European Aviation Safety Agency

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SAPOX - Safety Aspects of Pulse Oxygen Systems

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EASA 2009.OP.23 SAPOX STUDY REPORT

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1. ACKNOWLEDGEMENTS

This report presents the result of the study 2009.OP.23 – Safety Aspects of Pulse Oxygen system. This study has been performed under the EASA contract EASA.2009.C51.

2. ABBREVIATIONS & DEFINITIONS

AMC	Acceptable Means of Compliance
BMV	Breathing Minute Volume
CO	Carbone Monoxyde
COPD	Chronic Obstructive Pulmonary Disease
CS	Certification Specification
ESF	Equivalent Safety Finding
f	Breathing rate (in min-1)
FAR	Federal Aviation Regulations (FAR = US CFR Title 14)
$F\ O_2$	Oxygen fraction
$F_A\ O_2$	Oxygen fraction of mean alveolar gas
$F_E\ O_2$	Oxygen fraction in expired gas
$F_I\ O_2$	Oxygen fraction in inhaled gas
NTPD	Normal Temperature Pressure Dry
Same abbreviations for CO_2: $F\ CO_2$, $F_A\ CO_2$, $F_E\ CO_2$,	
O_2	Oxygen
P_B	Barometric pressure
P_{B0}	Barometric pressure at sea level
$P\ O_2$	Oxygen partial pressure
$P_a\ O_2$	Oxygen partial pressure in arterial blood
$P_A\ O_2$	Oxygen partial pressure in mean alveolar gas
$P_E\ O_2$	Oxygen partial pressure in expired gas
$P_I\ O_2$	Oxygen partial pressure in inhaled gas
Same abbreviations for CO_2: $P\ CO_2$, $P_A\ CO_2$, $P_E\ CO_2$,	
$P_A\ H_2O$	Water vapor partial pressure in alveolar gas
$P_T\ O_2$	Oxygen partial pressure in “tracheal” gas
	“tracheal gas” is defined as inhaled gas, heated to 37°C, saturated in water vapour
$P_T\ H_2O$	Water vapor partial pressure in tracheal gas
	The temperature of both tracheal gas and alveolar gas is 37°C. Then P_TO_2 and $P_A\ O_2$ = 63 hPa (47 mm Hg)
Pax	Passenger(s)
R	Respiratory quotient; R is the ratio (in volume) between CO_2 production and O_2 consumption by the body.
$S_a\ O_2$	Oxygen saturation of the arterial blood
$S_p\ O_2$	“Pulse saturation”; it’s S_aO2 measured with a pulse oximeter – a method which analyses the signal obtained by difference between systolic and diastolic phase of the cardiac flow.
SRT	Single Reaction Time
TSO	Technical Standard Order
TUC	Time of Useful Consciousness
V	Volume

$\dot{V}O_2$	O_2 consumption (in liters [STPD] per minute)
$\dot{V}CO_2$	CO_2 production (in liters [STPD] per minute)
$\dot{V}_E$	Minute volume (or BMV – Breathing Minute Volume)
$\dot{V}_A$	Minute alveolar volume (alveolar volume is tidal volume minus dead volume
V_T	Tidal volume
V_D	Dead volume
$V_E N_2$	Mean (minute) volume of expired nitrogen
$V_I N_2$	Mean (minute) volume of inhaled nitrogen
Conditions of measure of gaseous volumes	
BTPS	Body Temperature and Pressure, Saturated
ATPD	Ambient Temperature and Pressure, Dry
STPD	Standard Temperature and Pressure, Dry

3. EXECUTIVE SUMMARY

The requirements of EASA Certification Specification CS 25.1443 Minimum Mass Flow of Supplemental Oxygen, in particular CS 25.1443(c) and (e), correspond to constant flow oxygen systems and test methodologies available at the inception of the rule forty years ago. They do not specifically correspond to how human subjects would respond when actually subjected to decompression conditions.

The aim of this study was to develop both equivalent requirements and associated Acceptable Means of Compliance (AMC) using the measurement of arterial oxygen saturation (S_aO_2) of hemoglobin as a more efficient way to assess the performance of oxygen systems to be installed in aircraft. Additionally, the revised requirement will be independent of the technology used.

The project has been divided into 3 main steps:

1. **Literature survey** to assess the minimum SaO2 levels that provide an equivalent protection to the risk of hypoxia in comparison to the current regulations;
2. **Human tests** aimed to confirm recommended S_aO_2 levels while exposing individuals to various altitudes;
3. **Test results analysis** to substantiate and refine recommendations.

Consequently:

- Minimum baseline S_aO_2 levels for human beings exposed to altitude have been proposed;
- Proposed levels have been experimentally assessed to offer a safe protection against hypoxia in comparison to the current regulations;
- New wording has been proposed to describe the minimum performance requirements in CS 25.1443(c) and CS 25.1443(e). Furthermore, Acceptable Means of Compliance (AMC) related to CS 25.1443(c) are proposed for Oxygen systems and Equipment certification purposes (Appendix 2).
- Moreover, the notion of medical use is added to chapter (d), in order to take into account the use of portable oxygen equipment for medical purposes.

4. BACKGROUND

Current requirements were issued more than forty years ago and were limited by the test methodologies available at that time. The evaluation of tracheal partial pressure of oxygen was a good indicator for sufficient oxygenation and was easier to perform. However, this parameter does not accurately correspond to how human subjects actually respond to phased oxygen delivered during decompression conditions.

New designs of oxygen systems propose to incorporate new technologies, e.g. TSO-C64b mask or pulse oxygen system, to protect passengers from the harmful effects of hypoxia in the event of an in-flight depressurization. The proposed systems will not meet the specific oxygen delivery requirements of CS 25.1443(c). Several airframe manufacturers applied for Equivalent Safety Finding (ESF) to allow substantiation of the system's performance using parameters developed through comparative human subject testing in lieu of the mass flow performance requirements.

The ESF already granted are based on very particular designs which make it difficult to use them as justification for changes of the current regulation in CS 25. One indicator of an individual's degree of oxygenation is the level of arterial blood oxygen saturation (S_aO_2). Research is needed to justify baseline S_aO_2 levels and an acceptable method to evaluate proposed design performance against S_aO_2 levels established.

The significant advantage of amending the existing regulation reflecting on the new designs of Oxygen systems is that less oxygen would be needed to protect passengers from the harmful effects of hypoxia than it would be needed to support current supplemental oxygen systems. Current systems deliver a significant amount of oxygen not contributing to blood oxygenation at the lung alveoli membrane level (dead volume effect). Such an amount can therefore be considered as wasted after exhalation to atmosphere. Expected benefits of these new designs of Oxygen systems facilitated by amendment of the regulations are:

1) reduced weight of the airplane since less oxygen is needed to be carried,

2) lower fire hazard because less oxidizer is on board of the airplane.

3) operational flexibility due to increased duration of existing oxygen supply

5. AIMS AND OBJECTIVES

The current version of CS 25.1443 does not specify a minimum mass flow of supplemental oxygen to be provided. It requires a determination of the minimum mass flow of supplemental oxygen that is necessary to maintain a mean tracheal oxygen partial pressure during inspiration. The mean tracheal oxygen partial pressure is the parameter used to evaluate the performance of oxygen systems.

These requirements were issued more than forty years ago and were limited by the test methodologies available at that time. The measurement of tracheal partial pressure of oxygen was a good indicator of the blood oxygen saturation and was easily converted to a concentration of oxygen versus altitude. Oxygen concentration versus altitude was an easier parameter to measure and could be tested using a breathing machine in an altitude chamber. However, this parameter does not accurately correspond to how human subjects actually respond to phased oxygen delivered during decompression conditions.

The aim of this study is to develop equivalent requirements for CS 25.1443 and associated Acceptable Means of Compliance (AMC) based on measurement of arterial oxygen saturation (S_aO_2) of hemoglobin. Measurement of arterial oxygen saturation (S_aO_2) is a more efficient way to assess the performance of oxygen systems to be installed in aircraft. Additionally, the revised requirement will be independent of the technology used to deliver supplemental oxygen.

Detailed objectives were therefore established to:

- Propose new Certification Specifications CS 25.1443(c) and associated Acceptable Means of Compliance for Passenger equipment;
- Propose new Certification Specifications CS 25.1443(e) and associated Acceptable Means of Compliance for Portable Equipment;
- CS 25.1443(d), specifications for first-aid oxygen equipment, have been excluded from the scope of the study since their foundations can be found in the medical field and they are not primarily based on altitude hypoxia protection considerations.

6. LITERATURE REVIEW

6.1. Commercial Aviation Passengers protection against cabin depressurization during high altitude flight

Object: Passengers of EASA CS-25 and US CFR Title 14 (FAR) Part 25 certified aircrafts. Passenger airplanes are flying longer distances at higher altitudes for many reasons. Improvement of passenger comfort by avoiding the hazards associated with decreased atmospheric pressure and the effects of hypoxia is a primary objective. The advantage of decreased fuel consumption related to operating at higher altitudes continues to drive operations to higher levels. Since the first studies on cabin aircraft pressurization in the 1930s, the risk of depressurization of the enclosure has existed. The first studies are dated from this period.

The pressurization system is designed to restore the cabin pressure to values above the ambient barometric pressure. Describing the cabin pressure characteristics in terms of an absolute pressure is somewhat theoretical in nature. To provide a more intuitive reference, this concept is usually expressed by the pressure's equivalent altitude. This is called the cabin altitude, which is thus different from the aircraft altitude except in the case of a depressurization.

Current requirements for the cabin pressurization of aircraft used in commercial air transportation are specified in CS 25, § 841 (1). The maximum cabin altitude is specified at 2500 m (8,000 ft), with a typical average value closer to 1800m (6,000 ft).

The cabin pressurization system is therefore the primary mode of protection for individuals against the effects of altitude. Exposure to altitude has several effects, among which hypoxia (oxygen deficit) is the most serious due to a very quick onset rate. It can be compensated by the administration of supplemental oxygen. This is the purpose of the emergency oxygen equipment available to passengers during flight at high altitude, in case of pressurization system failure.

The altitude induced hypoxia, especially in the context of the quick depressurization of the cabin during high altitude flight is the highest risk scenario. This scenario is the basis for how oxygen systems are designed and certified to protect passengers against altitude hypoxia.

6.2. The atmosphere

The atmosphere is defined by its pressure, composition and temperature. *Throughout the altitude range used by aviation, pressure changes and the chemical composition of the atmosphere remains constant.*

The atmosphere's pressure, called barometric pressure (P_B), varies with altitude according to a roughly exponential curve (Figure 1, 0). To mean sea level, barometric pressure (P_{B0}) is equal, on average, to 1013.25 hPa (760 mm Hg) and varies between 960 and 1040 hPa.

The chemical composition of the atmosphere is constant throughout the range of altitude encountered in aeronautics (up to 30,000 m - 100,000 ft - at least), except for water vapor and some minor components of the atmosphere. Table 1 shows the composition of air, this table is limited to only a few rare gases. Much of the water vapor is found in the lower layers of the atmosphere. Ozone is encountered mainly in the stratosphere.

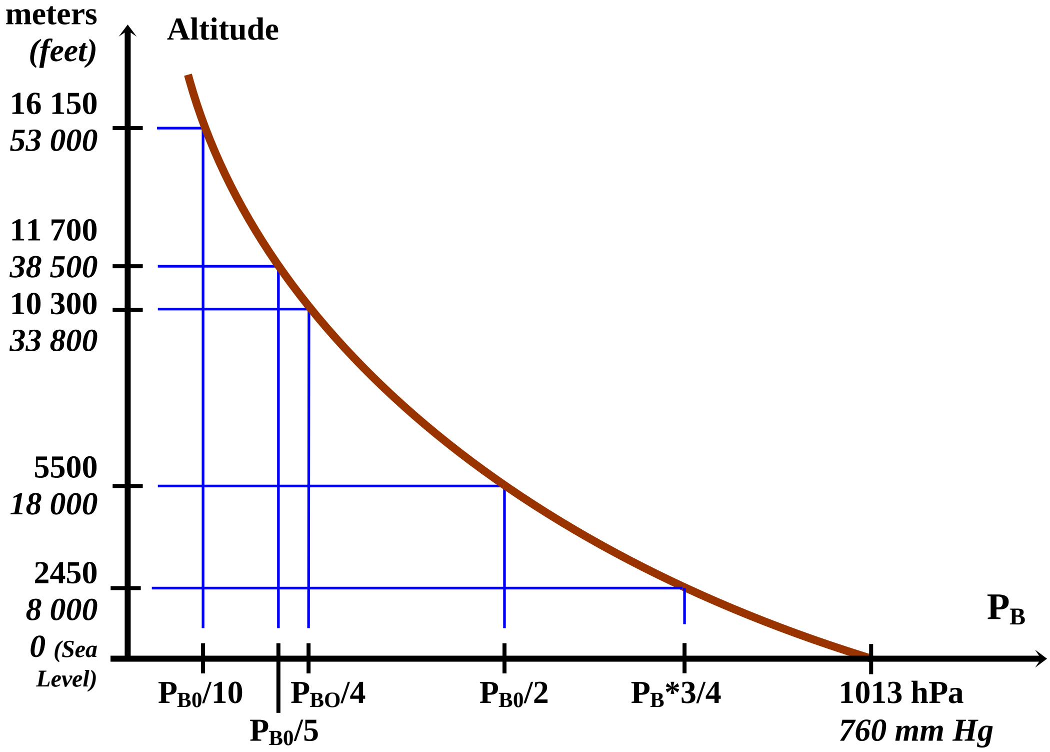

Figure 1. Barometric pressure (P_B) related to altitude (Z).

Altitude		Barometric pressure	
ft	*m*	hPa	*mm Hg*
0	*0*	1013,2	*760,0*
10,000	*3,048*	697.0	*522.7*
20,000	*6,096*	466.0	*349.5*
30,000	*9,144*	301.5	*226.1*
40,000	*12,192*	188.2	*141.2*
45,000	*13,716*	148.2	*111.1*

Gas	Chemical symbol	Fraction	Remarks
Nitrogen	$\mathbf{N_2}$	**78,101 %**	**Constant**
Oxygen	$\mathbf{O_2}$	**20,946 %**	**Constant**
Water vapor	H_2O	2 %	Very variable
Argon	Ar	0,917 %	Constant
Carbon dioxide	CO_2	0,033 %	Variable
Ozone	O_3	0,0,0005 %	Very variable

Table 1. Composition of atmospheric air up to 30,000 m (100,000 ft) at least

As a result of changes in altitude of the respective barometric pressure (variable) and the chemical composition of air (constant), the partial pressure of oxygen in the air decreases with altitude (Dalton's law) . Its decay curve is a simple dilation of the decay curve of barometric pressure, in a ratio 0.21.

However, the living organism is a thermal aerobic system As such, it requests a certain function of O_2 partial pressure. This represents the mass of oxygen per unit volume. This concept is exactly the same when applied to aircraft engine. Prevention of lower partial pressure of oxygen at altitude is based on finding a technology that allows it to maintain a sufficient value. Technological solutions are based on the physical application of Dalton's law ($PO_2 = P_B * FO_2$). During exposure to altitude, the target of PO_2 is reached by both techniques, not exclusive of one another, but only by these two techniques: maintaining P_B at a sufficient value (like inside a cabin or a suit), and inhalation of an air suitably enriched with oxygen by using a system that regulates breathing oxygen enrichment according to the ambient altitude.

The consequences of exposure of human to altitude are dictated by the laws of physics of gases:

- Boyle-Mariotte's Law: P.V = constant;
- It is useless in this regard, to supplement the Boyle-Mariotte's law by Charles law (temperature impact) because the gases concerned are at body temperature, so temperature is almost constant (around 37°C);
- Dalton's law, already mentioned above, and which one part expresses the calculation of the partial pressure of gas in a mixture, a product of the fraction of this gas by the total gas pressure;
- Henry's law, which describes the solubility of a gas in a liquid.

Applications of these different physical laws of gases in a sudden depressurization event are:

- Boyle's law: the risk of barotraumas, which is to say, trauma due to pressure changes subsequent to altitude changes. This risk is not taken into account in cases of cabin depressurization - even if the consequences can be quite painful for the staff, but in this context, whether this risk is vulnerable, it is not lethal;
- Dalton's law: its application to the depressurization of the airplane is the reduction of the partial pressure of oxygen: the risk that we take into account.
- Henry's law: the risk of altitude decompression sickness (DCS), which appears after a few minutes delay. As the plane is supposed to make an emergency descent, this risk is not taken into account. However, this risk limits the maximum exposure time to altitude.

The decrease of the temperature related to altitude increase is not a significant risk. We do not take it into account. The reason is that the human body heat exchange with the atmosphere are exchanges by convection, one of the main components of the calculation is the pressure of surrounding gas. At altitude, the pressure is reduced, the thermal exchanges by convection are also reduced, at least for exposure times corresponding to the time profile of the event.

Altitude induced hypoxia is the primary risk to be considered during the depressurization of the airplane. The focus of this analysis is the altitude hypoxia condition.

6.3. Altitude hypoxia

Hypoxia means "oxygen deficit". *Anoxia* means "without oxygen."

6.3.1. Classifications

Classification of states according to their duration of hypoxia application

Hyperacute or fulminant hypoxia occurs in a few seconds, through a brutal and total decompression of the cabin or by sudden interruption of the supply of oxygen at high altitude in a non or insufficient pressurized cabin, and is responsible for an inaugural syncope (= without prior symptoms).

Acute hypoxia occurs within minutes by slow exposure (in minutes) at an average altitude of around 4,000 to 6,000 m and is responsible for mental disorders of all types and all levels of severity.

Extended hypoxia is spread over several hours, at altitudes of around 2,500 to 3,500 m. The main symptom is fatigue.

Chronic hypoxia is encountered during visits or lives in the mountains.

Classification of states according to their type of hypoxia

Ambient hypoxia is caused by a decrease in PO_2 ambient gases: it is encountered at high altitude or during administration to the sea level of gas mixtures with F_IO_2 <0.21. It is also called hypoxic hypoxia.

Anemic hypoxia or hypemic hypoxia is due to a reduced ability of blood to carry oxygen (hemorrhage, carbon monoxide (CO) poisoning).

Circulatory hypoxia is observed when blood does not reach organs to be infused in good quantities. In aeronautics, is one of the issues due to long-term accelerations in G_Z [stagnant hypoxia].

Histotoxic hypoxia is observed when toxic inhibits the biochemical mechanisms of cellular metabolism (histotoxic: cell toxicity), the toxic characteristic is the radical CN (cyanide). The oxygen reaches the cells but they cannot use it.

The description of these various states of hypoxia is important to consider when several causes of hypoxia are encountered simultaneously. One example of this type of combined exposure is the transportation in altitude of a patient with a pathological respiratory deficit.

6.3.2. Symptoms of exposure to altitude conditions (acute hypoxia)

Hypoxia causes two characteristic symptoms, the sensation of breathlessness (dyspnea) and headache, increased by exercise and sleep. Fatigue is felt for several hours following exposure to hypoxia.

For many reasons, the major autonomic functions (breathing, circulation) are little changed by exposure to altitude, as long as it remains compatible with survival.

Nevertheless, hypoxia causes very important disorders to relation functions: sensory acquisition, operation of the central nervous system, bringing actuation of the motion system. These disorders, in their form known as "acute" are disorders of consciousness, followed by unconsciousness. As it stands "hyperacute," which is the fast exposure to high altitude, it is a loss of consciousness without prior symptoms.

In its crudest form, the consequences of exposure to hyperacute hypoxia can be described by two numbers: the loss of consciousness occurs within 5 seconds after stopping the supply of oxygen to the brain and permanent damage of the system CNS appear after 3 minutes of complete deprivation of oxygen.

The rapid depressurization of a plane flying at high altitude exposes the personal to a risk of hyperacute hypoxia.

Moreover, exposure to altitude can lead to Decompression Sickness, due to the transformation of the Nitrogen dissolved into the body tissues into gases. This causes pains, first located in joints. These effects will not be part of this study, as it is not related to hypoxia issues.

6.3.3. Calculate the oxygen supply to body tissues

There are two steps in the calculation used to determine the intake of oxygen in the inspired gas that is delivered to body tissues. The first is to establish a relationship between inspired gas and alveolar gas (gas present inside the lungs). The second step is related to the blood transporting the oxygen.

6.3.3.1. Relationship between inspired gas and alveolar gas

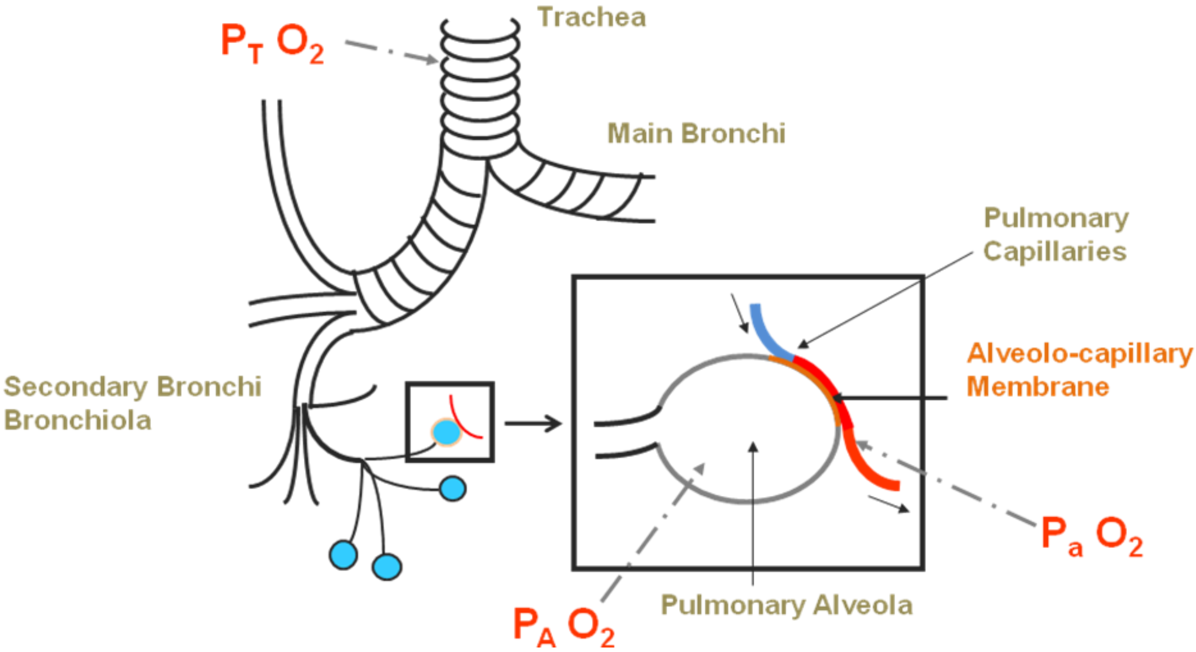

Figure 2. Anatomy background - ventilation

Relationship between alveolar and breathing gas are visible in the Figure 2 above.

The inspired gas is defined by its pressure and its composition. The equations have been established at the end of the 1940s. They have been fairly widely published (eg Otis AB. 1965). We reproduce these equations below, noting that they are only valid for steady state and under physiological conditions close to normal.

In stable conditions, alveolar gases and inspired gases are united by a series of relationships. The respiratory quotient R is defined as the ratio of the amount of carbon dioxide released from the consumption of oxygen, i.e.:

$$R = \frac{\overset{o}{V} CO_2}{\overset{o}{V} O_2}$$

The respiratory quotient is rarely equal to one. Thus, the volume of expired gas is almost always different from the volume of inspired gas. In reality, the respiratory quotient is generally lower than one.

Let V_T be the tidal volume (volume at each respiratory cycle), V_D the dead volume (volume at the end of inspiration remains in the upper airways and is not involved in pulmonary gas exchange), f is the frequency of breathing. Expiratory flow per minute V_E is defined by the product of tidal volume by using V_T ventilation frequency f and is written:

$$\overset{o}{V}_E = f \, . \, V_T$$

Alveolar flow, defined as the difference between tidal volume and dead space, is written:

$$\dot{V}_A = f \,.\, (\dot{V}_T - \dot{V}_D)$$

Cellular flow is not identical to the inspiration and expiration as VO_2 and VCO_2 are not equal (R ≠ 1). V_{AI} and V_{AE} are respectively the notations for these two flows. F_IO_2 and F_AO_2 are the fractions of oxygen in the inspired gas and mean alveolar gas, it is possible to represent oxygen consumption as the difference between the amount of oxygen entering the lungs and that which exits them:

$$\dot{V}O_2 = (\dot{V}_{A_I} \,.\, F_I\, O_2) - (\dot{V}_{A_E} \,.\, F_A\, O_2)$$

The amount of carbon dioxide released is expressed in a similar way, knowing that the fraction of inspired gas is normally close to zero in a normal atmosphere:

$$\dot{V}CO_2 = (\dot{V}_{A_E} \,.\, F_A\, CO_2)$$

The respiratory quotient can be written by combining the last two equations:

$$R = \frac{\dot{V}CO_2}{\dot{V}O_2} = \frac{\dot{V}_{A_E} \,.\, F_A\, CO_2}{\dot{V}_{A_I} \,.\, F_I\, O_2 - \dot{V}_{A_E} \,.\, F_A\, O_2}$$

Or, dividing both terms of the fraction by V_{AE}:

$$R = \frac{F_A\, CO_2}{\frac{\dot{V}_{A_I}}{\dot{V}_{A_E}} \,.\, F_I\, O_2 - F_A O_2}$$

The problem is then to estimate the relationship V_{AI} / V_{AE}. This estimation can be done by considering that in steady-state, metabolically inert respiratory gases balance (here reduced to nitrogen alone) is zero, that is to say:

$$\dot{V}_I\, N_2 = \dot{V}_E\, N_2$$

Now it is possible to evaluate separately V_IN_2 and V_EN_2 by simply considering these values as the difference between the total volume and volume of the other two gases, oxygen and nitrogen:

$$\dot{V}_I\, N_2 = \dot{V}_{A_I} \,.\, (1 - F_I\, O_2)$$

$$\dot{V}_E\, N_2 = \dot{V}_{A_E} \,.\, (1 - F_A\, O_2 - F_A\, CO_2)$$

These two equations can be combined into:

$$\dot{V}_I\, N_2 = \dot{V}_{A_I} \,.\, (1 - F_I\, O_2) = \dot{V}_E\, N_2 = \dot{V}_{A_E} \,.\, (1 - F_A\, O_2 - F_A\, CO_2)$$

Thus:

$$\frac{\dot{V}_{A_I}}{\dot{V}_{A_E}} = \frac{1 - F_A\, O_2 - F_A\, CO_2}{1 - F_I\, O_2}$$

The equation for R can be rewritten, taking account of the latter:

$$R = \frac{F_A\ CO_2}{\frac{1 - F_A\ O_2 - F_A\ CO_2}{1 - F_I\ O_2} . F_I\ O_2 - F_A\ O_2}$$

A simple algebraic calculation can recombine this equation to:

$$F_A\ O_2 = F_I\ O_2 - F_A\ CO_2\ (F_I\ O_2 + \frac{1 - F_I\ O_2}{R})$$

In the pulmonary alveoli, the inspired gases are at 37 ° C are saturated with water vapor:

$P_A\ H_2O$ = 63 hPa = 47 mm Hg

Total alveolar pressure is very close to the barometric pressure. Alveolar gas pressure dry can be written:

$$P_A = P_B - P_A\ H_2O$$

Knowing that the product of pressure by the fraction is equal to the partial pressure, each term of the equation describing F_AO_2 can be multiplied by P_A, which allows writing:

Eq.1:
$$P_A\ O_2 = F_I\ O_2\ (P_B - P_A\ H_2O) - P_A\ \ CO_2\ (F_I\ O_2 + \frac{1 - F_I\ O_2}{R})$$

This equation can be altered in various ways. It can first be simplified in symbolic form. In the absence of significant hypoxia, i.e., whether P_AO_2 is maintained at a sufficient value, P_ACO_2 and R can be considered as practically constant, respectively equal to 53 hPa (40 mmHg) and 0,83. P_AH_2O is constant (63 hPa = 47 mm Hg). The equation can be written in the following symbolic form:

$P_A\ O_2 = f\ (P_B\ , F_I\ O_2)$

This equation expresses, using a symbolic form, that a sufficient value of P_AO_2 can only be assured by two techniques: maintaining a sufficient value to P_B (pressurization systems cabins) or to maintain a sufficient F_IO_2 value (through inhalation of oxygen enriched mixtures).

It can also be rearranged to highlight F_IO_2:

$$F_I\ O_2 = \frac{P_A\ O_2 + \frac{P_A\ CO_2}{R}}{P_B - P_A\ H_2O - P_A\ CO_2\ .(1 - \frac{1}{R})}$$

In this form, this equation can be rewritten with the numerical values of P_AH_2O, P_ACO_2 and R described above. If the pressures are expressed in hPa, the equation becomes:

$$F_I\ O_2 = \frac{P_A\ O_2 + 63{,}8}{P_B - 52{,}1}$$

If the pressures are expressed in mmHg, it becomes:

$$F_I\ O_2 = \frac{P_A\ O_2 + 48}{P_B - 39}$$

These equations describe the values $F_I\ O_2$ should be taken based on altitude and a given value of P_AO_2. They are one of the theoretical basis for the design of aviation oxygen inhaler.

6.3.3.2. The transfer of oxygen by the blood

The second remarkable milestone of the transport of oxygen is represented by the transfer of oxygen by the blood. Certainly, oxygen can be dissolved in the blood but the amount of oxygen carried is very low because oxygen is sparingly soluble in water at 37 ° C (about 3 ml (STPD) per 1000 ml of blood at standard sea level's PaO_2). Living organisms have developed a way to transport oxygen much more effectively, which is to bind oxygen reversibly on a dedicated molecule. This molecule is hemoglobin. The binding of oxygen on the hemoglobin molecule is a function of various factors, including the PCO_2 and pH premises, so that the hemoglobin molecule picks up oxygen in the lung environmental and chemical conditions and releases oxygen to the body's tissues. The amount of oxygen carried by blood is about 200 ml (STPD) of oxygen per litre of blood.

Finally, the change in oxidation state of the hemoglobin molecule causes a change in its color spectrum. A photometric method allows separate measurement of the total amount of hemoglobin and the amount of hemoglobin in its oxidized form. The relationship between the results of these two measures allows estimation of the "blood oxygen saturation", expressed as the ratio between the amount of oxygen carried and the maximum amount of oxygen that blood can carry.

The transport of oxygen by the blood is related to an enzymatic type chemical relationship. Its shape is complex, shown in Figure 3.

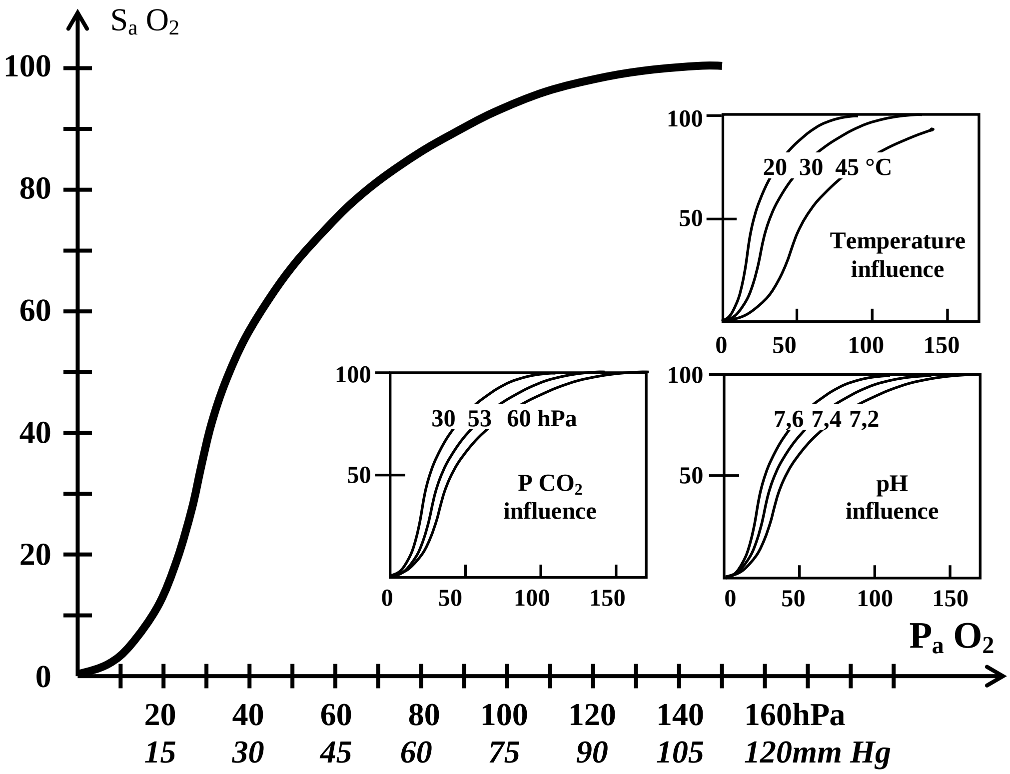

Figure 3. Dissociation curve of hemoglobin: relationship between the saturation of arterial oxygen (S_aO_2) and the partial pressure of oxygen (P_aO_2). This relationship depends on the temperature, pH and partial pressure of carbon dioxide in the blood. The partial pressures of gases are expressed in hPa.

6.3.3.3. What are the allowable values of PO_2?

Tolerance to hypoxia as a function of the altitude exposure is described based on the findings obtained both in laboratory and in flight as well as on the physiological and psychomotor effects observed. They can be divided into four altitude zones of tolerance. The initial description of the "zones of tolerance," date from the German writers of the 1930s. They appear in the work of Ruff and Strughold[1]. Their description is presented from the dissociation curve of hemoglobin (Figure 3, reproduced in Figure 4). In this classical description, the values are valid for a population of flight personnel (clinically healthy), the lower limit of expected values.

a - the indifferent zone is between 0 and 1,500 m (0 and 5,000 ft), no physiological response of hypoxic origin becomes manifest.

b - the full compensation zone is between 1,500 and 3,500 m (5,000 and 12,000 ft), the body compensates hypoxia by appropriate cardio respiratory responses. However, two functions are not compensated: night vision and learning ability. In addition, physiological reactions necessary may cause some *fatigue*. The civil regulation recognizes the altitude of 8,000 ft as the maximum permissible in the commercial transport of passengers (FAR and CS-25 § 841).

c - The incomplete compensation zone is between 3,500 m to 6000 m (between 11,500 ft and 18,500 ft to 20,000 ft). It is characterized by the risk of psychiatric disorders, typical of acute hypoxia.

d - The critical zone is located beyond 5,500 to 6,000 m (18,500 to 20,000 ft). It is characterized by the risk of hypoxic syncope, which occurs even faster as the altitude gets higher. Without correction of the situation, hypoxic syncope ends with death.

The main thresholds of human tolerance to altitude hypoxia recognized by the aviation regulations are:

- 5,000 ft for normal flight without any physiological impairment;
- 8,000 ft to the threshold of prolonged hypoxia and without excessive fatigue;
- 12,000 ft for the threshold for use of oxygen in all conditions. The threshold of 8,000 ft is that of civil aviation. The threshold of 12,000 ft is that of military regulations (STANAG 3198 AMD) and is quoted in the FAR regulations (Part 91, Part 121 & Part 135).

[1] **Ruff S, Strughold H.** Grundriβ der Luftfahrtmedizin. Johann Ambrosius Barth, 1939, Verlag – Leipzig

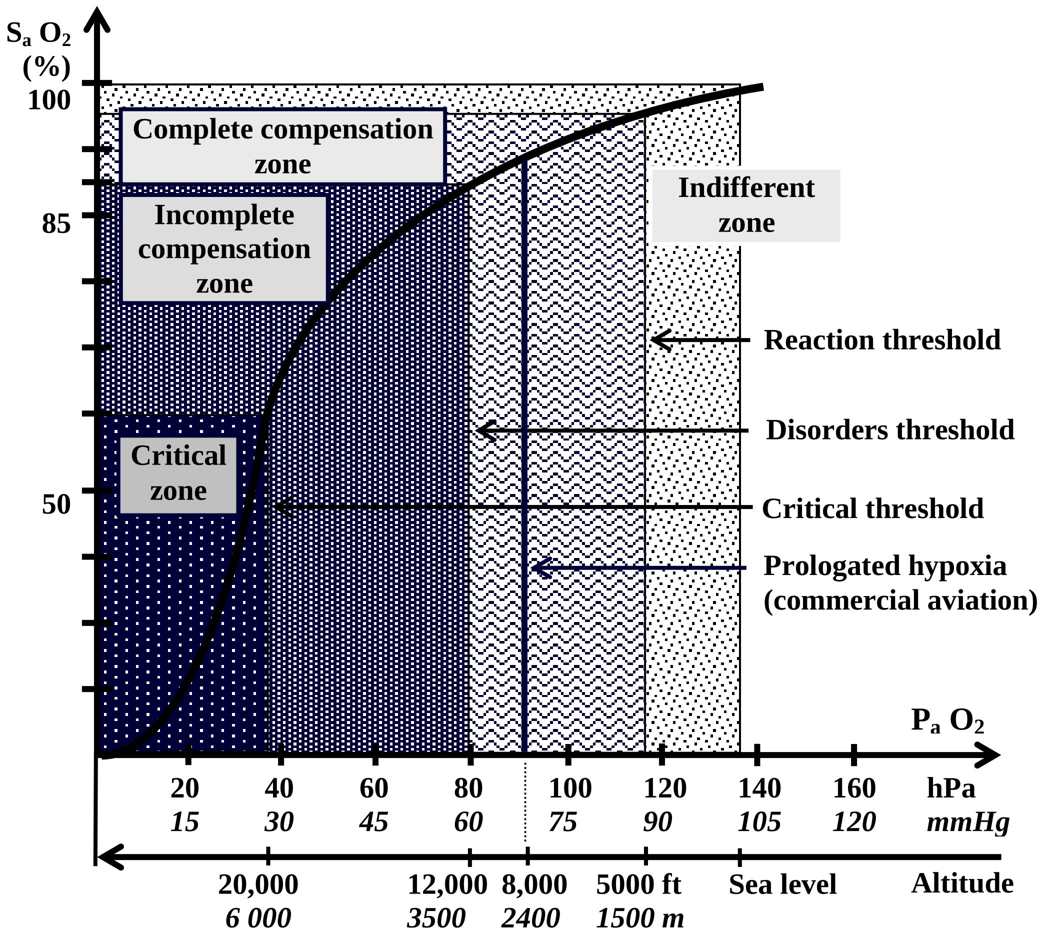

Figure 4. Zones of tolerance to hypoxia in relation to altitude for long term exposure (see text).

6.3.3.4. Numerical relationships S_AO_2/P_AO_2

Figure 4 is used to transcribe the altitude limits of tolerance zones in limit values of P_AO_2, P_aO_2 and S_aO_2. We recognize that, especially at altitude, $P_AO_2 = P_aO_2$ (respectively: partial pressure of oxygen in alveolar gas and arterial blood). The link altitude - P_AO_2 is obtained by the alveolar gas equation and by measuring or assessing P_ACO_2 and R in laboratory.

This link establishes the correspondence between P_aO_2 and S_aO_2. We use the relationship published by Kelman (1966), written in the form of a polynomial, valid when P_aO_2> 10 hPa.

These links establish the following equivalences (Table 2):

Altitude ft	Altitude m	P_B hPa	$P_A CO_2$ hPa	R	$P_A O_2$ hPa	$S_a O_2$ %
0	0	1013	53	0,83	138	97,6
5,000	1524	843	51	0,85	106	95,7
8,000	2438	753	48	0,87	91	93,7
10,000	3048	697	47	0,95	84	92,2
12,000	3658	645	45	1	77	90,1
14,000	4267	595	45	1	67	85
15,000	4572	572	45	1	62	82

Table 2. Equivalence altitude / oxygen partial pressure in alveolar gas.

Discussion on the allowable values of S_aO_2: above table shows that for an average population, a value of S_aO_2 equal to 90% corresponds to exposure to an altitude of 12,000 ft. This altitude is considered as the upper limit of the complete compensation zone for the population mean. In Figure 4, the value of 85% appears: it corresponds to the lowest value reasonably likely.

Similarly, 85 and 82% saturation correspond to exposure to the altitude of 4300m (14,000ft) and 4600m (15,000 ft). 4600m (15,000 ft) altitude was recognized as the upper limit of the complete compensation zone (instead of 12,000 ft at present) until the 1960s. Described effects were a decrease in performance against a complex psychomotor task, a decrease of short term memory and reduced physical performance (Luft, 1965). This decrease in psychomotor and physical abilities is perfectly acceptable for passengers in an emergency situation.

6.3.3.5. The mechanism of hyperacute hypoxia and time of useful consciousness

The sudden exposure to altitude hypoxia causes an immediate decrease in the partial pressure of oxygen in the lungs at an extremely low level, incompatible with the maintenance of consciousness. It should be noted that the comparison with the loss of ventilation at sea level is not relevant: it is impossible to "hold" his breathing to extend the time before loss of consciousness. Indeed, it is the gas contained in the lungs which represents the supply of oxygen to the body. Due to decompression, the lung is purged of its gas reserves (mass and partial pressure);

the intrapulmonary and blood partial pressures of oxygen are reduced to extremely low levels.

The exposure time leading to the loss of consciouness can be described as a function of altitude. This is the concept conventionally expressed as the time of useful consciousness (TUC). For altitude values about 12,200m (40,000 ft), the TUC barely exceeds 10 seconds. Protective equipment against altitude hypoxia must be established and made functional in this very short time.

6.4. Passenger protection against the risk of hyperacute hypoxia: theoretical calculation

Passenger protection is required by the CS-25 and FAR 25, § 1443. These rules are based on a theoretical calculation that is investigated in this section. In their principles and in their original version, these texts probably date from the 1950s; some of the documents that were used to develop them are lost.

§1443: For passengers and cabin crew members, the minimum mass flow of supplemental oxygen required for each person at various cabin pressure altitudes may not be less than the flow required to maintain, during inspiration and while using the oxygen equipment (including masks) provided, the following mean tracheal oxygen partial pressures:

(1) At cabin pressure altitudes above 3,000 m (10,000 ft) up to and including 5,600 m (18,500 ft), a mean tracheal oxygen partial pressure of 100 mmHg when breathing 15 litres per minute, BTPS, and with a tidal volume of 700 cm^3 with a constant time interval between respirations.

(2) At cabin pressure altitudes above 5,600 m (18,500 ft) up to and including 12,200 m (40,000 ft), a mean tracheal oxygen partial pressure of 83•8 mmHg when breathing 30 litres per minute, BTPS, and with a tidal volume of 1100 cm^3 with a constant time interval between respirations.

6.4.1. Values used for the breathing minute volume

the assumption made is that an anxious reaction of the passengers with hyperventilation (30 litres per minute) occurs. This level of hyperventilation is not sustainable over a minute or two because hyperventilation causes a substantial reduction in CO_2 partial pressure of the blood, causing major disturbances that can lead to a crisis of tetany. This period of hyperventilation can match the phase of rapid descent of the aircraft to the limit set of 18 500 ft. Then the value of 15 litres per minute is chosen, which also corresponds to a significant breathing minute volume, although with less severe consequences than during the previous phase. These figures were clearly defined by a large margin.

6.4.2. Alveolar or blood oxygen partial pressure requirements from the current regulations in CS 25

The text expresses the oxygen requirement in terms of "tracheal oxygen pressure". In historical texts, tracheal gas is the gas inhaled, supposedly dry, warmed to 37°C and saturated with water vapor at this temperature. At 37 ° C, the partial pressure saturated with water vapor is 63 hPa. Tracheal partial pressure of oxygen (P_TO_2) is:

$P_T\,O_2 = F_I\,O_2$ x (P_B – 63)

However, P_TO_2 is not the parameter meaningful for the human being. It is needed to consider the alveolar oxygen pressure. Compared to the equation already described above (Eq.1), P_TO_2 represents the first part of the equation. P_AO_2 is obtained by subtracting the second member of the equation F_TO_2:

$$\mathbf{P_A\ O_2 = F_I\ O_2\ (P_B - P_A\ H_2O) - P_A\ \ CO_2\ (F_I\ O_2 + \frac{1 - F_I\ O_2}{R})}$$

In the described conditions, the term [P_ACO_2 x (F_IO_2 + (1-F_IO_2) / R)] is about 50 hPa. Under normal conditions, P_ACO_2 is equal to 53 hPa. At maximum altitude, F_IO_2 is close to 1, the term (F_IO_2 + (1-F_IO_2) / R) is obviously close to 1. When this term increases slightly, P_ACO_2 decreases with time because of hyperventilation. We therefore assume a rather theoretical value of 50 hPa as the difference between P_TO_2 and P_AO_2.

The two values specified in paragraph 1443 are P_TO_2 = 100 and 83.8 mmHg or 133.3 and 111.7 hPa. In terms of P_AO_2, they correspond to approximately 80 and 60 hPa. According to the algorithm used above, these values correspond to a theoretical S_aO_2 of 91 and 80%.

6.4.3. Cabin crew protection

In case of cabin crew hypoxia protection, physical activity has to be considered, see §7.3 and after.

6.4.4. Equipment and regulation

To continue the argument: the requirement of P_AO_2 = 80 hPa for a long time is acceptable in a diversion situation after an event as rare as a depressurization. Under the same conditions, a requirement leading to a P_AO_2 equivalent to the altitude of 4,600 to 4,900m (15 to 16,000ft) is also acceptable. The question is: how to obtain this value of P_AO_2, and what are the supporting evidences ?

The technology adopted for the passenger's (stationary) and cabin crew's (portable) equipment is continuous flow oxygen masks fitted with economizer bag. The principle of the economizer bag and associated valves is to admit oxygen as the first fraction of the gas mixture inhaled. But it is a fixed amount of oxygen. Although the amount of oxygen inhaled is known, the tidal volume is not. Therefore, the continuous flow oxygen system has a structural weakness: it does not control the fraction of oxygen, which remains unknown, and dependent on tidal volume. If it is small, the fraction of oxygen is high, leading to an over-consumption of oxygen. If instead the tidal volume is high, the fraction of oxygen is low. There is therefore no adjustment, other than theoretical, supply of oxygen to the subject in terms of ventilation behaviour.

The second criticism that can be made to this system lies in the theoretical aspect of the alveolar gas equation and calculation of their composition depending on the characteristics of inspired gas. We emphasized that these calculations are valid only in steady-state under physiological conditions considered as normal (or close to).

And indeed, the result of these calculations can be a useful guide when calculating the necessary enrichment of oxygen in high altitude with altitude change rate relatively slow (a 40,000 ft altitude reached in 5 minutes is considered as "slow").

However these equations are not operative when the rate of altitude change is very high. Under these conditions, laboratory experiments show P_ACO_2 values comprised between 25 and 30 hPa (Marotte et al., 1990). Instantly, the R value can reach 1.2, or 1.5. The second member of the alveolar gas equation ([P_ACO_2 x (F_IO_2 (1-F_IO_2) / R)]) is much smaller than 50 hPa (likely near 30 hPa). But at the same time, after a rapid pressure decrease, there is residual nitrogen in the lung which disappears in about 1 minute.

It is therefore complex process of gas exchange, difficult to modelize on purely theoretical basis, and in any case not with equations written for the steady-state conditions, even if they can be kept as a "first approach" value.

During the 1970s, appeared a new generation of devices, which allowed overcoming for these studies the theoretical aspect of the alveolar gas equation. These are the oximeters, capable of measuring very quickly and accurately the blood oxygen saturation. This measure is much closer to the supply of oxygen to tissues than is the calculation of alveolar gas.

The first device on the market was proposed by the U.S. firm Hewlett-Packard (47201A ear oximeter). It was developed for - and had flown in - the Skylab orbiting laboratory. It was hardened against specific environmental conditions of Skylab, and therefore well suited for aeronautical studies. Unfortunately, it was heavy, bulky... and very expensive ! In 1977, the French Aerospace Medicine Laboratory of the Flight Test Centre worked on the theme of the use of oximetry as a method of proof for the development of systems of continuous flow oxygen.

The following devices, known as pulse oximeters have maintained acceptable performance but have been greatly miniaturized, cost was also greatly reduced.

A change in the development strategy of oxygen systems is then possible, defining the requirement of supplying oxygen to the nearest target, which is the brain tissue, using the measurement of oxygen saturation rather the theoretical calculation of alveolar gas.

6.5. Conclusion

Multiple sources have been reviewed including the alvealoar gas equations and various publications which included experimental data (see §6 above and §12).

This review suggests that for cabin pressure altitude above 18500 ft, the equivalent minimum saturation is estimated in the range of 80 to 85%. The threshold value of 84% is retained for further analysis performed through the experimental tests.

The values for mean tracheal oxygen partial pressure prescribed in EASA CS-25 can thus be translated into arterial oxygen saturation levels as follows::

- A minimum arterial blood oxygen saturation level of 90% is acceptable for cabin occupants at rest being exposed to altitude for a sustained period of time without any major impairment;

- A minimum arterial blood saturation level of 84% is acceptable for cabin occupants at rest being exposed to altitude for a limited period of time with only minor impairment.

Note: the reading of equivalent SaO2 values is obtained by considering the mean values for the transport of oxygen by the blood (Fig 3).

7. METHODOLOGY

The experimental approach is divided in 3 phases. The experiments of the first phase are conducted without use of supplemental oxygen and aim to demonstrate the effect of altitude induced hypobaric hypoxia and to validate the proposed S_aO_2 level (§6) for hypoxia assessment. Phase two is concerned with the performance of stationary oxygen systems for airplane passenger while phase three addresses the situation of cabin crew operating portable oxygen equipment at elevated diversion altitude.

7.1. Tests Phase 1

7.1.1. Test Protocol Major Steps

Refer to Appendix 1 (§0) for Test set-up general requirements.

A. Selection of a statistically representative panel of test subjects (see 7.1.2).

B. Test subjects exposed to various altitude steps (from 5,000 ft up to a maximum altitude considered as safe for the subject, 16,000 ft considered safe for the subject) (see 7.1.3).

C. Continuous measurement and recording of S_aO_2 on each test subject (see 7.1.4).

D. During each altitude step test subjects will be submitted to a sequence of pass/fail unit tests (see 7.1.5).

E. Summary chart per subject:

Altitude (ft)	S_aO_2 (%) (To be recorded continuously after equilibrium)	SRT (3min)	"D2" Test (3min)	Mask/Belt-Test (3min)	PASS/FAIL
Ground		P/F	P/F	P/F	
5,000		P/F	P/F	P/F	
8,000		P/F	P/F	P/F	
10,000		P/F	P/F	P/F	
12,000		P/F	P/F	P/F	
14,000		P/F	P/F	P/F	
16,000		P/F	P/F	P/F	
Ground		P/F	P/F	P/F	

Table 3. Test Summary Chart

Note 1: altitude exposure will be interrupted upon clinical supervisor decision

F. Identification of statistically significant correlations between $Sa0_2$ levels and global Pass/Fail results.

7.1.2. Selection of a statistically representative panel of test subjects

The typical arterial oxygen saturation of healthy subjects is about 95 - 98% under sea level conditions, decreasing with age and certain diseases compromising oxygen uptake in the lungs, under which the most important is the COPD cluster (Chronic Obstructive Pulmonary Disorders). One of the most important causes of COPD with rising frequency at higher age is a smoking career, leading to a degeneration of respiratory epithelia correlating with time and amount of smoking, usually expressed as "pack years" (of cigarettes). Those individuals presumably represent the most vulnerable part of a given passenger population and therefore will show an increased reaction to hypoxia at a loss of cabin pressure, and likewise will show the lowest effect of supplemental oxygen. Therefore, in order to protect a major fraction of passengers against hypoxia at altitude, any given equipment could preferably be tested on this vulnerable part of the population, avoiding a majority of possible subjects with a high re-oxygenation without statistical value, while tests at the lower end of the capability of oxygen uptake will result in improved statistical output at a reasonable number of tests.

Hence a stratified sampling approach is used for selection of test subjects. The aim is to select two groups. The first and larger group contains individuals older than 50 years and no known respiratory diseases (see Guenard, 1998). The second and smaller group contains subjects who are or were smokers. The second group permits an investigation of a very sensitive population, with COPD (see Akero et al., 2005) or similar health problems relevant to oxygen utilization at altitude.

Distribution and quantitative statistical parameters (as median, percentiles, deviation) of the arterial oxygen saturation will be assessed. With the known age distribution of the population and the incidence of COPD it is possible to translate the estimated statistical parameter to the whole population. Among general demographic sources, results from a previous study - ICE, Ideal Cabin Environment - where about 1200 subjects have been tested at different altitudes in an EU-sponsored project, will be used for this purpose.

The data set contains measurements from 1161 participants regarding the S_aO_2. The minimum age was 18, the maximum age 85 and the mean 45 years. Data of the arterial oxygen saturation was collected at pressure equivalents to heights of 2231, 4000, 6000 and 8,000 feet (700, 1200, 1800 & 2400m). (see also Section 11.1.2)

An investigation of younger people is - as mentioned above - not necessary, because a finding of critical arterial oxygen saturation among this population is very unlikely and would require an unrealizable large sample.

The great advantage of the stratified sampling in comparison to simple random sampling is the increase of statistical efficiency. With random sampling and a reasonable sample size only very few subjects would fall in to the sensitive category and the precision of estimation would be quite poor.

7.1.3. Test subject exposition to various altitude steps (from 5,000 ft – 1500m up to a maximum altitude of 16,000 ft – 4900m)

The sequence of events is summarized in chart E; beginning at sea level(approximately ground level at Cologne, where experiments were performed), the whole set of tests to be performed is exercised for base-line data assessment of individual abilities, to be compared to performance at altitude starting with test-#1 and proceeding to test-#n as outlined.

After completion of the sea level series, the chamber is evacuated to 5,000 ft – 1500m. as the next level, allow for a 3 min. equilibration interval and then repeat the whole test series, resulting in a total time of about 13 min for each altitude.

In this manner, all planned altitude levels as summarized in Table 3 will be executed, those individuals eventually subjected to test abortion staying in the chamber under supplemental oxygen for the remaining time. If all subjects have to be put to supplemental oxygen before reaching the highest planned altitude level, the chamber run is finished and pressure returned to sea level.

7.1.4. Continuous measurement and record of S_aO_2 on each test subject

Continuous Monitoring of arterial oxygen saturation represents a primary pass/fail criterion. Any consistent measurement below 70% at rest leads to immediate test abortion, 75% will be the lowest limit to be tolerated during regular testing, not admitting any preposition for the final criteria to be derived. In this test set-up abortion means the provision of supplemental oxygen with saturation coming up to at least 85%.

7.1.5. Test Sequence

7.1.5.1. Test 1:Single Reaction Time (SRT)

A stimulus is presented on a hand-held personal computer in irregular intervals, the subject has to press a response key as fast as possible; the time interval between stimulus presentation and key action is measured (reaction time) and displayed for 3 seconds as feedback in order to maintain motivation for each single trial. Total test time for one series is 3 min., to be performed at each altitude investigated. Any reaction within 300 ms is acceptable, depending on individual abilities of the subject; any reaction time longer than 500 ms is considered a lapse. Failing to show any reaction - despite being alerted by the inside observer - may be rated as test failure and - in combination with S_aO_2 monitoring -lead to test abortion.

7.1.5.2. Test 2:D2

Two different letters (d or p) are presented consecutively over a time period of 3 min., accompanied by a maximum of 4 vertical lines, 2 above and/or 2 below. The target object is a "d" with 2 lines:

'''

ddd

,,,,

On which the subject has to respond with the "yes"-key; all other combinations have to be answered with the "no"-key. This construct is known as a choice reaction task, where mental processing has to be performed before each response. Thus, the complexity of this test is much higher compared to Test#1, possibly giving a better insight into some of the more subtle effects of hypoxia.

After each reaction the next item is presented immediately (self-paced), both reaction time and correctness of each response is stored for further evaluation. Thus both error rate and reaction time can be used as a measure of performance. Like in Test 1, a subject's total failure to deliver any reaction despite intervention of chamber personnel, will lead to abortion together with relevant S_aO_2 readings.

7.1.5.3. Test 3:Mask Handling Activities

-Sit down

-Fasten Seat Belt

-Don the Mask

-Don a 2nd Mask to a Puppet

-Doff the Mask from the Puppet

-Doff the Mask

-Unfasten Seat Belt

7.2. Tests Phase 2: Validation of existing technology by following optimised flow rules in altitude chamber

Based on the results of the first test series a second set of experiments will be focusing on the use of supplemental oxygen. Subjects will be exposed to altitude of up to 40,000 ft protected by conventional passenger oxygen masks. It is aimed to use the 10 most compliant subjects of the previous trial in order to demonstrate the performance of current flow guidelines. To indicate potential for O_2 savings within the current standards the flow rates of supplemental oxygen used during the experiment will be optimised based on high performance flow curves for supplemental oxygen established in earlier experiments of DLR and AVOX.

Proposed protocol:

• Use the 10 most sensitive (compliant) subjects of previous experiment
• Use available "hi-efficiency" oxygen flow curves (established by DLR / AVOX) to optimize the flow of supplemental oxygen at each altitude level
• Demonstrate long term protection (S_aO_2 at least 90%) at least up to 30,000 ft – 9144m
• Demonstrate short term protection (S_aO_2 at least 84%) at 40,000 ft – 12192m

7.3. Tests Phase 3: Requirements of supplemental oxygen for cabin crew

The aim of this part is to address the situation of Cabin Crew during and after a depressurisation event. While Flight Deck Crew is expected to stay in the cockpit and to use stationary demand equipment in case of an emergency, Cabin Crew might be caught by the event in the middle of their duties and are expected to assist passengers at diversion altitude.

In case of a depressurisation event Cabin Crew members are instructed to sit down immediately, this implies to take a seat on a passengers lap if no other seating accommodation is available. They are considered to use the same Oxygen equipment as seated passengers and to remain seated during emergency decent until the airplane levels off at diversion altitude.

However, during diversion at elevated altitude (> 10,000 ft / 3000 m) Cabin Crew is assumed to move through the cabin for the purpose of assisting passengers. In order to be mobile under these conditions they use portable oxygen sources with a manual flow adjustment providing two settings: 2 and 4 lpm (NTPD).

The assistance of passengers after an emergency situation will involve physical exercise. Exercise leads to a higher oxygen demand of the body. Under hypobaric conditions even walking must be considered a significant effort. The physiological response to an increased demand of oxygen is an increase of breathing minute volume (BMV). From a present-day perspective the actual demand on Cabin Crew activity in this kind of situation remains unclear. Therefore it is not possible to make a clear statement on the oxygen demand, respectively the expected breathing minute volume, of Cabin Crew members operating portable equipment.

At present, the portable oxygen equipment used by Cabin Crew is specified for First Aid/Medical purpose according to CS 25.1443 d) and assumed to fulfill the requirements for portable equipment for crew member use specified in CS 25.1443 e), referencing to 1443 a) for constant flow equipment which requires a P_TO_2 of 149 mmHg with a breathing minute volume of 15 lpm (BTPS). For demand equipment subparagraph b) requests 122 mmHg at 20 lpm, suggesting that values under a) only use a certain point of equipment performance to define a spectrum of oxygen substitution. From a physiological point of view a BMV of 15 lpm (BTPS) assumed in CS 25.1443 e) does not represent a typical BMV of a person performing physical exercise. Average persons usually reach a BMV of 15 lpm at very low workload (e.g. slowly walking on leveled ground) and will already exceed 30 lpm (BTPS) at a moderate exercise level.

To understand the implications of current regulations the requirements for continuous flow equipment for Flight Deck crew specified in CS 25.1443 a) can be expanded into Table 5. As specified in CS 25.1443 a) the P_TO_2 is kept constant at 149 mmHg and the BMV is 15 lpm (BTPS) at all altitudes. A similar table can be found in SAE AIR 825/14 for passenger supply at rest, assuming a (lower) constant P_TO_2 of 100 mmHg and a BMV of 15 lpm (BTPS) for altitudes up to 18,500 ft and a P_TO_2 of 83.4 mmHg and a BMV of 30 lpm (BTPS) for altitudes above 18,500 ft.

In Table 5, Column VO_2 shows the necessary amount of oxygen flow to meet CS 1443 a) crew regulations, F_IO_2 is the fraction of Oxygen in the inhaled gas. For comparison the two yellow columns on the right of Table 5 represent the SAE passenger values. It should be considered that the method of calculation used in both tables is based on ideal dispensing units that do not exist in practice. A detailed explanation of the algorithm can be found on pp. 21/22 of the SAE document.

(A)	(B)	(D)	(E)	(H_Crew)	SAE Pax	(H)
h/kft	P_B/mmHg	BMV/NTPD	fO_2%	VO_2/lpm	lpm	VO_2/lpm
10	522,8	8,91	31,32	1,169	15	0,008
11	502,8	8,53	32,69	1,268	15	0,107
12	483,5	8,17	34,14	1,364	15	0,203
13	464,8	7,82	35,67	1,456	15	0,296
14	446,6	7,48	37,28	1,546	15	0,385
15	429,1	7,15	39,00	1,633	15	0,472
16	412,1	6,84	40,81	1,718	15	0,557
17	395,7	6,53	42,74	1,799	15	0,639
18	379,8	6,23	44,77	1,878	15	0,717
19	364,4	5,94	46,95	1,954	30	0,819

(A)	(B)	(D)	(E)	(H_Crew)	SAE Pax	(H)
h/kft	P_B/mmHg	BMV/NTPD	fO_2%	VO_2/lpm	lpm	VO_2/lpm
20	349,5	5,67	49,25	2,028	30	0,968
21	335,2	5,40	51,71	2,100	30	1,103
22	321,3	5,14	54,32	2,168	30	1,247
23	307,9	4,88	57,12	2,235	30	1,381
24	294,9	4,64	60,11	2,299	30	1,511
25	282,4	4,41	63,30	2,361	30	1,634
26	270,3	4,18	66,72	2,421	30	1,753
27	258,7	3,96	70,39	2,479	30	1,869
28	247,4	3,75	74,34	2,535	30	1,981
29	236,6	3,55	78,59	2,589	30	2,088
30	226,1	3,35	83,18	2,641	30	2,191

Table 4. Crew Oxygen Consumption at pTO2 = 149 mmHG and 15 lpm Breathing Minute Volume" (Yellow Fields: Pax Requirements for Comparison)

As shown in Table 5 the required oxygen flow at 20 kft is approximately 2 lpm (NTPD) as in 2). At this condition, a portable setting of 2 lpm (NTPD) O_2 flow will lead to roughly 50% oxygen in the inhaled gas volume. In contrast, column VO_2^{SAE} shows that 0.97 lpm (NTPD) oxygen flow will yield a P_TO_2 of 83.4 mmHg at a BMV of 30 lpm (BTPS) at the same altitude. In consequence, 20,000 ft (6,100m) is the limit of current portable crew equipment in the 2-lpm-setting, assuming a BMV of only 15 lpm (BTPS). This represents only a very light workload. Therefore, if expecting cabin crew to physically assist passengers (e.g. lifting a disabled or injured person) at elevated diversion altitude after cabin depressurisation, higher workload and consequently higher BMV need to be considered. Within certain limits also the acceptance of a lower P_TO_2 seems reasonable.

Primarily, increasing BMV at a given altitude with fixed oxygen flow will progressively dilute supplemental oxygen and therefore decrease oxygen partial pressure, which can be likewise expanded into a table, this time at constant altitude and oxygen flow (20,000 ft / 2 lpm NTPD) with variation of BMV:

BMV/lpm BTPS	BMV/lpm NTPD	fO_2 %	P_TO_2 mmHg
15	5,665	49,3	149,0
16	6,043	47,5	143,6
17	6,420	45,9	138,9
18	6,798	44,5	134,7
19	7,176	43,3	131,0
20	7,553	42,2	127,6
21	7,931	41,2	124,5
22	8,309	40,2	121,8
23	8,686	39,4	119,2
24	9,064	38,6	116,9
25	9,442	37,9	114,8
26	9,819	37,3	112,8
27	10,197	36,7	110,9
28	10,575	36,1	109,2
29	10,953	35,6	107,7
30	11,330	35,1	106,2
31	11,708	34,6	104,8
32	12,086	34,2	103,5
33	12,463	33,8	102,3
34	12,841	33,4	101,2
35	13,219	33,1	100,1
36	13,596	32,7	99,1
37	13,974	32,4	98,1
38	14,352	32,1	97,2
39	14,729	31,8	96,3
40	15,107	31,6	95,5

Table 5. Breathing Minute Volume compared with F_IO_2

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As can be seen from Table 6, a BMV of 35 lpm (BTPS) leads to a P_TO_2 of 100 mmHg*. This is specified in CS 25.1443 c) as the required P_TO_2 for passengers at cabin pressure altitudes between 10,000 ft and 18,500 ft. This should likewise yield an arterial oxygen saturation of approximately 90%, which has been accepted as useful limit for sufficient oxygenation in previous work. However, unlike passenger situation (rest), this P_TO_2 is connected to physical exercise, which in principle may aggravate hypoxia with lower saturation by higher oxygen consumption as a secondary moderator to actual equipment performance. This combination of effects should in principle lead to a rather sharp limit in the performance of the discussed equipment.

In order to find a safe starting point for the proposed trial a preliminary set of experiments was conducted. In order to achieve defined P_TO_2 levels demand equipment was used to supply the subjects with a variety of gas mixtures, containing different fractions of O_2. It was found that with a fraction of 33% O_2 in the inhaled gas and a workload of 80 W on a bicycle ergometer, the arterial saturation at 20 kft is at 90% or slightly above compatible with the BMV = 35 lpm (BTPS) entry in Table 6, therefore defining the limit condition at which a portable with a flow of 2 lpm (NTPD) should still be able to sustain typical (light) crew activities.

It is proposed to demonstrate this conclusion in a limited number of human trials at 20 kft, titrating the necessary oxygen flow to maintain 90% arterial saturation with a passenger mask at a BMV of approximately 35 lpm (BTPS), stimulated by a work load of 80 W. This is exactly the same procedure as used for passenger equipment / passenger requirements to produce the "Hi-Efficiency" data for SAPOX Phase 2. However, with the expectation of much higher tidal volume at physical exercise the effect of unused oxygen in dead space for the theoretical equipment should be much lower, in this way decreasing the advantages of any pulse based equipment.

*It may be noted that the table also shows that 25.1443 a) + b) are nearly identical at 20 kft; the b)-requirement of 122 mmHg for demand equipment at a BMV of 20 lpm (BTPS) is met at a BMV of approximately 22 lpm (BTPS) with continuous flow equipment at a setting of 2 lpm (NTPD), making the a)-requirement slightly more protective. Therefore it can be concluded that in this constellation two totally different altitude depending oxygen dispensing devices show an equivalent level of hypoxia protection, once more proving the inherent consistency of the whole set of rules applicable in EASA and FAA regulations.

Phase 3 protocol aim is to test current system (2 & 4 lpm) to check if they comply with this requirement:

- 5 test subjects will be submitted to a 20,000ft altitude, while performing an 80W effort
- Oxygen supply values will start at 2 lpm (NTPD) of supplemental oxygen and decrease until the threshold of 90% of S_aO_2 is reached
- NB: Status on 4Lpm for a 25kft altitude will be given by analysis

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8. OVERVIEW OF TEST DATA

8.1. Phase 1

Biometrics of Subjects

• n = 36 (15 f + 21 m)

• Age: 60 years (52 - 73)

• Weight: 78 kg (55 - 102)

• Height: 175 cm (158 - 190)

• Smoking: 16 Ex & Current, max. 50 PJ; Majority between 10 and 40 PJ; no Significant Spirometric Deficits

Figure 5. Test runs installation example

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8.1.1. Phase 1 test measurements

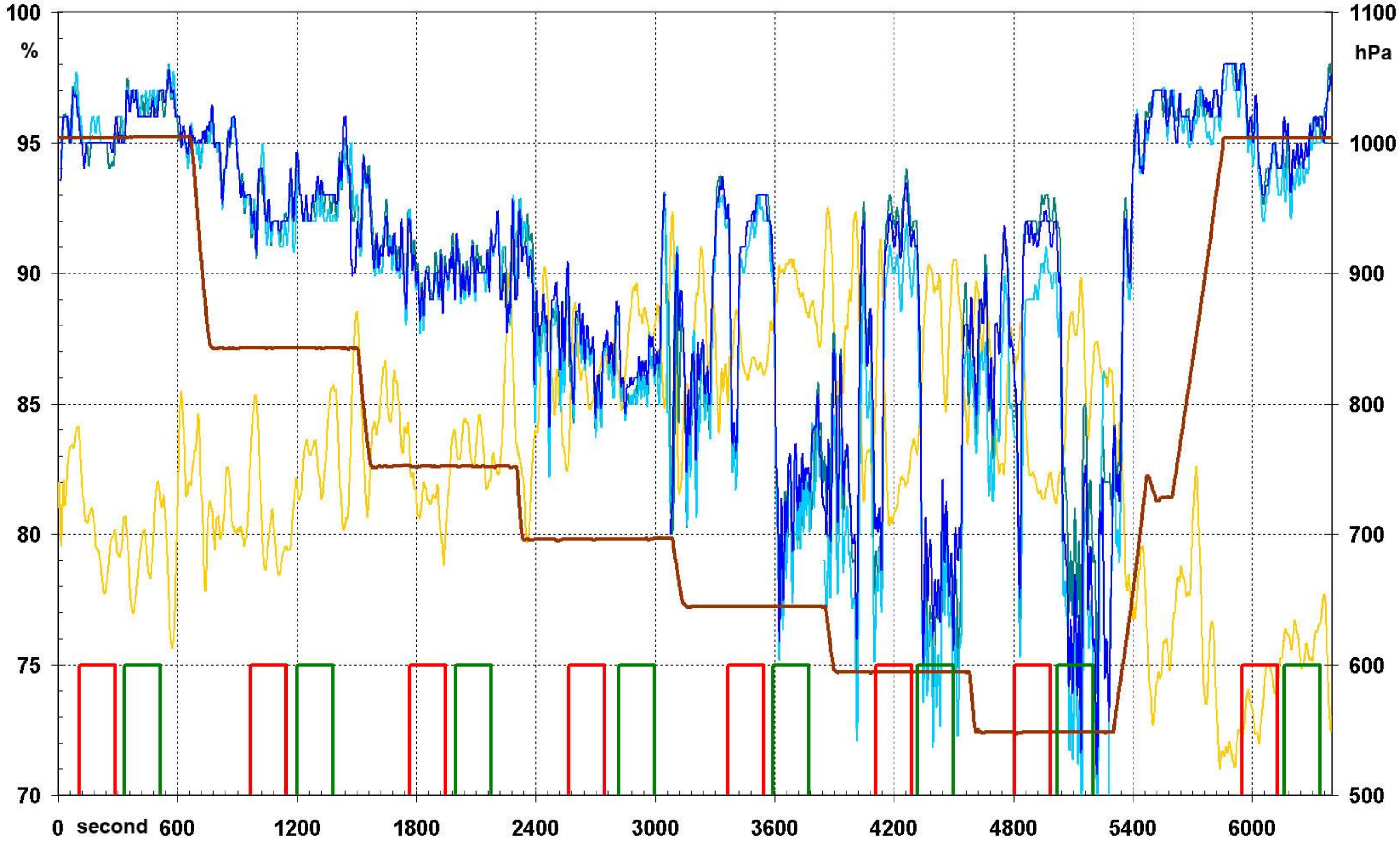

Figure 6. Summary of a complete phase 1 test run (Subject #19)

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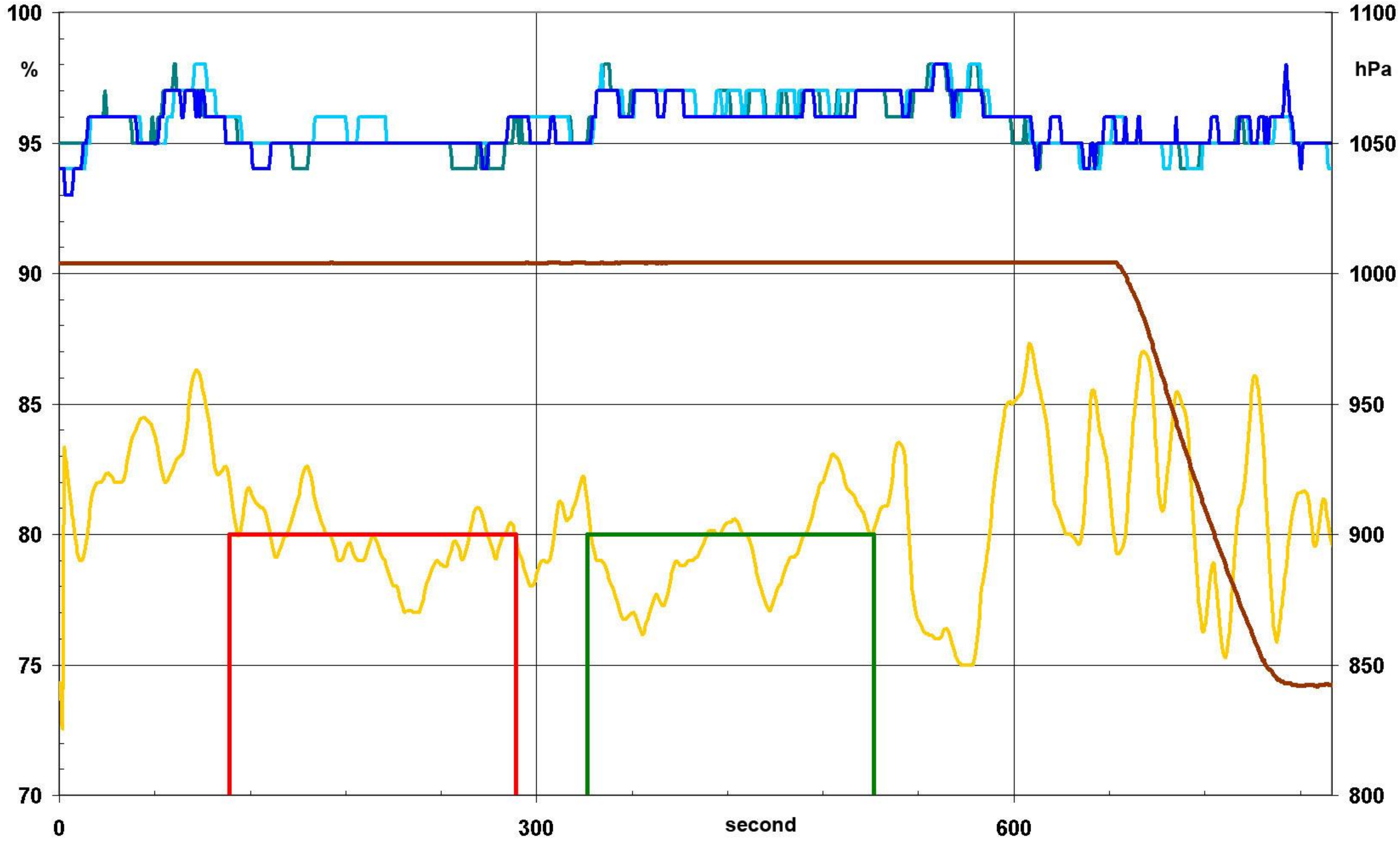

Figure 7. Zoom at ground level before testing (Subject #19)

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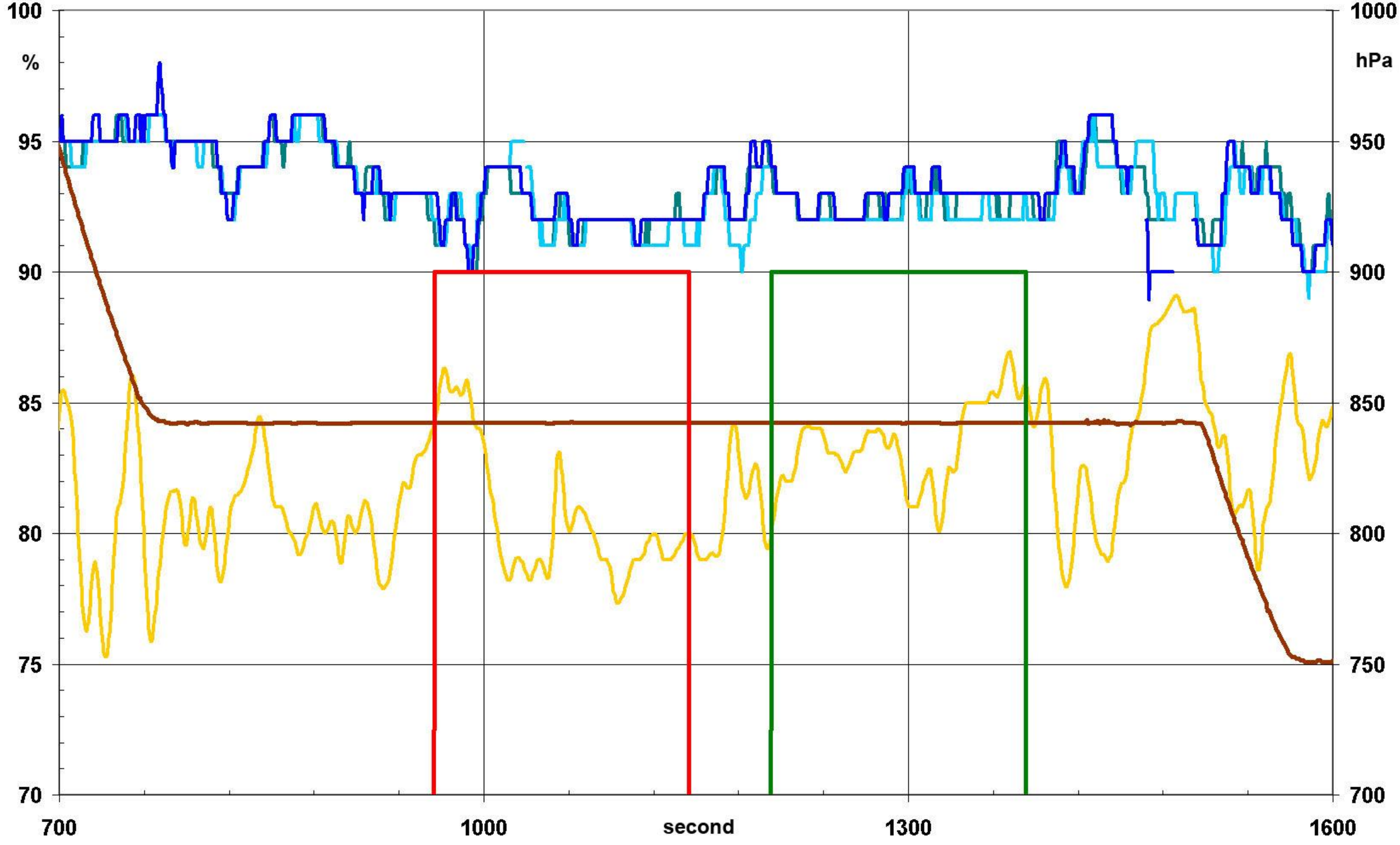

Figure 8. Zoom at 5 kft (Subject #19)

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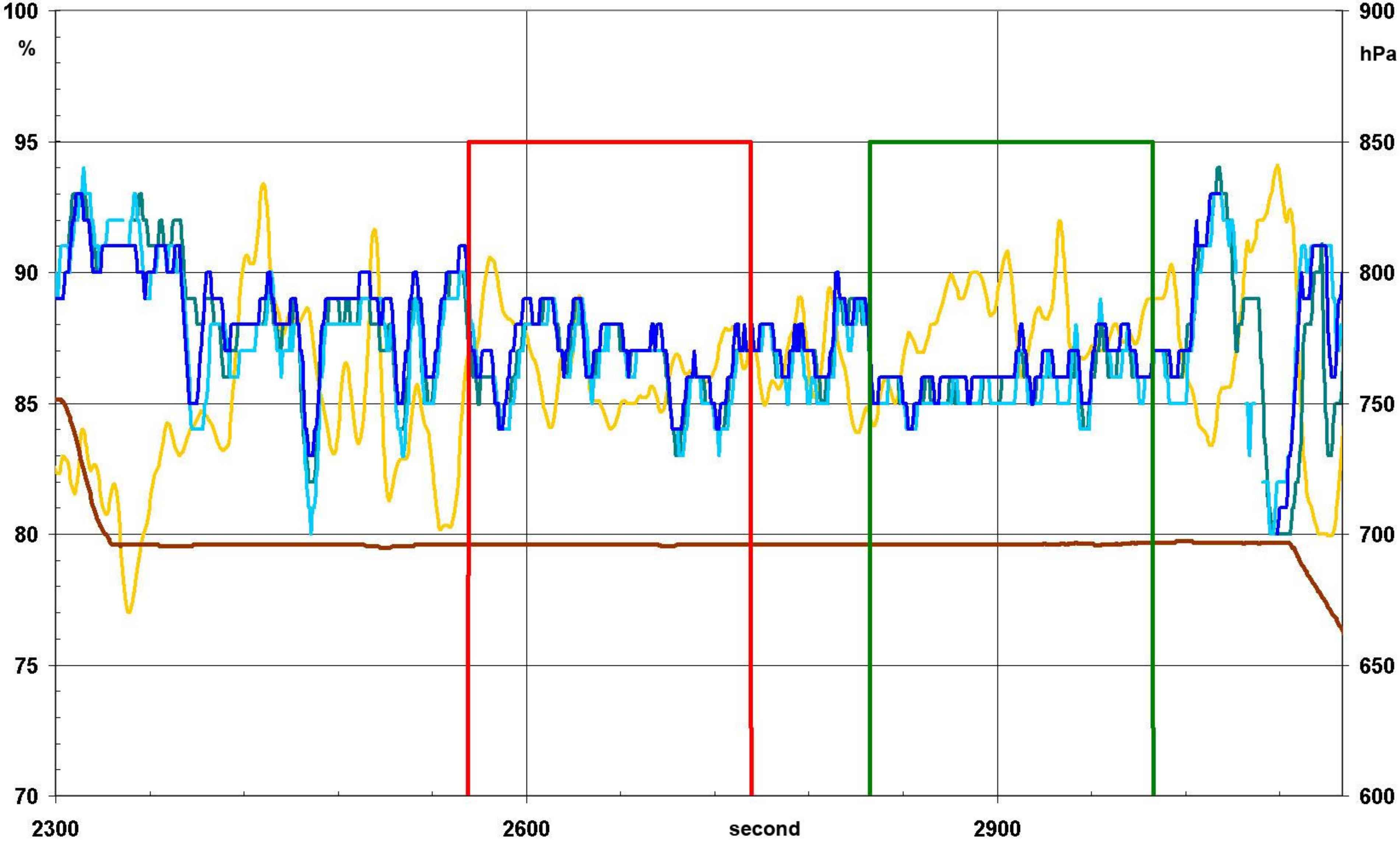

Figure 9. Zoom at 10 kft (Subject #19)

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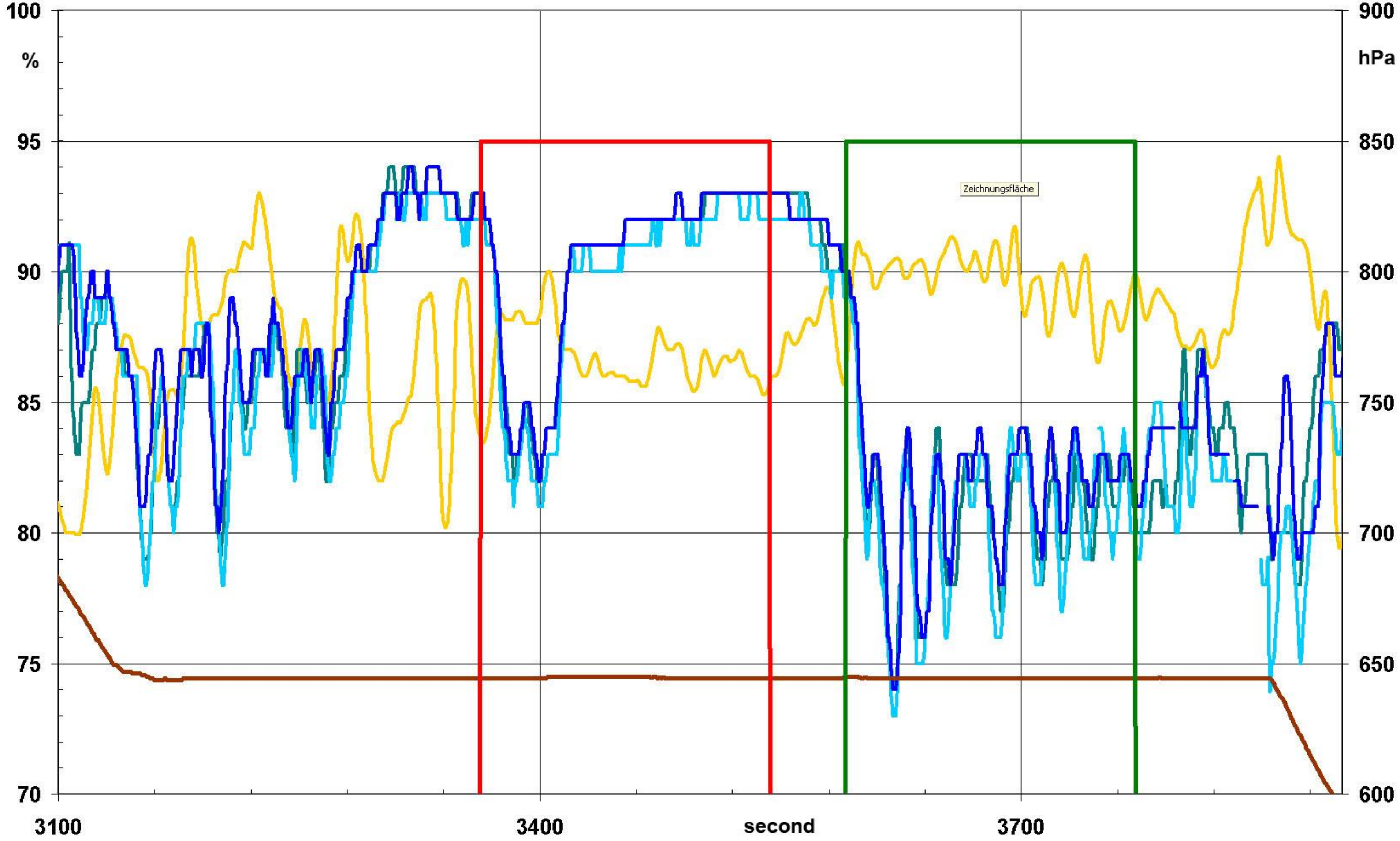

Figure 10. Zoom at 12 kft (Subject #19)

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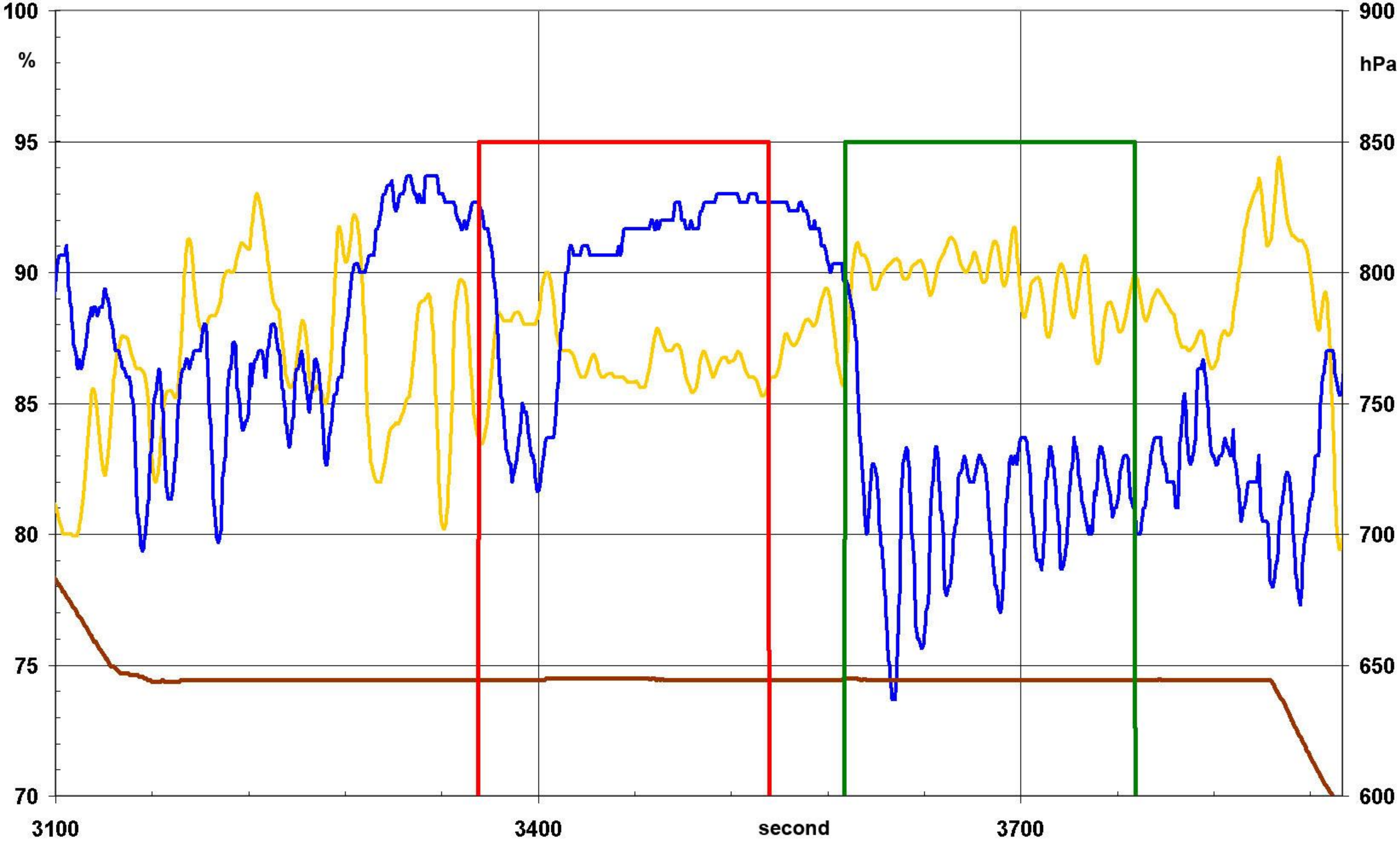

Figure 11. Zoom at 12 kft with averaged saturation measurements (Subject #19)

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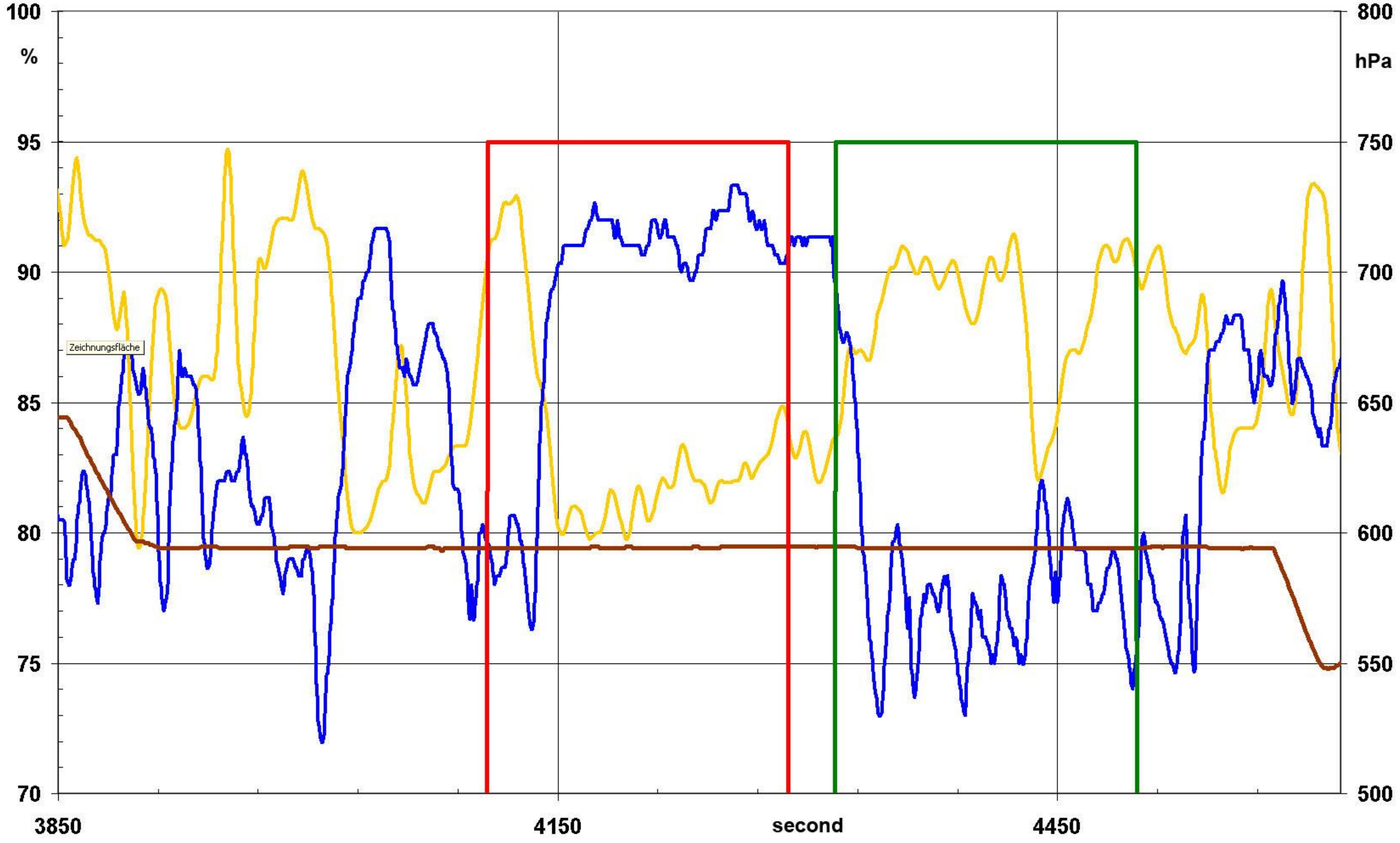

Figure 12. Zoom at 14 kft (Subject #19)

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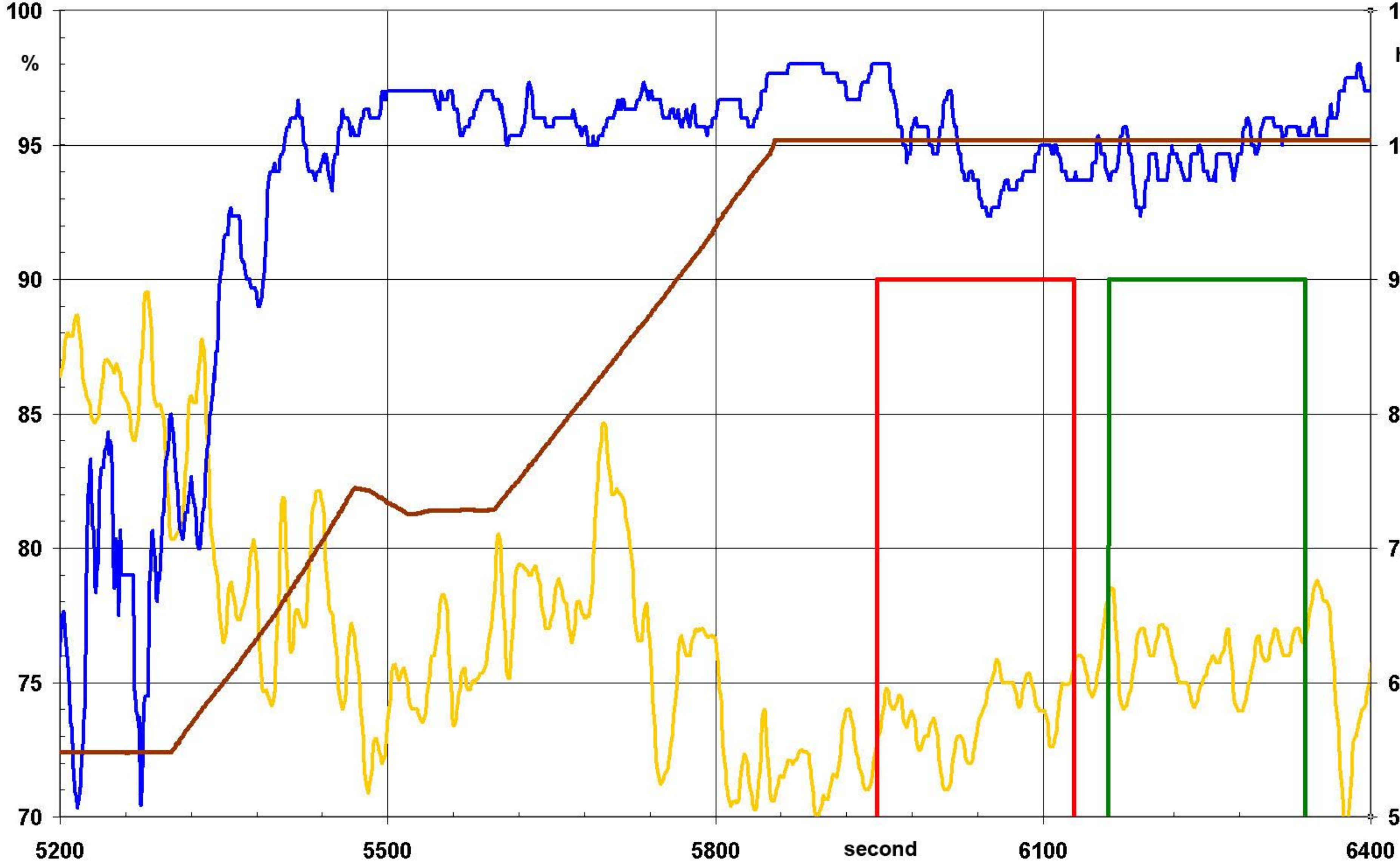

Figure 13. Zoom at ground level after test procedure (Subject #19)

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Taking some Oxygen at 16,000 ft!

Figure 14. Subject breathing oxygen at 16 kft.

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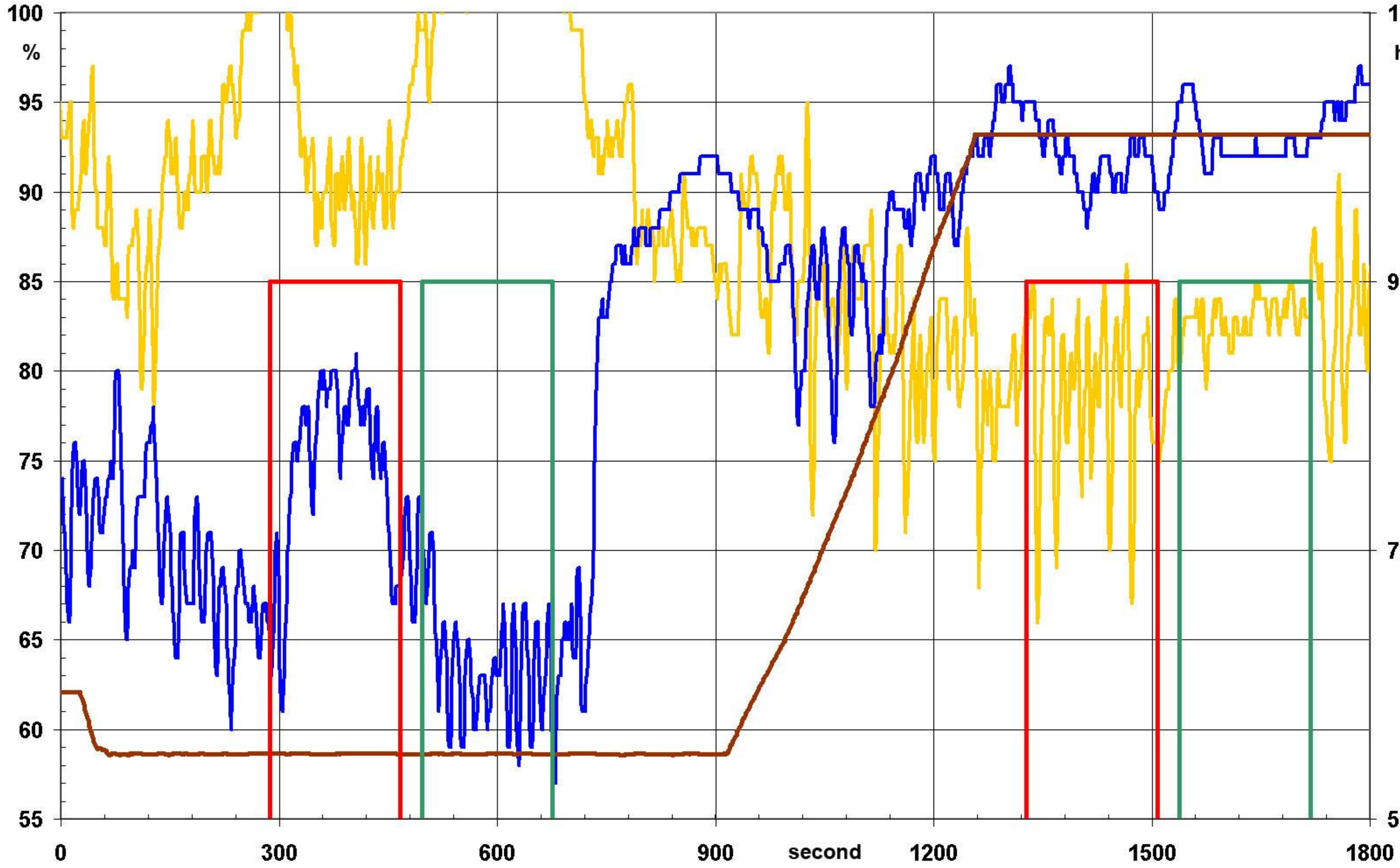

Figure 15. Leap of blood saturation after administering supplemental oxygen at 16kft

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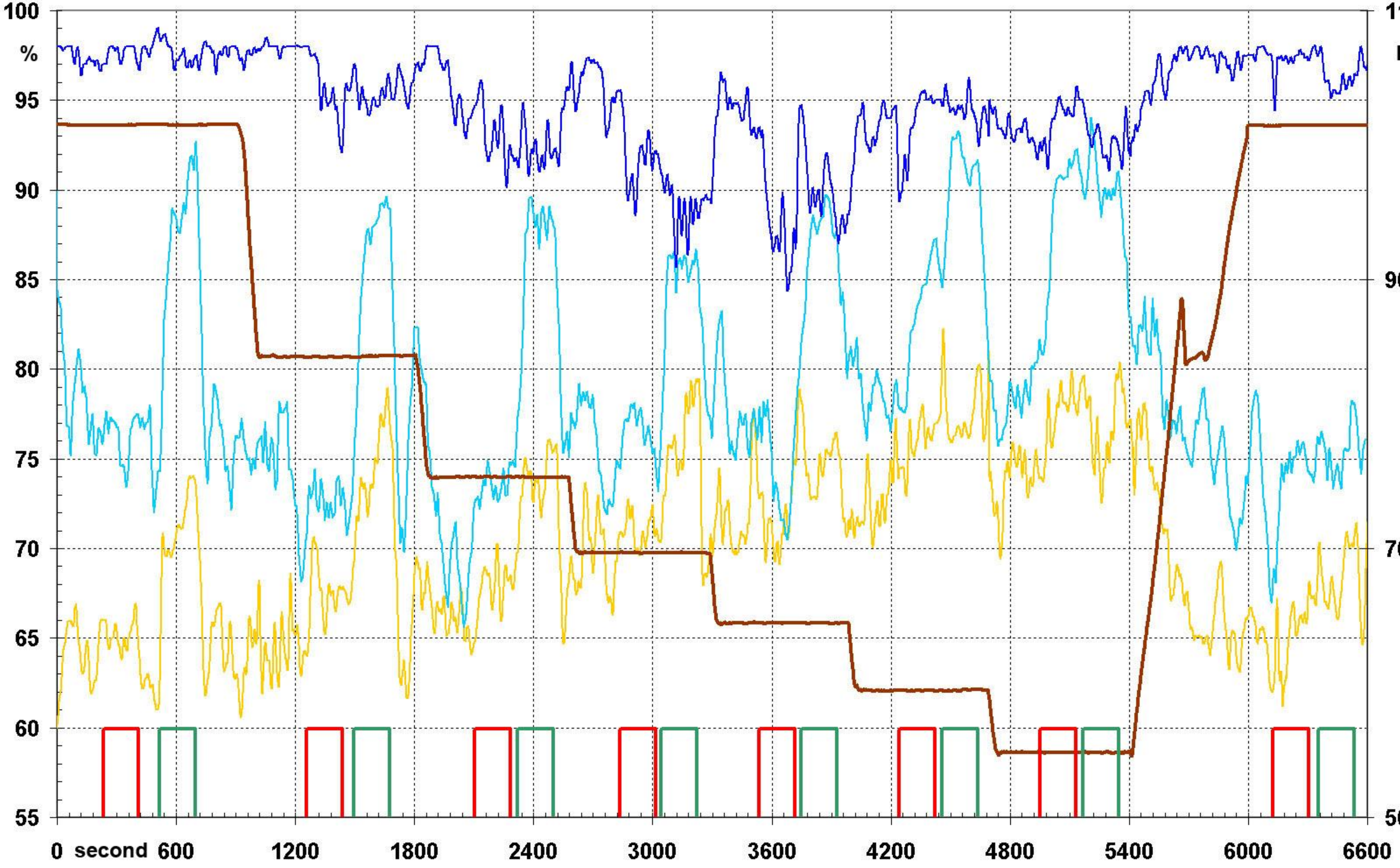

Figure 16.Individual results are broadly distributed amongst subjects

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Previous figures description

Figure 6-10 (Subject #19): The three bluish curves show oxygen saturation, SpO_2 (left scale, %). Ambient pressure is represented by tick brown line (right scale, hPa) and heart rate is indicated by gold-colored graph. Time intervals of SRT-Test are marked with red and D2-Test with green bars. Time scale is given in seconds.

Figure 11-15 (Subject #19): The blue curve shows oxygen saturation, SpO_2 (averaged score of three independent measurements, left scale, %). Ambient pressure is represented by tick brown line (right scale, hPa) and heart rate is indicated by gold-colored graph. Time intervals of SRT-Test are marked with red and D2-Test with green bars. Time scale is given in seconds.

Figure 16: In addition a light blue graph to indicate changes of breathing volume is added.

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8.1.2. Phase 1 test synthesis

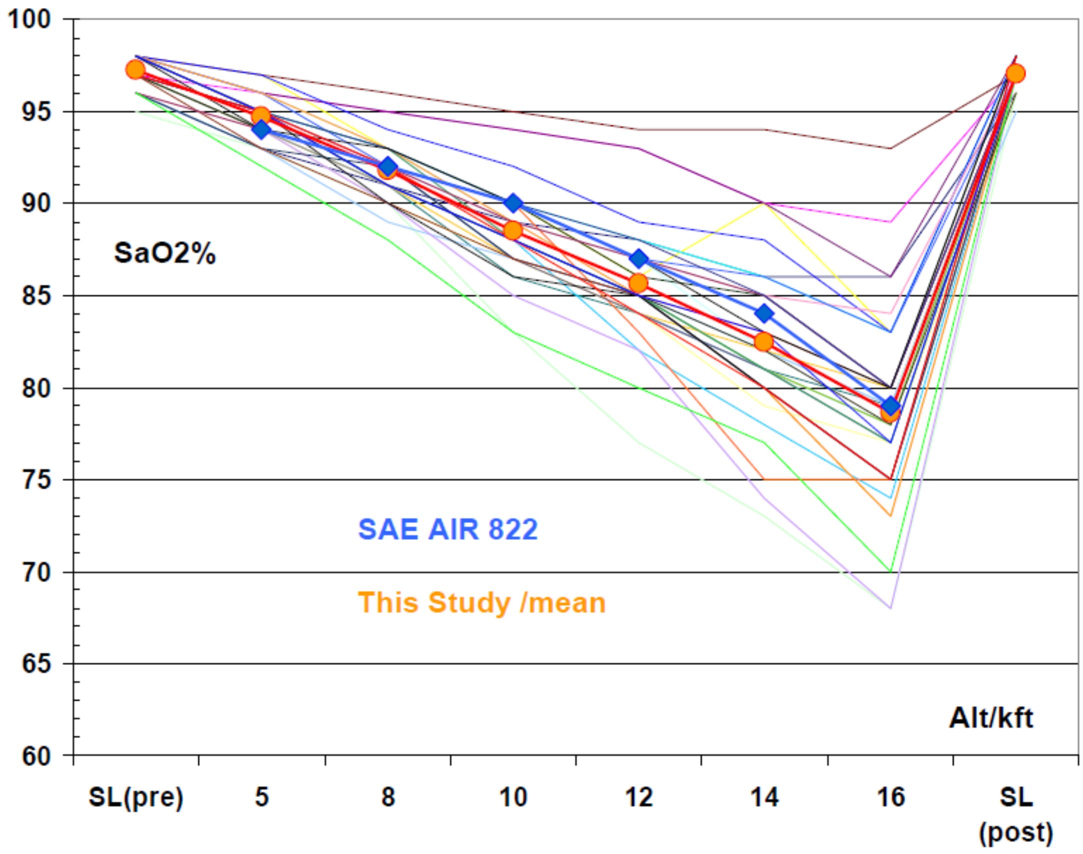

Figure 17. Sapox phase 1 measurements compared to Literature (SAE AIR 822).

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8.2. Phase 2

8.2.1. 10 subjects breathing supplemental oxygen from standard Pax-Masks, flow rates at 30, 25 20, and 15 kft are optimised by the use of "Hi-Efficiency" flow curves. At 40 kft the conventional flow of 3.1 lpm (NTPD) is used to guarantee a maximum of safety.

8.2.2. Phase 2 subject selection

5 Subjects were out of Bottom Ten of Phase 1 (ranked by average saturation of 14 + 16 kft unprotected exposure), 4 more were ranked # 12, 14, 20, and 26 + 1 new subject not involved in Phase 1.

Phase 1 subjects		
#	Subj.	#SpO2 (14kft+16kft)/2
1	VP 11	70,5
2	VP 15	71
3	VP 35	73,5
4	VP 22	75
5	VP 9	76
6	VP 16	76,5
7	VP 21	76,5
8	VP 24	77,5
9	VP 25	77,5
10	VP 32	77,5
11	VP 34	77,5
12	VP 12	78
13	VP 23	79
14	VP 26	79
15	VP 18	79,5
16	VP 19	79,5
17	VP 7	80
18	VP 28	80
19	VP 36	80
20	VP 10	80,5
21	VP 13	80,5
22	VP 20	81
23	VP 29	81,5
24	VP 33	81,5
25	VP 27	82,5
26	VP 30	82,5
27	VP 31	82,5
28	VP 4	84,5
29	VP 14	84,5
30	VP 17	84,5
31	VP 8	85,5
32	VP 1	86
33	VP 3	86,5
34	VP 5	88
35	VP 2	89,5
36	VP 6	93,5
1 New Participant(68 yrs./25 pack year still 1980)		

Table 6. Phase 2 test subjects selection among phase 1 subjects

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8.2.3. Phase 2 measurements

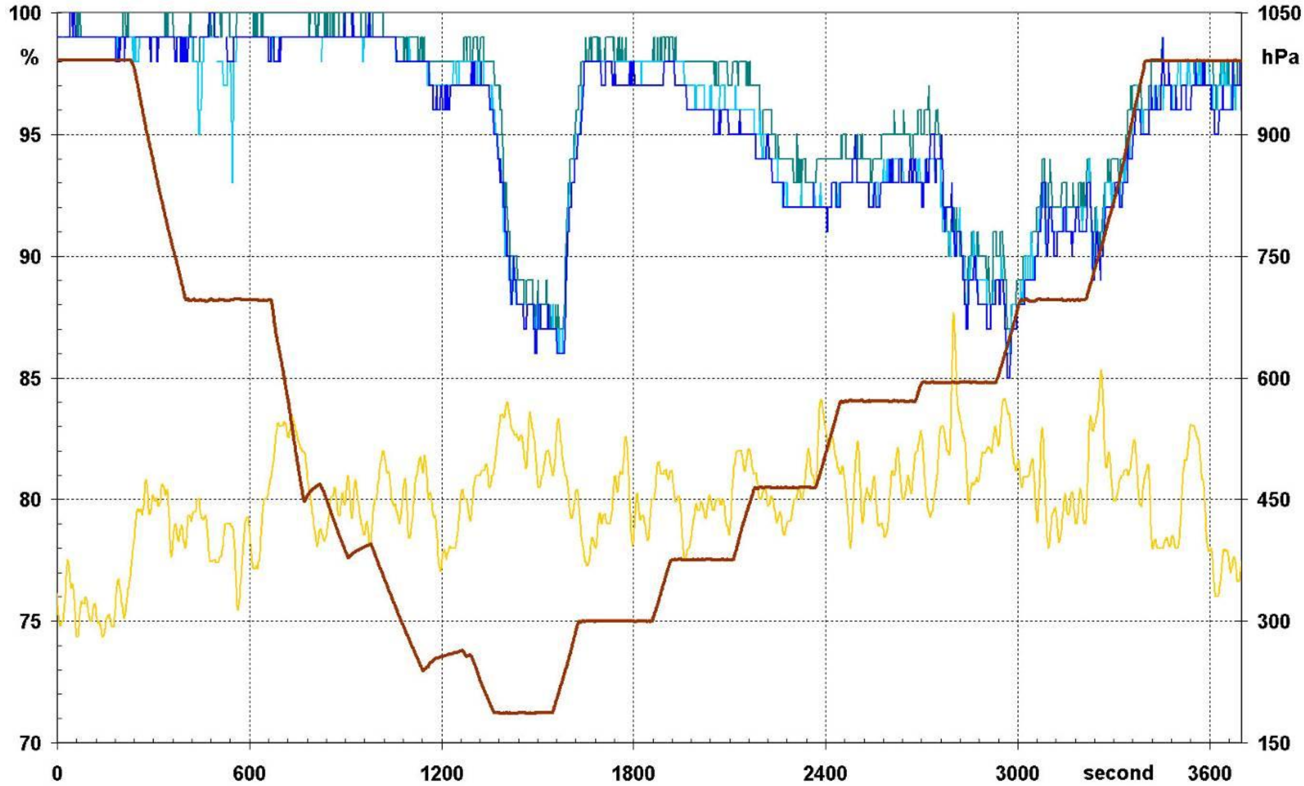

Figure 18. Summary of a complete phase 2 test run (Subject #3)

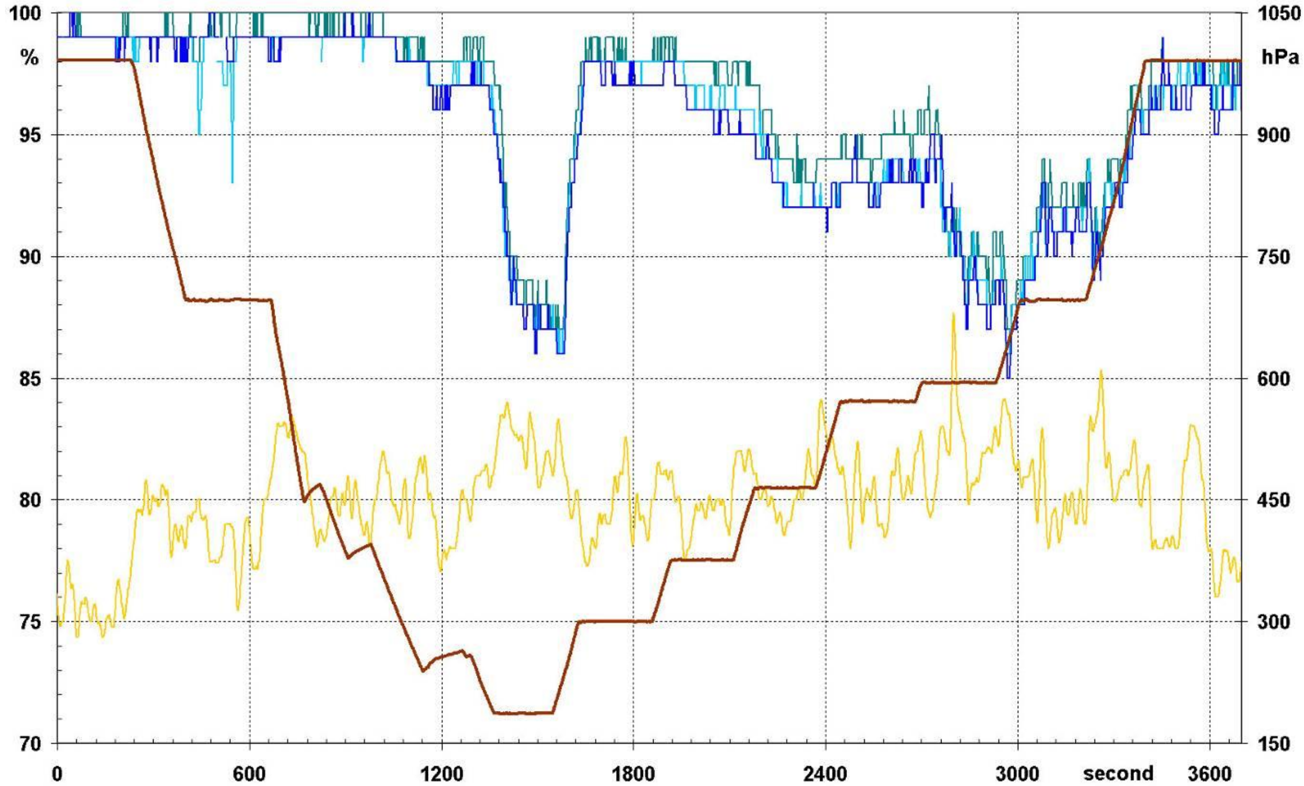

Figure 19. Summary of a complete phase 2 test run (Subject #10)

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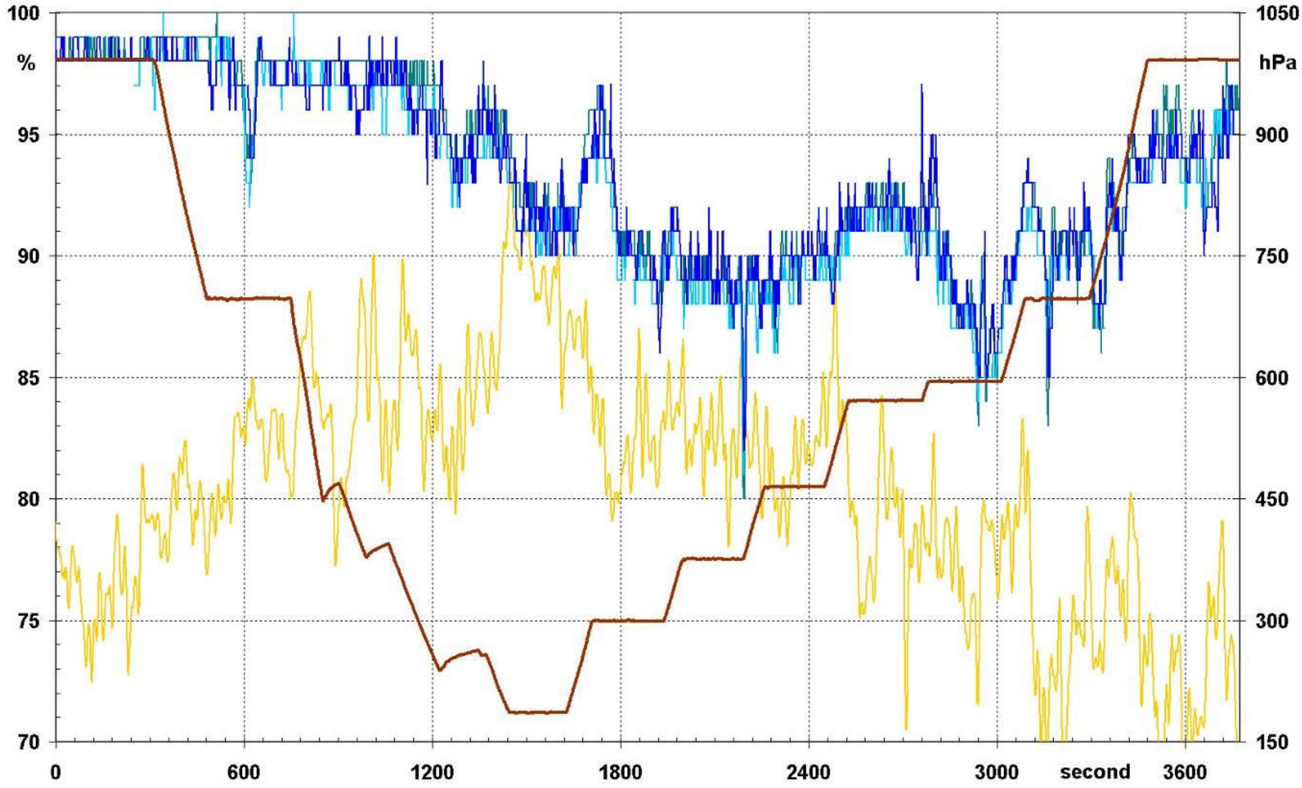

Figure 20. Summary of a complete phase 2 test run (Subject #7)

10 out of 10 subjects maintained a saturation above 87% at 40 kft, 9 were above 90% at all other other altitude levels tested with supplemental oxygen (15, 20, 25, 30 kft). 1 subject (number seven – see Figure 20), as it happens ranked # 1 of the low saturation list, showed average values of 88-89%, with a short drop below 86% for about 8 seconds (minimum reached was 80 - 82 for 3 seconds).

<u>Previous figures description:</u>

Figure 18: Summary of a complete phase 2 test run (Subject #3). The three bluish curves show oxygen saturation, SpO_2 (left scale, %). Ambient pressure is represented by tick brown line (right scale, hPa) and heart rate is indicated by gold-coloured graph. Time intervals of SRT-Test are marked with red and D2-Test with green bars. Time scale is given in seconds.

Figure 19: Summary of a complete phase 2 test run (Subject #10). The three bluish curves show oxygen saturation, SpO_2 (left scale, %). Ambient pressure is represented by tick brown line (right scale, hPa) and heart rate is indicated by gold-coloured graph. Time intervals of SRT-Test are marked with red and D2-Test with green bars. Time scale is given in seconds.

Figure 20: Summary of a complete phase 2 test run (Subject #7). The three bluish curves show oxygen saturation, SpO_2 (left scale, %). Ambient pressure is represented by tick brown line (right scale, hPa) and heart rate is indicated by gold-coloured graph. Time intervals of SRT-Test are marked with red and D2-Test with green bars. Time scale is given in seconds.

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8.3. Phase 3

8.3.1. Phase 3 Test Set-up

The 5 subjects were exposed to physical exercise on a bicycle ergometer at 20 kft in order to simulate a typical scenario for cabin crew after a depressurisation event. Subjects were breathing supplemental oxygen from a passenger mask, supplied via a precision mass flow controller. Starting point of the experiment was a flow setting of 2 lpm oxygen / NTPD, this corresponds to the recommended setting of portable oxygen equipment used by cabin crew. The initial exercise level was 80 W and participants were instructed to treadle at constant cadence of 65 rpm during the whole test procedure. In the course of the experiment oxygen flow was stepwise decreased until the subjects' arterial oxygen saturation dropped below 90%. Each reduction of oxygen flow was followed by an equilibration period of 4 minutes of workout.

Once the limiting oxygen flow for the 80 W exercise level was reached, the ergometer workload was reduced to 50 W. After an adaptation interval the test procedure was repeated until the subjects' saturation reached the 90% limit for the lower exercise level.

Figure 21. Test setup of phase 3: Subject on bicycle ergometer in altitude chamber, breathing oxygen from a passenger mask.

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8.3.2. Phase 3 Measurements

The principle of flow titration is shown in Figure 22 at 20,000 ft. Ergometer setting is 30 W only, in order to demonstrate the regular decrease of oxygen saturation and flow via multiple steps. Starting with a supplemental oxygen flow of 2 lpm and a baseline saturation of 99% the flow is reduced by steps of 0.1 lpm every 4 minutes in order to allow adaptation of metabolic parameters. The rather sharp transition below 90% saturation occurs with the step from 1.0 to 0.9 lpm presumably aggravated by the combination of oxygen reduction and ventilatory stimulation by beginning hypoxia.

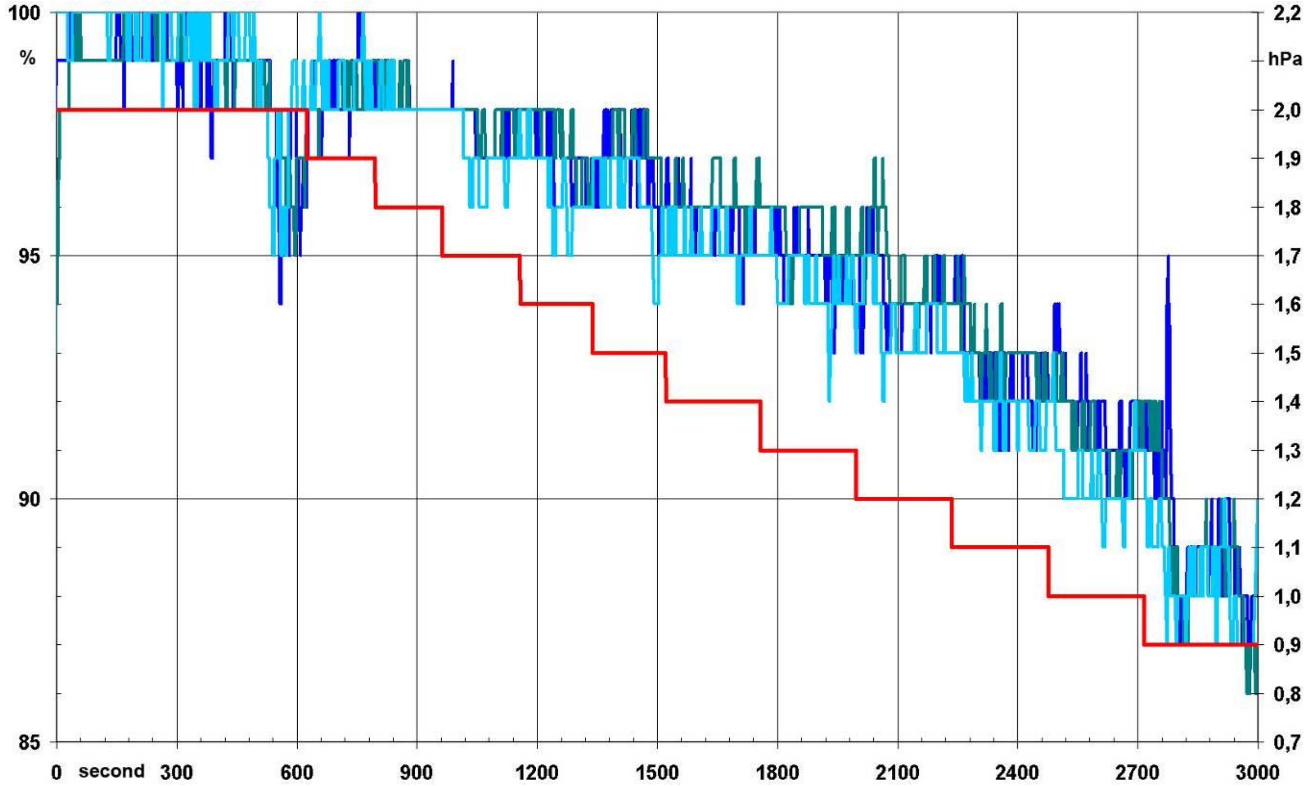

Figure 22.Saturation trend of a subject exercising 30 W on a bicycle ergometer. The bluish graphs show the saturation readings of three pulse oximeters in percent (left scale) and the red coloured graph represents supplemental oxygen flow in l/minute (right scale).

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9. RESULTS AND OUTCOMES

9.1. Phase 1 results

9.1.1. Test outcomes

SaO_2 values at altitude showed large interindividual variation. Alongside with normal diversity of subjects' physiological predisposition SaO_2 values were strongly influenced by individual breathing pattern. SaO_2 equilibrium values were estimated by expert opinion from the recorded saturation curves in order to allow further analysis. In order to confirm the proposed saturation values (§6) to offer the required level of protection a statistical analysis considering the EU population is performed in the following sections.

9.1.2. Statistical analysis

9.1.2.1. Arterial Oxygen Saturation

The aim of the analysis is to allow a prediction of the 5%-quantil ($q_{0.05}$) of the arterial oxygen saturation (S_aO_2; if measured by pulse oximetry, also written as SpO_2),) depending on age and ambient air pressure. The 5%-quantile for any setting is defined as

$$P(Y < q_{0.05}) \leq 0{,}05 \leq P(Y \leq q_{0.05}).$$

This means that the probability that Y has a higher value than q0.05 is 95%. In the case that Y represents the arterial oxygen saturation and q0.05 is the 5%-quantile of a distinct population, the probability that 95% of the population have a higher SpO2 value than q0.05 is approximately 1.

For the calculation of the conditional quantile, data from two studies were combined and analysed. One part of the data derives from the ICE-Study, which was performed in the cabin simulator of the Fraunhofer-Institute in Holzkirchen. The data set contains measurements from 1161 participants. The minimum age was 18, the maximum age 85 and the mean 45 years. Data of the arterial oxygen saturation was collected at pressure equivalents to heights of 2231, 4000, 6000 and 8,000 feet.

The other part of data derives from the study, which was performed in the Institute of Aerospace Medicine at the DLR in Cologne in 2010 for this report. Altogether 36 participants were reviewed under pressure equivalences of 214, 5,000, 8,000, 10,000, 12,000, 14,000, 16,000 feet. The minimum age was 50, the maximum age 73 and the mean 60 years. One participant was excluded from the analysis, due to irregular values.

The data was analysed with the quantile regression method [Koenker & Basset, 1978] that allows the estimation of the distribution of the response variable conditional on any set of regressors. In our case the regressors are age and altitude equivalent air pressure. Because the effect of the air pressure is not quite linear, the formula

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$$q_\pi = \beta_0 + \beta_1 * 1{,}15^{Altitude/1000} + \beta_2 * Age + \beta_3 * Age * 1{,}15^{Altitude/1000} \quad (1)$$

Was used to model the conditional quantiles. The β's are estimated by

$$\beta_\pi = \text{argmin} \sum_i (p (y_i - x'\beta_i)), \ (2)$$

Whereas p(.) is the so-called check function. For further details see Koenker & Basset (1978).

	Value	Std. Error	t-value	Pr(>|t|)
Intercept	99,32857	0,43715	227,21745	0,000
$1{,}15^{Altitude}$	-1,77904	0,18216	-9,76649	0,000
Age	-0,08173	0,0098	-8,34373	0,000
Age * $1{,}15^{Altitude}$	-0,00853	0,00364	-2,34356	0,01914

Table 7. Estimated values of the quantile regression model with the 5%-quantile of the arterial oxygen saturation as dependent variable.

Erreur ! Source du renvoi introuvable. displays the estimated coefficients of the quantile regression model with 5%-quantile of the arterial oxygen saturation as dependent variable and altitude (substitutional for the air pressure) and age as independent variables using formula (1).

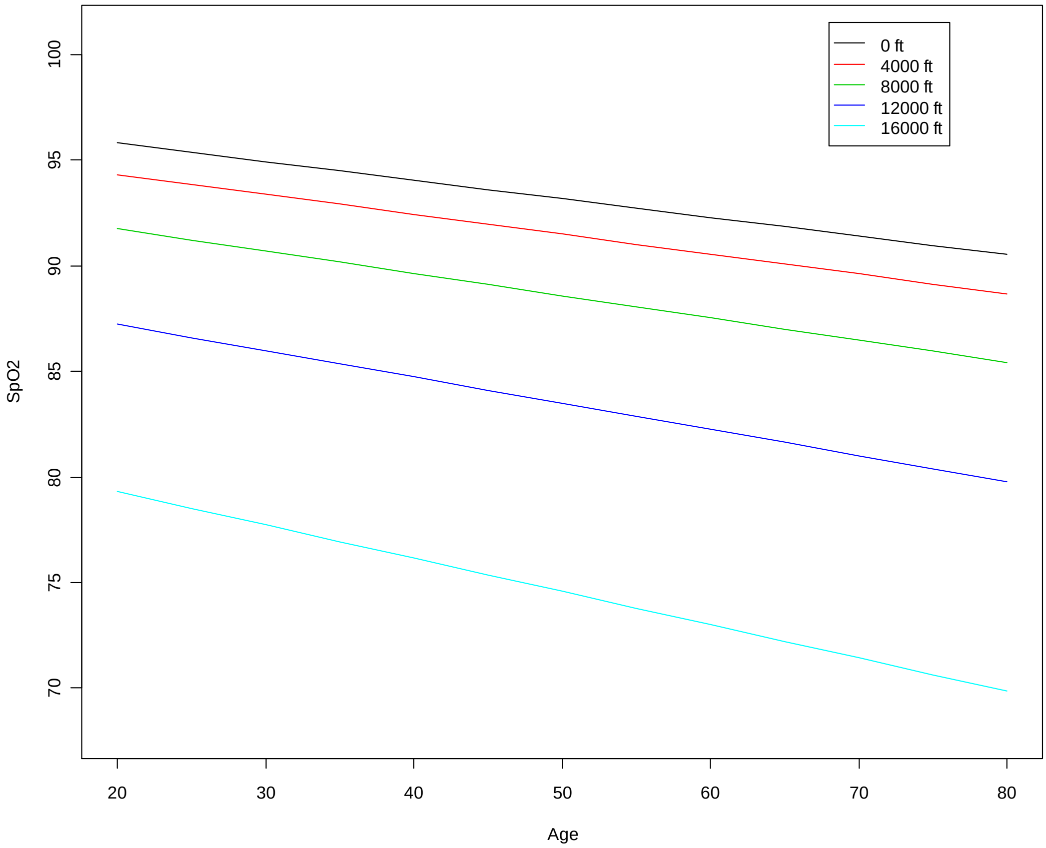

Figure 23. 5%-quantiles depending on age for different altitude levels. Computed with the quantile regression model.

The smoking history of the participants did not show a significant effect in the analysis. Therefore information on the smoking career (stated by the subjects during

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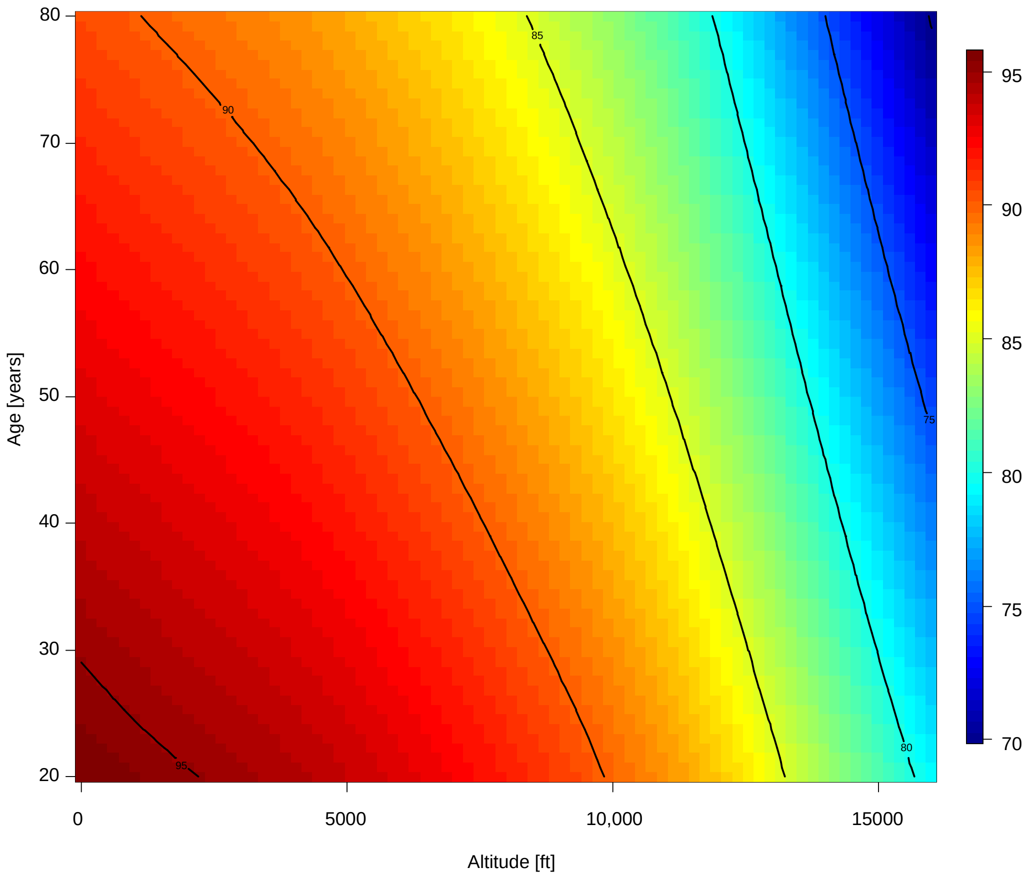
the medical examination prior to the experiments) is not included in the model. Apparently the influence of smoking on breathing function was not strong enough in our population to induce a significant decrease of saturation (unlike age). Most of the smokers in our study had ceased smoking at some time in the past, the maximum life consumption was 50 pack years, not expected to cause severe changes in the respiratory system.

As **Erreur ! Source du renvoi introuvable.** shows all coefficients are negative. That means that with increasing altitude and age the arterial oxygen saturation decreases. The negative interaction term means that with increasing age the decrease of the oxygen saturation due to altitude becomes more severe. That allows the assumption that older people are becoming more sensitive to changes in pressure conditions. All effects are statistically significant and the main effects are even highly significant.

Erreur ! Source du renvoi introuvable. shows the relationship between age and oxygen saturation for different altitudes. The lines represent the conditional 5%-quantiles for the according age and altitude. The plotted 5%-quantiles were computed



with the quantile regression model.

Figure 24.Contour plot of the 5%-quantiles depending on age and altitude levels. Computed with the quantile regression model.

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Figure 25 shows partly the same data as 0, but with a higher resolution due to the illustration as a contour plot. On the y-axis age is plotted and on the x-axis the altitude. The colours and contour lines represent the associated 5%-quantile. As can been seen 5%-quantiles for people between 20 and 30 years drop under 90 at far higher altitudes than those of people between 70 and 80 years. At about 10,000 ft. the differences due to age are becoming smaller.

So far the figures only provided information about the distribution of SpO2 for one certain age group. Yet the aim is to allow an estimate of the 5%-quantile for a population with a distinct age distribution.

This is possible if we calculate the conditional distribution of SpO2 for each age group. In a second step a joined distribution is generated by a weighted junction of the age specific distribution. The weights are derived from the proportion of the corresponding age group in the population. In this document the age distribution of the EU (27 countries) was used to calculate the 5%-quantiles. Figure 25 shows the age distribution of the EU in the year 2008 as published on the web page of Eurostat. Collective data for the EU was only available until the age of 84 years.

For the calculation of the joined distribution of SpO2 the proportions of all age groups below 18 years were added to the proportion of the group of 18 years and then excluded form the calculation. Thus the proportion of the age group of 18 years is set to 20,1% and the proportions of all age groups below 18 are set to zero.

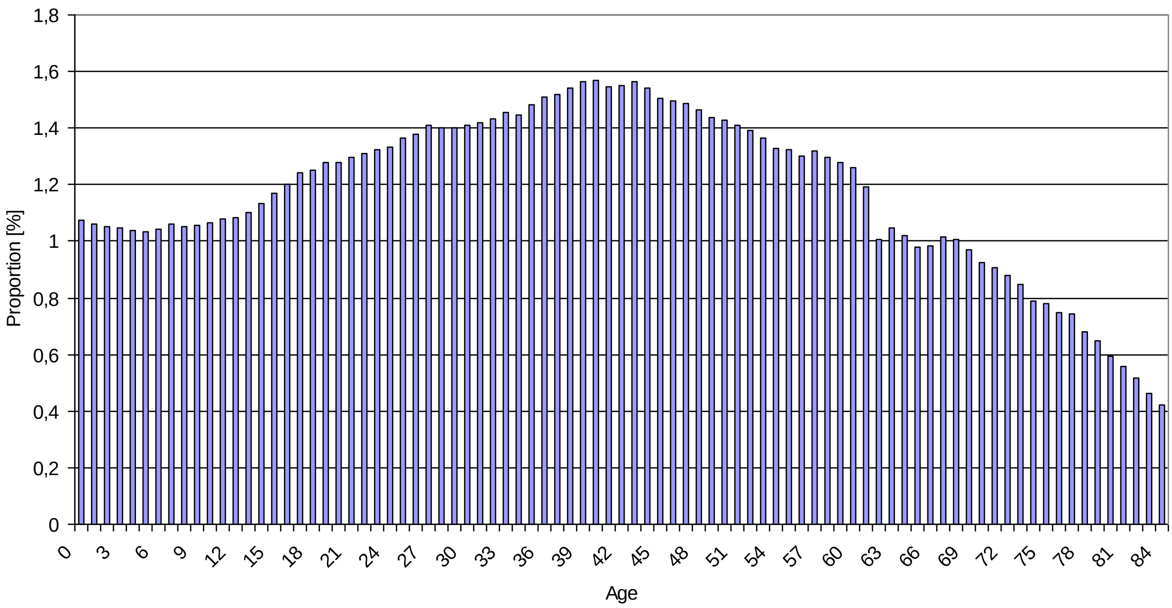

Figure 25. Plot of age distribution of the EU in the year 2008.

The reason for this approach is that no experimentally gained data is available for age groups below 18 years. Anyway there should be no significant differences in these age groups referring to the distribution of SpO_2.

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Figure 25 displays the estimated decrease of the 5%-quantile of oxygen saturation due to increased altitudes for the EU population based on the calculated joined distribution of SpO_2. Table 8 shows the same data in table form.

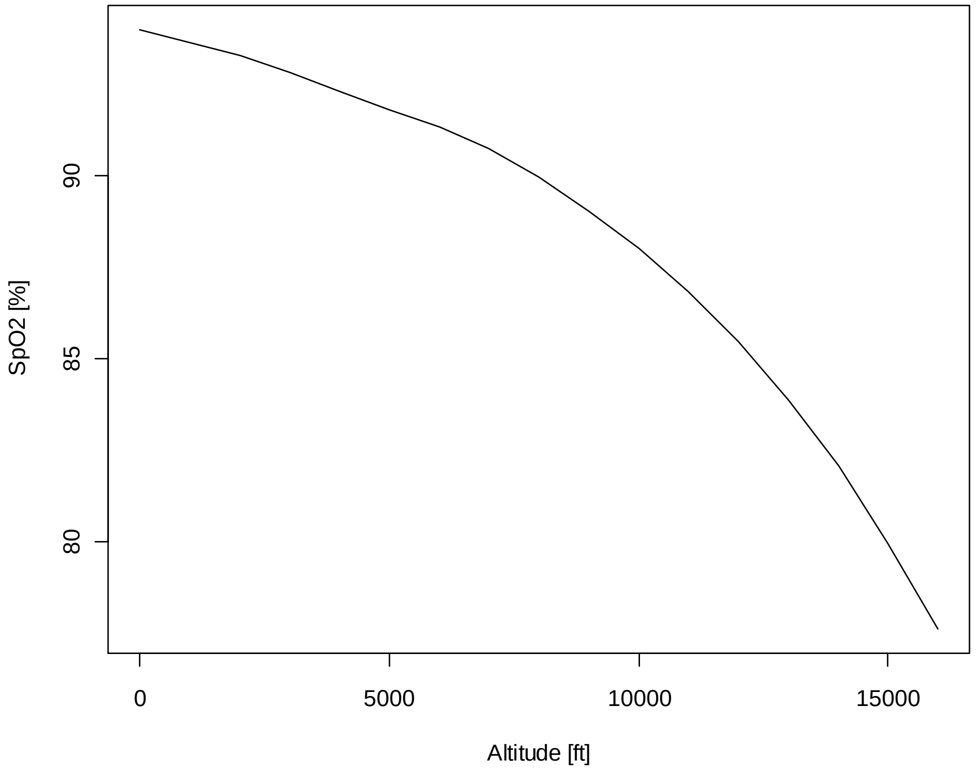

Figure 26. Plot of the 5%-quantiles depending on altitude for the mean age (40.1) in the EU. Computed with the quantile regression model.

Altitude	5%-quantile SpO2
0	94,0125
1000	93,67708
2000	93,29899
3000	92,84044
4000	92,32842
5,000	91,83754
6000	91,358
7000	90,76582
8,000	89,9808
9000	89,0513
10,000	88,02318
11000	86,84366
12,000	85,45983
13000	83,88065
14,000	82,07456
15,000	79,96303
16,000	77,60675

Table 8. Estimated 5%-quantiles of the EU-population for different altitude levels.

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9.1.2.2. Performance Test

9.1.2.2.1. Single Reaction Time Test

The single reaction time test (SRT) is a performance test, which is able to measure the vigilance and the ability to react to a stimulus. The test is implemented in PDA and the stimulus is a green light on the top of the device. The task is to press a button in the middle of the device as fast as possible when the green light flashes. The reaction time is recorded and the procedure starts again. This sequence endures for three minutes. The test was conducted at each altitude level and twice at ground level (at the start and the end of the experiment).

The gained data was analyzed with a linear mixed effects model [e.g. Diggle et al., 2002]. The question of interest is, if the arterial oxygen saturation affects the measured performance. Therefore a linear mixed effects model was computed with the mean reaction for each altitude and participant as dependent variable and the arterial oxygen saturation and age as independent variables. The results are shown in Table 9. The coefficient of the SpO2 is negative and highly significant, thus with decreasing SpO2 the reaction time increases. More precisely the reaction time increases by 0,6 milliseconds if the arterial oxygen saturation drops by one Percent.

	Value	Std. Error	DF	t-value	p-value
(Intercept)	289,20069	62,26677	205	4,644543	0,000
SpO2	-0,64121	0,15258	205	-4,202394	0,000
Age	0,13037	1,01241	33	0,128776	0,8983

Table 9. Results of the linear mixed effects model with reaction of the SRT as dependent and age and SpO2 as independent variable.

The relationship between SpO_2 and reaction time is also illustrated in **Erreur ! Source du renvoi introuvable.**. In a former study it could be shown that at a blood alcohol concentration of 0.8 $^0/_{00}$ implicates an impairment of 25.5 ms on average [Elmenhorst, 2009].

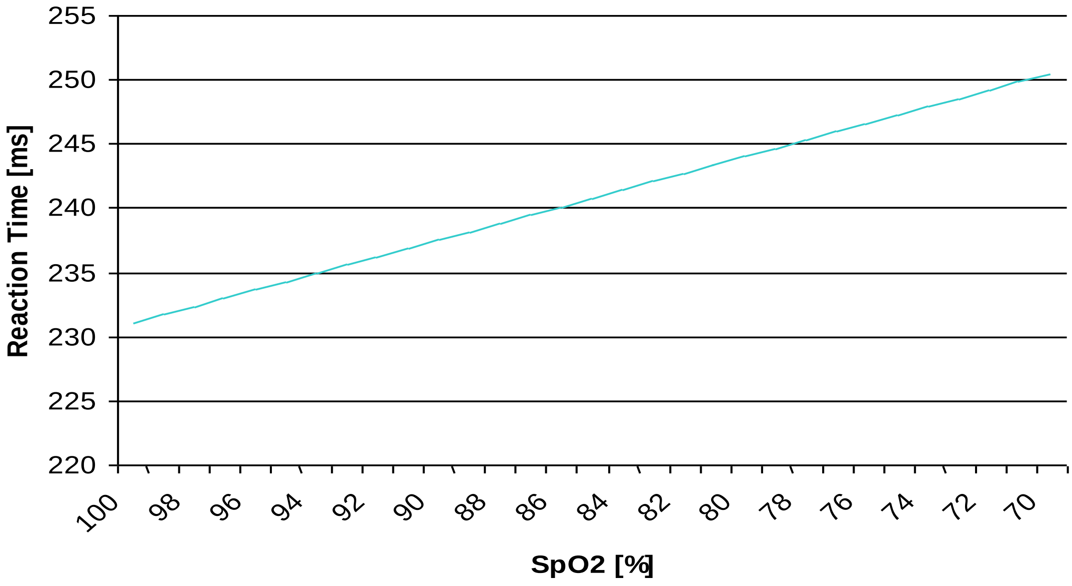

Figure 27. Plot of increase of reaction time due to decrease in SpO_2 as estimated by linear mixed model.

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9.1.2.2.2. d2 – Test

The d2-Test is a pattern recognition test. Within three minutes different patterns are presented. The task is to classify as many objects as possible. The test is performed on a netbook and the test is implemented in Visual Basic.

The gained data was again analyzed with a linear mixed effects model. Contrary to the results of SRT there couldn't be found any significant linear effects of performance due to changes in SpO_2. But there as a significant decrease in performance below a saturation of 87%, as it can be seen in Table 10. The performance decreases by almost 5 correctly specified items, if the SpO_2 is below 87%. If we set the threshold further down the loss in performance decreases in a greater extent, e.g. below 85% the decrease add up to nearly seven items less.

The repetition number is necessary to adjust for the training effect, which was presented in this test setting.

	Value	Std. Error	DF	t-value	p-value
(Intercept)	194,09591	4,738758	204	40,95924	0,000
SpO_2 < 87%	-4,96954	2,269062	204	-2,19013	0,0296
Repetition No	5,65798	0,53954	204	10,48667	0,000

Table 10. Results of the linear mixed effects model with reaction of the SRT as dependent and age and SpO_2 as independent variable.

9.1.2.2.3. Assistance with oxygen mask on Dummy

At all test altitudes but 16,000 ft all subjects were able to apply the oxygen mask to their faces and to "assist" the dummy with attaching the mask to its face. At 16,000 ft subjects #9, #11, #15 and #35 needed to receive supplemental oxygen and consequently did not perform the testing procedure at that altitude stage.

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9.2. Phase 2 results

This test was focused on the application of supplemental oxygen via conventional passenger masks. To guarantee a maximum of validity and comparability of the phase 2 experiments we aimed at selecting the 10 designated subjects from the 36 phase 1 participants. In the recruitment process we approached subjects who had shown the highest sensitivity to hypobaric hypoxia first, 9 of them consented to participate in this second test run in the decompression chamber as shown in Table 6, we were able to attract 5 out of the 10 most susceptible subjects of phase 1 to participate in the phase 2 experiments. These 5 subjects had shown an average saturation below 78 % at the 14/16 kft exposures. Additionally 4 further subjects with average saturations of 78 – 83% and 1 new subject entered the study.

In order to demonstrate the protection level of the current standards for stationary passenger oxygen systems and to indicate potential for oxygen savings a set of optimized and therefore minimized oxygen mass flows was used throughout the experiment. The “hi-efficiency” flow rates were obtained from experimental data of DLR and AVOX. The low oxygen partial pressure at 40,000 ft is extremely critical and therefore the conventional flow rate was kept. Such conditions should only occur for a very short period of time and the high mass flow will ensure an excess of oxygen flushing from each mask so that even passengers with poorly fitted masks will be breathing almost pure oxygen. Table 12 compares the standard flow rates of SAE-AIR825 and the optimized mass flows used in this experiment.

Altitude ft	Current Oxygen Flow Requirements SAE-AIR825 lpm NTPD	"Hi-Efficiency"Oxygen Flow Requirements lpm NTPD
15,000	*0.47*	0.30
20,000	*0.97*	0.40
25,000	*1.64*	0.70
30,000	*2.20*	1.00
40,000	*3.04*	3.10

Table 11. Comparison of current and "Hi-Efficiency" recommendations for supplemental oxygen.

With 3.1 lpm (NTPD) of supplemental oxygen 10 of 10 subjects passed the short term 84% saturation criterion at 40 kft, the worst affected subjects dropped to 87%, average saturation within the population was 90.9% (+/- 3.4 %). Table 12 shows the individual results of the 40 kft exposure and summarises the biometrics of the subjects.

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Subject #	Gender	Age years	Height cm	Weight kg	Saturation (%) at 40 kft and 3.1 lpm supplemental oxygen
1	f	56	168	65	87 (pass)
2	m	53	172	74	91 (pass)
3	m	73	175	82	88 (pass)
4	f	64	170	80	95 (pass)
5	m	57	185	80	93 (pass)
6	f	61	168	70	95 (pass)
7	m	67	174	90	90 (pass)
9	f	56	172	70	88 (pass)
9	m	65	175	85	95 (pass)
10	m	68	165	62	87 (pass)

Table 12. Biometrics of subjects and response to 40 kft short term exposure while breathing 3.1 lpm supplemental oxygen.

During the following course of the testing procedure 9 of 10 subjects maintained a stable saturation above 90% at all other stages (30, 25, 20 and 15 kft). The Pax masks were supplied with the “hi-efficiency” oxygen mass flows shown in **Erreur ! Source du renvoi introuvable.**.

The one subject who did not meet the 90% criterion at all times was the one who had shown the highest sensitivity to altitude induced hypoxia (70.5% at 16 kft) of all phase 1 participants and needed to receive supplemental oxygen on the 16 kft stage of phase 1. The saturation trend of this particular subject is shown in Figure 28, it presented an unsuspicious saturation of 90% during the 40 kft exposure, yet once the oxygen flow was reduced to 1.0 lpm (NTPD) at 30 kft his saturation deteriorated to 88%, reached it’s low point of 87% at 25 kft and recovered finally at 20 kft to 90%. On the descent from 25 kft to 20 kft this subject experienced a sharp saturation drop to 81% for a very short period of time (2-3 heart beats). The record of the subjects’ breathing movement (measured via induction plethysmography, basically an elastic chest strap) showed that this event was most likely induced by a breath-hold of 15 seconds. The total amount of time the subject spent below 85% was less than 10 seconds (Figure 28) and the event is not considered to be physiological meaningful for the assessment of the subjects' overall saturation at that altitude stage.

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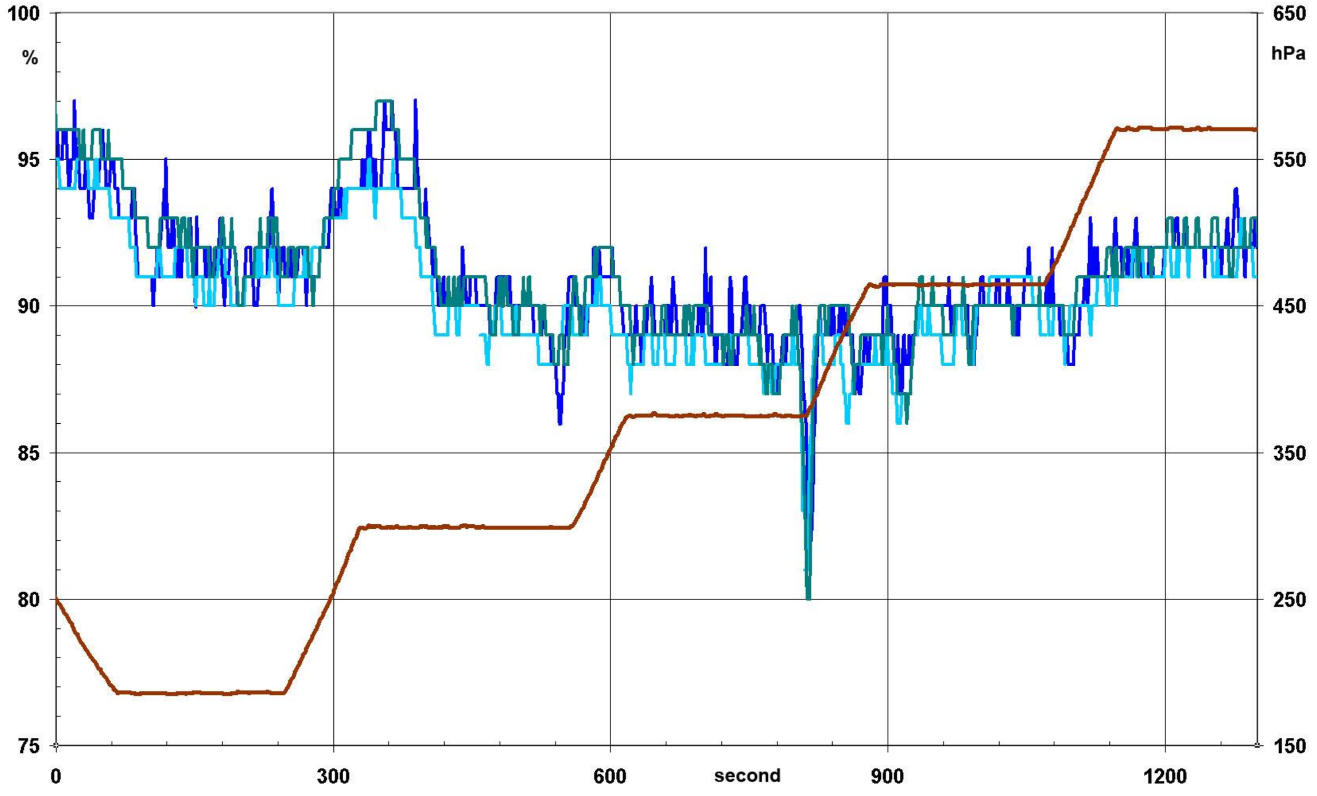

Figure 28.Saturation trend of subject #7, bluish graphs represent readings of three pulse oximeters (left scale, %) and brown curve depicts the ambient pressure (right scale, hPa) in altitude chamber.

Table 13 summarises the findings for each subject of the phase 2 experiments, as described above all subjects but # 7 satisfied the 90% criterion during all altitude stages.

Subject #	Saturation (%) at 30 kft and 1.0 lpm	Saturation (%) at 25 kft and 0.7 lpm	Saturation (%) at 20 kft and 0.4 lpm	Saturation (%) at 15 kft and 0.3 lpm
1	94	96	93	94
2	96	94	92	94
3	96	94	92	94
4	97	96	95	96
5	93	92	92	94
6	98	98	97	97
7	88	87	90	91
9	95	95	91	97
9	96	95	95	95
10	97	96	92	93

Table 13. Individual results of phase 2 experiments.

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Figure 29 depicts the results of phase 2 in a box plot. Each red box represents the subjects' saturations (ordinate) at one altitude stage (abscissa). The bottom end of each box corresponds to the 25th-percentile and the top end to the 75th-percentile. The thick black line within the boxes represents the median of the series and the whiskers indicate the 150th-interpercentile range. It can be seen from this that the "Hi-Efficiency" mask flow recommendations (**Erreur ! Source du renvoi introuvable.**) seem to guarantee a higher level of safety at greater altitudes. Within this population the finding is significant ($p < 0.05$, Wilcoxon-test) for 30, 25 and 20 kft, however it has to be considered that a population of 10 is too small for a global statement.

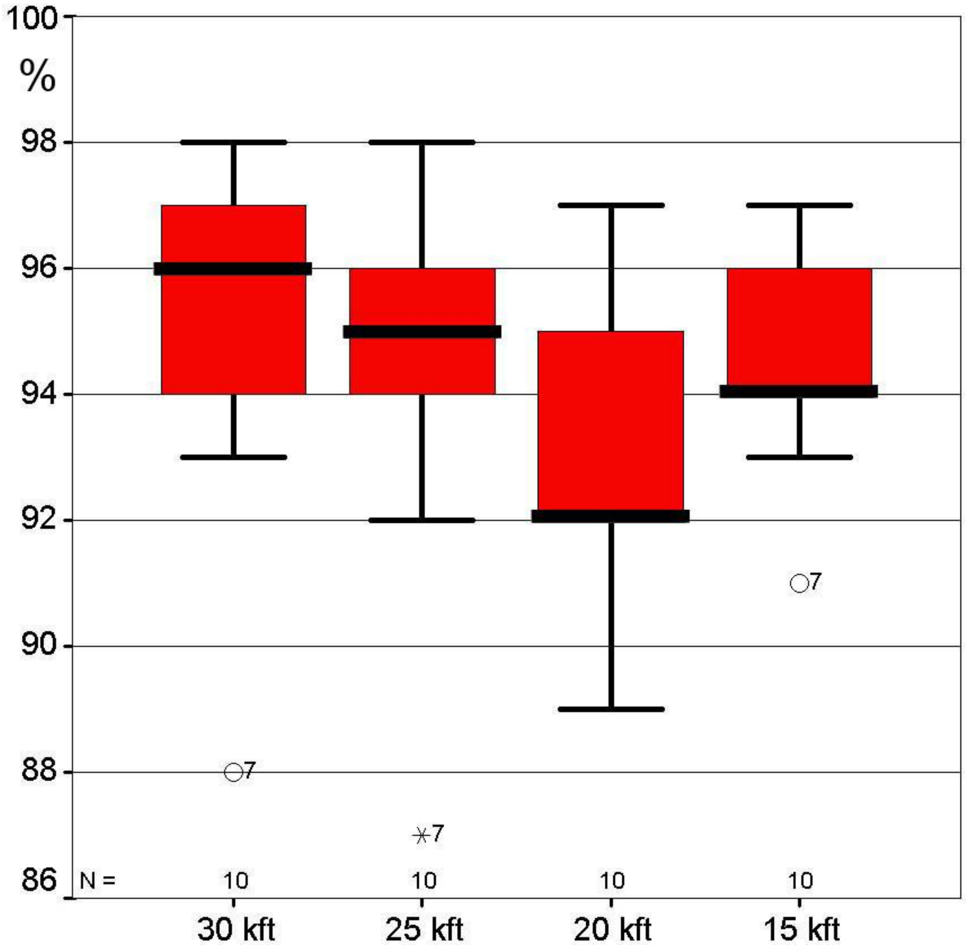

Figure 29. Box plot of the SAPOX phase 2 results, subject #7 is indicated as outlier

At 40 kft the theoretical maximum for the tracheal oxygen partial pressure is 94 mmHg if breathing pure oxygen. This results from the low ambient pressure at this altitude. Therefore it is evident that it is not possible to ensure a saturation level above 90% without applying pressure ventilation.

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9.3. Phase 3 results

The test set up of phase 3 was designed to investigate the situation of Cabin Crew working at elevated diversion altitude after a depressurisation and emergency descent. In that situation Cabin Crew members are using portable oxygen equipment for hypoxia protection while moving through the cabin. They are expected to assist passengers after the emergency event and this will involve a certain level of physical exercise (e.g. lifting injured or disabled passengers or moving equipment that has broken loose). Physical exercise leads to a higher demand of oxygen and, as the body tries to supply itself with the required oxygen, an increased BMV. Crew portable equipment is basically a gas cylinder with standard Pax masks. The regulator of the portable is providing a 2 lpm and 4 lpm (NTPD) setting for continuous oxygen flow. An increased BMV leads to a dilution of the supplemental oxygen in the inhaled gas. In this scenario the body is not capable of covering it’s increased need of oxygen by increasing the BMV and therefore the available oxygen sets a limit to the possible workload. At present there is no experimental data available either giving information on cabin crew exercise scenarios or supplemental oxygen requirements as a function of exercise at altitude.

9.3.1. 2lpm setting

Two litres per minute are the initial setting of crew portables. The devices are equipped with a standard passenger mask. Starting point of the experiment was an exercise level of 80 W on a bicycle ergometer at 20 kft. Figure 21 shows the test set up in the altitude chamber. The initial oxygen mass flow of 2 lpm (NTPD) was stepwise reduced as long as the subject maintained a saturation of at least 90% after an equilibration period of 4 minutes at each flow setting. In subjects #1-4 (age 27-31 yrs.) the initial 2 lpm (NTPD) setting was just sufficient to maintain a SpO_2 of 90 % or slightly above, with 1.9 lpm (NTPD) their blood oxygen saturation dropped straight below 90% (except Subject # 3 who undercut 90% at 1.85 lpm (NTPD)). In the two older subjects of the population (#5/6, age 58/62 years) saturation dropped significantly below 90% (83/84%) even with the initial 2 lpm (NTPD).

After determining the individual response to a workload of 80 W, the ergometer was set to 50 W, a more moderate exercise level. Subsequently, the test procedure of stepwise reduction of oxygen flow was repeated to find the transition between sufficient oxygenation and beginning hypoxia at the lower exercise level. In the case of 50 W, most subjects were able to maintain work with an oxygen flow of less than 2 lpm (NTPD); however, one subject (# 6) was already slightly below 90 % at this initial flow. When testing the ventilatory response to 50 W at ground level, this subject showed a breathing minute volume of more than 35 lpm (BTPS), which was the calculated limit of the BMV to maintain a tracheal oxygen partial pressure of 100 mmHg, corresponding to a saturation of 90 %. In all other subjects, the measured ventilation at ground level was below 30 lpm (BTPS) at 50 W.

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Typically, the required oxygen mass flow to maintain a saturation of 90% can be approximated between the last two flow settings considering the trend of the subjects' saturation curve. **Erreur ! Source du renvoi introuvable.** summarises the results of the 6 subjects tested in phase 3:

Subject #	Gender	Age years	Height cm	Weight kg	lpm (80W)	lpm (50W)
1	m	28	182	79	1.95	1.45
2	f	31	178	73	2.00	1.40
3	m	30	188	78	1.85	1.30
4	f	27	168	54	1.95	1.30
5	m	62	179	85	2.00 (84%)	1.70
6	m	58	184	94	2.00 (83%)	2.00 (88%)

Table 14. Biometrics of phase 3 participants and oxygen flow limits for the 90% saturation criterion.

As it turns out, the potential for a reduction of flow rates is much less in case of cabin crew than in the passenger case. For cabin crew physical exercise and a consequently increased BMV must be considered. However, the result of the increased tidal volume at exercise is that a larger fraction of inhaled gas of each breath will be transferred into the deeper parts of the respiratory system where the gas exchange takes place. Therefore the effect of the dispensing unit will show characteristics much closer to an ideal device. The initial assumption that an exercise level of 80 W at 20 kft could be sufficiently covered by the portable setting of 2 lpm (NTPD) could not be maintained by actual testing, as there may be individuals significantly exceeding the assumed ventilation limit value of 35 lpm (BTPS). A 50 W exercise level seems to be safely covered even for persons with a poor ventilation profile. However, the actual workload cabin crew members might be confronted with in the field remains unclear. Unless there is a realistic scenario to assess the activity of cabin crew after a depressurisation event it is purely hypothetical to discuss feasible workloads at elevated diversion altitude.

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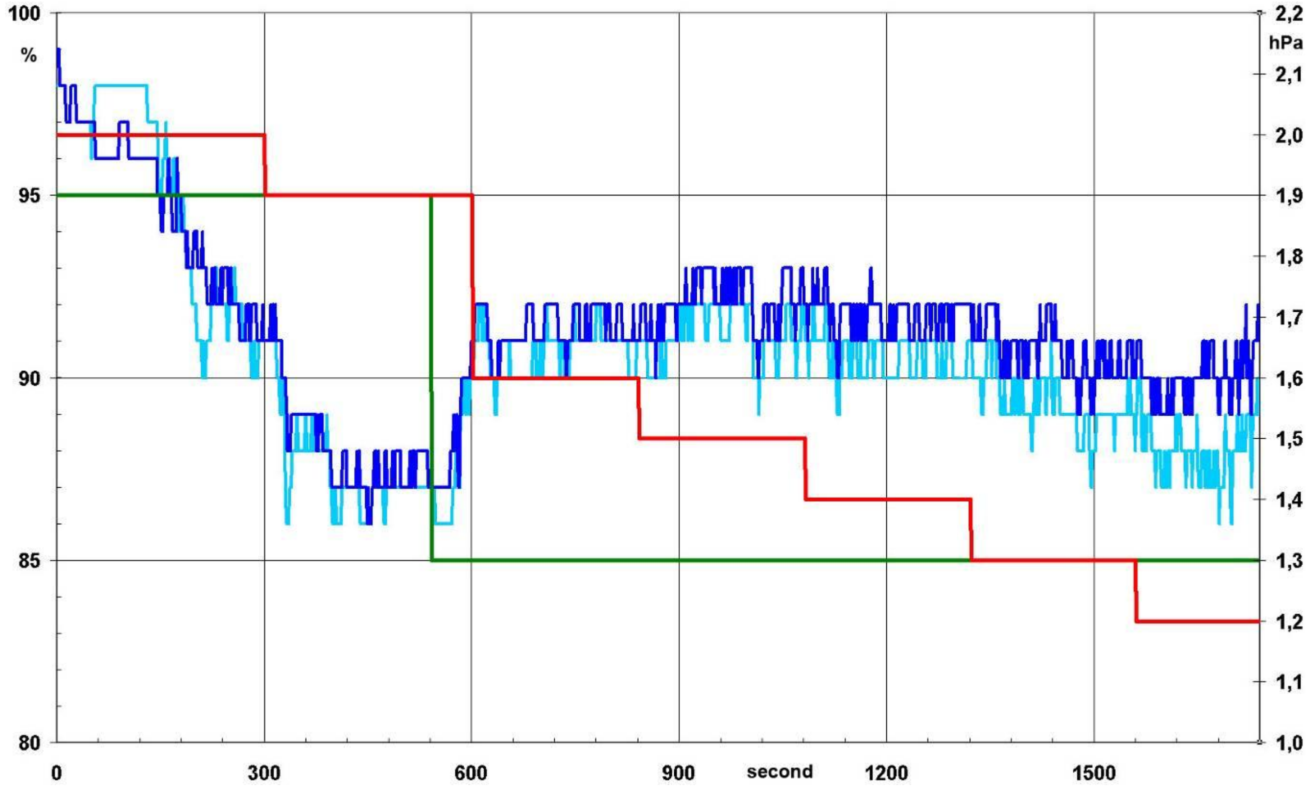

Figure 30. Example of phase 3 flow titration experiment (Subject #4).

The thick green mark indicates the ergometer wattage (no scale), 80 W on the left and 50 W on the right side of the chart. The bluish graphs represent blood saturation in percent (left scale) and the current oxygen flow in l/minute (right scale) is indicated by the red graph.

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9.3.2. 4 lpm setting

Although the 4 lpm (NTPD) setting of current portables is mainly justified by medical purposes, it may as well be used by cabin crew at higher altitude or increased workload. The altitude limit for cabin crew intervention and portable use is 25 kft. Table 16 shows the effect of an increasing BMV on the oxygen fraction in the inhaled gas volume and the resulting tracheal oxygen partial pressure at 4 lpm (NTPD) supplemental oxygen at 25 kft.

BMV/lpm BTPS	BMV/lpm NTPD	fO_2 %	P_TO_2 mmHg
15	4,408	92,7	218,2
16	4,702	88,2	207,6
17	4,996	84,2	198,3
18	5,290	80,7	190,0
19	5,584	77,6	182,6
20	5,877	74,7	176,0
21	6,171	72,2	169,9
22	6,465	69,9	164,4
23	6,759	67,7	159,4
24	7,053	65,8	154,9
25	7,347	64,0	150,6
26	7,641	62,3	146,7
27	7,934	60,8	143,1
28	8,228	59,4	139,8
29	8,522	58,1	136,7
30	8,816	56,8	133,7
31	9,110	55,7	131,0
32	9,404	54,6	128,5
33	9,698	53,6	126,1
34	9,992	52,6	123,8
35	10,285	51,7	121,7
36	10,579	50,8	119,7
37	10,873	50,0	117,8
38	11,167	49,3	116,0
39	11,461	48,5	114,3
40	11,755	47,8	112,6
41	12,049	47,2	111,1
42	12,342	46,6	109,6
43	12,636	46,0	108,2
44	12,930	45,4	106,9
45	13,224	44,9	105,6
46	13,518	44,3	104,4
47	13,812	43,8	103,2
48	14,106	43,4	102,1
49	14,400	42,9	101,0
50	14,693	42,5	100,0
51	14,987	42,0	99,0
52	15,281	41,6	98,0
53	15,575	41,3	97,1
54	15,869	40,9	96,2
55	16,163	40,5	95,4
56	16,457	40,2	94,5

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BMV/lpm BTPS	BMV/lpm NTPD	fO_2 %	P_TO_2 mmHg
57	16,751	39,8	93,8
58	17,044	39,5	93,0
59	17,338	39,2	92,2
60	17,632	38,9	91,5

Table 15. Tracheal Oxygen partial pressure at 25 kft / 4 lpm O_2 versus BMV

As shown in Table 16 at 4 lpm (NTPD) a breathing minute volume of approximately 50 lpm (BTPS) results in an equivalent PTO2 as a BMV of 35 lpm (BTPS) with 2 lpm (NTPD) at 20 kft, namely a tracheal oxygen pressure of 100 mmHg. In the experiments conducted with 2 lpm (NTPD) of supplemental oxygen this has been shown to be the critical threshold in accordance to the 90% saturation criterion.

At 25 kft and an oxygen flow of 4 lpm (NTPD) the 149 mmHg criterion of the current CS 1443 a) is still reached at a BMV of 25 lpm (BTPS), considerably more than the BMV of 15 lpm (BTPS) assumed in CS 1443 a).. Considering the CS 25.1443 b) criterion of 122 mmHg at a BMV of 20 lpm (BTPS) for demand equipment, a continuous mass flow of 4 lpm (NTPD) results in a P_TO_2 of 122 mmHg at a breathing minute volume of 35 lpm (BTPS), which is considerably higher than the regulation requires and will therefore provide a large safety margin.

9.3.3. Phase 3 discussion

The experiments carried out in Phase 3 aimed to consider the situation of cabin crew after a depressurisation event. The results highlight the fact that the amount of supplemental oxygen needed to protect cabin crew members at altitude is highly dependent on the amount of exercise imposed on them. However, the general problem with the discussion of an appropriate workload is a lack of information regarding tasks and demands cabin crew might be confronted in the emergency situation. For further discussion the development of a scenario for cabin crew activity at elevated diversion altitude is required. The scenario needs to simulate the physical as well as the cognitive demands of such a situation.

9.3.4. Phase 3 conclusion

Tests conducted on subjects supplemented with 2 lpm (NTPD) of oxygen demonstrate the dependence of oxygen demand relative to the physical exercise a person is exposed to. An adequate level of protection can only be provided up to 20,000 ft if a moderate level of physical activity is guaranteed.

It can be estimated that 4 lpm (NTPD) of supplemental oxygen at 25,000 ft result in a level of protection better than 2 lpm (NTPD) at 20,000 ft , assuming the same constrains to physical and mental activity mentioned earlier. Therefore the 4 lpm (NTPD) setting originally prescribed for medical purposes should be considered an option for the supply of cabin crew members to increase protection at increased workload at high altitude. However, at rest or a moderate workload the 4 lpm (NTPD) setting of a portable device would waste large quantities of oxygen and in consequence diminish the operation time of the device by 50% without necessity.

Thus, a constant flow supply sized for worst case requirement is not optimized for cabin crew protection. During rest phases, the resulting overconsumption implies to carry a quantity of oxygen on board far above the actual amount to support cabin crew after decompression.

Equipment sensitive both to altitude and to the level of exercise performed would be highly desirable.

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10. CONCLUSIONS

The analysis of existing data and the results of a series of experimental tests allow to define the equivalent arterial oxygen saturation levels to the current FAA and EASA requirements set for the protection of passengers against the risk of hypoxia (tracheal oxygen partial pressure) as follows:

- 84% level can be considered as acceptable for short duration exposure (maximum 1 min);

- 90% can be considered as acceptable for long term duration[2] exposure (above 1 min);

The specific experimental tests on human subjects performed and the comparison with existing larger experimental data allows to support that these proposed levels provide a safe level of protection against hypoxia for individuals at rest exposed at altitudes up to at least 40,000 ft.

A new wording has therefore been proposed to describe minimum performance enclosed in CS 25.1443(c) and CS25.1443(e). Furthermore, Acceptable Means of Compliance (AMC) related to CS 25.1443(c) are proposed for Oxygen systems and Equipment certification purposes (Appendix 2).

The definition of these equivalent protection levels based on a true physiological parameter is proposed to replace 'technology-dependent' requirements and to support the approval of more efficient oxygen systems (requiring less oxygen in storage).

Moreover, the notion of medical use is added to CS25.1443(d), in order to take into account the use of portable oxygen equipment for medical purposes.

The process to establish adequate oxygen saturation levels for cabin crews during in-flight depressurization events and taking into account the level of physical effort required has been determined and related recommendations are exposed in section 11.

[2] Maximum exposure time would be limited by high terrain flight conditions or decompression sickness.

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11. RECOMMENDATIONS

The present study proposed an approach to enable the prescription of accurate minimum performance levels required from oxygen systems aimed to protect passengers and seated cabin crew members.

The same approach should then be used to propose wordings for chapters CS25.1443 a, b and e as well in order to issue a new set of regulations regardless of technology.

The way to define new rules applicable to cabin crew members on duty has already been paved:

> Tests conducted during Phase 3 enabled us to foresee an approach to achieve the same results for cabin crew members while performing flight duties.
>
> Further human tests shall be conducted to be able to prescribe accurate minimum performance levels required from oxygen systems aimed to protect cabin crew members while performing flight duties. Human test protocol would especially have to be revisited to take into account the duties (both physical & cognitive: to be assessed) imposed on this specific population of aircraft occupants.

The approach to define new rules applicable to flight deck crew members on duty would probably be very similar.
Human test protocol would especially have to be revisited to take into account the duties (both physical & cognitive: to be assessed) imposed on this specific population of aircraft occupants.
It is assumed that steps A (selection of representative subjects) and D (Pass/Fail criteria) defined for the Phase 1 of the test protocol would subsequently need amendments in order to take such specificities into account.

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12. REFERENCES

12.1.Reference Documents

Certification Specifications CS 25 - §25.1443

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12.2. Applicable Standards

FAA TSO C64b	Oxygen Masks Assembly, Continuous Flow, Passenger
EASA ETSO C64a	Oxygen Masks Assembly, Continuous Flow, Passenger
FAA TSO C78a	Crewmember Demand Oxygen Masks
EASA ETSO C78	Crewmember Demand Oxygen Masks
FAA TSO C89a	Oxygen Regulators, Demand
EASA ETSO C89	Oxygen Regulators, Demand
FAA TSO C99a	Protective Breathing Equipment
EASA ETSO C99	Protective Breathing Equipment
SAE standards	
AIR 825/14	Basic System Design, Schematics, charts & tables
AS 1046C	Minimum Standards for Portable Gaseous Oxygen systems
AS 8025A	Passenger Oxygen Masks
AS 8026A	Crewmember Demand Oxygen Masks for Transport Category Aircraft
AS 8027	Crew Member Oxygen Regulators, Demand
AS 8031A	Personal Protective Devices for Toxic and Irritating Atmospheres, Air Transport Flight Deck (Sedentary) Crew Members
AS 8047	Performance Standards for Cabin Crew Portable Protective Breathing Equipment for Use During Aircraft Emergencies.
AS 8048	Passenger Protective Breathing Equipment
NATO standards:	*NATO (North Atlantic Treaty Organization) Standardization Agency(NSA),* NATO HQ, EVERE, 1110 BRUXELLES (Belgique)
STANAG 3198 AMD	Functional Requirements Of Aircraft Oxygen Equipment And Pressure Suits

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13. APPENDIXES

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APPENDIX 1 - Test Set Up General Requirements

Test Set Up General Requirements

The passenger mask shall be supplied during testing with **air,** a switch to oxygen will occur if an individual subjects runs into the "fail" condition at any altitude (see §9.2).

The amount of oxygen delivered to the mask is provided by a precision mass flow controller, which is adjusted to the individual altitude at which this procedure might be necessary.

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Altitude Chamber Pictures

Figure 31. DLR Altitude Chamber

The here above picture shows the DLR Altitude Chamber in Köln. The chamber has been equipped with a back up demand oxygen system.

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Figure 32. DLR Altitude Chamber with Test Stand and Operator Seat

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Altitude Chamber Test Safety Concept

In addition to the back up demand oxygen system, it shall be possible to supply each passenger oxygen mask with adjustable 100% oxygen flow. The flow shall be adjustable between 0,2 to at least 3,1 lpm.

A Portable Pulse Oximeter with sufficient battery capacity is also part of the test equipment.

During the altitude tests an aeronautical doctor shall be present inside and/or outside the altitude chamber.

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Altitude Chamber Check List

The following checks of the system and the test persons have to be performed before Altitude chamber tests.

Check No.	Description	Result (OK/not OK)	Remarks
1	Physiological Conditions of Test Persons		
2	General Safety Instructions for the Altitude Chamber Tests		
3	Altitude Chamber Test Sequence Briefing		
4	Functional Check of the Back Up Oxygen system		
5	Functional Check of the Passenger Mask System		
6	Pulse Oximeter Battery Status/Function		
7	Communication Signs during Altitude Chamber Test Trials		

Table 16. DLR Altitude Chamber Check List

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APPENDIX 2 - New wording proposed for CS 25.1443

13.1. Current CS 25.1443

CS 25.1443 Minimum mass flow of supplemental oxygen

(a) If continuous flow equipment is installed for use by flight-crew members, the minimum mass flow of supplemental oxygen required for each crew member may not be less than the flow required to maintain, during inspiration, a mean tracheal oxygen partial pressure of 149 mmHg when breathing 15 litres per minute, BTPS, and with a maximum tidal volume of 700 cm3 with a constant time interval between respirations.

(b) If demand equipment is installed for use by flight-crew members, the minimum mass flow of supplemental oxygen required for each crew member may not be less than the flow required to maintain, during inspiration, a mean tracheal oxygen partial pressure of 122 mmHg, up to and including a cabin pressure altitude of 10668 m (35,000 ft), and 95% oxygen between cabin pressure altitudes of 10668 m (35,000) and 12192 m (40,000 ft), when breathing 20 litres per minute BTPS. In addition, there must be means to allow the crew to use undiluted oxygen at their discretion.

(c) For passengers and cabin crew members, the minimum mass flow of supplemental oxygen required for each person at various cabin pressure altitudes may not be less than the flow required to maintain, during inspiration and while using the oxygen equipment (including masks) provided, the following mean tracheal oxygen partial pressures:

(1) At cabin pressure altitudes above 3048 m (10,000 ft) up to and including 5639 m (18,500 ft), a mean tracheal oxygen partial pressure of 100 mmHg when breathing 15 litres per minute, BTPS, and with a tidal volume of 700 cm3 with a constant time interval between respirations.

(2) At cabin pressure altitudes above 5639 m (18 500 ft) up to and including 12192 m (40,000 ft), a mean tracheal oxygen partial pressure of 83·8 mmHg when breathing 30 litres per minute, BTPS, and with a tidal volume of 1100 cm3 with a constant time interval between respirations.

(d) If first-aid oxygen equipment is installed, the minimum mass flow of oxygen to each user may not be less than 4 litres per minute, STPD. However, there may be a means to decrease this flow to not less than 2 litres per minute, STPD, at any cabin altitude. The quantity of oxygen required is based upon an average flow rate of 3 litres per minute per person for whom first-aid oxygen is required.

(e) If portable oxygen equipment is installed for use by crew members, the minimum mass flow of supplemental oxygen is the same as specified in subparagraph (a) or (b) of this paragraph, whichever is applicable.

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13.2. Proposed CS 25.1443 wording

CS 25.1443 Minimum mass flow of supplemental oxygen

(a) If continuous flow equipment is installed for use by flight-crew members, the minimum mass flow of supplemental oxygen required for each crew member may not be less than the flow required to maintain, during inspiration, a mean tracheal oxygen partial pressure of 149 mmHg when breathing 15 litres per minute, BTPS, and with a maximum tidal volume of 700 cm3 with a constant time interval between respirations.

(b) If demand equipment is installed for use by flight-crew members, the minimum mass flow of supplemental oxygen required for each crew member may not be less than the flow required to maintain, during inspiration, a mean tracheal oxygen partial pressure of 122 mmHg, up to and including a cabin pressure altitude of 10668 m (35,000 ft), and 95% oxygen between cabin pressure altitudes of 10668 m (35,000) and 12192 m (40,000 ft), when breathing 20 litres per minute BTPS. In addition, there must be means to allow the crew to use undiluted oxygen at their discretion.

(c) For passengers and cabin crew members at rest, the minimum mass flow of supplemental oxygen required for each person at various cabin pressure altitudes may not be less than the flow required to maintain, while using the oxygen equipment (including masks) provided, the following oxygen blood saturation levels for 95% of the population:

(1) for short duration exposure (maximum 1 min), a minimum oxygen blood saturation level of 84%.

(2) for long term duration[3] exposure (above 1 min), a minimum oxygen blood saturation level of 90%.

(d) If first-aid / medical oxygen equipment is installed, the minimum mass flow of oxygen to each user may not be less than 4 litres per minute, STPD. However, there may be a means to decrease this flow to not less than 2 litres per minute, STPD, at any cabin altitude. The quantity of oxygen required is based upon an average flow rate of 3 litres per minute per person for whom first-aid oxygen is required.

(e) If portable oxygen equipment is installed to protect cabin crew members against hypoxia, the minimum mass flow of supplemental oxygen may not be less than the flow required to sustain typical cabin crew physical activities after decompression, at cabin pressure altitudes above 3048 m (10,000 ft) up to and including 7620 m (25,000 ft) for 95% of the population.

[3] Maximum exposure time would be limited by high terrain flight conditions sickness.

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13.3. Current AMC to CS 25.1443 wording

No AMC in EASA CS 25 current issue (at the date of this report).

13.4. Proposed AMC to CS 25.1443(c) wording

Experimental Acceptable Means of Compliance should be designed in a way to demonstrate that required minimum levels of S_aO_2 are met when individuals are exposed to various altitude levels.

1.<u>Test subjects selection</u>

Use 10 sensitive (compliant) subjects.

To ensure that 95% of the passengers' population is protected, subjects shall be selected upon the part of the population most sensitive to altitude. From this, the selection process can be made even more powerful by experimentally finding the most sensitive persons of this sub-group, e.g. based upon their S_pO_2 levels, breathing air at high altitude.
An example can be found for European population as of January 2011: an individual having a S_pO_2 level below 80% at 15,000ft belongs to the most sensitive 5%.

2.<u>Performance Tests</u>

<u>Minimum performance levels:</u>

- 84% S_aO_2 for short duration exposure (less than 1 min);
- 90% S_aO_2 for long term exposure (for over 1 min).

For this test, the subject's arterial blood oxygen saturation shall be determined by use of the continuous recording oximeter. Throughout the test, a drop below the required minimum blood oxygen saturation level shall not be allowed. The blood oxygen saturation values achieved shall be recorded at each interval of altitude at which a test is made.

<u>Procedure:</u>

Oxygen pre-breathing should be provided to subjects before ascending to altitude, as a protection against Decompression Sickness.

- Ascend to 9144 m (30,000 ft) with the subject wearing a pressure demand type mask and breathing 100% oxygen.
- Level off and have the test subject put on the test mask.
- The oxygen supply to the test mask at this and subsequent levels shall be set according to the equipment specifications.
- Ascend to the maximum altitude that approval is desired, level off, remain at this altitude until the oxygen saturation has stabilized, but in no case remain for less than three minutes at this altitude.
- Record the lowest values for blood oxygen saturation obtained. The reading shall not fall below the required values.
- Should this happen, immediately increase the oxygen flow to the mask and make the required changes to meet the required minimum blood oxygen saturation level.
- Descend at 2286 m (7500 ft) intervals recording the blood oxygen saturation at each interval.

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The validity of performance tests shall be demonstrated by testing 10 devices on at least 10 sensitive human subjects (selected accordingly to paragraph 1), except that only well indoctrinated subjects may be exposed to altitudes greater than 12 192 m (40,000 ft).
Each subject shall be tested at increments of not more than 2286 m (7500 ft) altitude between 3048 m (10,000 ft) and the maximum altitude for which approval is desired with the mask held in place by the suspension device.

For these tests, the subject shall wear the mask in an altitude chamber, and the oxygen flows to the mask at the various altitudes between 3048 m (10,000 ft) and the maximum altitude that approval is desired shall be set according to the equipment specifications. During the testing if the subject's arterial blood oxygen saturation falls below the minimum required blood oxygen saturation level, the oxygen flow to the mask shall be increased sufficiently to bring the blood oxygen saturation to the required values (at least 84% for any altitude above 10668 m (35,000ft), at least 90% for any other altitude).
No test results may be discarded without adequate reason and full written explanation.
Subject selection data shall be provided along with the test results.

Test implementation advices:
Continuous monitoring of arterial oxygen saturation represents a primary pass/fail criterion. Any consistent measurement below 70% at rest leads to immediate test abortion, 75% will be the lowest limit to be tolerated during regular testing. In this test set-up abortion means the provision of supplemental oxygen with saturation coming up to at least 85%.

Acceptance criteria:
The fraction of subjects passing the test without the need to increase the flow setting shall fulfil the 95% protection criteria.

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