Spring 2021

Improving the Monitoring of Post-Operative Patient Mobility

Owen T. Lacey
University of Akron, otl1@uakron.edu

Alexandria Magyar-Averin
University of Akron, alm231@uakron.edu

Elena Ewing
University of Akron, ece14@uakron.edu

Samuel Elliott
University of Akron, soe1@uakron.edu

Cameron Lazor
University of Akron, cel52@uakron.edu

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Samuel Elliot
Biomedical Engineering Department
The University of Akron
Akron, USA
soe1@uakron.edu

Elena Ewing
Biomedical Engineering Department
The University of Akron
Akron, USA
ece14@uakron.edu

Owen Lacey
Biomedical Engineering Department
The University of Akron
Akron, USA
otl1@uakron.edu

Cameron Lazor
Biomedical Engineering Department
The University of Akron
Akron, USA
cel52@uakron.edu

Alexandria Magyar Averin
Biomedical Engineering Department
The University of Akron
Akron, USA
alm231@uakron.edu

I. Introduction

Post-operative care is vital in a patient's surgical recovery. Semple et. al claimed that "The first 30 days following surgery have been identified as a major focus area in health care" [1]. Monitoring patients' mobility during this time is vital in ensuring their health and wellbeing following surgery. Physical activity is not just important for physical healing through ensuring blood circulation, but for mental healing as well. In an interview with Liz Dewitte, an organ transplant procurement coordinator, and Andrea Zantopulos, a medical laboratory scientist, post-operative delirium was discussed as a reason for mental healing [2]. Dewitte and Zantopulos explained that delirium is a "sudden confusion", it changes a patient's mental function. It can cause patients to become sleepy and inactive, restricting proper blood circulation from a lack of activity [2]. Several conducted interviews established that physical activity is essential in ensuring a successful post-operative recovery process.

Currently, a patient's mobility score is hand-derived by physical therapists or nurses. Due to time limitations, these medical professionals cannot account every mobile activity so the score only reflects a fraction of the patient's mobile time. When a score is determined, it becomes stationary until more time is available to derive another mobility assessment score. Thus, a system is needed that can continuously monitor a patient and provide a mobility assessment score in line with established and validated methods. This allows medical professionals to simply interpret the output mobility score and prescribe the necessary amount of movement. In total, these efforts will ensure all patients are receiving optimal care during their post-operative recovery.

Research of current marketed solutions revealed two distinct product types: physical devices and analytical systems. The most promising products encompass both approaches. Patented ideas partially addressing this clinical are available, one of which is a "patient support apparatus with patient information sensors" [3]. Here, integrated force gauges monitor a patient's weight while positioned in a surgical bed, but it fails to provide monitoring of movement outside of the surgical bed environment [3]. Another patent addresses post-operative patient mobility through a "pressure-based weight monitoring system, which determines improper walking or running" [4]. This patent provided guidance in its use determining the post-operative activities patients undergo. Many system-based patents found defined systems with numerous sensor hubs used to monitor patient location, but these systems could not monitor their specific activities [5]. Outside of patented technology, there are numerous commercial devices that can be utilized in monitoring post-operative mobility. Some can collect and display numerous data for interpretation, which can cause confusion due to lack of training and understanding. For example, the ActiGraph brand of wearable activity and sleep monitoring devices can output data via Microsoft Excel, but the data can be subjective to the physician or nurse reviewing it [6].

II. User Needs

The first design stage served in establishing the project's clinical need and its user needs, or stakeholder requirements. To keep track of the project timeline and goals a Gantt Chart was utilized, as seen in Figure 1. Research into current marketed solutions and patents occurred to establish a knowledge base of relevant technologies. The stakeholder requirements were derived through interviews with ten medical professionals having differing experiences with post-operative care. Questions were developed to gather information on their experience with post-operative complications specific to movement. They provided consistent confirmation that movement monitoring and accountability is crucial for the success of patient recovery. During recovery, information on the patient regarding their movement can be difficult to track due to shift changes within the nursing staff, variance in movement requirements, and a lack of a quantifiable system to ease discrepancies between patients and healthcare professionals. Since communication and continuous patient monitoring is challenging, it is desired by the stakeholders that

heart rate be among the recorded data. This information aids the stakeholders in determining if patients are actively completing their movement requirements.

A post-operative patient's recovery process is crucial to their physical and mental wellbeing. One of the biggest factors in creating a successful recovery plan is clear communication. The inconsistencies in the interpretation of movement requirements between different parties makes communication difficult. This led to a stakeholder requirement for a simple device to provide accurate and quantitative data for a reliable adjustment of recovery plans. This simplicity creates demonstratable patient accountability for recovery plans. Through this research, the project scope became clearer. This project is dedicated to engineering a medical device that monitors and quantifies the mobility of post-operative patients that is easily understood by medical professionals and patients alike.

III. Design Inputs

The clinical need and stakeholder requirements served as inputs into the design inputs stage. Here the engineering requirements were derived using quality functional deployment, or QFD. These engineering requirements guided the development of the device and an initial route for solutions. The most important customer requirement to convert was the quantification of patient movement. This led to the following engineering requirements: sensor input information, data availability, heart rate and accelerometer divisions, and numerical scale output. These engineering requirements serve in gathering patient information from physical sensors to determine a representative value of their post-operative movement.

Three other engineering requirements derived from the customer requirements included physical sensor inputs, code runtime, and device runtime. The physical sensor inputs requirement allowed for proactive thought surrounding a solution with a small footprint and ideal location for patient use and comfort. The code and device runtime requirements provided guidelines for ensuring the solution would function and respond to inputs sufficiently for diagnostic analysis and patient treatment. Figure 2 has more information regarding the coordination of the customer and engineering requirements.

IV. Design Process

Once the design inputs were determined, the initial design process began. Potential solutions were brainstormed using a variation of Method 635. Brainstorming was broken down into three categories: functional device concepts including data processing and gathering, form factor, and device output. From here, decision matrices were utilized to weigh the discussed options. Down select analyses and results concerning these options can be viewed in Figures 3 and 4. After team discussions, research and preliminary failure modes and effects analysis (FMEA) risk assessment for each technology, the pulse oximeter, accelerometer, external application, Bluetooth communication, and wrist-based location were selected for use in the developing solution. In establishing which components were utilized, the accelerometer data to gather and utilize for mobility assessment scoring was also determined. It was determined that gathering accelerometer data to convert to a static value of steps would be the most appropriate for our developed solution. From here, novel code could be developed to indicate when steps are completed by a patient. A numerical scale output was selected for use with this data. The Boston University Activity Measure for Post-Acute Care (AM-PAC) was selected for use after deliberation with Dr. Vazquez at the Cleveland Clinic (D. Vazquez, personal communication, October 21, 2020). Specifically, the Basic Mobility Domain was selected as it was most applicable to patient movement in terms of steps. Ensuring a validated process for scoring is selected allows for a more seamless integration of our developed solution into a hospital environment.

V. Design Outputs

In the design output stage, component selection ensued. A PulseSensor and Arduino Nano 33 BLE Sense were selected to satisfy the pulse sensor, accelerometer, and Bluetooth communication requirements defined in the design process stage. The accelerometer used in the Arduino Nano 33 was part of an onboard LSM9DS1 9-Axis Inertial Measurement Unit, a device using a combination of accelerometers, gyroscopes, and magnetometers to determine position changes from a wide variety of perspectives. For this project, only the 3-axis accelerometer package of the IMU was utilized, as acceleration data was the most pertinent to the project needs. Initially Evothings Studio was selected as the external application platform, but after further deliberation and experimentation, MATLAB App Designer was chosen. This application would display input step and heart rate data as well as an output AM-PAC mobility score, the software flow chart for which can be found in Figure 5. In coming to these decisions, decision matrices were utilized, which can be found in Figures 6 and 7. Notably, these matrices pointed out the benefits of the Arduino Nano 33 BLE Sense. When compared to other available Arduino Nanos, this one had the advantage of an onboard accelerometer and bluetooth module. Since the team had some unfamiliarity with the Arduino Nano's accelerometer, an Adafruit accelerometer was chosen as an alternative/backup to ensure accelerometer data could be reliably gathered. These decision matrices pointed out the advantages and disadvantages of using MATLAB App Designer over Evothings Studios. Finally, a power source, in the form of a lithium-ion battery was selected for implementation in the solution. This battery was specified as capable of supplying 3.7V for 2000mAh.

An external casing was then designed to house the chosen electronic components. Another decision matrix was used to determine various component placement within the device, seen in Figure 8. Ultimately, the lithium-ion battery was placed on the bottom of the case, with vertically layered components above it to provide stability and a passive casing not interfering with patient activities. The PulseSensor would be placed outside of the casing with an external plug-in port. This allowed for easy accessibility to accurate information from the fingertip. In providing structure to the case, three plastic boards were designed to support the electronic components. These boards were spaced vertically with brass spacers, and when fully assembled, acted as one part. These designs can be

found in Figures 9 through 13. The two case pieces fit together vertically and are fastened together with 4 countersunk. Figure 14 outlines the complete device casing assembly, and it includes the bill of materials of all included components in its construction.

Finally, a conversion of the AM-PAC Basic Mobility Domain for use with step and heart rate data could be completed and coded into MATLAB. First, from the Basic Mobility Domain, various patient activities were selected. The score associated with each activity was taken from the chart in Figure 15. Using the bathroom, moving between the bed and chair, walking within the room/hallway, walking around the hospital floor, power walking, and light-weight exercise were selected as the events to monitor. Each of these activities were allocated a score in accordance with the AM-PAC; this score is derived from the threshold between whether a patient can complete an activity with some difficulty or cannot complete it at all. After team discussion and simulation, each of these activities were assigned a threshold step and heart rate value. The input data from the device could then be utilized to see whether a patient completed an activity. Here, the periodic increase and stabilization of collected steps can be filtered to determine when a movement activity has occurred and which AM-PAC activity was completed.

To determine when a step has been taken, the current data from each axis of the accelerometer is measured, and the magnitude of the entire vector is then determined by squaring each value, summing them, and taking the square root of the resulting sum. This value is then compared to a threshold value, and if the value is greater than the threshold, then a step is considered to have been taken. This threshold value was experimentally determined to increase the code's accuracy. Figure 16 gives a sample of collected x-axis, y-axis, and z-axis accelerometer data (in g) displayed per sample taken. Here, two simulated steps are taken; the x-axis represents the superior/inferior motion of the wrist, the y-axis represents the medial/lateral motion of the wrist that is relatively minimized during normal walking gait, and the z-axis represents the anterior/posterior motion of the wrist. During walking gait, the periodic swinging of the arms results in sudden decrease, increase, and stabilization of the x-axis and z-axis acceleration values. With it being periodic, this data can thus be utilized in determining when a step occurs according to recorded accelerometer values.

VI. Design Verification

Once the design had been developed and finalized, an analysis of the design to verify its satisfaction of all engineering requirements ensued. Though a full beta prototype was unavailable at this stage in the design process, an alpha prototype with partial functionality provides a benchmark. Here, two Arduino Unos were utilized: one with a PulseSensor and one with an Adafruit accelerometer. Both electronic components had supplemental code libraries ready for use from the manufacturer. Data were readily available for collection and could be tested against other industry standard devices. On top of code collection and accuracy, ensuring the alpha prototype has mechanisms to store and export data, rapid code runtime, and sufficient device runtime are essential. The verification summary table, found in Figure 17 outlines the verification tests, target values, and the results.

The results largely verified the developed design's ability to meet the engineering requirements. The accuracy of gathered heart rate data was identical to the Metene fingertip pulse oximeter, an industry standard, at ±1 beats per minute. The measured code runtime of the designed beta prototype fell well below the engineering requirement target of less than 3 minutes. Successful demonstrations occurred showing the code implemented for storing and exporting data. Calculations were performed to ensure the designed beta prototype's battery could provide continuous operation for at least 36 hours. These were done by summing the specified mA draw of each component and multiplying by the desired runtime of 36 hours. Then, this value was divided by 0.8 to account for battery degradation over time. After this was determined, a battery requirement of about 1150mAh was determined with the current battery selection exceeding this requirement. One area where the verification testing failed, however, was in the collection of accelerometer data in the form of steps. When a prescribed 50 steps were taken, an Apple Watch recorded 52 steps while the Adafruit accelerometer only recorded 22 steps. When analyzing the Adafruit accelerometer's supplemental code, a large amount of calibration time was found that prevented the gathering of accelerometer information over about half of the working time of the accelerometer.

VII. Medical Device

The completed beta prototype addressing the initial clinical need is shown in Figure 18. A video link of the working design can be found in Figure 19. Problems determined during verification testing were resolved during this stage in the implementation of novel code for determining when patients were taking steps. This differed from the code used in the original alpha prototype, given manufacturer provided code for the Adafruit accelerometer caused a surplus of calibration time that was eliminated during the switch to the Arduino Nano 33 BLE Sense. The completed beta prototype will demonstrate the ability to accurately record step information from accelerometer data and be used with heart rate data. These inputs are then exported via Bluetooth and allow for the calculation of an AM-PAC score. During this stage, however, the external application was cut from the scope of the project due to difficulties learning and sufficiently implementing this system into the prototype solution. Instead, the output data from the physical device was recorded via Bluetooth to a Microsoft Excel file for further analysis and historical record. Ultimately, the developed solution aids in describing the patient's mobility throughout the day for medical professionals.

VIII. Validation Testing

With a completed prototype solution, validation testing could begin to address how the solution meets the stakeholder requirements defined in the user needs stage. During testing, the completed beta prototype was utilized and assessed with four validation tests: physical device interference, device use, input data analysis, and output data analysis. The input data analysis addresses the accuracy of the collected steps and heart rate data. Here, the prototype will be attached to a simulated patient alongside a Metene pulse

oximeter. The simulated patient will then walk 120 steps during which step and heart rate data is collected. This was then repeated with only 60 steps being taken. This data will then be compared to the prescribed steps and Metene pulse oximeter. If the collected steps fall within ±5 steps and the heart rate fall within ±2BPM, each test will receive a pass. The interference and output data analysis tests follow a similar format; full validation testing protocols can be found in Figure 20. The device uses test functions as a demonstration of the device's capability to connect to the external application over bluetooth and successfully transfer data.

The results largely validated the developed design's ability to meet the stakeholder requirements and address the clinical need effectively. The physical beta prototype device did not significantly inhibit common patient activities including using a smartphone, opening a door, drinking fluids, etc. The device was able to connect to Bluetooth reliably and remain connected as the simulated patient performed mobility-based activities. The data collected was also consistently output to a Microsoft Excel file for AM-PAC scoring and historical record. Similarly to the verification testing, the accuracy of the collected step and heart rate data was analyzed. Here, the novel steps code provided an accurate solution to the previously failed verification test. The heart rate data continued to be exported within ±2BPM of the Metene pulse oximeter. Finally, the collected data was used to calculate an AM-PAC mobility score, and the scores came out accurate when compared to the expected averages due to multiple mobility activities occurring.

IX. Risk Mitigation Process

During each gate in the FDA's medical design process, risk assessments were performed using FMEA. This process identified outlying risks, their severity, and methods for mitigating these risks throughout the design process. Each risk was allocated a value from 1 to 10, based on group discussions and literature, for the risk's severity, occurrence, and detection. The risks with the highest risk priority number (RPN) comprised the most pressing potential hazards present in our device. The FMEA summary can be found in Figures 22 and 23. The risk with the highest RPN concerned the data processing application crashing, rendering output data inaccessible for mobility assessment. To mitigate this risk, MATLAB code was implemented to save input step, input heart rate, and output AM-PAC scores in an external spreadsheet for access outside the application environment. This mitigation also addressed another potential hazard regarding data overflowing and overwriting previously recorded step, heart rate, or AM-PAC score data. Another pressing potential hazard concerned the sufficient powering of all device components. Here, battery calculations were performed alongside previously discussed component specifications to ensure a properly sized battery was selected for use. Here, a 3.7V 2000mAh (milliamp-hour) battery was selected for use alongside a PowerBoost Charger capable of converting the 3.7V to 5.0V and charging the device and a 3.3V Buck Converter capable of converting the 5.0V to 3.3V to ensure compatibility with all device components and overall device safety. In performing research and calculations regarding each hazard, mitigations were created such that each of these risks could be diminished to an acceptable level for clinical use.

X. Marketing and Manufacturing Considerations

The market for this device is hospitals looking to help patients with post-operative care. The size of the market is quite large as there are 6,090 hospitals within the United States and "48 million surgical inpatient procedures" [9] [10]. This gives a scale of how many patients may need to be monitored post-surgery. At this point in time, an estimated manufacturing cost would be about $431.04, after doubling the material cost of $67.35 for labor cost, doubling that total for company overhead and adding sixty percent for margin. Project expenses and the wholesale prices can be found in Figure 24. This sell price is not competitive in terms of the physical device itself. A FitBit HR sells for around $150 [9]. This makes the physical device not very competitive with the current technology at this point from a price standpoint. On the other hand, our device is offering an app solution with the physical device. The current marketing of application solutions is turning toward subscription-based services. Since apps require constant updates to keep current, a subscription cost could bridge the profit gap by dropping the initial price.

XI. Summary Feasibility Discussion

This design is a proof of principle for the established clinical need. The developed solution proves that a physical activity monitoring system can be created to monitor the activity of the patient and return a validated patient movement score to the hospital staff. In this case, it was able to generate an estimated AM-PAC score based on its Basic Mobility Domain. The coding of the device could be improved to cover an increased number of AM-PAC guidelines, giving a more accurate patient score. Further testing of the established AM-PAC software would provide more information in determining more accurate scores. Overall, this proof of principle prototype shows that the development of this type of solution is possible.

XII. Discussion, Lessons Learned, and Conclusions

Throughout the development of our solution, our team encountered a few obstacles, notably during the design outputs and medical device stages of the FDA's design process. As we moved into the design outputs stage, the overarching scope of our selected project and solution came into view. To develop a proper solution, a good amount of outside learning pertaining to app development and electronics was required. This resulted in each team member becoming exclusively assigned to one task a piece as opposed to sub-teams. On top of each team member working largely independently, the ongoing COVID-19 pandemic hindered plans further. Most of our team members came down with COVID-19, halting their progress as they fought and recovered from the novel virus. Learning curves inhibited other team members from stepping in to assist. COVID-19 and the exposure of our team members to it drastically limited the ability for in-person work.

When time became a constraint for our team, we worked together to ensure all current stage requirements were met appropriately. Team members were compassionate and understanding with each other when illness, family emergency, or other situations arose. Had the true scope of the project been known prior to the final design process stages, our team would have worked to develop a smaller scope for our project. To this

point, focusing our efforts on developing an extremely accurate, easily implementable electronic device would have better focused our scope. If more time were allocated to clinical need research, a clinical need outside the realm of electronics could have been developed.

XIII. Future Work

In the development of the solution to the clinical need, an innovative solution has been created addressing this gap in the market. However, given more time, resources, and knowledge, a more refined and standardized solution can be developed. The current solution presents itself as modular with larger-sized components. With the electrical knowledge, the current design's size can be drastically reduced into a nimbler package. The background code implemented can be refined to function more efficiently with more failsafes counteracting improper use. One of the larger areas for future improvement lies in the code's detection of an increasing number of patient post-operative actions. Currently, the designed device gathers and compares data against select actions in the AM-PAC's Basic Mobility Domain as it pertains to step and heart rate data. The AM-PAC mobility scoring system incorporates actions past walking including sitting down, standing up, body shifting, walking up and down stairs, bending over, etc. With more movement possibilities, improvements can be made in sensor inputs, data collection, and AM-PAC score calculation to encompass a wider range of patient post-op activity.

XIV. Individual Roles and Responsibilities

Samuel Elliott acted as the design lead throughout the design process, and his efforts were essential in beta prototype development. He aided in deriving the design inputs and outputs from the engineering requirements, as well as spearheading the design process. He worked in selecting the most fitting electronic components for use in the developed solution. Sam completed a vast majority of the device's prototyping and troubleshot some communication and coding issues that arose.

Elena Ewing acted as the product manager throughout the design process. She oversaw customer and stakeholder communication and executed interviews to determine the clinical need. She performed further research into the clinical need to aid in determining the engineering requirements. Elena then shifted focus to education and implementation of an external application solution.

Owen Lacey acted as the team administrator throughout the development of the medical device. He worked as a meeting moderator and sparked productive conversation regarding action items throughout the design process. He developed engineering requirements via quality functional deployment (QFD), identified potential risks via failure modes effects analyses (FMEA), dissected AM-PAC documentation to derive a method for calculating a mobility score, and developed code to input, calculate, output, and save various data gathered from the patient. Finally, he worked in defining, developing, and executing the verification and validation protocols.

Cameron Lazor acted as the quality lead throughout the gate-design process. Cameron completed many stakeholder interviews and researched to aid in establishing the clinical need. He oversaw the documentation process alongside Alexandria, notably in the documentation of the verification and validation plans and reports. Further, he served as a consultant during all verification and validation activities.

Alexandria Magyar Averin acted as management of the project. She was responsible for discussion facilitation and moderated team dynamics issues throughout the design process. She focused on the development and the design of the external case and internal supporting structures in SolidWorks and provided a source for 3D printing these components. Furthermore, Alexandria organized the documentation throughout the team's Google Drive to meet DHF standards.

XV. Professional and Ethical Responsibilities

As biomedical engineers, we are expected to operate using the highest standards of integrity and honor. That ethical responsibility requires us to work while keeping public health, safety, and equity in the highest regard. Professional responsibilities require this team to conduct themselves ethically and lawfully to enhance the reputation of this device and the engineering profession. Throughout the design process of this device, this team operated abiding by these ethical responsibilities while maintaining a respectful and professional outlook.

Acknowledgment

Our success in developing the clinical need and solution is due in part to Dr. Daniel Vazquez at the Cleveland Clinic. While in the process of establishing the clinical needs to be addressed, he provided insight into some unmet clinical needs. Later, during the development of a solution to this clinical need, he provided insight and documentation pertaining to the validated AM-PAC mobility assessment system. This information was used to develop code mirroring the AM-PAC system as closely as possible.

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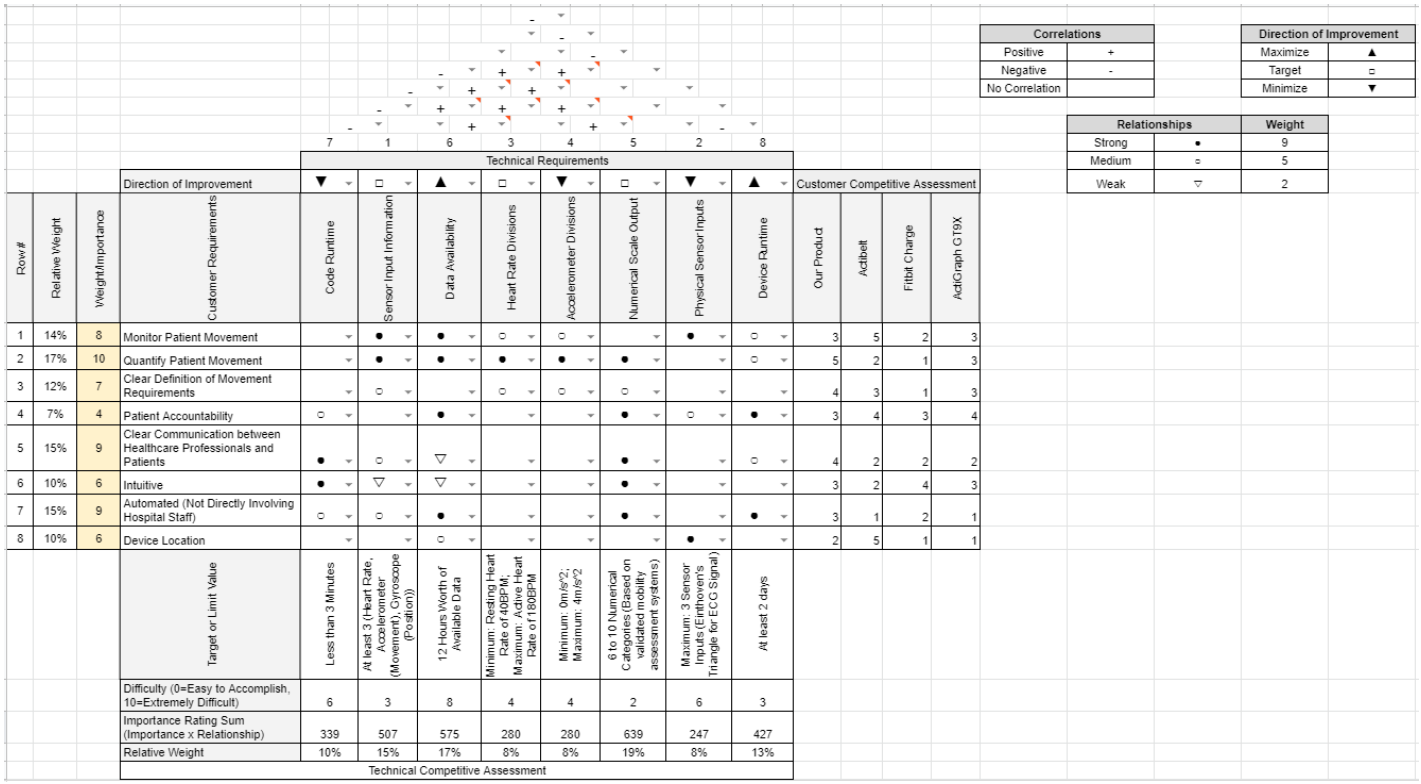
Appendix A: Definition of Project Goals and Timeline

TASK NAME	START DATE	DAY OF MONTH*	END DATE	DURATION* (WORK DAYS)	DAYS COMPLETE*	DAYS REMAINING*	TEAM MEMBER	PERCENT COMPLETE
Team Formation and Regulation								
Discuss and Complete Team Agreement 220.10	9/14	14	9/21	7	7	0	TEAM	100%
Creation of Gantt Chart	9/24	24	9/25	1	1	0	Owen	100%
Gate 1 - User Needs								
Determining Clinical Need to Address	9/16	16	9/22	6	6	0	TEAM	100%
Stakeholder Interviews	9/16	16	10/4	18	18	0	TEAM	100%
Research Need, Solutions, etc.	9/21	21	9/25	4	4	0	TEAM	100%
Gate 1 Presentation	9/21	21	9/29	8	8	0	TEAM	100%
Gate 2 - Design Inputs								
Quality Functional Deployment for Development of Engineering Requirements	10/7	37	10/16	9	9	0	Alex, Cam, Owen	100%
Risk Assessment for Development of Engineering Requirements	10/16	46	10/23	7	7	0	Cam, Ellie, Owen, Sam	100%
Gate 2 Presentation	10/26	56	11/2	7	7	0	TEAM	100%
Gate 3 - Design Process								
Concept Generation	11/6	67	11/16	10	10	0	TEAM	100%
Quality Function Deployment for Selection of Ideal Concept	11/18	79	11/25	7	7	0	Ellie, Sam	100%
Risk Assessment for Selection of Ideal Concept	11/16	77	11/24	8	8	0	Alex, Cam, Owen	100%
Gate 3 Presentation	11/23	84	11/30	7	7	0	TEAM	100%
Gate 4 - Design Outputs								
Device Specifications	1/11	133	1/29	384	384	0	Sam, Owen	100%
Device Drawings	1/11	133	1/19	8	8	0	TEAM	100%
Major Components and Vendors	1/19	141	2/8	20	20	0	Alex, Ellie, Owen, Sam	100%
Analytical Modeling and Calculations	1/11	133	1/29	18	18	0	TEAM	100%
Verification	1/27	149	2/12	16	16	0	Alex, Cam, Owen	100%
Risk Assessment	1/27	149	2/8	12	12	0	Owen	100%
Validation Plans and Procedures	1/27	149	2/12	16	16	0	Cam, Owen	100%
Gate 4 Presentation	2/14	167	2/15	1	1	0	TEAM	100%
Gate 5 - Medical Device								
Medical Device Fabrication, Assembly, and Validation	2/19	172	4/5	45	11.25	33.75	TEAM	25%
Risk Assessment Summary	2/19	172	3/19	28	28	0	Owen	100%
Gate 5 Presentation	4/16	228	4/26	10	2.5	7.5	TEAM	25%
Honors Research Proposal								
Cover Sheet to Honors College	9/25	25	10/1	6	6	0	Owen	100%
First Draft to Sponsor and Readers	10/7	37	10/28	21	21	0	TEAM	100%
Final Draft to Sponsor and Readers	11/24	85	11/28	4	4	0	TEAM	100%
Final Draft to Honors College	11/29	90	11/30	1	1	0	TEAM	100%
Final Report Draft to Sponsor and Readers	2/19	172	3/22	31	12.4	18.6	TEAM	40%
Final Report to Honors College	3/22	203	4/16	25	10	15	TEAM	40%

Figure 1: Gantt Chart



Correlations	
Positive	+
Negative	-
No Correlation	

Direction of Improvement	
Maximize	▲
Target	□
Minimize	▼

Relationships		Weight
Strong	●	9
Medium	○	5
Weak	▽	2

				7	1	6	3	4	5	2	8			
				Technical Requirements										
			Direction of Improvement	▼	□	▲	□	▼	□	▼	▲	Customer Competitive Assessment		
Row#	Relative Weight	Weight/Importance	Customer Requirements	Code Runtime	Sensor Input Information	Data Availability	Heart Rate Divisions	Accelerometer Divisions	Numerical Scale Output	Physical Sensor Inputs	Device Runtime	Our Product	Actibelt	Fitbit Charge	ActiGraph GT9X
1	14%	8	Monitor Patient Movement		●	●	○	○		●	○	3	5	2	3
2	17%	10	Quantify Patient Movement		●	●	●	●	●		○	5	2	1	3
3	12%	7	Clear Definition of Movement Requirements		○		○	○	○			4	3	1	3
4	7%	4	Patient Accountability	○		●			●	○	●	3	4	3	4
5	15%	9	Clear Communication between Healthcare Professionals and Patients	●	○	▽			●		○	4	2	2	2
6	10%	6	Intuitive	●	▽	▽			●			3	2	4	3
7	15%	9	Automated (Not Directly Involving Hospital Staff)	○	○	●			●		●	3	1	2	1
8	10%	6	Device Location			○				●		2	5	1	1
			Target or Limit Value	Less than 3 Minutes	At least 3 (Heart Rate, Accelerometer (Movement), Gyroscope (Position))	12 Hours Worth of Available Data	Minimum: Resting Heart Rate of 40BPM; Maximum: Active Heart Rate of 180BPM	Minimum: 0m/s^2; Maximum: 4m/s^2	6 to 10 Numerical Categories (Based on validated mobility assessment systems)	Maximum: 3 Sensor Inputs (Einthoven's Triangle for ECG Signal)	At least 2 days				
			Difficulty (0=Easy to Accomplish, 10=Extremely Difficult)	6	3	8	4	4	2	6	3				
			Importance Rating Sum (Importance x Relationship)	339	507	575	280	280	639	247	427				
			Relative Weight	10%	15%	17%	8%	8%	19%	8%	13%				
			Technical Competitive Assessment												

Figure 2: Stage 1 QFD Engineering Requirements

	Sensors/Base Device Quality "Wishes"	Low Number of Degrees of Freedom (as little "motion artifact" as possible)	Easy Setup for Physicians, Nurses, Patients, etc.	Non-Inhibiting of Daily Activities	Comfortable	Convenient for Manual Access	Patient Understanding of Working Principles (Ease of Communication)	Weight		
	Weight (1-5)	5	3	2	4	2	4	3		
Torso-mounted with electrodes for ECG collection (accelerometer, gyroscope)	Value	5	3	4	2	3	4	2		
	Product	25	9	8	8	6	16	6	Total	78
Ankle-mounted with integrated FSR to gather pressure information from walking	Value	5	3	4	2	1	2	4		
	Product	25	9	8	8	2	8	12	Total	72
Thigh-mounted activity monitor (accelerometer, gyroscope, pulse oximeter)	Value	3	3	2	1	1	5	3		
	Product	15	9	4	4	2	20	9	Total	63
Wrist-mounted activity monitor (accelerometer, gyroscope, pulse oximeter)	Value	2	5	4	5	5	5	4		
	Product	10	15	8	20	10	20	12	Total	95
Arm-mounted activity monitor (accelerometer, gyroscope, pulse oximeter)	Value	2	4	4	3	5	5	4		
	Product	10	12	8	12	10	20	12	Total	84
Waist / Belt-mounted with electrodes for ECG collection (accelerometer, gyroscope)	Value	5	3	4	4	4	4	2		
	Product	25	9	8	16	8	16	6	Total	88

Figure 3: Down Select Analysis for Device Location

	Data Analysis Quality "Wishes"	Accessibility to Outputs	Simple Outputs	Need to Store Data	Intuitiveness	Rapid Availability of Outputs		
	Weight	5	3	3	2	4		
App Analysis (Andriod or iOS)	Value	4	5	3	4	4		
	Product	20	15	9	8	16	Total	68
Device Display Output	Value	5	4	1	2	5		
	Product	25	12	3	4	20	Total	64
Computer Analysis using Developed Code (MATLAB)	Value	2	3	3	2	1		
	Product	10	9	9	4	4	Total	36

Figure 4: Down Select Analysis for Data Display

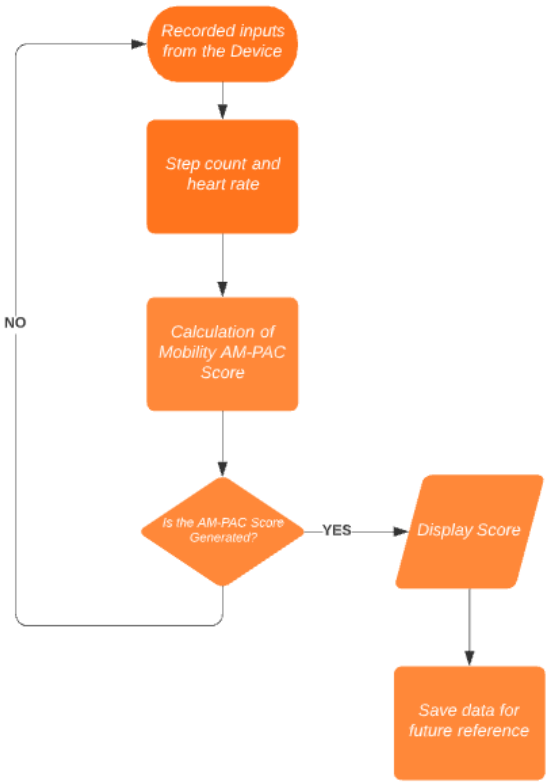


Figure 5: Software Flow Chart

Row #	Relative Weight	Weight/Importance	Device Characteristics	MATLAB App Designer	Evothings Studio
1	18%	7	Ease of Use / Development	○	●
2	21%	8	Functionality	●	▽
3	26%	10	Design Possibilities	●	▽
4	21%	8	Ease of Access for Stakeholders	▽	●
5	15%	6	Connectivity (Bluetooth)	○	○
			Importance Rating Sum (Importance x Relationship)	623	515
			Relative Weight	55%	45%

Figure 6: Software Decision Matrix

Row #	Relative Weight	Weight/Importance	Device Characteristics	Arduino Nano (Base) + Accelerometer + Bluetooth Module	Arduino Nano 33 BLE Sense + Accelerometer	Arduino Nano 33 BLE Sense
1	24%	8	Battery Life	▽	○	●
2	12%	4	Lightweight	▽	○	○
3	12%	4	Size	▽	○	○
4	21%	7	Comfortable for Patient Use	▽	○	●
5	30%	10	Accuracy of Data	▽	●	▽
			Importance Rating Sum (Importance x Relationship)	200	621	591
			Relative Weight	14%	44%	42%

Figure 7: Electronics Decision Matrix

				Device / Casing Form Factor (Organization of Physical Device Components)						
Row #	Relative Weight	Weight/Importance	Device Characteristics	Vertically-Layered Components	Single Layer of Components	Lithium Ion Battery at Bottom of Device Body	Lithium Ion Battery on Side of Device Body	Heart Rate Sensor within Casing	Heart Rate Sensor Outside of Casing with Plug-In Port	Heart Rate Sensor Outside of Casing with Internal Connection
1	14%	6	Size	○	▽	●	○	●	○	○
2	9%	4	Accessibility of Device Components for Repair / Replacement	▽	●	●	○	○	●	▽
3	14%	6	Weight	○	○	○	○	N/A	N/A	N/A
4	9%	4	Center of Gravity	▽	○	●	▽	N/A	N/A	N/A
5	18%	8	Comfortable for Patient Use	●	○	●	▽	●	○	○
6	20%	9	Accuracy of Heart Rate Data	N/A	N/A	N/A	N/A	▽	●	●
7	16%	7	Sterilization	●	○	N/A	N/A	○	●	○
			Importance Rating Sum (Importance x Relationship)	480	393	518	236	452	568	441
			Relative Weight	16%	13%	17%	8%	15%	18%	14%

Figure 8: Decision Matrix for Form Factor and Device

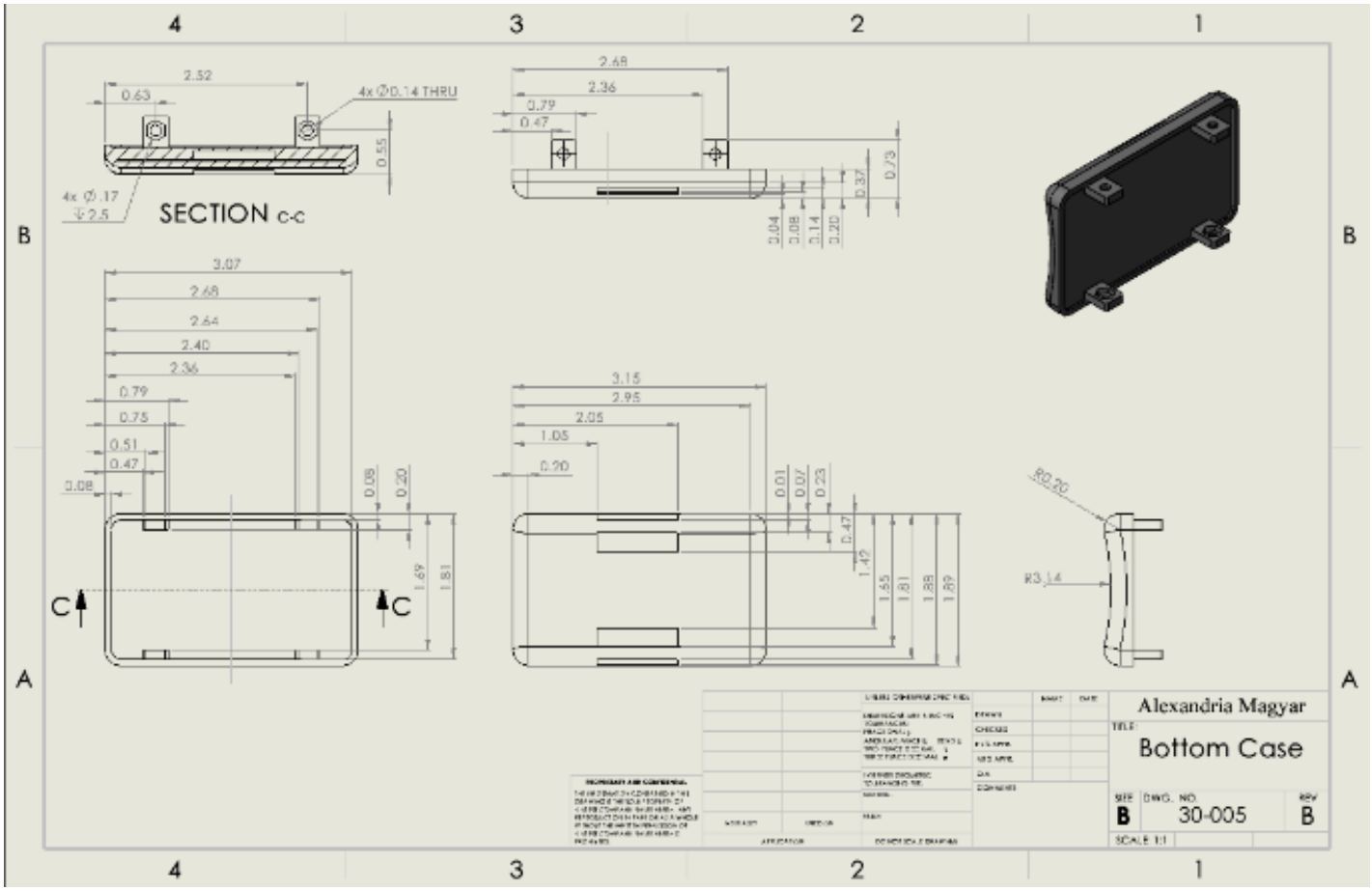


Figure 9: SolidWorks Drawing of Bottom Case Component

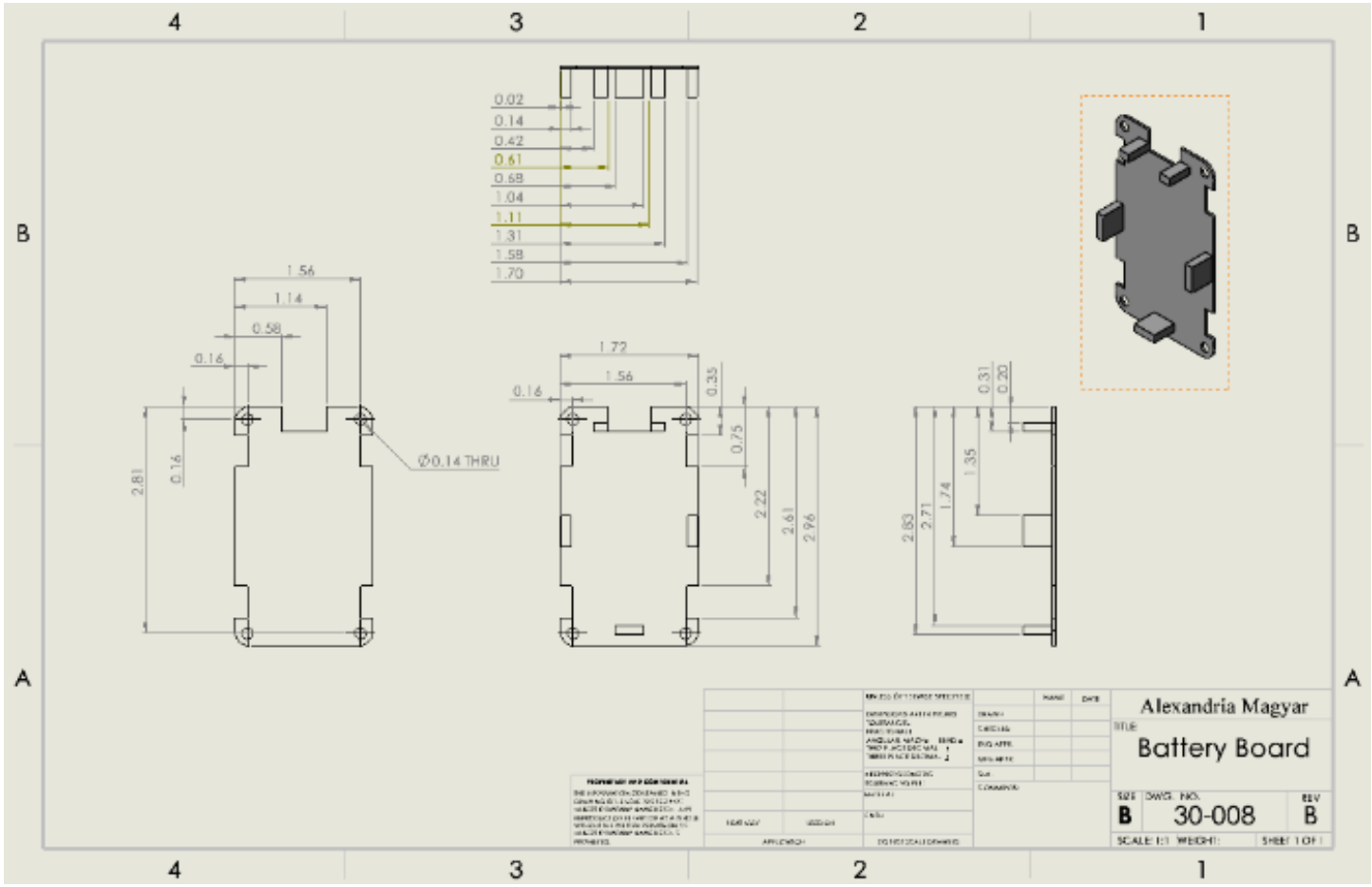


Figure 10: SolidWorks Drawing of Battery Board Case Component

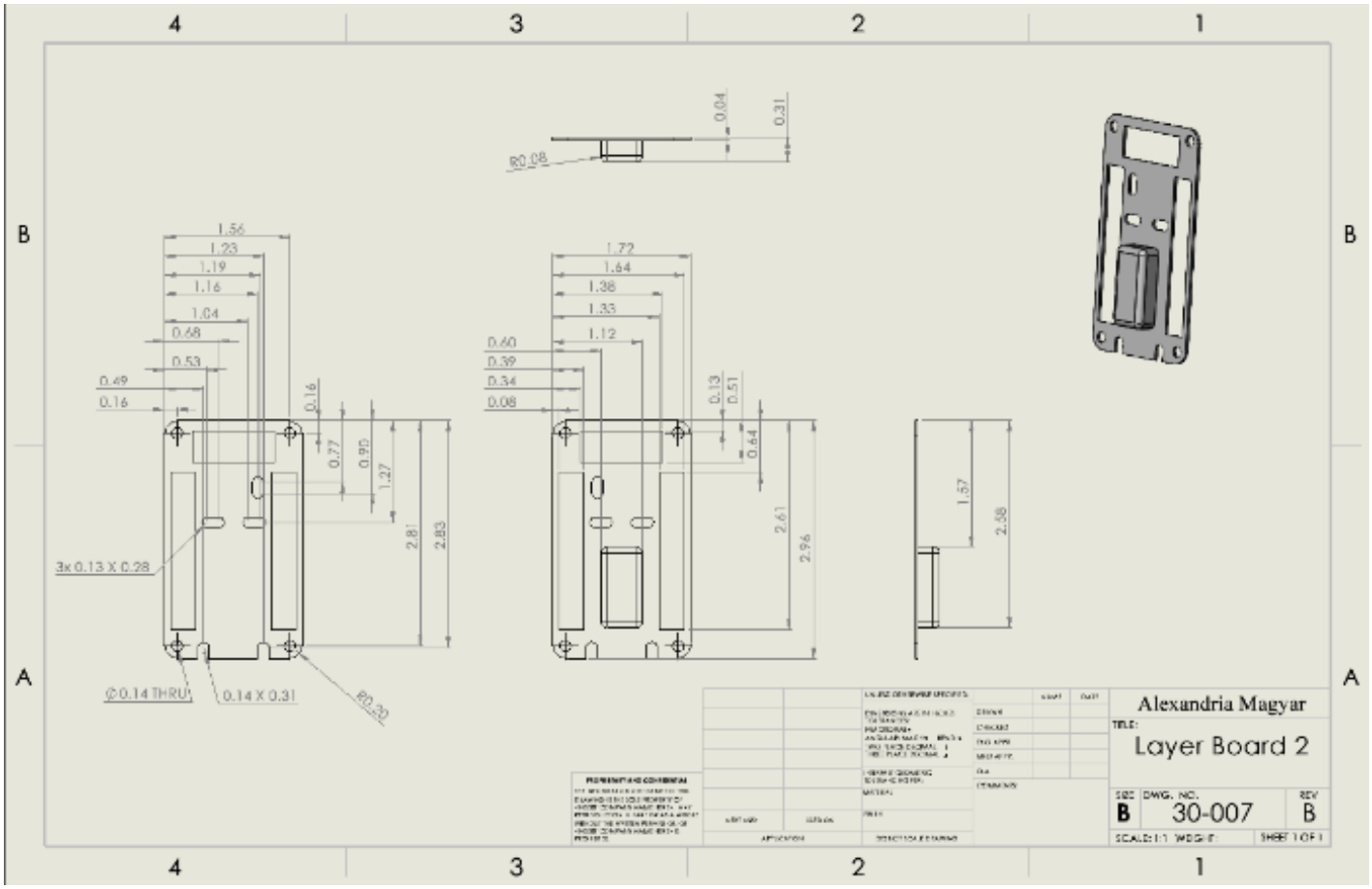


Figure 11: SolidWorks Drawing of Layer Board 2 Case Component

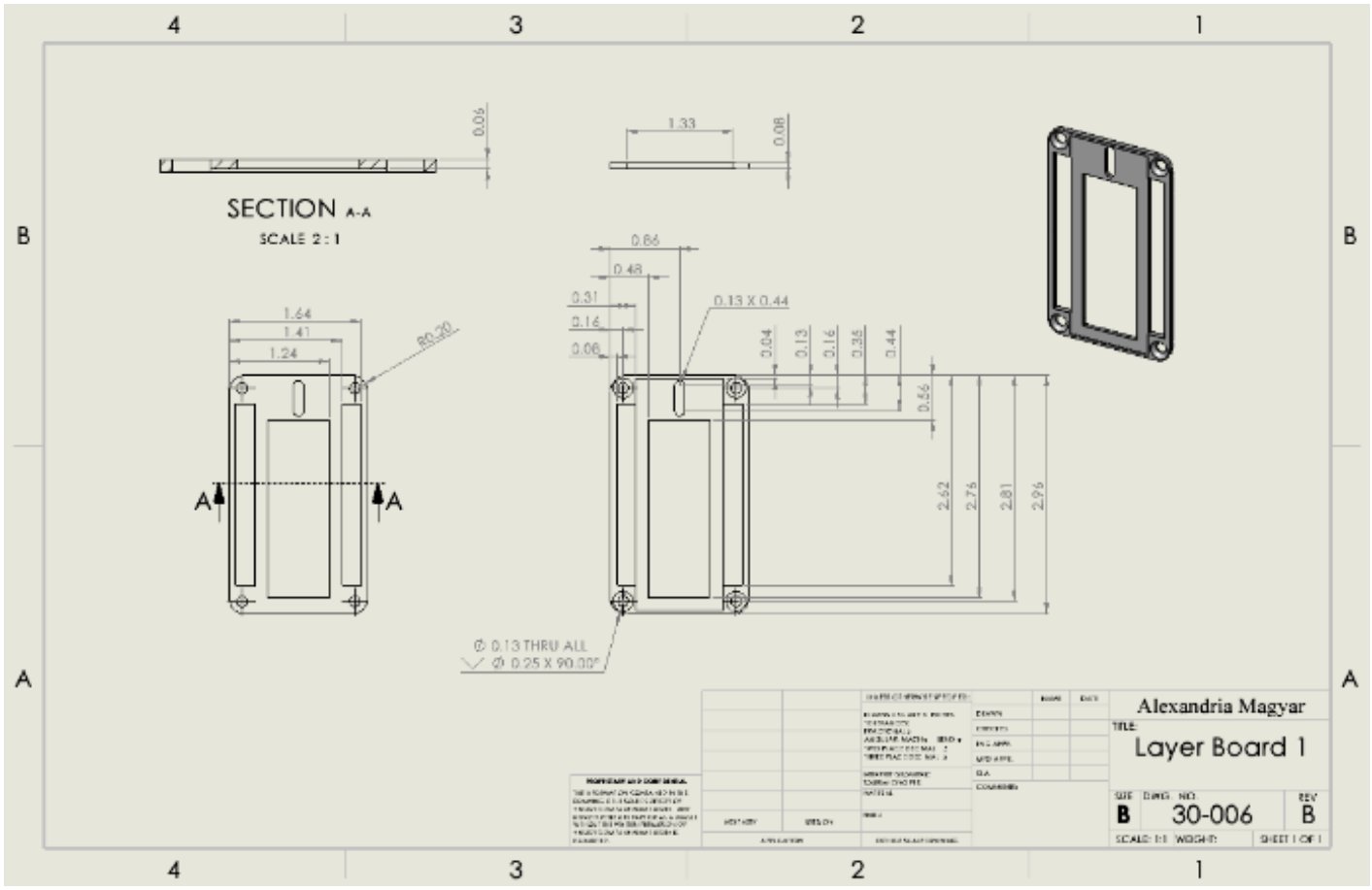


Figure 12: SolidWorks Drawing of Layer Board 1 Case Component

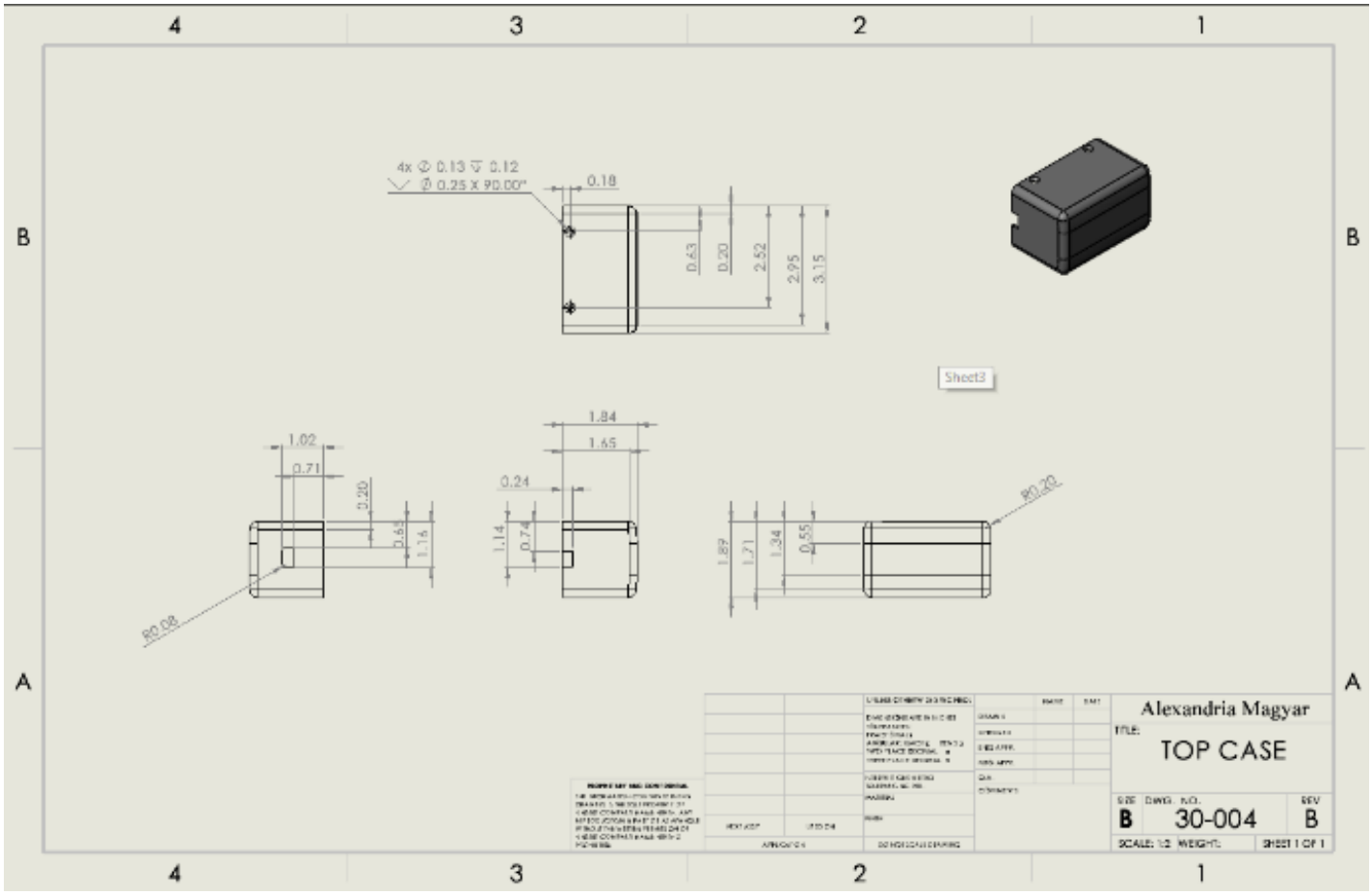


Figure 13: SolidWorks Drawing of Top Case Component

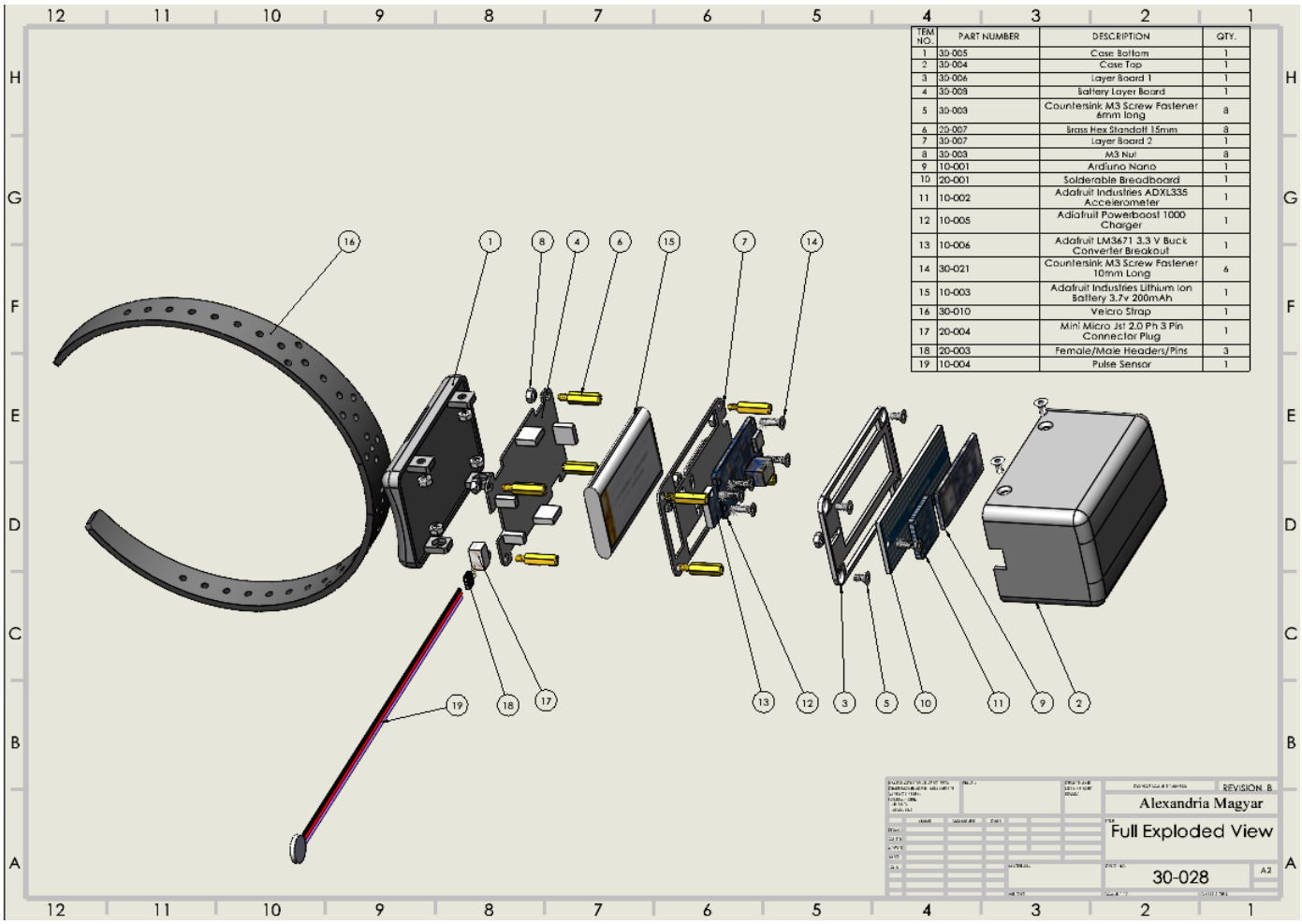


Figure 14: SolidWorks Exploded Assembly of Device Casing and Electronics

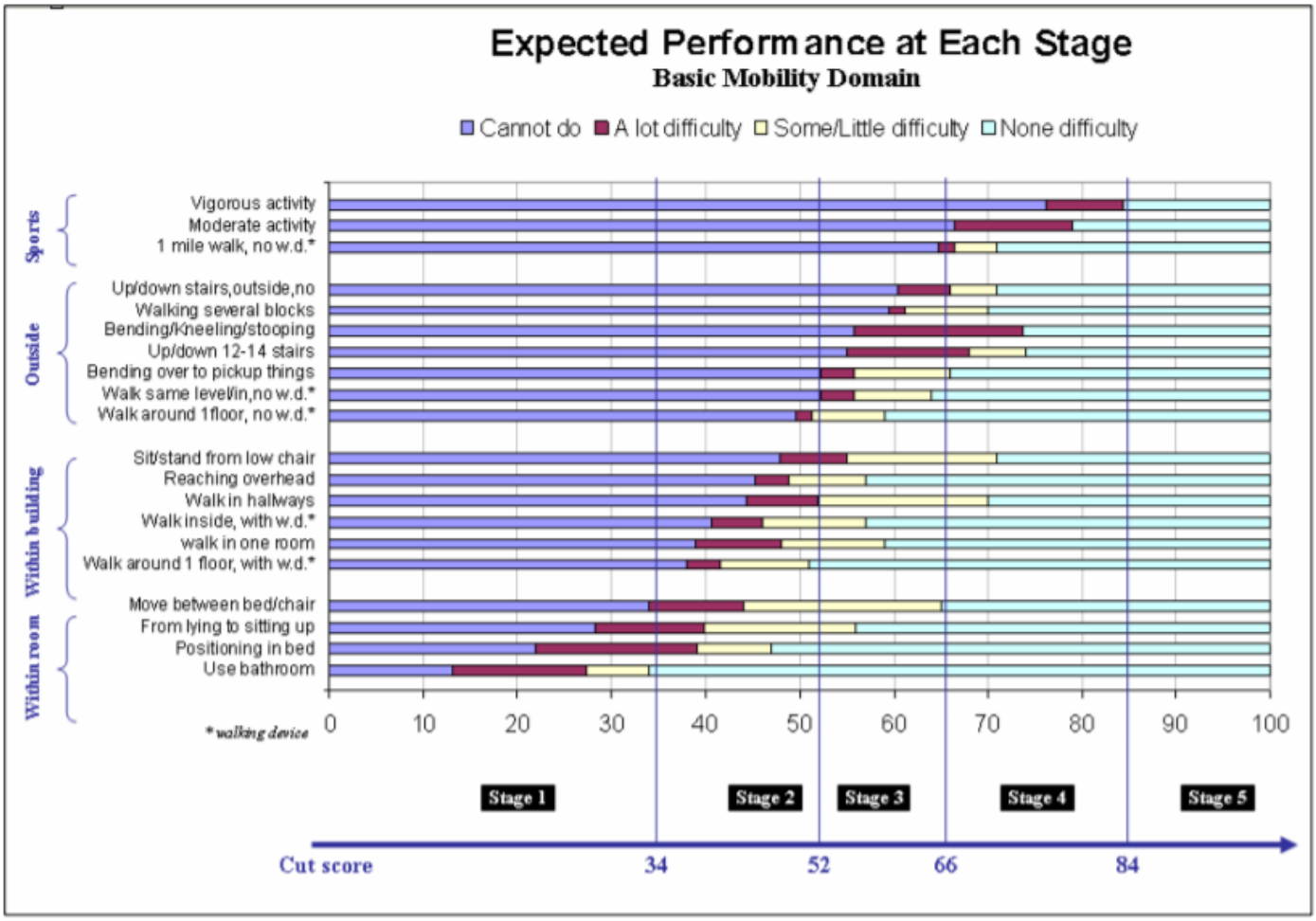


Figure 15: AM-PAC Basic Mobility Domain

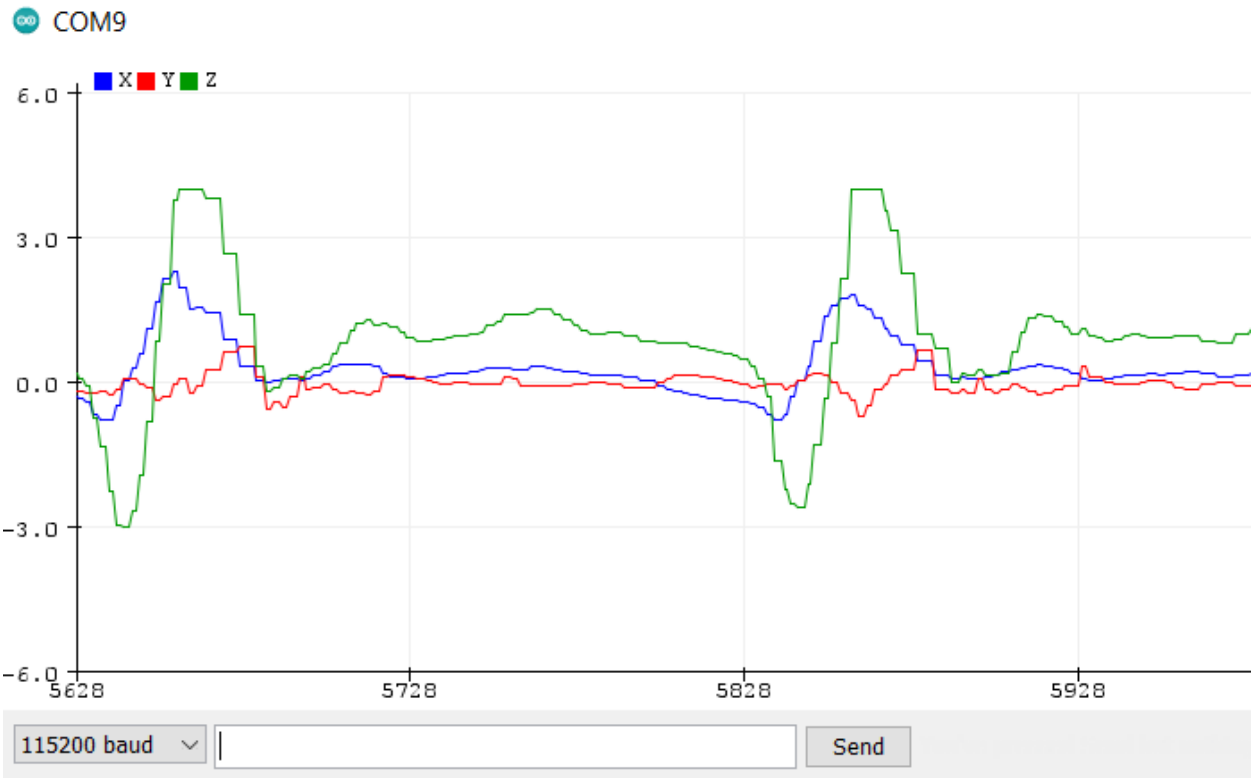


Figure 16: Sample of Gathered Acceleration Information (X-Axis: Sample; Y-Axis: Acceleration in g)

APPENDIX D: TABULATED DESIGN VERIFICATION PROCESS AND RESULTS

Verification Protocol								
Test Number	**Test Name**	**Engineering Requirement Addressed**	**Acceptance Criteria**	**Tested By**	**Protocol Document**	**Sample Size**	**Sample Type**	**Results**
1	Sensor Reading, Output, and Accuracy Verification	Accelerometer Data	± 5 Steps	SOE, OTL	702.00	3	Alpha	FAIL
		Heart Rate Data	± 2 BPM	SOE	702.00	3	Alpha	PASS
		Sensor Input	See Accel. Data and Heart Rate Data Acceptance Criteria	SOE, OTL	702.00	3	Alpha	PASS
		Sensor Input Information	See Accel. Data and Heart Rate Data Acceptance Criteria	SOE, OTL	702.00	3	Alpha	PASS
		Initial Numerical Scale Output	Static Display of Output Values	SOE, OTL	702.00	3	Alpha	PASS
2	Data Availability Verification	Data Availability	Demonstration of Ability to Store & Export Data	OTL	702.00	1	Analytical	PASS
3	Code Runtime Verification	Code Runtime	< 3 Minutes	ECE, OTL	702.00	3	Alpha	PASS
4	Device Runtime Verification	Device Runtime	≥ 36 Hours	OTL	702.00	1	Analytical	PASS

Figure 17: Verification Summary Table

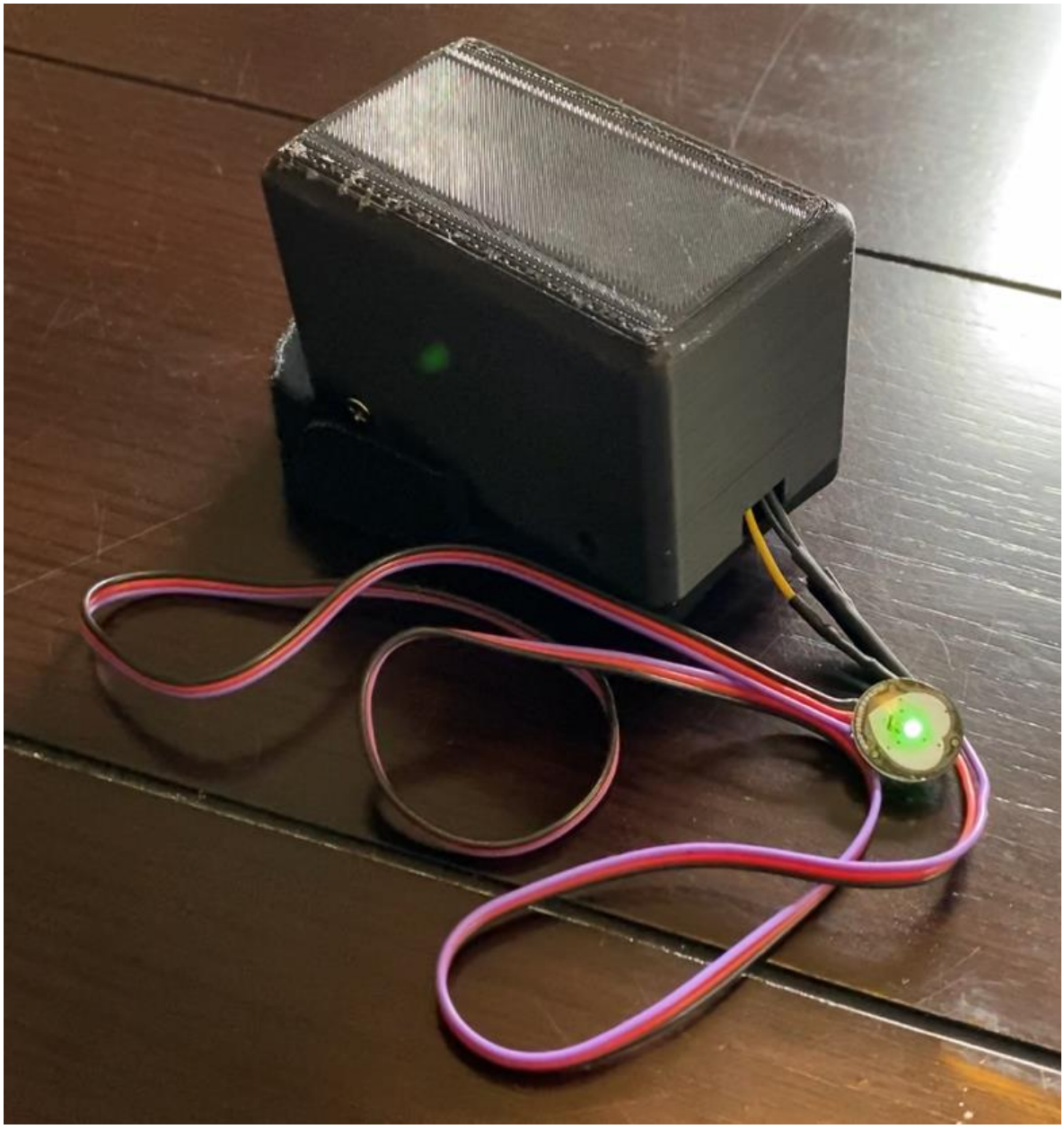


Figure 18: Completed Beta Prototype Figure

TO BE COMPLETED

Figure 19: Video Link of Functional Beta Prototype

APPENDIX F: TABULATED DESIGN VALIDATION PROCESS AND RESULTS

Test Name	Customer Requirement Addressed	Test Description	Acceptance Criteria	Sample Size/ Type	Rationale
Physical Device Interference	Device Location	Assess the device's size and location as patients engage in common activities. Simulate and demonstrate interference caused by device.	Interference Score less than or equal to 4	4 units/ Beta	The device should not hinder a patient's ability to perform common tasks while in post-operative care.
Device Use	Automated	Demonstrate connectivity to the movement assessment device and gathering of desired output information. Demonstrate lack of outside user interaction in use of device.	Demonstration of connectivity and display of information	1 unit/ Beta	The ease of use of the device is key in ensuring medical professionals aren't slaving over the process of post-operative movement assessment.
	Intuitive				
Input Data Analysis	Quantify Patient Movement	Simulate patient post-op activity, and analyze display of number of steps taken and heart rate. This information should be clearly laid out and easy to understand.	± 5 Steps and ± 2 BPM in relation to the prescribed movement	3 units/ Beta	The display of accurate patient movement information is crucial in the calculation of a verifiable AM-PAC mobility score.
	Monitor Patient Movement				
Output Data Analysis	Clear Communication	Simulate patient post-op activity and analyze the output AM-PAC mobility score in comparison with AM-PAC literature. Demonstrate similarities between the literature and charts and output information from our movement assessment device.	± One Level of the targeted AM-PAC mobility level	3 units/ Beta	Comparing output AM-PAC mobility scores against AM-PAC literature will ensure that calculations using input data are accurate or inaccurate in comparison with validated movement assessment system.
	Clear Definition of Movement Requirements				
	Patient Accountability				

Figure 20: Validation Testing Guidelines and Protocols

Validation Protocol/Results								
Test Number	Test Name	User Need Addressed	Acceptance Criteria	Tested By	Protocol Document	Sample Size	Sample Type	Results
1	Physical Device Interference	Device Location	Interference Score less than 4	TEAM	802.00	4	Beta	PASS
2	Device Use	Automated	Demonstration of connectivity and display of information	TEAM	802.00	1	Beta	PASS
		Intuitive						
3	Input Data Analysis	Quantify Patient Movement	± 5 Steps and ± 2 BPM in relation to the prescribed movement	TEAM	802.00	3	Beta	PASS
		Monitor Patient Movement						
4	Output Data Analysis	Clear Communication	± One Level of the targeted AM-PAC mobility level	TEAM	802.00	3	Beta	PASS
		Clear Definition of Movement Requirements						
		Patient Accountability						

Figure 21: Validation Summary Table

APPENDIX G: SUMMARY OF RISK MITIGATION ACTIVITIES

No.	Name of Risk	Summary of Risk	SEV	OCC	DET	RPN	Risk Mitigation	Accept Risk? Y/N	Residual Risk? Y/N
1	App Output: App Crash	Coding failure leads to inability to access data from device.	6	7	4	168	Coding that saves the inputs to the AM-PAC mobility score calculation and outputs into a date-stamped Microsoft Excel sheet for access in case of application failure.	YES	NO
2	Lithium Ion Battery: Harm to patient	Poor quality or faulty battery leads to serious patient harm.	9	2	9	162	Test components prior to full assembly of prototype to determine faults in the components.	YES	NO
3	Adafruit Accelerometer: Unable to detect steps	Insufficient power to function leads to lack of sufficient data for analysis of AM-PAC score.	10	2	7	140	Battery calculations ensure sufficient voltages and currents are available for each device component.	YES	NO
4	Processor: Error in coding	Insufficient power to function leads to lack of sufficient data for analysis of AM-PAC score.	10	2	7	140	Battery calculations ensure sufficient voltages and currents are available for each device component.	YES	NO
5	Data: Data Overflow	Data overflowing and overwriting current patient data leads to inaccurate AM-PAC score.	8	3	5	120	Tabular storing of data for future access in a date-stamped Microsoft Excel sheet	YES	NO
6	Processor: Error in coding	Coding failure leads to lack of AM-PAC mobility score output.	6	5	4	120	Coding that saves the inputs to the AM-PAC mobility score calculation into a date-stamped Microsoft Excel sheet for future access.	YES	NO
7	Adafruit Accelerometer: Wildly fluctuating readings	Aging of accelerometer component leads to misrepresentation of movement information and inaccurate AM-PAC score.	5	3	7	105	Coordination with patient to ensure output AM-PAC mobility score is truly representative of their activites throughout the day.	YES	NO
8	Adafruit Accelerometer: Unable to detect steps	Faulty connections with processor or primary device leads to lack of sufficient data for analysis of AM-PAC score.	10	2	5	100	Test components prior to full assembly of prototype to determine faults in the components.	YES	NO
9	PulseSensor: Unable to detect heartbeat	Vasoconstriction due to cold extremities leads to lack of sufficient data for analysis of AM-PAC score.	5	10	2	100	Fingertip glove casing to sew sensor into to ensure the fingertip is up to temperature and avoiding vasoconstriction due to potentially cold surrounding environments. Instruct patients to rub their hands together or cup the desired finger in their hand to provide additional heat.	YES	NO
10	App Output: Insufficient Data Display	Improper variable assignment leads to lack of sufficient data for analysis of AM-PAC score.	8	3	4	96	Testing of code with sample data ensures input data is allocated to the correct variables for use in AM-PAC mobility score calculation.	YES	NO
11	Case / Seal: Outer case failure	Weak point in plastic case exposes circuitry and batteries, causing damage to crucial components.	7	4	3	84	High strength 3D filament material used with structural electronics supports within the device case to provide structure and protection to inner components.	YES	NO
12	PulseSensor: Unable to detect heartbeat	Poor contact with skin's surface leads to lack of sufficient data for analysis of AM-PAC score.	5	8	2	80	Included velcro band allows provides firm grip to fingertip for gathering of sufficient data.	YES	NO
13	Bluetooth: Connection Errors	Coding failure leads to lack of transfer of data for AM-PAC mobility score calculation.	6	3	4	72	Ensure accessibility of code for updating bluetooth connection information.	YES	NO
14	PulseSensor: Unable to detect heartbeat	Insufficient power to function leads to lack of sufficient data for analysis of AM-PAC score.	5	2	7	70	Battery calculations ensure sufficient voltages and currents are available for each device component.	YES	NO
15	Adafruit Accelerometer: Unable to detect steps	Faulty Accelerometer leads to lack of sufficient data for analysis of AM-PAC score.	10	1	7	70	Test components prior to full assembly of prototype to determine faults in the components.	YES	NO
16	Processor: Error in coding	Faulty processor leads to lack of AM-PAC mobility score output.	10	1	7	70	Test components prior to full assembly of prototype to determine faults in the components.	YES	NO

Figure 22: Design Process FMEA Summary – Risks 1 through 16

No.	Name of Risk	Summary of Risk	SEV	OCC	DET	RPN	Risk Mitigation	Accept Risk? Y/N	Residual Risk? Y/N
17	Overheating: Device burning patient	Excessive current draw leads to excessive device temperature & burning.	10	3	2	60	Include sealing method and clean wiring when assembling final prototype to avoid crossing currents or overloading electrical systems.	YES	NO
18	Overheating: Device burning patient	Short circuit within device leads to excessive device temperature & burning.	10	3	2	60	Include sealing method and clean wiring when assembling final prototype to avoid crossing currents or overloading electrical systems.	YES	NO
19	Data: Pre-Existing Patient Conditions	Pre-Existing conditions have ill effect on gathering of data for AM-PAC score calculation.	9	6	1	54	Adjustment of activity score scale to accommodate for patient conditions by physician.	YES	NO
20	PulseSensor: Unable to detect heartbeat	Faulty connections with processor or primary device leads to lack of sufficient data for analysis of AM-PAC score.	5	2	5	50	Test components prior to full assembly of prototype to determine faults in the components.	YES	NO
21	Adafruit Accelerometer: Wildly fluctuating readings	Excessive movement of sensors leads to misrepresentation of movement information and inaccurate AM-PAC score.	5	8	1	40	Allocate accelerometer movements into code to calculate steps the patient takes during recovery process.	YES	NO
22	Case / Seal: Patient bodily fluids invade device internals	Fluids device is subjected to enter device and cause damage to device internals.	8	5	1	40	Include sealing method (case designed or independent gasket) where case closes together.	YES	NO
23	Case / Seal: Sterilization process damages device internals	Fluids device is subjected to enter device and cause damage to device internals.	8	5	1	40	Include sealing method (case designed or independent gasket) where case closes together.	YES	NO
24	Bluetooth: Connection Errors	Faulty bluetooth module leads to lack of transfer of data for AM-PAC mobility score calculation.	6	1	4	24	Test components prior to full assembly of prototype to determine faults in the components.	YES	NO
25	Strap: Strap failure	Excessive forces applied to the strap leads to device being damaged or lost.	7	3	1	21	Visible inspection of strap component for defects and cracking. Device attached to patient by medical professional.	YES	NO
26	Prematurely Dying Device: Unable to collect data	Faulty battery leads to lack of data collection for analysis of AM-PAC score.	5	2	2	20	Test components prior to full assembly of prototype to determine faults in the components.	YES	NO
27	App Output: App Unavailable	App not downloaded leads to inability to access data from device.	3	5	1	15	Retrieval of phone with sufficient available battery and application to use for assessment.	YES	NO
28	App Output: Insufficient Data Display	Physician or nurse phone powered off due to low battery leads to lack of sufficient data for analysis of AM-PAC score.	3	5	1	15	Retrieval of phone with sufficient available battery and application to use for assessment.	YES	NO
29	Case / Seal: Outer case failure	Excessive forces applied to plastic case expose circuitry and batteries, causing damage to crucial components.	7	2	1	14	High strength 3D filament material used with structural electronics supports within the device case to provide structure and protection to inner components.	YES	NO
30	Strap: Strap failure	Defect in device strap leads to device being damaged or lost.	7	2	1	14	Test components prior to full assembly of prototype to determine faults in the components.	YES	NO
31	PulseSensor: Unable to detect heartbeat	Faulty PulseSensor leads to lack of sufficient data for analysis of AM-PAC score.	5	1	2	10	Test components prior to full assembly of prototype to determine faults in the components.	YES	NO

Figure 23: Design Process FMEA Summary – Risks 17 through 31

APPENDIX H: SUMMARY OF PROJECT EXPENSES AND PRODUCT MARKETING ANALYSIS

Bill of Materials						
Item Number(s)	**Part Number(s)**	**Quantity**	**Name**	**Project Expense**	**Wholesale Pricing**	**Explanation of Wholesale Pricing**
1 through 6	30-000 (includes 30-004, 30-005, 30-006, 30-007, and 30-008)	6	3D Printed Case for Electronics	Free	$10.00	For 1000 cases per year, single cavity molds could be used which would cost $1000 - $2000. Tooling the case would cost $13,500. A conservative estimate of $10 for one case will be assumed.
7 through 8	30-003 and 30-021	22	Fasteners (M3x6 Screw, M3x10 Screw, M3 Nut)	$14.99	$1.92	Assume we will use 22 pieces
9	20-007	8	Brass Hex Standoff 15mm	$7.99	$0.28	Assume we will use 8 pieces
10	10-001	1	Arduino Nano 33 BLE Sense with Headers	$32.99	$19.79	Assume 40% retail markup
11	20-001	1	Protoboard	$12.99	$0.30	Assume we will order 50 pieces
12	10-002	1	Adafruit Industries ADXL335 Accelerometer	$14.95	$3.70	Wholesale pricing
13	10-005	1	Adafruit Powerboost 1000 Charger	$19.95	$11.97	Assume 40% retail markup
14	10-006	1	Adafruit LM3671 3.3V Buck Converter Breakout	$4.95	$2.97	Assume 40% retail markup
15	10-003	1	Adafruit Industries Lithium Ion Vattery 3.7V 2000mAh	$12.49	$7.49	Assume 40% retail markup
16	30-010	1	Velcro Strap	$12.85	$0.75	Assume we will order 1000 pieces
17	20-004	1	Mini Micro JST 2.0 PH 3 Pin Connector Plug	$8.59	$0.75	Assume we will order 1000 pieces
18	20-003	1	Female/Male Headers/Pins	$7.99	$0.22	Assume we will order 1000 pieces
19	10-004	1	Pulse Sensor	$24.99	$1.84	Wholesale pricing
Total	----------	----------	----------	**$175.72**	**$61.99**	----------

Figure 24: Bill of Materials with Wholesale Price for Product Marketing Assessment