AST Commercial Human Space Flight Participant Biomedical Data Collection

P. Vernon McDonald, Ph.D.
James M. Vanderploeg, M.D., M.P.H.
Kieran Smart, M.D., M.Sc., M.P.H.
Doug Hamilton, M.D., Ph.D., M. Sc. E. Eng

Final Report
DOT Volpe Center Contract DTRT57-05-D-30103, Task Order #6
Subcontract 10153943 from The Aerospace Corporation

Prepared for:
Volpe National Transportation Systems Center
Cambridge, Massachusetts

Wyle Laboratories, Inc.
Technical Report #LS-09-2006-001
February 1, 2007

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE (DD-MM-YYYY)	2. REPORT TYPE	3. DATES COVERED (FROM - TO)
01-02-2007	Contractor Final Report	February 23 – September 29, 2006

4. TITLE AND SUBTITLE

AST Commercial Human Space Flight Participant Biomedical Data Collection

5A. CONTRACT NUMBER
DTRT57-05-D-30103

5B. GRANT NUMBER

5C. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)*

P. V. MCDONALD, J. M. VANDERPLOEG, K. SMART, AND D. R. HAMILTON

5D. PROJECT NUMBER
FA2R CL411

5E. TASK NUMBER
Task Order #6

5F. WORK UNIT NUMBER
FA2R CL411

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
U.S. Department of Transportation
Research and Innovative Technology Administration
Volpe National Transportation Systems Center
Safety Information Systems Division
Cambridge, MA 02142-1093

8. PERFORMING ORGANIZATION REPORT NUMBER
DOT-VNTSC-FAA-06016

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Department of Transportation
Federal Aviation Administration
Office of the Assoc. Administrator for Commercial Space Transportation
Washington, DC 20591

10. SPONSOR/MONITOR'S ACRONYM(S)
FAA AST-100

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT
PUBLIC RELEASE IS AUTHORIZED

13. SUPPLEMENTARY NOTES
*Wyle Laboratories, Life Sciences Group, Houston, TX 77058, subcontractor to The Aerospace Corporation, El Segundo, CA 90245-4691, under DOT Volpe National Transportation Systems Center contract no. DTRT57-05-D-30103, Task 6. Wyle Laboratories Report No. LS-09-2006-001

14. ABSTRACT

Recommendations are made for specific biomedical data, equipment, and a database that will increase the knowledge and understanding of how short duration, suborbital space flight missions with brief exposure to microgravity affects the human body. The focus of these recommendations is commercial space flight participants engaged in suborbital flight. These recommendations do not address commercial or government professional astronauts, nor do they address orbital space flight missions. The intended purpose of these recommendations is to provide FAA/AST, through the Volpe Center, guidance as to how the emerging commercial human space flight industry may define risks required for disclosure to suborbital space flight participants and proactively develop corrective actions to reduce such risks. Recommendations are made for the monitoring of vehicle and biomedical data before, during, and after flight, and within the context of preflight centrifugation. The primary biomedical systems of concern include cardiovascular, pulmonary, musculoskeletal, neurovestibular, and psychological. Gastrointestinal issues also need to be addressed. Recommendations for the type of biomedical equipment required to acquire the in-flight data are discussed, although specific recommendations are complicated by the absence of specific data describing the flight vehicle and passenger configurations likely to be encountered. Finally, several biomedical databases from NASA are briefly summarized. The recommendations and requirements for the design of a suitable database to accommodate the acquired commercial space flight data are based on two NASA databases, the Longitudinal Study of Astronaut Health database, and the Private Medical Conference database.

15. SUBJECT TERMS
biomedical, monitoring, commercial, suborbital, space flight, database

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19A. NAME OF RESPONSIBLE PERSON
A. REPORT	B. ABSTRACT	C. THIS PAGE			James N. Hallock, Ph.D.
U	U	U	UU	62	**19B. TELEPHONE NUMBER (INCLUDE AREA CODE)** (617) 494-2199

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Executive Summary

The Aerospace Corporation was tasked by the Volpe National Transportation Systems Center to provide technical support to the Federal Aviation Administration, Office of Commercial Space Transportation (FAA/AST) in the identification and recommendation of specific biomedical data, equipment, and a database that will increase the knowledge and understanding of how short-duration, suborbital space flight missions with brief exposure to microgravity affects the human body. Wyle Laboratories, Life Sciences Group, Houston, TX, provided substantial support as a subcontractor to Aerospace. It should be noted that there are no requirements for monitoring, data gathering, storage, or evaluation of biomedical data for either the flight crew or space flight participants[1] at this time. This document is based on the evaluation of the potential benefit of such a program, and refers specifically to commercial space flight participants, not commercial space flight professional crewmembers. The purpose was to provide FAA/AST, through the Volpe Center, technical support in defining potential medical risk factors that can be monitored before, during and/or after commercial human space flight through the identification and measurement of space flight participant biomedical parameters. This information can be used to disclose to the space flight participants any potential medical risks and also proactively develop corrective actions to reduce such risks. Recommendations are made for the monitoring of vehicle and biomedical data before, during, and after flight and also within the context of preflight centrifugation. Biomedical concerns are related to neurological, cardiovascular, pulmonary, musculoskeletal, neurovestibular, psychological, and gastrointestinal stresses that will be encountered. Recommendations are discussed for the type of biomedical equipment required to acquire the in-flight data, although specific recommendations are complicated by the absence of specific data defining the flight vehicle and passenger configurations likely to be encountered. Finally, several biomedical databases from NASA are briefly summarized. The recommendations and requirements for the design of a suitable database to accommodate the acquired commercial space flight data are based on two NASA databases, the Longitudinal Study of Astronaut Health database and the Private Medical Conference database.

[1] Federal Aviation Administration 14 CFR Parts 401, 415, 431, 435, 440 and 460

Scope

The Commercial Space Launch Amendments Act of 2004 requires that space flight participants, as defined in Federal Aviation Administration 14 CFR Parts 401, 415, 431, 435, 440 and 460, be completely informed of the risks associated with commercial space flight operations. The work summarized in this report will assist the FAA/AST in defining the risks required for disclosure to space flight participants and outlining potential corrective actions that will reduce such risks.

The goal of this task is the identification and recommendation of specific biomedical data, equipment, and a database that can be used to increase the knowledge and understanding of how short-duration suborbital space flight missions and brief exposure to microgravity affects the human body. For the purpose of this report, "short-duration exposure" is considered to be associated with suborbital flight profiles.

As our knowledge and understanding of the impact of suborbital space flight and the effects of short-term exposure to microgravity on the human body increases, so will the ability of operators to inform space flight participants about those risks. The contrary may also occur. The industry may conclude through the evolution of commercial space transportation that the risk is no different than other forms of transportation.

Note that the material presented and discussed in this report does not address recommendations for medical standards to be used in certifying participants for the purpose of suborbital flight. It is assumed that implementation of these recommendations would be on a voluntary basis by the commercial human space flight industry. In addition, the recommendations made in this report apply to the biomedical monitoring of those individuals who are permitted to fly suborbital flights. Consequently, one must assume that there will be a certain number of medical conditions that will not be seen in the suborbital flight participants, because operator medical qualification standards deem them an unsuitable risk for suborbital space flight.

In summary, the objective of acquiring the biomedical parameters recommended in this report is to characterize the cohort of space flight participants permitted to undertake suborbital flight. The recommended parameters are not requirements but rather, recommendations, which, if followed, should result in a more complete understanding of the human response to suborbital flight.

Acknowledgements

The authors wish to extend thanks to the Office of the Associate Administrator for Commercial Space Transportation, Federal Aviation Administration (FAA/AST), for the opportunity to work on this project. Specifically, gratitude is extended to Ms. Michelle S. Murray and Mr. David A. Gerlach at FAA/AST for valuable guidance on commercial launch vehicle regulatory and licensing needs. The authors also wish to thank the following personnel at the DOT Volpe National Transportation Systems Center, who provided valuable insight into relevant technical issues and government needs and regulations: Ms. Ann R. DiMare, who served as the Contracting Officer's Technical Representative (COTR), and Dr. James N. Hallock, who carefully reviewed and edited this report. Gratitude is extended to Mr. Robert W. Seibold, for his support and guidance as the Aerospace Corporation program manager. Finally, the authors thank Joyce Timler and Sean Wilson for editorial and technical assistance.

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1.0 Subtask 1

Identify in-flight and ground biomedical parameters that will allow for characterization of medical and biological effects experienced by the human body during space flight.

1.1 Introduction

A total of 452 people have flown in space[2]. Only seven completed suborbital flight, defined as an altitude greater then 100 km. Furthermore, greater than 95% of this total were professional astronauts/cosmonauts who had to pass stringent selection criteria to be initially selected and subsequently assigned to a mission. Therefore, it is a fact that professional astronauts/ cosmonauts are characterized by a high degree of physiological and psychological fitness that is not representative of the general commercial space flight participant population. Consequently, there is limited knowledge about the effects of space flight on the general public. The emergence of the commercial human space flight industry offers flight opportunities to all who can afford it and safely tolerate the stresses. Analysis of available data, in the context of the expected duration and flight profiles of the commercial space vehicles proposed by the initial operators, suggest that most of the effects on participants will be cardiovascular, pulmonary, neurovestibular, musculoskeletal, gastrointestinal and/or psychological in nature. The immediate effects on these body systems will come from the acceleration profiles of launch and reentry.

The aim of this program is to define the parameters recommended for preflight, in-flight, and postflight monitoring and data for storage and analysis. The monitored data will be used to assist with defining the medical and biological effects experienced by space flight participants during suborbital commercial space flight operations, however this does not include professional space flight crewmembers.

To facilitate more accurate interpretation of these data, we recommend the data set include environmental, vehicle, and flight profile parameters in addition to the biomedical parameters. These parameters are defined below.

1.2 Assumptions

Risk management for commercial space flight operations must be based on vehicle and human considerations. Assumptions associated with vehicles and participants will, in part, drive the types of data and methods used to determine how the data are to be gathered. To analyze how short-duration exposure to microgravity affects the human body, we have defined a number of assumptions associated with suborbital flights.

1.2.1 Vehicle

- A variety of vehicles will exist and will vary in the launch method, including vertical take off, and air launch from a carrier aircraft
- The flight duration is expected to last up to 3 hours in total, with up to 6 minutes spent in microgravity.

[2] As of 31 July 2006

- .Landing may include:
  - Parafoil
  - Glider
  - Ballistic (with parachute and attenuation) – in water and on land
  - Powered
- Maximum acceleration (G) forces are nominally expected to be up to 7G for short periods of time (less than 10 seconds), with up to 4G for longer periods (less than 30 seconds). The G forces on launch will be vehicle specific and dependant on the method of launch. The axis and duration of G forces in flight will depend on the layout and operations of the vehicle. The direction of the acceleration vector on the body will be an important factor defining the biomedical stress experienced. Vehicle operators are considering adaptable vehicle layouts that will focus on G_X when possible. Note that the FAA guidelines[3] state:

  "In general, the acceleration envelope recommended for the aerospace vehicle should not exceed $+4G_Z$ ($-2G_Z$), $\pm$ 4 G_X and $\pm$ $1G_Y$"
- Flight operations can be expected to be up to 400,000 ft.
- Vehicle cabin environment will be operator dependent. Options include
  - Shirt sleeve
  - Standard Nomex-type material flight suit
  - Pressure suit
- Operating pressure is likely to be equivalent to that between sea level and 8000 feet and will be operator/vehicle dependent.
- Atmosphere is likely to be 21% partial pressure O_2 (ppO_2).

1.2.2 Participant profile

- The number of participants may be up to 1000 per year, with flights as frequent as daily.
- The number of participants per vehicle will vary, with operators considering 1 to 6 participants per flight.
- There is no plan to fix the upper-age limit for participants. The FAA has identified 18 as the lower-age limit arguing that someone under the age of 18 cannot be considered able to provide informed consent. Operators may also wish to establish a higher minimum age for passengers for human space flight. The participants' median age is likely to be in the 50s, based on resource requirements for such flights. However, participants of a range of ages can be expected.
- Participant populations may fly when there is no precedent, for example;
  - Elderly > 77 years of age (e.g., John H. Glenn)
  - Participants with physical disabilities
  - Participants with concurrent pathology
  - Obese participants

  Except when these conditions interfere with safety, the operational aspects of the flight, or when conditions may deteriorate in the space environment (see Footnote 2).
- The scope and variety of the physical condition of participants is expected to be similar to that of the general public.
- Participants are expected to be able to perform emergency evacuation procedures without assistance and without compromising the safety of other occupants.

[3] Guidance for Medical Screening of Commercial Aerospace Passengers, DOT/FAA/AM-06/1, January 2006

- The Federal Aviation Administration (FAA) will require that operators inform space flight participants of the risks of space flight generally and of those associated with their vehicle and operations.
- Participants are expected to be directly involved with the flight operations for 3 to 5 days. This may or may not include preflight physical evaluations, depending on the operator.
- FAA guidelines advise a physical no more than two weeks before flight in certain circumstances.
- Physical exams:
  - The FAA Guidelines subdivide the participants into those experiencing up to $+3G_Z$ and those in excess of $+3\ G_Z$.
  - The FAA suggests a comprehensive medical history and physical examination with laboratory testing when acceleration may exceed +3Gz.
  - The initial proposals from vehicle operators show that $+3\ G_Z$ is likely to be exceeded, and therefore we can assume that all participants will require – according to the guidelines – a preflight physical.

1.3 History and Data Review

There have been only a few suborbital flights, i.e. an altitude of 100 km, in the history of human space flight and several very high-altitude balloon flights. The Russian Space program bypassed suborbital flight; Yuri Gagarin's first flight, lasting 108 minutes, was a single orbit of the Earth. However a failed Soyuz orbital launch became, by default, their only suborbital flight. Until 2004, U.S. suborbital flights were limited to two NASA Mercury flights and thirteen USAF North American Aviation X-15 program flights that reached 50 miles altitude. There were no other crewed suborbital flights until the two X-Prize flights by Scaled Composites LLC's SpaceShipOne on 29 September and 4 October 2004.

Table 1.3-1 Suborbital flights

Program	Flight	Altitude	Crew	Date
Mercury	MR-3	187.42 km	Alan B. Shepard	May 5, 1961
	MR-4	190.39 km	Virgil I. Grissom	July 21, 1961
X-15 Program	Flight 90	106.01 km	Joe Walker	July 19, 1963
	Flight 91	107.96 km	Joe Walker	August 22, 1963
Soyuz	18a	180 km	Vasili Lazarev & Oleg Makarov	April 5, 1975
SpaceShipOne	15P	100.124 km	Michael Melvill	June 21 2004
	16P	102.9 km	Michael Melvill	September 29, 2004
	17P	112.0 km	William Brian Binnie	October 4, 2004

As with orbital flight, the crewmembers involved to date have virtually all been professional, trained, healthy individuals. In addition, the data gathered in suborbital flight were aimed at scientific research and monitoring the health of crewmembers, based on the expectations of

human space flight characterized by the state of medical science in the late 1950s and early 1960s.

1.3.1 High-Altitude Balloon flights

Project Manhigh was a pre-space-age military project that used balloons to reach the upper layers of the Earth's atmosphere. The project began in December of 1955 to study the effects of cosmic rays on humans however the data returned was largely inconclusive. Nevertheless, important lessons learned would be later utilized in Project Mercury. Three balloon flights to the edge of space were made during the program:

- Man High 1 to 29,500 m (96,784 feet) by Captain J W Kittinger II on June 02, 1957
- Man High 2 to 30,900 m (101,516 feet) by Major David Simons on August 19-20, 1957
- Man High 3 to 29,900 m (98,097 feet) by Lieutenant Clifton McClure on October 08, 1958

The high-altitude record of 34,668 m (113,740 feet) was made on April 5, 1961 by Commander Malcom D. Ross and Lieutenant Victor A. Prather, Jr. of the U.S. Navy in the Strato-Lab program. Lt. Prather died when his pressure suit filled with water upon landing. (Ross, 1958)

1.3.2 NASA Mercury Program

The suborbital flight of Alan B. Shepard, Jr. on May 5, 1961 reached a peak of 116 statute miles for a downrange distance of 302 statute miles, and was weightless for less than 5 minutes (see Table 1.3.2-1).

Table 1.3.2-1 Mission Parameters

Duration	15 min 28 secs
Apogee	116.46 miles
Distance	302.77 miles
Maximum velocity	5,143 mph
Peak acceleration:	11 -Gx (108 m/s^2)

The second suborbital flight was made by NASA Astronaut I. Virgil Grissom on July 21, 1961. He traveled to an altitude of 118 statute miles, and 303 miles downrange. Both astronauts were launched on Redstone rockets, which had been in development since 1952.

The suborbital flights of Mercury monitored:

- Body temperature
- Respiration - measured by several different methods, none of which gave reliable respiration traces.
- Electrocardiogram (ECG) - this functioned well and provided excellent information on cardiac rate and rhythm.

One of the basic objectives of Project Mercury (both suborbital and orbital flight) was to evaluate human response to the space-flight environment. Those factors likely to elicit physiological responses included:

- Wearing a full-pressure suit although not pressurized in flight
- Confinement and restraint in the Mercury spacecraft with the legs at 90° elevated position
- Exposure to 100% ppO_2 at 5 psi atmosphere for the duration of the flight.
- Variation in cabin and suit temperature
- Acceleration forces of launch and reentry, varying periods of weightless flight
- Vibration
- Dehydration
- Lack of extended and/or regular sleep
- Changes in illumination inside the spacecraft
- Diminished food intake
- Anxiety/psychological stress

Results show that the peak physiological responses were closely related to critical in-flight events. The six NASA Mercury astronauts who flew a mission showed themselves capable of normal physiological function and performance during the accelerations of launch and reentry. They tolerated the vibration of launch and reentry well and there was no evidence of motion sickness. The heat loads imposed caused discomfort upon occasion but did not become a limiting factor in the missions.

It was not until the NASA Mercury Project MA-6 mission of John H. Glenn that blood pressure readings were taken because, until that time, no satisfactory system had been developed. Glenn's flight medical data are shown in Table 1.3.2-2.

Table 1.3.2-2 Summary of Human Flight Data for MA-6

Event	Pulse rate/min	Blood Pressure (BP)	Respiration Rate breaths/min
Lift-off	110		14
Spacecraft Separation	114		12
Weightlessness	Mean 86	Mean 129/70	8-14
Retrofire	96		12
Reentry	134		19

All six NASA Mercury crewmembers returned to Earth in a healthy condition. Weightlessness caused no problems according to the astronauts. They were able to conduct complex visual-motor coordination tasks proficiently in the weightless state. No evidence of body system dysfunction was discovered during the flights. Urination occurred normally in time and amount, and there was no evidence of difficulty in intestinal absorption in the weightless state. The principle findings were weight loss due to dehydration, especially in the orbital flights, with mild cardiovascular impairment. There were some signs of postflight orthostatic intolerance and

hemo-concentration, however signs of orthostatic hypotension were not noted in the suborbital flights (Link, 1965, Swenson 1989). Note, however, only 2 of the 6 flights were suborbital.

1.3.3 Joint USAF NACA/NASA X-15 Program

The X-15 had its first, unpowered glide flight on June 8, 1959, while the first powered flight took place on September 17, 1959. The program's final flight was performed on October 24, 1968. During the X-15 program, 13 flights met the U.S. criterion for a space flight by passing an altitude of 50 miles (80 km) and, out of these, 2 also qualified for the international Federation Aeronautique Internationale (FAI) definition of a space flight by passing the 62.1 mile (100 km) mark (see Table 1.3.3-1).

Table 1.3.3-1 X-15 Flights over 50 miles

Flight	Date	Altitude	Pilot
Flight 62	July 17, 1962	95,940 m	Robert M. White
Flight 77	January 17, 1963	82,810 m	Joe Walker
Flight 87	June 27, 1963	86,870 m	Robert Rushworth
Flight 90	July 19, 1963	106,010 m	Joe Walker
Flight 91	August 22, 1963	107,960 m	Joe Walker
Flight 138	June 29, 1965	85,527 m	Joseph H. Engle
Flight 143	August 10, 1965	82,601 m	Joseph H. Engle
Flight 150	September 28, 1965	90,099 m	John B. McKay
Flight 153	October 14, 1965	81,230 m	Joseph H. Engle
Flight 174	November 1, 1966	93,543 m	Bill Dana
Flight 190	October 17, 1967	85,500 m	Pete Knight
Flight 191	November 15, 1967	81,080 m	Michael J. Adams
Flight 197	August 21, 1968	81,530 m	Bill Dana

Aeromedical aspects of piloting a plane at hypersonic speeds and in space were a controversial aspect of the X-15 program. Some experts in aviation medicine viewed with great concern the flight environment that X-15 pilots would encounter. In particular, they were apprehensive of weightless flight, an unknown factor in the mid-1950s.

Along with other X-15 systems, the pressure suit underwent continuous improvement and updating. It operated satisfactorily on several flights in which partial cockpit pressurization was lost at altitudes above 100,000 feet. Although the suit was designed specifically for the X-15, its technology was utilized in other programs, notably NASA Mercury and Gemini. A major portion of medical monitoring was the development of instrumentation techniques as an integral part of the pressure suit. Originally the instrumentation recorded electrocardiogram, skin temperatures, oxygen flow, and suit pressures and, eventually, a means of measuring blood pressure in flight. The basic crew physiological measurements were heart rate, respiratory rate, and blood pressure.

Initial measurements revealed that heart rates averaged 145 to 160 beats per minute during the flight. On some flights, they rose as high as 185 beats per minute, and never fell below 145. Most of the increase in heart rate occurred before the X-15 was launched from the B-52, and

reflected anxiety and anticipation rather than direct physical stress. Later analyses confirmed the previous conclusions that psychological factors were the primary influence on heart rate.

1.3.4 NASA Gemini to Shuttle

Human space exploration activities over the past 45 years since the Mercury suborbital flights have used a variety of vehicles with widely differing mission objectives. However, since almost all the participants in these missions experienced extended exposure to microgravity, most of the biomedical data associated with these missions is not directly related to understanding the responses to suborbital flight, with the exception of the launch and re-entry. Table 1.3.4-1 provides a summary of the vehicle and mission types.

Table 1.3.4-1 Space Exploration Vehicles

Vehicle	Crewmembers Per Mission	Mission
Mercury (Orbital)	1	Orbital
Gemini	2	Orbital with rendezvous and docking tests
Vostok	1	Orbital with rendezvous tests
Voskhod	2 – 3	Orbital
Apollo	3	Orbital, Moon landing
Soyuz	3	Orbital with docking to Salyut/Mir/ISS
Apollo Soyuz Test Program	5 total	Orbital with docking
Skylab	3	Orbital Station
Salyut	2–3	Orbital Station
Shuttle	2 – 8	Orbital, with docking to Mir/ISS
Mir	3	Orbital Station
ISS	2 – 6	Orbital Station
Shenzhou	1 – 2	Orbital

Note: All space station missions have had visiting crewmembers at various times, increasing the number of crewmembers in orbit to a maximum of 10 at any one time.

These missions have used a variety of launch vehicles. The launch vehicles have all been vertical multistage rockets, the majority being "classical" rocket systems, with the crewmember(s) on top of the "stack" or, in the case of Shuttle and Buran (although no crewed orbital flights took place), parallel to the booster motors. The relevant factor of these operations for suborbital commercial space flight is the acceleration stress incurred in the ascent stage. In all cases the crews launched in a reclined position with acceleration in the Gx vector.

The main physiological effects experienced and observed in the NASA Gemini missions, all of which were orbital and therefore of limited relevance to short microgravity exposures, are summarized below:

- Postflight orthostatic intolerance

- Loss of exercise capacity
- Reduction in bone density
- Loss of red cell mass

The Apollo program showed similar findings to Gemini with the addition of:

- Vestibular disturbance
- Low caloric intake
- Dehydration and weight loss
- Cardiac dysrhythmias

The National Space Transportation System (NSTS)/Space Shuttle program has had much success but sadly two total failures resulting in the loss of Challenger OV-99 and Columbia OV-102 and the deaths of 14 crewmembers. However, an important legacy of the Space Shuttle will be the numerous medical and physiological experiments conducted during Spacelab missions. The Spacelab Module consisted of a large cylindrical main laboratory flown in the rear of the Space Shuttle cargo bay. The four Spacelab science flights were: Space Life Sciences-1 (STS-40, flown in 1991), SLS-2 (STS-58, flown in 1993), Life and Microgravity Spacelab (STS-78, flown in 1996) and Neurolab (STS-90, flown in 1998) all of which have contributed much to our knowledge of physiological adaptation to space flight. STS-107, launched on Jan 16th 2003, was the first flight of Spacehab Research Double Module and the first Extended Duration Orbiter (EDO) mission since STS-90. This 15-day, 21-hour mission was dedicated to research in physical, life, and space sciences, conducted in approximately 80 separate experiments, comprised of hundreds of samples and test points. The physiological results of these missions have reinforced the early findings related to short-duration exposure to space flight. In particular, they have expanded our understanding of the cardiovascular and neurological responses of microgravity in long-duration space flight, and are therefore not directly applicable to suborbital flight. The three longest STS missions were STS-80, 17 days, 15 hours; STS-78, 16 days, 21 hours; and STS-67, 16 days, 15 hours.

The operations, research activities, and biomedical data gathered on the Space stations, including Skylab, USSR Salyut, Russian Mir, and the NASA International Space Station (ISS) have focused on long-duration space flight and, consequently, have less relevance for the initial phases of commercial space flight.

1.3.5 G-profiles

There is little or no objective data available on the effects of acceleration stress on the general public, and therefore we have to draw inferences from the research on aircrew in centrifuge experiments and the data from space flight. Ground-based G-load exposure for training, experimental, and medical screening purposes typically use a centrifuge. Most studies of the effects of high acceleration have been made on healthy and young (mostly male) subjects in military human centrifuges. For approval of experimental protocols involving human subjects in centrifuge high-G exposures, certain pre-existing conditions, and risks with potential to cause injury, pain, or other more serious conditions were considered. The subjects were informed about these potential risks before participating in any high-G exposures. Potential risks include:

- Abnormal heart rate and rhythm

- Musculoskeletal pain or soreness
- Loss of consciousness
- Motion sickness
- Subcutaneous or scrotal hematoma
- Edema in the legs
- Injury to heart or blood vessels
- Spinal column injury
- Nerve injury
- Hernia
- Eye injury
- Petechiae
- Seizure

1.3.5.1 *Arrhythmia*

Extrapolating the available centrifuge data taken from healthy subjects concerning arrhythmia to the general population poses significant problems as ostensibly, none of the subjects in centrifuge trials had significant cardiopulmonary disorders. Nevertheless coronary artery disease (CAD) is the leading cause of death in developed nations, and accounts for 1 out of every 2.5 deaths in the U.S. Nearly half of asymptomatic CAD cases initially present as acute myocardial infarction (MI) or sudden death, and CAD is the leading cause of permanent withdrawal from flight status and non-accidental deaths in military and civil aviation flight crews. Due to the limited treatment and evacuation capabilities of most of the proposed suborbital commercial space flight vehicles, prevention of acute cardiac events is essential to passenger safety.

Arrhythmias have been observed to occur during centrifugal acceleration even in an apparently healthy cohort. McKenzie and Gilligham (1993) reported that in a series of 1,180 centrifuge training sessions involving professional aeromedical course attendees at the USAF School of Aerospace Medicine, 47 percent resulted in arrhythmias. Moreover, prescreening does not necessarily eliminate the occurrence of these arrhythmias. Hanada et al. (2004) observed that in a series of 195 male fighter pilots, 2.6 percent demonstrated ventricular tachycardia, 1.5 percent paroxysmal demonstrated supraventricular tachycardia, and 0.5 percent demonstrated paroxysmal atrial fibrillation, all of which were considered indications to stop the centrifuge training. Of significance here is the magnitude and direction of the G loading, as much as +9Gz (eyeballs down). Available design data from commercial suborbital space flight vehicles indicate acceleration forces will peak at +7G and, when possible, will be largely in the x-axis (eyeballs in). This force vector is substantially less stressful on the cardiovascular system than the positive z-axis accelerations.

Although symptomatic cardiac disease has been reported infrequently in astronauts, arrhythmia during space flight has been observed frequently. The Russian Space Program also has reported changes in R-, S-, and T-wave amplitude beginning in the second or third months of flight. This increase may simply be due to microgravity-induced anatomical alterations of the heart relative to other thoracic structures. Decrease in T-wave amplitude also may be due to altered potassium metabolism, which may relate to ventricular ectopy. Moreover, the Russian medical community

has reported to NASA that over the last 10 years of Mir operations, they observed approximately 31 abnormal electrocardiograms, 75 arrhythmias, and 23 conduction disorders.

Regardless, the use of arrhythmia to distinguish functional impairment secondary to an exacerbation of subclinical cardiac disease from the normal response of a healthy population during centrifuge runs of space flight is not straightforward. Any commercial space flight passenger who is suspected to have a high positive pretest probability to provocative functional cardiac testing should be considered for a more extensive medical exam to rule out CAD or any other pro-arrhythmogenic medical condition that might manifest itself during space flight. (i.e., cardiomyopathy, renal impairment, nutritional deficiencies) as detailed in the subsequent tables in section 1.4

1.3.5.2 *G-Forces*

The G forces that have been experienced to date by crewmembers on space flights during ascent have ranged from +3 to +11G_X (see Table 1.3.5.2-1)

Table 1.3.5.2-1 G-loads on launch

Vehicle	**Launcher**	**+G_X forces**
Mercury	Redstone	11
	Atlas	7.6
Gemini	Titan ll	7
Vostok	Vostok (R7)	7
Voskhod	Voskhod (R7)	7
Soyuz	Soyuz (R7)	7
Apollo	Saturn 1 B	4
	Saturn V	4
Shuttle		3
Shenzhou	Long March CZ-2F	Unknown

The G-profile of Mercury with the Atlas rocket (Fig. 1.3.5.2-1) shows a rapid rise in loads over two phases. Such forces place significant loads on the cardiovascular system and were considered tolerable only by crews who were physiologically healthy and appropriately trained.

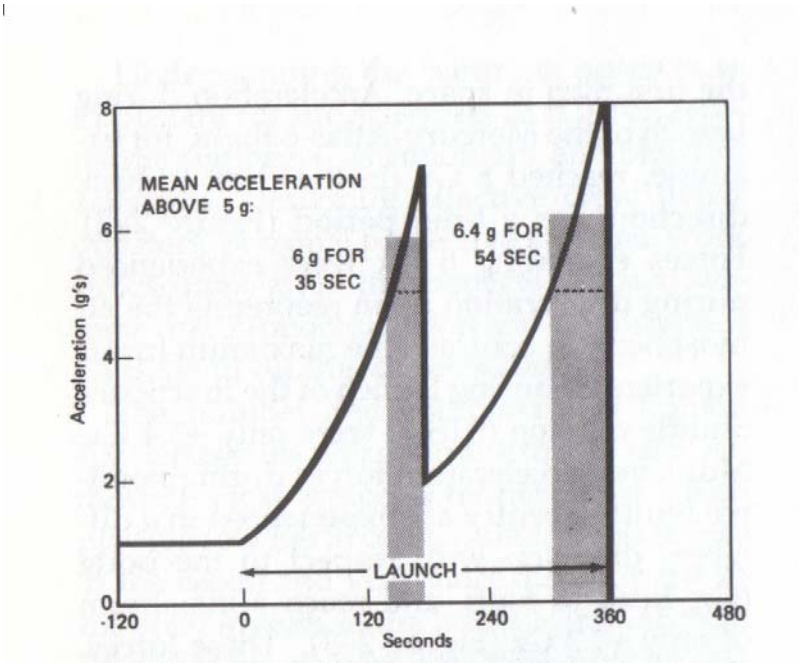


Figure 1.3.5.2-1 Acceleration profile of the launch phase of NASA Mercury Program (Adapted from Space Biology and Medicine 3rd Ed Vol. lll, Book 2, 1993)

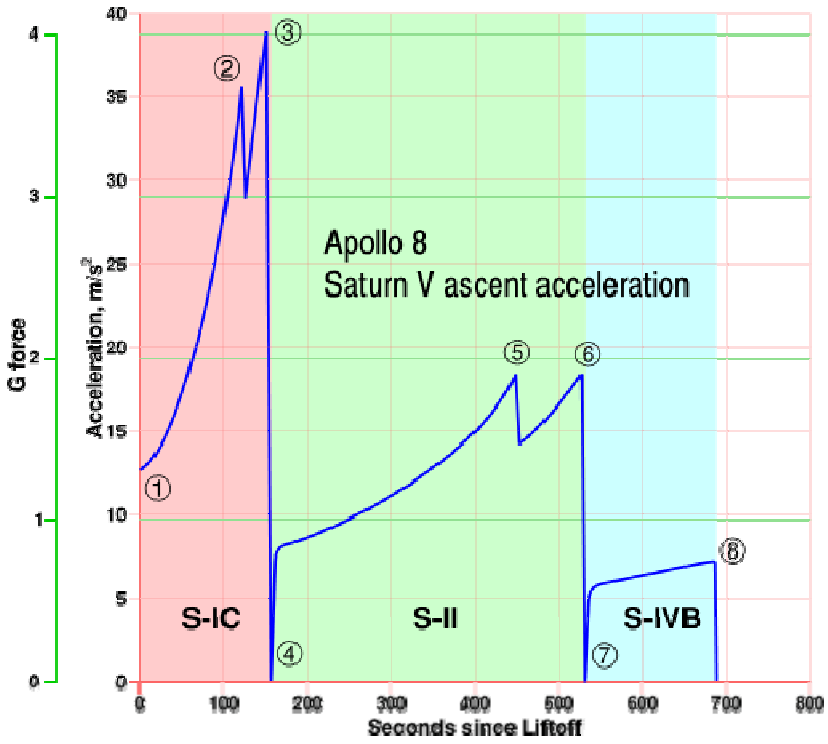


Figure 1.3.5.2-2 Apollo 8 Saturn V Ascent Acceleration (derived from the AS-503 Saturn V Flight Evaluation Report)

The Apollo launch data in Fig 1.3.5.2-2 show that this is a dynamic and complex vehicle-specific loads profile. The highest launch loads occur during:

1. **Launch.** The first stage of Apollo 8 delivered more thrust than expected to a launch vehicle that was lighter than most of the later Apollo-Saturns.
2. **S-IC inboard engine cut-off.** The graph to this point shows how steeply the acceleration is rising.
3. **S-IC outboard cut-off.** The overall thrust and acceleration rise have been reduced, reaching a peak of 4Gz at the time of S-IC cut-off.

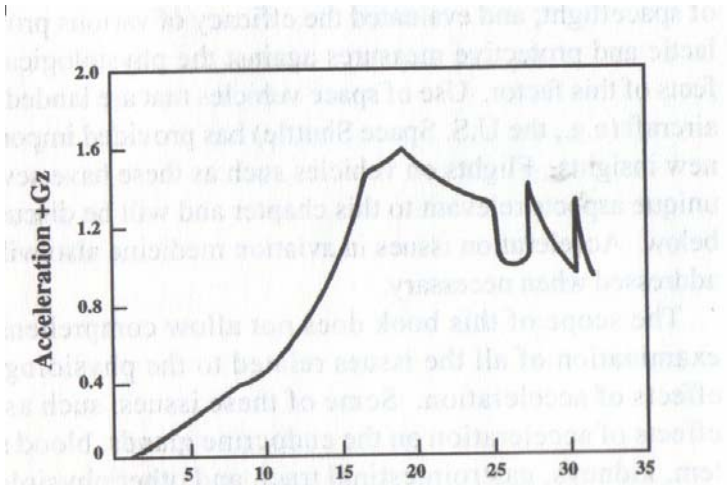
There is a significant difference in the ascent loads profile between the Apollo and Mercury programs. Both vehicles accelerated very quickly to the maximum G-limit. However, the Apollo launch was limited to +4Gz, whereas the Mercury could accelerate to +6Gz. The staging profiles also were very different. The Mercury staging acceleration would decline to 2 Gs during staging, while the Saturn staging would experience brief periods of zero-G acceleration/coasting.

This complexity of staging events may have biomedical implications for spaceflight participants. To determine specific biomedical effects on space flight participants, the launch load profile for each commercial RLV must be known and quantified.

1.3.5.3 *Reentry and Landing*

While the launch effects from orbital missions may be considered as evidence for the purpose of suborbital flight issues, any biomedical measurements during reentry are confounded by the effects of an extended stay in orbit. Therefore, correlating the biological effects on a crew of exposure to landing forces in a capsule or the Space Shuttle after an orbital mission of varying length, to a suborbital flight of 3 to 6 minutes, is not reliable. However, the Space Shuttle reentry profile (Fig. 1.3.5.3-1) provides an indication of the acceleration exposure levels for a lifting body style vehicle that lands on a runway during the reentry phase. Ballistic reentry with a capsule results in accelerations that are considerably higher.

Early crew capsule seats also had a landing attenuation system allowing for vertical movement with, for example, Apollo having 16.5 inches of range, as a hazard control during landing. The maximum landing loads experienced were during an Apollo-12 splashdown with 15 Gx occurring at an angle of 22 degrees. The crew reported this as being hard, but not causing significant physical difficulties.



+Gz exposure over the re-entry period of the Shuttle to landing

Figure 1.3.5.3-1 Space Shuttle reentry G_z-loads (from Space Biology and Medicine 3rd Ed. Vol. lll, Book 2, 1993)

1.3.5.4 *Launch Abort*

Known designs of commercial space passenger vehicles range from vertical rockets to lifting body gliders launched from a separate vehicle. For the vertical rocket design, G forces on an abort at the launch tower are potentially in excess of +20 G_X. Several Russian crews have had to abort immediately after launch and all survived, although injuries were reported as a result of the acceleration loads experienced. This could be a significant consideration for space flight participants in the vehicles that are planned to be launched vertically, where an abort during the initial stage of launch will use a booster rocket to take the capsule away from the vehicle. The launches on the Russian Soyuz to the NASA ISS, with commercial passengers (3 launches to date), show that with appropriate medical evaluation, training, supervision, and support, it is possible for space flight participants to take part in missions where this category of vehicle and launch-abort system is used. Those vehicles that are runway take off or air launched will not have this limitation.

1.3.5.5 *G Tolerance and Crewmember Seat Angle*

Reclining the seat improves +Gz tolerance by reducing the effective aortic valve/eye column height (Burns, 1975). The improvement in G tolerance is roughly linear with reduction in effective column height (i.e., at 75^o seat back angle, column height is reduced to one half and +Gz tolerance is almost doubled). At higher levels of G in the reclined position, tolerance becomes progressively limited by pain from contact with the seat, from chest compression, and from difficulty inhaling due to the increased weight of the anterior chest wall. These physiological symptoms limit this technique to about 14 to15 Gz maximum. Although reclined seats can dramatically improve +Gz tolerance, they are seldom used because of difficulty providing full use of displays and controls while providing adequate outside vision. However, this may not apply in commercial space flight where vehicle displays and controls are not of concern to the space flight participants except when they are required to take an active role, for example, in reapplying a seat harness after a period of microgravity.

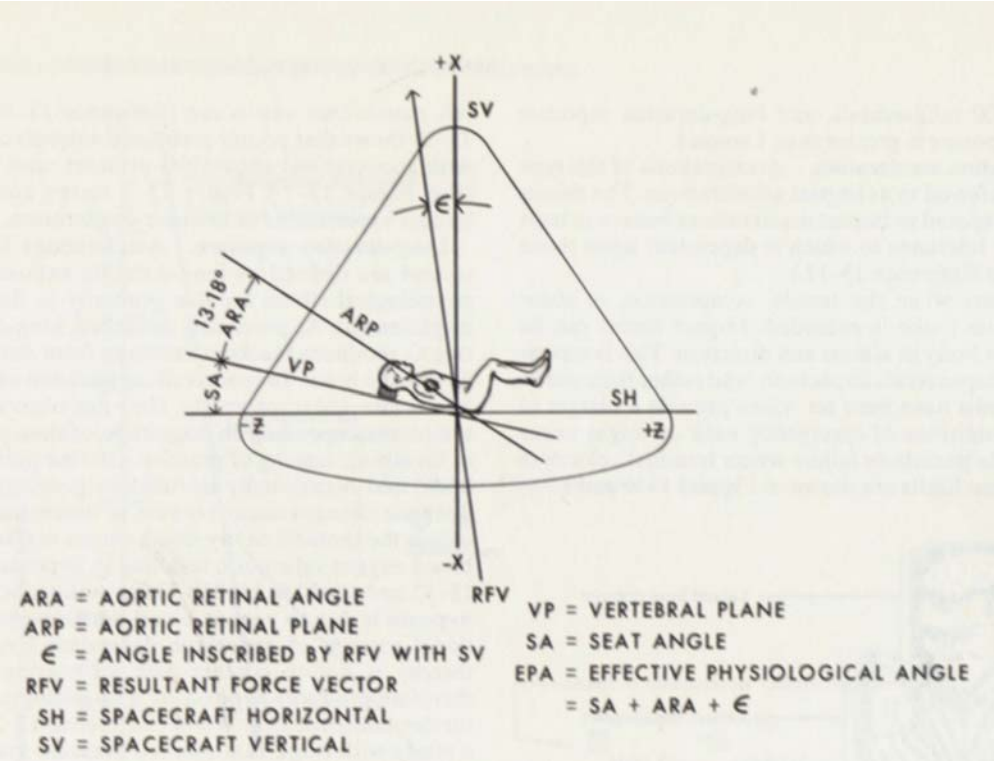


Figure 1.3.5.5-1 Seat Angle Parameters

(from Manned Spacecraft: Engineering Design and Operation, 1965)

Research during the early phase of capsule design has shown that subjects preferred a torso inclination of 12 degrees. For the Mercury Capsule, 7 astronauts preferred forward inclination angles of 3.5 to 8.5 degrees. Mercury and Gemini had crew seat angles with minimal seat elevation from the horizontal (see Fig. 1.3.5.5-1). The early Russian vehicle Voskhod had seat elevations of 20 degrees, whereas the Soyuz has a set angle of only a few degrees with the crewmembers' legs being raised above their hearts. Therefore, the seat angle is critical in ensuring that crewmembers can withstand +Gz stress, particularly as it affects the cardiovascular system (see Jurist, 2005 for a description of the mechanism involved in this effect).

1.3.5.6 *Analogs*

There are parallels in popular activities today that place participants under unexpected physical G-load stress, with serious and potentially adverse outcomes. Modern roller coaster rides can cause tachycardia and arrhythmias that place individuals with preexisting heart disease at risk of experiencing a cardiovascular event. For young healthy individuals, there is minimal risk for heart attack and arrhythmias from riding a roller coaster. However, for passengers with high blood pressure, a previous heart attack, an implanted pacemaker or defibrillator, and others with proven heart disease such as cardiomyopathy, there are risks from the forces of a roller coaster ride. The situation of most concern is a person with an unknown, undocumented, preexisting heart anomaly. The roller coaster event could then prove deadly. Participants with aneurysms

are also at increased risk of rupture due to the high acceleration, as a result of a pathologically weak arterial wall failing.

Studies of roller coaster rides show that the heart rates of riders increased dramatically during and after the ride. Emotional stress appeared to be a strong contributing factor in the rise in heart rates of riders, especially in women who had higher maximum heart rates than men. At rest, before riding the roller coaster, participants' average heart rates were 91, but after just over one minute on the ride, the riders' mean maximum heart rates reached an average 153 beats per minute (Kuschyk, 2005). Interestingly, this increase is thought to be related more to the psychological stress of the ride, similar to prelaunch cardiovascular response seen in crewmembers. However, studies have shown that after the ride stopped, a number of the participants had significant sinus arrhythmia (Kuschyk, 2005).

The autonomic nervous system response to a traumatic event, such as a roller coaster ride, causes an increase in heart rate, blood pressure, breathing rate, body temperature, and muscle tension. The after effects of the "adrenalin rush" can also lead to syncope or fainting due to a sudden drop in blood pressure during the recovery phase. It is possible suborbital flights could elicit similar physiological responses.

1.3.6 Summary

Suborbital commercial flights currently planned are likely to expose participants to short periods of microgravity for a period of minutes within a flight of several hours duration. Accelerations will be experienced mainly during launch, reentry, and landing and will range in duration from milliseconds to tens of seconds.

The duration of acceleration exposure is a critical factor in evaluating human tolerance to high accelerations. In general, acceleration pulses of less than 200 milliseconds are considered to be "impacts," and greater accelerations can be tolerated as the duration decreases. For acceleration exposures beyond a couple of seconds, it is physiological fluid dynamics that show the greatest negative effect. This includes cardiovascular effects and neurovestibular effects.

The G profile of commercial suborbital vehicles is likely to be of a significant magnitude (for nonprofessional crewmembers) with participants experiencing nominal levels of $4G_X$ for a period of a minute or more, with exposure up to $7G_X$ for shorter periods during launch and landing. While less stressful than equivalent acceleration forces in the z-axis, the magnitude and duration of x-axis acceleration may have important implications for participants depending on their preflight health status. As such, it is likely to be the most significant health-related vehicle parameter that needs to be acquired in commercial, short-duration suborbital flight. To evaluate space flight participants' responses to suborbital flight, it is critical that acceleration data be available for correlation with the biomedical parameters to be monitored.

1.4 Biomedical Parameters of Interest

1.4.1 Regulatory Issues

The FAA has developed the document "Guidance for Medical Screening of Commercial Aerospace Participants," DOT/FAA/AM 06/1, January 2006. These guidelines are designed specifically to enable operators to identify those participants whose medical conditions may result in an in-flight medical emergency or death, or may compromise the health and safety of vehicle occupants.

The FAA has decided against prescribing specific medical requirements for participants at this time, instead advising operators to follow the guidelines. There is a clear requirement placed on the operators to ensure that their customers – the spaceflight participants – are made aware of and consent to the potential medical risks of space flight. The guidelines do, however, address the issue of medical conditions that may contraindicate space flight participation, and advise final disposition by a physician trained or experienced in aerospace medicine. This includes:

> *Any deformities, diseases, illnesses, injuries, infections, tumors, treatments or other physiological or pathological conditions.*

These are very wide-ranging guidelines and as such include many conditions. In addition, the FAA guidelines state that an established diagnosis (of listed conditions) may contraindicate participation. We have considered these guidelines as a point of departure for defining a set of biomedical parameters for monitoring so that the parameters recommended are consistent with the conditions contraindicating participation.

1.4.2 Data Categories

By its very nature, the methods and data gathered over the different U.S. space programs since conception have changed with the mission and improved technology and feedback from the medical data gathered.

The total number of persons who have flown in orbit currently stands at 452[4]. US experience is comprised as follows:

- Shuttle (1981-2005) – 6,352 crew-days (17 years)
- Skylab (1973-1974) – 504 crew-days (1.4 years)
- NASA/Mir (1994-1998) - 849 crew-days (2.3 years)
- ISS (2000-2006) Currently in the sixth year of continuous human operations with 2 to 3-person crews

The priority for NASA and other space agencies now focuses on the long-term effects of space flight on human physiology, which is not necessarily the immediate concern of commercial space flight companies (see Appendix A). Thus, for commercial space operations, the data to be gathered falls into two categories, the physiological and environment/vehicle parameters. For

[4] As of 31 July, 2006

suborbital flight, we are interested in the acute physiological responses to short-duration space flight, as follows:

- Cardiovascular
- Respiratory
- Neurological:
  - Vestibular
  - Space Motion Sickness
  - Vision
- Musculoskeletal
- Hematological
- Psychological
- Gastrointestinal

Environmental /vehicle-related issues as follows:

- Acceleration
- Vibration
- Noise
- Radiation
- Temperature
- Habitability

1.4.2.1 *Physiological Responses*

On the basis of the existing data and the known effects of acceleration and microgravity on human physiology, the most important human biological system parameters to be monitored before, during, and after flight are cardiac, pulmonary, musculoskeletal, neurovestibular, and psychological. Gastrointestinal issues must also be addressed. Interestingly, the reported illness frequency seen in commercial aviation indicates the most common illness is gastrointestinal (22.3%), with cardiovascular (21.8%) and respiratory (10.2%) illnesses still relatively prevalent. Deaths in commercial aviation flight remain rare at 0.3/million passengers. Since space flight participants are likely to reflect the general aviation public, we may see a similar distribution of illness (Bagshaw, 1996; Cummings, 1998; Johnston, 1996).

1.4.2.1.1 Cardiovascular and Respiratory Systems

The cardiovascular system will be immediately affected by suborbital short-duration flight, as discussed earlier. As a result, this is the most significant physiological data point that should be monitored to characterize effects on space flight participants. This will, when possible, include in-flight monitoring of cardiac function.

The commercial jet aircraft cabin altitude pressurization limit is 8,000 ft above MSL pressure, which is also likely in suborbital spacecraft. This may adversely affect the respiratory system of those participants already compromised with conditions such as chronic obstructive pulmonary disease (COPD). A recent study concluded that a substantial proportion of older passengers - up to 44 percent of healthy passengers aged 65 years or more - may have inadequate arterial oxygen levels at 8,000 feet above MSL pressure, while breathing cabin air. However, it is important to

put this in perspective. In the context of civil commercial aviation, it is accepted in general that passengers who can walk 50 meters on the level or climb 10 steps without dyspnea should be able to tolerate the relative hypoxia at commercial aircraft pressurization levels (Muhm, DeHart, 2004).

1.4.2.1.2 Neurovestibular and Muscular System

The dynamic force environment of space flight will also manifest itself with effects on the neurovestibular and muscular system. While short term, they may have a significant impact on participants. This is particularly relevant as participants are likely to have an active role in aspects of vehicle operations related to health and safety. For example, participants may be expected to return to their designated seats after a period of weightlessness and reattach their own harness for reentry. In addition, they may be expected to egress the vehicle without assistance upon landing, or take particular action in an emergency situation. Avoiding adverse neurovestibular effects is important to ensure that the participants are able to comply with safety instructions especially during reentry and at landing.

1.4.2.1.3 Hematological System

Previous space flight experience has shown that there are unlikely to be significant changes to the endocrine, hematological, and immunological systems as a result of short-duration suborbital flight, except where extreme change in volume status (i.e. dehydration / volume overload) plays a significant role. Therefore, we recommend that only essential parameters be measured before and after flight to capture any changes that may occur to participants, when their pre-existing pathology indicates such an evaluation.

1.4.2.1.4 Psychological Effects

Previous space flight and analogs have shown that some experienced crew suffered from acute anxiety to disabling psychosis in reduced gravity and/or confined environments. Therefore, we recommend that space flight passengers who are identified as having a significant probability of an uncontrolled psychological episode should be further evaluated preflight and monitored during the flight.

1.4.2.1.5 Gastrointestinal Effects

Previous space flight and commercial airline passengers have shown that the most common acute illness encountered is gastrointestinal in nature. The causes for this are numerous, but in a microgravity environment may represent an additional collective risk to all occupants in the vehicle from uncontrolled release of bio-hazardous material. Immediate preflight screening should be designed to address any illnesses likely to increase the predisposition to gastrointestinal illness in flight.

1.4.2.2 *Biomedical Data Monitoring*

The degree to which space flight passengers will take part in this data gathering process will be determined after they have been evaluated according to space flight operator procedures. Adopting the recommendations from the FAA Guidance for Medical Screening of Commercial Aerospace Passengers, candidate passengers would be subject to a medical history and physical examination. Many space flight participants may have no clinically apparent pathophysiological issues, therefore significant preflight, in-flight and postflight monitoring is unlikely to reveal any

additional data about space flight that is not already known. The data that will be of interest to the operators of the vehicles is that which applies to individuals that are cleared to fly with certain pathology and/or physical issues.

The tables below summarize the parameters recommended for space flight participant monitoring in relation to suborbital space flight. The parameters should fulfill the objective of characterizing the cohort that is permitted to fly suborbital flights, resulting in a more complete understanding of the effects of suborbital flight on human physiology.

For illustration purposes, we can consider a potential commercial space flight participant with controlled congestive heart failure (CHF), that may manifest itself as clinically significant CHF in microgravity. Currently there is no data or experience in placing patients with subclinical diastolic dysfunction into space, nor the treatment of its sequelae. On a commercial passenger flight, for example, one just simply gets the patient upright and the pulmonary apices are able to function, however in microgravity this does not have the same result. The initial history and examination will make this pathology readily apparent to the examining physician, and such a passenger will require detailed evaluation to determine the consequence of microgravity. Therefore, it is recommended that this passenger be subject to testing before, during, and after flight as described in the subsequent tables related to cardiac dysfunction. Furthermore, cardiac monitoring during a preflight centrifuge run that are characteristic of acceleration forces during suborbital flight is also recommended.

The occurrence of subclinical or asymptomatic cardiovascular disease that can manifest itself in a space flight participant is also a possibility that presents an additional assessment problem. These passengers may pass through an initial history and examination that would fail to reveal the underlying pathology. Therefore, some consideration should be given to provocative testing to reveal asymptomatic disease that will become apparent in microgravity, and for which data would need to be gathered. The implication is that the threshold for deciding which passengers should be subject to additional testing should be low, and may include cohorts based, for example, on age.

Table 1.4.2.2-1 identifies the recommended initial screening. Tables 1.4.2.2-2, 1.4.2.2-4 and 1.4.2.2-6 identify the recommended preflight and postflight physiological parameters to be acquired from participants as identified in initial screening. Table 1.4.2.2-3 identifies a very specific list of parameters recommended for centrifuge monitoring, while 1.4.2.2-5 identifies parameters recommended for in-flight monitoring. The acquisition of biomedical data during preflight centrifuge runs and during flight will provide an opportunity to validate the efficacy of utilizing centrifugation as a reliable method of participant assessment under acceleration conditions similar to those associated with the vehicle flight profile. Table 1.4.2.3-1 describes parameters associated with the vehicle environment.

Table 1.4.2.2-1 Initial Preflight Physiological Evaluation

Parameter to Assess	System	Rationale
Personal medical History Screen – self completed	ALL	Participant history to identify all pertinent and relevant medical history, and potential areas of concern.
Personal medical History focused	ALL relevant areas	Physician determined history to clarify all pertinent and relevant medical history, and potential areas of concern.
Physical	ALL	General physical exam to identify pathology of concern in the space environment, and to determine the degree of further levels of assessment that are required.

Table 1.4.2.2-2 Preflight Physiological Assessment and Evaluation

Parameter to Assess	System	Rationale
ECG, BP, Heart Rate 24 Hour Holter Monitoring Echocardiogram Tilt table study	Cardiovascular	To identify and establish preflight baseline and potential pathology such as: • Hypertension • Dysrhythmia • Cardiac Artery Disease • Cardiomyopathy • Cardiac valve disease • Anemia
O_2 saturation Pulmonary function	Respiratory	To identify and establish preflight baseline and potential pathology for example hypoxia secondary to COPD, or other pulmonary pathology. These programs may fly participants who smoke and who may have a problem dependant on the cabin pressure and O_2 levels.
Neurological Function Rating Scale	Neurological Neurovestibular	Establish baseline preflight response, to evaluate effects of short-duration exposure, and the ability of participants to perform as required by operators.
Functional Capacity	Musculoskeletal review	Establish capability baseline. Relevant to emergency situations, and to the neurological evaluation. This is relevant to older and/or less physically able participants who will not necessarily have the musculoskeletal function of trained crewmembers.
Comprehensive Laboratory Analysis • Hematology • Chemistry Panel • Lipids • BUN • HBA1C	Hematological	To identify and establish preflight baseline and potential pathology. • Anemia • Hyperlipidaemia • Renal function • Glucose control
Psychological status		Establish the psychological/anxiety response to space flight to ensure suitability in the space environment. Previous space flight has shown that the main effect of immediate preflight anxiety is tachycardia.

Table 1.4.2.2-3 Centrifuge Physiological Parameters

Parameter to Assess	System	Rationale
ECG monitoring	Cardiopulmonary system	Participants with cardiac pathology may experience deterioration of the cardiopulmonary functioning under significant G-loads. This assessment will determine the effects of G_x at forces up to 7G.

Table 1.4.2.2-4 Immediate Pre-flight Physiological Parameters

Parameter to Assess	System	Rationale
History update	All	To ensure that there have been no significant changes in the physical status of those participants who have previously been identified with pathology.
Physical update	All	

Table 1.4.2.2-5 In-Flight Physiological Parameters

Parameter to Assess	System	Rationale
Heart rate ECG BP	Cardiovascular	Cardiovascular responses need to be fully characterized, especially in a broader cohort with pre-existing cardiovascular conditions.
O_2 saturation Respiratory rate	Respiratory	These data will compliment the cardiac data gathered and will assist in the evaluation of participants with respiratory pathology.

Table 1.4.2.2-6 Post-Flight Physiological Parameters

Parameter to Assess	System	Rationale
ECG, BP, Heart Rate 24-Hr Holter	Cardiovascular	To identify acute effect of exposure to microgravity for participants, particularly those with underlying pathology. This is likely to be the most affected system in short-duration flight.
Pulmonary function	Respiratory	To evaluate whether there have been changes secondary to exposure to high G and functional hypoxia (depending on level of vehicle pressurization).
Neurological Function Rating Scale	Neurological Neurovestibular	Establish baseline response from the immediate preflight test to evaluate effects of short-duration exposure, and the ability of participants to perform functions immediately after landing.
Visual fields	Vision	To establish postflight levels to evaluate the effects of flight. To identify potential changes, for example, in diabetes, that may have occurred.
Functional Capacity	Musculoskeletal review	Establish postflight capability. This is important to the capability of participants to help themselves in an emergency situation after landing, and is directly related to neurological evaluation. This is relevant to older participants who will not necessarily have the musculoskeletal function of trained crewmembers.
CBC Chemistry	Hematological	To evaluate the response of the participant physiology to exposure to microgravity - these changes have been recorded as far back as Mercury.
Psychological status		To establish cognitive and emotional response to the event.

Note: The timeline of these evaluations will extend from several months to immediately before flight and may be participant and vehicle dependent. This will need to be developed and established with the assistance and agreement of the flight providers and space flight participants.

1.4.2.3 *Environmental/Vehicle Data*

From the data presented, it is clear that the G profile of the vehicle must be monitored during all phases of flight to characterize the responses of the space flight participants. This profile will vary according to each vehicle and the methods of launch and landing. Other parameters that have been shown to be important include vibration, noise, radiation, and temperature. As a result, it is important to characterize these parameters and evaluate the extent to which they affect the participants during the flight. Recommended vehicle parameters are listed in Table 1.4.2.3-1.

Table 1.4.2.3-1 Vehicle Parameters

Environmental	System Affected	Potential Participant Effect
G-Profile • G_x • G_z	Cardiopulmonary	G-Profile over flight may have adverse physiological and/or pathological effects particularly on the cardiovascular response of compromised participants
Vibration	Neurovestibular, Vision, Musculoskeletal	Active participation in vehicle operations – e.g., plugging in cables, activating communication, re-securing their harness after free-floating weightless period. This will facilitate an assessment of the effects on neuromuscular coordination.
Noise	Cognition	Communication effects between crew and participants, Pain levels Comfort levels These are health and safety related issues, and experience in industry and space flight has determined the importance of minimizing noise levels
Cabin Temperature	Body habitus	Comfort
Ionizing Radiation	Ionize atoms/molecules in cells resulting in cell death/transformation/mutation from DNA damage.	Long-term consequences such as neoplasia and tetrogenicity
Habitability	Body habitus	Comfort Enjoyment Safety-related activities when required to carry out specific actions.

2.0 Subtask 2

Identify in-flight and ground biomedical equipment and requirements necessary to monitor, measure, and record the recommended parameters identified in Task 1.

2.1 Physiological Monitoring

The following requirements were used as the basis for reviewing available physiological monitoring systems for the purpose of in-flight biomedical monitoring[5] of suborbital flight participants:

- Built-in power supply (no vehicle power needed)
- Built-in data storage capability – minimum 3 hours
- Include sensors for:
  - Pulse rate
  - Blood Pressure
  - Electrocardiogram, ECG (Frank electrodes or equivalent)
  - Oxygen saturation
  - Respiration rate
  - Acceleration
- Portable (can be carried by participant)
- Noninvasive
- Technology Readiness Level[6] (TRL) 6-7
- Recording Bandwidth: (ECG – 0.47 Hz to 40 Hz)
- Analog-to-Digital (A/D) resolution: no less than 10 bits

Subtask 1 Limitations: No definitive design/concept of operations data are available for the commercial space flight vehicles. Specifically, at this time, we cannot define the operating environment beyond the assumptions stated in Section 1.2.1. No timeline, procedures, or plan to instrument the space flight participants currently exists. Neither do we know the exact vehicle seating configuration, whether participants will be wearing a pressure suit, and to what degree participants will be able/allowed to leave their seat during the weightless portion of the flight. Without this information, it is challenging to identify a single ideal system compatible with the potentially diverse design and operating specifications. It is most certainly desirable to collect the data during flight in a manner similar to ground-based controls.

Nevertheless, it is worth performing a review of the available technology given what we do know about the requirements. Ultimately, the required system will be comprised of

[5] Assume vehicle data such as cabin temperature, pressure, atmosphere composition, and acceleration are acquired and stored by other vehicle monitoring systems

[6] See Appendix C for definition

physiological sensors, a data acquisition system, and a data storage and analysis system. Fully integrated versions of such systems can be found in clinical institutions used for patient monitoring. This class includes products from such companies as Phillips, General Electric, Welch Allyn, and others. The advantages of the devices in this class include FDA approval and product performance in a clinical environment that represent good evidence for proven technology. Devices in this category can be considered TRL 9 (see Mankins, 1995, and Appendix C) for the environment in which they are being currently used. Certification of these devices for a suborbital space vehicle will need to be done, but these devices should nonetheless remain compatible with current standards[7]. These devices typically provide for the acquisition of data from multiple sensors, on-board storage, on-board visualization of data, and on-board power supply. The integration of these devices should be done in a manner that will not alter device safety or data acquisition reliability.

There are also examples of biomedical monitoring systems that have been created with more specialized applications in mind. For example, advances in fabric technology now permit physiological sensors and wiring to be woven into fabrics directly. Foster Miller Inc. (http://www.foster-miller.com) is engaged in some of the leading research in this domain with work aimed toward developing sensors that are wearable and comfortable. Vivometrics' LifeShirt System is literally built around an instrumented shirt to collect, analyze, and report on the subject's pulmonary, cardiac, and postural status. Optional peripheral devices that measure blood pressure, blood oxygen saturation, and other physiological parameters also can be added to the system. In this case, the "system" is made up of the shirt, a data logger, and software for analysis, plus any optional peripheral sensors. Thus, the system is not integrated into a single box as are the clinical monitoring systems described above. Systems like this with "wearable" components such as the LifeShirt might be considered as TRL 7-8.

Finally, one could choose to assemble a system from best-of-breed OEM components, such as the Nonin or Masimo pulse oximeters, and Del Mar or Accutracker blood pressure monitors. One example is The LifeGuard unit from Stanford University. It is a system built around a central data collection device that stores information obtained from peripheral devices (see http://lifeguard.stanford.edu/ for additional information).

Table 2.2-1 presents a summary of the technology evaluated in this review, including integrated patient monitoring systems, wearable systems, and OEM components.

Table 2.2-2 presents a summary of the portable ECG/BP monitoring technology that is currently available in the industry.

[7] IEEE (Institute of Electrical and Electronics Engineers) http://www.ieee.org
IEC International Electrotechnical Commission) http://www.iec.ch/
American Society of Mechanical Engineers http://www.asme.org/
AAMI (Association for the Advancement of Medical Instrumentation) http://www.aami.org/
FDA (Food and Drug Administration) FDA http://www.fda.gov/

2.2 Recommendations

In Section 2.1, a number of important requirements for defining a biomedical equipment system were deemed “to be determined.” In light of the fact that biomedical data will be gathered from participants riding in a wide variety of vehicles and configurations, we believe flexibility is the most important factor that the recommended system should possess. To this end, a system built from “best-of-breed” components will provide maximum flexibility.

Tables 2.2-1 and 2.2-2 summarize the specifications of several fully integrated and OEM products that meet the industry standards for their intended use. Ultimately, the intended use for space flight may make several of these products unsuitable in their present form, but perhaps minor modifications could mitigate this problem. Once a full set of requirements for the required monitoring is determined, the appropriate set of components can be selected.

Table 2.2-1
Integrated patient monitoring systems, wearable systems, and OEM components for biomedical monitoring

Company	Device	ECG	HR	SpO2	Resp	BP	Temp	Other	Weight	Dimensions	Website
NASA Ames/Stanford	LifeGuard	X	X	X	X	X	X	X	166 gm	12.9x10.0x2.0 (cm)	http://lifeguard.stanford.edu/
Philips	M3,M4,MP20, MP30	X	X	X	X	X	X	X	N/A	N/A	http://www.medical.philips.com/us/products/patient_monitoring/products/patient_monitors/
Welch Allyn	ProPaq LT	X	X	X	X	X			32 oz	5.4"x7.5"x2.1"	http://www.welchallyn.com/medical/products/catalog/detail.asp?ID=34209
VivoMetrics	LifeShirt 300S	X	X		X		X	X	11.8 oz	3.75"x1.75"x0.74" + shirt	http://www.vivometrics.com/
CAS Medical Systems	CAS 740		X	X		X	X		3.0 lbs	6.75"x8.5"x3.0"	http://casmed.com/bp_mon.htm
Rozinn	Cardio ID+ (or) RZ153+12	X	X						4 oz	2.78"x3.75"x0.78"	http://www.rozinn.com/
Philips	Zymed Digitrak	X	X						3.2 oz	3.4"x2.5"x0.8"	http://www.medical.philips.com/main/products/cardiography/products/holter/digitrak/
Braemer	DL800	X	X						4 oz	2.78"x3.75"x0.78"	http://www.braemarinc.com/
Braemer	DXP1000	X	X						5 oz	2.75"x4.37"x0.8"	http://www.braemarinc.com/
Del Mar Reynolds Medical	LifeCard CF	X	X						4.2 oz	3.8"x2.2"x0.7"	http://www.delmarreynolds.com/solutions.php?country=13&type=d&sid=354&pid=1442
Del Mar Reynolds Medical	LifeCard 12	X	X						N/A	3.8"x2.2"x0.7"	http://www.delmarreynolds.com/solutions.php?country=13&type=d&sid=354&pid=1443
Del Mar Reynolds Medical	Pressuro-meter P6		X			X			8.75 oz	5"x3.1"x1.1"	http://www.delmarreynolds.com/solutions.php?country=13&type=f&sid=1461
Mortara	H3+	X	X						N/A	N/A	http://www.mortara.com/htmdocs/news/index.php?id=4
Forest Medical	Trillium xxxx	X	X						10.75 oz	3.5"x6.4"x0.9"	http://www.forestmedical.com/products.htm
Midmark Diagnostics	IQmark Digital Recorder	X	X						4 oz	4.46"x2.75"x1.02"	http://www.midmarkdiagnostics.com/index.php?option=com_product&id=4&Itemid=31&uid=108

Table 2.2-1 (Con't.)
Integrated patient monitoring systems, wearable systems, and OEM components for biomedical monitoring

Company	Device	ECG	HR	SpO2	Resp	BP	Temp	Other	Weight	Dimensions	Website
Burdick	Vision 5L	X	X						4 oz	3.75"x3.0"x0.9"	http://www.burdick.com/products/holtermon/vision.htm
Masimo	Rad-5		X	X					13 oz	17.5x7.6x3.6 (cm)	http://www.masimo.com/pulseOximeter/Rad5.htm#rad-5
Nonin	PalmSAT 2500		X	X					7.4 oz	1.3"x2.8"x5.4"	http://www.nonin.com/products/2500.asp
Nonin	3100 WristOx		X	X					25 gm	1.75"x2.0"x0.75"	http://www.nonin.com/products/3100.asp
Nonin	Avant 2120		X	X		X			2.8 lbs	4.5"x7.5"x5.4"	http://www.nonin.com/products/2120.asp
Welch Allyn	ABPM-6100S		X			X			270 g	124x70x33 (mm)	http://www.welchallyn.com/medical/products/catalog/detail.asp?ID=33270
Rozinn	RZ250 ABP		X			X			8.75 oz	5"x3.1"x1.1"	http://www.rozinn.com/m.html
Suntech	Oscar 2		X			X			284 gm	12x7x3 (cm)	http://www.suntechmed.com/

Table 2.2-2
Portable ECG/BP monitoring technology

	Rozinn Electronics Cardio ID+ (RZ153+)	Rozinn Electronics RZ153+12	Philips Zymed Digitrak	Del Mar Reynolds LifeCard CF
Recording Duration	72 hours Max	72 hours Max	24 or 48 hours	48 hour
Recording Bandwidth	.05 - (60-80) Hz @ -3dB	.05 - (60-80) Hz @ -3dB	.05 - 60 Hz @ +0.83dB	0.05 - 40 Hz
A/D Resolution	8 to 12 Bit, No Compression	8 to 12, No Compression	12 bit/10 bit Recorded	12
Sample Rate	1024 sps Max	1024 sps Max	175 sps	1024 sps
Gain Settings	1/2X, 1X, 2X	1/2X, 1X, 2X		
Patient Connection	3-lead	12-lead (true, not derived)	12-lead EASI	3-lead
Number of Channels	2 or 3	12	3	3
Storage Medium	CF – Removable	CF - Removable	Flash - download USB	CF -– Removable
Storage Capacity	64 MB - 2GB	64 MB - 2GB	64 or 128 MB	90 MB
Power Requirement	1 AA Alkaline or Lithium	1 AA Alkaline or Lithium	1 AA Alkaline	1 AAA Alkaline
Weight	4 oz (113 g)	4 oz (113 g)	3.2 oz (90 g)	4.2 oz (118 g)
Dimensions (inches)	2.78"x3.75"x0.78"	2.78"x3.75"x0.78"	3.4"x2.5"x0.8"	3.8"x2.2"x0.7"
Dimensions (mm)	71 x 95 x 20 (mm)	71 x 95 x 20 (mm)	85.4 x 53 x 20.3 (mm)	96 x 57 x 18 (mm)
	Del Mar Reynolds LifeCard 12	**Braemer DL800**	**Braemer DXP1000**	**Forest Medical Trillium 1000**
Recording Duration	24 hour	24, 48, 72 hours	24 or 48 hours	24 hours
Recording Bandwidth	0.05 - 40 Hz	.05 - 60 Hz @ -3dB	.05 - 60 Hz @ -3dB	.05 - 100 Hz
A/D Resolution	12	8 - 10 bit	8 - 10 bit Sample/10 bit Rec.	12 bit
Sample Rate	4096 sps	128 - 512 sps	128 - 256 sps	256 sps
Gain Settings		1/2X, 1X, 2X	1/2X, 1X, 2X	Auto
Patient Connection	12-lead (true, not derived)	5 or 7 lead	5 or 7 lead	5 or 7 lead
Number of Channels	12	2 or 3	2 or 3	2 or 3
Storage Medium	CF - Removable	CF - Removable	NV Flash - download USB	NV Flash Card
Storage Capacity	256 MB	512 MB	128 MB	
Power Requirement	1 AAA Alkaline or NiMH	1 AA Alkaline or Lithium	2 AA Alkaline or NiMH	2 AA Alkaline
Weight	4.2 oz (118 g)	4 oz	5 oz (141 g)	10.75 oz (305 g)
Dimensions (inches)	3.8"x2.2"x0.7"	2.78"x3.75"x0.78"	2.75"x4.37"x0.8"	3.5" x 6.4" x 0.9"
Dimensions (mm)	96 x 57 x 18 (mm)	70 x 95 x 20 (mm)	70 x 111 x 20 (mm)	88.9 x 162.6 x 22.8 (mm)
	Forest Medical Trillium 4000	**Forest Medical Trillium 5000**	**Midmark Diagnostics IQmark Digital Recorder**	**Burdick Vision 5L**
Recording Duration	24 or 48 hours	24 or 48 hours	24 hour	24 or 48 hours
Recording Bandwidth	.05 - 100 Hz	.05 - 60 Hz	.05 - 100 Hz @ 3dB	.05 - 60 Hz @ -3dB
A/D Resolution	12 bit	10 bit	8 bit	8 - 10 bits, 4X oversampling
Sample Rate	1024 sps	512 sps	128 sps	200 sps
Gain Settings	Auto	1/2X, 1X, 2X		1X
Patient Connection	5 or 7 lead	5 or 7 lead	5 or 7 lead	5 or 7 lead
Number of Channels	2 or 3	2 or 3	3	3

Storage Medium	NV Flash Card	NV Flash Card	CF - Removable	CF - Removable
Storage Capacity			48 - 96 MB	128 MB - Removable
Power Requirement	2 AA Alkaline	1 AA Alkaline	2 AA Alkaline	1 AA Alkaline
Weight	10.75 oz (305 g)	4 oz (112 g)	4 oz (113 g)	4 oz (113 g)
Dimensions (inches)	3.5" x 6.4" x 0.9"	3.5" x 6.4" x 0.9"	4.46" x 2.75" x 1.02"	3.75" x 3.0" x 0.90"
Dimensions (mm)	88.9 x 162.6 x 22.8 (mm)	88.9 x 162.6 x 22.8 (mm)	113 x 70 x 26 (mm)	95 x 76 x 23 (mm)
	Mortara	**Mortara**		
	H3+	**H12+**		
Recording Duration	24 hours	12 or 24 hours		
Recording Bandwidth	Meets ANSI/AAMI EC38	Meets ANSI/AAMI EC38		
A/D Resolution	12 bit	20 bit		
Sample Rate	180 sps	180 or 1000 sps		
Gain Settings				
Patient Connection	5 lead	12 lead		
Number of Channels	2 or 3	12		
Storage Medium	Internal NV - download USB	CF - Removable		
Storage Capacity				
Power Requirement	1 AAA Alkaline	1 AA Alkaline or Lithium		
Weight	1 oz (28 g)	4 oz (125 g)		
Dimensions (inches)	2.5" x 1.0" x 0.75"	2.5" x 3.5" x 0.98"		
Dimensions (mm)	64 x 25 x 19 (mm)	64 x 91 x 25 (mm)		

3.0 Subtask 3

[Define] a biomedical safety database and identify the information technology equipment and requirements needed by AST to continuously analyze sensitive safety data generated from commercial space transportation activities. Identify compatibility with importing existing NASA data.

3.1 Introduction

The main repositories of biomedical data pertaining to human space flight at NASA are:

- The Electronic Medical Record (EMR) - astronaut digital health records in the Flight Medicine Clinic (supplemented by paper-based records)
- The Longitudinal Study of Astronaut Health (LSAH)
- The Life Sciences Data Archive (LSDA)

These principal digital repositories are supplemented by several other sources of medical data including:

- The Clinical Laboratory Information System (CLIS)
- The Private Medical Conference (PMC) database
- Medical Assessment Test (MAT) results

Each of these data sources are briefly described below. Note that all of these databases/repositories are located at NASA Johnson Space Center under the supervision of the Space Life Sciences Directorate and the Bioastronautics Contract team.

3.2 NASA Medical Databases

3.2.1 The Electronic Medical Record (EMR)

The EMR is used to document medical care provided to personnel seen in the Flight Medicine Clinic (FMC) and Occupational Medicine Clinic (OMC). Astronauts are seen in the FMC. All components of FMC office visits, physical exams, consultant reports and other medical care are fully documented in the EMR by clinical staff. The OMC implementation is currently restricted to annual physical examinations with plans for further development. The EMR software is a GE commercial off-the-shelf (COTS) product, Centricity. Centricity EMR (formerly Logician®) is an electronic medical record system that enables ambulatory care physicians and clinical staff to document patient encounters, streamline clinical workflow, and securely exchange clinical data with other providers, patients, and information systems. Additional information can be found at: http://www.gehealthcare.com/usen/img_info_systems/centricity_clin_info/products/emr.html

3.2.2 The Longitudinal Study of Astronaut Health

The LSAH is a study of the long-term health effects of space flight on U.S. astronauts. A control group of civil service employees also is monitored longitudinally for comparison. The LSAH database contains serial measures of physiological parameters collected at annual physical

examinations and during provision of clinical care for astronauts and comparison participants. The annual examination consists of a physician evaluation, vital signs, optometry, audiometry, ECG, pulmonary function test, pelvic exam, Pap smear, laboratory testing and other tests performed at the following intervals: dual energy X-ray absortiometry (DEXA - measures bone mineral density) scan every 3 years; exercise tolerance test every 5 years to age 40, every 2 years age 41-50, annually after age 50; colonoscopy at ages 40, 50, 60, 70, 80; mammogram baseline between age 35-39, every 2 years age 40-50, annually after age 50. Dental exams are conducted annually on the active astronauts only. Findings of office visits and consultant summary reports are documented for astronauts and comparison participants. Death certificates and other cause of death information also are obtained. Appendix B documents the complete physical and health measures collection schedule.

3.2.2.1 *Purpose*

The purpose of the LSAH is to investigate and describe the incidence of acute and chronic morbidity and mortality of astronauts and to determine whether the unique occupational exposures encountered by astronauts are associated with increased risks of either total or cause-specific morbidity or mortality. Specifically, the primary a priori hypotheses to be tested are: 1) astronauts are at different risk of total mortality than ground-based employees; and 2) astronauts are at different risk of total morbidity (defined as rate of incident cases of diseases/disorders, rate of hospitalizations and average number of hospitalization days per person) than ground-based employees. Risk is measured relative to civil service employees located at the NASA Johnson Space Center (JSC) who work and live, at least for a time, in the same geographical area as the astronauts, who participate in the OMC Employee Wellness Program by undergoing preventive health examinations; and who have volunteered to participate in the study.

3.2.2.2 *Design and Population*

A cohort study design is being utilized for this observational study. All astronauts selected for the NASA astronaut program are followed as “exposed” subjects from selection throughout the course of the study. Civil service employees who receive routine annual physical examinations at the OMC have been selected as comparison subjects using age, sex, and body mass index as selection criteria at a 3:1 ratio, and they are followed in the same manner as the astronauts. As new astronauts are selected, matching groups of comparison participants are identified and recruited. Morbidity, mortality, physical examination, and laboratory data are collected utilizing medical records routinely collected at the NASA-JSC OMC and FMC, medical consultant reports, hospital discharge summaries, death certificates, and, when available, autopsy reports.

3.2.2.3 *Confidentiality*

The personal medical data included in the databases of the LSAH are protected by the Privacy Act of 1974 and by the additional security procedures and policies of the LSAH and the NASA-JSC Clinics. Individual participant data are not included in reports or publications, only group data are presented. All study employees who have access to study records are research personnel who are specifically trained regarding the need for absolute confidentiality of study information. All LSAH personnel are required to sign a statement that they are aware that these data are protected under the Privacy Act and that they are aware of the consequences should they violate confidentiality.

3.2.3 The Life Sciences Data Archive

NASA's Life Sciences Data Archive (LSDA; lsda.jsc.nasa.gov) is a work in progress that provides information and data from space flight experiments funded by NASA. The archive includes investigations from 1961 (Mercury Project) through current missions (ISS and Space Shuttle) involving human, plant, and animal studies. The LSDA is a part of the Human Health and Performance Program of the Exploration Systems Missions Directorate, which is dedicated to "safe, sustained, affordable exploration of the Moon, Mars, and beyond." This site is intended for all audiences, from scientists and teachers to the general space enthusiast.

The LSDA currently serves as an archive for almost 1000 experiments. The Web site provides an interface to permit any individual to search for a particular experiment, parameter measured, experiment title, and several other factors. Public access and search are permitted.

3.2.4 Clinical Laboratory Information System

The Clinical Laboratory Information System is based on a COTS platform and stores laboratory test data from medical monitoring, clinical care, and life sciences research. The following panels are performed on astronauts and LSAH comparison participants: Serum Iron, Lipid Profile, Ionized Calcium, Serum Protein Electrophoresis, Immunoglobulins, Serology, and Thyroid Function tests. Specialized tests may be performed to support life sciences research as requested by a principal investigator.

3.2.5 Private Medical Conference

In-flight medical events that occur during NASA-ISS missions are documented in the PMC Tool, a proprietary tool developed and operated under the Bioastronautics Contract. Flight surgeons can document medical events and health-related concerns either real-time as they talk with ISS crewmembers or at their leisure afterwards. The PMC Tool contains medical event data such as chief complaint, time of onset, etiology, diagnosis, medication and other treatments prescribed, and outcome of the condition. This database also provides a place for flight surgeons to document nonmedical issues such as environmental concerns (air quality, water quality, noise, radiation, food, temperature), exercise countermeasure equipment operations, hardware operations, and assessment of mission impact based on medical condition or status of hardware or systems.

3.2.6 Medical Assessment Tests

An approved suite of MATs are conducted before, during, and after flight to monitor the health status of crewmembers. The list of medical requirements (MR) undergoes periodic revision as new evidence becomes available and as new methodologies become standard. The current MAT list is below, in Table 3.2.6-1. (ID = the numeric identification of the MR; D=Duration so L=Long duration = ISS, S=Short = Shuttle, BME = Bone, Muscle and Exercise discipline). The results of the medical monitoring tests are maintained in the medical records, LSAH, and the JSC laboratories that generated the data.

Table 3.2.6-1 Medical Assessment Tests

ID	D	Discipline	Title
MR001	L	Cardio	Operational Tilt Test
MR001	S	Cardio	Operational Tilt Test
MR003	L	Radiation	Radiation Biodosimetry
MR004	L	Radiation	In-flight Radiation Monitoring with Dosimeters
MR004	S	Radiation	In-flight Radiation Monitoring with Passive Dosimeters
MR005	L	Radiation	In-flight Radiation Monitoring with Tissue Equivalent Proportional Counter (TEPC) for Long-Duration Flights
MR005	S	Radiation	Radiation Monitoring using Shuttle TEPC for Short-Duration Flights
MR006	L	BME	Exercise Treadmill Test
MR007	L	Environmental	Toxicological Assessment Using the Dual Sorbent Tube
MR008	L	Environmental	Toxicological Assessment Using Compound Specific Analyzer-Combustion Products (CSA-CP)
MR009	L	Therapeutics	Pre- and Postflight Physical Exam for Long-Duration Crews
MR009	S	Therapeutics	Pre- and Postflight Physican Exam for Short-Duration Crews
MR010	L	Therapeutics	Clinical Laboratory Assessment for Long-Duration Flights
MR010	S	Therapeutics	Clinical Laboratory Assessment for Shuttle
MR011	L	Therapeutics	Resting ECG for Long-Duration Flights (Pre/Post)
MR012	L	Therapeutics	Dental Exam
MR013	L	Therapeutics	Audiometry for ISS
MR013	S	Therapeutics	Audiometry for Shuttle Crews
MR014	L	Therapeutics	Pre- and Postflight Opthalmology Examination for Long-Duration Flights
MR014	S	Therapeutics	Pre- and Postflight Opthalmology Examination for Short-Duration Flights
MR015	L	Therapeutics	Preflight Imaging Tests
MR016	L	Nutrition	Clinical Nutritional Assessment
MR017	L	Therapeutics	Private Medical Conferences (PMC)
MR017	S	Therapeutics	Private Medical Conferences (PMC) for Shuttle
MR018	L	Therapeutics	In-flight 30-Day Health Status Evaluation
MR019	L	BME	Heart Rate Monitoring
MR020	L	EVA	EVA Medical Examinations
MR021	L	Immunology	Crew Microbiology
MR021	S	Immunology	Crew Microbiology
MR022	S	Environmental	Shuttle Environmental Microbiology
MR024	L	Therapeutics	Body Mass Measurement

ID	D	Discipline	Title
MR025	L	Therapeutics	Postflight Medical Status Checks
MR026	L	BME	Postflight Rehabilitation
MR027	L	Behavior	Pre- and Postflight Operational Psychology and Behavorial Medicine Activities
MR029	L	Therapeutics	Pre- and Postflight Pulmonary Assessment
MR030	L	Radiation	Radiation Monitoring Using Charged Particle Directional Spectrometer (CPDS)
MR031	L	Behavior	Private Psychological Conferences (PPC)
MR032	L	Behavior	ISS Private Family Conferences (PFC)
MR032	S	Behavior	Private Family Conferences (PFC) for Shuttle Crews
MR034	L	Environmental	Toxicological Assessment Using Volatile Organic Analyzer (VOA)
MR035	L	BME	Bone Densitometry
MR036	L	Environmental	Toxicological Assessment Using Grab Sample Container (GSC)
MR037	L	Environmental	Toxicological Assessment Using Formaldehyde Monitoring Kit (FMK)
MR038	L	BME	Pre-EVA Fitness Evaluation: Arm Ergometry
MR039	L	Environmental	Toxicological Assessment Using the Carbon Dioxide Monitoring Kit (CDMK)
MR042	L	Neurology	Functional Neurological Assessment (Pre- and Postflight)
MR042	S	Neurology	Functional Neurological Assessment (Pre- and Postflight)
MR043	S	Environmental	Shuttle Air Quality Monitoring
MR050	L	Environmental	Microbial Analysis of ISS Surfaces Using the Surface Sampling Kit (SSK)
MR051	L	Environmental	Microbial Analysis of ISS Water Using the Water Microbiology Kit (WMK) and the Microbiology Water Analysis Kit
MR052	L	Environmental	Microbial Analysis of ISS Air Using the Microbial Air Sampler (MAS)
MR054	L	Environmental	ISS Potable Water Quality Monitoring
MR071	L	Cardio	Holter Monitoring
MR076	L	Immunology	Photodocumentation of Skin Injuries and Allergic Reactions
MR076	S	Immunology	Photodocumentation of Skin Injuries and Allergic Reactions
MR078	L	BME	Physical Fitness Evaluation: Functional Fitness
MR079	L	BME	Physical Fitness Evaluation: Isokinetic Muscle Function
MR080	L	BME	Cardiovascular Physical Fitness Evaluation: Cycle Ergometer (Graded Cardiovascular Test-Max and Submax)
MR081	L	BME	Physical Fitness Evaluation: Handgrip Dynamometry
MR082	L	BME	In-flight Exercise Plan
MR084	L	Environmental	Acoustic Monitoring & Countermeasures for Long Duration Flights
MR085	L	Behavior	Neurocognitive Assesment with WinSCAT (Space Fight Cognitive Assessment Tool for Windows)

ID	D	Discipline	Title
MR086	L	Neurology	On-Orbit Hearing Assessment
MR087	L	EVA	EVA Exercise Prebreathe Protocol for ISS Crewmembers
MR087	S	EVA	EVA Exercise Prebreathe Protocol for Shuttle Crewmembers
MR089	S	Therapeutics	Annual Medical Examinations

3.3 Recommendations for IT Equipment Needs and Design

To maximize compatibility with relevant NASA biomedical data, our recommendation is to archive commercial human space flight medical data in a manner consistent with the design of pertinent NASA databases. The two specific databases that are most relevant are the LSAH and the PMC database. LSAH represents the best source for comparative analyses of coded medical data. To supplement the largely objective data elements of LSAH, we propose that the PMC database be used to capture verbal reports from space flight participants concerning their subjective health response during this experience, coupled with relevant mission operations data.

The LSAH database is a central data repository, which contains approximately 45 years of private medical data on LSAH study participants. This repository combined with the LSAH Command Center represents a custom multi-tier enterprise-wide application and database solution developed in-house by software developers at Wyle Laboratories to support the LSAH.

The Command Center is a visual C# .NET Windows Software Forms application that is used by LSAH staff for data entry of study data as well as to view data for study participants. The Command Center utilizes .NET Remoting for the client application to communicate with the server layer. The Command Center application contains data entry forms, an online data dictionary, custom systematized nomenclature of medicine (clinical terms) (SNOMEDCT[8]) and International Classification of Diseases – Ninth Revision, Clinical Modification (ICD-9 CM) coding tools, reports, and various other tools used to manage the study. The LSAH central data repository is housed in normalized SQL Server 2000 databases. The LSAH production environment is shown in Fig. 3.3-1.

[8] SNOMED Clinical Terms (SNOMED CT) is a dynamic, scientifically validated clinical health care terminology and infrastructure that makes health care knowledge more usable and accessible. The SNOMED CT Core terminology provides a common language that enables a consistent way of capturing, sharing, and aggregating health data across specialties and sites of care. Among the applications for SNOMED CT are electronic medical records, ICU monitoring, clinical decision support, medical research studies, clinical trials, computerized physician order entry, disease surveillance, image indexing, and consumer health information services: http://www.snomed.org/snomedct/index.html

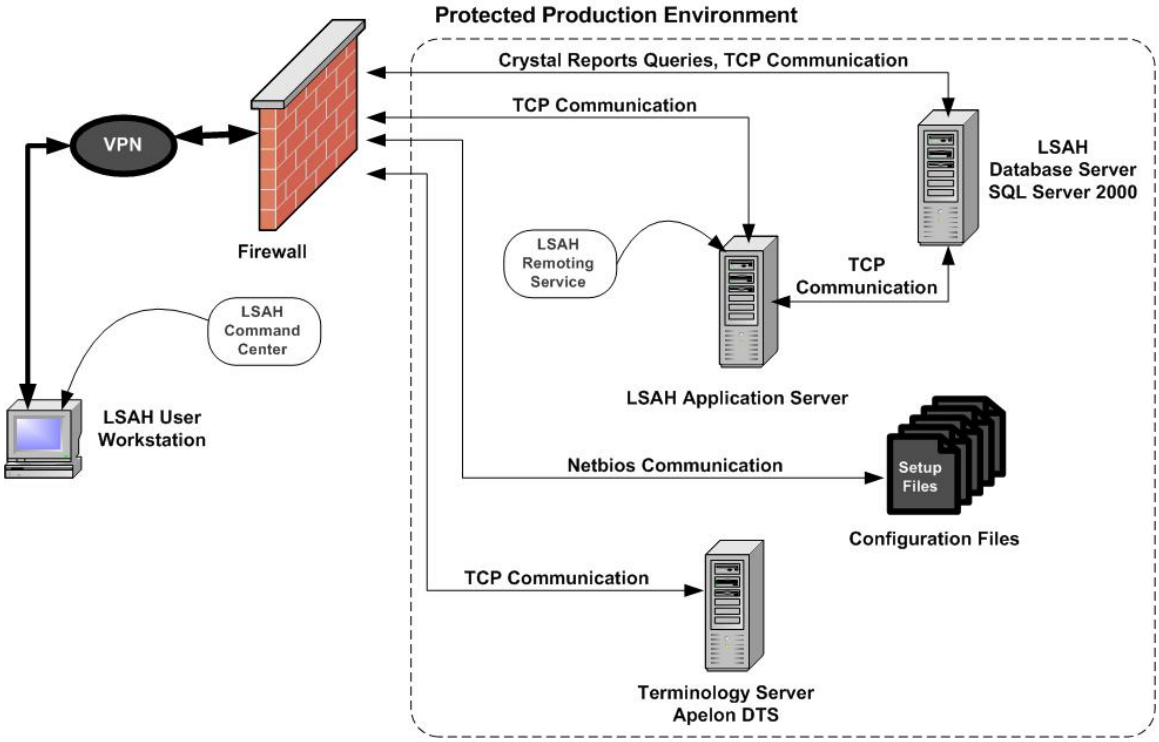


Figure 3.3-1 LSAH Production Environment

The PMC tool provides an intranet Web-based, centralized medical documentation and information management system for NASA-Shuttle and NASA-ISS missions. The tool is used by NASA flight surgeons to enter private medical data about ISS crewmembers gathered during in-flight private communications where any crew health or health-related environmental issues are reported. The PMC tool provides user data entry forms and summary reports to aid the flight surgeons with the management of in-flight crew health issues.

The PMC tool was developed using Microsoft ASP.NET software C# and SQL Server 2000 software as a multi-tier enterprise-wide application and database solution (see Fig. 3.3-2) developed at Wyle Laboratories. The electronic storage and structured format of the data collected for all current and past NASA-ISS Expedition crewmembers provides real-time data access to flight surgeons and other approved users who need to analyze medical information related to low-Earth orbit space flight.

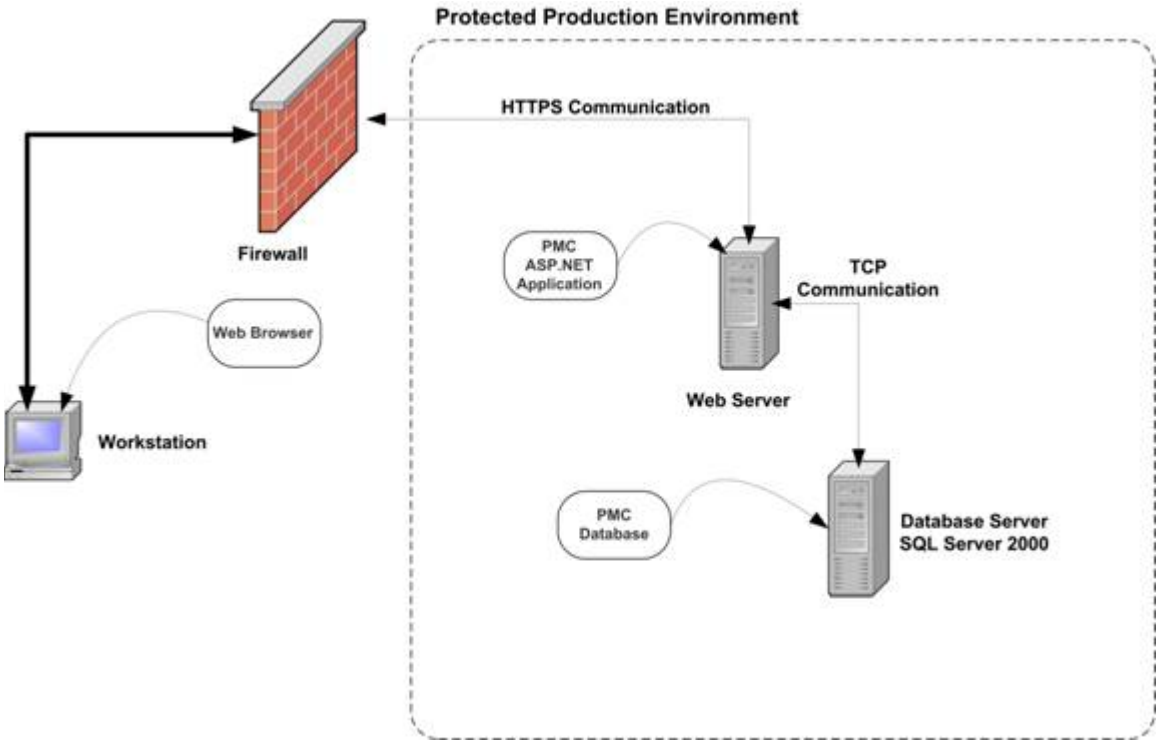


Figure 3.3-2 PMC Production Environment

The following recommendations are based on the assumption that an IT infrastructure to support the development and implementation of tools like the LSAH and the PMC databases does not currently exist. In addition, it is important to note, while the recommendations detailed below are based on the configuration used to develop tools like LSAH and the PMC database, there are many different ways to configure an infrastructure to support the development, testing, and deployment of .NET applications.

The suggested infrastructure for a Microsoft .NET application development environment is segmented into three environments as follows.

Development Environment:

- The main purpose of the development environment is to support the requirements gathering, analysis, design and development, and unit testing phases for a typical software development project.
    - Development machine - one per developer
    - MSDN Premium Subscription(s) - one per developer
    - Firewall - prevents unauthorized access to the environment and monitors inbound and outbound data traffic.

- Domain[9] Controller - controls access to environment resources. It stores user account information, authenticates users, and enforces security policy for the environment.
- Web Server - provides the files that form Web pages to Web users.
- Database Server - stores data, responds to requests for data, and processes data changes.
- Development Support Server - dedicated machine for Team Foundation Server (TFS) and other centrally deployed developer resources.
- TFS software - TFS integrates the most critical aspects of software development such as version control, work item tracking, and reporting together into a single, secure collaboration platform.

Test Environment:

- The main purpose of the test environment is to support the integrated system test and user acceptance test phases for a typical software development project. The software needed for this environment is provided under the MSDN Premium Subscription license described above.
  - Firewall
  - Domain Controller
  - Web Server
  - Database Server

Production Environment[10]:

- The main purpose of the production environment is to provide a secure and stable environment for the final deployment of developed applications. The software needed for this environment must be purchased separately. It is not provided under the MSDN Premium Subscription license described above.
  - Firewall (High Availability)
  - Domain Controller
  - Web Server
  - Database server
  - SQL Server 2005 Standard Edition - a comprehensive database software platform that runs on the database server and provides enterprise-class data management with integrated business intelligence tools.

Additionally, there are several infrastructure design considerations, such as server clustering and load balancing, that can provide improved performance, reduced system downtime, and increased reliability.

[9] A domain is defined as a group of computers and devices on a network that are administered as a unit with common rules and procedures.
[10] Each of the hardware components can be scaled up or out to improve system reliability and/or performance.

4.0 Acronyms

A/D	Analog to Digital
ANSI/AAMI	American National Standards Institute/Association for the Advancement of Medical Instrumentation
AST	Office of Commercial Space Transportation
BP	Blood Pressure
BUN	Blood Urea Nitrogen
CAD	Coronary Artery Disease
CBC	Complete Blood Count
CDMK	Carbon Dioxide Monitoring Kit
CHP	Congestive Heart Failure
CLIS	Clinical Laboratory Information System
CM	Command Module
COTR	Contracting Officer's Technical Representative
COTS	Commercial Off the Shelf
COPD	Chronic Obstructive Pulmonary Disease
CPDS	Charged-Particle Directional Spectrometer
DCS	Decompression Sickness
DEXA	Dual-Energy X-ray Absorptiometry
DOT	Department of Transportation
ECG	Electrocardiogram
EDO	Extended Duration Orbiter
EMR	Electronic Medical Record
FAA	Federal Aviation Administration
FAA/AST	Federal Aviation Administration, Office of Commercial Space Transportation
FAI	Federation Aeronautique Internationale
FDA	Federal Drug Administration
FMC	Flight Medicine Clinic
FMK	Formaldehyde Monitoring Kit
GSC	Grab Sample Container
HBA1C	Hemoglobin A1C
HDL	High-Density Lipids
HIV	Human Immunodeficiency Virus
IGA	Immunoglobin A
IGE	Immunoglobin E
IGG	Immunoglobin G
IGM	Immunoglobin M
ISS	International Space Station
LDL	Low-Density Lipids
LSAH	Longitudinal Study of Astronaut Health
LSDA	Life Sciences Data Archive
MAS	Microbial Air Sampler
MAT	Medical Assessment Test results

MCH	Mean Corpuscle Hemoglobin
MCHC	Mean Corpuscle Hemoglobin Concentrate
MCV	Mean Corpuscle Volume
MI	Myocardial Infarction
MR	Medical Requirements
MSDN	Microsoft Developer's Network
MSL	Mean Sea Level
NASA	National Aeronautics and Space Administration
NSTS	National Space Transportation System
OEM	Original Equipment Manufacturer
OMC	Occupational Medicine Clinic
PFC	Private Family Conference
PMC	Private Medical Conference
PPC	Private Psychological Conference
RBC	Red Blood Cells
RDW	Red Blood Cell Distribution Width
RLV	Rocket Launch Vehicle
SLS	Space Life Sciences
SNOMED	Systematized Nomenclature of Medicine
SSK	Surface Sampling Kit
STS	Space Transportation System
TFS	Team Foundation Server
TRL	Technology Readiness Level
USPTF	U.S. Preventive Services Task Force
VLDL	Very Low-Density Lipids
VOA	Volatile Organic Analyzer
WBC	White Blood Cells
WinSCAT	Space Fight Cognitive Assessment Tool for Windows
WMK	Water Microbiology Kit

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6.0 APPENDICES

Appendix A:
NASA's ORBITAL BIOMEDICAL DATA GATHERING

Appendix B:
PHYSICAL AND HEALTH MEASURES COLLECTION SCHEDULE – LSAH (Longitudinal Study on Astronaut Health)

Appendix C:
NASA TECHNOLOGY READINESS LEVELS

Appendix A

6.1 NASA's Orbital Biomedical Data Gathering

Current Data Gathering in Astronauts and Cosmonauts

Current human space flight activities with the ISS, Space Shuttle, Soyuz, and Shenzhou are focused on orbital space flight with missions lasting from several days to many months. As a result, the biological and physiological responses seen in these crews during the mission may not materialize in space flight participants on suborbital flights. In addition, professional crewmembers are also likely to be healthier than the typical space flight participant, therefore the underlying pathology in the participants may pose unique problems. Furthermore, there will be populations flying who have not as yet flown into space, for example teenage children, and pregnant females.

Long-term effects of exposure to short-duration flights

1. Neurological (postlanding)
2. Occupational (exposure to toxic material)
3. Neoplastic (i.e., The pathological process that results in the formation and growth of a neoplasm) risk in participants (from young participants exposed to radiation during commercial space flights)
4. Tetrogenicity (i.e., Disruption of the development of the fetus) in offspring (from females exposed to radiation – This may be an issue during commercial space flights if young females fly)

Data gathered during these previous orbital flights were between discrete points, however there was significant interaction between systems due to the physiology and potential pathology of the participants, and the consequences associated with the space environment. (Fig A-1)

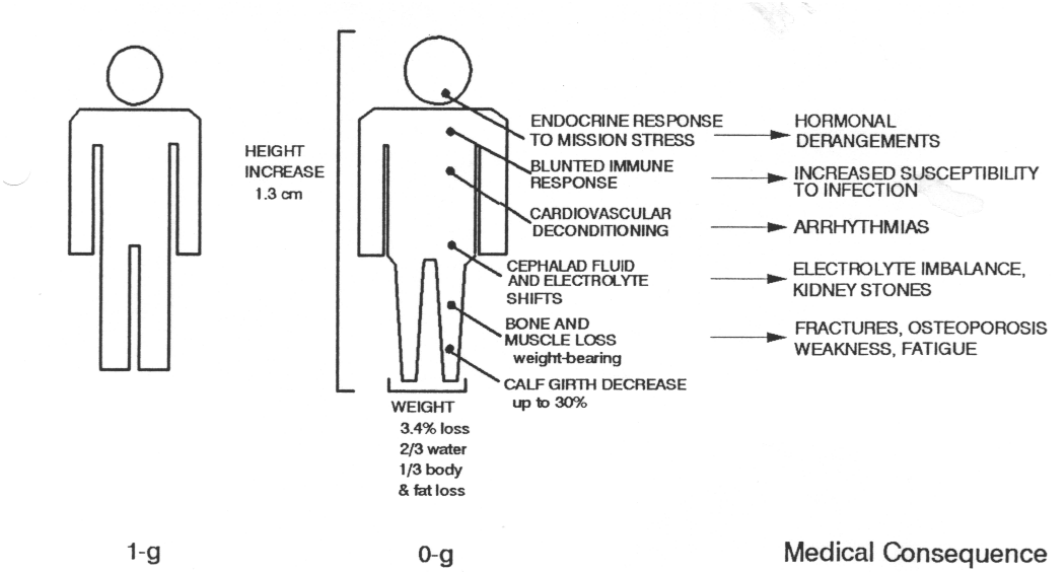

Fig A-1 Interaction between human systems in space flight

(Adapted from Space Biology and Medicine 3rd Ed Vol. lll, Book 2, 1993)

The current NASA Programmatic Review of Space Clinical Physiology in 2006, has formed teams organized by discipline that include researchers, flight surgeons, and operations personnel to look at what are considered to be the major areas of concern, particularly with long-duration exposure to microgravity:

1. Bone
2. Muscle
3. Cardiovascular
4. Nutrition
5. Pharmacology
6. Immunology
7. Neuroscience
8. Behavioral Performance

Much of the nonattributable data gathered on the astronauts and cosmonauts in the past 40 years has been published in peer-reviewed journals, NASA technical documents, and textbooks, and is widely available. However, it is important to note that there remains a cohort of data, particularly personal medical data, that is not open. Significant limitations in considering published space flight data are:

1. Most subjects have been male
2. Median age is approximately 45
3. The numbers of subjects used for much of the data is small and statistically insignificant
4. The crewmembers have had extensive training and conditioning preflight
5. Significant pathology has been ruled out preflight

6. The flight profiles have varied considerably with flights lasting just hours to up to 400+ days
7. Mission profiles have varied considerably depending on the vehicle

This does not mean that astronauts and cosmonauts have not had health problems. Indeed several crewmembers have had health issues that have impacted a mission. This is significant because commercial operations will be flying participants whose health status, in general, is unlikely to be as good as that that of professional crewmembers.

The challenge in commercial space flight, as with earlier scientific evaluation of space flight on human physiology, will be the interpretation and evaluation of the results, due to the complex and poorly understood effects of the interactions within human physiology and human pathology. (fig A-2)

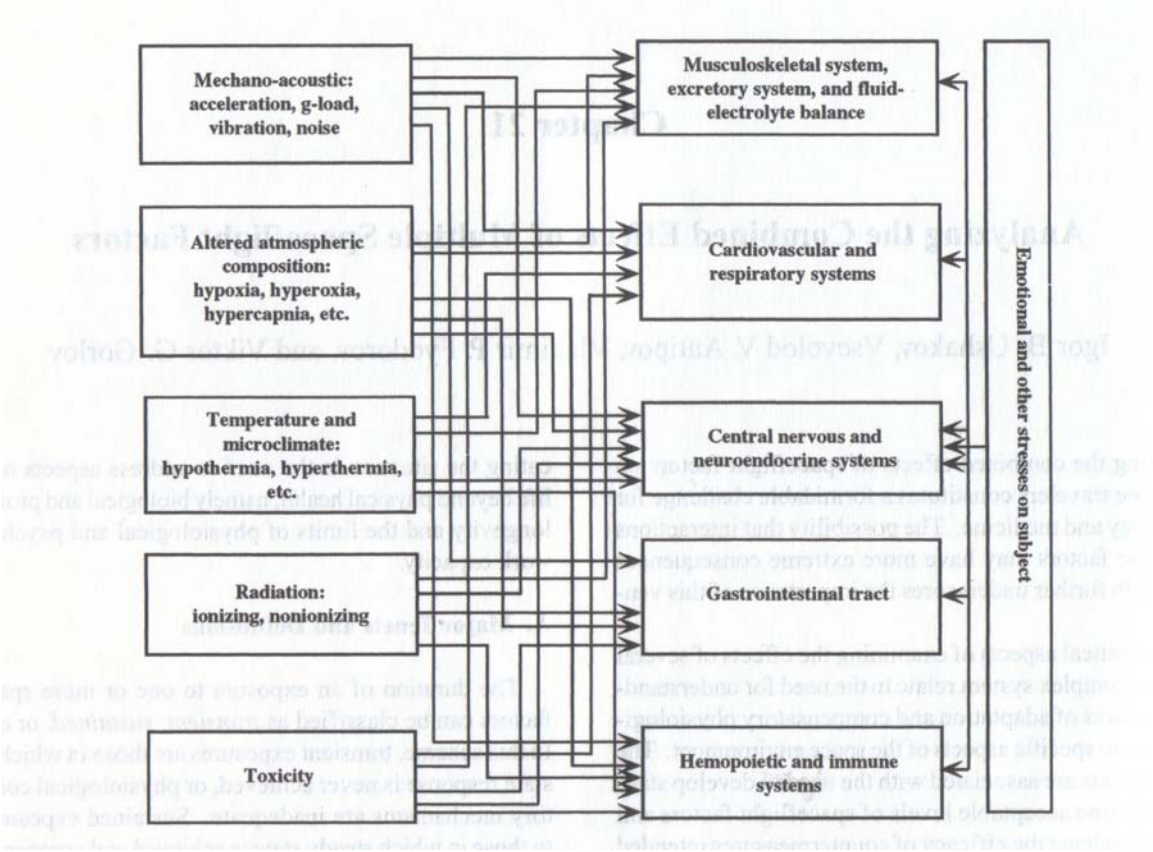

Fig A-2 Classification of flight factors with regard to their relationship to physiological systems

(Adapted from Space Biology and Medicine 3rd Ed Vol. lll, Book 2, 1993)

The following are examples of the health issues that have been faced by professional "healthy" crewmembers:

Health event	Program	Mission Impact
Motion sickness	All programs	EVA not scheduled for first 48 hours
Type 1 decompression sickness (DCS) in command module pilot	Apollo	
Kidney infection	Apollo	
Cardiac irregularity during lunar EVA	Apollo	Potential impact to mission success
Cardiac acute diaphoresis, fatigue, and bigeminy on orbit	Apollo	Myocardial Infarction (MI) 2 years postflight
Nitrogen Tetroxide leaked into capsule on reentry	ApolloSoyuz Test Project	Crew hospitalized postflight for chemical pneumonia
Intractable headaches after probable combustion event	SalyutSpace Station	Abandoned Salyut
Urinary tract infection	SalyutSpace Station	Early termination of the mission
Cardiac dysrhythmia	MirSpace Station	Early termination of the mission
Acute grief reaction due to lack of ground contact with family, privacy issues	MirSpace Station	Crew withdrew for 1 week
Urinary retention	Shuttle Program	Bladder catheterization
Acute behavioral change	Shuttle Program	Crew concerned about dangerous behavior
Excessive medication use prior to EVA	Shuttle Program	
Misuse of on-orbit medications	Shuttle Program	Performance impacts
Unexpected reaction to medications	Shuttle Program	Caused urinary retention
Cardiac abnormalities detected	ISS Program	Crew member pulled from EVA
Crew-crew interpersonal conflicts	All Programs	
Crew-ground interpersonal conflicts	All Programs	
Cardiac ischemia	Russian Program	MI six weeks postflight

Notes:

- Type 1 DCS is when nitrogen bubbles affect tissue around joints.
- Bigeminy is premature heart beats alternating with normal beats
- Dysrhythmia is an abnormality in an otherwise normal heart rhythm
- Ischemic is an condition in which blood flow is restricted in a part of the body

In addition, space flight has also resulted in the deaths of crewmembers:

3/23/61	Soyuz ground test	Cosmonaut Valentin Bondarenko died on 23 March 1961 in a fire in a spacecraft simulator with 100% oxygen environment.
1/27/67	Apollo 1	Fire in crew module during ground test, with 100% oxygen environment. Three crewmembers, Chaffee, Grissom and White, perished.
4/24/67	Soyuz 1	Parachute system did not deploy after reentry and capsule destroyed on impact, resulting in fatality of cosmonaut Komarov.
6/29/71	Soyuz 11	Cabin pressure failure during reentry. Three crewmembers, Dobrovolsky, Volkov and Patsayev perished.
1/28/86	STS-51L	Solid rocket booster seal failure resulted in Shuttle destruction. Seven crewmembers perished: Gregory B. Jarvis, Christa McCauliffe, Ronald E. McNair, Ellison S. Onizuka, Judith A. Resnik, Francis R. (Dick) Scobee, Michael J. Smith,
2/1/ 2003	STS-107	Columbia was destroyed on reentry, and all crew were lost. Michael Anderson, David Brown, Kalpana Chawla, Laurel Clark, Rick Husband, William McCool, Ilan Ramon

Appendix B

6.2 Physical and Health Measures Collection Schedule - LSAH

Measures	Astronauts	Comparisons	Notes
Physical exam	**Annual**	**Biannual**	
Sitting BP	Annual	Annual	
Standing BP	Annual	Annual	
Recumbent BP	Annual	Annual	
Pulse	Annual	Annual	
Height	Annual	Annual	
Weight	Annual	Annual	
Percent body fat (sum of four skinfolds)	Annual	Annual	
Temperature	Annual	Annual	
Review of systems	Annual	Biannual	
Significant interval history	Annual	Annual	
Summary of defects and diagnoses	Annual	Biannual	
Recommendations	Annual	Biannual	
Qualifying information	Annual	N/A	
Dental exam	Active duty only	N/A	
Acuity, distant and near vision, each eye and binocular	Annual	Biannual	
Color vision	Annual	Never	
Depth perception	Annual	Never	
Heterophorias	Annual	Never	
Intraocular pressure	Annual	Biannual	
Audiometry 500, 1000, 2000, 3000, 4000, 6000, 8000 Hz for each ear	Annual	Biannual	
ECG	Annual	Annual	
Pulmonary function by standard spirometry	Annual	Biannual	
DEXA scan	Triannually	Never	
Exercise tolerance test (85% max)	Age-specific intervals per USPTF guidelines	Age-specific intervals per USPTF guidelines	51+ = annually
Colonoscopy	Age 40, 50, 60	Age 40, 50, 60	
Proctosigmoidoscopy	Age 45, 55	Age 45, 55	
Mammogram	Age-specific intervals per	Age-specific intervals per	50+ = annually.

	USPTF guidelines	USPTF guidelines	
Pelvic exam	Annual	Biannual	
Pap smear	Annual	Biannual	
Comprehensive Laboratory Analysis			
Hematology	Annual	Annual	
WBC	Annual	Annual	
RBC	Annual	Annual	
Hemoglobin	Annual	Annual	
Hematocrit	Annual	Annual	
MCV	Annual	Annual	
MCH	Annual	Annual	
MCHC	Annual	Annual	
Platelet count	Annual	Annual	
RDW	Annual	Annual	
Reticulocyte count,	Annual	Annual	
Differential (neutrophils, lymphocytes, monocytes, basophils, eosinophils)	Annual	Annual	
Chemistry Panel:	Annual	Annual	
Glucose	Annual	Annual	
BUN	Annual	Annual	
Uric Acid	Annual	Annual	
Creatinine	Annual	Annual	
Total protein	Annual	Annual	
Total bilirubin	Annual	Annual	
Aspartate transaminase	Annual	Annual	
Alanine transaminase	Annual	Annual	
Alkaline phosphatase	Annual	Annual	
Lactate dehydrogenase	Annual	Annual	
Glutamyltransferase	Annual	Annual	
Sodium	Annual	Annual	
Potassium	Annual	Annual	
Chloride	Annual	Annual	
Phosphorus	Annual	Annual	
Calcium	Annual	Annual	
Magnesium	Annual	Annual	
Carbon dioxide	Annual	Annual	
Serum Iron:	Annual	Biannual	
Lipid Profile:	Annual	Annual	
Cholesterol	Annual	Annual	

Triglyceride	Annual	Annual	
VLDL	Annual	Annual	
HDL	Annual	Annual	
LDL	Annual	Annual	
Chol/HLD ratio	Annual	Annual	
Urinalysis:	Annual	Annual	
pH	Annual	Annual	
Specific gravity	Annual	Annual	
Color	Annual	Annual	
Appearance	Annual	Annual	
Protein	Annual	Annual	
Glucose	Annual	Annual	
Ketone	Annual	Annual	
Blood	Annual	Annual	
Bilirubin	Annual	Annual	
Urobilinogen	Annual	Annual	
Nitrite	Annual	Annual	
Leukocyte esterase	Annual	Annual	
WBC	Annual	Annual	
RBC	Annual	Annual	
Epithelial cells	Annual	Annual	
Mucus	Annual	Annual	
Ionized Calcium Profile:	Annual	Biannual	
Ionized Calcium	Annual	Biannual	
Ionized Calcium at 7.40	Annual	Biannual	
SPE Panel:	Triannual	Triannual	
Total Protein	Triannual	Triannual	Performed in association with DEXA scan
Albumin	Triannual	Triannual	Performed in association with DEXA scan
Alpha 1	Triannual	Triannual	Performed in association with DEXA scan
Alpha 2	Triannual	Triannual	Performed in association with DEXA scan
Beta	Triannual	Triannual	Performed in association with DEXA scan
Gamma	Triannual	Triannual	Performed in

			association with DEXA scan
A/G ratio	Triannual	Triannual	Performed in association with DEXA scan
Immunoglobin Panel:			
IGG	Triannual	Triannual	Performed in association with DEXA scan
IGA	Triannual	Triannual	Performed in association with DEXA scan
IGM	Triannual	Triannual	Performed in association with DEXA scan
Serology:			
Hep A total	Annual	Never	
Hep B Surface Antigen	Annual	Never	
Hep B Surface Antibody	Triannual	Triannual	Performed in association with DEXA scan
Hep C Antibody	Annual	Never	
RPR	Annual	Never	
CRP	Annual	Annual	
Anti-HIV	Annual	Never	
Thyroid Function Tests	Annual	Biannual	
Personal Medical History			
Self-report of personal medical history, checklist review of medical problems, hospitalizations	Annual	Annual	
Medical records from JSC clinics, private physicians, and hospitals			
Acute and chronic medical events	As events occur or are brought to attention	As events occur or are brought to attention	
Diagnoses	As events occur or are brought to attention	As events occur or are brought to attention	

Medical procedures	As events occur or are brought to attention	As events occur or are brought to attention	
Treatment	As events occur or are brought to attention	As events occur or are brought to attention	
Medications	As events occur or are brought to attention	As events occur or are brought to attention	
Recommendations	As events occur or are brought to attention	As events occur or are brought to attention	
Lifestyle Questionnaire	As appropriate	As appropriate	Sent in 1995 and 1998; Planning to revise questionnaire and send in 2007
Marital status and history	As appropriate	As appropriate	
Family medical history	As appropriate	As appropriate	
Reproductive history	As appropriate	As appropriate	
Smoking history	As appropriate	As appropriate	
Alcohol use	As appropriate	As appropriate	
Exercise and weight patterns	As appropriate	As appropriate	
Pilot experience	As appropriate	As appropriate	
Hormone use (women only)	As appropriate	As appropriate	
Death Records			
Death Certificate	As appropriate	As appropriate	
Hospitalization records	As appropriate	As appropriate	
Autopsy reports	As appropriate	As appropriate	
Postflight Medical Debrief	Postflight	N/A	

* USPSTF = U.S. Preventive Services Task Force

Appendix C

6.3 NASA Technology Readiness Levels [11]

Level 1. Basic principles observed and reported

Level 2. Technology concept and/or application formulated

Level 3. Analytical & experimental critical function and/or characteristic proof of concept

Level 4. Component and/or breadboard validation in laboratory environment

Level 5. Component and/or breadboard validation in clinical environment

Level 6. System/subsystem model or prototype demonstration in a relevant environment

Level 7. System prototype demonstration in an operational environment

Level 8. Actual system completed and "operationally qualified" through test and demonstration

Level 9. Actual system "operationally proven" through successful mission operations

[11] See Mankins, 1995