

Suited Ground Vacuum Chamber Testing Decompression Sickness Tiger Team Report

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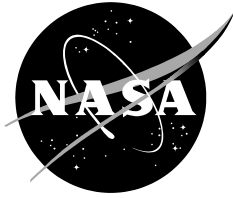
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ACRONYMS & DEFINITIONS

ATA	Atmosphere Absolute
BGI	bubble growth index
BGI360	computed bubble growth index in theoretical 360 minute half-time tissue compartment
CCB	Configuration Control Board
CEVIS	Cycle Ergometer with Vibration Isolation and Stabilization
CM	cutis marmorata
CMO	crew medical officer
CTSD	Crew and Thermal Systems Division
DCS	decompression sickness
EMU	extravehicular mobility unit
EVA	extravehicular activity
HH&P	Human Health and Performance
HH&P EVA-IPT	Human Health & Performance Extravehicular Activity Integrated Product Team
HHPD	Human Health and Performance Directorate
HSRB	Human Systems Risk Board
ISLE	In-suit Light Exercise
ISS	International Space Station
JSC	Johnson Space Center
LBA	lower body adynamia
mmHg	millimeters of Mercury
O ₂	oxygen
PB	prebreathe
P ₁ N ₂	computed tissue nitrogen partial pressure
P(DCS)	probability of decompression sickness
PMC	private medical conference
PO ₂	partial pressure of oxygen
PRP	Prebreathe Reduction Program
psi	pounds per square inch
psia	pounds per square inch absolute
P(serious DCS)	probability of serious decompression sickness
RAC	risk assessment code
SSATA	Space Station Airlock Test Article
SSPCB	Space Station Program Control Board
STS	Space Transportation System
TBDM	Tissue Bubble Dynamics Model
TR	tissue ratio
TR360	computed tissue ratio in theoretical 360 minute half-time tissue compartment
UPTD	unit pulmonary toxicity dose
USAF	United States Air Force
VGE	venous gas emboli

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EXECUTIVE SUMMARY

Suited vacuum chamber testing is critical to flight crew training, sustaining engineering, and development engineering. Most suited vacuum chamber testing at NASA's Johnson Space Center (JSC) involves crewmembers or human test subjects working at a hypobaric pressure of 4.3 psia, which requires that an oxygen prebreathe be performed prior to decompression to reduce the risk of decompression sickness (DCS). Since 1986, NASA's policy has been to require a 4-hour resting prebreathe for hypobaric chamber exposures of 4.2 psia lasting greater than 30 minutes. There have been no reports of Type II (i.e., serious, potentially life-threatening) DCS at NASA while using this prebreathe protocol. Several chamber runs, believed to be approximately 5% of all runs, are believed to have been terminated due to Type I DCS symptoms that were performance impairing; however, detailed records of DCS symptoms during suited vacuum chamber runs are not available. The adequacy of the 4-hour prebreathe protocol, as well as the processes by which prebreathe protocols and policies are established, became the subject of significant discussion in April 2018 when medical planning was initiated for chamber runs that were scheduled to occur later in 2018 that would last 8 hours or more with high metabolic rates.

In response, a "Tiger Team" was initiated by XX, EC5, and SA management on 4/23/18 with the direction to use a cross-discipline approach to assess the DCS risk associated with suited ground vacuum chamber testing at JSC based on existing DCS risk postures and mitigation protocols. The team was then to provide Extravehicular Activity (EVA) Office, Crew and Thermal Systems Division (CTSD), and Human Health & Performance Directorate (HHPD), and International Space Station (ISS) management with formal recommendations on modifications to existing protocols – if any. The goal of the Tiger Team was to provide consensus recommendations and the scope of the Tiger Team's assessment and recommendations was limited to suited vacuum chamber testing at 4.3 – 4.0 psia, with brief excursions to 3.5 psia. The Tiger Team did not evaluate ISS EVA prebreathe protocols for on-orbit operations.

The Tiger Team subsequently presented an out-brief describing their purpose, approach, and consensus observations and recommendations to the EVA Configuration Control Board (6/20/18), Human Systems Risk Board (6/21/18), and Space Station Program Control Board (8/21/18). All three boards accepted the team's consensus observations and recommendations. The Tiger Team's primary recommendations are summarized as follows:

1. Maintain the existing 4-hour prebreathe protocol for runs ≤ 2 hours (68% of all expected runs); add 30 minutes prebreathe for runs > 2 hours. Allow excursions of up to 15 minutes at 3.5 psi during Space Station Airlock Test Article (SSATA) Extravehicular Mobility Unit (EMU) training runs.
2. Require that any future changes to chamber prebreathes be recommended by the Human Health & Performance EVA-Integrated Product Team and approved by Chief Medical Officer (unless full concurrence of stakeholders AND no increase in risk posture).
3. Implement a process for the systematic diagnosis, tracking and analysis of DCS outcomes during suited vacuum chamber testing.
4. Update documentation to incorporate changes to requirements and improved estimates of Type I and Type II DCS risk.

5. Ensure Community Awareness of Type I DCS Likelihood and Consequences through out-brief presentations and publication of a Tiger Team report.

This document provides relevant background information (Section 1.0) before giving a detailed account of the team's approach in Section 2.0. A series of 14 consensus team observations in Section 3.0 precedes the consensus recommendations (Section 4.0) and finally a description of the management review and approval process (Section 5.0). Additional detail is provided in a series of Appendices.

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1.0 INTRODUCTION AND BACKGROUND

1.1 TEAM FORMATION AND PURPOSE

Human test subjects and crewmembers performing suited vacuum chamber ground testing at NASA Johnson Space Center (JSC) undertake an oxygen prebreathe prior to decompression to reduce the risk of decompression sickness (DCS) as prescribed by JPR 8080.4A. In April 2018, the Crew and Thermal Systems Division (CTSD) identified a need to conduct chamber tests lasting 8 hours or longer with high metabolic rates, which prompted questions by the medical officer regarding the adequacy of the 4-hour prebreathe protocol to protect against DCS. Increasing prebreathe durations by up to 80 minutes was proposed based on an initial analysis; however, that recommendation was not adequately vetted, either within Human Health and Performance (HH&P) or with chamber testing stakeholders. Stakeholders expressed concerns that the increased prebreathe introduced other significant operational and risk implications for test subjects who were already required to remain in the pressurized suit for more than 12.5 hours with no food and finite water and waste containment capacity. Additional concerns were expressed regarding JPR 8080.4A, which stated that “For exposures and durations not listed, the Human Health & Performance Extravehicular Activity Integrated Product Team (HH&P EVA-IPT) shall recommend and approve prebreathe requirements,” as there was no process in place to ensure adequate review and vetting of EVA-IPT recommendations.

In response, XX, EC5 and SA management initiated a “Tiger Team” on 4/23/18 with the direction to:

1. Use a cross-discipline approach to assess the DCS risk associated with suited ground vacuum chamber testing at JSC based on existing DCS risk postures and mitigation protocols.
2. Provide XX, EC, SA, and International Space Station (ISS) management with formal recommendations on modifications to existing protocols – if any.

The goal of the Tiger Team was to provide consensus recommendations.

The scope of the Tiger Team’s assessment and recommendations was limited to suited ground vacuum chamber testing at 4.3 – 4.0 psia, with brief excursions to 3.5 psia. ISS EVA prebreathe protocols are considered acceptable by HH&P and were not evaluated by the Tiger Team.

1.2 TEAM MEMBERSHIP

- Andrew Abercromby, Ph.D., Human Physiology, Performance, Protection & Operations / SK (Team Lead)
- Mary Cerimele, Cristina Anchondo, Systems Test Branch / EC4
- Raul Blanco, Space Suit and Crew Survival Systems Branch / EC5
- Chris Counts, Test Safety and Analysis; Institutional Review Board Safety / NA
- Scott Ross, EVA Chief Safety and Mission Assurance Officer / NA
- Stacie Cox, EVA Office / XX
- Shannan Moynihan, M.D., Deputy Chief Medical Officer; Health & Medical Tech Authority / SD

- Joseph Dervay, M.D., Space and Occupational Medicine Branch / Flight Surgeon / SD
- Robert Sanders. M.D., Human Test Support Group / SD
- Mike Gernhardt, Ph.D., EVA-Integrated Product Team / Prebreathe Reduction Program / ER
- Johnny Conkin, Ph.D., EVA Physiology / SK

1.3 NEED FOR SUITED VACUUM CHAMBER TESTING

Suited vacuum chamber testing is critical to flight crew training, sustaining engineering, and development engineering. At the current time, the ISS Program relies upon the training of flight crew in the Space Station Airlock Test Article (SSATA) at a rate of about seven vacuum runs per year. The ISS Extravehicular Mobility Unit (EMU) also requires testing events in the 11-foot chamber for the revalidation of refurbished EMUs prior to delivery for flight at the beginning of their maintenance interval, and for hardware special studies. Both of these types of events are long duration with relatively high workloads, but are infrequently performed. The 11-foot chamber testing is also critical to the completion of development of the Orion Environmental Control and Life Support and suit systems. With the start of the xEMU project, long tests will also be required in both the 11-foot chamber (vacuum) and in chamber B (thermal-vacuum) as to support the certification of the hardware. Shorter tests in the SSATA for airlock interface testing and crew training will also be required with xEMU. Table 1 contains the current best estimate of the required suited vacuum chamber events between now and 2028.

Table 1 – Expected Number and Type of Suited Vacuum Chamber Runs from 2018-2028

Run Location	Suit	Exposure Duration (hr)	Number of Planned Runs	Description
SSATA	ISS EMU	≤2	77	Used for crew training Standing, but low activity level
	xEMU			
11 Foot Chamber	OCSS	≤3	10	Used for development and qualification of the Orion ECLS and suit systems Standing, unknown activity level (ECLS objectives TBD)
	ISS EMU	≤6	4	Used to revalidate refurbished EMUs prior to beginning of 6 year ISS life Defined metabolic profile averaging 1000 BTU/hour via treadmill and arm push bar activities
		6 - 8	17	Used for consumable hardware validation and troubleshooting Defined metabolic profile averaging 1000 BTU/hour via treadmill and arm push bar activities
Chamber B	xEMU	8		

1.4 RISK OF DECOMPRESSION SICKNESS

1.4.1 TYPES OF DECOMPRESSION SICKNESS

DCS is often classified as either Type I or Type II; understanding the difference between these classifications is essential to understanding the risk mitigation approach and associated recommendations provided by the Tiger Team. In simple terms, Type I is often referred to as

“pain-only” and Type II as “serious.” NASA’s medical policy document JPR 1800.3C provides the following more-detailed classifications:

- 1) Mild DCS (Type I): symptoms involving joint pain, peripheral nervous system, or simple skin bends.
- 2) Serious DCS (Type II): symptoms involving the central nervous system, cardiovascular system (circulatory collapse/shock), pulmonary system (chokes).
- 3) Arterial Gas Embolism: evolved gas producing symptoms and signs consistent with passage of the gas to the arterial circulation; i.e., neurological manifestations.
- 4) Cutis Marmorata (CM), a sign of DCS that appears on the skin as a mottled pattern rash.

The JSC Medical Operations Board and the Medical Sciences Division Critical Control Board Aerospace Medical Board concluded that skin marbling should not be classified as Type II DCS. It is now placed in its own category. Skin marbling is classified as Type I DCS in the absence of serious symptoms (Conkin, 2002, see JPD 1800.2B, DCS Disposition Policy).

Importantly, the Tiger Team looked for and found no reports of untreatable Type I altitude DCS symptoms; in all cases, symptoms were fully resolved with no long-term health effects. As such, while symptoms can be painful and there is an ethical responsibility to limit that risk, it was recognized that Type I DCS symptoms do not represent a risk to life or long-term health if treated appropriately.

1.4.2 DECOMPRESSION SICKNESS RISK MITIGATION AT NASA

The risk of DCS can be reduced by oxygen prebreathe. Prebreathe gradually eliminates nitrogen from the body and thereby reduces the likelihood that nitrogen bubbles will expand inside the body during decompression, recognized as the cause of DCS symptoms (Conkin, 2001). A detailed historical description of the development and implementation of prebreathe protocols is available (Conkin, 2011) but is not included in this report. Waligora (Waligora, 2000) provides a chronology of the evolution of prebreathe protocols used by NASA from Gemini until the beginning of the Prebreathe Reduction Program (PRP), which is summarized below:

- Mid-Apollo Program: Change from 4-hour to 3-hour pre-launch prebreathe. Rationale not available.
 - Anecdotal reports of DCS during Gemini 10, Apollo 11
- 1978: United States Air Force (USAF) study (for NASA) finds 42% DCS with 3-hour prebreathe; concerns raised over safety of 3-hour prebreathe.
- 1982: Ground testing finds 36% DCS with 3.5-hour prebreathe; 21% DCS with 4-hour prebreathe; 23% with 10.2 psi staged protocol. 3.5-hour and Staged protocols approved for flight.
- 1983-86: Ground testing finds 10% DCS with 6-hour prebreathe; 0% DCS with 8-hour prebreathe.
- 1986: Post-Challenger center-wide safety review results in change from 3.5- to 4-hour prebreathe.
- 1993-4: Research study finds reduced DCS in simulated microgravity (vs. ambulatory) and with mild exercise during prebreathe.

- 1997+: Initiation of ISS Prebreathe Reduction Program; uses simulated microgravity and mild exercise to develop and validate Cycle Ergometer with Vibration Isolation and Stabilization (CEVIS), In-suit Light Exercise (ISLE) protocols (not applicable to ambulatory ground testing).

A minimum 3-hour in-suit prebreathe was performed before launch in all NASA programs except for the Space Shuttle Program since there was no depressurization on ascent. The on-pad prebreathe protected inactive astronauts from DCS after reaching orbit; during ascent, cabin pressure was reduced from 14.7 to 5.0 psia and atmosphere was simultaneously enriched to 100% O₂. Although this prebreathe was largely effective, an astronaut did write, years after leaving the space program, that he had symptoms consistent with DCS while at 5.0 psia. Michael Collins on Gemini X and later on Apollo 11 believed he had symptoms of pain-only DCS in his left knee that eventually resolved in the 100% O₂ atmosphere as the missions proceeded. This was not an unexpected outcome based on prebreathe validation trials reported by the USAF. The shuttle and now ISS astronauts have a resting 4.0-hour in-suit prebreathe. NASA performed tests of 3.5- and 4.0-hour prebreathes at JSC. The first of several protocols were evaluated with male volunteers in August 1982, and DCS after the first 3.5-hour prebreathe was reported in a subject and a Doppler technician. This was an inauspicious start to the validation of a 3.5-hour prebreathe. A 4.0-hour prebreathe reduced the incidence of DCS from 42% to 21% and the incidence of venous gas emboli (VGE) from 71% to 46% in data normalized to a 6-hour exposure to 4.3 psia in men that ambulated as part of exercise at 4.3 psia.

On April 12, 1981, the Space Transportation System (STS) became a reality. The first EVA from the shuttle was performed on April 7, 1983, using a 3.5-hour in-suit prebreathe. Shortly thereafter, a review of the 4.0-hour prebreathe results plus concerns from the USAF that females may be at higher risk of DCS compelled NASA to baseline the 4.0-hour in-suit prebreathe. Only three, two-person EVAs have been performed from the shuttle after a 3.5- or 4.0-hour in-suit prebreathe since April 1983. The 4.0-hour in-suit prebreathe remains an option on the ISS and to support ground-based testing.

Beginning in 1997, the PRP used Lower Body Adynamia (LBA) to simulate microgravity (see Section 1.4.3) in the development of the CEVIS, Campout, and ISLE prebreathe protocols for the ISS. The protective effect of LBA enabled reduced prebreathe durations for ISS microgravity EVAs but also made the PRP protocols inappropriate for use in ground chamber runs (or future planetary EVAs) that include ambulation.

1.4.3 EFFECT OF EXERCISE ON DECOMPRESSION SICKNESS RISK

The relationship between exercise and DCS risk is complex. Exercise under some conditions can reduce DCS risk by accelerating the elimination of nitrogen from the body, while exercise can also result in the formation of bubble nuclei, which can subsequently grow and result in DCS symptoms (Conkin, 2011).

Standing, walking, and even stepping are such ubiquitous activities in our daily experience that healthy people do not consider these as exercise. In reality, they represent substantial lower body exercise from the standpoint of kinematics. The muscles, joints, and bones in the lower body efficiently transport our body over a long distance without difficulty. It is well documented that

exercise of the lower body increases the risk and severity of Type I pain-only DCS in the feet, ankles, knees, and hips (Conkin & Powell, 2001).

“Spacewalk” during an EVA in low Earth orbit is a misnomer. Astronauts do not walk in the conventional sense but only anchor their legs to a stable structure so that the upper body can affect some task. We characterize the lack of musculoskeletal activity and therefore the lack of dynamic forces in the lower body over several days of adaptation to microgravity and during EVAs as Lower Body Adynamia (LBA). We define LBA as restricted lower-body movement, particularly walking or even a standing posture through contraction of antigravity muscles, during both the denitrogenation phase at site pressure and during the exercise phase while at altitude. In simpler terms, if you do not ambulate (walk) in a gravity field, then you are considered adynamic. LBA is a dichotomous explanatory variable in many of our DCS regressions since about 30% of our tests were conducted (see Table 1 in Appendix G) without ambulation at altitude.

In a recent research study (Conkin et al., 2017), significantly greater DCS incidence (20% vs. 0%) was observed when subjects ambulated before and during the decompression vs. remaining non-ambulatory throughout (Figure 1). Significantly greater Grade IV Venous Gas Emboli (VGE) was also observed among ambulatory subjects; Grade IV VGE represents the highest score assigned to bubbles moving with the blood through the pulmonary artery on the way to the lungs to be filtered (removed) from the venous blood.

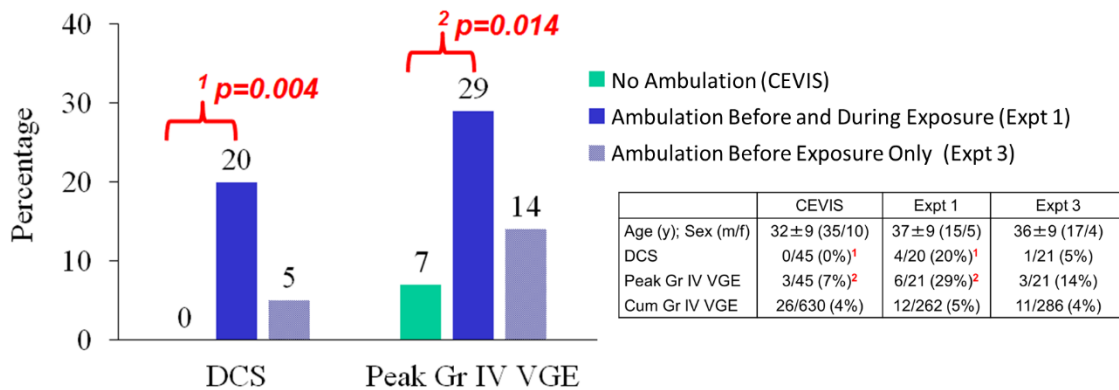


Figure 1 – Effect of ambulation on DCS and Grade IV VGE.

1.4.4 COMPARING RESEARCH DATA WITH OBSERVED INCIDENCE

Astronauts and cosmonauts working in space suits pressurized to between 3.7 and 5.8 psia have not reported DCS during EVAs. In contrast, U.S. and Russian research subjects who evaluate operational prebreathe protocols in altitude chambers report approximately 20% DCS for similar or identical prebreathe protocols. How do we reconcile these disparate observations? Technicians have reported pain-only DCS at JSC during suit development, and at least one astronaut recollected pain in a knee on two occasions after depressurization to 5.0 psia in the spacecraft. So, DCS is possible both in space and in a space suit at 1g.

A research setting designed specifically to monitor for DCS certainly differs from an operational or training setting in which other tasks are the focus of the EVA. Subjects wearing an O₂ mask

who are otherwise comfortable in a shirtsleeve environment at 1g are not the same as astronauts or suit technicians who are surrounded by 100% O₂ and maneuver in restrictive and often uncomfortable space suits. It is reasonable to assume that subjects may have difficulty differentiating between normal discomfort associated with working in a space suit and mild Type I DCS symptoms as compared with test subjects in DCS research studies who perform equivalent physical activity but without wearing a space suit. Importantly, the consequences of reporting potential DCS symptoms differ greatly between DCS research studies and spaceflight EVAs or engineering chamber testing. DCS research studies are conducted specifically to identify DCS symptoms, should they occur, and failure to report symptoms would confound the very purpose of the test. Conversely, suited altitude exposures, whether on the ground or in space, are conducted to complete engineering or mission objectives that may not be accomplished if the suited exposure were to be terminated as a consequence of symptom reporting. Recognizing this, suited subjects can be expected to err on the side of under-reporting potential DCS symptoms if there is any doubt in their mind as to the cause of any discomfort that they are feeling in the suit. The regular prompting for DCS symptoms during DCS research studies is another important difference from suited exposures during which there are currently no routinely scheduled prompts to enquire about DCS symptoms.

A bias to not report mild discomfort in an operational or training setting is routinely observed in pilot training where qualification to fly is compromised if DCS is reported during hypobaric training activities. The U-2 experience provides an example of the difference between operational and research reports of DCS. Seventy-five percent of respondents to a questionnaire said they had DCS symptoms at least once during their careers flying U-2 aircraft, but rarely reported their symptoms to the flight surgeon (Bendrick et al., 1996). NASA's DCS disposition policy (Table 2), established in 2002, protects a subject's ability to resume suited testing (or EVAs) after reporting Type I DCS symptoms as soon as 72 hours after resolution of symptoms. However, prior to establishment of this policy, test subjects could jeopardize their position as a space suit test subject or their flight status as an astronaut in the event that they reported DCS symptoms. Even following implementation of NASA's DCS disposition policy, it is possible that test subjects and astronauts are not fully aware of its existence.

Table 2 – NASA's DCS Disposition Policy (from JPD 1800.3 DCS Manual)

SITUATION	TIME TO DUTY	TIME TO REDUCED PRESSURE EXPOSURE	MEDICAL EVALUATION AND STATUS
Minor DCS (Type I)	24 hours following resolution of symptoms.	Aircraft/Chamber Ops./Immersion Facilities: 72 hours after resolution of symptoms. <u>Space Flight:</u> 72 hours if symptoms resolve upon repress, otherwise 7 days after symptoms resolve.	<u>Aircraft/Chamber Ops./Immersion Facilities:</u> MO/FS evaluation. AMB review not required. <u>Space Flight:</u> CMO evaluation and PMC as soon as practical. AMB review not required.

DCS outcome data from 925 human altitude exposures at a range of prebreathe durations were collected and used during shuttle prebreathe protocol development. In the classification of DCS symptoms, a category referred to as Grade 3 was used, which represented DCS symptoms that actually interfered with task performance. It is notable that, based on this large data set, a 4-hour prebreathe was associated with 23.4% total DCS symptoms, and 4.7% Grade 3 symptoms. This is consistent with the observation of approximately 5% reported Type I DCS among ground chamber test subjects and may suggest that additional cases of Type I DCS may have occurred but were not reported due to difficulty in differentiating between suit-related pain/discomfort and mild Type I DCS symptoms, lack of regular querying for symptoms by medical officers during suited runs, and/or under-reporting due to the real or perceived consequences of terminating a suited test due to reporting DCS.

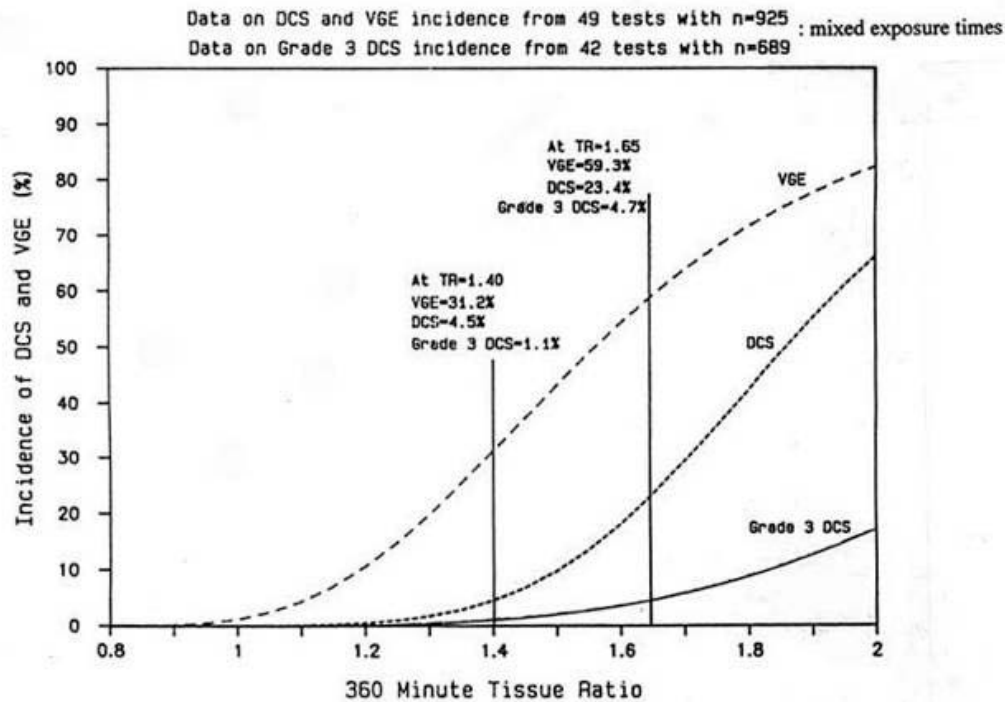


Figure 2 – Space Shuttle prebreathe ground trial DCS data. A 4-hour prebreathe results in a 360-minute tissue ratio of 1.65.

1.5 TREATMENT OF DECOMPRESSION SICKNESS

Once diagnosed, treatment of DCS consists of immediate repressurization to site level, oxygen administration, examination by the medical officer, and transportation via ambulance to the Sonny Carter Training Facility, where the patient is treated in a hyperbaric chamber. In over 90% of altitude DCS cases in the literature, symptoms resolve upon repressurization to site pressure (Conkin et al., 2015, Muehlberger et al., 2004), but may return without intervention. Once diagnosed with DCS, subjects at JSC are still provided hyperbaric treatment regardless of symptom resolution. While ground level oxygen is used in the case of symptom resolution by 10k feet in the military, recurrent or delayed symptoms have been observed in 1.4% of cases following ground level oxygen (Krause & Pilmanis, 2000). A USN treatment table 5 is the gold standard for treatment in these cases or those remaining symptomatic, and is the approach currently used by NASA for DCS treatment.

2.0 APPROACH

The Tiger Team’s formal kickoff meeting was held on 5/2/18, the primary objective of which was to clearly define and agree upon the team’s purpose, scope, schedule, and approach. In support of this objective, prepared briefings were presented to the team on the following topics:

- NASA's Need for Suited Vacuum Chamber Ground Testing – (Blanco, Cerimele)
- NASA's Current DCS Risk Posture for Suited Vacuum Chamber Ground Testing – (Sanders)
- NASA's Approach to Estimating DCS Risk and Developing ISS Prebreathe Protocols – (Gernhardt)

These topics had been identified prior to the kickoff as being important in establishing a foundational level of knowledge and understanding upon which to base the subsequent Tiger Team approach and schedule. A detailed review of the risk-based methodology used to develop ISS EVA prebreathe protocols by the Prebreathe Reduction Program (PRP) was provided, and discussed as an approach that could be adapted for the purposes of the Tiger Team’s effort. The research data associated with the development of non-ambulatory prebreathe protocols for ISS is not directly applicable to the ambulatory ground-based testing that was the focus of this team (see Section 1.4.3). However, based on the success of the PRP methodology (Gernhardt et al., 2013, Conkin, 2011), the team agreed that the prospective definition of acceptable risk criteria and the consideration and quantification (where possible) of operational, engineering, cost, medical, and ethical drivers would facilitate a comprehensive and systematic approach to meeting the Tiger Team’s objectives.

By the conclusion of the kickoff meeting, the team had reached consensus on a proposed work plan and schedule, shown in Table 3 and Figure 3. The work plan and schedule were informally reviewed and approved by HH&P and EVA management the following day. The briefing to the Space Station Program Control Board (SSPCB) was ultimately rescheduled for August 21, 2018, at the request of ISS Program management.

Table 3 – Tiger Team Work Plan

Task	Date
Work Plan Approved by HH&P, EVA Management	May 7, 2018
Programmatic Success Statement Defined	May 11, 2018
Model Options Developed	May 18, 2018
Recommended Deliverable Created	May 25, 2018
EVA Configuration Control Board	June 20, 2018
Human System Risk Board	June 21, 2018
Institutional Review Board	June 21, 2018
Space Station Program Control Board	June 26, 2018

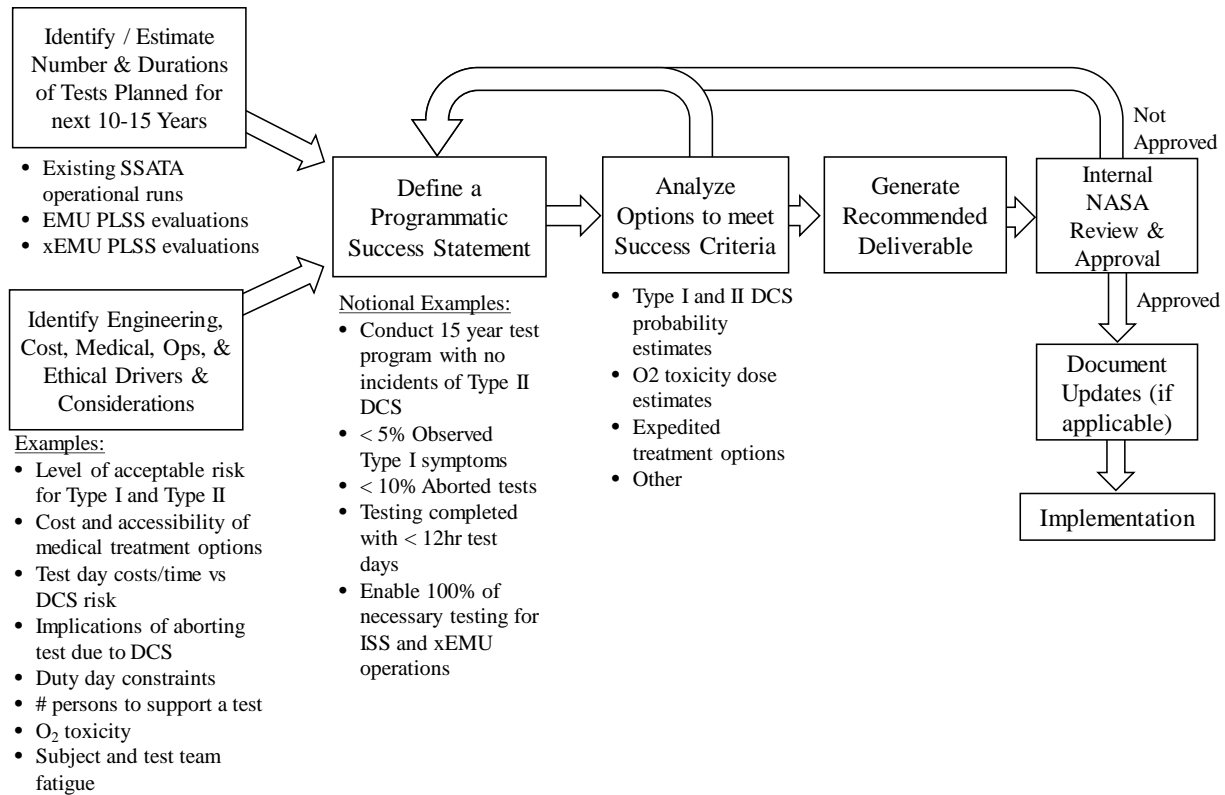


Figure 3 – Methodology flowchart.

2.1 PROGRAMMATIC SUCCESS AND ACCEPTABLE RISK DEFINITION

Having agreed upon a systematic methodology, the team’s focus moved to the discussion and definition of programmatic success and acceptable risk. Before discussing specific acceptable risk levels, the team agreed on a philosophical approach to achieving success and agreed upon the following statements:

- Avoid Type II (serious) DCS. Operate in decompression stress regime in which there have been no reports of Type II DCS.
- Limit Type I DCS risk (and thus risk of aborting chamber runs) to levels that are consistent with accomplishing engineering and training objectives within programmatic cost and schedule constraints.

The team agreed that the potentially life-threatening consequences of Type II DCS mean that – while rapid access to hyperbaric treatment is essential – reliance on successful treatment of Type II DCS to mitigate the risk was not an acceptable approach. Instead, the team agreed to an approach of reducing decompression stress to levels at which there have been no reports of Type II DCS, either at NASA or elsewhere in the literature.

Recognizing that there are no documented cases of Type I altitude DCS in which symptoms have not been successfully treated, and that JSC test subjects and crewmembers will have rapid access to hyperbaric treatment, the team concluded that the primary consequence of Type I DCS symptoms during chamber runs are cost and schedule related if runs are aborted early as a

consequence of Type I DCS. The team therefore agreed that the acceptable level of Type I DCS risk should be defined such that the number of runs that are ended early due to Type I DCS does not exceed that which can be accommodated within programmatic cost and schedule constraints.

Based on the philosophy described above, the following criteria were created and agreed upon as the Acceptable Risk Definition:

1. Zero predicted incidents of Type II DCS at 0.95 probability across all planned suited vacuum chamber runs between 2018-2028.
2. Less than 1/1000 (0.1%) predicted risk of Type II (serious) DCS for any single suited vacuum chamber run.
3. Less than 20% risk of Type I DCS for any single suited vacuum chamber run.

2.2 MODELING APPROACH

As shown in the methodology flowchart (Figure 3), the definition of acceptable risk criteria was followed by analysis of options to meet those criteria. This was accomplished through the process shown in Figure 4.

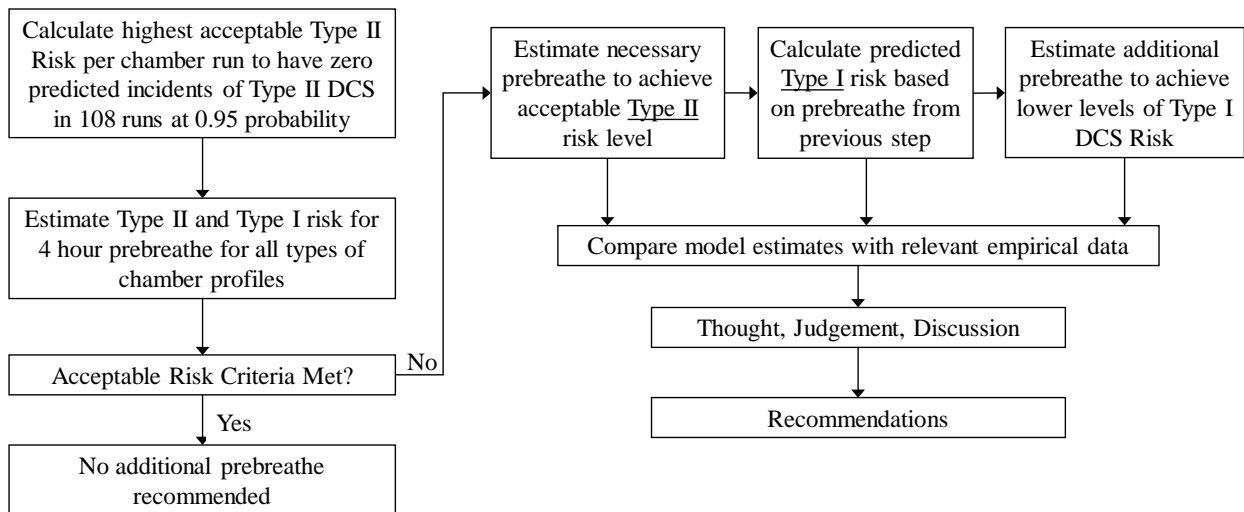


Figure 4 – Modeling approach.

2.2.1 DECOMPRESSION SICKNESS MODELS

Summary of Data-Driven Probability Models:

Statistical descriptions of DCS outcome from hypobaric exposures using logistic regression and survival analysis as well as biophysical modeling of tissue bubble dynamics have made significant advances in the last 20 years. The integration of both approaches has produced sophisticated probabilistic models. Probabilistic modeling requires 4 items: (a) a data set that contains a dichotomous response variable, i.e., the presence or absence of DCS, and 1 or more explanatory variables; (b) an expression of decompression dose in terms of explanatory variables; (c) a function, such as the logistic function, that structures the dose model so the outcome is a probability of DCS [P(DCS)]; and (d) a parameter estimation routine on a computer

that uses maximum likelihood. Simple descriptions of decompression dose such as TR360 (see below) approximate the true dose while models concerning tissue bubble dynamics strive to define true dose through diffusion-based physics and consideration of mass-balance. All approaches, however, are limited since the link between decompression dose and the expression of a symptom is not yet determined, and thus remains probabilistic. One reasonable expectation from modeling is that fewer trials, or even no trials, are performed before accepting a variation of a tested protocol if the model computes an acceptable P(DCS) or P(Serious DCS).

Denitrogenation and Tissue Ratio as Decompression Dose

Fundamental to our understanding of the P(DCS) is to first understand how we calculate a tissue ratio (TR). TR is a simple index of decompression dose, first used at the turn of the century by Haldane, that defines the limit to direct ascent for divers. A decompression dose can also be computed from a biophysical model that addresses bubble growth, such as the maximum size a theoretical bubble achieves, the rate of growth of that bubble, or the summed volume from a collection of bubbles competing for inert gas. TR is the ratio of computed P_1N_2 in a theoretical tissue to ambient pressure. Equation 1 defines P_1N_2 and P_2 is the ambient pressure after depressurization. Prebreathing 100% O_2 or O_2 -enriched mixtures before a hypobaric exposure prevents DCS, so it is necessary to account for the use of O_2 -enriched mixtures as part of the expression for decompression dose. After pN_2 in the breathing mixture changes, such as during a switch from ambient air to a mask supplied with 100% O_2 , the pN_2 that is reached in a designated tissue compartment after a specific time is P_1N_2 :

$$P_1N_2 = P_0 + (P_a - P_0) (1 - e^{-k \times t}), \quad \text{Eq. 1}$$

where P_1N_2 is calculated for the tissue after t min, P_0 is the initial pN_2 in the compartment, P_a is the ambient pN_2 in the breathing mixture, and t is the time at the new P_a in minutes. The TR constant k is equal to $\ln(2) / t_{1/2}$, where $t_{1/2}$ is the half-time for pN_2 in the 360-min compartment.

The particular half-time compartment is a statistical construct that optimizes TR360 to the observed dichotomous DCS or serious DCS outcomes from a collection of trials. A long 360-min half-time is associated with long prebreathe times tested by NASA. The half-time compartment is simply a surrogate linked to the actual process at the tissue level that dictates the true evolved gas condition. Equation 1 describes the simple case in which P_a changes instantaneously, a step-change. This form is sufficient in most applications since donning or removing an O_2 mask changes P_a within a few breaths.

Tissue Bubble Dynamics Model and Bubble Growth Index as Decompression Dose

Whether a bubble grows or dissolves depends on the sum of the flux of all gases in the bubble, each of which diffuses independently. The Tissue Bubble Dynamics Model (TBDM) (Gernhardt 1991) is a biophysical model of bubble growth and resolution in tissue as defined by Eq. 2:

$$\frac{dr}{dt} = \frac{-\frac{\alpha D}{h} \left(P_B - vt + \frac{2\gamma}{r} + \frac{4}{3} \pi r^3 M - P_t - P_{\text{met}} \right) + \frac{rv}{3}}{P_B - vt + \frac{4\gamma}{3r} + \frac{8}{3} \pi r^3 M}, \quad \text{Eq. 2}$$

where r is the bubble radius (cm), t is time (sec), α is Ostwald N_2 solubility ($0.0125 \text{ cm}^3_{\text{gas}}/\text{cm}^3_{\text{tissue}}$ for water at 37°C), D is the diffusion coefficient ($2.0 \times 10^{-8} \text{ cm}^2/\text{sec}$ for water), h is bubble film thickness ($3.0 \times 10^{-4} \text{ cm}$), P_B is initial ambient pressure (dyne/cm²), v is ascent or descent rate (dyne/cm²×t), γ is surface tension (30 dyne/cm), M is tissue modulus of elasticity, the ratio of bulk modulus (H) of $2.5 \times 10^8 \text{ dyne/cm}^2$ to articular cartilage volume ($H/\text{cm}^3_{\text{tissue}} = M$, dyne/cm²×cm³) times bubble volume $\frac{4}{3}\pi r^3$ to compute a deformation pressure (dyne/cm²), P_t is total tissue tension of all inert gases (dyne/cm²) in the general model but is specifically tissue N_2 tension (P_1N_2) in this application, and P_{met} are metabolic gas ($O_2+CO_2+H_2O$) tensions ($1.76 \times 10^5 \text{ dyne/cm}^2$, or 132 mmHg). Eq. 2 is a first-order nonlinear differential equation; however, it has no closed-form solution and must be solved numerically with the aid of a computer. The Bubble Growth Index (BGI) is a unitless index of bubble growth, defined as the ratio of bubble radius at some time t , usually the beginning of a repressurization, to an initial stabilized micronuclei radius of 3 micrometers (μm).

Tissue Bubble Dynamics Logistic Regression Model for Type I DCS

Data for the Eq. 3 regression were from a subset NASA studies (see Appendix) that included exercise at altitude (Abercromby et al., 2015). There were 84 cases of DCS in 668 exposures.

$$P(\text{DCS}) = \frac{\exp(-3.477 + 0.05 \times \text{BGI360})}{[1 + \exp(-3.477 + 0.05 \times \text{BGI360})]} \quad \text{Eq. 3}$$

where BGI360 is the computed BGI in the 360 min half-time tissue compartment from the TBDM.

Cuff 1 Logistic Regression “Threshold” Model

Data for the Cuff 1 logistic regression “Threshold” model (Eq. 4) were a combination of NASA and USAF studies that included exercise at altitude. There were 89 cases of DCS in 914 exposures. The cuff 1 designation is inclusive of the cuff 1, 2, 3, and 4 classifications so should be interpreted as the P(DCS) for any classification of DCS.

$$P(\text{cuff 1}) = \frac{\exp(-1.222 + 3.552 \times \ln(\text{TR360} - 0.78))}{[1 + \exp(-1.222 + 3.552 \times \ln(\text{TR360} - 0.78))]} \quad \text{Eq. 4}$$

The unpublished model was used during the Prebreathe Reduction Program (PRP) in the development of ISS prebreathe protocols. The model does not provide time-dependent estimates of DCS risk, but an effort during PRP found no documented cases of Type II DCS under decompression profiles with a P(cuff 1) of less than 15%. Based on this previous application, the team used and referred to the model as a “Type II Threshold model” rather than a model to estimate P(cuff 1).

Risk Function Regression Model for Serious (Type II) DCS

Time-dependent estimates of Type II DCS risk were made using a previously published Risk

Function regression model (Conkin, 2001). A risk function regression (Eq. 5) was performed on 258 altitude tests that included 79,366 exposures available from the Hypobaric Decompression Sickness Database. There were 918 exposures classified as serious DCS (Type II), about 1.15% of all exposures. These data are from men exposed to hypobaric pressures less than 8 hours. The risk function improves over the logistic regression in that the time at altitude is an explanatory variable. Also, the presence or absence of repetitive exercise and the ability to optimize the half-time compartment are part of this regression. It is not clear that a long 360-minute half-time compartment would be ideal to describe serious DCS, especially if serious DCS results from bubbles moving into critical areas instead of stationary bubbles mechanically distorting tissues.

$$P(\text{Serious DCS}) = 1 - \exp^{-r_c}, \quad \text{Eq. 5}$$

where $r_c = (PN_2180 / P2)^c \times (1 + (\text{EXER} \times d)) \times a \times [(1 / b^2) \times (1 - (b \times t + 1) \times \exp^{-b \times t})]$

where PN_2180 is the calculated N_2 pressure (psia) in the 180-minute half-time compartment just prior to ascent to the final test altitude $P2$ (psia), EXER is the presence (1) or absence (0) of repetitive exercise while at $P2$, and t is time at altitude (hrs). The parameters a , b , c , and d are estimated from the statistical regression using 79,366 exposures. The parameter values are: $a = 0.000613$, $b = 1.794$, $c = 4.267$, and $d = 4.752$.

In the development of the Type II Risk Model, symptoms of Type II DCS were considered to involve the central nervous system, the cardiovascular system (circulatory collapse/shock), and the pulmonary system (the chokes). Symptoms related to unusual presentation of headache and inappropriate fatigue are also included under Type II DCS. Type II DCS symptoms are considered serious DCS. This category includes but is not limited to the following: substernal disturbances (pulmonary chokes); involvement of the sensory, motor, and cognitive pathways of the brain and spinal cord; sudden collapse (neurocirculatory collapse); and even unexplained weakness. Pulmonary chokes make up a substantial percentage of this category. Signs and symptoms of serious DCS not specifically attributed to arterial gas emboli would also appear in this category. Disturbances of the skin, such as rashes, mottling, paresthesia, and edema, which appeared as the only sign or symptom were not considered serious DCS in this analysis because there is no agreement on a classification of skin disturbances into either Type I or Type II DCS.

2.2.2 SPACE STATION AIRLOCK TEST ARTICLE RUN DURATIONS

Cumulative DCS risk increases with exposure duration, and exposure duration is an input parameter in the Type II Risk model and Type I TBDM model. The actual duration of the projected chamber runs listed in Table 1 is unknown, and so the maximum possible duration for each run type was assumed in most cases. However, ISS EMU SSATA runs represent 68% of all expected runs, and the content and duration of these runs is well understood and not expected to change in the future. Analysis of the 27 most recent ISS EMU SSATA runs indicated an average duration of 53 minutes, or 54 minutes excluding an outlier of < 25 minutes (Figure 5). To estimate the cumulative risk, an average duration of 55 minutes was assumed for future ISS EMU SSATA runs. To estimate the *individual risk* per SSATA run (or any other ≤ 2 hr run), the maximum duration of 2 hours was assumed.

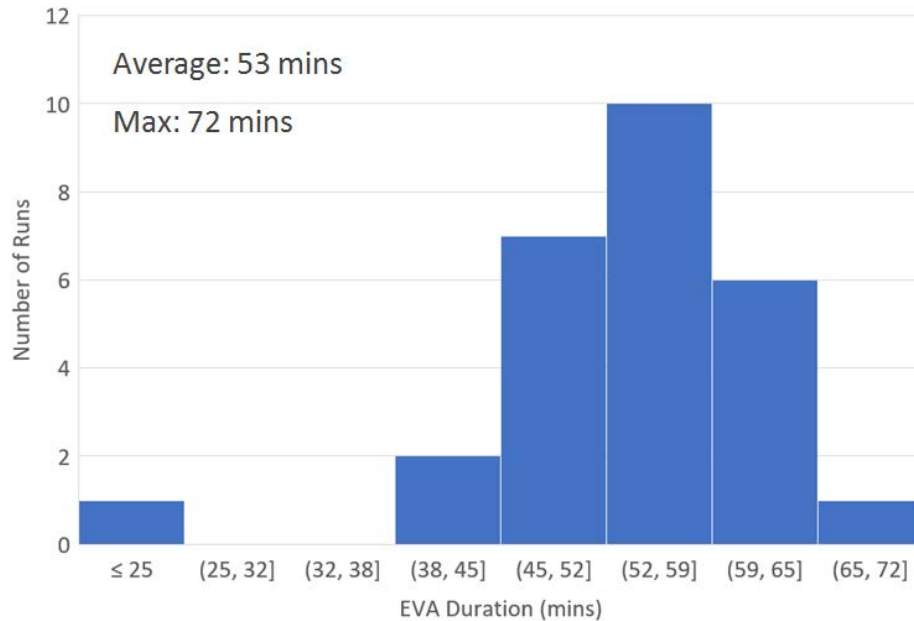


Figure 5 – SSATA run duration data for most recent 27 SSATA runs as of June 2018.

2.2.3 EXCURSIONS TO 3.5 PSIA DURING INTERNATIONAL SPACE STATION EXTRAVEHICULAR MOBILITY UNIT SPACE STATION AIRLOCK TEST ARTICLE RUNS

SSATA runs include purge valve operations that briefly drop suit pressure as low as 3.5 psia. The duration of these excursions to 3.5 psia typically range from 5 to 8 minutes. The purpose of this operational mode is to expose the crewmember to the performance of the EMU’s backup systems and warning messages. The timing of when each suit will reach its programmed response and the total duration at that condition, depends on the idiosyncrasies of each suit’s performance, the metabolic rate of the crewmember, their ability to sense the subjective changes, and their proficiency at stepping through the procedures.

JPR 8080 currently permits “a brief transition of less than 5 minutes from nominal 4.3 – 4.0 psia to 3.5 psia.” Since the typical training session often exceeds that limit by a few minutes, the Tiger Team factored that phase of testing into its overall risk analysis.

For runs < 2 hours, model predictions indicated that extending the transitory 3.5 psia condition to as long as 15 minutes increased the risk of Type I DCS by only 0.8%. Existing models of Type II DCS are unable to estimate the change in risk associated with brief excursions during a longer exposure, but the team’s consensus was that any increase in Type II DCS risk would be very minimal and the overall Type II DCS risk in the short SSATA runs would still be acceptable even with excursions to 3.5 psia of up to 15 minutes. Therefore, the consensus was to update the guiding documents to accept the longer duration without increasing prebreathe duration.

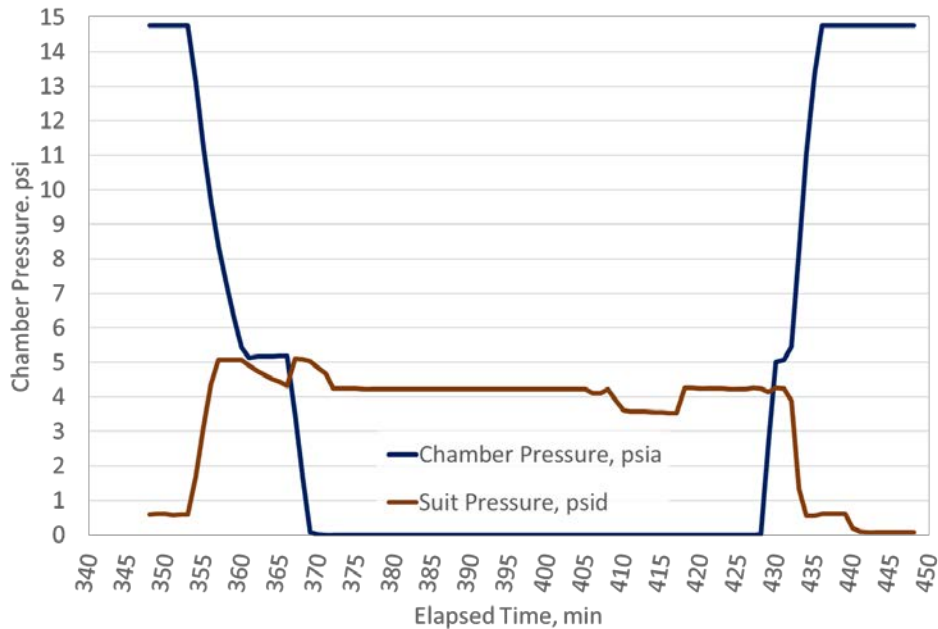


Figure 6 – Example SSATA run pressure profile.

2.2.4 CALCULATING HIGHEST ACCEPTABLE TYPE II RISK

The binomial cumulative distribution function was used to calculate the highest acceptable Type II Risk per chamber run that would result in zero predicted incidents of Type II DCS in 108 runs at 0.95 probability (Table 4). This initial estimate assumed equal risk for all types of planned runs.

Table 4 – Highest Acceptable Type II Risk to Meet Acceptable Cumulative Risk Criteria, Assuming Equal Risk for All Runs

Run Location	Suit	Exposure Duration (hr)	Number of Planned Runs	Risk of Type II DCS		
				Max Allowable		
				PDCS per Run	Risk per Run (1 in x)	Prob. of 0 Cumulative Incidents
SSATA	ISS EMU	55 min	73	0.047%	2110	96.6%
	xEMU	≤ 2	4	0.047%	2110	99.8%
11 Foot Chamber	OCSS	≤3	10	0.047%	2110	99.5%
	ISS EMU	≤6	4	0.047%	2110	99.8%
		6 - 8	17	0.047%	2110	99.2%
xEMU	8					
Chamber B						
Probability of 0 Type II incidents in 108 runs:						95.0%

2.2.5 ESTIMATED TYPE II AND TYPE I RISK FOR 4-HOUR PREBREATHE

DCS risk was estimated based on the existing 4-hour prebreathe. It is important to note that, when using the models to estimate DCS risk, denitrogenation was assumed to begin at the start

of the 12-minute purge and continue until the end of the 20-minute depressurization down to 4.3 psia. The model estimates of risk are shown in Table 5 for each run type as well as the cumulative Type II risk across all 108 projected chamber runs. From Table 5, it can be seen that the existing 4-hour prebreathe meets the maximum acceptable Type II risk for each type of run (i.e., less than 0.1% risk) and the Cuff 1 model estimates that the risk for each type of run is below the threshold for Type II symptoms. However, neither the cumulative Type II risk ($\geq 95\%$ probability) nor the maximum acceptable Type I risk ($< 20\%$) criteria are met.

Table 5 – Estimated Type I and Type II DCS Risk Associated with Current 4-hour Prebreathe

Run Location	Suit	Exposure Duration (hr)	Number of Planned Runs	Prebreathe Time (hr)*	Risk of Type II DCS			Risk of Type I DCS		
					Risk Model			Cuff 1	TBDM All DCS	
					PDCS per Run	Risk per Run (1 in x)	Prob. of 0 Cumulative Incidents	PDCS per Run	PDCS per Run	Risk per Run (1 in x)
SSATA	ISS EMU	55 min	73	4:00	0.043%	2348	96.9%	Below Type II Threshold	5.0%	20
	xEMU	≤ 2	4		0.076%	1316	99.7%		7.9%	13
11 Foot Chamber	OCSS	≤ 3	10		0.084%	1184	99.2%		10.0%	10
		≤ 6	4		0.087%	1150	99.7%		19.2%	5
	ISS EMU	6 - 8	17		0.087%	1149	98.5%		23.8%	4
xEMU	8									
Chamber B										
Probability of 0 Type II incidents in 108 runs:					94.1%					

* Prebreathe durations assume 12 minute purge and 20 minute depress.

** SSATA Runs assume up to 15 mins at 3.5 psi at end of run.

2.2.6 ESTIMATED PREBREATHE TO MEET ACCEPTABLE RISK CRITERIA

When model estimates indicated that the acceptable risk criteria are not met by the existing 4-hour prebreathe, the Type II Risk model was used to estimate the additional prebreathe required to meet the Type II cumulative risk criterion. The predicted Type I DCS risk was then calculated based on the prebreathe durations necessary to meet the Type II cumulative risk criterion. While multiple variations on prebreathe durations were considered, analyzed, and discussed by the team, the preferred combination by consensus decision is shown in Table 6, from which it can be seen that all three of the acceptable risk criteria are met by adding 30 minutes of prebreathe to chamber runs lasting more than 2 hours.

Table 6 – Prebreathe Durations Meeting Acceptable Risk Criteria

Run Location	Suit	Exposure Duration (hr)	Number of Planned Runs	Prebreathe Time (hr)*	Risk of Type II DCS			Risk of Type I DCS		
					Risk Model			Cuff 1	TBDM All DCS	
					PDCS per Run	Risk per Run (1 in x)	Prob. of 0 Cumulative Incidents	PDCS per Run	PDCS per Run	Risk per Run (1 in x)
SSATA	ISS EMU	55 min	73	4:00	0.043%	2348	96.9%	Below Type II Threshold	5.0%	20
	xEMU	≤ 2	4		0.076%	1316	99.7%		7.9%	13
11 Foot Chamber	OCSS	≤ 3	10		0.052%	1938	99.5%		8.8%	11
		≤ 6	4		0.053%	1882	99.8%		16.1%	6
	ISS EMU	6 - 8	17		0.053%	1881	99.1%		19.5%	5
xEMU	8									
Chamber B										
Probability of 0 Type II incidents in 108 runs:					95.1%					

* Prebreathe durations assume 12 minute purge and 20 minute depress.

** SSATA Runs assume up to 15 mins at 3.5 psi at end of run.

2.2.7 ESTIMATED ADDITIONAL PREBREATHE TO ACHIEVE LOWER TYPE I DCS RISK

Although the 19.5% predicted Type I DCS risk meets the acceptable risk criteria for Type I DCS (< 20%), options for further reducing Type I DCS risk during longer chamber runs were evaluated using the TBDM Type I model. Analysis indicated the following:

For runs > 6 hours, compared with the 4:30 prebreathe:

- 15 minutes additional PB (4:45 total) reduces Type I predicted risk by 1.8% (from 19.5% to 17.7%)
- 40 minutes additional prebreathe (5:10 total) reduce Type I predicted risk by 4.5% (from 19.5% to 15.0%)

The results of this analysis were subsequently used to inform the team discussion of whether the benefit of the Type I risk reduction provided by 15 to 40 minutes of additional prebreathe outweighed the negative implications of further extending prebreathe times beyond 4:30 (see Sections 2.3 and 2.4).

It was agreed by all team members that additional prebreathe was not necessary to further reduce Type II risk for longer runs, although this would be an added benefit if it was decided to further increase prebreathe durations beyond 4:30.

2.3 IMPLICATIONS OF HIGHER TYPE I DECOMPRESSION SICKNESS INCIDENCE

The team looked for and found no reports in NASA records or in the literature of untreatable Type I altitude DCS. While Type I DCS symptoms can be painful, and there is an ethical responsibility to limit that risk, it was agreed by the team that Type I risk should be limited to levels that are consistent with accomplishing engineering and training objectives within programmatic cost and schedule constraints (see Section 2.1). Because a chamber run will be immediately terminated if DCS is diagnosed, a 19.5% Type I DCS risk means that approximately 1 out of every 5 such chamber runs could be ended before completion of the test objectives, resulting in cost and schedule impacts. However, it was also recognized and agreed by the team that additional prebreathe for Type I DCS risk reduction must be balanced against other risks to the subject and the program that are introduced by the longer prebreathe.

2.4 OPERATIONAL AND OTHER IMPACTS OF INCREASED PREBREATHE OPTIONS

Team members from the Systems Test Branch briefed the rest of the team on the considerations, challenges, and constraints associated with different types of suited vacuum chamber runs using the existing 4-hour prebreathe, and then highlighted implications of extending prebreathe durations beyond 4 hours.

The duty day for both the suited crewmember and the test team was analyzed for the worst-case situations of performing EVAs lasting both 6 hours (typical) and 8+ hours, which is anticipated in the planned METOX testing. The duration of the METOX life test is open-ended, because the success criteria comes when the METOX “breaks through,” identifying its maximum useable time. Breakthrough is expected to take 8 hours but may take several minutes longer.

Several factors played into the analysis of the duty day for the test team:

- JSC Safety Handbook 1700.1 limits the shift duration for hazardous operations team members to 12 hours with a minimum of 10 hours time-off between shifts;

- The requirement for some test team members to return to duty at the Neutral Buoyancy Laboratory by 8:00 am with 10 hours of rest beforehand: The test team staff has a finite number of certified individuals available to cover the shifts; and
- There is a roughly 6-hour block in the middle of the run during which the operations dictate that the shifts for the Rescue Technicians and Chamber Operators must overlap.

Factors that were considered in discussions about increasing suited time in the duty day for the crewmember included:

- Test subject fatigue from adding extra hours in a difficult environment;
- Increasing the duration of discomfort before the time at vacuum even started, which could make it more difficult to distinguish between normal aches and pains and DCS Type I symptoms;
- Increased exposure to oxygen at elevated pressures contributing to possible oxygen toxicity risk;
- Using up the METOX capacity prior to the start of the testing regime;
- Limited capacity on the Maximum Absorption Garment;
- Finite drinking water (32 oz) and lack of in-suit nutrition for the test duration.

The study team recognized the importance of preserving margin in the duty day schedule for possible troubleshooting and the uncertainty over the time it will take to meet the success criteria for the hardware. When longer prebreathe times were evaluated – adding up to 70 minutes was considered – it was evident that the shift scheduling constraints could preclude accomplishment of the upcoming METOX test objectives under nominal test conditions, much less leave any margin for troubleshooting unexpected events.

Considering both test subject fatigue, added discomfort, and the limitations on the rest of the test team as a whole, the option of adding 30 minutes to the prebreathe was agreed upon to meet the acceptable risk criteria for Type I and Type II DCS risk. Additional prebreathe to further reduce the Type I risk was decided against. A 30-minute addition to the test duration remains a schedule challenge; however, it does preserve roughly 30 minutes of schedule margin for troubleshooting. The question of increased risk of oxygen toxicity was addressed and was found to be insignificant for any of the options considered (see Appendix D).

Table 7 – Current and Planned Duty Days for Test Subject and Test Team

Type	Previous Time	Previous Duration	Recommended Time	Recommended Duration
Test Subject Duty Day				
Standard 6 hour	7:00a-8:00p	13 hours	7:00a-8:30p	13.5 hrs
METOX 8+ hour	7:00a-10:00+p	15+ hours	6:30a-10:00+p	15.5+ hrs
Test Team Duty Day				
Standard 6 hour	6:00a-9:00p	15 hours	6:00a-9:30p	15.5 hrs
METOX 8+ hour	5:00a-10:00+p	17+ hours	4:30a-10:00+p	17.5+ hrs

2.5 COMPARING MODEL PREDICTIONS WITH EMPIRICAL DATA: TYPE II THRESHOLD

Appendix G contains data excerpts from NASA-funded prebreathe research as well as selected summaries from our NASA DCS Literature Database. The data about serious DCS are detailed enough such that computed decompression stress for current prebreathe options can be compared to computed DCS in publications that reported the incidence of serious DCS (Conkin, 2001), as seen below in Figure 7. It is important to recognize that prebreathe times shown on Figure 7 assume an additional 12 minutes of denitrogenation during the suit purge and 20 minutes during depressurization to operating pressure. Given these assumptions, it can be seen that the recommended prebreathe protocols are in a decompression stress regime in which there have been no documented cases of Type II DCS in 2,188 exposures.

Additionally, cases meeting the following criteria were reviewed from NASA and literature DCS databases:

1. Exercise during any part of the exposure.
2. Time at altitude ≥ 2 hours.
3. Altitude ≥ 3.5 psia and ≤ 6.0 psia.
4. Prebreathe ≥ 3 hours, results in computed $PN_{2360} \leq 8.2$ psia.
5. Serious DCS recorded in the literature report.
6. Adequate detail of prebreathe and ascent conditions available.

No cases of serious DCS were found at decompression stresses equivalent to those being recommended by the team. Detailed results of the literature database search are included as an Appendix.

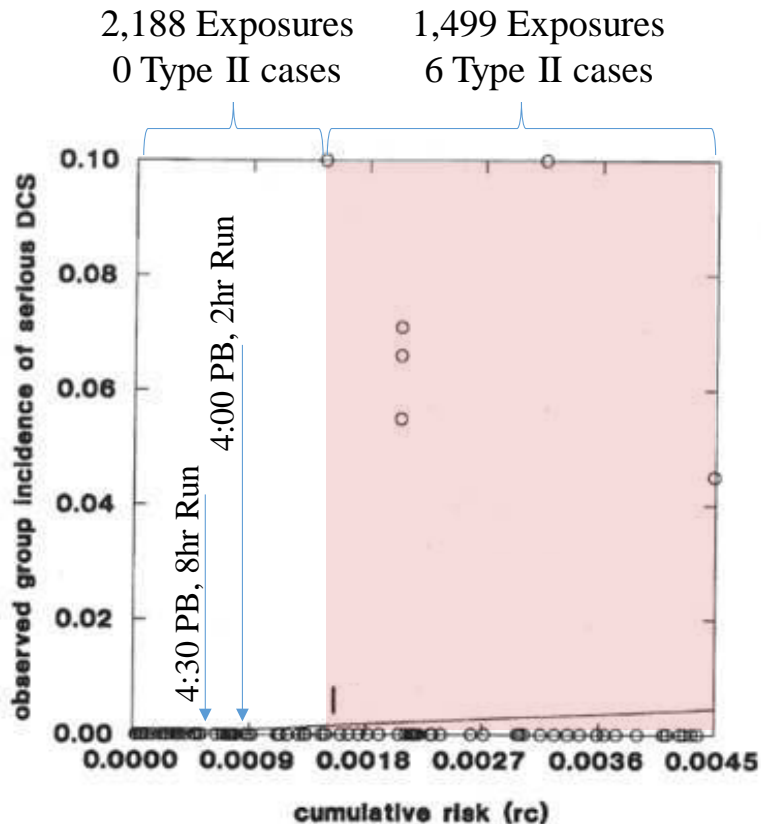


Figure 7 – Comparison of recommended prebreathe risk levels with observed Type II DCS incidence threshold. Purge (12 min) and Depress (20 min) are reason that “4:00 PB” is shown below threshold; total time = 4:32.

3.0 OBSERVATIONS

Having examined all available pertinent information, the team discussed and agreed on each of the following observations:

1. NASA has a record of safe and successful suited vacuum chamber testing; no Type II DCS symptoms have been reported and all reported Type I cases have been successfully treated.
2. 30 years of DCS research has been conducted since NASA’s ground prebreathe protocols were last reviewed.
3. Estimated risk of at least one Type II DCS case is greater than 5% in next 10 years using current 4-hour protocols.
4. Model estimates of Type I DCS risk with current 4-hour prebreathe protocols are up to 23.8% for an 8-hour run.
5. Observation of ~5% Type I DCS that is painful enough to affect performance is consistent with research data showing 23.4% Type I DCS, of which 4.7% interfered with performance.

6. Difference between suited and unsuited DCS incidence may be due to: difficulty in differentiating between suit-related pain/discomfort and mild Type I DCS symptoms; lack of regular querying for symptoms by medical officer during suited runs; and the consequences of terminating a suited test due to reporting DCS.
7. Cumulative risk of DCS increases with increased exposure duration, but limited data exists for exposures > 6 hours.
8. Test subject briefings, informed consent, and hazard analyses do not accurately reflect our current understanding of DCS risk.
9. Elements of the Hazard Analysis for EMU Ground Testing are based on flight rather than ground-based hazards; DCS hazards are combined with other pressure-related hazards.
10. Planned excursions to 3.5 psia during SSATA runs occasionally exceed the 5-minute limit allowed by JPR 8080.4.
11. Increased risk and discomfort due to fatigue, hunger, dehydration, and limited Maximum Absorption Garment capacity are difficult to quantify, but are real implications of longer prebreathes.
12. Current DCS treatment protocols and disposition policies are adequate.
13. The current process (in JPR 8080.4) by which changes to prebreathe protocols are reviewed and approved is inadequate.
14. The current process for the tracking of suited vacuum chamber DCS outcomes is inadequate.

4.0 RECOMMENDATIONS

Based on the team’s consensus observations, described in the previous section, a series of recommendations were formulated, discussed, refined, and agreed upon by the entire team. The consensus recommendations and associated rationale are organized into the following categories: Requirements Updates, DCS Diagnosis and Tracking, Documentation & Implementation; and Community Awareness.

4.1 REQUIREMENTS UPDATES

#	Recommendation	Rationale
1	<p>Update Ground Chamber Prebreathe Requirements</p> <p>A. Maintain 4-hour PB for runs \leq 2 hours (68% of expected runs)</p> <p>B. Add 30-minute prebreathe for runs > 2 hours</p> <p>C. Allow excursions of up to 15 minutes at 3.5 psi during SSATA runs</p> <p>D. Any future changes to chamber prebreathes to be recommended by HH&P EVA-IPT and approved by Crew Medical Officer (CMO) (unless full concurrence of stakeholders AND no increase in risk posture)</p>	<ul style="list-style-type: none"> • Decreases overall DCS risk vs current prebreathe reqts • Leaves large majority of runs with existing 4-hour PB • Increased PB for longer runs to achieve acceptable Type II risk • Recommend accepting higher Type I risk (up to 20%) for longer runs when traded against longer PB, increased fatigue, discomfort, dehydration and hunger • Make documentation consistent with current operations • Enforcing 5-minute limit would reduce Type I risk by only 0.8% but would impact test objectives

4.1.1 PREBREATHE TABLE

The team recommended that the prebreathe durations in Table 8 supersede those currently defined in JPR 8080. The estimates of Type I and Type II risk assume exposure durations of 2 hours, 3 hours, 6 hours, and 8 hours, respectively, for each of the four rows. The risk estimates for the 2-hour exposure assume that 15 minutes of the 2 hours is spent at 3.5 psia. Excursions to 3.5 psia should be limited to the minimum duration necessary to complete test objectives and are not to exceed 15 minutes. All prebreathe durations assume 12 minutes of purge and 20 minutes of depress. In the event that a shorter purge or depress is to be used, prebreathe duration should be increased by the same amount.

Table 8 – Recommended Prebreathe Durations and Associated Type I and Type II Risk Estimates for Suited Vacuum Chamber Runs

Exposure Duration (hr)	Prebreathe Time (hr)*	Estimated Risk of Type II DCS		Estimated Risk of Type I DCS	
		PDCS per Run	Risk per Run (1 in x)	PDCS per Run	Risk per Run (1 in x)
0.5 - 2**	4:00	0.08%	1316	7.9%	13
2.01 - 3	4:30	0.05%	1938	8.8%	11
3.01 - 6		0.05%	1882	16.1%	6
> 6.01		0.05%	1881	19.5%	5

* Prebreathe durations assume 12 minute purge and 20 minute depress

** Assumes up to 15 minutes at 3.5 psi

4.1.2 PREBREATHE CHANGE PROCESS

The team recommended the following changes to the wording in JPR 8080.

From:

- For exposure and durations not listed, the HH&P EVA-IPT shall recommend and approve prebreathe requirements.

To:

- For recommendations coming out of the HH&P EVA-IPT, if there is no change to risk posture or there is a decrease in risk posture, and full stakeholder concurrence is attained, the HH&P EVA-IPT has the authority to make the decision and is required to inform SD, SA, CMO and stakeholder management of their decision.
- For recommendations coming out of the HH&P EVA-IPT that do increase risk posture, a written rationale for risk acceptance should be provided to CMO for their evaluation and decision. If the topic warrants a meeting or board review that will be determined and scheduled.
- If there are any concerns, the default position of having the HH&P EVA-IPT forward a written rationale for their recommendation to CMO for their evaluation and decision is the path forward.

4.2 DECOMPRESSION SICKNESS DIAGNOSIS AND TRACKING

#	Recommendation	Rationale
2	Implement Process for Systematic Diagnosis, Tracking and Analysis of DCS Outcomes <ul style="list-style-type: none"> A. Symptom Tracking, Archiving & On-going Analysis B. DCS Diagnosis criteria C. Test Termination Criteria 	<ul style="list-style-type: none"> • Suited subjects not currently queried for DCS symptoms; no formal database for documenting of outcomes • Test Termination & DCS Diagnosis Criteria reduce subjectivity in DCS diagnosis; may help differentiate between suit-induced symptoms vs. DCS • Uncertainty in DCS model predictions; risk estimates should be evaluated against observed DCS outcomes

4.2.1 SYMPTOM TRACKING, ARCHIVING AND ONGOING ANALYSIS

Unlike DCS research studies in which subjects are frequently prompted for DCS symptoms and results are carefully archived and analyzed, suited vacuum chamber subjects are not queried for DCS symptoms at all, nor is there a defined process for the documentation of any DCS symptoms that may arise.

The team agreed on the recommendation that suited vacuum chamber test subjects be monitored and queried for DCS symptoms approximately every 20 minutes by the medical officer via a private medical conference (PMC) and recorded using a paper copy of a standard form (Table 9). Suit-related symptoms will also be tracked and recorded during this evaluation.

Due to the brevity of the “SSATA training run” (i.e., crew orientation to Class 1 hardware and EVA emergency procedures) and potential time impact of multiple PMCs, the query may be primarily by the test director asking the crewmember “do you need a private loop?” with just one medical officer conducted PMC towards the midpoint of the run.

The timing of prompts for symptoms will be protocol driven rather than clock driven to minimize impact to operations, thus intervals may fluctuate in timing, but should not exceed 30 minutes.

Table 9 – DCS Symptoms Tracking Log Excerpt with Example Entries



CTSD DCS SYMPTOMS TRACKING LOG

Instructions:

1. Query subject every 20 minutes beginning at start of exposure for the following symptoms (PET).
2. Log the test Clock Time.
3. Place an 'X' in the *Paresthesia, Headache* or *Other symptom column* if subject reports experiencing either of these symptoms.
4. Refer subject to the *Fatigue and Pain Ratings Scales* and record number reported by subject.
5. Record any subject comments during the query period or at any time when provided by the subject. Enter comments by placing a numbered footnote in the symptom block for each corresponding comment (or by listing the specific time).

Name (Last, First, MI): Wannabee, Ina Suit				Age: 36	Position: <input type="checkbox"/> Crew <input checked="" type="checkbox"/> Test Subject		Date: 6/22/2018	
<input checked="" type="checkbox"/> B7 <input type="checkbox"/> B32		Test: PLSS 3001 Verification				MO: Sanders		
Epoch	PET	Local Time	Symptoms					Comments
			Paresthesia	Headache	Fatigue	Pain	Other	
1	0:00	1258			0		1 – no c/o, ready to start exercise	
2	0:20	1318			1		3 – CM c/o 1/10 numbness/tingling in L thumb,	
3	0:40	1338	1		2		Doesn't believe there is weakness, no pain	
4	1:00	1359	0		2		Will monitor	
5	1:20	1417	1		3	3	5 - return of SX 1/10 in L thumb, now 3/10 pn in	
6	1:40						Rt wrist, believes it will affect push bar use	
7	2:00							

Upon completion of each run, the paper copy of the DCS Symptom Tracking Log for the run will be electronically scanned and the electronic file will then be associated with the subject's records in the Exposure Incident System (formerly Exercise and Injury System) data archive.

The tracking of overall DCS outcomes for each run (i.e., no DCS, Type I, Type II) will be accomplished using a custom spreadsheet (Table 10) stored on a secure NASA Sharepoint site accessible only to Human Test Support Group and H-3PO EVA Physiology personnel. The spreadsheet automatically compares DCS outcomes for each category of chamber run against the model-predicted DCS incidence and will alert the user in the event that there is a 70% probability that the observed DCS incidence exceeds model predictions. Under these conditions, it is expected that the adequacy of prebreathe protocols would be re-evaluated. Additional details of the risk review criteria are included as an Appendix.

Table 10 – Hypobaric Chamber DCS Archive Excerpt



Hypobaric Chamber DCS Archive

Human Test Support Group (HTSG)
Human Physiology, Performance, Protection & Operations (H-3PO) Lab

POC: robert.w.sanders@nasa.gov
POC: andrew.abercromby@nasa.gov

Table 1: Summary Table (do not edit; will update automatically).

Run Duration	≤ 2 hr		2-3 hr	3-6 hr	> 6 hr	Physiological Training
	EMU Training	Other				
# Runs Completed	0	0	0	0	0	0
# Type I Observed	0	0	0	0	0	0
Type I Pause Criteria	2	2	2	2	2	TBD
Type II Stop Criteria	1	1	1	1	1	1
Model Estimated PDCS	5.0%	7.9%	8.8%	16.1%	19.5%	TBD

Instructions: Enter details of each chamber exposure into Table 2 (below) using one row/entry per person per exposure. If the # Type I Observed is equal to the Type I Pause Criteria for any Run Type, there is a 70% probability that Observed DCS > Predicted DCS for that Run Type. This should be immediately reported to the NBL Medical Director.

Table 2: Data entry table.

Log ID	Date	Chamber	Run Type	Prebreathe (h:mm)	Duration at Altitude (h:mm)	Planned Operating Pressure (psia)	DCS Outcome (0,1,2)	Name of person entering data; Other Notes
001								
002								
003								
004								
005								

4.2.2 POST-TEST DECOMPRESSION SICKNESS DIAGNOSIS CRITERIA

DCS is not always a clear-cut pathology. There is no Gold Standard diagnostic criteria to eliminate positive or negative diagnostic error (Conkin et al., 2006). Even with treatment, resolution may be partial, and not diagnostic. At NASA, a retrospective review was completed and a post-test decision tree for diagnosis was created, adapted from a similar approach used during DCS research studies based on the accumulated wisdom about NASA and USAF experience with DCS symptoms and measured VGE (Conkin et al., 2006, 1998) (Ryles and Pilmanis, 1996). This flowsheet is specific to the diagnosis of DCS, but in doing so, loses sensitivity. That is, if the criteria are met, it is indeed DCS; however, if these criteria are not met, it does not rule out DCS. This does not surpass physician opinion for the diagnosis, but can help to clarify, after the fact, if the physician remains unsure. As such, this criteria will be applied, in retrospect, to all cases and reviewed. The flowsheet is included below:

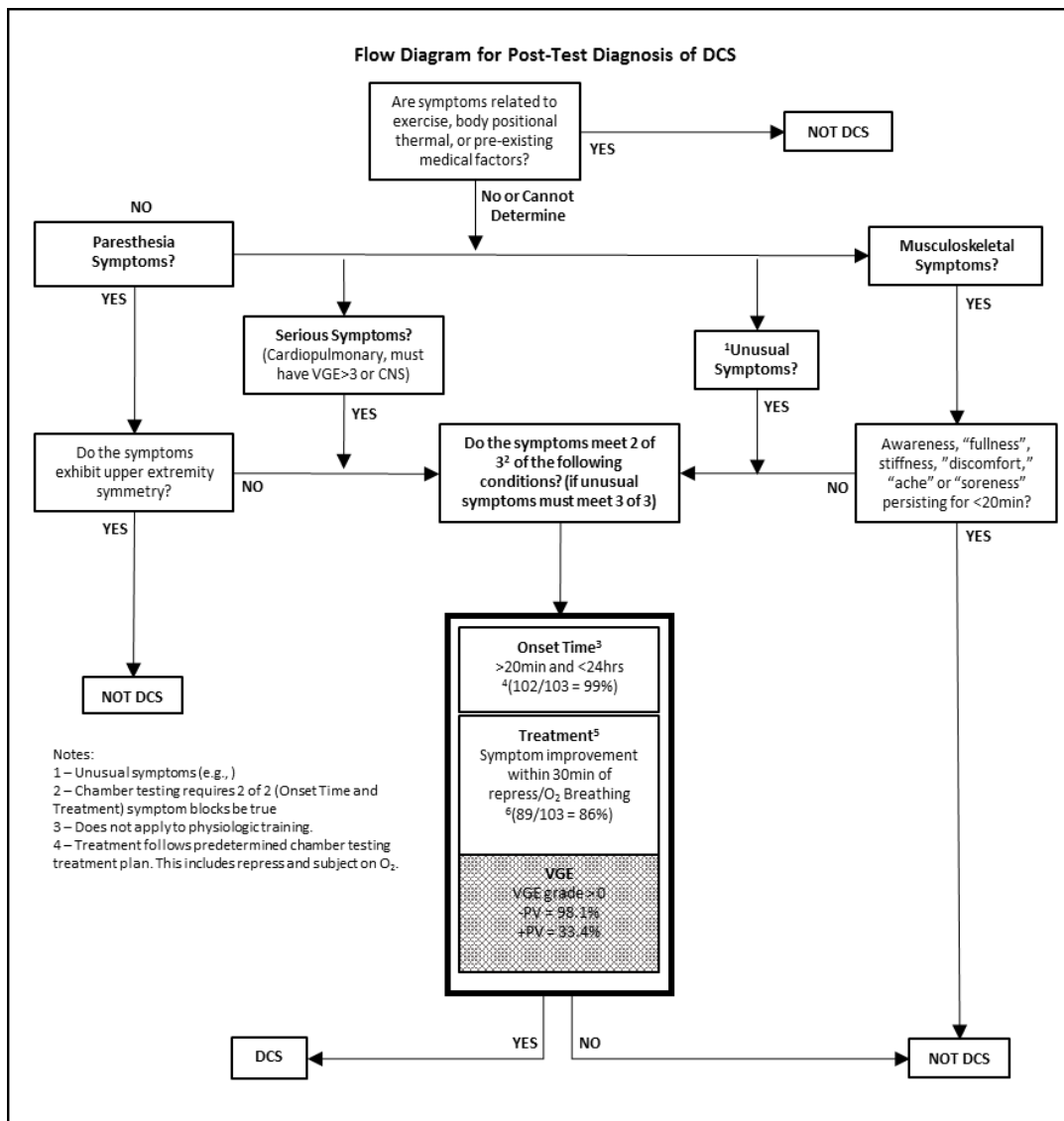


Figure 8 – Post-test DCS diagnosis criteria flowchart.

4.2.3 TEST TERMINATION CRITERIA

DCS is not always the obvious or clear process described in the text books. No two physicians have the same training or experience in diagnosing DCS (Conkin et al., 2006). Furthermore, the majority of physicians will see very few or zero cases in their career. The resultant lack of confidence, along with the impact of stopping a run can place an unfair burden on the console physician. To help with the decision making, and to empower the entire test team with the ability to be a part of the decision process, the following test termination criteria, based on research experience (Ryles and Pilmanis, 1996; Conkin et al., 2014), were recommended by the team:

- *Brief test subjects to report all symptoms as they occur*
- *A PMC with medical officer is conducted approximately every 20 minutes (every 30 minutes for runs ≤ 2 hrs) to query the subject regarding symptoms*
- *Test Termination Criteria for Suited Chamber Ground Tests:*
 - DCS has occurred in the judgement of the medical officer
 - If the following criteria are reported at any time, the test will be terminated as soon as possible, whether or not the medical officer has diagnosed DCS:
 - Migratory, trunkal, dermatomal, or multiple site paresthesia
 - Multiple symptoms of any degree, or multiple site symptoms not definitively attributable to the suit
 - Serious symptoms including cardiopulmonary, central neurological, cerebral, or any symptoms not attributable to peripheral neurological system

4.3 DOCUMENTATION AND IMPLEMENTATION

#	Recommendation	Rationale
3	Update documentation to incorporate changes to requirements and risk estimates <ul style="list-style-type: none"> A. DCS Hazard Analyses B. Informed Consent C. Test Subject Briefing (inc. Disposition Policy) D. JPR 8080.4A (memo first, document later) 	<ul style="list-style-type: none"> • Recommended requirements updates would supersede existing requirement documents • Documentation does not accurately reflect our current understanding of DCS risk • Separate DCS from Rapid Pressure Change Hazard Analysis

4.3.1 HAZARD ANALYSIS

The Hazard Analysis for the 11-foot chamber (the SSATA Hazard Analysis is essentially identical) was reviewed to determine if the entries appropriately addressed DCS as well as pressure changes. What was found was that the risk of DCS, as well as all other pressure changes, was aggregated into a single risk titled “Rapid Ambient Pressure Change” that included documentation for both ground and on-orbit DCS risks. Since risk from DCS is present whether or not there is a rapid pressure change, the Tiger Team recommended that the Hazard Analysis be revised.

To better align the various risks and their controls, the Tiger Team made the following recommendations:

1. *Identify DCS as a stand-alone risk:* An expectation is that DCS is going to happen at some point during the 10-year planned period of EMU testing. There is no practical method to remove all risk of DCS. Hypobaric DCS is unique as a risk since the very act of recovering an individual that is experiencing DCS back to a normal atmospheric pressure acts to control some risk and is a required function of the activity. The addition of hyperbaric treatment as an immediate mitigation makes DCS unique in that it can effectively reverse the undesirable effects of DCS almost instantly.

Hazards are generally reviewed before and after controls are in place; however, DCS has been assessed both before and after controls and also after mitigation. In the case of DCS, the initial Risk Assessment Code (RAC) for DCS 1 and 2 is assigned based on no prebreathe. Controls for DCS are the use of appropriate prebreathe and planned repressurization. The RAC following mitigation documents risk after use of hyperbaric facilities for treatment. See **Table 11**, below.

A significant section on supplemental notes is included in the DCS risk.

Causes in the DCS risk include:

- a. Crewmember (CM) Physiologic Response
 - b. DCS Susceptibility due to CM current health status
 - c. Gas Pockets of nitrogen trapped within in the suit
 - d. Introduction of nitrogen into the breathing gas supply
 - e. CM movement throughout test may induce DCS due to microscopic bubble formation within tissue (tribonucleation), metabolic rate, test subject stress levels, and positioning during evaluations.
 - f. Rapid suit depressurization from suit rupture, sharp edges or SSA integrity fault
2. *Separate Rapid Ambient Pressure Change into two separate risks: Rapid Ambient Pressure Increase and Rapid Ambient Pressure Decrease.* With the separation of this risk from DCS, these now address barotrauma as the consequence.
 3. *Incorporate changes to the risk of toxic environments to better address the risk from oxygen toxicity.*
 4. *Remove all notes in the Hazard Analysis that applied only to on-orbit operations.* A number of notes and reports documented in the Hazard Analysis were only relevant to on-orbit operations and did not have any bearing on chamber or 1-g operations. These acted only to dilute the importance of the notes that actually had relevance to ground operations.

Table 11 – Risk Assessment Codes for Type I and Type II DCS During Suited Ground Vacuum Chamber Testing

Risk Assessment Codes	DCS 1	DCS 2
Prior to Controls	II B 1	I B 1
Control with Pre-breathe and Planned Repressurization	II C 3	I E 4
Addition of Hyperbaric Treatment for Symptoms	II D 4	I E 4

Was: II C 3 Was: I E 4

Consequence Class	Likelihood Estimate				
	A Likely	B Probable	C May Occur	D Unlikely	E Improbable
I – Catastrophic	1	1	2	3	4
II – Critical	1	2	3	4	5
III – Moderate	2	3	4	5	6
IV - Negligible	3	4	5	6	7

4.3.2 INFORMED CONSENT

Test subjects sign an informed consent prior to participating in suited vacuum chamber runs to ensure that they are aware of and fully understand the purpose of the test, how the data will be used, and any potential hazards that the test subject may be exposed to, including DCS. The team recommended the following changes to the informed consent:

From:

Serious conditions and discomforts are possible during this type of testing, but they are rare. No severe Type II DCS symptoms such as an arterial gas embolism have been encountered in any of these tests while the less severe Type I DCS symptoms which include minor joint pain or skin paresthesia occur in about 1% to 2% of tests even after a full four hour prebreathe period.

To:

Serious conditions and discomforts are possible during this type of testing, but they are rare. There have been no reports of serious symptoms of DCS Type II at this level of decompression risk. DCS Type II symptoms include central neurological or cardiopulmonary symptoms and can be life-threatening. The risk of DCS Type II associated with this test is estimated to be less than one in one thousand. The risk of less severe DCS Type I symptoms, which can include mild to severe joint pain, is estimated to be up to one in five, with tests of longer duration and higher physical activity levels having the highest risk of Type I symptoms. Previous tests similar to this have resulted in approximately 5% DCS Type I symptoms, which include joint pain and single extremity tingling or numbness. All reported symptoms resolved with treatment (recompression to ground level or in a hyperbaric chamber along with oxygen breathing). There has been no case of permanent disability associated with DCS at this level of decompression risk.

4.3.3 TEST SUBJECT BRIEFING

Test subjects are briefed by the test director and by the medical officer prior to testing. Although the DCS risk estimates in the Informed Consent will be updated to reflect current best understanding of the DCS risk (see previous section), test subjects do not always pay close attention to the many details provided in what can be a lengthy informed consent document. The team recommended the following updates to the test subject briefing to further ensure test subject awareness of the DCS risk, the obligation to report symptoms, the DCS disposition policy (Table 2), and the symptom querying protocol:

- **Disposition policy:** *Test subjects experiencing Type I DCS symptoms will receive hyperbaric medical treatment and may return to work 24 hours following resolution of symptoms. Subjects may return to chamber, diving, or aircraft ops 72 hours after resolution of symptoms.*
- **Obligation to report symptoms:** *Test subjects should not attempt to self-diagnose DCS but should report any and all symptoms to the medical officer*
- **Predicted Risk:** *The risk of DCS Type II associated with this test is estimated to be less than 0.1%. The risk of less severe DCS Type I symptoms, which can include mild to severe joint pain, is estimated to be up to 20%, with tests of longer duration and higher physical activity levels having the highest risk of Type I symptoms.*
- **DCS Symptom Querying Protocol:** *A Private Medical Conference with the medical officer will be conducted approximately every 20 min (every 30 min for runs \leq 2 hours) to query the subject regarding symptoms.*

4.3.4 MEMORANDUM/JPR 8080.4A UPDATES

The team recommended that, following approval from the EVA Configuration Control Board (CCB), Human Systems Risk Board (HSRB), and SSPCB, the updates to the vacuum chamber prebreathe requirements defined in JPR 8080 be formalized via the immediate release of a memorandum from the JSC CMO and the Director of the Human Health & Performance Directorate (HHPD). The wording of the memorandum was drafted and submitted to HHPD management, and the signed version is included as an Appendix.

The memorandum was released on July 18, 2018, after approval by the HSRB and EVA CCB but prior to the final out-brief presentation to the SSPCB, which was rescheduled from June 26 to August 21, 2018. This decision was made after an out-of-board discussion between EVA Office and ISS Program management, from which it was concluded that ISS Program non-concurrence with the recommended prebreathe updates was unlikely.

Updating of the JPR 8080.4A document itself was already underway to incorporate modifications related to flying and diving, with a revision scheduled in 2019. The team therefore recommended that incorporation of the updated vacuum chamber prebreathe requirements into JPR 8080.4A occur as part of the scheduled document revision in 2019. Implementation of the updated vacuum chamber prebreathe requirements would take effect immediately per the CMO and HHPD memorandum.

4.4 COMMUNITY AWARENESS

#	Recommendation	Rationale
4	Ensure Community Awareness of Type I DCS Likelihood and Consequences A. Tiger Team Out-brief Presentation B. Tiger Team Report	<ul style="list-style-type: none"> • Improved monitoring and longer chamber runs may both increase likelihood of Type I DCS symptom diagnosis • Community should be aware that <u>Type I DCS is likely to occur during planned chamber testing but unlikely to cause severe harm or occupational illness</u>, so that organizational responses are informed and appropriate

4.4.1 TIGER TEAM OUT-BRIEF PRESENTATION

The team prepared an out-brief presentation, including background, purpose, approach, observations, and recommendations. The presentation was briefed to the EVA CCB, HSRB, and SSPCB, each of which was well-attended by members of the EVA, Human System, and ISS communities. During each of the briefings, the importance of ensuring community awareness regarding DCS risk estimates, DCS consequences, and DCS disposition policy was stressed.

It was explained that, while the team's recommendations would not change DCS risk for runs of up to 2 hours duration and would lower the DCS risk for runs greater than 2 hours, the

combination of improved monitoring and more long-duration chamber runs may both increase the likelihood of Type I DCS symptom diagnosis.

It was also stressed that the NASA community should be aware that Type I DCS is likely to occur during planned chamber testing but that it is unlikely to cause severe harm or occupational illness. As such, organizational responses in the event of Type I DCS reports should be informed and appropriate.

4.4.2 TIGER TEAM REPORT

The purpose, membership, approach, observations, and recommendations of the team are documented in this report. The team recommended that the report be appropriately archived and made easily available for future reference. At time of writing, this report and the out-brief presentation are expected to be archived and available for reference via the EMU Special Problem Resolution Team website (<https://nasa-ice.nasa.gov/portal/web/eva/site-master?siteId=2508620097>) and the NASA Technical Report Server (<https://ntrs.nasa.gov/>).

4.5 SUMMARY OF RECOMMENDED CHANGES

Consensus recommendations of the team are summarized in Table 12.

Table 12 – Summary of Tiger Team Recommended Changes

	From	To
Prebreathe for runs ≤ 2 hours	4:00	No change
Prebreathe for runs > 2 hours	4:00	4:30
Prebreathe change process	HH&P EVA-IPT approval	HH&P EVA-IPT recommend, CMO Approval
Hazard Analysis	DCS Combined with Rapid Ambient Pressure Changes	Separate Hazard Analysis for DCS
Hazard Analysis RAC: Type I	II C 3	II D 4 (assumes treatment)
Hazard Analysis RAC: Type II	I E 4	No change
Test Termination Criteria	Subject reports → Medical Officer judgement	Medical Officer Queries Subject + Objective Criteria
Symptom Tracking, Archiving & Analysis Process	None	Defined Process
DCS Disposition Policy	24-hour Return to duty; 72-hour Return to chamber/flying/diving	No change
DCS Treatment Protocols	Hyperbaric treatment for all DCS symptoms	No change

5.0 MANAGEMENT REVIEW AND APPROVAL OF TEAM RECOMMENDATIONS

The Tiger Team Out-brief presentation was briefed to the EVA CCB (June 20, 2018), HSRB (June 21, 2018) and the SSPCB (August 21, 2018). All three boards concurred with all of the team's recommendations, commended the team on their work, and directed that the recommendations be implemented as described.

6.0 REFERENCES

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JPD1800.2B:

<http://server-mpo.arc.nasa.gov/services/CDMSDocs/Centers/JSC/Dirs/JPD/JPD1800.2B.pdf>

7.0 APPENDICES

APPENDIX A: DCS HAZARD ANALYSIS WORKSHEET

Updates to the Hazard Analysis are shown for the 11-foot chamber. Updates for other vacuum chambers will follow.

STB-HA-371
Revision: E

Hazard Analysis for the Manned EMU Vacuum Level Certification in 11-Ft Chamber

Crew and Thermal Systems Division
Systems Test Branch

October 9, 2018
Revision: E

Verify this is the correct version before use.



Crew and Thermal Systems Division
Engineering Directorate
Lyndon B. Johnson Space Center
Houston, Texas

Crew and Thermal Systems Division Systems Test Branch	Hazard Analysis for Manned EMU Vacuum Level Certification in 11-Ft Chamber	
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Table 3 - Hazard Summary Table

Hazard		Consequence/Likelihood/RAC		Disposition
		Before Controls	After Controls	
1	Asphyxia/Hypoxia/Hypercapnia	I/B/1	I/E/4	Closed/Controlled
2	Smoke/Fire	I/B/1	I/E/4	Closed/Controlled
3	Uncontrolled Electrical Energy	I/B/1	I/E/4	Closed/Controlled
4	Personnel Entrapment	I/B/1	I/E/4	Closed/Controlled
5	Pressure System Breach/Rupture	I/B/1	I/E/4	Closed/Controlled
6	Human Error	I/B/1	I/E/4	Closed/Controlled
7	Toxic/Corrosive Materials/Gases	II/B/2	II/D/4	Closed/Controlled
8	Contamination	II/B/2	II/D/4	Closed/Controlled
9	Loss/Failure of Subsystem	I/B/1	I/E/4	Closed/Controlled
10	Adverse System Condition/Configuration	I/B/1	I/E/4	Closed/Controlled
11	Decompression Sickness (DCS)	Type I DCS: II/B/2	Type I DCS: II/C/3	Closed/Accepted
		Type II DCS: I/B/1	Type II DCS: I/E/4	Closed/Controlled
12	Rapid Ambient Pressure Decrease	Type I DCS: II/B/2	Type I DCS: II/C/3	Closed/Accepted
		Type II DCS: I/C/2	Type II DCS: I/E/4	Closed/Controlled
13	Rapid Ambient Pressure Increase	Type I DCS: II/B/2	Type I DCS: II/C/3	Closed/Accepted
		Type II DCS: I/C/2	Type II DCS: I/E/4	Closed/Controlled

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Table 4 - EMU Safety Analysis Reports

Hazard Number	Potential Hazard	Hazard Classification & NCR
ISS-EMU-UNQ-01	EMU Battery Leakage/Rupture	Controlled
ISS-EMU-UNQ-02	Fire/Explosion	Controlled
ISS-EMU-UNQ-03	Touch Temperature Exceedances	Controlled
ISS-EMU-UNQ-04	Electric Shock & Molten Metal During EMU Operations	Controlled
ISS-EMU-UNQ-05	Burst/Rupture of EVA O2 Pressurized Vessels, Lines, Fittings, or Components	Accepted Risk
ISS-EMU-UNQ-07	Loss of Habitable Environment: Space Suit Loss of Oxygen and Pressure	Accepted Risk
ISS-EMU-UNQ-08	Loss of Habitable Environment: Space Suit Over pressurization	Accepted Risk
ISS-EMU-UNQ-09	Loss of Habitable Environment - Excessive CO2 in the Ventilation Loop	Accepted Risk
ISS-EMU-UNQ-10	Loss of Habitable Environment: Contamination of the EMU Leading to Loss of ECLSS or Toxicity	Accepted Risk
ISS-EMU-UNQ-12	Decompression Sickness	Controlled
ISS-EMU-UNQ-15	Susceptibility to/Contact With Sharp Edges, Corners, Pinch Points, and Entanglements/Entrapment Hazards	Accepted Risk
ISS-EMU-UNQ-16	Loss of Habitable Environment - Loss of EMU Cooling Capability	Accepted Risk
ISS-EMU-UNQ-17	Loss of Habitable Environment - Excessive Liquid in the EMU Helmet	Accepted Risk
ISS-EMU-UNQ-18	Water Contamination of EMU Systems	Accepted Risk
ISS-EMU-UNQ-20	EMU Mechanism Hazards - Composite	Accepted Risk
ISS-EMU-UNQ-21	EMU Shatterable Materials	Controlled
ISS-EMU-UNQ-23	Exposure to Cold Resulting in Injury	Accepted Risk:
ISS-EMU-UNQ-24	EMU Suited Crew Exposure to Excessive Noise	Controlled
ISS-EMU-UNQ-25	Structural Failure	Accepted Risk

The hazards listed in table 4 were reviewed and assessed for 11-Foot ground testing applicability.

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A.11 Decompression Sickness (DCS)

Severity / Likelihood / Risk Assessment Code	Type 1	Before Controls	After Controls	After Mitigation
	Type II	II / B / 2	II / C / 3	II / D / 4
		I / B / 1	I / E / 4	I / E / 4

Disposition	Closed/Eliminated	Closed/Controlled	Closed/Accepted	X	Open/No Action
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Hazard Description and Consequence
 Chamber occupants exposed to or not adequately prepared for activities at a lower than ambient pressure may be subject to formation of venous gas emboli or nitrogen microbubbles within various tissues. These conditions can cause musculoskeletal and other systemic pain, difficulty breathing, cardiovascular compromise, and neurological complications

Supplemental Notes

- There are two Decompression Sickness (DCS) types that correspond to both severity and location of the symptoms.
 - Type I DCS has less significant symptoms that involve the skin, musculoskeletal system, or lymphatic system.
 - Type II DCS has more significant symptoms that involve the central nervous system, cardiovascular system, or pulmonary system.
 - Type II DCS is more serious, may have a worse outcome, and can lead to death. However, in most cases with appropriate treatment there can be full resolution of symptoms.
 - There is a unique form of skin DCS known as cutis marmorata. This appears as a red and blue marbling that appears on the abdomen. This form of DCS is often associated with neurologic DCS, (Type II), if left untreated.
- An individual's susceptibility to DCS is undefinable.
- Only controls that have been agreed to for use in ground based chamber operations (1-g) should be used. On-orbit (zero-g) controls that have not been specifically approved for ground operations can make DCS more likely.
- Medical screening for individual "susceptibility" to DCS is controversial and not performed at NASA-JSC. Medical screening for controllable risk factors (dehydration, illness, etc) is performed prior to any chamber run.
- DCS is unique as a hazard in that in addition to the controls that are in place for all events (prebreathe, including oxygen breathing during suit purge and depressurization, and repressurization), rapid hyperbaric oxygen treatment can control most DCS symptoms and minimize long-term consequences. Availability and use of this treatment as a mitigation once DCS has occurred is critical to the evaluation of the actual hazard present in altitude testing.
- Medical personnel and an operational hyperbaric chamber are required to be on standby to treat test subjects with DCS symptoms.
- JPR 1800.3 provides the policy for the medical disposition of human test personnel and CMs who incur decompression-related disorders.
- Incapacitated CM calls for zero altitude emergency repress IAW STB-M-181.

1.	Cause	CM Physiologic Response
----	-------	-------------------------

1.1	Control	<ol style="list-style-type: none"> 4:00 hour in-suit prebreathe for all chamber runs up to 2-hours in duration. 4:30 hour in-suit prebreathe for all chamber runs in excess of 2-hours in duration. Test Subject will gently move arms and legs approximately every 15-minutes during prebreathe. 12-minute suit purge with 100% oxygen to wash residual nitrogen out of suit. Prebreathe breach protocol for ≤10-minutes interruption requires a repeat of the 12-minute suit purge plus 2 times (2x) the interruption duration time to be added to the pre-breath time. Prebreathe breach protocol for >10 minutes interruption requires a repeat of the 12-minute purge and a restart of the prebreathe clock. Total prebreathe time shall not exceed a 6-hour duration. <p>NOTE: Test Director will assess effects of the extended time required due to a prebreathe breach in accordance with the Work Shift Limits for Hazardous Duty (JPR 1700.1 Section 5.8.10) and terminate the test immediately if the Hazardous Duty Limits would be exceeded.</p> <ol style="list-style-type: none"> Test will be terminated if any of the following occur: <ol style="list-style-type: none"> DCS has occurred in the judgement of the medical officer Any of the following occur at any time
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		<ul style="list-style-type: none"> i) Migratory, truncal, dermatomal, or multiple site paresthesia ii) Multiple symptoms of any degree or multiple site symptoms not attributable to the suit. iii) Serious symptoms including cardio-pulmonary, central neurological, cerebral, or any symptoms not attributable to peripheral neurological system.
	Verification	Review of DTP Test Rules
	Mitigation	<ul style="list-style-type: none"> a. Hyperbaric chamber with medical staffing and certified operators will be available throughout testing. b. Medical Officer will initiate hyperbaric treatment (US Navy, Air Force, Comex, Catalina Consolidated treatment tables) based on treatment protocols and DCS severity.
	Verification	Review of DTP Test Rules.
2.	Cause	DCS Susceptibility due to chamber occupant's current health status
2.1	Control	Test subjects and rescue technicians undergo a pre-exposure medical readiness evaluation on the day of the exposure to check for reversible risks of hypobaric exposure including DCS. These include at a minimum appropriate sleep and eating, significant dehydration, congestion, and temporary Eustachian tube dysfunction.
	Verification	<ul style="list-style-type: none"> 1) Review of test subject reduced pressure training 2) Physician certification of test subject readiness on day of test
3.	Cause	Gas pockets of nitrogen trapped within the suit
3.1	Control	<ul style="list-style-type: none"> a. 12-minute suit purge with 100% oxygen to wash residual nitrogen out of suit. b. Test Subject will gently move arms and legs approximately every 15-minutes during prebreathe. c. Prebreathe breach protocol for ≤ 10-minutes interruption requires a repeat of the 12-minute suit purge plus 2 times (2X) the interruption duration time to be added to the pre-breath time. d. Prebreathe breach protocol for > 10 minutes interruption requires a repeat of the 12-minute purge and a restart of the prebreathe clock. Total prebreathe time shall not exceed a 6-hour duration. <p>NOTE: Test Director will assess effects of the extended time required due to a prebreathe breach in accordance with the Work Shift Limits for Hazardous Duty (JPR 1700.1 Section 5.8.10) and terminate the test immediately if the Hazardous Duty Limits would be exceeded.</p>
	Verification	Review of DTP Test Rules
4.	Cause	Introduction of nitrogen into the breathing supply (facility/PLSS)
4.1	Control	<ul style="list-style-type: none"> a. Oxygen supplies are sampled for content and purity. b. SSA air circulation fan is verified "off" prior to change out of Metox/LiOH canister, if occurring during prebreathe
	Verification	<ul style="list-style-type: none"> a. Review of Oxygen sampling TPS b. Review of test readiness verification sheet c. Review of Statement of Readiness Memorandum (certification letter) to TRRB Chairman d. Review of DTP
5.	Cause	CM movement throughout test may induce DCS due to microscopic bubble formation within tissue (tribonucleation), metabolic rate, test subject stress levels, and positioning during evaluations.
5.1	Control	<ul style="list-style-type: none"> a. JPR 1800.3 policy describes the communication, monitoring, and oversight requirements for test subjects engaged in activities that involve pressure excursions with the potential to result in decompression-related disorders. b. Test will be terminated if any of the following occur: <ul style="list-style-type: none"> i. DCS has occurred in the judgement of the medical officer ii. Any of the following occur at any time <ul style="list-style-type: none"> a. Migratory, truncal, dermatomal, or multiple site paresthesia b. Multiple symptoms of any degree or multiple site symptoms not attributable to the suit. c. Serious symptoms including cardio-pulmonary, central neurological, cerebral, or any symptoms not attributable to peripheral neurological system. iii. Test subject request for any reason c. Rescue techs and medical monitors are present during testing.
	Verification	<ul style="list-style-type: none"> a. Review of DTP and review of STB-M-181 and JPR 1800.3. b. Review of EMU certification and readiness status at TRRB. c. Review of test termination criteria.

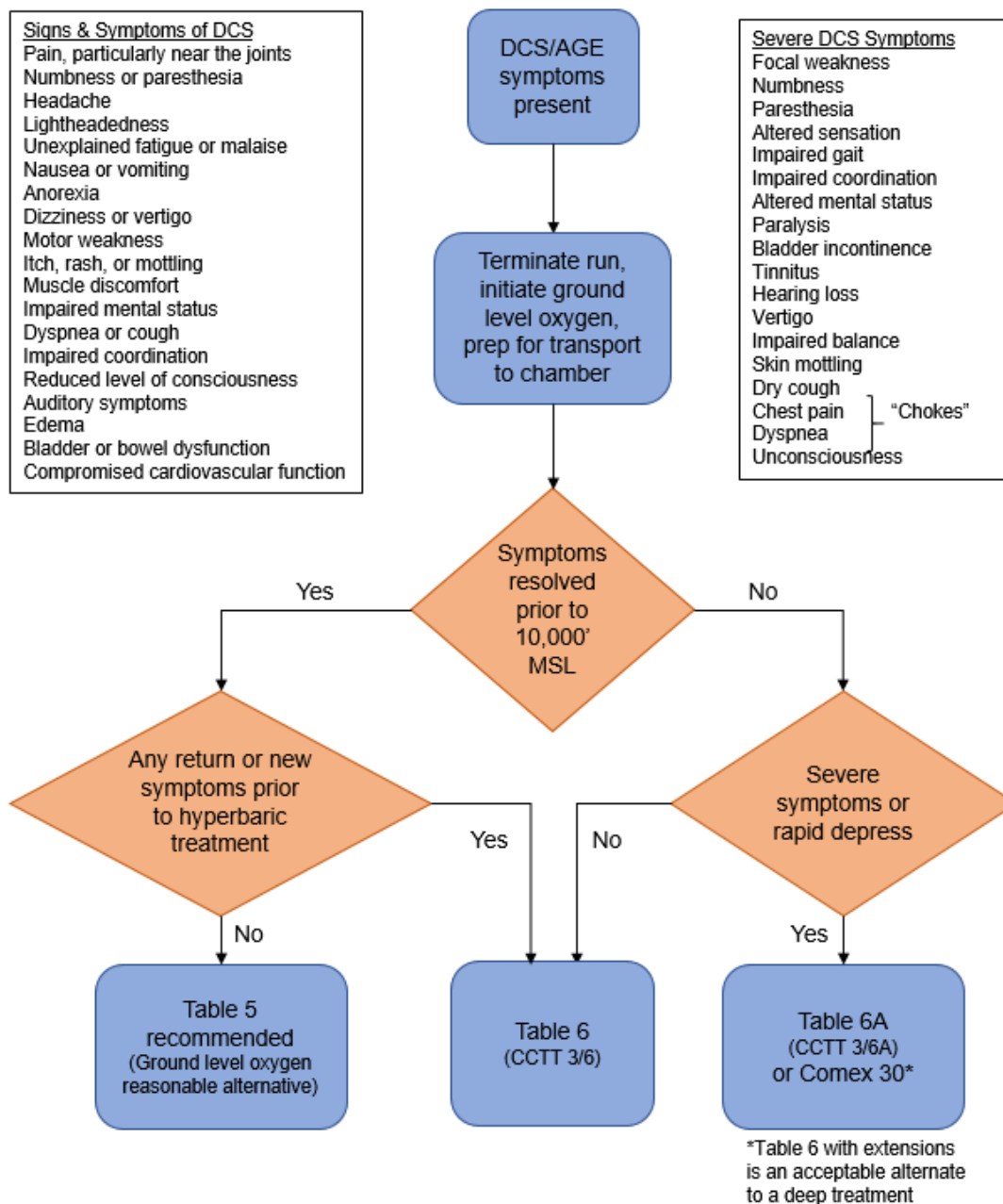
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6.	Cause	Rapid suit depressurization from suit rupture, sharp edges or SSA integrity fault
6.1	Control	a. Test system sharp edges/points have been removed/minimized by design and chamber approved tape is utilized to further minimize chamber edges in close proximity of the EMU. b. Chamber inspection is performed to ensure sharp edges/points are adequately removed.
	Verification	a. Review of sharp edge inspection TPS b. Review of test readiness verification sheet c. Review of Statement of Readiness Memorandum (certification letter) to TRRB Chairman
6.2	Control	a. EMU undergoes pressure testing and inspections prior to main chamber vacuum run. b. Chamber Emergency Re-pressurization is IAW STB-M-181 as directed by the DTP.
	Verification	a. Review of DTP, STB-M-181, and JPR 1800.3 b. Review of EMU certification and readiness status at TRRB.
6.3	Control	a. Hyperbaric chamber support is available b. DTP defines actions for hyperbaric chamber loss during test.
	Verification	a. Review of hyperbaric chamber readiness b. Review of DTP.
7.	Cause	Loss of Hyperbaric chamber support (needed for treatment of DCS)
7.1	Control	Test is terminated if hyperbaric chamber support is not restored within 15 minutes.
	Verification	Review of DTP Test Rules.
8.	Cause	Feedwater Refill at Vacuum
8.1	Control	DTP cautions, if suit pressure falls below 4.05 psia, water fill procedure will be paused until suit pressure is brought back up to 4.3 psia. Suit pressure must be above 4.0 psia during recharge to remain below 20% Type I DCS risk criterion.
	Verification	Review of caution statement in DTP.
8.2	Control	Suit pressure is monitored throughout fill process
	Verification	Review of DTP.

HAW Approval
Responsible Engineer, Manager, or Test Director/Date:
Branch Chief/Date: (For Closed/Accepted Disposition Only)

APPENDIX B: DECOMPRESSION SICKNESS TREATMENT ALGORITHM

DCS is not always the obvious or clear process described in the text books. Furthermore, the vast majority of physicians may see zero or at most a single case in their career. The resultant lack of experience and the plethora of treatment tables in the literature can make selection of the appropriate treatment process equally challenging. To improve performance, confidence, and consistency for supporting physicians, the following DCS treatment flowchart based on history and symptoms was developed to help guide a supporting physician through the decision process for treatment.



Consider extensions for severe or refractory symptoms

APPENDIX C: MEMORANDUM

National Aeronautics and
Space Administration
Lyndon B. Johnson Space Center
2101 NASA Parkway
Houston, Texas 77058-3696



July 18, 2018

Reply to Attn of: SA-18-058

TO: XX/Manager, Extravehicular Activity Office
FROM: SA/Johnson Space Center Chief Medical Officer
SUBJECT: Prebreathe Protocols for Extravehicular Activity (EVA) Ground Testing

The Suited Ground Vacuum Chamber Decompression Sickness Tiger Team is working to update prebreathe requirements in JPR 8080.4A. As an interim step and to allow the Engineering Team to plan chamber runs, this memorandum documents the updates to prebreathe requirements, allowable pressure profiles, and prebreathe change process for suited ground vacuum chamber testing at Johnson Space Center, as currently defined in JPR 8080.4A. This memorandum does not affect flight EVA prebreathe protocols.

The updates described herein are based on observations and consensus recommendations made by the Suited Ground Vacuum Chamber Decompression Sickness Tiger Team. These recommendations were reviewed and approved by the EVA Configuration Control Board (June 20, 2018), planned for August 21, 2018 and the Human System Risk Board (June 21, 2018). A Space Station Program Control Board is scheduled for August 21, 2018 for final approval of the Tiger Team's recommendations.

Prebreathe Requirements for 4.0 – 4.3 psia Runs > 30 Minutes

Effective immediately, Table 1 (enclosed) of this memorandum supersedes the relevant portion of JPR 8080.4A Table 2-1. The original Table 2-1 directed a 240 minute (4-hour) prebreathe preceding exposures to 4.0 psia (32,000 ft altitude) lasting more than 30 minutes. The updated table requires a 240 minute prebreathe for exposures up to 2 hours, and a 270 minutes prebreathe for exposures greater than 2 hours. These prebreathe durations assume an additional protective benefit of 12 minutes during suit purge and 20 minutes during depressurization.

Allowable Pressure Profiles

Effective immediately, this memorandum supersedes the current JPR 8080.4A text below Table 2-1 as follows:

From:

For use only with EMU training and testing activities where a brief transition of less than 5 minutes total from nominal 4.3 – 4.0 psia to 3.5 psia is allowed.

To:

For use only with suited training and testing activities where a single excursion to 3.5 psia is permitted, but should be limited to the minimum duration necessary to complete test objectives and is not to exceed 15 minutes.

Prebreathe for Exposures and Durations Not Listed

Effective immediately, this memorandum supersedes JPR 8080.4A Section 2.2 paragraph (a) as follows:

From:

Table 2-1 lists pre-approved oxygen prebreathe protocols for exposures in JSC hypobaric chambers. For exposures and durations not listed, the Extra Vehicular Activity Integrated Product Team shall recommend and approve prebreathe requirements.

To:

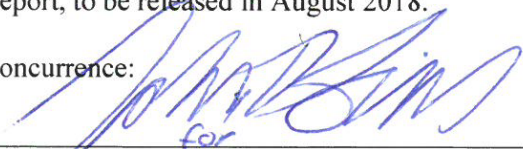
Table 2-1, in combination with Table 1 of Memorandum SA-18-036, lists pre-approved oxygen prebreathe protocols for exposures in JSC hypobaric chambers. For exposures and durations not listed, recommendations will be formulated by the Medical Operations EVA-IPT with inputs from stakeholders. If the Med Ops EVA-IPT recommendation results in no change to human risk posture or there is a decrease in human risk posture, and full stakeholder concurrence is attained, the Med Ops EVA-IPT has the authority to make the decision and is required to inform SD, SA, CMO and stakeholder management of their decision.

For Med Ops EVA-IPT recommendations that do increase risk posture, a written rationale for risk acceptance should be provided to CMO for their evaluation and decision. If the topic warrants a meeting or board review, that will be determined and scheduled.

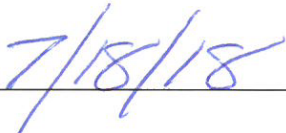
If there are any concerns, the default position is that the Med Ops EVA-IPT will forward a written rationale for their recommendation to CMO for their evaluation and decision.

Detailed rationale for the changes defined in this memorandum are provided in the Tiger Team Outbrief presentation (available in EDMS), and are further documented in the Tiger Team Final Report, to be released in August 2018.

Concurrence:




Catherine A. Koerner
Director, Human Health and Performance

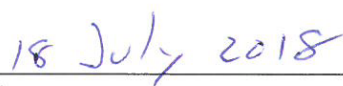


Date

Approval:



Terrance A. Taddeo, M.D.
Johnson Space Center Chief Medical Officer



Date

APPENDIX D: OXYGEN TOXICITY

A Unit Pulmonary Toxicity Dose (UPTD) of 694 units is considered the threshold for detectable changes in the lung such that you expect a 2% decrease in pulmonary vital capacity in 50% of subjects. Limit is based on an analysis by Lambertsen in 1999. 1 UPTD unit is equivalent to a 1-minute exposure to a PO₂ of 1 Atmosphere Absolute (ATA).

Based on UPTD threshold for pulmonary symptoms, there is no risk of pulmonary symptoms during the training or testing using the EMU with a lengthy 4.5-hour prebreathe.

Event	PO ₂ (psia)	PO ₂ (ATA)	O ₂ Dose Duration (min)	UPTD**	Cumulative UPTD
Purge	15*	1.020	12	12.67	12.67
Prebreathe	15*	1.020	270	285.4	298.0
Depress	11	0.748	15	5.67	303.7
EVA	4.3	0.29	---	0***	303.7
Repress	11	0.748	15	5.67	309.4

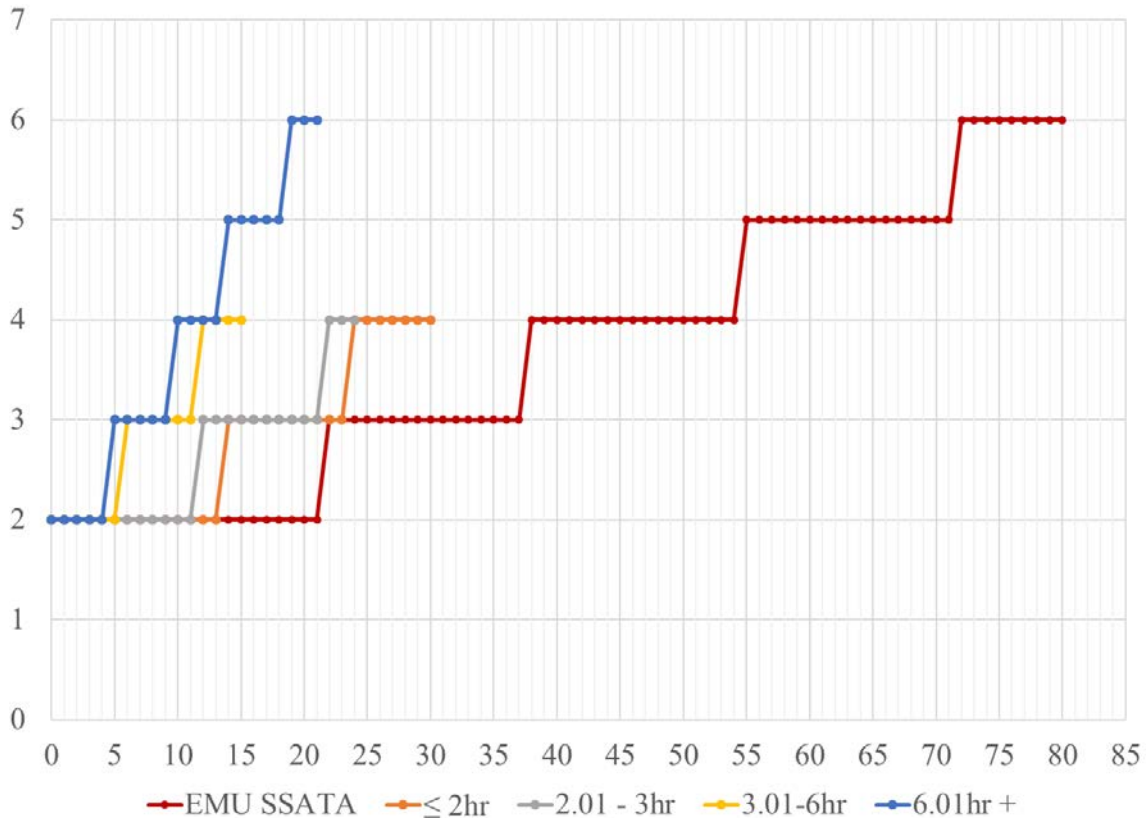
*includes slight suit over-pressure

**UPTD = time(min) x (2 x PO₂(ATA) - 1)^{1.3868}

***Note: there is no accumulation of O₂ dose with PO₂ at 0.5 ATA (7.35 psia), so no additional O₂ dose during any length of EVA at 4.3 psia. Mid-value of PO₂ was used for pressure transitions when mid-value PO₂ was > 0.5 ATA.

APPENDIX E: RISK REVIEW CRITERIA FOR ONGOING ANALYSIS OF OBSERVED VS. PREDICTED DCS OUTCOMES

The figure below identifies the cumulative Type I DCS incidence at or above which there is a $\geq 70\%$ probability that the observed Type I DCS incidence is greater than the model-predicted incidence. Under these conditions, referred to as “risk review criteria,” model predictions should be updated to incorporate the most recent data, and the updated estimates of Type I DCS risk, as well as observed incidence data should be reported to HHPD, EVA, CTSD, and ISS program management, who would then provide direction and/or a request for additional analyses or information.



Risk review criteria are defined only for two or more cases of Type I DCS within a given run type, due to the low statistical power that would be associated with comparisons of observed vs predicted DCS when very few runs have been performed. Stated differently, meaningful comparisons of observed vs model-predicted DCS incidence is not possible until an adequate number of trials have been conducted.

For all types of chamber runs, any incidence of observed Type II DCS should result in immediate suspension of chamber testing to allow for the adequacy of existing prebreathe protocols to be re-evaluated.

In addition to the risk review criteria described above, the number and types of runs being performed will be compared against the assumptions used by this team in the estimation of overall programmatic risk. Risk estimates will also be updated based on best available models and data.

APPENDIX F: NASA DCS RESEARCH RESULTS AND LITERATURE DATA FROM HYPOBARIC DCS DATABASE

Table F1 is a summary of NASA-funded research tests from 1983 through 2016. Table F2 is a summary of Type II cases from NASA-funded research tests.

Table F1 – Summary of NASA-Funded Research Tests (1983 – 2016)

Test	P2 (psia)	duration (hr)	sample m f	mean age	DCS cases	DCS (%)	Mean TR360	mean BGI	VGE (any Grade)	VGE (Grade IV)
1a	4.3	3	11 0	34.5	4	36.3	1.75	29.7	7	4
1b	4.3	3	13 0	32.3	3	23	1.81	56.3	11	7
1b10.2	10.2	12	13 0	32.3	0	0	1.13	19.7	n/a	n/a
1c	4.3	3	12 0	32	4	33.3	1.64	53.7	7	6
1c10.2	10.2	12	12 0	32	0	0	1.13	19.7	n/a	n/a
1d	4.3	3	3 0	39.6	2	66.6	1.7	58.6	3	2
1d10.2	10.2	18	3 0	39.6	0	0	1.13	21.9	n/a	n/a
2a	4.3	4	23 0	31.6	7	30.4	1.69	35.7	15	8
2b	4.3	4	22 0	31.5	6!	27.3	1.74	64.7	10	7
2b10.2	10.2	12	22 0	31.5	0	0	1.13	19.5	n/a	n/a
3a	4.3	6	28 0	31	6	21.4	1.6	41.9	13	11
3b	4.3	6	35 0	30.1	8	22.8	1.67	45.2	20	8
3b10.2	10.2	12	35 0	30.1	0	0	1.01	1	n/a	n/a
3c	4.3	6	14 0	32.5	3	21.4	1.35	29.7	5	1
3d	4.3	6	12 0	28.5	2	16.6	1.4	32.5	5	2
4a	4.3	3	12 0	30.1	1	8.3	1.67	28	7	3
4a10.2	10.2	12	12 0	30.1	0	0	1.01	1	n/a	n/a
4b	4.3	3	12 0	30.1	0	0	1.1	36.4	2	1
4c	4.3	3	12 0	30.1	0	0	1.36	18.7	4	1
4d	4.3	3	12 0	30.1	0	0	0.94	19	0	0
4e	4.3	3	12 0	30.1	0	0	1.34	18	4	1
4f	4.3	3	12 0	30.1	0	0	0.92	17.7	0	0
5a	4.3	6	19 19	31.5	4	10.5	1.31	28.5	11	4
5b	4.3	6	11 0	32	0	0	1.04	1	0	0
6	6	6	15 14	32.9	1	3.4	1.22	21.1	3	0
610.2	10.2	24	15 14	32.9	0	0	0.89	1	n/a	n/a
7a	6.5	3	11 0	28.2	4!!	36.3	1.78	25.6	8	6
7b	6.5	3	11 0	28.2	2	18.2	1.78	25.6	8	4
8a	6.5	3	29 11	32.4	7	17.5	1.78	25.6	20	13
8b	6.5	3	30 11	32.6	10!	24.4	1.78	25.5	22	17
9a	6.5	3	15 9	32.1	1	4.1	1.78	25.6	12	7
9b✓	6.5	3	14 9	33.8	2!	8.7	1.78	25.6	6	1
9c	4.3	3	9 2	34.8	3	27.3	1.66	25.6	5	4
9d✓	4.3	3	6 1	36.4	0	0	1.66	24.7	2	0
9e✓	4.3	3	7 0	34.5	0	0	1.46	21.4*	2	0
10	10.11	3	14 5	31.7	1	5.2	1.22	17	6	3
11a✓	4.3	4	16 12	33.2	3	10.7	1.85	38.5	9	4
11b	6.5	2	1 3	39.5	0	0	1.75	18.2	1	0
P I✓	4.3	4	35 14	29.4	9	18.3	1.87	41.7*	24	2
P II✓	4.3	4	38 12	32.2	0	0	1.85	40.8*	15	3
P III✓	4.3	4	8 2	29.4	2!	20	1.92	43.4*	2	1
P IV✓	4.3	4	50 15	30.4	8	12.3	1.9	42.8*	26	9
V-1✓	4.3	4	7 3	31.2	3	30	1.99	43.9*	6	2
V-2✓	4.3	4	2 2	42	1!	25	2.02	42.7*	4	2
V-3✓	4.3	4	39 11	36.9	7	14	1.86	41.3*	25	5
V-4✓	4.3	4	4 3	31.1	3	42.8	1.75	35.8*	3	1
V-5✓	4.3	4	38 11	32.1	2	4.1	1.73	36.3*	14	8
Nuc-1	4.3	4	16 5	36.4	4	20.0#	1.85	40.8*	13	6
Nuc-3✓	4.3	4	32 9	36	2	4.8	1.85	40.9*	11	4

P2 is the ambient pressure in the altitude chamber, ! one case was classified as Type II DCS; !! 2 were classified as Type II DCS. n/a is not applicable since monitoring for VGE was not performed. *prebreathe included prescribed exercise, all others were resting during prebreathe. # one case of LVGE in Nuc-1 was removed early so total count for %DCS = 20. ✓ indicates tests done with no ambulation at P2.

Table F2 –Type II Details from NASA-Funded Research

Test	ID	Mean TR360	Mean BGI360
2b	18-02	1.74	64.7
7a	123-01	1.78	25.6
7a	121-01	1.78	25.6
8b	149-01**	1.78	25.5
9b	182-01	1.78	25.6
Phase III	D980714C	1.92	43.4*
Phase V-2	D030327A	2.02	42.7*

*prebreathe included prescribed exercise, all others were resting during prebreathe.

**only sign of DCS was skin mottling, considered Type II DCS at the time but not now.

Table F3 shows a summary of Type I and 2 DCS associated with TR360. For reference, a TR360 of 1.7 is computed after a 240 min 100% O₂ prebreathe prior to 4.3 psia exposure. Data were selected based on exercise as part of the exposure, time at altitude ≥ 2 hours, altitude ≥ 3.5 psia or ≤ 6.0 psia, prebreathe ≥ 3 hours, results in computed PN2360 ≤ 8.2 psia (this excludes the NASA tests done at 6.5 psia where 4 of 5 cases of Type II occurred, serious DCS had to be recorded in the literature report, and enough detail about the prebreathe and ascent conditions had to be provided. This selection resulted in 83 records with 1,362 exposures (1,306 male and 56 female). There were 6 cases of serious DCS and 258 total cases of DCS (all DCS). One conclusion is that serious DCS did not occur at TR360 < 1.70.

Table F3: Literature Survey of Type II Cases Associated with TR360

n	serious	DCS	%DCS	location	TR360	Altitude (psia)	Time @ altitude (min)
26	1	11	42.3	Allen*	2.157	3.5	180
22	1	6	27.2	NASA, 2b	1.74	4.3	240
14	1	8	57.1	**Vann	1.77	4.3	240
18	1	8	44.4	Vann	1.77	4.3	240
10	1	2	20	Vann	1.70	4.3	240
15	1	5	33.3	Vann	1.77	4.3	240
Total 105	Total 6	Total 40	Average 38.1%	---	---	---	---
Total 1257	Total 0	Total 218	Average 17.3%	---	1.68 ± 0.33 SD	4.1 ± 0.52 SD	198 ± 75 SD

*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.

**Vann RD, Gerth WA. Factors affecting tissue perfusion and efficacy of astronaut denitrogenation for extravehicular activity. *F.G. Hall Hypo / Hyperbaric Center, Duke University Medical Center, Durham NC, March 31, 1995.*

Table F4 shows examples of long exposures > 360 min with minimum prebreathe that drive out large %DCS but no serious DCS cases reported. Even 60 to 120 min of prebreathes were effective for serious DCS in these few long-duration tests. The selection resulted in 7 tests with 241 exposures and 156 cases of DCS but no serious DCS reported.

Table F4: Literature Survey of Type II Cases Associated with Exposures > 360 min

report	expos	PB (min)	PN2360 (psia)	TR360	P2 (psia)	exer	Alt time (min)	DCS cases	%DCS	Serious cases
Allen, 41	36	120	9.05	1.81	5.0	1	540	18	50.0	0
Allen, 42	32	120	9.05	1.81	5.0	1	540	3	9.3	0
Olson, 256	82	60	10.15	2.07	4.90	1	480	64	78.0	0
Webb, 260	25	66	10.04	1.84	5.46	1	480	21	84.0	0
Webb, 261	38	66	10.04	2.28	4.40	1	480	30	79.0	0
Krutz, 262	14	66	10.04	2.28	4.40	0	480	8	57.0	0
Krutz, 263	14	66	10.04	2.28	4.40	1	480	12	86.0	0

Table F5 shows a summary of Type I and 2 DCS associated with 6-hour tests with long prebreathe. Data were selected based on exercise as part of exposure, exposure time ≥ 360 min, $P2 \geq 3.5$ psia and ≤ 6.0 psia, and $PN2360 \leq 8.2$ psia – this selection produced only 6-hour tests. The selection resulted in 16 tests with 337 exposures and 51 cases of DCS but no serious DCS reported. These are examples of 6-hour tests with long prebreathe that drive out low %DCS and no serious DCS cases reported.

Table F5: Literature Survey of Type II Cases Associated with Long Prebreathe and 360-minute Exposures

Report	Expos	PB (min)	PN2360 (psia)	TR360	P2 (psia)	exer	Alt time (min)	DCS cases	%DCS	Serious cases
Chadov, 157	69	complex	7.77	1.83	4.25	1	360	0	0	0
Chadov, 158	51	complex	8.04	1.89	4.25	1	360	1	2.0	0
Waligora, 212	28	60	6.89	1.60	4.30	1	360	6	21.0	0
Conkin, 213	14	complex	5.81	1.35	4.30	1	360	3	21.0	0
Conkin, 215	35	complex	7.16	1.66	4.30	1	360	8	23.0	0
Conkin, 217	12	complex	6.06	1.42	4.30	1	360	2	16.0	0
Waligora, 237	19	375	5.63	1.31	4.30	1	360	1	5.0	0
Waligora, 238	19	375	5.63	1.31	4.30	1	360	3	16.0	0
Waligora, 239	11	495	4.47	1.04	4.30	1	360	0	0	0
Conkin, 241	15	complex	7.36	1.27	6.00	1	360	1	7.0	0
Conkin, 243	14	complex	7.36	1.27	6.00	1	360	0	0	0
Genin, 291	12	complex	6.77	1.75	3.87	1	360	1	8.3	0
Kazakova, 306	11	330	6.14	1.75	3.50	1	360	8	72.7	0
Kazakova, 307	6	480	4.60	1.31	3.50	1	360	4	66.6	0
Kazakova, 308	6	300	6.51	1.86	3.50	1	360	4	66.6	0
Kazakova, 309	15	360	5.80	1.65	3.50	1	360	9	60.0	0

Table F6. Appendix C Data from: Conkin J. Evidence-based approach to the analysis of serious decompression sickness with application to EVA astronauts. NASA Technical Publication 2001-210196, January 2001.

Number of male subjects	Number of serious DCS cases	Cumulative risk computed from Eq. 4	Literature reference for data
11	0	0.0000221	67
20	0	0.0000311	24
54	0	0.0000599	24
7	0	0.0000613	30
12	0	0.0000805	17
343	0	0.0001117	11
57	0	0.0001126	24
17	0	0.0001553	17
19	0	0.0001592	67
33	0	0.0002140	47
8	0	0.0002528	17
11	0	0.0002623	55
12	0	0.0003011	18
12	0	0.0003014	18
9	0	0.0003041	19
2	0	0.0003299	50
12	0	0.0003312	18
19	0	0.0003356	19
14	0	0.0003562	50
4	0	0.0003663	18
17	0	0.0004067	46
33	0	0.0004119	47
6	0	0.0004713	28
25	0	0.0004923	24
30	0	0.0005199	24
379	0	0.0005257	60
65	0	0.0005257	60
10	0	0.0006456	54
15	0	0.0006963	46
52	0	0.0007049	24
14	0	0.0007335	17
6	0	0.0007447	28
169	0	0.0007592	60
80	0	0.0007592	60
2	0	0.0007707	10
19	0	0.0007984	46
29	0	0.0008692	45
28	0	0.0008937	67
19	0	0.0009187	46

Number of male subjects	Number of serious DCS cases	Cumulative risk computed from Eq. 4	Literature reference for data
92	0	0.0011149	60
156	0	0.0011149	60
33	0	0.0011359	47
17	0	0.0011393	12
31	0	0.0011900	24
9	0	0.0012870	54
6	0	0.0012870	54
7	0	0.0012870	54
54	0	0.0013241	24
12	0	0.0013351	23
23	0	0.0014542	67
7	0	0.0014542	65
16	0	0.0014542	65
10	0	0.0014542	65
9	0	0.0014542	65
10	0	0.0014542	65
12	0	0.0014542	65
10	1*	0.0014542	65
12	0	0.0014841	23
11	0	0.0014888	21
31	0	0.0016031	3
12	0	0.0016620	23
8	0	0.0017443	40
29	0	0.0018096	45
137	0	0.0018110	3
70	0	0.0019010	46
14	1**	0.0020534	65
8	0	0.0020534	65
18	1***	0.0020534	65
15	1****	0.0020534	65
11	0	0.0020534	65
10	0	0.0020534	65
11	0	0.0021070	17
6	0	0.0021483	4
116	0	0.0021483	4
6	0	0.0021632	69
11	0	0.0021736	70
12	0	0.0021736	70
12	0	0.0021736	70
12	0	0.0021736	70
12	0	0.0021744	70
20	0	0.0021931	27
12	0	0.0022104	23
33	0	0.0022975	47
15	0	0.0023138	18
12	0	0.0023795	70

Number of male subjects	Number of serious DCS cases	Cumulative risk computed from Eq. 4	Literature reference for data
16	0	0.0026148	25
16	0	0.0027148	40
33	0	0.0029726	3
10	0	0.0029937	45
71	0	0.0030242	60
245	0	0.0030242	60
17	0	0.0031507	44
10	1	0.0031617	30
5	0	0.0032571	9
5	0	0.0033582	7
9	0	0.0034521	40
12	0	0.0035851	18
12	0	0.0035879	18
12	0	0.0036410	20
14	0	0.0037336	39
10	0	0.0038969	65
10	0	0.0038969	65
35	0	0.0040997	17
20	0	0.0041304	9
20	0	0.0042329	61
10	0	0.0042690	71
12	0	0.0043211	18
65	0	0.0043674	60
144	0	0.0043674	60
22	NASA 1+	0.0044859	17
19	0	0.0045711	25
13	0	0.0046881	20
9738	19	0.0046882	49
12	0	0.0046883	20
15	0	0.0046885	20
26	1	0.0048661	3
10	0	0.0049007	45
31	0	0.0051126	26
31	0	0.0051133	26
10	0	0.0051670	71
18	0	0.0051889	1
32	0	0.0052850	26
9	0	0.0053272	2
10	0	0.0054088	20
11	0	0.0054088	20
10	0	0.0054089	20
43	0	0.0054927	69
3	0	0.0055450	17
4337	26	0.0055902	49
46683	327	0.0057076	49

Number of male subjects	Number of serious DCS cases	Cumulative risk computed from Eq. 4	Literature reference for data
13	0	0.0061861	17
17	0	0.0062445	20
143	0	0.0064134	60
122	0	0.0064134	60
5	0	0.0065557	7
17	0	0.0066437	44
17	0	0.0067401	44
10	0	0.0068550	71
4	0	0.0070485	48
6	0	0.0072742	16
29	0	0.0075382	4
21	0	0.0075683	22
11	0	0.0080222	45
8	0	0.0081807	12
29	0	0.0081995	4
25	0	0.0085500	69
29	0	0.0085567	4
117	0	0.0087149	33
29	0	0.0087802	4
12	0	0.0090126	23
10	0	0.0092788	71
62	0	0.0101890	34
62	0	0.0101890	32
11	0	0.0117627	19
11	NASA 2++	0.0117627	19
68	0	0.0119851	8
15	0	0.0121555	55
59	NASA 0+++	0.0121555	41
14	NASA 1++++	0.0121555	55
22	0	0.0123891	22
42	0	0.0135366	52
14	0	0.0135366	2
23	0	0.0136429	51
23	0	0.0136429	51
195	0	0.0142129	33
82	0	0.0149730	53
143	0	0.0152264	8
4	0	0.0157824	12
83	0	0.0161814	15
100	0	0.0162003	32
585	0	0.0182575	59
434	0	0.0182575	64
24	1	0.0182826	62
126	0	0.0182826	63
15	0	0.0185912	8

Number of male subjects	Number of serious DCS cases	Cumulative risk computed from Eq. 4	Literature reference for data
35	0	0.0188430	3
23	3	0.0200716	56
23	3	0.0200716	56
50	0	0.0204305	38
35	2	0.0207115	66
55	8	0.0207115	66
128	0	0.0209092	32
38	0	0.0214761	69
14	0	0.0214761	39
90	0	0.0217385	35
90	0	0.0217385	35
17	0	0.0225183	44
27	0	0.0227023	72
27	5	0.0227023	30
13	0	0.0232692	29
8	0	0.0234289	9
20	0	0.0237584	9
21	0	0.0237584	9
24	2	0.0240438	57
24	5	0.0240438	57
36	0	0.0241504	23
14	0	0.0245397	29
180	1	0.0254102	32
14	0	0.0269339	44
7664	145	0.0270627	49
27	5	0.0283400	31
27	5	0.0283400	31
14	2	0.0290479	29
93	0	0.0298568	32
78	0	0.0300170	8
35	0	0.0308453	3
14	3	0.0309177	48
29	0	0.0310131	4
14	1	0.0321544	44
5	0	0.0323172	7
145	0	0.0325107	32
6	0	0.0347234	4
49	0	0.0352455	64
25	0	0.0358841	12
18	0	0.0382146	44
15	1	0.0387692	44
18	0	0.0387692	44
15	0	0.0387731	36
204	4	0.0415954	32
50	0	0.0427898	38

Number of male subjects	Number of serious DCS cases	Cumulative risk computed from Eq. 4	Literature reference for data
105	1	0.0427898	38
84	0	0.0454109	59
77	6	0.0455288	35
121	12	0.0459043	5
112	18	0.0459043	5
223	11	0.0532187	32
23	7	0.0537845	56
23	3	0.0537845	56
33	3	0.0587407	12
27	3	0.0608337	72
27	0	0.0608337	72
27	3	0.0608337	30
14	1	0.0623528	29
14	1	0.0623528	29
29	2	0.0624716	68
14	0	0.0625533	29
24	8	0.0644286	57
24	8	0.0644286	57
94	20	0.0853625	14
29	11	0.1022634	68
29	10	0.1213644	68
21	1	0.1244325	73
12	0	0.1315500	23
24	5	0.1630117	58
24	6	0.1630117	58
27	2	0.1630117	31
14	4	0.1670823	29
14	1	0.1670823	29
14	1	0.1670823	29
14	2	0.1670823	29
50	3	0.1790864	37
29	13	0.2158145	68
167	60	0.2230230	13
90	36	0.2257103	14
136	44	0.2257103	14
118	12	0.2260429	43
36	2	0.2640416	6
204	12	0.2748659	42
29	8	0.5882192	68

* from Duke University (1995), numbness in right hand that appeared 1 hr into test, and cleared on descent from 4.3 psia to site pressure. No hyperbaric treatment provided.

** from Duke University (1995), dizziness, nausea, and hot flash in head. No hyperbaric treatment provided.

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

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

+ 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 2 hr of ground level oxygen.

++ from NASA/JSC (1989), first case reported pain in right knee, headache, and later blurred vision. No hyperbaric treatment provided, but 2 hr of ground level oxygen. Second case reported pain in hands, pain in right knee, then later pain behind right eye with throbbing headache. Treatment Table 6 provided.

+++ from NASA/JSC (1990), classified as Type II based only on skin mottling on right side of chest 2 hr into exposure, but not counted as serious DCS in this analysis. Treatment Table 5 provided.

++++ from NASA/JSC (1992), had skin mottling on chest during test plus hypotension on standing after test, which may have been due to an extensive bed rest period. Treatment Table 5 provided.

Threshold of Serious DCS at Low r_c

at $r_c \leq 0.0045$ there are 109 tests with total exposures = 3,687. There are six tests with serious DCS:

exposures	serious	serfrac	r_c	institution
4-hr PB, 6-hr no exercise at 4.3 psia			0.000254	computed from model
10	1	10%	0.00145	Duke, 1995
4-hr PB, 6-hr exercise at 4.3 psia			0.00146	computed from model
14	1	7.1%	0.00205	Duke, 1995
18	1	5.5%	0.00205	Duke, 1995
15	1	6.7%	0.00205	Duke, 1995
10	1	10%	0.00316	NRC Comm. on Aviat. Med., 1943
22	1	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