



**DEPARTMENT OF ELECTRICAL AND COMPUTER ENGINEERING**

**EEL 4920 SENIOR DESIGN I**

**SPRING 2015**

**StableWear:  
A Hand Tremor Suppression Orthosis**

Team # 9

Carlos Hernandez

Norvin Holness

Camille Jones

Emilio Lopez

Michel Perez

Senior Design I Final Proposal

Submitted To:

Senior Design I Instructor: Professor Wilmer Arellano

Mentor: Dr. Gustavo Roig Ph.D.

April 27, 2015

## TABLE OF CONTENTS

LIST OF TABLES .....	I-1
LIST OF FIGURES .....	I-1
ABSTRACT.....	I-1
I. EXECUTIVE SUMMARY .....	I-1
A. Introduction .....	I-1
B. Problem Statement .....	I-1
1) Objectives.....	I-1
2) Constraints.....	I-2
C. Operating Environment .....	I-2
D. Intended User(s) and Uses.....	I-2
E. Background.....	I-2
F. Intellectual Property.....	I-3
G. The Team.....	I-3
H. Globalization .....	I-3
I. End Product Description .....	I-4
II. PROBLEM STATEMENT .....	II-1
A. Project Objectives .....	II-1
1) Functional.....	II-1
2) Marketable.....	II-1
3) Safe.....	II-1
4) User-friendly .....	II-1
B. Constraints.....	II-2
III. ASSUMPTIONS AND LIMITATIONS .....	III-1
A. Assumptions .....	III-1
B. Limitations .....	III-1
IV. NEEDS FEASIBILITY ANALYSIS.....	IV-1
A. Needs Analysis.....	IV-1
1) Client Interview .....	IV-1

2) User Survey .....	IV-2
3) Brainstorming.....	IV-3
B. Needs Specification.....	IV-5
C. Feasibility Analysis .....	IV-1
1) Technical .....	IV-1
2) Resource .....	IV-1
3) Economical.....	IV-2
4) Schedule .....	IV-2
5) Operational .....	IV-2
6) Cultural.....	IV-2
7) Legal.....	IV-2
8) Market .....	IV-2
D. Marketability .....	IV-5
V. RISK ANALYSIS.....	V-1
A. Risk Summaries.....	V-1
1) Technical .....	V-1
2) Resources .....	V-1
3) Economic.....	V-1
4) Schedule .....	V-1
5) Legal.....	V-2
6) Marketing .....	V-2
VI. OPERATING ENVIRONMENT.....	VI-1
A. Ergonomics.....	VI-1
B. Noise.....	VI-1
C. Water Resistance .....	VI-1
D. Temperature .....	VI-1
VII. INTENDED USER(S) AND INTENDED USE(S).....	VII-1
A. Intended User .....	VII-1
B. Intended Use.....	VII-1
VIII. BACKGROUND.....	VIII-1
A. Glove Mouse .....	VIII-1

1) Project Summary .....	VIII-1
2) Technology Review.....	VIII-1
3) System Description .....	VIII-1
B. Micron: Microsurgical Tremor Cancellation .....	VIII-3
1) Project Summary .....	VIII-3
2) Technology Review.....	VIII-3
3) System Description .....	VIII-3
C. Tremor Quantification via Ambulatory Monitoring System.....	VIII-5
1) Project Summary .....	VIII-5
2) Technology Review.....	VIII-5
3) System Description .....	VIII-5
IX. INTELLECTUAL PROPERTY .....	IX-1
A. Patent 1: US Patent # 20040015116 A1.....	IX-1
1) Summary .....	IX-1
2) Claims Summaries.....	IX-1
3) Non Infringement .....	IX-1
B. Patent 2: US Patent # 7966074 B2 .....	IX-2
1) Summary .....	IX-2
2) Claims Summaries.....	IX-2
3) Non Infringement .....	IX-3
C. Patent 3: US Patent # 20100174342 A1.....	IX-3
1) Summary .....	IX-3
2) Claims Summaries.....	IX-4
3) Non Infringement .....	IX-4
X. STANDARDS CONSIDERATIONS .....	X-1
A. ISO 13485:2003 .....	X-1
B. ISO 10993 .....	X-2
C. IEC 60601-1-11.....	X-3
D. ISO9001: 2008 .....	X-4
XI. GLOBALIZATION .....	XI-1
A. Global Awareness .....	XI-1

B.	Global Perspective.....	XI-1
C.	Global Engagement .....	XI-2
D.	World Trade Organization (WTO).....	XI-2
E.	Eliminating Barriers .....	XI-2
F.	Collaboration Tools .....	XI-3
G.	International Contacts .....	XI-3
XII.	HEALTH AND SAFETY .....	XII-1
XIII.	ENVIRONMENTAL CONSIDERATIONS.....	XIII-1
XIV.	SUSTAINABILITY CONSIDERATIONS .....	XIV-1
XV.	MANUFACTURABILITY CONSIDERATIONS .....	XV-1
A.	Simplify design and reduce number of parts.....	XV-1
B.	Standardize and use common parts and materials.....	XV-1
C.	Mistake-proof product design and assembly (Poka-Yoke).....	XV-1
XVI.	ETHICAL CONSIDERATIONS AND SOCIAL IMPACT.....	XVI-1
A.	Ethical Considerations.....	XVI-1
B.	Social Impact.....	XVI-3
XVII.	CONCEPT DEVELOPMENT .....	XVII-1
A.	Option 1.....	XVII-2
1)	Advantages .....	XVII-2
2)	Disadvantages.....	XVII-2
B.	Option 2.....	XVII-3
1)	Advantages .....	XVII-3
2)	Disadvantages.....	XVII-4
A.	Option 3.....	XVII-4
1)	Advantages .....	XVII-5
2)	Disadvantages.....	XVII-5
B.	Concept Selection.....	XVII-5
XVIII.	END PRODUCT DESCRIPTION AND OTHER DELIVERABLE .....	XVIII-1
A.	End Product Description .....	XVIII-1
B.	Functions .....	XVIII-1
1)	Level 0 Functionality Diagram .....	XVIII-1

2)	Level 1 Functionality Diagram .....	XVIII-2
3)	Level 2 Functionality Diagram .....	XVIII-3
C.	Specifications .....	XVIII-8
D.	Other Deliverables.....	XVIII-8
XIX.	PLAN OF ACTION .....	XIX-9
A.	Statement of Work (SOW).....	XIX-9
1)	Scope of Work.....	XIX-9
2)	Location of Work .....	XIX-10
3)	Period of Performance.....	XIX-10
4)	Deliverables Schedule .....	XIX-10
5)	Responsibilities .....	XIX-10
B.	Work Breakdown Structure (WBS) .....	XIX-11
1)	Phase 1: Electrical Design.....	XIX-12
2)	Phase 2: Signal Processing.....	XIX-12
3)	Phase 3: Software Design.....	XIX-12
4)	Phase 4: Emitter Design .....	XIX-13
5)	Phase 5: Testing and Debugging.....	XIX-13
C.	Project Milestones .....	XIX-14
1)	Gather readings from sensor into microcontroller .....	XIX-14
2)	Process sensor readings .....	XIX-14
3)	Emitting signal .....	XIX-14
4)	Testing and debugging .....	XIX-14
D.	Charts .....	XIX-14
1)	Gantt chart .....	XIX-14
2)	PERT chart .....	XIX-15
XX.	MULTIDICIPLINARY ASPECTS .....	XX-1
A.	Carlos Hernandez .....	XX-1
B.	Norvin Holness.....	XX-1
C.	Camille Jones .....	XX-1
D.	Emilio Lopez .....	XX-2
E.	Michel Perez .....	XX-2

XXI.	PERSONNEL.....	XXI-1
XXII.	BUDGET.....	XXII-1
XXIII.	RESULTS EVALUATION.....	XXIII-1
XXIV.	LIFE LONG LEARNING .....	XXIV-1
XXV.	CONCLUSION.....	XXV-1
XXVI.	REFERENCES .....	XXVI-1
XXVII.	APPENDIX .....	XXVII-2
A.	Client Interview Questions.....	XXVII-2
B.	User Survey .....	XXVII-3
C.	Team Contract.....	XXVII-5
D.	Intellectual Property Contract .....	XXVII-6
XXVIII.	SENIOR DESIGN II PROCEDURES .....	XXVIII-1

## LIST OF TABLES

TABLE. I. Client Interview Responses .....	IV-1
TABLE. II Survey Results Summary .....	IV-2
TABLE. III Suggested Attributes & Objectives .....	IV-4
TABLE. IV Need Specification .....	IV-5
TABLE. V Technical Feasibility .....	IV-3
TABLE. VI Resource Feasibility.....	IV-3
TABLE. VII Economic Feasibility .....	IV-3
TABLE. VIII Schedule Feasibility .....	IV-3
TABLE. IX Cultural Feasibility .....	IV-4
TABLE. X Legal Feasibility .....	IV-4
TABLE. XI Market Feasibility .....	IV-4
TABLE. XII Feasibility Analysis Table .....	IV-4
TABLE. XIII Weighted Scale.....	IV-5
TABLE. XIV Risk Analysis Table .....	V-3
TABLE. XV Actions to Risk Analysis .....	V-4
TABLE. XVI Style vs Functionality Analysis of Availabe Options .....	XVI-2
TABLE. XVII Style vs Functionality Weight of Available Options.....	XVI-2
TABLE. XVIII Concept selection .....	XVII-5
TABLE. XIX weighted concept selection .....	XVII-6
TABLE. XX Concept Comparison .....	XVII-6
TABLE. XXI Level 0 Representation .....	XVIII-2
TABLE. XXII Level 1 Functionalities .....	XVIII-3
TABLE. XXIII Triaxial Gyroscope Functionality.....	XVIII-4
TABLE. XXIV Analog Filter Functionality .....	XVIII-5
TABLE. XXV Level 2 Representation of Microcontroller .....	XVIII-5
TABLE. XXVI Level 2 Representation of FES Damper .....	XVIII-6
TABLE. XXVII Power Supply Functionality .....	XVIII-7
TABLE. XXVIII Technical Specifications.....	XVIII-8
TABLE. XXIX Summary Outline .....	XIX-11
TABLE. XXX 100% Rule .....	XIX-13
TABLE. XXXI Budget .....	XXII-1
TABLE. XXXII Material Cost .....	XXII-2



## LIST OF FIGURES

Fig. 1 Level 0 Representation .....	I-4
Fig. 2 Level 2 Representation .....	I-4
Fig. 3 Fishbone Diagram.....	IV-3
Fig. 4 Risk Analysis Fishbone Diagram .....	V-3
Fig. 5 Glove Mouse Finished Prototype .....	VIII-2
Fig. 6 Glove Mouse Logical Block Diagram.....	VIII-2
Fig. 7 Illustration of Micron System.....	VIII-4
Fig. 8 Micron System Diagram.....	VIII-4
Fig. 9 Illustration of Tremor Quantification Monitoring System .....	VIII-6
Fig. 10 Illustration of US Patent # 20040015116 A1 .....	IX-2
Fig. 11 Illustration of US Patent 7966074 B2.....	IX-3
Fig. 12 Illustration 1 of US Patent 20100174340 A1 .....	IX-4
Fig. 13 Illustration 2 of US Patent 20100174340 A1 .....	IX-5
Fig. 14 Graph of Weighted Values .....	XIII-2
Fig. 15 Detailed Values of Normalized Graph .....	XIII-3
Fig. 16 Concept Fan Diagram.....	XVII-1
Fig. 17 Option 1 .....	XVII-2
Fig. 18 Option 2 .....	XVII-3
Fig. 19 Option 3 .....	XVII-4
Fig. 20 Level 0 Representation .....	XVIII-2
Fig. 21 Level 1 Representation of StableWear .....	XVIII-3
Fig. 22 Level 2 Representation of Triaxial Gyroscope.....	XVIII-4
Fig. 23 Level 2 Representation of Active Analog Filter.....	XVIII-4
Fig. 24 Level 2 Representation of BeagleBone Black Microcontroller.....	XVIII-5
Fig. 25 Flow Chart Representation of Process.....	XVIII-6
Fig. 26 Level 2 Representation of FES .....	XVIII-6
Fig. 27 Level 2 Representation of Power Supply .....	XVIII-7
Fig. 28 Gantt Chart .....	XIX-15
Fig. 29 PERT Chart.....	XIX-16

## **ABSTRACT**

Individuals who are diagnosed with Multiple Sclerosis (MS), Parkinson's disease (PD), and essential tremor (ET) and other movement associated disorders are often affected by hand tremors. The tremors associated with each of these disorders are involuntary and uncontrollable. Patients who suffer from these disorders lose basic functionality of their hand. They often have difficulty performing simple tasks such as; brushing of teeth, cooking, picking up a fork to feed themselves, pushing a button on the elevator, and many more tasks that require basic functionality of the hand. Tremor related diseases lower the quality of life of the patients that they affect. There are various therapies, surgeries, and medications that serve to help correct the effects of these disorders by giving temporary functionality back to the hand. Though these methods are helpful, and guarantee accurate results, many patients are not able to afford any of these methods due to how expensive they are. These methods also only provide temporary treatment, which means that patients have to seek treatment multiple times per year. Through research we have found that there is currently no device available on the market that sufficiently addresses the reduction of tremors in the hand. We at Team StableWear have taken up the challenge of finding a solution to this issue. Through many hours of research and brainstorming we came up with the idea of developing a wearable device that will help improve the quality of life for those who suffer from tremors. StableWear is a wearable hand tremor suppression orthosis. It is an inexpensive, risk-free, non-surgical, and reversible method for returning basic functionality to the hand. StableWear is also a product that is designed to be aesthetically pleasing and comfortable to wear without drawing unnecessary attention due to it being easily hidden under clothing. We at Team StableWear hope to revolutionize the way how wearable tremor suppression devices are made and also improve the quality of life for those who suffer from tremor associated diseases.

## I. EXECUTIVE SUMMARY

StableWear	
Team Number: 9	Team Name: StableWear
Mentor: Gustavo Roig Ph.D	Team Leader: Carlos Hernandez
Team Member: Norvin Holness	Team Member: Camille Jones
Team Member: Emilio Lopez	Team Member: Michel Perez

### A. Introduction

The proposal for StableWear stemmed from the willingness our team to satisfy the needs of individuals who suffer from tremor associated disorders. These disorders include but are not limited to Parkinson's Disease (PD), Essential Tremor (ET), and Multiple Sclerosis (MS). There is currently no cure for either of the mentioned diseases, but patients can pursue the option of taking medication, going through therapy, and also doing invasive surgeries such as Deep Brain Stimulation (DBS) surgery. A lot of the mentioned options for treatment of tremor associated disorders are very expensive. According to the Parkinson's Disease Foundation, it cost an estimated \$2,500 per year for medications, and therapeutic surgery can cost up to \$100,000. Due to expensive methods of treatment, a lot of patients who suffer from these diseases cannot afford to take care of themselves. StableWear serves as a risk free, non-surgical and inexpensive approach to tackle this issue of involuntary tremors, by means of tremor suppression. It will be used for suppression of involuntary tremors in the hand.

### B. Problem Statement

The issue at hand is that there are no medical devices on the current market that are aimed towards the suppression of tremors

as a whole. Many products on the market only serve for one function, thus many patients with tremors have to use different devices for each function or task that they are trying to accomplish. At StableWear we aim to provide an inexpensive wearable device that will be able to accommodate any task that the user requires. This will eliminate the need for individuals to purchase numerous single-purpose devices to accomplish different tasks.

#### 1) Objectives

StableWear engineers are working tirelessly to alleviate the inconveniences for people suffering from involuntary tremors. Our goal is to provide the user with a product that is Functional and Reliable, Marketable, Safe, and User-friendly.

##### a) Functional

We aim to provide a device that is reliable, lightweight and able to worn for extended periods of time.

##### b) Marketable

Our device will be marketable based it being visually appealing, comfortable to wear, and its low cost.

*c) Safe*

Our device will be safe to wear, and will not inflict any harm to the user.

*d) User Friendly*

StableWear will be user friendly in that it will be easy to remove, power off and on, and also that it will be durable which will aide in the resistance to wear and tear.

**2) Constraints**

Team StableWear aims to provide a Wearable Tremor Suppression Orthosis that will comply with national and international standards and regulation. We also aim to provide a product that will cost no more than \$200.

**C. Operating Environment**

Since StableWear is a wearable hand tremor suppression device, the operation environment is very critical because a wearable device is prone to contact with many factors in the surroundings. Since it is a wearable the design and ergonomics of the device have made it aesthetically pleasing, while not drawing much attention to the area in which it is applied. We also took in the factor that the noise produced by the device would be an issue, thus we assure that it will operate as quietly as possible. We also understood that the device being mounted on the hand would probably come into contact with water a lot, thus we are delivering a product that is highly resistant to water. Finally, we took into consideration the temperature, and have implemented a design that will be able to operate in temperatures from -20 °C and 45°C.

**D. Intended User(s) and Uses**

The intended users of StableWear are those individual who suffer from Parkinson's Disease (PD), Essential Tremor (ET), Multiple Sclerosis (MS) and other tremor associated disorders. These are usually individuals who are in their late forty's and older. The intended use of StableWear is to improve functionality in the hand so that individuals may perform simple tasks on a regular basis. The product is aimed to improve their quality of life.

**E. Background**

The supporting background behind a project like StableWear comes from many different scholarly journals and references. We analyzed many different projects from IEEE on the issue of tremor suppression in the hand. We came across a multitude of different ways in which this project can be accomplished. We have found a lot of research that has been aimed in the same direction in which we would like to head, but there has not been any fruitful product placed on the market from a lot of these researchers. Through our background research we came across three projects. Firstly, the Mouse Glove, which is made up of motion detecting technology from a microcontroller mounted on the arm of the user. Secondly, Micron, which is an instrument that actively cancels hand tremors during eye surgery. Lastly, we came across the, Tremor Quantification via Ambulatory Monitoring System, which consist of two monitoring systems capable of recording hand tremors thigh measurement systems containing gyroscopes. All three

projects were very influential towards the design of StableWear.

#### ***F. Intellectual Property***

In the initial stages of the development of StableWear, we conducted research on many patents what are aimed to take the wearable approach of solving the issue of tremor suppression. Through our research we found three ideal patents that consist of a wearable tremor suppression orthosis. We read and analyzed each of these three patents so that we may not infringe on any of the claims that these patents are claiming to accomplish below:

1. US Patent # 20040015116 A1
2. US Patent # 7966074 B2
3. US Patent # 20100174342 A1

StableWear will not infringe on the claims of any approved patents recognized by the United States Patent and Trademark Office (USPTO), the World Intellectual Property Organizations (WIPO), and any other governing patent organizations thereof.

#### ***G. The Team***

Team StableWear consist of five Engineers; three Computer Engineers and two Electrical Engineers. All members of the team contribute to different aspects of their respective engineering fields. Carlos Hernandez is an Electrical Engineer with concentrations in Integrated Nano Technology and Data System Software. He is also the team leader, and is responsible for organizing the team meetings. Carlos will be responsible for the development of the damping system for StableWear. Norvin Holness in a Computer Engineer with concentrations in Embedded Systems, Bio-

engineering, and Network Engineering. Norvin will be responsible for the development of the Digital Signal Progressing of the hardware for StableWear. Camille Jones is a Computer Engineer with concentrations in Embedded Systems, and Computer Architecture and Microprocessor Design. Camille will be responsible for the programming of the embedded software for StableWear. Emilio Lopez is a Computer Engineer with concentrations in Embedded System and Data System Software. Emilio is responsible for Programming of the embedded system for StableWear. Lastly, Michel Perez is an Electrical Engineer with concentrations in Power/Energy Systems and Integrated Nano Technology. Michel will be responsible for the hardware design of StableWear. Each team member is well versed in their respective concentrations that will prove to be an asset towards the development of StableWear.

#### ***H. Globalization***

One of the project objectives of StableWear is to provide a product that is marketable. Our team has set international milestones for StableWear; we have discussed the possibility of extending beyond local markets eventually. We believe is a product that can make an impact beyond borders. Globalization serves the purpose of introducing our product into the international scene by making it compliant with international standards. The following are the standards that StableWear is going to comply with:

1. ISO 13485:2003
2. ISO 10993

3. IEC 60601-1-11
4. ISO9001: 2008

We would like to see our product be globally accepted, and changing the approach as to how individuals who suffer from hand tremors are treated. By complying with the listed standards we will be able to see our product expand into different markets.

### ***I. End Product Description***

The end product description is a breakdown of the individual modules of StableWear and how they work. This is done at three different levels. Level 0 provides a basic representation of the system, level 1 is a bit more descriptive, and level 2 is the most detailed representation. In its most basic form, StableWear is tremor cancelling device, this can be shown below in figure 1 which shows the level 0 representation of StableWear.

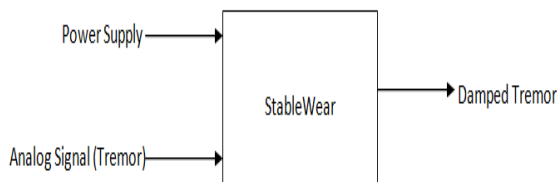


Fig. 1 Level 0 Representation

In general, StableWear is a wearable electronic device which eliminates or mitigates the oscillations caused by tremors in the arm. These tremors are brought on by various strains of imbalances in the nervous system. The device is made up of 5 main components; a power supply, a triaxial gyroscope, an analog filter, a BeagleBone

Black microcontroller and a Functional Electrical Stimulation damper.

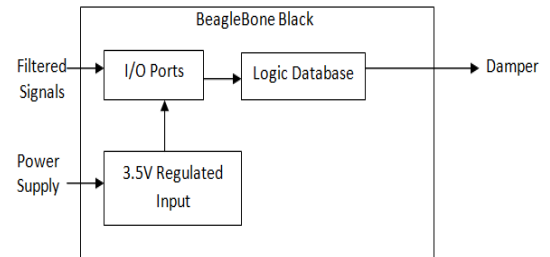


Fig. 2 Level 2 Representation

## **II. PROBLEM STATEMENT**

Patients who suffer from Parkinson's disease (PD), Multiple Sclerosis (MS) or Essential Tremor (ET) and other tremor associated disorders are limited to expensive medication and expensive surgeries or treatment used to try to improve their quality of life. There is currently no cure for any of these diseases. Due to the high cost to of treatment and surgery, many individuals who suffer from these diseases are often left untreated. There are also currently no devices on the market that aide in the total suppression of hand tremors. Usually patients have to purchase a tool for each task that they want to accomplish. For example, many patients who suffer from these disorders often have a special spoon or fork for eating, or custom made pencil or pen for writing. To solve this problem, we have designed, StableWear, which is a wearable device that is capable restoring functionality to the hand. StableWear will eliminate the need for expensive treatment and equipment, and will provide an inexpensive approach to improving the quality of life for those who suffer from hand tremors.

### ***A. Project Objectives***

Our goal is to provide the user with a wearable electronic device which will stabilize any involuntary movements experienced within the arm in order restore basic motor functions. This will aid in helping the user regain a sense of normalcy, and feel comfortable in wearing the device on a daily basis.

#### ***1) Functional***

1. The device should be lightweight.
2. The device should be wearable for extended periods of time.

#### ***2) Marketable***

1. The device should be visually appealing.
2. The device should be comfortable to wear.
3. The device must be affordable.
4. The power of the device should last all day.

#### ***3) Safe***

1. The device should be water resistant.
2. The device should not have sharp edges or any other feature which can cause injury.
3. The device should be well insulated.

#### ***4) User-friendly***

1. User should be able to attach and remove the device themselves.
2. The device material should be resistant to wear and tear.

## ***B. Constraints***

1. Comply with Federal Code of Regulation (CFR) FCC Part 15 testing standard for most electronic devices.
2. The device sale price should be less than \$200.
3. The device will not impair voluntary action with surroundings.

In conclusion, StableWear, serves as a device to facilitate patients that suffer from Parkinson's disease (PD), Multiple Sclerosis (MS) Essential Tremor (ET), and other tremor associated disorders. This device will be wearable and comfortable for the user's convenience, while providing maximum efficiency in tackling the issue of tremor suppression. StableWear will do its function, while still remaining aesthetically pleasing. We plan to revolutionize the field of wearable prosthesis, and to help give patients who suffer from tremor associated disorders a better quality of life.



### III. ASSUMPTIONS AND LIMITATIONS

In this section we will discuss the assumptions and limitations of our project. When developing StableWear, as with many complex wearable systems, assumptions and limitations are key to the success of the design. In regards to an assumption, it is not a physical limit that can be imposed by the client. Assumptions for a project like ours would include; the need for our product in the current market. In regards the limitations, they, on the other hand, are physical limits and are results of things that the team cannot control. Limitations for our project would include the amount of voltage and power that it consumes, the material that is used to design it, and accuracy of the data gathered. The assumption and limitations that we provide in the following section will serve as guidelines as to how our final project will function.

#### *A. Assumptions*

- The device will use active cancellation technology to counteract hand tremors.
- An accelerometer used in the device will be able to measure the excursion of the tremor.
- The device will contain an embedded Linux operating system programmed in C++ programming language.
- The device will be wireless and powered by a rechargeable battery.

#### *B. Limitations*

- The amount of power consumed by the various components will limit the operating time of the battery.
- The processing speed of the microcontroller will limit the functioning of the other components.
- The weight of the device will be inconvenient to patients with insufficient strength.

Knowledge of the assumptions and limitations are essential for final design, and ultimately the success of our project. We are confident that if we keep these objectives in mind, our final project will be steered in the right direction.

## IV. NEEDS FEASIBILITY ANALYSIS

This section focuses on finding the final design and key features of the final product. The information collected from the client and potential users in this section will be used to determine the constraints and limitations of the product. The fundamentals of the device are determined while the Feasibility Analysis determines potential problems which may be experienced.

### *A. Needs Analysis*

Before any new invention or project is implemented, there must exist some unique need or desire for such a device. Before implementation, a series of test and analysis are carried out however, inevitably, the success of such a device will heavily depend upon the interest and demand generated by its characteristics, features and productivity. In order to gain valuable information from potential users, simple surveys will be carried out and the results will be taken into consideration.

#### *1) Client Interview*

One of the main goals of this project is to produce a device which satisfies our client's needs. In an attempt to better serve our client, a short interview was carried out to determine some desirable features as well as to discover any concerns which may exist. Table I shows the results of this interview.

TABLE. I. CLIENT INTERVIEW RESPONSES

Question	Response
1) Have you heard of any similar devices before?	No
2) Would you publicly use a device like this?	Yes
3) Are there any particular features you would like to see incorporated into this device?	Safe, user friendly
4) Would you purchase this device?	Yes
5) How much would a user pay for such a device?	Less than \$200
6) What issues would you consider when purchasing a product like this?	It has to be accurate, safe
7) How great of an impact do you think such a device would have on society?	Very positive affect. Something like this is much needed
8) What do you like most about the project?	It is a very daunting task. I like the hard work the team is putting in
9) What do you like least about the project?	N/A

Table I shows the responses of our client to the provided questionnaire. The client expressed high interest in the StableWear product, stating that he was unaware of any similar devices currently available. This, along with the responses of our User Surveys shows that there is a general interest and demand for such a product. Using this questionnaire the StableWear team was also able to gain insight into some of the features potential users would be interested in seeing being incorporated into such a device. In addition to this, the client was also able to express his financial views pertaining to the product. After the questionnaire it was also determined that safety and accuracy are among the more important requirements for StableWear. Using the information gathered from the client, the StableWear team was able to determine some key features for the device.

## 2) *User Survey*

The StableWear is a wearable arm device which eliminates/minimizes the uncontrollable shaking experienced by persons suffering with Parkinson's disease (PD), Multiple Sclerosis (MS) and Essential Tremor disease. This survey was designed to gain information from potential users in order to better meet their needs and requirements. The information provided through this survey is confidential and will only be used to improve this product. Table II is a summary of the information collected.

TABLE. II SURVEY RESULTS SUMMARY

Question	Results
1) Gender	67% Male
2) Age	33% < 30, 22% 31-50, 29% 51-70, 16% above 70
3) After reading the above description, how interested are you in this product?	86% were Very Interested
4) Would you purchase this product?	89% said Yes
5) If yes, how much would you spend on this device?	54% said \$100-200
6) Are you or anyone you know affected by Parkinson's or Essential Tremor Disease?	43% said Yes
7) If yes, on a scale of 1 to 10, how bad are the arm's tremors? (1 being barely noticeable & 10 being immobilizing)	Average answer was 3

Table II shows summarization of all the related information gathered from the User Survey.

### 3) *Brainstorming*

After the initial client and user interviews, the group met in an effort to review the collected information and assess the feedback received. While brainstorming we focused on four main areas where we felt problems could arise; these were the device's design, process, the materials used for this project and its overall marketability. This can be seen in figure 3.

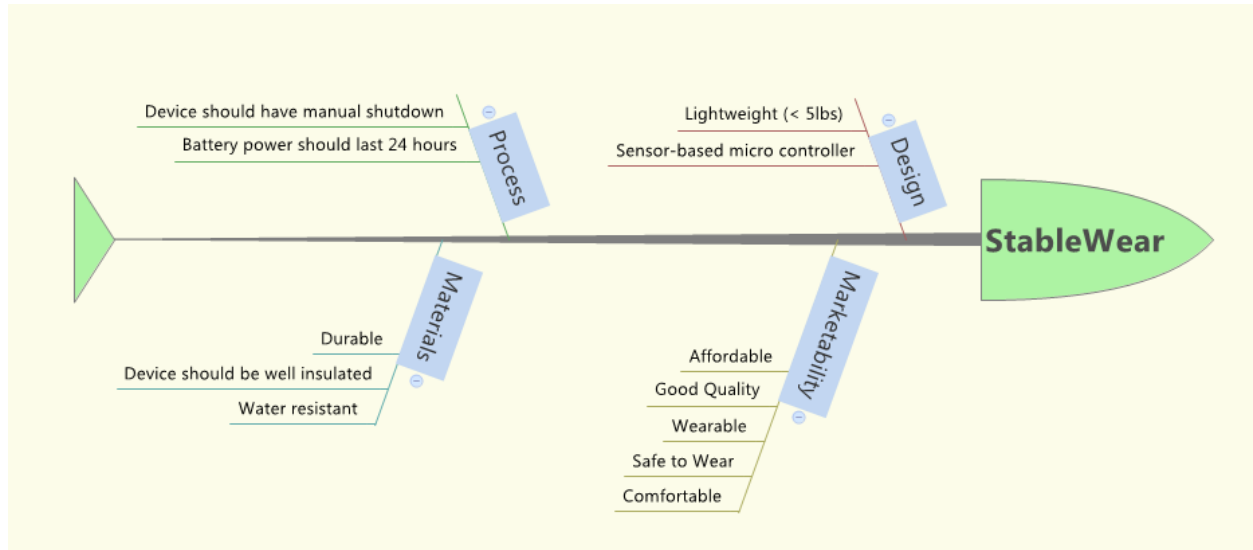


Fig. 3 Fishbone Diagram

Firstly, as a wearable device, it is essential that the product is lightweight and comfortable to wear. It should not hinder movement whatsoever; in fact it should do quite the opposite. In addition to this, the device must be safe to wear; there should be no danger of electrical shock or burns. Next, we looked at the device's expected processes. It was decided that there should exist some precautionary manual shut-down switch for when the device is not in use and in the case of emergencies. Also, the device should be able to function at least 24 hours without losing power. Thirdly, the materials used to produce this device should be durable. It should be resistant to water and a poor conductor of electricity. Moreover, the device should be of a high quality while maintaining an affordable price.

After, the team attempted to integrate the desires of the clients and users, as well as our own concerns. The following table of objectives was developed as a result of this process. The constraints and implementations for each objective were discussed and the necessary changes and improvements were made to the device's design.

TABLE. III SUGGESTED ATTRIBUTES &amp; OBJECTIVES

Source	Attribute	
Team	Device should be lightweight	Functional
Team	Device should be water resistant	Safe
Team	Device material should be resistant to wear & tear	Durable
Users	Device should be visually appealing	Marketable
Users	Device must be affordable	Marketable
Client	Device should be comfortable to wear	Marketable
Team	Device should be wearable for extended periods of time	Functional
Client	Device should not have sharp edges or any other feature which can cause injury	Safe
Client	Users should be able to attach device themselves	User friendly
Team	Device should be well insulated	Safe
Team	Power should last all day	Marketable

In summation, it can be seen that the majority of the project's information was gathered in this section. The information collected from the client and potential users were integrated with the team's desired characteristics to come up with a final list of objectives. A list of constraints were also developed using the information gathered in this section. As a result of this, the team was able to gain a better understanding of the desired requirements and modify the project's characteristics to better suit the users' needs.

After our analysis of the issue at hand, we found that there are no medical devices on the current market that are aimed towards the suppression of tremors as a whole. Many products on the market only serve for one function, thus many patients with tremors have to use different devices for each function or task that they are trying to accomplish. At StableWear we aim to provide an inexpensive wearable device that will be able to accommodate any task that the user

requires. This will eliminate the need for individuals to purchase numerous single-purpose devices to accomplish different tasks.

### ***B. Needs Specification***

In this section we will attempt to translate all the information gathered from the users and clients into more specific technical terms. We will also attempt to set constraints and limitations for each aspect of the device.

TABLE. IV NEED SPECIFICATION

Objectives	Engineering requirements	Justification
2	Low powered battery ( $\leq 9$ Volts)	Device must be quiet and not generate a lot of heat.
3,4	The skeleton of the device should be plastic	Device should be as light as feasibly possible in order to avoid mobility hindrance
1,3	Accelerometers and gyroscopes will be used	These sensors will accurately detect hand movements
<b>Marketing Requirements</b> <ol style="list-style-type: none"> <li>1. Device should be accurate</li> <li>2. Device should have a low output power</li> <li>3. Device must be lightweight</li> <li>4. Device should be low priced</li> </ol>		

Table IV shows the needs specifications of StableWear. In this table you can see the engineering requirements and the justification as to why the product needs these requirements.

In conclusion, it can be seen that the initial technical specifications of the device were determined in this section. Justification was provided for each specification and a summary of the results can be seen in the table above.

### ***C. Feasibility Analysis***

Upwards of 60,000 people are diagnosed with Parkinson's' disease in the United States. It is estimated that 10 million people in the United States suffer from Essential Tremor. Both conditions, affect the elderly and the youth, and are accompanied with tremors and stiffness in the limbs. In the early stages, Tremors cause a shaking or oscillating movement in the hands when the muscle is relaxed. The medical and engineering fields have both produced treatment such as medication and instruments to help patients cope with these conditions. The problem with these treatments is that they are irreversible and very costly on the patient. We have decided to develop a device with the potential to change the difficulties of those who suffer from tremors in their hand. The intention is to minimize the tremors with a device attached to the hand; therefore partially allowing use of the motor skills.

It is a challenge to implement an idea for a device to suppress tremors in the hand due to what is currently available on the market. The goal for our project is to create a new device in the industry. We are aware that the work that will be implemented is substantial for a project with this much potential. In accordance with our stated goals and potential challenges, the following feasibility analysis will recognize the technical, resource and economic aspects that may conflict with delivering the project. Information is key to understanding the cultural, legal, and market influence that this project may impose on those willing to use it. Research in the aspects of each topic in the feasibility analysis will assist us in understanding if this project is possible, and deliverable in the time being assessed.

#### ***1) Technical***

For the targeted project there is a limited known technology to implement in the device we seek to innovate. Technology for assistive devices is narrowed to set limited functions. Extensive research is required to develop a prototype that could potentially meet the set goal. The system requires an innovation that could be implemented into an all-purpose wearable usage device. The general goal is to create a system that can assist patients with tremors into being able to accomplish daily tasks with minimal difficulties in the process.

This wearable device has to be flexible and durable, it will be user friendly and highly manageable so that the user is independently self-strapping the wearable. Once the device is placed in the hand of the user, it can be set on and off at will to preserve battery usage. As long as the wearable is on it can counteract the involuntary tremors affecting the hand. Motor skills that require precise usage of the hand can be partially restored. After is set off and removed from the hand, it will accessible to be cleaned and recharged daily.

#### ***2) Resource***

Having assessed the demand of the project and the limited resources in regards to similar devices, the project will be challenge to assemble a prototype of unknown characteristics. Yet, there is plenty of technology affordable and ready to be used for prototyping. Designing a wearable has the constraint of size limitation; equipment to build is accessible at a reasonable cost. Our team was built with the intention to have an equally set of skill to achieve the desired outcome. The team is assembled by three electrical engineers, with knowledge of electronic circuits, and two computer engineers to program embedded systems. The team has met the required set of skills to design an electronic device and program the electronic device.

### **3) *Economical***

The budget for the projected prototype is estimated at approximately \$1000. The estimated budget is attainable due to the low cost of electronic components; although it has not been estimated the cost to build a final product available for consumers. Economically the prototype is feasible to produce, the objective is to find sponsor to increase our budget so that we can make more prototypes readily available.

### **4) *Schedule***

The project is scheduled to comply with specific milestones; our group has set it as priority to meet deadlines in a timely manner. There are plenty of group members to advance in time with the project; we have allocated a weekly meeting with progress reports for each individual. Our mentor will allot a meeting with the team every other week for proper guidance and delegation of tasks. The Preliminary Design Review and Critical Design Review has not been met yet, several meetings are required to draw a conclusion. Focused implementation of ideas will lead to concise PDR requirements, thus eventual CDR will be met.

### **5) *Operational***

The sole purpose of the wearable devices is to help those who suffer from hand tremors. This involuntary movement reduces life quality overall, the intent is to restore motor skill partially in the hand. The Wearable will be simple and efficient for regular usage. The operational model for this project is demanding. It will be a challenge to innovate, therefore the project operational risks is high.

### **6) *Cultural***

In recent times society is very conscious in topics that concern with health. Engineering in the field of science has been making an impact, prosthetic limbs, and reproductions of biological hearts are an example of this form of innovation. We believe our project will make an impact in local and global culture. Impairment in the hands causes changes in people drastically, thus rendering that person with limited function ability. Our wearable device will have a positive feedback because of the potential to restore an individual's life.

### **7) *Legal***

Electronic devices that are built for consumers to use have to meet the Federal Code of Regulation (CFR) FCC part 15 common testing standard for most electronic equipment. FCC Part 15 covers as well the technical specifications, administrative requirements and other conditions relating to the marketing of FCC Part 15 devices. Depending on the type of the equipment, verification, declaration of conformity, or certification is the process for FCC Part 15 compliance. Also recognition of similar devices has to be done before hand to prevent violation of patent infringements. The device will be solely built for the purpose mentioned.

### **8) *Market***

We have concluded that our product belongs in the market of needed items. We were able to categorize our product based on the perspective of the capabilities it will be built to accomplish. The potential to expand into a market solely relies on the benefits it will bring to society; our



product is intended to be a new breakthrough in the health industry. Our wearable device satisfies necessities for the targeted demographic; therefore they will support the device by purchasing it for themselves. We have knowledge of the need of such device after surveying that specific demographic we want to target. The positive feedback received leads us to a conclusion of a feasible project.

Although our surveys make our project feasible, we analyze the project using a rubric of possible and realistic measures. During this process we analyze different situations that might arise immediately or in the future that could put our project in jeopardy. Based on the survey, and using the rubrics specified in the table below, our project has an intermediate probability of completion.

TABLE. V TECHNICAL FEASIBILITY

Attribute	Score	Why?	Solution
Technical Feasibility			
Are there any technical limitations available?	2	Technology not available yet.	Search for solutions in other areas that deal with tremors.
Are new innovations required?	2	The project is different in several aspects from other projects.	Research and test every feasible idea.
Total	4		
Average	2		

TABLE. VI RESOURCE FEASIBILITY

Attribute	Score	Why?	Solution
Resource Feasibility			
Does the team have the skills required?	3	Basic knowledge in programming and electronics	Acquire more knowledge in designated topics for each area.
Team effort	4	Delegate task and complete them by team deadlines.	Team members will be held accountable for their progress toward the project.
Total	7		
Average	3.5		

TABLE. VII ECONOMIC FEASIBILITY

Attribute	Score	Why?	Solution
Economic Feasibility			
Project feasibility given resource limitation.	4	Cost of a prototype might not be substantial.	A small prototype does not require huge expenses.
Can we receive the necessary funding?	5	Many resources are needed.	Funds can be collected from team members and possible sponsor(s).
Total	9		
Average	4.5		

TABLE. VIII SCHEDULE FEASIBILITY

Attribute	Score	Why?	Solution
Schedule Feasibility			
Can we comply with set milestones?	3	Possible delay in implementing ideas	Dedicate more time to complete milestones.
Can we complete PDR	2	Is a wearable device, size constraints are substantial	Designate more time to achieve goals.
Total	5		
Average	2.5		

TABLE. IX CULTURAL FEASIBILITY

Attribute	Score	Why?	Solution
Cultural Feasibility			
Will our project have a strong cultural impact?	5	Technology in the medical field is highly regarded.	Positive feedback has been received from mentors and peers.
Total	5		
Average	5		

TABLE. X LEGAL FEASIBILITY

Attribute	Score	Why?	Solution
Legal Feasibility			
Possible regulation that can limit the project?	4	It is a project that does not portray as a potential hazard.	Need to comply with FCC standards.
Patent Infringement	4	The project cannot infringe on other patents.	Research on related ideas to ensure non infringement.
Total	8		
Average	4		

TABLE. XI MARKET FEASIBILITY

Attribute	Score	Why?	Solution
Market Feasibility			
Will companies or population invest in the product?	5	Devices that help with health related problems are in high demand.	Display the project to companies for possible subsidization to customers.
Is it a needed or wanted product?	5	Product is needed in the health industry.	Surveys conclude that this item is needed in the industry.
Total	10		
Average	5		

TABLE. XII FEASIBILITY ANALYSIS TABLE

	Technical	Resource	Economic	Schedule	Cultural	Legal	Marketing	G. Mean	Weighted
Technical	1.00	5.00	3.00	5.00	3.00	0.33	0.33	2.52381	0.25024
Resource	0.20	1.00	3.00	1.00	0.33	1.00	1.00	1.07619	0.10670
Economic	0.33	0.33	1.00	1.00	1.00	1.00	0.33	0.71429	0.07082
Schedule	0.20	1.00	1.00	1.00	0.33	1.00	1.00	0.79048	0.07838
Cultural	0.33	3.00	1.00	3.00	1.00	0.20	1.00	1.36190	0.13503
Legal	3.00	1.00	1.00	1.00	5.00	1.00	0.33	1.76190	0.17469
Marketing	3.00	1.00	3.00	1.00	1.00	3.00	1.00	1.85714	0.18414
Total								10.08571	1.00000

1 = Equal      3 = Moderate      5 = Strong      7 = Very Strong      9 = Extreme

TABLE. XIII WEIGHTED SCALE

Attribute	Weight	Score	W. Score
Technical	0.25024	2	0.50048
Resource	0.10670	3.5	0.37345
Economic	0.07082	4.5	0.31869
Schedule	0.07838	2.5	0.19595
Cultural	0.13503	5	0.67515
Legal	0.17469	4	0.69876
Marketing	0.18414	5	0.92070
Total	1	26.5	3.68318
Weighted Average			3.68318

In this section, we have explained how feasible our project is. There are eight aspects of our feasibility analysis: technical, resource, economic, schedule, operational, cultural, legal, and market. Each subsection in our feasibility analysis has an impact as to how we will approach the design of our project. Each section in the feasibility analysis were analyzed to see the potential risk of an unforeseen problem happening, how important that risk will be towards the completion of the project and also providing solutions towards these risk. Scores were tabulated for each section based on importance. Table XIII, provides the weighted scale of all the feasibility aspects of our project. Throughout this process we have concluded that our project is feasible.

#### ***D. Marketability***

More than 50,000 American's are diagnosed with Parkinson's disease each year. This disease is more common in older people, with most cases occurring after the age of 50. At present, there is no cure for Parkinson's; therefore the symptoms are not reversible. Treatments are available yet with limited efficiency among the Parkinson's symptoms. The wearable medical device market is growing at a compound annual growth rate of 16.4 percent a year, according to a Transparency Market Research report. Technology is transforming the health industry gradually, seeing the potential; the federal government and venture capitalists are channeling funds into the health industry like never seen before. We plan to introduce a project that will make a breakthrough in the health industry. We look forward to work with the health care system and programs to subsidize our product to make highly affordable to consumers.

This wearable has a high potential of success because of the target audience. People who suffer from tremor related diseases such as Parkinson's sometime require care from someone else for certain tasks because it decreases the functionality of basic motor skills.

Our product has a broad usability, by not restricting the usage to limited items. The market is substantial with very few competitors competing in it. According to the projections, the population age 65 and older is expected to more than double between 2012 and 2060, from 43.1 million to 92.0 million. Given the above-mentioned statistics our product can cover a market that has a high potential to be exploited.

Currently most of the products that help with tremors by producing items with extra weight added to the items. We have researched the market for a wearable that can help with hand tremors, and have only found one that partially helps with the usability of certain household utensils. This device requires for separate attachments to be purchased and somewhat limited to certain operations. Our product is relatively different in functionality; it intends to help with the hand usability, not limiting the product to certain items. The user will experience the partial stabilization of the hand motor skill. Our product will have higher purpose functionality, thus increasing the interest from people.

## **V. RISK ANALYSIS**

The StableWear project dares to go where no other hand tremor suppression orthosis has gone before. We hope that our product will give the user a better experience and overall quality of life when compared to the other devices that are currently on the market. We understand that the completion of the StableWear project is a very ambitious goal. In order to accomplish this goal, there are certain risks that need to be considered. We will identify each risk and categorize them in order to determine the likelihood of them happening. The likelihood of these risk occurring could hinder the progress and completion of the project. This section serves to provide insight on certain risk that we have identified as critical towards to success of our project.

### ***A. Risk Summaries***

There are many things that may happen throughout the course of the completion of the project. If these unforeseen events are not handled effectively, they may lead to the incompletion of the project. The following are some of the risk that we would like to give special attention to.

#### ***1) Technical***

The technical aspects of StableWear need to be taken into consideration to enable the completion of the project. Technical concerns such as, whether or not the technology is available to complete our goal is of prime concern. We also have to take into consideration that our technical approach may not solve the problem.

#### ***2) Resources***

The stability of the team is very critical to the completion of the project. The unforeseen loss of a team member will cause an unbalance in the anticipated workload for the project. Team knowledge in Control Systems and Digital Signal Processing is also critical.

#### ***3) Economic***

A risk that we are likely to come into contact with is the cost of the equipment needed to develop our product. Many of the components are available on the current market for competitive prices. Our lack of funding may inhibit the completion of the project.

#### ***4) Schedule***

Scheduling is one of the biggest factors that can affect the success of StableWear. It is one of the most important factors that will determine whether or not we complete the project on time. The project spans over three consecutive semesters hence the influence of vacation and availability over the summer is a risk to take into consideration. Team member availability is also an important factor; we will need to meet on a regular basis in order to meet certain milestones towards the completion of the project.

### **5) *Legal***

We have found many previous products that use technology that we would like to implement in our final product. Therefore, patent infringement is a major issue. Also there are FDA regulations that must be observed when developing medical orthotics.

### **6) *Marketing***

One risk that we have to take into consideration is marketing. Our ability to market StableWear will be used to measure how successful it will be compared to other products. Marketing risk include the product being too expensive to sell or manufacture, and no interest in the current market for the product.

A Fault-Tree Analysis was done in order to categorize the level of risk associated with each of the topics in the risk summaries section. A color-coded system was used to indicate the severity of each risk. The colors were used as follows; red for catastrophic, yellow for severe, white for moderate, and green for low. Catastrophic and severe events would greatly influence the incompleteness of the project is not dealt with effectively, while moderate and low events are easily manageable and aren't likely to cause the incompleteness of the project. Apart from being categorized by colors, these risks were also categorized into classes based on the likelihood of the risk happening and how the team will deal with them based on whether or not they pass a certain threshold. The classes are as follows; Class I, represents risks that are below the risk acceptance threshold and do not require active management, Class II, represents risks that lie on the risk acceptance threshold and require active monitoring, Class III, represents risks that exceed the risk acceptance threshold and require proactive management, and Class IV represent risks that significantly exceed the risk acceptance threshold and urgent and immediate attention. The Fault Tree Analysis is shown in figure 4, gives a brief analysis of potential risk under each section that we have chosen for our risk analysis. Table XIV shows the likelihood of the risk occurring while table XV explains the actions that we will be taken should certain risk occur.

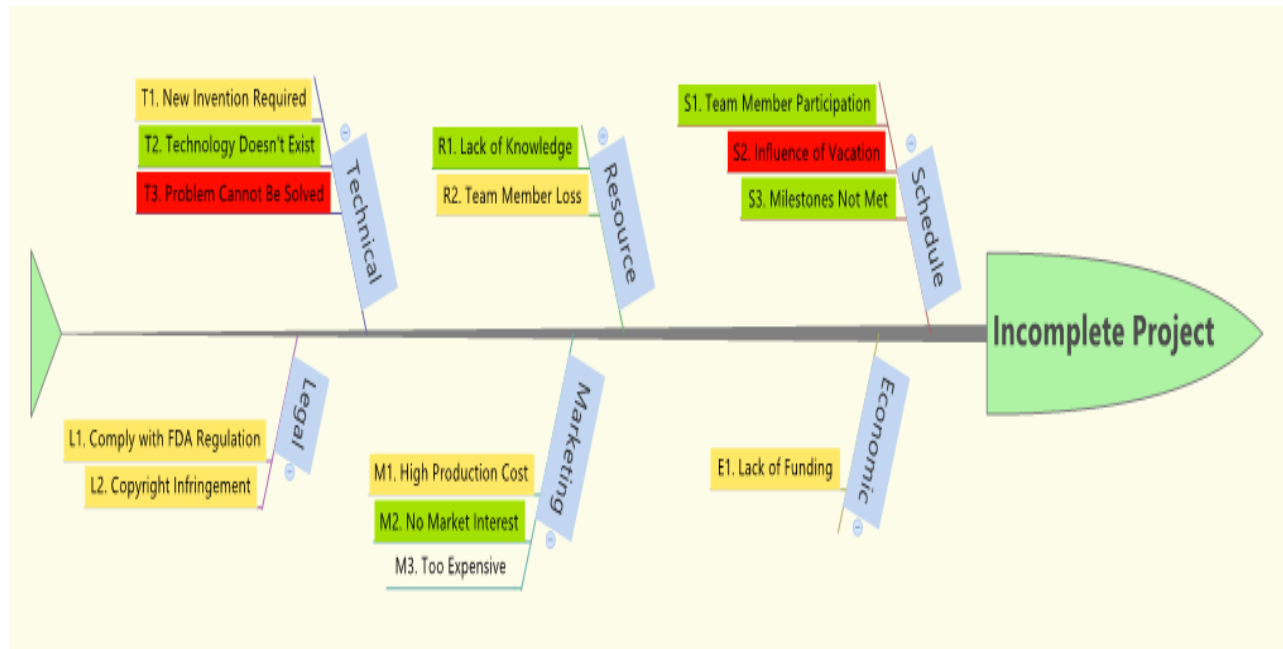


Fig. 4 Risk Analysis Fishbone Diagram

TABLE. XIV RISK ANALYSIS TABLE

		Likelihood of Occurrence			Legend
		Very Likely	Possible	Unlikely	
Undesirable Outcome	Class IV		T3,S2	T1, M1	Catastrophic
	Class III		E1, R2, L1, L2	M3	Severe
	Class II			S3,T2	Moderate
	Class I		R1	S1,M2	Low

Table XIV. shows the possibility of risk occurring, and how each risk may affect our project.

TABLE. XV ACTIONS TO RISK ANALYSIS

Risk	Actions
R1, S1,M2	Group must actively participate in research on how to make the product more marketable and to learn skills that are key to the development of the project
T3, S2	Group must dedicate more time research on problem solving, and members will be assigned task over the summer break.
E1	Group must raise sufficient funds per month through fundraising or find a sponsor
L1,L2,R2	Group must research on existing patents to avoid copyright infringement
T1, M1	Group must research on a more cost efficient way to deliver the final product
M3	None
S3, T2	Group must dedicate more time to the project

Table XV. shows the actions that will be taken in the case of a certain risk occurring.

In conclusion, we have found possible risks that have a potential of happening during our project and possible solutions to resolve them. Each risk was classified into classes and color-coded based on how we felt they would hinder our progress. We also defined our plan of action as to how we would deal with these risks, should they occur. Identifying these risks is critical for the success of StableWear. We hope that our methods of handling these risks are effective, and that any unforeseen risk that was not listed above, will not hinder the completion of StableWear.



## **VI. OPERATING ENVIRONMENT**

The location of operation for the hand tremor cancelling device, StableWear, is very important to its design specifications. Since the device is intended for human contact and use, important factors, including safety, convenience, and ergonomics will be considered in its design. The device's operating environment will influence the following design parameters:

### ***A. Ergonomics***

Anthropometric data must be collected and applied to the product. This data will affect the size, shape, and form of the product and thus make it ergonomic, to the benefit of the user. Since the product is intended for users middle-aged to elderly, the ergonomic design will not contain any sharp or pointy edges in order to prevent further injury to the user in case of an accidental fall while wearing the product.

### ***B. Noise***

Noise from components like actuators and other dynamic loads can be inconvenient to users. This is why minimizing StableWear's mechanical and electrical noise and ensuring it operates as quietly as possible is important.

### ***C. Water Resistance***

The device is expected to come into contact with water or operate in humid conditions. In order to prevent device failure and/or user injury, the product design should be somewhat water resistant. This will be accomplished by properly and safely enclosing all electronic and mechanical components.

### ***D. Temperature***

Due to its wearable attribute and proximity to human skin, it is crucial that all device components operate at a safe temperature. Ensuring the device will operate within a safe temperature range and the proper placement of its battery will help prevent system failure and/or user injury. StableWear must maintain stable operations between -20 °C and 45°C.

In conclusion, StableWear has the potential for great success. Keeping these goals in mind we hope to deliver a product that will meet these specifications. We are fully aware that obstacles may occur in the process of trying to achieve these goals, but we are dedicated to overcome all challenges in order to deliver the best and most efficient product possible.

## **VII. INTENDED USER(S) AND INTENDED USE(S)**

StableWear is a tremor suppression orthosis that will be designed to stop involuntary hand tremors. This section will consist of an in depth analysis of the intended users and used for StableWear.

### ***A. Intended User***

Essential Tremor and Parkinson's disease together affect nearly 13 million people in the United States. A lot of these people experience uncontrollable hand tremors which can dramatically worsen during periods of high stress or as they're purposely trying to achieve a specific task using their hands. Our product is intended to be utilized by these patients. Due to the product's ergonomic and user-friendly design, it is intended for people of all demographics, including both genders and all ages, including the elderly. It will improve their quality of life.

Parkinson's disease and Essential Tremor affects the nerve cells in the brain that produce dopamine and one of the main problems is that this disease can't be cured. The chemical or genetic trigger that starts the cell death process in dopamine neurons is the main subject of intense scientific study. Almost 200 years after Parkinson's was first discovered and after many new discoveries about biology of the disease, only a few projects had come out with a solution to help those suffering from tremors, one of the primary motor symptoms of this disease.

The team found that hand tremors are affecting a growing number of people of all ages, including 66 percent of military veterans. It is the team's purpose that it could help improve the quality of life for senior citizens, military veterans and many others in the community who must deal every day with the debilitating effects of hands tremors.

### ***B. Intended Use***

This device is intended to be used to reduce the tremors associated with the upper limbs. It is intended to be used by patients who suffer from Parkinson's disease, Essential Tremor, and other tremor related diseases. This device will serve to help these patients to become less reliant on other prosthesis that only serve for one function, also it will enable patients motor skills to return to normal function, and stability.

Our project focuses on movement symptoms and how to develop solutions for people affected by hand tremors, giving them the opportunity of using this device to perform day to day activities at a normal speed like dressing, grab objects, drink without spill or at least reduce by 80-90 percent the amount of content spilled from a cup.

By reducing the amplitude of tremors through damping, people will also improve at their regular work activities, which is really important considering that Parkinson's symptoms like

tremors obligates people to be unable to work ,even to do anything at home. The device is not intended to be use in any way to cure this disease, since is a treatable disease but not possible to remove from the human system.

In conclusion, our team decided to tackle the issue of hand tremor suppression to improve the quality of life of those who suffer from tremor associated disorders. StableWear will be designed to meet this goal.

## VIII. BACKGROUND

This section will consist of an analysis of three projects that were similar to our topic. We will describe them, and provide a review on the technology and how it is related to our goals and also a picture so that you will be able to see the direction in where we would like to go with our design. Two of these projects were developed to suppress tremors, in order to help make life easier for patients who suffer Parkinson's disease (PD) Multiple Sclerosis (MS) and Essential Tremor (ET). The Mouse Glove project is an exception to the suppression of tremors; we used this project as a visual representation as to how our final product may look, and also due to the fact that it involves a lot of programming related to the motion of the hand.

### A. *Glove Mouse*

"The Mouse Glove is a wireless computer pointing device with accelerometer based movement control. [This] implementation allows the user to wear a set of hardware and control a cursor through different hand orientations and finger presses [14]." This project and product was developed in 2014 by two Senior Electrical and Computer Engineering students at Cornell University; Adam Shih, and Hyodong Lee.

#### 1) *Project Summary*

The Mouse Glove allows users to operate their computers with their hands in free motion. This helps to alleviate from the hassle of wires and being limited to a desk. This project was very convenient to the field of technology; a lot of companies such as Logitech and Dell are now producing wireless mice, but the market has not yet seen a hands-free wireless mouse glove. The Mouse Glove is microcontroller based, which improves the way how the user interacts with the computer. This project was inspired a previous project on a sign language glove, which would sense the hand gestures and map form a sign language alphabet to a standard English alphabet.

#### 2) *Technology Review*

The design of this system consists of two main parts; a Glove and a Base Station. The Base Station consist of an AT90USB1286 microcontroller mounted on a Teensy ++ 2.0 board and a wireless transceiver. The Glove unit consists of an Atmega1284 microcontroller mounted onto a custom printed circuit board (PCB) and a transceiver. This microcontroller contains several single-channel analog-to-digital converters (ADC). Connected to the glove's microcontroller are 5 contact pads, a 3-axis accelerometer, 3 different colored LEDs, and 4 pins of an 8-pin DIP switch. Both of the device's transceivers operate between 902 and 928 MHz. As shown in figure 5, the device is powered by a single 9 Volt Battery.

#### 3) *System Description*

The Glove is where the operation of the device begins. It senses the user action via two types of Sensors; the Accelerometer and finger contact pads [14]. The Accelerometer, an essential component in this device, is used to measure the hand tilt and orientation. A user wearing the glove

can use his/her hand tilt movements and finger presses in order to operate it. Once the user initiates movement, the glove unit microcontroller, which is on the arm of the user, processes the input data from the glove. It then relays a message to a transceiver also mounted on the glove unit. This transceiver then transmits a wireless message to another transceiver mounted on the base station. The Base Station microcontrollers receive input data from the glove unit's wireless transceiver. This communication is processed via a universal asynchronous receiver/transmitter (UART). The receiving transceiver on the base station then forwards a message to the base station microcontroller. This microcontroller's analog to digital converter (ADC) converts the tilt voltage into digital bits. In the Final step; the microcontroller converts the message into a computer Human Interface Device (HID) user friendly format and enables the computer cursor to conduct the specified action. The device's logical block diagram is shown in figure 6.

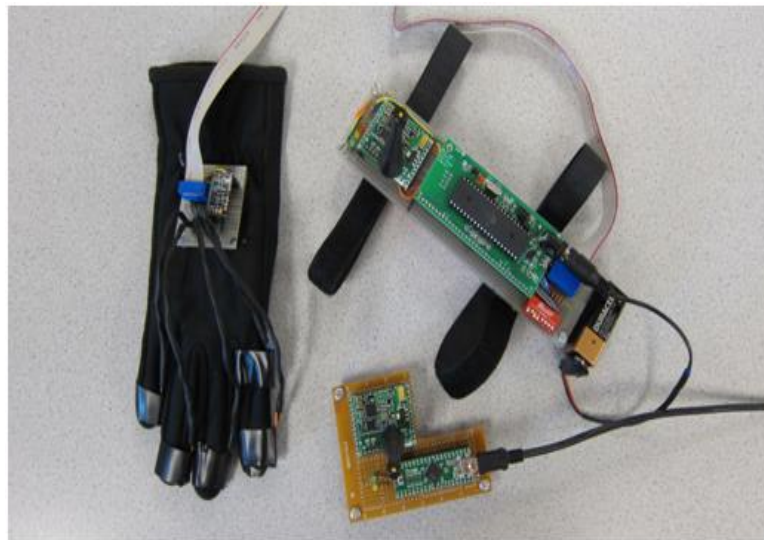


Fig. 5 Glove Mouse Finished Prototype [14]

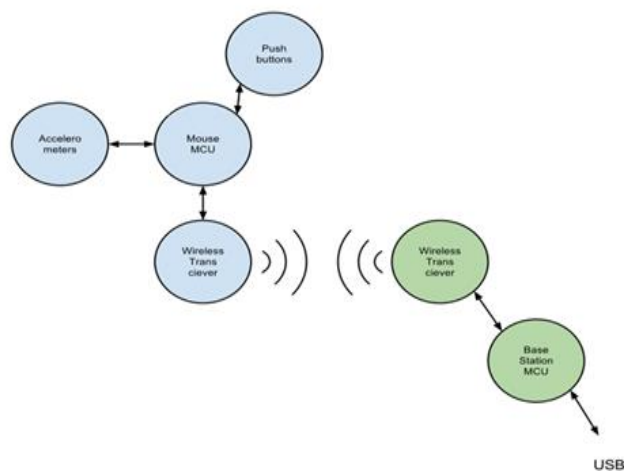


Fig. 6 Glove Mouse Logical Block Diagram [14]

## ***B. Micron: Microsurgical Tremor Cancellation***

Micron is an instrument that actively cancels hand tremor during eye microsurgery or other micro administrations. Its prototype was in part designed by Robert MacLachlan, Brian Becker, Jaime Cuevas Tabares, Gregg Podnar, Louis Lobes, and Cameron Riviere at Carnegie Mellon University and reported in February 2012 [11].

### ***1) Project Summary***

The Micron handheld tool senses its own motion, distinguishes between voluntary and unintended motion, and cancels out this unintended motion by actuating its tip, or point of contact. It is made up of three major systems; the handpiece, an optical position tracker, and supporting electronics. These components allow for hand tremors to be properly detected, filtered, and suppressed.

### ***2) Technology Review***

As shown in figure 7, the main components consist of the handpiece, optical tracking system, custom driver and signal conditioning electronics, data acquisition cards, and a PC running LabVIEW control software. The Micron handpiece weighs 40g and is composed of the manipulator as well as the position measurement components. Part of these components are infrared LEDs. These LEDs send out light with longer wavelengths than visible light. The optical tracking system consists of two position-sensitive-detector (PSD) cameras, signal conditioning electronics, infrared light-emitting diodes (IR LEDs), and an LED driver. A position sensitive detector (PSD) can measure a position of a light spot in one or two-dimensions on a sensor surface. The PSD cameras are made up of a PSD, a lens which focuses infrared light onto the PSD, and a long-pass infrared filter to reduce interference like ambient light.

### ***3) System Description***

As previously mentioned, the handpiece contains the piezoelectric manipulator. This manipulator actuates the handpiece tip in order to cancel the hand tremor. Infrared LEDs mounted on the handpiece allow the PSD cameras to track the handpiece position by detecting each LED's position in two degrees of freedom. Having two PSD camera systems allows each LED position to be triangulated in three dimensions. As shown in figure 8, the LED location signals then go through signal conditioning electronics including a bandpass filter. These signal and driver electronics interface all the different components to a controller PC. The tip of the manipulator is fixed when the system is on while the handle is moving to natural hand tremors by the user. Handheld testing by three eye surgeons and three non-surgeons showed a reduction in position error of between 32% and 52%.

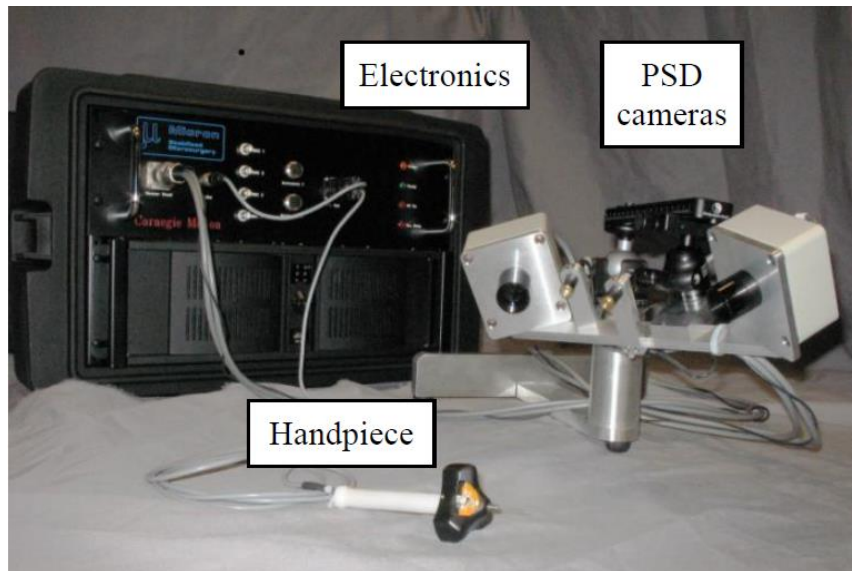


Fig. 7 Illustration of Micron System

Figure 5 shows Micron system, showing tool, position sensors, and electronics, from page 4 of [11]

### System Organization

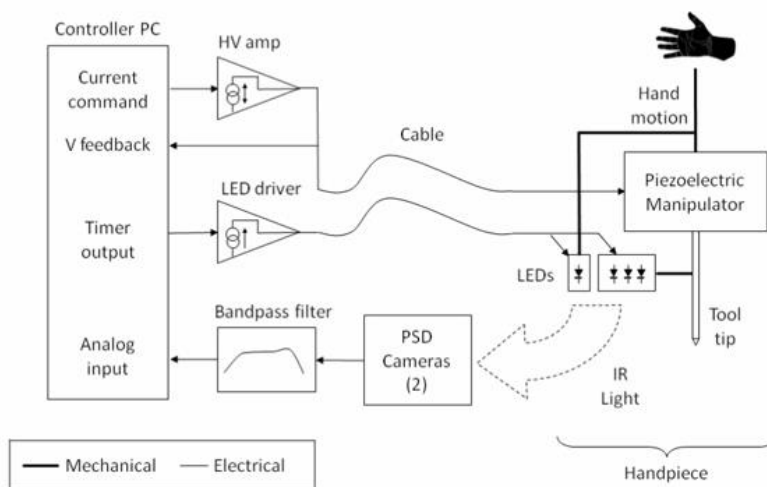


Fig. 8 Micron System Diagram [11]

### ***C. Tremor Quantification via Ambulatory Monitoring System***

This project was accomplished by Arash Salarian, Heike Russmann, Christian Wider, Pierre R. Burkhard, François J. G. Vingerhoets, and Kamiar Aminian at the Swiss Federal Institute of Technology in Lausanne, Switzerland in 2007 [13]. I consisted of two similar ambulatory monitoring systems capable of recording hand tremors through measurement systems containing gyroscopes instead of accelerometers.

#### ***1) Project Summary***

In order to record, or quantify hand tremors associated with Parkinson's disease and Essential Tremor, two ambulatory monitoring systems were designed and tested in two different studies. In each system, two sensor units, consisting of small gyroscopes, were attached to each of the subject's forearms. The system used in the second study allowed data to be measured for longer periods of time and users to wear the device more comfortably.

#### ***2) Technology Review***

The first monitoring system assembled consisted of two sensor units. They weighed 35g each and their range after calibration was  $\pm 1200$  °/s. A portable data logger with 8MB of memory was carried by the user. It featured a sampling rate of 200Hz and a 12-bit resolution of analog to digital conversion. This system was able to record up to 1h 20mins of continuous data.

As shown in part (b) of figure 9, engineers used two Autonomous Sensing Unit Recorders (ASUR) on the second monitoring system. Enclosed in the same device was a data logger, a rechargeable battery, and 64MB of flash memory. Each unit weighed 50g, the range of its sensor was also  $\pm 1200$  °/s, and its sampling rate was also 200Hz. This system was capable of recording up to 14h of continuous data.

#### ***3) System Description***

The first system's sensors were placed on the subject's wrists. As shown in part (a) of figure 9, each sensor included three small uni-axial gyroscopes directed towards the roll, yaw, and pitch directions. The gyroscopes were used to measure angular velocity of the forearm in their respective directions. The second system however, included two gyroscopes directed towards the roll and pitch directions. The third one was removed in order to reduce power consumption. The data logger and sensor diagram is shown in part (c) of figure 9 below.

The angular velocity signals from each gyroscope were analyzed separately. Once separated, each signal would go through a first degree infinite impulse response (IIR) filter with cutoff frequency  $f_c \approx 0.25\text{Hz}$  in order to remove its drift. The amplitude of the hand tremor was calculated by further filtering these signals using a bandpass 280° finite impulse response (FIR) filter with cutoff frequencies at 3.5Hz and 7.5Hz and then taking its root mean square (RMS) value. These cutoff frequencies were selected in order to eliminate readings from movements outside the range of frequencies associated with Parkinson's disease tremors. These filtered hand tremor



signals were saved by a data logger consisting of a microcontroller and flash memory. Both systems' data were then transferred to a PC after recordings for data analysis.

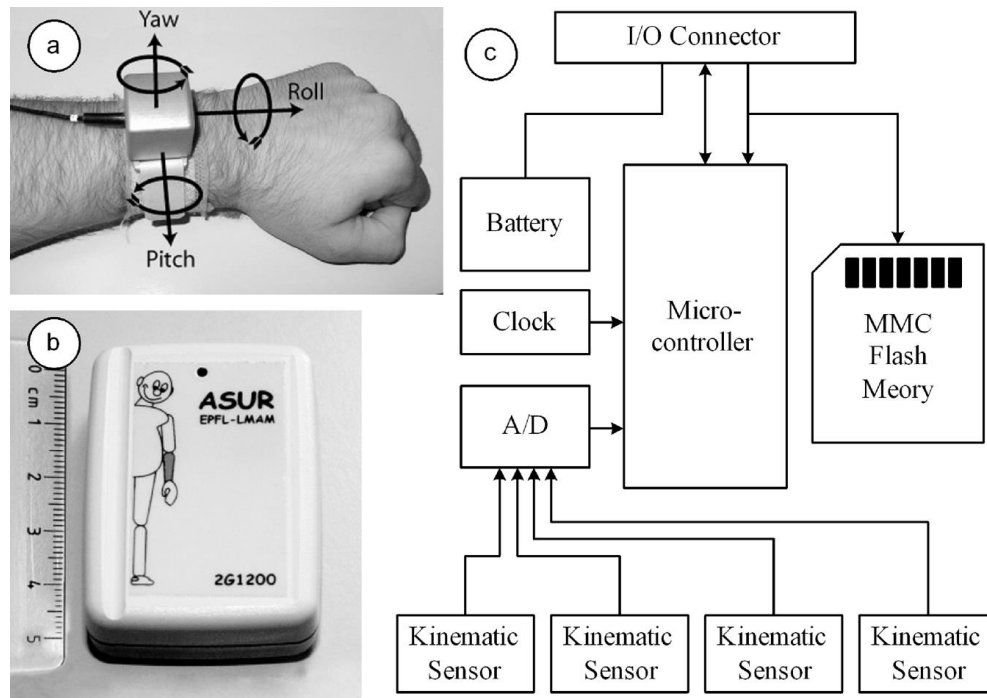


Fig. 9 Illustration of Tremor Quantification Monitoring System

Fig 9. Shows 3-D gyroscopic sensor from first monitoring system (a), Second monitoring system (b), and Block diagram of second monitoring system (c) from page 3 of [13]

Reviewing these projects has increased our knowledge of the existing technology related to both recording/quantifying tremors and suppressing them. They helped introduce us to active cancelling technology as well as the different possible ways of sensing tremors. These projects used accelerometers or gyroscopes in order to sense the movements. Digital signal processing techniques such as control systems containing algorithms would then filter out these sensor signals in order to remove unnecessary and disruptive signal properties. Microcontrollers help piece together all the data and interact with all components, eventually moving actuators to counteract the tremors.

## **IX. INTELLECTUAL PROPERTY**

In this section we will discuss three patents that we believe are very similar to the invention that we are proposing. All three patents have been approved and published by the United States Patent and Trademark Office. We will take an in depth look into each of these patents in order to see what the stated inventions are claiming to perform, and also to prove that our project will not be infringing on any of these patents.

### ***A. Patent 1: US Patent # 20040015116 A1***

“Firm-contact apparel prosthesis for tremor suppression and method of use thereof”

This patent was issued to Charles Handforth on January 22<sup>nd</sup>, 2004 and is described in the following section. [3]

#### ***1) Summary***

This invention defines a wearable tremor suppression prosthesis for patients who suffer from tremors associated with Essential Tremor or Parkinson’s disease. This method of treatment is inexpensive, risk free, non-surgical, and reversible. This firm-contact prosthesis for tremor suppression, as shown in figure 10, is a device for exerting direct sustained circumferential pressure selectively on one or more parts of the body in order to reduce tremors. This prosthesis is comprised of a sleeve, band or combination thereof that applies pressure around a body extremity such as an arm or wrist, but is not limited to any of these parts. This orthotic device is meant to reduce tremor amplitude and is designed to be small enough to be worn under a person’s clothing.

#### ***2) Claims Summaries***

The wearable suppression device is comprised of a band that is made of elastomeric material. This prosthesis is said to be consisted of a band having circumference; wherein said band will provide constant pressure throughout the entire circumference, in which this pressure will suppress the tremors. The device is said to be comprised of two parts that join together to complete one task. One part, consist of a glove connecting from the finger tips to the wrists; and the other a circumferential band that covers the for-arm.

#### ***3) Non Infringement***

We hereby declare that our product is not infringing upon this patent in the following ways; firstly, our invention is going to be comprised of a band controlled by a microcontroller circuit. This project is manually controlled, and involves no electronic or circuit components. Secondly; we have chosen a different approach. This project uses the method of applying pressure to stabilize the tremor movement. Our project will use a control system, programmed via a microcontroller mounted on the arm that will suppress and stabilize the motion of the hand

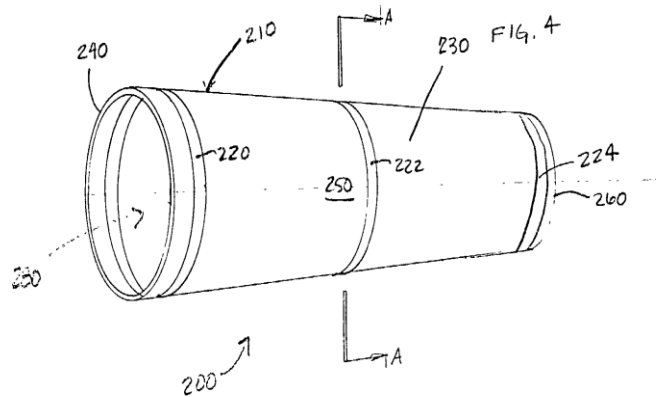


Fig. 10 Illustration of US Patent # 20040015116 A1

Figure 10. Shows a perspective view of the sleeve component of this invention [3]

## ***B. Patent 2: US Patent # 7966074 B2***

“Apparatus and Method Enhancing Muscular Movement”

This patent was issued to Kyu-yong Kim, Sang-youn Kim, and Byung-seok Soh on June 21<sup>st</sup> 2011. [6]

### ***1) Summary***

This patent defines a wearable apparatus that serves to enhance muscular movement. This device involves at least one muscle movement sensor to sense a result of an attempt to move a muscle. When movement is detected, a movement information sensor will analyze the movement. The purpose of this device is to serve as a method or apparatus for muscular movement formed by fibers or pads as clothes, and will recognize similar arrangement as to that of the human muscles causing it to enhance the muscular movement of elderly people who have weak muscular strength. To achieve these goals this invention includes a muscular movement actuator apparatus which also includes an Electro-Active Polymer (EAP) formed as clothing wearable over a surface of a muscle. As shown in figure 11, multiple electrodes will be placed in contact with the opposite lateral sides of the EAP, and then an electrical circuit will be connected to the electrodes, whereby a voltage applied to the electrical circuit causes a deformation of the EAP to enhance a movement of the muscle.

### ***2) Claims Summaries***

This invention consists of a wearable apparatus to enhance muscular movement. This wearable apparatus is to be comprised of at least one muscular movement sensor to sense a result of an initial muscular movement, a muscular movement actuator positioned external to a muscle; and a movement information controller to analyze the sensed result of the muscular movement. A movement actuator is to be mounted on the device. This actuator is to be adapted to enhance the movement of the muscle according to the muscular movement information generated by the movement information controller. This is done by actively controlling a deformation of the muscle movement actuator over the surface of the muscle. The actuator of this device is to include an Electro-Active Polymer (EAP) to enhance the movement of the muscle according to the generated

muscular movement information by actively controlling a deformation of the muscle movement actuator over the surface of the muscle.

### 3) *Non Infringement*

We hereby declare that our product is not infringing upon this patent in the following ways; firstly, our device will use similar wearable design approach, but our device is for detecting and controlling tremors in patients suffering from Parkinson's disease and/or Essential Tremor, by stabilizing the muscle. This device is similar to creating an artificial muscular sleeve to help the elderly enhance their muscular movement. Secondly, our device will incorporate the use of programmable microcontroller circuit in an effort to adapt to different suppression based on the amplitude of the frequency that is received. This device is based on an Electro-Active Polymer system that is reactive based on sensors placed on the polymer.

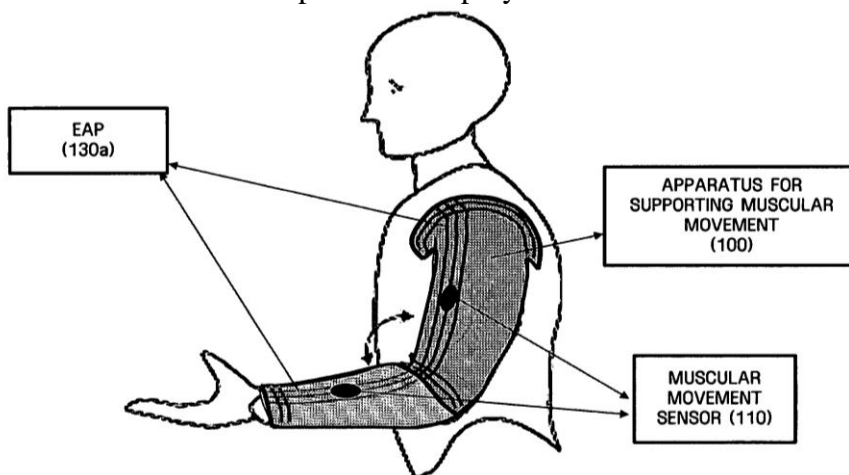


Fig. 11 Illustration of US Patent 7966074 B2

Fig 11. Illustrates the whole design of the invention [6]

### **C. Patent 3: US Patent # 20100174342 A1**

“Tremor Reduction Systems Suitable for Self-application and use in Disabled Patients.”  
This patent was issued to Leon Boston and Gal Ben-David on July 8<sup>th</sup> 2010. [2]

#### 1) *Summary*

This invention defines a bio-electrical device. This system is used as a method for reducing deleterious involuntary tremors in the human body. It seeks to provide an effective apparatus, system and method for reducing tremors at a location on the body by means of closed-loop Functional Electrical Stimulation (FES) device. This will be used on patients that require a reduction of involuntary muscular movements. This invention is described as an independent, highly reliable and accurate system for correcting involuntary movement of a single pair of muscles but may be easily extended to a multiplicity of muscles. The method for tremor suppression will include sensing muscle movements and providing Functional Electrical Stimulation to a muscle, which will be used via an apparatus in communication with the sensor via a band pass filter for filtering a tremor frequency. The muscle movements will be sensed by an accelerometer (MEMS) device.

## 2) *Claims Summaries*

This invention consists of a method for tremor reduction that comprises of sensing tremor movement of at least one part of the body. This will be done by providing Functional Electrical Stimulation to a muscle, generating a FES- muscle response relationship. The feedback from this relationship then tells the circuit what action to take in order to suppress the muscle. The FES circuit is adapted to generate pulses that are modulated by control signals that control contraction of the muscles. The response of the circuit is dependent on the amplitude of the muscles movements; therefore, if the muscle amplitude of the muscle increases it will require stronger muscle suppression from the device.

## 3) *Non Infringement*

We hereby declare that our product is not infringing upon this patent in the following ways; firstly, our device will not include a helmet, which is a part of the closed-loop Functional Electrical Stimulation. This Helmet is used to detect nervous system stimulation from the brain and the spine in order to control muscle movement. Secondly, our device will be operated by means of programmable microcontrollers such as the arduino. This circuit is operated based on a band pass filter. Lastly, our project will be more focused on a smaller wearable device that a patient can use in their everyday lives and in their homes; this project was focused more on a larger medical instrument that is not very comfortable to wear out in public without people noticing it.

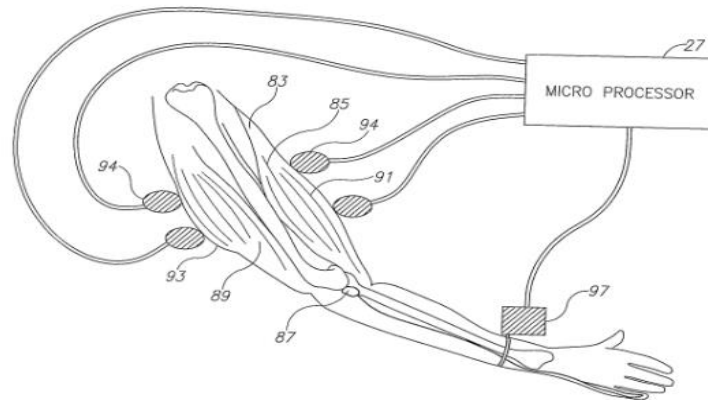


Fig. 12 Illustration 1 of US Patent 20100174340 A1

Fig 12. Shows a simplified illustration of a system for tremor reduction by means of closed-loop functional electrical stimulation, in accordance with an embodiment of the present invention. [2]

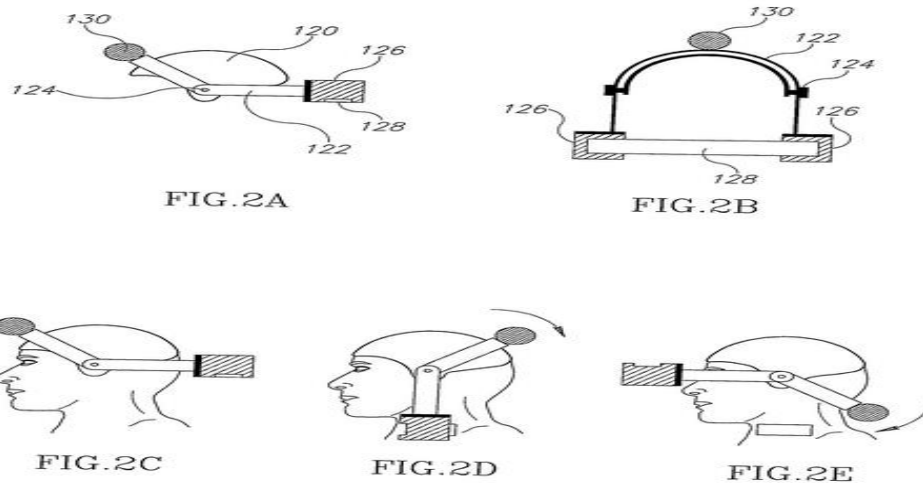


Fig. 13 Illustration 2 of US Patent 20100174340 A1

Fig 13. Shows a simplified illustrations of a system for tremor reduction by means of closed-loop functional electrical stimulation, for use as a helmet, in accordance with an embodiment of the present invention. [2]

In conclusion, all three patents shared a similar approach as to how to deal with the issue of tremor suppression. Extensive research and ideas were viewed in all three patents. In this section we discussed how Patent 1 used a similar approach as to how we want StableWear to look and to operate. We did not infringe on this patent due to the fact that our device will not be based on applying pressure, also it our design will not include a metal glove component, and finally, our product will be circuit based, with a microcontroller mounted on the sleeve, this device is purely manual. Patent 2 was a great idea that was developed in Samsung Labs in South Korea. This idea, is unique to how StableWear is intended to look and operate, but this device is basically and artificial muscular sleeve that takes a different approach as to how to enhance involuntary muscular movement. Finally, Patent 3 was a bio-electrical monitoring system that used a circuit coupled with a bandpass filter connected to feedback from neurological impulses from a helmet. The relationship between the bandpass filter and the information coming from the helmet was used to suppress the involuntary muscular movement. StableWear is intended to use a similar approach, but it will not incorporate a helmet component. StableWear is intended to tackle the issue of tremor, by means of suppression, while making the user feel comfortable and confident about wearing the device.



## **X. STANDARDS CONSIDERATIONS**

In order for a project to be marketable, the integration of world standards must be met. Standards provide minimum requirements, specification, guidelines and characteristics that make an end product consistent with materials, and the purpose that it is intended for. With the application of international standards we can successfully guarantee a product committed to be safe, reliable and of high quality. Our team has decided to incorporate the standards set by the World Trade Organization (WTO), ultimately this addresses business practices for a more efficient manufacturing and economical process. This will facilitate the expansion in to new markets with the help of a global trade. We will abide with local standards required by the Food and Drug Administration (FDA) throughout the development of StableWear. Our team is dedicated to commit to standards that have to be addressed in order for the design of StableWear to abide by the building and safety parameters set by these standards.

### ***A. ISO 13485:2003***

This international standard is set by the International Organization of Standard and is based off the ISO 9001 international standard with specific requirements to meet regulatory needs. This standard, applicable on a voluntary base, was designed in particular for medical device manufacturers; ISO 13485 addresses most or all of the quality system requirements in markets including Europe, Australia, Japan and Canada. The US Food and Drug Administration (FDA) does not formally recognize ISO 13485 certification, but US Good Manufacturing Practices quality system requirements overlap with the standard in many areas. ISO 13485 is also the basis for quality system regulations in other markets such as South Korea and Brazil.

This international standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and regulatory requirements applicable to medical devices and related services. This international standard is specific to organizations providing medical devices, regardless of the type or size of the organization. There are a wide variety of medical devices and some of the particular requirements of this international standard only apply to named groups of medical devices.

The standard sets a criterion for a device applicable in the aid of an individual, it applies to our device since is intended to be used by people suffering from hand tremors. Our device will be attached to the user without any physical perforation

Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used alone or in combination for human beings for one or more of the specific purpose(s) of

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury.
- Investigation, replacement, modification, or support of the anatomy of a physiological process.



One of the goals in the development of StableWear is to successfully comply with international standards for medical devices, therefore with this standard we intend to satisfy the minimum requirements for servicing the medical industry with our product.

## ***B. ISO 10993***

Biological evaluation of medical devices is new to us since we have never developed a wearable before. The acceptability of materials intended for patient contact is classified based on the amount of time that the material is expected to remain in contact with the patient. Ideally, a material that has already been validated for biocompatibility by the manufacturer can be located for use in the patient-contacting areas of your device. If not, ISO 10993 requires the manufacturer of the device to perform biocompatibility testing on the material in question. The device material should not directly or indirectly produce adverse local or systemic effects, be carcinogenic or produce adverse reproductive and developmental effects.

Therefore, evaluation of any new device intended for human use requires data from systematic testing to ensure that the benefits provided by the final product will exceed any potential risks produced by device materials.

We want to be able to develop a device that is compatible with any user, therefore when selecting the appropriate tests for biological evaluation of a medical device we must consider the chemical characteristics of device materials and the nature, degree, frequency and duration of its exposure to the body.

In general, the tests include; acute, sub-chronic and chronic toxicity, irritation to skin, eyes and mucosal surfaces, sensitization, nontoxicity, carcinogenicity, and effects on reproduction including developmental effects. Based on the most influential guideline for biocompatibility, which is the first part of this standard "ISO 10993- Part 1: Evaluation and Testing," this provides a methodology for choosing the proper biological evaluation test programmed for proper material utilization. From here it is possible to determine also which test program to utilize depending on the device category of which there are three: Surface, External Communicating and Implant, and the exposure period of the material: Limited (<24 hours), Prolonged (24 hours to 30 days) and Permanent (>30 days).

The ISO 10993 structure is set up as follows:

1. Evaluation and testing.
2. Animal welfare requirements.
3. Tests for nontoxicity, carcinogenicity and reproductive toxicity.
4. Selection of tests for interactions with blood.
5. Tests for in vitro cytotoxicity.
6. Tests for local effects after implantation.
7. Ethylene oxide sterilization residuals.
8. Clinical investigation of medical devices.
9. Framework for identification and quantification of potential degradation products.
10. Tests for irritation and delayed type hypersensitivity.
11. Tests for systemic toxicity.
12. Sample preparation and reference materials.

13. Identification and quantification of degradation products from polymeric medical devices.
14. Identification and quantification of degradation products from ceramics.
15. Identification and quantification of degradation products from metals and alloys.
16. Toxic kinetic study design for degradation products and leachable.
17. Establishment of allowable limits for leachable substances.
18. Chemical characterization of materials.
19. Physic-chemical, morphological and topographical characterization of materials.
20. Principles and methods for immunotoxicology testing of medical devices.

This standard shares common practices for the materials used in a wearable device that pertain extended usage. The direct skin contact certainly is a factor we must consider for different users; therefore suitable materials must be employed for a wearable that is subject to prolonged usage. StableWear is to be worn at least 8 hours daily; therefore the materials must be consistent with the above-mentioned standards to make it biocompatible with the general user.

### ***C. IEC 60601-1-11***

Since StableWear will be used in the patient's home, two guidance documents apply, they are the International Electrotechnical Commission (IEC) standard 60601-1-11 - Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in Home Care Applications and the Food and Drug Administration's (FDA's) document Draft Guidance for Industry and Food and Drug Administration Staff, and the Design Considerations for Devices Intended for Home Use. These address many of the safety and usability requirements that a wearable device or a system that includes a wearable device will need to comply with.

Regarding electromagnetic compatibility (EMC), wearable medical devices fall into the same category as other devices intended for use at home, and are generally subject to tighter EMC regulations than equipment intended for use in a healthcare facility. The governing standard is IEC 60601-1-2 - General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

IEC 60601-1 applies to all Medical Electrical Equipment and Medical Electrical Systems. Medical Electrical Equipment is defined in the standard as electrical equipment having an applied part or transferring energy to or from the patient or detecting such energy transfer to or from the patient and which is:

- Provided with not more than one connection to a particular supply mains; and
- Intended by its manufacturer to be used: in the diagnosis, treatment, or monitoring of a patient; or for compensation or alleviation of disease, injury or disability.
- This includes a wide range of medical devices, for example:
  - High Frequency Surgical Equipment
  - Cardiac Defibrillators
  - Patient Monitors
  - Therapeutic and Diagnostic Ultrasound Equipment
  - Medical Lasers
  - Patient Ventilators
  - Infant Incubators and Warmers

This standard makes the StableWear consistent with home usage. The wearable design should be wireless and self-contained within a single housing. Device components are wired together to create a system when the device is worn will inevitably cause patient discomfort or disconnect as the wires move on the device components or become tangled in the patient's clothing. The connections between components also create possible failure points.

#### ***D. ISO9001: 2008***

The ISO 9000 family focuses in various aspects of quality management and contains some of ISO's best-known standards. The standards provide guidance and tools for companies and organizations that want to ensure that their products and services consistently meet customer's requirements, and that quality is consistently improved.

There are many standards in the ISO 9000 family, including:

- ISO 9001:2008 - sets out the requirements of a quality management system.
- ISO 9000:2005 - covers the basic concepts and language.
- ISO 9004:2009 - focuses on how to make a quality management system more efficient and effective.
- ISO 19011:2011 - sets out guidance on internal and external audits of quality management systems.

We will introduce a product that endorses the level of quality laid out in this family of standards. We have done our diligence already that orients us in a path to adhere to these quality standards. The ISO 9000 series is based upon 8 principles, which are:

- Principle 1 – Customer focus
- Principle 2 – Leadership
- Principle 3 – Involvement of people
- Principle 4 – Process approach
- Principle 5 – System approach to management
- Principle 6 – Continual improvement
- Principle 7 – Factual approach to decision making
- Principle 8 – Mutually beneficial supplier relationships

We believe that by following these principals written by the International Organization of Standards (ISO) we will be able to complete a successful project, since satisfying many of these principles leads to a higher end product. Continual product improvement will be approached once a prototype has been built and proper funding received. Compliance with standards has the potential to make our product available to work in international grounds. Markets today have increased the expectancy in standards and we will satisfy these needs. In order to compete on this stage, where non-compliable products are easily dismissed, it is extremely important to observe and adhere to accepted international standards. We feel that implementing these standards previously mentioned that we have demonstrated awareness to the current state in the market and furthermore that we are prepared to meet relevant standards that will ensure that our product is viable.

The following are the standards that StableWear is going to comply with:

ISO 13485:2003

ISO 10993

IEC 60601-1-11

ISO9001: 2008

## **XI. GLOBALIZATION**

Our team has set international milestones for StableWear; we have discussed the possibility of extending beyond local markets eventually. We believe is a product that can make an impact beyond borders.

In this section we will discuss globalization. Globalization serves the purpose of introducing our product into the international scene by making it compliant with international standards. Information is key to understand the potential for StableWear to erupt in the global market; the chances of globalizing are high because of the very limited market for medical wearable devices that reduce hand tremors. We have conducted international contact in an effort to get feedback about the need for StableWear in international markets. We were able to do this by surveying reliable international sources; the feedback received was consistent enough for us to draw conclusions into visualizing about a global expansion. Although StableWear has high potential for international outreach, we understand that different countries respond to a different set of rules. Consideration for different norms in each country will be applied and understood in order to make StableWear an appealing product globally.

### ***A. Global Awareness***

In order to design a product that meets standards that can accomplish the ultimate goal of reaching across global barriers, we must incur on globalization. The consequences of not accomplishing international standard rules puts in jeopardy the final design of the project. For an example within the United States we face, an overwhelming, overly burdensome, and sometimes irrelevant Food and Drug Administration (FDA) regulatory process for the most sophisticated new medical devices. Occasional device recalls have caused great political pressure to be placed on the FDA because of their leniency with companies that introduce defective products that harmed patients. The most frequent causes of recalls are isolated lot-related subcomponent failure; manufacturing issues such as operator error, processing error, or in-process contamination; latent hardware or software issues; and packaging or labeling issues. The global trade highly demands projects to comply with its defined set of rules for the project to be marketable; it covers a wide array of nations that have agreed on single purpose for a unified global trade. We must comply with European Conformity (CE) marking to indicate that our product is compliant with European Union (EU) legislation which enables the free movement of products within the European market. By fixing the CE marking to a product, a manufacturer declares, on his sole responsibility, that the product meets all the legal requirements for the CE marking, which means that the product can be sold throughout the European Economic Area.

### ***B. Global Perspective***

As a group we have concluded that locally we have a market to work with. The survey we have conducted before gave us a solid insight in what to expect from a local perspective. The feedback we received was very influential to conclude we have a solid local market. Eventually

the product goals are to reach an international spectrum. To understand briefly if the market and minimum requirements for a product are met, we have interviewed contacts from other countries to give us an insight into what to expect.

As mentioned before we believe in this product will change the lives of those suffering from essential tremors. North America is very open and has high regards for products that improve the lives of those with health difficulties. StableWear needs to be projected beyond local market because tremors affect people worldwide, therefore the next step is to venture into finding possible ways to make StableWear available to global markets.

### ***C. Global Engagement***

Our team took the proper action towards Global Engagement by reaching out to standards rules for production, surveying locals for local markets and international contacts for a global spectrum. To make our product safe and reliable we researched and will work with international and local standards, which are subject to the World Trade Organization (WTO), the Food and Drug Administration (FDA) and the European Conformity (CE) to approve. Our surveys include individuals from different ages that gave substantial feedback of what they expect from our product. As a team we reached beyond borders by contacting friends living in different regions of the globe for an international feedback that makes our product consistent with international standards.

### ***D. World Trade Organization (WTO)***

The organization that establishes settlements between members among the global trade is the World Trade Organization (WTO), they set the set of rules for agreements such as covering goods, services and intellectual property. They spell out the principles of liberalization, and the permitted exceptions. They include individual countries' commitments to lower customs tariffs and other trade barriers, and to open and keep open services markets. They set procedures for settling disputes. The organization makes sure there is trade transparency among nations by making their laws and measures visible. The trade flows are very smooth because the organization efficiency to resolve trade quarrels. Also the trade capacity is substantial; it exerts their technical understanding in developing countries. The cooperation in these developing countries expands the infrastructures and skills in order extend the trade capacity.

Overall the organization the WTO has an extensive outreach in the public so it can create a global awareness of their activities.

### ***E. Eliminating Barriers***

Countries in general have benefited from the openness to trade global, as mentioned before there are always constraints to in the global market. Each country have their own entities looking out after their minimum requirements, the regulations are different in each country. Organizations have enough power to restrict a successful commercialization of a product if it doesn't comply with the standards they have set.

In the United States we face the requirements set by the Food and Drug Administration (FDA), as with our product we have to identify that a medical device is defined by law in the section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the classification, which may be found in the Code of Federal Regulations. This determines the regulatory path and regulatory requirements for medical devices. Aside from federal regulations, we face the barrier of introducing a medical device. The process of introducing new technology is often complicated and depends on consensus between physicians and administrations. Lack of cooperation and exchange of ideas between medical and engineering communities slows development, although certain major teaching institutions have initiated programs to speed innovation and bring new products to market faster. We plan to overcome this barrier by meeting FDA restrictions.

### ***F. Collaboration Tools***

Collaboration between team members is essential for the project completion. It is understood that the whole team will not be available at all times. As a team we use the free tools available to communicate and keep track of each team member progress. We use the wide available WhatsApp application to stay communicated via phone. This application allows the individual to send and receive messages in real time. As long as the team member connects to the internet via a service provider or anywhere Wi-Fi is available it can be very accessible to stay in contact at all times.

Secondly, we use a powerful tool available online from Google called Google Drive, this gives us access to collaborate and view each team member progress. Documents can be uploaded and edited; the system is not limited to computers. Work can be done and edited from tablets and phones. Simultaneous work can be performed from all users at any time. Google Drive makes the team effort more consistent by allowing cooperation from the entire member without the need to schedule meetings.

### ***G. International Contacts***

In order for our product to be successful on a global scale it has to meet the needs and demands of users from international markets. We organized a simple survey that gives an overview of the product to be built; among the questions we have included are those that can identify the demand for the product. We asked if our product would be accepted in their country and we asked for feedback that would make it compatible with their local market.

In order to obtain a very reliable feedback from across the globe and closer places as well, we have sent a small survey to known contacts in several countries. We have reached out to places like Taiwan, Honduras, Spain, and Barbados. Our contacts have been given a spectrum of questions that consider price range, demographics of people living with essential tremors, and accessibility to health care. Our contacts that reviewed our proposed project in Europe rated the project with a high positive feedback. For example Leonel Alfaro, an electronics engineer living in Spain, mentioned that our project objective is interesting as the general public in Europe is very health conscious. He commented that Spain recently won the prize for promoting the rights for people with disabilities that automatically identifies with StableWear as is intended to help those that are limited in functionality by the tremors in the hands.

From Taiwan, Victor Ulluoá commented that given his experience living 5 years there, he understands that our product is very appealing since Taiwan embrace equal rights for those with limited abilities. Victor also mentioned that further research will have to be done in the market, since the numbers are not very conclusive when it comes to measuring how many people suffer from essential tremors given that Taiwan has a lot of rural areas where doctors are not available.

The understanding that we have received from the international contacts has been greatly positive. They have all agreed that our product is beneficial to society, thus making it a product appealing to international commercialization. We can benefit from governments stimulus towards health industries, making StableWear a solid contender towards globalization.



## **XII. HEALTH AND SAFETY**

As with any other wearable electronic, the user's safety is of utmost importance to the StableWear team. As a result, this section is used to ensure that the device complies with all relevant international regulations to produce the safest device possible. In keeping with these regulations it will also ensure that the device is marketable internationally. Each regulation not only ensures the safety of each user but our surrounding environment as well.

The United States Consumer Product Safety Commission (CPSC) was established in 1972 and is the main entity, in the U.S, responsible for protecting the public against unreasonable injury from consumer products. To ensure the safety of our users, as well as our team and the environment, StableWear will strictly comply with all rules specified by the CPSC. By complying with these national standards StableWear will also meet the safety requirements of a number of other countries.

Because our device is a wearable electronic it will be in contact with the user's body, and hence skin, for extended periods of time. As a result, one of the main safety requirements StableWear must meet is that it must not hurt or cause harm to any part of the body. Moreover, the device must not cause irritation or increased levels of discomfort. It's for these reasons that the StableWear team will ensure the use of quality components when manufacturing the device. In addition to this, the sleeve will be made from spandex to maximize comfort and reduce the possibility of irritation. Also, the device will operate at a relatively low power to minimize the heat generated by the components and the rechargeable battery. The components and battery will also be well insulated to prevent the possibility of electrical shock and/or burns.

Another major concern for wearable electronic devices is that of Radio Frequency wave exposure. Many electronics emit RF waves when transmitting information. For years, it has been speculated that extended exposure to such waves could lead to cell damage and even cancer. To avoid this potential risk StableWear will be equipped with Bluetooth technology for any possible information transmissions needed.

As a final means of precaution, the final step will be to gain approval from the US Food and Drug Administration (FDA). Approval from this agency would mean that not only is the device safe for the user but it is safe for the team to produce as well.

In conclusion, it can be seen that the information gathered in this section is of high importance. Not only is it concerned with the safety of our future users but that of the team as well. Safety is one of the most important aspects of any device, whether old or new, and an unsafe device is simply unacceptable.



### **XIII. ENVIRONMENTAL CONSIDERATIONS**

When developing a new device there are several aspects to take into consideration. Not only should the potential human impact be investigated but that of the environment as well. In this section we will investigate StableWear's potential impact on the environment and how any possible negative effects can be avoided. One of the main factors that could impact the environment would be pollution generated from the device's component parts. This is commonly referred to as electronic waste or e-waste. By analyzing the various components to be used, the team developed a plan of action for the proper disposal of all generated waste. After consulting the Restriction of Hazardous Substances Directive (RoHS) it was determined that in order to be in compliance with the RoHS standards components made with high percentages of the following substances should be avoided:

- Mercury
- Cadmium
- Lead
- Polybrominated Biphenyls(PBB)
- Polybrominated Diphenyl Ether(PBDE)
- Hexavalent Chromium

These substances, among others, have been deemed as damaging to the environment and hence, indirectly, to ourselves. By avoiding use of these materials we not only produce a more environmentally friendly device but we also indirectly produce a more human-friendly device. These substances can also pose various health issues if they are in direct contact with exposed skin for extended periods of time. Because of these reason, team StableWear will avoid components which do not meet these specifications.

As a result of being a wearable electronic, StableWear must also adhere to the Hannover Principles. These principles basically state that there should be a respectable balance between technology, nature and humanity. The actions or uses of any of these should not bring harm or distress to any of the other. In addition, as previously mentioned, measures will be put into place for the proper disposal of all StableWear components. This will mitigate the problems caused by improper disposal of electronic components. Additionally, as with compliance of these principles, special attention will also be paid to the manufacturing phase of this project. We as a team will ensure that no, or as minimal as possible, environmental damage occurs as a result of the project's development.

There are many other aspects to take into account when determining the best choice of components when designing any device. There are also many things to take into consideration when it comes to the manufacturing, assembly and disposal of the various materials used to develop the device. To analyze StableWear's environmental impact if brought into manufacturing

the SimPro 7 program will be used to calculate the nominal representation. The program takes the materials being used to produce the device as its inputs. Using these materials it then calculates the impact this device will have on its environment. Figure 14 shows the graphical representation produced by the program SimPro7. Because the SimPro program was only a demo version all of the desired materials were not available, however, using those that were, the graph in figure 14 was produced.

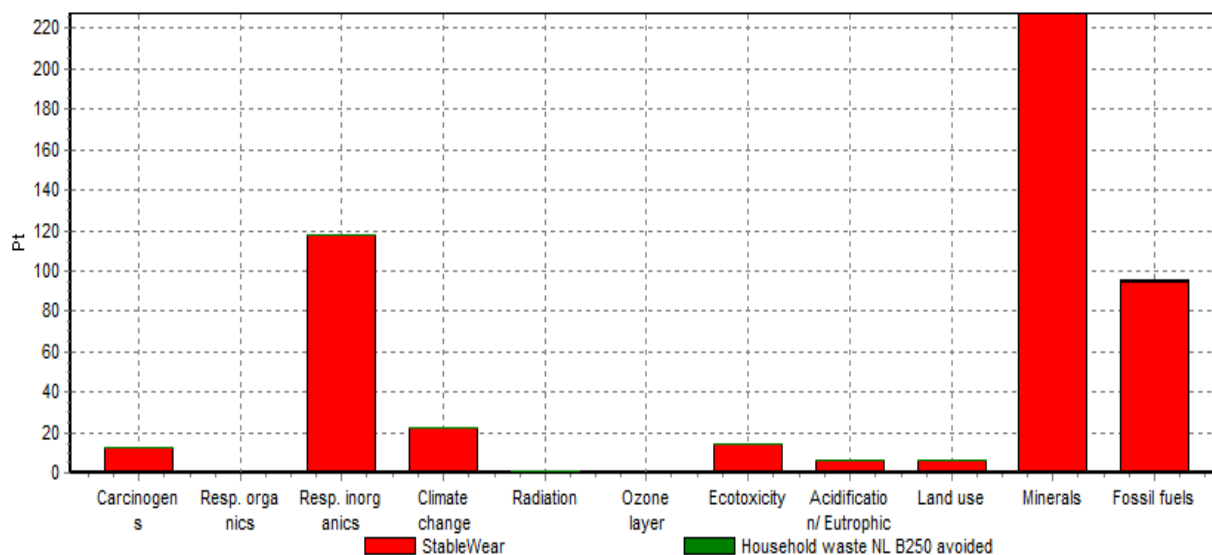


Fig. 14 Graph of Weighted Values of the Enclosure & Packaging for creation, operation and disposal of StableWear

To further describe or explain the previous figure, figure 15 was generated. It shows a more detailed description of the information gathered. The respective quantitative measurements were calculated and the environmental impacts can be gathered from it. The information displayed is a result of a specified lifecycle using 20 grams of Aluminium and 25 grams of Copper. However, one of the main materials being used in StableWear, spandex, was unavailable and therefore could not be analysed.

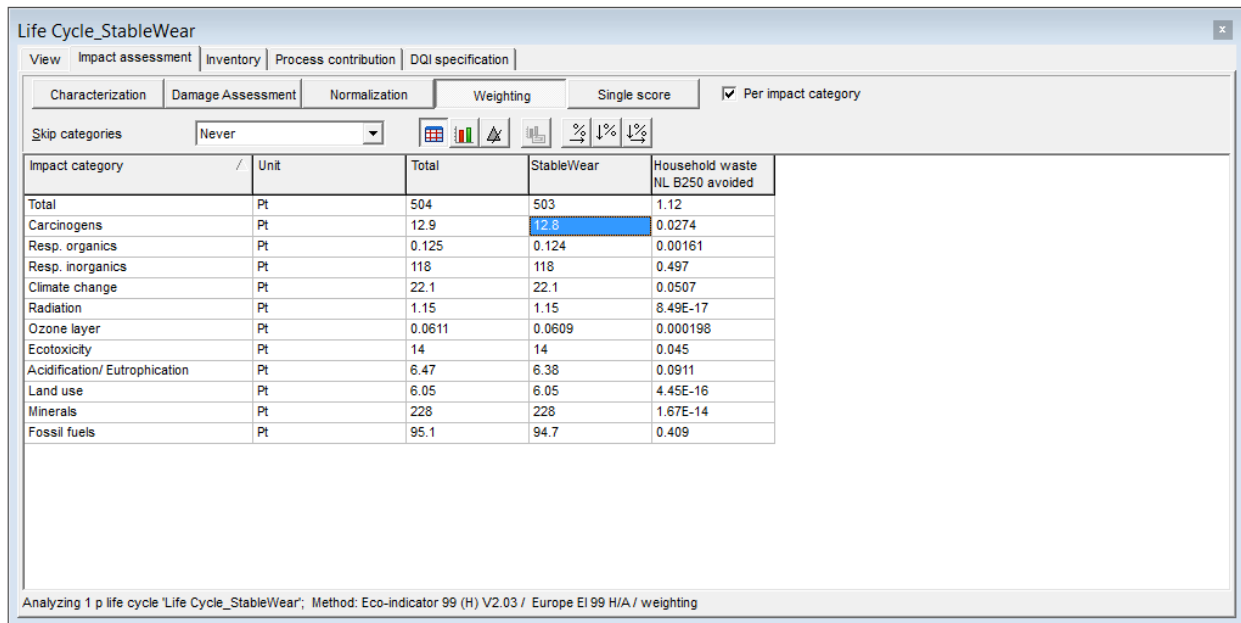


Fig. 15 Detailed Values of Normalized Graph

In conclusion, the results of the SimPro 7 program proved to be very useful. The tool provided the team with a means of comparing various material options in order to determine the best selection for StableWear. Using the information gathered in this section the device's environmental impact was investigated.



## **XIV. SUSTAINABILITY CONSIDERATIONS**

Green Engineering is the design, commercialization, and use of processes and products that are feasible and economical while reducing the generation of pollution at the source and minimizing the risk to human health and the environment. Our team exercises this practice and will continue integrating environmental impact assessment tools to StableWear's design. StableWear's design process also follows the Hannover Principles.

The Hannover principles are a set of statements prepared in 1992 by William McDonough architects and Dr. Michael Braungart [9]. These principles were commissioned by the city of Hannover, Germany at the World's Fair in 2000. They are intended for engineers, product developers, and architects to follow while designing their projects and focus on the projects' environmental impact and their effect on the sustainability of growth.

Our project is in compliance with the Hannover Principles. We will adhere to principles like "Create safe objects of long-term value". This entails not burdening "future generations with requirements for maintenance or vigilant administration of potential danger due to the careless creation of products, processes or standards" [9]. Our team has designed a device which features durable, long-lasting components. These components will work seamlessly, at high efficiency, and will not be subjected to stresses above their design parameters. Moreover, all components used will be RoHS components. This will ensure StableWear is a high-quality, long-lasting device and will not require any constant maintenance or repairs. Another principle we adhere to is to "Eliminate the concept of waste". This means to "evaluate and optimize the full life-cycle of products and processes, to approach the state of natural systems, in which there is no waste" [9]. StableWear will be manufactured using the "lean manufacturing" method. This will allow us to eliminate the seven major types of waste (transport, inventory, motion, waiting, overproduction, over processing, defects) from our manufacturing process.

In conclusion, StableWear features a design created by incorporating environmental and sustainability considerations. We will adhere to the Hannover Principles in order to be conscious of StableWear's environmental impact. Our team will continually refine StableWear's design to minimize use of materials, energy. This will allow our product to fit into the environment harmoniously and with minimum disruption or degradation of natural ecosystems.





## **XV. MANUFACTURABILITY CONSIDERATIONS**

Design for manufacturability is a practice of designing products in such a way that they are easy to manufacture. This practice is imperative to our product because a very high percentage of manufacturing costs are determined by design decisions. The goal of this practice, as well as our team's is for StableWear to be easily and economically manufactured while maintaining a high quality. Our team will carefully consider this practice during the design process by adhering to its principles. More specifically, we will adopt the previously mentioned lean manufacturing method to StableWear. We will especially focus on the following guidelines.

### ***A. Simplify design and reduce number of parts***

Reducing the number of parts used in StableWear is a great way of cutting down manufacturing costs. This has been and will continue to be accomplished by simplify its design. Products featuring fewer parts are easier to build and assemble, require less time, and result in higher quality [2]. Having less parts signifies having less required equipment and inventory space, handling and processing time, purchases, etc. StableWear's design has been improved through the concept selection process and continues to be upgraded. One example of part reduction in its design was removing three single-axis gyroscopes and replacing them by a single three-axis gyroscope. This has simplified our manufacturing process as well as improved our design.

### ***B. Standardize and use common parts and materials***

Standard components are individual parts or components manufactured in very large numbers or quantities. These components are cheaper than custom-built ones and significantly reduce product lead times due to their increased availability. This in turn, helps reduce production delays. Moreover, these parts' high availability makes it easier to replace them in case of a malfunction or design flaw. Having already been through its manufacturer's quality control processes and common knowledge of their reliability will help maintain StableWear's quality at a high level. Stable is and will continue to be designed around these standard components as long as they don't negatively affect any of the project objectives. Lastly, using standard components will make it easier to set up a mass production or assembly line. It is easier to train workers using standard parts than custom ones.

### ***C. Mistake-proof product design and assembly (Poka-Yoke)***

A poka-yoke device is one that prevents incorrect parts from being made or assembled, or easily identifies a flaw or error. It is a lean manufacturing concept introduced by former industrial engineer at Toyota Motor Corporation Shigeo Shingo. This concept ensures that proper conditions exist before actually executing a process step, preventing defects from occurring in the first place. StableWear features this fool-proof design by having only one option in how components and parts

are enclosed. This will eliminate different options, or alternate ways in which an assembly worker can attach components and parts and will therefore help reduce errors. An example of our implementation of this concept is supplying non-polarized components to our electronics configuration when possible.

In conclusion, StableWear has been and is currently being designed for manufacturability. Emphasizing on certain principles will keep manufacturing costs and time at a minimum as well as help maintain a high product quality. Simplifying the design and reducing its number of parts helps reduce cost and waste, and increases quality. Using standard parts and materials instead of custom-built ones helps reduce production delays and makes mass production assembly lines more efficient. Incorporating mistake-proof processes and practices helps reduce human error and maintain our product quality.



## XVI. ETHICAL CONSIDERATIONS AND SOCIAL IMPACT

In this section we will present some of codes in the IEEE Code of Ethics and discuss how our team is in compliance with them. We will then cover ethical dilemmas not necessarily covered by any specific codes and how to go about solving them. We will also analyze StableWear's social impact. This will be done by elaborating on our team's plan to make this device be capable of contributing to both local and global culture.

### A. Ethical Considerations

Ethical considerations, reflections, and actions can make a difference in whether a particular innovation, design, or research finding will help or harm society. Our project, StableWear, will be in compliance with the IEEE Code of Ethics throughout each step of the design process. It is understood that not all ethical issues can be addressed using the Code Model. This is why the Theory Model was used to help solve dilemmas outside the range of the Code Model.

Our team will carefully follow codes such as the first one listed on the IEEE Code of Ethics; "to accept responsibility in making decisions consistent with the safety, health, and welfare of the public, and to disclose promptly factors that might endanger the public or the environment" [4]. This is due to the fact that the safety and welfare of our users will be of outmost importance, especially since they will be largely made up of elderly people. Factors like electromagnetic radiation are important to the safety of our users, therefore we will comply with the Food and Drug Administration, FDA's requirements on radiation-emitting electronic products. Another code, "to be honest and realistic in stating claims or estimates based on available data" [4] will also be significant to our project. Our team will make sure all data, like technical specifications and efficiency, and any claims are verified multiple times before they are stated as facts. We recognize these statements can affect marketing and sales of our project and any discrepancies can misguide our intended users.

Lastly, our team is also in compliance with the code stating "to seek, accept, and offer honest criticism of technical work, to acknowledge and correct errors, and to credit properly the contributions of others" [4]. We are constantly receiving feedback from our mentor and are open to criticism from ourselves as well as individuals outside our group.

Since the Code of Ethics can't address certain ethical dilemmas, a Theory Model, which comprises ethical theories from western philosophy was used. Several options, or solutions to solve each dilemma were derived. These options were evaluated by applying the various theories. The theories are:

- 1) **Utilitarianism:** Option which will generate the greatest benefit (or least amount of harm) to the greatest number of people.
- 2) **Ethical Egoism:** Option which will safeguard and/or promote your own or your organization's best interests.
- 3) **Kantian Ethics:** Option which allows you to be willing to make your decision a rule or policy that you and others in your situation can follow in similar situations in the future.
- 4) **Rights Ethics:** Option which will respect the rights of individuals in society.

This model helped solve a dilemma our team will possibly encounter designing StableWear. The ethical dilemma is our team designing a product that is stylish rather than functional. This entails StableWear having sophisticated looks and feels while having limited or no functionality. This dilemma's possible options and each option's score based on each theory was tabulated in tables XVI & XVII.

Ethical Dilemma: For our ethical dilemma we were concerned if we were building a product that is more Stylish than Functional.

TABLE. XVI STYLE VS FUNCTIONALITY ANALYSIS OF AVAILABE OPTIONS

Option	Description
1	Continue prioritizing style over functionality.
2	Increase product functionality only if customers complain.
3	Prioritize functionality at the expense of style.
4	Prioritize functionality but not at the expense of style.

Table XVI indicates the options for solving our ethical dilemma in developing StableWear.

TABLE. XVII STYLE VS FUNCTIONALITY WEIGHT OF AVAILABLE OPTIONS

Option	Theories				Score
	<i>Utilitarianism</i>	<i>Egoism</i>	<i>Kantian</i>	<i>Rights</i>	
1	0.00	1.00	0.00	0.00	1.00
2	0.25	0.75	0.25	0.25	1.50
3	0.50	0.25	0.50	0.75	2.00
4	1.00	0.00	1.00	1.00	<b>3.00</b>

Table XVII indicates the Theory Model and consists of the tabulated scores based on our options for the Ethical Considerations in the development of StableWear.

Based on the Theory Model scores, option 4 is the best option for the Style vs. Functionality dilemma. This means our best ethical decision is prioritizing functionality but not at the expense of style, as it can be an important factor in the marketing process. Alternatively, choosing option 1 and continuing to prioritize style over functionality is the worst out of the options based on our model.

As engineers of StableWear we are aware of our obligations to society, our clients, and our profession. We must acknowledge, learn, and adhere firmly to the IEEE Code of Ethics. We realize this Code Model comprises general statements of moral principle and serves only as a guide. This is why a more thorough Theory Model will be used when a code does not address a particular situation central to an ethical dilemma.

## ***B. Social Impact***

Essential Tremor has a worldwide presence of 5-39 people for every 1000 across different populations and both Essential Tremor and Parkinson's disease together affect nearly 13 million people in the United States. These staggering numbers are the reason why our team firmly believes StableWear can make both a local and global difference. In order for StableWear to have a positive social impact, our team will become involved locally as well as adopt the strategy "glocalization".

"Think globally, act locally" refers to the idea that global issues can turn into action only by considering our local surroundings. This idea advises people to consider the health of the entire planet and the environment and to make responsible decisions starting in their local communities. Our team will adhere to this concept by giving StableWear a good environmentally-friendly design and developing strong local roots.

StableWear will have a positive impact on local culture through our team's local involvement efforts. Since our ultimate purpose is to help find a cure for Parkinson's disease and Essential Tremor, our team will help raise awareness and funds in our local community and eventually the rest of the country. This will be accomplished by coordinating fundraising events and offering StableWear free of charge to local patients affected by these diseases. This should also be a good business strategy as our team will have the opportunity to showcase our device to prospective patients.

Another way StableWear will help raise awareness of these pathological tremors is by people noticing the device on patients' arms. People who mistook sufferers' uncontrollable shaking for nervousness or having a cold will now realize these people suffer from something much worse.

StableWear will contribute to global culture by applying the strategy of "glocalization". Glocalization is a blend of the terms localization and globalization and refers to the adaptation of a product or service, specifically to each locality or culture in which it is sold [12]. It is important to realize that markets are different around the world. Like McDonald's various menu configurations around the world according to local culture, StableWear will feature different design modifications. Without compromising quality, our device will be modified to best fit the area of the globe in which it will be used.

Due to pathological diseases like Parkinson's and Essential Tremor's indiscriminating wrath, StableWear will need to be able to contribute to both local and global culture. By cementing our roots in the local community, this device will help raise awareness and fund research to create better treatments or a cure. By applying the strategy of glocalization, it will be possible to have a positive social impact on other cultures by modifying StableWear to best fit these communities.



## XVII. CONCEPT DEVELOPMENT

In this section we will explore three different options in which StableWear can be assembled. These options were derived from our team member's existing knowledge as well as new research efforts. We will list each option's pros and cons and score them based on importance in regards to each project objective. The option with the highest weighted score will then be selected for StableWear's design as long as it complies with each project constraint.

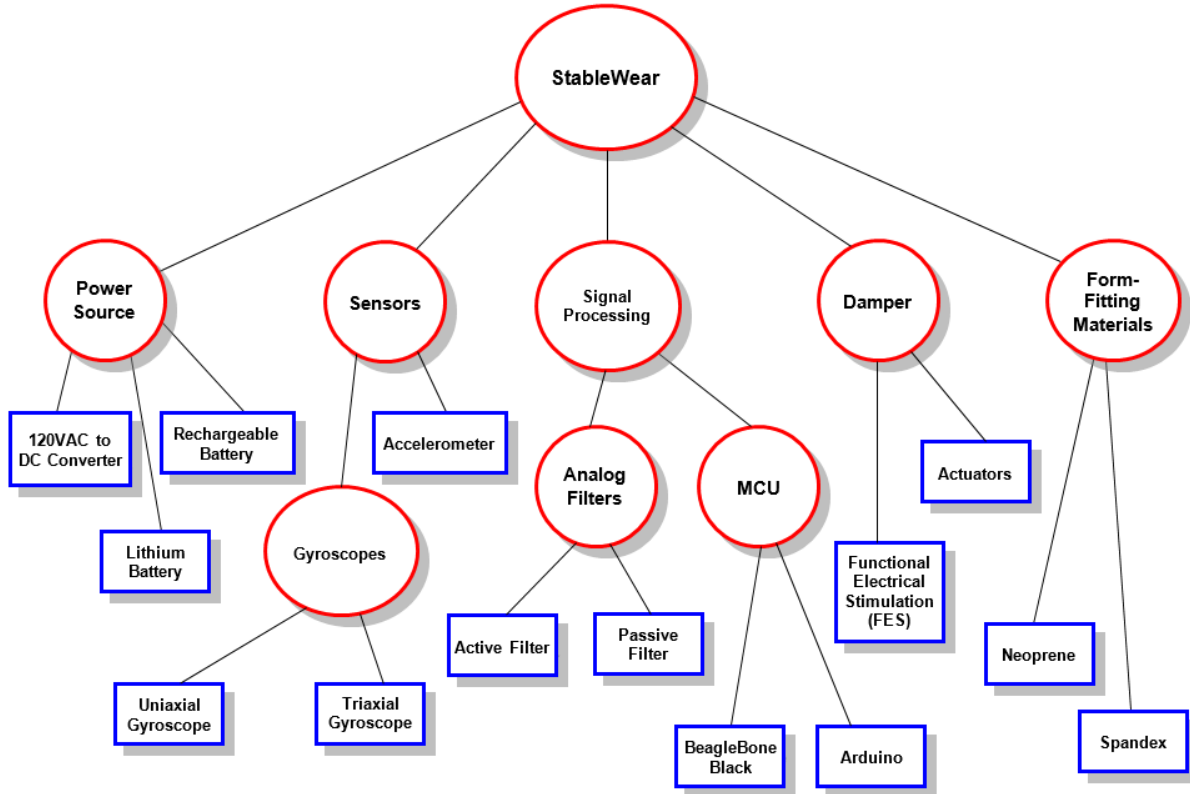


Fig. 16 Concept Fan Diagram

A product concept is a detailed description of an idea. Concept testing is usually used in product development and it is done in order to figure out whether a new product idea works before the product is marketed [15]. It entails the understanding of the dynamics of the product in order to showcase its best qualities and maximum features. Once our team analyzed the project objectives along with the user and client surveys, we researched and discussed possible ways of implementing these ideas. We then became aware of several possible key processes and components for StableWear. These are illustrated in the concept fan diagram in figure 16.



## A. Option 1

The first combination of StableWear's components and processes is illustrated in figure 17 and features a rechargeable battery, a triaxial gyroscope, active filters, a BeagleBone Black microcontroller, a Functional Electrical Stimulator (FES), and spandex material. The rechargeable battery will power all of the device components. A Triaxial gyroscope will measure angular velocity in three axes and allow for accurate recognition of tremors in 3D space. Active filters, or filters using op-amps and transistors, will enable us to cancel out unwanted signal frequencies and allow only frequencies associated with Parkinson's disease and Essential Tremor to be analyzed. The BeagleBone Black microcontroller will interpret data such as tremor signals and activate the damper in order to suppress tremors. The FES unit will stimulate certain muscles on the patient's arm and physically damp the tremors. Finally a sleeve made out of spandex material will cover the patient's arm and provide both support for and protection from the various components.

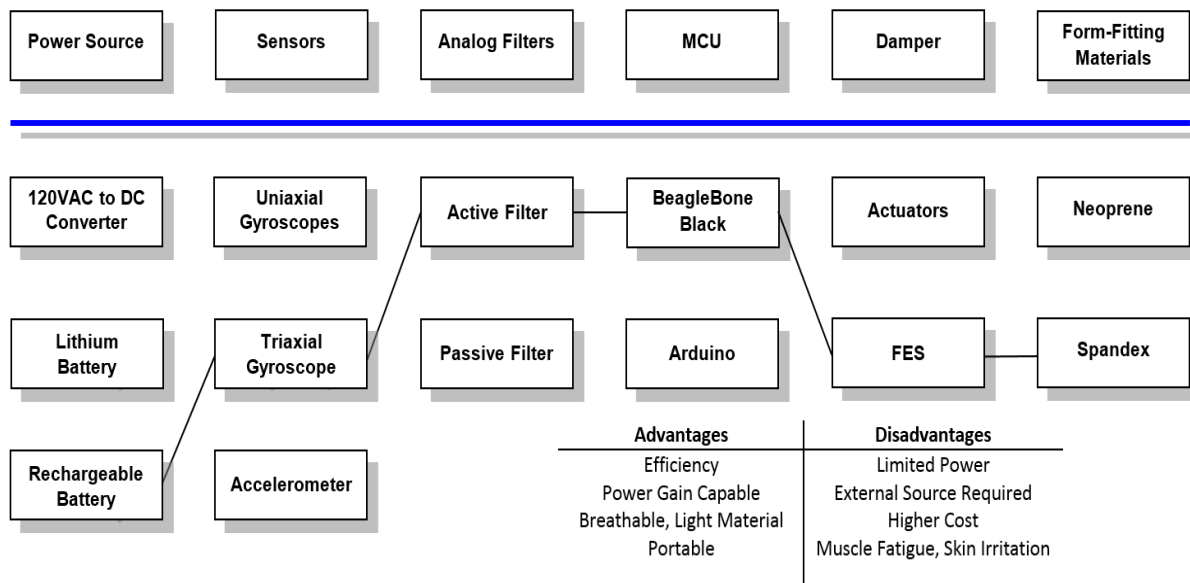


Fig. 17 Option 1

### 1) Advantages

There are several advantages to this option. Using a rechargeable battery will allow StableWear to be portable, an essential feature of the device. Using a triaxial gyroscope instead of multiple uniaxial ones will help consume less power and save space. Active filters instead of passive ones will also improve the power efficiency of the device. These filters are also capable of producing high power gains. Incorporating spandex material on the arm sleeve will have several benefits. Spandex is an excellent breathable, form-fitting material which can stretch up to 500% without tearing or ripping. This will eliminate the tedious task of producing different models of our wearable device to fit different-sized patients.

### 2) Disadvantages

The downside to this specific configuration is evident by a few factors. This device will have limited power to energize all the components because it will be operated by a battery. Passive filters require external power sources which will have to derive from the same battery, further

limiting our power source. This option will carry a high cost because it includes more expensive components used in active filters, the BeagleBone microcontroller, and the FES unit. Lastly, the FES unit can cause muscle fatigue on some people after extended use. It can also irritate the skin at the point of contact.

## B. Option 2

The second option for the interconnections of StableWear is illustrated in figure 18 and features a lithium battery, uniaxial gyroscopes, passive filters, an Arduino microcontroller, actuators, and spandex material. The lithium battery will power all of the device components. Several uniaxial gyroscopes will measure angular velocity in the pitch, roll, and yaw directions and quantify tremor signals. Passive filters, or filters composed of resistors capacitors and inductors, will enable us to cancel out unwanted signal frequencies and allow only frequencies associated with Parkinson's disease and Essential Tremor to be analyzed. An Arduino microcontroller will interpret data such as tremor signals and activate the damper in order to suppress tremors. Actuators located in key places will help damp tremors. A sleeve made out of spandex material will cover the patient's arm and provide both support for and protection from the various components.

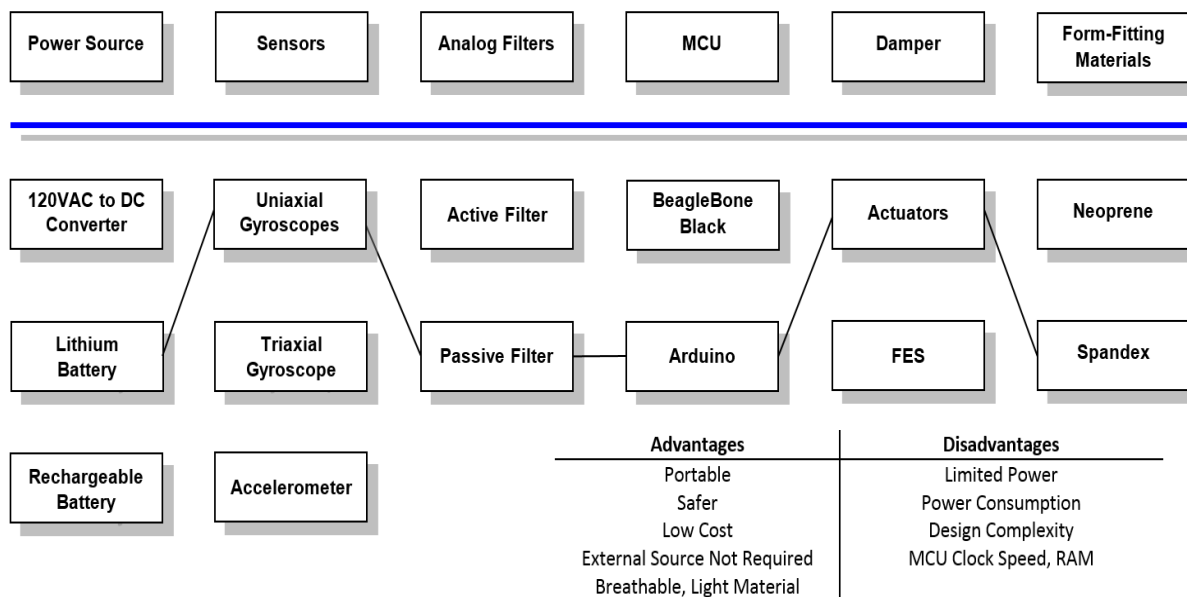


Fig. 18 Option 2

### 1) Advantages

Several advantages to this option exist. Using a lithium battery will allow StableWear to be portable, an essential feature of the device. Having the damper be composed of actuators will be safer as this will eliminate the method of muscle stimulation and the possible hazards associated with it. Implementing components like the Arduino microcontroller, passive filters, and actuators will decrease StableWear's production cost. Passive filters don't require an external source therefore extra energy consumption will be eliminated. Lastly, incorporating spandex material on the arm sleeve will have several benefits. Spandex is an excellent breathable, form-fitting material

which can stretch up to 500% without tearing or ripping. This will eliminate the tedious task of producing different sizes of our wearable device to fit different-sized patients.

## 2) *Disadvantages*

There are also some disadvantages to this option. This device will have limited power to energize all the components because of the battery. Moreover, components like uniaxial gyroscopes, passive filters, and dynamic loads like actuators will consume a large amount of power. Furthermore, incorporating multiple gyroscopes and actuators may complicate our design and make our team face difficult challenges. These components will require additional circuitry and research. Finally, the Arduino microcontroller has a clock speed around 40 times slower than a BeagleBone microcontroller as well as around 128,000 times less RAM. This decrease in processing power can be detrimental to our design.

### A. *Option 3*

The third and last option of StableWear's configuration of components and processes is illustrated in figure 19 and features a 120VAC to DC power source, a triaxial gyroscope, active filters, a Functional Electrical Stimulator (FES), and neoprene material. The 120VAC to DC converter will power all of the device components. A Triaxial gyroscope will measure angular velocity in three axes and allow for accurate recognition of tremors in 3D space. Active filters, or filters using op-amps and transistors, will enable us to cancel out unwanted signal frequencies and allow only frequencies associated with Parkinson's disease and Essential Tremor to be analyzed. A BeagleBone Black microcontroller will interpret data such as tremor signals and activate the damper in order to suppress tremors. The FES unit will stimulate certain muscles on the patient's arm and physically damp the tremors. Lastly, a sleeve made out of neoprene material will cover the patient's arm and provide both support for and protection from the various components.

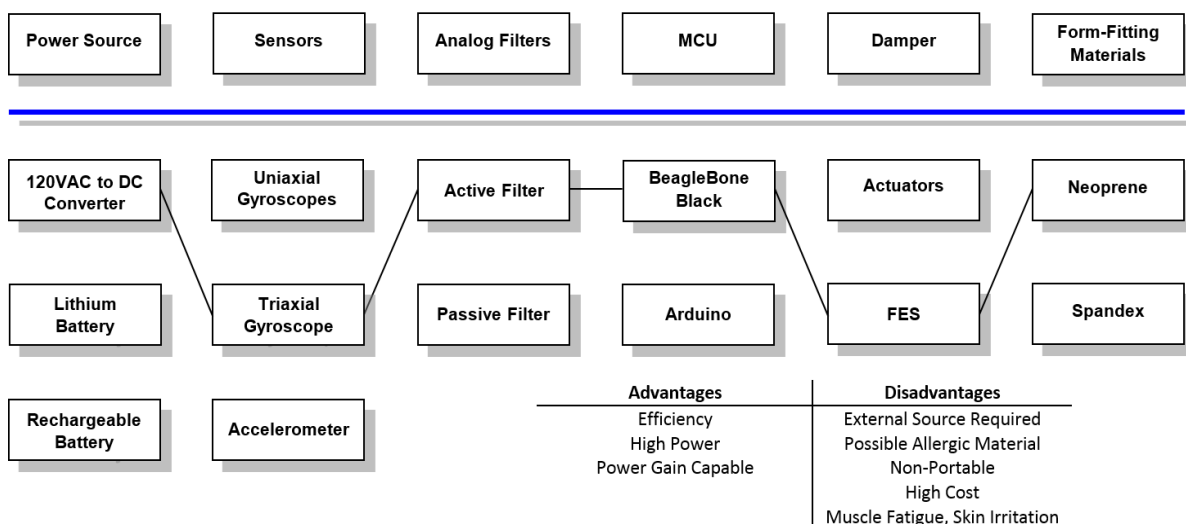


Fig. 19 Option 3

### 1) *Advantages*

This option has three major advantages. Using a triaxial gyroscope instead of multiple uniaxial ones will help consume less power and save space. Active filters instead of passive ones will also improve the power efficiency of the device. These filters are also capable of producing high power gains. On top of component efficiency, an AC to DC wall power source will supply all of StableWear's components allowing our device to have no power limitations.

### 2) *Disadvantages*

This option will feature a good amount of drawbacks. The AC to DC power source will cripple one of StableWear's key features, portability. It will not allow patients to freely wear the device due to the wall plug attachment. Furthermore, neoprene is known to have allergic reactions on some people. This will make our product unsafe to some customers. Production cost will also be a negative factor with this option. The AC to DC converter will require a bridge rectifier circuit along with a transformer, active components for the signal filters, the pricey BeagleBone microcontroller, and the FES unit. Lastly, the FES unit can cause muscle fatigue on some people after extended use. It can also irritate the skin at the point of contact.

## **B. Concept Selection**

Concept selection is the process of evaluating key concepts of your design which will satisfy customer needs and the product's design specifications [10]. It entails comparing the concept's strengths and weakness, evaluating them based on a certain criteria, and selecting one concept for further development or emphasis. The criteria used in StableWear's concept selection process was weight scoring.

The first step in our process was to quantify the importance of our project objectives. This was accomplished by listing them in the manner shown in table XVIII. The scoring scale applied ranged from 1 to 9 with a score of 1 being "equally" important and a score of 9 being "extremely" more important. The scoring was performed by comparing each project objective listed on the rows to each objective listed on the columns. For example, "Functional vs. User-Friendly" received the score of a 7. This means StableWear should be much more functional than user-friendly.

TABLE. XVIII CONCEPT SELECTION

	Functional	Marketable	Safe	User-friendly
Functional	1	5	2	7
Marketable	1/5	1	1/4	6
Safe	1/2	4	1	7
User-friendly	1/7	1/6	1/7	1

**1 = equal      3 = moderate      5 = strong      7 = very strong      9 = extreme**

Secondly, the geometric mean and weighted geometric mean of each of the objective's set of scores was calculated and tabulated in table XIX. The formulas used were:

$$GeometricMean = (A_1 \times A_2 \times \dots \times A_N)^{\frac{1}{N}} \quad Weight = GeometricMean / total \quad (1)$$

TABLE. XIX WEIGHTED CONCEPT SELECTION

	Functional	Marketable	Safe	User-friendly	G. Mean	Weight
Functional	1.00	5.00	2.00	7.00	2.8925	0.50
Marketable	0.20	1.00	0.25	6.00	0.7401	0.13
Safe	0.50	4.00	1.00	7.00	1.9343	0.33
User-friendly	0.1429	0.1667	0.1429	1.00	0.2415	0.04
<b>Total</b>					<b>5.8084</b>	

Lastly, each of the three concepts, or options were scored based on every project objective. This score was then multiplied by the objective weight found in table XIX in order to determine the weighted score. For each option, the weighted score of every objective was added. The option with the highest score was selected for further investigation and analysis as long as it complied with all project constraints. StableWear's scores are tabulated in table XX and clearly show option 1 as the strongest of the choices.

Option 1 featured a rechargeable battery, a triaxial gyroscope, active filters, a BeagleBone Black microcontroller, a Functional Electrical Stimulator (FES), and spandex material. Our team understands that concept selection helps eliminate ideas rather than pick the best. We also realize that our design process is fluid and our device might feature elements found in other, lower scoring options if they prove to be more beneficial or have more desired attributes.

TABLE. XX CONCEPT COMPARISON

Constraints		Option 1		Option 2		Option 3	
Comply with Federal Code of Regulation (CFR) FCC Part 15		Yes		Yes		Yes	
Device should not restrict user's voluntary range of motion		Yes		Yes		Yes	
Device sale price should be less than \$500		Yes		Yes		Yes	
Objectives	Weight	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
Functional	0.50	5	2.50	3	1.50	5	2.50
Marketable	0.13	5	0.65	4	0.52	3	0.39
Safe	0.33	4	1.32	5	1.65	4	1.32
User-friendly	0.04	5	0.20	4	0.16	3	0.12
<b>Total</b>			<b>4.67</b>		<b>3.83</b>		<b>4.33</b>

In conclusion, during the concept development process of our project design, our team researched and listed alternative choices for each of StableWear's key processes and components. Out of these choices, three main options, or concepts, were selected to be score based on their pros and cons. This allowed us to choose a dominant option. Although our final design concept might feature attributes from other options, this option will be selected for further investigation and testing and will be more thoroughly analyzed and explained in the end product description.

## **XVIII. END PRODUCT DESCRIPTION AND OTHER DELIVERABLE**

This section provides a detailed description of the final product. Block diagrams aid in describing the functionality of the system. These block diagrams exist in three levels; each displaying a different degree of detail. This section also introduces the other deliverables for this project.

### ***A. End Product Description***

The end product description is a breakdown of the individual modules of StableWear and how they work. This is done at three different levels. Level 0 provides a basic representation of the system, level 1 is a bit more descriptive, and level 2 is the most detailed representation.

In general, StableWear is a wearable electronic device which eliminates or mitigates the oscillations caused by tremors in the arm. These tremors are brought on by various strains of Essential Tremor Disease. The device is made up of 5 main components; a power supply, a triaxial gyroscope, an analog filter, a BeagleBone Black microcontroller and a Functional Electrical Stimulation damper. A description and function of each device will be provided in the subsequent subsection.

### ***B. Functions***

This section describes the functionalities of each component of the StableWear system. Each increasing level provides a more detailed description of the product's components and how they work together.

#### ***1) Level 0 Functionality Diagram***

This Level 0 representation provides the most simplistic view of the product. It shows the system's inputs as well as the output function of the system.

Figure 20 shows the main functions of StableWear. The system requires an input power supply as well as the analog signal generated by the arm's tremors. According to the magnitude of the tremor signals recorded, the system produces a signal to counteract the shaking in real-time. The output produced is the suppressed tremor. Table XXI shows the device's functions in a summarized fashion.

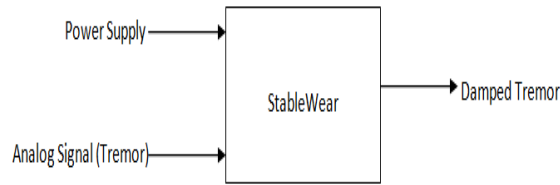


Fig. 20 Level 0 Representation

TABLE. XXI LEVEL 0 REPRESENTATION

Module	StableWear
Inputs	-Analog Input Frequency: Tremor/Arm Movement -DC Power
Outputs	-Damped Tremor
Functionality	Results in real-time tremor suppression using Functional Electrical Stimulation

## 2) Level 1 Functionality Diagram

Level 1 Representations provide a more detailed view of the StableWear system. It shows the main components used in the system and the flow of data through the system for each module. Figure 21 shows the simple flow of information through the StableWear system. A 9V rechargeable battery will be used to provide power to the components of the entire device. The analog oscillations produced by the shaking arm will be the input signals to the triaxial gyroscope. These oscillation readings are then broken down into their composite readings and produced as an output of this component. This information is then sent from the gyroscope to active analog filters. The analog filter then deciphers the wanted from the unwanted oscillation frequencies and passes the desirable information onto the BeagleBone Black microcontroller. Tremors brought on by Essential Tremors typically produce oscillations 3Hz-12Hz therefore oscillations outside of this targeted range are ignored. The microcontroller then processes this information and sends the relevant output to the damper component. Depending upon the input received from the microcontroller the Functional Electrical Simulation dampening system will output a small electrical shock to counteract the incoming tremor signals. The intensity of this shock will depend upon the magnitude of the incoming tremor signals.

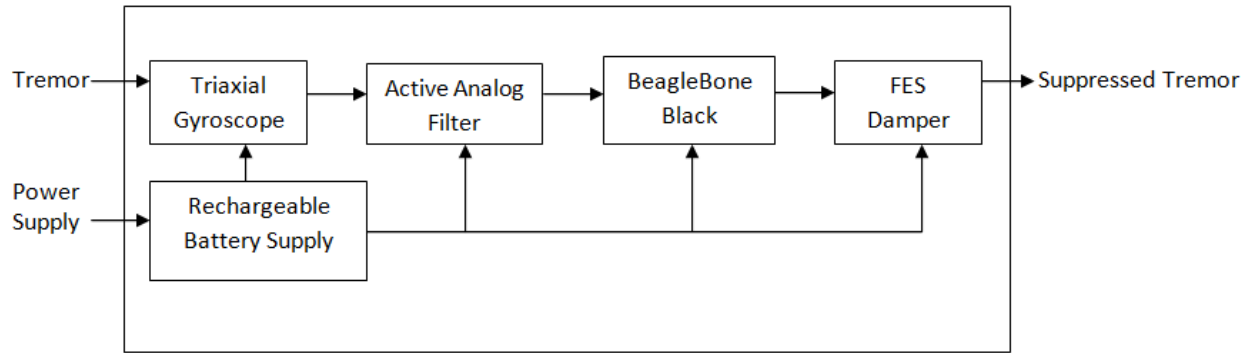


Fig. 21 Level 1 Representation of StableWear

TABLE. XXII LEVEL 1 FUNCTIONALITIES

Module	Triaxial Gyroscope	Filter	BeagleBone Black	FES Damper
Inputs	-Analog tremor signal -5V Power	-Data from Gyroscope -Power	Oscillations between 3-12Hz -Power	-Signal from microcontroller -Power
Outputs	-Oscillation readings	-Oscillations within the 3-12Hz range	Logical signal to FES	-Small electrical pulse
Functions	-Analyses the frequencies of the arm's tremor	-Gets rid of the undesired input signals -Ignores signals lesser than 3Hz and more than 12Hz	-Processes the oscillations -Activates FES	-Produces a small electrical current to target area which stimulates nerves and reduces tremor

### 3) Level 2 Functionality Diagram

Level 2 diagrams provide the most information about the device. Each module is explained in separate block diagrams with a description of all related inputs and outputs. Additionally, the function of each specific component is given.

Figure 22 shows the Level 2 block representation of the Triaxial Gyroscope. The gyroscope takes direct input from the tremors of the affected arm in. These analog input signals are then processed in real-time by the component transducers. These transducers determine the orientation and magnitude of each oscillation along 3 separate axes. This data is then passed and processed throughout the circuit where it is outputted to the filter.



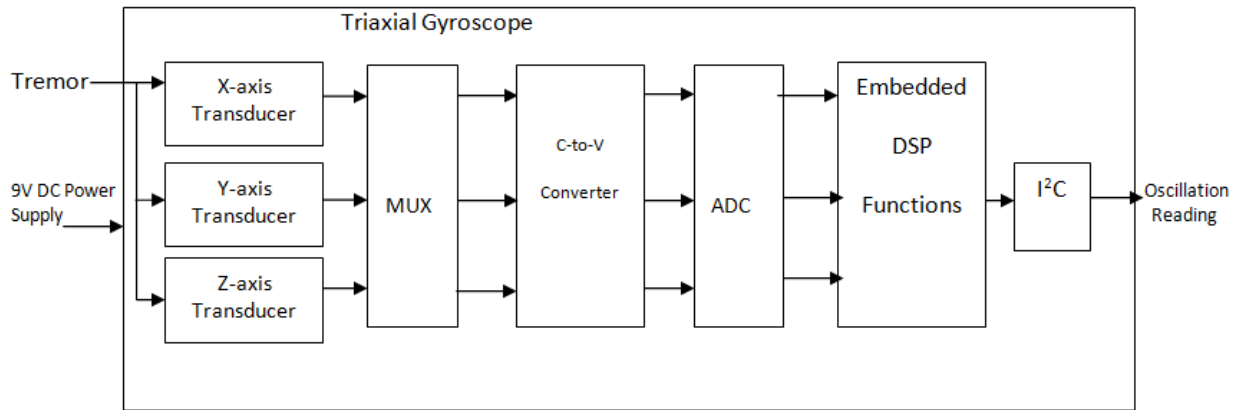


Fig. 22 Level 2 Representation of Triaxial Gyroscope

TABLE. XXIII TRIAXIAL GYROSCOPE FUNCTIONALITY

Module	Triaxial Gyroscope
Inputs	-Arm Tremor
Outputs	-Oscillation/frequency produced by arm's tremor
Function	-Senses angular velocity of the arm's shaking -Reads magnitude and frequency of each tremor oscillation in real-time -Output oscillation readings

As can be seen in figure 23 the active analog filter takes the outputted data from the gyroscope. Its function is to analyze the frequency of each oscillation and filter out the frequencies which go above 12Hz or below 3Hz. The tremors caused by Essential Tremor disease typically fall into this 3Hz- 12Hz range and, therefore, the device will ignore all other frequencies.

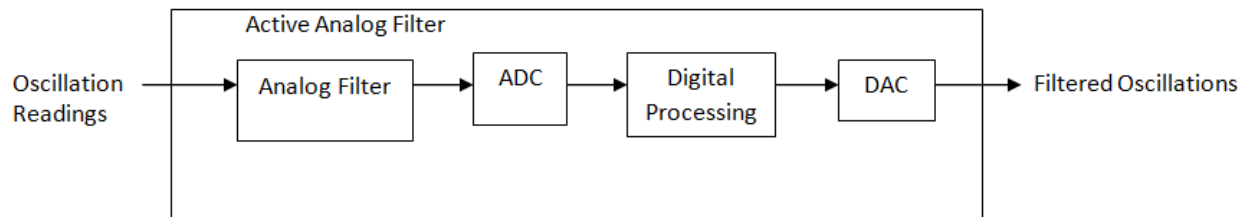


Fig. 23 Level 2 Representation of Active Analog Filter

TABLE. XXIV ANALOG FILTER FUNCTIONALITY

Module	Active Analog Filter
Inputs	-Oscillation readings from gyroscope
Outputs	-Oscillations within the target (3Hz-12Hz)
Function	-Reads information from gyroscope -Filters out oscillations outside of target area -Passes oscillations within target range onto microcontroller

Figure 24 shows the components of the BeagleBone microcontroller. This component has two inputs and acts as the main control for the entire device. The microcontroller is programmed accordingly. The inputted filtered oscillations are converted to logic level and processed and the appropriate signal is sent to the FES component. Table XXV also shows a flow diagram which demonstrates how the data will be processed.

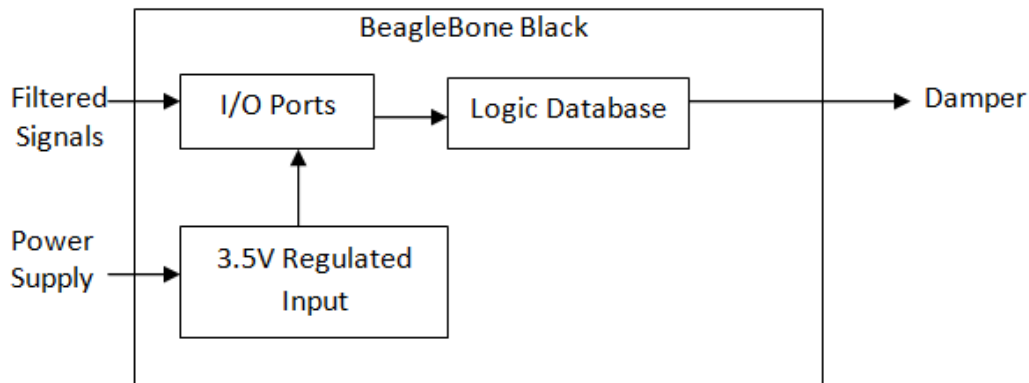


Fig. 24 Level 2 Representation of BeagleBone Black Microcontroller

TABLE. XXV LEVEL 2 REPRESENTATION OF MICROCONTROLLER

Module	BeagleBone Black
Inputs	-Filtered oscillations
Outputs	-Data to FES Damper system
Function	-Reads incoming filtered oscillations -Processes oscillations within the 3-12Hz range -Sends data to FES

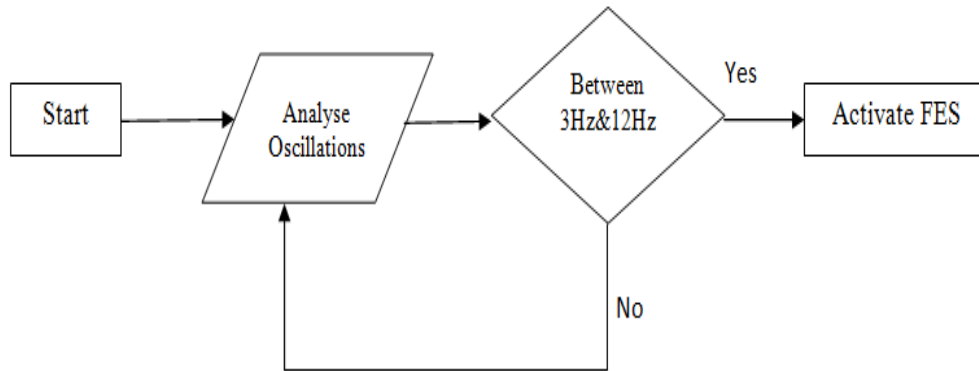


Fig. 25 Flow Chart Representation of Process

The Functional Electrical Stimulation component takes two inputs as can be seen in the figures below. Depending upon the output of the microcontroller, the stimulation component is activated. The system then processes the data from the microcontroller and sends out a small electric impulse in response.

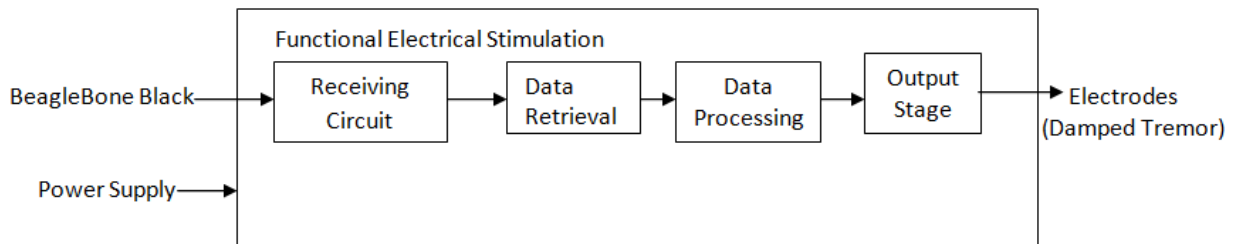


Fig. 26 Level 2 Representation of FES

TABLE. XXVI LEVEL 2 REPRESENTATION OF FES DAMPER

Module	Functional Electrical Stimulation Damper
Inputs	-Data from microcontroller
Outputs	-Small electrical impulses
Function	-Produces electrical impulses based on the data received from the microcontrollers

The rechargeable power supply (battery) provides power to the main components of the entire device. The battery is charged using a regular wall socket and will provide steady power to the device for an entire day. The figure 27 and table XXVII provides a description of the battery's functions.

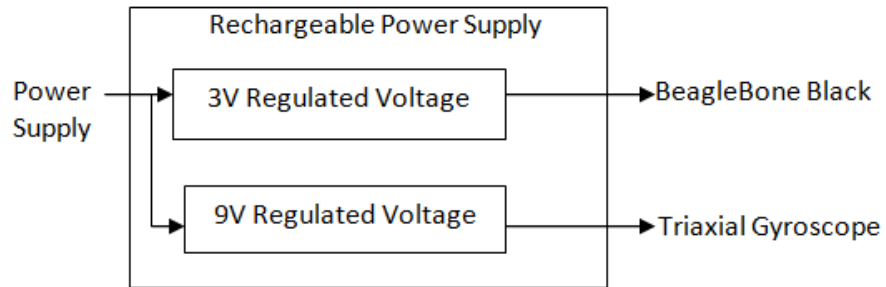


Fig. 27 Level 2 Representation of Power Supply

TABLE. XXVII POWER SUPPLY FUNCTIONALITY

Module	Rechargeable Power Supply
Inputs	-12V power supply
Outputs	-3.5V BeagleBone Black - 9V Triaxial Gyroscope -FES Damper
Function	- Provides power for entire device

In summation, it can be seen that this section was used to produce graphical representations of the StableWear device. The diagrams and tables produced provide brief descriptions of connections and functions of each module of the device.

### C. Specifications

This section of the project aids in the development of the more important objectives to be met by the development of this project. The table below shows the determined specs.

TABLE. XXVIII TECHNICAL SPECIFICATIONS

Modules		Inputs	Outputs
Level 0		-DC Power Supply -Analog Tremor Signal	-Suppressed Tremor
Level 1	Triaxial Gyroscope	-5V Power Supply -Analog Tremor Signal	- Oscillation Readings
	Analog Filter	-Gyroscope data -5V Power Supply	- Filtered oscillations
	BeagleBone Black	- Oscillation between 3&12Hz	Logical Signal to FES
	FES Damper	-Power Supply -BeagleBone signal	-Small electrical pulse
Level 2	Triaxial Gyroscope	-Arm Tremor - Input power	- Frequency readings produced by arm's tremor
	Active Analog Filter	-Gyroscope oscillation readings	- 3Hz-12Hz Oscillations
	BeagleBone Black	-Filtered oscillations (3-12Hz)	- Logic signal to FES Damper
	FES Damper	-Logical signal from BeagleBone	-Less than 700 mA electrical pulse
	Rechargeable Power Supply	-12V Power Supply	-9V Triaxial gyroscope -FES Damper

Table XXVIII. Shows the specifications of this device. In order for the device to function as desired, these specifications must be met.

### D. Other Deliverables

In addition to the descriptions provided above, the team will produce additional paraphernalia to ensure that the usage of StableWear is a simple and easy one. These items include:

- Power point with graphical representations
- User manual
- Complete diagrams and descriptions of each system component
- Demonstration of prototype

## **XIX. PLAN OF ACTION**

Plan of Action is a major component to project management, this section will discuss the general project strategy in order to have a successful project. Using different tools such as a Gantt chart, Program Evaluation and Review Technique (PERT) chart, and a Work Breakdown Structure (WBS), we will plan and coordinate our resources and tasks to reach milestones and goals. Using the WBS, the project is split up into three sub section of phase, tasks, and milestones. In combination of the three subgroups, we get a scope of the project, thus then reaching a general overview in which we can estimate a budget for the project. Following the WBS we will discuss the PERT chart which is used to represent the paths and critical paths of a project. A project may have several paths but the critical path is the path where it must be completed or else the project will be a failure. Last but not least, a Gantt chart is an important tool in project management, it's a way to display tasks against time. A Gantt chart provides start dates and end dates to tasks, as well as visually being able to compare one task to another in terms of time required to complete it. In this project we will use Open Workbench in order to assign resources and tasks to each team member to ensure a smooth flow of contribution of work into the project.

### ***A. Statement of Work (SOW)***

#### ***1) Scope of Work***

The Scope of Work is part of the SOW document that describes the work to be done in detail. This section includes all components of the work, such as hardware and software parts of it, as well as any mechanical and electrical aspects the project may need in order to reach completion. Using the variety of components of work, we will divide the project into phases in order to reach certain milestones during the development of the project. As we developed phases for the project it gave a better insight as to how much work each section will need and how to allocate our resources, now we will explain the phases of the project.

Phase 1 will be consisting of the electrical design, during this phase we will develop the power system of the device. This will include the power switch system, the ability to turn the device on and off on demand. The main part of this phase will be the development of a rechargeable system for the device in which can give a warning when the battery reaches a certain level of power, for the user to recharge. The final part of this phase will be getting a stable and efficient power flow through the embedded system and its sensors.

Phase 2 of our project is strictly signal processing. In this phase we will extract a signal from the human body, in this case the forearm. Using a gyroscope to read signals, we will then need to pass the signal through a filter where we will have a usable signal that our embedded system will be able to process at the next phase. During this phase the signal inputted into the embedded system will have a certain threshold of accuracy before being able to go to the next phase.

Phase 3 is the software design component, once a stable usable signal can be obtained from the gyroscope and filters, we will need to process the signal in order to detect it correctly or do any corrections or adjustment to it. Using digital signal processing (DSP) we will process the signal into various components. One would be to detect when the device is not placed correctly, another to detect abnormalities in the signal which might also signal that the device is not being placed correctly. Having this signal we will then dampen it by generating its complement signal using software development. The final aspect of this phase is to have the output signal ready to be transmitted into the emitter.

Phase 4 of our project is going to be getting the output signal generated in phase 3 to safely and reliably be outputted into the human body using an emitting device. This phase will go under a variety of safety testing, such as sweat, heat, cold, and any aspects that might disrupt the signal. The emitter will also have some safety features to not shock and burn the user, which is very unlikely but will be tested to ensure its safety.

Phase 5 is the final design, during this phase the project will get assembled and mounted into a sleeve. The final product will go under more testing to make sure it can be wearable for everyday uses and easily put on or removed. The conclusion of this phase will make it a stable device to wear that will not be slipping out of the users arm.

## ***2) Location of Work***

Our device should be portable and its components are all of small size. The location of work for the physical aspect of the project will be at the Florida International University (FIU) Engineering Center or at any team members home. The product will not be oversized so it can be stored securely into a case where all the parts and any spare parts can be stored together with it. The software implementation of this project can be done from any computer or lab. According to our OpenWorkbench, we have secured lab time and space in order for our team members to work on the hardware and software design of the project.

## ***3) Period of Performance***

The StableWear project will stretch the span of two semesters, beginning from January 2015 to December 2015. There will be a break for the summer semester, and it is accounted for in the Gantt chart, which will not delay the intended deadline.

## ***4) Deliverables Schedule***

By using the Open Workbench software we developed the Work Breakdown Structure to contribute to our schedule. Each phase will have certain tasks that we are expected to complete in a certain given time. Our project timeline will be the base to determine our progress and percent completion of our project. Given that we must complete at least 20 percent of our project by the end of Senior Design I, we are expected to meet this obligation and are on track to be on schedule for the whole project since we have given ourselves catch up time in order that any aspects of the project experiences an unexpected result.

## ***5) Responsibilities***

Our team is multi-disciplined, but the responsibilities associated with the project will be divided equally into each member. While dividing the work and giving team members certain responsibilities, we also took into account which team member has more specialization in certain fields over others. The hardware part of the project will be mostly the responsibility of Carlos Hernandez, Michel Perez, and Norvin Holness. The software part of the project will be responsibility of Camille Jones and Emilio Lopez. However strong collaboration is needed between the hardware and software part of the project, so both subgroups will be working very close together in the designs.

## ***B. Work Breakdown Structure (WBS)***

The Work Breakdown Structure is a hierarchical list of the project. This is a tree like structure in which it contains parent and child categories. Our parent category will be the Phase, followed by the tasks needed to complete the phase. Milestones will also be children of the Phases and will be included alongside the tasks. Using the “100%” rule, the WBS will be divided into three levels, first level will be the product itself, the second level are the phases and the third level is a complete list of tasks in order to complete the project. Each task will contribute to the 100% completion of the project, and each phase will also contribute to the 100% completion of the project. Using this structure it is easier to get an overview on how the progress for each itemized item or group is going.

The first component of the WBS we have is the Gantt chart which will breakdown the project into separate sections in order to take on a divide and conquer approach to complete the project. The Gantt chart contains the phases and tasks of the project. Each phase will be explained in detail in this section.

TABLE. XXIX SUMMARY OUTLINE

<b>PHASE</b>	<b>1.1</b>	<b>ELECTRICAL DESIGN</b>
<b>TASK</b>	1.1.1A	PURCHASE EQUIPMENT
<b>TASK</b>	1.1.1	POWER SYSTEM
<b>TASK</b>	1.1.2	BATTERY SYSTEM
<b>TASK</b>	1.1.3	POWER NOTIFICATIONS
<b>TASK</b>	1.1.4	PROTOTYPE ASSEMBLY
<b>PHASE</b>	2.1	SIGNAL PROCESSING
<b>TASK</b>	2.1.1	EXTRACT SIGNAL
<b>TASK</b>	2.1.2	FILTER SIGNAL
<b>TASK</b>	2.1.3	OBTAIN STABLE SIGNAL
<b>PHASE</b>	3.1	SOFTWARE DESIGN
<b>TASK</b>	3.1.1	DSP
<b>TASK</b>	3.1.2	DETECT ABNORMAL SIGNAL
<b>TASK</b>	3.1.3	DAMPEN SIGNAL
<b>TASK</b>	3.1.4	GENERATE OUTPUT SIGNAL
<b>PHASE</b>	4.1	EMITTER DESIGN
<b>TASK</b>	4.1.1	SEND SIGNAL TO EMITTER
<b>TASK</b>	4.1.2	SAFETY TESTING
<b>PHASE</b>	5.1	TESTING AND DEBUGGING
<b>TASK</b>	5.1.1	ASSEMBLE DEVICE
<b>TASK</b>	5.1.2	MOUNT ELECTRICAL EQUIPMENT
<b>TASK</b>	5.1.4	TEST FOR WEARABILITY
<b>TASK</b>	5.1.5	FINAL TESTING OF PRODUCT

Table XXIX is a summary of the different phases and task that are scheduled to occur towards the completion of StableWear.



### **1) Phase 1: Electrical Design**

- Objectives: To design and assemble the electrical components of the project. Connecting the gyroscope and emitters to the beagle bone to complete the prototype hardware assembly. This phase also includes the rechargeable battery installation to use power on the beaglebone without an outlet.
- Approach: First we will connect the gyroscope to the beaglebone and install the drivers and be able to receive any signal from it. Then connecting the emitter and send out a signal, using an oscilloscope measure that the signal output is accurate.
- Expected Results: At the end of this phase, we are expected to be able to input a low voltage signal, and emit a signal. As well as have a battery system that is rechargeable.
- Corresponding Tasks:
  - Install gyroscope and emitter to the beaglebone by installed the drivers and connecting the GPIO's to it.
  - Create a battery system in which it can be rechargeable and replaceable.
  - Setup a battery meter alert system, by LED or buzzer.
  - Assemble the prototype to be wearable for future testing on the next phases.

### **2) Phase 2: Signal Processing**

- Objectives: Process input signal using filters and software to manipulate the signal
- Approach: Using a filter to remove unneeded signals in order to isolate the signal we are looking for. Then once the filter reduces the noise of the signal we are looking for, then using software we will fix the signal in terms of making it more stable.
- Expected Results: Be able to extract the right signal needed for the project, free of noise and useable for signal processing.
- Corresponding Tasks:
  - Extract signal from the arm, by finding the right spot in the arm
  - Filter out the signal using filters on the analog signal, then processing it through software
  - Obtain a stable usable signal that can be inputted into a mathematical formula

### **3) Phase 3: Software Design**

- Objectives: Generate a signal to cancel off the original signal
- Approach: Mathematically get the input signal from the previous phase and process it with software in order to detect the signal and generate an output. Using software we will detect any abnormal signals and dampen it as well.
- Expected Results: Having a stable output signal with no abrupt changes or voltage spikes.
- Corresponding Tasks:
  - Digital signal processing
  - Program an abnormal signal detection software
  - Dampen signal in order to prepare for the output
  - Generate the final output and test with oscilloscope

#### 4) Phase 4: Emitter Design

- Objectives: Emit the output signal with the correct voltage in order to perform intended function
- Approach: Test different scenarios that may corrupt the signal.
- Corresponding tasks:
  - Use emitter to send signal to the arm.
  - Test it for safety using methods of interference such as water, or noise.

#### 5) Phase 5: Testing and Debugging

- Objectives: Have the final design ready, and be able to perform all the intended functions. Either a reduction or shaking in hand or removing it completely.
- Approach: Assemble the device fully and test it out in everyday scenarios. Also modify the source code where needed if an area needs improvement.
- Corresponding Tasks:
  - Assembling the device to be wearable and removed easily
  - Mount all the electrical devices into the sleeve
  - Rigorous testing to test its wear ability
  - Test and modify the device again if needed

Using a 100% rule, as shown in table XXX, we are able to translate the project into WBS levels, with the first level being the actual project. The next level is the phases, and finally the last WBS level would be the list of tasks. This table is useful to see the progress of the project because it takes into account that difficulty of each task.

TABLE. XXX 100% RULE

WBS LEVEL 1	%	#	WBS LEVEL 2	%	#	WBS LEVEL 3	%
StableWear	100	1	Electrical Design	19	1.1	Electrical Design	
					1.1.1a	Purchase Equipment	5
					1.1.1	Power System	5
					1.1.2	Battery System	3
					1.1.3	Power Notifications	3
					1.1.4	Prototype Assembly	3
		2	Signal Processing	23	2.1	Signal Processing	
					2.1.1	Extract Signal	10
					2.1.2	Filter Signal	5
					2.1.3	Obtain Stable Signal	8
		3	Software Design	28	3.1	Software Design	
					3.1.1	DSP	8
					3.1.2	Detect Abnormal Signal	8
					3.1.3	Dampen Signal	4
					3.1.4	Generate Output Signal	8
		4	Emitter Design	10	4.1	Emitter Design	
					4.1.1	Send Signal to Emitter	5
		5	Testing and Debugging	20	4.1.2	Safety Testing	5
					5	Testing and Debugging	
					5.1.1	Assemble Device	5
					5.1.2	Mount Electrical Equipment	5
					5.1.4	Test for wearability	5
					5.1.5	Final testing of product	5
Total	100			100			100

### ***C. Project Milestones***

Milestones are used to help our team stay on track, not only do they mark progress between team members, they also give an overview to the project manager or client as to if the project is on schedule.

#### ***1) Gather readings from sensor into microcontroller***

Filtering out the signal we need from the human body accurately into a digital usable form which can be manipulated and processed according to the needs of the task.

#### ***2) Process sensor readings***

DSP using software programming to process signal for alerts and output, with any corrections or alterations needed to be applied to the signal gathered.

#### ***3) Emitting signal***

This step will get the output signal and apply it into the human arm with a safe voltage that is needed to have an actual effect on the human arm

#### ***4) Testing and debugging***

This is the last milestone in which we will test it on a person to get a benchmark on how well the product is working and if any tweaks or adjustments need to be completed on the software aspect of the project.

### ***D. Charts***

Charts are crucial to a plan of action, the reason is that they give a visual on the progress of the project as well as the work needed to complete the project. Scheduling is one of the most important factors to the success of any project, with that being said the Gantt and PERT chart are two of the most widely used tools in project management. No matter the size of the project, with these tools you can generate a budget for the project and time needed to complete it. A budget should be developed using the Gantt chart because it is not a blind estimate, it has planning involved along with actual input of time, labor and equipment cost.

#### ***1) Gantt chart***

Gantt Charts is a type of bar chart used in project management. It is an illustration of the project timeline, with the inclusion of phases and tasks. The Gantt chart also contains the project milestones, this gives an overview of how well the progress of the project is going. A typical shape of a Gantt chart is a curved line, due to the dependencies between tasks which delay the start of other tasks. In our Gantt chart, the summer term is excluded so it can appear as if the following tasks of Power Notifications and Prototype Assembly may be the longest tasks to complete. Also from the Gantt chart, we can see that we also have a whole month of extra time if in fact the project is completed according to the chart. This gives us room for delays or any other issues that may occur, and still complete the project on time. Gantt Chart as shown in figure 28.

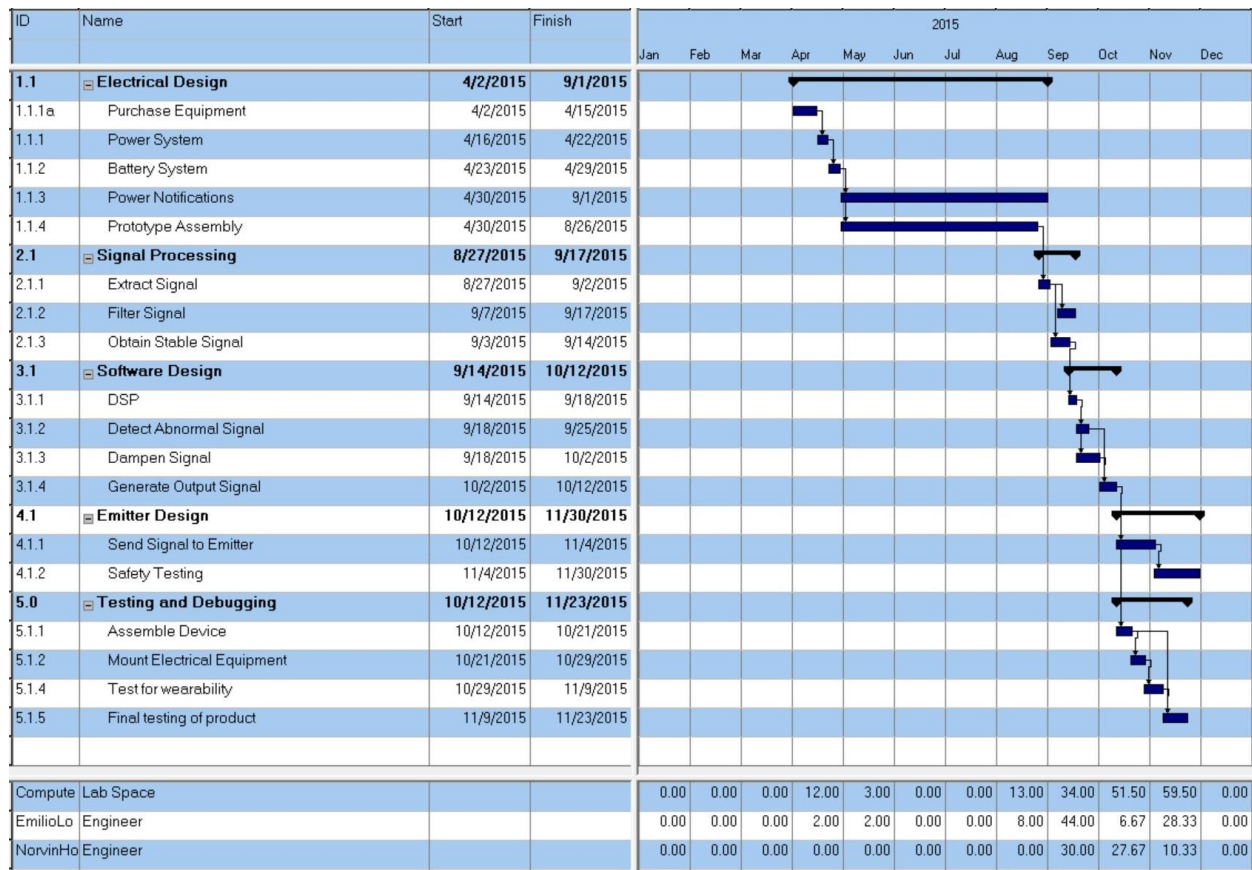


Fig. 28 Gantt Chart

In conclusion the Gantt chart shows the different phases of the project. It shows that some of the task are to run concurrently in order to meet the project deadline.

## 2) PERT chart

The purpose of a PERT Chart is to represent dependencies between tasks, it also gives an overview on which tasks should be prioritized. This chart also shows the critical path of the project, the path that must be completed for the project to be a success. Some tasks do not have as much importance as other so they can be delayed if an issue arises in another task. A decision like that would not slow down the overall progress of the project. According to our PERT chart, each phase must be completed fully in order to advance to next phase. However there is some room to focus on other tasks and delay the nondependent ones. With our teams' background, we are not expecting to have major delays that will slow down the critical path.

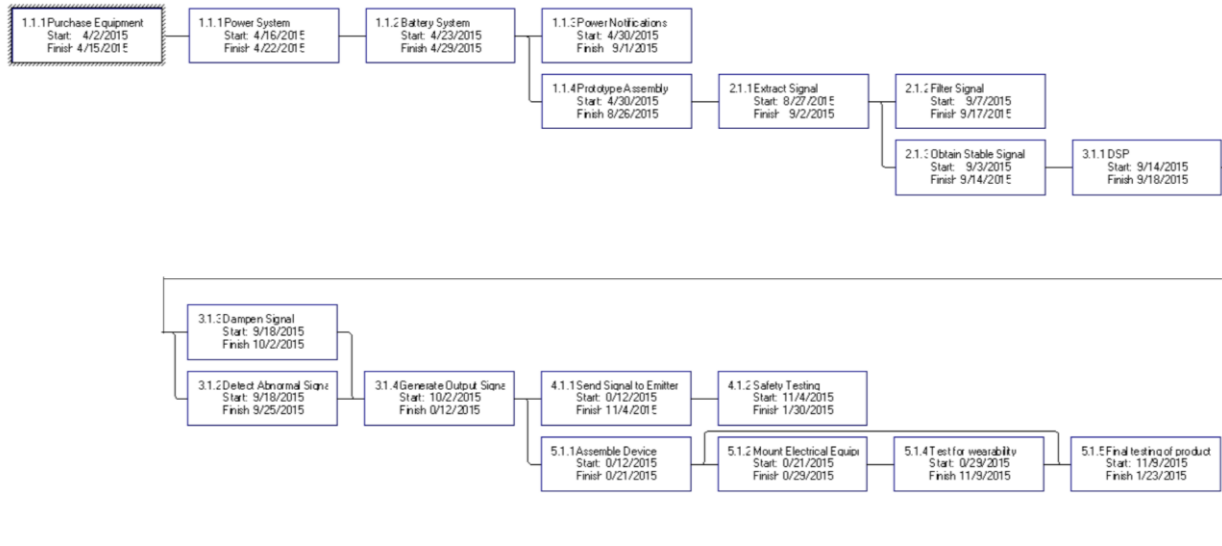


Fig. 29 PERT Chart

The plan of action sections outlines the time and work needed to complete the project by the deadline. Using the Gantt chart to generate a project timeline, we were able to plan the future of the project and became aware of any dependencies between one task and another. The Gantt chart also provided means of being productive throughout the whole progress due to the fact that time and lab space was also included into the Gantt chart. Our next chart was the PERT chart which is an overview on the dependencies of one or more task within themselves. The software used was Open Workbench, which makes it simple for us to update and modify the tables if needed, this software also lets us input actual time versus estimated time to view our progress on the meantime while going through each phase. Having a clear and accurate plan of action is crucial to the success of the project, which is why this section requires a great deal of careful planning.

## **XX. MULTIDICIPLINARY ASPECTS**

Our team consist of engineers from different backgrounds and areas of concentration coming together to make StableWear possible. Our team is made up of three Computer Engineers and two Electrical Engineers; each of the five cooperating to fulfill each objective aimed toward the completion of StableWear. Below is a detailed description of each team member's background and what each member will be contributing towards the development of StableWear.

### ***A. Carlos Hernandez***

An Electrical Engineer with concentrations in Integrated Nano Technology and Data System Software. As our team leader he always ensures that the team is meeting all its milestones toward the completion of StableWear.

- Experienced in Microcontroller Design
- Knowledge of Electronics and Circuit Design
- Proven team leader
- Fast Learner and Self-Motivated

### ***B. Norvin Holness***

A Computer Engineer with concentrations in Network Engineering, Embedded Systems, Bioengineering, and Control Systems. As a member of our team his knowledge of Medical Instrument Design and Control Systems in key to the design and functionality of StableWear.

- Experience in MATLAB programming and its applications
- Knowledge of Medical Instrument Design
- Great with Time Management and Team Planning
- Knowledge of Control Systems

### ***C. Camille Jones***

A Computer Engineer with concentrations in Network Engineering, Embedded Systems, and Computer Architecture & Microprocessor Design. As a member of our team she brings experience in C and Java programming which is critical for design of the microcontroller that will be used in the development of StableWear.

- Experience with C/C++/Java Programming
- Knowledge of Network Management and its applications
- Knowledge of Embedded Systems
- Experience in using Xilinx ISE and NI MultiSim

#### ***D. Emilio Lopez***

A Computer Engineer with concentration in Embedded Systems and Data System Software. As a member of our team he brings a wealth of knowledge and experience in difference programming languages, and also experience with microcontroller programming and computer applications.

- Experience in Java/ C++/ Visual Basic/ PHP/ HTML Programming
- Experience with MATLAB
- Knowledge of Microcontroller Programming
- Knowledge of Windows 8, 7, XP, MAC OS, and Linux

#### ***E. Michel Perez***

An Electrical Engineer with concentration in Power/Energy Systems and Integrated Nano Technology. As a member of our team he brings a wealth of knowledge in Power Systems and Electronics, and their design.

- Knowledge of Power Systems and Design
- Experience with using AutoCAD
- Experience in Electronics I and II
- Knowledge of Microsoft Office, Word, Excel, and Power Point

Each member of our team contributes a unique skill that will be utilized in the development of StableWear. Due to such variety in our team, we understand that some members may be stronger in certain areas than others. In order to for us to meet our milestones in developing an effective product, we will assign different task to individual members in their areas of expertise. This will ensure the success of StableWear.

## XXI. PERSONNEL

5560 SW 3<sup>rd</sup> Street  
Coral Gables FL 33134  
786-247-4389  
Chern236@fiu.edu

CARLOS HERNANDEZ

**OBJECTIVE** Senior electrical engineering student seeking a challenging position, where I may use my software and electronics skills & knowledge to contribute to the company success and as well as my own.

**SKILLS**

- Microsoft Office
- Java/ C/ C++ Programming Languages
- Electronics Design
- Fluent in Spanish and English

### EXPERIENCE

#### SIXT RENT A CAR

Rental Sales Agent

May 2012 – July 2014

- Delivered exceptional service by serving customers in a timely fashion
- Updated rental agreement files, notified customers of overdue rentals
- Managed opening and closing duties, including fleet check, daily reports and reconciliation of the cash drawer

#### NAVISTAR

Sales Administrative Assistant

March 2011 – April 2014

- Support and assist administrative managers with processing and following up on sales
- Prepare required registration forms and process payment of related fees
- Developed and updated the Operations Manual in charge of organizing information and material

### EDUCATION

#### FLORIDA INTERNATIONAL UNIVERISTY

*Bachelor of Science in Electrical Engineering*

[Expected 2015]

Concentration in Data System Software, Integrated Nano Technology

Miami, Florida

#### MIAMI DADE COLLEGE

*Associates of Arts in Electrical Engineering*

2009 – 2011

Miami, Florida



13010 NW 1st Street Apt #203  
Pembroke Pines FL 33028  
954-348-7717  
Nholn002@fiu.edu

## NORVIN HOLNESS

### OBJECTIVE

Well-rounded hardworking student focused on applying technical expertise to obtain a full-time position that will further enhance my knowledge in Computer and Electrical Engineering or a related field.

### SKILLS

- Microsoft Office
- C/C++ Programming Language
- AutoCAD
- MATLAB
- NI MultiSim
- Xilinx ISE
- Operating Systems: Linux, Windows, Ubuntu

### EXPERIENCE

#### FLORIDA INTERNATIONAL UNIVERSITY – MIAMI, FL

Tutor

September 2013 – Present

- Tutor for Mathematics, Chemistry, Microsoft Word & Excel
- Motivate students throughout the semester to ensure them of good academic standing
- Implement different study methods for student athletes

#### THE HOME DEPOT – PEMBROKE PINES, FL

Pro Loader

November 2012 – April 2013

- Restocked and organized store merchandise
- Greeted customers in a timely fashion while quickly determining their needs
- Provided excellent customer service

#### BJ'S WHOLESALE CLUB – PEMBROKE PINES, FL

Lot Attendant

May 2011 – December 2011

- Recommended merchandise to customers based on their needs and preference
- Organized shopping carts in the parking lot
- Loaded merchandise onto customers vehicles

### EDUCATION

#### FLORIDA INTERNATIONAL UNIVERSITY

*Bachelor of Science in Computer Engineering*

[Expected 2015]

Concentration: Network Engineering, Control Systems, Embedded Systems & Bioengineering

Miami, Florida

1599 SW 113<sup>th</sup> Avenue  
Miami FL 33174  
786-660-0799  
[Cjone103@fiu.edu](mailto:Cjone103@fiu.edu)

## CAMILLE JONES

**OBJECTIVE** To work in a dynamic, professional environment with the intentions of gaining experience that would enhance my knowledge and skill and improve my decision-making abilities through working with the business and its professionals.

**SKILLS**

- Microsoft Office
- C/C++/ Java Programming
- AutoCAD
- Xilinx ISE
- NI MultiSim

**EXPERIENCE** **FLORIDA INTERNATIONAL UNIVERSITY – MIAMI, FL**  
Desk Assistant September 2013 – Present

- Greet residents and visitors
- Assist residents with any concerns

**EDUCATION** **FLORIDA INTERNATIONAL UNIVERSITY**  
*Bachelor of Science in Computer Engineering* [Expected 2015]  
Concentration in Network Engineering, Embedded Systems, & Computer Architecture and Microprocessor Design  
Miami, Florida

**THE BARBADOS COMMUNITY COLLEGE**  
*Associates in Applied Science for Electronic and Computer Engineering* 2011  
Bridgetown, Barbados W.I.

11750 SW 8<sup>th</sup> Street Apt# 308  
Miami FL 33175  
305-458-0997  
[Elope164@fiu.edu](mailto:Elope164@fiu.edu)

EMILLIO LOPEZ

**OBJECTIVE** Obtain a challenging position as a software developer to make use of my creative abilities, analytical skills and strong knowledge of advanced technologies.

**SKILLS**

- Microsoft Office
- Java/ C++/ Visual Basic/ PHP/ HTML/ Joolma Programming
- Operating Systems: Windows, Linux, MAC, Ubuntu
- MATLAB
- AutoCAD
- Windows Server
- Fluent in Spanish, English and some Italian

**EXPERIENCE**

**PC SUPERSTAR**  
Owner November 2008 – Present

- Worked with high-end computers, network and data servers
- Designed software applications for computer maintenance & repairs
- Performed worked tailored to customer specifications

**FLORIDA INTERNATIONAL UNIVERSITY – MIAMI, FL**  
Learning Assistant September 2014 – December 2014

- Assisted Students with Calculus II during lectures
- Held office hours to help improve student understanding
- Reviewed course material with students on a weekly basis

**EDUCATION**

**FLORIDA INTERNATIONAL UNIVERISITY**  
*Bachelor of Science in Computer Engineering* [Expected 2015]  
Concentration in Data System Software, Embedded Systems  
Minor: Mathematics  
Miami, Florida

10951 SW 93<sup>rd</sup> Street  
Miami FL 33176  
786-267-1714  
[Amador\\_mike@yahoo.com](mailto:Amador_mike@yahoo.com)

## MICHEL PEREZ

**OBJECTIVE** Self-driven and highly motivated professional with experience in electrical wiring system installations looking to build a successful career as an Electrical Engineer in a well-established organization, contribute to its productive environment, and develop a lasting relationship.

---

**SKILLS**

- MATLAB
- Microsoft Office
- Electronic Design
- Power/ Energy Systems
- Knowledge of National Electric Code
- Fluent in Spanish and English

---

**EXPERIENCE**

**MACY'S – MIAMI, FL**  
Retail Commission Sales April 2014 – Present

- Assist customers in all aspects of service fulfillment by demonstrating use of propriety devices and applications
- Determine customer needs based on personal features and other customer preference related factors

**BECKMAN COULTER – MIAMI, FL**  
Mailroom/ Copy Center Customer Service Rep October 2008 – October 2012

- Pickup and delivery of mail and packaged between post offices
- Prepare outgoing mail
- Prepare special reports depicting mail volume by department, destination, and courier classification

---

**EDUCATION**

**FLORIDA INTERNATIONAL UNIVERSITY**  
*Bachelor of Science in Electrical Engineering* [Expected 2015]  
Concentration in Power/ Energy Systems, Integrated Nano Technology  
Miami, Florida

**MIAMI DADE COLLEGE**  
*Associates in Arts in Electrical Engineering* 2008 - 2012  
Miami, Florida

## XXII. BUDGET

The budget for StableWear will include the cost of the materials, the tools used to put the device together, lab space used, and also the compensation for the hours that each team member has dedicated toward the development of StableWear. Table XXXI shows a detailed list of the total estimated cost for the development of StableWear.

TABLE. XXXI BUDGET

ID	Phase Name	Start	End	Estimated Hours	Estimated Cost
<b>1.1</b>	<b>Electrical Design</b>	<b>4/2/2015</b>	<b>9/1/2015</b>	<b>93</b>	<b>\$2,360.00</b>
1.1.1a	Purchased Equipment	4/2/2015	4/15/2015	1	\$220.00
1.1.1	Power System	4/16/2015	4/22/2015	10	\$200.00
1.1.2	Battery System	4/23/2015	9/1/2015	20	\$400.00
1.1.3	Power Notification	4/30/2015	9/1/2015	15	\$300.00
1.1.4	Prototype Assembly	4/30/2015	8/29/2015	24	\$480.00
	Computer Lab	4/2/2015	9/1/2015	23	\$760.00
<b>2.1</b>	<b>Signal Processing</b>	<b>8/27/2015</b>	<b>9/17/2015</b>	<b>104</b>	<b>\$2,420.00</b>
2.1.1	Extract Signal	8/27/2015	9/2/2015	22	\$440.00
2.1.2	Filter Signal	9/7/2015	9/17/2015	22	\$440.00
2.1.3	Obtain Stable Signal	9/3/2015	9/14/2015	43	\$860.00
	Computer Lab	8/27/2015	9/27/2015	17	\$680.00
<b>3.1</b>	<b>Software Design</b>	<b>9/14/2015</b>	<b>10/12/2015</b>	<b>124</b>	<b>\$3,120.00</b>
3.1.1	DSP	9/14/2015	9/13/2015	20	\$400.00
3.1.2	Detect Signal	9/18/2015	9/25/2015	20	\$400.00
3.1.3	Dampen Signal	9/18/2015	10/2/2015	26	\$520.00
3.1.4	Generate Output Signal	10/2/2015	10/12/2015	26	\$520.00
	Computer Lab	9/14/2015	10/12/2015	32	\$1,280.00
<b>4.1</b>	<b>Emitter Design</b>	<b>10/12/2015</b>	<b>11/30/2015</b>	<b>90</b>	<b>\$2,360.00</b>
4.1.1	Send Signal to Emitter	10/12/2015	11/14/2015	22	\$440.00
4.1.2	Safety Testing	11/14/2015	11/30/2015	40	\$800.00
	Computer Lab	10/12/2015	11/30/2015	28	\$1,120.00
<b>5.1</b>	<b>Testing and Debugging</b>	<b>10/12/2015</b>	<b>11/23/2015</b>	<b>223</b>	<b>\$5,920.00</b>
5.1.1	Assemble Device	10/12/2015	10/21/2015	20	\$400.00
5.1.2	Mount Electrical Equipment	10/21/2015	10/29/2015	25	\$500.00
5.1.3	Test for Wearability	10/29/2015	11/9/2015	35	\$700.00
5.1.4	Final Testing of Product	11/9/2015	11/23/2015	70	\$1,400.00
	Computer Lab	10/12/2015	11/23/2015	73	\$2,920.00
<b>Total</b>				<b>634</b>	<b>\$16,180.00</b>

Table XXXI is an estimated cost of the total budget for the design of StableWear This list is subject to change should we come across any unforeseen changes and difficulties in our design.

TABLE. XXXII MATERIAL COST

Part	Unit Cost	Vendor	Quantity	Total Cost
BeagleBone Black	\$66.99	Vilros	1	\$66.99
9 Volt Rechargeable Battery	\$9.17	Energizer	1	\$9.17
Wire	\$0.00	Lab Equipment	14	\$0.00
Resistors	\$0.00	Lab Equipment	12	\$0.00
Spandex Sleeve	\$9.88	Elixer	1	\$9.88
Velcro Tape 15ft	\$20.71	Amazon.com	1	\$20.71
TENS Unit	\$34.00	Amazon.com	1	\$34.00
Tri-Axial Gyroscope	\$31.95	Jameco	1	\$31.95
LM 358 Op-amp	\$0.00	Lab Equipment	2	\$0.00
Capacitors	\$0.00	Lab Equipment	4	\$0.00
Accelerometers	\$0.00	Lab Equipment	4	\$0.00
Potentiometer	\$0.00	Lab Equipment	3	\$0.00
LM 741 Op-amp	\$0.00	Lab Equipment	3	\$0.00
Printer Circuit Breadboard	\$7.00	Vktech	7	\$49.00
BJT	\$0.00	Lab Equipment	1	\$0.00
MyDAQ Breadboard	\$0.00	Lab Equipment	1	\$0.00
Total				\$221.70

Table XXXII is an estimated cost of the material for the design of StableWear This list is subject to change should we come across any unforeseen changes and difficulties in our design.

## XXIII. RESULTS EVALUATION

Stable wear has decided that the final product will use FES stimulation as a mean to control the involuntary muscle movement. By far this is the most convenient solution to our main objective. It will make our product more practical to wear since no need to build a large device to counteract movements. Also it is the least invasive, as other alternatives require fixing the device to the body. Our initial device will consist of small sensors to detect the analog inputs in order to identify possible signals. We will use polyetheretherone materials that are non-toxic to human skin. This will prolong the usage of the device without creating irritability to the user. A lithium polymer battery will be used for recharging capabilities and extended usage; this will ensure that there will be no need for extra batteries. We will create a device that is lightweight and will operate with simplicity. Thus an embedded system such as the beaglebone will be used for processing power and its lightweight.

The main objectives for this project:

- Lightweight
- Durable
- Non-Invasive
- Easy operability
- Delivers hand operability
- Marketable

Currently our product is in a design phase, the goal is to make stable wear operate within the objectives we believe will make competitive product. Most of the components we are using for example are very light in weight; therefore we can build a product that doesn't weight much.

Quality is a priority as the final product must be a durable system since it will be used in a day-to-day basis. A non- invasive device will be built; non-toxic materials will be used for extended wear ability. Part of our non-invasive system is to make it so it is not necessary to have fixed to the user. We will minimize the functionality to the reducing oscillations to make the end product easy to operate by any individual.

Constraints to satisfy:

- Federal regulations
- One fits all
- Effective components

The team set several constraints for the project to make sure we deliver a consistent device. We will work strictly with federal regulations to assure that our product meets operability into the medical device markets. The design we want to implement must be a one size fits all, stable wear must be able to fit the majority of the users without the need for extra attachments.

The constraints were imposed to keep the product within workable parameters in terms of production and accomplishment by the team. We are adhering to federal regulations to make sure that when our product is built it will be safe from potential hazards identified by the federal regulations imposed. We also intend to work with international regulations to make sure that our product is identified as a safe device to be used in most parts of the world.

We have also identified that we need to design a product that one size fits all. This means that anyone, regardless of the size of their forearm will be able to adjust it accordingly to their size. The stable-wear will be built with components that meet high standards for effectiveness.

Standard to comply with:

A) ISO 13485:2003 - Medical devices -- Quality management systems

B) ISO 10993 - Biological evaluation of medical devices

C. 60601-1-11 - Medical electrical equipment

D. ISO9001: 2008 - Quality Management Systems

It is intended that Stable-Wear will comply with. ISO9001: 2008 to make sure we deliver a quality product for the market. We discussed the details of each standard to be used in our project. We mentioned the priority of adhering to each standard so Stable-Wear could be an efficient medical device. It is very important to comply with this ISO to prevent possible problems with regulatory commissions. Since we are entering a medical market it is strict that we deliver a product that is not potentially hazard.

Stable-Wear will be a legible product to market, since we researched the market as seen in the patent infringement section of the proposal. We have carefully analyzed the projects we have found that range in similarity to Stable-Wear and we are carefully planning a design that will not infringe on any of them.

In conclusion, Stable-Wear is in direction of a great product delivery, we have established the grounds for our objectives. We will work hard in the constraints of the project to guarantee its success. We will stay true to our idea and will not infringe on any other devices intended for similar purposes Stable-Wear will adhere to international standards to be a marketable product for international countries.





## **XXIV. LIFE LONG LEARNING**

There has been an increased demand in biomedical equipment in the past few years since devices have become more powerful and portable. It is important to keep our product, StabeWear, up to date as advances in technology occur. In order to continue supporting and upgrading our product, the teams' knowledge of new sensors and devices must be up to date. As well as any new methods of achieving the same task which is to stop tremor associated disease altogether. This project will keep meeting the best quality and performance our customers need.

Challenges that our project faces are converting the prototype design into a product that can be sold worldwide to any person that needs it. The next challenge would be to find a reputable sponsor which will fund the mass production of the product and promote it nationally or worldwide. With our prototype design we can show sponsors the potential of our product and why it should be sponsored.

Apart from having a sponsor to help our product grow in the market, intellectual capital is also important with our project. There are many professional societies which can offer thousands of journals and research that we may need for our project. The Institute of Electrical and Electronics Engineers (IEEE) would be one of the professional societies which consists of thousands of members, with an abundance of published material which can help us keep up to date with the latest technology and ongoing research.

Working together to develop and create a successful project, including all the challenges that come with it such as sharing knowledge and research, will fulfill our team's lifelong learning. Meeting deadlines, progress, as well as presentations have helped our team develop a professional responsibility which will only grow as we work on our professional careers. During Senior design II, we will use many outside resources such as Technical Societies and magazines in order to fully engage in our lifelong learning process to becoming a self-respected engineer.



## XXV. CONCLUSION

Team StableWear was founded on the necessity to provide a suitable wearable product for those patients who suffer from Parkinson's disease (PD), Multiple Sclerosis (MS), Essential Tremor (ET), and other tremor associated diseases. Each of these disorders either is or causes a different type of tremor, which are both involuntary and uncontrollable. The team came to the conclusion that there was a need for a device due to our team conducting research. The research was based on results from a survey and our client interview. The survey was aimed at an audience that was most vulnerable to getting a tremor associated disease, and also some with the disease, and persons who may have loved ones that suffer from one of these diseases. Our conclusion from this survey is that there is a demographic in our society that a product like StableWear can assist to a great extent. Upon formulating data from the survey we came into contact with a client that was interested in investing in our idea. The client requested that we provide to him a safe, user-friendly, wearable device that will assist in improving the quality of life for those who are affected by tremor associated diseases.

We began brainstorming ideas as to how to approach the design of a product that will both meet the client and the public's needs, and also be marketable. We conducted various research on products that were on the current market that assist in tremor suppression and also we identified different techniques of how to approach the issue of suppression of hand tremors. We came to the conclusion that we would develop a hand tremor suppression orthosis. This device, StableWear, will be a wearable sleeve that is sleek in design and aesthetically pleasing, while providing reliable and efficient damping mechanism for tremor suppression. Once a tremor is detected through the use of sensors and filters, the dampening mechanism will be activated to stabilize the hand so that it may return to normal function. Stabilizing the involuntary movement of the hand will be key in improving the quality of life for those who suffer from tremors.

The proposal for our project covered many sections that were necessary to prove the feasibility of developing StableWear. The proposal covered critical sections such as; the needs feasibility analysis, risk analysis, intended users and uses, background, intellectual property, standards considerations, budget, globalization, health and safety, concept development, manufacturability and sustainability. Brainstorming and analysis of these sections have helped us plan the direction of where we want our design to go, and also how we may meet the needs of our clients.

We plan to develop StableWear with the goal of not only improving the quality of lives of those who suffer from tremors, but to also spread global awareness of issues affecting patients who suffer from these diseases. World champion boxer Muhammad Ali was once quoted saying, "Parkinson's is my toughest fight." This statement speaks volumes since it is coming from a professional boxer. We at StableWear know that Parkinson's Disease (PD), Essential Tremor (ET) and Multiple Sclerosis (MS) are incurable and complicated diseases that affect the lives of millions

of people worldwide. Though StableWear is not the cure for tremor diseases, we hope that by putting it on the market, we may revolutionize the way how tremor associated diseases are treated, so that one day hopefully there is a cure for them.

Though the development of StableWear will not be an easy task, we are confident that in ourselves; as we are a team of promising engineers equipped with the knowledge and skills to achieve an efficient and reliable working product. We are grateful to have this opportunity to display what we have learned here at Florida International University towards the development of our capstone project.









## XXVI. REFERENCES

- [1] Anderson, David. "DESIGN FOR MANUFACTURABILITY." Article on Design for Manufacturability. 2014. Web. 20 Apr. 2015.
- [2] Ben-David, Gal, and Leon Boston. "Patent US20100174342 A1- Tremor Reduction Systems Suitable for Self-application and Use in Disabled Patients." Google Books. N.p., 8 July 2010. Web. 16 Feb. 2015.
- [3] Handforth, Charles A. "Patent US20040015116 A1- Firm-contact Apparel Prosthesis for Tremor Suppression and Method of Use Thereof." Google Books. N.p., 22 Jan. 2004. Web. 16 Feb. 2015.
- [4] IEEE Board of Directors. "IEEE Code of Ethics." IEEE. 1 Aug. 1990. Web. 18 Mar. 2015.
- [5] Jayanthi, Arkanksha. "10 Biggest Technical Advancements for Healthcare in the Last Decade." 10 Biggest Technological Advancements for Healthcare in the Last Decade. N.p., 28 Jan. 2014. Web. 15 Feb. 2015.
- [6] Kim, Kyu-yong, Sang-youn Kim, and Byoung-soek Soh. "Patent US7966074 B2– Apparatus and Method Enhancing Muscular Movement." Google Books. N.p., 21 June 2011. Web. 16 Feb. 2015.
- [7] Lee, Ellen. "5 Ways Technology is Transforming Health Care." Forbes. Forbes Magazine. 24 Jan. 2013. Web. 15 Feb. 2015.
- [8] Loureiro, R.C.V.; Belda-Lois, J.M.; Lima, E.R.; Pons, J.L.; Sanchez-Lacuesta, J.J.; Harwin, W.S., "Upper limb tremor suppression in ADL via an orthosis incorporating a controllable double viscous beam actuator," *Rehabilitation Robotics*, 2005. ICORR 2005. 9th International Conference on, vol., no., pp.119,122, 28 June-1 July 2005
- [9] McDonough, William. "The Hannover Principles: Design for Sustainability." McDonough Innovation. 1 Nov. 2012. Web. 20 Apr. 2015.
- [10] Okudan, G.E.; Shirwaiker, R.A., "A Multi-Stage Problem Formulation for Concept Selection for Improved Product Design," *Technology Management for the Global Future*, 2006. PICMET 2006, vol.6, no., pp.2528,2538, July 2006
- [11] Robert MacLachlan, Brian Becker, Jaime Cuevas Tabares, Gregg Podnar, Louis Lobes, and Cameron Riviere, "Micron: an actively stabilized handheld tool for microsurgery," *IEEE Transactions on Robotics*, Vol. 28, No. 1, pp. 195-212, February, 2012.
- [12] Rouse, Margaret. "What Is Glocalization? - Definition from WhatIs.com." SearchCIO. 1 May 2013. Web. 22 Mar. 2015.
- [13] Salarian, A., Russmann, H., Wider, C., Buckard, P., Vingerhoets, F., & Aminian, K. (2007, February 1). Quantification of Tremor and Bradykinesia in Parkinson's disease using a Novel Ambulatory Monitoring System. Retrieved February 17, 2015.
- [14] Shih, Adam, and Hyodong Lee. "Glove Mouse." – ECE 4760. Cornell University, Dec.2014.Web.10Feb2015.
- [15] Smith, Scott. "Concept Testing 101: How to Laser Focus Your Products and Priorities - Qualtrics." Qualtrics Concept Testing 101 How to Laser Focus Your Products and Priorities Comments. Qualtrics, 30 Apr. 2013. Web. 25 Mar. 2015.
- [16] Valtonen, Anna. "Back and Forth with Ethics in Product Development." Academia.edu. 17 Mar. 2015. Web. 17 Mar. 2015.
- [17] "United States Census Bureau." U.S. Census Bureau Projections Show a Slower Growing, Older, More Diverse Nation a Half Century from Now. N.p.,n.d. Web. 16 Feb. 2015.

## XXVII. APPENDIX

### *A. Client Interview Questions*

- a. Have you heard of any similar devices before?
- b. Would you publicly use a device like this?
- c. Are there any particular features you would like to see incorporated into this device?
- d. Would you purchase this device?
- e. How much would a user pay for such a device?
- f. What issues would you consider when purchasing a product like this?
- g. How great of an impact do you think such a device would have on society?
- h. What do you like most about the project?
- i. What do you like least about the project?

## ***B. User Survey***

The StableWear is a wearable arm device which eliminates/minimizes the uncontrollable shaking experienced by persons suffering with Parkinson's disease or Essential Tremor disease. This survey was designed to gain information from potential users in order to better meet their needs and requirements. The information provided through this survey is confidential and will only be used to improve this product.

1. Gender

☐ Male

☐ Female

2. Age

☐ Under 30

☐ 31-50

☐ 51-70

☐ Above 70

3. After reading the above description, how interested are you in this product?

☐ Not interested

☐ Slightly interested

☐ Very Interested

☐ Extremely Interested

4. Would you purchase this product?

☐ Yes

☐ No

Explain why or why not:

---

---

---

---

---

5. If yes, how much would you spend on this device?

☐ Under \$100

☐ \$100-200

☐ \$200-300

☐ \$300-400

☐ > \$400

6. Are you or anyone you know affected by Parkinson's or Essential Tremor Disease?

☐ Yes

☐ No

7. If yes, on a scale of 1 to 10, how bad are the arm's tremors? (1 being barely noticeable & 10 being immobilizing)

Additional	Comments:

**Thanks for Your Participation**

### ***C. Team Contract***

As a member of the

Team #	9	Team Name	StableWear
Semester	Spring 2015	Class Time	7:50 – 9:05 pm

We hereby agree to the following conditions:

1. I agree that I will participate in class and openly share my ideas and opinions with the other team members.
2. I will agree to honor any unanimous or majority vote decision that is established by the team.
3. In the case that I have an emergency or an unforeseen absence it is my responsibility notify ALL of my team members and to learn any new material that I missed out on.
4. I will complete and submit any assigned material by the team to the best of my abilities.
5. I accept that my performances are regularly monitored by the team. In case of negative performance I will be issued a written warning.
6. I agree that the team holds the right to release me after the third (3<sup>rd</sup>) warning, decided by the majority vote of the team members. I am thereof entitled to file an appeal to the class professor and request arbitration.
7. The following are reasons to be given a warning:
  - a. Unable to submit an assignment on time.
  - b. Lack of team participation and effort.
  - c. Obscene and improper conduct.
8. I am not allowed to abandon my team under any circumstances.

<b>Team Leader Name</b>	<b>Signature</b>	<b>Date</b>	<b>Roles</b>
Carlos Hernandez			Team Management & Software and Hardware Integration
<b>Team Member Name</b>	<b>Signature</b>	<b>Date</b>	<b>Roles</b>
Norvin Holness			Software and Hardware Design
Camille Jones			Microcontroller Programming
Emilio Lopez			Microcontroller Programming
Michel Perez			Power Supply & Electronic Connections

#### ***D. Intellectual Property Contract***

The following section explains our criteria for co-inventorship between all the team members, who will be the invention spokesman, how we plan to split the profit, and by the mechanism for which we will conduct intellectual property decision making.

We hereby agree to the following considerations:

i. This invention will be considered as a co-inventorship between all five members of our group. All members greatly contributed to the development and brainstorming of this project, thus all members are considered co-inventors.

ii. The Invention Spokesman will be Carlos Hernandez, due to his knowledge of the field and marketing ideas, and also with his ability to articulate himself through public speaking.

iii. We plan to distribute the profit from our project between team members in the following way:

20% to Carlos Hernandez

20% to Norvin Holness

20% to Camille Jones

20% to Emilio Lopez

20% to Michel Perez

iv. All major decisions regarding our invention will be decided by a majority decision. The team will conduct a vote for the best interest of our Invention and for the team. All ideas by team members will be taken into consideration until a final concrete decision is voted on.

v. All Intellectual Property decision making in regard to our invention will be made a majority decision. This includes, but is not limited to, sales, lending of rights, design process and details.

My signature below establishes that I agree to all of the conditions of the Intellectual Property Contract.

<b>Name</b>	<b>Signature</b>	<b>Date</b>
Carlos Hernandez		
Norvin Holness		
Camille Jones		
Emilio Lopez		
Michel Perez		

## XXVIII. SENIOR DESIGN II PROCEDURES

### Department of Electrical & Computer Engineering Florida International University SENIOR PROJECT PROPOSAL SUMMARY FORM

*(A full proposal must be submitted and approved along with this form No later than the end of EEL-4920each semester. All information must be completed)*

Course Number: EEL 4921C Semester: Spring Year: 2015

Reference Number: Team 9 Faculty Name: Gustavo Roig Ph.D

Senior I Instructor's Name: Wilmer Arellano

Team Leader Name: Carlos Hernandez PID: 3823538

Major: Electrical Engineering

Discipline / Specialization: Integrated Nano Technology & Data System Software

Telephone: 786-247-4389

Other Member Information:

Name	Student ID #	Major (e.g. Electrical, Computer, Civil)	Discipline / Area of Specialization (e.g. Communications, Powers, Transportation)
Norvin Holness	3597833	Computer Engineering	Network Engineering, Embedded Systems & Bio-engineering
Camille Jones	4054558	Computer Engineering	Network Engineering, Embedded Systems & Computer Architecture Design
Emilio Lopez	2581737	Computer Engineering	Data System Software & Embedded Systems
Michel Perez	4257999	Electrical Engineering	Power/Energy Systems & Integrated Nano Technology

## Proposed Project (Summary Only)

- A. Project Title: StableWear: A Hand Tremor Suppression Orthosis
- B. Design Specifications (Please List Items)
  - 1. The device will be wearable, inconspicuous and aesthetically pleasing.
  - 2. The device will be lightweight.
  - 3. The device will generate low voltage ( $\leq 9$  Volts).
  - 4. The device will be able to last all day via a rechargeable lithium battery.
  - 5. The device will be user friendly.
  - 6. The device will be resistant to wear and tear.
- C. Design Constraints (Standards, Economic Factors, Patents, Safety, Reliability, Ethics, Social Impact)

### Standards

The design of StableWear must comply with all standard concerning the development or wearable medical orthoses. Some of these standards may include, but are not limited to:

- a. ISO 13485:2003
- b. ISO 10993
- c. IEC 60601-1-11
- d. ISO9001: 2008
- e. Federal Code of Regulation (CFR) FCC part 15

### Safety

- a. The device should not injure or harm the user in any way.
- b. The device should not produce unreasonable stress or pressure on any part of the body.
- c. The device should not contain harmful materials (e.g., toxins, allergens, etc.)

### Economic Factors

- a. The device should cost less than \$200.
- b. The device budget for this project should not exceed \$1000.

### Patents

The design of StableWear must not infringe on any patents. Some of these patents may include, but are not limited to:

- a. Patent 1: US Patent # 20040015116 A1
- b. Patent 2: US Patent # 7966074 B2
- c. Patent 3: US Patent # 20100174342 A1

### Reliability

- a. The device should be durable and able to last several years.
- b. The device should effectively minimize involuntary motions while having very little effect on voluntary movement.



### Ethics

The ethical dilemma that we faced in the development of StableWear, is producing a product that was more stylish than functional. Through our analysis we concluded that it was more important to focus on a product that will be more functional than it is stylish.

### Social Impact

- a. The device should not attract particular attention.
- b. The device should not be embarrassing to wear or use.

- D. Initial research results. Analysis and synthesis, procedures to be pursued. Evaluation of alternate solutions.

Upon brainstorming a suitable idea for improving the quality of life for those who suffer from hand tremor related diseases, we came across a multitude of different ways in which we could solve this problem. Through numerous hours of research, we concluded that we will incorporate the use of Functional Electrical Stimulation (FES) for the suppression of tremors in our system. We will also consider using mechanical aspects such as incorporating the use of dampening fluid and rotary dampers or actuators in order exert an accurate dampening force for the hand tremor.

- E. Project Evaluation/Testing Criteria.

StableWear is a Hand Tremor Suppression Orthosis what will be tested by using the Transcutaneous Electrical Nerve Stimulation (TENS) to mimic the behavior of Tremors. The TENS Machine provides the same frequency of oscillation as those from patients who suffer from tremor associated diseases. StableWear will be able to detect the oscillation in the hand at the specified frequency range, and damp the oscillation of the tremor. This will provide improved functionality and control of the hand.

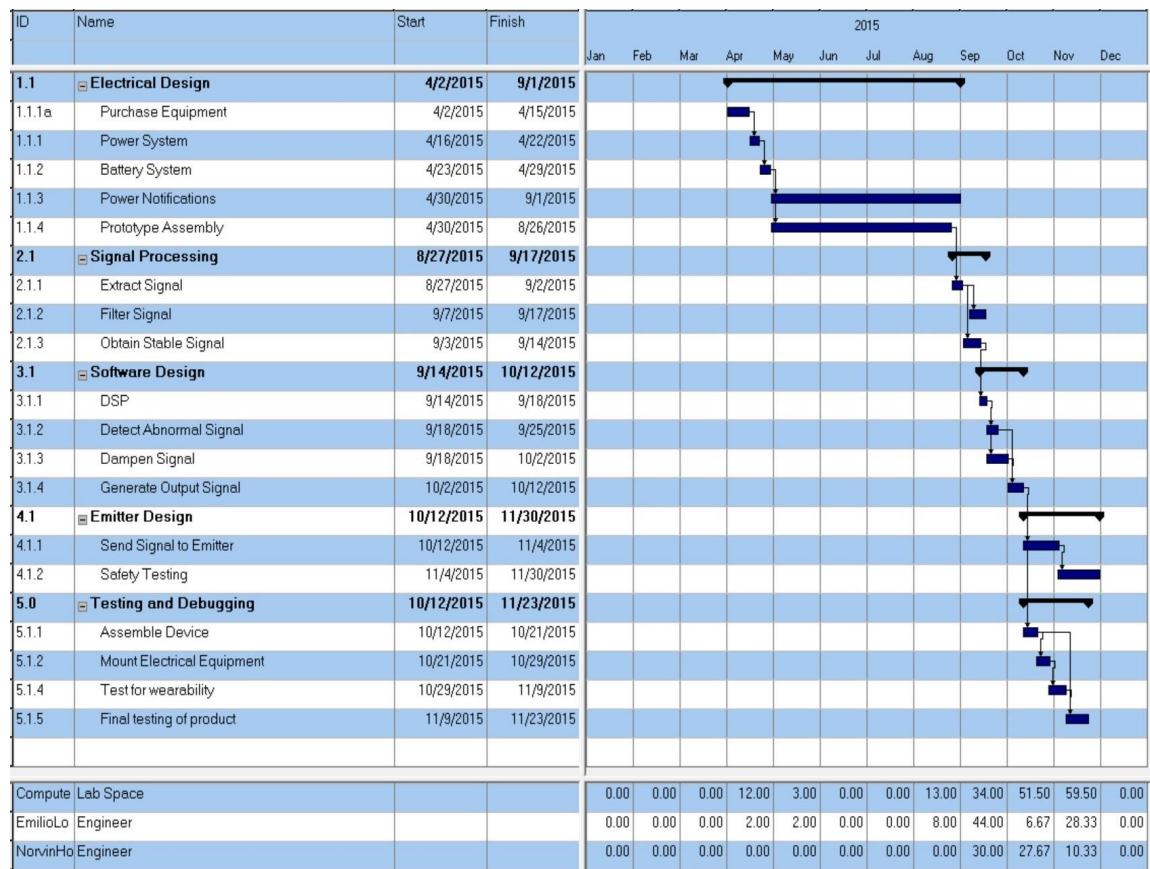
- F. Multi-Disciplinary Areas Involved in the Project

StableWear is a project that involves different disciplines in engineering such as Electrical Engineering, Computer Engineering, and Biomedical Engineering. Team StableWear consist of multi-disciplined engineers that have experience in each of these fields. Our multi-disciplined team is committed to delivering the best product possible.

- G. Team Assignments (Who will do what )

1. Carlos Hernandez is responsible for managing team meetings, he is also responsible for the hardware design of StableWear.
2. Norvin Holness is responsible for the hardware and software integration of StableWear.
3. Camille Jones is responsible for the programming and software design of StableWear.
4. Emilio Lopez is also responsible for the programming of the microcontroller software for the design of StableWear.
5. Michel Perez is responsible for the hardware design of StableWear.

H. Attach a schedule, including two or three intermediate milestone.



I. E-mail address and phone number and PID of ALL team members (Must be Completed)

Name	PID	E-mail Address	Phone Number
Carlos Hernandez	3823538	Chern236@fiu.edu	786-247-4389
Norvin Holness	3597833	Nholn002@fiu.edu	954-348-7717
Camille Jones	4054558	Cjone103@fiu.edu	786-660-0799
Emilio Lopez	2581737	Elope164@fiu.edu	305-458-0997
Michel Perez	4257999	Mpere599@fiu.edu	786-267-1714

	PRINT	SIGNATURE	DATE
Group Leader	Carlos Hernandez		
Team Member	Norvin Holness		
Team Member	Camille Jones		
Team Member	Emilio Lopez		
Team Member	Michel Perez		
Senior Design I Coordinator	Wilmer Arellano		
Mentor	Gustavo Roig Ph.D		