BioAsyst, LLC

12321 Middlebrook Road
Suite 150
Germantown, MD 20874
(301) 428-9818

Phase I SBIR Final Report

June 27, 2002

SCBA Oximetry for Fire Fighter Physiologic Monitoring

This material is based upon work supported by the Department of Health and Human Services (HHS), Center for Disease Control and Prevention (CDC), National Institutes of Occupational Health and Safety (NIOSH) under contract number 1 R43 OH04173-01. Any opinions, findings, and conclusions or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the views of the Department of Health and Human Services.

Principal Investigator: William P. Wiesmann MD
Co-Investigators: Sandy Bogucki MD, PhD; L. Alex Pranger, ME
Robert J. Winchell, MD; Margaret Kolka, PhD

Project Contact: Stephanie Shack
Grant Number: 1 R43 OH04173-01

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List of Abbreviations

AC	Alternating Current – in our context it is the pulsitile or cyclic component of a signal.
BCI	BCI, Inc., Waukesha, WI. A part of Smiths Group plc.
C	Capacitance
CPAT	Candidate Physical Agility Test
COTS	Commercial, off-the-shelf
CSV	Comma separated value (data file format with each entry separated by a comma)
DC	Direct Current – in our context it is the signal bias or the constant offset to a signal.
EMT	Emergency Medical Technician
GND	Ground – Reference level for electrical signals
HR	Heart Rate
HRV	Heart Rate Variability
Hz	Hertz – frequency of one cycle per second
I/O	Input / Output – generally refers to a processor signal that can be either an input or output signal.
IR	Infra-Red
IRB	Institutional Review Board
LED	Light Emitting Diode
LLC	Limited Liability Corporation
MAM	mean absorbance minima
MUX	Multiplexor – select one signal from several choices
NFPA	National Fire Protection Association
NIOSH	National Institute of Occupational Safety and Health
OEM	Original Equipment Manufacturer
PPE	Personal Protective Ensemble
R	Resistance
R	Ratio of Red to IR high and low points in the AC component of the light absorbance signal.
SBIR	Small Business Innovative Research [Grant]
SCBA	Self Contained Breathing Apparatus
SpO_2	% Oxygen Saturation obtained by pulse oximetry

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Abstract

SCBA Oximetry for Fire Fighter Physiologic Monitoring

This project adapted technologies currently used for patient monitoring in the clinical environment to real time physiologic monitoring of working firefighters. The work is aimed at reducing the occupational morbidity and mortality of the fireground through direct physiologic status monitoring and development of essential research tools for understanding the pathophysiology of non-traumatic disability on the fire ground. Reflectance mode oximetry sensors were mounted in the face pieces of commercially available self-contained breathing apparatus (SCBA) after the optimal separation distance of the emitting and detecting elements was empirically established. Oximetry processing boards that were optimized for both detection of the non-pulsatile (DC) waveform component and compatibility with wearable radiotransmitters were built and hardened for experimental use. A previously validated protocol of simulated, sequential fireground tasks was adapted for this project so that it could be performed within the controlled conditions of an environmental chamber. IRB-approved studies using local firefighters as voluntary subjects were then conducted to test the operational feasibility and reliability of the integrated SCBA-oximetry system. These preliminary experiments also correlated DC oximetry with physiologic status by simultaneously monitoring core temperature under conditions of compensable and uncompensable heat stress. The Phase 1 technical accomplishments and scientific results suggest that SCBA-based oximetry represents a viable future solution for remote, physiologic monitoring of fire ground personnel and a potentially valuable research tool for studying workers at risk for exertion-related heat stress while wearing personal protective equipment.

Significant Findings

With Phase I SBIR funding, BioAsyst, LLC has made substantial progress in demonstrating the feasibility of using Self Contained Breathing Apparatus (SCBA)-mounted oximetry as an indicator of the physiologic status of working firefighters.

Commercially available SCBA facemasks were retro-fitted with pulse oximetry sensors through factory fabrication after the optimal distance of the emitting elements from the detecting elements for reflectance mode oximetry was empirically established. NIOSH-compliant testing by the original SCBA manufacturer demonstrated that the modified masks retain their fit and functional properties.

We have developed and built oximetry processing boards that acquire the absorbance readings from the sensors, identifies the direct (DC) component and both records and radio-transmits the signal for real-time display on a laptop computer.

In order to control the size, weight and complexity of the processors, we established that a single, visible red emitting diode could be used in the DC oximetry sensor, rather than the dual frequency red/infra-red elements used in commercially available pulse oximeters.

After encountering initial difficulty with reliability of the mask under experimental firefighting conditions, we identified the problem to be sweat from the wearer short-circuiting the sensor elements in the mask. This was resolved by sealing the sensor window with a vapor permeable, water occlusive, skin dressing product called Tegaderm (3M).

The oximetry system was initially assessed for both ability to function under fire ground working conditions and ability to detect physiologic changes consistent with uncompensable heat stress. A firefighting simulation that could be performed under climatically controlled conditions in an environmental chamber was developed and validated for these purposes.

Ten currently active firefighters were recruited as subjects for IRB-approved experimentation. A physiologic sensing suite including our SCBA-based oximeters and commercially available, ingestible, core temperature capsules was used to monitor the subjects wearing full protective ensemble as they performed a sequence of simulated firefighting tasks in the heated environmental chamber. Control studies were also conducted on different days with the same subjects without the protective equipment and heat.

Signal processing algorithms were applied to derive oximetry data from the raw absorbance readings, and preliminary correlations with clinical observations were made. The subject-matched oximetry tracings are undergoing further analysis to distinguish whether subtle differences in the firefighters' physiological stress levels between the two conditions are consistently detectable through this modality. An acute and apparently diagnostic decrement in oxygen saturation was seen by mask-based DC oximetry in the one study subject who became symptomatically fatigued and had to terminate the protocol prior to completing it.

Usefulness of Findings

Fire Service

The value of high-risk worker monitoring for agencies such as the fire services is extensive. Sensors that monitor the health and operational fitness of personnel could greatly assist in real-time risk assessment and mitigation. Fire chiefs in the United States have clearly identified the need for accurate monitoring technology on the fire ground. Two areas of great concern regarding the deployment of emergency responders are knowledge of (1) the physical and toxic hazards posed by the environment, and (2) the physiologic status of the fire fighter. It is important to quickly acquire this information and relay it in a simple, intuitive format to the officer(s) having operational responsibility. To be deployable on the fire ground, a physiological monitoring system for firefighters would need to be small, lightweight, and could not involve wiring or connections that might tether or entrap a fire fighter operating inside a burning building. Additionally, since structure fires are unpredictable and require rapid responses, sensing systems that must be put in place ahead of time or donned as an extra step at the time of alarm are not practical. The monitored parameters must have some demonstrated correlation with clinically relevant physiologic changes. Finally, since most fire departments operate off the tax base in cities, towns or counties, any firefighter physiologic monitoring capability must have very modest acquisition and maintenance costs.

We have approached these technical requirements by integrating oximetry sensors into the respiratory protection worn by all firefighters during interior structural firefighting operations. Our empiric determination of the optimal emitter-detector element distance allowed us to use commercial off-the-shelf (COTS) sensors originally designed for transmission mode pulse oximetry in reflectance mode at the forehead. We had previously demonstrated that this was essential as COTS sensors designed for reflectance mode either didn't fit in the SCBA facemask or were exceedingly uncomfortable when the mask was tightened onto the face. In mask fabrication, we were also able to contain the supportive wiring in the SCBA's air line conduit, so no potential tethers were introduced into the protective ensemble. By demonstrating the feasibility of using a single rather than dual light frequency in the oximetry sensor, we were able to markedly decrease the size and weight of the processor required and to downsize the radio-transmitter power necessary for the smaller data packets. These findings offer significant ergonomic advantages, and the decreased power requirements and processing complexity will result in both lower cost and more robust devices when they become available to the fire service.

Our adaptation of the fire service candidate physical agility test (CPAT) which has previously been validated for its emulation of fire ground tasks into a protocol compatible with climate control using an environmental chamber is an important contribution to standardized studies of firefighter physiology and other, occupational, uncompensable heat stress. Using this IRB-approved protocol, we were able to identify a design problem with the facemask oximeters that caused the sensors to short out when sweating by the subjects was profuse. The interim solution of placing a thin, vapor-permeable, water occlusive layer over the sensor window demonstrates that the problem is not intractable, and a permanent solution will be investigated in the next phase of this project. Finally, the most significant finding from these preliminary studies is that the DC component of single wavelength (visible red) oximetry correctly detected the single instance of incapacitating physiologic stress among our experimental subjects. While it is important to perform extensive further studies to confirm a single observation of any phenomenon, this result is highly encouraging that SCBA-based DC oximetry may offer a practical, cost-effective, physiologic status monitor/alarm system for firefighters.

Other applications

The increasing risk of future conflicts involving chemical and/or biological weapons means that our forces will require personal protective equipment (PPE). Heat stress has consistently been a significant problem with deployed military forces. During World War II, more that 35,000 forces required hospitalization for heat stress, during the Six Days War, 20,000 Egyptians died from heat related injuries, and during the invasion of Granada between 2.9 and 4.8 % of our forces were treated for heat related injuries each day (1). The current U.S. military emphasis on preparation for Military Operations in Urban Terrain makes the military market similar to the civilian fire service with respect to requirements for protective equipment and medical support logistics.

This system can be used to remotely monitor the status of personnel who are wearing PPE, and is highly suitable to the needs of "confined space" applications where personnel cannot be visibly monitored. Industries such as fuel tank and aircraft maintenance, shipyards, mining, and utility services would all benefit from the features of the SCBA Oximetry system.

Numerous studies are conducted each year on the subject of heat stress, personnel response to wearing PPE, and other exercise and health models. SCBA-based Oximetry may be a suitable physiologic monitor for many of these studies. It may be used for direct, study data acquisition as part of a larger sensor suite. It may also find use in subject protection, with an alarm indicating the need to terminate testing and rehabilitate or medically evaluate the subject.

Scientific Report

Background

Firefighting involves heavy exertion with both dynamic (aerobic) and static, (anaerobic) components. This has been demonstrated through multiple studies measuring heart rates and oxygen demand of fire fighters. Examples of the activities involved in the initial attack on a burning structure include climbing ladders or stairs while carrying heavy tools or equipment, advancing charged hose lines of up to 2.5 inches in diameter, using chain saws or axes to ventilate roofs, using pike poles to breach and pull down ceilings or drywall, and carrying or dragging victims from the structure to safety. These activities are performed while wearing thermal and flame resistant personal protective ensembles (PPE) that quantitatively prevent evaporative loss of metabolic heat, in temperatures approaching or transiently exceeding 700° F (2). Firefighting PPE also includes self-contained breathing apparatus (SCBA). The SCBA is a demand-type positive pressure respirator worn in a backpack-style harness, and is responsible for about half of the 50 lb routinely worn by fire personnel. Firefighters also carry an additional 20-75 lb of equipment as they climb stairs, ladders or roof inclines. Fire incidents are unpredictable and require rapid intervention to save lives and property, precluding any possibility of 'warming up' as athletes routinely do before working out.

There is great variability in aerobic conditioning of firefighters, especially among volunteers who constitute 75-80% of the fire service. Many are smokers, overweight, or not physically conditioned to safely engage in this level or type of activity. Aerobic capacity is known to be the best predictor of heat tolerance in adults (3,4). The incidence of symptomatic heat-related illness on the fireground is unknown, though deaths directly attributed to this cause are rare. The importance of the combined physiologic stressors of firefighting can, however, be inferred from the disproportionate percentage of line-of-duty deaths due to acute myocardial ischemia (5,6).

Firefighters probably experience the following sequence of physiological changes during an initial fire attack. First, the combination of excitement and exertion required to don PPE cause the heart rate to increase (7-9). The heart rate virtually immediately reaches maximal levels as fireground tasks are begun (7-23). Muscular activity required to perform the tasks and intensified by the PPE load produces metabolic heat at the same time the firefighter enters the heated environment. Central blood volume is redistributed to the working muscles, as well as to dilating peripheral vasculature and sweating begins, but there is no effective heat loss due to the insulative properties of the fire fighters' PPE. Combined, these events should result in a very early decrement in stroke volume, and hence in cardiac output. Since the heart rate is already maximal, it cannot accelerate to compensate for the decreasing stroke volume, as occurs in aerobic exercise under normal climatic conditions. Sweating remains profuse despite its futility, and the core temperature rises (12,15), while ongoing fluid loss further exacerbates the decreasing cardiac output. These events are the hallmarks of uncompensable heat stress, and lead to exhaustion (24).

Uncompensable heat stress due to exercise in protective clothing has been studied using young military volunteers on treadmills in environmental chambers (24). Under these conditions, heart rates, core temperatures and oxygen demand rose more gradually than is seen in fire fighters. The so-called anaerobic threshold was reached much later in the military/treadmill tests than was observed in tests on fire fighters, where venous lactate levels begin to rise nearly concomitantly with onset of exercise. This is likely due to the high static load intrinsic to fire ground tasks. It was suggested above that in fire fighting, the heart rate reaches maximal so quickly that the predicted blood redistribution can only compromise cardiac output. This phenomenon has been reported by Smith *et al.* (12), who used immediate post-exercise 2-dimensional cardiac echo to estimate stroke volume based on aortic cross-sectional area.

Pulse oximetry is a well-established, non-invasive medical monitoring modality that measures arterial oxygen saturation through spectrophotometric techniques (25). The hardware utilized by these sensors has proven rugged enough to support application in extreme environments. Previous testing (26) indicated that the forehead is a suitable location for placing pulse oximetry sensors. In firefighters wearing SCBA, the requisite airtight face-to-mask seal maintained through a set of manually tightened head straps ensures continuous contact with the integrated sensors and decreases motion artifact, a common problem in clinical pulse oximetry. The value of continuous or real time pulse oximetry monitoring of firefighters, however, is questionable. Two parameters are derived from commercially available pulse oximeters: heart rate and oxygen saturation of arterial hemoglobin. Heart rates are known to be elevated and offer no known predictive advantage. Ability to sustain cardiac output would appear to be the limiting factor in work capacity of firefighters under conditions of uncompensable heat stress (24). Except in the presence of acute or chronic pulmonary pathology, ventilation is able to keep pace with oxygen demand until circulation becomes inadequate. Accordingly, arterial hemoglobin remains fully saturated until circulation is impaired, suggesting that changes in pulse oximetry in working firefighters would occur too late to serve as useful warnings on the fire ground.

In the critical care setting, subtler alterations in tissue perfusion are inferred by monitoring indirect indicators such as lactic acid production, biochemical markers of end organ injury and oxygen saturation of mixed venous blood. The latter parameter, while perhaps most sensitive, requires cannulation of the pulmonary artery and performance of co-oximetry on intermittently obtained blood samples. Once again, these markers would not appear amenable to real-time monitoring of working fire fighters.

Historically, non-invasive oximetry became clinically useful for monitoring respiratory status in the 1970's when it was recognized that regularly intermittent changes in the length of the oximeter's light path as it was transmitted through tissue beds resulted from arterial pulsations (25). Pulse oximeters now measure light absorption through living tissue via an alternating current (AC), or pulsatile, component and a direct current (DC) component see Figure 1. The percentage of oxygenated hemoglobin in the arterial compartment is reported after processing that essentially subtracts the static background absorption from the pulsatile component. The DC signal used by oximetry processors, but not reported by the device, represents static tissue absorption primarily due to hemoglobin in the venous and capillary beds. Early metabolic changes of hypovolemia and/or hypoperfusion, may, therefore, be detectable by measurement of changes in the DC signal.

Transcutaneous oxygen and carbon dioxide monitors were recently used as part of a non-invasive suite that also included pulse oximetry and estimation of cardiac output by thoracic bioimpedance. Data from this suite were found to correlate well with hemodynamic measurements by conventional, invasive devices in ICU patients (27). Analysis of the plethysmographic waveform generated by pulse oximeters was also found to correlate with volume status in mechanically ventilated patients under general anesthesia (28).

In pulse oximetry, different anatomic layers absorb the light transmitted by the light emitting diode (LED) and reflected back, primarily by bone, to the detecting element of the sensor (25). These include skin, with variable pigmentation, other soft tissue such as muscle and fat, arterial and venous blood. Light absorption increases during systole due to the increase in total hemoglobin contained in the transiently expanded arteries. This pulsatile, or AC, component generally amounts to no more that 2% of the total absorption in medical pulse oximetry systems and approximately 0.5% (from peak to peak within a cardiac cycle) of signal in our mask sensors.

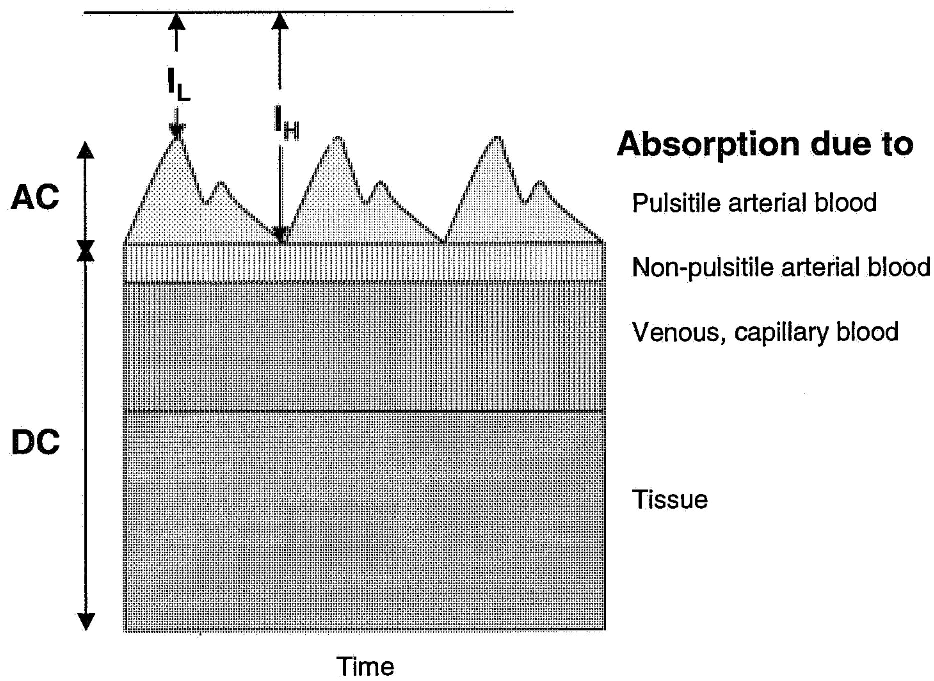

Figure 1: Contribution of various anatomic layers to total light absorption (y-axis) in pulse oximetry (redrawn from 25 and 26).

Because of the many variables that can contribute to the total absorption of light, commercial oximeters use a DC filtering circuit to remove this DC component, leaving only the AC signal, a plethysmographic waveform correlating to the rhythmic expansion of the arterial system with cardiac systole. Ratios of the amplitude between normalized versions of the red light and IR light are then used to calculate the oxygen saturation (SpO_2) value.

Table 1 Extinction coefficients for oxygenated and deoxygenated hemoglobin at Red and IR wavelengths (29)

Wavelength (λ), nm	Extinction coefficient (ε), L / (mmol · cm)	
	Hb (deoxygenated)	HbO_2 (oxygenated)
660 (Red)	0.81	0.08
940 (IR)	0.18	0.29

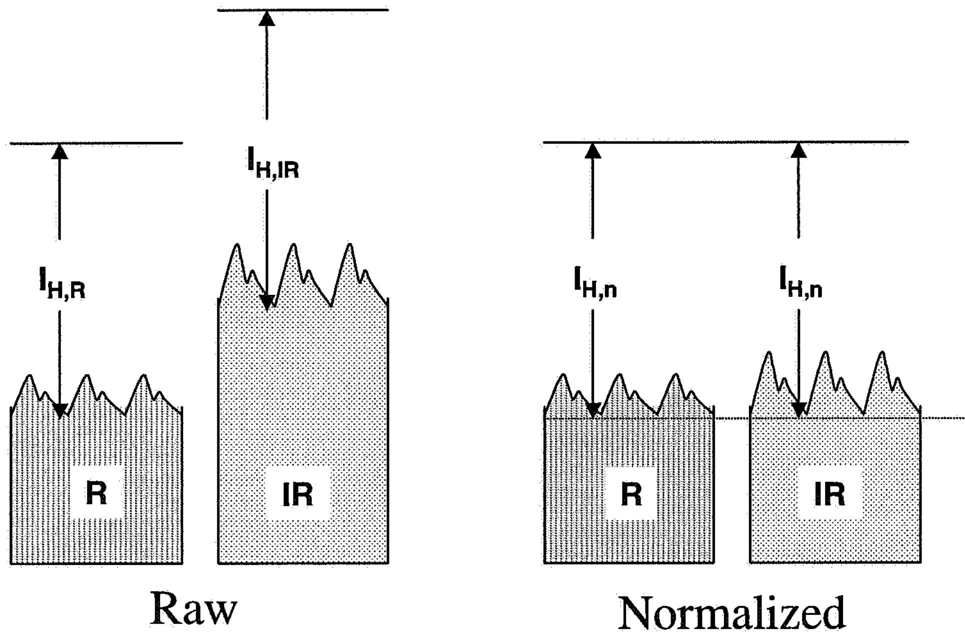

Figure 2: Ratio comparison and Normalization of red and IR signals. (redrawn from 29)

$$R = \frac{\ln(I_{L,R}/I_{H,R})}{\ln(I_{L,IR}/I_{H,IR})}$$ Equation 1

$$SpO_2 = \frac{\varepsilon_{Hb}(\lambda_R) - \varepsilon_{Hb}(\lambda_{IR})R}{\varepsilon_{Hb}(\lambda_R) - \varepsilon_{HbO_2}(\lambda_R) + [\varepsilon_{HbO_2}(\lambda_{IR}) - \varepsilon_{Hb}(\lambda_{IR})]R} \times 100\%$$ Equation 2

To estimate SpO_2, commercially available pulse oximeters compare the relative intensity of the Red and IR signals. This comparison allows us to distinguish between concentrations of oxygenated (HbO_2) and deoxygenated (Hb) hemoglobin. The Ratio R (Equation 1) is used to normalize the relative differences in the Intensity I of the Red and IR signals at both the high I_H and low I_L points (Figure 1) of the pulsatile (AC) component of the transmitted/reflected light intensity. The extinction coefficients ε of light for a given frequency of light ε(λ) passing through oxygenated (HbO_2) and deoxygenated (Hb) hemoglobin are used in combination with the Ratio to provide the final estimate of SpO_2 (Equation 2)(29).

It was hypothesized that the DC, or nonpulsatile component of transcutaneous oximetric monitoring would reflect earlier physiologic changes indicating that firefighters were nearing exhaustion of their cardiovascular compensatory mechanisms. This could result from decreased oxygen saturation of hemoglobin in the venous, capillary and other non-arterial tissue compartments consistent with previously observed elevations in venous lactate levels. Changes in DC oximetry might also indicate changes in blood volume circulating between the sensor's emitting and detecting elements due to vasodilation, constriction or generalized hypovolemia.

Specific Aims

Remote, non-invasive medical monitoring to identify physiological parameters that indicate exhaustion of normal compensatory mechanisms could prevent cardiovascular collapse, symptomatic heat illness and other adverse clinical outcomes. This type of monitoring, in real time, offers significant technical challenges. The sensor system must support rapid data collection, processing and effective transmission over sufficient distances to monitor personnel operating in hazardous environments. These sensors must continuously access biological signals, and must perform in severe environments without adding significant additional weight, impeding dexterity or compromising mobility of the wearer. The main objectives of Phase 1 of this project were:

1). To develop reliable, functional hardware (quality beyond prototypes), including sensorized SCBA facemasks, as well as hardware for processing, archiving, transmitting and displaying oximetry signals.

2). To use the hardware to collect data necessary to demonstrate the feasibility of oximetry monitoring during structural fire fighting,

3). To conduct a preliminary assessment of the utility of DC oximetry monitoring of firefighters through IRB-approved, experimental fire task simulations under controlled conditions.

Methodology

Sensorization of SCBA Facepiece

Signal Strength vs. Sensor Separation

Depending upon the manufacturer, commercial reflectance mode oximetry sensors generally have a space of about 1-inch between the sensor emitter LED's and the photo-detector. The sensors used in our masks are adapted transmission sensors (like a finger probe). They were selected because they are configured such that they can be flush-mounted through the rubber facepiece reflection that contacts the forehead, while their wiring and electronics fit into the space between the hard, transparent mask and the rubber reflection. The separation distance between the emitting and detecting components therefore had to be empirically determined for use in reflectance mode. The optimal distance between the LED emitters and detectors at the particular angle (T) imposed by the contour of the mask fitting the forehead (Figure 3) was determined using three volunteer subjects with differing face shapes and skin characteristics.

Sensors were placed on the subject's forehead in a darkened environment. The separation distance of the sensors (center to center) was then measured. The intensity of the signal was measured using an oscilloscope across the amplified photo diode circuit (Figure 11) output. Three measurements were taken between 5 and 10 seconds apart to allow complete extinction of the previous signal between measurements. This process was repeated for several separation distances between 14 mm and 60 mm (Figure 20).

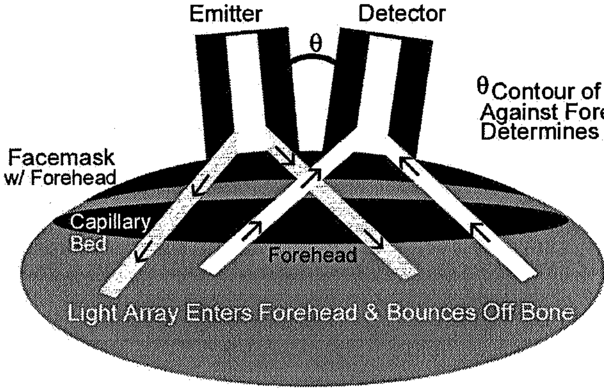

Figure 3: Diagrammatic representation of sensor placement for reflectance mode oximetry in firefighters' SCBA. Optimal distance of the emitter element from the detector element was empirically determined.

Mask Fabrication

BioAsyst, LLC looked extensively into oximeter sensor processor technology from Novametrics, Datex-Ohmeda, Nonin, Nellcor, and BCI. Of these technologies, the sensor elements used by BCI (Waukesha, WI) and manufactured by Quantum Devices (Barnfield, WI) was selected for this application.

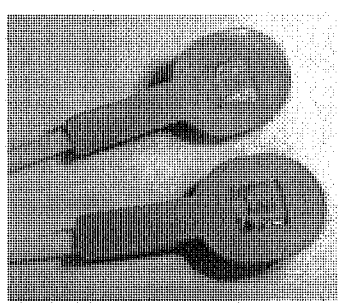

Figure 4: "Y" probe oximetry sensor elements

One of the most significant challenges to this project was integrating the sensor elements (Figure 4) into the mask in such a way that 1) The airtight seal is not compromised, and 2) The sensor elements are flush to the mask seal. If the sensor elements do not contact the forehead of the wearer, the data will be inaccurate or the sensor may not work. If the sensor elements protrude from the mask seal, it is extremely uncomfortable to the wearer.

Spirotroniq[R] S model SCBA face masks were provided by Interspiro, Inc of Branford, CT. Using the optimal separation for the two sensor elements previously determined by BioAsyst, the BCI oximetry sensors were added to the reflected rubber lining of the face piece that forms the seal with the wearer's forehead by Quantum Devices, Inc. (Figure 5). They were mounted to the opposite side of the lining with heat stable glue and similar rubber backing. The space between the forehead reflection and the clear shield attachment to the face piece provides a channel to accommodate the bulk of the LED emitter and detector components as well as the wiring. The wiring exits near the attachment of the low-pressure air line so that it can be easily added to the wiring bundle already prototyped by Interspiro, Inc. This is designed to run with the low pressure line, over the shoulder to an electronics box attached to the base of the SCBA harness.

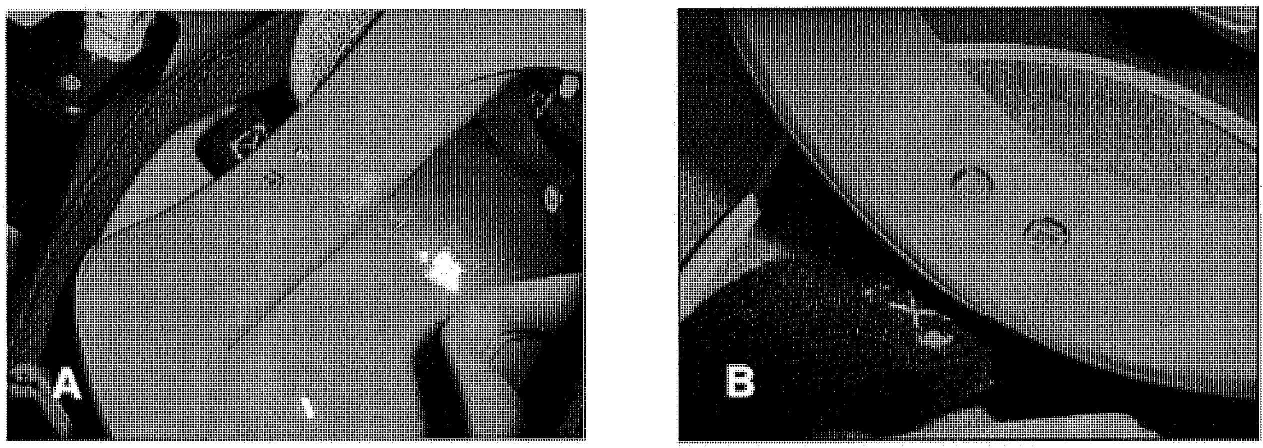

Figure 5: Sensor integration into SCBA mask. Panel A shows red LED with power on, and demonstrates position of the sensor elements in the forehead reflection. The clear shield and nose piece are also seen in this view. Panel B is a close-up view of the sensor elements showing that they are flush with the surface of the mask. If they were recessed, there would not be reliable skin contact for oximetry monitoring. If they protruded, the seal could be compromised and the mask uncomfortable to wear

Mask Integrity and Comfort

There are three critical areas of verification to ensure that the sensors have been properly integrated into the SCBA mask. First, the mask must be tested to verify that the data from the sensor elements correlate to data acquired by conventional oximetry sensors. Each of the trials using human subjects included a 1-2 minute period at the end of exercise when the volunteers wore both finger probe and mask-based oximeters. Experimental protocols and data are detailed below. Second, the mask must be formally tested to verify that the airtight seal has not been compromised and that its respirator functions are intact. Finally, users must wear the masks without discomfort from the sensor elements. The latter tests were subjective and performed through a simple survey during clinical trials in the environmental chamber. No wearer discomfort was reported and the sensors did not leave impressions on the wearers' foreheads, as had been the case with previous prototypes that were distinctly uncomfortable to wear for more than a few minutes.

To confirm that the post-manufacturing modification of the SCBA face pieces did not compromise their integrity as life safety devices, they were returned to Interspiro, Inc for automated, functional testing (Figure 6).

Figure 6: SCBA mask with integrated sensors and output wiring undergoing NIOSH compliant testing for seal integrity and respiratory function, courtesy of Interspiro, Inc., Branford, CT.

Electrical Protection of Sensor Elements

One factor that was shown to compromise the sensor signal was sweat. Sweat introduced two problems to the system. The first was that as the quantity of sweat between the detector and forehead increased, increased signal absorption was observed. This increased absorption was marginally greater in the IR than in the visible red tracing (data not shown). The second problem was that the sweat became sufficient to short-circuit the detectors and/or emitters, causing the system to read as if the sensor had become disconnected in some subjects during exercise.

The problem with sweat causing a short in the sensors first became apparent during physiologic experimentation with firefighter subjects when sudden loss of data from the sensorized masks occurred. Investigation of the problem afterwards in the engineering lab reproduced the effect using water.

A number of waterproofing solutions for sensor protection were tried and evaluated. No commercially available sealants combined optical transparency with the pliability needed for this application. Clear tapes compromised the comfort of the face fit with focal loss of elasticity. They also lost adhesion and allowed condensation to build up on the sensor side of the tape when exercising subjects started sweating. To improve elasticity and provide a vapor-permeable water barrier, Tegaderm^{R} (3M) dressing was used to protect the sensor window.

Development of Oximetry Processing Boards

Initial Processor Prototype

A pulse oximeter sensor is basically two diodes (red and infrared) that are turned on and off in rapid succession. The sensor also has a photodiode; it outputs a changing current value that is directly proportional to the amount of light to which the photodiode is exposed. A commercial unit completes some signal processing and analysis to calculate the arterial oxygen saturation and pulse rate of the patient. A commercial pulse oximeter's outputs are the oxygen saturation, pulse rate, and AC signal. To obtain a DC plethysmograph wave from a commercial pulse oximeter, a new circuit that utilizes a commercial pulse oximeter sensor, but not its controlling circuitry, had to be constructed.

Our initial plan was to modify a commercial oximeter system and to send its signal into our data processing algorithm. The board is a small, lightweight, low power system that accepts sensors from a variety of vendors. This approach would allow us to use the oxygen saturation tables already generated by the vendor to provide an oxygen saturation (SpO_2) value in addition to our desired "DC" values. The BCI OEM pulse oximeter board (Figure 7) was reported to provide access to both the SpO_2 values and the "full" plethysmographic wave.

The initial prototype generation of the oximetry system was therefore based on the OEM pulse oximeter board from BCI, Inc. This board has three primary operating protocols that are determined through jumper settings. Each of the different protocols provides a variety of options and advantages. For the operation of this prototype, a protocol that communicates through an RS-232, 3 wire, 19200 baud, even parity, 1 stop bit, 8 data bits interface was selected. The SCBA masks are fitted with 9-pin sub-miniature D connector that can connect directly to oximeter processors from BCI, Nonin and Nellcor. Because most manufacturers use a "lookup table" to translate the IR to red signal ratio into oxygen saturation (SpO_2) levels, it is important to note that the accuracy of the calculated SpO_2 value must be re-calibrated when using sensors and processors from different manufactures.

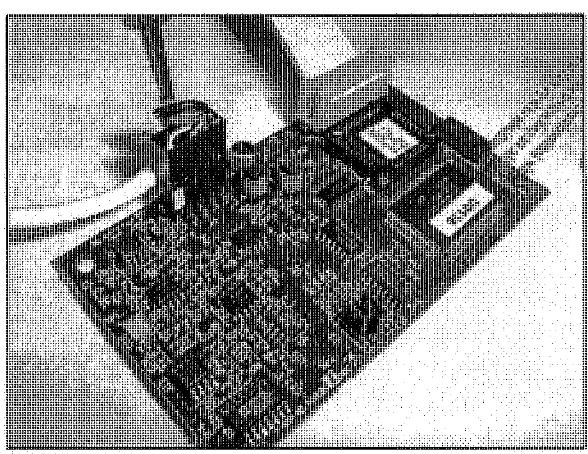

Figure 7: BCI OEM oximetry board

A serial cable was tethered between the oximetry processor board and a laptop computer for the present studies. The laptop computer operates in a "terminal" mode capturing a byte data stream from the oximeter processor. Using the BCI OEM board's protocol 2, the board generates 5 bytes at a rate of 120 Hz. Contained within the data packet are signal strength, the subject's heart rate (HR), the calculated SpO_2, the value of a plethysmographic wave, several bits of operating status and bits used to confirm the current averaging rates and scaling status as well as a data packet validity checksum. There is also a single bit used to indicate when the processor has calculated that a heartbeat has occurred. These data are currently kept in byte form while generated and used as a source file for analysis after a test protocol is completed.

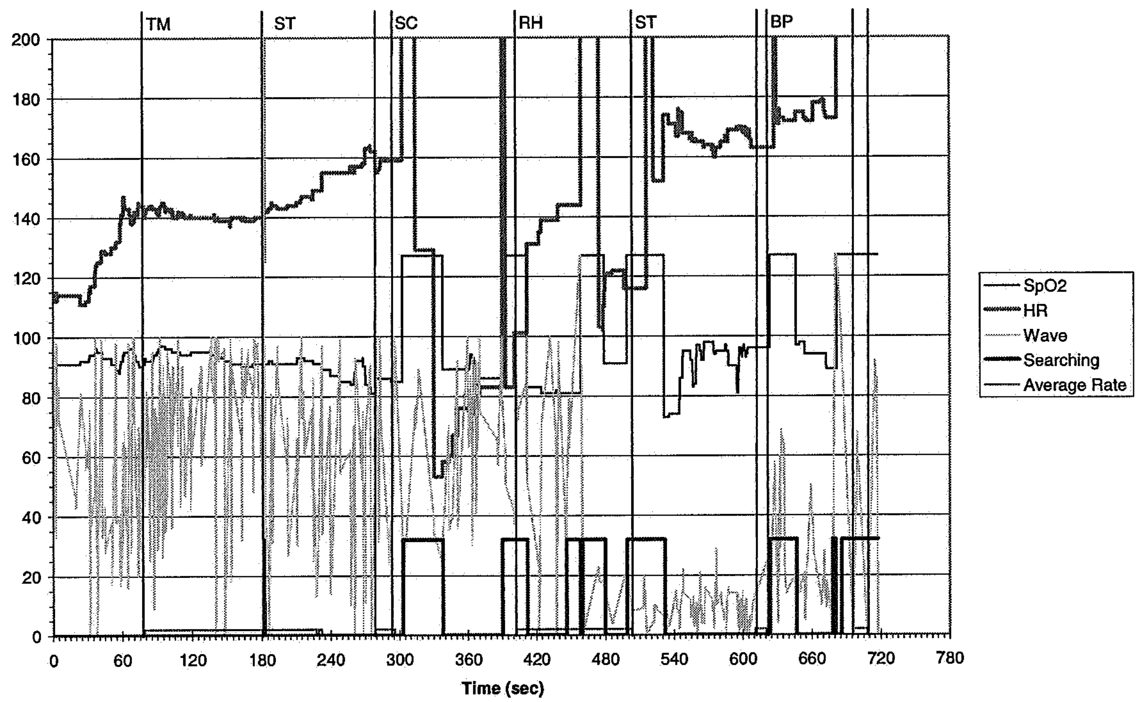

Figure 8: Data from subject performing the firefighting simulation protocol, acquired using initial prototype processing board hardwired to laptop computer carried by investigator to maintain proximity to subject. Note inability of the system to detect heart rate (HR) for minutes at a time, unreliable oxygen saturation values, widely variable plethysmographic wave and indication that system is 'searching' for signal over significant time periods.

There were a number of lessons that we learned testing this initial prototype. First, there was no easy solution for transmitting the board's output, and the nature of the fire fighter's activity during our clinical trials precluded hardwiring data acquisition system, worn by the subject, to the data analysis system housed in a laptop computer. Secondly, the full plethysmographic wave did not correspond to the "DC" component, or that feature was incorrectly implemented in the BCI OEM board. Finally, even with the improved sensor placement within the mask, the nature of the physical activity of the subjects caused frequent stretches of time during the clinical trial (Figure 8) where the BCI OEM boards algorithms could not accurately determine the SpO_2 or Heart Rate values. These times are designated by the "Searching" variable within the figure.

Digital, Transmitting Processor Prototype

Due to the numerous limitations of the adapted OEM board for processing the oximetry signal, and the lack of any suitable, commercially available alternatives, the decision was made to design and build our own processor board. This board would include output compatible with a radio transmission system, a transmitter, and would be optimized for DC signal acquisition.

In order to correlate the changing current to the amount of light being absorbed by the blood, the current needs to be translated into a changing voltage level. The photo diode of the oximeter sensors behaves electrically as a current source. For our purposes, to convert a signal output from its analog component to a digital value, the signal must be a voltage within the range of the Analog to Digital (A/D) converter's response range (typically 0 to 5 volts). Figure 9 provides a general design for an ideal current-to-voltage converter (30).

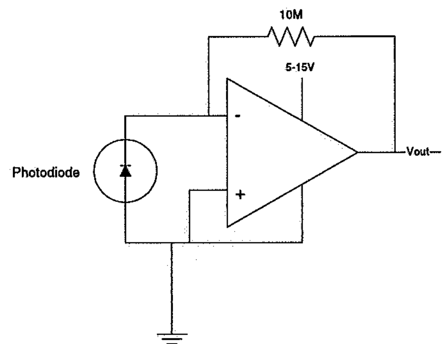

Figure 9: Ideal Current to Voltage Converter

If the input to the above circuit is the photodiode in the pulse oximeter, the voltage output is expected to be a DC signal coupled with an AC signal. The voltage output is very susceptible to noise from the surroundings, especially the 60Hz noise from power lines, other machines and lights. The use of a low pass filter will remove some of the 60Hz noise without affecting the signal. The frequency of the AC signal is below 5Hz and is usually around 1Hz. Figure 10 demonstrates the configuration used to implement a low pass filter.

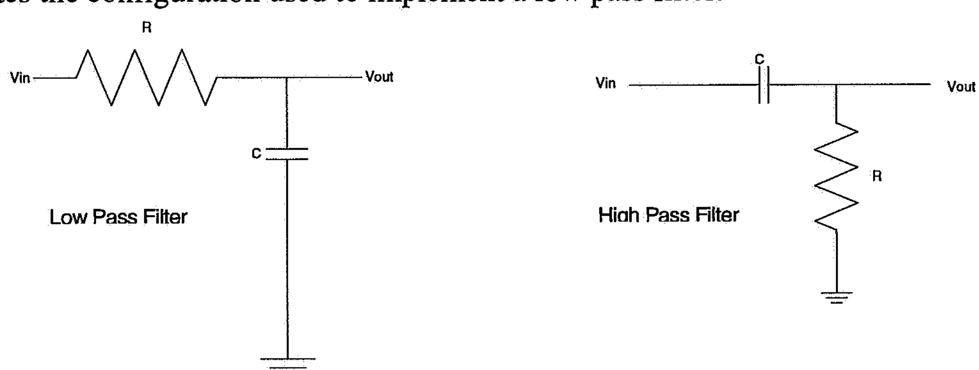

Figure 10: Low Pass Filter and High Pass Filter

The values of R and C can be determined using the following equation:

$$f_{3dB} = \frac{1}{2\pi RC} \qquad \text{Equation 3}$$

Using Equation 3 and switching the values of the resistor and capacitor of a low pass filter, a high pass filter can be constructed to see the pure AC signal without interference from the DC signal.

The final analog portion of the constructed circuit is found below. A filter frequency one order of magnitude smaller is needed in order to filter out most of the 60Hz noise. For the low pass filter, a filter frequency value of 6Hz was chosen. This filter is not a corner filter so there is not an immediate cut-off at 6Hz; instead, the values above the chosen frequency are attenuated. The higher the frequency value, the more a signal gets attenuated. The capacitor was designated to be 10uF due to availability; the resistor value was calculated to be 2654Ω. A resistor with a value of 2.7k Ω was used. Two low pass filters were used in order to further reduce the noise in the signal.

An optional high pass filter may be placed in series after the two low pass filters if one wishes to view the AC signal without being saturated by the DC signal. A frequency of 0.001Hz was used in Equation 3 to calculate the R and C values for the high pass filter. This frequency value ensures that the filter will have very little effect on the AC signal when removing the DC signal. Again, setting the capacitor value to 10uF, the resistor value was calculated to be 15 MΩ. A 10MΩ and a 4.7MΩ resistor were used in series to create the required 15MΩ.

Two inductors are added in order to prevent the introduction of noise from the digital portion of the circuit, which houses the processor, to this noise sensitive analog circuit. To further reduce the noise, the circuit was constructed on a perforated board that had an isolatable ground plane. A circuit design of the analog portion of the constructed pulse oximeter circuit is depicted in Figure 11.

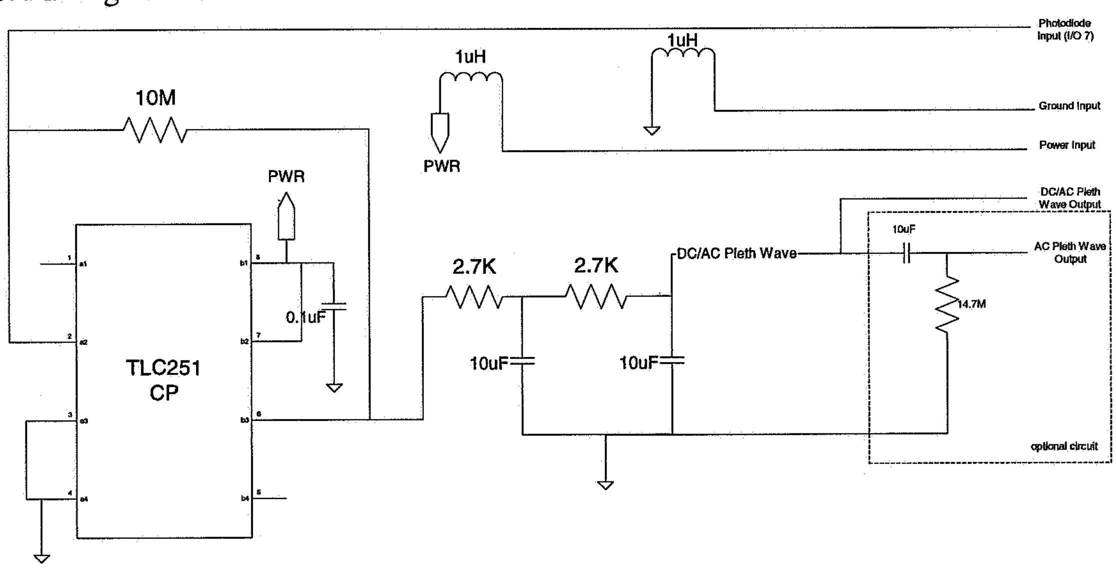

Figure 11: Analog Pulse Oximeter Circuit

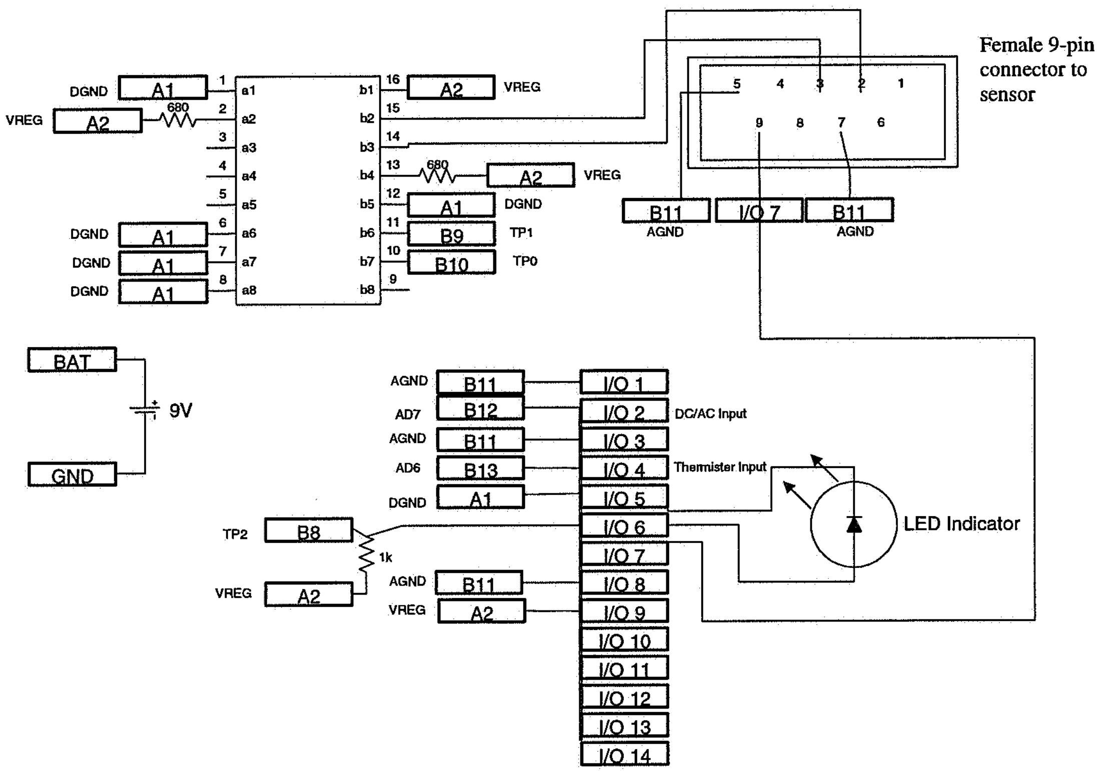

Figure 12: Digital Pulse Oximeter Circuit

The digital portion of the pulse oximeter circuit (Figure 12) was constructed on the I/O 8 board that accompanies the Tattletale Model 8 processor (Onset Computers). The digital portion includes the 9-pin connector to the sensor, a MUX chip used to select if the IR or Red LED on the sensor is activated, battery power supply, and the input/output interface to the analog board.

A complete parts list of the components necessary to construct the pulse oximeter circuit is found in Table 2. A complete circuit schematic on how to assemble the pulse oximeter circuit can be obtained by combining Figure 11 and Figure 12.

Table 2: Pulse oximeter circuit parts list

Part	Quantity	Comments
Resistor- 10 M (5%)	1	
Resistor- 10k (1%)	1	
Resistor- 2.7K	2	
Resistor-1k	1	
Resistor- 680	1	
Capacitor-10uF	2	
Capacitor- 0.1uF	1	
Inductor- 1uH	2	
TLC251 CP	1	
MM74HC4053N	1	
Generic LED (power indicator)	1	
14 Pin Header	2	part #: A102-ND (Digikey)
Wire wrapping Component Mount	4	part #: V1059-ND (Digikey)

14 Pin Wire wrapping Socket	3	
16 Pin Low Profile Solder Chip Mount	1	
Perforated Board with common ground plane	1	
Conn DB9 Female Gold Plastic Shell	1	Part #: CFP09G-ND (Digikey)
Submini Slide Switch	1	Part #: 275-407 (Radio Shack)
Tattle Tale I/O 8 board	1	
Tattle Tale Model 8	1	
Persistor Memory Board	1	
9V Battery	1	
9V Battery Clip	1	
Enclosure- 6"x3"x2"	1	part #: 207-1805 (Radio Shack)
BCI Compatible Pulse Oximeter Sensor	1	Manufactured by: Quantum Devices
Parts of Optional Circuit		
Resistor- 10M	1	
Resistor- 4.7M	1	
Capacior- 10uF	1	

A commercially available pulse oximeter sensor is connected to the device using the 9-pin, sub-miniature-D connector port. This circuit configuration allows software to control which of the two LEDs (red or IR) in the sensor is powered, as well as the duration of the power.

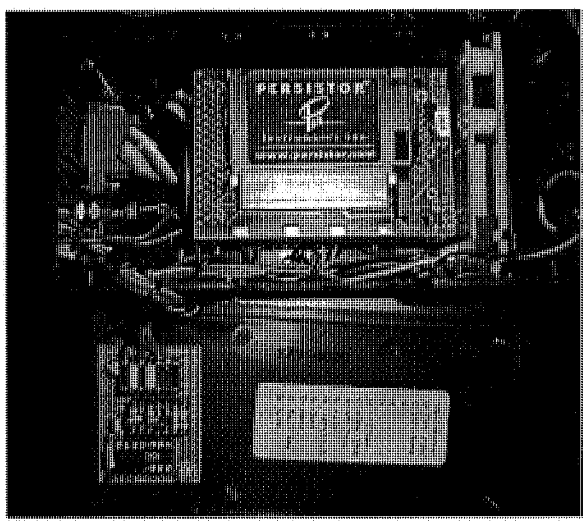

Figure 13: Final prototype data acquisition system, designed and built by BioAsyst.

The use of a single frequency of light as opposed to both visible red and IR light frequencies was debated in view of what we wanted to study and in the context of our processing hardware limitations. One of the original parameters we had planned to analyze was heart rate variability (HRV). To this end, it was necessary for the data acquisition system to reconstruct waves with a signal sampling frequency in the order of 200 Hz. The Tattletale processor could not acquire signals at this rate and perform the other essential tasks. To compensate, we began the system of acquiring data for 20 seconds, then processing it for 10 seconds, and repeating the process. Using this method, each 20-second block was sampled at a rate of 250 Hz (5000 samples in 20 seconds). The process of switching between the red and IR LEDs, however, would have significantly shortened this sampling frequency. Since other testing indicated that the red light was more robust and generally had greater "AC" amplitude necessary for HRV analysis, this was the selected frequency. Commercial oximeters, although they use both red and IR signals to calculate the SpO_2 value, only display one of these values as the plethysmograph wave.

"Red & IR" Data

In our original configuration, we desired to maximize our data acquisition frequency. As a result, we were able to gather data at 200 samples per second. At that speed, however, we could only use one light frequency at a time. After evaluating the signal strength of both the red and IR signals, we decided that the red LED provided the more robust signal.

One consequence of selecting a higher frequency of a single wavelength was that we would no longer be able to generate the estimated oximetry values typically used for medical diagnostics. However, as our primary interest was in the DC component of the light absorption signal, this provided adequate output for signal analysis.

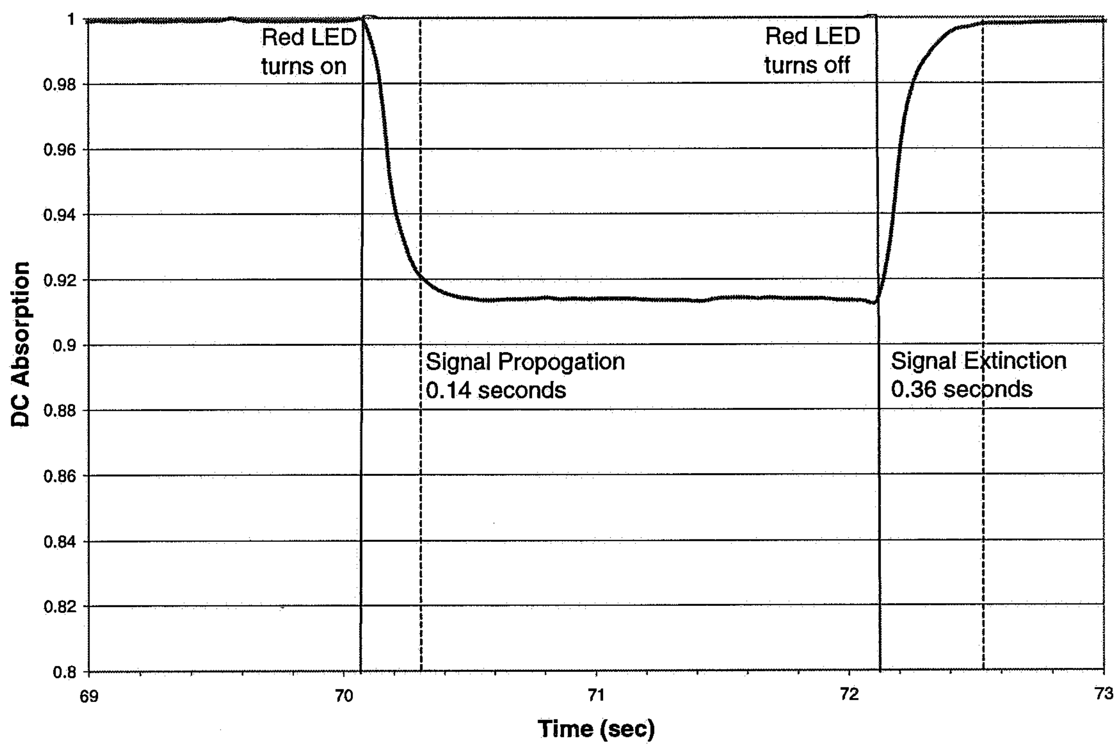

Figure 14: Time duration required for signal propagation from LED activation and signal extinction from LED deactivation

In some later comparative testing, we wanted to get a better interpretation of the differences between the red versus the Infrared signal. One of the difficulties we encountered was that from the point where either the red or IR LEDs were turned on, it took a small amount of time for the signal to stabilize. Furthermore, as each LED was turned off, it took a small amount of time for the signal to dissipate (Figure 14). The design of the oximetry system is such that a single photo detector is used to detect both the red and infrared light. To ensure that the un-dissipated light from the red LED did not affect the signal of the IR LED and vice versa, the switching had to be optimized to allow sufficient time for signal dissipation and stabilization before reading were taken. Using this method, we were able to program our prototype system to acquire two samples of each light frequency per second. An example of this data is shown below in Figure 15. To accomplish this the data acquisition frequency was reduced.

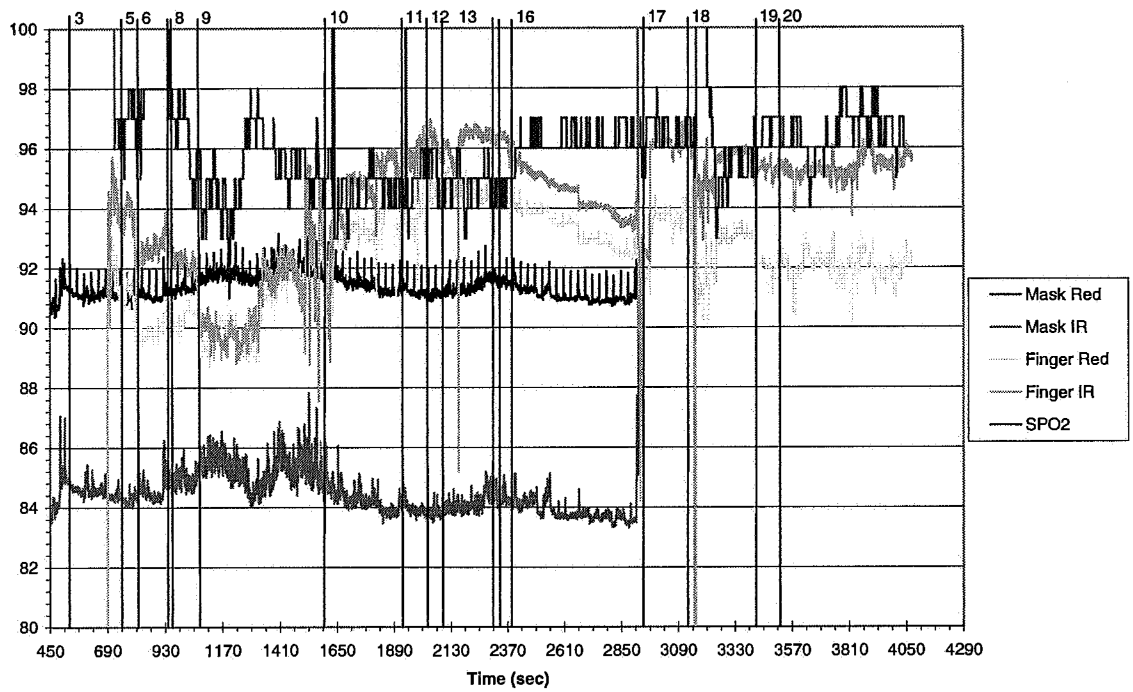

Figure 15: Data from treadmill run with mask and finger probes using red and IR emissions in the sensor. Time markers denote various changes in the physical activity of the subject or performance of the system.

In this particular example, the system was run simultaneously on both units. One was connected to the mask-based sensor and the other connected to a finger probe on the same subject while the subject was on a treadmill. About every 30 seconds there is a periodic spike in the mask red data that is an artifact resulting from turning on the red LED too early each time the acquisition loop is started. The acquisition loop takes about 30 seconds and acquires 60 red and 60 IR data points.

Experimental Model for Structural Firefighting

Development of a valid simulation for device testing

The SCBA mask-based oximetry system was tested using fire fighters performing simulated fire ground tasks under the controlled conditions of an environmental chamber. The chamber is one of several located in the John B. Pierce Laboratories at Yale University, and provides roughly 1,680 ft^3 of uniform, precisely controlled temperature and humidity conditions for conducting thermal stress experiments. The apparatus and equipment required to complete the simulations were arranged within the chamber to facilitate sequential completion of the tasks. Two investigators, one monitoring data acquisition and one prompting the fire fighter through the protocol while observing for hazards or signs of clinical decompensation, were present inside the chamber throughout each experiment.

To establish individual baselines for each subject under conditions where normal evaporative cooling was possible, the protocol was performed once with the participant wearing gym shorts, T-shirt, and SCBA, and the chamber temperature set at 65° F. An identical trial in full PPE and with the chamber maintained at 104° F was also performed on a different day by each fire fighter to assure technical feasibility and reliability of the equipment under these conditions. Chamber humidity was maintained at 45% with both temperatures. The temperature of the heated chamber was significantly lower than that encountered during structural fire fighting. It was selected to give a large margin of safety to the human subjects participating in the studies, precluding any danger of burns, which are regularly suffered in the line of duty despite the protective ensemble worn by fire fighters. For purposes of this study, an ambient temperature of 104° F was felt to be adequate to ensure that subjects, especially while wearing full PPE will not be cooled by passive release of metabolic heat through the skin into the environment.

It should be pointed out that full SCBA was worn and used by all subjects during protocols in both the heated/PPE and cool/No PPE conditions. It would have been possible to use the sensorized SCBA facemasks to monitor the subjects without carrying the rest of the apparatus or breathing the compressed air. This approach was considered since the SCBA is part of the PPE ensemble, and does add significant weight to the firefighter as well as increasing work of breathing when it is worn. It was found, however, that work of breathing through the facepiece with the breathing hatch open to ambient air was perceived to be the same as on compressed air, and still increased compared to no breathing apparatus. Furthermore, breathing compressed air through the facemask has a cooling effect on the face that alters subjects' perceived heat stress and exertional strain. Since a main objective was to demonstrate that the experimental sensor suite could distinguish heat stressed from non-stressed individuals, and the most important contributors to this difference should be the chamber temperature and thermal insulation worn by the subjects, the decision not to vary the breathing apparatus between the two trials was made.

The exercises and their sequence are roughly equivalent to the work that would be performed while consuming the first two cylinders of air on a fire ground. The practice of enforcing rest and rehabilitation of fire fighters after the second bottle is widespread in the fire service (31). The protocol was also designed to reproduce some of the emotional stimulation associated with working on the fire ground.

The total protocol and the individual tasks were defined by their relevance to actual fire fighting tasks. For example, the high rise hose pack used in task 3 comprised 3 connected 50 foot lengths of 1 ¾" canvas jacketed hoseline harnessed for carrying over the shoulder with webbed strapping. This is the standard configuration for hose carried by fire fighters to obtain water from standpipes in multi-storied buildings. The combination of walking and climbing for approximately 4 minutes was based on estimates of time taken to get from fire apparatus or nearby hydrants to the interior fire floor of commercial, multiple storied structures. The search pattern described in task 5 was based on that used to locate victims in degraded visibility due to smoke and/or darkness, and the environmental chamber was approximately the size of a room inside a typical residential occupancy. The rescue dummy was probably light compared with most U.S. adults. The effective weight of this loosely packed sand dummy normally used by fire personnel in training evolutions was greater because of its unwieldy limbs and the requirement that it be dragged over the uneven chamber floor or carried like an unconscious victim.

Fire fighting activities, after initial knockdown of the free burning phase and search of the occupancy for victims, focus on activities collectively known as overhaul. On the fire ground, these activities expose building compartments where unapparent fire may still be smoldering. The breach and pull apparatus used to simulate this phase of fire fighting was custom built for these studies, and is a smaller version of the Molitor Machine[R] developed for use in the standard, fire service Candidate Physical Agility Test (CPAT). The CPAT and each of its tasks were validated as essential job tasks for interior structural fire fighters by a joint labor-management fitness and wellness initiative commissioned by the International Association of Fire Fighters and International Association of Fire Chiefs. Under the same initiative, the counter-weights used in the breach-and-pull apparatus were determined by strain gauge analysis of the force required to penetrate and dislodge standard gypsum board walls and ceilings with a pike pole. The modified apparatus developed for the present studies is shorter than the proprietary Molitor Machine, due to height constraints of the environmental chamber, and was built with permission and assistance of the original inventor. It requires the subjects to perform the pike pole work on their knees (Figure 5), as if they were working in crawl spaces, which is not a rare occurrence in fire suppression. Total elapsed time to complete the study protocol approximates the CPAT, as well.

Experimental Protocol

The Yale University School of Medicine's Human Investigation Committee (IRB) approved these studies. The investigators obtained informed consent from each subject prior to participation in the study. All participants were Class A (interior structural) fire fighters and members of the Branford Fire Department, Branford, CT. All had unrestricted, NFPA compliant (32) medical clearance for full fire fighting duty from the Yale Occupational and Environmental Medical Program, within one year of participation in the study. Fire fighters taking beta-blockers or digoxin were ineligible to participate as their physiologic responses to exercise and/or stress could be blunted by these medications.

On study days, each off duty fire fighter scheduled to participate in that day's protocols was queried by a physician investigator regarding present health status prior to ingestion of the CorTemp[R] capsule. Of the 10 subjects recruited for the study, one was disqualified after he developed symptoms of gastroenteritis the preceding night. Saliva alcohol analysis was also performed prior to initiating the day's study. No firefighters were disqualified by oral temperature greater than or equal to 99.5 ^{o}F or a non-zero alcohol reading.

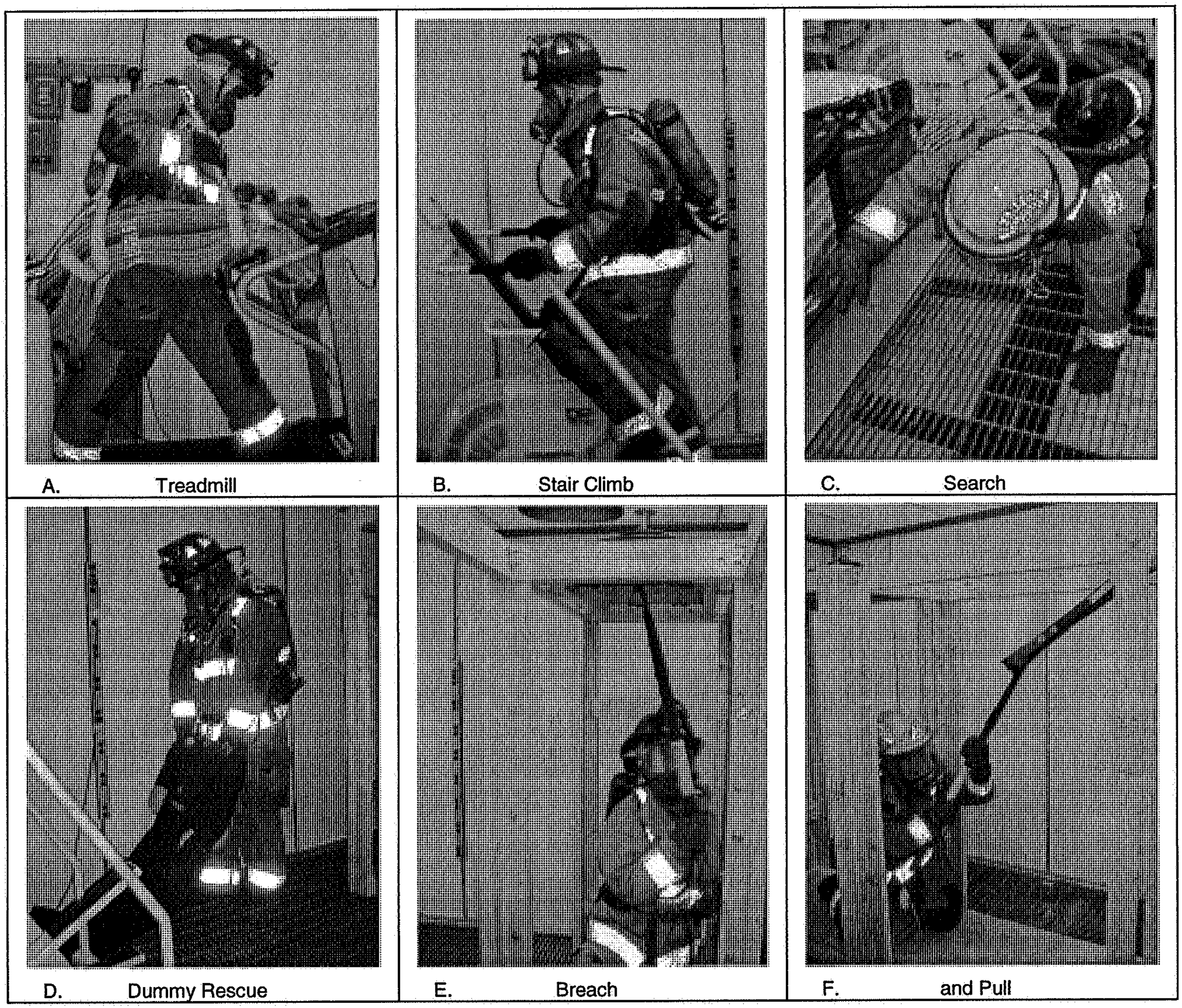

Figure 16: Subjects with apparatus and props used in firefighting task simulation protocol, shown inside the environmental chamber. The search and rescue evolutions were performed in the dark.

Ten firefighters between the ages of 20 and 50 went through the protocol (Figure 16) twice. When a loud alarm sounded, the subject donned turnout gear including SCBA as rapidly as possible, according to established practice, then picked up a harnessed 50 lb high rise hose pack and entered the chamber. Carrying the hose pack, the subject walked on a treadmill at 4 mph, 2% grade for 2 minutes, then dropped the hose pack and stood or walked for a transitional minute. The subject then proceeded to the stair climbing apparatus for an additional 2 minutes, followed again by a 1-minute recovery period. The subject then was directed to the door of the chamber where he was given a standard task force nozzle attached to a 50' length of 13/4" canvas-jacketed hose line that was bundled with duct tape for safe handling, and the lights inside the chamber were turned off. The subject then performed a right hand search around the periphery of the darkened 12' x 12' chamber while pulling the nozzle with him. With the chamber still dark, the subject dragged or carried a 120 lb rescue dummy from the corner where it was found during the search, back around the periphery of the chamber, and out of the door. Outside the chamber, the subject dropped the dummy, and rested as SCBA air cylinder change was simulated. The subject then re-entered the chamber, repeated the stair climb as above, again recovered for one minute, then performed a pike pole simulation consisting of pushing and pulling a breach and pull apparatus to volitional fatigue. The individual then exited the chamber and spent 1-2 minutes sitting in a chair with both SCBA and finger probe oximeters in place. All PPE was then removed and the firefighter rehydrated with oral water ad lib while clinical parameters were monitored until heart rates and temperatures had returned to normal. A minimum of 1 week separated each firefighter's first and second trials in the environmental chamber. This ensured that the first CorTemp capsule had been excreted and could therefore no longer transmit an interfering signal prior to ingestion of a capsule for the second trial.

Monitoring and Telemetry

Core Temperature

CorTemp® capsules, originally developed by the Applied Physics Lab at Johns Hopkins University in collaboration with the NASA Goddard Space Flight Center, were purchased from Human Technologies, Inc. Each ingestible, 2 cm, silicone coated capsule remains in the human digestive tract for about 3 days and contains a quartz thermo sensor, micro battery and telemetry system. The vibration frequency of the quartz correlates directly with ambient temperature. The resulting magnetic flux transmits a signal to the integrated triaxial antenna, which in turn sends it to a recording device. The capsule is FDA-approved, and is accurate to 0.1°C. One capsule was ingested by each firefighter 3 hours before his scheduled chamber time. The FitSense® monitoring system includes a pager-sized receiver/recorder worn on the belt. The core temperature monitoring system is commercially available and was generously loaned to the investigators for these studies.

Upon completion of the experiment and the rehabilitation and rehydration, the data from the CorTemp monitor was downloaded onto a portable PC and the monitor reset to acquire data from the next subject. Data was acquired at a frequency of one sample each 15 seconds. Data was generally acquired for about 10 minutes before the subject started the protocol through about 30 minutes of rehabilitation following the protocol.

Oximetry Data Capture

The prototype data acquisition system, as described earlier, is based upon a Tattletale Model 8 processor board (Onset Computers, MA) and our own custom signal processing circuit. The processor further utilizes a compact flash media card socket from Persitor to provide data storage. Compact Flash data cards with a 64 MB capacity were used to store the oximetry data. These cards provided more than an adequate amount of storage space for these trials. Raw data files were typically under 1 MB with comma separated value (CSV) files ranging between 4 and 8 MB in size.

One of the two prototype units would be connected to the subject's SCBA mask during the protocol. The second unit would be connected to a finger probe sensor that would be worn by the subject upon completing the protocol. The two units would operate simultaneously for about 1½ to 2 minutes before the subject removed the SCBA mask and that unit was turned off. The unit connected to the finger probe would then be used to monitor the subject through rehabilitation and rehydration until the subject was discharged from the study.

The raw form of the data was not suitable for direct analysis. A series of data conversion programs were developed using the Perl programming language to convert the raw form of the data into the full comma separated value (CSV) file and into a comma separated value (CSV) file for the 10 second mean DC data values. Time markers were then used to correlate the subjects' activities with the data time stamps in the CSV files. This data conversion was done once the subject had finished the experiment and the data cards were removed from the data acquisition system and installed into Microsoft Windows™ based portable computer, where the data conversion software was run and the data cards were cleared for their next use and reinstalled into the prototype Data Acquisition system.

Telemetry

The nature of the exercise protocol was such that it was not practical to tether the data acquisition system to a display in order to allow real-time monitoring of the subjects' data. However, without some form of real-time monitoring, it would not be possible to assess if the system was operating properly until after a subject had completed the trial. Thus it became necessary for us to introduce some form of wireless telemetry to the unit. A small, short range (<100 ft) 300 baud serial radio transmitter was connected to the prototype data acquisition system. An algorithm was then developed such that at the end of each data acquisition cycle (20 seconds) a 2 second sample of the data (Figure 19) would be transmitted to a receiver connected to a Microsoft Windows™ based portable computer.

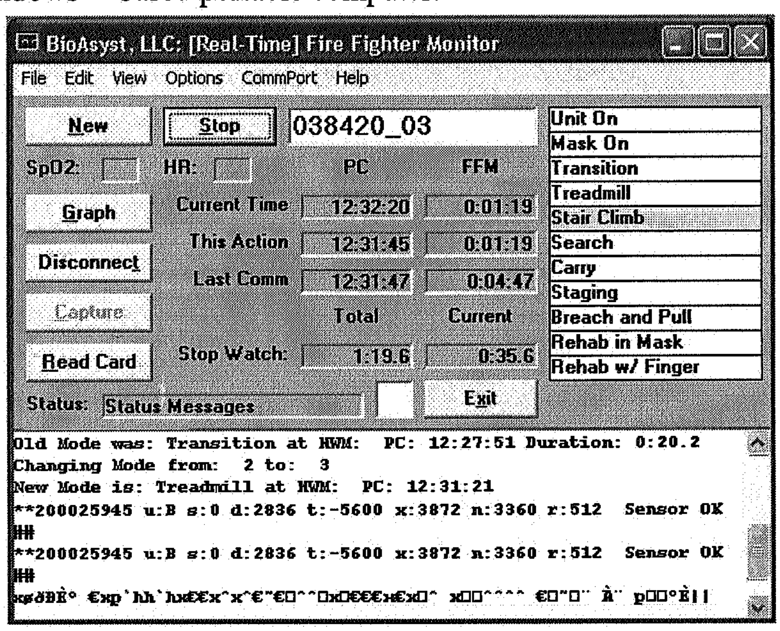

Figure 17: Screenshot of laptop based real-time monitoring program – data display

A program (Figure 17 and Figure 18) was written using Microsoft Visual Basic 5.0 to operate on the PC which would allow the near real-time analysis of the signal quality. This enabled us to assess conditions such as a sensor disconnect, low batteries, or other problems with the system which could then still be corrected during one of the subjects resting or transition phases, minimizing data loss. This program was designed as a research tool, not as a professional monitoring and analysis tool; however, developing the program provided insight into how a final monitoring system would need to perform in a commercial implementation of the system.

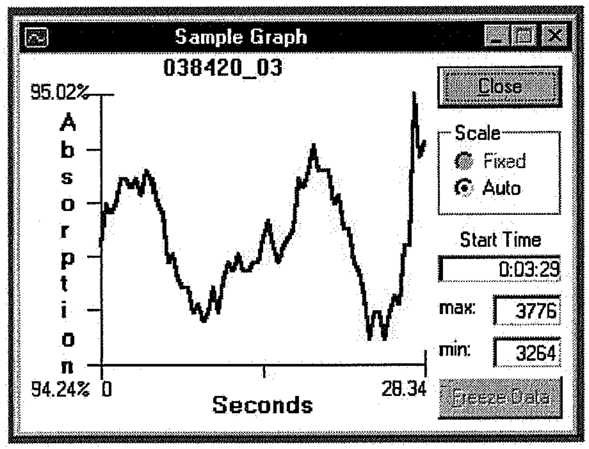

Figure 18: Screenshot of laptop based real-time monitoring program – graphic display

The program interface was also designed to log the incoming data packets as a record of performance. The right side of the program interface (Figure 17) also provided a single click method of adding timestamps for the various activities of the exercise protocol to the log file. This log file was then used to synchronize the various data acquisition elements: data from the mask, data from the finger probe, data from the CorTemp, and the subjects' activities.


```
**200026406 u:B s:0 d:2835 t:2475 x:3024 n:1216 r:1808  Sensor OK ##
**200026406 u:B s:0 d:2835 t:2475 x:3024 n:1216 r:1808  Sensor OK ##
_!8!!$$_Åòðéùûûùûðëëíëééíëéððòòòëðíòðððëíòòòíòéíëéçàààäééëðò||
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Figure 19: Sample data packet

Results and Discussion

Sensorization of SCBA Facepiece

Signal Strength vs. Sensor Separation

Starting at 6 cm, decreasing the distance between the detector and the emitters increased the reflectance measured. There was no significant difference in performance vs. separation distance once the sensors were within 1.9 cm, center to center. Changing signal strength did not affect the results. This is likely because the signal measured is a ratio of the red signal to the IR signal, which increases proportionally as the emitter and detector get closer. A final center-to-center separation of 1.27 cm was selected to provide adequate pliable material between the elements to maintain uniform tension on the rubber strip containing the sensors and integrity of the seal at the face piece/forehead interface. This distance also prevents larger wearers from exceeding the 1.9 cm limit when the inter-sensor rubber is stretched. The final separation of the two sensor components was found to provide a continuous signal as judged by both plethysmographic waveform and failure of the oximeter's processor to detect any time points with signal dropout for all wearers under both resting and active conditions.

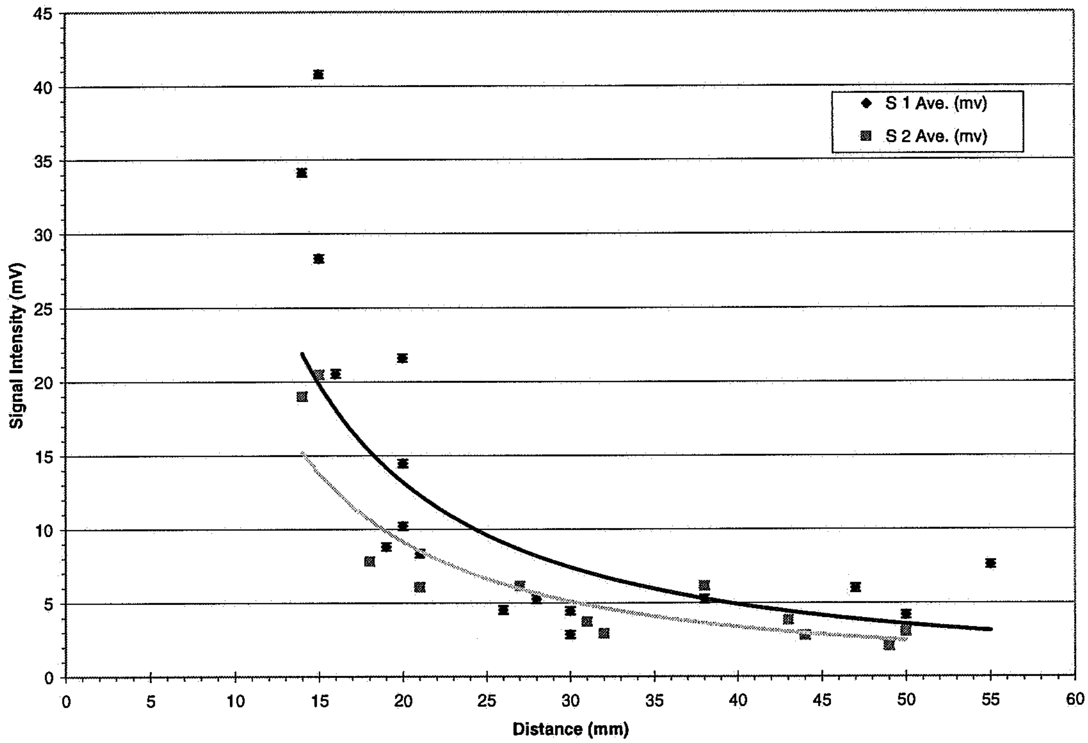


Figure 20: Signal strength at various separations

Mask Fabrication

The sensorized SCBA face mask for oximetry monitoring is depicted in Figure 5. The figure demonstrates both the location of the sensor elements in the forehead reflection and the fabrication quality resulting in stable, flush mounted sensors in all three masks.

The reliability of the sensors in the three masks was preliminarily tested by sequentially applying each mask to the same, experienced, resting firefighter twice. Each time a mask was donned, it was fitted to the face by the firefighter using subjectively normal strap tension. The mask was then connected to the processing board and DC absorption was recorded for a 2-minute period. Figure 21 shows the stable DC absorption signal that would be expected for a healthy, resting subject across all six recordings. Further, it demonstrates that the individual masks do not differ from each other with respect to signal strength, detection or integrity. The intermittent data acquisition pattern evident in the tracings was programmed into the processor board as discussed in the description of its construction, above.

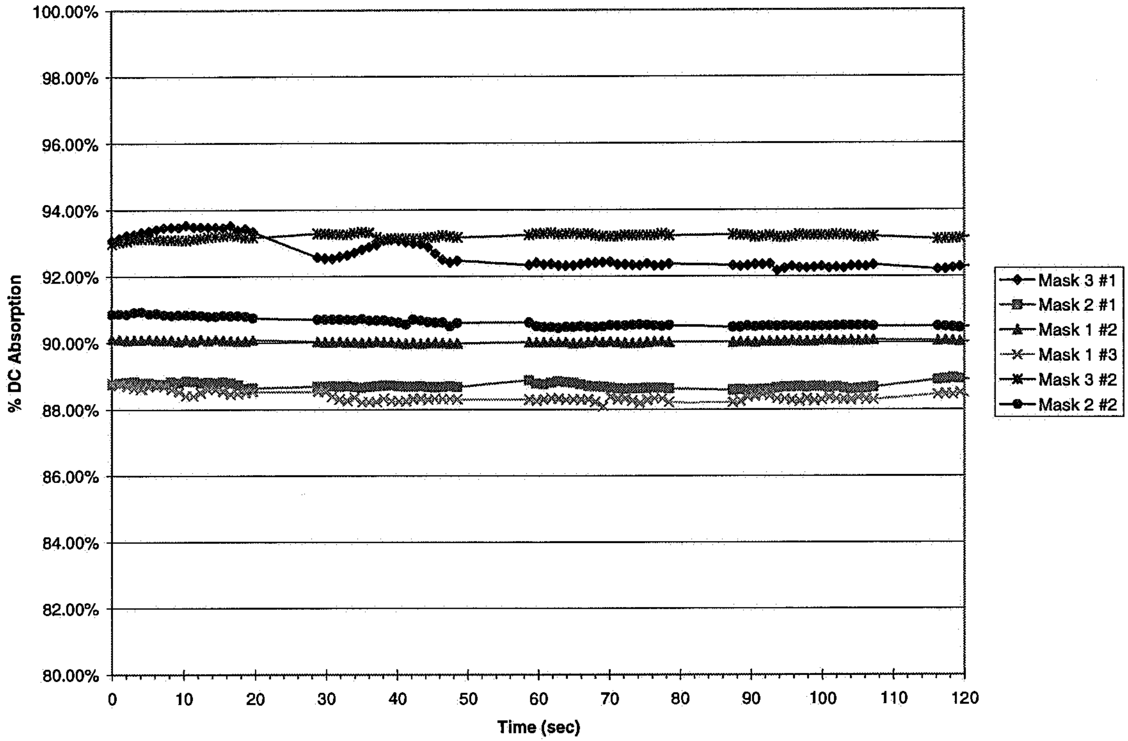


Figure 21: Reliability of oximetry sensors after installation in SCBA face masks

Mask Integrity and Comfort

On testing by the manufacturer, all of the sensorized masks exceeded NIOSH specifications for air pressure maintenance and ventilatory performance (Figure 22). Volunteer subjects also evaluated the modified masks for comfort; they were worn for up to an hour without difficulty. This is in contradistinction to previous prototypes in which the sensors protruded from the surface of the mask, causing localized pressure and discomfort to the forehead within a few minutes.

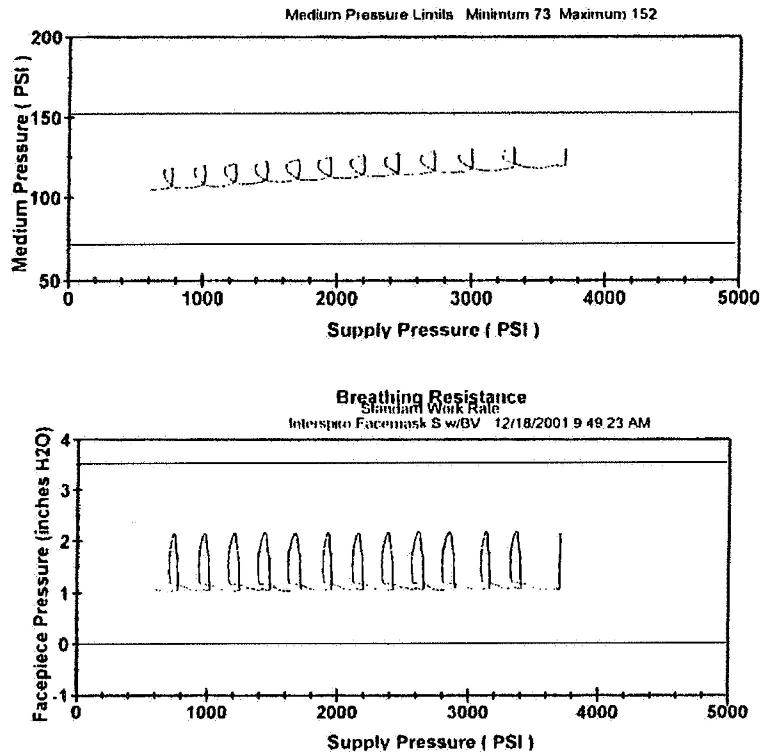


Figure 22: Sample results of air seal and ventilatory performance testing of modified SCBA masks

Electrical Protection of Sensor Elements

Addition of Tegaderm[R] dressings over the sensor windows in the SCBA masks was not perceptible to wearers of the mask, and it was found to adhere well, and completely protect the sensors from water penetration due to sweating (Figure 23). Further testing of a permanent solution, applied at the time of mask sensorization, will be essential. With the mask manufacturer, it will be necessary to demonstrate that neither air leak nor an avenue for penetration of toxic organic vapors is created by the use of this product to shield the electrical sensor elements from water.

One of the specific aims of the Phase 1 SBIR proposal was to assess the reliability of the sensorized facemask. That is, we planned to quantify and compare total time credible signal was received with total time the mask was worn. Ultimately, this quantitation was not useful as the problem with sensor elements shorting out with sweat occurred sporadically during the second set of trials, and was generally overcome by switching masks prior to initiation of exercise. There were several trials in which oximetry data were lost due to this cause, decreasing the total number of subjects with matching data for the two sets of climatic conditions. Although the formal trials were completed prior to identification and mitigation of the electrical problem, extensive informal testing of subjects sweating profusely while wearing the sensorized mask did not reveal any recurrence of the problem.

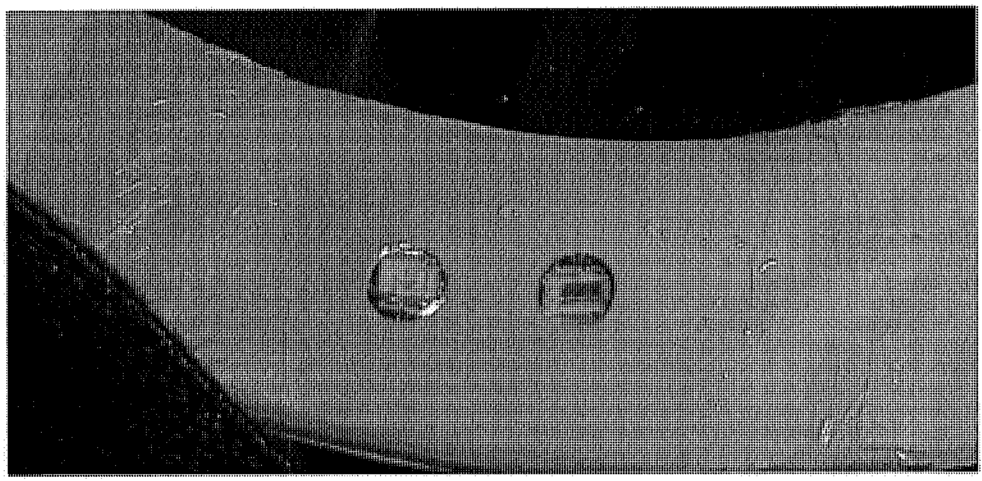


Figure 23: Tegaderm by 3M provides vapor permeable water barrier over sensor window to protect electrical elements from sweat.

Development of Oximetry Boards

BioAsyst, LLC fabricated two final prototype data acquisition systems, referred to as Units A and B. Each of these systems was tested to ensure that variability in the two-processor circuits would not be a significant factor in testing. These results (Table 3) indicated that variations between the two units were less than 0.6% of signal. BioAsyst further demonstrated that the flow of compressed air from the SCBA would not affect sensor performance by comparing it with data from the mask with the hatch open and the subject breathing ambient air. These tests also indicated that there was less than 0.6% variation in signal with the use of SCBA air.

Table 3: Consistency of final prototype oximetry processor boards under various conditions

Subject	Unit	Supply	Mean	Std Dev
1	Unit A	Air	89.16%	0.10%
1	Unit A	Open	89.33%	0.10%
1	Unit B	Air	89.31%	0.08%
1	Unit B	Open	89.37%	0.08%

Unit A vs. Unit B	0.10%
Supplied Air vs. Open Hatch	0.11%

Subject	Unit	Supply	Mean	Std Dev
2	Unit A	Air	97.45%	0.06%
2	Unit A	Open	97.40%	0.07%
2	Unit B	Air	98.54%	1.20%
2	Unit B	Open	97.43%	0.14%

Unit A vs. Unit B	0.55%
Supplied Air vs. Open Hatch	0.58%

These tests were conducted using two subjects who did not re-adjust the mask once it was initially tightened onto the face. Data readings were taken while the mask was "open" to room air and then while air was provided through the SCBA. Data readings were also taken using both the initial (modified BCI) and second generation data acquisition units for each of the "open" and SCBA "air" conditions. Although no differences between processing units or air delivery conditions were observed, there were marked differences between the stable absorbance values obtained from the two different subjects. This could be due to different physiologic baselines, but that possibility was ruled out by finger probe oximetry. Skin characteristics such as cornification and pigmentation are known to affect transcutaneous oximetry. This is corrected for in pulse oximetry by discarding the DC component of the absorption signal and using the AC component since that corresponds to the absorption attributable to the arterial compartment. The observed disparity in this study, however, is greater than would be expected from skin characteristics. In view of the results shown in Figure 45 where a similar magnitude of variability was observed, we attributed the differences primarily to the tightness of the mask fit, and recognize that in future field use, a baseline will need to be generated with each application of the facepiece.

Core Temperature Monitoring

Ten firefighters were recruited to participate as subjects in the study. A total of 9 completed the protocol as one was disqualified on the first day of testing due to acute gastroenteritis. Core temperature data were recorded for all 9 subjects in the cool chamber/ no PPE trial and for 8 of the 9 subjects in the warm chamber/ PPE trial. The CorTemp capsule ingested by 1 firefighter gave a baseline reading >38.5 °C prior to initiation of exercise. His oral temperature was found to be normal, however, so the subject was allowed to perform the protocol, and core temperature data for that trial were discarded.

Once initiated, most of the exercise has prescribed performance times. There was a tendency for subjects conducting the search and rescue simulation in the heat and PPE to take longer than under cool conditions without PPE (data not shown). This was likely due to a combination of factors. The PPE did slow progress through the chamber somewhat by its weight and cube. A training advantage may also have been evident during the second, cool/no PPE trial. On average, the firefighters performed the breach and pull almost twice as long under cool conditions and without PPE (Table 4), although there was marked variability among subjects. These two effects appear to have partially offset each other, as there was less than 1 minute difference between total exercise times in the heat and in the cool chamber.

Table 4: Average time (in minutes ± standard error of the mean) that subjects performed breach & pull (B&P) pike pole simulation, total time to complete the full exercise protocol. They were instructed to continue this exercise to volitional fatigue. The protocol was performed once by the subjects under warm conditions and wearing full PPE and once under cool conditions wearing T-shirts and gym shorts.

Environment	B&P Time (min) ± S.E.	Total Time (min) ± S.E.
Heat / PPE	1.95 ± 0.30	14.94 ± 0.42
Cool / no PPE	3.32 ± 0.82	15.78 ± 0.86

In order to compare changes in temperature and DC oximetry among subjects and between the two environmental conditions, the recorded data were time-normalized to the start of the treadmill exercise minus 1 minute. The Fitsense data logger recorded core temperature from the capsules every 15 seconds throughout the exercise and rehab period. These records were imported into Microsoft Excel spreadsheets for data reduction. The data were initially scanned to remove a small number of spurious readings. These were defined as individual values that were

≥ 2 °C different than the preceding and/or succeeding value in the record or that exceeded 42 °C, as they were considered nonphysiologic. Less than 1% of total data was lost in this process. Each core temperature data record, starting at 1 minute prior to initiation of the treadmill walk, was averaged by minute. Thus, core temperature values were charted each minute, and each 1-minute data point represents the geometric mean of the four 15-second readings logged by the recorder. The 1-minute period prior to treadmill walking, when the firefighter subjects were donning gear, settling the hose pack onto their shoulders and entering the chamber was used as the 0-point, or baseline.

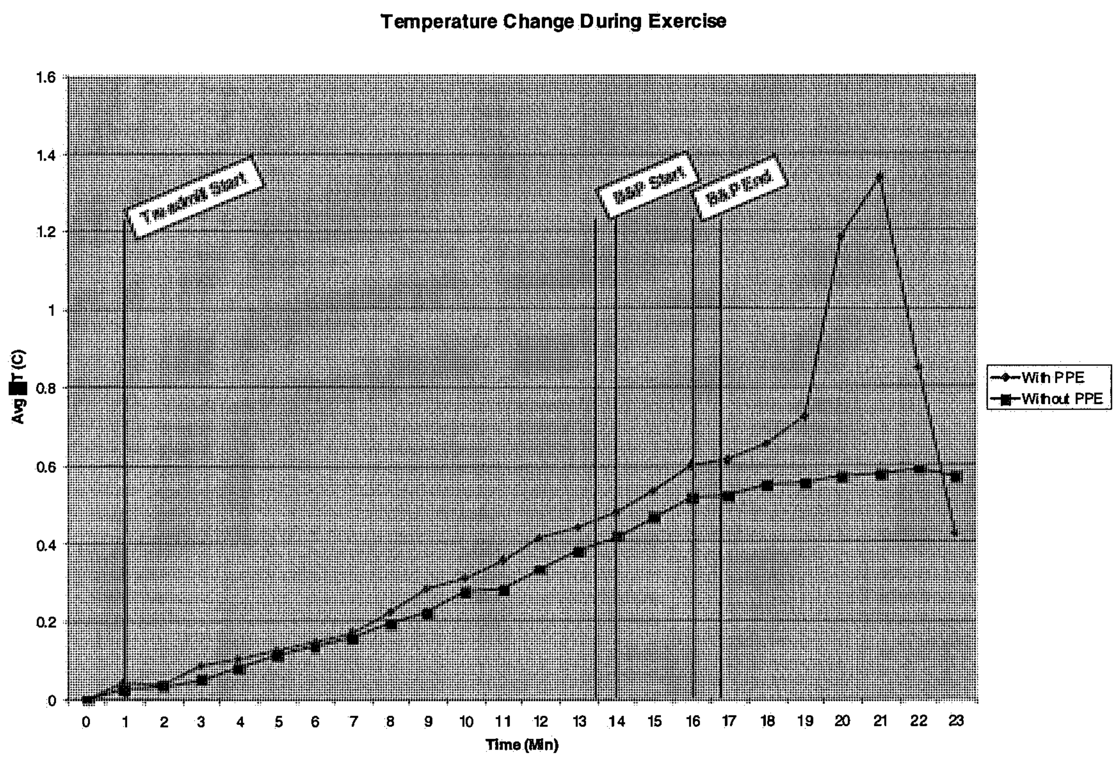


Figure 24: Average change in core temperature (ΔT) in °C during and after firefighting simulation in the environmental chamber. The red tracing is the average of trials in which subjects wore PPE and exercised in the heated chamber. The vertical red lines show the average beginning and ending times for the breach and pull exercise, the last in the protocol. The blue tracing and vertical line likewise refer to average ΔT and breach and pull start/end times without PPE in cool chamber.

Figure 24 shows that the type of work performed by firefighters induces early and impressive increases in core temperatures under both compensable and noncompensable climate conditions. Although there was a tendency toward greater core temperature increases in subjects during exercise in heat and PPE, the trend did not achieve statistical significance. A continued, precipitous rise in core temperature in subjects after completion of work in heat and PPE has been reported by others (12,15) and was observed in our studies. Interestingly, this effect seen in the averaged data appears to be attributable to a subpopulation of subjects, and was not consistently observed. In Figure 25, the minute-averaged plots of ΔT for each subject are superimposed on a single graph. Only three of the eight subjects exercising in the heat and none in the cool exhibited the post exercise temperature spikes. One of these three was unable to complete the protocol due to perceived fatigue and exited the chamber prior to beginning the breach and pull simulation. The precipitousness of the recorded rise in temperatures raises the specter of artifact. In each case, three or more minutes of averaged data demonstrate the phenomenon, and the rapid return to or below baseline corresponds to initiation of oral hydration that probably disproportionately cooled the upper GI tract where the capsules were residing. The effect was only observed in subjects working in the heat, and one of these three was the only one in either trial who was transiently symptomatic. Further experimentation with larger numbers, tighter control of capsule ingestion times, and maintenance of uniform distances to the core temperature data logger throughout the trials are required before the significance of this effect can be confirmed.

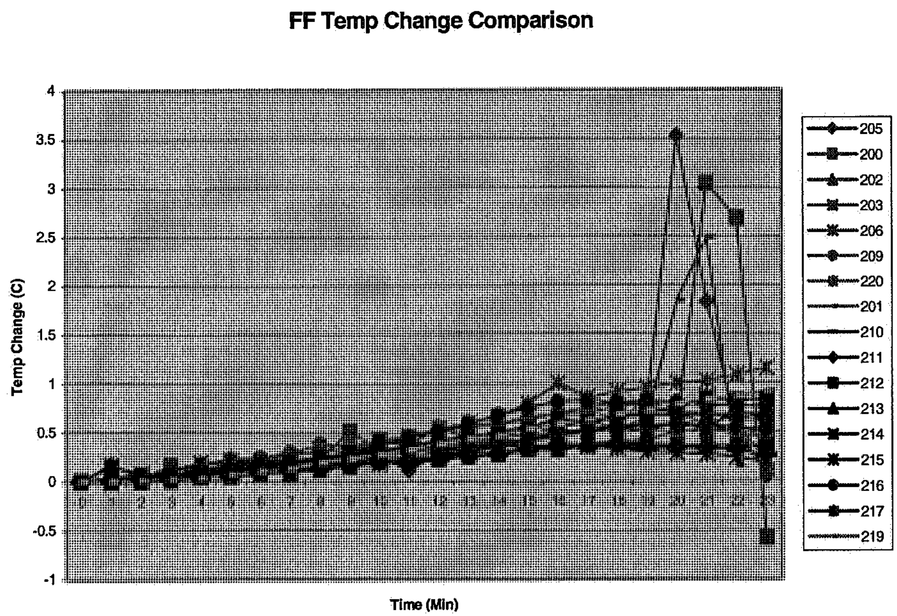


Figure 25: Individual plots of core temperature data.

It is not anticipated that core temperature monitoring will be part of a practical, fieldable sensor suite for real time monitoring of fire service personnel engaged in structural fire fighting. It is not feasible to either apply or insert thermometry probes during an emergency response. Since the occurrence of incidents is unpredictable, it is not possible to ingest capsules like those used in these studies, as they must be given time to traverse beyond the proximal small bowel before their readings reflect body core temperature. This does not diminish the importance of including core temperature monitoring in studies to elucidate the physiology of fire fighting and evaluate the predictive value of alternative parameters. A significant rise in core temperature is a reliable indicator that an individual has exceeded the capacity of his or her thermoregulatory and cardiovascular compensatory mechanisms. In the present study, we have established the practicality and reliability of the CorTemp and Fitsense monitoring technology for this experimental application. Although further studies are required, we have demonstrated a highly reproducible elevation of core temperature in firefighters performing the simulated workload in our protocol. This also helps to validate our experimental model for future work in both technology development for physiologic monitoring of firefighters, and for understanding the physiology of firefighting.

Oximetry Monitoring

Oximetry data were recorded for all 9 subjects under both warm/ PPE and cool/ No PPE conditions. Pictured below (Figure 26) is a 360 second sample of the raw data generated through the oximetry data acquisition system. As previously discussed in describing the processor board, the system gathers 5000 12-bit data points from the photo detector in the mask's sensor for about 20 seconds. The system then uses approximately 10 seconds to analyze and transmit the data before repeating the process.

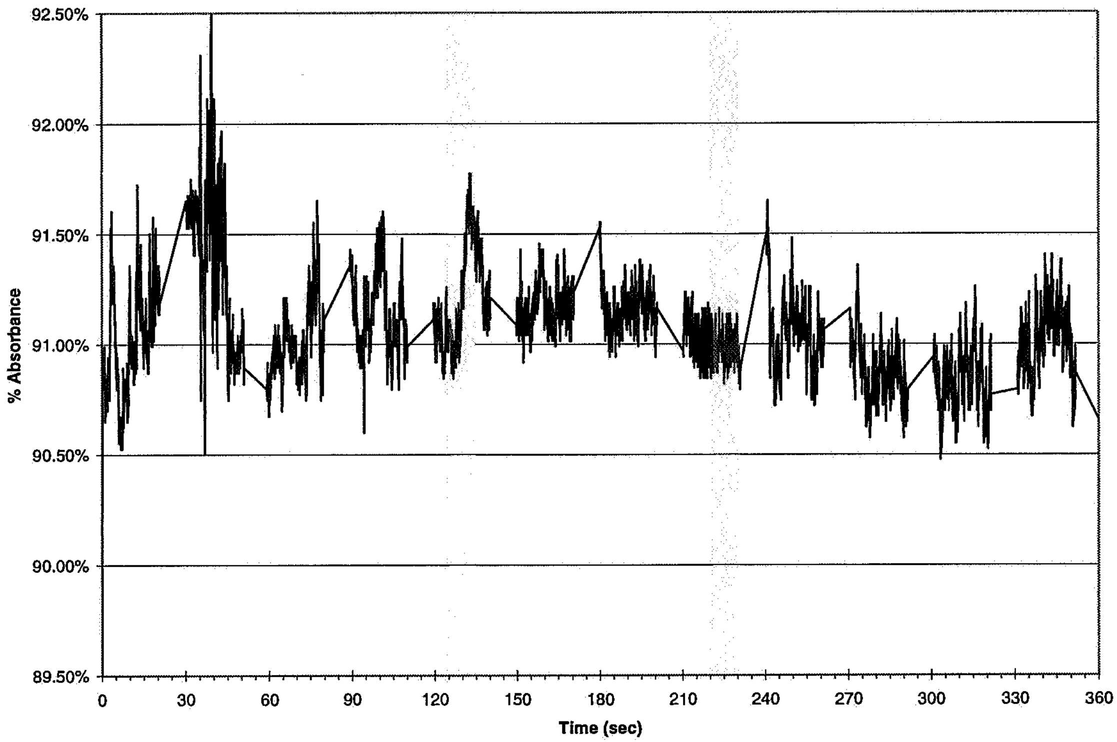


Figure 26: A small sampling (360 seconds) showing raw wave, total absorbance (AC and DC) data. In this case, the subject was wearing one of the sensorized masks with full PPE, and was in the environmental chamber at 40 °C.

As can be noted from raw absorbance data in Figure 26 above, the AC component of the (the upper and lower boundaries of data) typically amounts to little more than 0.33% of the total signal. In this example, the total returning light intensity was approximately 9% of the saturation level for the photodiode in the oximetry sensor. The lower boundaries are representative of the DC value. As can be seen, this value also changes over the course of time as the subject's activities change. The straight-line gaps in data result from the pattern of 20 seconds of data acquisition combined with 10 seconds of data processing used in our algorithm.

At 250 samples per second over 2000 or more seconds per trial, the quantity of data generated was tremendous. Furthermore, as our interest was in tracking changes in the DC component over time, we devised a method of data reduction for presenting the relevant data for our analysis. Each of the grayed areas in Figure 26 is represented in a close up below in Figure 27. This close-up allows us to see the pulsatile component of the signal atop the overall DC value. As the DC value increases or decreases (left), the AC component is likewise shifted from an otherwise stable value (right).

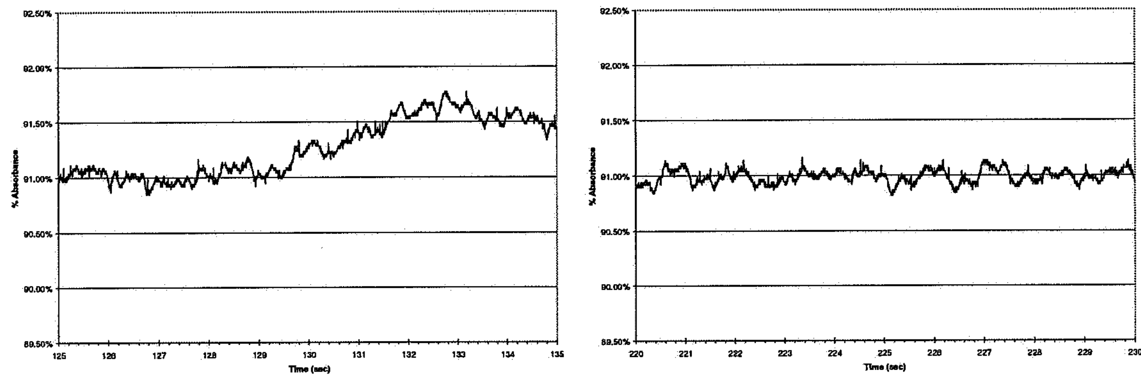


Figure 27: Close up of data samples from the graph above (10 second interval) of a stable DC absorbance (right) and an increasing DC absorbance (left).

Although low enough to preclude its use for HRV analysis, the sampling rate of the oximetry data acquisition system generated far more information than could be interpreted by simple observation of the continuous waveform. It was therefore necessary to develop techniques for data reduction to permit meaningful interpretation. Understanding that the raw absorbance data includes both the AC and DC components, we first developed a technique whereby for each 10 second interval, the relative minima (low graph points) were averaged to create a representative value that should exclude the positive deflections corresponding to arterial pulsations for that time interval. No attempt was made to exclude the 10-second periods when no signal was being recorded.

The collection of mean absorbance minima (MAM) was charted (Figure 28) to look for trends over time. In some cases, we were able to observe waveform changes that appeared to correspond in some way to the position, types of activities or levels of exertion of the monitored subjects. There did not, however, appear to be a reproducible pattern among subjects performing the simulations. As discussed before, each time the mask is removed and refitted, the "starting" absorbance does not necessarily correspond to earlier readings – only trends can be interpreted, thus the shift in the MAM level from the end of marker 12 to the start of marker 14 in Figure 28, where the mask was removed to re-hydrate the subject, cannot be judged to be on the same scale. We can only infer that the trend was decreasing prior to the mask being removed and that the trend continued to decrease once the mask was replaced.

For the purpose of comparison, the gray shaded area in Figure 28 represents the entire time covered by Figure 26 and the points labeled "A" and "B" are the result of reducing the time covered by the graphs in Figure 27 to a single data point.

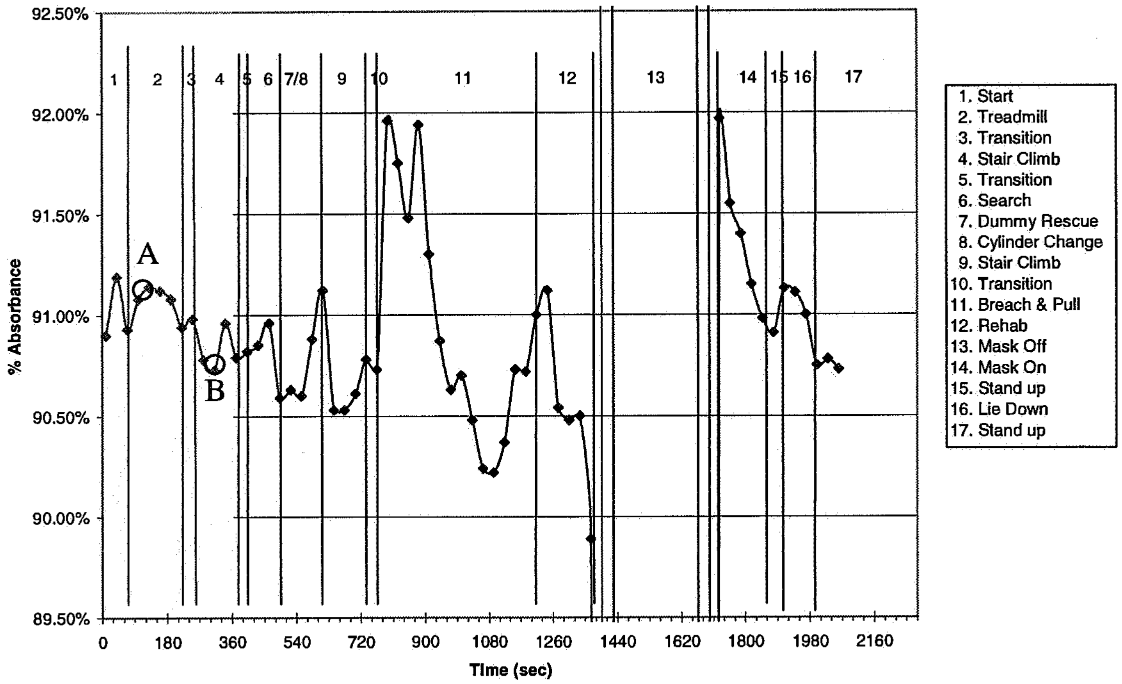


Figure 28: Sample data reduced by calculating mean absorbance minima for each ~10 sec. interval. The activities of the subject during segments (indicated by vertical bars) of the recording period are indicated by numbers across the top of the graph and the legend on the right.

The MAM tracing of the only firefighter who became symptomatically fatigued and was unable to complete the heat/PPE protocol did show a marked downward deflection that occurred precisely at the moment he indicated the need to exit the chamber and rest. That tracing is displayed in Figure 29. Once out of the chamber and sitting down (time period number 15), he was monitored by both facepiece and finger probe oximeters for 60 seconds. The finger probe tracing is the red plot. Both values continued to decrease until the mask was removed (loss of blue line tracing) and vigorous oral rehydration was initiated. The finger probe tracing then steadily recovered to his previous baseline (data not shown). The firefighter's symptoms, primarily fatigue and a sense of pre-syncope, resolved immediately upon sitting down, and did not recur. Although this was the most precipitous decrease in MAM observed in any of the trials involving any of the subjects, and it did occur in the only symptomatic subject, this observation must be considered suggestive rather than conclusive at the present time. Interestingly, a transient, steeply increased core temperature reading (See arrow) was also obtained just 1 minute prior to the time identified as notification of symptoms by the event marker. This is demonstrated in Figure 30. Once again, this is only an additional bit of suggestive evidence that physiologically significant data can be captured using this approach. It will be important to develop other, earlier markers of physiologic stress with which to correlate oximetric changes, as our simulation protocol is designed to exercise subjects only to volitional fatigue and not to symptomatic heat stress, dehydration or over-exertion.

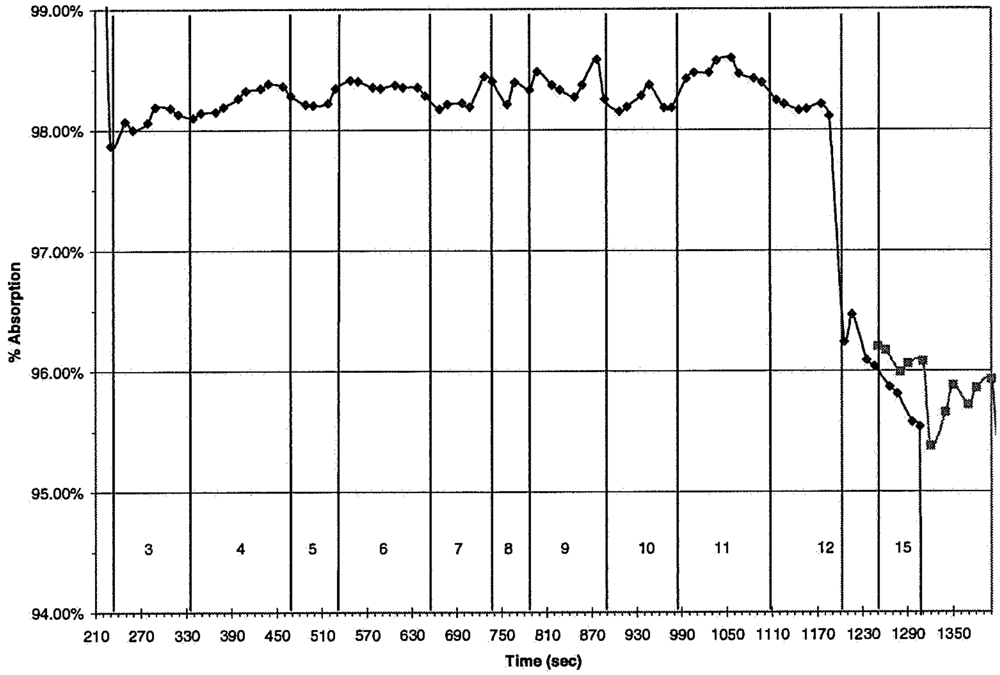


Figure 29: Mean absorption minima oximetry tracing of firefighter who became symptomatic during the protocol and asked to exit the chamber and rest. The vertical bars and numbers correspond to the same activities as described in Figure 28. The dotted vertical line seen in the activity #12 period is the event marker for his indication that he could not continue. The red tracing beginning with activity #15 (rehab) was obtained by finger probe. Following a 60-second overlap period when both mask and finger oximeters were worn, the SCBA with face mask as well as other PPE was removed for cooling and oral rehydration.

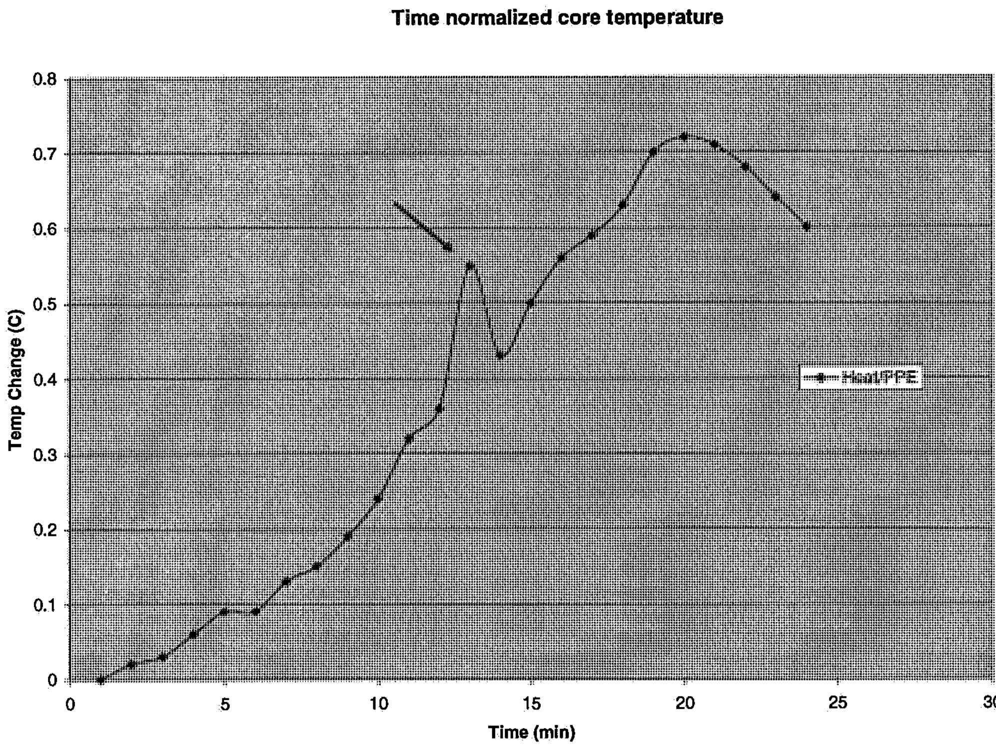
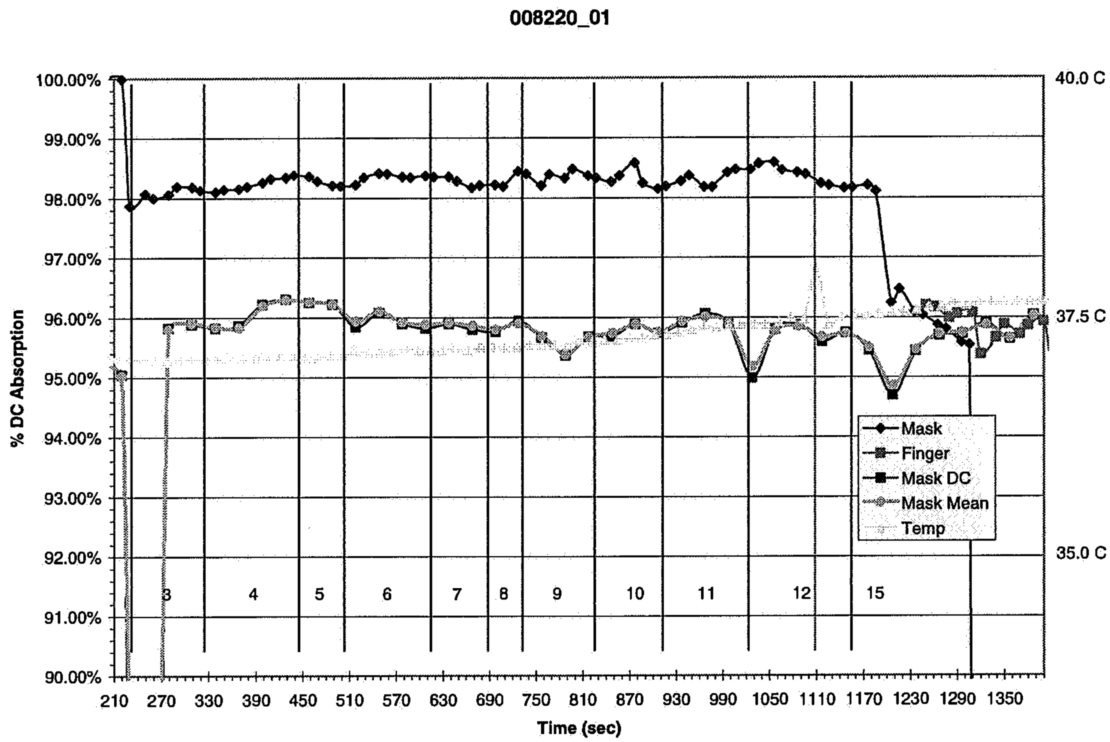


Figure 30: Core temperature tracing of subject who became symptomatic during exercise and had to leave chamber. It is time-normalized so that record begins 1 minute prior to initiation of treadmill exercise. In this case, this occurred at 330 seconds into oximetry recording, which accounts for the apparent discrepancy between the times in Figure 29 and Figure 30.

The same oximetry data were submitted to an alternative processing protocol to refine the waveform so that clinically significant trends in the DC component might be more readily distinguished from the baseline variability inherent in the MAM tracings. In this scheme, the raw input data from the mask sensors were first broken into segments corresponding to the continuous data collection periods to eliminate time averaging over the non-transmitting intervals (shown in Figure 28). A simple, interpolative filter for noise reduction was then applied. Using a 10-point running average, any single point that exceeded a threshold of 1% displacement from the average was dropped and replaced with the current moving average value. The filtered waveforms were then displayed using two different approaches. The tracings labeled 'DC' employed a frequency domain algorithm to find the 0 frequency component. Those labeled 'Mean' represent establishment of a simple arithmetic mean of the filtered wave for each data segment. The results of this analysis, compared with MAM data are shown in Figure 31.



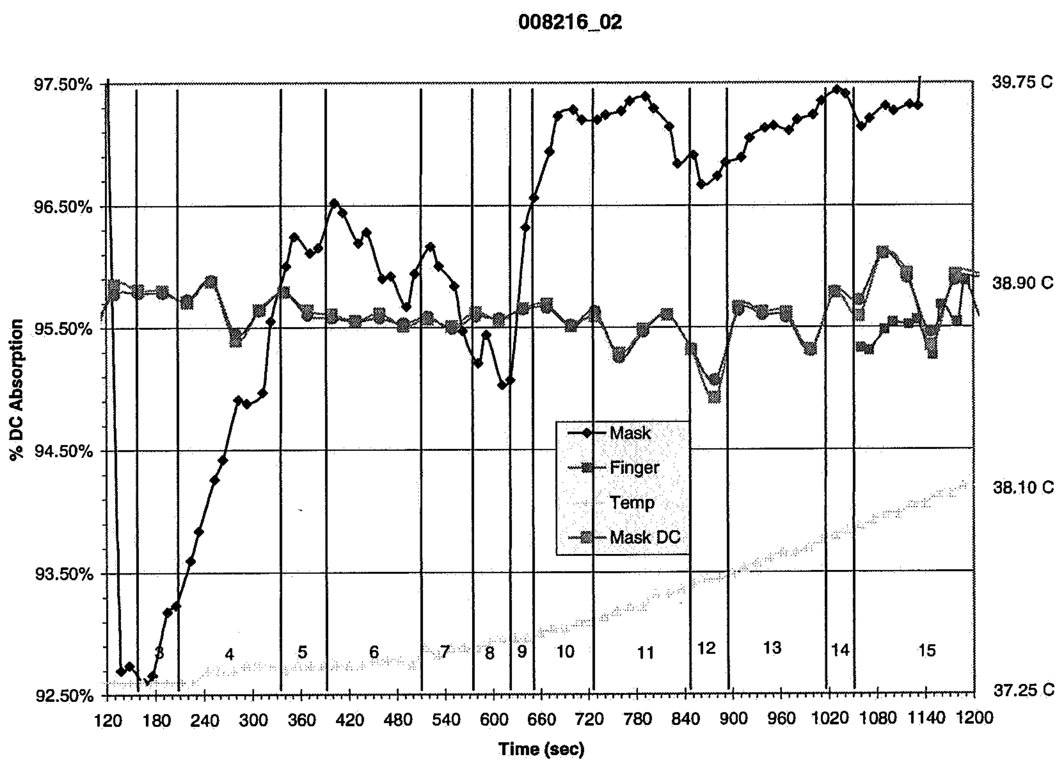


Figure 31: Oximetry tracings showing (A) SCBA mask data from Figure 29 and two additional signal processing algorithms. Graph B displays the oximetry data derived through the same formulations for the same firefighter's exercise under cool/no PPE conditions. The legends in A and B are the same. The numerical designations for the exercises are as described in Figure 28.

It is clear that the tracings generated by the Mask DC and Mask Mean algorithms are virtually identical, and this was true for all the oximetry data. These graphs differ significantly from those generated by the MAM operator, appear more physiologic, and correspond well with the tracings obtained by finger probe during rehabilitation following completion of exercise. Interestingly, in Figure 31A, it appears that a sharp fall in DC oxygen saturation similar to the one observed when the subject complained of inability to continue occurred midway through his final exercise. The cruder MAM processing did not detect the initial drop that was likely significant in the A graph, and appears to have been far more susceptible to artifact in the B graph. Further experimentation is now required to establish threshold limits or signature patterns indicating excessive physiologic stress.

The data obtained in the trials with firefighter subjects and processed as described in the preceding discussion are presently undergoing further statistical and transform analysis to identify sentinel alterations in the waveforms that can be correlated with the workloads. With only a single event of fatigue preventing further exercise during the trials, it will not be possible to demonstrate reproducibility of the suggestive findings shown above. As previously discussed, further quantification of the physiological correlates of SCBA-based DC oximetry will be a priority for further investigation.

Conclusions

With Phase I SBIR funding, BioAsyst, LLC has modified SCBA facemasks by retro-fitting them with pulse oximetry sensors through factory fabrication, and then demonstrating by NIOSH compliant respiratory device testing that the masks retain their fit and functional properties. We have developed and built oximetry processing boards that acquire the DC component and both records and transmits the signal for real-time display on a laptop computer. In order to control the size, weight and complexity of the processors, we established the feasibility of using a single, visible red emitting diode in the oximetry sensor, rather than the dual frequency red/infra-red elements used in commercially available pulse oximeters. After encountering initial difficulty with reliability of the mask under experimental firefighting conditions, we identified the problem to be sweat from the wearer short-circuiting the sensor elements in the mask. This was resolved by sealing the sensor window with a vapor permeable, water occlusive, skin dressing product called Tegaderm. To test the device, a firefighting simulation that could be performed under climatically controlled conditions in an environmental chamber was developed and validated. Ten currently active firefighters were recruited as subjects for IRB-approved experimentation. The physiologic monitoring suite included SCBA-based oximeters and ingestible core temperature capsules. Signal processing algorithms were applied to the resulting raw oximetry data, and preliminary correlations with clinical results were analyzed.

Further Research and Development

Feasibility Validation

Phase II will build upon the sensorized mask developed in Phase I, making manufacturing improvements as necessary. The main focus of Phase II, however, will be to more intensively analyze the data obtained in Phase I, further optimize both experimental conditions for lab-based physiologic studies, initiate field studies using live-burn opportunities afforded by fire training facilities, and to further develop the algorithms required to assess the possibility of individually customized alarm levels based on previously calibrated physiologic responses to fire ground heat and exertion. A smaller, more cost effective data acquisition and processing system for the DC oximeter sensor signals will also be developed in Phase II.

The final development of a reliable, user-customized physiologic monitoring system will lead to a Phase III for market research and manufacturing for commercialization. Companies involved in the manufacture of fire fighter protective equipment, including SCBAs, have already expressed interest in collaborative projects with BioAsyst, LLC. The ultimate goal of BioAsyst, LLC is to offer products for enhanced operational effectiveness and safety of personnel in hazardous environments such as the fire ground.

Sensor Integration

Optimized Light Frequency Selection

The Red and IR frequencies of light selected for this project were based upon the frequencies commonly used for pulse oximetry sensors. These frequencies have the advantage that in a final implementation of the system, data analogous to that of medical monitoring oximetry could be generated.

However, our experience in separately tracking data generated by the Red and IR frequencies (see Figure 15) indicate that each frequency sees the response to changes at different times and with differing magnitudes. This has led us to believe that although the selected frequencies do show the effects we are looking for, it is possible that selecting alternative or additional frequencies would optimize this effect.

To further this concept, we propose to design a mask capable of spectrophotometric analysis over a wide range of light frequencies. This experimental system would enable us to optimize the discrete frequencies that could be cost effectively integrated into the mask sensor.

Data Acquisition System

Optimized Data Acquisition System

The prototype system we developed was based upon a Tattletale data acquisition system. While this system is suitable for research, it has several prohibitive features for a commercial unit. The cost of the system is high, the size is large, and the programming language used limits the capabilities of the processor and slows the system down.

BioAsyst, LLC and our partners have been improving our experience in processor system development and now have the capability of designing our own data acquisition processor system to achieve the goals of this project. This approach has many advantages:

- The system would be optimized for our processing needs discarding the unused features of the tattletale. This would decrease the size and cost of the system.
- Programming the system would be in assembly language, increasing the speed of processing and our capabilities for real time data acquisition, analysis, and transmission.
- A commercially produced circuit board would integrate the processor, data storage, transmission, and signal amplification electronics. This would also reduce the size and cost of the current design and enable commercial sales of the unit.

Based upon our research to date, we believe that the new design is likely to be based upon a Motorola 68332 processor. This processor provides the necessary speed for signal analysis, and the foundation for memory storage and data acquisition capabilities sufficient to achieve our task. A final decision on the processor would be made in the early stages of any follow-on to the project.

Physiologic Investigation and Clinical Validation

A number of approaches to validation of our preliminary results, and using what we've learned in Phase I, are planned for Phase II of this project. First, the core temperature data must be confirmed through better standardization of the timing of capsule ingestion and precisely controlled location of the receiver/recorder device on the study subjects. More sophisticated signal processing transforms and activity-specific analytical comparison of the oximetry data must also be completed.

With certain enhancements, the experiments, themselves, must be repeated. Specifically, it is essential that additional parameters such as volume loss, finger-stick lactate levels and oxygen consumption be correlated with DC oximetry observations. Our engineering staff is currently engaged in development of an innovative solution that will allow us to use thoracic bio-impedance on the exercising firefighters to monitor and record cardiac output in real time. We believe this will provide us the most definitive correlation of the physiology of firefighting under conditions of uncompensable heat stress. With this information, we anticipate being ready with both testable estimates of alarm settings and technology with robust radio-transmitters in hardened devices that are ready for initial experimentation in the live burn environment.

Telemetry and Personnel Monitoring System

The data telemetry interface developed for the prototype system was sufficient for the research environment, however, is too limited for commercial implementation. There are several factors in the telemetry system that warrant improvement:

- Data transfer rate (bandwidth) needs to be sufficient to telemeter all data. Using two frequencies of light at 200 samples per second provides 6.4 kilobytes per second per unit. Once research has optimized the markers to look for, a reduced sampling frequency may be possible.
- The ability to have multiple data acquisition units transmit to a single base is also required. This would require the implementation of a packetized wireless data standard like 802.11 or Bluetooth. The bandwidth would also need to be sufficient to monitor all units implemented at a scene.
- The nature of radio communication problems in unknown environments and structures may make it necessary to implement a "repeater" system that could receive data from the data acquisition units and forward that data to the base system.

In addition, the monitoring software will need to be improved to make data interpretation on scene, by minimally trained personnel, possible. In general, a fire chief at the scene or a physician, nurse, paramedic, or EMT at the scene will be charged with monitoring the health of the fire fighters. This person will need to be able to quickly review the data from this system and make judgments based upon that data in addition to the other takes that they are performing at the scene. Our system cannot require specialized skills nor undo attention or the system will be unsuitable for use. The system will need to know how to establish individually correlated alarm settings to warn monitoring personnel of potential problems. As the system's sophistication improves, incidents of false alarms will need to be significantly reduced to gain acceptance.

Publications

Van Gelder, C., Pranger, L. A., Urias, A., Lo, R., Wiesmann, W. P., Winchell, R. J., Kolka, M. A., Stachenfeld, N., Bogucki, S.: "Physiologic Monitoring in Extreme Environments: Application of Micro-sensors and Embedded Processors to Predict Heat Stress in Fire Fighters." in *Biomedical Diagnostic, Guidance, and Surgical-Assist Systems* IV, Tuan Vo-Dihn, David A. Benaron, Warren S. Grundfest, Editors, Proceedings of SPIE Vol. 4615, pp 71-81 (2002).

References

1. Sawka MN. Overview of heat stress science. Presented at: Advances in Heat Stress Monitoring and Mitigation Conference. MIT May 6, 1999.

2. Lawson, JR. Firefighter's clothing and thermal environment of structural fire fighting. NISTIR 5804, 1996.

3. Kenny WL, Johnson JM. Control of skin blood flow during exercise. Med. Sci Sports Exercise 1992; 24(3):303-312.

4. Havenith G, Coenen JML, Kristemaker L, Kenny WL. Revelance of individual characteristics for human heat stress response is dependent on exercise intensity and climate type. Eur J Appl Physiol 1998; 77:231-241.

5. Fahy R, LeBlanc PR. US firefighters fatalities. NFPA J 2001; 95:67-74.

6. U.S. Fire Administration. Firefighter Fatalities in the United States in 2000. FEMA 2001.

7. Barnard, J., Duncan, H. Heart Rate and ECG Responses of Fire Fighters. J Occup Med 1975; 17(4): 247-250.

8. Kuorinka I, Korhonen O. Firefighters' reaction to alarm, and ECG and heart rate study. J Occup Med 1981; 23:762-766.

9. Lim CS, Ong CN, Phoon WO. Work stress of firemen as measured by heart rate and catecholamine. J Human Ergol 1987; 16:209-218.

10. Abeles FJ, DelVecchio RJ, Himel VH. A firefighter's integrated life protection system. Report of Contract #219454, Fire Department of the City of New York, 1974

11. Gledhill N, Jamnik V. Characterization of the physical demands of firefighting. Can J Spt Sci 1992; 17:3 207-213.

12. Smith D, Petruzzello SJ, Kramer JM et al. Physiological, psychophysical, and psychological responses of firefighters to firefighting training drills. Aviat Space Environ Med 1996; 67:1063-1068.

13. Louhevaara V, Smolander J, Tuomi T et al. Effects of an SCBA on breathing pattern, gas exchange, and heart rate during exercise. J Occup Med 1985; 27:213-216.

14. White MK, Vercruyssen M, Hodous TK. Work tolerance and subjective responses to wearing protective clothing and respirators during physical work. Ergonomics 1989; 32:1111-1123.

15. Faff J, Tutak T. Physiological responses to working with fire fighting equipment in the heat in relation to subjective fatigue. Ergonomics 1989; 32:629-638.

16. Motohashi Y, Takano T Influence of age on cardiorespiratory responses of firefighters during exercise in the heat. Industrial Health 1985; 23:289-293.

17. Pipes TV. Physiological responses of fire fighting recruits to high intensity training. J Occup Med 1977; 19:129-132.

18. Bennett BL, Hagan D, Banta G, Williams F. Physiological responses during shipboard firefighting. Aviat Space Environ Med 1994; 65:225-231.

19. Manning JE, Griggs TR. Heart rates in fire fighters using light and heavy breathing equipment: Similar near-maximal exertion in response to multiple work load conditions. J Occup Med 1983; 25:215-218.

20. Romet TT, Frim J. Physiological responses to fire fighting activities. Eur J Appl Physiol 1987; 56:633-638.

21. Duncan HW, Gardner GW, Bernard RJ. Physiological responses of men working in fire fighting equipment in the heat. Ergonomics 1979; 22:521-527.

22. Sothman MS, Saupe K, Jasenof D, Blaney J. Heart rate response of firefighters to actual emergencies. J Occup Med 1992; 34:797-800.

23. Skoldstrom B. Physiological responses of firefighters to workload and thermal stress. Ergonomics 1987; 30:1589-1597.

24. Montain SJ, Sawka MN, Cadarette BS et al. Physiological tolerance to uncompensable heat stress. Effects of exercise intensity; protective clothing, and climate. J Appl Physiol 1994; 77:216-222.

25. Jubran A. Pulse oximetry. In: Tobin MJ, editors. Principles and Practice of Intensive Care Monitoring. McGraw-Hill 1998; p 261-287.

26. Dassle AC. Reflectance pulse oximetry at the forehead improves by pressure on the probe. J Clin Monit 1995; 11(4):237-44.

27. Shoemaker WC. Early physiologic patterns in acute illness and accidents: toward a concept of circulatory dysfunction and shock based on invasive and noninvasive hemodynamic monitoring. New Horizons 1996; 4(4):395-412.

28. Partridge BL. Use of pulse oximetry as a noninvasive indicator of intravascular volume status. J. Clin. Monitoring 1987; 3:263-8.

29. Webster, J G, ed. Design of Pulse Oximeters. Institute of Physics Publishing 1997.

30. Horowitz, P, Hill, W, The Art of Electronics. Cambridge University Press 1989.

31. Dickinson ET, Wieder MA. In: *Emergency Incident Rehabilitation.* Brady/Prentice Hall Inc, Upper Saddle River NJ, 2000; 129 pp.

32. National Fire Protection Association. NFPA 1582 Standard on Medical Requirements for Fire Fighters and Information for Physicians. 2000 ed. NFPA, Quincy, MA.