



U.S. Department
of Transportation

**Federal Aviation
Administration**

Memorandum

Subject: **ACTION:** Project No. ST5040SE-A, Precise Flight
Oxygen Conserving Cannulas – Requesting Review of and
Concurrence with Equivalent Level of Safety (ELoS), 14
CFR Part 23, Section 23.1443, Minimum Mass Flow of
Supplemental Oxygen. **ACE-00-10**

Date: JAN 5 2001

From: Manager, Seattle Aircraft Certification Office,
ANM-100S

Ref.
No.: 190S-00-811

To: Manager, Standards Office, ACE-110
ATTN.: Doug Rudolph

Reply to J. Shelden
Attn. of: (425) 227-2624

Background:

Part 23, Section 23.1443, paragraphs (a)(1) and (a)(2) address oxygen partial pressures in the trachea of the oxygen user. This exact partial pressure of oxygen requires the use of closed masks or other forms of delivery systems where oxygen delivery can be precisely controlled or measured. The oxygen conserving cannula is not closed, as air can pass by the oxygen delivery prongs in the nasal cavities, therefore partial pressure measurement would not be practical. Paragraph (a)(3) provides a minimum flow rate of oxygen for any mask or cannula at altitude. Precise Flight, Inc. would like to compare performance of a standard cannula at the Part 23 required flow rate and the subsequent performance of oxygen conserving cannula at a flow rate less than the required FAA required flow rate. Precise Flight intends on installing this system on the Lancair Columbia 300 airplane.

Applicable Regulations:

Part 23, Section 23.1443, Minimum Mass Flow of Supplemental Oxygen.

Applicant Position:

An oxygen conserving cannula incorporates a reservoir to store oxygen during exhalation. The cannula conserves oxygen and supplies it at the initial important 200 ml inhalation of oxygen. The initial inhalation is the oxygen enriched air that reaches the alveolar level, as opposed to the remainder of the inhalation flow which serves to fill the lungs, and provides pressure for the gas exchange to take place at the cellular level.

Oxygen flowing throughout the ventilatory cycle is largely wasted. When accepting that or any similar model, it becomes apparent that a relatively small portion of the continuous flow oxygen reaches the alveolar level of the lungs.

Brian L. Tiep MD *PORTABLE OXYGEN THERAPY*, Futura Publishing Co.
1991 pg 222

The minimum oxygen flow rate that provides a full relative oxygen saturation level - SaO_2 indicated on the Finger Pulse Oximeter will be determined for the standard cannula. This level will be compared to the minimum flow rate allowed by the Part 23, Section 23.1443(a)(3). The delta difference in these two flow rates will be considered the minimum margin of safety.

Then the minimum oxygen flow rate that provides a full - SaO_2 indicated on the Finger Pulse Oximeter will be determined for the oxygen conserving cannula. The standard cannula flow rate delta difference will be added to the minimum rate to establish the acceptable flow rate for the oxygen conserving cannula thus preserving the minimum margin of safety.

Test data will account for a reasonable population of occupants and cabin pressure altitude variations from 12,500 to 18,000 feet. The airplane has a service ceiling of 18,000 feet with an approved oxygen system. The Finger Pulse Oximeter will be used for certification testing only to determine an acceptable flow rate, and not in service.

The pulse oximeter has some limitation for determining exact blood gas concentration.

The pulse oximeter measures the transmission of two wavelengths of light through skin, usually the finger. The red wavelength represents hemoglobin combined with oxygen, and the infrared wavelength represents unbound hemoglobin.

While pulse oximetry is not considered as accurate as the SaO_2 calculated by arterial blood gases. Pulse oximetry provides for the continuous measurement of SaO_2 , which is useful for trending.

Rick Carter PHd . *PORTABLE OXYGEN THERAPY*, Futura Publishing Co.
1991 pg 134

Pulse oximetry only provides a comparison of oxygen saturation for an individual and does not provide an accurate level of oxygen saturation in the blood. By limiting the test to a comparison and assuring that the oxygen conserving cannula and reduced flow rate provide an equal to or higher oxygen concentration for a single person than for a standard cannula and the Part 23 required flow rate, an equivalent level of safety can be found.

In therapeutic oxygen therapy, the model for Reservoir flow of Oxygen (oxygen conserving cannulas) versus Continuous Flow indicates that a similar oxygen saturation SaO_2 can be delivered at flow rates much less than those of the continuous flow system. This true for all patients, regardless of health condition.

By making a comparison of the two types of oxygen delivery and obtaining the delta difference in flow rates below individual oxygen saturation, the population incorporated into the Part 23 flow rate will be maintained. The result will be an oxygen concentration for the Oxygen Conserving Cannula System at a blood oxygen saturation level above or equal to the Part 23 continuous flow system.

Precise Flight, Inc. maintains the level of safety incorporated into the Part 23, Section 23.1443 will be met or exceeded with the use of oxygen conserving cannulas and their ability to provide high concentrations of oxygen in the first 200 ml of inspiration. This high concentration is a function of the oxygen reservoir and is standard for conserving oxygen in therapeutic use without compromising health or safety.

FAA Position:

The proposal detailed above in the applicant position section of this memo provides a level of safety that is equivalent to that provided by strict compliance with Part 23, Section 23.1443. Therefore, the FAA agrees that this equivalent level of safety criteria may be used for showing compliance.

Compensating Features:

1. The oxygen conserving cannula system will be shown to provide an oxygen concentration at a blood oxygen saturation level above or equal to the Part 23 continuous flow/standard cannula system as based on a comparative measurement using a Pulse Oximeter.
2. The oxygen conserving cannula system maintains the level of safety incorporated into the regulation Part 23, Section 23.1443 due to their ability to provide higher concentrations of oxygen in the first 200 ml of inhalation as compared to a continuous flow system.
3. The portable oxygen conserving cannula system has been safely used for years with a reduced flow rate by general aviation pilots without FAA approval required. The Lancair Columbia 300 has a certification basis where any oxygen system used in the airplane must be approved - including portable systems. Part 23, Section 23.1443 did not envision the oxygen conserving cannula operating with a highly reduced flow rate.

Recommendation:

We concur that the Precise Flight proposal detailed above in the applicant position section of this memo provides an equivalent level of safety as envisioned by the regulations and thus meets the requirements of Part 23, Section 23.1443.

Concurred by:



for Manager, Seattle Aircraft Certification Office, ANM-100S

12/8/2000
Date



Manager, Standards Office, ACE-110

1.05.01
Date



Manager, Small Airplane Directorate,
Aircraft Certification Services, ACE-100

1/5/01
Date

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ACE Minor revisions: (page 1 under "applicant position," changed "provide" to "provides")
(page 2, last paragraph, changed first sentence by spelling out "versus," changing "indicate" to
"indicates," and by breaking second sentence into two sentences.)

12/28/00; 1/4/01, Changed "inspiration" to "inhalation" per -111