

eHealth Monitoring Garment with Distributive Sensing

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TABLE OF CONTENTS

1. Introduction	1
2. Overall Project Summary	2
2.1. Approach	2
2.2. Phase II Summary	3
2.3. Performance to Objectives	4
2.4. Phase II Technical Results	5
3. Key Research Accomplishments	27
4. Conclusions	28
5. Publications, Abstracts, and Presentations	29
6. Inventions, Patents, and Licenses	30
7. Reportable Outcomes	30
8. Other Achievements	30
9. References	30

1. INTRODUCTION

This Final Report summarizes results Cornerstone Research Group, Inc. (CRG) has achieved under contract W81XWH18C0093, DHA Small Business Innovation Research (SBIR) Phase II project entitled, “eHealth Monitoring Garment with Distributive Sensing.” DHA awarded this contract under DoD SBIR 17.1 Topic DHA17-005, “Compression Garment with Embedded Electronics for Ambulatory Health and Performance Monitoring.” Recipients of this report needing further information are invited to contact the Principal Investigator, Ms. Kristin Cable (cablekm@crgrp.com, (937) 320-1877 extension 1127).

Soldiers in theatre or training missions are susceptible to excessive heat strain as a result of arduous environmental and operational conditions. These stressors are a result of both the demanding operations they are expected to complete and the austere environments they encounter while completing these operations. These soldiers are expected to perform very complicated tasks such as chemical, biological, radiological, and nuclear defense (CBRN) response, many times in combat conditions, and during long hours with heavy workloads. In these scenarios, soldiers may be wearing CBRN personal protective equipment (PPE) [23] as well as protective body armor, all while carrying heavy equipment in rucksacks and on the body. Each of these operational stressors can have a negative impact on the success of the task and the well-being of the soldier. In addition to these operational stressors, soldiers often encounter many environments that have a negative impact on their ability to complete tasks, including extreme temperatures (high and/or low), high humidity, intense sun exposure, and high altitude.

Each of the stressors individually can have a negative effect on health, well-being, and performance of a soldier; when combined, it becomes imperative that the soldiers are appropriately monitored during operations to optimize the success of missions and reduce illness and injury effects for these soldiers. A potential solution to meeting this need is real-time physiological status monitoring (PSM) technology. By monitoring key physiologic parameters, PSM systems can act as an early warning system, enabling proactive intervention as needed to ensure squad safety and performance readiness [25]. This ability to detect the likelihood of injury or serious illness allows leadership and team members to adjust a mission or task to both ensure mission completion and protect fellow soldiers, keeping the team healthy and ready to meet the demands of future missions. PSM systems can even be used in training to help soldiers recognize when they or team members are struggling, and need to make adjustments to protect everyone’s well-being.

While there are commercial PSM systems available in the marketplace, their design can be less than ideal for soldiers wearing multiple layers of gear and operating in confined and austere environments. Many PSM systems are attached to the body on the front of the torso with adhesives or with straps [24] that are often very constricting and uncomfortable. In addition, when combined with the bulk of their sensor modules, these systems can be an obstruction to certain movements (eg. laying prone). There are some PSM systems that are clothing-based, but these systems are often made with heavy fabrics that increase the thermal burden on the wearer. They also are designed with embedded wires that are routed from the PSM systems electronics module to the skin contact electrodes; these wires can be felt routed through the garment and complicate the ability to care for the garment.

The purpose of this effort was to develop a clothing-based sensor system that is comfortable to wear, does not add to the thermal burden, and is capable of providing accurate data for proper decision making [14, 21, 22]. A system with embedded electronics capable of transmitting relevant physiologic data to a mobile device for remote health monitoring offers leadership a support tool to aid decision-making and courses-of-action tailored to the individual and the mission.

2. OVERALL PROJECT SUMMARY

2.1. APPROACH

Physiological data from measured vital signs can be integrated to ascertain health status and provide actionable insight into a patient's well-being, thus enabling proactive intervention as needed. Commercial off-the-shelf (COTS) body-worn systems provide monitoring but struggle to provide both accuracy and comfort. Adhesive systems appear convenient but require skin surface preparation, are single or limited use, and may cause skin irritation [7,8]. Wrist-worn devices are convenient to use, but suffer from poor accuracy [25,26]. Chest straps are more accurate but have bulky electronic modules and are often extremely tight fitting to mitigate shifting of sensors during active physical motion.

As noted earlier, commercial clothing type systems also contain larger electronic modules and wiring that are too bulky and intrusive to be comfortably worn under protective clothing, negating any realized benefits [5,6]. The materials used in these systems are made of thicker materials that result in a higher thermal burden. Since a health monitoring system is meant to track thermal burden, a thicker material solution is counter-productive. Taking this into consideration, CRG's eHealth monitoring garment was designed to mitigate these existing barriers to usefulness and acceptability. CRG's approach blends the best features of these systems and distributes sensors and electronics to strategically placed locations throughout a compression garment to mitigate the bulkiness of the currently available products (Figure 1). Furthermore, CRG chose fabrics for the shirt with varying levels of compression and were breathable to add as minimal a thermal burden as possible, while at the same time maximizing comfort and acceptability of the system to wear.



Figure 1: COTS products and CRG's eHealth monitoring approach [1-10]

The distributed sensing approach utilizes the garment structure to keep low-profile, conformal sensor electronics in place eliminating bulky modules without compromising accuracy. Flexible circuitry is leveraged and combined with sensor(s) to form self-contained sensor islands with integrated power and wireless communication. Moreover, these islands were encapsulated to protect electronics and are removable to enable standard washing of the garment. A wireless receiver module can be integrated with a mobile device to communicate, retrieve, and display data from the sensor island in real-time. Figure 2 illustrates the prototype compression garment, sensor island, and mobile phone with application developed in this Phase II effort.



Figure 2: Phase II Prototype eHealth Garment with Sensor Island and Mobile Phone with App

2.2. PHASE II SUMMARY

For this Phase II program, CRG developed a wearable health monitoring system that leverages CRG's embedded sensors development experience and Clemson University's (Clemson, SC) extensive textile expertise to develop the integrated eHealth Monitoring Garment with Distributive Sensing. As illustrated in Figure 2, there is a band with a pocket in the lower left chest area that will hold a sensor island in position against the body. Sensor islands can be tailored to target specific biometrics and multiple islands with different configurations can be strategically placed on the garment for ideal performance [21-23]. CRG leveraged literature research from the Phase I that identified the lower left pectoral area as an optimal location [14,23] for capturing ECG data, as well as chest expansion/retraction providing the dimensional change ideal for a stretch respiration sensor. The four biometrics of interest include heart rate, breathing rate, skin temperature, and accelerometry. The sensor island wirelessly communicates via low-power radio frequency (RF) with a mobile phone that is outfitted with a paired RF receiver module as illustrated in Figure 2. A mobile application software was created for wireless communication with the garment-integrated flex sensor for remote monitoring. Estimated core body temperature was also incorporated into the mobile phone app by leveraging USARIEM's "Estimation of Human Core Temperature Based on Heart Rate System and Method" algorithm [19]. As ECG data can be used to derive heart rate, CRG elected to focus development of a sensor island for the lower left pectoral area to measure all four vitals for this Phase II.

As the sensor island is removable, it can be swapped out for a different type or used with a different garment. Also, using the same strategy, additional pockets can be incorporated to accommodate other sensor islands as needed for other sensing needs such as skin temperature at a different location. In addition, with the sensitive electronics being removable, standard garment laundering practices can be used with repeated washing to extend life of the garment. As the sensor island and the garment are separate articles, existing standard manufacturing processes in garment and electronics industries can be leveraged for lower cost manufacturing. Large capital investment with newer complex equipment is not necessary for neither garment fabrication nor electronics sensor island manufacturing.

In this Phase II effort, CRG developed prototype designs with custom miniaturized circuit designs for reduced size, improved power management, optimal sensor locations, wireless communication and advanced flexible circuit integration with the garment to fully demonstrate the system. CRG explored tradeoffs in sensor island size to assess larger sizes with more features and sensors considering power, runtime, and adaptability. CRG worked with Clemson for fabrication and testing to demonstrate prototype performance and design strategies to accommodate various body morphologies and body types. CRG also

developed a human test protocol and received approval from an independent Institution Review Board (IRB). Lab system testing was then expanded into human subject testing to provide feedback for refining designs based on practical field implementation challenges. CRG refined apparel design and fabrication efforts to meet program requirements with integrated flexible sensor circuits and assessed relevant human performance testing to validate sensor functionality and garment comfort and fit.



Figure 3: Prototype eHealth Garment Sensor System and example testing

In addition, CRG explored commercial opportunities and worked with teaming partners to develop manufacturing plans for the sensor devices and garment throughout the Phase II effort to prepare for beyond Phase II commercialization and transition opportunities. The Phase II results have demonstrated a Technology Readiness Level (TRL) of 5 and a Manufacturing Readiness Level (MRL) of 3. CRG believes that the Phase II performance objectives outlined in the program proposal have been achieved as noted below in Section 2.3 Performance to Objectives discussion. Details of the Phase II design tasks are further discussed in Section 2.4 Technical Results to review program outcomes, issues, and potential actions to address them as applicable.

2.3. PERFORMANCE TO OBJECTIVES

1. To Transition Breadboard Circuit Design to Flex Circuit Implementation

CRG assessed lessons learned from Phase I sensors development and testing to refine and transition the breadboard circuit design to a conformal, flex circuit platform. CRG met this objective by evaluating system components from Phase I effort that can be further developed and additional sensor technologies to improve robust sensing. CRG also evaluated tradeoffs between size, function, and run time with assessment of packaging the flexible sensor, further miniaturization, and power management strategies.

2. To Refine Sensor Integration with Garment Design

CRG assessed compression garment design and integration concepts derived in the Phase I effort and refined development of an integrated garment that is comfortable and does not impede movement while providing health status monitoring. CRG met this objective by examining approaches for redundancy and improved accuracy including optimal sensor locations that provide a balance between comfort and sensor performance. CRG also worked with partner Clemson to identify textiles for a compression garment that allows movement, while mitigating heat and moisture, and incorporating strategies to reduce weight/bulk and improve comfort.

3. To Develop System Control Software and Interface

Phase I effort leveraged evaluation kits and integrated software controls for initial sensors assessment. Also, user interface and some real-time monitoring in the Phase I effort included software developed for a personal computer (PC) application. To meet the objective of developing system control software and interface, CRG refined and further developed the controls software to support sensors system hardware and expanded user interface to a mobile cell phone. CRG designed both wired and wireless interfaces for system development for testing with setup and diagnostics, as well as functional operation.

4. To Demonstrate Garment Performance, Comfort, and Durability

CRG and partner Clemson fabricated an integrated garment that is comfortable to the wearer and does not impede movement while still providing the functionality of health status monitoring. CRG worked with Clemson for this objective to develop a comfortable garment and span sizes extra-small to extra-large with the initial focus on male sizing. These garments were subjected to testing for launderability and durability by Clemson and performed well. CRG also performed testing for female assessment with a modified COTS compression-style athletic undergarment with the CRG flex sensor unit. Test results demonstrating clear sensor signals and comfortability were promising and provided an area of focus for CRG to work with commercialization partner, University of Cincinnati, to evaluate manufacturers of an alternative technology for fabrication of athletic garments.

5. To Prepare for Phase III Technology Demonstration

To meet the objective of preparing for Phase III transition, CRG worked to actively socialize the technology to government and commercial representatives at tradeshow and conferences. CRG also worked to identify additional product variants to help drive commercialization. Market analysis including market size, barriers to entry, customer identification, and competitive product forms were also conducted to help understand what the appropriate business model should be for selling this technology.

2.4. PHASE II TECHNICAL RESULTS

TASK 1: DEVELOP HUMAN TESTING PROTOCOLS

The purpose of the task was for CRG to develop human testing protocols and to coordinate with the U.S. Army's Human Research Protection Office (Ft. Detrick, MD) to ensure all protocols were approved and documentation were in place to enable human subject research (HSR) testing in Phase II. CRG recognized that protocol development and approval can be a prolonged activity and planned this as one of the first tasks at the start of Phase II. This included compliance with DoD Instruction (DoDI) 3216.02 "Protection of Human Subjects and Adherence to Ethical Standards in DoD Supported Research," accepting the Institutional Review Board (IRB) determination of level of risk, ensuring that the study was compliant with applicable DoD regulatory requirements, and approving the protocol prior to implementation.

RESULTS

In preparation for HSR, CRG test administrators obtained cardiopulmonary resuscitation (CPR) training certifications and Collaborative Institutional Training Initiative (CITI) (Ft. Lauderdale, FL) certification for "Human Subject Research – Biomedical Basic" in accordance with The U.S. Department of Health & Human Services' 45 CFR 46, subpart A, "Federal Policy for the Protection of Human Subjects," also known as the Common Rule. Certificates for trained employees were kept on file at CRG. CRG was also in contact with the U.S. Army's Human Research Protection Office to assess the testing approval process and development of proper documentation to ensure that the study was compliant with applicable DoD regulatory requirements. At the early stages of the program, CRG was performing testing of the sensor equipment (not a human study). CRG developed an internal test plan for equipment testing

of Phase I sensor evaluation kits focusing on sizing and placement on the body. The document addressed plans to collect data from sensors utilizing project team members at CRG. The data collected from this testing was for refining the sensor system and was not nor will be published.

In parallel with the sensor system development, CRG prepared a test protocol for use with testing volunteers such as in running groups, soccer teams, or rock-climbing clubs. As the eHealth garment was in the early stages of development with designs not yet finalized at the time, concept design details were incorporated in the protocol for clarification. CRG submitted a proposal to Solutions IRB (Yarnell, AZ) for an expedited review based on an initial determination that the proposed activity was considered minimal risk human subjects research. CRG received initial IRB approval on 5/28/2019, and received a Human Research Protection Office (HRPO) Approval Memorandum from Human Subjects Protection on 11/13/19. Additionally, during COVID-19, CRG submitted an amendment to Solutions IRB outlining proposed safety measures to include the necessary social distancing and sanitation procedures to mitigate the risk of exposure of individuals involved in data collection to COVID-19. Solutions IRB approved this amendment on 7/7/2020. HRPO was then notified of the modifications and acknowledged the modification on 8/11/2020. CRG also submitted the appropriate continuing review documents after each IRB annual renewal approval. CRG was notified of approval for the recent annual report by Solutions IRB, extending the activity for another year through 05/27/2022. CRG subsequently submitted the appropriate continuing review paperwork to HRPO and received approval notice on 06/01/2021 to extend through 05/27/2022. This will allow CRG the option to perform human subjects testing with updated sensor systems if the opportunity arises.

TASK 2: REFINE AND IMPLEMENT CIRCUIT DESIGN

In addition to starting the HSR task at the beginning of Phase II, CRG also performed two sub-tasks to refine and implement the flexible eHealth sensor circuit design building from the Phase I effort. CRG first focused on evaluating the four different core sensor modalities (heart rate, breathing rate, skin temperature, and accelerometer). The goal was to validate that sensor placement of the garment were in the correct locations on the human to obtain accurate measurements. CRG consulted with a physiologist with expertise in emergency medicine to perform the testing and assess resultant measurement data from the various sensors for heart rate, respiration rate, skin temperature, and acceleration measurements. In addition to evaluating sensor location and validating resultant measured data, CRG also assessed sensor response to motion artifacts. CRG leveraged studies in the literature in Phase I to arrive at potential locations for sensor placement on the garment. CRG performed testing of a body-worn sensor system on a test subject performing multiple exercises to assess potential motion artifact issues. Results guided both sensor placement as well as garment construction to mitigate motion artifacts.

CRG then refined the circuit design of a complete sensor island system that included microcontroller, batteries, heart rate sensor, respiration sensor, temperature, and accelerometer. This was implemented in multiple iterations with results obtained through human validation testing for performance, fit, and function. The initial circuit boards fabricated were rigid boards for ease of debugging and testing. Once circuit designs were validated, flexible circuits were then fabricated. Once the flex circuits were successfully tested, they were encapsulated and custom dry electrodes connected to create the complete flexible sensor island unit. CRG focused on refining the design and size of the sensor island unit to create a form factor suitable for integration within the compression garment.

RESULTS

CORE SENSOR TECHNOLOGIES

For Phase II, CRG reassessed sensors identified in the Phase I effort for heart rate, respiration, skin temperature, and accelerometry (motion sensor/body position) to evaluate availability, updated sensors, and/or sensors with improved capabilities.

Heart Rate

ECG Sensing Method

CRG elected to continue heart rate sensing with the Analog Devices electrocardiogram (ECG) sensor. Although heart rate measurement only required calculation of the ECG signal peaks over time, the ECG waveform was helpful to assess motion artifacts during physical activity testing. The full waveform data may also provide additional insight into health status in future developments. CRG also continued to use Orbital Research Inc.'s (Cleveland, OH) commercially-available standard SilverBumps® dry electrodes (Figure 4) identified in Phase I and leveraged the ECG sensor evaluation kit to test the dry electrode performance. A test matrix was developed to assess sensor results when the dry electrodes were placed at different locations on the body and respective motion artifacts.

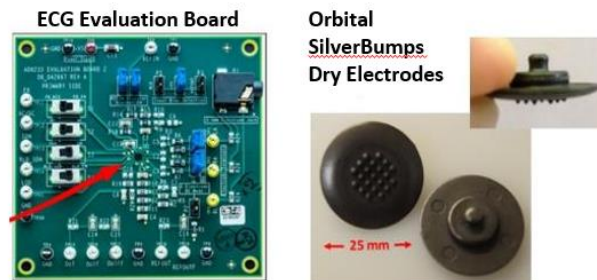


Figure 4: ECG evaluation board and dry electrodes

Assessment of the heart rate sensor was focused on understanding its performance when the two electrodes were placed at some distance apart and at different locations on the trunk of the body. As the lower left pectoral region is a prime location for heart rate detection, it was one of the first areas for obtaining measurements. CRG evaluated the difference in the ECG output signal when electrodes were placed at various distances apart from each other. An optimal distance for obtaining a good heart rate signal while also reducing the size of the sensor island was selected to minimize the effects of movement artifacts. In addition, the electrodes were placed at various other locations on the trunk including the upper left pectoral region, lower right pectoral area, as well as the upper left of the back behind the heart. Measurements were compared to the baseline signals obtained in the lower left pectoral region. The output signals at these other locations had recognizable waveforms for ECG measurements, but with reduced amplitudes.

As a result of this extensive study, CRG selected the lower left pectoral as an optimal location for a sensor island and worked with Clemson to create a band structure to hold the electrodes against the skin. The pocket presented a convenient solution that would allow the sensor island to be placed or removed easily. The other less optimal locations may provide opportunities for placement of additional sensor islands if redundancy was needed for ECG measurements. In addition, although only heart rate is required for many operational use scenarios, the ECG waveform is helpful to assess motion artifacts during physical activity testing.

PPG Sensing Method

As heart rate is a critical measurement, CRG assessed other potentially redundant methods for detection of heart rate such as a pulse oximeter. Figure 5 illustrates a photoplethysmogram (PPG) sensor

that is an optics-based integrated pulse oximetry and heart-rate monitor sensor module placed against the skin and measures light absorption. Testing was performed to assess the sensor's performance using the manufacturer's default gain and power settings and placed at different locations on the body including upper and lower pectoral areas. When placed at outer extremities such as the earlobe and fingertips as recommended by the manufacturer, the PPG waveforms were distinct waveforms with high amplitude signals compared to values obtained in the trunk area of the body.

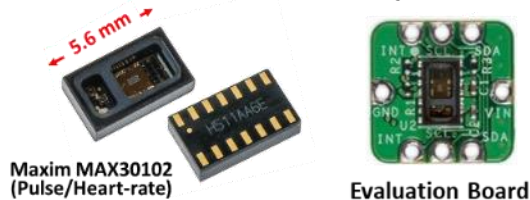
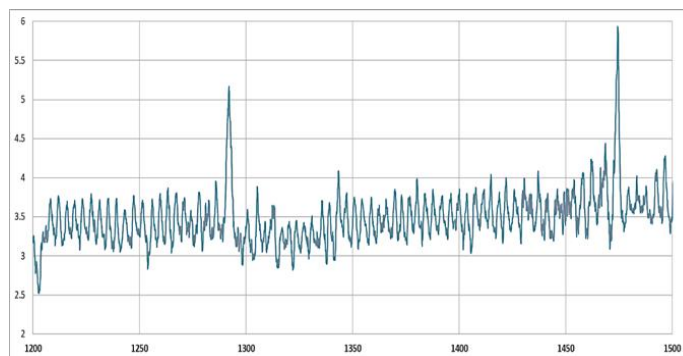


Figure 5: Integrated pulse oximeter/heart rate sensor and response

In all locations, user motion had a significant effect on the sensor output. As the sensor is an optical sensor employing two LEDs (red and IR) to transmit light into the tissue and a detector determines the changes in blood volume over time, inferred from the change in light intensity received. From literature reviews of research in this area with reflectance-based sensing, better results can be obtained by increasing the LED light output and increasing the number of detection diodes to increase sensitivity [12,13]. Adjustments were made to increase LED intensity and gain, but as this PPG sensor chip is a COTS self-contained sensor with integrated LED and detection diode, the results showed an improvement, but not to the level needed for more accurate sensing. Also, the packaging of this self-contained sensor had fixed locations for the LED and detection diode that allowed ambient light to enter and negatively affect the readings. In addition, literature reviews also confirmed CRG's finding that motion artifact was a major challenge with this technology [11-13]. Sophisticated filtering strategies may be used to address the challenge, but that would require higher power processing devices that will increase battery use. As a result of these negative issues and to reduce risk to the program schedule, CRG elected to set aside further evaluation of the PPG sensor and focus efforts on completing design with the ECG chip for the sensor island.

Respiration Rate

CRG continued to use the stretch sensor technology from Phase I that allowed for monitoring of movement and stretch for sensing breathing. The sensor leverages electroactive polymer (EAP) technology allowing for 100% reversible stretching (Figure 6). Sensor technical specifications list a resolution of 0.1% Strain ($\pm 50\mu\text{m}$ for a 50mm sensor) with a sensitivity of 0.026% Strain ($13\mu\text{m}$ for a 50mm sensor). CRG used the sensor to assess performance with different pre-strained conditions, at different locations on the body and respective motion artifacts.



EAP evaluation stretch
sensor
50 x 14 x 1.4 mm thick film

Figure 6: Electroactive polymer (EAP) stretch sensor

CRG worked with the stretch sensor vendor, to devise integration strategies to incorporate the sensor into CRG's sensor island concept. Testing on-body enabled assessment of stretch length verses chest expansion for comparison and algorithms analyzing frequency of length changes in calculation of breathing rates. CRG designed methods for securing and bonding the stretch sensor to the sensor island, while maintaining the appropriate elongation, elasticity, and pre-strain of the material for proper operation of breathing rate measurement.

Skin Temperature

CRG continued using the temperature sensor identified in Phase I for early testing in Phase II. Results from on-body testing of the temperature sensor compared against a thermocouple taped to the skin in proximity to the sensor indicated close correlation to within 1% to validate sensor performance. The sensor was placed at different locations on the torso including under left pectorals, above left pectorals, under right pectorals, back left, and armpit area. Minimal bilateral difference in temperature was noted and equilibration times were similar even at different locations.

In addition, CRG performed testing of the sensor with a layer of material between the sensor and the skin to assess insulative effects of material and temperature sensor performance. Two different materials were used including the protective thermoplastic urethane (TPU) film used with the Phase I prototype and an elastic material to emulate clothing. Results showed that at the skin body temperature of approximately 35.9 °C, the sensor was able to track the skin temperature but with a reduced value commensurate with the insulating material - measured approximately 35.78 °C (-0.35%) with the TPU material and 34.68 °C (-3.38%) with the elastic material. The assessment indicated that the temperature sensor can be covered with a thin-film protective material or thicker clothing material and still track the temperature as long as the offset is known and can be compensated in the final output value. As the pocket was used to hold the sensor island in place, the fabric material of the pocket became the layer between the temperature sensor and skin. The temperature offset was accounted for in the sensor island software.

Accelerometry (Motion Sensor/Body Position)

Acceleration data can be used to derive motion information to classify body postures or orientation. The sensor identified in Phase I was a 3-axis accelerometer that required additional processing and algorithm development to derive rotational data for potential fall detection. For Phase II, CRG identified a sensor that incorporated both linear and rotation acceleration including a combination accelerometer and gyroscope improving upon the accelerometer-only sensor from Phase I. The gyroscope function will streamline software development and improve accuracy if used for potential motion/fall detection algorithms. Body position can be assessed by detecting the orientation of the accelerometer by analyzing the acceleration vector due to gravity for identification of the dominant directional axis. By knowing the location and orientation of the accelerometer on the torso and assuming the acceleration signal will be due primarily to gravity, the orientation of the torso can be computed.

INTEGRATED FLEX SENSOR ISLAND

As the sensors were identified, CRG refined the sensor system schematic to miniaturize the preliminary Phase I design and began creating the printed circuit board (PCB) design to include the system micro-controller, sensors, and supporting circuitry. As rigid PCBs are easier to troubleshoot and modify, the approach was to first fabricate a rigid PCB, then refine and fabricate the flex PCB for the sensor island. CRG used rigid boards for early circuit implementation for ease of retrofitting during troubleshooting and debugging of both system hardware and software. CRG then transitioned to flexible circuits as sensor circuitry and garment designs were tested and refined.

Rigid Printed Circuit Board

For the initial rigid test PCB, CRG developed a small circuit board that included circuitry for detecting ECG signals with two electrodes, and that can be used to calculate the critical heart rate physiological data. Orbital's standard SilverBumps® dry electrodes with attachment nubs for ECG-type

connectors were used to connect with the heart rate sensor PCB (Figure 7). The goal was to quickly develop a board that allowed for understanding corresponding heart rate sensor performance, when dry electrodes are placed at different lengths apart, at different locations on the body, and respective motion artifacts. CRG then built on the design and added circuitry for the other sensors for full sensor island functionality with a flexible sensor PCB with integrated custom dry electrodes.

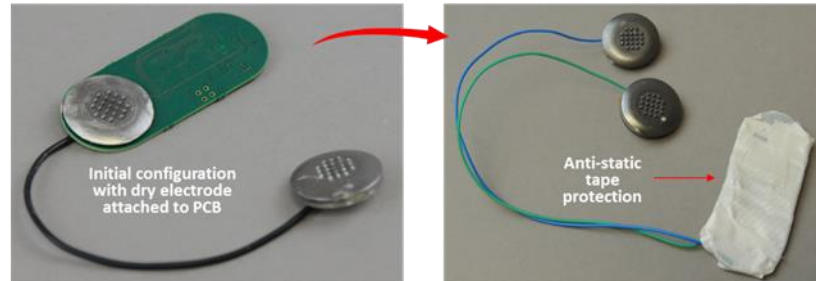


Figure 7: Custom rigid heart rate sensor PCB with dry electrode connections

The small board (1" x 2.5") with heart rate sensor and control circuitry allowed for initial on-body testing to monitor ECG waveforms and transfer data via USB to a PC for logging and review. During early testing, the rigid board appeared to act as a see-saw against the curved chest during motion which caused the electrode (on one end of rigid PCB) to intermittently lose contact with skin. CRG then elected to separate the electrode from the PCB and use both dry electrodes as free-standing electrodes with connections back to PCB as illustrated in Figure 7. This configuration enabled initial on-body testing to vet the circuit design and to understand best sensor locations to allow further development of the eventual flexible circuit design.

Flexible Printed Circuit Board

In parallel with on-body testing with the rigid test PCB, CRG continued to build from the initial ECG circuit design to create a flexible PCB layout of the flex sensor for integration with a garment. During initial review of the PCB layout by a flexible circuit vendor, it was noted that ball grid array (BGA) circuitry are micro-circuit designs. These very small integrated chips (ICs) added more complexity to the PCB assembly process resulting in higher costs, longer lead times, and limited choice of vendors. As a result, CRG elected to replace the ICs with a different chip package that was a little larger including the heart rate sensor (4 x 4 mm vs. 2 x 1.7 mm) and temperature sensor (2.1 x 2.4 mm vs. 1 x 1 mm) as a risk mitigation as the current chips have micro-BGA connections that were more difficult for PCB fabrication. The two new sensors were evaluated to ensure that they functioned properly and did not impact the sensor system design.

Upon receipt of the flex PCBs, CRG began systematic testing of the circuitry from preliminary hardware check and controlled power assessment, and then system programming. Preliminary hardware check-out included visual check of components, placement, and quality of soldering and trace integrity. CRG also used electronic equipment to check for shorts or other potential critical issues with circuitry before applying power. After successful power-up, CRG then programmed the system microcontroller in order to test the various sensors on the PCB. CRG resolved communications issues and was able to transmit data from the flex PCB wirelessly to a receiving test PC for displaying sensor measurements. This allowed CRG to test the software and hardware for the ECG sensor, temperature sensor, accelerometer, and breathing sensor. Previous testing before the flex PCB was available evaluated the sensors individually. The flex board integrated all four sensors and testing then focused on assessing operation of the combined software of the system.

After successful checkout of the individual flex PCBs, these flex units were then encapsulated (discussed in the following section) for protection before integration with a garment for on-body testing.

While all four sensing circuits (ECG, stretch sensor, skin temperature sensor, and accelerometer) were functional during early testing with the flex sensor island units, with iterative and repeated testing of the flex boards over time, challenges with intermittent signals were encountered. Intermittent ECG signals resulted in miscalculation for the heart rate measurement. Issues with intermittent ECG signals pointed to a need to reinforce additional portions of the flex circuit for more robust solder connections. Although portions of the flex circuit were designed with rigid reinforcements, this testing presented an area that did not have the full backing to keep connections robust for affected circuit chips. CRG reached out to the board vendor to request support with diagnosing solder joint issues with chips, possible repair of these circuits, and recommendations for future redesign of the flex circuit. CRG worked with the vendor to identify areas of improvement for a future board redesign such as relocating some of the sensitive circuit chips, such as the ECG chip, to a location that is better protected from wear-and-tear during handling of the flex sensor.

Future Improvements for Flexible Printed Circuit Board

For a future development effort, a second iteration of the flex PCB with recommended improvements from the board vendor would address the intermittent ECG signal challenges encountered. CRG used internal funds for an initial redesign of the flex circuit board layout to address these durability concerns for potential purchase in the future. In addition to placing circuit chips in more protected areas of the flex board, other improvements include larger trace widths and bending radius to mitigate cracking, rigid backing of all chip components, and more robust connections with some strain relief to improve durability.

Encapsulation (Protective Covering)

The material used for encapsulating the Phase I sensor island prototype circuit was a very rugged thermoplastic polyurethane (TPU) film that required a high processing temperature (over 140 °C) for good lamination. The high processing temperature could not be supported by some of the flexible circuitry and battery. As a result, for Phase II, CRG began assessing other concepts for packaging of the sensor island to encapsulate the flex circuit and stretch sensor. CRG leveraged in-house 3D printing for design of a mold tool for encapsulation with silicone. CRG iterated modifications to the encapsulation process to improve the silicone overmold protecting the flex board. The refinement to the mold design included the addition of more vent holes to allow the encapsulated silicone to cure more quickly. CRG also incorporated additional spacer mechanisms to support the flex circuit board to maintain center position while the silicone flowed above and below the flex board. An example of a mold iteration with special features in the mold design is shown in Figure 8.

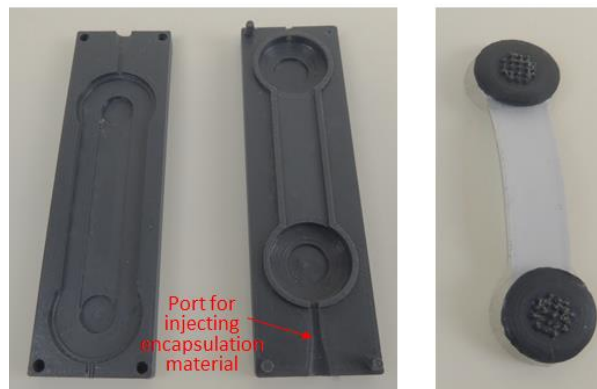


Figure 8: Example of encapsulation overmold design and resultant silicone sample

CRG continued refining the sensor island encapsulation designs to accommodate flex circuit components and dimensions, considering the manufacturing process for an economical and robust

package. CRG also experimented with different thicknesses with test articles to mitigate tearing and improve robustness of this sensor package. The various design iterations along with the final encapsulated flex sensor island example are illustrated in Figure 9. CRG performed these encapsulation processing steps in-house for quick turn-around and testing. For production type runs, CRG will work with a commercial packaging vendor. They have been a partner for other wearable encapsulation projects and are capable of both small (1-20) and large production runs in the hundreds of units.

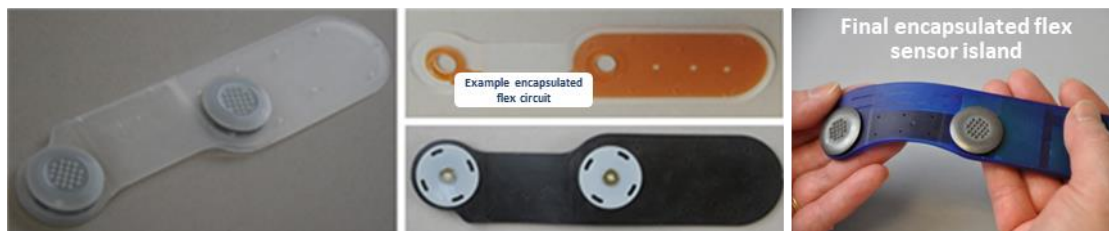


Figure 9: Examples of encapsulated test pieces and final flex sensor island

Custom Dry Electrodes

While flex PCB design proceeded, CRG worked with the dry electrode vendor to design a custom electrode for implementation with the flexible sensor island. The custom dry electrode was designed to be lower profile than the standard electrode and the center was able to be machined to accommodate a screw and washer for attachment to the flex sensor. CRG's revised dry electrode design allowed the garment which contained a compliant grommet to fasten to the electrode like a buttonhole. The buttonhole is on the inside of the shirt pocket that provided the opening for the dry electrode to protrude through and touch against skin to obtain the ECG signal.

After repeated testing and use, one issue that contributed to intermittent ECG signals was inconsistent conductive coating of the dry electrodes. It appeared the silver coating was degrading over time at the outer circumference edge, resulting in a discontinuity in conductivity between the front (skin contact surface side) and back (side that connects with the flex PCB circuitry) of the electrode. Prolonged and continuous use may be wearing away the coating at the sharp edges of the design as well, preventing proper signal conduction from the front to back side of the electrodes. As a result, the ECG signal present on the dry electrode surface in contact with the skin could not bridge past the edge of the electrode to the back side to make a connection with the flex circuitry. CRG reached out to the dry electrode vendor and they believe a redesign of the electrode geometry at the circumference edge will address these issues for future designs. After the issue was identified, CRG checked and verified that selected electrodes were conducting properly before use during Task 5 integrated system testing.

Future Improvements for Custom Dry Electrodes

For a future development effort, a second iteration of the custom electrode with improvements to reduce circumference edge sharpness will allow consistent front-to-back signal conduction. CRG will work with the vendor to redesign the electrode edge curvature to improve surface adhesion and signal conduction quality.

Flex Sensor Integration with Garment

For Phase II, CRG refined the initial buttonhole design from Phase I for attaching the flex sensor island to the garment structure. For integration of the grommet buttonhole (patent pending as noted in Section 6 - Inventions, Patents, and Licenses) with the garment band area, CRG first used a vulcanizing silicone rubber to create the grommets. One main issue was that the rubber material was too compliant and distorted when the garment chest band was stretched. CRG began evaluating reinforcement strategies to ensure the grommet was compliant enough for the electrode to be inserted and removed, but not distort and potentially contribute to motion artifact issues. CRG experimented with a different fabrication process that leveraged heat-activated, adhesive-backed material that was cut to shape and adhered to

target material as illustrated in Figure 10. CRG fabricated articles of fabric with the grommet buttonholes for Clemson to integrate into the eHealth shirt pocket. CRG used a standard garment iron for applying heat for the grommet application; however, attachment of the grommets at a higher temperature/higher pressure/longer dwell time with commercial production equipment like a heat press will produce more durable adhesion. For future fabrication, this step would be performed by Clemson the appropriate commercial equipment. The grommet attachment step has to be done precisely in order to achieve the necessary lamination strength to withstand repeated use and laundering and further discussed in Task 4 Design and Fabricate Garment with Clemson.



Figure 10: Examples of initial grommet-like buttonholes for dry electrode integration

2.4.1.TASK 3: DEVELOP SYSTEM CONTROLS AND COMMUNICATIONS

While Task 2 focused on the hardware aspects of the sensor system, this Task 3 was focused on development of the system software. Two sub-tasks were performed to first refine and further develop the controls software to support sensors and system hardware derived from Task 2, and second, to expand user interface software for communication between the sensor system and external devices. In the first sub-task, CRG refined and built upon software development from the Phase I effort to expand functionality of the sensor system. This entailed combining individual sensor algorithms from Phase I effort into one system level processor and developing additional software to advance sensor signal processing, data collection, and conversions as necessary. Functions incorporated into the system controls included sensor controls and processing, startup sequencing, data storage techniques, setup configurations, along with communications configuration and handshaking. In addition, in Phase I, CRG created a PC-based user interface software for monitoring data from test sensors. For Phase II, the software development expanded to include user interface for portable devices such as cell phones.

RESULTS

System Version Control

For software development tracking, CRG used the application GitHub (San Francisco, CA) for controlling and documenting software revisions for version control. GITHUB was developed specifically for software configuration management and is widely used around the world. CRG has maintained a GITHUB repository since the Phase I of the program. CRG's practice was to create the initial GITHUB repository and commit (a snapshot of the repository) stable increments during software development. Notes detailing code changes were entered with each commit. Commits are snapshots of the entire repository at specific times. Over time, commits tell a story of the history of a repository and include metadata in addition to the contents and message, like the author, timestamp, and more. GITHUB automatically tracks changes for each file committed initially and only commits files changed for each future commit. In addition to GITHUB's tracking, CRG also maintained a version and revision history of the software and correlated installation with the eHealth flex sensor devices.

CRG also applied version control to the garments and flex sensor assemblies including documentation of bills of materials (BOM), assembly process (encapsulation), and system checklists. Each shirt was

marked with a part number so that it can be differentiated. Each eHealth flex device was marked with a part number as well, so that it can be tracked during testing with the garment. Each of these eHealth flex devices was tracked in a spreadsheet that identified the embedded flexible circuit board, any modifications to that board, software version in the board, encapsulation mold used, encapsulation material, and assembly log.

For data that was collected during testing, actual files of test data were saved to the test graphical user interface (GUI) computer and ported to spreadsheets for post-processing and data analysis. CRG documented the different tests as data was used to assess sensor performance and software refinement. Video was added as another method of documenting the actual tests. Human subject test data was stored on a secure network file that was accessible only to authorized staff members.

System Controls Software

CRG reassessed and built upon software developed from the Phase I effort to expand functionality of the various sensors. Once the individual sensors were validated, sensor algorithms were then merged into one processor for system level control. CRG leveraged preliminary software for the ECG sensor from Phase I. CRG expanded the main software to incorporate controls for the combination accelerometer/gyroscope. The main processor (micro-controller) was able to communicate and read the 3-axis position and angular data from the combination accelerometer/gyroscope sensor. As the temperature sensor was changed to a different package from the initial micro-BGA type, new software was updated for the new sensor. Phase I leveraged the breathing sensor evaluation kit, so software for communicating with the breathing sensor was also developed in this effort.

In addition to sensor controls software, CRG also developed and tested functionality of the wireless radio frequency (RF) software and circuitry with the micro-controller transferring data to the RF circuit chips for transmission. CRG expanded this effort to enable the RF circuits to receive data and convert the data to useful sensor information. The RF transmitting circuit in the sensor island can wirelessly send out sensor data, and an RF receiving circuit (RF-to-USB converter PCB) is needed at the mobile device end to receive that data. This receiving circuit is part of a dongle/converter to convert RF to USB for connection to the mobile device with an app for displaying sensor data. The current system pairs one flex sensor to one RF converter board for communication. This RF-to-USB converter board can also connect to a computer and resident software can also display data as illustrated in Figure 11.

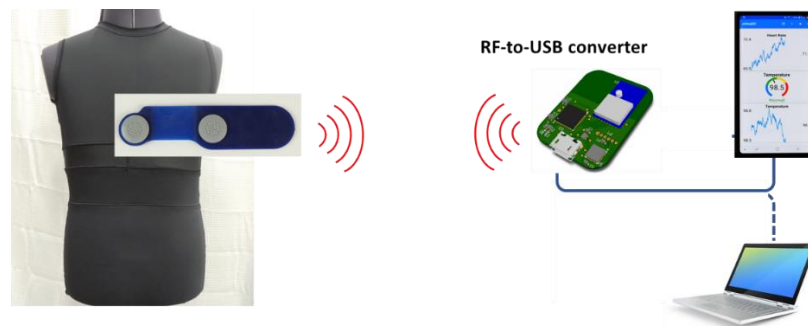


Figure 11: RF-to-USB converter PCB connects to mobile device or computer

In addition to system control software development, CRG created user interface software to assist with testing of sensors. There were two types of user interface for monitoring and displaying results from the sensors. The first was a user interface for the PC that was used for both development and testing. The second user interface was an app focused on providing remote monitoring with a mobile device such as a smart phone or tablet. Software for the processor and the Android-based mobile app were refined for better data communication and synchronization between the processor and the mobile device. The app displayed real-time measurements from sensors and discussed in more detail in the “Remote Mobile

Device Application” section. For the test PC GUI, CRG updated software to store the ECG wave form in temporary memory and then sends a block of data wirelessly to the test PC to display on the GUI. Figure 12 illustrates the GUI displaying the waveform of the ECG emulator device connected to the flex board and the derived heart rate. The ECG waveform was desirable as it was helpful to assess motion artifacts and effect on heart rate calculation during physical activity testing.

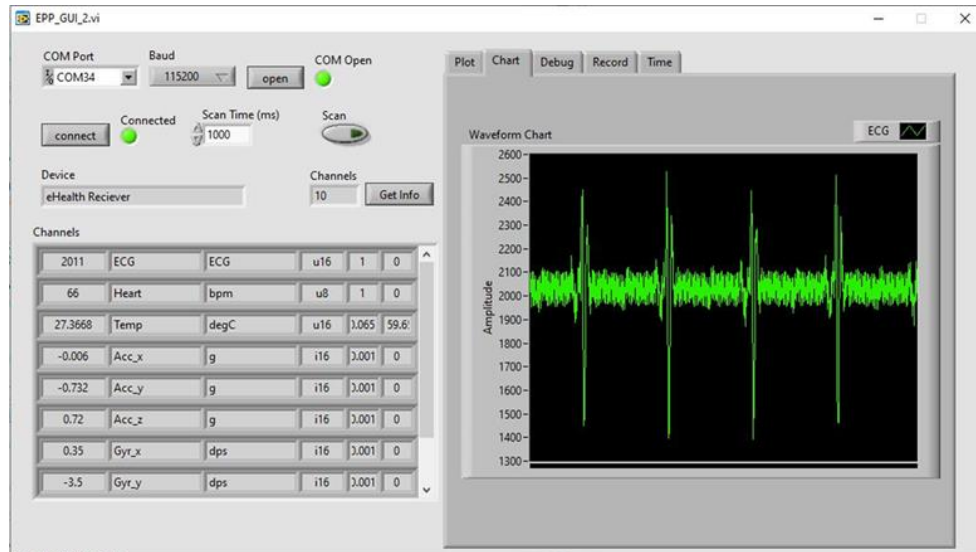


Figure 12: GUI displaying waveform of wireless data from ECG emulator device

In addition to the algorithm for converting ECG data to obtain a heart rate estimate, CRG also created software to calculate breathing rate from the stretch sensor. CRG initially leveraged a Fast Fourier Transfer (FFT) function in the microcontroller to calculate the breathing rate but was taxing for processor performance. CRG then assessed different approaches for the estimation and incorporated the breathing algorithm into the sensor system software and began to resume on-body testing to assess functionality. CRG used the breathing rate of a COTS PSM device from Zephyr (Medtronic Zephyr; Boulder, CO) to verify against CRG’s calculations. Results indicate that the breathing sensor was able to provide quality raw data that could be used to apply a rate conversion function to calculate a breathing rate. CRG translated those functions into code on the microcontroller to perform similar calculations and confirmed performance. Video cameras and verification with a secondary device (COTS Zephyr physiological monitoring system) was leveraged to correlate and sync sensor data with test subject motion. In addition to breathing rate, CRG also recorded data for the heart rate, skin temperature, and accelerometer.

Future Improvements for System Control Software

To enable early on-body testing, the micro-controller software was developed to read in measurements and wirelessly transmit sensor data to the PC test application, which stored the data to a hard drive for viewing and post-processing. To avoid disturbing this on-body testing, CRG developed software in a parallel effort to store sensor data in onboard memory on the flex circuit, as well as software to retrieve this data on a remote mobile device for users to review. Basic functions to write data to memory and then retrieving the data was developed and demonstrated to be functional, but transfer speeds were not optimized and were slow. For a future improvement, this local memory logging feature would be integrated into the current software used for the on-body testing to update the main system firmware. In addition, refinements to optimize and significantly reduce transfer speed would be needed for retrieving stored data.

Remote Mobile Device Application

As noted earlier, CRG developed an app for an Android-based mobile device to display sensor data. Initial development was focused on ensuring that the application was able to communicate with the flex sensor's micro-controller via a wired micro-USB port connected to a dongle/converter module on the phone. The sensor island was designed to communicate wirelessly with a portable device via low-power, tunable narrowband RF. CRG designed an RF-to-USB converter module or dongle to connect with the mobile device for communication to display sensor data (Figure 13). The RF circuitry was selected as it was lower power than Bluetooth and capable of longer distance transmission. CRG designed the converter circuit board that can be packaged as a standalone dongle or integrated with a phone case for added convenience. CRG reviewed the Open Body Area Network (OBAN) Abridged Messaging Specification (v33 beta7) and associated Tunable Narrowband Overview document from the Massachusetts Institute of Technology Lincoln Laboratory (MIT LL) (Lexington, MA) and assessed the mission messaging protocol outlined in reference documents. Software for the embedded wireless radio frequency (RF) circuitry was revised to accommodate messaging that followed formatting options of the OBAN messaging of sensor data. Static RF parameter configuration of the device during initial programming provided compliance with this format. Dynamic RF parameter tuning would be assessed in future efforts if needed to provide full OBAN functionality.

In addition, as an extension of this feature for remote monitoring with a mobile device, CRG also designed housing to accommodate the board with a 3D printed phone case. The case accommodated the board as well as the mobile phone used for remote monitoring. Figure 13 illustrates the prototype integrated phone case with access panel for the board to be secured and cable connected to the phone's USB port.

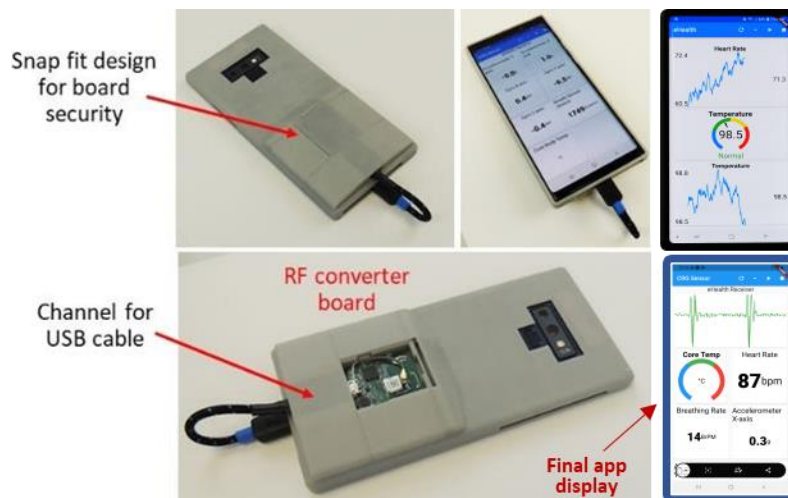


Figure 13: Phone case with integrated wireless RF-to-USB converter PCB

2.4.2.TASK 4: DESIGN AND FABRICATE GARMENT (CLEMSON)

As CRG focused on developing the flex sensor system, Clemson focused on development of the garment design. Together CRG and Clemson University worked to design, build, and test a garment to integrate with the hardware developed in Task 2. CRG leveraged Clemson's garment development expertise for the garment design and integration of the sensor hardware including respiration sensor integration, dry electrode integration, sensor package integration, and design refinement for production. In addition, CRG worked with Clemson for testing of the garment performance as a system. The garment was tested for permeability, launderability, and durability against the performance goal established in the

Phase I. These tests were conducted by Clemson, enabling the rapid testing of the garment employing standards which Clemson has used for previous military garments.

RESULTS

Garment Design

At the start of the program, CRG reviewed with Clemson lessons learned from the Phase I garment prototype and reassessed design approaches. Task 2 sensor testing, sensor placement, and performance were used to guide design efforts for the garment structure. Clemson re-assessed prototype garment from the Phase I effort and developed a work plan to refine the garment design for Phase II. Clemson initially began assessing shape patterns and design elements to assess fit, stability, and effects of upper body motion. With lessons-learned from the baseline Phase I garment, Clemson focused efforts on applying different patterns, stitching, and stretch properties of knit fabric to assess how upper body motion pulled at the area of the circumferential chest band. This upward stress meant that keeping the band in position required having a snug fitting band. Patterns and fabrics were adjusted to obtain a baseline pattern with better fit and free motion, while limiting upper movement of the chest band. Upper torso movement including trunk flexion, extension, lateral trunk flexion, trunk rotation (right and left) were assessed to determine the proper stretchable fabrics for fit and compression. This baseline pattern can accommodate short sleeves, but a sleeveless structure would further alleviate upward stress and keep the chest band in position through upper torso movement. The benefit is not only improved comfort but also much less circumferential pressure to keep the band in place with movement.

Clemson worked with the materials vendor to obtain a variety of new compression type fabrics with different motion stretch and different power stretch characteristics for refining the garment design. The materials vendor is a key partner and supplier of high-performance technical textiles to every branch of the U.S. Military and elite defense troops around the world. With initial trial configurations, Clemson set out to create a sleeveless test garment for CRG's evaluation and testing. In addition to a structure that can hold the electrodes in place during movement, the garment must be designed to allow the user to easily attach and remove the sensor island from the shirt. Clemson experimented with different materials, band widths, pocket (sensor island access) configurations, and multiple bands (Figure 14). Clemson also purchased new sewing equipment capable of sophisticated seam designs that were more amenable to stretchy compression fabrics. Clemson's equipment were the same types of machines used to fabricate small quantity prototypes as used in manufacturing by potential vendors. Clemson is very well connected to larger scale manufacturers and uses stitching and construction techniques which are translatable to production.

The large differences with the fabric characteristics (very light four-way stretch fabric vs. heavier, high-compression fabric vs. elastic fabric) presents special challenges to sewing the different sections together, while also achieving smooth and stretchy seams. Clemson initially used a stretchable "flatseam" method, but then improved upon the seams even more with the use of "ActiveSeam" by Merrow. This type of stitching is a very smooth, soft-to-the-touch, stretchy seam that is desirable for athletic apparel. Figure 14 illustrates the differences between the two types of seam stitches. The shirt on the left with the flatseam was the first sleeveless prototype garment which CRG used for initial sensor testing. The shirt on the right was an updated iteration with the new Merrow ActiveSeam stitching.



Figure 14: Clemson shirt trials of various configurations and stitching

Clemson created a sleeveless test garment for CRG's evaluation and testing that incorporated two banding layers around the chest area; the upper band was an elastic to provide compression for holding the sensor island in place. The lower band area was a comfortable compression material to transition the taught feel of the upper elastic band; this transitional second band area alleviates a "tourniquet" feel of the upper elastic band (patent pending as noted in Section 6 - Inventions, Patents, and Licenses). Also, to further alleviate shoulder movements affecting the band, the top and bottom white panels of the shirt used a lighter weight stretchy fabric. Clemson fabricated the shirts first in the white fabric that was available in stock and then later in a similar black fabric (Figure 15).



Figure 15: Clemson's shirts: (L) initial white fabric and (R) similar fabric black color

Garment Scale-up Production

Clemson's facility can support production in the range of 100-200 shirts for prototype applications. As noted earlier, Clemson uses similar equipment and the same types of machines used to fabricate small quantity prototypes as used in manufacturing by commercial vendors. For high-volume production, vendors such as Merrow Manufacturing could be leveraged. Merrow is a sewing equipment company that also operates a Berry compliant plant for high-production manufacturing of apparel. Merrow Manufacturing LLC is a 182-year-old, 8th-generation family-owned brand based in Fall River, MA, with centuries-long expertise in sewing and textiles.

Garment Testing

For durability assessment, Clemson focused on garment testing for launderability performance. The garments were subjected to typical home care with household detergent and washed more aggressively with other items (such as clothing and linen) instead of using standard detergent with a ballasted wash load. Incidental items like keys and hook/loop that happen in practice were also observed during some of the laundering. Clemson tested five shirts (XSmall, Small, Medium, Large, and XLarge) and subjected all

five shirts to 30 wash and dry laundry cycles. The wash cycle was performed in a top loading washing machine set for heavy duty and warm temperature with standard household detergent. The dry cycle was set for 60 minutes at high temperature. After each dry cycle, the shirts were inspected and data recorded of the assessment. The evaluation techniques looked at color change in the materials due to laundering, dimensional changes due to laundering, and visual changes such as durability of seams or damage by other items within the laundry load or laundry process.

Color fastness of the garments was assessed by three observers using the American Association of Textile Chemists and Colorists 9AATCC) EP1 test standard, an evaluation procedure that describes the use of a Gray Scale for visually evaluating changes in color of textiles resulting from colorfastness tests. The AATCC scale is 1 to 5 with 5 registering no observable color change. A 4 does have visible color change. A 4-5 splits the difference and is a real value, not an indication that the color change is somewhere between a 4 and a 5. The gray scales call the intermediate value '4-5' and observed results are tabulated in Table 1, demonstrating only slight shade change after 30 wash/dry cycles.

Table 1: Summary of color fast assessment

Color after 30 washes	Xsmall	Small	Medium	Large	Xlarge
Upper torso	4-5	4-5	4-5	4-5	4-5
	4-5	4	4-5	4-5	4-5
	4	4	4-5	4	4-5
Compression Band	4-5	4-5	4-5	4-5	4-5
	4-5	4-5	5	4-5	4-5
	4-5	4	5	4-5	4-5
Comfort Band	4-5	4-5	4-5	4-5	4-5
	5	4-5	4-5	4-5	5
	5	4-5	5	5	5

In addition to visual inspections, dimensional changes to the garments were also cataloged and shown in Table 2, indicating no significant shrinkage or percentage of change after 15 or 30 wash/dry cycles, relative to shirts before laundering.

Table 2: Summary of garment dimensions

Shirt measurements:	% Change in dimension									
	XSmall		Small		Medium		Large		XLarge	
	@15 cycles	@30 cycles	@15 cycles	@30 cycles	@15 cycles	@30 cycles	@15 cycles	@30 cycles	@15 cycles	@30 cycles
Center Back Length (to top of elastic)	0.00	0.00	1.10	1.10	0.00	0.00	1.50	1.50	0.00	2.04
Across Shoulders	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.83	2.48
Chest	0.89	0.89	0.82	0.82	0.00	0.00	0.65	0.65	0.00	0.60
Seat	1.32	1.32	1.64	1.64	0.00	0.00	0.00	0.00	1.15	1.15
Compression Band	1.04	2.08	0.00	0.94	0.81	1.63	0.71	2.86	1.29	3.23
Comfort Band	0.53	1.06	1.89	1.89	0.41	1.64	0.50	1.95	1.29	3.23
Front Center Length (to top of elastic)	1.54	1.54	0.00	0.00	-2.06	-2.06	0.00	0.00	1.39	2.78

The positive results after 30 laundering cycles were (a) color changes in all components (fabrics, thread and elastics) were minimal, (b) with the exception of a small amount of thread pulling at the neck of the Medium shirt caused by hooks, no damage to either fabrics or seams appeared, (c) no shrinkage except for a small amount of shrinkage of the elastic compression band and (d) with the exception of the size Large shirt, the grommets were not able to remain properly attached to the fabric band. This observation suggested that the grommets may not have been set correctly and Clemson identified the solution for future fabrication.

Delamination is a potential problem with fused apparel products, where typically the shell fabrics are fused with an adhesive, under heat and pressure. It often occurs when insufficient heat, dwell time or pressure was used in the processing. The grommets were an adhesive backed material that was fused with

a hot iron to the garment. CRG had fabricated the grommet panels and then sent them to Clemson to integrate into the garment as a pocket for the flex sensor. To assess the issue, Clemson leveraged their commercial heat press equipment for attachment of the grommets at a higher temperature, higher pressure, and longer dwell time. Test panels were fabricated and then subjected to laundry wash/dry cycles similar to shirt testing. As before, each laundering cycle included the wash cycle, followed by a 60-minute drying sequence. After 25 cycles, there was no evidence of any delamination indicating that attachment of grommets to the garment is durable if the attachment process is performed precisely in order to achieve the necessary lamination strength for laundering.

2.4.3.TASK 5: PERFORM INTEGRATED GARMENT TESTING

CRG performed on-body testing with the garment created in Task 4 to validate a prototype garment integrated with a flex sensor system. This task was performed in tandem with Task 2 through Task 4 as sensors, circuits, software controls, and garment designs became available for integrated system testing. In this task, a complete system test incorporating the sensors, the system processing, and user interface were evaluated for functionality and proper operation. CRG performed a battery of tests and employed secondary measurement methods to validate the four biometrics of interest including heart rate, breathing rate, skin temperature, and accelerometry for body position/motion. The effort performed during this task involved assessing failure points of the system, hardware or software-based, and making necessary modifications to address the issues. CRG consulted with Spokane & Associates (Dayton, Ohio) to execute human testing to assess performance and accuracy of sensors, measuring physiological signals on people of different sizes as well as under different activity types, positions, and postures.

RESULTS

Fit-and-Comfort Testing

To obtain fit and comfort assessments, CRG also participated in two field training exercise activities including Vigilant Guard and Chemical Biological Operational Analysis (CBOA) with Soldiers that provide field acceptability of the garment itself with non-functional flex sensor units. Both field exercises provided independent evaluation with favorable feedback for comfort:

Vigilant Guard (Dayton, OH Aug 5-7, 2019)

Vigilant Guard is the largest disaster response exercise in Ohio and this event was hosted locally by the Ohio National Guard and Ohio Emergency Management Agency and sponsored by U.S. Northern Command (NORTHCOM). CRG provided the shirts to the National Guard and they provided feedback at their discretion. Feedback was positive for comfort as they generally did not notice the garment during their activities. Three eHealth shirts with non-functional sensor islands were provided for evaluation of fit and comfort with Ohio National Guard personnel and their various gear during scenario-based training activities at the event.

Chemical Biological Operational Analysis (CBOA) (Camp Dawson, WV Aug 19-22, 2019)

This event was a test demonstration that DTRA took responsibility for coordinating the testing. For the training scenario-based CBOA event, CRG provided six shirts (4 size Lrg and 2 size Med) for nine different operators to assess fit and comfort in relation to the user gear and activities. Similar to the Vigilant Guard event, feedback was generally positive for comfortability of the shirts. DTRA also provided a Final Report Technical Package reviewing their testing and the technology assessment [28].

Summary of Garment-with-Sensors Testing

At the start of the program, CRG began using the first configuration of Clemson's sleeved compression garment with the adjustable chest strap for initial ECG sensor testing. It was noted that arm motion with the garment contributed significantly to noisy heart sensor signals. CRG then proceeded to

test the circuit without the garment and only use the adjustable strap to eliminate garment movement. It was noted that the strap alone, even under very tight compression, did not have the proper vertical support to keep electrodes from moving when subjected to body motion in the up/down direction.

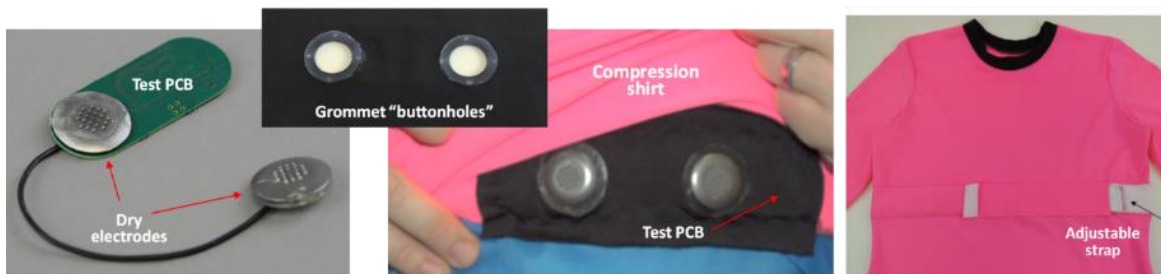


Figure 16: Initial Clemson garment configuration with sleeves

CRG shared test observations with Clemson to provide input for adjustments to the garment design. As CRG needed to press on with testing while Clemson worked to create the next iteration test garment (as discussed in Task 4), CRG elected to find a temporary solution that incorporated a compression band in a sleeveless configuration. CRG turned to a commercially available athletic undergarment with a wide band that can be modified to accommodate the dry electrodes. The goal was to perform some initial testing with the ECG circuit and dry electrodes to understand the different noise contributions from motion artifacts and strategies to isolate and measure the heart rate signals. This temporary garment was useful for initial testing to allow CRG to refine signal processing algorithms for adjustments and filtering as appropriate for more accurate heart rate sensing. CRG performed testing with the modified garment to assess sensor system performance during baseline sitting, walking, and jumping jacks. Results illustrated that the ECG signal became more “noisy” as the motion became more active; however, the signal presented distinguishable peaks that could be detected by a controls algorithm to calculate heart rate. CRG shared test observations with Clemson in effort to provide input for the new iteration garment.

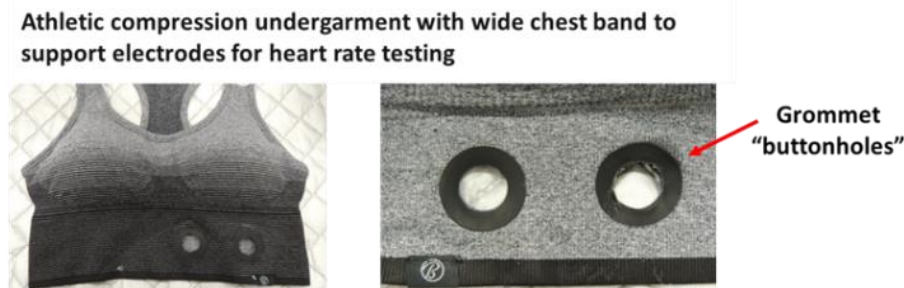


Figure 17: Test athletic undergarment modified for initial ECG sensor testing

Clemson then fabricated a new iteration sleeveless tank-style men’s shirt with band layers. CRG began testing the new shirt and incorporated the ECG sensor electronics (PCB insulated with a taping material) and dry electrodes with the shirt as shown in Figure 18. Similar to sensor testing with the athletic undergarment, baseline sitting, walking, and jumping jacks were performed to assess motion artifact response. Results also show that ECG signal became more “noisy” as the motion became more active, but with identifiable peaks for heart rate sensing. Initial testing with the new tank-style shirt showed promise that changes to the garment design by Clemson were helping to mitigate motion artifacts for the sensor system.



Figure 18: Clemson new iteration sleeveless tank-style men's shirt

CRG expanded testing to include two test subjects for the same size large-male shirt to obtain additional comparison data for sensor performance, shirt size, and fit. Two male staff members with different body measurements were tested to assess variations in chest width and tautness of chest band with regards to comfort and sensor performance. CRG followed Clemson's guidance for using ASTM Designation D5219–15 for Standard Terminology Relating to Body Dimensions for Apparel Sizing to measure the two test subjects and tabulated information for Clemson. The goal was to expand the test population to obtain a variety of body measurements for a standard size category (initially testing size-large male) and assess variances in the measurements against sensor performance and comfort. There were differences between the two test subjects even though both were categorized as male size large. Both subjects indicated that the shirt was comfortable, not too tight in the chest band area, and not difficult to don/doff. Results comparing the ECG sensor response between the two show that sensor signals with Male #2 was generally lower in magnitude and more susceptible to noise than measured with Male #1. This was seen at the early resting phase of the testing with no motion (sitting) and carried over into the more active portion of testing with walking and jumping jack activities. This initial data presented a glimpse of the range of sensor response among test subjects.

As ECG sensor testing with the rigid board was operational, CRG fully implemented a flex circuit design with the ECG sensor, breathing sensor, temperature, and accelerometer as discussed in Task 2 flex sensor design. As the flex sensor became functional, CRG moved forward with installing the encapsulated prototype into a garment for on-body testing. Testing was first performed with the new black shirt from Clemson for a medium sized male. Similar to the test setup in previous testing, the flex sensor wirelessly transmitted sensor data to a PC with user software that both displayed and stored sensor data. CRG first tested the encapsulated flex sensor on-person in a low-activity, sitting position to assess sensor performance capturing the response of the sensors including ECG, heart rate, breathing rate, skin temperature, and accelerometer variables. This initial testing performed while sitting demonstrated that the new encapsulated flex sensor was functional and able to transmit data; therefore, CRG proceeded to test the system with some stretching motion and walking on a treadmill for a quick assessment of performance. Results illustrated that stretching motions influenced the ECG waveform; however, the peaks which were used for heart rate calculations were still present. The algorithm needed to be optimized with signal filtering and processing to address these issues with motion artifacts. As with stretching, walking also influenced the ECG signal and required optimization of the algorithm to refine the heart rate calculation.

In addition to testing the new flex sensor with male test subjects, CRG expanded this initial testing to assess performance with a female test subject. As previous testing with a female athletic undergarment provided useful feedback, CRG used it again to assess response of the new encapsulated flex sensor. Results illustrated that the flex sensor continued to function and provided similar results as those captured for the male test subject. With assurance from these initial tests that earlier flex board issues can be managed with some fabrication refinements, CRG moved forward with more extensive on-body testing. The new evaluation focused on assessing accuracy of sensors with packaging, accuracy of algorithms for heart rate and breathing rate calculations, and effect of motion artifacts. CRG used the commercial

Zephyr physiological monitoring adhesive patch system as a secondary monitoring device for comparison with CRG's sensors. Zephyr's patch adheres to the upper chest near the sternum and did not interfere with CRG's chest band area.

CRG made improvements to the wireless communication algorithm, optimizing the synchronization to enable more robust data transfer. During these new testing sessions, CRG compared the flex prototype to the Zephyr biopatch sensor that used gel electrodes placed at the sternum area of the chest. Testing involved moving through a range of stretching motions based on a study on optimal ECG electrodes in a garment by Cho [14] and walking on a treadmill at various speeds. Data was visually inspected during live data collection, with very promising results. CRG continued to monitor the ECG signal as it provided insight from disruptions to the signal due to motion. In general, the calculated heart rate value followed the same trends as the Zephyr sensor. Some software refinement was helpful to improve the signal filtering to alleviate variances with some of the calculated data points. The initial data measured from the breathing sensor was the raw signal showing the stretch of the sensor. An algorithm was used to convert the raw stretch data into a breathing rate. This preliminary raw data was collected to help inform the data processing necessary to calculate and report an accurate breathing rate.

CRG completed multiple test sessions to assess the performance and consistency of sensors, and better understand fit and function of the garments. CRG also updated the LabView GUI to display individual sensor measurements to better aid in testing and debugging. This PC-based application allowed more details than a mobile device and was useful for development and diagnostics. Data was also stored and video was recorded to document test data for post processing as well. This test data from multiple users was informative and provided positive feedback that the sensing system in place was operational as validated with ability to track the Zephyr data. The goal was to perform more testing to assess variations in sensor response to different people, but also to more variety of motion and activities. These sessions with the test team helped to confirm that the sensor system could be used for human subject research with more users to provide statistically relevant data.

With the shift to human protocol testing, CRG began encountering issues with the flex sensor as more testing was performed. As noted earlier in Task 2 integrated flex sensor design discussion, durability matters with the flex board was found to be a contributing factor for sensor issues during human protocol testing of test volunteers. Future improvements to address the issues are discussed in Section 4 Conclusions. These prototype flex sensor units were functional during initial testing, and a second flex board iteration with design improvements noted would result in a more robust sensor system.

Table 3 is a list of the human protocol testing that was performed and includes tests performed and issues that were experienced. There are three sizes of male eHealth garments ranging from Small, Medium, and Large. CRG had planned on performing testing with at least six test subjects with two test subjects for each set of sizes. As CRG began experiencing issues with intermittent electrical connections for ECG and breathing sensors, testing efforts were delayed initially for troubleshooting. As noted earlier in Task 2 sensor refinement discussion, since the flex sensor vendor was unable to correct the connection issues with potential cracked traces, CRG resumed human testing with existing flex sensor and noted issues in the test data as reflected in Table 3. CRG completed testing with the planned six test subjects with two test subjects for each set of sizes available.

Table 3: List of Protocol testing for eHealth Garment

Test number	Test volunteer	Shirt size	ECG	Breathing	Accel	Temp	Notes
1	ID_1	Med	✓	✓	✓	✓	
2	ID_1	Med	✓*	✓	✓	✓	ECG intermittent issues
3	ID_2	Med	✓*	✓	✓	✓	ECG intermittent issues
4	ID_3	Large					ECG didn't function so stopped to troubleshoot
5	ID_4	Large	*	✓	✓	✓	ECG required pressing board to function
6	ID_5	Small	*	✓	✓	✓	ECG stopped functioning even pressed
7	ID_6	Small	*	✓*	✓	✓	ECG stopped functioning; breathing sensor intermittent
8	ID_3	Med	*	✓	✓	✓	ECG not functioning
9	ID_3	Large	*	✓	✓	✓	ECG not functioning

The first protocol test subject participated in two separate test sessions with the first session having all four sensors fully operational as noted in Table 3, and also reflected in results in Figure 19. The test duration was approximately 35 minutes with yoga stretches at the start, push-ups, crunches, and then transitioning over to treadmill exercises. As illustrated, accelerometer data reflected body position through the various motion and the temperature sensor showed an increase with exercise. The ECG signal exhibited some motion artifact during yoga stretches, but heart rate appeared reasonable with most activity. As heart rate is derived from the ECG, additional refinement of the algorithm may address motion artifact issues. Breathing rate estimates are derived from the stretch sensor and appeared reasonable with the activity, but may also be affected by motion artifact issues. Algorithm refinement for heart and breathing rate calculations are activities that are discussed for future improvements in Section 4 Conclusions. More human testing in a future development effort would provide more varied test data for refining algorithms for motion artifact. Also, Figure 20 illustrates test results for subject 1 for a second protocol test session. It was noted then that there were intermittent issues with the ECG that was affected by durability problems with the flex sensor. As explained earlier, protocol testing was continued with subsequent tests documenting issues encountered.

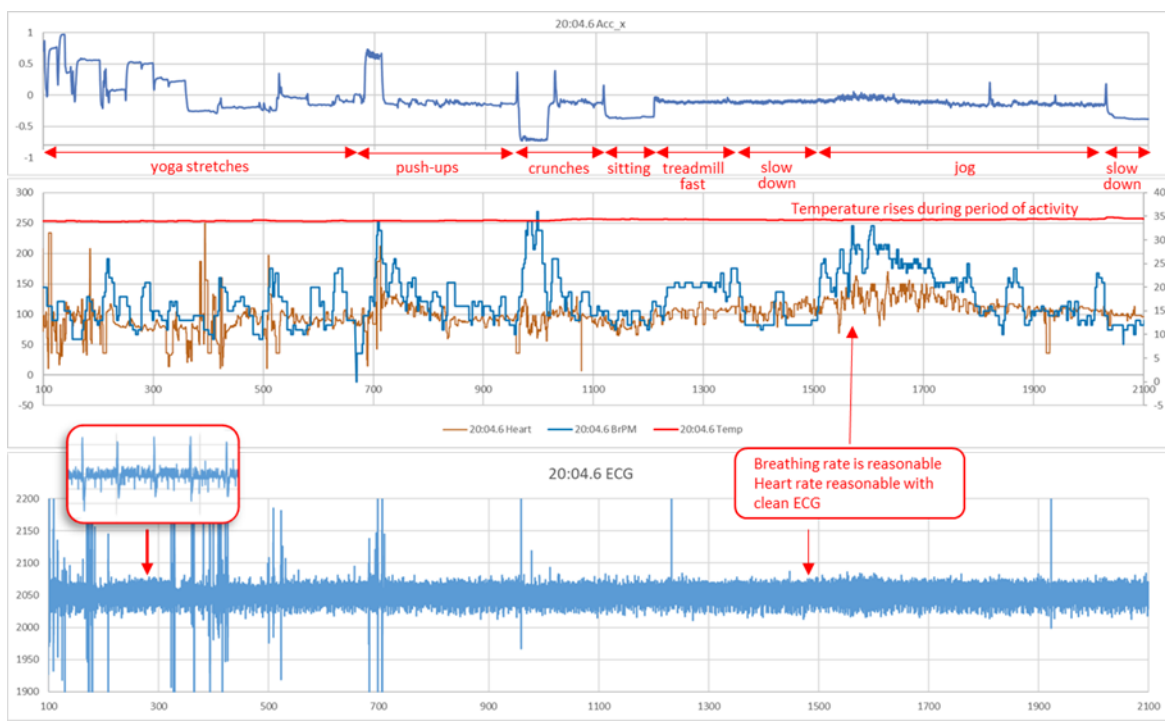
**Figure 19: Results of protocol testing with test subject 1 (ID-1/Test1)**



Figure 20: Results of protocol testing with test subject 1 (ID-1/Test2)

As part of CRG's test protocol, a questionnaire was provided for the volunteer's feedback. The feedback is useful for future refinements or enhancements to the system to improve acceptance of a final product. A summary of the responses to the various questions regarding fit and comfort are illustrated in Table 4. The overall fit of the garment received a favorable score average of 5.7 out of 7 towards moderately acceptable and performance impact received 4.9 out of 5 for no negative impact. Comfort received an overall average of 4.7 out of 7 towards slightly acceptable with a score of 3.3 out of 7 for a slightly tight garment.

Table 4: HSR questionnaire response summary

Fit		Comfort	
Body Area of Fit	Mean $\pm$ S.D.	Comfort of System	Mean $\pm$ S.D.
Overall	5.7 $\pm$ 1.7	Overall	4.7 $\pm$ 1.7
Chest	5.3 $\pm$ 1.8	Electrodes	5.7 $\pm$ 1.8
Back	6 $\pm$ 1.7	Under Sensor	5.6 $\pm$ 1.8
		Shirt Material	5.6 $\pm$ 1.4
1 = Very Unacceptable 2 = Moderately Unacceptable		1 = Very Unacceptable 2 = Moderately Unacceptable	
3 = Slightly Unacceptable 4 = Neither Acceptable or Unacceptable		3 = Slightly Unacceptable 4 = Neither Acceptable or Unacceptable	
5 = Slightly Acceptable 6 = Moderately Acceptable 7 = Very Acceptable		5 = Slightly Acceptable 6 = Moderately Acceptable 7 = Very Acceptable	
Tight/Loose		Performance Impact	
Body Area of Fit	Mean $\pm$ S.D.	Body Area of Fit	Mean $\pm$ S.D.
Overall	3.3 $\pm$ 1.7	Overall	4.9 $\pm$ 0.3
Chest	2.6 $\pm$ 1.8		
Back	3.7 $\pm$ 1.6		
1 = Very Tight 2 = Moderately Tight 3 = Slightly Tight 4 = Neither Tight nor Loose 5 = Slightly Loose 6 = Moderately Loose 7 = Very Loose		1 = Extreme Negative Impact 2 = Very Negative Impact	
		3 = Moderate Negative Impact 4 = Slight Negative Impact	
		5 = No Negative Impact	

Some puzzling results were noted as ratings for the comfort of the electrode, under the sensor area, and shirt material all have ratings of 5.6 or 5.7 on a 7-point scale. Yet the overall comfort rating is 4.7 on a 7-point scale as shown in Table 5. Upon review of the volunteer's feedback, it was noted that one

subject was able to perform testing twice but with different sized shirts each time. When the subject wore the Medium shirt which was much too tight for their size, the subject assigned a very low score of 2 for moderately unacceptable as noted for electrodes, under sensor chest area, and overall. This resulted in skewing the average score down to a 4.7 as the individual scores were relatively higher for that subject with a sized Large shirt, and the other volunteers. Results indicate that correct sizing is important for end user comfort and additional testing in future development efforts with more variability in physiology will provide insight into the types of size ranges needed for comfort and performance.

Table 5: HSR questionnaire response summary

Comfort

Comfort of System	Mean $\pm$ S.D.
Overall	4.7 $\pm$ 1.7
Electrodes	5.7 $\pm$ 1.8
Under Sensor	5.6 $\pm$ 1.8
Shirt Material	5.6 $\pm$ 1.4

1 = Very Unacceptable

2 = Moderately Unacceptable

3 = Slightly Unacceptable

4 = Neither Acceptable or Unacceptable

5 = Slightly Acceptable

6 = Moderately Acceptable

7 = Very Acceptable

	Comfort				
Vol	overall	electrodes	under sens	shirt mat	
1	6	7	6		7
2	6	6	7		6
3-M	2	2	2		4
3-L	4	4	4		6
4	7	7	7		7
5	3	7	6		3
6	5	7	7		6

2.4.4.TASK 6: TRANSITION TO OPERATIONAL USE

CRG assessed the results of Task 5 and identified additional refinements for the system and plans for transition of the eHealth Monitoring Garment to specific program offices in the DoD, National Aeronautics and Space Administration (NASA), and commercial customers. CRG worked to market the wearable monitoring innovation to entities within the Air Force, Army, and Navy such as the National Guard Bureau, US Marines, Special Forces Command, Program Executive Office (PEO) Soldier and other organizations. These efforts helped to establish final product formats, performance criteria, and potential early adopters for both government and commercial markets. Through these contacts from Phase I and Phase II, CRG worked to address the innovations directly to the pain points encountered in body-worn monitoring systems including accuracy, durability, and wearability with fit and comfort.

In addition, CRG worked with the University of Cincinnati (UC) (Cincinnati, OH) for support with commercialization and transitioning of the technology to the consumer market. The effort included providing support with market research to define target consumers and research product landscape. The effort also included design consultation for the commercial industry such as defining performance features and attributes appropriate for general market use, and determining appropriate manufacturing techniques, creating prototypes as appropriate, generating rough tech packs, initial pattern development, and material sourcing guidance for the consumer market.

RESULTS

Commercialization

The University of Cincinnati (UC), is ranked high among prestigious design schools with its College of Design, Architecture, Art, and Planning (DAAP). The university launched its Fashion Technology Center (FTC) in fall of 2019 (<https://www.uc.edu/news/articles/2019/09/n20857993.html>) featuring labs dedicated to computer-aided design/wearable futures, textile innovation, and apparel production with focus on working closely with industry on creating new ideas and capabilities. FTC provided consulting support for this program regarding adaptation of the garment for female users as well as to the consumer market. CRG's initial assessment in these areas with the modified COTS female sports bra garment with the flex sensor had shown promising results.

Upon inspection of the COTS garment, UC discussed a fabrication process that had become very popular for the sports apparel market, and appeared to have been used for a large part of the female athletic undergarment test sample. It is a whole garment circular knitting process that is capable of producing knitted items in their entirety on the machine without seams. The seam-free characteristics allow for continuity of the fabric, and has become popular for applications in smart garments and wearable technology that need conductive fibers to wrap around the entire body without interruption. The other advantage of this technology is that different types of knit patterns can be incorporated into the tubular design. Thus, the varying gradients of compression and elasticity of the eHealth garment band structure can be incorporated into the knitting process. UC provided CRG with a final report summarizing their research and commercialization efforts for this program [29].

Conferences and Field Exercises

Vigilant Guard (Dayton, OH Aug 5-7, 2019)

Vigilant Guard is the largest disaster response exercise in Ohio and this event was hosted locally by the Ohio National Guard and Ohio Emergency Management Agency and sponsored by U.S. Northern Command (NORTHCOM). CRG provided the shirts to the National Guard and they provided feedback at their discretion. Three eHealth shirts with non-functional sensor islands were provided for evaluation of fit and comfort with Ohio National Guard personnel and their various gear during scenario-based training activities at the event.

Chemical Biological Operational Analysis (CBOA) (Camp Dawson, WV Aug 19-22, 2019)

This event was a test demonstration that DTRA took responsibility for running the testing. For the training scenario-based CBOA event, CRG provided six shirts (4 size Lrg and 2 size Med) for nine different operators to assess fit and comfort in relation to the user gear and activities. Similar to the Vigilant Guard event, feedback was generally positive for comfortability of the shirts. DTRA also provided a Final Report Technical Package reviewing their testing and the technology assessment [28].

Military Health System Research Symposium (Kissimmee, FL Aug 19-22, 2019)

CRG discussed the eHealth Garment program during the poster presentation. CRG was also able to learn more about the Health Readiness and Performance System (HRAPS) initiative and USAMMDA's interest with patch sensors for physiological monitoring.

IPC E-Textiles 2020 (Virtual conference, October 1-2, 2020)

CRG participated in a virtual IPC E-Textiles 2020 conference on October 1-2, 2020. CRG presented this DHA program to develop PSM wearable technology as part of the section featuring military e-textile efforts and attached the slide presentation with the monthly report submission.

3. KEY RESEARCH ACCOMPLISHMENTS

- Created a compression garment PSM system for remote monitoring
- Demonstrated a low-profile, flexible circuit sensor that can be integrated into a garment for real-time vitals monitoring
- Created a garment design to limit sensor movement without compromising comfort
- Created garment design to be economical with standard industry fabrication process
- Demonstrated garment to be robust with launderability testing
- Demonstrated data collection for ECG, heart rate, breathing rate, temperature, and accelerometry for body position/motion
- Demonstrated wireless transfer of vitals data to a remote device
- Created a user application for an Android-based mobile phone

- Created a test protocol for human subject research
- Performed protocol testing with test subjects to assess the eHealth Physiological Monitoring Garment

4. CONCLUSIONS

In this Phase II program, CRG developed a wearable health monitoring system that leverages CRG's embedded sensors development experience and Clemson University's extensive textile expertise, to develop the integrated eHealth Monitoring Garment with Distributive Sensing. CRG refined sensor prototype designs with custom miniaturized circuit designs for reduced size, improved power management, optimal sensor locations, wireless communication, and advanced flexible circuit integration with the garment to fully demonstrate the eHealth Monitoring Garment with Distributive Sensing. CRG explored tradeoffs in sensor island size to assess larger sizes with more features and sensors considering power, runtime, and adaptability. CRG worked with Clemson for fabrication and testing to demonstrate prototype performance and design strategies to accommodate various body morphologies and body types. A mobile application software was created for wireless communication with the garment's integrated flex sensor for remote monitoring.

CRG also developed a human test protocol and received approval from an independent IRB. Lab system testing expanded into human subject protocol testing to provide feedback for refining designs based on practical field implementation challenges. CRG refined the apparel design and fabrication efforts to meet program prototype full-size garment requirements with functioning integrated flexible sensor circuits and assessed relevant human performance testing to validate sensor functionality and garment comfort and fit. In addition, CRG explored commercial opportunities and worked with teaming partners to develop manufacturing plans for the sensor devices and garment throughout the Phase II effort to prepare for beyond Phase II commercialization and transition opportunities. Initial transition of the physiological monitoring compression garment will concentrate on the needs of the military, then transition to commercial markets for wearable health monitoring applications. Bringing this technology to the broader growing commercial market will help reduce costs enabling more rapid expansion for military applications.

CRG believes that the Phase II performance objectives outlined in the program solicitation have been achieved. The Phase II results have demonstrated a Technology Readiness Level (TRL) of 5 and a Manufacturing Readiness Level (MRL) of 3. The flex sensor system developed in this program was fully functional but there were challenges with robustness that can be remedied with additional design iterations to further mature the product design. The following discussion outlines Future Improvements and Options for maturing the current technology to obtain a robust eHealth Garment for Physiological Monitoring with expanded communications features and flame-retardant (FR) assessments. CRG has and will continue to work to obtain additional funding, through socializing the technology, exploring other solicitations for physiological monitoring, as well as internal funding opportunities. Development of the proposed solution will greatly enhance squad capabilities, provide force health protection, and support performance readiness by facilitating the incorporation of integrated health monitoring with advanced equipment for effective execution of combat missions.

Recommendations for Future Improvements and Options

BASE:

This future improvement effort is focused on increasing the robustness of the flex sensor system and expanding the communications features to support multiple flex sensor units communicating to one mobile device. The current system pairs one flex sensor to one RF converter board for communication. The expanded communications would change from RF to the more widely used Bluetooth protocol. The advantage with Bluetooth is that it is already integrated with the mobile device and a separate converter board/dongle is not required. In addition, updating the software to incorporate the transfer of sensor data

to an application such as Leaderboard will allow for integration with squad monitoring. The garment design will stay the same for this effort. Future activities to further mature the sensor system for improved performance and capabilities will be similar in scope to the budget and schedule for a Phase I program.

Tasks include:

- Review and finalize flexible printed circuit board (PCB) layout to re-assess design updates for improved robustness
- Work with dry electrode vendor to redesign the electrode edge curvature to improve surface adhesion and consistent front-to-back signal conduction
- Use the encapsulation services of a commercial electronics encapsulation vendor as another measure towards robustness
- Update the main system firmware to integrate the local memory logging feature and file retrieval from a mobile device
- Modify hardware and software for Bluetooth communication
- Develop Sensor Bridge app to communicate with Leaderboard
- Modify hardware and software to allow multiple flex sensors to communicate to one mobile device
- Fabricate 3 prototype garment and flex sensor systems for delivery
- Cost: \$183,029 (9 months)

OPTION 1:

This option is focused on developing a new garment design (female) with athletic wear, knit technology that will use the robust flex sensors developed in the Base future improvement effort.

- Look at the knit type technology that was investigated by UC from the current Phase II
- Fabricate 3 prototype garment and flex sensor systems for delivery
- Cost: \$183,029 (Base) + \$121,558 (9 months total)

OPTION 2:

This option is focused on developing a new garment design (both) with FR technology that will use the robust flex sensors developed in the Base future improvement effort.

- Look at both the standard cut-n-sew method of fabrication similar to existing eHealth shirt but with FR-type fabrics and the knit-type method from Option 1 but with FR threads, or a hybrid of both methods.
- Fabricate 3 prototype garment and flex sensor systems for delivery
- Cost: \$183,029 (Base) + TBD (9 months total)

5. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS

PRESENTATIONS/CONFERENCES

- IPC E-Textiles 2020 (Institute for Interconnecting and Packaging Electronic Circuits)
- MHSRS 2019 (Military Health System Research Symposium)
- Cable, K., Young, T., and Cowgill, M. "eHealth Monitoring Garment with Distributive Sensing Final Report." Technical Report, U.S. Army Research Institute of Environmental Medicine, 2021.

6. INVENTIONS, PATENTS, AND LICENSES

Title	Docket Type	Docket Status	Inventors	Application Number	Application Date
HEALTH MONITORING GARMENT	PCT	Pending	Cable, Kristin M; Cridge, Mark C; Cupp, Gary N; Miller, Scott A; Nieman, Joshua E; Young, Trang T;	PCT/US19/42984	7/23/2019
HEALTH MONITORING GARMENT AND SYSTEM	US - Utility	Pending	Cable, Kristin M; Cridge, Mark C; Cupp, Gary N; Miller, Scott A; Nieman, Joshua E; Young, Trang T;	16/519,511	7/23/2019

7. REPORTABLE OUTCOMES

- Demonstration garment prototypes for integration with flex sensor unit for remote physiological monitoring
- Demonstration encapsulated flex sensor prototypes for vitals monitoring with wireless communication
- Demonstration user app for remote monitoring with an Android-base mobile device

8. OTHER ACHIEVEMENTS

Nothing to report.

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10. APPENDIX

List of participants supporting project

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This is the last page of the document