Navy Experimental Diving Unit
321 Bullfinch Rd
Panama City, FL 32407-7015

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Authors: Doggett, Travis M.
Hickey, Bradley W.
Jewell, Jennifer, A.

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Jewell, Jennifer A.

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14. ABSTRACT The U.S. Navy's premier tactical aircraft platforms, the F/A-18 and EA-18G, are experiencing physiological episodes (Phys Eps) of unexplained rapid cockpit pressure fluctuations. Some of these Phys Eps have resulted in Naval Aviator injuries collectively termed Physiological Events (PEs). According to the current Clinical Practice Guidelines, Aviation PEs occurring in the presence of rapid cockpit pressure fluctuations often result in aviators and aircrew being treated with hyperbaric oxygen therapy. Unfortunately, because the root cause remains elusive, it is unclear what pathology is being treated with hyperbaric oxygen. The Navy Experimental Diving Unit (NEDU) conducted the first-ever human subject research utilizing a unique purpose-built pressure vessel for human occupancy (PVHO) hypobaric chamber that could achieve rapid pressure fluctuations similar to those seen in the cockpit. The primary objective of this study was to elucidate whether manifestations resembling PEs would occur subsequent to rapid pressure oscillations in the absence of confounding factors such as breathing system resistance and to characterize any physiological symptoms that may result. Seventy human subjects were exposed to one of three randomly-selected pressure profiles provided by the NAVAIRSYSCOM F/A-18 and EA-18G Program Management Officer (PMA-265). Clinical and physiological data collected consisted of medical history and physical examinations, physiologic monitoring (heart rate, oxygen saturation, and 3-lead electrocardiogram tracings, nystagmus assessment via direct observation and eye-tracking movements, Doppler venous bubble monitoring, tympanograms, and cognitive function screening. There were no diagnosed cases of decompression sickness, arterial gas embolism, physiological events, or neurological changes secondary to exposure to the experimental rapid pressure fluctuations. Additionally, there was no evidence of a decline in cognitive function, presence of nystagmus or eye movement abnormalities to include difficulty locating visual search tasks, and no detectable venous gas bubbles (the data quality of most Doppler recordings was very poor and not interpretable). The negative findings, particularly no diagnosed Decompression Sickness (DCS) or PEs, provides important information and reassurance to Aviators, Aviation Leadership, and the Aeromedical Community that rapid pressure fluctuations in isolation are unlikely to cause significant harm to Aviators. However, the negative results of this study do not prove that rapid pressure fluctuations cannot result in PEs or DCS. With regard to DCS, the study findings are consistent with a probability of DCS of less than 5% which is consistent with the acceptable risk of approved U.S. Navy diving tables and schedules. The most advanced U.S. Navy altitude decompression model predicts a probability of much less than 1% for the experimental profiles in this study. With regard to PEs, the findings of this study suggest that PEs are not the result of rapid pressure fluctuations in isolation. This study suggests that the root cause is multifactorial and further research, particularly focused on the man-machine interface of the environmental control systems and breathing systems, is recommended.

15. SUBJECT TERMS

Physiologic Events; Physiologic Episodes; Decompression Sickness; Pressure Fluctuations

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ABSTRACT

The U.S. Navy's premier tactical aircraft platforms, the F/A-18 and EA-18G, are experiencing physiological episodes (Phys Eps) of unexplained rapid cockpit pressure fluctuations. Some of these Phys Eps have resulted in Naval Aviator injuries collectively termed Physiological Events (PEs). According to the current Clinical Practice Guidelines, Aviation PEs occurring in the presence of rapid cockpit pressure fluctuations often result in aviators and aircrew being treated with hyperbaric oxygen therapy. Unfortunately, because the root cause remains elusive, it is unclear what pathology is being treated with hyperbaric oxygen. The Navy Experimental Diving Unit (NEDU) conducted the first-ever human subject research utilizing a unique purpose-built pressure vessel for human occupancy (PVHO) hypobaric chamber that could achieve rapid pressure fluctuations similar to those seen in the cockpit. The primary objective of this study was to elucidate whether manifestations resembling PEs would occur subsequent to rapid pressure oscillations in the absence of confounding factors such as breathing system resistance and to characterize any physiological symptoms that may result. Seventy human subjects were exposed to one of three randomly-selected pressure profiles provided by the NAVAIRSYSCOM F/A-18 and EA-18G Program Management Officer (PMA-265). Clinical and physiological data collected consisted of medical history and physical examinations, physiologic monitoring (heart rate, oxygen saturation, and 3-lead electrocardiogram tracings, nystagmus assessment via direct observation and eye-tracking movements, Doppler venous bubble monitoring, tympanograms, and cognitive function screening. There were no diagnosed cases of decompression sickness, arterial gas embolism, physiological events, or neurological changes secondary to exposure to the experimental rapid pressure fluctuations. Additionally, there was no evidence of a decline in cognitive function, presence of nystagmus or eye movement abnormalities to include difficulty locating visual search tasks, and no detectable venous gas bubbles (the data quality of most Doppler recordings was very poor and not interpretable). The negative findings, particularly no diagnosed Decompression Sickness (DCS) or PEs, provides important information and reassurance to Aviators, Aviation Leadership, and the Aeromedical Community that rapid pressure fluctuations in isolation are unlikely to cause significant harm to Aviators. However, the negative results of this study do not prove that rapid pressure fluctuations cannot result in PEs or DCS. With regard to DCS, the study findings are consistent with a probability of DCS of less than 5% which is consistent with the acceptable risk of approved U.S. Navy diving tables and schedules. The most advanced U.S. Navy altitude decompression model predicts a probability of much less than 1% for the experimental profiles in this study. With regard to PEs, the findings of this study suggest that PEs are not the result of rapid pressure fluctuations in isolation. This study suggests that the root cause is multifactorial and further research, particularly focused on the man-machine interface of the environmental control systems and breathing systems, is recommended.

EXECUTIVE SUMMARY

The U.S. Navy's premier tactical aircraft platforms, the F/A-18 and EA-18G, are experiencing physiological episodes (Phys Eps) of unexplained rapid cockpit pressure fluctuations. Some of these Phys Eps have resulted in Naval Aviator injuries collectively termed Physiological Events (PEs). Although associated with rapid pressure fluctuations, the root cause of these PEs remains elusive. Additionally, the lack of understanding in the subtle differences between hypoxia, hypocapnia, and altitude decompression sickness, has hindered prompt recognition, diagnosis, and treatment of PEs. According to the current Clinical Practice Guidelines, Aviation PEs occurring in the presence of rapid cockpit pressure fluctuations often result in aviators and aircrew being treated with hyperbaric oxygen therapy. Unfortunately, because the root cause remains elusive, it is unclear what pathology is being treated with hyperbaric oxygen. The Navy Experimental Diving Unit (NEDU) partnered with the Naval Air Systems Command (NAVAIRSYSCOM) F/A-18 and EA-18G Program Management Office (PMA-265) and the Naval Surface Warfare Center - Panama City Division (NSWC-PCD) to investigate pressure-related PEs currently impacting the operational readiness of Naval Aviation. NEDU conducted the first-ever human subject research study utilizing a unique purpose-built pressure vessel for human occupancy (PVHO) hypobaric chamber. This hypobaric chamber known as the Fluctuating Altitude Simulation Technology (FAST) System is capable of replicating the rapid pressure fluctuations observed in both asymptomatic F/A-18 Phys Eps and symptomatic PEs.

The primary objective of this study was to elucidate whether manifestations resembling PEs would occur subsequent to rapid pressure oscillations in the absence of confounding factors such as breathing system resistance and to characterize any physiological symptoms that may result. Simultaneously, the study was designed to place bounds on the probability of decompression sickness (DCS) as the cause of PEs while also identifying areas and physiological symptoms worthy of future study. Seventy human subject volunteers were exposed to one of three randomly-selected pressure profiles provided by PMA-265. The pressure profiles consisted of a simulated take-off from sea-level, level flight, seven groups of rapid pressure fluctuations that included over-pressurizations and under-pressurizations, and descent back to sea-level. The maximum over-pressurization and under-pressurization excursions for all three profiles are the same with differing rates of pressure changes (maximum profile 0.8 psia/sec; nominal profile linearized based on Shock & Vibration Accelerometer Loggers (SLAMSTICK) data; and rate limited profile of 0.2 psia/sec). Clinical and physiological data collected consisted of history and physical examinations, physiologic monitoring (heart rate, oxygen saturation, and 3 lead electrocardiogram tracings), nystagmus assessment via direct observation and eye-tracking movements, Doppler venous bubble monitoring, tympanograms, and cognitive function screening.

Overall, there was no evidence of a decline in cognitive function in the subjects for any of the three pressure profiles. Using the CogScreenAH computer-based system, the Dual Task Performance test and Manikin Drill test were analyzed. The Dual Task Performance test required participants to simultaneously make judgements about whether letter and number sequences were very similar or identical while manipulating the keyboard to

maintain a cursor within a target zone. The Manikin Drill provides a picture of a person holding a flag. The image of the person can be a combination of facing forward/facing backward and right-side-up/upside-down. The test required subjects to mentally rotate the image of the person to determine which hand was holding a flag. Reaction time for both test battery exercises either remained unchanged or displayed a decreasing trend over the course of testing from Pre-Flight, Post-Flight, and 24hrs Post-Flight indicating an improvement in performance. Similarly, thruput, an efficiency score that provides a representation of mental processing abilities, remained either unchanged or exhibited an improving trend throughout testing from Pre-Flight to 24 hours Post-Flight. Interestingly, all subjects took the CogScreenAH test battery at least twice prior to each experimental exposure therefore these results are not indicative of improvement secondary to the practice effect. Visual search tasks and defined passage recital durations and fixations remained unchanged or demonstrated an improving trend from Pre-Flight to Mid-Flight for all three profiles. Additionally, no nystagmus was seen among the subjects via direct observation during experimental exposure or from the retrospective eye tracking data analysis. Most importantly, no decompression sickness (DCS), arterial gas embolism (AGE), neurological changes, or PEs were observed within 48 hours of experimental exposure. With regard to the evaluation of PEs, the following signs and symptoms were directly elicited: a feeling of cognitive slowing or being “off”; clumsiness; feeling of euphoria; disorientation; skin rashes; light headedness; vertigo; dizziness; sensation of disequilibrium; unexplainable fatigue; unexplainable nausea; difficulty breathing; vision changes; memory difficulties; difficulties communicating; anxiousness; symptoms similar to DCS I/II or AGE; personality changes; or changes in thought processes. These elicited signs and symptoms are consistent with the current clinical practice guidelines for the evaluation of possible Aviation PEs.

Although exploratory in nature, the results of this study support the expert consensus of NEDU scientists and physicians that DCS is unlikely to be the underlying pathophysiology of Aviation PEs. The negative findings of the study, particularly no diagnosed DCS or PEs, provides important information and reassurance to Aviators, Aviation Leadership, and the Aeromedical Community that rapid pressure fluctuations in isolation are unlikely to cause significant harm to Aviators. However, the negative results of this study do not prove that rapid pressure fluctuations cannot result in PEs or DCS. With regard to DCS, the study findings are consistent with a probability of DCS of less than 5% which is consistent with the acceptable risk of approved U.S. Navy diving tables and schedules. The most advanced U.S. Navy altitude decompression model predicts a probability of much less than 1% for the experimental profiles in this study. With regard to PEs, the findings of this study suggest that PEs are not the result of rapid pressure fluctuations in isolation. Rather, the root cause of PEs is likely multifactorial and further research, particularly focused on the man-machine interface of the environmental control systems and breathing systems, is recommended. A natural extension of this research would be the coupling of the FAST System with the actual life-support systems including the On Board Oxygen Generation System (OBOGS) and pilot masks/regulators.

This was an unprecedented exploratory human subject research study investigating rapid pressure fluctuation Physiologic Episodes associated with aviation PEs. In addition to the study findings, an important contribution was the development and validation of the FAST System. The FAST System has provided the U.S. Navy with an invaluable new research capability for future unmanned and manned research. It is recommended that the FAST System be incorporated in future PE testing when possible.

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The authors are grateful to the active duty service members who graciously volunteered as human subjects for this experimental study. Their acts of volunteerism demonstrate the core values of the United States Navy! We sincerely appreciate the time, energy, and support of the military and civilian personnel at the Navy Experimental Diving Unit, the NAVAIRSYSCOM F/A-18 and EA-18G Program Management Officer, and the Naval Surface Warfare Center Panama City Division. Finally, the authors would like to specifically thank those NEDU military and civilian personnel who volunteered their time and expertise immediately following Hurricane Michael in October 2018. These men and women acted as essential personnel during a mandatory evacuation period in order to ensure the critical findings of this study could be delivered to the Aviation community on target, on time!

CONTENTS

FIGURES & TABLES

Table No. Page No.

ABBREVIATIONS, ACRONYMS, AND SYMBOLS

AGE	Arterial Gas Embolism
AI	Associate Investigator
BMI	Body Mass Index
CNS	Central Nervous System
DCS	Decompression Sickness
ECG	Electrocardiogram
FAST	Fluctuating Altitude Simulation Technology
GLO	Ground Level Oxygen
HBO	Hyperbaric Oxygen
HM	Hospital Corpsman
IRB	Institutional Review Board
NAE	Naval Aviation Enterprise
NAVAIR	Naval Air Systems Command
NSA	Naval Support Activity
NEDU	Navy Experimental Diving Unit
NSWC-PCD	Naval Surface Warfare Center – Panama City Division
OBOGS	On Board Oxygen Generation System
PE	Physiological Event
Phys Ep	Physiological Episode
PI	Principal Investigator
PMA-265	F/A-18, EA-18G Program Office
PVHO	Pressure Vessel Human Occupancy
RCCA	Root Cause and Corrective Action
UMO	Undersea Medical Officer
VGE	Venous Gas Embolism
VST	Visual Search Task

INTRODUCTION

The Naval Aviation Enterprise (NAE) defines a Physiological Episode (Phys Ep) as an event where an aviator/aircrew has a loss in performance related to insufficient oxygen, cockpit pressure fluctuations, depressurization, or other factors during flight. The Phys Eps associated symptomology or injury in the presence of rapid cockpit pressure fluctuations have been classified as Physiological Events (PEs). The Chief of Naval Operations labeled PEs the top safety priority of naval aviation and the U.S. Navy[1]. Navy Air Boss VADM Shoemaker said, "PEs are a complex problem set that have challenged our ability to determine root cause for the failures and we aren't there yet. This is the NAE's number one safety priority and focus area and we are taking a 'resource unconstrained' approach to the problem[2]."

In 2010 the number of hazard reports related to PEs increased compared to the previous years, and have continued to rise sharply each year since 2012. PE reports in T-45s increased from 13 in 2012 to 38 in 2016. F/A-18 reports of PEs increased from 57 in 2012 to 114 in 2016[2]. Some of the increase in reported PEs can be credited to increased awareness regarding the PE phenomenon; however, the root cause of the problem has not been identified[2].

The majority of PEs occur in two airframes: the T-45 Goshawk advanced trainer, and the F/A-18 tactical aircraft (the A/B/C/D Legacy Hornets and E/F/G Rhino Hornets). The problem is not isolated to the U.S. Navy and Marine Corps as the Hornet airframe is utilized by a number of our allied partners' air forces including the Royal Australian Air Force and the Royal Canadian Air Force [2].

Currently, there are two broad catagories of PEs: one with decompression sickness (DCS)-like symptoms following cockpit pressure pertubations resulting from the aircraft cockpit pressurization system not operating as designed; another with various hypoxia-like symptoms associated with the breathing air supply system not providing adequate air volume, oxygen concentration, or purity[2].

While some PEs have been attributed to breathing problems, the majority of serious PEs have been associated with the aircraft cockpit pressurization system and cockpit pressure malfunctions[2]. The cockpit air pressure at typical cruising altitudes, 36000 – 40000 ft. above mean sea level (MSL), is equivalent to 10.92 psia or 8000 ft. MSL. The majority of reported cockpit pressure malfunctions consist of rapid fluctuations of cockpit pressure between 13.17 – 8.29 psia (3000 – 15000 ft.) from the baseline of 10.92 psia over a span of a 15 – 20 seconds. The reported cockpit pressure fluctuations are typically rapid with a max cockpit under-pressurization of approximately 8.29 psia (15000 ft.) and a max cockpit over-pressurization of approximately 13.17 psia (3000 ft.).This prompted a change to the "Naval Aviation Training and Operating Procedures Standardization" in 2016 requiring execution of emergency procedures after unexplained cockpit altitude changes equivalent to ±2000 feet of altitude[2].

NAVAIR and the NAVAIRSYSCOM F/A-18 and EA-18G Program Management Office (PMA-265) have been collecting cockpit pressure data within the cockpit of F/A-18s via Shock & Vibration Accelerometer Loggers (SLAMSTICKS). The Navy Experimental

Diving Unit (NEDU) has analyzed the data obtained from these SLAMSTICKS and calculated the probability of DCS (P_{DCS}) risk using modeling systems of decompression sickness based upon manned data[9]. In a brief to Navy Aeromedical Leadership demonstrating the exceedingly small risk of DCS and the minimal difference between two distinct flights, data from asymptomatic/nominal flight had a calculated P_{DCS} of 0.0003% while data from flight resulting in a PE had a calculated P_{DCS} of 0.0055%[9,10,11,12] (Appendix A, Fig. A1-4). For comparison, US Navy normal exposure diving P_{DCS} range from 2 to 5%[3]. In other words, the risk of DCS during a flight with rapid pressure fluctuations in the cockpit is exceedingly low based upon the DCS model currently utilized by the U.S. Navy.

To date, the root cause of the PEs remains elusive. Additionally, the lack of understanding of the subtle differences between hypoxia, hypocapnia, and altitude decompression sickness has hindered prompt recognition, diagnosis, and treatment of PEs. According to the current Clinical Practice Guidelines for Aviation PEs occurring in the presence of cockpit pressure fluctuations, aviators, aeromedical personnel, and aircrew diagnosed with a PE are often prescribed hyperbaric oxygen therapy (e.g. U.S. Navy treatment table 6). Unfortunately, because the root cause of the PE remains elusive, it is unclear what pathology is being treated with hyperbaric oxygen. Nonetheless, hyperbaric oxygen therapy is now considered the "standard of care" for the treatment of Aviation PEs. The use of therapeutic hyperbaric treatment for PEs is so prevalent that the Navy currently deploys recompression chambers on all aircraft carriers[4].

For this study, a Physiological Episode (Phys Ep) is defined as one of the following signs or symptoms as described in the current clinical practice guidelines for the evaluation and treatment of Aviation PEs:

A) One or more objective neurologic findings occurring during flight or within 48 hours after flight.
B) Manifestation of any of the following signs and symptoms:

1. A feeling of cognitive slowing, being "off", or clumsiness
2. A feeling of euphoria or elation
3. Disorientation
4. Skin rashes
5. Light-headedness, vertigo, dizziness, or sensation of disequilibrium
6. Unexplainable severe fatigue or drowsiness
7. Unexplainable severe nausea
8. Difficulty Breathing
9. Vision changes or complaints
10. Memory Difficulties or Difficulty Communicating (self-report and other party report)
11. Anxiousness / Nervousness
12. Symptoms similar to or consistent with DCS I / II or AGE
13. Unexplainable severe headache
14. Personality changes
15. Changes in thought processes

METHODS

GENERAL

NAVAIRSYSCOM PMA-265 sponsored and funded NEDU to investigate cockpit pressure fluctuations associated with recent Naval Aviation PEs in the fleet. NEDU was tasked to conduct unmanned and manned testing of pressure fluctuations involved in Naval Aviation PEs[5]. PMA-265 designed 3 pressure profiles for the study.

This first-of-its-kind rapid pressure fluctuation study was exploratory in nature. There were no proposed hypotheses tested. This study explored whether manifestations resembling PEs occurred with isolated pressure fluctuations in the absence of confounding factors such as breathing system resistance or variation in G-force. As a novel experimental study in a newly designed pressure vessel for human occupancy hypobaric chamber, the test results were not expected to provide a definitive answer to the root cause of PEs nor expected to definitely rule out decompression sickness as the cause of PEs. Rather, this first-of-its-kind study was intended to identify and characterize possible symptomology associated with rapid cockpit pressure fluctuations. The investigators acknowledged that no definitive conclusions could be made from the data collected. However, due to the operational need of the study, NEDU would strive to place bounds upon the probability of DCS, explore any symptomology that results from the experimental exposures, and possibly recommend diagnostic tests that the aeromedical community should perform as part of the clinical work-up of suspected PEs (i.e., cognitive assessments, tympanograms for barotrauma). Furthermore, this exploratory protocol was likely to provide new avenues of research and to provide human subject data in support of future hypothesis generation. The following data was collected from test subjects and described in this Technical Report:

1. Medical history and physical examinations
2. Physiologic monitoring: heart rate, oxygen saturation, and 3-lead electrocardiogram tracings
3. Eye tracking movements
4. Doppler venous bubble monitoring
5. Tympanograms
6. Cognitive screening with the CogScreenAH computer-based examination
7. Direct visual observation

EXPERIMENTAL DESIGN AND ANALYSIS

Research subjects were exposed to simulated “flights” in the Fluctuating Altitude Simulation Technology (FAST) System with two subjects participating in each flight. Seventy (70) total subjects were recruited to participate in one of three pressure profiles provided by PMA-265. Distribution of subjects were divided evenly between the three flight profiles and randomly assigned to one of the three flight profiles.

Subjects were equipped with Aerox Oxysaver Nasal Cannulas for the duration of the flights. They received supplemental oxygen at a rate determined by pulse oximetry to maintain oxygen saturation of > 90%. Based on a NEDU manned Form, Fit, and Function test, this rate equated to approximately 1.2 Liter per minute (L/min). Subjects were exposed to rapid pressure fluctuations consistent with one of three pre-determined flight profiles directed by PMA-265. These flight profiles simulated a take-off (decreasing pressure), stable flight at 10.92 psia (8000 ft. MSL), a series of pressure fluctuations (over- and under-pressurizations), stable flight at 10.92 psia, and landing (increasing pressure until return to ambient pressure).

During the flight profiles, subjects positioned a Doppler probe to a pre-marked area on their pre-cordial chest to allow for the monitoring and recording of any venous gas bubbles via Doppler bubble monitors. The subjects were allowed to dress for comfort during the study and were always allowed to keep one hand free and available for middle ear clearing maneuvers if necessary. Additionally, during the flight profiles, subjects wore Tobii eye-tracking glasses that recorded eye movement. On three occasions subjects completed an eye-tracking exercise administered by study personnel. Patient physiological monitoring consisting of three lead ECG monitoring and pulse oximetry were monitored continuously throughout the flight via Welch Allyn Propaq LT monitors.

Flight Profiles

The flight profiles tested were provided by the PMA-265 Root Cause and Corrective Action Committee (RCCA). The document describing these profiles is found in Appendix D – RCCA Human Testing Pressure Profiles. The profiles were a composites based on the data collected from hundreds of SLAMSTICK recordings from fleet F/A-18 Hornet tactical aircraft. Three profiles were developed and provided to NEDU for testing: Nominal, Rate-Maximized, and Rate-Limited profile. Graphical representations of these profiles, as well as how the pressure fluctuations are grouped, are found in the following Figures 1-3. The human testing pressure profiles were built on F/A-18 aircraft representative cockpit pressure changes. These profiles exposed the research subjects to the same over- and under-pressurizations; however, the rate of pressure changes varied among the profiles. Due to the differences in pressure change rates, the flight profiles varied in length from 30 to 45 minutes. The rate of change in pressure differed between profiles as discussed below.

The Nominal profile was designed as the "average" F/A-18 performance profile currently seen in the fleet and collected from SLAMSTICKS (Fig. 1). The test begins once the FAST System has been closed and secured. The chamber pressure is gradually reduced at a rate of -0.03 psia per second (psia/s) to a pressure of 11.78 psia which corresponds to approximately 6,000 ft. The pressure remains at this value for 120 s. The pressure then moves to pressure movement groups 1, 2, and 3 (represented by the red boxes in the figure). This group is representative of aircraft climbs from 6,000 ft where the cockpit pressure environment is required to change from "unpressurized" regulation to "isobaric" regulation. At this regulation change the cockpit altitude will tend to follow aircraft altitude before pressurizing down to 8,000 ft and regulating at this pressure. Group 1 depressurizes to 10.63 psia (8,690 ft) before returning to 10.92 psia (8,000 ft) where it remains for 60 seconds. Group 2 begins by moving down to 11.78 psia (6,000 ft) where it remains for 30 seconds before it depressurizes to 9.76 psia (10,895 ft) and returns to 10.92 psia (8,000 ft) where it remains for 60 seconds. Finally, group 3 pressurizes to 11.78 psia (6,000 ft) where it remains for 30 seconds then depressurizes to 8.29 psia

(15,010ft) and returns to 10.92 psia (8,000 ft) where it remains for 60 seconds[6] (Appendix D). The rate of depressurization and pressurization for these groups will vary between the 3 overall profiles. The test will then move into the 4 remaining pressure movement groups which again have been pulled from the F/A-18 population. Groups 4, 5, and 6, are linearized representations of actual cockpit pressure changes. Group 7 is also a linearized representation; however, the pressure values have been shifted by a constant in order to allow the movements to occur within the test environment. The pressure rates of change for Groups 4, 5, 6, and 7 will vary between the 3 profiles as detailed above[6] (Appendix D). Following Group 7, the FAST System will return to ambient pressure at a gradual rate of 0.03 psia/s.

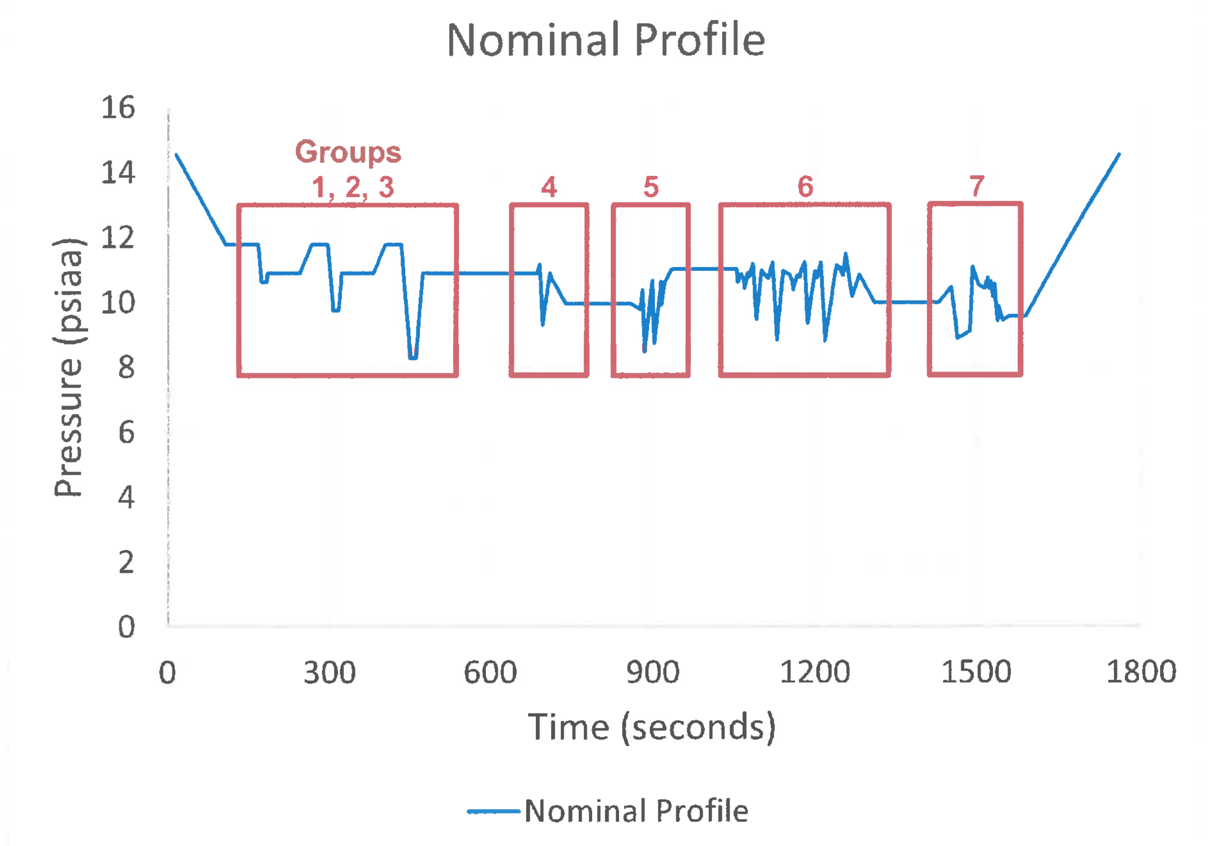


Figure 1: Nominal Profile

The Rate-Limited profile is identical to the nominal profile (Fig. 2). It possesses the same groups and number of pressure fluctuations and also features the same altitudes, both high and low elevation. However, the rates of change in pressure/altitude are limited to the mil standard 18927E[7]. This is the current standard, however, not the standard to which the F/A-18 was designed. Pressure rates of change are limited to between -0.2 and +0.2 psia/s[6] (Appendix D).

Figure 2: Rate-Limited Profile

The Rate-Maximized profile contains the same 8 groups of cockpit pressure movements covered in the Nominal profile (Fig. 3). It possesses the same groups and number of pressure fluctuations and also features the same altitudes, both high and low elevation. For Groups 1, 2 and 3 the pressure rate of change has been increased to that of a worst case representative cockpit pressure rate of change for this pressure feature. For Groups 4, 5, 6, and 7 the pressure rates of change have been increased to correspond to the maximum pressure rate of change that existed in or original aircraft pressure movement before it was linearized. Maximum rates of changes in pressure within this profile are 0.8 psia/s[6] (Appendix D).

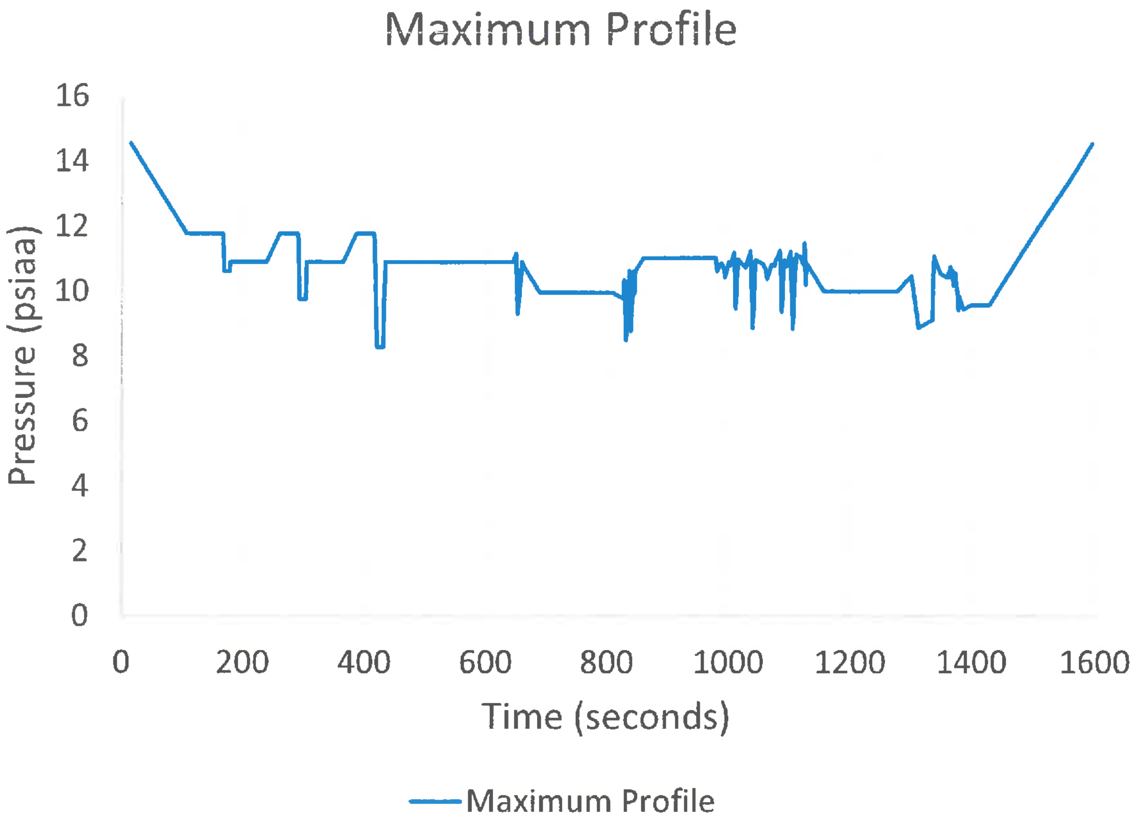


Figure 3: Rate-Maximized Profile

Classification of Experimental Outcomes

Classification of DCS

There is no gold standard test for DCS and no generally accepted case definition for DCS. As such, the diagnosis of DCS was clinically based. The Research Monitors at NEDU were responsible for the diagnoses and treatment of all PEs which may have included DCS. For research purposes, a retrospective analysis of any cases of DCS would be completed after completion of the study. A panel of at least 3 Undersea Medical Officers (UMO) would perform the analysis and determine whether it was more likely than not a case of DCS. In the final reporting of the study, any diagnosed cases of DCS would be reported in these two categories: more likely than not; unlikely.

Classification of Venous Gas Emboli (VGE) via Doppler Ultrasound

The classification of VGE via Doppler ultrasound for this study was planned to be based upon subjective grading scales of frequency and amplitude of signal[13]. For this study, the frequency and amplitude grade would not be combined into an overall grade. In a case of discordant data, the highest grading was to be used. To prevent the reporting of false positives or negatives in the final report, a subject matter expert experienced in grading Doppler recordings was available at NEDU to assist grading recordings that are difficult to classify. The grading of VGE was to be completed retrospectively via recordings.

Table 1: VGE Frequency Grading Scale

GRADE	FREQUENCY (# bubbles per cardiac period)
0	0
1	1-2
2	Several (3-8)
3	Rolling drumbeat (9-40)
4	Continuous sound

Table 2: VGE Amplitude Grading Scale

GRADE	AMPLITUDE (amplitude of bubbles compared to cardiac sounds)
0	No discernable bubbles
1	Barely perceptible: $A_b<<A_c$
2	Moderate amplitude: $A_b<A_c$
3	Loud amplitude: $A_b \approx A_c$
4	Maximum amplitude (masks cardiac sounds): $A_b>A_c$

- Where “A” = amplitude
- “$_b$” = bubble sounds
- “$_c$” = cardiac sounds

Classification of Physiologic Event

Per this study, a Physiologic Event (PE) was defined as one of the following:

A. One or more objective neurologic findings occurring during flight or within 48 hours after flight.
B. Manifestation of any of the following signs and symptoms:
    1. A feeling of cognitive slowing, being “off”, or clumsiness
    2. A feeling of euphoria or elation
    3. Disorientation
    4. Skin rashes
    5. Light-headedness, vertigo, dizziness, or sensation of disequilibrium
    6. Unexplainable severe fatigue or drowsiness
    7. Unexplainable severe nausea
    8. Difficulty Breathing
    9. Vision changes or complaints
    10. Memory Difficulties or Difficulty Communicating (self-report and other party report)
    11. Anxiousness / Nervousness
    12. Symptoms similar to or consistent with DCS I / II or AGE
    13. Unexplainable severe headache
    14. Personality changes
    15. Changes in thought processes

Risks and Discomforts

As a first-of-its-kind human subjects research study into the effects of rapid cockpit pressure fluctuations on human physiology, special care was made to identify all possible side-effects, symptoms, risks, and discomforts a subject may experience. These symptoms are listed below.

Decompression Sickness (DCS). According to the most advanced NEDU altitude DCS model, the probability of DCS occurring as a result of rapid cockpit pressure fluctuations is exceedingly low (approximately <0.00001% in all of the proposed profiles). To make this probabilistic determination, the 3 Region Unstirred Tissue Multiple Bubble (3RUT-MB) model[9] of altitude decompression sickness was utilized. Additionally, the expert consensus of NEDU is that these Aviation PEs are not a result of DCS. Decompression sickness can manifest in many ways, but commonly as joint or lymph node pain, skin rash, or neurological symptoms. Any diagnosis of DCS as determined by one of the Research Monitors (UMOs) will be treated immediately using appropriate U.S. Navy treatment tables. Additional medical treatments would be administered as necessary. Immediate treatment of DCS usually results in full recovery.

Arterial Gas Embolism (AGE). Tissue damage to any organ, including the brain, may result from the passage of gas bubbles into the arterial system. This may result from alveolar rupture from any cause. Any diagnosis of AGE as determined by one of the Research Monitors (UMOs) will be treated immediately using the appropriate U.S. Navy Treatment Table, with additional medical treatment administered as necessary. Immediate and appropriate treatment usually results in full recovery.

Other risks associated with rapid pressure fluctuations and/or the hypobaric environment apply to subjects participating in this protocol and are as follows:

Barotrauma. Damage to any enclosed air-filled body space, typically the ears, nose or sinuses may occur during pressurization (squeeze) or depressurization (reverse squeeze). Barotrauma involving the ears includes risk of round or oval window rupture with subsequent short or long term symptoms of vertigo that could require surgery to repair. Subjects may use Pre-Flight decongestants if necessary and will refrain from participating in the study with congestive symptoms. Subjects will be counseled prior to the test flights to avoid forceful Valsalva or other middle ear clearing maneuvers during the pressure fluctuations. Of note, an over-pressurization of at least 5.1 psia is typically required to rupture a healthy tympanic membrane.

"Draeger Ear". The breathing of elevated levels of PO_2 in the study may cause the middle ears of subjects to become filled with gas of high oxygen content. Absorption of this oxygen after the study "flights" may cause the inner ear volumes to decrease in a fashion similar to the Boyles law-driven decreases of middle ear volumes that occur with an ear squeeze during a diving descent. This condition, popularly known as "Draeger ear," carries a risk of hearing impairment and ear infection if not alleviated by periodic equalization of the ears with air for up to 24 hours after high PO_2 breathing has ceased. In order to mitigate the risk of Draeger ear, all subjects will be instructed to perform equalizing Valsalva maneuvers periodically after each flight until the maneuvers are no longer perceived to have effect.

Hypoxia and Hypocapnia. Hypoxia may occur if the oxygen delivery system of the FAST System fails. Hypocapnia may occur if the subject hyperventilates. The risk of hypoxia in this study is considered very low because subjects will be delivered supplemental oxygen at a rate to maintain a normoxic breathing mixture. The subjects will be monitored with pulse oximeters and a built in breathing system with emergency oxygen is always available. The risk of hypocapnia is considered low because the subjects will be visually and physiologically monitored. If the subjects breathing rate is noted to be rapid, the subject will be instructed to slow down the respiratory rate.

Accidents. Mechanical failures or human errors may cause mishaps such as contamination of breathing gas, failure of life support systems, or mechanical injuries. All flights will take place in the Fluctuating Altitude Simulation Technology (FAST) System and the FAST System Operators will control the flights and monitor all flights on site. Additional personnel including research investigators will be available on site and will assist subjects at critical points Pre-Flight, during flight, and Post-Flight and in the case of an emergency.

Oxygen Toxicity resulting from Hyperbaric Therapy. While the P_{DCS} for the 3 flight profiles to be tested is exceedingly low (<0.00001%), hyperbaric chamber treatment may need to be provided. Risk of pulmonary O_2 toxicity will be elevated if a subject must be treated for DCS or AGE by administration of hyperbaric oxygen (HBO) as a standard US Navy Treatment Table 6 is associated with 633 Unit Pulmonary Toxicity Dose (UPTD) Units. Symptoms of Pulmonary oxygen toxicity include small decrements in pulmonary function, cough, or chest discomfort. These decrements, signs, and symptoms are all expected to fully recovery with time. Risk of Central Nervous System (CNS) O_2 toxicity will be elevated if a subject must be treated for DCS or AGE by administration of hyperbaric oxygen (HBO). Signs and symptoms of CNS Oxygen Toxicity include convulsions (seizure activity), visual changes, tinnitus, twitching, irritability, nausea, and dizziness. CNS Oxygen Toxicity is expected to completely resolve without any sequelae. In the event of a CNS Oxygen Toxicity sign or symptom, it would be treated in accordance with the US Navy Dive Manual and the clinical judgment of the Research Monitors.

Loss of Consciousness. The loss of consciousness or an alteration in mental status for test subjects is not expected; however, there is a specific Emergency Procedure for this unexpected scenario in the FAST Technical Manual. If this were to happen, the test flight would immediately be halted, the Emergency Procedure initiated, and the subjects would immediately be brought back to ambient pressure in a safe manner. Medical personnel would immediately be available to evaluate the test subject and initiate appropriate medical care.

Permanent Injury or Disability. All of the above risks have been mitigated to be as safe as possible. Any diagnosed PEs, DCS, or AGE are expected to fully recover without any sequelae; however, there is a risk of permanent injury or disability. Please note there are no special exemptions for this study and any permanent injury or disability may result in being disqualified for special duty and/or military service.

EQUIPMENT AND INSTRUMENTATION

The following equipment was used in conjunction with this protocol. Standard operating procedures (SOPs) for selected devices were found in appendix D of the IRB-approved protocol and provided to personnel involved in conduction of the study.

Fluctuating Altitude Simulating Technology

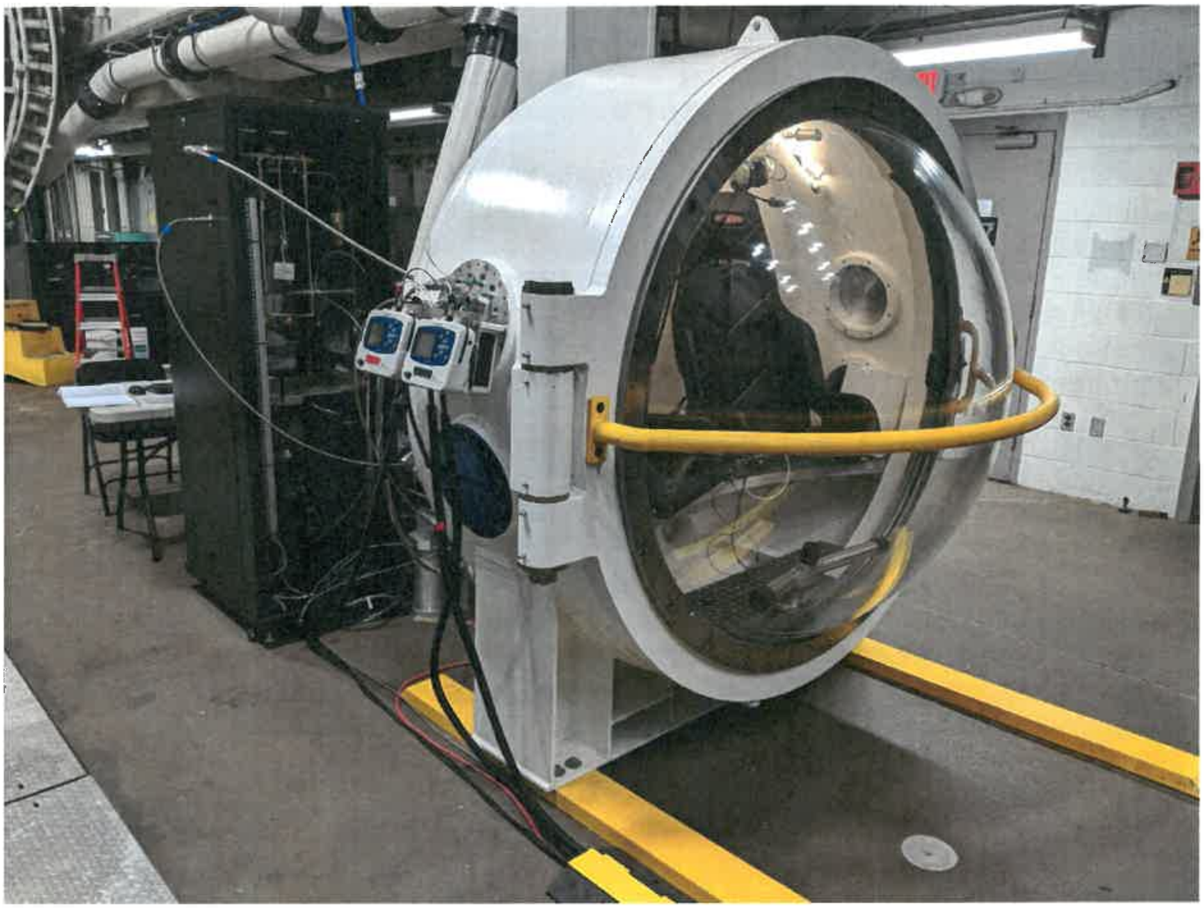


Figure 4: FAST PVHO Chamber and Control Rack (Left)

- (1) FAST System (Fig. 4).
    - (1) Double Occupant Altitude Chamber (PVHO Certified)
    - (1) Supply Air Control Rack Assembly
    - (1) System Control Computer with Monitor and Keyboard
    - (1) Exhaust Manifold Assembly
    - (1) Chamber Environmental Monitor and Laptop Recording Computer
    - (1) Bibs Emergency Oxygen Delivery System for Two Occupants
    - (1) Vacuum Volume Tank. (800 cuft)
    - (1) Kinney KT 300 Vacuum Pump
- Equipment/Consumables Supplied by the Facility to Support the FAST System

  - (1) High Pressure Air Supply (minimum of 1000 psia with 350 cfm delivery)
  - (1) Vacuum Pump Assembly (minimum of 100 cfm at 20 inHg vacuum)
  - (2) Aerox Oxysaver Cannulas [Model: 4110-701]
  - (3) Oxygen (aviator's grade) K type cylinders, minimum of 700 psia before flight
  - (1) Communication system for dual occupants (full duplex)
    - (1) AMRON Dive Comm Box [Model: 2830MS]
    - (2) David-Clark aviation headsets

CogScreenAH suite

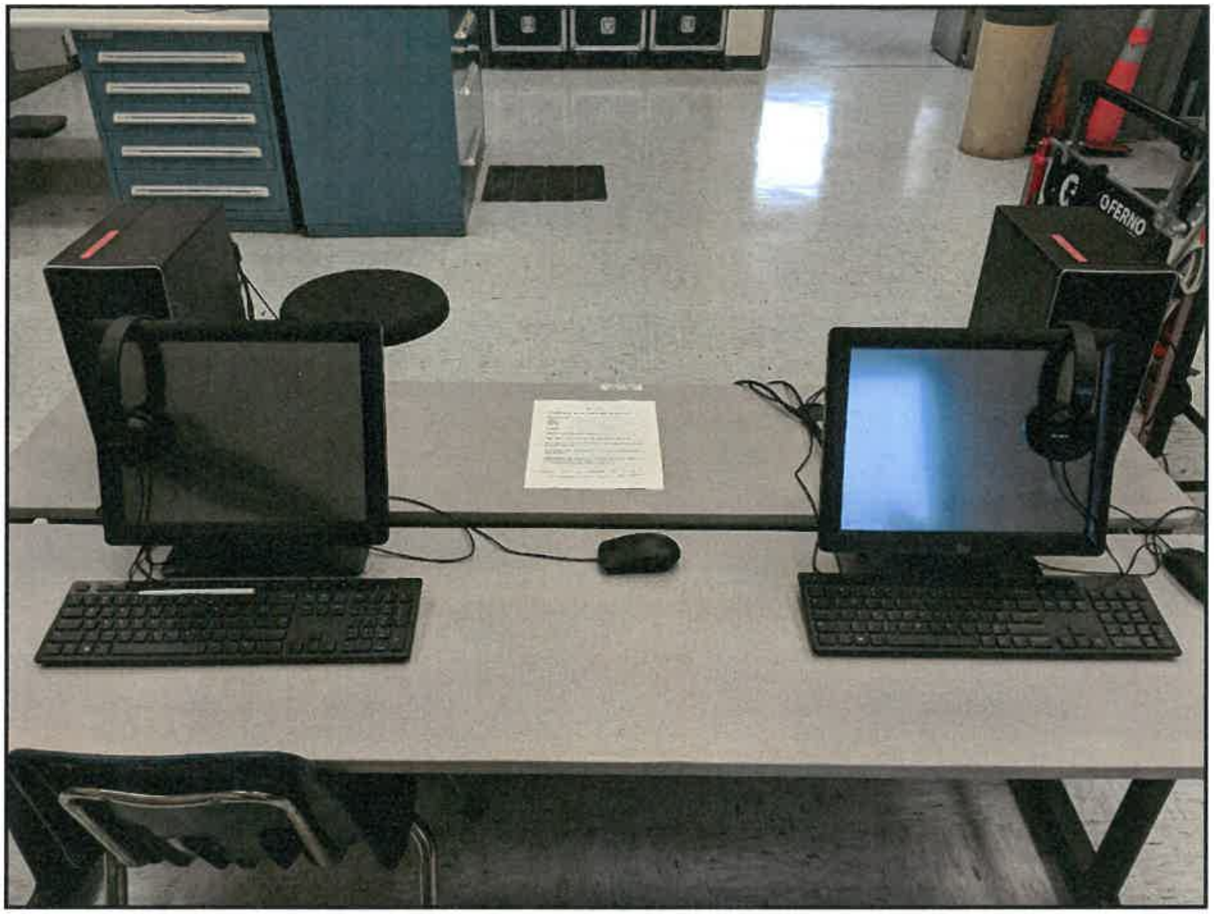


Figure 5: CogScreen Computer-Based Cognitive Testing System

- CogScreen System (Fig. 5)
  - (2) Dell computers loaded with CogScreenAH Aeromedical Edition cognitive assessment software. [Model: Inspiron 3650]
  - (2) ELO touchscreen monitors. [Model: E523163]
  - (2) Stylus pens for use with ELO touchscreen monitors.

Tobii Pro Glasses 2

Figure 6: Tobii Pro Glasses 2. Recording Unit (center), Glasses (right), and Laptop (left).

- (2) Head unit 50 Hz. [Model: TG020G-010117719454 and -010117719444]
    - Inside FAST System (Fig. 6).
- (2) Recording unit. [Model: TG020G-080107004761 and -080107015221]
    - Inside FAST System.
- (1) Dell laptop computer. [Model: Precision 7520]
    - Outside FAST System.
    - Controller and Analyzer software.
    - Connected to recording units via Cat VI 75 ft. cable potted into the FAST System.

Doppler Bubble Monitors

- (3) Techno Scientific Doppler bubble monitors [Model: DBM 9008]
    - Outside FAST System.
- (3) Audio-Technica noise canceling over-the-earphones [Model: ATH-M50x]
    - Outside FAST System.
- (3) Techno Scientific Precordial Doppler probes [Model: TSI-DP7-28]

    - Inside FAST System.
- (3) Sony Digital MP3 recorders [Model: ICD-UX560]
    - Outside FAST System.

Tympanometry

- (2) WelchAllyn Tympanometers [Model: TH286]
- (2) RadioEar over-the earphones [Model: 3045]

Propaq LT vitals monitor

- (2) WelchAllyn Propaq LT vitals monitors [Model: 802LT0S]
    - Connected via charging cradles to exterior of FAST System.
- (2) WelchAllyn ECG cable 3 attached snap-style leads [Model: 008-0880-00]
    - Potted into the FAST System.
- (6) ConMed adult diaphoretic ECG electrodes [Model: 1590-030]
- (2) Masimo LNCS DCI SpO2 reusable finger clip sensors [Model: LNC DCI]
- (2) Masimo 10 ft. extension cables (LNCS to monitor) [Model: LNC-10-DB9]

Potted into the FAST System.

PROCEDURES

Recruitment

Volunteers were solicited from within the U.S. Navy and Marine Corps with emphasis on the aviation community, particularly F/A-18 units. However, all subjects in a flight status (Flight Surgeons, Aerospace Physiologists, Aerospace Psychologists) were considered. If recruitment within the aviation community was unsuccessful for any reason or there are delays in arrival to NEDU, active duty and reserve military members from the local Naval Support Activity (NSA) Panama City region would be recruited. Subjects were solicited by email at NEDU, via announcements at NEDU, and via announcements or email (Appendix C) at other commands with appropriate permission from the respective command leadership. Volunteer recruitment occurred one on one (in-person or via phone) with the Task Leader(s) or his/her designee. Any group recruiting had an Ombudsman present.

All subjects were to be healthy, non-pregnant, active duty or reserve military adults between the ages of 18-60. Subjects were randomly assigned to a flight profile. Subjects could not be on light or limited duty. Subjects that were currently physically disqualified from either diving duty or aviation duty were not be eligible for participation. All subjects were briefed on the procedures, risks, and benefits of the study. A copy of the protocol was provided to each subject. Each subject was given ample opportunity to read the protocol and to ask questions prior to signing the Informed Consent document.

All subjects had a pre-participation medical record review and medical examination by a UMO. Individual data including the subject's date of birth, height, and weight were obtained. A smoking history was also obtained, and any orthopedic injuries, abnormal neurological findings, and use of medications were noted. Pre-participation medical information for each subject was recorded on a Subject Baseline Data Sheet.

Subjects were allowed to participate in their regular exercise programs before participating in a flight profile for this study, but were prohibited from performance of physical training or athletic exercise the day of their scheduled flight and for a period of 48 hours after completion of any flight profile. Nonobservance to this prohibition would be documented on the Subject Data Sheet. Subjects were prohibited from diving or flying, or other exposure to hyperbaric or hypobaric pressure for a minimum of 24 hours before they participated in a flight. The amount of sleep they obtained and amount of exercise they performed within the 24-hour period preceding each flight was documented in the Pre-Flight section of the Subject Data Sheet.

Consumption of more than one standard alcoholic drink (14 g alcohol, 12 ounces regular beer, 5 ounces wine, 1.5 ounces of distilled spirits) by subjects during the 24 hours before and 24 hours after test flight was prohibited[8]. This was to avoid masking of symptoms and dehydration. On the other hand, subjects were instructed to consume a minimum of 500 mL of non-caffeinated liquid on the morning of their flight to ensure that they are adequately hydrated.

The duty UMO interviewed subjects on the mornings of their scheduled flights to verify their fitness to participate. A subject would be excluded from participating for any of the following reasons: inability to clear ear (e.g. Valsalva maneuver), upper respiratory infection, new or changing joint pain, acute infectious disease, new traumatic injury, or any other complaint judged by the duty UMO to compromise the subject's fitness.

Subjects on a flight profile that was aborted prior to any rapid pressure fluctuations may participate in another flight on the same day. Subjects on a flight profile aborted under other circumstances could not participate in another flight on the same day, but could participate in a flight 48 hours later subject to approval by a UMO. Otherwise, subjects were prohibited from diving or flying for 48 hours after completing the flight, and all other experimental Post-Flight requirements applied.

Baseline and Follow-up Testing

During the week prior to the testing week, 24 hr Post-Flight, and 48 hr Post-Flight subjects performed the following testing procedures.

- At least 24 hours prior to the flight testing subjects completed two practice sessions of the CogScreenAH Aeromedical Edition (CogScreenAH), a cognitive battery used to test functions like simple reaction time, memory, spatial processing, and executive function. Two practice sessions to eliminate practice effect was a recommendation by the author and owner of the test battery. Subjects also completed this exam 24 hour after flight. This testing battery is currently in the process of being deployed to the fleet for use by the U.S. Navy Aeromedical community. It will gather baseline data from all aviators, aircrew, and aeromedical staff corps members as well as assess cognitive function following suspected physiological events (PE). The exam is computer-based, employing touchscreen monitors and styluses, and takes approximately 50 minutes to complete.

- A basic medical screening was conducted prior to testing. Medical screening included but was not limited to blood pressure, pulse, height, weight, temperature, electrocardiogram (ECG), neurological examination, and eye exam for nystagmus.
- A tympanogram was conducted prior to testing. Tympanometry is an examination to test the condition of the middle ear and mobility of the tympanic membrane (eardrum) and the conduction bones by creating variations of air pressure in the ear canal. It provides a valuable modality for the verification of middle ear hemorrhage or tympanic membrane rupture that could possibly occur during rapid pressure fluctuations.

Flight Day – General

Subjects reported to the Physiology Laboratory or designated area and completed the various forms which documented how they were feeling Pre-Flight. These forms included subject data sheets for evaluation and interviews Post-Flight. After completing the forms, subjects proceeded with Pre-Flight physiological testing (see Pre- and Post-Flight Testing).

Before entering the FAST System, subjects donned the Tobii Pro glasses, which were calibrated to track retinal movement during the flight. Once the glasses were calibrated, subjects entered the FAST and sat upright in a cockpit chair. Subjects donned the nasal cannula, the communications headset, and the pulse-oximetry sensor was placed onto their left index finger. The precordial Doppler probe was handed to the subjects and they were instructed to place the probe to the pre-marked area on their chest-wall. A communications check was performed and, once the operators completed Pre-Flight operating procedures, the door was closed and the flight began.

Protocol for Pre- and Post-Flight Testing

In addition to baseline and follow-up testing, all or a subset of the following testing occurred pre- and Post-Flight. All Post-Flight testing will occur within 30 minutes of exiting the FAST System.

1. Tympanometry was conducted pre-and Post-Flight. This examination tested the condition of the eardrum and assess if any barotrauma following the flight pressure profile may have manifested.
2. Doppler: Detection of venous gas bubbles pre- and Post-Flight was assessed and recorded with Doppler bubble monitors. Examination consisted of listening to blood flow with a precordial probe and Doppler bubble monitor.
3. Vitals: Vital signs consisting of ECG, blood pressure, and pulse-oximetry were collected via Propac monitors.
4. CogScreenAH: Subjects completed one test Pre-Flight and one test Post-Flight with the CogScreenAH examination, a cognitive battery used to test functions like simple reaction time, memory, spatial processing, and executive function.

Protocol for Flight Test

In addition to baseline, Pre-Flight, Post-Flight, 24 hr, and 48 hr follow-up testing; the following testing and data collection occurred during the flight inside the FAST System.

1. Doppler: On three occasions during the flight, the subjects were asked to hold the precordial Doppler probe to the pre-marked spot on their chest-wall. Detection of venous gas bubbles pre- and Post-Flight was assessed and recorded with connected Doppler bubble monitors outside the chamber. The PI or corpsman provided communication directions on where to move the probe until audible blood flow is detected. Approximately 30 seconds of blood flow was recorded each time.

2. Eye tracking: Retinal movement was tracked with the Tobii Pro Glasses 2 systems, which the subjects wore for the entire duration of the flight inside the FAST System. The Tobii glasses tracked the retina and determine if subjects were able to effectively focus on a target during the pressure changes in the flight. Eye-tracking assessment for the study consisted of two types of exercises. The first exercise was a visual search task (VST), where the subject had to search for a shape consisting of two specific colors. This involved three evolutions with a different color combination as the target and in a different location. Several shapes with two different color combinations are present, however, only one possesses the right combination as highlighted by the red box in the figure (in this particular example the target shape contains the colors green and red) (Figure 4). The color combinations included red/green, red/blue, and purple/gold. The second exercise consisted of the subjects reading a defined passage, in this case the NEDU mission statement (Fig. 7). The second exercise consisted of the subjects reading a defined passage, in this case the NEDU mission statement (Fig. 8).

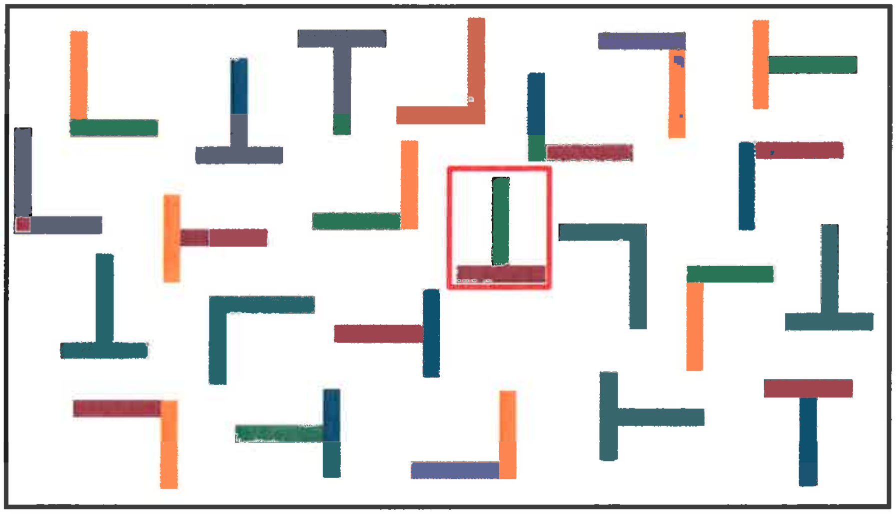
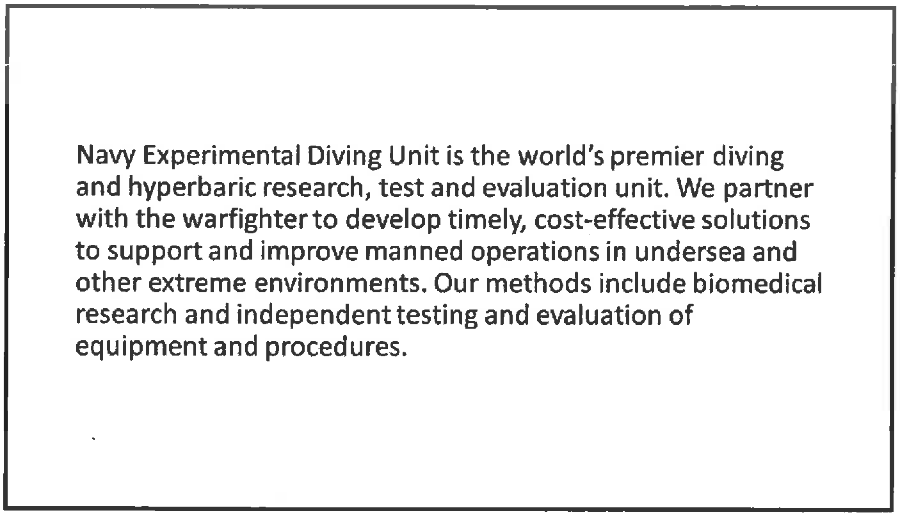


Figure 7: Visual Search Task (VST)



Navy Experimental Diving Unit is the world's premier diving and hyperbaric research, test and evaluation unit. We partner with the warfighter to develop timely, cost-effective solutions to support and improve manned operations in undersea and other extreme environments. Our methods include biomedical research and independent testing and evaluation of equipment and procedures.

Figure 8: Defined Passage Recital

3. Vitals: Vitals were recorded by Propaq and monitored by corpsman operators for the entirety of the flight. Vitals recorded during the flight consisted of pulse-oximetry and 3 lead ECG. Subject had 3-lead snap-style ECG electrodes attached to them during Pre-Flight testing. ECG cables were snapped to the electrodes and pulse-oximetry sensor clip was placed onto the left index finger upon entry into the FAST System.

General Precautions

Subjects were required to adhere to the following instructions while enrolled in the study:

1. Do not perform dives or flights for at least 24 hours before the scheduled flight testing in this experiment.
2. Do not start a new exercise program between your baseline testing, flight day, and associated physiological testing Post-Flight days.
3. Do not start a new smoking, smokeless tobacco, or nicotine supplement between your baseline testing, flight day, and associated Post-Flight testing days.
4. Subjects should refrain from taking elective medications and discuss any physician recommended medications with the PI and UMO. Additionally, subjects should discontinue using herbal or training supplements while enrolled.
5. Do not exercise at all the day of the scheduled flight. Also, refrain from strenuous exercise for 48 hrs after the flight. For this protocol, strenuous exercise is defined as any activity eliciting a sustained increase in heart rate above 70% of max, or any exercise session – cardiovascular or resistance training – lasting longer than 45 minutes.

Schedule

The testing schedule consisted of two flights per day. Two subjects per flight for a maximum of four subjects per day. For planning purposes, the typical weekly schedule consisted of two flights per day, two subjects per flight, on Monday, Tuesday, and Wednesday. This schedule accommodated Pre-Flight screening for new subjects and Post-Flight testing for the current subjects on Thursday and Friday. The testing schedule required a TAD time for subjects of approximately 8 days.

- Routine (2 flights/day – 4 subjects tested)
    - Week before testing
        - Wednesday: Arrival at NEDU
        - Thursday: Orientation, walkthrough of FAST system, and baseline medical.
        - Friday: Orientation, walkthrough of FAST system, and baseline medical
        - Saturday/Sunday: Off
    - Testing week
        - Flight day (Monday, Tuesday, or Wednesday):
            - 0700: Flight One Arrival
            - 0705: Med Checks and Hydration, FAST System OPs/Start-Ups.
            - 0820: Pre-Flight Brief
            - 0840: Flight One, 24/48hr Post-Check for previous flight subjects.
            - 0925: Land Flight One
            - 0926: Post Flight Exams and FAST System Re-Set OPs
            - 1130: Cleared for Departure.
            - 1200: Flight Two Arrival for Med Checks and Hydration
            - 1320: Pre-Flight Brief
            - 1340: Flight Two, 24/48hr Post-Check for previous flight subjects
            - 1425: Land Flight Two
            - 1426: Post Flight Exams and FAST System Re-Set Ops.
            - 1630: Cleared for Departure.
            - End of Flight day
        - Thursday

    - 0700: Wednesday Flight One 24hr Post-Check.
    - 0900: Wednesday Flight Two 24hr Post-Check.
    - 1000: Tuesday Flight One 48hr Post-Check
    - 1100: Tuesday Flight Two 48hr Post-Check
  - Friday
    - 0700: Wednesday Flight One 48hr Post-Check.
    - 0900: Wednesday Flight Two 48hr Post-Check.

Staffing

Testing procedures were conducted by the following personnel:

- FAST System Supervisor
- FAST System Operator
- 4 UMOs on station as research monitors.
- Biomedical Technician for monitoring subject's vital signs during flight.
- 2 Flight HM for visual monitoring of subjects and recording of Doppler data.
- Baseline HM

Emergency Procedures

Treatment of a Physiological Episode

A research monitor was to be immediately available to evaluate any subject complaints or possible PEs. The research monitor was to determine when the signs or symptoms first presented, and thus guide diagnosis and treatment decisions. The following criteria was used to treat suspected PE:

A. If the signs/symptoms first presented during the flight profile and are resolving or have resolved upon reaching ambient pressure, only observation and follow-up per protocol will be performed.

B. In the event that presenting signs/symptoms do not improve or worsen after reaching ambient pressure, the subject will be evaluated by a research monitor and treated accordingly. In cases where there is not an identifiable cause for the signs/symptoms (e.g. dehydration), 2 hours of ground level oxygen (GLO) provided by non-rebreather face mask should be considered but is not required.

C. In the event that a subject is treated with GLO and signs/symptoms continue to worsen, recompression treatment should be considered in accordance with the research monitor's clinical judgement.

D. In the event a subject has an objective neurological finding (e.g. weakness, confusion, etc.), recompression therapy should be considered immediately.

Termination Criteria

An individual flight was to be immediately terminated on occurrence of any of the following:

- Upon subject request for any reason.
- As directed by the Watch Supervisor or Investigator (PI or AI).
- Declaration of a medical emergency.
- Vital Signs Criteria:
    - HR <35 or >120 (sustained for greater than 30 seconds)
    - Pulse Oximetry <90% (sustained for greater than 30 seconds)

The subject's flight would be immediately terminated in accordance with relevant procedures in the IRB-approved protocol, the FAST System Technical Manual, or other NEDU procedures. Furthermore, if a particular flight profile elicited unexpected adverse events, PEs of an unexpected severity, or PEs at an unexpected rate as determined by the study investigators, Research Monitors, and Commanding Officer, that particular profile would be halted from testing until an IRB review could be accomplished. The other profiles could continue to be tested if they did not meet the threshold as described above.

RESULTS

DEMOGRAPHICS

70 healthy, active duty subjects successfully completed the study. 24 subjects were exposed to the maximum profile; 22 subjects were exposed to the nominal profile; and 24 subjects were exposed to the limited profile. 60 subjects were qualified in diving duty; 2 subjects were qualified aviators, and 8 subjects were neither qualified in diving or aviation duty. 69 subjects were male and 1 subject was female. 68 subjects were Caucasian and 2 subjects were African American. The age range of subjects was 23 years to 52 years. 10 subjects were in the 23-29 range; 42 subjects were in the 30-39 range; 15 subjects were in the 40-49 range; and 3 subjects were in 50-52 range.

DECOMPRESSION SICKNESS / ARTERIAL GAS EMBOLISM

There were no diagnosed cases of decompression sickness or arterial gas embolism. Detailed neurological examinations consistent with the U.S. Navy Diving Manual were performed during baseline medical screening, immediately Post-Flight, 2 hours Post-Flight, 24 hours Post-Flight, and 48 hours Post-Flight.

PHYSIOLOGIC EVENT

There were no diagnosed cases of Physiologic Events to include objective neurologic findings. The signs and symptoms as defined in the Physiologic Events Clinical Practice Guidelines were directly solicited immediately Post-Flight, 2 hours Post-Flight, 24 hours Post-Flight, and 48 hours Post-Flight. Per this study, a Physiologic Event (PE) was defined as one of the following:

One or more objective neurologic findings occurring during flight or within 48 hours after flight or the manifestation of any of the following signs and symptoms:

1. A feeling of cognitive slowing, being “off”, or clumsiness
2. A feeling of euphoria or elation
3. Disorientation
4. Skin rashes
5. Light-headedness, vertigo, dizziness, or sensation of disequilibrium
6. Unexplainable severe fatigue or drowsiness
7. Unexplainable severe nausea
8. Difficulty Breathing
9. Vision changes or complaints
10. Memory Difficulties or Difficulty Communicating (self-report and other party report)
11. Anxiousness / Nervousness
12. Symptoms similar to or consistent with DCS I / II or AGE
13. Unexplainable severe headache
14. Personality changes
15. Changes in thought processes

One subject did complain of a mild headache immediately following exposure to the rapid pressure fluctuations; however, it was not classified as an unexplainable severe headache. The subject's headache was resolved by the 2 hour Post-Flight examination.

CLINICAL FINDINGS

There were 5 cases of diagnosed grade 1 (mild) middle ear barotrauma; 1 case of mild frontal sinus barotrauma; 2 suspected cases of middle ear barotrauma where tympanogram changes were noted but the subject remained asymptomatic; 1 case of middle ear oxygen absorption syndrome (Draeger Ear); and 1 case of a mild headache that could not be further classified. All clinical findings completely resolved without treatment. The cases of middle ear barotrauma and sinus barotrauma were expected outcomes and are relatively common injuries associated with both diving and aviation duties. There were no cases of pulmonary barotrauma or pulmonary over inflation syndrome.

PHYSIOLOGIC MONITORING

Real-time physiologic monitoring of the subjects during rapid pressure fluctuation exposures consisted of a 3 lead electrocardiogram, finger pulse oximetry, direct visual observation, and continuous two-way voice communication. No study flights were aborted or terminated to include the flights with subjects subsequently diagnosed with mild sinus and middle ear barotrauma. Normal physiologic variation of the heart rate was noted and remained within the defined termination criteria for all subjects. Subjects were provided with supplemental oxygen via OxySaver nasal cannulas and remained normoxic throughout the experimental exposures. Real-time observation of pulse oximetry demonstrated minimal physiologic variation with all subjects remaining above 95% oxygen saturation at all times.

DOPPLER BUBBLE STUDIES / VENOUS GAS EMBOLI

Prior to the experimental exposure, subjects were evaluated by a cardiovascular technician and the Doppler Probe placement was marked on the subject's pre-cordial area. Upon entering the FAST System, but before experimental exposure to rapid pressure fluctuations, data was collected. During the test flight at 3 different periods following rapid pressure fluctuations, data was collected. Immediately upon completion of the experimental exposure, data was collected. In each case, approximately 30 seconds of Doppler data was collected.

Because of the unique nature of the FAST System, investigators did not have direct access to the subjects during the experimental exposures. Therefore, the subjects were required to place and manipulate the Doppler probe themselves following the instructions of investigators or technicians outside the FAST System. Unfortunately, this limitation resulted in very poor quality data for many subjects. Nonetheless, all data was analyzed by the study investigators and a representative sample of audio recordings were reviewed by a subject matter expert in decompression theory and Doppler venous gas emboli monitoring. In the available data sets where blood flow was heard, there were no detection of venous bubbles. Therefore, the defined grading scale of frequency and amplitude was not utilized.

COGNITIVE FUNCTION

In order to determine if participants experienced any cognitive deficits as a result of the rapid pressure fluctuations, participants completed the CogScreenAH cognitive test battery at three different time points: prior to flight, immediately Post-Flight, and 24-hours Post-Flight. In addition, all participants completed the CogScreenAH assessment twice prior to their Pre-Flight administration in order to prevent any learning effects (also known as practice effects) interfering with data collection.

CogScreenAH is a computer-administered battery of cognitive tests designed to rapidly assess changes in a variety of neurocognitive skills, including attention, reaction time, information processing skills, and executive functioning. The test consists of twelve unique tasks including mathematics problem solving, spatial processing, and managing two demanding tasks at once. According to the developer, CogScreenAH was initially designed to meet the Federal Aviation Administration's need for an instrument that could detect subtle changes in cognitive functioning. The CogScreenAH is an approved instrument for use in the medical re-certification evaluation of pilots with known or suspected neurological and/or psychiatric disorders.

The entire CogScreenAH test battery takes approximately 50 minutes to complete. Because the test is so thorough, not all comparison results are presented here. As all of the CogScreenAH results had similar findings, the most relevant and complex skills are presented in this report as representative of the entire test battery.

Two different performance metrics were investigated: reaction time and thruput. Reaction time is a measure of how quickly a participant is able to respond to the stimulus. Specifically, CogScreen reports reaction time as the median reaction time on correct trials of each task. For example, if the task requires determining whether two visual samples match, the participant's reaction time score would reflect the median representation of how quickly they gave a response after the comparison sample appeared on the screen. Reaction time scores are recorded in milliseconds. Thruput, on the other hand, is an efficiency score which reflects the number of correct responses per minute. The thruput formula is shown in Figure 9. Importantly, thruput incorporates both accuracy and speed, so it is less specific than either pure accuracy or pure speed scores, but it provides a good representation of mental processing abilities.

$$\text{THRUPUT} = \frac{(\text{Accuracy}/100) \text{ x } 60 \text{ seconds}}{\text{Median Response Time for Correct Trials}}$$

Figure 9: Thruput Calculation used by the CogScreen Software

Due to the descriptive nature of this study, hypothesis tests were not conducted on any of the data. Instead, mean performance on each task before and after the flight were visually compared between the three flight profiles to determine whether there was any deficit in performance as a result of the rapid pressure fluctuations. In each case, the individual test subjects acted as their own controls. There was a very large amount of data, so only select comparisons are included here; however, these comparisons are reflective of the pattern seen across all tasks. Of note, the CogScreenAH test battery was completed at least twice prior to the Pre-Flight test in order to eliminate the practice effect.

Reaction Time

The first set of comparisons were done on reaction time scores. Reaction time is a reflection of speed and as such, better performance is reflected by lower scores.

Manikin

The first comparison investigated was a Manikin drill, which required participants to mentally rotate the image of a person to determine which hand was holding a flag. This is a very basic test of spatial skills. As shown in Figure 10, reaction time on the Manikin drill decreased for all three profiles from Pre-Flight to Post-flight, indicating that participants improved their ability to determine which hand was holding the flag. Performance increased again from post-flight to 24-hour follow-up, though this improvement was minimal.

Importantly, there does not appear to have been any effect of flight profile on Manikin performance, nor was there an overall decrease in performance as a result of the altitude fluctuations.

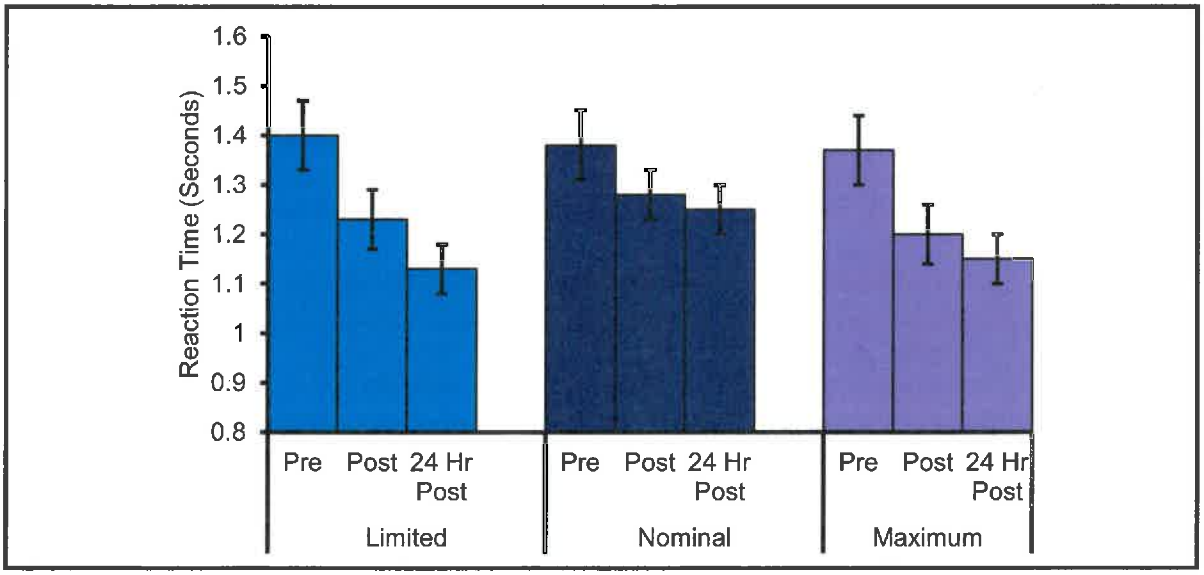


Figure 10: Visual Comparison Manikin Task Reaction Time

Dual Task Performance

The Dual Task Performance test required participants to make judgements about whether two letter and number sequences were either similar or identical while simultaneously monitoring a cursor and manipulating a keyboard to maintain the cursor within a target zone. This task was the most complex of the battery and required constant multitasking. As demonstrated in Figure 11, reaction time decreased from Pre-Flight to Post-Flight, indicating that performance on the Dual Task Performance test improved from Pre-Flight to Post-Flight. This improvement continued on the 24-hour follow-up.

Again, there does not appear to have been any effect of flight profile on performance, nor was there an overall decrease in Dual Task performance as a result of the rapid pressure fluctuations.

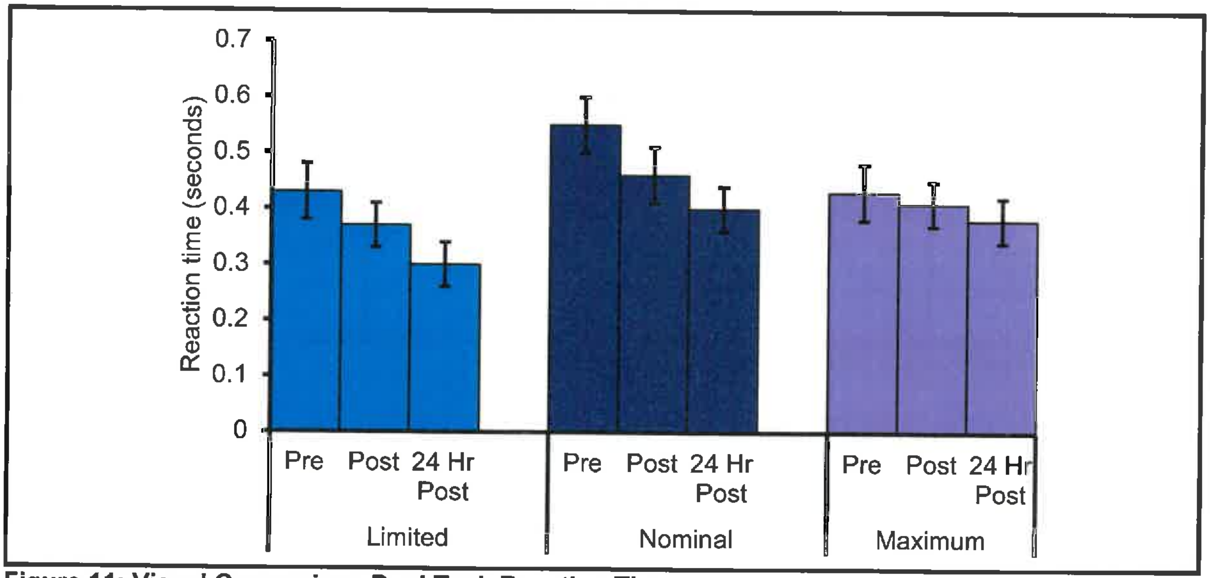


Figure 11: Visual Comparison Dual Task Reaction Time

Thruput

The same comparisons were made for the Thruput measure and are described below. Because Thruput is an efficiency score and represents the number of correct responses per minute, higher scores indicate better performance.

Manikin

Similar to the reaction time results, performance on the Manikin task appears to improve from Pre-Flight to Post-Flight for participants in all three flight profiles. Scores continue to improve, though less so, at the 24-hour follow up (Fig. 12).

Like the reaction time scores, there does not appear to have been any effect of flight profile on performance, nor was there an overall decrease in Manikin performance as a result of the altitude fluctuations.

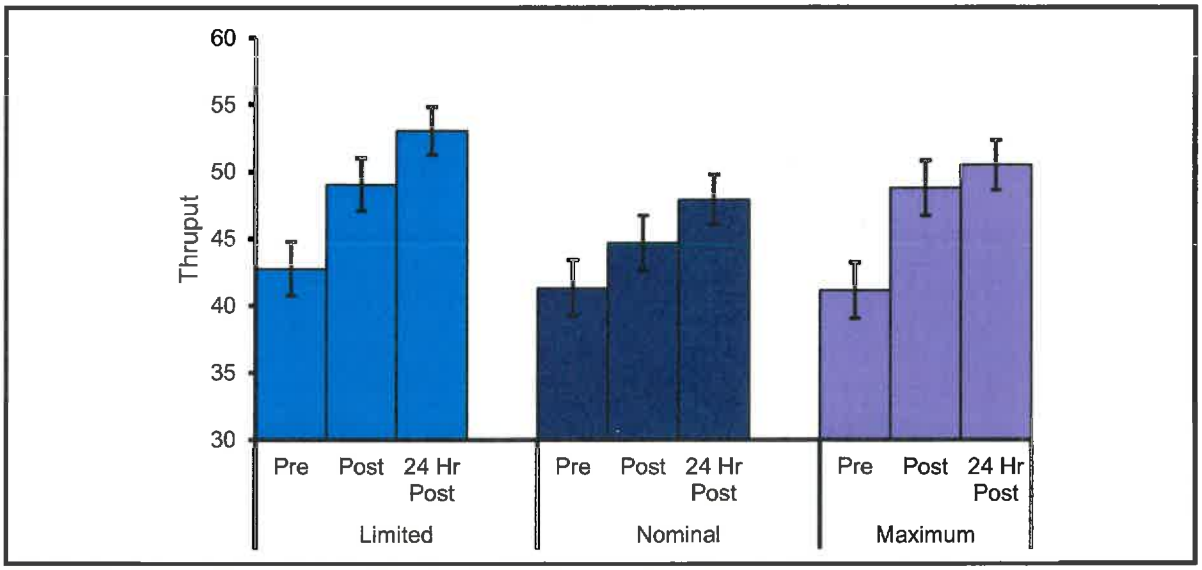


Figure 12: Visual Comparison Manikin Task Thruput Scores

Dual Task Performance

In keeping with previous patterns, performance on the Dual Task Performance task appears to improve from Pre-Flight to Post-Flight for participants in all three flight profiles. Scores continue to improve at the 24-hour follow up (Fig. 13).

As before, there does not appear to have been any effect of flight profile on performance, nor was there an overall decrease in Dual Task performance as a result of the rapid pressure fluctuations.

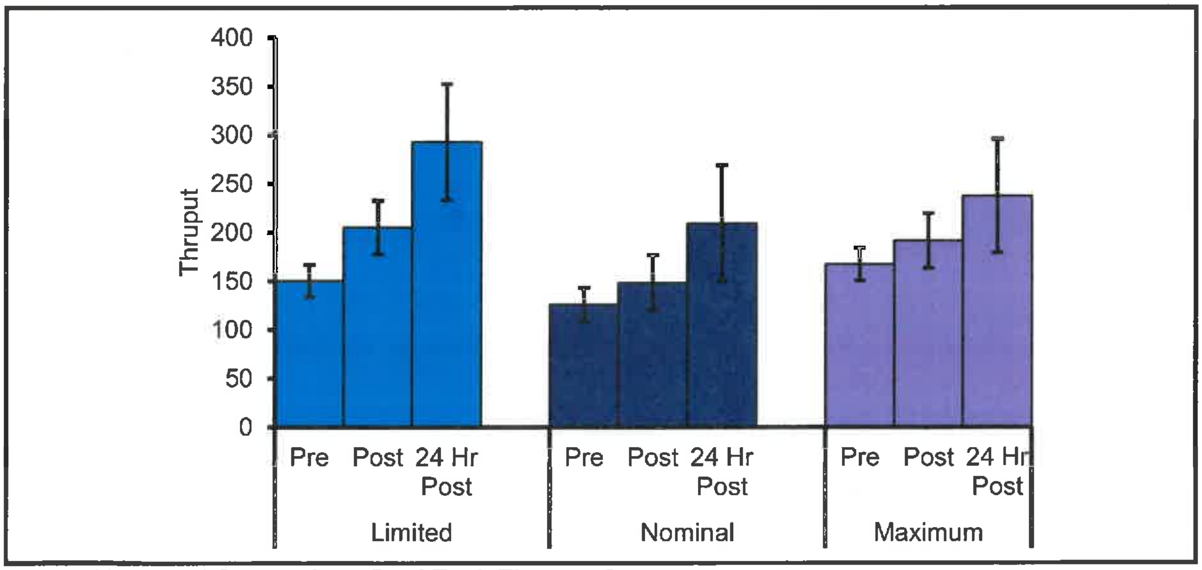


Figure 13: Visual Comparison Dual Task Thruput Scores

EYE-TRACKING

Eye-tracking measurements were accomplished by utilizing the Tobii Pro Glasses 2 wearable eye-tracker and Tobii Pro Lab analysis software. According to the manufacturer, this technology was designed to capture natural viewing behavior in any real-world environment while ensuring outstanding eye tracking robustness and accuracy. Tobii eye-tracking products have resulted in more than 9000 peer-review publications, 3000 more than the next competing provider. Robust tracking of all eye types, persistent calibration, and minimum data loss during extreme eye movements allows tracking a wide cross-section of the population and ensure supreme data quality. Slippage compensation, combined with a sampling rate of at least 50 Hz, enables collecting more data with even higher validity.

This study is the first time this technology has been used to evaluate eye movements during exposure to rapid pressure fluctuations. The Tobii glasses and software provided gaze and eye-tracking data during real-time exposure to rapid pressure fluctuations. The purpose of this technology and data collection was to provide real-time direct observation of eye movements (specifically evaluating for nystagmus during pressure fluctuations) and to collect eye-tracking and gaze data for retrospective analysis to determine if subtle signs of nystagmus were missed during direct observation.

The Tobii Pro Lab analysis software can calculate hundreds of metrics that are not relevant to this study. Thus two different performance metrics were investigated retrospectively: interval duration/target acquisition and fixation count. Interval duration is a measure of how quickly the subject is able to complete the exercise. In this study, the visual search task required searching for and locating a shape with a particular color combination. The subject's interval duration/target acquisition results reflected the median time from the start of searching to locating and focusing on the correct target. Tobii Pro Lab reports interval duration as time in seconds for each subject. Fixation count is the number of fixations a subject made during a given period of time where a fixation is defined as eye movement less than or equal to 30 degrees per second (Tobii Pro Lab manual). For the visual search task portion of the study, the participant's fixation count was the median number of fixations made between the start of searching to location and focusing on the correct target. This data is reported as a total number of fixations.

Eye-tracking assessment for the study consisted of two types of exercises. The first exercise was a visual search task (VST), where the subject had to search for a shape consisting of two specific colors. This involved three evolutions where the target was a different color combination, in a different orientation, and in a different location. Several shapes with different color combinations and orientations are present, however, only one shape possesses the correct color combination as highlighted by the red box in Figure 3. This example demonstrates the correct target as green and red. For the study, the color combinations evaluated included red/green, red/blue, and purple/gold. Subjects were not screened for color blindness prior to study enrollment and no color deficiencies were identified as a result of the study.

The second exercise consisted of the subjects reading a defined passage, in this case the NEDU mission statement (Fig. 4). The subjects were monitored real-time for signs of nystagmus while their speech was also monitored for fluidity, cadence, and correctness. No signs of nystagmus or abnormalities in speech were identified during real-time monitoring of the 70 subjects.

The eye-tracking assessment was completed twice during the day of exposure to rapid pressure fluctuations. A Pre-Flight assessment was conducted in conjunction with the initial medical evaluation before entering the FAST for the assigned flight. The second assessment was conducted while the subjects were inside the FAST during the flight profile and is described as the "Mid-Flight" test. This assessment was conducted after exposure to several rapid pressure fluctuations. Specifically, this assessment occurred between groups 6 and 7 of the Flight Profiles (reference the "Flight Profiles" section of this Report). For the Nominal profile, this was at 1400 seconds. For the Rate-Limited profile, this test took place at 1700 seconds. For the Rate-Maximized profile, this test took place at 1200 seconds. For all three flight profiles tested, the interval duration and fixation count metrics compared the Pre-Flight eye-tracking assessment to the Mid-Flight assessment in order to capture any potential changes secondary to rapid pressure fluctuations. Each subject served as their own control and the metrics between the three flight profiles tested were not compared to each other.

Visual Search Task

Eye-tracking data is both qualitative and quantitative. The qualitative data is illustrated as a heat-map marking where subjects' gaze was recorded on the VST. In this section of the report only the Rate-Maximized red/green VST heat-maps are included. The heat-maps for the Rate-Limited, the Nominal, and the Rate-Maximized red/blue and purple/gold VST can be found in Appendix A (Fig. A5-12). For all three profiles, subjects were able to locate and focus on the three required targets during the Pre-Flight test and during the Mid-Flight test. The heat-map images for the Rate-Maximized red/green VST Pre-Flight, Mid-Flight, and the overlay demonstrate that subjects located and focused on the correct target as highlighted by the red-hot gaze-cloud on the target (Fig. 14). Similar to the Rate-Maximized profile, subjects participating in the Rate-Limited and Nominal profiles did not display any difficulty in locating and focusing on the red/green, blue/red, or purple/gold targets between Pre-Flight and Mid-Flight (Appendix A, Fig. A5-12).

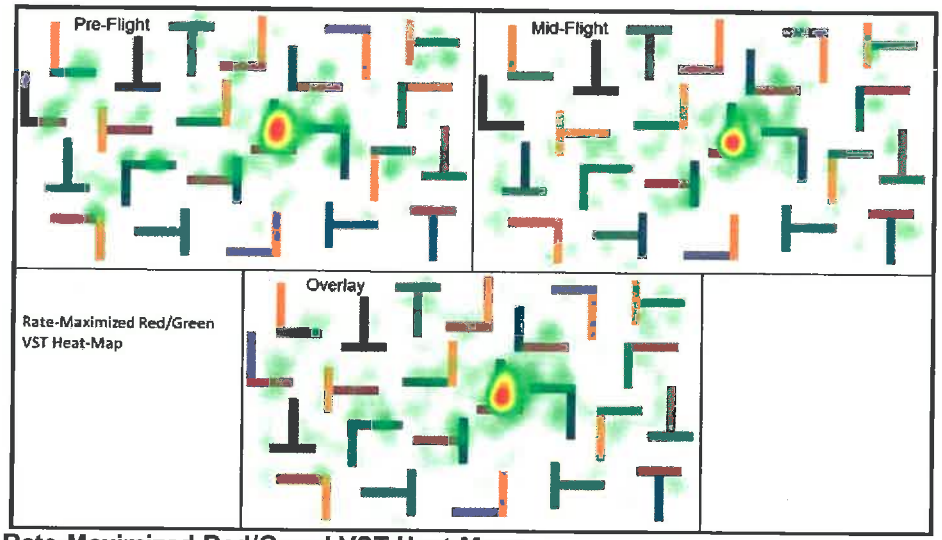


Figure 14: Rate-Maximized Red/Greed VST Heat-Maps

Interval Duration

The interval duration metric provides quantitative data, however, because this was an exploratory study, only descriptive statistics (means and error) are presented and graphed. Interval duration for the VST was called target acquisition and was the time (seconds) the subject took to find and focus on the correct target (red/green, red/blue, and purple/gold) for 2 seconds. For all three profiles tested, the target acquisition time remained unchanged (Fig. 15). The lone exception was in the subjects participating in the Rate-Maximized profile finding the purple/gold VST quicker during the Mid-Flight test compared to their baseline Pre-Flight. Interestingly, this finding indicates an improvement in performance after exposure to rapid pressure fluctuations.

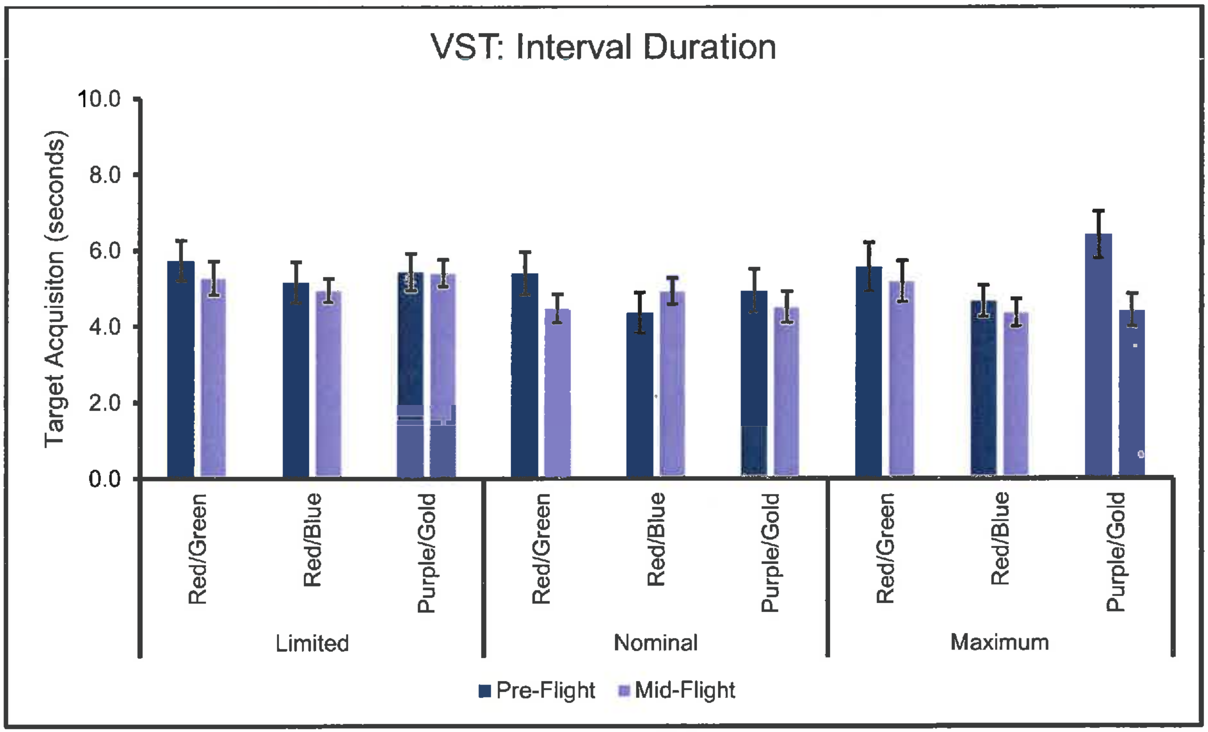


Figure 15: Visual Search Task Target Acquisition Time (seconds)

The second metric calculated was fixation count (number of fixations each subject took in a given period of time). For the VST, this is the amount of fixations made between initiating the search and locating/focusing on the required target. It is an efficiency indicator demonstrating how effective a subject was in finding the target. On average, the number of fixations between Pre-Flight and Mid-Flight for all three flight profiles were unchanged (Fig. 16). However, the red/green VST in the Nominal group and the red/blue and purple/gold VST in the Rate-Maximized demonstrate marked reduction in the number of fixations from Pre- to Mid-Flight testing. This suggests those subjects were more efficient in locating the required target. As with interval duration, the fixation count data suggests that rapid cockpit pressure fluctuations do not negatively affect the participant's ability to efficiently search for, locate, and focus on a specific target.

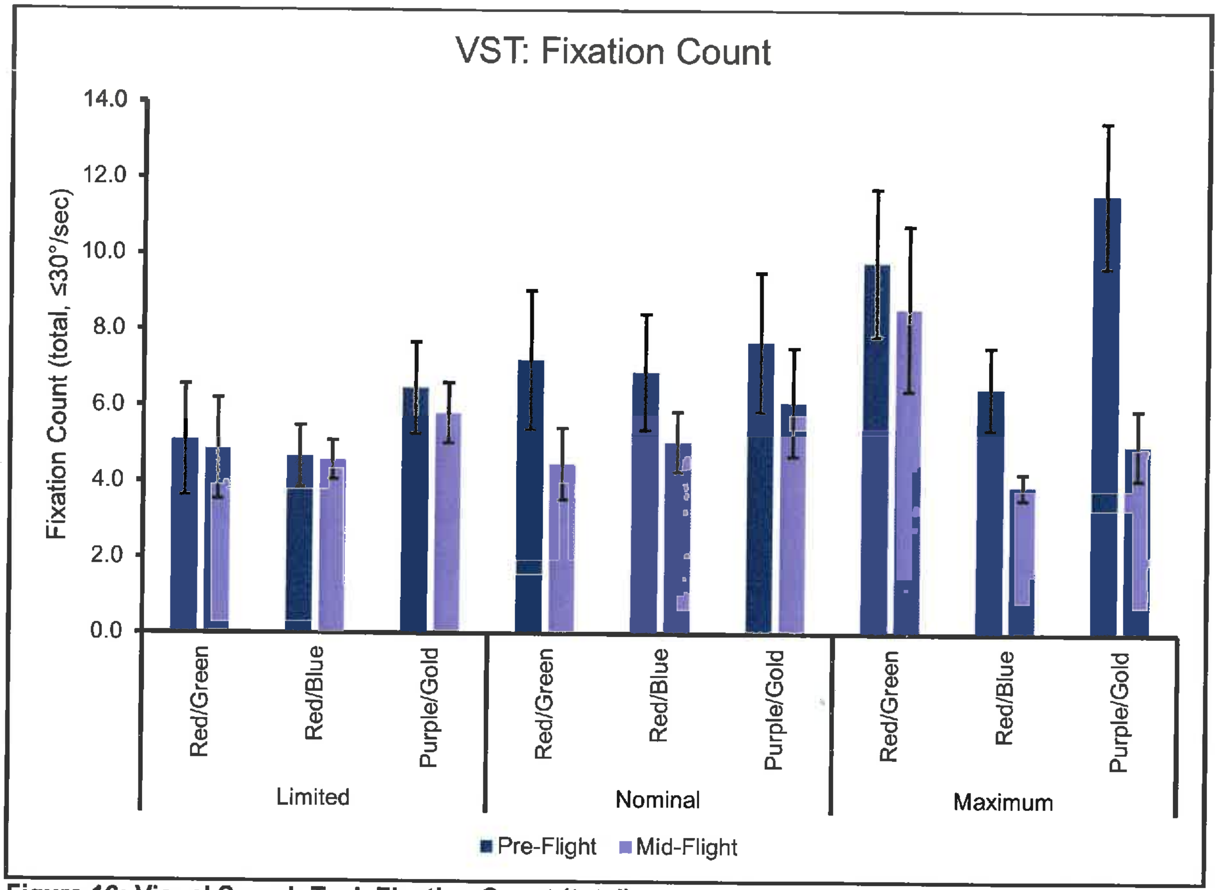
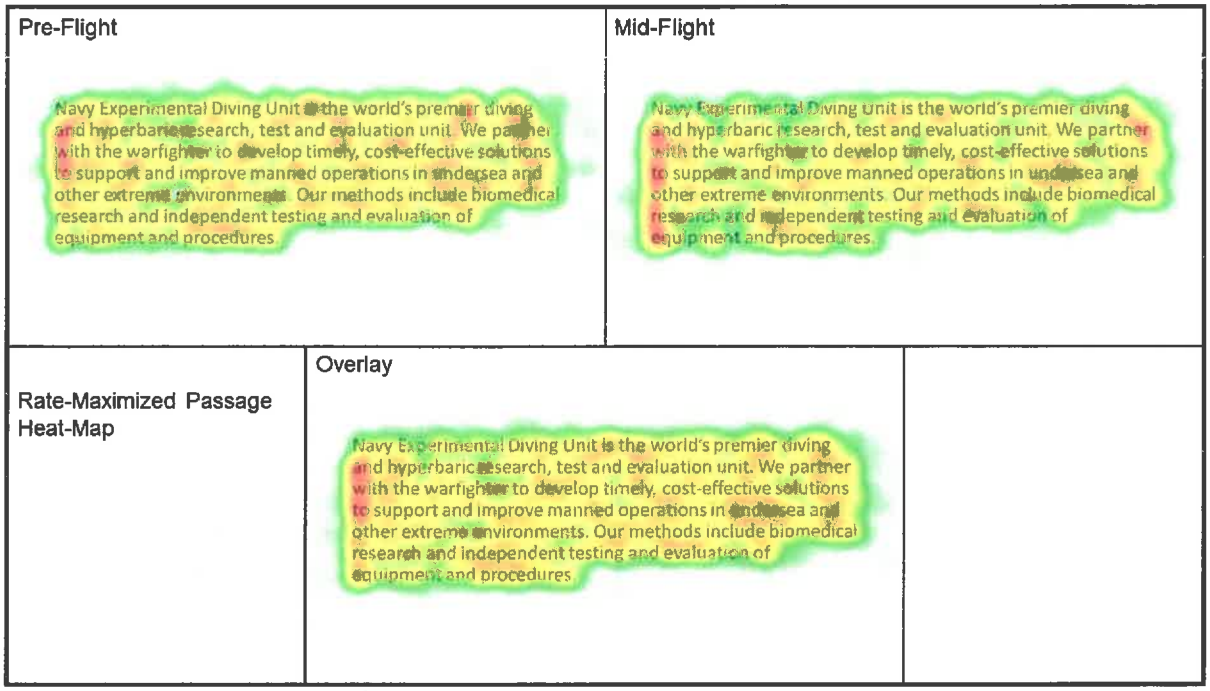


Figure 16: Visual Search Task Fixation Count (total)

Defined Passage Recital

Quantitative and qualitative data was obtained for the defined passage recital. The defined passage recital involved the subjects reading and reciting aloud the NEDU mission statement. The qualitative data is illustrated as a heat-map marking where subjects' gaze was recorded while reading the NEDU mission statement. As with the VST data only the Rate-Maximized heat-maps will be included in this section. The heat-maps for the Rate-Limited and the Nominal can be found in Appendix A (Fig. A13, A15). For all three profiles (Nominal, Rate-Limited, and Rate-Maximized), the subjects were able to locate and focus their gaze within the passage for both the Pre-Flight and the Mid-Flight test after having been exposed to rapid pressure fluctuations. If the subjects had demonstrated abnormalities in eye-tracking or gaze, it is expected that heat spots would have appeared outside the bounds of the passage. However, the Pre-Flight, Mid-Flight, and the overlay heat-map images for the subjects participating in the Rate-Maximized profile show that they were able to focus on the passage during their recital as red-hot gaze-cloud in the passage area (Fig. 17). Similar to the Rate-Maximized results, subjects participating in the Rate-Limited and Nominal profiles demonstrated the same ability to focus on the defined area of the passage during their recital in both the Pre-Flight and Mid-Flight tests (Appendix A, Fig. A13, A15).



Navy Experimental Diving Unit is the world's premier diving and hyperbaric research, test and evaluation unit. We partner with the warfighter to develop timely, cost-effective solutions to support and improve manned operations in undersea and other extreme environments. Our methods include biomedical research and independent testing and evaluation of equipment and procedures.

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Figure 17: Rate-Maximized Defined Passage Recital Heat-Maps

Interval Duration

As this was an exploratory study, only descriptive statistics (means and error) are presented and graphed. Interval duration was the time subjects took to read and recite aloud the NEDU mission statement. This was the total time in seconds from the start to the end of recitation. Subjects served as their own controls by performing the test Pre-Flight and then comparing it to the Mid-Flight test. The total time subjects took to read the passage was similar across the profiles and was unchanged between Pre-Flight and Mid-Flight testing. Subjects in the Rate-Limited profile took 20.1 ± 0.5 seconds Pre-Flight and 20.5 ±0.45 seconds Mid-Flight. In the Nominal profile, subjects took 18.5 ±0.8 seconds Pre-Flight to read and recite the passage compared to 19.4 ±0.8 seconds Mid-Flight. Finally, Rate-Maximized subjects took 20.1 ±0.5 seconds during the Pre-Flight test and 20.5 ±0.6 seconds Mid-Flight. The graphed data visually demonstrates that for the three profiles tested, subjects took the same amount of time to read the NEDU mission statement in Mid-Flight during the flight profile as their Pre-Flight tests (Fig. 18). In summary, this data would suggest that rapid cockpit pressure fluctuations on their own do not elicit abnormalities in eye-movement or gaze. Additionally, it appears there was no degradation in the cognitive ability to complete the task of reading a defined passage.

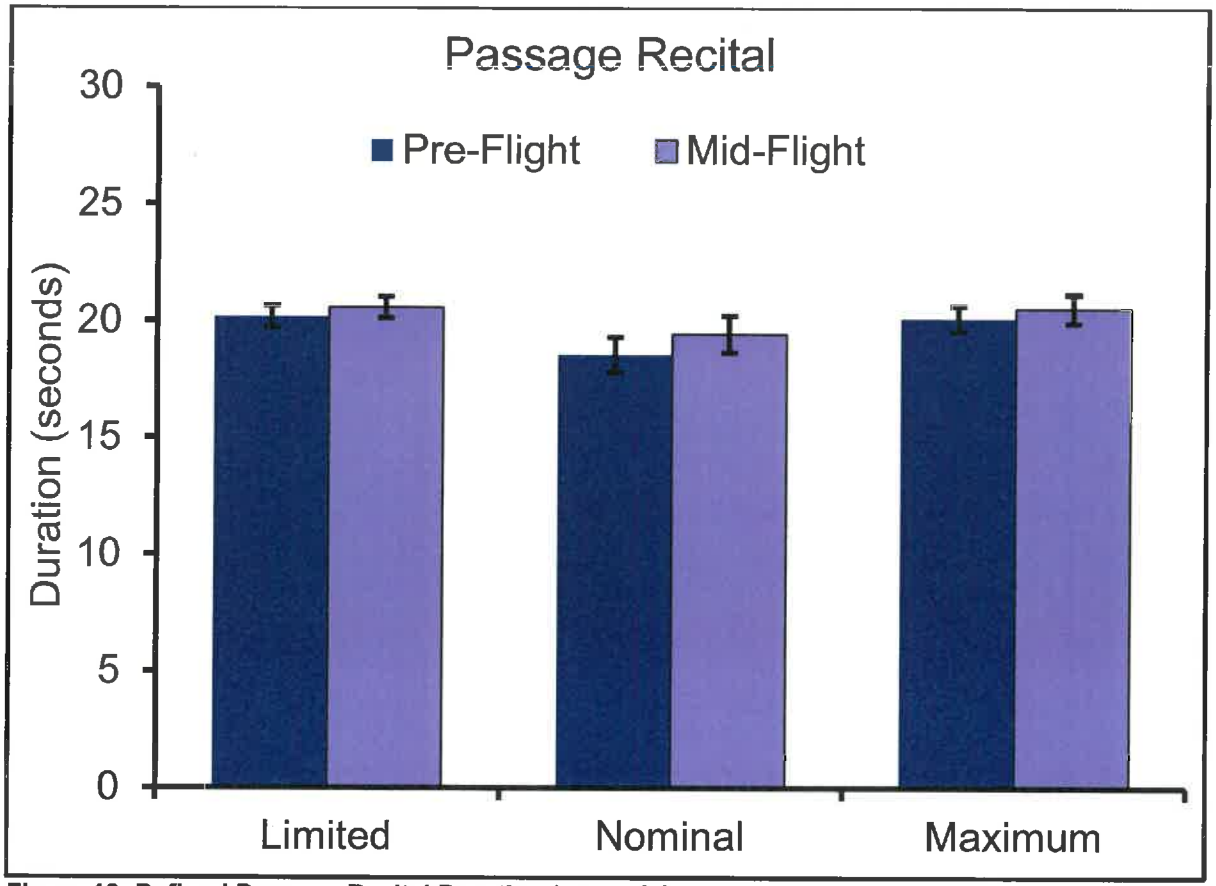

Figure 18: Defined Passage Recital Duration (seconds)

Fixation Count

Additionally, the subject's fixations during the passage recital were plotted to assess for abnormal eye movements such as nystagmus. When reading a defined passage, a subject with abnormal eye movements will have a significant number of fixations lying out of the bounds of the passage. The Tobii Pro Glasses allow for this assessment by providing the ability to map a subject's fixations and produce a gaze plot. An example of a gaze plot in a subject with nystagmus compared to a subject with normal vision is provided by Tobii. The subject with nystagmus had a significant number of fixations plotted above the defined passage as compared to the subject with normal vison (Fig. 19). The retrospective analysis of subjects participating in the Rate-Maximized profile did not display abnormal eye movements such as nystagmus. The gaze plots demonstrate the subject's fixations within the NEDU mission statement area for both Pre-Flight and Mid-Flight tests are lined up with the overlay (Fig. 20). Similar results were seen for the subjects participating in the Rate-Limited and Nominal profiles (Appendix A, Fig. A14, A16). The figures for these profiles are found in Appendix A supplemental figures section.

Related to the gaze plots, the fixation count metric was calculated. This is the number of fixations each subject took in a given period of time. For the defined passage recital, this was the amount of fixations made between initiating and completing the recitation of the defined NEDU mission statement. It is an efficiency indicator demonstrating how effective a subject was in reciting the passage. On average, the number of fixations between Pre-Flight and Mid-Flight for all three flight profiles were unchanged (Fig. 21). As with interval duration, the fixation count data indicates that rapid pressure fluctuations alone do not affect the participant's ability to efficiently read and recite a defined passage.

Gaze plot from a person with nystagmus

Gaze plot from a subject with normal vision

Figure 19: Example Fixation Plots Nystagmus vs Normal Vision

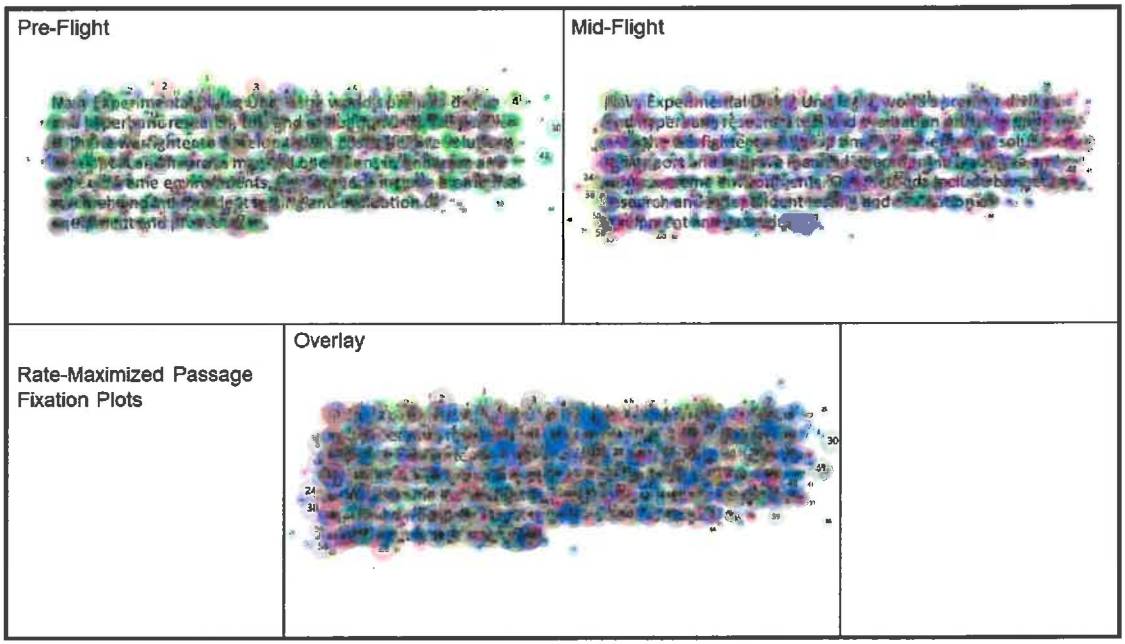

Figure 20: Rate-Maximized Defined Passage Recital Fixation Plots

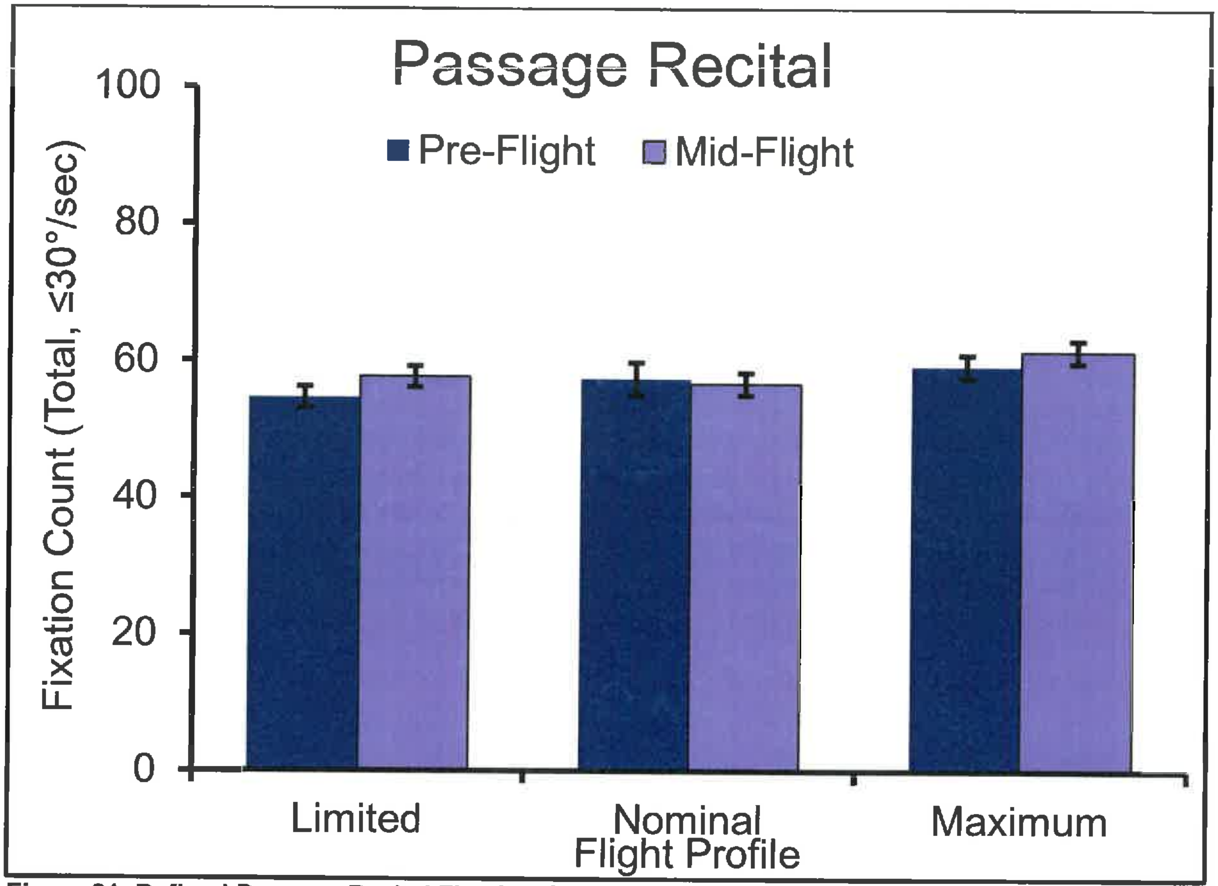

Figure 21: Defined Passage Recital Fixation Count (total)

DISCUSSION

The primary objective of this study was to elucidate whether manifestations resembling PEs occur subsequent to rapid pressure fluctuations in the absence of confounding factors (such as breathing system resistance) and to characterize any physiological symptoms. Simultaneously, the study was designed to place bounds on the probability of DCS as the cause of PEs while also identifying areas and physiological symptoms worthy of future study. Seventy human subject volunteers were exposed to one of three randomly-selected pressure profiles provided by PMA-265. The pressure profiles consisted of a simulated take-off from sea-level, level flight, seven groups of rapid pressure fluctuations, and descent back to sea-level. The maximum over-pressurization and under-pressurization excursions for all three profiles are the same with differing rates of pressure changes (maximum profile 0.8 psia/sec; Nominal profile linearized based on SLAMSTICK data; and limited profile 0.2 psia/sec). Physiological data collected consisted of history and physical examinations, physiologic monitoring (heart rate, oxygen saturation, and electrocardiogram 3 lead tracings), nystagmus assessment via direct observation and retrospective analysis of eye-tracking movements, retrospective Doppler venous bubble monitoring, tympanography, and cognitive function screening.

There were no diagnosed cases of Physiologic Events, Decompression Sickness, Arterial Gas Embolism, or Neurologic Changes. Real-time physiologic monitoring via direct observation, 3 lead electrocardiogram, and pulse oximetry revealed normal physiologic variation and no discernable changes resulting from exposure to rapid pressure fluctuations. Supplemental oxygen was provided throughout the experimental exposure and oxygen saturation levels remained greater than 95% for all subjects throughout the testing. The use of tympanometry was a very helpful adjunctive diagnostic tool used in conjunction with physical examination. Tympanometry changes post-flight were demonstrated in all cases of middle ear barotrauma, suspected middle ear barotrauma, and middle ear oxygen absorption syndrome. There were no identified venous gas bubbles as a result of these experimental exposures which is consistent with the expectations of NEDU decompression experts; however, the overall poor data quality limits any conclusions that can be drawn from this limited data analysis.

There was no evidence of a decline in cognitive function following experimental exposure to any of the three pressure profiles. The two most difficult and most applicable test subsets from CogScreenAH were analyzed (Dual Task Performance and Manikin Drill). Reaction time for both test battery exercises either remained unchanged or displayed an improving trend from Pre-Flight to 24 hours Post-Flight. Similarly, thruput, an efficiency score that provides a representation of mental processing abilities, remained either unchanged or exhibited an improving trend throughout testing from Pre-Flight to 24 hours Post-Flight.

Direct observation of eye movements and ability to read a passage correctly during the experimental exposures did not demonstrate any abnormalities to include nystagmus or cognitive changes. Retrospective analysis of eye-tracking exercises using the Tobii Pro Glasses 2 included evaluating for subtle signs of nystagmus and supplemental cognitive ability. Nystagmus is a condition where the eyes will make repetitive and uncontrolled movements to areas where otherwise a subject would not be focusing their attention, such as reading a defined passage. Eye-tracking assessment for the study consisted of two types of exercises. The first exercise was a visual search task (VST), where the subject had to search for a shape consisting of two specific colors. This type of exercise was chosen to replicate locating displays, button, or switches in the cockpit involved in the SOPs of flying an aircraft. It served as a supplemental cognitive assessment similar to the manikin exercise from the CogScreenAH test. This involved three evolutions with a different color combination as the target and in a different location. Several shapes with two different color combinations are present, however, only one possesses the right combination as highlighted by the red box in the figure (in this particular example the target shape contains the colors green and red) (Fig. 3). The color combinations included red/green, red/blue, and purple/gold. The second exercise consisted of the subjects reading a defined passage, in this case the NEDU mission statement (Fig. 4). This exercise tracked if the subjects manifested any nystagmus. Subjects were to read and simultaneously recite aloud the NEDU mission statement. Visual search tasks and defined passage recital durations and fixations remained unchanged or demonstrated an improving trend from Pre-Flight to Mid-Flight for all three profiles.

CONCLUSIONS

This study was exploratory in nature. The negative findings, particularly no diagnosed DCS or PEs, provide important information and reassurance to Aviators, Aviation Leadership, and the Aeromedical Community that rapid pressure fluctuations in isolation are unlikely to cause significant harm to Aviators. However, the negative results of this study do not prove that rapid pressure fluctuations cannot result in PEs or DCS. With regard to DCS, the study findings are consistent with a probability of DCS of less than 5% which is consistent with the acceptable risk of approved U.S. Navy diving tables and schedules. The most advanced U.S. Navy altitude decompression model[9] predicts a probability of much less than 1% for the experimental profiles in this study. With regard to PEs, the findings of this study suggest that PEs are not the result of rapid pressure fluctuations in isolation. However, do to the exceedingly low incidence of PEs compared to the total number of flight-hours logged by the F/A-18 community, conducting a properly powered, hypothesis-driven study to explore this would be unfeasible due to the number of subjects needed to test.

RECOMMENDATIONS

This was an unprecedented exploratory human subject research study investigating rapid pressure fluctuation Physiologic Episodes associated with aviation PEs. An important contribution of this study was the development and validation of the FAST System. The FAST System has provided the U.S. Navy with an invaluable new research capability for future unmanned and manned research. It is recommended that the FAST System be incorporated in future PE testing.

Although exploratory in nature, the results of this study support the expert consensus of NEDU scientists and physicians that decompression sickness is unlikely to be the root cause of Aviation PEs. Additionally, the findings suggest that pressure fluctuations in isolation are unlikely the root cause of Aviation PEs and therefore a multi-factorial cause is most likely. A natural extension of this research would be to explore the man-machine interface by coupling the FAST System with the aviation life-support system (including the On Board Oxygen Generation System, regulators, and masks).

It is the opinion of the investigators that tympanography should be a routinely available assessment tool for the clinical evaluation of aviators suspected of having a PE. The tympanography machines are relatively inexpensive, easy to use, and provide excellent clinical data when evaluating possible middle ear barotrauma or middle ear oxygen absorption syndrome. As demonstrated in this study, these injuries will occur in the presence of rapid pressure fluctuations and/or supplemental oxygen breathing.

It is the opinion of the investigators that CogScreenAH should be a routinely available assessment tool for the clinical evaluation of aviators suspected of having a PE. The neurocognitive signs and symptoms associated with PEs are the most difficult to evaluate and diagnose. This study demonstrates that the CogScreenAH is a useful tool that is easy to implement and would be a valuable neurocognitive screening tool. Of note, in order to be most effective, baseline data would need to be collected on Aviators at risk of experiencing PEs prior to experiencing a PE.

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APPENDIX A – SUPPLEMENTAL FIGURES

DCS RISK

Non-PE SLAMSTICK

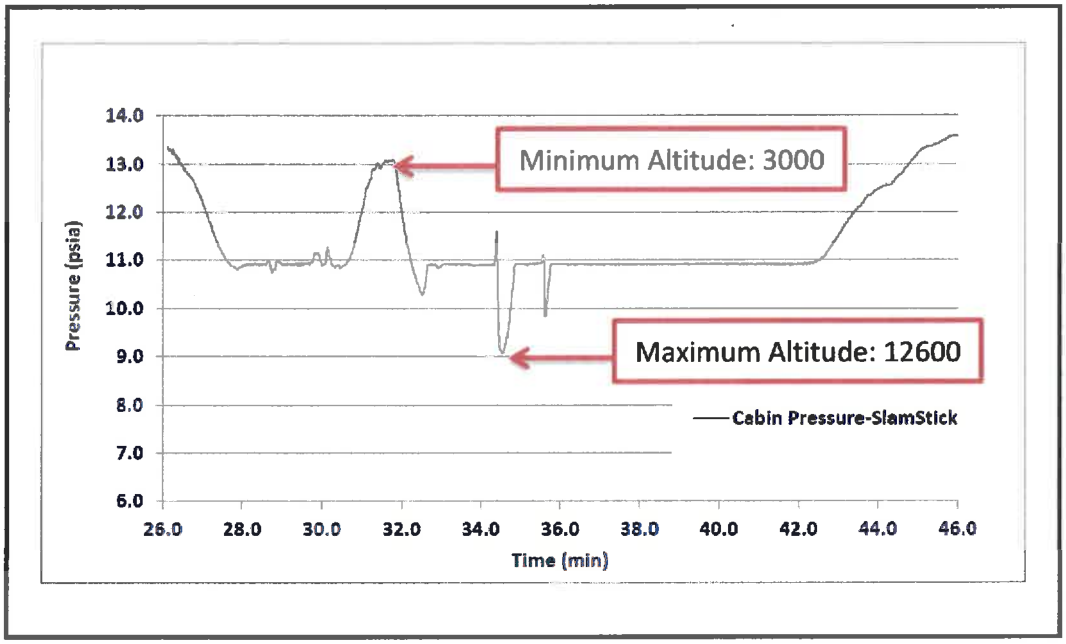
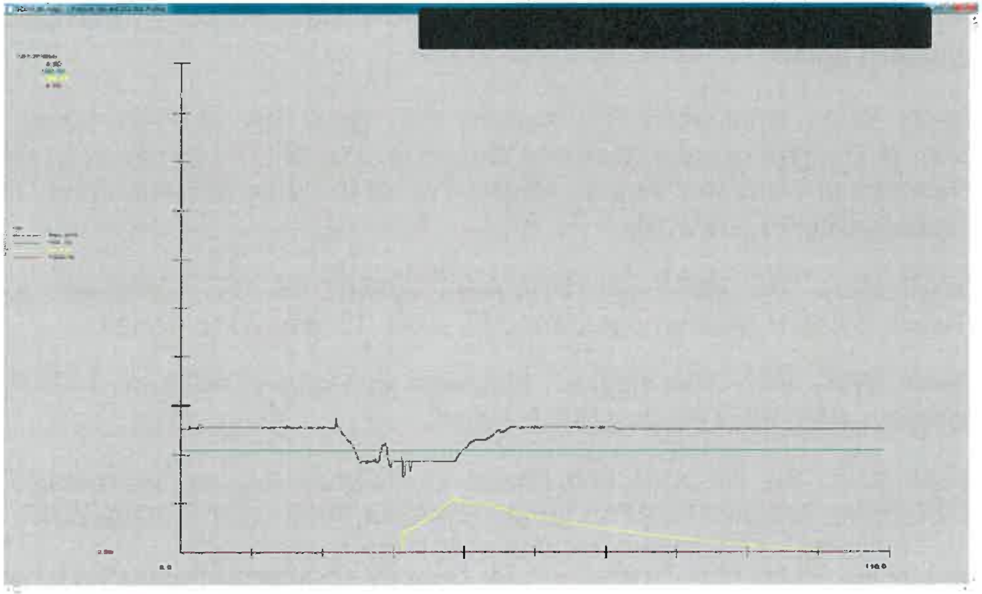


Figure A1: Non-PE SLAMSTICK Altitude Profile

V. **Depressurization Event (Asymptomatic)**

[redacted]



[redacted]

epressurization Event, Pressure (atm), Inspired FIO2, (air breathing assumed

Estimated PDCS = 0.0003% (Model A1309-3RUTMB-36).

Figure A2: Non-PE SLAMSTICK Probability DCS Risk

PE SLAMSTICK

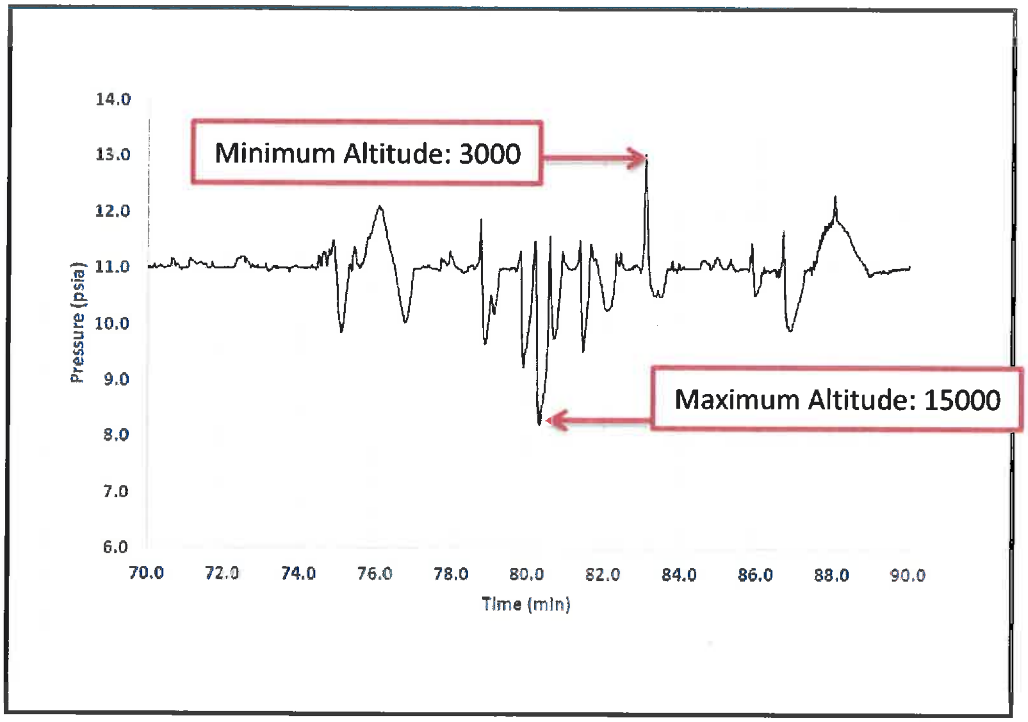
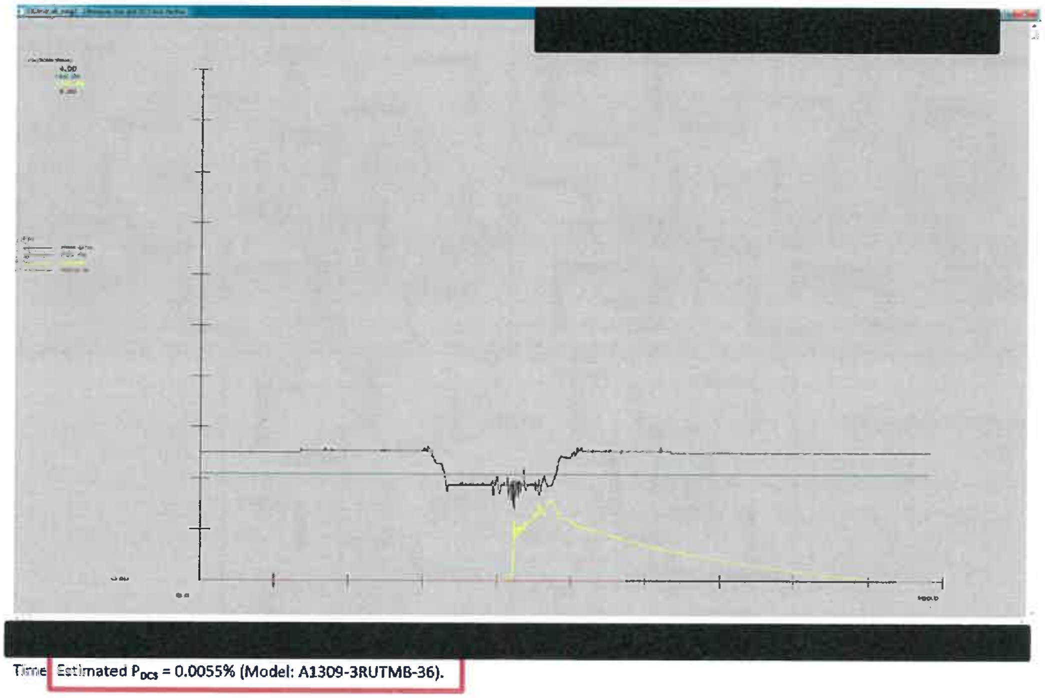


Figure A3: PE SLAMSTICK Altitude Profile

I.



[redacted]

[redacted]

Time Estimated P_{DCS} = 0.0055% (Model: A1309-3RUTMB-36).

Figure A4: PE SLAMSTICK Probability DCS Risk

EYE-TRACKING

Visual Search Task Supplemental Figures

Rate-Limited

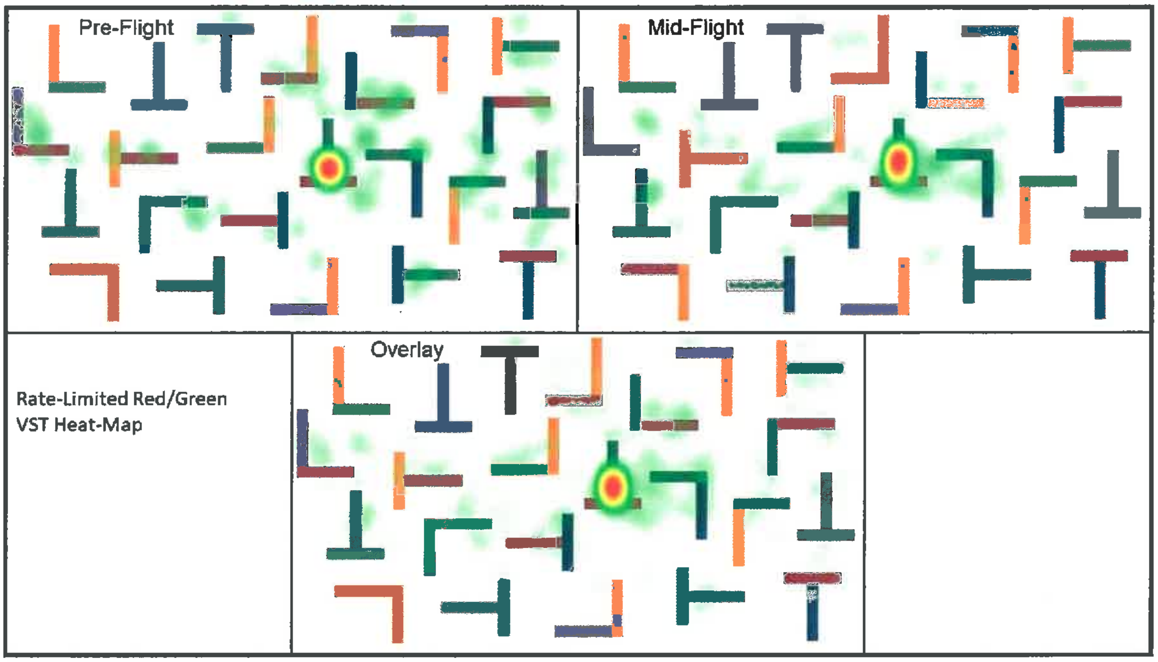


Figure A5: Rate-Limited Red/Green VST Heat-Maps

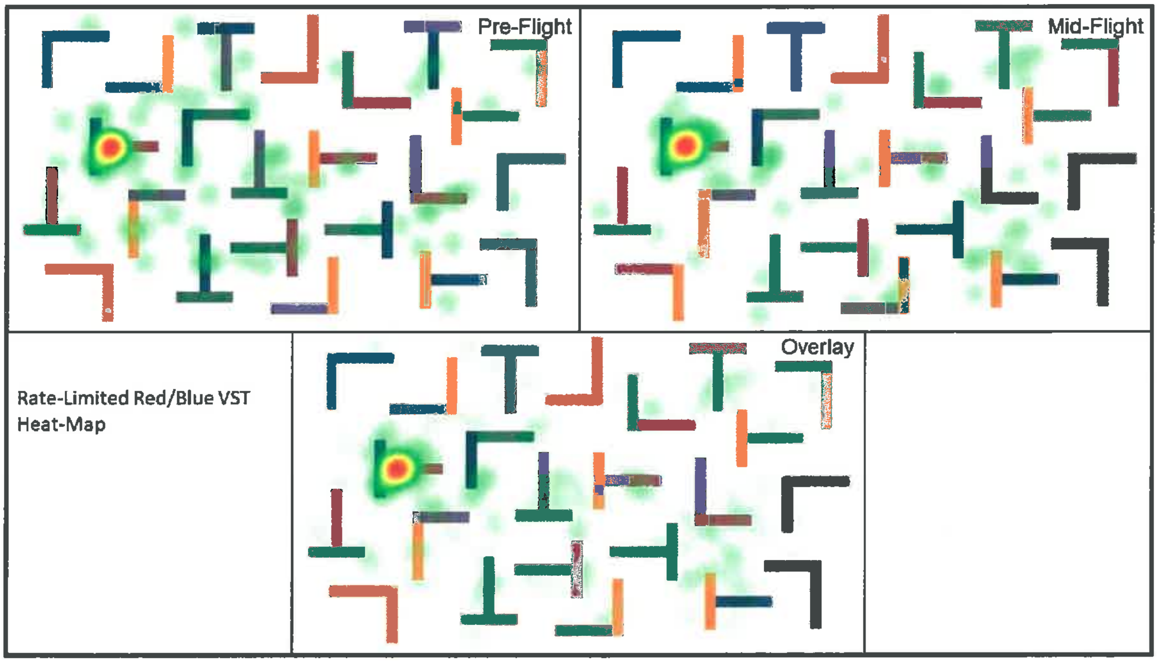


Figure A6: Rate-Limited Red/Blue VST Heat-Maps

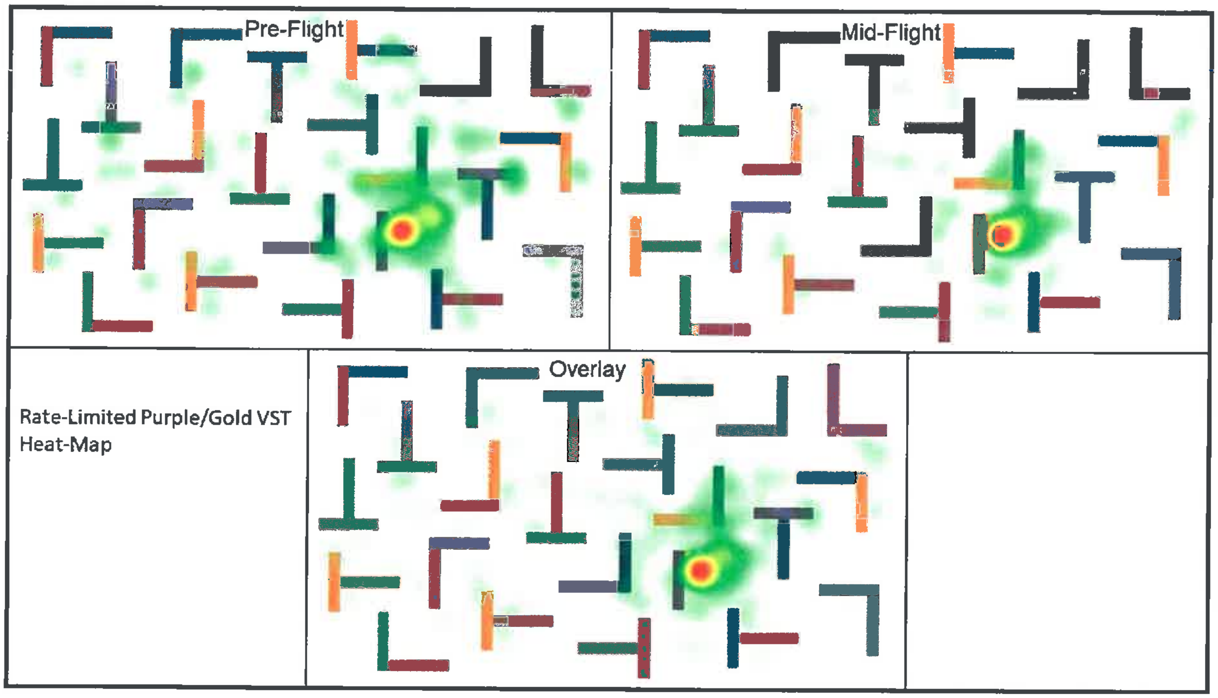


Figure A7: Rate-Limited Purple/Gold VST Heat-Map

Nominal

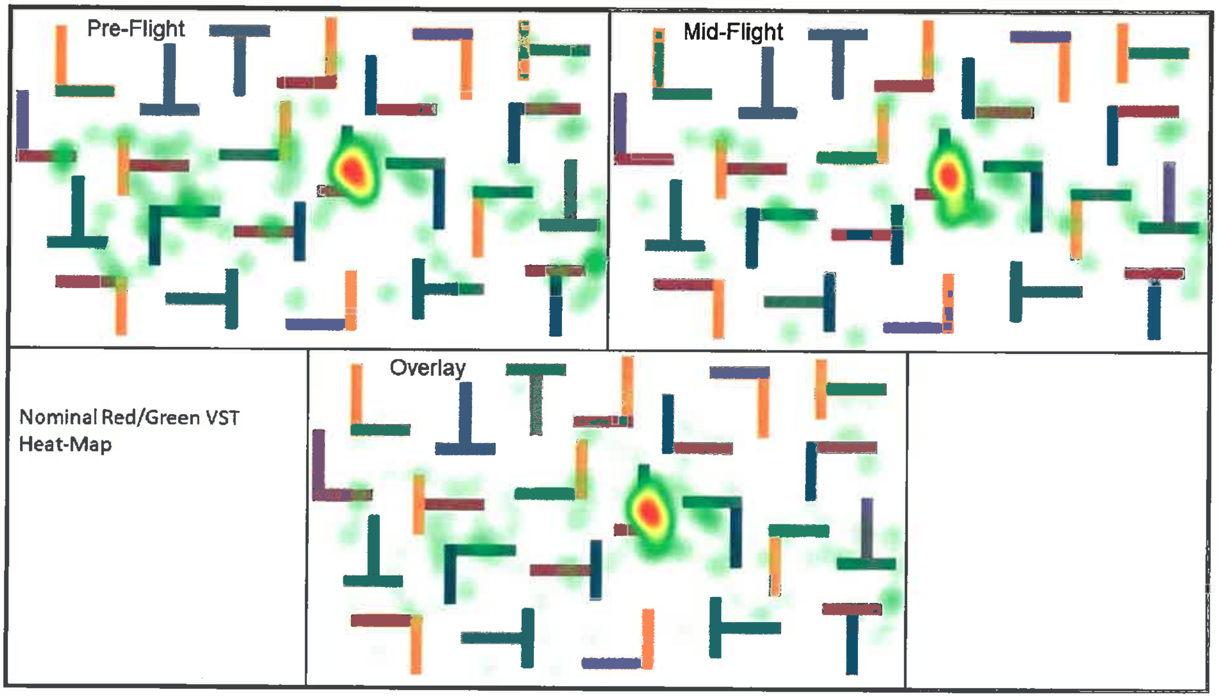


Figure A8: Nominal Red/Green VST Heat-Maps

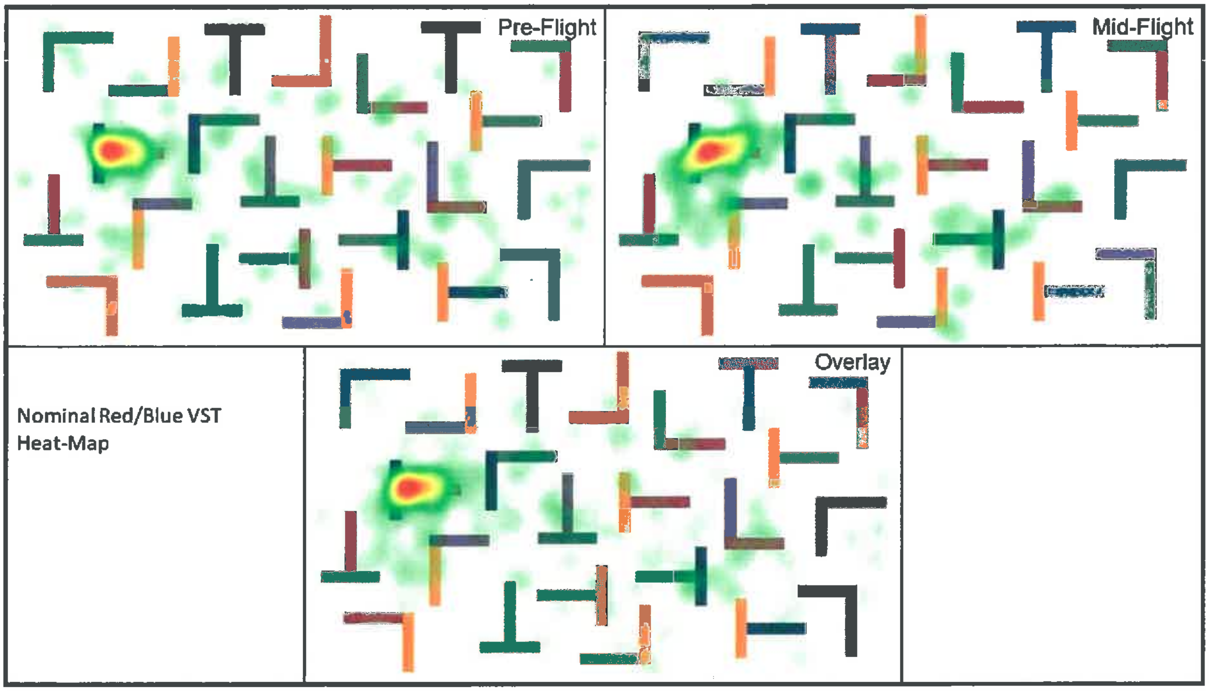


Figure A9: Nominal Red/Blue VST Heat-Maps

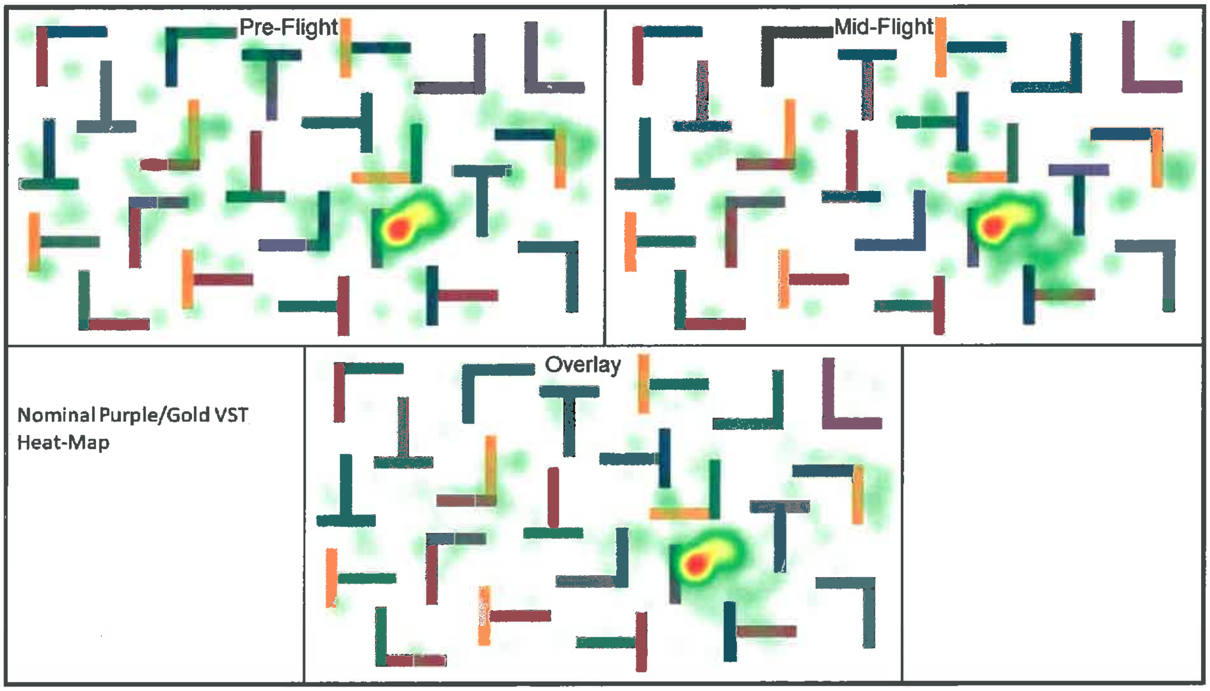


Figure A10: Nominal Purple/Gold VST Heat-Maps

Rate-Maximized

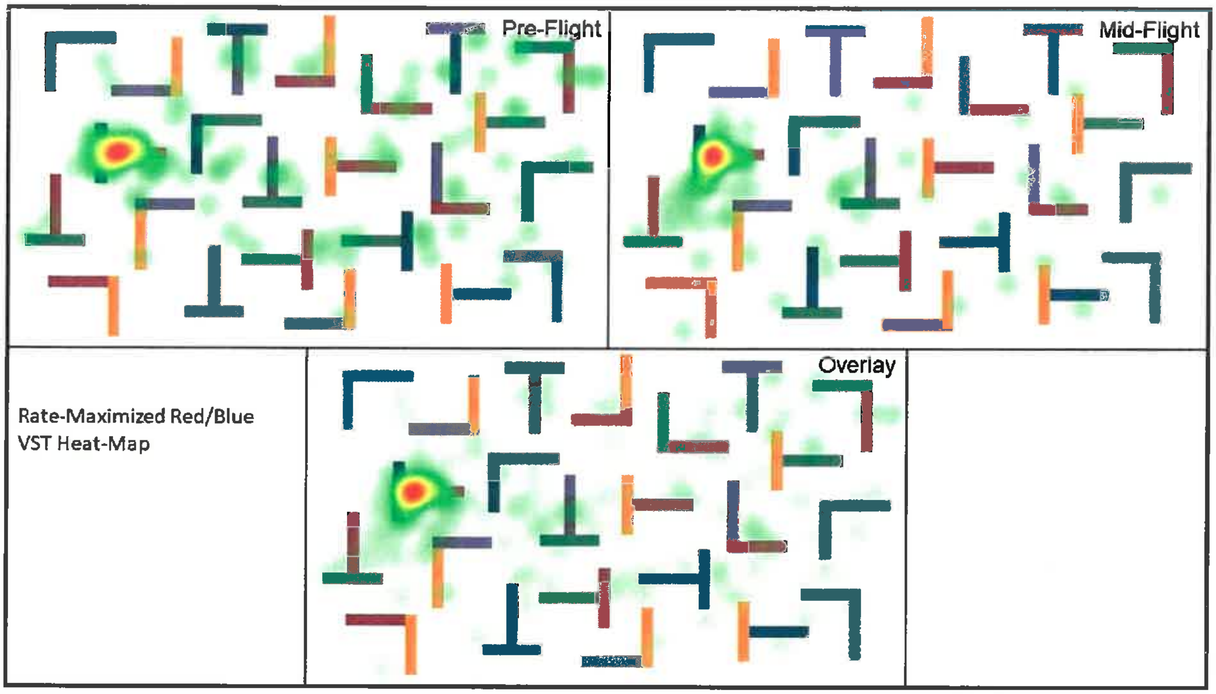


Figure A11: Rate-Maximized Red/Blue VST Heat-Map

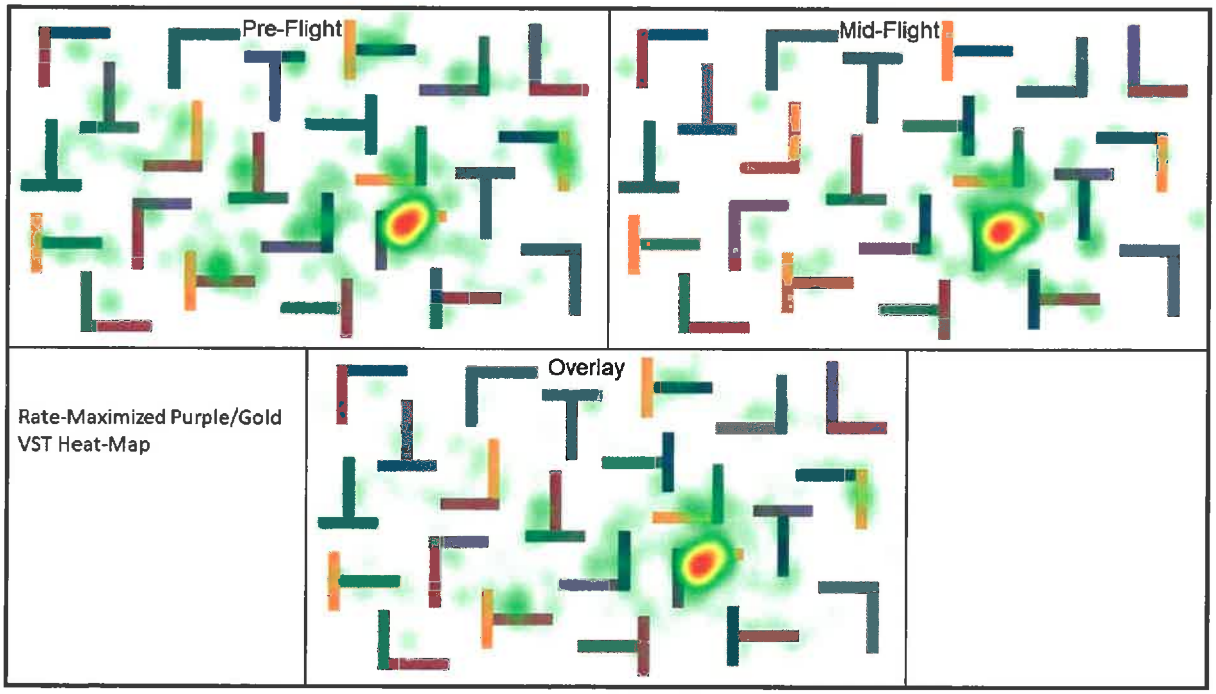


Figure A12: Rate-Maximized Purple/Gold VST Heat-Map

Defined Passage Recital Supplemental Figures

Rate-Limited

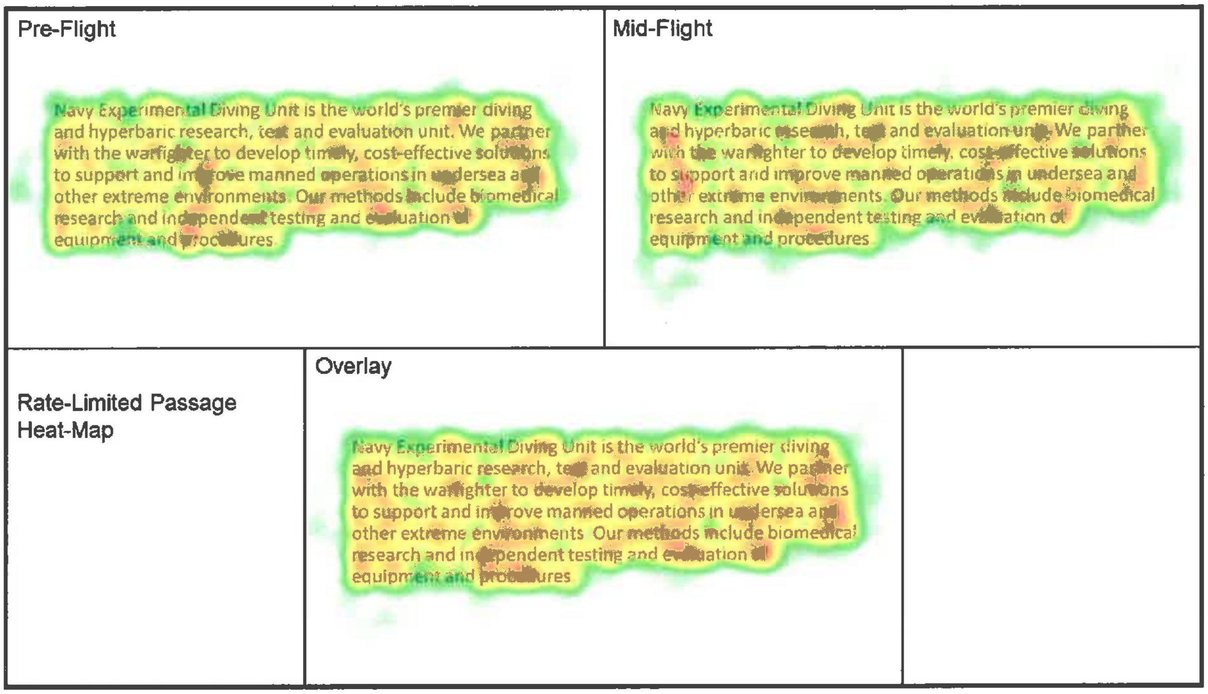


Figure A13: Rate-Limited Defined Passage Recital Heat-Maps

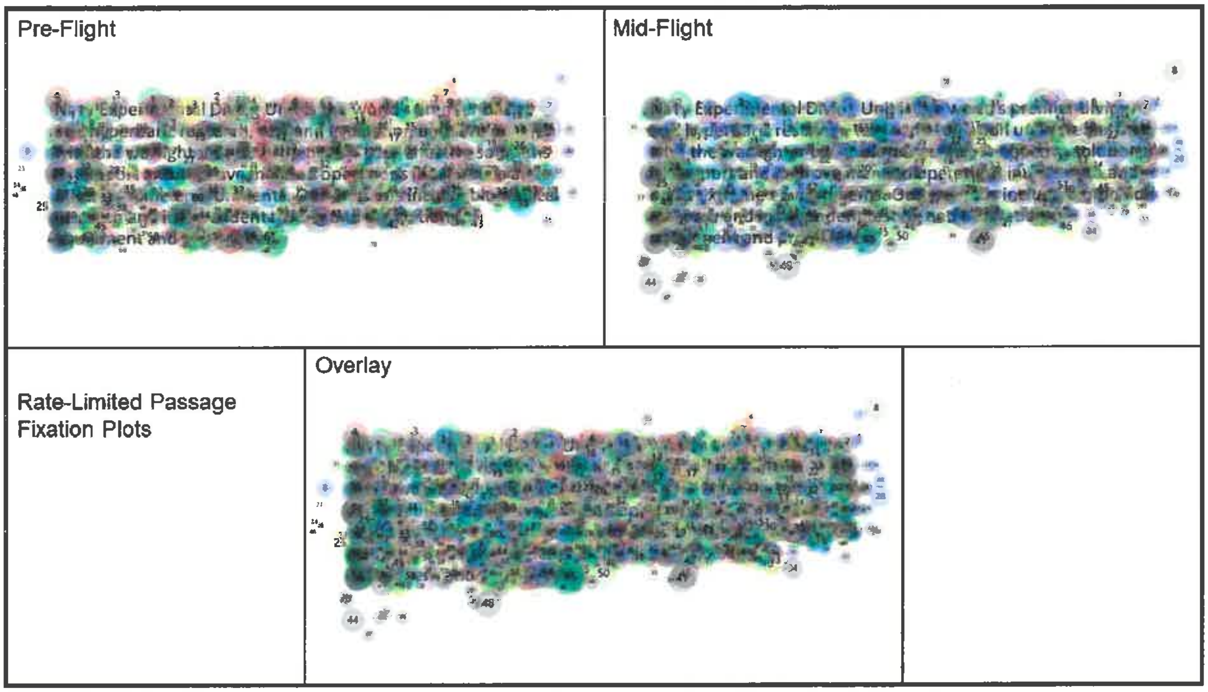
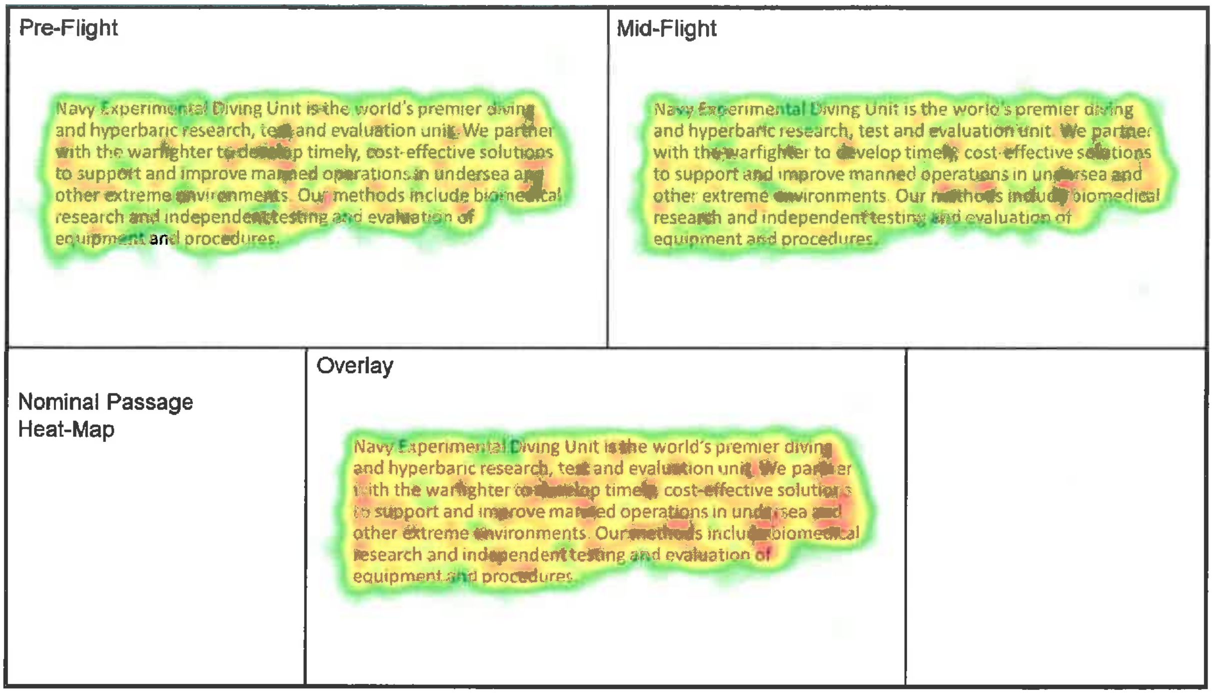


Figure A14: Rate-Limited Defined Passage Recital Fixation Plots

Nominal



Navy Experimental Diving Unit is the world's premier diving and hyperbaric research, test and evaluation unit. We partner with the warfighter to develop timely, cost-effective solutions to support and improve manned operations in undersea and other extreme environments. Our methods include biomedical research and independent testing and evaluation of equipment and procedures.

Figure A15: Nominal Defined Passage Recital Heat-Maps

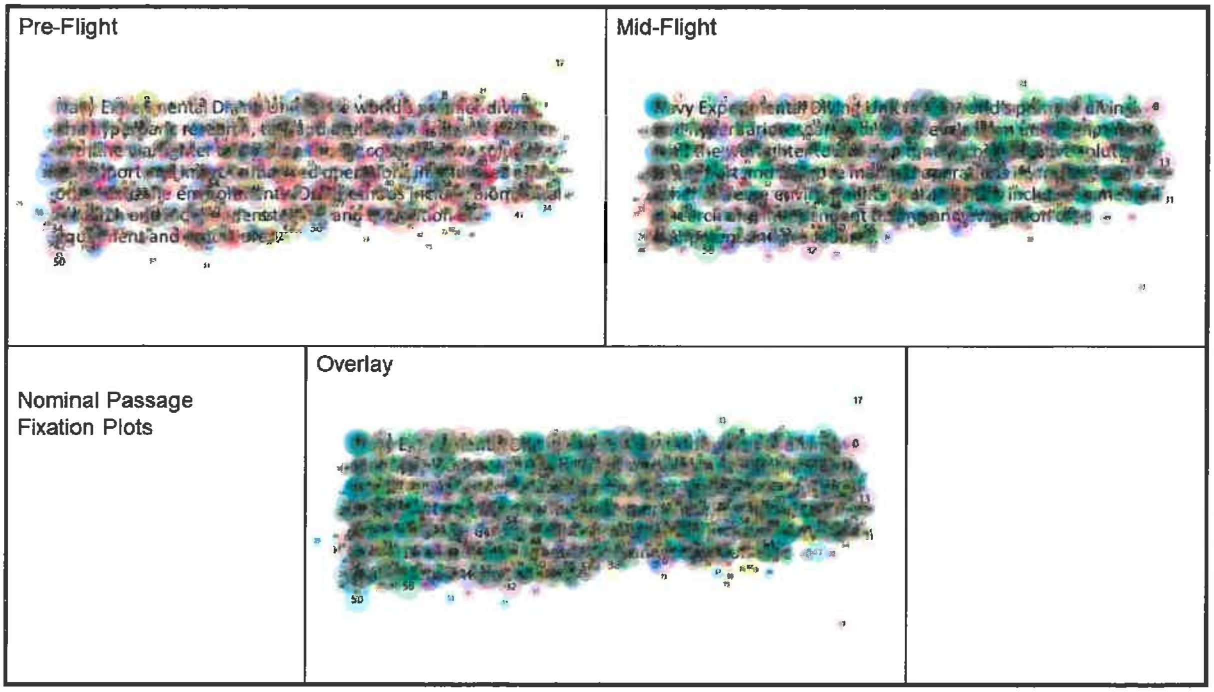
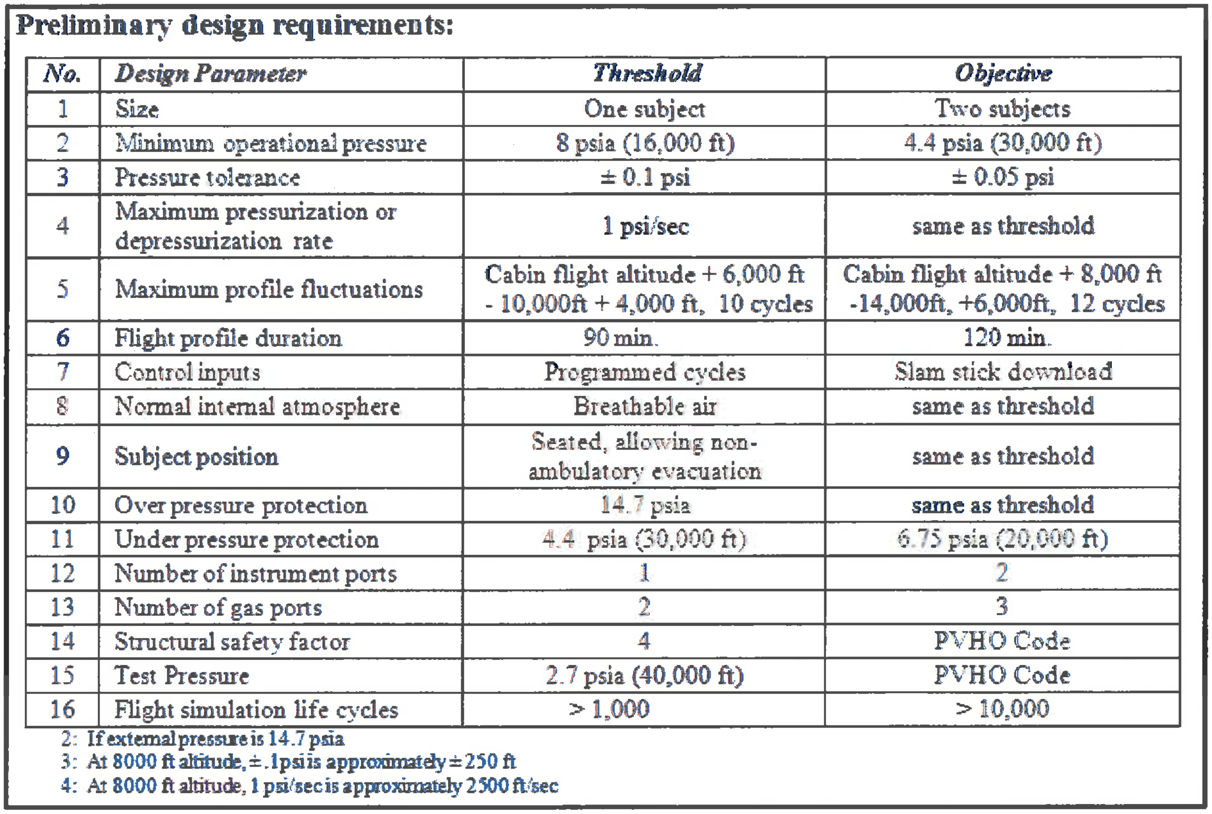


Figure A16: Nominal Defined Passage Recital Fixation Plots

APPENDIX B – FAST SPECIFICATIONS



Preliminary design requirements:

No.	*Design Parameter*	*Threshold*	*Objective*
1	Size	One subject	Two subjects
2	Minimum operational pressure	8 psia (16,000 ft)	4.4 psia (30,000 ft)
3	Pressure tolerance	± 0.1 psi	± 0.05 psi
4	Maximum pressurization or depressurization rate	1 psi/sec	same as threshold
5	Maximum profile fluctuations	Cabin flight altitude + 6,000 ft - 10,000ft + 4,000 ft, 10 cycles	Cabin flight altitude + 8,000 ft -14,000ft, +6,000ft, 12 cycles
6	Flight profile duration	90 min.	120 min.
7	Control inputs	Programmed cycles	Slam stick download
8	Normal internal atmosphere	Breathable air	same as threshold
9	Subject position	Seated, allowing non-ambulatory evacuation	same as threshold
10	Over pressure protection	14.7 psia	same as threshold
11	Under pressure protection	4.4 psia (30,000 ft)	6.75 psia (20,000 ft)
12	Number of instrument ports	1	2
13	Number of gas ports	2	3
14	Structural safety factor	4	PVHO Code
15	Test Pressure	2.7 psia (40,000 ft)	PVHO Code
16	Flight simulation life cycles	> 1,000	> 10,000

2: If external pressure is 14.7 psia
3: At 8000 ft altitude, ±.1psi is approximately ± 250 ft
4: At 8000 ft altitude, 1 psi/sec is approximately 2500 ft/sec

Figure B1: Fluctuating Altitude Simulation Technology (FAST) Specifications.

APPENDIX C – RECRUITING SCRIPTS

- EMAIL

HEALTHY VOLUNTEERS WANTED FOR AN AVIATION PHYSIOLOGICAL EVENT RESEARCH STUDY AT THE NAVY EXPERIMENTAL DIVING UNIT, PANAMA CITY, FL

Physically fit, healthy, non-smoking active duty and reservist volunteers between the ages of 18 and 60 years are needed for a research study at the Navy Experimental Diving Unit, NSA Panama City. The study will involve altitude and rapid cockpit pressure fluctuation exposure. Prior to the study, subjects must report to NEDU the Wednesday – Thursday prior to testing week for a baseline medical exam, familiarization and baseline cognitive exam, familiarization and baseline Doppler ultrasound exam, orientation and briefing on the flight protocol and procedures, and scheduling for the experimental day. The experiment day lasts 5-6 hours with follow-up procedures at 24 and 48 hours. Hazardous Duty Incentive Pay (HDIP) is authorized for this study. For more information, please contact travis.m.doggett@navy.mil or 850-230-3205.

APPENDIX D – HUMAN TESTING PRESSURE PROFILES

THEORY OF DESIGN

Profile Variation

The human testing pressure profile was built on F/A-18 aircraft representative cockpit pressure changes. The magnitudes and exact start and stop pressures for the profile groups will remain the same between the profiles. The rates of change between these start and stop pressures will be scaled to fit within the intent of the profile. The "Nominal" profile is most representative; however, it has been linearized which does reduce the maximum pressure change experienced. The "Maximized" profile takes many of the larger magnitude pressure movements and sets the pressure rate of change to be at the maximum that would have been experienced in the original aircraft profile. The "Limited" profile takes the "Nominal" profile and limits all pressure rates of change to fall between -0.2 psia/s and +0.2 psia/s.

Nominal Profile Features

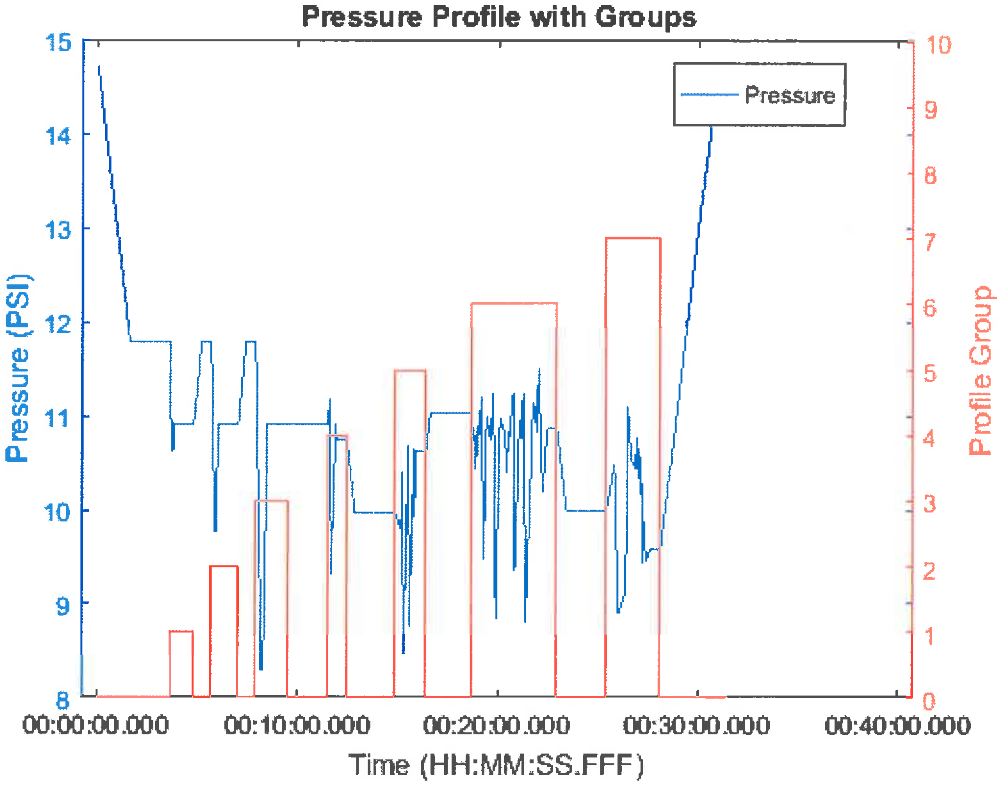
The test begins once the chamber has been closed and secured. The chamber pressure is gradually reduced at a rate of -0.03 psia per second (psia/s) to a pressure of 11.78 psia which corresponds to approximately 6,000 ft. The pressure remains at this value for 120s. The pressure then moves to pressure movement groups 1, 2, and 3. This group is representative of aircraft climbs from 6,000 ft where the cockpit pressure environment is required to change from "unpressurized" regulation to "Isobaric" regulation. At this regulation change the cockpit altitude will tend to follow aircraft altitude before pressurizing down to 8,000 ft and regulating at this pressure. Group 1 depressurizes to 8,690 ft (10.63 psia) before returning to 8,000 ft where it remains for 60 seconds, Group 2 begins by moving down to 6,000 ft where it remains for 30 seconds before it depressurizes to 10,895 ft (9.76 psia) and returns to 8,000ft where it remains for 60 seconds, and Group 3 again pressurizes to 6,000ft where it remains for 30 seconds then depressurizes to 15,010ft (8.29 psia) and returns to 8,000ft where it remains for 60 seconds. The rate of depressurization and pressurization for these groups will vary between the 3 overall profiles. Details of the pressure movements including rates of change can be found in the nominal profile table. The test will then move into the 4 remaining pressure movement groups which again have been pulled from the F/A-18 population. Groups 4, 5, and 6, are linearized representations of actual cockpit pressure changes. Group 7 is also a linearized representation; however, the pressure values have been shifted by a constant in order to allow the movements to occur within the test environment. The pressure rates of change for Groups 4, 5, 6, and 7 will vary between the 3 profiles as detailed above. Following Group 7, the chamber will return to ambient pressure at a gradual rate of 0.03 psia/s. The chamber will be opened following pressure equalization.

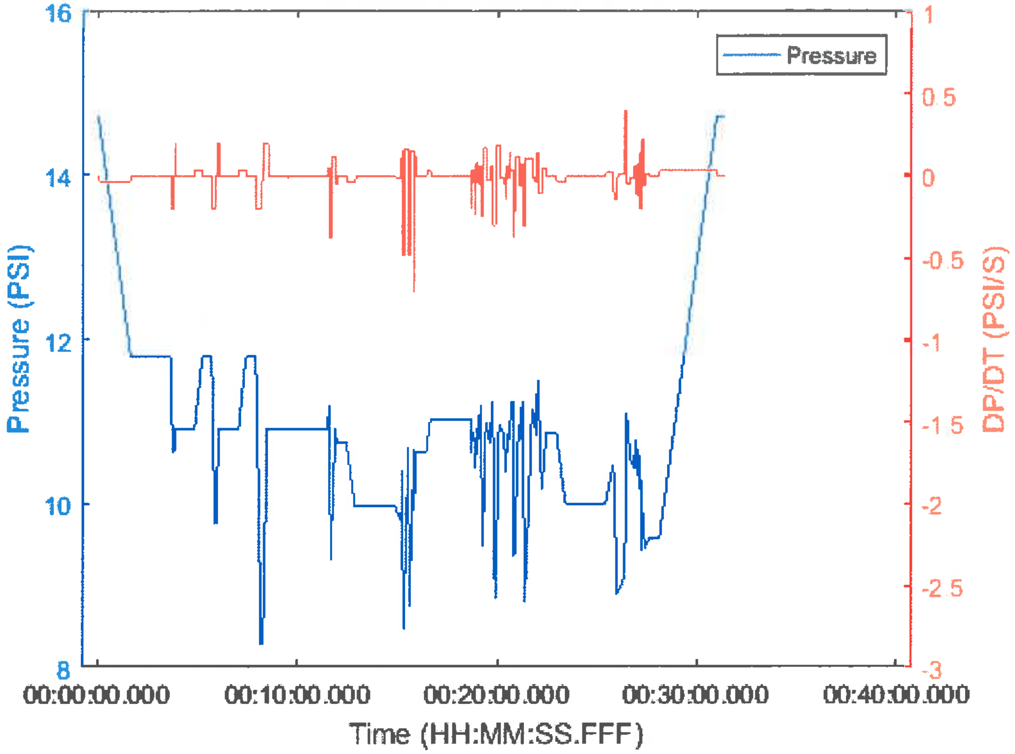
Tolerances

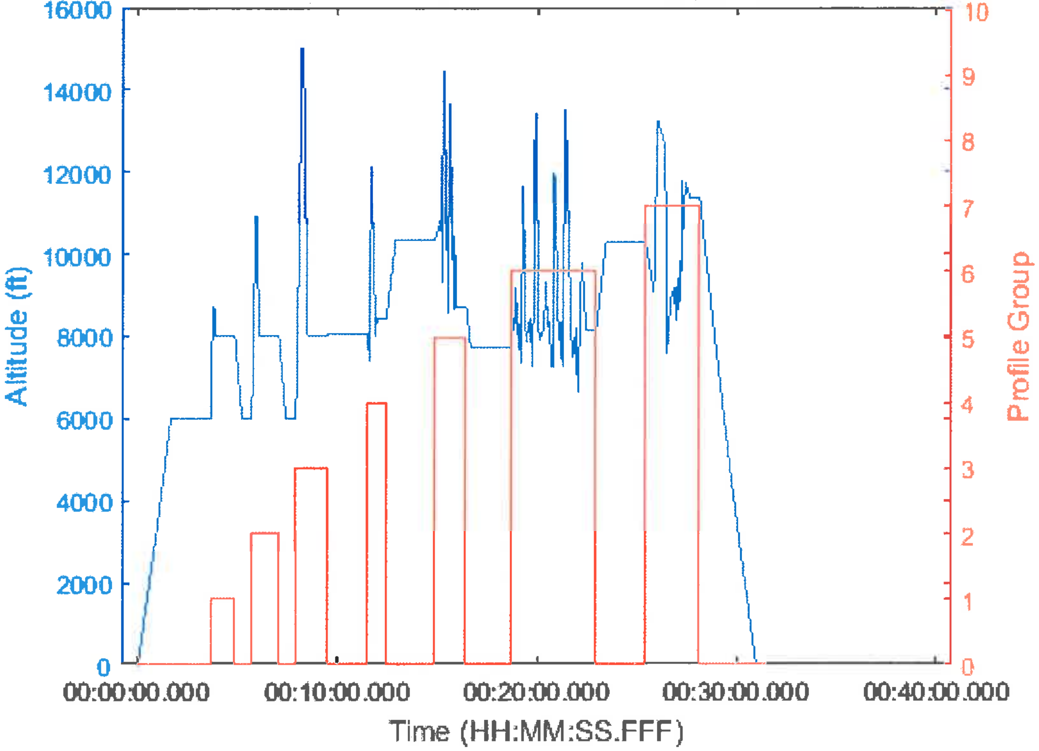
Parameter	Nominal (+)	Nominal (-)
End Pressure when DP/DT (+)	0.1	0.00
End Pressure when DP/DT (-)	0.00	0.1
-DP/DT for 90% of any transition data points with DT of 1s	0.0	0.05
+DP/DT for 90% of any transition data points with DT of 1s	0.05	0.0
DP/DT when in "Loiter Time" DT of 1s	0.05	0.05
Pressure when in "Loiter Time"	0.1	0.1

NOMINAL PROFILE DETAILS

The Nominal profile is comprised of aircraft cockpit pressure representative movements that have only been "linearized" to allow for test apparatus replication.

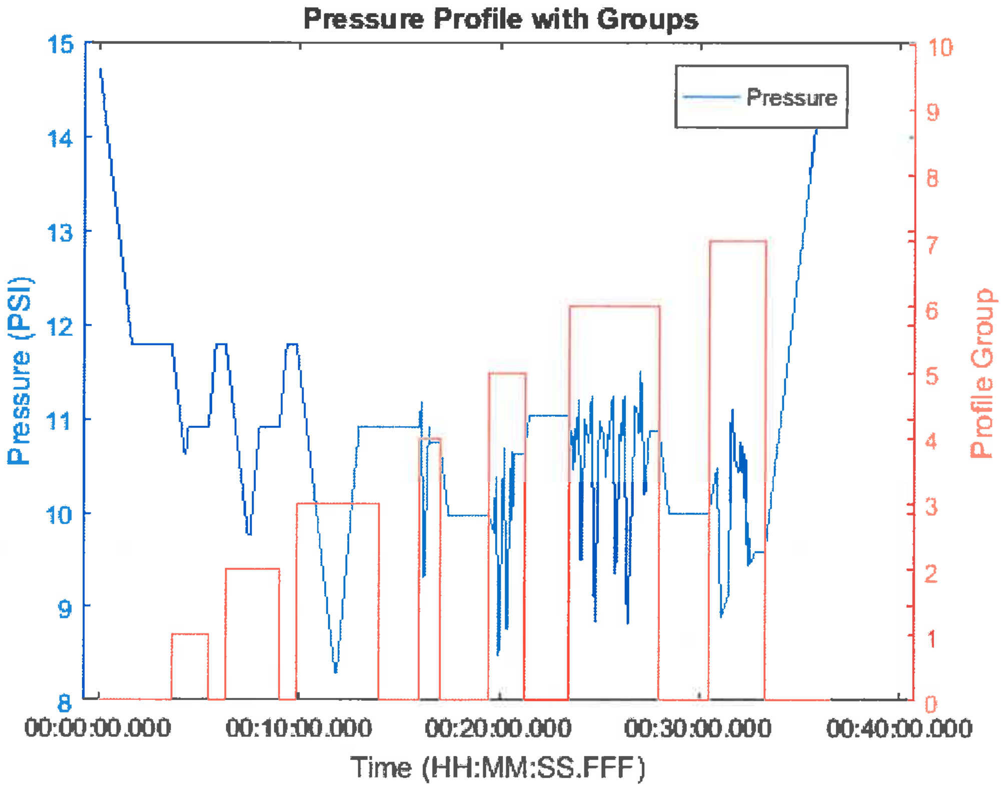


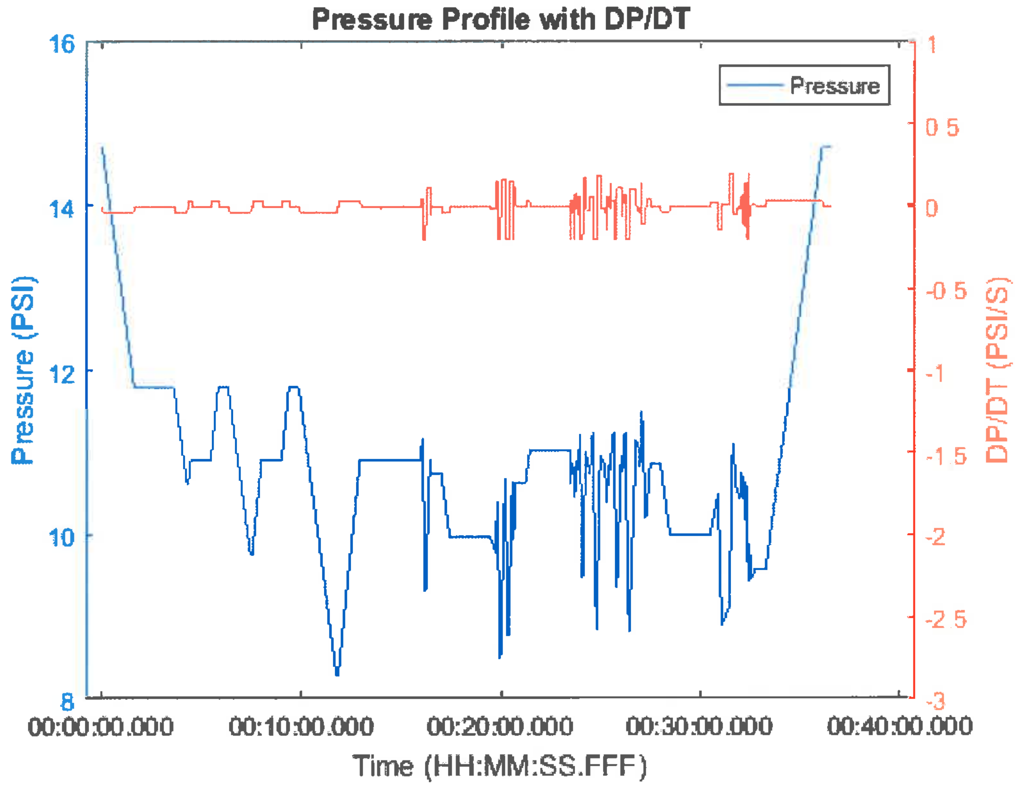

Pressure Profile with DP/DT

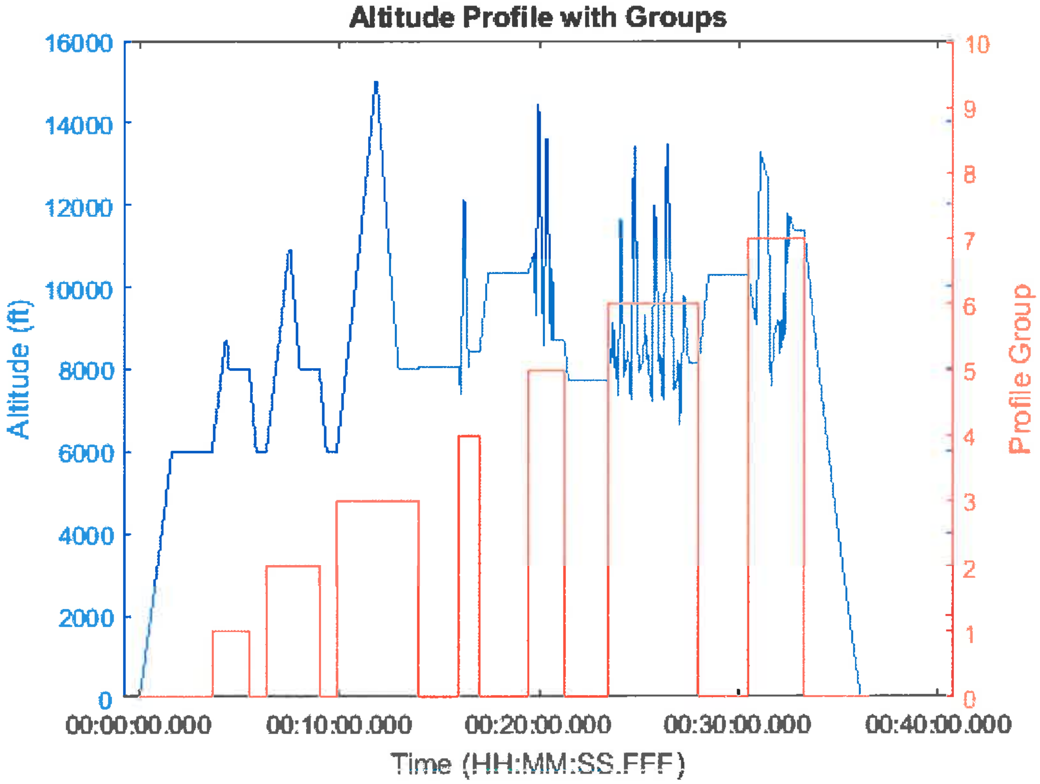

Altitude Profile with Groups

RATE LIMITED PROFILE DETAILS

The Rate Limited profile contains the same 8 groups of cockpit pressure movements covered in the Nominal profile. For Groups 1, 2 and 3 the pressure rate of change has been reduced to that of an "Average" aircraft. For Groups 4, 5, 6, and 7 the pressure rates of change have been limited to exist between -0.2 psia/s and +0.2 psia/s. The modified test points are highlighted in the rate limited profile table.

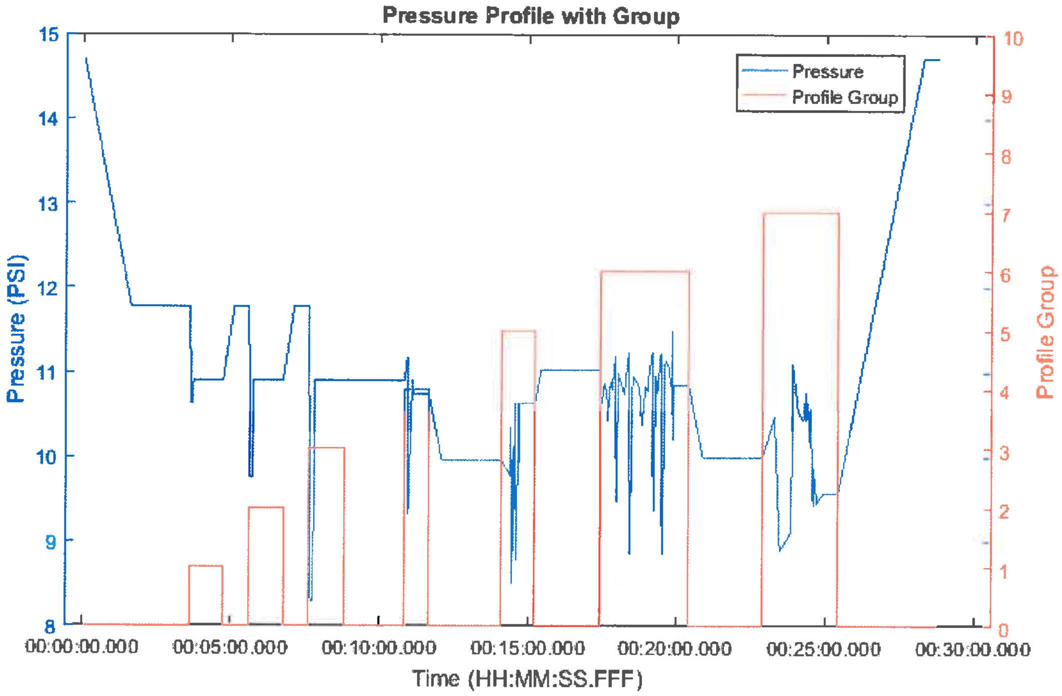


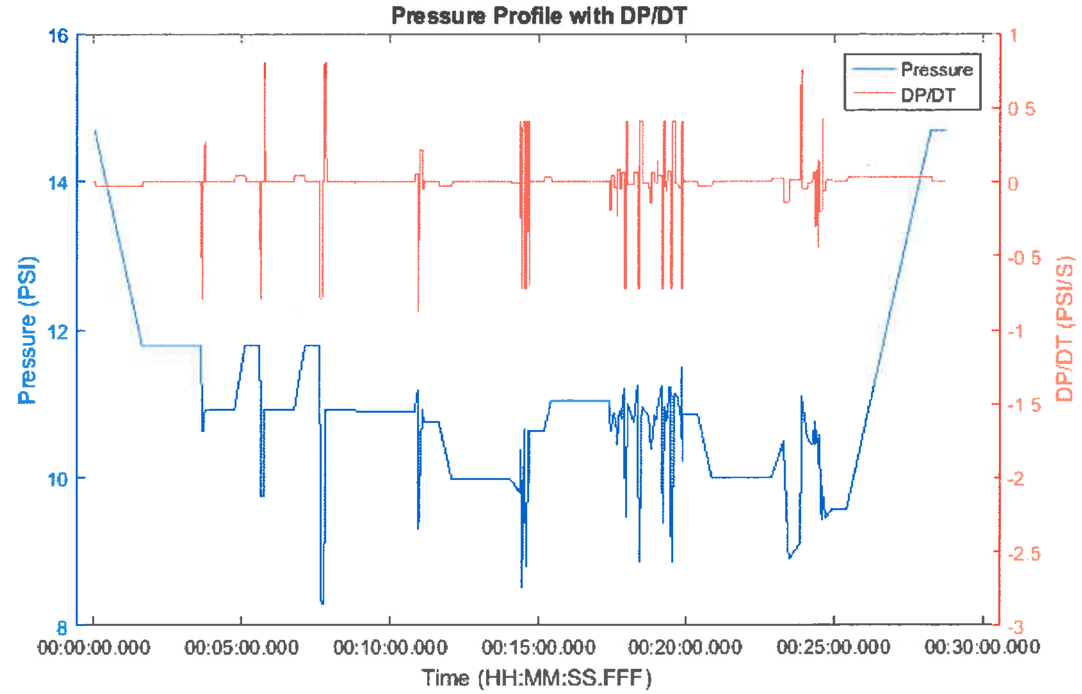

Pressure Profile with DP/DT
Pressure
Pressure (PSI)
16
14
12
10
8
DP/DT (PSI/S)
1
0 5
0
-0 5
-1
-1 5
-2
-2 5
-3
00:00:00.000
00:10:00.000
00:20:00.000
00:30:00.000
00:40:00.000
Time (HH:MM:SS.FFF)

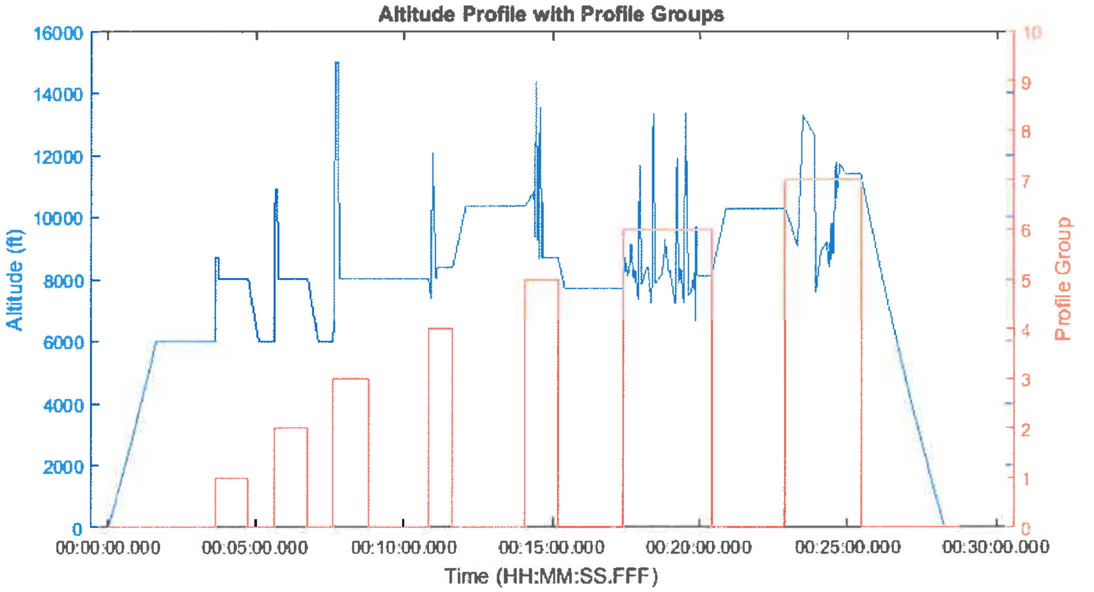

Altitude Profile with Groups
Altitude (ft)
16000
14000
12000
10000
8000
6000
4000
2000
0
Profile Group
10
9
8
7
6
5
4
3
2
1
0
00:00:00.000
00:10:00.000
00:20:00.000
00:30:00.000
00:40:00.000
Time (HH:MM:SS.FFF)

RATE MAXIMIZED DETAILS

The Rate Maximized profile contains the same 8 groups of cockpit pressure movements covered in the Nominal profile. For Groups 1, 2 and 3 the pressure rate of change has been increased to that of a worst case representative cockpit pressure rate of change for this pressure feature. For Groups 4, 5, 6, and 7 the pressure rates of change have been increased to correspond to the maximum pressure rate of change that existed in or original aircraft pressure movement before it was linearized. The modified test points are highlighted in the rate maximized profile table.




Pressure Profile with DP/DT
Pressure
DP/DT
16
14
12
10
8
Pressure (PSI)
1
0.5
0
-0.5
-1
-1.5
-2
-2.5
-3
DP/DT (PSI/S)
00:00:00.000
00:05:00.000
00:10:00.000
00:15:00.000
00:20:00.000
00:25:00.000
00:30:00.000
Time (HH:MM:SS.FFF)


Altitude Profile with Profile Groups
16000
14000
12000
10000
8000
6000
4000
2000
0
Altitude (ft)
10
9
8
7
6
5
4
3
2
1
0
Profile Group
00:00:00.000
00:05:00.000
00:10:00.000
00:15:00.000
00:20:00.000
00:25:00.000
00:30:00.000
Time (HH:MM:SS.FFF)

PROFILE TABLES

Nominal Profile

Movement	Start Pressure (PSIA)	End Pressure (PSIA)	Pressure Rate of Change (PSIA / s)	Loiter Time (s)
0	14.7	11.78	-0.03	120
1	11.78	10.63	-0.2	5
1	10.63	10.91	0.2	60
0	10.91	11.78	0.04	30
2	11.78	9.76	-0.2	5
2	9.76	10.91	0.2	60
0	10.91	11.78	0.04	30
3	11.78	8.29	-0.2	5
3	8.29	10.91	0.2	60
0	10.91	10.9	-0.01	120
4	10.9	11.18	0.05	0
4	11.18	9.29	-0.38	0
4	9.29	10.91	0.12	0
4	10.91	10.75	-0.05	30
0	10.75	9.97	-0.03	120
5	9.97	9.79	-0.01	0
5	9.79	10.4	0.15	0
5	10.4	8.47	-0.48	0
5	8.47	10.68	0.16	0
5	10.68	8.75	-0.48	0
5	8.75	10.65	0.15	0
5	10.65	9.93	-0.72	0
5	9.93	10.63	0.12	30
0	10.63	11.03	0.03	120
6	11.03	10.62	-0.2	0
6	10.62	10.86	0.04	0
6	10.86	10.87	0.01	0
6	10.87	10.67	-0.04	0
6	10.67	10.44	-0.23	0
6	10.44	10.9	0.08	0
6	10.9	10.89	-0.01	0
6	10.89	10.79	-0.05	0
6	10.79	11.2	0.06	0
6	11.2	9.47	-0.25	0
6	9.47	10.99	0.17	0
6	10.99	10.74	-0.02	0

6	10.74	11.24	0.06	0
6	11.24	8.84	-0.3	0
6	8.84	10.97	0.19	0
6	10.97	10.85	-0.01	0
6	10.85	10.66	-0.04	0
6	10.66	10.38	-0.14	0
6	10.38	10.83	0.06	0
6	10.83	10.88	-0.01	0
6	10.88	11.25	0.04	0
6	11.25	9.34	-0.38	0
6	9.34	10.96	0.12	0
6	10.96	10.95	-0.01	0
6	10.95	10.76	-0.06	0
6	10.76	11.24	0.07	0
6	11.24	8.81	-0.3	0
6	8.81	11.14	0.11	0
6	11.14	11.08	-0.01	0
6	11.08	10.83	-0.04	0
6	10.83	11.51	0.14	0
6	11.51	10.18	-0.11	0
6	10.18	10.86	0.05	30
0	10.86	10	-0.03	120
7	10	10.48	0.02	0
7	10.48	8.89	-0.14	0
7	8.89	9.12	0.01	0
7	9.12	11.1	0.4	0
7	11.1	10.54	-0.05	0
7	10.54	10.43	-0.01	0
7	10.43	10.76	0.06	0
7	10.76	10.43	-0.11	0
7	10.43	10.65	0.07	0
7	10.65	10.17	-0.12	0
7	10.17	10.59	0.14	0
7	10.59	9.42	-0.2	0
7	9.42	9.88	0.23	0
7	9.88	9.45	-0.06	0
7	9.45	9.58	0.01	30
0	9.58	14.7	0.03	30

Rate Limited Profile

Movement	Start Pressure (PSIA)	End Pressure (psia)	Pressure Rate of Change (PSIA / s)	Loiter Time (s)
0	14.7	11.78	-0.03	120
1	11.78	10.63	-0.03	5
1	10.63	10.91	0.04	60
0	10.91	11.78	0.04	30
2	11.78	9.76	-0.03	5
2	9.76	10.91	0.04	60
0	10.91	11.78	0.04	30
3	11.78	8.29	-0.03	5
3	8.29	10.91	0.04	60
0	10.91	10.9	-0.01	120
4	10.9	11.18	0.05	0
4	11.18	9.29	-0.2	0
4	9.29	10.91	0.12	0
4	10.91	10.75	-0.05	30
0	10.75	9.97	-0.03	120
5	9.97	9.79	-0.01	0
5	9.79	10.4	0.15	0
5	10.4	8.47	-0.2	0
5	8.47	10.68	0.16	0
5	10.68	8.75	-0.2	0
5	8.75	10.65	0.15	0
5	10.65	9.93	-0.2	0
5	9.93	10.63	0.12	30
0	10.63	11.03	0.03	120
6	11.03	10.62	-0.2	0
6	10.62	10.86	0.04	0
6	10.86	10.87	0.01	0
6	10.87	10.67	-0.04	0
6	10.67	10.44	-0.2	0
6	10.44	10.9	0.08	0
6	10.9	10.89	-0.01	0
6	10.89	10.79	-0.05	0
6	10.79	11.2	0.06	0
6	11.2	9.47	-0.2	0
6	9.47	10.99	0.17	0
6	10.99	10.74	-0.02	0
6	10.74	11.24	0.06	0
6	11.24	8.84	-0.2	0

6	8.84	10.97	0.19	0
6	10.97	10.85	-0.01	0
6	10.85	10.66	-0.04	0
6	10.66	10.38	-0.14	0
6	10.38	10.83	0.06	0
6	10.83	10.88	-0.01	0
6	10.88	11.25	0.04	0
6	11.25	9.34	-0.2	0
6	9.34	10.96	0.12	0
6	10.96	10.95	-0.01	0
6	10.95	10.76	-0.06	0
6	10.76	11.24	0.07	0
6	11.24	8.81	-0.2	0
6	8.81	11.14	0.11	0
6	11.14	11.08	-0.01	0
6	11.08	10.83	-0.04	0
6	10.83	11.51	0.14	0
6	11.51	10.18	-0.11	0
6	10.18	10.86	0.05	30
0	10.86	10	-0.03	120
7	10	10.48	0.02	0
7	10.48	8.89	-0.14	0
7	8.89	9.12	0.01	0
7	9.12	11.1	0.2	0
7	11.1	10.54	-0.05	0
7	10.54	10.43	-0.01	0
7	10.43	10.76	0.06	0
7	10.76	10.43	-0.11	0
7	10.43	10.65	0.07	0
7	10.65	10.17	-0.12	0
7	10.17	10.59	0.14	0
7	10.59	9.42	-0.2	0
7	9.42	9.88	0.2	0
7	9.88	9.45	-0.06	0
7	9.45	9.58	0.01	30
0	9.58	14.7	0.03	30

Rate Maximized Profile

Movement	Start Pressure (PSIA)	End Pressure (psia)	Pressure Rate of Change (PSIA / s)	Loiter Time (s)
0	14.7	11.78	-0.03	120
1	11.78	10.63	-0.79	5
1	10.63	10.91	0.8	60
0	10.91	11.78	0.04	30
2	11.78	9.76	-0.79	5
2	9.76	10.91	0.8	60
0	10.91	11.78	0.04	30
3	11.78	8.29	-0.79	5
3	8.29	10.91	0.8	60
0	10.91	10.9	-0.01	120
4	10.9	11.18	0.05	0
4	11.18	9.29	-0.87	0
4	9.29	10.91	0.21	0
4	10.91	10.75	-0.05	30
0	10.75	9.97	-0.03	120
5	9.97	9.79	-0.01	0
5	9.79	10.4	0.41	0
5	10.4	8.47	-0.72	0
5	8.47	10.68	0.41	0
5	10.68	8.75	-0.72	0
5	8.75	10.65	0.41	0
5	10.65	9.93	-0.72	0
5	9.93	10.63	0.41	30
0	10.63	11.03	0.03	120
6	11.03	10.62	-0.2	0
6	10.62	10.86	0.04	0
6	10.86	10.87	0.01	0
6	10.87	10.67	-0.04	0
6	10.67	10.44	-0.23	0
6	10.44	10.9	0.08	0
6	10.9	10.89	-0.01	0
6	10.89	10.79	-0.05	0
6	10.79	11.2	0.06	0
6	11.2	9.47	-0.72	0
6	9.47	10.99	0.41	0
6	10.99	10.74	-0.02	0
6	10.74	11.24	0.06	0
6	11.24	8.84	-0.72	0

6	8.84	10.97	0.41	0
6	10.97	10.85	-0.01	0
6	10.85	10.66	-0.04	0
6	10.66	10.38	-0.14	0
6	10.38	10.83	0.06	0
6	10.83	10.88	-0.01	0
6	10.88	11.25	0.04	0
6	11.25	9.34	-0.72	0
6	9.34	10.96	0.41	0
6	10.96	10.95	-0.01	0
6	10.95	10.76	-0.06	0
6	10.76	11.24	0.07	0
6	11.24	8.81	-0.72	0
6	8.81	11.14	0.41	0
6	11.14	11.08	-0.01	0
6	11.08	10.83	-0.04	0
6	10.83	11.51	0.41	0
6	11.51	10.18	-0.72	0
6	10.18	10.86	0.41	30
0	10.86	10	-0.03	120
7	10	10.48	0.02	0
7	10.48	8.89	-0.14	0
7	8.89	9.12	0.01	0
7	9.12	11.1	0.75	0
7	11.1	10.54	-0.05	0
7	10.54	10.43	-0.01	0
7	10.43	10.76	0.06	0
7	10.76	10.43	-0.45	0
7	10.43	10.65	0.07	0
7	10.65	10.17	-0.45	0
7	10.17	10.59	0.14	0
7	10.59	9.42	-0.2	0
7	9.42	9.88	0.75	0
7	9.88	9.45	-0.06	0
7	9.45	9.58	0.01	30
0	9.58	14.7	0.03	30