

**AWARD NUMBER:** W81XWH-17-1-0620

**TITLE:** Manual Wheelchair Virtual Seating Coach

**PRINCIPAL INVESTIGATOR:** Rory Cooper

**CONTRACTING ORGANIZATION:** University of Pittsburgh  
Pittsburgh, PA 15203

**REPORT DATE:** Sept 2019

**TYPE OF REPORT:** Annual

**PREPARED FOR:** U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

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|--|--|---|---|---|---|
| <b>1. REPORT DATE</b><br>Sept 2019   |  | <b>2. REPORT TYPE</b><br>Annual         |   | <b>3. DATES COVERED</b><br>1 Sep 2018 - 31 Aug 2019 |   |
| <b>4. TITLE AND SUBTITLE</b><br><br>Manual Wheelchair Virtual Seating Coach  |  |   |   | <b>5a. CONTRACT NUMBER</b>                          |   |
|  |  |   |   | <b>5b. GRANT NUMBER</b><br>W81XWH-17-1-0620         |   |
|  |  |   |   | <b>5c. PROGRAM ELEMENT NUMBER</b>                   |   |
| <b>6. AUTHOR(S)</b><br><br>Rory Cooper<br><br>E-Mail: rcooper@pitt.edu   |  |   |   | <b>5d. PROJECT NUMBER</b>                           |   |
|  |  |   |   | <b>5e. TASK NUMBER</b>                              |   |
|  |  |   |   | <b>5f. WORK UNIT NUMBER</b>                         |   |
| <b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b><br><br>The University of Pittsburgh<br>3520 FIFTH AVE<br>PITTSBURGH PA 15213-3320  |  |   |   | <b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>     |   |
| <b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b><br><br>U.S. Army Medical Research and Materiel Command<br>Fort Detrick, Maryland 21702-5012   |  |   |   | <b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>             |   |
|  |  |   |   | <b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>       |   |
| <b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b><br><br>Approved for Public Release; Distribution Unlimited  |  |   |   |   |   |
| <b>13. SUPPLEMENTARY NOTES</b>   |  |   |   |   |   |
| <b>14. ABSTRACT</b><br>The clinical literature indicates that performing a push up or pressure relief every fifteen minutes for two minutes or more can reduce the likelihood of developing pressure injuries. There has been little research to develop technology interventions to promote behavioral changes among manual wheelchair users (MWU) to promote active sitting and regular pressure relief (PR). The objective of the project is to further develop and evaluate the Manual Wheelchair Virtual Coach (MW-VC). This system has been developed consisting of sensors, artificial intelligence algorithms, and a user interface that tracks manual wheelchair users' changes in seated position, and coaches them to perform effective pressure reliefs. The entire system was updated based on the feedback received from focus groups and usability testing. Overall, participants rated the MW-VC highly for innovation, usefulness and compactness. We will continue to assess suitability of the device and make desirable changes and add additional features to complete the Pilot study. |  |   |   |   |   |
| <b>15. SUBJECT TERMS</b><br>Pressure Ulcers/injuries, Spinal cord injury, Center of Pressure, Pressure relief, Pressure sensors  |  |   |   |   |   |
| <b>16. SECURITY CLASSIFICATION OF:</b>   |  |   | <b>17. LIMITATION OF ABSTRACT</b><br><br>Unclassified | <b>18. NUMBER OF PAGES</b><br><br>23                | <b>19a. NAME OF RESPONSIBLE PERSON</b><br>USAMRMC |
| <b>a. REPORT</b><br><br>Unclassified   | <b>b. ABSTRACT</b><br><br>Unclassified | <b>c. THIS PAGE</b><br><br>Unclassified |   |   | <b>19b. TELEPHONE NUMBER</b> (include area code)  |

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**1. INTRODUCTION:**

The clinical literature indicates that performing a push-up or pressure relief every fifteen minutes for two minutes or more can reduce the likelihood of developing pressure injuries. Some clinicians and consumers believe that this may be too onerous, and that “active seating” is adequate; “active seating” is defined as user initiated frequent position changes in various directions to differing degrees. There has been little research to develop technology interventions to promote positive behavioral changes among manual wheelchair users to promote active sitting and regular pressure relief. The objective of the project is to further develop and evaluate the Manual Wheelchair Virtual Coach (MW-VC). This system consists of sensors, artificial intelligence algorithms, and a user interface that tracks manual wheelchair users’ changes in seated position, and coaches them to perform effective pressure reliefs.

**2. KEYWORDS:**

Pressure injuries, Spinal cord injury, Pressure relief, Force sensors, Artificial Intelligence

**3. ACCOMPLISHMENTS:**

**What were the major goals of the project?**

**Specific Aim 1:** To obtain a record of MW seated CoP patterns during usage by PwSCI and to relate that to surveys of activity, participation, and seating discomfort.

**Specific Aim 2:** To determine if virtual coach features of the MW reduce seating discomfort and improve adherence to CPG.

| <b>Major Task 1: Institution Approvals and Data-Safety &amp; Monitoring</b>  | <b>Timeline months</b> | <b>Percentage completed</b> |
|--|------------------------|-----------------------------|
| Coordinate DoD 2nd level IRB review (ORP/HRPO)   | 2-5                    | 100%                        |
| Submit PITT IRB amendments, adverse events and protocol deviations as needed   | 1-12                   | -                           |
| Submit annual IRB report for continuing review   | 12                     | 100%                        |
| <i>Milestone Achieved: All human subject approvals on file</i>   | 3                      | 100%                        |
| <b>Major Task 2: <u>Development Specific Aim 1 (DSA-1): Expert system and machine learning algorithms. (Completed in year 1)</u></b> |                        |                             |
| <b><i>Subtask1: Expert System Algorithms</i></b>   |                        |                             |
| Identify relationships between body characteristics and CoP for PR   | 1-3                    | 100%                        |
| Simulate expert learning algorithms in MatLab achieve 90% success rate   | 1-4                    | 100%                        |
| <i>Milestone Achieved: Expert system algorithms completed</i>  | 4                      | 100%                        |
| <b><i>Subtask 2: Machine Learning Algorithms</i></b>   |                        |                             |
| Test and validate machine learning algorithms using MatLab   | 3-5                    | 100%                        |
| <i>Milestone Achieved: Machine learning algorithms able to correctly</i>   | 6                      | 100%                        |

|  |     |      |
|--|-----|------|
| <i>detect active sitting 80% of the time without human intervention</i>  |     |      |
| <b>Major Task 3: <u>Development Specific Aim 2 (DSA-2): Design and implementation of the MW-VC application software.</u></b> |     |      |
| <b><i>Subtask 1: Application software graphical user interface</i></b>   |     |      |
| Write and test for operability of the user interface   | 1-3 | 95%  |
| <i>Milestone Achieved: GUI user interface operational</i>  | 3   | 95%  |
| <b><i>Subtask 2: Application software cloud connectivity</i></b>   |     |      |
| Write and test code for cloud connectivity   | 1-3 | 90%  |
| <i>Milestone Achieved: Cloud connectivity software completed</i>   | 3   | -    |
| <b><i>Subtask 3: Application software contextual awareness algorithms</i></b>  |     |      |
| Write and test code for contextual awareness algorithms  | 1-3 | 40%  |
| <i>Milestone Achieved: Contextual awareness software completed</i>   | 3   | -    |
| <b><i>Subtask 4: Application software ecological momentary assessment</i></b>  |     |      |
| Write and test code for ecologic momentary assessment algorithms   | 1-4 | 50%  |
| <i>Milestone Achieved: Ecological momentary assessment software completed</i>  | 4   | -    |
| <b><i>Subtask 5: Application software for behavioral coaching</i></b>  |     |      |
| Write and test code for behavioral coaching  | 1-4 | 60%  |
| <i>Milestone Achieved: Behavioral coaching software completed</i>  | 4   | -    |
| <b>Major Task 4: <u>Development Specific Aim 3 (DSA-3): Design, prototyping, calibration MW-VC.</u></b>                      |     |      |
| <b><i>Subtask 1: Affordable seating system sensing package – design (Completed in year 1)</i></b>                            |     |      |
| Create CAD and CAM files from mechanical and electronic components   | 1-2 | 100% |
| <i>Milestone Achieved: Complete solid models, drawings, parts-list</i>   | 2   | 100% |
| <b><i>Subtask 2: Affordable seating system sensing package - prototype</i></b>   |     |      |
| Create and refine prototype from mechanical and electronic components  | 1-3 | 90%  |
| <i>Milestone Achieved: Complete working prototypes for 3 wheelchairs</i>   | 3   | 80%  |
| <b><i>Subtask 3: Affordable seating system sensing package – calibration and validation</i></b>                              |     |      |
| Calibrate, validate, and refine prototype  | 3   | 70%  |
| <i>Milestone Achieved: Complete working prototypes for 3 wheelchairs</i>   | 3   | 80%  |
| <b>Major Task 5: <u>Development Specific Aim 4 (DSA-4): Conduct usability testing for Specific Aims 1-3.</u></b>             |     |      |
| <b><i>Subtask 1: Conduct usability testing</i></b>   |     |      |
| Recruit and enroll participants  | 1-3 | 90%  |
| Conduct focus group with MW-VC ( <i>Completed in year 1</i> )  | 6   | 100% |
| Refine design  | 2-5 | 60%  |
| <i>Milestone Achieved: Usability study completed and design refined</i>  | 5   | 90%  |
| <b>Major Task 6: <u>Development Specific Aim 5 (DSA-5): Conduct a Pilot Clinical Trial.</u></b>                              |     |      |
| <b><i>Subtask 1: Pilot Study</i></b>   |     |      |
| Coordinate all study steps, data collection and database requirements  | 4   | 0%   |

|   |       |      |
|---|-------|------|
| Finalize assessment measurements  | 4     | 0%   |
| <i>Milestone Achieved: Pilot Study begins</i>   | 6     | -    |
| Recruit participants and complete protocol (N=10)   | 6-10  | 0%   |
| <i>Milestone Achieved: Report findings from Pilot Study</i>   | 10    | -    |
| <b><i>Subtask 2: Determine modifications to protocol that are needed to implement larger scale study</i></b>            |       |      |
| Revise protocol, instruments, and measures  | 11    | 20%  |
| <i>Milestone Achieved: Protocol finalized</i>   | 12    | -    |
| <b>Major Task 7: Data Analysis</b>  |       |      |
| <b><i>Subtask 1: Monitor data collection rates and data quality</i></b>   |       |      |
| Perform analyses, share output and findings with all investigators  | 11-12 | 40%  |
| Dissemination of findings (abstracts, presentation, publications, DOD)  | 11-12 | 20%  |
| <i>Milestone Achieved: Report results from data analyses</i>  | 12    | -    |
| <b>Major Task 8: Development Specific Aim 6 (DSA-6): Write proposal for MW-VC Clinical Trial. (Completed in year 1)</b> |       |      |
| <b><i>Subtask 1: Prepare submission of proposal for clinical trial</i></b>  | 12    | 100% |
| <i>Milestone Achieved: Grant proposal submitted</i>   | 12    | 100% |

**What was accomplished under these goals?**

**Work related to: Major task 1**

**Accomplishment #1: Institution approvals and Data safety & monitoring**

- **Specific Objectives:**
  - Coordinate DoD 2nd level IRB review (ORP/HRPO)
  - Submit PITT IRB amendments, adverse events and protocol deviations as needed.
  - Submit annual IRB report for continuing review
- **Major Activities:**
  - 1) Since human subject testing is being conducted in two phases (5-day usability testing and 12-week pilot study), two separate IRBs were approved by the University of Pittsburgh. Both have been renewed.
  - 2) Continuing review documents have been submitted to the U.S. Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO).
- **Significant Results:** Continuing review has been approved by the PITT IRB and HRPO has acknowledged the receipt of the continuing review documents for the protocol.

## Work related to: Major task 2

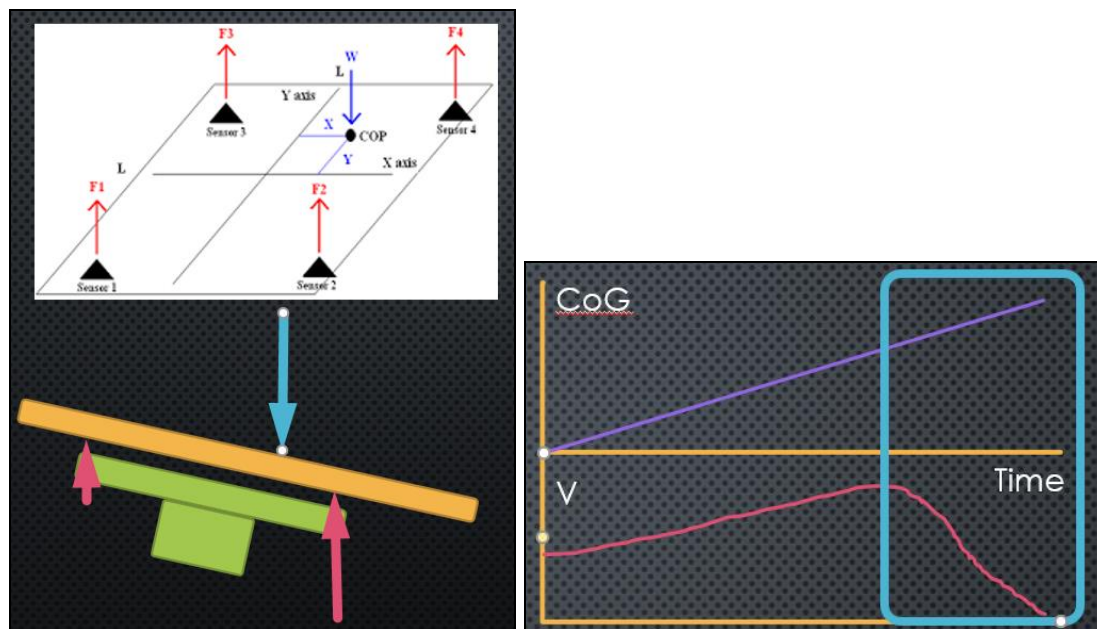
### **Accomplishment #2: Expert system and machine learning algorithms.**

- **Specific Objectives:**

- **Identify relationships between body characteristics and CoP for PR**
- **Simulate expert learning algorithms in MatLab achieve 90% success rate**
- **Test and validate machine learning algorithms using MatLab**

- **Major Activities:**

1. The quarter began with refining the decision tree method for classifying the types of pressure relief, based on input from clinicians. Continuous improvement is being made to ease the pressure relieving exercise parameters setup.
2. In the next quarter, PR determination based on the previously defined algorithm was incorporated into the software application to trigger the PR timer when the magnitude of change in center of pressure exceeded a specified value.
3. The figure.1 shows that the signal increases as the center of pressure moves further away from the center of the supporting cross piece. However, as the CoP moves outside of the supporting cross piece, the signal begins to decrease. This behavior was not observed in the previous prototype based on complementary strain gages bonded to the members of the cross piece. Possible causes that we are investigating include preloading of the load cells during assembly and calibration, or nonlinear behavior from the member of each pair of load cells that would be in tension at these extreme displacements overwhelming the signal from the member that is in compression. Either case may be addressed by increasing the number of analog-to-digital conversion channels and summing the responses in the digital rather than the analog domain.



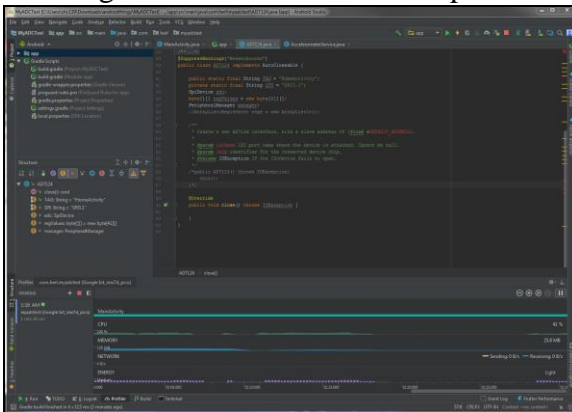
**Figure 1. Center of gravity (COG) Computation**

- **Significant Results:** The milestones of the subtask one and two were accomplished. The expert system algorithms were developed and completed. The machine learning algorithms were able to correctly classify active and passive sitting behavior to 100% of the time without human intervention using 1Hz sampling rate and 60-second learning window size.

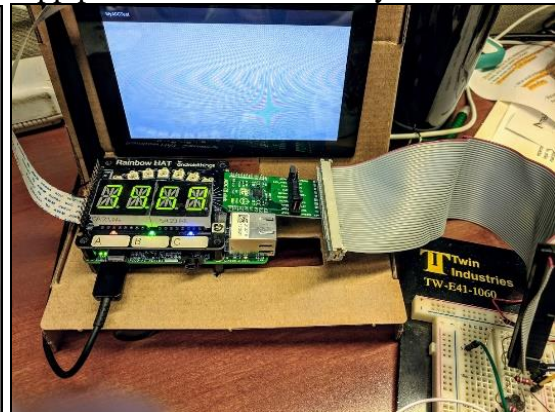
**Work related to: Major task 3, Subtask 1-5:**

**Accomplishment #3: Design and implementation of the MW-VC application software**

- **Specific Objectives:**
  - Write and test for operability of the user interface
  - Write and test code for cloud connectivity
  - Write and test code for behavioral coaching
- **Major Activities:**
  - 1) In the first quarter of year 2, we continued software development on the Android Things. Figure 2 below shows the development environment. The development tool provided real-time monitoring of the CPU, memory, network, and energy usage while the application was running on the device. We used this to visualize the coding process and identify the event handling. This also allowed us to optimize the app performance and battery life.



**Figure 2. Android Things development environment**

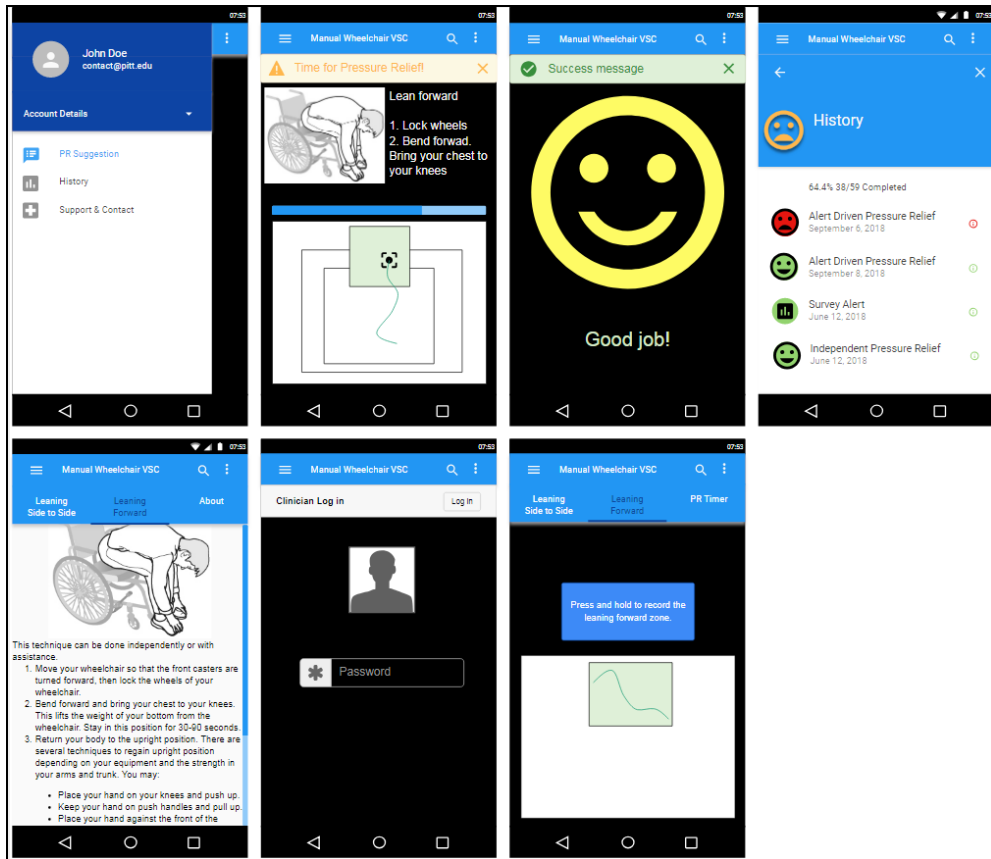


**Figure 3. Android Things onboard display**

Figure 3 shows the Android Things PICO Pi IMX7 board with onboard display and the ADC connected to testing analog input source. The onboard LEDs and segment display was used to show the app status. The green LED shows the sampling of the load cell voltages. The blue LED indicates the Bluetooth connection to the smartphone and the red LED flashes when an error occurs. Peripheral hardware test for the onboard sensors and general-purpose inputs and outputs (GPIOs) were performed. The ADC driver for the mikroBUS of the PICO Pi IMX7 were created and tested the connection for reliability and accuracy. The smartphone application was improved to include the latest graphic user interface (GUI) material design which provided better visibility to the contents and simplified interactions. Figure 4 shows the layouts of the material design. The pressure relief page was simplified to reduce the number of tapping. The help menu of pressure relief was improved allowing



better flow in viewing the information. Several tests were performed such as Bluetooth connection to the Android Things, cloud connection, data integrity for the behavioral coaching to ensure the robustness of application and data security for the long-term trial.



**Figure 4. Smartphone app component layouts**

2) In the following quarter, the smartphone application was further improved to include the latest graphical user interface (GUI) material design (Flutter by Google). Figure. 5 shows the layouts of the material design. The pressure relief page shows the relieving area and instructions of the relieving technique with a picture. The moving circle indicates the center of gravity on the seat which helps the user to shift weight correctly. A countdown timer under the circle helps the user know the remaining time left in this position. When sliding from the left side of the screen, there is an additional menu of reviewing performance data, changing clinical parameters and settings, and finding contact information. On the top of the screen, the Bluetooth icon shows the Bluetooth connection status. The information icon on the top right corner of the screen is the help menu that contains articles about the importance of performing pressure relieving exercises. Moreover, the data related to notification and reminders were successfully uploaded to the Firebase database as shown in Figure. 7, this data shows when the user received the reminder, when the pressure relief exercise was completed, how many times the user was notified and completed PR, etc. Figure. 6 shows a flowchart of the Server based computing and Figure. 8 shows MWVC Framework.

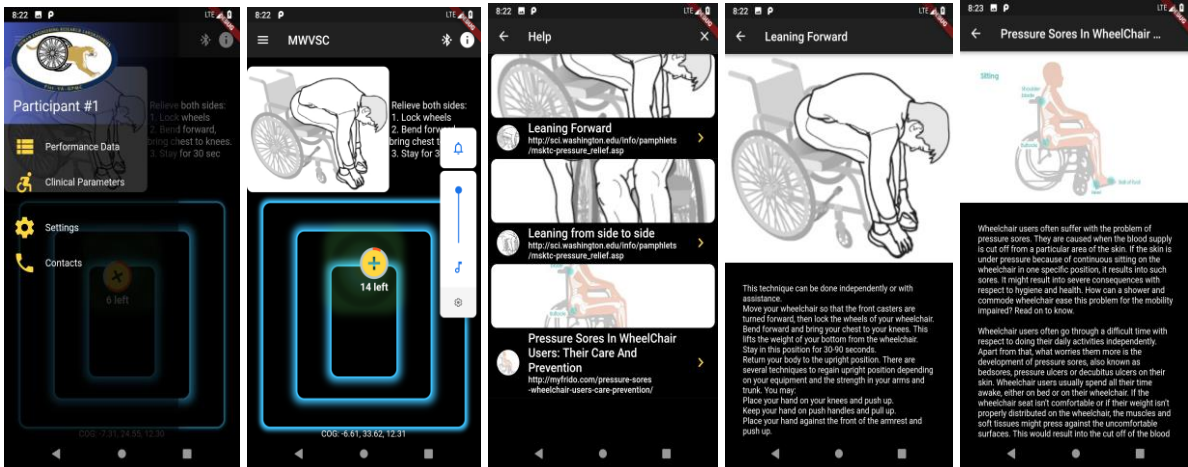


Figure. 5 Smartphone app component layouts

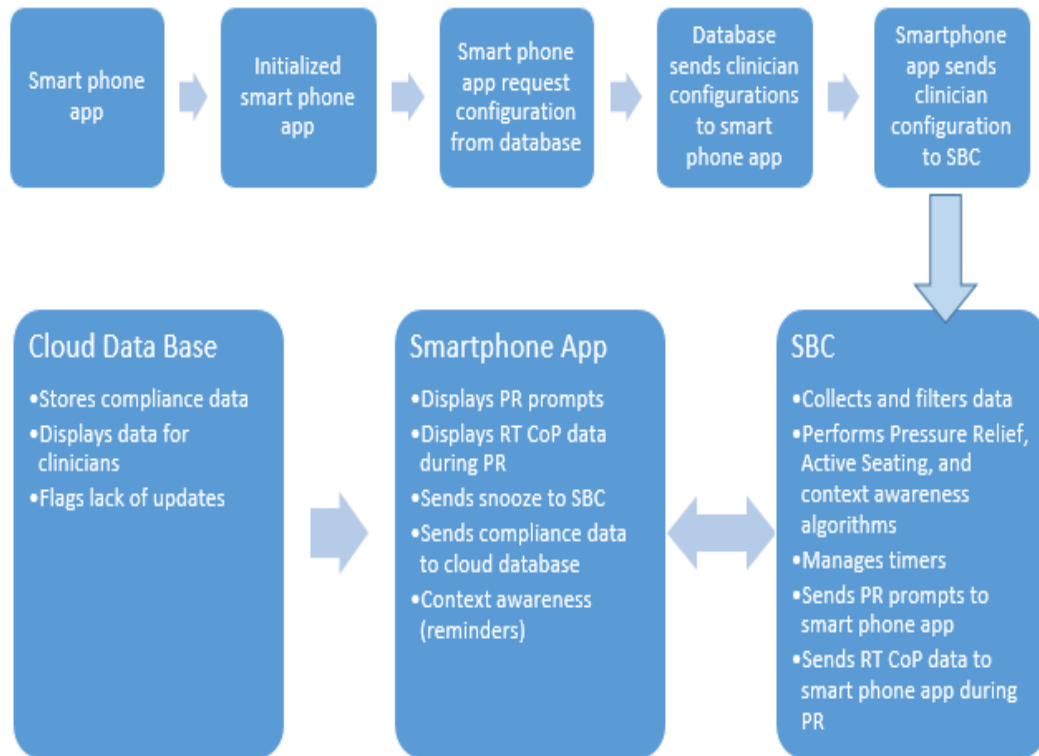


Figure 6. Server based computing (SBC) flowchart

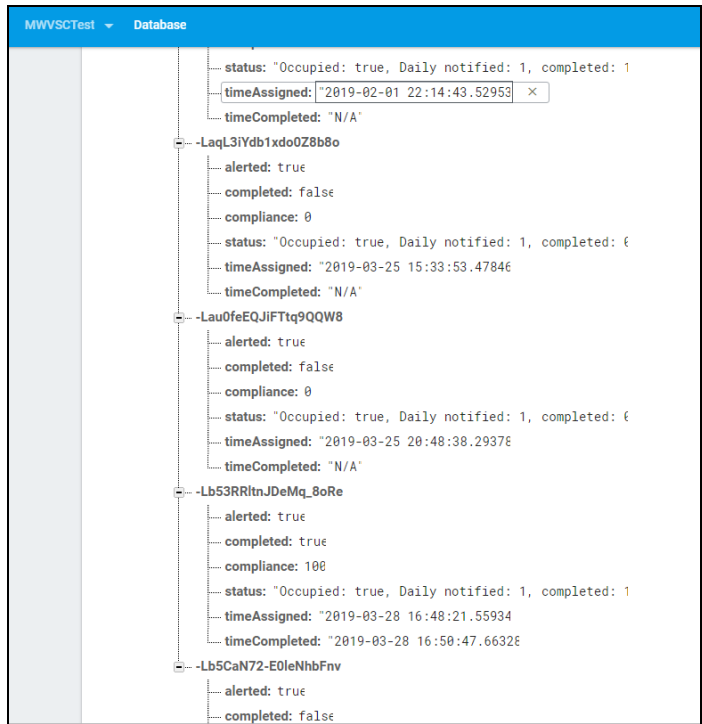


Figure 7. Firebase Database of the reported notifications and reminder

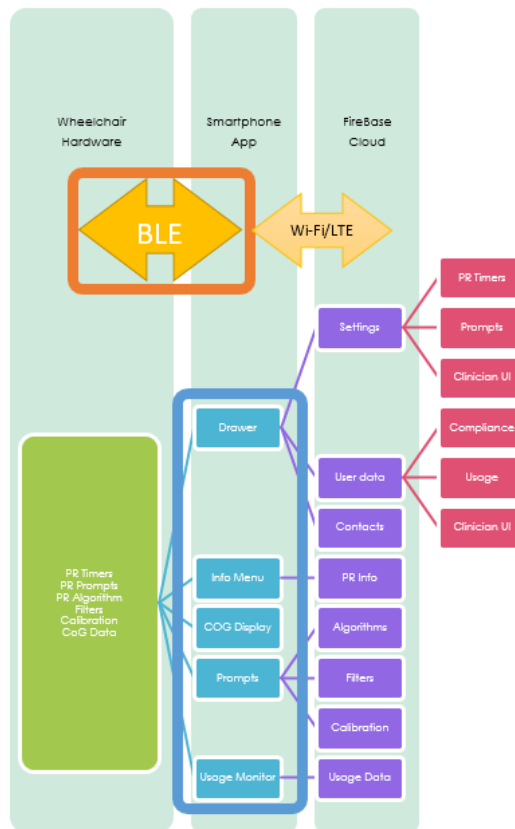


Figure 8. MWVSC Framework

3) In the last quarter, we have finalized the mobile application for the presentation of the CoP, coaching for pressure relieving exercises, detection of pressure relief types, data collection, and activity sharing to the cloud. In Figure. 9, the CoP is shown as the yellow circle that represents the location on the seat which is the rectangle. There are five portions on the seat that represent areas related to the pressure relieving exercises; the top triangle area is the location that produces effective forward lean pressure relief (PR). The two triangular areas on the sides are the effective side leans. The bottom black triangle area is the back of the seat and the central dark circle means the area does not qualify as PR. The PR areas turn green when the CoP is inside the effective area and the timer will start to show the seconds that the user must remain in this position. On top of the CoP interface, a picture and short description help to guide the user complete effective PRs. The application will upload the usage and movement to the cloud storage. We are still using Firebase developed by Google as platform for the cloud database (Figure. 10). It includes the system messages, CoP, PR completion, PR type, PR time, and BLE connection.



Figure. 9: Application on cellphone

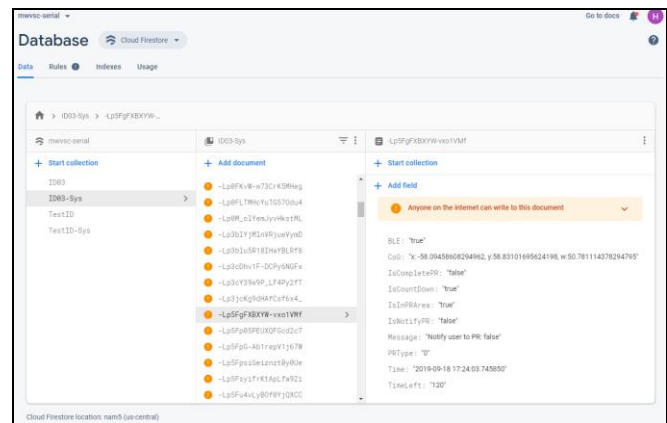


Figure. 10: Database for remote monitoring

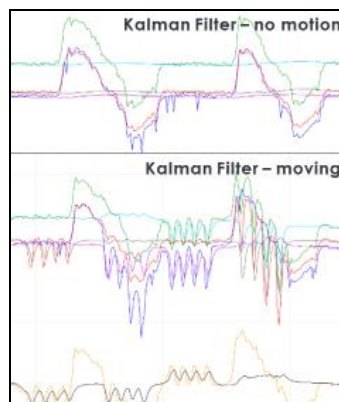
- **Significant Results:**

- BLE connection to a smartphone with data acquisition through notification.
- Firebase message uploading and downloading.
- Performance data list view from Firebase database.
- Moving-COG-dot UI modification for real-time monitoring.
- Data recording with BLE test
- **Flutter**, which is an open-source mobile application development framework created by Google was used for software development. The mobile application was examined for long term reliability. During the 5-day usability trial, the application uploaded daily usage to the cloud including application start time, menu exploration, error messages, and pressure relief reminders. However, some participants forgot to charge the system every day and the application was not able to acquire and upload the sensor data.

## Work related to: Major task 4

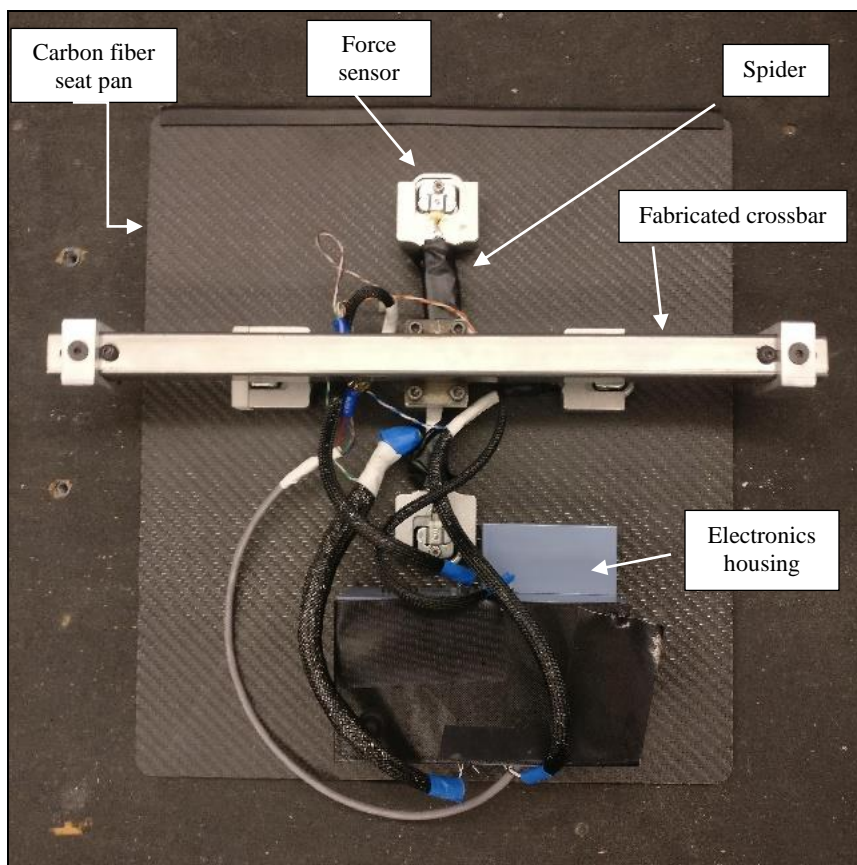
### Accomplishment #4:

- **Specific Objectives:**
  - Create CAD and CAM files from mechanical and electronic components
  - Create and refine prototype from mechanical and electronic components
- **Major Activities:**
  - 1) During the first quarter of year 2, the **electronics** for MWVC were tested for ADC readings and overall physical connectivity. The input readings from sensor hardware were confirmed in software against reading via a voltmeter. A test enclosure was developed for the electronics and a prototype was 3-D printed.
  - 2) In the next quarter, based on user feedback from the first few participants, some wires were rerouted to ensure they are not pulled as the wheelchair is loaded/unloaded from a vehicle. The analog front-end was functioning as intended. A new single board computer (Udoo Neo, made by Seco Inc.) was used to enable on board storage of load cell data during the trial, which could be subsequently processed to further improve our seated posture algorithms and conduct post hoc analysis of unexpected results. The new SBC also has the computing power to offload substantial portions of the algorithm from the phone, which improved smartphone battery life, and kept the android operating system from stopping the Virtual Coach as a resource intensive process.
  - 3) *Hardware:* Five amplifier PCBs were fabricated. The PCBs were tested to calibrate the no-load output voltage as 1.65V while supplying 3.3V. The gain resistors on the PCBs was calibrated using different weights from 1-50 lbs. ensuring that the dynamic range of the output voltages was within the 1.2V. A 3D printed housing was fabricated to hold the amplifier, battery, battery charging PCB, and the single board computer.
  - 4) *Signal processing (Figure.11):* In the last quarter, during the usability study, we found an extremely low-frequency drifting in the analog output signals possibly due to surrounding noises. The outputs start oscillating about every 20 seconds. We applied the Kalman filter for removing this low-frequency oscillation but also kept a quick response for the weight shifting. After applying Kalman filter, the noise was eliminated, and it still provides fast response to the weight changes. In addition, it also helps to improve the shifting from the increased temperature. Although we have tried to optimize the Kalman parameters for the system, we still record the original sensor data for further improvement if we find problems in the subject testing.

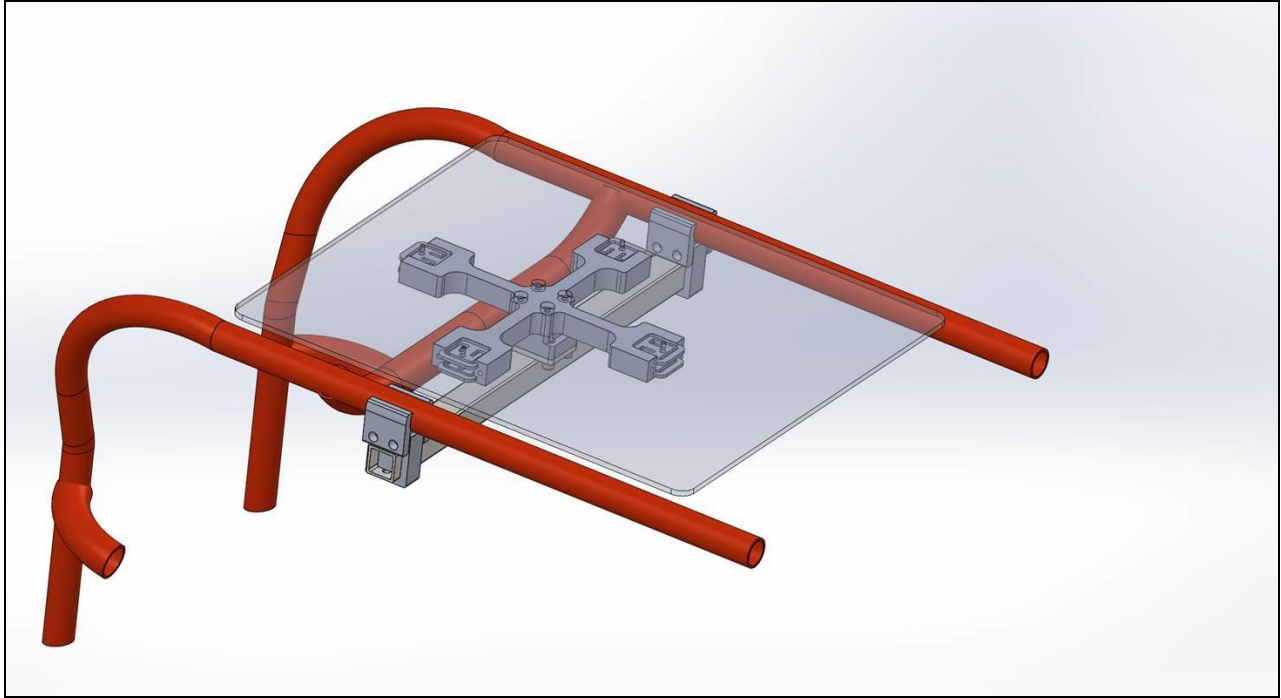


**Figure. 11 Kalman Filtered load cell readings**

**5) Mechanical updates:** There has been no significant changes in the overall mechanical design. As shown in figure. 12, the design still consists of a pilon, a “spider”, 8 half-bridge force sensors, a carbon fiber seat pan, and an electronics housing. The spider is a machined piece of aluminum that holds the 8 half-bridge in their proper configuration. The spider has 4 legs, with each leg having two grooves to accept two force sensors. An end cap on each leg holds the sensor in place. The pilon consists of machined aluminum and connects the spider to the frame crossbar. However, during the usability study, we noticed that when the spider was attached to the frame crossbar, it increased the floor to seat height. Therefore, we redesigned (figure. 13) and fabricated a new crossbar, mounting clamps, carbon fiber seat pan, and spider to resolve this issue. Additionally, this helped to compensate for the differences in the location of the crossbar in manual wheelchairs. A solid model of the device assembly is shown in figure 12. Since every individual’s manual wheelchair is different, there is a need to customize to ensure correct fitting.



**Figure 12. Hardware components**



**Figure 13. CAD drawing of the mechanical design**

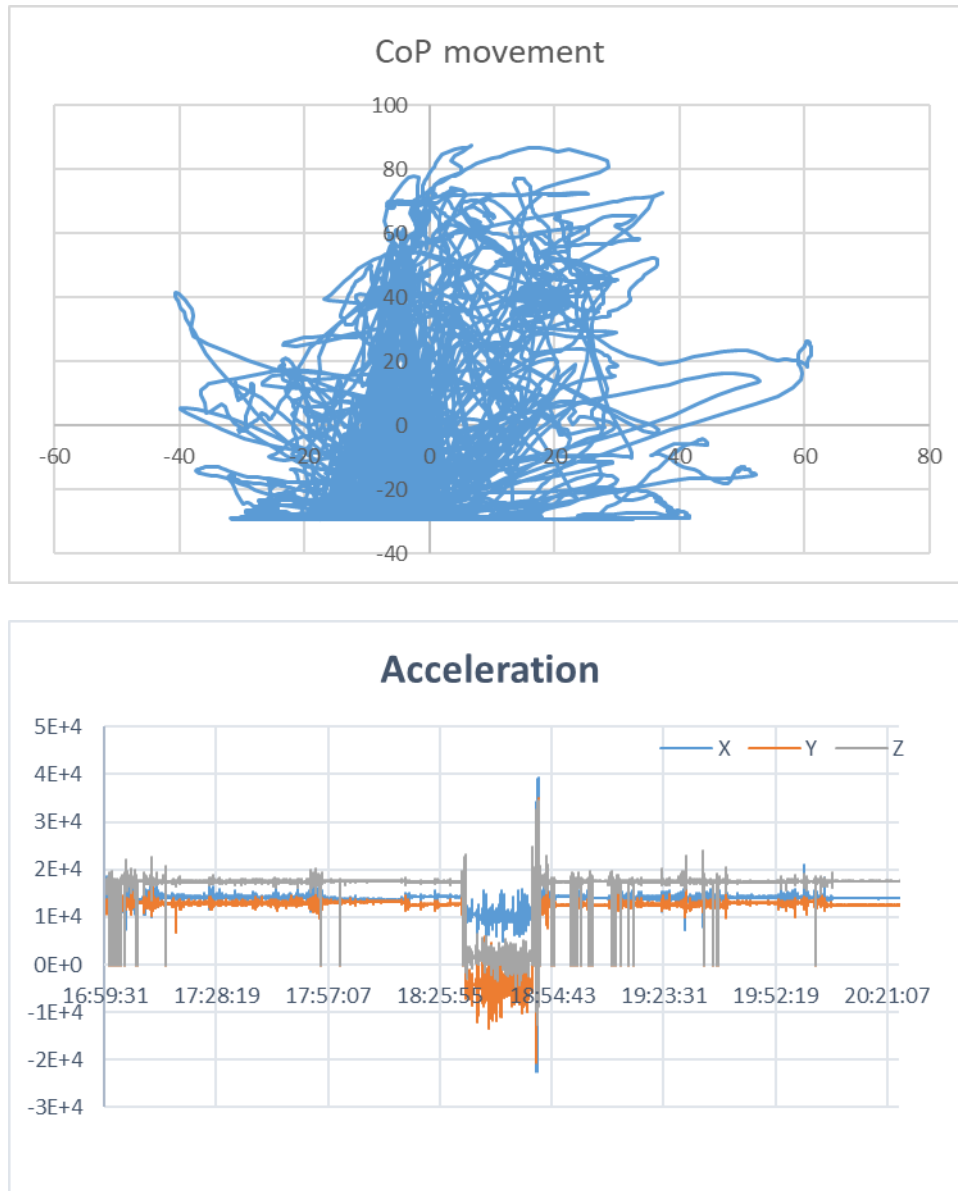
- **Significant results:**

- The electronics package has been made more robust, per participant feedback.
- We have gained the ability to store significant amounts of data on board for post-trial analysis. Software representation of loads corresponds with measured voltages and forces applied.
- All components were manufactured using CNC technologies (milling, waterjet, additive manufacturing), along with custom work holding fixtures, will allow for quick and labor efficient means of producing multiple iteration the device for the project. Figure 14 shows the assembled device on different manual wheelchairs. Multiple Spiders were manufactured along with a customized seat pans made from carbon fiber.



**Figure 14. Device assembly on a manual wheelchair**

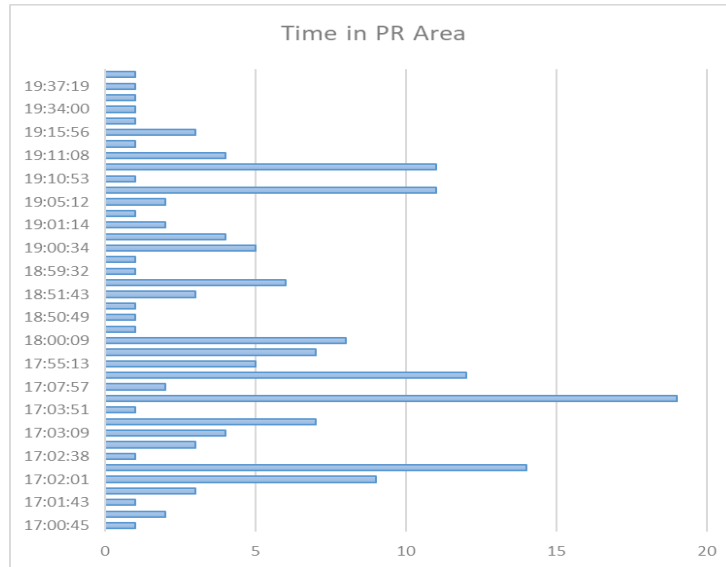
- The electronics were modified to include on-board storage for system messages and raw data. The test shows that it took about 2GB for one day data. Figure. 15 shows the CoP moving trajectory and acceleration of one participant. The trajectory helps to see user's moving habit and trend. For example, this participant moved more on the right than the left. We confirmed this during post-trial interview where the participant reported that he has concerns about bump on the left bottom skin and tended to lean to the right more in order to relieve the sitting pressure on the left. In addition, the acceleration data showed the activity on the chair. For example, there is no acceleration changes after 20:00 which might suggest the user was outside the chair.



**Figure 15. CoP moving trajectory and acceleration**

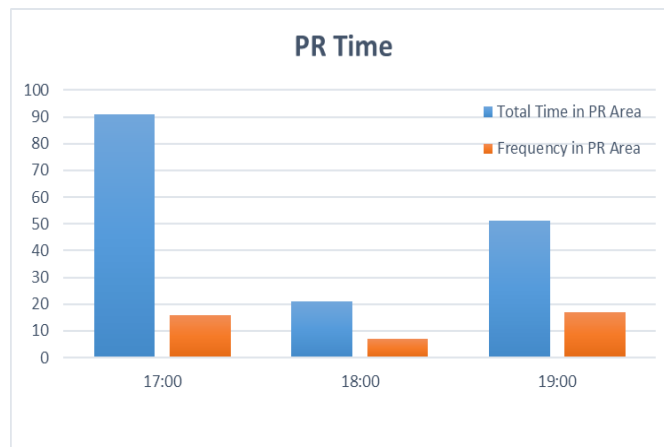


- For the pressure relief data, the single board computer recorded when and how long the user is inside the effective pressure relieving areas. The chart shows the duration from 17:00-20:00. It shows the user responded to the 30-minute reminder at 19:00 and 19:34. However, the user was able to remain the position for 19 seconds most.



**Figure 16. Pressure relief data**

- Figure. 17 shows how much time the participant stays in the effective pressure relieving areas. The participants stayed more time in pressure relieving areas between 17:00-18:00 and 19:00-20:00. The frequency is shown in orange color. In combination of the acceleration data, there are significant movement between 18:00 to 19:00 which might be indication of the participant was in transportation or moving. This explained the reduced pressure relieving exercises between 18:00 to 19:00. Therefore, the electronics not only shows the pressure relieving from CoP movements but also the daily activities from the inertia measurement unit which facilitate to explain and reasoning the daily usage on the wheelchair.



**Figure 17. Pressure relief time**

## Work related to: Major task 5

### Accomplishment #5: Conduct usability testing for Specific Aims 1-3.

- **Specific Objectives:**

- Recruit and enroll participants
- Conduct focus group with MW-VC
- Complete 5-days in home trial

- **Major Activities:**

As mentioned in the previous annual report, twenty participants (twelve males, age: 23-75) consisting of manual wheelchair users (MWU) and clinicians/caregivers participated in the focus group. We received several useful feedbacks which was incorporated into the design. Key issues were addressed before initiating the 5-day in home trial. We have enrolled **five** additional MWUs to test out the updated system. The study involved 2-3 visits; the initial visit where the individual's wheelchair measurements were taken to fabricate a customized seat pan; second visit involved fitting the device and explaining how to use the phone application; and the third visit to uninstall the system after 5 days and for the MWU to share their thoughts and opinions on using the coaching system. The usability study has established a basic framework for further improvement in the upcoming 12- week pilot study.

- **Significant results:**

- Focus groups/ structured interviews consisting of 10 Clinicians and 10 Manual wheelchair users have been completed. Overall, participants rated the MW-VC highly for innovation, usefulness and compactness.
- 5-day in home trial has been completed for four participants and 5<sup>th</sup> participant currently enrolled.
- The key issues are being addressed and will be remedied before the pilot study.

- **What opportunities for training and professional development has the project provided?**

In addition to supporting full time engineers and staff, this project has provided learning opportunities to the team. Members of the team – especially Dr. Chung – undertook significant self-study to implement a new low-cost, high capability, X86 II single board computer that can be additionally utilized in other projects.

- **How were the results disseminated to communities of interest?**

Through subject recruitment activities and personal experience with the system by research participants, we have increased awareness of the constant need for pressure injury prevention, as well as our unique solution for increasing the frequency and effectiveness of pressure reliefs. Presentations at funding competitions have exposed a wider community to the importance of pressure injury prevention.

- **What do you plan to do during the next reporting period to accomplish the goals?**

We will finish analyzing the results of the 5 day in home trial and make modifications to the system based on the objective data collected and participant feedback. We will begin the

twelve-week efficacy trial. We will also begin disseminating the data from the work done thus far through journal papers and presentations.

#### **4. IMPACT:**

- **What was the impact on the development of the principal discipline(s) of the project?**  
The in home trial of the Manual Wheelchair Virtual Coach demonstrated that it is possible to remotely monitor when manual wheelchair users are doing pressure reliefs, give them real-time feedback on whether their attempted pressure reliefs are likely effective, and gather more detailed information on their changes in seated position all while the user is performing his or her usual activities in the community.
- **What was the impact on other disciplines?**  
Nothing to Report.
- **What was the impact on technology transfer?**  
In July 2019 we filed an international patent application to protect intellectual property from this project in order to preserve value for a future independent company or licensing deal. We received a copy of the Written Opinion (WO), International Search Report (ISR) and the cited prior art references from the United States Patent and Trademark office (USPTO) acting as the International Searching Authority (ISA) for this PCT application. The Written Opinion is an initial preliminary non-binding opinion of the ISA about novelty, inventive step (no obviousness) and industrial applicability of the invention covered by the PCT application. We are happy to report that no objections to novelty, inventive step or to industrial applicability were raised by the ISA based on the prior art documents found during the search.
- **What was the impact on society beyond science and technology?**  
The MW-VC system, in its current form, provides a tool for both clinicians and manual wheelchair users to obtain objective data about the frequency and likely effectiveness of pressure relief maneuvers. By being lower cost than the current objective standard of pressure mapping, and with the ability to be used by any manual wheelchair user in his or her daily life, our current system already has the potential to improve pressure relief education and user behavior – leading to a reduction in pressure injuries.

#### **5. CHANGES/PROBLEMS:**

- **Changes in approach and reasons for change**  
No significant changes have been made to the overall objective and approach.

Originally, we intended to enroll ten subjects simultaneously for the five-day in-home trial. Since the purpose of this part of the study was to identify points of failure in the system and suggestions for improved ease-of-use, we chose instead to enroll five participants sequentially, so that we would have more iterative opportunities to improve the system, while making efficient use of project resources and study subject time.

- **Actual or anticipated problems or delays and actions or plans to resolve them**  
Successive iterations of the device have taken more time than originally allotted. However, they have allowed us to incorporate significant user feedback and identify potential failure modes that could have negatively impacted the timeline and subject completion of our longer-term study.

Delays while working on the device and application have resulted in loss of contact with some potential study participants originally identified in our focus group. However, we believe our continued efforts at recruitment will mitigate any impact on the remainder of the study.

- **Changes that had a significant impact on expenditures**  
No significant changes in expenditures.
- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**  
**Significant changes in use or care of human subjects:**  
No significant changes

## 6. PRODUCTS:

- **Publications, conference papers, and presentations**  
Nothing to report  
**Journal publications**  
Nothing to report  
**Books or other non-periodical, one-time publications.**  
Nothing to report  
**Other publications, conference papers and presentations**  
Nothing to report  
**Website(s) or other Internet site(s)**  
Nothing to report  
**Technologies or techniques**  
Nothing to report
- **Inventions, patent applications, and/or licenses**  
WHEELCHAIR PRESSURE ULCER RISK MANAGEMENT COACHING SYSTEM AND METHODOLOGY- PCT International application No: PCT/US2019/041327 (Filed July 2019)

- **Other Products**



**Figure. 18** Functional and user tested prototype, including mechanical hardware, electronics, imbedded software, android applications, and online database.

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

**What individuals have worked on the project?**

|   |   |
|---|---|
| <i>Name:</i>                                  | <i>Rory A Cooper</i>  |
| <i>Project Role:</i>                          | <i>PI</i>   |
| <i>Researcher Identifier (e.g. ORCID ID):</i> |   |
| <i>Nearest person month worked:</i>           | <i>1.2 Cal months (10% effort)</i>  |
| <i>Contribution to Project:</i>               | <i>Dr. Cooper has overseen all aspects of the research protocol.</i>  |
| <i>Name:</i>                                  | <i>Garrett Grindle</i>  |
| <i>Project Role:</i>                          | <i>Research Scientist and Engineer</i>  |
| <i>Researcher Identifier (e.g. ORCID ID):</i> |   |
| <i>Nearest person month worked:</i>           | <i>1.2 Cal months (10% effort)</i>  |
| <i>Contribution to Project:</i>               | <i>Dr. Grindle was involved in the design, prototype and calibration of MW-VC.</i>                            |
| <i>Name:</i>                                  | <i>Chengshiu Chung</i>  |
| <i>Project Role:</i>                          | <i>Postdoctoral Fellow</i>  |
| <i>Researcher Identifier (e.g. ORCID ID):</i> |   |
| <i>Nearest person month worked:</i>           | <i>2.4 Cal months (20% effort)</i>  |
| <i>Contribution to Project:</i>               | <i>Dr. Chung developed and tested machine learning algorithms, designed and implemented MW-VC application</i> |
| <i>Name:</i>                                  | <i>Josh Brown</i>   |
| <i>Project Role:</i>                          | <i>Electrical Engineer</i>  |
| <i>Researcher Identifier (e.g. ORCID ID):</i> |   |
| <i>Nearest person month worked:</i>           | <i>1.2 Cal months (10% effort)</i>  |
| <i>Contribution to Project:</i>               | <i>Mr. Brown contributed to the designed, prototyped and calibrated the MW-VC</i>                             |

*Name: Benjamin Gebrosky*  
*Project Role: Mechanical Engineer*  
*Researcher Identifier (e.g. ORCID ID):*  
*Nearest person month worked: 1.2 Cal months (10% effort)*  
*Contribution to Project: Mr. Gebrosky contributed towards hardware installation and wheelchair fitting.*

*Name: Nikitha Deepak*  
*Project Role: Research Coordinator*  
*Researcher Identifier (e.g. ORCID ID):*  
*Nearest person month worked: 1.2 Cal months (10% effort)*  
*Contribution to Project: Ms. Deepak was involved in IRB submissions, testing and reporting of progress.*

*Name: Andrea Sundaram*  
*Project Role: Graduate student researcher*  
*Researcher Identifier (e.g. ORCID ID):*  
*Nearest person month worked: 6 Cal months (50% effort)*  
*Contribution to Project: Mr. Sundaram has performed work in the development and Testing of machine learning algorithms and implementation of the MW-VC application. He has also worked to coordinate the project and promote it to outside groups.*

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**  
Nothing to Report
- **What other organizations were involved as partners?**  
None

## **8. SPECIAL REPORTING REQUIREMENTS**

Quad chart (See appendix)

## **9. APPENDICES:**

Quad chart

# Manual Wheelchair Virtual Seating Coach

SC160273

W81XWH-17-1-0620



PI: Rory Cooper

Org: Human Engineering Research Laboratories

Award Amount: \$148,922.00

## Study/Product Aim(s)

- Aim 1: To obtain a record of manual wheelchairs (MW) seated center of pressure (CoP) patterns during usage by people with spinal cord injuries (PwSCI) and to relate that to surveys of activity, participation and seating discomfort.
- Aim 2: To determine if virtual coach features of the MW reduce seating discomfort and improve adherence to Clinical Practice Guidelines (CPG).

## Approach

Develop a smart phone based coaching system consisting of force sensors to measure the weight distribution on wheelchair's seat and artificial intelligence algorithms to instruct the user on effective pressure relief (PR). Additionally, conduct usability testing and a pilot study of the MW-VC prototype with PwSCI and clinicians.



Figure 1



Figure 2

Figure 1: Prototype interfaced with participant's manual wheelchair  
Figure 2: Smartphone application

## Timeline and Cost

| Activities                                    | Q1 Y2       | Q2 Y2        | Q3 Y2        | Q4 Y2       |
|---|-------------|--------------|--------------|-------------|
| Expert System and Machine Learning Algorithms | [Green bar] |              | [Purple bar] |             |
| Application Software                          | [Green bar] |              | [Purple bar] |             |
| Seating Systems Sensing Package               | [Green bar] |              | [Purple bar] |             |
| Conduct Usability Testing                     |             | [Green bar]  | [Purple bar] |             |
| Pilot Study                                   |             |              |              | [Green bar] |
| Prepare Proposal for MW-VC Clinical Trial     | [Green bar] | [Purple bar] |              |             |
| <b>Estimated Budget (\$K)</b>                 | <b>3K</b>   | <b>3K</b>    | <b>3K</b>    | <b>3K</b>   |

Updated: 9/20/19

## Goals/Milestones

**Q1 Goal** – Initiate application software/hardware development to include expert system & machine learning algorithm, finalize protocol for usability study

- ✓ Institution approval (IRB, HRPO)
- ✓ Simulate expert learning algorithms in MatLab
- ✓ Test & validate machine learning algorithms using MatLab
- ✓ Complete solid models, drawings, parts-list

**Q2 Goal** – Design, prototyping, calibration of MW-VC and conduct usability testing

- ✓ Complete working prototype for wheelchairs
- ✓ Usability study completed and design refined

**Q3 Goal** – Begin pilot trial

- ✓ Protocol finalized and approved
- ✓ Recruit and enroll ten manual wheelchair users (MWU)
- ☐ Pilot study completed

**Q4 Goal** – Prepare proposal for MW-VC Clinical trial

- ✓ Protocol finalized
- ☐ Data analysis
- ✓ Grant proposal submitted

**Comments/Challenges/Issues/Concerns:** Nothing to report.

## Budget Expenditure to Date

Projected Expenditure: \$148,922.00

Actual Expenditure: \$136,687.67