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An efficient mass casualty breathing system for oxygen therapy

Determining the compatibility of the Pulmanex® Hi-OX® mask with the CAF's in-service oxygen concentrator, POGS 33

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Defence R&D Canada
Technical Report
DRDC Toronto TR 2013-126
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Canada

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IMPORTANT INFORMATIVE STATEMENTS

The investigation was funded by the Canadian Armed Forces Health Services Group Headquarters in collaboration with Defence Research and Development Canada.

In conducting the research described in this report, the investigators adhered to the policies and procedures set out in the Tri-Council Policy Statement: Ethical conduct for research involving humans, National Council on Ethics in Human Research, Ottawa, 1998 as issued jointly by the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council of Canada.

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Abstract

Defence Research and Development Canada was tasked by the Canadian Armed Forces (CAF) Health Services Group Headquarters to develop an efficient mass casualty breathing system for oxygen (O_2) therapy in remote areas. This report describes the second phase of the project to assess the performance of the Pulmanex® Hi-OX® mask (HIOX) when combined with the Portable Oxygen Generation System 33C (POGS), the CAF's in-service O_2 concentrator. First, unmanned tests were conducted to determine the quality and the quantity of the POGS product gas. Then, in human trials, nine participants (21 to 58 years) breathed O_2 at rest through the HIOX using the POGS as the O_2 supply. The test procedure consisted of three breathing periods of 5 min at either 2, 4 or 6 litres per min. Measurements included inhaled and end-tidal fractions of O_2 and carbon dioxide, O_2 arterial blood saturation, exhaled gas volume, and mask pressure. Subjective ratings of comfort and breathing effort were obtained after each breathing period. The unmanned testing showed that the POGS can safely be used to supply high concentrations of oxygen with no contaminants or toxic gases. Human testing revealed that the HIOX-POGS system delivered clinically useful O_2 levels. In terms of the measured dependent variables, the results obtained with the POGS proved to be as good as those of the compressed O_2. The use of the HIOX with an O_2 concentrator will provide sustained O_2 with increased efficiency and minimum risks associated with O_2 use during CAF medical operations.

Résumé

Recherche et développement pour la Défense Canada a été chargé par le Quartier général du Groupe des Services de santé des Forces armées canadiennes (FAC) de mettre au point un système d'oxygénothérapie utilisable auprès d'un grand nombre de blessés dans les régions éloignées. Le présent rapport décrit la deuxième phase du projet visant à évaluer le masque Pulmanex^{MD} Hi-OX^{MD} (HIOX) en association avec le Système portatif de production d'oxygène 33C (SPPO), le concentrateur d'oxygène (O_2) utilisé par les Forces armées canadiennes. La quantité et la qualité des gaz produits par le SPPO ont été effectuées. Dans les tests humains, neuf participants (de 21 à 58 ans) ont inhalé de l'O_2 au repos à l'aide du HIOX, le SPPO étant utilisé comme source d'approvisionnement en O_2. L'évaluation consistait en trois périodes d'inhalation de 5 min à des débits de 2 à 6 litres par min, séparées par une pause de 5 min durant laquelle les sujets respiraient de l'air. Au nombre des paramètres mesurés figuraient les fractions d'O_2 et de dioxyde de carbone dans l'air inspiré et en fin d'expiration, la saturation en O_2 du sang, le volume des gaz expirés et la pression au masque. Des mesures subjectives du confort et de l'effort d'inhalation ont été obtenues après chaque période d'inhalation. Les épreuves techniques ont révélé que le SPPO peut être utilisé en toute sécurité pour l'approvisionnement en oxygène avec des concentrations élevées d'O_2 et l'absence de contaminants ou de gaz toxiques. Les données recueillies chez les sujets ont montré que le système HIOX-SPPO fournissait des concentrations d'O_2 cliniquement utiles. Pour ce qui est des variables dépendantes mesurées, le SPPO s'avérait aussi bon que l'O_2 comprimé. Le recours au système HIOX-O_2 concentrateur permettra d'obtenir un approvisionnement continu en O_2, d'accroître l'efficience et de réduire les risques associés à l'utilisation d'O_2 durant les opérations médicales des FAC.

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Executive summary

An efficient mass casualty breathing system for oxygen therapy

F. Bouak; D.J. Eaton; DRDC Toronto TR 2013-126; Defence Research and Development Canada – Toronto; October 2013.

Background: Oxygen (O_2) therapy is regularly provided in the field, but available O_2 supplies often do not meet the therapeutic requirements, particularly when prolonged treatment is required. Weight, volume and risk restrictions dictate the amount of O_2 available in the field. Oxygen concentrators could eliminate this deficiency; however, their O_2 production rate does not meet the high supply flow rates needed for traditional O_2 masks. Defence Research and Development Canada was tasked by the Canadian Armed Forces (CAF) Health Services Group Headquarters (H Svc Gp HQ) to develop an efficient mass casualty oxygen breathing system for O_2 therapy in remote areas. This report describes the second phase of the project to determine the compatibility, the safety and the performance of the Pulmanex® Hi-OX® mask (HIOX), a low-flow rate, open-circuit mask, with the CAF's in-service O_2 concentrator, the Portable Oxygen Generation System 33C (POGS) from On Site Gas Systems, Inc. The POGS is an O_2 supply system that removes nitrogen (N_2) from ambient air and delivers to the patient O_2-enriched mixed gas of approximately 95% O_2; 4% Argon (Ar) and 1% others. This study also presents a breathing performance comparison between the POGS system and traditional pressurized cylinders.

Results: The unmanned testing showed that the POGS can safely be used to supply therapeutic oxygen. The gas sampling of the product gas showed high O_2 concentrations (95.2%) and no contaminant or toxic gas. Nine male and female volunteers between the ages of 21 and 58 years participated in the study. The test procedure consisted of 3 breathing periods of 5 minutes at 2, 4 or 6 litres per minute. Each breathing period was separated by a 5-minute air-break. Subjects sat comfortably and breathed O_2 at their own resting respiratory rate. Measurements included inhaled and end-tidal O_2, Ar and carbon dioxide (CO_2) fractions, arterial blood O_2 saturation, exhaled gas volume, and mask pressure. Subjective ratings of comfort and breathing effort were obtained after each breathing period. Subjects' data revealed that the HIOX-POGS system delivered clinically useful O_2 levels. In terms of measured dependent variables, the HIOX-POGS system proved to be as good as the combination HIOX-Cylinder. The use of the HIOX-POGS system will provide sustained O_2, increase the efficiency, and minimize weight, volume and risks associated with O_2 use.

Significance: The use of an O_2 concentrator appears to be a better and a safer choice than compressed oxygen cylinders. More oxygen would be available to treat more casualties. Given the effectiveness of the HIOX with the O_2 concentrator at both high and low oxygen flows, currently-used O_2 systems (i.e., high flow rate mask and O_2 cylinders or chemical generators) could be replaced for field operation in remote areas. This will benefit CAF's field hospitals, submarine escape and rescue survivor treatment, and, in the future, as smaller portable O_2 concentrators become available, the CAF's Search and Rescue operations.

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Sommaire

An efficient mass casualty breathing system for oxygen therapy

F. Bouak; D.J. Eaton ; DRDC Toronto TR 2013-126 ; Recherche et développement pour la défense Canada – Toronto; octobre 2013.

Contexte : De l'oxygène (O_2) est régulièrement administré sur le terrain, mais les réserves d'O_2 disponibles ne permettent pas souvent de combler les besoins thérapeutiques, en particulier lorsqu'un traitement prolongé est nécessaire. Des restrictions relatives au poids, au volume et au risque déterminent la quantité d'O_2 disponible sur le terrain. Des concentrateurs d'oxygène pourraient pallier cet inconvénient; toutefois, leur taux de production d'O_2 ne permet pas d'assurer les débits d'approvisionnement élevés dont on a besoin pour les masques d'O_2 classiques. Recherche et développement pour la Défense Canada a été chargé par le Quartier général du Groupe des Services de santé (QG Gp Svc S) des Forces armées canadiennes (FAC) de mettre au point un système d'oxygénothérapie utilisable auprès d'un grand nombre de blessés dans les régions éloignées. Le présent rapport décrit la deuxième phase du projet visant à vérifier la compatibilité, la sécurité et la performance du masque Pulmanex^{MD} Hi-OX^{MD} (HIOX), un masque à faible débit et à circuit ouvert, lorsqu'il est couplé au concentrateur d'O_2 utilisé par les FAC, le Système portatif de production d'oxygène 33C (SPPO) d'On Site Gas Systems, Inc. Le SPPO est un système d'approvisionnement en O_2 qui enlève l'azote (N_2) de l'air ambiant et fournit au patient des gaz mélangés enrichis en O_2 d'environ 95% d'O_2, 4% d'argon (Ar) et 1% d'autres gaz. Nous comparons également dans la présente étude la performance du SPPO avec celle des bouteilles d'O_2 comprimé classique.

Résultats : Avant d'effectuer des tests chez les humains, les épreuves techniques ont montré que le SPPO peut être utilisé en toute sécurité pour fournir de l'oxygène thérapeutique. L'échantillonnage des gaz du produit a mis en évidence des concentrations élevées d'O_2 (95,2%) et l'absence de contaminants ou de gaz toxiques. Neuf volontaires âgés de 21 à 58 ans ont participé à l'étude. L'évaluation consistait en trois périodes d'inhalation de 5 minutes à des débits de 2, 4 ou 6 litres par minute. Chaque période d'inhalation était séparée d'une pause de 5 minutes durant laquelle les sujets respiraient de l'air. Ces derniers étaient confortablement assis et ont inhalé de l'O_2 à leur propre rythme respiratoire au repos. Parmi les paramètres mesurés figuraient les fractions d'O_2 et de dioxyde de carbone du gaz inspirées et en fin d'expiration, la saturation en O_2 du sang artériel, le volume des gaz expirés et la pression au masque. Des mesures subjectives du confort et de l'effort d'inhalation ont été obtenues après chaque période d'inhalation. Les données recueillies chez les sujets ont montré que le système HIOX-SPPO fournissait des concentrations d'O_2 cliniquement utiles. Pour ce qui est des variables dépendantes mesurées, le système HIOX-SPPO s'avérait aussi bon que le HIOX-O_2 comprimé. Le recours au système HIOX-SPPO permettra d'obtenir un approvisionnement continu en O_2, d'accroître l'efficience et de réduire le poids, le volume et les risques associés à l'utilisation d'O_2.

Importance : L'emploi d'un concentrateur d'O_2 semble être une solution plus efficace et plus sûre que les bouteilles d'O_2 comprimé. On disposera ainsi d'une plus grande quantité d'O_2 pour traiter un plus grand nombre de blessés. Compte tenu de l'efficacité du HIOX utilisé avec des concentrateurs d'O_2 à des débits élevés et faibles, ce système pourrait remplacer les systèmes d'O_2 actuellement en service (soit le masque à débit élevé et les bouteilles d'O_2 ou les générateurs

chimiques) dans les opérations sur le terrain en régions éloignées. Ce système serait utile aux hôpitaux de campagne des FAC, ainsi que pour le traitement des survivants des opérations de sauvetage et de secours des équipes de sous-marins; dans l'avenir, lorsqu'on aura accès à des concentrateurs d'O_2 portatifs plus petits, il pourra aussi être employé dans les opérations de secours et de sauvetage des FAC.

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Acknowledgements

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1 Introduction

1.1 Background

Oxygen (O_2) is often given as a first aid treatment to casualties, but, in remote areas, available O_2 supplies often do not meet therapeutic requirements, particularly when prolonged treatment is required. Oxygen can be delivered from a supply to the casualty via a breathing unit in several ways. Pressurized cylinders are the most commonly-used O_2 supply. Oxygen can also be delivered from other systems, such as chemical O_2 generators or O_2 concentrators. Both compressed O_2 and chemical generators are neither an economical nor an efficient supply for remote areas. Their weight, volume, fire and explosive risks restrict the amount of O_2 that can be transported to the patient in the field.

Oxygen concentrators could eliminate this deficiency; however, their O_2 production rate does not meet the needs of traditional O_2 masks [1], which require high O_2 supply flows. A new promising low flow mask, the Pulmanex® Hi-OX® mask[1] (HIOX) was evaluated [2, 3]. It was demonstrated that the HIOX significantly exceeded the commonly used simple facemask in terms of performance and efficiency for O_2 flowrates between 4 and 9 litres per minute ($L \cdot min^{-1}$) STPD[2] [2]. The investigators also demonstrated that it was safe to use the HIOX with low flows (0.5 to 4 $L \cdot min^{-1}$) [3], allowing the use of oxygen concentrators to supply O_2 to this mask.

Defence Research and Development Canada (DRDC) proposed that the HIOX could form the basis of an oxygen therapy system that would be supplied by oxygen concentrators [2, 3]. This combination would increase the efficiency and eliminate the risk of transporting and using compressed oxygen in the field.

The Canadian Armed Forces (CAF) Health Services Group Headquarters (H Svcs Gp HQ) tasked DRDC to determine the compatibility and the safety of the HIOX with the CAF's in-service O_2 concentrator, the Portable Oxygen Generation System 33C (POGS) [4] by On Site Gas Systems, Inc.

1.2 Purpose

The objective of the present study is to test the compatibility of the HIOX using the POGS in terms of concentration, flowrate and temperature of the delivered O_2 and then, compare the results to those obtained using the HIOX in association with pressurized cylinders [2, 3]. The aim is to demonstrate that the HIOX is safe for use with an O_2 concentrator, thereby allowing the replacement of currently used O_2 systems (i.e., a high flowrate mask and O_2 cylinders or chemical

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[1] This was the mask's brand name when it was evaluated by DRDC. It was manufactured by VIASYS MedSystems. The mask is now a product of Ceretec Inc. (www.ceretecmed.com) and sold under the name: *Hi-Ox™ - High Oxygen Delivery Mask*. Although, the current version of the mask is slightly different, its operation remains the same (e.g., flow exchange) and Ceretec Inc. claims that the new HIOX has maintained the same performance as the former version.

[2] All flowrates are referenced to 0^oC and 101.3 kPa, dry gas, i.e., standard temperature and pressure, dry conditions (STPD) unless indicated otherwise.

generators) by the HIOX-O_2 concentrator system for a safe and sustained O_2 treatment of multiple casualties in remote areas. The study will benefit CAF's field hospitals, submarine escape and rescue survivor treatment and, eventually, Search and Rescue (SAR) operations as smaller O_2 concentrators become available.

1.3 Oxygen concentrator

Pressurized gas cylinders are traditionally used to supply patients with O2. Oxygen concentrators are relatively new (approximately 25 years) [5]. Their popularity is driven by the significant cost savings over traditional supplies and the "unlimited" availability of O_2 [6-8]. This is particularly evident in remote areas such as in rural Africa or in high altitude countries, where the supply of oxygen, produced locally or provided by transportation of O_2 cylinders, can be erratic, unreliable and expensive [9-12]. In some regions, resupply of O_2 can take months [5]. In Western countries, O_2 concentrators are commonly used for home O_2 therapy of patients with cardio-respiratory problems that cause hypoxemia [6, 7, 9]. Furthermore, their utilization is growing rapidly in hospitals. Friesen et al. [7] reported that 52 Canadian hospitals utilized O_2 concentrators for their daily operations in 1999 and several had made them their primary source of hospital O_2 to avoid the increased cost of cryogenic O_2.

Oxygen concentrators remove nitrogen (N_2) from ambient air (inlet) and delivers to the patient oxygen-enriched mixed gas (approximately 95% O_2, 4% Argon [Ar], and 1% others) [5]. Figure 1 illustrates the process of producing oxygen-rich gas. Room air is drawn through a series of bacteria and particulate filters, compressed by a centrifugal blower to a pressure of about 20 psi (1.4 atmospheres) and dried. It then passes through a column of zeolite which adsorbs N_2 while O_2 passes through. The adsorbed N_2 is then released and returned into the atmosphere, and the output gas is stored in a small reservoir before being supplied to the patient through a flow meter.

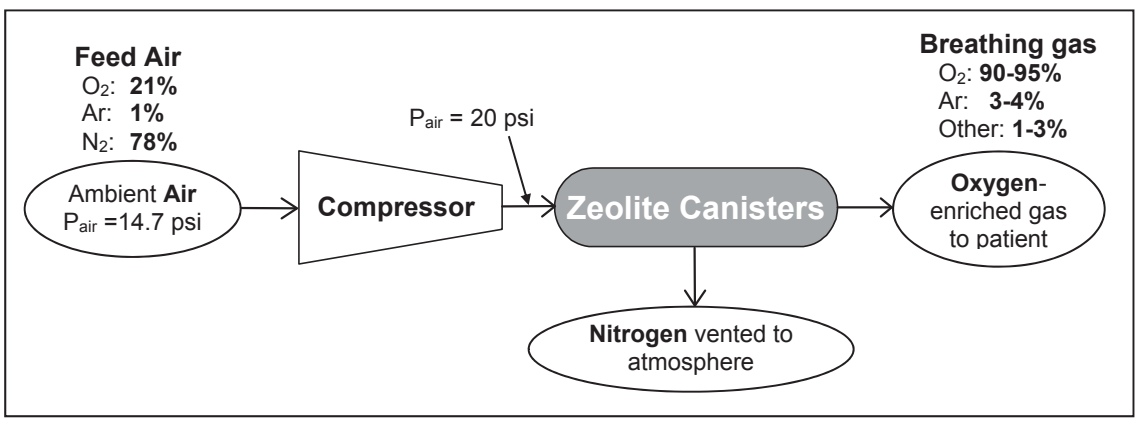

Figure 1: Operation diagram of an O_2 concentrator

Oxygen concentrators can deliver a continuous output of O_2-enriched breathing gas to the patient using a process called pressure swing adsorption (PSA). Typically, two canisters of zeolite are used. During the PSA cycle, the first canister absorbs N_2 (the O_2 production phase) while the second regenerates itself (the purge phase) by releasing N_2 to the atmosphere.

Current O_2 concentrators vary from large concentrators for remote (or field) hospitals to portable, battery-supplied units for individual patients. The O_2 concentrator used in this study is the POGS, the CAF's in-service O_2 concentrator (Figure 2). It is manufactured by On Site Gas Systems, Inc. (OSG) [4] and is cleared by the US Federal Drug Agency (FDA) for medical use (licence # K041664).

The POGS system consists of three main components (see Figure 2): a feed air compressor; an accessory kit with micro-booster to charge oxygen cylinders; and a generator which includes a molecular sieve concentrator, two gas analyzers (for O_2 and carbon monoxide [CO]) and an electronic control unit. The principal specifications and characteristics of POGS are in Annex A1.

The role of the feed air compressor is to supply compressed air to the generator. The Micro-booster has two roles. It fills O_2 cylinders using the oxygen provided by the generator and also provides backup O_2 from already filled cylinders through a regulator and the generator's O_2 outlet ports, in the event of power failure or interruption to the generator. The backup configuration can also provide additional O_2 supply in case of a high O_2 flow demand (e.g., mass casualty scenario) that exceeds the generator's output capacity [4]. There is also a high volume booster available as an optional component (see Annex A1).

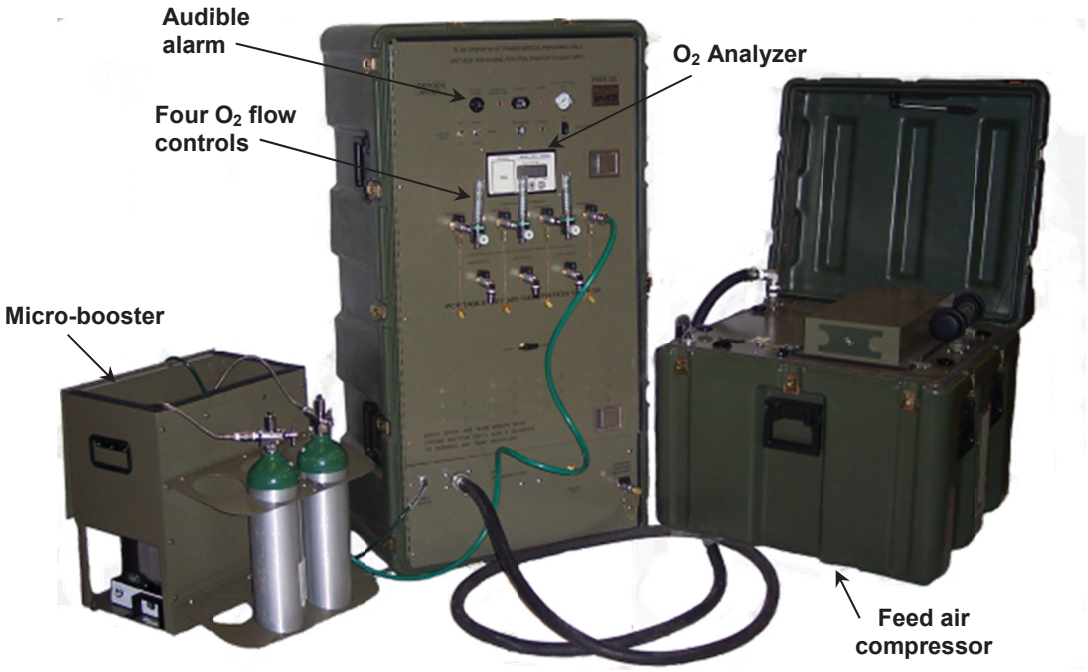

Figure 2: The Portable Oxygen Generation System 33C (POGS) [4]

OSG claims that their system provides medical grade dry air and oxygen (90-96% USP[3] depending on the output O_2 flowrate) at 50 psig and lower output pressures, and is compatible with commercial oxygen-consuming equipment and accessories such as cannulas, oronasal masks, ventilators and anaesthesia units in a field hospital. OSG claims that the maximum O_2 flow available from the POGS is 33 $L \cdot min^{-1}$.

This study had two components. First, unmanned tests of the POGS were conducted to verify the manufacturer-claimed quality of the delivered gas (e.g.; purity, flowrate, O_2 content, temperature, pressure and relative humidity). The second component involves an evaluation of the POGS-HIOX system by human subjects.

1.4 Hypotheses

Since the POGS provides lower oxygen levels than the standard pressurized tank (90-96% O_2 for POGS versus 100% O_2 for tanks), we hypothesized that the effect of the breathing gas supplied by the POGS through the HIOX mask would be different to the effect of a standard pressurized O_2 tank using the same breathing mask. Specifically, the O_2 concentration of the gas inhaled by the subjects breathing the POGS-generated gas would be lower. The effect on O_2 saturation was expected to be minimal or undetectable.

1.5 Assumptions

The assumptions are as follows:

1. There was no effect in the order of presentation of the conditions.

2. The subjects breathed at their resting breathing rate.

3. The mask was sealed adequately on all subjects.

4. The oxygen fraction from the POGS was consistent across all subjects.

[3] United States Pharmacopeia: The National Formulary. The United States Pharmacopeial Convention, Inc. (Rockville, MD)

2 Methods

2.1 Unmanned testing

2.1.1 POGS output gas analysis

Since the O_2-enriched gas produced by the POGS (i.e., product gas) is intended for breathing by humans, its quality is therefore critical. As a result, the product gas of the POGS was sampled and analyzed for O_2 concentration and also for detection of hazardous compounds such as CO_2, CO, particulates, condensed oil or traces of organic contaminants. Gas analysis and testing was performed by Maxxam Analytics Inc. [13], an independent laboratory accredited by the Canadian government.

POGS output gas was collected in a sample cylinder obtained from Maxxam. The general instructions were to flush the sample cylinder with the POGS-generated gas at a flow rate of 33 $L \cdot min^{-1}$ for 20 min and then fill the sample cylinder up to a specified pressure. The purpose is to collect oil and particulate matter on the filter as the gas flows through the cylinder. The sample cylinder was then sent back to Maxxam for a detailed gas analysis, and a test report was produced.

2.1.2 Effect of oxygen flow on output gas characteristics

The POGS was operated through a range of output gas flowrates from 2 to 60 $L \cdot min^{-1}$. For each flow condition, measurements were collected over a time period of 60 min at 10 samples per minute and included the oxygen concentration ($O_{2\text{-}POGS}$) using an O_2 analyzer (Servomex 570, 0-100% O_2, ± 0.1%), the temperature (T_{POGS}) using a thermistor (Yellow Spring Instrument, Model 44004) and the relative humidity (RH) using a hygrometer (Rotronic Hygromer™ H100D, ±2% RH for 0-100% RH at 25°C). A mean value of each measured variable was calculated for the last 10 min for analysis.

2.2 Human evaluation

2.2.1 Mask description

The Pulmanex® Hi-OX® Mask (Figure 3) is a commercial product manufactured by VIASYS MedSystems and approved by Health Canada for medical use (medical device licence: 38961). It is an open circuit continuous flow mask designed to improve gas usage efficiency, that is, low O_2 supply flowrates (Q_{O2}) combined with high O_2 concentration. If the patient ventilation rate is higher than the Q_{O2}, a one-way valve opens to let in ambient air to make up for the volume deficit between the oxygen delivered and the patient demand.

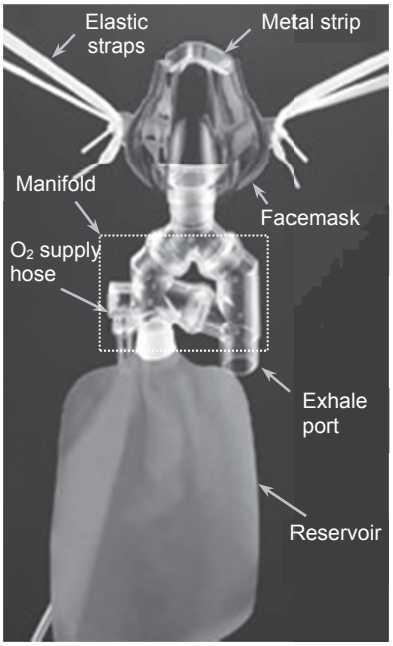

Figure 3: The Pulmanex® Hi-OX® mask

2.2.2 Subjects

The DRDC Human Research Ethics Committee (HREC) approved the experimental protocol. A total of nine military and civilian subjects volunteered to participate in this study. Ages were between 21 and 58 years. Table 1 summarizes their physical characteristics and Annex A2 lists their individual characteristics. All subject candidates were recruited from DRDC staff. Prior to inclusion in the study, all subjects gave their written consent after being informed of the details, discomforts and risks associated with the experimental protocol and then underwent a medical examination by a physician to determine respiratory symptoms and eligibility. Remuneration for participation complied with guidelines established by DRDC and the Department of National Defence (DND). Each subject committed a total time of about 70 minutes (min) for preparation and test run. None of the subjects withdrew from the study.

Table 1: Subjects Characteristics.

	Mean ± SD[1]	Range
Age *(yr)*	40 ± 12	21 – 58
Weight *(kg)*	83 ± 18	52 – 110
Height *(m)*	1.77 ± 0.11	1.58 – 1.93

[1] SD: Standard deviation

2.2.3 Experimental set-up and data acquisition

In addition to the POGS, breathing oxygen was provided by a K-cylinder (244 ft^3 STPD) using a high purity oxygen regulator (Matheson Gas Products, Model 3104C). The supply oxygen flowrates were adjusted using a computer-controlled mass flow controller (Brooks 5850 series, 0-10 $L \cdot min^{-1}$). A chain-compensated gasometer (Warren E. Collins, 120 L) was used to calibrate the flow controller.

Arterial blood oxygen saturation (SaO_2) was measured with a pulse oximeter (OXI by Radiometers Copenhagen) connected to the index or the middle finger of the subject's right hand. The measurements were taken before oxygen breathing (no mask was worn and subject breathed ambient air) and during oxygen breathing for each O_2 flowrate.

As shown in Figure 4, the oronasal mask was instrumented to measure O_2, CO_2 and Ar fractions, as well as the temperature and the pressure of the breathing medium inside the mask.

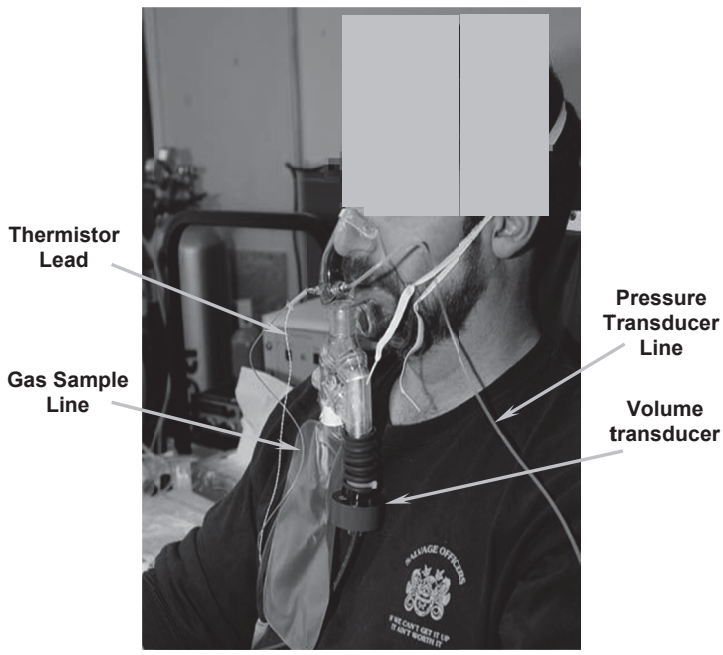

Figure 4: Details of the instrumented mask.

A gas sample line (Intramedic polyethylene tubing by Clay Adams, Model PE-60, 0.76 mm I.D. x 1.22 mm O.D. x 1 m long) and a thermistor (Yellow Spring Instrument, Model 44004) were inserted into the facemask about two centimetres from the subject's mouth and nose. The gas inside the mask was constantly sampled at a flowrate of 30 millilitres per minute. The sample line was connected to a mass spectrometer (Hiden HPR20) via a heated capillary line of about 1.9 m long. For the flowrate and the sample line length used in this experiment, the sample line delay was about 1.5 sec.

The mass spectrometer was calibrated before the start of each trial with two calibration gases (certification tolerance: ±0.02 mole %), a 100% O_2 calibration gas and a mixture of 5% CO_2, 75% O_2 and 20% N_2). Also, the mass spectrometer was calibrated for argon using air.

Measurement of instantaneous mask pressure was through a second sample line which penetrated the left side of the mask (Figure 4) and connected to a pressure transducer (Validyne DP-15, ±0.5 psi diaphragm).

Exhaled gas passed through a turbine volume transducer (Ventilation Measurement Modules by Interface Associates), incorporated in the exhale side of the HIOX, to compute the respiratory minute volume, $\dot{V}_E$, and the additional atmospheric air that was inhaled through the exhale port of the mask.

Data from the instruments were continuously measured at a sampling frequency of 50 Hz. All lines from the instruments were connected to a data acquisition (DAQ) card (National Instruments, PCI-6259 M series) via a terminal block (National Instruments, SCC-68). The DAQ card was installed into a desktop computer running Windows® (Microsoft Corporation, Redmond, WA, USA). All experimental data were stored on the hard drive of the computer for further computation and statistical analysis. The DAQ card and computer were controlled using custom-written software in LabVIEW™ (National Instruments Corporation, Austin, TX, USA).

Custom-written analysis software (in LabVIEW™) was used to derive variables from the measured values. Instantaneous O_2, CO_2 and Ar mask fractions (f_mO_2, f_mCO_2 and f_mAr respectively) were used to compute inhaled and end-tidal gas fractions in each breath. Inhaled CO_2 fraction (f_ICO_2) was taken at the time of the lowest f_mCO_2 in each breath while end-tidal values of all three gas components ($f_{ET}CO_2$, $f_{ET}O_2$ and $f_{ET}Ar$) were taken at the time of the highest f_mCO_2 in each breath. Peak and minimum values of f_IO_2 and f_IAr were determined from the maximum and the minimum values of f_mO_2 and f_mAr.

Minute-averaged values were then calculated for each computed fraction (inhaled and end-tidal). Finally, a mean value was calculated for the last two minutes of each breathing period for analysis.

Mask thermistor and pressure data were used for determining end-inhalation and end-tidal temperatures and peak inhale and exhale pressures (P_{Ins} and P_{Exp}), respectively.

Subjects rated their perceived level for breathing effort (BE) and mask discomfort (MD). Rating tests were based on a 0 – 10 subjective scale [14].

2.2.4 Procedure

Baseline anthropometric measurements (weight and height) were collected for each subject (see Annex A2).

All tests were carried out at DRDC, Toronto Research Centre and subjects went through the following procedures:

- Subjects were first briefed on the test procedures, the use of the breathing unit to be tested, and the psychophysical scales used to assess BE and MD.
- An attendant instructed the subject in the proper use and fit of the HIOX. The subject's arterial blood oxygen saturation was measured before going on O2. Then, the subject

donned the HIOX and was instructed to breathe calmly at his/her own resting respiratory rate from the mask.

- The experiment was single-blinded. The participants knew neither which O2 supply, i.e., POGS or pressurized O2, from which they were breathing nor did they know the O2 flowrate (QO2).
- The experiment was broken into six breathing periods, following a 3 (flowrates: 2, 4, 6 L·min-1.) x 2 (O2 sources: POGS and Cylinder) repeated measures design. All independent variables were within-subject factors. Breathing periods were 5 min each separated by 5 min air-breaks. Subjects rated BE and MD at the end of each 5-min period. During these air-breaks, subjects took off their masks and breathed air.

Any 5-minute breathing period was halted when one of the termination criteria listed in Annex B were met.

2.2.5 Statistical analysis

Subject's oxygen blood saturation, O_2, CO_2 and Ar concentrations, and mask pressures were analyzed using multi-factor, repeated measures analysis of variance (ANOVA) to determine any significant differences in the dependent variables between (a) the POGS and compressed O_2, and (b) the three O_2 flowrates (breathing periods). When statistical significance was present (at the 0.05 alpha level), the Tukey's Honesty Significant Difference test was used to determine significant main effects or interactions. Subjective rating for breathing effort and mask discomfort were analyzed using Friedman's non-parametric test to determine any significant differences in the dependent variables between the above-mentioned factors (a) and (b). All statistical analyses were performed using the Statistical Toolbox of MATLAB® (The MathWorks, Inc., Natick, MA, USA) [15].

3 Results

3.1 Unmanned testing

3.1.1 POGS output gas analysis

Maxxam provided a detailed gas analysis test report (see Annex C). The report shows that the analyzed gas sample was O_2 at 95.2% and no hazardous components were found; i.e., all contaminant traces were within the limits allowed by the Canadian Standard Association CSA Z305.6-1992, a standard for medical oxygen concentrator central supply system for use with non-flammable medical gas piping system [16].

3.1.2 Effect of the POGS output gas on O_2 fraction, temperature and relative humidity

The temperature of product gas remained steady throughout the evaluation at 22-23°C. This was not different from ambient temperature. The relative humidity of the output gas was dry[4] as the measured relative humidity was equal to zero at each output gas flowrate.

Figure 5 represents the performance curve of the POGS in terms of O_2 concentration as a function of the product gas flowrate. The O_2 concentration remained relatively steady at 95% up to a flowrate of 33 L·min^{-1}, the highest value recommended by the manufacturer. Then, the O_2 level decreased progressively while its variability (i.e., standard deviation of each flowrate's sample) increased with the increase of $Q_{O2\text{-}POGS}$ (i.e., O_2 level = 95.5± 0.0% at 33 L·min^{-1} versus 79.5±1.6% at 60 L·min^{-1}).

3.2 Human trials

A total of nine subjects volunteered to evaluate the HIOX-POGS breathing system at 2, 4 and 6 L·min^{-1}. Mean values of minute ventilation, arterial blood oxygen saturation, mask concentrations of O_2, CO_2 and Ar, mask pressures, and subjective ratings for breathing effort and mask discomfort, averaged across all 9 subjects, are shown in Figures 6 to 12.

3.2.1 Minute ventilation

The subjects breathed from the HIOX at their own resting respiratory rate. Overall, mean minute ventilation was almost constant (at 8 L·min^{-1} BTPS[5]) and although the POGS supplied minute ventilations appeared slightly lower and minute ventilation increased with oxygen flow, Figure 6, statistically, minute ventilation was unaffected by the type of O_2 supply ($p=0.73$) or oxygen flow ($p=0.85$). The current results were very comparable to the values obtained in previous studies [2, 3] at the same conditions.

[4] That is, below the detection threshold of the instrument.
[5] Body temperature (37 ^{o}C) and pressure (101.3 kPa), saturated (57 mm Hg)

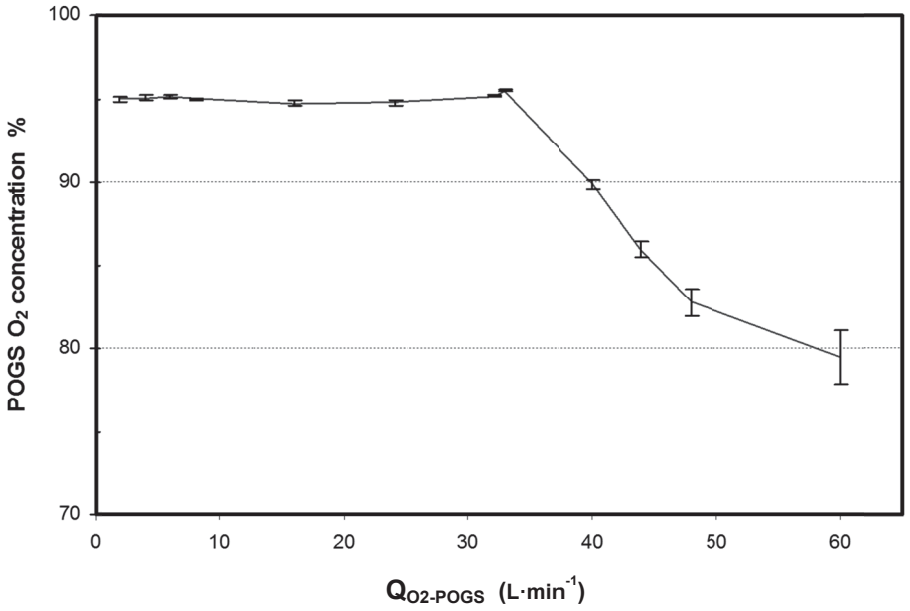

Figure 5: Performance curve of the POGS: Effect of the output gas flowrate on the O_2 level. Error bars are standard deviations.

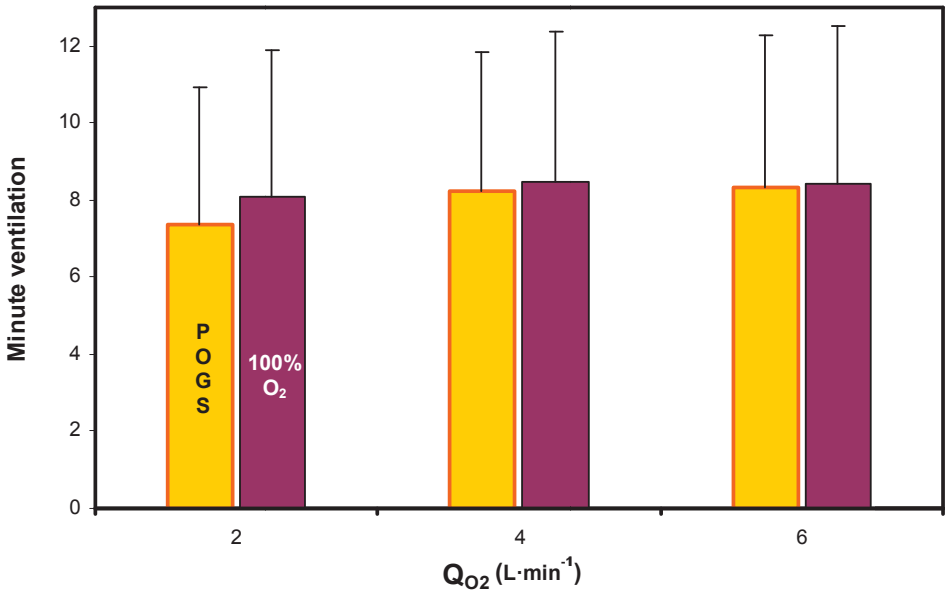

Figure 6: Minute ventilation (mean±SD) in $L \cdot min^{-1}$ BTPS

3.2.2 Arterial blood oxygen saturation, SaO_2

No significant difference was found between the two O_2 supplies (p=0.26). Figure 7 shows that the HIOX with either O_2 supplies significantly increased mean SaO_2 from the no-mask condition[6] (where SaO_2 was 95±2%) to over 98% (p<0.0001). As in the previous studies [2, 3], although no significant difference between 2, 4 and 6 $L \cdot min^{-1}$ was found (p=0.08), SaO_2 slightly increased with the increase of Q_{O2}.

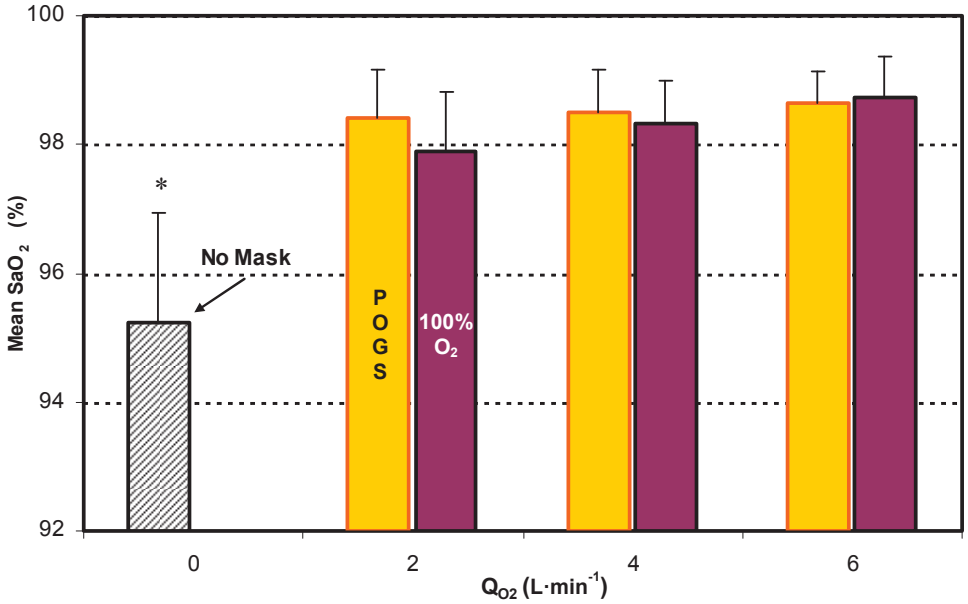

*Figure 7: Arterial oxygen saturation (mean±SD). No-Mask: subjects breathing ambient air. * No-Mask condition significantly different from O_2 breathing condition*

3.2.3 Oxygen fractions in the HIOX mask

The O_2 concentration delivered by the POGS to the HIOX at any time is shown in Table 2 as a function of Q_{O2}. Oxygen concentration increased very slightly with the increase of Q_{O2}.

Table 2: Oxygen level from the POGS (mean±SD)

Q_{O2} ($L \cdot min^{-1}$)	2	4	6
$fO_{2\text{-}POGS}$ (x 100)	95.03 ± 0.14	95.09 ± 0.13	95.15 ± 0.11

[6] No mask was worn for zero flow condition (0 $L \cdot min^{-1}$) and subject breathed ambient air.

Given the variation of O_2 level in the mask throughout inhalation [2, 17, 18], the authors chose to present the mean values of peak and minimum mask O_2 fraction to represent f_IO_2, as shown in Figure 8. The variation of end-tidal O_2 ($f_{ET}O_2$) is also shown in Figure 8. All three O_2 fractions increased significantly with Q_{O2}, regardless of the type of O_2 supply ($p<0.0001$). No significant difference was found between the two O_2 supplies in any of the three variables ($f_IO_{2\text{-peak}}$ ($p=0.24$), $f_IO_{2\text{-min}}$ ($p=0.53$), $f_{ET}O_2$ ($p=0.78$)). However, $f_IO_{2\text{-peak}}$ obtained with the POGS as a supply was lower than 100% O_2 regardless of Q_{O2}.

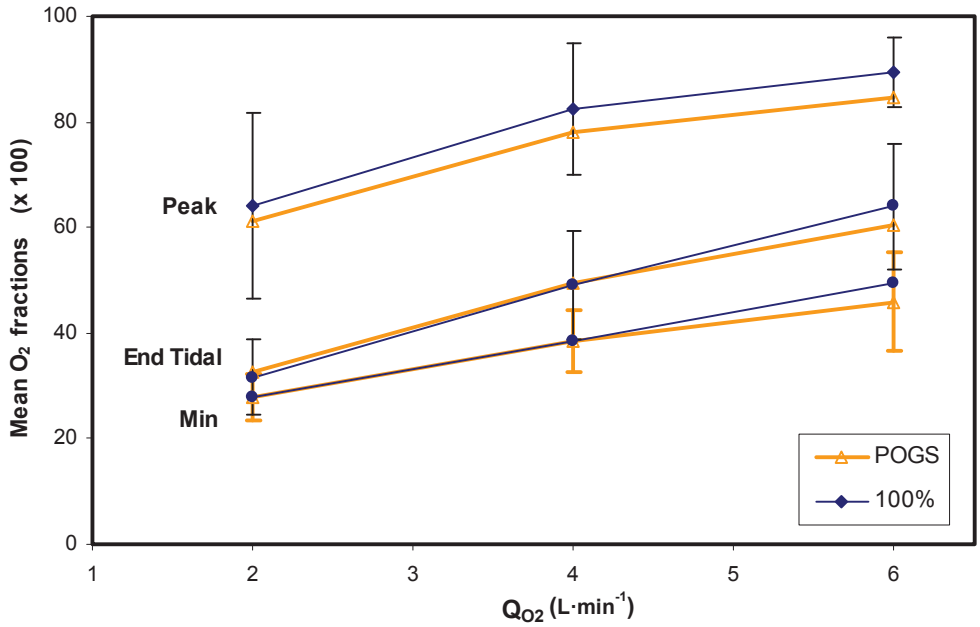

Figure 8: Oxygen fractions (mean±SD)

3.2.4 Argon fractions

With 100% O_2 from the cylinder, argon concentration was less than 1%. With the POGS, inhaled (peak and minimum values) and end-tidal Ar fractions (Figure 9) increased significantly with Q_{O2} ($f_IAr_{\text{-peak}}$ ($p=0.0075$), $f_IAr_{\text{-min}}$ ($p<0.001$), $f_{ET}Ar$ ($p<0.001$). The maximum inhaled mean value was 4.4±0.4%.

3.2.5 Inhaled and end-tidal carbon dioxide fractions

No significant difference was found between both O_2 supplies in either of the two variables ($p=0.64$ for f_ICO_2 and $p=0.80$ for $f_{ET}CO_2$). As shown in Figure 10, the degree of rebreathing in the HIOX with either supply was low (mean $f_ICO_2 < 0.005$). Oxygen flowrate had no significant effect on f_ICO_2 ($p=0.59$). The highest f_ICO_2 measured was 0.007 (0.7%) at 2 $L\cdot min^{-1}$. The effect of Q_{O2} on $f_{ET}CO_2$ was significant ($p=0.03$) for both supplies. End-tidal CO_2 decreased with the increase of Q_{O2}. The lowest $f_{ET}CO_2$ was 0.044 (4.4% by volume or a partial pressure of 33.4 mm Hg) at 6 $L\cdot min^{-1}$.

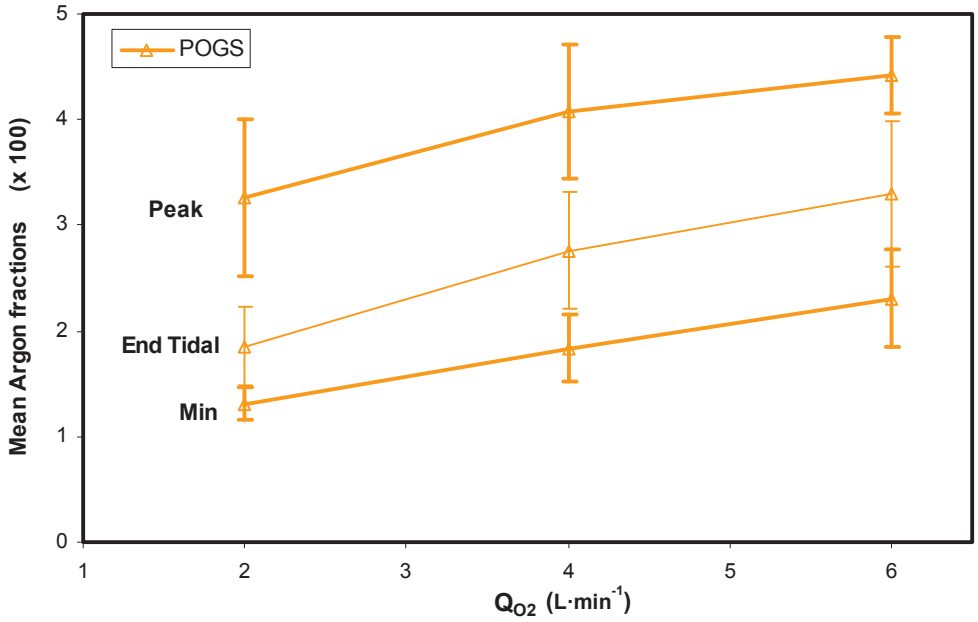

Figure 9: Argon fractions (mean±SD). Breathing gas supplied by the POGS

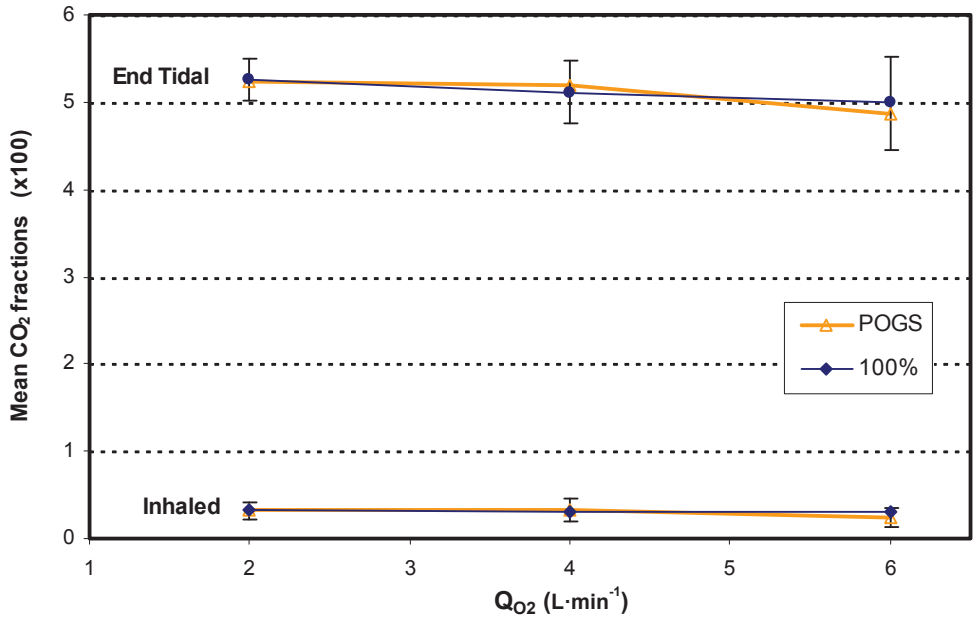

Figure 10: Inhaled and end-tidal CO_2 fractions (mean±SD)

3.2.6 Peak inhale and exhale pressures, P_{inh} and P_{exh}

In terms of breathing resistance, both P_{inh} and P_{exh} (Figure 11) were unaffected by the type of O_2 supply ($p > 0.88$) or Q_{O2} ($p > 0.81$).

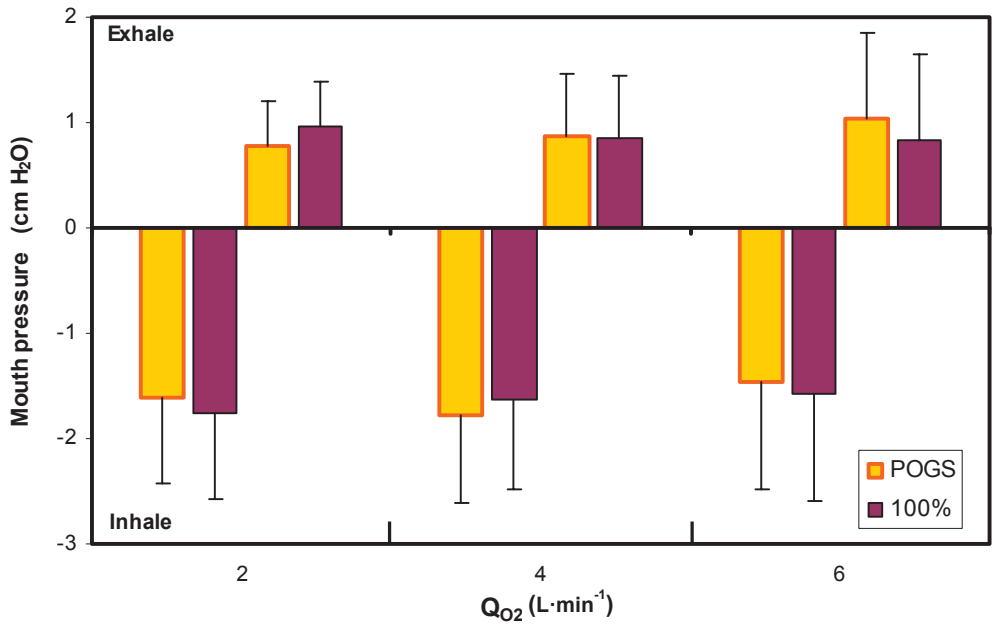

Figure 11: Mean peak inhale and exhale pressures

3.2.7 Mask discomfort (MD) and breathing effort (BE) subjective ratings

Both MD and BE (Figure 12) were rated below "slight" (i.e., <2 on a 10-point scale) for both O_2 supplies and all Q_{O2}. Although BE slightly decreased with the increase of Q_{O2}, both subjective variables (MD and BE) showed no statistical differences at different Q_{O2} and were unaffected by the type of O_2 supply ($p > 0.17$).

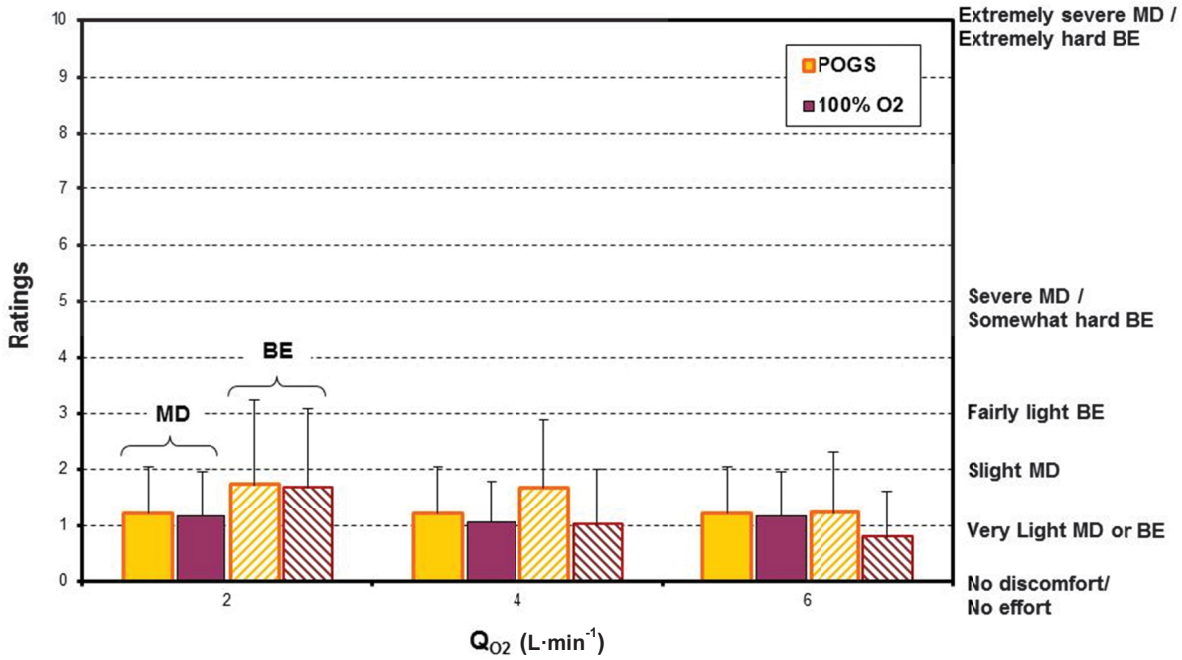

Figure 12: Mask discomfort (MD) and breathing effort (BE) ratings

4 Discussion and conclusion

This study was conducted to assess the respiratory effect of breathing oxygen-enriched gas using the CAF's in-service O_2 concentrator, the portable Oxygen Generation System 33C with the Pulmanex® Hi-OX® mask. The purpose was to demonstrate that the HIOX was safe for use with an O_2 concentrator, thereby allowing the replacement of currently used O_2 systems (i.e., the use of high flowrate masks with O_2 cylinders or chemical generators) with a combination of the HIOX and an O_2 concentrator for safe and sustained O_2 treatment of casualties in remote areas. The study is expected to benefit CAF's field hospitals, submarine escape and rescue survivor treatment and, in the future as smaller O_2 concentrators become available, CAF's SAR operations.

Tests of the POGS were conducted to determine the quantity and quality of the POGS-generated gas. At start up, the POGS required about 45 to 50 minutes to reach steady state in terms of O_2 concentration of the product gas. As demonstrated by the independent gas sampling and confirmed by these tests, the O_2 concentration was in the range of 94.9% to 95.5% for all O_2 flows up to 33 $L \cdot min^{-1}$. For higher flowrates, the O_2 concentration of the product gas decreased steadily with the increase of $Q_{O2\text{-}POGS}$. The reason for the declining O_2 concentration is the increased flow rate exceeds the N_2 adsorption rate of the zeolite. Consequently, more and more N_2 passes through the concentrator with the product gas as demand increases. It is noteworthy that the POGS maintained an O_2 concentration relatively high (about 80%) at 60 $L \cdot min^{-1}$. This may allow the treatment of a greater number of patients in a mass casualty situation. However, the O_2-enriched gas produced by the POGS at 60 $L \cdot min^{-1}$ must be sampled for hazardous compounds such as CO_2, CO and particulates to ensure its quality is maintained at high flowrates (> 33 $L \cdot min^{-1}$).

The results from testing the POGS with the HIOX on subjects indicated consistency with the literature and the POGS manufacturer's claims. The performance of the HIOX, in terms of the level of all dependent variables considered in this study, did not differ between either O_2 sources, except for Argon. Carbon dioxide fractions (peak and end-tidal), peak inhale and exhale pressures and subjective ratings in this study were comparable to the values obtained at O_2 flow rates of 8 and 9 $L \cdot min^{-1}$ in a previous study [2].

Figure 8 shows that the minimum value of inhaled O_2 fraction is lower than the O_2 end-tidal fraction. As discussed in previous investigations [2, 17, 18] , the variation of oxygen levels in the mask throughout inhalation is due to the sequential flow in the manifold of the mask which reduces O_2 requirement. On inhalation, the first fresh gas that fills the alveoli of the patient is high concentration O_2 from the reservoir of the mask. When the reservoir is empty, a small volume of CO_2 rich exhaled air and then fresh ambient air mix with the stream of fresh O_2. This is followed by ambient air at the end of inhalation, which drops the mask O_2 level to a minimum value. It has been clearly shown that the last diluted portion of inhaled gas fills the anatomical dead space volume (mouth and airways) and has no (or a minor) effect on alveolar gas exchange. Therefore the last portion of the inhaled gas and the first portion of the exhaled gas (from the anatomical dead space) have a lower O_2 concentration than the end-tidal O_2 fraction.

Argon is a colourless, odourless and non-explosive gas. It is found in the Earth's atmosphere at 0.93% by volume. According to the Air Liquide's material safety data sheet [19] which complies

with the Health Canada Workplace Hazardous Materials Information System (WHMIS) standard, argon can be breathed as long as O_2 level in the breathing mixture is maintained above 19.5%. Horrigan et al. [20] investigated the effect of accumulation of argon in inhaled gas by exposing eight subjects to an argon-enriched gas mixture (i.e., 80% Ar and 20% O_2) for 30 minutes. They found no evidence of inert gas narcosis and no change in O_2 or CO_2 tensions in muscle, suggesting no biological effect. Moreover, Friesen [21] indicated that the flow characteristics of an oxygen-enriched gas are not altered when argon is present in less than seven percent. In this study, the inhaled O_2 fraction was high (and well above the 19.5% limit), even at an O_2 flowrate of 2 $L \cdot min^{-1}$ (see Fig. 8), and the argon peak fraction in the inhaled gas was always low (i.e., less than 5%) for all O_2 flowrates (see Fig. 9). Using the HIOX as a breathing unit will add to the safety. Indeed, because of the HIOX design, the O_2 fraction of the breathing gas provided by this mask will never drop below 21%, the O_2 fraction in air, even with a loss of oxygen.

The potential for contamination of the POGS gas product was minimal. The gas sampling test results showed that no toxic gases such as CO, hydrocarbons or sulphur oxides were found in the output gas. This is consistent with the finding of Libby and al. [6] who tested and analyzed two gas supplies from two different O_2 concentrators after 24 hours of continuous operation. The POGS has 4 levels of filtering of both the air feed compressor's intake air and product gas of the generator. These filters include a supply air filter, a particulate filter, an inline particulate filter and a high efficiency particulate arresting (HEPA[7]) filter. Furthermore, Friesen [21] indicated that the zeolite molecular sieve has a filtering capability in addition to N_2 adsorption. It can effectively filter out most potential pollutants in air (e.g., motor vehicle exhaust, ethylene oxide and numerous hydrocarbons) and several chemical warfare agents such as mustard gas, sarin or cyanogen chloride [21]. Nevertheless, On Site Oxygen Systems, the POGS manufacturer, recommends locating the feed air compressor in a clean air environment, indoor or outdoor at no less than 50 feet from any source of CO.

As recommended by the manufacturer, the POGS requires regular maintenance, which includes changing the different filters periodically. Several investigators [5, 9, 11, 12] indicated that most O_2 concentrators are user-friendly, and easy to operate and maintain. It was also reported that the zeolite adsorption capability can last about 20 000 hours [5, 9]. Therefore, for an average use of 200 hours each month, an O_2 concentrator would give 8 to 10 years of use with routine maintenance.

Both sampling of the product gas and the engineering test confirmed the POGS manufacturer's claim that the gas generated by the POGS was dry, even when the relative humidity in ambient air was > 50%. Shrestha et al [5] showed that high humidity (100%) in tropical regions had no effect on the O_2 level of an oxygen concentrators' product gas. As per the international standard for oxygen concentrators (ISO 8358) [22] and the World Health Organisation guidelines, modern O_2 concentrators are required to be reliable to operate in rigorous environmental conditions including ambient temperatures of 5 to 43°C, relative humidity of up to 100%, and dusty environment.

With respect to power supply, the POGS, like all commercially available O_2 concentrators, is completely dependent on a reliable electrical power. It requires a maximum of 240 volts (V) three-phase alternating current (AC) for the feed air compressor and 120 VAC for the generator. The total power requirement is about 3 kilowatts (kW). In remote areas, this amount of power can

[7] The HEPA filter can remove at least 99.97% of airborne particles of 0.3 micrometres (μm) in diameter

be supplied by small portable generators. However, smaller O_2 concentrators require less electrical power (≤0.5 kW), which can easily be supplied by a battery/inverter system, small generators, or by using solar or wind energy in combination with batteries [9-11].

Oxygen concentrators have been used successfully at high altitude (1337 m [5] and 3900 m [9]). In both studies, the O_2 concentrators used were highly reliable. The POGS was not tested at altitude in this study, however On Site Oxygen Systems [4] claims that the POGS will produce O_2-enriched gas with a maximum flow of 28.5 $L \cdot min^{-1}$ at 1640 m (5000 ft) and 24.5 $L \cdot min^{-1}$ at 3280 m (10000 ft) versus 33 $L \cdot min^{-1}$ near sea level.

When compared to the other commonly-used O_2 systems (e.g., compressed gas cylinders and liquid tanks) O_2 concentrators were found to be the least expensive by two to four times [8, 9]. In a review of the efficacy and reliability of O_2 concentrators used over a period of six years at high altitude in Nepal, Shrestha et al. [5] calculated that the O_2 generated by one O_2 concentrator over one year was enough to pay its initial cost. As shown in Table 3, the cost saving is substantial in remote areas throughout the world and most recently in North America. In developing countries, O_2 concentrators were found more cost effective, despite the fact that the initial investment can be relatively high.

Table 3: Cost figures: O_2 concentrator versus cylinders tanks

Ref.	Location	Type of O_2 Supply	Annual use (L)	Annual use (hr)	Annual cost ($)	Cost per Volume (cent/m^3)	Annual Savings
[7]	Canada*	Pre O_2 Conc.				4.53	
		O_2 Conc.				1.70**	
[9]	Nepal (Asia)	Cylinder	76000	633	600	790	78%
		O_2 Conc.	264000	2200	442	170	
[11]	Nigeria (Africa)	Cylinder		6377	2320 to 9280****		73% (1 patient) 93% (4 patient)
		O_2 Conc.		6377	630****		
[12]	Senegal (Africa)	Cylinder	506250	5625	2890	570	50%
		O_2 Conc.			1445		
[21]	Canada						$183527 34-41% urban 50 % rural

* Hospitals data
** O_2 concentrator operating costs plus purchased O_2 backup
*** For a patient using just 1 $L \cdot min^{-1}$
**** For 1 to 4 patients

The combination of the HIOX with the POGS proved as good as the combination HIOX and compressed O_2. However, the use of the HIOX-POGS system will provide sustained O_2, increase the efficiency and minimize risks associated with O_2 use during CAF medical operations. The use of an O_2 concentrator appears to be a better and a safer choice than compressed oxygen tanks on their own. It has great potential for remote areas as more oxygen would be available to treat more casualties. Providing the availability of a power supply, an O_2 concentrator similar to the POGS can continually supply over 95% O_2 without any interruption to at least 4 persons. Moreover, when not in use with patients, the POGS has the capability to fill tanks for more O_2 availability.

Given the effectiveness of the HIOX with O_2 concentrators at both high and low oxygen flows, it can be recommended to replace currently-used O_2 systems (i.e., high flow rate mask and O_2 cylinders or chemical generators) for field operation in remote areas. This will benefit CAF's field hospitals, submarine escape and rescue survivor treatment, and, in the future, as smaller portable O_2 concentrators become available, the CAF's Search and Rescue operations.

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Annex A Specifications and characteristics

A.1 Specifications and characteristics of the POGS

Table A1: Specifications and characteristics of the POGS [4]

	Dimensions* m (inch)	Weight kg (lb)	Electrical power**
Feed Air Compressor	0.74 x 0.69 x 0.68 (29.1 x 27.0 x 26.6)	98 (215)	208-240 V/60 Hz/3 Phases/15.5 A
Generator	1.31 x 0.70 x 0.59 (51.6 x 27.6 x 23.4)	120 (265)	115 V/60 Hz/1 Phase /1 A
Micro-booster box	0.46 x 0.30 x 0.61 (18 x 12 x 24)	100 (220)	115 V/60 Hz/1 Phase/6 A
High volume-booster	0.87 x 0.70 x 0.59 (34.4 x 27.4 x 23.4)	125 (275)	115 V/60 Hz/1 Phase/19 A

* Length x Width x Height

** V: volt; Hz: Hertz; A: Ampere

A.2 Subjects' physical characteristics

Table A2: Subject's physical characteristics

ID	Sex	Age *year*	Weight *kg*	Height *cm*
S01	Male	29.2	88.5	188
S02	Male	30.1	86.0	193.5
S03	Female	21.2	52.0	158.0
S04	Male	40.1	83.5	172.0
S05	Male	42.7	95.5	182.0
S06	Male	55.1	71.5	172.0
S07	Male	45.6	61.0	169.0
S08	Male	58.0	110.0	182.0
S09	Male	37.7	95.5	174.0
Mean		40.0	82.6	176.7
SD		12.1	18.2	10.8

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Annex B Termination criteria

Experiments were stopped when any of the following criteria were reached:

- Subject request associated with fatigue, discomfort or any other reason.
- Arterial O_2 blood saturation goes below 90%.
- Total pure O_2 breathing duration reaches 60 minutes.
- Loss of O_2 supply.
- Oxygen fraction of the POGS's gas product drops below 85%.
- Inhaled O_2 fraction drops below 21%.
- Excessive breathing resistance (peak inhale or exhale pressures no greater than ±10 cm H_2O).
- Signs of subject hyperventilation.
- Loss of room ventilation.
- Any other event at the discretion of the Principal Investigator or Run Director, e.g., in case of loss of data acquisition.

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Annex C Sample gas test report

Maxxam Analytics Inc

Driven by service and Science
www.maxxamanalytics.com

Your Project #: L129

Attention: [redacted]
Defence R & D Toronto
Experimental Diving Unit
1133 Sheppard Ave W
PO Box 2000
Toronto, CN
CANADA M3M 3B9

Report Date: 2007/04/03

CERTIFICATE OF ANALYSIS

MAXXAM JOB #: A729525
Received: 2007/03/29, 09:42

Sample Matrix: Oxygen
Samples Received: 1

Analyses	Quantity	Date Extracted	Date Analyzed	Laboratory Method	Method Reference
Clean Air Matrix Screen (ppm levels) (1)	1	2007/04/02	2007/04/02	CAM SOP-00200	GC/FID
Anaesthetic Agents (1)	1	2007/04/02	2007/04/02	CAM SOP-00201	GC/ECD
Dewpoint (1)	1	2007/04/02	2007/04/02	CAM SOP-00205	Hygrometer
Water in Separated form (1)	1	2007/04/02	2007/04/02		
Halogenated Hydrocarbons (1)	1	2007/04/02	2007/04/02	CAM SOP-00201	GC/ECD
Nitrous Oxide (1)	1	2007/03/30	2007/04/02	CAM SOP-00203	GC/ECD
Odour (1)	1	2007/04/02	2007/04/02	CAM SOP-00205	
Oil & Particulates (1,2)	1	2007/04/02	2007/04/02	CAM SOP-00206	Gravimetric
Other Detected Compounds (1)	1	2007/04/02	2007/04/02	CAM SOP-00215	
Sulphur Compounds in Gaseous Samples (1,3)	1	2007/04/02	2007/04/02	CAM SOP-00220, -00208	GC/FPD Direct Inject
Non-methane hydrocarbons (methane equiv) (1,4)	1	N/A	2007/04/02	CAM SOP 00202	GC/FID

(1) This test was performed by Maxxam Analytics Mississauga
(2) Gravimetric
(3) GC/FPD (Gas Chromatography/Flame Photometric Detection)
(4) GC/FID

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- PRELIMINARY RESULTS -

DATE OF REPORT: April 4, 2007

REPORT #: A729525
LAB #: R57552

MEDICAL GAS PURITY REPORT OF ANALYSIS: O2 Concentrator

REFERENCE: Z305.6 - 1992, Medical Oxygen Concentrator Central Supply System: for use with Non-flammable Medical Gas Piping Systems

Hospital : DRDC TORONTO (POGS)

Location : FIELD HOSPITAL

Cylinder ID : L129

Date Submitted: March 29, 2007

Submitted By : Defence R & D Toronto
Experimental Diving Unit, 1133 Sheppard Ave W, PO Box 2000, Toronto ON M3M 3B9
[redacted]

ANALYSIS RESULTS

Components	Concentration Units	Maximum Allowable	Analysed Sample
Carbon Dioxide	ppmv	500	BMDL
Methane	ppmv	50	none detected
Carbon Monoxide	ppmv	5	none detected
Anaesthetic Agents	ppmv	0.1	none detected
Nitrous Oxide	ppmv	5	none detected
Non-methane hydrocarbons	ppmv	1/2 TLV	0.3
Halogenated Hydrocarbons	ppmv	5	none detected
Sulphur dioxide	ppmv	1.0	none detected
Atmospheric Dewpoint	°C	-45	-62
Water in separated form	N/A	none	none detected
Odour	N/A	none	none detected
Hydrocarbons -Condensed/Particulate	mg/m3	1.0	none detected
Other Detected Compounds	ppmv	1/2 TLV	none detected

The above sample was shown on analysis to be Oxygen Concentrator(O2=95.2%). Trace contaminants were within the limits allowed in Table 7 of the referenced standard.
BMDL - Below Method Detection Limit.

Approved by : Electronic Signature
Cathy Li, Air Quality Services
Air Lab Analyst

6740 Campobello Road, Mississauga, Ontario Canada L5N 2L8 Tel: 905-817-5700 Toll free:800-563-6266 Fax: 905-817-5777

List of symbols/abbreviations/acronyms/initialisms

A	Ampere
ANOVA	Analysis of Variance
Ar	Argon
atm	atmosphere
BE	Breathing effort
BTPS	Body temperature and pressure, saturated
CAF	Canadian Armed Forces
cm	Centimetre
CO	Carbon monoxide
CO_2	Carbon dioxide
DAQ	Data acquisition
D H Svcs Ops	Directorate of Health Services Operations
DND	Department of National Defence
DRDC	Defence Research and Development Canada
FDA	US Food and Drug Agency
f_{ET}	End-tidal fraction
f_I	Inhaled fraction
f_m	Instantaneous mask fraction
ft	Foot
H Svc Gp HQ	Health Services Group Headquarters
H_2O	Water
HIOX	Pulmanex® Hi-OX® mask
HREC	Human Research Ethics Committee
Hz	Hertz
kg	Kilogram
kPa	Kilo Pascal
$L \cdot min^{-1}$	Litres per minute
lb	pound
MD	Mask discomfort
min	Minute or minimum

mmHg	Millimetre of mercury
NRM	Non-rebreathing mask
O_2	Oxygen
OSG	On Site Gas Systems, Inc.
P_a	Barometric pressure
P_{exh}	Peak exhale mask pressure (cm H_2O)
P_{inh}	Peak inhale mask pressure (cm H_2O)
psi or psig	Pound square inch or pound square inch gage
Q_{O2}	Supply (or supplemental) oxygen flowrate ($L \cdot min^{-1}$)
$Q_{O2\text{-}POGS}$	Total oxygen flowrate of the POGS output gas
R&D	Research & Development
SaO_2	Arterial blood oxygen saturation
SD	Standard deviation
STPD	Standard temperature and pressure, dry conditions
USP	United States Pharmacopeia
V	Volt
$\dot{V}_E$	Minute ventilation (expiratory gas flow) ($L \cdot min^{-1}$ BTPS)
WHMIS	Workplace Hazardous Materials Information System
^oC	Degree Celsius
^oF	Degree Fahrenheit

Other subscripts

ET	End-tidal
I	Inhaled
peak	Maximum or peak value

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An efficient mass casualty breathing system for oxygen therapy : Determining the compatibility of the Pulmanex® Hi-OX® mask with the CAF's in-service oxygen concentrator, POGS 33

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Defence Research and Development Canada was tasked by the Canadian Armed Forces (CAF) Health Services Group Headquarters to develop an efficient mass casualty breathing system for oxygen (O_2) therapy in remote areas. This report describes the second phase of the project to assess the performance of the Pulmanex® Hi-OX® mask (HIOX) when combined with the Portable Oxygen Generation System 33C (POGS), the CAF's in-service O_2 concentrator. First, unmanned tests were conducted to determine the quality and the quantity of the POGS product gas. Then, in human trials, nine participants (21 to 58 years) breathed O_2 at rest through the HIOX using the POGS as the O_2 supply. The test procedure consisted of three breathing periods of 5 min at either 2, 4 or 6 litres per min. Measurements included inhaled and end-tidal fractions of O_2 and carbon dioxide, O_2 arterial blood saturation, exhaled gas volume, and mask pressure. Subjective ratings of comfort and breathing effort were obtained after each breathing period. The unmanned testing showed that the POGS can safely be used to supply high concentrations of oxygen with no contaminants or toxic gases. Human testing revealed that the HIOX-POGS system delivered clinically useful O_2 levels. In terms of the measured dependent variables, the results obtained with the POGS proved to be as good as those of the compressed O_2. The use of the HIOX with an O_2 concentrator will provide sustained O_2 with increased efficiency and minimum risks associated with O_2 use during CAF medical operations.

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Oxygen mask; Hi-OX; Oxygen Concentrator; POGS; Oxygen therapy

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