3-2003

Implementation and Validation of a Real-Time Wireless Non-Invasive Physiological Monitoring in a High-G Environment

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IMPLEMENTATION AND VALIDATION OF A REAL-TIME WIRELESS NON-INVASIVE PHYSIOLOGICAL MONITORING SYSTEM IN A HIGH-G ENVIRONMENT

THESIS

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THESIS

Presented to the Faculty

Department of Electrical and Computer Engineering

Graduate School of Engineering and Management

Air Force Institute of Technology

Air University

Air Education and Training Command

In Partial Fulfillment of the Requirements for the

Degree of Master of Science in Electrical Engineering

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March 2003

AFIT/GE/ENG/03-01

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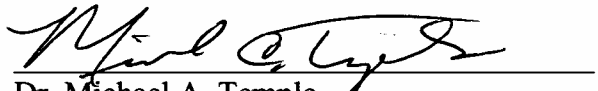

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ACKNOWLEDGEMENTS

I would like to express my sincere thanks to my advisor, Lt. Col. Mike Miller. His experience, knowledge and suggestions guided and supported me throughout the course of this research effort. I am also very grateful to all my friends and Don Smith for their support.

I would like to thank Mr. and Mrs. Grazier, who hosted me and made me feel as if I had been with my own family. Most significantly, I thank my family for raising and supporting me all my life. They always have made great contributions to my study motivation.

Finally, thanks to my government and Turkish Air Force for providing me such an opportunity.

H. Aydin AKCIVI

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ABSTRACT

The overall purpose of this research is to develop a system capable of real-time personal positioning and physiological monitoring. The system will be composed of a shirt having non-invasive physiological sensors, Global Positioning System (GPS) receiver, wireless data transceiver, and real-time PC-based control station. The specific purpose of this research phase was to determine the performance capabilities of a modified LifeShirt™ alone (without GPS) in a high gravitational force environment with the data being sent wirelessly in real-time.

The LifeShirt™ was modified with a real-time wireless transmission system. The modified LifeShirt™ system was tested in Air Force Research Laboratory Human Effectiveness (AFRL/HE) Dynamic Environment Simulator (DES) to compare the LifeShirt™ data to the data of DES health monitoring system. Eight high-G tests (up to 7.5 G's) were conducted for this research. The test results clearly indicated that the wireless system performed well in transmitting the LifeShirt™ physiology data in real-time.

IMPLEMENTATION AND VALIDATION OF A REAL-TIME WIRELESS NON-INVASIVE PHYSIOLOGICAL MONITORING SYSTEM IN A HIGH-G ENVIRONMENT

1.1 BACKGROUND

There have been astonishing developments in communication and computer systems, space-based radio navigation systems (such as the Global Positioning System (GPS)), and other sensor technology. It is now possible to transmit large amounts of data at a high rate in real-time. These developments have opened the doors to the possibility of monitoring a person's position and physiology together in real-time.

Real-time position and physiology monitoring will assist military or emergency control centers in determining people's health and location accurately in hazardous and everyday environments. Several examples include: firefighters, other outdoor workers operating in dangerous environments, medical patient monitoring outside a hospital environment, military operations, exercising sportsmen and pilots during flight. Control centers will have the ability to monitor a subject's health and location in real-time, and take immediate action if necessary. In addition, since the subject's position and physiology are known, if a physically dangerous situation occurs the monitoring can provide medical personnel with the critical physiological information required to perhaps save the life of the subject.

A special lightweight shirt with a GPS receiver and noninvasive physiological sensors is being developed to monitor people in various environments. The system will transmit GPS based position, velocity, and time (PVT) and physiological information such as electrocardiogram (ECG), pulse oximetry, and respiration to a central control base station. The data will be displayed on a computer screen for easy interpretation. Special software algorithms will analyze the physiological data in real-time and provide warnings in dangerous health situations. The general system concept is shown in Figure 1.

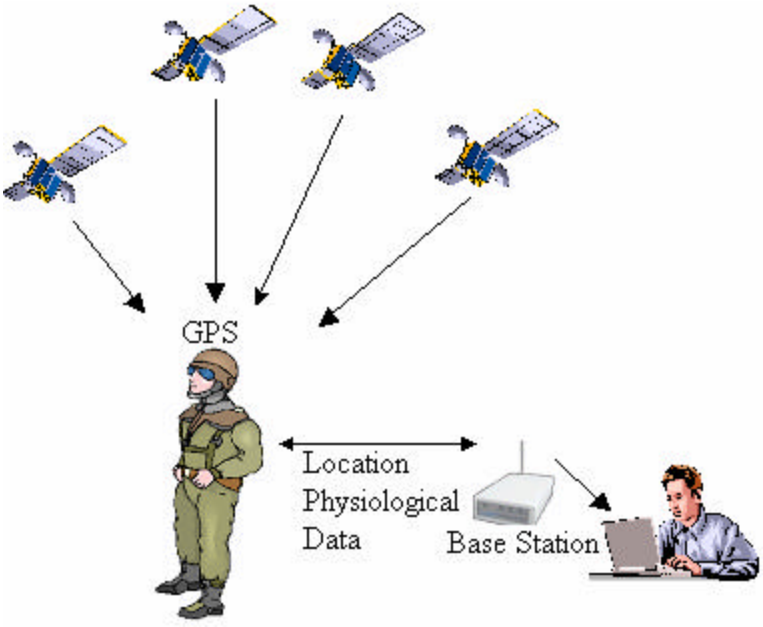


Figure 1. General system picture

1.2 PROBLEM

Even though physiological monitoring and positioning can each be done independently, not much has been done to fuse these two together for the purpose of monitoring personnel in everyday environments. Combining these two technologies into a lightweight, non-invasive shirt, with the capability to transmit physiological and positioning data to a central command center, will help people in many professions.

This research focuses on modifying a commercial-of-the-shelf (COTS), noninvasive, wearable, physiological monitoring system to research the real-time performance of the system in a high dynamic environment simulator.

1.3 SUMMARY OF THE CURRENT KNOWLEDGE

Real-time patient monitoring systems are currently being developed to provide medical personnel with the ability to watch and evaluate their patients functioning in their 'normal' environment from a remote site. These systems will monitor a patient's vital signs and provide the necessary physiological information required to diagnose a situation that might require medical attention. Currently, home health monitors only collect vital sign information and transmit the data via the Internet.

New wireless technologies will give medical personnel the ability to monitor patients suffering from diabetes, cardiovascular disease, and other serious illnesses. Knowing a patient's real-time health status can provide a unique opportunity to take preventive medical action to stop or slow complications. For the patients, these home monitoring technologies promise longer and better lives. For the health-care industry, the

potential payoff is lower treatment costs from fewer patient visits to hospitals and critical-care centers.

Among problems encountered in hospitals is increased costs associated with patient treatment. This increase makes it necessary to improve systems to reduce costs and, at the same time, to provide good patient care. Data monitor analyst Maryann Lombardo states, "The benefit to the patient is obvious--the prospect of better health. The health-care industry, however, must juggle the matrix of patient well-being, the immediate cost of the devices, and the potential for long-term savings[1]. "

Each year, $274 billion is spent to care for the 58 million Americans who have some form of cardiovascular disease, according to the Centers for Disease Control. Health-care agencies spend $98 billion a year to care for 16 million Americans with diabetes. The monitoring devices should reduce the need for emergency-room visits by 99% and hospitalizations by 92% [1].

VivoMetrics[2] is a company which has been working on wearable, noninvasive patient monitoring systems. The VivoMetrics LifeShirt™ concept is shown if Figure 2. Using the LifeShirt™, VivoMetrics can provide doctors and researchers with ambulatory monitoring products that will help them analyze and report collected data. One benefit is that patients need not stay at hospitals while being monitored. Therefore, patients are able to conduct “normal” activities while the physiological data is recorded via noninvasive methods.

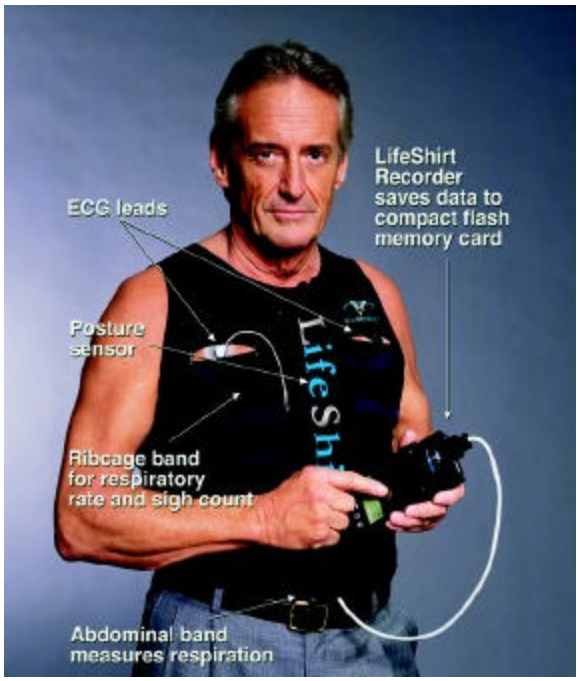


Figure 2. LifeShirt™ [3]

VivoMetrics developed the LifeShirt™ System which is capable of collecting data around the clock while people are active in their normal routines, including sleep. The shirt measures different types of respiratory parameters, cardiac function parameters, posture, and motility information. The system is intended to provide analysis of breathing patterns as an aid in classifying apneas as well as displaying heart rate changes from electrocardiographic waveforms in the wake and sleeping states as well as daily life. All the sensors and electronics used in the system are integrated within the shirt and a small handheld computer device. The data is recorded to a Data Card and evaluated in a data center at a later time [3].

Research is currently being conducted to monitor astronauts' health condition while in space or training. Since astronauts are subject to various degrees of stress, physiological monitoring is very important. The sensors and equipment used for monitoring must be comfortable, reliable, compatible with other spacecraft's equipment,

and must not interfere with the astronauts' primary mission. Continuous monitoring must be done to determine whether the astronaut is physiologically capable of continuing the mission.

The Smart HealthCare Management Systems (SHMS) is managed and operated by the AstroBionics Program as a Project under the Space Medicine element of the Bioastronautics Division [4]. The SHMS activity includes the development of a Personal Status Monitoring System and Device that is integrated with a Personal Physiological Monitoring System (PPM), a Personal Environmental Monitoring System (PEM), and a Personal Clinical-Biological Monitoring System (PCM). The SHMS Project is developing wearable/personal Physiological Status & Monitoring Systems (PSM) that contribute in controlling a feedback loop through data management for input in decision assessment for Astronauts and crew in space.

Also, runners require training to improve their chances for winning a race. Evaluating workouts using physiological, position, and velocity can help a coach evaluate performance and then improve performance in a more efficient and effective manner. Much equipment had been developed to monitor an athlete's health status. Miller [5] integrated heart rate data and GPS data together and transmitted them to a base station wireless in real-time. It correlated the runner's heart rate, velocity and position, allowing the coach to see a trainee's performance changes with respect to the runner's position and velocity. Thus, the runner's performance could be analyzed and improved in an effective way.

Researchers at Georgia Institute of Technology have developed the Georgia Tech Wearable Motherboard^{TM} (Smart Shirt), shown in Figure 3, for Combat Casualty Care

[6]. They wanted to take advantage of the advancements in telemedicine and information processing to have an effective and mobile information infrastructure that can be tailored to the individual's requirements.

Figure 3. Smart Shirt [6]

The Smart Shirt uses optical fibers to detect bullet wounds to the body. The Smart Shirt functions like a motherboard, with plastic optical fibers and other specialty fibers woven throughout the actual fabric of the shirt. A signal is sent from one end of the plastic optical fiber to a receiver at the other end to determine the exact location of a bullet penetration. The emitter and the receiver are connected to a Personal Status Monitor (PSM) worn at hip-level by the soldier. If the light from the emitter does not reach the receiver inside the PSM, it means that the Smart Shirt has been penetrated. The signal goes back to the PSM from the point of penetration to show the exact location of the soldier's wound to medical personnel [6].

The Smart Shirt also provides the monitoring of vital signs of soldiers in an unobtrusive way. Two methods are used to monitor the soldier's vital signs such as heart rate, temperature, respiration rate: through the sensors integrated into the T-shirt, and

through the sensors on the soldier's body, both of which are connected to the PSM. Information on the wound and the soldier's health condition are immediately transmitted electronically from the PSM to a medical triage unit located near the battlefield. The triage unit then dispatches the appropriate medical personnel to the scene. The Smart Shirt can help a physician figure out the condition of a soldier's injuries based on the heart rate and respiration rate. This information is important in providing the critical assistance to soldiers during the first hour of battle (also called the 'golden hour') in which there are numerous casualties [6].

Even though the shirt was developed for reducing the risk to diagnose a soldier's health condition properly on the field, and to help the triage procedures in saving the lives, it has a great potential for applications in fields like telemedicine, monitoring of patients, monitoring of astronauts, law enforcement and sportsmen. As the number of doctors decreases in rural areas, the doctor/patient ratio is reaching unacceptable levels for providing comfort for people living in such areas. When patients leave the hospital after having major surgeries (e.g., heart bypass), they experience a loss of the sense of security, because they feel "cut off" from the continuous watch and care they received in the hospital. This degree of uncertainty can greatly influence their post-operative recovery. Monitoring patients will have a positive psychological impact for their recovery. Fewer hospital visits directly translates into saving dollars [6].

Hoffman worked on developing an algorithm capable of determining the heart rate, the QT and PR intervals in an ECG signal [7]. This was the first known research effort using adaptive estimation to segment the ECG signal using a multiple model adaptive estimator (MMAE) based on the Kalman filter [8]. After some testing with

signals from the Massachusetts Institute of Technology (MIT) ECG database and signals from animal exanguination data, it was shown that the algorithm performed very well in identifying each segment of the ECG signal. This research made it possible to detect the cascade of events that leads to fatal irreversible shock in severe injury accidents. This analyzer could be added to a physiological monitoring system [7].

1.4 SCOPE

The overall purpose of this research is to develop a system capable of real-time personal positioning and physiological monitoring. The system will be composed of a shirt having sensors, GPS receiver, wireless data transceiver, and real time PC-based base station. The data transmitted to the base station will be processed, and necessary warning indications will be provided in case of dangerous health conditions. The specific purpose of this thesis effort is to determine performance capabilities using the LifeShirt^{TM} alone (without GPS) in a high gravitational force environment with the data being sent wirelessly in real-time.

1.5 APPROACH/METHODOLOGY

In this research, the modified Lifeshirt™ system is tested in the dynamic environment simulator (DES). The DES is a man-rated, three axis centrifuge used to simulate the acceleration stresses encountered by pilots. Pilots in high performance, maneuvering aircraft are subject to increased accelerations and gravitational (G) forces that cause great changes in their physiology. The DES is used to investigate the effects of sustained G forces on a pilot's performance and physiological state. The physiological

monitoring of a pilot in DES is typically accomplished using invasive methods. For this research the subject in the DES will wear the modified LifeShirt™ and be monitored by both the LifeShirt™ and the DES's normal physiological monitoring methods. The Lifeshirt™ data is transmitted wirelessly and compared to the data of DES health monitoring system. Thus, the accuracy of the wirelessly transmitted health data under G forces is calculated. Since this research is conducted indoors, the GPS position and velocity data are not transmitted.

2.1 INTRODUCTION

High gravitational (G) forces negatively affect a pilot's physiology. Fighter pilots are primarily affected by G forces which are directed towards their feet. The G-forces mostly occur during the high dynamic aircraft maneuvers associated with enemy engagement and in tight turns. Blood can not offer any resistance to centrifugal forces and goes down the body accordingly. This overly burdens the heart to supply blood to the head, which is the body's control center. G-forces greatly affect the circulatory and respiratory systems of the pilots [9].

Human centrifuges are used to duplicate the G-forces affecting pilots during flight. In addition, centrifuges give researchers the ability to conduct studies under safe and controlled conditions. Additionally, the G-tolerance of jet pilots, astronauts and others can be trained and measured in human centrifuges. Human centrifuges are also used to conduct medical research. During each test study, the physiological conditions of the subject are continuously monitored. In this way the G-tolerance and the changes in the physiology of the subject can be determined.

The purpose of this chapter is to review the physiological effects of G-forces on the human body and the ways to monitor these effects.

2.2 GRAVITATIONAL (G) FORCES

High performance aircraft pilots are subject to varying levels of G-forces. A G may be thought of as the force or "pull" of gravity upon a body. Depending on how strongly the pilot pulls or pushes the controls and how quickly the aircraft responds, the amount of G-force experienced by the pilot is affected. If the pilot pulls five positive G's

he or she would appear to weigh five times his or her normal weight. If the aircraft changes direction such that the pilot is thrown upward or outward, it is called pulling negative G. In this case the pilot feels weightlessness, i.e., the pilot's weight would be less than his or her normal weight [10]. How pilots are affected by G-forces is shown in Figure 4.

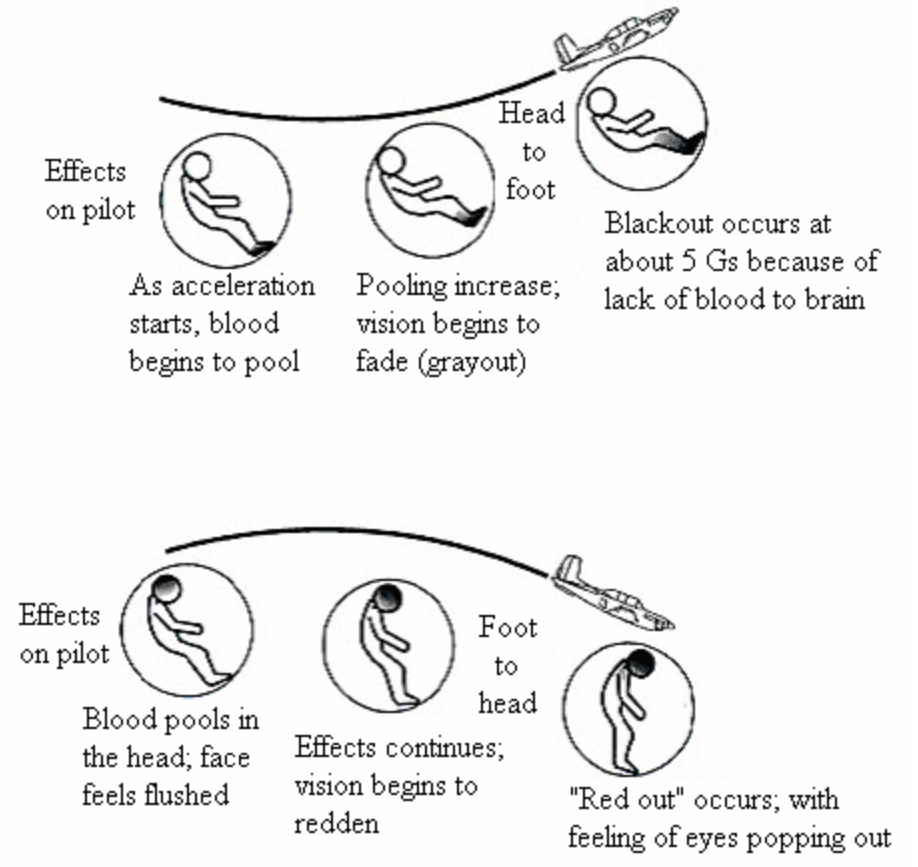


Figure 4. Effects of G-forces on human body [11]

G is described in three axes with respect to human body as x, y, and z. Each axis is described as positive or negative according to an international convention, as shown in Figure 5.

Direction of Acceleration	*Direction of Resultant Inertial Force*	*Physiological and Vernacular*	*Standard Terminology Descriptors*
Headward	Head to Foot	Positive G Eyeballs down	+Gz
Footward	Foot to Head	Negative G	-Gz
Forward	Chest to Back	Transverse A-PG Supine G Eyeballs in	+Gx
Backward	Back to Chest	Transverse P-AG Prone G Eyeballs out	-Gx
To the Right	Right to Left side	Left lateral G Eyeballs left	+Gy
To the Left	Left to Right side	Right lateral G Eyeballs right	-Gy

Figure 5. Types of G-forces and their effects [12]

2.3 PHYSIOLOGICAL EFFECTS OF G-FORCES

Physiological effects of G-forces change depending on the G-forces' magnitude, duration, and axis of application. Headward acceleration, which results in positive G (+Gz), is the most common G-force experienced by pilots. Negative G also occurs but is usually avoided by the pilots. Tolerance to transverse G (Gx) is much higher. Finally, Gy is not of great enough amplitude to cause problems in consciousness and is not a problem with modern day aircraft [3].

Increased +Gz forces increase the weight of the pilot. In addition, the shape and function of the internal organs can change. When the +Gz is higher than 3 or 4,

controlled motions and skills, speaking, vision, cardiovascular system and respiratory system are adversely affected [13].

2.3.1 CARDIOVASCULAR EFFECTS

The most dangerous effects of Gz forces are seen on the hydrostatic column between the heart and brain. The more +Gz increases the more the blood pressure to brain is decreased [13].

According to [14], "The brain is approximately 340 mm above the heart and the specific density of blood with respect to mercury is 1/13.6. Therefore, at 1.0 G there is a hydrostatic pressure gradient (PH) of:

$$PH = 340 \text{ mm} \times (1/13.6) \times 1 = 25 \text{ mm Hg.}$$

If one assumes an average heart level systolic blood pressure (Pa) of 120 mm Hg, then the brain level blood pressure is 120 - 25 = 95 mm Hg. At 5.0 G the PH of 125 mm Hg exceeds the average Pa of 120 mm Hg and the lack of blood flow causes unconsciousness. To understand this "blackout" phenomenon, all one has to do is remember that the average intraocular pressure is 20 mm Hg. This intraocular pressure is the pressure the retinal artery must overcome to supply blood to the retina. "Grayout" occurs as the retinal artery pressure in the periphery can no longer overcome the intraocular pressure and blood flow to the peripheral retina ceases. "Blackout" is explained by the complete lack of blood flow to the eye which causes it to cease to function before the brain does. Blackout precedes unconsciousness by about 0.8 +Gz (20mmHg/25mmHg)."

The cardiovascular system, which maintains the major physiologic activities, is adversely affected by increased Gz. Since the cardiovascular system provides the physiologic bases for human +Gz tolerance, most of the research is done in this area. Heart rate increases directly with increasing +Gz level. High sustained G exposures usually induce a maximum heart rate of about 170 beats-per-minute (bpm) and heart rates rarely exceed 200 bpm. An electrocardiograph (ECG) is required during research experiments to monitor subjects. If the normal ECG and consciousness are maintained, it is said that the physiological functions are performing normally. Any abnormality in the ECG is a reason to stop the research [15].

2.3.1.1 ELECTROCARDIOGRAM

Gayton describes an ECG as "The cardiac impulse passes through the heart, electrical currents spread into the tissues surrounding the heart, and a small portion of these spreads all the way to the surface of the body. If the electrodes are placed on the skin on the opposite sides of the heart, electrical potentials generated by these currents can be recorded; the recording is known as electrocardiogram [17]." The ECG can be used to detect normal activity, cardiac arrhythmia and pathologies as well as the presence of disease.

Furthermore, "The electrical potential of cells in the heart is related to the differences between concentrations of the intracellular and extracellular electrolytes. In the resting state myocardinal cells (those that make up the thick muscular middle layer of the heart wall and most of the heart mass) are negatively charged with respect to their surroundings. During a process called depolarization, these cells lose their negativity,

resulting in the cells contracting and this fundamental electrical event of the heart propagates from cell to cell producing a wave of depolarization that can be transmitted across the entire heart. Once depolarization is complete, a similar process called repolarization occurs which reverse what the previous process did and the result is that the myocardinal cells return to their original resting potential [18]."

Each portion of a heartbeat produces a different action potential. These action potentials are graphed as a series of up and down waves during an ECG. The first, called the P wave, is a small upward wave. It indicates atrial depolarization - the spread of an action potential from the sinoatrial (SA) node through the two atria. After a fraction of a second the P wave begins and the atria contracts. The second wave, called the QRS wave, begins as a downward deflection, continues as a large, upright, triangular wave, and ends as a downward wave at its base. This wave represents ventricular depolarization, that is, the spread of the action potential through the ventricles. The third wave is a dome-shaped T wave. This wave indicates ventricular repolarization. There is no wave to show atrial repolarization because the stronger QRS wave masks this event [19]. A normal ECG waveform is shown in Figure 6.

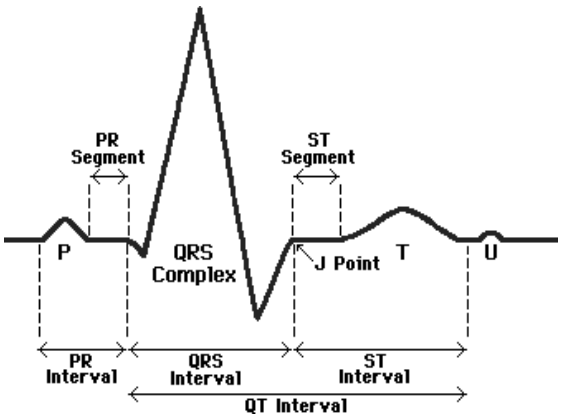


Figure 6. ECG Characteristic Waveform [7]

A two-dimensional ECG can be used to determine different types of cardiac situations. An ECG provides end-diostalic volume, end-systolic volume, cardiac output, heart rate, and ejection-fraction data using a single noninvasive method. Generally, the ECG tracing is used as a decision criterion to continue or stop centrifuge testing on the subjects in centrifuge labs. Changes occurring in the type and frequencies of abnormalities in the ECG waveform can cause the G-exposure to be stopped for the day. The magnitude of G loads directly affect the frequency of abnormalities. [13]

2.3.2 RESPIRATORY EFFECTS

Pulmonary functions and its related activities are highly important. The major limiting factors in a pilot's G-tolerance depends on the lung capacity and gas exchange across lung tissue under G-forces.

Positive acceleration up to 5.0 Gs does not cause much respiratory difficulty. Pulmonary ventilation increases 20 per cent at +3.0 Gz even though it increases 150 per cent at +5 Gz. Both the tidal volume, which is the volume of air moved during normal quiet breathing, and respiratory frequency increase. Because of reduced inspiratory capacity there will be a 10 per cent decrease in vital capacity, which is the greatest extreme in air volume moved between inspiration and expiration. As the G-forces increase the diaphragm is displaced downward. For example, at 5.0 Gs, the displaced diaphragm mainly increases the functional capacity by 450 ml and tidal volume by 150 ml. The descent of diaphragm caused by positive acceleration is minimized by using an anti-G suit [15,20].

Positive acceleration highly affects the distribution of blood flow through the lungs. The alveolar gas pressure is the same throughout the lung and it is not affected by acceleration, and the pressures in the pulmanory circuits are relatively small. As the acceleration increases, the blood flow (per centimeter) down the lung increases [20].

As the acceleration increases the oxygen saturation and the tension of the systemic arterial blood are reduced. Desaturation of the arterial blood becomes apparent at +3.0 Gz, and exposure to +5.0 Gz decreases the oxyhaemoglobin saturation to about 85 per cent [20].

2.3.2.1 RESPIRATORY MONITORING

Pulse oximetry is the technique most commonly used in respiratory monitoring. Pulse oximetry is a simple non-invasive method of monitoring the percentage of hemoglobin (Hb) saturated with oxygen. "Oxygen forms an easily reversible combination to give oxyhaemoglobin. The haemoglobin is contained in the red cells, and the normal concentration of haemoglobin is 15g/100 ml blood. The maximum amount of oxygen which can be combined with one gram of haemoglobin is 1.39 ml; so that the total amount of oxygen which can be carried in combination with haemoglobin in normal blood (oxygen capacity of the blood) is 1.39*15=20.8ml/100ml blood. The quantity of oxygen present in the blood in combination with haemoglobin is frequently expressed as the oxygen saturation of haemoglobin which is given by the relationship [20]:"

$$oxygensaturation\ ?\ \frac{conc.of\ oxygencombinedwithhaemoglobin}{oxygencapacityof\ blood}\ ?\ 100$$

“Pulse oximetry uses the principles of optical plethysmography and spectrophotometry to determine arterial oxygen saturation values. Optical plethysmography uses light absorbance technology to reproduce waveforms produced by pulsating blood. Spectrophotometry uses various wavelengths of light to perform quantitative measurements about light absorption through given substances. Using these two principles together, a sensor is attached to a patient which uses two LEDs - a red (660 nm) and an infrared (940 nm) light emitting diode - to transmit light through the vascular bed to a photodetector. The difference in intensity of transmitted light between red and infrared light is caused by the differences in the absorption of light by oxygenated (saturated) and deoxygenated (desaturated) hemoglobin. The resulting voltage difference is used to calculate the amount of oxygen saturation by comparing the value against tables contained in the pulse oximeter's memory [21]. “

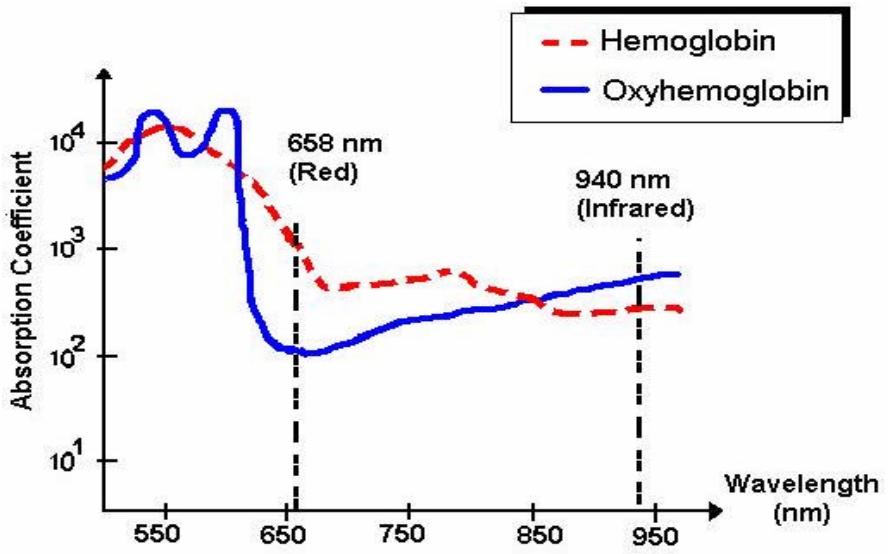


Figure 7. Absorption Coefficients for Hemoglobin and Oxyhemoglobin Relative to Light Wavelength (nm) [7].

"Well-oxygenated blood is generally bright red in color, and will absorb most of the light being transmitted through the oximeter. Poorly oxygenated blood is more dark red-to-purple in color, and will not absorb the beam of light as well. Another fascinating aspect of the pulse oximeter is its ability to distinguish between venous blood levels and arterial blood levels. The mechanics of this magnificent technology allows it to distinguish between the pulsating venous blood and the constant flow of arterial blood." [22].

Pulse oximetry is used in centrifuge testing to allow the physiologists to get the quantification of hydrostatic column effect (presence and absence of pulse at eye level) and the long-term effects of G on the cardiopulmanory system (arterial oxygen saturation). The LEDs used in pulse oximetry are mostly placed to the finger, earlobe or the bridge of the nose. In most centrifuge tests, the pulse oximetry sensor is typcially placed at the temple to monitor eye-level oxygen saturation in blood [13].

2.3.3 HYPOXIA

"The lack of adequate oxygen in one's body's metabolism is called hypoxia. This simply means that there isn't enough oxygen available to bring into your lungs with adequate partial pressure. Hypoxia corrupts the intracellular oxidative process and damages cellular function. Hypoxia results in brain damage, deterioration of performance, reduced visual ability and unconsciousness [15]." The effects of hypoxia upon flying skills and the symptoms of its onset are the same regardless of the cause of the hypoxia. However, hypoxia is sorted in four different types according to its primary cause:

1. *Hypoxic hypoxia:* Lack of oxygen in the tissues due to a decrease in the partial pressure of oxygen at altitude causes hypoxic hypoxia. It is also called as altitude hypoxia.
2. *Stagnant Hypoxia:* Reduction in the flow of blood to the tissues, and pooling of blood cause stagnant hypoxia. G-forces in the flight, heart failure, or continuous pressure breathing can cause stagnant hypoxia.
3. *Hypemic Hypoxia:* The reduction in the oxygen-carrying capacity of the blood causes hypedemic hypoxia. It may be caused by inhalation of carbon monoxide, anemia, and the formation of methaemoglobin. It is also called anemic hypoxia.
4. *Hystotoxic Hypoxia:* Interference of the tissue's ability to absorb or metabolize delivered oxygen causes hystotoxic hypoxia. Alcohol, certain narcotics and cyanide compounds can prevent the tissue cells from making full use of the oxygen available to them in the blood supply and this causes hystotoxic hypoxia. If histotoxic hypoxia occurs, blood oxygen saturation levels gets higher because the cells cannot remove the oxygen from the hemoglobin [23,24,20,15].

2.3.3.1 EFFECTS OF HYPOXIA

The effects of hypoxia are seen at the cellular level, because cells obtain their energy from oxygen. Since the visual, myocardinal and nervous tissues need the highest oxygen these tissues are affected more than the other tissues.

The effects of hypoxia on respiratory system are seen as an increase in the depth of breathing and respiratory rate. Aortic and carotid chemoreceptors sense the reduction

in oxygen pressure in the blood and cause the respiratory system to start compensatory efforts.

The cardiovascular system is more resistant to hypoxia than respiratory and nervous systems. Cardivascular responses are reflexive. For example, in the case of hypoxia reflex, adjustments increase the heart rate, increase systolic blood pressure and redistribute blood flow to improve circulation to the brain and the heart.

Hypoxia decreases the visual and cerebral performance as the retina of the eye and central nervous system, which both have a great need for oxygen. If the duration and the severity of hypoxia increase, the cerebral activity stops and it ends up with person's death [15].

2.4 HUMAN USE CENTRIFUGES

Centrifuges are used for experimentation and G training. Even though experimentation and training centrifuges have similar structures, their operation differs significantly. Every centrifuge has a center spindle connected to the drive system and a rigid arm that has an enclosed section, called the gondola.

Human-use centrifuges have two major performance characteristics, which are the maximum G level and its onset rate. The onset rate is the rate of change of the G vector within the gondola. High-G onset capability is an important consideration since high performance aircraft can have very high onset rates during air combat maneuvers (ACM). The centrifuge is brought to a low G-level, which is called "base G," before starting the high-G onset maneuver. This process reduces the torque requirement for the drive system.

There are two types of gondola angular control modes; passive and active. In the passive control mode, the gondola rotates freely in the roll axis. In the active control mode, the gondola drive motors, with computerized controls, are used to solve the acceleration vector equations. In this way, the G-vector is more effectively maintained.

In addition to the angular control modes, there are two control operations: closed-loop and open-loop. In closed-loop operations, the test subject is able to control the centrifuge using an aircraft-type control stick. In open loop operation, the subject is only able to stop the centrifuge. Additionally, visual tracking systems are always used to monitor the subjects. Furthermore, in sophisticated centrifuges, complicated invasive and noninvasive instrumentation equipment is used [15].

2.4.1 DYNAMIC ENVIRONMENT SIMULATOR (DES)

The DES, shown in Figure 8, is a man-rated, three-axis centrifuge, and it is used to simulate the acceleration stresses encountered by pilots. It has a radius of 5.8 meters to the center of the large spherical cab and can create a force of 20 Gs at a rotational velocity of 56 RPM. Its 163,000-kilogram weight is supported by a hydrostatic bearing system. The control system uses a digital computer and provides for automatic, manual, or closed loop modes of operation. It has been in the service since 1969 [25].

The DES is a key component in the Air Force Research Laboratory, Human Effectiveness Directorate's (AFRL/HE) modern Aerospace Medical Training Center. For training pilots to fly modern high performance aircraft, the DES is used for aircrew G-tolerance training, acceleration physiology research and development and medical

evaluations of flight personnel. It provides an increased understanding of the medical and physiological aspects of G-levels on a human [25].

Figure 8. Dynamic Environment Simulator (DES)

2.5 PROTECTION AGAINST G-FORCES

Most of today's modern fighter aircraft accelerate so quickly and turn so rapidly that they meet or exceed the physical limits of their pilots. Pilots must learn how to protect themselves from the high G-forces encountered in dynamic flight, to prevent aircraft loss or even the pilot's death.

There are several ways to increase a pilot's G-tolerance. With improved centrifuge training, physical conditioning, proper performance of the anti-G straining maneuver (AGSM), technical developments and improvements in the anti G-suit and valve, seat angle, positive pressure breathing, and recovery systems, the physiological effects of the high G forces in air combat can be minimized.

AGSM requires strong tensing of the extremity muscles to prevent venous pooling and a cyclic increase in intrathoracic pressure, by tightening the chest and abdominal muscles. An effective AGSM has improved G-tolerance up to four extra Gs.

The anti-G suit and anti-G suit valve, used to improve performance in the high G environment, had its beginning in the mid 1940s and was further developed in the 1950s and 60s. The anti-G suit inflates as the G-forces on the aircraft increases and prevents the pilot's blood from pooling. Anti-G suit and valves may increase an unprotected pilot's G-tolerance from +4.5 Gz to +5.5 Gz.

Increasing the seat angle is another factor in the G-improvement program. The standard tactical seat back angle is mostly 13 degrees. In the F-16 a 30-degree seat back angle is used to improve G-tolerance by an additional 1.0 G.

G-conditioning programs involve physical conditioning, centrifuge training and avoidance of G-degrading factors. It has been proven that aircrews practicing the anti-G straining maneuver in a realistic environment have improved their G-tolerance.

Positive pressure breathing, which involves forcing pressurized air into a pilot's lungs through a face mask, also increases blood pressure and helps respiration in high G environments. The major advantage in positive pressure breathing is the decrease in fatigue from breathing and performing AGSM [26,27,28].

2.6 TELEMETRY

Since wireless technology is used in many areas in our daily life, health care providers started to make use of this technology in monitoring patients. More and more health care providers are investing in wireless platforms to get more efficiency, more productivity, lower costs, reduced errors, and improved patient care by getting real-time

and real-world data. Wireless technology provides physicians the flexibility and mobility they need to support their critical decisions. Many health care providers use simple wireless technology, such as telemetry devices, to help monitor patients' vital signs from a distance. This enables physicians and nurses to monitor several patients at the same time, while they are simultaneously assisting others. Some areas using wireless technologies are:

1. Electronic Medical Records (EMRs): Patient medical records are processed online.

2. Electronic Prescriptions: Patient prescriptions are directly transferred to local pharmacies.

3. Digital Transcription: Physician's verbal notes are automatically translated and stored in an electronic format.

4. Digital Imaging: X-rays, MRIs, and other medical films are stored in an electronic format.

5. Voice-over-IP: Direct voice communications are provided with any faculty member in the same facility.

While wireless technology provides a lot of benefits to the health care industry, implementing a secured wireless environment is a problem. Health care providers must decide whether or not to send protected health information wirelessly, and are concerned about how to properly provide for the privacy of this transmitted information.

Many organizations think that using a local area network (LAN) is the most secure and cost-effective way to integrate wireless technologies into their environment. As the costs have dropped LANS have evolved as the platform of choice. The cost of base stations, the bridge between wireless devices and the network, and customer devices

(e.g., PDA) have decreased while memory capacities for client devices have increased. All these reasons make wireless networks practical and affordable [29].

2.6.1 SPREAD SPECTRUM

Spread spectrum (SS) techniques were first used in military guidance and communications systems during World War II. SS techniques produced highly jam-resistant communication systems. It is called spread spectrum because the transmission bandwidth employed is much higher than the minimum bandwidth required to transmit the information. If a system meets the following requirements, it is considered to be spread spectrum system [30]:

1. The signal occupies much more bandwidth than the required bandwidth to send the information.
2. Spreading is accomplished by a spreading signal.
3. At the receiver part, dispreading is done by the correlation of the received signal with a synchronized replica of the spreading signal [30].

Spread spectrum produces a wideband carrier which, although deterministic, has the statistical properties of white noise and a larger bandwidth than the message's bandwidth. This wideband carrier is created by Pseudo-Random Noise (PN) generators [31]. The basic technique is shown in Figure 9.

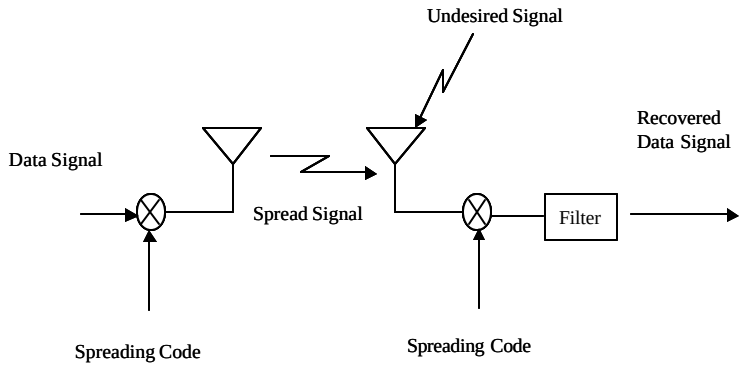


Figure 9. Basic spread-spectrum technique [30].

Spread spectrum techniques make it difficult for a jammer to despread the carrier and interfere with the signal. Spread spectrum systems use a *stored reference* technique. In this technique the spreading code signal is generated at both the transmitter and receiver. In this way the signal cannot be detected by just monitoring the transmission. Since the same code must be generated at both the transmitter and the receiver, the code sequence must be deterministic but appears random to unauthorized users.

2.6.2 DIRECT SQUENCE SPREAD SPECTRUM (DSSS)

In DSSS systems the carrier is first modulated with a data signal. The data-modulated signal is then modulated with a high-speed (wideband) spreading signal to spread the frequency domain content over a larger band, creating a lower power spectral density. Each data bit is modulated by PN sequence which is a random sequence of *chips* of plus and minus ones, achieving a second modulation of the data which is faster than the original data rate. As PN sequences have good autocorrelation properties, it is easy for the receiver to recover bit timing. The DSSS processing gain is the ratio of the bit time to chip time. The larger the processing gain, the better the autocorrelation properties,

and the better the ability to reject narrowband interference. The received signal is multiplied by the original PN sequence causing the data signal to be returned to its original form before being modulated by the PN sequence. Figure 10 shows the DSSS concept. The modulation choice for direct-sequence spectrum systems is mostly binary phase shift keying (BPSK) or quadrature phase shift keying (QPSK).

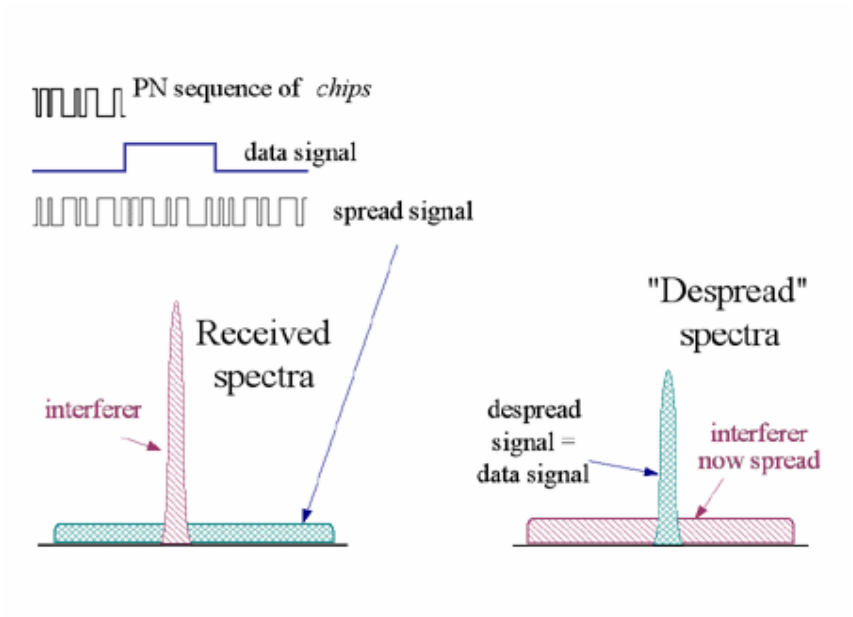


Figure 10. Direct Sequence Spread-Spectrum [24].

DSSS is considered bandwidth inefficient because it uses N chips to transmit a single bit of information. This is a tradeoff to achieve interference rejection, ensuring reliable communications in the presence of jamming. The power spectral density of the transmitted signal is also reduced, causing less interference to other systems operating at the same time on the same frequency band.

In addition, DSSS is minimally affected by the presence of multipath signals that are longer than a chip period, and even when delays are longer than a bit period, where other systems are crippled by Intersymbol Interference (ISI) [24].

2.6.3 FREQUENCY HOPPING SPREAD SPECTRUM (FHSS)

FHSS takes the data signal and modulates it with a carrier signal that hops from frequency to frequency as a function of time over a wide band of frequencies. With FHSS the carrier frequency changes periodically. The frequency hopping technique reduces interference because an interfering signal from a narrowband system will only affect the spread spectrum signal if both are transmitting at the same frequency at the same time. The most common modulation used in frequency hopping systems is M-ary frequency shift keying (MFSK), where $k = \log_2 M$ information bits are used to determine which of M frequencies is transmitted. The frequency synthesizer shifts the position of the M-ary signal set pseudorandomly over a hopping bandwidth W_{ss}. In an FH/MFSK system, the data symbol modulates a carrier whose frequency is pseudorandomly determined. At each frequency hop time a PN generator feeds the frequency synthesizer a frequency word (a sequence of l chips). The frequency hopping bandwidth W and the minimum frequency spacing between consecutive hop positions ? f, dictate the minimum number of chips necessary in the frequency word [30].

An example for 8-ary FSK and binary sequence with a data rate of R=150 bits/sec is shown in the Figure 11 [30].

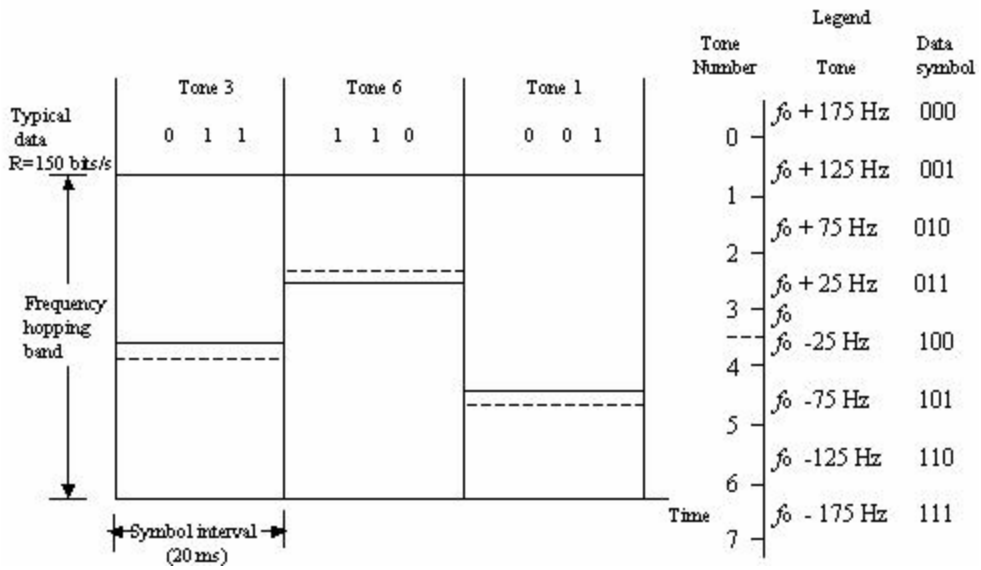


Figure 11. Frequency-hopping example using 8-ary FSK technique [30]

There are two types of frequency hopping techniques:

1. Slow- frequency hopping: the FSK symbol rate Rs is an integer multiple of the hop rate Rh. That is, several symbols are transmitted during one frequency hop.
2. Fast-frequency hopping: the hop rate Rh is an integer multiple of the symbol rate Rs. That is, the carrier frequency changes or hops several times during the transmission of one symbol [33].

2.7 CHAPTER SUMMARY

This chapter provided an overview of the G-forces and their effects on the human physiology. The types of G-forces and their effects on cardiovascular and the respiratory systems of the body were explained. As centrifuge labs are used in improving the G

tolerances of the pilots general information was given about the human use centrifuges. The protection methods against the G forces were also explained.

How wireless technology is used in patient monitoring was explained. As the wireless transmission system in the research used spread spectrum, general information about spread spectrum was given at the end of the chapter.

3.1 INTRODUCTION

The major research goal is to develop a non-invasive, real-time physiological monitoring system that is easy to use and comfortable to wear. In this chapter, the equipment required to collect real-time LifeShirt™ provided physiological data and the data processing tools and techniques are presented. First the LifeShirt™, the data concentrator (which is designed to integrate the physiological data for transmission in real-time), and the FreeWave transceivers are presented. Then the DES data collection systems are presented. Finally, the techniques used to parse and process the raw, real-time data collected wirelessly are presented.

3.2 EQUIPMENT

3.2.1 LIFESHIRT™

The LifeShirt™ is a noninvasive ambulatory recording device that continuously gets and stores respiration, electrocardiograph (ECG) and body position data on a Compact Flash™ memory card (Data Card) within a portable battery powered electronic module/Handspring Visor® (Recorder) worn on the body. The monitored subject can also put symptoms and activities into the Diary on the Recorder, and this becomes part of the recorded monitoring session.

The VivoMetrics' LifeShirt™ system is a sleeveless undergarment that has several noninvasive physiological sensors that provide data to a multi-channel cardiopulmonary digital recorder. The shirt is made of washable, Lycra material which has an array of physiologic sensors sewn into it to monitor cardiopulmonary functions.

The LifeShirt fits on the subject snugly and comfortably, and is said to be "unobtrusive" by users. An accelerometer is also located over the abdomen for recording body posture (lying down or upright) and activity (still, walking, running). Subject ECG is recorded by means of three electrodes placed directly onto the skin, two onto chest and one onto left side of abdomen. All sensors are connected via electrically conductive wires to a battery powered, custom designed electronic module having a flash memory card that is incorporated into a modified PDA (personal digital assistant) worn on the patient's belt. Symptoms, activities and medications can be entered into the PDA by the subject being monitored which then becomes part of the digital data stream. Any secondary diagnostic device with digital output, such as a pulse oximeter or blood pressure system, can be plugged into the serial port and its measurements then become part of the digital data stream. The system may be used to collect, store and send cardiac, respiratory, blood pressure, posture, activity, and emotional measures annotated with symptoms, types of activities and a medication diary to the VivoMetrics Data Center. The data from the flash memory card (data card) is uploaded to a personal computer or the data card can be sent to the Data Center for review and distribution to the clinical investigators or the patient's physician. For almost 25 years, studies have been going on to develop the LifeShirt System's sensor components and software [34, 35].

3.2.1.1 INDUCTIVE PLETHYSMOGRAPHY

The technology used in the LifeShirt is inductive plethysmography (IP). Figure 12 depicts the LifeShirt's™ working principles. Software for monitoring cardiopulmonary, IP sensors and, physiological signals are all fixed in the LifeShirt™. The sensors used consist of a sinusoidal arrangement of electrical wires that are excited through a very low current, electrical oscillator circuit (no electricity passes through the monitored individual). Movements of the body sections covered by the LifeShirt's™ sensors generate magnetic fields that are converted into voltage changes over time, i.e., waveforms. The waveforms are proportional to changes in cross sectional area and can be displayed as raw signals referenced to time on a computer screen and processed as instantaneous numerical values or one-minute median trends. The waveform type depends on the locations of the sensors over the body.

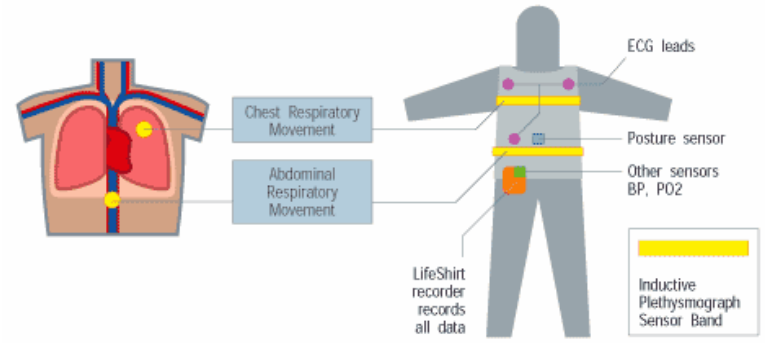


Figure 12. The working principles of LifeShirt™ [36]

Because of its design, inductive plethysmography reduces the signal interference and distortion that other monitoring technologies have. This helps clinicians get more accurate physiological data. In addition, electricity does not pass through the monitored individual with inductive plethysmography [35].

3.2.1.2 VIVOLOGIC

VivoLogic™ is composed of algorithms and programs (formerly known as Respitrace) that interpolate the data from LifeShirt™ sensors. VivoLogic™ uses the raw data and output parameters to determine physical and emotional health. VivoLogic™ then writes those parameters into the VivoMetrics database to be processed by VivoReports. Inductive plethysmographic sensors are placed the around rib cage (RC) and abdomen (AB), see Figure 3.1. VivoLogic's™ automatic calibration procedure sets the electrical gains of the sensors such that obstructive apnea is detected as a flat or nearly flat tidal volume trace associated with a 180 degree phase-shift between the RC and AB compartments. The tidal volume trace can be converted to ml by re-breathing a few times into a bag with a fixed, known volume (Spirobag) [37].

3.2.1.3 ELECTROCARDIOGRAPH

Electrocardiograph electrodes underneath the LifeShirt are composed of two carbon electrodes, which are placed on the upper chest and on the lateral surface of the abdomen to get a single selectable lead for heart rate and rhythm determinations. The R wave is detected in the ECG module and sent to the PDA to resolve this wave as a pulse to $\pm$ 1.0 msec. In turn, this R wave pulse permits computation of 1-minute trends of heart rate and respiratory sinus arrhythmia as well as serving as a timing reference for hemodynamic parameters. Since P-wave can be invisible in a single lead, a 12-lead ECG is necessary for accurate classification of arrhythmia. In addition, the raw ECG waveform is collected continuously in a ring buffer of the PDA and moved to a file on demand in the same way that a heart event monitor is utilized. Predefined pre-event and

post-event recording periods are added to this file. The ECG waveform file is subsequently uploaded off-line to the Data Center for medical review [35].

3.2.1.4 INTENDED USE

The LifeShirt™ system continuously records respiration, ECG and body position signals for subsequent presentation and analysis by a licensed physician who reviews the data processed by VivoLogic™ on a personal computer. In addition, signals from external devices such as a pulse oximeter and blood pressure monitor can be collected and displayed. The system is intended to provide analysis of breathing patterns as an aid in classifying apneas as well as displaying heart rate changes from electrocardiographic waveforms in the wake and sleeping states as well as activities of daily living. Applications may include pharmaceutical studies in which respiratory information is a useful indicator, or the general healthcare market where patients may be monitored at home and the data provided to their physicians as an aid to diagnosis and treatment. The LifeShirt™ System is an ideal tool in the search for new signatures of health and disease, since it collects data on such a wide range of parameters, correlated over time. It gives researchers the opportunity to monitor "real-world" physiology [35].

3.2.2 DATA CONCENTRATOR

The Data Concentrator shown in Figure 13 is mainly designed to format analog ECG data, respiration frequency data, and Nonin pulse oximeter data into an ASCII format for subsequent transmission to a central base station. The main components in the

Data Concentrator are a PIC 16F877 microcomputer, XR88C192 dual UART, an analog-to-digital (A/D) converter, and a MAX205E S232/TTL converter.

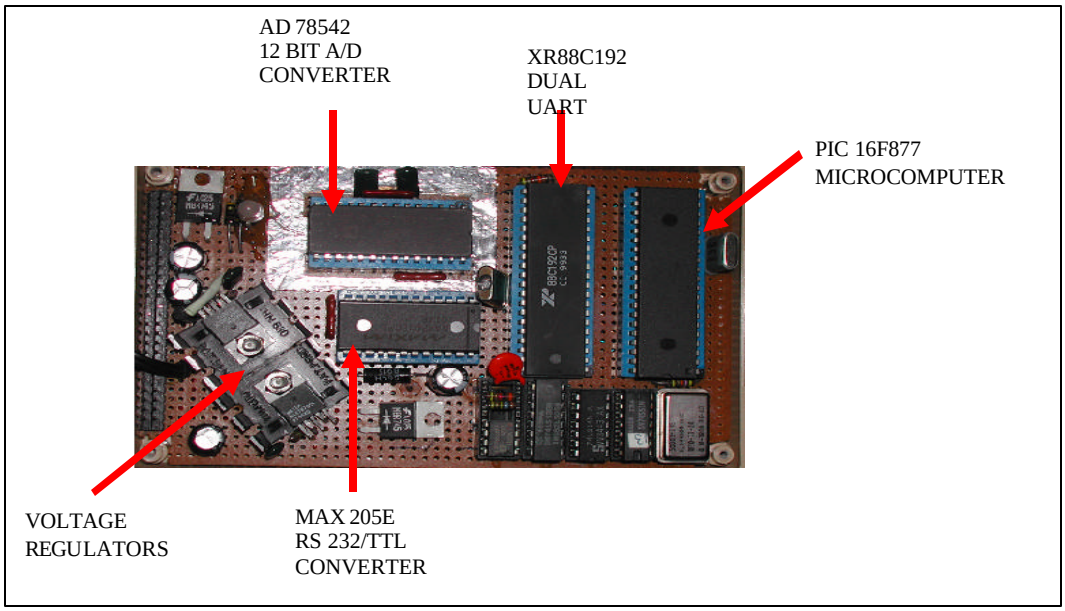


Figure 13. Data Concentrator

Power (+12 V DC provided by the Freewave transceiver) is converted into +3.3 V DC and +5.0 V DC by voltage regulators. The +3.3 V DC is used in the A/D conversion as reference voltage, and the +5.0 V DC is used in microcomputer, UART and the converter.

The microcomputer is programmed to output a 12-bit binary scale fraction value, from the ECG sensor, produced by the A/D converter. Additionally, the microcomputer inputs a gated counter value, which represents respiration. The UART section of the microcomputer inputs the ASCII data from pulse oximeter. The inputs are read and stored in temporary memory, which generates an interrupt, forcing the microcomputer to output the data to the external UART. The UART data are then sent to a Freewave modem to be transmitted at 115200 bits/sec. The Nonin pulse oximeter data is

assembled in 5-byte bursts. The microcomputer puts the Nonin pulse oximeter data to a temporary storage until it has 5-byte burst. It should also be noted that the data output by the microcomputer is parallel data. The data is converted into serial data by the external UART.

The ECG data coming from LifeShirt™ data recorder is analog. Therefore, the analog ECG data is digitalized by the A/D converter using the +3.3 V DC as reference voltage. The ECG data is presented by 12 bits and has a resolution of 0.8057 mV.

The two respiration bands in the LifeShirt™ output frequency values. The respiration values coming from the LifeShirt™ are multiplexed. The data is de-multiplexed in the data concentrator. When the upper/lower respiration value is received, the counter starts counting the upper/lower respiration values until the upper/lower respiration value no longer exists. Upon the completion of the respiration value counter resets itself to zero.

RS 232 converts the voltage from –9V and +9V to 0 and +5 volts. TTL converts the voltage from 0V and +5V to -9 and +9 volts. The block diagram of the data concentrator is shown in Figure 14.

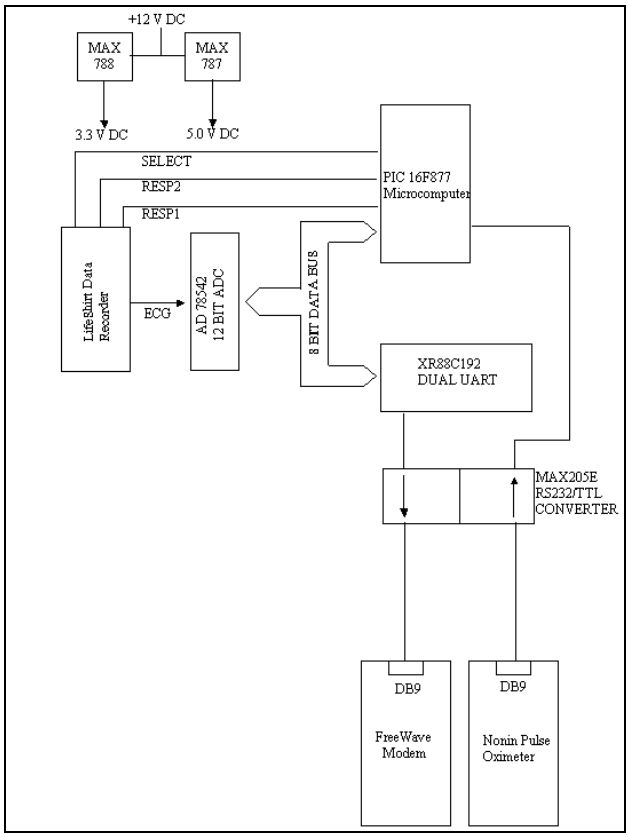


Figure 14. Block Diagram of Data Concentrator

The upper and lower respiration data, which are presented by two bytes, are sampled at 50 Hz. The ECG data, which is presented by two bytes, is sampled at 216 Hz. The Nonin pulse oximeter data, which is presented by one byte is sampled at 50 Hz. The sampled data stream is shown in the Figure 15.

SpO_2	ECG	UPPER RESP.	LOWER RESP.
3samp/s	216samp/s	50samp/s	50samp/s

Figure 15. Data sampling rates

3.2.3 FREEWAVE TRANSCEIVERS

There were two FreeWave transceivers used to transmit LifeShirt™ data to the base station: DGR-115H and DGR-09RFS, which are shown in Figures 16 and 17. Both are spread spectrum wireless data transceivers. They both use frequency hopping spread spectrum to provide secure communication by preventing detection and unauthorized access. Their baud rate (bits/sec) can be set up to 115200 for high-speed data communication. They have a 60 miles of line-of-sight range [38].

Figure 16. DGR-115H

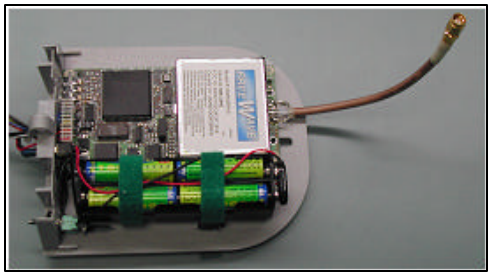


Figure 17. DGR-09RFS

The DGR-115H is used at the base station and DGR-09RFS is used with the data concentrator, since the DGR-09RFS is more compact and requires less power to operate.

The parameters are set to optimize the performance of the transceivers. All the adjustments are accomplished using the FreeWave setup program. The setup program was invoked by connecting the FreeWave transceiver to a hyperterminal program and

setting the baud rate to 19200 and putting the transceiver in setup mode. The setup menu terminal settings are shown in Table 1.

Table 1. Setup menu terminal setting [39]

Parameter	Setting
Baud Rate	19200
Data Bits	8
Stop Bits	1
Parity Check	Off
Carrier Detect	Off

The baud rate on each transceiver was set to 115200 for high-speed data communication. The transceiver's baud rate is its RS 232 data rate, which must match the rate of the instrument to which it is connected.

The transceivers are set up to provide a point-to-point communication as shown in Figure 18.

Figure 18. Master communicating to slave [39]

When operating in the point-to-point mode, the serial number of the master must be listed in slave and the serial number of the slave must be listed in master. The master transceiver must be programmed to call the slave to establish a communication link.

All Freewave transceivers require external antennas to function most effectively and have external jacks for external antennas. An Antenex EB8965C whip antenna is used in this research.

Table 2. Antenex EB8965C whip antenna specifications [40]

Model	Frequency	Center Frequency	Gain	Whip Style
EB8965C	806-896 MHz	851 MHz	5 dB	Closed Coil Collinear

3.3 CENTRIFUGE SETUP

3.3.1 EQUIPMENT AND FACILITIES

The Dynamic Environment Simulator (DES) was used to produce the sustained acceleration environment for the research. The seat was an ACES II configured with a 12-degree seat back and adequate restraint belts for positive sustained acceleration. The DES arm speed and cab position were under open loop computer control with hyper gravity experiences in the +Gz axis. The equipped subject at the seat is shown in the Figure 19.

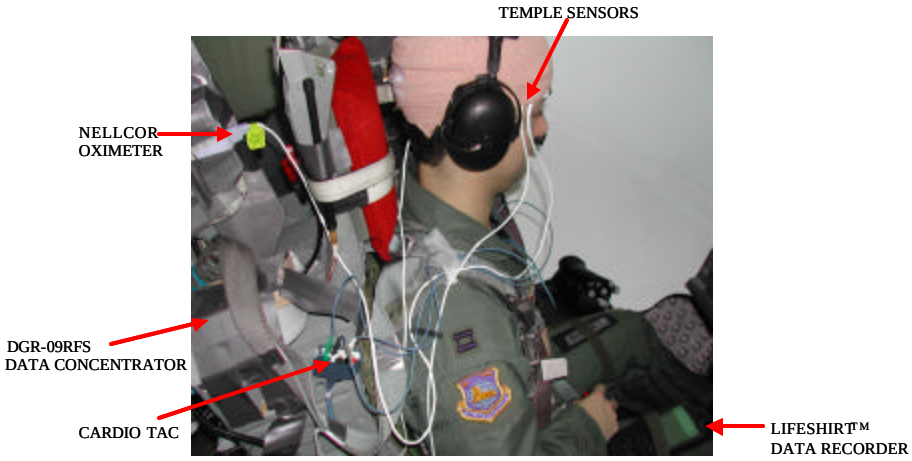


Figure 19. Subject in the centrifuge cab

During the test run, the centrifuge personnel at the control center, as shown in Figure 20, monitored the subject.

Figure 20. Centrifuge control station

3.3.2 PERSONAL EQUIPMENT

Subjects wore the following during each test: LifeShirt™, a standard issue flight suit, boots and anti-G suit during all G-exposures. Subjects were also instrumented with a three lead electrocardiogram separate from the LifeShirt™. Subjects were seated in the aircraft seat and secured in place with a lap belt and the G-suit pressure supply hose was connected into the G-valve pressure supply hose allowing for G-suit inflation during G exposure. The subject without the G-suit is shown in Figure 21.

Figure 21. Subject equipped for the test run

3.3.3 SUBJECTS

Four subjects were selected from volunteer members of the DES Sustained Acceleration Research Panel. These members were healthy, active duty, research volunteers from the Wright Patterson Air Force Base (AFB), Ohio. Their age ranged from 29 to 50 with an average value of 35. The average height was 69 inches and average weight was 172 pounds. Each had completed introductory training on the centrifuge and graduated upon demonstrating a capability to tolerate exposures up to +9 Gz acceleration. A qualified physician assured the health status of subjects via inspection of their health record. Subjects completed an approved informed consent form approved by an Institutional Review Board (IRB) from the Air Force Research Laboratory at Wright Patterson AFB, Ohio.

3.3.4 EXPERIMENTAL EXPOSURES

Subjects experienced a +5.0 Gz, 15 sec plateau as a warm-up run prior to a Simulated Aerial Combat Maneuver (SACM) profile with a maximum G-level of +7.5 Gz. The SACM profile consisted of a cyclic cycle ranging from +4.0 to +7.5 Gz, as shown in Figure 22.

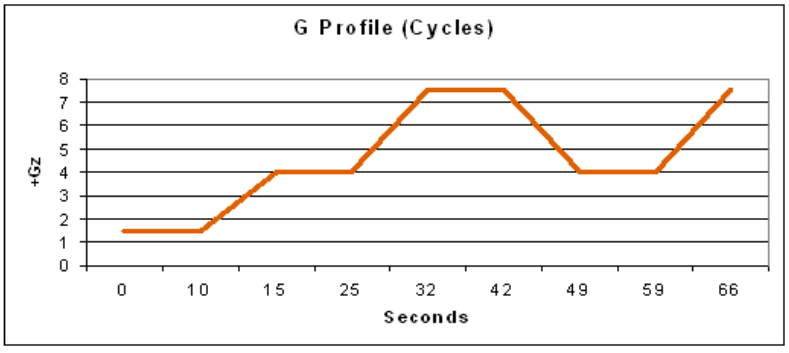


Figure 22. SACM G-profile

The end point of the trial was 95% loss of vision, twenty 4.0 to 7.5 G cycles, or subject fatigue (exhaustion) - whichever came first. The +Gz acceleration was applied at a rate of +0.5 Gz/s starting at baseline (1.5 Gz), and reaching 4.0 Gz. Subjects were held at +4.0 Gz for 10 seconds, and then accelerated at 0.5Gz/s until +7.5 Gz was reached. The subject was held at +7.5 Gz for 10 seconds, then decelerated to 4.0 Gz. After this cycle was completed, another cycle was initiated. The total time spent in the profile was recorded as the untrained performance of the subject. Data collection included the following dependent variables for each of the respiratory monitoring systems: ViVol, Inspiratory Tidal VolumeVeVol, Expiratory Tidal Volume Vent, Minute Ventilation qDEEL, Change in End-Expiratory Lung Volume RBVol, Running Baseline Tidal Volume and Br/M, Respiratory Rate, Oxygen Saturation.

3.4 DATA PROCESSING

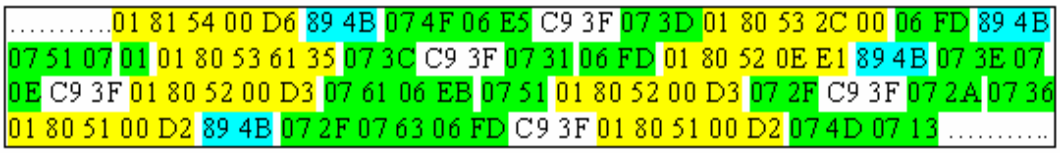
3.4.1 CAPTURING DATA

The first step in the process was to capture the real-time data sent from the LifeShirt™ system. In initial trials, a hyper terminal software package was used to capture the data. Unfortunately, the hyper terminal did not capture any data that was "00." This caused problems in parsing out the data because the 5- byte burst structure of the Nonin oximeter data was corrupted (see Section 3.4.2 for the Nonin data table).

Due to these difficulties, another software-based data capture routine, ComCap [41], was used. The ComCap software captures any ASCII data received through the serial communication port. In addition, Comcap has the capability to show the captured data in scrolling windows, and may be copied to be clipboard if required. The capture

file names are automatically generated with year, month, day, hour, minutes and seconds. ComCap can be used on Windows 98 and later 32-bit versions of Windows. The basic communications settings were specified (speed, parity, data bits). In addition, ComCap sets the RTS and DTR lines when the data capture feature is enabled and uses RTS for flow control.

Since all the physciological data is combined into a serial message for subsequent data transmission, it was very important to parse the data for processing. The Nonin oximeter data is sent in 5-byte bursts. All of the bursts start with "01." Upper respiration data is preceded by "C9" and lower respiration data is preceded by "89." ECG data is 12 bit data so it is always preceded by "05", "06", "07," "08," or "09." These headers make data parsing easy. The data sample captured by ComCap is shown in Figure 23.



01 81 54 00 D6: Nonin Pulse Oximeter Data
89 4B: Upper Respiration Data
C9 3F: Lower Respiration Data
07 4F: ECG Data

Figure 23. Captured Data Sample

3.4.2 OXYGEN SATURATION DATA

The Nonin oximeter data is sent in the format shown in Figure 3-11, with 5 bytes of data sent 75 times a second. Assuming a frame of data occurs every 1/3 sec, the first lines of data in every frame starts with "01." The start of every frame is determined by the status. If it is an odd number it shows the start of the frame. An oxygen saturation

value (SpO_2) is sent in every frame occurring at a 1/3 second rate. Thus, three SpO_2 values are sent in every second. These SpO2 values are shown in shaded boxes in the Figure 24. The valid SpO_2 values range from "0" to "100" in decimal values. Heart rate data is also sent 3 times a second, however the heart rate data is highly affected by motion artifacts. Because of this, heart rate data from this sensor can not be dependable.

Hz	BYTE					Hz	BYTE					Hz	BYTE				
1/75	1	2	3	4	5	1/75	1	2	3	4	5	1/75	1	2	3	4	5
1	01	STATUS	PLETH	HR MSB	CHK	26	01	STATUS	PLETH	HR MSB	CHK	51	01	STATUS	PLETH	HR MSB	CHK
2	01	STATUS	PLETH	HR LSB	CHK	27	01	STATUS	PLETH	HR LSB	CHK	52	01	STATUS	PLETH	HR LSB	CHK
3	01	STATUS	PLETH	SpO2	CHK	28	01	STATUS	PLETH	SpO2	CHK	53	01	STATUS	PLETH	SpO2	CHK
4	01	STATUS	PLETH	REV	CHK	29	01	STATUS	PLETH	REV	CHK	54	01	STATUS	PLETH	REV	CHK
5	01	STATUS	PLETH	*	CHK	30	01	STATUS	PLETH	*	CHK	55	01	STATUS	PLETH	*	CHK
6	01	STATUS	PLETH	*	CHK	31	01	STATUS	PLETH	*	CHK	56	01	STATUS	PLETH	*	CHK
7	01	STATUS	PLETH	*	CHK	32	01	STATUS	PLETH	*	CHK	57	01	STATUS	PLETH	*	CHK
8	01	STATUS	PLETH	*	CHK	33	01	STATUS	PLETH	*	CHK	58	01	STATUS	PLETH	*	CHK
9	01	STATUS	PLETH	*	CHK	34	01	STATUS	PLETH	*	CHK	59	01	STATUS	PLETH	*	CHK
10	01	STATUS	PLETH	SpO2 Slow	CHK	35	01	STATUS	PLETH	SpO2 Slow	CHK	60	01	STATUS	PLETH	SpO2 Slow	CHK
11	01	STATUS	PLETH	SpO2 B-B	CHK	36	01	STATUS	PLETH	SpO2 B-B	CHK	61	01	STATUS	PLETH	SpO2 B-B	CHK
12	01	STATUS	PLETH	*	CHK	37	01	STATUS	PLETH	*	CHK	62	01	STATUS	PLETH	*	CHK
13	01	STATUS	PLETH	*	CHK	38	01	STATUS	PLETH	*	CHK	63	01	STATUS	PLETH	*	CHK
14	01	STATUS	PLETH	E-HR MSB	CHK	39	01	STATUS	PLETH	E-HR MSB	CHK	64	01	STATUS	PLETH	E-HR MSB	CHK
15	01	STATUS	PLETH	E-HR LSB	CHK	40	01	STATUS	PLETH	E-HR LSB	CHK	65	01	STATUS	PLETH	E-HR LSB	CHK
16	01	STATUS	PLETH	E-SpO2	CHK	41	01	STATUS	PLETH	E-SpO2	CHK	66	01	STATUS	PLETH	E-SpO2	CHK
17	01	STATUS	PLETH	*	CHK	42	01	STATUS	PLETH	*	CHK	67	01	STATUS	PLETH	*	CHK
18	01	STATUS	PLETH	*	CHK	43	01	STATUS	PLETH	*	CHK	68	01	STATUS	PLETH	*	CHK
19	01	STATUS	PLETH	*	CHK	44	01	STATUS	PLETH	*	CHK	69	01	STATUS	PLETH	*	CHK
20	01	STATUS	PLETH	*	CHK	45	01	STATUS	PLETH	*	CHK	70	01	STATUS	PLETH	*	CHK
21	01	STATUS	PLETH	*	CHK	46	01	STATUS	PLETH	*	CHK	71	01	STATUS	PLETH	*	CHK
22	01	STATUS	PLETH	*	CHK	47	01	STATUS	PLETH	*	CHK	72	01	STATUS	PLETH	*	CHK
23	01	STATUS	PLETH	*	CHK	48	01	STATUS	PLETH	*	CHK	73	01	STATUS	PLETH	*	CHK
24	01	STATUS	PLETH	*	CHK	49	01	STATUS	PLETH	*	CHK	74	01	STATUS	PLETH	*	CHK
25	01	STATUS	PLETH	*	CHK	50	01	STATUS	PLETH	*	CHK	75	01	STATUS	PLETH	*	CHK

1/3 sec 2/3 sec 1 sec

Figure 24. Nonin Pulse Oximeter Data Format

3.4.3 ECG DATA

The ECG data recorded from the serial port is corrupted by noise. Therefore, a moving average filter is used to filter the data. The moving average filter is used to detect the trend of the rapidly changing signals (i.e it smoothes the data). The output of a moving average filter for an input $f(k)$ is given by:

$$y(k) = \frac{1}{M} \sum_{i=0}^{M-1} f(k-i)$$

where M is the width of moving average filter. The moving average filter regards each data point in the data window to be equally important when calculating the average (filtered) value [43]. A window size of five is used to smooth the raw ECG data. A sample of the smoothed, raw ECG data in shown in Figure 25.

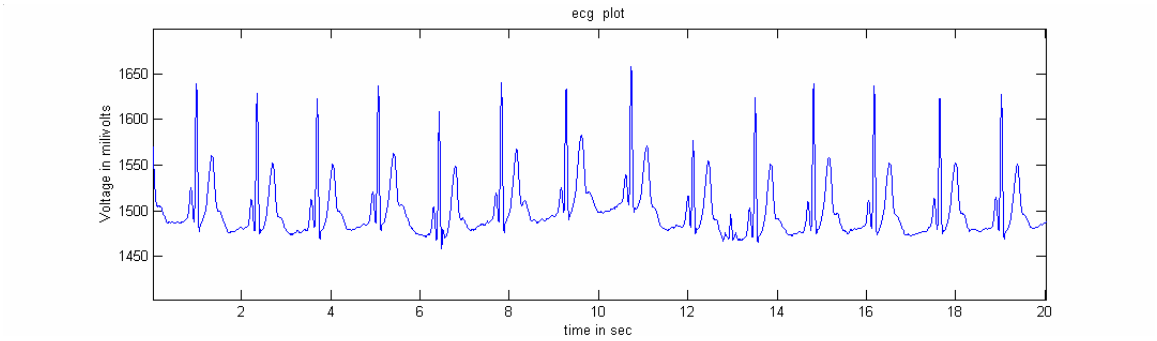


Figure 25. Smoothed Raw ECG Data

In order to perform the heart rate analysis, it is necessary to remove the noise and to suppress the "P" and "T" components of the ECG signal to get a single pulse per beat at the "R" wave location. The block diagram to get the "R" wave location is given in Figure 26.

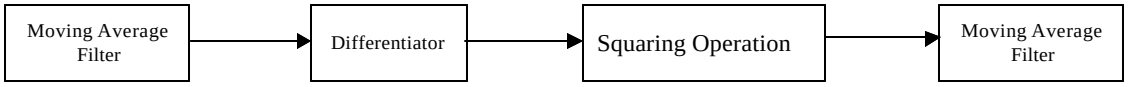


Figure 26. ECG Processing Block Diagram

The differentiator outputs the difference between successive sample points. In the third stage of the diagram, the differentiator output is squared to make the "R" wave location distinguished. Another moving average filter is then used to smooth the "R" waves. A window size of fifty is used to smooth the data. A sample of the smoothed, R wave data, is shown in Figure 27.

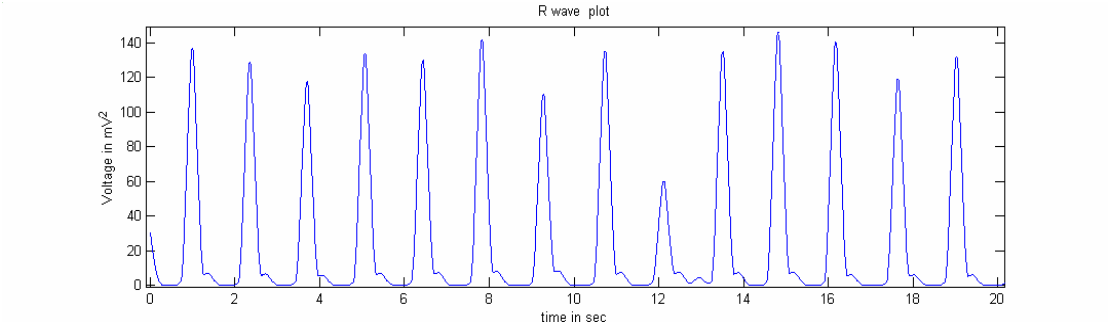


Figure 27. Smoothed R Wave Data

After determining the locations of the "R" wave peaks, the heart rate is calculated. The calculation depends on the time difference between successive "R" wave peaks:

$$Heartrate\ ?\ \frac{60}{timedifference(in\,\mathrm{sec})}(beats/\mathrm{min})$$

3.4.4 RESPIRATION DATA

Two types of respiration data are received through the serial port. They are separated by their data identifiers as previously mentioned. Each respiration data sample is sent 50 times a second. Figure 28 shows the raw respiration data plot. Notice that it is very difficult to detect the respiration cycles from the raw respiration plot.

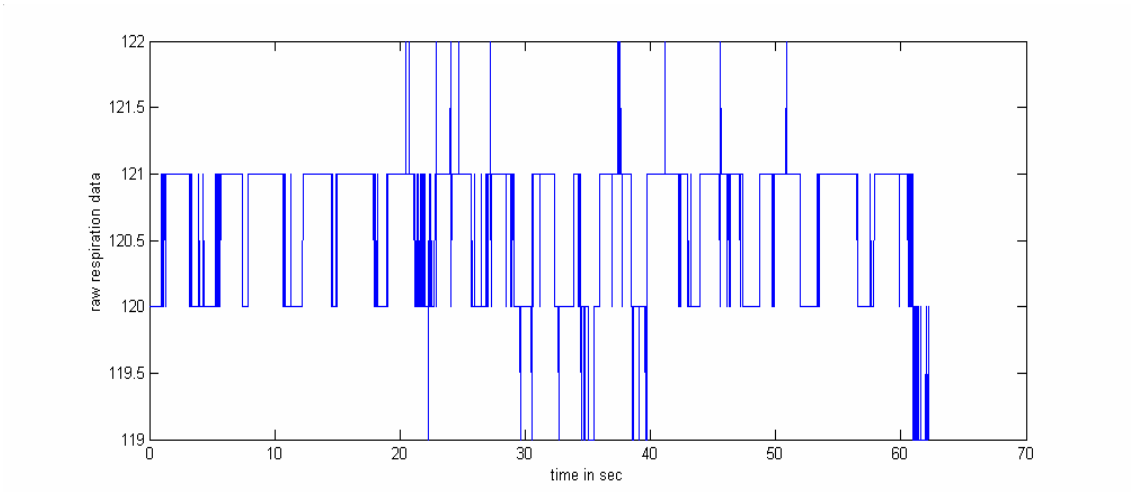


Figure 28. Raw Respiration Data

Therefore, a moving average filter with a window size of 50 is used to smooth the raw respiration data. Each breathing cycle is easily identified after the smoothing. Once the cycles are determined, the respiration rate is calculated by finding the time differences between successive peaks. The smoothed respiration data and calculated respiration rate are shown in Figure 29.

$$respirationrate\ ?\ \frac{60}{timedifference(in\,\mathrm{sec})}(beats/\mathrm{min})$$

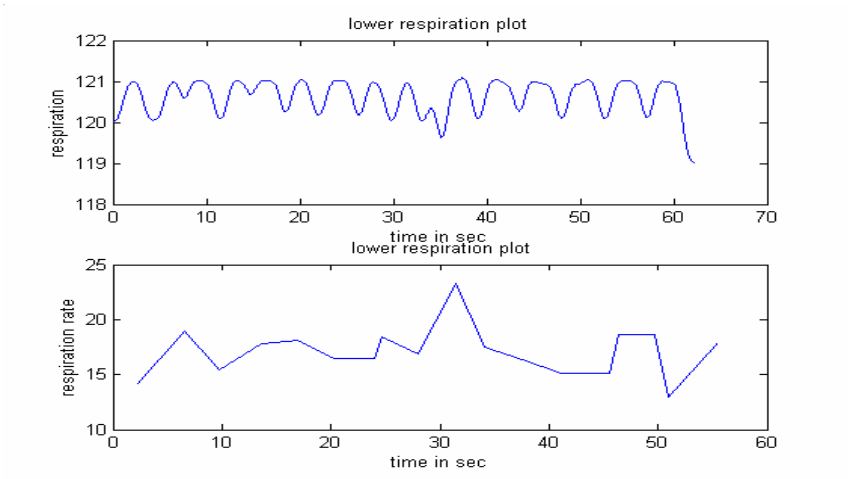


Figure 29.Respiration Plot

3.5 CHAPTER SUMMARY

This chapter provided an overview of the equipment used in the research; the procedures used to to collect the physiological data in real-time; and the methods used to process the data.

Descriptions of the LifeShirt^{TM} and its working principles, the data concentrator (designed to merge the raw physiological data for transmission in real-time), and the FreeWave transceivers were presented. Then the DES test setup required to collect data was presented. This chapter also described the methods used to parse and process the raw data.

4.1 INTRODUCTION

Wireless real-time data was collected from four different subjects in eight test-runs. The SACM profile, Figure 22, was performed during data collection. Wireless data storage started in the laptop memory card as soon as the centrifuge cab started spinning. The LifeShirt™ data recorder started saving data to its memory card after the respiration calibration process started. In addition, the G profile, oxygen saturation (provided by a Nellcor system), and heart rate data (provided by a Cardio Tac system) were also collected by the centrifuge facility two minutes prior to the +4.0 and +7.5 G exposure period.

In this chapter, wireless real-time data results are presented and analyzed. Changes in the physiological data with respect to +Gz are shown in the plots. In addition, data comparisons between the real-time wireless data, LifeShirt™ data, and data from the centrifuge facility are made.

As the number of samples is less than 30,a t-test is used in making the statistical analysis of the data comparisons. The t-test is based on hypothesis. The null hypothesis (H_o) assumes that the mean values of two data sets are statistically equal and the alternative hypothesis (H_a) assumes that the mean values of two data sets are statistically different. Throughout the analyses an a value of 0.05 is used. The value of a is called the level of the test and denotes the probability of a type I error, which occurs if H_0 is rejected when H_0 is true. The conclusion at any particular level of a results from comparing the p-value to a. If the specified value of a is greater than or equal to the p-value the null hypothesis is rejected for that value of a. If the specified value of a is less than p-value the null hypothesis is not rejected for that value of a [44].

4.2 WIRELESS PHYSIOLOGICAL DATA CHANGES WRT G-FORCES

It has been well documented (see Chapter 2) that +Gz forces have adverse effects on the cardiovascular and respiratory systems of the human body. These adverse effects are definitely seen in the test results presented in this chapter. In addition, data collected through wireless transmission indicated that the physiological parameters were also impacted by and correlated with the +Gz forces.

The hydrostatic column between the heart and the brain is impacted the most by the dangerous effects of +Gz forces. As the blood pools with increasing +Gz, the eye-level blood oxygen saturation value drops dramatically. To determine the blood oxygen saturation value levels near the brain, during each test run, the oximeter sensors were placed on the temple of the subject. Figure 30 shows the relative change in wireless oxygen saturation values (SpO2) with +Gz changes.

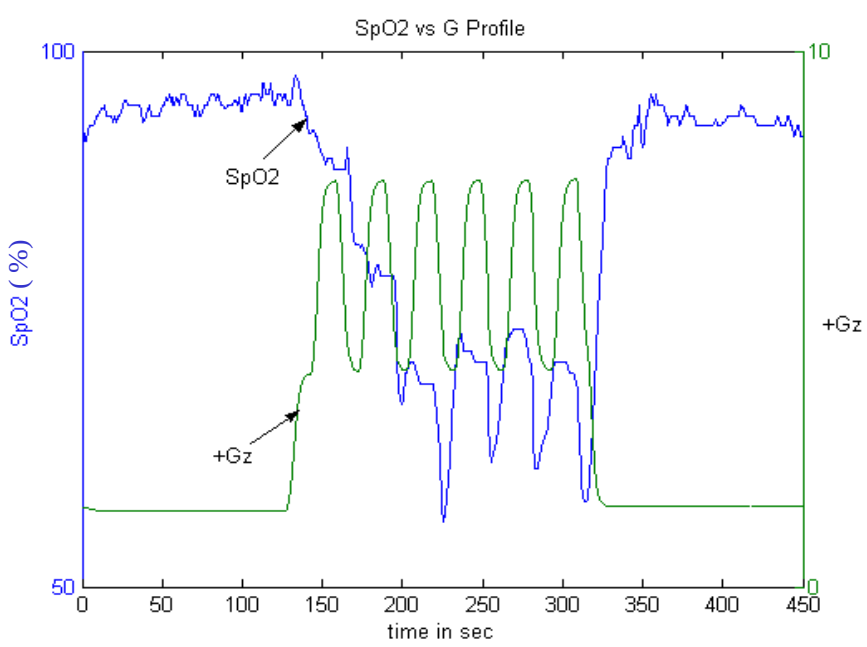


Figure 30. SpO2 vs G Profile

Notice that the oxygen saturation levels start droping as the +Gz increases and start recovering as the +Gz decreases. This cyclic change can be clearly seen in the figure as +Gz varies between +4.0 G and +7.5 G.

With respect to respiration rate, the respiratory frequency should increase as +Gz increases. This frequency change in wireless data is shown in Figure 31. The frequency cycles becomes denser when +Gz increases and returns to baseline values when the DES cab is brought to baseline again. As the subject starts to constrain his or her body during the G exposure, and starts to take deeper breathes, the baseline value for the LifeShirt™ bands also changes. This corresponds with a decrease in the baseline value under the G exposure.

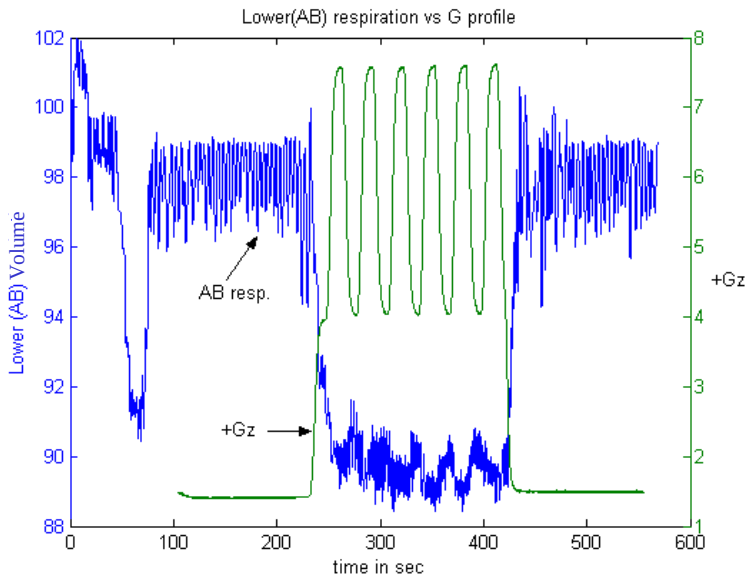


Figure 31. Respiration vs G Profile

There is also an impact to the heart under G-forces. When +Gz increases and blood starts to pool down, an extra burden is placed on the heart. To prevent a blackout,

the heart must supply blood to the brain. This results in an increase in the heart rate. Thus, the heart rate values increases proportionately as +Gz increases. This change in wireless heart rate data is clearly shown in Figure 32.

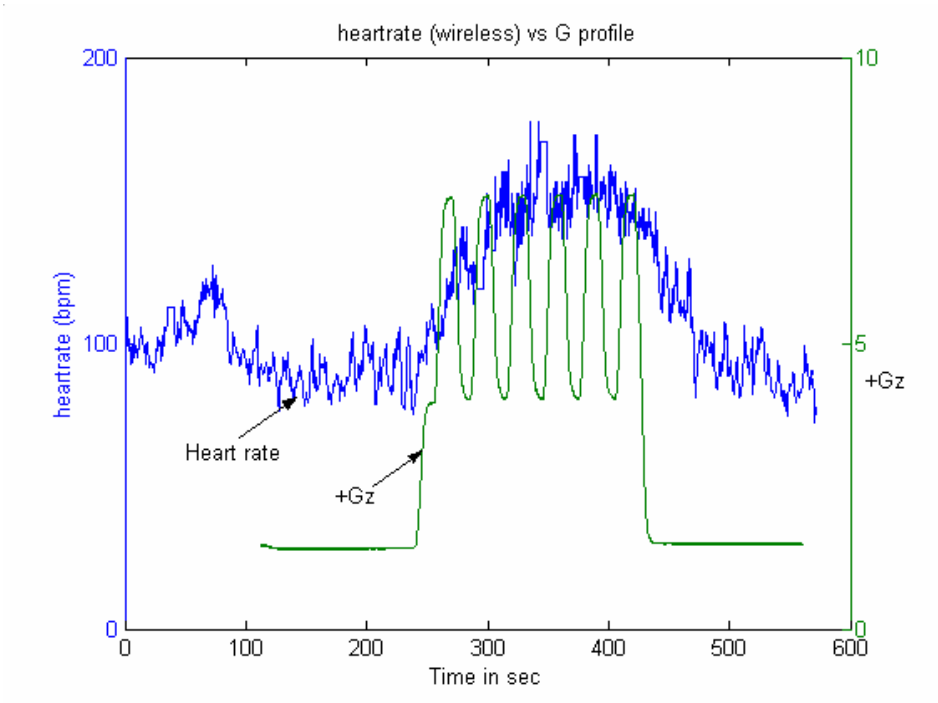


Figure 32. Heart rate vs G Profile

4.3 OXYGEN SATURATION COMPARISONS

For obtaining oxygen saturation data, two pulse oximeter sensors were placed on the subject's temples, one for the Nonin and one for the Vellcor system. In three of eight test runs, oxygen saturation data from the Vellcor system was not collected and in one of the test runs, the Nonin system produced corrupted data. Thus, when the testing was completed, only four sets of oxygen saturation data were compared.

In addition, the Nonin oxygen saturation data was only sampled at 3 Hz (this was a fixed sampling rate), versus the Nellcor oxygen saturation data, which was sampled at 25 Hz. Thus, to compare the data from these two sensors, each data set was averaged

over corresponding one second intervals. Both systems tracked the oxygen saturation changes with respect to changing +Gz . This is shown in Figure 33-36.

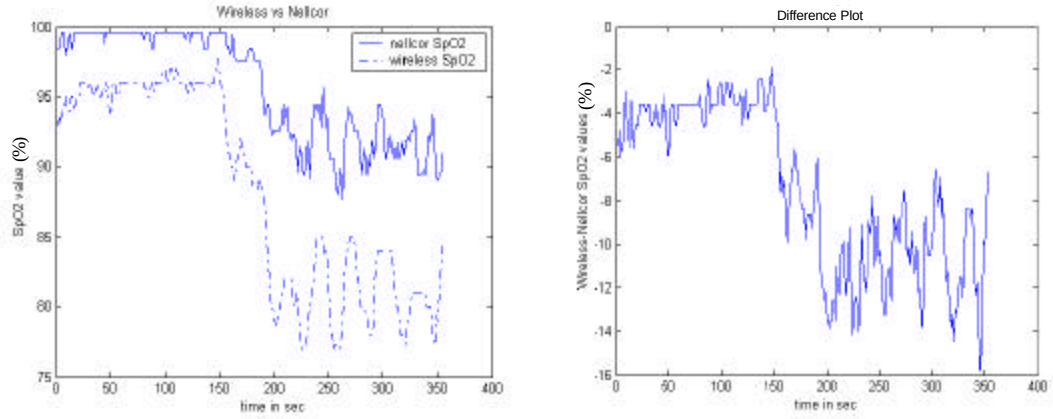


Figure 33. Wireless vs Nellcor and difference plots for Test Case 1

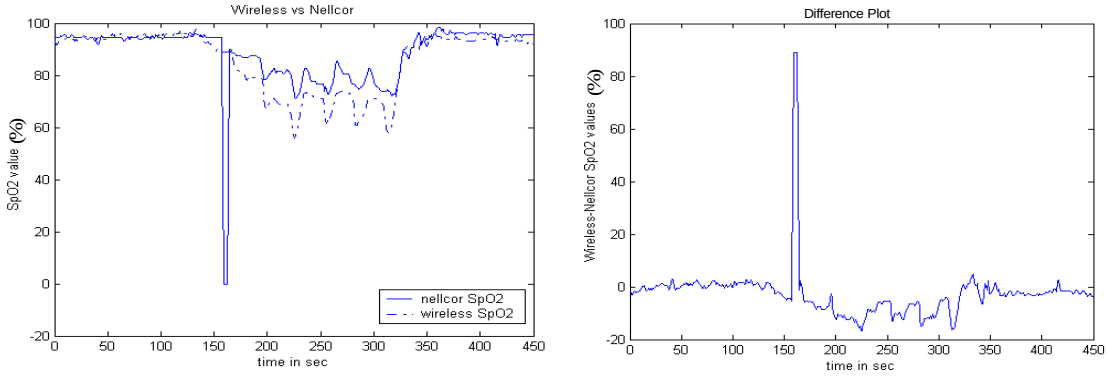


Figure 34. Wireless vs Nellcor and difference plots for Test Case 2

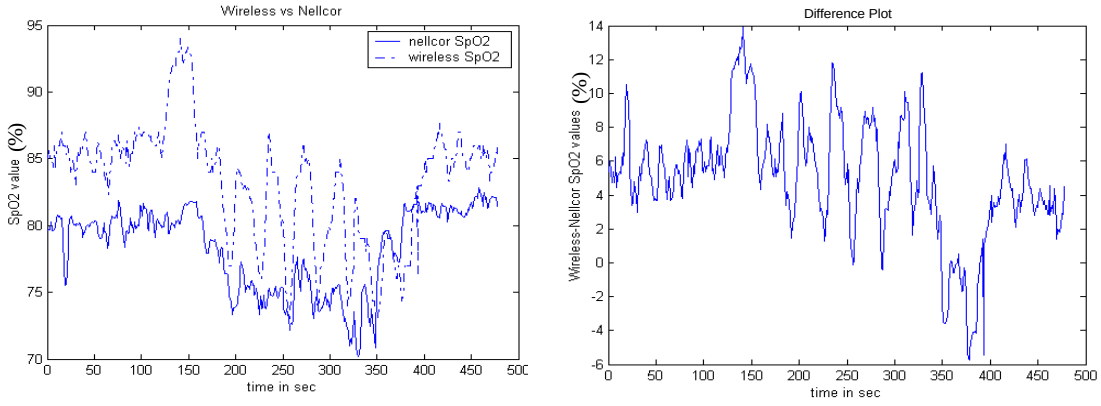


Figure 35. Wireless vs Nellcor and difference plots for Test Case 5

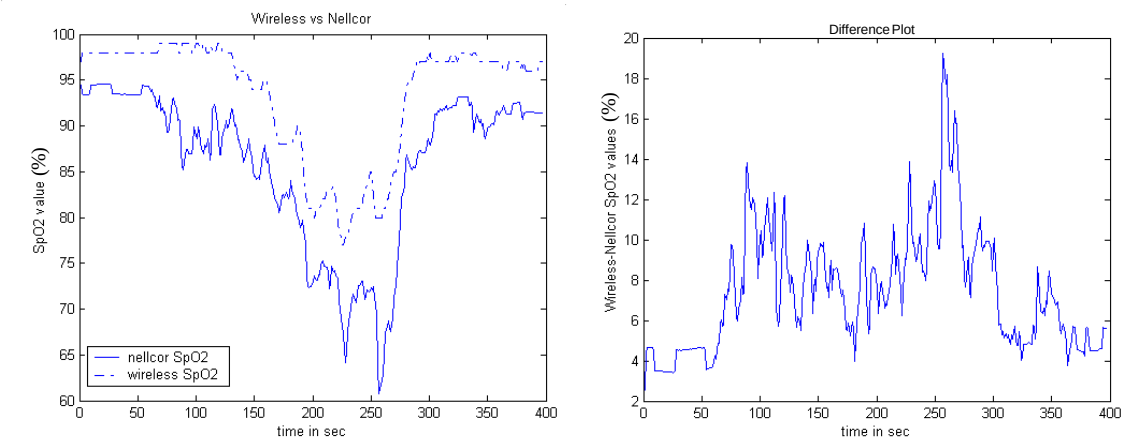


Figure 36. Wireless vs Nellcor and error plots for Test Case 8

Notice that oxygen saturation values for the two systems at the time when the DES cab was at baseline were not the same. This difference was caused by the different placement of the sensors (this was verified by testing various sensor placements, and noting the sensor outputs). These differences at the beginning remained relatively constant throughout the baseline exposure portion of each test run. However, during the +4.0 Gz and +7.5 Gz exposures, the oxygen saturation values tracked the +Gz changes, but the bias difference compared to the baseline deviated from the initial baseline value. According to [45] this is due to accuracy deterioration occurring in each oximeter system. This deterioration typically occurs after the oxygen saturation values drop below 80%. The mean and standard deviation of the errors are given in Table 3. Notice that the mean values at the baseline are almost the same as the difference of the values at the starting point.

Table 3. Mean and std of differences

	BASELINE		+4Gz &+7.5Gz	
	Mean	Std	Mean	Std
1st Test	-3.86	0.77	-9.3	3.12
2nd Test	0.46	1.19	-5.84	4.66
5th Test	5.64	1.27	4.74	3.9
8th Test	6.58	2.95	7.88	3.05

A statistical analysis was conducted on the four comparable data sets, using a t-test with a 95% confidence interval. As the p-values were greater than a, which was 0.05, the analysis indicated that there was not any significant statistical difference between the two data sets. The data at the baseline, +4.0 Gz and +7.5 Gz were analyzed separately and the results are shown in Table 4. Note that in the table, the Nell4G stands for the Nellcor measurements at +4.0 Gz and Non4G stands for the Nonin measurements at +4.0 Gz.

Table 4. Statistical analysis and the results for oxygen saturation comparison

Paired Samples Statistics

		Mean (%)	N	Std. Deviation (%)	Std. Error Mean(%)
Pair 1	NELL4G	83.5100	4	6.1488	3.0744
	NON4G	83.7675	4	8.8118	4.4059
Pair 2	NELL7G	84.1152	4	4.7348	2.3674
	NON7G	83.8801	4	5.7665	2.8832
Pair 3	BASENELL	91.3915	4	8.2557	4.1279
	BASENON	93.6089	4	5.5009	2.7504

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	NELL4G - NON4G	-.2575	2.7657	1.3828	-4.6583	4.1433	-.186	3	.864
Pair 2	NELL7G - NON7G	.2351	1.5839	.7919	-2.2851	2.7554	.297	3	.786
Pair 3	BASENELL - BASENON	-2.2174	4.8738	2.4369	-9.9727	5.5379	-.910	3	.430

4.4 RESPIRATION COMPARISONS

The respiration data was provided only by the LifeShirt™. It was collected simultaneously through the wireless data transmission system and the LifeShirt™ data recorder. When the respiration data was plotted, the two plots appeared to be mirror images of each other, as shown in Figure 37.

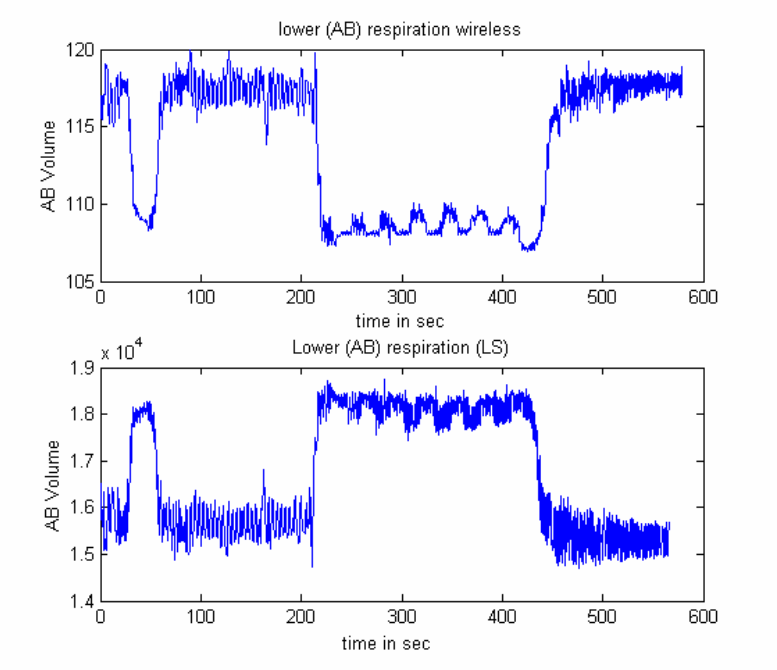


Figure 37. Wireless vs LifeShirt™ respiration plots

After multiplying the LifeShirt™ data by –1 and shifting it upward, it was seen that the two plots were almost identical (other than a bias) as shown in Figure 38. The difference between the original respiration plots is caused by the different respiration data processing methods, even though they both use the same source. The signals from the RIP bands are frequency modulated square waves with a nominal frequency of about 330 kHz. In the LifeShirt™, the period of the signals is measured by counting the number of RIP pulses. The 96 MHz clock pulses are counted during the time between the first pulse

and the last RIP pulses. This provides the number of RIP pulses and the time in which they occur. As the LifeShirt™ system outputs the time difference between the pulses and the wireless outputs the frequency of the pulses, two plots represent mirror images of each other.

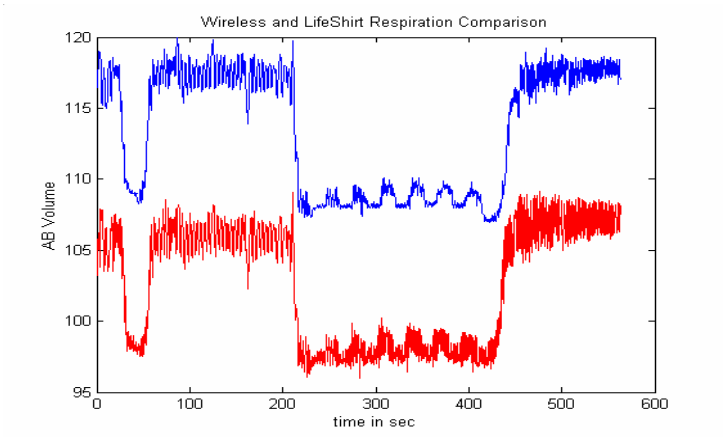


Figure 38. Wireless (Top Plot) vs LifeShirt™ (Bottom Plot) respiration plots

When the lower and upper respiration waveforms were compared to each other, it was noticed that the waveform characteristics were different, as shown in Figure 39. This is explained below.

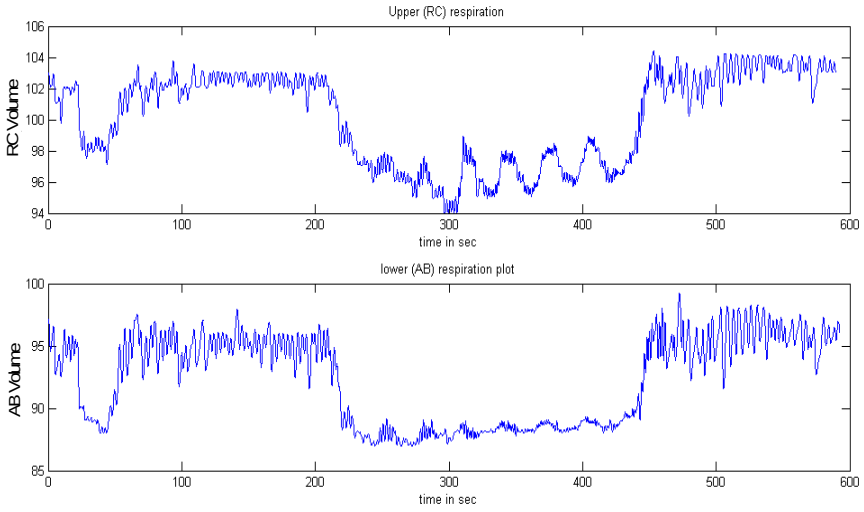


Figure 39. Upper vs Lower Respiration

Notice in Figure 39, that during the +4.0 Gz and +7.5 Gz exposures, the change in the excursion for the abdomen decreases notably. As the +Gz increases the G-suit inflates and the bladder puts more pressure on the abdomen, restricting its excursion, as designed.

Statistical analysis was made on respiration rate values for the eight test runs, using the t-test with a 95% confidence interval. The mean respiration rate values from the wireless system and LifeShirt™ were compared for the baseline period and the +4.0 Gz and +7.5 Gz exposure periods. For the baseline respiration rate, there was no significant difference between the values. However, for the +4.0 Gz and +7.5 Gz exposure periods, there was a significant difference between respiration rate values. This was caused by the two different methods used to calculate the respiration rate values. The statistical analysis results are given in Table 5. WL_BASE stands for wireless measurements during baseline +Gz exposure and LS_BASE stands for LifeShirt™ measurements during baseline +Gz exposure.

Table 5. Statistical analysis and the results for respiration rate comparison

Paired Samples Statistics

		Mean(Br/m)	N	Std. Deviation(Br/m)	Std. Error Mean(Br/m)
Pair 1	WL_BASE	20.3425	8	3.1973	1.1304
	LS_BASE	21.5250	8	6.3879	2.2585
Pair 2	WL_GZ	25.2563	8	1.6711	.5908
	LS_GZ	32.7750	8	7.4594	2.6373

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	WL_BASE - LS_BASE	-1.1825	5.2008	1.8388	-5.5305	3.1655	-.643	7	.541
Pair 2	WL_GZ - LS_GZ	-7.5187	6.5297	2.3086	-12.9777	-2.0598	-3.257	7	.014

4.5 ECG COMPARISONS

The ECG waveforms were collected via the wireless system and the LifeShirt™ data recorder. Only the heart rate data was collected at 25 Hz by the centrifuge facility. The waveforms from the wireless system and the LifeShirt™ data recorder were identical except for their amplitudes, which varied due to the different scaling factors used. Figure 40 shows sample ECG waveforms from the wireless and LifeShirt™ systems.

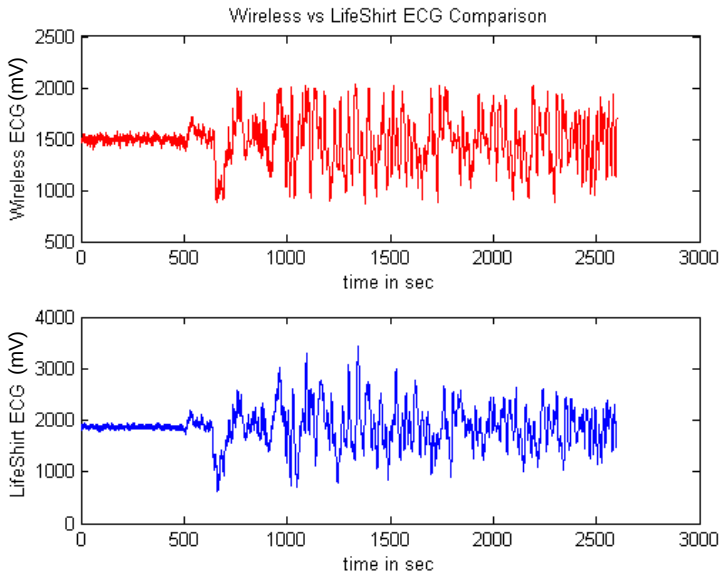


Figure 40. Wireless vs LifeShirt™ ECG comparison

When the DES cab was at the baseline, the ECG waveforms followed the normal ECG waveform trend as shown in Figure 41.

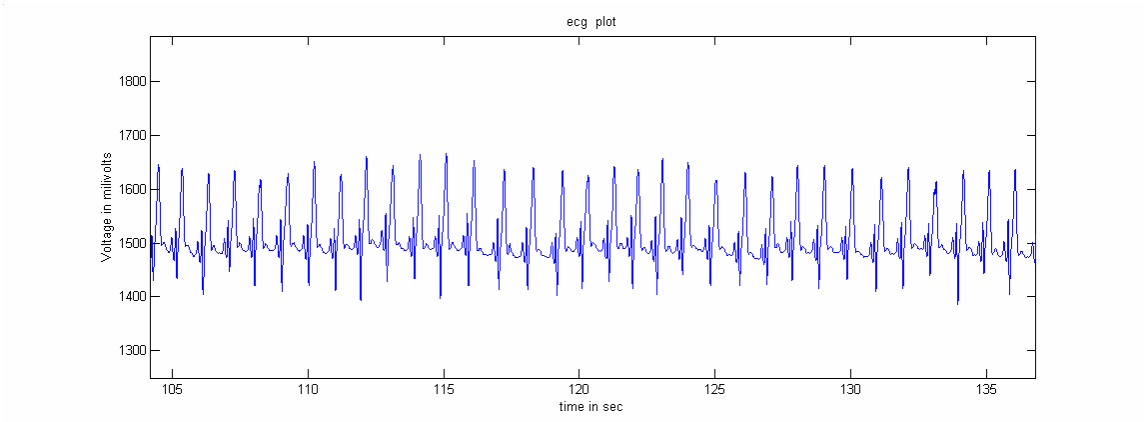


Figure 41. Normal ECG Plot

During the +4.0 Gz and +7.5 Gz exposures, the structure of the waveform changed. According to [46], the ECG could be corrupted by different types of noise. Two of these noise types are baseline drift with respiration and muscle contraction. Base line drift with respiration appears as a sinusoidal component at the frequency of respiration rate. This is added directly to the ECG signal. Muscle contractions cause the electromyographic noise, the magnitude of which is in milli-volt range.

As the subjects start contracting their muscles and conduct the G-straining maneuvers, the noise effects mentioned above corrupt the structure of the ECG waveform. The effect of baseline drift on the ECG is shown in Figure 42. Also an ECG waveform corrupted by electromyographic noise is shown in Figure 43.

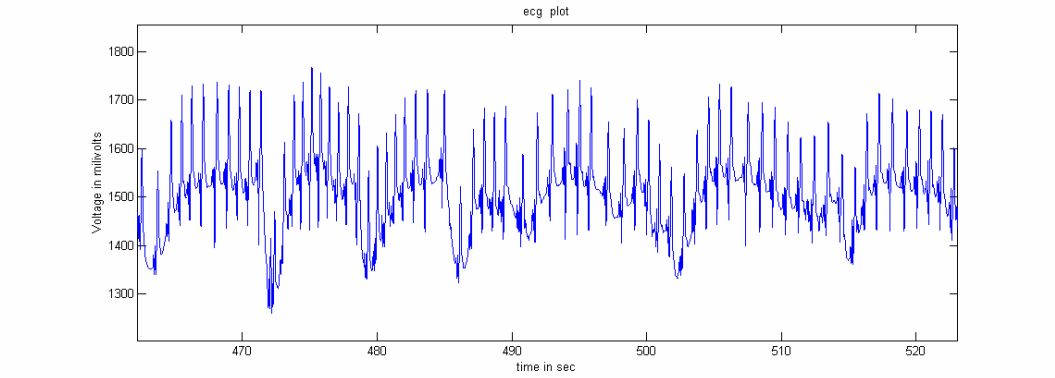


Figure 42. ECG having baseline drift with respiration

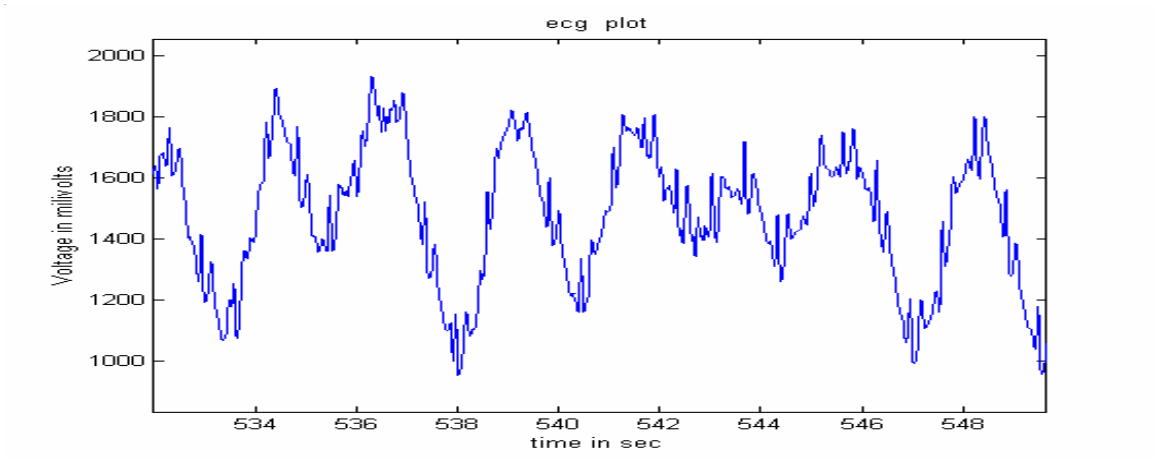


Figure 43.ECG corrupte d by muscle contraction

A statistical analysis was conducted to compare the LifeShirt™ results to those of the Cardio Tac normally used in the DES. The heart rate mean values were compared for the baseline period and the +4.0 Gz and +7.5 Gz exposure periods. As shown in Table 6, analysis results showed that there was no significant difference between the two measurement systems. The p-values were all greater than a.

Table 6. Statistical analysis and the results heart rate comparison

Paired Samples Statistics

		Mean(bpm)	N	Std. Deviation(bpm)	Std. Error Mean(bpm)
Pair 1	BL_LS_HR	85.6000	5	10.5499	4.7181
	BL_CA_HR	84.0400	5	9.8695	4.4138
Pair 2	Gz_LS_HR	110.6000	5	28.4394	12.7185
	Gz_CA_HR	116.0000	5	25.4067	11.3622

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	BL_LS_HR BL_CA_HR	1.5600	5.2219	2.3353	-4.9238	8.0438	.668	4	.541
Pair 2	Gz_LS_HR Gz_CA_HR	-5.4000	10.8766	4.8642	-18.9051	8.1051	-1.110	4	.329

4.6 CHAPTER SUMMARY

In this chapter the wireless real-time data results were presented and compared (when possible) to similar data taken by the LifeShirt™ and the DES facility. Comparison plots of the wireless system versus the LifeShirt™ show that they match each other proving that wireless transmission functioned well under the dynamic environment. In addition, the statistical analysis comparing the LifeShirt™ data to the DES physiological data verify the accuracy of the wireless data to a known and validated system.

5.1 CONCLUSION

The overall research goal is to develop a noninvasive physiological system to monitor people's health, position, and velocity in real-time. This thesis focused on researching, developing, and validating the ability to transmit physiological data, wirelessly, in real-time.

For the real-time transmission of physiological data, the LifeShirt™ physiological monitoring system (a noninvasive ambulatory recording device that continuously gets and stores respiration, electrocardiograph (ECG) and body position data in an internal memory card) was modified to make it capable of transmitting real-time data. The Air Force Research Laboratory, Human Effectiveness's DES and an approved research protocol were used to validate the real-time wireless system.

The test results clearly indicated that the wireless system performed well in transmitting the LifeShirt™ physiology data in real-time.

5.2 RECOMMENDATIONS

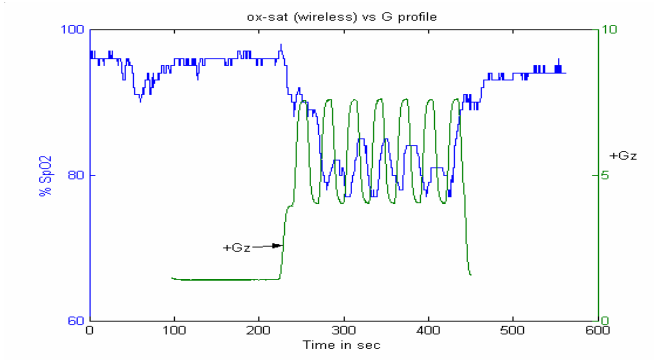
Eight test runs were conducted during this research. The analysis was conducted using only these eight data sets in an environment ranging from 1 to 7.5 G's. The results were excellent. However, further tests using different protocols could be helpful in validating the accuracy of the wireless system. In addition, the following recommendation for further research and development are provided:

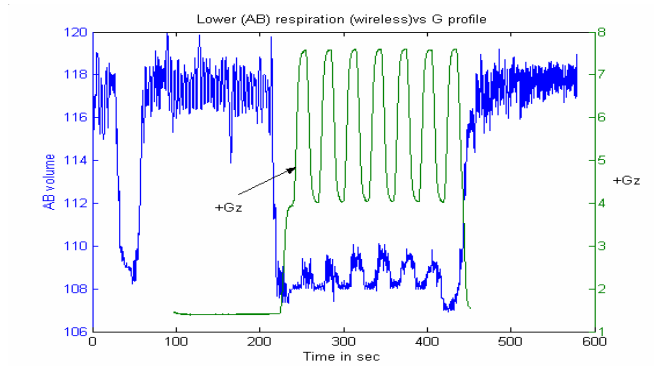
1. Given that the physiological data real-time transmission was done successfully during the test runs, the next step to satisfy the overall research goals would be to integrate GPS to the system. In this way it will be possible to transmit a person's physiological, position, velocity, and time data to a central base station.
2. Currently, the Data Concentrator is a hand-wired prototype that is large and fragile. To make it more usable and durable, a printed circuit board should be produced to make it more compact and sturdy.
3. Continue Greg Hoffman's work and develop a physiological warning system capable of giving warnings to a base control station in the event of dangerous physiological conditions.
4. Develop user friendly code to visually display the data in real-time., The important parameters should be displayed to give the monitoring personnel the ability to take the necessary action in the appropriate time frame.
5. The test runs were conducted in DES during this research. The system should also be tested in flights, on fire-fighters and athletes to get a better insight about the performance of the system.

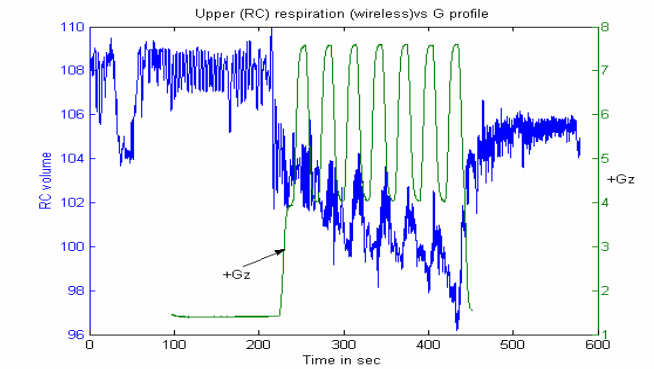
6. The only problem encountered in the wireless transmission was the synchronization of the data. To get the synchronization, sample data was collected for a very short period of time before every run to make sure that the data was synchronized. Cycling the power and the Nonin pulse oximeter provided synchronization. Microcomputer code should be rewritten in a way that first time through the pulse oximeter data routine microcomputer will automatically and reliably synchronize to the data.

APPENDIX A. WIRELESS PHYSIOLOGICAL DATA FIGURES FOR THE TEST RUNS

The following eight pages show the physiological data versus G profile plots for every test runs. The first plot on every page shows the oxygen saturation, the second the abdomen respiration, the third rib cage respiration and the fourth the heart rate. Only in the fourth test run, the Nonin output bad pulse data. This oxygen saturation data is missing on that page.







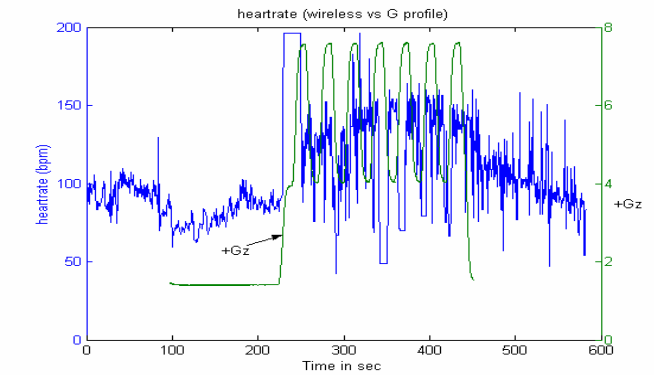


Figure 44. Plots for the first test run

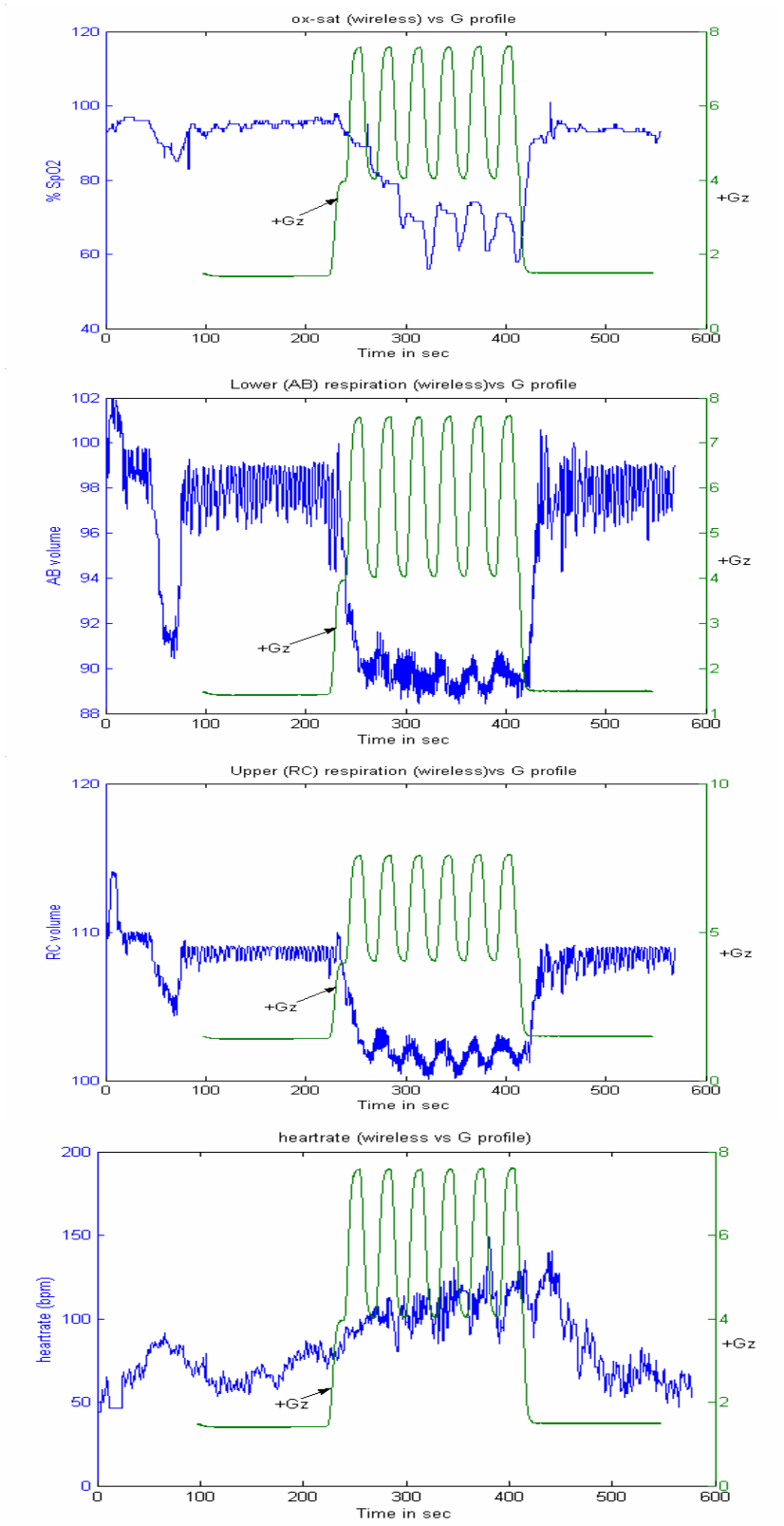


Figure 45. Plots for the second test run

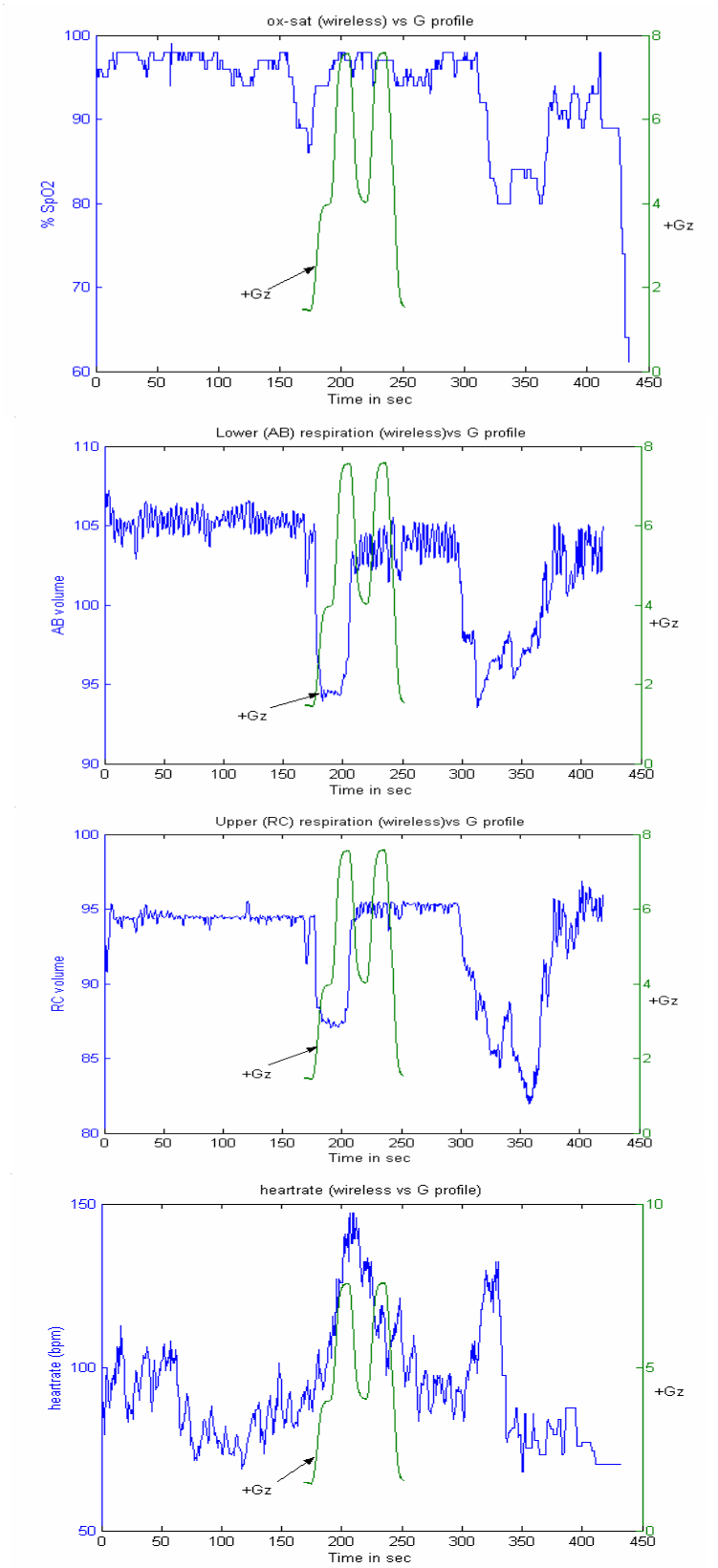


Figure 46. Plots for the third test run

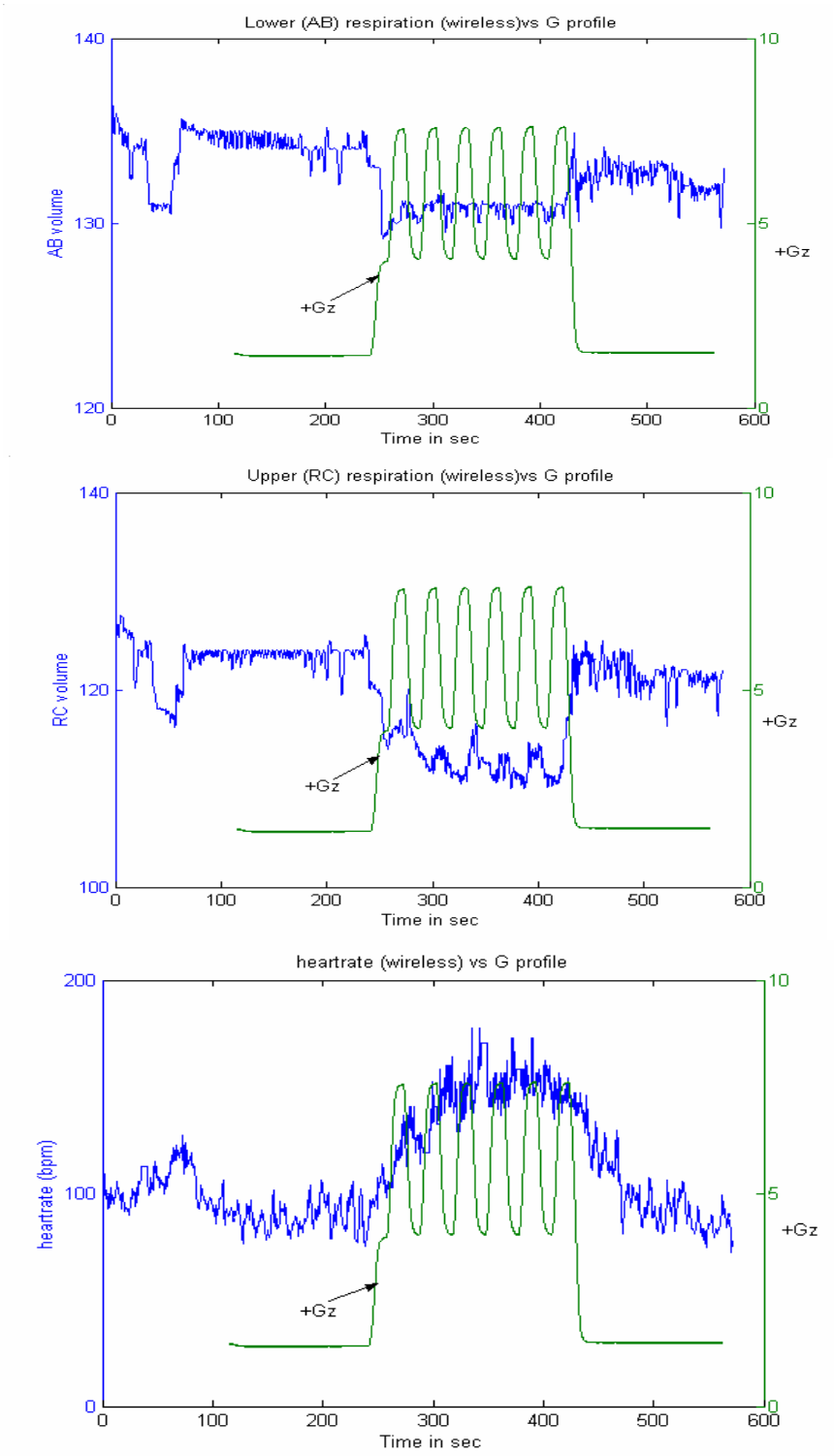


Figure 47. Plots for the fourth test run

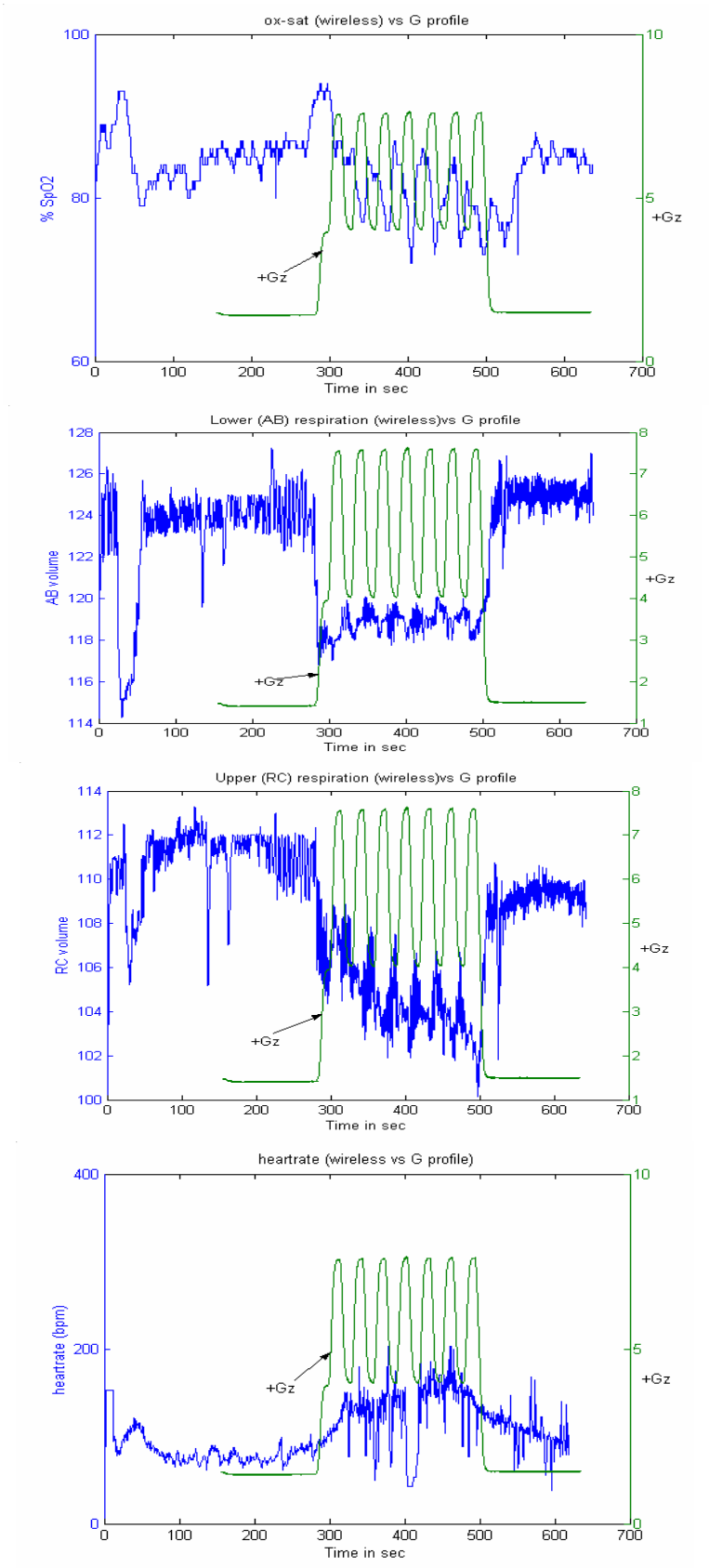


Figure 48. Plots for the fifth test run

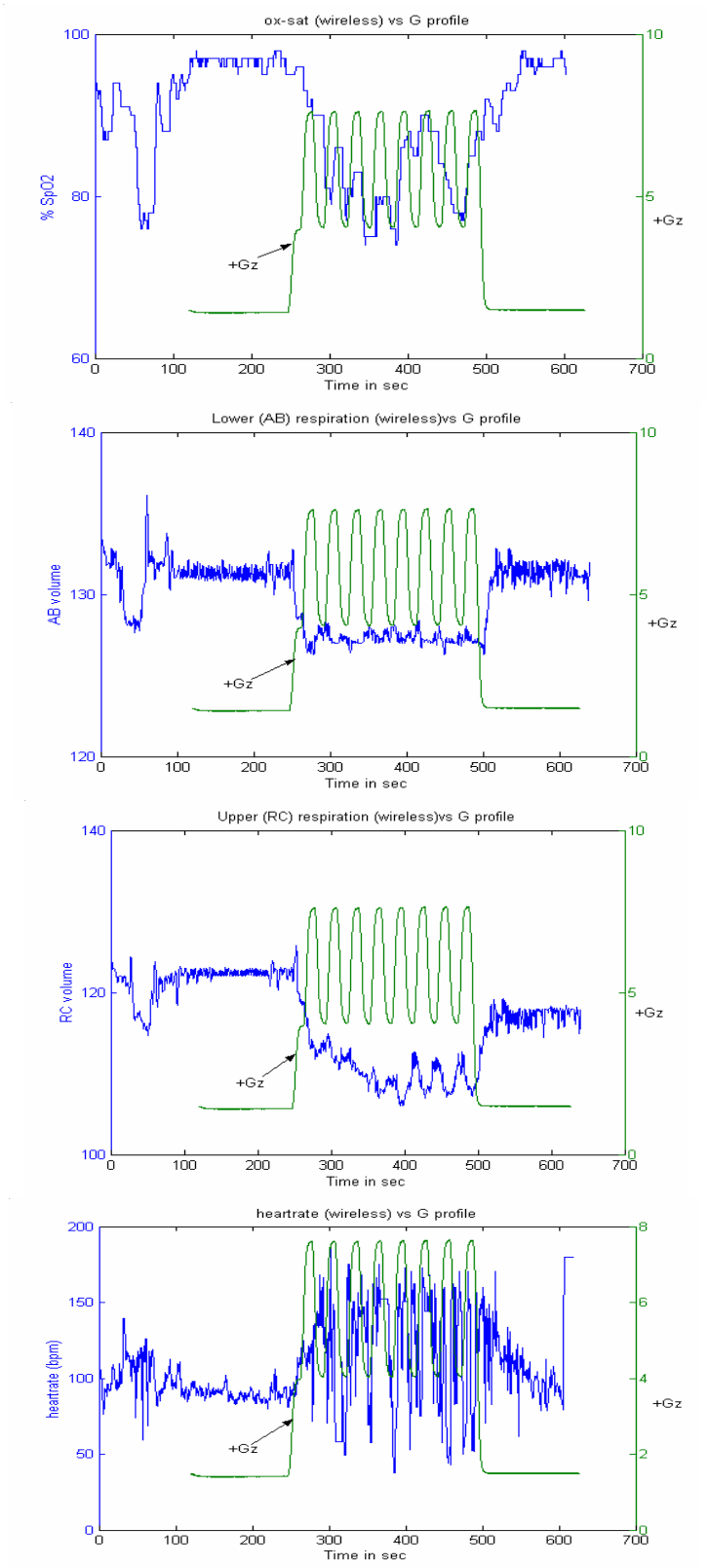


Figure 49. Plots for the sixth test run

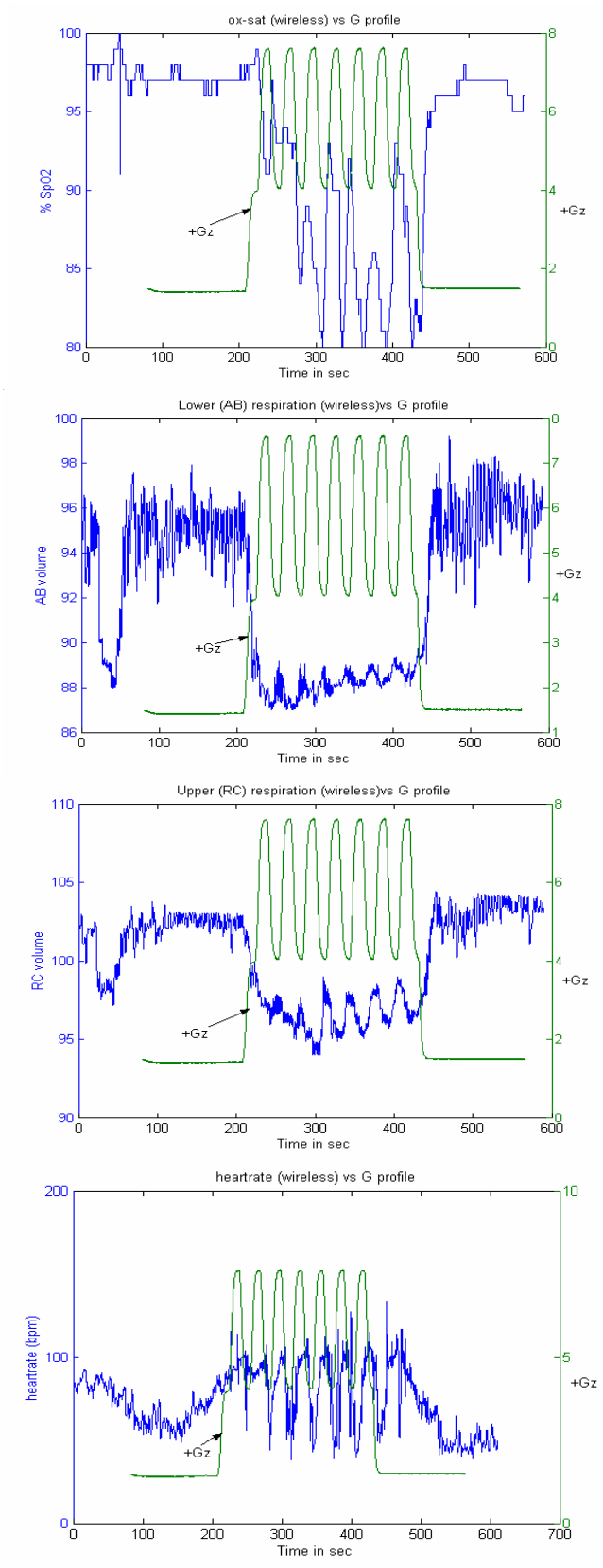


Figure 50. Plots for the seventh test run

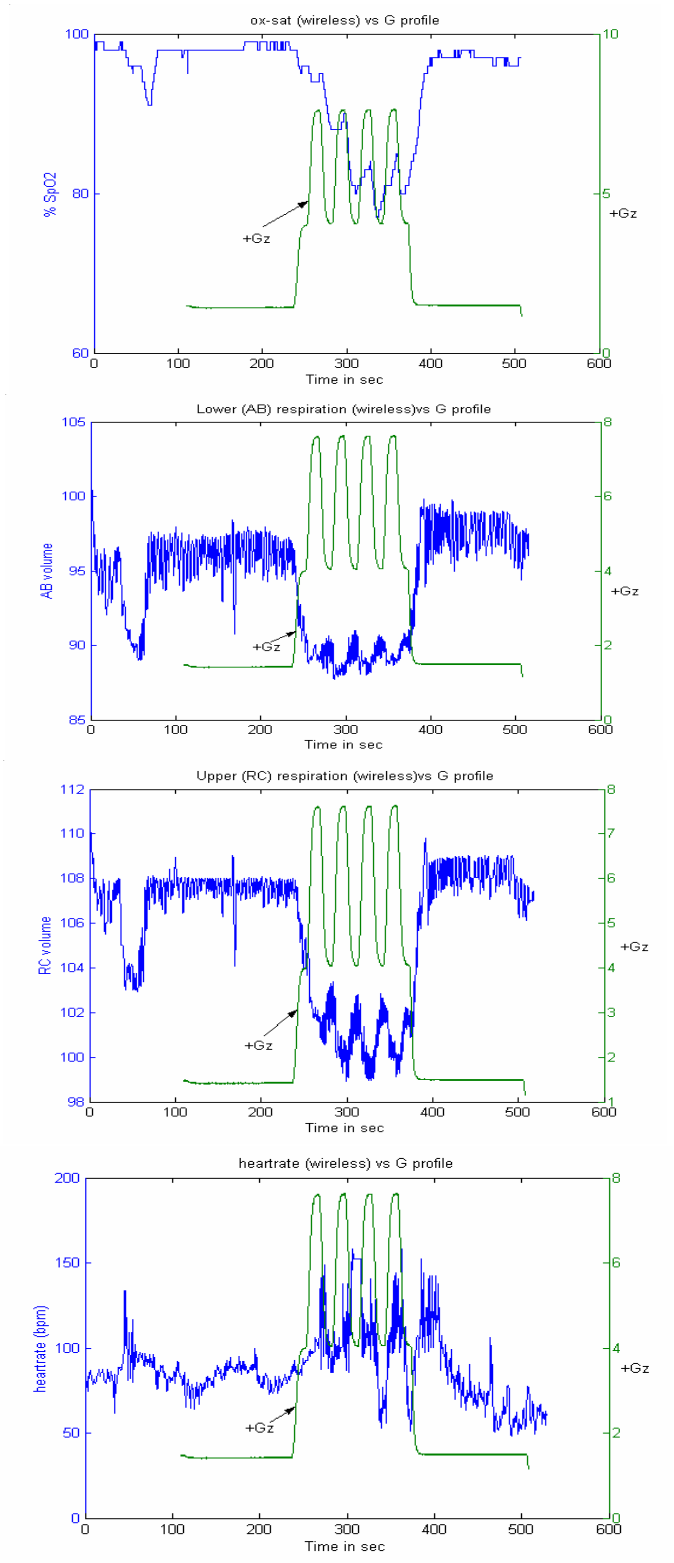


Figure 51. Plots for the eighth test run

APPENDIX B. RESEARCH PROTOCOL

To: AFRL IRB Wright Research Site
From: AFIT/ENG
Subject: REAL-TIME RESPIRATORY MEASURE IN A HIGH +Gz ENVIRONMENT
1. The undersigned have reviewed the protocol and affirm that it meets all requirements for ethical human experimentation as set forth in current Federal, DoD, Air Force, and AFRL guidance.

2. Specifically, we confirm that the proposed project meets the following criteria:
a. The investigators are fully qualified to carry out the proposed research and understand the duties required by AFRLI 40-1 para 1.4.
b. The proposal has undergone adequate peer review to ensure its scientific quality.
c. The research is relevant to valid Air Force needs.
d. The required information can only be obtained by use of human subjects.
e. The experimental design is adequate to resolve the hypothesis or answer the research question.
f. Every effort has been made to minimize the number of human subjects and the discomfort and risk to which each will be exposed.
g. The laboratory or other facility has undergone adequate safety inspection and is fully prepared to respond to medical emergencies. The medical monitor understands the duties contained within AFRLI 40-1, para 1.5.

3. The personnel and resources required to implement this protocol are available within the division or by arrangement with [give details]. It is the division's intention to carry out this research if the protocol is approved.

_____	_____
CHARLES GOODYEAR Statistical Consultant	CAPTIAN MARK ISAAC, USAF, MC, FS. Sustained Acceleration Panel Physician
_____	_____
Chief, Biodynamics and Acceleration Branch	Chief, Biodynamics and Protection Division

DEPARTMENT OF THE AIR FORCE
AIR FORCE INSITUTE OF TECHNOLOGY
WRIGHT-PATTERSON AIR FORCE BASE, OHIO

27 August 2002

To: AFRL IRB Wright Research Site
From: AFIT/ENG
Subject: REAL TIME RESPIRATORY MEASURE IN A HIGH +Gz ENVIRONMENT

1. Request division and IRB review of the protocol named above which should be considered as a freestanding protocol.

2. Request the following action by the IRB: approval of new protocol

3. As principal investigator, the undersigned affirms that the protocol complies with the requirements for human experimentation set forth in Federal code and the DoD, Air Force, and AFRL instructions implementing it. In addition, the undersigned agrees to:

a. Ensure that all human research conducted under this protocol will conform to the written, approved document, including any restrictions imposed during the approval process.

b. Monitor the progress of this research and notify the IRB in writing within 24 hours of any unexpected event or medical misadventure.

c. Notify the IRB, in a timely manner, if either the risk or the benefit of the research appears substantially different from those represented in the protocol, or if early results clearly resolve the hypothesis.

d. Provide progress and final reports for research as required by the IRB as well as notifying the IRB of any publications resulting from this protocol.

e. Ensure that the originals and copies of the signed Informed Consent Document for all subjects are filed as required by AFRLI 40-1 and that all records of completed research are provided to the IRB administrator of the AFRL/HE for permanent archiving.

_____

LtCol Mikel M. Miller
Principal Investigator
AFIT/ENG

1. **Title:** TIME RESPIRATORY MEASURE IN A HIGH +Gz ENVIRONMENT

2. **Principal Investigator:**

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E-mail address: Ed.Eveland@wpafb.af.mil

Lloyd Tripp Veridian Engineering, DSN 785-4391
E-mail address: Lloyd.Tripp@wpafb.af.mil

4. **Medical Monitors:**

MARK ISAAC, Capt, USAF, MC, FS, DSN 785-5492
E-mail address: Mark.Isaac@wpafb.af.mil

5. Facility:

Dynamic Environment Simulator (DES) human-rated centrifuge, Bldg. 33, Wright-Patterson AFB OH. The DES is currently operated and maintained under a delivery order contract with Veridian, Inc., 5200 Springfield Pike, Dayton OH 45431.

6. Objective:

To evaluate two off-the-shelf respiratory measurement systems (LifeShirt and Cos-Med) in the high-G environment.

7. Background and Relevance:

Maintaining appropriate lung volumes during the performance of the anti-G straining maneuver is vital to maintaining intrathoracic pressure and in turn eye-level blood pressure. Cote et al., 1986, has defined the relationship between lung volume and transmural intrathoracic pressure when they evaluated target lung volumes of 12.5, 25, 37.5, 50, 75, and 100 percent of inspiratory volume. Results from this study showed that 75 to 85 percent of maximum inspiratory volumes are optimum for generating the maximum intrathoracic pressure and that lower or higher volumes were related to lower intrathoracic pressures.

Some factors which drive the decrease in inspiratory and expiratory volumes include: +Gz acceleration, G-suit inflation, and restricted chest expansion. The decrease in respiratory function secondary to G-suit inflation has been recognized as a problem for the aerospace community since 1957, when Bondurant et al., demonstrated a 500cc decrease in functional residual capacity with G-suit pressure of 103 mm Hg (about 2 psi). In 1970, Espinosa documented changes in vital capacity (VC) with inflation of the G-suit to pressures of 20-30 mm Hg. Inflation of the G-suit to these low pressures yielded a change in VC of 17%.

The mechanisms associated with these changes seem to affect the abdominal bladder upon inflation. Riou et al., 1991, inflated military anti-shock trousers on subjects to pressures of 60 to 80 mm Hg. Subjects underwent computerized tomography in both an uninflated control and during suit inflation. Results showed the cephald shift of the diaphragm, which reduced the right and left lung height 14 and 8 mm respectively. From these results, one might speculate that as abdominal pressure increased so to would the degree of compression of the lower lung fields. The ability to measure respiratory parameters non-invasively, in real-time, and in a dynamic setting will provide researchers the tools needed to evaluate future G-protective systems. This protocol will evaluate two such respiratory monitoring systems in the dynamic setting of a high-G environment.

8. **Impact Statement:**

This research will lead to the selection of a respiratory monitoring system that will aid in the evaluation of current, and in the design of, advanced G-protection systems.

9. Experimental Plan:

a. Equipment and Facilities:

The Dynamic Environment Simulator (DES) will be used to produce the sustained acceleration environment for the study. The seat will be an ACES II configured with a 12-degree seat back and adequate restraint belts for positive sustained acceleration. The DES arm speed and cab position will be under open loop computer control with hypergravity experiences in the +Gz axis.

LifeShirt is a wearable vest with physiological sensors sewn into it, as shown in Figure 1. The sensors include EKG electrodes, respiration plethysmographic bands, and pulse oximetry. The LifeShirt™ is currently approved by the FDA. All of the sensors and processing algorithms are already approved by the FDA for medical use. The impedance sensors inside the material of the LifeShirt are sensitive to and measure changes in the chest diameter during respiration.

Figure 1. LifeShirt™ shown on subject with recorder device.

The K4 is a portable system that allows monitoring cardiorespiratory function during physical activities. K4 is light and compact that it doesn't affect the physical function during the test. The K4 measures the oxygen uptake in real time and has been successfully used in space applications. A new mask designed by COSMED, as shown in Figure 2, is expressively designed for assessing the respiratory and metabolic response in dynamic environments.

Figure 2. CosMed respiratory monitoring system.

b. Personal Equipment:

Subjects will wear a standard issue flight suit and anti-G suit during all G-exposures. The G-suit will be connected to an Alar High-Flow anti-G valve allowing for G-suit inflation during G exposure.

c. Subjects:

Eight participants will be selected from volunteer members of the DES Sustained Acceleration Research Panel. These members are healthy, active duty, research volunteers from the Wright Patterson AFB, Ohio. Each will have completed introductory training on the centrifuge and graduated upon demonstrating a capability to tolerate exposures up to +9 Gz acceleration. A qualified physician will assure the health status of subjects via inspection of their health record. Participants will complete an approved informed consent form approved by an Institutional Review Board from the Air Force Research Laboratory at Wright Patterson AFB, Ohio.

d. Duration of Study:

This protocol will require subjects to participate in three experimental test runs up to 12 minutes each. The length of each run will depend upon the subjects' ability to resist the effects of +Gz acceleration and endure several cycles of the changing G-levels. Data collection will require up to 12 weeks.

e. Experiential Exposures:

Subjects will experience a +5Gz, 15sec plateau as a warm-up run prior to a Simulated Aerial Combat Maneuver (SACM) profile with a maximum G-level of +7.5 Gz. The SACM profile will consist of +4 to 7.5 Gz cycles (Figure 3) that can be completed and the time duration into the series of acceleration cycles.

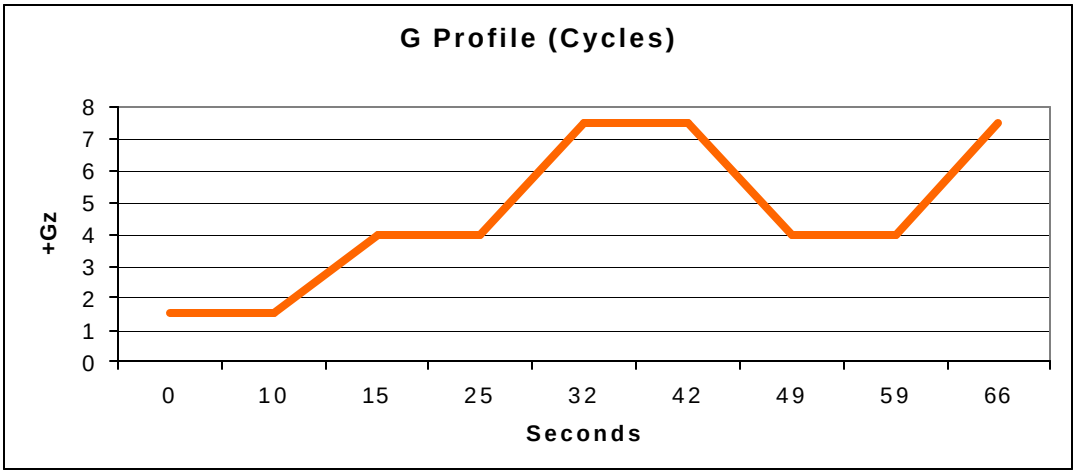

Figure 3. SACM G-profile.

The end point of the trial will be 95% loss of vision, twenty 4 to 7.5 G cycles, or subject fatigue (exhaustion) - whichever comes first. +Gz acceleration will be applied at a rate of +0.5Gz/s starting at baseline (1.5 Gz), and reaching 4Gz. The subjects will be held at +4Gz for 10 seconds, and then accelerated at 0.5Gz/s until +7.5 Gz is reached. The subject will be held at +7.5 Gz for 10 seconds, decelerate to 4 Gz, and begin another cycle. The total time spent in the profile will be recorded as the untrained performance of the subject. Data collection will include the following dependent variables for each of the respiratory monitoring systems: ViVol, Inspiratory Tidal VolumeVeVol, Expiratory Tidal Volume Vent, Minute Ventilation qDEEL, Change in End-Expiratory Lung Volume RBVol, Running Baseline Tidal Volume and Br/M, Respiratory Rate.

10. Statistical Analysis:

A t-test will be used to compare each of the measures from the mask and vest system. An F-test will be performed to look at the variance of the three measures obtained from each device.

11. Medical Risks:

Physiological changes include primarily a redistribution of the blood supply to various organs. The most commonly encountered acceleration (+Gz) causes a shift of blood from the head to the lower parts of the body. Because of this blood shift, loss of vision and even loss of consciousness may result. These effects have been well studied

and have been shown to be both without permanent effects and spontaneously reversible when the +Gz acceleration is reduced. As noted, subjects will be instructed in proper straining maneuvers to help prevent these effects of G stress. A medical monitor will be available for all testing.

G stress can affect the heart and lungs as well. Microscopic sacs in the lung (alveoli) may collapse, a condition known as atelectasis, which may be asymptomatic or result in a sensation of chest fullness or congestion. This type of atelectasis occurs more commonly after acceleration stress in the chest-to-back (+Gx) axis, and rapidly resolves with coughing. This type of acceleration is not planned in this study. Complete collapse of the lung (pneumothorax), though unlikely, is possible.

Effects upon the heart include irregularities of rhythm (cardiac arrhythmias), most of which are self-limiting and resolve with cessation of G stress. Very rarely a potentially serious arrthymia develops which is cause for discontinuing exposure.

In goats, swine, and dogs exposed to high levels of +Gz acceleration, small areas of bleeding in the inner lining of the heart (subendocardial hemorrhage) and electrocardiographic (ECG) evidence of decreased blood supply to the heart muscle (myocardial ischemia) have been noted. However, there have been no similar findings in primates or man. Small breaks in the skin capillaries (petechial hemorrhage) and bruises occasionally appear on the arms, trunk, or legs, but these are normally considered harmless.

Benefits of this research include information from which guidance can be formulated to assist military planners when deciding when to return pilots to service. Historically, the incidence of the described risks is very low. With this known low likelihood of medical problems or risks, and the consequences of possible G-LOC, which does occur, the benefits make this a worthwhile research project. Knowledge gained through this research can provide indications of how far substitution of simulator time can go without compromising G tolerance, possibly leading to loss of personnel and resources. The testing addresses the assistance to operational commanders listed in the impact statement (section 8).

12. Risk Mitigation:

Only subjects who have completed the acceleration indoctrination-training program will be used in this study. An anti-G suit will be used to help support eye-level blood pressure. Subjects will be monitored via a closed circuit monitoring system by the investigator and flight surgeon.

13. References:

Bondurant, S., Hickam, J.B., Isley, J.K. Pulmonary and circulatory effects of acute pulmonary vascular engorgement in normal subjects. J. Clin. Invest. 36:55, 1957.

Cote, R., Tripp, L.D., Jennings, T., Karl, A., Goodyear, C., Whiley, R. Effects of inspiratoryvolume on intrathoracic pressure generated by an L-1 maneuver. Aviat. Space and Environ. Med. 57:1035-1038, 1986.

Espinosa, M.H., Updegrove, J.H. Clinical Experience with the G-suit. Arch. Surg. 101:36-39, 1970.

Riou, B., Pansard, J.L., Viars, P. Ventilatory effects of medical antishock trousers in healthy volunteers. J. of Trauma. 31(11):1495-1502, 1991

APPENDIX C. CONSENT FORM FOR THE SUBJECTS

INFORMATION PROTECTED BY THE PRIVACY ACT OF 1974

Informed Consent Document
for

REAL-TIME RESPIRATORY MEASURE IN A HIGH +Gz ENVIRONMENT

1. Nature and purpose:

You have been offered the opportunity and have volunteered to participate in the Durability of G-Tolerance in the Absence of Repeated G-Exposure research study; your participation will occur sometime between 01 Nov 2002 and 28 Feb 2003. You have successfully completed the AFRL/HEPA Sustained Acceleration Stress Panel screening examinations and understand the possible effects associated with this type of study. The DES centrifuge is capable of rotating along three axes and has been approved for use with human volunteers. Spinning around the three axes allows this centrifuge to produce acceleration similar to that felt while performing maneuvers in jet aircraft.

The purpose of this research is to evaluate, in the DES centrifuge, the effects of high-G on lung function and the performance of two commercially available lung function measuring devices. The time requirement for each volunteer subject is anticipated to be 3 visits of approximately one half hour each. An additional 15 minutes of prep time for each session will be necessary to place electrodes on the body Approximately 12 volunteers will participate in this study.

2. Experimental procedures:

a) If you decide to participate, you have been advised that G-suit will be provided to help protect you from the effects of +Gz acceleration. You will also be required to rely on straining maneuvers to maintain vision during test runs. Self-adhesive electrocardiograph (EKG) electrodes will be placed on your torso for all runs. A medical monitor uses information from the electrocardiogram, created from the signals detected by the electrodes, to watch for abnormal heart rhythm during the experiment. Two small, non-invasive, portable, chest-mounted physiological monitors will be used to detect respiratory changes and oxygen uptake by sampling through a lightweight mask and vest.

b) During sustained acceleration stress exposures, the arm and cab of the DES will turn, producing G stresses. This study two experimental test days per person, with exposures not to exceed 7.5 times the normal gravitational stress in the head-to-foot direction (+7.5 Gz). You will be closely observed at all times and you may stop an

exposure at any time for any reason. Some motion sensations you may experience are a loss of orientation or position awareness when the DES accelerates, feeling like a climbing turn, and a tumbling sensation or feeling like a descending turn when the DES decelerates.

c) If, at any time, you choose to abort the test, you can stop testing and bring the centrifuge to a stop by pressing a B-stop button held in your hand as you learned during training. Proper function and use of this button is tested prior to beginning of each centrifuge visit as a part of the standard check-out procedure. Tests may also be stopped by the investigator or the medical monitor should it be necessary. The decision to stop will be based primarily on subject input, information shown on the medical displays, and visual observation of the subject.

3. Discomfort and risks:

Discomfort may consist of the feelings of exertion and fatigue commonly felt after strenuous exercise. There may be labored breathing, tightness in the muscles, and perspiration.

Physiological changes include primarily a redistribution of the blood supply to various organs. Acceleration (+Gz acceleration in the head-to-foot direction) causes a shift of blood from the head to the lower parts of the body. Because of this blood shift, loss of vision and even loss of consciousness (GLOC) can potentially occur. These effects have been studied and have been shown to be spontaneously reversible, when the +Gz acceleration is reduced. There are no permanent effects from acceleration known. As noted, you will be instructed in proper straining procedures to help prevent these effects of G stress.

G stress can affect the heart and lungs as well. Microscopic sacs in the lung (alveoli) may collapse, termed atelectasis, which may be asymptomatic or result in a sensation of chest fullness or congestion. This type of atelectasis occurs more commonly after acceleration stresses in the chest-to-back (+Gx) axis, but rapidly resolves with coughing. Complete collapse of a lung (pneumothorax), though unlikely, is possible.

Effects upon the heart include irregularities of rhythm (cardiac arrhythmia), most of which are self-limiting and resolve with cessation of G exposure. Very rarely a potentially serious arrhythmia develops, which will stop the exposure.

In goats, swine, and dogs exposed to high levels of +Gz acceleration, small areas of bleeding in the inner lining of the heart (subendocardial hemorrhage) and electrocardiographic (EKG) evidence of decreased blood supply to the heart muscle (myocardial ischemia) have been noted; however, there have been no reports of similar findings in man or monkeys.

Small breaks in the skin capillaries (petechial hemorrhage) and bruises occasionally occur on arms, trunk, or legs, but these are felt to be harmless. Because of the straining maneuvers, you will experience increases in both intra-abdominal and intra-thoracic pressure. This increased pressure might cause or worsen hernias, hemorrhoids, varicose veins, varicocele, and thrombophlebitis. If physical injury were to occur, it may

result in your physical disqualification from flight or other special duty. Fracture/dislocations are theoretically possible but have not been observed here. Muscle strains are also possible. They may be due to active straining or to your losing consciousness (GLOC) during profile.

Exposure to high G acceleration may affect the sex of offspring of male centrifuge volunteers. A study that compared low G individuals (non-rated and non-tactical pilots) to high G pilots showed a difference in the sex of offspring. The high G pilots had 40% male offspring, while the low G individuals had 50% male offspring. Additional occupational factors, which could not be controlled in the study, such as hypoxia and ionizing radiation exposure associated with flight in upper layers of the earth's atmosphere, may be related to the sex ratio effect observed in the experiment. Therefore, the contribution to the effect by G exposure alone is unknown. The effect may be limited to the months when high G flights are experienced.

Movement of the head under G may result in motion sickness. Motion sickness is commonly experienced during travel, and may involve nausea, vomiting, sweating, dizziness, headache, or lightheadedness. It is usually temporary, lasting at most several hours.

Spinal column trauma refers to injury that may occur to the spinal column, which is made up of bones called vertebrae and soft tissues such as discs, and ligaments that are connected to muscles and tendons. Due to high G acceleration and straining done by the subject during centrifuge rides, several stresses are applied to the spinal column. It is not uncommon to see strains like pulled muscles after several rides at 7 to 9 G. This is similar to the common backpain (Lumbago) a person gets after lifting heavy boxes that goes away after several days of rest and aspirin. Some evidence has been presented that fighter pilots frequently experience occupational stressors that might lead to neck soreness and possible cervical disk anomalies. This may be related to the higher performance capabilities of the aircraft they fly. The disk changes were found in senior fighter pilots who were frequently exposed to high +Gz accelerations during the 10 years prior to the study.

4. Precautions for female subjects:

If you are female, you have read, understood and signed the attached Addendum for Female Subjects.

5. Benefits:

You are not expected to benefit directly from this participation.

6. Entitlements and confidentiality:

a) Records of participation in this research study may only be disclosed according to federal law, including the Federal Privacy Act, 5 U.S.C. 552a, and its implementing regulations. Experimental data will be stored electronically in a computer file that identifies subjects with arbitrary numbers that cannot be traced back to your identity. LtCol. Mikel Miller, (5-6565, ext. 4278) is responsible for the storage of your consent form and the research records related to your participation in this study. These records will be stored in Building 33, Room 112.

b) You understand your entitlements to medical and dental care and/or compensation in the event of injury are governed by federal laws and regulations, and that if you desire further information you may contact the base legal office (88 ABW/JA, 257-6142).

c) If an unanticipated event (medical misadventure) occurs during your participation in these trials, you will be informed. If you are not competent at the time to understand the nature of the event, such information will be brought to the attention of your next of kin.

d) The decision to participate in this research is completely voluntary on your part. No one has coerced or intimidated you into participating in this program. You are participating because you want to participate. LtCol. Mikel Miller, AFIT/ENG (5-6565, ext. 4278) or the associate investigators at the Dynamic Environmental Simulator (DES), AFRL/HEPA, (5-5742), have adequately answered any and all questions you have about this research, your participation, and the procedures involved. You understand that LtCol. Mikel Miller, or the associate investigators will be available to answer any questions concerning procedures throughout this effort. For questions about medical aspects, injury, or any health or safety questions, contact Capt. Mark Isaac, AFRL/HEPA, (5-5492). For questions about the ethical aspects of this study, your rights as a volunteer, or any problem related to protection of research volunteers, you should contact Col. Richard Allnutt, Chair of CPHS, at 5-1236.

You understand that if significant new findings develop during the course of this research, which may relate to your decision to continue participation, you will be informed. You further understand that you may withdraw this consent at any time and discontinue further participation without prejudice to your entitlements. You also understand that the medical monitor may terminate your participation in any trial if she or he feels this to be in your best interest. Examples of medical reasons that would stop your study participation would be irregular heart rhythms and pregnancy.

7. You understand that your participation in this research study may be photographed, filmed or audio/videotaped. You consent to the use of these media for training purposes and understand that any release of records of your participation may only be disclosed according to federal law, including the Federal Privacy Act, 5-5 U.S.C. 552a, and its implementing regulations. This means personal information will not be released to an unauthorized source without my permission.8.

8. YOU FULLY UNDERSTAND THAT YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE. YOUR SIGNATURE INDICATES THAT YOU HAVE DECIDED TO PARTICIPATE HAVING READ THE INFORMATION PROVIDED ABOVE, AND THAT YOU ACKNOWLEDGE RECEIPT OF TWO COPIES OF THIS FORM, ONE FOR YOUR MEDICAL RECORDS AND ONE FOR YOUR OWN PERSONAL RECORDS.

Volunteer Signature_____ Date _____

Volunteer Social Security No. (optional)_____

Principal Investigator Signature _____ Date _____

Witness Signature _____ Date _____

Privacy Act Statement

Authority: We are requesting disclosure of personal information, to include your Social Security Number. Researchers are authorized to collect personal information (including social security numbers) on research subjects under The Privacy Act-5 USC 552a, 10 USC 55, 10 USC 8013, 32 CFR 219, 45 CFR Part 46, and EO 9397, November 1943 (SSN).

Purpose: It is possible that latent risks or injuries inherent in this experiment will not be discovered until some time in the future. The purpose of collecting this information is to aid researchers in locating you at a future date if further disclosures are appropriate.

Routine Uses: Information (including name and SSN) may be furnished to Federal, State and local agencies for any uses published by the Air Force in the Federal Register, 52 FR 16431, to include, furtherence of the research involved with this study and to provide medical care.

Disclosure: Disclosure of the requested information is voluntary. No adverse action whatsoever will be taken against you, and no privilege will be denied you based on the fact you do not disclose this information. However, your participation in this study may be impacted by a refusal to provide this information.

INFORMATION PROTECTED BY THE PRIVACY ACT OF 1974

BRIEFING ADDENDUM FOR FEMALE SUBJECTS

REAL-TIME RESPIRATORY MEASURE IN A HIGH +Gz ENVIRONMENT

1. Air Force need for information: There is limited information available concerning the use of female subjects under acceleration stress. Female subjects have been included occasionally in some high +Gz (acceleration force in the head-to-foot direction) studies. Female pilots in the USAF are now entering high performance aircraft and thus there is a real need for their inclusion in acceleration studies under controlled conditions.

2. Additional potential risk: There are several unique potential problems which must be considered if females are to be used as subjects in acceleration experiments.

a) **Pregnancy:** The effect of acceleration on the developing fetus is little understood. However, the potential for fetal injury, malformation, or even death cannot be ignored. For these reasons, pregnancy precludes participation in sustained acceleration exposures. Also, it is necessary to utilize effective contraceptive technique prior to and for the duration of experimental sustained acceleration stress exposures.

b) **Contraceptives:** The risk from the use of oral contraceptives in conjunction with sustained acceleration stress is unknown. To date, no increase in illness or adverse side effects has been noted with the use of oral contraceptives by female subjects participating in high G studies. However, oral contraceptives have been implicated in increasing the incidence of certain problems in the normal +1 Gz environment. Those most frequently encountered are inflammation of the large veins (thrombophlebitis), and the formation of blood clots in the veins (thrombosis). Although rare, the latter is a potentially fatal complication. The most common symptoms of these problems are leg pain and swelling. Current studies examine these problems in females in the normal +1 Gz environment. Deaths apparently due to the use of oral contraceptives alone have occurred in rare instances, however, studies during the early 1980's implicated a number of complicating factors such as smoking, hypertension, and diabetes, as synergistic.

c) Ovarian abnormalities: The ovary is subject to cystic enlargement and other conditions which may occur with or without symptoms. There is a possibility that high G exposure could increase the normal risk that such an enlarged cyst may burst, or that the ovary may twist about its support, cutting off the blood supply. This situation would possibly require major surgery to correct, with the attendant risk of loss of the involved ovary, bleeding, infection, or even death.

d) Menstrual flow: Sustained acceleration stress could theoretically result in menstrual flow alterations. To date, female subjects at this facility have not identified this as a problem, nor is it reported in the literature.

e) Breast support: The forces experienced during acceleration exposures under this protocol indicate that breast support must be used. The presence of breast implants will preclude participation in this protocol.

3. Overall risk: The risk that any female may be subject to on the DES is felt to be no greater than her risk as an operational pilot. Every effort will be made to protect the health and well being of the individual, and where doubt exists, the judgment of the medical monitor and the panel physician will remain conservative.

It is imperative that each potential female subject carefully considers the additional risks involved in her participation as a subject in acceleration experiments. She must take part in a full individual consultation in the above mentioned areas with a member of the OB/Gyn Department at the Wright-Patterson USAF Medical Center. She must then make her own decision, recognizing the areas of inadequate knowledge
as noted above, and discuss her planned contraceptive program with the medical investigator or medical monitor for the experiment.

Acknowledgment: I acknowledge that I have been briefed on the above topics and I understand the evidence for the risks associated with sustained acceleration.

Volunteer Signature_____ Date
_____

Volunteer Social Security No._____(Optional)

Principal Investigator Signature _____ Date
_____

Witness Signature _____ Date
_____

Privacy Act Statement

Authority: We are requesting disclosure of personal information, to include your Social Security Number. Researchers are authorized to collect personal information (including social security numbers) on research subjects under The Privacy Act-5 USC 552a, 10 USC 55, 10 USC 8013, 32 CFR 219, 45 CFR Part 46, and EO 9397, November 1943 (SSN).

Purpose: It is possible that latent risks or injuries inherent in this experiment will not be discovered until some time in the future. The purpose of collecting this information is to

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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From – To)*
25-03-2003	**Master's Thesis**	Jun 2002 – Mar 2003

4. TITLE AND SUBTITLE

IMPLEMENTATION AND VALIDATION OF A REAL-TIME WIRELESS NON-INVASIVE PHYSIOLOGICAL MONITORING SYSTEM IN A HIGH-G ENVIRONMENT

5a. CONTRACT NUMBER

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

H. Aydin Akcivi, First Lieutenant, TUAF

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAMES(S) AND ADDRESS(S)

Air Force Institute of Technology
Graduate School of Engineering and Management (AFIT/EN)
2950 Hobson Way, Building 640
WPAFB OH 45433-7765

8. PERFORMING ORGANIZATION REPORT NUMBER

AFIT/GE/ENG/03-01

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

10. SPONSOR/MONITOR'S ACRONYM(S)

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

12. DISTRIBUTION/AVAILABILITY STATEMENT

APPROVED FOR PUBLIC RELEASE; DISTRIBUTION UNLIMITED.

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The overall purpose of this research is to develop a system capable of real-time personal positioning and physiological monitoring. The system will be composed of a shirt having non-invasive physiological sensors, Global Positioning System (GPS) receiver, wireless data transceiver, and real-time PC-based control station. The specific purpose of this research phase was to determine the performance capabilities of a modified LifeShirt™ alone (without GPS) in a high gravitational force environment with the data being sent wirelessly in real-time.

The LifeShirt™ was modified with a real-time wireless transmission system. The modified LifeShirt™ system was tested in Air Force Research Laboratory Human Effectiveness (AFRL/HE) Dynamic Environment Simulator (DES) to compare the LifeShirt™ data to the data of DES health monitoring system. Eight high-G tests (up to 7.5 G's) were conducted for this research. The test results clearly indicated that the wireless system performed well in transmitting the LifeShirt™ physiology data in real-time.

15. SUBJECT TERMS

Physiological monitoring, vital-sign monitoring, ECG, Electrocardiogram, respiration, pulse oximetry, wireless transmission, centrifuge, G forces

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			**LtC Mikel M. Miller, USAF**
U	**U**	**U**	**U**	112	**19b. TELEPHONE NUMBER** *(Include area code)* (937) 255-6127, ext 4274; e-mail: mikel.miller@afit.edu

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39-18