REPORT DOCUMENTATION PAGE

Form Approved OMB NO. 0704-0188

1. REPORT DATE (DD-MM-YYYY)	2. REPORT TYPE	3. DATES COVERED (From - To)
04-01-2019	Final Report	1-Apr-2014 - 31-Mar-2015

4. TITLE AND SUBTITLE

Final Report: PhysioCam: A Noncontact System to Monitor Physiological Responses From a Distance

5a. CONTRACT NUMBER
W911NF-14-1-0158

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHORS

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAMES AND ADDRESSES

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8. PERFORMING ORGANIZATION REPORT NUMBER

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

U.S. Army Research Office
P.O. Box 12211
Research Triangle Park, NC 27709-2211

10. SPONSOR/MONITOR'S ACRONYM(S)
ARO

11. SPONSOR/MONITOR'S REPORT NUMBER(S)
65610-NS-DRP.4

12. DISTRIBUTION AVAILIBILITY STATEMENT

Approved for public release; distribution is unlimited.

13. SUPPLEMENTARY NOTES

The views, opinions and/or findings contained in this report are those of the author(s) and should not contrued as an official Department of the Army position, policy or decision, unless so designated by other documentation.

14. ABSTRACT

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	15. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			Stephen Porges
UU	UU	UU	UU		19b. TELEPHONE NUMBER 312-545-3495

RPPR Final Report
as of 28-Jan-2019

Agency Code:

Proposal Number: 65610NSDRP **Agreement Number: W911NF-14-1-0158**
INVESTIGATOR(S):

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Country: USA
DUNS Number: 608195277 EIN: 566001393
Report Date: 30-Jun-2015 Date Received: 04-Jan-2019
Final Report for Period Beginning 01-Apr-2014 and Ending 31-Mar-2015
Title: PhysioCam: A Noncontact System to Monitor Physiological Responses From a Distance
Begin Performance Period: 01-Apr-2014 **End Performance Period:** 31-Mar-2015
Report Term: 0-Other
Submitted By: Maria Davila Email: maria_davila@med.unc.edu
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Distribution Statement: 1-Approved for public release; distribution is unlimited.

STEM Degrees: **STEM Participants:**

Major Goals: Prototype a noncontact physiological monitoring system based on a COTS high quality digital video camera to monitor physiological activity from the human face. The PhysioCam will measure heart rate, breathing, and vasomotor activity with the accuracy and precision equivalent to contact measures. Physiological measures detected by the PhysioCam will be quantified in either real-time or offline modes. Unlike previous attempts to develop noncontact video based system, the PhysioCam will be designed from knowledge of the wavelengths of physiological processes. The prototype of the PhysioCam will be portable and inexpensively duplicated. The PhysioCam will consist of COTS hardware weighing approximately 15 kg; if implemented with a laptop the weight could be about 5 kg. Due to the availability of low cost COTS hardware, duplication costs would be approximately $6,500.

Accomplishments: The PhysioCam system is a noncontact technology that measures beat-to-beat heart rate with sufficient accuracy to monitor features of heart rate variability (HRV). The PhysioCam takes a unique approach to the standoff measurement of human arterial pulse via visible light imaging of a subject's face. The PhysioCam generates the pulse wave in "real-time"; the generated signal represents the beat-to-beat pattern from which heart rate variability (HRV) parameters and respiration rate can be measured.

Real time analyses with only a few milliseconds delay due to data processing. Therefore, the system could be reduced to a single processor that would not require access to large blocks of memory to derive a signal (i.e., each frame can be processed and then discarded).

The methods used were refined off-line and then implemented into the state-of-the-art PhysioCam software that functions in real-time. Although the current system is capable of tracking a single subject within the frame, the frame-by-frame process strategy will enable future applications to track multiple subjects within the view of a single camera. Since the pulse extraction is based only on the location within the current frame, the method could track pulse information when a subject's (or subjects') position changes between images as long as the subject is visible to the sensor.

The report includes a new method for tracking instantaneous heart rate, which includes a multi-stage editing tool. Traditional measures of heart rate variability are based on careful post hoc inspection of collected physiological signals. Even with the gold standard (i.e., electrocardiogram recordings), spurious noise or aberrant cardiac activity (e.g., pre-ventricular contraction) can significantly distort the physiological rhythms of interest. In designing our real-time measures of HRV parameters, we used a conservative approach to accept data into our processing stream. The results, during the seated cognitive task, confirm that the PhysioCam, in its current configuration, can provide

accurate measures of heart rate and HRV in settings requiring psychophysiological monitoring.

We are working to transition this prototype system into a standalone piece of hardware that can monitor vital signs in real-time from multiple subjects. We believe that such a device would be an asset to the security, public health, and marketing sectors.

Training Opportunities: Nothing to Report

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Results Dissemination: 03/25/2015: final conversations to evaluate PhysioCam at JHU-APL facilities in real work conditions (ACCURATE project). Expected to start on May 2015.

04/09/2015: UNC Innovation showcase. PhysioCam was selected as one of five UNC Innovations to Watch: Technologies and innovations developed in UNC laboratories.

Title: Novel Algorithms to Monitor Continuous Cardiac Activity with a Video Camera
Authors: Gregory F Lewis, Maria I Davila, Stephen W Porges
Publication date: June 2018
Conference: Proceedings of the IEEE Conference on Computer Vision and Pattern Recognition Workshops
Pages: 1282-1290
Description: Recent advances in computer vision methods have made physiological signal extraction from imaging sensors feasible. There is a demand to translate current post-hoc methods into real-time physiological monitoring techniques. Algorithms that function on a single frame of data meet the requirements for continuous, real-time measurement. If these algorithms are computationally efficient they may serve as the basis for an embedded system design that can be integrated within the vision hardware, turning the camera into a physiological monitor. Compelling results are presented derived from an appropriate algorithm for extracting cardiac pulse from sequential, single frames of a color video camera. Results are discussed with respect to physiologically relevant features of variability in beat-to-beat heart rate.

Title: Optimizing estimates of instantaneous heart rate from pulse wave signals with the synchrosqueezing transform
Authors: Hau-Tieng Wu, Gregory F Lewis, Maria I Davila, Ingrid Daubechies, Stephen W Porges
Publication date: May 2016
Journal: Methods of information in medicine
Volume: 55
Issue: 05
Pages: 463-472
Publisher: Schattauer GmbH
Description: Background: With recent advances in sensor and computer technologies, the ability to monitor peripheral pulse activity is no longer limited to the laboratory and clinic. Now inexpensive sensors, which interface with smartphones or other computer-based devices, are expanding into the consumer market. When appropriate algorithms are applied, these new technologies enable ambulatory monitoring of dynamic physiological responses outside the clinic in a variety of applications including monitoring fatigue, health, workload, fitness, and rehabilitation. Several of these applications rely upon measures derived from peripheral pulse waves measured via contact or non-contact photoplethysmography (PPG). As technologies move from contact to non-contact PPG, there are new challenges. The technology neces sary to estimate average heart rate over a few seconds from a noncontact PPG is available. However, a technology to precisely measure instantaneous heat rate (IHR) from non-contact sensors, on a beat-to-beat basis, is more challenging. Objectives: The objective of this paper is to develop an algorithm with the ability to accurately monitor IHR from peripheral pulse waves, which provides an opportunity to measure the neural regulation of the heart from the beat-to-beat heart rate pattern (i.e., heart rate variability). Methods: The adaptive harmonic model is applied to model the contact or non-contact PPG signals, and a new methodology, the Synchrosqueezing Transform (SST), is applied to extract IHR. The body sway rhythm inherited in the non-contact PPG signal is modeled and handled by the notion of wave-shape function. Results: The SST optimizes the extraction of IHR from the PPG signals and the technique functions well even during periods of poor signal to noise. We contrast the contact and non-contact indices of PPG derived heart rate with a criterion electrocardiogram (ECG). ECG and PPG signals were monitored in 21 healthy subjects performing tasks with different physical demands. The root mean square error of IHR estimated by SST is significantly better than commonly applied methods such as autoregressive (AR) method. In the walking situation, while AR method fails, SST still provides a reasonably good result. Conclusions: The SST processed PPG data provided an accurate estimate of the ECG derived IHR and consistently performed better than commonly applied methods such as autoregressive method.

Honors and Awards: Nothing to Report

Protocol Activity Status:

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Technology Transfer: Title: System and methods for measuring physiological parameters
Inventors: Stephen W. Porges, Maria I. Davila, Gregory F. Lewis
Assignees: University of Illinois, University of North Carolina at Chapel Hill
Date: June 26th 2018
Patent office: US
Patent number: 10,004,410
Application number: 15/105,674
Description: The present invention relates generally to a system and methods for measuring physiological parameters. More specifically, the present invention relates to a noncontact technology by which one or more physiological parameters of a subject may be efficiently and quickly detected. Among other advantages, the present invention can be used to assess and monitor vital signs of one or more subjects in a variety of contexts including for medical or security triage purposes, for use in healthcare waiting rooms, as part of human imaging systems, or during surgery.

PARTICIPANTS:

Participant Type: PD/PI
Participant: Stephen W Porges
Person Months Worked: 2.00 **Funding Support:**
Project Contribution:
International Collaboration:
International Travel:
National Academy Member: N
Other Collaborators:

Participant Type: Co PD/PI
Participant: Gregory F Lewis
Person Months Worked: 12.00 **Funding Support:**
Project Contribution:
International Collaboration:
International Travel:
National Academy Member: N
Other Collaborators:

Participant Type: Co-Investigator
Participant: Maria I Davila
Person Months Worked: 12.00 **Funding Support:**
Project Contribution:
International Collaboration:
International Travel:
National Academy Member: N
Other Collaborators:

Participant Type: Other Professional
Participant: Jacek Kolacz
Person Months Worked: 2.00 **Funding Support:**
Project Contribution:
International Collaboration:
International Travel:
National Academy Member: N
Other Collaborators:

ARTICLES:

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Publication Type: Journal Article Peer Reviewed: Y **Publication Status:** 1-Published
Journal: Methods of information in medicine
Publication Identifier Type: DOI Publication Identifier: 10.3414/ME16-01-0026
Volume: 55 Issue: 5 First Page #: 463
Date Submitted: 1/4/19 12:00AM Date Published: 5/1/16 10:39PM
Publication Location: Stuttgart, Baden Württemberg
Article Title: Optimizing estimates of instantaneous heart rate from pulse wave signals with the synchrosqueezing transform
Authors: Hau-Tieng Wu, Gregory F Lewis, Maria I Davila, Ingrid Daubechies, Stephen W Porges
Keywords: Instantaneous heart rate - synchrosqueezing transform - heart rate variability - PhysioCam - photoplethysmography
Abstract: Advances in sensor and computer technologies have enable ambulatory monitoring of dynamic physiological responses outside the laboratory/clinic. Applications rely upon measures from peripheral pulse waves measured via contact or noncontact photoplethysmography. Precise measure of instantaneous heat rate (IHR) is challenging. The objective of this paper is to develop an algorithm to accurately monitor IHR from peripheral pulse waves, which provides access to measure the neural regulation of the heart. The adaptive harmonic model is applied to model the contact or noncontact PPG, and a new methodology, the Synchrosqueezing Transform (SST), is applied to extract IHR. We contrast the contact and non-contact indices of PPG derived heart rate with a criterion electrocardiogram (ECG). 21 healthy subjects performing different physical tasks were monitored. The root mean square error of IHR estimated by SST is significantly better than commonly applied methods such as autoregressive (AR) method
Distribution Statement: 1-Approved for public release; distribution is unlimited.
Acknowledged Federal Support: **Y**

CONFERENCE PAPERS:

Publication Type: Conference Paper or Presentation **Publication Status:** 0-Other
Conference Name: IEEE Conference on Computer Vision and Pattern Recognition Workshops
Date Received: 04-Jan-2019 Conference Date: 21-Jun-0208 Date Published: 01-Jun-2018
Conference Location: Salt Lake City, Utah
Paper Title: Novel Algorithms to Monitor Continuous Cardiac Activity with a Video Camera
Authors: Gregory F Lewis, Maria I Davila, Stephen W Porges
Acknowledged Federal Support: **Y**

PATENTS:

Intellectual Property Type: Patent Date Received: **04-Jan-2019**
Patent Title: System and methods for measuring physiological parameters
Patent Abstract: The present invention relates generally to a system and methods for measuring physiological pa
Patent Number: 10,004,410
Patent Country: USA
Application Date: 30-Nov-2016 Application Status: 3
Date Issued: 26-Jun-2018

RPPR Final Report
as of 28-Jan-2019

University of North Carolina at Chapel Hill (Porges-PI)
Narrative Networks (N2) – Phase 2
Progress, Status and Management Report
Final Report

Period Covered by the Report
April 1st 2014 through March 31st 2015

Date of Report: April 16th 2015

Project Title: PhysioCam: a noncontact system to monitor physiological responses from a distance.
Contract/Grant Number: W911NF-14-1-0158
Total Dollar Value: $322,702.00
Program Manager: Dr. Justin Sanchez, DARPA/BTO

Submitted by:
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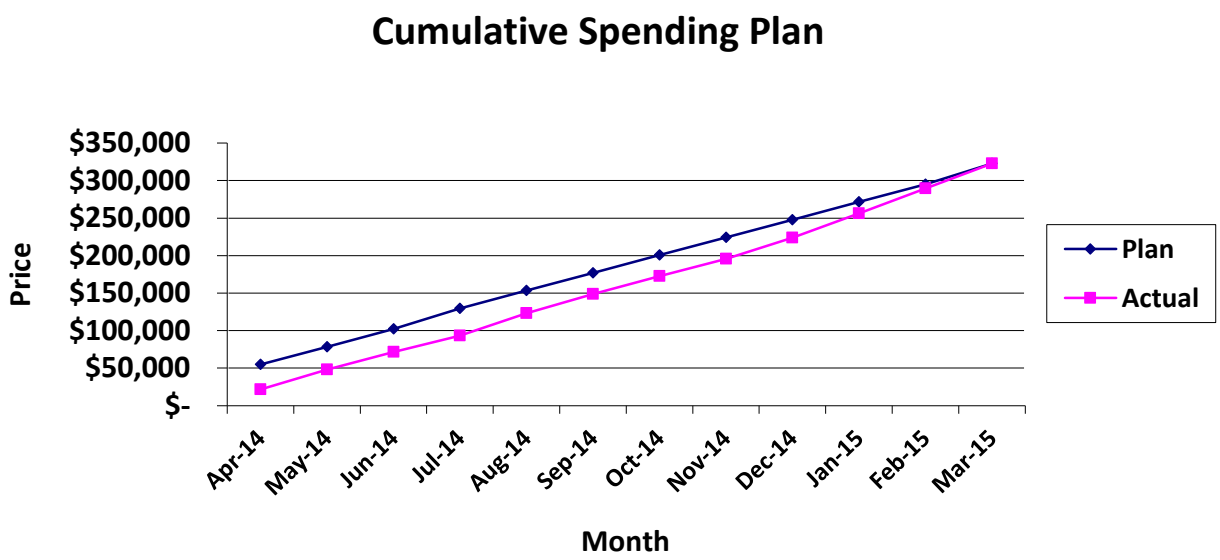
Security Classification – Unclassified
Do not mark document as confidential or business proprietary.

Technical Information – Financial Management

1. **Technical Progress / Quarterly Expenditure Report (Please provide cumulative spending graph).**

Figure 1. Cumulative spending Plan



Task status and task related financial expenditures for work performed during report period (01/01/2015 – 03/31/2015). Tasks are referenced to the SOW.

Task 1 – Develop specifications and purchase hardware components and software licenses. Features of cameras and lenses will be evaluated and ordered.
Status: Completed
$ 16,867.00

Task 2 – Verify TSWG software functioning with new hardware. Modify software to work with new cameras to perform at the level of precision (i.e., faster frame rate) demonstrated in the TSWG project.
Status: Completed
$ 11,832.00

Task 3 – Obtain IRB approval for criterion studies (i.e., seated during cognitive task, walking on treadmill).
Status: Completed
$ 27,700.00

Task 4 – Benchmark signal detection with contact measures
Status: Completed
$ 12,508.00

Task 5 – Refine region of interest (ROI) used to extract pulse information from the face to optimize signal stability and improve monitoring during slight head movements from seated participant.
Status: Completed.
$ 44,060.00

Task 6 – Implement motion tracking with Kinect
Status: Completed.
$ 39,638.00

Task 7 – Treadmill test of rapid pulse extraction
Status: Completed.
$ 13,898.00

Task 8 – Experiment to monitor contact and noncontact measures of physiology under two tasks.
Status: Completed.
$ 12,921.00

Task 9 – Complete integrated system for streaming and external synchronization
Status: Completed.
$ 25,142.00

Task 10 – Deliver system capable of streaming and synchronization.
Status: Completed.
$ 2,453.00

Task 11 – Offline quantification of physiological signals
Status: Completed.
$ 42,744.00

Task 12 – Implement real time quantification of signals
Status: Completed.
$ 42,744.00

Task 13 – Deliver final report and user manual
Status: Completed.
$ 39,187.00

Total expenditures for the reporting period - $ 100,010.00 – Accumulative - $ 322,702.00

				Plan					Actual				
	Task	Dates	Description	Direct labor	Supplies & Travel	Total direct cost	Indirect cost	Total cost	Direct labor	Supplies & Travel	Total direct cost	Indirect cost	Total cost
Phase I: Study Setup	Task 1	04/01/14 to 04/15/14	Specification & purchase of hardware	3,611	20,500	24,111	12,538	36,649	3,611	7,486	11,097	5,770	$ 16,867
	Task 2	04/16/14 to 05/15/14	Verify TSWG software functions with new hardware	7,784		7,784	4,048	11,832	7,784		7,784	4,048	$ 11,832
	Task 3	04/01/14 to 06/30/14	Develop IRB materials and obtain IRB	18,224		18,224	9,476	27,700	18,224		18,224	9,476	$ 27,700
Phase II: Improve algorithms to optimize precision and reduce distortion	Task 4	07/15/14 to 08/15/14	Benchmark signal detection with contact measures	7,878		7,878	4,097	11,975	7,878	351	8,229	4,279	$ 12,508
	Task 5	06/01/14 to 07/15/14	Refine ROI placement to optimize signal stability	23,255		23,255	12,093	35,348	23,255	5,732	28,987	15,073	$ 44,060
Phase III: Reduce distorting influences of body movement on pulse signals.	Task 6	07/15/14 to 09/15/14	Implement motion tracking with Kinect	23,255		23,255	12,093	35,348	23,255	2,823	26,078	13,560	$ 39,638
	Task 7	09/15/14 to 09/30/14	Treadmill test of rapid pulse extraction	7,783		7,783	4,047	11,830	7,783	1,360	9,143	4,754	$ 13,898
Phase IV: Evaluation of PhysioCam	Task 8	01/01/15 to 01/15/15	Experiment to monitor contact and noncontact measures of physiology under two tasks.	7,783		7,783	4,047	11,831	7,783	717	8,500	4,420	$ 12,921
Phase V: Prototype and delivery of PhysioCam	Task 9	10/01/14 to 11/15/14	Complete integrated system for streaming and external synchronization	15,472		15,472	8,045	23,517	15,472	1,069	16,541	8,601	$ 25,142
	Task 10	11/15/14 to 11/20/14	Deliver system capable of streaming and synchronization	1,614	2,500	4,114	2,139	6,253	1,614		1,614	839	$ 2,453
Phase VII: Deliver updated software. Online and Offline.	Task 11	01/01/14 to 03/15/14	Offline quantification of physiological signals	27,052		27,052	14,067	41,119	27,052	1,069	28,121	14,623	$ 42,744
	Task 12	01/01/14 to 03/15/14	Implement real time quantification of signals	23,350		23,350	12,142	35,492	25,693	88	25,781	13,406	$ 39,187
Phase VII: Final Report	Task 13	01/15/15 to 03/31/15	Deliver final report and user manual	19,743	2,500	22,243	11,566	33,809	22,087	119	22,206	11,547	$ 33,752
			Total cost	**186,804**	**25,500**	**212,304**	**110,398**	**322,702**	**191,491**	**20,813**	**212,304**	**110,398**	**$ 322,702**
			Total cost 1st Q	**39,515**	**20,500**	**60,015**	**31,208**	**91,223**	**39,515**	**7,486**	**47,001**	**24,441**	**$ 71,442**
			Total cost 2nd Q	**52,275**	**0**	**52,275**	**27,183**	**79,458**	**41,931**	**8,905**	**50,836**	**26,435**	**$ 77,271**
			Total cost 3rd Q	**42,287**	**2,500**	**44,787**	**23,289**	**68,076**	**44,368**	**4,303**	**48,671**	**25,309**	**$ 73,980**
			Total cost 4th Q	**52,727**	**2,500**	**55,227**	**28,718**	**83,945**	**65,677**	**119**	**65,796**	**34,214**	**$ 100,010**
			Total cost	**186,804**	**25,500**	**212,304**	**110,398**	**322,702**	**191,491**	**20,813**	**212,304**	**110,398**	**$ 322,702**

Actual Cost versus Planned Costs

	Cost ($)
Plan	$322,702.00
Actual	$322,702.00
Difference	$ 0.00

Observations

2. **Results or Problems and Solutions**
   Detail explanation are given in the "Executive Summary" section of this document.

3. **Significant Accomplishments Anticipated During Next Reporting Period**

4. **Publications**
   A full patent application has been filed with the support of the University of Illinois at Chicago (holder of the original IP developed during the TSWG task) and the University of North Carolina at Chapel Hill (site of the refinement of the IP to account for larger body movements). After a thorough review of the IP landscape and a negotiation of ownership between the Universities, the decision was made to file the full patent in December. We have received permission to share the patent application with the DARPA team, although we ask that dissemination of the document be limited to For Government Use Only. We are attaching the document as a separate file in the distribution of this report. The patent when published will acknowledge the funding by DARPA. The University of Illinois is in the process of documenting this funding on the filed patent application.

5. **Meetings and Events (please include meetings with subcontractors if applicable)**
   a) 03/25/2015: final conversations to evaluate PhysioCam at JHU-APL facilities in real work conditions (ACCURATE project). Expected to start on May 2015.
   b) 04/09/2015: UNC Innovation showcase. PhysioCam was selected as one of five UNC Innovations to Watch: Technologies and innovations developed in UNC laboratories.
   a) We will be meeting with a team of DRAPER Laboratories to evaluate the utilization of the PhysioCam as a stand-off device in one of their projects, in which noncontact physiological measures are required.

6. **Other:**
   Executive Summary to follow.

Executive Summary

The PhysioCam system is a noncontact technology that measures beat-to-beat heart rate with sufficient accuracy to monitor features of heart rate variability (HRV). The PhysioCam takes a unique approach to the standoff measurement of human arterial pulse via visible light imaging of a subject's face. Unlike other methods that have been reported in the literature (Poh, 2010; Wu, 2012), the PhysioCam generates the pulse wave in "real-time"; and unlike commercial products, the generated signal represents the beat-to-beat pattern from which heart rate variability (HRV) parameters and respiration rate can be measured. Unlike other approaches, the unit of measurement is a single frame of imaging data. This strategy enables real time analyses with only a few msec delay due to data processing. Therefore, the system could be reduced to a single processor that would not require access to large blocks of memory to derive a signal (i.e., each frame can be processed and then discarded), whereas other strategies are dependent on methods, such as component analysis, which depend on stacks of many frames to extract a signal.

The report outlines findings based on our real-time collection of image parameters. The methods used were refined off-line and then implemented into the state-of-the-art PhysioCam software that functions in real-time. Although the current system is capable of tracking a single subject within the frame, the frame-by-frame process strategy will enable future applications to track multiple subjects within the view of a single camera. Since the pulse extraction is based only on the location within the current frame, the method could track pulse information when a subject's (or subjects') position changes between images as long as the subject is visible to the sensor.

The report includes a new method for tracking instantaneous heart rate (see results from Task 4), which includes a multi-stage editing tool. Traditional measures of heart rate variability are based on careful *post hoc* inspection of collected physiological signals. Even with the gold standard (i.e., electrocardiogram recordings), spurious noise or aberrant cardiac activity (e.g., pre-ventricular contraction) can significantly distort the physiological rhythms of interest. In designing our real-time measures of HRV parameters, we used a conservative approach to accept data into our processing stream. The results, during the seated cognitive task, confirm that the PhysioCam, in its current configuration, can provide accurate measures of heart rate and HRV in settings requiring psychophysiological monitoring (see comments on Task 9 & 10).

While refining the PhysioCam, we identified two limitations in the current system, which we have proposed strategies to mitigate. First, we were unable to obtain the pulse signal from one subject with a dark skin tone. Although we had successfully monitored approximately 100 participants with a great diversity of skin tones with both the current and a previous version of the PhysioCam (TSWG Task 3325), the PhysioCam failed on a participant with high melanin content. We believe that the IR (Infrared) filter, which is inserted during the manufacture of the camera, restricts the wavelength of light being detected by the sensor sufficiently to distort the signal conveying the pulse wave (i.e., the detection of pulse in darker skin tones require monitoring longer wavelengths). This problem can be solved by a simple expansion of the wavelength range of the sensor (achievable by removing the near infra-red cutoff filter from the camera housing). Published research (Fredembach, 2009) suggests that in the NIR bandwidth passive illumination has minimal interaction with melanin, while also penetrating more deeply into the skin to interact with the changing hemoglobin distribution that is the basis of our signal.

Second, our improved motion tracking system did not eliminate the noise related to walking on the treadmill. We are now collaborating with Drs. Ingrid Daubechies (Duke University) and

Hau-Tieng Wu (University of Toronto) to implement a real-time version of their SynchroSqueeze Transformation as a replacement to our autoregressive spectral analysis. Initial results (see findings from Tasks 6 & 7) are promising. The periodic, but non-sinusoidal, nature of the motion artifact make it ideal for estimation by the SynchroSqueeze Transformation, which also tracks the pulse signal with suitable precision to estimate HRV parameters.

In addition to the support from DARPA, we have been fortunate to receive support from our current and past Universities in developing this intellectual property (IP). The University of Illinois at Chicago (75%) and the University of North Carolina at Chapel Hill (25%) entered an agreement to share ownership of the IP. With this agreement in place, they chose to pursue a full patent application at the expiration of the UIC provisional patent in December. Since that time, our group was selected by UNC as one of five "Innovations to Watch" and asked to present our technology to a group of several hundred interested members of the business community. We are working to transition this prototype system into a standalone piece of hardware that can monitor vital signs in real-time from multiple subjects. We believe that such a device would be an asset to the security, public health, and marketing sectors.

Phase I: Study Setup

Task 1: <u>Specification & purchase of hardware</u>

AMD FX-9590 8-core (4.0 GHz) CPU
32 Gb RAM
Win8 x64
Nvidia GeForce GTX 750 GPU
1394b Firewire Interface Card
Pt.Grey Grasshopper, model GRAS-03K2C-C (Fujinon manual zoom optics)
MS Kinect for Windows version 1.0
Modified version of the Kinect SDK v1.8 program "Face Tracking Basics-WPF"

- Modification made the tracking results visible to Labview via a UDP port connection

NI Labview 2014 (64-bit)

Task 2: <u>Verify TSWG software functions with new hardware</u>

The first iteration of the PhysioCam system incorporated the TSWG methodology with facial tracking being handled by the modified Kinect SDK program. This simple change increased the functional frame rate of the system from ~25 frames/second to nearly 50 frames/second. Further refinements of the facial tracking system were tested, including a synchronized tracking system which stored 5 frames of tracking information and 5 frames of imaging data from the Pt. Grey camera in circular buffers. This approach had a minimal impact on the precision of the facial tracking, increasing the coherence between the solution and the face location. However the trade-off was a reduction in the sustained frame rate. After pilot testing the system, we chose to remove the buffer/synchronization component and rely upon the skin mask step to stabilize our tracking solution. As noted in the comments on Tasks 6 & 7, the tracking performance did not increase the stability of the extracted signal during the treadmill walking task to the degree that was anticipated.

Task 3: <u>Develop IRB materials and obtain IRB approval</u>

The study was reviewed by both the UNC IRB (reference number 14-1560) and the US Army Medical Research and Material Command (HRPO Log Number A-18495) and approved for recruitment on October 10, 2014. The approval notices are attached in the Appendix.

Phase II: Improve algorithms to optimize precision and reduce distortion

Task 4: <u>Benchmark signal detection with contact measures</u>

In order to facilitate the automated editing of the extracted instantaneous heart rate, we adopted a novel approach to measuring the 'inter-beat interval'. Peak detection algorithms suffered from a delay in recovering from a shock to the system. Since changes in the interval were used to both measure HRV parameters and detect periods of instability, attempts to use pattern detection in the extracted interval series were subject to circularity issues. In essence, they could converge on a solution where all data was excluded and a complete reset was required. We chose to use a time-frequency method that monitored the energy distribution of the pulse wave to determine the confidence that could be assigned to each instantaneous heart rate measure. These auto-editing algorithms are outlined in the following figures. They illustrate: (1) a 5-second portion of the pre-processed pulse signal obtained from the camera, (2) the 'windowed' portion of data for the auto-regressive (AR) spectral analysis model, (3) the AR spectrum with instantaneous HR identified, and (4) the estimated 'IBI' (i.e., the inverse of the instantaneous HR) from each 5-second section of the file (overlapping windows move by 200ms per estimate).

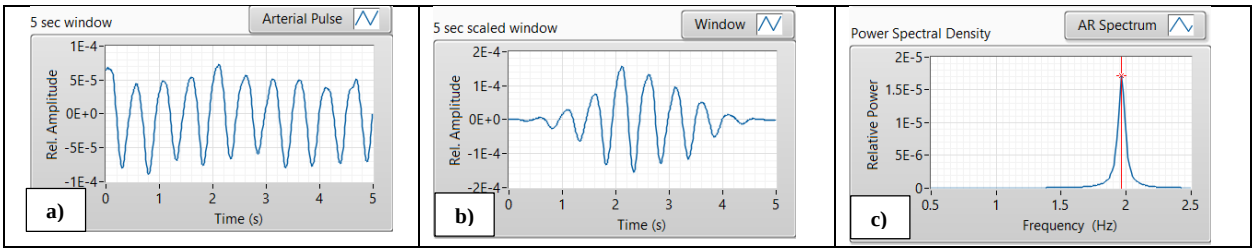


Figure 1. 5-second windows are used to analyze the pulse data; from left to right: a) 5 second window of the arterial pulse obtained by the PhysioCam in real time; b) a window function is applied to the section to facilitate the extraction of the frequency; c) predominant frequency in the 5 seconds window is obtained by an Auto Regressive Spectrum function, this frequency correspond to heart beat.

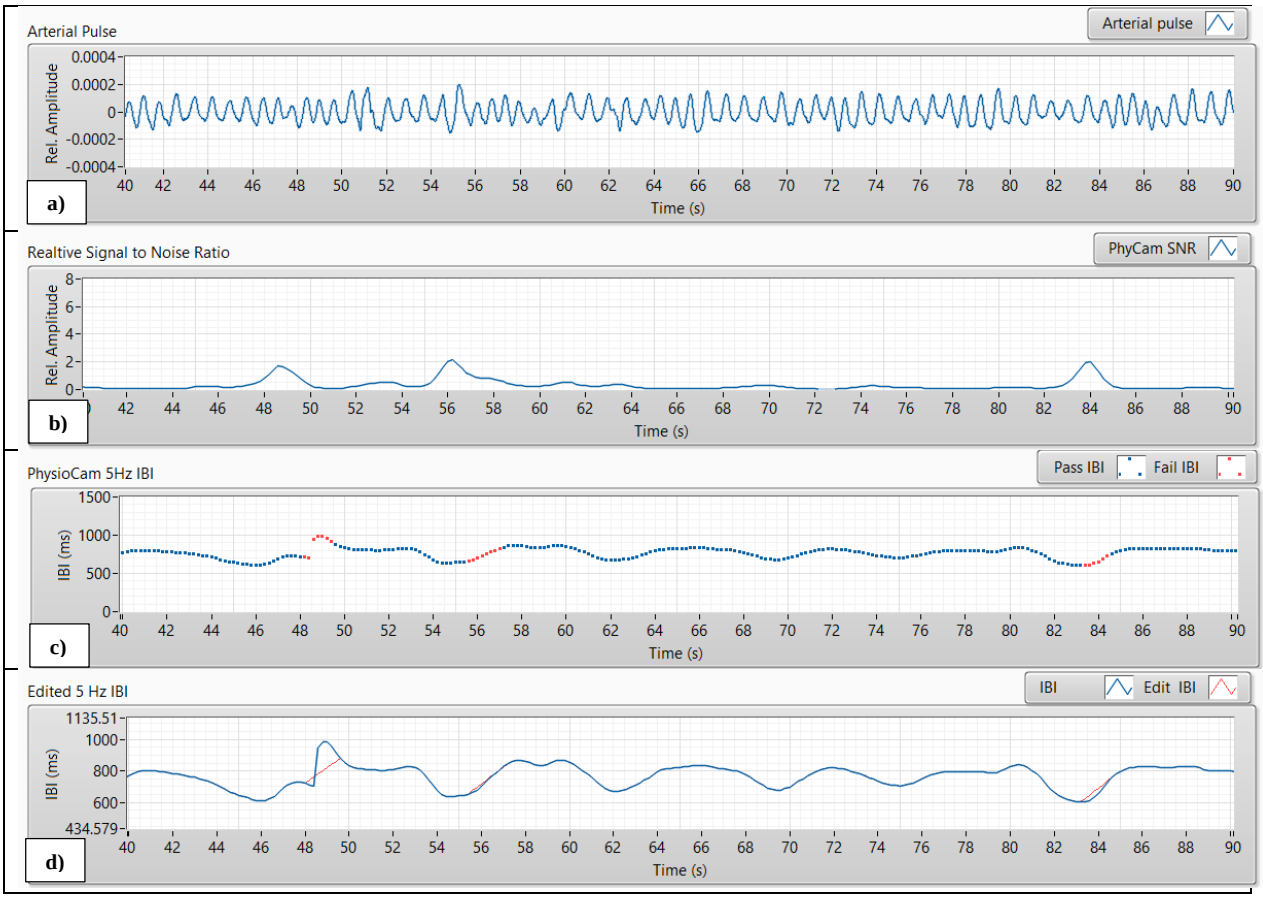
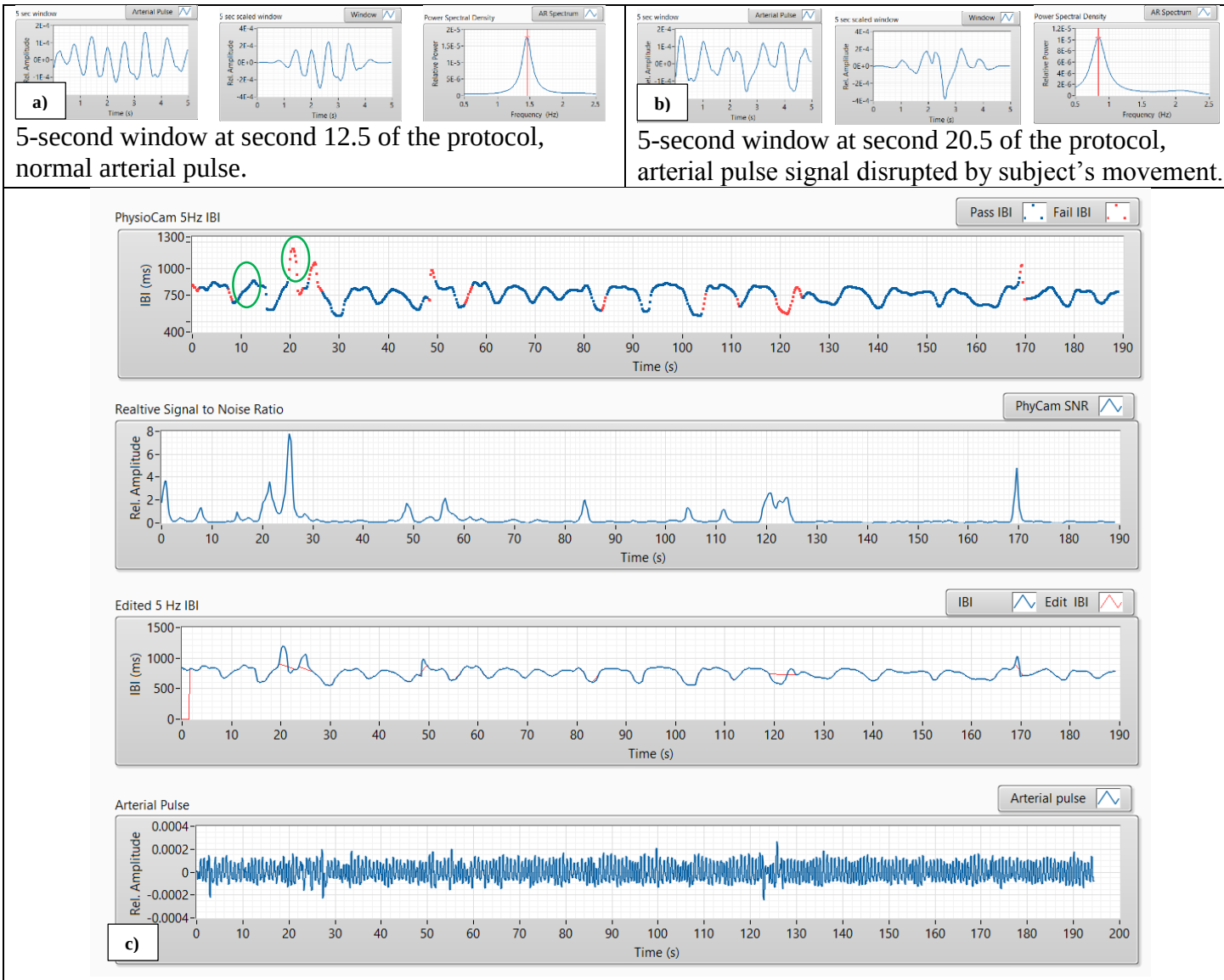


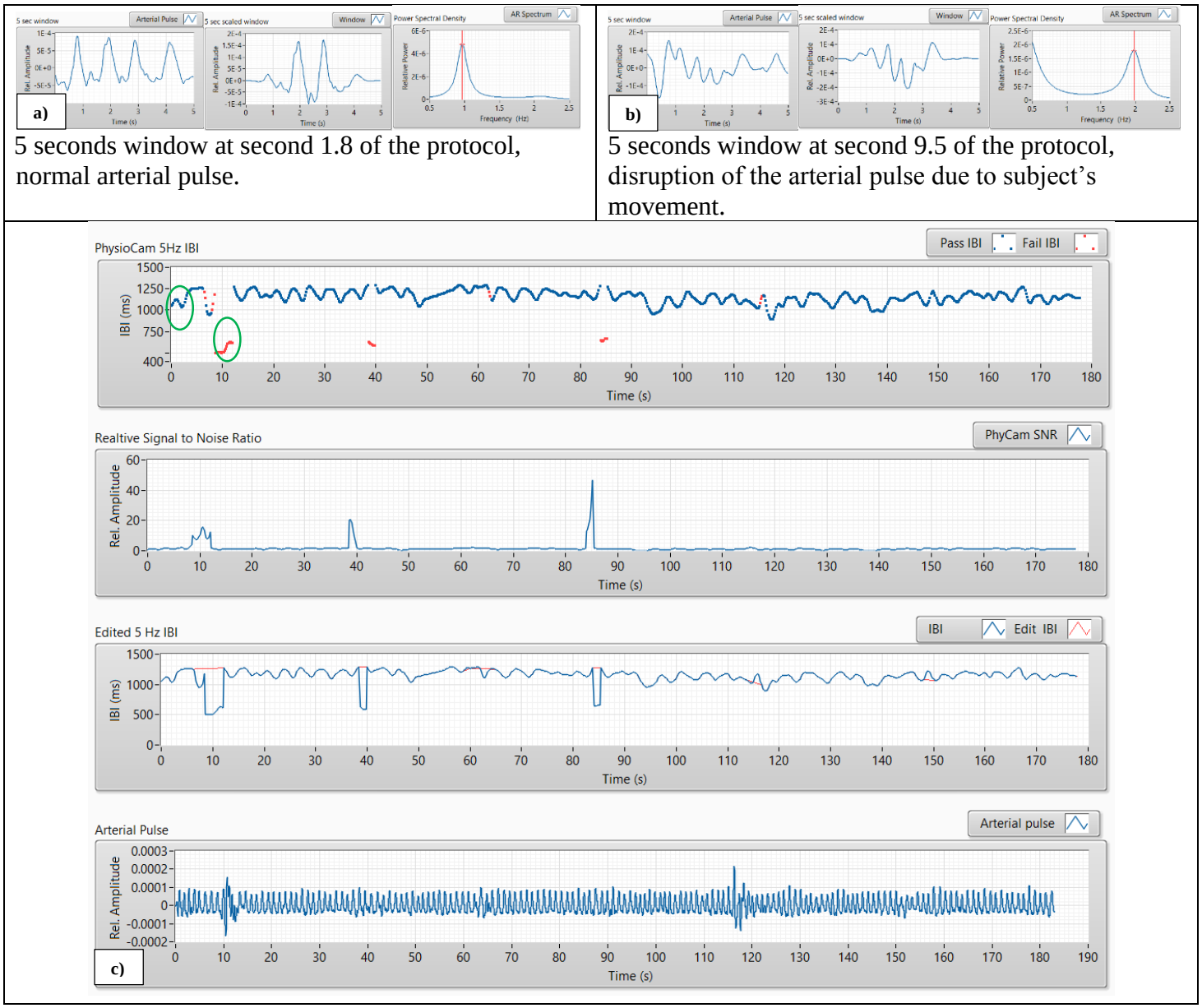
Figure 2. Time series Inter-Beat-Interval (IBI) extraction: a) arterial pulse form the PhysioCam; b) Signal to Noise Ratio obtained from the AR-Spectrum, a threshold helps to discriminate between good (Pass) IBI or bad (Fail) IBI; c) good IBI are represented in blue, bad IBI are represented in red; d) bad IBI are replace by a linear spline, producing the final edited IBI signal.



5-second window at second 12.5 of the protocol, normal arterial pulse.

5-second window at second 20.5 of the protocol, arterial pulse signal disrupted by subject's movement.

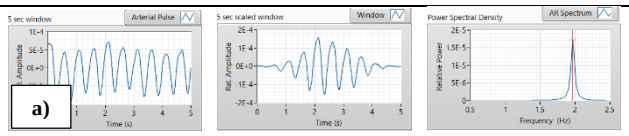
Figure 3. Subject 001 during baseline for the cognitive task. a) 5 second section of good arterial pulse data, the AR Spectrum is able to measure the heart beat; b) 5 second section of bad arterial pulse data (due to movement), the AR Spectrum is not able to measure the heart beat; c) the Signal to Noise Ratio informs the presence of defective data and triggers the auto editing tool.



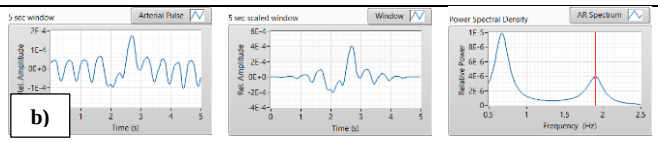
5 seconds window at second 1.8 of the protocol, normal arterial pulse.

5 seconds window at second 9.5 of the protocol, disruption of the arterial pulse due to subject's movement.

Figure 4. Subject 024 during baseline for the cognitive task. a) 5 second section of good arterial pulse data, the AR Spectrum is able to measure the heart beat; b) 5 second section of bad arterial pulse data (due to movement), the AR Spectrum is not able to measure the heart beat; c) the Signal to Noise Ratio informs the presence of defective data and triggers the auto editing tool.



5 seconds window at second 34 of the protocol, normal arterial pulse



5 seconds window at second 50 of the protocol, a premature ventricular contraction (PVC) occurs.

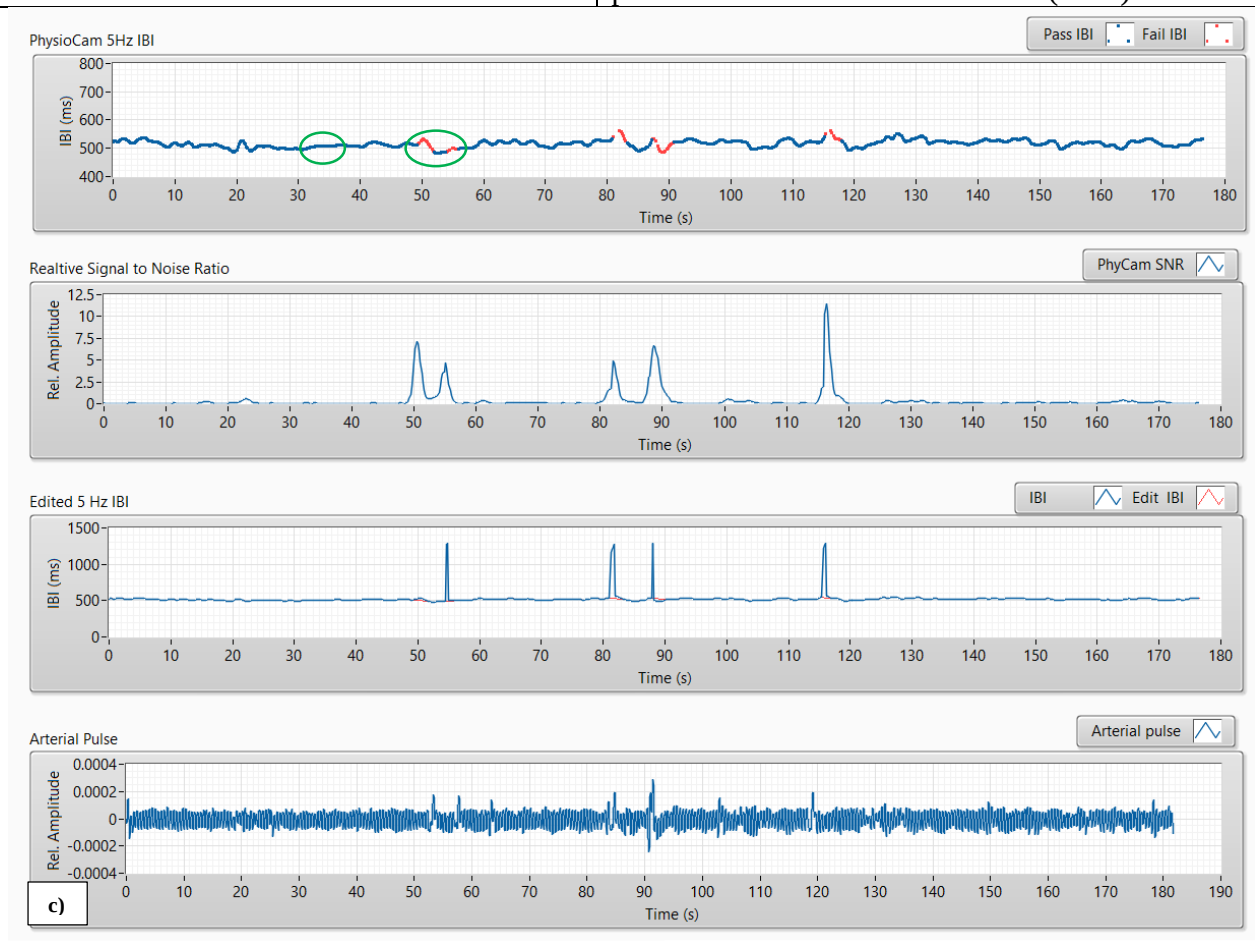
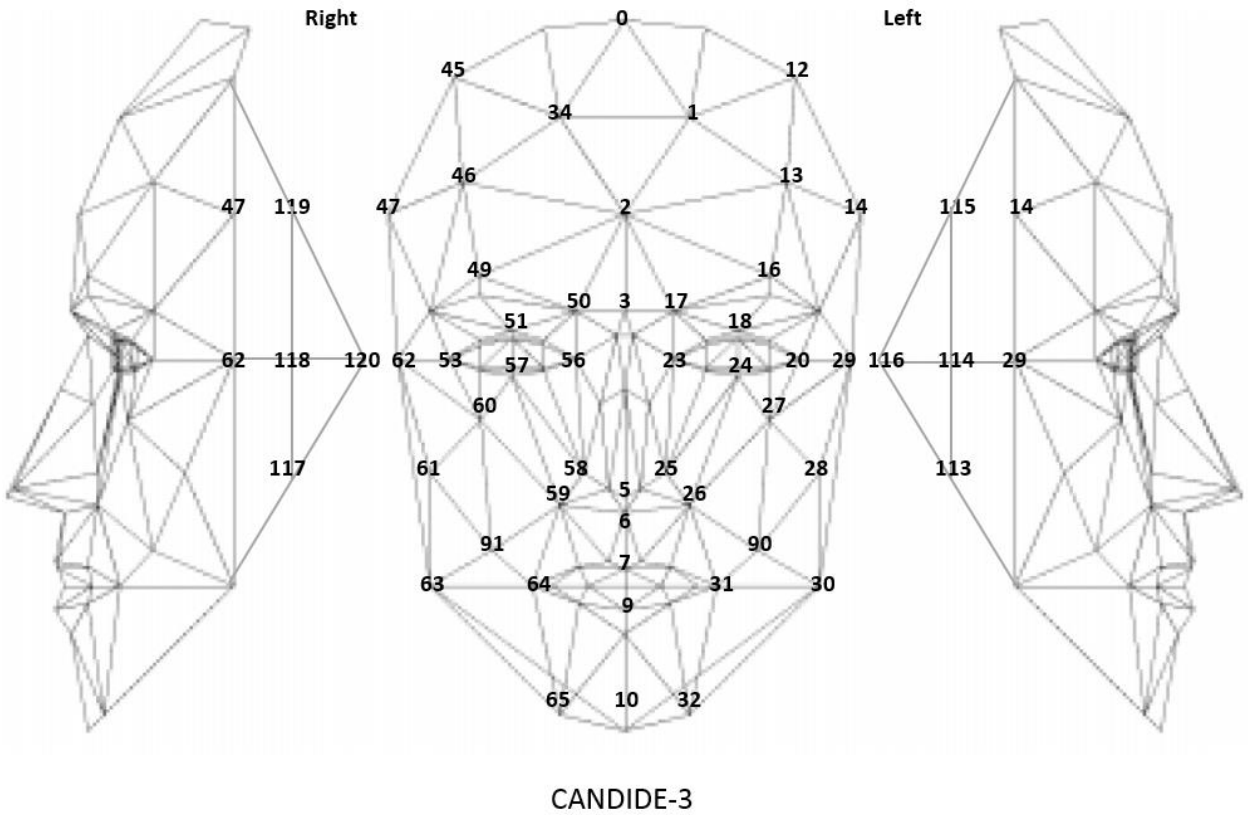


Figure 5. Subject 002 during baseline for the cognitive task. a) 5 second section of good arterial pulse data, the AR Spectrum is able to measure the heart beat; b) 5 second section of bad arterial pulse data (premature ventricular contraction), the AR Spectrum is not able to measure the heart beat; c) the Signal to Noise Ratio informs the presence of defective data and triggers the auto editing tool.

Task 5: <u>Refine ROI placement to optimize signal stability</u>



CANDIDE-3

Figure 6. CANDIDE-3 model used by the Face Tracking SDK to inform the pixel position of the subject's face.

The Kinect for Windows Software Development Kit (SDK) offers the Microsoft Face Tracking Software Development Kit (Face Tracking SDK). The SDK and the Face Tracking SDK, in conjunction with the Kinect device, facilitate the tracking of the subject's face in real time.
The Face Tracking SDK uses the CANDIDE-3 (model to parametrize the human face) as the output information data. X and Y coordinates of several vertices of the parametrize face are available in an array of 121 set of points; each point corresponds to an X and Y pixel position on the Kinect image output.
For example: Point # 6 will be the (X,Y) pair that relates to the pixel position of the Bottom middle edge of nose; point # 3 will be the (X,Y) pair that relates to the pixel position of the Midpoint between eyebrows; point # 28 will be the (X,Y) pair that relates to the pixel position of the Inner contact point between left ear and face; point # 60 will be the (X,Y) pair that relates to the pixel position of the Right cheek bone; to mention a few.
Points from the CANDIDE-3 array are translated to the color camera frame dimensions by a "camera registration" procedure; correcting for differences in the Field of View (FOV) between the Kinect device and the color camera. This points will be used to track the subject's face in real time in the color camera space.

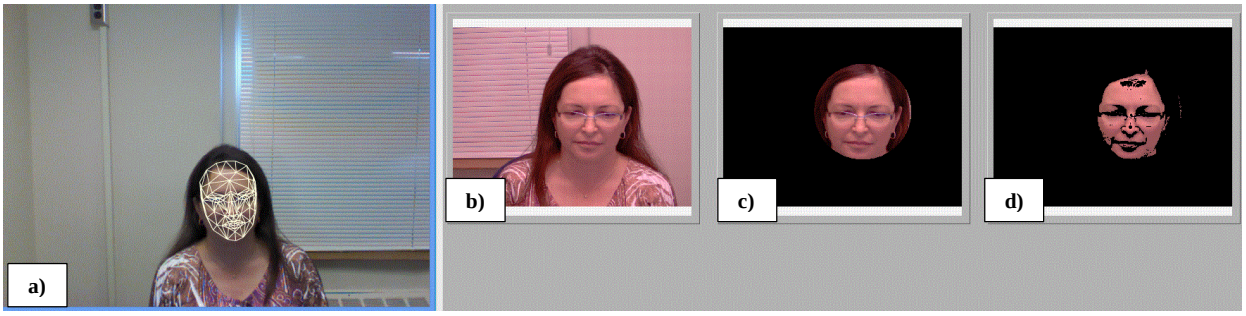


Figure 7. a) CANDIDE-3 model output from the Kinect camera, b) image capture by the color camera after setting manipulation, c) oval geometric mask, d) skin mask applied over geometric mask.

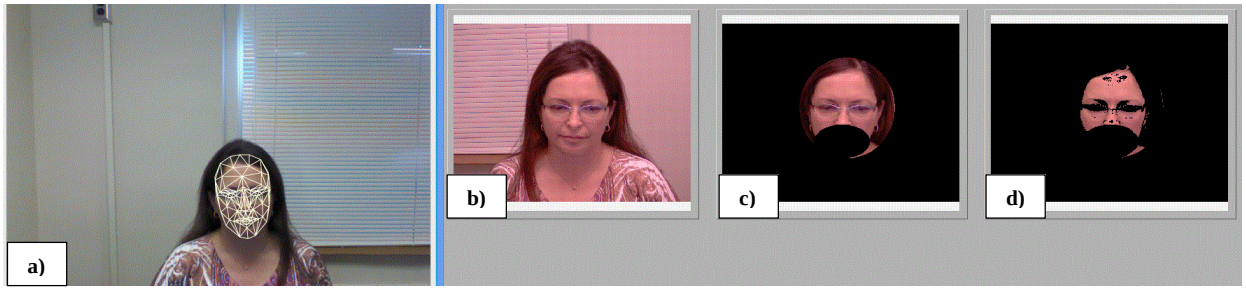


Figure 8. a) CANDIDE-3 model output from the Kinect camera, b) image capture by the color camera after setting manipulation, c) oval geometric mask with mouth area removed, d) skin mask applied over geometric mask. This approach minimizes signal distortion due to move movements while talking.

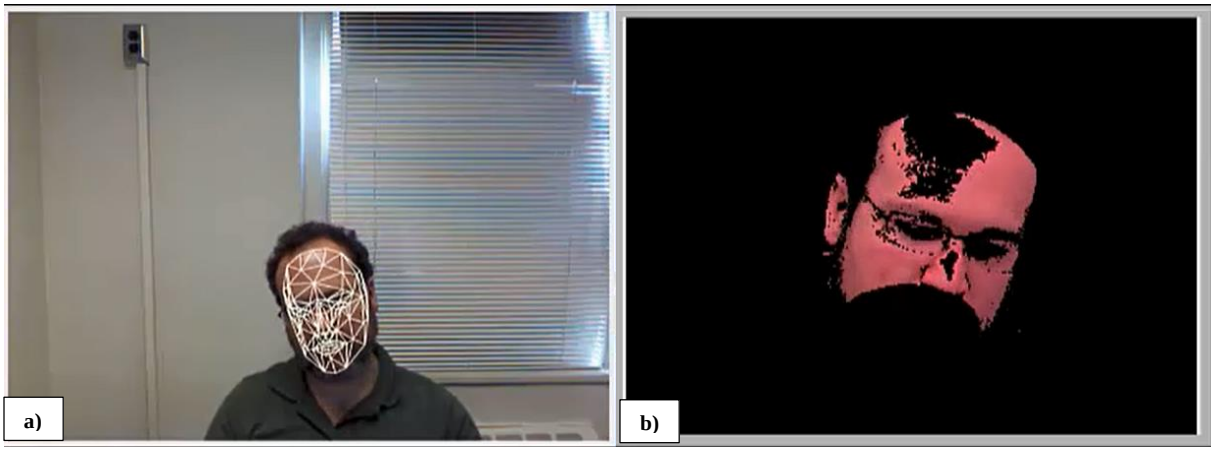


Figure 9. Final approach implemented for the PhysioCam. a) CANDIDE-3 model output from the Kinect b) pixels selection for the pulse extraction algorithm, after applying geometric and skin masks.

Summary of the benefits to using the Kinect sensor for motion tracking:

- Finds subjects rapidly on initialization
- Recalibrates quickly and automatically after an interruption
- Can be used in near field (2m or less) or far field (3-10m) settings
- Improves the real time PhysioCam frame rate

Phase III: Reduce distorting influences of body movement on pulse signals.

Task 6: Implement motion tracking with Kinect

Motion tracking significantly improved when the Kinect Face Tracking solution was integrated in the PhysioCam software. Using the Kinect to track motion, instead of the motion tracking algorithms dependent on the Frame-by-Frame processing within Labview significantly increased processing efficiency and increased the frame rate of the system to 50 frames a second. However, the improved tracking did not have the intended effect in eliminating motion artifact from the acquired signal.

An additional modification to the algorithm was made that enabled signal acquisition during periods of moderate body sway (e.g., standing on the treadmill). The frame level measurement changed from:

Mean(Accepted Green Pixel Values) / Mean(Accepted Red Pixel Values)

To:

Mean(Accepted [(Red Pixel Value – Green Pixel Value) / (MAX({red,green,blue} Pixel Value))]); operations within the [] are performed on each pixel.

Thus, the relative distance between red and green was calculated on a per-pixel level first, normalized by the total intensity of that pixel (the MAX value), and then the set of these calculations was used to generate a mean value. This reduced the impact illumination variations within the region of interest, but did not eliminate it. Thus, as shown in the following section, the walking task continued to confound the AR model of instantaneous heart rate.

Task 7: Treadmill test of rapid pulse extraction

Figure 10 illustrates the limitations of the current implementation of the PhysioCam. Movement due to walking on the treadmill produced periodic noise that confounded attempts to accurately extract pulse. In the following section, we illustrate an example of the results obtained with the current system (employing the AR model outlined in Task 4) and preliminary findings using the SynchroSqueeze Transform, a new approach to time-frequency analysis that may enhance the extraction of the pulse wave when the signal is confounded with periodic noise.

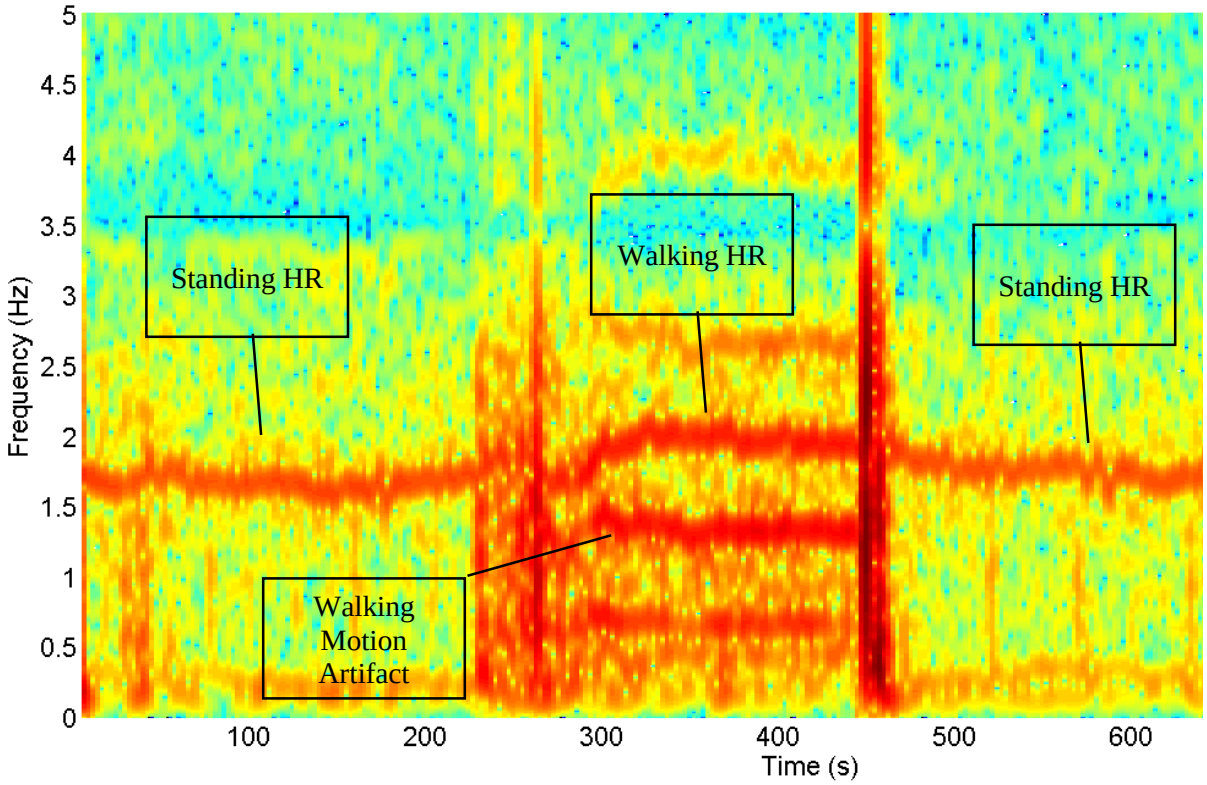


Figure 10. Spectrogram (Short-Time Fourier Transformation) of the PhysioCam analysis signal during standing→walking→standing tasks.

The subject is standing still on the treadmill at the start of the file through 220 seconds. As illustrated, the heart rate component of the pulse signal is easily identified in the spectrogram (see Figures 11 and 12 for examples of the two methods extracting instantaneous heart rate (IHR) from this segment of data). After a brief disruption from 220-270 seconds while the subject gets stable on the treadmill, the subject walks at a fixed pace from 280-420 seconds. The spectrogram clearly illustrates a new periodic component that is now embedded within the analysis signal. Figure 13 illustrates that the sliding window AR model is unable to isolate the heart rate component during this segment. However, as shown in Figure 14, the SST tracks heart rate despite the motion related noise.

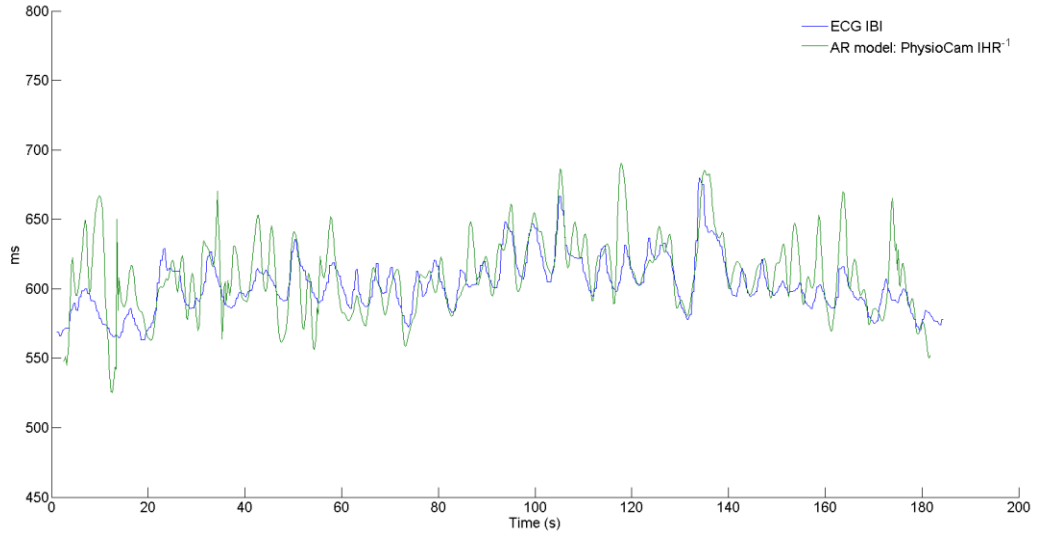


Figure 11. PhysioCam AR model estimate of IHR^{-1} during the standing baseline.

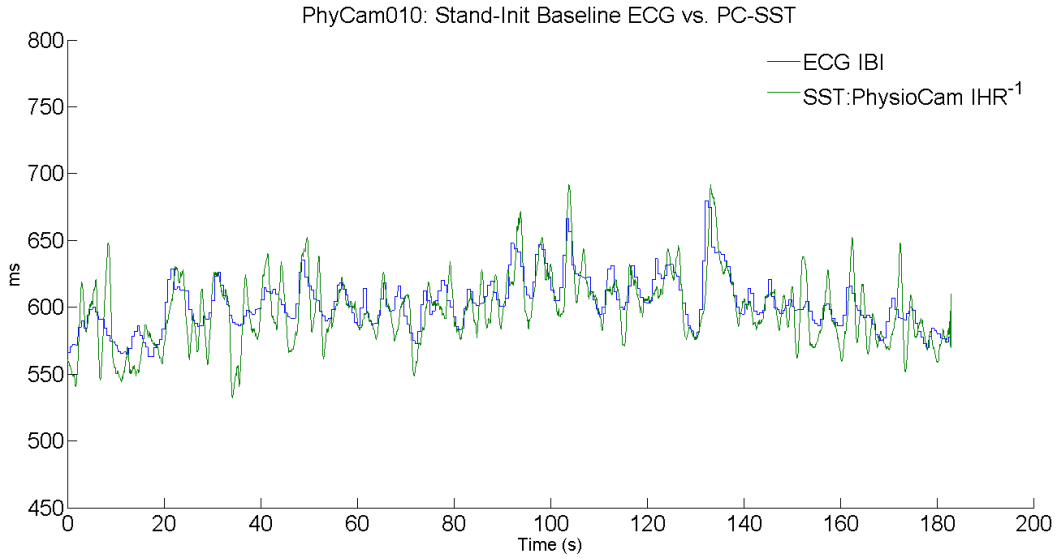


Figure 12. PhysioCam SynchroSqueeze Transform model estimate of IHR^{-1} during the standing baseline.

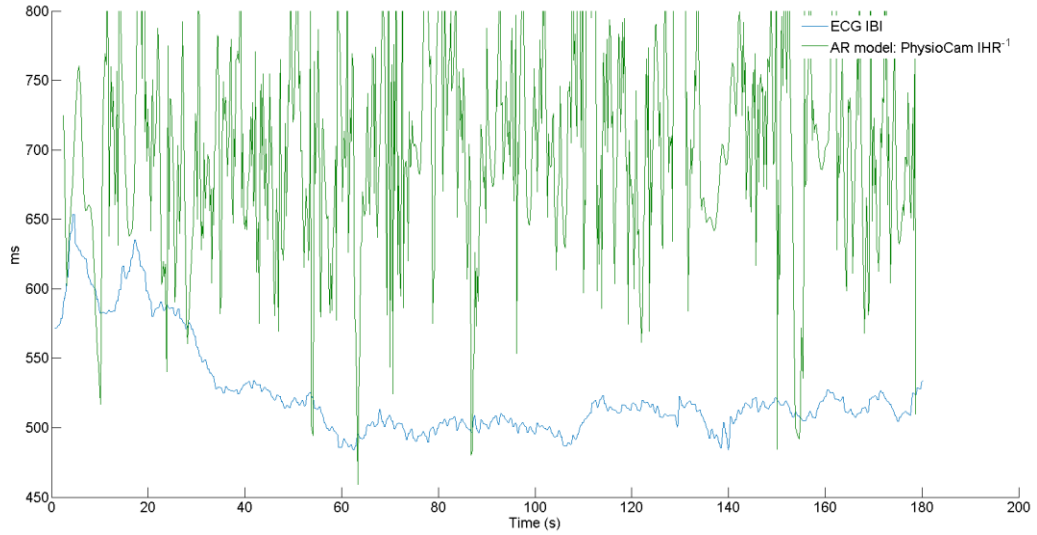


Figure 13. PhysioCam AR model Transform model estimate of IHR^{-1} during the walking test.

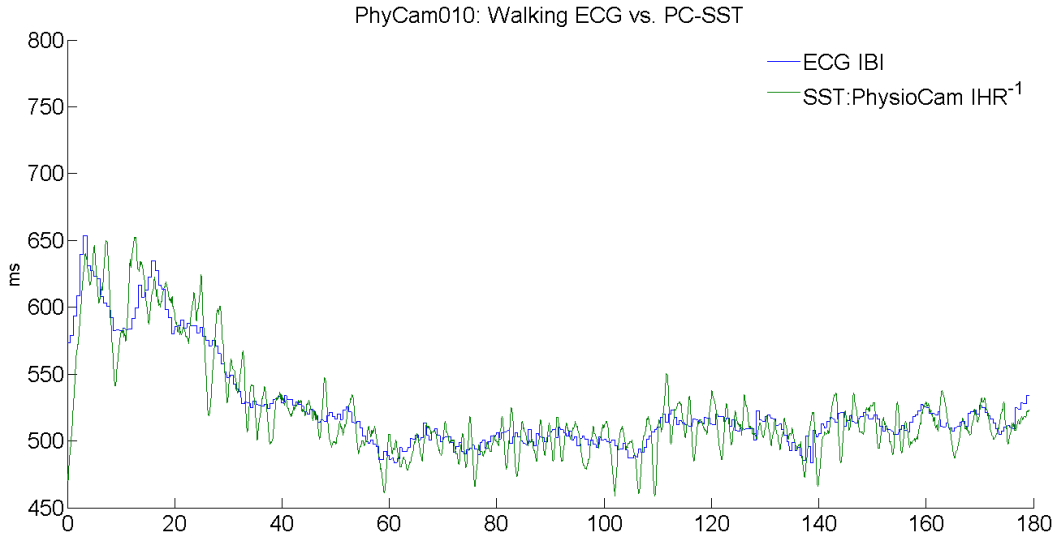


Figure 14. PhysioCam SynchroSqueeze Transform model estimate of IHR^{-1} during the walking test.

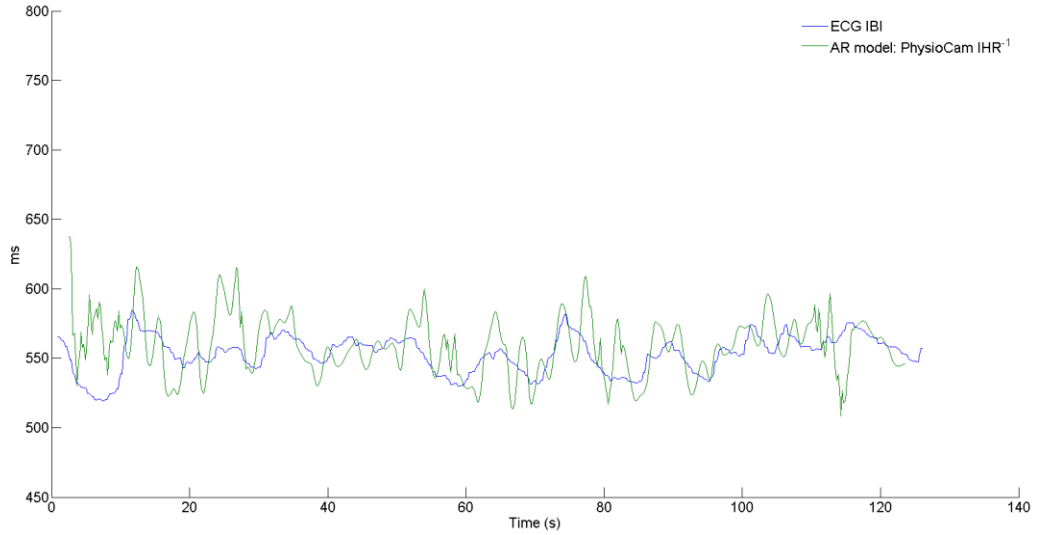


Figure 15. PhysioCam AR model Transform model estimate of IHR^{-1} during the final baseline.

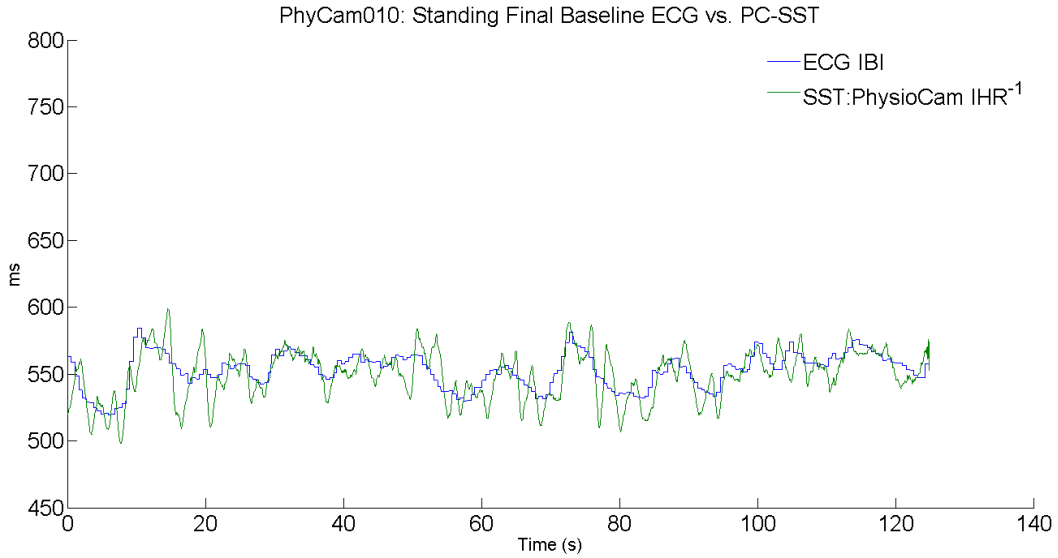


Figure 16. PhysioCam SynchroSqueeze Transform model estimate of IHR^{-1} during the final baseline.

The noise component is related to the changing angle and distance between three objects: the illumination sources, the face of the subject, and the sensor. The changing surface area of measurable pixels provides an estimate of the frequencies of this noise component, but attempts to backwards mask the motion artifact out of the analysis signal were unsuccessful. We believe that this is because the angle of incidence between the light-surface-sensor is more related to the noise than the number of pixels available for measurement. The most promising path forward for a real-time PhysioCam system capable of dealing with large amounts of movement related artifact appears to be the SynchroSqueeze Transformation. Since this approach was well beyond the scope of work, we have not committed much effort to optimizing the algorithm, but even the preliminary results indicate that the method is capable of measuring heart rate under our most challenging demand. In the final figure for this task, the average IBI derived from the ECG

signal is compared to the instantaneous heart rate derived from the SST. In most cases where the SST converged on a solution, it was highly correlated with the true heart rate of the subject.

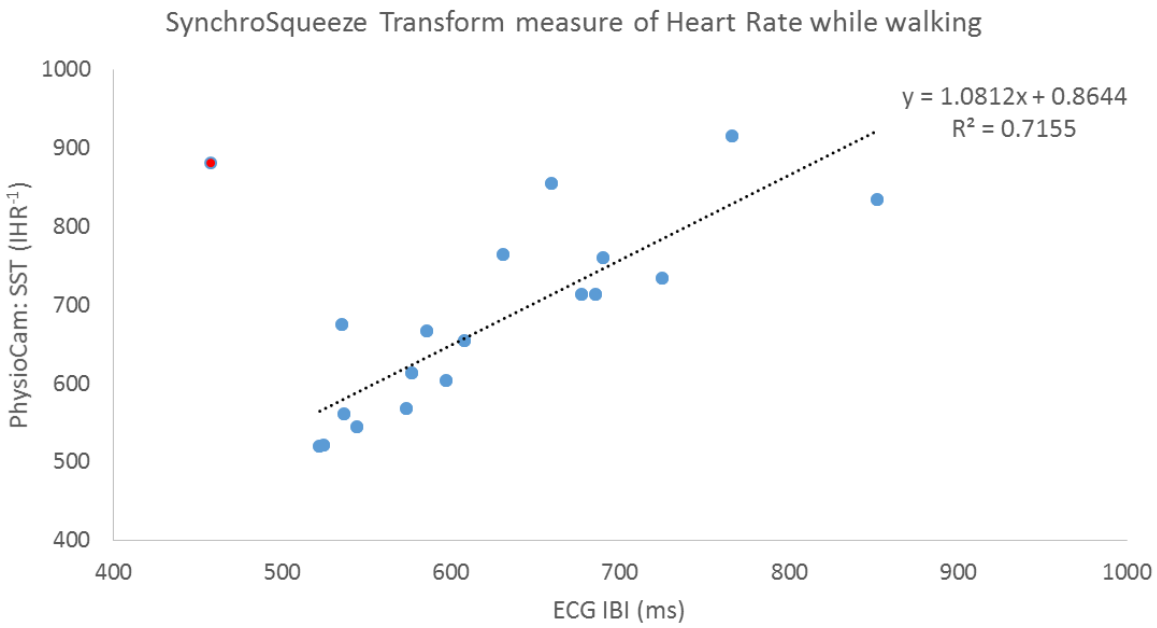


Figure 17. PhysioCam SynchroSqueeze Transform IHR^{-1} and ECG IBI correlation measure while walking test.

Phase IV: Evaluation of PhysioCam

Task 8: Experiment to monitor contact and noncontact measures of physiology under two tasks

Twenty-seven participants between the ages of 18 and 33 (M = 20.11, SD = 2.98) were recruited from the UNC psychology student subject pool. The gender mix was, 56% female and 44% male. Participants self-identified as White or Caucasian (62.96%), Asian (18.52%), Black or African American (3.70%), American Indian or Alaskan Native, Hispanic or Latino (3.70%), Asian, Hispanic or Latino (3.70%), Asian, White or Caucasian (3.70%), and White or Caucasian, Hispanic or Latino (3.70%).

Light conditions in the room were measured around the subject for each task. Mean and standard deviation values are listed in Table 1.

Table 1. Illuminance (Lux) in the experimental room for both tasks; cognitive and walking on the treadmill.

	N	Mean	Std. Dev	Min	Max
Seated Condition (Cognitive Task)	27	985.22	117.14	638.80	1258.40
Standing Condition (Walking Task)	26	582.74	103.67	381.80	739.60

Camera settings were manually adjusted for each subject for each of the two tasks with the objective to optimize the amount of light captured by the sensor over the proper exposure period of time. To analyze the resulting data, subjects were clustered by their reported ethnicity. These data will inform future efforts to automate the camera settings based on the subject's skin tone.

		Camera Settings							
		Seated Condition				Standing Condition			
White or Caucasian	N	Mean	Std. Dev	Min	Max	Mean	Std. Dev	Min	Max
Gain	19	62.37	26.07	48.00	125.00	86.11	42.59	48.00	159.00
Gamma	19	2129.84	363.01	1800.00	2780.00	2140.00	298.01	1800.00	2644.00
Saturation	19	1976.53	365.42	1140.00	2488.00	2129.21	380.94	1600.00	2851.00
White Balance	19	535.21	56.58	401.00	647.00	501.00	46.64	401.00	596.00
Shutter	19	350.00	0.00	350.00	350.00	350.00	0.00	350.00	350.00
Asian	N	Mean	Std. Dev	Min	Max	Mean	Std. Dev	Min	Max
Gain	7	55.29	19.28	48.00	99.00	56.57	22.68	48.00	108.00
Gamma	7	2288.43	546.06	1800.00	3097.00	2191.29	425.40	1800.00	2825.00
Saturation	7	1929.71	451.02	1600.00	2747.00	1811.14	278.37	1600.00	2384.00
White Balance	7	560.86	48.21	492.00	635.00	528.71	22.33	479.00	540.00
Shutter	7	350.00	0.00	350.00	350.00	362.86	34.02	350.00	440.00
Hispanic or Latino	N	Mean	Std. Dev	Min	Max	Mean	Std. Dev	Min	Max
Gain	3	48.00	0.00	48.00	48.00	82.00	58.89	48.00	150.00
Gamma	3	2020.67	382.21	1800.00	2462.00	2165.67	403.16	1800.00	2598.00
Saturation	3	1863.67	241.14	1600.00	2073.00	2090.67	316.63	1814.00	2436.00
White Balance	3	575.67	61.78	540.00	647.00	479.00	68.79	401.00	531.00
Shutter	3	350.00	0.00	350.00	350.00	380.00	51.96	350.00	440.00
American Indian or Alaskan Native	N	Mean	Std. Dev	Min	Max	Mean	Std. Dev	Min	Max
Gain	1	48.00	.	48.00	48.00	48.00	.	48.00	48.00
Gamma	1	1800.00	.	1800.00	1800.00	1800.00	.	1800.00	1800.00
Saturation	1	2073.00	.	2073.00	2073.00	2436.00	.	2436.00	2436.00
White Balance	1	540.00	.	540.00	540.00	401.00	.	401.00	401.00
Shutter	1	350.00	.	350.00	350.00	350.00	.	350.00	350.00
Black or African American	N	Mean	Std. Dev	Min	Max	Mean	Std. Dev	Min	Max
Gain	1	252.00	.	252.00	252.00	388.00	.	388.00	388.00
Gamma	1	1691.00	.	1691.00	1691.00	1800.00	.	1800.00	1800.00
Saturation	1	3058.00	.	3058.00	3058.00	2695.00	.	2695.00	2695.00
White Balance	1	479.00	.	479.00	479.00	531.00	.	531.00	531.00
Shutter	1	440.00	.	440.00	440.00	350.00	.	350.00	350.00

After setting the camera parameters, values for each frame were constrained in the Hue-Saturation-Luminance color plane. This process created a "Skin Mask" to assure that the pixels being analyzed correspond to the skin of the face. The skin mask values used are clustered by reported ethnicity.

		Skin Mask Settings							
		Seated Condition				Standing Condition			
White or Caucasian	N	Mean	Std. Dev	Min	Max	Mean	Std. Dev	Min	Max
Hue Minimum	19	223.53	15.46	170.00	240.00	221.53	17.03	172.00	245.00
Hue Maximum	19	33.84	31.77	3.00	116.00	32.21	30.77	0.00	110.00
Saturation Minimum	19	45.37	12.38	21.00	67.00	39.58	12.36	18.00	69.00
Saturation Maximum	19	116.42	19.21	77.00	152.00	124.21	24.06	90.00	173.00
Luminance Minimum	19	66.11	15.02	47.00	95.00	76.32	23.74	29.00	108.00
Luminance Minimum	19	156.11	22.26	118.00	204.00	147.53	17.50	110.00	204.00
Asian	N	Mean	Std. Dev	Min	Max	Mean	Std. Dev	Min	Max
Hue Minimum	7	222.71	7.18	220.00	239.00	223.57	9.45	220.00	245.00
Hue Maximum	7	49.86	24.07	23.00	93.00	55.86	25.98	11.00	98.00
Saturation Minimum	7	43.00	4.40	39.00	49.00	38.43	9.93	20.00	52.00
Saturation Maximum	7	123.71	38.53	105.00	211.00	113.71	8.20	110.00	132.00
Luminance Minimum	7	60.57	17.83	47.00	96.00	56.00	10.69	49.00	74.00
Luminance Minimum	7	149.14	11.55	140.00	165.00	132.00	16.92	105.00	145.00
Hispanic or Latino	N	Mean	Std. Dev	Min	Max	Mean	Std. Dev	Min	Max
Hue Minimum	3	230.00	15.62	220.00	248.00	215.33	27.30	186.00	240.00
Hue Maximum	3	53.33	19.86	31.00	69.00	45.00	25.98	15.00	60.00
Saturation Minimum	3	46.67	11.55	40.00	60.00	27.33	10.21	20.00	39.00
Saturation Maximum	3	114.33	7.51	110.00	123.00	131.67	19.86	110.00	149.00
Luminance Minimum	3	63.67	13.50	50.00	77.00	81.67	10.02	74.00	93.00
Luminance Minimum	3	140.00	0.00	140.00	140.00	154.33	8.96	144.00	160.00
American Indian or Alaskan Native	N	Mean	Std. Dev	Min	Max	Mean	Std. Dev	Min	Max
Hue Minimum	1	248.00	.	248.00	248.00	186.00	.	186.00	186.00
Hue Maximum	1	31.00	.	31.00	31.00	60.00	.	60.00	60.00

Saturation Minimum	1	40.00	.	40.00	40.00	23.00	.	23.00	23.00
Saturation Maximum	1	110.00	.	110.00	110.00	136.00	.	136.00	136.00
Luminance Minimum	1	64.00	.	64.00	64.00	78.00	.	78.00	78.00
Luminance Minimum	1	140.00	.	140.00	140.00	160.00	.	160.00	160.00
Black or African American	N	Mean	Std. Dev	Min	Max	Mean	Std. Dev	Min	Max
Hue Minimum	1	201.00	.	201.00	201.00	226.00	.	226.00	226.00
Hue Maximum	1	15.00	.	15.00	15.00	62.00	.	62.00	62.00
Saturation Minimum	1	41.00	.	41.00	41.00	56.00	.	56.00	56.00
Saturation Maximum	1	180.00	.	180.00	180.00	141.00	.	141.00	141.00
Luminance Minimum	1	38.00	.	38.00	38.00	75.00	.	75.00	75.00
Luminance Minimum	1	142.00	.	142.00	142.00	147.00	.	147.00	147.00

RESULTS

Results are presented for the two seated conditions: resting baseline and attention demanding cognitive task. For measures of HRV, variance was evaluated by the Porges-Bohrer methodology (see Lewis et al., 2012 for a review). Estimates were created by averaging complete 30-second epochs of pre-processed IBI data within each segment. If any epoch represented more than 50% auto-editing (see Task 4 for a review on this procedure), the epoch was not used to generate the HRV level. This same rule was applied in real-time when tracking the subject's physiological state. One subject did not have sufficient unedited data to generate an HRV estimate in the baseline condition.

During the attention demanding task, the participant watched a video. Participants were told that a crime would be committed during the video. They were instructed to watch closely, remember details, and be prepared to answer questions about what they saw. The task had the intended psychophysiological consequence of increasing heart rate (Heart Period decreased by 33.2 ms on average), and decreasing both measures of HRV (RSA dropped by 0.32 $Ln(ms^2)$, LF-HRV by the same amount). In the seated condition, average heart period values from the ECG and PhysioCam calculated from each subject were correlated above 0.99 during both the baseline and video tasks (N = 26). Average RSA values from the ECG and PhysioCam for each subject were significantly correlated during the baseline task ($r = 0.932$, $p < 0.001$, $N = 25$) and the video task ($r = 0.895$, $p < 0.001$, $N = 26$). Similarly, LF-HRV was highly correlated during the baseline ($r = 0.878$, $p < 0.001$, $N = 25$) and the video tasks ($r = 0.926$, $p < 0.001$, $N = 26$).

The sensitivity of the PhysioCam to the cognitive task was contrasted with the contact ECG-based measures of heart period, RSA and LF-HRV. The sensitivity to the tasks was evaluated with two statistical tests: Repeated Measures ANOVA and correlations between change scores (baseline versus cognitive task).

As listed in Table #2#, the F-values for the three dependent variables were similar between the two sensors. Thus, the data confirm that the standoff sensor is sensitive to the physiological changes associated with cognitive challenges.

Table #2#. Repeated Measures ANOVA: Effect Size for Time with Each Sensor, for each parameter.

	Sensor	Df	F	*p*
Heart Period	ECG	(1,25)	8.29	**0.008**
	PhysioCam	(1,25)	6.94	**0.01**
RSA	ECG	(1,24)	4.53	**0.04**
	PhysioCam	(1,24)	3.54	0.07
LF-HRV	ECG	(1,24)	5.41	**0.03**
	PhysioCam	(1,24)	6.53	**0.02**

Evaluation of the within-subject change scores revealed a similar pattern of findings. Pearson correlations of change scores (Video Task – Baseline) identified strong convergence between ECG and PhysioCam derived measures of heart period changes (r = 0.975, N = 26), LF-HRV (r = 0.892, N = 25) and RSA (r = 0.672, N = 25). All p-values were less than 0.001.

Figure $$$. Band-Altman Plot of 10Hz (Instantaneous Heart Rate) $^{-1}$ estimates from the PhysioCam and the matched inter-beat interval (IBI) from the ECG device. All subjects.

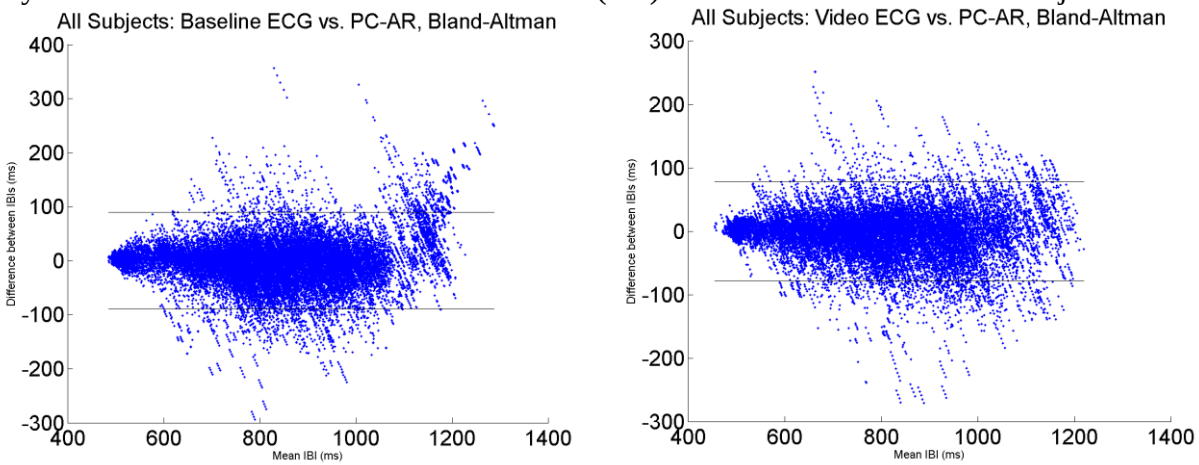


Figure 18. ECG vs. PhysioCam Auto Regressive Spectrum Bland-Altman plots for the two cognitive tasks.

Error bars represent the 95% confidence interval of the IBI difference. The majority of outliers are regions of automated editing that were excluded from HRV analysis. The Bland-Altman plots confirm that estimates of heart period by the PhysioCam are not biased and are independent of the true underlying heart period derived with the ECG.

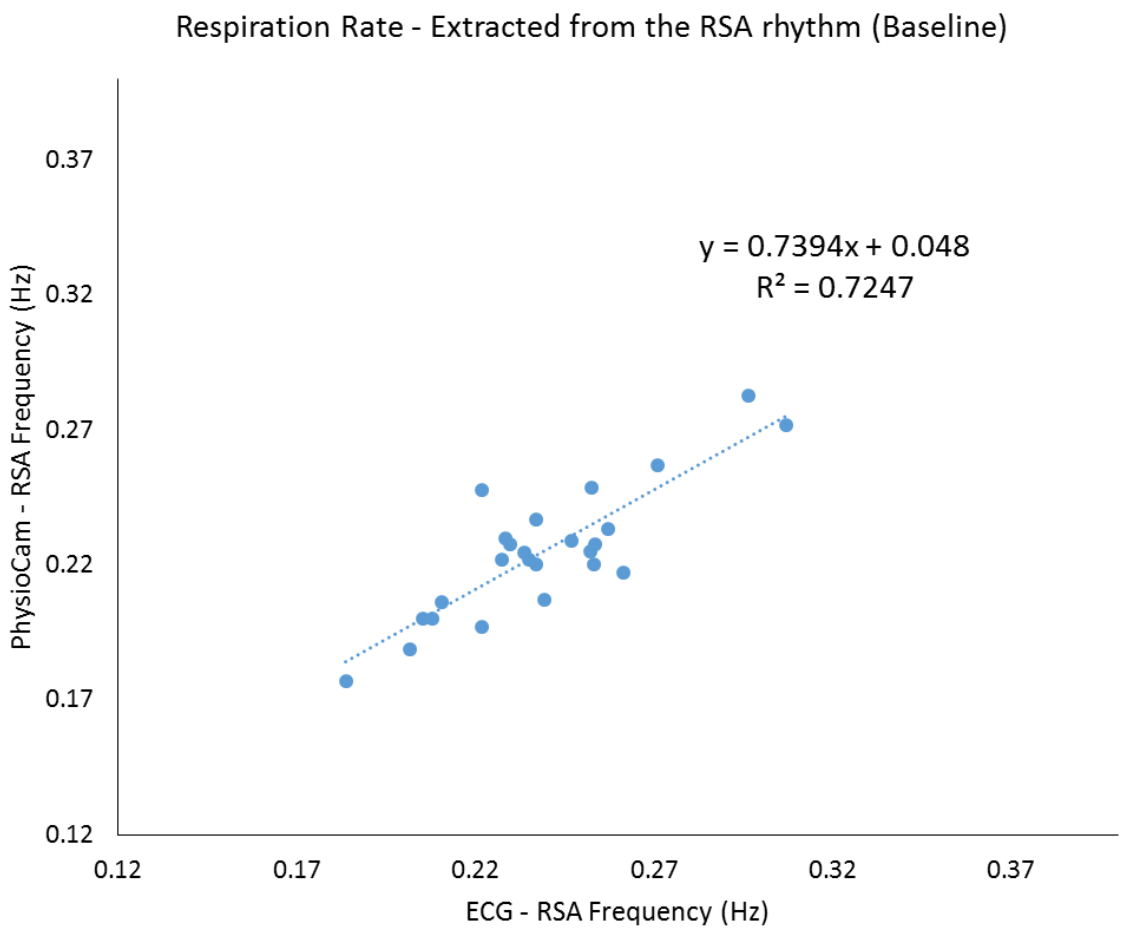


Figure 19. Respiration Rate obtained from RSA. PhysioCam vs. ECG correlation.

Finally, respiration rate can be reliably extracted from the frequency of the RSA rhythm (Denver, 2007). We confirmed that the PhysioCam system was capable of extracting this vital sign reliably. Correlations during both of the seated tasks were highly significant, and the respiration rate changes were also reliably tracked ($r = 0.91$, $p < 0.001$, $N = 25$).

Phase V: Prototype and delivery of PhysioCam

Tasks 9&10: <u>Complete and deliver integrated system for streaming and external synchronization</u>

Due to changes in the N2 program, these tasks were eliminated. Despite this change, we have maintained a relationship with Amy Haufler at the Johns Hopkins University Applied Physics Laboratory. They and their partners in the Air Force have continued to express interest in the PhysioCam technology. We have continued to develop the system and manual, in anticipation of a future testbed evaluation of the sensor. In the final months of this N2 task, we have worked with Dr. Haufler to support an internal R&D project at APL. In May, we will be delivering a working PhysioCam prototype to them for evaluation. There is considerable interest in standoff measures of physiological change due to cognitive load from several other partners of APL. We

will be piloting a real-time monitor of physiological stress response to cognitive demands within a small sample of APL employees. We hope that this collaboration can grow into a deployed application of the technology, providing an objective measure of trainee state during Air Force Command & Control training sessions. The support of DARPA has enabled the collaboration.

Phase VI: Deliver updated software. Online and Offline.

Tasks 11&12: <u>Offline and real time quantification of physiological signals</u>

Our approach to processing these data was to optimize development time, while maintaining our commitment to end the project with a functioning real time system. Thus, we implemented an initial model of instantaneous heart rate estimation, along with the ability to log the frame level parameters of interest in real time. We then refined our IHR model, based on the recorded data, and have now implemented all of the outline methods in real time. The current system collects, processes, auto-edits, and displays the parameters outlined in this report in real time while operating at a speed of 50 frames/second. We will be evaluating the sensitivity of the extracted parameters to cognitive demand in our upcoming collaboration with APL.

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Appendix A: IRB Documentation

From: Mahasreshti, Parameshwar J CIV USARMY MEDCOM USAMRMC (US)< parameshwar.j.mahasreshti.civ@mail.mil>
Sent: Friday, October 10, 2014 11:28 AM
To: Porges, Stephen W.
Cc: Bennett, Jodi H CIV USARMY MEDCOM USAMRMC (US); Martin, Martha E; Shands, Lanelle T CIV USARMY ARO (US); Iyer, S Purushothaman (Purush) CIV USARMY ARO (US); Lewis, Greg; USARMY RTP ARO Mailbox Protocol; Brosch, Laura R CIV USARMY MEDCOM USAMRMC (US); Evans, Sharon A CIV USARMY MEDCOM USAMRMC (US); Mattocks, Lisa A CIV DARPA (US); Zafar, Sahar CTR (US); Bratton, Bill E CTR USARMY USAMC (US); Englar, Nancy E CTR USARMY USAMC (US); Frank, Melanie A CTR USARMY MEDCOM USAMRMC (US); Frederick, Margaret M CTR USARMY MEDCOM USAMRMC (US); Mahasreshti, Parameshwar J CIV USARMY MEDCOM USAMRMC (US)
Subject: A-18495 HRPO Approval Memorandum (Proposal Log Number 65610-NS-DRP, Award Number W911NF-14-1-0158) (UNCLASSIFIED)

Classification: UNCLASSIFIED
Caveats: NONE

SUBJECT: Initial Approval for the Protocol, "PhysioCam: A Noncontact System to Monitor Heart Rate," Submitted by Stephen W. Porges, PhD, University of North Carolina Chapel Hill, Chapel Hill, North Carolina, in Support of the Proposal, "PhysioCam: A Noncontact System to Monitor Physiological Responses From a Distance," Proposal Log Number 65610-NS-DRP, Award Number W911NF-14-1-0158, HRPO Log Number A-18495

1. The subject protocol (dated 27 June 2014) was approved by the University of North Carolina Chapel Hill (UNCCH) Institutional Review Board (IRB) on 31 July 2014. This protocol was reviewed by the US Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) and found to comply with applicable DOD, US Army, and USAMRMC human subjects protection requirements.

2. This no greater than minimal risk study is approved for the enrollment of 30 subjects.

3. The Principal Investigator has a duty and responsibility to foster open and honest communication with research subjects. The USAMRMC strongly encourages the Principal Investigator to provide subjects with a copy of the research protocol, if requested, with proprietary and personal information redacted as needed.

4. The following are reporting requirements and responsibilities of the Principal Investigator to the HRPO. Failure to comply could result in suspension of funding.

a. Substantive modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the HRPO for approval prior to implementation. The USAMRMC ORP HRPO defines a substantive modification as a change in Principal Investigator, change or addition of an institution, elimination or alteration of the consent process, change to the study population that has regulatory implications (e.g. adding children, adding active duty population, etc.), significant change in study design (i.e. would prompt additional scientific review), or a change that could potentially increase risks to subjects.

b. All unanticipated problems involving risk to subjects or others must be promptly reported by telephone (301-619-2165), by email (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil), or by facsimile (301-619-7803) to the HRPO. A complete written report will follow the initial notification. In addition to the methods above, the complete report can be sent to the US Army Medical Research and Materiel Command, ATTN: MCMR-RP, 810 Schreider Street, Fort Detrick, Maryland 21702-5000.

c. Suspensions, clinical holds (voluntary or involuntary), or terminations of this research by the UNCCH IRB, the institution, the sponsor, or regulatory agencies will be promptly reported to the USAMRMC ORP HRPO.

d. Events or protocol reports received by the HRPO that do not meet reporting requirements identified within this memorandum will be included in the HRPO study file but will not be acknowledged.

e. A copy of the continuing review approval notification by the UNCCH IRB must be submitted to the HRPO as soon as possible after receipt of approval. According to our records, it appears the next continuing review by the UNCCH IRB is due no later than 30 July 2015. Please note that the HRPO conducts random audits at the time of continuing review and additional information and documentation may be requested at that time.

f. The final study report submitted to the UNCCH IRB, including a copy of any acknowledgement documentation and any supporting documents, must be submitted to the HRPO as soon as all documents become available.

g. The knowledge of any pending compliance inspection/visit by the Food and Drug Administration (FDA), Office for Human Research Protections, or other government agency concerning this clinical investigation or research; the issuance of inspection reports, FDA Form 483, warning letters, or actions taken by any regulatory agencies including legal or medical actions; and any instances of serious or continuing noncompliance with the regulations or requirements must be reported immediately to the HRPO.

5. Please note: The USAMRMC ORP HRPO conducts site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the USAMRMC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.

6. Do not construe this correspondence as approval for any contract funding. Only the Contracting Officer/Grants Officer can authorize expenditure of funds. It is recommended that you contact the appropriate contract specialist or contracting officer regarding the expenditure of funds for your project.

7. The HRPO point of contact for this approval is Margaret M. Frederick, PhD, CIP, Human Subjects Protection Scientist, at 301-619-2380/margaret.m.frederick.ctr@mail.mil.

8. Address future correspondence regarding this study to Alavy Sos, MS, CIP at 301-619-1118/alavy.sos2.ctr@mail.mil.

PARAMESHWAR MAHASRESHTI, PhD
Human Subjects Protection Scientist
Human Research Protection Office
Office of Research Protections
US Army Medical Research and Materiel Command

Note: The official copy of this memo is housed with the protocol file at the Office of Research Protections, Human Research Protection Office, 810 Schreider Street, Fort Detrick, MD 21702-5000. Signed copies will be provided upon request.

Classification: UNCLASSIFIED
Caveats: NONE

To: Stephen Porges
Psychiatry

From: Biomedical IRB

Approval Date: 9/25/2014
Expiration Date of Approval: 7/30/2015
RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)
Submission Type: Modification
Expedited Category: 1.No IND/IDE,4.Noninvasive clinical data,7.Surveys/interviews/focus groups,6.Voice/image research recordings,Minor Change to Previously Approved Research
Study #: 14-1560

Study Title: PhysioCam: A noncontact system to monitor heart rate

This submission has been approved by the IRB for the period indicated. It has been determined that the risk involved in this modification is no more than minimal. Unless otherwise noted, regulatory and other findings made previously for this study continue to be applicable.

Submission Description:

After submitting the approved IRB package to the US Army MEDCOM's IRB (which was required by the terms of the contract with DARPA), they have requested two minor changes to the consent form. (1) We revised a statement on page 2, referring to the demographic questions we would ask. The statement in the consent included items which were not in fact asked for on the demographic form, and these items have been removed. (2) We explicitly listed representatives of the Dept of Defense as potential personnel who might review study data (page 4).

Investigator's Responsibilities:

Your approved consent forms and other documents are available online at http://apps.research.unc.edu/irb/irb_event.cfm?actn=info&irbid=14-1560.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:
Maria Davila-Hernandez, Psychiatry
Keri Heilman, Psychiatry
Greg Lewis, Psychiatry