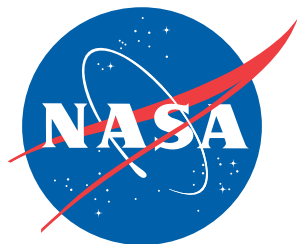


NASA/TM-2011-217062/Volume II  
NESC-RP-10-00659



# In-Suit Light Exercise (ISLE) Prebreathe Protocol Peer Review Assessment

## *Appendices*

*Timothy K. Brady/NESC  
Langley Research Center, Hampton, Virginia*

*James D. Polk  
Johnson Space Center, Houston, Texas*

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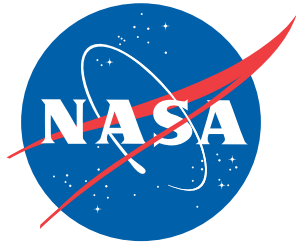
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National Aeronautics and  
Space Administration


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February 2011

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Prebreathe Protocol Peer Review Assessment  
Volume II**

**NRB Review Date: December 14, 2010**

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## Appendix A. Agenda - NESC In-Suit Light Exercise (ISLE) Prebreathe Protocol Peer Review

### Agenda

#### NESC In-suit Light Exercise (ISLE) Prebreathe Protocol Peer Review

**USRA  
3600 Bay Area Blvd  
14 October 2010**

- 0800 – 0830 Continental Breakfast (30)
- 0830 – 0835 Call to order with facility and safety comments: J.D. Polk (5)
- 0835 – 0845 Introduction of Panel and Attendees: J.D. Polk (10)
- 0845 – 0850 Charge to the Panel: J.D. Polk (5)
- 0850 - 0910 Flight Director's Perspective and Operational Drivers: Derek Hassmann (20)
- 0910 - 0920 Campout Prebreathe Protocol Experience: Joe Dervay (10)
- 0920 - 1005 ISLE presentation: Mike Gernhardt (45)
- 1005 - 1020 Break (15)
- 1020 - 1040 Statistical and Modeling Analysis of Phase V-5 Data: Johnny Conkin (20)
- 1040 – 1125 Operational Implementation of ISLE Protocol: Mike Gernhardt (45)
- 1125 - 1130 Reiteration of the Charge: J. D. Polk (5)
- 1130 - 1230 Questions from the Committee and Discussion (60)
- 1230 - 1330 Working Lunch (60) **Closed session.**
- 1330 - 1630 Deliberation of Committee (3 hrs) **Closed session.**

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## Appendix B. In-Suit Light Exercise (ISLE) Prebreathe Protocol Peer Review Panel Members and Attendees

### Peer Review Committee Members

- Dr. J.D. Polk, Chief, Space Medicine Division, JSC SLSD (non-voting)
- Dr. Michael Duncan, Deputy Chief Medical Officer, Space Medicine Division, JSC SLSD (non-voting)
- Mr. Tim Brady, NESC Lead, NESC Systems Engineering Office (SEO) (non-voting)
- Col. Pat Forrester, NESC Astronaut Representative
- Dr. Nigel Packham, JSC S&MA

### Voting members

- Dr. Caroline Fife, Consultant, The University of Texas Health Science Center at Houston
- Dr. Bruce Butler, Consultant, The University of Texas Health Science Center at Houston
- Dr. Ralph Frankowski, Professor of Biostatistics, The University of Texas School of Public Health
- Dr. Richard Jennings, Consultant, The University of Texas Medical Branch
- Dr. Richard Moon, Consultant, Duke University Medical Center
- Dr. Paul Sheffield, Consultant, International ATMO, Inc.
- Dr. Keith Van Meter, Consultant, Keith Van Meter and Associates


### Presenters

- Derek Hassmann
- Joe Dervay
- Mike Gernhardt
- Johnny Conkin
- Alan Feiverson


### Attendees

- Dr. J.D. Polk
- Mr. Tim Brady
- Dr. Caroline Fife
- Dr. Bruce Butler
- Dr. Ralph Frankowski
- Dr. Richard Jennings
- Dr. Richard Moon
- Dr. Paul Sheffield
- Dr. Keith Van Meter
- Dr. Nigel Packham




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- Col. Pat Forrester
- Mr. Johnny Conkin
- Mr. Al Feiveson
- Dr. Joe Dervay
- Mr. David Francisco
- Mr. Derek Hassmann
- Dr. Mike Gernhardt
- Ms Megan Murphey
- Mr. Henry Rotter
- Mr. Mike Mankin
- Dr. Philip Foster
- Mr. Neal Pollock
- Dr. Nancy Currie

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## Appendix C. In-Suit Light Exercise (ISLE) Prebreathe Protocol Peer Review Committee Final Report

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**Appendix C**  
**In-Suit Light Exercise (ISLE) Prebreathe Protocol**  
**Peer Review Committee Final Report**  
**November 9, 2010**

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### 3.0 List of Team Members, Ex Officio Members, and Others

#### Peer Review Committee Members

- Dr. J.D. Polk, Chief, Space Medicine Division, JSC SLSD (non-voting)
- Dr. Michael Duncan, Deputy Chief Medical Officer, Space Medicine Division, JSC SLSD (non-voting)
- Mr. Tim Brady, NESC Lead, NESC Systems Engineering Office (SEO) (non-voting)
- Col. Pat Forrester, NESC Astronaut Representative
- Dr. Nigel Packham, JSC S&MA

#### Voting members

- Dr. Caroline Fife, Consultant, The University of Texas Health Science Center at Houston
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- Dr. Ralph Frankowski, Professor of Biostatistics, The University of Texas School of Public Health
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- Dr. Richard Moon, Consultant, Duke University Medical Center
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- Dr. Keith Van Meter, Consultant, Keith Van Meter and Associates


#### Presenters

- Derek Hassmann
- Joe Dervay
- Mike Gernhardt
- Johnny Conkin
- Alan Feiverson

#### Attendees

- Dr. J.D. Polk
- Mr. Tim Brady
- Dr. Caroline Fife
- Dr. Bruce Butler
- Dr. Ralph Frankowski
- Dr. Richard Jennings
- Dr. Richard Moon
- Dr. Paul Sheffield
- Dr. Keith Van Meter
- Dr. Nigel Packham
- Col. Pat Forrester
- Mr. Johnny Conkin

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- Mr. Al Feiveson
- Dr. Joe Dervay
- Mr. David Francisco
- Mr. Derek Hassmann
- Dr. Mike Gernhardt
- Ms Megan Murphey
- Mr. Henry Rotter
- Mr. Mike Mankin
- Dr. Philip Foster
- Mr. Neal Pollock
- Dr. Nancy Currie


#### 4.0 Executive Summary

The atmospheric pressure of the International Space Station (ISS) is 14.7 pounds per square inch (psi), or sea level, whereas the pressure inside the suits used for extravehicular activity (EVA) is 4.3 psi. Thus the performance of extravehicular EVA by National Aeronautics and Space Administration (NASA) astronauts involves the risk of decompression sickness (DCS). This risk is mitigated by the use of oxygen (O<sub>2</sub>) "prebreathe" to effectively washout tissue nitrogen (N<sub>2</sub>) prior to EVA. The family of prebreathe protocols developed for the demanding EVA schedule of ISS construction has performed well in 331EVAs without reported incidence of DCS. However, with the retirement of shuttle, high pressure oxygen will become a very limited resource. The "In-suit light exercise" (ISLE) protocol offers several potential benefits including the potential to save 6 lbs of oxygen per EVA, and the fact that it does not require astronaut isolation in the air lock overnight as does the "campout" PB. In ground-based testing of ISLE, the measured incidence of DCS was 4.3% which met the accept criteria at the 95% CI level. Although the Grade IV VGE incidence of 16.7% was within the accept criterion of  $\leq 20\%$ ; the upper confidence limit failed to meet the 95% CI. In addition, questions existed as to whether the "light exercise" requirement could be validated by perceived exertion, or necessitated confirmation by the oxygen sensor in the EMU. At the request of the NESC, the peer review Team convened on October 14, 2010. The major recommendations of the committee were that the ISLE protocol is acceptable for operational use as a PB option prior to EVA. Furthermore, since the necessary oxygen consumption rate of 6.8 ml.kg<sup>-1</sup>.min<sup>-1</sup> is barely above resting and is virtually guaranteed by the nature of normal pre-EVA tasks, the use of the EMU suit oxygen sensor is not necessary to determine whether adequate metabolic rate has been achieved. However, collection of oxygen sensor readings may be useful for research.

#### 5.0 Consultation Plan

A Charter established the ISLE PB Protocol Review within the NESC. It defined the mission, responsibilities, membership, and conduct of operations for this consultation. This consultation was initiated out-of-board by the authority of the NESC Director, Ralph Roe. NESC's mission is to perform value-added independent testing, analysis, and

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assessments of NASA projects to ensure safety and mission success. The objective of this consultation was to review the physiological, modeling and operations data related to ISLE PB Protocol DCS risk regarding the use of the ISLE PB protocol. Specific questions were posed to the review Committee in the Charge, with the findings and recommendations to be documented in a written report and out-briefed to the NRB and identified stakeholders.

The ISLE PB Protocol review Committee was led by Dr. J.D. Polk, Chief, Space Medicine Division, JSC SLSD and the Deputy lead Mr. Tim Brady, NESC Systems Engineering Office (SEO). Dr. Caroline Fife from the University of Texas Health Science Center, Houston was tasked with assembling the independent voting members of the Panel. The Lead and Deputy Lead identified the critical areas of information necessary for the Committee briefing, and assembled the presenters. Informational materials were circulated to the voting and non-voting members prior to the meeting date. Presentations were made during a convened meeting on October 14, 2010 at the Center for Advanced Space Studies in Houston, Texas, to educate the review Committee about the background of PB protocol development, physiology of altitude DCS, statistical methods for development and analysis such as modeling, the specific details of the various PB protocols, and some aspects of operations which are pertinent to this review (e.g., available equipment, physical limitations, etc.). Presenters included Tim Brady who presented the charge, Mike Gernhardt who presented the research summary, Joe Dervay who presented ISLE, Megan Murphy who presented the timeline, and Johnny Conkin and Feiveson, who presented Modeling Methods.


After the Charge was reviewed by Mr. Brady, the Committee was allowed to deliberate privately with the input of the non-voting members under the supervision of Mr. Brady, Dr. Packham, and Pat Forrester, NESC Chief Astronaut. The EVA Integrated Product Team (IPT) presenters remained available during Committee deliberations to answer the questions which arose.

#### **Analysis Techniques Used**

The Committee consisted of seven voting members (C Fife, R Jennings, B. Butler, R. Frankowski, P. Sheffield, R. Moon, and K. Van Meter), as well as Tim Brady, JD Polk, Nigel Packham and Pat Forrester, non-voting members.

The Committee deliberated for approximately four hours. The Committee requested Dr. Frankowski to estimate the number of subjects which would have been necessary to reach the 95% confidence interval (CI) for the Phase V-5 accept/reject criteria. Dr. Gernhardt answered questions posed by the Committee via telephone during their deliberations. Deliberations continued via a series of emails. Key statements were crafted by the members and emailed to the voting members who voted via email using a "Delphi" approach. Draft statements were revised until there was unanimous agreement by the voting members. A draft report prepared by Dr. Fife was circulated via email. Dr. Polk and Tim Brady reviewed the report with regard to the accuracy of the background information and the NASA procedural details. The final report was submitted to the NRB for approval on November 4, 2010.

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## 6.0 The Charge

- Is the ISS In-Suit Light Exercise Prebreathe Protocol acceptable for operational use with the O<sub>2</sub> tank pressure transducer readings as guidance for controlling the crew metabolic rate during the light exercise period?
- Is the ISS In-Suit Light Exercise Prebreathe Protocol acceptable for operational use using ratings of perceived exertion (RPE) of 7 or greater as a control to insure adequate metabolic rate has been achieved during the light exercise period?
- What if any additional controls would be recommended for implementation of the In-Suit Light Exercise Prebreathe Protocol for routine operational use on ISS?

## 7.0 ISLE and the Statement of the Problem


### 7.1 Background of PB Testing

The testing of PB protocols has evolved since the 1970's. A variety of methods have been used including ground based testing of specific PB protocols with the later addition of "adynamia" (no ambulation) simulations, mathematical modeling based on accumulated data from closely related studies, and multi-center prospective trials to evaluate specific PB techniques. NASA's goal is not the performance of DCS research. The primary goal is the development of safe and effective counter-measures for EVA. A secondary goal is a better understanding of PB mechanisms. Thus, these prospective trials have been designed with operational considerations in mind and with carefully defined *a priori* accept/reject criteria.

Early PB protocol development focused only on delivering acceptable/effective counter-measures. Later development focused on increased efficiency and improved scientific understanding of counter-measure mechanisms. The evolution of the over-arching goals of PB research is reflected in the changing design of the trials. Early on, Dr. James Waligora tested many PB protocols (3, 3.5, 4 hours) in which the DCS incidence ranged from 20-36 percent. Exercise simulated the arm movement of the crank on the Shuttle payload doors and other Shuttle contingency tasks. In testing the four-hour "In-suit" PB protocol and the one-hour 10.2 psi "staged decompression," specific "R" values were identified for acceptable tissue tensions, and "reject" criteria were identified ("Grade 3 DCS, any Type II, pain limiting performance, etc."). In the 10.2 psi staged decompression PB ground-based tests, a DCS incidence of 23 percent was observed.

In the late 1990's, the EVA requirements for ISS necessitated PB protocols which were more time and operationally efficient. Research which enabled this program to proceed included the recognition that ground-based microgravity simulation was an important experimental variable, and the discovery that exercise significantly enhances N<sub>2</sub> off-gassing (e.g. 10 minutes exercise at 75 percent oxygen intake (VO<sub>2</sub>) peak during a one

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hour PB protocol was equivalent to four-hour resting O<sub>2</sub> PB). The goal was to reduce the PB time by 50% over the 4 hour protocol while maintaining or increasing the safety margins, and to certify this protocol in time for the installation of the ISS joint airlock. A two-hour exercise PB protocol for ISS was developed by 1999. During that period, the EVA culture was transformed to a “diving environment” mentality with a clear DCS treatment and disposition policy which did not penalize astronauts for reporting DCS should it occur (JPG 1800.3). Improved on-orbit treatment protocols were developed which allow in-suit recompression breathing oxygen (4.3- 8 psi over ambient).

Over the years, a “family” of 4 PB protocols has thus been developed which allowed flexibility similar to that used in diving. These have had extensive use with EVAs on ISS. The family of PB protocols currently in use are as follows:

- *3.5 hour in-suit; 4.0 hour in-suit*
- *10.2 psi staged PB*
- *2 hour exercise*
- *“Campout”.*


The PB protocol selected for each EVA is based on operational, technological and astronaut preference factors. There have also been some occasions in which unintended “breaks” in campout protocol necessitated moving to an alternative PB schedule (e.g. exercise). This has happened on 5 occasions due to technical issues such as mask detachment, or the automatic depressurization of the air lock as a result of an alarm. Thus, the availability of multiple PB options has provided much needed flexibility.

## **7.2 EVA Protocol Metrics (as of 17 August 2010)**

- *3.5 hr In-Suit PB, first STS EVA*
  - 2 person EVA in one use
- *4.0 hr In-Suit PB*
  - 4 person-EVAs in two uses
- *10.2 psi Staged PB*
  - 151 person-EVAs in 75 uses
- *Exercise PB*
  - 38 person-EVAs in 19 uses
- *Campout PB*
  - 136 person-EVAs in 68 uses

In 331 EVAs there have been no reported cases of DCS. Discussions with astronauts, and the clear protocols allowing return to EVA status if DCS would be reported (assuming certain conditions are met) indicate that these statistics do not reflect a lack of reporting but indeed, **the absence to date of recognized DCS symptoms related to EVA over the past 10 years**. Possible reasons for this are discussed below.



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Initially, *acceptable risk* in ground based PB protocol development was defined by the following parameters:

*The highest DCS risk consistent with a 95 percent probability that two of three members would always be available for EVA was 21 percent, and that during testing, DCS and grade IV venous gas emboli (VGE) incidence would be below the threshold for any reported case of Type II DCS.*

Acceptable DCS risks were further *reduced* to account for related medical factors such as an on-orbit treatment delay of 30-45 min for re-pressurization, and the presence of a patent foramen ovale (PFO) which might result in neurological symptoms due to arterialized venous gas. To address this issue, experimental ground based protocol design further specified that Type I DCS remain at a threshold below which no cases of type II DCS have been reported in the literature. In 244 Tests with 7692 exercising subjects, neurological DCS is not observed until the incidence of Type I DCS exceeds 15% (Gernhardt ML, et al. Design of a 2-hour prebreathe protocol for space walks from the international space station. 71st Annual Scientific Meeting of the Aerospace Medical Society, Houston, Texas, Abstract No. 43, pp. 49, May 14 - 18, 2000).


**Thus, for Phase V-5, now termed the “In-Suit Light Exercise (ISLE) PB Protocol, the accept limit was a DCS incidence less than or equal to 15% at 95% Confidence Limit (CL), and Grade 4 VGE less than or equal to 20% at 95% CL. The reject limit was a DCS incidence of greater than 15% at 70% CL, and Grade 4 VGE greater than 20% at 70% CL. The protocol was also rejected if there was a case of DCS classified as Type II.**

***It must be noted that the a priori accept/reject criteria established in testing protocols for ISS were far more rigid than those used for testing the Shuttle PB protocols. In fact, the limits for ISLE were more conservative than any previous EVA PB trial.***

### 7.3 Statement of the Problem

In ground based testing, the measured incidence of DCS with ISLE was 4.3% (2 cases of Type I DCS in 47 trials). The upper one-sided exact binomial confidence limit for the true incidence of DCS was 12.8%. There were no cases of Type II DCS with ISLE. This met the accept criteria of  $\leq 15\%$  DCS at 95% confidence level.

In ground based testing, the measured incidence of Grade IV VGE was 16.7% (8 cases of Grade IV VGE in 48 trials). The upper 95% one-sided exact binomial confidence limit for the true incidence of Grade IV VGE was 28.1%. Although the point estimate of VGE incidence of 16.7% is within the accept criterion of Grade IV VGE  $\leq 20\%$ ; the upper confidence limit fails to meet the 95% confidence level requirement. The upper 64% confidence limit for Grade IV VGE was 19.96%. Thus, to qualify for acceptance, the 95% CI requirement would have to be reduced to a 64% CI requirement. Alternatively, one could look at these results from a Bayesian perspective wherein we wish to make a probability statement about P(VGE) given the experimental results of 8 cases in 48 trials. Using a (conservative) uniform prior for P(VGE), the posterior distribution of

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P(VGE) given the data is distributed as Beta(9,41) distribution. With this posterior distribution, the probability that P(VGE) exceeds 20% is about 33.2% (personal communication Alan Feiveson October 14, 2010). Despite the failure of Grade IV incidence to meet the 95% CI requirement for acceptance, the Bioastronautics EVA-IPT unanimously agreed that the V-5 "ISLE" protocol should move forward for consideration for operational use. What are the operational issues which are driving ISLE consideration even though it did not meet accept criterion at the 95% CI? For station-based EVA, the Campout PB has worked well except for the relatively minor logistical issue of isolation. It has some advantage over the exercise PB in that the exercise bicycle is not necessary, and is often preferred for those who find the mask uncomfortable. However, high pressure oxygen will become a very limited resource once shuttle missions are over. For some years, until an engineering solution is developed and delivered to ISS, there will be no way to recharge the high pressure oxygen supply. Post shuttle retirement, support of ISS could require 8 EVA per year, although a realistic requirement is 1-2 EVA per year.

The ISLE PB protocol has the potential to offer several benefits, specifically that it:

- Is expected to save 6 lbs of oxygen per EVA, a substantial savings when high pressure oxygen supply becomes limited
- Does not require astronaut isolation in the air lock overnight as does campout
- Requires less crew time on PHS mask (which can be uncomfortable and difficult to use)
- Could be a better down-mode option if a campout protocol is broken (as has occurred 5 times to date)
- Allows astronauts to "get out the door" 13 to 30 min earlier than CEVIS protocol
- Diminishes the "rushing" to prepare for campout
- Does not require crew to either do a bathroom break on their 120 foot PB hose or use piddle packs
- Does not require VO<sub>2</sub> peak testing as exercise prescription is based on weight only (6.8 ml/kg-min)
- Is a simpler procedure overall than CEVIS

ISLE has some potential operational disadvantages and/or challenges:

- Astronauts would "get out the door" about 60 minutes later than campout
- It requires about 100 min in-suite PB time vs. 50 min in-suit on campout
- **It presupposes a certain (minimal) level of exercise in-suit during the PB (more on this below) which could use oxygen sensor readings (see below) as a general, non-required, guide of activity.**

#### 7.4 The development of ISLE

The study was peer reviewed by the Lambersten Committee and the accept/reject criteria were more conservative than any previous EVA prebreathe trial including a 6 hr prebreathe. It was a sequential, multi-center trial, utilizing informed consenting subjects representative of astronaut population in terms of age, gender, fitness, % body fat.

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The mission driver of a 95% probability that 2 of 3 crew members would be available for EVA throughout ISS program, combined with additional medical/operational considerations resulted in the following accept/reject limits:

- Accept: DCS  $\leq 15\%$  and Grade IV VGE  $\leq 20\%$ , @ 95% CL Reject: DCS  $\geq 15\%$  or Grade IV VGE  $\geq 20\%$ , @ 70% C or any case of Type II DCS

There was a 50 trial minimum to control type II error to less than 1%. The research plan anticipated testing up to four protocol options. Previous Phase V in-suit exercise protocols did not incorporate a 10.2 psi depress/repress, and PRP data (all protocols) showed that the 10.2 psi depress/repress significantly reduced DCS and VGE. Thus, a 10.2 psi depress/repress was added to V-5.

Below are the PRP summary results:

Protocol	n	%DCS (n)	%VGE (n)	%GIV VGE (n)
I	47	19.1 (9)	48.9 (23)	4.2 (2)
II	45	0 (0)	31.1 (14)	6.6 (3)
III	9	22.2 (2)*	11.1 (1)	11.1 (1)
IV	56	14.3 (8)	41.0 (23)	12.5 (7)
V-1	9	33.3 (3)	55.5 (5)	22.2 (2)
V-2	3	33.3 (1)*	100.0 (3)	66.6 (2)
V-3	48	14.6 (7)	52.1 (25)	10.4 (5)
V-4	6	50.0 (3)	50.0 (3)	16.6 (1)
V-5	48**	4.2 (2)	29.2 (14)	16.6 (8)


\*Includes one case of Type II DCS

\*\* based on 48 acceptable trials for Grade IV VGE and 47 trials for DCS

The V-5 protocol consists of 60 min of oxygen on mask while doing EVA prep followed by a 10.2 psi depress (light exercise at 5.8 ml/kg-1/min-1) on enriched air (0.265% oxygen). This is followed by a 30 min suit donning at 10.2 psi, and then 50 min in-suit light activity (6.8 ml/kg-1/min-1), equivalent to walking a mile in 70 min, breathing oxygen. It must be noted that this degree of exercise can be achieved with minimal effort. There is a final 50 minute in-suit PB at rest, breathing oxygen.

Rest	Prebreathe				Flight Simulation	
	Light Exercise (EVA Prep) (5.8 mL*kg <sup>-1</sup> *min <sup>-1</sup> )		Light In-Suit Exercise (6.8 mL*kg <sup>-1</sup> *min <sup>-1</sup> )		Ascent Rest	30,300 ft Light Exercise
	Depress to 10.2 psi	Repr				
	40 min	20 min	5	45 min		
	60 min	30 min	50 min	50 min		
130 min	190 min			30 min	240 min	
Air	Oxygen	0.265 Oxygen	Oxygen			

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The measured incidence of Grade IV VGE was 16.7% (8 cases in 48 trials). This was within the accept criterion of  $\leq 20\%$  Grade IV VGE, but not at the 95% confidence level. With the low incidence of DCS in the Phase V-5 protocol, the increased incidence of Grade IV VGE could not be explained based on age, gender, aerobic fitness, total oxygen consumption, total prebreathe time, or relationships between DCS and Grade IV VGE in PRP and NASA historical results.

It is possible that considering only Grade IV VGE and not considering the effects of lower grades or the persistence of decompression stress reduces the sensitivity to differences between protocols. The prebreathe studies included VGE sampling in each 20 minute block of time (epoch) spent at suit pressure. There was no significant difference (two-sided Fisher exact p-value = 0.56) in the total number of epochs with Grade IV VGE for Phase V-5 and the approved-for-flight Phase II protocols (3.5% and 4.1%, respectively). However, Phase V-5 had significantly (two-sided Fisher exact p-value = 0.02) lower pooled Grade III-IV VGE than Phase II (6.8% vs. 10.6%, respectively). Given that combined Grade III and IV VGE are generally associated with statistically increased risk of DCS, it may be that a strict focus on Grade IV VGE only may be a less than comprehensive measure of decompression stress. The duration of VGE grade at the highest grade level within an epoch is not measured, only the notation of maximal VGE Grade.


The laboratory protocol does not include the additional safety margin built into the flight protocol including the configuration checks, leak check, purge and 5 psi suit over-pressurization during crewlock depress. All of these add approximately 25 minutes of oxygen prebreathe that was conservatively not performed on the laboratory protocol. In other words, in practical use, astronauts performing V-5 would get more oxygen PB than subjects in ground based testing.

### 7.5 Additional Analysis

Drs. Conkin and Feiveson presented supplemental analysis of V-5 data for additional insight into a variety of issues which might impact decision making. These analyses are presented below in the form of questions and answers. The additional analysis presupposes that the VGE data collected over 25 years is “perfect” and contains no DCS diagnostic error, no bias in VGE grading, and that maximum VGE is adequate information.

*Q: Does accounting for the frequency of 0 VGE improve the confidence in the observations from V-5?*

Since the predictive value (PV) is 98% for “no VGE” and PV is only 32% for “VGE” in current NASA data, the question arose as to whether accounting for grade 0 VGE could provide more confidence in the observed 4.2% DCS than is suggested by the high Grade IV incidence?

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Data were stratified on the presence or absence of symptoms, and used random effects models for  $P(S|VGE)$  and  $P(DCS|VGE, S)$  to represent test-test variation and estimate standard error of  $P(DCS)$  estimate. The final random effects regression equation is as follows:

$$P(DCS) = (0.0166 \cdot n_0 + 0.188 \cdot n_{123} + 0.514 \cdot n_4) / n,$$

where  $n_0$  is the number of trials within a specific test that were assigned maximum VGE grade of Grade 0,  $n_{123}$  is the number of Grade I, II, or III,  $n_4$  is the number of Grade IV, and  $n$  is the total number of trials in a specific test. The regression equation provides for a computed  $P(DCS)$  for a test given the counts of maximum VGE grades for the trials in the test.

A. The estimated  $P(DCS)$  given maximum VGE grade and symptoms is as follows:

test	n	observed DCS	one-side 95% CL*	estimated P(DCS)	one-side 95% CL
V-5	47**	0.042	0.128	0.112	0.171

Q: *What is the likely operational effect of a Type I DCS?*

A literature analysis was presented to gather information regarding the operational impact of Type DCS as a function of the probability of the severity of DCI which cannot be determined due to stop rules. Data from 1971 in a retrospective analysis of data going back to 1941 (Allen), converted all symptoms into a scale of 1-4 (something worse than intolerable pain that cleared on descent).

A. If there was a test which gave 30% DCS, the expectation is that there will be mild categories of DCI, and thus a low operational impact.


Q: What is the estimate of Type I DCS probability given the maximum VGE grades from V-5?

A. The estimated  $P(DCS)$  for Phase V-5 is 11.2% compared to 4.2% from direct count in the ground based study. The one-sided upper 95% CL is 17.1%. The estimated  $P(DCS)$  was 9.1% for Phase II compared to 11.2% for V-5 which is not very different and is likely of little practical importance.

Q. What might be the effect of diagnostic error on the data in V-5?

A. *The computed  $P(DCS)$  accounting for diagnostic error was 4.5% compared to 4.2% from direct count. Since 44/47 trials had no report of any symptoms, then there was no*

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*significant contribution from diagnostic error since you diagnose DCS based on symptoms.* This analysis suggests that after accounting for diagnostic error, the DCS impact of DCS for Phase V is low..

*Q: Why is the observed incidence of DCS difference from ground based studies?*

- A. Astronauts enjoy greater protection from DCS than expected after Campout, probably through additional operational prebreathe, other protective factors in microgravity (e.g. resolution of bubble micronuclei). There are additional amounts of oxygen which may not be accounted for, and there is additional exercise in the suit.
- B. There is a fundamental effect of microgravity on the biology of bubble formation and symptom development, the mechanism of which is not understood.

#### **7.6 Issues Relating to the Flight Rule for ISLE**

Megan Murphey reviewed the EVA MOD Prebreathe Protocol Comparisons and the committee assessed the differences between ISLE, exercise, campout and 4 hour in-suit PB protocols with regard to time from post sleep to start of EVA, air lock isolation, mask time, PB time, ISS recommended crew day length and METOX cans used.

With regard to METOX cans used, ISLE would use about the same number of cans although there are operational details regarding the re-use of partially spent cans. **If ISLE is approved then it would represent another acceptable protocol that can go into the “basket of tools from which to choose.” The decision will be based on operational issues such as oxygen availability, CO2 canisters, time available, isolation of campout and other factors. However, it is likely that after the retirement of Shuttle, ISLE will be the preferred PB protocol due to its ability to save high pressure oxygen.**

#### **7.7 Issues Relating to the Oxygen Tank Pressure Sensor**

Dr. Gernhardt presented data suggesting that the drop in the oxygen tank sensor pressure could be used as a guideline to control the ISLE metabolic rate during in-suit PB. However, this method it is complicated by the following:

- Thermal transients associated with purge and tank refill
  - Tank pressure drops during purge at 10.2 psi, and at 14.7 psi, tanks are then recharged and thermal cooling causes tank pressure transients
- As-donned leak rate of suit
  - The suits typically leave earth with leaks of 100 sccm or less, however as donned the leak rates could be as much as 999 sccms and still pass the leak check
- Tank pressure sensor error and Display Control Module (DCM) rounding error
  - The difference between any two tank pressure readings could have an error of up to 2.6 psi. The DCM could have a rounding error of .49 psi.



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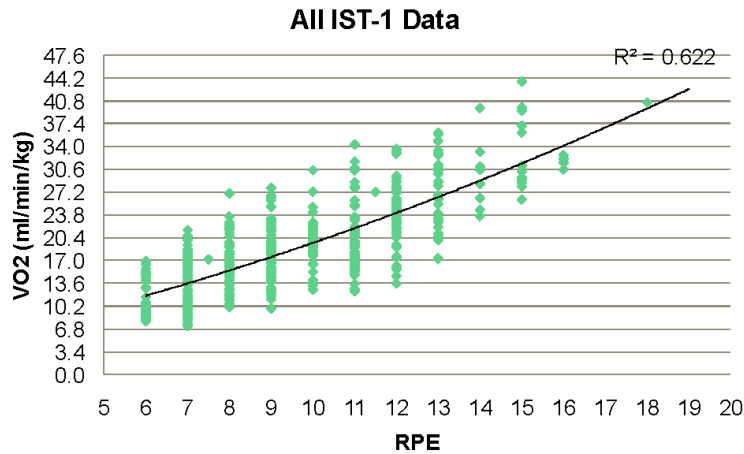
Version:  
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## Phase V-5 In-Suit Light Exercise (ISLE) Prebreathe Protocol

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The Committee was provided with a detailed description of engineering work-arounds for these limitations. However, subsequent discussion focused on the On- Orbit Engineering Assessment Exercise Prescription Table for an 80 Kg subject. ISLE requires that the in-suit exercise be performed at "light activity" (6.8 ml/kg-1/min-1), equivalent to walking a mile in 70 min. This is only slightly more activity than "no exertion at all." **Data were compelling (see graph below) that it would be virtually impossible for astronauts to FAIL to perform this level of exertion, simply by remaining awake in the suit during the 50 minutes.** Thus, while the oxygen sensor readings may be noted, it did not appear necessary, and the previously discussed issues with accuracy argued against relying on it for this purpose.



The perceived exertion scale seemed a viable and perhaps equally reliable tool for assessing oxygen prebreathe exertion.

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6	No exertion at all
7	Extremely light
8	
9	Very light
10	
11	Light
12	
13	Somewhat hard
14	
15	Hard (heavy)
16	
17	Very hard
18	
19	Extremely hard
20	Maximal exertion


The crewmember must exercise with an RPE of 7 (e.g. they are performing some exertion vs. an RPE of 6 which is no exertion) to ensure that an adequate exercise intensity was achieved. Further discussion with Dr. Gernhardt revealed that **in ground based testing, the exercise was specifically that of the LOWER LEGS and instructing crew members to move their lower legs would be required.** Discussion ensued as to whether prescribing a certain number of leg movements was necessary but Dr. Gernhardt did not feel that this would be necessary to achieve the required exertion.

Data from the suit O<sub>2</sub> tank sensor pressure drop may provide useful information and thus would be valuable to collect.

### 8.0 Prior Safety Committee Work

It is important to note that there was no specific ground-based testing of the Campout PB. The safety of Campout PB was assessed based on modeling data and information obtained from Phase IV human trials. Phase IV of the Exercise PB study was a 2-hour PB with 95 minutes of light exercise, and a 30 minute suit donning period at 10.2 psia breathing 26.5 % O<sub>2</sub>. This ground-based test of Phase IV was nearly identical to the day-of-EVA Campout PB procedure, which has the same amount of O<sub>2</sub> PB, and the same or slightly more metabolic activity during O<sub>2</sub> PB. Phase IV trials resulted in 14% DCS in 57 subjects which did not quite meet the accept criteria for ISS EVA, but this incidence was lower than the ground tests of the Shuttle 10.2 psia staged protocol. Compared to Phase IV, the Campout PB protocol had an extra hour of O<sub>2</sub> PB, and 8 hours and 40 minutes overnight campout at 10.2 psia. Modeling data suggested that Campout would be a safe protocol for EVA, **and the safety Committee accepted Campout on this basis in 2005 on the argument that it was “analytically more conservative,” even though there was no ground-based testing for validation.** The logistic regression model predicted Campout to have 2.8% DCS (1.2% to 5.9%, 95% CI)



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based on Conkin's work. Nevertheless, there have been no reports of symptoms linked to DCS in 136 person EVAs with 68 uses of campout from the ISS. **Thus, it appears that the campout PB protocol in actual EVA use is safer than the model predicts.** The possible physiological and operational reasons for this have been previously discussed.

The modeling techniques used to assist in the development of the PB protocols are well known in medicine and physiology having been used to develop, for example, the cardiac risk score from the Framingham Study data, as well as in pharmaceutical trials, and the techniques of which are accepted by the Food and Drug Administration. It is important to note that, **utilizing modeling techniques, the risk of DCS is almost the same for all the PB protocols, and the confidence intervals overlap.** There is a tendency to rank the risks within "acceptable risks" even when the differences are small. **Given the overlapping confidence intervals, it may be impossible to detect a real difference in risk between the PB protocols, based on modeling.**


Analysis of the 95 percent Bayesian CLs for the risk differences suggest that the Shuttle ground simulation over estimates the DCS risk in EVA, while ISS ground EVA simulation may provide an accurate prediction of DCS risk (it is possible that the risk of DCS in ISS ground-based trials and EVA are the same). The higher correlation between ISS ground-based trials and predicted DCS risk during EVA may be due to improved ground-based trial design.

## 9.0 Proposed Solutions

### 9.1 Going from Evidence to Findings and Recommendations

Since the prebreathe safety Committee first met in 2005, a significant focus in clinical medicine has been the methodology by which research data is evaluated for its relevance to clinical practice guidelines. If a practice guideline working group makes a recommendation, how much confidence can be placed in that recommendation? The "GRADE" working group has published extensively on this topic. Their methods focus on the development of *clinical* practice guidelines based on the results of *medical* research. Thus, these GRADE methodologies are only partially relevant to the process of reviewing *physiological* experiments for the development of NASA *operational* protocols. Clearly the process of evaluating DCS counter-measures is quite different than the process of evaluating practice guidelines for stroke prophylaxis. However, we have been asked to weigh various types of DATA, specifically: randomized, controlled trials, predictive models, and "real world practice" (i.e. EVAs), and to synthesize this diverse information in order to make recommendations for prevention of disease (i.e. DCS). Since there are some similarities, the safety committee has attempted to utilize some "GRADE" techniques to assist us in weighing the data presented and establish the level of confidence which can be placed in our recommendations.

Like the GRADE working group, we have used the following definitions: the *quality of evidence* indicates the extent to which one can be confident that an estimate of effect is

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correct. The *strength of a recommendation* indicates the extent to which one can be confident that adherence to the recommendation will do more good than harm.

There are 3 determinants of the strength of a recommendation: 1) The balance between the desirable and undesirable consequences of the alternative management strategies, on the basis of the best estimates of those consequences, 2) the quality of the evidence, and 3) the values of the stakeholders. When advantages far outweigh the disadvantages, then the strength of a recommendation may increase. If the consequences of the choice are relatively unimportant, even strong evidence supporting a recommendation may not matter. If the consequences are VERY important, then evidence with less strength may take on a much more prominent role. (Going from evidence to recommendations. Gordon H Guyatt, Andrew D Oxman, Regina Kunz, Yngve Falck-Ytter, Gunn E Vist, Alessandro Liberati, Holger J Schünemann BMJ 2008;336;1049-1051)


## 9.2 Confidence Interval Calculations

The ground-based DCS data presented for ISLE met the criteria for acceptance of this PB protocol. However when grade IV VGE data were included, it did not meet the criteria for acceptance at the predetermined 95% CL for VGE Grade IV incidence  $\leq$  20% nor did it meet the criteria for *rejection* of Grade IV VGE  $>$  20% at the predetermined 70% CL. The lower 70% one-sided exact binomial confidence limit for the true incidence of Grade IV VGE was 13.3%. Thus, ISLE could neither be accepted nor rejected based on the accept/reject limits and the reported ground-based V-5 protocol data alone.

There are two main factors that control the width of a confidence interval; 1) sample size, and 2) the true underlying incidence of Grade IV VGE in the study population relative to the criterion value of 20% incidence for accept/reject limits. It is not possible to detect small differences in VGE incidence from 20% without a very large sample size. For example, if the Grade IV VGE incidence is 16.7% in the study population then a sample of at least 336 subjects would be required to satisfy the current VGE 20% acceptance criteria. The implication is that for VGE acceptance small differences between ground-based VGE incidence and the criterion value of 20% requires very large samples.

Sample size requirements can also be illustrated by recasting the rejection criteria as a traditional test of hypothesis. Suppose the null hypothesis is  $H_0: \text{Prb}(\text{Grade IV VGE}) = 20\%$  and the alternative hypothesis is  $AH: \text{Prb}(\text{Grade IV VGE}) \geq 25\%$ . Then at the 5% level of significance a sample of size 400 would be required to detect the alternative hypothesis with power equal to approximately 75%. If the alternative hypothesis is taken to be that  $\text{Prb}(\text{Grade IV VGE}) \geq 30\%$ . Then a sample size of approximately 100 would have 75% power at the 5% level of significance. Small differences require large samples and large differences require relatively smaller sample sizes.

These examples are presented only to suggest that with the extensive amount of VGE data now available it may be time to reconsider the current accept/reject criteria for the incidence of Grade IV VGE.

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### 9.3 Specific Committee Recommendations:

#### 9.3.1. Strong recommendation based on a moderate level of evidence:

An oxygen consumption of  $6.8 \text{ ml.kg}^{-1}.\text{min}^{-1}$  is barely above resting, and is virtually guaranteed by the nature of normal pre-EVA tasks. Thus, light lower body exercise in the suit will ensure an oxygen consumption of at least  $6.8 \text{ ml.kg}^{-1}.\text{min}^{-1}$  without the use of EMU suit oxygen sensor measurements as part of the ISLE prebreathe protocol.

#### 9.3.2 Strong recommendation based on a low level of evidence

Even though not necessary to accurately determine whether adequate metabolic rate has been achieved, in-suit oxygen sensor readings collected during the light exercise period may be valuable for future research if collected with very specific and clear-cut objectives.


#### 9.3.3 Strong recommendation based on moderate level of evidence

The ISLE protocol is acceptable for operational use as a PB option prior to EVA.


### 9.4 Additional Observations and Recommendations by the Panel

The Committee recognizes that, based on our experience, Type I or “pain only bends” goes away with simple repressurization with or without the respiration of oxygen. Were it not to respond to repress it would not endanger the life of an astronaut even though it might affect operations. If serious DCS were to occur during EVA, the most probable mechanism would be via arterialization of VGE. This is because appropriate oxygen prebreathe would eliminate nitrogen from well-perfused tissues so that supersaturation would be highly unlikely and thus autochthonous bubble formation in the brain or spinal cord could not occur during EVA. Therefore, the rationale for including VGE in the experimental reject criteria was to protect against the rare but potentially devastating problem of a serious case of DCS arising from arterialization of these venous bubbles. Thus, the committee deliberates with seriousness the question of whether we are in fact, being asked to alter carefully crafted accept/reject criteria *post hoc*. The following observations were made:

- Observation: Over the past 10 years, ground based accept/reject research criteria have become ever more strict even as data have accumulated demonstrating the complete *absence* of DCS reporting during EVA. The Committee raises the issue as to whether JSC ought to revisit the accept/reject criteria of ground based trials in light of the safety data from EVA.
- Observation; Another issue relates to the possibility whether the identified protocol has too many failure points, adding additional and unpredictable risks. The campout protocol reportedly has 21 potential failure points and protocol V has fewer failure points. It is not sure how and if the greater simplicity of the ISLE protocol impacts operations including lower risk of failure.

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- Observation: Phase V-4 was rejected early due to higher rates of DCS. The Committee discussed the phenomenon of a “cluster effect” of DCS which has been well described in statistical analyses. Such a cluster could cause the discontinuation of what might turn out to be a potentially viable protocol.
  
- Observation: The early discontinuation of a trial raised numerous comments regarding ground-based trial design requirements. The Committee recognizes the continuous progress of the research group as it has worked to refine and improve methodology. The next logical step may be to adopt a more “pharmaceutical Phase I and Phase II clinical trials” approach in which similar numbers of subjects are enrolled in each protocol even if early cases of DCS occur (unless Type II DCS occurs or the reject criteria are clearly met). This will enable protocols to be evaluated against each other in terms of relative risk. Not only might this further refine our understanding of decompression physiology, but it has distinct advantages in building a more robust model.
  
- Although the explanation remains obscure, there is now a significant body of EVA data that support the notion that ground based trials overestimate the likelihood of DCS in microgravity, and by inference, VGE as well. This experience was a factor in the Panel’s recommendation to proceed with operational use of ISLE. Doppler data in microgravity would be extremely valuable, both to confirm this hypothesis and for use in future predictive studies. Thus, the Committee felt strongly that data regarding VGE on-orbit would be of immense value in interpreting the predictive value of future ground based protocols.

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## Appendix D. NESC ISLE Peer Review: Ops Perspective



## NESC ISLE PEER Review: Ops Perspective

*JSC Mission Operations Directorate  
Flight Director Office*

*DA8/J. Derek Hassmann  
10/14/10*

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## ISS EVA Overview



- **First ISS based EVA executed on STS-104/7A (7/01) followed by 79 EVAs to support ISS assembly**
  - **22 EVAs used CEVIS Exercise Protocol**
    - 18 EVAs during Shuttle missions
    - 4 stage EVAs
  - **68 EVAs used Campout Protocol**
    - 54 EVAs during Shuttle missions
    - 12 stage EVAs
  
- **Six additional EVAs are planned prior to Shuttle retirement**
  - **Two EVAs planned for STS-133; four EVAs planned for STS-134**
  - **If STS-135 is baselined then it may include additional EVAs**



Mission Operations Directorate  
Flight Director Office

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## Post Shuttle ISS EVA Outlook



- **Post Shuttle retirement ISS consumables will support up to eight EVAs per year although EVAs are not expected to be executed at this rate**
  - **Assuming no failures of critical external equipment then the actual rate is likely to be 1-2 EVAs per year**
  - **O<sub>2</sub> is the limiting consumable to support EVAs**
- **ISLE protocol has the potential to offer several benefits**
  - **Expected to save ~6 lbm O<sub>2</sub> per EVA (13 lbm vs 19 for campout)**
  - **Does not require isolation in airlock overnight**
    - **Evening before and morning of EVA are more “normal” as compared to campout**
  - **Less crew time on PHA mask can be uncomfortable and difficult to use**
  - **ISLE could be a better downmode option if a campout protocol is broken**



Mission Operations Directorate  
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## Appendix E. NESC ISLE Prebreathe Protocol Review

# NESC ISLE PREBREATHE PROTOCOL REVIEW



**JOSEPH DERVAY, M. D.  
OCTOBER 14, 2010  
USRA**



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## Campout Prebreathe EVA History

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### **As of 17 August 2010:**

- 3.5 hr In-suit PB, first STS EVA
  - 2 person EVA in 1 use
- 4.0 hr In-Suit PB
  - 4 person-EVAs in 2 uses
- 10.2 psi Staged PB
  - 151 person-EVAs in 75 uses
- Exercise PB
  - 44 person-EVAs in 22 uses



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## Campout Prebreathe EVA History

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- Total Campout EVAs – 68 (Sept 06 – Aug 10)
  - With Shuttle docked: 56
  - ISS only: 12
- Number per year:
  - 2006: 7
  - 2007: 20 (8 ISS)
  - 2008: 16 (1 ISS)
  - 2009: 13
  - 2010: 12 (3 ISS)



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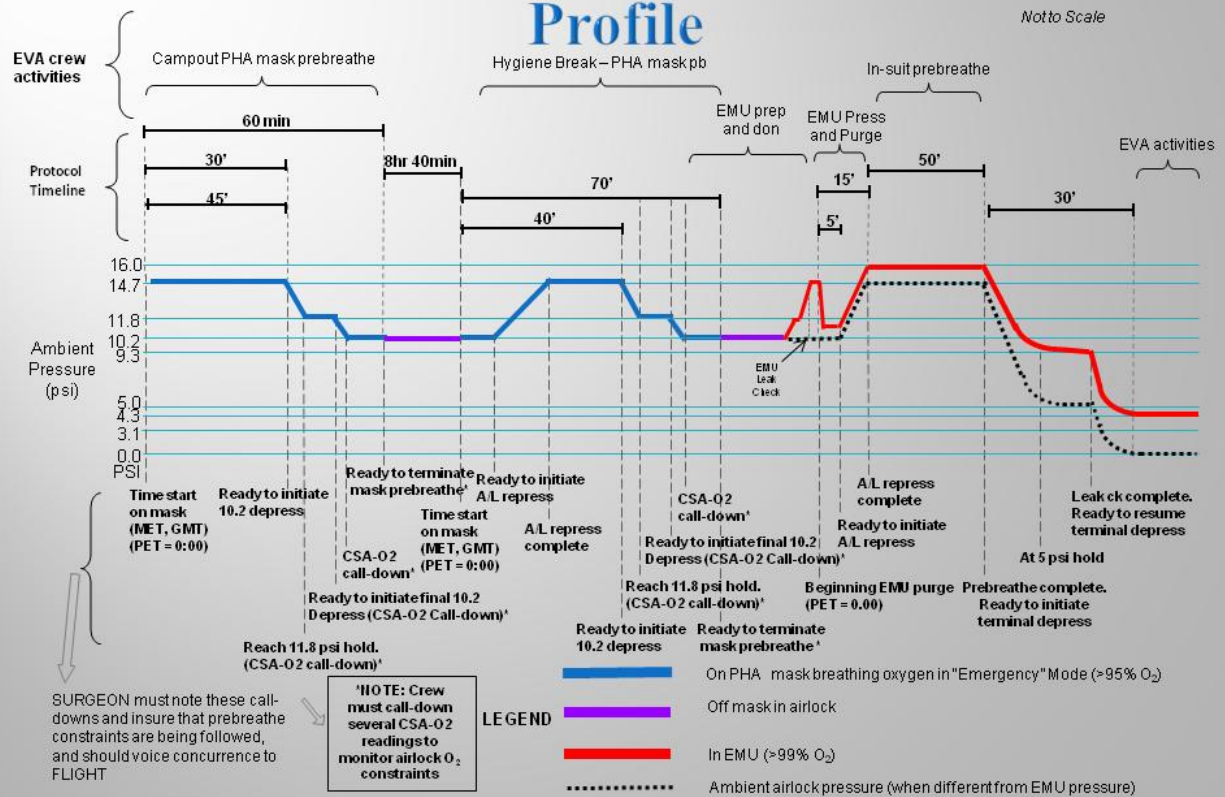
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## Phase V-5 In-Suit Light Exercise (ISLE) Prebreathe Protocol

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**Final**


# Campout Prebreathe Protocol Pressure Profile



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## Breaks in Campout P/B History

- 5 Breaks in prebreathe
  - Exp 14: PHA reg. detached from mask during initial mask P/B prior to overnight stay. Reg. held in place. 1.5 min break in P/B (3 min payback).
  - STS-124, EVA1: Comm Cap pigtail became loose during in-suit phase (A/L at 14.7). Helmet removed, reconnected pigtail. 3:05 min break in P/B (6:10 min payback).
  - STS-128, EVA2: Comm Cap chin strap came undone during in-suit phase (A/L at 14.7) . Helmet removed, strap redone. 3.5 min break in P/B (7 min payback).

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## Breaks in Campout P/B History (Cont.)


- STS-129, EVA2: False Depress Alarm onboard while crew 2.5 hours into sleep in A/L, Auto response repressed A/L. Campout canceled due to time to reconfig A/L (1.5 hr), Exer. P/B scheduled next day, wake up time delayed, Exer. P/B successfully executed.
- STS-129, EVA3: Drink Bag bite valve came off tube stem, crew in suit (A/L just arrived at 14.7). Depressed back to 10.2, expecting to change out drink bag. Able to reinstall same bite valve, repressed back to 14.7. Delayed start of 50 min in-suit P/B by ~1 hr.

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## Campout Update

- **Logistic regression model predicted 2.8% DCS (1.2% - 5.9%, 95% confidence interval).**
  - Regression inputs were 1.437 tissue ratio based on proposed campout prebreathe protocol, the presence of lower body adynamia, and exercise during the EVA.
  - Regression model and other details are in: Conkin J, Powell MR. Lower body adynamia as a factor to reduce the risk of hypobaric decompression sickness. Aviat Space Environ Med 2001 ; 72:202-14.
- **No reports of symptoms linked to DCS in 136 person-EVAs with 68 uses of campout from the ISS.**
  - From the binomial distribution, given no DCS in 136 EVAs there is a very low probability that even the lower estimate of 1.2% DCS is being realized [ $P_0 = (1-P)^N = 0.988136 = 0.19$ ].



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## Campout Update

---

- **Conclusions:**
  - Astronauts enjoy greater protection from DCS than expected after Campout, probably through additional operational prebreathe, other protective factors in microgravity; and/or
  - The regression model over-estimated the true P(DCS); and/or
  - Astronauts are not reporting low intensity symptoms assuming that the true P(DCS) <<< 5%.



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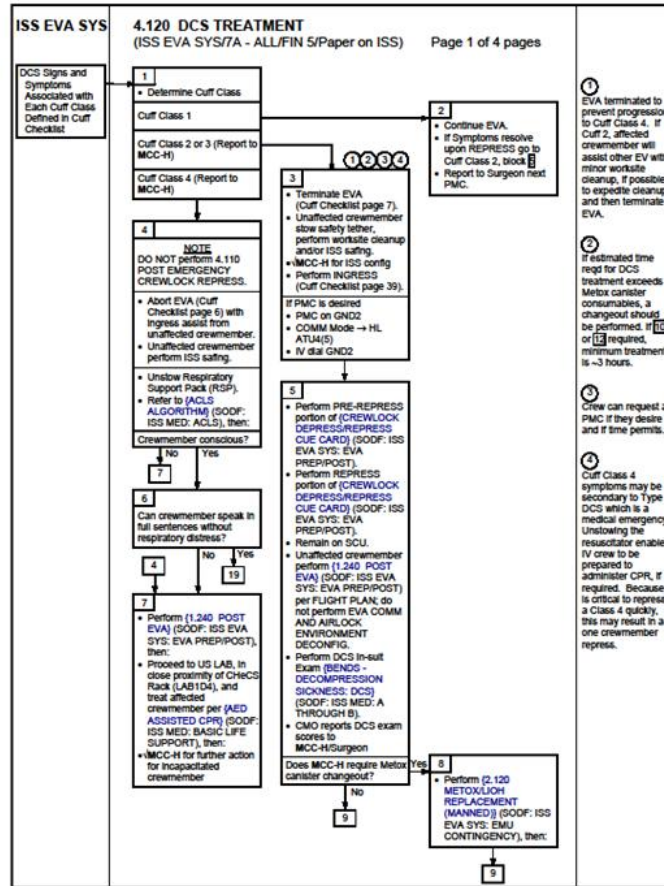
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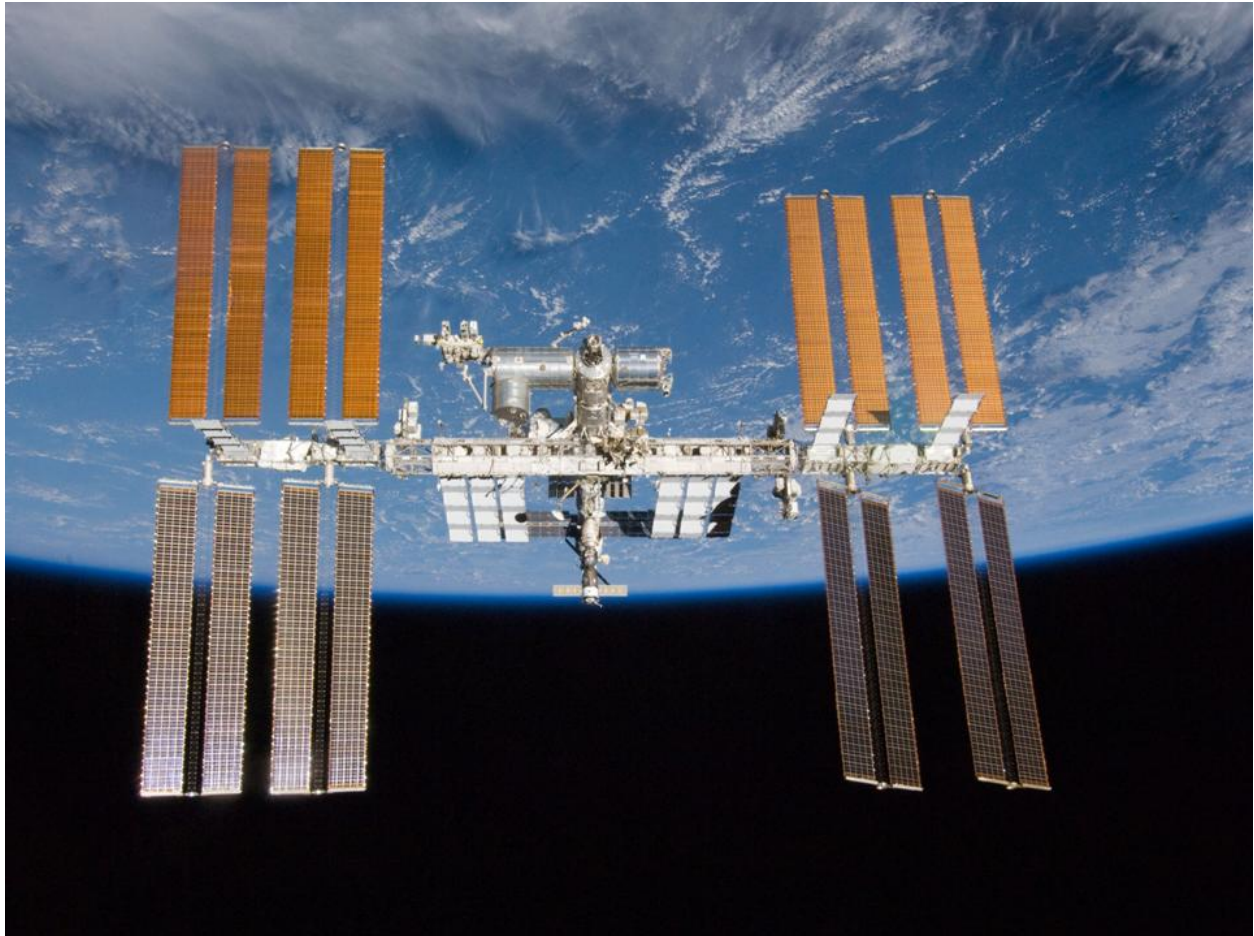
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## Appendix F. In-Suit Light Exercise (ISLE) Prebreathe Protocol

# In-Suit Light Exercise (ISLE) Prebreathe Protocol




Michael L. Gernhardt, Ph.D.

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## Introduction - Board Review Status

- ◆ **Historically known as In-Suit Exercise Prebreathe (PB) Protocol**
  - Phase V (1-5) research in collaboration with Duke University
  - V-5 now termed, "In-Suit Light Exercise (ISLE) PB Protocol"
  
- ◆ **Board reviews completed**
  - Life Science EVA IPT
    - Unanimous approval to move forward for consideration of operational use
  - Medical Operations Board (MOB) – 6/21/10
    - Unanimous MOB approval to allow further appropriate reviews
  - EVA System Project Office/XA CCB - 7/14/10
    - Approved
  - Space Medicine (SM) Configuration Control Board (CCB) 7/15/10
    - Approved
  - Space & Life Sciences Directorate (Flight Activities Control Board) –
    - August 18, 2010


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## **Introduction - Board Review Status (continued)**

### **◆ Upcoming Reviews**

- Space Station Program Control Board (SSPCB)
  - Date TBD
- Joint Operation Panels (JOPs)
  - Date TBD
- NASA Engineering & Safety Center (NESC)
  - High level final scientific review
  - Oct 14, 2010, at USRA
  - Dr. Caroline Fife, to Chair voting members

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## Introduction – EVA Protocol Metrics

### ♦ EVA Protocol Metrics (as of 17 August 2010)

- 3.5 hr In-Suit PB, first STS EVA
  - 2 person EVA in one use
- 4.0 hr In-Suit PB
  - 4 person-EVAs in two uses
- 10.2 psi Staged PB
  - 151 person-EVAs in 75 uses
- Exercise PB
  - 38 person-EVAs in 19 uses
- Campout PB
  - 136 person-EVAs in 68 use





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## Overview of Phase V-5 In-Suit Light-Exercise Prebreathe Protocol




**Mike Gernhardt, Ph.D.**

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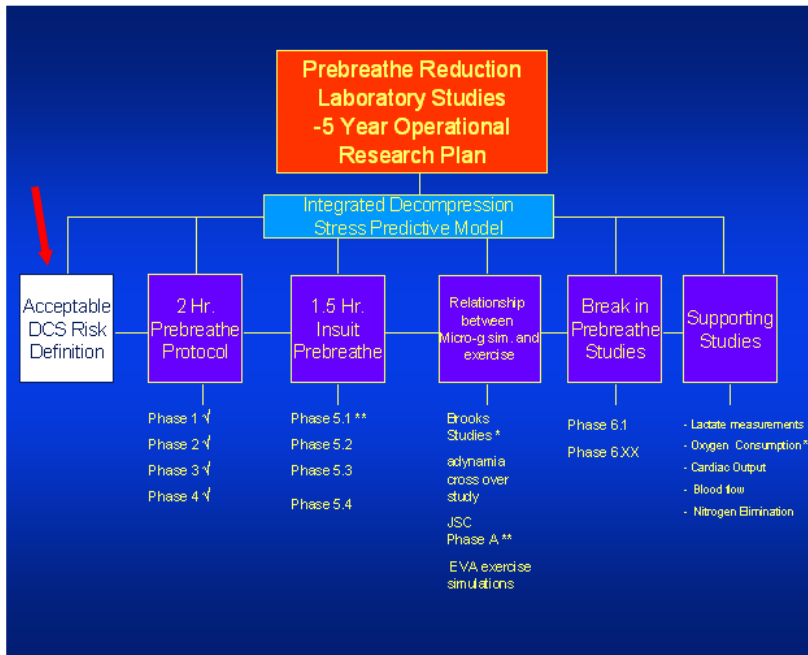
## Prebreathe Reduction Program

- ◆ **Initiated in late 1997 to address the limitations of campout**
  
- ◆ **Objective: Develop, test, certify and implement a 2hr prebreathe protocol for EVA from ISS by July 1999 (the installation and first use of the ISS joint airlock)**
  - Reduce the prebreathe time by 50% over the 4 hr protocol and maintain or increase the safety margins
  - Enabling research protocols were not operationally feasible ( too long or very high DCS risk)
  
- ◆ **Develop an integrated decompression system, not just a prebreathe protocol**
  - DCS disposition Policy, improved treatment protocols, definition of acceptable DCS risk, reduced prebreathe protocol with improved safety, integrated longer term research plan


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## Prebreathe Reduction Program




- ◆ Start by defining acceptable DCS risk for ISS mission and developing accept/reject limits for countermeasure trials
- ◆ Early development focused on delivering acceptable/effective counter measure
- ◆ Later development focused on increased efficiency and improved scientific understanding of counter measure mechanisms

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## DCS Risk Definition and Contingency Plan

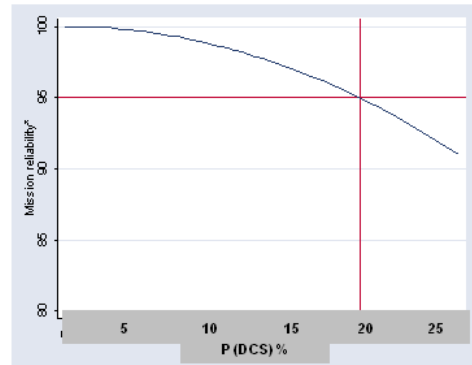
- ◆ **Assembled team of scientists, flight docs, crew members, MOD personnel, flight directors, statisticians and outside agencies involved with similar operations (USAF, USN)**
- ◆ **One year rigorous, data driven process**
  - Systematically define the issues and mission drivers that affect acceptable risk
  - Collect and analyze historical data focused toward the key drivers
  - Determine the medical and operational impacts of different risk levels
    - Developed much improved on-orbit treatment protocols
      - Crewmembers remain under pressure (4.3- 8 psi over ambient) breathing O<sub>2</sub> vs. ambient pressure air break (30+ mins) followed by 8.3 psi O<sub>2</sub> in the suit.
  - Established clear DCS disposition policy (JPG 1800.3)
    - One Type I DCS, go for EVA in 72 hours
    - Second Type I DCS, or Type II DCS, out of rotation without AMB waiver
  - Establish Flight rules for prebreathe procedures and DCS management

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## DCS Risk Definition and Contingency Plan

- Applied DCS disposition policy to the EVA assembly and maintenance model of the ISS (~484 EVAs from shuttle and ISS).
- Defined highest DCS risk consistent with a 95% probability that 2 of 3 crew members would always be available for EVA
  - Highest DCS risk – 21%
- Acceptable DCS risks were further reduced to account for related medical factors
  - On-orbit treatment
  - Delay of 30-45 min for re-pressurization
  - PFO considerations (added grade IV VGE)
  - Long term health risks
- Subjected DCS and grade IV VGE to constraint that they be below a threshold at where there has ever been a report of type II DCS in the literature





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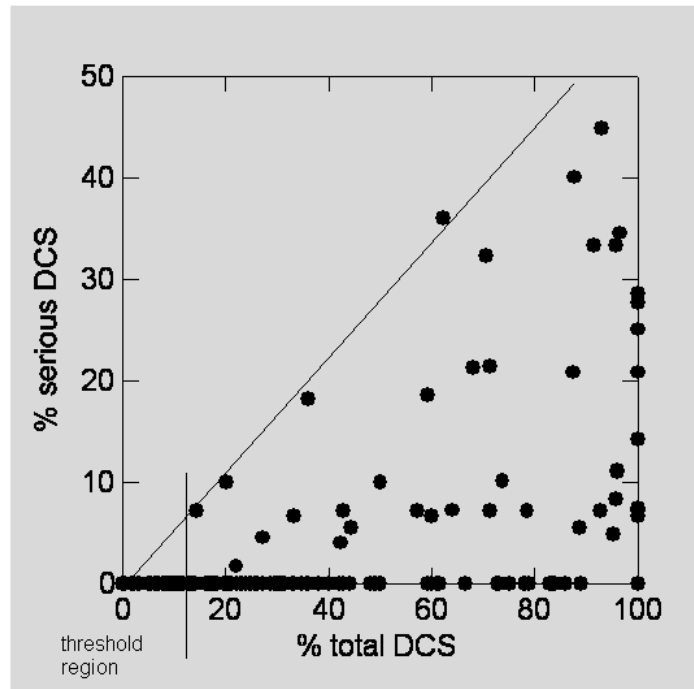
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### Threshold below which there were no type II DCS in 244 Tests with 7692 Exercising Subjects



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## Accept / Reject Levels for Prebreathe Trials

- ♦ **The mission driver of 95% probability that 2 of 3 crew members available for EVA throughout ISS program, combined with additional medical/operational considerations resulted in the following accept/reject limits:**
  - Accept: DCS  $\leq 15\%$  and Grade IV VGE  $\leq 20\%$ , @ 95% c.I
  - Reject: DCS  $> 15\%$  or Grade IV VGE  $> 20\%$ , @ 70% c.I
    - Any case of Type II DCS
  
- ♦ **Peer reviewed by the Lambertsen Committee. More conservative:**
  - than any previous EVA prebreathe trial including a 6 hr prebreathe
  - All trials of shuttle EMU and Russian Orlan prebreathe protocols
  
- ♦ **Closed (200 trials) sequential, multi-center trial, informed consenting subjects representative of astronaut population (age, gender, fitness, % body fat)**
  
- ♦ **50 trial minimum to control type II error to less than 1%**
  - Review of the data, continuation of the trials if probability of future acceptance  $> 50\%$
  
- ♦ **Planned for testing up to four protocol options**



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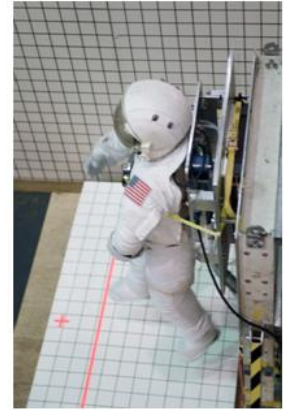
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## **Phase V In-Suit Light Exercise (ISLE) Prebreathe Protocol**



### **Laboratory Physiological Testing**


- Determine decompression efficacy of intermittent exercise prebreathe protocols
- Decompression to 4.3 psi - Doppler and TTE monitoring
- Simulated EVA work at 4.3 psi
- Trials at Duke, DCIEM and NASA

### **In-suit Exercise Control and Loads Test**

- Determine how accurately crew can control exercise in suit vs lab ergometer (used in decompression trials)
  - tank pressure, heart rate and cadence
- measure loads, and accelerations
- Volume/Displacement measurements

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## Overview of Phase V In-Suit Exercise Protocol Testing

<b>Pretest</b>	Test Subject Recruitment → Subject Inclusion/Exclusion Criteria → Establish Exercise Prescription and Perform VO <sub>2 peak</sub> Test → Enter Study																								
	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Age Group</td> <td style="width: 20%;">25-34</td> <td style="width: 20%;">≤50%</td> <td style="width: 30%;"></td> </tr> <tr> <td></td> <td>35-60</td> <td>≥50%</td> <td></td> </tr> <tr> <td>Inclusion</td> <td>Male</td> <td>Female</td> <td></td> </tr> <tr> <td>VO<sub>2 peak</sub> (mL·kg<sup>-1</sup>·min<sup>-1</sup>)</td> <td>&gt;35</td> <td>&gt;30</td> <td></td> </tr> <tr> <td>Gender</td> <td>80-85%</td> <td>15-20%</td> <td></td> </tr> <tr> <td>Body Fat</td> <td>≤30%</td> <td>≤35%</td> <td></td> </tr> </table>	Age Group	25-34	≤50%			35-60	≥50%		Inclusion	Male	Female		VO <sub>2 peak</sub> (mL·kg <sup>-1</sup> ·min <sup>-1</sup> )	>35	>30		Gender	80-85%	15-20%		Body Fat	≤30%	≤35%	
Age Group	25-34	≤50%																							
	35-60	≥50%																							
Inclusion	Male	Female																							
VO <sub>2 peak</sub> (mL·kg <sup>-1</sup> ·min <sup>-1</sup> )	>35	>30																							
Gender	80-85%	15-20%																							
Body Fat	≤30%	≤35%																							
<b>Test</b>	Perform Intermittent Prebreathe Exercise with Individual Prescription - Protocol 1,2,3,4 → Perform 4 hrs. Simulated EVA - Doppler monitoring - Suit simulator → Apply Test Termination Criteria																								
<b>Analysis</b>	Diagnosis of DCS by Independent Medical Officer → Apply Data Inclusion/Exclusion Criteria → Test of Hypothesis																								
	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">           Definitions of DCS from NASA DCS Policy Document JPD 1800.2 Case Specific DCS Definitions 11/22/02         </td> <td style="width: 50%;">           Adynamia break, number steps minimized/counted            Altitude time ≥230 min, excluding depressurization time            4.1 &lt;Final Altitude EVA Pressure ≥4.4 psia            Depress times ≤5 min of specified time, exercise &lt;30% deviation, average of 10%         </td> </tr> </table>	Definitions of DCS from NASA DCS Policy Document JPD 1800.2 Case Specific DCS Definitions 11/22/02	Adynamia break, number steps minimized/counted Altitude time ≥230 min, excluding depressurization time 4.1 <Final Altitude EVA Pressure ≥4.4 psia Depress times ≤5 min of specified time, exercise <30% deviation, average of 10%																						
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## Phase V-5 Protocol

- ◆ **Previous Phase V in-suit exercise protocols did not incorporate 10.2 psi depress/repress**
- ◆ **PRP data (all protocols) were analyzed showing 10.2 psi depress/repress significantly reduced DCS and VGE**
- ◆ **10.2 depress/repress added to V-5**
- ◆ **Also included light exercise equivalent to walking a mile in 70 min.**

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## Phase V-5 Laboratory Protocol

- ◆ 60 min on mask while doing EVA prep and 10.2 psi depress (light exercise at  $5.8 \text{ mL} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$ )
- ◆ 30 min suit donning at 10.2 psi
- ◆ 50 min in-suit light activity ( $6.8 \text{ mL} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$ )
- ◆ 50 min final in-suit PB at rest

Rest	Prebreathe				Flight Simulation	
	Light Exercise (EVA Prep) ( $5.8 \text{ mL} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$ )		Light In-Suit Exercise ( $6.8 \text{ mL} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$ )		Ascent Rest	30,300 ft Light Exercise
	Depress to 10.2 psi		Repress			
	40 min	20 min	5	45 min		
	60 min	30 min	50 min	50 min		
130 min	190 min				30 min	240 min
Air	Oxygen	0.265 Oxygen	Oxygen			

- ◆ **Laboratory protocol does not include additional safety margin built into the flight protocol including:**
  - ◆ Configuration checks, leak check, purge and 5 psi suit overpressure during crewlock depress- all of which add ~ 25 mins of prebreathe that was conservatively not performed on the laboratory protocol.



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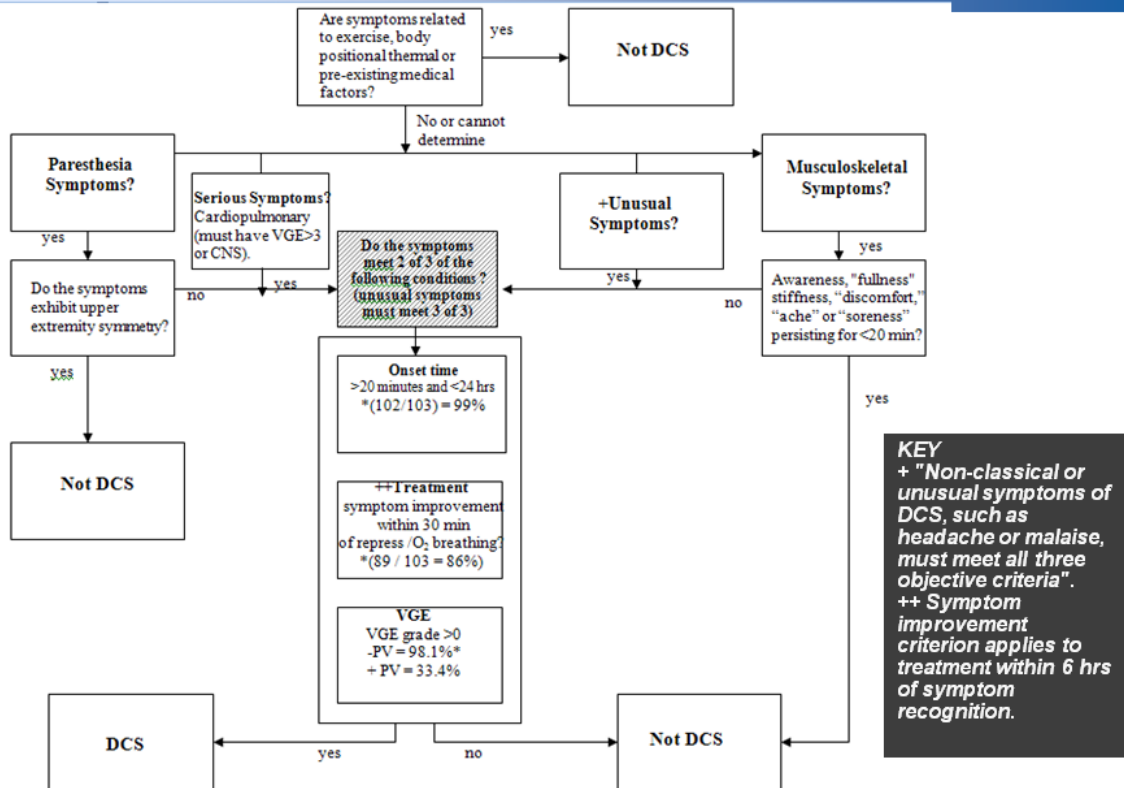
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### DCS Diagnosis Flow Diagram (\*from NASA historical data)



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# RESULTS

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## PRP V-5: Subject Characteristics

Subjects completing exposures						
Gender	Age (years)	Weight (kg)	Height (m)	BMI (kg·m <sup>-2</sup> )	Fat (%)	VO <sub>2 peak</sub> (ml·kg <sup>-1</sup> ·min <sup>-1</sup> )
M=36	37.3±8.1	84.8±10.9	1.74±0.06	26.1±2.9	14.1±4.7	44.8±7.5
F=11	35.5±8.4	61.2±4.3	1.61±0.06	21.9±1.2	17.9±3.5	41.0±8.0
Subject with exposure ending prematurely due to presence of LVGE (no symptoms)						
M=1	34.4	71.9	1.62	25.6	7.9	62.1



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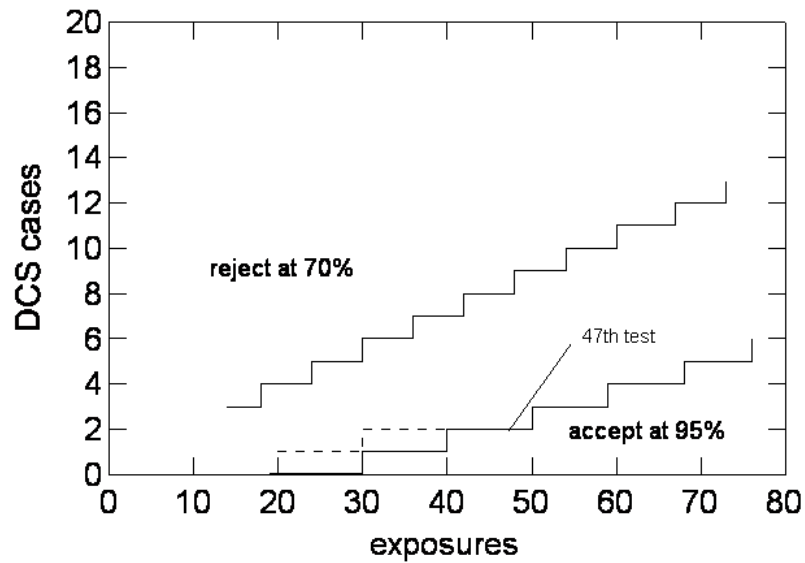
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### V-5 Accepted Based on DCS Outcome







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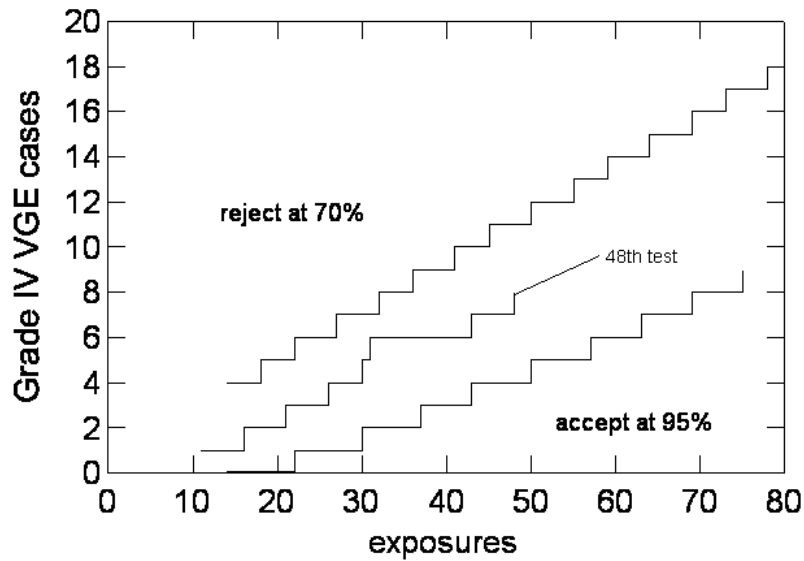
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### V-5 neither Accepted Nor Rejected based on Grade IV VGE



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## PRP Summary Results

Protocol	n	%DCS (n)	%VGE (n)	%GIV VGE (n)
I	47	19.1 (9)	48.9 (23)	4.2 (2)
II	45	0 (0)	31.1 (14)	6.6 (3)
III	9	22.2 (2)*	11.1 (1)	11.1 (1)
IV	56	14.3 (8)	41.0 (23)	12.5 (7)
V-1	9	33.3 (3)	55.5 (5)	22.2 (2)
V-2	3	33.3 (1)*	100.0 (3)	66.6 (2)
V-3	48	14.6 (7)	52.1 (25)	10.4 (5)
V-4	6	50.0 (3)	50.0 (3)	16.6 (1)
V-5	48**	4.2 (2)	29.2 (14)	16.6 (8)

\*Includes one case of Type II DCS

\*\* based on 48 acceptable trials for Grade IV VGE and 47 trials for DCS

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## PRP V-5: DCS and VGE Presentation

DCS			VGE <sup>2</sup>			
Type I	Latency <sup>1</sup> (min)	Type II	Any Non-Zero Grade	Any Non-Zero Grade Latency <sup>1</sup> (min)	Grade IV	Grade IV Latency <sup>1</sup> (min)
2/47 (4.2%)	139±44 (61-95)	0/47 (0%)	14/48 (29%)	105±62 (40-219)	8/48 (17%)	154±62 (84-220)

<sup>1</sup> Latency computed from time of arrival at exposure altitude

<sup>2</sup> One subject removed from study prematurely due to the presence of LVGE (presenting grade III VGE). This subject was excluded from computation of the DCS incidence since the exposure was stopped prematurely. Since the subject had Grade IV VGE, however, the case was used to compute the VGE incidence.

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## PRP V-5: DCS Case Descriptions

### ◆ **D0100**

- 21 yo female experienced sudden onset of 5/10 right knee pain following a 58 minute exposure at 4.3 psi (30,250 feet). Doppler bubble studies prior to the onset of pain were rated at grade IV VGE. Pain was sharp, constant and circumferentially involved the entire right knee. It was of a character similar to her usual knee pain following a very long and strenuous run. It did not change in intensity or quality with position, palpation or pressure. **The intensity of pain decreased to 2/10 at 26,000 feet, 1/10 at 20,000 feet and fully resolved at 17,000 feet (three minutes after beginning recompression).** The patient was examined after return to ambient pressure and then given a USN TT5.

### ◆ **D0113**

- 39 yo male complained of a 3-6/10 constant, shooting pain in his right knee that quickly extended into his right thigh after 93 min at altitude. He then reported a mild non-specific right knee "ache" for 20 min prior to noting the frank right knee pain. Prior Doppler studies identified grade IV VGE. **The subject left 30,000 ft with full resolution of symptoms while passing 8000 ft.** The patient was examined after return to ambient pressure and then given a USN TT5.

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# DISCUSSION



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### Comparison of Counts of Maximum VGE Grade through Time

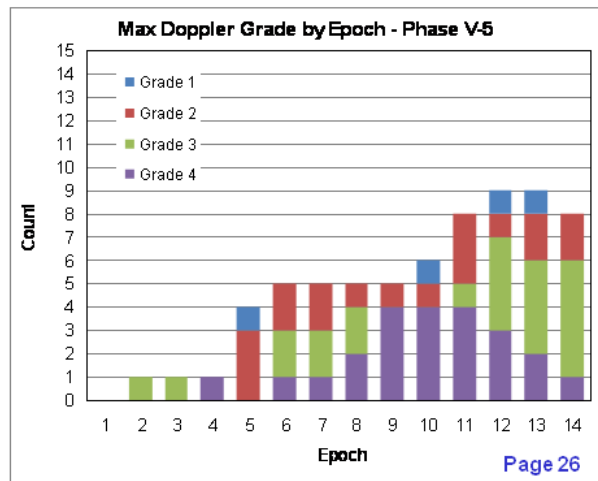
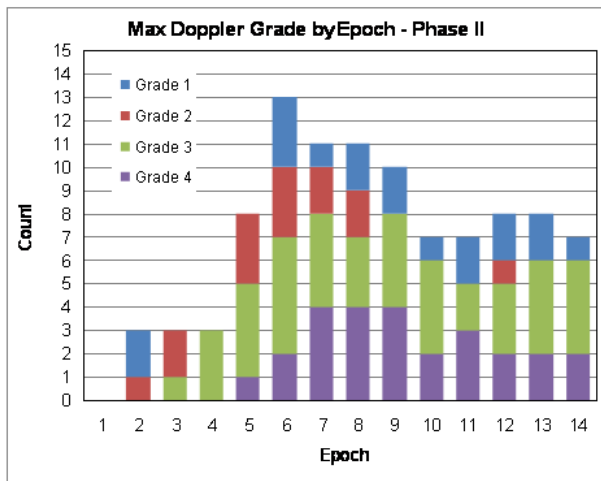
VGE	Phase II	Phase V-5
0	531	591
I	18	4
II	14	18
III	41	22
IV	26	23


Pooled Grade III-IV VGE  
contrast (10.6% vs. 6.8%)

Chi square = 5.84;  $p < 0.05$

Fisher exact =  $p = 0.01$

VGE	Phase II	Phase V-5
High Grade	67	45



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## Effect of 10.2 PSI Depress-Repress

10.2 Staged condition	%DCS	DCS latency (min)	%VGE	VGE latency (min)	%Grade IV VGE	Max VGE mean	ETR*
No (n=66)	21.2	128	54.5	99	15.2	1.51	1.875
Yes (n=204)	10.3	100	36.6	95	10.2	0.93	1.823
p-value	<b>0.02</b> $\chi^2$	0.058 t-test	<b>0.01</b> $\chi^2$	0.71 t-test	0.27 $\chi^2$	<b>0.01</b> t-test	<b>0.00</b> t-test

\*based on 270 records

*Since differences in DCS and VGE outcome can be attributed to the staged condition AND the ETR, 37 exposures with lower ETR were removed from the dataset to result in similar ETR for both conditions.*

10.2 Staged condition	%DCS	DCS latency (min)	%VGE	VGE latency (min)	%Grade IV VGE	Max VGE mean	ETR*
No (n=66)	21.2	128	54.5	99	15.2	1.51	1.875
Yes (n=167)	12.6	100	38.3	90	9.6	0.94	1.873
p-value	0.09 $\chi^2$	0.058 t-test	<b>0.02</b> $\chi^2$	0.46 t-test	0.22 $\chi^2$	<b>0.01</b> t-test	0.68 t-test

\*based on 233 records



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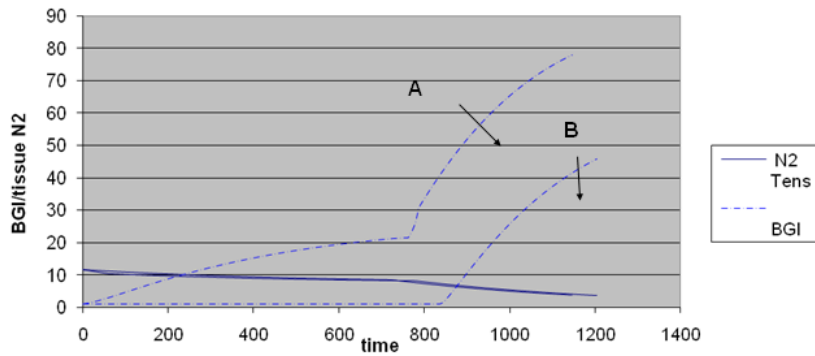
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### 10.2 PSI Staged Decompression Protocol


DCS and VGE results of 10.2 staged decompression procedure, without initial 60 minute prebreathe (A) and with an initial 60 minute

10.2 psi w and w/o 1 hr prebreathe



Protocol	n	DCS (%)	DCS Mean Onset Time (min)	DCS Minimum Onset Time (min)	VG E (%)	VGE Mean Onset time (min)	VGE Minimum Onset time (min)
A	22	27 <sup>1</sup>	134 ± 75	17	45	43 ± 43	1
B	35	23	194 ± 90	90	57	123 ± 72	24




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## Comparison of Operational Factors of Different Prebreathe Protocols

Components	Phase IV	V-4	V-5
Total Light Exercise (min)	95	150	140 <sup>1</sup>
Suit Simulator (min)	95	150	60
Leg Ergometry (min)	0	0	50
Total Light Exercise on O <sub>2</sub> (min)	80	150	110
In-Suit Prebreathe (min)	40	160	100
Total Prebreathe (min)	120	160	160
10.2 Depress	Yes	No	Yes
Total VO <sub>2</sub> (mL·kg <sup>-1</sup> )	604	905	863 <sup>1</sup>
Upper/Lower Body Work	All upper	All upper	51% U 49% L
Post-Exercise/Pre-Depress Rest (min)	40	0	50

<sup>1</sup> Total light exercise includes 30 min of suit simulator exercise conducted at 10.2 psi to simulate suit donning. All other times refer only to oxygen breathing periods

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## Comparison of EVA Prebreathe Protocols SUMMARY TABLE



PROTOCOL COMPARISON	ISLE	Exercise	Campout	4 Hr In-Suit
Post Sleep / Pre-Sleep Durations (GGR&C Guidelines are met)	1:10 [1] / 2:00	1:30 / 2:00	0:50 [1] / 2:00	1:30 / 2:00
Time from Post Sleep to start of EVA	4:57	4:50	4:15	6:15
Post EVA Ops (not including H2O, METOX)	1:00	1:00	1:00	1:00
EVA PETI (Time to not exceed recommended crew day length)	6:30 / (6:13)	6:30 / (6:00)	6:30	6:30 / (4:35)
Additional Time needed above recommended ISS crew day length (15:30 per GGR&C) to allow a 6:30 EVA duration [2]	0:17	0:30	None (-0:45)	1:55
Airlock Isolation	1:44	2:12	11:59	none
Mask Time (minimum)	1:00	1:20	2:10	none
Prebreathe In-Suit Time (minimum) [3]	2:35 [4]	1:45	1:20	4:30 [4]
Depress/Repress Cycles	2	2	3	1
METOX Cans Used per CM: EMU*/ A/L Scrubbing**/ Cans Req'd***	1.25 (1) / 0.5 / 6 (4)	1 / 0.5 / 4	1 / 1 / 4	1.5 / 0 / 4
EVA PB O2 Usage (planning numbers) [5]	18-20 lbs	25 lbs	25 lbs	10 lbs

[1] For Campout, 40 min of Post Sleep occurs during Hygiene Break. For ISLE, 20 min of Post Sleep occurs during EVA Prep.

[2] For ISS crew, Post Sleep duration is 1:30 and Pre Sleep duration is 2:00. Total crew day length is 15:30. [REF: SSP 50261-01, REV A GENERIC GR&C (COLLATED MASTER - THRU DCN 016) 12/22/04]

[3] Does not include time in-suit for EMU Donning activities nor EMU PURGE. Does include time during C-Lk depress to vacuum.

[4] An additional purge of 2 min will be required after the METOX Changeout. Apprx. 0.4 lbs of additional O2 used for the 2-min purge.


[5] Apprx. Values for total O2 for both CMs. These are conservative numbers used for planning purposes. Generally see lower numbers. However, using the conservative numbers also accounts for other EMU and Airlock maintenance activities which require the use of some O2.

\* For ISLE and 4 hr In-suit protocols: canisters used in first part of in-suit prebreathe before changeout may be used again on a subsequent EVA day for the same first part of in-suit prebreathe. 4 hr In-Suit cans can be used twice. ISLE cans can be used four times.

\*\* CO2 Removal Receptacle which scrubs CO2 from A/L anytime isolated requires 2 METOX canisters (cannot use 1 canister). The METOX canisters used for A/L scrubbing during Exercise or ISLE protocols can be used again in the CO2RR during a subsequent Exercise or ISLE protocol.

\*\*\* Physical count of canisters required to run protocol. ISLE may not require METOX Changeout, if consumables can support. If changeout not reqd, use values in ().

10/06/2010


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## Light Exercise Prescription based on O<sub>2</sub> tank Pressure Drop

Male Subject Assumed Body weight: 85 Kg Assumed O <sub>2</sub> Consumption: 6.8 cc/Kg/min Assumed Leak Rate: 0 cc/min			Female Subject Assumed Body weight: 65 Kg Assumed O <sub>2</sub> Consumption: 6.8 cc/Kg/min Assumed Leak Rate: 0 cc/min		
Elapsed Time (min)	Increase in O <sub>2</sub> Consumption (cc)	Decrease in O <sub>2</sub> Bottle Pressure (psi)	Elapsed Time (min)	Increase in O <sub>2</sub> Consumption (cc)	Decrease in O <sub>2</sub> Bottle Pressure (psi)
0	0	850.0	0	0	850.0
5	2890	843.8	5	2210	845.3
10	5780	837.7	10	4420	840.6
15	8670	831.5	15	6630	835.9
20	11560	825.4	20	8840	831.2
25	14450	819.2	25	11050	826.4
30	17340	813.0	30	13260	821.7
35	20230	806.9	35	15470	817.0
40	23120	800.7	40	17680	812.3
45	26010	794.6	45	19890	807.6
50	28900	788.4	50	22100	802.9
55	31790	782.2	55	24310	798.2
60	34680	776.1	60	26520	793.5

$$\Delta P_{O_2} \text{ (psi/min)} = 0.0021315 * \Delta V_{O_2} \text{ (cc/min)}$$

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## In-Suit Light Exercise Protocol

### ◆ Pros


- Less O<sub>2</sub> usage than campout (one less 10.2 psi depress/repress cycle, and 60 mins mask O<sub>2</sub> vs 130 mins with campout)
  - Less cycles on depress pump
- Get out the door > 13 to 30 mins earlier than CEVIS protocol
- Less mask time for crewmembers than campout
- No isolation in the airlock overnight
  - Minimize operational impacts from false alarms
- Crew doesn't have to rush tool and suit configs in order to prepare for campout on the timeline
- Crew doesn't have to do bathroom break on 120 foot prebreathe hose, or use piddle packs during overnight campout
- No VO<sub>2</sub> peak test required as exercise prescription is based on weight only (6.8 ml/kg-min)
- Simpler procedures than CEVIS protocol

### ◆ Cons

- Get out the door ~ 60 mins later than campout
- 100 mins in-suit prebreathe time vs. 50 mins on campout
- Possible issues related to metox conditioning.

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# NASA Prebreathe Reduction Program (PRP) Phase V-5 Study: Exercise Tasks



**Neal W. Pollock, Ph.D.**

Center for Hyperbaric Medicine and Environmental Physiology  
Duke University Medical Center

Study funded by the National Aeronautics and Space Administration



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## **PRP EXERCISE STRATEGIES**




Suit simulator set up for multiple semi-recumbent intermittent light exercise simulating astronaut tasks



Suit simulator set up for leg ergometry

NWP Pollock, PhD

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## EVA SUIT SIMULATOR EXERCISES

- ◆ 6 exercises
  - sit-ups, arm pulls, full body pulls, torque wrenching, hand gripping, leg pedaling
- ◆ Subjects will cycle through
  - specific exercises
  - Doppler/2-D echo monitoring
  - Rest break
- ◆ 4 minute intervals for each
  - pace guided by an automated task prompter



NWPollock, PhD





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### **CROSS-ARM PULLS**



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### **HAND GRIP**



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### **FULL BODY PULL**



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### SIT-UP



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# TORQUE WRENCHING



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## LEG PEDALING



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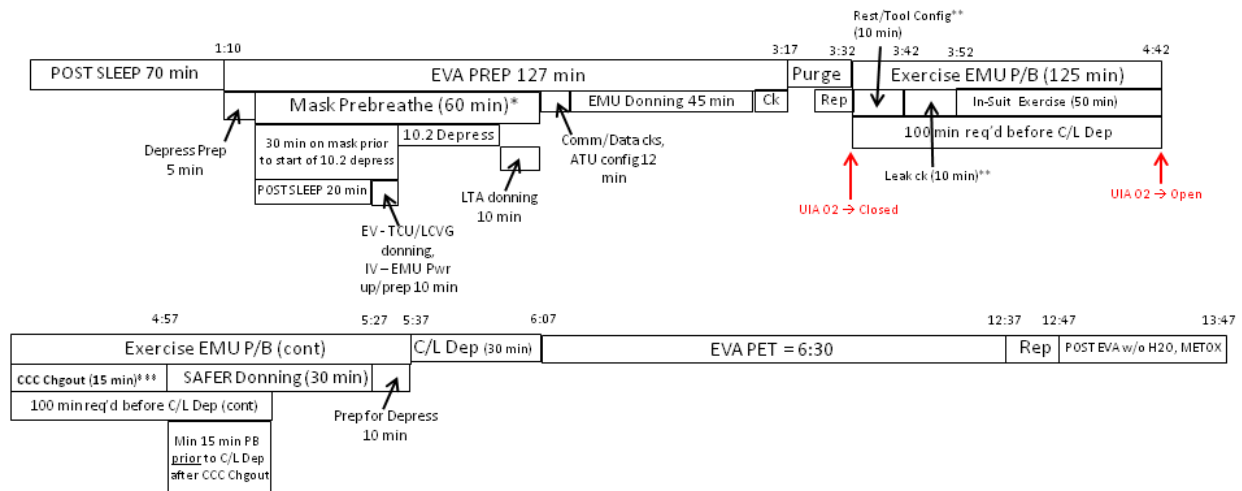
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## Time Comparison of Protocols



### In-Suit Light Exercise Prebreathe Timeline for EVA Day (w/CCC Changeout)



\* Assume 20 min of Mask PB may be done in parallel with POST SLEEP.

\*\* Due to uncertainty in O2 tank cool down effects and suit leak vs. crewmember breathe down rates, 20 min of EMU PB will be done prior to 50 min of in-suit exercise.

\*\*\* CCC changeout allows for max EVA PET capability. Changeout maybe optional, if not required for consumables, total timeline is 15 min shorter. An additional purge of 2 min will be required after the CCC Changeout.

Note: Assume depress/pump and EMERG MPEV & ALVAJ; 30 min C-Lk depress without built in hold at 5psi; 15 min CCC Changeout without PB pause during 2 min purge. With 2 hours of Pre-sleep, ISS Crew Day length = 15:47.

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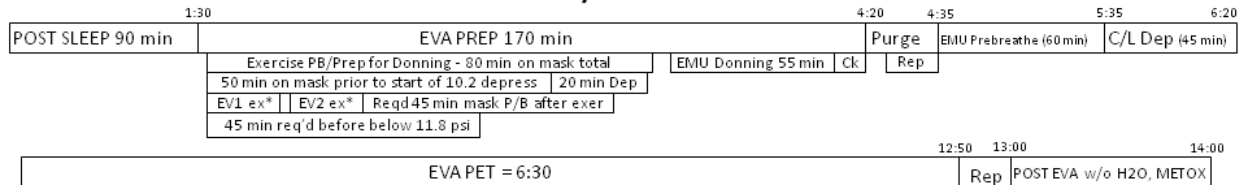
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### Time Comparison of Protocols

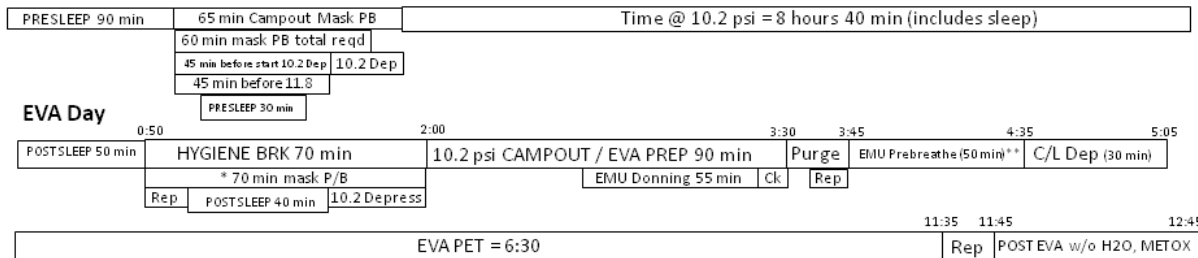


#### CEVIS Exercise Protocol Timeline for EVA Day



\* EV1 must start exercise within 10 min after PB initiate, EV2 must start exercise within 25 min after PB initiate to maintain 45 minute of masktime after exercise per FR  
Note: Assume depress pump and EMERG MPEV & AL VAJ; 45 min C-Lk depress with built in hold at 5psi PET = 25. With 2 hours of Pre-sleep, ISS Crew Day length = 16:00.

#### ISS 10.2 Campout Protocol Timeline



\* 70 min mask P/B to begin only after 8hr 40 min at 10.2 psi per FR. Assume 40 min of HYGIENE BREAK may be done in parallel with POSTSLEEP. Note that IV may be able to begin the EVA Prep activities during the Hygiene Break, which could possibly result in an additional 10 minute savings in the timeline.

\*\* In order to satisfy the accept criteria for ISS EVA protocols, an additional 10 minutes of in-suit prebreathe was added to the medical Campout protocol making the total in suit EMU Prebreathe for Campout = 50 min.

Note: Assume depress pump and EMERG MPEV & AL VAJ; 30 min C-Lk depress without built in hold at 5psi. With 2 hours of Pre-sleep, ISS Crew Day length = 14:45.

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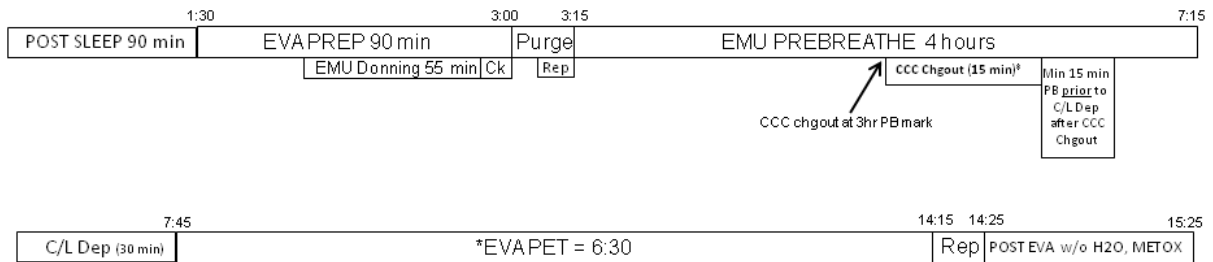
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## Time Comparison of Protocols




### 4 hr In-Suit Protocol Timeline for EVA Day



<sup>†</sup>CCC changeout would be performed 3 hours into prebreathe activities (manned) to allow for max EVA PET capability.


Note: Assume depress pump and EMERG MPEV & AL VAJ; 30 min C-Lk depress without built in hold at 5psi; 15 min CCC Changeout without PB pause during 2 min purge. With 2 hours of Pre-sleep, ISS Crew Day length = 17:25.

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## **Decrease in O<sub>2</sub> Bottle Pressure**

- ◆ **Assumptions for O<sub>2</sub> Bottle**
  - Volume = 480 cu inches
  - Temperature = 65° F
  - Initial Pressure = 850 psi
  
- ◆ **Using the Gas Equation,**
  - O<sub>2</sub> Depletion Rate (psi/min) = 0.0021315 x VO<sub>2</sub> (cc/min)
  
- ◆ **Therefore, after an elapsed time of TBD minutes**
  - O<sub>2</sub> Bottle Pressure (psi) = 850.0 - 0.0021315 x VO<sub>2</sub> (cc/min) x TBD (min)


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## O<sub>2</sub> Bottle Pressure Decrease with Pre-breathe Exercise & Suit Leak Rate of **50 cc/min**

Male Subject Assumed Body weight: 85 Kg Assumed O <sub>2</sub> Consumption: 6.8 cc/Kg/min Assumed Leak Rate: <b>50.0 cc/min</b>			Female Subject Assumed Body weight: 65 Kg Assumed O <sub>2</sub> Consumption: 6.8 cc/Kg/min Assumed Leak Rate: <b>50.0 cc/min</b>		
Elapsed Time (min)	Increase in O <sub>2</sub> Consumption plus Leak (cc)	Decrease in O <sub>2</sub> Bottle Pressure (psi)	Elapsed Time (min)	Increase in O <sub>2</sub> Consumption plus Leak (cc)	Decrease in O <sub>2</sub> Bottle Pressure (psi)
0	0	850.0	0	0	850.0
5	3140	843.3	5	2460	844.8
10	6280	836.6	10	4920	839.5
15	9420	829.9	15	7380	834.3
20	12560	823.2	20	9840	829.0
25	15700	816.5	25	12300	823.8
30	18840	809.8	30	14760	818.5
35	21980	803.1	35	17220	813.3
40	25120	796.5	40	19680	808.1
45	28260	789.8	45	22140	802.8
50	31400	783.1	50	24600	797.6
55	34540	776.4	55	27060	792.3
60	37680	769.7	60	29520	787.1

$$\Delta P_{O_2} \text{ (psi/min)} = 0.0021315 * \Delta V_{O_2} \text{ (cc/min)}$$

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## O<sub>2</sub> Bottle Pressure Decrease with Pre-breathe Exercise & Suit Leak Rate of **100 cc/min**

Male Subject Assumed Body weight: 85 Kg Assumed O <sub>2</sub> Consumption: 6.8 cc/Kg/min Assumed Leak Rate: <b>100 cc/min</b>			Female Subject Assumed Body weight: 65 Kg Assumed O <sub>2</sub> Consumption: 6.8 cc/Kg/min Assumed Leak Rate: <b>100 cc/min</b>		
Elapsed Time (min)	Increase in O <sub>2</sub> Consumption plus Leak (cc)	Decrease in O <sub>2</sub> Bottle Pressure (psi)	Elapsed Time (min)	Increase in O <sub>2</sub> Consumption plus Leak (cc)	Decrease in O <sub>2</sub> Bottle Pressure (psi)
0	0	850.0	0	0	850.0
5	3390	842.8	5	2710	844.2
10	6780	835.5	10	5420	838.4
15	10170	828.3	15	8130	832.7
20	13560	821.1	20	10840	826.9
25	16950	813.9	25	13550	821.1
30	20340	806.6	30	16260	815.3
35	23730	799.4	35	18970	809.6
40	27120	792.2	40	21680	803.8
45	30510	785.0	45	24390	798.0
50	33900	777.7	50	27100	792.2
55	37290	770.5	55	29810	786.5
60	40680	763.3	60	32520	780.7

$$\Delta P_{O_2} \text{ (psi/min)} = 0.0021315 * \Delta V_{O_2} \text{ (cc/min)}$$



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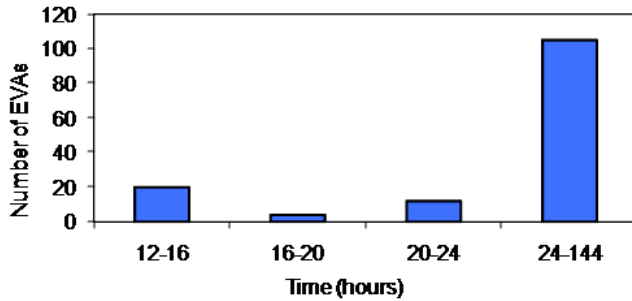
Title:

**Phase V-5 In-Suit Light Exercise (ISLE)  
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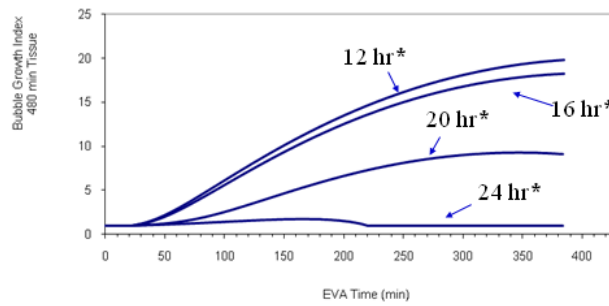
**Flight Experience – Shuttle 10.2 psi staged Protocol**




**Figure 5. Time at 10.2 psi prior to shuttle EVA**

**Figure 6. Theoretical Tissue Bubble growth as a function of 10.2 exposure time**

\* Reflects the 40 min in-suit prebreathe used in ground and early shuttle flights. Later flights incorporated 75, 60 and 40 min prebreathes for 12, 24 and 36 hr exposures, respectively



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# **INTRODUCTION AND BACKGROUND**



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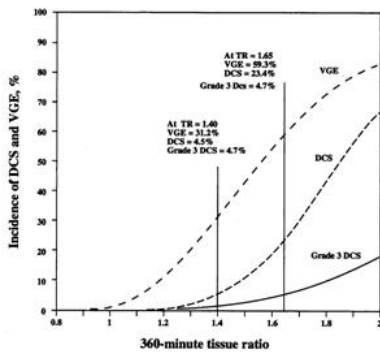
## Phase V-5 In-Suit Light Exercise (ISLE) Prebreathe Protocol

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### Defining and Controlling Risk in Operational Research Programs – Example of Prebreathe Reduction Program (PRP)

#### Background



Shuttle Prebreathe Ground Trials (~ 25% DCS, ~ 5% symptoms that would terminate an EVA.) Acceptable Risk?

- 4 hour prebreathe
- 10.2 psi staged protocol
- 146 EVAs exposures with no reports of DCS

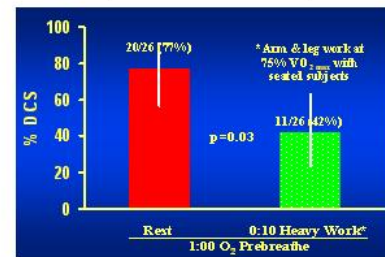
#### ISS Overnight Campout



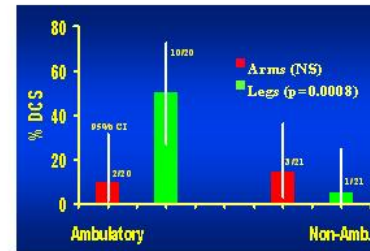
#### Limitations

- Timeline, back to back EVAs,
- O<sub>2</sub> usage, ISS O<sub>2</sub> concentration
- crew isolation and comfort

#### Enabling Counter Measure Research ( NASA TRL 3/4)



#### USAF prebreathe exercise



#### Duke, NASA micro-gravity simulation (non-ambulation)



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**Enabling Research**

Air Force Research Laboratory  
Brooks AFB, Texas



Dual-Cycle Ergometer used for Exercise-Enhanced Prebreathe

**10 minutes 75% VO<sub>2</sub> peak, 88% lower body, 12% upper body**

**ORIGINAL RESEARCH**

### Exercise-Enhanced Preoxygenation Increases Protection From Decompression Sickness

JAMES T. WEBB, M.S., Ph.D., MICHELLE D. FISCHER, B.S.,  
CELESTINE L. HEAPS, B.S., M.A., and ANDREW A. PLEMANS,  
M.S., Ph.D.

**Webb JT, Fischer MD, Heaps CL, Plemans AA. Exercise-enhanced preoxygenation increases protection from decompression sickness. *Aviation Space Environ Med* 1995; 67:618-24.**

**Introduction:** Prevention of decompression sickness (DCS) during exposure to altitude equivalent of 30,000 ft (9144 m) requires extensive denitrogenation to preparation for extravehicular activity (EVA). Present NASA policy is to denitrogenate using a 19.2 psia staged decompression of the entire Shuttle for at least 12 h, including 150 min of preoxygenation breathing 100% oxygen at 14.7 psia prior to decompression, before decompression to the 4.3 psia (30,000 ft, 9144 m) suit pressure. This staged decompression provides the same or better protection from DCS as a 3.5- or 4-h preoxygenation used on earlier Shuttle (EVA) for high altitude reconnaissance flights at similar cockpit altitudes, a 1-h preoxygenation is currently required. **Aim:** We have investigated the use of a 1-h and a 15-min preoxygenation period, each beginning with 10-min of dual-cycle ergometry performed at 75% of each subject's peak oxygen consumption (VO<sub>2</sub>peak) to enhance preoxygenation efficacy by increasing perfusion and ventilation. **Study:** Subjects accomplished a 1-h preoxygenation with exercise, a 15-min preoxygenation with exercise, or a 1-h resting preoxygenation before exposure to 4.3 psia for 4 h while performing light to moderate exercise. **Results:** Incidence of DCS following the 1-h preoxygenation with exercise (42%, n = 26) was significantly less than that following the 1-h resting preoxygenation (77%, n = 26). Incidence and onset of DCS following the 15-min preoxygenation with exercise (66%, n = 22) was not significantly different from the incidence following the 1-h resting control. **Conclusions:** Preoxygenation with exercise has been shown to provide significantly improved DCS protection when compared with resting preoxygenation.

**EXPOSURE TO THE ALTITUDE** equivalent of 30,000 ft (4.3 psia, 9144 m) during extravehicular activity (EVA) or high altitude reconnaissance flight involves a risk of decompression sickness (DCS) (18,21). Formation and growth of gas emboli are believed to have a central role in the clinical manifestations of DCS. Venous gas emboli (VGE) and tissue gas emboli are formed due to tissue supersaturation with nitrogen following decompression from ground level.

Denitrogenation is the process of removing nitrogen from the tissues by inspiring gas with a lower partial pressure of nitrogen than contained in the body fluids and tissues. Denitrogenation reduces the potential for nitrogen supersaturation and subsequent gas emboli formation during the decompression. Breathing 100% oxygen prior to decompression (preoxygenation or prebreathing) is a common method of denitrogenating to reduce the risk of DCS (26). Improvement in denitrogenation efficiency would have application in both the space program and high altitude aviation.

Denitrogenation before extravehicular activity (EVA): Prior to EVA from the Space Shuttle's 14.7 psia environment (160 mm Hg P<sub>O<sub>2</sub></sub>), a staged decompression is the primary method of denitrogenation (21) because it has been shown to provide protection comparable to a 6-h preoxygenation at 14.7 psia. The staged decompression procedure begins with 1 h of preoxygenation at 14.7 psia, followed by decompression of the entire Shuttle to 10.2 psia for at least 12 h while the crew breathes 26% oxygen (137 mm Hg P<sub>O<sub>2</sub></sub>), equivalent to breathing atmospheric air at about 4200 ft (1280 m), and then an additional 40-min period of breathing 100% oxygen at 10.2 psia before decompression to 4.3 psia. The staged decompression results in a 360-min theoretical tissue ratio (TR) of nitrogen (Final Tissue pN<sub>2</sub>/Absolute Ambient Pressure) that is close to the TR resulting from a 4-h preoxygenation (1.70 vs 1.65, 8). However, the staged method also results in engineering problems such as reduced instrument cooling capacity due to lower air density. Time-efficient preoxygenation techniques allowing decompression directly from 14.7-4.3 psia while providing protection comparable to staged decompression would be preferable.

**Preoxygenation before high altitude flight:** A 1-h preoxygenation is presently required prior to most high altitude flights. Surveys of the high altitude reconnaissance community (both active and retired) have revealed that over 60% had experienced DCS and that 42% of the flights involved symptoms, many with neurologic involvement (5). An improvement in the preoxygenation procedure could increase pilot safety and enhance operational efficiency and responsiveness.

From ERGIC Life Sciences Inc. © T. Webb, M. D. Fischer, and C. L. Heaps, and High Altitude Protection Research, Armstrong Laboratory (A. A. Plemans), AL/C375, 206 Colington Drive, Suite 25, Brooks AFB, TX.

This manuscript was received for review in April 1995. It was revised in September and December 1995, and was accepted for publication in December 1995.

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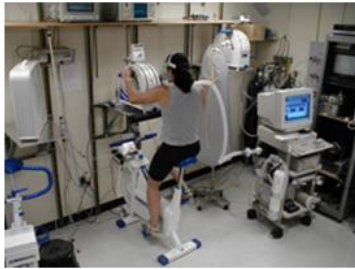
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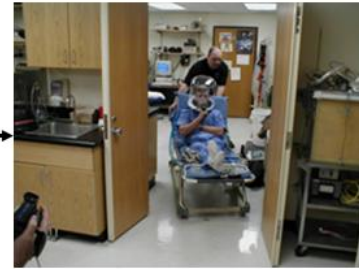


### Multi-Center Study: NASA, Duke, DCIEM, Hermann UT



**Exercise 10 mins @ 75%  $V_{O2peak}$   
And/or light exercise (160-253 Kcal/hr)**

2 hr oxygen prebreathe



**Micro-gravity simulation  
(non-ambulation)**



**Simulated EVA exposure at  
4.3 psi 4 hrs**



**Use of "Suit Simulator" for  
EVA Exercise**



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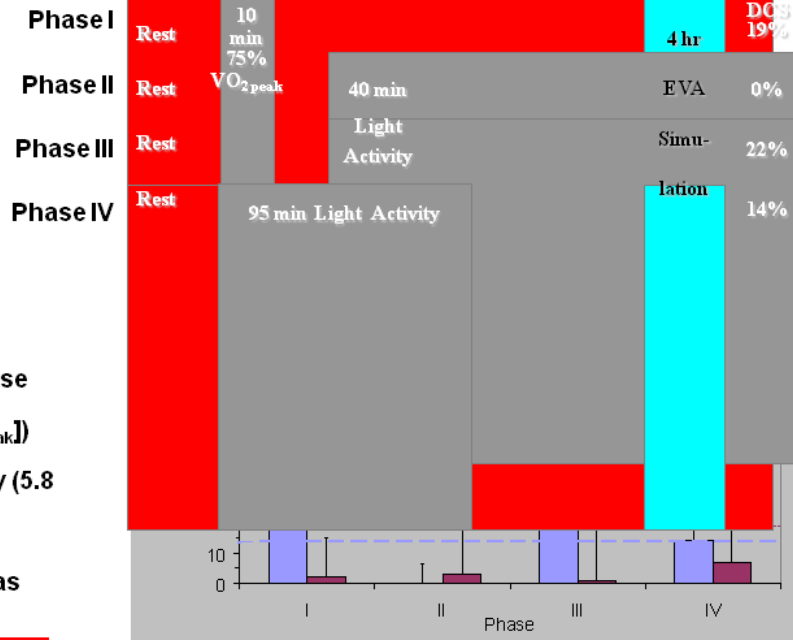
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### Prebreathe Trials



- High intensity exercise (75% peak oxygen consumption [ $\dot{V}O_{2\text{peak}}$ ])
- Low intensity activity (5.8  $\text{mL}\cdot\text{kg}^{-1}\cdot\text{min}^{-1} \dot{V}O_2$ )
- Neither High or low intensity exercise was acceptable
- Coupling High with low intensity exercise was acceptable

**DCS and Grade IV VGE observations** (shown with 95% upper confidence limit bars dashed lines indicating accept levels for DCS and VGE incidences)

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## **Exercise Prebreathe Protocol: Experience to Date**

- Overview - The exercise prebreathe protocol has been used successfully on 34 EVAs from the International Space Station (ISS) - no DCS
  - Five Shuttle assembly flights and two increment EVAs
    - Starting in July 2001
  - These assembly missions would have been difficult or impossible to execute as base-lined without the protocol





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### **A United States Airlock: Doorway to Space**



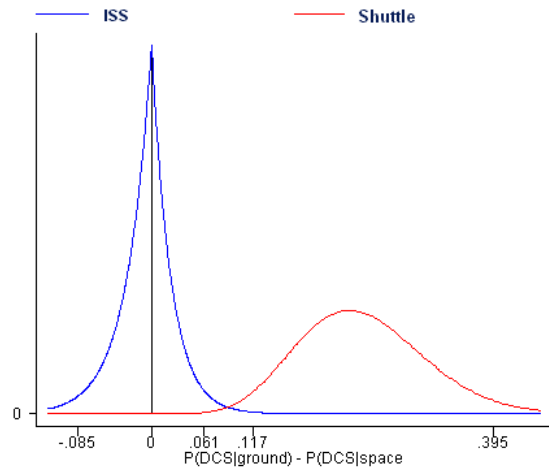
**U.S. "Quest" Airlock**



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## DCS Ground Trials vs. Space Shuttle and ISS



**Figure 4.** 95% Bayesian Confidence limits for  $P\{DCS|ground\}-P\{DCS|space\}$


- Using uniform priors, the 95% Bayesian confidence limits for the risk difference ( $P\{DCS|ground\}-P\{DCS|space\}$ ) were  $-8.5$  to  $+6.1\%$  for the ISS protocol and  $+11.7$  to  $+39.5\%$  for the Shuttle protocol.
- The point estimates of the differences were  $0\%$  for the ISS protocol and  $+22.9\%$  for the shuttle protocol.
- The results suggest that the Shuttle ground simulation overestimates the DCS risk in EVA, while the ISS ground EVA simulation provides an accurate prediction of the DCS risk in EVA (including the possibility that there is zero difference between ground and space).

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## STS-134 Flight Specific Schedule/Milestones

- ◆ **TBD – Exercise Mini sim (currently Exercise PB protocol)**
  - If In-Suit Light Exercise (ISLE) approved may go away or be replaced with I.S.L.E. mini-sim/tabletop
- ◆ **September 2010**
  - 9/15/10- Midflow Review (XA & DX support) – date may change
- ◆ **October 2010**
  - 10/14/10 NESC review of ISLE protocol
  - ~wk of 10/18/10 – simpack (procedures) due approx 1 week before sim
  - 10/29/10 – FD7/EVA 2 sim (currently Campout PB protocol)
- ◆ **November 2010**
  - 11/15/10 – Flight Rules CR final cutoff (flight specific)
- ◆ **December 2010**
  - ~wk of 12/6/10 – simpack (procedures) due approx 1 week before sim
  - 12/16/10- FD5/EVA 1 sim (currently Campout PB protocol)
- ◆ **January 2011**
  - TBD in Jan – CoFR1 /CoFR2
  - 1/3/11 – SODF cutoff (flight specific)
  - 1/6/11 – Exercise PB Tabletop (2hr class, the 4hr training class already complete)\*
  - 1/13/11 – Last ISS Prep and Posttraining session
    - If ISLE approved will need to add 1 more ISS P&P to crew training – must add before Jan's final ISS P&P, won't be time after Jan's ISS P&P to add training
  - 1/17/11 – Flight Rules Rev A PCN cutoff (flight specific)
- ◆ **February 2011**
  - 2/26/11 – STS-134 Launch


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## ISLE , STS-134 Flight Specific Schedule/Milestones

### ♦ Milestones

- ISLE protocol
  - First major deadline is sims starting in October for crew and Flight Control Team (FCT) training
  - Ideally ready for training for October sim
  - Must make December sim at a minimum
    - Procedures & flight rules ready for simpacks
- Flight rules submitted and signed off by management
  - Consists of B13-255 – prebreathe protocols [BME], B15-55 – Go/No-Go for EMU PB [EVA MOD]
  - Ideally submitted by November cutoff, **broken if procedures & flight rules cannot be delivered December sim for FCT and crew training**
  - Must be submitted in time for January cutoff
- Final procedures in workflow signed off by management by Jan deadline
  - Includes EVA Prep, & EMU Prebreathe
  - **Abort for STS-134 if January deadlines for flight rules and procedures cannot be met**
- Crew Training
  - Oct/Dec sims
  - Additional P&P &/or Final P&P before Jan.
  - required at ISS P&P (January)

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## Appendix G. Estimated P(DCS) from Venous Gas Emboli


# Estimated P(DCS) from Venous Gas Emboli



Johnny Conkin, Ph.D. and Alan H. Feiveson, Ph.D.

NESC Review : In-suit Light Exercise Protocol  
October 14, 2010




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## introduction

- ◆ **Motivation for analysis was that V-5 had 71% Grade 0 cases and Phase II had 69%, but V-5 also had 16% Grade IV compared to 6% in Phase II.**
  - Since -PV is 98% for no VGE and +PV is only 32% for VGE in current NASA data:
    - could accounting for Grade 0 provide more confidence in our observed 4.2% DCS than suggested by high Grade IV incidence?
  
- ◆ **We provide a supplemental analysis for additional insight.**
  - Our approach does not supersede the official criteria to accept a prebreathe protocol: DCS  $\leq$  15% at 95% CL, and Grade IV VGE  $\leq$  20% at 95% CL, and no Type II DCS.
  - There is no accept criterion based on our integrated DCS – VGE approach --- **estimated** P(DCS) given maximum VGE grade and symptoms.
  
- ◆ **NASA is committed to the comprehensive and transparent review of all data related to crew safety, health, and performance.**

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## **Spencer Bubble Scale – circa 1975**

**Grade 0:** The complete lack of bubble signals in all cardiac cycles.


**Grade I:** The occasional bubble signal detected in a cardiac cycle with the majority of cardiac cycles free of bubble signals.

**Grade II:** When many, but less than half, of the cardiac cycles contain bubble signals.

**Grade III:** When most of the cardiac cycles contain bubble signals, but not overriding the cardiac motion signals.

**Grade IV:** When bubble signals are detected continuously through the cardiac cycles such that the signal overrides the amplitude of the cardiac motion and blood flow signals.

1. Powell MR. Doppler ultrasound monitoring of venous gas bubbles in pigs following decompression with air, helium, or neon. *Aerospace Med* 1974; 45:505-8.
2. Spencer MP. Decompression limits for compressed air determined by ultrasonically detected blood bubbles. *J Appl Physiol* 1976; 40:229-35.
3. Neuman TS, Hall DD, Linaweaver PG. Gas phase separation during decompression in man: ultrasound monitoring. *Undersea Biomed Res* 1976; 3:121-30.

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## Data – 819 records mostly no symptoms and no VGE

test	n	DCS	VGE
1a	11	4	7
1b	13	3	11
...	...	...	...
V-5	47	2	13
<b>Σ40</b>	<b>Σ819</b>	<b>Σ118</b>	<b>Σ337</b>

Max VGE	No symptoms	Symptoms No DCS	Symptoms DCS
0	<b>441</b>	33	8
1,2,3	130	16	36
4	66	15	74
<b>totals</b>	<b>637</b>	<b>64</b>	<b>118</b>

We assume data collected over 25 years is “perfect”:  
no DCS diagnostic error,  
no bias in VGE grading, and  
maximum VGE is adequate information.

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**approach to analysis: using current V-5 data only**

$$\begin{aligned}
 P(\text{DCS}) &= P(\text{DCS}|\text{VGE}=0)P(\text{VGE}=0) \\
 &\quad + P(\text{DCS}|\text{VGE}=1,2,3)P(\text{VGE}=1,2,3) \\
 &\quad + P(\text{DCS}|\text{VGE}=4)P(\text{VGE}=4)
 \end{aligned}$$

		DCS		
		No	Yes	Total
	0	34	0	34
VGE	1-3	6	0	6
	4	5	2	7
		45	2	47

$$= (0/34)(34/47) + (0/6)(6/47) + (2/7)(7/47) = 2/47 = 0.043$$

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## using historical DCS|VGE information

$$\begin{aligned}
 P(\text{DCS}) &= P(\text{DCS}|\text{VGE}=0)P(\text{VGE}=0) \\
 &\quad + P(\text{DCS}|\text{VGE}=1,2,3)P(\text{VGE}=1,2,3) \\
 &\quad + P(\text{DCS}|\text{VGE}=4)P(\text{VGE}=4)
 \end{aligned}$$

		All Tests					V-5		
		DCS					DCS		
		No	Yes	Total			No	Yes	Total
	0	474	8	482		0	34	0	34
VGE	1-3	146	36	182	VGE	1-3	6	0	6
	4	81	74	155		4	5	2	7
		701	118	819			45	2	47

$$= (8/482)(34/47) + (36/182)(6/47) + (74/155)(7/47) = 0.108$$

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## final modifications

- ◆ Also stratify on presence / absence of symptoms (S).
- ◆ Use random effects models for  $P(S|VGE)$  and  $P(DCS|VGE, S)$  to represent test-test variation and estimate standard error of  $P(DCS)$  estimate.
- ◆ Final regression equation:

$$P(DCS) = (0.0166 \cdot n_0 + 0.188 \cdot n_{123} + 0.514 \cdot n_4) / n$$



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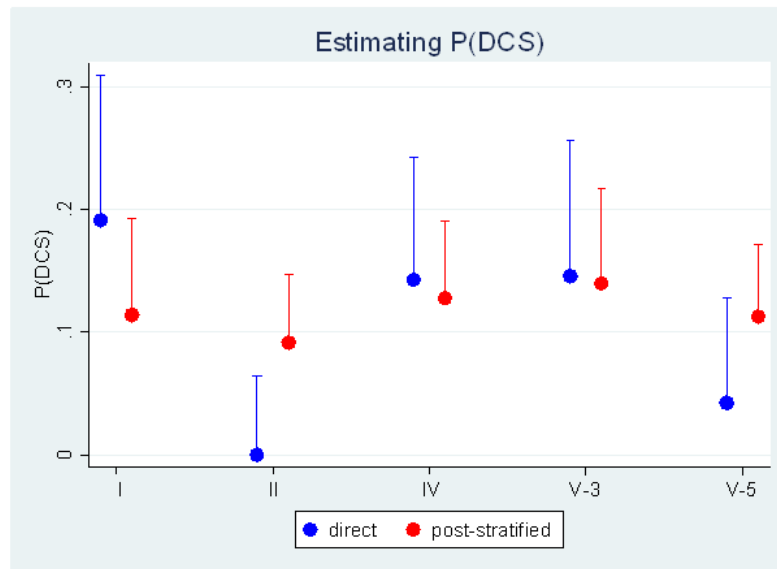
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### estimated P(DCS) given maximum VGE grade and symptoms



test	n	observed DCS	one-side 95% CL*	estimated P(DCS)	one-side 95% CL
V-5	47**	0.042	0.128	0.112	0.171

\*Exact Confidence Limits from Binomial Distribution.

\*\* 48<sup>th</sup> subject had Grade IV in left ventricle and was removed early from test without DCS outcome.



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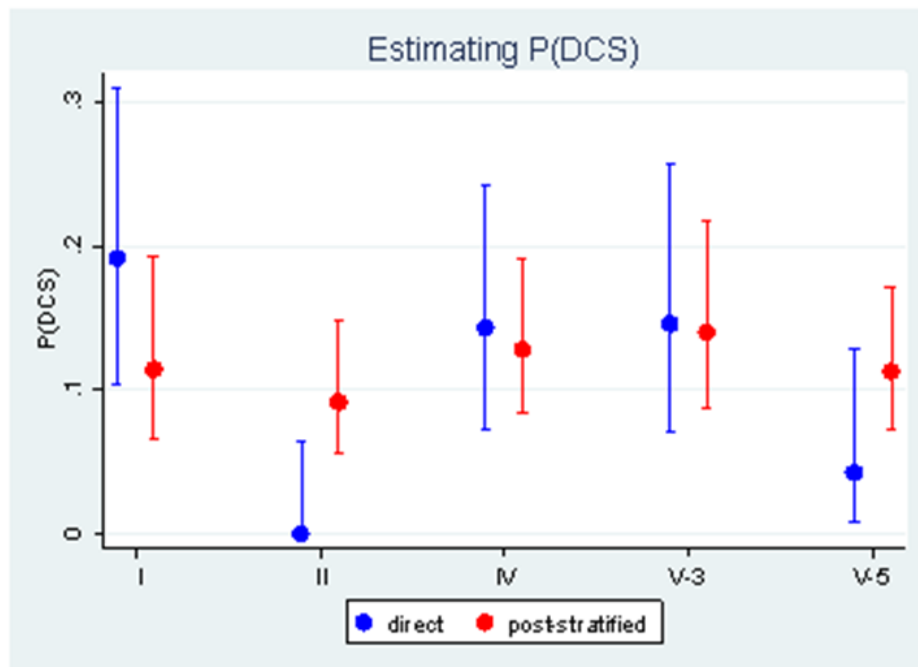
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### operational impact of DCS

Operational impact of DCS  
is a  $f$  [P(DCS) and severity  
of DCS].

V-5 has low impact. ←

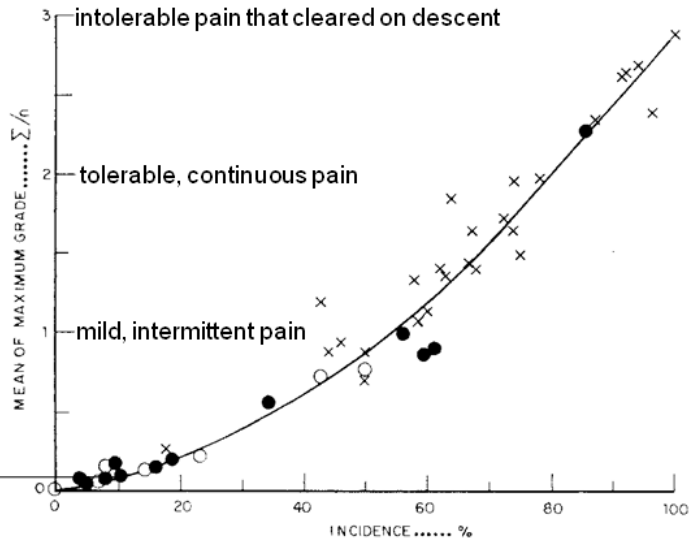



Fig. 4. Incidence and mean grade of altitude decompression sickness from 1942 to present: Crosses, 26 types of exposure with no information on body fat (Table II); Circles, 13 types of exposures (Table I), if filled F > 12 kg, if not filled F < 12 kg.

522 *Aerospace Medicine* • May, 1971

Allen TH, Maio DA, Bancroft RW. Body fat, denitrogenation and decompression sickness in men exercising after abrupt exposure to altitude. *Aerospace Med* 1971;42:518-24.

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## DCS diagnostic error – based on 135 records with symptoms

### PPV AND NPV OF MO'S AND RESULTS FROM V-5.

stratum(z)	V P R	$\lambda_z$	PPV (pz)	1 - NPV (qz)	Nz	Sz
0*	---	0	---	---	44	0
1	0 0 0	0.471	0.787	0.254	0	0
2	0 1 0	0.471	0.856	0.101	1	0
3	0 1 1	0.698	0.772	0.112	0	0
4	1 0 0	0.647	0.794	0.402	0	0
5	1 1 0	0.647	0.845	0.163	0	0
6	1 1 1	0.827	0.847	0.285	2	2
<b>Total</b>					<b>47</b>	<b>2</b>

\* for stratum 0 there was no case description since the subject did not report a symptom  
irregardless if VGE were present.

$\lambda_z$ : true DCS rate of stratum z.

$X_i$ : MO's diagnosis of subject i.

$Y_i$ : true DCS status of subject i.

$N_z$ : number of subjects within stratum z.

$S_z$ : MO's diagnosis of total DCS cases within stratum z.

$T_z$ : true total DCS cases within stratum z.

$p_z = p(Y = 1 | X = 1, Z = z)$  (PPV)

$q_z = p(Y = 1 | X = 0, Z = z)$  (1 - NPV)


6

$$\lambda = \sum N_z / N * \lambda_z = 0.0452$$

$$z = 0$$

Conkin J, Klein JS, Acock KE. Description of 103 cases of hypobaric decompression sickness from NASA-sponsored research (1982 to 1999). NASA Technical Publication 2003-212052 Houston: Johnson Space Center, July 2003.


Conkin J, Sung H-G, Feiveson AH. A latent class model to assess error rates in diagnosis of altitude decompression sickness. *Aviat Space Environ Med* 2006; 77:816-824.

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## conclusions:

- ◆ **The estimated P(DCS) for V-5 is 11.2% compared to 4.2% from direct count.**
  - The one-sided upper 95% CL is 17.1%.
- ◆ **The estimated P(DCS) was 9.1% for Phase II compared to 11.2% for V-5 – not very different.**
  - I understand V-5 better.
  - Our analysis is just one of many ways to understand V-5.
- ◆ **No significant issue in V-5 after accounting for DCS diagnostic error.**
- ◆ **I conclude that the DCS **impact** of V-5 is low.**

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**additional information**

# ADDITIONAL INFORMATION



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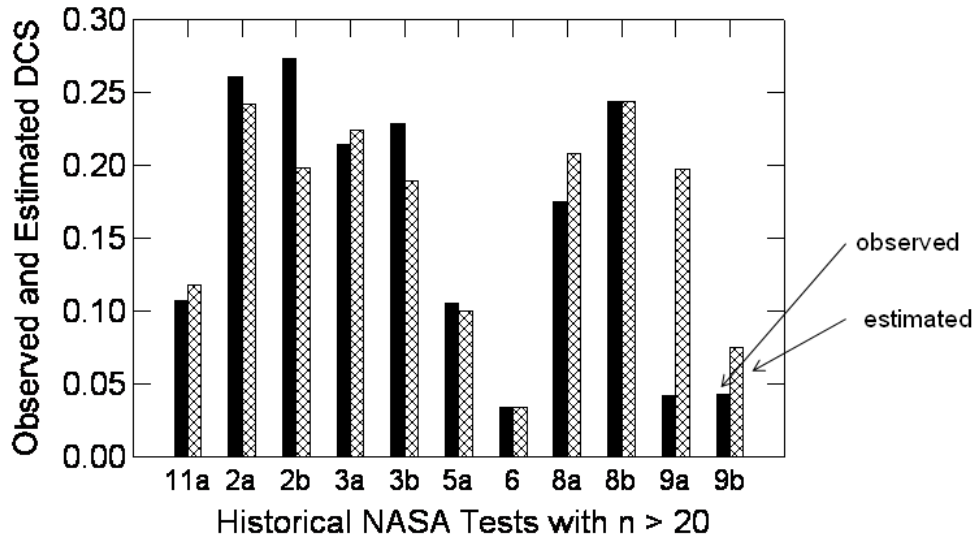
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### select historical NASA tests



2a: 3.5 h PB then 4.3 psi

2b: 12 h 10.2 psi + 40 min PB then 4.3 psi

3a: 4.0 h PB then 4.3 psi

3b: 1.0 h PB + 12 h 10.2 psia + 40 min PB then 4.3 psi

5a: 6.0 h PB then 4.3 psi

6 : 2.0 h PB + 24 h 10.2 then 6.0 psi with 60% O<sub>2</sub>

8a: no PB control then 6.5 psi

8b: no PB pre-exercise then 6.5 psi

9a: no PB then 6.5 psi ambulatory

9b: no PB then 6.5 psi adynamic

11a: 3.0 h PB then 4.3 psi adynamic



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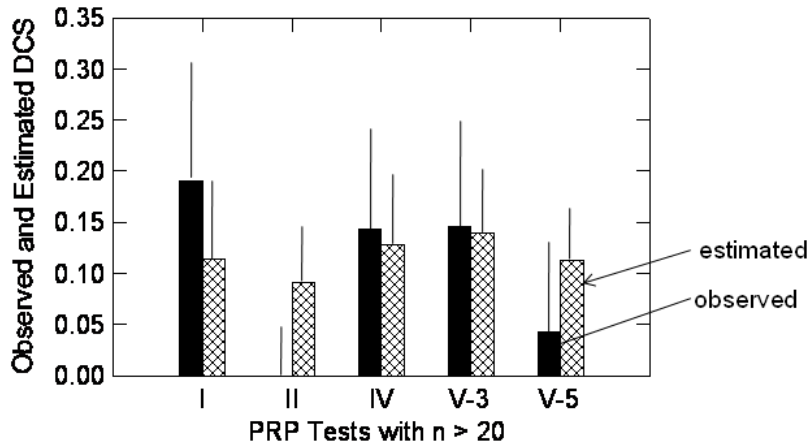
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### estimated P(DCS) given maximum VGE grade and symptoms


$$P(\text{DCS}) = (0.0166 \cdot n_0 + 0.188 \cdot n_{123} + 0.514 \cdot n_4) / n$$



test	n	observed DCS	one-sided 95% CL*	estimated P(DCS)	one-sided 95% CL
V-5	47**	0.042	0.128	0.112	0.171

\*Exact Confidence Limits from Binomial Distribution.

\*\* 48<sup>th</sup> subject had Grade IV in left ventricle and was removed early from test without DCS outcome.

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## summary measures of NASA and Air Force Data

### DCS and VGE Associations

source	DCS1 VGE1	DCS0 VGE1	DCS1 VGE0	DCS0 VGE0	sensitivity	specificity	+PV	-PV
Air Force	280	230	55	302	0.835	0.567	0.55	0.85
Air Force subset	59	168	16	243	0.786	0.591	0.26	0.94
NASA	109	229	8	473	0.931	0.673	0.32	0.98
NASA PRP subset	31	79	4	156	0.885	0.664	0.28	0.97

#### Conclusions:

1. + and – PV are not independent of mean DCS incidence – unfortunately.
2. + and – PV are similar between data with similar mean DCS incidence.



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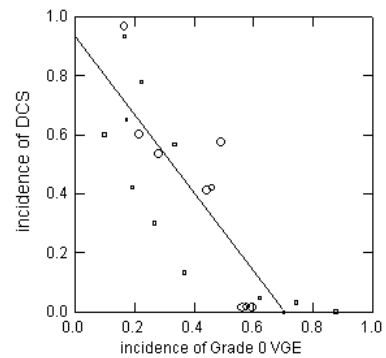
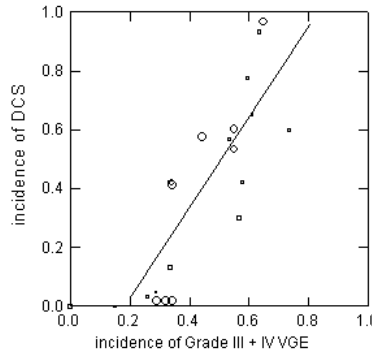
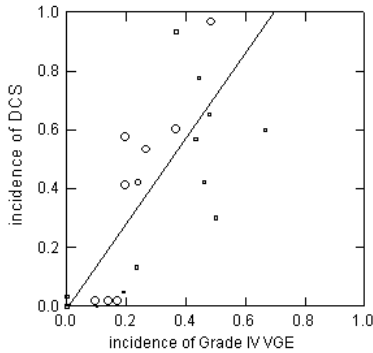
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### Air Force DCS and VGE



### DCS and VGE R<sup>2</sup>

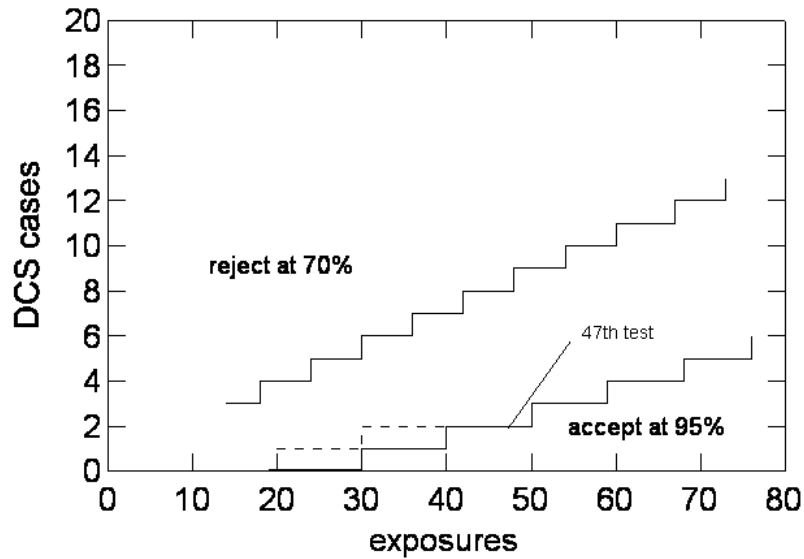
source	n	DCS	% DCS	Grade IV	Grade III + IV	Grade 0
NASA	819	117	14.3	0.466	0.416	0.526
NASA PRP subset	270	35	13.0	0.085	0.023	0.353
<b>Air Force</b>	<b>867</b>	<b>335</b>	<b>38.6</b>	<b>0.557</b>	<b>0.684</b>	<b>0.688</b>
Air Force subset	486	75	15.4	0.427	0.297	0.514



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**$\leq 15\%$  DCS @ 95% UCL**



After 47 trials and two cases of DCS, the V-5 protocol is acceptable with  $\leq 12.8\%$  at 95% confidence.



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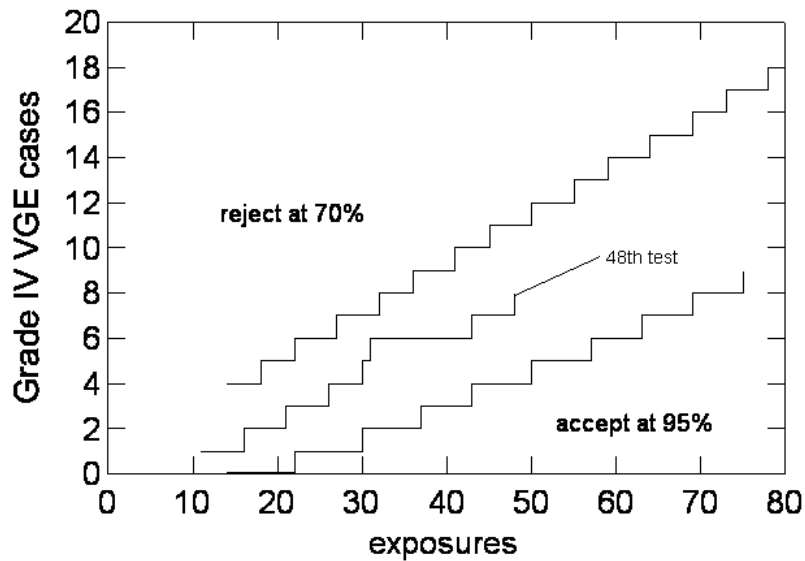
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$\leq 20\%$  Grade IV VGE @ 95% UCL



After 48 trials and 8 cases of Grade IV VGE, the V-5 protocol did not reach the accept condition, only  $\leq 28\%$  Grade IV VGE at 95% confidence.



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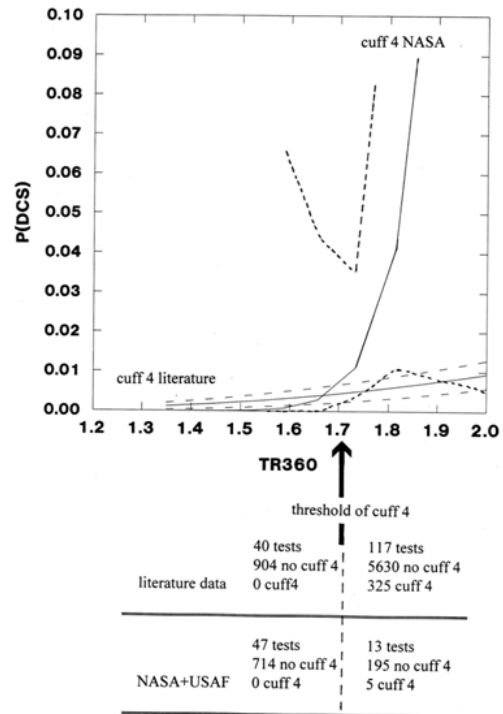
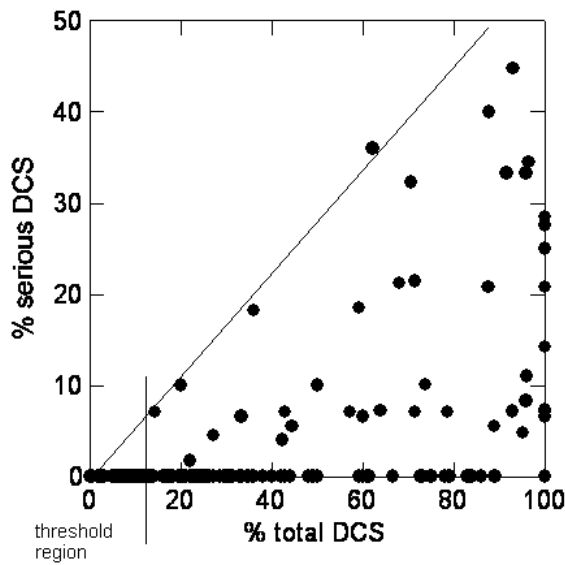
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### TR = 1.70 and threshold for serious DCS

244 tests with 7692 exercising subjects





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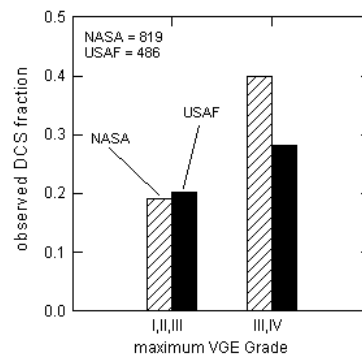
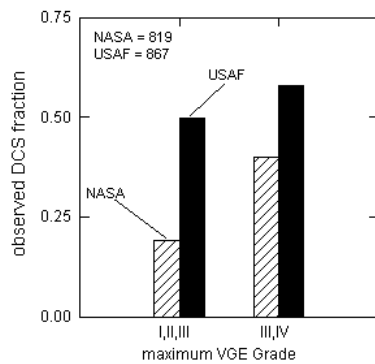
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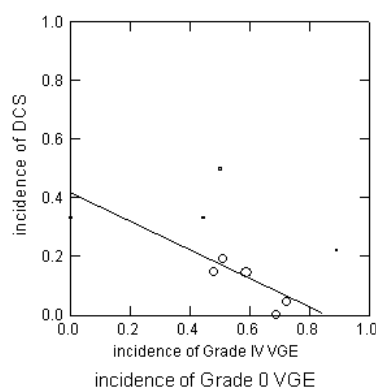
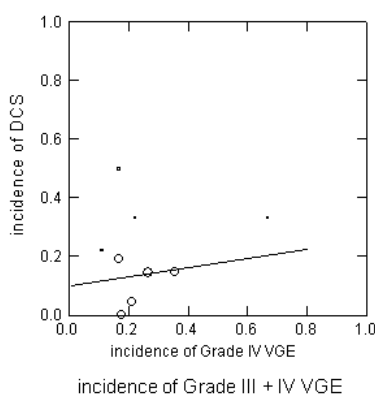
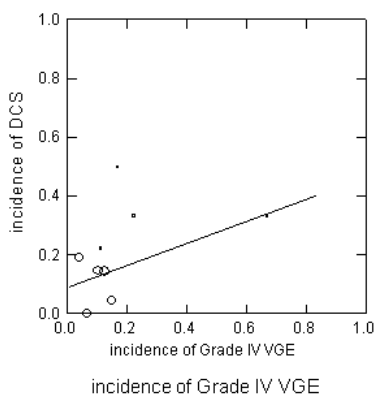
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### PRP data




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## Grade IV VGE

### VGE Accept Condition Based on Grade IV VGE

test	n	Grade IV n	Grade IV %	@ 95% UCL	≤20% Grade IV	≤30% Grade IV @ 1.70 TR
I	47	2	4.2	12.8	Yes	Yes
II	45	3	6.6	16.3	Yes	Yes
III	9	1	11.1	43.0	No	No
IV	56	7	12.5	22.2	No	Yes
V-1	9	2	22.2	55.0	No	No
V-2	3	2	66.6	--	--	--
V-3	48	5	10.4	20.7	No	Yes
V-4	6	1	16.6	58.1	No	No
V-5	48	8	16.6	28.1	No	Yes


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## Grade III + IV VGE

### VGE Accept Condition Based on Combined Grade III + IV VGE

test	N	Grade III + IV n	Grade III + IV %	@ 95% UCL	≤30% Grade III + IV	≤41% Grade III + IV @ 1.70 TR
I	47	8	17.0	28.5	Yes	Yes
II	45	8	17.7	29.8	Yes	Yes
III	9	1	11.1	43.0	No	No
IV	56	15	26.7	38.2	No	Yes
V-1	9	2	22.2	55.0	No	No
V-2	3	2	66.6	--	--	--
V-3	48	17	35.4	48.3	No	No
V-4	6	1	16.6	58.1	No	No
V-5	48	11	23.0	35.2	No	Yes

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## Waligora chart - NASA + Air Force

### Relationship Between Total DCS Symptoms and Various Grades of Gas Emboli

NASA /Airforce Data Base: (n=914)

Based on model relating incidence to R Value

R	Symptoms %	Gr 4 Emboli	Gr 3 Emboli	Gr 3&4 Emboli
1.64	15	26	10.3	37.3
1.90	30	43.7	13.9	55
2.22	50	64.2	18.7	72.2

Airforce Data Base: (n=1928)

Based on average incidence

Typical conditions: Altitude 30 000 ft, Prebreathe 1 hr , R about 2.3

Symptoms %	Gr 4 Emboli	Gr 3 Emboli	Gr 3&4 Emboli
38.9	31.0	15.0	46.0





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## Accept – Reject Criteria

Number Exposures	Accept at 95%		Reject at 70%	
	15% DCS	20% VGE (4)	15% DCS	20% VGE (4)
30	1	2	6	
32				8
36			7	9
37		3		
40	2			
41				10
42			8	
43		4		
45				11
48			9	
50	3	5		12
54			10	
55				13
57		6		
59	4			14
60			11	
63		7		



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### aviator bubbles

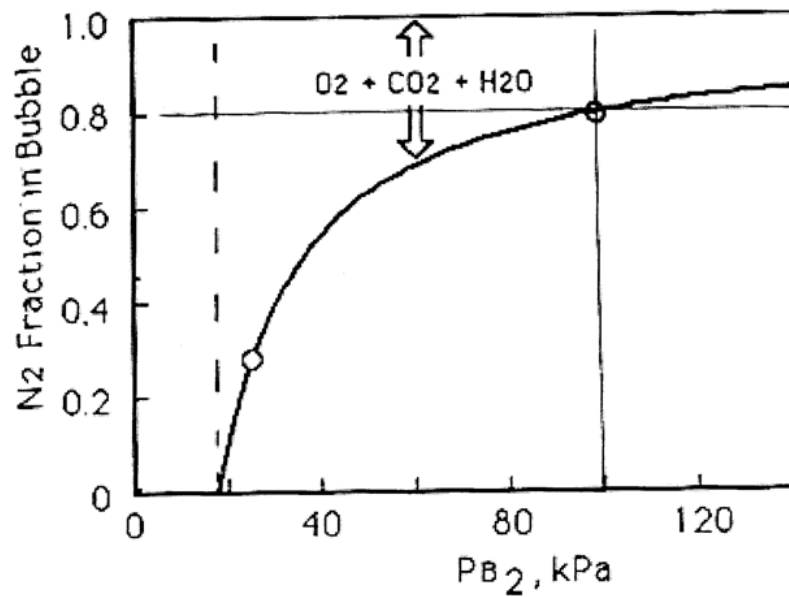


figure from: Van Liew HD, Burkard ME. Simulation of gas bubbles in hypobaric decompressions: roles of O<sub>2</sub>, CO<sub>2</sub>, and H<sub>2</sub>O. *Aviat Space Environ Med* 1995; 66:50-5.



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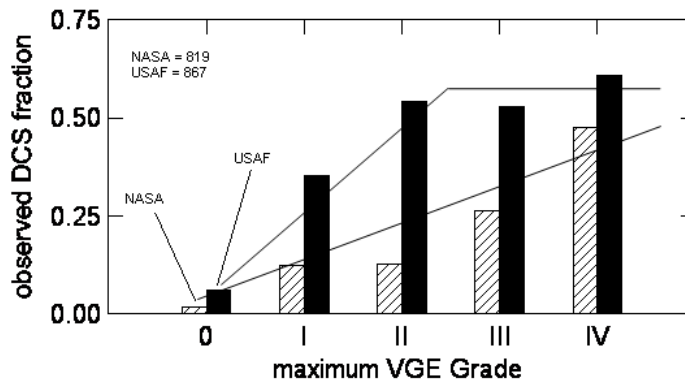
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### DCS and VGE Grade – large samples



#### Conclusions:

1. More DCS is associated with higher VGE grade.
2. Grades II, III, and IV loose correlation with DCS in Air Force data.
3. Air Force has more DCS than you might expect (assume) with Grade 0.



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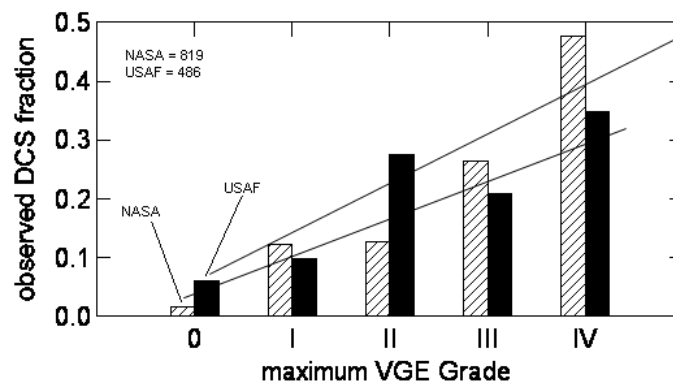
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### DCS and VGE Grade Combined – Air Force subset



#### Conclusions:

1. VGE grade and correlation with DCS is better when mean DCS is similar between Air Force and NASA data.
2. Air Force has more DCS than you might expect (assume) with Grade 0.

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## **bubbles and bends**

### ◆ **Common Ground**

- There is no argument against evolved gas as the primary insult for DCS.
- But it's problematic that VGE in pulmonary artery are linked to site of symptoms.
- We use 30 years of VGE data to estimate hypobaric DCS.

### ◆ **Using VGE to understand, limit, and predict DCS is not new.**

- Gutvik CR et al. Parameter estimation of the copernicus decompression model with venous gas emboli in human divers. *Med Biol Eng Comput* 2008; 48:625-36.
- Eftedal OS et al. Validation of decompression procedures based on detection of venous gas bubbles: a bayesian approach. *Aviat Space Environ Med* 2007; 78:94-9.
- Conkin J et al. Information about venous gas emboli improves prediction of hypobaric decompression sickness. *Aviat Space Environ Med* 1998; 69:8-16.



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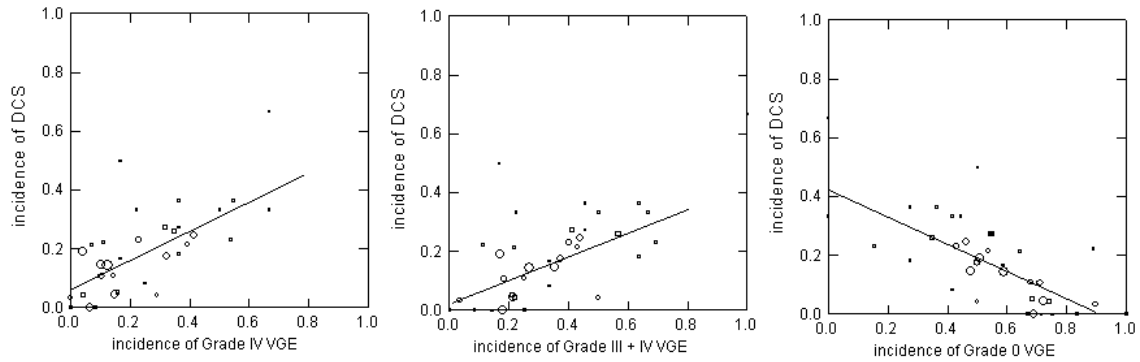
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### NASA DCS and VGE



### DCS and VGE R<sup>2</sup>

source	n	DCS	% DCS	Grade IV	Grade III + IV	Grade 0
NASA total	819	117	14.3	0.466	0.416	0.526
PRP only	270	35	13.0	0.085	0.023	0.353

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## Waligora 1987 – Test 5a

### The Effect of Extended O<sub>2</sub> Prebreathing on Altitude Decompression Sickness and Venous Gas Bubbles

JAMES M. WALIGORA, M.S., B.S., DAVID J. HERRIGAN, JR., M.S., B.S., and JOHNNY CONKIN, B.S.

Space Biomedical Research Institute, NASA/Johnson Space Center, Houston, Texas

WALIGORA JM, HERRIGAN DJ JR, CONKIN J. *The effect of extended O<sub>2</sub> prebreathing on altitude decompression sickness and venous gas bubbles.* Aviat. Space Environ. Med. 1987; 58(9, Suppl.):A110-2.

The purpose of this study was to determine the effect of extended O<sub>2</sub> prebreathing on symptom and bubble incidence during decompressions simulating extravehicular activity. The 38 subjects breathed O<sub>2</sub> for a 6-h period prior to decompression to 4.3 psi. The subjects performed upper body exercise for 6 h. Subjects were monitored with a Doppler bubble detector and were encouraged to report all symptoms. Eight subjects were exposed to the same protocol after an 8-h prebreathe. Venous bubbles were detected in 18 of 38 subjects decompressed after the 6-h prebreathe. Four of these subjects reported symptoms of altitude decompression sickness. No symptoms or bubbles were detected in the eight subjects who had prebreathed 8 h. The incidence of symptoms and bubbles when combined with prior data on 3.5- and 4.0-hour prebreathes showed an inverse correlation to prebreathing time. The incidence of symptoms was higher than has been reported for subjects exposed to decompression of shorter duration with less activity.

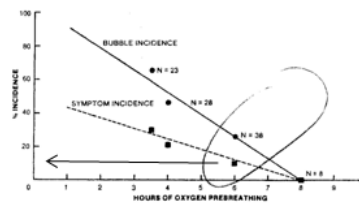


Fig. 1. The incidence of venous gas bubbles and symptoms of decompression sickness during simulated EVA at 4.3 psi.

1. 6 hr prebreathe then ambulatory exposure for 6 hrs at 4.3 psia compares well with estimated P(DCS) for V-5.
2. 6 hr prebreathe with ambulation  $\cong$  V-5 with no ambulation.



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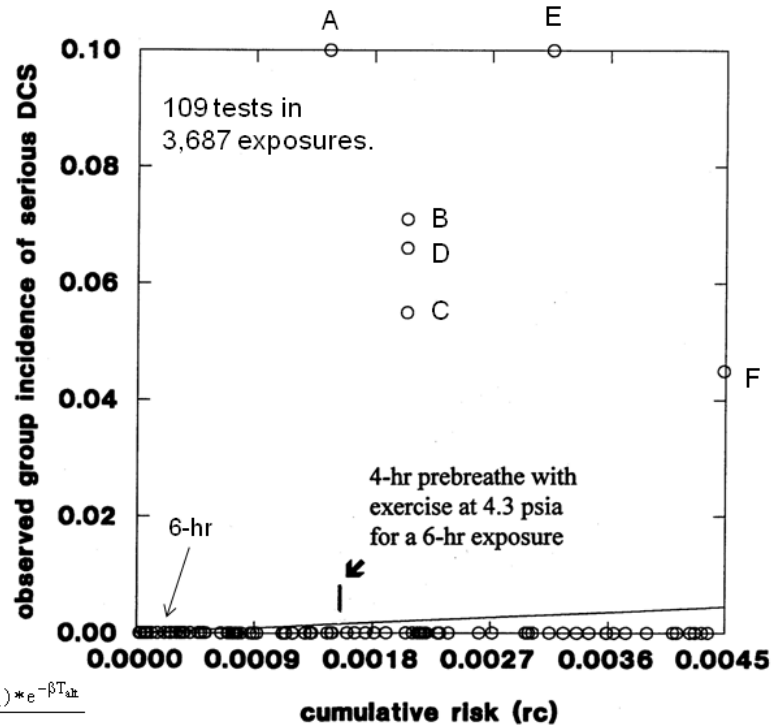
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### threshold for serious DCS - 258 tests with 79,366 exposures

6-hr PB plus 6-hrs at 4.3 psia  
with exercise from Waligora  
(1987) =  $r_c = 0.0002$ .



$$P(\text{serious DCS}) = 1 - e^{-r_c}$$

$$r_c = \chi * \left( \frac{PIN_2}{P_2} \right)^\alpha * [1 + EXER * \epsilon] * \frac{1 - (1 + \beta T_{alt}) * e^{-\beta T_{alt}}}{\beta^2}$$

Conkin J. Evidence-based approach to the analysis of serious decompression sickness with application to EVA astronauts. NASA Technical Publication 2001-210196, Houston: Johnson Space Center, January 2001.





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### threshold for serious DCS (continued)

exposures	serious cases	%serious DCS	r <sub>c</sub>	institution
6-hr PB, 6-hr exercise at 4.3 psia			0.00020	computed from model
5-hr PB, 6-hr exercise at 4.3 psia			0.00054	computed from model
10	1 (A)	10%	0.00145	Duke, 1995
4-hr PB, 6-hr exercise at 4.3 psia			0.00146	computed from model
14	1 (B)	7.1%	0.00205	Duke, 1995
18	1 (C)	5.5%	0.00205	Duke, 1995
15	1 (D)	6.7%	0.00205	Duke, 1995
10	1 (E)	10%	0.00316	NRC Comm. on Aviat. Med., 1943
22	1 (F)	4%	0.00449	NASA staged 10.2 psia
9,738	19	0.2%	0.00469	report by Motley, 1945
26	1	3.8%	0.00487	report by Allen, 1971
4,337	26	0.6%	0.00559	report by Motley, 1945
46,683	327	0.7%	0.00571	report by Motley, 1945


(A) from Duke University (1995), numbness in right hand that appeared one hr into test, and cleared on descent from 4.3 psia to site pressure. No hyperbaric treatment provided.

(B) from Duke University (1995), dizziness, nausea, and hotflash in head. No hyperbaric treatment provided.

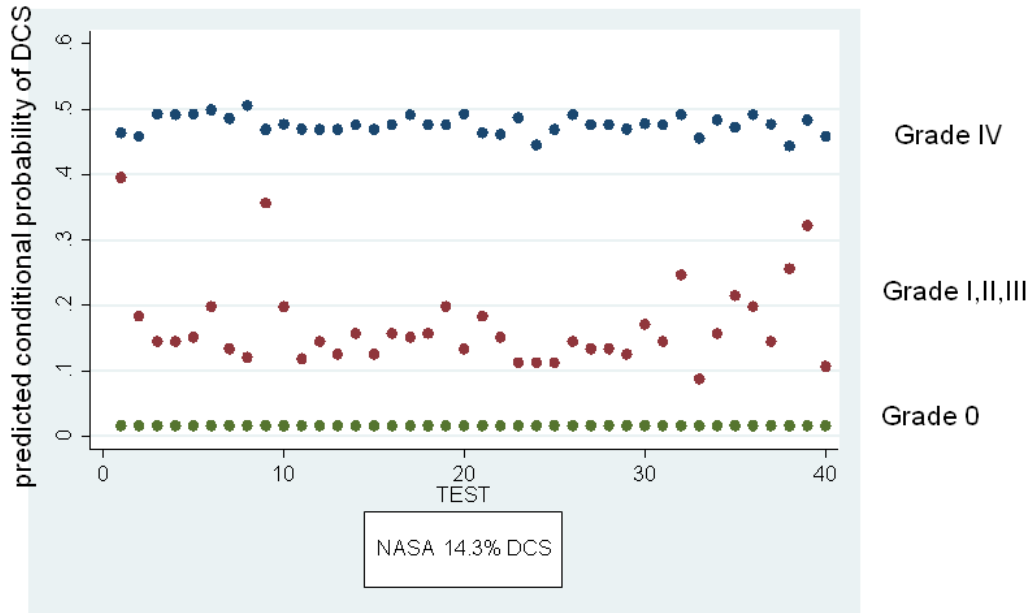
(C) from Duke University (1995), blurred vision during test. Treatment Table 6 provided.

(D) from Duke University (1995), numbness and tingling in left shoulder. Treatment Table 6 provided.


(F) from NASA / JSC (1982), sudden onset of fatigue, cold sweat, and skin mottling on chest after report of pain in right knee. No hyperbaric treatment provided, but two hrs of ground level oxygen.

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 **constancy of conditional probabilities across all tests**



Variation in predicted conditional probability of DCS for three categories of maximum VGE grade across all tests.

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## regression results

```

Mixed-effects logistic regression          Number of obs   =      819
Group variable: test                     Number of groups =       40
                                          Obs per group:  min =        3
                                                           avg =       20.5
                                                           max =        56
Integration points =      7              Wald chi2(3)    =     165.36
Log likelihood = -237.10692             Prob > chi2     =      0.0000

```

	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]
dcS					
vge0	-4.103236	.3641543	-11.27	0.000	-4.816965 -3.389507
vge(1,2,3)	-1.480364	.209801	-7.06	0.000	-1.891566 -1.069162
vge4	-.0912511	.1735972	-0.53	0.599	-.4314954 .2489932

Random-effects Parameters	Estimate	Std. Err.	[95% Conf. Interval]
test: Identity			
sd(_cons)	.2870721	.2751847	.0438568 1.879079

LR test vs. logistic regression: chibar2(01) = 0.38 Prob>=chibar2 = 0.2695

The inverse-logit transformations (estimated conditional probabilities of DCS)

	mean(ph)
0	.0162507
(1,2,3)	.1853724
4	.477203



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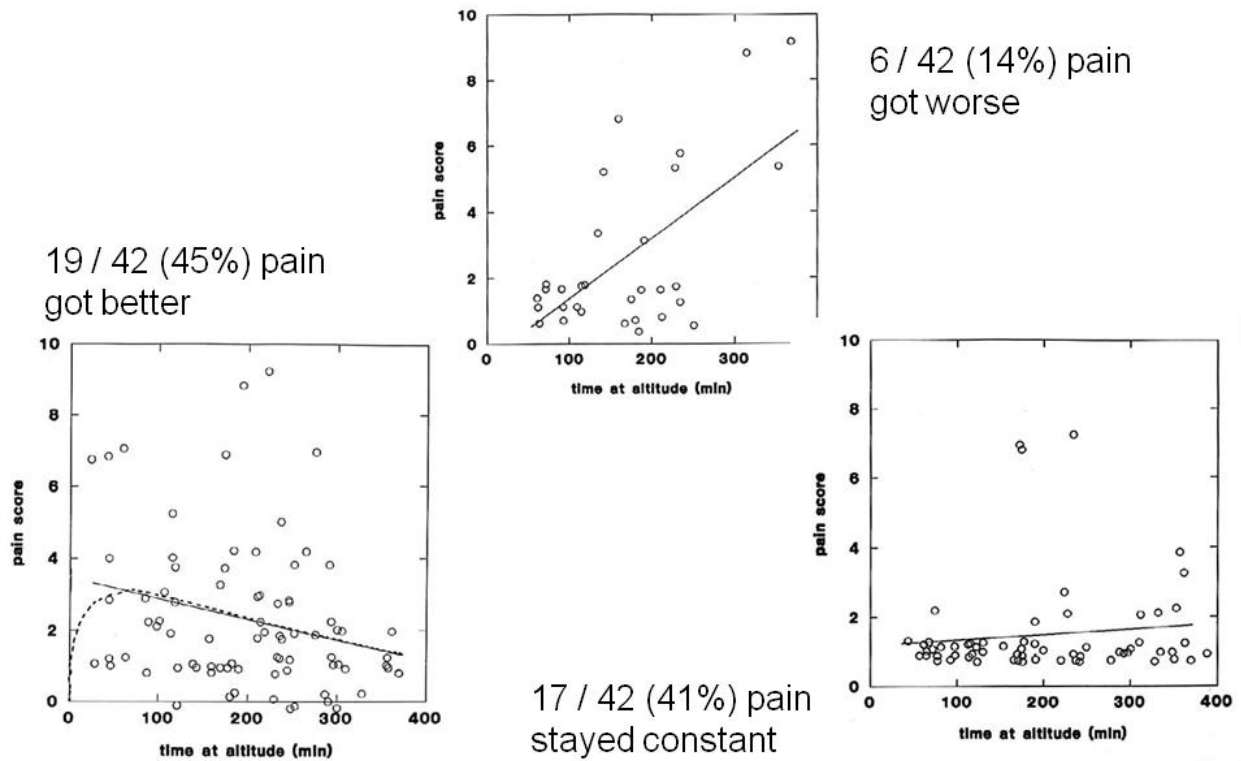
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### operational impact of DCS (continued)



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## Appendix H. Operational Implementation of In-Suit Light Exercise (ISLE) Prebreathe Protocol





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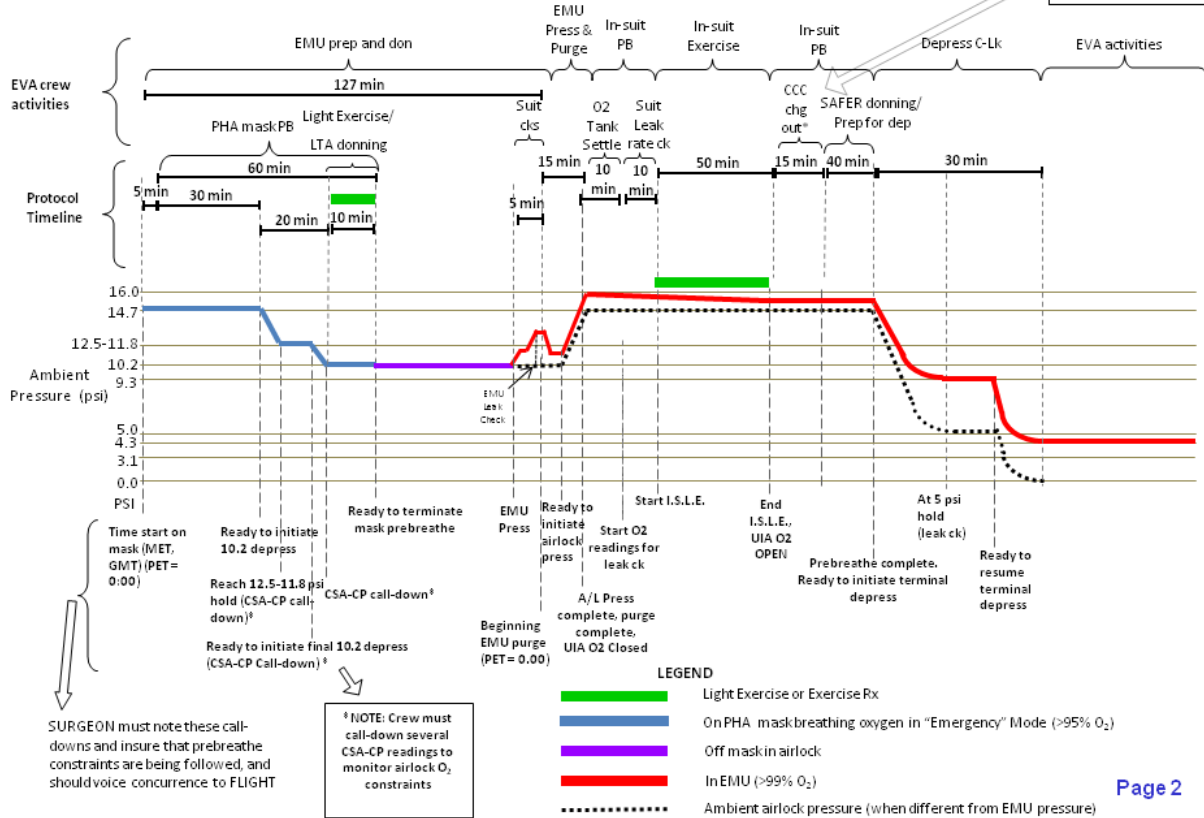
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**DRAFT**

### ISLE Prebreathe Protocol Pressure Profile

Not to Scale

\* NOTE: CCC change out maybe optional, if NIR, reduce timeline/PB by 15 min




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## Suit Integration Issues

- ◆ **We would like to use the O<sub>2</sub> tank pressure drop as a guideline to control the ISLE metabolic rate, but it is complicated by the following:**
  - ◆ **Thermal transients associated with purge and tank refill**
    - Tank pressure drops during purge at 10.2 psi, and at 14.7 psi, tanks are then recharged and thermal cooling causes tank pressure transients
  - ◆ **As-donned leak rate of suit**
    - The suits typically leave earth with leaks of 100 sccm or less, however as donned the leak rates could be as much as 999 sccms and still pass the leak check
  - ◆ **Tank pressure sensor error and Display Control Module (DCM) rounding error**
    - The difference between any two tank pressure readings could have an error of up to 2.6 psi. The DCM could have a rounding error of .49 psi.


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## Relationship Between O<sub>2</sub> Tank Pressure and VO<sub>2</sub>

- ◆ **Assumptions for O<sub>2</sub> Bottle**
  - Volume = 480 cu inches
  - Temperature = 65° F
  - Initial Pressure = 850 psi
  
- ◆ **Using the Gas Equation,**
  - O<sub>2</sub> Depletion Rate (psi/min) = 0.0021315 x VO<sub>2</sub> (cc/min)
  
- ◆ **Therefore, after an elapsed time of TBD minutes**
  - O<sub>2</sub> Bottle Pressure (psi) = 850.0 - 0.0021315 x VO<sub>2</sub> (cc/min) x TBD (min)




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## Overview of ISLE Methodology

- ◆ **Perform on-orbit uncrewed engineering characterization of the purge and tank thermal transients**
  - Carry out test long enough until rate of tank pressure drops asymptotes to a constant value, which would be the as tested suit leak rate
  - Use this data to provide a curve that describes the thermal transients associated with the purge procedures
- ◆ **Have crew perform long ( 20-25 min) leak check following purge.**
  - Subtract an assumed conservative resting metabolic of 5 ml/kg-min
  - Subtract the characterized thermal transient pressure drop
  - Add 2.6 psi tank pressure error plus .49 DCM rounding error.
  - The remaining pressure drop will be a conservative estimate of a combination of “as donned suit leak rate” and the combined tank O<sub>2</sub> pressure drop and DCM error
  - The conservative error will be distributed over the 20-25 minute period therefore reducing the uncertainty in combined sensor error and suit leak rate.
  - This allows a conservative estimate in psi/min that can be combined with the ISLE prescription of 6.8 ml/kg-min to calculate the tank pressure drop targets for the ISLE

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## **On-Orbit Engineering Assessment**

- ◆ **Have the staged crew perform engineering evaluation without the crew in the suits**
- ◆ **Perform the 8 minute purge, with the suits in pri mode, downlinking the data every 20 seconds.**
- ◆ **This will allow the thermal transient pressure drops to be characterized without the human in the loop**
- ◆ **This will allow us to perform a 25 minute leak check starting within minutes of the purge.**
- ◆ **The thermal transient pressure drop can then be subtracted from the total pressure drop over the 25 minutes. This combined with the conservative assumption of a 5 ml/kg-min resting metabolic rate, will allow the combined suit leak rate/sensor and DCM rounding error to be characterized over a 25 minute period vs. a 10 minute period**



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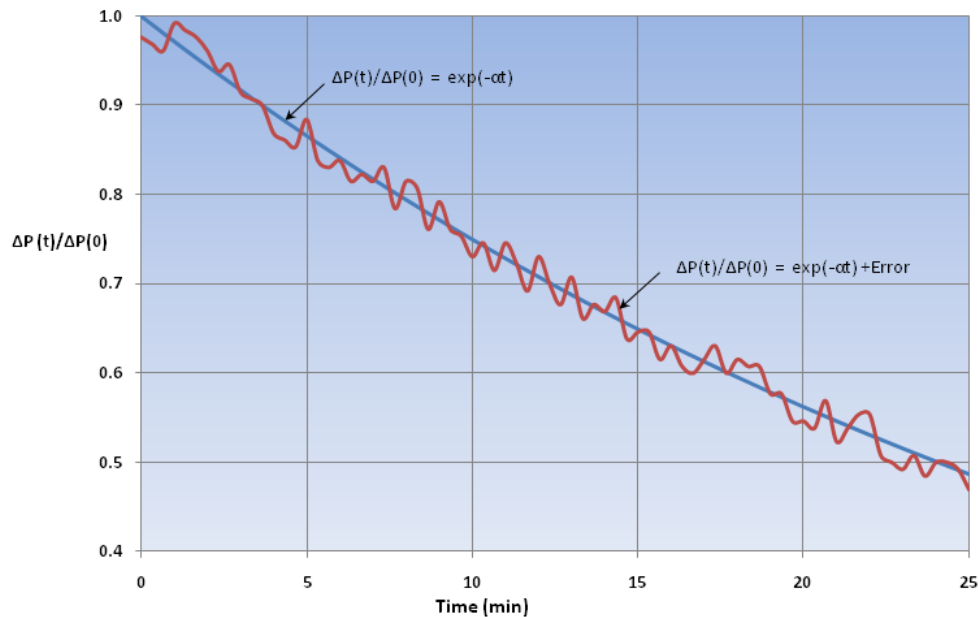
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### Example of Pressure Drop Due to Thermal Transient Including Randomized Error



The multiple data points every 20 seconds will serve to smooth out and minimize the error vs only a few readings


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## **Integrated Methodology for Controlling ISLE**


- ◆ **Assume just for example that the on-orbit thermal pressure drop test shows that the tank pressure drops 32 psi in 25 minutes**

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## Example


1. Astronaut performs 25 min suit leak check with initial tank pressure of 850 psi
2. Astronaut observes pressure drop over 25 min to be 59 psi (eg. the tank pressure at the end of 25 min was 791 psi)
3. Assume observed pressure drop of 59 psi is actually 2.6 psi and 0.49 lower than true pressure drop, due to worst-case tank pressure sensor error and DCM error respectively so we use a pressure drop value of 62 psi over the 25 mins.
4. But we know from the thermal evaluation that 32 psi is from the thermal transients

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## Example (continued)


5. Calculate combined suit leak and sensor error rate in psi/min
  - Calculate total tank pressure drop  
(take 850-788 psi which 62 psi)
  - Then subtract the pressure drop due to thermal  
(62 psi – 32 psi thermal = 30 psi)
  - Then subtract the assumed conservative resting metabolic rate  
(5 ml/kg/min x 80 kg x 25 mins= 21.3 psi)
  - Thus the effective leak rate plus sensor and display error = 8.7 psi over 25 minutes (assuming only one wiper jump).
  - This is 0.348 psi/min

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## Example (continued)

6. Calculate 50 min exercise prescription based on 6.8 ml/kg-min  
( $6.8 \text{ ml/kg-min} \times 80\text{kg} \times 50 \text{ mins} \times 0.021315 \text{ psi/min} = 57.9 \text{ psi}$ )
7. Calculate the effective suit leak and sensor error conservative margin  
( $0.348 \text{ psi/min effective leak rate} \times 50 \text{ min} = 17.4 \text{ psi}$ )
8. Add calculated Exercise prescription and Effective suit leak and sensor error conservative margin to determine tank pressure drop target /milestone  
( $50 \text{ min Exercise tank pressure drop target} = 57.9 \text{ psi plus } 17.4 \text{ psi} = 75.3 \text{ psi}$ )
9. Add 2.6 psi for sensor error and 0.49 psi for display error to get a target of 78 psi, which is approximately 35% more pressure drop than for the exercise alone

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## Example (continued)

- ◆ However in this example 35% more pressure drop accounts for the suit leak rate which will be normalized across the protocol
- ◆ So the suit leak rate is normalized and the conservative margin becomes the assumption of 2.6 psi sensor error plus .49 DCM error divided by the 25 minute leak check to get a per minute error that is incorporated into the 50 min light exercise prescription and then adding another 2.6 psi plus .49 psi to the final 50 minute tank pressure target
- ◆ So for this example ( which for illustration purposes only assumed 100 sccm leak rate) really the subject is exercising at 67 psi, which is approximately 16% more or 7.9 ml/kg-min, which is lower met rate than a slow walk
- ◆ Even if the suit leak rate is 999 sccm the observed leak rate will be normalized so that additional exercise will not be required
  - Because we are characterizing the as donned leak rate, we do not have exercise to account for it. The conservative margin accrues only from adding the combined tank pressure sensor and DCM error both to the pressure drop observed from the leak check and then again to the pressure drop for the 50 min tank pressure drop target





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**Strawman Exercise Rx and Control Procedures (cont.)**

**Crewmember**

1. Completes 20-25 minute leak check (TBD)
2. Observes final tank pressure
3. Uses table to identify Leak Rate Exercise Prescription Table with appropriate targets

John Doe	Jan Doe
Leak Rate Exercise Rx	Leak Rate Exercise Rx
Crewmember Weight = 85kg	Crewmember Weight = 65kg
assume 5ml/kg-min Met Rate	assume 5ml/kg-min Met Rate
psi drop (over 25 min)	psi drop (over 25 min)
50	46
51	47
52	48
53	49
54	50
55	51
56	52
57	53
58	54
59	55
60	56
61	57
62	58
63	59
64	60
65	61
66	62
67	63
68	64
69	65
70	66



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Exercise Prescription Table for 62 psi Observed Leak check pressure drop  
Crew Member - John Doe 80.0 kg body weight

Initial Tank Pressure	FIRST STAGE		SECOND STAGE		
	10 Min Target	25 Min Milestone	Stage II Initial Tank Pressure	35 Min Target	50 Min Milestone
850	835	812	812	760	737
849	834	811	811	759	736
848	833	810	810	758	735
847	832	809	809	757	734
846	831	808	808	756	733
845	830	807	807	755	732
844	829	806	806	754	731
843	828	805	805	753	730
842	827	804	804	752	729
841	826	803	803	751	728
840	825	802	802	750	727
839	824	801	801	749	726
838	823	800	800	748	725
837	822	799	799	747	724
836	821	798	798	746	723
835	820	797	797	745	722
834	819	796	796	744	721
833	818	795	795	743	720
832	817	794	794	742	719
831	816	793	793	741	718
830	815	792	792	740	717
829	814	791	791	739	716
828	813	790	790	738	715
827	812	789	789	737	714
826	811	788	788	736	713
825	810	787	787	735	712
824	809	786	786	734	711
823	808	785	785	733	710
822	807	784	784	732	709
821	806	783	783	731	708
820	805	782	782	730	707
			781	729	706
			780	728	705
			779	727	704
			778	726	703
			777	725	702
			776	724	701
			775	723	700
			774	722	699
			773	721	698
			772	720	697

### Exercise Prescription Table for 80 Kg subject, 62 psi suit leak rate based on 25 min suit purge leak check

Note - exercise Rx Targets and milestones provided in this table are actually based on adding 2.6 to the observed pressure drop (eg 14.6 psi)



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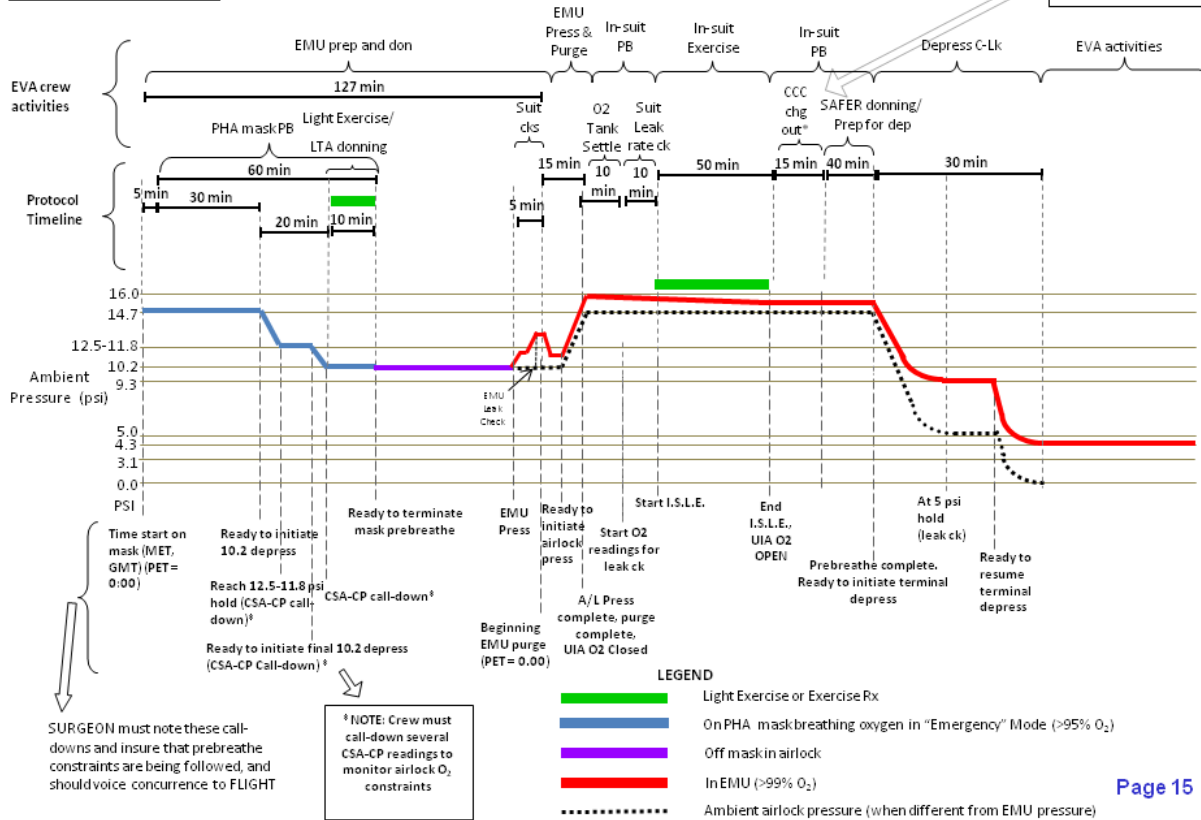
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**DRAFT**

### ISLE Prebreathe Protocol Pressure Profile

Not to Scale

\* NOTE: CCC change out maybe optional, if NIR, reduce timeline/PB by 15 min




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## Conservative Margin


- ◆ In addition to the conservatism built into the exercise prescription methodology, there is built in safety margin to the way we tested the protocol and the way we will implement it for flight
- ◆ We have an exercise prebreathe model that provides a statistically significant prediction and fit of all of our exercise prebreathe testing. That model can be used to estimate the sensitivity of the DCS outcome to exercise level and also to account for the additional prebreathe that occurs during operations vs. the laboratory trials

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## Conservative Implementation


- ◆ This type of modeling analysis approach was used during flight implementation of the CEVIS protocol to show that even if CEVIS had a smart failure that went unrecognized, the protocol would protect against DCS to acceptable levels.
- ◆ Application of this model to the ISLE protocol is in work and will need to be vetted through the Med Ops EVA-IPT to deal with the development of flight rules to address various breaks in exercise and suit failures including complete failure of the O2 tank pressure transducer.

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## **Additional conservatism built into flight procedures vs. Laboratory Trials**

- ◆ 57 minutes at 10.2 psi vs. 30 mins in Laboratory trials
- ◆ 5 min configuration checks
- ◆ 4 min purge at 10.2 psi, plus 7 min repress to 14.2 psi, additional 3 min purge
- ◆ 2 min purge associated with metox changeout
- ◆ Between 0-25 mins more prebreathe if full time taken for met-ox change out and safer donning
- ◆ An additional 12 minutes of prebreathe before supersaturation begins due to the fact crewmember is at 5 psi over ambient pressure in the suit during airlock depress to 5 psi
  - 11 mins depress to 5 psi ( 10 psi ambient) plus one minute leak check.

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## NASA Exercise Prebreathe Model (NEPM)

- ◆ The partial pressure for a specific inert gas that is reached in a designated tissue compartment after a specific time is calculated by the NEPM using the following equation:

$$P_1 = P_0 + (P_a - P_0) \times (1 - e^{-k \cdot t})$$

- ◆ where  $P_1$  = the inert gas partial pressure in the tissue after "t" minutes,  $P_0$  = initial inert gas partial pressure in the compartment,  $P_a$  = inspired inert gas partial pressure. The following function defines the rate constant (k, min<sup>-1</sup>) in an exponential inert gas washout equation in terms of the normalized O<sub>2</sub> consumption, x (mL O<sub>2</sub>/kg/min):

$$k = 1 / (e^{-\lambda x} * C)$$

- ◆ Logistic regression was used to fit the  $\lambda$  and C constants to DCS incidence in 204 altitude exposures with 21 cases of DCS

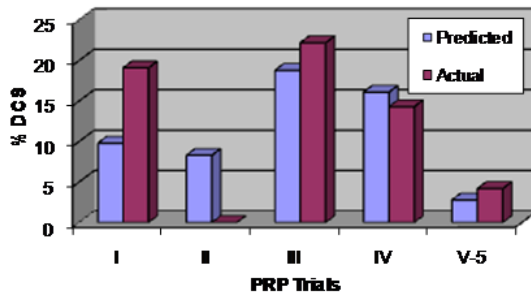


Fig. 1. Actual vs. NEPM-Predicted DCS incidence for 204 human altitude exposures during NASA prebreathe reduction protocol. Hosmer-Lemeshow p=0.98.

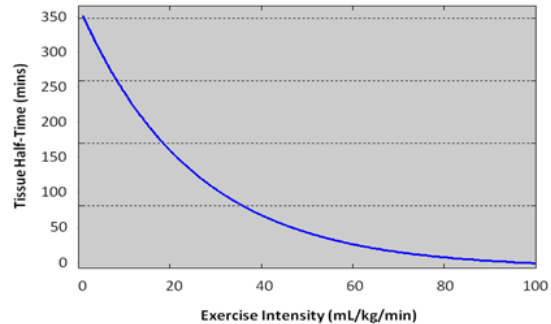



Fig. 2. Half-time variation with exercise level (mL O<sub>2</sub>/kg/min) for a 360 minute half-time compartment as calculated by the NEPM.

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## Logistic Regression Model Prediction & Goodness-of-Fit

test	n	10.2 condition	Prebreathe rest (min)*	Mean ETR**	Gender % male	Observed %DCS	%DCS ⊙
I	47	1	170	1.820	70.2	19.1	9.8
II	45	1	85	1.802	77.7	0	8.3
III	9	1	85	1.893	88.8	22.2	18.8
IV	56	1	85	1.875	78.5	14.3	16.1
V-1	9	0	76	1.931	77.7	33.3	***
V-2	3	0	86	1.984	33.3	33.3	***
V-3	48	0	60	1.790	79.1	14.6	***
V-4	6	0	42	1.711	50.0	50.0	***
V-5	47	1	80	1.690	76.6	4.2	2.8

\*resting prebreathe time after last exercise, which includes 30 min ascent to 4.3 psia

\*\* ETR is exercise tissue ratio with  $\lambda = 0.04$  for these regressions.

\*\*\* regression model did not include these data.

model	n	DCS counts	null model LL	model LL	improvement over null model	H-L**
⊙*	204	21	67.62	63.79	P=0.0056, 1 df	0.982, 5 bins

\*With  $\lambda = 0.04$  for exercise tissue ratio in these regressions.

\*\* H-L is Hosmer-Lemeshow P-value where  $> 0.05$  indicates good fit of predicted and observed DCS. LL is absolute value of log likelihood number from maximum likelihood logistic regression.

$$\odot P(\text{DCS}) = \frac{\exp(-20.94 + 10.29 \cdot \text{ETR})}{(1 + \exp(-20.94 + 10.29 \cdot \text{ETR}))} \quad n = 204 \text{ with } 21 \text{ DCS}$$





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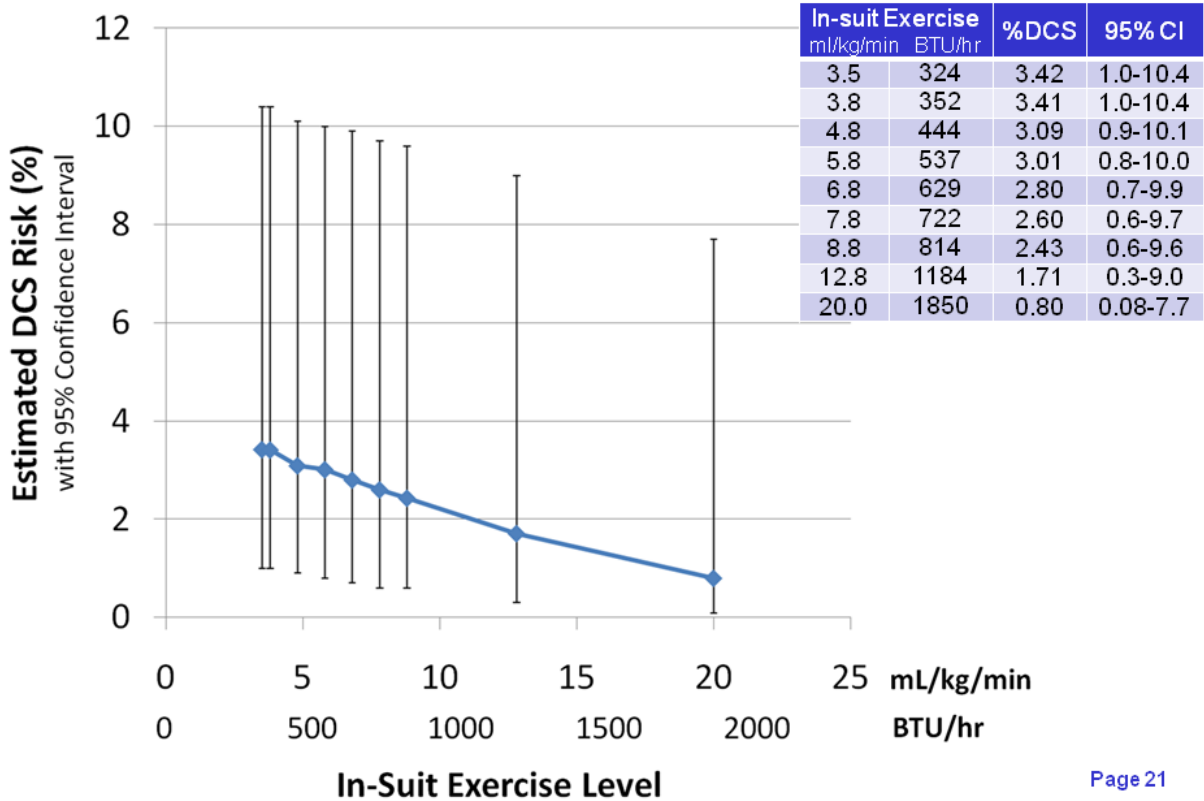
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### Effect of Exercise Intensity on P(DCS) during V-5 In-Suit Light Exercise Protocol



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## P(DCS) with Additional Operational Prebreathe Margin

Condition	ETR*	%DCS	95% CI
V-5 @ 6.8 ml/kg/min in-suit	1.690	2.80	0.70 – 9.9
Operational 1 @ 6.8	1.465	0.28	0.01 – 6.33
@ 5.8	1.471	0.30	0.01 – 6.40
@ 4.8	1.477	0.32	0.01 – 6.47
@ 3.8	1.483	0.34	0.01 – 6.55
@ 3.5	1.484	0.34	0.01 – 6.56
Operational 2 @ 6.8	1.549	0.66	0.05 – 7.44
@ 5.8	1.556	0.71	0.06 – 7.54
@ 4.8	1.562	0.76	0.07 – 7.63
@ 3.8	1.568	0.81	0.08 – 7.72
@ 3.5	1.570	0.82	0.08 – 7.75

Operational 1: 57 min at 10.2 psia, 20 min resting before in-suit exercise, 25 min additional post-exercise rest, and 12 min additional depress.

Operational 2: 57 min at 10.2 psia, 20 min resting before in-suit exercise, and 12 min additional depress.

\*ETR is exercise tissue e ratio with  $\lambda = 0.04$  for this regression.

$$P(\text{DCS}) = \frac{\exp(-20.94 + 10.29 \cdot \text{ETR})}{1 + \exp(-20.94 + 10.29 \cdot \text{ETR})} \quad n = 204 \text{ with } 21 \text{ DCS}$$



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**NESC-RP-10-00659**

Version:  
**1.0**

Title:

## Phase V-5 In-Suit Light Exercise (ISLE) Prebreathe Protocol

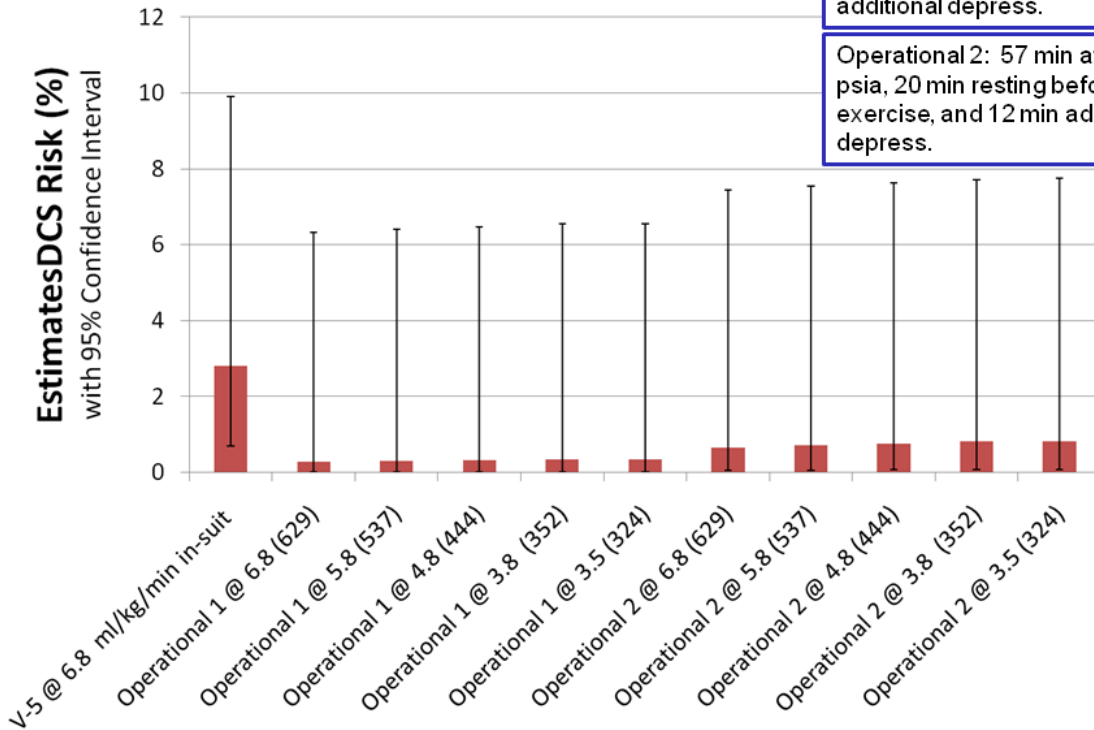
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### P(DCS) with Additional Operational Prebreathe Margin

Operational 1: 57 min at 10.2 psia, 20 min resting before in-suit exercise, 25 min additional post-exercise rest, and 12 min additional depress.

Operational 2: 57 min at 10.2 psia, 20 min resting before in-suit exercise, and 12 min additional depress.



Operational Prebreathe Conditions. Exercise units: mL/kg-min (BTU/hr)



## Ratings of Perceived Exertion (RPE) Scale

By definition, RPE of 7 indicates that you are at least doing something more than resting, but it's going to be very, very light work (about 6.8 ml/min/kg)	6	No exertion at all	} Too low
	7	Extremely light	
	8		} Target range for the ISLE protocol
	9	Very light	
	10		
	11	Light	} Higher than preferred, but ok
	12		
	13	Somewhat hard	} Too high, might lead to fatigue that could inhibit EVA performance
	14		
	15	Hard (heavy)	
	16		
	17	Very hard	
	18		
	19	Extremely hard	
20	Maximal exertion		



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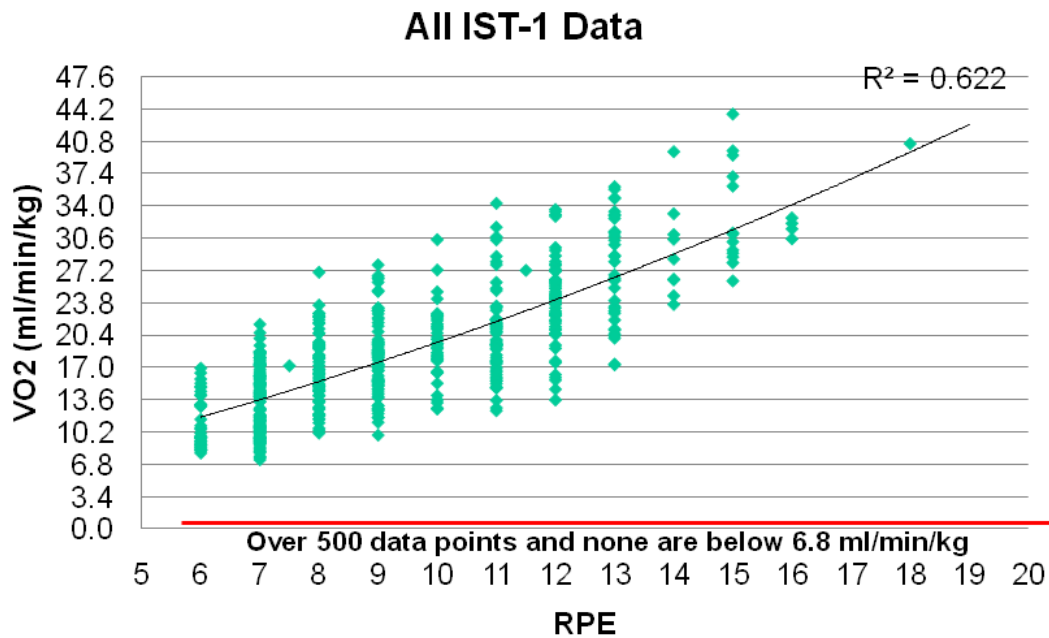
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## Phase V-5 In-Suit Light Exercise (ISLE) Prebreathe Protocol

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### RPE/VO<sub>2</sub> Relationship





Title:

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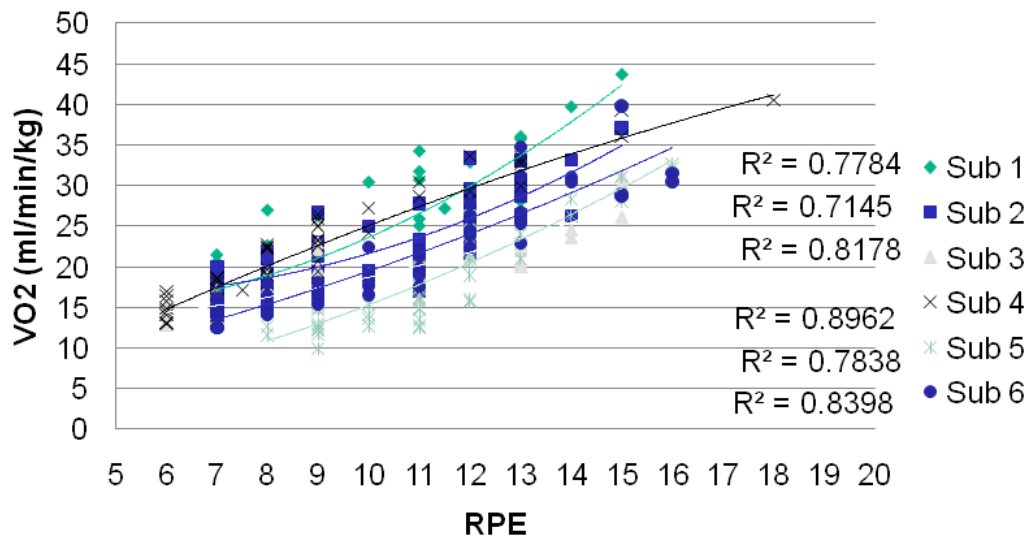
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**RPE/VO2 by subject (suited)**

RPE/VO2 correlations improve when we look at regressions for individual subjects

**Suited IST-1 Data**




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## Summary and Recommendations

- ◆ **Use the control that the crewmember must exercise with an RPE of 7 ( e.g. they are performing some exertion vs. an RPE of 6 which is no exertion) to ensure that an adequate exercise intensity was achieved.**
- ◆ **Use the suit O2 tank pressure as additional information and situational awareness that the appropriate exercise has been performed. However if sensor information is not available, default to flight rule constraints for EVA.**
  - We can use the suit O2 tank pressure drop with reasonable assumptions for guidelines/situational awareness and to ensure that we don't over exercise but that we appreciate the majority of the safety margin that has been built into the protocol
  - For example we do not assume any sensor error for the 25 minute leak check, but then add the 2.6 psi + .49 psi to the final tank pressure drop target, then our quick look worst case would be we under exercise by 5-6% depending on the weight of the subject.

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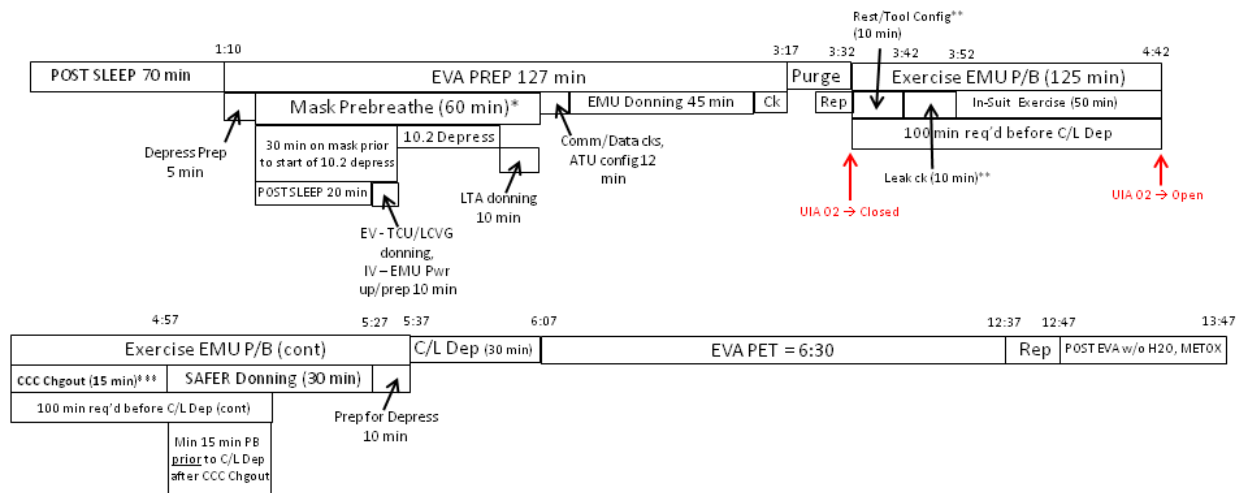
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### Time Comparison of Protocols



#### In-Suit Light Exercise Prebreathe Timeline for EVA Day (w/CCC Changeout)




\* Assume 20 min of Mask PB may be done in parallel with POST SLEEP.

\*\* Due to uncertainty in O2 tank cool down effects and suit leak vs. crewmember breathe down rates, 20 min of EMU PB will be done prior to 50 min of in-suit exercise.

\*\*\* CCC changeout allows for max EVA PET capability. Changeout maybe optional, if not required for consumables, total timeline is 15 min shorter. An additional purge of 2 min will be required after the CCC Changeout.

Note: Assume depressump and EMERG MPEV & ALVAJ; 30 min C-Lk depress without built in hold at 5psi; 15 min CCC Changeout without PB pause during 2 min purge. With 2 hours of Pre-sleep, ISS Crew Day length = 15:47.

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## Time Comparison of Protocols



### CEVIS Exercise Protocol Timeline for EVA Day

1:30	EVA PREP 170 min	4:20	4:35	5:35	6:20
POST SLEEP 90 min	Exercise PB/Prep for Donning - 80 min on mask total 50 min on mask prior to start of 10.2 depress   20 min Dep EV1 ex*   EV2 ex*   Req'd 45 min mask P/B after exer 45 min req'd before below 11.8 psi	EMU Donning 55 min	Ck	Purge	Rep
				EMU Prebreathe (60 min)	C/L Dep (45 min)
				12:50	13:00
EVA PET = 6:30				Rep	POST EVA w/o H2O, METOX

\* EV1 must start exercise within 10 min after PB initiate, EV2 must start exercise within 25 min after PB initiate to maintain 45 minute of mask time after exercise per FR  
 Note: Assume depress pump and EMERG MPEV & AL VAJ; 45 min C-Lk depress with built in hold at 5psi PET = 25. With 2 hours of Pre-sleep, **ISS Crew Day length = 16:00.**


### ISS 10.2 Campout Protocol Timeline

PRESLEEP 90 min	65 min Campout Mask PB	Time @ 10.2 psi = 8 hours 40 min (includes sleep)			
	60 min mask PB total req'd 45 min before start 10.2 Dep   10.2 Dep 45 min before 11.8				
	PRESLEEP 30 min				
<b>EVA Day</b>					
0:50	2:00	3:30	3:45	4:35	5:05
POSTSLEEP 50 min	HYGIENE BRK 70 min * 70 min mask P/B	10.2 psi CAMPOUT / EVA PREP 90 min	Purge	EMU Prebreathe (50 min)**	C/L Dep (30 min)
	Rep	POSTSLEEP 40 min	10.2 Depress	EMU Donning 55 min	Ck
				Rep	
EVA PET = 6:30				Rep	POST EVA w/o H2O, METOX

\* 70 min mask P/B to begin only after 8hr 40 min at 10.2 psi per FR. Assume 40 min of HYGIENE BREAK may be done in parallel with POST SLEEP. Note that IV may be able to begin the EVA Prep activities during the Hygiene Break, which could possibly result in an additional 10 minute savings in the timeline.

\*\* In order to satisfy the accept criteria for ISS EVA protocols, an additional 10 minutes of in-suit prebreathe was added to the medical Campout protocol making the total in suit EMU Prebreathe for Campout = 50 min.

Note: Assume depress pump and EMERG MPEV & AL VAJ; 30 min C-Lk depress without built in hold at 5psi. With 2 hours of Pre-sleep, **ISS Crew Day length = 14:45.**

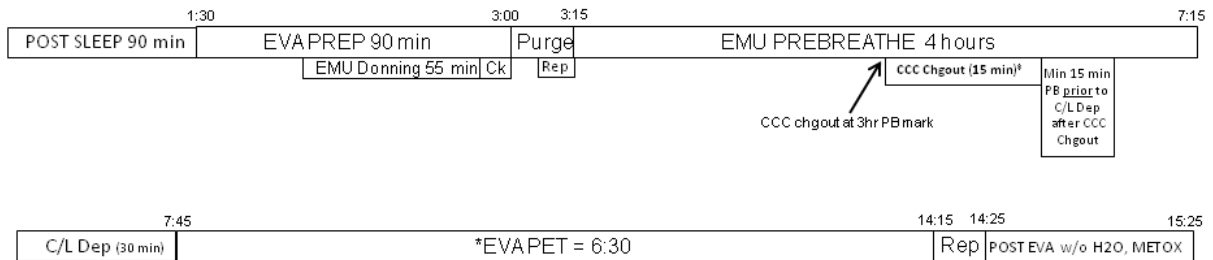
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## Time Comparison of Protocols



### 4 hr In-Suit Protocol Timeline for EVA Day



\*CCC changeout would be performed 3 hours into prebreathe activities (manned) to allow for max EVA PET capability.

Note: Assume depress pump and EMERG MPEV & AL VAJ; 30 min C-Lk depress without built in hold at 5psi; 15 min CCC Changeout without PB pause during 2 min purge. With 2 hours of Pre-sleep, **ISS Crew Day length = 17:25**.



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# EVA Day Activity Lengths



Activity	Campout	Campout Procedure	Exercise	Exerc Procedure
Post Sleep (75 min STS/90 min ISS)	50 min (40 min during Hyg Bk)	--	90 min	--
Verifying A/L Equipment	0 min (during Mask PB)	Campout Overnight Mask PB	*1 min	EVA Prep
CEVIS &/or PHA setup	*2 min	Campout Overnight Mask PB	*7 min	EVA Prep
Activating CO2 Removal	*2 min	Campout Overnight Mask PB	*2 min	EVA Prep
Mask PB (+ Exercise)	130 min	Campout Overnight (60 min)/Hyg Bk (70 min)	80 min	EVA Prep
Depress to 10.2 psi	0 min (during Mask PB)	Campout Overnight/Hygiene Break	0 min (during Mask PB)	EVA Prep
Prebreathe @ 10.2 psi (in A/L)	8:40 hr	Campout Overnight Mask PB	0 min (none Exerc Procedure)	--
Power Up EMU	5 min	Hygiene Br. <u>or</u> EVA Prep	0 min (pwr up during Mask PB)	EVA Prep
Batt V/SOP P ck, open EMU (helmet/LTA)	*5 min	Hygiene Br. <u>or</u> EVA Prep	*0 min (cks/open EMU during Mask PB)	EVA Prep
Dress (TCU, LCVG), Biomedical setup (biomed), comm cap/pigtail	*10 min	EVA Prep	*10 min (dress/bio setup during Mask PB)	EVA Prep
Comm/data/biomed cks, pwr restart ck	*8 min	EVA Prep	*8 min	EVA Prep
ATU config	*2 min	EVA Prep	*2 min	EVA Prep
EMU Donning	55 min	EVA Prep	55 min (LTA donning during Mask PB)	EVA Prep
Checking EMU	5 min	EVA Prep	5 min	EVA Prep
	90 min	EVA Prep Total	170 min	EVA Prep Total

Bolded items have different activity lengths between protocols

\*Times estimated (most "educated guesses") – lengths not listed separately in published procedures

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## EVA Day Activity Lengths




Activity	Campout	Campout Procedure	Exercise	Exerc Procedure
Purge @ 10.2	5 min	EMU Purge	5 min	EMU Purge
Repress A/L	7 min	EMU Purge	7 min	EMU Purge
Purge @ 14.7	3 min	EMU Purge	3 min	EMU Purge
<b>In-Suit PB (+light exercise)</b>	<b>50 min</b>	<b>EMU PB</b>	<b>60 min</b>	<b>EMU PB</b>
PHA/CSA-O2 clean-up, Tool Config	0 min (during EMU PB)	EMU PB	0 min (during EMU PB)	EMU PB
SAFER Donning	0 min (during EMU PB)	EMU PB	0 min (during EMU PB)	EMU PB
REBA/WVS on, CO2 RR term	0 min (during EMU PB)	EMU PB	0 min (during EMU PB)	EMU PB
Preparing for Depress	0 min (during EMU PB)	EMU PB	0 min (during EMU PB)	EMU PB
<b>Crewlock Depress</b>	<b>30 min</b>	<b>C-Lk D/R CC</b>	<b>45 min</b>	<b>C-Lk D/R CC</b>
Post Depress	0 min (during EVA PET)	C-Lk D/R CC	0 min (during EVA PET)	C-Lk D/R CC
EVA	6:30 hr	--	6:30 hr	--
Pre-Repress	0 min (during EVA PET)	C-Lk D/R CC	0 min (during EVA PET)	C-Lk D/R CC
Crewlock Repress	10 min	C-Lk D/R CC	10 min	C-Lk D/R CC
PostEVA w/o H2O, METOX	60 min	Post EVA	60 min	Post EVA
Pre-Sleep	120 min	--	120 min	--
	<b>14:45 hrs</b>	<b>Day of EVA</b>	<b>16:00 hrs</b>	<b>Day of EVA</b>

Bolded items have different activity lengths between protocols

\*Times estimated (most "educated guesses") – lengths not listed separately in published procedures

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## EVA Day Activity Lengths



Activity	ISLE	ISLE Procedure	4 hr In-Suit	4 hr Procedure
Post Sleep (75 min STS/90 min ISS)	70 min (20 min during EVA PB)	--	90 min	--
Verifying A/LEquipment	* 1 min	EVA Prep	0 min (none for in-suit PB)	--
CEVIS &/or PHA setup	* 2 min	EVA Prep	0 min (none for in-suit PB)	--
Activating CO2 Removal	* 2 min	EVA Prep	0 min (none for in-suit PB)	--
Mask PB	60 min	EVA Prep	0 min (none for in-suit PB)	--
Depress to 10.2 psi	0 min (during Mask PB)	Mask PB	0 min (none for in-suit PB)	--
Power Up EMU	0 min (during Mask PB – IV)	EVA Prep	5 min	EVA Prep
Batt V/SOP P ck, open EMU (helmet/LTA)	0 min (during Mask PB – IV)	EVA Prep	* 5 min	EVA Prep
Dress (TCU, LCVG), Biomedical setup (biomed), comm cap/pigtail	* 2 min (dress/bio setup during Mask PB)	EVA Prep	* 10 min	EVA Prep
Comm/data/biomed cks, pwr restart ck	* 8 min	EVA Prep	* 8 min	EVA Prep
ATU config	* 2 min	EVA Prep	* 2 min	EVA Prep
EMU Donning	* 45 min (LTA donning during Mask PB)	EVA Prep	55 min	EVA Prep
Checking EMU	5 min	EVA Prep	5 min	EVA Prep
	127 min	EVA Prep Total	90 min	EVA Prep Total

Bolded items have different activity lengths between protocols

\*Times estimated (most “educated guesses”) – lengths not listed separately in published procedures

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## EVA Day Activity Lengths



Activity	ISLE	ISLE Procedure	4 hr In-Suit	4 hr Procedure
Purge @ 10.2	5 min	EMU Purge	5 min	EMU Purge
Repress A/L	7 min	EMU Purge	7 min	EMU Purge
Purge @ 14.7	3 min	EMU Purge	3 min	EMU Purge
<b>In-Suit PB (+light exercise)</b>	<b>125 min (+15 min CCC chgout, +10 min rest)</b>	<b>EMU PB</b>	<b>240 min (+15 min CCC chgout)</b>	<b>EMU PB</b>
PHA/CSA-O2 clean-up, Tool Config	0 min (during EMU PB)	EMU PB	0 min (during EMU PB)	EMU PB
SAFER Donning	0 min (during EMU PB)	EMU PB	0 min (during EMU PB)	EMU PB
REBA/WVS on, CO2 RR term	0 min (during EMU PB)	EMU PB	0 min (during EMU PB)	EMU PB
Preparing for Depress	0 min (during EMU PB)	EMU PB	0 min (during EMU PB)	EMU PB
Crewlock Depress	30 min	C-Lk D/R CC	30 min	C-Lk D/R CC
Post Depress	0 min (during EVA PET)	C-Lk D/R CC	0 min (during EVA PET)	C-Lk D/R CC
EVA	6:30 hr	--	6:30 hr	--
Pre-Repress	0 min (during EVA PET)	C-Lk D/R CC	0 min (during EVA PET)	C-Lk D/R CC
Crewlock Repress	10 min	C-Lk D/R CC	10 min	C-Lk D/R CC
PostEVA w/o H2O, METOX	60 min	PostEVA	60 min	PostEVA
Pre-Sleep	120 min	--	120 min	--
	<b>15:47 hrs</b>	<b>Day of EVA</b>	<b>17:25 hrs</b>	<b>Day of EVA</b>

Bolded items have different activity lengths between protocols

\*Times estimated (most "educated guesses") – lengths not listed separately in published procedures

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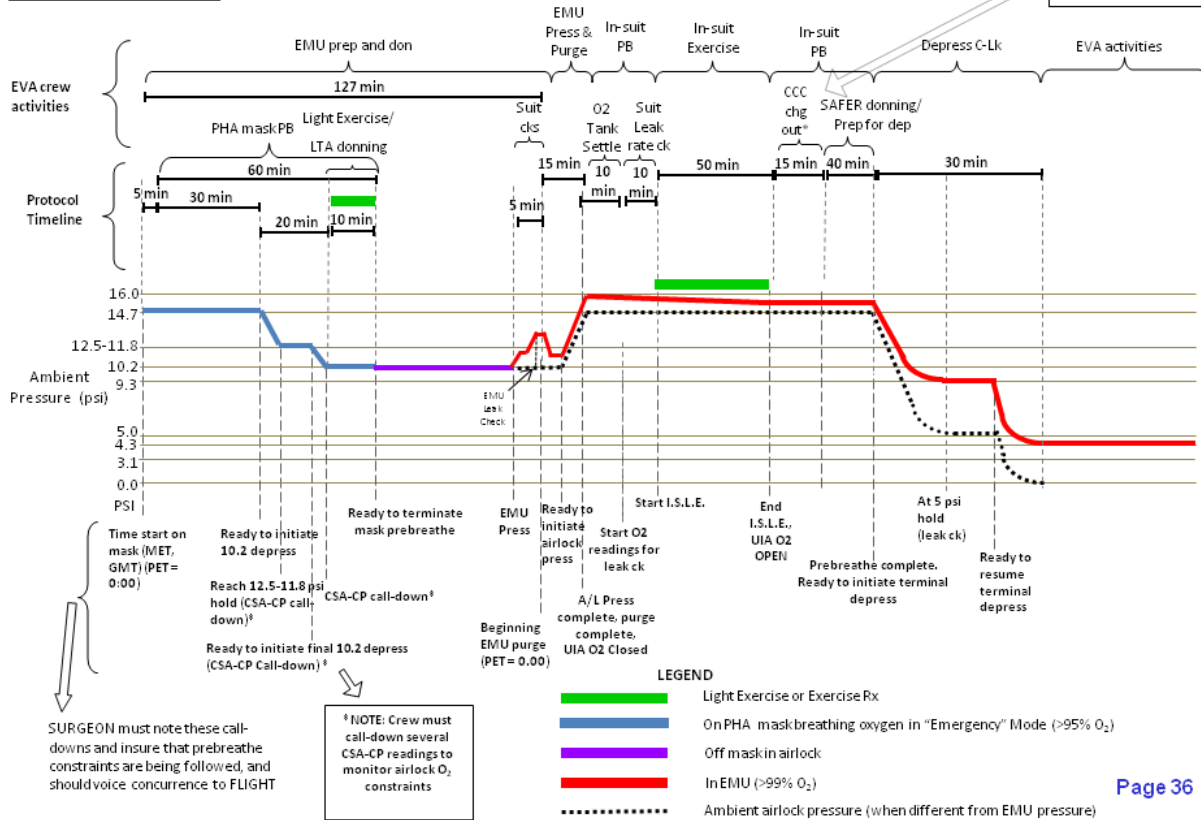
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**DRAFT**

### ISLE Prebreathe Protocol Pressure Profile

Not to Scale

\* NOTE: CCC change out maybe optional, if NIR, reduce timeline/PB by 15 min







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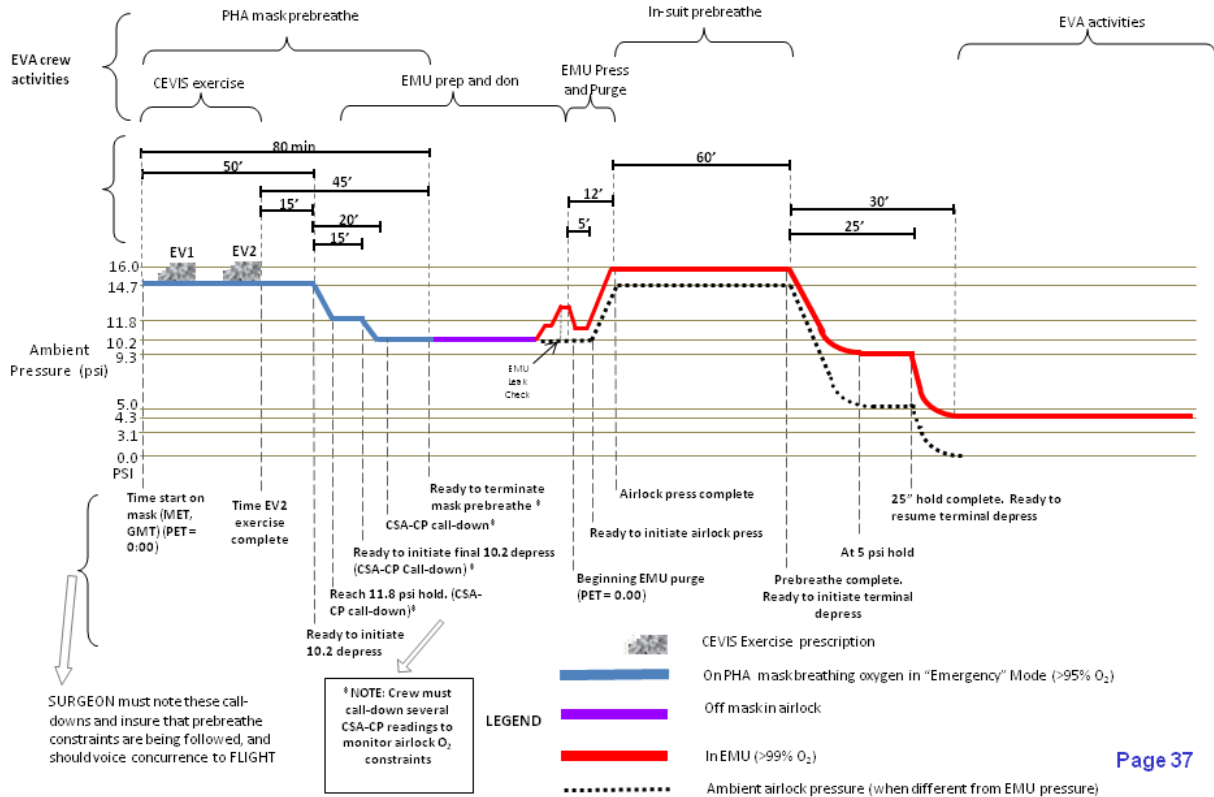
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### CEVIS Exercise Prebreathe Protocol Pressure Profile

*Not to Scale*



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## Appendix I. EVA MOD Prebreathe Protocol Comparisons



# EVA MOD Prebreathe Protocol Comparisons


DX3/Megan Murphey

NESC Review

October 14, 2010

10/14/2010

1

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## Comparison of EVA Prebreathe Protocols SUMMARY TABLE



PROTOCOL COMPARISON	ISLE	Exercise	Campout	4 Hr In-Suit
Post Sleep / Pre-Sleep Durations (GGR&C Guidelines are met)	1:10 [1] / 2:00	1:30 / 2:00	0:50 [1] / 2:00	1:30 / 2:00
Time from Post Sleep to start of EVA	4:57	4:50	4:15	6:15
Post EVA Ops (not including H2O, METOX)	1:00	1:00	1:00	1:00
EVA PETI (Time to not exceed recommended crew day length)	6:30 / (6:13)	6:30 / (6:00)	6:30	6:30 / (4:35)
Additional Time needed above recommended ISS crew day length (15:30 per GGR&C) to allow a 6:30 EVA duration [2]	0:17	0:30	None (-0:45)	1:55
Airlock Isolation	1:44	2:12	11:59	none
Mask Time (minimum)	1:00	1:20	2:10	none
Prebreathe In-Suit Time (minimum) [3]	2:35 [4]	1:45	1:20	4:30 [4]
Depress/Repress Cycles	2	2	3	1
METOX Cans Used per CM: EMU*/ A/L Scrubbing**/ Cans Req'd***	1.25 (1) / 0.5 / 6 (4)	1 / 0.5 / 4	1 / 1 / 4	1.5 / 0 / 4
EVA PB O2 Usage (planning numbers/expected numbers) [5] (lbs)	~ 19 / ~ 13	25 / 20.5	25 / 18.75	10 / 7.4

[1] For Campout, 40 min of Post Sleep occurs during Hygiene Break. For ISLE, 20 min of Post Sleep occurs during EVA Prep.  
 [2] For ISS crew, Post Sleep duration is 1:30 and Pre Sleep duration is 2:00. Total crew day length is 15:30. [REF: SSP 50261-01, REV A GENERIC GGR&C (COLLATED MASTER - THRU DCN 016) 12/22/04.]  
 [3] Does not include time in-suit for EMU Donning activities nor EMU PURGE. Does include time during C-Lk depress to vacuum.  
 [4] An additional purge of 2 min will be required after the METOX Changeout. Apprx. 0.4 lbs of additional O2 used for the 2-min purge.  
 [5] Planning numbers = Apprx. Values for total O2 for both CMs. These are conservative numbers used for planning purposes. Generally see lower numbers, as seen in the expected numbers. However, using the conservative numbers also accounts for other EMU and Airlock maintenance activities which require the use of some O2.  
 \* For ISLE and 4 hr In-suit protocols: canisters used in first part of in-suit prebreathe before changeout may be used again on a subsequent EVA day for the same first part of in-suit prebreathe. 4 hr In-Suit cans can be used twice. ISLE cans can be used four times.  
 \*\* CO2 Removal Receptacle which scrubs CO2 from A/L anytime isolated requires 2 METOX canisters (cannot use 1 canister). The METOX canisters used for A/L scrubbing during Exercise or ISLE protocols can be used again in the CO2 RR during a subsequent Exercise or ISLE protocol.  
 \*\*\* Physical count of canisters required to run protocol. ISLE may not require METOX Changeout, if consumables can support. If changeout not reqd, use values in ( ).



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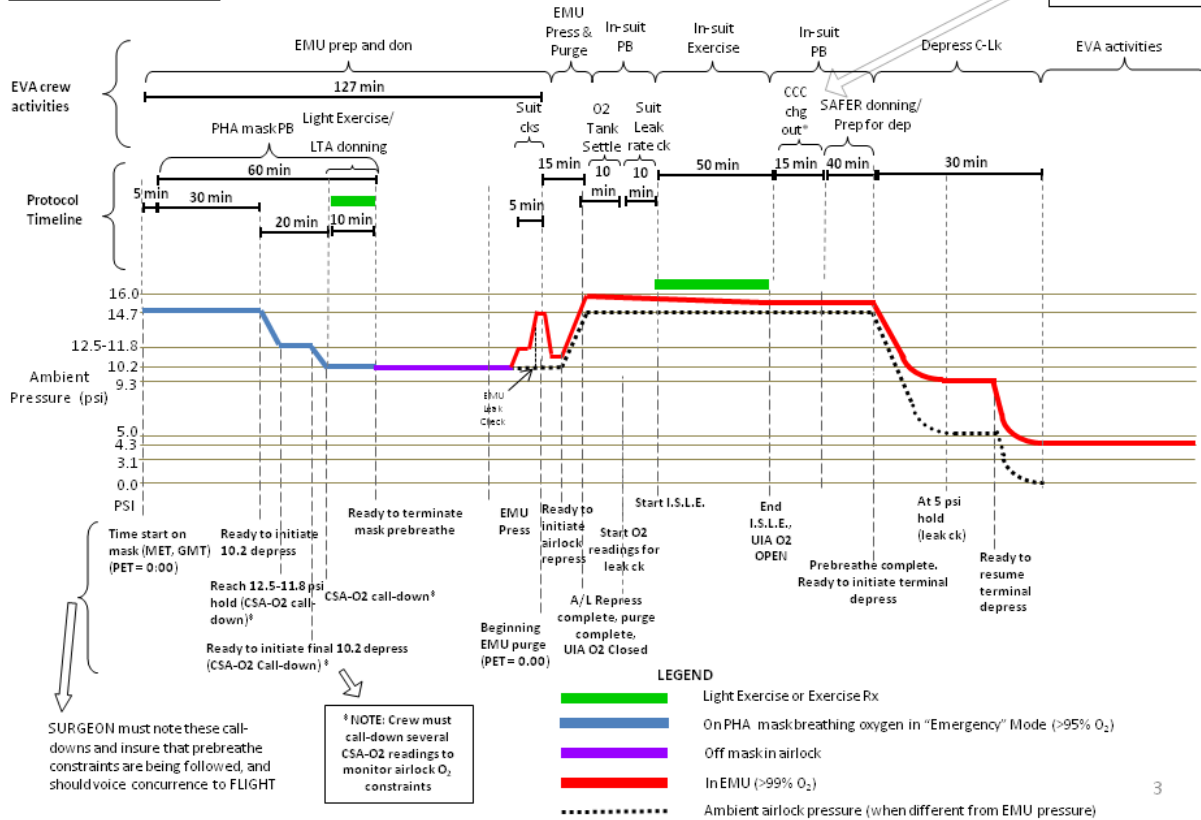
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**DRAFT**

### ISLE Prebreathe Protocol Pressure Profile

Not to Scale

\* NOTE: CCC change out maybe optional, if NIR, reduce timeline/PB by 15 min





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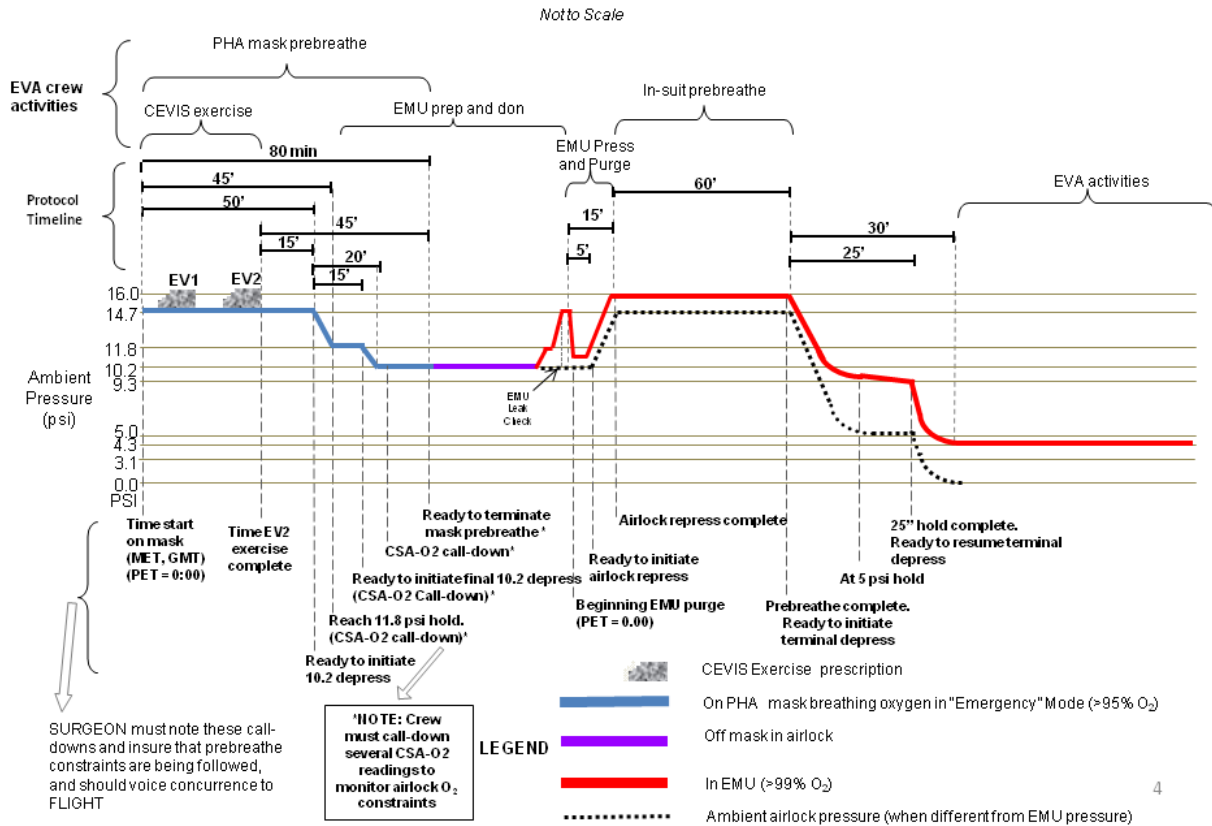
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### CEVIS Exercise Prebreathe Protocol Pressure Profile





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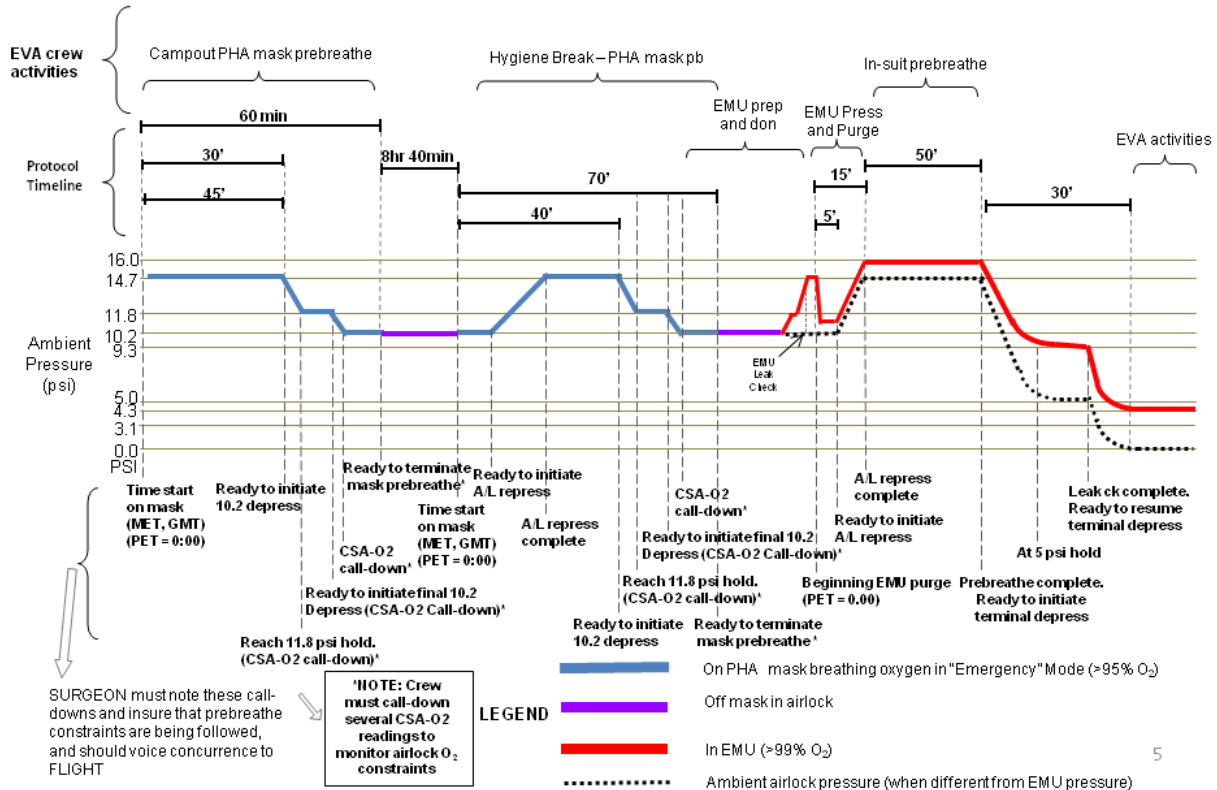
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### Campout Prebreathe Protocol Pressure Profile

*Not to Scale*





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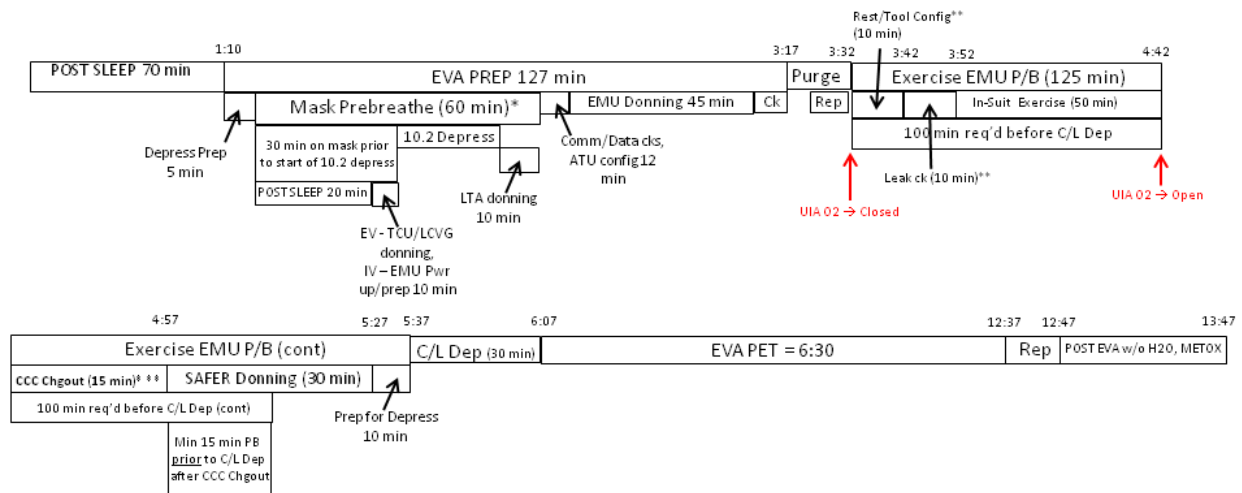
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## Time Comparison of Protocols



### In-Suit Light Exercise Prebreathe Timeline for EVA Day (w/CCC Changeout)



\*Assume 20 mins of Mask PB may be done in parallel with POST SLEEP.

\*\*Due to uncertainty in O2 tank cool down effects and suit leak vs. crewmember breathe down rates, 20 min of EMU PB will be done prior to 50 min of in-suit exercise.

\*\*\*CCC changeout maybe optional, if not required for consumables, total timeline is 15 min shorter.

Note: Assume depress pump and EMERG MPEV & ALVAJ; 30 min C-Lk depress without built in hold at 5psi. With 2 hours of Pre-sleep, ISS Crew Day length = 15:47.



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## Phase V-5 In-Suit Light Exercise (ISLE) Prebreathe Protocol

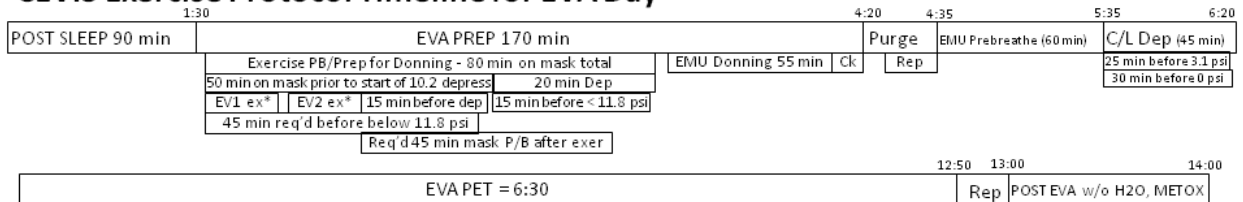
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## Time Comparison of Protocols

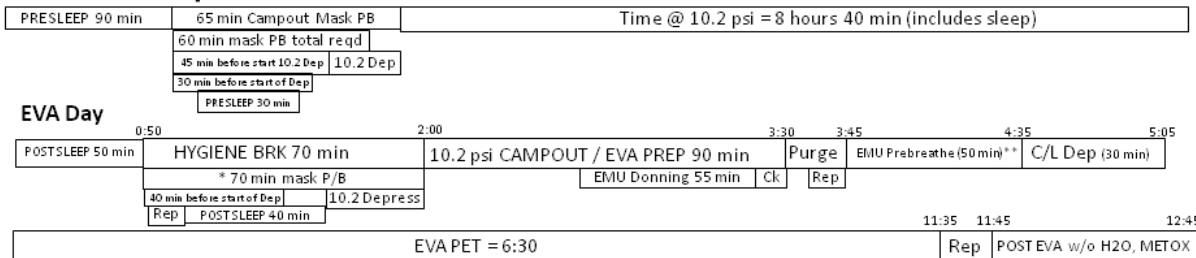


### CEVIS Exercise Protocol Timeline for EVA Day



\* EV1 must start exercise within 10 min after PB initiate, EV2 must start exercise within 25 min after PB initiate to maintain 45 minute of mask time after exercise per FR  
Note: Assume depress pump and EMERG MPEV & AL VAJ; 45 min C-Lk depress with built in hold at 5psi PET = 25. With 2 hours of Pre-sleep, **ISS Crew Day length = 16:00.**

### ISS 10.2 Campout Protocol Timeline



\* 70 min mask P/B to begin only after 8hr 40 min at 10.2 psi per FR. Assume 40 min of HYGIENE BREAK may be done in parallel with POST SLEEP. Note that IV may be able to begin the EVA Prep activities during the Hygiene Break, which could possibly result in an additional 10 minute savings in the timeline.

\*\* In order to satisfy the accept criteria for ISS EVA protocols, an additional 10 minutes of in-suit prebreathe was added to the medical Campout protocol making the total in suit EMU Prebreathe for Campout = 50 min.

Note: Assume depress pump and EMERG MPEV & AL VAJ; 30 min C-Lk depress without built in hold at 5psi. With 2 hours of Pre-sleep, **ISS7 Crew Day length = 14:45.**





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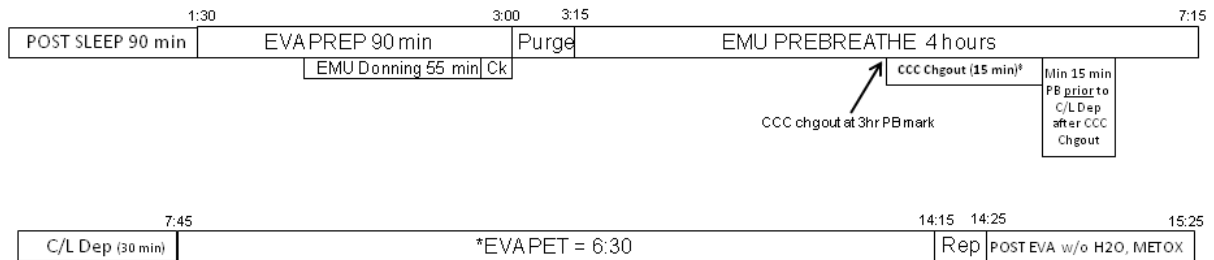
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## Time Comparison of Protocols



### 4 hr In-Suit Protocol Timeline for EVA Day




\*CCC changeout would be performed 3 hours into prebreathe activities (manned) to allow for max EVA PET capability.

Note: Assume depress pump and EMERG MPEV & AL VAJ; 30 min C-Lk depress without built in hold at 5psi; 15 min CCC Changeout without PB pause during 2 min purge. With 2 hours of Pre-sleep, ISS Crew Day length = 17:25.

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# BACK-UP CHARTS

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# EVA DAY ACTIVITIES TIME BREAKDOWN

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# EVA Day Activity Lengths



Activity	Campout	Campout Procedure	Exercise	Exerc Procedure
Post Sleep (75 min STS/90 min ISS)	50 min (40 min during Hyg Bk)	--	90 min	--
Verifying A/L Equipment	0 min (during Mask PB)	Campout Overnight Mask PB	*1 min	EVA Prep
CEVIS &/or PHA setup	*2 min	Campout Overnight Mask PB	*7 min	EVA Prep
Activating CO2 Removal	*2 min	Campout Overnight Mask PB	*2 min	EVA Prep
Mask PB (+ Exercise)	130 min	Campout Overnight (60 min)/Hyg Bk (70 min)	80 min	EVA Prep
Depress to 10.2 psi	0 min (during Mask PB)	Campout Overnight/Hygiene Break	0 min (during Mask PB)	EVA Prep
Prebreathe @ 10.2 psi (in A/L)	8:40 hr	Campout Overnight Mask PB	0 min (none Exerc Procedure)	--
Power Up EMU	5 min	Hygiene Br. <u>or</u> EVA Prep	0 min (pwr up during Mask PB)	EVA Prep
Batt V/SOP P ck, open EMU (helmet/LTA)	*5 min	Hygiene Br. <u>or</u> EVA Prep	*0 min (cks/open EMU during Mask PB)	EVA Prep
Dress (TCU, LCVG), Biomedical setup (biomed), comm cap/pigtail	*10 min	EVA Prep	*10 min (dress/bio setup during Mask PB)	EVA Prep
Comm/data/biomed cks, pwr restart ck	*8 min	EVA Prep	*8 min	EVA Prep
ATU config	*2 min	EVA Prep	*2 min	EVA Prep
EMU Donning	55 min	EVA Prep	55 min (LTA donning during Mask PB)	EVA Prep
Checking EMU	5 min	EVA Prep	5 min	EVA Prep
	90 min	EVA Prep Total	170 min	EVA Prep Total

Bolded items have different activity lengths between protocols

\*Times estimated (most "educated guesses") – lengths not listed separately in published procedures

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## EVA Day Activity Lengths



Activity	Campout	Campout Procedure	Exercise	Exerc Procedure
Purge @ 10.2	5 min	EMU Purge	5 min	EMU Purge
Repress A/L	7 min	EMU Purge	7 min	EMU Purge
Purge @ 14.7	3 min	EMU Purge	3 min	EMU Purge
<b>In-Suit PB (+light exercise)</b>	<b>50 min</b>	<b>EMU PB</b>	<b>60 min</b>	<b>EMU PB</b>
PHA/CSA-O2 clean-up, Tool Config	0 min (during EMU PB)	EMU PB	0 min (during EMU PB)	EMU PB
SAFER Donning	0 min (during EMU PB)	EMU PB	0 min (during EMU PB)	EMU PB
REBA/WVS on, CO2 RR term	0 min (during EMU PB)	EMU PB	0 min (during EMU PB)	EMU PB
Preparing for Depress	0 min (during EMU PB)	EMU PB	0 min (during EMU PB)	EMU PB
<b>Crewlock Depress</b>	<b>30 min</b>	<b>C-Lk D/R CC</b>	<b>45 min</b>	<b>C-Lk D/R CC</b>
Post Depress	0 min (during EVA PET)	C-Lk D/R CC	0 min (during EVA PET)	C-Lk D/R CC
EVA	6:30 hr	--	6:30 hr	--
Pre-Repress	0 min (during EVA PET)	C-Lk D/R CC	0 min (during EVA PET)	C-Lk D/R CC
Crewlock Repress	10 min	C-Lk D/R CC	10 min	C-Lk D/R CC
PostEVA w/o H2O, METOX	60 min	Post EVA	60 min	Post EVA
Pre-Sleep	120 min	--	120 min	--
	<b>14:45 hrs</b>	<b>Day of EVA</b>	<b>16:00 hrs</b>	<b>Day of EVA</b>

Bolded items have different activity lengths between protocols

\*Times estimated (most "educated guesses") – lengths not listed separately in published procedures

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## EVA Day Activity Lengths



Activity	ISLE	ISLE Procedure	4 hr In-Suit	4 hr Procedure
Post Sleep (75 min STS/90 min ISS)	70 min (20 min during EVA PB)	--	90 min	--
Verifying A/LEquipment	* 1 min	EVA Prep	0 min (none for in-suit PB)	--
CEVIS &/or PHA setup	* 2 min	EVA Prep	0 min (none for in-suit PB)	--
Activating CO2 Removal	* 2 min	EVA Prep	0 min (none for in-suit PB)	--
Mask PB	60 min	EVA Prep	0 min (none for in-suit PB)	--
Depress to 10.2 psi	0 min (during Mask PB)	Mask PB	0 min (none for in-suit PB)	--
Power Up EMU	0 min (during Mask PB – IV)	EVA Prep	5 min	EVA Prep
Batt V/SOP P ck, open EMU (helmet/LTA)	0 min (during Mask PB – IV)	EVA Prep	* 5 min	EVA Prep
Dress (TCU, LCVG), Biomedical setup (biomed), comm cap/pigtail	* 2 min (dress/bio setup during Mask PB)	EVA Prep	* 10 min	EVA Prep
Comm/data/biomed cks, pwr restart ck	* 8 min	EVA Prep	* 8 min	EVA Prep
ATU config	* 2 min	EVA Prep	* 2 min	EVA Prep
EMU Donning	* 45 min (LTA donning during Mask PB)	EVA Prep	55 min	EVA Prep
Checking EMU	5 min	EVA Prep	5 min	EVA Prep
	127 min	EVA Prep Total	90 min	EVA Prep Total

Bolded items have different activity lengths between protocols

\*Times estimated (most “educated guesses”) – lengths not listed separately in published procedures

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## EVA Day Activity Lengths



Activity	ISLE	ISLE Procedure	4 hr In-Suit	4 hr Procedure
Purge @ 10.2	5 min	EMU Purge	5 min	EMU Purge
Repress A/L	7 min	EMU Purge	7 min	EMU Purge
Purge @ 14.7	3 min	EMU Purge	3 min	EMU Purge
<b>In-Suit PB (+light exercise)</b>	<b>125 min (+15 min CCC chgout, +10 min rest)</b>	<b>EMU PB</b>	<b>240 min (+15 min CCC chgout)</b>	<b>EMU PB</b>
PHA/CSA-O2 clean-up, Tool Config	0 min (during EMU PB)	EMU PB	0 min (during EMU PB)	EMU PB
SAFER Donning	0 min (during EMU PB)	EMU PB	0 min (during EMU PB)	EMU PB
REBA/WVS on, CO2 RR term	0 min (during EMU PB)	EMU PB	0 min (during EMU PB)	EMU PB
Preparing for Depress	0 min (during EMU PB)	EMU PB	0 min (during EMU PB)	EMU PB
Crewlock Depress	30 min	C-Lk D/R CC	30 min	C-Lk D/R CC
Post Depress	0 min (during EVA PET)	C-Lk D/R CC	0 min (during EVA PET)	C-Lk D/R CC
EVA	6:30 hr	--	6:30 hr	--
Pre-Repress	0 min (during EVA PET)	C-Lk D/R CC	0 min (during EVA PET)	C-Lk D/R CC
Crewlock Repress	10 min	C-Lk D/R CC	10 min	C-Lk D/R CC
PostEVA w/o H2O, METOX	60 min	PostEVA	60 min	PostEVA
Pre-Sleep	120 min	--	120 min	--
	<b>15:47 hrs</b>	<b>Day of EVA</b>	<b>17:25 hrs</b>	<b>Day of EVA</b>

Bolded items have different activity lengths between protocols

\*Times estimated (most "educated guesses") – lengths not listed separately in published procedures

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**Appendix J. NASA Prebreathe Reduction Program (PRP)  
Phase V-5 Study: Exercise Tasks**

# NASA Prebreathe Reduction Program (PRP) Phase V-5 Study: Exercise Tasks



**Neal W. Pollock, Ph.D.**

Center for Hyperbaric Medicine and Environmental Physiology  
Duke University Medical Center

Study funded by the National Aeronautics and Space Administration





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### **PRP EXERCISE STRATEGIES**




Suit simulator set up for multiple semi-recumbent intermittent light exercise simulating astronaut tasks



Suit simulator set up for leg ergometry

NW Pollock, PhD

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## EVA SUIT SIMULATOR EXERCISES

- ◆ 6 exercises
  - sit-ups, arm pulls, full body pulls, torque wrenching, hand gripping, leg pedaling
- ◆ Subjects will cycle through
  - specific exercises
  - Doppler/2-D echo monitoring
  - Rest break
- ◆ 4 minute intervals for each
  - pace guided by an automated task prompter



NW Pollock, PhD



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### **CROSS-ARM PULLS**



NW Pollock, PhD



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### **HAND GRIP**



NW Pollock, PhD



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### **FULL BODY PULL**



NW Pollock, PhD



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## SIT-UP



NW Pollock, PhD



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# TORQUE WRENCHING



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# LEG PEDALING



NW Pollock, PhD



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## Appendix K. Prebreathe Reduction Program – Phase V Research Summary

### PREBREATHE REDUCTION PROGRAM - PHASE V RESEARCH SUMMARY

Michael L. Gernhardt, Neal W. Pollock  
August 09, 2010

#### Background

Astronauts must undergo denitrogenation prior to performing extravehicular activity (EVA) in low-pressure space suits, in order to reduce the risk of decompression sickness (DCS). Several countermeasures can be used to reduce decompression stress: oxygen breathing time prior to decompression (prebreathe), reduced ambulation and lower body musculoskeletal stresses (microgravity simulation), exercise during the oxygen prebreathe to increase tissue perfusion and expedite nitrogen removal, and post-exercise rest to facilitate resolution of any micronuclei (sites for gas phase separation and growth) generated during the exercise period through tribonucleation or other musculoskeletal stress-assisted mechanisms. The prebreathe reduction program (PRP) was initiated to evaluate oxygen prebreathe protocols which combined microgravity simulation with different patterns of exercise to effectively reduce the baseline four hour oxygen prebreathe time required to control decompression stresses to acceptable levels.

Completion of the first four phases of the PRP program, yielded a successful two hour prebreathe protocol that combined an initial 10 minute period of heavy exercise (75% of peak oxygen consumption measured during a graded maximal test [ $\text{VO}_2$  peak]) on a cycle ergometer, followed by light intermittent exercise (24 minutes exercise over a 40 minute period at an intensity 5.8 ml/kg-min), followed by a final 40 minutes of resting prebreathe. Laboratory simulations of this protocol (Phase II) were clearly superior to the others tested, with no DCS in 45 subject-exposures. The protocol was first implemented operationally during STS-104 in July 2001. A total of 34 spacewalks employed this protocol, the last pair on April 08, 2003, with no complications. The limitation of the existing 'out-of-suit exercise protocol is its reliance on a complicated infrastructure that includes the possibility of up to 21 single-point failures, and high oxygen usage associated with the open-circuit oxygen delivery system.

The objective of Phase V was to investigate the viability of establishing an equally effective prebreathe protocol that could be conducted completely in the closed-circuit space suit, with the result of limiting the failure modes and significantly reducing the demand on oxygen consumables. Phase V will utilize the same accept/reject criteria as the previous PRP trials:

Accept for DCS  $\leq 15\%$  and/or Grade IV VGE  $\leq 20\%$ , at 95% confidence level (CL)

Reject for DCS  $>15\%$  and /or Grade IV VGE  $>20\%$ , at 70% CL, or any case of Type II DCS

These accept/reject criteria were based on the consensus result of a one year program, the NASA DCS Risk Definition and Contingency Plan (Gernhardt, 2000) involving the USAF, USN, NASA Flight Surgeons, Flight Directors, Astronauts, Researchers and Statisticians. The accept criteria are below a threshold below which there has not been a report of Type II DCS in more than 130,000 hypobaric exposures. In order to meet the accept criteria the observed DCS risk in 50 trials must be  $<6\%$ . This is a lower DCS risk than observed in any of the previous ground trials conducted for the Shuttle Program (Waligora et al., 1984) or the Russian Space Program (Barer, 1995). In addition to the conservative accept criteria for these ground trials, the



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operational prebreathe protocols will have an additional prebreathe time of approximately 20 minutes or more, associated with the suit purge, leak checks and slower crewlock depress rates. The objective of the prebreathe reduction program is to develop more efficient prebreathe protocols without incurring additional DCS risk. Any prebreathe protocol that meets these stringent accept criteria will be extremely safe and robust for operational use.

The PRP results are summarized in Table 1. Individual DCS case descriptions appear in Appendices I-1 to I-5. Case definitions defining DCS for Phase V work appear in Appendix II.

Table 1. Prebreathe Reduction Program Summary

Protocol	Site <sup>1</sup>	Exposures Completed			DCS			Cuff				Max Doppler VGE				
		Males	Females	Total	Ambig.	Type I	Type II	1	2	3	4	0	I	II	III	IV
<b>PRP-I</b>	D	18	8	26	0	5	0	4	1	0	0	10	10	2	3	1
	H	15	6	21	0	4	0	2	2	0	0	14	2	1	3	1
	C	0	0	0												
	Totals	33	14	47	0	9	0	6	3	0	0	24	12	3	6	2
<b>PRP-II</b>	D	12	4	16	0	0	0	0	0	0	0	11	3	1	1	0
	H	16	6	22	1	0	0	1	0	0	0	18	0	1	3	0
	C	7	0	7	0	0	0	0	0	0	0	2	1	0	1	3
	Totals	35	10	45	1	0	0	1	0	0	0	31	4	2	5	3
<b>PRP-III</b>	D	7	1	8	0	1	1	1	0	0	1	7	0	0	0	1
	H	1	0	1	0	0	0	0	0	0	0	1	0	0	0	0
	Totals	8	1	9	0	1	1	1	0	0	1	8	0	0	0	1
<b>PRP-IV</b>	D	15	3	18	0	0	0	0	0	0	0	12	5	1	0	0
	H	12	5	17	0	4	0	2	2	0	0	12	0	1	4	0
	C	17	4	21	2	4	0	1	3	0	0	9	1	0	4	7
	Totals	44	12	56	2	8	0	3	5	0	0	33	6	2	8	7
<b>PRP-V-1</b>	D	7	2	9	0	3	0	1	2	0	0	4	0	2	1	2
	Totals	7	2	9	0	3	0	1	2	0	0	4	0	2	1	2
<b>PRP-V-2</b>	D	1	2	3	0	0	1	0	0	0	1	0	0	1	0	2
	Totals	1	2	3	0	0	1	0	0	0	1	0	0	1	0	2
<b>PRP-V-3</b>	D	23	5	28	0	3	0	0	3	0	0	12	3	4	7	2
	C	15	5	20	0	4	0	1	4	0	0	11	1	0	5	3
	Totals	38	10	48	0	7	0	1	7	0	0	23	4	4	12	5
<b>PRP-V-4</b>	D	3	3	6	0	3	0	2	1	0	0	3	0	2	0	1
	Totals	3	3	6	0	3	0	2	1	0	0	3	0	2	0	1
<b>PRP-V-5</b>	D	11	36	47	0	2	0					34	0	3	3	8
	Totals	11	36	47	0	2	0					34	0	3	3	8

<sup>1</sup> D = Duke; H = Hermann; C = DRDC

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### Phase V Trials

Phase V trials were conducted between November 2002 and March 2008. Exposures were completed for Protocol V-1 11/25/02-1/22/03; V-2 3/4/03-3/27/03; V-3 5/12/03-12/16/03; V-4 8/17/04-9/15/05; and V-5 10/13/06-3/28/08.

One of the elements evaluated in the Phase V protocols was the use of intermittent exercise, an effort driven by both practical and theoretical considerations. Exercise in the suit can generate local hot spots and in a pilot study astronauts preferred brief periods of exercise followed by rest rather than a continuous 10 minute exercise period. Additionally, there is an inherent asymmetry between the rapid onset of blood flow in response to exercise and the gradual relaxation of blood flow following the cessation of exercise. Theoretically, the use of intermittent exercise should result in more cumulative blood flow and nitrogen elimination for a given amount of total exercise, achieving a better balance between inert gas elimination and micronuclei generation.

### Protocol V-1

Protocol V-1 employed 20 minutes of intermittent exercise (two minutes of exercise followed by two minutes of rest) at an intensity targeting 60%  $VO_{2\text{ peak}}$ . The exercise was conducted in the first 44 minutes of the prebreathe period. Subjects remained at rest for the duration of the prebreathe period. An overview of the protocol appears in Figure 1.

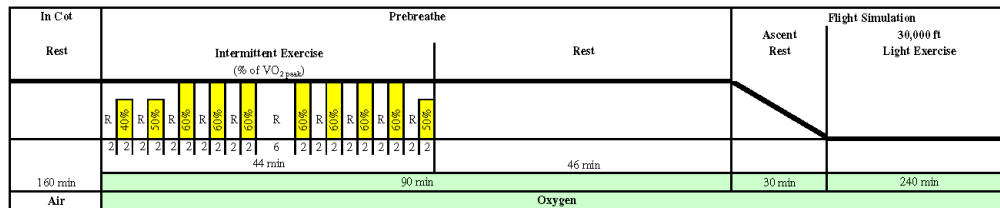


Figure 1. Graphic Timeline of PRP Phase V-1 Protocol


Ten subjects participated in the trials conducted at Duke University. Descriptive characteristics appear in Table 2.

Table 2. Descriptive Characteristics of Phase V-1 Test Subjects (mean±SD)

Gender	Age (years)	Weight (kg)	Height (m)	BMI <sup>1</sup> (kg·m <sup>-2</sup> )	Body Fat <sup>2</sup> (%)	$VO_{2\text{ peak}}$ (mL·kg <sup>-1</sup> ·min <sup>-1</sup> )
M = 7	32.6±6.8	82.4±10.0	1.76±0.09	24.7±3.1	14.9±4.1	45.7±4.7
F = 2	27.9±2.4	57.2±5.3	1.62±0.00	20.4±1.9	16.1±5.5	42.2±6.3
Total = 9	31.5±6.3	76.8±14.2	1.73±0.10	23.7±3.3	15.2±4.1	44.9±4.9

<sup>1</sup> BMI = body mass index

<sup>2</sup> estimated by the lower of seven-site or three-site skinfold computation

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Three cases of Type I DCS and one case of ambiguous symptoms were observed during the first 10 subject-exposures. Summary descriptions of the patterns of DCS and venous gas emboli (VGE) appear in Tables 1 and 3. Case reports were presented previously. All cases were mild and resolved with repressurization to ground level. All subjects were then treated with two hours of ground level oxygen with no complications.

Table 3. Summary of DCS and VGE in Phase V-1 (mean±SD)

Type I	DCS		VGE			
	Latency <sup>1</sup> (min)	Type II (0%)	Any Non-Zero Grade (56%)	Any Non-Zero Grade Latency <sup>1</sup> (min) 99±71 <sup>3</sup>	Grade IV (22%) 2/9	Grade IV Latency <sup>1</sup> (min) 100.0±31.1
3/9 (33%)	77.3±14.2 <sup>2</sup>	0/9 (0%)	5/9 (56%)	99±71 <sup>3</sup>	2/9 (22%)	100.0±31.1

<sup>1</sup> Latency computed from time of arrival at exposure altitude

<sup>2</sup> all three cases of DCS in males

<sup>3</sup> only one of six cases of VGE in females

One V-1 trial was terminated early due to ambiguous symptoms. The case was subsequently classified as not DCS, but because of the early termination it did not meet the criteria of a 230 minute exposure to be used for test of the hypothesis. Descriptive characteristics and the time course of symptoms/VGE of the affected subject appear in Tables 4 and 5, respectively.

Table 4. Descriptive Characteristics for Subject with Ambiguous Symptoms in Phase V-1 (mean±SD)

Gender	Age (years)	Weight (kg)	Height (m)	BMI <sup>1</sup> (kg·m <sup>-2</sup> )	Body Fat <sup>2</sup> (%)	VO <sub>2,peak</sub> (mL·kg <sup>-1</sup> ·min <sup>-1</sup> )
F=1	28.1	64.0	1.72	20.3	20.6	37.4


<sup>1</sup> BMI = body mass index

<sup>2</sup> estimated by the lower of seven-site or three-site skinfold computation

Table 5. Symptom and VGE Summary for Subject with Ambiguous Symptoms in Phase V-1 (mean±SD)

Ambiguous Symptom Latency <sup>1</sup> (min)	Grade	VGE Latency <sup>1</sup> (min)
50	2	72

<sup>1</sup> Latency computed from time of arrival at exposure altitude

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Protocol V-1 was rejected based on both DCS (3/9 = 33.3%) and Grade IV VGE (2/9 = 22.2%) using the *a priori* accept/reject criteria. Individual DCS case descriptions appear in Appendix I-1.

**Protocol V-2**

Protocol V-2 employed 20 minutes of intermittent exercise (an initial two minute warm up targeting 50% VO<sub>2 peak</sub> followed by two minutes of rest, then six, three minute periods targeting 60% VO<sub>2 peak</sub> exercise, each followed by two minutes of rest). The exercise was conducted in the first 34 minutes of the prebreathe period. Subjects remained at rest for the duration of the 90 minute prebreathe period. An overview of the protocol appears in Figure 2.

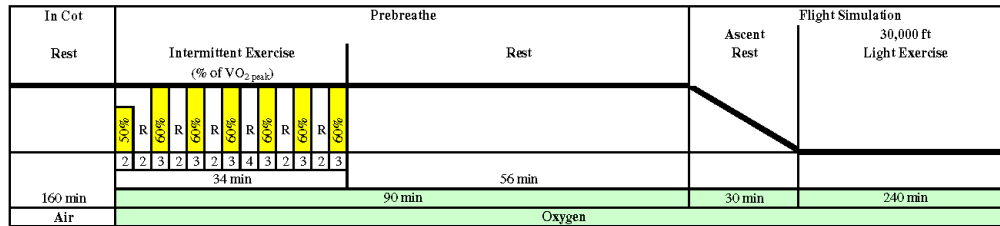


Figure 2. Graphic Timeline of PRP Phase V-2 Protocol

Four subjects participated in the trials conducted at Duke University. Descriptive characteristics appear in Table 6.

Table 6. Descriptive Characteristics of Phase V-2 Test Subjects (mean±SD)

Gender	Age (years)	Weight (kg)	Height (m)	BMI <sup>1</sup> (kg·m <sup>-2</sup> )	Body Fat <sup>2</sup> (%)	VO <sub>2 peak</sub> (mL·kg <sup>-1</sup> ·min <sup>-1</sup> )
M = 1	40.1	113.2	1.84	31.2	22.0	38.5
F = 2	38.8±5.5	62.9±4.2	1.59±0.01	23.2±1.3	18.4±6.5	33.3±3.0
Total = 3	39.2±4.0	79.7±29.2	1.67±0.15	25.9±4.7	19.6±5.0	35.0±3.7

<sup>1</sup> BMI = body mass index

<sup>2</sup> estimated by the lower of seven-site or three-site skinfold computation

One case of Type II DCS, with pulmonary involvement, was observed during the first four subject-exposures. The subject (with a VO<sub>2 peak</sub> of 31 mL·kg<sup>-1</sup>·min<sup>-1</sup>) was treated with hyperbaric oxygen (USN Treatment Table 6) and completely resolved within 20 minutes, with no residual symptoms. Summary descriptions of the patterns of DCS and venous gas emboli (VGE) for subjects completing trials appear in Tables 1 and 7. The VGE summary for the asymptomatic subject in the aborted trial appears in Table 7. The case definitions used to define decompression sickness for the purpose of Phase V appear in Appendix II.


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Table 7. Summary of DCS and VGE for Subjects Completing Phase V-2<sup>1</sup> (mean±SD)

Type I	DCS Latency <sup>2</sup> (min)	Type II	Any Non-Zero Grade	VGE Any Non-Zero Grade Latency <sup>2</sup> (min)	Grade IV	Grade IV Latency <sup>2</sup> (min)
0/3 (0%)	128	1/3 (33%)	3/3 (100%)	29±19	2/3 (67%)	81±45

<sup>1</sup> One subject with no DCS symptoms did not complete the trial as it was aborted to treat the other subject who developed symptoms.

<sup>2</sup> Latency computed from time of arrival at exposure altitude

Descriptive characteristics and the time course of symptoms/VGE of the affected subject appear in Tables 8 and 9, respectively.

Table 8. Descriptive Characteristics for Asymptomatic Subject in Aborted Phase V-2 Trial (mean±SD)

Gender	Age (years)	Weight (kg)	Height (m)	BMI <sup>1</sup> (kg·m <sup>-2</sup> )	Body Fat <sup>2</sup> (%)	VO <sub>2</sub> peak (mL·kg <sup>-1</sup> ·min <sup>-1</sup> )
M=1	50.6	70.8	1.69	23.0	17.4	41.4

<sup>1</sup> BMI = body mass index

<sup>2</sup> estimated by the lower of seven-site or three-site skinfold computation


Table 9. VGE Summary for Asymptomatic Subject in Aborted Phase V-2 Trial (mean±SD)

Any Non-Zero Grade	Any Grade Latency <sup>1</sup> (min)	Max Grade	Max Grade Latency <sup>1</sup> (min)	Flight Duration (min)
1/1 (100%)	15	1	15	153

<sup>1</sup> Latency computed from time of arrival at exposure altitude

The prospective reject criterion was met with one serious case in the first three exposures (no serious DCS is tolerated). The acceptance criteria of DCS ≤15% at 95% CL was based on an analysis that indicated there had never been a report of Type II DCS in a large literature database (over 100,000 subject-exposures) when the total DCS symptoms were less than 15%. The observation of a case of Type II DCS in the protocol V-2 trials is consistent with a total DCS risk of greater than 15%.

Protocol V-2 was rejected based on both DCS (serious 1/3 = 33.3%) and Grade IV VGE (2/3 = 66.6%) using the *a priori* accept/reject criteria. Individual DCS case descriptions appear in Appendix I-2.

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### Protocol V-3

Protocol V-3 combined moderate intensity intermittent exercise and low intensity exercise periods. The protocol began with 20 minutes of intermittent exercise conducted in the first 36 minutes of the prebreathe (an initial two minute rest period was followed by a two minute warm up exercise targeting 50%, the subjects then repeated a pattern of 3 minutes exercise at 60% VO<sub>2</sub> followed by two minutes rest). Subjects remained at rest for 14 minutes following the intermittent exercise. Forty minutes of light exercise in the suit simulator was then conducted, and the remaining 30 minutes of the prebreathe period was spent at rest. An overview of the protocol appears in Figure 3.

In Cot Rest	Prebreathe				Flight Simulation													
	Intermittent Exercise (% of VO <sub>2peak</sub> )		Rest	Light Exercise	Ascent Rest	30,000 ft Light Exercise												
	R	50%	R	60%	60%	60%	60%	60%	60%	60%	Transfer							
	2	2	2	3	2	3	2	3	4	3	2	3	2	3	14	40 min (24 min in cot exercise)	30 min	
	36 min				84 min													
	120 min				30 min		240 min											
130 min																		
Air	Oxygen																	

Figure 3. Graphic Timeline of PRP Phase V-3 Protocol

Fifty subjects participated in the trials conducted at Duke University and Defense Research Development, Canada-Toronto (DRDC). Descriptive characteristics appear in Table 10.

Table 10. Descriptive Characteristics of Phase V-3 Test Subjects (mean±SD)

Gender	Age (years)	Weight (kg)	Height (m)	BMI <sup>1</sup> (kg·m <sup>-2</sup> )	Body Fat <sup>2</sup> (%)	VO <sub>2peak</sub> (mL·kg <sup>-1</sup> ·min <sup>-1</sup> )
M = 38	37.3±8.1	84.8±10.9	1.74±0.06	26.1±2.9	14.1±4.7	44.8±7.5
F = 10	35.5±8.4	61.2±4.3	1.61±0.06	21.9±1.2	17.9±3.5	41.0±8.0
Total = 48	36.9±8.1	79.9±13.8	1.71±0.08	25.2±3.2	14.9±4.7	44.0±7.6

<sup>1</sup> BMI = body mass index

<sup>2</sup> estimated by the lower of seven-site or three-site skinfold computation

Seven cases of Type I DCS were observed. Each was resolved with no residual. Summary descriptions of the patterns of DCS and venous gas emboli (VGE) for subjects completing trials appear in Tables 1 and 11. The case definitions used to define decompression sickness for the purpose of Phase V appear in Appendix II.


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Table 11. Summary of DCS and VGE for Subjects Completing Phase V-3 (mean±SD with % or range)

Type I	DCS Latency <sup>1</sup>	Type II	Any Non-Zero Grade	VGE Any Non-Zero Grade Latency <sup>1</sup>	Grade IV	Grade IV Latency <sup>1</sup>
	(min)			(min)		(min)
7/48 (15%)	139±44 (61-95)	0/48 (0%)	25/48 (52%)	105±62 (40-219)	5/48 (10%)	154±62 (84-220)

<sup>1</sup> Latency computed from time of arrival at exposure altitude

Two V-3 subject-trials were excluded from analysis due to technical errors resulting in single cycles of inappropriate work intensity being completed by the subjects. Descriptive characteristics and the time course of symptoms/VGE of the affected subject appear in Tables 12 and 13, respectively.

Table 12. Descriptive Characteristics of Phase V-3 Test Subjects Disqualified from Hypotheses Testing due to Protocol Deviations (mean±SD)

Gender	Age (years)	Weight (kg)	Height (m)	BMI <sup>1</sup> (kg·m <sup>-2</sup> )	Body Fat <sup>2</sup> (%)	VO <sub>2</sub> peak (mL·kg <sup>-1</sup> ·min <sup>-1</sup> )
M =1	34.4	71.9	1.62	25.6	7.9	62.1
F =1	41.5	59.1	1.62	21.0	18.6	33.3

<sup>1</sup> BMI = body mass index

<sup>2</sup> estimated by the lower of seven-site or three-site skinfold computation


Table 13. VGE Summary of Phase V-3 Test Subjects Disqualified from Hypotheses Testing due to Protocol Deviations (mean±SD)

Any Non-Zero Grade	Any Non-Zero Grade Latency <sup>1</sup>	Max Grade	Max Grade Latency <sup>1</sup>
	(min)		(min)
1/2 (50%)	80	3	132

<sup>1</sup> Latency computed from time of arrival at exposure altitude

Phase V-3 was completed with 48 trials without reaching an accept or reject decision. The accept conditions from binominal confidence limits would have been met with 3 DCS/50 trials, and 5 Grade IV VGE/50 trials, while the reject conditions would have been met with 9 DCS/50 trials and 12 Grade IV VGE/50 trials. The research proposal called for completion of 50 trials followed by a review of the data by the investigator team and DSMB, followed by a decision to either terminate the testing of the protocol and test another protocol or continue testing up to 102 trials. The decision to continue up to 102 trials would be based on the probability of reaching a successful result along with schedule and budget considerations. The observations of 7/48 DCS were not consistent with a probability of greater than 50% of reaching an accept condition by the



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completion of 102 trials. Additional considerations make it not advisable to continue testing of the V-3 protocol. These include:

1. “Low fit” subjects with  $VO_{2\text{ peak}} \leq 35 \text{ mL}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$  (3/4 DCS-75%) were observed to have a statistically significant increased risk of DCS on the V-3 protocol compared to “high fit” subjects with  $VO_{2\text{ peak}} > 35 \text{ mL}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$  (4/44-9.0 %) ( $p < 0.01$  Fishers Exact Test). See Figure 4.

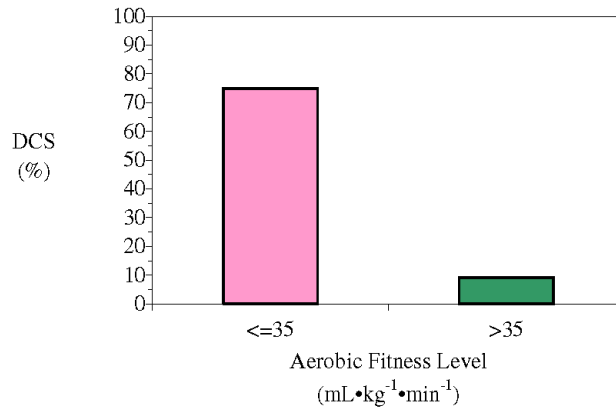



Figure 4. DCS Risk as a Function of Fitness with Fitness-Indexed Prebreathe Exercise Intensities

2. It was recently discovered that the accuracy of the oxygen tank pressure transducer in the Class I (flight) space suit was only accurate to 2.6 psi. A series of tests performed with astronaut subjects in Class 3 (training) space suits, demonstrated that they could control exercise intensity in the suit, using oxygen tank pressure drop targets, to within  $\pm 10\%$  of control tests with the same astronauts using a laboratory ergometer. The in-suit tests incorporated oxygen consumption measurements using a mass spectrometer (Perkins-Elmer 1100A) and software simulator of the Class I space suit oxygen tank that incorporated the advertised specification accuracy of  $\pm 0.5$  psi. The  $\pm 2.6$  psi accuracy of the Class I pressure transducer is not sufficient to accurately control the exercise intensity using short duration exercise targeting  $60\% VO_{2\text{ peak}}$ .

Protocol V-3 was completed without meeting either accept or reject criteria for DCS (mild 7/48 = 14.6%) but was rejected on the basis of Grade IV VGE (5/23 = 21.7%) using the *a priori* accept/reject criteria. Individual DCS case descriptions appear in Appendix I-3.

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**Protocol V-4**

Protocol V-4 moved away from the effort to employ high intensity/short duration intermittent exercise. Instead, it incorporated 150 minutes of intermittent light activity (5.8 ml/kg-min) in a 160 minute prebreathe conducted completely at 14.7 psi. An overview of the protocol appears in Figure 5.

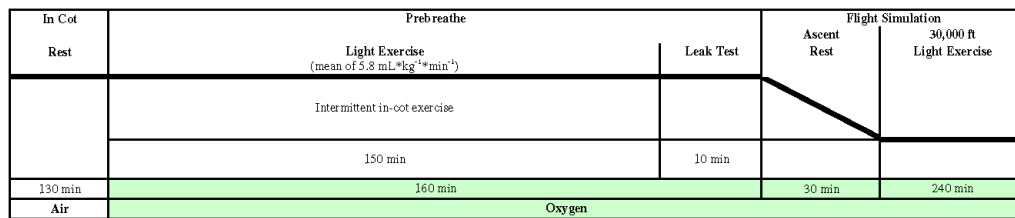


Figure 5. Graphic Timeline of PRP Phase V-4 Protocol

Six subjects participated in the trials conducted at Duke University. Descriptive characteristics appear in Table 14.

Table 14. Descriptive Characteristics of Phase V-3 Test Subjects (mean±SD)

Gender	Age (years)	Weight (kg)	Height (m)	BMI <sup>1</sup> (kg·m <sup>-2</sup> )	Body Fat <sup>2</sup> (%)	VO <sub>2</sub> peak (mL·kg <sup>-1</sup> ·min <sup>-1</sup> )
M =3	29.0±0.0	79.8±18.9	1.82±0.10	23.7±4.1	11.5±5.1	45.2±7.2
F =3	34.0±13.1	63.2±9.3	1.71±0.12	21.6±2.7	19.9±2.4	42.6±3.0
Total = 6	31.5±8.7	71.5±16.1	1.77±0.12	22.7±3.3	15.7±5.8	43.9±5.2


<sup>1</sup> BMI = body mass index

<sup>2</sup> estimated by the lower of seven-site or three-site skinfold computation

Three cases of Type I DCS were observed. Each was resolved with no residual. The case reports are detailed in Appendix I in Phase V-4. Summary descriptions of the patterns of DCS and VGE for subjects completing trials appear in Tables 1 and 15. The case definitions used to define DCS for the purpose of Phase V appear in Appendix II.

Table 15. Summary of DCS and VGE for Subjects Completing Phase V-4 (mean±SD with % or range)

Type I	DCS Latency <sup>1</sup>	Type II	Any Non-Zero Grade	VGE Any Non-Zero Grade Latency <sup>1</sup>	Grade IV	Grade IV Latency <sup>1</sup>
	(min)			(min)		(min)

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3/6 (50%)	156±38 (127-199)	0/6 (0%)	3/6 (50%)	118±49 (64-160)	1/6 (17%)	176
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<sup>1</sup> Latency computed from time of arrival at exposure altitude

No V-4 trials had to be excluded from analysis due to technical errors.

Protocol V-4 was rejected based on DCS (mild 3/6 = 33.3%) but could be accepted based on Grade IV VGE (1/6 = 16.7%) using the *a priori* accept/reject criteria. Individual DCS case descriptions appear in Appendix I-4.

### Protocol V-5

Protocol V-5 included 190 minute protocol (160 minutes oxygen prebreathe with 30 minutes for suit donning at 10.2 psi/0.265 oxygen) with 90 minutes of upper body light exercise (mean 5.8 mL·kg<sup>-1</sup>·min<sup>-1</sup>) using the suit simulator, followed by 50 minutes of light leg ergometer exercise at approximately 6.8 mL·kg<sup>-1</sup>·min<sup>-1</sup> using a leg ergometer mounted on the suit simulator, followed by 50 minutes of rest before depress to 4.3 psia. Breathing gases will be 0.98-1.00 oxygen for the first 60 minutes, then 0.265 oxygen for 30 minutes during an excursion to 10.2 psi for simulated suit donning, then 0.98-1.00 oxygen for the remainder of the exposure. An overview of the protocol is shown in Figure 6.

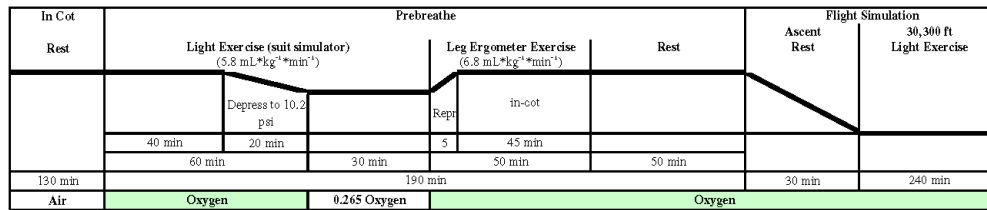


Figure 6. Graphic Timeline of PRP Phase V-5 Protocol


Forty-nine subjects participated in the trials conducted at Duke University. Descriptive characteristics for the 47 completing the trials appear in Table 16.

Table 16. Descriptive Characteristics of Phase V-5 Test Subjects Completing Trials (mean±SD)

Gender	Age (years)	Weight (kg)	Height (m)	BMI <sup>1</sup> (kg·m <sup>-2</sup> )	Body Fat <sup>2</sup> (%)	VO <sub>2</sub> peak (mL·kg <sup>-1</sup> ·min <sup>-1</sup> )
M =36	34±9	81.6±11.2	1.79±0.07	25.3±2.6	13.7±4.7	44.7±7.3
F =11	26±9	60.6±8.4	1.68±0.08	21.5±2.0	20.7±3.8	38.8±7.6
Total = 47	32±10	76.7±13.8	1.77±0.09	24.4±2.9	15.3±5.4	43.3±7.7

<sup>1</sup> BMI = body mass index

<sup>2</sup> estimated by the lower of seven-site or three-site skinfold computation

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Two cases of Type I DCS were observed. Each was resolved with no residual. Summary descriptions of the patterns of DCS and venous gas emboli (VGE) for subjects completing trials appear in Tables 1 and 17.

Table 17. Summary of DCS and VGE for Subjects Completing Phase V-5 (mean±SD with % or range)

Type I	DCS Latency <sup>1</sup> (min)	Type II	Any Non-Zero Grade (29%)	VGE <sup>2</sup> Any Non-Zero Grade Latency <sup>1</sup> (min) 111±56 (24-204)	Grade IV (17%)	Grade IV Latency <sup>1</sup> (min) 121±46 (56-197)
2/47 (4.2%)	76±25 (58-93)	0/47 (0%)	14/48 (29%)	111±56 (24-204)	8/48 (17%)	121±46 (56-197)

<sup>1</sup> Latency computed from time of arrival at exposure altitude

<sup>2</sup> One subject was removed from the study prematurely in accordance with the a priori protocols due to the presence of LVGE. This subject was excluded from computation of the DCS incidence since the exposure was stopped prematurely. Since the subject had Grade IV VGE, however, the case was used to compute the VGE incidence.

One V-5 subject was excluded from the analysis of DCS since the trial was ended after 96 min at altitude due to the presence of LVGE (asymptomatic). Descriptive characteristics and the time course of VGE of the affected subject appear in Tables 18 and 19, respectively.

Table 18. Descriptive Characteristics of Phase V-5 Test Subject Disqualified from DCS Hypotheses Testing due to Early Removal for Asymptomatic LVGE (mean±SD)

Gender	Age (years)	Weight (kg)	Height (m)	BMI <sup>1</sup> (kg·m <sup>-2</sup> )	Body Fat <sup>2</sup> (%)	VO <sub>2</sub> peak (mL·kg <sup>-1</sup> ·min <sup>-1</sup> )
M =1	40	84.0	1.75	27.4	20.0	45.1


<sup>1</sup> BMI = body mass index

<sup>2</sup> estimated by the lower of seven-site or three-site skinfold computation

Table 19. VGE Summary of Phase V-5 Test Subject Disqualified from DCS Hypotheses Testing due to Early Removal for Asymptomatic LVGE (mean±SD)

Any Non-Zero Grade Latency <sup>1</sup> (min)	Max Grade	Max Grade Latency <sup>1</sup> (min)
24	IV	76

<sup>1</sup> Latency computed from time of arrival at exposure altitude

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Phase V-5 reached the conclusion of 47 completed trials in terms of DCS assessment and 48 completed trials in terms of VGE assessment without reaching accept or reject decision points. The accept conditions from binominal confidence limits would have been met with no more than 3 DCS/50 trials, and no more than 5 Grade IV VGE/50 trials. The reject conditions would have been met with 9 DCS/48 trials and 12 Grade IV VGE/50 trials. The protocol could have been accepted on the basis of DCS if no more than one of three more subjects (to complete 50 exposures) developed symptoms. No decision could be made within the 50 exposure limit based on VGE regardless of the outcome of two more exposures.

Protocol V-5 could be accepted based on DCS (mild 2/47 = 4.3%) but could neither be accepted nor rejected on the basis of Grade IV VGE (8/48 = 16.7%) using the *a priori* accept/reject criteria. Individual DCS case descriptions appear in Appendix I-5.

#### Evaluating Protocol V-5


The frequency of DCS and VGE in the PRP trials is summarized in Table 20. DCS was highly variable across protocols. Phase II produced the lowest frequency (0/45 = 0%) and has been transitioned to successful operational use on orbit. Protocol V-5 has the next lowest frequency (2/47 = 4%), a rate not significantly different from Phase II (Fisher Exact p=0.258).

Table 20. PRP DCS and VGE Frequency by Exposure

Protocol	DCS Frequency (%)	VGE Frequency (Any Non-Zero Grade) (%)	VGE Frequency (Grades III and IV) (%)
I	19	49	17
II	0	31	18
III	11 <sup>1</sup>	11	11
IV	14	41	27
V-1	33	56	33
V-2	33 <sup>1</sup>	66	66
V-3	15	52	35
V-4	50	50	17
V-5	4	29	23

<sup>1</sup> Single case of DCS with neurological symptoms

Based on DCS alone, Protocol V-5 could be accepted in accordance with the *a priori* accept/reject criteria established for the PRP research (Figure 7). The situation is more complicated for VGE. The frequency of Grade IV VGE in the Phase II trials met the accept criterion. While the difference in Grade IV VGE between Protocol V-5 and Phase II did not

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reach statistical significance ( $3/45 = 6.7\%$  and  $8/48 = 16.7\%$ , respectively; Fisher Exact = 0.088), the frequency in the Protocol V-5 trials was high enough that it could not be accepted but not so high that it could be rejected (Figure 8).

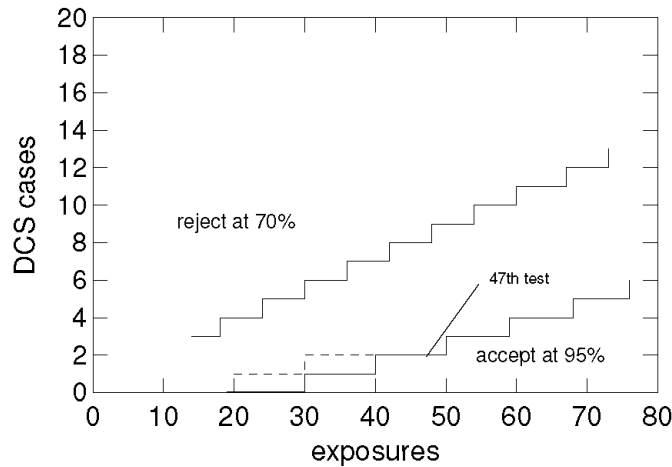


Figure 7. Protocol V-5 yielded 2 cases of DCS in 47 trials (4.3%), thus exceeding the threshold to accept ( $\leq 15\%$  DCS at 95% confidence). (Results determine the risk DCS is  $\leq 15\%$  at 98% confidence and  $\leq 13\%$  at 95% confidence).

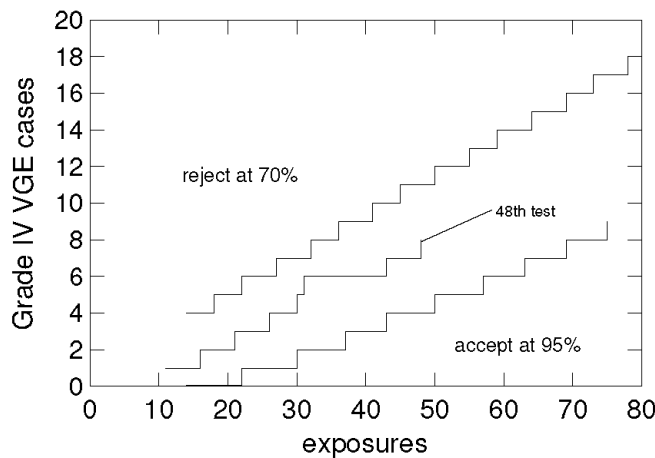



Figure 8. Protocol V-5 yielded 8 cases of Grade IV VGE in 48 trials (16.7%), thus failing to reach either the threshold to accept ( $\leq 20\%$  Grade IV VGE at 95% confidence) or to reject ( $> 20\%$  at 70% confidence). (Results determine that Grade IV VGE is  $\leq 20\%$  at 64% confidence; 21 additional trials with no Grade IV VGE would be needed to reach an accept condition).

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The *a priori* reject criterion for Grade IV VGE was selected as an arbitrary limit. Our database does not include any cases of neurological DCS in the absence of Grade IV VGE. Controlling for Grade IV VGE could practically limit the importance of right-to-left VGE passage through a patent foramen ovale and/or arteriovenous pulmonary shunts.

Post hoc assessment of the VGE distribution across trials indicates that a singular focus on Grade IV VGE may not fully address the implications. Overall, Protocol V-5 had significantly more cases with either Grade III or IV VGE than Phase II ( $11/48 = 22.9\%$  vs.  $4/45 = 8.9\%$ ; Fisher Exact 0.043). However, the case base approach does not address the potential influence of the persistence of VGE within a given exposure. The distribution of all non-zero VGE observations by epoch are shown for Phase II ( $n=99$ ) and Protocol V-5 ( $n=67$ ) in Figures 9 and 10. The total number of epochs with Grade IV VGE observed was not significantly different between Phase II and V-5 ( $26/630 = 4.1\%$  vs.  $23/658 = 3.5\%$ , respectively; Fisher Exact = 0.328). In contrast, the total number of epochs with either Grade III or IV VGE was significantly higher in Phase II than in V-5 ( $67/630 = 10.6\%$  vs.  $45/658 = 6.8\%$ , respectively; Fisher Exact = 0.010). While the absolute risk of DCS cannot be determined by VGE, the relative risk increases in the presence of high VGE grades. The observation of a lower frequency of high VGE grades over the entire duration could indicate that the total decompression stress of Protocol V-5 may be lower than Phase II.



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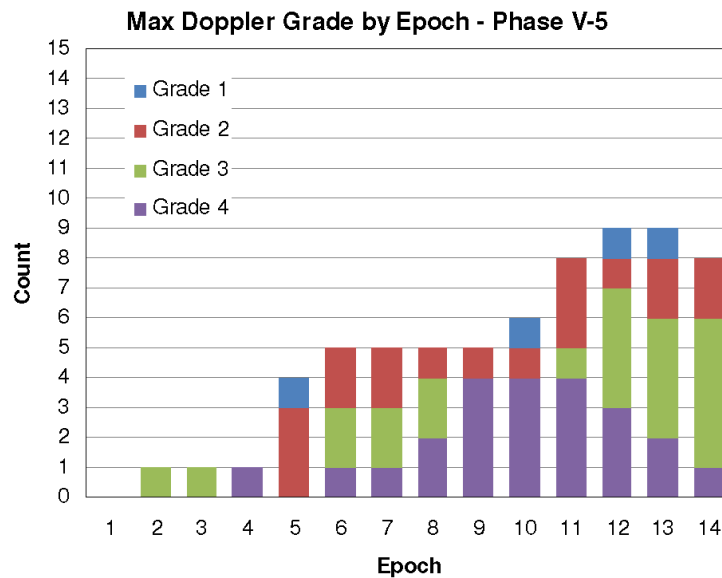
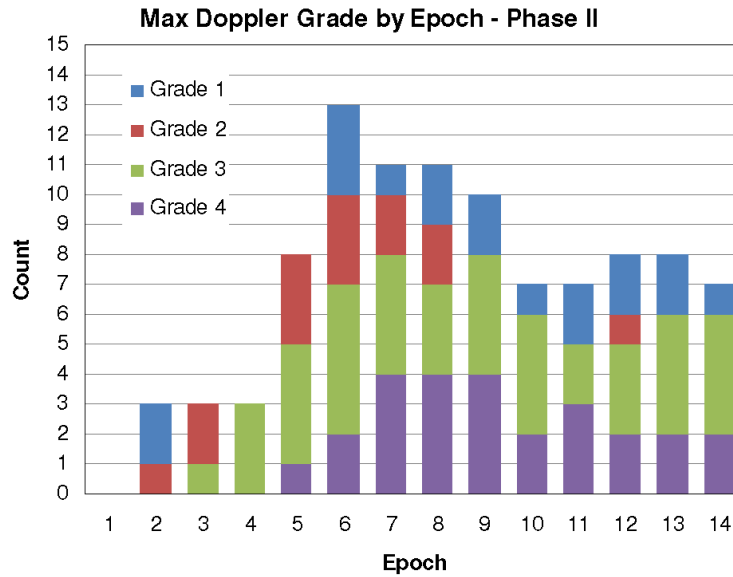
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Figures 9 and 10. VGE Distribution by Epoch and Grade for Phase II and Phase V-5 Protocols




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**Appendix I-1  
Phase V-1 Incident Reviews**

Phase V-1 studies were conducted at Duke University between 11/25/02 and 01/22/03. A total of 10 subjects participated in the trials. Four of the 10 subjects were removed from the chamber while at altitude in response to reports of symptoms.

The research protocol was completed as prescribed for each study. The only notable aberration occurred during the study in which D0014 and D0016 participated. This was our first trial with three large male subjects and all three participants reported inadequate flow through the breathing regulators during the two final 60%  $VO_{2\max}$  exercise periods. None of the subjects chose to stop the procedure. It is not expected that this event affected the results. Two pieces of evidence support this belief: 1) head tent  $PO_2$  was verified at  $>0.98$  during the prebreathe so even if gas was drawn in from around the mouthpiece it would not break the prebreathe; and 2) the third participant who completed the altitude exposure with no symptoms (and Grade 0 VGE throughout), expressed the greatest degree of discomfort with breathing resistance during the prebreathe.


Each subject reporting symptoms was repressed to the surface and treated with two hours of surface oxygen. None have evidence of residual or return of symptoms.

A summary for each case follows. Consult note narratives and clinical assessments were taken from the written record provided by the medical officer managing the case. Doppler scores and additional documentation were compiled from data recorded during the study by the investigator team. Scientific assessments were made by the physician in retrospect following completion of the clinical case and study and review of case specific definitions of DCS. For this investigation, the scientific assessment will be used for the categorization of DCS.

**D0005**

CONSULT NOTE NARRATIVE:

He had successfully completed the prebreathe protocol, and was about 130 minutes into the 30,000 foot exposure when he began to notice a very mild, but steady, right knee pain. This pain was slightly off the midline, on the medial side of the right knee, at the joint line. It is somewhat sharp, but deep. The pain did not subside, but grew slowly, but steadily worse. He has no history of knee pain, or previous knee injury. At 150 minutes into the flight he reported the pain to the tender. This was reported to the study physician, and at 155 minutes the patient was removed from the chamber, per protocol. The pain was reported initially at a 2/10, and increased to a 3/10 just before descent. The patient was noted to have a 4/4 Doppler score while moving his right lower extremity, and a large amount of bubbles were observed in the right heart on 2D echocardiography when the patient moved his lower extremity. The patient was returned to surface. During the surface the pain rapidly improved, and was a 0.5/10 at the surface. After breathing oxygen on the surface for 5 minutes the pain was barely noticeable.

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DOPPLER SCORES:

The subject had maximum Doppler Grade 3 VGE (re-classed as Grade 4 upon review) in the affected limb, Grade 0 in all other limbs throughout.

CLINICAL ASSESSMENT:

Altitude DCS (Type I).

SCIENTIFIC ASSESSMENT:

Mild DCS (Type I).

**D0010**

CONSULT NOTE NARRATIVE:

At 30,000 feet she performed a series of “cot” exercises including the simulated torque wrench task. This task was first performed at 16 min into the flight without difficulty. However, minutes (2-3?) after beginning the second torque wrench session, 48 min after arrival at altitude she developed USAF Grade 1 pain (“intermittent mild to moderate pain, joint awareness or fullness”) in her wrist which lessened (waxed and waned) with the exercise. She did not develop other symptoms and she was observed. Because this pain lasted >30 min she was removed from the exposure as per the NASA protocol. Upon recompression to sea level altitude she reported a gradual disappearance of her pain.

CLINICAL ASSESSMENT:

Because:

- 1) the subject met the criteria for removal from the study.
- 2) the discomfort subsided with recompression
- 3) the pain was not reproduced by “mimic” exercise

we are not able to rule out the possibility of mild (type 1) DCS

DOPPLER SCORES AND ADDITIONAL DOCUMENTATION:

The subject had maximum Doppler Grade 2 VGE in left leg in the final session (1h:15 at altitude); Grade 0 in all other limbs throughout.

Note: While primary symptoms (described in consult note) were reported in the right wrist, the subject did mention after repress that she developed left ankle pain just prior to repress (1.5/10) that disappeared during repress.


SCIENTIFIC ASSESSMENT:

Ambiguous.

**D0014**

CONSULT NOTE NARRATIVE:

At approximately 13:22 or 1h:02 after reaching altitude and after the third exercise period the subject noticed the onset of a sharp right shoulder pain. This waxed and waned between 2 to 4

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out of 10 in severity. It was not worse with movement. The shoulder pain was also accompanied by some transient R wrist and forearm pain. He did not develop other symptoms and he was observed. However, because this pain was constant in nature >5 min (did not resolve completely) he was removed from the exposure as per the NASA protocol. Upon recompression to 18,000 feet altitude he reported a gradual disappearance of his pain and was pain free at sea level.

CLINICAL ASSESSMENT:

Can not rule out altitude DCS. All symptoms have resolved now at sea level.

DOPPLER SCORES AND ADDITIONAL DOCUMENTATION:

The subject had maximum Doppler Grade 3 VGE (re-classed as Grade 2 upon review) in right arm and left leg; right leg was Grade 0 throughout; left arm had maximum score of Grade 1.

Note: While primary symptoms (as described in consult note) were reported in the right shoulder, the subject also described to investigators a dull and localized knee pain (2-3/10) that commenced suddenly at 1h:25 at altitude that also disappeared during repress.

SCIENTIFIC ASSESSMENT:

Mild DCS (Type I).

**D0016**

CONSULT NOTE NARRATIVE:

At 13:40 or 120 min after reaching altitude and after the third exercise period the subject noticed the onset of a sharp left ankle pain. This pain was constant but the severity waxed and waned between 2 to 4 out of 10. It was worse with movement. By 13:45 the pain began to radiate to the left knee and thigh. He did not develop other symptoms and he was observed. However, because this pain was constant in nature >5 min (did not completely resolve) he was removed from the exposure as per the NASA protocol. Upon recompression to sea level he reported a gradual disappearance of his pain and was pain free within 5 min of arriving at sea level.

CLINICAL ASSESSMENT:


Can not rule out altitude DCS. All symptoms have resolved now at sea level.

DOPPLER SCORES:

The subject had maximum Doppler Grade 3 VGE in left leg (re-classed as Grade 4 upon review); Grade 0 in all other limbs throughout.

SCIENTIFIC ASSESSMENT:

Mild DCS (Type I).

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**Appendix I-2  
Phase V-2 Incident Review**

Phase V, Protocol 2 studies were conducted at Duke University on 03/04/03 and 03/27/03. A total of four subjects participated in the trials. One of the four subjects developed serious symptoms while at altitude which resulted in the premature cessation of the second trial.


The research protocol was completed as prescribed for the first study and as prescribed up to the point of cessation in the second study. There were no breaks in adynamia for any of the four subjects.

The case summary follows. Consult note narratives and clinical assessments were taken from the written record provided by the medical officer managing the case. Doppler scores and additional documentation were compiled from data recorded during the study by the investigator team. Scientific assessments were made by the physician in retrospect following completion of the clinical case and study and review of case specific definitions of DCS. For this investigation, the scientific assessment will be used for the categorization of DCS.

**D0022**

CONSULT NOTE NARRATIVE

**HISTORY OF PRESENT ILLNESS:** Subject D0022 is a 43 yo female who was a study participant in a NASA altitude study (NASA prebreathe reduction phase 5, protocol 2). She was in good health and had no reported pre-existing medical problems according to her pre-study medical examination. She is a recreational scuba diver (last dive over 1 month ago) and was well acquainted with the study protocols as well as its potential risks. Today she reported to the Duke HBO center at 7:00 am. After a final briefing she began the study with the required stationary (rest) period at 7:35. She was recumbent, breathing room air until 10:15 when she began to breathe 100% O<sub>2</sub> and started the prescribed exercise protocol. She continued the intermittent exercise until 10:49 and then she rested until she began the altitude ascent at 11:45. She reached the study altitude of 30,000 feet at 12:15. At that time she began the simulated EVA exercises. 100% O<sub>2</sub> was breathed during this entire time. She did well until 14:23 when she developed the gradual onset of nausea without vomiting. Later questioning (after recompression to surface pressure) revealed that she also had developed some mild shortness of breath, throat fullness and cough around this time, but this was not communicated. The covering physician (JF) was called to evaluate her and remarked that at 14:24 she reported nausea, malaise and weakness which progressed to lightheadedness by 14:25. The covering physician was not concerned that the reported degree of nausea was a severe enough symptom to remove her from the study at that time. However, at approximately 14:26 it became known to the covering physician that she had had grade 4 venous gas emboli during the course of the study. At that time the covering physician requested a repeat L sided echo which was transmitted to the outside monitor. No L sided bubbles were observed, however, due to the rapid progression of the symptoms of increasing nausea combined with light headedness and the apparent anxiety and distress of the subject the covering physician elected to evacuate her from the altitude chamber. At 14:33 Delta chamber was depressurized with an attendant to lock out the subject. However, by the time the

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lock was able to be opened (14:40) the subject was in too much distress to be able to stand without assistance. At that point the covering physician began to suspect that the reported symptoms might represent the precursors to pulmonary decompression sickness and it was elected to abort the entire flight (14:41) to allow her to be extracted as soon as possible. By 14:49 the subject had been recompressed to surface pressure and while remaining on 100% O<sub>2</sub> she was removed from the chamber on a stretcher. She was taken to an adjacent room for an abbreviated history and physical exam by the covering physician.

History and physical (14:51 to 15:02).

Upon reaching the surface she reported mild but improving respiratory distress. On exam at that time she was diaphoretic, and flushed, however she did not have tachypnea and O<sub>2</sub> saturation was 100%. Her HR was 60. BP was not immediately taken but she appeared well perfused. She was oriented x 3, CN were grossly normal. She had very soft rales at the bases but these were noted to clear within minutes (see second pulmonary exam in alpha chamber below). There was no S3 or S4 on cardiac exam. Her neurological exam was normal with symmetrical motor strength, normal cognition and normal cranial nerves.


A diagnosis of altitude DCS with pulmonary involvement was made and it was elected to treat her with hyperbaric oxygen. The subject was walked, with escorts on either side, to alpha chamber so that the examining physician could continue to observe both her strength as well as her neurological status as reflected by her gait and balance. Her gait was "cautious" but otherwise normal and although she was able to stand on one foot she was weak. By the time she reached alpha chamber she was able to stand without assistance, however she still complained of feeling weak and tired. In alpha, her lungs were also reexamined to note any interim improvement. No rales were heard on the second chest exam, however the background noise level was high. Although the issue was briefly discussed during the examination period, no chest x-ray or blood study was obtained in the interest of beginning treatment as rapidly as possible and because the patient seemed to be improving at ground level pressure. The examination and transport of the patient to alpha chamber was totally completed at 15:08. A TTE revealed no VGE. The final preparations were made and the chamber was pressurized at 15:09.

By 15:11, she had been compressed to 60 fsw and she reported improvement of her shortness of breath. At 15:30 all symptoms were reported to be gone and she was joking with the chamber attendant in light hearted conversation. A brief neurological exam in the chamber revealed a normal gait, normal Romberg and normal heel to toe walking as observed by me over the video monitor.

The decision was made to complete a full USN Table 6.

Addendum: 3/28/03 10:00 am

After the treatment there were no recurrent symptoms and she felt subjectively much better. Vital signs were normal (BP 114/ 78, HR 70) and her lungs were clear. Subject D0022 was sent to the Duke emergency room for a chest x-ray. The covering physician was called with the report at 21:50. No abnormalities were seen by the reading radiologist and the patient was discharged home.

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The following morning (3/28/03, 9:59 am) the subject was called by the covering physician and reported that she had had no recurrence of her symptoms and the she was in her normal state of health. She was advised to call for any symptoms or questions that might arise.

John J Freiburger, MD, MPH - Physician  
Ward Reed, MD - Inside tender  
Michael Natoli, MS - Standby tender

HEADTENT GAS COMPOSITION

Subjects breathe on a mouthpiece within an oxygen-filled headtent throughout the exercise portion of the prebreathe protocol. This subject's  $F_{iO_2}$  was maintained at  $0.998 \pm 0.002$  (0.995-0.999) through this period. The mouthpiece is then removed and subjects breathe from the headtent for the duration of the trial. Headtent gas was sampled at 30 minute intervals following the completion of prebreathe exercise. The  $FO_2$  was  $0.989 \pm 0.001$  (0.986-0.989; n=3) at ground level and  $0.967 \pm 0.003$  (0.962-0.970; n=5) at altitude for this subject.  $FCO_2$  was  $0.009 \pm 0.004$  (0.004-0.014; n=3) at ground level and  $0.009 \pm 0.004$  (0.004-0.014; n=5) at altitude.

DOPPLER SCORES

The subject developed Grade 1 VGE at rest after seven minutes at altitude (1222). Grade 3 VGE were observed with movement of the left arm after 39 minutes at altitude (1254). Grade 4 VGE were observed with movement of left arm and right leg after 2h:09min at altitude (1424), the final Doppler assessment.

TRANSTHORACIC ECHO IMAGING

No left-sided gas emboli (LVGE) were observed in the subject at any point in the trial. Right-sided VGE (RVGE) were consistently visible upon movement after 41 minutes at altitude (1254) when the first Grade 3 Doppler signal was recorded. RVGE were consistently visible at rest after 1h:15min at altitude (1331).

CLINICAL ASSESSMENT


Altitude DCS (Type II).

SCIENTIFIC ASSESSMENT

Altitude DCS (Type II).

FOLLOW UP EVALUATION

A bubble contrast study was conducted following the completion of the study. No atrial shunting was observed at rest, although some atrial shunting was observed following Valsalva.

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**Appendix I-3  
Phase V-3 Incident Reviews**

Phase V, Protocol 3 studies were conducted at Duke University and DRDC-TO from 05/01/03 through 12/16/03. A total of 50 subjects participated in the trials with six developing symptoms classified as Type I DCS.

The research protocol was completed as prescribed for 45 out of 50 subject cases. Five cases had deviations: three were exercise-related deviations during the prebreathe exercise and two involved pressure deviations outside allowable limits during the EVA exposure. No symptoms attributed to decompression sickness arose during the trials that deviated from the research protocol. There were no breaks in adynamia for any of the subjects.

The case summary follows. Consult note narratives and clinical assessments were taken from the written record provided by the medical officer managing the case. Doppler scores and additional documentation were compiled from data recorded during the study by the investigator team. Scientific assessments were made by the physician in retrospect following completion of the clinical case and study and review of case specific definitions of DCS. For this investigation, the scientific assessment will be used for the categorization of DCS.

**C0015 (06/12/03; DRDC-TO)**

**Consult Note**

PROTOCOL L-382


TESTING OF 1.5 HR IN-SUIT REDUCED PRE-BREATHE PROTOCOL FOR EVA

At 14.50h on the afternoon of 12 Jun 03, experimental Subject C0015 stated that she felt some fullness in her left ankle. Her Doppler scores at the time were all zero. At the time this was not described as pain, so it was decided to monitor her. She had no previous history of left ankle problems. The subject was a healthy young female with no known risk factors for altitude DCS. By 15.00h, the subject stated that the fullness was a discomfort that was 1-2/10 at rest and with movement. It had progressed from an undulating feeling to a discomfort that was constant. At the same time, her Doppler scores suddenly increased to 3 in the left leg and 2+ in the right leg. TTE also indicated bubbles on the right side of her heart.

By 15.15h, the left ankle pain was 1-2/10 at rest, and 3/10 with movement. Doppler scores were also increasing; they were 3+ in the left leg and 3 in the right leg. This met NASA criteria for protocol termination due to Type I altitude DCS pain only; it was decided to terminate the flight. The subject was placed in the air lock and brought back down to ground level. During descent her left ankle pain had completely resolved by the time the lock reached 27,000 ft. She remained asymptomatic at ground level and did not require hyperbaric recompression. She was, however, placed on 100% GLO<sub>2</sub> for 2 hrs. Her Doppler scores returned to zero, and she had no further problems. On follow-up the next morning she remained well.

Final Assessment: Type I altitude DCS pain only, resolved on descent



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**C0011 (06/26/03; DRDC-TO)**

**Consult Note**

EVA run

Subject: Age 45, Ht. 174cm (5'8"), Wt. 66 kg (146 lbs)

Subject C0011 had a completely normal run until she had been at altitude for 96 minutes. She then, at 1406, developed grade 3- bubbles in her right leg. At 1422 she had grade 3 bubbles in her right leg and at 1442 she had grade 4 bubbles in her right leg and grade 3+ bubbles in her chest at rest. This was just after the right arm torque station. She was completely asymptomatic.

At 1454 Subject C0011 reported the development of a 'feeling of fullness' in her right ankle. At 1458 she had KM grade 4 (443) (Spencer Grade 3) bubbles in her right leg and no bubbles in her chest at rest. She had just finished the hand station. She reported that the feeling of fullness in the right ankle was still present, and that she occasionally got a very mild, deep, 'shooting' pain in her leg, like a 'shower of bubbles' (she had no knowledge of her bubble scores). I elected to observe this probable DCS symptom for a few more minutes.

At 1508 Subject C0011 reported that the fullness and occasional pain was still present but less. At 1514 she had grade 4 bubbles in her right leg and grade 3- bubbles in her chest at rest. She had just completed the PS/AS2 station. The pain in her ankle was now constant at 3/10 so the decision was made to lock her out. The 'fullness' and pain were definitely better by 20,000 ft during the descent and completely resolved by 5,000 ft.

Subject C0011 was continued on 100% oxygen on the surface for two hours and encouraged to drink large amounts of fluids. She was examined and found to have absolutely no residual signs or symptoms of the DCS. Incidental note is made of a very mild headache that started yesterday and had continued unchanged during the run.

At approximately 1700, when the post-run questionnaire was being given, Subject C0011 revealed that she had noticed a slight lack of coordination and 'unsteadiness' while she was having pain in her right ankle at altitude. There were no 'objective' signs of these problems noticed by the observers and they apparently resolved during descent. I would not put too much importance on these comments and would certainly not consider them symptoms of neurological DCS. Subject C0011 was quite 'introspective' at this point in time. Surface O2 was discontinued at 1730. She remained completely asymptomatic.


**Diagnosis** – Altitude DCS, mild, type I

**Risk Factors** – Currently having menstrual period

**D0042 (08/25/03; Duke)**

**Consult Note**

REASON FOR CONSULT: Patient is a 47 year old male subject for the NASA study at the Duke Center for Hyperbaric Medicine and Environmental Physiology who is being treated for

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mild symptoms of decompression illness following a 215 minute exposure to a simulated altitude of 30,000 feet.

**HISTORY OF PRESENT ILLNESS:** Patient is an otherwise healthy 47 year old male who was participating in a NASA research protocol to a simulated altitude of 30,000 feet (on head tent oxygen) who experienced onset of left ankle and left knee pain after 215 minutes into the altitude/exercise exposure. Initial onset of a steady ache at the top of the left ankle was noted at 15:30. Symptoms were somewhat variable and improved with exertion. Severity eventually reached 3/10 over the next few minutes. Doppler bubble grades earlier in the exposure were grade 3 at 1 hour of flight followed by grade 1. Repeat Doppler after 220 minutes of altitude exposure (immediately following symptom onset) revealed grade 2 bubbles. Subject's condition following completion of the Doppler study showed no further change in symptomology with continued 3/10 deep dull ache in the left knee ankle and shin. The subject was electively brought out of the chamber at 15:39, reaching the surface at 15:46. Severity of the constant leg/ankle ache during compression decreased to less than 1/10 severity over the left ankle. He remained on surface oxygen while undergoing physical examination.

**REVIEW OF SYSTEMS:**

Constitutional: weight, energy normal  
 Eyes: no visual problems reported  
 ENT: hearing normal, no tinnitus, no sinus disease  
 Cardiovascular: no chest pain, palpitations or DOE  
 Respiratory: no SOB or wheezing, no h/o asthma  
 GI: no N/V/D  
 Musculoskeletal: denies weakness; dull "achy" sensation in left ankle 1/10 intensity  
 Integumentary: intact skin, no rashes  
 Neurological: no acute changes, denies seizures  
 Psychiatric: no anxiety

**PAST MEDICAL HISTORY:** non-contributory

**PAST SURGICAL HISTORY:** none

**MEDICATIONS:** aspirin


**ALLERGIES:** NKDA

**SOCIAL HISTORY:** past tobacco abuse 1-2 ppd X 19 years (quit 14 years ago)

**FAMILY HISTORY:** Non-contributory

**ON EXAMINATION:**

Constitutional: General appearance of patient: WDN male in NAD  
 Eyes: grossly normal bilaterally  
 ENT: hearing grossly nl bilaterally; lips, teeth and gums: nl; pink moist mucous membranes  
 Oropharynx: clear; tongue nl rom; posterior pharynx clear

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Neck: nl ROM  
 Respiratory: nl effort, symmetrical  
 Cardiovascular: rrr; nl pulses; no c/c/e  
 Gastrointestinal: Abdomen soft NT  
 Genitourinary: deferred  
 Musculoskeletal: nl ROM without pain upper and lower extremities bilaterally; 5/5 strength bilaterally UE, LE  
 Skin: warm, dry  
 Neurologic: CN II-XII intact bilaterally; Gait normal, tandem gait, Romberg nl; sharpened Romberg 15 sec (baseline)  
 Sensation intact LT bilaterally  
 Psychiatric: judgment and insight nl  
 Mental status: Alert and oriented X3

LABORATORY / RADIOGRAPHIC STUDIES: grade 2-3 Doppler during altitude exposure

CLINICAL ASSESSMENT: DCS-1 following 215 minutes exposure to 30,000 feet.

PLAN OF TREATMENT: Plan to treat with USN TT-5 with extension or modification pending response to hyperbaric oxygen.

ADDENDUM: The patient was compressed on a USN TT5 at 16:04. He experienced 100% relief of all symptoms at 16:07 upon reaching 60 fsw. He completed the remainder of the treatment without problem or difficulty. He was discharged to home with instructions to contact us for recurrence of symptoms. He was advised to maintain hydration and will call us in the morning.

ADDENDUM 2: The patient reported no further problems or residual during telephone call-in approximately 15 hours following the completion of treatment.


Bryant W. Stolp, M.D., Ph.D.

#### HEADTENT GAS COMPOSITION

Subjects breathe on a mouthpiece within an oxygen-filled headtent throughout the exercise portion of the prebreathe protocol. This subject's  $F_{I}O_2$  was maintained at  $1.000 \pm 0.001$  (1.000-1.004) through this period. The mouthpiece is then removed and subjects breathe from the headtent for the duration of the trial. Headtent gas was sampled at 30 minute intervals following the completion of prebreathe exercise. The  $FO_2$  was  $0.986 \pm 0.002$  (0.984-0.989; n=5) at ground level and  $0.950 \pm 0.006$  (0.940-0.956; n=7) at altitude for this subject.  $FCO_2$  was  $0.006 \pm 0.003$  (0.003-0.010; n=5) at ground level and  $0.017 \pm 0.005$  (0.010-0.024; n=7) at altitude.

#### DOPPLER SCORES

Grade 3 VGE were first observed upon movement of the right arm in Epoch 3. The grade declined to 2 and 1 through Epochs 4 and 5, respectively. The grade decreased to 0 in Epoch 9. Grade 2 VGE were observed following movement of both right and left legs in Epochs 11 and 12. There were no further Doppler assessments.

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TRANSTHORACIC ECHO IMAGING

No left-sided gas emboli (LVGE) were observed in the subject at any point in the trial.

SCIENTIFIC ASSESSMENT

Altitude DCS (Type I).

**C00108** (09/16/03; DRDC-TO)

**Consult Note**

PHYSICIAN'S SUMMARY – EVA PRP V-3TRIAL AT DRDC TORONTO

At 15.27h on the afternoon of 16 Sept 03, three hours into the pre-breathe protocol, 59-yr. old experimental subject C0108 reported 2-3/10 left knee discomfort. The discomfort was constant at rest and with movement, and had been gradually getting worse for 7-8 minutes. At the time, Doppler scores indicated Gr. 4 bubbling in his left leg. He had no previous history of left knee problems, was well hydrated and had no known risk factors for altitude DCS. This met NASA criteria for protocol termination due to Type I pain only altitude DCS, and it was decided to terminate the flight. By the time the airlock had reached altitude and he was transferred into it at 15.40h, his left knee pain had increased to 5/10.

During descent, his knee pain gradually improved. By 27,000 ft it had decreased to 2/10, by 21,000 ft it was 1/10, and as the chamber broke through 18,000 ft, he reported complete resolution of the knee pain. He remained asymptomatic at ground level and did not require hyperbaric recompression. He was, however, treated with GLO<sub>2</sub> for 2hrs and was orally re-hydrated. He had no further problems, and on follow-up the next morning he remained well.

Final Assessment: **Type I altitude DCS pain only**, resolved on descent

Note: Grade 4 bubbling referred to in physician's summary is a Kisman-Masurel Grade 4 and not a Spencer Grade 4.


**C027** (09/30/03; DRDC-TO)

**Consult Note**

PROTOCOL L-382

TESTING OF 1.5 HR IN-SUIT REDUCED PRE-BREATHE PROTOCOL FOR EVA

At 14.14h on the afternoon of 30 Sept 03, just under two hours into the pre-breathe protocol, experimental subject C027 reported a mild sensation in the muscle of her left thigh. She did not describe it as a pain or discomfort, and it was not felt to be related to altitude DCS. Doppler scores at the time in her left leg were noted to be Gr. 3+. By 14.26h, subject noted that the sensation in her thigh had now migrated to her left knee. By 14.33h, the sensation in her knee had definitely become a pain. It was constant, and slightly worse with movement. She was still bubbling Gr. 3+ in her left knee, and now Gr. 4- in her right knee. By 14.39h, she stated the pain was 5/10 and worsening. This met the NASA criteria for protocol termination due to Type I pain

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only altitude DCS, and it was decided to terminate the flight. By the time the airlock reached altitude, and she was transferred into it at 14.43h, the left knee pain had increased to 6/10.

During descent, her knee pain gradually improved. By 27,000 ft it had decreased to 4/10, by 22,000 ft it was 3/10, and as the chamber broke through 16,000 ft, she reported complete resolution of the knee pain. She remained asymptomatic at ground level and did not require recompression therapy. She was, however, treated with 100% oxygen (GLO<sub>2</sub>) for 2hrs. post-flight, as per treatment protocol for altitude DCS that resolves during descent, and was orally re-hydrated. Of note, she was menstruating at the time of the experiment. She had no further problems, and on follow-up the next morning she remained well.

Final Assessment: Type I altitude DCS pain only, resolved on descent

**D0051 (10/09/03; Duke)**

**Consult Note**

Reason for Consult: Evaluation for altitude decompression sickness following NASA research protocol with subject exposure to 30,250 feet simulated altitude.

**HISTORY OF PRESENT ILLNESS:** The patient is a healthy 25 year old male subject for NASA Protocol 3, Trial 15 at the Duke University Center for Hyperbaric Medicine and Environmental Physiology who developed right shoulder pain following a 76 minute exposure at 30,250 feet simulated altitude while breathing 100% oxygen. The patient performed a two hour pre-breathe with 100% oxygen prior to flight, then was taken to 30,250 feet over 30 minutes. After 76 minutes at altitude, while breathing oxygen and performing various mild exercise, he complained of a 4/10 deep steady dull pain in his right shoulder that was present at rest and did not change with arm motion. Doppler bubble detector revealed grade 2 at epoch #3 and grade 3 at epoch #4 immediately prior to onset of symptoms. The shoulder pain decreased in severity to a 3/10 immediately prior to recompression to surface and resolved during the descent. Oxygen therapy was continued during physical examination at 1 ATA.

**REVIEW OF SYSTEMS:** negative except as above

**PAST MEDICAL HISTORY:** non-contributory

**PAST SURGICAL HISTORY:** right hand 10/01, right index finger 6/02, 7/03


**MEDICATIONS:** none

**ALLERGIES:** NKDA

**SOCIAL HISTORY:** single

**FAMILY HISTORY:** Non-contributory

**ON EXAMINATION:**

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120/80, 60  
Height 71 in  
Weight 173 lb

SYSTEMS: (pre- and post-flight physical examination by Dr. Freiberger on chart nl and without change)

CN II-XII grossly intact  
sensation grossly intact bilaterally to LT  
5/5 muscle strength UE/LE flexion/extension  
nl gait  
nl Rhomberg, sharpened Rhomberg  
mini mental status nl

LABORATORY / RADIOGRAPHIC STUDIES:  
Hb 15.2  
FVC 5.89

CLINICAL ASSESSMENT: Mild altitude decompression sickness following 76 minutes exposure to 30,250 feet on oxygen and with mild exercise.

PLAN OF TREATMENT: Subject was electively brought out of the altitude chamber and all symptoms resolved during recompression to 1 ATA while breathing 100% oxygen. Examination at the surface was at baseline and without deficit. We plan to prophylactically treat with USN TT5 and reevaluate following therapy.

Bryant W. Stolp, MD, Ph.D.

HEADTENT GAS COMPOSITION

Subjects breathe on a mouthpiece within an oxygen-filled headtent throughout the exercise portion of the prebreathe protocol. This subject's  $F_{iO_2}$  was maintained at  $0.995 \pm 0.009$  (0.976-1.003) through this period. The mouthpiece is then removed and subjects breathe from the headtent for the duration of the trial. Headtent gas was sampled at 30 minute intervals following the completion of prebreathe exercise. The  $FO_2$  was  $0.990 \pm 0.003$  (0.986-0.993; n=4) at ground level and  $0.976 \pm 0.003$  (0.973-0.979; n=3) at altitude for this subject.  $FCO_2$  was  $0.004 \pm 0.001$  (0.003-0.005; n=4) at ground level and  $0.009 \pm 0.001$  (0.008-0.010; n=3) at altitude.

DOPPLER SCORES


Grade 2 VGE were first observed upon movement of the right arm in Epoch 3. The grade increased to 3 in Epochs 4. There were no further Doppler assessments.

TRANSTHORACIC ECHO IMAGING

No left-sided gas emboli (LVGE) were observed in the subject at any point in the trial.

SCIENTIFIC ASSESSMENT

Altitude DCS (Type I).

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**D0057** (11/06/03; Duke)

**Consult Note**

Reason for Consult: Evaluation and treatment of mild Type-1 DCS during experimental altitude exposure.

**HISTORY OF PRESENT ILLNESS:** Patient is an otherwise healthy 45 year old tri-athlete who was participating in NASA Protocol 3 Trial 19 at 30,000 ft simulated altitude. She underwent an uneventful ascent to simulated altitude of 30,000 ft at 12:05 following a 2 hour oxygen pre-breathe and began an intermittent dynamic and static exercise protocol. At 13:51 she complained of “itchy dry skin” and a “prickly” sensation on both arms and legs of a 4/10 severity. She had no neurological deficit or complaint of pain. At 14:47 she complained of 6/10 tingling in her left forearm during arm exercise that resolved during rest. At 14:57 she complained of 7/10 tingling and pain that decreased but did not resolve during rest. The subject was brought down from altitude after a 2 hours 51 minute exposure. Symptom decreased in severity from 7/10 to 1.5/10 upon reaching the surface. She was examined and taken to Alpha Chamber for treatment of mild Type-1 DCS.

**REVIEW OF SYSTEMS:** non-contributory and documented in pre-flight ROS and Physical

**PAST MEDICAL HISTORY:** Hashimotos Disease

**PAST SURGICAL HISTORY:** Right shoulder surgery

**MEDICATIONS:** synthroid

**ALLERGIES:** NKDA

**SOCIAL HISTORY:** active tri-athlete


**FAMILY HISTORY:** non-contributory

**ON EXAMINATION:** unchanged from pre-flight exam except for subjective altered sensation in an 8 X 3 cm area on the dorsum of the left forearm.

**LABORATORY / RADIOGRAPHIC STUDIES:** none

**CLINICAL ASSESSMENT:** Mild altitude Type 1 DCS manifested as altered forearm sensation/pain following 171 minutes exposure at 30,000 ft on oxygen during mild exercise.

**PLAN OF TREATMENT:** Plan to treat on USN TT-5 or conversion to TT-6 pending response on compression and initial oxygen at 60 fsw.

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ADDENDUM: Subject noted decreased sensation/pain on compression to 60 fsw with complete resolution within 2 minutes of breathing oxygen at 60fsw. She completed the USN TT-5 without problem or complication. Exam on surface non-focal and unchanged from pre-flight physical.

Bryant W. Stolp, M.D., Ph.D.

HEADTENT GAS COMPOSITION

Subjects breathe on a mouthpiece within an oxygen-filled headtent throughout the exercise portion of the prebreathe protocol. This subject's  $F_{I}O_2$  was maintained at  $1.000 \pm 0.002$  (0.997-1.002) through this period. The mouthpiece is then removed and subjects breathe from the headtent for the duration of the trial. Headtent gas was sampled at 30 minute intervals following the completion of prebreathe exercise. The  $FO_2$  was  $0.988 \pm 0.001$  (0.987-0.989; n=4) at ground level and  $0.971 \pm 0.003$  (0.968-0.976; n=6) at altitude for this subject.  $FCO_2$  was  $0.004 \pm 0.001$  (0.002-0.005; n=4) at ground level and  $0.005 \pm 0.002$  (0.004-0.008; n=6) at altitude.

DOPPLER SCORES

No VGE were observed in Epoch 1 through Epoch 9 when Doppler assessment ended.


TRANSTHORACIC ECHO IMAGING

No left-sided gas emboli (LVGE) were observed in the subject at any point in the trial.

SCIENTIFIC ASSESSMENT

Altitude DCS (Type I).



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**Appendix I-4  
Phase V-4 Incident Reviews**

Phase V, Protocol 4 studies were conducted at Duke University from 08/11/04 through 9/08/04. A total of six subjects participated in the trials with three developing symptoms classified as Type I DCS.

The research protocol was completed as prescribed for all subject cases. There were no breaks in adynamia for any of the subjects.

The case summary follows. Consult note narratives and clinical assessments were taken from the written record provided by the Medical Officer managing the case. Doppler scores and additional documentation were compiled from data recorded during the study by the investigator team. Scientific assessments were made by the physician in retrospect following completion of the clinical case and study and review of case specific definitions of DCS. For this investigation, the scientific assessment will be used for the categorization of DCS.

**D0063 (08/17/04)**


Consult Note  
Protocol PRP V-4

**HISTORY OF PRESENT ILLNESS:** The patient is a healthy 29 year old male subject for NASA Prebreathe Reduction Protocol Phase V-4, Trial 1 at the Duke University Center for Hyperbaric Medicine and Environmental Physiology who developed right knee and ankle pain following a 2h:22min exposure at 30,250 feet simulated altitude while breathing 100% oxygen. The patient performed a 160 min pre-breathe with 100% oxygen prior to flight, then was taken to 30,250 feet over 30 minutes. After 2h:22min at altitude, while breathing oxygen and performing various mild exercises, he complained of a 5/10 deep steady dull pain in his right knee and 3/10 ankle pain that was present at rest and did not change with motion. The reported severity of the knee pain was increased to 6/10 and ankle pain to 5/10 two minutes later. The flight was aborted at this time. Upon review, Doppler bubble monitoring revealed a maximum of grade 2 venous gas emboli (VGE) during the exposure. Right-side venous gas emboli (RVGE) were visible with transthoracic echocardiography immediately prior to onset of symptoms. Both knee and ankle pain decreased in severity upon recompression to surface, the knee reaching 0/10 and the ankle 1/10. The knee pain returned to a 2/10 level two minutes into the immediate post-flight period. There were no complaints of motor weakness, shortness of breath or cognitive disturbances reported.

**REVIEW OF SYSTEMS:** negative except as above

**PAST MEDICAL HISTORY:** non-contributory

**PAST SURGICAL HISTORY:** s/p craniotomy for subdural hematoma after MVA 5 years previously

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**MEDICATIONS:** none

**ALLERGIES:** NKDA

**SOCIAL HISTORY:** single

**FAMILY HISTORY:** Non-contributory

**ON EXAMINATION:**

Blood pressure 116/66 mm Hg, heart rate 64 bpm (in recompression chamber during USN Treatment Table 5)

Height 67.5 in

Weight 131 lb

**SYSTEMS:** (pre- and post-flight physical examination by Dr. Freiburger on chart normal and without change)

**CN II-XII** grossly intact

sensation grossly intact bilaterally to LT

5/5 muscle strength UE/LE flexion/extension

nl gait, minimal difficulty with tandem gait. (probably within normal limits and not significantly different from pre-flight exam)

nl Romberg, sharpened Romberg

mini mental status nl (including orientation, serial sevens, memory)

**LABORATORY / RADIOGRAPHIC STUDIES:**

Hb 15.2

FVC 5.89

**CLINICAL ASSESSMENT:** Mild altitude decompression sickness following 2h:22min exposure to 30,250 feet on oxygen and with mild exercise.


**PLAN OF TREATMENT:** Subject was electively brought out of the altitude chamber and symptoms improved during recompression to 1 ATA while breathing 100% oxygen. Examination at the surface was at baseline and without neurological deficit. We plan to treat with USN TT5 and reevaluate following therapy.

**ADDENDUM:** Symptoms were completely resolved upon reaching the TT5 treatment depth. The subject remained symptom free immediately following treatment and at 18 hour follow up.

John J. Freiburger, MD, MPH

**HEADTENT GAS COMPOSITION**

Subjects breathed within an oxygen-filled headtent throughout the prebreathe protocol at ground level. Headtent gas was sampled at 30 minute intervals. This subject's FIO<sub>2</sub> was 0.985±0.002 (0.981-0.987; n=7) and FCO<sub>2</sub> was 0.005±0.001 (0.004-0.006; n=7) through this period. Values

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during the subsequent altitude exposure were FIO<sub>2</sub> of 0.955±0.003 (0.952-0.961; n=5) and FCO<sub>2</sub> of 0.008±0.001 (0.006-0.010; n=5).

#### **DOPPLER SCORES**

Upon review, transient Grade 2 VGE were noted in Epoch 4 and Epoch 8 (the final measure recorded at altitude).

#### **TRANSTHORACIC ECHO IMAGING**

Right-side gas emboli were visible in Epoch 8 (the final monitoring cycle) just prior to symptom development and immediately upon reaching the surface. No left-sided gas emboli (LVGE) were observed in the subject at any point in the trial.

#### **SCIENTIFIC ASSESSMENT**

Altitude DCS (Type I).

#### **D0068 (08/31/04)**

Consult Note

Protocol PRP V-4

#### **HISTORY OF PRESENT ILLNESS:**

The patient is a 28 year old otherwise healthy female experimental subject with non-contributory past medical history who was participating in a NASA simulated altitude exposure experiment to 30,000' and experienced onset of 2/10 left ankle pain following a 3hr19min stay at altitude. She completed a 160 minute 100% oxygen pre-breathe with intermittent exercise prior to ascent and was symptom free at 30,000' until following 3h20min of intermittent exercise when she reported that she had been experiencing a sharp, constant pain in her left foot for the previous minute. The pain slowly progressed to her ankle then lower extremity over the next couple of minutes. The intensity and character did not change at rest or with exercise. The patient symptom report form was reviewed at 3:25 and the decision to bring the subject back to ambient pressure was made. Doppler ultrasound studies performed prior to the onset of symptoms revealed grade 3 bubbles at epoch 10 after 2hr30min hours at altitude with progression to Grade 4 at epoch 12 immediately prior to symptom onset. The subject remained on oxygen and was brought back to ambient pressure 3 hours 30 minutes at altitude. Symptoms resolved completely at 10,000' during descent.

#### **REVIEW OF SYSTEMS:**

Non-contributory and documented in pre-flight ROS and Physical

#### **PAST MEDICAL HISTORY:**


Ruptured ear drum years ago

80 lb weight loss past year (exercise and dietary change)

#### **PAST SURGICAL HISTORY:**

Tonsillectomy 1982

LEEP 2001

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**MEDICATIONS:**

Nordette

**ALLERGIES:**

NKDA

**SOCIAL HISTORY:**

single, physically active

**FAMILY HISTORY:**

Non-contributory

**ON EXAMINATION:**

Examination following descent was entirely normal with the patient back to baseline. Muscle strength, sensation and reflexes were intact and equal bilaterally.

**LABORATORY / RADIOGRAPHIC STUDIES:**

B-Hcg—neg

EKG NRS @ 77; no acute changes

Na 140, K 4.1, Ca 1.21, Hct 41

PFT no obstructive, restrictive disease

**ASSESSMENT:**

Mild altitude Type 1 DCS manifested as left joint pain following 3 hours 19 minutes exposure at 30,000 ft on oxygen during mild intermittent exercise.

**PLAN OF TREATMENT:**

Subject was without complaint and taken to Alpha chamber for prophylactic treatment with USN TT5 following resolution of Type 1 DCS with descent from altitude.

**ADDENDUM:**

Subject tolerated compression without problem or complaint. She remained asymptomatic throughout the remainder of the treatment. She was advised to avoid heavy exercise, maintain hydration and to call me should she experience any recurrence of symptoms. She was given appropriate phone numbers and pager numbers for the medical and experimental staff and discharged to home.

**Bryant W. Stolp MD, PhD**


**Asst. Prof. Anesthesiology**

**Assoc. Cell Biology**

**Additional Technical Information**

HEADTENT GAS COMPOSITION

Subjects breathed within an oxygen-filled headtent throughout the prebreathe protocol at ground level. Headtent gas was sampled at 30 minute intervals. This subject's F<sub>I</sub>O<sub>2</sub> was 0.987±0.002

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(0.985-0.990; n=7) and FCO<sub>2</sub> was 0.005±0.001 (0.003-0.006; n=7) through this period. Values during the subsequent altitude exposure were F<sub>I</sub>O<sub>2</sub> of 0.953±0.008 (0.940-0.964; n=7) and FCO<sub>2</sub> of 0.010±0.003 (0.006-0.014; n=7).

#### DOPPLER SCORES

Grade 3 VGE were noted in Epoch 10 in the RL. This increased to grade 4 VGE in Epoch 11 and remained grade 4 during Epoch 12 (the last Epoch monitored at altitude). Lower grade VGE were detected in all other limbs during the final two Epochs.

#### TRANSTHORACIC ECHO IMAGING

Right-side gas emboli were visible in Epochs 10 and 11 just prior to symptom development. No left-sided gas emboli (LVGE) were observed in the subject at any point in the trial.

#### SCIENTIFIC ASSESSMENT

Altitude DCS (Type I).

#### D0061 (09/15/04)

Consult Note

Protocol PRP V-4

#### **HISTORY OF PRESENT ILLNESS:**

The patient is a 49 year old otherwise healthy female experimental subject with non-contributory past medical history who was participating in a NASA simulated altitude exposure experiment to 30,000' and experienced onset of 4/10 left ankle pain following a 2hr 22min stay at altitude. She completed a 160 minute 100% oxygen pre-breathe with intermittent exercise prior to ascent and was symptom free at 30,000' until following 2h 7min of intermittent exercise when she reported that she had been experiencing a slight (1 on a 0 to 10 scale), intermittent pain on the top inside of her left foot. The pain progressed to the outside of the top of her left foot, increased to a grade 3 intensity, and became constant 12 minutes later. The intensity and character did not change at rest or with exercise. The intensity increased to grade 4 two minutes later and the decision to bring the subject back to ambient pressure was made. Doppler ultrasound studies performed at to the onset of symptoms revealed grade 2 bubbles at epoch 8 after 2hr9min hours at altitude. The subject remained on oxygen and was brought back to ambient pressure after 2 hours 24 minutes at altitude. Symptoms decreased in intensity at 15,000' and resolved completely at 5,500' during descent. Of note, the subject also had minimal brief left great toe pain (grade 2/10) 31 minutes into the exposure which decreased after 9 minutes and became intermittent and was totally resolved 76 minutes into the exposure.

#### **REVIEW OF SYSTEMS:**

Eyes: no visual problems reported


ENT: hearing normal, no tinnitus, no sinus disease

Cardiovascular: no chest pain

Respiratory: no SOB or wheezing

GU: denies incontinence

Musculoskeletal: denies weakness

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Neurological: pain per HPI, otherwise none reported.

**PAST MEDICAL HISTORY:**

**PAST SURGICAL HISTORY:** Basal Cell Carcinoma of face resection

**MEDICATIONS:** Ibuprofen prn, Sudafed prn

**ALLERGIES:** Unknown

**SOCIAL HISTORY:**10-12 drinks per week. No tobacco

**FAMILY HISTORY:**Non-contributory

**ON EXAMINATION:**

Respiration 14

Supine BP 134/80

Pulse Rate 80

Height: 5'10"

Weight 130 lbs

**SYSTEMS:**

Constitutional:

General appearance of patient: 50 yo female appearing much younger than stated age in NAD

Eyes: Normal

Respiratory:

Assessment of respiratory effort: Normal

Auscultation of lungs: CTAB

Gastrointestinal :

Abdomen soft

Lymphatic:

No apparent swelling.

Musculoskeletal:

Exam Ankle Joints: FROM, No swelling, Proprioception intact.

Neurologic:

Cranial nerves II-IV, VI-XII, IX-XII intact. CN V, XIII not examined due to head tent on patient.

DTR: Patellar normal, Brachioradialis normal

Gait, tandem gait, Romberg, modified Romberg: Normal

Strength:                      Right    Left

Bicep/ Tricep                      5/5                      5/5

Wrist extensor/flexor              5/5                      5/5

Hand Intrinsic                      5/5                      5/5


Quads/ Hamstrings              5/5                      5/5

Tibialis Anterior/Gastroc        5/5                      5/5

Extensor Hallucis Longis        5/5                      5/5

Psychiatric:

Patient's judgment and insight: Intact

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Mental status: A&O x 4  
Mood and affect: Normal  
B-Hcg—neg  
PFT no obstructive, restrictive disease

**ASSESSMENT:**

Mild altitude Type 1 DCS manifested as left joint pain following 2 hours 22 minutes exposure at 30,000 ft on oxygen during mild intermittent exercise.

**PLAN OF TREATMENT:**

Subject was without complaint and taken to Alpha chamber for prophylactic treatment with USN TT5 following resolution of Type 1 DCS with descent from altitude.

**ADDENDUM:**

Subject tolerated compression without problem or complaint. She remained asymptomatic throughout the remainder of the treatment. She was advised to avoid heavy exercise, maintain hydration and to call me should she experience any recurrence of symptoms. She was given appropriate phone numbers and pager numbers for the medical and experimental staff and discharged to home.

John Longphre MD  
Duke Hyperbaric Medicine Fellow

**ATTENDING NOTE:**

I have seen and examined this patient and I am in agreement with the assessment and plan outlined above.

John J. Freiburger, MD, MPH

**HEADTENT GAS COMPOSITION**

Subjects breathed within an oxygen-filled headtent throughout the prebreathe protocol at ground level. Headtent gas was sampled at 30 minute intervals. This subject's FIO<sub>2</sub> was 0.987±0.003 (0.981-0.989; n=7) and FCO<sub>2</sub> was 0.003±0.001 (0.002-0.004; n=7) through this period. Values during the subsequent altitude exposure were FIO<sub>2</sub> of 0.965±0.004 (0.958-0.970; n=5) and FCO<sub>2</sub> of 0.014±0.004 (0.010-0.020; n=5).

**DOPPLER SCORES**


Grade 2 VGE were noted in Epoch 8 in the LL. No VGE were detected in any other limbs or at any other times.

**TRANSTHORACIC ECHO IMAGING**

Right-side gas emboli were visible in Epoch 8 just after symptom development. No left-sided gas emboli (LVGE) were observed in the subject at any point in the trial.

**SCIENTIFIC ASSESSMENT**

Altitude DCS (Type I).

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**Appendix I-5  
Phase V-5 Incident Reviews**

Phase V, Protocol 5 studies were conducted at Duke University from 10/13/06 through 3/28/08. A total of 49 subjects participated in the trials with two developing symptoms classified as Type I DCS.

Trials were ended prematurely for two subjects. One male withdrew after experiencing psychological discomfort wearing the headtent at start of the oxygen prebreathe. One male was removed after observation of the presence of left ventricular gas emboli (LVGE). Grade 4 right ventricular gas emboli (RVGE) were present when the LVGE were observed. The subject remained asymptomatic during and after exposure.

There were no breaks in adynamia for any of the subjects.


Case summary information follows. Consult note narratives and clinical assessments were taken from the written record provided by the Medical Officer managing the case. Doppler scores and additional documentation were compiled from data recorded during the study by the investigator team. Scientific assessments were made by the physician in retrospect following completion of the clinical case and study and review of case specific definitions of DCS. For this investigation, the scientific assessment will be used for the categorization of DCS.

**D0100 (05/15/07)**  
Consult Note  
Protocol PRP V-5

**REASON FOR CONSULT:** Female is a 21 year old healthy subject for NASA altitude research project who experienced sudden onset of altitude decompression symptoms in her right knee.

**HISTORY OF PRESENT ILLNESS:** Female is an otherwise healthy research subject who was participating in a NASA research protocol studying decompression in space at 30,000 feet (IRB #0076) who experienced sudden onset of 5/10 right knee pain following a 58 minute exposure at 4.3psi (30,250 feet). Prior to the altitude exposure she underwent an uneventful 160 minute oxygen pre breathe at 1 ATA consisting of light intensity exercise for 110 minutes followed by a 50 minute rest prior to ascent. Doppler bubble studies prior to the onset of pain were rated at grade 4 venous gas emboli. Pain was sharp, constant and circumferentially involved the entire right knee. It was of a character similar to her usual knee pain following a very long and strenuous run. It did not change in intensity or quality with position, palpation or pressure. I was immediately notified of symptom onset, reviewed the events and after communication with the inside tender concerning the patients condition initiated recompression to surface pressure (within 5 minutes of symptom onset). The intensity of pain decreased to 2/10 at 26,000 feet, 1/10 at 20,000 feet and fully resolved at 17,000 feet (three minutes after beginning recompression). The patient was examined after return to ambient pressure and then immediately taken into Bravo chamber for treatment with a USN TT5 (compression begun 26 minutes following onset of pain).



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**REVIEW OF SYSTEMS:** Non-contributory: see NASA Study Medical History form.

**PAST MEDICAL HISTORY:** Non-contributory: see NASA Study Medical History form.

**PAST SURGICAL HISTORY:** Non-contributory: see NASA Study Medical History form.

**MEDICATIONS:** Non-contributory: see NASA Study Medical History form.

**ALLERGIES:** Environmental.

**SOCIAL HISTORY:** Student.

**FAMILY HISTORY:** Non-contributory.

**ON EXAMINATION:** (pre exposure history, physical, labs, PFT, EKG on NASA Study Medical History form).

Physical examination unchanged from pre flight physical history. Muscle strength 5/5 upper and lower extremities, neurological exam grossly normal to LT, vibration throughout. Reflexes 1+ upper extremities bilaterally, 2-3+ right knee, 2+ left knee, 1+ ankle; All joints/extremities with full range of motion and no discomfort.

**ASSESSMENT:** Acute onset Type 1 altitude decompression sickness in an otherwise healthy 21 yo female with full resolution of symptoms upon partial recompression to ambient pressure.


**PLAN OF TREATMENT:** We will prophylactically treat with USN TT5 in order to avoid potential recurrence of pain tonight. We will administer 600 mg ibuprofen upon completion of treatment and follow up with repeat physical examination today and tomorrow.

Pt was treated on 5/15/07 with a USN TT5 immediately after interview and examination following the flight. Compression and decompression were without incident. Physical findings remained unchanged and normal throughout. The patient was given 600 mg ibuprofen following treatment and advised to contact us should she develop any symptoms overnight. She was advised to call in the morning for additional follow up.

Addendum:

5/16/07: Subject called to report she feels normal and is without complaint. No recurrence of symptoms overnight.

Bryant W. Stolp MD, PhD  
Asst. Prof., Anesthesiology

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#### ADDITIONAL TECHNICAL INFORMATION

**HEADTENT GAS COMPOSITION:** Subjects breathed within an oxygen-filled headtent throughout the prebreathe protocol at ground level. Headtent gas was sampled at 30 minute intervals. This subject's  $F_{I}O_2$  was  $0.988 \pm 0.006$  (0.982-0.992; n=6) and  $FCO_2$  was  $0.004 \pm 0.002$  (0.002-0.009; n=6) through this period. Values during the subsequent altitude exposure were  $F_{I}O_2$  of  $0.970 \pm 0.009$  (0.965-0.980; n=3) and  $FCO_2$  of  $0.012 \pm 0.006$  (0.005-0.016; n=3).

**DOPPLER SCORES:** Grade 3 VGE were noted after right leg movement in Epochs 2 and 3 and increased to grade 4 in Epoch 4 (the final measure recorded at altitude).

**TRANSTHORACIC ECHO IMAGING:** RVGE were visible after right leg movement in Epochs 2-4. No LVGE were observed in the subject at any point in the trial.

**SCIENTIFIC ASSESSMENT:** Altitude DCS (Type I).

**D0113 (08/20/07)**

Consult Note  
Protocol PRP V-5


**REASON FOR CONSULT:** Evaluation and Treatment for pain only decompression sickness of the right knee following experimental altitude exposure to 30,000 ft.

**HISTORY OF PRESENT ILLNESS:** The patient is an otherwise healthy 39 year old male who was participating in NASA protocol PVST21 at 30,000 ft simulated altitude in the Duke Hypobaric chamber. The subject participated in a 2.5 hour oxygen pre-breathe prior to ascent to altitude. Ascent to 30,000 ft began at 1220 with arrival at 1250. The subject began a series of intermittent dynamic and static exercise protocols until 1423 when he complained of a 3-6/10 constant, shooting pain in his right knee that quickly extended into his right thigh. On questioning after the flight it was noted by the subject that he experienced a mild non-specific right knee "ache" for 20 minutes prior to noting the frank right knee pain. The decision by the subject to notify inside tenders was made after flexing the knee when the sharp pain became clearly apparent. The Medical Officer was notified at 1424. On questioning, it was noted that the pain did not change in character or intensity with motion. The decision to bring the subject back to surface pressure was made at 1426. The subject left 30,000 ft at 1434 with full resolution of symptoms by 1436 while passing 8000 ft. He reached the surface at 1438, was transferred on oxygen to Bravo chamber. The subject had no complaints and the physical exam at this time was normal and non-focal for any deficits.

**REVIEW OF SYSTEMS:** Non-contributory and documented in pre-flight ROS and physical exam.

**PAST MEDICAL HISTORY:** Restless leg syndrome.

**PAST SURGICAL HISTORY:** None.

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**MEDICATIONS:** Crestor, klonopin.

**ALLERGIES:** NKDA.

**SOCIAL HISTORY:** Moderate weekly exercise.

**FAMILY HISTORY:** Non-contributory.

**ON EXAMINATION:** Non-focal and unchanged from pre-flight.

**LABORATORY / RADIOGRAPHIC STUDIES:** None.

**ASSESSMENT:** Mild altitude Type 1 DCS manifested as right knee pain following exercise protocol during 1.5 hour exposure at 30,000 ft with 2.5 hour oxygen pre-breathe with full resolution of symptoms during return to normobaric condition.

**PLAN OF TREATMENT:** Plan to treat on USN TT5.

**ADDENDUM:** Exam following USN TT5 non-focal and unchanged from pre-flight physical. Pt discharged and to present for follow-up exam in AM.

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Asst. Prof., Anesthesiology


#### **ADDITIONAL TECHNICAL INFORMATION**

**HEADTENT GAS COMPOSITION:** Subjects breathed within an oxygen-filled headtent throughout the prebreathe protocol at ground level. Headtent gas was sampled at 30 minute intervals. This subject's  $F_{I}O_2$  was  $0.986 \pm 0.002$  (0.984-0.988; n=6) and  $FCO_2$  was  $0.004 \pm 0.002$  (0.002-0.006; n=6) through this period. Values during the subsequent altitude exposure were  $F_{I}O_2$  of  $0.963 \pm 0.006$  (0.956-0.973; n=5) and  $FCO_2$  of  $0.008 \pm 0.005$  (0.002-0.016; n=5).

**DOPPLER SCORES:** Grade 2 VGE were noted in Epoch 5 after right leg movement. This increased to grade 4 VGE in Epoch 6 (the last Epoch monitored at altitude). Lower grade VGE were detected after left leg movement in Epoch 5 (grade 1) and after movement of both left arm and left leg in Epoch 6 (grades 1 and 3, respectively).

**TRANSTHORACIC ECHO IMAGING:** RVGE were visible in Epochs 5 and 6. No LVGE were observed in the subject at any point in the trial.

**SCIENTIFIC ASSESSMENT:** Altitude DCS (Type I).

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**Appendix II**  
**Case Specific Definitions of DCS for PRP Phase V**  
 (11/21/02)

**The following case specific definitions of DCS should be applied post hoc.** The sensitive test termination criteria and aggressive treatment philosophy described in the Phase V proposal should be used in real time to terminate the test and treat test subjects with suspected DCS. These case specific definitions of DCS are applicable to the Phase V research program, and have been based on NASA historical data from exposures simulating extravehicular activity. They are not meant to be used as general definitions for altitude DCS under all operational and exposure conditions.

It is recognized that there will be limitations associated with any specific definitions of DCS. The following definitions of DCS should be considered guidelines for the diagnosis of DCS. *The Medical Officer can diagnosis DCS even if the case does not fall within these guidelines.* However, the Medical Officer should provide clear rationale as to why the diagnosis of DCS was made. Once DCS has been diagnosed, the classification of DCS into Type I or Type II should be made by the independent Medical Officer, consistent with the definitions of DCS in the JSC DCS Disposition Policy document (JPG 1800.3)


**OBJECTIVE DEFINITIONS**

In order to be classified as DCS a symptom must meet two of the following three objective criteria. Non-classical or unusual symptoms of DCS, such as headache or malaise, must meet all three objective criteria.

**1. Onset time: DCS should occur greater than 20 minutes and less than 24 hours after reaching altitude.**

*Rationale:* In the JSC historical data, including the PRP studies, only 1 in 103 cases of DCS at JSC occurred <20 min (17 min). In the previous PRP studies Phases I-IV that incorporated microgravity simulation, the earliest report of DCS was 31 minutes

**2. Treatment: DCS symptoms should show improvement within 30 minutes of oxygen breathing at ground level or within 30 minutes of treatment in a hyperbaric chamber provided the treatment was administered within 6 hours.**

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*Rationale:* In the NASA historical database 89/103 cases (86%) of DCS showed improvement during the initial re-pressurization to ground level. In several hundred cases of DCS observed at the Brooks High Altitude Protection Laboratory, approximately 98% showed improvement during repressurization or during the first 30 minutes of oxygen breathing, and approximately 99% of all Type I DCS resolved with 2 hrs of ground level oxygen

**3. VGE: DCS should have a non-zero VGE grade at some time during the hypobaric exposure.**

*Rationale:* In the NASA historical database and Prebreathe Reduction Program (PRP) data (708 exposures / 103 cases of DCS), the negative predictive value of having no VGE (of any grade) was 98.1%. The absence of any VGE is a good diagnostic for not having DCS. Conversely the positive predictive value of VGE is not a useful diagnostic for DCS (positive predictive value of any grade of VGE and grade 4 VGE is 33.4% and 50.3%, respectively). It is recognized that there could be some bias in these data since the tests were not blinded and the Medical Officers could have been using VGE as a diagnostic tool.

**SUBJECTIVE DEFINITIONS**

Subjective evaluations may be useful in establishing the diagnosis.


**4. Differential diagnosis: Signs or symptoms of DCS should not be attributable to exercise, thermal, body position, or preexisting medical conditions as determined from the physical examination and medical histories.**

*Rationale:* Ground based tests of the EVA exercise simulations have provided data on the types of symptoms associated with the exercises. These data will be available to the Medical Officer, along with physical exams and medical histories to help with the differential diagnosis of DCS.

**5. Paresthesia: Symmetrical paresthesias of the upper extremities are not considered DCS.**

*Rationale:* Paresthesia is a soft symptom and can potentially be attributed to thermal, exercise or hyperventilation factors. The probability of having two bubbles at the exact same place on both sides of the spinal cord or brain, or symmetrically at the same local nerves, are very low. There were two cases in the PRP Phases I-IV that involved bilateral paresthesia, one included tingling in both hands (Duke), and another tingling and numbness in both wrists (Hermann). These cases were both aggressively treated as type II DCS. However, they were subsequently determined to be due to hyperventilation and bilateral carpal tunnel syndrome, respectively, and were not diagnosed as Type II DCS.

**6. Musculoskeletal: Intermittent or constant musculoskeletal awareness, 'fullness' or 'stiffness,' 'discomfort,' 'ache' or 'soreness' that does not persist for more than a total of 20 minutes can be decompression stress, but is not DCS.**

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*Rationale:* These minor musculoskeletal symptoms that do not rise to the level of recognizable pain, would not likely be recognized by a suited EVA astronaut, both because of the other more intense local pains generated by the suit itself, and because they would likely resolve before the astronaut repressed in the airlock (space walks typically planned for 6.5 hours, and the majority of DCS symptoms in the NASA historical database occur within four hours.)

**7. Chokes: Pulmonary Decompression Sickness (commonly referred to as “chokes”) must have VGE grade III or higher.**

*Rationale:* Unlike most other symptoms of DCS there is a causal association of VGE and the symptoms of pulmonary DCS. Chokes is normally characterized by a triad of symptoms: non-productive cough, substernal pain and dyspnea. Due to the sensitive test termination criteria used in the Phase V study all three of the symptoms that characterize the chokes might not have time to present. Given the historical data on chokes in USAF research (Balldin and Pilmanis, 2002) and the causal relationship between VGE and chokes, it is reasonable to assume that there must be severe VGE (grade III or IV) in order to elicit pulmonary DCS symptoms.

The above objective and subjective criteria have been integrated into a flow diagram Figure II-1 that should be used for the post hoc diagnosis of DCS.

**Reference**

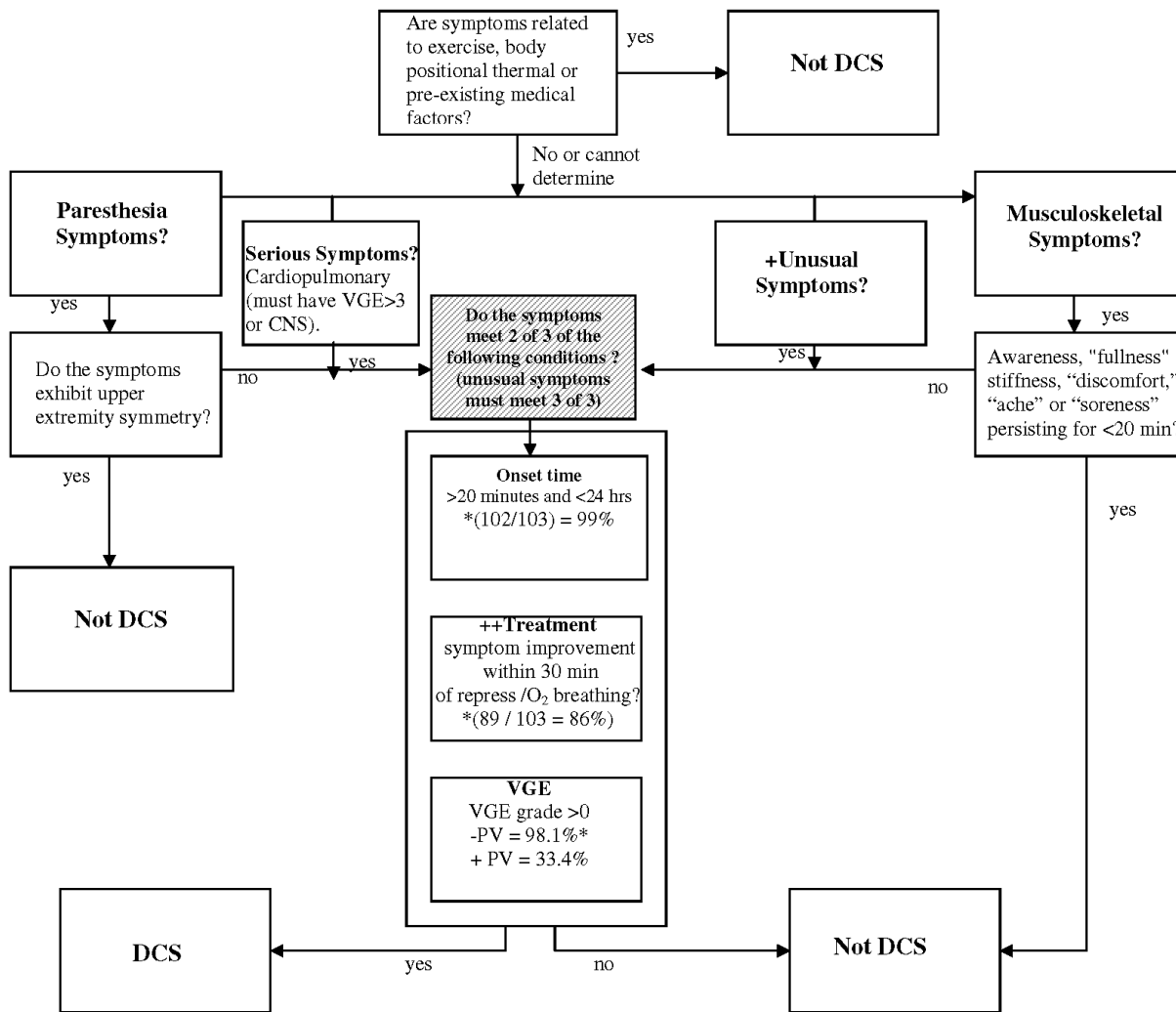
Balldin UI, Pilmanis AA. Pulmonary decompression sickness at altitude: early symptoms and circulating gas emboli. *Aviat Space Environ Med* 2002; 73(10): 996-999.



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**Figure II-1. DCS Diagnosis Flow Diagram**  
 (\*- from NASA historical data)  
 +Non-classical or unusual symptoms of DCS, such as headache or malaise, must meet all three objective criteria".  
 ++-Symptom improvement criterion applies to treatment within 6 hrs of symptom recognition.

**REPORT DOCUMENTATION PAGE**

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<b>14. ABSTRACT</b> The performance of extravehicular activity (EVA) by National Aeronautics and Space Administration astronauts involves the risk of decompression sickness. This risk has been mitigated by the use of oxygen "prebreathe" to effectively wash out tissue nitrogen prior to each EVA. Now that the Space Shuttle Program (SSP) is being retired, high-pressure oxygen will become a limited resource. The In-Suit Light Exercise (ISLE) Prebreathe Protocol offers several potential benefits including its potential to save 6 pounds of oxygen per EVA. At the request of the NASA Engineering and Safety Center, the peer review convened on October 14, 2010. The major recommendation of the Review Committee was that the ISLE protocol was acceptable for operational use as a prebreathe option prior to EVA. The appendices to Volume I of the report are contained in this document.					
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