

SCBA Oximetry for Fire Fighter Physiologic Monitoring

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Table of Contents

Title Page	1
Table of Contents	2
List of Abbreviations	6
List of Figures	8
List of Tables	12
Abstract	14
Significant Findings	15
Translation of Findings	17
Fire Service	17
Other Occupations	18
General Use	18
Sports/Exercise/Fitness Monitoring	18
Medical Monitoring	19
Outcomes, Relevance, and Impact	22
Value of SBIR Project, Expected Outcome and Impact	24
Scientific Report	26
Background	26
Specific Aims	30
Tasks	31
Procedures	31
Human Subjects Research	31
Experimental Protocol (Phase I)	31
Core Temperature (T _c) and Other Physiologic Monitoring	31
Personal Protective Ensemble (PPE)/Self-Contained Breathing Apparatus (SCBA) ...	32
Experimental Protocol (Phase II) CPAT-Like (STP) Studies (Yale)	34
Experimental Protocol (Phase II) Treadmill Studies (LEP) and VO ₂ Max (UConn)	34
Protection of Human Subjects	35
1. Risks to Subjects	35
A. Human Subjects Involvement and Characteristics	35
B. Sources of Materials	35
C. Potential Risks	36
2. Adequacy of Protection Against Risks	36
A. Recruitment and Informed Consent	36
B. Protection Against Risk	36
3. Potential Benefits of Proposed Research to Subject and Others	38
4. Importance of Knowledge to Be Gained	38
Collaborating Sites	39
Population Sample	39
Sources	39
Data Safety and Monitoring	39
Methodology	40
Phase I	40
Core Temperature	41
Experiment Design	42

Sequential task protocol (STP)	42
Linear exercise protocol (LEP)	42
Analysis	42
Results	43
Sequential Task Protocol	43
Linear Exercise Protocol (LEP)	44
DC Oximetry	45
Perceived Exertion	51
Physiologic Response	52
Phase II	56
Task 1: Production of a limited supply of SCBA units sensorized for DC oximetry based on revised specifications	56
LEDs and Detectors	56
Integration of Sensors into SCBA Facepiece	57
Optimization of emitter, photodiode distance for reflectance mode oximetry	57
Preservation of mask integrity	58
Oximetry across different levels of skin pigmentation	59
Design of Data Acquisition System	60
Task 2: Correlation of DC oximetry values and trends with other physiologic parameters experimentally monitored in fire fighters	73
Physiologic Correlation Studies	74
Analysis of Physiologic Correlation Study Data	75
Task 3: Development of an oximetric variability index and correlation with DC oximetry values as well as the other monitored physiologic parameters	76
Data Filtering	76
Variance Analysis	77
Task 4: Establishment of acceptable ranges and alarm thresholds for DC oximetry and oximetric variability index	77
Task 5: Field Testing SCBA units with the DC oximetry monitoring system under controlled fire service emergency operational conditions	79
System Accuracy	79
Ergonomics	80
System Performance	80
Monitoring System	80
Design Review: Redesign Recommendations	80
Mask Mold with Sensors Design and Fabrication	81
Field Studies	81
System Performance	81
Monitoring System – Base Station	81
*Results and Discussion	82
Data Decomposition and Time Syncing	82
Initial Analysis and Exclusion of Foot-Fall Artifact	95
Preprocessing:	96
Correlation analysis between Foot Fall Meter (FFM) data and red/IR pleth signal	97
Statistical methods	102
Visual Inspection	104

Raw Accelerometer Data:	105
Problems syncing the raw accelerometer data:	105
Frequency Analysis.....	106
Raw accelerometer data frequency analysis:	107
Variance Analysis	109
Results.....	110
Further analysis of accelerometer data and pleth data	110
VO ₂ Max	112
Heart Rate Data	117
RPE Data.....	117
Skin Pigmentation.....	120
Final Design Review: Redesign Recommendations	124
Conclusions.....	124
General.....	124
Core Body Temperature.....	125
Publications List.....	126
Inclusion of Gender and Minorities Study Subjects	127
Inclusion of Women.....	127
Inclusion of Minorities.....	127
Inclusion of Children	128
Materials available for other Investigators	129
Commercialization Report	163
Company.....	163
Market, Customer, and Competition	163
The Market.....	163
Fire Service	163
Other Applications	164
Market Acceptance	165
Strategic Alliances, Partnerships, or Licensing Agreements	165
Marketing and Sales Strategy	165
Competition.....	165
Marketing.....	166
1. Technical Marketing	166
2. OEM Sales	166
3. Retro-Fits	166
4. Other	167
IP Protection	167
Production and Marketing Plan	167
SCBA Applications.....	167
Military Applications	168
Sports Applications.....	169
Fitness Applications.....	170
Revenue Stream	172
Future Work.....	173
Core Body Temperature	173
DC Oximetry, Hydration and Impedance.....	173

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Proposed Additional Research and Development	174
Active Field Studies.....	175
Human Studies Issues	176
Expectations of Results.....	176

List of Abbreviations

AC	Alternating Current – in our context it is the pulsatile or cyclic component of a signal.
BCI	BCI, Inc., Waukesha, WI. A part of Smiths Group plc.
BFD	Branford, CT Fire Department
BI	BioImpedance
BMI	Body Mass Index
BSA	Body Surface Area
C	Capacitance
C	Temperature Celcius
CHS	Compensated Heat Stress
CO	Carbon Monoxide
COTS	Commercial, off-the-shelf
CPAT	Candidate Physical Ability Test
CSV	Comma separated value (data file format with each entry separated by a comma)
DAQ	Data Acquisition unit
DC	Direct Current – in our context it is the signal bias or the constant (slow changing) offset to a signal.
EEPROM	Electrically eraseable programmable read only memory
EMT	Emergency Medical Technician
FF	Fire fighter
FF	Footfalls
FFT	Fast Fourier Transform
FFM	Foot Fall Monitor (accelerometer to record subject's steps/gait on treadmill)
GND	Ground – Reference level for electrical signals
HR	Heart Rate
HRV	Heart Rate Variability
HWM	Hazardous Worker Monitor (Sekos Inc's designation for the data acquisition unit for DC oximetry monitoring).
Hz	Hertz – frequency of one cycle per second
IC	Incident Commander
IDLH	Immediately Dangerous to Life or Health
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

Principal Investigator/Program Director (Last, First, Middle): Wiesmann, William P.

MAM mean absorbance minima
MSI Mine Safety Appliance, Inc. (Pittsburgh, PA)
MUX Multiplexor – select one signal from several choices
NASA National Air and Space Administration
NFPA National Fire Protection Association
NIOSH National Institute of Occupational Safety and Health
NSR Non-Significant Risk
OEM Original Equipment Manufacturer
PASS Personal Alert Safety System
PPE Personal Protective Ensemble
PSD Power Spectral Density
R Resistance
R Ratio of Red to IR high and low points in the AC component of the light absorbance signal.
RPE Relative Perceived Exertion
RTC Real-Time clock
SBIR Small Business Innovative Research [Grant]
SCBA Self Contained Breathing Apparatus
SpO₂ % Oxygen Saturation obtained by pulse oximetry
STP Sequential Task Protocol
UCHS Uncompensated Heat Stress (Subjects in PPE in Heat)

List of Figures

Figure 1: Contribution of various anatomic layers to total light absorption (y-axis) in pulse oximetry ^{25,26}	28
Figure 2: Ratio comparison and Normalization of red and IR signals ³⁰	29
Figure 3: The basis of this technology is founded on the premis that physiologically relevant data is contained in the changes (shaded area) in the DC component of oximetry data. Depicted here in as a change over short (12 seconds, left) and longer (7 minutes, right) time periods.....	30
Figure 4: During Phase II human trials, a Jacob's Ladder was used to replace a stair climb activity during the STP (Figure 5) activity.	34
Figure 5: 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. During Phase II, the stair climb was replaces with a Jacob's Ladder (Figure 4).	41
Figure 6: Averaged exercise duration and core temperatures of FF's performing the protocol under warm (red) and cool (blue) conditions. FF's reached the breach and pull apparatus more quickly without PPE, in cool temperatures, and performed this task longer before reaching volitional fatigue than they did in the heat.....	45
Figure 7: Alternating time intervals of recorded oximetry data. For each 30-second interval, there are 20 seconds of absorbance readings separated by 10 seconds during which data were displayed rather than recorded. These 10-second intervals appear as straight lines connecting the intervals of compressed waveforms.	46
Figure 8: Mean absorbance minima (MAM) tracing of a subject completing the exercise protocol. The vertical bars indicate the time stamps delineating the tasks being performed, beginning with weighted treadmill walk (4) and ending with rehab (15).....	47
Figure 9: Mean absorption minima (MAM) tracing of fire fighter who became symptomatic during the protocol and needed to exit the chamber early for rest and rehabilitation. The vertical bar (at 12.55 seconds) shown in activity 12 indicates the time stamp marking the subject's indication that he could not continue. The red (finger probe oximetry) and blue (face mask oximetry) overlap for a period of about 60 seconds before the SCBA unit was turned off, and the face piece was removed.....	47
Figure 10: Absorbance tracings showing (top graph) SCBA mask data from Figure 8, and the results of two additional signal processing algorithms: Mask DC, and Mask Mean. These were derived as described in text above. The lower graph shows data from the same subject on a different day, when he completed the protocol without PPE and in the cooled chamber. The DC and Mean tracings are virtually identical as the lines appear to be superimposed. In both graphs, the core temperature recordings appear in yellow and the temperature scale is shown on the right, vertical axis.	48
Figure 11: Tegaderm TM from 3M used to protect LED electronics from sweat.	50
Figure 12: RPE data from five subjects from the post Phase I studies.....	52

Figure 13: Raw (unfiltered) oximetry tracings in exercising fire fighter using red and IR LEDs in the sensor elements. At this scale, the plethysmographic pattern corresponding to arterial pulsations is evident. The typical negative deflection corresponding with volitional fatigue is also seen.53

Figure 14: Log ratio of Red:Infrared (Equation 1) signal for the entire data set (left) and for one minute of oximetry data (right) obtained from a subject whose treadmill exercise was similar to, but shorter than the one shown in Figure 10. The ratio tracing demonstrates stability of the ratio and the low amplitude of motion artifact. The mean log ratio (0.534 + 0.121) of the data set and one minute sample (0.470 + 0.065) are consistent with the 0.5 ratio that would be predicted if the subject's SpO₂ was 100%.54

Figure 15: Matched data for 3 subjects during continuous exercise to volitional fatigue in the heat. DC oximetry is displayed above (in pink), and oximetric variability for the same subject is shown below (in blue). In each case, data display was discontinued at the point where the DC tracing terminated with a straight line to an absorbance of 100, indicating removal of the sensorized face mask by the subject.55

Figure 16: Oximetric variability over exercise time (in seconds) of the one subject who did not show a diagnostic change in DC oximetry readings as he reached volitional fatigue.56

Figure 17: LED integration into the SCBA mask (left) and the completed system (right).....57

Figure 18: 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.57

Figure 19: Signal strength (mV) at various separations (mm)58

Figure 20: Sample results of air seal and ventilatory performance testing of modified SCBA masks.....59

Figure 21: Photo segments from the forehead sensor site used to quantify fire fighter skin pigmentation levels. Luminosity histograms and calculated means for each of five subjects are on a scale between 0 and 255. The upper right shows 10-second IR plethysmograms (DC+AC) from the 5 subjects. The lower right graph plots the average DC signal vs. the pigmentation luminosity of the subject, and shows no correlation.60

Figure 22: Block diagram for data acquisition system design.61

Figure 23: Matched sets of DC MAM oximetry (top) and Variance (bottom) for the last two minutes of data for three subjects during treadmill trials at U Conn.78

Figure 24: The footfall monitor is shown resting (unsecured) on the treadmill.....95

Figure 25: Plot showing repeated data from the IR pleth sensor. The y-axis is the IR pleth raw value, the x-axis is the corresponding time stamp for that data point. Repeated data from ~580 and ~675 seconds have different values, where as repeated data from ~663 and ~680 seconds has the same value.....97

Figure 26: plot showing inconsistent spacing of data points in time in FFM peak data. The y-axis is the value of the time stamp in seconds. The x-axis is the sample number.....97

Figure 27: Plot showing red absorbance (green line), IR absorbance (red line), and FFM peaks. The peaks of the plethysmogram do not seem to match up to the FFM peaks when compared visually.104

Figure 28: Another example of red and IR absorbance plotted together with the FFM peaks. The peaks of the pleth do not correlate with the FFM peaks.....104

Figure 29: Example from figure 4 zoomed in further. Note that the peaks from the pleth and FFM peaks do not line up.105

Figure 30: Another example of pleth data and FFM peaks. Note the inconsistent and rapid foot fall frequency (e.g. between 163 and 164 seconds). Also note the absence of a recognizable pulse signal.105

Figure 31: Red pleth data in red, raw accelerometer data in blue. In this snap shot, there is a recognizable pulse in the pleth data. Occasionally, the pulse lines up with the accelerometer data, but not consistently. This observation is inconclusive as the syncing of the data within times of less than 0.1 seconds is questionable.....105

Figure 32: Raw accelerometer data from Uconn subject 018568. The red data shows accelerometer data reported as from Event 2: "tm" to Event 4:"ext" indicating the start and end of treadmill exercise. A reexamination of the redundant data however, correctly assigns the blue region of data to the treadmill exercise.....106

Figure 33: Power spectral density (PSD) analysis of red/IR pleth signals and FFM peak signals for the first 300 seconds of treadmill data in Uconn Subject018568. The red and IR PSDs are very similar. However, there is no distinct heart rate peak between 1 and 2.5 Hz as expected for a subject undergoing exercise. The FFM peak data has a PSD that resembles white noise. If the oscillations in the pleth data were caused by the FFM peaks, the PSDs would be similar but they are not....107

Figure 34: Raw Accelerometer data (FFM sensor) showing footfall data (y-axis: 300±50) and the macrochanges (x-axis: 4.3×10^4 - 4.8×10^4 , etc.) that accompany moving the sensor from one experiment apparatus to another (treadmill to ladder climb).108

Figure 35: Power spectral density from raw accelerometer data from UConn subject 018568. The biggest peaks occur around 18 and 21 Hz. This cannot be the result of foot falls.....108

Figure 36: Zoomed in PSD for raw accelerometer data from UConn subject 051868 for the first 300 seconds of treadmill activity. We would expect to see a strong peak around 2-3 Hz (a normal step rate) and harmonics. Instead we see a strong peak at 7.25 Hz and smaller peaks at 1.7, 2.5, 3.3, 4.2, and 4.9 Hz. From examining the plot, it is impossible to tell what the actual foot fall rate is (excluding the peak at 7.25 Hz as it is not feasible to step that fast). This indicates that the raw accelerometer data is not a good measure of foot falls.....109

Figure 37: Example of Variance of red/IR pleth data (top) and FFM peak data (bottom).....110

Figure 38: UConn Subject 018568 IR vs. Accelerometer Data110

Figure 39: Potential Synchronization of Step and Pleth data.111

Figure 40: Power Spectral Density (PSD) for Accelerometer data (left) and IR DC Oximetry data (right).....111

Figure 41: Raw accelerometer data and raw IR.112

Figure 42: Measured vs. Estimated VO₂ max values for subject population.....113

Figure 43: Sample RPE and respiratory rate data for subject 018569 in PPE and heat.118

Figure 44: RPE data from subjects in STP with (left) and without (right) heat and PPE.118

Figure 45: Selected RPE data from subjects in LEP with heat and PPE.....118

Figure 46: Change in Plasma Osmolarity.....119

Figure 47: Change in Plasma Volume.....119

Figure 48: Initial Lactates.....119

Figure 49: Change in Lactates.....120

Figure 50: Calculated variance at study time points for Red (left) and Infra-Red (right) light frequency absorption (UConn treadmill studies).....121

Figure 51: Calculated variance at study time points for Red (left) and Infra-Red (right) light frequency absorption (Yale STP studies).121

Figure 52: Variance data (red frequency) for all subjects during the last two minutes of each subject's STP test.....122

Figure 53: Average (all subjects) change in red frequency absorption variance for last two minutes of subject's STP test activity.....123

Figure 54: Slopes of data trendlines over time (30 seconds, 60 seconds, 120 seconds) for subjects during treadmill trials.....123

Figure 55: Matched data of variance (top) and Slopes of data trendlines (bottom) over time (30 seconds, 60 seconds, 120 seconds) for subjects during CPAT trials with PPE and Heat.124

Figure 56: Pretest data sample of subject 018580 wearing a mask then wearing a "Y"-probe sensor. Initial data for each includes adjusting the sensor, once data is stable, subject holds breath (Valsalva maneuver) as long as then can and release. "A" and "C" points designate when the sensor unit is removed from the subject (data value goes to zero), the "B" point represents when the sensor is unplugged from the data unit (data value goes to ~1).....152

Figure 57: Sample footfall peak data for subject on treadmill.157

List of Tables

Table 1.	Extinction coefficients for oxygenated and deoxygenated hemoglobin at Red and IR wavelengths.....	28
Table 2.	Human subject test sites and assurances.....	39
Table 3.	Subject Population Characteristics	43
Table 4.	Mean measured Tc, Tc increase, and HS for STP.....	44
Table 5.	Times for task completion.....	44
Table 6.	Mean measured Tc, Tc increase, and HS for LEP.....	45
Table 7.	Objective evidence of Physiologic stress (LEP).....	54
Table 8.	Generations and Capabilities of Data Acquisition System Designs	61
Table 9.	Software code (Assembly) for DSPIC processor running HWM sensor unit	62
Table 10.	Software code (C) for DSPIC processor running FFM sensor unit (footfall.c).....	67
Table 11.	Trial Duration, Variance, and RPE for LEP	78
Table 12.	Data sources and time synchronization method.....	82
Table 13.	Data collection chart example.....	84
Table 14.	Software code (perl 4.0) used in generating trend data files.....	85
Table 15.	Data analysis source files.....	95
Table 16.	Variance Analysis Matlab file	98
Table 17.	CorrFFM_PGP_Yale Analysis Matlab file.....	100
Table 18.	CorrFFM_PGP_UConn Analysis Matlab file.....	101
Table 19.	Treadmill Correlation coefficient	103
Table 20.	STP Correlation coefficient	103
Table 21.	VO ₂ max measurements for subjects. Estimated VO ₂ max is not an accurate measure of true VO ₂ max.....	112
Table 22.	Times (in sec) to reach Breach and Pull activity and to Complete STP.....	113
Table 23.	Industrial Standards for Shift Workers in Heat ⁴⁸	116
Table 24.	Heart Rate Data for Subjects in LEP	117
Table 25.	Phase II subject skin pigmentation analysis.....	120
Table 26.	Data file names and included data	129
Table 27.	Subject Ids corresponding to the same individual	130
Table 28.	UConn (Treadmill Studies) Data files	130
Table 29.	Yale (STP) Data files.....	136
Table 30.	Format of _pretest data (events)	152
Table 31.	Suggestions for (magnitude) scaling data for 'SubjectID_A_All.xls'	153
Table 32.	Format of 'SubjectID_A_All.xls'.....	154
Table 33.	Format of 'SubjectID_A_All.csv'.....	155
Table 34.	Format of 'SubjectID_A_Events.csv'	156
Table 35.	Events shorthand descriptions.....	156
Table 36.	Format of 'SubjectID_A_FFpeaks.csv'	157
Table 37.	Format of 'SubjectID_A_Red.csv'.....	157
Table 38.	Format of 'SubjectID_A_IR.csv'	157
Table 39.	Format of 'SubjectID_A_DI.csv'.....	157
Table 40.	Format of 'SubjectID_A_MAM.csv'	158
Table 41.	Format of 'SubjectID_A_LRRIR.csv'	158
Table 42.	Format of 'SubjectID_A_Var.csv'	158

Table 43.	Format of ' <i>SubjectID_A_CTHR.csv</i> '	158
Table 44.	Format of ' <i>SubjectID_ct.csv</i> ' – raw output of CorTemp unit	158
Table 45.	Format of ' <i>uconn SubjectID.csv</i> ' – processed output of CorTemp unit	159
Table 46.	Format of ' <i>SubjectID_ffm.dat</i> ' – raw output of footfall monitor	159
Table 47.	Format of ' <i>SubjectID_ffmFFM.csv</i> '	159
Table 48.	Format of ' <i>SubjectID_ffm.ffm</i> ' – (from Table 10).....	160
Table 49.	Sample of ' <i>SubjectID_ffm.txt</i> ' – Subject 018568, treadmill only data, events recorded by footfall monitor.	160
Table 50.	Format of ' <i>SubjectID_ffmHWM.csv</i> '	160
Table 51.	Format of ' <i>SubjectID.dat</i> '	161
Table 52.	Format of ' <i>SubjectID.ffm</i> '	161
Table 53.	Sample of ' <i>SubjectID.txt</i> ' – Subject 024503, STP, events recorded by Hazardous Worker Monitor (HWM) PC.	161
Table 54.	Format of ' <i>SubjectIDFFM.csv</i> '	162
Table 55.	Format of ' <i>SubjectIDHWM.csv</i> '	162
Table 56.	Fire fighters per Shift Lacking SCBA and SCBA Units At Least 10 Years Old, by Size of Community	163
Table 57.	Leading SCBA manufacturers.	165

Abstract

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 and 2 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, Sekos, Inc. (formerly BioAsyst, LLC) 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 its completion.

With Phase II efforts the results were consistent with previously observed trends. Improved hardware and signal processing allowed for footfall data (motion artifact) to be isolated as a contributor to the signal. Data mining failed to establish a more definitive analysis technique than the previously identified variance analysis; however, such analysis also did not refute the earlier results. The results of the analysis continues to indicate that an individual calibration of the

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system should not be required. However, challenges with the rejection of "false" positives remain.

Translation 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 Ability 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 Occupations

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 than 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 day¹. 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.

General Use

Sports/Exercise/Fitness Monitoring

The human body's thermoregulation system can be stressed by many conditions. Athletes, like workers operating in confined/restricted spaces or firefighters are subject to extreme environmental conditions, wear protective clothing and heavy equipment that can impede their evaporative cooling mechanisms, and exert physiological stresses on their systems.

A human's thermoregulation system normally adjusts to meet physiological stresses that occur with exertion. At the onset of exercise, healthy adults experience a rapid increase in cardiac output. Stroke volume also increases with augmentation of venous return from the periphery and resulting inotropic enhancement based on Frank-Starling forces governing myocardial contractility. As exercise progresses, blood volume is redistributed to the working muscles to meet oxygen demands, and to the skin for dissipation of the heat being produced by the muscles. Ongoing exercise decreases stroke volume due to vascular redistribution of blood volume together with volume loss due to sweating. Cardiac output is maintained by compensatory increase in heart rate to an individual maximum dependant upon the individual's age and conditioning. Respiration rates also increase during exercise. The combination of

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

increased respiratory rates, evaporative sweat loss and redistribution of blood to capillary beds in the skin provide adequate cooling to maintain body temperatures within acceptable parameters.

This thermoregulatory process can be impeded when a person is involved in heavy exertion with dynamic/aerobic and static/anaerobic components. Firefighters' activities, for example, require carrying heavy equipment while wearing thermal and flame resistant protective ensembles (including self-contained breathing apparatus, SCBA) that quantitatively prevent evaporative loss of metabolic heat. This is due to the nature of their protective gear and the work environment (in temperatures in range of 700 degrees F. and upwards), which collectively prevent heat dissipation to the environment. Under these conditions, the cardio-accelerator compensation that normally maintains cardiac output during exercise is lost resulting in an almost immediate reduction in cardiac output with initiation of exertion and sweating. Decreased cardiac output leads to a constriction of the peripheral vasculature to maintain systolic blood pressure, which in turn leads to a rapid rise in core temperature that remains even after exercise ceases. The effect is that of a cascade of sequential failure of compensatory mechanisms. Although not nearly to the same extreme, professional, collegiate, and even high school sports uniforms and protective gear can likewise impede the proper dissipation of heat.

Remote, non-invasive medical monitoring would greatly reduce the chance of impending failure if it was capable of identifying physiological parameters that indicate the achievement of near-maximal work capacity prior to cardiovascular collapse, symptomatic heat illness or other adverse clinical outcomes.

Each year heat-related illness and dehydration syndromes affect thousands of athletes at all levels and is a leading cause of preventable sports injury and death. Rigorous outdoor training in the summer months is correlated to increased risk. Football players, due to their heavy protective equipment, are particularly vulnerable. Outcomes from heatstroke are related to the length of temperature elevation. When therapy is delayed, the mortality rate may be as high as 80%; however, with early diagnosis and immediate cooling, the mortality rate can be reduced to 10%, which highlights the need for early detection.

Data to date, while not yet compelling, is highly indicative that DC oximetry monitoring can be used to determine when the subject has reached a point of volitional fatigue. One of the goals of exercise is to take a body as far as it can go without reaching over a breaking point. It is likely that a system such as this one could be adapted to safely optimize an individual's exercise program.

As with the fire fighter focused system, the sensor system must support rapid data collection, processing and effective transmission over sufficient distances to monitor the person(s) operating in the particular environment. These sensors must input/access individual biological signals, under time constraints, or must perform in severe environments without adding excessive weight to the wearer or impede dexterity or mobility of the wearer.

Medical Monitoring

Pulse oximetry is a well-established, non-invasive medical sensor that detects alterations in hemoglobin oxygen saturation and measures arterial oxygen saturation based on spectrophotometric principles. Pulse oximetry is particularly useful because of the nature and amount of physiologic information that can be derived from it. Vital signs such as heart rate, blood pressure and arterial oxygen saturation are relatively late indicators of compromised tissue

perfusion in patients being monitored for severe medical or surgical conditions. Increased heart rate is a nonspecific sign that is associated with fever, emotional state, endocrine abnormalities and several other factors. When used as an indicator of volume depletion, tachycardia is relatively insensitive, requiring loss of 15-25% of total intravascular volume. This translates to 7-10 liters of fluid from a 70 kg adult. Loss of blood pressure is even less sensitive, and arterial oxygen saturation is maintained until full cardiovascular collapse occurs. Pulse oximetry would therefore appear to have minimal value in detecting sub-clinical fluid depletion or cardiovascular inadequacy for work demands in an arena involving individuals subject to extreme environments or hazardous work conditions.

In the critical care setting, subtle alterations in tissue perfusion are inferred by monitoring indirect indicators such as lactic acid production, biochemical markers of end organ injury and oxygen saturation in mixed venous blood. Testing mixed venous blood requires cannulation of the pulmonary artery and performance of co-oximetry on intermittently obtained blood samples. Current oximetry technology again appears not to be amenable to real-time monitoring.

Studies suggest that the earliest metabolic changes of hypoperfusion are detectable by measurement 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 was found to correlate well with hemodynamic measurements by conventional, invasive devices in ICU patients. Analysis of the plethysmographic waveform generated by pulse oximeters was also found to correlate with volume status in mechanically ventilated patients under general anesthesia. These findings suggest that both the AC and DC components should be monitored (as opposed to only the AC) for accurate results.

Current pulse oximeters measure light absorption through living tissue via an alternating current (AC) or pulsatile component (Figure 1, Figure 2) and a direct current (DC) component. The AC component is the pulsatile expansion of the arteriolar bed with arterial blood, while the DC component represents the absorbencies of the tissue beds such as venous blood, capillary blood and nonpulsatile arterial blood²⁵.

Based on the assumption that arterial blood provides the only pulsatile absorbance between the light source and its photodetector, current pulse oximeters utilize light-emitting diodes in the red and infrared regions. These wavelengths allow oxyhemoglobin and hemoglobin to absorb light at different rates. Specifically, hemoglobin absorbs greater light in the red region, whereas oxyhemoglobin absorbs greater light in the infrared region. The diodes are rapidly switched on and off and the pulse oximeter then measures the AC or pulsatile component of light absorbance at each wavelength and then divides this by the corresponding DC component to obtain a computation that is independent of ambient light intensity, and that can be utilized to calibrate against direct arterial blood measurements. Utilizing the pulsatile signals and other computational schemes pulse oximeters also measures pulse rates.

While effective, current pulse oximeters have inherent drawbacks and suffer from uniform accuracy, particularly when fractional oxygen saturation is 80% or less. Studies on non-critically ill and critically ill patients showed that current pulse oximeters did not provide accurate readings when fractional oxygen saturation was at 63%.

State-of-the-art pulse oximeters provide sufficient accuracy medical monitoring of potentially hypoxemic conditions in resting individuals in controlled environments. However,

Principal Investigator/Program Director (Last, First, Middle): Wiesmann, William P.

they do not provide satisfactory monitoring for early signs of physiologic stress under extreme conditions as needed by firefighters and others working or operating under extreme conditions. Therefore, there is a need to provide a manner of noninvasive physiological monitoring that overcomes the drawbacks of the prior art.

No system or methodology that uses pulse oximetry can provide such measurements, as current pulse oximeters only evaluate pulsatile signals (while using the DC signal for mathematical calculations only). This correlates with oxygen saturation of arterial blood, which is maintained by physiologic compensatory mechanisms until cardiovascular collapse intervenes. This occurs too late to be valuable in monitoring firefighters, as this is the condition that is to be prevented, not simply observed.

The advantage of this system is that it overcomes the drawbacks of current pulse oximeters by providing a methodology and system that is capable of measuring DC components as well as the AC components, for optimal monitoring and accuracy in extreme conditions, as described herein below.

Outcomes, Relevance, and Impact

More than half of fire fighter line-of-duty deaths occur on the fire ground, although structures fires comprise less than 10% of fire service emergency call volume^{2,23,24}. A majority of these deaths are attributed to heart attacks and other manifestations of physiologic stress^{23,24}. Although two fire recruits died of heat stroke during training exercises in the past year, full blown heat stroke is infrequently given as the major cause of occupational mortality in the fire service. The contribution of uncompensable heat stress^{1,27} to the overall category of physiologic stress leading to myocardial infarction and or cardiovascular collapse is unknown, but is probably substantial. The incidence of symptomatic heat related illness and nonfatal stress are likewise unknown, as occupational illness and injury reporting in the fire service is not reliable.

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^{3,4,5}. The heart rate virtually immediately reaches maximal levels as fireground tasks are begun^{3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18}. The muscular activity required in performing 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.

² International Association of Fire Fighters. 1994 Death and Injury Survey. 1995. Washington, DC.

³ Bamard, J., Duncan, H. Heart Rate and ECG Responses of Fire Fighters. *J Occup Med* 1975; 17(4): 247-250.

⁴ Kuorinka I, Korhonen O. Firefighters' reaction to alarm, and ECG and heart rate study. *J Occup Med* 1981; 23:762-766.

⁵ Lim CS, Ong CN, Phoon WO. Work stress of firemen as measured by heart rate and catecholamine. *J Human Ergol* 1987; 16:209-218.

⁶ Abeles FJ, DeVecchio RJ, Himel VH. A firefighter's integrated life protection system. Report of Contract #219454, Fire Department of the City of New York, 1974

⁷ Gledhill N, Jamnik V. Characterization of the physical demands of firefighting. *Can J Spt Sci* 1992; 17:3 207-213.

⁸ 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.

⁹ 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.

¹⁰ Motohashi Y, Takano T Influence of age on cardiorespiratory responses of firefighters during exercise in the heat. *Industrial Health* 1985; 23:289-293.

¹¹ Pipes TV. Physiological responses of fire fighting recruits to high intensity training. *J Occup Med* 1977; 19:129-132.

¹² Bennett BL, Hagan D, Banta G, Williams F. Physiological responses during shipboard firefighting. *Aviat Space Environ Med* 1994; 65:225-231.

¹³ 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.

¹⁴ Romet TT, Frim J. Physiological responses to fire fighting activities. *Eur J Appl Physiol* 1987; 56:633-638.

¹⁵ Duncan HW, Gardner GW, Bernard RJ. Physiological responses of men working in fire fighting equipment in the heat. *Ergonomics* 1979; 22:521-527.

¹⁶ Sothman MS, Saupé K, Jasenof D, Blaney J. Heart rate response of firefighters to actual emergencies. *J Occup Med* 1992; 34:797-800.

¹⁷ Skoldstrom B. Physiological responses of firefighters to workload and thermal stress. *Ergonomics* 1987; 30:1589-1597.

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^{18,19}, while ongoing fluid loss further exacerbates the decreasing cardiac output. These events are the hallmarks of uncompensable heat stress, and lead to exhaustion²⁷.

Further, they represent definitive mechanisms to defeat each of the major physiologic strategies for thermoregulation in working firefighters.

The current program was built on the premise that some form of remote physiologic status monitoring of working FF's can decrease fire ground morbidity and mortality by recognizing exhausted personnel before they are incapacitated. As a candidate technology for this purpose, oximetry would appear to have many advantages. The enabling technology has been widely used for more than 20 years, and it has been very successfully ruggedized by Emergency Medical Services providers for the out-of-hospital setting. The sensors are non-invasive and produce a very robust signal, providing continuous data on heart rate, oxygen saturation of circulating hemoglobin, and characteristic waveforms representing beat-to-beat oxygen saturation. The sensors can be integrated into FF protective ensembles so that the monitoring capability does not compromise either response times or the integrity of the suits. The required combination of sensors, transmitters and power supplies would not add significant weight, external tethering or "cube" that could encumber a fire fighter, decreasing essential mobility or dexterity during fire ground operations. Furthermore, the size of the data stream would allow continuous remote monitoring via radio-telemetry within reasonable bandwidth and without interference with voice communications. Finally, pulse oximeter output could be very useful if coupled with some kind of FF identification and location technology. Like similar systems proposed for the 'smart' battlefield, the combination of vital signs and location would allow incident commanders to make better decisions regarding the salvageability of FF's lost or trapped in conflagrations, and to vector more effective rescue efforts where appropriate.

Pulse oximetry, as currently used in acute care clinical monitoring, however, is unlikely to achieve our objective of detecting exhaustion in FF's prior to collapse. This is because heart rates predictably remain at or near maximal during firefighting, so that function doesn't offer any obvious advantage. In the absence of underlying pulmonary disease, arterial oxygen saturation reported by currently available pulse oximeters will generally be preserved regardless of heat stress, myocardial ischemia, carbon monoxide toxicity and other physiologic threats to fire service personnel, until cardiovascular collapse intervenes. It should be noted that work in progress in other labs has incorporated additional wavelengths of light into pulse oximeters in order to simultaneously measure arterial carboxyhemoglobin and methemoglobin levels along with oxygen saturation. These functions may prove useful in the future for monitoring responders potentially exposed to these hazards, though they are not directly applicable to our stated objective.

We hypothesized that the DC, or nonpulsatile component of transcutaneous oximetric monitoring would detect physiologic changes indicating that fire fighters were nearing

¹⁸ 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.

¹⁹ 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.

exhaustion. In theory, hemoglobin in the venous, capillary and other non-arterial tissue compartments is relatively desaturated when local and circulating lactate levels begin to rise. As previously discussed, elevated lactate levels are consistently observed during experimental FF simulations. Changes in DC oximetry might also indicate changes in blood volume circulating between the sensor's emitting and detecting elements due to compensatory alterations in regional circulation or generalized hypovolemia.

Value of SBIR Project, Expected Outcome and Impact

Each year, an average of 50 fire fighters (FF's) die due to heart attack and related physiologic problems brought on by the extreme aerobic effort and muscular exertion of structural fire fighting, and exacerbated by the heavy, thermo-protective, waterproof clothing and intense temperatures of the fire ground. One of the most dangerous situations on the fire ground occurs when a fire fighter becomes incapacitated during an interior structure attack, and needs to be rescued. Rescue operations are complicated by the inherent hazards of the fire ground, which include poor visibility from smoke and darkness, inadequate and ineffective voice communications, instability of burning structures, and evolving fire conditions.

It is our belief that a system capable of monitoring the physiologic health of FF's on the fire ground and providing an unobtrusive measurement of volitional fatigue to promote the timely removal of FF's from fire operations into rehab will reduce the need for fire fighter rescue operations due to health reasons and may reduce overall fire ground related deaths. Our system offers a dramatic improvement over current methods, as it takes the onus away from the individual fire fighter and allows the fire commander to coordinate crew rotation on a personal basis without interfering with fire ground operations.

With the completion of this effort, Sekos Inc. has developed a sensor system design and data demonstrating the system detects volitional fatigue while the fire fighter is still capable of self-rescue.

The data generated during human trials and field studies has and will continue to be used to generate peer-reviewed publications and public presentations. These articles will be used to demonstrate the effectiveness of the system, and to generate interest within the fire community in acquiring the technology.

Completion of this Phase II effort positions Sekos Inc. and its corporate collaborator(s) to engage the interest of additional partners and resources to stage further trials and evaluations until sufficient data on the system's effectiveness can be acquired to be compelling. With this additional data in hand, the system can be developed for fire-service affordable manufacturing and full beta testing. The Phase III work will include evaluation of command module function, reliability and durability of the system over time in the field with multiple deployments, and the ergonomics of the individual units. Sekos Inc. will conduct standard, pre-release marketing research in conjunction with the SCBA manufacturer. This final phase will be facilitated by the strong working relationships with both large municipal and smaller suburban fire departments maintained by the research group headed by Sekos Inc. The readily available fire service test bed for the product is further defined by Interspiro's substantial U.S. market share, and includes both military and municipal fire departments with which Sekos Inc. already has offers of cooperation. Sekos Inc. and Interspiro will continue to collaborate during the field evaluation stages, taking advantage of Interspiro's experience bringing innovative technologies into SCBA products.

Principal Investigator/Program Director (Last, First, Middle): Wiesmann, William P.

Importantly, Interspiro currently has a product line in which it is incrementally introducing technologies including head-up warning display and through-mask access. The Sekos Inc. oximetry components are entirely compatible with this product line, as the Phase I & II prototypes have demonstrated. This collaboration continues to help direct the project toward early commercialization of both an SCBA product line featuring DC oximetry for physiologic status monitoring, and an after-market package through which older models and other manufacturer's products may be upgraded to include this capability. Sekos Inc. continues to monitor development of promising technologies that will expand the spectrum of hemoglobinopathies detected by LED-based oximeters. The ability to continuously and non-invasively measure carboxyhemoglobin and methemoglobin are particularly relevant to structural fire fighting. Although this technology is several years away, we envision including it in future iterations of the sensorized mask system. Our processor and telemetry systems will be designed to leave room for the addition of future technologies and sensors.

The ultimate goal of Sekos Inc. is to offer products for enhanced operational effectiveness and safety of personnel in hazardous environments such as the fire ground. In addition to the proposed physiologic monitor project and previous environmental monitoring projects, Sekos Inc. is actively engaged in developing personnel accountability and locator products. The resulting comprehensive incident management system will be marketed for deployment after field trials demonstrate that the cumulative information from physiologic, environmental and position sensors improves operational decision making in the field and enhances the safety of personnel.

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°F²⁰. 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^{21,22}. 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^{23,24}.

Uncompensable heat stress due to exercise in protective clothing has been studied using young military volunteers on treadmills in environmental chambers²⁷. 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.*¹⁸, who used immediate post-exercise 2-dimensional cardiac echo to estimate stroke volume based on aortic cross-sectional area.

²⁰ Lawson, JR. Firefighter's clothing and thermal environment of structural fire fighting. NISTIR 5804, 1996.

²¹ Kenny WL, Johnson JM. Control of skin blood flow during exercise. *Med. Sci Sports Exercise* 1992; 24(3):303-312.

²² Havenith G, Coenen JML, Kristemaker L, Kenny WL. Relevance of individual characteristics for human heat stress response is dependent on exercise intensity and climate type. *Eur J Appl Physiol* 1998; 77:231-241.

²³ Fahy R, LeBlanc PR. US firefighters fatalities. *NFPA J* 2001; 95:67-74.

²⁴ U.S. Fire Administration. Firefighter Fatalities in the United States in 2000. FEMA 2001.

Pulse oximetry is a well-established, non-invasive medical monitoring modality that measures arterial oxygen saturation through spectrophotometric techniques²⁵. The hardware utilized by these sensors has proven rugged enough to support application in extreme environments. Previous testing²⁶ 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 stress²⁷. 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 pulsations²⁷. 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 patients²⁸. Analysis of the

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

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

²⁷ Montain SJ SM, Cadarette BS, Quigley MD, McKay JM. Physiological Tolerance to Uncompensable Heat Stress: Effects of Exercise Intensity, Protective Clothing, and Climate. J Appl Physiol. 1994;77(1):216-222.

²⁸ 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.

plethysmographic waveform generated by pulse oximeters was also found to correlate with volume status in mechanically ventilated patients under general anesthesia²⁹.

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 sensor²⁵. 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 than 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.

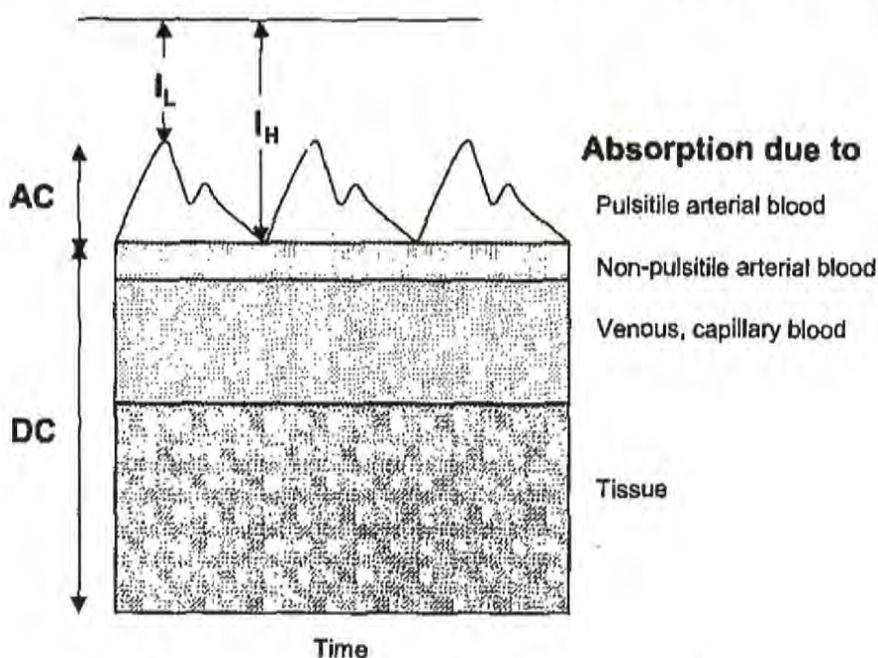


Figure 1: Contribution of various anatomic layers to total light absorption (y-axis) in pulse oximetry^{25,26}.

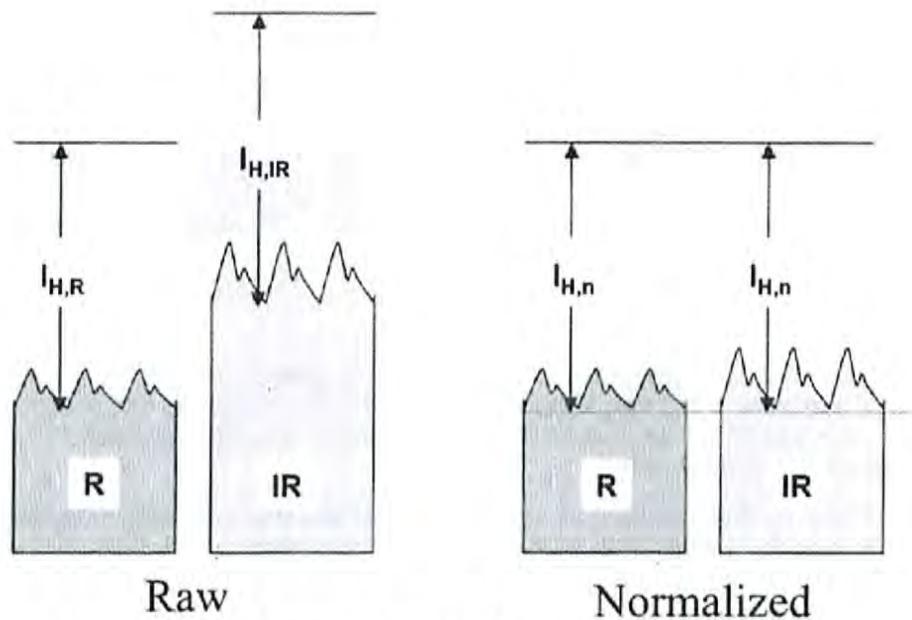
Because of the many variables that can contribute to the total absorption of light, commercial oximeters use a DC filtering circuit to remove this DC component, leaving only the AC signal, a plethysmographic waveform correlating to the rhythmic expansion of the arterial system with cardiac systole. Ratios 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 wavelengths³⁰

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

²⁹ Partridge BL. Use of pulse oximetry as a noninvasive indicator of intravascular volume status. *J. Clin. Monitoring* 1987; 3:263-8.

³⁰ Webster, J G, ed. *Design of Pulse Oximeters*. Institute of Physics Publishing 1997.

Figure 2: Ratio comparison and Normalization of red and IR signals³⁰.

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

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

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 $\epsilon(\lambda)$ 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)³⁰.

Commercial pulse oximeters are looking exclusively for these measurements, and thus changes in the DC component of the received signals are discarded using a high pass filter. Significant changes in the DC component (Figure 3) generally occur over a "longer" period of time, say greater than two seconds (0.5 Hz) than the frequency of the plesmographic signal (the AC component) which corresponds to heart rate, say 50-180 BPM (0.83 to 3 Hz). Thus by discarding all signals below 0.5 Hz, the DC component is removed and the AC component becomes much easier to calculate.

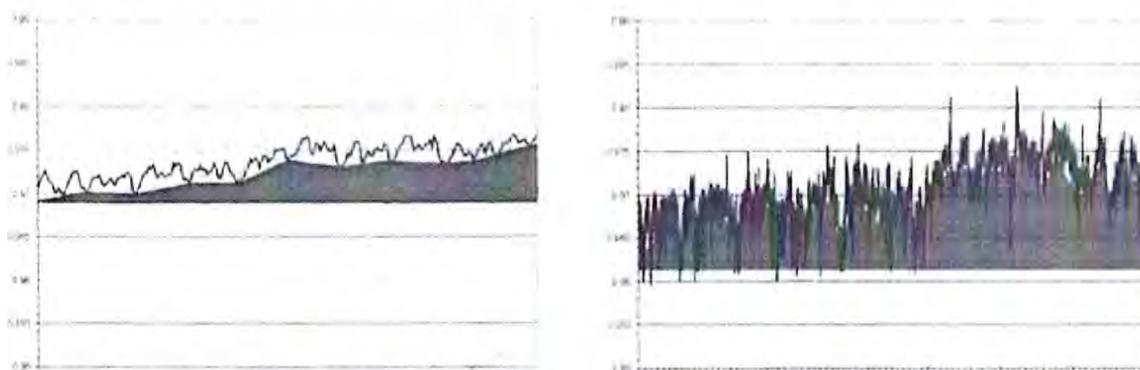


Figure 3: The basis of this technology is founded on the premise that physiologically relevant data is contained in the changes (shaded area) in the DC component of oximetry data. Depicted here in as a change over short (12 seconds, left) and longer (7 minutes, right) time periods.

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

Previous work by Sekos Inc. and others demonstrated that pulse oximeters function reliably in reflectance mode on the forehead. **SCBA-Based Oximetry for Fire Fighter Physiologic Monitoring**, a collaborative project involving Sekos Inc. and its academic partners, is built on this premise. In Phase I of this NIOSH SBIR-funded initiative, working prototypes were developed and used in a small pilot study. The feasibility of integrating oximeters capable of telemetering data to a remote monitoring station into functioning SCBA was demonstrated. Reliable signals from subjects performing simulated fire suppression tasks while wearing full protective ensembles in the heat were recorded. Preliminary results suggested that acute changes in the DC, or non-pulsatile component of the oximetry waveform, may correspond to a state of physiologic fatigue in working FF's. This observation has been reliably reproduced in subsequent studies conducted to confirm its validity. To further pursue development of this promising technology, this Phase II proposal aims were:

1) Develop and build the system hardware for the next generation prototype device.

The design of the prototype device used in post Phase I studies will be modified in Phase II. For data acquisition, an upgraded processor will be integrated with data storage, transmission, and signal amplification electronics onto a circuit board. Before the system can be operationally deployed on the fire ground, it must be capable of receiving and processing transmissions from multiple units simultaneously. The current monitoring software will also be upgraded to include local data interpretation capability and integrated alarm thresholds.

2) More precisely define the physiologic processes reflected in the SCBA mask oximetry waveforms, in order to establish monitoring parameters and alarm thresholds.

Hypothetical algorithms for detecting exhaustion of the normal mechanisms maintaining thermoregulation and tissue perfusion prior to entering the final common pathway to cardiovascular collapse through the use of DC oximetry will be evaluated. The Phase I experiments must be repeated and must include the physiologic correlates measured in the supplemental studies performed since the completion of Phase I. Specifically, volume loss, lactate levels, pH, Rating of Perceived Exertion (RPE), and oxygen consumption will be measured concomitantly with DC oximetry observations in IRB-approved studies using current FF's as subjects. Both experimental models of exertion in a heated environmental chamber that have previously been used in this project will be employed. Linear approach to fatigue will involve weighted treadmill walking in PPE and heat, while the complex, intermittent exercise protocol on customized props simulates work on the fire ground. The magnitude of DC oximetry changes in various individuals along with indices of oximetric variability will be recorded. With this information, we will be able to establish alarm thresholds that can then be tested in the operational environment.

3) Demonstrate reliable functioning of the system.

Fire ground conditions present a challenging environment for electronic devices as they are likely to get hot, soaked, jostled and isolated from receiving units by distance, concrete, rebar, extraneous electromagnetic interference and local, geophysical features. Experience with radio transmission under a wide range of fire ground conditions suggests that the system may also require repeaters to eliminate loss of data due to radio dead spots.

Tasks

The specific tasks to achieve the overall aims of the project included:

- (1) **Production** of a limited supply of SCBA units sensorized for DC oximetry based on revised specifications following the above studies.
- (2) **Correlation** of DC oximetry values and trends with other physiologic parameters experimentally monitored in FF's, voluntarily serving as human subjects during simulated firefighting evolutions, under conditions of uncompensable heat stress.
- (3) **Development** of an oximetric variability index and correlation with DC oximetry values as well as the other monitored physiologic parameters.
- (4) **Establishment** of acceptable ranges and alarm thresholds for DC oximetry and oximetric variability index.
- (5) **System Testing** these fully NIOSH- and NFPA- compliant SCBA units with the DC oximetry monitoring system under fire service emergency operational conditions, including live burns, at fire training academies.

Procedures

Human Subjects Research

Experimental Protocol (Phase I)

Core Temperature (T_c) and Other Physiologic Monitoring

T_c was monitored during all experimentation performed to evaluate SCBA-based oximetry as a modality for detection of physiologic stress in firefighters. CorTemp[®] FDA-approved

capsules were purchased from HTI Technologies, Inc. (Palmetto, FL). Each ingestible, 2 cm, silicone coated capsule remains in the human digestive tract for 1-3 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 accurate to $\pm 0.1^{\circ}\text{C}$. One capsule was ingested by each firefighter approximately 3-12 hours before his scheduled chamber time. The FitSense[®] (Southborough, MA) monitoring system for the CorTemp[®] capsules includes a pager-sized receiver/recorder worn on the belt.

Upon completion of each experiment including rehabilitation and rehydration, the data from the CorTemp[®] monitor were downloaded onto a portable PC and the monitor reset to acquire data from the next subject. Data were acquired at a frequency of one sample every 15 seconds. Data acquisition began about 10 minutes before the subject started the protocol and continued through about 30 minutes of rehabilitation following the protocol. Tc data obtained every 15 s were averaged to provide mean values for each minute throughout the protocol. Physical characteristics of FFs were recorded; body mass index (BMI) and body surface area (BSA, by the Dubois method) were calculated.³¹ HS values in kJ $[(\Delta\text{Tc}) \cdot (\text{wt in kg}) \cdot (3.49 \text{ kJ}^{\circ}\text{C} \cdot \text{kg})]$, where ΔTc is the net change in Tc during FF task, and $3.49 \text{ kJ}^{\circ}\text{C} \cdot \text{kg}$ is the average specific heat of body tissues, were determined for each participant. Crude Tc data were filtered to exclude artifact from analysis. Readings that were $\geq 2^{\circ}\text{C}$ different from previous or following time points and those exceeding 42°C were excluded from determination of mean 1-minute values. Excluded artifact represented $< 0.01\%$ of data collected, and all 1-minute mean readings were based on at least 2 out of 4 possible data points.

All analyses of temperature and physiologic data were performed using version 8.02 of the SAS statistical package.³²

Personal Protective Ensemble (PPE)/Self-Contained Breathing Apparatus (SCBA)

FFs' PPE included helmet (Cairns & Brother, Clifton, NJ), hood and gloves (Nomex[™], WLGore & Associates, Elkton, MD), coat and bunker pants (Globe Mfg, NH), and leather or rubber boots depending on firefighters' personal preference. Each full set satisfied NFPA 1971, Standard on Protective Ensemble for Structural Fire Fighting.³³ SCBAs were NFPA-1981 compliant Interspiro Spiromatic S-2 model units with 30-minute carbon-fiber air cylinders filled to 4,000 psi.³⁴ Because coat and bunker pants are composite materials (outer shell, moisture barrier, and thermal barrier), they are rated for total heat loss (THL, measures evaporative heat transfer, or breathability) and thermal protective performance (TPP, measures thermal insulation) ratings as outlined by the NFPA.

Sequential, Simulated Fire Task Model (STP)

The Yale University School of Medicine's Human Investigation Committee (Institutional Review Board, IRB) approved these studies. The investigators obtained informed consent from

³¹ DuBois D, DuBois EF. A formula to estimate the approximate surface area if height and weight are known. Arch Intern Med. 1916; 17:863-71).

³² SAS/STAT software: changes and enhancements, through release 6.11. Cary, NC: SAS Institute, Inc, 1996.

³³ National Fire Protection Association NFPA 1971: Standard on Protective Ensemble for Structural Fire Fighting. Quincy, MA, 2000.

³⁴ National Fire Protection Association NFPA 1981: Standard on Open-Circuit Self-Contained Breathing Apparatus for Fire and Emergency Services. Quincy, MA, 2002.

each of 10 subjects who volunteered to participate in the study. All participants were career or volunteer Class A (interior structural) fire fighters, aged 20-50 years and members of the Branford Fire Department, Branford, CT. All had received unrestricted, NFPA compliant³⁵ medical clearance for full fire fighting duty from Yale's Occupational and Environmental Medical Program, within one year of study participation. 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[®] capsule. Saliva tests for bloodstream alcohol and oral temperatures were also taken prior to initiation of experiments.

A fire fighting simulation of sequential tasks that could be performed under climatically controlled conditions in an environmental chamber was adapted from the internationally recognized and validated fire service Candidate Physical Ability Test (CPAT)³⁶ for use in evaluating SCBA-based oximetry as an indicator of physiological exhaustion in firefighters. The chamber is one of several located in the John B. Pierce Laboratories at Yale University, and provides roughly 1,680 ft³ of uniform, precisely controlled temperature and humidity conditions for conducting thermal stress experiments. The apparatus and equipment required for the fire task 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 compare oximetry responses under conditions where normal evaporative cooling was possible with conditions of uncompensable heat stress, this protocol was performed once with the chamber temperature set at 18°C and the participant wearing gym shorts, T-shirt, and SCBA, then a second time with the chamber temperature at 40°C and the subject in full PPE and SCBA. Chamber humidity was maintained at 45% with both temperatures. Tc data was transmitted to a recording device carried by the subjects in a PPE pocket or in a fanny pack. 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.

The experimental protocol, designated as the Sequential Task Protocol, or STP, is described in detail in *Methodology* starting on page 40, and is pictured in Figure 5. When a loud alarm sounded, the subject rapidly donned PPE (including SCBA), and proceeded to complete simulated fire tasks in a pre-determined sequence. Figure 5A demonstrates a FF walking on a treadmill with a harnessed 50 lb high-rise hose pack. Figure 5B shows the FF on a stair climbing apparatus. The lights inside the chamber were turned off, and the subject began a right hand search around the periphery of the darkened 12' x 12' chamber dragging a 50' length of 1 3/4" canvas-jacketed hose line (Figure 5C). After finding the 120 lb rescue dummy and with the chamber still dark, the subject dragged or carried the dummy back around the periphery of the chamber, and out of the door (Figure 5D).

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

³⁵ National Fire Protection Association NFPA 1582: Standard on Medical Requirements for Fire Fighters and Information for Fire Department Physicians. Quincy, MA, 2000.

³⁶ International Association of Fire Fighters and International Association of Fire Chiefs. The Fire Service Joint Labor Management Wellness/Fitness Initiative. Candidate Physical Ability Test. Washington, DC: International Association of Fire Fighters, Department of Occupational Health and Safety, 2000.

above, and then performed an overhaul simulation consisting of pushing and pulling a pike pole against standardized weight resistance in a modified Molitor[®] breach and pull apparatus to volitional fatigue (Figure 5E-F). 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 orally rehydrated with water *ad libitum* while clinical parameters were monitored until heart rates and temperatures had returned to normal. Times at the start and completion of the breach and pull task as well as the full protocol were recorded.

Experimental Protocol (Phase II) CPAT-Like (STP) Studies (Yale)

The most significant change in the protocol between Phase I and Phase II studies was that the stair climb (Figure 5B) was replaced with a Jacob's Ladder³⁷, which is a much better approximation for the fire fighter's CPAT test.



Figure 4: During Phase II human trials, a Jacob's Ladder was used to replace a stair climb activity during the STP (Figure 5) activity.

In addition to this experimental change, RPE (perceived exertion) questions were asked of the fire fighters at 2-minute intervals throughout the trial, and pre-and post blood samples were drawn and analyzed for the subjects.

Experimental Protocol (Phase II) Treadmill Studies (LEP) and VO₂ Max (UConn)

A second protocol for testing the oximetry system using firefighters exercising in heat was developed and approved by the IRBs at both Yale University and the University of Connecticut. This experiment took place in an environmental chamber at the University of Connecticut Human Performance Laboratory at the University of Connecticut, Storrs, CT.

The protocol was simplified so that FFs exercised on a single apparatus (treadmill) in the heat (40°C) to volitional fatigue, while wearing PPE with SCBA and a 75 lb vest and without intervening recovery periods. The subjects' starting conditions were better standardized by having them pre-hydrate with one liter of water the night before the experiments were conducted. SCBAs were supplied with a constant air supply via Interspiro's Air Source Cart (Branford, CT) so that FFs were not limited by length of air supply. Tc, and maximum Tc (Tcmax) were measured. HS was calculated as described above. Several assays of fluid status including urine

³⁷ <http://www.jacobsladderexercise.com/>

specific gravity, plasma hemoglobin and hematocrit, and serum glucose and lactate levels were measured. Ratings of perceived exertion (RPE) were recorded.

RPE is a subjective measurement for which modified Borg Scales were used;³⁸ these and thirst and thermal scales were recorded throughout each subject's exercise routine to quantify progression from the rested to fatigued state.^{39,40} At 2-minute intervals, an investigator held up a series of cards with ordinal scales rating the intensity of their sense of 1) overall fatigue (6-20 scale), 2) lower extremity fatigue (6-20 scale), 3) central (cardiovascular) fatigue (6-20 scale), 4) thirst (1-9 scale), and 5) heat (0-8 scale). FF's indicated by pointing the number on each card that described their current perception, and these were recorded with the time of exercise.

Protection of Human Subjects

1. Risks to Subjects

A. Human Subjects Involvement and Characteristics

Human studies using the sensorized masks involved active FF's between the ages of 18 and 50 from the Branford, CT Fire Department. Participation in the study was voluntary, and each subject signed informed consent prior to entry into the protocol. All subjects were cleared for duty by the Yale University Occupational Health Program using NFPA 1582, Standard on Comprehensive Occupational Medical Programs for Fire Departments. FF's having a history of ischemic cardiac disease were cleared for participation by the Yale University cardiologist who follows them, and had documented negative exercise stress testing within the preceding 6 months.

B. Sources of Materials

The human studies associated with this project are neither randomized nor blinded. They are not a part of or incidental to any clinical evaluation or treatment of the subjects. Participants in this study are volunteers from the Branford Fire Department, Branford, CT, and one fire training academy for the field trial. The nature of the study and any risks were fully explained and volunteers signed consent forms in accordance with the requirements of both the Yale University and University of Connecticut IRB's. Dr's. Bogucki and Armstrong conducted the volunteer selection, informed consent process and risk explanation in accordance with the requirements of the IRB's.

Each individual completed the study protocol in the chamber with no one except the investigators in or near the chamber unless the participant specifically requested the presence of others. The list of investigators who were present and had access to the data were provided to each subject as part of the HIPAA compliant informed consent process. There was no attempt to segregate participants in the field trials; the evolutions were predetermined by training staff, not the investigators. All recorded data was kept strictly confidential, and was maintained in a locked Yale office. All reported outcomes were reduced or aggregate data from which individual performances cannot be deduced. Unless specifically requested to do so for some reason by a study participant, the investigators and company will not release any records or data relating to that individual.

³⁸ Borg G. Perceived exertion as an indicator of somatic stress. *Scand.J.Rehab.Med.* 1970; 2:92-98.

³⁹ Young AJ. Microclimate cooling during upper and lower body exercise. *J App Physiol* 1987; 63: 1218-1223.

⁴⁰ Toner MM, Drolet LL, Pandolf KB. Perceptual and physiological responses during exercise in cool and cold water. *Perceptual Motor Skills* 1986; 62:211-218.

Once data collection is completed, data analysis was conducted at all sites. Only Dr. Bogucki at the Yale site has access to personally identifiable data on study participants. Data analysis conducted at the Sekos Inc. and Dartmouth sites was performed with anonymous subject identifiers for which only Dr. Bogucki has the key. Identifiers were created so that all data relating to a single subject could be correlated. Dr. Wiesmann and Mr. Pranger have completed the on-line course from the Office of Human Research Protections (OHRP), and are thus able to handle data at the Sekos performance site. All of the academic collaborators have similarly completed the courses required by their respective IRB's.

C. Potential Risks

There was a significant time commitment totaling 3 days of combined travel and working out in the Environment Chamber facilities. The small but finite risk of highway travel to and from the subjects' homes or fire head quarters to the study site was understood. Although unlikely based on previous experience, participation in this study could have resulted in heat-related illness, muscle strains, transient dehydration, or other physiologic responses to a brief period of heavy exertion in a warm environment.

The CorTemp^R capsule could theoretically break open and cause gastric irritation, although this has not been previously documented. Children who have accidentally ingested similar components have not been harmed. Since there are metal parts inside the pill, subjects received warnings not to undergo a MRI study for any reason until after the pill has been eliminated from the gastrointestinal tract. The CorTemp receiver was kept available to determine whether a transmitting capsule is still present in a subject who needs to know for any reason.

2. Adequacy of Protection Against Risks

A. Recruitment and Informed Consent

A general announcement was made to the Branford Fire Department's union soliciting participation in the study at the regular monthly meeting of International Association of Fire Fighters, Local 2533. Inclusion and exclusion criteria were explained at that time. A similar announcement was made at the regular business meeting of Rescue Company 1, a volunteer unit of the Branford Fire Department that is also located at Fire Headquarters with the career engine company. Additional volunteer companies were planned to be approached to participate only if necessary to recruit the target number of participants described in the proposal. A small financial inducement payable upon completion of the study was offered to participants.

At the fire training academies, the investigators coordinated study times with training staff schedules. One or two days prior to beginning the studies, the investigators addressed the class and distributed the study information including the informed consent document. Potential participants were given the opportunity to ask questions both in the group, and following the presentation, individually.

B. Protection Against Risk

This study attempted to safely simulate the demands placed on individuals during the early stages of structural fire fighting in order to understand physiologic responses. These responses are known to differ from other types of uncompensable heat stress¹¹. The current best hypothesis for the physiologic sequence of events comprising the hemodynamic and thermal responses to firefighting has been briefly described above. Based on the relevant literature and fire fighting experience, the environmental temperature setting and the total duration of exercise were

selected for these experiments to provide the widest possible margin of safety. That is, the tasks are similar to those performed on initial fire attack and the conditions will provide exogenous heat while not allowing dissipation of endogenously generated body heat. However, the trials did not continue nearly long enough for either hemodynamic compromise or significant elevation in body temperature to occur. The ambient conditions and exercise duration chosen elicit detectable alterations in heart rate, body temperature, and, perhaps, in the non-pulsatile (DC) oximetry readings. A detectable decrease in arterial oxygen saturation over such a short exercise period was not anticipated. These studies were designed to demonstrate whether these parameters can be continuously monitored through the integrated sensors and radiotelemetry under these mild conditions. Monitoring the FF's during their routine training exercises characterizes the nature and magnitude of the changes in these parameters resulting from the extreme conditions in which they actually work and train.

There was a significant time commitment totaling 3 days of combined travel and working out in the Environment Chamber facilities. The small but finite risk of highway travel to and from the subjects' homes or fire head quarters to the University of Connecticut was understood. Participation in this study could have resulted in heat-related illness, muscle strains, or other unanticipated responses to a brief period of heavy exertion in a warm environment. The investigators minimized the chances of such adverse outcomes through the following safeguards:

- 1) Assuring current medical clearance for structural fire fighting duty
- 2) Assuring the absence of current symptoms or medications that would predispose subjects to development of medical problems during this testing
- 3) Selecting 104°F as the maximal ambient temperature to which subjects will be exposed
- 4) Continuous visual, audio- and physiological monitoring of subjects while they are completing the protocol in the chamber
- 5) Making it clear to each subject that he must discontinue the protocol immediately if he becomes fatigued, nauseous, short of breath, lightheaded, or experiences chest tightness or muscle soreness, and that he is free to discontinue working in the chamber at any time for any reason
- 6) Having a Board Certified Emergency Medicine physician fully equipped with cardiac monitor/defibrillator as well as advanced life support pharmaceuticals and airway adjuncts present during all work in the chamber

In the unlikely event of a study-related injury or medical complication, the following arrangements were prepared:

- 1) Participation in the study is considered a BFD training and equipment testing activity. Although the FF's will be off duty rather than 'on the clock', the department has agreed to assume liability through its normal insurance and compensation support for the activity. This relationship with the BFD does not in any way affect the voluntary nature of participation in the study and does not give the department access to the individual results obtained. The chief of the department will be given the names of those traveling to the University of Connecticut prior to departure on each study day.
- 2) Any acute illness or injury that occurs during work in the chamber at Yale and requires urgent medical evaluation in the opinion of the study participant or the monitoring staff will be evaluated at the Yale-New Haven hospital with which Yale's

Section of Emergency Medicine has a standing agreement for emergency medical coverage.

- 3) Any illness or injury that appears to be related to participation in the study and develops after the participants have returned to Branford will be evaluated and treated through the Emergency Department at Yale-New Haven Hospital, and coordinated by Dr. Bogucki.
- 4) Any injury resulting from a traffic accident occurring en route to or returning from Yale will be managed as medically appropriate, including transport via local EMS to the nearest trauma facility if needed.

The oximetry sensor array posed a non-significant risk (NSR) to the study subjects. The sensor array is entirely non-invasive, using optical techniques to measure the reflectance of light frequencies off the forehead. The sensors are currently used clinically to monitor arterial oxygen saturation in humans. The electromagnetic power levels of the light and sensor electronics do not pose a hazard to humans.

The CorTemp[®] device is a medication-sized capsule that is swallowed by the participant a few hours before participating in the study trial. The FDA has approved this device for human use. It is not generally used by FF's during training exercises, but was used during our study to correlate any observed alterations in monitored parameters with core temperature. The CorTemp device is currently approved for research use and was used in accordance with directions. This device is considered to be a NSR device.

As discussed above, there was no incremental risk to subjects wearing the sensorized face masks with their SCBA in the field studies. They simply participated in their routine training exercises with the rest of their class.

3. Potential Benefits of Proposed Research to Subject and Others

SCBA Oximetry for Fire Fighter Physiologic Monitoring is focused on correlating changes in DC oximetry waveforms generated by sensors integrated into SCBA face pieces with a state of volitional fatigue in FF's. We believe this is the point in the continuum between initiation of exertion in the heat and total incapacitation at which a working FF can no longer safely perform demanding tasks in an IDLH environment, but is still able to exit the hazard zone without assistance. While it may seem intuitive that FF's could recognize the subjective symptoms of fatigue and extricate themselves from a hazard zone to the rehab area, it is part of fire service culture that individual FF's ignore signs of personal limitations and danger to effect rescue or interior fire suppression. FF's are rarely willing to admit they are tired, as this will cause their entire crew to abandon emergency operations in favor of rehab. A noninvasive, easily telemetered means of recognizing this condition would remove the critical timing of crew rotation through work/rest cycles from individual discretion to command decisions made at the chief or company officer level. The fire fighter subjects thus will benefit from a product that potentially reduces fire fighter injuries and/or deaths.

4. Importance of Knowledge to Be Gained

The physiological response of FF's during exertion differs from that of athletes and the military due to the intensity of heat, the weight and thermal properties of PPE, the respiratory challenge of using SCBA, and the combination of aerobic/static exercise. This research contributes to the development of a noninvasive device to recognize severe fatigue for use in

environments where reliable detection has not been possible. The development of an earlier warning system that unlike the PASS alarm, alerts personnel when self rescue from an IDLH environment is still possible, serves to provide an added level of safety and may contribute to a reduction in FF line-of-duty deaths and injury due to physiologic stress.

Collaborating Sites

Human Clinical Trials were conducted according to the IRB approved protocol only at the University of Connecticut site or the Yale University site. Data Analysis was conducted at all sites. Only Dr. Bogucki or Dr. Van Gelder at the Yale Site has access to personally identifiable data on study participants. Data Analysis conducted at the Sekos Inc. and Dartmouth sites utilized anonymous subject identifiers for which only Dr. Bogucki and Dr. Van Gelder have the key. Identifiers were created so that all data relating to a single subject could be correlated. No other sites have access to any subject data.

Table 2. Human subject test sites and assurances.

Site	Location	Activity	OHRP assurance number
Sekos	Germantown, MD	Engineering, Data	SPA S-21995-01, FWA00007376
Yale	New Haven, CT	Data Analysis	FWA 00002571, IRB00000595
U. Connecticut	Storrs, CT	Human Trials	MPA #M1023 (8/31/04)
Dartmouth College	Manchester, NH	Data Analysis	FWA 00003095
Quantum Devices	Barnfield, WI	Mask Modification	No access to Subjects or Data
Interspiro	Branford, CT	Mask Testing	No access to Subjects or Data

Population Sample

The population studied included only currently active and medically cleared firefighters who were trained and qualified to wear SCBA. With the exception of the field trials, the population was limited to members of one local fire department. This department was selected because it is the only one in the area that provides the appropriate level of annual medical evaluation to adequately control the risk of participation to subjects.

Sources

All human trials were conducted at the University of Connecticut site. Collaborating sites with an appropriate need and protections will have access to non-personally identifiable data from those studies. Collaborative sites will not conduct independent human research.

Data Safety and Monitoring

The Yale University and University of Connecticut IRB's require a compliant data safety and monitoring plan to be implemented prior to enrolling subjects. The approved protocols under which the Phase I and post-Phase I studies were conducted provided for monthly review of the aggregate data and submission of summary reports yearly. Without these reports, annual approval would not be granted. There are no anticipated long-term adverse effects associated with these studies, they are not blinded, and there are no longitudinal components to the research. There is no intervention involved that would require periodic comparison of the welfare of an experimental population with a control group. Any potentially adverse outcomes from these studies would be recognized at the study location with investigators present, or within 24 hours. Any adverse outcome related or potentially related to participation in these studies would be reported to the IRB's at both institutions immediately or on the next business day, as well as be included in the annual report. CorTemp capsules are already FDA approved for this application;

any adverse outcome related to ingestion of these capsules will be reported directly to the FDA as well as to both IRB's. There are no other drugs or medical equipment issues that would be under FDA purview involved.

Methodology

Phase I

Under the efforts of the Phase I SBIR, BioAsyst LLC (now Sekos Inc.) 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 FF's. After the optimal distance (2.65 ± 0.15 cm) of the emitting elements from the detecting elements for reflectance mode oximetry at the forehead was empirically established, commercially available SCBA facemasks were modified to include pulse oximetry sensors. NIOSH-compliant testing by the original SCBA manufacturer demonstrated that the sensorized masks retain their fit, seal and functional properties. Sample test data from the modified masks are shown in the Phase I Final Report, and the full set of test results are available upon request. We developed and built oximetry processing electronics that acquire the absorbance readings from the sensors, and then both record and radio-transmit the signal for real-time display on a laptop computer. Initially, in order to accommodate processing, data storage, and telemetry limitations, a single, visible red LED (662nm) was used as the DC oximetry sensor, rather than the dual frequency red/infra-red system used in commercially available, medical grade, pulse oximeters.

The Phase I prototype system was assessed for its functionality under fire ground working conditions and its ability to detect physiologic changes consistent with uncompensable heat stress. A fire fighting simulation of sequential tasks that could be performed under climatically controlled conditions in an environmental chamber was adapted from the internationally recognized and validated fire service Candidate Physical Ability Test (CPAT) for these purposes. Nine currently active FF's completed the IRB-approved protocol, comprising several timed events such as: carrying a high-rise hose pack on a treadmill and stair stepper, a search and rescue task performed in the dark, and exercise to volitional fatigue on a breach and pull apparatus. Each subject performed the protocol once wearing full PPE with the chamber heated to 40°C and on a separate day repeated it without PPE and with the chamber at 20°C (Figure 5).

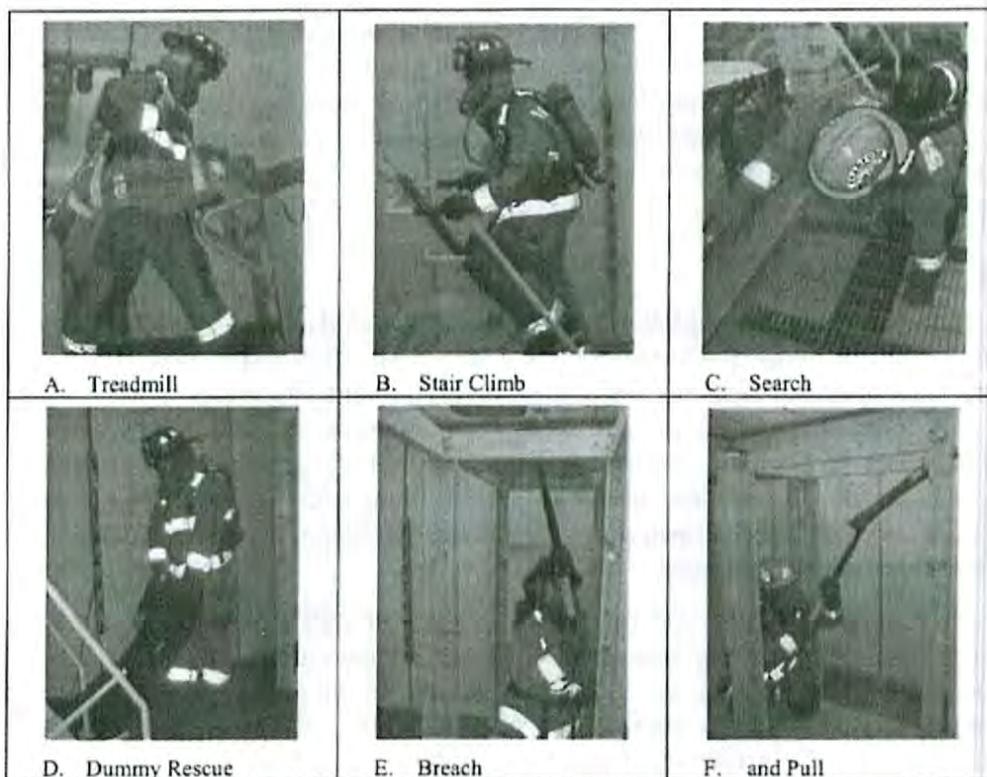


Figure 5: Subjects with apparatus and props used in firefighting task simulation protocol, shown inside the environmental chamber. The search and rescue evolutions were performed in the dark. During Phase II, the stair climb was replaced with a Jacob's Ladder (Figure 4).

Core Temperature

Firefighters (FFs) depend on their protective clothing, or personal protective ensemble (PPE), to allow them to function in temperatures approaching 700°F.²⁰ The outer shell, moisture barrier and thermal barrier of PPE prevent most of the evaporative cooling that should result from sweating. High sweat rates actually increase the weight of the PPE and resultant work performed by the FF.¹⁷ Interior structural firefighting involves heavy work; aerobic activity and working muscles compound metabolic heat production while the most important physiologic cooling mechanisms are significantly impeded by the PPE.

Previous reports have documented rapid temperature elevations in working FFs,^{18,19} confirming that the capacity of the normal thermoregulatory system is exceeded under such conditions, causing uncompensable heat stress (UCHS)²⁷. These factors are thought to contribute to the substantial cardiovascular morbidity and mortality associated with fire suppression. FF deaths are not decreasing despite advances in technology and a marked decrease in the number of structure fires. There is no existing experimental method to reliably study UCHS in working FFs.

The core temperatures of the fire fighter subjects were recorded every 15 seconds by ingestible thermosensors transmitting to a recording device carried by the subjects in a pocket of the PPE or in a fanny pack (during non-PPE trials). Times to complete the evolutions in the chamber were also recorded. Figure 6 summarizes these data.

Both trials (with heat/PPE and cool/no PPE) resulted in increased T_c . Maximum T_c (T_{cmax}) reached was 40.4°C (with heat/PPE). Given the small n and short exercise period, T_{cmax} data do not actually reach statistical significance. Three FFs demonstrated an increase in T_c (with heat/PPE) $\geq 2.5^{\circ}\text{C}$. Most of their rapid rise in T_c occurred after completion of the study protocol and resulted in the late peak in Figure 6 (left).

Experiment Design

Sequential task protocol (STP)

FFs performed simulated fire ground tasks, as described in detail below, in an environmental chamber located in the John B. Pierce Laboratories at Yale University, New Haven, CT. The chamber provides roughly $1,680\text{ ft}^3$ of uniform, precisely controlled temperature and humidity conditions. 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 FF through the protocol while observing for hazards or signs of clinical decompensation such as confusion or ataxia, were present inside the chamber throughout each experiment.

For the first sequential task trial, participants wore full PPE and self-contained breathing apparatus (SCBA), and the environmental chamber temperature was set at 40°C (UCHS conditions). Although far below the thermal extremes of the fire environment, a maximal ambient temperature of 40°C was chosen since subjects would not be cooled by passive transfer of metabolic heat through the skin into the environment.

One week later, all participants performed identical tasks wearing gym shorts, T-shirt, and SCBA with the chamber temperature at 18°C for the second sequential task trial (CHS conditions). Chamber humidity was maintained at 45% for both temperatures, and air velocity in the chamber was maintained at 0.05 m/s .

Linear exercise protocol (LEP)

A second protocol simulating a continuous rather than intermittent workload took place in an environmental chamber at the University of Connecticut Human Performance Laboratory, Storrs, CT. FFs completing this trial wore full PPE including SCBA, as well as a 75 pound weight vest (to simulate carrying a high-rise hose pack) and walked on a treadmill until exhaustion. The environmental chamber was set at 40°C , and chamber humidity and air velocity were maintained as described above for the Yale chamber.

Subsequent to all trials, FFs were allowed to drink water *ad libitum*. Each subject rested and was monitored until all parameters had returned to baseline. Post-experiment instructions were given to each FF.

Analysis

Physical characteristics of FFs were recorded; body mass index (BMI) and body surface area (BSA, by the Dubois method) were calculated.³¹ T_c and T_{cmax} were measured. T_c data were obtained every 15 seconds and averaged to provide mean values for each minute throughout the protocol. Time to T_{cmax} was determined.

T_c crude data were filtered to exclude artifact from analysis. Readings that were $\geq 2^{\circ}\text{C}$ different from previous or following time points and those exceeding 42°C were excluded from

determination of mean 1-minute values. Excluded artifact represented <0.01% of data collected, and all 1-minute mean readings were based on at least 2 data points.

Heat storage values in kJ were determined for each participant,

$$(\Delta T_c) \cdot (wt \text{ in kg}) \cdot (3.49 \text{ kJ/}^\circ\text{C} \cdot \text{kg}) \quad \text{Equation 3}$$

where ΔT_c is the net change in T_c during protocol, and $3.49 \text{ kJ/}^\circ\text{C} \cdot \text{kg}$ is the average specific heat of body tissues.^{41,42}

For the STP, times at the start and completion of the breach and pull task as well as the duration of the full protocol were recorded. For the LEP, total exercise times were recorded.

All analyses were performed using version 8.02 of the SAS statistical package. Paired t-tests were performed to compare data, with statistical significance established at $p \leq 0.05$.

Results

Sequential Task Protocol

Of the ten subjects initially recruited for the study, one reported symptoms of gastroenteritis the night before the first trial and was excluded. All subjects were experienced FFs, and familiar with the simulated tasks. Years of experience and physical characteristics are shown in Table 3. They were not acclimatized to hot working (environmental) conditions, as the study took place in New England during winter. Pills were ingested approximately 3 h prior to the UCHS trials (mean 221 min, range 190-263 min), and approximately 8 h prior to the CHS trials (mean 477 min, 317-665 min range).

Table 3. Subject Population Characteristics

	STP		LEP	
	Mean (n=9)	(range)	mean (n=5)	(range)
Age (years)	30.9	(21-35)	30.8	(23-37)
Weight (kg)	98.6	(84-118)	99.5	(85-115)
Height (cm)	180.3	(175-188)	182.9	(178-183)
Body Mass Index (BMI) (kg/m ²)	30.5	(23.8-37.4)	29.4	(24-35.7)
Body Surface Area (BSA) (m ²)	2.18	(2.07-2.34)	2.21	(2.11-2.35)
FF Experience (yr)	13	(6-17)	11.5	(7-16)

Nine FFs completed two trials each. One T_c sensor failed, leaving 17/18 complete data sets. One FF (of nine) fatigued prior to completion of the full list of tasks under UCHS conditions.

All trials under both conditions resulted in increased T_c . The highest T_{cmax} reached was 40.4°C (UCHS). Under CHS conditions, T_{cmax} averaged 37.79°C (range $37.46\text{-}38.12^\circ\text{C}$) whereas trials under UCHS conditions resulted in a mean T_{cmax} of 38.94°C (range $37.78\text{-}40.44^\circ\text{C}$) ($p=0.0298$). See Table 4 for T_c increase data; $>1.5^\circ\text{C}$ increase was seen under UCHS conditions. Figure 6 (left) summarizes the T_c increase data; all FFs in both trials reached their T_{cmax} after conclusion of exercise.

A wide range of heat storage values was observed throughout the study (131 kJ to 1205 kJ). The average heat storage was 578 kJ (range 211.33-1205.25kJ) in UCHS conditions and 210.83

⁴¹ O'Brien C, Hoyt RW, Buller MJ, Castellani JW, Young AJ. Telemetry pill measurement of core temperature in humans during active heating and cooling. *Med Sci Spt Exer.* 1998;30(3):468-472.

⁴² Brown-Brandl TM, Yanagi T, Xin H, Gates RS, Bucklin R, Ross GS. A New Telemetry System for Measuring Core Body Temperature in Livestock and Poultry. *Applied Engineering In Agriculture.* 2003;19(5):583-589.

kJ (range 131.43-327.75kJ) in CHS conditions (Table 4). There was a subset of subjects that demonstrated an increase in T_c (UCHS) $\geq 2.5^\circ\text{C}$, and thus showed a very significant rise in heat storage (mean 1073 kJ, $p=0.0002$) compared to the other FFs performing work under UCHS conditions. In CHS conditions, they did not show a significant change in heat storage compared to the others ($p=0.1063$). These three FFs had a significantly faster rate of T_c increase under UCHS conditions than the others (Table 4). Most of this rapid rise in T_c occurred after completion of the study protocol (Figure 6 left).

Table 4 shows duration of total exercise as well as breach and pull times. UCHS conditions did not influence times for completion of these tasks significantly. The average length of time FFs performed the STP was <16 min.

The average exercise times are shown in Figure 6 (left). The end of the Breach and Pull task was the end of the total exercise, as shown by the second red (UCHS) or blue (CHS) dashed line. Note that FFs took longer to reach the breach and pull task in UCHS, and then fatigued more rapidly, for slightly shorter total exercise duration.

Table 4. Mean measured T_c , T_c increase, and HS for STP.

	No Heat/NoFPE (SEM)		Heat/FPE(SEM)		p-value
T_c Max ($^\circ\text{C}$)	37.79	($\pm 0.07^\circ\text{C}$)	38.94	($\pm 0.37^\circ\text{C}$)	0.0298*
T_c increase ($^\circ\text{C}$)	0.63	($\pm 0.07^\circ\text{C}$)	1.64	($\pm 0.42^\circ\text{C}$)	0.0556
Heat Storage (kJ)	211	($\pm 21.77\text{kJ}$)	578	($\pm 151.47\text{kJ}$)	0.0548

Table 5. Times for task completion.

	No PPE (STP)	Heat/PPE(STP)	p-value
Breach and Pull (min)	3.3 (± 0.82 min)	1.9 (± 0.33 min)	0.2020
Total Exercise (min)	15.8 (± 2.6 min)	15.0 (± 1.3 min)	0.5178
Time of $T_{c_{\max}}$ (min)	19.8 (± 2.5 min)	20.38 (± 1.4 min)	0.412

Linear Exercise Protocol (LEP)

Five FFs completed the protocol. Years of experience and physical characteristics were similar to the STP study group (Table 3). Total exercise times on the treadmill before onset of volitional fatigue ranged from 10 to 31 minutes. Two capsules failed, leaving three complete T_c data sets. The two subjects whose capsules did not register nevertheless completed the entire protocol to obtain all other data. The other three FFs had a core temperature $> 38^\circ\text{C}$ when they stopped (Table 6), and their temperatures continued to rise after they began recovery. One subject exceeded 39°C before core cooling was observed on the monitor. Each reached T_{\max} at least 8 minutes after completion of exercise.

FFs indicated 5 types of subjective fatigue, as shown in Figure 12. Each of the five FFs showed a linear increase in all five RPEs for a total of 25 RPE tracings. As is evident on the graphs in Figure 12, the scales are 6-20 for overall fatigue, lower extremity fatigue, and central fatigue. 17 Thirst (1-9 scale) 18 and thermal fatigue (0-8 scale) 19 were indicated by each FF at the same time points, and also represent steadily increasing fatigue.

Table 7 shows that four out of five objective measurements of physiologic stress were significant. Mean weight loss due to sweating over the short exercise protocol was >0.6 kg, and the increase in red blood cell concentration was also significant. Every FFs' serum lactate increased, and the mean increase was significant. Changes in serum glucose were not significant and are not shown, though the initial glucose measurements demonstrated that FFs were

normoglycemic prior to exercise. Urine specific gravity did not change. All mean values are shown \pm standard error.

Table 6. Mean measured T_c, T_c increase, and HS for LEP.

	mean	range
T _{cmax} (°C)	38.6	38.4-39
T _c increase (°C)	1.185	0.69-1.815
Heat Storage (kJ)	371	227.3 - 574.5

A wide range of heat storage values were seen for the entire study (131 kJ to 1205 kJ). The difference between HS levels with PPE and without PPE trended towards significance, averaging 578 kJ (range 211.33-1205.25kJ) with PPE and 210.83 kJ (range 131.43-327.75kJ) without PPE (p=0.0548).

Both *total exercise* as well as *breach and pull* times were shorter under heat/PPE conditions. Without PPE, mean time of final breach and pull exercise was 3.32 min before stopping due to fatigue, and 1.88 min with PPE. FFs reached the breach and pull apparatus more quickly without PPE, in cool temperatures, and performed this task longer before reaching volitional fatigue than they did in the heat (15.81 min vs 14.96 min with PPE) (Table 4 and Figure 6).

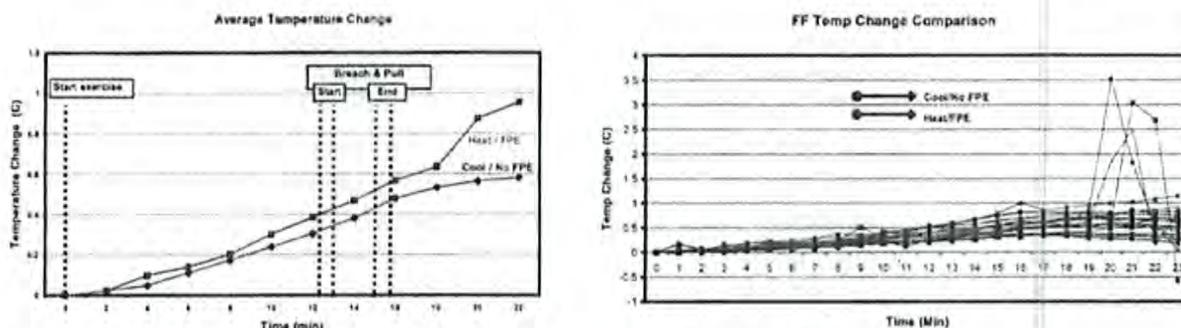


Figure 6: Averaged exercise duration and core temperatures of FF's performing the protocol under warm (red) and cool (blue) conditions. FF's reached the breach and pull apparatus more quickly without PPE, in cool temperatures, and performed this task longer before reaching volitional fatigue than they did in the heat.

Over this short exercise period, the average change in core temperatures was not statistically significant. During rehab after completion of exercise in the heat, a subpopulation (3 out of 9) of subjects displayed a marked, rapid rise in core temperature, resulting in the late peak seen in the graph. Further studies needed to be performed to determine whether this is was consistent observation.

DC Oximetry

DC oximetry data were obtained from the exercising subjects through the sensorized SCBA face piece connected to our signal processing electronics, using a single, red LED sensor emitting at 660 nm. The data were recorded for 20-second intervals alternating with 10-second intervals during which the sensor output was processed, stored and telemetered. This was done to ensure ongoing data acquisition throughout the protocol, as well as to monitor any major changes in the FF's that might indicate a need for us to suspend the experiment and medically evaluate the subject. An example of the resulting, discontinuous oximetry tracing recorded while one of

the subjects performed the chamber evolutions appears in Figure 7. The limitation of recording only intermittent data was overcome in our post Phase I studies.

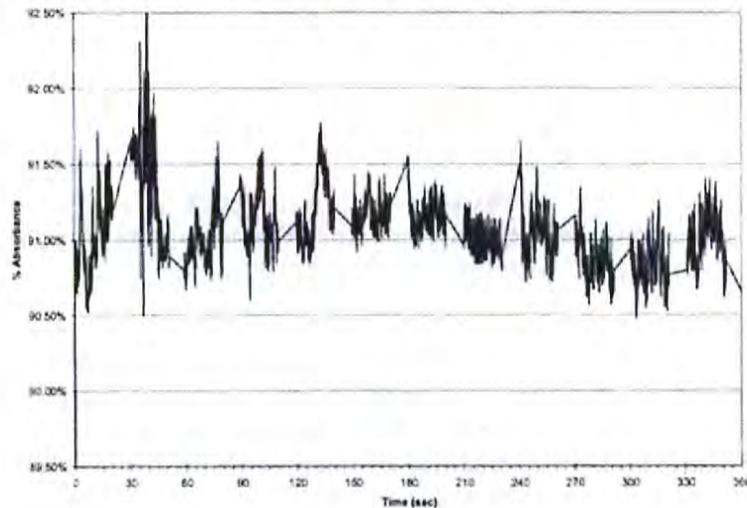
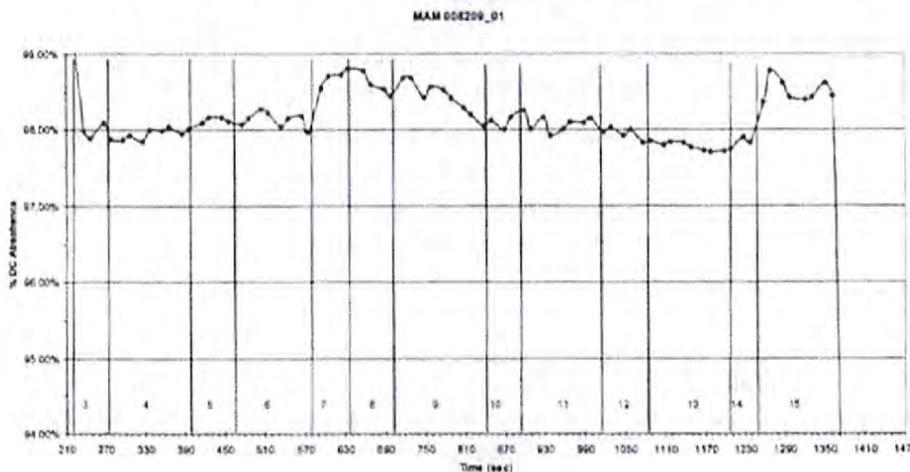


Figure 7: Alternating time intervals of recorded oximetry data. For each 30-second interval, there are 20 seconds of absorbance readings separated by 10 seconds during which data were displayed rather than recorded. These 10-second intervals appear as straight lines connecting the intervals of compressed waveforms.

The plethysmographic peaks corresponding to arterial pulsations were filtered out of the signal by calculating mean absorbance minima (MAM) for each 10-second interval. This isolated the DC signal and reduced the excessive information within the archived waveforms. No attempt was made to exclude the 10-second periods in which no signal was recorded; the MAM calculator was also not synchronized with the 30-second recording/monitoring cycles within the datasets. An example of a MAM tracing of one of the exercising subjects appears in Figure 8.



Task Description
(see Figure 3)

1. Alarm (Start)
2. Gear On (PPE)
3. Air Bottle On
4. Treadmill
5. Transition
6. Stair Climb
7. Transition
8. Search
9. Rescue drag
10. Out of chamber
11. Stair Climb.2
12. Transition
13. Breach & Pull
14. Exit Chamber
15. Rehab

Figure 8: Mean absorbance minima (MAM) tracing of a subject completing the exercise protocol. The vertical bars indicate the time stamps delineating the tasks being performed, beginning with weighted treadmill walk (4) and ending with rehab (15).

The MAM tracing of the only fire fighter who became symptomatically fatigued and was unable to complete the heat/PPE protocol showed 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 9.

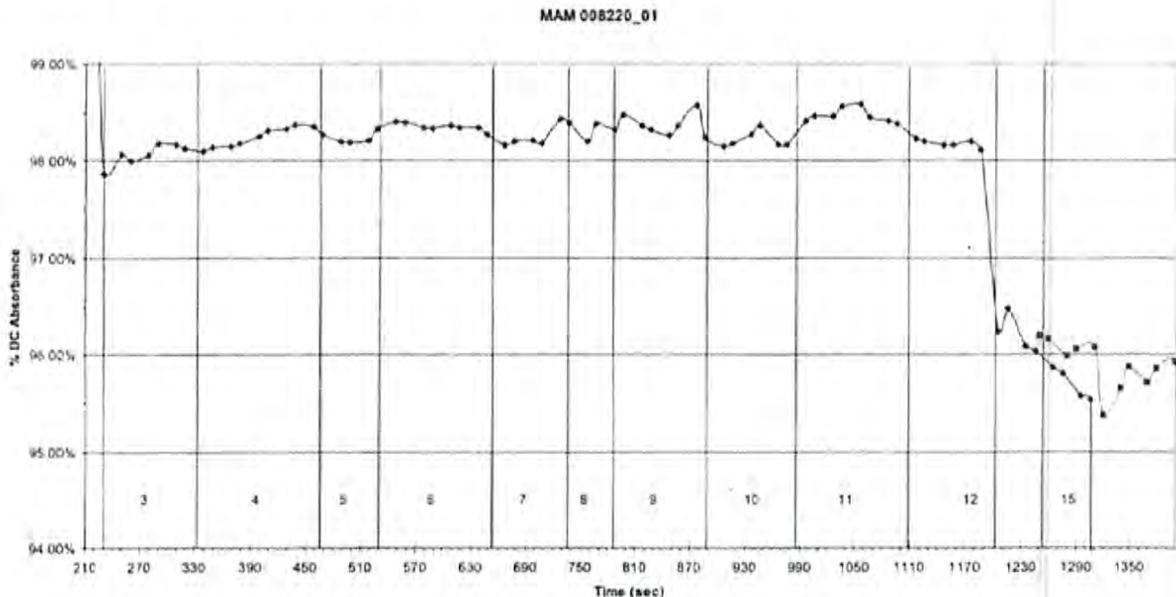


Figure 9: Mean absorption minima (MAM) tracing of fire fighter who became symptomatic during the protocol and needed to exit the chamber early for rest and rehabilitation. The vertical bar (at 12.55 seconds) shown in activity 12 indicates the time stamp marking the subject's indication that he could not continue. The red (finger probe oximetry) and blue (face mask oximetry) overlap for a period of about 60 seconds before the SCBA unit was turned off, and the face piece was removed.

The symptoms and discontinuation of the protocol occurred at approximately 1170 seconds (19 min, 30 sec) during the rest period (activity 12 on the graph) after the second stair climb. Once out of the chamber and sitting down (time period 15 on the graph), he was monitored by both face piece and finger probe oximeters for 60 seconds. 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 stabilized at about 96% absorbance for the remainder of this subject's time in rehab (data not shown).

In addition to MAM, the oximetry data were submitted to an alternative processing protocol to refine the waveforms 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 20-second data recording periods to eliminate time averaging over the periods in which no data were captured. 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 Hz 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 10.

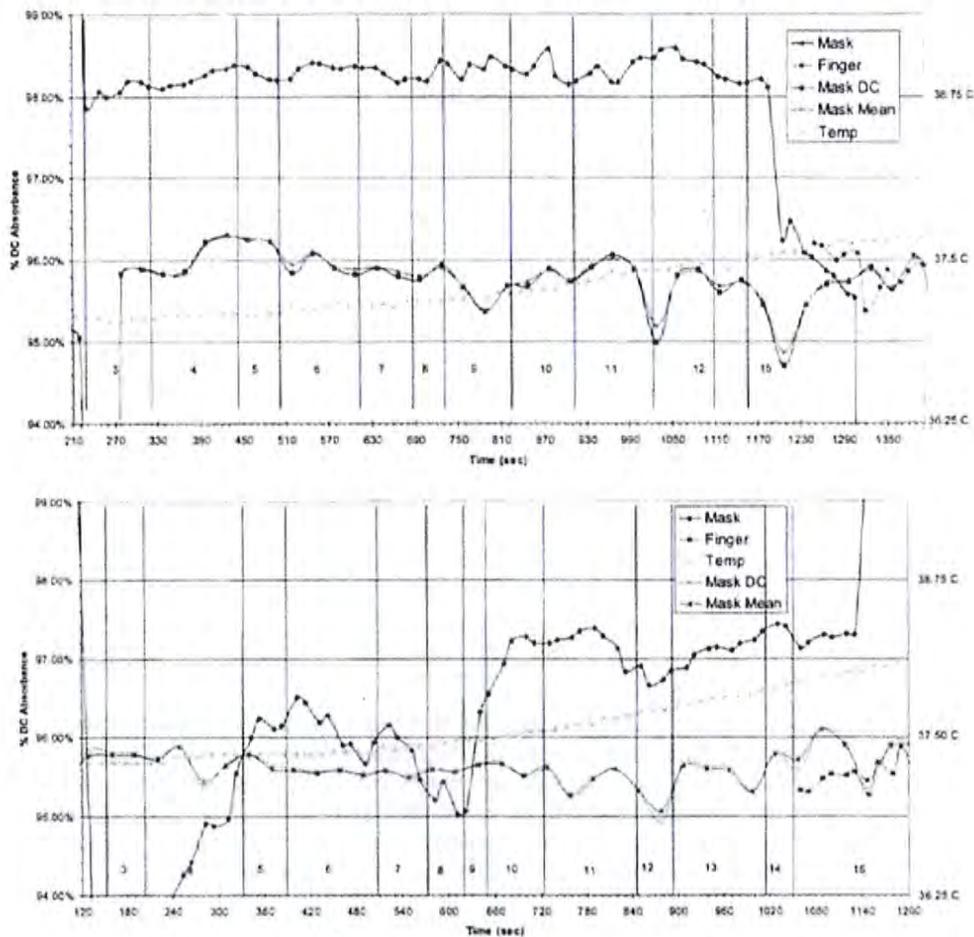


Figure 10: Absorbance tracings showing (top graph) SCBA mask data from Figure 8, and the results of two additional signal processing algorithms: Mask DC, and Mask Mean. These were derived as described in text above. The lower graph shows data from the same subject on a different day, when he completed the protocol without PPE and in the cooled chamber. The DC and Mean tracings are virtually identical as the lines appear to be superimposed. In both graphs, the core temperature recordings appear in yellow and the temperature scale is shown on the right, vertical axis.

These filtering and processing techniques resulted in DC Absorbance tracings that remained within fairly narrow tolerances throughout exercise. A tendency toward increased variability of these DC and Mean waveforms as the subjects neared volitional fatigue was noted, and this effect was greatest in the individual who became symptomatic and was unable to continue. The observation of the marked negative deflection of the MAM signal that was seen only in the symptomatic subject and the trend toward increased variability in the amplitude of the DC and Mean signals as all subjects approached volitional fatigue (data not shown) suggested that this

technology could prove useful in monitoring FF's under conditions of uncompensable heat stress with further research and development.

Interpretation of the results of these trials was complicated by several factors. There was intermittent loss, and in some cases complete loss of oximetry data from some of the subjects due to a problem with sweat short-circuiting the mask electronics. This resulted in only 4 complete, matching sets (heat/PPE and cool/no PPE) of usable data out of 9 sets performed. This small sample size severely limited our ability to statistically analyze or draw general conclusions from our data.

The Phase I prototype oximetry sensors also had significant intrinsic limitations. They used only a single wavelength LED in the visible red range. Although oxygenated and deoxygenated hemoglobin are known to absorb differently at this frequency, the lack of absorbance data at a second frequency precluded estimation of oxygen saturation. This would have required determination of ratios with absorbance at either the isosbestic wavelength (805 nm), as in classical oximetry studies, or a near IR wavelength as is done in commercially available pulse oximeters. Even at the single wavelength, the recorded data were discontinuous, as discussed above. Limitations in the signal processing electronics did not allow the data to be recorded and transmitted to the monitoring software simultaneously. For these initial studies, it was considered essential to have a means of knowing whether the system was acquiring data and if there were discernable changes in the absorbance tracings that might correlate with physiologic decompensation of the subject. The choice to monitor as well as record was vital since this was the first systematic, controlled study conducted using these prototypes. The resulting loss of approximately 1/3 of the total information from the recorded data, however, caused significant problems with signal analysis.

The fire attack evolution performed in the heated environmental chamber was the best qualitative simulation fire fighting activities reported thus far in physiologic studies of FF's. In retrospect, however, it was probably not ideally suited to answer the research question at hand. First, it was too complex; the interposed rest periods in the protocol made it difficult to follow a pattern of progressive physiologic changes. The size of the air cylinders used was not adequate to allow the subjects to keep going to full volitional fatigue. To standardize the effect of the change from cylinder to ambient air across all subjects, the hatches on the face pieces were opened and the air cylinders turned off prior to beginning the final (breach and pull) task. The loss of the cooling effect of the SCBA air on the face undoubtedly increased subjective perception of heat and fatigue during this task. This, together with joint fatigue and boredom were more commonly reported as the reason for termination than was a true sense of exhaustion. This emphasizes the final limitation of these studies: the only physiologic parameter that was monitored along with DC oximetry was core temperature. The core temperature data clearly showed that the protocol induced the type of heat stressed previously observed in working FF's. These experiments did not look at any of the other typical correlates of exertional heat stress such as sweat loss, or other indicators of dehydration, changes in blood pH or lactic acid, or a standardized scale of subjective rating of perceived exertion (RPE).

Although these experiments helped establish the technical feasibility of monitoring working FF's using SCBA-based oximeters, a combination of equipment constraints and protocol complexity resulted in only a single observation of an apparently diagnostic deflection in the DC oximetry tracing coinciding with symptomatic fatigue in a fire fighter. Thus, it was not clear that proof-of-concept had been achieved.

Prior to concluding Phase I efforts, Sekos Inc. had solved the problem of sweat from the subject's forehead short-circuiting the oximeter electronics (Figure 11). After evaluating a number of possible solutions to this problem, the sensor window was covered with a vapor permeable, water occlusive skin dressing product that protected the electronic sensor elements from sweat. In extensive interim testing, this problem has not recurred.



Figure 11: Tegaderm™ from 3M used to protect LED electronics from sweat.

Since the completion of Phase I, Sekos Inc. has developed a second generation DC oximetry monitoring system using both red and infrared (IR) LED's. The new system also includes improved processing, higher sampling frequency and continuous, rather than intermittent telemetry. A new protocol for testing the system using firefighters exercising in the heat was developed in collaboration with research partners at Yale University and the Human Performance Laboratory at the University of Connecticut, and was approved by the IRB's at both institutions.

The protocol was simplified from the Phase I studies in that the FF's exercised on a single apparatus (treadmill) in the heat (40°C) while wearing PPE and a 75 lb vest (simulating carrying hose packs and tools) to volitional fatigue, without intervening recovery periods. The subjects' starting conditions were better standardized by having them pre-hydrate with one liter of water the night before the experiments were conducted. Additional evidence of physiologic stress was obtained by monitoring core temperature, several assays of fluid status, serum glucose and lactate levels, and ratings of perceived exertion (RPE) using the 20-point Borg scale.

Five FF's completed the protocol. Total times of exercise on the treadmill ranged from 10 to 31 minutes. The three FF's who were monitored by the ingestible CoreTemp capsules had a core temperature $\geq 38^{\circ}\text{C}$ when they stopped, and their temperatures continued to rise after they began rehabilitation. One subject exceeded 39°C before core cooling was observed on the monitor. Weight loss and other fluid status data are summarized in Table 7.

Perceived Exertion

RPE is a subjective measurement and was recorded every 2 minutes throughout each subject's exercise routine to demonstrate the linear progression from the rested to fatigued state. A 20-point Borg Scale was used³⁸. At each 2-minute interval, an investigator held up a series of cards with scales from 0-20 rating the intensity of their sense of 1) overall fatigue, 2) lower extremity fatigue, 3) central (cardiovascular) fatigue, 4) thirst, and 5) heat. FF's indicated the point on each card that described their current perception, and these were recorded. Graphic representations of these data appear as Figure 12.

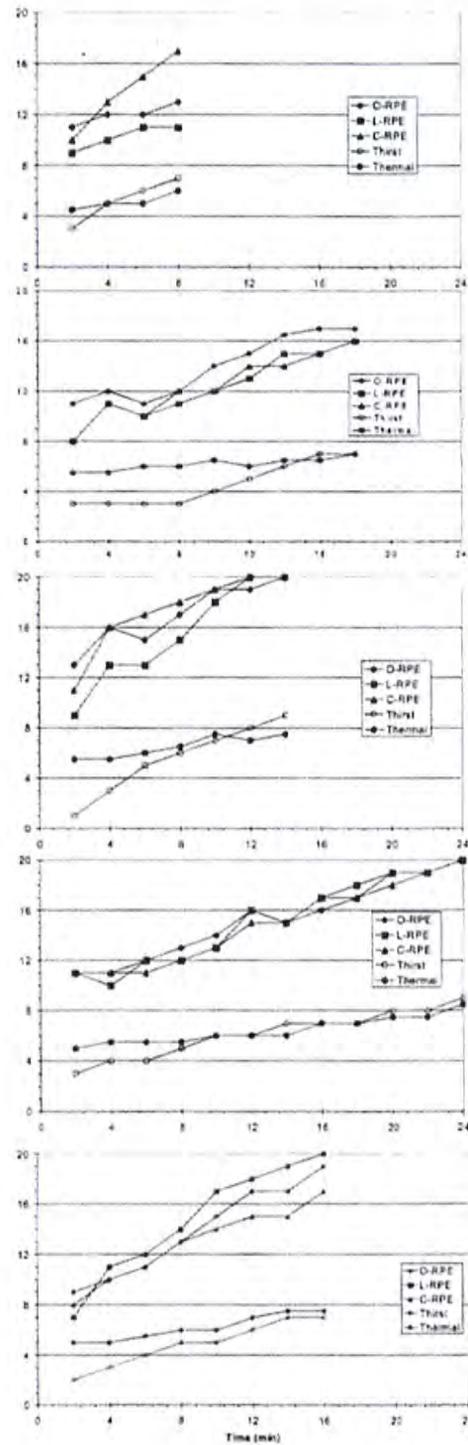


Figure 12: RPE data from five subjects from the post Phase I studies.

Physiologic Response

Oximetry tracings using the IR emitters were found to closely approximate those obtained with the red LED, but were generally more sensitive to changes in physiologic status of

exercising subjects. This relationship was quantified by comparing the ratio of the magnitudes of the plethysmographic (AC) component of the red and IR signals (Equation 1). The ratio remained generally stable during the exercise protocol as would be expected for subjects not having significant changes in arterial oxygen concentration (Figure 14). Using the absorption spectra generated specifically for transcutaneous oximetry by Casciani *et al* (2), it would be predicted that the ratio of red:IR absorbance at the wavelengths used in the mask sensors (662 nm, 905 nm) would approximate 0.5 for an individual whose hemoglobin oxygen saturation is 100%. The source data from the graph of the ratios over one subject's full 10 minutes of exercise is depicted in Figure 13, and shows a mean of $0.534 (\pm 0.121)$ (SEM). A representative 1-minute sample from the middle of the exercise period has a mean of $0.481 (\pm 0.067)$. These values correlate well with the expected oxygen saturation of the subjects. The stability of this waveform also indicates that motion artifact is not substantially impacting this data sample.

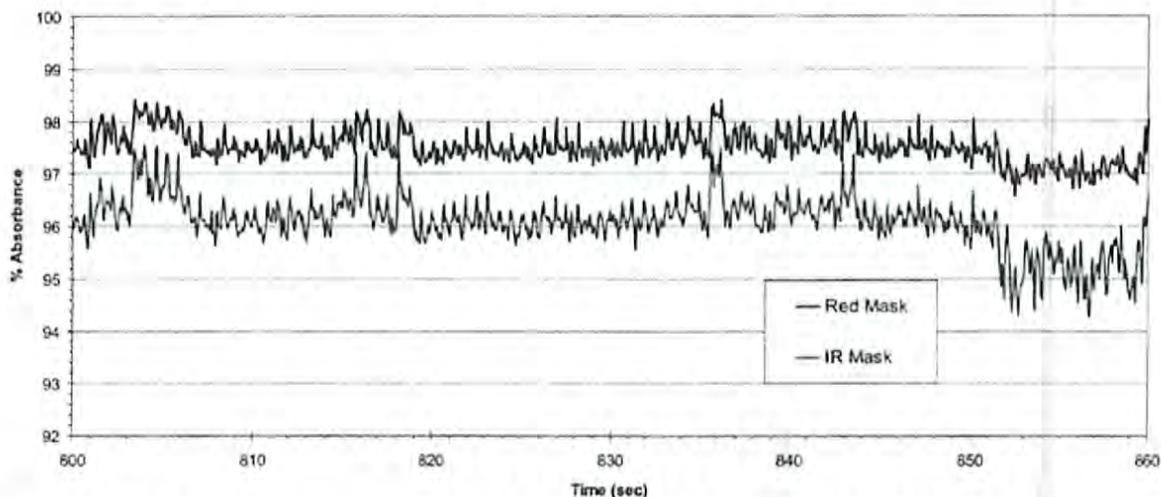


Figure 13: Raw (unfiltered) oximetry tracings in exercising fire fighter using red and IR LEDs in the sensor elements. At this scale, the plethysmographic pattern corresponding to arterial pulsations is evident. The typical negative deflection corresponding with volitional fatigue is also seen.

As described in Table 7, mean weight loss due to sweating over the short exercise protocol was 0.6 kg, and the expected increases in urine specific gravity and red blood cell concentration were also observed. Marked increases in serum lactate were documented and have been reported in FF's by previous investigators⁴³

⁴³ Gledhill N, Jamnik V. Characterization of the physical demands of firefighting. *Can J Spt Sci* 1992; 17:3 207-213.

Table 7. Objective evidence of Physiologic stress (LEP).

Subject	Δ Wt (kg)	Δ Urine Spec Gravity	Δ Hb/ Δ Hct (%)	Δ Lactate (mM/L)
1	-0.4	+0.012	+0.65/+2.33	+3.1
2	-0.6	+0.003	+0.85/+1.70	+0.75
3	-0.5	+0.001	+0.54/+2.53	+3.65
4	-0.7	-0.002	+1.22/+0.83	+1.35
5	-0.9	0.000	-0.04/+2.34	+3.8
mean	-0.62 \pm 0.09	+0.003 \pm 0.003	+0.66/+1.95	+2.53 \pm 0.70
p-value	0.0020	0.3146	0.0357/0.0034	0.0153

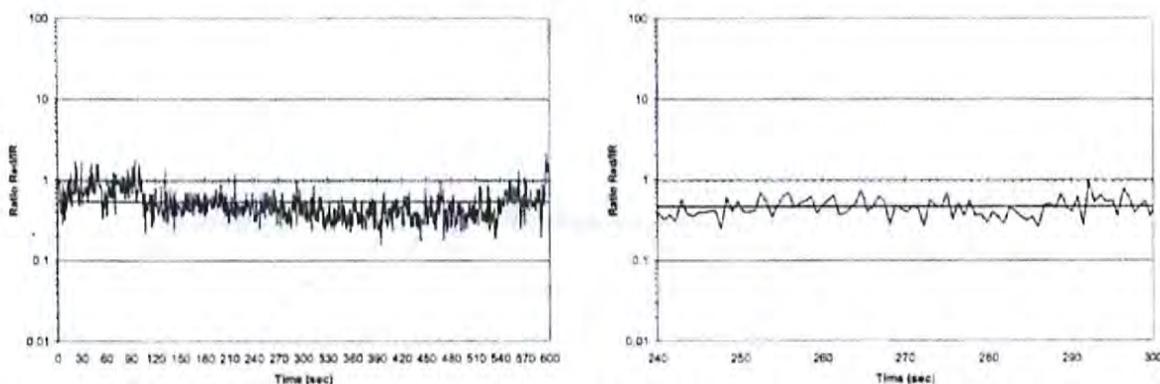


Figure 14: Log ratio of Red:Infrared (Equation 1) signal for the entire data set (left) and for one minute of oximetry data (right) obtained from a subject whose treadmill exercise was similar to, but shorter than the one shown in Figure 10. The ratio tracing demonstrates stability of the ratio and the low amplitude of motion artifact. The mean log ratio (0.534 ± 0.121) of the data set and one minute sample (0.470 ± 0.065) are consistent with the 0.5 ratio that would be predicted if the subject's SpO_2 was 100%.

During the initial Phase I studies, a relatively precipitous deflection in the oximetry tracing was observed with onset of symptomatic fatigue in the only fire fighter who was unable to complete the protocol due to exhaustion. We questioned whether the waveform became more variable as the subject approached fatigue. In the post Phase I set of studies, a simplified protocol designed so subjects would experience a more linear approach to exhaustion was used. To obtain DC and Mean absorbance tracings, the oximetry signals were digitized at 20 Hz and noise reduction was achieved by subjecting the 40 data points in each 2-second interval to standard 5- or 10-point moving average algorithms. An estimate of variance in the oximetry signal was obtained using a time/domain measure of variability previously developed by Dr. Winchell. A readily observable decrease in absorbance was observed 10 to 30 seconds before 4 out of the 5 subjects indicated they were unable to continue exercising. Sample tracings from 3 of the subjects are displayed in Figure 15.

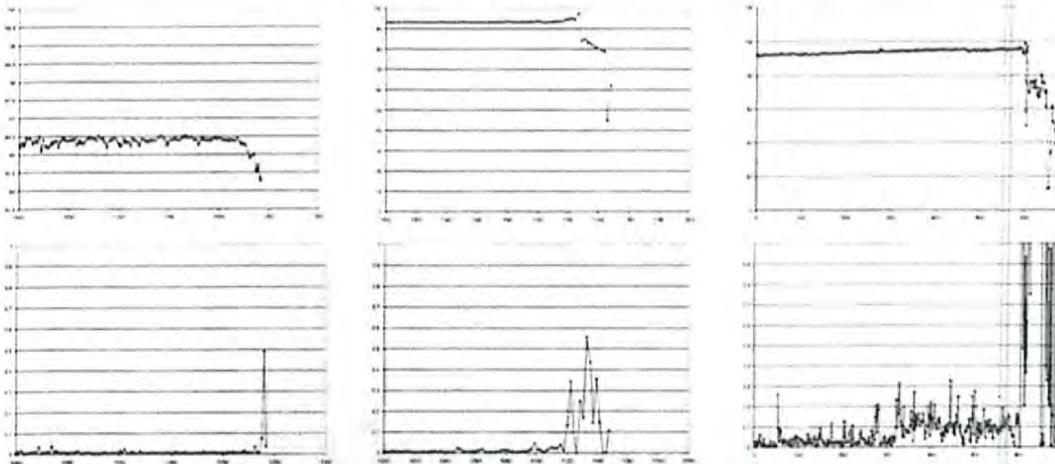


Figure 15: Matched data for 3 subjects during continuous exercise to volitional fatigue in the heat. DC oximetry is displayed above (in pink), and oximetric variability for the same subject is shown below (in blue). In each case, data display was discontinued at the point where the DC tracing terminated with a straight line to an absorbance of 100, indicating removal of the sensorized face mask by the subject.

A tendency toward increased oximetric variability as the subjects became more fatigued is clearly evident in two of the 3 matched plots shown in Figure 15. Interestingly, this trend was also seen in the one subject who did not show a decrease in his DC oximetry value prior to discontinuing exercise due to fatigue. The subject's oximetric variability tracing is shown in Figure 16.

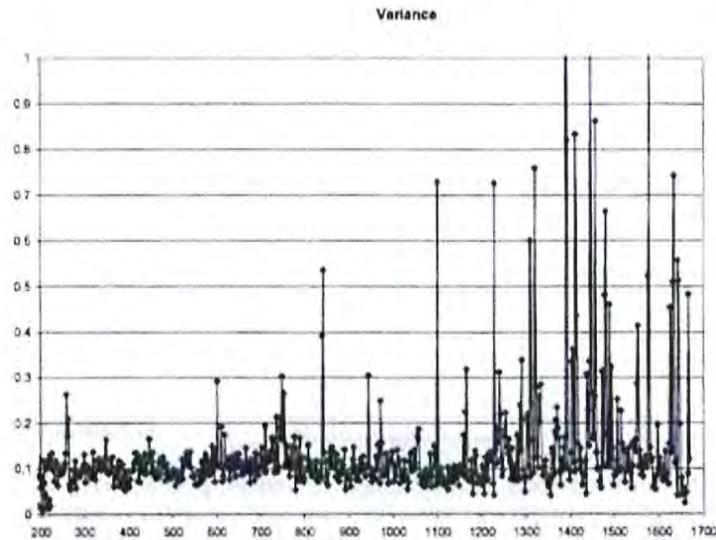


Figure 16: Oximetric variability over exercise time (in seconds) of the one subject who did not show a diagnostic change in DC oximetry readings as he reached volitional fatigue.

Phase II

Task 1: Production of a limited supply of SCBA units sensorized for DC oximetry based on revised specifications

LEDs and Detectors

Our Phase I prototype masks used a single detector to measure the absorbance of both the red (662nm) and IR (905nm) light. Quantum Devices, Inc (Barneveld, WI) presently produces the emitter – detector pairs used in the BCI pulse oximetry probes and, during Phase I, integrated these sensors into our prototype SCBA masks. Quantum Devices is experienced with integrating LEDs and VCSELs (Vertical Cavity Surface Emitting Laser) into circuit components for medical applications, and agreed to assist us in the selection of light sources and detectors, and their integration into SCBA masks for these experiments. During Phase II, Quantum Devices modified additional masks as required for our studies in a method similar to that of Phase I.



Figure 17: LED integration into the SCBA mask (left) and the completed system (right)

Integration of Sensors into SCBA Facepiece

FF subjects surveyed after wearing the sensorized masks reported no wearer discomfort over periods of 30 to 60 minutes. The sensors did not leave impressions on wearers' foreheads, as had been the case with previous prototypes that were distinctly uncomfortable to wear for more than a few minutes.

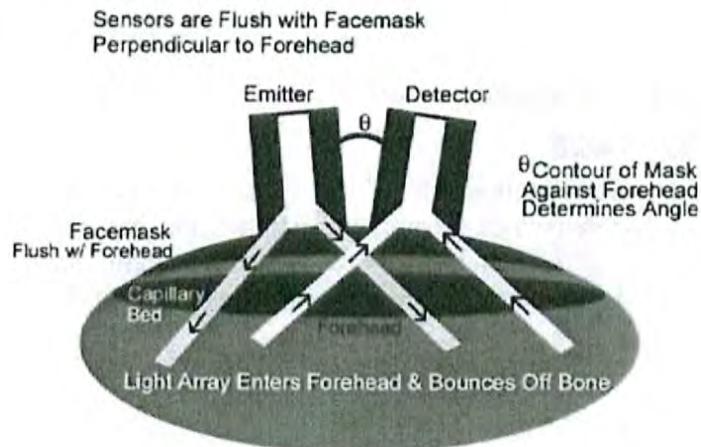


Figure 18: Diagrammatic representation of sensor placement for reflectance mode oximetry in firefighters' SCBA. Optimal distance of the emitter element from the detector element was empirically determined.

Optimization of emitter, photodiode distance for reflectance mode oximetry

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 (Figure 19). Changing signal strength did not affect the results. A final center-to-center separation of 1.27 cm gave the greatest signal strength while providing adequate pliable material between the elements to maintain uniform tension on the rubber strip containing the sensors (Figure 17) 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.

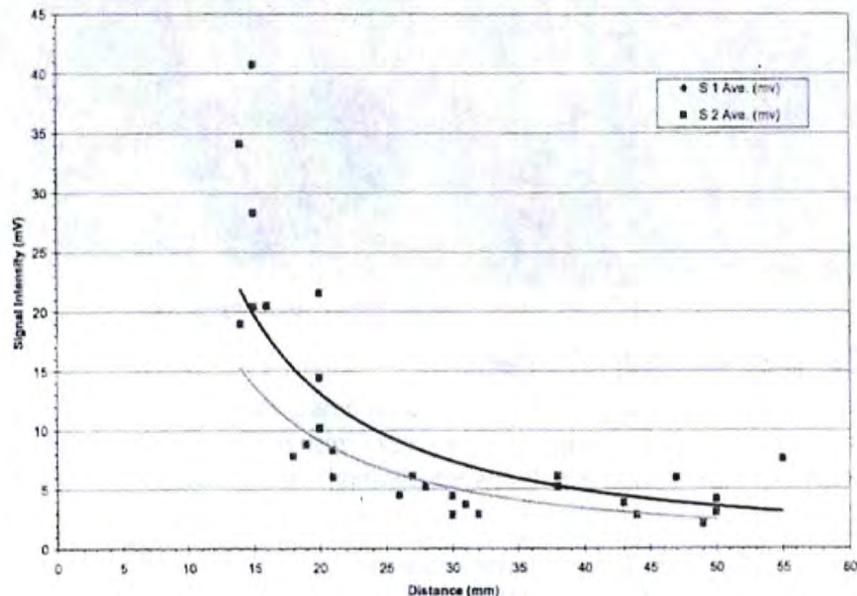


Figure 19: Signal strength (mV) at various separations (mm)

Preservation of mask integrity

On ventilatory dynamic testing, all of the sensorized masks exceeded NFPA 1852 specifications⁴⁴ for all parameters of air pressure maintenance and ventilatory performance, at both standard and maximal ventilatory workloads demonstrating that the sensorized masks retained their fit, seal and functional properties. Sample test data from the modified masks are shown in Figure 20.

⁴⁴ NFPA 1852. Standard on Selection, Care, and Maintenance of Open-Circuit Self-Contained Breathing Apparatus (SCBA), 2002 edition, Quincy MA.

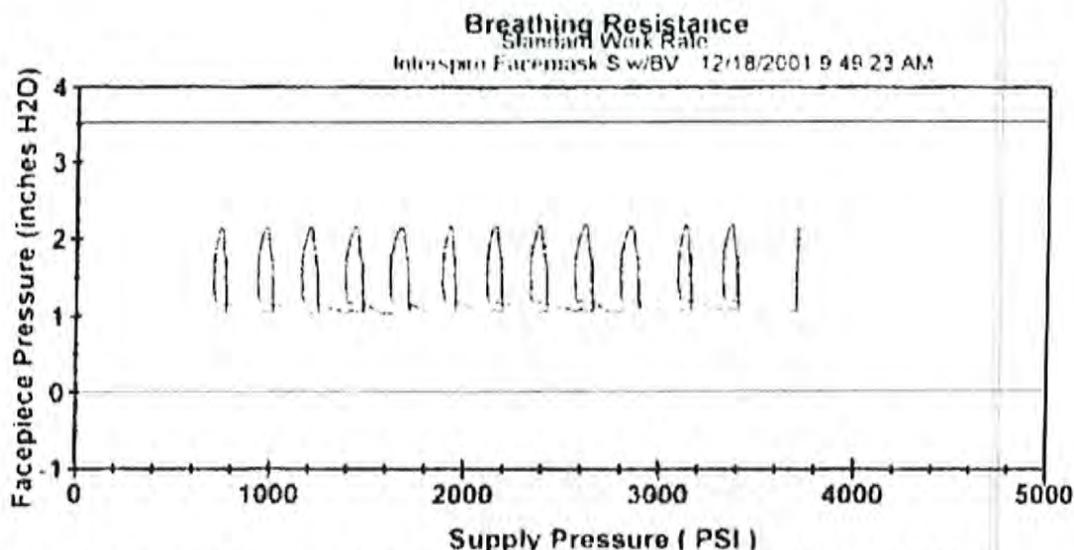


Figure 20: Sample results of air seal and ventilatory performance testing of modified SCBA masks.

Oximetry across different levels of skin pigmentation

A concern raised in a review of our Phase I results was a need to address system function for a variety of different subject skin pigmentations. It should be recalled that pulse oximeters using the same wavelength(s) of light are effective across racial lines. To provide objective evidence that the same is true of the SCBA-based oximetry system, its reliability was tested on a panel of individuals with a range of apparent skin pigmentation due to diverse racial backgrounds and environmental tanning. Subjects 1-3 were African-Americans, while subjects 4 and 5 were Caucasian. Skin hues were described by luminosity histograms generated by digitally sampling (Adobe Photoshop 5.5) color photographs taken at a fixed distance from the subjects' foreheads under constant, fluorescent lighting. This method was modified from that described by Weatheral and Coombs⁴⁵ and applied to transcutaneous near IR spectrometry in consultation with Dr. Soller. The data are shown in Figure 21.

⁴⁵ Weatheral, I.L.; Coombs, B.D. Skin color measurements in terms of CIELAB color space values. *J. Invest. Dermatol.* 99:468-473 (1992)

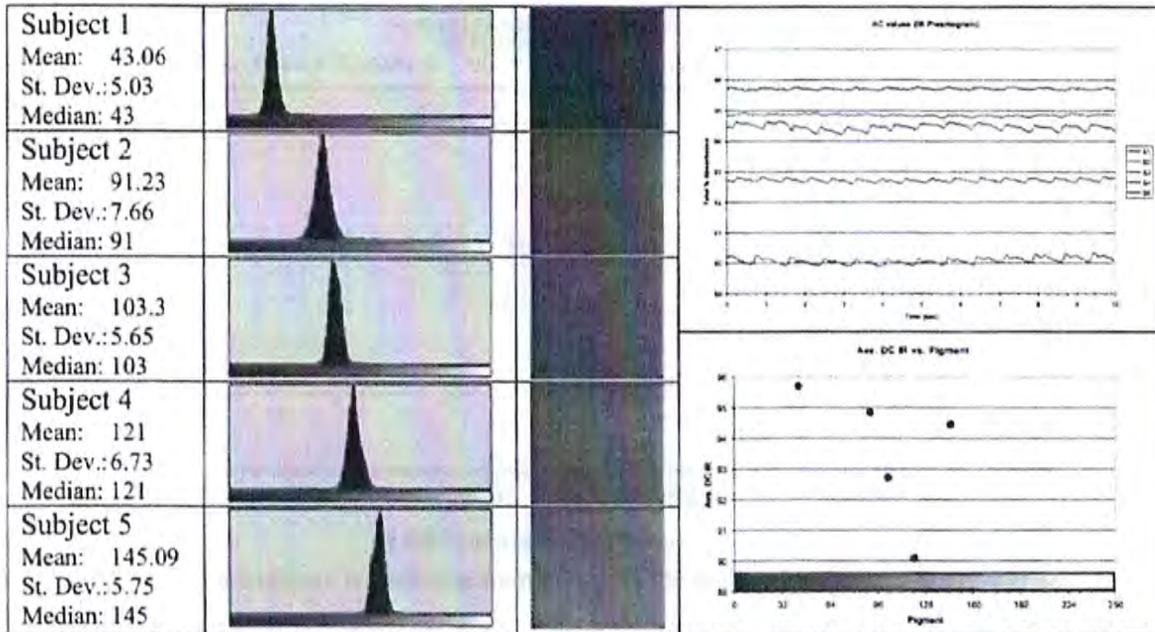


Figure 21: Photo segments from the forehead sensor site used to quantify fire fighter skin pigmentation levels. Luminosity histograms and calculated means for each of five subjects are on a scale between 0 and 255. The upper right shows 10-second IR plethysmograms (DC+AC) from the 5 subjects. The lower right graph plots the average DC signal vs. the pigmentation luminosity of the subject, and shows no correlation.

The SCBA oximetry system, like traditional pulse oximetry, functions adequately with various levels of skin pigmentation, including very dark skinned, African-American FF's. The mean absorbance levels of the tracings vary between 90 and 96%, and show no correlation with skin color. We have previously observed that absorbance varies within this range according to how tightly the supporting straps are pulled when donning the mask (Data not shown).

As the system's intended function is not to track absolute values of DC oximetry but to look for changing trends, in particular to look for increasing variance, the initial starting value of the mean DC level is of little importance. As a result, initial DC starting levels due to the tension applied to the sensor (so long as there is *some* signal) or due to a subject's skin pigmentation would not effect overall operation of the system.

Design of Data Acquisition System

The current implementation of the data collection instrument (Figure 22) consists of the following components: an LED drive circuit, a photodiode filter and amplification circuit, a microcontroller, a Radio Frequency (RF) transmitter, a serial port, and a power supply.

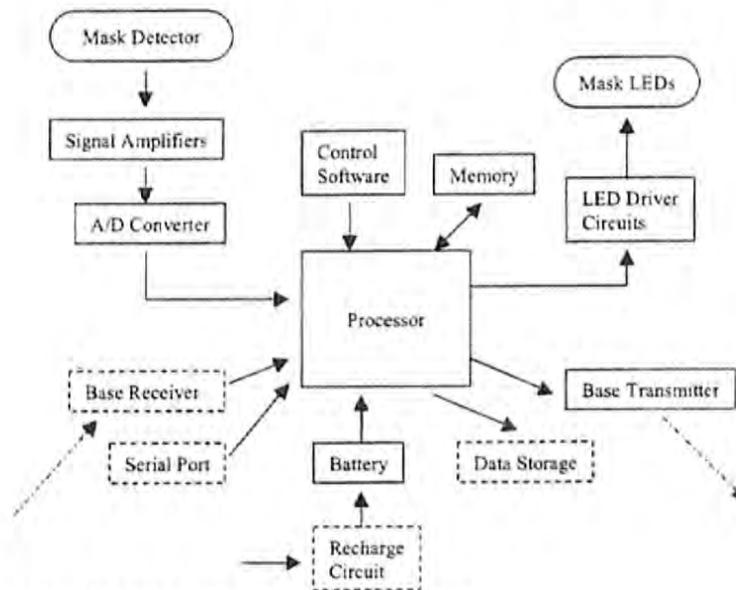


Figure 22: Block diagram for data acquisition system design.

The microcontroller alternately drives the Red and IR LEDs at a fixed voltage directly from its output pins. Each time one of the LEDs is switched on, the light reflected through the tissue of the subject's forehead is collected by a photodiode and converted to a current. The current is converted into a voltage and amplified by a transimpedance amplifier. The voltage then passes through a passive low pass filter, is amplified again, and finally passes through a second low pass filter. Both low pass filters have a corner frequency of 10Hz. The conditioned signal is presented to the Analog to Digital converter inputs of the microcontroller and digitized with a resolution of 12bits at a sampling frequency of approximately 19Hz. The microcontroller formats the digital data according to an established data transmission protocol, and sends it to the RF transmitter. An RF receiver connected to a PC recovers the data and transfers it to the PC via the computer's serial port. Custom software on the PC simultaneously displays the streaming waveform and archives it to a data file for storage. Alternatively, data can be streamed directly from the data collection instrument to the computer via the instrument's onboard serial port. All firmware for the microcontroller is stored in EEPROM, which protects it from accidental erasure and retains its integrity almost indefinitely (>200 years) without requiring power.

Table 8. Generations and Capabilities of Data Acquisition System Designs

Generation	Capabilities
Pre-Phase I	Modified SCBA mask (uncomfortable sensor placement) with a medical grade pulse oximeter for output - no data storage or recording.
Early Phase I	Modified SCBA mask with OEM oximeter with Plethysmogram (AC)
Late Phase I	Modified SCBA masks with red light, DC data acquisition system (20 seconds of acquisition, 10 seconds of processing, storage, and transmit)
Post Phase I	Modified SCBA masks with red and IR DC continuous data acquisition system with continuous, full fidelity telemetry
Phase II	Minor improvements to system. Display and data analysis techniques were focus.

Each generation of our analysis system (Table 8), has enhanced the capabilities of the previous system and improved the quality and type of data available to us.

The nature of the analog signal recovered from the photodiode imposes special restrictions on the filtering and amplification circuitry used. Because each LED is only on for a fraction of a

second and then turned off again, the analog signal collected from the photodiode is discontinuous. This requires that special care be taken in the timing of LED switching and the design of the analog filters such that the filters are able to respond accurately during the short time that each LED is on. These timing issues proved to be one of the major factors limiting the frequency with which we could sample the red and IR light absorbance. However, results to date seem to indicate that although not a high frequency signal (~20Hz), it is sufficient for construction of DC oximetry, plesmographic and heart rate values.

Prior to Phase II efforts, the telemetry system employed requires that a separate receiver module be paired with the transmitter module in each subject's instrument. The receiver hardware contained only one receiver module per board, and only two receiver boards could be easily connected to a PC. Therefore, monitoring more than two subjects simultaneously required the use of multiple PCs. Sekos Inc. has improved radio transmission systems such that a single base unit would be capable of receiving data from up to seven additional units. This level would be sufficient for the monitoring of a single entry team, however, is not yet sufficient for a single station to adequately monitor an entire fireground.

The telemetry system incorporates OEM transceiver modules from Aerocomm Inc. These modules address all of the problems encountered with earlier telemetry systems. Specifically, they are supposed to be configurable into a network of up to forty-eight units, in which all transceivers may communicate with a single base station. In practice, this is not effectively achievable in our application. The radio transmission power of each transceiver can be dynamically controlled by the microprocessor allowing range and battery life to be optimized. Error correction capabilities are built into the telemetry system architecture, and the total system bandwidth of 115.2 Kbps is sufficient to accommodate the aggregate bandwidth that we anticipate if the maximum number of transceivers were streaming oximetry data simultaneously (approximately 80Kbps).

The utility and effectiveness of the commercial implementation of this system will depend upon the ability to adequately process data from the sensors. The signal processing electronics will need to be small, lightweight, and packaged for heat resistance and durability. The system will need to run for several hours under fire fighting conditions, and for even longer in standby mode before a battery exchange or recharge is required.

Software code used in the acquisition or analysis of data has been included in the report, as the interpretation of how data was acquired or the formulas applied for noise rejection and value calculation is directly relevant to the interpretation of the results of this effort. Software code used in the real-time display or other similar matters has not been included, as this software does not reflect on the actual meaning of the data. The relevant code for operating the data acquisition system is included in Table 9 below. The relevant code for operating the footfall monitor is included in Table 10 below.

Table 9. Software code (Assembly) for DSPIC processor running HWM sensor unit

```
.....  
; NIOSH Pulse O2 Controller  
;  
; Firmware Version: 1.0  
; Date: 5/13/03  
;  
; 52ms Period, 2800µs pulse width  
;  
;.....
```

```

list    p=16c773
#include <p16c773.inc>

__CONFIG _CP_OFF & _WDT_OFF & _HS_OSC & _PWRTE_ON & _BODEN_OFF

;***** Variable Definitions
CBLOCK 0x020
    _w, _status           ; Variables to store context registers
    OutputSelect         ; Select between IR and LED output.
    Counter
    InnerC
    OuterC
    DataMarker           ; Will be set to either 0x80 for LED value
                        ; or 0x40 for IR value
    TMR0Init             ; Initial value to which TMR0 is set
    TMR0Counter          ; Number of times TMR0 rolls over before
                        ; full ISR executes
    TMR0CntInit         ;
ENDC

IRDelay    EQU 0xFF
LEDDelay   EQU 0xFF

;*****
ORG    0x000           ; processor reset vector

nop
clrf   PCLATH         ; ensure page bits are cleared
goto  Main           ; go to beginning of program

ORG    0x004           ; Interrupt Handler
goto  IntHandler

Main

nop
bcf   STATUS, RP0     ; Go to Bank 0
movlw 0xFF
movwf InnerC
movwf OuterC
movlw 0x000           ; Initial Value of TMR0
movwf TMR0Init
movlw 0x002           ; Go through 2 TMR0 cycles per period
movwf TMR0CntInit
movwf TMR0Counter

; Initialize PortC
movlw 0x003           ; Turn on PORTC.0 and PORTC.1 so that both
movwf PORTC           ; LED and IR are off
bsf   STATUS, RP0     ; Switch to Bank1
clrf  TRISC ^ 0x080   ; Make all PortC pins outputs
bcf   STATUS, RP0     ; Back to Bank0

; Initialize PortB
movlw 0xFF
movwf PORTE           ; Initialize PORTE so that all
                        ; Least significant byte LEDs are off
bsf   STATUS, RP0     ; Go to Bank 1
clrf  TRISB ^ 0x080   ; Set all the PORTE bits to Output
bcf   STATUS, RP0     ; Back to Bank0

; Initialize PortA
clrf  PORTA           ; Initialize PORTA by clearing all pins
                        ; Leave PortA default of inputs

; Initialize A/D Converter Module
bsf   STATUS, RP0
movlw 0x0BC
movwf ADCON1 ^ 0x080 ; Right justified format and vref = an3
bcf   STATUS, RP0     ; Go back to Bank 0

```

```

movlw 0x089      ; Setup ADCON0 for ADC Conversion
movwf ADCON0    ; ADCS1:ADCS0 - 10 for /32 Clock
                ; Unimplemented - 0
                ; CHS1:CHS0 - 00 for RAO/ANG
                ; Go_Done - 0
                ; ADIF - 0
                ; ADON - 1

; Initialize USART
; Baud=9600
; Fosc=20MHz, BRGH=1 => SPBRG=0x081 from table 10-4 in data sheet
;
bsf STATUS, RP0 ; Switch to Bank 1
movlw 0x081     ; SPRG=D'129 for 9600 baud
movwf SPBRG    ;
movlw 0x004     ; Clear the SYNC bit to enable Asynch tx/rx and
movwf TXSTA    ; set the BRGH bit to High Speed Asynch mode
bcf STATUS, RP0 ; Back to Bank 0
bsf RCSTA, SPEN ; Turn on the Serial Port
bsf STATUS, RP0 ; Switch to Bank 1
bsf TXSTA, TXEN ; Enable the transmitter
bsf TXSTA, TRMT ; Indicate TSR empty
bcf STATUS, RP0 ; Back to Bank 0

; Initialize TMR0 and Prescaler
;
; OPTION_REG
; bit7 1 PortB pull-ups disabled
; bit6 1 Interrupt edge select, don't care
; bit5 0 TMR0 uses Internal instruction cycle clock
; bit4 1 TMR0 source edge select, don't care
; bit3 0 Prescaler assigned to Timer0 module
; bit2:0 111 Prescaler rate select bits, Rate=1:256
; 0b011010101 = 0x0D6
;
bsf STATUS, RP0 ; Switch to Bank1
movlw 0x0D7     ; Still in bank 1, Configure
movwf OPTION_REG ; OPTION_REG
bcf STATUS, RP0 ; Switch back to bank 0

movf TMR0Init, w ; Start timer at 127
movwf TMR0

; Enable Global Interrupts and Timer0 Interrupt
movlw (1 << GIE) + (1 << TOIE)
movwf INTCON    ; Enable Interrupts

; Wait for interrupts -- While waiting flash Status LED
; We use a nested for loop to delay
; Loop
; for(int i=255; i>0; i--) {
;   for(int j=255; j>0; j--) {
;   }
; }
; changeLED()
;
Loop
decfsz InnerC, 1 ; Decrement Inner loop and skip next instr
goto Loop       ; if result = 0
movlw 0x0FF     ; Reset Inner loop
decfsz OuterC, 1 ; Decrement Outer loop and skip next instr
goto Loop       ; if result = 0
movlw 0x0FF     ; Reset Outer loop
btfss PORTC, 3  ; If PORTC.3 is set, skip next instr.
goto SetStatus  ; Go set status
bcf PORTC, 3    ; PORTC.3 is set, so clear it.
goto Loop       ; repeat.

SetStatus
bsf PORTC, 3    ; PORTC.3 isn't set, so set it.
goto Loop

```

```

IntHandler
  movwf   _w           ; Save Context Registers
  movf    STATUS,w     ; - Assume TMRO is the only enabled
  movwf   _status     ; Interrupt

  bcf     STATUS, RPO  ; Ensure that we're in Bank0
  movf    TMROInit, w  ; Start timer at 127
  movwf   TMRO         ;
  decfsz  TMROCounter, 1 ; Decrement the TMRO Counter
  goto    IntEnd      ; If value isn't 0, return from ISR

  btfsc   OutputSelect, 0 ; If Bit0 of OutputSelect is set, go to LED_On,
  goto    LED_On      ; otherwise, turn on IR.

IR_On
  bcf     STATUS, RPO  ; Make sure we're in Bank0
  bcf     PORTC, 0     ; Pull PORTB.1 low to turn IR on.
  bsf     OutputSelect, 0 ; Set OutputSelect.0 so that it will turn on
  ; the LED next
  movlw   0x40        ; Set DataMarker to signify IR value
  movwf   DataMarker ;
  goto    ADConv     ; Start the ADConv

LED_On
  bcf     STATUS, RPO  ; Make sure we're in Bank0
  bcf     PORTC, 1     ; Pull PORTB.2 low to turn LED on.
  bcf     OutputSelect, 0 ; Clear OutputSelect.0 so that it will turn on
  ; the IR next
  movlw   0x80        ; Set DataMarker to signify IR value
  movwf   DataMarker ;

ADConv
  bcf     STATUS, RPO  ; Go to Bank0
  ; 1
  movlw   0x0FF        ; Load 255 into W reg for delay
  movwf   Counter     ; Each 255 - 155µs @ 20Hz system Clock
  decfsz  Counter, 1  ; Delay to let acquisition cap charge
  goto    $-1
  ; 2
  movlw   0x0FF        ; Load 255 into W reg for delay
  movwf   Counter     ;
  decfsz  Counter, 1  ; Delay to let acquisition cap charge
  goto    $-1
  ; 3
  movlw   0x0FF        ; Load 255 into W reg for delay
  movwf   Counter     ;
  decfsz  Counter, 1  ; Delay to let acquisition cap charge
  goto    $-1
  ; 4
  movlw   0x0FF        ; Load 255 into W reg for delay
  movwf   Counter     ;
  decfsz  Counter, 1  ; Delay to let acquisition cap charge
  goto    $-1
  ; 5
  movlw   0x0FF        ; Load 255 into W reg for delay
  movwf   Counter     ;
  decfsz  Counter, 1  ; Delay to let acquisition cap charge
  goto    $-1
  ; 6
  movlw   0x0FF        ; Load 255 into W reg for delay
  movwf   Counter     ;
  decfsz  Counter, 1  ; Delay to let acquisition cap charge
  goto    $-1
  ; 7
  movlw   0x0FF        ; Load 255 into W reg for delay
  movwf   Counter     ; Each 255 - 155µs @ 20Hz system Clock
  decfsz  Counter, 1  ; Delay to let acquisition cap charge

```

```

goto    $-1
; 8
movlw  0x0FF          ; Load 255 into W reg for delay
movwf  Counter
decfsz Counter, 1    ; Delay to let acquisition cap charge
goto   $-1
; 9
movlw  0x0FF          ; Load 255 into W reg for delay
movwf  Counter
decfsz Counter, 1    ; Delay to let acquisition cap charge
goto   $-1
; 10
movlw  0x0FF          ; Load 255 into W reg for delay
movwf  Counter
decfsz Counter, 1    ; Delay to let acquisition cap charge
goto   $-1
; 11
movlw  0x0FF          ; Load 255 into W reg for delay
movwf  Counter
decfsz Counter, 1    ; Delay to let acquisition cap charge
goto   $-1
; 12
movlw  0x0FF          ; Load 255 into W reg for delay
movwf  Counter
decfsz Counter, 1    ; Delay to let acquisition cap charge
goto   $-1
; 13
movlw  0x0FF          ; Load 255 into W reg for delay
movwf  Counter
decfsz Counter, 1    ; Delay to let acquisition cap charge
goto   $-1
; 14
movlw  0x0FF          ; Load 255 into W reg for delay
movwf  Counter
decfsz Counter, 1    ; Delay to let acquisition cap charge
goto   $-1
; 15
movlw  0x0FF          ; Load 255 into W reg for delay
movwf  Counter
decfsz Counter, 1    ; Delay to let acquisition cap charge
goto   $-1
; 16
movlw  0x0FF          ; Load 255 into W reg for delay
movwf  Counter
decfsz Counter, 1    ; Delay to let acquisition cap charge
goto   $-1
; 17
movlw  0x0FF          ; Load 255 into W reg for delay
movwf  Counter
decfsz Counter, 1    ; Delay to let acquisition cap charge
goto   $-1
; 18
movlw  0x0FF          ; Load 255 into W reg for delay
movwf  Counter
decfsz Counter, 1    ; Delay to let acquisition cap charge
goto   $-1

bsf    ADCON0, GO      ; Turn on the ADC
btfsc  ADCON0, GO_DONE ; Poll the Go_Done bit until it's cleared
goto   $-1             ; indication A/D conversion complete

btfss  OutputSelect, 0 ; At this point if IR is on, OutputSelect.0 is
goto   LED_Off         ; set. If that is the case, turn IR off.
; Otherwise, turn LED off

IR_Off
bsf    PORTC, 0        ; Turn IR off
goto   WriteResult

LED_Off
bsf    PORTC, 1        ; Turn LED off

```

```

WriteResult
    bcf     STATUS, RPO           ; Make sure we're in bank0
    movf   DataMarker, w        ; Load 0x80 or 0x40 into w depending on IR or LED
    addwf  ADRESH, w           ; Add high byte of conversion to w. High byte should
                                ; be of the form 0x0*. When added should yield 0x8*
                                ; or 0x4*.
    movwf  TXREG                ; Send out SCI
    nop                                         ; Give up instr cycle so that TXIF can be cleared
    btfss  PIR1, TXIF          ; Test to see if TXREG empty
    goto   $-1                  ; Wait until TXREG empty

    bsf   STATUS, RPO           ; Switch to Bank1
    movf  ADRESL, w             ; Load Low ADC result
    bcf   STATUS, RPO           ;
    movwf TXREG                ; Send out SCI
    nop                                         ; Give up instr cycle so that TXIF can be cleared
    btfss  PIR1, TXIF          ; Test to see if TXREG empty
    goto   $-1                  ; Wait until TXREG empty

    movf  TMROCntinit, w       ; Reset TMROCounter with initial value
    movwf TMROCounter         ;

IntEnd
    bcf   INTCON, TOIF         ; Reset the Interrupt Flag
    movf  _status, w           ; retrieve copy of STATUS register
    movwf STATUS              ; restore pre-ISR STATUS register contents
    swapf _w, f                ; restore pre-ISR W register contents
    swapf _w, w                ; restore pre-ISR W register contents
    retfie                     ; return from interrupt

end

```

Table 10. Software code (C) for DSPIC processor running FFM sensor unit (footfall.c)

```

/*
 * Signals Sampled Rate      Bytes      Rate      Code
 * Sensor Channel0 (SCH0)    2           200Hz     0000
 * Sensor Channel1 (SCH1)    2           200Hz     0001
 *
 * Data Protocol:
 * 4 Byte Packet (SCH1, SCH2, BATT, THM1, THM2)
 * Byte 1
 *   bit7:4    1010
 *   bit3:0    Code
 * Byte 2
 *   bit7:4    Code
 *   bit3:0    4 MSb of Conversion
 * Byte 3
 *   bit7:0    8 Lsb of Conversion
 * Byte 4
 *   bit7:4    Unit ID
 *   bit3:0    1010
 *
 */

/**
 * Firmware Build: 102
 */

#include "Footfall.h"
#include "delay.h"

void main() {

    unsigned char portB_ = 0;

    g_pstCounter = 0xFF;
    g_pseudoTimer = 0x00;
    g_gen_counter1 = 0x00;
    g_gen_counter2 = 0x00;

```

```
g_portBPresses = 0x00;
g_portBCountdown = 0x00;

DelayMs(10);
init_ports();
init_usart();
init_timer1();
init_timer2();
init_adc();

// Turn on Timer1
TMR1ON = 1;
// Enable Timer1 Interrupts
TMR1IE = 1;

// Turn on Timer2
TMR2ON = 1;
// Enable Timer2 Interrupts
TMR2IE = 1;
sendPseudoTimestamp();

// Enable change on
RBIE = 1;
// Read PortB to clear interrupt flags and set value
portB_ = PORTB;
RBIF = 0;

// Enable peripheral interrupts
PEIE = 1;
// Enable global interrupts
GIE = 1;

RC0 = 1;
RA4 = 0;

while(1) {
    /* We want a slight delay after a button depress to try to avoid
     * switch bounce. When pushbutton is depressed, PORTB interrupts
     * are disabled and g_portBCounter is set to 0xFF. The main routine
     * then decrements this counter until it reaches 1 at which time
     * PORTB interrupts are re-enabled and the counter is decremented to 0.
     */
    if(g_portBCountdown > 0){
        if(g_portBCountdown == 0x01){
            portB_ = PORTB;
            RBIE = 1;
            g_portBCountdown--;
        }
        else
            g_portBCountdown--;
    }
    continue;
}

void init_ports()
{
    // All PORT A pins are input
    TRISA = 0b11111111;

    /* PORT B Pin Assignments
     *
     * RB7    Output
     * RB6    Output
     * RB5    Input -- Interrupt on Change
     * RB4    Output
     * RB3    Output
     * RB2    Output
     * RB1    Output
     * RB0    Output
    */
}
```

```

*/
TRISB = 0b00100000;

// All PORT C pins output
TRISC = 0x00;
RC3 = 1;          // Enable SCL as Input for I2C mode
RC4 = 1;          // Enable SDA as Input for I2C mode

// Set unused output pins low.
RC1 = 0;
RC2 = 0;
RC5 = 0;

RB1 = 0;

return;
}

void init_usart()
{
    // Initialize SPBRG, RCSTA, and TXSTA registers.
    SPBRG = SCI_SPBRG; // See SCI_SPBRG definition

    SPEN = 1;          // Turn on the Serial Port

    TX9 = 0;          // Select 8-bit Transmission
    SYNC = 0;          // Asynchronous Mode
    BRGH = 1;          // High Speed Asynchronous

    // Disable TX/RX interrupts
    TXIE = 0;
    RCIE = 0;

    TXEN = 1;          // Enable Transmitter
    RCEN = 1;          // Enable Receiver

    return;
}

/* 20MHz Clock input => .2us Instruction clock.
 * We want to sample the accels at 200Hz, or every 5 ms.
 * 5000us/.2us => 25,000 Instruction cycles.
 *
 * Timer1 is a 16 bit timer. 65535-25000 => 40535d, 9E57h
 * initial value.
 *
 * T1CON
 * bit7:6    0    Unimplemented
 * bit5:4    00    1:1 Prescale value
 * bit3      0    Timer1 Oscillator off
 * bit2      0    Bit ignored when Timer1 uses internal clk
 * bit1      0    Use internal clock
 * bit0      0    Don't turn Timer1 on just yet.
 */
void init_timer1()
{
    T1CON = 0x00;

    // Set Timer1 registers to 0x9E57
    TMR1H = 0x9E;
    TMR1L = 0x57;

    return;
}

/* Timer2 Initialization -- Used to generate pseudotimestamp
 * 20MHz Clock input => .2us Instruction clock.
 * Timer 2 has a 1:16 Prescaler, and a 1:16 Postscaler
 * Max Time Delay: .2us*16*256*16 => 13.1072 ms
 *
 * T2CON

```

```

* bit7      0      Unimplemented
* bit6:bit3 1111  TOUTPS3:TOUTPS0 1:16 postscalar
* bit2      1      TMR2ON
* bit1      11     T2CKPS1:T2CKPS0 1:16 prescalar
*
*/
void init_timer2(){
    T2CON = 0x7F;
    TMR2 = 0x00;

    return;
}

/*
* ADCON0
* bit7:6    10     ADCS1:ADCS0 Fosc/64
* bit5:3    000    CHS3:CHS1 Analog Channel select
* bit2      0      A/D conversion not in progress
* bit1      0      Unimplemented
* bit0      1      Turn ADC module on
*
* ADCON1
* bit7      1      Right justified ADC result
* bit6      1      ADCS2 Fosc/64
* bit5:4    00     Unimplemented
* bit3:0    0000  AN7:AN0 Analog Inputs, VRefH=VCC, VRefL=VDD
*/
void init_adc()
{
    ADCON0 = 0b10000001;
    ADCON1 = 0b11000000;

    return;
}

void putch(char c)
{
    // Wait until the transmit buffer is empty to load next char.
    //while(!TXIF && CTS_4490)
    while(!TXIF)
        continue;

    TXREG = c;
    return;
}

void putch_isr(char ch)
{
    // Wait until the transmit buffer is empty to load next char.
    //while(!TXIF && CTS_4490)
    while(!TXIF)
        continue;

    TXREG = ch;
    return;
}

unsigned int doADConversion_isr(unsigned char channel){
    unsigned int result = 0;

    // Sensor Channel 0 is smaped on AN0
    if(channel == ADC_AN0){
        CHS2 = 0;
        CHS1 = 0;
        CHS0 = 0;
    }
}

```

```
// Sensor Channel 1 is sampled on AN1
else if(channel == ADC_AN1){
    CHS2 = 0;
    CHS1 = 0;
    CHS0 = 1;
}

else
    return 0xB BBB;

//DelayUs(50):

ADGO = 1;
while(ADGO)
    continue;

result = (unsigned int)ADRESH;
result = (result<<8) + (unsigned int)ADRESL;

return result;
}

void interrupt isr(void){

    unsigned char portB_ = 0;

    // use RC1 to time isr execution time
    //RC1 = 1;

    // Timer 1 Interrupt
    if(TMR1IF){
        TMR1H = 0x9E;
        TMR1L = 0x57;
        // TMR1H = 0x00;
        // TMR1L = 0x00;

        processADC_isr(doADConversion_isr(ADC_AN0), ADC_AN0);

        if(RC0)
            RC0 = 0;
        else
            RC0 = 1;

        TMR1IF = 0;
    }
    // Timer 2 Interrupt
    else if(TMR2IF){
        TMR2 = 0;

        g_pstCounter--;
        if(g_pstCounter == 0x00){
            g_pseudoTimer++;
            sendPseudoTimestamp_isr();
            g_pstCounter = 0xFF;
        }

        if(RC1)
            RC1 = 0;
        else
            RC1 = 1;
        TMR2IF = 0;
    }
    //
    else if(RBIF){
        RBIE = 0;
        portB_ = PORTE;
        RBIF = 0;
        g_portBPresses++;
        g_portBCountdown = 0xFF;
        putch_isr(0xAD);
    }
}
```

```
        putch_isr(0xD0);
        putch_isr(g_portBPresses);
        putch_isr(0x0A);
    }
    else
        return;
}

void processADC_isr(unsigned int value, char data_type){

    unsigned char pbyte1 = 0x00;
    unsigned char pbyte2 = 0x00;
    unsigned char pbyte3 = 0x00;
    unsigned char pbyte4 = 0x00;

    if(data_type == ADC_AN0){
//      RC1 = 1;
        pbyte1 = 0xAC;
        pbyte2 = (0x0F & (char)(value >> 8)) + 0xC0;
        pbyte3 = (0x00FF & value);
        pbyte4 = UNIT_ID;

        putch_isr(pbyte1);
        putch_isr(pbyte2);
        putch_isr(pbyte3);
        putch_isr(pbyte4);
//      RC1 = 0;
    }
    else if(data_type == ADC_AN1){
        pbyte1 = 0xA2;
        pbyte2 = (0x0F & (char)(value >> 8)) + 0x20;
        pbyte3 = (0x00FF & value);
        pbyte4 = UNIT_ID;

//      pbyte2 = 0x10;
//      pbyte3 = g_gen_counter2;
//      g_gen_counter2++;

        putch_isr(pbyte1);
        putch_isr(pbyte2);
        putch_isr(pbyte3);
        putch_isr(pbyte4);
    }

    return;
}

void sendPseudoTimestamp_isr(void){
    unsigned char pb1 = 0x00;
    unsigned char pb2 = 0x00;
    unsigned char pb3 = 0x00;
    unsigned char pb4 = 0x00;

    pb1 = 0xAB;
    pb2 = 0xB0;
    pb3 = g_pseudoTimer;
    pb4 = UNIT_ID;

    putch_isr(pb1);
    putch_isr(pb2);
    putch_isr(pb3);
    putch_isr(pb4);

    return;
}

void sendPseudoTimestamp(void){
    unsigned char pb1 = 0x00;
    unsigned char pb2 = 0x00;
    unsigned char pb3 = 0x00;
}
```

```
unsigned char pb4 = 0x00;

pb1 = 0xAB;
pb2 = 0xB0;
pb3 = g_pseudoTimer;
pb4 = UNIT_ID;

putch(pb1);
putch(pb2);
putch(pb3);
putch(pb4);

return;
}
```

Task 2: Correlation of DC oximetry values and trends with other physiologic parameters experimentally monitored in fire fighters

This series of studies addresses the general aim of further defining the physiologic correlates of the observed transcutaneous IR light absorbance phenomena. While we will continue to use the term DC oximetry for this parameter, it should be clear that it is likely a more complex hybrid index based primarily, but not solely, on the ratio of oxygenated to deoxygenated hemoglobin in the tissue bed under the SCBA face mask. Other contributors may include blood flow or perfusion to the area, the presence of cytochromes, other oxidative enzymes, or inflammatory mediators that absorb in these frequencies. In addition to the 662nm and 905nm wavelengths, the isosbestic wavelength for oxy- and de-oxyhemoglobin, 805nm, will be used to assess whether changes observed near end of exercise are primarily due to desaturation of hemoglobin in the nonpulsatile compartments or due to other factors such as volume or other molecular moieties that absorb in the NIR range.

The Phase II physiologic correlation studies form a bridge between the feasibility work successfully performed during and subsequent to Phase I, and additional testing that will transition the device into initial production by our collaborating manufacturer. It is therefore important that these studies be designed to simulate the uncompensable heat stress of fire fighting as closely as possible under the constraints of environmental chamber size and ethical use of human subjects.

The Phase II studies collected and compared DC oximetry responses to a weighted treadmill exercise like that performed in post-Phase I experiments with responses obtained in simulated fire ground evolutions similar to the Phase I protocol. This duplicates the small, pilot, post-Phase I studies, and provide sufficient data to confirm those results while facilitating comparison between the linear and discontinuous models of firefighting-specific exercise to volitional fatigue. The subjects performed these tasks wearing full structural firefighting PPE in ambient temperatures that preclude thermoregulatory heat dissipation through surface exchange with the environment. Previous studies have demonstrated that such conditions reproduce the thermal stress of firefighting better than continuous aerobic work.

With these two sets of data, hypothetical alarm set points were calculated which can then be translated into both monitoring station and sensor unit alarms.

The experimental design of the fire ground simulation has also been modified slightly from that used in Phase I to improve our ability to compare data across multiple trials. The major modifications include replacement of tasks that are performed to completion during the protocol with tasks that are performed for a timed period. The final event will still be performed to

volitional fatigue, and will therefore vary in length with different subjects and trials. A ladder climber replaced the stair climbing apparatus to better emulate the combined upper and lower body workloads intrinsic to fireground operations. While it is true that stair climbing is frequently a major early demand in firefighting, this is virtually always done while carrying heavy tools or hauling hose lines, which substantially alters the character of the exercise. In addition to core temperature, which was monitored in the Phase I studies, respiratory rates (to identify the ventilatory breaks indicating changes in metabolic and thermoregulatory status), venous pH and lactate, sweat loss, air use and subjective ratings of perceived exertion were all monitored. VO_2 MAX was determined prior to the studies and retrospectively correlated with the results. In these experiments, subject sample size and number of trial repeats are also increased over previous experiments to ensure statistical validity of the results.

Physiologic Correlation Studies

The fire fighting simulation studies were carried out in environmental chambers in association with the Human Performance Laboratory at the University of Connecticut. Twenty currently active FF's from the Branford, CT fire department participated in the study. The inclusion and exclusion criteria were the same as those used in the Phase I studies, except that members who are 18-20 years of age were eligible to participate in addition to those 21 and older. The subjects were compensated for their participation. VO_2 MAX was determined for each subject by treadmill testing, using a metabolic cart with spirometry within a month of initiation of these studies. Because it was used to subjectively quantify the workload and fatigue experienced throughout the exercise sequence, the participants were familiarized with Rating of Perceived Exertion (RPE) on the Borg Scale.

Each fire fighter performed the protocol three times, with at least one week between each set of trials. Two different exercise protocols were used. The first replicated the post-Phase I treadmill protocol designed to provide a simple, linear approach to volitional fatigue. The second and third comprised a sequence of simulated fire ground tasks slightly modified from the protocol used in the Phase I studies. All were performed with subjects in full PPE and with the environmental chamber set at 40°C. Core body temperature was monitored using CorTemp^R capsules ingested several hours prior to initiation of the study to ensure passage beyond the proximal small bowel. Baseline heart rates were recorded. The protocol began after nude weight was recorded, venous blood drawn for determination of hemoglobin, pH, glucose, and lactate levels, and urine collected for specific gravity. The subject then donned full turnout gear including coat, bunker pants, boots, hood, gloves, helmet, and the sensorized SCBA. The Interspiro SCBAs were fitted with 60-minute air cylinders for the fire task simulation studies, and the quick connect mechanism was used to supplement the cylinders from the air supply cart for the treadmill studies.

For the weighted treadmill protocol, each subject wore a 75-lb weighted vest under his or her PPE. As described in the post-Phase I studies, this approximates the weight carried by a FF when transporting a high-rise hose pack and/or tools for structure ventilation. Use of the vest distributes the weight more comfortably, however, and minimizes the effect of local (arm and shoulder) muscle fatigue that could shorten the overall exercise if the high-rise pack were carried in its normal harness. The subject walked on the treadmill in the heated environmental chamber at a rate of 4 mph with a 2% grade, indicating RPE to an investigator holding up cards as previously described, every 2 minutes, to the point of volitional fatigue. When fatigued, the subject exited the chamber, and sat in a chair provided in the laboratory. The SCBA and other

PPE were removed with assistance from the investigators, and the subject was provided towels. Post-exercise nude weight was then recorded, and urine collected. All pre-exercise lab studies were repeated on venous blood obtained at this point, and the subjects were given water for oral rehydration. When heart rates returned to baseline, and core temperatures were less than 37.5°C, the subjects were discharged with follow-up instructions regarding the presence of the CorTemp capsules and methods to contact the investigators if any symptoms develop.

For the fire ground simulation protocol, the subject entered the chamber carrying a harnessed 50 lb high-rise hose pack over the shoulder, and walked at 4 mph on a treadmill at 2% grade, for 2.5 minutes. Upon dismounting the treadmill, the subject dropped the hose pack and proceeded to the ladder climbing apparatus for 2.5 minutes of climbing. The pace of the climb was established using a metronome, and the resistance settings are adjusted to each subject's weight. Upon completion of this exercise, the subject proceeded to the corner of the environmental chamber located to the right of the entrance portal, at which time the lights were turned off. From this corner, the subject performed a right hand search on hands and knees around the periphery of the darkened chamber while pulling a 'task force tip' nozzle attached to 1.75" hose line, bundled and tied for safety. After 3 minutes of search, the investigator inside the chamber directed the subject to the location of a 160 lb rescue dummy. The subject dragged the dummy backwards around the periphery of the chamber, which is still dark, for 2 minutes. The subject then repeated the 2.5 minutes on the treadmill with the hose pack and the 2.5 minutes on the ladder climber. Finally, the subject performed a pike pole breach and pull simulation using a modified Molitor Machine to volitional fatigue. If the low air alarm sounded before the subject has reached volitional fatigue, back-up cylinders on a rescue air cart were connected to the subjects 'buddy breathing' hook-up in the air line by study staff present in the chamber, allowing him/her to continue the exercise without stopping to replace the air cylinder. Thirty seconds prior to the end of exercise on each apparatus, and every 2 minutes during the breach and pull simulation, the subject was asked for subjective ratings of heat, respiratory effort, muscle fatigue, and overall exertion using the 20-point Borg scale as described previously, and these were recorded. During the initial and final 30 seconds of each individual task, one investigator also counted and recorded the subject's respiratory rate.

When fatigued, the subject exited the chamber and the post-exercise sequence of labs and monitoring described above following the weighted treadmill protocol was completed. The fire ground simulation exercise protocol roughly simulates the work that would be performed while consuming the first two 30-minute cylinders of air on a fire ground. The practice of enforcing rest and rehabilitation of FF's after the second bottle is widespread in the fire service⁴⁶.

Output from the core temperature system and the mask oximeter was transmitted as previously described by radio telemetry to a laptop computer at the site, where both real time monitoring and recording will take place throughout the firefighting task simulations in the chamber and the rehab.

Analysis of Physiologic Correlation Study Data

Data collected during these studies include 1) DC oximetry values over time, 2) urine specific gravity as well as venous hemoglobin, glucose, pH and lactate levels obtained before

⁴⁶ National Fire Protection Association. NFPA 1582 Standard on Medical Requirements for Fire Fighters and Information for Physicians. 2000 ed. NFPA, Quincy, MA.

and after exercise, 3) respiratory rates and changes in respiratory rate during each timed task, 4) core temperature, 5) RPE for each task as well as for the entire protocol, and 6) approximate sweat lost by each subject and other estimates of intravascular volume contraction over the course of the experiment, and 7) heart rates prior to exercise and then monitored throughout the rehab period until pre-exercise rates are achieved.

The oximetry data was collected, filtered, signal averaged and graphed as we have described above in the Phase I reports and in Task 3 below. The raw core temperature data was likewise filtered for artifact as required. Both sets of data were normalized to time and task to facilitate comparison among subjects and trials. The improved oximetry equipment together with the modifications of the discontinuous protocol facilitated a comparison of the DC oximetry response to the approach to volitional fatigue in the linear (weighted treadmill) vs. the discontinuous (fire ground simulation) exercise protocols.

Oximetry data from each timed segment of exercise was also be analyzed for variability, changes measured by slope of the best fit line, difference between maximum and minimum values, and difference between entry and exit values for that segment. Means and standard errors of the mean are calculated from the resulting ordinals and compared using basic, descriptive statistical methods. Relationships between DC oximetry patterns and body mass index (calculated by standard formula using pre-exercise height and weights), VO_{2MAX} , and other measured physiologic parameters were similarly evaluated.

Additional, distinctive signatures in the oximetry trends that are associated with symptomatic fatigue and alteration in the other measured parameters were sought using neural net-based, pattern recognition software and other techniques of data mining. This is the particular area of expertise that Dr. McGrath's information technology group at Dartmouth brought to the effort, and these studies largely occurred in her labs. The main emphasis of this work was to continue to focus on the DC oximetry data collected near the end of the protocol, as each subject approaches volitional fatigue in order to define hypothetical alarm values. The data collected during the other segments was also analyzed using these methods so that specific effects of certain types of exercise or movements on the DC oximetry waveform, if present, could be detected and characterized. The reduced oximetry data for the individual, timed task segments was compared with the corresponding core temperature changes, RPE results, respiratory rates and respiratory rate changes recorded for those tasks, generating coefficients of correlation for each parameter.

Task 3: Development of an oximetric variability index and correlation with DC oximetry values as well as the other monitored physiologic parameters

Variability statistics were extracted from the raw data obtained during the correlation studies using the same methods as those in the post-Phase I supplemental studies. Using methods similar to those published for determining heart rate variability, an index of oximetric variability was established, a component as essential actual DC oximetry trends in contributing to the total monitoring capability of the system. Dr. Winchell, who has extensive experience in variability analysis of waveforms as demonstrated by his published work in the use of heart rate variability monitoring in trauma and critical care patients, assisted with these studies.

Data Filtering

The process used to analyze the data depicted in Table 15 was first developed during Phase I and subsequently refined during the post Phase I studies. First, the raw data acquired by the

sensor system is divided into two-second intervals. A noise filter is applied to a moving average of each time series of the data points within each interval. The average of each interval is taken, and noise is removed by observing, for each data point, the forward average of the next ten data points and comparing that value to the data point. If the data point is within a specific threshold of that average, the data point is accepted. This process is repeated for the backward average, looking at the previous 10 data points. If the data point fails either or both of these tests, the process is repeated for the next ten data points beyond or before respectively. If the data point is unable to pass any of the threshold tests, it is considered noise, and is replaced with the mean of the forward-10 and backward-10 averages.

Variance Analysis

For each two-second interval, the mean value of that interval is plotted at the time point for the center of the average (mask mean value). A root-mean-square (RMS) algorithm is applied to the mask mean value to derive the mask DC value. This process pulls the DC component out of the mean. Plots of these two values tracked nearly identically for all of the Phase I and post Phase I oximetry data.

The index of variability is a traditional variance measure of the value of all filtered data within each 2-second interval, and is acquired using the VAR formula:

$$V = \frac{n \sum x^2 - (\sum x)^2}{n(n-1)} \quad \text{Equation 4}$$

Physiologic correlation studies provide data samples detailing an expected variance range (i.e. 0.5% DC Absorbance) and can be used to establish reasonable trigger points for alarms which minimize false positive and negative readings. Variability is taken for each (2 second) interval (i.e. the variability of the 19 samples/second) and compared against that value for the next 2 second interval and so on. During our Phase II efforts, we continued to use this basic algorithm; however, values for the threshold (currently 1%), the size of the data interval (2 seconds) and the size of the moving average (10 data points) require further optimization. The signal filtering and processing algorithms will be integrated into the program running on the laptop computer that receives the data, so that mask DC values and index of variability are concurrently displayed and recorded. This step is required for the adaptation of the device from its current research configuration to a fieldable, real-time monitor capable of providing timely alarms.

Task 4: Establishment of acceptable ranges and alarm thresholds for DC oximetry and oximetric variability index

Our original premise at the time of our Phase I application was that in the commercial implementation of the system, alarm values would require calibration for each individual user. Each user would perform an activity similar to the CPAT that would be used to profile what changes should be expected for the individual while performing firefighting tasks. Deviations from this expected behavior could then be observed by our system and used to set an alarm value.

The results of our Phase I, post Phase I, and Phase II studies indicate that it should not be necessary to calibrate the system to each individual. Although rapid DC deflections (either upward or downward) are present in most subjects Figure 23 as they approach volitional fatigue,

even in the cases where this was not observed, the variability index of the data clearly and dramatically increases (Figure 53). In the limited number of subjects monitored by this technique to date, the pattern of increased variability was not consistent, though the increase itself was. A steady rise that began early in the protocol and continued throughout the exercise was observed in one subject, whereas a precipitous surge over the final 30-60 seconds of exercise was more common.

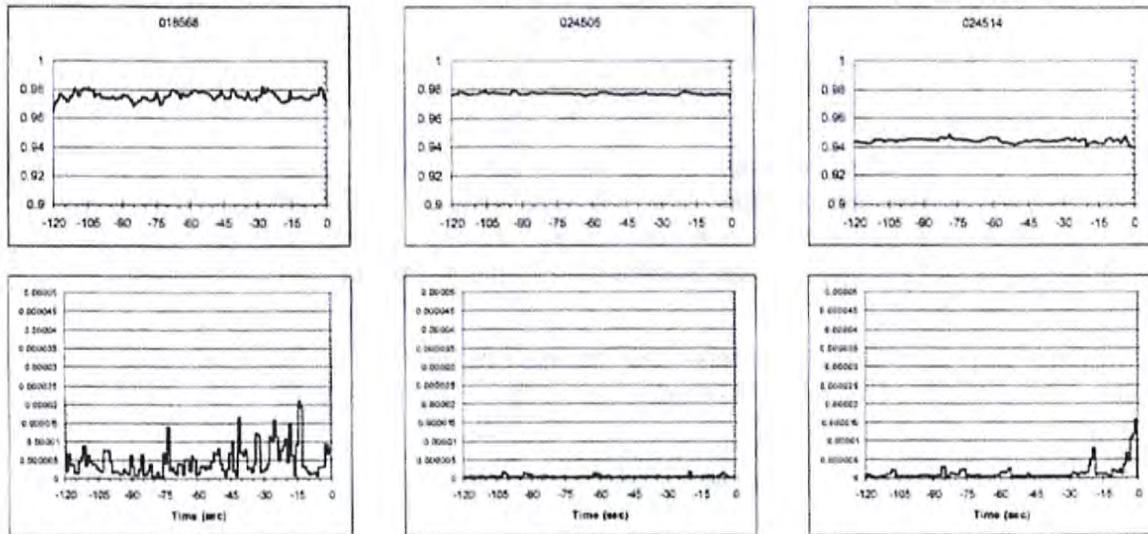


Figure 23: Matched sets of DC MAM oximetry (top) and Variance (bottom) for the last two minutes of data for three subjects during treadmill trials at U Conn.

Shown in the data in Figure 23 above, in many of the subjects, some downward trending of the MAM DC oximetry can be observed, particularly in the last 30 seconds before the subject self-reported the need to end the trial. This effect is even more pronounced when observing the variance data, as the frequency and magnitude of variance spikes increase up through the end of the trials. However, this also showcases one of the limitations of the mechanism of human trials. While it was our desire that subjects should exercise for as long as they could without injuring themselves, this was a self-reported state. In the case of subjects 018568 (left) and 024514 (right), these subjects exercised the treadmill for just over 20 minutes each before ending their trials, subject 024505 (center) went for only 15 minutes of activity, and we believe that the subject did not exert themselves as fully as the others.

Table 11. Trial Duration, Variance, and RPE for LEP

Subject ID	Exercise Duration (sec)	Start RPE	End RPE	Ave Variance (last 2 minutes)
018568	1258	30.5	72.5	$48.15 \pm 42.10 \times 10^{-7}$
024505	902	26	65.5	$4.93 \pm 2.88 \times 10^{-7}$
024514	1227			$13.08 \pm 19.62 \times 10^{-7}$
024520	656	39	54	$21.21 \pm 30.13 \times 10^{-7}$

Logistically, the system, based upon the post Phase I and Phase II studies, should be much easier to implement and operate commercially than the one originally proposed in Phase I. Our post Phase I studies suggest that this may be possible. As described above in Tasks 2-4, our Phase II efforts helped establish the magnitude of the mask DC value deflection and/or the variability index value that appears to correlate with volitional fatigue in the FF subjects.

Hypothetical alarm settings can be established based on either a sudden rapid deflection (up or down) in the DC oximetry value, or by the overall variance in the running-averaged DC oximetry increasing above a still yet to be determined threshold. The system will incorporate a single alarm based on absolute index of variability or an alarm based on the rate of increase of variability or a magnitude of deflection in the mask DC waveform or a slope function. The final alarm triggers are likely to be based upon a combination of all these parameters.

As will be discussed further in the results section, one reason why a true variability threshold value could not be determined with our current data sets is that other than the one subject who actually reached volitional fatigue, all other subjects ended their trial protocol at a self-reported level of being tired. While our test environment attempted to recreate many of the factors influencing fire fighters while performing their work, including the adrenaline surge associated with the alarm call itself, in the end no test subject would be expected to risk their own health for the sake of a clinical trial, and thus the point at which they would have ended our data gathering would be much earlier than the point they would end their own operations on a real fireground. Furthermore, to use this laboratory setting value as the threshold by which to recall the fire fighters from operations would meet with resistance and system acceptance if the system was deemed to recall personnel while they consistently felt they had more effort to give.

Task 5: Field Testing SCBA units with the DC oximetry monitoring system under controlled fire service emergency operational conditions

Phase II efforts originally envisioned taking a fully operation multi-user system with locally and base station implemented alarm settings into field tests during live burn training exercises. These studies were conducted under controlled conditions at a training facility that uses Class A fires in order to validate system functionality under conditions of heat, smoke and distance in excess of the laboratory setting. Key points for consideration included:

- System Accuracy – Does the system identify FF's who are exhausted and need rest, rehydration and/or cooling (rehabilitation) before they can perform additional work? (Establish rate of false negatives). Does the alarm activate when individuals are still working comfortably and do not require immediate rehabilitation? (Establish false positive rate).
- Ergonomics – will the operation of the system interfere with other operations of the FF?
- System Performance – Is the system adequately hardened to operate reliably under fireground conditions, throughout protracted incidents, and on different days with interim storage?
- Monitoring System – will the system monitor multiple subjects simultaneously, and are warnings and alarms effectively displayed?

Although we are confident of the system technology and alarm parameters and do not anticipate any changes will be required for the algorithms, field testing will identify the need for additional physiological data or modification to the alarm settings. Field testing will also provide an invaluable opportunity to demonstrate the durability, ease-of-use, and reliability in the field.

System Accuracy

Once we have finalized our algorithms for processing and analyzing the data from our sensor array, software simulators will be used to ensure that the processor software correctly responds.

Data acquired during the physiologic correlation studies can be fed into the simulator to ascertain that the onset of decompensation is correctly determined with data measured by the system. This predicted outcome will then be compared against the other physiologic data collected to determine the accuracy of the assessment.

Ergonomics

Any necessary redesign regarding the placement of the data acquisition system and its cabling will be incorporated into a final design for commercial sales. Design modifications will be based on interviews with the subjects and analysis of the field trials, under which a number of actual fire fighting activities will have been performed.

System Performance

The physiologic correlation study is designed to emulate typical activities of the fire fighter through their first two bottles of air. After this time, a fire fighter would typically be required to rehabilitate prior to resuming fire fighting activities. The absolute minimum acceptable performance period for the data acquisition system is the duration of two bottles of air (≤ 45 minutes each). Although it is possible to perform tasks such as a battery exchange during this period of rehabilitation, from a practical and commercial standpoint, the system must perform much longer. Prior to, and again during the correlation studies, the operational performance of the system is assessed. Our Phase I prototype data acquisition system was able to operate reliably for approximately 4 hours; greater performance was anticipated and achieved with the new design.

Monitoring System

The physiologic correlation studies are intended to develop the data necessary to set alarms that will be triggered when the markers of volitional fatigue are detected by the system. Real-time monitoring of data is necessary to verify the quality of the data, and was implemented for the Task 4 studies in the environmental chamber. Real-time data analysis at a monitoring station was not the primary focus of the field studies. Furthermore, unlike the commercial implementation of the system, for these studies, only one subject was monitored at a time, and thus monitoring multiple personnel simultaneously is not required. These studies do provide an opportunity to test aspects of the monitoring system under development, including the display methods by which subject data is presented.

The monitoring system program operates on a portable PC. In the commercial implementation, this PC is likely to be dedicated to the task of monitoring personnel. The PC will be connected to the telemetry system receiver unit, and will be designed to sort data packets from the multiple data acquisition units into the correct data files. As algorithms for alarm conditions become more refined, the monitoring system will apply these algorithms to the data received and trigger alarms for monitoring personnel. Some algorithm processing will occur locally at each unit's data acquisition system; however, the vast majority of high level processing will occur at the monitoring station. The analysis algorithms previously described will be refined, based on the data acquired during the physiologic correlation studies.

Design Review: Redesign Recommendations

An evaluation of the above criteria was conducted to address any discovered shortcomings. These recommendations were then incorporated into the final design fabricated for the field trials.

Mask Mold with Sensors Design and Fabrication

LED emitter(s) and photo-detector(s) were selected and integrated into the masks for the physiologic correlation studies. The results of our previous Phase I study indicate that the sensor elements can be integrated into the SCBA masks without compromising the NIOSH required fit check test.

The product life of an SCBA mask is generally 10 years. The sensor elements are estimated to last about two years in this environment. The most susceptible element will be a window designed to protect the sensor from the sweat of the fire fighter, while not interfering with mask performance or oximetry signal acquisition. As a result, the sensor elements within the mask may need to be replaceable. Interspiro and Sekos Inc. are collaborating to modify the mask design in a manner that allows the SCBA masks to be cost effectively modified, pass CBRN certification and permit the scheduled replacement of the sensor elements. Ten SCBA masks were constructed according to this design for use during the field studies. These units will also be compared against those designed for the physiologic correlation study to evaluate if the manufacturing process results in improvement or degradation of sensor performance.

Users will test the masks to verify that they can be worn without significant discomfort from the sensor elements or other support hardware. This test will be subjective and performed through simple survey during clinical trials in the environmental chamber. If wearer discomfort is reported, further modification of the sensor support and attachment mechanism will be undertaken. FF subjects surveyed after wearing the Phase II sensorized masks reported no wearer discomfort for periods up to 60 minutes.

Field Studies

In order to best simulate the spectrum of physiologic challenges that routinely confront working FF's, field trials were conducted in two different locations, with different climates and training/simulation capabilities. All of these studies were conducted incidentally to regularly scheduled training exercises for recruits enrolled at the respective facilities. It is recognized that the unpredictability of actual emergency response is lacking from these trials. Such unpredictability makes field trials of equipment or protocols difficult, as the amount of time spent waiting in between emergency calls is time and cost prohibitive. Field studies conducted at fire training academies allows us to assess the system's performance under conditions of heat, smoke, fire, soaking water, potentially interfering radio communications and realistic distances of sensorized personnel from monitoring stations. In addition, the timing sequence, duration, and intermittent stress of the fireground are more precisely simulated than they can be in environmental chamber studies.

System Performance

If the system remains operational for the entire duration of each subject's use during the field trials, the operational performance (durability, power, etc.) is considered a success. Any failures of the system in the field will be evaluated, to determine how best to reduce the future risk of similar failures.

Monitoring System – Base Station

The effectiveness of the monitoring system is determined by the ability to warn personnel monitoring the FF's' health of adverse conditions. In this respect, it is evaluated by the same criteria as physiologic assessment above. The monitoring system's utility is also measured by

how the information is presented to the monitoring personnel. Comments from these personnel will be used to improve the final implementation of the system.

Evaluation criteria include:

- What are the instances of false positive or negative readings?
- Does the graphic display show the necessary information for making decisions? Is it clearly presented? Is it understandable?
- Are alarms presented so that they are promptly responded to?
- What other information would be a benefit?

*Results and Discussion

Data Decomposition and Time Syncing

One of the greatest logistical challenges to this effort was a means of time synchronizing data collected in a number of venues and systems. Separate data device collections included:

Table 12. Data sources and time synchronization method

<u>Data Source</u>	<u>Time recording method</u>
The CorTemp monitor	real time clock (RTC)
Data recorded by the PC connected to the footfalls monitor	PCs real-time clock and time sync buttons
Data recorded by the PC connected to the HWM monitor	PCs real-time clock and time sync buttons
RPE interviews	Time based on stopwatch
Pre/Post weight	Post weight: stopwatch and PC time sync buttons
CPAT activity durations	Time based on stopwatch

The method selected for assuring that timed events in the data files are correlated as closely as possible was as follows:

1. At the beginning of each day, the two PCs were started. The PC system clocks were opened and set to the same time. (Accuracy ± 0.5 sec).
2. Previous data on the CorTemp monitor was cleared. The unit was then programmed with the calibration number for a subject's CorTemp Pill (taken 3-12 hours earlier). This also time synchronized the CorTemp monitor's RTC to the PC's system clock. This time (in real time) is noted in the notebook or on a subject's data collection table (Table 13).
3. Once a subject was ready to begin a trial and had passed a pre-trial interview, the subject was weighed and blood was drawn.
4. The PC software for monitoring the HWM is started (a new data file session is created using the subject's CorTemp pill serial number as the subject ID). The time is noted.
5. The PC software for monitoring the FFM is started (a new data file session is created using the subject's CorTemp pill serial number with a `_ffm` designator is used as the file/subject ID).
6. Once both PCs are running, the "mark event" button is pressed on both units at the same time (Accuracy ± 0.5 sec) so that the resulting data files can be time synchronized after the trial. See the `subjectID_A_Events.csv`, `subjectID.txt`, and `subjectID_ffm.txt` files. The time (± 1 sec.) is noted.
7. A stopwatch is started and at the same time the "mark event" button is pressed on both PCs at the same time (Accuracy ± 0.5 sec) so that the resulting data can be time

- synchronized after the trial. See the *subjectID_A_Events.csv*, *subjectID.txt*, and *subjectID_ffm.txt* files. The time (± 1 sec.) is noted.
8. The HWM sensor unit is switched on and begins to transmit data at the same time the "mark event" button is pressed on both PCs at the same time (Accuracy ± 0.5 sec) so that the resulting data can be time synchronized after the trial. See the *subjectID_A_Events.csv*, *subjectID.txt*, and *subjectID_ffm.txt* files. The time (± 1 sec.) is noted.
 9. A push button on the FFM sensor unit is pressed and this event is logged in the *subjectID_ffm.ffm* and *subjectID_ffm.csv* data files at the same time the "mark event" button is pressed on both PCs at the same time (Accuracy ± 1 sec) so that the resulting data can be time synchronized after the trial. See the *subjectID_A_Events.csv*, *subjectID.txt*, and *subjectID_ffm.txt* files. The time (± 1 sec.) is noted.
 10. While the subject rests outside, a simulated fire alarm call is triggered and the subject begins to put on their fire gear. The time real time and stopwatch times (± 1 sec.) are noted. At the same time the "mark event" button is pressed on both PCs at the same time (Accuracy ± 1 sec) so that the resulting data can be time synchronized after the trial. See the *subjectID_A_Events.csv*, *subjectID.txt*, and *subjectID_ffm.txt* files.
 11. Shortly after this time, when the subject is properly wearing their SCBA, the HWM sensor unit begins to transmit meaningful data rather than the preceeding signal noise. From this point forward all recorded times are generally based on the stopwatch, although real time may also be noted. This time is noted when a viable HWM DC Ox signal is observed on the real-time display (± 1 sec.) is noted.
 12. The subject then begins the treadmill activity. In all processed data files, the time of this event signifies time zero (0). By using this time, rather than the alarm time as was used in Phase I, the total duration of Physical activity for both the STP trials and the treadmill only studies can be related. The "mark event" button is pressed on both PCs at the same time (Accuracy ± 1 sec) so that the resulting data can be time synchronized after the trial. See the *subjectID_A_Events.csv*, *subjectID.txt*, and *subjectID_ffm.txt* files. The time (± 1 sec.) is noted.
 13. From this point forward, each time there is a significant event, planned (on treadmill, off treadmill, on ladder, etc.) or unplanned (subject stumbles on treadmill, etc.) The "mark event" button is pressed on both PCs at the same time so that the resulting data can be time synchronized after the trial and the time (± 1 sec.) is noted. On occasion, however, one or the other of the PCs may miss the event, in which case the events numbers on the two units may be different, however, the real-time that the event is recorded on the PC can be used to relate events on the HWM (OxPC, Table 13) to the FFM (FFM PC, Table 13). Whenever possible, the value of the last heartbeat counter (Table 47, Table 48, Table 51, and Table 55) received by the PC from the HWM or FFM sensor unit is also noted (HW Stamp, Table 13, "HWM counter" / "FFM counter") whenever possible. The meaning of the event marker is recorded in the *subjectID_A_Events.csv*, *subjectID.txt*, and *subjectID_ffm.txt* files using the shorthand described in Table 35.

14. Whenever data systems are then turned off at the conclusion of the subject's trial, the time is also noted.

Table 13. Data collection chart example

S/N: 024510

Sensor Unit: Red / Mask 1

OxPC	FFM PC	HW Stamp	Planned Events	PC Time	SW Time	Notes
			Start CorTemp Unit	10:19:20		37.24°C
			Start DAQ SW	10:33:46		
2	2		Start Stopwatch	10:34:50	0	
3	3		Start Sensor Unit	10:35:20	31	
4	1	6/2	Sync with FFM	10:38:58	4:08	
5	2	15/2	Alarm	10:43:49	9:00	
			Mask On		10:33	
6	3	20/2	Treadmill		12:09	
			PE		13:54	
7	4		Off Treadmill		14:39	
8	5	26/8	Ladder Climb		15:10	
			PE		16:55	
9	6		Off Ladder		17:38	
10			Search and Rescue		18:50	
11		30/13	End Search and Rescue		20:15	
12	7	37/13	Treadmill #2		21:30	
			PE		23:15	
13	8	42/16	End Treadmill #2		24:00	
14	9	42/18	Ladder #2		24:43	
		45/18	PE		26:21	
15	10		End Ladder #2		27:08	
16	11	49/23	Breach and Pull		27:57	
17			End Breach and Pull		29:50	
18	12		Exit Chamber		30:05	
19			Stop FFM Data			Time not noted
			Mask Off		30:51	
20		56	Y probe on		31:49	
21		65	Undress / Take Weight		37:23	Data loss while in
24			Return from Weight		48:58	Bathroom
25		85	Rehydrate		49:18	
26		96	End Data Collection		54:48	
			End CorTemp Data	11:29:38	56:18	

Following the subject trials, the HWM and FFM data files were processed per the code shown in Table 14. The effects of this processing, in addition to time synchronization was to perform noise rejection algorithms and to apply MAM, variance, ratio, and other analyses to the data. This code created formatted data files with time in seconds (with zero being the start of treadmill activity) in the first column and the relevant data in subsequent columns. Detailed

descriptions on these file formats can be found in Table 33, Table 34, and Table 36 through Table 43. It is this formatted data that is used in the subsequent analysis.

A variation of Robert Winchell's noise removal algorithm was used on the LED and IRLED data. All LED and IR LED data was converted to % Absorbance (i.e. a value between 0 and 1) using the formula described above. For each data point, the prior 10 data points were evaluated, and if the value of that data was different from the average of those 10 data points by greater than 0.0075, the value was considered noise, and replaced with the average of the 10 prior data points. It is of concern that the number of data points rejected because of this noise threshold in the trials for 018569, 018570, 018571, 018574, 018575, 018578, 018579, 018582 and 018586, seemed excessively high, usually for the IRLED value, and this should be reevaluated.

A similar mechanism was used for the foot fall monitor, where only (maximum) peaks within a block of 21 data values, whose peak was at least 3 points greater than the running average of the 21 data points were recorded.

Table 14. Software code (perl 4.0) used in generating trend data files

```
#!/usr/bin/perl

my $subjectid;
my $datablocks;
my $pobuff;
my $block;
my $postr;
my @infileext = (".txt", ".dat", ".ffm", ".FFM.csv", ".HWM.csv");
my @infilelist;
my @outfilelist;
my $outfileoverwrite;
my @HWMeventtimes;
my $realtimerzero;
my $startevent;
my $NoiseReductionRunningAverage = 10;
my $NoiseReductionThreshold = 0.0075;

# for each subject number, there should be the following data files:
# ../(subjectid)/(subjectid).txt      Notation Files for Events
# ../(subjectid)/(subjectid).dat      Raw, Binary, R/IR Data received by radio system
# ../(subjectid)/(subjectid).ffm      FFM data if both when to single pc (usually 0 bytes)
# ../(subjectid)/(subjectid)FFM.csv
# ../(subjectid)/(subjectid)HWM.csv
# ../(subjectid)_ffm/(subjectid).txt
# ../(subjectid)_ffm/(subjectid).dat  R/IR data if both when to single pc (usually 0 bytes)
# ../(subjectid)_ffm/(subjectid).ffm  Raw, Binary, FFM Data received by radio system
# ../(subjectid)_ffm/(subjectid)FFM.csv
# ../(subjectid)_ffm/(subjectid)HWM.csv
# ../uconn(last3subjectid).csv        Core Temp and Heart Rate Data
# ../(subjectid)RPE.csv                Rating of Percieved Exertion (not currently part of data set)

# Time of 0 sec is considered to be: starting the treadmill.

# Output files to be created (in current directory):
# [ 0] (subjectid)_A_Events.csv        Time (real), Time (sec), 0|100|0, Event ID, Event Text,
# Event Source (HWM|FFM)
# [ 1] (subjectid)_A_Red.csv           Time (sec), % Absorbance
# [ 2] (subjectid)_A_IR.csv            Time (sec), % Absorbance
# [ 3] (subjectid)_A_FFpeaks.csv       Time (sec), 0|100|0
# [ 4] (subjectid)_A_CTHR.csv          Time (sec), CT, HR
# [ 5] (subjectid)_A_DI.csv            Time (10 sec), % Red Data Intrgrity, % IR Data Intrgrity
# Data Analysis shall include:
# [ 6] (subjectid)_A_MAM.csv           Time (1 sec), Red MAM, IR MAM, Delta
# [ 7] (subjectid)_A_TSD.csv
# [ 8] (subjectid)_A_LRRIR.csv         Time (1 sec), Log Ratio of Red vs. Infrared
# [ 9] (subjectid)_A_Var.csv           Time (2 sec), Var Red, Var IR
# All this data is then combined into the mega file:
```

```

# [10] (subjectid)_A_All.csv

if( $ARGV[0] eq "" ) {
  print "Subject ID: ";
  $subjectid = <STDIN>;
  chop( $subjectid );
} else {
  $subjectid = $ARGV[0];
}

print "Checking Input Files\n";
my $ifli = 0;
for( $i=0; $i<${#infilesext+1}; $i++ ) {
  my $filename = "..\\" . $subjectid . "\\" . $subjectid . $infilesext[$i];
  $infilelist[$ifli++] = $filename;
  #print "DEBUG: [$ifli] $filename\n";
}
for( $i=0; $i<${#infilesext+1}; $i++ ) {
  my $filename = "..\\" . $subjectid . "_ffm\\" . $subjectid . "_ffm" . $infilesext[$i];
  $infilelist[$ifli++] = $filename;
  #print "DEBUG: [$ifli] $filename\n";
}
$infilelist[$ifli++] = "..\\" . $subjectid . "_ct.csv";
#$infilelist[$ifli++] = "TBD";

for( $i=0; $i<${#infilelist+1}; $i++ ) {
  my @filestats;
  my $filename = $infilelist[$i];
  if( check_file( $filename ) ) {
    @filestats = stat $filename;
    #($dev,$ion,$mode,$nlink,$uid,$gid,$rdev,$size,$atime,$mtime,$ctime,$blksize,$blocks) = stat
    $filename;
    ($sec, $min, $hour, $mday, $mon, $year, $wday, $yday, $isdst) = localtime( $filestats[9] );
    #mdate = localtime( $filestats[9] );
    $mdate = sprintf "%2d/%02d/%02d %2d:%02d:%02d", $mon-1, $mday, $year-100, $hour, $min, $sec;
    my $mode = "";
    if($filestats[2] eq "33060") {$mode="Read-Only";}
    if($filestats[2] eq "33206") {$mode="Writeable";}
    #print "$filename, $mode, $filestats[7] bytes, $mdate\n";
    printf "%32s: %9s, %7d bytes, $mdate\n", $filename, $mode, $filestats[7];
    #print "$filename, $mode, $size bytes, last modified on: $mtime\n";
  } else {
    printf "%32s: file missing!\n", $filename;
  } # if .. else .. check_file
}

# Check for Output Files - Overwrite? (All (1), Yes (2), No(-1), None (0), NewFile(3))
$ofli = 0;
$outfilelist[$ofli++] = $subjectid . "_A_Events.csv";
$outfilelist[$ofli++] = $subjectid . "_A_Red.csv";
$outfilelist[$ofli++] = $subjectid . "_A_IR.csv";
$outfilelist[$ofli++] = $subjectid . "_A_FFpeaks.csv";
$outfilelist[$ofli++] = $subjectid . "_A_CTHR.csv";
$outfilelist[$ofli++] = $subjectid . "_A_DI.csv";
$outfilelist[$ofli++] = $subjectid . "_A_MAM.csv";
$outfilelist[$ofli++] = $subjectid . "_A_TBD.csv";
$outfilelist[$ofli++] = $subjectid . "_A_LRRIR.csv";
$outfilelist[$ofli++] = $subjectid . "_A_Var.csv";
$outfilelist[$ofli++] = $subjectid . "_A_All.csv";

my $overwrite_all = -1;
for( $i=0; $i<${#outfilelist+1}; $i++ ) {
  my @filestats;
  my $filename = $outfilelist[$i];
  if( check_file( $filename ) ) {
    if( $overwrite_all == 1 ) {
      printf "%32s: file will be overwritten.\n", $filename;
      $outfileoverwrite[$i] = 1;
    } else {
      if( $overwrite_all == 0 ) {
        printf "%32s: file will not be changed.\n", $filename;
      }
    }
  }
}

```

```

$outfileoverwrite[$i] = 0;
} else {
  @filestats = stat $filename;
  ($sec, $min, $hour, $mday, $mon, $year, $yday, $isdst) = localtime( $filestats[9]
);
  $mdate = sprintf "%2d/%02d/%02d %2d:%02d:%02d", $mon+1, $mday, $year-100, $hour, $min,
$sec;
  my $mode = "";
  if($filestats[2] eq "33060") {$mode="Read-Only";}
  if($filestats[2] eq "33206") {$mode="Writeable";}
  printf "%32s: %9s, %7d bytes, $mdate\n", $filename, $mode, $filestats[7];
  print "    Overwrite file? (A)ll, (Y)es, (N)o, None (X) ";
  $subjectid = <STDIN>;
  chop( $subjectid );
  if( $subjectid eq "All" or $subjectid eq "A" ) { $overwrite_all = 1; $outfileoverwrite[$i] =
1;}
  if( $subjectid eq "all" or $subjectid eq "a" ) { $overwrite_all = 1; $outfileoverwrite[$i] =
1;}
  if( $subjectid eq "Yes" or $subjectid eq "Y" ) { $outfileoverwrite[$i] = 2;}
  if( $subjectid eq "yes" or $subjectid eq "y" ) { $outfileoverwrite[$i] = 2;}
  if( $subjectid eq "None" or $subjectid eq "X" ) { $overwrite_all = 0; $outfileoverwrite[$i]
= 0;}
  if( $subjectid eq "none" or $subjectid eq "x" ) { $overwrite_all = 0; $outfileoverwrite[$i]
= 0;}
  if( $subjectid eq "No" or $subjectid eq "N" ) { $outfileoverwrite[$i] = -1;}
  if( $subjectid eq "no" or $subjectid eq "n" ) { $outfileoverwrite[$i] = -1;}
  if( $outfileoverwrite == -1 ) { printf "%32s: file will not be changed.\n", $filename; }
  if( $outfileoverwrite == 2 ) { printf "%32s: file will be overwritten.\n", $filename; }
}
} else {
  printf "%32s: new file will be created.\n", $filename;
  $outfileoverwrite[$i] = 3; # New File
} # if .. else .. check_file
}

# Verify the Event Number for Starting the Treadmill based on HWM data(3)
print "-----\n";
open( HWMETF, "<$infilelist[0]" ) or print "Cannot open file $infilelist[0]: $!\n";
@ift = <HWMETF>;
close( HWMETF );

$HWMDAQStart = substr $ift[0], 0, 28;

# [x] look for first instance of Treadmill, TM, tm.
$startevent = -1;
$found = -1;
for( $i=0; $i<$#ift+1; $i++ ) {
  $event = index( $ift[$i], "Event ", 0 );
  $dash = index( $ift[$i], "--", 0 );
  if( $event != -1 ) {
    $eventnumber = substr $ift[$i], $event+6, $dash-$event-7;
    $eventnote[$eventnumber] = substr $ift[$i], $dash+3;
    chop $eventnote[$eventnumber];
    $HWMeventtimes[$eventnumber] = substr $ift[$i], 0, 28;
    print "Event $eventnumber at $HWMeventtimes[$eventnumber] $eventnote[$eventnumber]\n";
  }
  if( $found == -1 ) {
    $found = index $ift[$i], "tm";
    if( $found == -1 ) { $found = index $ift[$i], "TM"; }
    if( $found == -1 ) { $found = index $ift[$i], "Treadmill"; }
    if( $found == -1 ) { $found = index $ift[$i], "treadmill"; }
    if( $found != -1 ) {
      $realtimezero = $HWMeventtimes[$eventnumber];
      $startevent = $eventnumber;
    }
  }
} # for i
print "-----\n";
print "Please confirm from your notes that the Treadmill action began at ";
print "event $startevent\naccording to the HWM data. (enter a new number if wrong. ";

```

```

print "type 'shift' if a\ntime shift is needed). > ";
# [ ] enter in correct event if wrong.
$timeshift = 0;
$newnumb = <STDIN>;
chop( $newnumb );
if( $newnumb eq "shift" ) {
  print "By how many seconds is the event time off by (use '-nnn' to make earlier)? ";
  $timeshift = <STDIN>;
  chop( $timeshift );
  print "Please confirm from your notes that the Treadmill action began at ";
  print "event $startevent\nwith a time shift of $timeshift seconds according ";
  print "to the HWM data.\n(enter a new number if wrong) > ";
  $newnumb = <STDIN>;
  chop( $newnumb );
} # if shift
if( $newnumb != "" ) { print "New Start Event Number: $newnumb\n"; $startevent = $newnumb; }

$StartAnalysisTime = time();
# Events File
print "FILE: $outfilelist[0]\n";

$shr = substr $HWMDAQstart,11,2;
$smn = substr $HWMDAQstart,14,2;
$sscc = substr $HWMDAQstart,17,2;
$shds = ($shr*60+$smn)*60 + $sscc - $bts;
#print " [DEBUG] $HWMDAQstart, $shr:$smn:$sscc, HDS: $shds\n";

if( $outfileoverwrite[0] > 0 ) { $writefilelist .= "$outfilelist[0], "; open( EVTOUT,
">$outfilelist[0]" ) or print "Cannot open file $outfilelist[0]: $!\n"; }
  print EVTOUT "Time (real), Time (sec), Event Value, Event ID, Event Text, Event Source
[HWM|FFM]\n";
  $bshr = substr $HWMeventtimes[$startevent],11,2;
  $bmn = substr $HWMeventtimes[$startevent],14,2;
  $bscc = substr $HWMeventtimes[$startevent],17,2;
  $bts = ($bshr*60+$bmn)*60 + $bscc + $timeshift;
  $tsec = $shds - $bts;
  $startsec = $tsec;
  $tsml = $tsec - 1;
  $tspl = $tsec + 1;
  print EVTOUT "$HWMDAQstart,$tsml,0,-1,\n";
  print EVTOUT "$HWMDAQstart,$tsec,100,-1,Start DAQ,HWM\n";
  print EVTOUT "$HWMDAQstart,$tspl,0,-1,\n";
  for( $i=0; $i<$#ift+1; $i++ ) {
    if( length($HWMeventtimes[$i]) > 0 ) {
      $shr = substr $HWMeventtimes[$i],11,2;
      $smn = substr $HWMeventtimes[$i],14,2;
      $sscc = substr $HWMeventtimes[$i],17,2;
      $tsec = ($shr*60+$smn)*60 + $sscc - $bts;
      $tsml = $tsec - 1;
      $tspl = $tsec + 1;
      print EVTOUT "$HWMeventtimes[$i],$tsml,0,$i,\n";
      print EVTOUT "$HWMeventtimes[$i],$tsec,100,$i,$eventnote[$i],HWM\n";
      print EVTOUT "$HWMeventtimes[$i],$tspl,0,$i,\n";
    } # if $HWMeventtimes[$i] != ""
  } # for i
close( EVTOUT );

open( HWMDATA, "<$infilelist[4]" ) or print "Cannot open file $infilelist[4]: $!\n";
  @hwmdata = <HWMDATA>;
close( HWMDATA );

$writefilelist = "";
if( $outfileoverwrite[1] > 0 ) { $writefilelist .= "$outfilelist[1], "; open( REDOUT,
">$outfilelist[1]" ) or print "Cannot open file $outfilelist[1]: $!\n"; }
if( $outfileoverwrite[2] > 0 ) { $writefilelist .= "$outfilelist[2], "; open( IROUT,
">$outfilelist[2]" ) or print "Cannot open file $outfilelist[2]: $!\n"; }
if( $outfileoverwrite[5] > 0 ) { $writefilelist .= "$outfilelist[5], "; open( DIOUT,
">$outfilelist[5]" ) or print "Cannot open file $outfilelist[5]: $!\n"; }
if( $outfileoverwrite[6] > 0 ) { $writefilelist .= "$outfilelist[6], "; open( MAMOUT,
">$outfilelist[6]" ) or print "Cannot open file $outfilelist[6]: $!\n"; }

```

```

if( $outfileoverwrite[8] > 0 ) { $writefilelist .= "$outfilelist[8]. "; open( LROUT,
">$outfilelist[8]" ) or print "Cannot open file $outfilelist[8]: $!\n"; }
if( $outfileoverwrite[9] > 0 ) { $writefilelist .= "$outfilelist[9]. "; open( VAROUT,
">$outfilelist[9]" ) or print "Cannot open file $outfilelist[9]: $!\n"; }
chop $writefilelist;
chop $writefilelist;
print "FILES: $writefilelist\n";
print REDOUT "Time(sec),Red Abs.\n";
print IROUT "Time(sec),IR Abs.\n";
print DIOUT "Time(sec),Red Integrity,IR Integrity\n";
print MAMOUT "Time(sec),Red MAM,IR MAM,MAM Delta";
print LROUT "Time(sec),Red max,Red min,Red delta,IR max,IR min,IR delta,R:IR,ln(R:IR)\n";
print VAROUT "Time(sec),Red Var,IR Var\n";
$рни = 0;
$рnc = 0;
$ири = 0;
$иrnc = 0;
$рac = 0; # running average count (for MAM)
$aver = 0; # running average count (for Ratio R:IR)
$aversum = 0;
$averi = 0;
$redvari = 0;
$irvari = 0;
for( $i=0; $i<#$hwmdata+1; $i++ ) {
($PCTs,$HWMpts,$RedVal,$IRVal,$HWMevent) = split(/./, $hwmdata[$i]);
if( $PCTs > 0 ) {
$colG = $PCTs * 10;
$newtime = $colG + $startsec;
$diddiff = $newtime - $redtime;
$diunits = abs($diddiff / (10/191));
$diredpi = 1 - ($diunits / 19);
$diddiff = $newtime - $irtime;
$diunits = abs($diddiff / (10/191));
$diiirpi = 1 - ($diunits / 19);
#printf " [DEBUG] DI: %4.3f, %4.3f, %0.3f, %2d, %1.3f, %1.3f\n", $redtime, $newtime,
$diddiff, $diunits, $diredpi, $diiirpi;
printf DIOUT "%4.3f, %1.3f, %1.3f\n", $newtime, $diredpi, $diiirpi;
$рac = 0;
} else {
if( $RedVal > 0 ) { $colG = $colG + (10/191); }
} # if .. else .. PCTs > 0

if( $RedVal > 0 ) {
$RedAbs = (4096 - $RedVal) / 4096;
$lastred[$рни] = $RedAbs;
$redtime = $colG + $startsec;
$рни = $рни % $NoiseReductionRunningAverage;
$рас = 0;
for( $rai=0; $rai<$NoiseReductionRunningAverage; $rai++ ) {
$рас += $lastred[$rai];
} # for $rai
$ра = $рас / $NoiseReductionRunningAverage;
$difff = abs($RedAbs - $ра);
$sisnoise = " ";
if( $difff > $NoiseReductionThreshold ) { $sisnoise = "NOISE"; $рnc++; $RedAbs = $ра; }
#printf "[DEBUG] %5d, %2d %3.4f %3.4f %1.4f %6s\n", $i, $рни, $ра, $RedAbs, $difff,
$sisnoise;
# (subjectid)_A_Red.csv Time (sec), % Absorbance
printf REDOUT "%0.2f, %3.4f\n", $redtime, $RedAbs;
$рни++;
$redMAMdata[$рac] = $RedAbs;
$рvi = $redVari%38; $redVari++;
$redVarData[$рvi] = $RedAbs;
} # if RedVal

if( $IRVal > 0 ) {
$IRAbs = (4096 - $IRVal) / 4096;
$lastir[$ири] = $IRAbs;
$irtime = $colG + $startsec;
$ири = $ири % $NoiseReductionRunningAverage;
$ирас = 0;

```

```

for( $irai=0; $irai<$NoiseReductionRunningAverage; $irai++ ) {
  $iras += $lastir[$irai];
} # for $irai
$ira = $iras / $NoiseReductionRunningAverage;
$difff = abs($IRAbs - $ira);
$sisNoise = " ";
if( $difff > $NoiseReductionThreshold ) { $sisNoise = "NOISE"; $sirnc++; $IRAbs = $ira; }
#printf "[DEBUG] %5d, %2d %3.4f %3.4f %1.4f %6e\n", $i, $irni, $ira, $IRAbs, $difff,
$sisNoise;
# (subjectid)_A_IR.csv          Time (sec), % Absorbance
printf IROUT "%0.2f, %3.4f\n", $irtime, $IRAbs;
$irni++;
$irmAMdata[$irac] = $IRAbs;
$irVarData[$irVari++%38] = $IRAbs;
} # if IRVal

# [x] Approximate the Red vs. IR values such that in any given 1/2 second interval
# the max value is the peak and the min value is the trough (discard movements
# greater than some TBD interval. The delta between max and min shall be treated
# as the magnitude of the red or ir's respective pleth wave.
# 1/2 second is approx. 10 data points. Share the "last9" of the
# $(red|ir)MAMdata[$index]
if( $RedVal > 0 ) {
  if( $irac%9 == 8 ) {
    $lredmax = 0;
    $lredmin = 100;
    $lirmax = 0;
    $lirmin = 100;
    #printf LROUT "%3.2f,%2d,",$redtime,$irac;
    printf LROUT "%3.2f,",$redtime;
    for( $liriri=$irac-8; $liriri<$irac+1; $liriri++ ) {
      #printf LROUT "%3.4f,",$redMAMdata[$liriri];
      if( $redMAMdata[$liriri] > $lredmax ) { $lredmax = $redMAMdata[$liriri]; }
      if( 0 < $redMAMdata[$liriri] and $redMAMdata[$liriri] < $lredmin ) { $lredmin =
$redMAMdata[$liriri]; }
      if( $irmAMdata[$liriri] > $lirmax ) { $lirmax = $irmAMdata[$liriri]; }
      if( 0 < $irmAMdata[$liriri] and $irmAMdata[$liriri] < $lirmin ) { $lirmin =
$irmAMdata[$liriri]; }
    } # for $liriri
    $lreddelta = $lredmax - $lredmin;
    $lirdelta = $lirmax - $lirmin;
    $ratio = $lreddelta - $lirdelta;
    $R = 0;
    if( $lredmin > 0 and $lredmax > 0 and $lirmin > 0 and $lirmax > 0 and $lredmax != $lredmin
and $lirmax != $lirmin ) {
      #print " [DEBUG] log($lredmin/$lredmax)/log($lirmin/$lirmax)\n";
      $R = log($lredmin/$lredmax)/log($lirmin/$lirmax);
    } # if > 0
    printf LROUT "%3.4f, %3.4f, %3.6f,",$lredmax, $lredmin, $lreddelta;
    printf LROUT "%3.4f, %3.4f, %3.6f,",$lirmax, $lirmin, $lirdelta;
    printf LROUT "%3.6f, %3.6f\n", $ratio, $R;
    $saveRsum += $R; $saveRi++;
  } # if $irac%9=8
} # if RedVal

# [x] Create Red and IR mam values.
if( $IRVal > 0 or $RedVal > 0 ) {
  if( $irac%19 == 18 ) {
    # [x] create a red MAM data point
    # [x] create an ir MAM data point
    $RedMAMsum = 0;
    $IRMAMsum = 0;
    $RedDiv = 19;
    $IRDiv = 19;
    for( $smami = $irac-18; $smami<$irac+1; $smami++ ) {
      $RedMAMsum += $redMAMdata[$smami];
      if( $redMAMdata[$smami] == 0 ) { $RedDiv--; }
      #printf " [DEBUG] (RedMAM): %3d, %3.4f %3.4f\n", $smami, $redMAMdata[$smami], $RedMAMsum;
      $IRMAMsum += $irmAMdata[$smami];
      if( $irmAMdata[$smami] == 0 ) { $IRDiv--; }
      #printf " [DEBUG] (IRMAM): %3d, %3.4f %3.4f\n", $smami, $irmAMdata[$smami], $IRMAMsum;
    }
  }
}

```

```

    #printf MAMOUT "\n... [DEBUG] (MAM), %3d, %3.4f, %3.4f", $mami, $redMAMdata[$mami],
    $IRMAMdata[$mami];
    } # for mami
    $RedMAMval = $RedMAMsum / $RedDiv;
    $IRMAMval = $IRMAMsum / $IRDiv;
    #printf " [DEBUG] (RedMAM): %0.2f, %3.4f\n", $redtime, $RedMAMval;
    #printf MAMOUT "%0.2f, %3.4f\n", $redtime, $RedMAMval;
    $MAMdelta = $RedMAMval - $IRMAMval;
    printf MAMOUT "\n%0.2f, %3.4f, %3.4f, %3.4f", $redtime, $RedMAMval, $IRMAMval, $MAMdelta;
    } # if $rac%19=9
    if( $IRVal > 0 ) { $rac++; }
    } # if IRVal or RedVal

# [ ] Data variance is calculated every 1 second for the prio 2 seconds worth of data
# according to the formula  $V = (nEx^2 - (Ex)^2) / n(n-1)$ , where E is the (Sum).
if( $RedVal > 0 ) {
    if( $redVari%19 == 18 ) { # 38 number is 2 sec used for data, new point every 1 sec (19)
        $redSum = 0;
        $redSumSqr = 0;
        #print " [DEBUG] ($redVari) ";
        for( $rvk=0; $rvk<38; $rvk++ ) {
            #printf "%3.3f, ", $redVarData[$rvk];
            $redSum += $redVarData[$rvk];
            $redSumSqr += $redVarData[$rvk]*$redVarData[$rvk];
        } # for rvk
        #print "\n";
        $redVar = ((38 * $redSumSqr) - ($redSum * $redSum)) / (38*37);
        #if( $RedVal > 0 ) { printf " [DEBUG] R %3.2f, %3.6f, %3.6f, %3.7f\n", $redtime,
        $redSum, $redSumSqr, $redVar; }
    } # if redVari
    } # if IRVal or RedVal
    if( $IRVal > 0 ) {
        if( $irVari%19 == 18 ) { # 38 number is 2 sec used for data, new point every 1 sec (19)
            $irSum = 0;
            $irSumSqr = 0;
            for( $irvk=0; $irvk<38; $irvk++ ) {
                $irSum += $irVarData[$irvk];
                $irSumSqr += $irVarData[$irvk]*$irVarData[$irvk];
            } # for irvk
            $irVar = ((38 * $irSumSqr) - ($irSum * $irSum)) / (38*37);
            #if( $IRVal > 0 ) { printf " [DEBUG] I %3.2f, %3.6f, %3.6f, %3.7f\n", $irtime, $irSum,
            $irSumSqr, $irVar; }
        } # if irVari
    } # if IRVal or RedVal
    if( $IRVal > 0 ) { printf VAROUT "%3.2f, %3.8f, %3.8f\n", $irtime, $redVar, $irVar; }

} # for i
print " ... Red noise count: $rnc\n";
print " ... IR noise count: $irnc\n";
$aveR = $averSum/$aveRi;
printf " ... Average log ratio R:IR: %4.6f\n", $aveR;
close( VAROUT );
close( LROUT );
close( MAMOUT );
close( DICUT );
close( IROUT );
close( REDOUT );

print "FILE: Soutfilelist[3]\n";
open( FFMEVT, "<$infilelist[5]" ) or print "Cannot open file $infilelist[5]: $!\n";
@ffmevt = <FFMEVT>;
close( FFMEVT );
$FFMDAQstart = substr $ffmevt[0], 0, 28;
$fhR = substr $FFMDAQstart, 11, 2;
$fmin = substr $FFMDAQstart, 14, 2;
$fsec = substr $FFMDAQstart, 17, 2;
$ffmepoch = ($fhR*60+$fmin)*60 + $fsec;
$ffmdtime = $ffmepoch - $bts;
#print " [DEBUG] $ffmepoch, $ffmdtime, $ffmevt[0]\n";

open( FFMDATA, "<$infilelist[8]" ) or print "Cannot open file $infilelist[8]: $!\n";

```

```

@ffmdata = <FFMDATA>;
close( FFMOUT );
if( $outfileoverwrite[3] > 0 ) { open( FFMOUT, ">$outfilelist[3]" ) or print "Cannot open file
$outfilelist[3]: $\n"; }
printf FFMOUT "Time (sec), FFM, delta Time (sec)\n";
$lastaccel;
$lastaccltime;
$peakcount = 0;
$priorpeaktime = 0;
$checknumb = 20; # include zero, use an even number (200 = 1 sec)
$average = 304;
$minaccel = 3; # minimum magnitude of peak to count.
for( $i=0; $i<$#ffmdata; $i++ ) {
  ($pcts, $ffmpts, $accel, $event) = split /,/, $ffmdata[$i];
  if( $pcts > 0 ) { $ffmtime = $pcts*10; }
  if( $accel > 0 ) {
    $average = $average + (($accel - $average)/($i+2));
    $ffmtime = $ffmtime + 1/200;
    #printf " [DEBUG] %4.3f, %4d\n", $ffmtime, $accel;
    # Look for peaks
    for( $j=0; $j<$checknumb; $j++ ) {
      $lastaccel[$j] = $lastaccel[$j+1];
      $lastaccltime[$j] = $lastaccltime[$j+1];
    } # for j
    $lastaccel[$checknumb] = $accel;
    $lastaccltime[$checknumb] = $ffmtime;
    $accelmax = 0;
    for( $j=0; $j<$checknumb+1; $j++ ) {
      if( $lastaccel[$j] >= $accelmax ) { $accelmax = $lastaccel[$j]; $maxi = $j; }
    } # for j
    $sisPeak = 280;
    if( $maxi == ($checknumb/2) ) {
      $accelval = $lastaccel[($checknumb/2)] - $average;
      if( $accelval > $minaccel ) {
        $peakcount++;
        $peaktimedelta = $lastaccltime[($checknumb/2)] - $priorpeaktime;
        $ffmptime = $lastaccltime[($checknumb/2)] + $ffmdtime;
        #print " [DEBUG] $peakcount, $ffmptime, $lastaccltime[($checknumb/2)]\n";
        printf FFMOUT "%4.3f, 0, %4.3f\n", ($ffmptime - 0.001), $peaktimedelta;
        printf FFMOUT "%4.3f, %4.3f, %4.3f\n", $ffmptime, $accelval, $peaktimedelta;
        printf FFMOUT "%4.3f, 0, %4.3f\n", ($ffmptime + 0.001), $peaktimedelta;
        $priorpeaktime = $lastaccltime[($checknumb/2)];
      } # if accelval > minaccel
    } # if peak is 2 (middle)
    if( $accel > 0 ) { printf FFMOUT "%4.3f, %4d, %4d\n", $ffmtime, $accel, $sisPeak; }
  } # if accel > 0
} # for i
printf " ... Foot fall peaks: %5d, Average: %3.3f\n", $peakcount, $average;
close( FFMOUT );

open( CTDATA, "<$infilelist[10]" ) or print "Cannot open file $infilelist[10]: $\n";
@ctdata = <CTDATA>;
close( CTDATA );

print "FILE: $outfilelist[4]\n";
# [x] Correct time by making Start Treadmill as Time 0 sec.
$cttm = 0;
if( $outfileoverwrite[4] > 0 ) { open( CTOUT, ">$outfilelist[4]" ) or print "Cannot open file
$outfilelist[4]: $\n"; }
printf CTOUT "Time(sec), Temp(C), HR(BPM)\n";
$firstcttime = -1;
for( $i=103; $i<$#ctdata; $i++ ) { ## 103 bypasses header and pil data in file
  ($colA, $colB) = split /,/, $ctdata[$i];
  chop ($colB);
  $cttag = substr( $ctdata[$i], 0, 1 );
  if( $cttag eq "H" ) { $cthr = $colB; }
  if( $cttag eq "T" and $colB ne "8888.88" ) { $ctmin = substr( $colA, 1, 2 ); $ctsec = substr(
$colA, 4, 2 ); $cttemp = $colB; }
  if( $cttag eq "R" and $colB ne "888.8" ) { $ctmin = substr( $colA, 1, 2 ); $ctsec = substr(
$colA, 4, 2 ); $cthr = $colB; }
  $cttime = ( $cthr * 60 + $ctmin ) * 60 + $ctsec;
}

```

```

    if( $cttag eq "T" and $firstcttime < 0 ) { $firstcttime = $cttime; $cttm = $firstcttime -
    $bts; }
    $cttime = $cttime - $firstcttime + $cttm;
    #printf "[DEBUG] %3d %s %2d:%02d:%02d %3d > %s", $i, $cttag, $cthr, $ctmin, $ctsec, $cttime,
    $ctdata[$i];
    #printf "[DEBUG] %2d:%02d:%02d %3d %4.2f %4.2f\n", $cthr, $ctmin, $ctsec, $cttime, $cttemp,
    $cthr;
    #if( $cttag eq "T" or $cttag eq "R" ) { printf CTOUT "%3d, %s, %02d:%02d:%02d, %3d, %4.2f\n",
    $i, $cttag, $cthr, $ctmin, $ctsec, $cttime, $colB; }
    if( $cttemp eq "8888.88" ) { $cttemp = ""; }
    if( $cthr eq "888.8" ) { $cthr = ""; }
    ## Bad data is relaced with a copy of the prior valid data entry ##
    if( $cttag eq "R" ) { printf CTOUT "$cttime, $cttemp, $cthr\n"; }
    #if( $i % 24 == 0 ) { print "Hit Enter to Continue!"; $instr = <STDIN>; }
    } # for i
    #print " [DEBUG] CT epoch: $firstcttime, DAQ epoch: $hds, TM epoch: $bts, CT-TM: $cttm, DAQ-
    TM: $startsec\n";
    close( CTOUT );

$EndAnalysisTime = time();
$AnalysisTime = $EndAnalysisTime - $StartAnalysisTime;
$atmin = int($AnalysisTime/60);
$atsec = $AnalysisTime%60;
printf "The Analysis of data for subject %s took %2d minutes and %2d
seconds.\n", $ARGV[0], $atmin, $atsec;

$omax = 0;
if( $outfileoverwrite[10] > 0 ) { $writefilelist .= "$outfilelist[10], "; open( ALLOUT,
">$outfilelist[10]" ) or print "Cannot open file $outfilelist[10]: $!\n"; }
print "Creating Mega File ... \n";
## REDOUT "Time(sec), Red Abs.\n";
## IROUT "Time(sec), IR Abs.\n";
## DIOUT "Time(sec), Red Integrity, IR Integrity\n";
## MAMOUT "Time(sec), Red MAM, IR MAM, MAM Delta\n";
## LROUT "Time(sec), Red max, Red min, Red delta, IR max, IR min, IR delta, R:IR, ln(R:IR)\n";
## VAROUT "Time(sec), Red Var, IR Var\n";
print ALLOUT "Events Data, Red Absorbance, IR Absorbance, Data Integrity, Ratio R:IR, Mean
Absorbance, Variance, Foot Falls, CoreTemp Data, \n";
print ALLOUT "Time(sec), Event Val, Time(sec), Red Abs. (%), Time(sec), IR Abs. (%), Time(sec), Red
Int. (%), IR Int. (%), Time(sec), R/IR, ln(R:IR), Time(sec), Red MAM, IR MAM, d MAM, Time(sec), Red Var, IR
Var, Time(sec), FF Val, Time(sec), Temp(C), HR(BPM)\n";

open( OD_EVT, "<$outfilelist[0]" ) or print "Cannot open file $outfilelist[0]: $!\n";
@od_evt = <OD_EVT>;
close( OD_EVT );
for($i=1; $i<$#od_evt;$i++) {
    chop( $od_evt[$i] );
    ($d1,$ALL_A[$i],$ALL_B[$i],$d2,$d3,$d4,$d5) = split(/,/, $od_evt[$i]);
} # for i (evt)
if( $i > $omax ) { $omax = $i; }

open( OD_RED, "<$outfilelist[1]" ) or print "Cannot open file $outfilelist[1]: $!\n";
@od_red = <OD_RED>;
close( OD_RED );
for($i=1; $i<$#od_red;$i++) {
    chop( $od_red[$i] );
    ($ALL_C[$i],$ALL_D[$i]) = split(/,/, $od_red[$i]);
} # for i (red)
if( $i > $omax ) { $omax = $i; }

open( OD_IR, "<$outfilelist[2]" ) or print "Cannot open file $outfilelist[2]: $!\n";
@od_ir = <OD_IR>;
close( OD_IR );
for($i=1; $i<$#od_ir;$i++) {
    chop( $od_ir[$i] );
    ($ALL_E[$i],$ALL_F[$i]) = split(/,/, $od_ir[$i]);
} # for i (ir)
if( $i > $omax ) { $omax = $i; }

open( OD_DI, "<$outfilelist[5]" ) or print "Cannot open file $outfilelist[5]: $!\n";
@od_di = <OD_DI>;

```

```

close( OD_DI );
for($i=1; $i< $#od_di; $i++) {
  chop( $od_di[$i] );
  ($ALL_G[$i], $ALL_H[$i], $ALL_I[$i]) = split(/./, $od_di[$i]);
} # for i (di)
if( $i > $omax ) { $omax = $i; }

open( OD_RIR, "<$outfilelist[8]" ) or print "Cannot open file $outfilelist[8]: $!\n";
@od_rir = <OD_RIR>;
close( OD_RIR );
for($i=1; $i< $#od_rir; $i++) {
  chop( $od_rir[$i] );
  ($ALL_J[$i], $d1, $d2, $d3, $d4, $d5, $d6, $ALL_K[$i], $ALL_L[$i]) = split(/./, $od_rir[$i]);
} # for i (rir)
if( $i > $omax ) { $omax = $i; }

open( OD_MAM, "<$outfilelist[6]" ) or print "Cannot open file $outfilelist[6]: $!\n";
@od_mam = <OD_MAM>;
close( OD_MAM );
for($i=1; $i< $#od_mam; $i++) {
  chop( $od_mam[$i] );
  ($ALL_M[$i], $ALL_N[$i], $ALL_O[$i], $ALL_P[$i]) = split(/./, $od_mam[$i]);
} # for i (mam)
if( $i > $omax ) { $omax = $i; }

open( OD_VAR, "<$outfilelist[9]" ) or print "Cannot open file $outfilelist[9]: $!\n";
@od_var = <OD_VAR>;
close( OD_VAR );
for($i=1; $i< $#od_var; $i++) {
  chop( $od_var[$i] );
  ($ALL_Q[$i], $ALL_R[$i], $ALL_S[$i]) = split(/./, $od_var[$i]);
} # for i (var)
if( $i > $omax ) { $omax = $i; }

open( OD_FF, "<$outfilelist[3]" ) or print "Cannot open file $outfilelist[3]: $!\n";
@od_ff = <OD_FF>;
close( OD_FF );
for($i=1; $i< $#od_ff; $i++) {
  chop( $od_ff[$i] );
  ($ALL_T[$i], $ALL_U[$i], $d1) = split(/./, $od_ff[$i]);
} # for i (ff)
if( $i > $omax ) { $omax = $i; }

open( OD_CT, "<$outfilelist[4]" ) or print "Cannot open file $outfilelist[4]: $!\n";
@od_ct = <OD_CT>;
close( OD_CT );
for($i=1; $i< $#od_ct; $i++) {
  chop( $od_ct[$i] );
  ($ALL_V[$i], $ALL_W[$i], $ALL_X[$i]) = split(/./, $od_ct[$i]);
} # for i (ct)
if( $i > $omax ) { $omax = $i; }

for( $oi=1; $oi< $omax; $oi++ ) {
  #for( $ltr="A"; $ltr<"W"; $ltr++ ) {
  # print "\$ALL_$ltr[$oi] -> $ALL_$ltr[$oi], ";
  # print "$oi, $ltr\n";
  #) # for $ltr
  print ALLOUT "$ALL_A[$oi], $ALL_B[$oi], $ALL_C[$oi], $ALL_D[$oi], $ALL_E[$oi], ";
  print ALLOUT "$ALL_F[$oi], $ALL_G[$oi], $ALL_H[$oi], $ALL_I[$oi], $ALL_J[$oi], ";
  print ALLOUT "$ALL_K[$oi], $ALL_L[$oi], $ALL_M[$oi], $ALL_N[$oi], $ALL_O[$oi], ";
  print ALLOUT "$ALL_P[$oi], $ALL_Q[$oi], $ALL_R[$oi], $ALL_S[$oi], $ALL_T[$oi], ";
  print ALLOUT "$ALL_U[$oi], $ALL_V[$oi], $ALL_W[$oi], $ALL_X[$oi]\n";
} # for oi

close( ALLOUT );

exit 0;

### -----
sub check_file {
  my $checkfile = @_;

```

```

my $isFile = 1;
foreach $checkfile (@_) {
  #print " <FONT COLOR=\"#0000FF\">File is: ";
  stat($checkfile);
  #print "present\n" if -e _;
  if( -e _ ) {
    #print "present";
    $isFile = 1;
  } else {
    #print "missing";
    $isFile = 0;
  }
  #print " </FONT><BR>\n";
}
return( $isFile );
} # sub check_file()

```

Table 15. Data analysis source files

Data Type	File Source
Event Timestamps	'subjectID A Events.csv'
Foot Fall (FFM) accelerometer peaks	'subjectID A_FFpeaks.csv'
Raw accelerometer data	'subjectID ffmFFM.csv'
RED DC Oximetry data	'subjectID A Red.csv'
IR DC Oximetry data	'subjectID A IR.csv'
Core Temp and Heart Rate (CTHR) data	'subjectID A CTHR.csv'

Initial Analysis and Exclusion of Foot-Fall Artifact

The following analysis was performed on data from the Yale and UConn exercise experiments (Table 15). This data was already time-stamped and filtered using the Winchell's data rejection algorithm. The goals of this initial analysis were:



Figure 24: The footfall monitor is shown resting (unsecured) on the treadmill.

- I. Using Winchell filtered data:
 - a. Correlation analysis between Foot Fall Meter (FFM) data and RED/IR pleth signal
 - i. Standard cross correlation methods
 - ii. Look at the power spectral density of both signals. If the frequency peaks are similar for a given time segment, then the data is well correlated.

- iii. Compare the variance of the FFM signal with the pleth signal. Are the trends similar? Do the peaks line up?
- b. Compare heart rate calculated from pleth waveform to that recorded in the core temp data files.
 - i. Run our peak detection algorithm and compute instantaneous heart rate.
 - ii. Do a sliding 20 second average on the instantaneous heart rate and compare to the heart rate measurements from the core temp files. How similar are they?
- II. Using an alternate data filtering technique (most likely the Savitzky-Golay method) do the same correlation and peak detection analysis.

All analysis was done using Matlab® 7.0. The m-files containing the analysis code are included (Table 16 - Table 18).

Preprocessing:

The data being analyzed had some bugs that needed to be worked out before standard signal processing and statistical techniques could be used on them. The problems detected were:

1. Some of the data was out of order and/or repeated.
2. Repeated data for the same time stamp did not always have the same value. While repeated data is not so uncommon in wirelessly transmitted data, one would expect the values for the same time stamp to be equal. This was not always the case (see Figure 25).
3. The sample interval was not consistent. For the pleth and foot fall meter data, there were gaps in inconsistent spacing of the data time stamps (see Figure 26).

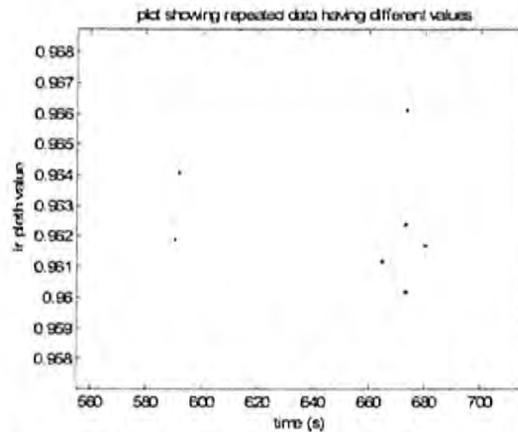


Figure 25: Plot showing repeated data from the IR pleth sensor. The y-axis is the IR pleth raw value, the x-axis is the corresponding time stamp for that data point. Repeated data from ~580 and ~675 seconds have different values, whereas repeated data from ~663 and ~680 seconds has the same value.

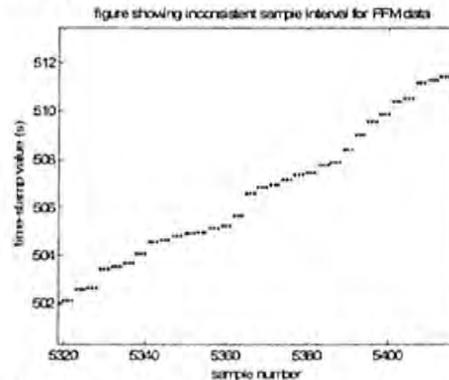


Figure 26: plot showing inconsistent spacing of data points in time in FFM peak data. The y-axis is the value of the time stamp in seconds. The x-axis is the sample number.

To correct these problems, Dartmouth collaborators wrote an algorithm that:

1. Sorts the data with respect to the time stamp.
2. Removes repeated data. If the data of a repeated sample time had different values, the last element of that array was chosen.
3. Re-sampled the data at 19.1 Hz (corresponding to the pleth sensor which collected 191 samples in 10 seconds). Re-sampling was performed using linear interpolation.

This algorithm was performed on the pleth data and the foot fall meter peaks data.

Correlation analysis between Foot Fall Meter (FFM) data and red/IR pleth signal

A major goal of this initial analysis was to determine if the small peaks in the pleth data were a result of the heart rate or simply a motion artifact caused by the mask shaking as the participants moved and walked on the treadmill. The Matlab scripts `corrFFM_PPG_YALE.m` and `corrFFM_PPG_UCONN.m` look for correlation in the IR and RED pleth data and the FFM data using standard statistical methods, visually, and using the power spectral density.

Table 16. Variance Analysis Matlab file

```

% varianceAnalysis
% analyze variance of pleth and FFM for yale or uconn data

% set either yale or uconn flag to 1 to analyze that data set
YALE_FLAG = 0;
UCONN_FLAG = 1;

if YALE_FLAG == 1
    disp('the following analysis is for YALE data');
    disp('if you want to analyze UCONN data instead, change the variable UCONN_FLAG to 1 and
YALE_FLAG to 0 and rerun this script');
    % load data from all subjects
    if -exist('YALE')
        chkFile = dir('YALE_DATA.mat');
        if (chkFile.bytes > 0)
            disp('Loading YALE data file...');
            load YALE_DATA.mat;
        else
            saveYaleData % reads data from cd and stores it into YALE_DATA.mat
        end
    end
    DATA = YALE;
elseif UCONN_FLAG == 1
    disp('the following analysis is for UCONN data');
    disp('if you want to analyze YALE data instead, change the variable YALE_FLAG to 1 and
UCONN_FLAG to 0 and rerun this script');
    % load data from all subjects
    if -exist('UCONN')
        chkFile = dir('UCONN_DATA.mat');
        if (chkFile.bytes > 0)
            disp('Loading UCONN data file...');
            load UCONN_DATA.mat;
        else
            saveUConnData % reads data from cd and stores it into UCONN_DATA.mat
        end
    end
    DATA = UCONN;
end

% DATA should have the following fields
% startTM: 2
%         stopTM: 4
%         ffmTime: [14685x1 double]
%         ffm: [14685x1 double]
%         ffmFlag: 1
%         redTime: [34441x1 double]
%         red: [34441x1 double]
%         redFlag: 1
%         irTime: [34433x1 double]
%         ir: [34433x1 double]
%         irFlag: 1
%         ctTime: [164x1 double]
%         ct: [164x1 double]
%         hrTime: [164x1 double]
%         hr: [164x1 double]
%         cthrFlag: 1
%         events: {28x1 cell}
%         subjectID: '018568'
%         eventsFlag: 1
%         accelComputerTS: [309155x1 double]
%         accelFFM_PTS: [309155x1 double]
%         accel: [308534x1 double]
%         accelEvent: [309155x1 double]
%         accelFlag: 1
%         ffmTimeSorted: [14685x1 double]
%         ffmSorted: [14685x1 double]
%         resampledFfmTime: [1x27916 double]
%         resampledFfm: [1x27916 double]
%         redTimeSorted: [34433x1 double]

```

```

%      redSorted: [34433x1 double]
%      resampledRedTime: [1x36132 double]
%      resampledRed: [1x36132 double]
%      irTimeSorted: [34304x1 double]
%      irSorted: [34304x1 double]
%      resampledIrTime: [1x36132 double]
%      resampledIr: [1x36132 double]
%      accelTime: [1x308534 double]
%      redVar: [1x1899 double]
%      timeRedVar: [1x1899 double]
%      irVar: [1x1899 double]
%      timeIrVar: [1x1899 double]

% compute variance using a 2 second sliding window that increments by 1
% second for each step. Then plot the variance of red, ir, and ffm on same
% figure.

for i = 1:length(DATA)

    figure;
    set(gcf, 'name', ['variance for subject ' num2str(i) ' + ' DATA{i}.subjectID], 'numbertitle',
    'off');

    % variance of red pleth
    if DATA{i}.redFlag == 1
        if ~isfield(DATA{i}, 'redVar') % check to see if variance has already been calculated and
saved in structure
            t = DATA{i}.resampledRedTime;
            red = DATA{i}.resampledRed;
            count = 1;
            startIndex = 1; rightIndex = 1;
            while rightIndex < (length(t)-19*2)
                leftIndex = startIndex;
                rightIndex = startIndex + 19*2;
                redVar(count) = var(red(leftIndex:rightIndex));
                timeRedVar(count) = t(rightIndex);
                startIndex = startIndex + 19;
                count = count + 1;
            end % while
            DATA{i}.redVar = redVar;
            DATA{i}.timeRedVar = timeRedVar;
            clear timeRedVar redVar;
        end
        hold on;
        subplot(2,1,1);
        plot(DATA{i}.timeRedVar, DATA{i}.redVar/max(DATA{i}.redVar), 'b--');
        smoothedData = smooth(DATA{i}.redVar/max(DATA{i}.redVar), 11);
        hold on; plot(DATA{i}.timeRedVar, smoothedData, 'b', 'linewidth', 2);
    end % end if redflag

    if DATA{i}.irFlag == 1
        if ~isfield(DATA{i}, 'irVar')
            t = DATA{i}.resampledIrTime;
            ir = DATA{i}.resampledIr;
            count = 1;
            startIndex = 1; rightIndex = 1;
            while rightIndex < (length(t)-19*2)
                leftIndex = startIndex;
                rightIndex = startIndex + 19*2;
                irVar(count) = var(ir(leftIndex:rightIndex));
                timeIrVar(count) = t(rightIndex);
                startIndex = startIndex + 19;
                count = count + 1;
            end % while
            DATA{i}.irVar = irVar;
            DATA{i}.timeIrVar = timeIrVar;
            clear timeIrVar irVar;
        end
        hold on;
        subplot(2,1,1);

```

```

plot(DATA{i}.timeIrVar, DATA{i}.irVar/max(DATA{i}.irVar), 'r--');
smoothedData = smooth(DATA{i}.irVar/max(DATA{i}.irVar), 11);
hold on; plot(DATA{i}.timeIrVar, smoothedData, 'r', 'linewidth', 2);
ylim([0 mean(DATA{i}.irVar/max(DATA{i}.irVar))]);
ylabel('Pleth Variance');
legend('RED var', 'smoothed RED var', 'IR var', 'smoothed IR var');

end % end if irflag

if DATA{i}.ffmFlag == 1
if ~isfield(DATA{i}, 'ffmVar')
t = DATA{i}.resampledFfmTime;
ffm = DATA{i}.resampledFfm;
count = 1;
startIndex = 1; rightIndex = 1;
while rightIndex < (length(t)-19*2)
leftIndex = startIndex;
rightIndex = startIndex + 19*2;
ffmVar(count) = var(ffm(leftIndex:rightIndex));
timeFfmVar(count) = t(rightIndex);
startIndex = startIndex + 19;
count = count + 1;
end % while
DATA{i}.ffmVar = ffmVar;
DATA{i}.timeFfmVar = timeFfmVar;
clear timeFfmVar ffmVar;
end
hold on;
subplot(2,1,1);
xlim([0 max(DATA{i}.timeFfmVar)]);
subplot(2,1,2);
plot(DATA{i}.timeFfmVar, DATA{i}.ffmVar/max(DATA{i}.ffmVar), 'g--');
smoothedData = smooth(DATA{i}.ffmVar/max(DATA{i}.ffmVar), 11);
hold on; plot(DATA{i}.timeFfmVar, smoothedData, 'g', 'linewidth', 2);
xlim([0 max(DATA{i}.timeFfmVar)]);
xlabel('time (s)'); ylabel('FFM variance');
legend('FFM var', 'smoothed FFM var');
end % end if ffmflag

end % end for i

% save variance data for later use
if YALE_FLAG == 1
YALE = DATA;
save YALE_DATA YALE;
end
if UCONN_FLAG == 1
UCONN = DATA;
save UCONN_DATA UCONN;
end

```

Table 17. CorrFFM_PGP_Yale Analysis Matlab file

```

% corrFFM_PPG_YALE
% correlate footfall peaks and ppg data from YALE treadmill experiments

% load data from all subjects
if ~exist('YALE')
chkFile = dir('YALE_DATA.mat');
if (chkFile.bytes > 0)
disp('Loading data file...');
load YALE_DATA.mat;
else
saveYaleData % reads data from cd and stores it into YALE_DATA.mat
end
end

for i = 1: length(YALE)
if YALE{i}.ffmFlag == 0

```

```

disp(['no ffm peak data available... not performing correlation caclulations for subject
' num2str(YALE{i}.subjectID)]);
else
% grab data from the large 'YALE' data structure
ffmTime = YALE{i}.resampledFfmTime;
ffm = YALE{i}.resampledFfm; % these are the peaks of the ffm
redTime = YALE{i}.resampledRedTime;
red = YALE{i}.resampledRed;
irTime = YALE{i}.resampledIrTime;
ir = YALE{i}.resampledIr;

% find indices of ffm, red, and ir that have timestamps between 0 and
% 300 seconds
ffmInd = find(ffmTime >=0 & ffmTime <= 300);
redInd = find(redTime >=0 & redTime <= 300);
irInd = find(irTime >=0 & irTime <= 300);

% first do a visual inspection of foot fall meter and pleth absorbance
% for this time window
disp(['plotting footfall peaks and red/ir absorbance for subject ' num2str(i), ': ',
YALE{i}.subjectID]);
figure;
stem(ffmTime(ffmInd), ffm(ffmInd));
hold on;
plot(redTime(redInd), red(redInd), 'r', irTime(irInd), ir(irInd), 'g');
ylim([0.8 1.03]);
set(gcf, 'name', ['FFM and pleth raw data for Subject ' YALE{i}.subjectID ], ...
'numbertitle', 'off');

% plot power spectral density (PSD) of ffm, red/ir
Fs = 19.1; % sample frequency
figure;
subplot(3,1,1); periodogram(red, [], 'onesided', length(red), Fs); ylabel('red power');
subplot(3,1,2); periodogram(ir, [], 'onesided', length(ir), Fs); ylabel('ir power');
subplot(3,1,3); periodogram(ffm, [], 'onesided', length(ffm), Fs); ylabel('ffm power');
set(gcf, 'name', ['Power Spectral Density - subject', YALE{i}.subjectID], ...
'numbertitle', 'off');

minSize = min([length(ffmInd), length(redInd), length(irInd)]); % minsize is used to truncate
all vectors to the same length
[r_red_ffm, p_red_ffm] = corrcoef(red(redInd(1:minSize)), ffm(ffmInd(1:minSize)));
[r_ir_ffm, p_ir_ffm] = corrcoef(ir(irInd(1:minSize)), ffm(ffmInd(1:minSize)));
[r_red_ir, p_red_ir] = corrcoef(red(redInd(1:minSize)), ir(irInd(1:minSize)));

corrcoefs.r_red_ffm(1) = r_red_ffm(2,1);
corrcoefs.r_ir_ffm(1) = r_ir_ffm(2,1);
corrcoefs.r_red_ir(1) = r_red_ir(2,1);
zoom on;
disp('press any key to continue...');
pause
end
end
disp('Correlation coefficients are in the 'corcoefs' data structure');

```

Table 18. CorrFFM_PGP_UConn Analysis Matlab file

```

% correlateFootFallWithPPG
% correlate footfall peaks and ppg data from uconn treadmill experiments

% load data from all subjects
if -exist('UCONN')
chkFile = dir('UCONN_DATA.mat');
if (chkFile.bytes > 0)
disp('Loading data file...');
load UCONN_DATA.mat;
else
saveUConnData % reads data from cd and stores it into UCONN_DATA.mat
end
end
end
for i = 1:length(UCONN)

```

```

% grab data from the large 'UConn' data structure
ffmTime = UCONN{i}.resampledFfmTime;
ffm = UCONN{i}.resampledFfm; % these are the peaks of the ffm
redTime = UCONN{i}.resampledRedTime;
red = UCONN{i}.resampledRed;
irTime = UCONN{i}.resampledIrTime;
ir = UCONN{i}.resampledIr;

% find indices of ffm, red, and ir that have timestamps between 0 and
% 300 seconds
ffmInd = find(ffmTime >=0 & ffmTime <= 300);
redInd = find(redTime >=0 & redTime <= 300);
irInd = find(irTime >=0 & irTime <= 300);

% first do a visual inspection of foot fall meter and pleth absorbance
% for this time window
disp(['plotting footfall peaks and red/ir absorbance for subject ' num2str(i)]);
figure;
set(gcf, 'name', ['FFM and pleth raw data for Subject ' UCONN{i}.subjectID ], 'numbertitle',
'off');
stem(ffmTime(ffmInd), ffm(ffmInd));
hold on;
plot(redTime(redInd), red(redInd), 'r', irTime(irInd), ir(irInd), 'g');
ylim([0.8 1.03]);
title(['FFM and pleth raw data for Subject ' UCONN{i}.subjectID ]);

% plot PSD of ffm, red/ir
Fs = 19.1; % sample frequency
figure;
set(gcf, 'name', ['Power Spectral Density for Subject ' UCONN{i}.subjectID ], 'numbertitle',
'off');
subplot(3,1,1); periodogram((red-mean(red)), [], 'onesided', length(red), Fs); ylabel('red
power');
subplot(3,1,2); periodogram((ir-mean(ir)), [], 'onesided', length(ir), Fs); ylabel('ir
power');
subplot(3,1,3); periodogram(ffm, [], 'onesided', length(ffm), Fs); ylabel('ffm power');

minSize = min([length(ffmInd), length(redInd), length(irInd)]); % minsize is used to truncate
all vectors to the same length
[r_red_ffm, p_red_ffm] = corrcoef(red(redInd(1:minSize)), ffm(ffmInd(1:minSize)));
[r_ir_ffm, p_ir_ffm] = corrcoef(ir(irInd(1:minSize)), ffm(ffmInd(1:minSize)));
[r_red_ir, p_red_ir] = corrcoef(red(redInd(1:minSize)), ir(irInd(1:minSize)));

corrcoefs.r_red_ffm(i) = r_red_ffm(2,1);
corrcoefs.r_ir_ffm(i) = r_ir_ffm(2,1);
corrcoefs.r_red_ir(i) = r_red_ir(2,1);
disp('press any key to continue...');
pause
end

disp('Correlation coefficients are in the 'corcoefs' data structure');

```

Statistical methods

Using the standard method to calculate the correlation coefficient r (Equation 5), The correlation coefficient was calculated between the RED signal and the FFM signal; the IR signal and the FFM signal; and the RED and IR signals for time = 0 to 300 seconds (where time = 0 is when the subject started walking on the treadmill). These results are summarized in the tables below.

$$r(x, y) = \frac{Cov(x, y)}{\sqrt{Cov(x, x) \times Cov(y, y)}} \quad \text{Equation 5}$$

Table 19. Treadmill Correlation coefficient

UCONN SubjectID	Correlation Coefficients		
	red-FFM	ir-FFM	red-ir
'018568'	0.078	0.097	0.794
'024505'	0.048	0.047	0.838
'024511'	0.045	0.069	0.854
'024512'	0.121	0.069	0.906
'024513'	-0.050	-0.082	0.838
'024514'	0.017	0.026	-0.120
'024517'	0.053	0.036	0.893
'024518'	0.108	0.082	0.833
'024519'	-0.068	-0.033	0.730
'024520'	0.104	0.110	0.971
average	0.046	0.042	0.754
stdev	0.064	0.060	0.314

Table 20. STP Correlation coefficient

YALE SubjectID	Correlation Coefficients		
	red-FFM	ir-FFM	red-ir
'018567'	-0.014	-0.039	0.684
'018569'	0.039	0.030	0.995
'018570'	-0.028	-0.040	0.871
'018571'	0.047	0.050	0.980
'018572'	NaN	NaN	NaN
'018573'	-0.026	-0.011	0.953
'018574'	0.028	0.028	0.850
'018575'	-0.043	-0.051	0.838
'018576'	-0.038	-0.047	0.961
'018577'	-0.014	0.006	0.794
'018578'	-0.022	-0.034	0.908
'018579'	0.014	0.017	-0.003
'018580'	-0.046	-0.029	0.924
'018581'	0.019	0.032	0.918
'018582'	-0.015	-0.011	0.142
'018583'	0.039	0.034	0.297
'018584'	-0.028	-0.009	0.777
'018585'	0.008	0.014	0.666
'018586'	0.035	0.030	0.963
'024501'	0.015	0.023	0.432
'024503'	-0.026	-0.034	0.106
'024504'	0.035	0.044	0.956
'024506'	-0.006	-0.026	0.501
'024507'	0.004	-0.032	0.330
'024508'	-0.055	-0.037	0.708
'024510'	NaN	NaN	NaN
average	-0.003	-0.004	0.690
stdev	0.031	0.033	0.311

The RED and IR signals had the highest correlation on average that is not surprising given that the sensors were co-located and measure very similar signals. Neither the RED nor IR signals correlated with the FFM peaks signal. This would mean that the peaks in the RED and IR signals are not caused by footfalls given that the FFM peaks signal is an accurate measure of steps. However, on visual inspection and frequency analysis of the FFM peaks data, it did not seem likely that the FFM peaks data is actually the footfalls of the subjects. This is explained further in the following section.

Visual Inspection

The correlation scripts also plot the red and IR absorbance along with the FFM peaks. If the peaks in the pleth were caused by foot strikes, we would expect them to line up visually. This is not the case. See examples in Figure 27 - Figure 29.

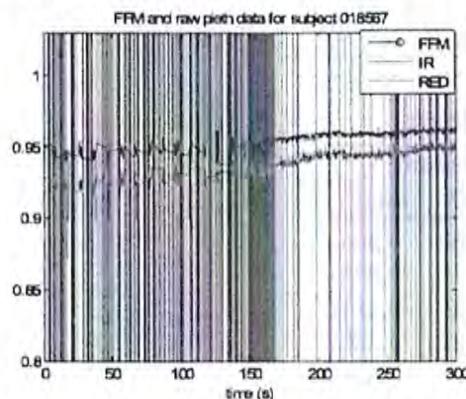


Figure 27: Plot showing red absorbance (green line), IR absorbance (red line), and FFM peaks. The peaks of the plethysmogram do not seem to match up to the FFM peaks when compared visually.

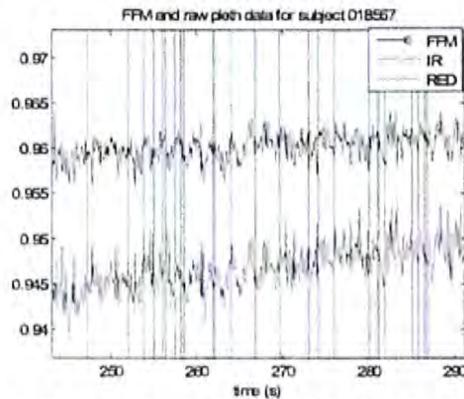


Figure 28: Another example of red and IR absorbance plotted together with the FFM peaks. The peaks of the pleth do not correlate with the FFM peaks.

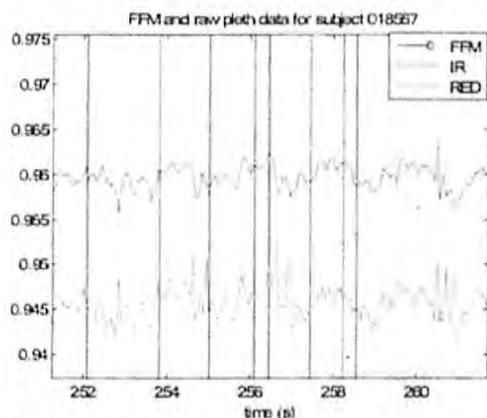


Figure 29: Example from figure 4 zoomed in further. Note that the peaks from the pleth and FFM peaks do not line up.

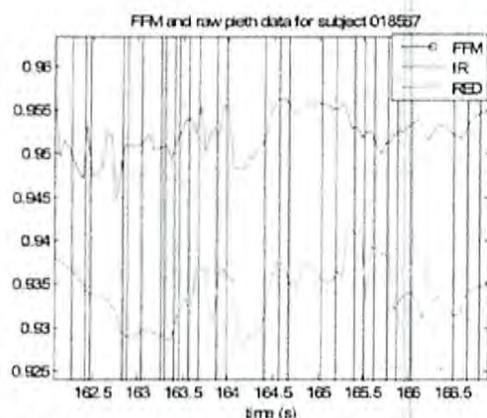


Figure 30: Another example of pleth data and FFM peaks. Note the inconsistent and rapid foot fall frequency (e.g. between 163 and 164 seconds). Also note the absence of a recognizable pulse signal.

Raw Accelerometer Data:

The following figure shows an example of the raw accelerometer data approximately synced with the red pleth data. Here there are visible pulses that do not correspond to spikes in the accelerometer data.

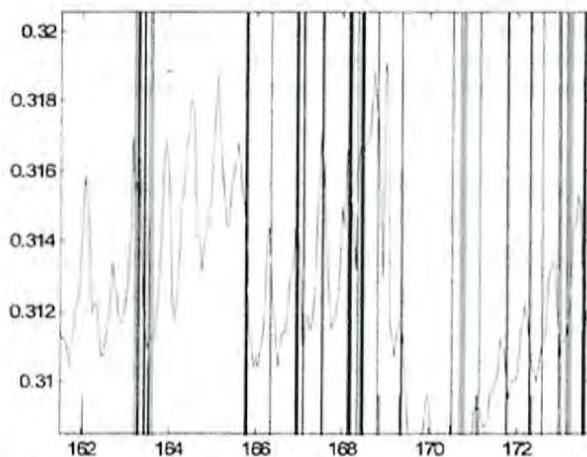


Figure 31: Red pleth data in red, raw accelerometer data in blue. In this snap shot, there is a recognizable pulse in the pleth data. Occasionally, the pulse lines up with the accelerometer data, but not consistently. This observation is inconclusive as the syncing of the data within times of less than 0.1 seconds is questionable.

Problems syncing the raw accelerometer data:

The raw accelerometer data was tagged with event codes (0-7) that were described in a text file. The indices corresponding to the beginning and end of treadmill activity were found and data between these indices were plotted. The figure below shows an example of this. The data file event index incorrectly reports the event number, and thus it appears as if the treadmill

activity only lasted for 4 minutes (the red region). One would expect the activity of the accelerometer to increase during treadmill activity, but according to the event tagged data, this was not the case. However, a reexamination of redundant data sources, including the time stamps in the 018586.txt events log file itself, reveals this error and allows us to correctly interpret that the blue region of the data represents the actual time spent by the subject on the treadmill. Thus, to sync the data with the pleth as in Figure 7, either the index where it looked like there was an abrupt change in activity or the time as determined from the alternative data sources is used to set the time for this index to equal "0" to sync with the start of treadmill activity in the other data.

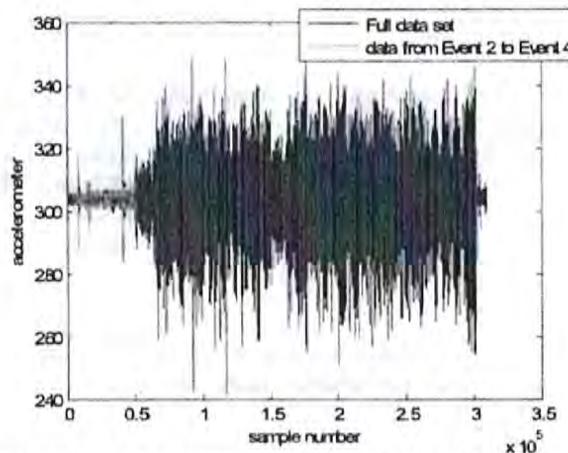


Figure 32: Raw accelerometer data from Uconn subject 018568. The red data shows accelerometer data reported as from Event 2: "tm" to Event 4:"ext" indicating the start and end of treadmill exercise. A reexamination of the redundant data however, correctly assigns the blue region of data to the treadmill exercise.

Frequency Analysis

Finally, the Matlab scripts plot the Power Spectral Density (PSD) for the red/IR pleth signals and the FFM peak signals for the first 300 seconds of treadmill activity. Figure 33 below shows an example of this. The red and IR signals have a similar PSD that we would expect. However, we do not see a strong peak corresponding to a heart rate for this period. Although there are segments in the pleth signal where there is a discernable heart rate, the PSD shows that it is not consistent enough to be used for heart rate or SpO₂ calculations (an accurate pulse height is needed for this). The PSD for the FFM peaks is a flat line that is the same as white noise. If the FFM peaks were foot falls and caused the oscillations in the pleth signal, then the PSDs would look similar, but they do not.

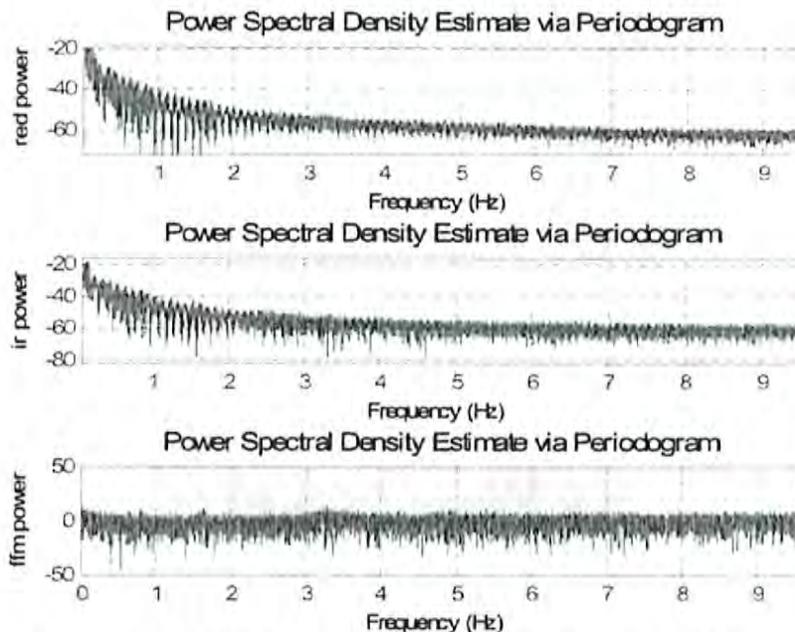


Figure 33: Power spectral density (PSD) analysis of red/IR pleth signals and FFM peak signals for the first 300 seconds of treadmill data in Uconn Subject018568. The red and IR PSDs are very similar. However, there is no distinct heart rate peak between 1 and 2.5 Hz as expected for a subject undergoing exercise. The FFM peak data has a PSD that resembles white noise. If the oscillations in the pleth data were caused by the FFM peaks, the PSDs would be similar but they are not.

Raw accelerometer data frequency analysis:

PSDs of the raw accelerometer data were also plotted (Figure 35 and Figure 36). The main peaks were around 20 Hz that could not result from a step rate. These peaks could have resulted from interference with the pleth sensor, which has a sample frequency of around 20 Hz, or it could be a frequency generated by the treadmill itself. We would expect to see a strong peak between 2 and 3.5 Hz (a normal step rate) but we do not see this. There are small peaks at 1.7, 2.5, 3.3, 4.2, and 4.9 Hz. However from examining the peaks, it is impossible to tell which peak corresponds to the actual step rate. Thus, the raw accelerometer data should not be considered an accurate measurement of footfalls.

In this case it become important to consider the method of data collection. In the case of the STP protocol at Yale, the FFM sensor unit was placed on, but not secured to, the piece of equipment in use. This was necessary, as the relative short duration for the subject to be on each piece of equipment and then the need to move the sensor to the next piece of equipment while the subject was also moving from one piece of equipment to the next required the ability of the researchers to pick up and move the equipment as needed. In raw data, this is seen in Figure 34 the acceleration data sweeping well above the typical footfall and other movement activity envelope (300 ± 50 on the y-axis).

The unsecured nature of the sensor is important because it lowers the dampening coefficient that would be applied to a signal. In this case, each time the subject takes a step on the treadmill, the treadmill “bounces” from the associated force. This bounce also causes the FFM sensor in turn to bounce, as it is free to move in relation to the treadmill. Both of these “bounces”

eventually dampen in much the way a dropped ball bounces several times, with decreasing height, until eventually coming to rest. Further complicating the analysis, the treadmill (or whichever piece of equipment is in use at the time) and the FFM sensor each have different dampening coefficients, and that the bounce associated with a subject's step may not subside before the next step causes the system to bounce again. Additional signal complications will also result from the placement of the FFM sensor, which was typically to one side of the equipment, and would thus receive a stronger bounce from, in the case of the treadmill, a subject's left foot step than a subject's right foot step.

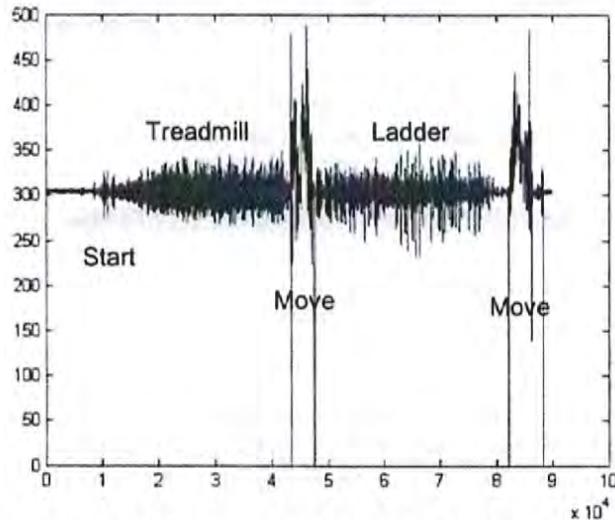


Figure 34: Raw Accelerometer data (FFM sensor) showing footfall data (y-axis: 300 ± 50) and the macrochanges (x-axis: 4.3×10^4 – 4.8×10^4 , etc.) that accompany moving the sensor from one experiment apparatus to another (treadmill to ladder climb).

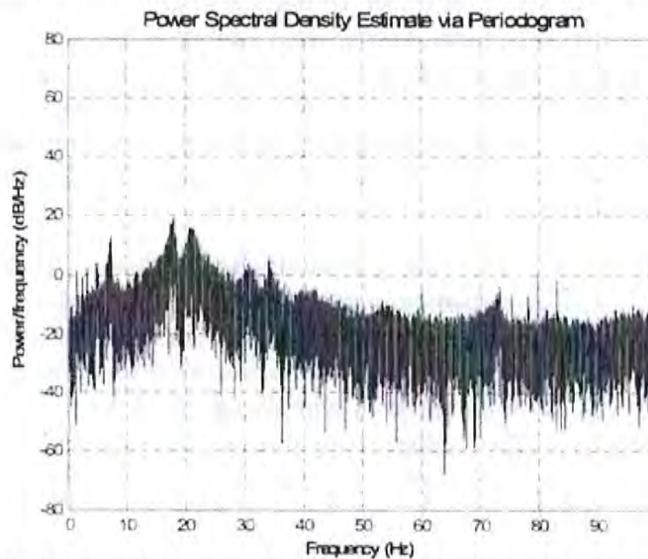


Figure 35: Power spectral density from raw accelerometer data from UConn subject 018568. The biggest peaks occur around 18 and 21 Hz. This cannot be the result of foot falls.

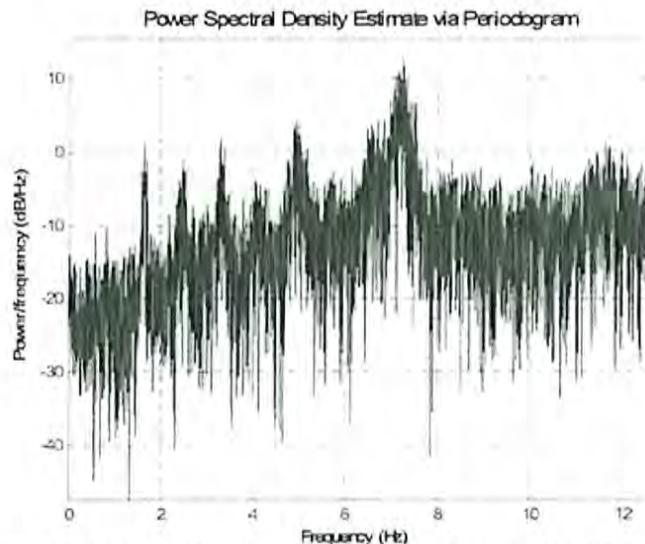


Figure 36: Zoomed in PSD for raw accelerometer data from UConn subject 051868 for the first 300 seconds of treadmill activity. We would expect to see a strong peak around 2-3 Hz (a normal step rate) and harmonics. Instead we see a strong peak at 7.25 Hz and smaller peaks at 1.7, 2.5, 3.3, 4.2, and 4.9 Hz. From examining the plot, it is impossible to tell what the actual foot fall rate is (excluding the peak at 7.25 Hz as it is not feasible to step that fast). This indicates that the raw accelerometer data is not a good measure of foot falls.

It was beyond the planned scope of this research to determine the actual damping factor of each piece of equipment (as this would also vary with each subject, and the load, or mass, that the subject was carrying with each activity). The purpose of the footfall monitor was to discriminate that the pulses observed in the DC Oximetry data were not solely or even by the majority a result of motion artifact of the subject's activity. To this goal, we believe that the data holds this to be true.

Variance Analysis

The Matlab script "varianceAnalysis.m" computes the variance in a two second sliding window that increments by one second every step. Variance is calculated using the standard formula:

$$\sigma^2 = \frac{\sum_{i=1}^N (x_i - \mu)^2}{N} \quad \text{Equation 6}$$

The variance was calculated this way for the red/IR pleth signals and the FFM peak signals from the UConn and Yale experiments and plotted for each subject (see Figure 12 for an example). To make trend viewing easier, this value was smoothed using a simple moving average and plotted on top of the original data. In this initial analysis, there were no trends quantified. This will be investigated further in future analysis.

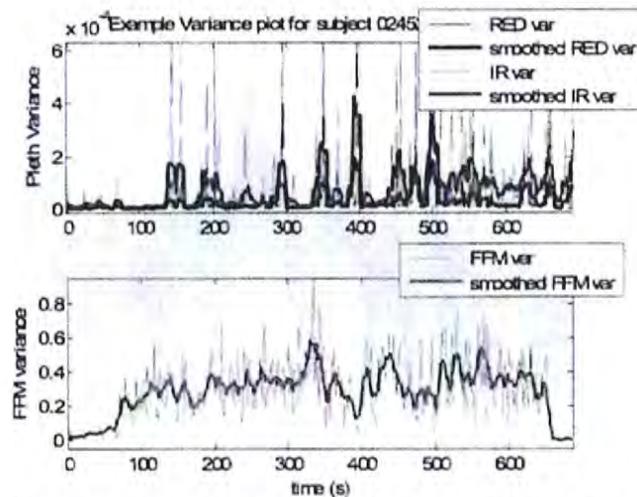


Figure 37: Example of Variance of red/IR pleth data (top) and FFM peak data (bottom).

Results

1. The red and IR pleth signals do not correlate with the FFM peak data.
2. The red and IR pleth signals do correlate with each other.
3. The FFM peak data is most likely not the actual foot strike and so should not be used for comparison to the pleth data.
4. The peaks in the pleth data are not consistently due to a heart rate and can not be used for heart rate or SpO₂ calculations.
5. The raw accelerometer data has inconclusive spectral peaks and can not be used to determine foot fall rate.
6. Variance of the pleth data was plotted for both the UConn and Yale data in a two second sliding window and will be analyzed further in future work.

Further analysis of accelerometer data and pleth data

The following plots are from UCONN subject 018568

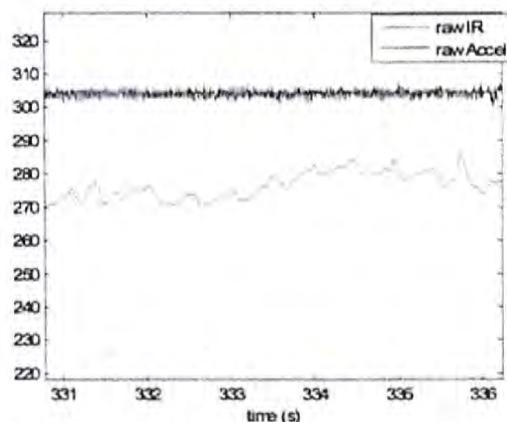


Figure 38: UConn Subject 018568 IR vs. Accelerometer Data

Raw pleth waveform (red) and raw accelerometer data before start of treadmill. Pleth data peaks will generally correlate with heart beats of the subject. Plot shows 12 – 13 beats in 6

seconds ~ 120 bmp. That is a high HR for just standing there, but not unheard of in fire fighters as they psych up for the upcoming activity.

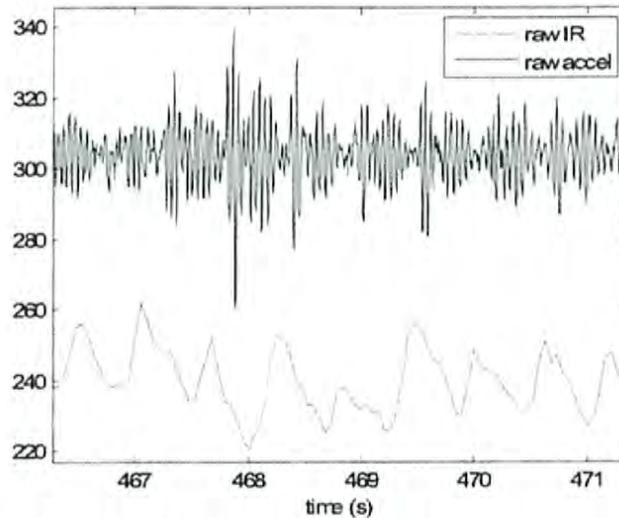


Figure 39: Potential Synchronization of Step and Pleth data.

One case to be made for the potential dependent relationship between oximetry data and motion artifact (footfalls) is demonstrated in Figure 39 where we can see that there are 9 “steps” (blue) and 9 “beats” (red) in this 5.5-second window. This data corresponds to a signal frequency of 1.6 Hz (96 BPM heart rate / 96 steps per minute) that corresponds to a main frequency band in the power spectral density of both signals. In this example, a conclusion that could be drawn is that the subject is either stepping in sync with his heartbeats or these are not heartbeats. However, it is also important to note that the shape of the Oximetry data (in this case we are looking at the AC component) is the classic shape for a plesmogram (Figure 1) and is a reasonable physiologic value, and would thus lead to high confidence that this data is in fact the AC component of oximetry. Thus more scrutiny to the meaning of and interpretation of the footfall monitor data is warranted.

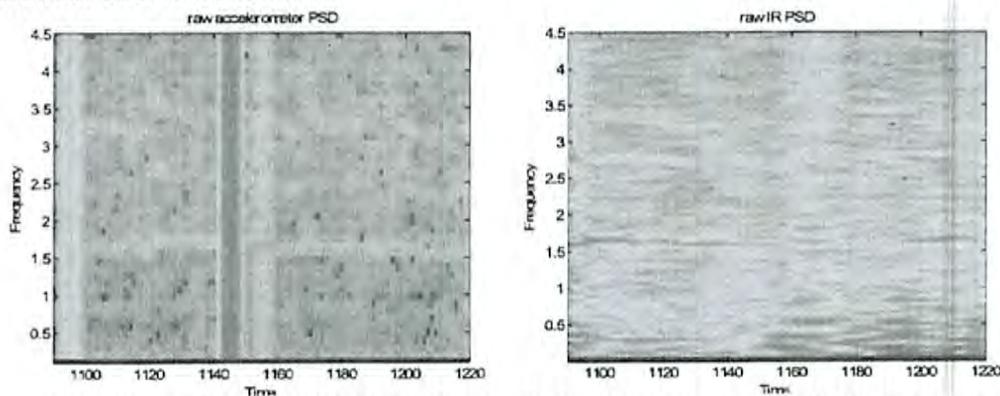


Figure 40: Power Spectral Density (PSD) for Accelerometer data (left) and IR DC Oximetry data (right).

Plot on left shows the power spectral density (PSD) of the raw accelerometer data. The plot on the right shows the PSD of the raw IR pleth for approximately the same time period when the

subject was on the treadmill. They both have a suspiciously similar frequency band around 1.6 Hz (about 100 beats per minute if it were a heart rate or steps per minute if it corresponds to walking). In the raw IR data, the next frequency band is around 2.75 Hz (about 165 bpm if it were a heart rate). This is most likely the heart rate but it is less strong than the frequency band relating to the footsteps

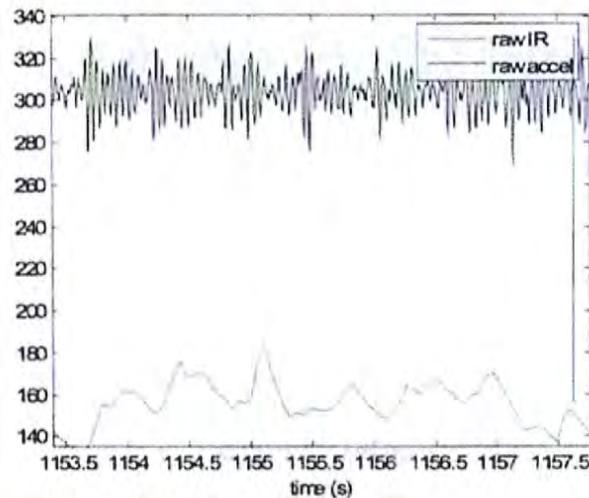


Figure 41: Raw accelerometer data and raw IR.

Raw accelerometer data and raw IR data segment from the window used to calculate the PSD. Here the subject is still on the treadmill. There are about 7 “beats” and 7 “steps” in this 4.3-second window. Once again this corresponds to the 1.65 Hz frequency line (about 100 cycles per minute). It seems possible that the actual heartbeats could be obscured by the footsteps. 100 steps per minute is a reasonable pace where as 100 beats per minute during heavy exercise is not reasonable.

VO₂ Max

Table 21. VO₂ max measurements for subjects. Estimated VO₂ max is not an accurate measure of true VO₂ max.

subject #	incline %	speed (mph)	VO2max (ml/kg/min)	Estimated VO2max	Real - Estimated
505	15	3.5	43.1	38.2	4.9
509	17	3.5	42.5	41.6	0.9
511	15	3.5	36.5	38.2	-1.7
512	17	3.5	39.8	41.6	-1.8
513	17	3.5	40.9	41.6	-0.7
514	15	3.5	37.0	38.2	-1.2
517	15	3.5	28.7	38.2	-9.5
518	15	3.5		38.2	Meas. Vo2max not attained
519	17	3.5	41.5	41.6	-0.1
520	17	3.5	41.5	41.6	-0.1
568	19	3.5	42.6	45.0	-2.4

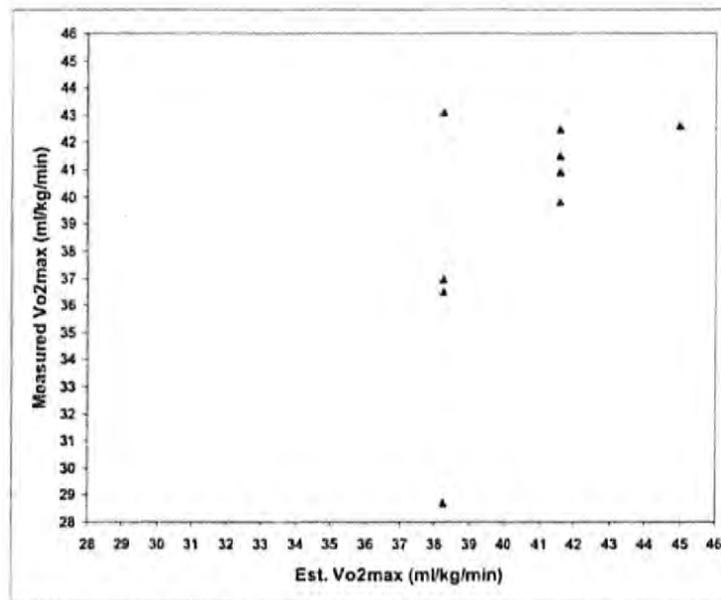
Figure 42: Measured vs. Estimated VO₂ max values for subject population.

Table 22. Times (in sec) to reach Breach and Pull activity and to Complete STP.

STP 1 (PPE and Heat)				STP 2 (no PPE and Heat)			
ID	Time to B&P	Total Time	Duration B&P	ID	Time to B&P	Total Time	Duration B&P
018572		373	0	024507		661	0
018578	1196	1318	122	018585	860	975	115
018579	854	964	110	018582	913	1081	168
018571		944	0	018581		440	0
018574		348	0	018584		633	0
018575		576	0	018580		795	0
018570		819	0	024510	945	1058	113
018576		880	0	024504	926	1132	206
018569	928	1058	130	024506	977	1123	146
018573		772	0	024501	964	1022	58
018586	829	889	60	024508	845	938	93
018577		311	0	024503		249	0
018567	880	913	33				
AVE	937.40	781.92	35.00	AVE	918.57	842.25	74.92
StDev	149.13	300.34	52.16	StDev	50.18	288.89	75.46

One of the objectives of these studies was to develop protocols for evaluation of UCHS physiology in FFs. Despite developments of training standards and new technology, line-of-duty deaths in FFs have not decreased appreciably in recent years. When UCHS physiology in FFs is better understood, the information may be used to guide work-rest cycles and to identify appropriate clinical parameters that should be monitored during work or rehabilitation. Ultimately, better understanding of this physiology may help reduce line-of-duty deaths.

Obtaining accurate, continuous Tc as a marker of UCHS was of prime importance. Tc values were measured using ingestible capsules in all studies reported here. Measuring Tc using such telemetry capsules has been validated during rest and exercise, and under various environmental conditions.⁴¹ The data filtration techniques developed for this work revealed clear trends in Tc,

and were similar to methods used by others.^{42,47} In some subjects, there were marked fluctuations in the raw T_c data. These were blunted when the interval between ingestion time and exercise was increased (as in the second STP trial). Other authors have also observed rapid changes in core temperatures,^{47,48} suggesting that intermittent rectal temperatures may miss rapid, transient elevations in T_c (potentially underestimating T_{max}). In addition, using ingestible capsules facilitated greater freedom of movement during strenuous work when compared with rectal probes. This allowed the study protocols to better approximate the job tasks associated with structural firefighting.

One of the derived parameters used to describe study outcomes was HS. HS values indicate the degree of heat stress experienced by subjects because they consider an individual's body mass as well as the change in core temperature. Heavy workloads together with high temperatures have been shown to result in HS rates that greatly exceed what would be expected if the two factors were simply additive,^{17,49} suggesting that HS may be a particularly good marker of UCHS in FFs.

Both T_c values and calculated HS levels have been used to set limits for workers in elevated temperatures (see Table 7);^{17,48} In general, HS values correlate well with the time in hot environments that is tolerated by workers.^{7,50} Importantly however, the standards mentioned above pertain to protracted exposure to heat, e.g. workers in industrial settings involving 8-hour shifts in smelting facilities. FFs that perform short but intense work cycles in heat may not develop the thermal tolerance of workers who acclimate to their hot environments over weeks or years. The standards were designed for and assume a heat-acclimated work force, and therefore may not be stringent enough to protect FFs.

The first experimental model (STP) simulates the initial phases of an interior fire attack, allowing study of the physiology of heat stress in experienced FFs using sensor technology. Of typical tasks associated with the fire rescue services, interior structural firefighting while wearing SCBA demands the most energy of FFs.⁵¹ Environmental temperatures may reach very high levels within structural fires.¹ The STP was designed to most closely simulate the most demanding, early stages of structural firefighting. It was based as nearly as possible on the Candidate Physical Ability Test (CPAT), a rigorous screening test for fire service applicants that has been validated to correlate with actual critical job functions in the United States and Canada.¹⁵ The CPAT was modified to create the STP so that 1) all tasks could be performed within an environmental chamber under tightly controlled conditions of heat and humidity, 2) the subjects would use SCBA because the increased work of breathing adds to the physiologic demands of firefighting, and 3) brief rest periods were built into the task transitions to better simulate structural fire suppression.

⁴⁷ Laursen PB, Suriano R, Quod MJ, et al. Core Temperature and Hydration Status During an Ironman Triathlon. *Br J Sports Med.* 2006;40:320-325.

⁴⁸ Brake DJ, Bates GP. Deep body core temperatures in industrial workers under thermal stress. *J Occup Med.* February 2002;44(2):125-135.

⁴⁹ Guidotti TL. Human Factors in Firefighting: Ergonomic-, Cardiopulmonary-, and Psychogenic Stress-related Issues. *Int Arch Occup Environ Health.* 1992;64:1-12.

⁵⁰ Menze R, McMullen MJ, White LJ, Dougherty JM. Core temperature monitoring of firefighters during hazardous materials training sessions. *Prehosp Disaster Med.* 1996;11(2):108-111.

⁵¹ Jurriaan B, Mol E, Visser B, Frings-Dresen MHW. The Physical Demands Upon (Dutch) Fire-fighters in Relation to the Maximum Acceptable Energetic Workload. *Ergonomics.* March 15 2004;47(4):446-460.

The Breach and Pull apparatus designed for the last task in the STP is a shorter version of the eight-foot high, steel Molitor Machine^R used in the CPAT. It was modified to fit into the environmental chamber with the assistance of its original inventors. The machine simulates the overhaul phase of fire fighting. The shorter apparatus required the subjects to perform the pike pole work on their knees, as if they were working in crawl spaces (not a rare occurrence in fire suppression). This modification of the machine likely served to eliminate most of the usual contribution of the lower extremities to the breach and pull task, making it almost entirely an upper body exercise. Upper body exertion has been shown to result in disproportionate cardiovascular stress.⁵² It is notable that the heavy exertion necessary to break through walls and ceilings to look for smoldering fire is required when the FF may already be fatigued and dehydrated. As in the standardized CPAT,⁵³ this was the final task in the STP.

Much of FFs' work on the fireground involves intermittent anaerobic work,^{7,49,54} however, most studies of heat stress have evaluated subjects performing only continuous aerobic work.^{17,55,56} Previous methodologies used to study FFs in heat have had limitations such as using SCBA or PPE but not both,⁵⁷ measuring only heart rate,⁵⁸ and inadequate representation of volunteer FFs in the subject pool.⁵⁹ One of the few studies of intermittent exercise in heat involved healthy male subjects age 19-43 years, and found that this type of exercise leads to higher core body temperatures than continuous work under similar conditions.⁶⁰ In addition, a study looking at cardiovascular effects of repeated, strenuous live-fire drills found significant reduction in stroke volume after 20 minutes of performing such drills.⁶¹ Since heart rate is sustained at or near maximum throughout a fire response,^{13,17} any decrease in stroke volume immediately translates to decreased cardiac output, further compromising FFs' ability to physiologically compensate for the heat stress.

The core temperature data clearly show that the STP, when performed in heat and PPE, induced uncompensable heat stress (UCHS) in experienced FFs. The FF subjects reached significantly higher T_c (p<0.03) when under these conditions than they did working without PPE in cool conditions. This occurred during their very short work times prior to onset of volitional

⁵² Mackinnon SN. Relating heart rate and rate of perceived exertion in two simulated occupational tasks. *Ergonomics*. 1999;42(5):761-766.

⁵³ IAFF/IAFC. *The Fire Service Joint Labor Management Wellness/Fitness Initiative. Candidate Physical Ability Test*. Washington, DC: International Association of Fire Fighters, International Association of Fire Chiefs; 2000.

⁵⁴ Kales SN, Soteriades ES, Christophi CA, Charitani DC. Emergency Duties and Deaths from Heart Disease among Firefighters in the United States. *NEJM*. March 22 2007;356(12):1207-1215.

⁵⁵ Selkirk GA, McLellan TM. Physical Work Limits for Toronto Firefighters in Warm Environments. *Journ Occup Environ Hygiene*. April 2004;1(4):199 - 212.

⁵⁶ White MK, Hodous TK, Vercruyssen M. Effects of Thermal Environment and Chemical Protective Clothing on Work Tolerance, Physiological Responses, and Subjective Ratings. *Ergonomics*. 1991;34(4):445-457.

⁵⁷ Kraning II KK, Gonzalez RR. Physiological consequences of intermittent exercise during compensable and uncompensable heat stress. *J Appl Physiol* 1991;71(6):2138-2145.

⁵⁸ Jurriaan B, Mol E, Visser B, Frings-Dresen MHW. The Physical Demands Upon (Dutch) Fire-fighters in Relation to the Maximum Acceptable Energetic Workload. *Ergonomics*. March 15 2004;47(4):446-460.

⁵⁹ Karter Jr. MJ. *U. S. Fire Department Profile Through 2005*. Quincy, MA: Fire Analysis and Research Division, National Fire Protection Association; October 2006.

⁶⁰ Kraning II KK, Gonzalez RR. Physiological consequences of intermittent exercise during compensable and uncompensable heat stress. *J Appl Physiol* 1991;71(6):2138-2145.

⁶¹ Smith DL, Manning TS, Petruzzello SJ. Effect of Strenuous Live-fire Drills on Cardiovascular and Psychological Responses of Recruit Firefighters. *Ergonomics*. 2001;44(3):244-254.

fatigue. Both Tc and HS were markedly increased, and the values recorded exceeded industrial standards for working shifts in hot environments.⁴⁸

A subset of FFs in the STP reached very high HS values (up to 1205 kJ) in UCHS. Whether the great temperature elevation seen in our sub-population of FFs means that they are at increased risk for occupational heat stress, represents an unrelated benign observation, or was an equipment artifact should be evaluated in a larger study.

No significant difference in time to complete a) the last task (Breach and Pull) or b) the entire protocol was observed between the UCHS and cool experimental conditions. Only two of the STP tasks did not have pre-set times for completion. These were the search and rescue, performed until the dummy was removed from the chamber by the subject, and the Breach and Pull, which was performed to volitional fatigue. The total protocol time may have been prolonged under UCHS conditions despite relatively shorter Breach and Pull times because the dummy rescue task was mechanically more difficult in PPE than without it. Both 'learning' of the task and the mechanical advantage offered by the lack of PPE may have contributed to the tendency (not statistically significant) toward faster completion of this part of the protocol. Despite the lack of statistically significant differences in total time to fatigue, FFs subjectively reported greater ability to continue the Breach and Pull exercise under cool conditions. This is consistent with previous studies showing decreased RPEs while working under mild ambient conditions and wearing fewer protective garments.^{17,18}

The experiments comprising the STP did not evaluate other typical correlates of exertional heat stress such as sweat loss, indicators of dehydration, changes in blood pH or lactic acid, or a standardized scale of RPE. The LEP was developed to objectively measure more parameters that might reflect FFs' physiologic response to heat stress. Although the LEP comprised only one task, it still included both aerobic and static physiologic loads, as well as the thermal stresses of the heated environment and PPE. Five of the initial nine FFs performed this protocol of inclined treadmill walking while wearing a weighted vest, full fire protective ensemble and using SCBA. HS values for FFs working under the LEP were also elevated above industrial standards (Table 23).⁴⁸ Others also have observed maximal thermal response under similar UCHS conditions¹⁷ and limited exercise tolerance.⁵⁷

Table 23. Industrial Standards for Shift Workers in Heat⁴⁸

Maximum heat storage (acclimatized workforce)	389 kJ
Maximum heat storage (unacclimatized workforce)	324 kJ
Maximum core temperature	38.5°C
Maximum increase in core temperature	1.0°C

Weight loss, increased hemoglobin/hematocrit and increased lactate levels consistent with volume loss and anaerobic metabolism requirement were documented in these short exercise trials, and have been reported in FFs by previous investigators.^{7,18} Urine specific gravity did not change, and would not be expected to over such short durations of exercise.

RPE and heat stress were shown to correlate well in a previous study where FFs voluntarily discontinued experiments under hot conditions in protective clothing.¹⁷ In another study, no subjects were able to complete the UCHS protocol. All either voluntarily withdrew or showed obvious signs of incapacitation and the trial was terminated.⁵⁷ Both clinical signs of UCHS (ataxia and confusion) and subjective exhaustion were documented. In these studies, rectal

temperatures increased significantly but skin temperatures did not, suggesting that surface temperature techniques may not be appropriate for monitoring heat storage in working FFs.

Core temperatures for all FFs continued to rise after exercises under both protocols. Others have shown similar results after completion of exercise.^{48,50,55,57} The cumulative evidence underscores the need for rehabilitation areas at fire scenes and incorporation of cooling periods in rest cycles, as advocated by others.^{17,55,62} Results of the present study indicate that temperatures continue to rise for as much as 8 minutes after initial post-exposure cooling and rehydration have begun.

FFs in the current study, under both protocols, worked for less than 20 minutes. This is likely because the STP (intermittent work) and the LEP (aerobic work performed under weights and PPE) were each more physiologically demanding than typical aerobic exercises such as walking or running. Increased working time may be seen with lighter equipment, more permeable clothing and with establishment of work rest cycles.¹⁷ The short duration of exercise in these studies calls into question the recommended '2-bottle rule' traditionally used by fire departments⁶³ as a convenient marker for the end of the first work cycle and initiation of rehabilitation. If FFs use 15-20 minutes of air from a 30-minute cylinder, they may be completing 30 to 45 minutes of work under conditions of UCHS. This equation is even worse with the use of 45 or 60-minute SCBA air cylinders.

With significant pressure (which may also be partially self-induced) to rescue lives and save property, FFs may not heed internal cues warning of impending exhaustion. FFs performing interior structural fire suppression may need objective data or limits to know when to exit. 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. As such, it is essential to correlate this critical indicator with other easily observable parameters.

Heart Rate Data

Table 24. Heart Rate Data for Subjects in LEP

Subject ID	018568	024505	024509	024511	024512	024513	024514	024517	024518	024519	024520
Average - Pre LEP (BPM)	100.08	117.69	123.13	113.28	123.11	125.93	121.44	114.55	124.08	103.94	122.37
Std Dev - Pre LEP (BPM)	12.40	16.99	24.58	6.65	22.72	17.26	13.17	9.24	21.89	12.16	13.98
Average - Last 2 min (BPM)	90.53	139.03	145.23	160.05	120.67	149.62	170.13	97.60	116.97	163.25	128.22
Std Dev - Last 2 min (BPM)	10.29	15.55	1.94	1.10	28.65	15.98	10.56	16.32	20.32	17.69	33.21
Max HR - LEP (BPM)	165.6	172.7	146.4	161.6	180.8	175.7	187.8	168.6	167.6	197.9	185.8
Time to Max (sec)	1353	643	663	803	723	43	1223	643	463	1063	663
Duration of LEP (sec)	1258	902	803	846	622	234	1228	621	295	1135	656

RPE Data

⁶² Carter JB, Banister EW, Morrison JB. Effectiveness of Rest Pauses and Cooling in Alleviation of Heat Stress During Simulated Fire-Fighting Activity. *Ergonomics*. 1999;42(2):299-313.

⁶³ *Emergency Incident Rehabilitation. FA-114: FEMA/USFA; July 1992.*

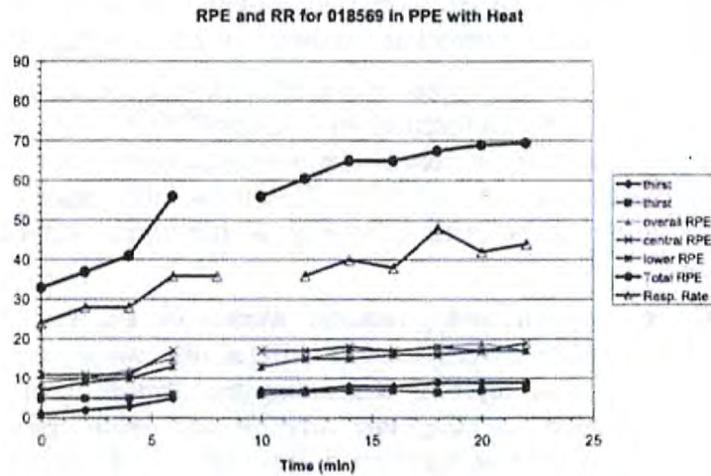


Figure 43: Sample RPE and respiratory rate data for subject 018569 in PPE and heat.

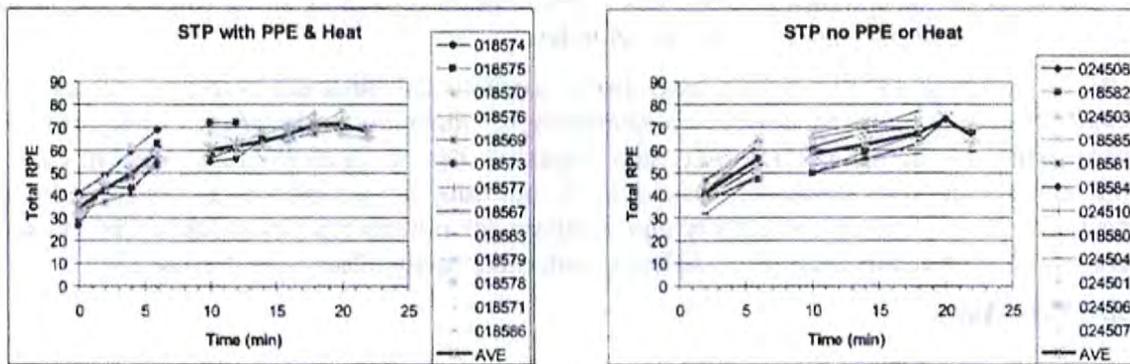


Figure 44: RPE data from subjects in STP with (left) and without (right) heat and PPE.

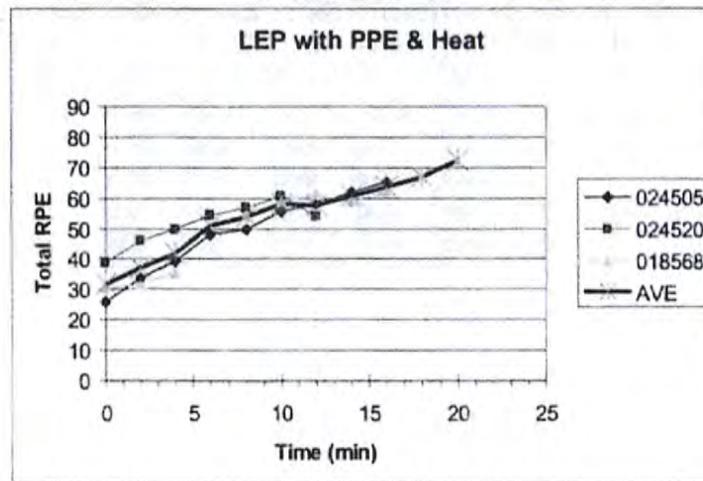


Figure 45: Selected RPE data from subjects in LEP with heat and PPE.

Slope of RPEave trendline for LEP with PPE and Heat:

$$RPE(t) = 1.8663(t) + 35.489$$

Slope of RPEave trendline for STP with PPE and Heat: $RPE(t) = 1.4812(t) + 42.262$

Slope of RPEave trendline for STP without PPE and Heat: $RPE(t) = 1.2779(t) + 43.914$

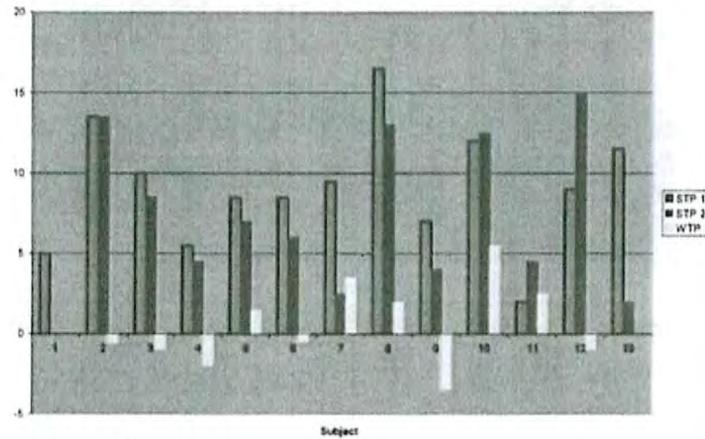


Figure 46: Change in Plasma Osmolarity

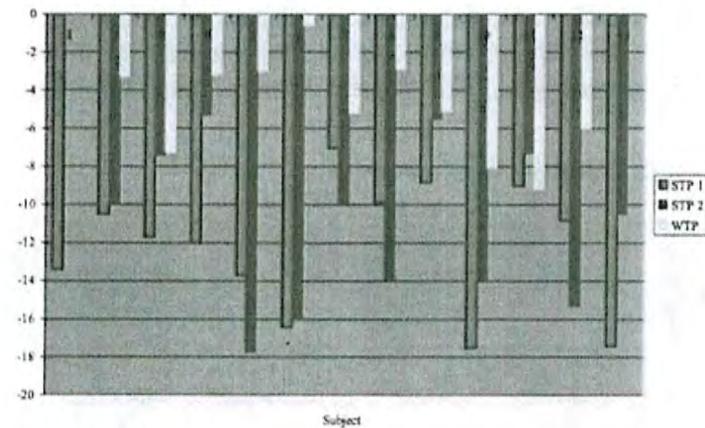


Figure 47: Change in Plasma Volume

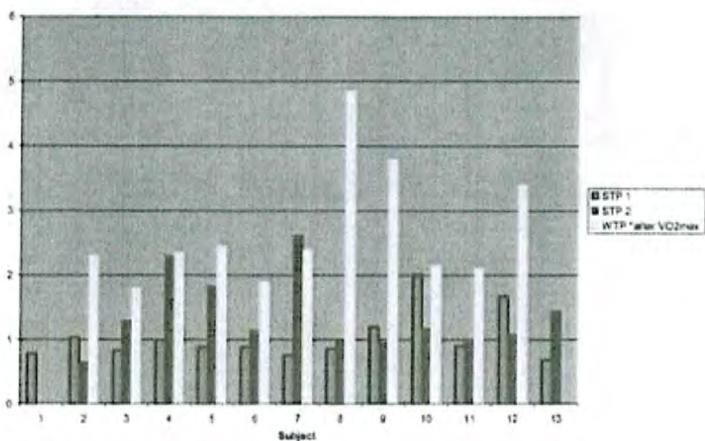


Figure 48: Initial Lactates

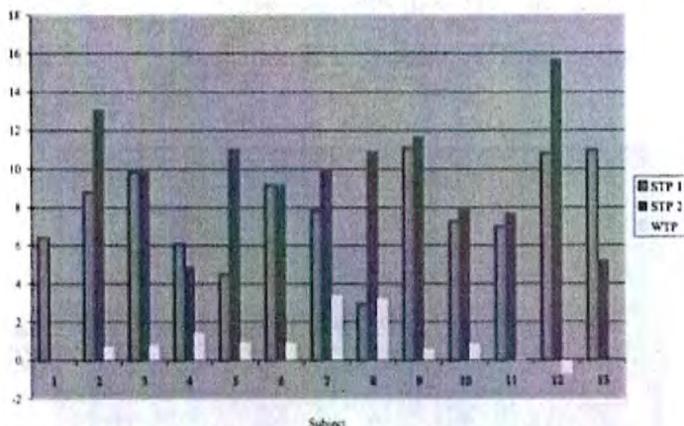


Figure 49: Change in Lactates

Skin Pigmentation

In order to address previous concerns regarding the functionality of the system across a variety of ethnic and racial backgrounds (see *Oximetry across different levels of skin pigmentation* on page 59), the subjects' foreheads were photographed and the technique previously described was applied for analysis. The system remains functional across a variety of skin pigmentations.

Table 25. Phase II subject skin pigmentation analysis

Subject	018572	018578	018579	018571	018574	018575	018570
Skin							N/A
Histogram							N/A
Mean	162.43	162.09	157.41	167.35	162.07	126.49	N/A
Std Dev	5.37	4.29	6.14	4.70	9.36	6.80	N/A
Subject	018576	018569	018573	018586	018577	018567	
Skin							
Histogram							
Mean	181.06	177.95	164.93	153.56	146.93	122.38	
Std Dev	10.41	6.97	6.14	11.21	4.59	19.99	

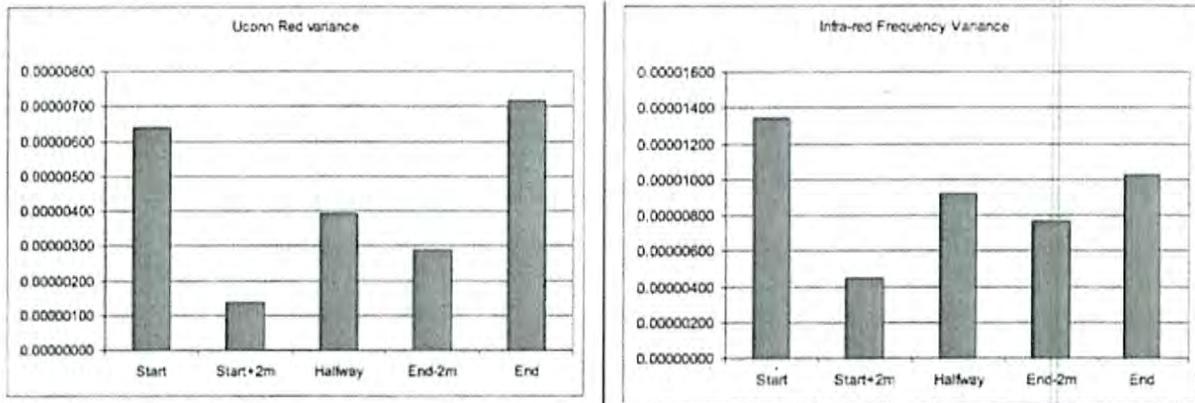


Figure 50: Calculated variance at study time points for Red (left) and Infra-Red (right) light frequency absorption (UConn treadmill studies).

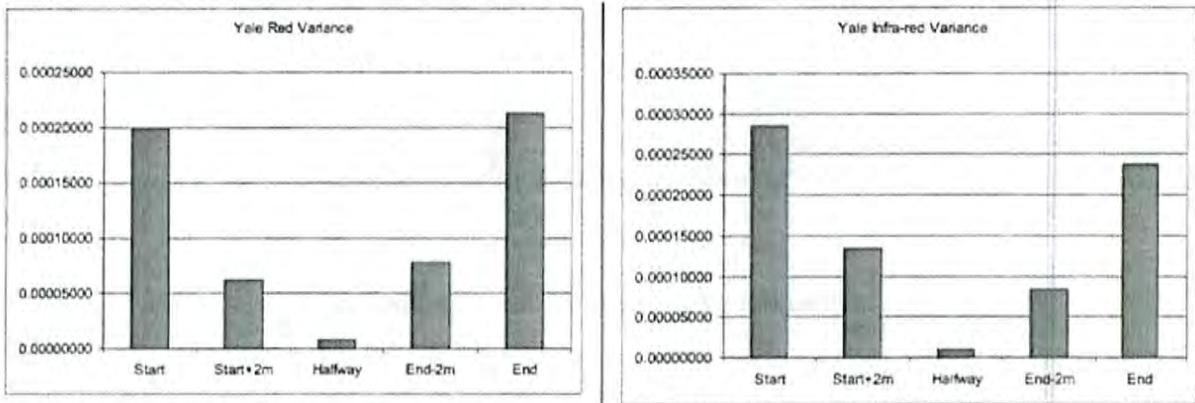


Figure 51: Calculated variance at study time points for Red (left) and Infra-Red (right) light frequency absorption (Yale STP studies).

(1s) Variance of (1s) Averaged Red Data by Subject

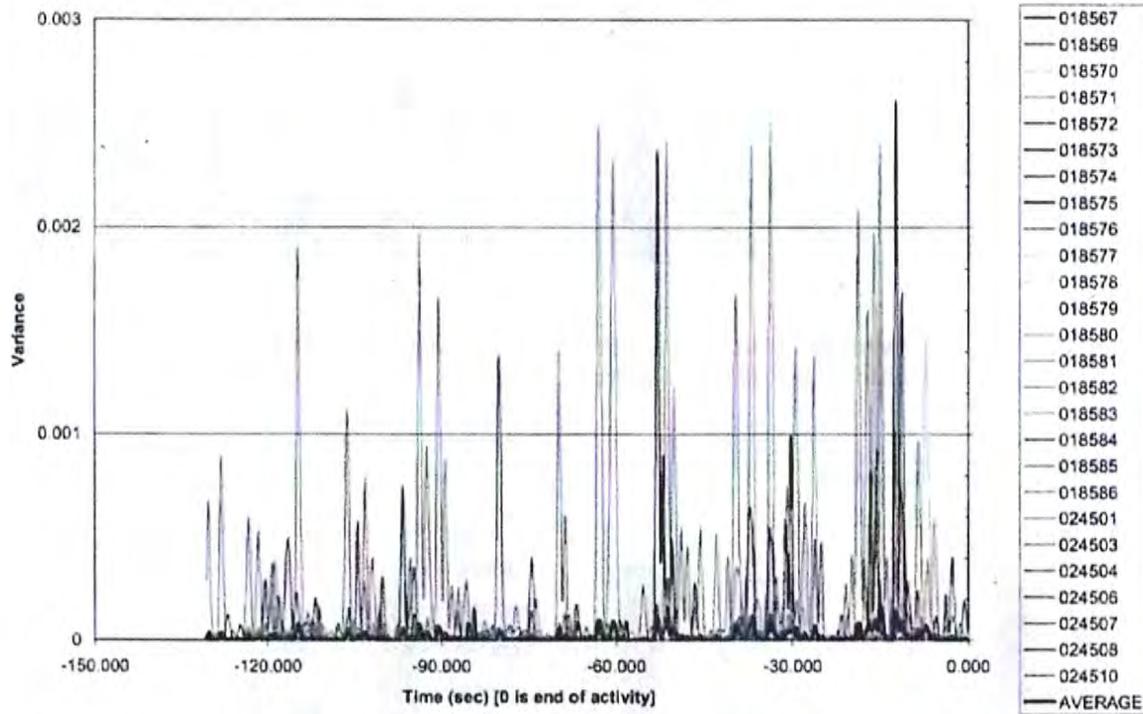


Figure 52: Variance data (red frequency) for all subjects during the last two minutes of each subject's STP test.

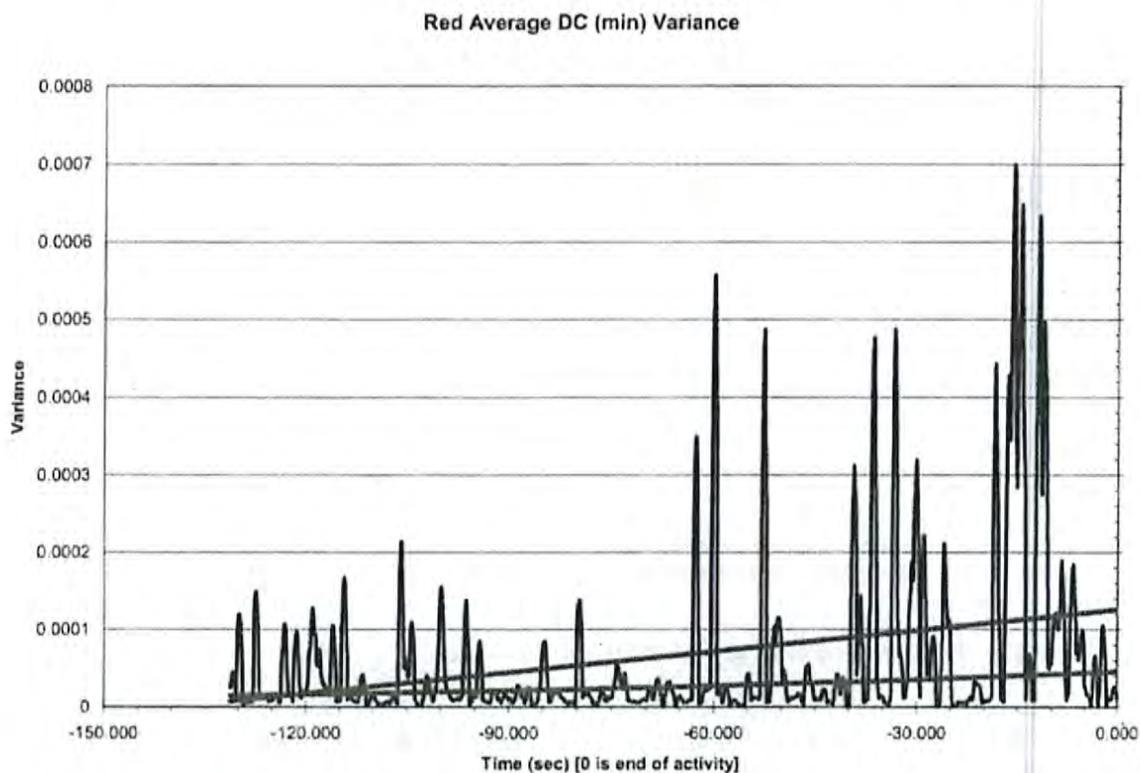


Figure 53: Average (all subjects) change in red frequency absorption variance for last two minutes of subject's STP test activity.

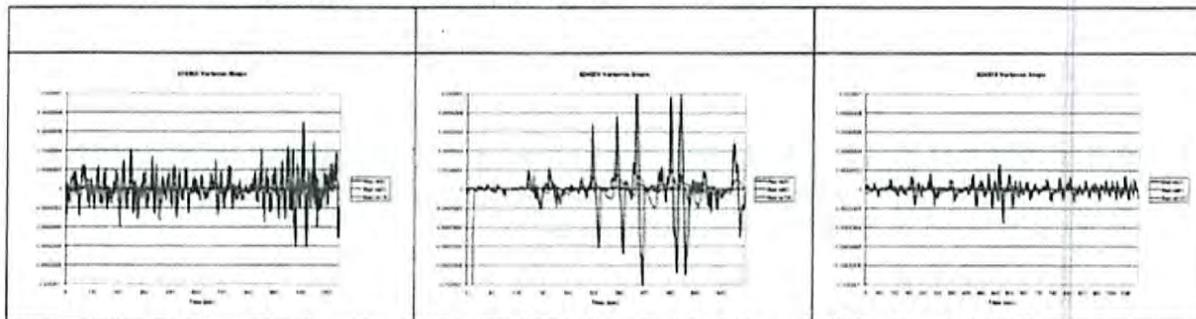


Figure 54: Slopes of data trendlines over time (30 seconds, 60 seconds, 120 seconds) for subjects during treadmill trials.

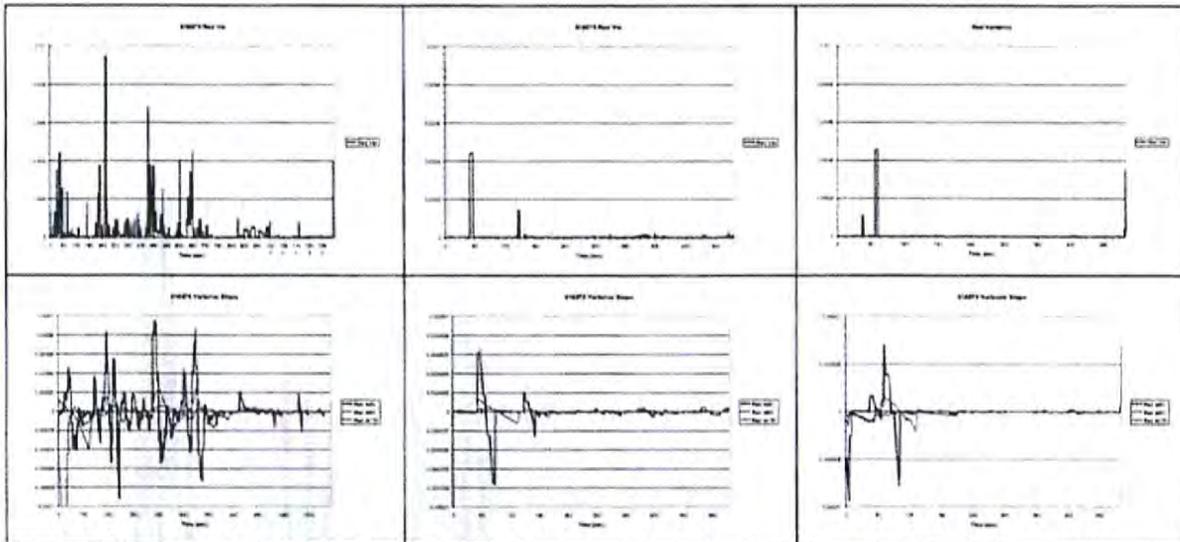


Figure 55: Matched data of variance (top) and Slopes of data trendlines (bottom) over time (30 seconds, 60 seconds, 120 seconds) for subjects during CPAT trials with PPE and Heat.

Final Design Review: Redesign Recommendations

We anticipate that very few, if any hardware changes should be required between the field study units and those we prepare for commercial sales. We do anticipate that field applications of our units may require cabling and packaging modifications to withstand rigorous usage outside the laboratory setting or research and training environments. We further anticipate that the algorithms employed in the data acquisition system's software shall also require a further refinement before commercial unit sales. We further anticipate that the software developed for the monitoring station will require significant modification as feedback from incident command personnel can be incorporated into its usability and utility. The data and experience we gain during the field trials shall provide us with the information necessary to make these changes.

Should new and more accurate analysis be developed that should require substantially more powerful data analysis, it may be necessary to either upgrade the internal processor to accommodate these needs, or to transmit a greater quantity of data to a central monitoring base station which would then have more processing power available for analysis. However, the DsPIC currently in use in this system in addition to being specifically designed to optimize digital signal analysis is significantly underutilized, leaving a wide range of software improvements that could be developed before the hardware would require upgrading or revision.

Conclusions

General

Two primary impediments remain for commercial readiness of this technology:

1. A much greater quantity of subject data would be required to provide convincing results to a level required before fire departments would be willing to invest in purchasing this technology.
2. The difficulties with separating actual volitional fatigue alarms from similar false positive signals will need to be resolved before users will accept the technology.

Core Body Temperature

Under this effort, an experimental model that simulates the initial phases of an interior fire attack to study the physiology of UCHS in FFs has been developed. As expected, performance of FFs tasks in PPE and a hot environment result in substantial increases in Tc and HS compared with performance of the same tasks without heat and PPE. These and changes in other physiological parameters that were measured here are consistent with the few previous studies that have monitored working FFs. A subset (33%) of subjects showed an exaggerated Tc response to exercise in UCHS conditions. Further study with larger numbers of subjects will be required to confirm this observation, rule out artifact, and correlate it with other parameters. Half of FFs in this study showed T_{max}, increase in Tc, and HS values that exceeded recommended industrial standards (Table 23) for 8 hour shifts of working in hot environments.

Publications List

Van Gelder CM, Pranger LA, Urias A, Lo R, Wiesmann WP, Winchell RJ, Kolka MA, Stachenfeld N, Bogucki S. Physiologic monitoring in extreme environments: Application of micro-sensors and embedded processors to predict heat stress in fire fighters. Oral presentation at Society for Photo-Optical Instrumentation Engineers (SPIE), San Jose CA, January 2002. In Biomedical Diagnostic, Guidance, and Surgical-Assist Systems IV, T Vo-Dihn, DA Benaron, WS Grundfest, Editors, Proc SPIE 2002; 4615:71-81.

Van Gelder CM, Pranger LA, Wiesmann WP, Stachenfeld N, Bogucki S. An Experimental Model of Heat Storage in Working Firefighters. Moderated Poster presentation, National Association of EMS Physicians, Florida, January 2003.
Oral presentation, Section of Emergency Medicine, Yale University School of Medicine 3rd Annual Research Day, June 2003.
Oral presentation, Connecticut College of Emergency Physicians 2003 Annual Meeting, November 2003. Prehosp Emerg Care Apr/June 2008; 12(2), In-press.

Van Gelder CM, Pranger LA, Armstrong L, Wiesmann WP, Baxter G, Winchell R, Bogucki S. Using DC Oximetry to Detect Exhaustion in Working Firefighters. Accepted for poster presentation, New England Regional SAEM Conference, April 2004.
Moderated Poster presentation at SAEM Annual meeting, Florida, May 2004.
Oral presentation, Section of Emergency Medicine, Yale University School of Medicine 4th Annual Research Day, June 2004.
Oral presentation, IEEE Homeland Security, Boston MA, April 2005.
Abstract in Acad Emerg Med 2004; 11(5):605.

Van Gelder CM, Pranger LA, Burns K, Armstrong L, Wiesmann WP, Bogucki S. Physiological Effects of Simulated Firefighting Tasks Compared with Continuous Exercise, in Heat and PPE. Oral presentation, NAEMSP annual meeting, Tucson AZ, January 2006.
Abstract in Prehosp Emerg Care, Jan/Mar 2006; 10: 108.

Wiesmann, W.P., Draghic, N.D., and Pranger, L.A., *Telemedicine in Evolution Implications for Expeditionary Medicine in Expedition Medicine: Wilderness, Remote, and Extreme Environments*, ed. Drs. Gregory H. Bledsoe, Michael J. Manyak, and David A. Townes Cambridge University Press, NY, 2008.

Inclusion of Gender and Minorities Study Subjects

Inclusion of Women

Only Branford Fire Department members who are qualified to wear SCBA and are cleared for duty without restriction by its NFPA 1582-compliant occupational medical program were eligible to participate in these studies. To wear SCBA, Branford FF's are required by the State of Connecticut to be certified to at least the Fire Fighter I level. Efforts were made to recruit qualified women for this study.

Inclusion of Minorities

Only Branford Fire Department members who are qualified to wear SCBA and are cleared for duty without restriction by its NFPA 1582-compliant occupational medical program were eligible to participate in these studies. To wear SCBA, Branford FF's are required by the State of Connecticut to be certified to at least the Fire Fighter I level. There was minority representation in the Phase I and post-Phase I studies. Efforts were made to include minority members of the department in recruitment efforts for the Phase II studies.

One primary concern regarding our study was would the technique be applicable to individuals of any skin color. Although the general applicability of the underlying pulse oximetry technology is well established, we undertook a small study to explicitly confirm that the system will operate across different skin pigmentations often associated with different racial or ethnic groups and backgrounds. These results are summarized in Figure 21 and the accompanying discussion on page 60.

Inclusion of Children

Only Branford Fire Department members who are qualified to wear SCBA and are cleared for duty without restriction by its NFPA 1582-compliant occupational medical program were eligible to participate in these studies. To wear SCBA, Branford firefighters are required by the State of Connecticut to be certified to at least the Firefighter I level. For this reason, it was not possible to include children under the age of 18.

Materials available for other Investigators
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For our studies, there were a total of 13 subjects.

12 subjects completed both CPAT trials (with and without PPE and heat)

11 subjects also completed the VO2 max studies

11 subjects also completed the Treadmill studies at UConn.

Data which may be made available to other researchers performing similar work will include:

Table 26. Data file names and included data

Data Type	State	File Source	Notes
Processed data with graphs and analysis	Formatted	'subjectID A All.xls'	
Processed data time synchronized	Processed	'subjectID A All.csv'	
Event Timestamps	Processed	'subjectID A Events.csv'	
Foot Fall (FFM) accelerometer peaks	Processed	'subjectID A FFpeaks.csv'	
Raw accelerometer data	Processed	'subjectID ffmFFM.csv'	
RED DC Oximetry data	Processed	'subjectID A Red.csv'	
IR DC Oximetry data	Processed	'subjectID A IR.csv'	
Internal measure of data integrity or loss	Processed	'subjectID A DI.csv'	
Mean Absorbance Minima	Processed	'subjectID A MAM.csv'	
The AC components of Red and IRsignals	Processed	'subjectID_A_LRRIR.csv'	Used for Ratio an natural log ratio.
Calculated Variance (Winchell algorithm)	Processed	'subjectID A Var.csv'	
Core Temp and Heart Rate (CTHR) data	Processed	'subjectID A CTHR.csv'	
Processed Core Temp and HR Data	Processed	'uconn subjectID.csv'	Last 3 of subject ID
Core Temp and HR Data from CorTemp	Raw	'subjectID ct.csv'	
Raw serial communication from HWM unit	Raw	'subjectID ffm.dat'	Should be 0 bytes
Raw serial communication from FFM unit	Raw	'subjectID ffm.ffm'	
Events recorded on FFM unit	Raw	'subjectID ffm.txt'	
Raw Foot falls into time, value table	Min. proc.	'subjectID ffmFFM.csv'	
Raw DC Ox data into time, value table	Min. proc.	'subjectID ffmHWM.csv'	Should be small
Raw serial communication from HWM unit	Raw	'subjectID.dat'	
Raw serial communication from FFM unit	Raw	'subjectID.ffm'	Should be 0 bytes
Events recorded on HWM unit	Raw	'subjectID.txt'	
Raw Foot falls into time, value table	Min. proc.	'subjectIDFFM.csv'	Should be small
Raw DC Ox data into time, value table	Min. proc.	'subjectIDHWM.csv'	
Raw serial communication from HWM unit	Raw	'subjectID pretest.dat'	
Raw serial communication from FFM unit	Raw	'subjectID pretest.ffm'	Should be 0 bytes
Events recorded on HWM unit	Raw	'subjectID pretest.txt'	
Raw Foot falls into time, value table	Min. proc.	'subjectID pretest FFM.csv'	Should be small
Raw DC Ox data into time, value table	Min. proc.	'subjectID pretest HWM.csv'	

Table 27. Subject Ids corresponding to the same individual

Subject #	Post Phase 1 TM	LEM	VO ₂ max	STP in PPE	STP without PPE
1				018572	018583 024507
2		024514	514	018578	018585
3		024519	519	018579	018582
4		024518	518	018571	018581
5		024513	513	018574	018584 (female)
6		024512	512	018575	018580
7		024511	511	018570	024510
8		024520	520	018576	024504
9		024509	509	018569	024506
10		024505	505	018573	024501
11		018568	568	018586	024508
12		024517	517	018577	024503
13				018567	

Table 28. UConn (Treadmill Studies) Data files

Date	Time	Size	File or Directory
\Phase II\Data\UConn0503			
3/1/2005	11:37 AM	13,119	024509_ct.csv
3/2/2005	10:25 AM	8,575	024517_ct.csv
3/2/2005	11:17 AM	6,625	024513_ct.csv
3/2/2005	12:03 PM	5,995	024511_ct.csv
3/2/2005	12:39 PM	4,931	024512_ct.csv
3/3/2005	10:35 AM	7,915	018568_ct.csv
3/3/2005	11:29 AM	6,775	024514_ct.csv
3/3/2005	12:19 PM	6,385	024520_ct.csv
3/3/2005	12:59 PM	5,537	024505_ct.csv
3/3/2005	1:53 PM	6,797	024519_ct.csv
3/3/2005	1:58 PM	4,402	uconn505.csv
3/3/2005	1:59 PM	5,206	uconn520.csv
3/3/2005	1:59 PM	2,929	uconn514.csv
3/3/2005	2:00 PM	6,702	uconn568.csv
3/3/2005	2:01 PM	2,527	uconn518.csv
3/3/2005	2:03 PM	506	uconn512.csv
3/3/2005	2:03 PM	3,664	uconn511.csv
3/3/2005	2:04 PM	4,448	uconn513.csv
3/3/2005	2:04 PM	7,489	uconn517.csv
3/3/2005	2:05 PM	5,807	uconn509.csv
3/2/2005	1:14 PM	4,885	024518_ct-x.csv
3/2/2005	1:15 PM	4,885	024518_ct.csv
3/3/2005	1:54 PM	5,464	uconn519.csv
6/28/2005	1:51 PM	19,456	Estimated_VO2max Jun05.xls
23 Files		151,024	bytes
\Phase II\Data\UConn0503\024512_ffm			
3/2/2005	12:32 PM	844,925	024512_ffm.dat
3/2/2005	12:13 PM	0	024512_ffm.ffm
3/2/2005	12:32 PM	405	024512_ffm.txt
3/2/2005	12:32 PM	1,690,387	024512_ffmFFM.csv
3/2/2005	12:32 PM	912	024512_ffmHWM.csv
5 Files		2,536,629	bytes
\Phase II\Data\UConn0503\024518_ffm			

3/2/2005 1:02 PM	610,197	024518_ffm.dat
3/2/2005 12:48 PM	0	024518_ffm.ffm
3/2/2005 1:02 PM	556	024518_ffm.txt
3/2/2005 1:02 PM	1,220,829	024518_ffmFFM.csv
3/2/2005 1:02 PM	698	024518_ffmHWM.csv
5 Files	1,832,280 bytes	\\Phase II\Data\UConn0503\018568_ffm
3/3/2005 10:18 AM	1,324,351	018568_ffm.dat
3/3/2005 9:51 AM	0	018568_ffm.ffm
3/3/2005 10:19 AM	413	018568_ffm.txt
3/3/2005 10:18 AM	2,649,635	018568_ffmFFM.csv
3/3/2005 10:18 AM	1,452	018568_ffmHWM.csv
5 Files	3,975,851 bytes	\\Phase II\Data\UConn0503\024514_ffm
3/3/2005 11:13 AM	1,484,957	024514_ffm.dat
3/3/2005 10:42 AM	0	024514_ffm.ffm
3/3/2005 11:13 AM	408	024514_ffm.txt
3/3/2005 11:13 AM	2,970,999	024514_ffmFFM.csv
3/3/2005 11:13 AM	1,632	024514_ffmHWM.csv
5 Files	4,457,996 bytes	\\Phase II\Data\UConn0503\024520_ffm
3/3/2005 11:59 AM	864,644	024520_ffm.dat
3/3/2005 11:41 AM	0	024520_ffm.ffm
3/3/2005 11:59 AM	406	024520_ffm.txt
3/3/2005 11:59 AM	1,729,856	024520_ffmFFM.csv
3/3/2005 11:59 AM	939	024520_ffmHWM.csv
5 Files	2,595,845 bytes	\\Phase II\Data\UConn0503\024505_ffm
3/3/2005 12:47 PM	1,027,925	024505_ffm.dat
3/3/2005 12:24 PM	0	024505_ffm.ffm
3/3/2005 12:47 PM	406	024505_ffm.txt
3/3/2005 12:47 PM	2,056,582	024505_ffmFFM.csv
3/3/2005 12:47 PM	1,128	024505_ffmHWM.csv
5 Files	3,086,041 bytes	\\Phase II\Data\UConn0503\024519_ffm
3/3/2005 1:33 PM	1,276,880	024519_ffm.dat
3/3/2005 1:05 PM	0	024519_ffm.ffm
3/3/2005 1:33 PM	455	024519_ffm.txt
3/3/2005 1:33 PM	2,554,720	024519_ffmFFM.csv
3/3/2005 1:33 PM	1,414	024519_ffmHWM.csv
5 Files	3,833,469 bytes	\\Phase II\Data\UConn0503\024509
3/1/2005 11:23 AM	216,397	024509.dat
3/1/2005 10:49 AM	0	024509.ffm
3/1/2005 11:24 AM	542	024509.txt
3/1/2005 11:23 AM	1,399	024509FFM.csv
3/1/2005 11:23 AM	458,433	024509HWM.csv
5 Files	676,771 bytes	\\Phase II\Data\UConn0503\024517
3/2/2005 10:17 AM	231,187	024517.dat
3/2/2005 9:01 AM	0	024517.ffm
3/2/2005 10:18 AM	606	024517.txt

3/2/2005 10:18 AM	1,311 024517FFM.csv
3/2/2005 10:18 AM	490,300 024517HWM.csv
5 Files	723,404 bytes
	\\Phase II\Data\UConn0503\024513
3/2/2005 10:56 AM	177,118 024513.dat
3/2/2005 10:28 AM	0 024513.ffm
3/2/2005 10:59 AM	551 024513.txt
3/2/2005 10:59 AM	1,111 024513FFM.csv
3/2/2005 10:59 AM	363,168 024513HWM.csv
5 Files	541,948 bytes
	\\Phase II\Data\UConn0503\024511
3/2/2005 11:55 AM	270,763 024511.dat
3/2/2005 11:24 AM	0 024511.ffm
3/2/2005 11:56 AM	547 024511.txt
3/2/2005 11:56 AM	1,455 024511FFM.csv
3/2/2005 11:56 AM	583,243 024511HWM.csv
5 Files	856,008 bytes
	\\Phase II\Data\UConn0503\024512
3/2/2005 12:35 PM	166,827 024512.dat
3/2/2005 12:14 PM	0 024512.ffm
3/2/2005 12:36 PM	550 024512.txt
3/2/2005 12:36 PM	951 024512FFM.csv
3/2/2005 12:36 PM	363,659 024512HWM.csv
5 Files	531,987 bytes
	\\Phase II\Data\UConn0503\024518
3/2/2005 1:08 PM	142,042 024518.dat
3/2/2005 12:48 PM	0 024518.ffm
3/2/2005 1:08 PM	744 024518.txt
3/2/2005 1:08 PM	831 024518FFM.csv
3/2/2005 1:08 PM	295,804 024518HWM.csv
5 Files	439,421 bytes
	\\Phase II\Data\UConn0503\018568
3/3/2005 10:23 AM	279,415 018568.dat
3/3/2005 9:49 AM	0 018568.ffm
3/3/2005 10:23 AM	554 018568.txt
3/3/2005 10:23 AM	1,463 018568FFM.csv
3/3/2005 10:23 AM	603,998 018568HWM.csv
5 Files	885,430 bytes
	\\Phase II\Data\UConn0503\024514
3/3/2005 11:19 AM	322,046 024514.dat
3/3/2005 10:41 AM	0 024514.ffm
3/3/2005 11:19 AM	623 024514.txt
3/3/2005 11:19 AM	1,695 024514FFM.csv
3/3/2005 11:19 AM	697,453 024514HWM.csv
5 Files	1,021,817 bytes
	\\Phase II\Data\UConn0503\024520
3/3/2005 12:04 PM	192,724 024520.dat
3/3/2005 11:40 AM	0 024520.ffm
3/3/2005 12:04 PM	728 024520.txt
3/3/2005 12:04 PM	1,023 024520FFM.csv
3/3/2005 12:04 PM	417,712 024520HWM.csv
5 Files	612,187 bytes

		\Phase II\Data\UConn0503\024505
3/3/2005 12:51 PM	215,755	024505.dat
3/3/2005 12:25 PM	0	024505.ffm
3/3/2005 12:51 PM	601	024505.txt
3/3/2005 12:51 PM	1,151	024505FFM.csv
3/3/2005 12:51 PM	454,568	024505HWM.csv
5 Files	672,075	bytes
		\Phase II\Data\UConn0503\024519
3/3/2005 1:38 PM	278,346	024519.dat
3/3/2005 1:06 PM	0	024519.ffm
3/3/2005 1:38 PM	691	024519.txt
3/3/2005 1:38 PM	1,455	024519FFM.csv
3/3/2005 1:38 PM	608,234	024519HWM.csv
5 Files	888,726	bytes
		\Phase II\Data\UConn0503\test050301ffm
3/1/2005 10:10 AM	13,480	test050301ffm.dat
3/1/2005 10:10 AM	0	test050301ffm.ffm
3/1/2005 10:10 AM	171	test050301ffm.txt
3/1/2005 10:10 AM	27,001	test050301ffmFFM.csv
3/1/2005 10:10 AM	61	test050301ffmHWM.csv
5 Files	40,713	bytes
		\Phase II\Data\UConn0503\024509_ffm
3/1/2005 11:19 AM	1,206,480	024509_ffm.dat
3/1/2005 10:48 AM	0	024509_ffm.ffm
3/1/2005 11:19 AM	404	024509_ffm.txt
3/1/2005 11:19 AM	2,413,883	024509_ffmFFM.csv
3/1/2005 11:19 AM	1,371	024509_ffmHWM.csv
5 Files	3,622,138	bytes
		\Phase II\Data\UConn0503\024517_ffm
3/2/2005 10:13 AM	1,149,482	024517_ffm.dat
3/2/2005 8:51 AM	0	024517_ffm.ffm
3/2/2005 10:13 AM	454	024517_ffm.txt
3/2/2005 10:13 AM	2,299,717	024517_ffmFFM.csv
3/2/2005 10:13 AM	1,270	024517_ffmHWM.csv
5 Files	3,450,923	bytes
		\Phase II\Data\UConn0503\024513_ffm
3/2/2005 10:53 AM	924,993	024513_ffm.dat
3/2/2005 10:22 AM	0	024513_ffm.ffm
3/2/2005 10:53 AM	598	024513_ffm.txt
3/2/2005 10:53 AM	1,850,558	024513_ffmFFM.csv
3/2/2005 10:53 AM	1,018	024513_ffmHWM.csv
5 Files	2,777,167	bytes
		\Phase II\Data\UConn0503\024511_ffm
3/2/2005 11:50 AM	1,248,789	024511_ffm.dat
3/2/2005 11:02 AM	0	024511_ffm.ffm
3/2/2005 11:51 AM	402	024511_ffm.txt
3/2/2005 11:50 AM	2,498,467	024511_ffmFFM.csv
3/2/2005 11:50 AM	1,380	024511_ffmHWM.csv
5 Files	3,749,038	bytes
		\Phase III\Data\UConn0503\Analyze
4/25/2005 12:43 PM	1,078	files.txt
4/25/2005 12:45 PM	209	files.csv

6/1/2005	6:11 PM	562,536	018568_A_Red.csv
6/1/2005	6:11 PM	1,270	018568_A_Events.csv
6/1/2005	6:11 PM	562,419	018568_A_IR.csv
6/1/2005	6:11 PM	4,580	018568_A_DI.csv
6/1/2005	6:11 PM	3,941	018568_A_CTHR.csv
6/1/2005	6:11 PM	302,510	018568_A_FFpeaks.csv
6/1/2005	6:11 PM	114,982	018568_A_MAM.csv
6/1/2005	6:11 PM	296,143	018568_A_LRRIR.csv
6/1/2005	6:11 PM	1,113,354	018568_A_Var.csv
6/1/2005	6:11 PM	3,106,542	018568_A_All.csv
6/2/2005	12:49 PM	20,058,112	018568_A_All.xls
6/8/2005	12:59 PM	1,387	024505_A_Events.csv
6/8/2005	12:59 PM	433,156	024505_A_Red.csv
6/8/2005	12:59 PM	432,911	024505_A_IR.csv
6/8/2005	12:59 PM	3,655	024505_A_DI.csv
6/8/2005	12:59 PM	89,471	024505_A_MAM.csv
6/8/2005	12:59 PM	230,151	024505_A_LRRIR.csv
6/8/2005	12:59 PM	862,022	024505_A_Var.csv
6/8/2005	12:59 PM	223,901	024505_A_FFpeaks.csv
6/8/2005	12:59 PM	2,272	024505_A_CTHR.csv
6/8/2005	12:59 PM	2,395,484	024505_A_All.csv
6/8/2005	1:03 PM	1,246	024509_A_Events.csv
6/8/2005	1:04 PM	431,478	024509_A_Red.csv
6/8/2005	1:04 PM	432,149	024509_A_IR.csv
6/8/2005	1:04 PM	4,492	024509_A_DI.csv
6/8/2005	1:04 PM	87,375	024509_A_MAM.csv
6/8/2005	1:04 PM	227,624	024509_A_LRRIR.csv
6/8/2005	1:04 PM	860,140	024509_A_Var.csv
6/8/2005	1:04 PM	223,989	024509_A_FFpeaks.csv
6/8/2005	1:04 PM	7,977	024509_A_CTHR.csv
6/8/2005	1:04 PM	2,393,247	024509_A_All.csv
6/8/2005	1:04 PM	1,251	024511_A_Events.csv
6/8/2005	1:04 PM	550,310	024511_A_Red.csv
6/8/2005	1:04 PM	550,687	024511_A_IR.csv
6/8/2005	1:04 PM	4,572	024511_A_DI.csv
6/8/2005	1:04 PM	113,416	024511_A_MAM.csv
6/8/2005	1:04 PM	287,653	024511_A_LRRIR.csv
6/8/2005	1:04 PM	1,090,883	024511_A_Var.csv
6/8/2005	1:05 PM	232,367	024511_A_FFpeaks.csv
6/8/2005	1:05 PM	2,576	024511_A_CTHR.csv
6/8/2005	1:05 PM	3,006,401	024511_A_All.csv
6/8/2005	1:05 PM	1,251	024512_A_Events.csv
6/8/2005	1:05 PM	329,540	024512_A_Red.csv
6/8/2005	1:05 PM	329,659	024512_A_IR.csv
6/8/2005	1:05 PM	3,123	024512_A_DI.csv
6/8/2005	1:05 PM	68,253	024512_A_MAM.csv
6/8/2005	1:05 PM	175,690	024512_A_LRRIR.csv
6/8/2005	1:05 PM	659,154	024512_A_Var.csv
6/8/2005	1:05 PM	182,844	024512_A_FFpeaks.csv
6/8/2005	1:05 PM	1,755	024512_A_CTHR.csv
6/8/2005	1:05 PM	1,835,667	024512_A_All.csv
6/8/2005	1:06 PM	1,252	024513_A_Events.csv

6/8/2005	1:06 PM	361,531	024513_A_Red.csv
6/8/2005	1:06 PM	361,655	024513_A_IR.csv
6/8/2005	1:06 PM	3,656	024513_A_DI.csv
6/8/2005	1:06 PM	74,054	024513_A_MAM.csv
6/8/2005	1:06 PM	188,232	024513_A_LRRIR.csv
6/8/2005	1:06 PM	714,206	024513_A_Var.csv
6/8/2005	1:06 PM	70,421	024513_A_FFpeaks.csv
6/8/2005	1:06 PM	3,050	024513_A_CTHR.csv
6/8/2005	1:06 PM	1,929,228	024513_A_All.csv
6/8/2005	1:07 PM	1,423	024514_A_Events.csv
6/8/2005	1:07 PM	658,421	024514_A_Red.csv
6/8/2005	1:07 PM	658,588	024514_A_IR.csv
6/8/2005	1:07 PM	5,274	024514_A_DI.csv
6/8/2005	1:07 PM	134,551	024514_A_MAM.csv
6/8/2005	1:07 PM	344,046	024514_A_LRRIR.csv
6/8/2005	1:07 PM	1,300,019	024514_A_Var.csv
6/8/2005	1:08 PM	213,835	024514_A_FFpeaks.csv
6/8/2005	1:08 PM	3,085	024514_A_CTHR.csv
6/8/2005	1:08 PM	3,555,679	024514_A_All.csv
6/8/2005	1:26 PM	1,390	024517_A_Events.csv
6/8/2005	1:26 PM	464,753	024517_A_Red.csv
6/8/2005	1:26 PM	465,100	024517_A_IR.csv
6/8/2005	1:26 PM	4,157	024517_A_DI.csv
6/8/2005	1:26 PM	94,413	024517_A_MAM.csv
6/8/2005	1:26 PM	242,885	024517_A_LRRIR.csv
6/8/2005	1:26 PM	922,531	024517_A_Var.csv
6/8/2005	1:26 PM	189,128	024517_A_FFpeaks.csv
6/8/2005	1:26 PM	4,471	024517_A_CTHR.csv
6/8/2005	1:26 PM	2,538,762	024517_A_All.csv
6/8/2005	1:28 PM	1,377	024518_A_Events.csv
6/8/2005	1:28 PM	275,746	024518_A_Red.csv
6/8/2005	1:28 PM	275,770	024518_A_IR.csv
6/8/2005	1:28 PM	2,757	024518_A_DI.csv
6/8/2005	1:28 PM	55,540	024518_A_MAM.csv
6/8/2005	1:28 PM	145,644	024518_A_LRRIR.csv
6/8/2005	1:28 PM	550,833	024518_A_Var.csv
6/8/2005	1:28 PM	84,324	024518_A_FFpeaks.csv
6/8/2005	1:28 PM	1,790	024518_A_CTHR.csv
6/8/2005	1:28 PM	1,497,981	024518_A_All.csv
6/8/2005	1:28 PM	1,661	024519_A_Events.csv
6/8/2005	1:28 PM	564,607	024519_A_Red.csv
6/8/2005	1:28 PM	564,366	024519_A_IR.csv
6/8/2005	1:28 PM	4,548	024519_A_DI.csv
6/8/2005	1:28 PM	115,226	024519_A_MAM.csv
6/8/2005	1:28 PM	296,048	024519_A_LRRIR.csv
6/8/2005	1:28 PM	1,117,237	024519_A_Var.csv
6/8/2005	1:29 PM	371,964	024519_A_FFpeaks.csv
6/8/2005	1:29 PM	3,187	024519_A_CTHR.csv
6/8/2005	1:29 PM	3,149,999	024519_A_All.csv
6/8/2005	1:30 PM	1,674	024520_A_Events.csv
6/8/2005	1:30 PM	385,193	024520_A_Red.csv
6/8/2005	1:30 PM	384,857	024520_A_IR.csv

6/8/2005	1:30 PM	3,254	024520_A_DI.csv
6/8/2005	1:30 PM	78,477	024520_A_MAM.csv
6/8/2005	1:30 PM	204,320	024520_A_LRRIR.csv
6/8/2005	1:30 PM	768,144	024520_A_Var.csv
6/8/2005	1:30 PM	180,374	024520_A_FFpeaks.csv
6/8/2005	1:30 PM	2,876	024520_A_CTHR.csv
6/8/2005	1:30 PM	2,123,622	024520_A_All.csv
112 Files		73,622,047 bytes	
250 Files		117,580,935 Bytes	

Table 29. Yale (STP) Data files

Date	Time	Size	File or Directory
\Phase II\Data\Yale0502			
2/17/2005	11:08 AM	7,495	024507_ct.csv
2/16/2005	10:03 AM	8,643	024506_ct.csv
2/15/2005	10:22 AM	8,275	024504_ct.csv
2/15/2005	11:31 AM	7,975	024501_ct.csv
2/10/2005	9:32 AM	7,399	018586_ct.csv
2/18/2005	10:16 AM	7,435	018584_ct.csv
2/18/2005	9:11 AM	6,835	018581_ct.csv
2/18/2005	12:40 PM	7,855	018580_ct.csv
2/7/2005	12:35 PM	7,501	018579_ct.csv
2/7/2005	11:23 AM	48,128	018578_ct.xls
2/7/2005	11:20 AM	8,205	018578_ct.csv
2/11/2005	10:00 AM	7,427	018577_ct.csv
2/9/2005	9:25 AM	7,585	018576_ct.csv
2/8/2005	1:30 PM	6,415	018575_ct.csv
2/8/2005	12:25 PM	7,129	018574_ct.csv
2/9/2005	11:44 AM	7,825	018573_ct.csv
2/7/2005	10:06 AM	4,365	018572_ct.csv
2/8/2005	11:20 AM	10,023	018571_ct.csv
2/8/2005	2:49 PM	50,688	018570_ct.xls
2/8/2005	2:45 PM	8,275	018570_ct.csv
2/9/2005	10:34 AM	7,675	018569_ct.csv
2/11/2005	11:30 AM	9,835	018567_ct.csv
2/18/2005	11:33 AM	8,695	024510_ct.csv
2/14/2005	1:36 PM	5,635	018583_ct.csv
2/14/2005	12:52 PM	6,587	018585_ct.csv
2/14/2005	2:20 PM	5,185	024503_ct.csv
2/14/2005	10:44 AM	7,795	024508_ct.csv
2/14/2005	11:56 AM	7,825	018582_ct.csv
7/8/2005	1:04 PM	177,664	018578_ct_manual.xls
7/8/2005	1:11 PM	152,064	018579_ct_manual.xls
29 Files		624,438 bytes	
\Phase II\Data\Yale0502\024510_pretest			
2/18/2005	10:30 AM	36,576	024510_pretest.dat
2/18/2005	10:24 AM	0	024510_pretest.ffm
2/18/2005	10:32 AM	524	024510_pretest.txt
2/18/2005	10:32 AM	341	024510_pretestFFM.csv
2/18/2005	10:32 AM	75,841	024510_pretestHWM.csv
5 Files		113,282 bytes	

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\Phase II\Data\Yale0502\024510_ffm
2/18/2005 11:05 AM 1,314,681 024510_ffm2.dat
2/18/2005 10:38 AM 0 024510_ffm2.ffm
2/18/2005 11:06 AM 754 024510_ffm2.txt
2/18/2005 11:06 AM 2,630,150 024510_ffm2FFM.csv
2/18/2005 11:06 AM 1,503 024510_ffm2HWM.csv
5 Files 3,947,088 bytes
\Phase II\Data\Yale0502\024510
2/18/2005 11:29 AM 976,788 024510.dat
2/18/2005 10:33 AM 0 024510.ffm
2/18/2005 11:30 AM 1,396 024510.txt
2/18/2005 11:30 AM 2,623 024510FFM.csv
2/18/2005 11:30 AM 837,170 024510HWM.csv
5 Files 1,817,977 bytes
\Phase II\Data\Yale0502\024508_ffm
2/14/2005 9:27 AM 1,204,835 024508_ffm.dat
2/14/2005 9:02 AM 0 024508_ffm.ffm
2/14/2005 9:28 AM 755 024508_ffm.txt
2/14/2005 9:28 AM 2,410,177 024508_ffmFFM.csv
2/14/2005 9:28 AM 1,386 024508_ffmHWM.csv
5 Files 3,617,153 bytes
\Phase II\Data\Yale0502\024507_pretest
2/17/2005 10:23 AM 102,369 024507_pretest.dat
2/17/2005 10:11 AM 0 024507_pretest.ffm
2/17/2005 10:23 AM 424 024507_pretest.txt
2/17/2005 10:23 AM 509 024507_pretestFFM.csv
2/17/2005 10:23 AM 209,593 024507_pretestHWM.csv
5 Files 312,895 bytes
\Phase II\Data\Yale0502\024507_ffm
2/17/2005 10:45 AM 834,757 024507_ffm.dat
2/17/2005 10:26 AM 0 024507_ffm.ffm
2/17/2005 10:45 AM 780 024507_ffm.txt
2/17/2005 10:45 AM 1,670,014 024507_ffmFFM.csv
2/17/2005 10:45 AM 948 024507_ffmHWM.csv
5 Files 2,506,499 bytes
\Phase II\Data\Yale0502\024507
2/17/2005 11:04 AM 909,835 024507.dat
2/17/2005 10:26 AM 0 024507.ffm
2/17/2005 11:04 AM 1,117 024507.txt
2/17/2005 11:04 AM 1,663 024507FFM.csv
2/17/2005 11:04 AM 564,482 024507HWM.csv
5 Files 1,477,097 bytes
\Phase II\Data\Yale0502\024506_pretest
2/16/2005 8:58 AM 544 024506FFM_pretest.csv
2/16/2005 8:58 AM 231,316 024506HWM_pretest.csv
2/16/2005 8:58 AM 109,309 024506_pretest.dat
2/16/2005 8:44 AM 0 024506_pretest.ffm
2/16/2005 8:58 AM 525 024506_pretest.txt
5 Files 341,694 bytes
\Phase II\Data\Yale0502\024506_ffm
2/16/2005 9:35 AM 1,353,023 024506_ffm.dat
2/16/2005 9:05 AM 0 024506_ffm.ffm

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2/16/2005	9:35 AM	899	024506_ffm.txt
2/16/2005	9:35 AM	2,706,850	024506_ffmFFM.csv
2/16/2005	9:35 AM	1,572	024506_ffmHWM.csv
	5 Files	4,062,344	bytes
			\\Phase II\Data\Yale0502\024506
2/16/2005	9:57 AM	946,447	024506.dat
2/16/2005	9:05 AM	0	024506.ffm
2/16/2005	9:57 AM	1,395	024506.txt
2/16/2005	9:57 AM	2,319	024506FFM.csv
2/16/2005	9:57 AM	819,442	024506HWM.csv
	5 Files	1,769,603	bytes
			\\Phase II\Data\Yale0502\024504_pretest
2/15/2005	9:00 AM	31,867	Subject 19.dat
2/15/2005	8:56 AM	0	Subject 19.ffm
2/15/2005	9:00 AM	318	Subject 19.txt
2/15/2005	9:00 AM	173	Subject 19FFM.csv
2/15/2005	9:00 AM	66,954	Subject 19HWM.csv
	5 Files	99,312	bytes
			\\Phase II\Data\Yale0502\024504_ffm
2/15/2005	9:51 AM	1,588,292	024504_ffm.dat
2/15/2005	9:17 AM	0	024504_ffm.ffm
2/15/2005	9:51 AM	964	024504_ffm.txt
2/15/2005	9:51 AM	3,177,592	024504_ffmFFM.csv
2/15/2005	9:51 AM	1,835	024504_ffmHWM.csv
	5 Files	4,768,683	bytes
			\\Phase II\Data\Yale0502\024504
2/15/2005	10:18 AM	1,036,392	024504.dat
2/15/2005	9:16 AM	0	024504.ffm
2/15/2005	10:19 AM	1,197	024504.txt
2/15/2005	10:19 AM	2,839	024504FFM.csv
2/15/2005	10:18 AM	1,005,636	024504HWM.csv
	5 Files	2,046,064	bytes
			\\Phase II\Data\Yale0502\024503_ffm
2/14/2005	1:00 PM	437,093	024503_ffm.dat
2/14/2005	12:51 PM	0	024503_ffm.ffm
2/14/2005	1:00 PM	492	024503_ffm.txt
2/14/2005	1:00 PM	874,453	024503_ffmFFM.csv
2/14/2005	1:00 PM	528	024503_ffmHWM.csv
	5 Files	1,312,566	bytes
			\\Phase II\Data\Yale0502\024501_pretest
2/15/2005	10:36 AM	46,481	024501_pretest.dat
2/15/2005	10:29 AM	0	024501_pretest.ffm
2/15/2005	10:36 AM	369	024501_pretest.txt
2/15/2005	10:36 AM	278	024501_pretestFFM.csv
2/15/2005	10:36 AM	98,262	024501_pretestHWM.csv
	5 Files	145,390	bytes
			\\Phase II\Data\Yale0502\024501_ffm
2/15/2005	11:04 AM	1,149,289	024501_ffm.dat
2/15/2005	10:39 AM	0	024501_ffm.ffm
2/15/2005	11:04 AM	897	024501_ffm.txt
2/15/2005	11:04 AM	2,299,266	024501_ffmFFM.csv
2/15/2005	11:04 AM	1,347	024501_ffmHWM.csv

5 Files	3,450,799 bytes
	\Phase II\Data\Yale0502\024501
2/15/2005 11:28 AM	842,088 024501.dat
2/15/2005 10:39 AM	0 024501.ffm
2/15/2005 11:28 AM	1,282 024501.txt
2/15/2005 11:28 AM	2,247 024501FFM.csv
2/15/2005 11:28 AM	802,368 024501HWM.csv
5 Files	1,647,985 bytes
	\Phase II\Data\Yale0502\018773_testdata
2/9/2005 10:50 AM	21,817 018773_testdata.dat
2/9/2005 10:47 AM	0 018773_testdata.ffm
2/9/2005 10:50 AM	171 018773_testdata.txt
2/9/2005 10:50 AM	131 018773_testdataFFM.csv
2/9/2005 10:50 AM	46,956 018773_testdataHWM.csv
5 Files	69,075 bytes
	\Phase II\Data\Yale0502\018586_testdata
2/10/2005 8:38 AM	25,352 018586_testdata.dat
2/10/2005 8:31 AM	0 018586_testdata.ffm
2/10/2005 8:38 AM	171 018586_testdata.txt
2/10/2005 8:38 AM	341 018586_testdataFFM.csv
2/10/2005 8:38 AM	55,039 018586_testdataHWM.csv
5 Files	80,903 bytes
	\Phase II\Data\Yale0502\018586_ffm
2/10/2005 9:06 AM	1,039,773 018586_ffm.dat
2/10/2005 8:43 AM	0 018586_ffm.ffm
2/10/2005 9:06 AM	708 018586_ffm.txt
2/10/2005 9:06 AM	2,080,003 018586_ffmFFM.csv
2/10/2005 9:06 AM	1,180 018586_ffmHWM.csv
5 Files	3,121,664 bytes
	\Phase II\Data\Yale0502\018586
2/10/2005 9:27 AM	321,878 018586.dat
2/10/2005 8:43 AM	0 018586.ffm
2/10/2005 9:27 AM	1,042 018586.txt
2/10/2005 9:27 AM	1,983 018586FFM.csv
2/10/2005 9:27 AM	719,112 018586HWM.csv
5 Files	1,044,015 bytes
	\Phase II\Data\Yale0502\018585_ffm
2/14/2005 11:37 AM	1,170,881 018585_ffm.dat
2/14/2005 11:12 AM	0 018585_ffm.ffm
2/14/2005 11:37 AM	948 018585_ffm.txt
2/14/2005 11:37 AM	2,342,411 018585_ffmFFM.csv
2/14/2005 11:37 AM	1,373 018585_ffmHWM.csv
5 Files	3,515,613 bytes
	\Phase II\Data\Yale0502\018584_pretest
2/18/2005 9:28 AM	55,348 018584_pretest.dat
2/18/2005 9:22 AM	0 018584_pretest.ffm
2/18/2005 9:28 AM	375 018584_pretest.txt
2/18/2005 9:28 AM	285 018584_pretestFFM.csv
2/18/2005 9:28 AM	113,832 018584_pretestHWM.csv
5 Files	169,840 bytes
	\Phase II\Data\Yale0502\018584_ffm
2/18/2005 9:49 AM	752,880 018584_ffm.dat

2/18/2005	9:33 AM	0	018584_ffm.ffm
2/18/2005	9:49 AM	631	018584_ffm.txt
2/18/2005	9:49 AM	1,506,215	018584_ffmFFM.csv
2/18/2005	9:49 AM	854	018584_ffmHWM.csv
	5 Files	2,260,580	bytes
			\\Phase II\Data\Yale0502\018584
2/18/2005	10:13 AM	678,010	018584.dat
2/18/2005	9:33 AM	0	018584.ffm
2/18/2005	10:13 AM	1,046	018584.txt
2/18/2005	10:13 AM	1,807	018584FFM.csv
2/18/2005	10:13 AM	670,118	018584HWM.csv
	5 Files	1,350,981	bytes
			\\Phase II\Data\Yale0502\018583_ffm
2/14/2005	12:19 PM	573,304	018583_ffm.dat
2/14/2005	12:06 PM	0	018583_ffm.ffm
2/14/2005	12:19 PM	492	018583_ffm.txt
2/14/2005	12:19 PM	1,146,993	018583_ffmFFM.csv
2/14/2005	12:19 PM	664	018583_ffmHWM.csv
	5 Files	1,721,453	bytes
			\\Phase II\Data\Yale0502\018582_ffm
2/14/2005	10:27 AM	1,083,746	018582_ffm.dat
2/14/2005	10:04 AM	0	018582_ffm.ffm
2/14/2005	10:27 AM	807	018582_ffm.txt
2/14/2005	10:27 AM	2,168,172	018582_ffmFFM.csv
2/14/2005	10:27 AM	1,250	018582_ffmHWM.csv
	5 Files	3,253,975	bytes
			\\Phase II\Data\Yale0502\018581_pretest
2/18/2005	8:28 AM	65,489	018581_pretest.dat
2/18/2005	8:21 AM	0	018581_pretest.ffm
2/18/2005	8:28 AM	408	018581_pretest.txt
2/18/2005	8:28 AM	327	018581_pretestFFM.csv
2/18/2005	8:28 AM	136,847	018581_pretestHWM.csv
	5 Files	203,071	bytes
			\\Phase II\Data\Yale0502\018581_ffm
2/18/2005	8:49 AM	606,453	018581_ffm.dat
2/18/2005	8:35 AM	0	018581_ffm.ffm
2/18/2005	8:49 AM	583	018581_ffm.txt
2/18/2005	8:49 AM	1,213,266	018581_ffmFFM.csv
2/18/2005	8:49 AM	702	018581_ffmHWM.csv
	5 Files	1,821,004	bytes
			\\Phase II\Data\Yale0502\018581
2/18/2005	9:08 AM	568,578	018581.dat
2/18/2005	8:36 AM	0	018581.ffm
2/18/2005	9:09 AM	904	018581.txt
2/18/2005	9:08 AM	1,463	018581FFM.csv
2/18/2005	9:09 AM	472,478	018581HWM.csv
	5 Files	1,043,423	bytes
			\\Phase II\Data\Yale0502\018580_pretest
2/18/2005	11:47 AM	40,060	018580_pretest.dat
2/18/2005	11:40 AM	0	018580_pretest.ffm
2/18/2005	11:47 AM	327	018580_pretest.txt
2/18/2005	11:46 AM	271	018580_pretestFFM.csv

2/18/2005 11:47 AM	84,764 018580_pretestHWM.csv
5 Files	125,422 bytes
	\Phase II\Data\Yale0502\018580_ffm
2/18/2005 12:09 PM	900,873 018580_ffm.dat
2/18/2005 11:50 AM	0 018580_ffm.ffm
2/18/2005 12:09 PM	718 018580_ffm.txt
2/18/2005 12:09 PM	1,802,288 018580_ffmFFM.csv
2/18/2005 12:09 PM	1,036 018580_ffmHWM.csv
5 Files	2,704,915 bytes
	\Phase II\Data\Yale0502\018580
2/18/2005 12:37 PM	902,348 018580.dat
2/18/2005 11:50 AM	0 018580.ffm
2/18/2005 12:37 PM	1,211 018580.txt
2/18/2005 12:37 PM	2,167 018580FFM.csv
2/18/2005 12:37 PM	762,421 018580HWM.csv
5 Files	1,668,147 bytes
	\Phase II\Data\Yale0502\018579_ffm
2/7/2005 12:10 PM	1,297,328 018579_ffm.dat
2/7/2005 11:37 AM	0 018579_ffm.ffm
2/7/2005 12:10 PM	398 018579_ffm.txt
2/7/2005 12:10 PM	2,595,586 018579_ffmFFM.csv
2/7/2005 12:10 PM	1,427 018579_ffmHWM.csv
5 Files	3,894,739 bytes
	\Phase II\Data\Yale0502\018579
2/7/2005 12:31 PM	1,340,807 018579.dat
2/7/2005 11:37 AM	0 018579.ffm
2/7/2005 12:32 PM	1,082 018579.txt
2/7/2005 12:31 PM	2,271 018579FFM.csv
2/7/2005 12:31 PM	852,574 018579HWM.csv
5 Files	2,196,734 bytes
	\Phase II\Data\Yale0502\018578_ffm
2/7/2005 10:49 AM	1,322,380 018578_ffm.dat
2/7/2005 10:17 AM	0 018578_ffm.ffm
2/7/2005 10:50 AM	381 018578_ffm.txt
2/7/2005 10:49 AM	2,645,615 018578_ffmFFM.csv
2/7/2005 10:49 AM	1,562 018578_ffmHWM.csv
5 Files	3,969,938 bytes
	\Phase II\Data\Yale0502\018578
2/7/2005 11:15 AM	2,439,802 018578.dat
2/7/2005 10:15 AM	0 018578.ffm
2/7/2005 11:15 AM	1,578 018578.txt
2/7/2005 11:15 AM	2,639 018578FFM.csv
2/7/2005 11:15 AM	892,807 018578HWM.csv
5 Files	3,336,826 bytes
	\Phase II\Data\Yale0502\018577_pretest
2/11/2005 9:15 AM	95,145 018577_pretest.dat
2/11/2005 9:04 AM	0 018577_pretest.ffm
2/11/2005 9:15 AM	171 018577_pretest.txt
2/11/2005 9:15 AM	488 018577_pretestFFM.csv
2/11/2005 9:15 AM	228,592 018577_pretestHWM.csv
5 Files	324,396 bytes
	\Phase II\Data\Yale0502\018577_ffm

2/11/2005	9:32 AM	516,428	018577_ffm.dat
2/11/2005	9:20 AM	0	018577_ffm.ffm
2/11/2005	9:32 AM	647	018577_ffm.txt
2/11/2005	9:32 AM	1,033,168	018577_ffmFFM.csv
2/11/2005	9:32 AM	654	018577_ffmHWM.csv
	5 Files	1,550,897	bytes
			\\Phase II\Data\Yale0502\018577
2/11/2005	9:56 AM	572,072	018577.dat
2/11/2005	9:19 AM	0	018577_ffm
2/11/2005	9:57 AM	983	018577.txt
2/11/2005	9:56 AM	1,663	018577FFM.csv
2/11/2005	9:56 AM	550,894	018577HWM.csv
	5 Files	1,125,612	bytes
			\\Phase II\Data\Yale0502\018576_testdata
2/9/2005	8:17 AM	23,196	018576_testdata.dat
2/9/2005	8:14 AM	0	018576_testdata.ffm
2/9/2005	8:17 AM	171	018576_testdata.txt
2/9/2005	8:16 AM	131	018576_testdataFFM.csv
2/9/2005	8:17 AM	49,300	018576_testdataHWM.csv
	5 Files	72,798	bytes
			\\Phase II\Data\Yale0502\018576_ffm
2/9/2005	9:00 AM	1,179,029	018576_ffm.dat
2/9/2005	8:33 AM	0	018576_ffm.ffm
2/9/2005	9:00 AM	625	018576_ffm.txt
2/9/2005	9:00 AM	2,358,893	018576_ffmFFM.csv
2/9/2005	8:59 AM	1,317	018576_ffmHWM.csv
	5 Files	3,539,864	bytes
			\\Phase II\Data\Yale0502\018576
2/9/2005	9:20 AM	915,127	018576.dat
2/9/2005	8:34 AM	0	018576.ffm
2/9/2005	9:21 AM	954	018576.txt
2/9/2005	9:21 AM	2,111	018576FFM.csv
2/9/2005	9:21 AM	785,629	018576HWM.csv
	5 Files	1,703,821	bytes
			\\Phase II\Data\Yale0502\018575_testdata
2/8/2005	12:43 PM	2,423	018575_testdata.dat
2/8/2005	12:42 PM	0	018575_testdata.ffm
2/8/2005	12:44 PM	171	018575_testdata.txt
2/8/2005	12:44 PM	124	018575_testdataFFM.csv
2/8/2005	12:44 PM	5,431	018575_testdataHWM.csv
	5 Files	8,149	bytes
			\\Phase II\Data\Yale0502\018575_ffm
2/8/2005	1:10 PM	967,490	018575_ffm.dat
2/8/2005	12:46 PM	0	018575_ffm.ffm
2/8/2005	1:10 PM	535	018575_ffm.txt
2/8/2005	1:10 PM	1,935,644	018575_ffmFFM.csv
2/8/2005	1:10 PM	1,086	018575_ffmHWM.csv
	5 Files	2,904,755	bytes
			\\Phase II\Data\Yale0502\018575
2/8/2005	1:25 PM	681,266	018575.dat
2/8/2005	12:47 PM	0	018575.ffm
2/8/2005	1:25 PM	724	018575.txt

2/8/2005	1:25 PM	1,671	018575FFM.csv
2/8/2005	1:25 PM	646,471	018575HWM.csv
	5 Files	1,330,132	bytes
			\\Phase II\Data\Yale0502\018574_ffm
2/8/2005	11:56 AM	634,442	018574_ffm.dat
2/8/2005	11:42 AM	0	018574_ffm.ffm
2/8/2005	11:56 AM	171	018574_ffm.txt
2/8/2005	11:56 AM	1,269,325	018574_ffmFFM.csv
2/8/2005	11:56 AM	663	018574_ffmHWM.csv
	5 Files	1,904,601	bytes
			\\Phase II\Data\Yale0502\018574
2/8/2005	12:21 PM	927,260	018574.dat
2/8/2005	11:36 AM	0	018574.ffm
2/8/2005	12:21 PM	1,070	018574.txt
2/8/2005	12:21 PM	1,832	018574FFM.csv
2/8/2005	12:21 PM	737,977	018574HWM.csv
	5 Files	1,668,139	bytes
			\\Phase II\Data\Yale0502\018573_ffm
2/9/2005	11:17 AM	948,256	018573_ffm.dat
2/9/2005	10:57 AM	0	018573_ffm.ffm
2/9/2005	11:17 AM	577	018573_ffm.txt
2/9/2005	11:17 AM	1,897,136	018573_ffmFFM.csv
2/9/2005	11:17 AM	1,066	018573_ffmHWM.csv
	5 Files	2,847,035	bytes
			\\Phase II\Data\Yale0502\018573
2/9/2005	11:40 AM	783,697	018573.dat
2/9/2005	10:56 AM	0	018573.ffm
2/9/2005	11:40 AM	1,032	018573.txt
2/9/2005	11:40 AM	1,999	018573FFM.csv
2/9/2005	11:40 AM	679,415	018573HWM.csv
	5 Files	1,466,143	bytes
			\\Phase II\Data\Yale0502\018572_ffm
2/7/2005	9:49 AM	0	018572.ffm
2/7/2005	10:02 AM	151	018572.txt
2/7/2005	10:02 AM	1,239,989	018572FFM.csv
2/7/2005	10:02 AM	619,783	018572ffm.dat
2/7/2005	10:02 AM	678	018572HWM.csv
	5 Files	1,860,601	bytes
			\\Phase II\Data\Yale0502\018572
2/7/2005	10:01 AM	760,018	018572.dat
2/7/2005	9:40 AM	0	018572.ffm
2/7/2005	10:01 AM	1,006	018572.txt
2/7/2005	10:01 AM	973	018572FFM.csv
2/7/2005	10:01 AM	282,182	018572HWM.csv
	5 Files	1,044,179	bytes
			\\Phase II\Data\Yale0502\018571pretest
2/8/2005	10:16 AM	119,660	018571pretest.dat
2/8/2005	9:59 AM	0	018571pretest.ffm
2/8/2005	10:17 AM	320	018571pretest.txt
2/8/2005	10:17 AM	743	018571pretestFFM.csv
2/8/2005	10:17 AM	262,751	018571pretestHWM.csv
	5 Files	383,474	bytes

		\\Phase II\Data\Yale0502\018571_ffm
2/8/2005 10:51 AM	902,750	018571_ffm.dat
2/8/2005 10:30 AM	0	018571_ffm.ffm
2/8/2005 10:51 AM	229	018571_ffm.txt
2/8/2005 10:51 AM	1,806,110	018571_ffmFFM.csv
2/8/2005 10:51 AM	983	018571_ffmHWM.csv
5 Files	2,710,072	bytes
		\\Phase II\Data\Yale0502\018571
2/8/2005 11:15 AM	1,185,286	018571.dat
2/8/2005 10:31 AM	0	018571.ffm
2/8/2005 11:16 AM	892	018571.txt
2/8/2005 11:16 AM	2,097	018571FFM.csv
2/8/2005 11:16 AM	778,865	018571HWM.csv
5 Files	1,967,140	bytes
		\\Phase II\Data\Yale0502\018570_pretest
2/8/2005 1:40 PM	5,786	018570_pretest.dat
2/8/2005 1:40 PM	0	018570_pretest.ffm
2/8/2005 1:41 PM	171	018570_pretest.txt
2/8/2005 1:41 PM	59	018570_pretestFFM.csv
2/8/2005 1:41 PM	13,022	018570_pretestHWM.csv
5 Files	19,038	bytes
		\\Phase II\Data\Yale0502\018570_ffm
2/8/2005 2:05 PM	953,767	018570_ffm.dat
2/8/2005 1:44 PM	0	018570_ffm.ffm
2/8/2005 2:05 PM	615	018570_ffm.txt
2/8/2005 2:05 PM	1,908,161	018570_ffmFFM.csv
2/8/2005 2:05 PM	1,065	018570_ffmHWM.csv
5 Files	2,863,608	bytes
		\\Phase II\Data\Yale0502\018570
2/8/2005 2:42 PM	731,501	018570.dat
2/8/2005 1:44 PM	0	018570.ffm
2/8/2005 2:42 PM	895	018570.txt
2/8/2005 2:42 PM	2,647	018570FFM.csv
2/8/2005 2:42 PM	1,115,062	018570HWM.csv
5 Files	1,850,105	bytes
		\\Phase II\Data\Yale0502\018569_ffm
2/9/2005 10:12 AM	1,156,350	018569_ffm.dat
2/9/2005 9:47 AM	0	018569_ffm.ffm
2/9/2005 10:12 AM	757	018569_ffm.txt
2/9/2005 10:12 AM	2,313,353	018569_ffmFFM.csv
2/9/2005 10:12 AM	1,341	018569_ffmHWM.csv
5 Files	3,471,801	bytes
		\\Phase II\Data\Yale0502\018569
2/9/2005 10:31 AM	875,580	018569.dat
2/9/2005 9:46 AM	0	018569.ffm
2/9/2005 10:31 AM	1,034	018569.txt
2/9/2005 10:31 AM	2,047	018569FFM.csv
2/9/2005 10:31 AM	809,428	018569HWM.csv
5 Files	1,688,089	bytes
		\\Phase II\Data\Yale0502\018567_pretest
2/11/2005 10:15 AM	9,286	018567_pretest.dat
2/11/2005 10:09 AM	0	018567_pretest.ffm

Principal Investigator/Program Director (Last, First, Middle): Wiesmann, William P.

2/11/2005 10:15 AM	171 018567_pretest.txt
2/11/2005 10:15 AM	271 018567_pretestFFM.csv
2/11/2005 10:15 AM	19,320 018567_pretestHWM.csv
5 Files	29,048 bytes
	\\Phase II\Data\Yale0502\018567_ffm
2/11/2005 10:40 AM	961,650 018567_ffm.dat
2/11/2005 10:19 AM	0 018567_ffm.ffm
2/11/2005 10:40 AM	723 018567_ffm.txt
2/11/2005 10:40 AM	1,923,889 018567_ffmFFM.csv
2/11/2005 10:40 AM	1,066 018567_ffmHWM.csv
5 Files	2,887,328 bytes
	\\Phase II\Data\Yale0502\018567
2/11/2005 11:27 AM	1,167,726 018567.dat
2/11/2005 10:18 AM	0 018567.ffm
2/11/2005 11:28 AM	1,111 018567.txt
2/11/2005 11:28 AM	3,183 018567FFM.csv
2/11/2005 11:28 AM	1,104,411 018567HWM.csv
5 Files	2,276,431 bytes
	\\Phase II\Data\Yale0502\analyze
6/8/2005 1:33 PM	2,825 018567_A_Events.csv
6/8/2005 1:33 PM	1,109,735 018567_A_Red.csv
6/8/2005 1:33 PM	1,110,569 018567_A_IR.csv
6/8/2005 1:33 PM	9,954 018567_A_DI.csv
6/8/2005 1:33 PM	220,725 018567_A_MAM.csv
6/8/2005 1:33 PM	569,959 018567_A_LRRIR.csv
6/8/2005 1:33 PM	2,171,984 018567_A_Var.csv
6/8/2005 1:33 PM	38,705 018567_A_FFpeaks.csv
6/8/2005 1:33 PM	5,423 018567_A_CTHR.csv
6/8/2005 1:33 PM	5,785,507 018567_A_All.csv
6/8/2005 1:35 PM	2,665 018569_A_Events.csv
6/8/2005 1:35 PM	754,105 018569_A_Red.csv
6/8/2005 1:35 PM	753,794 018569_A_IR.csv
6/8/2005 1:35 PM	6,400 018569_A_DI.csv
6/8/2005 1:35 PM	152,452 018569_A_MAM.csv
6/8/2005 1:35 PM	390,387 018569_A_LRRIR.csv
6/8/2005 1:35 PM	1,480,873 018569_A_Var.csv
6/8/2005 1:36 PM	39,795 018569_A_FFpeaks.csv
6/8/2005 1:36 PM	3,829 018569_A_CTHR.csv
6/8/2005 1:36 PM	3,950,674 018569_A_All.csv
6/8/2005 1:36 PM	2,265 018570_A_Events.csv
6/8/2005 1:36 PM	1,041,310 018570_A_Red.csv
6/8/2005 1:36 PM	1,041,542 018570_A_IR.csv
6/8/2005 1:36 PM	8,132 018570_A_DI.csv
6/8/2005 1:36 PM	211,167 018570_A_MAM.csv
6/8/2005 1:36 PM	539,900 018570_A_LRRIR.csv
6/8/2005 1:36 PM	2,042,317 018570_A_Var.csv
6/8/2005 1:37 PM	50,096 018570_A_FFpeaks.csv
6/8/2005 1:37 PM	4,265 018570_A_CTHR.csv
6/8/2005 1:37 PM	5,446,354 018570_A_All.csv
6/8/2005 1:37 PM	2,007 018571_A_Events.csv
6/8/2005 1:37 PM	716,761 018571_A_Red.csv
6/8/2005 1:37 PM	716,903 018571_A_IR.csv

6/8/2005	1:37 PM	6,538	018571_A_DI.csv
6/8/2005	1:37 PM	144,846	018571_A_MAM.csv
6/8/2005	1:37 PM	369,187	018571_A_LRRIR.csv
6/8/2005	1:37 PM	1,407,166	018571_A_Var.csv
6/8/2005	1:37 PM	191,266	018571_A_FFpeaks.csv
6/8/2005	1:37 PM	5,634	018571_A_CTHR.csv
6/8/2005	1:38 PM	3,833,869	018571_A_All.csv
6/8/2005	1:40 PM	1,577	018572_A_Events.csv
6/8/2005	1:40 PM	270,155	018572_A_Red.csv
6/8/2005	1:40 PM	270,814	018572_A_IR.csv
6/8/2005	1:40 PM	3,095	018572_A_DI.csv
6/8/2005	1:40 PM	54,582	018572_A_MAM.csv
6/8/2005	1:40 PM	139,597	018572_A_LRRIR.csv
6/8/2005	1:40 PM	534,053	018572_A_Var.csv
6/8/2005	1:40 PM	35	018572_A_FFpeaks.csv
6/8/2005	1:40 PM	29	018572_A_CTHR.csv
6/8/2005	1:40 PM	1,413,829	018572_A_All.csv
6/8/2005	1:41 PM	2,813	018573_A_Events.csv
6/8/2005	1:41 PM	689,055	018573_A_Red.csv
6/8/2005	1:41 PM	689,131	018573_A_IR.csv
6/8/2005	1:41 PM	6,330	018573_A_DI.csv
6/8/2005	1:41 PM	138,134	018573_A_MAM.csv
6/8/2005	1:41 PM	357,349	018573_A_LRRIR.csv
6/8/2005	1:41 PM	1,355,554	018573_A_Var.csv
6/8/2005	1:41 PM	19,271	018573_A_FFpeaks.csv
6/8/2005	1:41 PM	3,952	018573_A_CTHR.csv
6/8/2005	1:41 PM	3,605,199	018573_A_All.csv
6/8/2005	1:41 PM	2,351	018574_A_Events.csv
6/8/2005	1:41 PM	680,565	018574_A_Red.csv
6/8/2005	1:41 PM	682,050	018574_A_IR.csv
6/8/2005	1:41 PM	5,702	018574_A_DI.csv
6/8/2005	1:41 PM	138,788	018574_A_MAM.csv
6/8/2005	1:41 PM	353,055	018574_A_LRRIR.csv
6/8/2005	1:41 PM	1,343,433	018574_A_Var.csv
6/8/2005	1:41 PM	18,404	018574_A_FFpeaks.csv
6/8/2005	1:41 PM	3,292	018574_A_CTHR.csv
6/8/2005	1:42 PM	3,570,024	018574_A_All.csv
6/8/2005	1:42 PM	1,756	018575_A_Events.csv
6/8/2005	1:42 PM	597,190	018575_A_Red.csv
6/8/2005	1:42 PM	598,473	018575_A_IR.csv
6/8/2005	1:42 PM	5,274	018575_A_DI.csv
6/8/2005	1:42 PM	121,462	018575_A_MAM.csv
6/8/2005	1:42 PM	311,318	018575_A_LRRIR.csv
6/8/2005	1:42 PM	1,180,624	018575_A_Var.csv
6/8/2005	1:42 PM	22,149	018575_A_FFpeaks.csv
6/8/2005	1:42 PM	2,915	018575_A_CTHR.csv
6/8/2005	1:42 PM	3,139,725	018575_A_All.csv
6/8/2005	1:42 PM	2,407	018576_A_Events.csv
6/8/2005	1:42 PM	778,724	018576_A_Red.csv
6/8/2005	1:42 PM	778,957	018576_A_IR.csv
6/8/2005	1:42 PM	6,584	018576_A_DI.csv
6/8/2005	1:42 PM	157,656	018576_A_MAM.csv

6/8/2005	1:42 PM	401,690	018576_A_LRRIR.csv
6/8/2005	1:42 PM	1,529,428	018576_A_Var.csv
6/8/2005	1:43 PM	23,628	018576_A_FFpeaks.csv
6/8/2005	1:43 PM	3,738	018576_A_CTHR.csv
6/8/2005	1:43 PM	4,069,963	018576_A_All.csv
6/8/2005	1:43 PM	2,038	018577_A_Events.csv
6/8/2005	1:43 PM	559,041	018577_A_Red.csv
6/8/2005	1:43 PM	560,120	018577_A_IR.csv
6/8/2005	1:43 PM	5,298	018577_A_DI.csv
6/8/2005	1:43 PM	112,963	018577_A_MAM.csv
6/8/2005	1:43 PM	290,539	018577_A_LRRIR.csv
6/8/2005	1:43 PM	1,102,607	018577_A_Var.csv
6/8/2005	1:43 PM	16,752	018577_A_FFpeaks.csv
6/8/2005	1:43 PM	3,566	018577_A_CTHR.csv
6/8/2005	1:43 PM	2,931,894	018577_A_All.csv
6/8/2005	1:43 PM	3,410	018578_A_Events.csv
6/8/2005	1:43 PM	835,589	018578_A_Red.csv
6/8/2005	1:43 PM	836,448	018578_A_IR.csv
6/8/2005	1:43 PM	8,358	018578_A_DI.csv
6/8/2005	1:43 PM	165,660	018578_A_MAM.csv
6/8/2005	1:43 PM	431,158	018578_A_LRRIR.csv
6/8/2005	1:43 PM	1,634,871	018578_A_Var.csv
6/8/2005	1:44 PM	153,724	018578_A_FFpeaks.csv
6/8/2005	1:44 PM	29	018578_A_CTHR.csv
6/8/2005	1:44 PM	4,419,035	018578_A_All.csv
6/8/2005	1:45 PM	2,446	018579_A_Events.csv
6/8/2005	1:45 PM	818,357	018579_A_Red.csv
6/8/2005	1:45 PM	818,584	018579_A_IR.csv
6/8/2005	1:45 PM	7,067	018579_A_DI.csv
6/8/2005	1:45 PM	164,828	018579_A_MAM.csv
6/8/2005	1:45 PM	422,449	018579_A_LRRIR.csv
6/8/2005	1:45 PM	1,604,591	018579_A_Var.csv
6/8/2005	1:45 PM	37,661	018579_A_FFpeaks.csv
6/8/2005	1:45 PM	29	018579_A_CTHR.csv
6/8/2005	1:45 PM	4,275,435	018579_A_All.csv
6/8/2005	1:46 PM	3,091	018580_A_Events.csv
6/8/2005	1:46 PM	759,393	018580_A_Red.csv
6/8/2005	1:46 PM	760,270	018580_A_IR.csv
6/8/2005	1:46 PM	6,838	018580_A_DI.csv
6/8/2005	1:46 PM	150,619	018580_A_MAM.csv
6/8/2005	1:46 PM	388,233	018580_A_LRRIR.csv
6/8/2005	1:46 PM	1,492,693	018580_A_Var.csv
6/8/2005	1:46 PM	32,838	018580_A_FFpeaks.csv
6/8/2005	1:46 PM	3,968	018580_A_CTHR.csv
6/8/2005	1:46 PM	3,973,084	018580_A_All.csv
6/8/2005	1:47 PM	2,188	018581_A_Events.csv
6/8/2005	1:47 PM	468,392	018581_A_Red.csv
6/8/2005	1:47 PM	469,202	018581_A_IR.csv
6/8/2005	1:47 PM	4,714	018581_A_DI.csv
6/8/2005	1:47 PM	93,558	018581_A_MAM.csv
6/8/2005	1:47 PM	244,642	018581_A_LRRIR.csv
6/8/2005	1:47 PM	928,473	018581_A_Var.csv

6/8/2005	1:47 PM	23,637	018581_A_FFpeaks.csv
6/8/2005	1:47 PM	3,094	018581_A_CTHR.csv
6/8/2005	1:47 PM	2,469,951	018581_A_All.csv
6/8/2005	2:14 PM	2,035	018583_A_Events.csv
6/8/2005	2:15 PM	3,476	018585_A_Events.csv
6/8/2005	1:50 PM	2,588	018584_A_Events.csv
6/8/2005	1:50 PM	668,833	018584_A_Red.csv
6/8/2005	1:50 PM	669,480	018584_A_IR.csv
6/8/2005	1:50 PM	5,631	018584_A_DI.csv
6/8/2005	1:50 PM	135,412	018584_A_MAM.csv
6/8/2005	1:50 PM	346,667	018584_A_LRRIR.csv
6/8/2005	1:50 PM	1,317,615	018584_A_Var.csv
6/8/2005	1:51 PM	25,539	018584_A_FFpeaks.csv
6/8/2005	1:51 PM	3,646	018584_A_CTHR.csv
6/8/2005	1:51 PM	3,506,828	018584_A_All.csv
6/8/2005	1:51 PM	2,664	018586_A_Events.csv
6/8/2005	1:51 PM	655,067	018586_A_Red.csv
6/8/2005	1:51 PM	655,231	018586_A_IR.csv
6/8/2005	1:51 PM	6,290	018586_A_DI.csv
6/8/2005	1:51 PM	130,001	018586_A_MAM.csv
6/8/2005	1:51 PM	338,788	018586_A_LRRIR.csv
6/8/2005	1:51 PM	1,291,638	018586_A_Var.csv
6/8/2005	1:51 PM	41,632	018586_A_FFpeaks.csv
6/8/2005	1:51 PM	3,623	018586_A_CTHR.csv
6/8/2005	1:51 PM	3,443,261	018586_A_All.csv
6/8/2005	1:59 PM	3,333	024501_A_Events.csv
6/8/2005	1:59 PM	812,512	024501_A_Red.csv
6/8/2005	1:59 PM	813,928	024501_A_IR.csv
6/8/2005	1:59 PM	7,048	024501_A_DI.csv
6/8/2005	1:59 PM	163,070	024501_A_MAM.csv
6/8/2005	1:59 PM	420,296	024501_A_LRRIR.csv
6/8/2005	1:59 PM	1,598,031	024501_A_Var.csv
6/8/2005	1:59 PM	33,420	024501_A_FFpeaks.csv
6/8/2005	1:59 PM	4,058	024501_A_CTHR.csv
6/8/2005	1:59 PM	4,254,990	024501_A_All.csv
6/8/2005	2:00 PM	3,083	024504_A_Events.csv
6/8/2005	2:00 PM	1,014,372	024504_A_Red.csv
6/8/2005	2:00 PM	1,015,632	024504_A_IR.csv
6/8/2005	2:00 PM	8,874	024504_A_DI.csv
6/8/2005	2:00 PM	202,374	024504_A_MAM.csv
6/8/2005	2:00 PM	520,398	024504_A_LRRIR.csv
6/8/2005	2:00 PM	1,988,887	024504_A_Var.csv
6/8/2005	2:01 PM	42,723	024504_A_FFpeaks.csv
6/8/2005	2:01 PM	4,247	024504_A_CTHR.csv
6/8/2005	2:01 PM	5,297,710	024504_A_All.csv
6/8/2005	2:01 PM	3,619	024506_A_Events.csv
6/8/2005	2:01 PM	821,757	024506_A_Red.csv
6/8/2005	2:01 PM	822,976	024506_A_IR.csv
6/8/2005	2:01 PM	7,283	024506_A_DI.csv
6/8/2005	2:01 PM	164,590	024506_A_MAM.csv
6/8/2005	2:01 PM	423,153	024506_A_LRRIR.csv
6/8/2005	2:01 PM	1,614,487	024506_A_Var.csv

6/8/2005	2:02 PM	43,678	024506_A_FFpeaks.csv
6/8/2005	2:02 PM	4,559	024506_A_CTHR.csv
6/8/2005	2:02 PM	4,304,838	024506_A_All.csv
6/8/2005	2:02 PM	2,424	024507_A_Events.csv
6/8/2005	2:02 PM	560,853	024507_A_Red.csv
6/8/2005	2:02 PM	560,799	024507_A_IR.csv
6/8/2005	2:02 PM	5,288	024507_A_DI.csv
6/8/2005	2:02 PM	111,567	024507_A_MAM.csv
6/8/2005	2:02 PM	289,214	024507_A_LRRIR.csv
6/8/2005	2:02 PM	1,104,486	024507_A_Var.csv
6/8/2005	2:02 PM	17,730	024507_A_FFpeaks.csv
6/8/2005	2:02 PM	2,430	024507_A_CTHR.csv
6/8/2005	2:02 PM	2,935,092	024507_A_All.csv
6/8/2005	2:04 PM	3,626	024510_A_Events.csv
6/8/2005	2:04 PM	833,863	024510_A_Red.csv
6/8/2005	2:04 PM	834,998	024510_A_IR.csv
6/8/2005	2:04 PM	8,317	024510_A_DI.csv
6/8/2005	2:04 PM	166,762	024510_A_MAM.csv
6/8/2005	2:04 PM	429,109	024510_A_LRRIR.csv
6/8/2005	2:04 PM	1,637,725	024510_A_Var.csv
6/8/2005	2:04 PM	35	024510_A_FFpeaks.csv
6/8/2005	2:04 PM	4,453	024510_A_CTHR.csv
6/8/2005	2:04 PM	4,344,669	024510_A_All.csv
6/8/2005	2:14 PM	3,486	018582_A_Events.csv
6/8/2005	2:14 PM	777,914	018582_A_Red.csv
6/8/2005	2:14 PM	779,254	018582_A_IR.csv
6/8/2005	2:14 PM	7,072	018582_A_DI.csv
6/8/2005	2:14 PM	155,395	018582_A_MAM.csv
6/8/2005	2:14 PM	400,949	018582_A_LRRIR.csv
6/8/2005	2:14 PM	1,529,741	018582_A_Var.csv
6/8/2005	2:14 PM	39,115	018582_A_FFpeaks.csv
6/8/2005	2:14 PM	3,932	018582_A_CTHR.csv
6/8/2005	2:14 PM	4,076,189	018582_A_All.csv
6/8/2005	2:14 PM	424,703	018583_A_Red.csv
6/8/2005	2:14 PM	424,779	018583_A_IR.csv
6/8/2005	2:14 PM	3,922	018583_A_DI.csv
6/8/2005	2:14 PM	85,697	018583_A_MAM.csv
6/8/2005	2:14 PM	222,043	018583_A_LRRIR.csv
6/8/2005	2:14 PM	842,130	018583_A_Var.csv
6/8/2005	2:15 PM	14,469	018583_A_FFpeaks.csv
6/8/2005	2:15 PM	2,343	018583_A_CTHR.csv
6/8/2005	2:15 PM	2,236,269	018583_A_All.csv
6/8/2005	2:15 PM	544,792	018585_A_Red.csv
6/8/2005	2:15 PM	545,347	018585_A_IR.csv
6/8/2005	2:15 PM	5,460	018585_A_DI.csv
6/8/2005	2:15 PM	108,847	018585_A_MAM.csv
6/8/2005	2:15 PM	279,836	018585_A_LRRIR.csv
6/8/2005	2:15 PM	1,074,570	018585_A_Var.csv
6/8/2005	2:15 PM	39,118	018585_A_FFpeaks.csv
6/8/2005	2:15 PM	3,038	018585_A_CTHR.csv
6/8/2005	2:15 PM	2,866,975	018585_A_All.csv
6/8/2005	2:16 PM	1,897	024503_A_Events.csv

6/8/2005	2:16 PM	346,305	024503_A_Red.csv
6/8/2005	2:16 PM	345,833	024503_A_IR.csv
6/8/2005	2:16 PM	3,632	024503_A_DI.csv
6/8/2005	2:16 PM	69,426	024503_A_MAM.csv
6/8/2005	2:16 PM	182,519	024503_A_LRRIR.csv
6/8/2005	2:16 PM	686,272	024503_A_Var.csv
6/8/2005	2:16 PM	14,058	024503_A_FFpeaks.csv
6/8/2005	2:16 PM	1,979	024503_A_CTHR.csv
6/8/2005	2:16 PM	1,824,771	024503_A_All.csv
6/8/2005	2:16 PM	3,217	024508_A_Events.csv
6/8/2005	2:16 PM	534,010	024508_A_Red.csv
6/8/2005	2:16 PM	534,140	024508_A_IR.csv
6/8/2005	2:16 PM	5,674	024508_A_DI.csv
6/8/2005	2:16 PM	104,832	024508_A_MAM.csv
6/8/2005	2:16 PM	277,900	024508_A_LRRIR.csv
6/8/2005	2:16 PM	1,052,707	024508_A_Var.csv
6/8/2005	2:16 PM	54,822	024508_A_FFpeaks.csv
6/8/2005	2:16 PM	3,902	024508_A_CTHR.csv
6/8/2005	2:16 PM	2,817,642	024508_A_All.csv
259 Files		180,823,423 bytes	
Directory of d:\Seko ts\NIOSH-S \Phase II\Data\Yale0502\018582			
2/14/2005	11:52 AM	919,834	018582.dat
2/14/2005	11:02 AM	0	018582.ffm
2/14/2005	11:53 AM	1,491	018582.txt
2/14/2005	11:53 AM	2,247	018582FFM.csv
2/14/2005	11:53 AM	803,745	018582HWM.csv
5 Files		1,727,317 bytes	
\Phase II\Data\Yale0502\018582_pretest			
2/14/2005	11:00 AM	34,267	018582_pretest.dat
2/14/2005	10:50 AM	0	018582_pretest.ffm
2/14/2005	11:00 AM	367	018582_pretest.txt
2/14/2005	11:00 AM	292	018582_pretestFFM.csv
2/14/2005	11:00 AM	71,576	018582_pretestHWM.csv
5 Files		106,502 bytes	
\Phase II\Data\Yale0502\018583			
2/14/2005	1:34 PM	505,686	018583.dat
2/14/2005	1:05 PM	0	018583.ffm
2/14/2005	1:34 PM	834	018583.txt
2/14/2005	1:34 PM	1,223	018583FFM.csv
2/14/2005	1:34 PM	433,583	018583HWM.csv
5 Files		941,326 bytes	
\Phase II\Data\Yale0502\018583_pretest			
2/14/2005	1:02 PM	32,786	018583_pretest.dat
2/14/2005	12:59 PM	0	018583_pretest.ffm
2/14/2005	1:02 PM	518	018583_pretest.txt
2/14/2005	1:02 PM	180	018583_pretestFFM.csv
2/14/2005	1:02 PM	67,003	018583_pretestHWM.csv
5 Files		100,487 bytes	
\Phase II\Data\Yale0502\018585			
2/14/2005	12:49 PM	937,068	018585.dat
2/14/2005	12:12 PM	0	018585.ffm
2/14/2005	12:50 PM	1,341	018585.txt

2/14/2005 12:50 PM	1,711 018585FFM.csv
2/14/2005 12:50 PM	563,096 018585HWM.csv
5 Files	1,503,216 bytes
	\Phase II\Data\Yale0502\018585_pretest
2/14/2005 12:09 PM	29,738 018585_pretest.dat
2/14/2005 12:04 PM	0 018585_pretest.ffm
2/14/2005 12:09 PM	369 018585_pretest.txt
2/14/2005 12:09 PM	201 018585_pretestFFM.csv
2/14/2005 12:09 PM	62,161 018585_pretestHWM.csv
5 Files	92,469 bytes
	\Phase II\Data\Yale0502\024510_ffm_first
2/18/2005 10:35 AM	12 024510_ffm.dat
2/18/2005 10:33 AM	0 024510_ffm.ffm
2/18/2005 10:37 AM	463 024510_ffm.txt
2/18/2005 10:37 AM	194 024510_ffmFFM.csv
2/18/2005 10:37 AM	244 024510_ffmHWM.csv
5 Files	913 bytes
	\Phase II\Data\Yale0502\024503
2/14/2005 2:16 PM	517,688 024503.dat
2/14/2005 1:50 PM	0 024503.ffm
2/14/2005 2:16 PM	855 024503.txt
2/14/2005 2:16 PM	1,111 024503FFM.csv
2/14/2005 2:16 PM	349,593 024503HWM.csv
5 Files	869,247 bytes
	\Phase II\Data\Yale0502\024503_pretest
2/14/2005 1:47 PM	38,186 024503_pretest.dat
2/14/2005 1:42 PM	0 024503_pretest.ffm
2/14/2005 1:47 PM	369 024503_pretest.txt
2/14/2005 1:47 PM	229 024503_pretestFFM.csv
2/14/2005 1:47 PM	78,333 024503_pretestHWM.csv
5 Files	117,117 bytes
	\Phase II\Data\Yale0502\024508
2/14/2005 10:41 AM	963,227 024508.dat
2/14/2005 10:01 AM	0 024508.ffm
2/14/2005 10:41 AM	1,404 024508.txt
2/14/2005 10:41 AM	1,759 024508FFM.csv
2/14/2005 10:41 AM	529,765 024508HWM.csv
5 Files	1,496,155 bytes
	\Phase II\Data\Yale0502\024508_pretest
2/14/2005 9:56 AM	98,742 024508_pretest.dat
2/14/2005 9:44 AM	0 024508_pretest.ffm
2/14/2005 9:57 AM	531 024508_pretest.txt
2/14/2005 9:57 AM	488 024508_pretestFFM.csv
2/14/2005 9:57 AM	209,048 024508_pretestHWM.csv
5 Files	308,809 bytes
658 Files	303,197,424 Bytes

Files with the `_pretest` or `_testdata` designator was data collected on that subject prior to the subject beginning the STP protocol. This data was generally used to verify hardware functioning, however could also be used to create a pre-test baseline for the subject. Key factors to remember if doing this, is that each time a mask or probe is attached to the patient, the DC oximetry value at that time, cannot be related to the DC oximetry value of other times because

the DC baseline value changes based on the tightening of the mask or headband. However, changes in this baseline (trends up or down, or increases in signal variance) should still relate to that from other data collections.

A data file containing the PC time stamps relating to the real time at which events occurred for the PC connected to the HWM data acquisition unit during the time, before the trial started, when mask adjustments were being made and the subject was being familiarized with the equipment. This data is organized as follows:

Table 30. Format of _pretest data (events)

Day Month Date Hour:Minute:Second Timezone Year Event Number and Description

The events used during the pre test were usually:

1. Subject dons the mask
2. There may or may not be a subject holds breath or performs a valsalva
3. There may or may not be a subject resumes breathing
4. Subject removes the mask
5. Subject dons the forehead sensor
6. There may or may not be a subject holds breath or performs a valsalva
7. There may or may not be a subject resumes breathing
8. Subject removes the forehead sensor

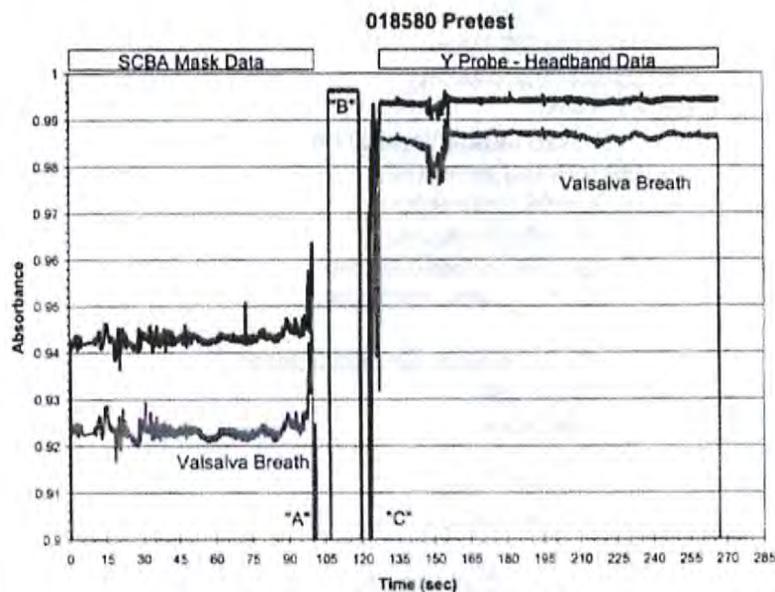


Figure 56: Pretest data sample of subject 018580 wearing a mask then wearing a "Y"-probe sensor. Initial data for each includes adjusting the sensor, once data is stable, subject holds breath (Valsalva maneuver) as long as then can and release. "A" and "C" points designate when the sensor unit is removed from the subject (data value goes to zero), the "B" point represents when the sensor is unplugged from the data unit (data value goes to ~1).

Although the acquisition system was originally designed to simultaneously collect data from the HWM and FFM units, in practice this was not done, and each system's data was collected by a separate PC. For this reason, the _ffm file designator was used to note data collected on the PC connected to the FFM unit. It is also for this reason that *_ffm.dat files are empty and *_ffmHWM.csv files are without data. The HWM unit was not connected to the PC collecting

that data. Similarly, the *.ffm and *FFM.csv files on the non _ffm files as that PC was connected to the HWM unit, but not the FFM unit.

For all time values, 0 time is designated as the moment the subject first steps onto the treadmill (a treadmill is also the first exercise in the STP protocol).

The files *SubjectID_A_All.xls* and *SubjectID_A_All.csv* combine the major data items from all the prior analysis files into one giant spreadsheet. This is intended to make it easier to use tools such as excel to simultaneously graph relevant data. However, please note that each data filed has its own time stamp column, to accommodate disparities in frequency that data is recorded for different parameters. Also note that the scale may need to be adjusted to see data items on the graph at the same time.

Table 31. Suggestions for (magnitude) scaling data for 'SubjectID_A_All.xls'

Since most LED and IR LED data is in the range of 0.8 to 1.0, this is the suggested Y data scale range.

Scaled Events = IF(Events Val=0,0.8,1)

Scaled Red Integrity = IF(ABS(Red Int)<=1, 1-((1-13)*0.2), 0.8)

Scaled IR Integrity = IF(ABS(IR Int)<=1, 1-((1-13)*0.2), 0.8)

Scaled R/IR = IF(R/IR<0.001,0.9+N3*2,0.9)

Scaled ln(R:IR) = 0.9 + (lnR:IR - 0.56) / 25

Scaled Red Var = IF(Red Var < 0.02, 0.8+1000*Red Var, 1)

Scaled IR Var = IF(IR Var < 0.02, 0.8+1000*IR Var, 1)

Scaled Foot Falls = 0.8 + FF Val / 1000

Scaled Temp = 0.9 + (Temp - 37.5) / 50

Scaled Heart Rate = IF(AF23="", 0.8, 0.8 + HR / 1000)

Table 32. Format of 'SubjectID_A_All.xls'

Column A	Events Time	seconds
Column B	Event value	Each event is given a value of 100, and one second to each side of an event is given a value of 0 so that events will be graphed as spikes, aligned with other data timelines.
Column C	Red Absorbance Time	seconds. Approximately 19 samples per second, unless data point was discarded.
Column D	Red Absorbance value	A value of 1 would indicate that no transmitted light was received at the detector. A value of 0 indicates that the detector was saturated.
Column E	IR Absorbance Time	seconds. Approximately 19 samples per second, unless data point was discarded.
Column F	IR Absorbance value	A value of 1 would indicate that no transmitted light was received at the detector. A value of 0 indicates that the detector was saturated.
Column G	Data Integrity time	seconds
Column H	Red Data Integrity	A measure of signal noise calculated each 10 seconds based upon the number of data points which are discarded due to an algorithm to calculate if the value is believable or a noise spike. A 1 indicates that all data points in that interval were kept. A zero indicates that no values were kept.
Column I	IR Data Integrity	see note above.
Column J	Time Red to IR Ratio	seconds
Column K	Red to IR Ratio	Strict ratio of Red Absorbance (max to min, AC component) to IR Absorbance (max to min, AC component) see Figure 2.
Column L	Log Red to IR Ratio	Natural log of of Red Absorbance (max to min, AC component) to IR Absorbance (max to min, AC component) ratio see Equation 1, used to calculate traditional SpO ₂ .
Column M	Mean Absorbance Time	Seconds
Column N	Red MAM	A calculation of the Red "DC" component value (Mean absorbance minimum).
Column O	IR MAM	A calculation of the IR "DC" component value
Column P	delta MAM	The difference between the Red and IR Mean Absorbance Minimum
Column Q	Variance Time	seconds
Column R	Red Variance	Calculated using Winchell's 2 second running average variance.
Column S	IR Variance	Calculated using Winchell's 2 second running average variance.
Column T	Foot Fall Time	seconds
Column U	Foot Fall value	Output of accelerometer placed on equipment (treadmill, ladder climb, breach and pull). Should generally correspond to walking steps on a treadmill, movement on the ladder, and large spikes for breach and pull efforts.
Column V	Core Temp Time	seconds. Approximately every 20 seconds.
Column W	Core Temp	Celcius
Column X	Heart Rate	Beats per minute as calculated by the Core Temp Unit

Table 33. Format of 'SubjectID_A_All.csv'

Column A	Events Time	seconds
Column B	Event value	Each event is given a value of 100, and one second to each side of an event is given a value of 0 so that events will be graphed as spikes, aligned with other data timelines.
Column C	Red Absorbance Time	seconds. Approximately 19 samples per second, unless data point was discarded.
Column D	Red Absorbance value	A value of 1 would indicate that no transmitted light was received at the detector. A value of 0 indicates that the detector was saturated.
Column E	IR Absorbance Time	seconds. Approximately 19 samples per second, unless data point was discarded.
Column F	IR Absorbance value	A value of 1 would indicate that no transmitted light was received at the detector. A value of 0 indicates that the detector was saturated.
Column G	Data Integrity time	seconds
Column H	Red Data Integrity	A measure of signal noise calculated each 10 seconds based upon the number of data points which are discarded due to an algorithm to calculate if the value is believable or a noise spike. A 1 indicates that all data points in that interval were kept. A zero indicates that no values were kept.
Column I	IR Data Integrity	see note above.
Column J	Time Red to IR Ratio	seconds
Column K	Red to IR Ratio	Strict ratio of Red Absorbance (max to min, AC component) to IR Absorbance (max to min, AC component) see Figure 2.
Column L	Log Red to IR Ratio	Natural log of of Red Absorbance (max to min, AC component) to IR Absorbance (max to min, AC component) ratio see Equation 1, used to calculate traditional SpO ₂ .
Column M	Mean Absorbance Time	Seconds
Column N	Red MAM	A calculation of the Red "DC" component value (Mean absorbance minimum).
Column O	IR MAM	A calculation of the IR "DC" component value
Column P	delta MAM	The difference between the Red and IR Mean Absorbance Minimum
Column Q	Variance Time	seconds
Column R	Red Variance	Calculated using Winchell's 2 second running average variance.
Column S	IR Variance	Calculated using Winchell's 2 second running average variance.
Column T	Foot Fall Time	seconds
Column U	Foot Fall value	Output of accelerometer placed on equipment (treadmill, ladder climb, breach and pull). Should generally correspond to walking steps on a treadmill, movement on the ladder, and large spikes for breach and pull efforts.
Column V	Core Temp Time	seconds. Approximately every 20 seconds.
Column W	Core Temp	Celcius
Column X	Heart Rate	Beats per minute as calculated by the Core Temp Unit

Table 34. Format of 'SubjectID_A_Events.csv'

Column A	Date and Time	Full Date and Time code (i.e. Fri Feb 18 10:34:08 EST 2005) of event
Column B	Events Time	Seconds
Column C	Event value	Each event is given a value of 100, and one second to each side of an event is given a value of 0 so that events will be graphed as spikes, aligned with other data timelines.
Column D	Event ID	Sequential number of events. The monitoring software has a "click here" button that is used to time sync events with things going on during the test.
Column E	Event Text	A short description of the event (i.e. subject gets on treadmill, subject gets off treadmill, etc.) See Table 35 for descriptions.
Column F	Event Source	HWM means that the event was recorded on the PC collecting data from the Hazardous worker monitor unit (DC Oximetry sensor system). FFM means the event was recorded from the PC connected to the Foot Falls monitor. In general, most events were simultaneously recorded on both systems.

Table 35. Events shorthand descriptions

Start DAQ	The PC recording data is turned on and begins to transmit data
sw	A stopwatch is started. The stopwatch is used to manually record events and to track that subject spends the correct amount of time on each activity. This event is used to synchronize stopwatch times to the recorded data.
red/green/blue unit on	The HWM unit is turned on and begins to transmit data. The color refers to which of the test systems was used in this test
ffm	The foot falls monitor (accelerometer) is turned on and begins to transmit data
Alarm	The subject receives a simulated fire alarm call and begins to put on their firegear.
tm	The subject begins to use the treadmill
otm	Off treadmill, the subject ends the treadmill activity
l	Ladder, the subject begins the ladder climb
ol	off ladder. Subject completes ladder activity
sr	Subject begins the search and rescue activity
esr	Subject ends the search and rescue activity
tm2	The subject begins another treadmill activity
etm	Subject ends treadmill activity
bp	Subject begins the breach and pull activity
ebp	Subject ends the breach and pull activity
exit	Subject leaves the environmental chamber
end ffm	The foot falls monitor is turned off
y	The subject has previously removed their mask (and the oximetry sensor) and is now connected to the HWM using a "Y" probe oximeter inside a headband. This allows the subject to rehydrate (but not yet) and rehab while still recording data. Data taken from the Mask and the Y probe cannot be directly compared.
Weight	The sensor is likely disconnected, or signal may be lost while subject goes to take a post-test weight.
Back	The subject has returned from the weight recording.
Rehydrate	The subject is now beginning to drink water
End data	The PC stops recording subject data and the HWM is turned off.
Anything else	Other unplanned, or unexpected events may also be recorded. Where possible the description should indicate what the event was, otherwise, please refer back to laboratory notebooks for specific details. Not all shorthands were recorded exactly the same, however, this should indicate the likely meanings of those events.

Table 36. Format of 'SubjectID_A_FFpeaks.csv'

Column A	Foot Fall Time	seconds
Column B	Foot Fall value	A peak detection algorithm is applied to the output of the (FFM) accelerometer. Like with the events monitor, the value to either side of the peak is set to 0, so that the peaks show up as singular spikes.
Column C	Delta Time	The time between peeks, used to determine the believability of data as if it relates to walking on the treadmill or some other activity, of if the signal is noise.

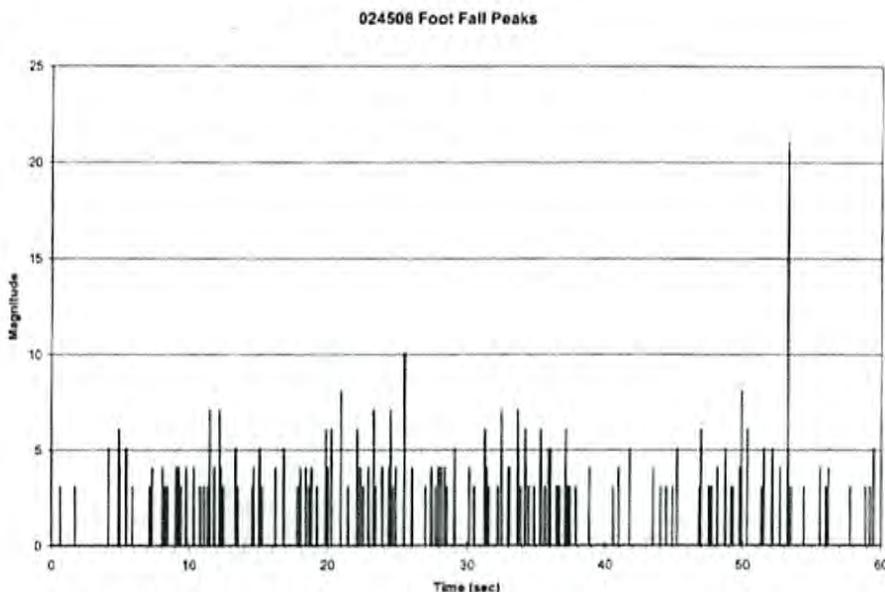


Figure 57: Sample footfall peak data for subject on treadmill.

Table 37. Format of 'SubjectID_A_Red.csv'

Column A	Red Absorbance Time	seconds. Approximately 19 samples per second, unless data point was discarded.
Column B	Red Absorbance value	A value of 1 would indicate that no transmitted light was received at the detector. A value of 0 indicates that the detector was saturated.

Table 38. Format of 'SubjectID_A_IR.csv'

Column A	IR Absorbance Time	seconds. Approximately 19 samples per second, unless data point was discarded.
Column B	IR Absorbance value	A value of 1 would indicate that no transmitted light was received at the detector. A value of 0 indicates that the detector was saturated.

Table 39. Format of 'SubjectID_A_DI.csv'

Column A	Data Integrity time	seconds
Column B	Red Data Integrity	A measure of signal noise calculated each 10 seconds based upon the number of data points which are discarded due to an algorithm to calculate if the value is believable or a noise spike. A 1 indicates that all data points in that interval were kept. A zero indicates that no values were kept.
Column C	IR Data Integrity	see note above.

Table 40. Format of 'SubjectID_A_MAM.csv'

Column A	Mean Absorbance Time	Seconds
Column B	Red MAM	A calculation of the Red "DC" component value (Mean absorbance minimum).
Column C	IR MAM	A calculation of the IR "DC" component value
Column D	delta MAM	The difference between the Red and IR Mean Absorbance Minimum

Within each ½ second interval, a maximum and minimum values are recorded for each of the Red and IR % Absorbances. The Delta between these values is considered to be the "amplitude" of the Red or IR plesmogram. A ratio (R:IR) is created where the magnitude of the IR delta is subtracted from the magnitude of the Red delta. In addition a (natural) log ratio is created according to the formula:

$$\ln(R:IR) = \log(\text{Red}_{\min}/\text{Red}_{\max}) / \log(\text{IR}_{\min}/\text{IR}_{\max}) \quad \text{Equation 7}$$

If a subject is at 100% oxygen saturation, this log ratio should be approximately 0.5. However, our analog to digital conversion is not accurate enough, given the very small magnitude of the plesmogram compared to the overall signal, to invest too much faith in this ratio, at this time.

Table 41. Format of 'SubjectID_A_LRRIR.csv'

Column A	Time Red to IR Ratio	Seconds
Column B	Red max	The "last" peak value of red absorbance
Column C	Red min	The "last" minimum value of red absorbance
Column D	Red delta	The difference between the peak and minimum values of red absorbance
Column E	IR max	The "last" peak value of IR absorbance
Column F	IR min	The "last" minimum value of IR absorbance
Column G	IR delta	The difference between the peak and minimum values of IR absorbance
Column H	Red to IR Ratio	Strict ratio of the Red Absorbance delta (max to min, AC component) to IR Absorbance delta (max to min, AC component) see Figure 2.
Column I	Log Red to IR Ratio	Natural log of of Red Absorbance (max to min, AC component) to IR Absorbance (max to min, AC component) ratio see Equation 1, used to calculate traditional SpO ₂ .

Table 42. Format of 'SubjectID_A_Var.csv'

Column A	Variance Time	seconds
Column B	Red Variance	Calculated using Winchell's 2 second running average variance.
Column C	IR Variance	Calculated using Winchell's 2 second running average variance.

Table 43. Format of 'SubjectID_A_CTHR.csv'

Column A	Core Temp Time	seconds. Approximately every 20 seconds.
Column B	Core Temp	Celcius
Column C	Heart Rate	Beats per minute as calculated by the Core Temp Unit

Table 44. Format of 'SubjectID_ct.csv' – raw output of CorTemp unit

Column A	Event Type/Time	Hhh -> The Hour (of the day) of data collection Tmm:ss -> The Temperature at mm:ss Rmm:ss -> The heart rate at mm:ss.
Column B	Data Value.	Heart Rate, Temperature, or 8888.88 Signal Error code
		For full details on this format, contact HQ Inc. ⁶⁴

⁶⁴ <http://www.hqinc.net>

Table 45. Format of 'uconn SubjectID.csv' – processed output of CorTemp unit

Column A	Date and Time	in m/d/yyyy h:mm format
Column B	Temperature	in Celcius
Column C	Heart Rate	in Beats per Minute (BPM)
Column D	Event	Generally unused as subjects did not manipulate the CorTemp monitor during trials
Column E	Manual	Generally unused as subjects did not manipulate the CorTemp monitor during trials. Corresponds to an infrequent signal dropout.

Table 46. Format of 'SubjectID_ffm.dat' – raw output of footfall monitor

Binary output of serial link connecting the HWM to the monitoring PC, however as this PC (_ffm) was only connected to the footfall monitor. This file will have no data.

Table 47. Format of 'SubjectID_ffmFFM.csv'

Column A	Computer Timestamp	A running counter incremented by the PC recording the data every 10 seconds.
Column B	FFM PTS	A running counter incremented by the FFM units' processor.
Column C	Accelerometer Value	12 bit A-D value converted to decimal (0-4095) (Equation 8).
Column D	Event marker	Triggered by a push button on the FFM unit. Should correspond to the ffm sync event in the file 'subjectID A Events.csv'

The Computer Timestamp is a value generated by the PC recording the data that will increment every 10 seconds.

The FFM_PTS or Hardware Time Stamp (or heartbeat) is a number incremented by the data acquisition unit approximately each 3.2 seconds from when the unit is turned on.

The Accel signal is the value of the accelerometer signal (is this an 8 bit A-D value centered at approximately 304. Positive and negative accelerations caused by footfalls or by the motion of the FFM from test instrument to test instrument (Figure 34).

The Accelerometer value (columns C) is determined by the following:

$$\text{Accelerometer_value} = (m \times 256) + ll \quad \text{Equation 8}$$

Where m is the decimal value of the four most significant bytes of the A-D conversion from the data packet (Table 48), and where ll is the decimal value of the eight least significant bytes of the A-D conversion.

It is important to note, that the value of the "Event Marker" does not always correspond to the event numbers (Figure 32), and should be checked against the HWM and FFM events files for confirmation and reasonableness before maing analysis dependent upon these values.

Binary output of serial link connecting the FFM to the monitoring PC is documented in Table 48 below. Each packet is appended to the (*.ffm) file as received.

Table 48. Format of 'SubjectID_ffm.ffm' – (from Table 10)

Byte	1	2	3	4	Meaning
Data Packet Format (in Hex)	AC	cm	11	0A	Typical Byte: AC C0 2D 0A
	A				Start nibble (A=1010)
	c	c			Code: 0 (0000) Heartbeat counter/ Timestamp. C (1100) Used for FFM (~200Hz) D (1101) Used to signify the pushbutton press. The value of C is repeated in both byte 1 nibble 2 and byte 2 nibble 1.
		m			The four most significant bits of the 12 bit A-D conversion of the Red or IR LED signals received at the photodetector. Will be zero for heartbeat counter.
			11		The eight least significant bits of the 12 bit A-D conversion of the Red or IR LED signals received at the photodetector. For heartbeat counter, a sequential value between 0 and 255, which then resets to zero. Used to verify packet order and delivery, synchronize output data, and to allow monitoring PC to make sure HWM sensor unit is still operating.
				0	The Unit ID number 0 for FFM
				A	End nibble (A=1010)

Table 49. Sample of 'SubjectID_ffm.txt' – Subject 018568, treadmill only data, events recorded by footfall monitor.

Thu Mar 03 09:51:17 EST 2005	Data Aquisition Started
Thu Mar 03 09:51:47 EST 2005	Event 0 -- start red unit
Thu Mar 03 09:53:07 EST 2005	Event 1 -- sync ffm
Thu Mar 03 09:57:21 EST 2005	Event 2 -- tm
Thu Mar 03 10:18:19 EST 2005	Event 3 -- end tm
Thu Mar 03 10:18:34 EST 2005	Event 4 -- ext
Thu Mar 03 10:18:51 EST 2005	Stop Button pressed...Stopping Acquisition
Thu Mar 03 10:19:03 EST 2005	Closing File.

Table 50. Format of 'SubjectID_ffmHWM.csv'

Column A	Computer Timestamp	A running counter incremented by the PC recording the data every 10 seconds.
Column B	HWM_PTS	Since the PC connected to the FFM (_ffm) was not connected to the HWM, this column will have no data values.
Column C	Red LED value	Since the PC connected to the FFM (_ffm) was not connected to the HWM, this column will have no data values.
Column D	IR LED value	Since the PC connected to the FFM (_ffm) was not connected to the HWM, this column will have no data values.
Column E	Event marker	Should correspond to the events in the file 'subjectID_A_Events.csv'

Binary output of serial link connecting the HWM to the monitoring PC is documented in Table 51 below. Each packet is appended to the (*.dat) file as received.

Table 51. Format of 'SubjectID.dat'

Byte	1	2	3	4	Meaning
Data Packet Format (in Hex)	A <i>c</i>	<i>cm</i>	<i>ll</i>	<i>iA</i>	Typical Byte: A1 12 D3 2A
	A				Start nibble (A=1010)
	<i>c</i>	<i>c</i>			Code: 0 (0000) Heartbeat Counter (~2Hz) 1 (0001) Red LED Value (~19Hz) 2 (0010) IR LED value (~19Hz) The value of <i>c</i> is repeated in both byte 1 nibble 2 and byte 2 nibble 1.
		<i>m</i>			The four most significant bits of the 12 bit A-D conversion of the Red or IR LED signals received at the photodetector. Will be zero for heartbeat counter.
			<i>ll</i>		The eight least significant bits of the 12 bit A-D conversion of the Red or IR LED signals received at the photodetector. For heartbeat counter, a sequential value between 0 and 255, which then resets to zero. Used to verify packet order and delivery, synchronize output data, and to allow monitoring PC to make sure HWM sensor unit is still operating.
				<i>i</i>	The Unit ID number: 0 (0000), 1(0001), 2(0010), or 3(0011)
				A	End nibble (A=1010)

Binary output of serial link connecting the FFM to the monitoring PC is documented below.

Table 52. Format of 'SubjectID.ffm'

Since the PC connected to the HWM was not connected to the FFM unit, this file will have no data.

Table 53. Sample of 'SubjectID.txt' – Subject 024503, STP, events recorded by Hazardous Worker Monitor (HWM) PC.

```

Mon Feb 14 12:51:18 EST 2005 Data Acquisition Started
Mon Feb 14 12:51:48 EST 2005 Event 0 -- red unit on
Mon Feb 14 12:52:24 EST 2005 Event 1 -- ffm
Mon Feb 14 12:52:59 EST 2005 Event 2 -- alarm
Mon Feb 14 12:55:23 EST 2005 Event 3 -- tm
Mon Feb 14 12:57:54 EST 2005 Event 4 -- otm
Mon Feb 14 12:58:23 EST 2005 Event 5 -- l
Mon Feb 14 12:59:32 EST 2005 Event 6 -- ol
Mon Feb 14 13:00:24 EST 2005 Event 7 -- stop ffm
Mon Feb 14 13:00:33 EST 2005 Event 8 -- exit
Mon Feb 14 13:01:52 EST 2005 Event 9 -- y
Mon Feb 14 13:05:50 EST 2005 Event 10 -- weight
Mon Feb 14 13:08:22 EST 2005 Event 11 -- back
Mon Feb 14 13:15:48 EST 2005 Event 12 -- stop data
Mon Feb 14 13:16:03 EST 2005 Stop Button pressed...Stopping Acquisition
Mon Feb 14 13:16:04 EST 2005 Start Button pressed...ReStarting Acquisition
Mon Feb 14 13:16:07 EST 2005 Closing File.

```

Table 54. Format of 'SubjectIDFFM.csv'

Column A	Computer Timestamp	A running counter incremented by the PC recording the data every 10 seconds.
Column B	FFM_PTS	Since the PC connected to the HWM was not connected to the FFM unit, this column will have no data.
Column C	Accelerometer Value	Since the PC connected to the HWM was not connected to the FFM unit, this column will have no data.
Column D	Event marker	Since the PC connected to the HWM was not connected to the FFM unit, this column will have no data.

Table 55. Format of 'SubjectIDHWM.csv'

Column A	Computer Timestamp	A running counter incremented by the PC recording the data every 10 seconds.
Column B	HWM_PTS	Since the PC connected to the FFM (_ffm) was not connected to the HWM, this column will have no data values.
Column C	Red LED value	To resolve issues of data dropout, each data point, Red or IR is on one line each. There should be approximately 19 of each one-second the system operates. This value corresponds to a 12 bit (0-4095) "Raw" output of the Analog to Digital conversion circuit on the HWM unit. The lower the value, the less signal (light) reached the photo detector. Absorbance is determined according to Equation 10.
Column D	IR LED value	See note above.
Column E	Event marker	Should correspond to the events in the file 'subjectID_A_Events.csv'

The value of the Red or IR LED (columns B and C) is determined by the following

$$AtoDvalue = (m \times 256) + ll \quad \text{Equation 9}$$

Where m is the decimal value of the four most significant bytes of the A-D conversion from the data packet (Table 51), and where ll is the decimal value of the eight least significant bytes of the A-D conversion.

$$\text{Absorbance} = \frac{4096 - AtoDvalue}{4096} \quad \text{Equation 10}$$

Commercialization Report

Company

Sekos Inc., founded in 2001, is a small privately held technology development company specializing in remote physiologic monitoring devices for the home care and hazardous worker markets, personnel accountability products, sensors for chemical and biologic weapon detection, building sensors to determine structural stability, life support devices and minimally invasive medical diagnostic tools.

Our products are designed to serve the emergency services and medicine environment and the consumer home health care market for chronic illness management; each system is designed to be user-friendly, support Internet connectivity and independently provide a full scope of treatment capability.

Sekos has recently spun off its ventilator products and programs to Automedx, Inc, which is now manufacturing and selling the FDA cleared SAVE (Simplified Automated Ventilator).

Market, Customer, and Competition

The Market

Fire Service

The primary market for this device is domestic fire departments, which is comprised of approximately 1.2 million FF's working in 48,500 total fire stations. According to the *Needs Assessment Study of the U.S. Fire Service*, an estimated 36% of FF's per shift does not have SCBA equipment, and 45% of available units are at least 10 years old.

Table 56. Fire fighters per Shift Lacking SCBA and SCBA Units At Least 10 Years Old, by Size of Community⁶⁵

Population Protected	Estimated Percent of FF's per Shift Not Equipped With SCBA	Estimated Percent of SCBA Units That Are At Least 10 Years Old
1,000,000 or more	0%	26%
500,000 to 999,999	2%	13%
250,000 to 499,999	2%	21%
100,000 to 249,999	2%	24%
50,000 to 99,999	3%	25%
25,000 to 49,999	7%	27%
10,000 to 24,999	13%	33%
5,000 to 9,999	26%	38%
2,500 to 4,999	37%	41%
Under 2,500	48%	53%
Total	36%	45%

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, and have place particular emphasis on monitoring 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) with operational

⁶⁵ The Needs Assessment Study of the U.S. Fire Service December, 2002

responsibility. To be deployable on the fire ground, a physiological monitoring system for firefighters must be small, lightweight, and cannot 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 fire fighter 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 FF's 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 unmodified 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. 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.

This system is intended to provide an adjunct safety device addressing the prevalent problem of volitional fatigue experienced by FF's combating a structural fire. FF's are compelled to make every effort to salvage a burning structure, and are often unable or unwilling to recognize the normal symptoms of physiological fatigue/exhaustion signaling the need for rest and rehydration, especially where civilian rescue may be required. Unlike a Personal Alert Safety System (PASS) alarm, which sounds when a FF has been motionless for >20 seconds, this system provides an alert to the FF while the FF is still mobile and capable of self-rescue.

Other Applications

This system is designed for remote physiological monitoring under acute exertion in extreme environments. As such, in addition to the fire fighter market, it has direct application to other hazardous working environments involving PPE; it is highly suitable for industries where heat stress is a consistent problem and in "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. This system provides a significant resource for timely, accurate physiological monitoring of human subjects. It will help to protect the study recruits, by indicating the need to terminate testing and medically evaluate and rehabilitate the subject. It may be used for direct study data acquisition as part of a larger sensor suite.

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 PPE and medical support logistics. SCBA and PPE protection is required for soldiers and other first

responders countering acts of terror involving harmful chemicals, pathogens or radioactive materials. Our device will be designed to meet the required level of protection against these agents.

Market Acceptance

Although the fire service as a whole is very receptive to technological innovations, cost constraints of such publicly funded organizations severely limit the products and services they can purchase. As a result, a clear benefit from the innovation or technology must be demonstrated to gain market acceptance. It is our plan to use peer reviewed literature and testing results from a limited placement of the system into a few selected and high profile departments to clearly demonstrate the benefits of incorporating our system into their fire operations.

Strategic Alliances, Partnerships, or Licensing Agreements

Sekos Inc. has had a long-standing cooperative relationship with Interspiro (Branford, CT) in developing advanced products for the fire service market. Interspiro has expressed interest in the further development of this system upon the successful completion of the Phase II efforts.

This research effort was included in materials presented to MSA, Inc. (Mine Safety Appliance, Pittsburgh, PA) in a NASA sponsored Technology Infusion Forum on September 8, 2006. This meeting has been followed up with numerous teleconferences and a site visit to Sekos' facilities by MSA on 12/20/2006. Although this dialog has not yet resulted in a transfer of technology or other licensing arrangement, a dialog with MSA continues.

Although Sekos anticipates licensing the technology to SCBA manufacturers, no formal agreements have yet been established.

Marketing and Sales Strategy

Competition

The leading SCBA and related device manufactures are identified in Table 57 below.

Table 57. Leading SCBA manufacturers.

Company	Product(s)
3M	AirMate 2000
Mine Safety Appliances Co.	Advantage 3000
Neutronics	BioPak 240
Cairns Air	Pioneer Pro, Pioneer
Dalmation Fire & Safety	reconditioned SCBAs
Draeger Safety Manufacturing	AirBoss Plus
International Safety Instruments	Viking, Magnum Plus
Interspiro	Spirotek, Spiromatic-S, CBWD mask
FlameFighter Corp.	SCBA Seating products, SCBA Brackets and related items
Sabre	ProPak
Survivair	Pather SCBA
Scott	several models

Since the proposed system is considered a disruptive technology, it does not currently have any direct competitors. In the research environment, there are many academic institutions working with companies to place sensors on FF's to monitor physiologic parameters, however, at present no such system is available for use in the field. As a result, our position on competition

will be to aggressively protect and expand our intellectual property position, secure relationships with the SCBA manufacturers, keep our products at a price point acceptable to the fire service, and retain a good reputation with the fire service so that when the inevitable competitors enter the market, we can retain the dominant market share.

Marketing

There are several marketing avenues that we plan to engage in, including technical marketing, OEM sales, trade journal advertising, trade show booths, and an Internet web site.

1. Technical Marketing

An important aspect of future success for this project is demonstrating to the fire service that the system is an affordable and easily implemented solution to their urgent need for a greater margin of job safety. An important way to do this is to generate peer reviewed, published literature demonstrating the efficacy of the system under both experimental and emergency incident conditions. To this end, we plan to publish the technical, research, and field testing aspects of this project in the peer-reviewed literature. This is made possible by designing the testing process according to rigorous scientific standards and by using the system to answer related questions under controlled conditions. In addition, Sekos principals would continue to make regular presentations to emergency services audiences at national meetings, apprising them of progress and results of these studies. The key personnel for this project have a significant number of publications and presentations on subjects in the field of biomedical technology, emergency medical care, occupational health and safety of emergency responders, and sensor development and deployment.

2. OEM Sales

Sekos Inc. believes that one of our most successful markets will be that of sales to Original Equipment Manufacturers (OEM). In particular, we believe that SCBA manufacturers are an excellent client base. Making the sensor array an integral component of the SCBA is the most suitable arrangement. This direct integration ensures that the sensor system will be utilized on the fire ground and provides the sensors with environmental protection. Furthermore, it enables SCBA manufacturers to control placement of the sensor array's indicator display and ensure that all seals and SCBA components remain fully operational. Derivative versions of the sensor may also be sold to other OEMs. For example, mining and confined space equipment could include our sensor array to warn workers of hazardous atmospheres, - in effect, a digital canary. The sensor system also has application to professional/collegiate sports for athletic training monitoring purposes.

3. Retro-Fits

The large number of SCBA already in use, and the relatively long service duration of these units must also be considered. In this case, existing SCBA equipment can be brought to Sekos Inc. where the sensor array can be retrofitted. This is not a simple process; any modification made to this equipment must be tested and verified. For this reason, allowing fire departments to retrofit the equipment themselves would be discouraged.

4. Other

Sekos Inc. anticipates using a variety of additional marketing strategies as appropriate. These will include the use of trade journals and booths at trade shows. Sekos Inc. maintains a web page (www.sekos.biz) that may be utilized as a marketing tool for our products.

IP Protection

Sekos Inc. and its principles have been very aggressive in securing the rights to the intellectual property that we have developed in house or in conjunction with one of our partnerships. Below is a list of patents issued or pending related to the technology presented herein. The material covered in Patent 7,181,264 resulted in part from discoveries during our Phase I efforts. Other patents were based on results and efforts prior to the start of Phase I of this SBIR.

1. Integrated Physiologic Sensor System, BioAsyst LLC (now Sekos Inc.), W.P. Wiesmann, L.A. Pranger, M.S. Bogucki. Patent Granted March 13, 2001, Patent Number 6,199,550.
2. Integrated Physiologic Sensor System, BioAsyst LLC (now Sekos Inc.), W.P. Wiesmann, L.A. Pranger, M.S. Bogucki. Patent Granted August 19, 2003, Patent Number 6,606,993.
3. Integrated Physiologic Sensor System, BioAsyst LLC (now Sekos Inc.), W.P. Wiesmann, L.A. Pranger, M.S. Bogucki. Patent Granted August 23, 2005, Patent Number 6,934,571.
4. Method and Apparatus for Noninvasive Physiologic Monitoring; Sekos Inc., W.P. Wiesmann, L.A. Pranger, M.S. Bogucki, Patent Granted February 21, 2007, Patent Number 7,181,264.

Production and Marketing Plan

Owing to the requirements of SCBA certification, sales of the system will need to be paired with the sale of SCBA ensembles. Thus, the actual sales and distribution of the system will occur using the infrastructure of the SCBA manufacturer. Sekos Inc. may eventually consider getting into after market SCBA modifications in which case the sales strategy will revolve around Internet orders and the development of direct relationships with fire departments interested in the technology without the cost of replacing their current SCBAs.

SCBA Applications

Any modification to an SCBA mask requires that the final product be extensively tested and validated to NIOSH and NFPA standards. As such, the Sekos Inc. believes that the components of this system that are integrated into the mask (the sensor elements and connector) will need to be incorporated into the production process of the SCBA manufacturer. We envision two paths for producing the data acquisition/transmission unit. First, Sekos could use a contract manufacturer to build a stand-alone unit and cabling that will be attached to the connector on an SCBA mask that has the sensor elements. The second path is to license the circuit and firmware of the data acquisition/transmission unit to SCBA manufacturers to include in a data processing computer that may already be a part of their SCBA ensemble. For example, one of Interspiro's current SCBA systems already has a small computer used to monitor air-tank pressure and mask seal integrity. Rather than burden FF's with yet another device, these devices could be combined into a single integrated system.

In this market, after-market mask modifications will be difficult to certify to NIOSH and NFPA standards, and even if certified, the manufacturer of the SCBA mask would be unwilling to guarantee their product after such a modification. For this reason, partnerships, sales or licensing of our system directly to SCBA manufacturers is the most viable path for selling the system. Our sales efforts need to be directed on two fronts. The first is to convince the end users (the FF's and their departments) to demand this capability from their SCBAs. This can be achieved by getting our product viewed and understood by the FF's by showcasing at trade shows, publishing peer-reviewed literature demonstrating the added values of the system, advertising in relevant journals, and even direct site visits and demonstrations at fire stations. Viral marketing (AKA "word-of-mouth") is one of the most effective means of penetrating the fire service market; having a good reputation and "buzz" about our product will be critical to success. The second path will be to market directly to the SCBA manufacturers. Alternately, one SCBA manufacturer may be interested in an exclusive license or purchase of the technology to further their own marketing efforts and market share. SCBA manufacturers may also be interested in our system's integral telemetry capabilities, allowing them to piggyback SCBA system signals, further enhancing their existing SCBA offerings. However, in general, we believe that SCBA manufacturer interest will be driven by the demand from the FF's.

As the system becomes more prevalent in the market place, user acceptance improves, and value is demonstrated, we believe that this system will eventually become a part of NFPA standards, and thus a requirement for all SCBA ensembles. Recent examples of this migration from new-product to standard include a PASS alarm that goes off if a fire fighter remains immobile for too long. Sekos believes that this system should become part of the required standards within 10 years of the product becoming available to the market.

Military Applications

This product has the potential to satisfy several military needs. One need is the ability to monitor injured soldiers on a battlefield; our system has the potential to operate as a traditional pulse oximetry sensor, deriving heart rate, oxygen saturation, and respiratory rate. A second need of the military is to assess the operational fitness, fatigue, and hydration of soldiers in the field. This ability will enable battlefield planners to have improved awareness of when soldiers, or a unit, need to be pulled back to rest, and a new, fresh unit deployed. Sekos Inc. believes that with further study, the data produced by our system will correlate with these military needs.

Marketing and manufacturing for military deployment is significantly different than other markets, as a product used on the battlefield must be built according to military specifications (MILSPEC). Sekos plans to use a contract manufacturer familiar with MILSPEC to produce our system. Portions of the system (like the telemetry system) will need to be redesigned for specific military needs. Upon completing Phase II, Sekos intends to seek additional funding from the military to adapt this system to their needs and requirements. A military investment, even a small amount, is critical for product acceptance. Were Sekos to use raised funds to produce this unit for the military, marketing would be hampered by a lack of ownership within the military. Military market acceptance requires that the military have a sense of active participation in the technology development process.

Military market acceptance is dependant upon convincing military planners that the data provided by the system is valuable and germane for their uses. Initially, Sekos anticipates marketing the device to domestic military training bases for use in conjunction with training

exercises. This application will be easier to gain initial acceptance in, as it does not necessitate some of the requirements for a battlefield deployed system. An additional benefit to starting with this market segment is that soldiers in training will become familiar with the system and its benefits, leading to easier acceptance when finally deployed to battlefields. The product will need to be commonly produced, and issued a National Stock Number (NSN) to make it available for purchase.

Sports Applications

As previously described, the human body's thermoregulation system can be stressed by many conditions. Athletes, like workers operating in confined/restricted spaces or firefighters are subject to extreme environmental conditions, wear protective clothing and heavy equipment that can impede their evaporative cooling mechanisms, and exert physiological stresses on their systems.

A human's thermoregulation system normally adjusts to meet physiological stresses that occur with exertion. At the onset of exercise, healthy adults experience a rapid increase in cardiac output. Stroke volume also increases with augmentation of venous return from the periphery and resulting inotropic enhancement based on Frank-Starling forces governing myocardial contractility. As exercise progresses, blood volume is redistributed to the working muscles to meet oxygen demands, and to the skin for dissipation of the heat being produced by the muscles. Ongoing exercise decreases stroke volume due to vascular redistribution of blood volume together with volume loss due to sweating. Cardiac output is maintained by compensatory increase in heart rate to an individual maximum dependant upon the individual's age and conditioning. Respiration rates also increase during exercise. The combination of increased respiratory rates, evaporative sweat loss and redistribution of blood to capillary beds in the skin provide adequate cooling to maintain body temperatures within acceptable parameters.

This thermoregulatory process can be impeded when a person is involved in heavy exertion with dynamic/aerobic and static/anaerobic components. Firefighters' activities, for example, require carrying heavy equipment while wearing thermal and flame resistant protective ensembles (including self-contained breathing apparatus, SCBA) that quantitatively prevent evaporative loss of metabolic heat. This is due to the nature of their protective gear and the work environment (in temperatures in range of 700 degrees F. and upwards), which collectively prevent heat dissipation to the environment. Under these conditions, the cardio-accelerator compensation that normally maintains cardiac output during exercise is lost resulting in an almost immediate reduction in cardiac output with initiation of exertion and sweating. Decreased cardiac output leads to a constriction of the peripheral vasculature to maintain systolic blood pressure, which in turn leads to a rapid rise in core temperature that remains even after exercise ceases. The effect is that of a cascade of sequential failure of compensatory mechanisms. Although not nearly to the same extreme, professional, collegiate, and even high school sports uniforms and protective gear can like likewise impede the proper dissipation of heat.

Remote, non-invasive medical monitoring would greatly reduce the chance of impending failure if it was capable of identifying physiological parameters that indicate the achievement of near-maximal work capacity prior to cardiovascular collapse, symptomatic heat illness or other adverse clinical outcomes.

Each year heat-related illness and dehydration syndromes affect thousands of athletes at all levels and is a leading cause of preventable sports injury and death. Rigorous outdoor training in

the summer months is correlated to increased risk. Football players, due to their heavy protective equipment, are particularly vulnerable. Outcomes from heatstroke are related to the length of temperature elevation. When therapy is delayed, the mortality rate may be as high as 80%; however, with early diagnosis and immediate cooling, the mortality rate can be reduced to 10%, which highlights the need for early detection.

Data to date, while not yet compelling, is highly indicative that DC oximetry monitoring can be used to determine when the subject has reached a point of volitional fatigue. One of the goals of exercise is to take a body as far as it can go without reaching over a breaking point. It is likely that a system such as this one could be adapted to safely optimize an individual's exercise program.

As with the fire fighter focused system, the sensor system must support rapid data collection, processing and effective transmission over sufficient distances to monitor the person(s) operating in the particular environment. These sensors must input/access individual biological signals, under time constraints, or must perform in severe environments without adding excessive weight to the wearer or impede dexterity or mobility of the wearer.

Fitness Applications

A Single Fitness Measure

What is fitness?

Being correctly adapted to ones environment

Competent in day to day tasks

Able to minimize ailment

Current Measures for Fitness

VO 2 max test (treadmill protocol)

Graded exercise test (step test)

Strength test (back leg dynamometer)

Flexibility (sit and reach)

Blood Pressure

Body Mass Index / %Body Fat

Current Measures for Activity

Accelerometers

Computer Science and Applications Monitor (CSA)

Tritrac (RSD)

Biotrainer Activity Monitor

Drawbacks of Current Fitness Tests and Accelerometers

Fitness tests

need to be performed in a sterile environment

cannot be performed alone

Accelerometers

validity varies by location (lab vs. field)

position on body can change values

One Fitness Test

There is no single test out there that can evaluate all of these variables

There is no device that can easily register improvement in

Why is it needed?

Quality of Life

Correct balance between cardiovascular and muscular strength

"It is important to prove prospectively that regular exercise among relatively unfit persons actually prevents events in proportion to change in fitness"⁶⁶

Fitness Related to Mortality

Cooper Clinic Mortality Risk Index⁶⁷

Death increased over 100% from moderate to low cardiorespiratory fitness

Same with Body Mass Index (BMI)

Presence of type II Diabetes increased risk by over 400%

Hypertension and Heart Rate increased risk by more than 200%

What information can be used?

Cardiovascular Information

"Heart-rate profile during exercise and recovery is a predictor of sudden death"⁶⁸

Increase in risk with Heart Rate Reserve less than 89 bpm

Increase in risk with decrease in heart rate of less than 25 bpm one minute after exercise

Heart Rate

Has a correlation to

Relative VO₂

Energy Expenditure

MET level

Bioelectrical Impedance

⁶⁶ Kraus, William E. Where Does Fitness Fit In? N Engl J Med 2005;353(5): 517-519

⁶⁷ Janssen, Ian, The Cooper Clinic Mortality Risk Index Clinical Score Sheet for Men. Am J Prev Med 2005; 29(3): 194-203

⁶⁸ Jouven, Xavier, Heart-Rate Profile during Exercise as a Predictor of Sudden Death. N Engl J Med 2005; 352(19): 1951-58

Principal Investigator/Program Director (Last, First, Middle): Wiesmann, William P.

Measure both HR and cardiac output (CO)

Relatable to VO₂

Relatable to MET level

Measure wave forms

Alert exerciser to abnormal heart rhythms

Portable and easily accessible

Quantifiable Value

The combination of these variables can result in a quantifiable value

A value that can also be related to muscle strength, blood pressure, etc.

Easy way to assess FITNESS

Revenue Stream

Sekos Inc. anticipates that the revenue stream created by this product will predominately result from licensing the technology or partnering with SCBA manufacturers. Once a compelling case for the technology can be made from acquired data, Sekos expects that it would support, sufficiently promote, and coordinate marketing, sales and production in tandem with SCBA manufacturers.

Future Work

Core Body Temperature

During the STP, all subjects completed the protocol in heat and PPE first, and at least a week later repeated the protocol without heat or PPE. Future, larger studies should consider randomizing which protocol each FF completes first to minimize the introduction of systematic bias related to familiarity with the apparatus and protocol. This would complicate study logistics as it takes several hours to change and stabilize the temperature in the chamber.

Wide variations in stomach temperatures and increased temperatures seen near the liver and working (abdominal) muscles may account for more data fluctuation seen with shorter time intervals between ingestion of the capsule and initiation of exercise (mean 221 min in first STP trial vs 477 min in the second).⁴¹ Manufacturer instructions state that capsules should be ingested at least 2 hours prior to data collection.⁶⁹ In the present studies, less apparent temperature fluctuation was observed when pills were ingested 6-8 hours prior to trials. As has been noted by others,⁴⁷ extending the interval between capsule ingestion and protocol performance increases the likelihood of "pill failure" that occurs in some subjects due to rapid passage through the gastrointestinal tract. Monitored ingestion of the pills with careful timing of subsequent research trials may decrease the number of "pill failures" in future studies. Overall, these pills are feasible for study but not for occupational use where hazardous environments occur unpredictably, and pill transit time throughout the GI tract cannot be controlled.

The small number of subjects in this study limits significant findings to 1) higher T_{max} were measured for FFs working in UCHS conditions and 2) maximal T_c and the apparent rate of T_c increase were significantly higher in a subset of the FF subjects. An increased sample size would allow further evaluation of trends seen for T_c increase and heat storage. Studying additional variables such as lactate production and oxygen consumption may reveal additional insights into the physiology of UCHS associated with structural firefighting.

Currently, without remote monitoring, FFs rely on their partners or their own evaluation of physiologic decompensation. Further work is needed to elucidate the physiology of heat stress in fire fighting, and to identify predictive physiological parameters that indicate the onset of UCHS and fatigue prior to incapacitation or other adverse clinical outcomes. The results of such studies may prove beneficial to fire personnel, if relevant parameters can be remotely and noninvasively monitored on the fire ground.

* DC Oximetry, Hydration and Impedance

The primary aim of proposed future work should be to significantly increase the number of subjects used in data gathering and analysis for the SCBA-based Oximetry monitor. The increased participant sample size will dramatically increase our statistical power and allow us to examine further trends across both gender and minorities.

* The secondary aim of this investigation would be to examine whether a small impedance device integrated into SCBA or PPE can accurately monitor changes in hydration in healthy

⁶⁹ CorTemp Core Body Temperature Monitoring System User Manual r4.3.1. Palmetto FL: HQInc. Wireless Systems and Design:p. 23.

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young adults who are exercising in extreme heat. We hypothesize that bio-electric impedance technology can accurately track changes in fluid status. Such data may help to explain the observed correlation of DC oximetry with fatigue in FFs, or it may provide a second, independent indicator of their physiologic status.

Evaluating central hemodynamic changes using a non-invasive cardiac output (CO) monitor in active firefighters may serve to validate the hypothetical model of sequential physiologic events that are thought to occur in the early stages of an interior fire attack. These changes have never been proven in fire suppression activity, and potentially, use of the CO monitor would have wider applications. This study proposes to determine the feasibility of using such a monitor to noninvasively follow changes in CO during controlled simulations of the early phases of interior, structural firefighting. The device is compact, portable and has the necessary parameters (both measured and calculated) to correlate to the physiological parameters identifying decompensation. Cardiac output measurements during exercise testing obtained with impedance cardiography correlate well (averaging 0.86) with other standards.

Proposed Additional Research and Development

The proposal for additional studies should address two aspects of the previous research efforts. The first increases the number of subjects used in data collection, and the second incorporates the acquisition of impedance data. We would propose to use this effort to expand the number of subjects and include an additional 40 (or more) subjects in the data collection phase. This increased subject pool will enable the system to better understand, capture, and respond to individual variability in the operation of the system and the resulting data. This is of particular importance when validating the warning algorithms, to ensure that the system is generic, and has not simply learned the behaviors of the initial test subjects.

- * Bioelectrical impedance will be investigated as a safe, non-invasive method to estimate hydration status. Means for measuring impedance is well suited to our existing methods of sensor integration into SCBA. Few investigations have looked at using bioelectrical impedance analysis (BIA) to estimate changes in body fluid compartments⁷⁰. The technique offers the potential be used to monitor changes in the body hydration levels through heat-induced dehydration for fire fighters and rescue workers⁷¹.

Dr. Armstrong's work asserted that traditional wrist-to-ankle BIA was not an appropriate method for accurately predicting changes in total body water. Some investigators have suggested that one reason for this deficiency is that one of the important assumptions underpinning the application of BIA is violated in the whole body protocol, namely, that the body is a single conducting cylinder with uniform resistivity¹. Further, they note that the major contributor to body mass (~46%) is contained in the trunk region. In contrast, much of the whole body impedance is dominated by the impedance of the arm, which contains only approximately 4% of the body mass⁷². Thus, even relatively large changes in trunk fluid volume may not significantly change wrist-to-ankle impedance, and hence the predicted water volume⁷³. Therefore, we believe

⁷⁰ Armstrong, Nutr. Rev. 2005

⁷¹ Shirreffs, Nutr. Rev. 2005

⁷² Thomas, Acta Diabetol 2003

⁷³ O'Brian, Int J Sports Med 2002

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that a segmental methodology, in which the impedances of the arm, leg, trunk and brain are measured separately, may overcome these difficulties⁷⁴.

Ag/AgCl electrodes (Silver Circuit, Sentry Medical Products, Irvine, CA) and will be placed on known landmarks to assess previously described segmental impedances. In addition, we are excited about the possibilities that assessing brain impedance may offer in monitoring physiologic changes in the brain. Dr. Harvey Ko, a biomedical engineer at the Johns Hopkins Applied Physics Lab has previously worked with Sekos personnel and would be viewed as a valuable resource for his great deal of expertise in developing electromagnetic sensors for biomedical applications. Dr. Ko would be a natural partner for the team develop the protocols for assessing impedance of the brain⁷⁵. He believes that the technique will be useful for monitoring the progression or regression of brain edema as well as dehydration⁷⁶.

A cerebral impedance sensor shall be integrated into the SCBA masks prior to the additional subject trials, so that simultaneous data can be gathered for both DC oximetry and impedance data. In addition, a thoracic impedance sensor shall also be used. Following these trials, the data will be analyzed to determine the correlation between each of these data, and subject fatigue. Data analysis will be used in the development of indices for assessing when a FF should be removed from their current task and redirected to rehab, and to assess when rehab has been sufficient and the FF can return to operations.

Active Field Studies

FFs would undergo the actual Candidate Physical Ability Test (CPAT) at the facilities located in Meriden CT. CO monitoring will be performed before and after the test, to detect changes in cardiac output and correlated with physiologic parameters such as lactate production, which was studied in our previous Phase II sequential task trials in the environmental chambers at both Yale and the University of Connecticut. In addition, FFs will undergo similar sequential task trials at the Connecticut Fire Academy where a State-of-the-art Fire Training Facility utilizes computer controlled propane fires in the Burn Building Scenario. The same CO monitor and physiologic data will be obtained. CPAT testing would be conducted to evaluate the FF's physiologic response to the most well-validated and reproducible exercise developed for FFs. The addition of a live-fire training facility will enable the comparison of physiologic and oximetric data obtained in simulated tasks to data obtained in live fire situations. It is expected that subjects will be able to perform longer in fire conditions.

A very limited field study should be implemented following the successful conclusion of the additional human trials and the validation of the warning algorithms utilizing one or two fire crews (4-8 subjects). In this study, the subjects' current SCBA mask will be replaced with the new sensorized masks, which would be worn during performance of normal day-to-day operations in order to determine the reliability and effectiveness of the system when applied to actual fire scenes over a period. Data will be transmitted wirelessly from the sensor unit and recorded to a PC connected to their apparatus. At this stage, the real-time monitoring of the resulting data will be at the discretion of the incident commander.

⁷⁴ Wotton, Ann N Y Acad Sci 2000; Franckowiak, J Strength Cond Res 2003

⁷⁵ Ko, IEEE Trans Biomed Eng 1988

⁷⁶ Ko; Nelson, J Appl Physiol 1971

Human Studies Issues

Continuing research would involve conducting additional human subject trials. As a result, it will be necessary for us to apply to the institutional review boards (IRB) at both Yale University and the University of Connecticut to add subjects to the currently approved protocols, and to have the addition of the impedance monitor evaluated for the risks to the subjects. All these activities are perceived as a low additional risk from the sensor instruments and test protocol compared to the activities the FFs would otherwise be engaged in, and IRB approval is anticipated. During our trials, an Emergency Medicine Board certified physician will always be present to evaluate the subject before, during and after the test. Standard ACLS equipment including defibrillation capabilities are kept on scene during all trials. Local FFs including both career (full-time) and volunteer (part-time) male and female personnel will participate voluntarily. Subjects will sign informed consent prior to testing. All subjects will be cleared for duty using NFPA 1582.

Expectations of Results

The current program was built on the premise that remote physiologic status monitoring of working FFs can decrease fire ground morbidity and mortality by recognizing exhausted personnel before they are incapacitated. FFs experience the following sequence of rapid physiological changes during initial attack on a structure fire. First, the combination of catechol excess and exertion required to don PPE and respond to a fire scene cause the heart rate to increase. The heart rate virtually immediately reaches maximal levels as fire ground tasks are begun. Muscular activity required to perform fire suppression and rescue tasks with heavy tools while wearing bulky, cumbersome PPE profoundly increases metabolic heat production at the same time the firefighter enters the heated environment. Central blood volume is redistributed to the working muscles where its temperature increases, and then to dilating peripheral vasculature and sweating begins. Heat dissipation into the environment is inadequate due to extreme environmental temperatures and humidity inside the fully insulating PPE. Normally, cardiac output increases approximately 3 L/min for each 1°C (1.8°F) rise in core body temperature, but is unable to do so here. FFs exhibit a very early decrement in stroke volume due to fluid loss and redistribution of the blood volume. The already maximal heart rate cannot accelerate to compensate for the decreasing stroke volume, as occurs in aerobic exercise under normal climatic conditions, so cardiac output probably decreases with stroke volume. Sweating remains profuse despite its futility, and the core temperature rises. These events are the hallmarks of uncompensable heat stress, and lead to exhaustion.

Further, they represent definitive mechanisms to defeat each of the major physiologic strategies for thermoregulation in working firefighters. Uncompensable heat stress due to exercise in protective clothing has been studied using young military volunteers on treadmills in environmental chambers. Under these conditions, heart rates, core temperatures and oxygen demand rose more gradually than is seen in FFs. The so-called anaerobic threshold was reached much later in the military treadmill tests than was observed in tests on FFs, where venous lactate levels began to rise nearly concomitantly with onset of exercise. This is likely due to the high static load (anaerobic muscle activity) intrinsic to fire ground tasks, superimposed on the early, relative hypoperfusion resulting from vascular redistribution and rapid volume loss. Smith et al, who used immediate post-exercise 2-dimensional cardiac echo to estimate SV based on aortic cross-sectional area, observed this phenomenon¹⁸. To reduce morbidity and mortality on the

fireground, a more complete understanding of cardiovascular physiology and establishment of reliable markers for the sequential stages of uncompensable heat stress in firefighters are essential.

DC oximetry is advantageous to remotely monitor physiologic status in working FFs. The sensors are rugged, non-invasive and produce a very robust signal, and can be integrated into FF protective ensembles so that the monitoring capability does not compromise response times or the integrity of the PPE. The required combination of sensors, transmitters and power supplies would not add significant weight, external tethering or "cube" that could decrease essential mobility or dexterity during fire ground operations. The size of the data stream would allow continuous remote monitoring via radio-telemetry within reasonable bandwidth and without interference with voice communications. Finally, DC oximeter output could be very useful if coupled with some kind of FF identification and location technology; the combination of physiologic status and location would allow incident commanders to make better decisions regarding working FFs including those who become lost or trapped in conflagrations, and to vector more effective rescue efforts where appropriate.

It is our belief that a system capable of monitoring the physiologic health of FF's on the fire ground and providing an unobtrusive measurement of volitional fatigue to promote the timely removal of FFs from fire operations into rehabilitation will reduce the need for FF rescue operations due to collapse or incapacitation, and may reduce overall fire ground deaths. Our system offers a dramatic improvement over other proposed solutions as it does not rely on vital signs such as heart rate, (which is a very poor indicator of physiologic status during exercise) pulse oximetry, (arterial oxygen saturation remains normal until after cardiovascular collapse has occurred) or core temperature (which cannot be remotely and non-invasively monitored).

This system is intended to provide an adjunct safety device to detect the point at which FFs, due to physiologic exhaustion, cannot safely continue rescue or suppression operations. Unlike a Personal Alert Safety System (PASS) alarm, which sounds when a FF has been motionless for >20 seconds, this system provides an alert to both the FF/IC while the FF is still mobile and capable of self-rescue.

This effort complements the goals of the FF life safety initiative, including improved fitness and conditioning. This system will help focus greater attention on the integration of risk management with incident management at all levels, including strategic, tactical, and planning responsibilities by providing incident commanders with an additional tool to protect FF from catastrophic outcomes due to the physiologic demands of firefighting.

The proposed additional research would go a long way towards providing the additional validation of the underlying physiologic principals upon which the Oximetry monitoring system is based. Without this additional validation, acceptance of the technology within the market, particularly the cost-conscious fire service, is unlikely.

1. The first part of the document discusses the importance of maintaining accurate records of all transactions. It emphasizes that this is crucial for ensuring the integrity of the financial statements and for providing a clear audit trail.

2. The second part of the document outlines the various methods used to collect and analyze data. It describes how different types of data are gathered and how they are processed to extract meaningful information. This section also covers the use of statistical techniques to identify trends and patterns in the data.

3. The third part of the document focuses on the interpretation of the results. It explains how the data is analyzed to draw conclusions and make informed decisions. This section also discusses the importance of communicating the findings effectively to the relevant stakeholders.

4. The fourth part of the document provides a summary of the key findings and conclusions. It highlights the main points of the study and discusses the implications of the results. This section also includes recommendations for future research and for improving the current process.

5. The final part of the document is a conclusion that summarizes the overall findings and provides a final assessment of the study. It also includes a list of references and a bibliography of the sources used in the research.