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Understanding Pilot Breathing – A Case Study in Systems Engineering

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Cobham Mission Systems (VigilOX): Ryan Edmonds, Zoe Rabinowitz, Lucas Mesmer, Bill Siska, Rob Schaeffer and, and Aaron Rood. Pilot Breathing data analysis, finding of interactions in the pilot-life support system, would not have been complete without the open dialogue the NASA team had with Cobham, and the dedication of the named engineers. Cobham supported NASA with maintenance, updates, drawings, ConOps, and insight to software. When a specific request was made for process improvement, Cobham worked the issue promptly As Cobham manufactures both breathing regulators and the test instrument used, their insight into the “system” was invaluable.

Naval Air Warfare Center: G. Alston Rush, Ph.D., Biomedical Engineer, NAVAIR Aircraft Division (NAWCAD) Human Systems Engineering Department. The team would like to acknowledge the proactive support, technical interchanges, loaning of additional instruments and tangible engineering solution contributed by Alston and the NAVAIR team, which measurably increased data retained quantity and quality. Pete Zingarelli was instrumental in the technology transition plan of the In Mask Water Vapor and CO2 Sensor (IMCWS) designed under PBA by Lance Christensen, JPL senior scientist.

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Position Paper

Understanding Pilot Breathing – A Case Study in Systems Engineering

June 24, 2021

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Signatories declare the findings, observations, and NESC recommendations compiled in the report are factually based from data extracted from program/project documents, contractor reports, and open literature, and/or generated from independently conducted tests, analyses, and inspections.

Abstract

Pilot Breathing Assessment Systems Engineering (PiBASE) serves as a case-study to demonstrate the value of systems engineering and inclusion of the human element throughout the lifecycle. The “art and science” of systems engineering, its processes, tools and systems view are present and essential in many aspects of the Pilot Breathing Assessment (PBA), implemented to develop processes to measure pilot breathing parameters. Systems Engineering can be aligned with all branches of the PBA scope, from the tailored test campaign collecting in-flight pilot data; to understanding the human-machine system interactions and finding mechanisms that could lead to pilot physiological episodes (PEs[1]); and lastly in the full life cycle of instrument development for pilot breathing monitoring. The PiBASE study interprets the PBA from the perspective of systems engineering addressing the complex interaction with human physiology as an integral part of the whole.

This position paper assesses PBA’s driving requirement to collect missing data on pilot breathing pressure, flow, rate, oxygen and CO_2, simultaneously with aircraft data (e.g., altitude, velocity, G-force, cabin pressure). Repeat measures data were collected over a 2-year period from 5 NASA test-pilots flying 8 flight profiles on NASA F-15 and F/A-18 (A, B) aircraft. With over 100 instrumented test flights, objective and subjective data recorded, PBA met its primary requirement. In addition, analysts investigated the underlying interactions between pilots and aircraft life-support systems that cause Breathing Sequence Disruptions (BSD, a temporal or volumetric mismatch between pilot breathing demand pressure and response air flow delivered) and diminished oxygen which may lead to pilot PEs causing mission aborts. Methods applied included Modeling through “first-principles,” control models, causal additive models, mixed effects modeling, machine learning and statistics. PiBASE demonstrates the use of subjective data and culture/ organizational background to augment objective systems data. The most impactful outcomes were achieved when engineers, physicians and pilots worked together.

Under the systems engineering approach, the conditions that lead to breathing stress could be statistically interpreted to assess if they are more likely equipment, activity, or human variability related. In contrast to machine or computer systems, humans present a high-level of variability in response to the same stimuli as they are subject to subtle changes in health-state and mental stress. Systems-thinking led to a better understanding of the human-machine system under study. A multi-disciplinary approach and cross-cutting methods led to tools which can detect breathing disharmony, objectively compare life support system (LSS) designs and flag LSS or an aircraft in need of maintenance. In the design, development, test, and evaluation (DDTE) of the new In-Mask Carbon dioxide and Water vapor Sensor (IMCWS) for pilots, many of the interdisciplinary processes of systems engineering were reflexively applied, contributing to the success of the realized product meeting the needs of pilots and researchers.

PiBASE demonstrates the importance of including Human Factors (HF) SMEs as integral part of systems engineering into the study design on equal footing with mechanical, computer, and electrical systems. It shows how multi-disciplinary data analysis can pinpoint subtle perturbations that normally go unnoticed but may accumulate over time to add to pilot fatigue and compromised pilot state beyond compensation. The report describes how systems concepts

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[1] A Physiological Episode (PE) is an occurrence when a pilot experiences loss in performance related to insufficient oxygen, depressurization, or other factors during flight.

like hysteresis, pressure/flow mismatch, and system time delays are applied to physiological data to explain BSDs. These findings impact the Aircraft Program Office and pilot communities, systems and discipline engineers. Understanding the breathing dynamics will help Life Support engineers and physicians further develop spacesuits to better accommodate the complex human system.

Executive Summary

The Pilot Breathing Assessment Systems Engineering (PiBASE) position paper serves as a case-study of systems engineering that accommodates the human as a distinct part of the whole. It acknowledges that a successful machine design intended for human use must include human systems biology/physiology as an integral part of planning, design, and implementation.

Systems engineering is a methodical, disciplined approach for the design, realization, technical management, and operations of a complex system. At NASA, this approach has evolved over the years of space flight and aeronautics and has become the "logical way of thinking". According to the NASA Systems Handbook NASA/SP-2007-6105:

> *"…Systems engineering is the art and science of developing an operable system capable of meeting requirements within often opposed constraints. Systems engineering is a holistic, integrative discipline, wherein the contributions of structural engineers, electrical engineers, mechanism designers, power engineers, human factors engineers, and many more disciplines are evaluated and balanced, one against another, to produce a coherent whole that is not dominated by the perspective of a single discipline."*

In short, systems engineering represents the fundamental principles under which NASA operates and strives to fully integrate engineering subsystems into a complete whole.

An important challenge to systems engineering is the integration of human factors into the machine. Like engineered machines, human systems biology is also highly complex, but has some important differences. Human response to external stimuli is less consistent as it varies in time, between people, and is affected by the psychology/feelings/perceptions at the time. This is summed up succinctly by Dawn M. Schaible, Director of the Engineering Directorate at NASA Langley Research Center:

> *"While many people understand the concept of a human as being part of a system, what may not be appreciated completely is the highly variable, highly sensitive, non-deterministic nature of humans. In a functional overview of a system, engineers can predict with a good amount of certainty that a particular input into a pump, or valve, or resistor, etc., will result in a particular output. There is typically minimal unit-to-unit variability across like hardware components that come from the same manufacturer. The same cannot be said about humans. This is what makes Humans Systems Integration particularly complicated and requires skills and expertise not often considered in the team composition early in the system development."*

Pilot Breathing Assessment (PBA) Study:

This case study was performed because the PBA extends beyond traditional mechanical, computer, electrical, power, and hydraulic systems engineering and encompasses detailed human physiological parameters. In the design stages of PBA, the team recognized that:

- human data are fundamentally different from engineering data in that individuals have large within- and between-subject variance; that is, any individual physiological measurement may be affected by unknown factors.
- human data acquisition requires a "repeat measures" strategy to help sort true effects from random effects.

NESC gathered comprehensive in-flight data and explored system interactions under the Pilot Breathing Assessment. PBA was the first to combine 8 data collection methods on human and jet on 100+ flights over 2 years. The design of PBA was to collect data from multiple pilots, multiple aircraft, and multiple flight profiles and then repeat them as resources permitted.

PiBASE/PBA Background – Investigating Physiological Events

Modern jet-fighter aircraft are marvels of aerospace engineering comprised of complex systems including propulsion, navigation, maneuvering, life support, communications, and weapons delivery all working together. However, when a mission cannot be completed, there is a natural inclination to search for a single fault that can be corrected. This approach is not often successful due to the overall complexity of such a "system of systems" wherein subsystems and components may each be operating within their nominal ranges, yet in aggregate exceed some critical limits. To diagnose and ultimately avoid such disruptions, engineers have implemented a "systems engineering" approach for the design and operation of state-of-the-art aircraft.

Despite best engineering efforts, there are mechanisms (e.g. see section 3.2, Section 4 and section 6.3.2) that adversely affect the human operator. These are known as "physiological episodes" (PEs) wherein the pilot can no longer function to safely complete a mission. Over the past 10 years, NASA has supported the military in understanding PEs and applying expertise in life support gleaned from operating aircraft and spacecraft under adverse conditions. NASA's recently released "Pilot Breathing Assessment" (PBA) report is the first comprehensive study of the machine-human interaction in real-world flight operations that collects physiological data including breathing rate, volumes, flows, pressures, and oxygen consumption along with standard operational data-streams such as altitude, speed, and acceleration. Prior to the PBA study, aircraft breathing systems were developed using default values, and sometimes erroneous assumptions about human physiological variance and needs.

As discussed in detail in the report NASA Engineering and Safety Center (NESC) NESC-RP-18-01320 V.1.2 NESC PBA (Vol. 1&2)[2] which was released on 11/19/2020, PBA was successful for a number of significant reasons:

- PBA developed test methods with a focus on repeat measures,
- PBA focused on pilot breathing demands with a pilot performing tasks in an actual flight environment,
- PBA linked real-world flight events to pilot physiological behavior, and
- PBA established a baseline of pilot pulmonary function and the effects of flying on pilot physiology.

The PBA study collected >40 data-streams with temporally linked human (pilot breathing) and aircraft measurements at 20 Hz resolution representing 115 individual instrumented sorties. Summary data were compiled as 1-min flight blocks and interpreted with respect to meta-data including pilot, aircraft, breathing configuration, and flight profile. This provided the first comprehensive view into the effect of flying activity on human breathing needs. Statistical analyses identified flight minutes with physiological indicators of higher stress (e.g., elevated breathing rate, pressures, and tidal volumes), that were then further investigated at 20 Hz resolution to assess breathing gear performance in response to flight parameters. The high-resolution targeted investigations yielded enlightening information with respect to PEs. It was

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[2] Pilot Breathing Assessment, November 19, 2020

determined that breathing pressures and air-flows were often mismatched, resulting in increased effort by the pilot in maintaining sufficient ventilation. Although humans are quite adaptable to such breathing stress, repeated hysteresis in pressure/flow parameters adds to the burden of flying. The PBA study is the first to document such breathing sequence disruptions (BSD) within the context of using on-demand mask/regulator systems and liquid oxygen (LOX) supply.

Systems Engineering aspects:

The PBA study was chosen as a case-study herein to demonstrate that treating the human component on equal footing with other flight systems like the computer, electrical, mechanical, aeronautic, power, and hydraulic systems is crucial for understanding total performance. This case study shows in detail how proper physiological data can be used to integrate the LSS into the overall aircraft system. LSSs are more complex than realized and need to be treated as part of the whole integrated system. The major outcomes of the PBA study are used to demonstrate how future design efforts could benefit from including human physiology as an integral part of design and proposes that unanticipated adverse interactions could be avoided. PiBASE addresses a number of concepts that have been missing from previous engineering investigations regarding human nature/performance within an engineered system and the incidence of apparently random physiological events. These concepts are:

- The human – machine interactions are critical and non-linear. Individually they may be subtle, yet together they have an impact on pilot health.
- Breathing system disruptions can occur even when breathing air is supplied from a LOX tank. Human-jet interactions are complex.
- Human physiology is more variable, but also more adaptable than the machine.
- Human adaptability can overcome defects in the engineered system, but at a cost.
- Human psychology can lead to overconfidence in the absence of hard data.
- Culture affects communications. Pilots won’t always report problems if they believe it could get them grounded.
- Simple measures of oxygen and pressure are insufficient in assuring life support.
- High resolution data of breathing (timing, volume, flow, pressure) are critical in PE diagnostics.

As such, PiBASE is an exploration of the PBA study that explains the underlying systems engineering aspects of integrating the human factor into the product lifecycle.

PiBASE topics

This case study does not introduce new data; all the information relied on herein has already been published in the extensive NASA publication of the PBA assessment. The value developed here is to demonstrate how such a complex study has a basis in sound systems engineering principles despite the admittedly random effects introduced by human physiological data.

However, this case study can stand alone. It is constructed of a series of sections that reprise the PBA study sufficiently for a complete understanding, and then develops how PBA fits into the framework of systems engineering. What makes PiBASE important is human factors integration into the engineering framework. The background of PBA and the resultant themes of systems engineering are laid out in a logical progression of the following sections:

PiBASE covers the following SE topics:

- Systems Engineering and its application in PBA; Integration of human factors into the system; The value of HSI — Section 2
- Causal Investigation evolution to match the complexity of the System — Section 3
- System of Systems Approach: system control with human in-the-loop; Human as a System — Section 4
- Examples of SE: Tailoring Concept of Operations for Physiological testing (AFRC) — Section 5
- Interpreting in-flight breathing data with engineering flight data (systems analysis) — Section 6
- Fundamental differences (variability) between human data and engineering data
    - Importance of repeat measures when dealing with humans to sort true vs. random effects — Sections 6, 8
- Instrument design for physiological testing — Section 7
- Considering the effects of organizational culture as an SE factor — Section 8
- Using PBA findings to improve design, testing and maintenance — Sections 9, 10

Summary:

The PiBASE case study demonstrates a detailed implementation of systems engineering wherein information is collected from the human system in conjunction with traditional engineering and performance data. The report shows that apparently random events could occur despite nominal performance of engineered subsystems. One main example developed herein is oxygen delivery to the pilot. Before breathing data were integrated into aircraft diagnostics, it was assumed that if oxygen concentration and pressure in the supply were within certain ranges, that the pilot was safe. This was not true; analysis of the mechanical interactions in providing breathing gas *via* on-demand regulator and mask systems showed a series of potential BSDs causing adaptation by the pilot in tidal volume, exerted lung pressure, breathing rate and breathing frequency. Such changes require additional physical effort, and can lead to distraction, fatigue, and mild hypoxia during flight operations. Now that these subtle effects are documented, preventative systems engineering measure can be implemented.

Another important outcome from PiBASE is a recognition that fighter pilots tolerate and adapt to breathing systems disruption on a regular basis. According to pilot interviews, these events are either not reported, or if reported, many are adjudicated as “unexplained.” Now that specific detailed data have shown that there are physio-engineering explanations, corrective actions can be taken before an adverse outcome PE occurs.

The inclusion of human systems data has been demonstrated as a valuable component in diagnosing pilot life support. The pilot-state affecting mechanisms described in this case study are multi-disciplinary in nature and incorporate a systems view, enabling explanations for subjective pilot anecdotes, and paths forward to corrective actions.

Team List

Name	Discipline	Organization
Core Team		
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Lance Christensen	Senior Scientist	JPL
Jon Haas	Engineering Physics	WSTF
Kellie Kennedy	Human Factors	LaRC
James “Clue” Less	Research Test Pilot	AFRC
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Erin Moran	Technical Editor	LaRC/AMA

Acknowledgements

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NASA Systems Engineering Communities (and within that, the Human Systems Integration engineers): The PiBASE team expresses gratitude for the overwhelming support of the many enthusiastic, expert engineers who offered their wisdom and guidance on this project.

1. Narrative History of Physiological Episodes (PE) and the Pilot Breathing Assessment (PBA) Motivation

Introduction

1.1 Motivation and Scope of Case Study

Pilots of high performing jets have reported symptoms during flight which affect their "ability to (safely) perform their missions"[1]. These symptoms sometimes are better noticed by a co-pilot or "wingman" and not by the pilot themselves. In some cases, negative health effects have lingered for months or caused permanent disability. The NESC has been involved in the study of these episodes, termed *Physiological Episodes* since 2012.

Physiological Episodes (PE), definition: The US Navy defines a PE to be an "**occurrence when a pilot experiences loss in performance related to insufficient oxygen, depressurization, or other factors during flight**." Reported symptoms include tingling, lack of focus, feeling of doom, feeling and manifesting as if intoxicated, blurred or spotty vision, dizziness, disorientation, or cognitive impairment. The seriousness and impact of these symptoms, as well as their rising rates, elevated this issue to the level of a congressional hearing in 2017. The NESC was a 'third party' tasked to perform an independent assessment of PEs. According to the NESC report[3], "physiological episodes happen to people, not aircraft." The Hon. Michael R. Turner (chairman of the subcommittee) after talking to the Secretary of the Air Force concluded[4] that "the human body as a sensor is perhaps different than just our technological sensors and can give us a gap in the information or data that we are receiving."[1] It is important to trust the subjective reports of the pilots having these issues, but objective data are needed as well, to tie together the human and aircraft systems and the way they influence each other for analysis. One of the key NESC findings was there were no quantitative in-flight data from the pilot interface. The NESC report recommended that in-flight testing be performed to gather the missing data.

1.2 Solving the Black Box Problem

The NESC Pilot Breathing Assessment (PBA, 2018-2020) was set up as a first attempt to fill the gap in the missing data from pilots (the so-called Black Box problem). Pilot respiratory rates, tidal volumes, and air composition in high-performance aircraft are not well understood or documented. **The scope of the PBA** was to:

- develop a process to measure these parameters that were standardized, systematic, and relatively easy to perform;
- develop new instrumentation systems that are smaller, lighter, more capable, and more energy-efficient; and
- assist in better understanding the causes of PEs with the hope that this understanding will lead to design improvements and ultimately improve pilot health, safety, and performance.

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[3] NASA Engineering and Safety Center Technical Assessment Report. F/A-18 and E/A-18 Fleet Physiological Episodes. September 14, 2017. NESC-RP-17-01205

[4] Subcommittee on Tactical Air and Land Forces, Washington, DC, February 6, 2018. Hon. Michael R. Turner (chairman of the subcommittee) presiding.

After more than 100 pilot- and aircraft-instrumented flights, the NESC PBA team issued more than 100 impactful findings and recommendations. The success of the PBA was in large part due to the Systems Engineering[5] approach. This was applied to the human-in-the-loop testing, to the analysis folding in the aircraft and human as a system-of-systems, and to the development of a new instrument, the In-Mask CO_2 and Water-vapor Sensor (IMCWS). For all these reasons, PBA emerged as a case study for systems engineering with human systems integration (HSI).

The scope of this Pilot Breathing Assessment Systems Engineering (PiBASE) case study was to:

- Examine the PBA from a Systems Engineering and HSI perspective,
- Give examples of systems analysis as the key to the success of complex investigations
- Highlight interactions and findings related to the SoS under study, including the human
- Present the Systems Engineering process of the IMCWS instrument developed during the PBA as a case example

1.2.1 LSS Desired Outcome – Pilot Performance

Human life support systems (LSS), especially those that provide breathing gas, are pervasive in modern society. They are found in aircraft, space vehicles, and submarines, in adverse environments for firefighters, divers, laboratory workers, first responders and other high-risk workers, as well as in medical applications for oxygen supplementation and ventilators. LSS all have one thing in common: they invoke complex systems engineering with mechanical, electronic, pneumatic and software components that additionally have to interact with human physiology. Essentially, LSS has to be treated as a "system of systems" (SoS) to be successful.

The explicit and obvious goal of any LSS is to sustain life in an otherwise inhospitable environment or situation. In the tactical jet this is similarly true; however, in this case, the LSS has a more subtle implied objective: maintaining pilot performance. The tactical jet environment places incredible physical stresses on the pilot. These stresses are at the limit of human capacity even under nominal flights. G-force levels can exceed those at which untrained and unacclimated individuals will lose consciousness. Unlike the nearly constant-pressure environment of commercial airlines, rapid changes in cabin pressure are commonplace in modern fighter aircraft cockpits. Additionally, protective gear worn by the pilot can both enhance and restrict performance. All these elements interact, and all can affect pilot health and performance.

The integrated LSS needs to actively compensate for changes to the environment and give the pilots what they need, when they need it (near-real-time, with minimal lag and effort): pressure, temperature, airflow and breathing gas quality which includes O_2 concentration. The PBA study found that while individual sub-systems and components may be working as they are designed or specified, they may not be achieving their ultimate and implied objective – ensuring pilot health and performance. If, for example, a pilot is being delivered adequate oxygen, but cannot inhale deeply or often enough, they will become hypoxic (i.e. the body does not get enough oxygen). If all that is being measured is breathing gas quality and flow, the monitoring system will be blind to the effect and insensitive to the desired outcome. The system appears to work, but the pilot suffers.

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[5] Systems Engineering is defined as "a methodical, multi-disciplinary approach for the design, realization, technical management, operations, and retirement of a system"

PBA took the first steps towards connecting measurements to desired outcomes using an approach sensitive to sub-system or component interactions. Instead of measuring what the machine was doing/, the PBA data measured real-time human physiological responses to the machine and changing environment. This is one step closer to measuring pilot performance, and at minimum allows one to take advantage of other research on human performance responses to measurable physiological parameters. This analysis was augmented by combining subjective reports from pilots of their in-flight experiences.

1.3 Historical Design and Monitoring Philosophy

The idea that simple but achievable measurements can tell one how an LSS is operating has become mainstream in tactical jet LSS design. For example, the late model (E/F/G) F/A-18 uses an on-board oxygen generation system (OBOGS) that monitors the O_2 concentration and outputs a warning if the concentration drops below a predetermined level in the gas delivered to the pilot's breathing regulator. All this can tell us is that a concentration above some threshold is present, but does not inform on pressure, flow or timing. Monitoring O_2 concentration can indicate an important component fault but has little value on evaluating immediate pilot health. In addition to not being relatable to pilot health, O_2 concentration data tells us little about the function of the overall LSS when viewed as a SoS. The point is that in thinking about an LSS, one needs to start with the concept of human system integration requirements (HSIR), integration of the human as an element of the system to ensure that all components cooperate effectively to perform a successful function (see Section 2.2).

1.4 An Improved Conceptual Model

Improving pilot health and performance necessitates moving away from the aforementioned historical monitoring and design philosophy. The PBA team took a step in that direction by examining data on pilot breathing responses to changes in machine and environmental parameters. Connection of this data to pilot condition was aided by the use of the Oxygen Transport Model (OTM)[6]. The OTM was created as a conceptual model to help connect readily measurable parameters (e.g., breathing gas flow and pressure, CO_2 and O_2 concentration in the breathing system, and pilot respiration rate) to known human physiological responses. However, this is not a direct measure of pilot health or performance. It is still a proxy, albeit more useful than an O_2 monitor upstream of the pilot, but nonetheless dependent on assumptions of the connection between human (and individual) health and performance and the available measurable parameters. Conceptually, a complete end-to-end measurement would be sensitive to, for example, oxygen availability in the pilot's central nervous system (and/or other direct health metrics) along with some objective measure of task performance and relate those objective metrics to the dynamic environmental and machine state. Clearly, at this time, such measurements are impractical; but understanding their conceptual value allows one to better evaluate the assumptions and limitations of one's current understanding of the human-machine-environment interactions and how designed systems can affect that relationship. Moving closer to the ideal begins with an appreciation of human limits and needs. This aspect of System Engineering (SE) is the subject of HSIR, which is discussed further in Section 2.3.

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[6] Reference to previous NESC reports.

1.5 History of Physiological Episodes

1.5.1 Background

The modern jetfighter is a complex weapons system operating at high speeds with rapid changes in altitude and direction; this subjects the pilot to high G-forces and rapid changes in cabin pressure. Subtle deficiencies in LSS, or unexpected interactions between components in the overall aircraft system can cause in-flight PEs which adversely affect pilot performance and jeopardize their health and safety.

The NESC has been assisting the United States military services in understanding and mitigating PEs in high-performance fighter aircraft since 2012. PEs are broadly defined as adverse effects on the pilot that prevent completion of an assigned mission; their mitigation is considered a "top safety priority" in the flight services. PEs range in severity in symptomatology from nausea, dizziness, shortness of breath, headache, and ear pain all the way to cognitive impairment and loss of consciousness that can lead to loss of life[7]. In some PE cases hardware failures (e.g., pressure related) were found to be contributors. In many others however, the USN and USAF have struggled unsuccessfully in finding root cause(s) for PEs based on engineering systems analyses.

At the behest military senior leadership, NESC teams of subject matter experts have analyzed the occurrence of PEs in a series of studies to bring "fresh eyes" to this difficult problem. Specifically, three studies have been completed regarding different phases of the PE problem. The first two studies relied entirely on flight and PE data provided by USAF and USN, respectively; the third study was independently conducted by NASA.

1.5.2 NESC Study 1: F-22 Life Support System (LSS) Independent Analysis

In May 2012, US Air Force requested NASA assistance to determine the cause of hypoxia-like symptoms experienced by F-22 pilots. At the time, there were 21 documented incidents, later referred to as "unexplained PEs", one of which resulted in the loss of aircraft and pilot. Briefly, the NESC team of subject matter experts reviewed documents provided by Air Force, interviewed F-22 pilots, and investigated potential vulnerabilities of the OBOGS, environmental control system (ECS), and the aircrew flight equipment (AFE).

The main results from the study revolved around the complexity of the F-22 system, and the lack of integration of human factors into the design, operation, and maintenance of human LSSs. The upper pressure garment (UPG) worn for high-G maneuvers could excessively constrict breathing. An in-line contamination filter, installed without the data to justify it, contributed to difficulty breathing. The team found that the emergency oxygen system had to be manually activated (precluding recovery by an unconscious pilot), and that the activation handle (green ring) was difficult to reach even under the best conditions. The team also found that the incident medical response protocols did not capture in-flight data related to symptoms known from ground testing. Overall, the report provided 16 Findings, 13 Observations, and 23 NESC Recommendations.

The NESC report (NESC RP-12-00792) was submitted to US Air Force in 2012.

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[7] Ref. F-22 accident report and maybe others

Subsequently, the Air Force performed two major corrective actions: 1) The "anti-G Combat Edge" upper garment performance was reviewed and ultimately discontinued. 2) All F-22 aircraft were retrofitted with an emergency oxygen system that activated automatically.

1.5.3 NESC Study 2: F/A-18 and E/A-18 Fleet Physiological Episodes

In March 2017, the NESC assembled a multi-disciplinary team of subject matter experts at the request of the USN to review F/A-18 and E/A-18 aircraft PE resolution efforts, identify factors that could lead to PEs, and evaluate performance of aircraft subsystems related to pilot life support. This was a highly complex endeavor that characterized 258 reported PEs with respect to medical reports and aircraft parameters; an OTM was developed to articulate the factors leading to PEs, assessed in-flight toxics exposure measurements, and to evaluate the USN's causal analysis efforts.

The main conclusions from this study were that individual PEs have many contributing factors and so appear random when evaluated using standard root cause analysis methodologies which seek to identify typically a single fault in an otherwise functional system; in short, the incidence of a PE is most often brought on by a complex interaction between human and machine systems which was not understood during the system design development and integration phase. The team found that the primary obstacle to resolving the PE issue is the complete lack of in-flight human performance data (e.g., breathing volume, timing, rate, and pressures), coupled with incomplete capture of air supply and cabin pressure data. The team evaluated potential contamination in the OBOGS air supply based on in-flight measurements of volatile organic compounds (VOCs) provided by the USN and found that there is indeed some breakthrough of VOCs from ambient and bleed air to the pilot's mask and cabin air, but the concentrations do not reach levels of concern with respect to human toxicity. Upon investigating Navy maintenance data, the team found that OBOGS sieve beds can become partially saturated with water that compromises oxygen output. The team also found that bench testing of OBOGS systems does not simulate the in-flight needs of the pilot.

The NESC report has detailed analyses of the medical aspects of PEs, flight and aircraft systems parameters, and the various efforts of Navy for PE reduction. The team provided 72 findings, 43 Observations, and 24 NESC Recommendations. The report (NESC RP-17-1205, Vol 1, 258 pgs., Vol 2, 139 pgs.) was submitted to USN and US Congress Armed Services Committee in September 2017.

The team briefed senior USN leadership at NAVAIR headquarters in Patuxent, Maryland, and as part of a Blue-Ribbon Commission convened by the Navy in April 2018.

1.5.4 NESC Study 3: Pilot Breathing Assessment (PBA)

The NESC experience in the previous two assessments provided insight into two overarching themes for developing, operating, and maintaining high-performance aircraft LSSs in the face of apparently random adverse outcomes:

1) Test like you fly (TLYF) and fly like you test.
2) PEs happen to pilots, not to aircraft.

Both themes support the underlying philosophy that the real-world of human physiological response cannot be decoupled from the systems engineering, maintenance, and diagnostics of LSS. The only way to understand the apparently random incidence of PEs is to develop a systems interaction framework that simultaneously provides data for human and aircraft parameters under realistic in-flight conditions.

The NESC assessments reinforced the notion that PEs were most often the result of a stack-up of factors encompassing the integrated human, machine LSS, and environment, rather than one failed component. This is one reason the classical Root Cause and Corrective Action (RCCA) approach was so ineffective in understanding PEs. When examined in isolation individual systems and components appeared to operate within their design envelopes, at least most of the time. Additionally, most of the PEs identified that resulted from a stack-up of multiple factors appeared to manifest as hypoxic hypoxia[8]. In summary, what became clear is that instrumented pilot response data in the actual flight environment was necessary to finally understand the complex interactions that appeared to be responsible for PEs.

In June 2018, NASA implemented the PBA study independently from previous studies performed by the USN and USAF. PBA was designed from the ground up to address the "complex system of systems" interactions wherein pilot physiological responses were treated as the dependent (outcome) variables. This was a unique approach; previous military studies were observational and focused on retrospective analyses of PE flights. The PBA study was prescriptive; scripted flights were conducted with in-flight pilot and aircraft instrumentation capturing high resolution data of breathing parameters (breaths/minute, tidal volume, inhalation/exhalation flow rates and pressures) along with cabin pressures, delivery oxygen concentrations flows and pressures. All flights were conducted at the Armstrong Flight Research Center (AFRC) with NASA ground personnel, NASA test pilots, and NASA F-18 and F-15 aircraft.

The PBA team documented a series of conditions that could lead to hypoxia and other breathing dysfunctions despite that the aircraft systems were providing nominal oxygen levels and gas flows. A statistically significant data set describing pilot breathing response to a variety of flight segments including ascents, descents, high-G turns, altitude/pressure, as well as different configurations of mask/regulators gear were documented.   The team further developed machine learning tools that identify adverse impacts on pilot physiology. These were applied to all F-15 and F-18 flights from the study as well as some F-35 ground test data provided by Air Force to develop a scoring system for tracking the human-aircraft interactions that can lead to PEs.

PBA flight operations were conducted from June 2018 to August 2020. A detailed final report[9] was disseminated to Department of Defense (DoD) stakeholders on November 19, 2020. Follow-up briefings were delivered to senior management at the USAF and USN.

As an ancillary project, PBA collaborated with NASA's Jet Propulsion Laboratory, Pasadena CA to develop a miniaturized optical sensor which was directly implanted inside the MBU-20P pilot mask capable of resolving concentrations at 100 Hz resolution. This extraordinary new instrumentation was successfully flight tested by PBA and the technology was turned over to the Navy for further development.

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[8] In this type of hypoxia, the tissues do not have enough oxygen because there is a lack of oxygen in the blood flowing to the tissues.

[9] NESC Pilot Breathing Assessment, November 19, 2020. NESC-RP-18-01320

The results from this study completely changed the landscape of physiological episode investigation and mitigation and showed unambiguously that the three-fold systems interactions of human, environment and machine are critical in understanding life support in challenging and dynamic environments such as those encountered in high-performance aircraft.

1.6 Pilot and Aircraft – a Complex System of Systems (with data only on half of the system)

The human body has evolved to live and breathe in a stable environment on the earth's surface with 1-g gravitation, one atmosphere pressure, and a plentiful (functionally infinite) supply of air at approximately 21% oxygen/79% nitrogen. As accelerated psychophysiological demands are placed upon a human body, breathing and cardiovascular function change to accommodate, with the general implicit understanding that there will be a plentiful supply of atmospheric breathing air provided by the environment.

Modern high-performance aircraft are complex machines that harnesses the power of a turbine engine (or two) using sophisticated electronics, hydraulics, computers, and a high-tech airframe. The jet can operate at high speeds with three-dimensional acceleration (9g or more) along with rapid changes in altitude and cabin pressure (0 to 50,000 feet, 1 to 0.1 atm). In the midst of this array of technology and performance, sits the human pilot in charge. However, in contrast to the natural atmosphere of a terrestrial environment, the environment inside a tactical jet aircraft must be manufactured synthetically by a machine.

For the purposes of this study, the systems in a jet aircraft may be grouped into two distinct types: operational and life support. Operational systems allow the aircraft to fly and maneuver, deploy weaponry, and perform a mission; LSSs serve to keep the pilot functioning optimally as a human being within the performance requirements of a biological entity. While significant resources have gone into the specification of requirement sets and development of performance parameters for aircraft mission operational systems (i.e., avionics, flight controls, engine management), significantly less development has gone into the systems which support the pilot's vital functions and biological requirements. In fact, even the basic psychophysiological demands of a pilot in a modern high-performance aircraft are not well understood.

When pilots experience PEs, the standard practice has been to look for a fault in a hardware component or subsystem using a "fault tree" style troubleshooting approach. The expectation is that the problem occurred for a specific mechanical reason and can be identified, fixed, and avoided in future. However, this approach may prove insufficient when viewing the problem as one of larger system function between pilot and aircraft as an integrated system and viewing the problem itself as a shortcoming of design in system integration architecture.

Conclusion

The aforementioned studies on the complex aircraft-human system demonstrated that a well-functioning design of a LSS needs to begin with HSIR. To do so necessitates building an understanding of human-machine-environment systematic interactions; this requires an understanding of how the human system responds to and influences the non-human mechanical, electronical, pneumatic, and software subsystems of the machine. Furthermore, the entire system should be treated as a holistic entity and tested as such in the flight environment.

The PBA experience and this case study demonstrate the importance of rigorous human factors (HF) and HSI (see definitions in section 2.3) practices from conception throughout the lifecycle and posits that recursive testing will continue to update the original design assumptions resulting in the improvement of mission success and human safety.

2. Systems Engineering and Integration with a Human component

Introduction

In the late 1940's, Bell Labs began formalizing methods to better organize and analyze complexity in systems and initiated the term "Systems Engineering". In the 1950's and 1960's, these techniques were applied, formalized, and proven through the completion of complex aerospace defense projects such as the DoD's Missile Defense Program and NASA's Apollo Program. NASA continuously revised and improved its systems engineering processes and documented them in a Systems Engineering (SE) handbook in 1995. The most recent 2016 revision of the SE handbook includes two additional volumes of expanded guidance. The NASA SE processes are scalable from large space missions to small research projects. NASA produced additional SE documents to inform the adaptation of general SE processes to diverse types of projects including aircraft research, technology development, and fault management (FM) efforts.

This section describes the governing NASA SE documents that apply to PBA and shows how they flow down to the AFRC documents implemented by PBA. Next, is a description of the generic NASA SE tools and the process for tailoring and adapting these tools to for FM research project involving manned aircraft. Finally, the timeline and activities that were used to successfully conduct PBA are described, mapped to the project timeline, and compared with the standard NASA SE processes.

2.1 Governing Documents and Definitions

NASA defines SE as both "a methodical, multi-disciplinary approach for the design, realization, technical management, operations, and retirement of a system" and "the art and science of developing an operable system capable of meeting requirements within often opposed constraints."

The strategic policy directive for engineering program and project management at NASA is NPD 7120.4E. The program and project management requirements flow down to NPR 7120.8A which describes requirements for formulating and executing research and technology programs and projects. The SE requirements flow down to NPR7123.1C "NASA Systems Engineering Processes and Requirements". This document describes how SE is conducted on NASA projects and references the SE handbook and expanded guidance volumes.

Rather than developing a new system, PBA was a research effort which involved measuring parameters in the pilot breathing system. PBA supports the larger goal to gain insight into the cause of PE. Since the PE is an anomaly produced by a normally functioning system, the PBA lends itself to FM SE processes. These processes are described in the SE handbook and expanded guidance volumes and are covered in greater depth in NASA-HDBK-1002, "Fault Management (FM) Handbook, Draft 2", April 2012.

The governing SE documents require HSI to be incorporated into all phases of the Systems Engineering process in accordance with NASA-STD-3001, NASA Space Flight Human System Standard Volume 1 and Volume 2, NPR 8705.2, Human-Rating Requirements for Space Systems, and NASA/SP-2015-3709, Human Systems Integration (HSI) Practitioner's Guide".

The FM handbook derives FM for human-rated system from NPR 8705.2B, "Human-Rating Requirements for Space Systems". This document specifies: "a human-rated system accommodates human needs, utilizes human capabilities (i.e., human in the loop), controls hazards with sufficient certainty to be considered safe for human operations, and provides the capability to safely recover from emergency situations". Section 3.0 of NASA/SP-2015-3709 provides guidance on mapping HSI into the "SE Engine."

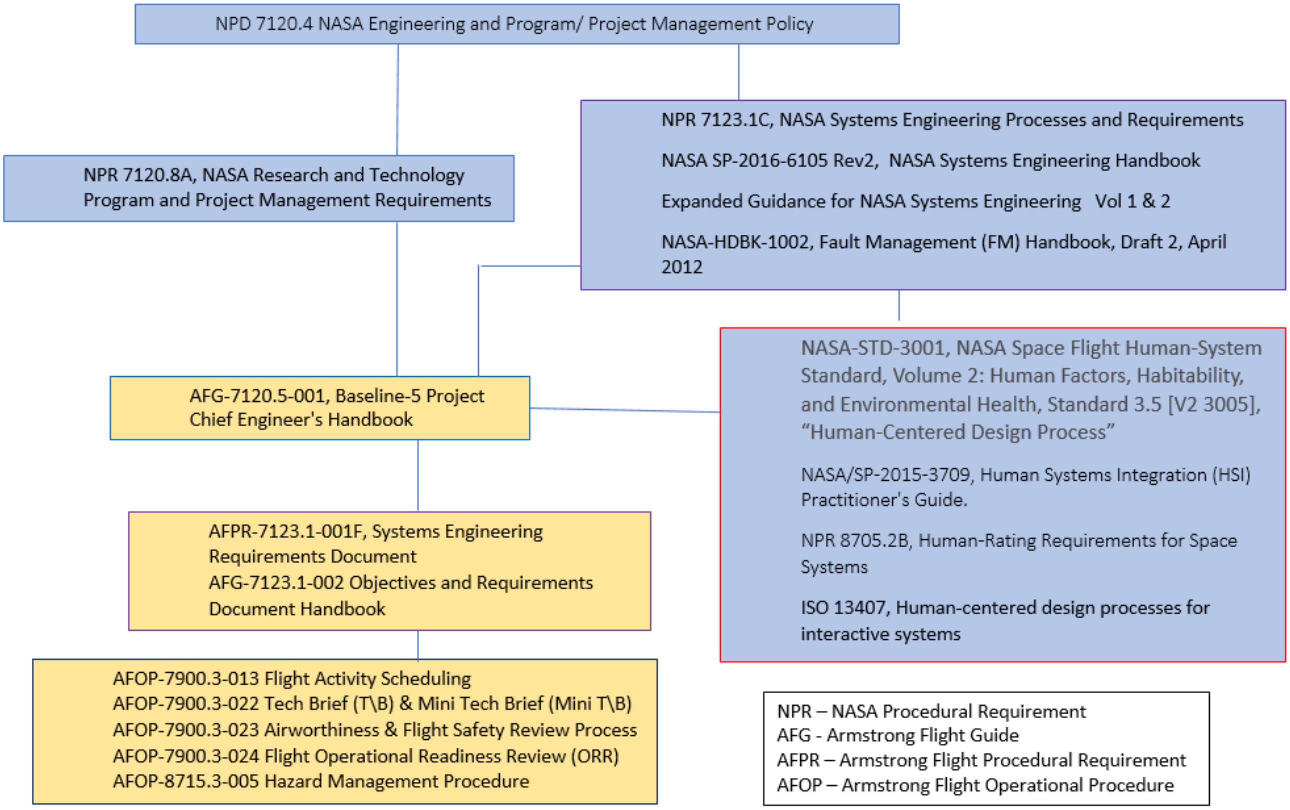

Figure 2.1. PBA Governing Documents

NASA-STD-3001 describes a "Human-Centered Design Process". Human-centered design is a performance-based approach that focuses on making a design usable by the human throughout the system's life cycle. The Human-Centered design process is described in ISO 13407, "Human-centered design processes for interactive systems" with early and frequent user involvement, performance assessment, and an iterative design-test-redesign process. Although NASA-STD-3001 was written for human space flight programs, it applies to all systems with a "human in the loop".

Each NASA Center maintains center level documents that tailor the high-level NPR documents for the type of work conducted at that particular center. The PBA flight tests were performed under AFG-7120.5 "Project Chief Engineer's Handbook" which was produced by the Research and Engineering directorate at AFRC and describes how research projects are conducted on aeronautic research platforms. AFG-7120.5 includes HSI requirements from NASA-STD-3001 for defining the HSI with the aircraft research platform. Other AFRC documents applicable to PBA include AFPR-7123.1-001F "Systems Engineering Requirements Document, AFG-7123.1-002 Objectives and Requirements Document Handbook, AFOP-7900.3-013 Flight Activity

Scheduling, AFOP-7900.3-022 Tech Brief (T\B) & Mini Tech Brief (Mini T\B), AFOP-7900.3-023 Airworthiness & Flight Safety Review Process, AFOP-7900.3-024 Flight Operational Readiness Review (ORR), and AFOP-8715.3-005 Hazard Management Procedure.

2.1.1 Systems Engineering Process

The SE process spans the entire project lifecycle from assessing stakeholder objectives and requirements and initial product formulation through design, build, integration, testing, operation, and sustainment. The steps in the SE process are specific to both the type of project and the agency or organization with ownership of the project. Figure 2.2 compares the generic project lifecycle for projects in the DoD, NASA, and the International council on Systems Engineering (INCOSE) with the project timeline for PBA.

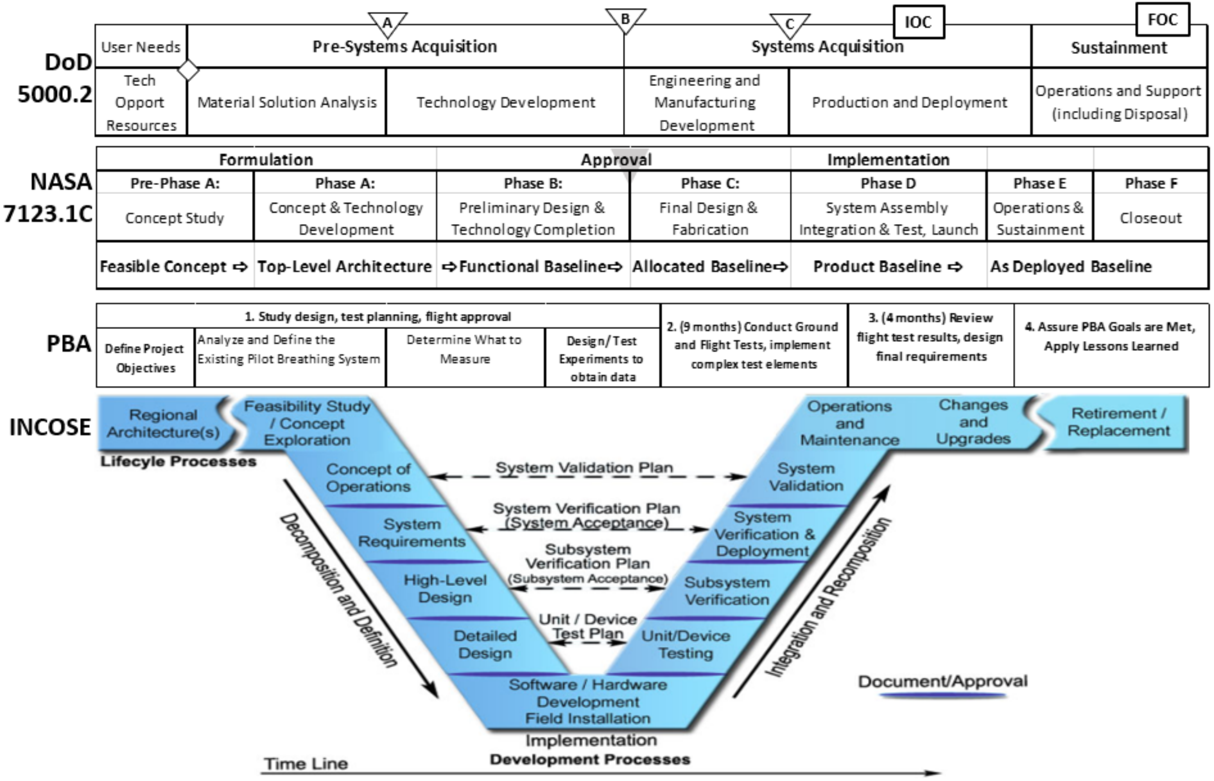

Figure 2.2. PBA project lifecycle compared with DoD, NASA, and INCOSE project lifecycle.

INCOSE illustrates the project lifecycle with a "V" shaped diagram illustrating the "flowdown" of requirements from high levels of assembly to lower levels of assembly on the left leg of the "V". The system design occurs at the bottom of the "V", and the Verification of these requirements occurs on the right leg of the "V". As low-level assemblies are produced, a verification process ensures that all the requirements at the same level on the left leg of the "V" are fulfilled before proceeding to the next higher level of assembly. The horizontal lines connecting the legs of the "V" illustrate the verification process.

NASA describes the SE process as an "Engine" that is located at every horizontal line in the "V". The SE "Engine" takes requirements from a high level of assembly and derives requirements for the next lower level of assembly. Similarly, it verifies products at lower levels of assembly and delivers them to the next higher level of assembly. Both processes are aided by Technical

Planning, Technical Control, Technical Assessment and Decision Analysis. Collectively, these are SE processes that drive the “engine”.

While the 2017 NASA/A-18 PE assessment was a causal investigation of PEs already occurred or occurring in the US Navy Fleet, due to the PE rate of 1/1000 flights, the PBA did not anticipate to generate or document a PE during its ~100 flights. Thus, the PBA was more like a FM process, focusing on understanding and managing off-nominal system behaviors. A Fault Management Systems Engineer (FMSE) works to identify and articulate resiliency and recovery properties, and to search for potential hazardous interactions between subsystem and system designs. A FMSE will identify and analyze “anomalies” to understand their relationships to subsequent faults. An “anomaly” is not a “failure”, it is an unexpected performance of an intended function. It could occur when a device is operating within specification, but not at the anticipated value. While an anomaly is not a failure, and most anomalies do not result in failures; an anomaly can be a predictor of future faults. For example, an anomaly could be an increase in the temperature of a component that is within normal operating range, but higher than expected. This anomaly could predict the overheating failure of a neighboring component. PBA monitored the flight and human systems to identify anomalies that could lead to a PE when combined with other parameters.

FM consists of four elements: *monitoring*, *assessment*, *decision* and *fault mitigation and recovery*, as shown in Figure 2.3. These elements are guided by the FM strategy and system design, and are implemented through software, hardware and/or processes/procedures on both flight and ground systems. A monitoring system may consist of sensors, transducers, gauges, probes, and data acquisition systems that facilitate further reasoning by an assessment module about system state. Fault mitigation and system recovery actions are decided based on the state assessment. Mitigation and recovery actions can be autonomous, automated, or human-controlled. PBA addressed Monitoring and Assessment and produced recommendations for Decision and Fault Mitigation and Recovery (see Pilot Breathing Assessment, Technical Section 10: Development of a Diagnostic Test of In-Flight Breathing System Performance)

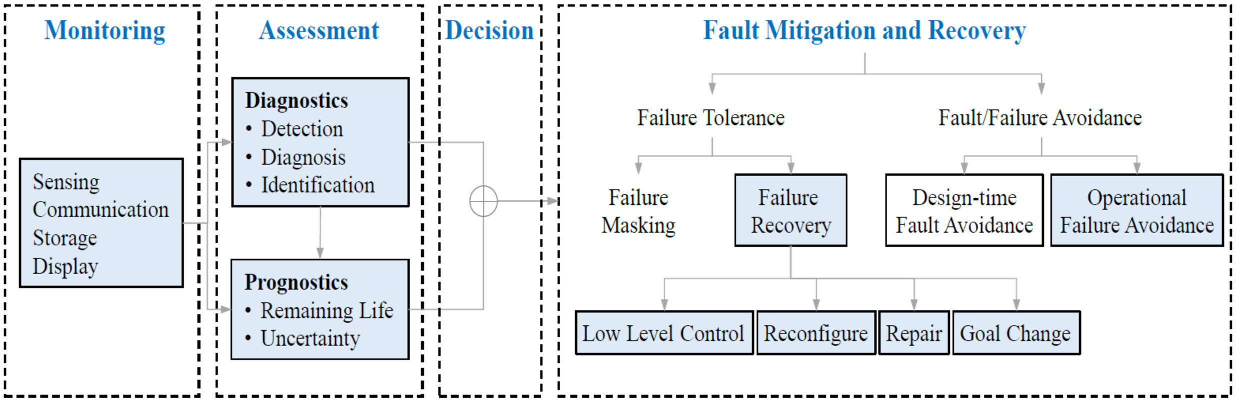

Figure 2.3. Functional elements of a fault management system.

2.2 Systems Engineering Tools and Products

SE tools and products that comprise the SE “engine” fall into one of four categories: Requirements, Architecture, Concept of Operations (ConOps), and Analysis. As the PBA test campaign was unique in the inclusion of human physiological testing on an aircraft platform, this case study presents how these tools were tailored for the PBA in Section 5. As for the F/A-18 system, the NASA team does not have insight to its original requirements and implementation from the 1980’s. To aid post-deployment testing and analysis the NASA team created several models involving a systems’ view of the architecture and applied systems thinking to unite the machine-human signals (see Section 6).

2.2.1 Requirements

The Technical Requirements Definition Process transforms the stakeholder expectations into a definition of the problem and then into a complete set of validated technical requirements expressed as “shall” statements that can be used for defining a design solution for the Product Breakdown Structure (PBS) and related enabling products. The process of requirements definition is a recursive and iterative one that develops the stakeholders’ requirements, product requirements, and lower level product/component requirements.

2.2.2 Architecture

The system architecture can be seen as the strategic organization of the functional elements of the system, laid out to enable the roles, relationships, dependencies, and interfaces between elements to be clearly defined and understood. It is strategic in its focus on the overarching structure of the system and how its elements fit together to contribute to the whole, instead of on the particular workings of the elements themselves. It enables the elements to be developed separately from each other while ensuring that they work together effectively. Several products are used to describe the architecture including a “Bill of Materials” (BOM), block diagram, Product Breakdown tree structure. The system architecture also includes the physical layout of the product. This includes circuit diagrams, mechanical assembly drawings, wiring drawings, data flow, etc.

2.2.3 Concept of Operations (ConOps)

The ConOps describes the overall high-level concept of how the system will be used to meet stakeholder expectations, usually in a time sequenced manner. It describes the system from an operational perspective and helps facilitate an understanding of the system goals. It stimulates the development of the requirements and architecture related to the user elements of the system. It serves as the basis for subsequent definition documents and provides the foundation for the long-range operational planning activities.

2.2.4 Functional Analysis

Functional analysis is the primary method used in system architecture development and functional requirement decomposition. It is the systematic process of identifying, describing, and relating the functions a system should perform to fulfill its goals and objectives. Functional analysis identifies and links system functions, trade studies, interface characteristics, and rationales to requirements. It is usually based on the ConOps for the system of interest. The process involves analyzing each system requirement to identify all functions that need to be performed to meet the requirement. Each function identified is described in terms of inputs, outputs, failure modes, consequence of failure, and interface requirements. The process is repeated from the top down so that sub-functions are recognized as part of larger functional areas. Functions are arranged in a logical sequence so that any specified operational usage of the system can be traced in an end-to-end path.

2.2.5 Pilot Breathing Assessment Project as a System and as a System of Systems (SoS)

PBA collected data on the pilot breathing system and identified anomalies that could predict or result in a PE. The PBA lifecycle mapped to the INCOSE project lifecycle "V" as shown in Table 2.1. In the formulation phase, the stakeholder objectives were defined. The aircraft/pilot system architecture and ConOps was defined. Variables to be controlled and parameters to be measured were derived. Additional systems required to measure this data were defined. A ConOps for the test flights was defined and the flight plans were approved. The mission was conducted, the ground and flight data were analyzed, and conclusions were derived.

2.2.5.1 PBA Requirements

The PBA scope was to collect key pilot physiological data on pilots flying the F/A-18 and F-15 aircraft to enable understanding of the complex human system interaction with the complex aircraft environment. The project lifecycle included four phases:

1. Study design, test planning, flight approval.
2. Incrementally implement several complex flight test elements into the assessment (9 months).
3. Review flight test results, design final flight requirements (4 months).
4. Apply lessons learned from the first three phases to ensure flight data are consistent and the PBA goals and requirements were achieved.

Four Stakeholder Objectives were identified, which decomposed into two levels of requirements as shown in Table 2.1. Requirement 1.2 was fulfilled by JPL using its own processes to design, prototype and build an IMCWS. The experiments were conducted in accordance with the Project Chief Engineer's Handbook, AFG-7120.5-001 and the NESC Technical Assessment Plan. The Objectives and Requirements Documentation Process follows AFRC systems engineering document AFG-7123.1- 002.

Table 2.1. PBA Objectives and Requirements

	PBA Project-Level Objectives & Requirements
1	**Enable measurement of pilot breathing**
1.1	Utilize the Vigilox Pilot Breating System
1.1.1	Complete the Safety Review AFG-7900.3-001, Airworthiness and Flight Safety Review, Independent Review
1.1.2	Complete the Wind Blast Test AFOP 7900.3-006 Aircrew Flight Operations Manual AFOP, Cockpit Safety Review, Work Order System
1.1.4	Complete Pathfinder Flights AFG-7900.3-001, Airworthiness and Flight Safety Review, Independent Review
1.2	Measure Carbon Dioxide and Water Vapor in the Mask (IMCWS) JPL Project - used JPL processes
	Define Technical Requirements
	Define Human Requirements
	Define System Architecture with Product Breakdown Structure
	Define Concept of Operations
	Design IMCWS Prototype, test, improve 3 x iterations
	Produce Final Design
	Fabricate and integrate with Pilot Masks
2	**Measure aviation conditions that may affect pilot breathing**
2.1	Instrument aircraft systems flight data
2.1.1	Implement TTC Data Recorders
2.1.2	Implement NAVAIR QIK systems
3	**Time syncronize flight data with pilot breathing data**
3.1	Design a data management plan
4	**Conduct a flight test campaign as broad range as practically possible**
4.1	Conduct a Tech Brief with flights encompassing the following parameters - AFG-7900.3-001 Section 4.0
4.1.1	Aircraft types: F/A-18A, F/A-18B, F-15D
4.1.2	Pilot population: 5 pilots
4.1.3	Aircrew equipment types: USAF/ Air Force, USN/Navy
4.1.4	Flight conditions: High Altitude, Aerobatics, Control, Down Low, Elimination of Cabin Pressure, Functional Check Flight, Ground only, Health Check

2.2.5.2 Define System Architecture

When creating a diagram of the system architecture, it is critical to ensure that the diagram include the system of interest and all the interfaces with other systems. In the 2017 NESC F/A-18 PE assessment for the USN, the aircraft system that was studied was based on the aircraft systems alone, with the human only considered as an interface of the breathing system as shown in Figure 2.4. A fault tree analysis of this system revealed no faults in the system because the breathing system was delivering air as designed without consideration of the needs of the pilot.

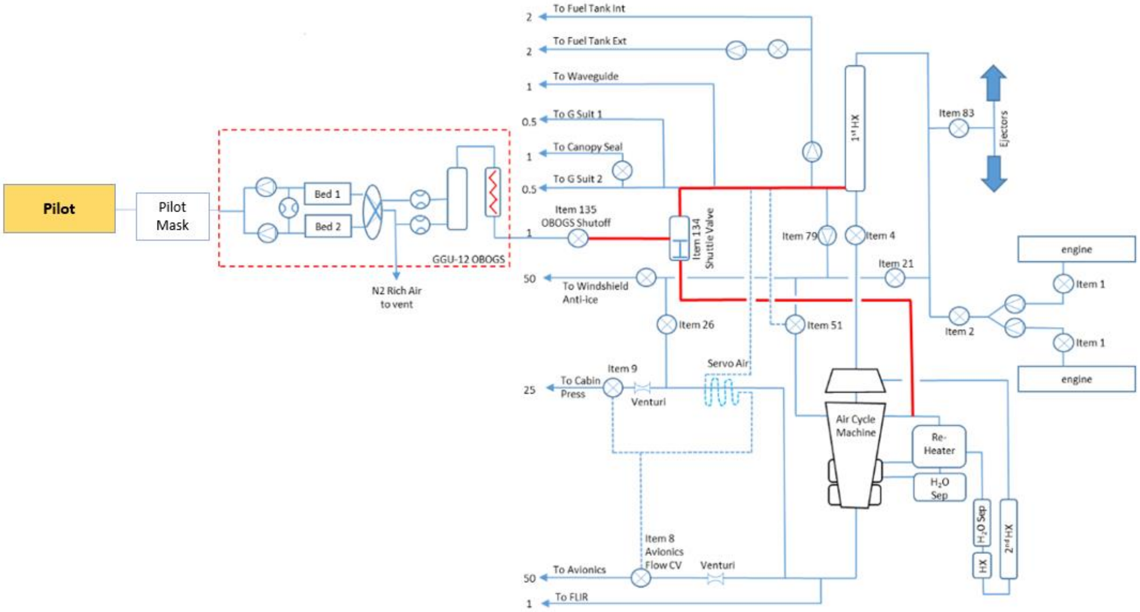

Figure 2.4. Example of systems diagram centered on aircraft.

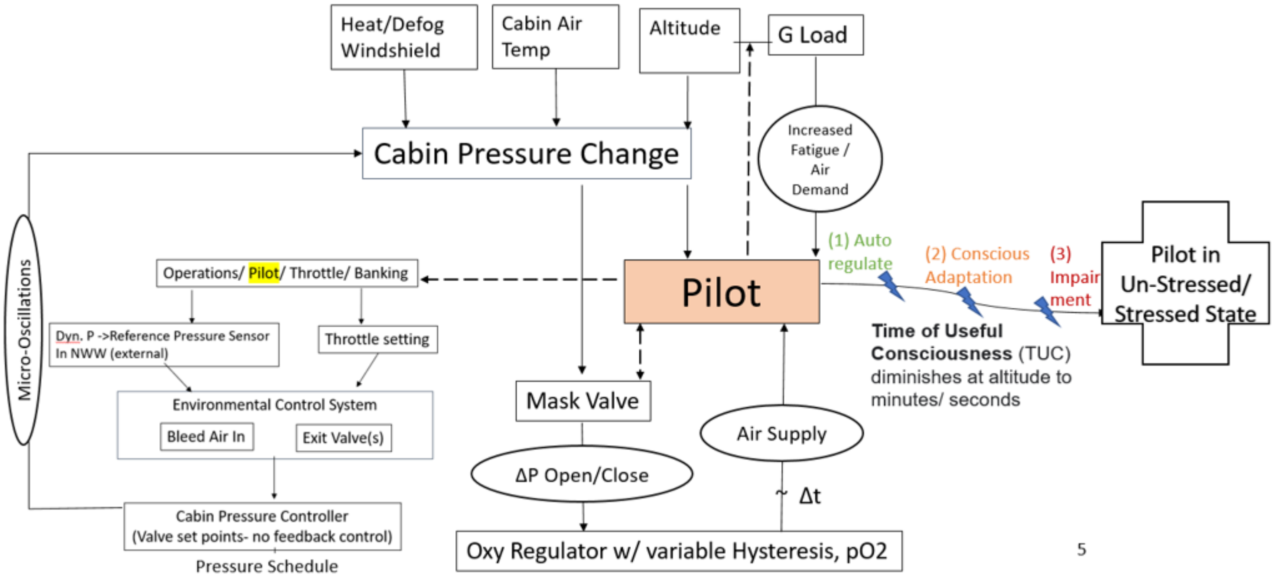

Figure 2.5. Example of systems diagram centered on pilot.

By understanding that pilot breathing episodes happen to pilots, and not to aircraft, the PBA team was able to assess the pilot interfaces and response by re-arranging the block diagram of the system to locate the human at the center of the diagram as shown in Figure 2.6 (variations of this model are expanded upon in Sections 3.2. and 4.2). A HSI Plan was developed to ensure that all factors affecting the pilot, both internally and externally to the aircraft were considered and evaluated. The HSI Plan is helpful in understanding all the critical operating scenarios and successful validation of the SoS. Once the pilot was placed in the center of the systems diagram, other interfaces affecting the performance of the pilots were identified and considered. These interfaces included both the physical interfaces to the aircraft, and the human factors interfaces which include a range of stressors imposed by the flight environment. The system representing the pilot was expanded to include: how stressors affect the pilot’s need for oxygen, the physiological pathways for oxygen to get to the brain, and the numerous conditions and states that change the absorption of oxygen into the blood and delivery of the correct amount of oxygen to the brain.

2.2.5.3 Design Solution Definition

The F/A-18 aircraft has continually varying dynamic states, cockpit pressure, environmental control, life support gear, etc. The pilot’s responses to these interfaces, training, lung volume, adaption, coping, are also dynamic. When stresses are additive and applied overtime, they have a nonlinear effect. The Human as a System (HAAS, see definition in Section 4) design model was incorporated to ensure these affects were accounted for. The PBA team designed flight scenarios that would progressively apply a wide range of stressors to both the pilot and the aircraft breathing systems so that the effects of these layered stressors could be studied over time. For authenticity, this effort was led by a DoD pilot. In addition to collecting in-flight physiological data, pre- and post-flight interviews were conducted with pilots to assess both the pilot’s perceptions and their ability to self-assess their conditions.

2.2.5.4 Product Realization

PBA practiced HSI using an interdisciplinary and comprehensive management and technical process that focuses on the integration of human considerations into the system acquisition and development process. The system optimized human well-being and overall system safety, performance, and operability by designing with an emphasis on human capabilities and limitations as they impact and are impacted by system design across mission environments and conditions (nominal, contingency, and emergency) to support robust integration of all humans interacting with a system throughout its life cycle.

As required by NASA/SP-2015-3709, Human Systems Integration (HSI) Practitioner's Guide, the HSI design included all the humans involved in the test flights, not just the pilots. This included the AFRC’s life support specialists, PBA project subject matter experts including flight surgeons, physiologists, and life support researchers from across the agency. Combined system testing was performed on the ground in simulated aviation environment to ensure that all the gear and procedures were compatible with the humans and the team was comfortable and familiar with the procedures and equipment. The resulting data revealed different physiological responses from the pilots when performing ground tests than in flight tests. The pilots were interviewed before and after each flight with questions that were carefully worded and presented to minimize individual bias and interpretation of the questions.

The PBA study required input from both medical and engineering experts to model and analyze the system, including interfaces between human and mechanical systems. The fields of medicine and engineering have inherently different methods and cultural norms for analyzing problems and effecting solutions. These methodologies are often at odds with the pilot's perspective as an integrated and invested operator of the system. To ensure smooth operation, the PBA worked towards a common organizational leadership (of the PBA team), inclusion of all communities of practice in all phases, identifying cultural differences, and developing a common lexicon.

2.2.5.5 Monitoring through Analysis

The system models (see section 3.2, 4.2 and Section 6) considered detailed mechanisms in the pilot's physiology for controlling breathing patterns and incorporating oxygen from the aircraft systems, through the lungs, into the bloodstream, and ultimately to the brain. This included the detailed mechanisms in the brain for controlling respiration in the lungs, intricate receptors in the lungs and bloodstream that stimulate the brain, and the mechanisms for absorbing gasses into the bloodstream through the lungs and the process of entering a state of hypoxia. These physiological functions and responses were compared against the full range of conditions experienced by the pilot inside the aircraft, the anticipated physiological response to those conditions was predicted, as well as the physiological sensations that the pilots would experience when undergoing those conditions. The complex interactions of these numerous parameters were analyzed, and the results were incorporated to update the OTMs. (Note, the OTM is a causal, conceptual model, not a mathematical one. See Section 3.2). Additionally, the pulmonary volumes and respiration rates measured in the PBA test flights were compared with cabin pressure and other aircraft breathing system and support gear parameters so that the response of the physiological systems to the environmental interfaces could be characterized.

The causal investigation of the PEs was based on NASA's historic investigations into "Close Calls," unplanned events that fall short of a mishap, but have mishap "potential". Of the 13 accident investigation methods found in [Katsakiori et al., 2009], three, including Fault Tree Analysis (FTA), represent logical interaction between causes and events, rather than a theoretical model of causation. These methods will fail to identify the cause of a close call when the unplanned event is the result of the interaction of elements in a system, but all the components are individually operating as designed, as in the 2017 NESC F/A-18 PE Assessment for the US Navy. Often, the interaction of systems in the real-world results in component responses that are non-linear, creating an "emergent" response.

PBA therefore studied the interaction of latent and active failures in the system by studying the whole system, rather than a sequence of events leading up to a failure. PBA utilized methods similar to Causal Analysis based on System Theory (CAST), for learning from losses so as to avoid them in the future [Leveson, 2019], and System Theoretic Process Analysis (STPA) as a proactive technique to identify loss scenarios in advance so as to prevent them [Leveson 2016], [Leveson and Thomas, 2018], and System-Theoretic Accident Model and Processes (STAMP), extends causality to include component interaction accidents, and enforces behavioral safety constraints rather than simply preventing failure.

2.2.5.6 Assessment

The PBA study determined that the cabin pressure experiences micro-oscillations. The mechanical pressure regulators over and under compensate, causing the cabin pressure to dither. Because the pilot's mask pressure is referenced to the cabin pressure, this changes the relative pressure difference required for the pilot to trigger air with inhale and exhale. In the best case, the pilot must divert attention from flying to timing their breathing against the cockpit pressure. In the worst case, the cockpit pressure varies in a phase shift with the pilot's breathing and prevents the pilot's chest muscles from being able to expand the lungs sufficiently to trigger the mask to release air.

Additionally, the F/A-18 Aircraft Oxygen System (AOS) uses a reference from an ambient pressure tap that is located in the nose wheel well, therefore, cabin pressure relative to the nose pressure sets the partial pressure oxygen. Since the nose wheel pressure is a function of both altitude, air speed and angle of attack (AOA), a maneuver that requires a rapid change in these parameters will result in changes of oxygen provided to the pilot. This could manifest in varying partial pressure of oxygen ($ppO_{2)}$ in case of a steady oxygen concentration regime (US Navy provides near 100% O_2), or in changes of oxygen concentration (variable O_2 concentration in F/A-18 USAF configuration).

2.2.5.7 Apply Lessons Learned

In the final phase of the PBA lifecycle, the team identified several lessons learned and future work.

To identify when a close call has occurred, it is necessary to define when the range of normal operation has been exceeded. The PBA study explored how the "failure" point of the pilot should be defined in terms of being unable to perform critical duties. The study also explored how to quantify when a "failure" has occurred, given that the point of failure is different for each pilot, and changes from flight to flight based on the condition of the pilot during the flight. Further, rather than a discrete failure point, through a series of adaptations, the human undergoes progressive states of decompensation (Sections 3.2 and 4). The PBA study was unable to define a general range of acceptable conditions due to the limited number of pilots and many flight configurations in the study.

Parameters should be monitored long-term for change. Pilot/workplace culture and organizational culture, and risk acceptance can all affect how problems are discovered, reported, and documented. A change in either the aircraft configuration, or the way the system is operated and stresses the pilot could change the safe operational ranges of the flight.

2.3 Human Systems Integration (HSI)

HSI, as defined by the NASA Community of Practice, is a required interdisciplinary integration of the human as an element of the system to ensure that the human and software/hardware components cooperate, coordinate, and communicate effectively to perform a specific function or mission successfully. This dovetails with its definition specified in NASA's System Engineering Processes and Requirements document (NPR 7123.1B). For example, an interdisciplinary and comprehensive management and technical process that focuses on the integration of human considerations into the system acquisition and development process to:

- enhance human system design
- reduce life-cycle ownership cost
- optimize total system performance

The definition of HSI varies across government agencies, industries, and academia, but whether it is defined as a philosophy, a systems engineering approach, a set of processes, or a goal, the underlying foundational principles are the same.

History of HSI at NASA and the Department of Defense (DoD)

The field of HSI grew out of the industrial engineering and experimental psychology disciplines and lessons learned during World War II, when practitioners observed unsafe and operationally difficult system designs. After World War II, the U.S. armed services acknowledged the need for greater attention to human-centered design, and the field of HSI began to develop. The primary objective at that time was to address the rapid increase in mishaps, staffing demands, and personnel and training costs, and reduce total life-cycle systems costs. The military adopted the practice to control costs and improve mission success.

The foundation for HSI within NASA began with initial standards written in 1965, MSFC-STD-391, Human Factors Engineering Program. The document established minimum human factors requirements to promote the maximum effectiveness and reliability of humans as a system component. Within the standard, a “system” was defined as an optimal combination of mission and support personnel, equipment, facilities, and procedures. In 1966, Human Engineering Design Criteria, MSFC-STD-267A was released. It presented human engineering design principles and practices to be used by engineers in designing equipment to improve performance of operator, maintenance, and control personnel, reduce skill requirements and training time, and increase the reliability of personnel-equipment combinations. With these standards, NASA was able to improve human-rated simulators and mission resulting in improved aviation safety and crew resource management.

In the late 1990’s, the DoD faced a rapid and broad increase in life cycle system costs. It became evident that “inclusion of the human elements required to develop, deploy, and operate a system needed to become standard in life cycle systems engineering and program and project management”. In the words of Army General Max Thurman, “we must quit manning the equipment and start equipping the man”. With this principle in mind, the DoD was the first United States government agency to establish the need to recognize inclusion of the human element early and thoroughly in the system design process, and thus commanded in 2003 that a “total system approach” must apply HSI to all developments.

In 2008, an update was made to NASA’s NPR 8705.2B, Human-Rating Requirements for Space Systems, to include “additional emphasis on the process of achieving human rating, emphasis on application dependency, and emphasis with respect to Systems Engineering context and analysis. The human-rating requirements define and implement processes, procedures, and requirements necessary to produce human-rated space systems and define a human-rating certification path for program managers (PMs) and their teams to follow in conjunction with traditional program management milestones”.

NASA published the Human Integration Design Handbook for Human Space Flight in 2010, which further heightened NASA’s focus on human-centered design (HCD). HCD is accomplished through proper implementation of HSI. HCD is a performance-based approach with a prime objective of creating designs that are usable by humans throughout a system’s life cycle. The approach concentrates on user involvement early and frequently in the course of design development, performance assessment/evaluation, and a systematic and iterative design-test-redesign process.

With a continuance of incorporating the methodology and application of HSI within NASA's system engineering approach, the first formal definition of HSI in NASA documentation was included in the 2013 NASA document, NPR 7123.1B, NASA Systems Engineering Processes and Requirements. It was followed in 2014 by NASA/TP-2014-218556, Human Integration Design Processes (HIDP). Additionally, in 2015, NASA-STD-3001, NASA Space Flight Human-System Standard, Volume 2: Human Factors, Habitability, and Environmental Health, was updated with a new requirement for HCD. Also in 2015, the NASA HSI Practitioner's Guide (HSIPG) was published as a guide on HSI and advancing HSI efforts across all NASA mission types, and underscores the significance and need of HSI application in all system design.

2.3.1 Value of HSI

"The goal of HSI is to ensure that HSI is carefully considered and planned from the outset of any NASA program or project." Inclusion of HSI within a systems engineering approach provides enormous value (Table 2.2). Otherwise, there are a number of impacts to a program or project if HSI is *not* properly applied in the earliest stages of a project and appropriately funded.

Table 2.2. Value of HSI

Value of HSI	Impacts and Risks if HSI is Not Applied
Maximizes total system performance, safety, and operations by considering the human in the system's design, engineering, and operational environments	Increased risk to human life and hardware/software
Identifies human capabilities and limitations within system design	Increased risk of rework
Identifies and mitigates risks to programs and projects of record and performs trades across cost, schedule, and technical performance	Increased risk to schedules
Reduces life cycle cost	Increased life cycle cost

HSI improves systems performance. Incorporating HSI places human concerns on par with other aspects of system design. The INCOSE System Engineering Handbook (2015) states that "the primary objective of HSI is to ensure that human capabilities and limitations are treated as **critical system elements**, regardless of whether humans in the system operate as individuals, crews, teams, units, or organizations." The human in the system denotes all personnel in the system, including "system owners, users/customers, operators, maintainers, assemblers, support personnel, logistics suppliers, personnel trainers, and peripheral personnel." As the system is made up of hardware, software, data, procedures, and humans, it is important to examine these components individually, the interfaces between the components, and the integration of the components. Total system performance hinges on the effectiveness of the integrated interaction of hardware, software, environment, *and* human elements.

2.3.2 Implementing HSI

HSI is to be implemented at the outset of a project and applied iteratively throughout the system development life cycle from pre-Phase A through Phase F. It supports continuous improvement and systematically infuses information from past designs, operational use, and user feedback into systems development. There are many negative impacts if HSI is excluded or not properly applied and funded at the earliest stages of a project. Those impacts include increased risk to human life, hardware, software, rework, and schedules, and increased life cycle cost.

HSI incorporates collaboration across a number of interdependent domains, specifically, human factors engineering, habitability and environment, operations engineering, reliability, maintainability and supportability, training, and safety. Within the PBA case study, examples of operations engineering, supportability, and safety representation are described in Section 5 (i.e., AFRC example). Examples of human factors engineering are presented in Section 7 (i.e., systems engineering applied to physiology measurement instrument development).

HITL activities are an integral and beneficial component of the iterative HCD process. As described by NASA's Office of the Chief Health and Medical Officer (STD-3001 Technical Brief, 2021).

> *"Human-in-the-loop (HITL) activities are part of an iterative, human-centered design process that includes one or more humans representing the end user. When employed properly during the developmental design process, HITL activities can reveal design issues that could otherwise lead to inefficient and ineffective designs with poor user satisfaction and inadequate workload levels on crew. HITL testing can also identify sources of human errors that results in negative consequences, including catastrophic events. HITL tests are also used to verify that final designs meet specific human performance requirements related to operability, legibility, usability, workload, and error.*
>
> *HITL tests are to be conducted with a strategically selected sample of test subjects based on the type of scenario or tasks tested, the method of testing, the metrics begin measured, and other important factors such as novelty of the tasks or interface. Human-in-the-Loop testing, during both development and verification, is scoped by the Task and Error Analysis. The results of HITL testing should be analyzed and issues flagged for follow-up with the system designers.* ***Testing conducted at appropriate times in the development cycle can find issues that otherwise would not be apparent until after the design is finalized, requiring costly redesigns or increasing risk*** *of human error during flight."*

The PBA used iterative human-in-the-loop testing as an effective tool to reveal opportunities to increase safety and reliability of systems, improve performance by reducing the likelihood of errors, mitigate safety related design induced errors, increase situation awareness, reduce cognitive demands, reduce fatigue, increase functional efficiency, and mitigate potential system failures.

Human Factors and F-18 Aircraft Development

According to Merriman and Karn (2019), between 1969 and 2019, significant developments were made of USN aircraft cockpit design to enhance physiological and life support performance in aircraft including OBOGS. They also noted that personnel assigned to monitor progress in human factors engineering and crew station design with exploratory and advanced research and development programs were a major influential factor to rapid technology transfer. That is, the USN integrated crew station design engineering and human factors with positive results.

During full scale development of the F/A-18 aircraft between 1976 and 1981, the document “Human Engineering Mission Analysis” was created and served as the “standard against which subsequent engineering trade studies such as function allocation, task analysis and design alternatives evaluation and human engineering test and evaluation results were compared” and the source of “critical mission/pilot performance segments” (Hitchcock, 1982). It was the first time a USN aircraft human engineering program gave equal attention to designs for both air and ground crews, and “balanced emphasis” was given to system operators and maintainers. Hitchcock (1982) identified a number of ground rules followed for human engineering, but none specifically addressed life support interaction associated with pilot breathing gear. Navy and contractor human engineering personnel were beneficially integrated into the core engineering group rather than systems engineering, logistics support, or design assurance groups alone. Numerous design simulations and reviews with participation by designers, maintainers, and pilots alike were instituted. According to Hitchcock (1982), the human engineering program for the F/A-18 was well-justified, with concentration on critical features such as “mission analysis, operator/maintainer balanced attention, contractor/Navy team approach, multiple design reviews, human integration into the core design team, dynamic simulation of critical mission segments, user participation in design development, and special focus on ground support, test and training equipment." **The AOS was not mentioned in the Hitchcock report.**

Note an important distinction: the engineering process applied to the F/A-18 was referred to as “Human Engineering,” and not full Human *Systems* Integration. Indeed, in the *F-18 Human Engineering Program - A Retrospective View* (Hitchcock et al., 1982), the authors enumerate the care given to the cockpit layout (throttle controls, overhead display and readouts, functional reach), which suggests a focus on Human Factors. Human factors is a subset of HSI. Human factors is to human systems integration as mechanical engineering is to systems engineering. The fact that the AOS, a life supporting subsystem, was not mentioned in the Hitchcock report is telling. Perhaps the disconnect is that they focused on Human Factors during development and not HSI – which would explain why they thought they did the right things but in fact did not go far enough. This would be a key takeaway for awareness in implementing HSI and makes defining/discussing the HF/ HSI differences more important.

HSI Implementation Examples in the PBA Test Campaign and Product Lifecycle

Many HSI products and activities are produced and occur early in the system engineering lifecycle. Later examples of HSI implementation include human in the loop testing and evaluation and maturation of human-related test articles.

Definition of the ConOps, specific HSI tasks, and allocated roles and responsibilities between different organizations at AFRC were accomplished by following many of the best practices specified in the Human Systems Integration (HSI) Practitioner’s Guide (Nov 2015, pp 1-5 – 1-6). The process to integrate pilot-in-the-loop testing where the pilots themselves were also instrumented involved an iterative conceptual design and prototyping. Additional details are discussed in Section 5, AFRC operations. A life support specialist defined aircrew-system interfaces and interactions and provided requirements, standards, and guidelines to ensure the entire system operated as designed with effective accommodation of the human. Flight profiles were designed by a pilot and iterated by pilots and analysts. For repeatability and as standard operating procedure, flight profile instructions regarding execution (e.g., velocity, altitude) are captured and distributed to pilots via flight cards. Information and findings flowed to and from pilots and analysts via debriefs, questionnaires, and data analysis reports. Instructions to increase uniform execution were iterated for the flight cards, spirometry and questionnaires. All forms of data collection centered on the human, with flight data being the primary driver for design and schedule, augmented by spirometry and questionnaires implemented in a later phase.

Another example of incorporating HSI practices included development of the IMCWS. The IMCWS design was motivated by the need to inform on the physiological state of the pilot through the time-dependent behavior of CO_2 and water vapor (see mini case study described in Section 7). Increased resolution of CO_2 and water vapor signals can identify problems in mechanical airflow to and from the pilot. Pilot fit, comfort, and range of motion were drivers in the design to ultimately mitigate physiological risks associated with mechanical flow abnormalities. This was a challenge given the reduced working volume in the mask to install a needed sensor. “This may be perhaps the most difficult stakeholder expectation to meet since the mask itself, regardless of any components that are implemented inside it, is designed to have minimal internal volume to prevent as little rebreathing as possible and therefore and very little room in which to implement a fast-response sensor that can withstand the environmental challenges, like humidity, inside the mask.” (Lance Christensen, instrument product design lead). Fabrication techniques and fit changes were iterated to improve the pilot experience, and initial verification and validation were carried out with human-in-the-loop and in-flight testing.

For HSI to be effective, a program must acknowledge that the human is as important as other components of the system and supports HSI with equal emphasis and resources. HSI must be considered and established in program and project planning early and applied iteratively throughout the system development life cycle. Include all personnel that interface with a system in the expected environment (e.g., end users, ground controllers, monitors, trainers, integration and test workers, manufacturers, maintainers, and logistics staff). Successful HSI depends on integration and collaboration of multiple domains, leveraging and applying their interdependencies and forming a common basis upon which to make informed decisions.

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3. Causal Investigation – the Past and Present

3.0.1 Historical perspective

Causal investigations are often conducted in response to major accidents, to determine their causes so as to prevent recurrence. Prominent NASA examples include the Space Shuttle Challenger disaster, which gave rise to the Rogers Commission Report, and the Space Shuttle Columbia disaster, which gave rise to the Report of the Columbia Accident Investigation Board. Investigations are also conducted when there is a no death or injury, but a major loss of some kind. NASA uncrewed spacecraft examples include investigations into the losses of the Mars Climate Orbiter and the Mars Polar Lander.

NASA uses the term "mishap" and corresponding "mishap investigation" to encompass an unplanned event caused by NASA operations or NASA-funded Research & Development projects resulting in personnel injury, occupational illness, major property damage, or mission failure prior to completion of the primary mission. NASA also conducts investigations into "close calls" – events that fall short of the mishap criteria, but have mishap "potential". One such is that of water intrusion into an astronaut's suit during extravehicular activity (EVA) [Hansen et al., 2013]. It is this last category that most closely matches the pilot breathing studies. Literature traces consideration of close calls back to the "domino theory" [Heinrich, 1931] and his concept of a pyramid whose base is of "Near Misses" or "Non-Injury Accidents", middle segment is of "Minor Accidents/Injuries" and apex is of "Serious Accident"/"Major Injury" with relative sizes of 300:29:1. In simple terms, a category of near-misses turn into minor accidents, and a subset of those turn into serious accidents. The near-misses with the potential to be a serious injury or fatality (SIF) (e.g., see the discussion in [Cooper, 2019]), NASA defines as a "close call". The intent of the pyramid theory is that eliminating the non-injury incidents will eliminate the serious incidents.

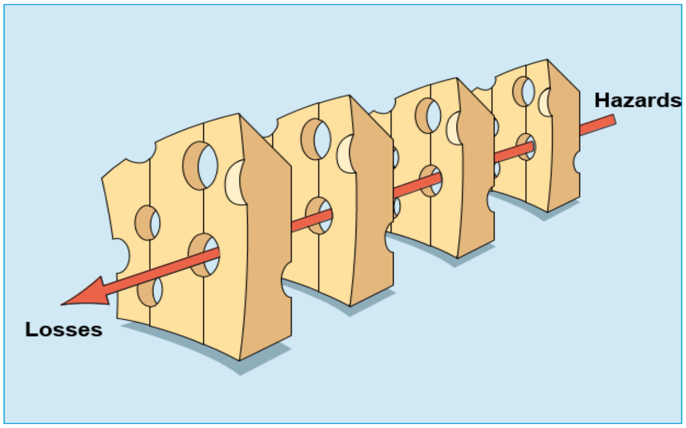


Figure 3.1. "The Swiss cheese model of how defenses, barriers, and safeguards may be penetrated by an accident trajectory. [Reason, 2000]

The field of accident investigations and prevention was significantly influenced by James [Reason 1990], [Reason 2000] through his introduction of the concepts of accident causation as an interaction between latent and active failures, and the often cited "Swiss cheese" model of accident causation, Figure 3.1. In this model the defensive layers are imperfect, portrayed as (not necessarily static) holes, so that if the holes line up it is possible for a hazard to pass through all the barriers and lead to an accident.

A discussion of the heritage and nature of accident causation models and accident investigation methods is to be found in [Katsakiori et al., 2009]. Its abstract includes a sentence especially pertinent to the pilot breathing study: "*The evolution of accident causation models over time shows a shift from the sequence of events to the representation of the whole system*". It summarizes the following 13 accident investigation methods:

1. Fault tree analysis [Ferry, 1988]

2. Management oversight and risk tree (MORT) [Johnson, 1980]
3. Multilinear events sequencing (MES) [Benner, 1975]
4. Systematic cause analysis technique (SCAT) [Kjellén and Hovden, 1993]
5. Causal tree method (CTM) [Leplat 1978]
6. Occupational Accident Research Unit (OARU) [Kjellén and Larsson, 1981]
7. TRIPOD [Wagenaar et al., 1994]
8. Accident evolution and barrier function (AEB) [Svenson, 2000]
9. Integrated safety investigation methodology (ISIM) [Ayeko, 2002]
10. Norske Statesbaner (NSB) [Skriver et al., 2003]
11. Work accidents investigation technique (WAIT) [Jacinto, C. and Aspinwal, 2003]
12. Health and Safety Executive (HSG245) [HSE, 2004]
13. Control change cause analysis (3CA) [Kingston 2007]

Furthermore, it lists its Objective to be to "*…make an evaluation of the above described accident investigation methods…* and its goal includes to "*…help investigators make a choice between the large number of [accident investigation] methods available*". It observes that "*FTA, MES, CTM and tree techniques, in general, are not based in any known theoretical model of accident causation. They simply represent the logical interrelationships between causes and events*," whereas it associates the other ten investigative methods to accident causation models (see Figure 1. in [Katsakiori et al., 2009]). Fault tree analysis is described further in [Harms-Ringdahl, 2001], tracing its use back to the 1960's. As stated therein, "*The method is of greatest value for complicated technical systems where a functional failure can have serious consequences, and also where considerable resources can be allocated for hazard analysis*".

3.0.2 Accident Investigation Methods Very Briefly Described

The following are the 13 accident investigation methods covered in [Katsakiori et al., 2009], with summaries of each condensed from that source as indicated by italics:

- Fault tree analysis [Ferry, 1988] "*an undesired event (an accident) is selected and all the possible things that can contribute to the event are diagrammed as a tree in order to show logical connections and causes leading to a specified accident*".
- Management oversight and risk tree (MORT) [Johnson, 1980] This involves generating a MORT diagram: "*… a logic tree (the accident being the top event) with three main branches: S-factors, the specific oversights and omissions associated with the accident being investigated, Rfactors or assumed risks, which are risks known but for some reason not controlled, and M-factors, which are general characteristics of the management system that contributed to the mishap*".
- Multilinear events sequencing (MES) [Benner, 1975] "*…a charting technique, which shows events chronologically ordered on a time-line basis. It is based on the view that an accident begins when a stable situation is disturbed. A series of events can then lead to an accident*".
- Systematic cause analysis technique (SCAT) [Kjellén and Hovden, 1993] "*SCAT is presented as a chart which contains five blocks corresponding to five stages in the accident causation process. …[1] the accident description, …[2] the most common categories of contact that could have led to the accident …[3] the most common immediate causes of this contact, …[4] underlying causes, …[5] safety management practices that should be addressed to prevent accidents from occurring*".
- Causal tree method (CTM) [Leplat 1978] "*…accidents result from variations or deviations in the usual process. … those related to the individual, the task, the equipment and the*

environment, respectively. The tree starts with the end event (the accident) and works backwards".

- Occupational Accident Research Unit (OARU) [Kjellén and Larsson, 1981] "*The method has two levels of reasoning: describing the accident sequence, and finding the determining factors. The state of lack of control is characterised by the presence of deviations in the system. The accident sequence has three phases: the initial (when there are deviations from the normal process), the concluding phase (which is characterised by loss of control and ungoverned flow of energy), and the injury phase …*".
- TRIPOD [Wagenaar et al., 1994] "*…organisational failures are the main factors in accident causation. An accident occurs when one or more barriers (controls/defenses) fail. Unsafe acts (active failures) are the direct reason for the failure of barriers which do not just occur but they are generated by underlying mechanisms acting in organisations. These mechanisms … cover human, organisational and technical problems*".
- Accident evolution and barrier function (AEB) [Svenson, 2000] "*An accident is modelled as a series of interactions between human and technical systems…it is possible to stop/interrupt the development of the sequence between any two successive errors (human or technical) through adequate barrier functions… The aim of investigation with AEB is to describe the accident evolution in a flow diagram, showing human and technical errors*".
- Integrated safety investigation methodology (ISIM) [Ayeko, 2002] "*… determine the sequence of events and identify underlying factors and unsafe conditions. … assess the level of risk associated with such unsafe conditions or underlying factors and examine the status of barriers (physical or administrative) in order to identify those that are less than adequate. …options for controlling risk have to be considered. The goal of ISIM is to ensure that both accident investigation and safety deficiency analysis are integrated. The risk control option analysis is a key step of ISIM aiming at generating recommendations and strategies for safety improvement*".
- Norske Statesbaner (NSB) [Skriver et al., 2003] "*focuses on human, technical and organisational interaction … identifies the sequence of events and where barriers were broken or missing, … addressing factors such as procedures/documentation, training, communication, human-systems interface, tools and equipment, work preparation and local management, organisational management, work environment and task completion*".
- Work accidents investigation technique (WAIT) [Jacinto, C. and Aspinwal, 2003] "*two sequential phases … identification of active failures in the sequence of events and the consequences … [and] influencing factors associated with the working environment and the workplace, for each of the identified active failures*".
- Health and Safety Executive (HSG245) [HSE, 2004] "*It follows Reason's accident causation model. The starting point is the event and the method provide aids for finding facts with specific structured questions. The aim of the analysis is to set out the reasons why this happened and find immediate, underlying and root causes*".
- Control change cause analysis (3CA) [Kingston 2007] "*… views an accident/incident as sequence of events in which unwanted changes occur. In terms of fact finding, the method is designed to identify events in the sequence which are ''significant'' in the sense that they reduce control and allow further unwanted changes to occur. With the set of significant events established, the investigator can identify barriers and controls that could have prevented them or limited their effects, can then establish the shortcomings of each*

> *barrier/control and reason about the processes and management arrangements that allowed the barrier or control problems to exist at the time of incident*".

Application of fault tree analysis to the Pilot Breathing situation served to eliminate many possible causes, but ultimately failed to identify the culprit(s). In hindsight, a plausible explanation for this is that it was not a component "failure" or a pilot "error," but rather due to an unanticipated interaction among the several systems involved, even when they are all operating "to spec". Professor Nancy Leveson is a proponent of this position (e.g., [Leveson et al., 2003], [Leveson 2004]), arguing the following:

> *Since World War II, we are increasingly experiencing a new type of accident that arises in the interactions among components (electromechanical, digital and human) rather than in the failure of individual components. Perrow coined the term system accident to describe it [21].*
>
> [Leveson, 2004], where reference *[21]* is [Perrow 1984]

Her insights are echoed in the Aviation Safety Platform, where it lists three categories of accident causation models.

> **Complex non-linear:** *accidents are the results of a combination of mutually interacting variables occurring in real world environments. Understanding of these interactions through careful analysis is the only way to understand and prevent accidents. A systemic model which focuses on interactions and functions of the system rather than just individual events. Accidents are regarded as emergent rather than resultant phenomena (i.e., are not predictable).*
>
> https://www.aviationsafetyplatform.com/pedia/understanding-safety/general/accident-causation

One of the (many) examples Leveson cites is the loss of the Mars Polar Lander (MPL), in which, as she points out, the hardware and software all performed as their requirements specified, but there was a system design flaw allowing an unintended and fatal interaction. As described in the formal report of the MPL mishap [Albee et al., 2000], a lack of flowdown of requirements to the Software Requirements Specification (SRS) led to the software being developed to an incomplete set of requirements. The software then performed to those requirements, but by doing so, caused the loss. Furthermore, that lack may also have led to omission of certain tests during development that, had they been performed, would have exposed the problem. Lastly, when the one remaining test actually performed that had the capability to expose the problem, its initial run was with an incorrect wiring configuration. The configuration was corrected, and unfortunately only a portion of the test was rerun, and so did not encompass the problematic scenario. Interestingly, the mishap report appears to indicate discovery of the actual problem stemmed from a serendipitous event: "*The touchdown sensor problem was found during a test run on the 2001 Lander when a test engineer pushed a button indicating a touchdown too early in the test. He released the button when he realized his error and was surprised when thrust termination occurred prematurely. That led to a failure analysis that uncovered the software problem.*" [Albee et al., 2000 – page 122].

What can be concluded from all this?

- There are numerous accident investigation methods, each with their own strengths and weaknesses, and each with varying degrees of applicability to the situation at hand. Care should be taken in choosing which to apply.
- **Many methods may be ill-suited to complex systems, where problems can manifest even when all the components work to specification**, because the problem stems from unanticipated interactions among those components, absent of component faults or failures.
- Correct and complete flowdown of requirements from the composite system level to the individual components is vital; flaws can short-circuit the testing process, leaving blind spots that are hard to recognize.
- Taking a systems perspective offers the best prospects in these challenging system situations. Leveson's pair of approaches are based on this thinking - Causal Analysis based on System Theory (CAST), for learning from losses so as to avoid them in the future [Leveson, 2019], and System Theoretic Process Analysis (STPA) as a proactive technique to identify loss scenarios in advance so as to prevent them [Leveson 2016], [Leveson and Thomas, 2018]

3.1 Application of Systems View – based on the work of Dr. Leveson

This section applies a "Systems View" to pilot breathing. This approach is based on the work by Dr. Nancy Leveson, Professor of Aeronautics and Astronautics and also Professor of Engineering Systems at MIT. For more information on her background and prolific activities, see her home page at MIT: http://sunnyday.mit.edu/

As was mentioned in the introductory section, Dr. Leveson has identified *unanticipated interactions* among the components of a system as a source of failure in today's complex systems. The PBA exemplified this phenomenon, with its discovery of unanticipated interactions such as the "disharmony" between the jet's air supply system and physiological aspect of the pilot's breathing. Although the PBA study was not aware of Dr. Leveson's approach at the time, it can be seen to have been compatible with many of the precepts of that approach. Here Leveson's approach is shown and could have been explicitly followed by PBA, both for system design, as an investigative technique.

Caveat: we are not experts on Dr. Leveson's approach, nor has she reviewed our descriptions, so they may contain misinterpretations and other flaws, in which case they are solely our responsibility.

3.1.1 System-Theoretic Accident Model and Processes (STAMP)

STAMP is Dr. Leveson's accident causality model based on the theoretical foundation of systems theory. As described in [Leveson, 2012], "*Using … STAMP… changes the emphasis in system safety from preventing failures to enforcing behavioral safety constraints. Component failure accidents are still included, but our conception of causality is extended to include component interaction accidents*". STAMP provided the theoretical foundation for both STPA (System-Theoretic Process Analysis) – a hazard analysis technique [Leveson & Thomas, 2018], and CAST (Causal Analysis based on Systems Theory) – an accident analysis technique [Leveson, 2012 – Section 11], [Leveson, 2019]. There is burgeoning participation in workshops on STAMP, conducted annually since 2012 - http://psas.scripts.mit.edu/home/stamp-workshops/

3.1.2 Applying STPA – Guidance Taken from Leveson & Thomas, 2018

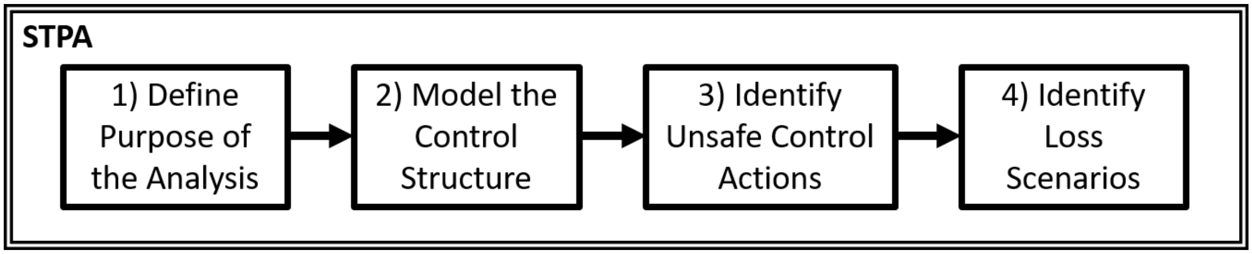


Figure 3.2. The steps in basic STPA – a redrawn part of [Leveson & Thomas, 2018 – Figure 2.1]

The first step of STPA, to “Define Purpose of the Analysis,” divides into four parts:

1. Identify losses
2. Identify system-level hazards
3. Identify system-level safety constraints
4. Refine hazards (optional)

For military aircraft, the following result from the consideration of “Identify losses”

L-1: Failure of combat mission
L-2: Loss of life or injury to the pilot
L-3: Loss of or damage to the jet
L-4: Incomplete training mission – even if the pilot and jet are unharmed, this would be an undesirable result, albeit not of the magnitude as the other three.

The next part, “Identify system-level hazards,” is done by first identifying the system to be analyzed and the system boundary. For our case, the system is the jet and its pilot, while the environment is that in which the jet operates. The system-level hazards are then the system states or conditions that will lead to a loss in worst-case environmental conditions, using Leveson & Thomas’ definition “*A hazard is a system state or set of conditions, that, together with a particular set of worst-case environmental conditions, will lead to a loss*”. Then, following the guidance

<Hazard specification> = <System> & <Unsafe Condition> & <Link to Losses>

H-1: Jet is uncontrolled during a portion of the flight [L-1, L-2, L-3, L-4]
H-2: Jet is inadequately controlled during a portion of the flight [L-1, L-2, L-3, L-4]

Now system-level constraints are determined, using the definition “A system-level constraint specifies system conditions or behaviors that need to be satisfied to prevent hazards (and ultimately prevent losses)” and guidance

<Safety Constraint> = <System> & <Condition to Enforce> & <Link to Hazards>

SC-1: The pilot’s environment within the jet must be maintained so as to allow the pilot to sustain full cognitive function (i.e., be conscious and unimpaired) [H-1, H-2]
SC-2: The pilot’s environment within the jet must be maintained so as to allow the pilot to focus on control of the jet (i.e., not be distracted) [H-2]

There are of course other safety constraints, for example that the jet be maintained so as to not suffer malfunctions during flight, that the pilot have the physical and mental capacity to operate the jet, and have been adequately trained to do so – for the purposes of the PBA and this study, important as they are, these are not considered further here.

At this stage a refinement of the above two safety constraints seems appropriate, by considering what are pertinent conditions of the pilot's environment that must be maintained. These are:

- Temperature – deviation from a nominal range would perturb or even incapacitate the pilot
- Air supply – consciousness could be impaired or even lost entirely if pressure, composition, or humidity are not maintained within nominal ranges
- G-loads – excessive G-loads could cause loss of consciousness
- Orientation changes (e.g., spinning or tumbling) could disorient the pilot

These conditions were all thought to be well understood in designing the F/A-18 and other fighter aircraft pilot environments. As noted in the PBA report, "*Before PBA, it was generally accepted that providing adequate oxygen (O_2) line pressure and mask flow was sufficient to meet pilot breathing requirements for all high-performance aircraft operations*."

However, Physiological Episodes experienced by pilots revealed this not to be the case. The PBA drilled into the interaction between pilot physiology and jet-provided air supply, finding "*PBA has shown that the subtleties in parameter stability, timing and sequencing of the pilot-machine interface are critical*."

The second step of STPA is to "Model the Control Structure" serves as a guideline for the detailed expositions elsewhere in this case study. The control structure below is a *highly* abstracted view of the at the core of the matter:

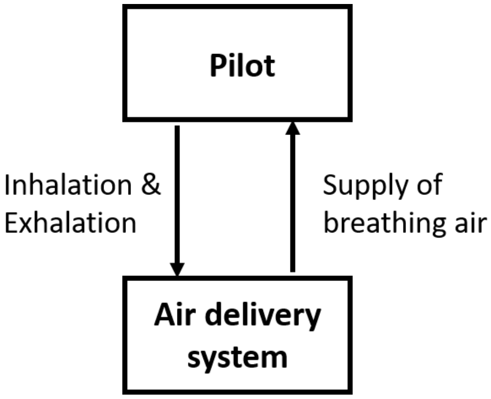


Figure 3.3. Building block for modeling the control structure.

The situation becomes considerably more complicated when the following considerations are factored in:

- The physiology and control of breathing by the pilot
- The mechanical components of the air delivery system
- The highly dynamic environment hosting both the pilot and air delivery system

A hint at this is an expansion in the above figure.

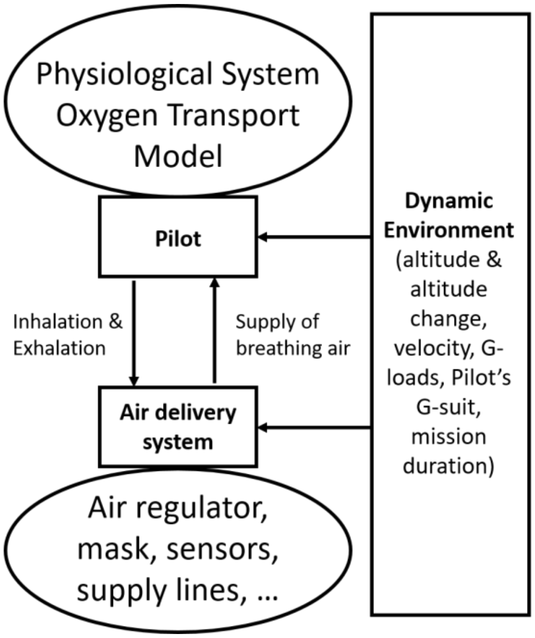


Figure 3.4. An example of complexity created by considering human physiology, system components and the environment.

Additional models and descriptions of interactions are in the following sections:

- Section 3.2, "The Oxygen Transport Model", presents a key aspect of the pilot's physiological system
- Section 4.2.2, "Cabin Pressure Control System" through 4.2.5 "Models: Operation and Control" expands upon the air delivery system
- Section 4.1 "Human Breathing System and Control" addresses the interactions between environment, pilot and air supply system, which are further expanded in Section 6 "PBA Tools and Findings related to SE"

In the spirit of the STPA approach, the driving need is to maintain the pilot's complete cognitive function and full attention on flying the jet (the latter implying the pilot is *not* distracted by the need to explicitly concentrate on breathing). "Unsafe Control Actions" in STPA terminology can detract from maintaining these conditions, and arise when, for example, the air delivery system's air supply response to the pilot's inhalation is mis-timed (starts after a small, but physiologically significant delay, or continues too long). Elucidating what the requirements on the air supply system should be (including establishing their adequacy), specifying them in terms of procurement requirements, and then measuring their satisfaction in delivered products, is the very heart of the problem.

Dr. Leveson's NASA Interactions

During 2020 the NASA Safety Center hosted two presentations of the work of Dr. Leveson and her colleague, Dr. John Thomas:

- "A New Approach to Safety and Cybersecurity Analysis" 8-5-2020 presentation by Dr. Nancy Leveson – video recording at https://nsc.nasa.gov/features/detail/a-new-approach-to-safety-engineering-gets-stamp-of-approval

- "A Systems Approach to Safety and Security Using STPA" 9-15-2020 presentation by Dr. John Thomas – video recording at https://nsc.nasa.gov/features/detail/a-systems-approach-to-safety-and-security-using-system-theoretic-process-analysis
- Author of several NASA APPEL courses, 2008
- Commented on NASA's SSP Challenger and Columbia losses [Leveson, 2007].

3.2 The Oxygen Transport Model

NESC assessment teams involved with projects related to pilot breathing and PEs have created a graphical representation of the entire pilot/plane system associated with pilot breathing. These graphical representations have evolved and changed over time, as more information becomes available. The NESC assessment team refers to these graphical representations as the OTM.

There are several iterations of the OTM. Each iteration of the OTM has some common elements:

- The model graphically represents the entire system
- Some aspect of the model takes the perspective of an oxygen molecule that travels from the source of the pilot breathing system (LOX tank or jet bleed air inlet) through the pipes and mechanical elements of the pilot breathing system, into the pilot's lungs, into the pilot's bloodstream, and eventually to the tissues in the pilot's brain. The OTM generally emphasizes PE events that affect cognitive function, so the eventual destination of oxygen is the tissues in the pilot's brain.
- The model includes a representation of the pilot, the mechanical elements of the pilot breathing system, and the environmental conditions of flight.
- The model lists available sources of data and evidence.
- The model lists, or infers, missing evidence or data that would be helpful in understanding causes of PEs, but is not presently available.
- The model graphically represents system interactions that may contribute to PEs.

OTM – 2017 Version

The first iteration of the OTM was published in the F/A-18 Independent Assessment Final Report in 2017. The OTM was developed to help describe some key findings, observations, and recommendations, which are listed below:

- The PE community was reviewing a considerable amount of engineering data about the mechanical components of the aircraft (Integrity Data) but there was very little data about the health and performance of the pilot.
- To prevent hypoxia which affects cognitive function, the job of the pilot breathing system is to deliver oxygen to the tissues in the pilot's brain. From a system engineering perspective, it is a long and complicated path from the source of oxygen to the tissues in the pilot's brain. The CRU-99 oxygen sensor is a helpful tool, but it cannot measure "downstream" parts of the system.
- There are many possible system interactions that can contribute to a PE. Without in-flight data about pilot breathing, it is hard to establish which of these system interactions most significantly contribute to a PE.

The primary purpose of the 2017 OTM was to help explain a recommendation to measure pilot heath and performance in-flight, particularly pilot breathing. The 2017 assertion was that measuring pilot breathing is likely key to understanding the causes of PEs. The 2017 version of the OTM is shown in Figure 3.5.

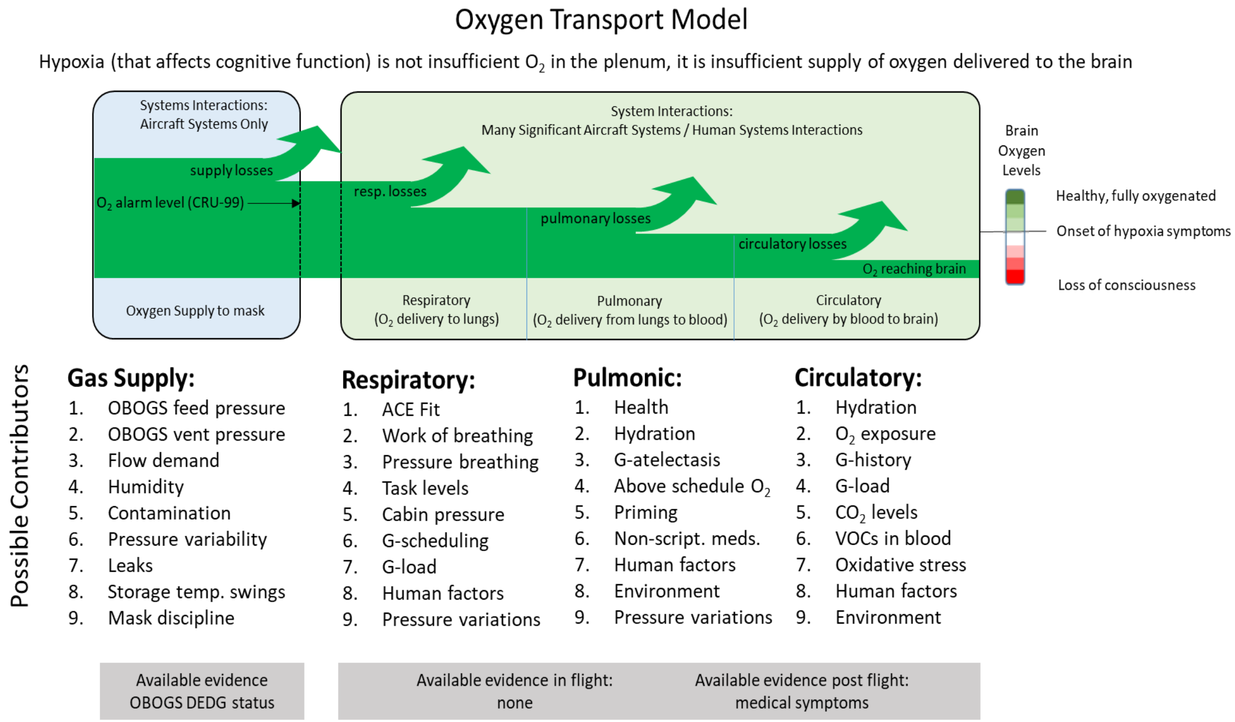


Figure 3.5. 2017 Version of the OTM.

OTM – 2018 Version

The second iteration of the OTM was prepared in the early planning stages of the Pilot Breathing Assessment to identify measurements needed to fill key data gaps. Due to lack of data, the pilot breathing system was considered a black box.

OTM – 2019 Version

A series of OTM graphics, each highlighting one system interaction, were prepared in 2019. These graphics highlighted the new evidence available from the PBA test flights (hysteresis, phase shift, pressure without flow, etc.). These graphics highlighted that PBA data could identify specific system interactions, such as cabin pressure fluctuations at the same cadence as pilot breathing trigger a feedback cycle between the pilot and the mask exhalation valve, resulting in incomplete exhalation and reduced breath volume.

The OTM graphical model retains a graphical element that reminds the reader that an oxygen molecule must travel through a pilot breathing system that is long and complex, before the oxygen molecule can reach the tissues in the pilot's brain.

In the context of a case study about systems engineering and HSI, the 2019 version of the OTM highlights several concepts important to system engineering and HSI:

- The entire pilot breathing system – from LOX tank to the tissues in the pilot's brain – is graphically represented.
- System control-response interactions are graphically described.

- The types of system control-response interactions are complex. Some parts of the system are controlled by the pilot, some are controlled by mechanical components in the pilot breathing system, some are controlled by flight environmental conditions.
- Smaller scale system interactions, involving some of the components in the system, fit within the context of a larger system.
- New data, and new ways to interrogate and present data, make it possible to identify and quantify a specific system interaction.

Figure 3.6 shows an example of one of the OTM graphical representations of a specific system interaction (first prepared in 2019).

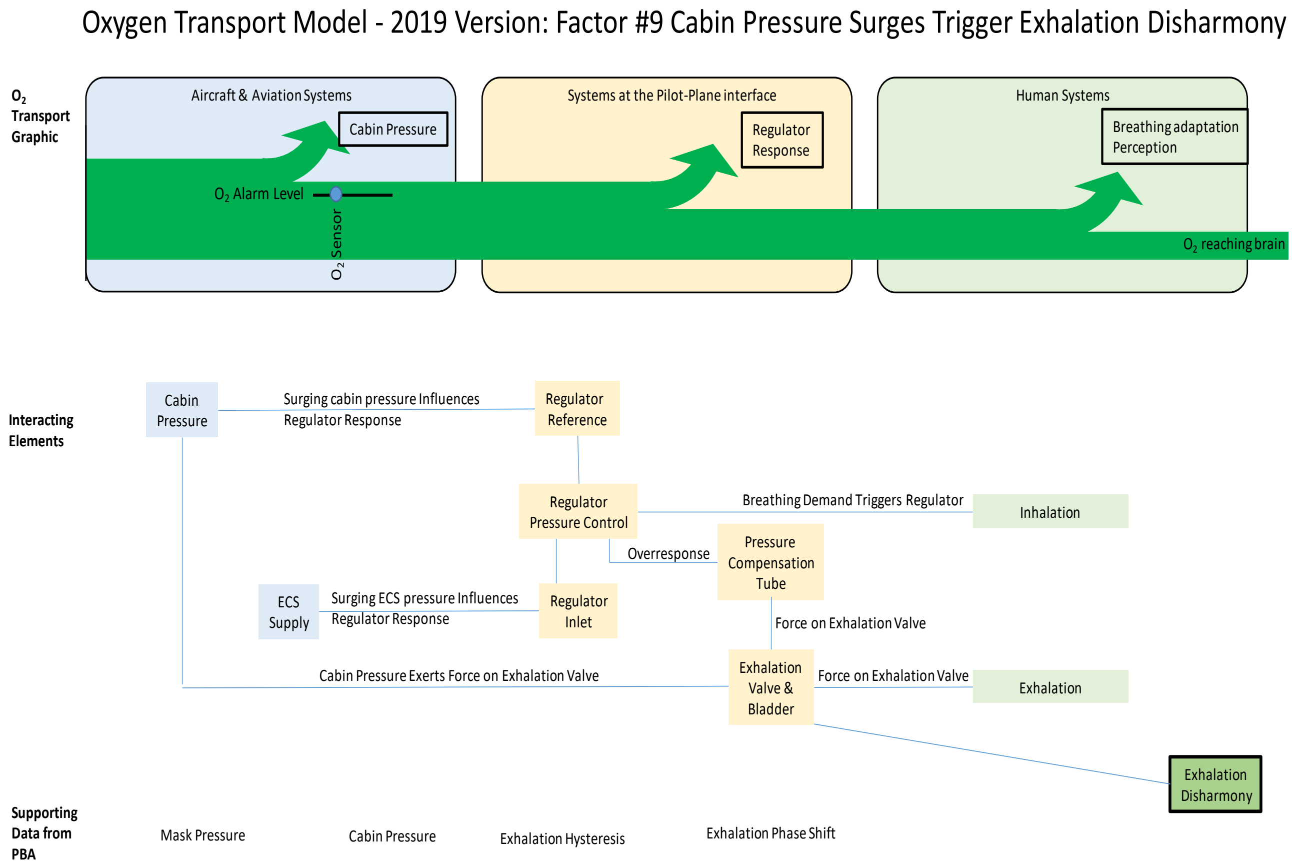
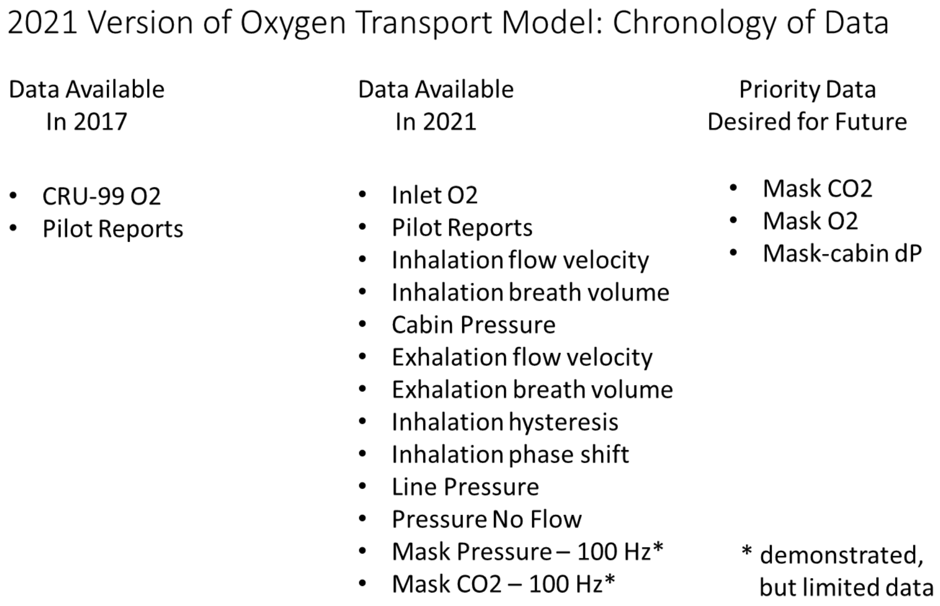

Oxygen Transport Model - 2019 Version: Factor #9 Cabin Pressure Surges Trigger Exhalation Disharmony

Figure 3.6. 2019 Version of OTM.

OTM – 2021 Version

There is now a significant amount of data (Table 3.1), factors related to pilot-plane interactions are complicated, and there are many different perspectives.

Table 3.1. Chronology of Types of Data Available



2021 Version of Oxygen Transport Model: Chronology of Data

Data Available
In 2017

- CRU-99 O2
- Pilot Reports

Data Available
In 2021

- Inlet O2
- Pilot Reports
- Inhalation flow velocity
- Inhalation breath volume
- Cabin Pressure
- Exhalation flow velocity
- Exhalation breath volume
- Inhalation hysteresis
- Inhalation phase shift
- Line Pressure
- Pressure No Flow
- Mask Pressure – 100 Hz*
- Mask CO2 – 100 Hz*

Priority Data
Desired for Future

- Mask CO2
- Mask O2
- Mask-cabin dP

* demonstrated,
but limited data

Table 3.1 highlights the dramatic increase in the kinds of data produced by PBA. Mask Pressure and Mask CO_2 levels are annotated with an asterisk (*), highlighting the fact that these measurements were successfully made in-flight, but the number of test flights using this sensor suite is low. The capability of measuring mask pressure and carbon dioxide levels inside the mask has been demonstrated, but there is too little data for any statistical analysis (the PBA had only 5 flights with the IMCWS instrument). The in-mask sensor data suggests that in the future, priority data will include measuring both carbon dioxide and oxygen inside the mask with good time discrimination, and a referenced measurement of the pressure difference between mask and cabin with good time discrimination.

As part of the 2021 PiBASE case study assessment that focuses on systems engineering and HSI, the OTM is reviewed, refined, and updated. In 2021, our understanding of the pilot breathing system and causes of PEs has outgrown a single simple graphic. The classic OTM is augmented by 6 new graphics (Table 3.2).

Table 3.2. Perspectives of Pilot Breathing System Assessment

Classic OTM. Pilot Breathing System (from the perspective of an O_2 molecule)		
Air Crew Breathing Model Part 1	Air Crew Breathing Model Part 2	Air Crew Breathing Model Part 3
Signal Response Interactions	System Interaction Example #1	System Interaction Example #2

Each additional perspective describes a set of mechanisms and interactions ultimately affecting the oxygen getting to the pilot (Figures 3.7 through 3.12). One figure marks the minute by minute changes during the course of a flight. One figure maps the control-feedback relationships in a pilot breathing system. Another figure maps the mechanical connections between physical elements in a pilot breathing system.

The first figure in the series is the classical OTM evolved.

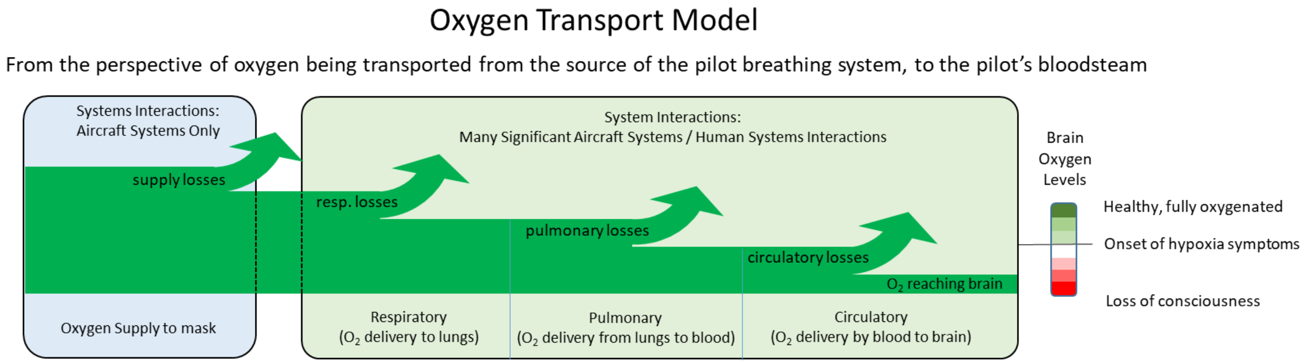


Figure 3.7. The classic OTM represents eroding margins in Pilot Breathing System, from the perspective of an O_2 molecule.

Figure 3.7 graphically describes oxygen flow through the pilot breathing system – taking the perspective of oxygen molecules flowing from supply, through pilot breathing system, to the tissues in the pilot's body. The figure graphically describes they types of losses that can slow the delivery of oxygen to the tissues in the pilot's body.

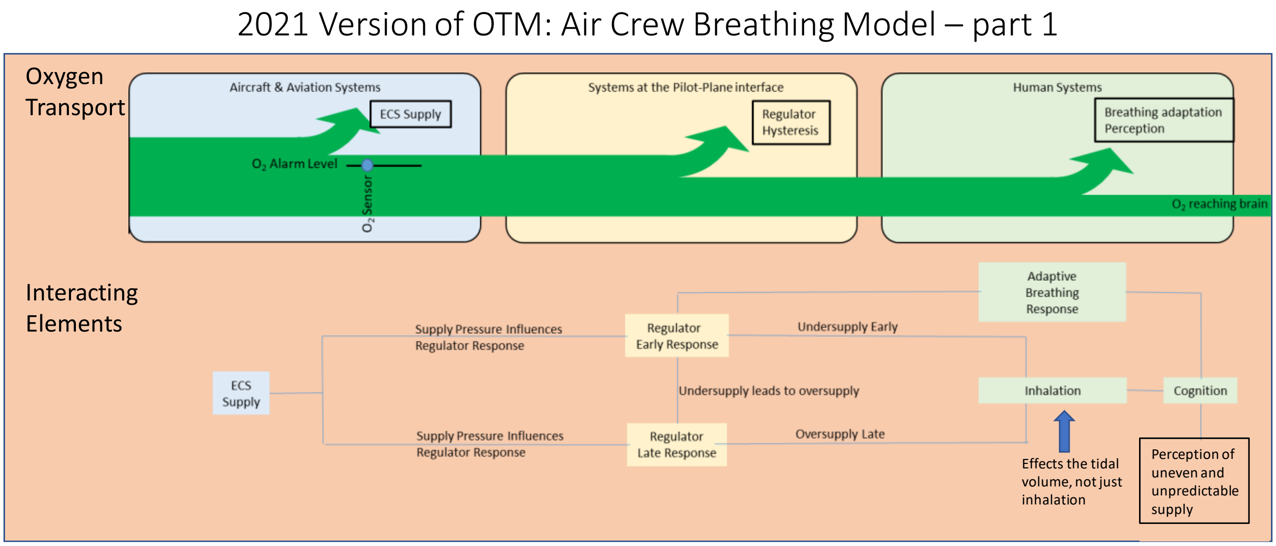


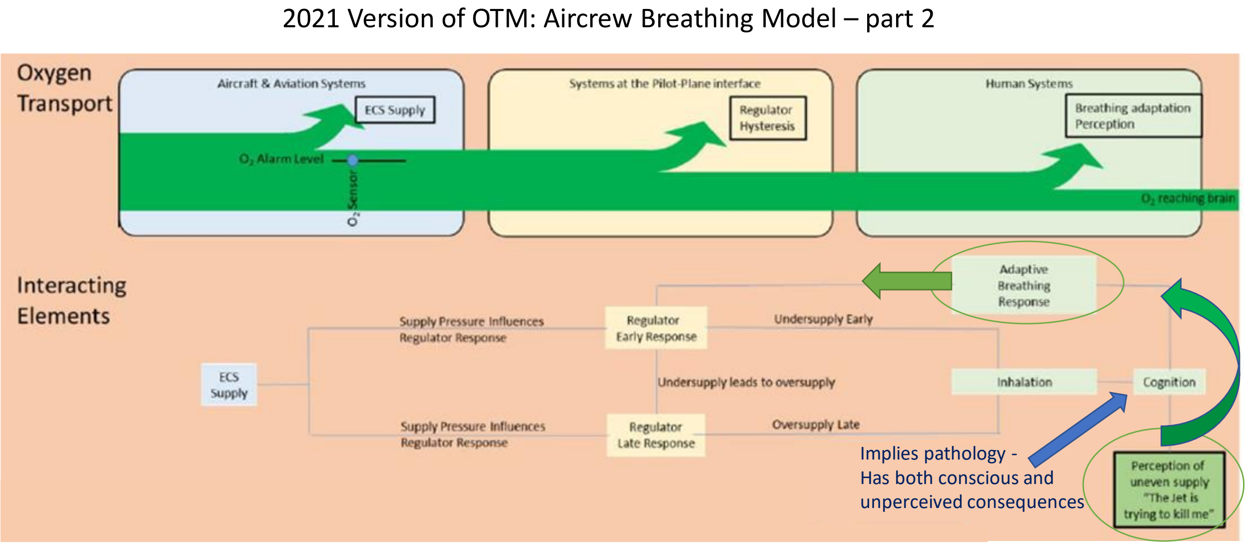
Figure 3.8. Air crew breathing model – part 1.

Figures 3.8 through 3.10 describe a progression of events over time, with special emphasis on describing pilot-plane system interaction from the perspective of the pilot. These three figures are referred to at the Air Crew Breathing Model. An explanation of the model, and the progression of events are described.

The original oxygen transport diagram conveyed the fact that despite a high percentage (30% - 100%) oxygen being generated or supplied, there could be losses in volume or concentration of oxygen. On the receiving end of this oxygen is the complex human system, which itself contains many interacting subsystems.

In Figure 3.8 the inhalation box is now shown as affected by tidal volume (changes) and has outputs to Perception and Cognition. In AOS design, not only inhalation (pressure) must be considered, but the volumes and oxygen content of the inhaled gases and exhalated volumes. Ultimately, it is the tidal volume and oxygen concentration that are primary human interaction elements of the pilot breathing system. To complete the model, the physiologic interactions and consequences must also be considered.

1) Mechanoreceptors are activated when the lungs expand to their physical limit, and their signaling allows the expiration to begin. Pressure and flow must be regulated for both inhalation and exhalation. A high amount of airway pressures in either inspiration and/or expiration can result in barotrauma. Excessive pressures will result in over inflation and decrease the tidal volumes. This ultimately leads to diminishing the amount of oxygen in the lungs available to transport to the body.
2) The Peripheral chemoreceptors come into play by monitoring the blood chemistry. The decrease in pH or pO_2 (partial pressure of O_2) or increase in pCO_2 (partial pressure of CO_2), resulting from decreased tidal volume or oxygen concentration, causes these receptors to stimulate the respiratory center. This will be in an effort to increase the amount to oxygen supplied to the body.
3) The central chemoreceptors will detect the altered blood chemistry to preserve oxygenated blood to the brain. This is also a stimulant to the respiratory center to increase the inspiratory rate and volume.


2021 Version of OTM: Aircrew Breathing Model – part 2

Implies pathology -
Has both conscious and
unperceived consequences

Figure 3.9. Air crew breathing model – part 2.

Part 2 of the Air Crew Breathing Model illustrates that impediments to inhalation has both unperceived and conscious consequences.

The progression to cognition in this case implies pathology only. This has a broader context and cognition has many parts. Cognition encompasses the mental functions by which knowledge is acquired, retained, and used as well as the perception of the environment and awareness of the body's functions. The brain's cognitive processes are not only carried out consciously and deliberately, but also functions and physiological controls are carried out unconsciously and automatically. So, the decrease in tidal volume or oxygen concentration will trigger the peripheral chemoreceptors and mechanoreceptors to increase the volume of oxygen. This will result in respiratory center stimulation and increasing tidal volume by elevating the minute/alveolar ventilation. This results in expansion of the functional air exchange by the raising of breath rate and inhaled volume. This adaption of breathing then places an increased demand on the regulator to provide the tidal volumes, but that may already be limited in its response. This can result in a cycle of pilot demand and lack of regulator provision of the demand. If slow enough this will eventually lead to the perception of shortness of breath or lack of oxygen. This will now initiate conscious increases in breathing and a larger demand on the regulator. If the pilot breathing system is unable to respond to the demand, then central (brain) hypoxia will result. If the pilot breathing system has considerable inability to meet the demand, then a rapid onset of diminished consciousness may occur.

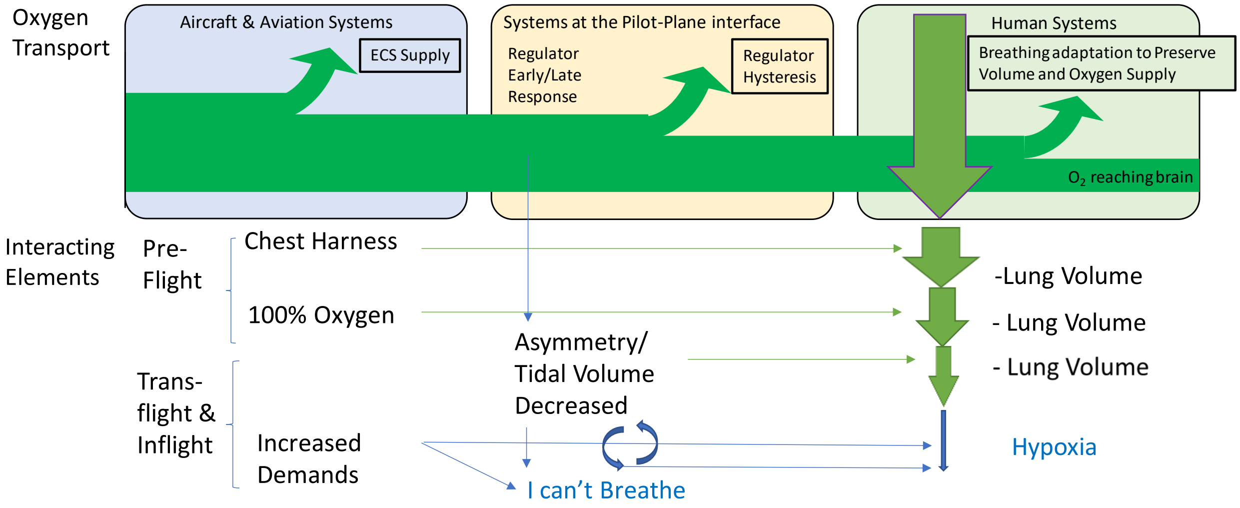


Figure 3.10. Air crew breathing model – part 3.

Part 3 of the Air Crew Breathing Model describes interactions between tidal volume and oxygen supply, as a progression that changes over time.

Temporal relationship may be made now from pre-flight at the top to hypoxia onset at the bottom in the lower section of the chart. So, starting with the aircraft and aviation system, we start to see the loss of physiological reserves. The chest harness can cause chest wall restriction and result in not only diminished tidal volumes to the lung, but a decrease in cardiac output of oxygenated blood to the body. The addition of 95 to 100% (hyperoxic oxygen) further decreases the lungs available volume and further decreases the physiological reserves. Now the pilot is dependent on the pilot breathing system to provide adequate volume and concentration from the system while airborne. If the regulator has a significant amount of asymmetry, the peripheral and central receptors trigger an increase in breathing rate and inspired volume. This will further place a demand on the limited capacity of the regulator and worsens the response and the asymmetry. This turns into a subconscious, then a conscious demand for more oxygen and volume. Now the perception of lack of air is prominent as the brain does not have the oxygen to fuel the metabolic processes. This cycle worsens with increased demand and subsequent lack of meeting the required volume or concentration of oxygen and hypoxia results.

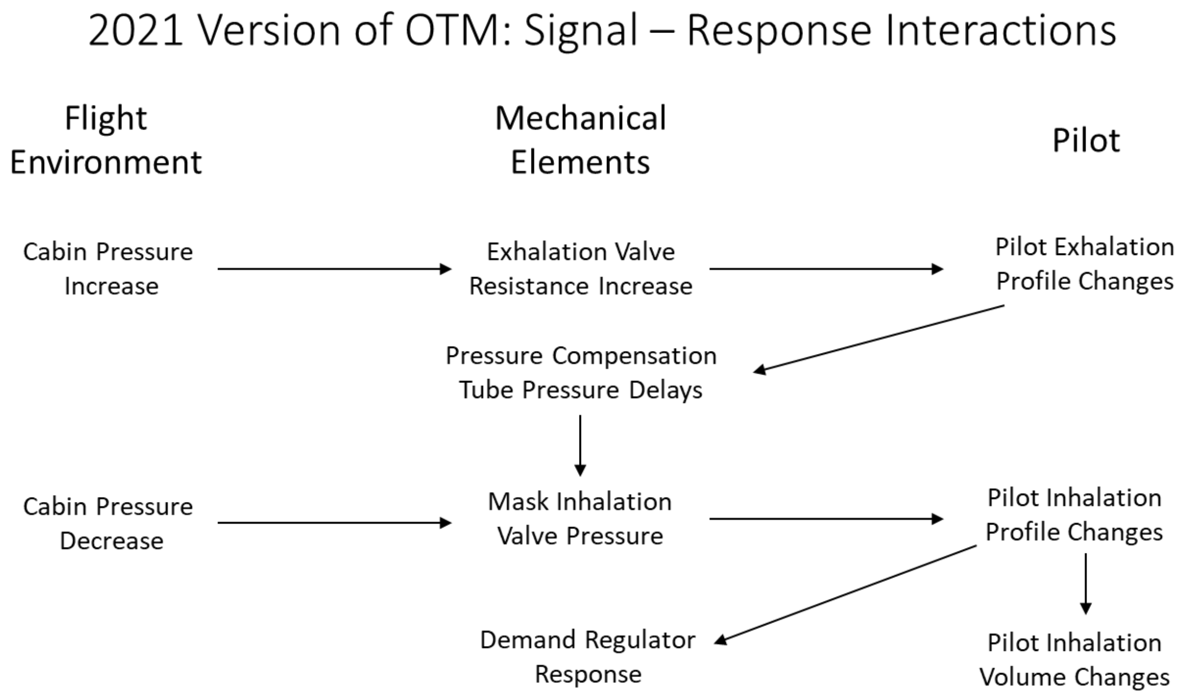


Figure 3.11. Signal response interactions.

Figure 3.11 describes one set of signal response interactions for different elements in the pilot breathing system. This specific example describes the interacting elements involved when cabin pressure flutters – first increasing and then decreasing. These system interactions were recognized prior to PBA, but the extent of the interaction could not be quantified because cabin pressure fluctuation and pilot adaptation and mechanical element response could not be measured in a lab on the ground. It is important to note that even though this is a relatively simple system interaction – that was qualitatively understood, the signal response interactions are complex. Flight environment changes trigger changes to the pilot and changes to the mechanical elements of the pilot breathing system. The pilot is simultaneously the driving signal in some signal response interactions, and the responding element in other signal response interactions. PBA data was able to measure and quantify some of these interactions.

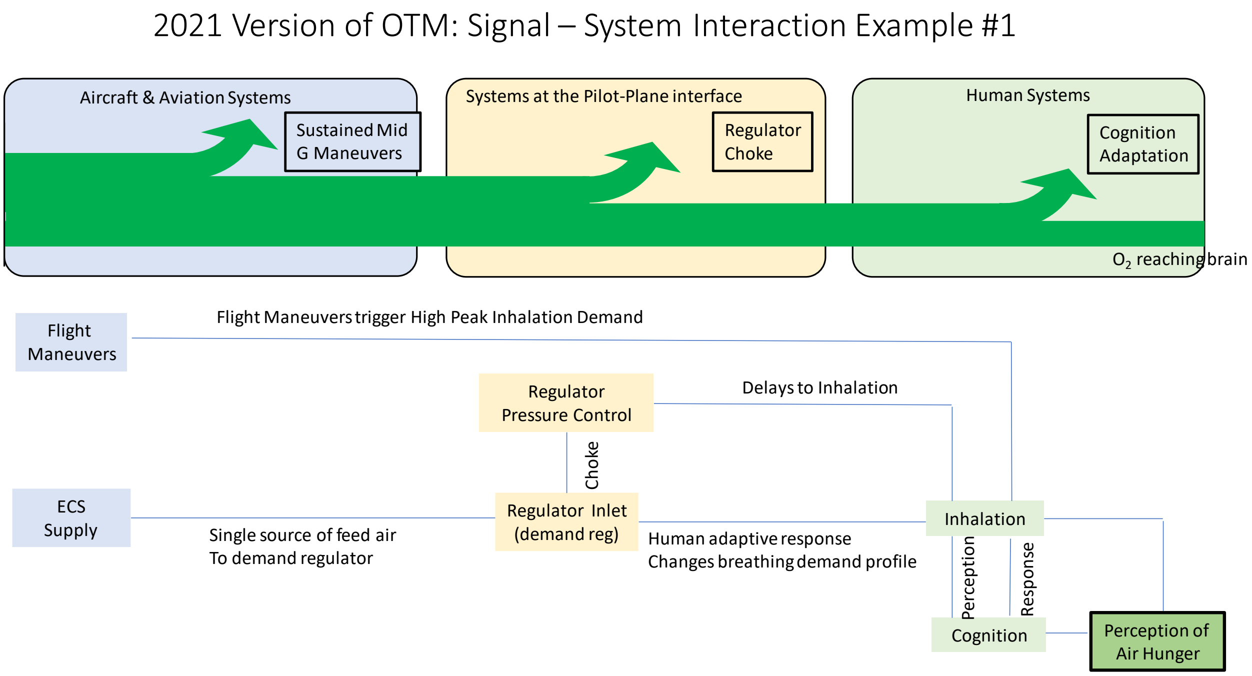


Figure 3.12. System interaction example #1.

Figure 3.12 graphically describes one example scenario, showing system interactions between aircraft and aviation systems, hardware elements directly involved with pilot breathing, and the pilot. This scenario highlights the interactions associated with mid-G flight maneuvers (not extreme high, maneuvers, but maneuvers resulting in 3 to 5G). These mid-G flight maneuvers cause a change in pilot breathing; pilots refer to this type of breathing as “anti-g straining maneuvers”. The change in inhalation pattern triggers a change in regulator response. This loop can continue and strengthen for subsequent breaths if the flight maneuver continues. Initially, the effects are not perceived by the pilot. Eventually, the pilot can perceive air hunger. This is one example of a system interaction that has long been suspected by subject matter experts, but ground tests cannot create the conditions that produce these system interactions. PBA provided the data to quantify the extent of these system interactions in-flight. From a systems engineering perspective – measuring system level interactions in a “fly like you test and test like you fly” environment is essential.

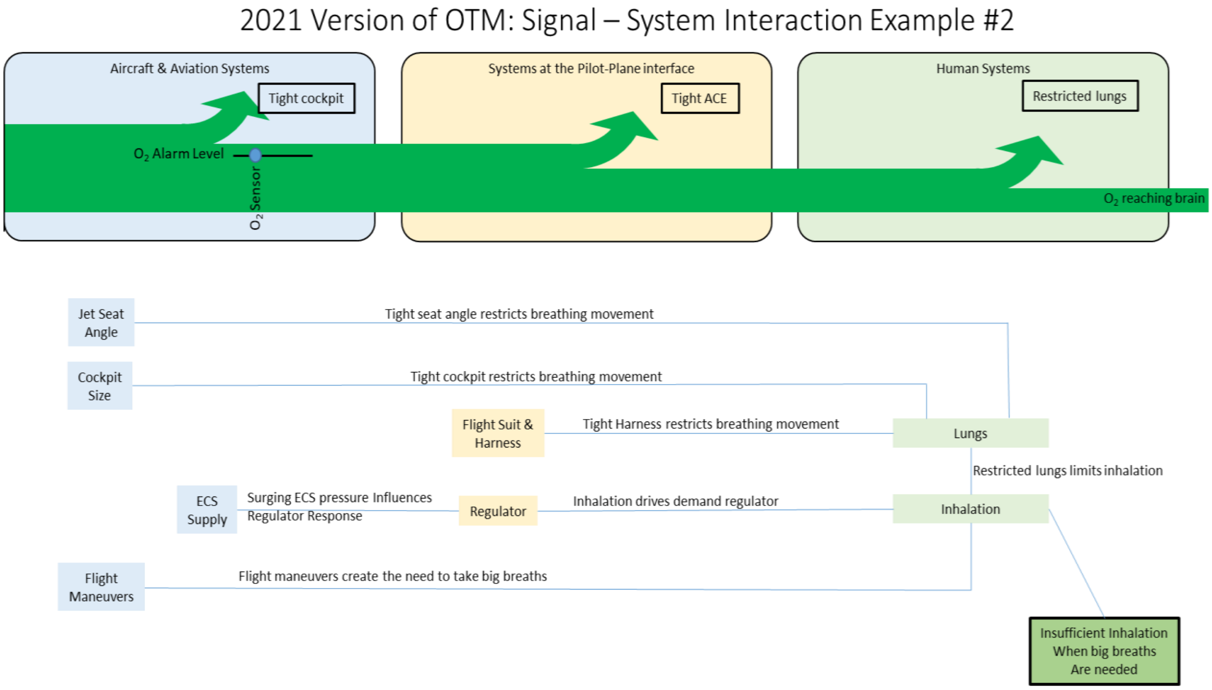
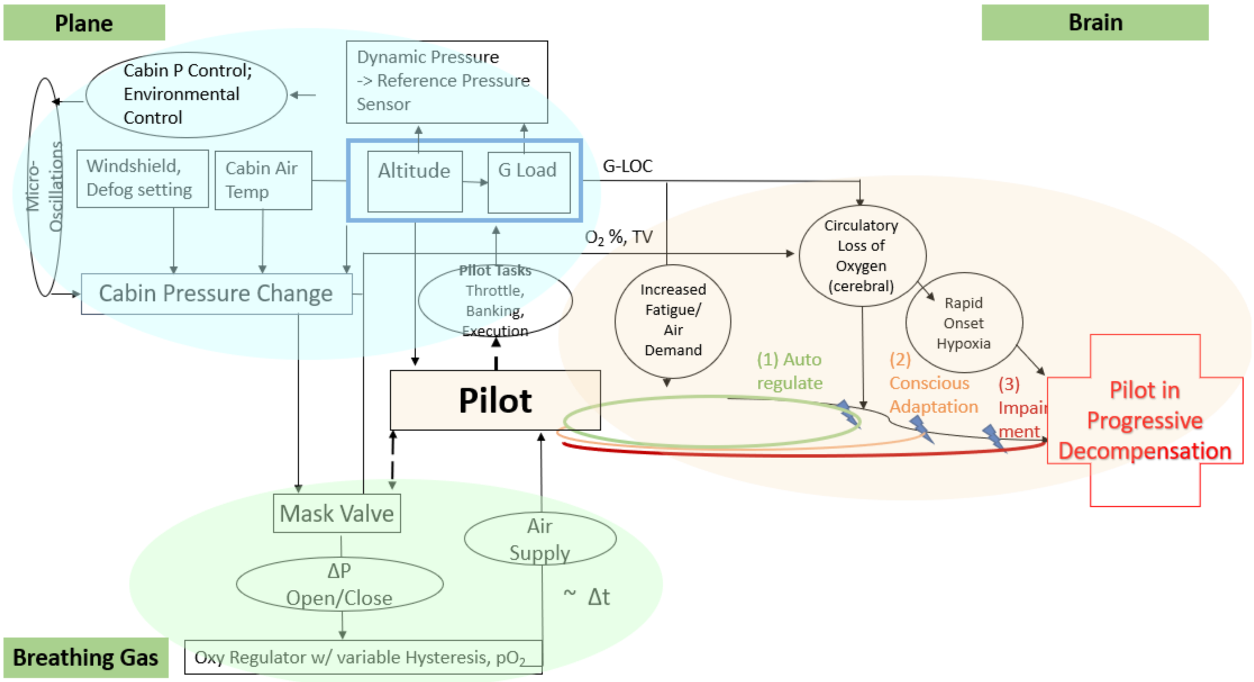


Figure 3.13. System interaction example #2.

Figure 3.13 highlights the effects of harness fit and being seated in the cockpit, and reduction of forced vital capacity (FVC), as indicated by spirometry measurements before donning the flight gear and upon taking a seat in the cockpit fully harnessed. A comparison of pre-flight spirometry, and post-flight spirometry can quantify additional impact to the pilot’s FVC, limiting maximum breath volume. This is an observation which adds to the erosion of margins or reserves in the human system. More on this topic is in Section 4 and Section 6.4.

3.2.1 The Plane-Brain Diagram



O2 schedule per State of AC. Needs to be driven by Pilot State

Figure 3.14. Shows simultaneous interactions between the plane's function and the pilot physiology with the critical component of brain function highlighted.

The model in Figure 3.14 regards the Human as a System (HAAS) with central and peripheral nervous control of oxygen supply and mechanisms that lead to progressive cognitive impairment.

On the left-hand side are the aircraft/aircrew breathing system and its interactions. The plane's systems interact and are affected by the altitude and the cabin pressure compensation. Altitude also affects the rate and duration of plane performance and the onset on g-loads. The aircrew breathing system also interacts with the pilot and cabin pressure affecting the tidal volume and Oxygen concentration supplied to the pilot. The plane's systems and dynamic environment places stress on and diminishes physiological reserves. The pilot compensates and drives demands on the system, which if not fully compliant with the demand, results in further pilot demands on the system. The human system receives input and constantly adjusts to the environment, forming a feedback loop. If adequate to the demand, the human autoregulates in 1) the **Autoregulation Circuit**. If the system fails to meet the demand, the pilot has varying degrees of mild symptoms and now consciously tries to adapt in 2) **Conscious Adaptation.** If this feedback circuit still does not accommodate demand various last-ditch physiological compensation attempts to fill the demand but represents a failing system. This **Impairment cycle** results in frank uncompensated hypoxia and compromised performance or at the worst end unconsciousness. The stresses of dynamic flight can rapidly deteriorate physiological compensation if the human is subjected immediately to overwhelming stressors and can result in **immediate decompensation** and rapid unconsciousness.

The human is the most complex part of the system and (jet) pilots are subject to complex and variable conditions and breathing system responses, progressively affecting the pilot's

state. This section shows the complexity of the human-machine-environment systems and interactions, each of which are discussed in greater detail in Sections 4 and 6.

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4. The Pilot-Jet System of Systems (SoS)

Introduction

The PBA treated the F/A-18 and its pilot as a SoS. On the one hand there is the complex aircraft, the F/A-18, a solid jet in many configurations performing over four decades, with varying dynamic states, pressurization, environmental control and life support functions However, the pilot who, like all F/A-18 pilots, is professionally trained to operate the jet, yet has individual characteristics (lung volume, adaptation and coping, chaotic) that influence his performance. *System of systems* (SoS) is the viewing of multiple, dispersed, independent *systems* in context as part of a larger, more complex *system*. The human is a system with multiple subsystems; the a*ircraft systems* are those required to operate an aircraft efficiently and safely. There is some reluctance[1] that by highlighting the parts of the SoS and defining them separately, the only way to make progress towards a safer and more effective human + machine experience is to consider them as one system characterized by joint interactions. The PBA has regarded the entire human-machine system as a whole, so much so that detecting "disharmony" regardless of boundaries proved to be the key towards major findings. In terms of SoS, and considering everything acted on and by the human, the environment, (the effects of) dynamics, and time is also considered. (Breathing adaptation is a time/path dependent process. Not only time of delivery of oxygen matters, but cumulative stresses from T-hours to T-minutes contribute to a present state).

The reason why we elect to refer to the articles under study as a SoS is to underline the fact that "the Human is the most complex part of the system" (James Less, PBA test pilot). Thus, the human is more than just a component or even a subsystem. We observe that "the HHFB (Habitability and Human Factors Branch at NASA Johnson Space Center) has been promoting the **Human-As-A-System** (HAAS) design model to **NASA's Systems Engineering** (SE) process since 1987. The HAAS model stresses that systems are ultimately designed for the humans; the humans should therefore be considered as a system within the systems. To facilitate **humans** accomplishing mission objectives, the human factors discipline should play a prominent role in the systems design so that human and machine interfaces are properly designed."[2] It is in this spirit that we frame the ensuing content.

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4.0.1 Pilot Perspective on Systems Engineering Approach to PBA

Human Factors (HF) and HSI are established fields that have long been applied to the design and testing of high-performance military aircraft. However, much of that effort has not been significantly different from how HF or HSI would be applied to design and testing of an automobile. Automotive engineers must ensure that the seat can be adjusted to accommodate a range of drivers' body types to permit the driver to access the controls, view the displays, check the mirrors, and see out the windows. For customer satisfaction, the seats must be comfortable. For safety, the restraints and airbags need to be sized and positioned to ensure survivability in a crash. Similar factors are critical in the design of a fighter aircraft cockpit, with an ejection seat substituted for the automotive airbags.

A pilot breathing system in a fighter aircraft requires an additional level of consideration for proper integration. Breathing systems are not unique to aircraft; they are used by scuba divers, firefighters, and as medical ventilators. SCUBA divers are trained to regulate their breathing and taught to follow strict protocols for dives and ascents. Firefighters may be expected to put forth considerable exertion in their duties, but the ambient atmospheric pressure around them is essentially constant at near sea level pressure. A medical ventilator is designed to breathe for an unconscious patient incapable of breathing for themself. In a fighter aircraft, the pilot needs to be focused on execution of a series of time-critical and cognitively demanding mission tasks, often under the physical demands of elevated G-forces. In addition, the cabin pressure can vary rapidly from near sea level pressure to almost 18,000 feet pressure altitude. The pilot's sub-conscious breathing demands provide the signal the breathing system should be responding to and accommodating.

The pilot is not just a <u>user</u> of the breathing system, but a fully integrated <u>component</u> of the system. The PBA project recognized that the pilot is part of a SoS and needs to be analyzed as such. As the pilot is the most complex part of this SoS, the PBA project included physiologists and doctors trained in aerospace medicine on the team to help understand the interactions between the pilot and the breathing system. The PBA team would not have been as successful without a complete and thorough application of the Systems Engineering approach.

Design and Conduct of the Experiment

Even though very few pilots have the background to understand their own physiology to the degree needed in a study such as the PBA, it was essential to have pilots involved from the beginning in designing the test procedures and flight profiles.

Adhering to the maxim 'test like you fly' the PBA developed mission profiles designed to represent operational maneuvers with each of the profiles targeting a portion of the flight envelope. While none of the profiles directly mimicked an actual combat or training flight profile, the maneuvers were representative of typical fighter maneuvers and were chosen to present flight conditions which would stress the pilot breathing system, to include the pilot. The maximum Gs flown were bounded at 5 Gs. Some of the events and maneuvers were included with the expectation that they would later be repeated with an OBOGS-based breathing system, even though the PBA used only LOX-based systems.

High-performance military fighters and trainers regularly conduct a variety of missions. The PBA recognized that a SoS approach including the pilot would not be sufficient if we did not present this system with a wide range of flight parameters. Like most of the other components in a fighter aircraft, the breathing system and pilot need to be tested at conditions throughout the flight envelope of the aircraft. Since the team did not know ahead of time which conditions would yield the most interesting data, the PBA project used initial data analysis along with pilot feedback to refine the maneuvers and profiles during most of Phase 1.

While it was essential to the PBA project that we treat the pilot as an integral part of the overall breathing system, this did add tremendous complexity to the experiment and made strict repeatability impossible. Unlike other components of an electro-mechanical system, the pilots were not all manufactured to the same exacting aerospace tolerances, though for PBA the five

NASA test pilots studied all had similar flight experience, age, and overall health. One of the goals of the PBA project was to identify variability between pilots, and even among the fairly homogenous study group, this variability was seen. However, even the same pilot presented different results on different days. The human component can be affected by what they did the day prior, how well rested they were, their level of nutrition and hydration, or possibly even their expectation of what they would do after the flight. Since all these factors could not practically be controlled, the PBA employed pre-flight and post-flight surveys to record the pilots' self-assessments of their physical and mental states for later use in the event unexplained results were observed.

To minimize additional variation in the execution of the various events and maneuvers prescribed in the test profiles, the details to specify precisely how each maneuver would be flown (throttle, pressure altitude, calibrated airspeed) were captured in the "flight cards." To ensure pre-flight and post-flight spirometry was done the same by all the pilots, a flight surgeon trained each pilot on the proper technique and a life support technician monitored all spirometry tests.

Pilot Opinions, Comments, and Self-Assessment

Unlike a system component, such as the breathing regulator, the human component can actually provide post-flight opinions and comments on how it felt, how hard it was working, and how well it thinks it performed. While the pilots may not be able to detect subtle differences in the breathing system, in all cases where the pilots commented on something they observed, whether a minor annoyance or a more significant issue with breathing, the pilots' observation were later supported by data measured on the flight. The pilots took notes in flight and then debriefed their observations with the team after the flight as well as noted these comments in a post-flight report.

One component of the PBA test matrix was use of two different types of flight gear, referred to in the PBA report as "Air Force" and "Navy" gear because each configuration was typical of the flight gear used by each Service. The gear included the flight harness and oxygen regulator. The Navy gear had a more restrictive harness the pilot had to wear and the oxygen regulator (CRU-103) provided a small, continuous "safety pressure" in the pilot's mask. The Air Force harness was subjectively more comfortable to wear and the oxygen regulator (CRU-73) did not have the safety pressure. All five pilots preferred the Air Force gear for comfort and observed that the Air Force regulator was easier to breathe through than the Navy regulator. Data gathered during the PBA showed measurable effects of the more restrictive harness and the CRU-103, which degraded the pilots' physiology and could be contributory to PEs.

As noted above, the pilots conducted pre-flight and post-flight surveys to assess their physical and mental condition along with their perceptions of how the flight went. This is important data to include in any test involving a human component, though it does complicate the experiment as humans have limitations in their ability to self-assess their condition and performance. In addition, there are some aspects of the fighter pilot culture which can complicate efforts to obtain open and honest feedback; this is discussed more in Section 8.2.

4.1 Human Breathing System and Control

This case study approaches the HAAS, and presents human breathing, specifically pilot breathing in an adverse, fast-changing environment from a system view. A fighter or advanced trainer aircraft imparts a stressful environment to a pilot. These aircraft impart several physiological risks including hypoxia from altitude, and rapid changes in acceleration and vectors of the fighter's flight path that result in increased gravitational forces. This section explores the human system in light of the environment the pilot is placed in. Examining the human breathing system control will aid in deducing the problem parameters that may result in a PE and the data that needs to be acquired to help solve the issues. In the case of the PBA, inflight measurements of oxygen concentrations, CO_2 exhalation, volumes of inhalation and exhalation, pressures in the mask and cabin, flow of gasses and repository rates. The inflight physiological measurements were compared with baseline measurements to see the differences. This section will explore the rationale behind these measurements and the importance of making them inflight.

The human anatomy is made up of 10 systems, of which the central nervous system, respiratory system and cardiovascular system are the most crucial in their interaction as it relates to breathing and its regulation. Understanding the physiology and control of breathing will build into a physiological system analyses and the mechanical interactions. The act of breathing is an automatic rhythmic act that is controlled by the brain and brainstem automatically. Nerve connections to the muscles of the thorax and abdomen trigger movement to actively expand and allow passive contraction of the chest wall. The expansion and contraction of the airways and lungs then produce pressure gradients that move air into and out of the lungs. The respiratory rhythm and the length of each phase of respiration are set by reciprocal stimulatory and inhibitory interconnection of these brain-stem control centers.

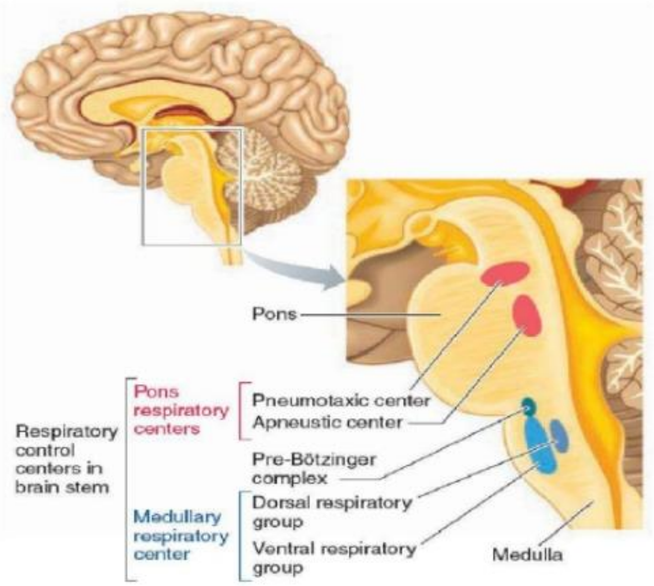
The respiratory system has the critical ability to adjust breathing patterns to changes in both the internal demands of metabolism and the external environment. Ventilation increases and decreases in proportion to swings in oxygen consumption and CO_2 production. These are affected by the changes in metabolic rate. Increasing metabolic demands triggers an increase in minute volumes (volume inspired over 1 minute) and vice versa. The respiratory system is also able to compensate for perturbations in the mechanics of breathing. These include airway narrowing from an asthmatic attack or allergic reaction. Adjustments in breathing also are made when the mechanical advantage of the respiratory muscles is altered by postural changes or by movement.

Respiration is controlled by brain regions that stimulate the contraction of the diaphragm and the intercostal muscles. These areas, collectively called respiratory centers, are summarized here:

1) Medullary inspiratory center. This is located in the medulla oblongata and generates rhythmic nerve impulses that stimulate contraction of the inspiratory muscles (diaphragm and external intercostal muscles). Expiration normally occurs when inspiratory muscles relax, but with rapid breathing, the inspiratory center facilitates expiration by stimulating the expiratory muscles (internal intercostal muscles and abdominal muscles) to contract. This increases the work/effort of breathing. The medullary center is made up of several subsets of neurons.
    a. Dorsal respiratory groups (DRG): These are composed mainly of inspiratory controllers. The DRG controllers initiate the basic rhythm of breathing by generating inspiratory impulses. These neurons signal the motor nerves of diaphragm and external intercostal muscles to contract. The DRG has inputs to the ventral respiratory groups (VRG), but the VRG does not signal the DRG. The Vagus and Glossopharyngeal nerves transmit sensory data to the

    DRG from the lungs, airways, peripheral chemoreceptors, and mechanoreceptors. These signals are used to modify the breathing pattern.
    b. VRG: This area has both inspiratory and expiratory control regions and primarily active in exercise and stress. The VRG sends inspiratory impulses to airways (laryngeal and pharyngeal muscles) and respiratory muscles (diaphragm and external intercostals) to increase the minute volume.
    c. Other VRG neurons send expiratory signals to abdominal muscles and internal intercostals if these are required for active exhalation.
2) Pheumotaxic area. This area is located in the pons and it acts by inhibiting the inspiratory center. This action limits the contraction of the inspiratory muscles and prevents the lungs from overinflating.
3) Apneustic area. This region is collocated in the pons adjacent to the pheumotaxic area. Its function is to stimulate the inspiratory center, prolonging the contraction of inspiratory muscles.

Figure 4.1 shows the anatomic location of the respiratory centers.



https://www.slideshare.net/Muhammadasif909/control-of-respiration-187224512

Figure 4.1. Cerebral location of the respiratory centers illustrating the proximity of the regions in the brain stem.

The respiratory control centers receive information about how well the conditions that are affected by respiration are operating by the use of neural sensors. There are two groups of neural sensors, chemoreceptors and Mechanoreceptors. Chemoreceptors detect changes in blood oxygen levels and change the acidity of the blood and brain. Mechanoreceptors monitor the expansion of the lung, the size of the airway, the force of respiratory muscle contraction, and the extent of muscle shortening.

4) Central chemoreceptors (nerves of the central nervous system), located in the medulla oblongata, monitor the chemistry of cerebrospinal fluid. When CO_2 from the plasma enters the cerebrospinal fluid (fluid surrounding the brain), it forms HCO_3^- and H^+, and the pH of the fluid drops (becomes more acidic). In response to the decrease in

pH, the central chemoreceptors stimulate the respiratory center to increase the inspiratory rate.

5) Peripheral chemoreceptors (nerves bundles of the peripheral nervous system) that are located in aortic bodies (in the wall of the aortic arch) and in carotid bodies (in the walls of the carotid arteries), monitor the blood chemistry. An increase or decrease in pH, and increase in pCO_2 (partial pressure of CO_2), or a decrease in pO_2 (partial pressure of O_2), causes these receptors to stimulate the respiratory center. Mechanoreceptors are principally stretch receptors in the walls of bronchi and bronchioles are activated when the lungs expand to their physical limit. These receptors signal the respiratory center to discontinue stimulation of the inspiratory muscles, allowing expiration to begin. This response is called the inflation (Hering-Breur) reflex. The Hering-Breur reflex is a normal and a protective reflex to prevent overdistention and barotrauma. Pulmonary stretch receptors activate with excessive stretching of the lung during large inspirations. Once activated, they send signal through the vagus nerve to the inspiratory area in the medulla and apneustic center of the pons. The response from the inspiratory area is to inhibit inhalation and the apneustic center is inhibited from activating the inspiratory area. This curtails inspiration and subsequently allows expiration to occur. This reflex is imporatant in preventing overdistention of the lungs with excessive pressure and the resulting barotrauma (alveolar and small airway bursting).
6) There are also peripheral receptors in the airways and in the alveoli that are excited by rapid lung inflations and by chemicals such as histamine, bradykinin, and prostaglandins. These peripheral chemoreceptors critical functions are to defend the lung against inhaled noxious material. When stimulated, these receptors constrict the airways and cause rapid shallow breathing, and this restricts the penetration of injurious substances into the bronchial tree. These receptors are enervated by the vagus nerve. Stimulation of irritant receptors can also induce coughing.

Figure 4.2 illustrates the interactions of all the respiratory control centers.

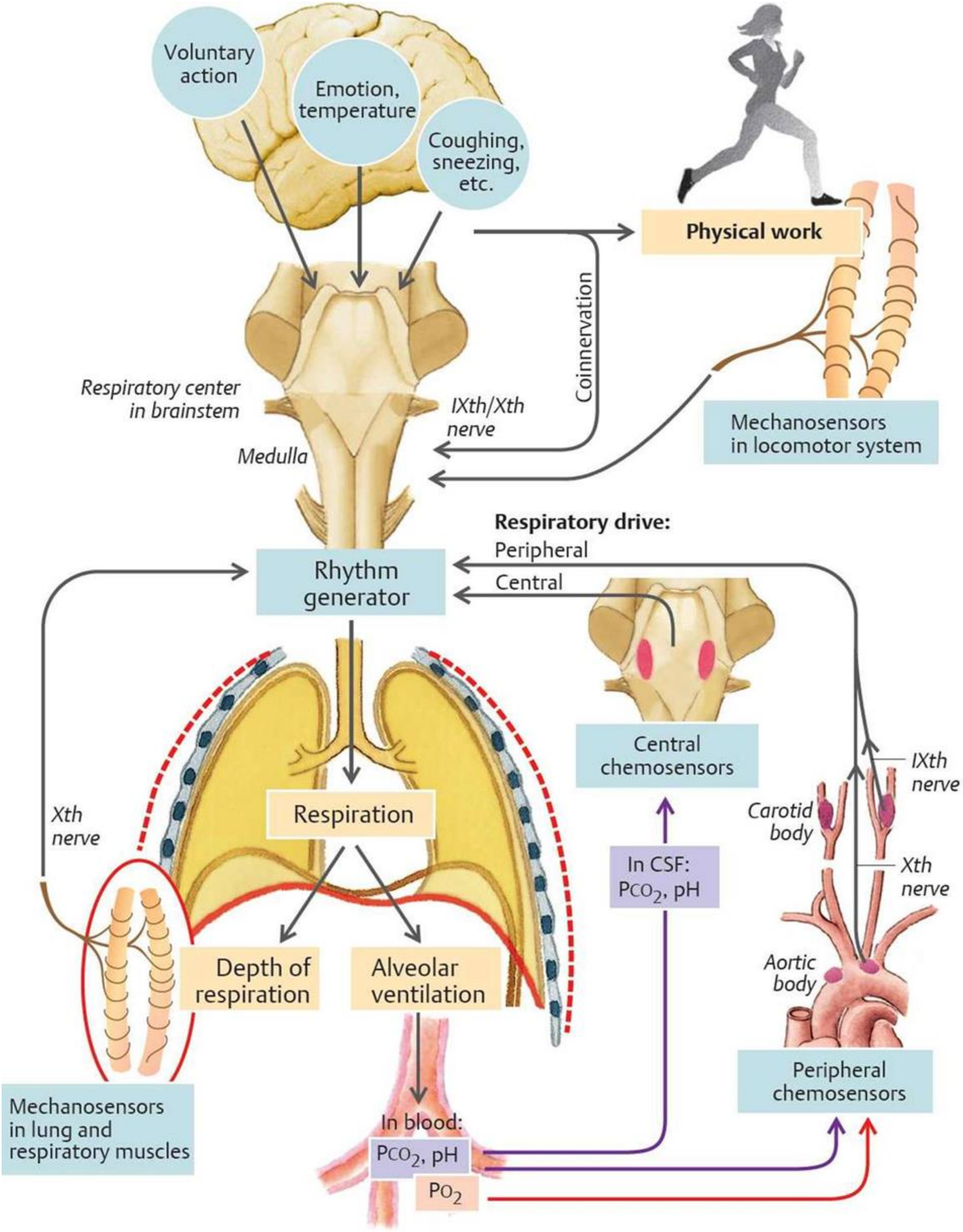


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Figure 4.2. Illustration of the respiratory control centers.

The human system in action.

The best way to demonstrate the functions of the respiratory control system is to go over some of the interactions that affect the controls. Hypoxia (reduction of oxygen supply to tissues) below metabolically acceptable physiological levels (due to high altitudes or decreased concentration or volume of oxygen), stimulates the carotid and aortic bodies to increase respiratory intake of oxygen. These chemoreceptors are the principal arterial detectors of hypoxia, but are not the exclusive ones. This aortic arch and carotid arteries are extraordinarily well perfused and responds to minute changes in the ppO_2. The primary detection of low oxygen content are changes in the ppO_2 in arterial blood flowing rather than to the oxygen content of that blood (Oxygen saturation which is the amount of oxygen combined with hemoglobin). The decrease partial pressure of O_2 results in the carotid body increasing its signaling rate hyperbolically. Additionally, to the hypoxic response, there is an increased signal linearly if the partial pressure of carbon dioxide in the arteries is raised. The arterial O_2 partial pressure rises and falls with pulmonary (lung) inspiration and expiration. The carotid body senses these changes and responds more to rapid than to slow changes in the partial pressure of CO_2. Larger oscillations in the partial pressure of CO_2 in the respiratory cycle are observed as metabolic production is increased (as with exercise). The amplitude of the partial pressure variations is reflected in the proportion of carotid body signals to and integrated by the brain. This allows the brain to detect changes in the metabolic rate and external conditions to produce the appropriate adjustment in ventilation. The aortic bodies in the arch of the aorta also sense the acute changes in the ppO_2. It is not as well tuned as the carotid body to responding to changes in the partial pressure of carbon dioxide. The aortic bodies are responsible for many of the cardiovascular effects (increasing heart rate and blood pressure) of hypoxia.

Central control of respiration. One of the most powerful stimulants of breathing is carbon dioxide and the most potent central vasodilators. With a rise in the arterial partial pressure of carbon dioxide, ventilation increases nearly linearly. Ventilation normally increases by two to four liters per minute with each mmHg increase in the partial pressure of CO_2. CO_2increases the acidity of the blood, plasma, and the extracellular fluid. When dissolved in water, carbon dioxide forms carbonic acid, which lowers the pH. The acidic extracellular fluid surrounding the cells easily passes into cells and thus decreases the interior pH of cells. The central chemoreceptors respond to the effects of CO_2 and acidity depending on the more prominent stimulus and feedback from all the peripheral nerves. Studies have shown that even if both the carotid and aortic bodies are removed, the brain responds to inhaled carbon dioxide and stimulates breathing to remove the excess CO_2. This observation reveals there are additional receptors that respond to changes in the partial pressure of CO_2. Current evidence points to the medullary VRG as the sensitive neuron groups. This has importance in using end tidal CO_2 in the mask as this can give an indication of the respiratory function and adequacy of the system responses.

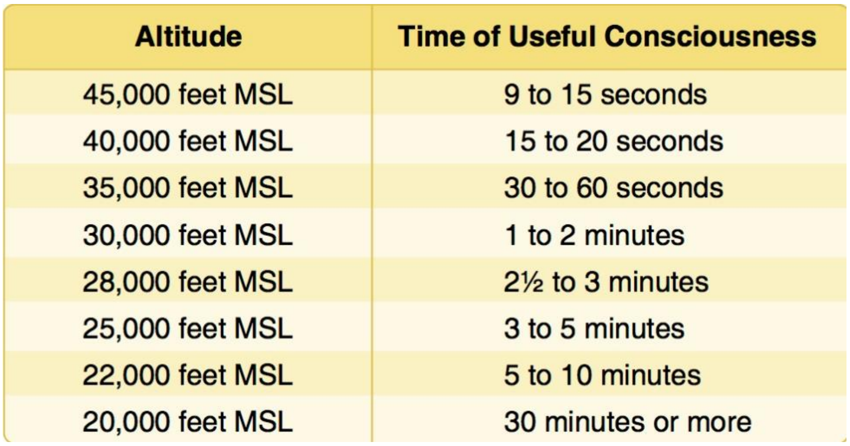
The lung and muscle groups also have feedback sensory neurons that can affect respiratory patterns. These are particularly important if lung function is impaired. These sensors help to maintain tidal volume and ventilation to normal levels or support increased demands. Length changes of a muscle affect the amount of generated force produced when the muscles are stimulated. There is a length at which the force generated by muscle tissue is maximally performed. Receptors, in the respiratory muscles measure muscle length and act to increase the motor stimulus to the respiratory muscles. If increased stiffness of the lung or resistance to the movement of air are detected due to impeded muscle shortening, then an increased stimulus is generated. This results in the diaphragm and intercostal muscles to increase the force generated to improve ventilation. Tendon organs, another receptor in muscles, monitor the changes in muscle contraction force. Excessive force stimulates these tendon organ nerves and causes a decrease in motor discharge to the respiratory muscles and helps to prevent the muscles from damaging themselves.

Inflation of the lungs is stopped, and exhalation is initiated by the Hering-Breuer reflex. This neural feedback is initiated by lung expansion, which in turn excites the airway stretch receptors. Stimulation of these receptors will correspondingly initiate signals to the medulla by the vagus nerve. This will shorten the inspiratory times as tidal volume (the volume of air inspired) increases, accelerating the frequency of breathing. If proper lung inflation is prevented, the reflex allows inspiratory time to be lengthened, helping to preserve tidal volume. There are airway and alveolar sensors that are activated by inflammatory stimulating chemicals. These are formed when noxious chemicals are detected in the airways. These aid in expelling and inhibit the infiltration of these toxins into the respiratory system. These can trigger shallow and rapid breathing, but this response is overridden if the tidal volume or oxygen delivery is impeded and hypoxia occurs.

An examination of exercise is also warranted to look at respiratory control. This parallels the pilot responding to a G-load in a fighter aircraft. A large increase is seen in metabolic rate and carbon dioxide production occurs with exercise or pulling G’s. This also can result in a lactic acid increase if anaerobic exercise is undertaken. Cells produce lactic acid when carbohydrates are anaerobically metabolized and most importantly without oxygen. If high-intensity exercise is undertaken, muscles expend energy extremely rapidly and the muscle groups outrun the circulatory system's ability to provide them with oxygen. This is a localized hypoxia. A consequence of that is that the muscle cells rely more on anaerobic metabolism and produce lactic acid. This can increase levels in the bloodstream and produce a lactic acidosis. Lactic acid is reversed by the body’s metabolism, but that results in increased production of CO_2. Thus, both the metabolic increase in exercise and the subsequent secondary lactic acid production will increase carbon dioxide in the blood stream. The respiratory control responds to these exercise changes by increasing minute ventilation to keep the partial pressure of CO_2 in arterial blood nearly unchanged. This preserves acid–base homeostasis, provides an increase in oxygen delivery and decreases the amount of lactic acid that can be produced.

4.1.1 The Fighter Environment

Modern fighter aircraft have been associated with unusual and unexpected health concerns for their pilots and an intense scrutiny on the cause of the physiological events. Thus, an examination of the stressors of the very dynamically changing environment of the fighter can lend to insight into the difficulties of respiratory control. The domain is so dynamic that ground based testing does not examine all the various combinations of effects and the human interactions in this flight environment. The first consideration is the most prominent problem is hypoxia. The total air pressure decreases with increasing altitude and, consequently, the partial pressure of oxygen (ppO_2) declines as well. In a healthy individual, oxygen saturation of hemoglobin is impacted, and the body physiologically compensates. A climb from the surface to 10,000 feet altitude, air pressure decreases by 25%, the saturation of hemoglobin with oxygen declines from about 98% to 90%. Symptoms in this region are few in fit individuals, with the exception of a gradual onset of significant deterioration in night vision. Other symptoms are subtle and usually not consciously perceived. The brain and heart are the most sensitive organs with respect to pO_2 and extract more oxygen from arterial blood than most other tissues. These organs functions can be affected when blood oxygen saturation is reduced. Above 10,000 feet altitude, the amount of oxygen in the blood begins to decrease much faster than the decrease in air pressure. At 20,000 feet altitude, the concentration of oxygen in the blood is only 65% saturation. These levels result in considerable tissue hypoxia and normal human function is significantly interrupted. These effects are also cumulative over time. The hypoxia is reflected in the Time of Useful Consciousness (TUC) or Effective Performance Time. These are the elapsed intervals of time from the exposure to an oxygen-poor environment or oxygen supply is diminished until the time when the ability to properly function is lost. At this point, an affected individual is no longer capable of taking normal corrective or protective action and proceeds to unconsciousness. A key point is that TUC is not the time to total unconsciousness.



Altitude	Time of Useful Consciousness
45,000 feet MSL	9 to 15 seconds
40,000 feet MSL	15 to 20 seconds
35,000 feet MSL	30 to 60 seconds
30,000 feet MSL	1 to 2 minutes
28,000 feet MSL	2½ to 3 minutes
25,000 feet MSL	3 to 5 minutes
22,000 feet MSL	5 to 10 minutes
20,000 feet MSL	30 minutes or more

Figure 4.3. Shows the TUC reduces with altitude, pressure, and the reduction of breathable oxygen.

http://expertaviator.com/2012/04/19/oxygen-requirements-time-of-useful-consciousness-and-intercept-procedures/

TUC is affected by either decreased oxygen to and in the lungs and/or the cardiovascular system is unable to supply the oxygen. The respiratory response to the response to hypoxia is to first increase minute volume (tidal volume or the volume of each breath and rate), and then increase the cardiac output of the heart (increase the rate and volume of blood to the body) and preferentially shunt blood to critical organs (e.g., the brain and heart).

Another risk of altitude is decompression sickness. This is a rapid loss of cabin pressure resulting in expeditious decrease in total pressure surrounding the pilot. Decompression sickness describes a condition arising from dissolved gases coming out of solution into bubbles inside the body on depressurization. Rapid decompression is a critical problem, but aerospace engineers have incorporated protections into the design of aircraft and life support equipment that prevents this occurrence. The prevention against hypoxia and decompression sickness is cabin pressurization. This allows pilots to maintain an altitude equivalent to 8,000 feet with a cruising altitude up to 40,000 feet MSL (Mean Sea Level – distance above the sea).

Fighter aircraft engage in rapid changes in acceleration and the vectors of the fighter's flight path that result in alterations in the gravitational forces implied on the pilot. These can be positive or negative forces that cause an increase in anaerobic work to counteract these forces. G-force induced G-loss of consciousness (G-LOC) occurs from excessive and sustained G-forces draining blood away from the brain. This diminished blood flow which results in rapid or progressive cerebral hypoxia. Cerebral (brain) hypoxia leads to impairment in cognitive and motor functions depends upon on the amount and duration of the G-forces.

The human body has limits to the amount and intensity that can be tolerated. Tolerance is dependent on the magnitude of the applied acceleration force, force direction, and duration of the force. An individual's tolerance is based on age, weight, height, blood pressure and anaerobic fitness. If tolerance is exceeded, then physiological decompensation occurs with potential severe injuries. If vision loses hue and the perception of the visual field turns gray, it is described as "Gray-out". The decreasing blood flow to the eye results in a progressive loss of peripheral vision which is labeled as "Tunnel Vision". A-LOC (Almost Loss of Consciousness) is loss of vision without unconsciousness. G-LOC is the lack of blood flow that can support brain function. "Red-out" describes the reddening of vision from negative G-forces which drive the lower eyelid into the field of vision.

The effective cardiovascular and respiratory regulatory mechanisms ensure that the delivery of O_2 to all regions of the body are sufficient to match the metabolic demands of each region. A rapid onset of G-loading requires an immediate cardiovascular response. This is particularly critical for the heart and brain; whose metabolic activity is high and can vary greatly in different circumstances. G-loads can require an enormous increase in blood flow together with a vast increase in O_2 extraction from the blood. These cardiovascular responses are produced by a combination of local and neural mechanisms, as shown in the following Figure 4.4. Central control of blood pressure is influenced by the blood oxygen, CO_2 and the blood pressure (BP) as illustrated in the following diagram.

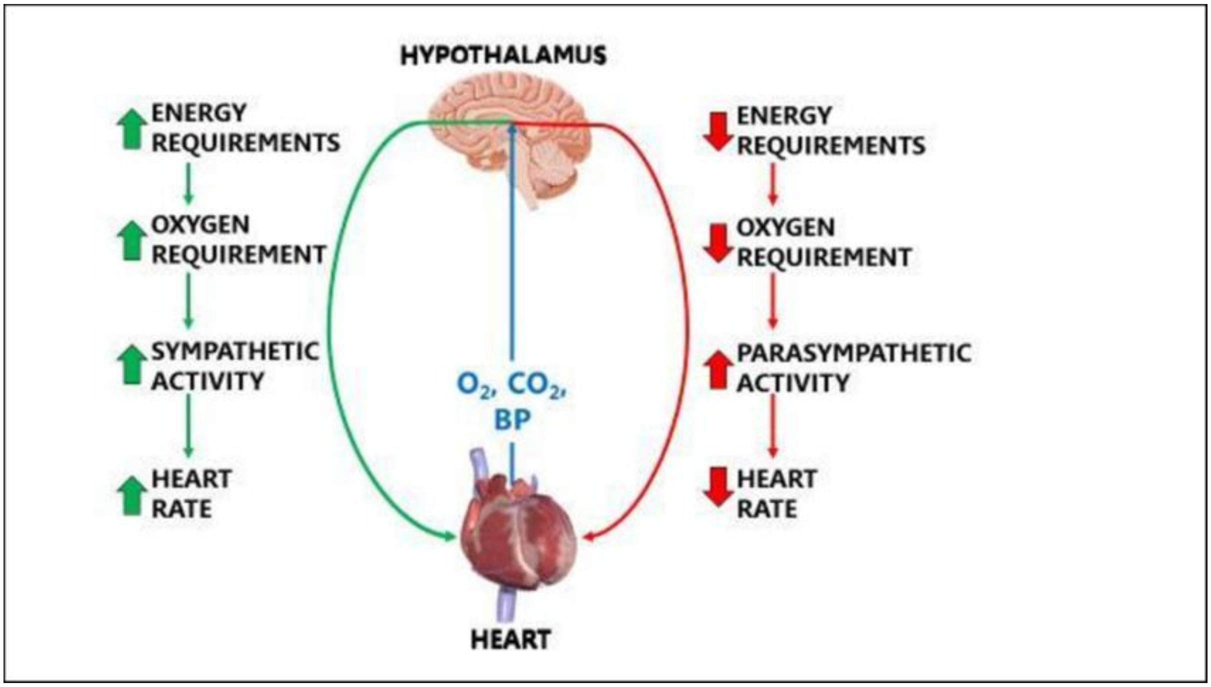


Figure 4.4. Shows a simplified cardiovascular control of cardiac output (amount of blood pumped).
https://www.researchgate.net/figure/Heart-control-Suggested-route-of-action-for-a-change-in-heart-rate-by-changing-the_fig1_303565614

Local mechanisms are also important and include metabolic, endothelial, and myogenic components which result in vasodilation in metabolically active skeletal muscle vascular beds, leading to large increases in local blood flow provided the arterial pressure (tissue perfusion pressure) is maintained or increased. The increase in O_2 extraction from the blood also depends on both local factors (local acidosis, increased CO_2). These peripheral as well as central regulatory mechanisms maintain the arterial blood po_2 (PAO_2) despite the large demands.

The control of some cardiovascular parameters is far more complex than the respiratory system and has far more branches than the respiratory system. Take for instance mean arterial pressure, which is the relative measure of blood flow, and considered a more accurate measurement than just the systolic blood pressure. Mean arterial pressure depends on both cardiac output (volume of blood being pumped by the heart) and all the associated elements of that output and the total peripheral resistance, which requires inputs to the system controls on its own. Moreover, sometimes a control element in one system interacts with another element that is not directly connected. A physiological system with such complex interactions among parameters makes it difficult to delineate elements of overriding priority from those of lesser weight. In examination of physiological controls, conditions isolating individual subsystems rarely apply to a real person. This makes determining the source of a physiological insult (specifically a PE) extremely difficult. Figure 4.5 illustrates the complex cardiovascular control system in action with its various branches and connected interactions. This is to illustrate the heart's complicated control system.

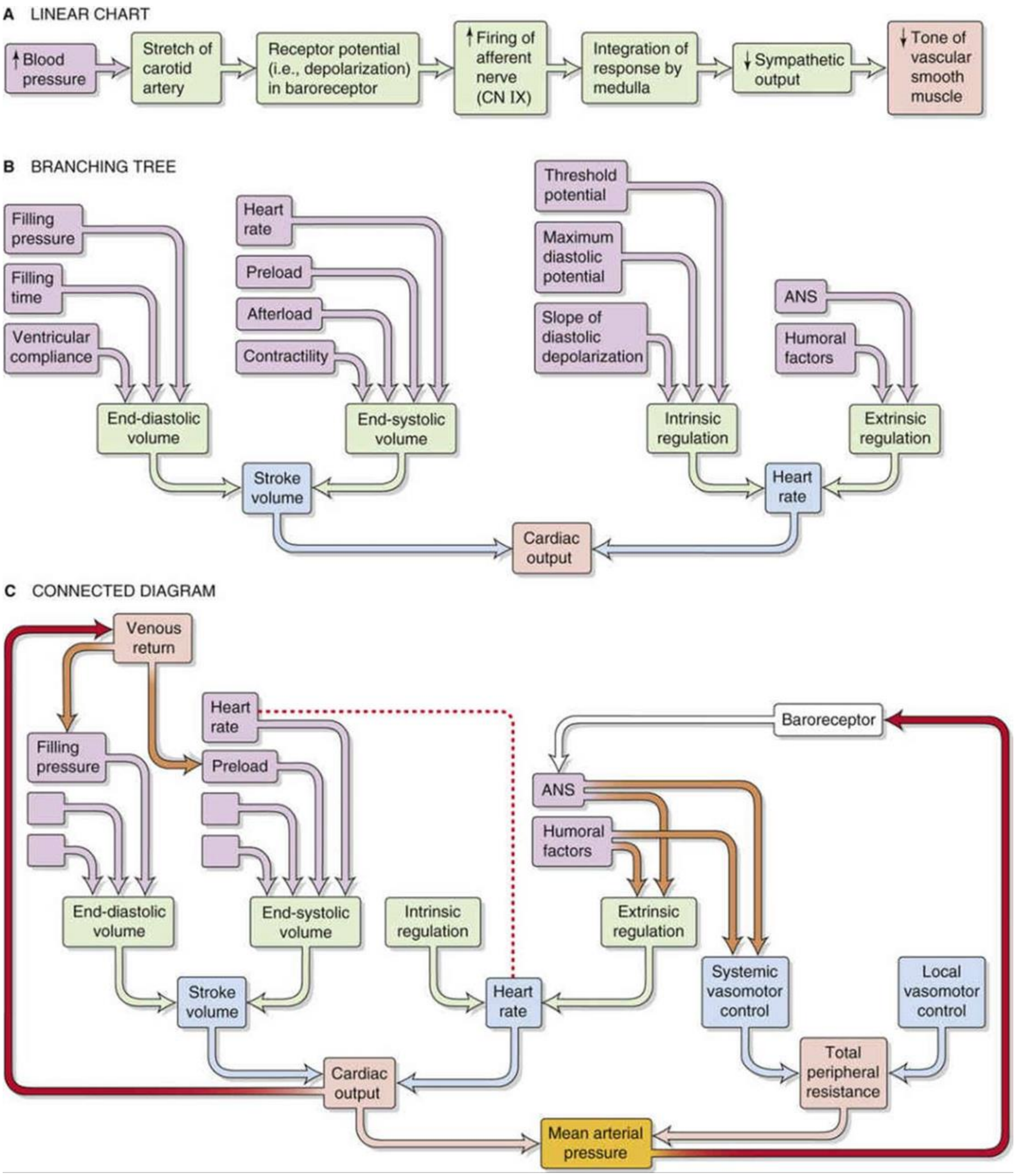


Figure 4.5. The complex cardiovascular control system in action with its various branches and connected interactions.

https://doctorlib.info/physiology/medical/135.html

Cardiovascular system control diagram: In the top line (A) you see the individual control of blood pressure. In the second line (B) are the control mechanisms of Cardiac Output (Heart Rate X Stroke Volume) that determine the amount of blood the heart pumps. In the final line (C), all the preceding system controls are integrated into an overall control diagram for the blood vessel control of blood pressure.

Ventilatory activity interacts with the cardiovascular controls in response to heart rates via stimulation of the peripheral chemoreceptors. In addition, the action of the respiratory muscles during inspiration causes intrathoracic pressure to become more negative, thereby increasing venous return. A third interaction is that the evaporative loss of water during breathing reduces total body water and, ultimately, blood volume. In conjunction with the cardiovascular responses, the respiratory centers respond to a G load increase in CO_2 and decrease in tissue O_2 by increasing minute ventilation. This is to keep the partial pressure of CO_2 in arterial blood adequate to meet the tissue needs. This also attempts to preserve the acid–base homeostasis. A consequence of a maximal increase in respiratory effort (work of breathing) that must be considered is the muscular increase in CO_2 and lactic acid production as well as fatigue of the muscles. Overall, the principle control system involved in the fighter physiological episode analysis is the respiratory system. This is the primary human/machine interface and the focus of the Aircrew Breathing Analysis. The principle system and direct control mechanisms impacted by Aviation Hypoxic Hypoxia is the respiratory system.

Oxygen to the Tissues

To understand the respiratory function, the principle function of the respiratory system must be examined. Put simply the respiratory system is responsible for gas exchange. This is accomplished by inspiration of metabolically needed oxygen and exchange with and exhalation of the metabolic waste gas carbon dioxide and other biological waste products. This system also helps maintain pH levels by exhaling larger amounts of CO_2 to compensate for increased CO_2 production or other acid insults to the system. Inspiration depends on two factors of oxygen inhalation; 1) concentration of oxygen and 2) volume of oxygen. Oxygen levels are measurable in units of concentration and specifically the partial pressure. Oxygen concentration remains a constant 21% within normal habitable altitudes, proportional to the root of the molecular weight. Dalton's law dictates that the pressure of a mixture of gases is the sum of the partial pressures of the individual gases. Total atmospheric pressure by implication is the pressures of oxygen and nitrogen. These vary according to altitude above sea level and barometric pressure of that associated altitude. The pressure of the normal atmosphere at sea level is 760 mm Hg. The pressure, but not the concentration of oxygen, decreases with altitude.

The other primary factor in inhalation of oxygen is the volume of air that is inspired. If the volume of air is not adequate to provide the proper amount of oxygen, then the body needs to increase that volume. Even in 100% concentration of oxygen, if the total oxygen volume is deficient to provide to the tissues, then the body must compensate or suffer tissue hypoxia. This results in hyperpnea or increasing the volume of inhaled air. Increase in volume may be followed or accompanied by an increase in the rate of breathing. Hyperpnea is response to the chemoreceptor and mechanoreceptors to the brain. Simply, deeper breathing provides an increase in oxygen intake. This is often confused with hyperventilation. Hyperventilation is a rate of depth of breathing in excess of what the body requires. This is sometimes called overbreathing. The minute ventilation exceeds metabolic demands, resulting in hemodynamic and chemical changes that produce an arterial alkalosis. This is primarily due to a drop in arterial partial pressure of carbon dioxide ($PaCO_2$) or essentially you ”blow off too much CO_2”. Unfortunately, hyperventilation has been ascribed as a cause of physiological incidents. Pathological or symptomatic alkalosis is characterized by a decrease in the hydrogen ion concentration of arterial blood below 40 nmol/L, or pH over 7.45. In the ascribed case it would be caused by CO_2 loss due to hyperventilation (respiratory alkalosis). As an aside, the blood draws used to imply hyperventilation must be analyzed in the context of pH, bicarbonate (an excess that can cause alkalosis) and not just CO_2. The pH’s have been within a fairly normal limit. Also there has been no documented increase in minute ventilation that would result in an excessive loss of CO_2**,** except in one US Navy case where it was obvious that a panic reaction or psychogenic dyspnea had occurred.

Pulmonary Volumes

The system under control. The primary system controls regulate the volume of inhaled oxygen. This is affected by concentration of oxygen at various cabin altitudes and the volume of that inhaled oxygen. In the PBA analysis the FVC was tested with Spirometry. The PBA derived tidal volumes in flight from the flows and pressures from the VigilOx data. Thus, we will now look at the volumes of the receptacle, principle gas exchanger, and storage tank for oxygen, the lungs.

Pulmonary volumes were explored in the PBA and are repeated here. pulmonary volumes are the different volumes of air present in the lungs and airways at different phases of the respiratory cycle.

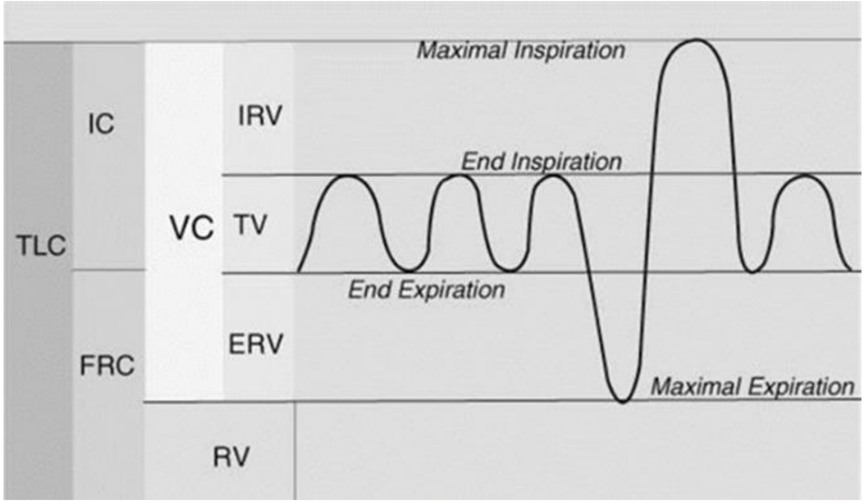


Figure 4.6. Pulmonary volumes from NESC Document #: NESC-RP-18-01320, Vol. 1, November 2020 Pilot Breathing Assessment, November 19, 2020.

The volume of air that is moved with each breath is defined as the tidal volume (TV). At rest TV is approximately 0.5L or 500 mL, which can increase greatly with exertion. When relaxed, the lung has a volume of air within defined as functional residual capacity (FRC). This is made up of the expiratory residual volume (ERV) and residual volume (RV). The expiratory reserve volume (ERV) is the additional air that can be forcibly exhaled after the expiration of a normal TV. The RV is made up of physiological dead space (air that does not undergo gas exchange – see following section). This residual volume is typically fixed for an individual in the range of

1.2 L or 1200 mL. Active inhalation will expand the lungs to a volume greater than FRC, and passive exhalation will return lungs to FRC.

VC is the maximum volume of air that can be moved in the lungs – a maximum effort inhalation followed by a maximum effort exhalation. Typically, VC is on the order of 5L or 5000mL. Total lung capacity (TLC) is the sum of VC and RV. Inspiratory capacity (IC) is the maximum volume of inhale from FRC. Inspiratory reserve (IRV) and expiratory reserve (ERV) represent the volumes of air that can be moved at end inspiration and end exhalation, respectively. The FVC measured by spirometry is the amount of air that can be forcibly exhaled from your lungs after taking the deepest breath possible, as measured by spirometry. An understanding of the volumes gives insight into the functional air exchange of the lungs and thus important measurements in PBA. The FVC via spirometry at baseline was compared to the volumes that resulted once crew harnesses were donned, the post flight volumes indicating the overall effects on volumes with flight and the recovery times to get back to baseline after doffing harnesses.

Dead Space: Air that does not undergo gas exchange is referred to as physiologic dead space. The total dead space volume is made up of alveolar and anatomical dead space. Alveolar dead space is the gas that remains in the individual air sacs or alveoli to keep the alveoli open (RV). Anatomic dead space refers to air in the conducting passageways of the respiratory system, including the nose, mouth, pharynx, larynx, trachea and airways up to the terminal bronchioles. Oxygen and carbon dioxide do not significantly exchange between gas and blood while in the conducting airways. This physiologic dead space, or residual volume, is approximately 150 mL in an average adult.

Dead space will increase with use of aircrew equipment, the largest contribution coming from the mask. Total dead space in an aircrew breathing system is the physiological + mechanical dead space. If the mechanical face mask volume is not totally evacuated of exhaled breath, a higher CO2 content can be rebreathed, and this contributes to the gas exchange in a negative manner. Essentially it now contributes to physiological inhaled gas and will increase the content of CO_2 to the lungs. Mechanical dead space can also become additional retained (unexhaled) air with excessive expiratory pressure. This dead space does not participate in gas exchange and can lead to increased alveolar CO_2. Increased physiologic dead space (e.g., atelectasis or retained air) limits gas exchange and can contribute to hyperinflation. Furthermore, following a rapid decompression event, dead space volume will cause an immediate reduction in available inspired oxygen, potentially leading to hypoxia. As a principle, added dead space volume by aircrew equipment should be no more than 150 mL. One could control (minimize) the mechanical dead space through design and flow regulation.

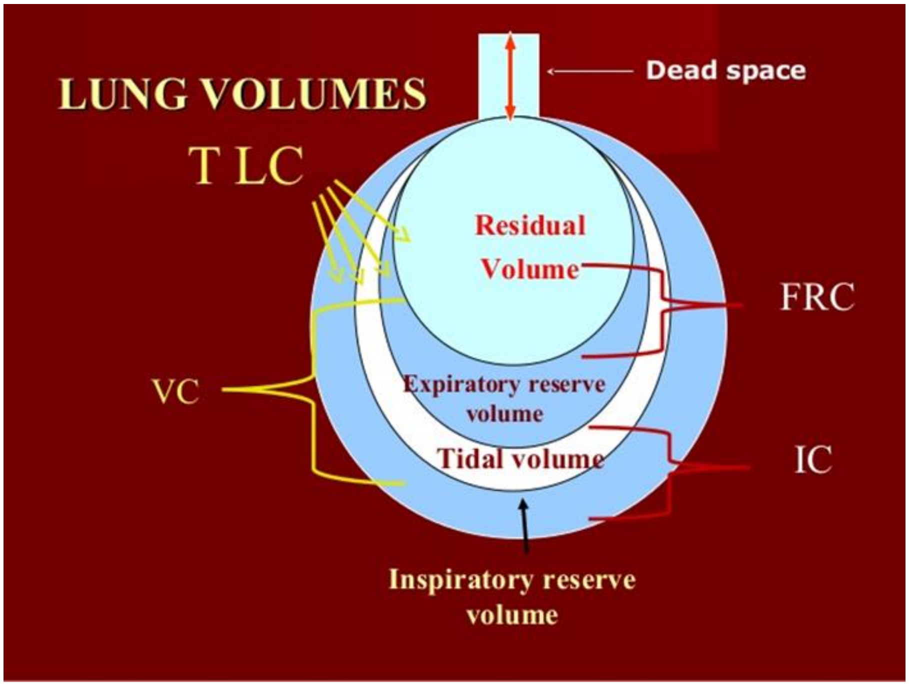


Figure 4.7. Illustration of the lung and alveolar volumes from NESC Document #: NESC-RP-18-01320, Vol. 1, Nov 2020 Pilot Breathing Assessment, November 19, 2020.

TLC = Total Lung Capacity
VC = Vital Capacity
FRC = Functional Residual Capacity
IC = Inspiratory capacity

<u>Ventilation Rates</u>: Pulmonary ventilation is the volume of gas per unit time entering the lungs, often defined as MV in units of L/min. Alveolar ventilation is the volume of gas per unit time that functions in gas exchange, accounting for dead space. The alveolar ventilation rate (AVR) is the expression of this functional exchange of air, defined below:

AVR	=	frequency	X	(TV – dead space)
(ml/min)		(breaths/min)		(ml/breath)

Flow of gas across the capillary wall into the blood stream within individual alveoli is influenced by the partial pressures of gasses in the alveoli. An effective breathing gas system would be tailored to maintain the oxygen content within the alveoli at physiological levels (about 104 mmHg) while minimizing the toxicity associated with high inspired oxygen.

AVR is negatively influenced by decreased TV and increased dead space. The body has many mechanisms to alter ventilation in response to fluctuations in gas exchange and composition in the blood stream. These are the parameters monitored by the chemoreceptors. An increase in pH or pCO_2 (partial pressure of CO_2), or a decrease in pO_2 (ppO_2) causes these receptors to stimulate the respiratory centers. In response to increased PCO_2, the body will increase ventilation in a linear fashion. For every 1 mmHg increase in PCO_2 above normal (range 35 to 45 mmHg), ventilation will increase by 2 to 3 L/min. Ventilation will increase first elevating the TV and then by raising the respiratory rate. In an otherwise healthy adult, this drive will increase to a point past which central respiration fails, usually in the arterial range of 60 to 80 mmHg PCO_2. The ventilatory response to high PCO_2 is increased in the presence of hypoxia. The ventilatory response to hypoxia is based on Hemoglobin saturation and the provision of adequate blood flow to the lungs. Compensation to hypoxia occurs when the O_2 saturation is below about 95 to 96% or a drop in arterial oxygen contraction of 10 to 20 mmHg. This is done by various combinations of increased lung volume and respiratory rate. Maximal compensation is reached at an arterial oxygen pressure of 50 to 60 mmHg.

Gas exchange at the alveoli is connected to capillaries and is influenced by and has impacts on the cardiovascular system. This ratio of ventilation (V) of the lung to perfusion with blood (Q) is referred to as ventilation-perfusion ratio or V/Q. It is normal for the upright lung under the force of gravity to have more blood flow to the lower regions of the lung, and lesser blood flow near the apices. These regional differences are physiologic. Conditions which alter local ventilation or perfusion will adversely impact the function of the lung and the efficiency of respiration.

What can go wrong? Deductive reasoning, fault reduction and physiological decompensation.

An investigation of the causes of hypoxia symptoms must involve the causes of lack of oxygen to the tissues. This starts at the system(s) in the pilot that is/are most affected. The pilot was the subject of interest as they were the ones manifesting hypoxia symptoms. In the case of root cause investigations, you must deduce backwards from the result (a pilot having hypoxia in an aircraft) to find the root cause(s). This type of Inductive reasoning (*"bottom-up logic"*) is the exact opposite of Deductive reasoning (*"top-down logic"*).

Most of the investigations assumed that it was one piece of equipment or part of the system affected by particular device that was the root cause of physiological incidents. Rather than examining the system from a human physiology standpoint, the focus was on one part of the mechanical system. Since LOX supplied aircraft had been flying for decades without problems, then the assumption was that the new piece of the equation, OBOGS were at fault. Rather than looking at the causes of hypoxia at the human level, the root cause investigations were limited in scope. The failure to find mechanical faults or a decrease in oxygen concentration from the OBOGS led to dead ends in the analysis.

4.1.2 Definitions of Causes of Decreased Ventilation

To home in on a system analysis, the pilot having hypoxia in an aircraft should be the starting point (the top of the logic reduction). Now it is asked what can go wrong to cause hypoxia and work backwards? The following explores the causes to decreased ventilation with the resulting impairment of gas exchange.

Atelectasis: Term applied to describe collapse of alveoli, the functional end-units of the lung. The alveoli themselves are dependent on an adequate amount of gas (primarily Nitrogen) to remain open. Collapsed alveoli will cease to participate in gas exchange until reopened, perhaps by coughing or deep breathing. Atelectasis of any kind will result in reduced lung function and can cause symptoms of chest pain, irritation, or cough.

Absorption Atelectasis: One of the disadvantages to excessive O_2 is absorption atelectasis. Normally, the pressure of nitrogen within the alveolus will maintain patency through the breath cycle. If the small airways are closed off, O_2 trapped in the alveoli can be absorbed by the blood, thus effectively absorbing most (if not all) of the gas in the alveoli if there is no significant offgassing of nitrogen from the blood into the alveolus. With little or no gas pressure to keep the alveolus open, it will collapse. If nitrogen is removed from the alveolus, as is the case when breathing concentrated O_2, the body will rapidly absorb available O_2 within the alveolus. This will decrease the pressure of gas within the alveolus and lead to alveolar collapse. There is a critical point at which inspired oxygenated gas entering the alveolus is balanced by O_2 uptake by the bloodstream, with atelectasis becoming increasingly likely with inhaled gasses composed of 60% or more of concentrated O_2. Referred to as Denitrogenation Absorption Atelectasis (DAA), this can cause significant and cumulative changes in lung ventilation and perfusion over time. This is a primary consideration with Navy aircraft that only use high concentrations of O_2.

Acceleration Atelectasis: Under vertical acceleration forces, + G, there will be regional changes in blood flow in the lungs which will lead to the formation of acceleration atelectasis. When a fighter pilot makes very tight turns while flying an aircraft, the resulting centrifugal force tends to push the blood from the top part of their head down into the lower parts of the trunk and the legs. This is known as “pulling G’s,” and in most modern fighter aircraft, the amount of G’s pulled can be up to nine times the force of gravity (i.e., “9 G’s”). In the lung, the effect of pulling G’s is to “push” the blood and upper lung segments down on the lower parts of the lung. As a result, there will be a larger number of collapsed airways due to the increased effective “weight” on the lower lung under G forces. At $+5\ G_z$ and greater, the upper half of the lung will effectively be non-perfused. This non-perfused lung is effectively ventilated dead space. Because the lower regions of the lung have increased blood flow and collapsed, will result in no ventilation, but high perfusion. This can result in shunting of deoxygenated blood to mix with oxygenated blood in circulation, lowering the oxygen content in arterial circulation. The overall result is that acceleration atelectasis of the lower portions of the lung portions limits pulmonary volumes which normally play a more significant role in ventilation due to higher perfusion.

Hyperoxia: Inspiration of higher oxygen concentration, necessary with increases in altitude with less oxygen, has a multitude of undesirable adverse effects as concentrations increase. This results in physiological decreases in reserves. A potential benefit of breathing 100 percent O_2 tends to wash out nitrogen from the body’s tissues and could thereby serve as a useful risk mitigator against decompression sickness. This is valuable if the pilot is exposed to low oxygen tension at high altitudes. For the purposes of this systems analysis, hyperoxia leads to absorption atelectasis and thus can reduce the volume of gas exchange volume in the lungs. For a fuller examination on the effects of hyperoxia, please refer to the PBA report.

Rapidly Oscillating Hyperoxic Concentrations: During the T-6 Safety Investigation Board for unexplained PEs, it was determined that fluctuating oxygen can cause hypoxic like symptomology. This was especially prominent in oscillations (reductions) in concentration occurred if the pilot was exposed to hyperoxic ($\geq$ 80% O_2) concentrations at altitude. Drops in 20 to 40% from hyperoxic concentrations have been shown to significantly decrease alveolar oxygen extremely rapidly and are overcome by any psychological reserves. This overcomes the chemoreceptor response to the hypoxic conditions.

Oscillation Pressure Effect on Surfactant: Surfactant is the coating that helps to prevent alveolar collapse. Pressure oscillations facilitate atelectasis formation by displacing surfactant. In combination with decreased nitrogen and/or acceleration, this further increases the amount of atelectasis in the lungs. Higher pressure oscillations can also cause barotrauma to the airways and alveoli. High pressure oscillations potentiate lung damage through a variety of mechanisms. High pressure oscillations cause mechanical stress and strain within the lungs, as the mechanical force applied to the pulmonary epithelium lining the airway and the alveoli initiates a resultant inflammatory response within the lungs. An inflammatory response can spread to other organs causing secondary barotrauma. The Hering-Breur protective reflex to prevent overdistention and barotrauma will attempt to compensate, but the continual repetitive overpressure will result in barotrauma.

Asynchrony: is a pervasive problem in mechanical ventilation of critical patients, but is a contributing factor in aircrew breathing systems. One form of asynchrony (dysynchrony) involves timing of mechanical triggering of the system to the pilot's individual breaths. Asynchrony is defined as the triggering or cycling of a breath that either leads or lags the pilot's inspiratory effort. Regarding the size of a breath, asynchrony means the inspiratory flow or TV does not match the patient's demand (too much/little, too early/late). Asynchrony will lead to increased work of breathing, excessive fatigue of respiratory muscles, and non-specific respiratory discomfort. Volume and flow mismatches can cause micro-trauma in the form of barotrauma due to alveolar over distention even if the pressures are not excessive in the traditional sense of high peak inspiratory or expiratory pressure (PIP/PEEP). Asynchrony is a subtle problem for which patients have no way to perceive or communicate its presence directly.

Inspiratory Resistance: O_2 delivery equipment (e.g., O_2 supply, hose, mask, etc.) imposes resistance to flow for the pilot. In general, resistance to flow through O_2 delivery equipment can have negative effects. These are decreased respiratory minute volume, decreasing lung ventilation and subsequent decreases in Alveolar ventilation, reduced VC, and increased total respiratory work per minute. These will increase fatigue and worsen respiratory effort over time. The diaphragm is particularly susceptible in this regard. If the central control systems are overwhelmed with significant hypoxia or hypercarbia, subjective breathing difficulties will occur. This is an increased conscious appreciation of breathing resistance, ranging from mild to the sensation of impending asphyxia. Individuals vary in their responses to O_2 delivery system resistances, and the same individual may vary his own responses. Susceptible individuals may, at times, hyperventilate and exhibit symptoms of hypocarbia (low CO_2 levels).

Airway pressures: A high amount of airway pressures, whether inspiratory and/or expiratory, have been shown to cause barotrauma. Pulmonary barotrauma with aircrew equipment results from excessive positive mechanical pressure ventilation. Excessive positive pressure will lead to overdistention and the increased pressures in the alveoli units lead to inflammatory changes. This can eventually lead to alveolar rupture, which results in leakage of air into the extra-alveolar tissue. Again, the Hering-Breur reflex to prevent overdistention and barotrauma will attempt to compensate, but the continual repetitive overpressure will result in barotrauma.

Inspiratory Over Pressure: Inspiratory flow is determined by tidal volume/inspiratory time. High flow rates will result in higher peak airway pressures. Excessive inspiratory pressures will in turn result in increased intrathoracic pressure and lead to potential hemodynamic consequences (particularly decreased venous return, leading to decreased cardiac output and at worst, hypotension (low blood pressure). High airway pressures may result in inadequate ventilation if peak inspiratory pressure is too high, the excess pressure can cause overdistention of the alveoli to the point that they lose structural integrity and collapse.

Excessive expiratory pressure - Hyperinflation: Inappropriate and excessive exhalation pressures will lead to dynamic hyperinflation. Hyperinflation is the increase in lung volume (over inflation) that occurs whenever insufficient exhalation time prevents the respiratory system from returning to its normal resting end-expiratory equilibrium volume between breath cycles. This results in trapped air, inability of the pilot to initiate a breath, and an increased work of breathing. Hyperinflation also results in limited inhalation volumes, as the excessive exhalation volume is not displaced. This increases the physiologic dead space. In the case of dynamic expiratory hyperinflation, volumes of both inspiration and exhalation are decreased, TV is diminished and a state of hypoventilation results. Persistent breathing dysfunction (oscillations, lung over-inflation, and forceful exhalation) can cause long term changes to pulmonary function. Mechanoreceptors will attempt to prevent or limit these effects.

Excessive expiratory pressure - Decreased Cardiac Output: High exhalation pressures have pulmonary pathophysiological consequences, but can also cause cardiovascular perfusion problems. Normal respiratory dynamics function as a negative pressure system during inhalation. As described, the diaphragm descends and produces a negative pressure in the airways that draws air for gas exchange. This same negative intrathoracic pressure decreases the right atrial pressure and draws blood from the inferior vena cava and increases venous return to the heart. The increased airway exhalation pressure is reflected in the airways and alveoli. This in turn is transmitted to the thoracic cavity and decreases the negative pressures from the diaphragm (creating a positive pressure). This increases right atrial pressure, decreasing venous return. This affects the pulmonary flow and decreases overall heart volume. This has a doubling effect of decreasing cardiac output as well as less effective cardiac function. This can result in overall drop in mean arterial pressure, which in a fighter aircraft can result in brain hypoxia. This loss in mean arterial pressure will trigger a response to increase the cardiac output by increasing the stroke volume with increased heart contractions and/or heart rate.

Chest Wall Restriction from Flight Crew Equipment: The survival equipment if tight on the upper chest will result in chest wall restriction. This will significantly reduce the inspiratory flows. A chest harness above the pressures of the mask will result in a difficult inhalation (as was the case in the F-22). The result is that chest wall restrictions decrease the pilot’s chest wall movement, and thereby keeps him or her from being able to take in a full deep breath. This limits the tidal volume that a pilot can inhale and results in dropping the amount of O_2 and exhaling an adequate amount of CO_2. Likewise, without being able to take deep breaths, it is more difficult to cough adequately and inhibits effective reversal (clearance) of the atelectasis. The chemoreceptors will attempt to correct this lack of inadequate gas exchange by increasing the minute volumes.

Chest Wall Restriction – Pulmonary: Chest wall restriction has numerous consequences on the lung and ultimately breathing functions. Studies have shown that restrictions in chest wall expansion have reductions in VC, resulting in an altered breathing pattern, and also reduced cardiac output. Specifically, this has been shown to decrease the tidal volumes, decreased compliance (i.e., increased stiffness) of the chest wall, and a reduction in exercise capacity. These lung volume decreases result in hyperpnea (Subjects trying to increase the lung volumes by either increasing the time of inspiration, or volumes of inhalation). Thus, work of breathing (the energy expended to inhale and exhale) and muscle fatigue are noticeably increased.

Chest Wall Restriction -Cardiac Output: Another possible outcome of chest wall restriction is a decrease in the amount of blood pumped by the heart over a given period of time, an amount known as the cardiac output (CO). Pure chest wall restriction is unlikely to be strong enough to cause a significant reduction in cardiac output in healthy adults. A significant reduction more than likely results from a combination of many factors. In the dynamic fighter environment these are likely to be high-G flight, atelectasis, chest wall restriction from flight gear, in various combinations, impinge on the cardiac output. It is also helpful to keep in mind that pulling G's in a fighter aircraft is very demanding physically, so the pilots are in effect experiencing such factors while exercising (i.e., pulling G's), and while attempting to recover from exercise. This increases the metabolism, driving up demand to expel CO_2 and increase the intake of oxygen.

Conclusion

The above framework can serve as a brief guide to develop an understanding of some of the vulnerabilities of the respiratory system. Many of the physiological properties of the lung will vary between breaths or within an individual breath to maintain the proper balance of oxygen and CO_2 within the blood. The control system and the inputs and outputs of the system to maintain homeostasis within the pilot were examined. This highly tuned, highly responsive system will respond consciously and subconsciously to external forces. The body will make efforts and attempt to restore alveolar ventilation. If there are external forces at work limiting the pilot's physiological response, the emanation will be undesirable symptoms of dyspnea, nausea, cough, or worse. If the human's physiologic reserve is depleted rapidly, or insidiously, the pilot may acutely become incapacitated. A pilots respiratory control system will respond reflexively and unconsciously to perturbations of O_2 delivery to the tissues. If these have a larger cumulative or isolated decrease in physiological reserve, then conscious symptoms and active intervention occurs to correct the perturbation(s). If response mechanisms are overwhelmed, then various levels of hypoxia occur and with pathological consequences up to unconsciousness or ultimately death. Then, the violently dynamic nature of high-performance aircraft was explored, and found that the magnitude of even small, consistent perturbations can have cumulative and devastating effects, even if the breathing gas systems are functioning within current design specifications. The dynamically dynamic human system is constantly responsive to pressure, volume and time, and so any fluctuation will result in changes that affect the function of the entire system. Lastly, the causes of the physiological degradation or failure that can result in hypoxia was examined.

In designing a system, the human control system and its inputs should be considered and incorporated into the engineering for the man-machine interfaces. These considerations should include:

1) Hyperoxia – Not to use excessive oxygen relative to the altitude to prevent atelectasis and the decreased tidal volumes, diminished cardiac volumes with higher G_z and the chest wall increased work of breathing.
2) Rapid Oscillating Hyperoxic concentrations – Large rapid excursions of oxygen lead to decreased alveolar oxygen tension and accelerated cerebrovascular constriction in specific brain regions resulting in regional hypoxia.
3) Breathing System Asynchrony
    a. Asynchronous timing – mechanical triggering of breath should not lag or lead the pilots breathing cycles. Lagging a breath diminishes tidal volumes of oxygen delivered to the pilot. Leading a breath (oversupply) induces restricted volumes physiologically and can lead to hyperinflation and triggering the Hering-Breur reflex.
    b. Asynchronous volumes or flow – The inspiration flow or volume that does not match the pilot's inspiratory effort. Too much volume causes a physiological reaction to limit the volume to prevent hyperinflation. If excessive a

    premature Hering-Breur reflex activation can result in tidal volume limitation. Too low a volume reduces the oxygen supply and triggers chemoreceptor increases in minute volume.
    c. Asynchrony leads to increased work of breathing, excessive fatigue of respiratory muscles, and non-specific respiratory discomfort. Excessive flow or pressure will result in alveolar micro-trauma.

4) Inspiratory overpressure - This can result in an increase in dead space volume over time and decrease the available oxygen.
5) Expiratory overpressure – This results in dynamic hyperinflation, air trapping (increased dead space), and decreased inspired TV. Another cause of decreased oxygen supply. This can also decrease venous return to the heart causing deceased cardiac output and reduced circulatory pressure and volume (decreased blood pressure). This results in hypoxia and triggers the central chemoreceptors to increase respiratory drive.
6) Inspiratory and expiratory overpressure combined – This results in increased dead space volume more rapidly than just inspiratory or expiratory overpressure.
    i. Expiratory dynamic hyperinflation results in worsened air trapping (increased dead space) by additional decreased inspiratory TV.
    ii. Higher likelihood of larger areas of micro-trauma and barotrauma.
    iii. The combined effect further worsens the individual decreases in venous return to the heart. Substantial reduction in cardiac output and reduces circulatory pressure and volume (decreased blood pressure). This further reduces the supply of O_2 to the brain.

HSI combines the knowledge gained by insight into the physiology and physiological controls of the human system and derives the requirements for the pilot breathing system. Designers must take these into consideration for design, verification, validation and troubleshooting of the pilot breathing systems. These human elements were the drivers for the instrumentation systems to examine the physiological impacts to the human in the flight environment for PBA. Essentially the composition (inspired and expired), flow, pressure, and timing of the breathing air were the parameters that were explored. Thus, substantial understanding of the human machine interactions were derived.

4.1.3 Testing the Human System

A common part of the development cycle is “testing to failure” to explore the performance of the component. Operationalizing “failure” is somewhat difficult for the human system. Human system failure could be defined as death or loss of consciousness (LOC), but if the human system is unable to perform their mission-essential duties, then arguably, this system has failed to serve the intended purpose.

Hypoxia research clearly demonstrates the human system will experience cognitive impairment prior to LOC. The effects of hypoxia during rapid onset can be obvious and the exposed individual may be able to intervene using skills acquired during hypoxia training. However, slow onset hypoxia which is much more insidious. At 15,000 ft, the TUC is listed at 30 to 40 minutes; but at what point is the human system effectively failed? If this occurs during a period of high workload, the human can fail to detect the slow loss of skill masked by physiological recovery response and an ever-increasing workload. If this occurs during a period of low workload, such as straight and level flight, the cognitive system can degrade prior to overt signs of performance decrement.

Of primary importance is to identify when the human system has degraded to the point of failure, meaning, when the human system is no longer cognitively mission-capable. One obvious example of human system degradation is the loss of color vision (Vingrys & Garner, 1987). This is reliably demonstrable and was included in the USAF Hypoxia Recognition Training course as a night vision simulation in the altitude chamber. The chamber is fixed at 18k ft with dim lighting. The subject holds a color wheel in front of them, removes their mask, and continues to fixate on the color wheel for a period of five minutes. The subject then dons their mask and experiences the sudden return of color vision, often failing to detect any color blanching and/or loss. This loss of color vision is a clear indication that the human system is experiencing some level of performance degradation. During conditions of dim light, researchers found that oxygen concentration levels equivalent to an altitude of 8,000 ft can reduce contrast acuity, dynamic contrast sensitivity, and chromatic sensitivity (Connolly, 2011).

The previous example identified the loss of color vision at relatively low altitude as an overt indicator of human system degradation. Another example speaks directly to cognitive degradation and pilot workload. A NASA team studied the impact of mild normobaric hypoxia induction on aircraft pilot performance and psychophysiological state (Stephens, Kennedy, Crook, Williams, & Schutte (2017); Stephens, Kennedy, Napoli et al., (2017). A within-subjects design involved non-hypoxic (sea level) and hypoxic (15,000 ft) exposures while pilots performed three 10-minute tasks. The simulated altitude was conducted using the Reduced Oxygen Breathing Device 2 (ROBD2) which is the same device featured in both Navy and Air Force hypoxia training programs. Being at a relatively low altitude for such a short period of time, there were no statistically significant differences in performance metrics. However, there was a statistically significant increase in perceived workload in the flight simulation task. This finding suggests that the pilots overcame the mild cognitive impairment by increasing their task effort to maintain equivalent performance. As increased workload will deplete cognitive resources faster, prolonged exposure could overwhelm the human system past compensation thus exhibiting detectable performance failures. This study also collected psychophysiological data to assess the response to mild hypoxia and found the potential for biomarkers to determine hypoxia onset.

4.2 Pilot and Aircraft as an Integrated Whole: A Complex System of Systems

Introduction

The environment inside an enclosed aircraft cockpit is an artificially created atmosphere. As originally conceived in the early days of aviation, aircraft did not have enclosed cockpits or any type of breathing system for the pilot. However, as aircraft evolved to longer durations and at higher altitudes, the natural ambient environment travelled by the aircraft began to exceed the envelope of pressures (specifically total atmospheric pressure and ppO_2) at which a human could effectively breathe and comfortably or safely operate. Thus, it became necessary to enclose the aircraft cockpit and provide both a supply of breathing air to the pilot and a pressurized cabin environment in which the pilot could safely breathe this supplied air. It is important to make the distinction that a pressurized environment is required a pilot to effectively breathe a gas supply at altitude, as even pure oxygen cannot be absorbed by the human body’s tissues unless the ambient pressure is high enough to support it. See more details on this phenomenon in the medical physiology section of this case study.

As Aircraft Life-Support Systems (heretofore abbreviated as LSS) and cabin pressure systems began to be developed, they were originally designed to exist independent of the aircraft's other systems. In World War II (WW II) era aircraft through to the late 20th century, it was commonplace for pilots to breathe off a self-contained bottle of pressurized LOX. As the pilot breathed the supply of pressurized oxygen, their breathing generally occurred relatively independently of the aircraft's performance or movements, aside from g-loading which is discussed elsewhere. As oxygen breathing systems became more widely used, the altitudes which could be reached by aircraft expanded, necessitating a pressurized cockpit to supply sufficient ambient cabin environment for a human body to retain sufficient oxygen within the body's tissues. The cabin pressurization systems, needing a relatively large and constant mass flow of gas, became fed by engine bleed air, in one of the first direct integrations of the pilot's support systems and the aircraft's operational flight systems via the aircraft's engine. Through to the modern era, most aircraft are pressurized via bleed air from the engines, including all aircraft used to collect data in this study.

As the pilot's systems became connected to the aircraft's systems, the pilot and aircraft began to function as one integrated system and can now functionally be considered as such. However, the evolution of aircraft and LSSs for aircraft has to date been remiss in treating the aircraft and pilot as integrated components in a larger aircraft-human system. This is a critical distinction, as this study will show.

The aircraft used in this study were all LOX aircraft (see Figure 4.8), where the pilot's breathing gas supply is separate from other aircraft systems. A large share of modern military aircraft no longer uses LOX, as the supply of oxygen which can be stored in an onboard tank is relatively limited. As aircraft have developed and evolved to suit longer missions, many aircraft have adapted to OBOGS which are regenerable concentrating oxygen from the engine bleed air. This additional connection provides yet another point for human/aircraft integration and thus direct interaction and creation of complex compounding and diminishing effects. For the purposes of this study, LOX aircraft were the only aircraft made available, and the use of LOX aircraft may in fact be ideal for initial work as represented here, because the overall interactions are less complex in an isolated LOX layout versus a more heavily integrated OBOGS aircraft where the multiple connection points will reasonably lead to even more complex and potentially negative interactions.

4.2.1 Mechanical Overview

Aircraft configuration

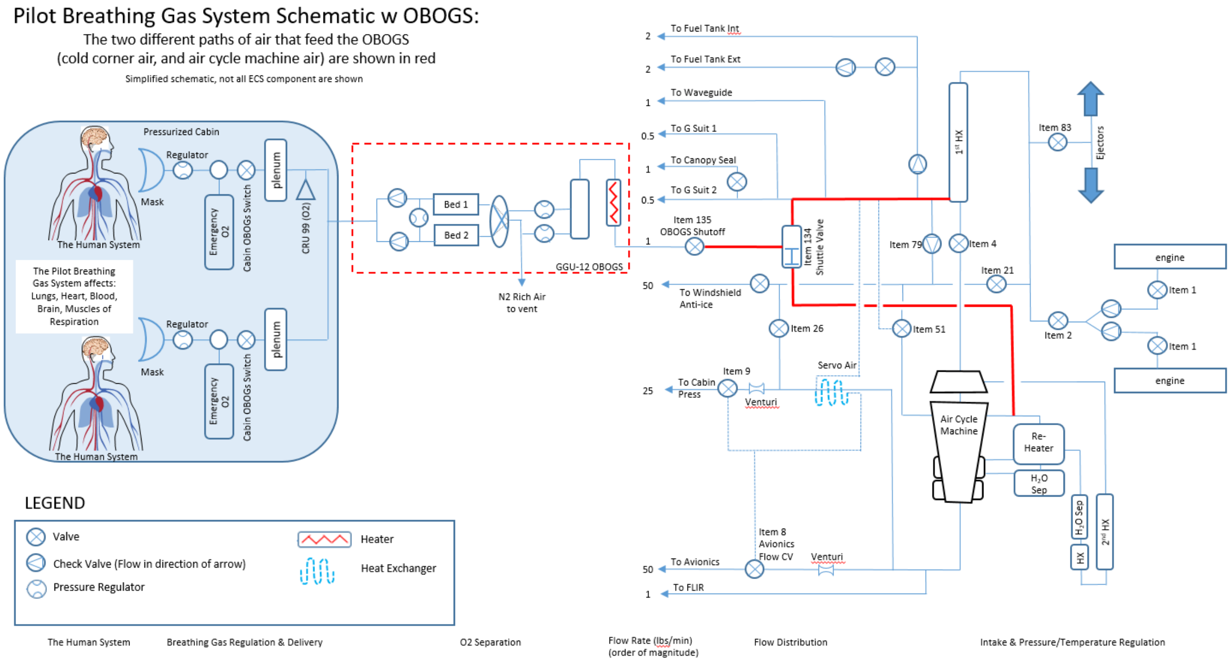


Figure 4.8. Integrated pilot breathing system in an OBOGS aircraft.

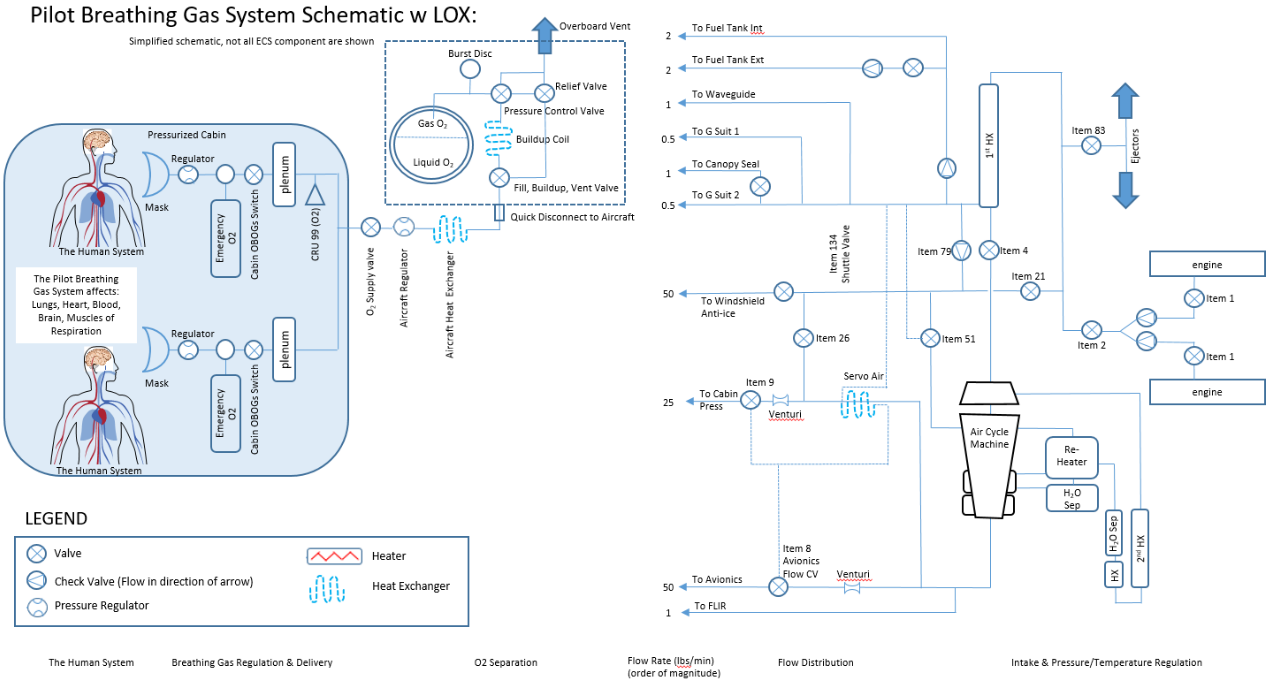


Figure 4.9. Integrated pilot breathing system in a LOX aircraft.

Cabin Pressure Control Machine Integration

The cabin pressure control system of the aircraft used for this study may be represented by Figure 4.10, representative of an F-18 cabin pressure control system. It should be noted that some individual aircraft may or may not have all specific branched outputs, but the pressurized cabin represented by the blue square on the left hand side of the diagram is largely representative of the pressurized cabin typical of aircraft used. The cabin pressure control system of the jet is fed a continuous inrush of air from the aircraft's engines, coming from the early-stage compressor in the engine and known as "bleed air". As can be seen in the diagram, engine bleed air is used to feed multiple aircraft systems, of which the pilot breathing system is just one. Other systems include fuel tank pressurization, avionics cooling, and "muscle pressure" or actuation pressure for various pneumatic systems. In armed military aircraft with advanced weapons, sensing, and transmitting/receiving equipment, engine bleed air is frequently used to feed and cool these systems also. The systems to supply air pressure to the pilot's cabin is thus connected to the bleed air supply, with valves at the branch-offs to other systems. In the newer models some valves are software controlled with complex "priority" and "reverse priority" rules with no clear hierarchy of the cabin over the other systems in the aircraft. Thus, in cases where large demands are made on bleed air by the various systems connected to the network, the pilots' systems can be found wanting or even entirely starved of supply pressure or mass air flow for short or possibly moderately extended periods. (Cabin pressure is not a parameter natively recorded in the F/A-18's Memory Unit).

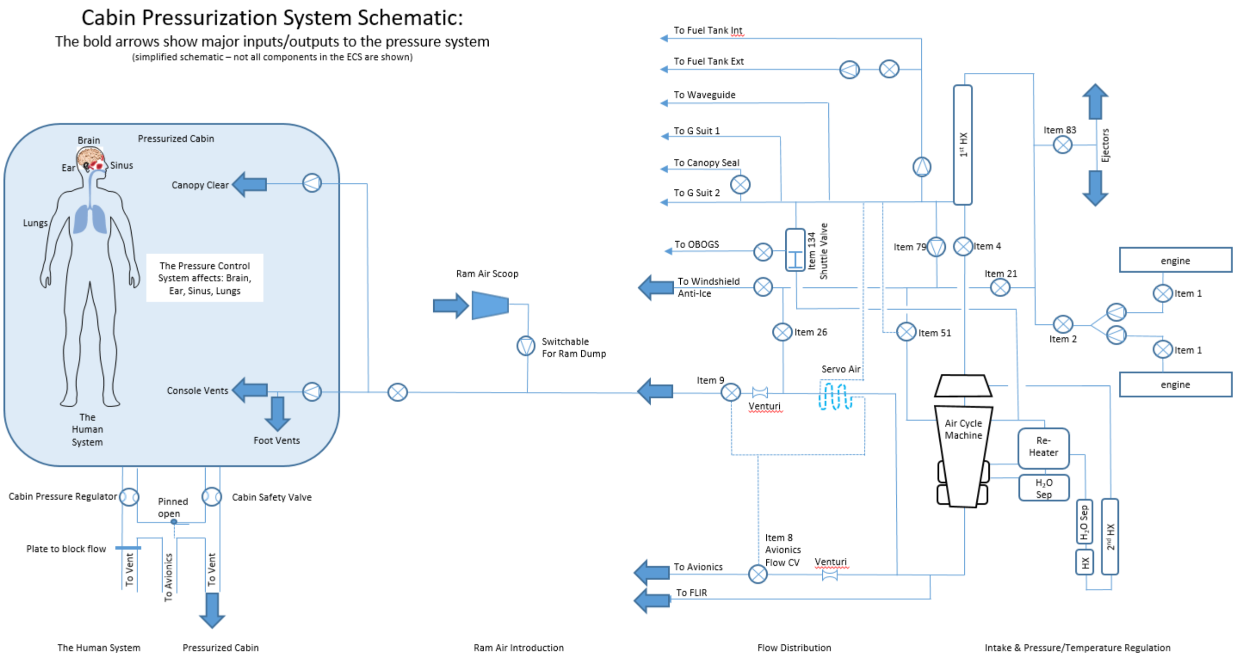


Figure 4.10. Integrated pilot cabin pressure control system.

The cabin pressure control system of the F-18 (seen in Figure 4.10) is representative of the cabin pressurization system in most tactical jet aircraft. The engines push bleed air through an integrated aircraft system with continuous flow, however, as with the pilot breathing system, the pilot's cabin feed must compete for bleed air with the other aircraft integrated systems, here represented by the Fuel Tank Pressurization, Waveguide, Pilot's G suit, and OBOGS (in OBOGS equipped aircraft). As with the pilot breathing system, any significant change in demand by these interconnected systems can result in a sudden change to available cabin pressurization air. The continuous feed of incoming air into the cabin must be regulated by exhausting it so that the cabin does not become over-pressurized. The cabin pressure regulation system in the F-18 consists of a mechanical cabin pressure regulator as shown in Figure 4.11. A pressure feed port (seen at the top) provides reference pressure (in most F-18 variants the reference pressure is acquired via a line through to the aircraft's nose wheel well) to a set of valves which in turn balance the diaphragm, which then opens and closes to vent air as needed to maintain cabin pressure. It should be noted that the engine bleed air provides enough mass flow to over-pressurize the cabin in a matter of seconds should all pressure ventilation capability fail. To allow for redundancy in the case of failure, a Cabin Safety Valve, which is effectively a second cabin pressure regulator (which may or may not have a different set point) provides a backup capability. These two regulators, the cabin pressure regulator and cabin safety valve, may also act as a cross-coupled system in some dynamic behaviors, and give rise to micro-oscillations affecting a third regulator, the pilot's oxygen regulator. (See Section 6.1.2).

Cabin Pressure Regulator Overview

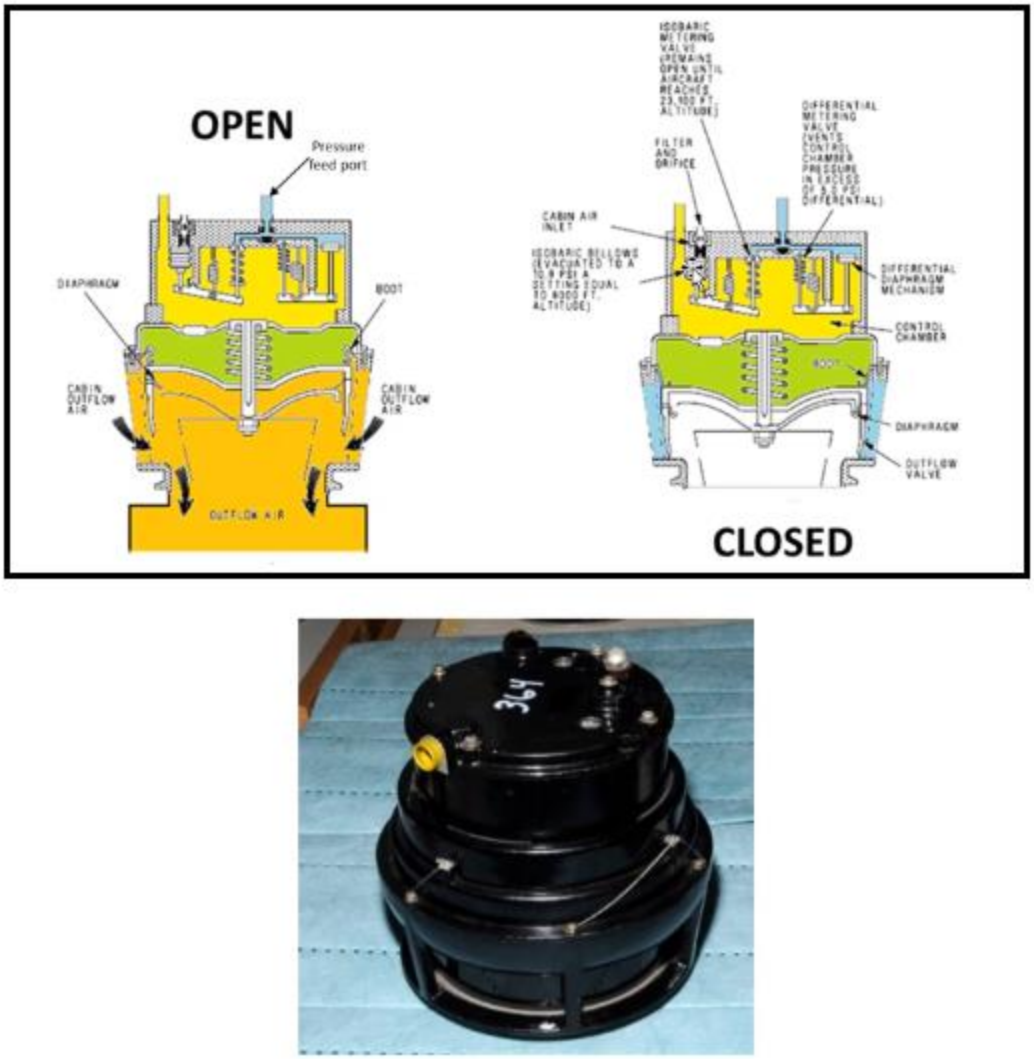


Figure 4.11. Cabin pressure regulator cross-section (top) and in exterior view (bottom).

4.2.2 Cabin Pressure Control System

In this section the F/A-18 Cabin Pressure control system is discussed and contrasted with NASA designs. NASA has significant experience in the design of manned pressure systems. In the environment of space, maintaining a safe and comfortable pressurized cabin environment is paramount to the safe and successful operation of a manned spacecraft.

Because gas is compressible and reacts volumetrically according to pressure, a pressurized cabin environment can be compared to a spring. Similar to a spring, or trying to balance a broom on one hand, a pressurized gas volume will “bounce” or swing and oscillate if compressed, with pressure rising and falling in response to an energy input. Thus, a pressurized cabin volume can be either dynamically stable, with pressure changes tending to dampen out to a stable pressure, or dynamically unstable, with pressure changes becoming amplified and causing oscillating swings in the overall pressure of the volume.

For a typical spacecraft system (Figure 4.12), air is introduced in an “on demand” fashion, meaning that air is not constantly flowing into the cabin volume. Although there are positive and negative pressure control valves, these are strictly for contingency operation to protect against structural failure in the case of a failed air introduction system. This system is relatively complex, as it requires an active logic controller linked to a pressure sensor and automated valve, but it is very stable and can maintain pressure to a very tight control band.

When pressure increases on a spacecraft system, the response follows an approximate logical path

1. The Pressure sensor indicates that the cabin pressure is below the desired setpoint, triggering the logic controller to open the valve to introduce air.
2. Air is introduced until cabin pressure rises to approach control point
3. The Pressure sensor indicates rising pressure, logic controller observes pressure approaching control point
4. The Logic controller closes air introduction valve, ideally the logic controller is designed to “lead” the valve as pressure approaches control point, so that flow is stopped at or near target without significantly exceeding it.

It should be noted that the pressure sensor is usually near the point where air is being introduced, so that pressure measurements reflect the incoming air pressure as accurately as possible. Additionally, as stated in step (4), an active logic controller can be designed to lead/lag the introduction of air to compensate for the time required to practically actuate the valve, as well as the settling time for the pressure in the cabin volume, such that the pressure is controlled very tightly, with minimal oscillation. In this model, the entire cabin does not need to actually reach the setpoint before the control logic is triggered, so overshoots and oscillations in cabin pressure are kept to a minimum. The fact that air is introduced on-demand, in combination with the quick response time, serve to make this system dynamically stable as described earlier, such that excursions or oscillations in cabin pressure are kept to a minimum, and any excursions that do occur are quickly damped out.

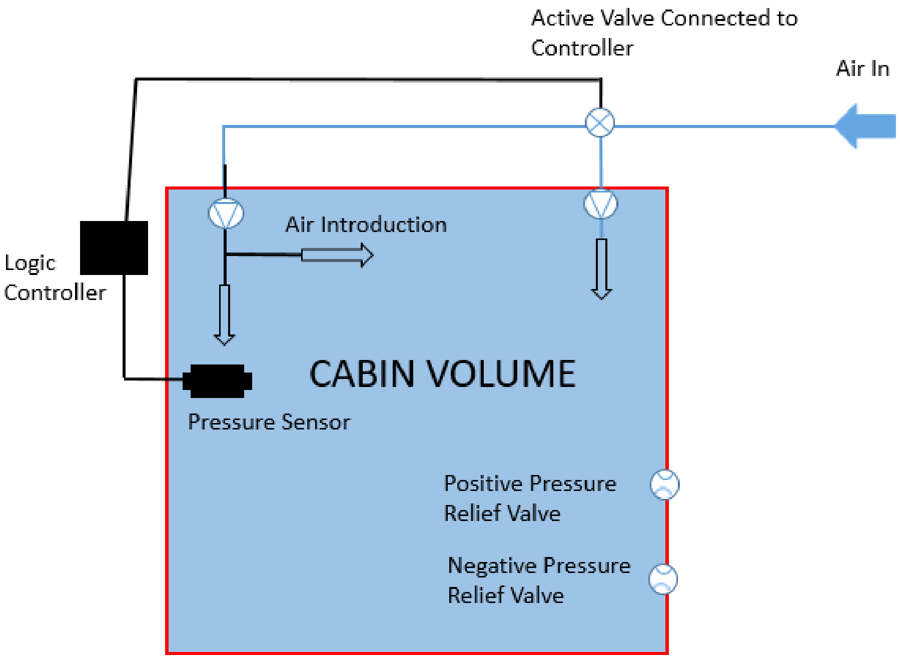


Figure 4.12. Typical spacecraft cabin pressure system.

The F-18 cabin pressure control system (Figure 4.13) is somewhat different. As described previously, air is constantly fed in from the engine bleed (air for the avionics is being handled through a different path and valves), and then vented constantly by the cabin pressure regulator (as designed) and/or the cabin safety valve (in the case of a malfunctioning system). It should be noted that just the nature of a constant-feed system tends toward dynamic instability; the constant incoming flow of air must be managed and mitigated, or the system quickly tend toward instability. When the pressure rises in the F-18 cabin control system, the following approximate sequence takes place:

1. Cabin pressure reaches setpoint, but because the cabin pressure regulator is passive rather than actively controlled, the entire cabin must reach pressure before the pressure regulator opens
2. Pressure regulator opens, but the practical time required for valve actuation means that cabin pressure continues to rise until regulator is fully open. It should be noted that valve actuation time can also be highly variable dependent on regulator age and service history, and dependent on whether just the cabin pressure regulator or both the regulator and cabin safety valve are actuating.
3. Cabin pressure drops until pressure regulator senses the control point has been reached, but the regulator valve takes time to close, during which pressure continues to drop. This cycle is also beholden to the practical mechanical constraints listed in the previous step.
4. In multiple cases, the cabin pressure is now below the control point again, triggering a return to (1). This is now a case of induced oscillation and dynamic instability.

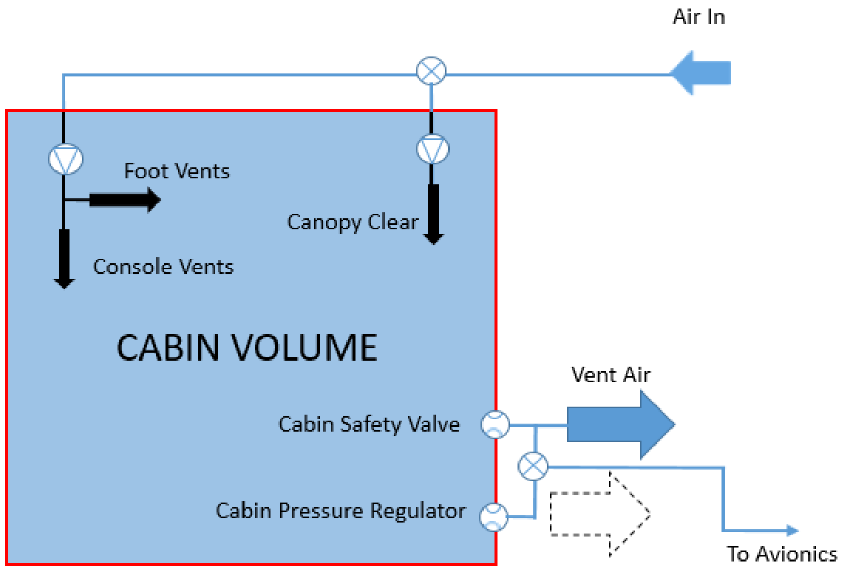


Figure 4.13. F-18 cabin pressure system.

Several important factors contribute to the dynamic instability inherent to the F-18 cabin pressure control system design. First and foremost is the continuous pressure influx from engine bleed. As in the model of a broom balanced upside-down, constantly pulled out of position by gravity, the constant influx of air drives the system constantly toward pressure instability, dependent on the cabin pressure regulator and cabin safety valve to "catch" the constantly fluctuating pressure in the manner of a moving hand keeping the broom balanced. This dynamic instability means that any fault in the system, even a momentary hang up in the regulator, almost immediately introduces a consequent pressure excursion. Compounding this instability, the passive, un-instrumented nature of the cabin pressure regulator and cabin safety valve means that the system is very slow to respond to any oscillations or excursions, this is a slow hand balancing the broom. As yet another factor, the cabin pressure regulator and cabin safety valve are both set/adjusted to follow identical pressure schedules. This means that the two valves are highly prone to "fight" each other as they near control points, with one introducing oscillations in the other, much like balancing two brooms in the same hand. The cabin pressure control system as it was designed, as it was built, and as it is currently fielded, highly prone to dynamic instability and resultant pressure excursions.

4.2.3 Cabin Pressure Schedule

The cabin pressure in the aircraft's cockpit is controlled via a schedule, see Figure 4.14. The pressure inside the cockpit raises with aircraft altitude. From sea level to 8,000 feet, the cabin pressure is effectively unpressurized, equal to the exterior ambient atmosphere. From 8,000 feet upwards to 23,000 feet, the aircraft cockpit is maintained at an air pressure equivalent to 8,000 feet. Past 23,000 feet, the cabin pressure rises again on a 5 psig differential slope with increasing altitude.

As the cabin pressure control system is a mechanical system (see Figure 4.15), there is a determinate lag between change in aircraft altitude and mechanical system response. This lag can be measurably observed, and in practical use can interact as a periodic function which may have a compounding or subtracting influence on the integrated human and machine system. This lag may or may not have been designed into the aircraft system, but it exists because the cabin pressure control system exists as an actual system, and a mechanical system at that, which has multiple interconnected mechanical components (Figure 4.11) vs a theoretical system which could respond instantly without lag. If the system is to be made stable and thus behave predictably in the larger SoS, this lag must be understood and planned.

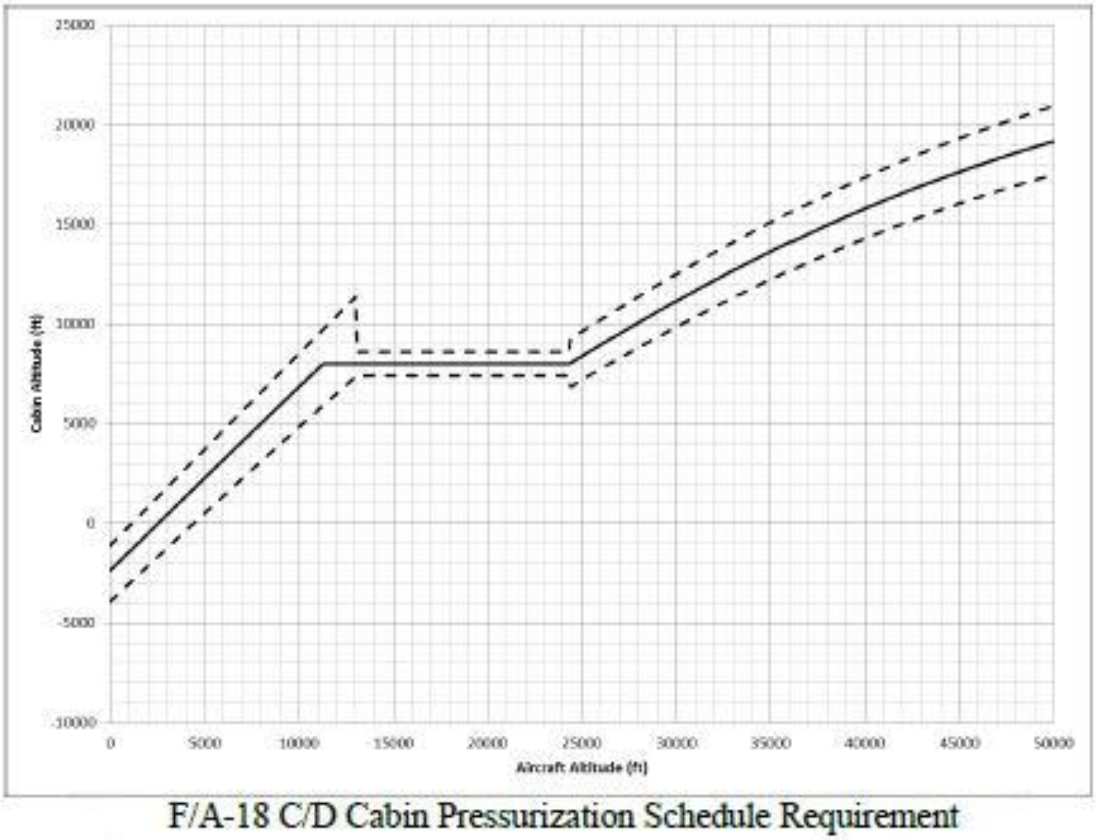


Figure 4.14. Cabin Pressure Control Schedule. The dashed line represents allowed deviation.

4.2.4 Connecting Architecture Model And Human State

Two Distinct Systems

As outlined in the introduction of this section, the pilot breathing and cabin pressurization systems have evolved along with increased aircraft performance and mission capability over the entire development history of aviation. However, in the research and investigation performed by this team, it has been consistently revealed that **the pilot breathing and cabin pressurization systems are typically developed as stand-alone systems**, rather than as an integrated part of the aircraft. Thus, the development cycle of the systems supporting the pilot may be assumed to be developed as a set of “stovepiped” components whose behaviors are not accounted for in the larger system integration map of the aircraft. Additionally, this stove piping of the pilot’s LSSs also provides a de facto break between the aircraft as an aviation system and the pilot as a human system. This functional break may have very significant consequences to the end result of the pilot-aircraft system.

Control Logic and Modeling

For the next section, the complex behaviors of the aircraft's mechanical systems and the pilot's physiological systems will be heavily simplified into a set of state diagrams to show the interconnected relationships and interactive behaviors.

Cabin Pressure Regulator Machine integration

In Figure 4.15, the state diagram for the cabin pressure control system shows how a typical aircraft control input by the pilot moves through the integrated aircraft system to result in pressure variation in the cabin. It should also be noted that, once the system is operational in the aircraft, the maintenance and system design factors are outside of the loop, as can be seen either side of this figure.

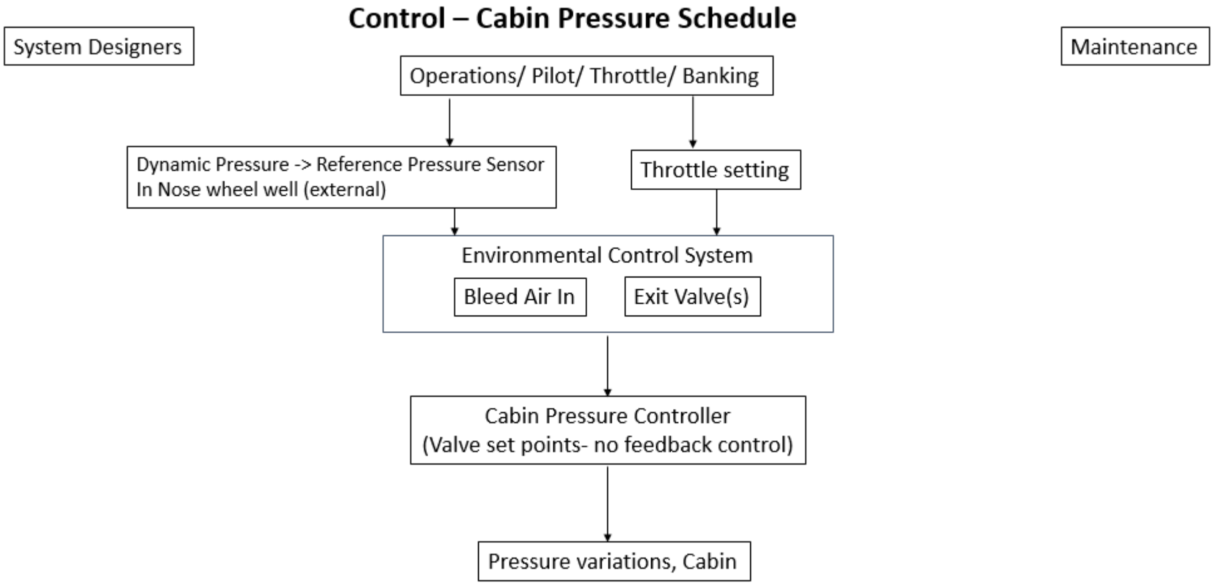


Figure 4.15. Integrated Cabin Pressure Control Logic Diagram

In Figure 4.16, the interconnection has been added between the aircraft, cabin pressure control system as seen in Figure 4.15, the pilot's breathing system, and the actual pilot. It should now be noted that the interaction has become significantly more complex, with multiple interconnected inputs and a new output of a potentially stressed or unstressed pilot.

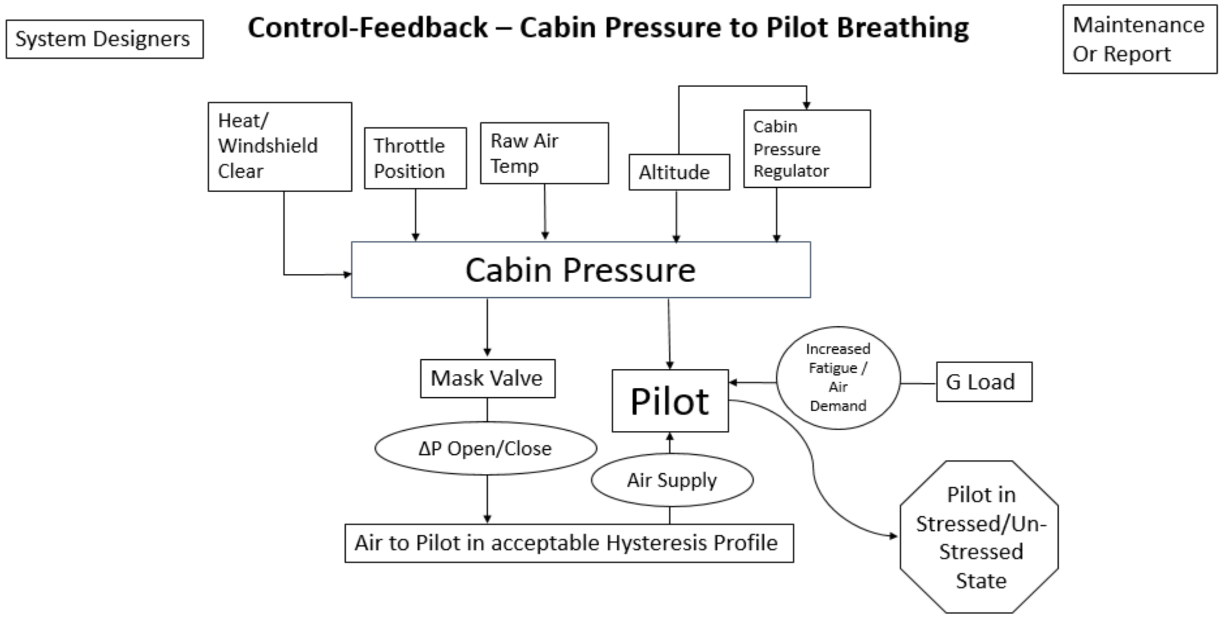


Figure 4.16. Integrated Cabin Pressure to Pilot Breathing Control Feedback Logic Diagram

Figure 4.17 combines Figures 4.15 and 4.16, creating a very complex integrated system. It should also be noted at this point that the pilot, with the human body being perhaps the most complex system of all, is minimally represented in this simple state diagram. (For additional details regarding pilot physiology, see Figure 3.15). Nevertheless, the system state interaction can be seen to have become extremely complex, with any one input following a varied path across multiple states before potentially pushing the pilot through multiple resulting stressed results.

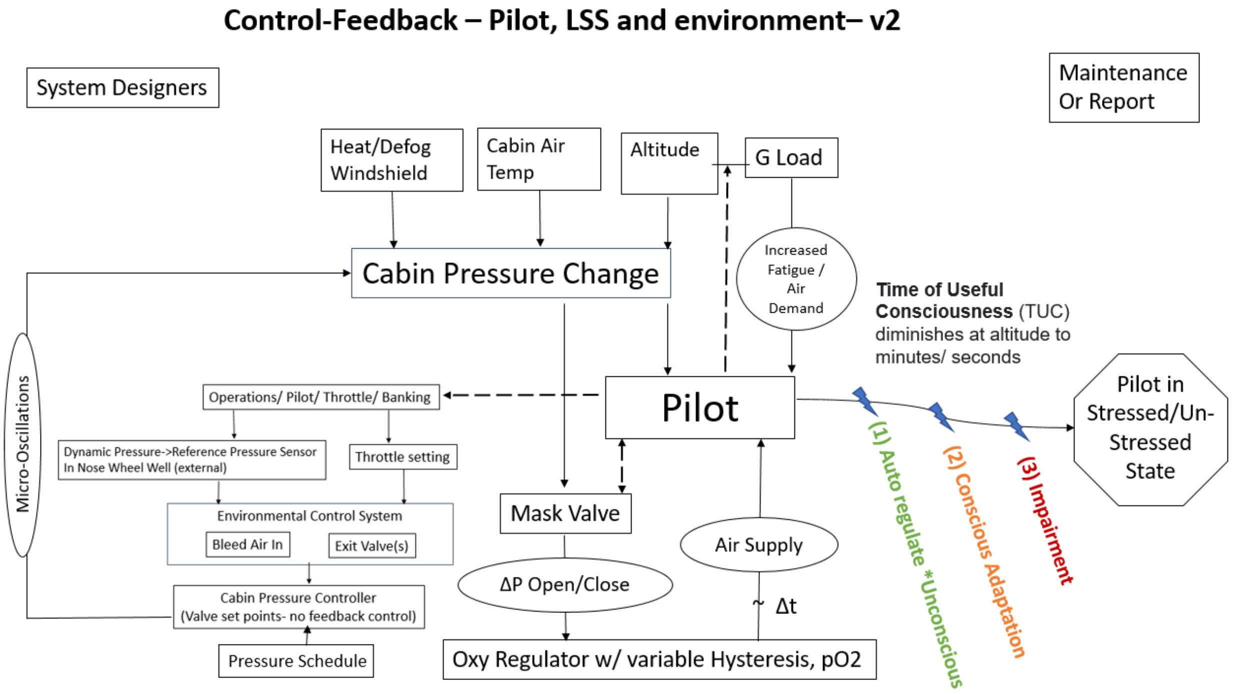


Figure 4.17. Full cabin control integrated logic diagram.

Note- The TUC or Effective Performance Time is the period of elapsed time from the interruption of normal air supply or exposure to an oxygen-poor environment (1) until the time when the ability to function usefully is likely to be lost at which point an affected individual would no longer be capable of taking normal corrective or protective action (3).

4.2.5 Models: Operation and Control

It is important to note that in the complex SoS modeled, no one input or effect stands in isolation, every input has at least one connected output, and in many cases several outputs, some of which may not be logical or even intended in the original design. It is important to understand in both modeling and operation that complex effects are to be expected, and any single change is likely to have multiple effects. As the pilot controls the aircraft, their control inputs as required for aircraft operation and mission execution may have direct and indirect impacts on their immediate and future physiological state via their breathing, with the unintended impacts perhaps best expressed as cross-coupling, as in aircraft control systems.

4.2.5.1 Interactive behaviors

As the various behaviors and effectors in the system are actuated or executed, their single input drives multiple outputs, and those multiple outputs may in turn drive several others in a cross-coupled relationship.

4.2.5.2 Theoretical vs Actual Behaviors

All of the modeling used in this section is a set of state diagrams to show interconnectivity in complex systems. For obvious reasons, the real-world phenomena of behaviors will be much more complex than the simple diagrams represented. However, even the simple state diagrams can be shown to become extremely complex when applied as an interconnected system. Thus, it follows that in a real-world scenario with an aircraft and human pilot, both of which have potentially thousands of compounding factors, relatively minor inputs can quickly accelerate through multiple compounding cycles.

Conclusion

As described in this section, the aircraft and pilot do not exist in isolation, but rather as a heavily interconnected pilot-aircraft system with multiple interconnected behaviors. If the pilot is to be effectively supported by the aircraft, and the aircraft in turn to be effectively operated by the pilot, then the full complex SoS interaction must be both understood, evaluated, and designed for as an integrated whole. Perturbations in exterior physical phenomena (pressure altitude, acceleration) and any significant change to either the aircraft (weapons loading, mission duration, mission profile) or the pilot (physical conditioning, rested or tired state, longer or shorter mission) may have direct impacts on multiple parameters which can then reverberate through the entire system.

4.3 Integrating the Medical, Engineering and Test Pilot Communities

The operation of high-performance aircraft, spacecraft or submarines is much more than just sitting inside a sophisticated machine. In addition to the engineering aspects of navigating the environment, be it air, vacuum or water, the machine must also interact with the human to take instruction and to support life. Integrating human physiology with machine engineering as well as with the culture of the operator community has always been considered important but has not generally been implemented successfully. Recently, NASA's Office of the Chief Health and

Medical Officer has published a white paper exploring this topic and providing guidance for the *"…culture and practice among engineering, life sciences, and health and medical disciplines in the context of human systems integration (HSI)"* (Doarn et al. 2019). The ensuing discussions are based, in part, on concepts expressed in this document, and explained within the context of the PiBASE study.

Conceptual background:

The concept of integration of sub-systems is a common theme within scientific disciplines whether biological, psychological, electrical, hardware, software or mechanical. In each of these broad categories, the function of the whole is generally more complex that the sum of the individual components.

Consider two examples, the human heart, and the engine of an automobile:

Human: In the human biological system, the function of the heart is affected by the oxygen transport from the lungs, the electrical signals from the brain, the energy from metabolism, and the performance demand from the muscles. In return, the heart provides the systemic circulation that supports the cellular function of the other organs.

Machine: In a mechanical system like a car, the function of the engine is affected by subsystems for lubrication, coolant, fuel, and ignition as well as overall power capability, drive train, transmission and wheels. In return, the engine provides the power to move the vehicle, charge the battery, and pump the fuel and hydraulic fluids.

In both examples, a "system of systems" operates the human or car as a whole. When something goes wrong, subject matter experts (medical doctor or automotive engineer, respectively) can diagnose the symptoms and propose solutions. However, this is where the similarity ends.

Medicine:

In medicine, the main tool is "differential diagnosis" using a series of steps beginning with questioning the patient, such as: "where does it hurt?", "when did it start?", "is there a family history of cancer?", "are you taking any medication?", followed by standard physiologic measurements of blood pressure, body temperature, heart rate, breath sounds, range of motion, and analysis of blood and urine samples. The diagnostic procedure is based on the "outlier" concept, which are any observations or measurements falling outside some statistical limits of normality are the key to the problem. Actions to deal with the problem fall into three categories:

- Intervention: These include advice to lose weight, eat more vegetables, get exercise, prescription of antibiotics for infection, analgesics for pain, and blood pressure medication and statins for long term health management.
- Surgery: These include repair of traumatic injuries, stabilization of broken bones, removal of tumor, appendix, gall bladder, etc., redirection of blood flow (angioplasty, bypass), replacement of knee and hip joints, etc.
- Recovery: These include outpatient visits to a physical therapist, psychological counseling, medical monitoring, or inpatient care for respiratory support, blood transfusion, kidney dialysis.

Medicine also relies in large part on encouraging the human systems to heal themselves.

Engineering:

In the realm of engineering-based repair and maintenance, the main tools are observation of performance and subsequent parts replacement. As an example, consider the modern automobile; the car can be "interviewed" electronically to assess function, but cannot offer an opinion as to how it feels or where it hurts. If a component is failing (e.g., water pump, fuel injector, shock absorber, brake drum, etc.), it can be quickly replaced. If the problem is systemic, then more extensive replacement/repairs (engine, transmission, suspension) are necessary. These are solutions not as readily available for human systems; unlike replacing an engine in a car, a heart transplant in a human is highly invasive and carries appreciable risk of death. Whereas much of human systems repair and maintenance relies on drug therapy and biological healing, engineering relies in large part on finding and replacing defective parts to assure smooth operation for the expected lifetime of the whole machine.

Culture of Communities:

Within individual disciplines, the system interactions are generally well understood. Each field, whether based in medicine, biology, chemistry, computer science, electrical or mechanical engineering, etc., has its own culture and *"way of doing things"* to diagnose, repair and maintain the human, computer, car, airplane, etc. entities. As such, the experts responsible for the functioning of the human body have a very different approach than do the experts dealing with the effective performance of mechanical systems. A few recommendations from the massive NASA white paper mentioned above (Doarn, 2019) address these issues by recommending to:

1. *Address cultural differences, primarily between engineering and medical/life sciences communities, early in the career paths of practitioners.*
2. *Develop a common lexicon and common means of communication, methods, and practices that are recognizable and understandable by all.*
3. *Recognize that dynamic tension exists between Technical Authorities and program/project management. Serious conflicts can arise… when differences of opinion between technical authorities and program managers potentially affect budgets and schedules*
4. *Include all responsible and relevant communities of practice in all phases of the project/program, from design to operations… Inclusion of communities late in the process has demonstrably untoward and sometimes tragic effects.*
5. *Stress the importance of organizational leadership in achieving successful HSI… Communication and understanding between diverse communities of practice must be inculcated as an organizational core value, repeatedly emphasized by leadership as an imperative.*

In short, NASA has provided the broad philosophy of successful human machine integration. The paraphrased excerpts above are representative of a much larger framework developed in the Doarn report, but serve as an underpinning for this section of the PiBASE Case Study.

Human Systems Integration:

The biggest problems appear when the engineering and medical disciplines collide in diagnosing failures of highly complex machines that are operated by highly complex humans. In the realm of high-performance military jets, when something relatively minor goes wrong, there is a culture of *"pilot error"* by the administrative community, *"faulty component"* by the engineering community and "*cost of doing business*" by the pilot community. In serious mishaps (loss of pilot or aircraft), the assignment of cause (and blame) becomes very contentious; program management does not want to accept responsibility for a systemic failure in the program; engineering wants to perform a root cause analysis and assign blame to a faulty component or sub-system that can be quickly modified or replaced in all jets, and the pilot community wants an answer now, before another incident or disaster occurs.

The original NASA studies of Air Force (F-22) and Navy (F-18) data have shown that engineering data alone, without studying the human element cannot diagnose the reason for PEs. This should have been obvious from the start, after all, a PE is a "physiological event" and would logically require physiological data to resolve.

The PBA study has shown that in-flight pilot breathing data are crucial for understanding the human – machine interaction, and that previously unknown behaviors of the mask/regulator system in response to pilot breathing demand can affect pilot performance.

The established root-cause style analyses of engineered systems could not make sense of the incidence of PEs. Engineering data analyses require consistency and repeatability, whereas the interaction between the pilot physiology and the aircraft systems modifies the outcome to the extent that PEs appear random. Only when the second part of the interaction (pilot physiology) is considered along with engineering data could the factors leading to pilot stress be clarified.

Reference:
Doarn CR, Travis TW, Currie-Gregg NK, Nicogossian AE, Weyland M, Shepanek M, Null C, Buckland DM, Miller SB, Liskowsky D, Fuller D. Engineering, Life Sciences, and Health/Medicine Synergy in Aerospace Human Systems Integration: The Rosetta Stone Project—An Executive Summary. New Space. 2019 June 1;7(2):110-3.

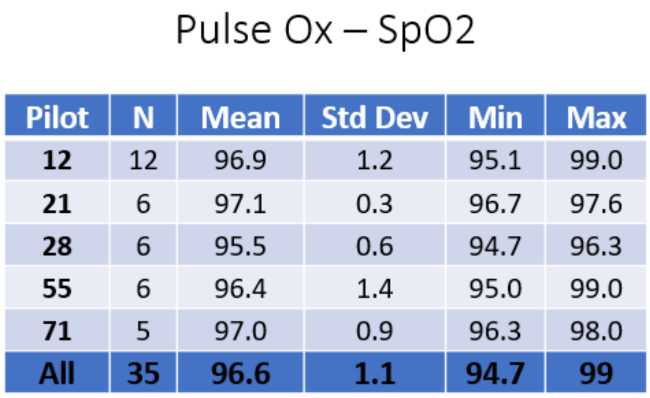
4.3.1 Example: Uniting Multi-disciplinary Data and Fields

The recurring theme of this case study, and that of PBA, is to collect and interpret data while applying a multi-disciplinary view and systems thinking. For the PBA, in-flight pilot-data was determined as the primary missing data set, thus a priority. The understanding of the human in-flight experience is enriched by physiological monitoring on the ground (objective data) and pre/post flight questionnaires (subjective data, following the mantra of "listen to your pilots"). The idea was to perform the following (in chronological order):

- QB 1-time baseline questionnaire to establish ROBD and PE history, if any; comprehensive set of 197 questions regarding any past symptomology, or remarks on aircrew flight equipment or aircraft experience
- Q1 the pilots to fill out a pre-flight questionnaire (e.g., hydration, rest)
- A baseline vitals* measurement taken in the **briefing room, without flight gear**, and outside of the aircraft.
- B vitals **in gear, in the aircraft**, pre-flight
- F keep track of the flight profile (high/low altitude, aerobatic), measure mask pressure and delivered oxygen together with aircraft variables
- C vitals **in gear, in the aircraft**, pre-flight.
- D vitals in the briefing room, without flight gear, post flight to represent **recovery**.
- R pilot to report a debrief
- Q2 post-flight questionnaire

*Vitals in this case refer to measurements including pulse oximetry SpO_2, and Spirometry Testing with extended resting Tidal Volume.

To investigate pilots' oxygen levels pre- and post-flight, Pulse Oximetry measurements were taken on the ground using a Masimo Rad-97. This medical-grade model provides noninvasive and continuous monitoring pulse oximetry. The parameter utilized and reported on in the PBA report was SpO$_2$, **oxygen saturation** in the blood expressed as the percentage of oxygen-carrying hemoglobin relative to the amount of hemoglobin not carrying oxygen. Healthy individuals at sea level usually exhibit O$_2$ saturation values between 96% and 99%, with the Center for Disease Control stating oxygen saturation of 95 to 100% is normal for healthy children and adults. All pilots started at healthy SpO$_2$ readings (Figure 4.18), yet 42% were below the mean of 94.8% post flight (measurement C). Most concerning are the lowest SpO$_2$ values, which for the PBA data were **91% and 92%**. The low measurements are even more disconcerting when measured post flight being supplied near-100% O$_2$, in which case the saturation or SpO$_2$ should be 99 to 100%.



Pulse Ox – SpO2

Pilot	N	Mean	Std Dev	Min	Max
12	12	96.9	1.2	95.1	99.0
21	6	97.1	0.3	96.7	97.6
28	6	95.5	0.6	94.7	96.3
55	6	96.4	1.4	95.0	99.0
71	5	97.0	0.9	96.3	98.0
All	**35**	**96.6**	**1.1**	**94.7**	**99**

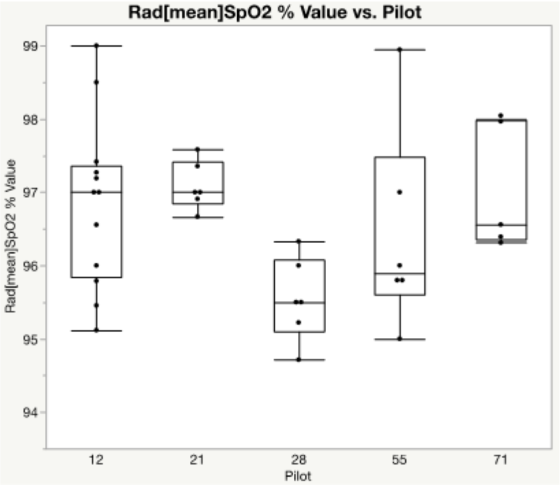


Figure 4.18. Shows healthy blood oxygen saturation in pilots pre-flight. There are variations within pilots and same pilot day-to-day, all readings are in a healthy range.

In this case study it is appropriate to highlight the instance which led to the 91% SpO$_2$ (Figure 4.19), measured upon landing flight 99. We do so in the spirit of systems engineering, which by its definition calls for a multi-disciplinary approach. This section presents the rich and varied sources of objective and subjective data which the team took great effort to collect.

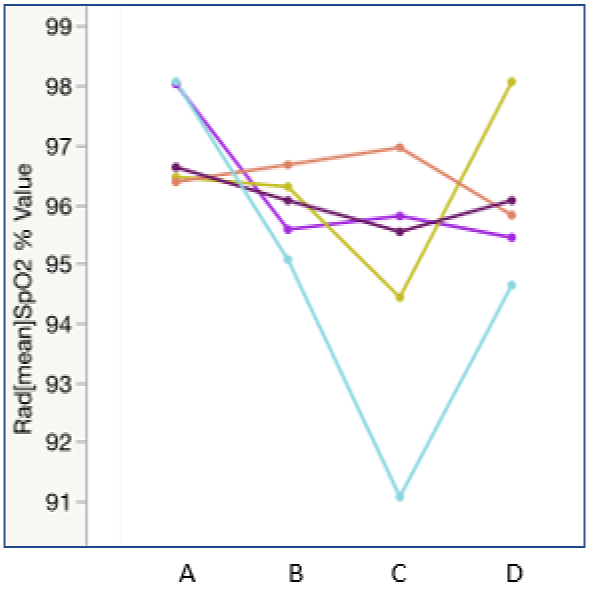


Figure 4.19. Shows the SpO_2 measurements of pilot 71, with the light blue trace containing the low 91% SpO_2 measurement.

This trace represents the greatest A-to-C drop and the greatest B-to-C drop.

- The pilot flew flight 99, profile E. Profile E was part of a focused priority in which the effects of dynamic pressure change on the pilot were studied through horizontal maneuvering, while decoupling/ disabling the cabin pressure schedule (Figure 4.20).
  - In the central 30 minutes of the flight, altitude was kept near 8,000 feet. The ensuing cabin pressure deviations are solely due to dynamic pressure brought on by “wing-tipping,” throttling velocity and Gs. The sub-minute **oscillations of ambient pressure on the body and supplied ppO_2 were between 570 and 610 mmHg.**
  - 100% Oxygen was supplied and a constant 3 mmHg of positive pressure by the CRU-103 oxygen regulator.
- As a result of non-pressurization, there was no air conditioning in the cabin. This was discussed with the pilots, and a consensus was reached to move forward with the tests. The naturally climbing temperature in a low-altitude flight, in a small enclosed space, was worsened as the starting temperature was an already high 28 degrees C (compared to a possible 15 degrees C), resulting in an end **34 degrees C** (Figure 4.21).

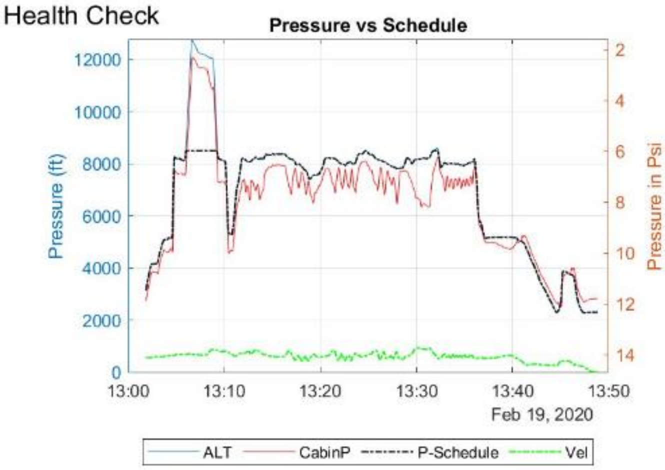


Figure 4.20. Altitude profile and repeated cabin pressure changes equivalent to 1000 feet per 30 seconds brought on by horizontal maneuvering, and 5G forces.

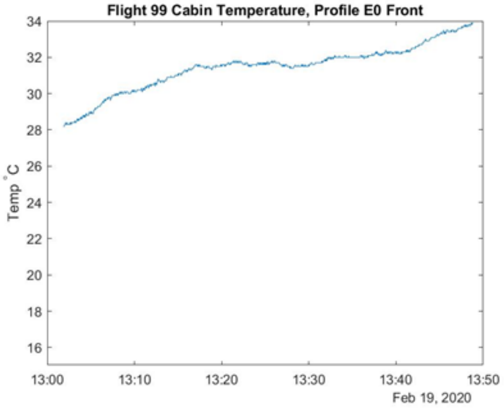


Figure 4.21. Temperature in the cabin climbing from 28 degrees to a hot 34 degrees C. The lower end of the temperature scale of 15 degrees C represents a typical measured value by end-of-flight.

High altitude and dynamic, aerobatic maneuvering (a form of exertion) have compound effects on the body (Figure 4.22). At high altitude, the reduced ppO_2 results in arterial desaturation; respiration is then driven by the arterial chemoreceptors, rather than medullary partial pressure of carbon dioxide (PCO_2), and with any physical exertion the necessary increases in ventilation are very large[1]. High temperature is a third factor. When the effects of exercise are measured in heat (40° C vs 18° C in the study), prefrontal cortex oxygen saturation (ScO_2) was 10 % lower at exhaustion in the hot trials compared with cold. "Findings indicate that changes in SmO_2 (oxygen saturation in the muscle) and ScO_2 are associated with the development of thermal and cardiovascular strain during exercise to exhaustion in the heat. In locomotor muscles, a potential reduction in oxygen delivery may develop, whereas in the brain, the progressive reduction in ScO_2 may induce mental fatigue."[2] There is a large amount of literature directly addressing the combined effects (changes in blood oxygen, effects on the brain and performance impairment) of exercise and heat on the body by Cheuvront, Gonza'lez-Alonso, and Nybo, to name a few [7-13].

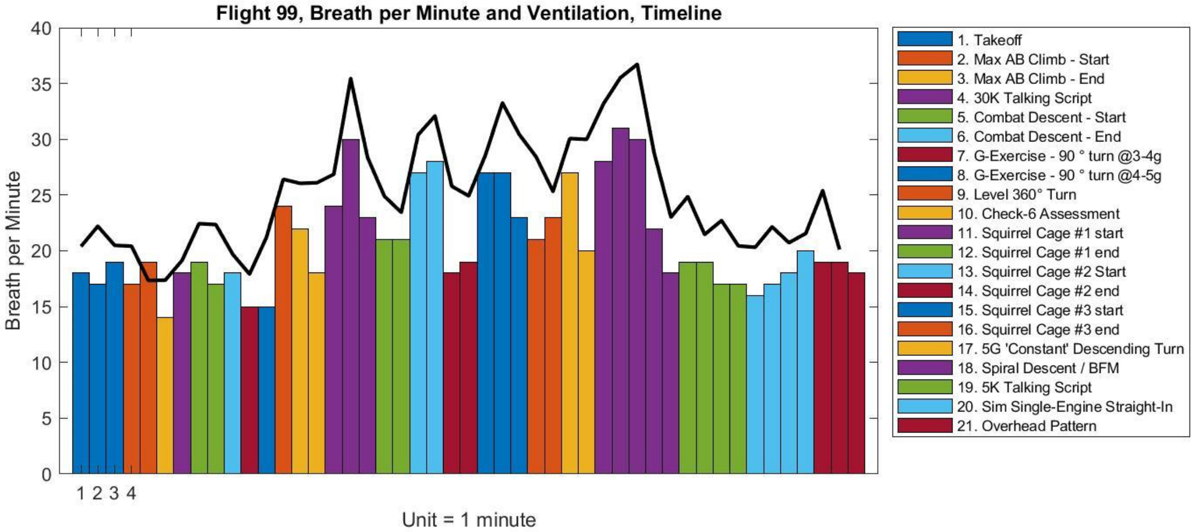


***Figure 4.22. Bars representing respiration rates changing with flight segment between 15 to* 30.**

The trace represents Minute Ventilation (L) changing from 18 L at rest at altitude to 37 L during maneuvering.

Altitude exposure and exercise are likened in the study "Acute Mild Hypoxic Hypoxia Effects on Cognitive and Simulated Aircraft Pilot Performance" (Bouak 2018)[3] in which the effects of acute mild hypoxic hypoxia (HH) and physical activity on physiological measures, signs and symptoms, mood, fatigue, cognition, and performance on a simulated flight task were investigated between 8,000 ft (2438 m) and 14,000 ft (4267 m). The increase of the reported HH symptoms during the rest period after altitude exposure was similar to the increase during the rest period after exposure to exercise. Minute ventilation can double with light exercise, and it can exceed 40 Lpm with heavy exercise[4]. In the case of the pilot on flight 99, Minute ventilation of 34 L would represent moderate exercise on the ground, followed by "rest periods," with the sequence repeated four times… Bouak's findings confirm the anecdotal and surveyed reports of the occurrence of classic HH signs and symptoms by Royal Canadian Air Force and other helicopter pilots at low altitude levels[5], and are consistent with published studies[6].

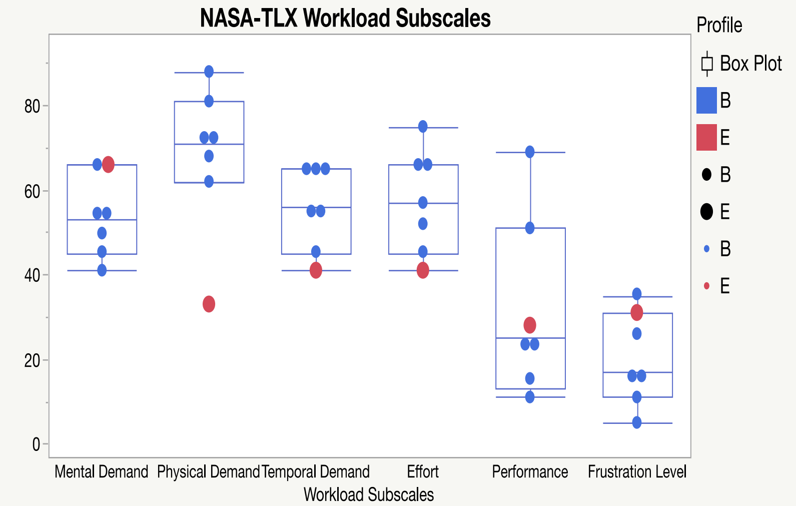
The post-flight questionnaire contained subjective self-report questions related to physical and cognitive experiences during flight. This questionnaire included the NASA Task Load Index (NASA-TLX) workload rating scale and for pilots to provide a subjective rating of perceived workload (Hart & Straveland, 1988). Workload is defined as the cognitive resources required for an individual to perform a task at a specific level. The NASA-TLX is a multi-dimensional scale of workload with six subscales that assess a different dimension of workload: mental demand, physical demand, temporal demand, performance, effort, and frustration level (Hart, 2006; Hart & Straveland, 1988). Each subscale has a single item scored. After completing the flight, pilots indicated the individual magnitude of the six workload elements by moving a slider bar along a corresponding line ranging from 0 to 100. As demonstrated by Hart (2006) the additional weighting scale was not included.

Pilot perception is captured in the post exposure questionnaires via the NASA-TLX (Table 4.1).

Table 4.1. A Subset of Answers to Post-flight Questionnaire Commenting on Pressure, Heat and Pilot Perception of Mental Demand, Physical Demand, Temporal Demand, Frustration Level as Part of TLX Score Dimensions

Pressure in ears	Feeling sweaty	Please describe:	Mental Demand	Physical Demand	Temporal Demand	Frustration Level
1	2	"With no pressurization there is no AC so the plane was hot, especially with the G-suit and Navy gear"	66 (Mean 51)	33 (Mean 73)	41 (Mean 57)	**31** (Mean 15)

The NASA pilot reported "no difficulties," which is in-line with pilot sub-culture (Section 8.2). Pertaining to physical demand, the highest G on this flight was 5 Gs for sustained 30 seconds or less. The rightmost 4 columns are part of the NASA-TLX- workload rating scale (Hart & Straveland, 2009). The NASA-TLX, 6 dimensions of workload are rated within a 100-points range on a slider scale. These ratings are then combined to the task load index. Compared to pilot 71's mean values, his frustration index showed a 2x increase compared to his means. All other flights in this dataset by pilot 71 were Profile B, which is comparable to E, the former with vertical maneuvering vs horizontal. This explains the lower score of flight 99 (E) in the physical demand (Figure 4.23), even though G levels acting on the body were identical in B and E profiles by design.



		Profile		
NASA TLX Subscale		B	E	All
Mental Demand	Mean	51.7	66	53.7
	Std Dev	8.8		9.7
Physical Demand	Mean	73.7	33	67.9
	Std Dev	9.4		17.6
Temporal Demand	Mean	58.3	41	55.9
	Std Dev	8.2		9.9
Effort	Mean	60.2	41	57.4
	Std Dev	10.9		12.3
Performance	Mean	31.8	28	31.3
	Std Dev	23.2		21.2
Frustration Level	Mean	18.2	31	20
	Std Dev	10.8		11

Note: Profile B n = 6, E = 1

Figure 4.23. The TLX scores reflect the subjective experience of workload of Pilot 71. The dots designated "E" represent flight 99.

Pilot 71 rated Mental Demand and Frustration Level on flight 99 high, the latter tying in with his free-form comment regarding heat.

Conclusion

In this example a multi-disciplinary approach is shown by uniting 5 different areas of data collection, from human factors to engineering. This was a flight selected to demonstrate one observed extremely large difference (capitalizing on data) and this treatment is a methods demonstration not applied for all flights. The positives in the case of the pilot on flight 99 were a high starting SpO_2 of 98% and a high FVC measured at 5.5 L pre-flight (A) to 5 L post-flight (C). Moderate-high pressure changes, Gs and high temperature were present. The next 3 rankings of end SpO_2 of 92% were from different profiles. As the OTM suggests, there are multiple combinations, ways of diminishing reserves leading to mild to pronounced hypoxia. These (based on data) are a lower starting SpO_2, highly variable FVC, micro-oscillations impeding accurate oxygen gas delivery, high respiratory rates due to mental effort in low-terrain flights or moderate-high Gs in aerobatics.

The global view presented in this section would not have been possible without multi-disciplinary collaboration considering the pilot, cabin environment coupled with the breathing gas supply, all ultimately acting on the pilot's physiology. Such interactions are complex ,see Figure 4.24.

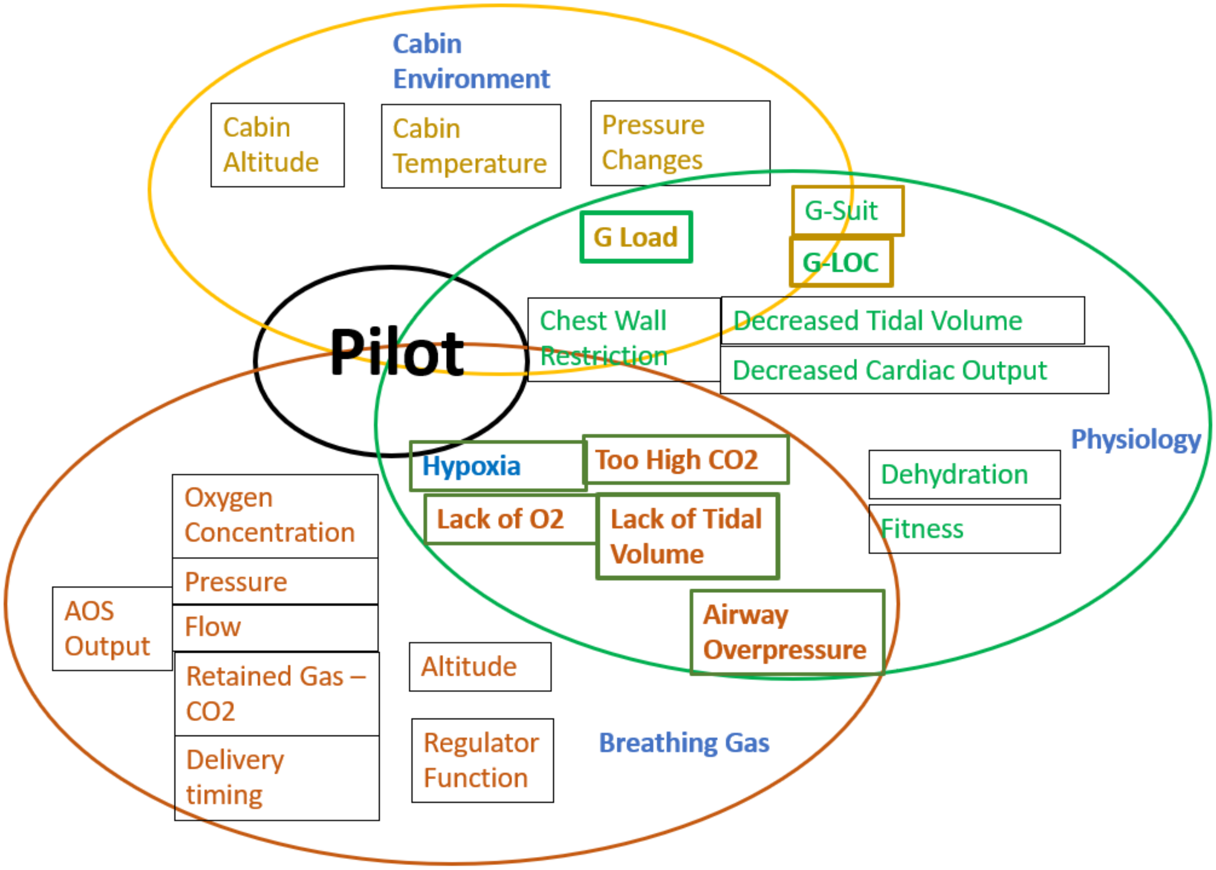


Figure 4.24. Shows the pilot acting on its cabin environment and interacting with the AO. Cabin environment affects the breathing gas delivery, and both act on the pilot's physiology.

Figure 4.24 illustrates the important overlaps in system regimes that can affect the pilot. The three systems are

- the cabin environment,
- breathing gas composition and
- the human physiology.

All the systems overlap, but here the critical overlaps are illustrated.

- The cabin environment affects how the human responds.
- The **G-Load** is induced by the plane and the cabin environment.
- G-loads place a demand on the **physiology** to compensate. Both factors place demands on the third system, the **breathing gas**.
- The G-suit and G straining maneuvers by the pilot function are **physiological responses,** but place demands on the **breathing gas supply**.
- The boxes of the **O_2** and **CO_2** from the breathing gas affect the **physiological function** of the pilot and place a demand on the **breathing gas supply** or aircrew breathing system.

The **Oxygen concentration** and how the **gas pressure** is supplied, concentration of CO_2 coupled with **Tidal Volume** supply are critical to **pilot physiology.** If the pilot demand created **aircraft/ cabin environment** is unmet **physiologically** by the **breathing gas system**, the end result will be **Hypoxia**.

Through the PBA and this case study, multiple models are composed, none of them absolute, but each increasing the body of knowledge on mechanisms possibly leading to PEs.

Conclusion

These PBA results show unambiguously that HSI is crucial in diagnosing systemic failures. Breathing system sensors, cabin pressure, oxygen delivery and flow monitoring along with engineering data streams, bring the community one step closer towards understanding and preventing of a PE on any given flight.

Underlying issues revolve around the vertical silos in current practice among the medical, engineering, and pilot communities. Integrating these three groups at all stages of the development, operations, and diagnostics phases of complex systems like jet-fighter aircraft is necessary to alleviate systemic failures.

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5. PBA Process: the AFRC example, creating PBA's hybrid Class instrumenting Aircraft and Human

Introduction

Section 4 introduced ***"The Pilot-Jet System of Systems (SoS)."*** In this section, the various tasks, planning, and implementation of the PBA test campaign are described to collect and study comprehensive data on all parts of the system, including the most complex part, the human.

The NESC initiated the Pilot Breathing Assessment (PBA) as a result of two previous assessments performed, one for the USAF in 2012 for the F-22 and the other for the USN in 2018 for the F/A-18. As a result of these assessments, the NESC team noted that the understanding of key pilot physiological parameters was lacking. This was primarily because data needed to make sound judgments with regards to HSI did not exist. The goal behind PBA was to use NASA-owned F/A-18 and F-15 aircraft to obtain in-situ pilot breathing data as a key step towards learning how a complex human system (the pilot) interacts in a complex aircraft system (the jet) while operating in a complex environment (the flight environment).

PBA flights began in the summer 2018 and measured pilot respiratory rates, tidal volumes, and air composition in flight. Five NASA test pilots flew six different flight profiles in six jets, consisting of four F/A-18s and two F-15D airframes at NASA AFRC. The assessment logged over 100 flights and gathered over 4,750 minutes of analyzable data on pilot-machine-environment states.

The assessment was conducted in four phases in which Systems Engineering processes at NASA AFRC were followed. Phase 1 consisted of study design, test planning, and flight approval. The second phase incrementally implemented several complex flight test elements into the assessment over the next nine months. Phase 3 consisted of a four-month review of Phase 2 flight test results and a reevaluation and re-prioritization of the final flight requirements prior to the final phase. The team identified lessons learned from the first three phases to ensure flight data gathered were consistent, achieved the PBA project goals and requirements. While Phase 2 flights were experimental, Phase 4 flights were more directed towards specific hypotheses and priorities. Also, in Phase 4 the team had to repeat certain Phase 2 flights to replace incomplete data sets.

This section details the systems engineering processes from the initial planning by the NESC for assessment approval and the processes followed and uniquely tailored at AFRC to successfully accomplish to goals and requirements of PBA.

5.1 Test Planning

The NESC initiated PBA to gather critically important flight data that was identified as missing in the NESC F/A-18 assessment in 2017. NESC follows systems engineering processes in defining and implementing assessments. The first step in the process for gaining assessment approval through the NESC is defined in the Technical Assessment Plan (NESC-PL-18-01320).

At AFRC, the primary systems engineering document used to guide flight projects through the flight clearance process is AFG-7900.3-001, Airworthiness and Flight Safety Review, Independent Review, Technical Brief, and Mini-Tech Brief. AFRCs Project Chief Engineer's Handbook, AFG-7120.5-001 has tailored the agency's Engineering and Program/Project

Management Policy Directive (NPD 7120.4) and its' Program and Project Management Processes and Requirements (NPR 7123.1C) to describe how research projects are conducted on aeronautics platform at AFRC. This section describes the initial planning performed by the NESC and AFRC.

5.1.1 NESC Technical Assessment Planning

The NESC follows systems engineering processes in defining and implementing independent assessments for the agency. A major goal of the NESC is to acquire engineering data and conduct analysis to support system level findings and provide the agency's programs and projects with the information they need to conduct better testing, make better decisions, and improve designs. In addition, the NESC falls under the NASA statutory authority established by Congress to conduct research on aerospace vehicles (51 US Code Sec 20102(b)) and partner with DoD counterparts and aircraft manufacturers to help make their systems and aircraft better and safer. (Sec 20113(f)) & Sec 20114).

One of the first steps in an NESC assessment is to perform a Technical Assessment Plan (NESC Technical Assessment Plan[10]) to develop the initial proposal. To develop a technically viable plan, key NESC and AFRC personnel were required to help scope the project and develop an initial plan. The plan is then presented to the NESC Review Board (NRB) for approval. Unique to this plan were Health Insurance Portability and Accountability Act (HIPAA) requirements affecting data handling.

5.1.2 AFRC Test Planning

5.1.2.1 Airworthiness and Flight Safety Review

Airworthiness and Flight Safety Review is a systems engineering process followed at AFRC for a project to gain approval to fly. The process is governed by AFG-7900.3-001 Airworthiness and Flight Safety Review, Independent Review, Technical Brief, and Mini-Tech Brief. As stated in this document, the airworthiness process:

> *… applies to all flight activities and hazardous ground tests involving aircraft, Unmanned Aerial Systems (UAS), critical flight systems, and/or experimental facilities for which the Center has any airworthiness, ground, flight or range safety responsibility or that involve Center personnel utilizing non-National Aeronautics and Space Administration (NASA) assets.*

To accomplish this important task, an Airworthiness and Flight Safety Review Board (AFSRB) has been established by the AFRC Center director. The AFSRB Chairperson is AFRCs Center Chief Engineer. The board consists of the directorate chiefs and other key personnel at the center.

The airworthiness process is **highly adaptable** to accommodate the wide variety of projects that are implemented at AFRC. Flight projects vary considerably in scope, complexity, duration, criticality and requirements. According to the airworthiness document,

*To properly **tailor** the project with the most appropriate processes,* an initial meeting between PBA team members, the AFRC planning team, and the Center Chief Engineer was convened after NRB approval.

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[10] NESC-PR-011-TP-03.1, Version 1.1

Given the PBA project goals, the best course to follow was the Technical Brief option, as outlined in Section 4.0 AFG-7900.3-001). Figure 5.1 shows the flowchart that defines the tech brief process at AFRC.

5.1.2.2 Technical Brief option (Section 4.0 AFG-7900.3-001, AFOP-7900.3-022)

The Technical Briefing is one of the more important tools used by the Center to ensure the safe and efficient conduct of the flight test mission. Its major function is to continue the review process after the AFSRB has made its final recommendations and a program moves into the flight or test phase. All specific requirements to accomplish the Center's tech brief process are contained in AFOP-7900.3-022.

Figure 5.1 shows the flow chart describing the logical framework to execute the tech brief process.

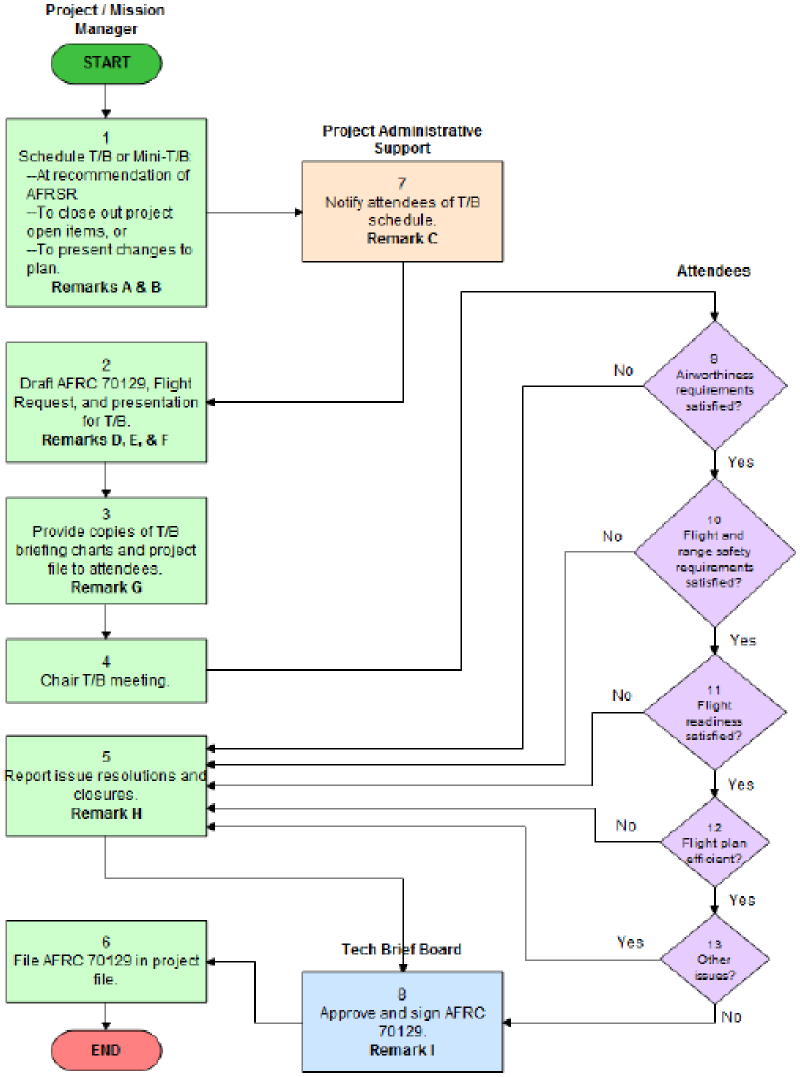

Figure 5.1. Technical brief or mini-technical brief flowchart.

The tech brief process allows for a block of flights of a research aircraft. This allowed PBA to safely introduce new features and methods into the pilot breathing assessment as they were ready. This incremental approach allowed the project to proceed through the flight test plan more efficiently and present a more complete picture of the flight test results.

5.1.2.2.1 Tech Brief Purpose

There are two purposes of the tech brief as described in AFOP-7900.3-022.

First, the individual project office is given the opportunity to present its goals and plans to a group of peers. These peers represent all the various disciplines at the Center, with special emphasis on the areas of interest that are being explored during the proposed flight tests. A project, in this way, receives the benefit of the experience and expertise of projects conducted previously. The peer review, using past experiences, is a proven way of identifying missing features and lessons learned.

The second purpose of tech briefs is to present a current assessment of project risks to the Center management team. It allows management to reconsider its understanding of the risks involved prior to each flight. This helps ensure that any identified risks that cannot be eliminated or reduced are accepted at the appropriate level of authority and responsibility.

The unique risks for PBA stemmed from HSI of the VigilOX test equipment interfacing with the pilot’s oxygen supply and mask. Helpful to the PBA were positive VigilOX safety reports by the Navy.

5.1.2.2.2 Tech Brief Committee Representation

As described in Figure 5.1, the outcome of the Tech Brief process is a signed flight request (AFRC 70129). This clearance is required before a flight project can conduct testing. One of the most important aspects of the Tech Brief Process is the inclusion of every AFRC organization who shares responsibility for some aspect of safety. These organizations are required signatories on the flight request approval.

5.1.2.2.3 Tech Brief Topics/Outline

The Tech Brief committee comprehensively reviews all aspects of the project prior to flight. The presentation to the committee includes the following topics: a review of past flights (if any), Objectives of the proposed **flight (or block of flights), the flight plan (including planned maneuvers, risks, limits, constraints, ConOps and contingencies), configuration changes, control room operations, accepted risks, mandatory requirements** (mission rules, aircraft operating limits, weather constraints, so-called “go/no-go” instrumentation, required documentation, and required personnel), open items (that must be cleared prior to flight). In this regard, planning, considering risks and constraints, operations, requirements and configuration control are all parallel to systems engineering practices. Some of the PBA’s constraints were: being deemed lower priority, impacting aircraft and personnel availability and turnover; aircraft availability further reduced by flight-hours left on airframes before removal for mandatory maintenance, which increased the number of unique aircraft used as a variable.

5.1.2.3 Objectives and Requirements Development

Objectives and system-level requirements are typically baselined for AFRC projects through the Objectives and Requirements Document (ORD) process, as described in AFG-7123.1-002. The ORD is considered a “best practice” at AFRC and is referenced in the Project Chief Engineer’s

Handbook (AFG-7120.5-001). The ORD serves three primary purposes, to document 1) the project-level objectives, 2) the preliminary system concept and, 3) initial requirements for facilities and organizational support required. This section presents details from the ORD defined by PBA.

5.1.2.3.1 Project-level Objectives

The following project-level objectives were identified for PBA in the ORD:

Enable measurement of pilot breathing. Previous studies underscored the need of HSI in testing when investigating events affecting the human. The project identified human breathing data as essential to understand the PE problem. To gather this vital dataset, a flight proven, pilot breathing system was needed. In the interim between the NESC F/A-18 Independent assessment and PBA, NESC had conducted a comprehensive review of all existing pilot-worn systems and determined that VigilOX was the most comprehensive and highest Technical Readiness Level (TRL) option.

Enable measurement of aviation conditions that may affect pilot breathing. This was part of the systems approach, as the PBA set out to study pilot and aircraft data as one dynamic system to understand cause and effect. Aircraft instrumentation requirements were driven by the need for research aircraft flying PBA missions were to gather and time synchronize flight data with pilot breathing data. Unfortunately, the depot maintenance schedule for the F/A-18s (previously described) significantly impacted the flight test plan. This complicated the system concept, along with the fact that not all AFRC jets had the same instrumentation system capability. In fact, some aircraft had no research instrumentation system capability and installing such systems were problematic for technical, schedule, and cost considerations.

Conduct a flight test campaign that measures pilot breathing and aviation conditions. This comprehensive campaign will be conducted across a range of aircraft types, pilot population, aircrew equipment types, and flight conditions that is as broad as practically possible. Tests will be repeated as many times as practically possible.

Aircraft Types. The project initially requested AFRC F/A-18s exclusively to reduce the number of independent variables in the data analysis. After iterating between the project requirements and AFRC constraints, it became clear that this **limitation would exceed the project schedule and resources** if such a requirement was levied. F-15D aircraft were offered as a means to gather flight data more efficiently and also opened the design space for HSI investigation in another airframe.

Figure 5.2 shows the aircraft types, models, and tail numbers in the support aircraft fleet at AFRC in support of PBA. Two F/A-18A models (single-seat), two F/A-18B models (dual-seat), and two F-15D models (dual seat) are shown.

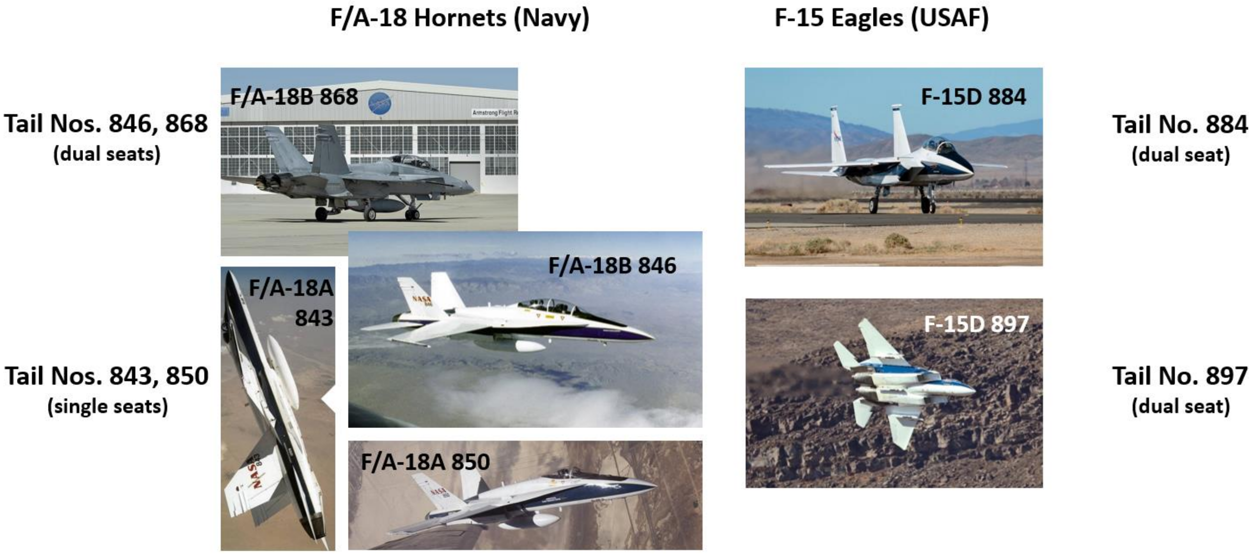

Figure 5.2. NASA AFRC aircraft used in PBA.

Pilot population. Given the large number of sorties required, the project quickly understood the need to include as many AFRC research pilots as were available and qualified to fly F/A-18s and F-15. Having five pilots was essential in achieving the data required while achieving the overall project goal of staying within schedule and the resources available. Using multiple pilots also allowed the unique ability for within- and between-parameter statistical analyses of the various profiles, flight activities, and aircrew equipment configurations as they could all be repeated by the same individuals within the logistical constraints of the study.

Aircrew Flight Equipment (AFE). Personal breathing gear (masks), attendant regulators, and other air supply hardware serve as the “front-line” interface between the aircraft and the pilot. Even small differences in individual components, and the related complex interactions between multiple components, can become critical. Within the PBA study, gear configurations were categorized as “USAF/Air Force” and “USN/Navy” types. These were not identical to all setups used by active USAF or USN pilots, but rather representative of key differences in equipment setup; in the repeat measures design, most PBA pilots flew across service platforms. Generalizing, notwithstanding the targeted use (DoD, NASA, aircraft or space platform), testing multiple AFEs yielded tools to evaluate the efficiency of important LSS design elements, such as oxygen regulators, in a fast changing pressure environment.

Flight conditions. A key design requirement of PBA was the use of scripted flight profiles to produce comprehensive, time-synchronized datasets of pilot breathing together with key aircraft state parameters in a consistent, systematic, methodical, and repeatable way. This was important not only for the PBA team to be able to develop a statistical baseline for comparison across aircraft, AFE configuration, and pilots, but also to provide a template for U.S. military services to consider adapting. Pilots were integrated in the flight script design process.

Table 5.1 provides the names and single-letter descriptor for the scripted profiles A through H developed and flown in PBA. Each profile was designed with specific detailed instructions for the pilot to gather a comprehensive dataset of breathing response across a broad set of flight conditions. These instructions were captured on a set of flight cards that were executed for each PBA sortie.

Table 5.1. PBA Scripted Flight Profiles

Profile A:	High Altitude	The intent of Profile A was to investigate the effects of high-altitude exposure on the pilot's breathing dynamics.
Profile B	AeroBatics	This profile was designed to require a higher breathing effort from the pilot. This profile used aerobatics and elevated G maneuvers to represent the breathing dynamics a pilot would experience on a Basic Fighter Maneuvers (BFM) training sortie
Profile C	Control	Benign profile flown at a relatively constant, medium altitude with low breathing effort. Effects of different settings for the aircraft Environmental Control System (ECS) were investigated and the ECS was characterized at various speeds.
Profile D	Down low	This profile was designed to stay below 8,000 ft PA so that the cabin pressure remained equal to outside atmospheric pressure. The maneuvers are similar to those a military pilot would execute on a low-altitude tactical training sortie. This profile was intended to investigate breathing dynamics at a cabin altitude below that at which supplemental O_2 is normally required while demanding a moderate breathing effort from the pilot.
Profile E	Elimination of Cabin Pressure Schedule	Profile E was intended to replicate a Profile B sortie while flying under 12,000 feet.
Profile F	Functional Check Flight	Covers most of the flight envelope in altitude and airspeed and was intended to investigate the effects of the aircraft breathing system settings on pilot breathing dynamics with scripted breathing efforts from the pilot.
Profile G	Ground only	Profile G was a baseline ground script breathing exercises to be executed before or after Profile F, creating also a double designation G/F or F/G.
Profile H	Health Check	A compilation of maneuvers the PBA team believes will challenge a breathing system and help to identify anomalies and deficiencies.

Repeat measures. Develop test methods with a focus on repeat measures: A major objective is to develop a process and methodology to measure key physiological parameters that was standardized, systematic, and relatively easy to perform.

It is important to express that the first 50 flights were exploratory, without specific hypotheses. The PBA being the first large-scale pilot-instrumented test campaign, researchers did not know what they did not know. Additionally, from previous experience, PEs occur in 0.1% of flights, and not in segments which would intuitively seem tasking (e.g., high G). PE data also shows that some humans are more susceptible to PEs than others and have multiple episodes.

The PBA study was planned with a balanced repeat-measures cross-over design; the objective was to fly each profile with each of five pilots and accumulate two flights of each. This allowed assessment of within- and between- profile/pilot/jet variance components of the influences on pilot breathing. The systems engineering aspect of this design lends itself to a mixed-effects modeling approach wherein changes in physiological breathing parameters could be interpreted as a function of flight profile, individual pilot, and aircraft type. As modern mixed effects models use a restricted maximum likelihood (ReML) approach, any imbalance in the design matrix is resolved with small concession in parameter confidence. For example, even if pilot X only flies a single Profile A in an F-18, then the surrounding data for the other profiles and aircraft still allow variance estimates for pilot X/Profile A for both jet types. The purpose is to discern the effects of the aircraft environment and that of individual human response.

There were even more repeat measures considering that flight profiles are made up of repeat building blocks, such as “combat descent,” high-G “turn.” These are referred to as “flight segments,” whose data (pilot breathing and aircraft state) were aggregated to develop a statistical reference data set, published in the PBA report as the Pilot Breathing Almanac.

5.1.2.3.2 Preliminary System Concept of Operations

Figure 5.3 presents the unique operating paradigm that was implemented at AFRC to meet the overall PBA objective of comprehensively assessing pilot breathing in a tactical environment. Many flight projects that utilize the support fleet at AFRC often involve an experiment carried by an aircraft or a modification to an aircraft. Because the experiment or modified aircraft is one-of-a-kind, all flights are flown with that experiment or modification on a single tail number. In addition, many of the AFRC flight projects utilize a smaller number of pilots who fly all the flights. However, after iterating between the project requirements and AFRC constraints, it became clear that if this more common operating model for the support fleet was implemented for PBA, **it would exceed the project schedule and resources**. Therefore, the entire support aircraft fleet, flown by as many as pilots that were qualified for those airframes, were offered as a means to gather flight data more efficiently. Using multiple pilots also allowed the unique ability for within- and between-parameter statistical analyses of the various profiles, flight activities, and aircrew equipment configurations as they could all be repeated by the same individuals within the logistical constraints of the study.

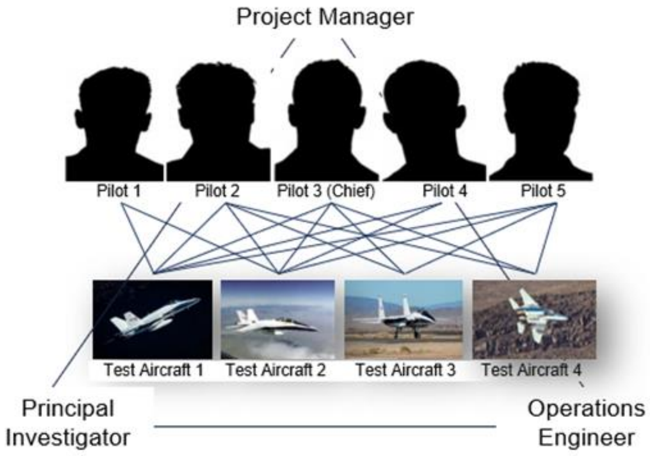

Figure 5.3. Flight project paradigm for the Pilot Breathing Assessment requiring many pilot-aircraft combinations.

5.1.2.3.3 Initial Requirements for Facilities and Organizational Support Required

Initial requirements for facilities and organizational support required were defined in the ORD. These facilities included the Dryden Aeronautical Test Range (DATR), Control Room, and the Life Support Labs.

5.2 HSI at AFRC

This section defines the SE documents that PBA followed regarding HS design, integration, testing, verification at AFRC. In addition, PBA followed many of the best practices for HSI as defined in NASA/SP–2015-3709, Human Systems Integration (HSI) Practitioner's Guide, Nov 2015, pp 1-5 – 1-6. These included defining the ConOps, the specific HSI tasks, and the allocation of roles and responsibilities between different organizations at AFRC. The process to integrate PBA unique breathing systems involved an iterative conceptual design and prototyping, pilot-in-the-loop testing, testing with representative pilot population, and finally, in-situ (in flight) monitoring of human-system performance during flight. This section describes the HSI process followed by PBA to meet the assessment requirements.

5.2.1 Key Personnel

The primary personnel that were involved in developing HSI plans, the execution, and ultimately obtaining flight clearance for PBA were AFRC's life support specialists (Code 423) the pilots (Code 410), operation engineers (Code 430), and PBA project subject matter experts, which included flight surgeons, physiologists, and life support researchers from across the agency. All played critical functions in the integration of all PBA flight hardware for flight.

Much of what is discussed in this section for HSI, however, is performed by the Life Support Branch at AFRC. This branch is entrusted with all aspects of HSI and throughout the entire project lifecycle. The life support specialist have the important job, among many, of defining aircrew-system interfaces and interactions and provides requirements, standards, and guidelines to ensure the entire system operates as designed with effective accommodation of the human component. They are responsible for integrating the aircrew maintaining the pilot's AFE. This equipment comprise the essential pieces of hardware designed to meet the pilot's physiological needs during the highly dynamic conditions produced by these high-performance aircraft.

The AFRC-PBA LSS team consisted of three highly experienced life support specialists. The life support specialist team was able diagnose subtle post-flight anomalies in pilot AFE and aircraft LSS and could confirm pilot observations of breathing discomfort encountered during flight. They were an important resource for the PBA team to better understand factors in the AFE that might have affected the test results.

5.2.2 Life Support Reference Documents

HSI reference documents used by the life support specialists are provided based on the two AFE configurations flown in PBA. Guiding HSI documents for helmets, oxygen masks, and harnessing were provided for both the USAF and USN AFE configurations.

5.2.3 HSI Testing to enable PBA

Bench testing and wind blast testing are examples of ground-based testing throughout the HSI process and were applied to the PBA and the Cobham VigilOx instrument. The ground test philosophy "Test like you fly", or TLYF, guides the process to represent flight conditions, as much as possible, as a means to reduce risk of hazards developing in flight. A final way of surfacing HSI problems is through Combined Systems Testing (CST). CST of human systems is conducted with the pilot in the cockpit and simulating the flight environment as much as possible. These problems can be identified early and mitigated prior to flight.

5.2.4 Review Committees

All tests that involve the use of human subjects requires approval from NASA’s Institutional Review Board (IRB), the AFRC Cockpit Review Committee, and ultimately, AFRCs Tech Brief Committee.

5.2.5 HSI Process for Approving VigilOX to Fly at AFRC

5.2.5.1 Human-System Definition

One of the first and most vital exercises in the successful integration of the human and the system involve accurately defining the HSI conceptually. While this seems obvious on the surface, it is surprising how often this is neglected in engineering systems in which the human plays a vital role, such as a pilot flying high performance jets. As an example, in the NESC F/A-18 PE Assessment for the USN, many schematics and conceptual diagrams depicted the aircraft system architecture alone and did not include the pilot or aircrew in any of these engineering drawings.

Building on the Breathing Gas System (BGS) defined by the NESC in the USN study, Figure 5.4 shows the PBA human-system concept for the AFRC F/A-18 LOX breathing gas system. The human and AFE are shown in the blue highlighted box while the aircraft LOX breathing system is shown in the upper right-hand side of the figure. Notice the BGS for the LOX system is a self-contained system, unlike the more modern OBOGS design, which are coupled to the aircraft bleed-air / propulsion system.

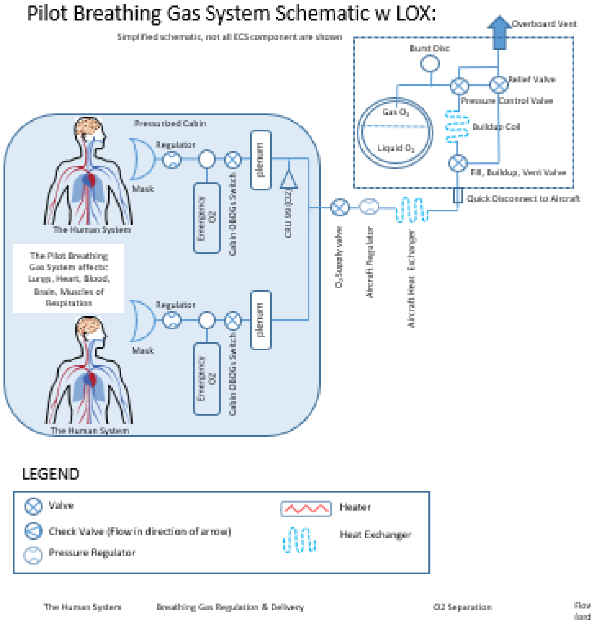

Figure 5.4. Breathing gas supply system schematic.

5.2.5.2 Preliminary Safety Review of VigilOX

A preliminary safety review of VigilOX was conducted in Feb 2018. This review was organized by the project Principal Engineer, and included personnel from the LSS branch, the pilot's office, the VigilOX manufacturer, and HSI SMEs, both from AFRC and Johnson Space Center (JSC). The manufacturer of VigilOX, Cobham, was helpful by providing detailed documentation and sample test articles which helped significantly the review and risk reduction. A preliminary review of the loads and materials used in VigilOX was also included as part of the review. Cobham provided an overview of the materials used and the types of testing that was performed in the product development. Since VigilOX was to be integrated on the pilots AFE and within the cockpit environment, the hazards related to materials flammability, electrical fires, and outgassing could be assessed.

VigilOX Data Download Processes were reviewed as a first step towards developing a project-wide plan for recording, retrieving, uploading, time-synchronizing, and processing the data from all the variety of instrumentation systems used in PBA.

5.2.5.2.1 Different Pilot Mounted Configurations

As the team was examining pilot breathing in different AFEs, the VigilOX equipment was also mounted differently to be compatible with the AFE and regulator used. For the Air Force-like configuration the oxygen regulator and VigilOx were dash-mounted, while for the US Navy-like configuration these were body-mounted.

5.2.5.2.2 Previous Testing/ Flight Clearance Rationale by USN

Previous work conducted by the services to experimentally characterize and evaluate VigilOX was reviewed as part of the Safety Review. Technical reports summarizing results from ground and flight testing by the USN (T-45, F/A-18) and the USAF (T-38, F-35, T-6) were reviewed, as well as results from ROBD Testing.

5.2.5.2.3 Gap Analysis for PBA Flight Clearance

As helpful as the previous studies were, there were many additional tasks unique to PBA that were identified as a result of this preliminary assessment. One such example included the need to conduct additional wind blast testing. The USN wind blast testing was conducted by a USN contractor, but logically focused exclusively on USN AFE. Additional wind blast testing was required to address the PBA requirement to gather and analyze breathing data with a pilot outfitted in USAF AFE and demonstrate the pilot could safely eject from the cockpit, if necessary.

5.2.5.3 Wind Blast Testing

Previous wind blast testing was identified in the gap analysis as insufficient to gain clearance to fly VigilOX in the F/A-18 and the F-15 in Air Force AFE configuration. To address the gap between the wind blast testing of VigilOX performed by the Navy and what was required by PBA, the NESC sponsored the windblast testing of VigilOX pilot breathing sensor system hardware. The testing was performed at the facilities of Dayton T Brown, Bohemia New York. Life support specialists and JSC defined the test matrix of additional wind blast testing to be performed for flight certification.

Test results in the AFRC F-18 and F-15 AFE configuration were unambiguous: there were no issues with these three tests – everything associated with the VigilOX system remained intact and secure throughout the tests, for both the USN and USAF AFE configurations.

5.2.5.4 HSI Preliminary Design

5.2.5.4.1 Life Support Design and Integration

A preliminary design involving the integration of VigilOX within the pilot's AFE was performed by the LS personnel. Their expertise in following the military technical orders are used as the basis for the HSI design. LS follows DoD regulations, USAF Aviation Life Support Technical Bulletins, Air Force Instructions to ensure adequate fit and function of the modified AFE design.

5.2.5.4.2 Pilot Fit Checks

Figure 5.5 shows the life support specialist fitting a pilot with the modified AFE, which includes VigilOX prior to ground testing. These checks verified that the preliminary design could be successfully integrated with the pilots AFE and gather the breathing data required for PBA.

Figure 5.5. Life support specialist fitting a pilot with the modified AFE with VigilOX.

5.2.5.5 Cockpit Safety Review

AFRCs Cockpit Safety Review Process is defined in Aircrew Flight Operations Manual AFOP 7900.3-006.

According to AFOP 7900.3-006

> *All modifications to crew stations that have potential impact to the integrity of egress and life support systems or aircraft control, are reviewed by a standing committee known as the Cockpit Safety Review Committee.*
>
> *The committee will consult as required to review initial cockpit design and installation prior to flight. The committee will decide whether the proposed modifications require further cockpit safety review or pose no hazard and do not require further committee action.*
>
> *In addition to permanent modifications, loose equipment (cameras, binoculars, etc.) that may be carried by flight crew personnel on a given mission is also within the charter of the Cockpit Safety Review Committee (CSRC), which maintains a list of those cameras, both film and video, that are approved for cockpit use.*

AFRCs Cockpit Review Committee (CRC) reviewed and approved the integration plans, preliminary designs, and wind blast test results. The CRC conducted these reviews throughout PBA as new hardware was proposed.

5.2.5.6 Operations Engineering - Work Order System

Any changes to the cockpit configuration required the use of the AFRC work order system and coordination with the CSRC, as defined in AFOP 7900.3-013 – Work Order System. Specific guidance states:

> *Work orders for cockpit modifications under the jurisdiction of the CSRC will be approved by a member of that committee. The operations engineer is responsible for coordinating* ***Cockpit Safety Review Committee*** *reviews and approvals. Because work often needs to be performed before proper evaluation of the final product can occur, approval by the committee will be required after install but prior to WO buy-off to allow non-conformances to be annotated in the comments section, corrective action to take place, and subsequent inspections and reviews to occur.*

Such work orders (WO) and review system further guaranteed the safety of the PBA pilots even while interfaced with instruments in-line with the LSS.

5.2.5.7 In-situ Monitoring of Human-System Performance During Flight

Perhaps one of the most important aspects of flight research at AFRC is the ability to use highly trained research pilots to provide vital feedback of human system performance at many levels.

As established in NPR 7900.3D (3.7.5.2), the NASA research “Pilot In Command [PIC] of a NASA aircraft is responsible, at all times, for the safe operation of the aircraft and the safety of its occupants and is the final authority as to whether a flight will occur."

For PBA, the **pilots proved to be a valuable resource for both gathering and interpreting the HSI data collected and for ensuring flight safety**. Their training and experience helped them to recognize the subtle effects of the different AFE configurations and minor equipment malfunctions as well as the differences in breathing needs while flying different profiles. In many instances during PBA the pilots gave immediate feedback on the effects or anomalies they experienced during flight. Detailed in-flight comments were also noted on their flight cards, relayed in **post-flight debriefs** and captured in their post-flight **written reports**. This information was instrumental in ensuring the HSI was working as intended, guiding PBA analysts to a more focused investigation. With pilots serving as a first-alert system, PBA could quickly evaluate how the pilot’s breathing parameters were affected. Well-trained PBA pilots served as the first line of communication for “bad-breather[11]” jets or faulty AFE by noting unexpected breathing results. An innovative feature of the VigilOX was repurposed and used as a time-stamp event marker. Pilots actuated a push-button at the start of each maneuver and notable event. This feedback was extremely helpful to data analysts as it could alert them quickly to a potential problem and help them to identify precisely when in the flight profile the problem happened. This information gave analysts detailed information on where to look in the flight data and helped them better understand what specific anomalies, like sticky inhalation valves, look like in the breathing data.

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[11] “Bad breather” and “good breather” are subjective evaluations pilots give to specific aircraft in reference to the work of breathing and breathing disruptions they encounter in those jets. “Good breathers” allow more unencumbered breathing while “bad breathers” require increased effort or compensation by the pilot to obtain sufficient oxygen.

As another layer of flight safety, control room staff was in nearly constant communication with the aircrew during the flight and could assist with any in-flight emergencies, if needed. The interaction between the control room personnel were instrumental in validating the pilot's notes of maneuver times and conditions. Additionally, project scribes helped note pilot comments and anomalies, and captured maneuver times and conditions in real-time during the flight. These time-stamps were key to accurately parsing the copious amount of flight data for analysis.

5.2.5.8 Pathfinder Flights for Safety

AFRC Tech Brief process relied heavily on AFRC life support specialists and pilot expertise to design and integrate PBA hardware within the Support Aircraft Fleet. However, since these modifications involved the integration of critical pieces of new hardware directly in-line with the pilot's breathing system, the project advocated performing what are known as "pathfinder" flights. Pathfinder flights were used to safely gather flight data in a limited fashion to reduce risk and better inform the Tech Brief Committee for flight approval.

The purpose of the pathfinder flights were to assess VigilOX system compatibility with flight gear across anticipated flight envelope for follow-on testing, The rationale behind such flights is made based on the critical modifications being proposed and the understanding that the only viable way to evaluate this modifications is in flight.

These flights proposed the use of a two-seat F-15D, so that the front-seat pilot could be outfitted with the proposed AFE design, modified with VigilOX, and the rear-seat pilot could serve as a safety pilot in the event of some unforeseen issue with the new breathing system during flight.

5.3 Aircraft Instrumentation Systems

5.3.1 Teletronics Technology Corporation (TTC) Data Recorders

The support aircraft were outfitted with flight data instrumentation systems referred to as "TTC recorders" for recording aircraft parameters with two removable solid-state recorder cartridges to facilitate the process of downloading flight data after every sortie. The TTC recorded the aircraft Memory Unit (MU) data and derived parameters of interest to PBA.

5.3.2 NAVAIR QIK System

Figure 5.6 shows one of the aircraft recorders used in PBA, referred as the "QIK System", courtesy of the USN NAVAIR China Lake, CA. F/A-18 850 used such a system, which was designed, built, and flight tested by NAVAIR. The QIK system used standard communication and power protocols that interfaced efficiently with the F/A-18 aircraft systems.

Figure 5.6. USN QIK System on F-18, TN850

5.3.3 Integration Challenges

The most significant challenge in using the SAF was the difference between platforms in terms of data instrumentation capability. Some support aircraft were equipped with very mature data systems, some with limited capability and some with none. In addition, the parameters stream on the 1553 bus varied from one aircraft to another. For example, some aircraft could record an important parameter called “weight-on-wheels”. This parameter was useful to the analysis team by automating the data analysis process to define the duration of a sortie. However, several support aircraft did not record these parameters, making the use of scripts for automating data analysis more challenging. In the end, analysts chose the necessary and sufficient data streams common to four different platforms and worked with instrumentation engineers on a common naming convention for all data.

5.4 Flight Data Management Plan

New data management processes were developed to support the large number of PBA-unique human data systems, aircraft instrumentation, and time-alignment and synchronization requirements for these disparate systems. Due to the complex operating model (see section on the pilot proficiency model), the PBA/AFRC project team members across the center needed to be assembled often very quickly to align with the pilot/aircraft availability flight rule. In addition, the use of multiple aircraft with varying degrees of instrumentation capability posed challenges in the data management processes at AFRC.

Figure 5.7 shows the data workflow process developed to support the unique requirements of PBA. The flowchart defines the element work-flow, from the early flight planning stages to the ultimate uploading of all datasets required by PBA analysts.

The process starts by developing the bi-weekly plans for data gathering, culminating with all the flight datasets uploaded to PBA data servers and available to analysts. The chronological flow of each task is defined as well as the organizations and responsible personnel performing the tasks. Data from VigilOX (.csv format), spirometry/capnography, life support reports, aircraft data (in MatLab .mat, .csv, and Section 10 formats), communication audio files, and copies of flight cards are downloaded, processed, and uploaded to the project data server within 24 hours of the completion of a flight.

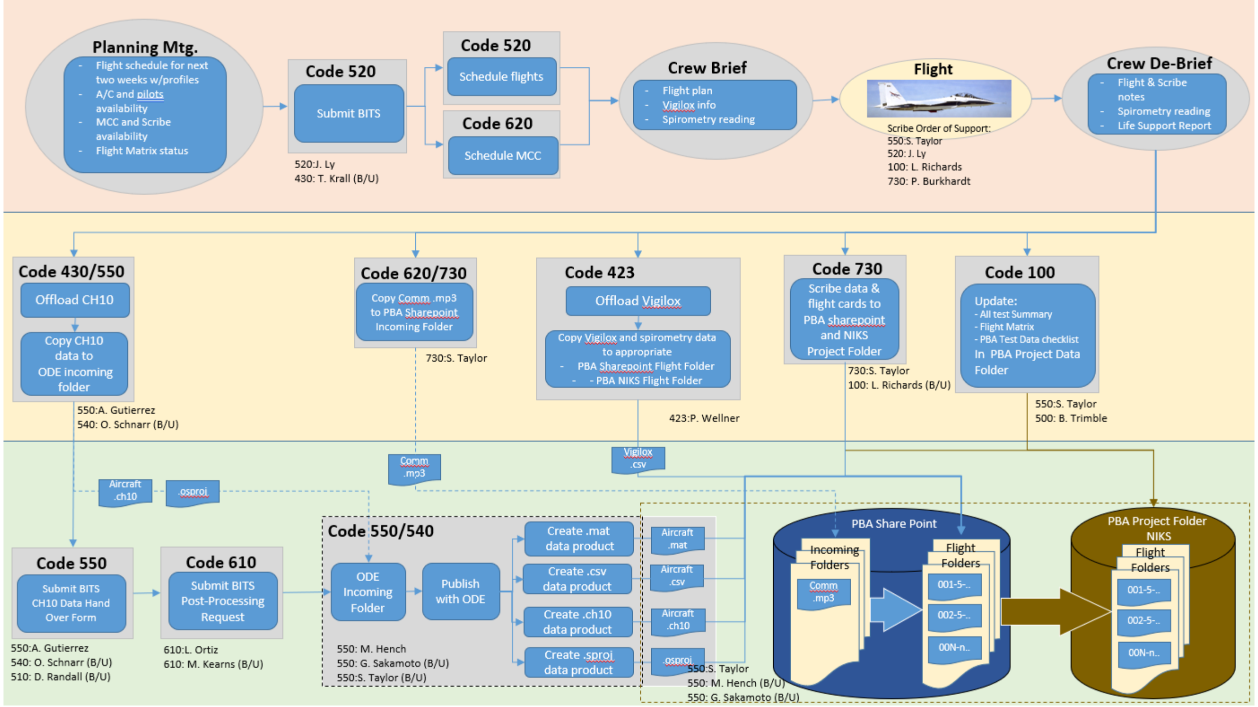


Figure 5.7. Workflow data delivery process.

5.5 Tech Brief Summary

As described in Section 5.1.2.2, Tech Brief process, as defined in AFG-7900.3-001was followed to incrementally roll-out PBA test systems and methods as they were being developed. Tech Briefs were also given for an unexpected result occurred during a PBA flight. A final Tech Brief was given to gain Center approval to fly the JPL IMCWS. Table 5.2 shows the Tech Briefs given by PBA project to AFRC Technical Briefing Committee. In most cases, the successful completion of the tech brief resulted in the approval for another block of flights.

Table 5.2. Summary of Tech Briefs Given for PBA Flight Clearance

Date	Purpose of Tech Brief	Category
5/21/2018	Approval of Pathfinder Flights	Tech Brief
7/24/2018	Approval of PBA Phase 1 (F-15/F-18, VigilOX, USAF AFE)	Tech Brief
10/9/2018	Approval of Spirometry and USN AFE	Mini-Tech
2/21/2019	Unexpected Flight Results: Flight 29; Approval to Resume Flying	Tech Brief
4/15/2019	Approval to Fly Madgetech Pressure Sensor	Mini-Tech
5/20/2019	Approval of PBA Phase 2 (Refined Priorities and Methods)	
12/5/2019	Approval to Fly Profiles E & H	Tech Brief
3/2/2020	Approval to Fly Modified USN Regulator	Tech Brief
6/18/2020	Approval to Return to Center and Resume PBA Flights	Tech Brief
7/23/2020	Approval to Fly JPL Mask	Tech Brief

Such modular and iterative design allowed the investigation process to branch in whatever direction was necessary as informed by newly acquired trends, findings and formation of hypotheses.

5.6 Summary

This section provided the detailed procedures for implementing a systems engineering study that includes the human measurement component on equal footing with all other engineering subsystems. In addition, the section discusses the human studies aspects and the approval processes. This was possible because AFRC personnel were uniquely qualified as they perform flight test research as part of the mission which includes life support and medical expertise. At AFRC, the typical mission revolves around testing aircraft individually in a vertically integrated procedure. The PBA variant multiplexed this approach to allow for statistically relevant analyses through the use of multiple aircraft, multiple pilots, and multiple flight profiles coupled with a repeat test framework.

Relevant Document for Aircraft Missions

Authority Documents
NPR 7120.5 NASA Program and Project Management Processes and Requirements
NPR 7123.1B NASA Systems Engineering Requirements

Referenced Documents:
NASA/SP-2007-6105 NASA Systems Engineering Handbook
AFG-7120.5-001, Baseline-5 Project Chief Engineer's Handbook
AFG-7123.1-002 Objectives and Requirements Document Handbook
AFOP-7900.3-013 Flight Activity Scheduling
AFOP-7900.3-023 Airworthiness & Flight Safety Review Process
AFOP-8715.3-005 Hazard Management Procedure
AFOP-7900.3-024 Flight Operational Readiness Review (ORR)
AFOP-7900.3-022 Tech Brief (T\B) & Mini Tech Brief (Mini T\B)
NASA-STD-3001, NASA Space Flight Human-System Standard, Vols 1 and 2.

6. PBA Tools and Findings Related to Systems Engineering

Introduction

The military jet environment is different from passenger aircraft in that it experiences high rates of change in altitude, velocity and high G-forces. Thus, the jet environment, the ambient pressure in the cabin, oxygen supply lines and pilot breathing need to be studied together as a system.

6.1 Systems Interactions

The cabin environment is acting on the pilot, and the dynamic pressure is changing the cabin pressure to a greater extent than previously understood.

6.1.1 Modeling Dynamic Pressure

Data shows that cabin pressure is much more varying than the cabin pressurization schedule calls for. Non-altitude related cabin pressure changes were documented in all altitude bands, including the Isobaric designated regions of the Pressure Schedule (Figure 4.14) spanning between 8,000 to 23,000 ft.

To capture the extent of dynamic pressure acting on the pilot (and on environmental control) the team studied the effects of dynamic forces below 8,000 ft, void of the engagement of any cabin pressurization. Of interest is the highlighted dynamic segment with a straight-and-level Mach 1 portion followed by a 360 turn G-load combination (Figure 6.1).

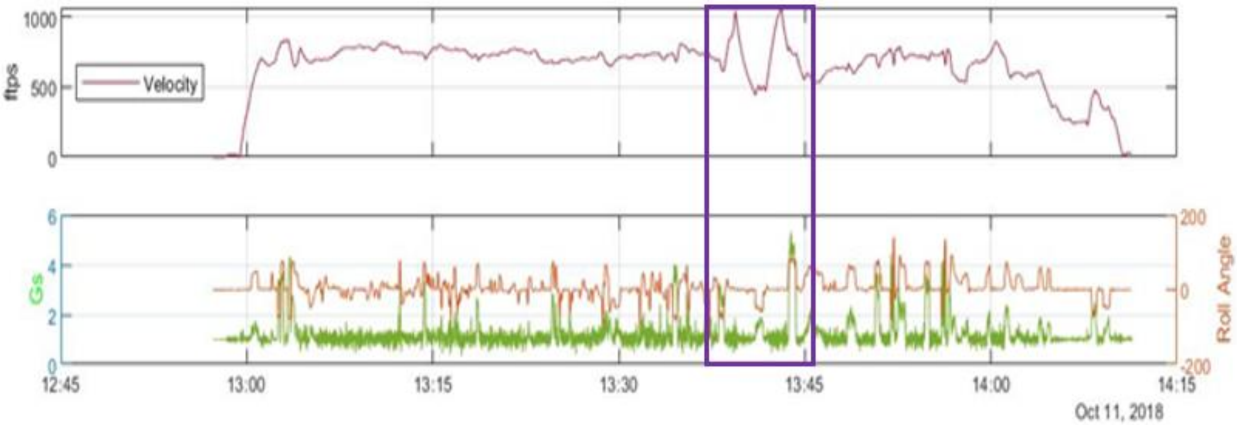


Figure 6.1. Profile D represents a low altitude flight with a maneuver of varying velocity to Mach 1, change in G load and Roll angle, highlighted in the boxed region.

The effects of dynamic pressure are captured by applying “first-principle” **modeling, a very useful system’s engineering tool**. With the following formula we can approximate, with the current data streams, the pressure felt in the cabin.

$$Total\ Pressure = Static\_P + Dynamic\_P = Static\_P + a*Velocity^{x} + b*G + max\ (k*roll,\ m*pitch)$$

Formula 1

The efficacy and necessity of the Dynamic Pressure Formula are demonstrated in the “before” and “after” agreements of ambient (outside) pressure and cabin (inside) pressure in an unpressurized zone (Figures 6.2 and 6.3)

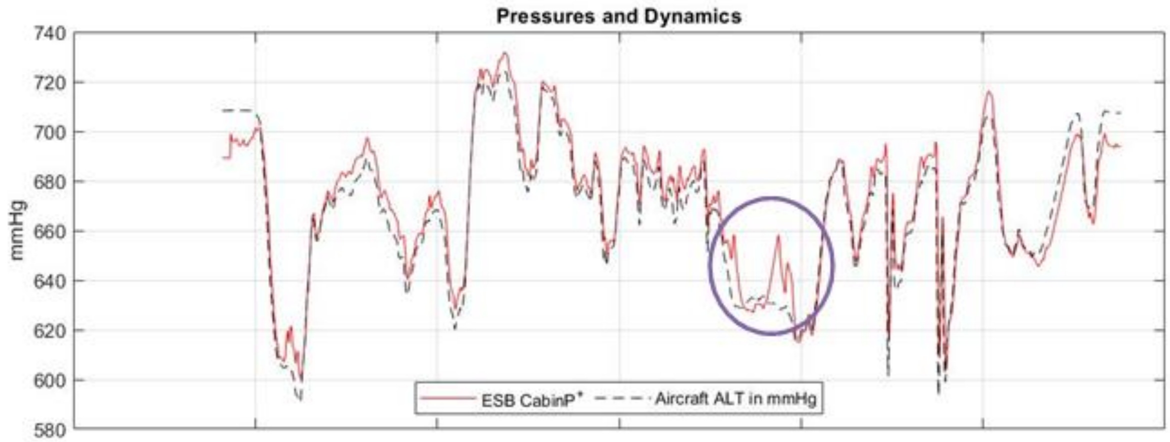


Figure 6.2. Raw outer and inner pressure data. Before applying the dynamic pressure formula, the ambient and cabin pressure signals do not match/overlap in the circled region.

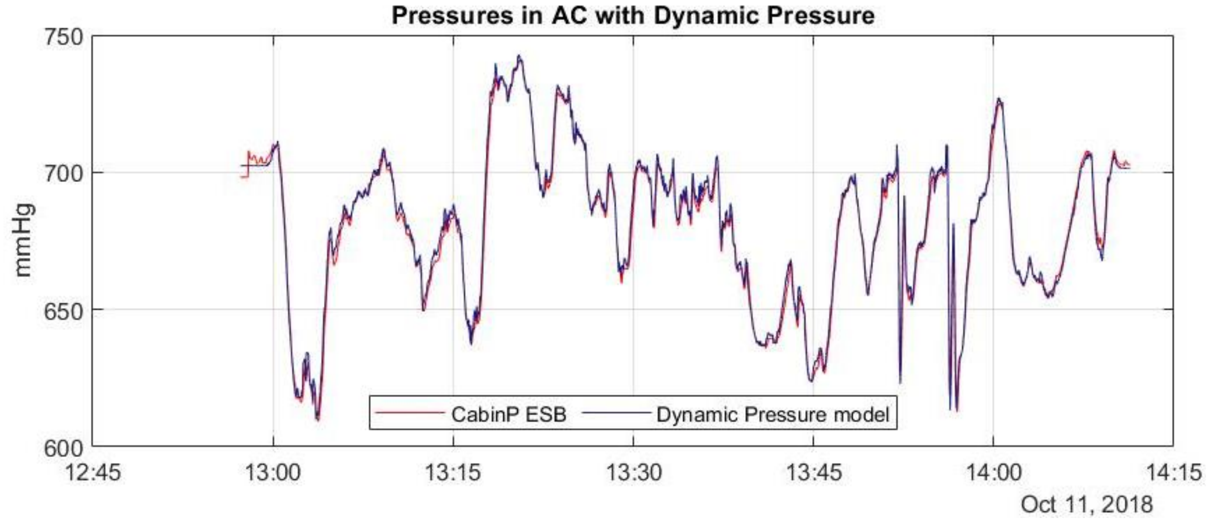


Figure 6.3. After applying Formula 1, Static + Dynamic pressures match the measured cabin pressure.

Before the total pressure formula, the cabin pressure and aircraft altitude converted to pressure do not overlap in the circled region of velocity and attitude change. The 1st divergent peak is caused by rapid acceleration to Mach 1; the 2nd was over velocity change and a 360 turn, adding G load. 30 mmHg difference is 10x the pressure change of an inhale, and is **equivalent to 1,500 ft change in altitude acting on the pilot.**

In the chain of events, the F/A-18 reference pressure sensor senses the added pressure in the most sensitive location of the aircraft, located in the Nose Wheel Well (Figure 4.11). Partial pressure oxygen is adjusted in accordance with cabin pressure, to deliver the scheduled O_2 concentration. A change in partial pressure O_2 changes the oxygen absorption in cells, CO_2 and blood pH, creating conditions for hypoxia.

These changes due to dynamic pressure acting on the aircraft, were later independently confirmed by Boeing, who produced their independent formula to predict such pressure changes.

The second example of dynamic pressure comes from an isobaric region, through which the cabin is to maintain pressure equivalent to 8,000 ft for altitudes up to 23,000 ft. Data shows that this is only the case as long as there are no sudden changes in velocity, Gs or attitude. Notice in Figure 6.4 how the cabin pressure trace follows the G-Force curve and does not stay isobaric.

The takeaway from both scenarios (Figures 6.2 and 6.4) is that pilots of dynamic jets experience **pressure transients in the cabin a lot** more than presumed by the pressure schedule. This is crucially important because the **pilot's oxygen regulator works off a reference pressure**, taken from the cabin ambient environment.

Analysts "learned" to anticipate the movement of the cabin pressure signal when associated with maneuvering. However, **another, higher frequency pattern emerged, which did not line up with physical changes** (see ESB Pressure signal in Figure 6.4.a).

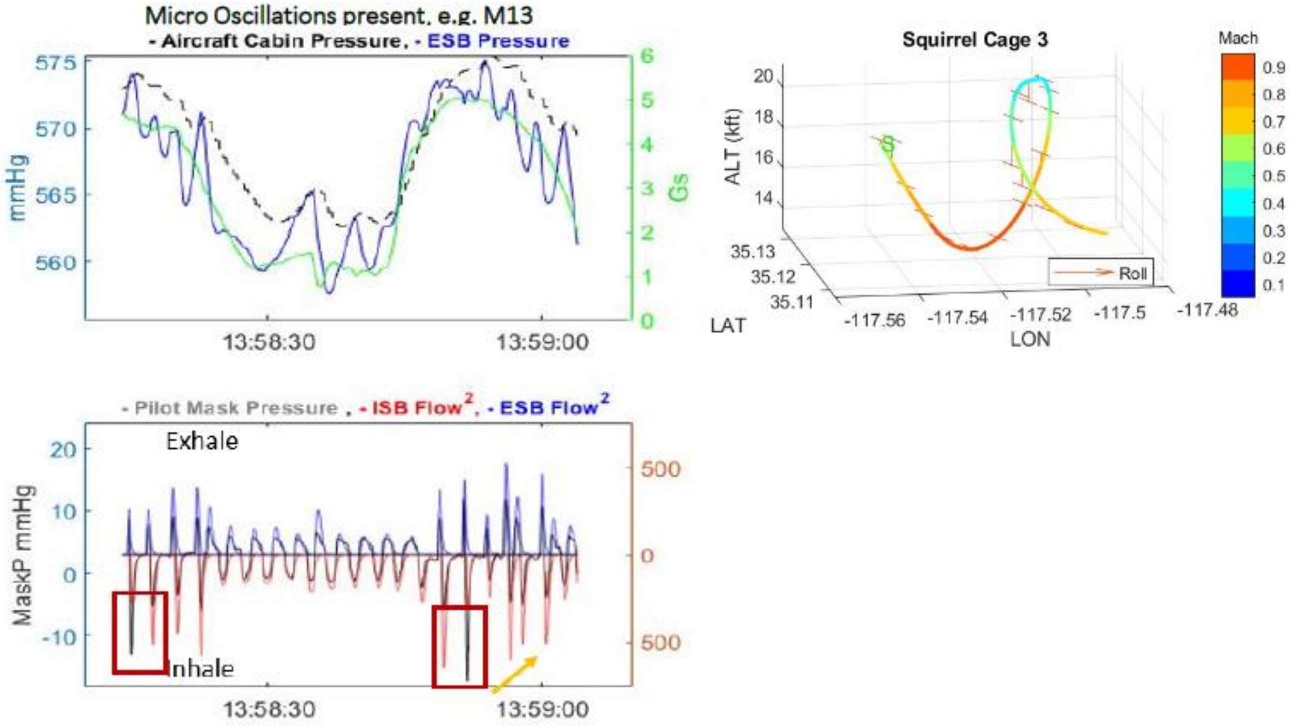


Figure 6.4.a, b, c (clockwise). A. The mathematically smoothed cabin pressure (dashed line) follows the trend of the green line representing changing G levels as modeled per our formula. The true, unfiltered cabin pressure is further disturbed by an oscillating signal with the amplitude of human breathing. B. Shows the pressure change is occurring in an isobaric region. C. Pilot air delivery is negatively impacted as shown by the mismatch of pressure and flow.

6.1.2 Micro Oscillations are a Control Problem

What is the cause of micro-oscillations (Figure 6.4.a)?
To answer this question, we follow the air flow through the aircraft. In the F/A-18 legacy aircraft air continuously flows through the avionics and cabin from the intake bleed air. Per engineering drawings, the cabin has an exit valve(s), with set points at the 8,000 and 23,000 ft equivalent pressure, and the exit valve lets out the amount of air to keep the cabin on the pressure schedule.

However, if the valve adjustment is out of calibration, when the steady state is disturbed by an external force (dynamic pressure), the mechanical control can over-, then under-compensate. As there is no other feedback, this oscillating state persists.

6.1.3 How Do Micro-oscillations Affect the Air-Delivery System?

The oxygen regulator, in this case a finely tuned CRU-103, is designed to set a 3-mmHg positive pressure, *relative to ambient*. The pilot as he/she inhales/ exhales, creates a differential pressure signal. The pilot's signal then adds with the cabin pressure which itself is oscillating. These 2 signals can add constructively or destructively, as in Figure 6.4.c.

Looking at the data channels again as a system, and looking in the 4th temporal dimension as well, these "micro-oscillations" were either triggered by or exacerbated by abrupt throttle movement, or at the end of a dynamic maneuver, and were sustained in a pressurization system which had difficulty reaching or returning to steady state.

The key in the above lesson is "reference pressure." Though the pocket of air inside the regulator will eventually equalize to the cabin pressure, instant pressure upsets act at different rates on the cabin, reference pressure and the human, creating these transient of non-equilibrium and pressure-flow disharmony. During G-breathing, the ramp-up half of the trained, short inhalation is less than a half second long. If the right volume of air does not reach the pilot in time, the pilot perceives difficulty breathing (see discussion on Flight 29).

Taking the systems approach, parts of the system involved in the cabin pressure micro-oscillations are identified, being acted on by a dynamic force upset:

- Pressure sensor in the Nose Wheel Well (NWW) serving as reference pressure for the cabin environment
- Derivative of bleed air incoming to the cabin
- Cabin Exit Valve
- No feedback in the Control Loop → persistent Micro-Oscillations in Cabin Pressure

A misadjusted valve can create an underdamped response, and due to the ongoing assault of dynamic forces, this oscillation perpetuates. This effect is compounded by the inaccuracy of a 2nd reference pressure found in the pilot's oxygen regulator.

Theses interactions become a lot more complex once we add the pilot and the breathing system, in the presence of micro-oscillations acting on pilot breathing (CRU-103 example)

- Pressure sensor in NWW serving as reference pressure for the cabin environment, with dynamic pressure upset
- Derivative of bleed air incoming to the cabin
- Cabin Exit Valve → oscillating cabin pressure
- Pilot (breathing) demand pressure (change) in mask, differential pressure
- Mask Inhale/ Exhale valve (depending on the design)
- Supply line experiencing a net pressure change
- Oxygen Regulator, body mounted, with compartment for reference pressure, not updating at the same rate as cabin pressure and supply line pressure
- Safety pressure mechanism (additional compartment and balanced spring in the regulator)
- Response air flow

Both above examples are depicted in a control diagram form in Section 4. The net effect of pressures acting on the LSS (inconsistent reference pressures in a rapidly changing environment, lack of control) is causing the pilot not receiving the air he/she needs, when he/she needs it.

Further, cabin pressurization could be a problem for an entire, or even multiple flights, and as there is no feedback, it never corrects itself. The amplitude of these oscillations is not large enough to show up on the analogue altimeter or cause a feeling of falling, but they are the exact right amplitude of a breath, thus just large enough to interfere with the breath supply. **Without real-time or post-flight monitoring, this no-feedback control problem can persist.**

6.2 Cross Cutting

6.2.1 Can Cabin Pressure Health Be Quantified?

Applying tools from mathematics and Electrical Engineering it is possible to find these "bad breather" airplanes (definition in Section 5.2.5).

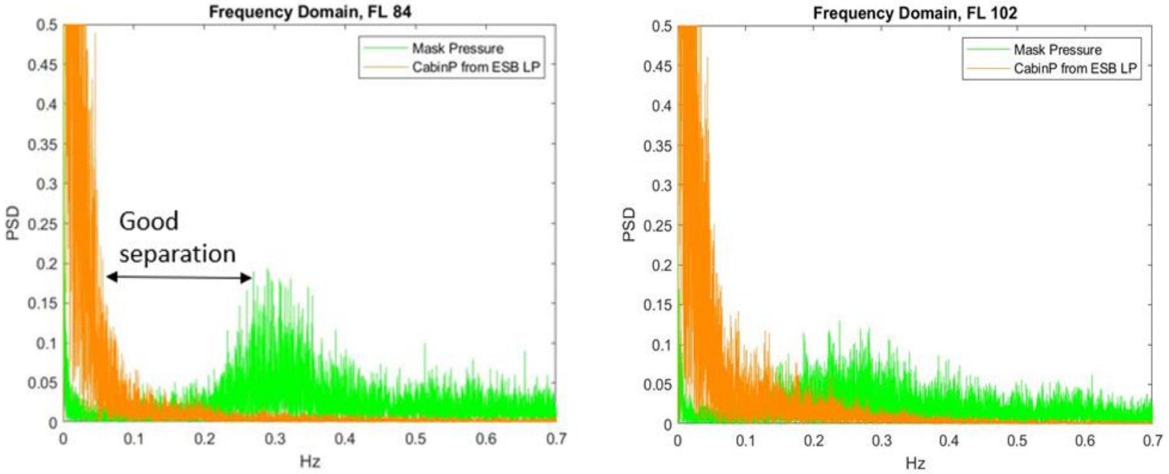


Figure 6.5 a. and b. A. is an example of a "good breather jet" with the orange mechanical signal not interfering with the green cadence of breathing. B. is an example of cabin pressure micro-oscillations, and a more spread, somewhat overlapping frequency of breathing.

In this first **cross-cutting** example, the team applied the Fast Fourier Transform (FFT) to break out the frequency components of the aircraft's cabin pressure variation. In a healthy aircraft, the cabin pressure change should be non-cyclical. The novel approach is that in this **model**, the team bridged the human-machine divide with FFT applied to electro-mechanical signals and applied them to human breathing/ physiology. The overlap of the two power spectra is a powerful tool to spot machine interference on human breathing.

Conclusion: cross-cutting as applied to modeling is a powerful systems engineering/ analysis tool. Pressure power spectrum is a "fingerprint" for jets and can help with preventative maintenance.

6.2.2 Cross Cutting Example 2. Breathing as a Signal – Phase Shift between Human and Machine

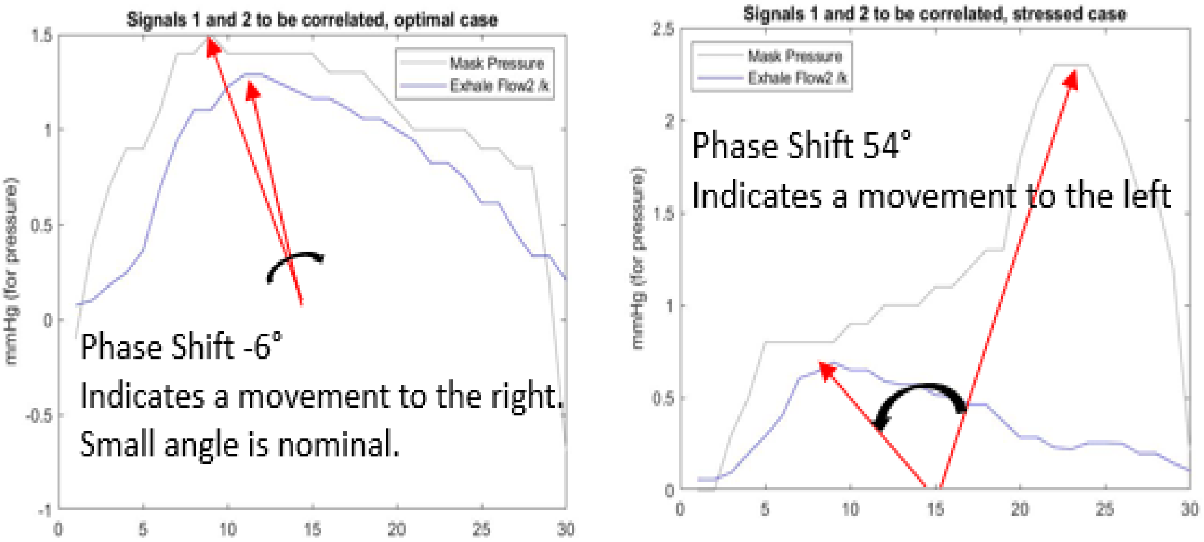
Description of the subsystem for this tool

- Mask Pressure – demand signal from the human
- Air flow (due to the sensors, inhalation and exhalation are two separate flow signals)

Analysts applied an Electrical Engineering toolbox to Human Physiology. The two coupled signals representing demand and response, should overlap in a well-adjusted system.

The Mask Pressure represents the Human signal, the Flow is the machine Response

A correlation tool returns delay in response from delta pressure to flow, in Time domain → normalized per breath length → yields Phase Shift as a numerical tool for characterizing the LSS. Effects of micro-oscillations also increase the phase shift (e.g., FL29).



Phase Shift -6°
Indicates a movement to the right.
Small angle is nominal.

Phase Shift 54°
Indicates a movement to the left

Figure 6.6. Ideal Phase Shift (left): pressure and flow lines should overlap with small lag. The Phase Shift Tool spots Pressure build-up (right, positive phase shift shown) or slow response (when shift is large and negative).

This tool can be used in the SE process to help validate a LSS design. Distributions are characteristically different for different AFE, which includes oxygen regulator design. Examples below.

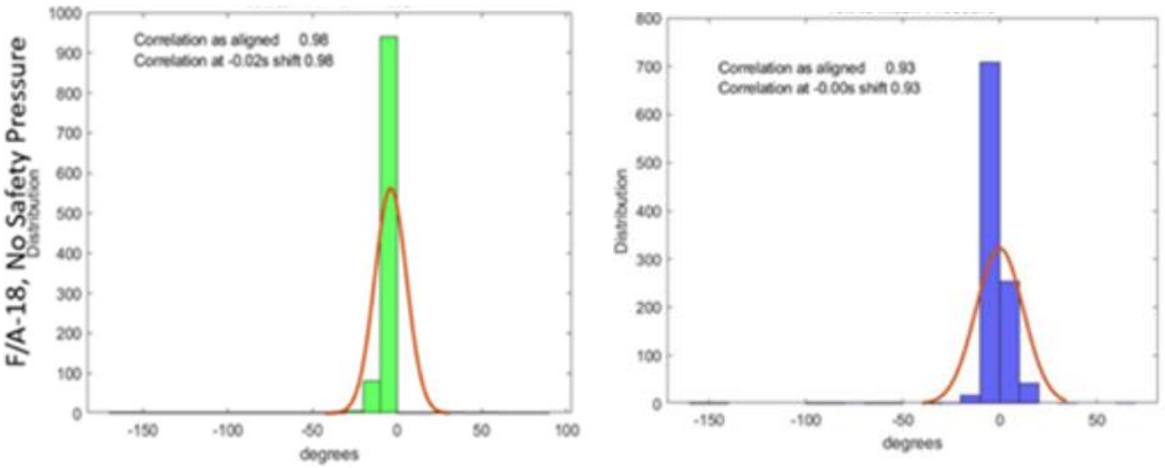


Figure 6.7. Flight 90, ideal, low Phase Shifts in USAF configuration with CRU-73 regulator. Most breaths fall into the [-10, 0] bin.

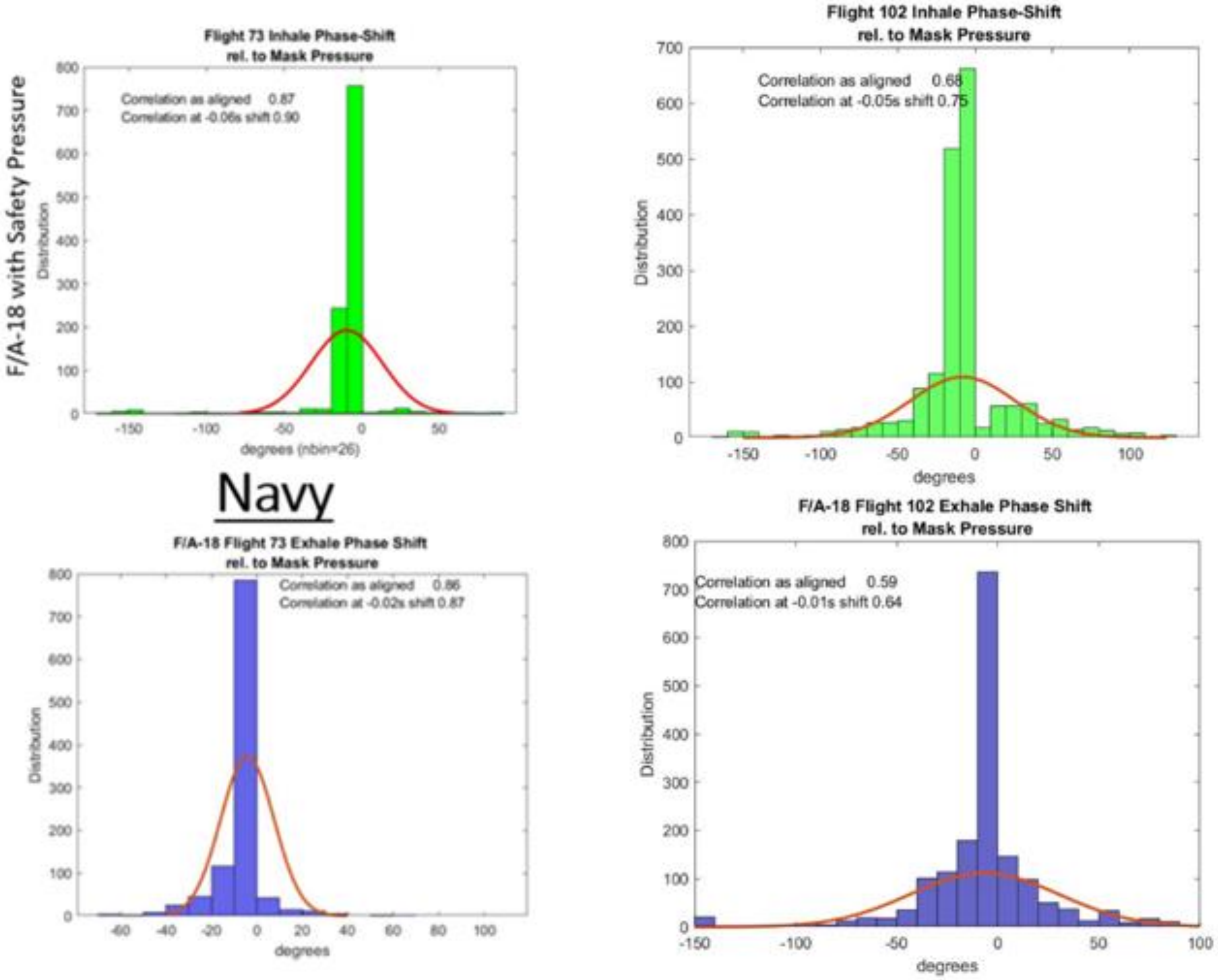


Figure 6.8. Examples of the more sluggish CRU-103 on a healthy jet (left) and same regulator compounded by the presence of micro-oscillations (right) means a worse breathing experience for the pilot.

6.3 Systems Analysis - Connecting Human Demand- System Response

6.3.1 Can the merit of a regulator design be visualized/quantified? Sub-Systems Analysis - Connecting Human demand- System Response. Hysteresis

The LSS is always one step (mostly less than 0.1 second) behind. As the pilot ramps up his inhalation, the flow he/she experiences is matching his delta pressure from an instant ago. As he/she ramps down, he/she is still getting the high flow rate matching the previous instant. This plots as a function that is not 1-to-1, and the max distance between y values is hysteresis (Figure 6.9).

Description of the subsystem in this analysis:

- Line Pressure (pilot demand is one component, translated)
- Cabin Pressure
- Air Flow

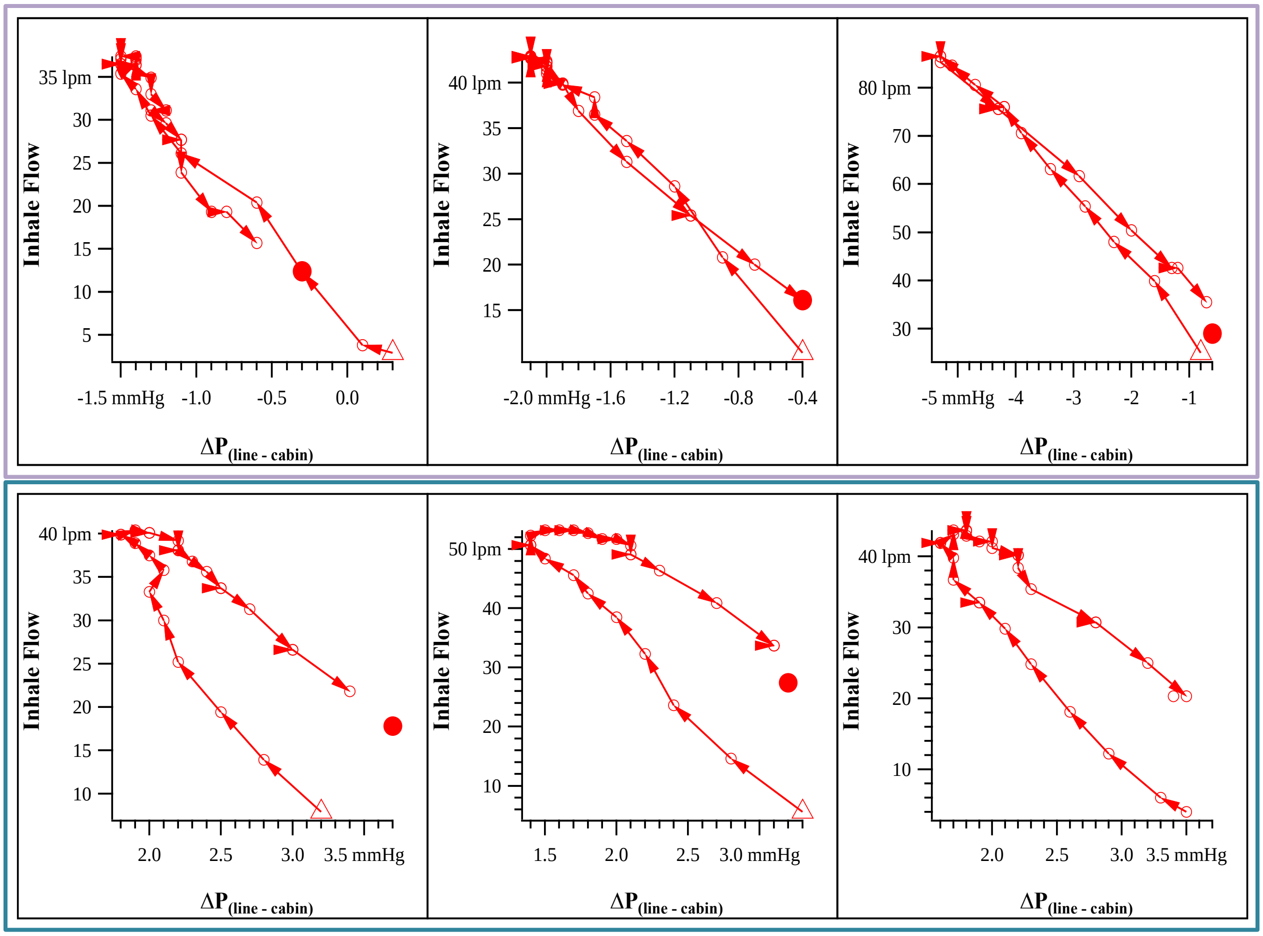
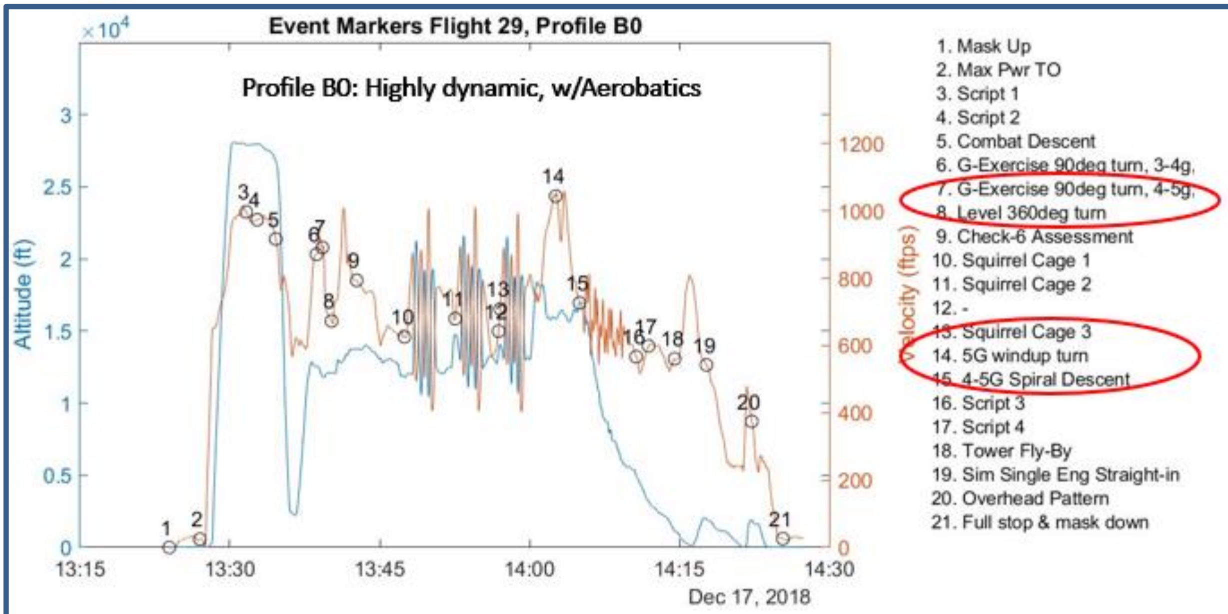


Figure 6.9. Characterization of 2 AFE designs. The AF diluter demand regulator CRU-73 (top) is closer to open air breathing; the Navy-used regulator CRU-103 (bottom) with safety pressure is a bit more sluggish. As there is a delay in delivery, less air is delivered in the ramp-up phase and more in the ramp-down phase, their difference being the mathematical definition of hysteresis.

6.3.2 Putting it all Together: Using PBA Tools for Causal Analysis for Flight 29

Flight 29 was flown on December 17, 2018. It was the pilot's 5th flight with VigilOX. His previous flights were using the Air Force CRU-73 AFE; Flight 29 was with the Navy-used CRU-103 oxygen regulator with safety/ positive pressure. This was his 1st dynamic profile B.

As a credit to pilot subculture, as we now know, the pilot felt difficulty breathing on 5 occasions through the flight, highlighted in Figure 6.10.



- M7: “Could not exhale completely. It was more difficult than normal to exhale quickly through the mask. Felt as if exhaling against a partially closed valve or having to exhale against positive pressure.”
- M8: “Difficult to exhale completely in a quick fashion. Very hard to take a “quick breath” due to extra time required to exhale breath completely. Under g-force, this resulted in a partial exhalation and ensuing partial inhalation therefore an “incomplete breath.” This resulted in several partial breaths and eventual oxygen starvation. Quick, full breaths under g were not possible.”
- M13: “Could not exhale completely in a short period of time (as if the exhale path was partially blocked).”
- M14: “Ran out of oxygen due to partial breaths due to trouble exhaling quickly. I could not have continued this maneuver much longer than 1-minute due to inability to get a full breath.”
- M15: “After 4 minutes, was out of breath and could not complete further.”

Figure 6.10. Pilot experiences difficulty breathing on 5 occasions, during elevated Gs. Completes dynamic profile with 1 maneuver cut short. Parts from the filed post-flight report are attached to bring in the human narrative.

Facts related to Flight 29 are:

- G maneuvers alone, in the 4 to 5 G range, are not a concern for seasoned test pilots, but it adds a strain onto the human and mechanical system. Inhalation is particularly short during G breathing, thus a small latency in air delivery can miss the inhalation on-ramp
- The CRU-103 regulator flown is an accepted design, but it is more sluggish than others (“tiring, a distraction”). Safety Pressure breathing takes some getting used to.

- Micro-oscillations contribute to low flight-health scores, but not always severe enough to be commented on by pilots. (Can go unnoticed, and manifest as fatigue). On tail 850 micro-oscillations were present through the flight.

Taking the above 3 items together as **multiple factors eroding reserves**, they create the circumstances for pilot difficulty breathing to occur on Flight 29. A perfect example of everything being in spec, yet together they caused a breathing problem to the pilot. (See Section 3.2, OTM)

Tying in the human physiology, as discussed in Sections 4 and 5, when the human system reaches a stressed state, and that has crossed cognitive awareness, he/she consciously adepts by increasing breathing rate or tidal volume/minute ventilation.

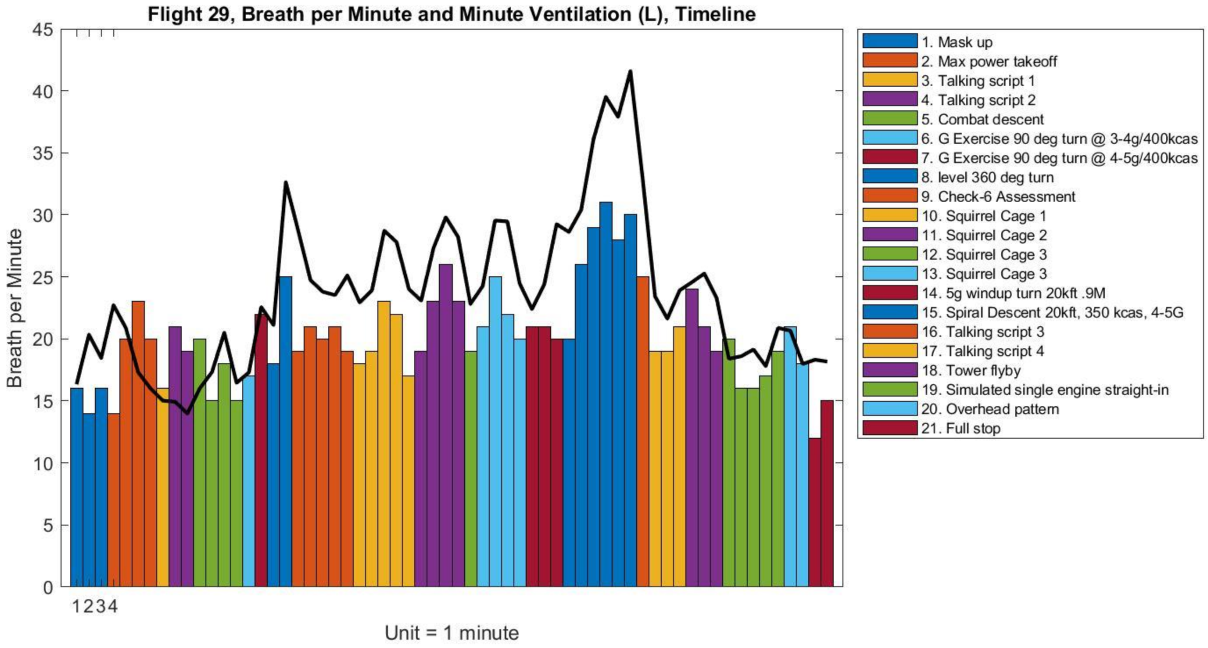


Figure 6.11. Flight 29 data ties in and identifies Markers 8 and 15 as the most stressful periods in flight. The pilot could not finish the full duration of Spiral Descent. Both Breathing Rate and Minute Ventilation are highest there.

Conclusion

The PBA tested the Human side and Machine side of the air delivery interface in different configurations to find disharmony and BSDs. These disruptions also manifested and breathing rate and tidal volume changes. A thorough understanding of subsystem design and functionality was necessary to set up the models and draw appropriate conclusions. Modeling systems interactions is a powerful design or test tool. It does not replace engineering or diagnostic knowledge, but rather it augments them by bringing them together.

6.4 Human Variability

Overview

Human variability must be considered during the experimental design phase in any experiment that involves a human or an item a human is expected to use.

> "While many people understand the concept of a human as being part of a system, what may not be appreciated completely is the highly variable, highly sensitive, non-deterministic nature of humans. In a functional overview of a system, engineers can predict with a good amount of certainty that a particular input into a pump, or valve, or resister, etc., will result in a particular output. There is typically minimal unit-to-unit variability across like hardware components that come from the same manufacturer. The same cannot be said about humans. This is what makes Humans Systems Integration particularly complicated and requires skills and expertise not often considered in the team composition early in the system development."
> – Dawn Schaible, Director of the Engineering Directorate at NASA Langley

Human variability is important to consider through the engineering lifecycle from requirements definition, design reviews, incremental testing and verification and validation. Human variability is the foundational consideration in human-centric research, ultimately, people are different and understanding, predicting, modifying those areas of variability requires particular attention. Some of the many areas of variability can stem from:

- Different Human
- Same Human on Different Days
- Different environment
- Different task
- Different equipment
- Inconsistent reporting
- Varied understanding of the questions

Even this level of human variability only describes the human variability with a few interactions of task, and with equipment. Figure 6.12 by Czair and Nadir (2012) provides a visualization to show that these Person-Task-Equipment interactions are just the first level and also play across each other.

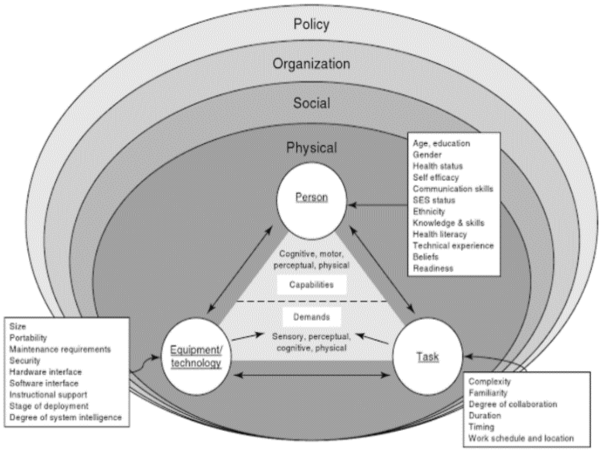


Figure 6.12. Person-Task-Equipment graph (Czair & Nadir, 2012).

Interactions also exist within, and are influenced by, several other layers including the environment set by the physical setting, social/culture, organizational mandates/culture, and local and global policies. If the researcher cannot control sources of variability, as is common in applied settings, collecting as much information about factors that typically induce variability then researcher can explain some of the variance and remove it. In doing so, the researcher can draw conclusions or predictions about how the human might be expected to perform in similar settings.

In this section, spirometry data are presented to look at the aspects of Different Human and Same Human Different Day. The effects of different environment, task and equipment are more difficult to decouple from this data set. Further conclusion from mixed effects modeling using the flight-data set can be found in the full PBA report. The pilots selected for the PBA study had very few initial individual differences. However, enough variability was observed that it was not reasonable to collapse across the pilot variable, meaning to consider all observations of the pilots as one data set with aggregate means, standard deviations, and maximum/minimum agnostic to individual pilot variability.

The sample of pilots for the PBA study had little variability in terms of obvious individual differences. All five PBA research pilots were highly experienced, male, and self-reported as Caucasian. The average age of pilots was 54.8 years with a standard deviation (Std Dev) of 2.56; height was 72 inches (Std Dev = 1.73), and weight in lbs. was 186.6 (Std Dev = 18.28). They were all graduates of USAF Test Pilot School, had an average of 17 years test flight experience, served between 2 and 5 years as flight instructors, and have each flown over 7000 hours across a variety of aircraft more than 3500 hours of which have been in high-performance jets in various configurations. These individuals all lived and worked near AFRC. Please see Appendix 9 in the Pilot Breathing Assessment report for a full discussion of other individual difference variables and specifics including diet, exercise, and hydration.

Why generalizability is important. Assumptions and limitations of the data.
Despite a seemingly homogeneous sample, the variability seen in the spirometry and SpO_2 readings was still great enough to preclude collapsing across individual, meaning to use all pilots as one data set without data consideration for the individual differences across pilots.

As reported previously, the scope of PBA was to measure human responses in a dynamic flight environment:

PBA Scope

- Pilot respiratory rates, tidal volumes, and air composition in high performance aircraft are not well understood or documented. Therefore, the intent of this assessment is to:
    - develop a process to measure these parameters that is standardized, systematic, and relatively easy to perform;
    - develop new instrumentation systems that are smaller, lighter, more capable, and more energy-efficient; and
    - assist in better understanding the causes of PEs.

PBA directly achieved the desired goal by developing new standards and methods to serve as a baseline for collecting, presenting, and analyzing data related to the use of the VigilOX and pilot breathing in flight. This technology achievement required observations across a wide range of variable combinations. The opportunity to collect other data on the ground became available and within the prioritized flight profiles. As these added features were not the primary goal of the study, it was not possible to conduct an experimental format featuring reduced variable conditions. Here, statistical significance testing was not possible, however, these data can be used for future hypothesis generation for focused studies that offer experimental control.

As these data were collected in an observational format during applied research, there were common limitations for this design. In this instance, these limitations included pilot availability, varied recent altitude exposure, equipment modifications, and inconsistency in Rad/Spiro/Questionnaire data collection application. Aspects of each of these elements have been previously known to impact human subject data observations and were collected for future exploration. This section will briefly mention in terms of the possible data impact (see Sections 5 and 9.1.2 for more information on constraints).

- The pilots task scheduling during the PBA testing period was not exclusive to one assessment. Many pilots flew in the 48 hours prior to data collection. These prior exposure flights had high variability in altitude, length, and g load. Summary information about those flights was collected and documented in aggregate in Appendix 9 of the PBA report.
- Equipment availability and modifications occurred due improvements to the VigilOX and the nature of the NASA fleet. This excluded any possibility of controlling for aircraft or VigilOX build. As now demonstrated by PBA, these aircraft have cabin pressure signatures and should be considered as a variable.
- Spirometry, Rad-97, and the questionnaire were initiated midway through the experimental data collection timeline. The Spirometry and Rad-97 had unique difficulties with the flight line setting and the collection protocol had to be improved.

To determine plausible explanations for data variations and generalizability or predictive relationships for human subject data, human variability must be considered and controlled for using a design that includes enough observations or sample. Considering these constraints, the result was a small data set with several variables with high likelihood for interactions and individual measures with high individual variability. The remainder of the section demonstrates that the human is already a variable and the inclusion of humans in an experimental loop requires greater variable control with an experimental matrix designed to target hypotheses of interest.

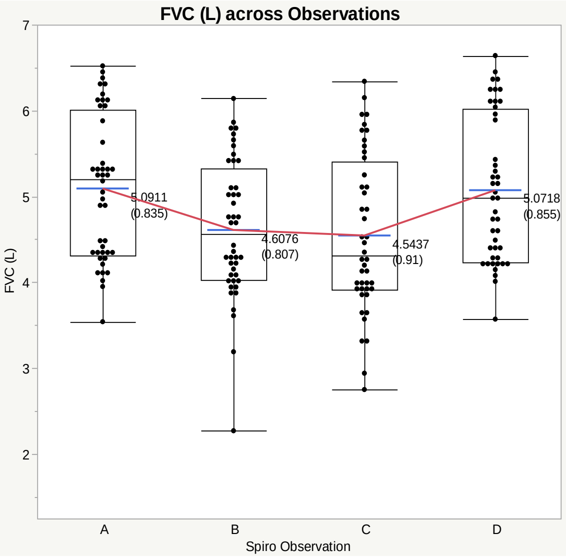
Forced Vital Capacity (FVC) Example

The data used for this example is the FVC data captured during the PBA study. The MIR SpiroDoc Spirometer with Breath Oscilloscope was used to measure pilot lung and breath volume changes. The observed FVC measurements were taken for pilots in the front and rear seat. FVC was captured on 55 flights with 11 flights excluded due to missing or erroneous observations across any of the four matched collection points (baseline, pre-flight, post-flight, recovery). All observations were assessed for accuracy and quality and 44 total sets were retained. The SpiroDoc was calibrated following the manufacturer guidelines prior to the first data capture associated with each flight. There are four associated FVC data observations per flight and captured at specific time periods per flight.

A. Baseline measurement taken in the **briefing room, without flight gear**, outside the aircraft.
B. **In gear, in the aircraft**, pre-flight.
C. In gear, in the aircraft, **post-flight**.
D. In the briefing room, without flight gear, post flight to represent pseudo-**recovery**.

All data are shown are raw values for demonstration. Differences from baseline (Delta) and unit standardization methods are commonly utilized for improved comparisons and were explored in this study, however, as shown in upcoming graphs, the sparse nature of the data and unequal observations with high variability reduced options for this data set.

The grand means of the raw FVC measurements are presented in Figure 6.13 showing individual observations in dots with boxplots. The means and standard deviations are recorded with a line drawn across means. There was a clear overall decrease from A (baseline) to B, a decrease to C, and a near-baseline return in D. The greatest mean drop of FVC occurs between the un-incumbered measurement A, and donning the AFE + sitting in the cockpit, B. Between points B and C, start and end of a flight, there is a lesser mean drop, but still lower than Baseline (A). Thus, the mean change is a negative change. At the pseudo-recovery point (D), the mean FVC returns close to, but slightly below, the Baseline (A).



FVC (L) N = 44

Spiro Test	Mean	Std Dev	Min	Max	Range
All	**4.83**	**0.88**	**2.27**	**6.64**	**4.37**
A	5.09	0.83	3.54	6.52	2.98
B	4.61	0.81	2.27	6.14	3.87
C	4.54	0.91	2.75	6.34	3.59
D	5.07	0.86	3.57	6.64	3.07

Figure 6.13. Mean FVC across all four timepoints showing individual observations with overlaid boxplots.

Figure 6.14 shows the same information as above, but with information broken out by pilot: the raw FVC measurements with individual observations and boxplots with across observation time point by pilot. The mean, standard deviations, minimum and maximum observed, and the range between the minimum and maximum are shown in table format. Most pilots show a decrease in FVC across observation periods with the largest being between the A (Baseline - no gear briefing room observations) and B (observation in the gear in the aircraft). However, this variance is not equal. For example, compared to the variance observed in the sample pilots, pilot 12 shows very little overall variance across the flight period observations and across the observations in the experiment with his min-max range across observations being 1.03. At the other end of the spectrum, pilot 28 shows the largest variance with a minimum/maximum range across observations at 3.1. Beyond range, the pilots had a range of personal norms with pilot 12 among the constant lowest and pilot 21 among the constant highest.

Pilot	**Spiro Test**	**Mean**	**Std Dev**	**Min**	**Max**	**Range**
12	A	4.21	0.23	3.54	4.48	0.94
	B	4.07	0.2	3.61	4.43	0.82
	C	3.98	0.24	3.57	4.46	0.89
	D	4.22	0.22	3.57	4.57	1
21	A	6.2	0.19	5.88	6.52	0.64
	B	5.58	0.33	4.76	6.14	1.38
	C	5.74	0.34	5.06	6.34	1.28
	D	6.24	0.2	5.94	6.64	0.7
28	A	5.09	0.2	4.89	5.37	0.48
	B	3.71	0.88	2.27	4.69	2.42
	C	3.36	0.48	2.75	3.92	1.17
	D	4.84	0.18	4.63	5.12	0.49
55	A	5.24	0.11	5.05	5.31	0.26
	B	4.92	0.19	4.7	5.11	0.41
	C	4.74	0.34	4.35	5.25	0.9
	D	5.31	0.33	5.05	5.89	0.84
71	A	5.36	0.19	5.22	5.63	0.41
	B	4.95	0.14	4.77	5.09	0.32
	C	4.87	0.25	4.52	5.06	0.54
	D	5.26	0.2	4.98	5.43	0.45

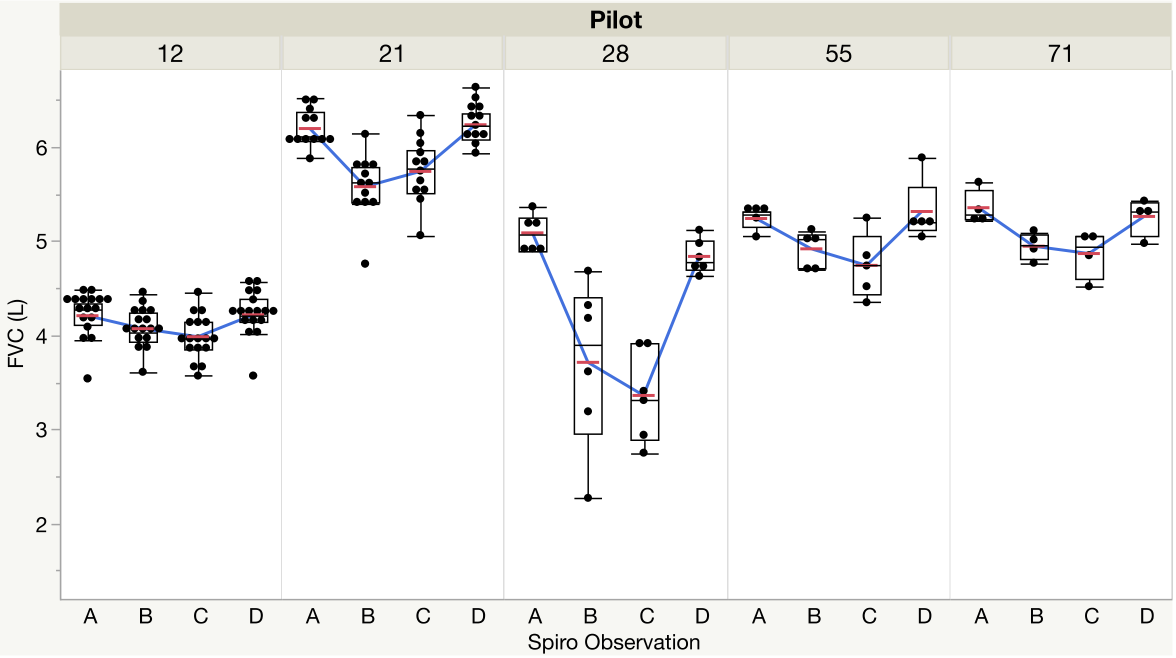
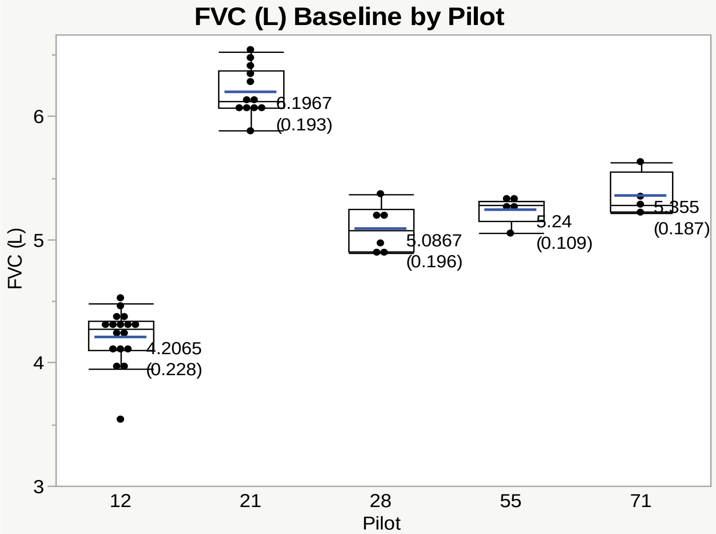


Figure 6.14. Raw FVC measurements with individual observations and boxplots with across observation time point by pilot.

Looking at pilot FVC baselines are especially informative because it decouples effects of gear or the upcoming flight. Figure 6.15 shows the raw FVC measurements with individual observations and boxplots at Baseline (A) by pilot. The mean, standard deviations, minimum and maximum observed are shown in table format. This demonstrates that natural variability at Baseline (A) between pilots (different pilots) and within pilots (same pilot different day). The lowest baseline mean being pilot 12 at 4.21 L (Std Dev = 0.23) and the highest baseline mean being pilot 21 at 6.2 L (Std Dev =0.19). This is the kind of variability to consider as all humans have a natural range of any physiological function that varies throughout the day, day to day, and across their life. The human itself is a variable and prediction of that human under different settings at different times requires particular kinds of testing to predict and account for in the study. Regarding systems engineering and requirements generation to enable human performance, inter-personal and intra-personal differences must be considered.



FVC (L) Baseline by Pilot

Pilot	N	Mean	Std Dev	Min	Max
All	**44**	**5.09**	**0.83**	**3.54**	**6.52**
12	17	4.21	0.23	3.54	4.48
21	12	6.2	0.19	5.88	6.52
28	6	5.09	0.2	4.89	5.37
55	5	5.24	0.11	5.05	5.31
71	4	5.36	0.19	5.22	5.63

Figure 6.15. The differences in baseline measurements of FVC of 5 pilots.

The standard deviation of the means is 0.83 L. Intra-personal variability was itself varying between 0.26 to 0.94 L. The greatest difference impacting design is the 2.98 L between the extrema.

Figure 6.16 shows the overall experimental matrix for the FVC flights captured and broken down across three main variables of interest: Profile, Pilot, and Flight Crew Configuration. The spirometry was finalized for collection and implemented in Phase 4 of the PBA which included the second batch of flights. Other measures that did not include spirometry, SpO_2, and questionnaires were collected throughout and have a different distribution. The primary driver for Phase 4 was to complete the original flight matrix. Therefore, specific priorities were flown, along with certain flight profiles and pilot combinations repeated to replace Phase 2 flights with compromised data. Comparisons directly targeting spirometry were not available, but the opportunity to collect any spirometry data was beneficial.

The natural limitations of this applied development work such as pilot availability, additional flight profiles, and spirometry timing/protocol development meant that there were unequal or unobserved areas of the matrix. The human variability shown above coupled with sparse or missing samples meant the team could not confidently surmise other possible hypotheses related to profile or equipment configuration from this data set.

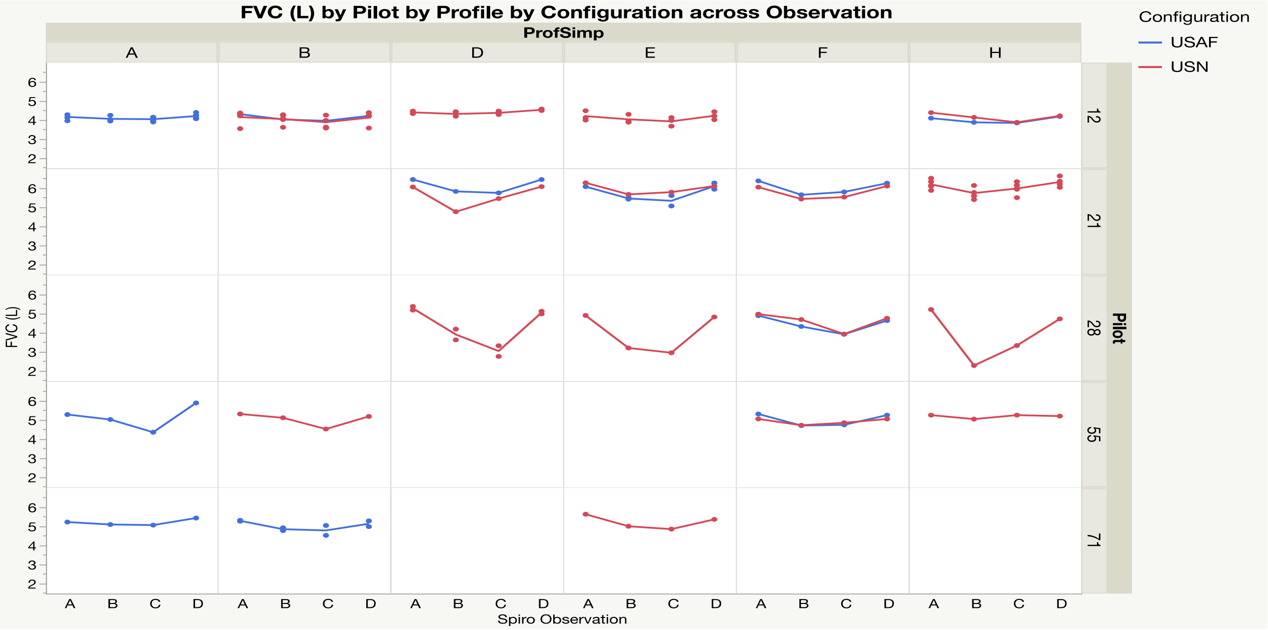
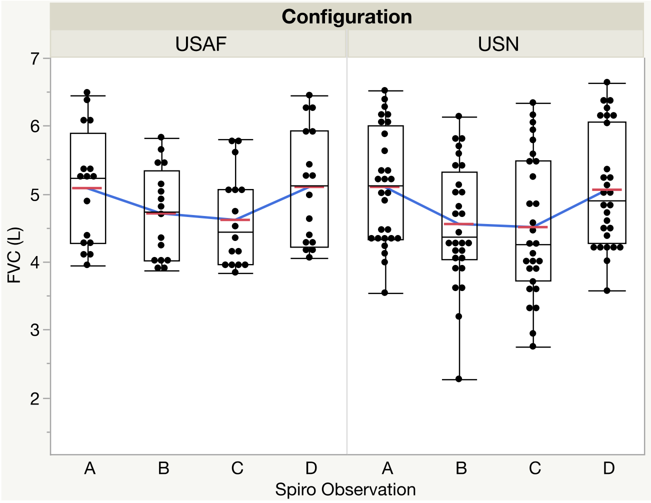


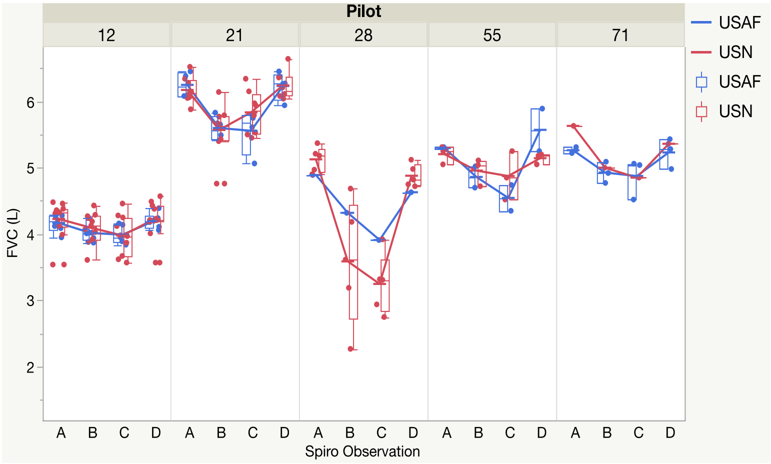
Figure 6.16. PBA observed FVC experimental matrix by pilot, profile, and equipment configuration.

A balanced experimental matrix is required for Human in the Loop Research to draw accurate conclusions. The spirometry data has observation gaps and unequal sample sizes. This is important to consider because if a researcher solely reviewed each of these elements individually, incorrect conclusions could easily be made. As an example, for spirometry measurements, profile A was only flown in USAF configuration and, due to availability, did not happen to include pilots with typically high (21) and typically variable (28) FVCs. Profile H was primarily flown in USN configuration and did include pilots with typically high (21) and typically variable (28) FVCs.

Considering the grand means in AFE configurations (USN vs USAF) without consideration differences in pilot, suggests that AFE has a similar mean, but a great deal of difference in variability with the USN having a much wider distribution and lower minimum observed values (Figure 6.17). However, upon consideration of the configuration and pilot, first, these variations are driven primarily by one pilot (28) who has typically low readings which impacts the mean in an unequal way. This pilot has five observations in the USN configuration, but only one sample in the USAF configuration meaning these lower reading observations influence the USN mean more than the USAF. However, these lower lows are somewhat hidden because to Pilot 21 has higher typical readings and has 11 USN observations and 6 in USAF pulling the USN mean back towards the middle, but with much greater variation in observed scores.



Configuration	Spiro Test	Mean	Std Dev	Min	Max	Range
USAF	A	5.08	0.85	3.95	6.45	2.5
	B	4.71	0.67	3.87	5.83	1.96
	C	4.61	0.7	3.84	5.8	1.96
	D	5.1	0.86	4.06	6.45	2.39
USN	A	5.1	0.84	3.54	6.52	2.98
	B	4.55	0.88	2.27	6.14	3.87
	C	4.51	1.02	2.75	6.34	3.59
	D	5.06	0.87	3.57	6.64	3.07



Pilot	Configuration	N	Mean	Std Dev	Min	Max	Range
12	USAF	6	4.09	0.15	3.84	4.39	0.55
	USN	11	4.13	0.28	3.54	4.57	1.03
21	USAF	4	5.91	0.4	5.06	6.45	1.39
	USN	8	5.95	0.39	4.76	6.64	1.88
28	USAF	1	4.44	0.42	3.91	4.89	0.98
	USN	5	4.21	0.96	2.27	5.37	3.1
55	USAF	2	5.07	0.47	4.35	5.89	1.54
	USN	3	5.04	0.24	4.52	5.31	0.79
71	USAF	3	5.07	0.25	4.52	5.43	0.91
	USN	1	5.21	0.35	4.85	5.63	0.78

Figure 6.17. FVC(L) by flight crew equipment only, and then by FCE and Pilot to demonstrate the impact of variability and sample on grand means.

In PBA, a wide net was cast to observe pilot breathing and the pilot-machine system across a wide range of observations. PBA variables included five pilots, two gear configurations, six profiles, and two seating positions. The FVC data demonstration did not examine individual aircraft as a variable, though evidence was found in PBA that each aircraft has a fairly unique pressure signature. To effectively examine human individual differences, the experimental design matrix must be created with specific intention to answer the most desired hypotheses. Conclusions that could be drawn from these data were that pilots' FVC did decrease from baseline after donning flight gear, and then exhibited a further decrease following the flight. Finally, FVC approached, but did not return entirely to baseline for all pilots by the time of the pilot debrief, which occurred up to an hour later. This is expected; variability for all types of human breathing parameters including pulmonary function must be directly considered. For example, Figure 6.18 shows one of the most striking results from PBA mixed effects modeling on in-flight data, in that breathing rate variability was mostly a response to within- and between-pilot differences, rather than differences imposed by the aircraft environment.

Human variability was also assessed from flight data using mixed modeling effects. The trait that stood out the most was breathing rate, or breaths per minute.

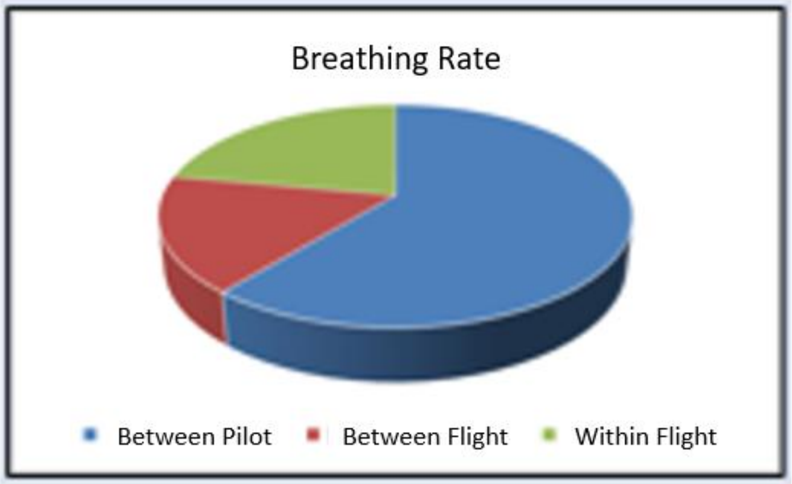


Figure 6.18. Greatest variance in breath per minute is found between pilots.

The five AFRC test pilots had extremely similar external demographic variables. Even so, the individual differences observed in the data revealed over and under representation of pilot characteristics. Despite a seemingly extremely homogeneous sample, individual difference will remain a factor that requires special consideration at the outset of any study that includes a human. In a situation like this, intentional selection of matched samples from the observations for comparisons might be used to detect observational phenomenon for guidance in hypothesis generation for future examination.

Experimental design is a critical element of any study involving a human and entirely dependent on the prioritization of the study goals and the experimental design plan. There are no ultimate safety checks for experimental design quality prior to or following a study outside of possible review organization and fundamental design flaws are easy to make. Similarly, there are no automatic safety checks to ensure data meet the assumptions required for the desired hypothesis testing. Without adequate guidance from an SME in experimental design and statistical testing parameters, the findings that go into the world may be incorrect and conclusions based on those findings may have severe consequences. If designed to do so, sparse data samples can be overcome with advanced statistical techniques and data modeling. However, the absence of observations coupled with already sparse data with many variables cannot be overcome.

All research has a cost in time, process, development, subjects, and equipment. Applied work such as the nature of PBA frequently has difficult decisions when it comes to hypothesis prioritization and study completion on time and on budget. During the development process, hypotheses of interest need to be examined to ensure some are not diametrically opposed to others and deconflicted prior to data collection if possible. Importantly, in studies that feature development, it may become clear that not all valued hypotheses remain within reach and clear delineations must be assessed in terms of what is in scope and no longer in scope. Hypotheses driven future experiments involving humans greatly benefit from early involvement of a human factors SME and proper experimental design along with mid-experiment shifts in expectations and prioritization. These re-planning periods are common in exploratory applied research. In PBA, the scope was to collect a wide variety of pilot data, which has provided innumerable opportunities for future hypothesis generation and testing. In this way, the project requirement was met, and new fields of research are opening to build on the observed phenomenon detected therein.

6.5 PBA Findings Related to Systems and Systems Engineering

(*Key Finding)

The PBA assessment report resulted in many new findings, observations and NESC recommendations to help NASA and the armed services understand the pilot-aircraft interaction. Those that were particularly relevant from a systems engineering perspective are re-iterated here. Without the statistical and data-mining tools engendered by the "*systems of systems*" concept that includes the human on equal footing, these outcomes would have been impossible.

The numbering scheme below is transferred directly from the original PBA report to allow easier cross referencing.

PBA Technical Section 2- Fundamentals of Pilot Breathing

F.2-1. Pilots subconsciously adjust their breathing to accommodate to changes in the mechanical supply system.

Although this seems an obvious statement based on human response under normal day-to-day experience, the objective breathing data identify specifically how much and when breathing is adjusted during flight. It is only when these adjustments reach a conscious level that the pilots may report anomalies in the system. The main point is that even unconscious responses can affect performance in the cockpit.

PBA Technical Section 5: Summary Information and Statistical Analyses based on 1-min Data Compilations

F.5-2. Higher breathing rates (BPM) are associated with aggressive aerobatic maneuvers.

F.5-9. Mixed effects models of six dependent pilot physiological response metrics indicated that most variability was likely due to flight/equipment related factors.

F.5-17. Peak inspiratory flow is not strongly correlated with aircraft velocity, delta cabin pressure, or G-force, but rather with differences in flight profile.

This block of findings demonstrates the first steps in identifying the effects that flight activities exert on the pilot breathing physiology. The most striking of these was the statistical observation that variability in response is more a function of the situation, rather than of fundamental differences between individual pilots. To reconcile this with the thesis of PiBASE Section 6.4, Human Variability, human differences do exist, as extracted from baseline measurements, and even in-flight data relating to rate of breathing. Once airborne, the effects of flight profile in an aerobatic jet are stronger than individual differences.

PBA Technical Section 6: Engineering Analysis of Pilot Breathing

F.6-2. PBA quantified aspects of flight that affect the human breathing system function and Air Crew Breathing System interactions.

F.6-3*. *PBA found systematic disharmony between pilot breathing demand and breathing system delivery as indicated by magnitudes and timing of the pressure and flow data channels.*

F.6-5*. *When PBA pilots reported subjective perceptions of difficulty breathing or experienced physiological symptoms, these were corroborated by in-flight objective measurements.*

F.6-8. The supply of the pilot breathing system can cause BSDs by 1) misalignments in time relative to demand, 2) excessive inspiratory and/or expiratory pressure impeding inhalation and/or exhalation, 3) flow restriction of inhalation and exhalation volumes especially under dynamic conditions.

F.6-11. PBA identified cabin pressurization issues due to increase of dynamic pressure (affected by airspeed, G's, maneuvers, throttle position, and system settings). These changes also affect the entire breathing system.

F.6-13. BSDs (deviations from normal linear pressure flow relationships) are not measured as part of acceptance testing or routine maintenance of aircrew breathing systems and no requirements exist to prevent excessive BSDs.

F.6-21. Even small amplitude cabin pressure oscillations (e.g., a few mmHg) will impact the regulator reference pressure and response. The severity of the combined effect determines the impact to pilot breathing.

F.6-24. PBA discovered that aircraft cabin pressure fluctuates in a manner which can have both a primary impact to the pilot's physiology, and a secondary impact through oscillatory fluctuation in reference pressure for the pilot's breathing regulator, resulting in complex impacts to pilot breathing.

This list may highlight measurements PBA took that established the linkage between changes in pilot response and attempted to isolate the causes to non-pilot sources, either environmental or equipment or both, or a breakdown in the compensation of equipment to environmental change thus requiring the pilot to compensate.

PBA Technical Section 7: Pilot Physiology and Medical Outcomes

F.7-2*. *PBA spirometry found that the Aircrew Flight Equipment (AFE) and being harnessed to the seat reduced measured available lung volume prior to flight. Functional Vital Capacity (FVC) measurements taken from PBA pilots just prior to take off revealed a large decrease in FVC mean from baseline.*

F.7-3*. *PBA spirometry found further decreased Functional Vital Capacity (FVC) in PBA pilots immediately after landing as compared to the respective immediate pre-flight*

These are more measurements taken directly on the human that document changes on the human system, despite human compensation and presence of life support.

PBA Technical Section 11: Almanac of Pilot Breathing

F.11-1. Segmentation allows comparisons of like segments from different profile flights, and can help identify an outlier or unexpected behavior, which otherwise would be washed out if looking at the entire flight. The Almanac provided in Section 11 provides a good baseline for breathing on F/A-18 legacy aircraft with LOX air supply, under different regulator configurations.

Conclusion

Design, implement, and operate well-integrated systems in such a way that they most optimally match the desired form, fit and function of the system (stakeholder objectives), including the human element. In testing, when the human element is involved, plan for and integrate measurements regarding the human system with measurements from the rest of the system, and test under operational conditions. This is the lesson and goal of successful system engineering and integration in this application.

7. Systems Engineering Applied to Instrument Development. Mini Study: JPL In-Mask CO_2 and Water Vapor Sensor

Introduction

The purpose of this section is to discuss SE principles applied to the IMCWS project which, as its name implies, provided a CO_2 and water vapor sensor integrated into the pilot mask. IMCWS was a subtask of the much larger NESC Pilot Breathing Assessment (PBA). The goal of PBA was to understand the role human and aircraft interaction plays in PEs and to develop data to inform future standards for breathing systems.

IMCWS informs on both pilot mask airflow and pilot physiology. This is a blessing and a curse because while measurements inform on both processes, they need to be disentangled. Fortunately, as shown in Figure 7.1, airflow and respiration signals can be separated. IMCWS returns data similar to a capnography instrument. Features akin to end-tidal CO_2 can be quantified and other breathing waveform nuances attributable to respiration discerned. Concurrently, inhalation valve problems and retention of exhaled gas within the mask are also clearly visible and distinct from the respiration profile.

The IMCWS project was a 2.5-year instrument development project. It began in early 2018 with conception and ended in mid-2020 with successful flight demonstration. The project involved design, development, test, and evaluation (DDTE). Engineering design and tests as well as project reviews were more rigorous than typical prototype flight instrument development because pilot safety was directly impacted by the sensor.

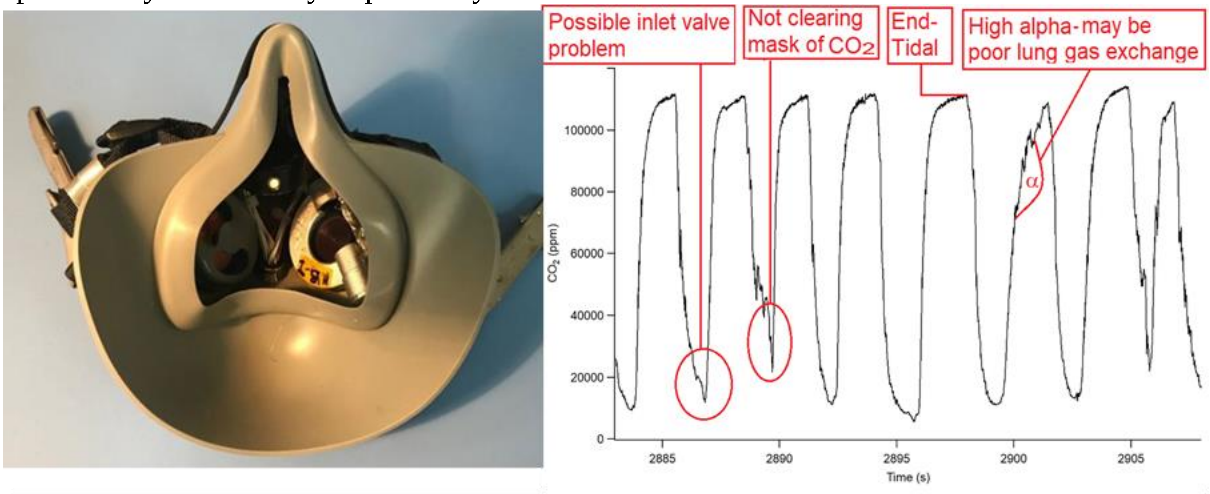


Figure 7.1. Left: IMCWS optical head (silver) mounted inside mask. Right: CO_2 time-series from PBA flight showing both airflow and respiratory indications.

During IMCWS development, the PBA team flew the VigilOX sensor suite (manufactured by Cobham) to gather data on pressures, flow, and gas composition during flights. The VigilOX suite proved an indispensable tool that unmasked previously unrecognized interactions between the human and aircraft. The most critical interactions were BSDs defined as timing and sequencing mismatches in breathing and delivery of air to the pilot. They are deviations from normal linear pressure flow relationships and are measured as breathing phase shift and hysteresis. Objective measures of BSDs were developed to correlate phenomena such as safety pressure and cabin pressure fluctuations with abnormal pilot breathing and mask valve response -

both caused gas regulators to deliver air out of step with pilot demands. High-G flight maneuvers and rapid altitude changes could also cause BSDs. These subtle disruptions often went unnoticed, but their effect could accumulate to transform simple breathing into complex disrupted patterns. All PBA flights experienced BSDs. These findings derived from analysis of VigilOX data helped refine the role and development of IMCWS.

By the time the IMCWS Systems Requirement Review (SRR) was conducted in mid-2018, the PBA team had studied enough results from the VigilOX suite to help direct development of the IMCWS technology. IMCWS's role was not an incremental improvement to an already existing sensor suite providing important insights, but rather as a significant leap forward in applying NASA-derived human exploration technologies in an unprecedented way. By pursuing IMCWS, JPL focused on providing information not obtainable even by existing cutting-edge systems like VigilOX, namely CO_2 and water vapor inside the mask.

Because PEs are uncommon, it is difficult to accrue statistically robust correlations between PEs and measurements by IMCWS or VigilOX. However, it may prove useful to target expressions of physiological stress expressed in CO_2 and water vapor time profile breathing anomalies (BAs) which may occur more frequently. For clarity, we distinguish PEs, BSDs, and BAs. PEs are hard to recognize in sensor data since they are a human phenomenon – it is very difficult to directly measure a pilot losing consciousness. On the other hand, BSDs can be described and quantified from a sensor suite like the VigilOX. Here, we go one step further and contend that the IMCWS tool, since its measurements can be tied to pilot respiration, may also provide quantifiable BAs via CO_2 and water vapor in-mask monitoring. It may be that every PE has indications of BAs, but only a small fraction of time periods with BAs elevate to PEs. This suggests that there may be many BAs occurring which are not quantified. If true, BAs, as well as BSDs, may provide enough quantifiable feedback to more efficiently determine sources of PEs.

IMCWS can be viewed from both the perspective of fitting within a larger pilot-support system or as a subsystem all by itself. Here, IMCWS is discussed from the latter perspective of the IMCWS product itself. Following NPR 7123.1, System Design Processes are described first. which involve Requirements Definition and Processes and Technical Solution Definition processes involved in developing IMCWS. Then ,describe Technical Management Processes are described, which involve Technical Planning Process, Technical Control Processes, the Assessment Processes, and Technical Decision Analysis Process. Product Realization Processes is then described, which involve Product Transition Process, Evaluation Processes, and Design realization Processes.

In this section, the project from the perspective of SE detailed in the NASA Systems Engineering Handbook (SP-2016-6105 Rev 2) and the NASA Systems Engineering Processes and Requirements (NPR 7123.1A) is discussed. The framework described in these documents is used as a comprehensive tool to convey the system engineering involved. Several members of the IMCWS team had been immersed in SE for larger (> $10M) projects such as Mars Curiosity and Perseverance. IMCWS was on a smaller scale (< $0.5M) and the SE engineering and output products reduced. However, the **many of the interdisciplinary process of systems engineering are ingrained in all projects and reflexively applied**.

7.1 System Design Processes

7.1.1 Stakeholder Expectations and Technical Requirements Definition

Stakeholders and Motivation

The stakeholders were the NESC PBA team, the Navy, the Airforce, and the general aviation community interested in physiological episodes. It is expected that IMCWS can identify problems in mechanical airflow to and from the pilot. These include faulty valves which cause timing issues related to BSDs and compromised regulators. It is expected that IMCWS also inform on the physiological status of the pilot through the time-dependent behavior of CO_2 and water vapor.

Precision and Accuracy

Stakeholders stated precision and accuracy goals for IMCWS that were comparable with commercial sensors. The precision of commercial devices is typically ±0.5 mmHg partial pressure CO_2 in 760 mmHg air which equates to several hundred ppm in mixing ratio. The accuracy of commercial devices is generally ±8% of reading. Because it is unknown what accuracy is required for disentangling respiration and mechanical airflow, a more demanding goal was established. Tunable laser spectrometers routinely demonstrate ±2% or better accuracy over large dynamic ranges in pressure and temperature; thus the aim is for what the team thinks is an attainable 2% accuracy.

Instrument Speed

Capnography instruments often operate between 20 to 40 Hz. However, expected IMCWS measurement frequency was raised based on the deliberation of the PBA team who concluded that higher frequency provides added benefit in terms of more refined CO_2 respiration information as well as enabling the identification of fast mechanical flow valve issues such as fluttering inlet and exhaust valves. Feedback from medical experts on the PBA team was that measurements of carbon dioxide should be made at a cadence fast enough to resolve nuances in human respiration. A review of commercially available capnography instruments uncovered that some high-performance devices make measurements at 100 Hz (e.g., CLEO from Infinum) so that was chosen as the measurement rate.

Using these inputs from the PBA team, the IMCWS team did a trade study incorporating their experience with the technical ramifications of making measurements at various cadences and determined that going to 100 Hz was worth the increase cost in complexity of signal filtering and data reduction.

Dynamic Range

The mask has to make CO_2 and water vapor measurements with conditions inside the mask between 0 and 44 °C, 376 to 1084 mbar, 0 to 80 % relative humidity. These conditions were derived from expected PBA flight profiles of the NASA F-18 to be encountered during field testing. It is recognized that this may have to expanded if the IMCWS is to be adopted using aircraft outside of the NASA PBA aircraft.

Size and Placement

IMCWS has an optical head inside the mask, an electronics box mounted on the pilot, and a cable connecting the two. There was a stakeholder expectation that the electronics box be no bigger than several decks of cards so that as little space on the pilot vest is needed. Also, a stakeholder expectation was that the instrument measure inside or right next to the mask. Further, it was recognized from testing of the VigilOX that being down the end of the hose and subsequent mixing of the gas adds undesirable lag on the signal.

Another stakeholder expectation was that the instrument be invisible to the pilot. Aside from the obvious reason of comfort, it is important not to perturb the system under study so as not to be a contributing reason for physiological or mechanical flow abnormalities. Also, the PBA study relies on studying subtle changes in pressure, flow, gas concentration, etc. which can be correlated to expressions of physiological episodes. If the instrument itself induces a change in either the performance of the mask, for example via a gas leak or pilot discomfort, then it complicates even more the association PEs with BSDs and/or PAs. This may be perhaps the most difficult stakeholder expectation to meet since the mask itself, regardless of any components that are implemented inside it, is designed to have minimal internal volume to prevent as little rebreathing as possible and therefore and very little room in which to implement a fast-response sensor that can withstand the environmental challenges, like humidity, inside the mask.

In addition to the constraint that the instrument needs to be implemented inside the mask, the supporting electronics outside the mask need to be implemented on the pilot’s body which is crowded by many different support equipment. For the PBA project, we eventually set a technical specification of a metal box with dimensions 4×6×2” and mass 300 g, which is larger than the initial stakeholder desire of several decks of cards. This change occurred roughly half-way through the IMCWS project and after feedback and comparison with NAVAIR equipment when wind blast testing was done and helped electronics development maintain schedule. Further, the physical specification of the electronics box included placement of the turn-on switch, the marker button, and the length of the electronics cable between the electronics box and the sensor head within the mask so that it would not interfere with other items on the vest as well as movement of the pilot.

Safety

Stakeholder expectations also include that the instrument be safe to the pilot. Focusing on the parts of the sensor that are internal to the mask, the key safety considerations are the active electrical components in the optical head and wiring inside the mask. The IMCWS sensor has several components for which current and voltage are applied including the laser and pressure sensor. The sensor head has to remain fixed within the mask for mechanical stability. The sensor head wires had to be routed around existing microphone components inside the mask. There had to be a virtually no chance that any of these components overheat. Further, the epoxies and coatings used in the optical head were required to pass inspection by JPL and JSC safety engineers for use in human environment.

AFRC and JPL mission safety engineers expected that IMCWS be tested and pass a wind blast test and rapid decomposition test to ensure that in case of pilot ejection, IMCWS does not risk the pilot safety.

Cost

IMCWS cost will eventually be a consideration in USN and USAF utilization calculations since it is desired that the sensor be used fleetwide in relatively large quantities. IMCWS is a mid-IR tunable diode laser instrument. Mid-IR tunable lasers are considerably more expensive than Nondispersive infrared (NDIR) sensors which are commonly used for capnography instruments. However, the expectations and derived requirements made the choice of mid-IR tunable diode lasers attractive. Mid-IR lasers simply use a beam of light from laser to detector. NDIR require reflective surfaces to collect the light into the detector. Surfaces add size and complexity in keeping them void of moisture. Further, the many-fold advantage in mid-IR laser accuracy will likely prove to be important when decomposing time-series data into respiration and mechanical airflow phenomena.

Environmental Conditions

The environmental conditions (e.g., pressure, temperature, electromagnetic interference (EMI) IMCWS is subjected to are more extreme than typical commercial capnography instruments. The pressure inside the mask can get to around 0.4 atm whereas typical commercial instruments are only operated at local barometric pressure. At low mask pressures, the CO_2 volumetric ratio can be as high as 15% (while maintaining roughly the same partial pressure regardless of mask pressure). Radiation requirements were not incorporated but, in the future for long duration flights at higher altitudes, some consideration of radiation effects on electronics should be considered.

7.1.2 Logical Decomposition

The system is decomposed on two levels as shown in Figure 7.2. The first is the physical instrument model which has three parts:

- The optical head which is mounted inside the mask on the exhaust valve and contains the laser, detector, and pressure sensor.
- The electronics box which excites the laser, captures the raw data from the pre-amp and pressure and temperature sensors in the optical head. It timestamps, and writes data to a solid drive (SD) disk, has the safety cutoff controls in case the optical head and/or electronics box overheats, contains batteries, and has a time-sync button that is used to synchronize via a push of a button mounted on the housing the IMCWS data with data acquired from other sensors; and the
- Shielded cable linking the two.

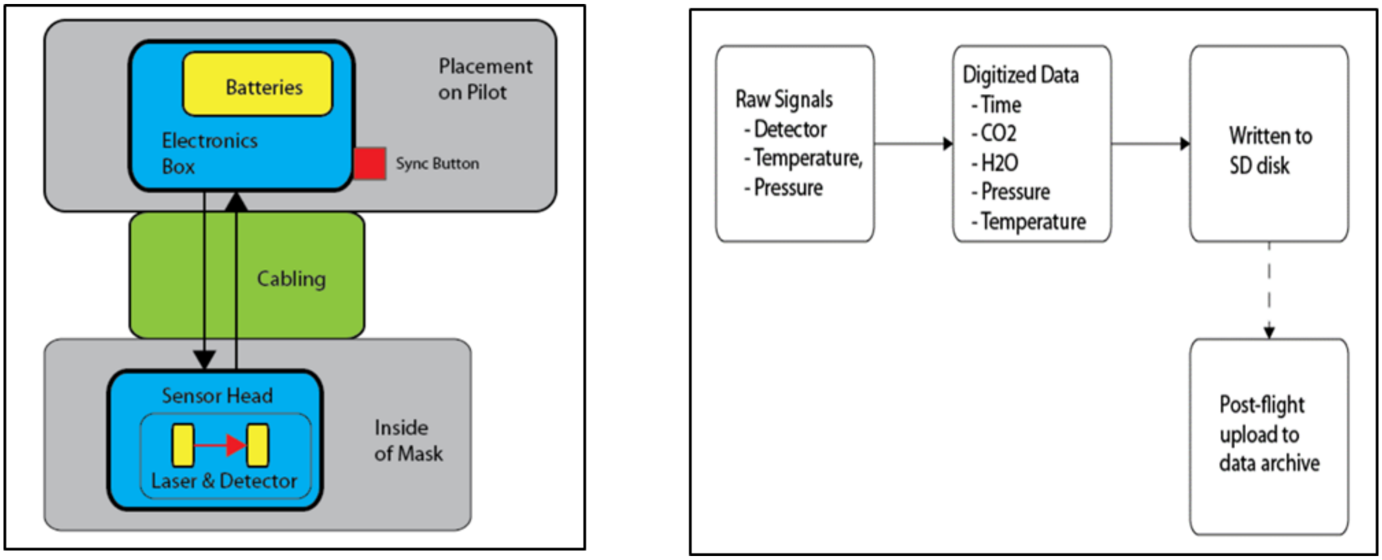


Figure 7.2. System Architecture. Left: Physical instrument model. Right: Data Flow Model.

The next system decomposition level is the data model. Raw signals which include the preamp signal, temperature sensor, and pressure sensor, are digitized by the analog-to-digital converters in the system and placed into memory inside the microcontroller. The digitized preamp signal is then reduced by algorithms in the microcontroller into CO_2 and $H_2O(v)$ partial pressures. Together, this digital data (CO_2, H_2O, Pressure, Temperature) is time-stamped by the microcontroller clock into one packet. A packet is generated every 10 milliseconds. The packets are then written to an SD disk. After the flight, the SD disk is removed, and the data are uploaded to the data archive and immediately made available to PBA team members. It is hoped that future versions of the instrument will be interfaced with some aircraft telemetry system so that digitized packets are available real-time to the pilot and/or ground personnel. The current IMCWS ground support equipment supports real-time data visualization and some analysis of waveforms – for example alerting user that CO_2 is out of normal range, the cadence of breaths, and the end-tidal CO_2 and H_2O value.

Almost all requirements discussed above impose design restrictions on the physical model. Precision and accuracy set limitations on the laser beam path and ultimately the size of the sensor head. The instrument speed also heavily influences the sensor head and imposes design considerations such as why to mount the sensor on the exhaust valve so that analyte is refreshed each breath. Precision and accuracy factor into the cabling because of potential EMI issues which were uncovered during EMI emissions and susceptibility tests at JPL. The cabling also impacts the size of the instrument and where the electronics box can be placed.

7.1.3 Design Solution Definition

A design solution that meets requirements of precision and accuracy, size, instrument speed, safety, dynamic range, and environmental conditions was achieved. The stakeholder expectations of transferability to the commercial sector was ranked below these technical and safety requirements.

Trades

To meet measuring sample rate requirements developers traded non-invasive analysis (open path) vs enclosed cell. Adding a pump would also risk violating requirements for size. An open-path configuration requires far less optical head mechanical structure which reduces size and minimizes any conflict with the pilot's face. Further, an open-path configuration allowed the design solution to be non-interfering with air flow. The optical head did not overlap the exhaust valve and had no effect on flow characteristics through the exhaust valve.

Tunable Laser Spectroscopy (TLS)

To meet precision and accuracy, size, and speed requirements, tunable laser spectroscopy was employed. By being a spectroscopic technique, the tunable laser can rapidly scan over a chemical fingerprint and ratio the power off and on the chemical resonance. This gives this technique an inherent advantage in precision and accuracy over NDIR or other techniques that have to rely on stable backgrounds and thus have to use reference cells to compensate. TLS does not need reference cells. The fingerprint scan is its own reference.

Further, the use of mid-IR lasers means that the size of the instrument need only be inches or shorter and not require any reflective surfaces. NDIR requires reflective surfaces which is hard to design into an open-path system without issues of mirror condensation being a hindrance.

To ensure precision requirements were met at 100 Hz instrument measurement rate, wavelength modulation spectroscopy (WMS) had to be employed. WMS is more complicated than normal direct absorption spectroscopy and requires modulation and demodulation of the laser and detector signal. However, the additional electronics needed for this were about 1×1 cm^2 on a PCB and the added complexity in firmware was limited additional subroutines.

Laser Specifications

To meet safety and size requirements, the specifications imposed on the commercial laser were that it had to operate between 30 and 40 °C. Commercial tunable semiconductor lasers do not typically operate above 40 °C. Tunable lasers usually operate below 25 °C. The small size of the optical head means there is not much heat-sinking capacity for the laser. The power injected to the laser is 400 mW while only 10 mW is emitted in the output beam. By specifying lasers that operated > 30 °C, we keep the optical head size small as well as keep total power draw of the instrument low because cooling the laser is a large fraction of the overall energy budget. Thus, smaller batteries could be used.

The wavelength chosen was 2683 nm which enabled the open-path measurements with only a few cm optical pathlength. This wavelength also permitted measurement of water vapor. Lastly, the laser technology at this wavelength was sufficiently mature so that lasers could operate above 30 °C.

Fast Pressure Sensor

The Pressure sensor (TE Connectivity MS5803) is a high technology readiness item and has been available as COTS for greater than 15 years. The speed of the sensor surpasses 100 Hz, its size is only 8-mm diameter, and it can measure accurately even when exposed to small amounts of liquid water. It has 0.5% FSO accuracy and can cover the dynamic range needed during flight. A difficulty with the sensor was its output is digital which means that communication between it and the electronics box needs additional wires inside the mask and that the communication would be subject to EMI interference. However, it was determined through EMI testing and proper sizing of the wires inside the mask that these additional wires could be accommodated and the performance and size characteristics outweighed these difficulties.

Sensor Placement

The exhaust valve provided the best placement solution for the optical head. It has structural integrity to provide support to keep the path from laser to detector aligned, it is located in an area of active flow so measurements there are no ‘dead spaces’, it avoids conflicting with the microphone, and placing it there keeps the mask nose area free for the pilot to perform the Valsalva operation in which the pilot can pinch their nose through the soft rubber of the mask to clear their ears.

The initial design solution for placement of the electronics box was to mount the electronics box to the pilot’s upper left front harness based on the Airforce suit configuration. This provided clear design definition on where to place connectors and buttons as well as the length of the connection cable. However, the placement design solution changed to the Navy suit configuration where the electronics box is tied to a vest on the front of the pilot. This mid-project course correction was relatively minor.

Alternative Design Solutions

Alternative design solutions were analyzed and some tested. It was, and is still, unknown if the pressure sensor needed to be implemented inside the mask. Alternatively, a small tube extending to the electronics box could be employed. This is used by VigilOx. The PiBASE team decided against it because of fear of clogging and uncertainty what the timing between its measurement of pressure versus the TLS measurement of CO_2 and water vapor.

Another alternative design considered was placing the sensor in the nasal cavity of the mask. This was considered because of the difficulty of not interfering with the pilots face if it is mounted on the exhaust valve. Three iterations and appropriate clocking of the sensor were required before the test pilots felt that the optical head mounted on the exhaust valve was acceptable for test flights. A better solution from an interference standpoint would be to mount the optical head in the space above where the pilot’s nose is located, near the entrance of the microphone. However, there is a maneuver called Valsalva that is used by the pilots to clear their ears which requires pinching their nose. This would not be possible if the sensor was in the nose portion of the mask. Further, the mounting point in the nose, the microphone base, is small and much less structurally robust than the exhaust valve. Lastly, and perhaps most importantly, the nose volume may be a dead volume that is not entirely flushed out every breath whereas the exhaust valve can be assured to be refreshed every breath. This trade underlines the importance of HSI, involving the user population early for their input on ConOps and constraints, testing and iterating recursively.

7.2 Technical Management Processes

7.2.1 Technical Planning Processes

There were several technical and programmatic meetings between JPL, the rest of the PBA team, Gentex (pilot mask manufacturer) and AFRC (aircraft engineers and pilots). Some of these meetings can be re-cast as more formalized project reviews. Also, some project reviews were conducted before JPL participation to determine motivation for IMCWS. These reviews are:

- Mission Concept Review (MCR): The NESC team, at PBA conception and before the IMCWS project started, developed and reviewed the concept of having a measurement system developed by JPL. This concept study settled on using the already-prototyped Cobham VigilOX system, but recognized at this early stage some issues with VigilOX (CO_2 sensor placement, susceptibility to humidity).

- System Requirements Review (SRR): This was after the IMCWS project started. The SRR panel comprised of a multi-disciplinary team, including an SME in physiology (flight surgeon). Their input was very valuable and guided important changes in the requirements, such as increase in sampling rate. A hands-on demonstration of the next level system, the mask, and understanding the physical constraints was also very valuable. It helped crystalize a viable path forward. This underlines the importance of involving the right set of SMEs (in this case, human factors experts) early in the design.
- A Preliminary Design Review (PDR) was held in December 2018 where the first breadboard IMCWS was demonstrated to the PBA team (meeting #2). Feedback included making it smaller and focusing more resources on IMCWS at the expense of other projects the NESC PBA team was interested in such as an in-mask flow sensor.
- A Critical Design Review (CDR) was held in June 2019 in the form of a JPL visit to AFRC. This included a demonstration of an improved breadboard design and assessment of the final flight design with the AFRC pilots that use the sensor in flight (meeting #5). The feedback included **changing the orientation** of the sensor head on top of the exhaust valve and **shrinking** the sensor head several millimeters. It also included **re-routing** the in-mask wiring so that it conflicted less with the in-mask microphone.
- There was a System Acceptance Review (SAR) at JPL in which the AFRC PBA project managers and one pilot attended along with JPL engineers (meeting #6). This went over the system as a whole. At JPL, it was titled a ‘Table Top’ Review. Concerns about pilot safety were the most discussed topic and the issue of rapid decompression became a flagged concern. It was because of this meeting that a subsequent **rapid decompression test** was conducted, mainly to **address the concern** of the laser window becoming dislodged and becoming an inhalation hazard in the event of a pilot ejection.
- AFRC led the Flight Readiness Review (FRR) which started before the COVID-19 shutdowns and finished a week before flights in Aug 2020 (meetings #8 and #9). These FRRs were comprehensive covering topics including IMCWS motivation and role in the larger PBA project, performance, desired outcome, but most importantly safety to the pilots and aircraft.
- After the six IMCWS test flights, there were Post-Flight Assessment Reviews (PFARs) of its performance and any observations that might impact its implementation and future design, such as pilot comfort (meeting #11).
- There were post mission discussions between JPL, NESC, and the Navy as to what steps to do next. These constitute Disposal Readiness Review (DRR). The outcome of these discussions were that JPL and Navy would formulate a JPL-Navy project focused on hardening the IMCWS so that it could be used fleetwide, adding oxygen sensing in the mask, and working with the Navy to transfer the technology to a third-party instrument manufacturer.

The bolded actions demonstrate the importance of periodic reviews, as feedback received was incorporated and enabled the success of the final design. These processes were especially important when designing a subsystem, which together with the larger assembly (i.e., the mask) had to provide proper fit and function at the human interface (the pilot's face).

7.2.1.1 Interface Management

Throughout the project, a constant discussion topic was ensuring that the end product would interface correctly with the aircraft breathing support system. Initially, IMCWS was designed to interface with the Airforce pilot breathing system as opposed to the USN configuration. This was to take advantage of the harness mounting already built for the VigilOX which easily interfaces with the Airforce configuration. The gas inlet and outlet are different between these systems. The design of the electronics box which is situated outside the mask needs to accommodate the placement of regulators and other support equipment on the pilot vest. To manage this issue, JPL incorporated the design changes uncovered while visiting the NAVAIR facility such that the electronics box would better integrate with the usual USN configuration of the vest. Subtle things like the placement of the straps along one or another axis made a large difference on straining the cabling. However, accommodating the Navy design came at an expense of the Airforce configuration since it required the securing of extra metal clips on the back of the electronics box to better secure itself on the air intake manifold.

7.2.1.2 Technical risk Management

Another unforeseen technical issue that arose was the ensuring that the mask seals properly on the pilot after mask fitting. Due to the safety requirement that the optical head inside the mask stay affixed and have nearly zero chance of dislodging from its location on the outlet valve, a strong epoxy was used to bond the optical head to the outlet valve. Earlier designs did not have this adhesion step, but rather used friction to bond the optical head on top of the valve. The implications of using epoxy are that adjustments or replacements cannot be rapidly made. This **issue manifested itself when fitting the first mask to one of the pilots**. The final safety verification step is checking for is a gas seal around the pilot's face. The first mask with integrated IMCWS optical head failed this test - there was a small leak. The JPL manufacturing process requires heating the entire valve with the optical head in an oven at 60 °C for 8 hours to cure the epoxy. This temperature is well below the temperature that could deform the plastics inside mask. Regardless, deformation remained a culprit for the leak.

Fortunately, a back-up mask with integrated IMCWS passed the leak test which enabled the demanding flight schedule to be kept on track while the leaking mask could be fixed. There was no time to do a full analysis at JPL as to determine the root cause of the leak so the decision was made to simply replace the optical head and use a lower temperature curing process.

After the leaking mask was repaired at JPL, it was delivered to AFRC. It again failed the final leak test. Subsequent tightening of the exhaust tubing showed that the leak was along the outside of the valve rather than from inside the valve. This suggests that the initial leak may have also originated from the same cause – a loose seal between the mask and exhaust tube rather than the components inside the valve being deformed by heat. This is a lesson learned. In retrospect, it would have been prudent to spend a few hours at AFRC on the leak instrument to verify whether the leak was from the inside or outside the valve. The implications are important – if there is a high propensity of leak around the outside of the valve, then some design relief should be considered in future optical heads to improve sealing outside the valve. If, on the other hand, the manufacturing process is indeed the culprit, the manufacturing processes need to be modified.

7.2.1.3 Configuration Management

Configuration management was very important for several reasons. There were many design iterations based on mechanical design due to **pilot comfort, safety concerns** such as rapid decompression, requirements such as ensuring it can work with ill-defined USN and USAF configurations. Second, early in the project, a project requirement was established that there be a technology transfer to the Navy and/or selected instrument manufacturer with concurrent considerations that the solution be able to be implemented by a vendor. Thus, different configurations of the instrument were tested that otherwise would not have been tested such as 'easy – to remove' friction fitting rather than permanent bonding of optical head to valve. This would allow the sensors and valves to be **routinely maintained** without time-intensive and expensive process of detaching epoxy-bonded sensor to valves. Third, going to 100 Hz and requiring more robust disk writing of data required a **change in microprocessor** which entailed significant changes in software.

The IMCWS went through three major prototype/fit check iterations. **After each of the three prototypes were built, they were evaluated by AFRC test pilots**. The first iteration prototype optical head needed significant redesign – the mask microphone could not be positioned properly, and the optical head contacted the pilot's face uncomfortably. The second iteration optical head was substantially smaller – the microphone could be positioned, and the sensor contacted the pilot's face only if the mask was pushed in from the outside. However, the wire harnessing took more space than necessary. The third and final configuration used smaller gauge wires, and a more efficient routing pattern. All prototypes used the narrow version of the Gentex mask, to ensure fit for all mask sizes.

7.2.1.4 Technical Data Management

As per JPL's New Technology Reporting (NTR) program, enough technical information must be recorded in case the technology is to be patented. Here, it was acknowledged from project inception that the technology would be transferred to the Navy so it was important to log not just the major technical findings and descriptions, but also the not-typical tricks-of-the-trade which can make adoption of new technology easier. For example, alignment of the lasers to prevent optical standing waves and feedback to the laser requires a fair amount of experience because the standing wave and feedback signals are subtle and often only uncovered in V&V testing by, at which time, extensive resources have been expended. It is difficult to have metrics available during the alignment process by which to rapidly verify alignment (and hence sensor accuracy) so it is best to demonstrate through **hands-on testing** what signals to look for. However, for the technology transfer to be success, this knowledge has to be documented.

7.2.1.5 Technical Assessment

After the six test flights, the technical readiness level (on a scale of 1 to 9, as defined in Appendix E of NPR 7123.1B) is assessed to be level 6: System prototype has been demonstrated in a relevant environment in flight.

7.2.1.6 Technical Decision Analysis

The PBA project may be further developed by the Navy. It will be important to have a methodology for determining if technical progress has been made.

7.3 Product Realization

7.3.1 Product Implementation

The IMCWS is shown in Figure 7.3. The key components are the optical head inside the mask and associated in-mask wiring, the cable connecting the mask to the external electronics box, and the electronics box.

The external power box is mounted to the pilot’s suit using the either a mounting bracket (USAF configuration) or snaps (USN configuration). The box has an easily accessible power toggle switch to rapidly shut the unit off in case of malfunction, a “super bright LED” status light facing the pilot, and event-marker button mounted on the front of the electronics box similar to the VigilOX system. The cable has a twist-lock Bendix connection at the electronics box and a tight friction fit Glenair connection at the mask.

The IMCWS design was modified to not adversely affect pilot range of motion. However, during the six flight tests at AFRC, it was noted that a smaller connection to the electronics box than the Bendix and a smaller electronics box itself would improve pilot range of motion.

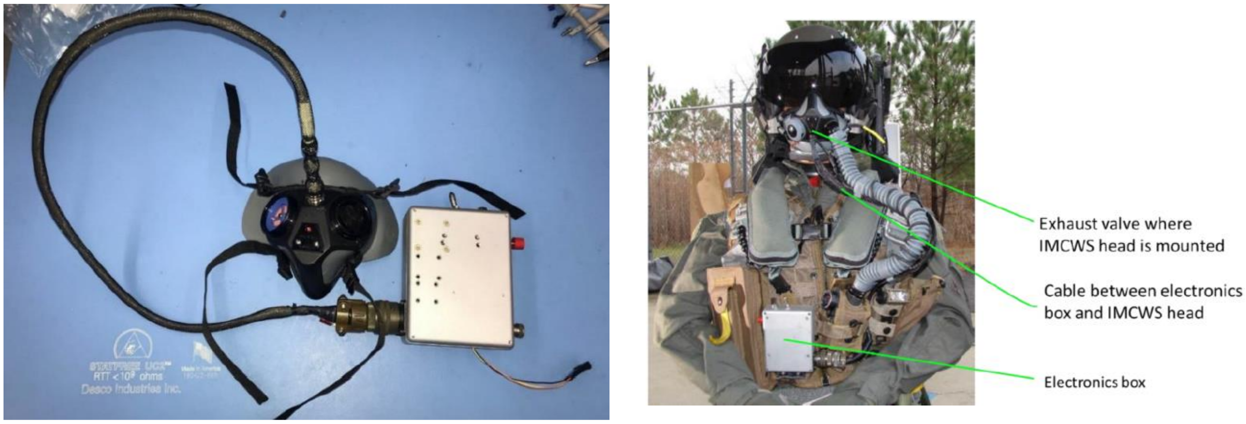


Figure 7.3. Product implementation. Left: IMCWS. Right: IMCWS integrated into Navy breathing system.

The IMCWS laser is integrated with a heat sink for thermal control. The laser heat sink, the pressure and temperature sensors, and the detector are all structurally mounted onto a single mounting fixture. The mounting fixture is epoxied to the outside structure of the exhalation valve. The mounting fixture does not impede air flow through the exhalation valve and does not affect valve function.

The mounting fixture orients the analysis region to measure gas concentration immediately above the exhalation valve port. The opto-mechanical design is a single pass configuration. The tunable laser spectroscopic measurement requires a measurement of gas pressure and temperature and accordingly, the accuracy of these sensors is better than 1% and the speed of the pressure sensor faster than 100 Hz. Pressure and temperature measurements are made adjacent to the laser analysis region.

7.3.2 Product Integration

IMCWS integrates with either the Navy or Airforce pilot breathing system. However, once a configuration is chosen, it cannot be easily changed due to the needed orientation and epoxy step of mounting the optical head to the exhaust valve. The orientation is not symmetric, so one of the two configurations needs to be chosen. In future versions, this product integration issue (easy swappable between configurations) will be addressed.

7.3.3 Product Verification

IMCWS verification tests were done at various times throughout development. The list of verification requirements is tabulated in Table 7.1.

The requirement of pilot comfort was not verified until SAR. This was a somewhat subjective test that depended on individual pilot faces and their tolerance to the presence of an object inside the mask. The most difficult case, a pilot whose facial features most fit the inner volume of the mask, was chosen for verification.

Verification of accuracy, precision, and measurement rate were done through laboratory tests with cylinders of known gas concentration. These tests were done flowing known gas concentrations over the instrument in a temperature and pressure-controlled chamber.

Table 7.1. Verification Requirements and Methods

IMCWS Requirement	**Verification Method**		
	FM Unit	**FT Unit**	**MV unit**
IMCWS Performance (Chamber functional Test)	T	T	NR
IMCWS Performance (Thermal performance Test)	NR	T	NR
IMCWS Assembly Life	NR	NR	NR
Mechanical			
Interface	I	I	I
Mass			
Mass attached to mask	D	D	D
Mass outside of mask	D	D	D
Electrical			
Interface	I	I	I
Power Source	D	D	NR
Power Indicator Switch	T	T	NR
Sensor Schematic	I	I	NR
Design and Construction			
Leadwire	D	D	D
Structural Attachment of Components	A	A	A
Materials, Parts, and Processes	D	D	D
Toxicity and Outgassing	D	D	D
Electrical Bonding and Shielding	D	D	D
Lead Restraint	NR	NR	T
Interchangeability	D	D	D
Maintainability	D	D	D
Mechanical Stress Analysis	A	A	A
Workmanship	I	I	I
Contamination Control			
Cleanliness	I	I	I
Identification and Marking	I	I	I
Safety	D, A,T,I	D, A,T,I	D, A,T,I
Environments			
	T	NR	NR

Table 7.1. Verification Requirements and Methods

IMCWS Requirement	Verification Method		
	FM Unit	**FT Unit**	**MV unit**
Operational	NR	T	NR
Non-Operational	NR	T	NR
Transportation and Handling	I	I	I
Vibration	I	I	NR
Static loads	A	A	A
Wind Blast	NR	NR	T
Decompression	NR	NR	T

Key to Verification Methods: (T) Test, (A) Analysis, (I) Inspection, (D) Demonstration. (NR) indicates Not Required.

7.3.4 Product Validation

Product validation was achieved via six test flights of two different IMCWS sensors integrated into two masks for two different pilots. Validation was successful for both the Navy and Airforce configurations. IMCWS was flown in series with the VigilOX sensor suite and thus CO_2, water vapor, and pressure could be compared between the two systems.

The IMCWS CO_2 measurements were 10% higher than the VigilOX measurements on average. It is unclear what is the cause of this discrepancy. The VigilOX measurements are made at the end of an exhaust tube after the exhaust valve so they do not measure the temporal waveforms observed by IMCWS, but it is expected that the time average should be similar. The accuracy specifications of the IMCWS are ± 2% as verified in laboratory experiments.

The water vapor measurements could not be compared since liquid water gets trapped within the exhaust line rendering VigilOX measurements almost always near 100% relative humidity while IMCWS measurements can drop to below 20% relative humidity inside the mask due to dry inlet gas.

The pressure comparison between the VigilOX and IMCWS showed agreement to ±2 mbar on average which is well within both systems accuracy specifications.

7.3.5 Product Transition

Real-time feedback of the IMCWS sensor to the aircraft LSS would entail a level of testing and documentation that greatly exceeds that done during this prototype development because the sensor would move towards higher criticality.

Sections 4 through 7 provided tangible examples of applied systems engineering. To provide a comprehensive view, a discussion is merited on how systems (humans and machines), unintended events and their treatment are influenced by non-tangible aspects of organization and culture.

8.0 Indirect Aspects of Systems Engineering (culture and communications)

Introduction

The NESC has a history of understanding complex systems, identifying safety issues that have been incompletely understood, and identifying the underlying causes of problems affecting complex engineering systems.

The ability to identify, understand, and describe hidden issues affecting complex systems it is in large part due to successful implementation of systems engineering best practices by NESC assessment teams.

8.1 Culture DoD's Readiness - Pilot Subculture - Culture of reporting)

This case study emphasizes the importance of taking a SE view of interfaces, control, feedback, interactions and outcomes (positive and negative) involving a complex SoS. In particular, it focuses on how it was critical to include the human (pilot) as part of that system when the PBA team addressed the study of pilot breathing. Previous sections have discussed the physiology of breathing, the variability between humans, and the variability of an individual pilot's response from day to day. Another factor to consider when examining a SoS involving a human is the professional culture in which that human operates. This is not intended to be an exhaustive study of the military pilot culture but, based on the authors' observations from both outside and within this community, will show that certain cultures impact efforts to get complete and honest feedback on the problem from the human component.

The DoD culture is not homogenous; the different services have their own cultures, and different units or components within each service have sub-cultures. A common theme across the military, at least at a leadership level, is the need for combat readiness and this results in the military working to instill a "can do", "no complaining" culture on its service members. Within the aviation communities of the USAF, USN, USMC and other countries, the opportunity to fly fighter aircraft is still highly sought after and many military pilots spent much of their lives dreaming about and working toward that achievement.

There will naturally be a tendency among fighter pilots to not acknowledge, much less report, any physiological issues that might get them temporarily "grounded" or permanently removed from flying duties. This is not much different from the commercial pilot community where their livelihoods depend on passing an annual medical exam. Anecdotally, many commercial pilots have two doctors; one they go to each year to receive a clean bill of health and another they go to when they need medical care.

The military culture is also more accepting of risk than the civilian world and flying high performance combat aircraft is considered more hazardous than many other assignments in the military. Military pilots are all volunteers for flying duties and most will acknowledge "I knew what I signed up for" or "it comes with the territory". Acknowledging physiological problems, especially without clear-cut data to explain them, can feel like "letting down the team" or a "sign of weakness".

All cultures change over time, and the military is a cross-section of the nation's larger culture. Decades ago, a physiological issue, if the pilot even acknowledged it, would likely be viewed as a problem with the pilot. Modern day pilots have grown up with ever-improving technology and are more likely to expect scientific data on the problem along with a technological solution. At the same time, today's pilots will still be wary of reporting issues if they have the potential to affect their medical clearance.

To secure participation and negate the cultural challenges to candid feedback from the pilots in the PBA study, the team protected the pilots' comments and medical data. In addition, when the pilots commented on breathing issues they observed, the PBA team showed them the data from the flight, making it clear the team believed what the pilots were saying and were looking for objective explanations. While culture can complicate the study of a system involving a human component, with proper privacy measures in place and regular communication between the team and the pilots, the PBA project was able to overcome these obstacles.

Culture Affects the Jet Design Pilots are Flying

The charter and nature of organization is intertwined with the resulting culture. For the DoD, there are other factors such as global political climate, and the DoD culture and acquisition posture are not stationary and has changed across time periods such as World War I, Vietnam, Cold War, Iraq, and now. The US is regarded as the supreme military power of the world. The number one goal communicated was a culture of "Readiness." The key requirements for new technology acquisitions are driven by the desire to be stealthier and to deliver more power, faster, than the other. This is shown in research lines where money for testing current systems might instead go to a forward-looking new technology. Even the new F-35 helmet exists to provide more information to the operator and provide an advantage in executing the mission.

In the 1970's when the F/A-18 was designed, even when it was retrofitted with OBOGS, PE was not coined yet and concepts like "ease of breathing" was not a concept discussed in acquisition meetings. At the time, no written pilot accounts or in-flight pilot data was readily available to suggest that something more or different was needed. The issue today is different: manufacturers of a subsystem are designing in a vacuum with no integrated testing. NASA advocates the value of systems engineering and systems view, but in practice that is different when it comes to the subsystems which go in a military jet. A Requirement's Document "flow-down" should address this, but systems are becoming exponentially complex and lack sufficient modeling to understand how these systems will interact in operation.

Another issue is related to the testing of the proposed solutions (e.g., an electrical system designed to anticipate the breathing needs of the pilot, a mechanical solution to increase speed of flow, and even a mask solution with multiple valves). The merits of these ideas are unknown, and the manufacturers are not engaged in the kind of pilot in-situ data testing that would be required for validation.

Organizational Culture of a Service Member

In every organization there is an overarching culture and individual subcultures. The same is true for the DoD which has a wide variety of culture. For example, the Aviation and Submarine communities is similar in appearance (following orders, wearing uniforms, etc.), however, there are of course many differences. For example, aviation relies more on the individual. Although the pilot is part of the team, during flight, the pilot operates in a more localized decision chain. The submarine community entirely relies on teamwork and proper task execution at all times as the entire crew could be placed in jeopardy. The different services have different sub-cultures, generally along the lines of what different units or communities do. Even within the military pilot community, different types of aircraft or different combat missions have different sub-cultures. It would be difficult to say with credibility that the DoD culture is X or that the pilot sub-culture is Y. However, there are certainly some commonalities among the military pilot sub-culture which are not conducive to complete and forthcoming reporting of physiological problems.

Specific aspects of the military culture include high prioritization on the collective over the individual with items such as uniformity, teamwork, camaraderie, hard work, trust, hierarchy, orderliness. To be a serviceperson is to be part of a tight knit, cohesive group/unit achievement where the unit's goals are placed ahead of one's personal goals. Key features of the military method and structure for consistent operation include

- Hierarchical/vertical structure
- More exact rules of conduct
- Defined roles, rank and status (defined/assigned military occupational career fields)
- Consistency across units/organizations
- Clearly defined career progression
- Additionally, veterans often share a bond in beliefs, traditions, values, and the importance of rank and structure

Authority, Leadership, and Orders

As a civilian, an individual's workplace leader has authority over that person while they are at work, but in the military, a service member's leader or commander has authority over almost all aspects of their life, even when the service member has a "day off." Commanders in the military are responsible for their subordinates' conduct on and off duty. For example, a service member's commander may be notified if the service member become intoxicated, bounces a check, has a fight with their spouse, if their children are going hungry, or if they get in trouble with the law.

Orders are issued from the top of the chain of command to the lowest-ranking members of the unit. The commander may encourage dialogue, may review recommendations for different courses of action from their subordinates, and may weigh various inputs in making their final decision; but once an order is issued, the decision is considered final. The order is executed without question. Service members who hesitate in executing an order or who publicly question an order run the risk of at least being formally or informally disciplined and at worst risking the lives of their fellow service members. The military teaches its soldiers/sailors to become leaders, take charge, and make vital decisions. In absence of someone in charge, the military member takes charge himself. When giving an order, it is expected that it only needs to be given once. But if conditions change, the individual is expected to use his best judgement and training.

The Institution, the Culture, and the People perform their jobs properly, it is the commander and/or the senior ranking enlisted member, or non-commissioned officer (NCO), who must ensure that these requirements are met. In the civilian sector, seldom will someone under the age of 25 be placed in charge of large numbers of personnel and equipment. However, it is commonplace for newly minted second lieutenants, fresh out of college Reserve Officer Training Corps (ROTC) or other commissioning sources, to be placed in charge of 50 or more service members and thousands—or in some cases millions—of dollars' worth of equipment. They are responsible for the lives and safety of those who work for them. In a garrison (noncombat) environment, this poses little stress and minimal risk of the loss of life or property. But in a combat environment, the stress level increases exponentially, and these young officers quickly lose their greenness as they are hardened by combat, death, and loss. A leader is responsible for the development of subordinates. Leaders are responsible for training the officers below them and to take care in how those leaders, in turn, took care of their troops. During a visit to an aircraft carrier during active operations, the professionalism and skill demonstrated by the Nation's young men and women was extremely impressive from the maintainers during night maintenance on the aircraft to those on deck ensuring safe landings. In fact, when we visited the bridge, the Captain proudly introduced the young female helmsman as one of the newest members aboard the ship, saying that this experience was an important aspect of training as all should understand such responsibility.

Each military unit from the largest (combatant commands) to the smallest (teams composed of four to five service members) has a very clear chain of command. The chain of command is based solely on the rank of the individual and there is one assigned officer in charge (the commander) and/or one enlisted or NCO at each level who bear all responsibility for the unit. As an individual achieves certain benchmarks, including time in service, time at the current rank, and military education requirements, he or she is promoted up the chain of command. With each promotion comes additional responsibilities that usually include oversight of a greater number of lower-ranking service members and more equipment. Regardless of rank and the number of individuals for whom a higher-ranking service member is responsible, it is the job of the man or woman in charge to ensure that their service members are adequately trained in their jobs, have the necessary equipment to do their jobs, are getting the necessary sleep and food to remain at peak performance, and are following the rules and regulations that dictate military performance on and off the job. During this work, it was observed the direct leadership was most in touch with the concerns of their pilots, maintainers, and medical staff and were frequently proactive in trying to find salutations while waiting for upper leadership to determine a course change. This was evident in several bases in the form of pilots being provided SlamSticks or Garmin watches to attempt to track pressure fluctuation data for analysis. In the handling of PE reports, for example, the report would flow up the chain, but there would be a limit of information returning and the adjudication would not flow back down to the pilots reporting the event. Leadership would disseminate messaging regarding the state of corrective actions, but such messaging would be overly generalized which fostered a culture of mistrust.

The legitimacy of the chain of command is one of the most important characteristics of the military culture. Maintaining the integrity of the chain of command is critical to the effective functioning and mission success of the military unit. Orders are issued from the top of the chain of command to the lowest-ranking members of the unit. The commander may encourage dialogue, may review recommendations for different courses of action from their subordinates, and may weigh various inputs in making their final decision; but once an order is issued, the decision is considered final. It is also designed to identify clear lines of authority and responsibility and to eliminate any confusion in the decision-making process. Living and working within the constraints of the unit chain of command dictate how the individual functions within the organization as well as how the unit functions as a whole.

Intentional and Unintentional Influence of Leadership

As previously discussed, the military culture is critical to overall mission success and individual success and is typically set at a high level. Unfortunately, this can have some unintended consequences when it comes to reporting adverse impacts of job performance. Many are typically strong positive influences; however, these can be subject to aspects of human nature that can hamper efforts to get complete and honest feedback from the individuals involved, the human component in the SoS. These types of human characteristics are not unique to the DoD and can result in individuals or organizations to ignore, deny, or dispute problems with their product, system, tactics, and more. Numerous instances of companies rushing products to market with known flaws that engaged in various methods to discourage employees who might speak out. Human susceptibility to bias is common. Each person has a different vantage point and has different motivations that subconsciously or consciously interact with the information they receive. Some individuals may unintentionally or intentionally resist or subvert what the data are telling them which may hamper efforts to address a problem. Ultimately, culture can directly affect the ability to analyze and address the problem through an inability to gain accurate data. The organizational climate/culture has a lot of influence on how individuals choose to report, particularly when there is a chilling effect. Industrial/Organizational Psychologists spend their lives dedicated to addressing issues like these in the workplace.

In an organization like the military, there is certainly more risk acceptance than in the civilian world. Military aviation has risks, more so when flying fighter aircraft. This can exhibit as a top-down organizational culture of “you knew what you signed up for” and a bottom-up culture of “I knew what I signed up for.” At this time, crashes remain the primary cause of fatal mishaps followed by mid-air collisions. PEs remain a high visibility issue despite the low causal losses, which indicates they are happening regularly enough to get the pilot community’s attention. Over the last several years, the culture among pilots has greatly improved to maintain visibility. However, this was not always the case. Organizational cultures change over time as missions and technologies change and this can be a change for the good, or for the bad. The DoD is still a cross-section of our nation’s larger culture and as our national culture changes, so does that of the DoD. Though difficult to back up with data, the military culture regarding PEs has evolved from “I’m fine” to “must be a personal problem” to “this jet is not right, and someone needs to do something about it.” Unfortunately, the culture in the pilot corps and in leadership do not always track quickly but eventually leadership gets the message. For example, the 2017 “Shut up and color” patches generated by the pilot community had a lasting impact.

However, leadership has a strong role to play when setting expectations. To only consider the outcomes and not the context can result in the error management techniques that do not positively impact the error rate. For example, to serve the needs of the mission, F/A-18 flights have become increasingly lengthy (8+ hours). The products that serve the biological needs of a well-hydrated pilot have varied acceptance/usability throughout the pilot community. Because of this, pilots reduce the need to urinate by decreasing their water intake, referred to as “tactical dehydration.” Dehydration is a contributing factor for several physiological problems. However, a hydrated pilot needs to urinate, and the organization needs (the increased length of flight without improved urination solutions) are incompatible. The human identified an alternative solution that introduced other complications.

The F/A-18 has experienced enormous change in function and use that has extended beyond the original design vision and lifecycle. Without established HSI requirements and appropriate verification and validation, the human system was often forced to compensate for design and/or planning inadequacies with alternative solutions. Often in organizations, there is the official way and the actual way to perform a task. Nearly every aspect of the USN has been examined to identify and define Standard Operating Procedures (SOPs). Like most distributed organizations, from uniform to task performance, each element of Navy operation has a SOP to provide specific instruction to ensure consistent performance across the organization. Also, like all organizations, changing aspects of the job or technology can result in an SOP that no longer matches the task. When individuals operate outside of the ascribed policy, this might be termed deviant (as in a deviation from normal). Coined by Vaughan (1996), the term "normalization of deviance" is used to describe the concept wherein behaviors that clearly deviate from the established protocol or process seem commonplace because they occur so frequently. Normalization of Deviance is common in an environment without well-fitting standards and was found during the investigation through interview. For example, paper maintenance manuals were replaced with touchscreens as an improve, but instead they did not match the limitations of the task and instead encouraged working from memory rather than manual. Another example is expecting a product that was tested and designed for emergency use only to be sufficiently designed for use in regular operation. A third example is pilots removing masks that are uncomfortable or fit poorly. Each of these deviations can create negative consequence that are not obvious or immediate leading others to adopt the behavior which soon becomes a dangerous norm.

Trust in Leadership

Changes that are poorly considered or implemented, or lacking, delayed, erroneous, over-generalized top-down communications about fault correction can produce lasting impacts beyond the single incident. Subsequent modifications made to the same area or even more generalized areas can have reduced adaptation as the community begins to doubt the organization. In the NESC's 2017 PE investigation, there was a breakdown of trust within the pilot community as supported by interviews conducted by the NASA team, culminating in the instructor-initiated stand-down of the T-45s, and the demand of decompression sickness (DCS) treatment without DCS diagnoses.

Over the course of interviews conducted with F-18 and F-35 pilots, several themes began to surface throughout the pilot and the maintainer community that indicated a loss in trust in leadership. Organizational support, leadership, and trust are extremely complex topics commonly researched by individuals in fields such as Industrial-Organization (I/O) Psychology, Organizational Behavior (OB), Industrial and Labor Relations (ILR), and Human Resource Management (HR). To gain perspective of the research in these domains, I/O is defined as "the scientific study of working and the application of that science to workplace issues facing individuals, teams, and organizations" (SIOP, 2017). Whole dissertations are dedicated to the study of humans in the workplace and the topics explored herein. To maintain scope and focus, only a targeted subset of support literature will be included as example literature to encourage further exploration and investigation. "When individuals do not trust their leaders, they are more likely to consider quitting, because they may be concerned about decisions that the leaders might make (owing to perceptions of lack of integrity, fairness, honesty, or competence) and not want to put themselves at risk" (Dirks & Ferrin, 2002).

Dirks and Ferrin (2002) conducted a large-scale meta-analysis on the antecedents and outcomes of trust in leadership in the military. The meta-analysis included 106 studies (published and unpublished) for a total of 27,103 individuals. The commonly accepted definition of trust is "a psychological state comprising the intention to accept vulnerability based upon positive expectations of the intentions or behavior of another." Dirks and Ferrin identified two primary perspectives within trust: relationship based, and character-based. In a hierarchical relationship, the follower has a character-based perspective of trust in leadership relating to the leader's character and the subsequent influence on the follower's sense of vulnerability. The need for trust primarily arises in situations that involve risk and clarified the role of interpersonal trust in risk taking. Due to the leader's ability to make decisions that significantly impact the follower, the followers assess the integrity, dependability, fairness, and ability of the leader. These assessments can influence work behavior and attitudes (Dirks & Ferrin, 2002).

Figure 8.1 provides the Dirks and Ferrin Framework for Trust in Leadership developed through meta-analysis. This framework refers to the direct leader and/or organizational leadership as the "leader" and notes that the antecedents and outcomes do differ depending on leadership referent (direct leader or organizational leadership). This model also considers attribution error, meaning that followers can attribute the impact of a policy implementation to the character of the direct leader, even if the decision came from higher up the chain. The character-based perspective is associated with cognitive definitions of trust which explore issues such as reliability, integrity, honesty, and fairness. Among the identified antecedents belonging to the "Leader Actions and Practices" is "Unmet Expectations" and "Perceived Organizational Support." Among the outcomes include "Belief in Information" and "Satisfaction with Leader."

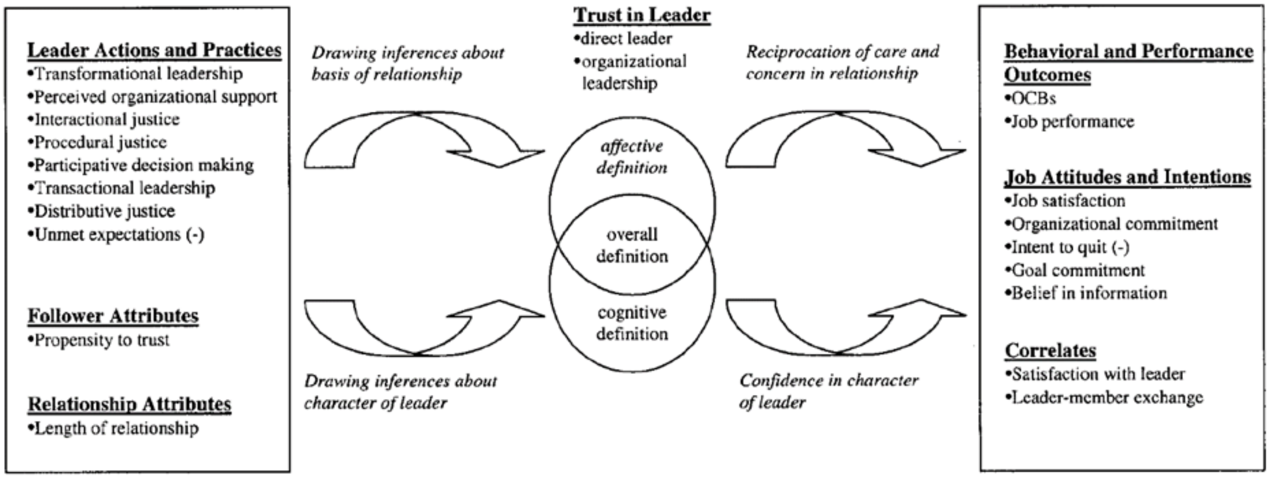


Figure 8.1. Framework for trust in leadership by Dirks and Ferrin (2002). "Concepts in italics represent processes and concepts that are parts of the theoretical model, but were not examined empirically because of insufficient data.

Over the course of the F/A-18 and F-35 interviews conducted for this investigation, several themes began to surface throughout the pilot and the maintainer community. Of the current model, these themes include the antecedents of Perceived Organizational Support, Unmet Expectations, and Interactional Justice. Easily the most stressed outcome state was Belief in Information. Considering the current state of the PEs and the amount of misinformation, this component was particularly troublesome towards the goal of mitigating the problem at hand. Communication from leadership to the pilot community was reported as very poor in terms of PE frequency, PE results/adjudication process, and PE solutions. For example, during F-18, interested parties for PE flights such as the pilot, wing commander, flight surgeon, and others are not notified by the PE adjudication board of investigation results.

Trust in leadership is an important aspect to an organization. The role of pilot is an occupation; however, it would be remiss not to mention that the occupation of flying a fighter jet is highly desired and military service includes required years of service. Although turnover behavior is somewhat different than in civil aviation, turnover and attitudes can exist. A military pilot could choose not to reenlist at the end of active service in favor of the private sector or request to move airframes. Dirks and Ferrin (2002) noted that an individual who has lost trust may be “unwilling to commit to the goals set by a leader, for fear of putting oneself at risk” and spend energy “covering their backs” in an effort to stay safe. In the operational environment of a fighter jet, diverted attention is not ideal and over-sampling the cabin altitude gauge can be highly dangerous when in formation flight.

When an individual has a lack of trust in leadership, but is still required to perform a risky task, that individual can experience cognitive dissonance. This psychological stress will impact behaviors and attitudes related to that job performance. For example, it may exhibit as a decreased threshold for fearfulness and panic as was the case for an individual who experienced an off-nominal event that was non-threatening; however, the anomaly caused him to panic, and he/she then did experience very real symptoms related to hyperventilation and high blood pressure. Unfortunately, for this individual to realize the anomaly was non-threatening, he/she needed to rely on information that was now suspect due to his lack of trust. In the absence of direct, clear, and individualized information the community will attempt to draw its own conclusions. Humans have a natural tendency to attempt to increase predictability and reduce the psychological stress of an otherwise random threat. To this effect, several pilots reported they tried to find out the cause of a PE, including asking maintainers, other pilots, and engineers. Gathering information in this way leaves room for inaccuracies and misinformation to spread quickly and gather consensus. However, without Trust in Leadership, information produced in videos, testimonials, and Situation Reports makes little difference in the population’s perspective on PE progress.

A mitigation for this could be through a speedy adjudication process with increased transparency such as reporting to the pilot the finding in the case of his/her PE. Other opportunities of focus could include improvements to perceived organizational support by way of increased pilot interaction. Unmet expectations might be modulated by way of increased overall awareness of the PE mitigation effort to directly combat potentially serious misinformation. The overall impact of culture is a crucial factor to consider in terms of a top-down directive and the impact on the bottom-up information collection.

8.2 Questionnaire Research Methodology

Standardized research methodology can help produce **data-driven solutions with measurable outcomes.** Human research seeks to study individuals to develop probabilistic findings that generalize to the greater population using empirical evidence rooted in theoretical. The human cognitive or psychological state data are typically assessed within the form of self-report such as questionnaire (“on a scale of 1-10 how do you feel?”) or interview (“tell me what happened).” Through a field called psychometrics, you can develop sound procedures designed to detect or assess the human.

Exploring phenomena using established and appropriate scientific procedure can empirically separate fact from fiction by utilizing evidence-based observations designed to falsify or support a hypothesis. The goal of empirical research is to realize understanding through the targeted observation and experience, and analysis. However, in operational environments the traditional scientific method may appear impractical as initial detection of the phenomenon and hypotheses development may be difficult and nearly impossible to test. Unclear expectations may yield solutions based on inaccurate assumptions that produce unintended consequences when implemented. Fortunately, there are specific research methodology practices designed to operate within such complicated parameters.

8.2.1 Survey Design, Development, and Interpretation

A questionnaire is a primary method of measurement for self-report psychological phenomena. These data are subjective as they are based entirely on the individual's perspective in their current state. Objective data are those collected using an outside measurement. For example, an individual might subjectively report experiencing symptoms they perceive to be a high fever. The actual state of the body temperature can be measured objectively by way of a temperature measurement. This temperature measurement can confirm or refute the subjective report of high fever which can be used to govern the appropriate mitigation strategy. The experience of in-flight adverse symptomology currently allows only subjective report as a data collection method. This can begin an objective process included medical testing; however, many symptoms are transient with no objective measurement capable of confirming or refuting the pilot experience in the cockpit once on the ground. Self-report data collection is commonly used across many disciplines and in this case would consist of self-report via a questionnaire with some portions completed by the pilot and others completed via interview by a medical professional. These reports consist of an individual's experience and the medical team's interpretation of the reported symptoms. Little objective data are produced from the aircraft to accompany the subjective experience and the objective data collected by medical often occurs after lengthy time delay when the situational factors are no longer present.

Typically, subjective data are collected via a questionnaire or interview (structure, unstructured, or semi-structured). To ensure appropriate interpretations and meaningful conclusions can be drawn from these data, a questionnaire must be psychometrically sound and address features such as dimensionality, reliability and validity and include sound data collection methodology related to how the data are gathered, analyzed, and interpreted. A fundamental concept of measurement is that measurement is often imperfect. This imperfection means the observed value reflects some amount of error therefore the true value cannot be not known. The True Score Theory states that the observed value (X) equates to the true value (T) and the addition of an unknown amount of error (e). In the example of PEs reporting, we know that within the population of all USN pilots, some pilots have had a PE and some have not. But, because we cannot know the actual True Score, we know there are sources of unexplained error and cases of incorrect classification. For example, some PE symptoms are clearly pressure fluctuations such as "ears popping" while others such as "difficulty breathing" could be either induced by the aircraft or by the human subjective state.

8.2.2 PBA Specific Questionnaire

The subjective query portion of PBA had two main goals. First, to gain insight on the individual differences, experiences, and demographics of the subjects used in this study as they relate to the PBA study variables. Second, as an opportunity to collect information related to previous in-flight experiences from five elite pilots with high expertise, high flight hours, numerous airframe exposures, and extensive training that includes verbalization of experience. These two goals were attempted using a combination of written questionnaire and pseudo-structured post-experiment interview.

The questionnaire portion included three parts, each targeting a portion of the reporting that would provide insight into the subjects for the study. The first questionnaire (Pre-Test) involved demographics that would not change frequently such as previous flight experience, airframes, common symptoms experienced as a pilot, PE history, and normal diet and exercise routines. This questionnaire was taken only once. The second questionnaire (Pre-Flight) involved the subjects reporting about factors that change daily and might impact the study variables of interest such as recent altitude exposure, diet, fluid intake, and any current symptoms. This questionnaire was completed prior to each flight. The third questionnaire (Post-Flight) involved the subjects reporting about the experience during flight and any usual events that might impact the collected data.

Conclusions from Answers from Pilot Pre-Flight Questionnaires

Pilots completed questionnaire to indicate elements related to pilot physiological state and readiness normal to that pilot. The pre-flight questionnaire completed the day-of a flight included an indication if they followed their normal routine for diet, hydration, exercise, and sleep habits via yes/no, open-response, and Likert-style (e.g., "strongly agree to strongly disagree"), questions for elaboration as needed.

- Approximately 95% (78) of the pilot responses indicated normal eating and hydration habits prior to flight.
- All pilots indicated a normal hydration habit.
- Of the pilot responses 85% (69) indicated a normal exercise routine prior to flight with the 15% (12) non-normal reports presenting a reduction in exercise typically related to time constraints.
- Approximately 90% (74) of the pilot responses indicated normal sleeping habits prior to flight with the 10% (8) non-normal responses listed as due to a required shift to a night schedule, an extended period of wakefulness in the night, and an earlier than usual morning wake time.
- Only 16% (13) of the pilot responses indicated feeling unusually tired or fatigued in the last week leading up to the flight.

The pilot responses indicated a nominal state of fit and mission readiness as expected by the professional nature of highly trained and experienced NASA test pilots and typical of pilot subculture (see Section 8.2 on Culture). Questions such as these are informative to describe the state of the pilot for use in the event of unusual data to identify potential precursors or alternative explanations. As adverse in-flight experiences can occur in unexpected ways and during what might have otherwise been relatively normal flight conditions.

Highlights from Responses from Post-Flight Questionnaires

NASA test pilots are involved in multiple projects that require juggling of schedules to accommodate aircraft availability, ground logistics and weather. PBA-specific flights were often interleaved with other pilot responsibilities as opportunities arose. Pilots completed the post-flight questionnaire within a day after the flight. Pilots answered several questions associated with in-flight experiences with a few minor elevations as expected and a workload questionnaire (reference PBA Appendix 9: Results of Pilot Questionnaires and Interview open-response for the full results). The most informative portion of the questionnaire came from the open-response comments where the pilot could communicate any information on breathing experience, symptomology, and any additional thoughts following that specific flight. Questionnaires were administered for 78 scripted PBA sorties; pilots made every effort to fill them out within the time constraints of "other duties as assigned" resulting in a total completion rate of 74%. This was an excellent result as each pilot was represented more than ten times. There were 48 additional comments across 4 open-response questions in 58 completed post-flight questionnaires.

The responses were aggregated and analyzed for emergent properties that reveal common themes generalizable to the content area. Here, clusters are conceptual groupings that emerged after the identification of similar statements and the subsequent interpretation of shared characteristics. This analysis method is well-supported in the literature but does require advanced expertise in human subject data collection and the subject matter area to conduct with precision and accuracy while avoiding common commission or omission errors. These free-form answers also enable additional exploratory analysis for specific flights and segments to identify objective data signatures that confirm or explain the subjective report. Such signatures can then form the basis of semi-supervised machine learning, to enable algorithms to pick out such anomalies in the future (See section on "Pressure-No-Flow" - PNF tool in the PBA report). The top three clusters that emerged are described.

1. The first, and largest, emergent cluster is related to the human breathing system interface in the aircraft and the impact to breathing. One pilot reported "After flight feels like you cannot take as full of a deep breath as before flight." As this study was known to be an exploration of pilot breathing in flight, it is unsurprising that this cluster contains the most responses. Concerns related to the mask valve malfunction had the most comments of the study with 7 of 58 flights with reported noticeable valve inconsistencies. Many commented that during maximum inhalation/ exhalation exercises "valves in the mask seemed to collapse," feedback that may be important for the designed-for limits of the mask and valves. Comments like "I experienced periodic breathing "in" stoppages with the mask, regulator, or hoses; I needed to relax for a couple breaths (breathe out) before the oxygen would flow again" are extremely important because they can direct analyst attention and aid preventative maintenance.

2. The second cluster was the subjective experience between the USAF and USN configuration of the flight crew equipment and the non-safety/safety pressure. The majority of comments that included reference to the USN AFE's safety pressure were negative. There were no comments on the USAF AFE.
   - *Navy gear makes you feel more restricted, especially when doing spirometry in the cockpit.*
   - *I flew the AF and NAVY configurations back-to-back. I noticed I could "max out" the amount of air provided by the Navy regulator during maximum inhalation events. I could never "max out" the AF regulator (CRU-73.) There was always plenty of airflow no matter how hard I inhaled or exhaled through the CRU-73. On the Navy regulator, if I inhaled extremely hard, I would experience what felt like a hose collapse or momentary valve stick (or regulator running out of air). Max breathing through the Navy system seemed more restrictive than the AF system.*
   - *During the forcible exhales, the mask would inflate like a balloon and if I didn't hold it to my face, the seal around my nose would blow out.*
   - *With the USN gear it required more effort to breathe than with the USAF/NASA gear. Under relaxed breathing the positive pressure assisted inhalation, but exhalation requires some effort against the pressure.*

- *When exhaling forcefully, the mask filled up as if resisting the airflow. Normal for USN regulator.*
- *After first High g event (5g) rear pilot asked me how I felt and I said I felt like I needed to cough, so I did. Dry cough probably due to 100% O_2 of the Navy gear.*

Most DoD pilots either fly in an USAF configuration or a USN configuration for the entirety of their career with no chance for comparison. This can normalize the experience with the designated equipment. Four of the five NASA pilots had previously flown USAF configuration with only one having had experience flying the USN configuration for an extended period of time. However, this study provided the opportunity for a subjective comparison along with objective findings. The subjective comments regarding the regulator design coupled with objective data analysis (see Section 6) provide a compelling story to provide to aircraft oxygen supply manufacturers. This is another example where information gathered from "listening to pilots" is supported by all objective data tools. The NASA PBA team engaged with the Honeywell corporation in this area. Honeywell was very receptive and positive in receiving and interpreting the PBA findings.

3. The third cluster is related to discomfort due to elevated temperatures and to pressure which mostly manifested as pain in the ears. Among these comments are several negative references to temperature exposure including indications that the temperature was a detriment to the pilot/mission. Prior interviews with pilots (e.g., PBA, F/A-18, F-35, T6) indicated that operating in a high temperature environment is an incredibly common hazard faced by flight crew. Operational procedures and guidelines exist (such as water intake) but reports of "tactical dehydration" are equally common within the fleet. Heat should be more consciously considered including the elapsed exposure time and heat accumulation with the appropriate mitigations deployed, as an impact on mission readiness. Although impossible to remove all heat risk, other strategies should be examined to reduce the risk of thermal dangers prior to and during mission performance. See workplace standards via the Occupational Safety and Health Administration (OSHA) and/or National Institute for Occupational Safety and Health (NIOSH) for further insight (OSHA, 2017). Cockpit size is often minimized for fuel efficiency and aerodynamics; heat is an often down-played contributor to stress, fatigue and dehydration (which has a role in mechanisms leading to hypoxia), thus it should be part of the inputs in the cockpit design trade space.

Pressure in the ears is unavoidable for jet pilots. Cabin pressure fluctuations in the F/A-18 fleet were commonly reported and could range from very small to very large in magnitude. Elsewhere in this case study discusses the importance of small and large oscillations in cabin pressure and the impact on the flight equipment. Here, pilots note awareness to pressure changes by the ear sensation which is frequently used as the primary indicator of an unusual change in pressure. Comments about the sluggishness and poor visibility of the cabin altimeter indicator suggested that the human system (e.g., pilots' ears) were a faster responding pressure instrument than the one designed for the cockpit. One misconception was that pressure changes are limited to rapid changes in altitude or air turbulence. Comments like "the pressure in the ears occurred during the nose slice maneuvers" match objective data supporting that the effects of dynamic pressure are present during horizontal or straight-and-level maneuvering as well and come across even in regimes slated as Isobaric.

> The effects of dynamic pressure are, at times, 1000 to 2000-foot drop equivalent (see Section 6 for data). In terms of mechanisms affecting pilot states, pressure changes require adaptation. Pilots are exposed to a greater number of pressure changes than previously expected which indicates continuous and repeated adaption that may diminish physiological system reserves.

Narrative responses coming from a subculture that is trained “not to complain” require greater handling and interpretation. When pilots volunteer information, particularly information about adverse physiological experiences, attention should be paid and followed-up. Open-response statements, though more difficult to analyze, are extremely useful for hypothesis generation and data exploration. These subjective statements combined with objective data enable a cross-validation for each category of data and can provide stronger support and hypotheses for such complex mechanisms as pilot breathing in a dynamic and demanding environment.

This section provides only the highlights; the complete questionnaire and the tabulated responses are available in Appendix 9 of the PBA report.

Future Work – Lessons Learned

After completion of the final data flight of the experiment, each pilot completed a single one-on-one debrief to engage in a summary discussion and overall opinion of the entire experiment, profiles, equipment, and perceptions of breathing in flight across numerous air frames. As noted, the open response questions and interview-style engagement yielded the richest information from the structured questionnaire.

In the case of PBA, the structured questionnaire used during post-flight was not sufficiently targeted due to the exploratory nature of this study and the logistical limitations of the test pilots. In human subject research, a semi-structured interview is a qualitative research method frequently used to collect individual instances of subjective experience and can provided context to better examine and explore the data. For this type of sample, as detected by the greater information gathered in open-response and interview format, an immediate in-person debrief using a semi-structured interview during the flight debrief with audio recording for transcription and database entry would be preferred instead of the post-flight questionnaire. This method would allow expanded pilot commentary and follow-up questions related to any potential unexpected events or symptomology and enabled the interviewer to improve questioning (researcher) through access to non-verbal communications and speech response patterns. These data could then be used to develop an improved structured questionnaire for future deployment with a test implementation and revision cycle conducted specific to intended population sample as per psychometric standards and practices.

Questionnaire development must be appropriately conducted otherwise the data could be meaningless or uninterpretable. The kind of questions must be appropriate for the desired data and include dichotomous (Yes/No), rank order, level of agreement (continuous or Likert), cumulative score, and text box. The wording of the question must be thoughtful and carefully examined to craft questions that help the researcher identify information about the individual taking the questionnaire. Questions that are leading, double-barreled, out of context, confusing, biased, loaded, embarrassing, revealing, or offensive may reduce the accuracy of those data. A leading question is one that suggests one answer more than another or provide no alternative answer such as “When was your last PE” with no answer option to indicate never having had a PE. Furthermore, a question that lacks sufficient context or relevancy is basically useless such “do you like airplanes?” when the desired information was actually the frequency of severe ear pain when flying. A double-barreled question asks two questions that could have different answers, for example “When was your last PE and were you dehydrated at the time?” which assumes you ever had a PE, and requires a “when” response, and a “Yes/No” response.

Of particular concern in questionnaire development is to create the questions to be answerable with the level of information impossible for the individual. For example, in an aircraft with pressure swings and a steam gauge sitting beyond the nominal gaze, a query regarding the “Aircraft Altitude” and “Cabin Altitude” is more likely to yield estimated or expected information. This can be better addressed by asking estimate or range questions. Other questions, such as “Central Nervous System Changes,” that indicated a Yes/No response should instead be a text box to allow description and a clear explanation of the question. A questionnaire should be developed with the direct engagement of a methodological expert (psychometrics) along with subject matter experts such as pilots, flight medical, and first responders to ensure the questions effectively discriminate a case from a non-case and only ask questions that are pertinent to the situation and no more. Without careful interpretation, damaging question deplete the respondent’s trust in the questionnaire and can lead to reduced questionnaire validity. Further decrease in willing respondents is if the respondents never hear the results or reporting of the de-identified and aggregated results or how solutions map to their data contribution efforts. That experience impacts the likelihood of a respondent to continue to respond in the future, effectively poisoning the well for any future questionnaires.

Future Work - Specific Questionnaire Development Guidance for In-Flight Breathing

The goal of subjective data collection is to learn about a phenomenon of interest by asking individuals in a population of interest. The impetus might be to better understand information detected from a single observations or anecdotal evidence. Most frequently, a researcher cannot collect information for the entire population (e.g., all pilots) so using established methodology can permit the use of inferential statistics to generalize conclusion from those data to the broader population. Following established methodology will reduce error in the data and increase the likelihood that the conclusions drawn from those data are accurate and the solutions associated to those conclusions are relevant to the problem.

The development of a questionnaire to determine the subjective experience of breathing in-flight must be completed using SMEs and formalized psychometrics principles expertise. The goals of an early post-flight interview are to identify the optimal question and wording to gain the desired information, and to identify the most common statements and responses related to the subjective experience of breathing systems in flight. These are a few thoughts for consideration:

1. During the semi-structured interview, there will be a few structured questions designed to begin the creation of a structured questionnaire.
2. The goal is to iterate and develop these questions to ultimately create a formal questionnaire designed to capture the subjective experience of the pilot during the flight to improve the health of the aircraft in the fleet.
3. The resulting questionnaire should have high sensitivity to detect mild increases in flight symptomology and high discriminability to distinguish among the many potential related causes. For example, pressure fluctuations can be cabin, mask, or line and can have different causes. Factor analysis will permit question improvement, help determine how many factors are present, identify the factors that explain the most

variance, identify any needed weighting, and provide a down-selection opportunity to only include as many factors as necessary to understand the data. Ideally this questionnaire should enable the reason for the experience in **as few questions as possible.**

4. Target questions should include elicitation of specific observations about their flight, the aircraft, comparisons to other aircraft, or specific segment of the flight. Responses may include a dichotomous response (yes/no) or numeric response (e.g., Likert-Type 1-7, or scale 1-100) followed by an open-ended response period for the pilot to provide any specific examples or comments. If Likert-Type scales are used, they should have a range of no less than 1-7 to permit more rigorous statistical interpretation.
5. All subjective statements require operationalization. This is the process of defining a nebulous concept variable in terms of a measurable factor. The subjective term "Difficult" needs to be defined and described to ensure equal perspective across subjects. For example: what is the subjective performance of the breathing system during flight. Is a breathing system "difficult" or "easy"? Is a 1 like sucking rubber? or filling up like a balloon? Is a 7 like no pressure fluctuations? Or are pilots just conceptualizing "easy" as "normal"? This operationalization will be generated throughout a psychometric questionnaire development process with SMEs.
6. Suggested areas for exploration and required operationalization:
    a. The subjective performance of the breathing system during flight.
    b. The inhalation and ability to easily take in full deep breaths.
    c. The exhalation and ability to fully and easily exhale.
    d. Extent to which the pilot perceived being distraction related to thinking about breathing
    e. Extent to which the pilot was able to focus entirely on the flight
    f. Extent to which any adverse physical or cognitive symptoms or discomfort occur during flight

Successful questionnaire development requires professional expertise in formal psychometric methodology, funding, time, and access to numerous members of the target audience and subject matter experts for testing. This individual or company should have expertise in survey design such as knowledge elicitation and psychometric methodology including factor analysis (exploratory and confirmatory).

8.3 Communications: NASA Successful as a Neutral Third Party Conducting Interviews

As of today, there is no other way to gather the personal thoughts or subjective experiences except to ask. When asking questions that are sensitive in nature, the researcher must exercise additional cautions. When a workplace asks questions of a worker that could influence the worker's ability to stay employed, the worker is placed at a disadvantage. Concerns that an employer could use the provided information in a punitive way can lead to individuals choosing not to provide data, or worse, provide inaccurate data. Individuals opting out of a questionnaire provides no further information because the researcher cannot report the reason for why a respondent did not respond. However, there are statistics that can be done to increase the responses in the future and some light inferences that can be made. When a respondent provides inaccurate or false information, it is basically impossible to separate true and false responses.

Best practices of developing the questionnaire itself can help mitigate several factors associated with a respondent not reporting or reporting inaccurately but when the chilling factor is related to the anonymity of the data, that concern must be mitigated by the research design and the collectors.

One of the elements that was crucial to our work over the last several years was the neutral third-party status of NASA and the NESC. The NASA brand inspired trust and a level of professionalism that resonated with every group of individuals we encountered from maintainers to pilots to high ranking servicemembers. In the F/A-18 work, numerous interviews were conducted at locations across the continental United States, Australia, and even while at sea.

Pilots, maintainers, and medical professionals were forthcoming with their discussions with our team and felt at ease providing their story and including the good and bad portions. Medical professionals were able to report that they felt unprepared and unsupported in treating their pilots. Maintainers reported feeling disconnected from modifications to the aircraft that the “the Engineers” on the opposite coast were telling them to do. Pilots reported dropping the mask regularly due to discomfort or eye-irritation and indicating inconsistent training on the impact of a mask drop and free-flow on how the OBOGS functions. Pilots brought other pilots to us who had never reported any of their numerous suspected PEs for fear of retribution or being sent away from their squadron for treatment. These “bad” stories helped NESC better understand the inconsistencies in the PE reports and draw more clear lines amongst them for cluster identifications. This trust was paramount to our findings and our success. NASA interviewers cannot be everywhere when trust is needed for the full story to be learned, however, there is a way to impart the same level of trust in the form of a NASA controlled data reporting system. The Aviation Safety Reporting System (ASRS)[12] is the gold standard for Aviation Data and has been modeled in 16 other countries and numerous other disciplines. This section will describe more about this system.

One method for managing respondent concerns associated with confidentiality is to conduct the questionnaire via a neutral third-party reporting system. In the 1960’s, data associated with aviation near misses and accidents were being amassed, but concerns related to legal liability and disciplinary action meant that those data were being siloed within individual organizations or not reported at all. The absence of information and the inability to examine those data across the broad field of aviation meant that safety trends were impossible to detect in any way that could be used to prevent adverse events. In the mid-70’s two commercial aircraft misunderstood an Air Traffic Control clearance near Dulles 6 weeks apart which took them too low too early. The first aircraft avoided the mountain, the second collided. The first crew reported the incident, and a cautionary notice was issued by the airline to all their pilots, but the airlines did not have a universal system for shared reporting. The National Transportation Safety Board (NTSB) investigation revealed the previous near-miss report and ultimately, this incident was the final incentive for the development of an aviation safety reporting system for the entire aviation community. The FAA was a regulatory and enforcement position and would naturally dissuade those in the aviation community from reporting for fear of retribution or punishment. As a non-regulatory research organization, NASA was well suited to serve as a neutral third party.

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[12] https://asrs.arc.nasa.gov/
https://asrs.arc.nasa.gov/publications/callback/cb_260.htm

NASA served a critical role in the development and operation of the ASRS and continues today. In the 43 years of operation, NASA has processed 1.7 million reports using a process that accurately assesses the safety value of each report while ensuring total reporter confidentiality. This system is the premier source aviation safety and human factors in the world. The foundation of this system rests on this system being confidential, voluntary, and non-punitive with immunity (See Paragraph 9. c. FAA Advisory Circular No. 00-46E). There have been zero confidentiality infractions in the history of the ASRS.

This reporting service does not just cover pilots. The ASRS welcomes reports from anyone in the aviation community such as pilots, air traffic controllers, cabin crew, dispatchers, maintenance technicians, ground personnel and others involved in aviation operations. Reports can be about any circumstance which might compromise safe flight such as a defective runway navigation aid, unusual aircraft system behavior, a confusing ATC procedure, or maintenance inconsistencies. ASRS currently intakes and categorizes more than 8,990 reports per month quickly to ensure enough time to issue an Alert, if needed.

Ultimately, as designed, the ASRS has no direct authority and cannot correct safety issues and relies on the aviation community to act when ASRS issues an alerting message based on de-identified information provided in the reports. These alerting messages are designed exclusively to relay safety information to aviation organizations to evaluate the information for possible corrective actions. In addition to these self-generated notifications, the ASRS is also using the tremendous amount of data available to conduct Quick Response data analysis in 2 to 10 days and for requests from US government agencies (e.g., FAA, DOT, NTSB, NASA, and U.S. Congress). A recent example was related to the B737 MAX Aircraft Safety Reports (SR 7284) for the NTSB.

This model has been followed in the international aviation community as well with 16 countries setting up similar systems. Other disciplines are also applying the ASRS model including railroad, medicine, security, firefighting, maritime, law enforcement, and more. This method could easily be applied to the DoD for aviation safety concerns. NASA can apply the ASRS method to provide a fully secure third-party system to enable a better understanding of the problems that exist in the military aircraft community. This system could provide a venue for military pilots to report concerns while ensuring national security as the highest priority. This system can enable trend analysis and track gripes after modifications, but prior to any major incident or accident. By ensuring a more wide-spread data collection system with individual protections can increase the likelihood of data accuracy used to determine best application of resources to solve wide-spread issues.

9. Design for Mission Success/Mission Assurance

This section provides guidance on how to develop and maintain future system-of-systems, especially when human physiology is involved. A recurrent theme throughout this case study has been the importance of taking a "system of systems" viewpoint to encompass the entire context in which those systems are combined. In the case of flying jets, the human – the pilot – is a system. The human system can be "designed" only to the extent of fitness criteria and training (e.g., to learn to perform "G-breathing" to improve tolerance to G-loads [Section 6.1.3], to recognize onset of hypoxia), and *thus the impetus must be on the other system(s) to be designed, tested and maintained to accommodate the human.*

9.1 Development

As recounted in Section 2.2.2 [Hitchcock et al., 1982], the development of the F-18 took a "system of systems" perspective that encompassed not only the pilots and jets, but also the personnel who would have to maintain the jets. Attention to the pilot was via a "rigorous Human Factors program," covering aspects such as designing and assessing the controls the pilot would use, and the means by which the jet would provide information to the pilot. While there is mention of involving a "physiologist/anthropologist," including taking into consideration the "elimination of vertigo-inducing head movement," there is no mention of the physiology of breathing.

As discussed in Section 4.2, there has been an evolution in aircraft LSSs and breathing systems, from their relative independence of other aircraft systems, to their interdependence (e.g., the OBOGS), making it crucial that such systems also be included in the SoS perspective. Section 4.3.2 further elaborated the need to integrate medical considerations along with engineering and anthropomorphic ones. This should start from design conception and be carried through the entire lifecycle.

9.2. Maintenance

The NASA Systems Engineering Handbook states: "*The purpose of Phase E is to conduct the prime mission to meet the initially identified need* ***and to maintain support for that need*** *… Systems with complex sustainment needs* ***or human involvement will likely require evaluation and adjustments*** *that may be beyond the scope of operators to perform*". Breathing systems for pilots of jet aircraft exemplify these aspects.

As a system continues to be used, perhaps for years or decades past its initial conception and deployment, its original design may become less well suited, even unsatisfactory, in situations that have diverged from those for which it was originally crafted. The challenge addressed in this section is how to recognize when adjustments are needed.

During the original design of a system it is desirable to avoid "fragility," as might be caused by overoptimizing to the specific circumstances envisioned at the time for how that system will be used. It is effective to make the system suitable for a *range* of conditions, so that it will continue to be appropriate as and when conditions do evolve. However, there are practical limits to the extent to which that is possible, and it is implausible to foresee the long-term evolution of those conditions, so it remains important to recognize when a system needs change. For a maintainable system, adopt agility versus fragility. Accept that one can't design to a perfect end state (the F/A-18 has been operational for 4 decades) and plan to evolve the design based on additional data obtained during the phases of operations. Another ideal is to have recorded the assumptions and tradeoffs made during the original design, since these will be a good basis for triggering scrutiny as the situation changes. This is the focus of the large field of work on “design rationale,” namely how to capture such information as design takes place, and how to use it thereafter. However, long-recognized impediments to, especially the capture, exist [Lee, 1997]. There are tradeoffs – the less information that is captured, the easier it will be to do so, yet the utility of that information will be limited. Conversely, capturing more information is burdensome at design time, and, if effort is not put into organizing that information, the harder it will be to use in the future. A major thrust of engineering activity that offers the promise of improving upon this is Model Based Engineering (MBE), defined in [NDIE, 2011] as “An approach to engineering that uses models as an integral part of the technical baseline that includes the requirements, analysis, design, implementation, and verification of a capability, system, and/or product throughout the acquisition life cycle”. Among its many perceived benefits, by providing immediate utility to designers to formally representation their system concepts, design rationale will be captured as design takes place.

9.2.1 Detecting Changing Conditions of Use

Complementary to the above, a viable approach is to adopt practices to detect situational divergences and assess whether they that threaten to undermine the design (and if so determined, respond accordingly). Preferably, these practices should be applied as situational changes are considered, rather than implementing the changes and after the fact looking to see what happened.

The following are indicators of change areas that might warrant consideration, with examples drawn from the pilot breathing experiences.

Changes to the scenarios in which the system is used. In pilot breathing, these include both changes that might affect the conditions the mechanical breathing system is exposed to, *and* changes the pilot will directly experience, for example:

- Longer durations of use – longer flight times mean the pilots may experience cumulative fatigue, which could make them more susceptible to physiological episodes, and they may be performing new activities, such as eating and drinking, that could adversely impact the breathing equipment
- Different mission conditions, such as more aggressive maneuvering increasing G loads on pilots with effects on their breathing, more rapid changes in throttle, altitude and airspeed with effects on the pressurization of the cockpit and therefore on both the mechanical breathing system itself as well as the pilot
- Changes to equipment other than the breathing systems itself (e.g., changes to harnesses or other flight gear worn by pilots may cause physical constrictions and so affect breathing)

Modifications to the system - a modification will presumably have been purposefully introduced (e.g., in pilot breathing, addition of the anti-G reference pressure inlet to compensate for G-loads)

- Look for changes between pre- post-modification
    - Did the modification achieve its intended purpose?

  - Were there any unanticipated side effects?
  - Consider whether additional measurements should be collected

Key to the above is to have means in place to capture the measurements that will reveal change. These should cover:

- **Context** – measurements of the conditions in which the system is deployed. For the pilot breathing exercise, in-flight measurements of the planes and their sorties were plentiful (e.g., cabin pressure, temperature, altitude, acceleration, 3-axis velocity, etc.).
- **Equipment** – measurements of the performance of the system itself, for example the VigilOX system's measurements of air flow and CO2 partial pressure. As the pilot breathing exercise showed, measurements of conditions *as close as possible to those the pilot actually experiences* are desirable – the development of the in-mask sensor exemplified getting very close to the actual breathing.
- **Physiological measurements** of the human – these are simultaneously the most important but least accessible, and furthermore are subject to greater human variability from one human to another, and for the very same human from one day to the next.

> "F.7-7 PBA found pilot Oxygen Saturation (SpO2) measurements taken immediately after flight were below the < 93.5% cutoff indicating critical physiological impacts due to hypoxia. Especially problematic is that the vast majority of the lowest SpO2 readings are found in the 100% supplied oxygen configuration (CRU-103) throughout the flight. *There were no pilot subjective reports of hypoxia symptoms*."

Particularly notable was this example from the PBA report:

- **Subjective reports:** When humans are involved, subjective reports should be encouraged and gathered. *These reports should not be restricted to only events that would be of obvious importance such as "Physiological Episodes" as defined by the US Navy.* For example, relatively innocuous anomalies, such as reports of post-flight fatigue, can be revealing of underlying conditions of potential concern. A wide range of reporting may help reveal symptoms that could, in some circumstances, lead to infrequent, but critical events.

To encourage communications, collection of these reports should be standard practice, and results made available in an anonymized manner. This would compensate for reluctance to report abnormalities for fear of being stigmatized (e.g., as an inferior pilot – see Section 8.2 for discussion of the pilot culture), and help calibrate uniformity (e.g., seeing such reports from others would let an individual realize it is not a personal idiosyncrasy, but a recurring phenomenon). In the commercial aviation arena, the Aviation Safety Reporting System, ASRS, "captures confidential reports, analyzes the resulting aviation safety data, and disseminates vital information to the aviation community" (https://asrs.arc.nasa.gov/).

Proactive actions should be taken to initiate such reporting, e.g., include mention of it in training, repeated from time to time, and perhaps to start with in-depth interviews where a skilled interviewer can prompt appropriate kinds of introspection that might otherwise not be considered. This recorded data should be regularly analyzed for trends, especially increasing frequencies of occurrence, and for associations. As this is done, it is important to avoid pitfalls such as “normalization of deviance,” [Vaughan, 1996] leading to complacency when no obviously bad consequence has yet been observed. Anomalies may be valuable leading indicators of troublesome phenomena.

References

NASA Systems Engineering Handbook, Section 3.8 Project Phase E: Operations and Sustainment

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10. Conclusion

10.1 The PBA story – Successes and Challenges; Lessons Learned

Introduction

Case studies are like fables. The Harvard Business Review holds that, especially for success stories,

> *"their recommendations can be useful, but only in the way that fables are. No one reads "The Tortoise and the Hare" and, faced with a chance to bet on such a race, chooses the tortoise. Rather, people take from this tale the idea that there is merit in perseverance while arrogance can lead to a downfall. Similarly, success studies should be treated not as how-to manuals but as sources of inspiration and fuel for introspection. Their value is not in what you* read *in them but what you read* into *them*[1]*."*

The PiBASE case study provided a comprehensive view of Systems Engineering at NASA both from a central HQ and an individual center perspective. An SE lens was applied on PBA operations as well as aspects of the aircraft/LSS - pilot system. This summary describes how a team approach using systems engineering concepts resolved technical challenges and ultimately led to project success. Lessons learned are outlined to assist the engineering and flight communities in future studies.

10.1.1 Successful Outcomes

This paper demonstrated some important SE threads which were essential to PBA's success. Those threads were:

- PBA and PiBASE built an effective, *multidisciplinary* team with the necessary skills, and these SMEs *collaborated* by adopting systems thinking.
- Tailored SE with emphasis on the spirit behind the letter.
- Started with stable, defined ConOps, which was iterated as the team became better informed through data and analysis.
- Engineering Analysis was based on tailored data collection (on human and machine), processing, and visualization. Quantitative tools (collapsible into flight scores) and key metrics were established.
- Emphasis was placed on the Human System. SMEs assessed human factors and machine-human interfaces and interactions. Physiological findings were laid out, and mechanisms through which a decompensated pilot state can develop were expanded upon (see Section 3.2, OTM).
- Throughout PBA and PiBASE the team made intelligent use of models. Developed strategies through cross-cutting to deal with complex systems (e.g., Phase Shift Analysis).
- The team worked with the manufacturer to understand and improve current human-metrics instrumentation for the flight environment, and in parallel implemented a more stable, higher resolution IMCWS.
- PBA provided data, knowledge captured (Almanac, product transition), findings and recommendations (with rationale) for future use to help identify and potentially resolve future in-flight issues.

Some of these concepts are expanded upon below, due to their significance for the PBA case study.

10.1.1.1 Tailored Systems Engineering. Emphasis on the Spirit Behind the Letter

AFRC had to transition from a well-oiled aircraft-testing assembly line and adapt to testing the human in conjunction with the aircraft, without negatively impacting pilot health and safety in a high-stakes, highly dynamic, outside the human comfort-zone environment. The NASA SE handbook and ideology provided guidance, while tailoring was equally important. To accomplish this, PBA's AFRC contingent consulted with chief engineers, members capitalized on the aggregate systems engineering experience and underwent additional training.

10.1.1.2 Teams and Systems Thinking: Every Person on a Project Team Can Contribute to Better Systems Engineering

Stephen Kapurch[2] (Office of the Chief Engineer, NASA Headquarters) states that the objective is to *"transform systems engineering from a task performed by individuals to a logical systems approach performed by* ***multidisciplinary teams****"* – and PBA has certainly done that. The team integrated a flight surgeon, pilots, human factors SME, engineers (life support, electrical), engineers acting as analysts, a chemist and DoD and LSS manufacturing knowledge base. Only with this multi-faceted background was it possible to understand ***The System***, which starts with the human (pilot), extends to his environment (aircraft cabin and dynamic state of the jet), has a duplex relationship with Life Support, and continuously feeds back subconsciously (autonomously) or consciously to the human receptors, for action by the human subsystems (respiratory, circulatory) or as directed by the central nervous system.

Within a team, various SMEs who have been either formally trained in its science, or have been on teams where its art has been practiced, consciously or subliminally adopt a way of "systems thinking," creativity and best practices which that lead to mission success. This was the case for the PBA core team and the IMCWS design team. The success of the PBA validates the idea that "*a systems perspective does not just belong to the person who wears the "systems engineer" badge. Even though you might be a thermal engineer, you need to understand the requirements that are allocated from the system above and flow down to the subsystem below your system. You need to know what your margins are and how you fit into the overall project. That way, when you conduct trade studies or select a design, you understand how your system operates within a bigger whole. Educating just systems engineers is insufficient. NASA as a whole is adopting a systems approach*[2]." Through this systems perspective, the PBA team could bring an electro-mechanical dynamic system (aircraft and LSS) to a common denominator with the human system and study the interactions as one. The outcome was that the electro-mechanical subsystems and the human in the loop have margins, and that an erosion of margins on the support side can lead to the erosion of margin on the human side. This can lead to difficulty breathing as documented in PBA flight 29, and if unchecked provides the mechanism leading to PEs (occurrence 1/1000 flights), as illustrated in the PBA defined Oxygen Transport Model.

10.1.1.3 Emphasis on Human Systems Integration and Human Factors

AFRC had to transition from a well-oiled aircraft-testing assembly line and adapt to testing the human in conjunction with the aircraft, without negatively impacting pilot health and safety in an environment outside the human comfort-zone. This was a human-centric investigation augmented by interviews, baseline vital measurements, questionnaires, pilot involvement through every step of the project via two-way communication. A key takeaway is that "acceptance" of a jet should not be just of aircraft performance; the jet and the pilot should pass acceptance as a holistic system within a relevant flight environment. Lastly, SMEs had to learn the Pilot Subculture and view the qualitative data in this context.

10.1.1.4 Engaging Private and Public Partners

The team initially studied all available information regarding relevant systems in the operation of F-15 and F-18 fighter aircraft. The team engaged NAVAIR engineers for a course in environmental control system functions and schematics, gained access to Boeing software control documentation through the Physiological Episodes Assessment, reviewed all available PE reports, accessed thousands of hours of aircraft flight data, and collaborated with the manufacturer of the test equipment. Through data exchange and insight into their processes, the team was able to understand the limitations and recommend improvements. PBA engineers sought out the oxygen regulator design which led to understanding the importance of local reference pressure versus ambient in a dynamic system, consulted SMEs who led relevant or parallel laboratory studies, and most importantly, listened to the pilots. As all these blocks of information were aggregated, a full picture of the system emerged allowing new insights for diagnosing and mitigating effects leading to PE incidents.

10.1.2 Challenges Encountered and Lessons Learned

Availability of specific aircraft, instrumentation, and pilots (given other projects and maintenance cycles), made flight **scheduling** for a balanced study **challenging**. Controlling the repetition of 5 flight profiles added to the scheduling complexity, but with creativity and coordination AFRC was able to re-schedule and implement all planned flights, including ones with the new IMCWS instrument. Although performance signatures (quirks) of individual aircraft were hard to control for, increasing the number of aircraft and performing repeat analyses provided insight into cabin pressure effects that otherwise would have been missed. Statistical calculations could control for some variance and imbalance in the dataset, but future studies will benefit from these observations.

An ongoing challenge is how to use what the PBA learned to realize reduction of PE incidents and their severity. The lesson being that these problems cannot be solved without understanding the interacting SoS nature of the problem. Sometimes the complexity is the problem and a solution would not be found if the situation is oversimplified.

10.1.2.1 Lessons from PBA Operations

a. <u>Problem solved.</u> Individual flight data benefitted from vendor implemented hardware and software updates throughout the study (as requested by the team). These introduced small variances in the data that needed to be controlled for using mixed-effects statistical models.

b. <u>Insights may be found in unlikeliest of places.</u> The PBA team was granted permission from the Airworthiness and Flight Safety Review Board to test a regulator with modified sensitivity. Anomalies were found showing an oscillating air-supply signal in great disharmony with breathing timing. This observation led to the discovery of similar (but more subtle) signatures in other flights of standard unmodified gear. Discerning such micro-oscillations of pressure and flow became a valuable tool for identifying human – machine interactions.

c. Project Managers need to be prepared to wear multiple hats and perform SE tasks, such as develop certain documents, including the Objectives and Requirements Document (ORD), when a dedicated Chief Engineer/Systems Engineer's availability is limited

d. More instruments meant more problems. One of the instruments on PBA had a serial number with a 30% failure rate (due to susceptibility to environment). Given the systems' nature of the PBA, when any one of the three instruments failed, the whole flight's data could not undergo uniform analysis protocols and thus is excluded. In co-dependent analysis, greater the number of instruments, greater the probability of encountering systematic data failure, impacting schedule and cost. Given slack in the schedule and margin in the budget, PBA was able to repeat most of these flights.

10.1.2.2 Lessons Regarding the Test Campaign, including Testing the Human

a. Tests should be designed to allow sufficient balance in the data to be able to discern the effect(s) of variables (aircraft tail number, AFE type, test equipment version and serial number). The initial test engineering design needed to evolve as experience was gained and adjusted real-time to account for unsuccessful flights, which resulted in imbalance of some data sets.

b. Pilot scripts were too busy, initially. In PBA, flights were designed with high task-saturation for efficiency. Breathing data were found impacted by specific events in the preceding 3 to 5 minutes (Gs, rapid pressure changes and tasks), leading to confounding of some results. Scripts were adjusted accordingly.

c. New data gathering methods require a period of familiarization. The application of spirometry and Rad-97, and questionnaire collection were practices new to AFRC, and therefor were inconsistent at first. The protocol was improved throughout the study. A consistent application and methodology would be best served by an on-site research team trained and focused on consistent and repeated application of the research protocol throughout the fixed data collection time window.

d. PIs should be prepared to inspire the buy-in of their test population. Collecting physiological data on professionals while performing their duties tends to be viewed as invasive or distracting; AFRC pilots are highly experienced test pilots and so are accustomed to research activities, as such, they were easily integrated into the full testing lifecycle to the success of many PBA goals. Even then, some human factor activities, such as questionnaire response, remained a lower priority for the pilot, and did not always get completed, or were completed with stock answers.

The human is the most complex part of the system and cause-and-effect outcomes in a human system need to be treated with care.

> *"The fact is that when an enterprise ignores human-systems integration (or fails to consider it well enough), there will inevitably be consequences—many unpredicted, and many undesired. The arguments certainly become easier when the BIG undesired consequence occurs, because then nobody can deny or dispute the "theoretical" concerns. But waiting for bad things to happen before acting seems to be extremely unintelligent." – G. Bendrick, Flight Surgeon, FAA.*

10.2 PiBASE Value to the Jet Fighter and Space Flight Engineering Communities

The original NASA PBA report represents the detailed investigation of the pilot-aircraft interactions. This PiBASE case-study takes the original report one step further and interprets the PBA within the context of systems engineering. PBA was already performed using NASA's systems engineering concepts, and PiBASE groups existing data into system models and multi-disciplinary examples. This case-study was deemed warranted as it is an excellent example of human systems integrated on equal footing with traditional engineering concepts. Its content has a wide reach, encompassing project and program manager communities, discipline and systems engineers, SMEs in Human Factors and Human Systems Integration, Safety and Mission Assurance SMEs and Mishap Investigators.

In a broader view, *"any type of closed system breathing (i.e. Spacesuit or emergency/ contingency breathing system) will be directly impacted by the breathing dynamics. Therefore, an understanding of the breathing dynamics will help Life Support engineers and physicians further develop spacesuits to accommodate the human no matter what type of environment they are in. NASA is continuing to expand the limits of human space flight to well beyond earth orbits and the moon. But without an understanding of the human dynamics and the interaction with either a suit or breathing system, we are going into guess work. Spanning aerial, atmospheric and space studies, uniting multidisciplinary SMEs to better understand our universe, that is where our uniqueness lies in NASA."*

David Alexander MD, NASA Flight Surgeon.

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Acronyms List

ΔP	Differential Pressure
AB	Afterburner
A-LOC	Almost Loss of Consciousness
ACAT	Aeromedical Crisis Action Team
ACE	Angiotensin-Converting Enzyme
ACE	Air Crew Equipment
ACES	Advanced Concept Ejection Seat
ACM	Air Combat Maneuvering
ACM	Air Cycle Machine
ACS	Automatic Pilot Control System
ACSC	Air Conditioning System Controller

ADRAC	Altitude Decompression Sickness Risk Computer
AEB	Accident Evolution and Barrier Function
AF	Air Force
AFB	Air Force Base
AFB	Airframe Bulletin
AFC	Air Frame Change
AFCE	Automatic Flight Control Equipment in the USAF
AFE	Aircrew Flight Equipment (see also ACE and ALSE)
AFRC	Armstrong Flight Research Center or Air Force Reserve Command
AFSRB	Airworthiness and Flight Safety Review Board
AGARD	Advisory Group for Aerospace Research and Development
AGE	Arterial Gas Embolism
AGL	Above Ground Level
AGSM	Anti-G Straining Maneuver
AI	Artificial Intelligence
ALS	Amyotrophic Lateral Sclerosis
ALSE	Aircrew Life Support Equipment (see also ACE and AFE)
ALSS	Aviation Life Support Systems
AMB	Aviation Mishap Board
AMSO	Aeromedical Safety Officers
AMPSS	Aircrew Physiologic Monitoring Sensor Suite
ANN	Artificial Neural Network
AOA	Angle of Attack
AOS	Aircraft Oxygen System
ARC	Ames Research Center
ARWG	Aeromedical Reference and Waiver Guide
ASCC	Air Standardization and Coordination Committee
ASD	Atrial Septal Defect
ASL	Arterial Spin Labeling
ASME	Aeromedical Subject Matter Expert
ASO	Aviation Safety Officer
ASRS	Aviation Safety Reporting System
ASTM	American Standard Test Method
ATAGS	Advanced Tactical Anti-G Suit
ATC	Air Traffic Control
AVR	Alveolar Ventilation Rate
BFM	Basic Fighter Maneuvering (USN) Basic Fighter Maneuvers (USAF)
BGS	Breathing Gas System
BOM	Bill of Materials
BP	Blood Pressure
BSD	Breathing Sequence Disruption
CAST	Causal Analysis based on System Theory
CDR	Critical Design Review
CO	Cardiac Output
CO	Carbon Monoxide
CO_2	Carbon Dioxide

ConOps	Concept of Operations
CR	Comprehensive Review
CRC	Cockpit Review Committee
CSRC	Cockpit Safety Review Committee
CST	Combined Systems Testing
CTM	Casual Tree Method
DAA	Denitrogenation Absorption Atelectasis
DATR	Dryden Aeronautical Test Range
DCS	Decompression Sickness
DDTE	Design, Development, Test, and Evaluation
DoD	Department of Defense
DOT	Department of Transportation
DRG	Dorsal Respiratory Group
DRR	Disposal Readiness Review
ECLSS	Environmental Control and Life Support System
ECS	Environmental Control System
EMI	Electromagnetic Interference
ERV	Expiratory Residual Volume
EVA	Extravehicular Activity
FAA	Federal Aviation Administration
FFT	Fast Fourier Transform
FM	Fault Management
FMSE	Fault Management Systems Engineer
FRC	Functional Residual Capacity
FRR	Flight Readiness Review
FTA	Fault Tree Analysis
FVC	Forced Vital Capacity
G	Gravity
G-LOC	Gravity-induced Loss Of Consciousness
H_2O	Water
HAAS	Human as a System
HCD	Human-Centered Design
HF	Human Factors
HFE	Human Factors Ergonomics or Engineering
HH	Hypoxic Hypoxia
HHFB	Habitability and Human Factors Branch
HIDP	Human Integration Design Processes
HITL	Human-In-The-Loop
HR	Human Resources
HRCP	Human Rating Certification Package
HSE	Health and Safety Executive
HSI	Human System Integration, Horizontal Situation Indicator
HSIPG	HSI Practitioner's Guide
HSIR	Human System Integration Requirements
I/O	Industrial-Organization
IC	Inspiratory Capacity

ILR	Industrial and Labor Relations
IMCWS	In-Mask Carbon Dioxide and Water Vapor Sensor
INCOSE	International Council on Systems Engineering
IRB	NASA's Institutional Review Board
IRIA	Reporting of Incidents and Accidents
IRV	Inspiratory Reserve Volume
ISIM	Integrated Safety Investigation Methodology
ISS	International Space Station
JSC	Johnson Space Center
LOC	Loss of Consciousness
LOX	Liquid Oxygen
LSS	Life Support System
MBE	Model Based Engineering
MCR	Mission Concept Review
MES	Multilinear Events Sequencing
Mid-IR	Mid-Infrared
Mini T/B	Mini Tech Brief
MORT	Management Oversight and Risk Tree
MPL	Mars Polar Landing
MSL	Mean Sea Level
MU	Memory Unit
NASA-TLX	NASA-Task Load Index
NCO	Non-Commissioned Officer
NDIR	Nondispersive Infrared
NESC	NASA Engineering and Safety Center
NIOSH	National Institute for Occupational Safety and Health
NPR	NASA Procedural Requirement
NRB	NESC Review Board
NTR	New Technology Reporting
NTSB	National Transportation Safety Board
O_2	Oxygen
OARU	Occupational Accident Research Unit
OB	Organizational Behavior
OBOGS	On-Board Oxygen Generation System
ORD	Objectives and Requirements Documentation
ORR	Operational Readiness Review (Flight)
OSHA	Occupational Safety and Health Administration
OTM	Oxygen Transport Model
P_ACO_2	Partial Pressure of Carbon Dioxide, or Blood Carbon Dioxide
P_AO_2	Partial Pressure of Oxygen; Minimum Alveolar O_2 Pressure; Arterial Oxygen Level
PAO_2	Alveolar Oxygen Level
PBA	Pilot Breathing Assessment
PBS	Product Breakdown Structure
pCO_2	Concentration of Carbon Dioxide
PDR	Preliminary Design Review

PE	Physiological Episode
PFAR	Post-Flight Assessment Reviews
PiBASE	Pilot Breathing Assessment Systems Engineering
PIC	Pilot In Command
PIP	Peak Inspiratory Pressure
pO_2	Concentration of Oxygen
PPB	Positive Pressure Breathing
$ppCO_2$	Partial Pressure of Carbon Dioxide
ppO_2	Oxygen Partial Pressure
ppO_2 or PPO_2	Partial Pressure of Oxygen
RCCA	Root Cause Corrective Action
ReML	Restricted Maximum Likelihood
ROBD	Reduced Oxygen Breathing Device
RV	Residual Volume
SAR	System Acceptance Review
SCAT	Systematic Cause Analysis Technique
SD	Solid Disk
SE	Systems Engineering
SIF	Serious Injury or Fatality
SME	Subject Matter Expert
Std Dev	Standard Deviation
SOP	Standard Operating Procedure
SOS	System of Systems
SpO_2	Oxygen Saturation or peripheral hemoglobin saturation
SR	Safety Report
SRR	Systems Requirement Review
SRS	Software Requirements Specification
STAMP	System-Theoretic Accident Model and Processes
STPA	System Theoretic Process Analysis
TLC	Total Lung Capacity
TLX	Task Load Index (NASA)
TLYF	Test-Like-You-Fly
TRL	Technical Readiness Review
TRR	Test Readiness Review
TTC	Teletronics Technology Corporation
TUC	Time of Useful Consciousness
TV	Tidal Volume
UAS	Unmanned Aerial Systems
UPG	Upper Pressure Garment
USAF	United States Air Force
USN	United States Navy
V	Ventilation Ratio
VC	Vital Capacity
VOC	Volatile Organic Compound
VRG	Ventral Respiratory Group
WAIT	Work Accidents Investigation Technique

WMS	Wavelength Modulation Spectroscopy
WO	Work Order
WWII	World War II

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14. ABSTRACT

This position paper assesses the Pilot Breathing Assessment's driving requirement to collect missing data on pilot breathing pressure, flow, rate, oxygen and CO2, simultaneously with aircraft data. Repeat measures data were collected over a 2-year period from 5 NASA test-pilots flying 8 flight profiles on NASA F-15 and F/A-18 (A, B) aircraft. This Pilot Breathing Assessment Systems Engineering (PiBASE) position paper serves as a case-study of systems engineering that accommodates the human as a distinct part of the whole. It acknowledges that a successful machine design intended for human use must include human systems biology/physiology as an integral part of planning, design, and implementation.

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