

**AWARD NUMBER:** W81XWH-17-1-0221

**TITLE:** Development of the Wheelchair In-Seat Activity Tracker (WiSAT)

**PRINCIPAL INVESTIGATOR:** Stephen Sprigle

**CONTRACTING ORGANIZATION:** GEORGIA TECH RESEARCH

**CORPORATION REPORT DATE:** July 2020

**TYPE OF REPORT:** Annual Progress Report

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

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# REPORT DOCUMENTATION PAGE

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|   |                    |                     |  |  |  |   |                            |  |  |
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| <b>13. SUPPLEMENTARY NOTES</b>  |                    |                     |  |  |  |   |                            |  |  |
| <b>14. ABSTRACT</b><br>Pressure ulcers remain a critical problem for persons with spinal cord injury (SCI), with negative consequences on nearly every aspect of their lives. Research and clinical experience suggests that weight shifts are an important part of promoting tissue health. This project seeks to design a commercially-viable system to inform wheelchair users about their weight-shifting activity as a means to promote healthy behaviors and prevent pressure ulcers. Termed the WiSAT (Wheelchair In-seat Activity Tracker), it will have impact on wheelchair users, their clinicians and researchers. Such a product can empower wheelchair users with knowledge about their behaviors associated with pressure ulcer prevention |                    |                     |  |  |  |   |                            |  |  |
| <b>15. SUBJECT TERMS:</b> pressure ulcer; wheelchair; weight shift; spinal cord injury; behavioral change; interactive technology   |                    |                     |  |  |  |   |                            |  |  |
| <b>16. SECURITY CLASSIFICATION OF:</b>  |                    |                     |  |  |  | <b>17. LIMITATION OF ABSTRACT</b>               | <b>18. NUMBER OF PAGES</b> | <b>19a. NAME OF RESPONSIBLE PERSON</b> |  |
| <b>a. REPORT</b>  | <b>b. ABSTRACT</b> | <b>c. THIS PAGE</b> |  |  | <b>19b. TELEPHONE NUMBER</b> (include area code) |   |                            |  |  |
| Unclassified  | Unclassified       | Unclassified        | Unclassified                           |  | 17   | USAMRMC   |                            |  |  |

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INTRODUCTION:

Pressure ulcers remain a critical problem for persons with spinal cord injury (SCI), with negative consequences on nearly every aspect of their lives. Research and clinical experience suggests that weight shifts are an important part of promoting tissue health. This project seeks to design a commercially-viable system to inform wheelchair users about their weight-shifting activity as a means to promote healthy behaviors and prevent pressure ulcers. Termed the WiSAT (Wheelchair In-seat Activity Tracker), it will have impact on wheelchair users, their clinicians and researchers. Such a product can empower wheelchair users with knowledge about their behaviors associated with pressure ulcer prevention

- KEYWORDS: pressure ulcer; wheelchair; weight shift; spinal cord injury; behavioral change; interactive technology

ACCOMPLISHMENTS:

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

|  | <b>Timeline</b> |
|--|-----------------|
| <b>Task 1. Develop WiSAT hardware and mobile app</b>                                     | 1-12            |
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- **What was accomplished under these goals?**

**Task 1. Develop WiSAT hardware and mobile app**

WiSAT System can be described as having three goals:

1. Measure In-Seat Activity
2. Process and classify data into in-seat activity metrics
3. Provide users with reporting of in-seat activity

To achieve these goals WiSAT has 3 functional subsystems: a hardware module, classification algorithms, and a mobile phone application. Status of each subsystem will be presented in this section.

## **Hardware module design:**

Previously, the hardware design went through many iterations. Extensive testing of the battery, inductive charging system, and logger circuitry was conducted in order to define the necessary logger specifications. The seat sensors were received from Tekscan and quality tested. Most firmware issues had been addressed. At this time, the hardware and firmware design is fixed and multiple modules have been fabricated for deployment in the pre-clinical trial and distributed to trial sites.

Over the past year, only minor evaluation of the hardware system has been needed. The design of the data acquisition hardware (WiSAT module) is considered fixed at this time. We received production units from Gulf Coast Data Concepts in Q4 of year 2 of the grant period. The current specification table is included in the Appendix.

## **Mobile phone app development**

At the end of Year 2, the app's overall design and UI had been solidified and it was in active development. Key features related to Bluetooth communication, management of database size and synchronization and algorithm integration were being developed and tested.

Through the current reporting period, the major changes were as follows:

1. Project Management changes and updates to ensure detailed issue tracking and frequent communication with app developers which led to faster turnarounds for testing and QA.
2. iOS App has had numerous updates related to the key features mentioned above.
  - a. To ensure continuous Bluetooth communication between hardware and the app, a major change made was to prioritize the app's use of device resources when in the background on all targeted versions of iOS. This was completed in Q2.
  - b. Database size management issues, data collection backlog issues and data corruption handling issues were investigated and resolved in Q3.
  - c. Major enhancements related to user experience such as the ability to skip one or more initialization leans and to connect to a different data logger were implemented.
3. The iOS app was published on the Apple App Store at the end of Q2. Subsequent updates made to the app have also been published to the App Store - a significant outcome that has allowed clinical partners to use the full system and provide feedback.
4. Numerous algorithm features that were considered beyond minimum viable product (MVP) milestones have now been implemented and integrated into the app.

Android app development was paused at the end of Q2. Issues with ensuring continuous Bluetooth communication with the hardware as well as limitations on battery usage led to the team's time and energy being focused on creating a viable iOS app build. After the iOS app was published, updated Android builds provided by the app developer were tested on different hardware in Q4 to evaluate viability. As of now, further development on the Android app is paused. Future iterations of WiSAT will rely on processing user data on-board the data logger to reduce the need for continuous Bluetooth communication.

The data flow diagram for the mobile phone app is listed in Appendix 2. Examples of the UI screens from the app are shown in Appendix 4.

## **Task 2: Develop classification algorithms**

At the end of Year 2, the algorithms developed for classifying user activity were refined to work in real-time in order to be integrated into the app. Multiple data sets were collected to train the algorithm on identification of weight shifts and in-seat movement. The accuracy of the algorithms in calculating user activity was measured and reported.

Through the current reporting period, the biggest focus was on translating the existing MATLAB code into Java and Swift code for integration with the mobile apps. This included multiple iterative rounds of piecewise and full system testing and updates to the code, done in collaboration with the app developers.

As a result of continued testing on the app as well as through collected data sets, some new features were incorporated into the algorithm as stand-alone code and in the mobile app.

1. 3 cushion type-specific classifiers were trained and tested, taking into account the type of cushion that the participant uses.
2. The app requires users to complete standard leans as part of their initialization. We identified and addressed situations where a user might skip one or more of the leans. This change required algorithm and app side updates and was deployed in Q3.
3. The algorithm now counts full pressure reliefs (user getting fully off-chair as part of a pressure relief exercise) as weight shifts. This correction of an earlier oversight was implemented and integrated into the app in Q4.
4. The threshold for occupancy classifier was changed to avoid inaccuracies in calculations of seat occupancy. It was seen from field data that the total force response from the sensors decreased during extended use compared to initialization, which could lead to a user's in-seat session to be labelled as out-of-seat. To improve the accuracy in this situation, we reduced the threshold.

At this time, algorithm development is largely concentrated on fixing bugs in the app implementation and is dependent on issues found through tests done in the field with different participants. User outputs from usability and pre-clinical trials will be collected and their raw sensor data will be post-processed to ensure that the algorithm implementation is accurate based on comparison with stand-alone code.

## **Task 3 Engage wheelchair users in usability studies**

Usability evaluation has occurred in previous reporting periods and continued into Year 3. The current focus is System Usability which allows participants to use WiSAT for a short period of time. To date, a total of five subjects have been recruited for the study with three subjects having completed the study. The goal is to enroll 10-15 participants for this study.

In order to test system usability, subjects were set up with the WiSAT equipment and app for a minimum of a week. At the end of the week, the raw data from the logger was collected and analyzed to determine the mat and logger performance. The subjects' daily app outputs were monitored through the API database to ensure the equipment and app were working correctly. At the end of the study, each participant took a modified version of the Software Usability Measurement Inventory (SUMI) to gauge user satisfaction with the app. Users were also asked for their open-ended feedback on the WiSAT system as a whole. Results from this study will be used to improve aspect of training, initialization and to establish criteria for the next version of the WiSAT logger and app.

All subjects were able to use the WiSAT system during evaluation. The main areas of user feedback concerned logger placement and charging. Most users expressed hesitation about placing the logger inside of the cushion and expressed a preference to having the logger placed in a bag attached to their chair. Some of the users had difficulty with using the inductive charger due to the loggers placement in their cushions. The current inductive charging system is an off-the-shelf module that was retrofit to the WiSAT data logger. Future logger versions will have the inductive charging module built in and will be better designed to fit the concerns brought up by this usability study.

#### **Task 4: Pre-Clinical Trial to assess acceptability, usability and impact of WiSAT**

This pre-clinical trial is designed to assess three important constructs: acceptability, usability and impact. The first objective of the trial is to improve the acceptability and usability of the WiSAT prototype by engaging users during and after a long-term user trial. The second objective is to assess whether WiSAT can change the behavior of wheelchair users at risk for pressure ulcers by increasing in-seat movement activities (i.e., volitional pressure reliefs and weight-shift activity). The trial is being coordinated and administered at the University of Pittsburgh in collaboration with the Hines VA. Seventy-six individuals who are full time manual wheelchair users at risk for pressure injury are targeted for enrollment. Pitt had previously obtained IRB and HRPO approval, and the Hines VA obtained IRB approval during this reporting period. The activities over the reporting period involved trial preparations and initiating participant enrollment. Additionally, the University of Pittsburgh registered the study with ClinicalTrials.gov.

Preparations involved development of the data collection databases, code to calculate outcome measures and determine whether participants will receive active notifications, and the manual of procedures. The University of Pittsburgh developed data collection databases to capture the mobile app data and clinical data during the trial. The API endpoint database provides a data portal to access the data transmitted by the mobile app for each participant including tables providing user information, activity history, connection history, device information, error logs, participant goals, initialization shifts, in-seat history, month archives, weight shift activity and scaling factors. Procedures were developed at Pitt to check the error logs and data tables daily and troubleshoot as needed. A REDCap database was developed to collect clinical data, for both Pitt and VA sites. REDCap is used to record baseline and endpoint clinical data, distribute survey measures to participants, and to collect additional information throughout the study (e.g., document equipment changes, pressure ulcer status changes, adverse events). The REDCap database has been created and tested by Georgia Tech, Pitt, and Hines VA. Measures were added to the baseline visit survey and the semi-structured interview was modified to better assess the participants' experience with WiSAT. Additionally, the University of Pittsburgh registered the study with ClinicalTrials.gov. The study has been approved and placed on the ClinicalTrials.gov site.

Additionally, a skin health education protocol has been created by the University of Pittsburgh. This protocol will be used to inform the research participants about pressure ulcers and weight shift behavior during their initial study visit. This protocol was created using recent published literature and best practices for skin health.

During this reporting period, Georgia Tech created a MATLAB function for the University of Pittsburgh to manage and process the force sensor data stored in the API endpoint to report hourly and daily

behavior and whether or not goals were met. The University of Pittsburgh tested this code and then created second function to compare how often goals were met with a pre-defined threshold to aid in efficiently determining active versus passive feedback mode for participants. To operationalize the active mode versus passive mode decision, updated literature searches and team consensus occurred. This decision is made 6 weeks after the participant has started the study. If the participant is moved into active mode, they will start to receive notification to help them meet their goals. If the participants are in passive mode, they will not receive notifications. These functions allow the researchers to visualize the information available to the participants on the app, are essential for deciding active versus passive mode, and provide a robust data set for overall analysis.

In addition, the team at the University of Pittsburgh has created a manual of procedures for the research staff to follow and reference at both clinical sites. This manual of procedures explicitly outlines the study procedures, how to access the various databases and the troubleshooting guide. The troubleshooting guide and detailed manual for all of WiSAT's sub-systems was created and distributed by Georgia Tech.

The Hines VA site received their local IRB approval. Since the approval, the University of Pittsburgh has worked on setting up the Hines VA for study procedures. For example, meetings have occurred to transfer the REDCap database to the VA REDCap servers and training has occurred. Regular weekly meetings between Georgia Tech and Hines VA are occurring to ensure that they are prepared to enroll participants when enrollment begins.

The University of Pittsburgh enrolled the first participant and screened and scheduled other participants before the COVID-19 response paused enrollment. Additional mailings, both physical mailings and electronic mailings, have been sent out from registries to recruit more participants. We have continued to recruit and screen participants through some recruitment platforms that had already been put in motion. The first participant's data and experience has provided us with valuable information to improve the data collection and app delivery. Georgia Tech and the University of Pittsburgh worked together to troubleshoot and resolve the participant's issues.

The Pitt and the Hines VA can commence recruitment when the local pandemic restrictions are lifted. To address the recruitment time lost, the length of participation was shortened from 5 months to 2.5 months. We have modified our IRB to allow remote data collection and return of equipment through mail to reduce in-person activities. We are also currently working to add Georgia Tech to the Pitt IRB to have 3 recruitment sites.

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

Not applicable

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

Because we have been measuring weight shift behaviors for several years, we are able to report findings and from the current project in combination with results from prior

work. Conference presentations, attended primarily by clinicians and researchers, have included aspects of the current project.

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

Our goal is to deploy and complete the pre-clinical trial at the University of Pittsburgh and Hines VA

- **IMPACT:**

- **What was the impact on the development of the principal discipline(s) of the project?**

This project represents translation of prior research into technology development. As a result, the technology development activities will extend clinical capabilities and will represent new technology innovation. Because the activities up to this point were formative, impact on disciplines was not a goal.

- **What was the impact on other disciplines?**

*Nothing to Report*

- **What was the impact on technology transfer?**

The objective of the project is to develop a commercial product, the WiSAT. Consistent with that objective, all development activities within the reporting period were designed to advance technology development and to position it for licensing.

Project staff continually engaged potential partners and identified two companies who expressed tangible interest. We relayed this information to Georgia Tech's Office of Technology Licensing engaged them about licensing the WiSAT technology

- **What was the impact on society beyond science and technology?**

- Nothing to Report

- **CHANGES/PROBLEMS:**

- **Changes in approach and reasons for change**

- 

- **Actual or anticipated problems or delays and actions or plans to resolve them**

- The pre-clinical trial is delayed due to suspension of all human subject activities as a result of the pandemic. The DoD offered a 12-month no-cost extension for projects affected by the pandemic and we were provided with this extension through June 2021.
- In addition we altered the timeframe of the pre-clinical trial to balance the need for valid data with the reality that we do not know when subject recruitment and enrollment will re-commence. This proactive change has already been approved.

- **Changes that had a significant impact on expenditures**
  - Suspension of human subject research activities has adversely impacted the budgets of Georgia Tech and the clinical sites. The nature of sponsored projects does not permit furloughing of employees due to suspension of research. Certainly there was no mandate to do so from the sponsor. As such, the project incurred costs, and is still incurring costs for personnel despite the suspension of the pre-clinical trial. We have worked with the clinical sites and have received an estimate of additional resources needed to complete the trial. Budget amendments will be submitted to provide those resources in the coming year.
- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents** Nothing to report
- **Significant changes in use or care of human subjects:** none
- **Significant changes in use or care of vertebrate animals.:** N/A
- **Significant changes in use of biohazards and/or select agents:** N/A
- **PRODUCTS:**
  - **Publications, conference papers, and presentations:** none
    - **Journal publications.** *none*
    - **Books or other non-periodical, one-time publications.** None
    - **Other publications, conference papers, and presentations.**
  - **Website(s) or other Internet site(s);** None
  - **Technologies or techniques:** None
    - **Inventions, patent applications, and/or licenses**  
Wheelchair in-seat activity tracker US Patent number 10,357,186, July 23, 2019
    - **Other Products:** none
- **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**
  - **What individuals have worked on the project?**

|                            |   |
|----------------------------|---|
| Name                       | Stephen Sprigle   |
| Project role               | PI  |
| Research ID (ORCID)        | <a href="https://orcid.org/0000-0003-0462-0138">0000-0003-0462-0138</a>   |
| Annual Person-month effort | 2.0   |
| Contribution to project    | Overall project management include liaison between DoD, Georgia Tech and clinical sites; design duties include project management and design team coordination. |

|              |                     |
|--------------|---------------------|
| Name         | Sharon Sonenblum    |
| Project role | Senior Investigator |

|                            |  |
|----------------------------|--|
| Research ID (ORCID)        | <a href="https://orcid.org/0000-0003-0462-0138">0000-0003-0462-0138</a>  |
| Annual Person-month effort | 3.0  |
| Contribution to project    | Lead investigator on developing detection algorithms; other design activities include WiSAT module and seat sensor |

|                            |   |
|----------------------------|---|
| Name                       | <i>Yogesh Deshpande</i>   |
| Project role               | Research engineer   |
| Research ID (ORCID)        |   |
| Annual Person-month effort | 4.0   |
| Contribution to project    | Project management; mobile application development; hardware and firmware development |

|                            |  |
|----------------------------|--|
| Name                       | <i>Kathleen Jordan</i>   |
| Project role               | Program Support Coordinator  |
| Research ID (ORCID)        |  |
| Annual Person-month effort | 3.0  |
| Contribution to project    | sensor characterization and validation; human subject data collection and analysis |

|                            |  |
|----------------------------|--|
| Name                       | <i>Darryl Adderly</i>  |
| Project role               | Developer and tester   |
| Research ID (ORCID)        |  |
| Annual Person-month effort | 6  |
| Contribution to project    | Development of in-house data validation tools, testing and QA of mobile app. |

|                            |  |
|----------------------------|--|
| Name                       | <i>Drake Rucker</i>  |
| Project role               | Developer and tester   |
| Research ID (ORCID)        |  |
| Annual Person-month effort | 3  |
| Contribution to project    | Development of in-house data validation tools, testing and QA of mobile app. |

- **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?**
  - **Organization:**

University of Pittsburgh, School of Health and Rehabilitation Sciences  
 Forbes Tower, Suite 5044  
 Pittsburgh, PA 15260  
 Partner PI: Patricia Karg
  - **Partner's contribution to the project**  
 As defined in the scope of work, YR3 effort from the University of Pittsburgh focused on finalizing preparations and initiating the trial protocol. They also assisted the Hines VA on completing IRB submission and approval, setting up a separate VA REDCap database, as well as training to initiate recruitment once the pandemic restrictions are lifted. Finally, Pitt deployed the system on one participant before enrollment stopped due to pandemic restrictions. The participant continued during the pandemic and completed the trial, providing valuable information to improve the data collection and app delivery.
  - **Financial support** : YR3 funding of \$142,277
  - **In-kind support:** none
  - **Facilities:** no specialized facilities required for effort in YR3
  - **Collaboration:** Partner staff developed detailed protocol for Pre-clinical trial, developed data collection instruments and processes, tested protocol and hardware, and commenced recruitment before having to cease research activities.
  - **Personnel exchanges:** none
- **Organization:**

VA Center of Innovation for Complex Chronic Healthcare (CINCCH)  
 Edward Hines, Jr. Hospital  
 Hines IL 60141  
 Partner PI: Marylou Guihan
- **Partner's contribution to the project:** Partner contributed to defining the pre-clinical protocol and overall discussions of WiSAT design. Secured approval of local IRB.
  - **Financial support** : 46887.17
  - **In-kind support:** none
  - **Facilities** *none in YR2*
  - **Collaboration** Partner contributed to defining the pre-clinical protocol and overall discussions of WiSAT design. Secured approval of local IRB, worked with Pitt to setup REDCap data collection on the VA network, and participated in protocol training with the Pitt and Georgia Tech teams to prepare for enrollment.
  -

- **Personnel exchanges** *none*
- **Other.**
- **APPENDICES:**

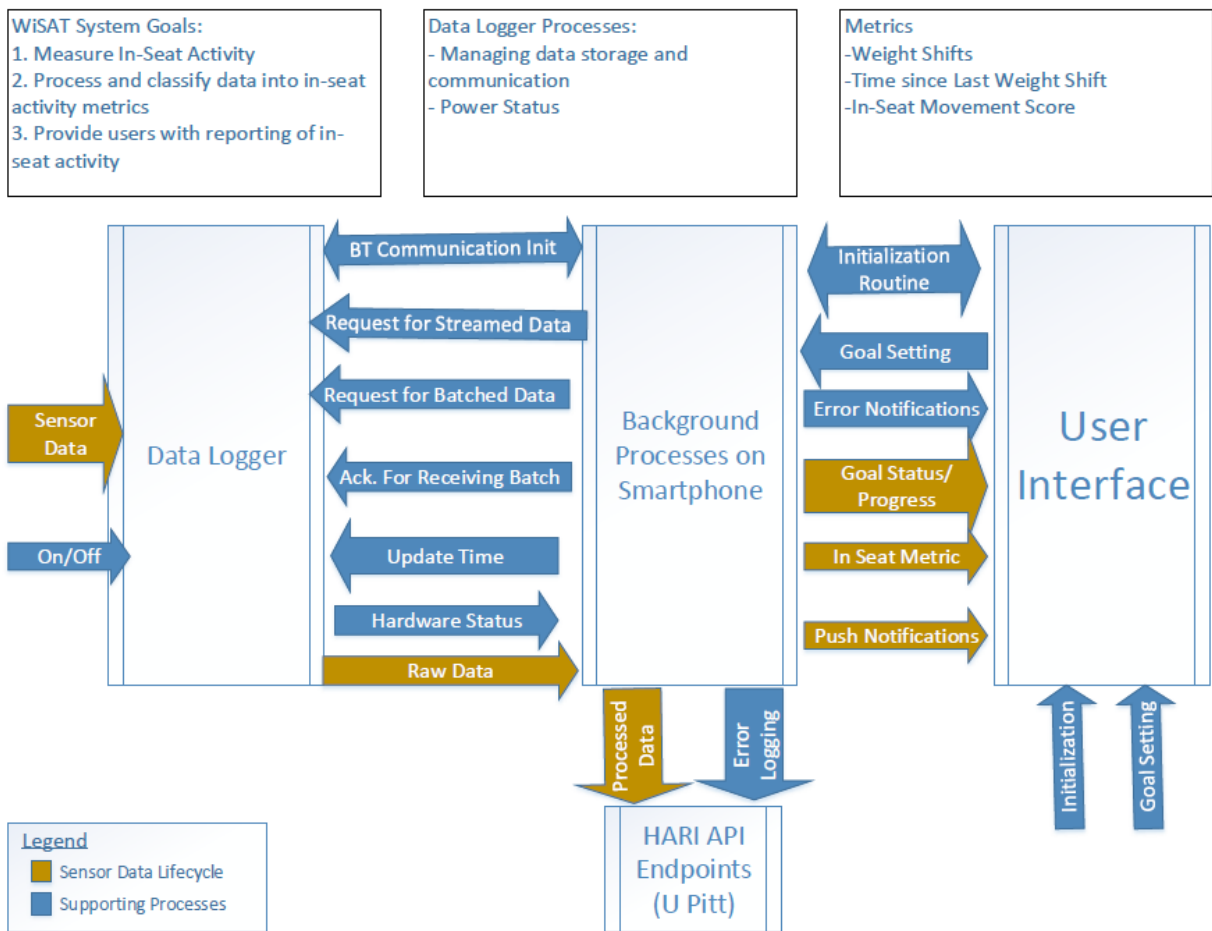
Appendix 1. Hardware Specification Table

|                              | <b>Requirements</b>   |
|------------------------------|---|
| Form factor                  | 2.5in x 1.75in x 0.8in  |
| Case and connectors          | <p>Case contains openings for microUSB and seat mat connector. Also contains LED indicators and on/off switch.</p> <p>Connector to inductive charging receiver: microUSB</p> <p>Connector to seat mat: 8-pin output Clincher 67516-208LF</p> <p>“Pig-tail” extension will be made of <a href="https://www.digikey.com/product-detail/en/parlex-usa-llc/PSR1635-08/AF08-100-ND/127259">https://www.digikey.com/product-detail/en/parlex-usa-llc/PSR1635-08/AF08-100-ND/127259</a></p> <p>The inductive charging module’s receiver is mounted externally to the datalogger case using a plate with magnets embedded at 2 corners to ensure pairing and alignment with transmitter across a cushion cover.</p> |
| Processor                    | Cortex-M4 Processor   |
| Battery life                 | Approx. 2 days  |
| Indicators and on-off switch | <ul style="list-style-type: none"> <li>* on-off switch</li> <li>* power indicator</li> <li>* data collecting / transmitting indicator</li> </ul>  |
| Pressure Sensors             | <ul style="list-style-type: none"> <li>* Custom mat produced by Tekscan, FFC material, Six pressure sensors (comparable performance to Flexiforce A502 <a href="https://www.tekscan.com/products-solutions/force-sensors/a502">https://www.tekscan.com/products-solutions/force-sensors/a502</a>) positioned on a mat with cut-lines to allow for users with cushions ranging from 14.5” to 20”</li> </ul>  |
| Battery Charging             | <p>Primarily via inductive charger connected to data-logger’s microUSB port with a USB type-B connector.</p> <p>Alternatively using type-A or type-B USB connector plugged into a wall socket.</p> <p>The inductive charging receiver is mounted on the logger as specified above.</p> <p>The inductive charging transmitter attaches to the receiver through the cushion cover using magnets attached to the custom-made transmitter casing.</p> <p>With an estimated 2 day life, instructions will be for user to charge daily.</p>   |
| Communication                | Bluetooth 4.0 Low-Energy (Telit 53330-02)   |
| Data storage                 | <p>Collecting data for up to 4 months at 4 Hz sampling, storing all data for recovery at end of study.</p> <p>8 GB of flash memory</p>  |

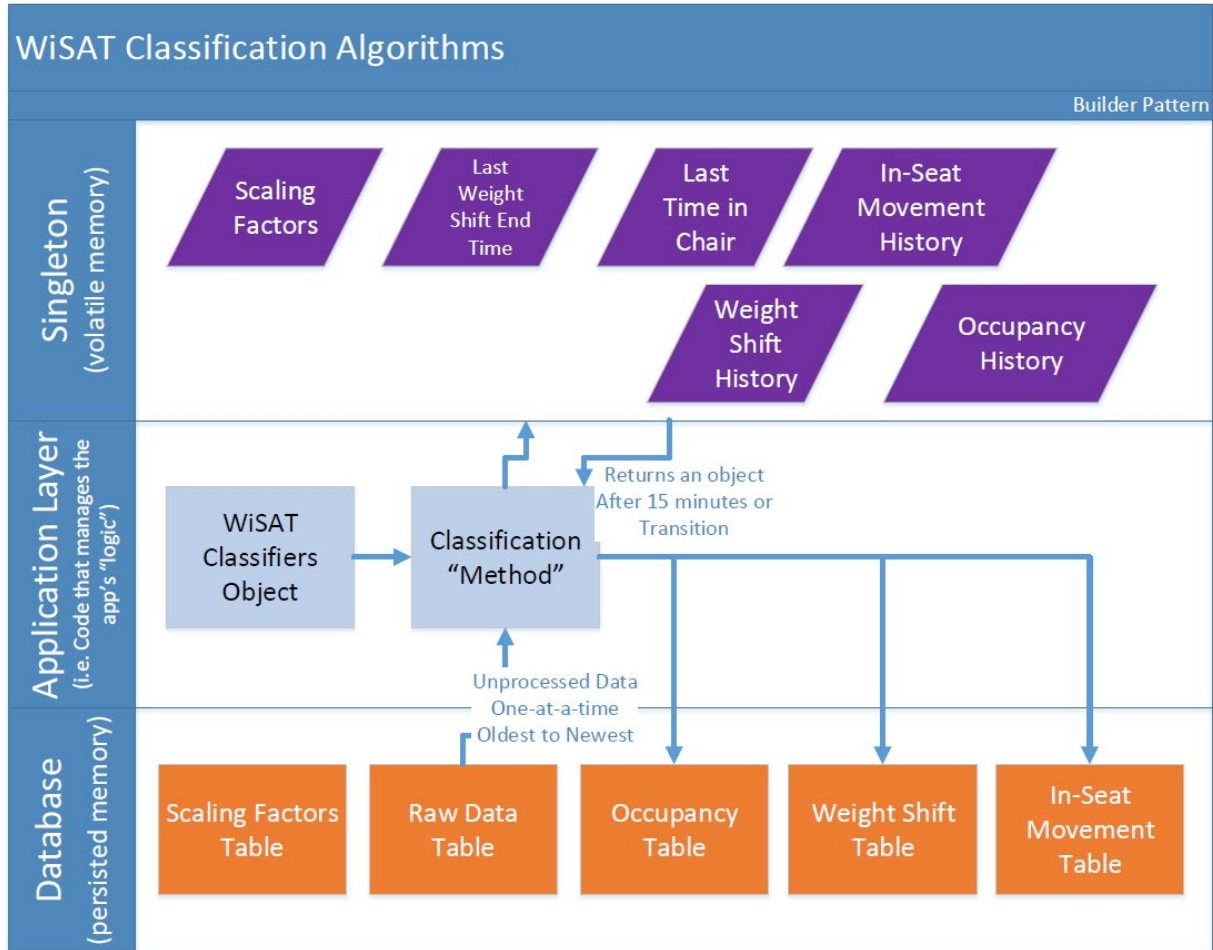
|                             |   |
|-----------------------------|---|
| Data Access/Transmission    | Current app receives data as flat JSON files.<br>Data can be accessed for post-processing by connecting the logger to a computer via USB.       |
| System Status communication | System status gets transmitted to the mobile app upon request. App receives info about current timestamps, data being logged, and battery life. |

APPENDIX 2

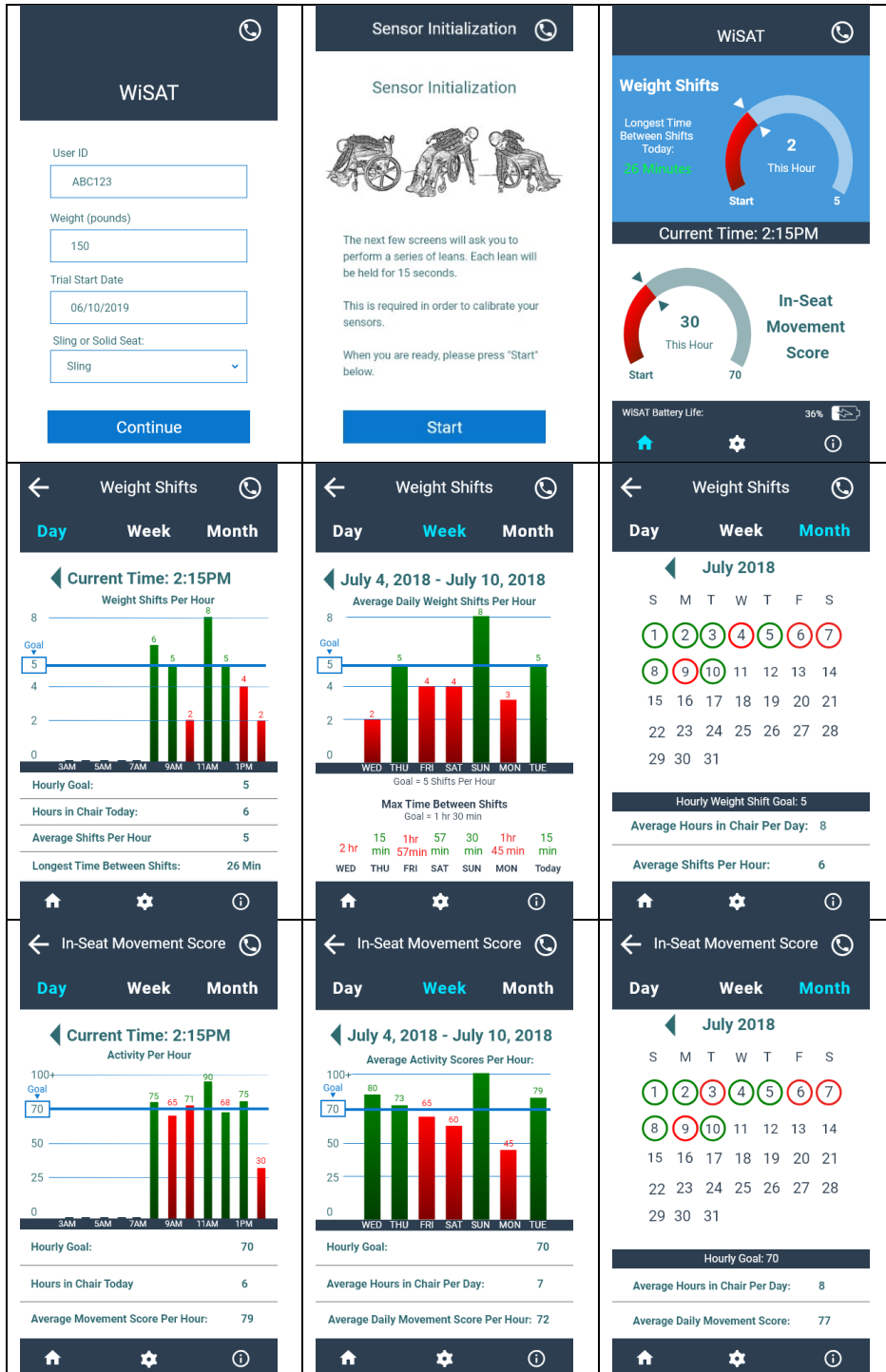
Mobile Phone App Flow Diagram



### Appendix 3. WiSAT Classification Algorithm



**APPENDIX 4:** Several examples of the UI screen from mobile phone app, including initial set-up screens, Home Screen and data screens for Day, Week and Month



Appendix 5. WiSAT Seat sensor

