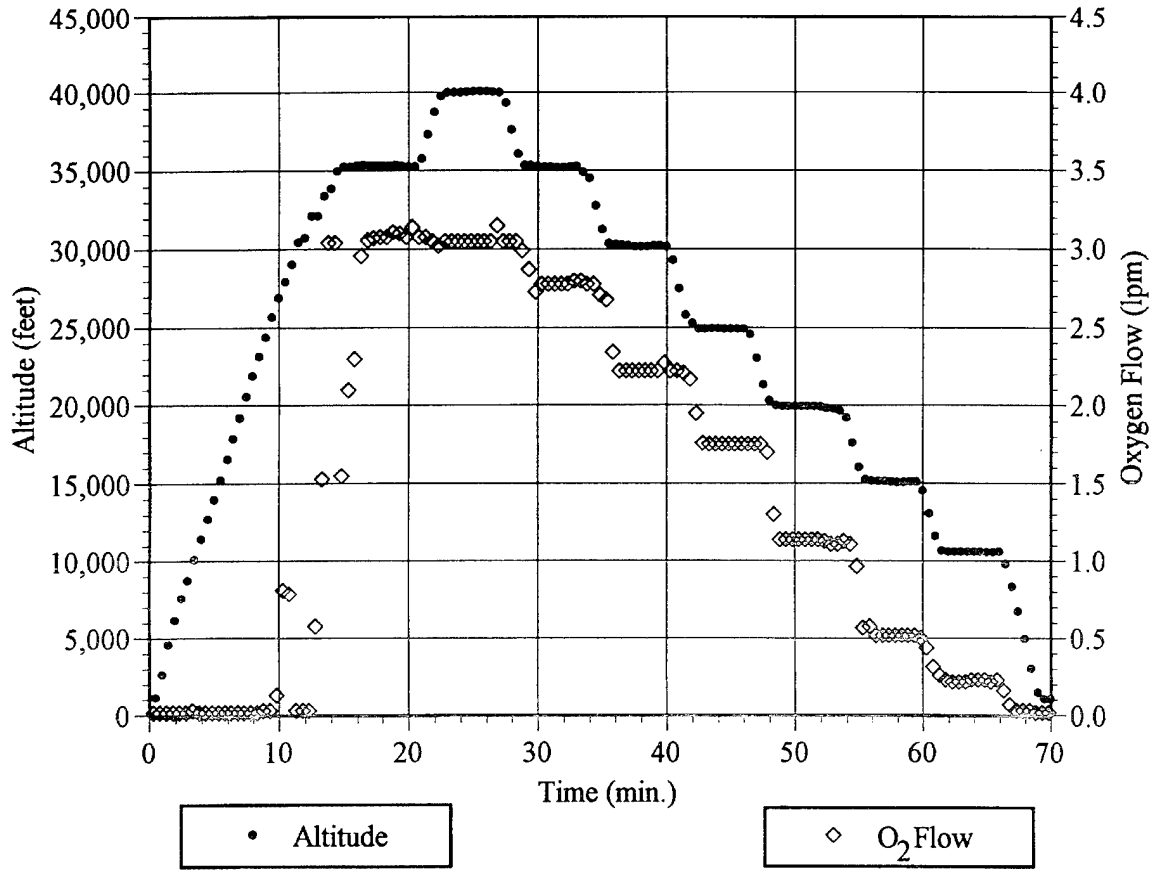

Figure 4. Average oxygen flow to the mask during the altitude tests. Total time at altitude has been extended to allow accurate calculation of average values during periods of ascent and descent.

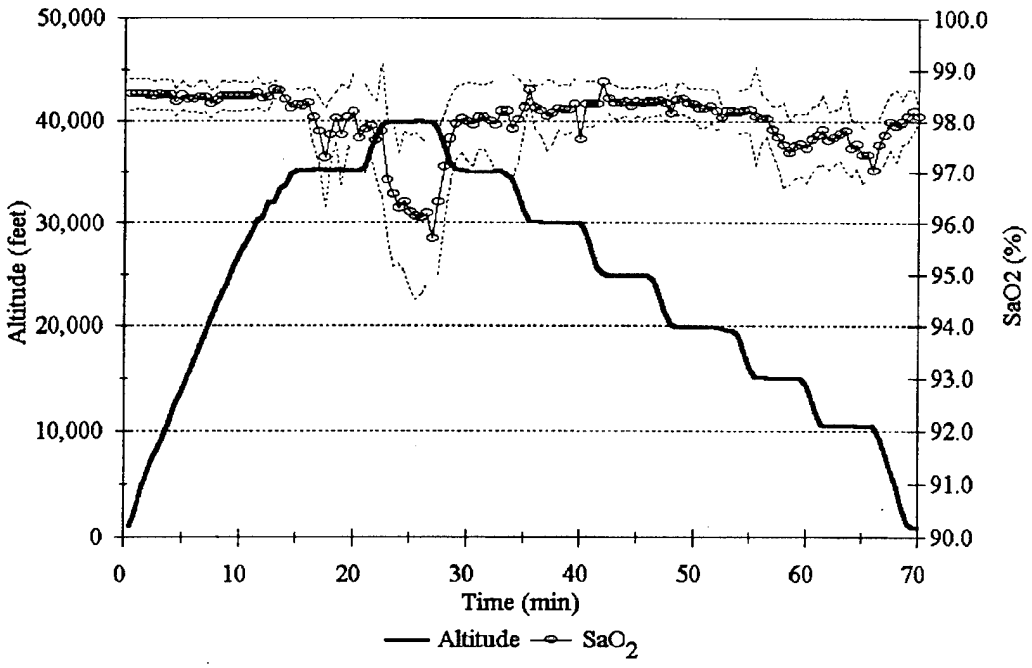

Figure 5. SaO_2 data during the 40,000-foot altitude exposures. Data are averaged over 30-second intervals. The dashed lines are located ± 1 standard deviation from the mean.

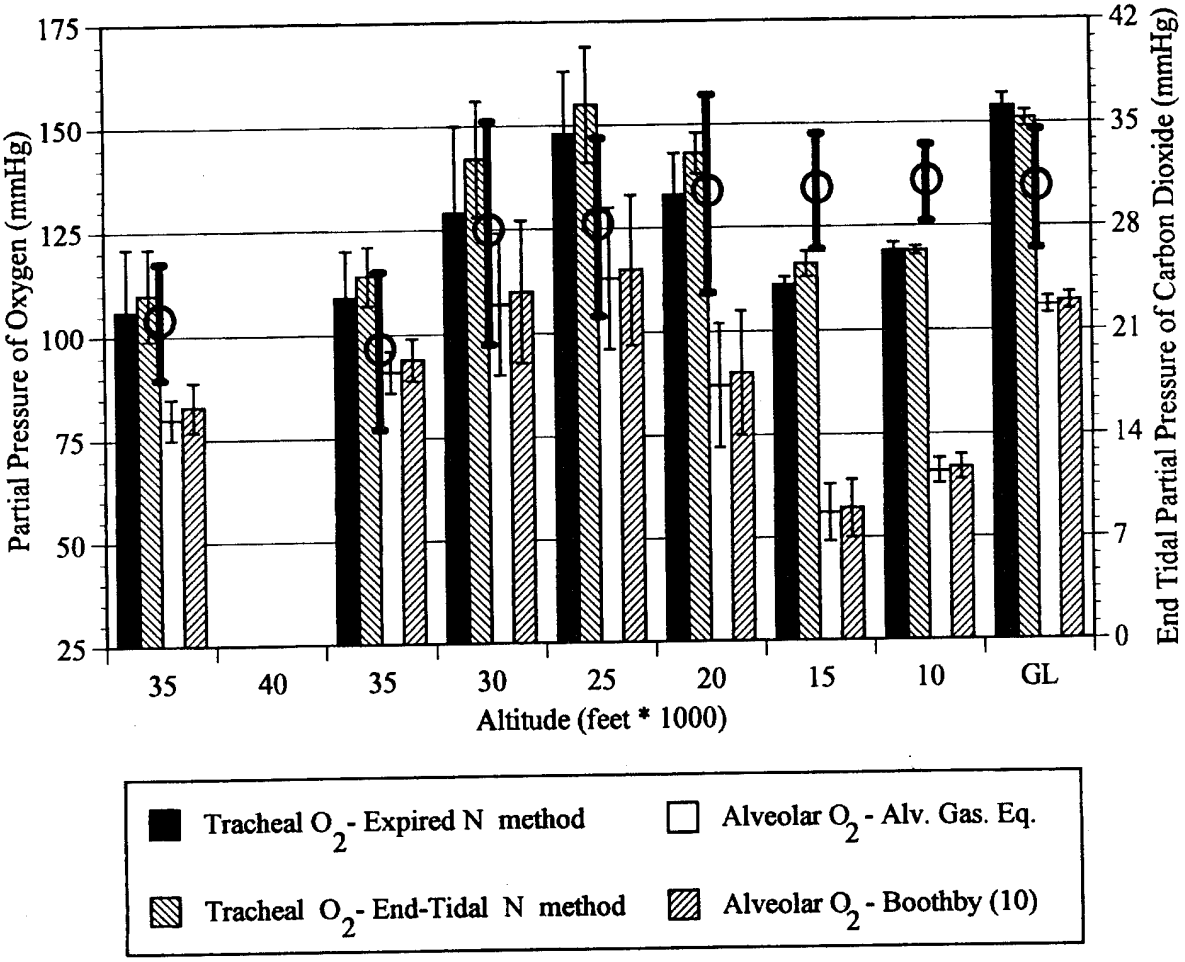

Figure 6. Tracheal and alveolar estimates of oxygen partial pressure during the last minute of exposure at each altitude are depicted by the bar graphs using the Y-axis on the left. The end tidal carbon dioxide partial pressure is represented by the large circles (avg±s.d.) scaled to the Y-axis on the right.

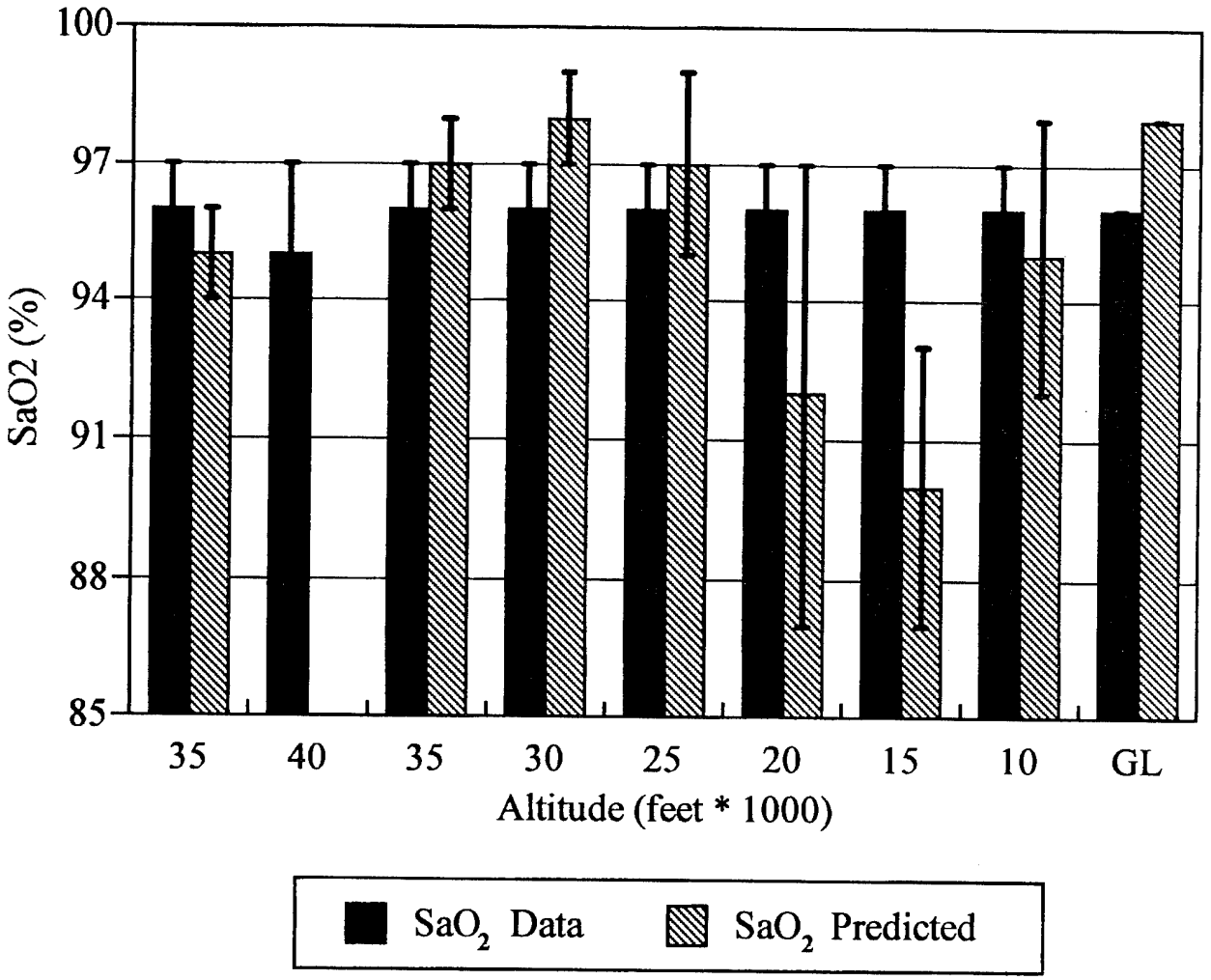

Figure 7. Average blood oxygen saturation values during the last minute at each altitude compared to theoretical SaO2 values based on estimates of alveolar partial pressure of oxygen.

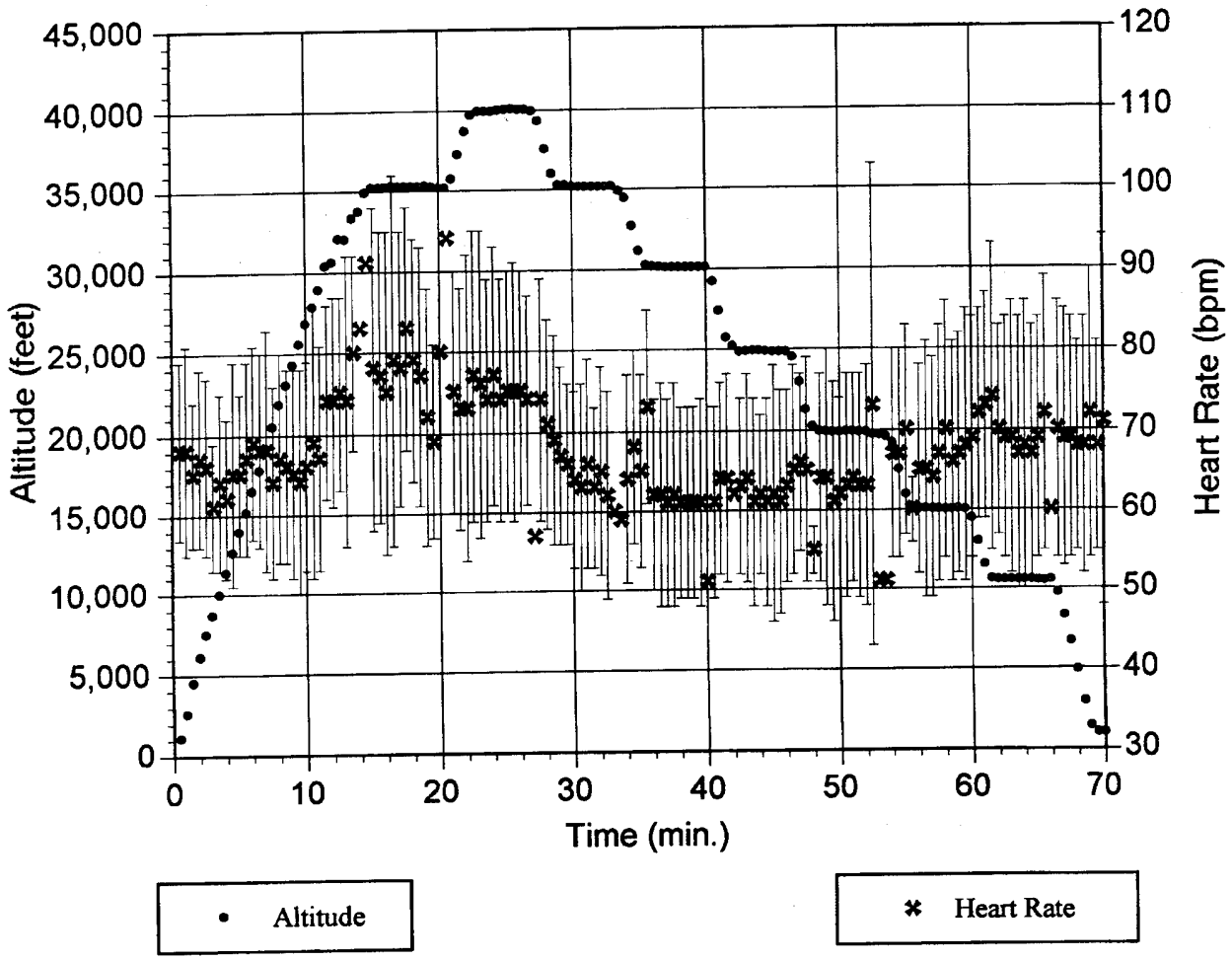

Figure 8. Subject heart rates during altitude exposure.

7.4 in Figure 7. Measured SaO_2 values are ±0.5% for all altitudes. It is not clear why there was a decrease in the theoretical value for SaO_2 at 15,000 and 20,000 feet altitudes.

At no time during the altitude exposures did any of the test subjects demonstrate explicit signs of anxiety about the flight. Heart rate data are plotted in Figure 8. There was a tendency for heart rate to increase slightly during the initial exposure at 35,000 feet. This may reflect some apprehension, or it may have been due to physical activity of switching from the aviator's breathing mask to the continuous flow passenger oxygen mask. Similarly, ventilatory rate remained consistent at normal resting levels throughout the duration of the altitude exposure (Figure 9). Unfortunately, ventilatory data were not obtained at the 40,000 foot altitude, due to malfunctioning of the mass spectrometer. No significant change in ventilatory pattern was observed at 40,000 feet by the investigator, chamber operators, or medical monitors that

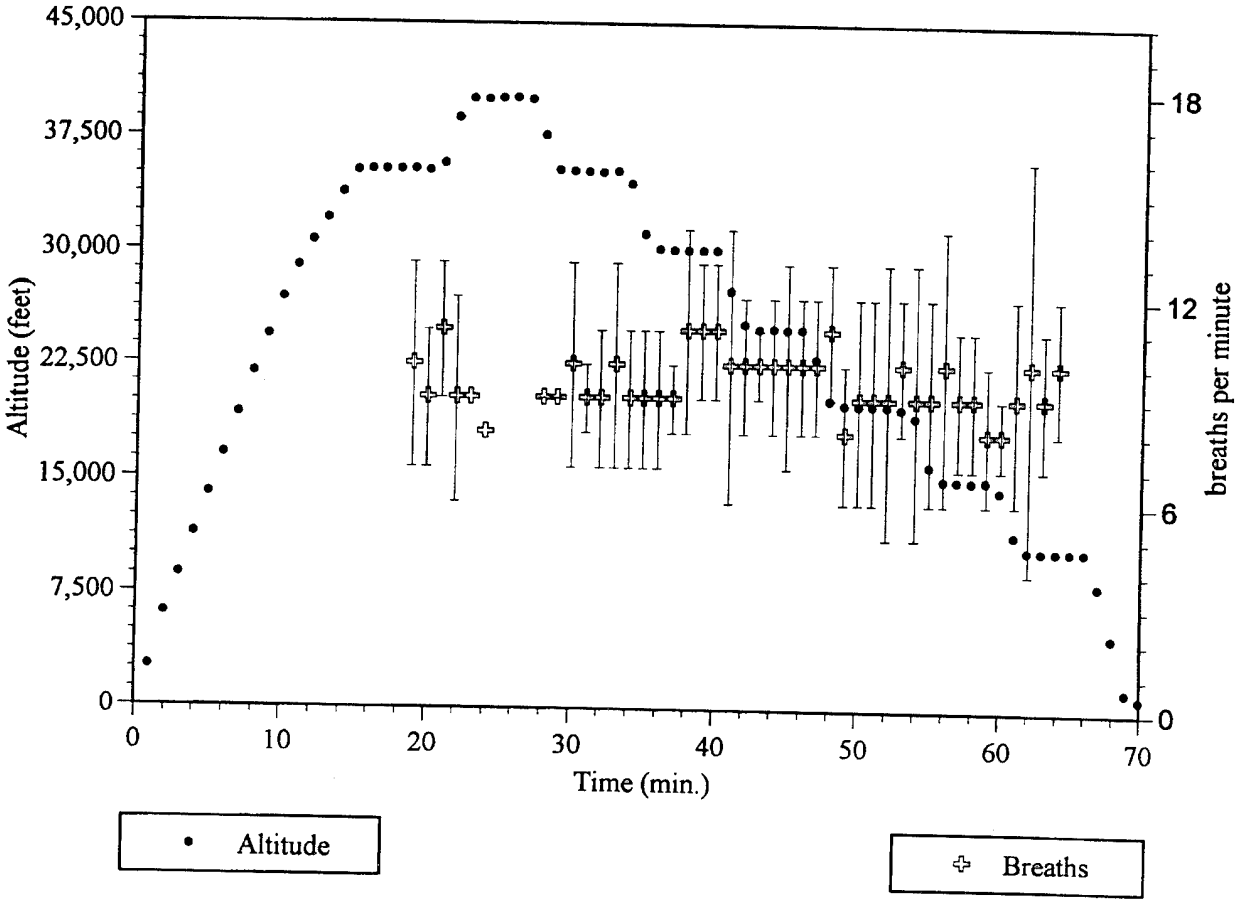

Figure 9. Average ventilatory rate during altitude exposure.

would suggest a change in ventilatory rate. Review of videotapes made during the chamber flights supported the observations of the research team.

Any time a human being is exposed to high altitudes, there is the possibility of decompression sickness (DCS). The occurrence of DCS in human subjects is positively correlated with increases in altitude and time spent at altitude. Due to the inherent risks associated with altitude exposure to 40,000 feet, every reasonable effort was made to minimize the risk of DCS and to ensure the safety of the subjects prior to, and during, these experiments. At no time during the altitude exposure did a subject mention or describe sensations or symptoms indicative of DCS. Subjects spent roughly four minutes at each altitude (Figure 10). On average, subjects spent 28.25 ± 1.26 min. at altitudes above 25,000 feet, and 16.75 ± 1.04 min. at altitudes above 35,000 feet.

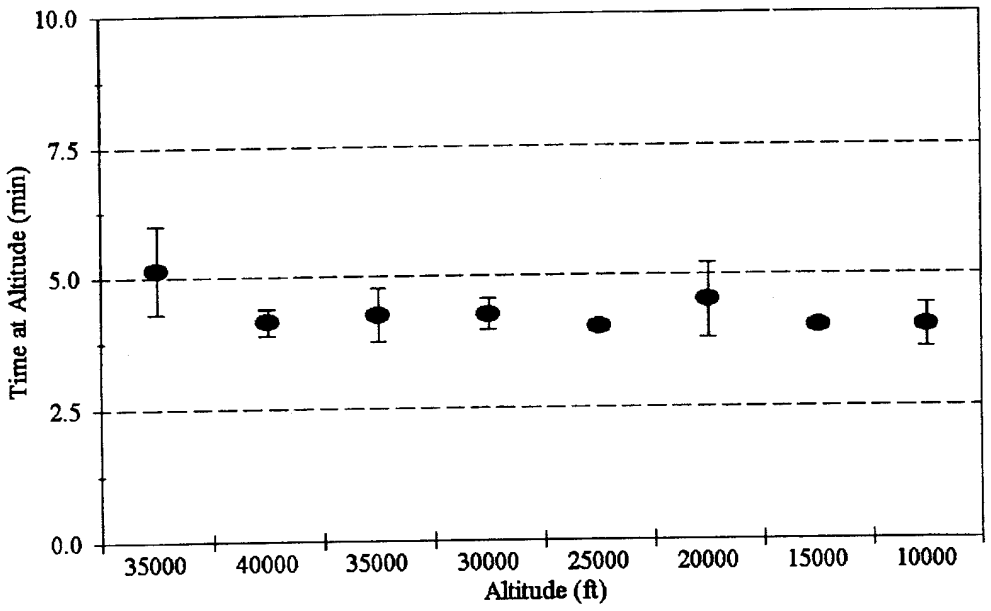

Figure 10. Average time at each altitude for the tests.

DISCUSSION

Performance capabilities of supplemental oxygen equipment designed for use by aircraft passengers have been an item of interest for at least 50 years. Early testing of constant flow type masks was done by the military (11). Their interests, concerns, and involvement soon spread into the realm of commercial aviation (7, 12). During the 1940s and early 1950s, passenger oxygen mask design was limited to a flight ceiling of 25,000 feet. As aviation progressed and the flight capabilities of common carrier aircraft increased, the need to develop a passenger oxygen mask that could be used at altitudes up to 40,000 feet was obvious.

The mid- to late-1950s produced numerous manufacturer and government investigations into passenger oxygen mask development (13, 14, 15, 16, 17). Minimum standards for materials, testing, and performance of this type of mask were set forth in a National Aerospace Standard (NAS) 1179 in 1959. This subsequently became a part of the Federal Aviation Administration's (FAA's) TSO-C64, which first became effective in 1961 (1). The Federal Aviation Administration's primary effort in developing a simple, reliable, and versatile method of testing passenger oxygen mask capabilities was done through a contract with a subsidiary of the Bendix Corporation (19). This report identified the technological problems with measuring expired oxygen concentrations for mask evaluation purposes. It went on to recommend the use of pulmonary nitrogen washout as the method of choice for measuring mask leakage and estimating expired oxygen concentrations.

The Bendix report was included as an attachment supporting the use of the nitrogen washout procedure in the TSO-C64 Qualification Test Report originally submitted for the Puritan-Bennett 174080/81 series mask in 1965 (20). In the original mask certification report, P_AO_2 values were derived from tracheal PO_2 estimates, and SaO_2 levels were estimated from the oxygen dissociation curve. Oximeter readings were consistently 5-10% lower than predicted. The difference was ascribed to the effects of exercise. However, at PO_2 levels above 95 mmHg, only a 1 to 2% change in SaO_2 would be expected to be caused by moderate exercise. The discrepancy was not addressed in the report that was subsequently published from the test data (5).

SaO_2 data collected in our present tests were consistent with P_AO_2 estimates, except at an altitude of 15,000 feet, where recorded values actually exceeded predicted values. This may be explained by the long oxygen prebreathe before altitude exposure. If body stores of oxygen had been increased during the prebreathe, that oxygen could have maintained SaO_2 at normally high levels during re-equilibration of body gas stores. A quantitative analysis of the time course and changes in volume of body gas stores resulting from breathing different gas mixtures would benefit the analysis of this, and similar data.

Changes in nitrogen body stores deserve similar consideration. Previous reports have not addressed the question of re-equilibration of nitrogen in the body at altitude and/or after a prebreathe on 100% oxygen. At altitude, a pressure gradient exists for stores of all gases to leave the body. Returning to an ambient air mixture or dilution, after an extended 100% oxygen prebreathe, will create a pressure gradient for N_2 to dissolve in the blood and to re-equilibrate with storage sites. N_2 stores are estimated to be approximately 60 ml/kg in humans (20). This represents 4.5 l of N_2 in a 75 kg person. If the vast majority of this N_2 were lost during an extended prebreathe, reuptake upon breathing a nitrogen containing gas mixture could influence O_2 estimates based on N_2 readings. This would tend to increase P_AO_2 and P_ACO_2.

Aerospace Standard 8025 states that the total percentage of oxygen in the inspired gases reaching the lungs may be estimated by adding the percentage of O_2 and CO_2 in the expired end tidal gases, or by subtracting the percentage of N_2 in the expired end tidal gases from unity. AS-8025 does not state the criteria that should be used to determine the end tidal point, but does state that measurements should be taken at stabilized conditions. Assuming that *stabilized* means *steady state*, gas equilibriums across the alveolar membrane may not reach steady state levels during a three-minute period at altitude. This is particularly true when the O_2 flow to the mask is diluted with an unknown amount of ambient air on a breath by breath basis.

Although improvements in technology now allow rapid measurement of expired O_2 and CO_2 levels, this capability does not overcome the volume and flow measurement problems associated with continuous flow, phase-dilution oxygen mask testing. The techniques used in the past for mask testing are probably valid estimates that fall within the range of experimental error. They can, and will, continue to be used until the problems associated with estimating tracheal or alveolar PO_2 by expiratory gas analysis are more finely resolved. Currently, measurement of blood oxygen saturation appears to be the best variable to monitor in assessing the ability of the mask to prevent severe hypoxia at altitude. Unfortunately, SaO_2 is relatively insensitive to small changes in P_AO_2 above 70 mmHg. The technology for making SaO_2 measurements has become highly refined in recent years, and is readily available at a reasonable cost for most testing facilities. The greatest challenge to the accuracy of mask testing of this type is probably not the measurement techniques utilized, but the test protocol designs.

An extended oxygen prebreathe and minimum amounts of time spent at altitude are a much different scenario than that in which a passenger mask is expected to perform. In an actual decompression incident, individuals are probably going to be hypoxic and hyperventilating, to some extent, when they don the mask. Test protocols and/or models need to be developed and implemented that examine mask performance capabilities in more realistic settings. Of course, the major problem with realistic test protocols is the increased risk of hypoxia and DCS for the test subjects. The primary reasons for doing a 100% oxygen prebreathe is to minimize body N_2 stores, which are considered to make a significant contribution to the development of gas emboli and decompression sickness. The appropriate balance between realistic testing, which gives reliable insights into the protection offered by passenger oxygen masks, and the health risk associated with performing such testing, deserves discussion.

In these tests, we have found that the series 174095 continuous flow passenger oxygen mask manufactured by Puritan-Bennett Corporation can prevent hypoxia, consistent with TSO-C64 and SAE AS-8025. Respiratory gas analysis and blood oxygen saturation recordings both indicated whole body oxygenation levels above baseline regulatory limits.

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