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

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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

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Table of Contents

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?**

	Timeline
Task 1. Develop WiSAT hardware and mobile app	1-12
Task 2: Develop classification algorithms	1-6
Task 3 Engage wheelchair users in usability studies	13-20
Task 4: Pre-Clinical Trial to assess acceptability, usability and impact of WiSAT	19-36

- **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:

Over the past year, hardware design has gone through many iterations. At this time, the hardware design is fixed and multiple modules have been fabricated for deployment in the pre-clinical trial. The firmware, however, might still require modification prior to deployment. A specification table is maintained to report the hardware and firmware. The current table is contained in Appendix 1. A brief reporting of key design iterations is listed here.

<u>Battery</u>. We defined and tested the battery and inductive charging components that will be used in the WiSAT. Two 500 mAh batteries (Powerstream's GMB652535-PCB) have been sourced and tested that can fit within the enclosure and provide the required power to support 2 days of operation without charging.

<u>Inductive charging system</u>. A commercially available inductive charging system was selected that require minimal modification for integration. The receiver is mounted externally to the WiSAT module and connected via the micro-USB port. The module is mounted to a plate with imbedded steel disks for attachment to the transmitter. The transmitter is packaged in a custom-designed housing with embedded magnets. This packaging design allows the transmitter to magnetically attach to the receiver/module when the module in located in the cushion cover, the wheelchair frame or the outside of the cushion. This receiver-transmitter combo has been tested against different cushion covers and has been verified as a viable option.

<u>Firmware</u>. Extensive testing evaluation and re-design of the firmware was required over the past year. A few of the issues identified and addressed included

- File System Capacity
- Logger Response Time
- Missing Files
- Timer Reset
- Sample Rate Error
- Bluetooth communication errors
- Module circuitry for seat sensor

Further updates will address outstanding issues in Bluetooth communication and file corruption. This update cycle is anticipated to be final for this iteration of the system.

<u>Logger Circuitry.</u> The WiSAT module contains an inverting amplifier circuit to measure the seat sensor voltages and amplify them for the analog-to-digital converter. The internal circuit was re-engineered to provide an optima response over the loading conditions expected. This was an iterative process that reflected different wheelchair cushions; wheelchair seat surfaces (i.e., sling versus solid) with respect to the new manufactured seat sensor. The outcome was a revised circuit that was sent to GCDC for incorporation into the final module hardware.

WiSAT module. Based upon the described activities, the design of the WiSAT module (or data logger) hardware has been fixed and underwent production of 30 units. This hardware module might still require upgrades in firmware but the hardware is ready for deployment

Seat sensor. The production seat sensors from Tekscan were recieved. This triggered a quick quality evaluation which found the sensors met all specifications. They have a much higher inter-sensor consistency than the handmade seat sensors. This is important as it will result in better machine learning algorithms and simplifies initialization. A small percentage of seat sensors have been identified as sensitive to static discharge, resulting in a mechanical flaw in the material. QA testing is being used to eliminate these sensors from use. Seat sensors have been fabricated for use (including adding connectors and foam pucks) and have been individually calibrated.

Mobile Phone app

Extensive effort was spent in designing the mobile phone app and Apeiro Technologies was selected as the subcontractor to develop the Android and IOS versions. Over the past 12 months, weekly meetings are held with Apeiro to review progress, discuss testing results, and answer questions regarding the upcoming week's development tasks review project status and identify issues. In accordance with the principles of the Agile methodology and Iterative and Incremental development model, Apeiro delivers "pre-release" builds of the mobile app to Georgia Tech for verification after implementing significant changes. This allows flaws and revisions to be identified early in the development lifecycle.

The application development is complex and requires multiple points of integration and interaction. The data flow diagram for the mobile phone app is listed in Appendix 2. The software must interface with the hardware module and the API endpoint to which data is transmitted. It also must work in concert with the classification algorithms that use raw data to classify weight shifts and in-seat movements. It also must interface with the user.

With respect to the latter, a small usability study was deployed to evaluate and refine the screens used with the mobile app. The methods followed a traditional usability study design and resulted in several changes to the UI. Appendix 3 depicts several of the final screen designs that are incorporated into the application.

Mobile app development is delayed. Completion was proposed for April 2019, but, at this writing, development is still underway. Many factors contributed to this delay including, hardware and firmware issues with the WiSAT module, including Bluetooth communication, challenges in understanding Android and iOS management of push notifications, inconsistency in algorithm integration and database operation.

The short term goal is to have functional builds of both Android and iOS apps for the pre-clinical trial. Further refinement and updates are anticipated subject to user feedback from the trial.

Task 2: Develop classification algorithms

The goal of developing the classification algorithm includes multiple steps and smaller goals. These goals, as defined in the proposal, were:

1. Refine algorithm to classify weight shift and pressure relief behaviors in real-time.
2. Develop initialization procedures.
3. Determine algorithm accuracy.

Refine Algorithm

A large data set was collected across users (including data from 18 wheelchair users and 24 able-bodied participants), a variety of wheelchair cushions and wheelchair surfaces on our prototype and post-fabrication mat designs to train and validate an occupancy and weight shift classifier.

Occupancy: Only one of the two occupancy classifiers determined previously were implemented, as it was determined that all data would be sent from the data logger to the mobile app, rather than processing occupancy on board of the data logger. This additional process adds complexity to the system in exchange for limited power savings. Furthermore, when the data logger is charging (which will often occur when the wheelchair is unoccupied for extended periods of time), data transmission will be halted anyway, mitigating the need for this additional process. It is likely that this will change on a future logger version.

Weight Shift: With a much larger data set available, including 24 training sets lasting 15 minutes and 15 validation sets lasting 90 minutes, we have trained our weight shift classifier on all of the new data. At first, this presented problems as early subjects did not complete sufficient numbers of successful weight shifts to provide adequate training data. As a result, we added additional weight shifts to the protocol and increased the duration of weight shifts as well, allowing us to improve upon our pool of training data. We have selected the features that will be included in the classifier (change in center of pressure and normalized total load). We made changes to the scaling of total load to increase its role in the classifier. Previously, changes in total load were very small (except during full push up pressure reliefs), and therefore the changes were seen as insignificant.

In-Seat Movement Score: In our previous work studying weight shifts using a research tool, in-seat movement was studied by post-processing the data with an elaborate individualized truth data set available. For the consumer product, we needed to replace this with the simplified initialization. This included: 1) using the training data sets collected in the lab to define an estimate of mat sensitivity with respect to the center of pressure displacements, and 2) individualizing a threshold for the amount of center of pressure movement needed to constitute in-seat activity based on the initialization. The algorithm was tuned on the 15 minute training sets and 75% of data sets were able to reach an error rate less than 25%. Those exceeding 25% often had errors that were less concerning (such as increased activity in a time period that was otherwise active, rather than spontaneous activity detected when there was none).

Tilt-In-Space: One additional application of the weight shift algorithm is in wheelchair users who use tilt-in-space wheelchairs. Their mechanisms of weight shift look different than those performed by manual wheelchair users, as they are often achieved by tilting the wheelchair backwards, resulting in a posterior shift in the center of pressure. The algorithms developed for the WiSAT were not trained on this cohort, but as the WiSAT may eventually be deployed to users of tilt-in-space, preliminary data on tilt-in-space has been collected. It takes a significant tilt to produce a weight shift, as our previous research has indicated. For these tilts, there is significant reduction in normalized total load (or load on the seat compared with upright total load). Since this is one of the features being provided to weight shift classifier, a significant reduction in this feature leads to these points being correctly classified as weight shifts, even though the posterior shift in center of pressure is something unfamiliar to the classifier.

In cases where the tilt produces a successful weight shift without a corresponding reduction of total load on the WiSAT sensor, we were able to use the absolute value of the center of pressure to simulate a front lean in the classifier. This was seen to improve performance of the classifier for back tilts. Further investigation into this approach is needed to ensure there are not any unintended consequences of using these absolute values. Furthermore, a larger tilt-in-space data set is needed, including data from wheelchair users, to confirm the success of the classifier in this population.

Transition to Real-Time: One aspect of the transition to near real-time has to do the redefining the algorithm implementation and architecture, from something that has access to all of the time series data at once, to something receiving the data in small batches. That implementation, and the interaction between the algorithm and mobile application has been far more complicated than anticipated and, as mentioned elsewhere, has led to delays.

Initialization Procedures

The different classifiers described previously require scaling factors. What this means is that during the initialization phase, participants will be asked to complete a few movements: sitting upright and 3 different leans. The entire process is short (less than two minutes), and that data is used to inform the classifier about the total loads to expect when the chair is occupied and the extent of movement during a lean. To that end, we have begun to focus on optimizing how we collect initialization data (in terms of user instructions). The procedure and mathematical processing of that information has been implemented in the mobile app, although more usability testing of the instructions would be beneficial.

The role of the initialization data was also defined and evaluated thoroughly. Ideally, users will perform large leans during initialization and this will be used to scale the lean data. However, some users will be unable to complete large leans, and in some directions they may not be able to lean at all, and adjustments are needed when only small leans or no leans are performed. Testing determined that if the user performs a smaller weight shift, but still moves their center of pressure by a certain amount, the scaling factors automatically produced work well for the algorithm. When the center of pressure shift (as measured by the WiSAT) is lower than a certain threshold, it is preferable to discard the user's training data and substitute an average training value instead.

Algorithm Accuracy

Validation of the algorithm is done both on 15 minute training sets and on 90-minute data sets collected with concurrent truth data.

Weight Shifts: When evaluated on a randomly sampled set of 15-minute training data on which the classifier was not trained, the classifier performs with 92% sensitivity and 42% specificity. While this raises a concern that it is over-sensitive, it is important to note that we are only considering segments where an individual attempted to do a lean and was unsuccessful in our specificity calculation. Analysis on 90-minutes of scripted an un-scripted behavior produced 72% sensitivity and 77% specificity.

In-Seat Activity Score: On 90-minute data sets the majority of subjects had activity scores within 25% of the activity score calculated on their truth data. There were two cases that did not meet the desired 25% threshold, and in both cases, no algorithm changes would have solved the problem, as the issue had to do with damping of the signal. That is to say, the transient movements were dampened and not measured at all on the WiSAT. Therefore, we opted to proceed with our algorithm and focus on improvements in future iterations of sensor design.

- **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 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 in Years 1 & 2 are 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 who has been engaging 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**
    - Nothing to report
  - **Actual or anticipated problems or delays and actions or plans to resolve them**
    - The pre-clinical trial is delayed due to delays in both hardware and software development. These development delays are coupled since the subsystems must operate together. The issues were detailed above. This is a very complicate project with multiple subsystems working together. We continue to address problems on a daily basis and

have added different types of support with skills to help address the problem. We speak to the software developer every week and the hardware/firmware developer frequently as well. We have taken more of a lead role in addressing software problems. I think we realized that the developers were not as skilled in deploying the algorithm as we believed. We also have defined a means to jointly test code in all locations using the same approach and same dataset; This allows us to troubleshoot more efficienctly.

- **Changes that had a significant impact on expenditures**
  - The primary impact on expenditures concerns the clinical sites. They are delayed in commencing the trial yet must be staffed to commence the clinical trial. We continue to work with Pitt regularly to perform testing of the entire system. Because Himes VA is still obtaining IRB approval, they are not experiencing as large an impact on the delay. The delay did not result in additional expenditures with our contractors. Earlier, we had made modifications in response to adding scope of effort, but did not add to their contracts as a result of delays.
  - **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.**

  Presentations:
  Design of Medial Device Conference, Minneapolis, April 2019
  HFES 2019 Healthcare Symposium

  - **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
    Issue Notification from the Patent Office, indicating that a patent will issue for the invention on 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)	0000-0003-0462-0138
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)	0000-0003-0462-0138
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	*Yogesh Desphpande*
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	*Kathleen Jordan*
Project role	Program Support Coord
Research ID (ORCID)	
Annual Person-month effort	**3.0**
Contribution to project	**sensor characterization and validation; human subject data collection and analysis**

Name	*JJ O'Brien*
Project role	**Graduate student; project management**
Research ID (ORCID)	
Annual Person-month effort	**4**
Contribution to project	**Project management; WiSAT module design; WiSAT module to mobile phone communication; mobile phone app development; human subject data collection**

- **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, YR2 effort from the University of Pittsburgh focused on obtaining local IRB and HRPO Approvals, which was done. They also assisted the Hines VA on these activities. Technical activities included establishing the API Endpoint for data acquisition. Finally, Pitt tested beta versions of the entire WiSAT system in advance of deploying the pre-clinical trial
    - **Financial support** : YR2 funding of $$68181
    - **In-kind support**: none, in YR2
    - **Facilities:** no specialized facilities required for effort in YR2
    - **Collaboration:** Partner staff participated in conference calls and email exchanges as a part of developing the protocol and WiSAT training and evaluation.
    - **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. Development and submission of local IRB application.
    - **Financial support :** 46887.17
    - **In-kind support**: none
    - **Facilities** *none in YR2*
    - **Collaboration** Partner staff participated in conference calls and email exchanges as a part of developing the protocol and IRB and WiSAT design
    - **Personnel exchanges** *none*
    - **Other.**

- **APPENDICES:**

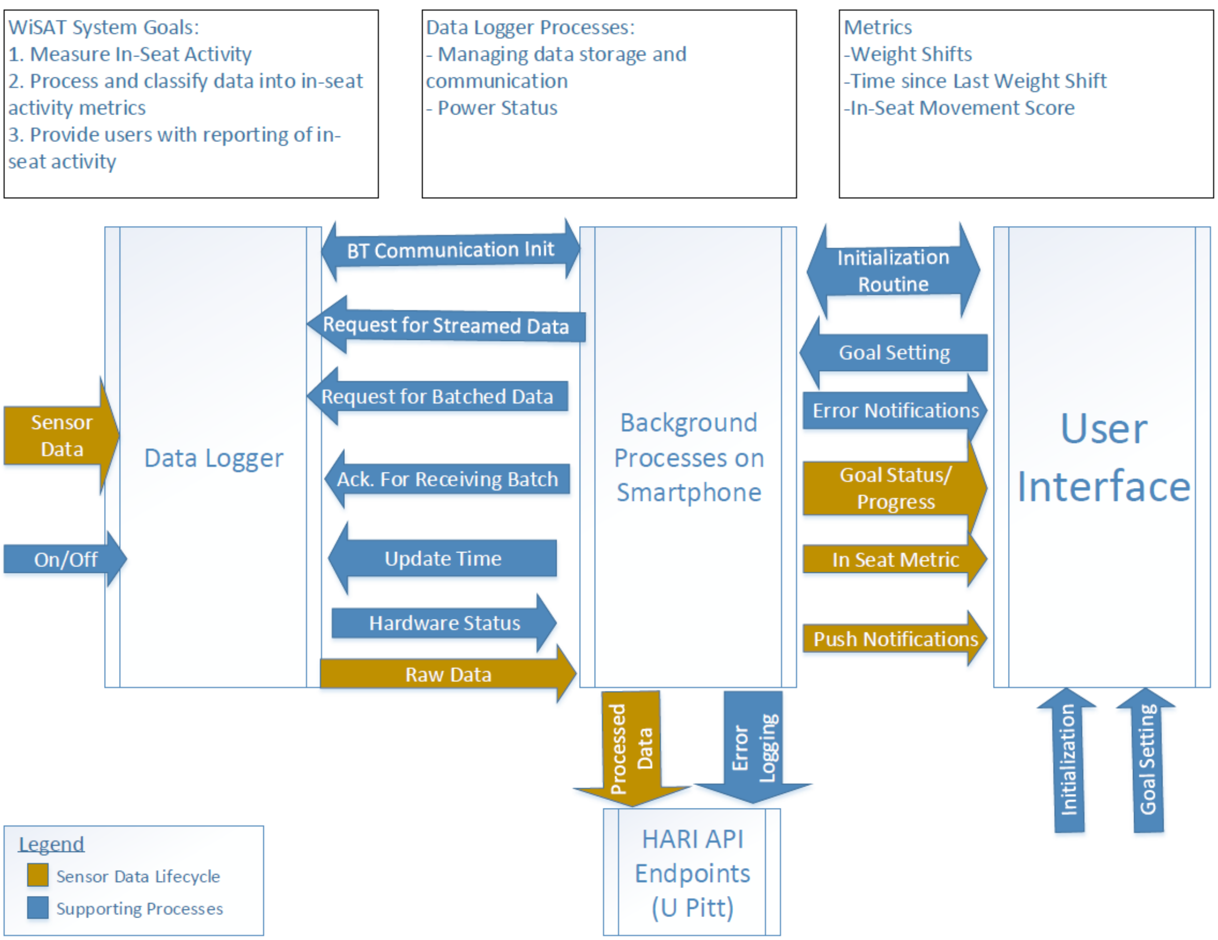
Appendix 1. Specification Table

	Requirements
Form factor	* No bigger than 2x3x ½
Case and connectors	Connector to inductive charging receiver: microUSB Connector to seat mat: 8-pin output Clincher 67516-208LF “Pig-tail” extension will be made of https://www.digikey.com/product-detail/en/parlex-usa-llc/PSR1635-08/AF08-100-ND/127259 The inductive charging module’s receiver is mounted externally to the datalogger case using a plate with steel disks embedded
Processor	Cortex-M4 Processor
Battery life	* Minimum:2 days with expected Bluetooth transmission / full power mode of 12 hours per day, assuming sleep mode when chair is not occupied.
Indicators and on-off switch	* on-off switch * power indicator * data collecting / transmitting indicator
Pressure Sensors	* Custom mat produced by Tekscan, FFC material, Six pressure sensors (comparable performance to Flexiforce A502 https://www.tekscan.com/products-solutions/force-sensors/a502) positioned on a mat with cut-lines to allow for users with cushions ranging from 14.5” to 20”
Battery Charging	Primarily via inductive charger connected to data-logger’s microUSB port with a USB type-B connector. Alternatively using type-A or type-B USB connector plugged into a wall socket. The inductive charging receiver is mounted on the logger as specified above. The inductive charging transmitter attaches to the receiver through the cushion cover using magnets attached to the custom-made transmitter casing.
Communication	Bluetooth 4.0 Low-Energy (Telit 53330-02)
Data storage	Collecting data for up to 4 months at 4 Hz sampling, storing all data for recovery at end of study. 8 GB of flash memory (also to accommodate situation when phone and user are separated)
RAM	
Data Access/Transmission	Current app receives data as flat JSON files. Data can be accessed by connecting the logger to a computer via USB.

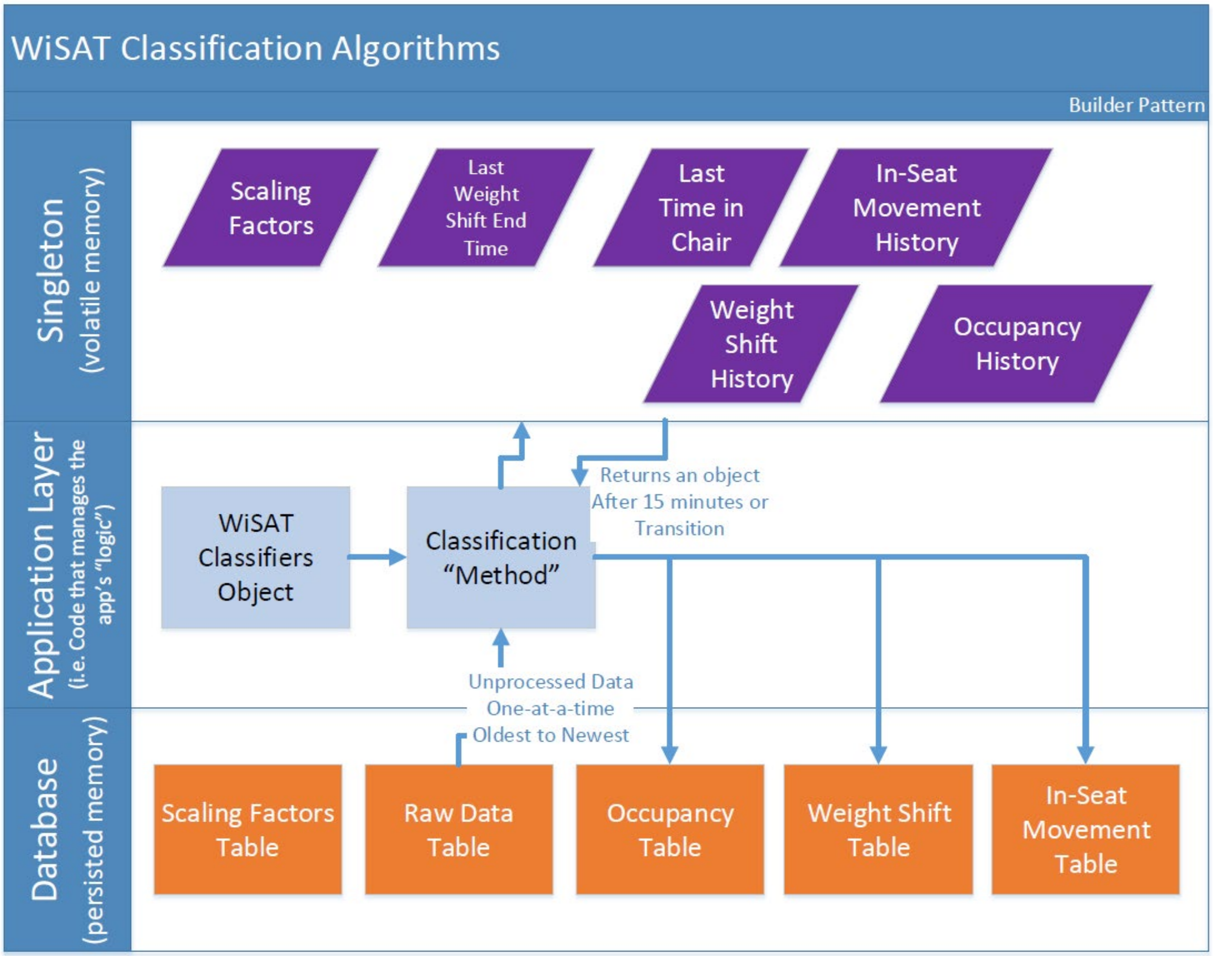
User management	With a 2 day life, instructions will be for user to charge daily. Charging options are described in "Battery Charging" [Inductive charging with micro USB charging as back-up] Mobile app displays a battery level of device based on information received from the module. It also notifies user about low battery status through push notification.
System Status	System status will be transmitted to the mobile app upon request

APPENDIX 2

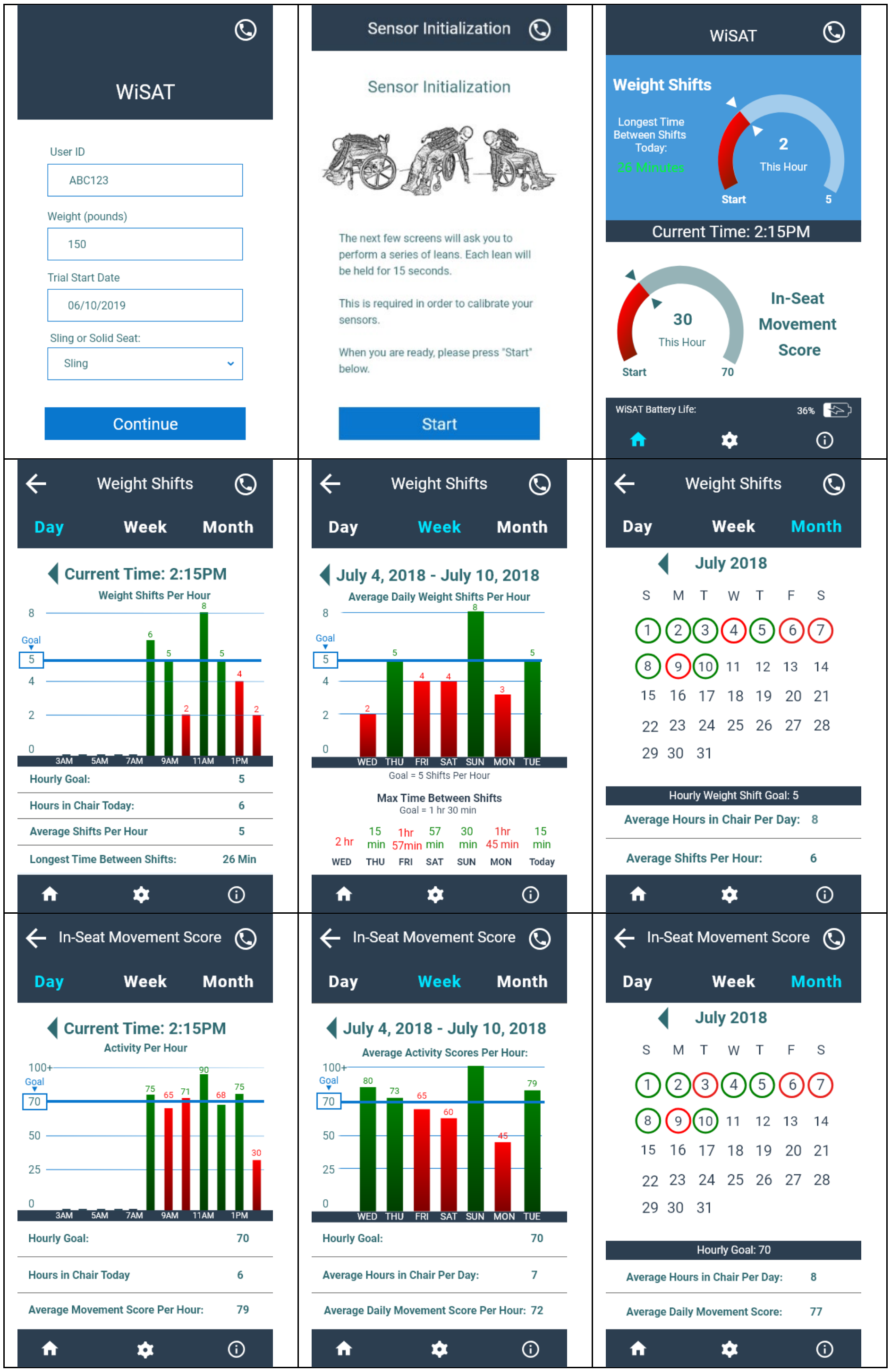
Mobile Phone App Flow Diagram



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