BME 4908 SENIOR DESIGN PROJECT
Design History File

Design of VibroBeats

Submitted in partial fulfillment of the
requirements for the degree of

BACHELOR OF SCIENCE
in
BIOMEDICAL ENGINEERING

04/14/2022

Project Team 6
Bianca Castello
Jacob Bharat
Yency Perez
Maria Chiang
Mario Civil

I have read this report, evaluated its contents (see attached evaluation form), and recommend that it be approved.

____
Dr. Zachary Danziger

This Senior Design Project Report and its Faculty Evaluation is approved.

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Dr. Jorge Riera
Chair, Department of Biomedical Engineering

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Section 1: Market Requirements

1a. Clinical Research

Patients with Parkinson's have trouble balancing due to degenerative motor function from lack of dopamine resulting in an increased risk of falling and difficulty walking. Studies have shown at least 540,000 people in the United States affected by Parkinson's Disease will fall each year with a large proportion (50–86%) falling recurrently. There are currently 1.2 million people in the United States that are diagnosed with Parkinson's Disease and there are about 60,000 people diagnosed each year in the United States[12]. The changes in the brain that causes patients to have lower dopamine levels directly affect balance and make it difficult to walk. Balance is usually controlled by the autonomic nervous system and Parkinson's causes this reflex to be assigned to the area of the brain that requires thinking and balance becomes a more difficult process[8]. Proprioceptors are vital in sensing balancing and being able to walk. The proprioceptors are sensory receptors in the joints. muscles, tendons, and skin that help to sense movement and spatial position.

Currently, patients with Parkinson's disease that experience difficulty walking and balancing do not have access to treatments such as vibration therapy outside of clinical settings. The treatments available for these motor symptoms are general vibration therapy, lifestyle changes, physical therapy, and deep brain stimulation. General Vibration Therapy is stimulation therapy that helps with alleviating motor symptoms without the music that enhances relief and relaxation. Lifestyle Changes use exercise and nutrition to promote increased overall health and slow the progression of symptoms. Physical Therapy helps treat the loss of movement and helps patients gain control over motor symptoms. Deep Brain Stimulation is an invasive surgical procedure that treats advanced Parkinson's Disease and movement disorders.

Vibration therapy is a commonly used form of treatment because vibrations help to lessen pain and reduce tremors. Vibration therapy is commonly used to reduce stiffness and it causes increases in dopamine levels in the brain because of a deficiency of dopamine. Targeted vibration therapy delivers low-frequency vibrations as a form of acoustic therapy and Vibroacoustic therapy helps patients more when music is combined with vibrations. Vibroacoustic therapy has been shown to be very helpful to Parkinson's patients when vibration sounds can be heard and felt[14]. The benefits include having decreased body stiffness, reduced tremors, and longer walking ability. The vibration frequency that generally works better is a set frequency that is higher than 20 Hertz [6] and 300 Hertz is able to significantly reduce the motor symptoms of Parkinson's Disease for a longer period of time. Targeted Vibration therapy between 20 to3100 Hertz Frequency significantly helps patient's symptoms while reducing the likelihood of adverse symptoms from affecting the patient[5].

1b. Interviews

This interview was conducted with our Project sponsor, Dr. Ben Weinstock on November 8, 2021.

Question: What area(s) do we want to target? Shin, Foot, Ankle

Answer: He does an evaluation and checks how they move their arms and legs. He checks balance and the sensations; the main three: vision, vestibular system, proception; that heavily impact balance and movement. When they learn proprioception, it causes major balance and walking issues. He generally stimulates the foot, side of the shin bone, the sole, the toe.

Question: What do you believe the best form would be for this device? Sock or Sleeve or Ankle Monitor?

Answer: Joint Receptors respond to pressure and stimuli that can be worn as a sock or garment to stimulate the receptors in the sole of the foot.

Question: What do you currently use?

Answer: Whole body vibration therapy devices and massage guns are currently what he uses. A boot or platform pushes down on two points of the big toe and it puts pressure. One minute causes a major dopamine release. The effect lasts up to 72 hours based on a study in Italy.

Question: How long is the therapy?

Answer: Continuous stimulus becomes habituated, so this is not good. It would be best to do it intermittently or timed. One or Two songs would be best but the sessions usually last between 60-90 seconds.

Question: Does he want patients to be able to walk with this?

Answer: He does not want patients walking or moving in it.

Question: Where do you want the music coming from? Do you want the music to play or just the vibrational rhythms?

Answer: The music should not come from the device itself. The music can come out of headphones which can be wired or wireless.

1c. Market Data

The market data for Parkinson's Disease Therapeutics Market was valued at around 5.18 billion USD in 2020 and is projected to grow at more than 6.5% CAGR between 2021 and 2027[8]. Current market research shows that this device can be used in hospitals, clinics, rehabilitation centers, and for at-home therapy use. With an increase in demand and funding because of the growing market, there is a need for this form of the therapeutic device to exist. This type of device is not also limited to Parkinson's patients because this form of therapy can help others with movement disorders. There is an estimated reward for this device was about $10.5 Million dollars if 20% of the 1.2 million Parkinson's patients choose to buy this device at $150 US dollars. The current modalities of this device include Vibeplate and Neurobeats. Vibeplate is a whole-body vibration device that is extremely expensive and heavy, which is mostly limited to clinical use. Neurobeats is the previous version of his project that included electrical and vibrational stimulation connected to music from a person's phone via Bluetooth. Neurobeats was not functional for an hour and because it was large and bulky making it difficult for patients to have a normal range of mobility. Current companies that are creating vibration therapy devices either whole-body vibration or targeted vibration without music include: Charco Neurotech creating Cue1, Medical Technology Ltd creating Kneease, Resonate Forward LLC creating VibeForward, Various Companies creating Massage guns, and Vibeplate co. creating Vibeplate.

1d. Market Requirements

Based on the research done and the interview done by Dr.Weinstock helped with creating the market requirements for the needs identified.

The current needs of the customer are that the device must be lightweight, water-resistant, and flexible. The initial market requirements determined include a device carrier composed of a flexible and soft material that was adjustable to a range of foot sizes. The device should have a wireless power source that connects with a smartphone to play music to stimulate an area near proprioceptors on the lower leg for a minimum of 2 minutes. The device carrier should be put on and taken off with tremors. These were the current needs identified, but there were flaws in the market requirements that were initially created. The initial market requirements were vague and not suitable, so they were altered based on the needs.

The second iteration of the market requirements were created based on the feedback from the committee and further research. The device should be under 0.9kg with max dimensions of 100m x 60 mm that allows for patients' normal range of mobility with no external attachments. The device must have a wireless power source and play music via Bluetooth for1 an hour from the phone on a single charge. One hour of use on a single charge allows the patient to use the device 5 sessions a day for 7 days a week with each session lasting about 90 seconds each. The device should be water-resistant with an IPX4 rating to allow for incidental water contact and sweat. The device should stretch 17.78cm-25.4cm in length and gender independent to accommodate a range of foot sizes. The device should be placed on and taken off if a patient has excessive tremors and the device should be biocompatible. The device should stimulate the proprioceptors of the lower leg and ankle such as the long flexor muscle, posterior tibial tendon, Achilles tendon to release neurotransmitters and help with a patient's balance. The vibration frequency can be increased or decreased within a safe frequency range to allow for the best treatment intensity for a patient. These needs have been identified from speaking to Dr. Ben Weinstock from Physical Therapy and research in what Parkinson's Disease is and current treatments of Parkinson's Disease. Dr. Weinstock described his needs for the product since he wanted a device that can be used while he performs other treatments at the same time. He also wanted the device to be available for at-home treatment without the need for assistance. The research was done on the symptoms, treatments, music therapy, and vibration therapy.

The final iteration of the market requirements was created based on the feedback from Dr.Christie and following the guidelines of Market Requirements. Market requirements should not be very specific or have a definitive design at this stage in the project. The device should be a lightweight device that does not interfere with the normal range of motion when walking for elderly patients.The device must operate for an adequate number of sessions in one week on a single charge without external cords or wires connecting to a stationary power source and be able to pair wirelessly to a smartphone to play music on the therapy device. The device should be able to resist moisture, such as small splashes and sweat to allow for incidental water contact and sweat. The device should be adjustable to a range of foot sizes to make it one size fits most. The device should be worn and removed by a stage 3 Parksinon's patient. and material will not cause irritation to skin when worn for the duration of treatment. The device should have targeted vibration stimulation to receptors on the lower leg at a beneficial frequency to treat balance and walking problems. These needs were determined by revising the second iteration of Market Requirements that was done from the previous draft.

Initial Market Requirements

- Lightweight and compact system that allows for patients' normal range of mobility. The device must be sweat-resistant.
- The device carrier is composed of a flexible and soft material.
- Must have a wireless power source.
- Able to connect with a smartphone to play music.
- Adjustable to a range of foot sizes.
- Device carriers can be put on with tremors.
- Must be biocompatible.
- Must play the tune for a minimum of 2 minutes.
- Stimulates an area near proprioceptors on the lower leg.

Second Iteration of Market Requirements

- Lightweight device under 0.9kg with max dimensions of 100m x 60 mm that allows for patients' normal range of mobility.

- The device must be water-resistant with an IPX4 rating.
- No external attachments to allow for patient mobility.
- Able to connect with Bluetooth to a smartphone to play music.
- Can stretch 17.78cm-25.4cm in length and gender independent.
- Device carrier can be put on with tremors.
- Must be biocompatible.
- Must play the tune for a minimum of 1 hour.
- Stimulates the proprioceptors on the lower leg around the long flexor muscle, posterior tibial tendon, Achilles tendon.
- Vibration intensity can be increased or decreased within a safe frequency range.
- The device provides feedback on the set level of intensity.

Final Market Requirements

- Lightweight device that does not interfere with the normal range of motion when walking for elderly patients.
- The device is able to resist moisture, such as small splashes and sweat.
- The device must operate for an adequate number of sessions in one week on a single charge without external cords or wires connecting to a stationary power source.
- Can be worn and removed by a stage 3 Parksinon's patient.
- Material will not cause irritation to skin when worn for the duration of treatment.
- The device should operate for a minimum of one hour on a single charge.
- Adjustable to a range of foot sizes to make it one size fits most.
- Targeted vibration stimulation to receptors on the lower leg at a beneficial frequency to treat balance and walking problems.
- Able to pair wirelessly to a smartphone to play music on the therapy device.

1e. References

[1] Cochen De Cock, V., Dotov, D., Damm, L., Lacombe, S., Ihalainen, P., Picot, M. C., Galtier, F., Lebrun, C., Giordano, A., Driss, V., Geny, C., Garzo, A., Hernandez, E., Van Dyck, E., Leman, M., Villing, R., Bardy, B. G., & Dalla Bella, S. (1AD, January 1). *Beatwalk: Personalized music-based gait rehabilitation in parkinson's disease*. Frontiers. Retrieved November 15, 2021, from https://www.frontiersin.org/articles/10.3389/fpsyg.2021.655121/full.

[2] *A comprehensive critique of ... - journals.uncc.edu*. (n.d.). Retrieved November 15, 2021, from https://journals.charlotte.edu/ujop/article/view/849/1121.

[3] Ge, H.-L., Chen, X.-Y., Lin, Y.-X., Ge, T.-J., Yu, L.-H., Lin, Z.-Y., Wu, X.-Y., Kang, D.-Z., & Ding, C.-Y. (2020, May 14). *The prevalence of freezing of gait in parkinson's disease and in patients with different disease durations and severities*. Chinese Neurosurgical Journal. Retrieved November 15, 2021, from https://cnjournal.biomedcentral.com/articles/10.1186/s41016-020-00197-y.

[4] *Good vibrations: Using sound to treat disease*. University of Toronto News. (n.d.). Retrieved November 15, 2021, from https://www.utoronto.ca/news/good-vibrations-using-sound-treat-disease.

[5] H;, M. A. A. Q. J. A. (n.d.). *The effects of long-term 40-Hz physioacoustic vibrations on motor impairments in parkinson's disease: A double-blinded Randomized Control Trial*. Healthcare (Basel, Switzerland). Retrieved November 15, 2021, from https://pubmed.ncbi.nlm.nih.gov/32353963/.

[6] Leuk, J. S. P., Low, L. L. N., & Teo, W.-P. (2020, August 14). *An overview of acoustic-based interventions to improve motor symptoms in parkinson's disease*. Frontiers in aging neuroscience. Retrieved November 15, 2021, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7457064/.

[7]Lord SR;Bindels H;Ketheeswaran M;Brodie MA;Lawrence AD;Close JCT;Whone AL;Ben-Shlomo Y;Henderson EJ; (n.d.). *Freezing of gait in people with parkinson's disease: Nature, occurrence, and risk factors*. Journal of Parkinson's disease. Retrieved November 15, 2021, from https://pubmed.ncbi.nlm.nih.gov/32116261/.

[8]Parkinson's disease therapeutics market size: Global report 2027. Global Market Insights, Inc. (n.d.). Retrieved December 8, 2021, from https://www.gminsights.com/industry-analysis/parkinsons-disease-therapeutics-market.

[9]*Physical therapy*. VibePlate. (2021, April 27). Retrieved November 29, 2021, from https://vibeplate.com/physical-therapy/.

[10]SD;, Z. W. S. G. C. T. Y. Y. C. (n.d.). *Prevalence of freezing of gait in parkinson's disease: A systematic review and meta-analysis*. Journal of neurology. Retrieved November 15, 2021, from https://pubmed.ncbi.nlm.nih.gov/34236501/#:~:text=Background%3A%20Freezing%20of%20gait%20%28FOG%29%20is%20considered%20one,PD%20vary%20widely%2C%20ranging%20from%205%20to%2085.9%25.

[11]Sharififar, S., Coronado, R. A., Romero, S., Azari, H., & Thigpen, M. (2014, July). *The effects of whole body vibration on mobility and balance in parkinson disease: A systematic review*. Iranian journal of medical sciences. Retrieved November 15, 2021, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4100042/.

[12]*Statistics*. Parkinson's Foundation. (n.d.). Retrieved November 15, 2021, from https://www.parkinson.org/Understanding-Parkinsons/Statistics.

[13]Thompson, W. R., Yen, S. S., & Rubin, J. (2014, December). *Vibration therapy: Clinical applications in Bone*. Current opinion in endocrinology, diabetes, and obesity. Retrieved November 15, 2021, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4458848/.

[14]*VAT frequencies & music*. Inner Solutions... for a Sound Lifestyle. (n.d.). Retrieved November 15, 2021, from https://innersoulutions.com/vibroacousticfrequency-and-music-cds-mp3s/.

[15]Wu, S., Ning, H.-T., Xiao, S.-M., Hu, M.-Y., Wu, X.-Y., Deng, H.-W., & Feng, H. (2020, September 17). *Effects of vibration therapy on muscle mass, muscle strength and physical function in older adults with sarcopenia: A systematic review and meta-analysis*. European Review of Aging and Physical Activity. Retrieved November 15, 2021, from https://eurapa.biomedcentral.com/articles/10.1186/s11556-020-00247-5.

1f. Meeting Minutes

"Team 6"

Report Date: 11/05/2021

Team Meeting

Attendees	**Status**			
Jacob Bharat	P			
Bianca Castello	P			
Maria Chiang	P			
Mario Civil	P			
Yency Perez	P			

P = Present L = Late AE = Absent (Excused) A = Absent
Cc: Attendees

Facilitator: Bianca
Note Taker: Jacob
Time Keeper: Jacob

Agenda

<table>
<tr><th>Discussion Points</th><th>Comments</th></tr>
<tr><td>Research</td><td>
We need to start doing research for our different parts to get our project going.
It will be divided and assigned as follows:
Jacob: Bone Conduction and Vibration Therapy
Yency: Parkinson’s Disease and Music Therapy
Maria: Business Need and Current Modalities
Jacob, Maria, and Yency should have this done by 11/7.
Mario and Bianca: Hardware based on Market Requirements(MR) and Budget Research.
Mario and Bianca should have this done by 11/9.
</td></tr>
<tr><td>Division of Parts</td><td>
In the division of parts, Design Inputs, Concept, and House of Quality should be done together as a group.

<u>Part 1</u>
Problem Statement:
Proposed Solution:
The Clinical Need:
The Business Need:
Market Requirements
Current Modalities
Project Scope

<u>Part 2</u>
Solidworks
Design Inputs
Design Concepts
House of Quality
Project Cost/ Budget
Standards
Hazard Analysis
Constraints

<u>Part 3</u>
Technology Assessment - Mario
Regulatory Assessment - Bianca
Verification Tests- Bianca
Applied Science - Yency
Inclusion/Exclusions- Jacob
Project Success Factors -Maria</td></tr>
</table>

	Determination of Domestic & International Standards Solution impact on society in a global and contemporary Accomplishment Milestones Project Plan Written Proposal: DHF
Future Steps	• Part 1 must be done 11/7 except for MR. • MR should be done by 11/8. • Part 2 should start on 11/8. • Hardware Research and Budget should be done by 11/9. • Part 2 should be completed and Part 3 will begin on 11/10. • Part 3 should be completed on 11/12. • Powerpoint must be completed and practiced by 11/14.

Action Item	**Person Responsible**	**Assigned Date (11/5)**	**Status**
• Bone Conduction and Vibration Therapy • Inclusions/ Exclusions	Jacob	Due 11/8	
• Parkinson's Disease and Music Therapy • Applied Science • Hazard Analysis	Yency	Due 11/8	
• Business Need and Current Modalities • Project Success Factors	Maria	Due 11/8	
• Hardware based on Market Requirements(MR) and Budget Research. • Technology Assessment	Mario	Due 11/8	
• Hardware based on Market Requirements(MR) and Budget Research. • Regulatory Assessment	Bianca	Due 11/8	

"Team 6"

Report Date: 11/07/2021

Team Meeting

Attendees	Status			
Jacob Bharat	P			
Bianca Castello	P			
Maria Chiang	P			
Mario Civil	P			
Yency Perez	P			

P = Present L = Late AE = Absent (Excused) A = Absent
Cc: Attendees

Facilitator:	Bianca
Note Taker:	Jacob
Time Keeper:	Jacob

Agenda

Discussion Points	Comments
Research	• Jacob Spoke about his research on Bone Conduction and Vibration Therapy. His focus was on Targeted Vibration Therapy and specific hertz that is useful. • Bianca has done research on Hardware based on Market Requirements(MR) focusing on very small parts and looking at the budget that is needed based on the parts that are being found. • Bianca is still researching and waiting for a finalized MR to final budget and research. • Mario had some research done about technology assessment. • Maria had done some of the business research, but is missing current modalities.
Part 1 Updates	• Jacob modified that previously part 1 rough draft that was created and made it a more finalized version. • Project Scope must be revisited when putting on the final version. We must decide if it is focusing on fixing the last group's mistakes with circuitry or just moving as normal. • Market Requirements need to wait on PT Meeting. • Maria has not done the current modalities.

Part 3 Updates	• Jacob has finished the Inclusions and Exclusions, since it was very short and already given he will work on something else for Part 3. • Bianca was not able to get part 3 done by 11/7. • Mario technology assessment was still in progress. • Maria project success factors are in progress.
Design	• We went through some Market Requirements, Design Input, and Design Concepts • The Design Concepts was to discuss with the PT.
Questions	• What Bone(s) do we want to target? Shin, Foot, Ankle • Sock or Sleeve or Ankle Monitor • What do you currently use • What positions of vibration do you target it in • How long is the therapy • Is it one point of contact, or is it moving or multiple areas at once? • What does he want to see? His Vision? • Does he want patients to be able to walk with this? • What kind of music? • Where do you want the music coming from? Do you want the music to play or just the vibrational rhythms? • Current vibration rhythms you use? • Are you aware of the frequency or amplitudes that you currently use? • Vibration then walking or continuous vibration while walking? • Budgeting or Money?

Action Item	**Person Responsible**	**Date**	**Status**
• Bone Conduction and Vibration Therapy • Inclusions/ Exclusions	Jacob	Assigned Date (11/5)Due 11/7	Done
• Parkinson's Disease and Music Therapy • Applied Science	Yency	Assigned Date (11/5)Due 11/8	Done
• Business Need and Current Modalities • Project Success Factors	Maria	Assigned Date (11/5)Due 11/8	In Progress
• Hardware based on Market Requirements(MR) and Budget Research. • Technology Assessment	Mario	Assigned Date (11/5)Due 11/8	In Progress
• Hardware based on Market	Bianca	Assigned Date (11/5)Due 11/8	In Progress

Requirements(MR) and Budget Research. • Regulatory Assessment			
• Solution • Accomplishment • Project Plan Program	Jacob	Assigned Date (11/7) Due 11/9	Done
• Regulatory Assessment	Yency	Assigned Date (11/7) Due 11/9	Done
• Verification Tests	Bianca	Assigned Date (11/7) Due 11/9	Done

"Team 6"

Report Date: 11/08/2021

Team Meeting

Attendees	Status			
Jacob Bharat	P			
Bianca Castello	P			
Maria Chiang	P			
Mario Civil	P			
Yency Perez	P			

P = Present L = Late AE = Absent (Excused) A = Absent
Cc: Attendees

Facilitator: Bianca
Note Taker: Jacob
Time Keeper: Jacob

Agenda

Discussion Points	Comments
PT Meeting	• What Bone(s) we want to target? Shin, Foot, Ankle • Sock or Sleeve or Ankle Monitor • What do you currently use • How long is the therapy • What does he want to see? His Vision? • Does he want patients to be able to walk with this? • Where do you want the music coming from? Do you want the music to play or just the vibrational rhythms?

	• Current vibration rhythms you use? • Are you aware of the frequency or amplitudes that you currently use? • Budgeting or Money?
Answers	• He does an evaluation and checks how they move their arms and legs. • He checks balance and the sensations; the main three: vision, vestibular system, proception; that heavily impact balance and movement. When they learn proprioception, it causes major balance and walking issues. • Joint Receptors respond to pressure and stimuli that can be worn as a sock or garment to stimulate the receptors. • Music overrides a lot of problems and helps to close the release of neurotransmitters. • Continuous stimulus becomes habituated, so this is not good. It would be best to do it intermittently or timed. One or Two songs. • A boot/platform pushes down on two points of the big toe and it puts pressure. One minute causes a major dopamine release. Effect lasts up to 72 hours. In Italy. • Not him losing business • Not Moving with it • Current vibration therapy is a few minutes. • No walking with it. • He generally stimulates the foot, side of the shin bone, the sole, the toe. Would like the in sole or the sole of the foot. • Won't be there till the end of the week but will look for the name of the device so we can look at frequency and amplitude. • Headphones are a good option. • Paypal
Part 1 Updates	• Market Requirements were completed based on the PT meeting and previous market research. • Maria’s part is unknown because Maria left early, must receive an update.
Part 2 Updates	• Design inputs, house of quality, and design concepts were completed. • The rest of part 2 was divided up among the members and was expected to get done by 11/10, so the next scheduled team meeting. • The team worked together to create the design inputs for each market requirement, so that each design input was measurable and verifiable. • The team completed the house of quality and established the relationships within the house of quality to get the design concepts.

Part 3 Updates	• Majority of the parts were divided among members and expected to be done by 11/10. • Three topics were tabled to get done during the next meeting.
Future	• 11/10 will be focused on a project plan and PowerPoint.

Action Item	**Person Responsible**	**Date**	**Status**
• Standards • Hazard Analysis	Yency	Assigned 11/8 Due 11/10	
• Solidworks	Mario	Assigned 11/8 Due 11/10	
• Fix up and make language pretty • Project Cost/ Budget	Jacob	Assigned 11/8 Due 11/10	
• Project Cost/ Budget	Bianca	Assigned 11/8 Due 11/10	
• Constraints • Solution impact on society in a global and contemporary	Maria	Assigned 11/8 Due 11/10	
• Business Need and Current Modalities • Project Success Factors	Maria	Assigned Date (11/5)Due 11/7	In Progress 11/8
• Hardware based on Market Requirements(MR) and Budget Research. • Technology Assessment	Mario	Assigned Date (11/5)Due 11/9	In Progress 11/8
• Hardware based on Market Requirements(MR) and Budget Research. • Verification Tests	Bianca	Assigned Date (11/5)Due 11/9	In Progress 11/8
• Accomplishment • Project Plan Program	Jacob	Assigned Date (11/7) Due 11/9	11/8 Done
• Regulatory Assessment	Yency	Assigned Date (11/7) Due 11/9	11/8 Done

Team 6 Senior Team Meeting Minutes

Date: January 13,2022

I. Call to Order

A. Meeting Called to Order at: 02:41 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Present
Dr. Christie	Current Faculty Advisor/Mentor	Present

III. Approval of Last Meeting's Minutes
   A. Jacob Motions, Bianca Seconds

IV. Unfinished Business
   A. This was the first meeting of the semester.

V. New Business
   A. Dr. Christie asked us to look into a previous iteration of the device that we are doing.
      1. We informed him that we are aware and working on improving the previous device because it was not functioning properly.
      2. We told us to reach out to our sponsor for the DMR, DHF, and DHR.
   B. Dr. Christie questioned our research and decision making on specific things. He said to find a paper or research that states why targeting a location is important and why that relates to neurotransmitter release. State the reasons to use targeted vibration therapy rather than whole body vibration therapy.
      1. Define where exactly this location is and why
      2. Create a 7 minute presentation as a summary that covers and explains all of this.
      3. Depending on our next meeting and the further research, we may have to reimagine our device and solution
   C. Dr.Christie asked us to come up with meeting minutes and an agenda for each meeting.
      1. The meeting minutes should be much better and be a professional set of minutes

D. Future meetings will be focused on looking at the Market Requirements(MR) and Design Inputs(DI).
    1. Reviewing and Revising our MRs and DIs.

E. Our meeting time will be the same. It will be Thursdays at 2:30PM every other week in odd weeks starting from the first week of class.

VI. Due Dates/ Task
    A. By Next Meeting with Dr.Christie
        1. Come up with an agenda and meeting minutes.
        2. Create a small presentation.

VII. Meeting Adjournment
    A. Meeting Adjourned at 03:05 p.m.

Team 6 Senior Team Meeting Minutes

Date: January 19, 2022

I. Call to Order
    A. Meeting Called to Order at: 05:05 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Present at 5:17

III. Approval of Last Meeting's Minutes
    A. Jacob Motions, Bianca Seconds

IV. Unfinished Business
    A. Spoke about the last meeting with Dr. Christie.
        1. We need to find a paper and research for location targeting and neurotransmitter release are related. Why does the location help?
            a) Yency was in the process of creating a PowerPoint. We discussed anatomy and location targets. We reviewed some of our old research and looked for some new research.

B. Spoke about the research that was done over winter break to get ahead.
    1. App
        a) We looked at the different ways and platforms that can be used to code apps on different operating systems. We will create an app to read the song as a waveform to play the amplitudes of the music in vibrations. The songs will come from a pre-downloaded song library.
        b) Some coding languages that were seen were Java, Swift, Kivy, Python from Apple; Android has some other languages and Android is thought to be easier to code for apps than apple.
    2. Coding
        a) We have to do 2 types of coding. One coding for the app and translating the song to vibration. One coding is the Bluetooth/circuit/vibration device to vibrate based on the information received from the app. This coding has more flexibility in languages that can be used such as MATLAB, Python and Arduino.
    3. Vibration
        a) The vibration motors that Jacob was looking at do not have the ability to change in amplitude, only in the RPM. This limits what we can change and have variables. The vibration will likely be based solely on speed and frequency which is the main variable that we want patients to control so it must vibrate at a constant rate for each setting.
    4. Bluetooth
        a) Look at the different Bluetooth profiles and how they affect each other to see what Bluetooth profile the device must be coded as so that audio can be played simultaneously through a different output.

C. Spoke about the design of the device
    1. We looked at the feedback or display to show how the setting changed.
    2. We looked at different LEDs that can be used.
        a) Led scale with multiple LEDS
        b) A single clear LED that can change color denoting different settings,
    3. We spoke on how the device can be encased so that the device is chargeable, waterproof and able to display the feedback.
        a) Looked at portable chargers with certain plastic covers for the charging port and silicone encasing.

V. New Business

A. Assigned people as point person for certain aspects of the project
    1. Yency: Anatomy expert, locating the tendons and muscles that are being targeted and why. Jacob will act as the helper.
    2. Maria and Mario will work together on figuring out the outsourcing.
    3. Maria and Bianca will work together on what is needed for the circuitry and how to assemble it.
    4. Jacob will do the meeting minutes for this semester. Maria will act as the helper.
    5. Yency, Bianca, and Maria will work together on the coding for the app and device.
B. We spoke about the design and the possibility of additional design issues.
    1. The sock material or device carrier may have to be designed or changed because current design might not be suitable or effective.
    2. This was speculation so this was tabled to a later meeting.
C. The question was brought up of how the funding and purchase procedures will go.
D. We needed to know what materials are necessary for the project and what we need to outsource by our Monday meeting on 1/24.

VI. Due Dates/ Task
  A. Tasks to get done by Friday (1/21/2022)
      1. Send out the charter form to be signed by Dr. Christie and Dr. Weinstock.
      2. Send the pledge form to Dr. Weinstock to fill out and send to Claudia Estrada.
  B. Tasks to get done by the Monday (1/24/2022) Meeting
      1. Jacob- lab info and where to get lab materials.
      2. Mario- finding out the process we have to go through to make purchases for the project. How do we go through the BME department?
      3. Yency- understanding the anatomy and position of the device with references on why we choose this spot instead of other options.
      4. Maria- finding similar projects and codes we can use as reference. Understanding what electrical pieces we need.
      5. Bianca- finding out what app and how to program it to connect to Bluetooth and what coding language we need to use. Helping with circuit components.
  C. Additional Tasks
      1. Jacob- If done with lab resources and work spaces, start on the solidworks design and try to get it by Monday. Do meeting minutes

VII. Meeting Adjournment
  A. Meeting Adjourned at 08:54 p.m.

Team 6 Senior Team Meeting Minutes
Date: January 20,2022

I. Call to Order
    A. Meeting Called to Order at: 03:04 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Present
Dr. Christie	Current Faculty Advisor/Mentor	Present

III. Approval of Last Meeting's Minutes
    A. Jacob Motions, Bianca Seconds

IV. Unfinished Business
    A. Present the scientific research and powerpoint presentation to Dr. Christie.
        1. Receive feedback and guidance to decide on next steps
    B. Dr.Christie asked to look out our meeting minutes from the last meeting.
        1. He reviewed the meeting minutes from 1/13/2022 and got a recap.
    C. Dr.Christie stated that he was not sure why a sock and the placement was necessary.
        1. Our follow-up email did not answer all of his questions, so Dr.Christie wanted our team to clear up his questions further.

V. New Business
    A. Scientific Research
        1. Yency summarized our scientific research and presented them to Dr.Christie. Yency used a powerpoint presentation to explain each of the main scientific aspects of our project. Yency spoke about the music, vibroacoustic therapy, proprioceptors, anatomy and the specific targeted location. We spoke about the sock pocket area and placement. How this is targeted.

a) Yency went further in dept with the brain pathways these locations are related to and how they are effective. With targeting these receptors.

b) Yency spoke on our decisions and positioning. The positioning was chosen to target the most applicable tendons while being small and lightweight.

c) Yency spoke on the device carrier design. The purpose of the sock and how it relates to the targeted location.

B. Dr.Christie had feedback on the presentation

1. Yency did a great job and had a great presentation. Even the title was what he was looking for. [Period good job Yency]

C. Make sure the Project Plan and the meeting minutes are in the correct format.

D. Bring the MRs and DIs

1. Make sure we bring rationale for each DI
2. Remember the four questions that we need to answer.

VI. Due Dates/ Task

A. Bring our Project Plan in the correct format using Microsoft Project.

B. Bring our Market Requirements and Design Inputs with scientific rationale for each Design Input. Make sure to answer the 4 questions.

C. Global Learning Training

VII. Meeting Adjournment

A. Meeting Adjourned at 03:18 p.m.

Team 6 Senior Team Meeting Minutes

Date: January 24,2022

I. Call to Order

A. Meeting Called to Order at: 06:05 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present

Mario Civil		Present

III. Approval of Last Meeting's Minutes
   A. Jacob Motions, Bianca Seconds
IV. Unfinished Business
   A. Charter and Donation
      1. Submitted the charter form to be signed by Dr. Christie and Dr. Weinstock.
      2. Dr. Weinstock filled out the donation/pledge form and sent it to Claudia Estrada.
   B. Tasks that should be completed today
      1. Jacob- lab info and where to get lab materials.
      2. Mario- finding out the process we have to go through to make purchases for the project. How do we go through the BME department?
      3. Yency- understanding the anatomy and position of the device with references on why we choose this spot instead of other options.
      4. Maria- finding similar projects and codes we can use as reference. Understanding what electrical pieces we need.
      5. Bianca- finding out what app and how to program it to connect to Bluetooth and what coding language we need to use. Helping with circuit components.
V. New Business
   A. Updates
      1. Bianca
         a) Went over the research and over that she did in relation to the finding out what app and how to program it to connect to Bluetooth and what coding language we need to use
         b) Found launganges that could be used such as java, c++, kivy, android studio,
      2. Maria
         a) Found different research papers and codes of similar things that we are trying to do.
         b) https://www.section.io/engineering-education/audio-signals-processing-using-matlab/
         c) https://github.com/tyiannak/pyAudioAnalysis#:~:text=%20pyAudioAnalysis%20is%20a%20Python%20library%20covering%20a,provides%20easy-to-call%20wrappers%20to%20execute%20audio%20analysis%20tasks.
         d) https://amath.colorado.edu/pub/matlab/music/

3. Discussion of Next Steps
    a) Create an app where the app has pre-downloaded songs with the songs read and analyzed so the vibrations can be sent directly to the device.
    b) Jacob will ask Cris about this.
4. Yency
    a) Yency already gave the presentation about the anatomy and pinpointed the specific spot. Yency does not think we should go too far deep into the anatomy.
    b) Keep doing research.

B. Global Learning Training

C. Next Meeting with Christie
1. Bring our Project Plan in the correct format using Microsoft Project.
2. Bring our Market Requirements and Design Inputs with scientific rationale for each Design Input. Make sure to answer the 4 questions.
    a) Accomplishments
    b) Next Steps
    c) Threats
    d) Mitigations

VI. Due Dates/ Task

A. Yency will figure out hertz needed

B. Bianca will try and build a simple app

C. Jacob work on the Solidworks

D. Mario will figure out how we will buy things

E. DIs Rationale
1. Yency-The first one and the stretchy one
2. Jacob-Time Focused
3. Maria -Bluetooth
4. Mario-Stimulate, intensities
5. Bianca-Water Resistant

F. Can we sketch our sock not in solidworks.

VII. Meeting Adjournment

A. Meeting Adjourned at 08:28 p.m.

Team 6 Senior Team Meeting Minutes

Date: January 26,2022

I. Call to Order

A. Meeting Called to Order at: 05:10 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present at 5:20
Maria Chiang		Present
Mario Civil		Present at 5:20

III. Approval of Last Meeting's Minutes
   A. Jacob Motions, Bianca Seconds

IV. Unfinished Business
   A. Jacob has not completed the Solidworks
   B. Bianca has not completed to simple app yet

V. New Business
   A. Electronics: Look up the electronics and find the best one that will suit our device and put it on the doc so that we can send it to claudia to purchase soon.
      1. Bianca: Vibration Motor
      2. Mario: Charging Port
      3. Jacob: Battery
      4. Maria: Microchip
      5. Yency: Arduino
   B. We had a discussion about the reasoning for getting each electronic and went through it and its features together.
      1. We will compile a doc of all the links with things we need to order.
   C. Global Learning Training
   D. Next Meeting with Christie
      1. We have our Project Plan in the correct format using Microsoft Project.
      2. We discussed our Market Requirements and Design Inputs with scientific rationale for each Design Input

VI. Due Dates/ Task
   A. Yency will figure out hertz needed
   B. Bianca will try and build a simple app
   C. Jacob work on the Solidworks

D. DIs Rationale
    1. Yency-The first one and the stretchy one
    2. Jacob-Time Focused
    3. Maria -Bluetooth
    4. Mario-Stimulate, intensities
    5. Bianca-Water Resistant
E. Can we sketch our sock not in solidworks.

VII. Meeting Adjournment

A. Meeting Adjourned at 08:36 p.m.

Section 2: Design Inputs

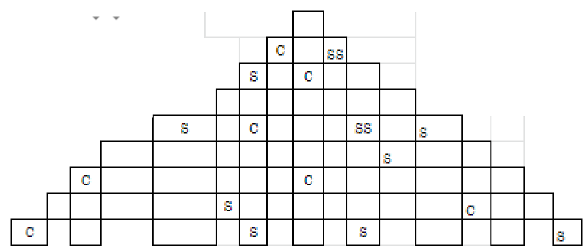
2a. Quality Function Deployment (QFD)

The quality function deployment, also known as the house of quality, was performed by comparing the market requirements to the design inputs to determine how each thing interacts with each other. Some things support or contradict each other, so this allows us to understand how each market requirement and design input impact each other. This allowed us to create our design concept of what our device will be and see which design concept will be used for the design of our project.

Figure 1: First Quality Function Deployment (QFD)

QFD: House of Quality

Correlations	
Strongly Support	SS
Strongly Contradict	CC
Contradict	C
Support	S
No Correlation	



Row #	Design Inputs / Market Requirements	1. Device dimensions will be equal to or under 100mm x 60 mm and device should be made of low density material, less than 1 kg per cubic meter.	2. The resolution of the intensity changes per click +/- .5 Hz.	3. The device's circuitry will be enclosed inside a case able to withstand a minimum of 50 liters of water sprayed at pressure of 50-150 kPa continuously for 5 minutes at any direction.	4. Device will have a wireless power source.	5. Device uses radio waves on a frequency band between 2.4 - 2.5 GHz.	6. Device has a maximum elastic modulus of 4GPa.	7. Device will be put on and taken off with no size adjustments needed.	8. Material will not cause any irritation to the skin after wearing device for a minimum of 1 hours.	9. Devices will have a battery capacity to operate for at least 1 hour on a single charge.	10. Low frequency sound will be delivered to the patient (20-40 Hz).	MR Priority	Design Concepts A	B	C
1	Lightweight device under 0.9kg with max dimensions of 100m x 60 mm that allows for patients normal range of mobility.	SS	C	C	SC	C	S		S	SC		5	3	5	5
2	Vibration intensity can be increased or decreased within a safe frequency range.		SS							C	S	5	5	5	5
3	Device must be water resistant with an IPX4 rating .			SS		C				SC	C	5	1	5	5
4	No external attachments to allow for patient mobility.	C		S	SS	SS		S		C		5	5	5	5
5	Able to connect with Bluetooth to a smartphone to play music.					SS						5	5	5	5
6	Can stretch 17.78cm-25.4cm in length and gender independent.						SS	S	S			3	1	5	5
7	Can be put on and taken off with tremors	SS					SS	SS				5	3	1	5
8	Must be Biocompatible								SS			5	5	5	5
9	Must play tune for a minimum of 1 hour		C			C				SS		5	5	5	5
10	Stimulates the proprioceptors on the lower leg around the long flexor muscle, posterior tibial tendon, achilles tendon.		SS	C						S	SS	5	5	5	5
	Total											240	188	220	240

A Fabric shin guard with electrical vibration components embeded around ankle and bottom of shin. With a rechargable battery.

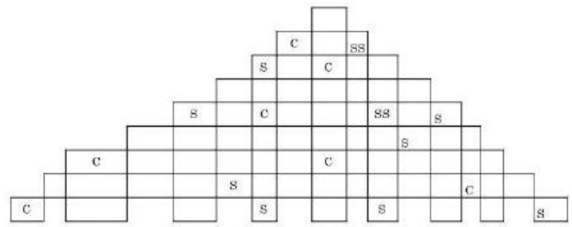
B Thin adjustable band with vibration motors along band length. Rechargable battery in untit.

C Fabric sock with outside pocket on anckle which fits portable vibration device. Device is enclosed with silicone casing and contains battery.

Figure 2: Second Quality Function Deployment (QFD)

QFD: House of Quality

Correlations	
Strongly Support	SS
Strongly Contradict	CC
Contradict	C
Support	S
No Correlation	



Row #	Design Inputs / Market Requirements	1. Device dimensions will be equal to or under 100mm x 60 mm and device should be made of low density material, less than 1 kg per cubic meter.	2. The device includes an LED displaying the resolution change +/- 10 Hz when manipulating the vibration intensity.	3. The device should be able to withstand a minimum of 50 liters of water sprayed at pressure of 50-150 kPa continuously for 5 minutes at any direction.	4. Use a rechargeable battery as a wireless power source with battery power to operate for 1 hour.	5. Using Bluetooth technology to synchronize with a smartphone and play music in the form of vibrational rhythm.	6. Can stretch between 22cm to 31cm in length.	7. The device should take no more than 1 minute for a stage 3 Parkinson's patient to wear and remove.	8. Device carrier must be biocompatible.	9. Battery capacity depends on power consumption to allow the device to operate for at least 1 hour on a single charge.	10. Use 20-100 Hz frequency vibration that will be delivered to the patient's lower leg such as the achilles tendon and the long flexor muscle.	MR Priority	Design Concepts A	B	C
1	Lightweight device that does not interfere with the normal range of motion when walking for elderly patients.	SS	C	C	SC	C	S		S	SC		5	3	5	5
2	Vibration intensity can be increased or decreased with a feedback mechanism.		SS							C	S	5	5	5	5
3	The device is able to resist moisture, such as small splashes and sweat.			SS		C				SC	C	5	1	5	5
4	The device must operate for 1 hour on a single charge without external cords or wires connecting to a stationary power source.	C		S	SS	SS		S		C		5	5	5	5
5	Able to pair wirelessly to a smartphone to play music on the therapy device.					SS						5	5	5	5
6	Adjustable to a range of foot sizes to make it one size fits most.						SS	S	S			3	1	5	5
7	Can be worn and removed by a stage 3 Parksinon's patient.	SS					SS	SS				5	3	1	5
8	Material will not cause irritation to skin when worn for the duration of treatment.								SS			5	5	5	5
9	The device should operate for a minimum of one hour on a single charge.		C			C				SS		5	5	5	5
10	Targeted vibration stimulation to receptors on the lower leg at a beneficial frequency to treat balance and walking problems.		SS	C						S	SS	5	5	5	5
	Total											240	188	220	240

A Fabric shin guard with electrical vibration components embeded around ankle and bottom of shin with a rechargable battery.

B Thin adjustable band with vibration motors along band length and rechargable battery in unit.

C Fabric sock with outside pocket on anckle which fits portable vibration device. Device is enclosed with silicone casing and contains battery.

2b. Design Input

The Design Inputs are based on the market requirements based on the current needs identified. The discussions and feedback from our professor helped to improve the design inputs which create measurable and verifiable design inputs.

The initial design inputs were not fully measurable and verifiable, which are as follows.

- Less than 1.5lb

- Device carrier material must use fabrics that are elastic.
- Device electrical components should be enclosed in a water resistant casing.
- Device should be battery operated.
- Must have wireless or bluetooth connectivity to play music audibly.
- The device carrier will be a sock with stretchable fabric that can fit various foot sizes
- The device will seamlessly be secured to the device carrier.
- Devices must be composed of polymers and bioinert materials.
- Devices must have a battery capacity to operate for at least 30 minutes on a single charge.

The second iteration of the design inputs were created and improved after research and feedback from the committee while ensuring consistency among International standard units.

Table 1: Second Iteration of Design Inputs

Market Requirement	**Design Input**
Lightweight device under 0.9kg with max dimensions of 100mm x 60mm that allows for patients normal range of mobility.	Device dimensions will be equal to or under 100 mm x 60 mm and the device should be made of low density material, less than 1 kg per cubic meter.
Device must be water resistant with an IPX4 rating .	The device's circuitry will be enclosed inside a case able to withstand a minimum of 50 liters of water sprayed at pressure of 50-150 kPa continuously for 5 minutes at any direction.
No external attachments to allow for patient mobility.	Will have a wireless power source.
Can be put on and removed with tremors	Device will be put on and taken off with no size adjustments needed.
Must be biocompatible	Material will not cause any irritation to the skin after wearing the device for a minimum of 1 hours.
Must play tune for a minimum of 1 hour.	Devices will have a battery capacity to operate for at least 1 hour on a single charge.
Can stretch 17.78cm-25.4cm in length and gender independent.	Material will have a minimum elastic modulus of 4 GPa
Stimulates the proprioceptors on the lower leg	Low frequency vibration will be delivered to

around the long flexor muscle, posterior tibial tendon, achilles tendon.	the patient (20-40 Hz).
Vibration intensity can be increased or decreased within a safe frequency range.	The resolution of the intensity changes per click +/- 5 Hz.
Able to connect with Bluetooth to a smartphone to play music.	Device uses radio waves on a frequency band between 2.4 - 2.5 GHz.
The device provides feedback on the set level of intensity.	Device has a visual feedback that shows the level of intensity of vibration.

The final iteration of the design inputs was created by speaking to Dr.Christie and revising the Market Requirements and Design Inputs with Rationale to fit the guidelines of each thing. Design Inputs represents how the need will be accomplished and the reasoning for how that Design Input relates to the Market Requirement.

Table 2: Final Iteration of Market Requirements, Design Inputs, and Verification Tests

#	**Market Requirements (What & Why)**	**Design Input (How) Rationale Below**	**Method of Verification (Verification Test)**
1	Lightweight device that does not interfere with the normal range of motion when walking for elderly patients.	Device dimensions will be equal to or be under 100mm x 60 mm and the device should weigh less than 1 kg. Rationale The use of a cuff weight (1.1kg) does not seem to reduce the limb circumduction[1] No significant differences were found in cadence and stride length. Therefore, the side of the ankle is approximately 3-3.5inches, which is about 90 mm.	We will use a ruler to measure the dimensions and ensure it's within the constraints. We will use the scale to ensure that the device is less than 1 kilogram. ISO 5725-1:1994(en) Accuracy (trueness and precision) of measurement methods and result

2	The device is able to resist moisture, such as small splashes and sweat.	The device should be able to withstand a minimum of 50 liters of water sprayed at pressure of 50-150 kPa continuously for 5 minutes at any direction*- see 3.1 <u>Rationale</u> Due to the selection of an elastic fabric material for the device carrier, two scenarios benefit directly from the device being water resistant. 1) Walking sessions will be performed regularly as a complementary treatment for Parkinson's, sweat and moisture penetrating the device carrier can be inhibited by the encasing. [2] 2) Excessive sweating can be a consequence of damage to the autonomic nervous system as Parkinson's progresses or a side effect of anti-parkinson's medications. To battle this possibility, having the circuitry enclosed and covered is critical. "Wallace advises: 'Any IP rating which ends with a number greater than (e.g. IPX1 or IP51) should be sweat-proof. However, many regard the standard as IPX4 for water resistance and we'd recommend this as the minimum for real durability.' [3] Further up the scale, an IPX4 water rating can handle water splashes, whilst IPX5 is certified for protection against low pressure jets of water from any angle for three minutes. In terms of working out, these ratings can handle a medium sweaty session such as a run."[4]	Standard IPX4 using the Ingress Protection Test. IEC 60529 IP Rating (Water Resistance)
3	The device must operate for an adequate number of sessions in one week on a single charge without external cords or wires connecting to a stationary power source.	Use a rechargeable battery as a wireless power source with battery power to operate for 1 hour. <u>Rationale</u> The use of a rechargeable power source to operate the device will reduce the risk of electric shock due to wire damage, and it will cause less noise and interference to surroundings, making it more convenient for the patient to move freely. One hour of use on a single charge allows the patient to use the device 5 sessions a day for 7 days a week with each session lasting about 90 seconds each. [5]	We can test if the battery power capacity and if is rechargeable by using a multimeter. **Devices with rechargeable batteries – including products certified to IEC 60601-1 – must comply with IEC 62133** IEC 60601-1-11:2010 -Ed 1.0 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment[6]

4	Can be worn and removed by a stage 3 Parksinon's patient.	The device carrier is made of a flexible material allowing for a stage 3 Parkinson's patient to wear and remove it without assistance in 5 minutes or less. <u>Rationale</u> Considered mid-stage, loss of balance and slowness of movements are hallmarks. The person is still fully independent, but symptoms significantly impair activities. Current tools to aid in putting on socks for patients with mobility problems.After stage 3, the patient is usually unable to care for themselves. [6] Generally, patients give up after 2-5mintunes after not being able to achieve a task on their own. Independence is the vision that drives our concept, hence, the device carrier will take less than 5 minutes to be worn.	We would use a stopwatch to time how long it would take for the wearing and removal of the device carrier. IEC 62366 is the international standard that covers the application of usability engineering to medical devices. This standard helps medical device manufacturers consider human factors by offering a standardized process for analyzing, specifying, developing, and evaluating the usability of their medical device.[8]
5	Material will not cause irritation to skin when worn for the duration of treatment.	Device carrier must be biocompatible. <u>Rationale</u> Biocompatibility testing is part of an overall risk management process to protect humans from potential biological risks stemming from the use of medical devices. The evaluation of biocompatibility testing data for a particular device is used as evidence in establishing the device's biological safety.	Use find materials that are already biocompatible. Find reference and evidence that supports biocompatibility. ISO 10993-10:2010 describes the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce irritation and skin sensitization.[7] ISO 10993-10:2010 includes: pretest considerations for irritation, including in silico and in vitro methods for dermal exposure; details of in vivo (irritation and sensitization) test procedures; key factors for the interpretation of the results. Instructions are given for the preparation of materials specifically in relation to the above tests and several special irritation tests are described for application of medical devices in areas other than skin. Biocompatibility The agency has existing guidance on devices that have contact with the human body, which will remain in effect until the draft document is finalized.

			The draft guidance applies to medical devices that contact intact skin surfaces only; have limited (24 hours or less), prolonged (24 hours to 30 days), and long-term (more than 30 days) contact durations, including repeat uses; and are composed of certain types of materials. The materials include several synthetic polymers and a small number of fabrics. The synthetic polymers include: Polyethylene terephthalate (PET) Polymethylmethacrylate (PMMA) Polyoxymethylene (POM) Polyphenylsulfone (PPSU) Polypropylene (PP) Polyurethane (PU) Silicone The fabrics include: Polyurethane fabrics, including Lycra Cotton fabrics Polyamide fabrics, including nylon Silk fabrics [13]
6	The device should operate for an adequate number of sessions in one week on a single charge. Combined with #3	Battery capacity depends on power consumption to allow the device to operate for at least 1 hour on a single charge. <u>Rationale</u> This is operating on a single charge for 5 days with 2 sessions per day, so a normal work week. “. Each treatment includes five sessions and each session is composed of one minute whole body vibration and one minute rest…. Each session is 10 minutes in both groups and all participants will receive one and twelve treatment sessions for short-term and long-term effect respectively. ” [10]	A stopwatch would be used to measure how long the device will function with the battery fully charged until it runs out of charge. Devices with **rechargeable batteries** – including products certified to IEC 60601-1 – must comply with **IEC 62133**
7	Adjustable to a range of foot sizes to make it one size fits most.	Can stretch between 22cm to 31cm in length. <u>Rationale</u> In the US, the average shoe size is 11 for men and 8.5 for women. Globally, the average shoe size for men is between 9 and 12 with an average of 10.5, and women’s average shoe size is between 7 and 9 with an average of 8. With our population being Parksion’s patients who are elderly, our size range was slightly larger due to the change in foot size the elderly undergo. Elderly people often have	will use a ruler to measure the dimensions and ensure its within the constraints. ISO 7250-3:2015 ISO 7250 consists of the following parts, under the general title *Basic human body measurements for technological design*:

		their foot size and shape shrink or swell. The average range for men's foot size internationally is between263 mm to 292 mm. The average range for women's foot size internationally is between 241mm to 257 mm. . To accommodate for the varying foot sizes and the possible changes, the range will be 220 mm to 310 mm. https://www.loveatfirstfit.com/guides/what-is-the-most-popular-sneaker-size-for-men-and-women/ https://www.footankleinstitute.com/blog/are-your-shoes-the-right-size/	*— Part 1: Body measurement definitions and landmarks* *— Part 2: Statistical summaries of body measurements from national populations* *— Part 3: Worldwide and regional design values for use in ISO equipment standards* [12]
8	Targeted vibration stimulation to receptors on the lower leg at a beneficial frequency to treat balance and walking problems.	Use 20-300Hz frequency vibration that will be delivered to the patient's lower leg such as the achilles tendon and the long flexor muscle. <u>Rationale</u> VAT delivers passive low-frequency sound vibrations (20–300 Hz) in contrast to RAS, the latter, an active form of acoustic therapy. In clinical settings, VAT supports the idea that patients should not only listen to music in isolation but sense vibrations as well (Warth et al., 2015). The VAT involves transducers embedded into chairs or mattresses, which send vibrations to and through the body. [10]	Oscilloscope: Measure the vibrational frequency output from the device. ISO 5349-1:2001 Mechanical vibration — Measurement and evaluation of human exposure to hand-transmitted vibration — Part 1: General requirements [11]
9	Able to pair wirelessly to a smartphone to play music on the therapy device.	Using Bluetooth technology to synchronize with a smartphone and play music in the form of vibrational rhythm. <u>Rationale</u> Bluetooth consumes low power.	Use a stopwatch to measure the lag between the music playing and the vibrational rhythm to determine if the lag is within an appropriate and not noticeable range. ISO 5725-1:1994(en) Accuracy (trueness and precision) of measurement methods and result

2c. Design Concepts

All the possible ways the objectives could be accomplished resulted in the evaluation of multiple concepts. Fabric shin guard with electrical vibration components embedded around the ankle and bottom of shin, including a rechargeable battery. The first design concept, figure 1, was having the circuitry and vibration motors placed inside a fabric ankle band. Wires and vibrators positions are not constrained and spread throughout the band to target multiple areas. This device is not fully water-resistant and is made as a one size fits all product.

Thin adjustable band with vibration motors along band length and rechargeable battery integrated. The second design concept, shown in figure 2, is where the circuitry and vibration motor is placed within a silicon band. Vibration motors are spread throughout the band allowing for spatial vibration patterns. The device is rechargeable and adjustable to many sizes. There is a latch that adjusts sizes and secures the device to the patient which may be difficult for Parkinson's patients to wear and remove.

The last design concept, shown in figures 3 and 4, is a fabric sock with an outside pocket on the ankle which fits a portable vibration device. Shown in figure 3, is where device circuitry is placed into a 100mm x 60mm plastic container coated with silicone, making it water resistant. The device is slid into a pocket stitched onto the side of a sock that sits close to the ankle. The device is rechargeable and is made as a one size fits most product that covers a wide range of sizes. The device can also be placed in a variety of holders, such as a strap.

To foster and optimize creativity, many carriers have been searched and continuous discussion among team members was encouraged. The team looked at different ways to address the problem and discussed together how these different solutions can be incorporated when creating the design concept.

The formulation of the engineering solution is that the device will be encased in plastic to protect the circuitry from the outside environment and to keep components in place. The case will be coated in silicone for water resistance. The sock should be made from a biocompatible material so it does not cause irritation or allergic reactions. The battery will be rechargeable to increase mobility. Bluetooth connectivity from the smartphone to the device for wireless music-based vibrations allows patients to move during sessions.

This design concept is suitable for the solution to address the need. The utilization of small transducers will allow our system to transmit low-frequency sound vibrations (20-100 Hz) through the patient's skin reaching the proprioceptors located in tendons around articulations. This sends signals to muscles and their motor units to help improve balance when walking. The device encasing will allow the device to be water-resistant for multiple uses and protection from electric shock. The sock will allow for a wide range of foot sizes to practically use it, as well as patients being able to wash and reuse the device. The rechargeable battery will allow for the music-synced vibration to play for at least 1 hour. Bluetooth connectivity will allow the device to operate wirelessly and allow for greater mobility.

Below are figures of sketches in Solidworks based on the design concepts that the team envisioned to address the problem

Figure 3: The First Design Concept

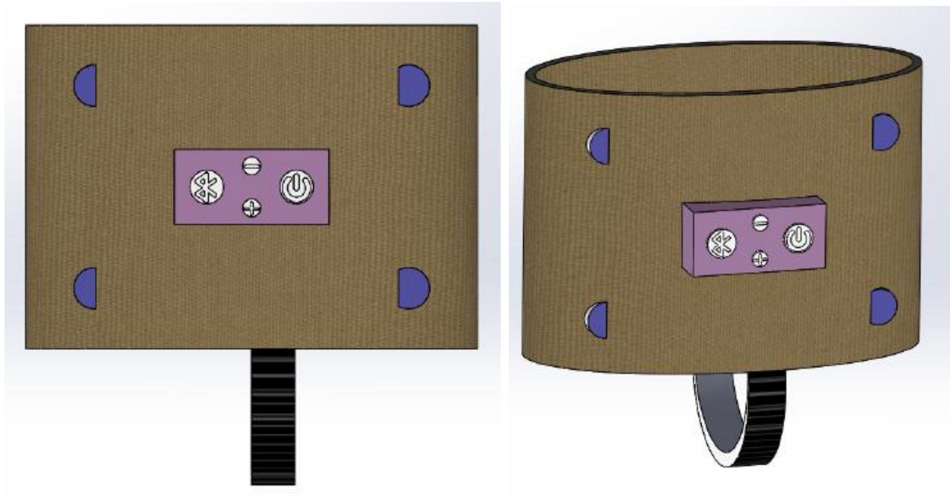


Table 3: Pros and Cons of First Design Concept

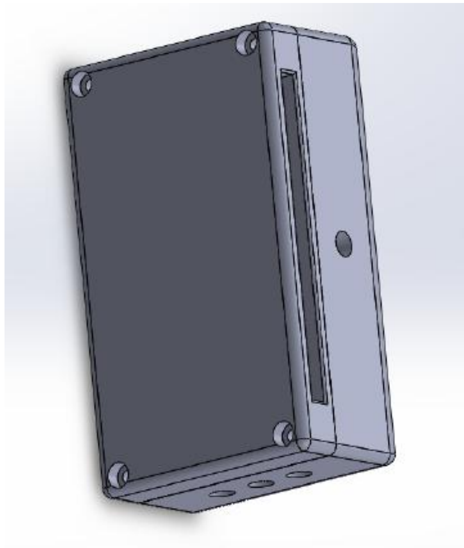
Pros	Cons
• Stimulates the entire ankle • One size fits all	• Not sweat or water resistant • Not Washable

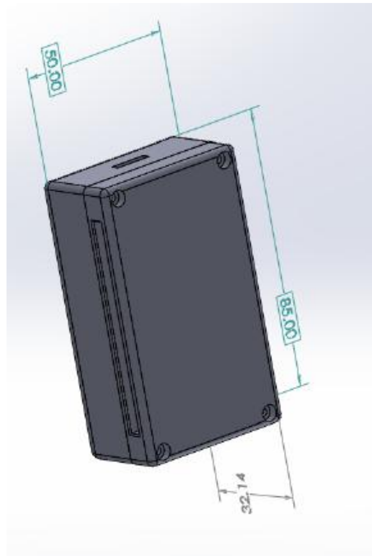
Figure 4: The Second Design Concept (Image on the Right includes dimensions)

Table 4: Pros and Cons of Second Design Concept

Pro	**Con**
• Waterproof • Adjustable Band	• Difficult to wear with tremors.

Figure 5.1: The Original Design Concept Vibrating Device (Image on the Right includes dimensions)





After designing the actual circuitry for the vibration device, we implemented an updated version of the design concept to better fit the circuit components. The updated version is shown in figure 5.2.

Figure 5.2: Updated version of the Design Concept Vibrating Device

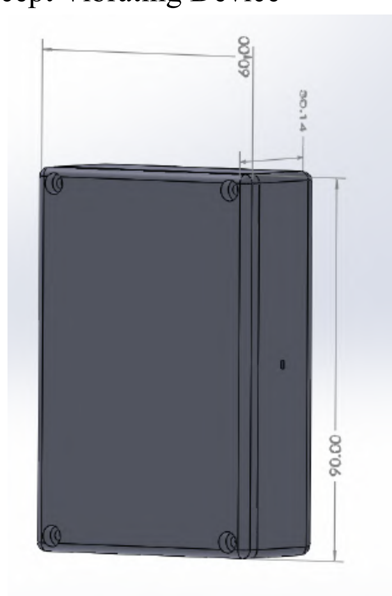


Figure 6: The Final Design Concept Device Carrier (Image on the Right includes dimensions)

Table 5: Pros and Cons of Third Design Concept

Pro	**Con**
● One size fits most ● Washable	● Stimulation at single location

2d. References

[1] Jung, T., Lee, D. K., Charalambous, C., & Vrongistinos, K. (2010, January 5). *The influence of applying additional weight to the affected leg on gait patterns during aquatic treadmill walking in people poststroke*. Archives of Physical Medicine and Rehabilitation. Retrieved February 24, 2022, from https://www.sciencedirect.com/science/article/pii/S0003999309007680#fig2

[2] *Sweating (parkinson's disease)*. whatwhenhow RSS. (n.d.). Retrieved February 24, 2022, from http://what-when-how.com/parkinsons-disease/sweating-parkinson%E2%80%99s-disease/

[3] Stanford Parkinson's Community Outreach. (n.d.). *Sweating and temperature regulation in PD*. Stanford Parkinson's Community Outreach. Retrieved February 24, 2022, from https://med.stanford.edu/parkinsons/symptoms-PD/sweating.html#articles

[4] Welsh, K. (2021, January 12). *How to tell if your headphones are sweat-proof – and why it matters for workouts*. fitandwell.com. Retrieved February 24, 2022, from https://www.fitandwell.com/features/sweat-proof-headphones-how-to-tell

[5] *1 battery powered equipment - it's the future*. Pitchcare. (n.d.). Retrieved February 24, 2022, from https://www.pitchcare.com/news-media/battery-powered-equipment-it-s-the-future.html

[6] *Microbiological testing for medical devices | TÜV süd*. (n.d.). Retrieved February 24, 2022, from https://www.tuvsud.com/en-us/industries/healthcare-and-medical-devices/medical-devices-and-ivd/medical-device-testing/chemical-or-biological-testing-of-medical-devices/microbiological-testing

[7] *ISO 10993-10:2010*. ISO. (2021, November 16). Retrieved February 24, 2022, from https://www.iso.org/standard/40884.html

[8] *IEC 62366-1:2015*. ISO. (2021, June 3). Retrieved February 24, 2022, from https://www.iso.org/standard/63179.html

[9]*The advantages and disadvantages of feedback devices*. Smart Lifting & Motion Control Solutions. (n.d.). Retrieved February 24, 2022, from https://www.columbusmckinnon.com/en-us/resources/duff-norton-blogs/feedback-devices/#:~:text=Advantage%3A%20Improve%20stability,the%20stability%20of%20your%20movement

[10]*The effect of whole body vibration in individuals with parkinson's disease - full text view*. Full Text View - ClinicalTrials.gov. (n.d.). Retrieved February 24, 2022, from https://clinicaltrials.gov/ct2/show/NCT03777501

[11]*ISO 5349-1:2001*. ISO. (2021, September 14). Retrieved February 24, 2022, from https://www.iso.org/standard/32355.html

[12]*ISO 7250-3:2015*. ISO. (n.d.). Retrieved February 24, 2022, from https://www.iso.org/obp/ui/#iso:std:iso:7250:-3:ed-1:v1:en

[13] https://www.fda.gov/media/85865/download

2e. Meeting Minutes

"Team 6"

Report Date: 11/15/2021

Team Meeting

Attendees	**Status**			
Jacob Bharat	P			
Bianca Castello	P			
Maria Chiang	P			
Mario Civil	P			
Yency Perez	P			

P = Present L = Late AE = Absent (Excused) A = Absent
Cc: Attendees

Facilitator: Bianca
Note Taker: Jacob
Time Keeper: Jacob

Agenda

Discussion Points	**Comments**
House of Quality	• Jacob finished the House of Quality Analysis.
Project Success Factors	• We went through the project success factors and discussed the risk/mitigation for each factor. • There were some concerns with the circuitry and device pairing but we came to a conclusion.
Current Modalities	• Maria went through some current modalities that were related such as neurobeats and a diagnostic vibrating device. • Since the device was diagnostic we choose to exclude it because it does not relate to our modality. • We will keep the neurobeats because it was a previous model of the current version. • We will include a predicted model of what we are doing. • We will add a device that is similar to vibration therapy but with no music.
Standards	• All the standards for each aspect of the device were listed but they need to be gone through in depth to see if everything applies.

Hazard Analysis	• All the hazard analysis was completed thoroughly. • Hazards such as circuitry and water proof were discussed.
Requirements	• We discussed the requirements for our presentation, our written proposal, and DHF. • We will be answering the questions from the Final Presentation FAQ. • We will try to finish most of the powerpoint and work before the Interim Presentation.
Future	• focus on the project plan and PowerPoint. We will make sure to finish the powerpoint up to the project scope (making all the necessary revisions and touch ups), project plan, divide, assign, possible practice, and finish as much as possible of the powerpoint after.

Action Item	**Person Responsible**	**Date**	**Status**
• Standards • Hazard Analysis	Yency	Assigned 11/8 Due 11/10	Done
• Solidworks	Mario	Assigned 11/8 Due 11/10	In Progress 11/17
• Fix up and make language pretty • Project Cost/ Budget	Jacob	Assigned 11/8 Due 11/10	In Progress
• Project Cost/ Budget	Bianca	Assigned 11/8 Due 11/10	Done
• Constraints • Solution impact on society in a global and contemporary	Maria	Assigned 11/8 Due 11/10	Constraints Not Done
• Business Need and Current Modalities • Project Success Factors	Maria	Assigned Date (11/5)Due 11/7	In Progress 11/11

• Hardware based on Market Requirements(MR) and Budget Research. • Technology Assessment	Mario	Assigned Date (11/5)Due 11/9	Needs to touch up
• Hardware based on Market Requirements(MR) and Budget Research. • Verification Tests	Bianca	Assigned Date (11/5)Due 11/9	Verification tests not done
• Evaluation of multiple concepts • Formulation of Engineering Solution	Bianca	Assigned (11/10) Due 11/11	
• Suitability/adequacy of the solution to address the need	Jacob	Assigned (11/10) Due 11/11	

Team 6 Senior Team Meeting Minutes

Date: January 27,2022

I. Call to Order
   A. Meeting Called to Order at: 02:15 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Present
Dr. Christie	Current Faculty Advisor/Mentor	Present at 2:41 PM

III. Approval of Last Meeting's Minutes
   A. Jacob Motions, Bianca Seconds

IV. Unfinished Business
   A. Make sure the Project Plan and the meeting minutes are in the correct format.
   B. Bring the MRs and DIs

1. Make sure we bring rationale for each DI
2. Remember the four questions that we need to answer.
    a) Accomplishment
    b) Next Steps
    c) Threats
    d) Mitigations

V. New Business

A. Agenda for Regular Schedule Meeting
    1. Project Plan
    2. Go Over MRs, DIs and Rationale

B. Project Plan
    1. Feedback: we have 17 items on our project plan for this semester.
    2. We went through a supermarket example for detailed steps to make a sandwich from beginning to end .
    3. We need to rearrange some things and make it much more detailed. “Drill it down to the bones and add some meat”
        a) Flesh it out and make it specific
        b) Bianca was assigned to do and update the project plan.
        c) Dr.Christie would like to see our updated project plan next week for an ad hoc before

C. Elevator Speech
    1. Why are we doing it? Sell the device .
    2. Scope
    3. What is the device?

D. MRs and DIs
    1. The Market Requirement should be high level. No Numbers in the Market Requirements. Only put specific with the DIs
    2. The Design Input is the rationale and scientific reasoning. These should be specific with numbers.
    3. Feedback
        a) Why do you want it lightweight? So it doesn’t interfere with Gaits.
        b) Apply the rationale and research.
        c) Are we dealing with an adult patient or someone else? Why is this specific weight? Find who you are addressing.
        d) Each DIs must have an Individual reasons and rationale
        e) Multiple DIs can go for one MR.
        f) Device must be resistant to small splashes and sweat.. IPX4 Rating for our DI.
        g) Revisit #3 MR and DI… MR must be more crisp

h) Revisist, Revise and Reconstitute #4 as well. What Bianca said was a much better thing to write
i) Do not use the phrase “put on”... fill in the blank _____ on within 1 minute
j) Biocompatible.. What you have in the DI should be in the MR. “1 hour on a single charge” should be in the MR.

E. Dr. Christie wants a communion cup for his office because it's a great design.
F. Bring our Design Concepts for the next meeting
G. Fix our MRs and DIs for the next meeting
H. Bianca was unsure about the wireless MR. Go back to the ones we started on and lock in the trajectory but we will go more in depth for the next meeting.

VI. Due Dates/ Task
A. Global Learning Training
B. Bianca has to update and make the Project Plan much more detailed by the next ad hoc meeting.
C. Fix our MRs and DIs
D. Bring our Design Concepts
E. Instead of Agenda in the Minutes…. It should be New Business. Agenda can be a new business
F. Dr. Christie would like an ad hoc meeting next Thursday at 3pm.
    1. Dr. Christie needs to upload on canvas.
G. Ask if we can sketch the sock design not in solidworks?
H. What is the design freeze?
I. Can you explain how the device verification would work? Would we have to ship it to our sponsor if he can’t really test it?
J. We need to continue our design, coding, app and circuitry on Wednesday.
K. We should start reaching out to Dr.Weinstock about updates on our project to keep him informed as the midterm sponsor assessment will likely be based on that.

VII. Meeting Adjournment
A. Meeting Adjourned at 03:18 p.m.

Team 6 Senior Team Meeting Minutes
Date: January 31,2022

I. Call to Order
A. Meeting Called to Order at: 06:08 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Present

III. Approval of Last Meeting's Minutes
    A. Jacob Motions, Bianca Seconds
IV. Unfinished Business
    A. Make sure we bring rationale for each DI
        1. Remember the four questions that we need to answer.
            a) Accomplishment
            b) Next Steps
            c) Threats
            d) Mitigations
V. New Business
    A. Agenda for Regular Schedule Meeting
        1. Go Over MRs, DIs and Rationale
        2. Project Plan
        3. Design Concepts
    B. MRs and DIs
        1. MR is what and why
        2. DI is the How
    C. Elevator Speech
        1. Components:
            a) Why are we doing it? Sell the device .
            b) Scope
            c) What is the device?
        2. General Statements
            a) Provides an affordable wireless, lightweight wearable device that can be worn over the ankle and will connect to a person's smartphone to play music synchronized with vibration therapy for these patients.

b) This device can help Patients with Parkinson’s that have trouble balancing by increasing dopamine resulting in a decreased risk of falling and improving ability to walk.

c) Provides and restores independence for patients with parkinson’s.

d) It is portable and will have a positive effect on dopamine production due to the added music component.

e) Alleviate the symptoms for patients with Parkinson’s resulting in enhanced balance when walking.

D. Global Learning Training

1. Our topic: Mental Health

a) Find articles or research papers

(1) Try it by tomorrow.

b) Make a research doc and copy descriptions/analysis. Put notes under each thing. Annotated bibliography.

c) Work on it on Wednesday.

E. Bianca has to update and make the Project Plan much more detailed by the next ad hoc meeting.

F. Jacob Show the Solidworks design.

G. Fix our MRs and DIs

1. We worked on reforming our MRs and DIs based on the feedback from Christie. We were able to work through them all and revise them. Rationale is needed for a few.

2. Find rationale for the following MRs and DIs.

a) Maria do 1

b) Yency do 2 & 7

c) Mario do 3

d) Jacob do 5 & 7

e) Bianca do 10

H. Bring our Design Concepts

1. We briefly discussed and went over the design concepts we came up with last semester. We made some minor changes and included the original solidworks sketch excluding the sock. The sock is unable to be shown appropriately in solidworks.

I. If we get the pieces in by this week, we will have an in person meeting either monday or wednesday to start the wiring and circuitry.

VI. Due Dates/ Task

A. Ask Christie if these are right because we followed your advice but it contradicts what Sharastani told us last semester.

B. Rationale/references should be completed by Wednesday, only reviewing whatever was not done.
C. Global Learning Training
    1. Have a couple articles on doc about global learning and mental health
    2. We will have a discussion on Wednesday about the topic and paper.
    3. Have a general idea.
D. Bianca has to update and make the Project Plan much more detailed by the next ad hoc meeting.
E. Bring our Design Concepts
F. Dr. Christie ad hoc meeting next Thursday at 2:30pm.
G. Ask if we can sketch the sock design not in solidworks?
H. We need to continue our design, coding, app and circuitry on Wednesday.
I. We should start reaching out to Dr.Weinstock about updates on our project to keep him informed as the midterm sponsor assessment will likely be based on that.

VII. Meeting Adjournment
A. Meeting Adjourned at 08:25 p.m.

Team 6 Senior Team Meeting Minutes
Date: February 2,2022

I. Call to Order
A. Meeting Called to Order at: 05:45 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Present at 6:00PM

III. Approval of Last Meeting’s Minutes
A. Jacob Motions, Bianca Seconds

IV. Unfinished Business
   A. Go over the following things from last Meeting
      1. Design Input Rationale
      2. Global Learning
      3. Project Plan
   B. Global Learning Training
      1. Have a couple articles on doc about global learning and mental health
         a) Social Media connecting
         b) Psychologist collaborating for accessibility
         c) Different POV from all of us and a specific area
         d) Self awareness and mindfulness movement
      2. We split up the work for this assignment and we are talking about the stigma
      3. Everyone get it done by Sunday by noon
      4. Yency will be in charge of the final editing and the abstract.
   C. Project Plan
      1. Bianca has to update and make the Project Plan much more detailed by the next ad hoc meeting.

V. New Business
   A. Elevator Pitch
      1. Yency will give it to Danziger
      2. Maria will give it to Christie
   B. Fix our MRs and DIs
      1. We went over our DI Rationales.
   C. If we get the pieces in by this week, we will have an in person meeting either monday or wednesday to start the wiring and circuitry.
   D. What will we discuss with Danziger?
      1. We aren't sure what a mentor does for us, so we would like to know what your role in our project is?
      2. This is our idea and what we are thinking, what do you think about it?
      3. We are unsure about the app interface and the coding aspect, so we were wondering if you could give us some advice on that.

VI. Due Dates/ Task
   A. Ask Christie if these are right because we followed your advice but it contradicts what Sharastani told us last semester.
   B. Ask if we can sketch the sock design not in solidworks?
   C. What is the design freeze?
   D. Bianca and Jacob will work on the project plan.

E. We will work on global training separately and Yency will put it together on Sunday.
F. We need to continue our design, coding, app and circuitry on Wednesday.
G. We should start reaching out to Dr.Weinstock about updates on our project to keep him informed as the midterm sponsor assessment will likely be based on that.
    1. Meet sometime next week and sometime the week before spring break.

VII. Meeting Adjournment
A. Meeting Adjourned at 09:15 p.m.

Team 6 Senior Team Meeting Minutes
Date: February 3,2022

I. Call to Order
A. Meeting Called to Order at: 10:54 a.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Present at 11:03 AM
Dr. Danziger	Faculty Advisor/Mentor	Present at 11 AM

III. Approval of Last Meeting's Minutes
A. Jacob Motions, Maria Seconds

IV. Unfinished Business
A. This is our first meeting with Dr. Danziger

V. New Business
A. Elevator Pitch
    1. Yency gave the Elevator pitch to Dr.Danziger
B. Introductions
    1. Dr.Danziger asked what we already have or started with for our project.
        a) We don't have anything but we will be starting in the next few meetings.

2. Dr.Danziger: Have we been meeting with our sponsor? Do they like our progress?
    a) We have not been meeting with Dr. Weinstock recently, but we will begin meeting with him regularly starting next week.
3. Dr.Danziger was asking about possible problems or difficulties that may arise with our design.
    a) Dr.Danziger asked us about the location, and we informed him it was a decision we made based on research and the design. This allows for a little more leeway in where exactly the device targets.

C. Coding Advice from Dr.Danziger
1. Creating a song library with pre converted wave files.
2. Real time translation is not great because we do not have wave files on the smartphone.
3. Real time music streaming
    a) Doing it in real time would be difficult because we have to get the raw wave data, filter it and analyze. By the time that is done, the music will have moved on, so there will be a lag.
4. Have a selected set of songs and analyze that beforehand, so the music stays synched with the music.

D. What will we discuss with Danziger?
1. We aren't sure what a mentor does for us, so we would like to know what your role in our project is?
    a) We can go to him whenever we get stuck or to ask if we are on the right track. We can go for advice and meet with him or go to him when we would like help.
2. This is our idea and what we are thinking, what do you think about it?
    a) Answered based on his primary questions after the scope.
3. We are unsure about the app interface and the coding aspect, so we were wondering if you could give us some advice on that.
    a) Needing an app is dependent on how easy it is to get the data out of the phone.
4. How often would we be meeting or how often do you recommend?
    a) Based on how much we want. As much or as little as we want.

E. Stochastic Resonance
1. Dr.Danziger brought this term up and related it to what we are doing.
    a) He thinks this is what is happening with what we are doing
2. We should look more into it.

F. Team Problems

1. Towards the end of the semester, Dr.Danziger spoke on team problems that may occur because of individual efforts and impending deadlines.
    a) Dr.Danziger would be open to helping mediate these issues.

VI. Due Dates/ Task
  A. Global Learning Training
  B. We need to continue our design, coding, app and circuitry on Wednesday.
  C. We should start reaching out to Dr.Weinstock about updates on our project to keep him informed as the midterm sponsor assessment will likely be based on that.
    1. We should ask Dr.Weinstock what songs he or his patients would be interested in so that we can create a song library for our device.
  D. We should research different music genres and songs that would be the most effective as treatment.

VII. Meeting Adjournment
  A. Meeting Adjourned at 11:42 a.m.

Team 6 Senior Team Meeting Minutes
Date: February 3,2022

I. Call to Order
  A. Meeting Called to Order at: 02:03 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Present
Dr. Christie	Faculty Advisor/Mentor	Present at 2:53PM

III. Approval of Last Meeting's Minutes
  A. Jacob Motions, Yency Seconds

IV. Unfinished Business
  A. Elevator Pitch

B. Project Plan

C. MRs, DIs, and Rationale

1. We began going through our new MRs, DIs and Rationale, we ignored the old ones.
2. We had to change the formatting of our design specifications. Make the 4th column method of verification or verification tests.
3. Put the DI rationale under each DI in the 3rd column.
4. Do we need a standard for each verification test?
   a) Find references, relating or supporting tests.
5. A standard does not match an MR, a standard matches a verification tests. We have to find verification tests for DIs and possibly standards to the method of verification.
6. Delete all the old versions, and make the point 1 into regular points.
   We need to tighten up some things. We should not put a solution for the DI. We should not include the encasing.
7. Jacob figures out the methods of verification.
8. Get the average time of a healthy person and compare it to the parkinson's patient, then find the proper time. Find who much loss occurs and use that time to compare.
9. Evidence Based and Data Driven
10. Use information and material that is already proven to be biocompatible. We do not have to test and do verification tests, just find information that supports.
11. Full Blast multiplied by 2 for a safety factor and use that to calculate. Find the actual power demand and safety factor to find the exact electrical specifications.
12. We only got through 6 MRs and DIs.

V. New Business

A. Design Concepts

B. Questions

1. Ask if we can sketch the sock design not in solidworks?
   a) Still try to do it because we need to do simulations.
2. What is the design freeze?
3. Can you explain how the device verification would work? Would we have to ship it to our sponsor if he can't really test it?

VI. Due Dates/ Task

A. Global Learning Training

B. We need to continue our design, coding, app and circuitry on Wednesday.

C. We should start reaching out to Dr.Weinstock about updates on our project to keep him informed as the midterm sponsor assessment will likely be based on that.

VII. Meeting Adjournment

A. Meeting Adjourned at 03:05 p.m.

Team 6 Senior Team Meeting Minutes

Date: February 7,2022

I. Call to Order

A. Meeting Called to Order at: 06:30 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present at 6:36 PM
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Present

III. Approval of Last Meeting's Minutes

A. Jacob Motions, Bianca Seconds

IV. Unfinished Business

A. MRs, DIs, and Rationale

1. We previously got through 6 MRs and DIs.
2. We used the majority of our meeting discussing verification tests for each Design Input and the standards that can be used for each Test.
3. We were unable to find standards for 2 DIs and finish the rationale for #4.
    a) Yency will be doing #4 for rationale and standard
    b) Bianca will be doing the standard #7.
    c) Deadline for this is Wednesday by 5PM

B. Weinstock

1. We should ask Dr.Weinstock what songs he or his patients would be interested in so that we can create a song library for our device.

2. We should research different music genres and songs that would be the most effective as treatment.
    a) Jacob will do research on the Music that releases dopamine and is good for VAT.
    b) Deadline for this is Wednesday by 5PM
3. We need to meet soon. We do not necessarily need to meet twice.
4. Show him the solidworks, MRs, and the sock. Show him the progress. Explain the project and design. Tell him that we recently met with our Faculty Mentor and ask if Weinstock would be interested in meeting. Let him know if there are any changes we would let him know. Ask him how he likes our current progress.

C. Elevator Pitch
1. Maria will give it to Christie

V. New Business

A. If we get the pieces in by this week, we will have an in person meeting either monday or wednesday to start the wiring and circuitry.
1. We will email Claudia sometime 2/8 to find an update on the pieces.

B. Design Concepts
1. We reviewed the design concepts.

C. Go over solidworks

D. Questions
1. Ask if we can sketch the sock design not in solidworks?
    a) Still try to do it because we need to do simulations.
2. What is the design freeze?
3. Can you explain how the device verification would work? Would we have to ship it to our sponsor if he can't really test it?

VI. Due Dates/ Task

A. Wednesday we will need to email Weinstock for availability.

B. Tuesday Morning an email should be sent out to Dr. Zicarilli about meeting.

C. In Person Meeting on Wednesday 2/9 at 5PM-9PM.
1. Start our tasks as assigned in the project plan.

D. Meet with Zicarilli
1. Maria or Mario will need to meet to find a meeting.
    a) Available Friday Morning
    b) Available Thursday anytime. Preferably 10am-2pm
2. They need to research the materials for the solidworks.
    a) Possibly PLA
3. Set up a time, show our solidworks, tell him our plan, and ask for his advice. Logistics and Materials?

a) Ask questions about printing.

E. Yency and Mario will be switching roles. Yency will be coding and Mario will be physical.

F. KiCAD

1. We will be doing circuitry focused on circuitry
2. Bianca will try to work on this but not required
3. Mario will bring the bluetooth Module.

G. App

1. Jacob will be working on this before Wednesday but not required.

H. Device Coding

1. Yency will try working on this before Wednesday but not required.

I. We should start reaching out to Dr.Weinstock about updates on our project to keep him informed as the midterm sponsor assessment will likely be based on that.

1. We will send out an email on Wednesday.
2. We should start reaching out to Dr.Weinstock about updates on our project to keep him informed as the midterm sponsor assessment will likely be based on that.

VII. Meeting Adjournment

A. Meeting Adjourned at 09:16 p.m.

Team 6 Senior Team Meeting Minutes

Date: February 9,2022

I. Call to Order

A. Meeting Called to Order at: 05:41 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Present

III. Approval of Last Meeting's Minutes
    A. Jacob Motions, Yency Seconds
IV. Unfinished Business
    A. MRs, DIs, and Rationale
        1. We were unable to find standards for 2 DIs and finish the rationale for #4.
            a) Yency will be doing #4 for rationale and standard
            b) Bianca will be doing the standard #7.
            c) Deadline for this is Wednesday by 5PM
            d) Done
    B. We should research different music genres and songs that would be the most effective as treatment.
            a) Jacob will do research on the Music that releases dopamine and is good for VAT.
            b) Deadline for this is Wednesday by 5PM
            c) https://www.prsformusic.com/m-magazine/news/study-reveals-effective-songs-music-therapy/
            d) genres most likely to support relaxation are classical, soft pop and certain types of world music. https://doi.org/10.1093/jmt/48.3.264
            e) As for musical genres, a few studies suggest that slow orchestral music works best. In general, music in which there's about one beat per second, has many low tones, and a lot of strings but not much percussion and brass is probably a better choice than, say, Metallica or John Phillips Sousa.
    C. Elevator Pitch
        1. Maria will give it to Christie
        2. Maria reviewed it.
V. New Business
    A. Design Concepts
        1. We reviewed the design concepts.
    B. Questions
        1. Ask if we can sketch the sock design not in solidworks?
            a) Still try to do it because we need to do simulations.
        2. What is the design freeze?
        3. Can you explain how the device verification would work? Would we have to ship it to our sponsor if he can't really test it?
    C. Work on our tasks from project plan, we worked the entire meeting performing our tasks
VI. Due Dates/ Task
    A. In Person Meeting on Wednesday 2/9 at 5PM-9PM.

        1. Start our tasks as assigned in the project plan.
    B. Meet with Zicarilli
    C. KiCAD
        1. We will be doing circuitry focused on circuitry
        2. Bianca will try to work on this but not required
        3. Mario will bring the bluetooth Module.
    D. App
        1. Jacob will be working on this before Wednesday but not required.
    E. Device Coding
        1. Yency will try working on this before Wednesday but not required.
    F. We should start reaching out to Dr.Weinstock about updates on our project to keep him informed as the midterm sponsor assessment will likely be based on that.
        1. We will send out an email on Wednesday.
        2. We should start reaching out to Dr.Weinstock about updates on our project to keep him informed as the midterm sponsor assessment will likely be based on that.
            a) Show him the solidworks, MRs, and the sock. Show him the progress. Explain the project and design. Tell him that we recently met with our Faculty Mentor and ask if Weinstock would be interested in meeting. Let him know if there are any changes we would let him know. Ask him how he likes our current progress.

VII. Meeting Adjournment
    A. Meeting Adjourned at 09:05 p.m.

Team 6 Senior Team Meeting Minutes
Date: February 10,2022

I. Call to Order
    A. Meeting Called to Order at: 02:40 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present

Maria Chiang		Present
Mario Civil		Present
Dr. Christie	Faculty Advisor/Mentor	Present

III. Approval of Last Meeting's Minutes
   A. Jacob Motions, Yency Seconds
IV. Unfinished Business
   A. Elevator Pitch
      1. Maria gave a great elevator pitch. She went off
      2. Toastmasters is an org that is dedicated to the art of listening and speaking.
   B. Project Plan
   C. MRs, DIs, and Rationale
      1. We only got through 6 MRs and DIs. Need to Review the rest and verification tests.
      2. The DI for #3 is not really a DI, it is more of a constraint. We need to change it to be more generic, instead of so restrained. The MR was good but needed the addition of " operate for 1 hour on a single charge."
      3. We need rationale for #4.
      4. Maybe take out #6, i do not remember
      5. Feedback:
         a) Dr. Christie is happy with it but #3 must be fixed and #4 needs the rationale.
V. New Business
   A. Design Concepts
      1. Make sure to separate the pros and cons.
      2. The image and description is descriptive enough.
      3. Designer must show several views
         a) Exploded: where all the parts blow up and form dots that show how they attach. Components diagram
         b) Isometric
         c) Top View
         d) Side View
      4. Make it the MVP and show out all the benefits.
      5. We need to show the circuit board and blow it up such as the insides.
      6. You can show in solidworks, we need pictorial drawing. We should try to show in solidworks how it interacts with the sock and what it will look like.

7. Let's do some risk analysis. How will the sock and device interface with the body and skin?
8. Do an impact test, some simulations for dimensions. Simulation is mandatory. Drawing is needed.

B. Questions
1. What is the design freeze?
    a) Premanufacturing Agreement
        (1) Don't need the circuit or coding for this.
        (2) Whatever you can buy, do not make
2. Can you explain how the device verification would work? Would we have to ship it to our sponsor if he can’t really test it?
    a) Only based on verification tests

VI. Due Dates/ Task
A. We need to do the pre manufacturing agreement
B. We need to do the drawings and the sock.
C. We need to continue our design, coding, app and circuitry on Wednesday.
D. We should start reaching out to Dr.Weinstock about updates on our project to keep him informed as the midterm sponsor assessment will likely be based on that.

VII. Meeting Adjournment
A. Meeting Adjourned at 03:29 p.m.

Team 6 Senior Team Meeting Minutes
Date: February 14,2022

I. Call to Order
A. Meeting Called to Order at 06:12 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Present

III. Approval of Last Meeting's Minutes

   A. Jacob Motions, Maria Seconds

IV. Unfinished Business

   A. Elevator Pitch

      1. Someone Else?

   B. Project Plan

      1. We still haven't gone over it with Christie yet.

   C. MRs, DIs, and Rationale

      1. The DI for #3 is not really a DI, it is more of a constraint. We need to change it to be more generic, instead of so restrained. The MR was good but needed the addition of " operate for 1 hour on a single charge."
      2. We need rationale for #4.
      3. Maybe take out #6, i do not remember
      4. Feedback:
         a) Dr. Christie is happy with it but #3 must be fixed and #4 needs a rationale.
      5. He also followed up with concerns of being specific in the MR for one of them.

V. New Business

   A. Design Concepts

      1. Make sure to separate the pros and cons.
      2. The image and description is descriptive enough.
      3. Designer must show several views
         a) Exploded: where all the parts blow up and form dots that show how they attach. Components diagram
         b) Isometric
         c) Top View
         d) Side View
      4. Make it the MVP and show out all the benefits.
      5. We need to show the circuit board and blow it up such as the insides.
      6. You can show in solidworks, we need pictorial drawing. We should try to show in solidworks how it interacts with the sock and what it will look like.
      7. Let's do some risk analysis. How will the sock and device interface with the body and skin?
      8. Do an impact test, some simulations for dimensions. Simulation is mandatory. Drawing is needed.

B. Mario and Maria put together a list of materials to send to Claudia to be based off what they discussed with Zicarelli
    1. Things that need to be bought.
        a) Screws
        b) LEDs
        c) Waterproof buttons
        d) Rubber USB cover
        e) Silicone spray
        f) Velcro straps
    2. We discussed the solid work design and looked at the new version. We need to see the validity of buttons.
    3. We went over how to do the exploded view and what is needed.

VI. Due Dates/ Task
A. We need to do the pre manufacturing agreement
B. We need to do the drawings and the sock.
C. We need to continue our design, coding, app and circuitry on Wednesday.
D. We should start reaching out to Dr.Weinstock about updates on our project to keep him informed as the midterm sponsor assessment will likely be based on that.

VII. Meeting Adjournment
A. Meeting Adjourned at 07:45 p.m.

Team 6 Senior Team Meeting Minutes
Date: February 16,2022

I. Call to Order
A. Meeting Called to Order at 06:00 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present

Mario Civil		Present

III. Approval of Last Meeting's Minutes
   A. Jacob Motions, Maria Seconds

IV. Unfinished Business
   A. Elevator Pitch
      1. Someone Else?
   B. Project Plan
      1. We still haven't gone over it with Christie yet.
   C. Design Concepts
      1. Make sure to separate the pros and cons.
      2. The image and description is descriptive enough.
      3. Designer must show several views
      4. Exploded: where all the parts blow up and form dots that show how they attach. Components diagram
         a) Isometric
         b) Top View
         c) Side View
      5. Make it the MVP and show out all the benefits.
      6. We need to show the circuit board and blow it up such as the insides.
      7. You can show in solidworks, we need pictorial drawing. We should try to show in solidworks how it interacts with the sock and what it will look like.
      8. Let's do some risk analysis. How will the sock and device interface with the body and skin?
      9. Do an impact test, some simulations for dimensions. Simulation is mandatory. Drawing is needed.
      10. We discussed the solid work design and looked at the new version. We need to see the validity of buttons.
      11. We went over how to do the exploded view and what is needed.

V. New Business
   A. We were working on our individual tasks together.
      1. Mario and Mario on Solidworks
      2. Bianca and Yency on Arduino
      3. Jacob on App
   B. Senior Showcase
      1. April 14th is Drop dead day for everything
         a) Everything must be done and due

(1) DHF
(2) DMR
(3) Abstracts
(4) Presentation
(5) Poster
(6) Video Presentation.

2. Oral Presentation on April 21st in OCB
    a) Half a day affair
    b) Business Professional
3. Poster Competition will be the 22nd of April in OCB
    a) 1:30pm-4:30pm and setup by noon.
    b) Laptop showing all manufacturing and devices and work.
    c) Business Professional

C. After the 3rd of March there is nothing due. We think he means 6th of March.

VI. Due Dates/ Task

A. We need to do the pre manufacturing agreement
B. We need to do the drawings and the sock.
C. We need to continue our design, coding, app and circuitry on Wednesday.
D. We should start reaching out to Dr.Weinstock about updates on our project to keep him informed as the midterm sponsor assessment will likely be based on that.

VII. Meeting Adjournment

A. Meeting Adjourned at 09:09 p.m.

Section 3: Feasibility Assessment

3a. Technology Assessment

The investigation of available technologies to produce the device was based on electronic components as well as on the available materials suitable for the device carrier and hardware for the circuitry. The most adaptive components to the system were selected such as a DC vibration motor for efficiency and compact size, a 3.7 V lithium rechargeable battery for better power capability, a Bluetooth audio receiver board, and a microchip for an efficient interface connection. The circuit encasing will be made of Polycarbonate which is highly biocompatible and resistant to heat and tear, and will be enclosed in a silicone sleeve to prevent contact with the patient's skin. However, the prototypes will be 3D printed utilizing PLA wire.
For the device carrier, Cotton was preferred to Polyester and Nylon for higher biocompatibility and lower allergic reaction rate, as well as stretchability and flexibility.

Table 6: Vibration Device Technology Assessment

Concept (Materials)	**Pros**	**Cons**
HiLetgo Single USB Charging Converter Board	● Wireless power source.	● USB-A Port is larger.
Adafruit Mini Lipo w/Mini-B USB Jack	● The Micro USB port is smaller.	● Possible Short Circuit
Adafruit Industries Lithium Ion Battery	● Thin (29.0mm x 36.0mm x 4.8mm)	● Brand dependent (can destroy battery)
3.7 V Lithium-Ion Battery Rechargeable	● Dimensions (37.0mm x 16.5mm x 2.8mm) ● High capability	● Length is larger.
Vibration Lra Motor 1.2v Coinx	● Low power consumption	● AC motor ● Larger
Vibration motor BMV0803 H2.7	● Small Round - 0.315" Dia (8.00mm) ● DC motor (More energy efficient)	

Bluetooth Audio Receiver Board	• Universal Micro USB 5V power supply • 3.7-5V lithium battery power conversion	
Microchip ATtiny85	• Low power • Small and cheap	• Challenging to debug for errors
TL494 Chip	• PWM signal control • AC to DC converter • 5 V internal regulator • No delay in synchronization	• Requires another OP-Amp

Table 7: Device Carrier Technology Assessment

Concept (Materials)	**Pros**	**Cons**
Cotton	• Soft and Stretch • Lightweight • Biocompatible	• Wrinkle
Polyester	• Flexible • Lightweight • Wrinkle resistant	• May cause allergic reaction
Polycarbonate	• Biocompatible • Strong and lasting • High heat resistance	• Tear / scratch
Silicone	• Biocompatible • High thermal stability • Can act as a waterproof seal	

3b. Risk Assessment

There were four potential hazards associated with the use of our device. First, there could be an allergic reaction to the device carrier material which is cotton. Some patients may have an allergy to cotton and this may trigger some skin rash or irritation. However, the probability of this event occurring is remote, and the severity is low. To mitigate that risk, we carefully investigated the biocompatibility rate of cotton, and a tag will be displayed to list the materials of the device. Next, we identified an electric shock hazard, due to the circuit components of the system. Since the device will be securely encased in a polycarbonate box covered with a silicone sleeve, this risk is mitigated allowing the probability of occurring to be remote, along with low severity. The following hazard identified for our device use is related to electrical injury due to water penetration inside the device hardware. This may cause circuitry corrosion and provoke eventual injury to the patient. However, once again the probability of this event happening is remote, as the device carrier will be separated from the circuit box, and the severity is marginal. Lastly, we considered exposure to vibration as a potential hazard to elderly patients due to the focus of the project being vibration therapy. The risk will be mitigated by limiting therapy sessions up to 1 hour and allowing low frequency ranges from 20 Hz to 300 Hz only.

3c. Cost Assessment

The electronic components and the different materials selected allow us to produce a device at a relatively low cost ($136 worth of materials). This will certainly have an outstanding impact on the market for PD patients since it will be available at a fair price for in-home as well as in-clinic therapy sessions. The ultimate goal of our device is to bring an affordable and efficient vibration therapy opportunity for PD patients, which will be lightweight and could potentially help them avoid trips to the therapist's office as often as before. Vibration Motors and a Bone transducer were included to create a vibration effect of the device to cause the case to vibrate. The Bluetooth receiver is used to connect the smartphone to the device to make it wireless along with the power source and charging port. The microchip helps to control it with the speaker to possibly play music. The hard casing and silicone will be used to enclose the device, and the sock will act as the device carrier. Each component was compared based on the pros and cons of available components using the technology assessment. The quantity of each component was taken to account to minimize the budget provided by our sponsor while maximizing the results.

Table 8: A table of the projected cost assessment for this project is included below:

Item	**Cost**
Vibration motor	$22.45
Bluetooth Audio Receiver Board	$2
Power source	$10
Lithium charging port	$5
Bone conduction Transducer	$8.95

Microchip ATtiny85	$2
Speaker	$6
Sock	$10
Hard casing	$15
Silicon	$5
Shipping & Packaging	$22
Shipping Total =	**$22**
Materials Total=	**$86**
Overall Total=	**$108.40**
Item	**Cost**

Table 9: A table of the actual cost assessment for this project as of 4/10/2022 is included below:

Materials, Devices, and Components Purchased			
Materials/ Components	**Quantity**	**Cost**	**Total**
Linear Vibration Motor	1 unit	$3.21	$3.21
Lithium Battery	1 unit	$13	$13
Arduino Nano 33IoT	1 unit	$23.30	$23.30
Fabric Device Holder	1 unit	$16	$16
PLA Filament	1 spool	$23	$23
Screw	4 units	$0.90	$3.60
Velcro Strap	1 Unit	$8.49	$8.49
Project Display	1 unit	$15	$15
Mini PCB	1 unit	$9.99	$9.99
Charging board	1 unit	$4.99	$4.99
Converter	1 unit	$9.88	$9.88
Coin Vibration Motor (10 pack)	1 unit	$10.99	$10.99

Coin Vibration Motor(4 pack)	1 unit	$5.99	$5.99
Headphones	1 unit	$14.85	$14.85
5mm Vertical Slide Switch	1 unit	$5.99	$5.99
Total Material Cost =			$182.24

Table 9.1: A table of the actual product cost assessment as of 4/10/2022 is included below:

Product Cost Assessment			
Lithium Battery	1 unit	$13	$13
Fabric Device Holder	1 unit	$16	$16
PLA Filament	1 spool	$23	$23
Screw	4 units	$0.90	$3.60
Project Display	1 unit	$15	$15
Mini PCB	1 unit	$9.99	$9.99
Charging board	1 unit	$4.99	$4.99
Converter	1 unit	$9.88	$9.88
Coin Vibration Motor(4 pack)	1 unit	$5.99	$5.99
Headphones	1 unit	$14.85	$14.85
5mm Vertical Slide Switch	1 unit	$5.99	$5.99
Total Material Cost =			$136.26
Labor	2 Hours	$50	$50
Overhead	(40% of Labor + 14% of Material)	$39.08	$39.08
Total Product Cost=			225.37

3d. Regulatory Assessment

Given that the device is non-invasive, it would be considered a Class I Medical Device by the FDA classification, posing low to moderate risk to the patient. Further analysis of the system leads it to fall under the category of physical medicine therapeutic device: § 890.5975 - Therapeutic vibrator, making it subject to the limitations in § 890.9 and is required to follow general controls, which are the baseline requirements of the Food, Drug, and Cosmetic (FD&C) Act. This FDA class allows the device to be exempt from 510(k), Pre-Market Approvals (PMA), and Investigational Device Exemption (IDE).
As displayed in the table below, there were five standards to consider for the project. The first one is Safety Requirements for Electrical Equipment (IEC 61010-1) which regulates the electrical components for measurement, control, and laboratory use. Next, the standard for software used in medical devices (ISO 62304) which defines the life cycle requirements of the software we use to program the system and to display the feedback produced by the device. Biological evaluation of medical devices part one or ISO 10993 which applies to evaluation of materials and medical devices that are expected to have direct or indirect contact with the patient's body during intended use. To test the first standard compliance, the IEC 62353 will be considered, and to verify the market requirement and design inputs of water resistance, the IP Rating IEC 60529 will be utilized.

Table 10: Engineering Standards

Standard	**Name**
IEC 61010-1	Safety Requirements for Electrical Equipment
ISO 62304	Software used in Medical Devices
ISO 10993	Biological evaluation of medical devices — Part 1: Evaluation and Testing within a risk management process
IEC 62353	Medical electrical equipment
IEC 60529	IP Rating (Water Resistance)
ISO 5725-1:1994	Accuracy (trueness and precision) of measurement methods and result
IEC 62366	International standard that covers the

	application of usability engineering to medical devices
IEC 60601-1	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance
ISO 7250	Basic human body measurements for technological design: — Part 1: Body measurement definitions and landmarks — Part 2: Statistical summaries of body measurements from national populations — Part 3: Worldwide and regional design values for use in ISO equipment standards
ISO 5349-1	Mechanical vibration — Measurement and evaluation of human exposure to hand-transmitted vibration — Part 1: General requirements

3e. Meeting Minutes

"Team 6"

Report Date: 11/19/2021

Team Meeting

Attendees	Status			
Jacob Bharat	P			

Bianca Castello	P			
Maria Chiang	P			
Mario Civil	P			
Yency Perez	P			

P = Present L = Late AE = Absent (Excused) A = Absent
Cc: Attendees

Facilitator: Bianca
Note Taker: Jacob
Time Keeper: Jacob

Agenda

Discussion Points	**Comments**
Today	• 11/19 will be focused on the project plan and PowerPoint. We will make sure to finish the powerpoint up to project scope (making all the necessary revisions and touch ups), project plan, divide, assign, possible practice, and finish as much as possible of the powerpoint after • We made some touch ups to all the areas on the PowerPoint up to scope.
Updates	• 11/12-verification tests and project plan • 11/15-mock and practice, project plan • All feasibility assessments have been completed individual based on assigned parts and will go through final review today while completing powerpoint

Action Item	**Person Responsible**	**Date**	**Status**
• Solidworks	Mario	Assigned 11/8 Due 11/17	No
• Fix up and make language pretty • Project Cost/ Budget	Jacob	Assigned 11/8 Due 11/10	In Progress
• Project Cost/ Budget	Bianca	Assigned 11/8 Due 11/10	Done

• Constraints • Solution impact on society in a global and contemporary	Maria	Assigned 11/8 Due 11/10	Constraints Done
• Business Need and Current Modalities • Project Success Factors	Maria	Assigned Date (11/5)Due 11/7	Done
• Hardware based on Market Requirements(MR) and Budget Research. • Technology Assessment	Mario	Assigned Date (11/5)Due 11/9	Done
• Hardware based on Market Requirements(MR) and Budget Research. • Verification Tests	Bianca	Assigned Date (11/5)Due 11/9	Verification tests not done
• Evaluation of multiple concepts • Formulation of Engineering Solution	Bianca	Assigned (11/10) Due 11/11	Done
• Suitability/adequacy of the solution to address the need	Jacob	Assigned (11/10) Due 11/11	Done as group

Section 4: Design

a. Simulation Results

This device incorporates all the functions required in the construction of a pulse-width-modulation (PWM) control circuit on a single chip. Designed primarily for power-supply control, this device offers the flexibility to tailor the power-supply control circuitry to a specific application. The TL494 chip contains two error amplifiers, an on-chip adjustable oscillator, a dead-time control (DTC) comparator, a pulse-steering control flip-flop, a 5V, 5% precision regulator, and output-control. The oscillation provides a positive sawtooth waveform to the dead-time and PWM comparators for comparison to the various control signals. The frequency of the oscillator is programmed by selecting timing components R_T and C_T (resistor and capacitor). This chip sends out two out-of-phase signals creating DC from the AC music signal, acting as a comparator or operational amplifier.
The frequency of the oscillator becomes:

$f_{OSC} = 1/R_T \times C_T$

For the push-pull application:

$f = ½(R_T \times C_T)$

An auxiliary cable was utilized to transmit the music signal waveform into the chip to analyze it and transform it into a stable vibration. The cable was cut to expose the internal wires: white and red for out-putting music signal, to which a 1k Ohm resistor was soldered and connected to jump wired to facilitate and secure connection to board. The copper wire was simply soldered to a jump wire. This allowed for the manipulation of the average music signal using an oscillator machine to observe the waveforms produced and control the frequency of the vibration. Headphones with bluetooth components integrated to each earbud were obtained to satisfy the market requirement of a wireless device, to which the same soldering work was performed and the smartphone was utilized as a signal provider to the headphones. A B10K potentiometer was determined to be the perfect component to manually establish the frequency range the device outputs and the function for this was decided to be a voltage divider. A second potentiometer was utilized, B20K with the purpose of obtaining a variable resistance with a range of 0K Ohm to 20K Ohm. This allows the circuitry to control the DTC (dead-time control) or PWM duty-cycle. Diodes were added as flyback diodes to loop the current back to the motor, since the current would resonate otherwise and would not allow the motor to turn off when the music signal is off. The capacitor used was a 100Hz low pass filter that allowed only the bass of the signal to be input for the motor, acting as an imaginary impedance. The vibration motor was soldered to jump wires to improve board connections. After testing the vibration with the music signal, we were able to synchronize them without delay with a maximum frequency range of 20-300Hz, which concors with the low-frequency vibration therapy as indicated in literature. The music rhythm was able to be transmitted into the vibration, as well as, heard by the user using the other earbud.

While this design worked fine, the filtering of the peaks needed to be more precise. The executive decision of interveting the order of the chips used (TL494 and LM358) was made with the intention of using the latter mentioned as a peak detector, low-pass filter, and amplifier. The former chip mentioned was kept simply as the wave comparator. This fixed the precision of the filter and allowed the song “Eye of the Tiger” to vibrate accurately throughout the motor.

Figure 7: Schematic of the TL494 Chip

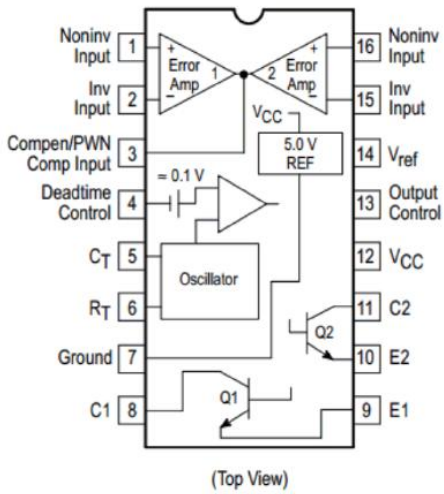


Figure 8: Schematic of the LM358

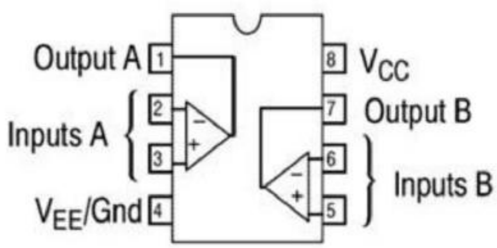


Figure 9: Simulation Diagram of Device’s electrical components

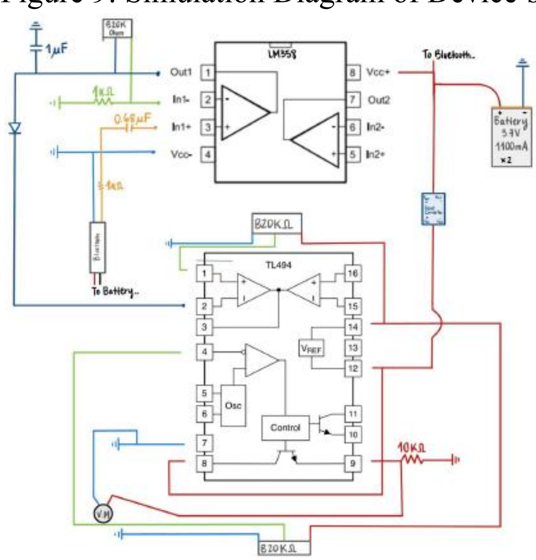
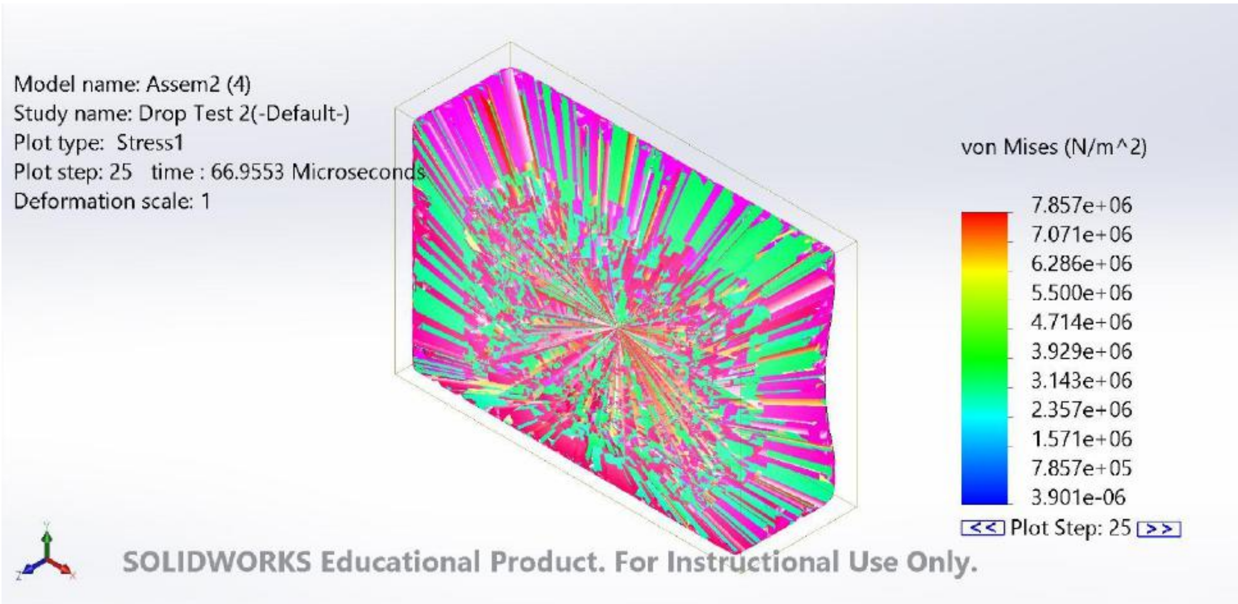


Figure 10: Drop Test Stress Analysis of the Device Case



b. Prototype Sub-System Tests

Protoype Sub-System Tests is not within the scope of this senior design project nor would it be applicable when testing in this project. Prototype Sub-System Tests occurs when we test for multiple parts that comprise an assembly, but our entire device is only one unit.

c. Patent Search Results

The patents listed below that are related to our device, specifically devices that convert sound waves into a form of vibration. Patents that are related to vibration devices used as a form of physical therapy are also considered and included below.

Document Identifier	**Publication date**	**Current International Class:**	**Abstract**
US 20160203685 A1	Jul 14, 2016	H04R 1/02 (20060101); G09B 21/00 (20060101); G08B 6/00 (20060101)	A wearable haptic device is provided. The wearable haptic device includes a band having at least one haptic device attached to the band. A power source is operatively connected to the *vibration* device. The

			vibration device may further include an input configured to connect to a *music* playing device. The *vibration* device produces a *vibration* based on the output of the *music* playing device.
US 201202962 44 A1	Nov 22, 2012	A61H 1/00 (20060101); A61H 23/00 (20060101); A61H 23/02 (20060101); A61H 1/02 (20060101)	A vibrating footboard having a base plate and an intermediate plate coupled to each other, by first *vibration*-damping elements, at least one eccentric mass electric motor coupled to the intermediate plate, and two groups of upper plates capable to support feet of a user coupled to the intermediate plate through second *vibration*-damping elements. The vibrating footboard allows the user to undergo a neuromuscular stimulation, for both *therapy* and athletic enhancement.

d. Animal and/or Cadaver Tests

Animal and/or Cadaver Testing is not within the scope of this senior design project nor would it be applicable when testing.

e. ALT Results

ALT Results is not within the scope of this senior design project nor would it be applicable when testing in this project.

f. Reliability Determination

This is related to the pursuant to the verification test. This is related to the performance of the verification protocol and the verification tests. The verification tests will determine the short-term reliability of the device based on data collection and evaluation.

g. Meeting Minutes

Team 6 Senior Team Meeting Minutes

Date: February 23,2022

I. Call to Order
    A. Meeting Called to Order at 05:15 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Present

III. Approval of Last Meeting's Minutes
  A. Jacob Motions, Maria Seconds

IV. Unfinished Business
  A. Elevator Pitch
    1. Someone Else?
  B. Project Plan
    1. We still haven't gone over it with Christie yet.
    2. Design Concepts
    3. Make sure to separate the pros and cons.
    4. The image and description is descriptive enough.
    5. Designer must show several views
    6. Exploded: where all the parts blow up and form dots that show how they attach. Components diagram
      a) Isometric
      b) Top View
      c) Side View
    7. Make it the MVP and show out all the benefits.
    8. We need to show the circuit board and blow it up such as the insides.
    9. You can show in solidworks, we need pictorial drawing. We should try to show in solidworks how it interacts with the sock and what it will look like.
    10. Let's do some risk analysis. How will the sock and device interface with the body and skin?
    11. Do an impact test, some simulations for dimensions. Simulation is mandatory. Drawing is needed.
    12. We discussed the solid work design and looked at the new version. We need to see the validity of buttons.
    13. We went over how to do the exploded view and what is needed.

V. New Business

A. We were working on our individual tasks together.
    1. Mario and Mario on Solidworks
    2. Bianca and Yency on Arduino
    3. Jacob on App
B. Senior Showcase
    1. April 14th is Drop dead day for everything
        a) Everything must be done and due
            (1) DHF
            (2) DMR
            (3) Abstracts
            (4) Presentation
            (5) Poster
            (6) Video Presentation.
    2. Oral Presentation on April 21st in OCB
        a) Half a day affair
        b) Business Professional
    3. Poster Competition will be the 22nd of April in OCB
        a) 1:30pm-4:30pm and setup by noon.
        b) Laptop showing all manufacturing and devices and work.
        c) Business Professional
C. After the 3rd of March there is nothing due. We think he means 6th of March.

VI. Due Dates/ Task
   A. We need to do the pre manufacturing agreement.
   B. What is our project report?
   C. We need to do the drawings and the sock.
       1. Reask about the sock and redo the sock,
   D. We need to continue our design, coding, app and circuitry on Wednesday.
   E. We should start reaching out to Dr.Weinstock about updates on our project to keep him informed as the midterm sponsor assessment will likely be based on that.

VII. Meeting Adjournment
   A. Meeting Adjourned at 09:19 p.m.

Team 6 Senior Team Meeting Minutes

Date: February 24,2022

I. Call to Order
   A. Meeting Called to Order at: 02:20 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Present
Dr. Christie	Faculty Advisor/Mentor	Present

III. Approval of Last Meeting's Minutes
    A. Jacob Motions, Yency Seconds

IV. Unfinished Business
    A. Reviewed MRs and DIs right off the bat.
    B. Design Concepts
        1. Make sure to separate the pros and cons.
        2. The image and description is descriptive enough.
        3. Designer must show several views
            a) Exploded: where all the parts blow up and form dots that show how they attach. Components diagram
            b) Isometric
            c) Top View
            d) Side View
        4. Make it the MVP and show out all the benefits.
        5. We need to show the circuit board and blow it up such as the insides.
        6. You can show in solidworks, we need pictorial drawing. We should try to show in solidworks how it interacts with the sock and what it will look like.
        7. Let's do some risk analysis. How will the sock and device interface with the body and skin?
        8. Do an impact test, some simulations for dimensions. Simulation is mandatory. Drawing is needed.

V. New Business
    A. Questions
        1. Premanufacturing Agreement
            (1) Don't need the circuit or coding for this.

(2) Whatever you can buy, do not make

2. Can you explain how the device verification would work? Would we have to ship it to our sponsor if he can't really test it?
    a) Only based on verification tests

VI. Due Dates/ Task
    A. We need to do the pre manufacturing agreement
    B. We need to do the drawings and the sock.
    C. We need to continue our design, coding, app and circuitry on Wednesday.
    D. We should start reaching out to Dr.Weinstock about updates on our project to keep him informed as the midterm sponsor assessment will likely be based on that.

VII. Meeting Adjournment
    A. Meeting Adjourned at 03:29 p.m.

Team 6 Senior Team Meeting Minutes

Date: March 7,2022

I. Call to Order
    A. Meeting Called to Order at 06:15 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Present
Asad Mirza	Outsourcer	Present

III. Approval of Last Meeting's Minutes
    A. Jacob Motions, Maria Seconds

IV. Unfinished Business
    A.

V. New Business

A. Circuit Consultation
    1. Look like we will have to get a better battery for input,
    2. Use scope to help read output
    3. Might need potentiometer
B. We went through the next steps for the project and determined what is needed to get done and how we will be moving forward as we are behind schedule.
C. We gained some context and got past a roadblock.

VI. Due Dates/ Task
    A. Continue to work on individual tasks

VII. Meeting Adjournment
    A. Meeting Adjourned at 09:19 p.m.

Team 6 Senior Team Meeting Minutes
Date: March 9,2022

I. Call to Order
    A. Meeting Called to Order at 06:15 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Absent

III. Approval of Last Meeting's Minutes
    A. Jacob Motions, Maria Seconds

IV. Unfinished Business
    A. Continue to work on individual parts.
        1. Jacob is working on the simulations of the vibration based on music rhythm using an LED.

2. Yency was able to get a complete simulation of the circuit done and is working on the circuit
    a) Yency is having trouble with making the vibrating motor work
3. Bianca is working on the app and making it connect via bluetooth with the arduino
4. Maria is looking into the additional materials that are needed for the device.

V. New Business
    A. No New Business

VI. Due Dates/ Task
    A. Continue to work on individual tasks

VII. Meeting Adjournment
    A. Meeting Adjourned at 09:54 p.m.

Team 6 Senior Team Meeting Minutes

Date: March 24,2022

I. Call to Order
    A. Meeting Called to Order at: 02:30 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Present
Dr. Christie	Faculty Advisor/Mentor	Present

III. Approval of Last Meeting's Minutes
    A. Jacob Motions, Yency Seconds

IV. Unfinished Business
    A. Reviewed MRs and DIs right off the bat.
    B. Design Concepts

1. Designer must show several views
    a) Exploded: where all the parts blow up and form dots that show how they attach. Components diagram
    b) Isometric
    c) Top View
    d) Side View
2. Let's do some risk analysis. How will the sock and device interface with the body and skin?
3. Do an impact test, some simulations for dimensions. Simulation is mandatory. Drawing is needed.

V. New Business
  A. Silicon Talk -Maria
    1. Topics
        a) Types of Products
        b) Whole or Separate components
        c) Mold
    2. Worse case: The aesthetics and appearance might be compromised with a spray
    3. The silicone may not stick to the material.
    4. Do trials on pieces of the substrate to see how well it works or holds.
    5. Human error, someone with a steady hand spraying it might have it come out better
    6. Dip might have concerns with residuals
    7. Try both and see which is more functional
    8. See which coating adheres better to the substrate
    9. Explore neoprene
    10. Look at manufacturing process and ensure functionality is conserved
  B. Vibration Motor Talk - Yency
    1. Topic
        a) Check Resistor Formula
        b) Ask if he knows someone
        c) Show simulation
    2. Reach out to professors and electrical grad students to see if they can help
    3. Go to electrical engineering name starts with a B
        a) Ou Bai
  C. Power Talk -Bianca
    1. How to connect battery to arduino, connect/transfer that increased voltage to current.
  D. Frequency Talk -Jacob
    1. How to specify it or cody it.

VI. Due Dates/ Task
   A. Nothing from Dr. Christie
VII. Meeting Adjournment
   A. Meeting Adjourned at 03:02 p.m.

Team 6 Senior Team Meeting Minutes
Date: April 7, 2022

I. Call to Order
   A. Meeting Called to Order at: 02:00 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Absent
Micheal Christie	Faculty Advisor	Present

III. Approval of Last Meeting's Minutes
   A. Bianca Motions, Jacob Seconds
IV. Unfinished Business
   A. Where are we at?
      1. Jacob gave a recap of what we are doing, before his Wifi and data started disrespecting him.
V. New Business
   A. -Bianca, the Bluetooth arduino with the LED example but with motors at set vibration tempos
   B. -Jacob, yours is the Matlab one with arduino, music translated to vibration and music heard from the computer
   C. - Maria, new design from electrical peeps (not arduino) vibration at tempo of music through Bluetooth, no intensity change or music heard outside
   D. What meets the MRs
      1. Maria- Model using the Headphones Bluetooth Module

            a) Wouldn't: 9
        2. Bianca- Arduino Bluetooth with random vibration
            a) Wouldn't: 10, 2, ~9, ~6, ~3
        3. Jacob- Wired Arduino
            a) Wouldn't: 10, 2, 3, ~9
    E. Cut off date for the prototype build before we go to backup.
    F. Use documentation not paperwork.
    G. We need to ask Dr. Christie.
        1. Prototype Sub-System Tests
            a) If we had an assembly, we would have to test each individual thing.
        2. Patent Search Results
            a) USPTO.gov.
            b) Find the devices that are closest to what we have. Do a deep dive and comparison.
                (1) 2-3 that are best.
            c) If there is nothing similar, we have claims about each aspect.
            d) List each feature of the product and recommend the features.
        3. Patent Opportunities
            a) The listing the unique features
        4. Reliability Determination
            a) Part of verification tests. More extensive. I Want to show that the prototype behavior is stable.
            b) Make a statement that is related to the pursuant to the verification test. That is related to the performance of the verification protocol. Make a statement that is related to the verification tests. that will demonstrate the
    H. Cutoff point to write up our report and address that in our live presentations. We should be speaking about our verification tests and what was pending. State it, don't shy away!
    I. Request a meeting that I will show videos. Can't allow access. He will have to play the video, email him and it will be after hours.

VI. Due Dates/ Task
    A. How do we fill out the billing information for the poster?
    B. How do we fill out the Ferpa form?
        1. Can we get an example to show how to fill each section or can we go over each section.

VII. Meeting Adjournment
    A. Meeting Adjourned at 9:37 p.m.

Section 5: Design Outputs

a. Engineering Drawings

The first Solidworks design (figure 11.1) is the case assembly with the cover attachment and the main body connected. It also features a curved surface to hug the ankle, the screws to secure the main body to the cover attachment. It includes the holes for the buttons, the holes for the LED display feedback, and the hole for the USB port. All the electrical components will be connected and assembled to be contained within the case. The case with the electrical components will be assembled and coated in silicone. The vibration device will sit on the ankle and transmit the vibration produced from the vibration motors inside the case. The device will be placed in a sock with a side pocket to target the exit area. The sock will include a fabric pocket that is held next to the ankle on the fit to hold the vibration device taut to the body to send vibrations to the lower leg. However, an updated version has been implemented to better fit the market requirements of water resistance and electrical hazard mitigation. Therefore, the holes for leds and buttons are substituted by a unique switch that will control the power input, while the USB charging port hole will be maintained. The circuit main components will be safer and better protected against the ingress of water, as shown in figure 11.2.

Figure 11.1: Assembled Case Solidworks original

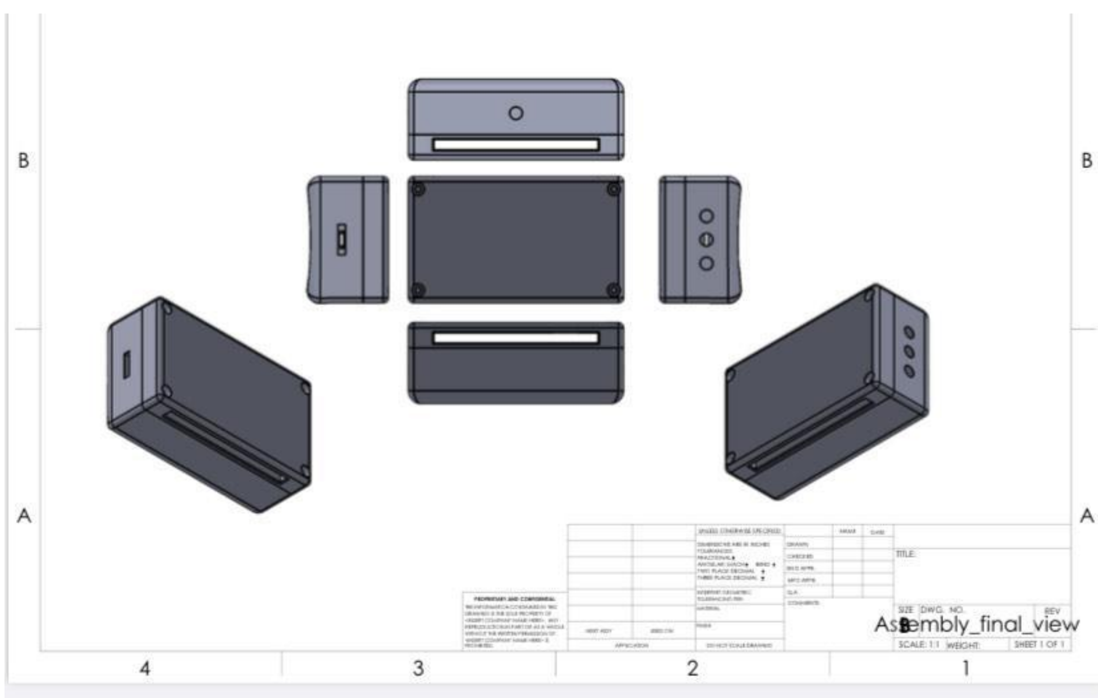


Figure 11.2: Updated design concept Solidworks

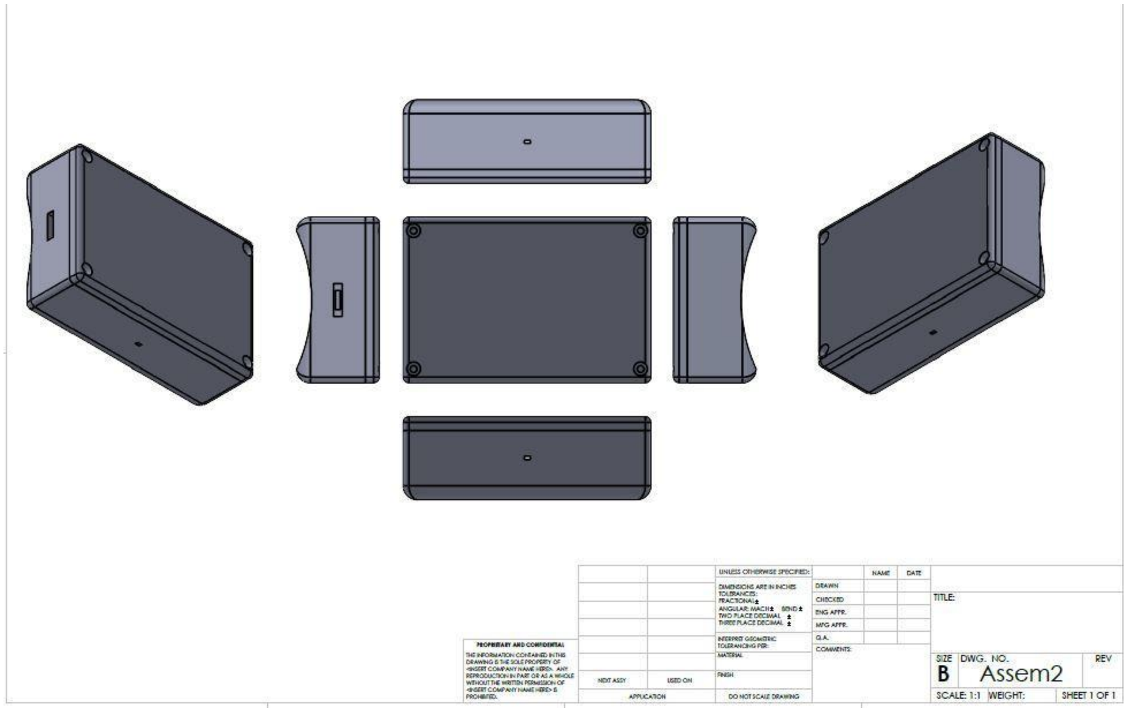
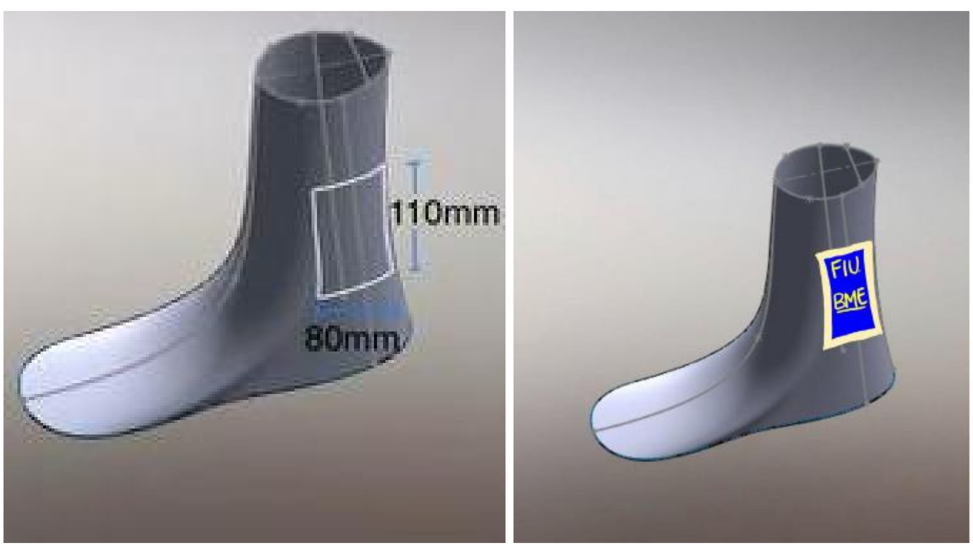


Figure 12: Device Carrier with a Device pocket



The case assembly is divided into two components which are the main body and the cover of the case. The main body includes the area where all the electrical components are housed and it includes all the entry points to the assembled circuit for the device to work. The cover of the case includes a slit so that it is possible to put a strap through it that makes the device independently functionally without the need for a sock. There will also be 4 screws to connect the cover to the main body of the case.

Figure 13: Main Body of the Case

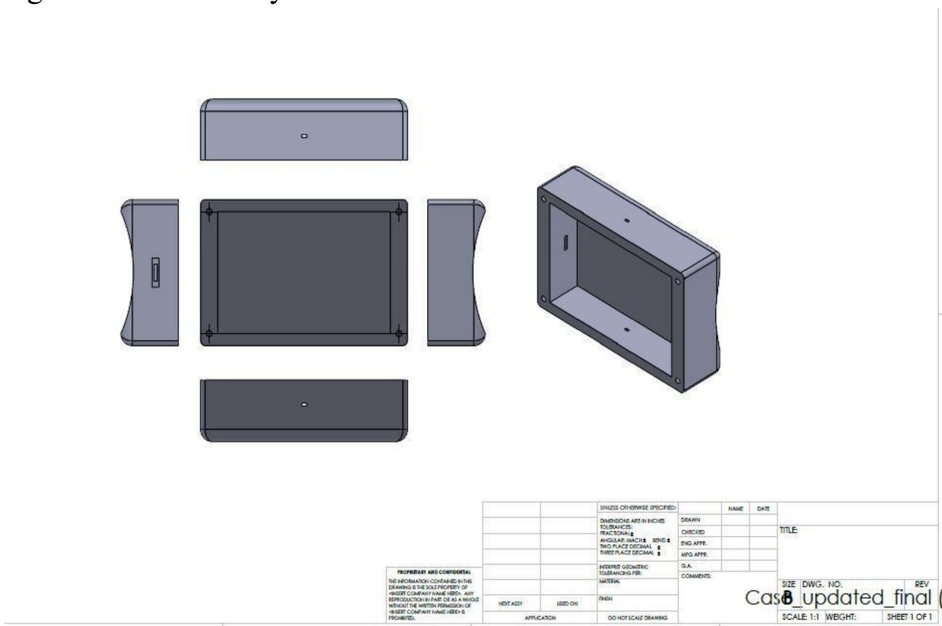


Figure 14: Cover for the Case

Figure 15: Vibration Motor

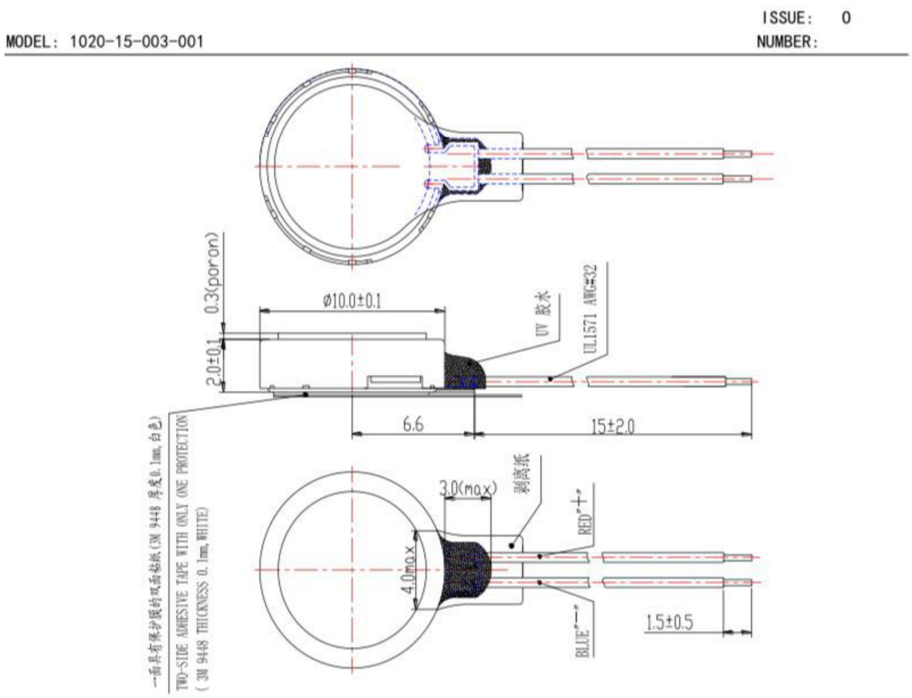
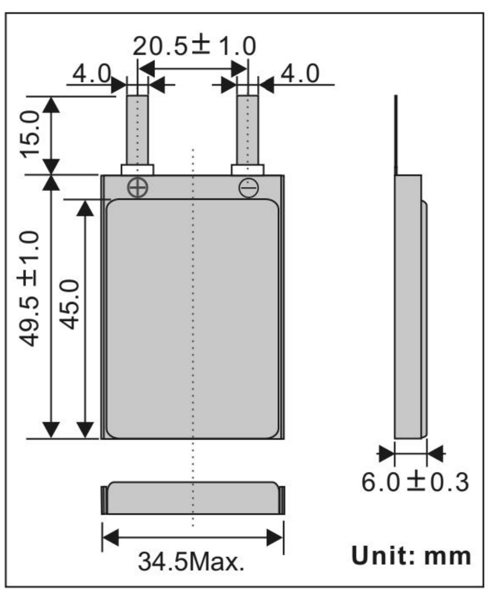


Figure 16: Li-Polymer Battery



b. Material Specifications

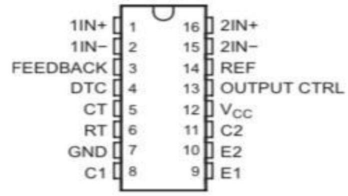
Table 11. Material Specifications for the TL494 Integrated Circuit

TL494 microcontroller	
Operating Voltage	**7V**
Input Voltage(Limit) (VCC)	**40V**
Collector output current	**250 mA**
Oscillator frequency	**1KHz - 300 KHz**
Timing capacitor	**0.47 nF - 1000 nF**
Timing Resistor	**1.8 KΩ - 500 KΩ**
Operating free-air temperature	**0 C - 70 C**
Width	**6.35 mm**
Length	**19.3 mm**
Weight	**8 g - 10 g**

TL494 Configuration

Figure 17: Pins configuration

D, DB, N, NS, OR PW PACKAGE
(TOP VIEW)



Pin Functions

PIN		TYPE	DESCRIPTION
NAME	NO.		
1IN+	1	I	Noninverting input to error amplifier 1
1IN-	2	I	Inverting input to error amplifier 1
2IN+	16	I	Noninverting input to error amplifier 2
2IN-	15	I	Inverting input to error amplifier 2
C1	8	O	Collector terminal of BJT output 1
C2	11	O	Collector terminal of BJT output 2
CT	5	—	Capacitor terminal used to set oscillator frequency
DTC	4	I	Dead-time control comparator input
E1	9	O	Emitter terminal of BJT output 1
E2	10	O	Emitter terminal of BJT output 2
FEEDBACK	3	I	Input pin for feedback
GND	7	—	Ground
OUTPUT CTRL	13	I	Selects single-ended/parallel output or push-pull operation
REF	14	O	5-V reference regulator output
RT	6	—	Resistor terminal used to set oscillator frequency
V_{CC}	12	—	Positive Supply

Table 12. Material Specifications for the Vibration Motor

DC Vibration Motor Model : 1020-15-003-001

Operating Voltage	**DC 2.5 - 3.5 V**
Rated current	**80 mA or less**
Operational frequency	**200Hz - 235 Hz**
Motor construction	**10-mm flat coreless**
Acceleration	**1.3 - 1.8 G**
Allowable Temperature change	**20 C - 70 C**
Insulation resistance	**10MΩ(Min)**
Weight	**0.9 g**
Terminal resistance	**75Ω max**

Mechanical noise	**50dB-A (Max)**
Rated speed	**10 000 rpm min**

Table 13. Material Specifications for the Battery

LP 603449 3.7v 1100 mAh battery

Nominal Capacity & Voltage	**1100 mAh, 3.7 V**
Standard Charge Method	**CC/CV (CV end current 22mA)**
Standard Charge current	**0.2C (220mA)**
Charge Max Voltage	**4.200±0.020V**
Standard Discharge Current	**of 0.2C (220mA)**
Cut-off Voltage	**2.750±0.005 V**
Maximum Charge Current	**1C (1100mA)**
Maximum Discharge Current	**2C (2200 mA)**
Charge Temperature	**0 ~ 45 ℃/Discharge Temperature: -20 ~ +60 ℃/Storage Temperature: -20 ~ +25 ℃**
Size	**34.5 x 51 x 6.3mm (WxLxH)**
Weight	**22g**

Table 14. Materials Specifications for the Device Carrier

Fabric Device Holder (Sock)

Composition	**76% Cotton, 21% Polyester, 3% Spandex**
Size	**Women's shoe size 7-13 and mens shoe size 6-13**
Pocket width	**80mm/3.3 inches across**
Pocket height	**110mm/4.4 inches high**

Zipper	**ruggedized**
Manufacturer	**Flippysox**

Materials

Table 15. Materials Specifications for the Polylactic Acid Filament

Polylactic Acid Filament (PLA)	
Composition	**Polylactic Acid (PLA)**
Net Weight	**1 kg or 2.2 lbs**
Diameter	**+/- 0.05 mm**
Roundness	**+/- 0.07mm**
Print Temperature	**190-225 degrees c**
Density	**1.24 g/cm^3**
Tensile Strength	**50 MPa**
Flexural Strength	**80 MPa**
Impact Strength(untouched) IZOD	**96.1J/m**

Table 16. Materials Specifications for the Cotton

Cotton	
Strength	**28-30 grams force per tex(GPT)**
Fiber Diameter(Micronaire)	**2.0-7.0**
Elastic Recovery at 2% Extension	**74%**
Breaking Elongation (dry)	**3-9.5**
Tensile Strength (g per tex/g per denier) a. **Dry** b. **Wet**	a. **27- 44 / 3.0 - 4.9** b. **28 - 57 / 3.3 - 6.4**

Water absorbing Capacity	**>24 grams of water per gram of fabric**
Density (g/cm3)	**1.54**
Degree of Polymerization	**9,000-15,000**
Thermal Resistance	**Dry heat above 300 degrees F will cause gradual decomposition**

Table 17. Materials Specifications for the Polyester

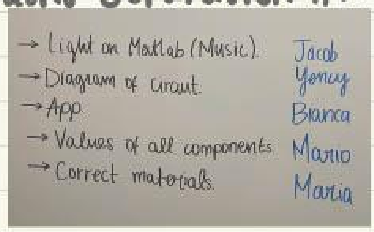
Polyester	
Strength **a. Dry** **b. Wet**	 **a. 27-54** **b. 27-54**
Density	**0.601-2.20 g/cc**
Viscosity	**110-180000 cP**
Tensile Strength	**10.0-123 MPa**
Modulus of Elasticity	**1.00-10.6 GPa**
Flexural Yield Strength	**53.8-256 MPa**
Compressive Yield Strength	**71.0-214 MPa**
Electrical Resistivity	**1.00e+12 - 1.00e+14 ohm-cm**

c. Engineering Notebook

All notes and documentation is written explicitly in the meeting minutes and are attached to the respective sections that the minutes most pertain to.

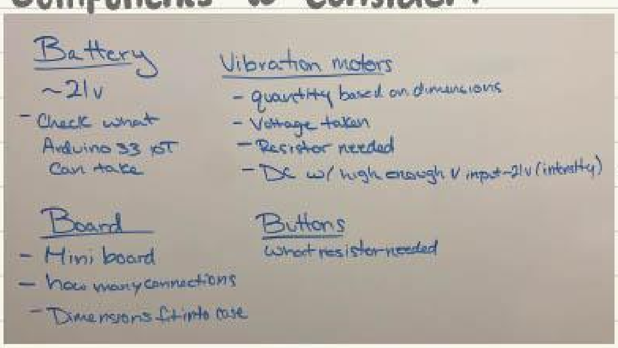
DESIGN NOTES

Tasks Separation #1:



- Jacob B. created a code in Matlab using an audio reader build-in function to play the selected music as vibration, which was tested using an LED.
- Yency P. was responsible for creating the circuitry logic incorporating all separate components (LED feedback mechanism, push buttons to increase or decrease the frequency, etc).
- Bianca C. worked on obtaining a Bluetooth connection from the arduino and developing a user interface to allow the user to change the selected song or turn the device on and off.
- Mario C. colaborate with Maria C. to research and verify the electrical values of all components needed for the circuitry.

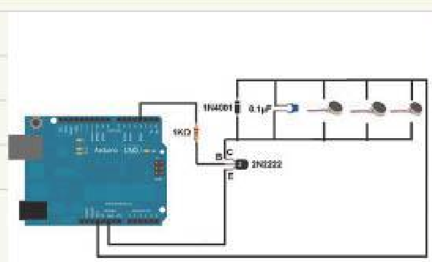
Components to Consider:



- Many chracteristics to keep in mind for 4 categories of components we required. All these were researched and agreed opon next meeting.

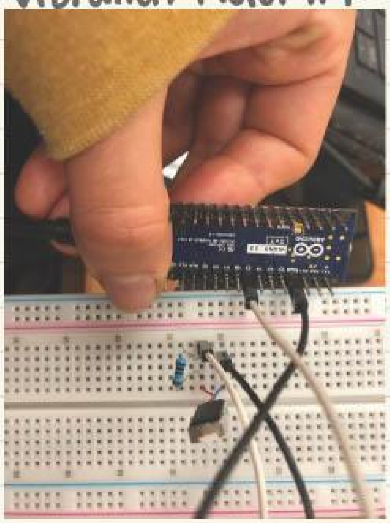
Vibration Motor Connection:

- The beggining stages of the circuit that allow us to build a proper connection of



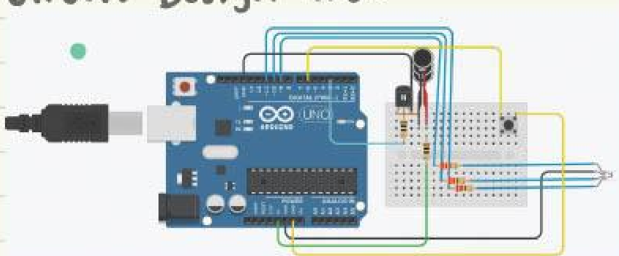
multiple vibration motors powered by 5V. Design #1.

Vibration Motor #1:



- The first vibration motor that was considered was a linear motor (LRA) power by the arduino nano 33 IoT and utilizing a 10Ω resistor as intermediate. This first try was unsuccessful because it was for an AC motor.
- The decision was made of changing the motor used to a coin vibration motor, as well as, the redesign of the circuit.

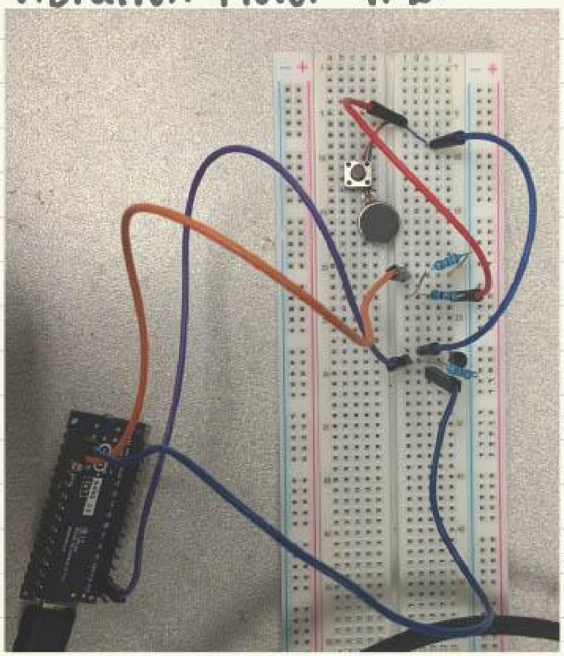
Circuit Design #2:



- The second circuitry was made integrating 3 vibration motors, a transistor, 4 resistors (2 = 1Ω for the vibration motor and 3 = 220Ω for the RGB light), 1 push-button to switch in between three predetermine percentage voltage to be output from the PMW pin 3 (as shown in the simulation) simultaneously interchanging between three different colors representing the 3 different frequencies.

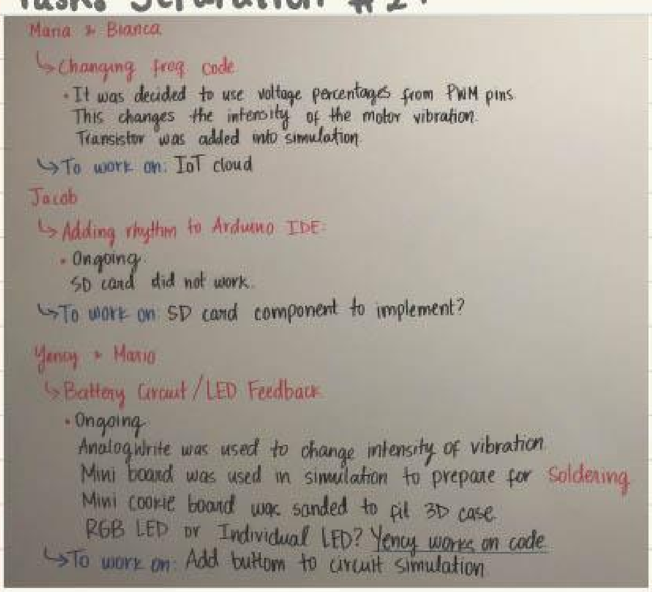
- The new vibration motor internal components are displayed on the left picture.

Vibration Motor #2:



- The redesign circuitry was tested without the RGB light. Arduino nano was coded using Matlab at any frequency, connecting the arduino to the V_{IN} to supply power. The circuit was able to make the motor vibrate, however, syncronyzation to music rhythm was not successful. Soldering the motor to jump wires and obtaining the correct resistors was considered to solve these problems.

Tasks Separation #2:



Maria + Bianca
↳ Changing freq code
- It was decided to use voltage percentages from PWM pins.
  This changes the intensity of the motor vibration.
  Transistor was added into simulation.

↳ To work on: IoT cloud

Jacob
↳ Adding rhythm to Arduino IDE
- Ongoing.
  SD card did not work.

↳ To work on SD card component to implement?

Yency + Mario
↳ Battery Circuit / LED Feedback
- Ongoing.
  AnalogWrite was used to change intensity of vibration.
  Mini board was used in simulation to prepare for Soldering.
  Mini cookie board was sanded to fit 3D case.
  RGB LED or Individual LED? Yency works on code

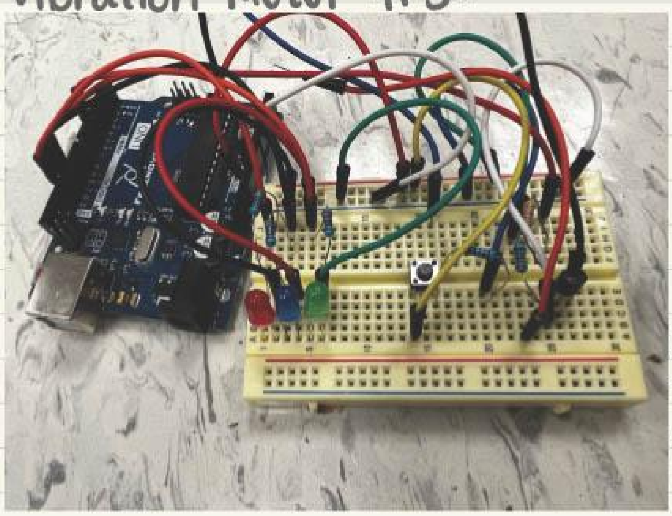
↳ To work on: Add buttom to circuit simulation.

- Maria and Bianca were in charge of investigating how to store codes into the arduino using a IoT cloud, as well as, figuring out how to change frequencies specified on the MR.
- Jacob was responsible for obtaining music rhythm vibration using Arduino IDE instead

of Matlab since the circuitry works coded on the IDE, we agreed IDE is not able to analyze music waveforms and an SD card to store songs might be needed.

- Yency and Mario will figure out how to code for different frequencies of vibration, being mindful of dimensions (such as using a mini board) while fixing and preparing for a new circuitry design. Yency was successful at coding the RGB with changing frequency to use color coordination as feedback mechanism.

Vibration Motor #3:



- The RGB was exchanged for 3 individual LED lights that will interchange with every push of the button. We were not successful because the "transistor" was a temperature sensor. Help was needed.

- At this point we stop working on our own and started getting help from two undergraduate electrical engineers.
- It was agreed that the arduino nano 33 IoT was not powerful, fast, nor capable of handling all requirements need to fully operate as expected.

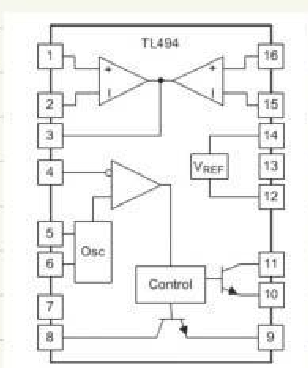
TL 494 CHIP

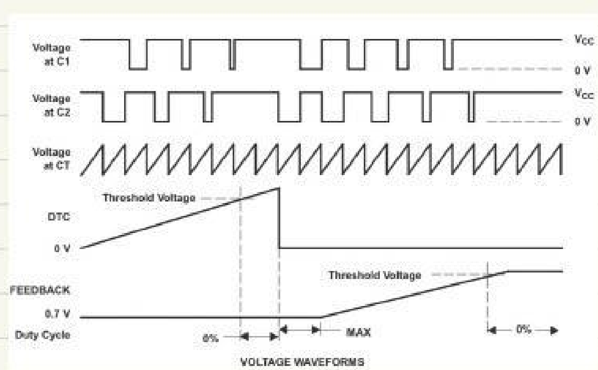
This device incorporate all the functions required in the construction of a pulse-width-modulation (PWM) control circuit on a single chip. Designed primarily for power-supply control, this device offers the flexibility to tailor the power-supply control circuitry to a specific application.
The TL494 chip contains two error amplifiers, an on-chip adjustable oscillator, a dead-time control (DTC) comparator, a pulse-steering control flip-flop, a 5-V, 5% precision regulator, and output-control.
The oscillator provides a positive sawthooth waveform to the dead-time and PWM comparators for comparison to the various control signals. The frequency of the oscillator is programmed by selecting timing components R_T and C_T (resistor and capacitor).
The frequency of the oscillartor becomes:

$$f_{osc} = \frac{1}{R_T \times C_T}$$

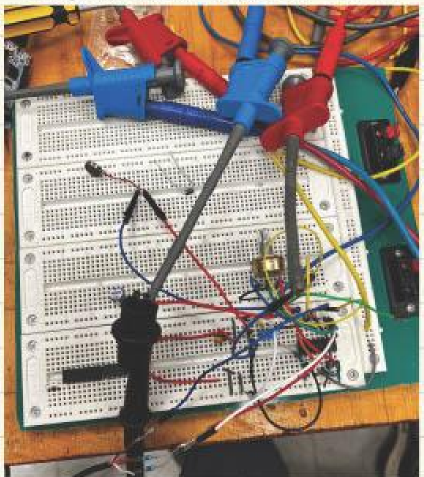
Push-pull applications:

$$f = \frac{1}{2(R_T \times C_T)}$$

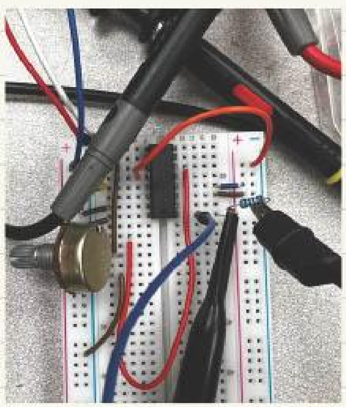




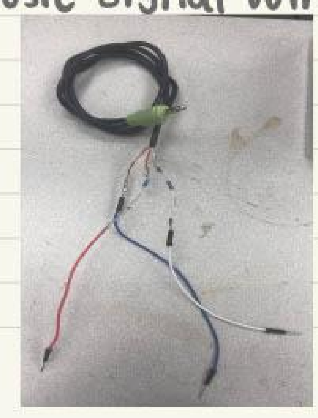
Vibration Motor #4:



Vibration Motor #5:



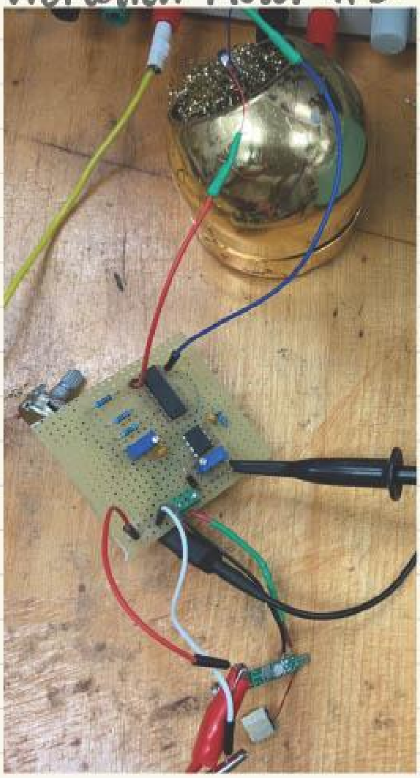
Music Signal Wire:



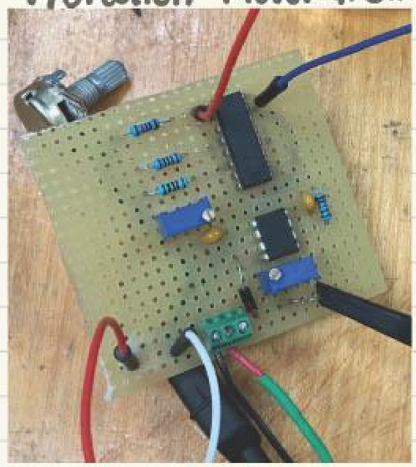
- An auxilliary cable was utilized to transmit the music signal waveform into the chip to analyze.
- The cable was cut to expose the internal wires: white and red for outputting music signal, to which we solder 1kΩ resistors and jump wires to facilitate and secure connection to the board. The copper wire was simply solder to a jump wire.
- This allowed us to manipulate the average signal using an oscillator to observe the waveforms produce and control the frequency of the vibration.
- A potentiometer was determine to not be enough to control the frequency range.
- A B500K potentiometer worked fine, however it means having to manually turn it to control frequency while in use, instead of the MR stating to predetermine 3 levels of intensity by pushing a button. Voltage divider function was used.
- The vibration motor was solder to jump wires to improve board connections. After testing the vibration with the music signal, we were able to synchronize them without delay with a maximum frequency range of 0-300 Hz (low-frequency vibration therapy as indicated in literature).

While this last circuitry worked fine, more precision is needed to isolate the peaks of the song.

Vibration Motor #6:



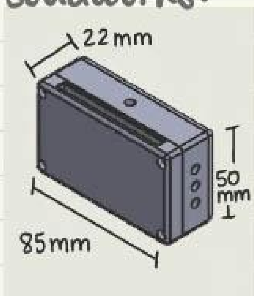
Vibration Motor #6.1:



- Precision was acquired by inverting the chips, the LM358 goes first to amplify the music signal, allow low frequencies to be transmitted to the motor by creating a low-pass filter, as well as, acting as a peak detector. The TL494 captures the signal and acts as a comparator to convert the AC signals into the DC signals the vibration motor understands. There are 3 different potentiometers, the first one is a B10kΩ and it acts as a voltage divider changing the ratio between two resistors, allowing intensity to be controlled. The second x third potentiometers are both B50kΩ act as varible resistors to control precision of the peaks felt by the motor. This allowed for minimum delay between the music heard and the rhythm felt by the device.

MANUFACTURING NOTES

Solidworks:



- The case consider many aspects important to the market requirements, such as being restricted by small dimentions and light-weight design. The rounded corners allow the device to slip into a carrier with ease. The 4 orifacies seen in the picture will secure the top portion of the case close off. The 3 orifacies on the front will hold the 3 LEDs which functions as the feedback mechanism. The 1 oriface on the side of the case will house the power button.

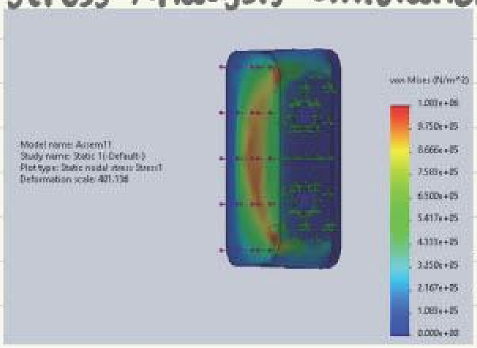
PETG top:

PLA bottom:

Size Comparison:

- The top of the case includes a slit so it is possible to pass a strap through, making the device independent and adjustable to the proper location of interest. The case was printed on the Ender 3 3-D Printer in the maker space. The purpose of the usage of two different materials was to determine the wire filament that can take the most amount of stress. The verification was acquired by performing a stress analysis. Two portion took ~4 hours and bottom was ~6 hours.

Stress Analysis Simulation:



- This Solidworks simulation demonstrated tha PLA was a better candidate for our purpose since the difference between them was relatively minimal, however, PLA is more affordable.

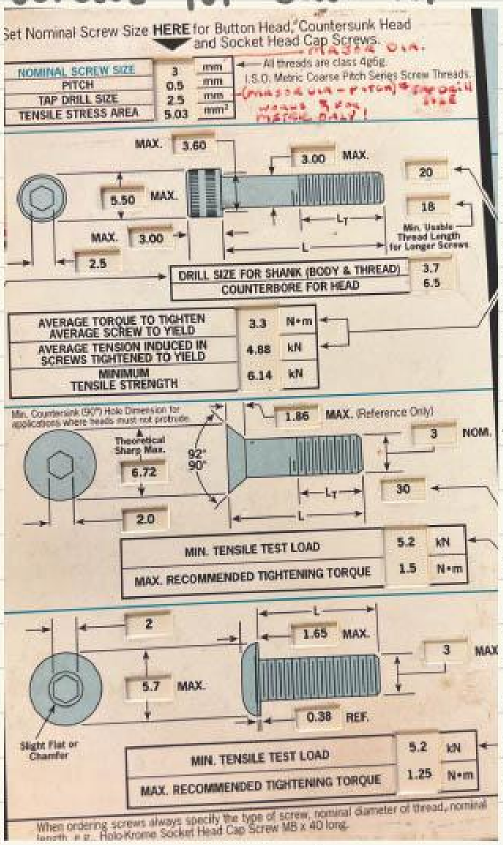
Chracteristic Comparison:

- As observe in this picture, strength, part quality, stiffiness are greater in PLA than in PETG.

Curvature of Case:

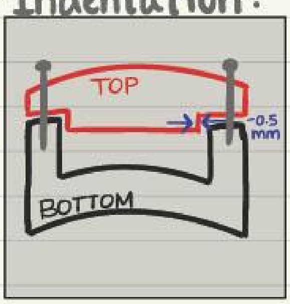
- The bottom portion of the case will have a curvature that can be perfectly Laid against the patients skin as seen in the picture. This allows the vibrations generated by the device to be spread out along the whole surface area. The case required further work, such as sanding the rough areas, treating it with alcohol to melt and smoothing out the larger top and button sections of it. This is done to prevent friction againts the device carrier, decreasing the difficulty of use.

Screws for Case Top:



● A consultation with Mr. Zicarelli allowed us to identify the correct screws to use for the secure closure of the device. Afte analyzing various possibilities, a 3mm x 0.5 pitch screw was agreed upon. This means a 2.5mm diameter in the top of the case to allow this screw to be place is needed to be design. A small indentation around the inner side of the top portion of the case to further secure the closure and provide a degree of insulation, which concurs with our water resistance market requirement. This extrusion will be of 0.5 mm in the direction of the bottom portion.

Indentation:



● The diagram displayed showcases both the location of the screws and the indentation on a frontal plane view. Mr. Zicarelli also recommended PlastiDip to increase the level of protection againts moisture.

Device Carrier:

• This Solidworks model represents the device that will assit with proper localization of the vibration, is responsible for carrying the enclose circuitry inside of a pocket, which is indicated by the blue FIU <u>BME</u>. This design supports the difficulties experienced by the targeted population of Parkinson's patients.

Targeted Anatomy:

• After performing extensive research about the benefits of localized/targeted vibration therapy and various meetings with our sponsor (Dr. Weinstock), it was decided the Long Flexor Muscle and the Achilles Tendon represented the largest area possessing proprireceptors, which are intereonnected in muscle and tendon fibers. These receptors are responsible for the limbs' spatial awareness, which is lost due to the chronic motor degeneration caused by the disease.

d. Procedures & Test Procedures

The circuitry was assembled at the EPSi Laboratory Group of Dr. Arif Sarwat in the Electrical Engineering Department (Room 3920) where a system with a Peak Detector integrated along with a low pass filter and an amplifier was designed to filter, amplify and detect low frequency peaks using potentiometers and adjusting their calibration to acquire clear and precise triggers. The two chips exchange location, first one that acquires the music signal is the LM358 to amplify the signal, allowing low frequencies (0-300 Hz) to be transmitted to the second chip (TL 494) by creating a low-pass filter, as well as, acting as a peak detector. The TL494 captures the signal and acts as a comparator to convert the AC signals into the DC signals the vibration motor understands. There are 3 different potentiometers, the first one is a B10K and it acts as a voltage divider changing the ratio between two resistance (0K ohm - 10K ohm), allowing intensity to be controlled. This potentiometer was later changed to another B20K ohm potentiometer to fit inside the case of the device. The second and third potentiometers are both B20K act as variable resistors to control precision of the peaks felt by the motor. This allowed for minimum delay between the music heard and the rhythm felt by the device. Many of the components needed were provided, an oscilloscope to observe behavior of waveforms, a function generator, a DC Power supply machines were borrowed for testing and measuring critical values, such as frequency and voltage. A soldering iron, tin wire, a dremel, and a voltmeter were also utilized in the process of manufacturing. The team agreed to not split the music signal to the device and a speaker to save power. Wireless headphones were implemented because one of them was added to the circuit as a music signal transmitter and the other one left for the user to listen to the songs simultaneously.

e. Patent Opportunities

Through examination and comparison of patents that contain key words associated with our music vibration device we have concluded that many similar devices have been made that incorporate music and transform it into a congruent vibration pattern. There are many devices made for entertainment that use this technology such as vibrating game sets. The first device listed uses this technology to help deaf people understand sound through their other senses by converting sound waves into vibrations so they are able to experience sound in a different form. The second device listed also uses vibration, this is more similar to our project since the vibration is targeted to the foot and is used for physical therapy practices. Our project is unique in the way that the vibration and music is combined but also used for targeted vibration aiding in physical therapy. This would allow us to apply for a patent even though similar technology has been used. The combination of the technology, purpose and location are unique and should be viable when applying for a patent.

f. Meeting Minutes

Team 6 Senior Team Meeting Minutes

Date: April 4,2022

I. Call to Order
    A. Meeting Called to Order at: 06:30 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Present

III. Approval of Last Meeting's Minutes
   A. Jacob Motions, Bianca Seconds

IV. Unfinished Business
   A. Arduino-
      1. Maria and Yency met with some Electrical Engineering students and they advised them that the Arduino is not good enough for what we are trying to do.
      2. The arduino is too slow to send music with the size of the file to play over bluetooth and vibrate properly.

V. New Business
   A. TL494- A microcontroller that is able to properly connect and process the signal.
   B. We used an already programmed bluetooth wireless headphone set. It already has the bluetooth protocol and is able to connect.
   C. The internal bluetooth headphones have a chip and board which will search for bluetooth signals and will act as a receiver.
   D. The phone will act as a signal and will be the transmitter for the music to be played.
   E. The bluetooth headphone was stripped and connected to the vibration motors to connect to the headphones bluetooth board. This will complete the device.
   F. What needs to be done is finding and playing the different vibration frequency intensity to meet one of the design inputs.

VI. Due Dates/ Task
   A. We need to ask Dr. Christie.
      1. Prototype Sub-System Tests
      2. Patent Search Results
      3. Reliability Determination
      4. Engineering Notebook

5. Patent Opportunities

VII. Meeting Adjournment

A. Meeting Adjourned at 9:37 p.m.

Team 6 Senior Team Meeting Minutes

Date: April 7, 2022

I. Call to Order

A. Meeting Called to Order at: 02:00 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Absent
Micheal Christie	Faculty Advisor	Present

III. Approval of Last Meeting's Minutes

A. Bianca Motions, Jacob Seconds

IV. Unfinished Business

A. Where are we at?

1. Jacob gave a recap of what we are doing, before his Wifi and data started disrespecting him.

V. New Business

A. -Bianca, the Bluetooth arduino with the LED example but with motors at set vibration tempos

B. -Jacob, yours is the Matlab one with arduino, music translated to vibration and music heard from the computer

C. - Maria, new design from electrical peeps (not arduino) vibration at tempo of music through Bluetooth, no intensity change or music heard outside

D. What meets the MRs

1. Maria- Model using the Headphones Bluetooth Module

            a) Wouldn't: 9
        2. Bianca- Arduino Bluetooth with random vibration
            a) Wouldn't: 10, 2, ~9, ~6, ~3
        3. Jacob- Wired Arduino
            a) Wouldn't: 10, 2, 3, ~9
    E. Cut off date for the prototype build before we go to backup.
    F. Use documentation not paperwork.
    G. We need to ask Dr. Christie.
        1. Prototype Sub-System Tests
            a) If we had an assembly, we would have to test each individual thing.
        2. Patent Search Results
            a) USPTO.gov.
            b) Find the devices that are closest to what we have. Do a deep dive and comparison.
                (1) 2-3 that are best.
            c) If there is nothing similar, we have claims about each aspect.
            d) List each feature of the product and recommend the features.
        3. Patent Opportunities
            a) The listing the unique features
        4. Reliability Determination
            a) Part of verification tests. More extensive. I Want to show that the prototype behavior is stable.
            b) Make a statement that is related to the pursuant to the verification test. That is related to the performance of the verification protocol. Make a statement that is related to the verification tests. that will demonstrate the
    H. Cutoff point to write up our report and address that in our live presentations. We should be speaking about our verification tests and what was pending. State it, don't shy away
    I. Request a meeting that I will show videos. Can't allow access. He will have to play the video, email him and it will be after hours.

VI. Due Dates/ Task
    A. How do we fill out the billing information for the poster?
    B. How do we fill out the Ferpa form?
        1. Can we get an example of how to fill each section or can we go over each section.

VII. Meeting Adjournment
    A. Meeting Adjourned at 9:37 p.m.

Section 6: Design Verifications

6a. Design Verification Protocols

Verification tests were selected to ensure the project was completed within the boundaries of our expected market requirements and design inputs. Completion of all verification tests show that the project is successful. Verification tests were also determined by taking into account no form of patient testing will be used. Displayed below is the table that defines the verification tests that will be used to test four of the design inputs, ensuring that the basic functionalities of the device are met to consider device success.

Table 18. Summary of Design Verification Protocols.

Design Input	Verification Tests
Device dimensions should be equal to or under 100mm x 60 mm and it should be made of low-density material less than 1 kg per cubic meter.	Measuring Tape: Ensure all required dimensions are met. Scale: Measure the weight of the electrical components and the device carrier ensuring less than 1 kg. **Protocol Test 1**
Using Bluetooth technology to synchronize with a smartphone and play music in the form of vibrational rhythm.	Stopwatch: To measure the lag between the music playing and the vibrational rhythm to determine if the lag is within an appropriate and not noticeable range. **Protocol Test 2**
Low-frequency vibration will be delivered to the patient (20-100 Hz).	Oscilloscope: Measure the vibrational frequency output from the device. **Protocol Test 3**
The device's circuitry must be enclosed inside a case able to withstand a minimum of 50 liters of water sprayed at a pressure of 50-150 kPa continuously for 5 minutes in any direction.	The Ingress Protection Test: This test determines the exact levels that a device is able to withstand against moisture. **Protocol Test 4**
The device must have a battery capacity to operate for at least 1 hour on a single charge.	Battery Capacity Test: Accelerated cycle life testing of batteries is conducted as a means to assess whether a battery will meet its life cycle requirements. **Protocol Test 5**

Material will not cause irritation to skin when worn for the duration of treatment.	Biocompatibility Research: Use find materials that are already biocompatible. Find reference and evidence that supports biocompatibility. **Protocol Test 6**

This was the final iteration of the Design Verification protocols with the verification tests properly formatted in the correct way.

6b. Design Verification Reports

Verification Test Report 1	
Project Description: Music Vibration Device	**REVISION NO.: 1**
Team: Bianca Castello, Jacob Bharat, Maria Chiang, Mario Civil, Yency Perez	**Page** 1 of 1
TITLE: *Measurement Test Protocol, Vibration Device and Carrier, Ensuring the measurements are within specified constraints.*	

1. **PURPOSE**

The purpose of this protocol is to measure the dimensions and weight of the device components to ensure it is within the constraints.

2. **SCOPE**

The scope of this test is to measure the length, height and width of the vibration device, sock, and the sock pocket, as well as measure the weight of the vibration device.

3. **REFERENCE DOCUMENTS**

There will be two standards that will be referenced for the measurements of the device. These *standards are ISO 5725-1, which is for the accuracy of measurement methods and results, and IDO 7250-3:2-15, which is for the basic human body measurements for technological designs.*

4. OVERVIEW/BACKGROUND

This protocol is necessary for ensuring that the device is compliant to one of the most important market requirements, especially to be successful. This protocol is used to measure the length and height of the vibration device so that it fits properly on a patient's ankle so that the targeted vibration is specific. If the targeted vibration were not specific and extruding pieces were not in contact with the ankle, the device would be less effective. The weight of the device should be lightweight because this device will be used on Parkinson's patients who experience difficulty balancing and walking. A heavy device would be counterintuitive by making it more difficult to walk and balance for the patient. The device carrier or the sock should be stretched to the maximum length and measured because this device is meant for a range of individuals across multiple demographics, therefore the device must be adjustable and fit a wide range of foot sizes for patients of all genders.

5. OBJECTIVES

The first objective is that the device dimensions will be equal to or fall under 100 millimeters by 60 millimeters and the device should not weigh more than 1 kilogram. The second objective is that the device carrier or the sock can stretch to between 220 mm to 310 mm in length.

6. TEST EQUIPMENT

- *Ruler with Centimeters measurement*
- *Scale in kilograms and grams*
- *Clasps*

7. MATERIAL

There are no materials that are non-reusable for this protocol.

8. SETUP

The setup is laying the vibration device on a flat and leveled surface. The setup for the sock or the device carrier is to use the clothing pins on a long, sturdy surface and stretching it to the maximum length.

9. SAMPLE SIZE

The sample size is that there should be 20 tests for the specific device with 0 failures to be an *appropriate sample size using a guide for experimental sample size.*

10. EXPECTED RESULTS/HYPOTHESIS

The expected result from this protocol is that the sock or the device carrier will stretch up to 310 mm in length and fit the vibration device in the sock pocket. The expected result will also be the vibration device will be under a kilogram falling under the dimensions of 100 millimeters by 60 millimeters.

11. PROCEDURE

The procedures will be separated into two parts: one for the vibration device and one for the device carrier.

Part 1: Vibration Device

1. *The first step will be to place the vibration surface on a flat, leveled surface.*
2. *Measure the length of the device, which is from the bottom where the USB port is located to the top where the display feedback is located.*
3. *Measure the width of the device.*
4. *Measure the height of the device, which is from the bottom of the curve meant to hug the ankle to the top of the case cover.*
5. *Weigh the device with all the contained components on a scale.*
6. *Write results in the data collection sheet.*

Part 2: Device Carrier(Sock)

1. *Attach clasps to the top of the sock and the bottom of the sock.*
2. *Attach the clasps to a sturdy, long surface that is completely straight in length.*
3. *Push the clasps in opposite directions of each other to stretch the sock and continue to stretch the sock as much as possible, then tighten the clasps in place.*
4. *Measure the length of the sock when maximally stretched.*

12. DATA COLLECTION SHEET

Table 19: Measurement Verification Test Results

Measurements Test Protocol					
	Test #1	Test #2	Test #3	Test #4	Test #5
Data Collected by	Maria and Bianca	Maria and Bianca	Maria and Bianca	Maria and Bianca	Maria and Bianca
Date and Time of Collection	4/10/22 10:58pm	4/10/22 11:00pm	4/10/22 11:03pm	4/10/22 11:05pm	4/10/22 11:06pm
Length of Device (mm)	89 mm	89 mm	89 mm	89 mm	89 mm
Width of Device (mm)	58 mm	58 mm	58 mm	58 mm	58 mm
Height of Device (mm)	29 mm	29 mm	29 mm	29 mm	29 mm
Weight of Device (grams)	86 g	86 g	87 g	87 g	90 g
Height of Device Carrier (mm)	245 mm-312 mm	246mm-312 mm	246 mm-312 mm	246 mm- 313 mm	246 mm- 313 mm

13. ACCEPTABLE CRITERIA

- *The device should have dimensions of 90 mm x 60 mm x 30.15 mm and weight of less than 1 kg.*
- *The height of the stretched sock should be no less than 310 mm*

14. RESULTS

The device case that contains the electrical components is within the boundary limits of 100 mm x 60. The device was measured to be 90 mm x 60 mm x 30 mm. Just reaching the border of our constraints therefore satisfying our market requirement of the device dimensions and weight.

15. APPENDIX

1. References: *V determining the experimental sample size - web.cortland.edu*. (n.d.). Retrieved March 3, 2022, from https://web.cortland.edu/romeu/ExperSampSizeQR&CII.pdf
2. Result Pictures

Figure 18: Width of Device

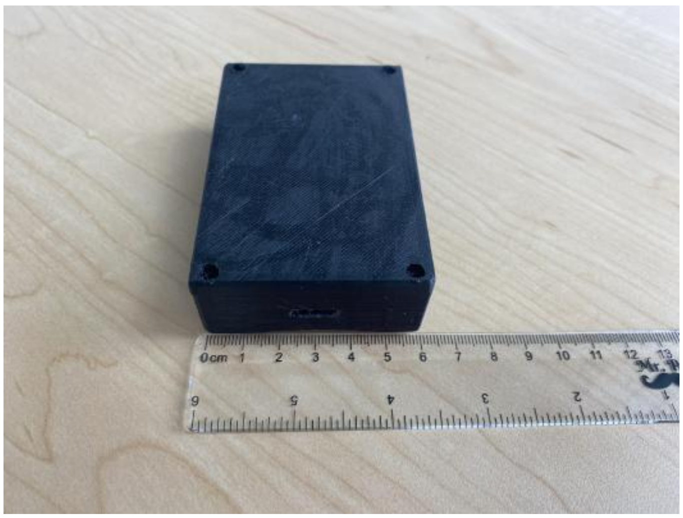


Figure 19: Height of Device

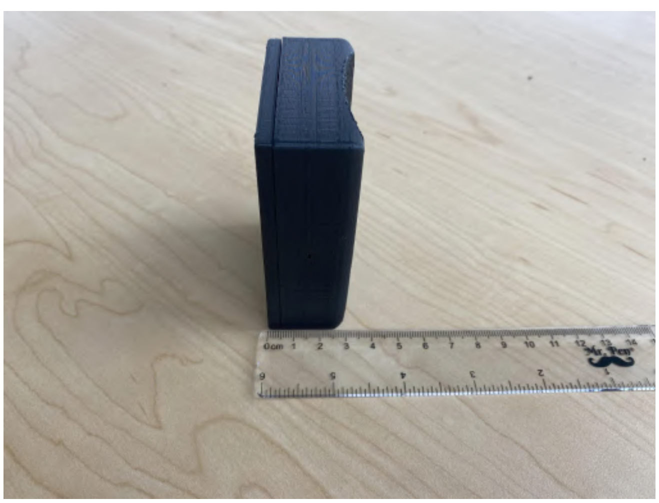


Figure 20: Length of Device

Verification Test Report 2	
Project Description: Music Vibration Device	**REVISION NO.:**
Team: Bianca Castello, Jacob Bharat, Yency Perez, Maria Chiang, Mario Civil	**Page** 1 of 1
TITLE: *Stopwatch Test Protocol, Vibration Device, Measuring device functionalities.*	

1. **PURPOSE**

The stopwatch protocol will be used to determine the functionality of certain aspects of the device by measuring how long aspects of the device take.

2. **SCOPE**

The scope of this test will measure the lag of the music playing compared to the vibrational rhythm.

3. REFERENCE DOCUMENTS

n/a

4. OVERVIEW/BACKGROUND

This protocol will measure the length of lag between the music playing and the vibrational rhythm to ensure it is within a just noticeable range. The device will be connected via Bluetooth to sync with the music and play both sound and vibration at the same time to provide treatment that targets different senses. A large would cause confusion and decrease effectiveness for the patient.

5. OBJECTIVES

The main objective is measuring the lag between the music playing and the vibrational rhythm that is connected to a smartphone via Bluetooth.

6. TEST EQUIPMENT

- *Stopwatch*
- *Bluetooth Pairing System*
- *Smartphone*

7. MATERIAL

There are no materials that are non-reusable for this protocol.

8. SETUP

The setup of this proe requires preparing an audio file with very spaced out distinctive audio markers to make it easier to identify the lags.

9. SAMPLE SIZE

The sample size is that there should be 6 tests for the specific device with 0 failures to be an appropriate sample size using a guide for experimental sample size.

10. EXPECTED RESULTS/HYPOTHESIS

The expected result will be that the vibration device will use Bluetooth technology to synchronize with a smartphone and play music in the form of vibrational rhythm under a just noticeable difference.

11. PROCEDURE

1. *The first step is to get a stopwatch ready. Ensure the vibration device is fully charged.*
2. *Connect the device through Bluetooth and have the subject hold the device.*
3. *Have the subject start the stopwatch immediately but the subject must not hear or see the music.*
4. *Allow some time to elapse and randomly start the music to play, record the time that is on the stopwatch when the music begins to play.*
5. *The subject will stop the stopwatch when they begin to feel vibrational rhythm from the music, record the lag time.*

12. DATA COLLECTION SHEET

Table 20: Stopwatch Verification Test Results

Stopwatch Test Protocol						
	Test #1	Test #2	Test #3	Test #4	Test #5	Test #6
Data Collected by	Jacob	Jacob	Jacob	Jacob	Jacob	Jacob
Date and Time of Collection	4/10/22 5:26 PM	4/10/22 6:04 PM	4/10/22 6:49PM	4/10/22 7:12PM	4/10/22 8:08 PM	4/10/22 8:32PM
Recorder plays musical rhythm (minutes: seconds)	00:32.00	00:15.45	1:12.15	2:48.16	00:54.18	1:59.27
Time subject registers vibration (seconds)	32.66	16.31	1:13.34	2:49.38	0:55.13	2:00:35
Lag Time (seconds)	.66	.46	.79	.82	.55	.68

13. ACCEPTABLE CRITERIA

The device should have latency no greater than 1 second so the delay is not noticeable.

14. RESULTS

Table 21: Lag Time Acceptance

Lag Time	Acceptable
0.66	Yes
0.46	Yes
0.79	Yes
0.82	Yes
0.55	Yes
0.68	Yes

Verification Test Report 3

Project Description: Music Vibration Device	**REVISION NO.:**
Team: Bianca Castello, Jacob Bharat, Maria Chiang, Mario Civil, Yency Perez.	**Page** 1 of 2
TITLE: *Oscilloscope Test Protocol, Vibration Device, Ensuring the vibrational frequency output is correct.*	

1. **PURPOSE**

The purpose of this protocol is to measure the vibrational frequency output from the vibration device.

2. SCOPE

The scope of this test is to measure vibration frequency generated from the vibration device.

3. REFERENCE DOCUMENTS

There will be one standard that will be referenced for this type of measurement of the device. This standard is ISO 5349-1:2001 for Mechanical vibration, which is measurement and evaluation of human exposure to hand-transmitted vibration.

4. OVERVIEW/BACKGROUND

This protocol is necessary for ensuring that the device is compliant to other important market requirements, especially to be successful. This protocol is used to measure the vibrational frequency output from the device to ensure it matches the vibrational frequency required. This is extremely important because the vibration frequency is specific to effective treatment for Parkinson's patients. It is also specific to achieving an adequate treatment with the right vibrational frequency output.

5. OBJECTIVES

The main objective is that the device will deliver a vibrational frequency of 20 to 300 Hertz in the form of music.

6. TEST EQUIPMENT

- *Oscilloscope*

7. MATERIAL

There are no materials that are non-reusable for this protocol.

8. SETUP

The setup is to ensure the program is open with the song and audio file already analyzed and the vibrational frequency set to 20 hertz.

9. SAMPLE SIZE

The sample size is that there should be 20 tests for the specific device with 0 failures to be an appropriate sample size using a guide for experimental sample size.

10. EXPECTED RESULTS/HYPOTHESIS

The expected result from this protocol is that the device will emit vibration at a frequency *ranging from 20 Hz to 300 Hz.*

11. PROCEDURE

1. *Turn the device on and play music through the program.*
2. *When the device begins to vibrate, use the oscilloscope to measure the vibrational frequency of the device.*
3. *Allow for the device to play at the same frequency for 30 seconds before changing the resolution intensity.*
4. *Move the device resolution intensity one notch higher and each time, record the intensity over a 30 second period each time.*
5. *Record Results for each resolution intensity.*

12. DATA COLLECTION SHEET

Table 22: Oscilloscope Verification Test Results

	Oscilloscope Test Protocol				
	Test #1	Test #2	Test #3	Test #4	Test #5
Data Collected by	Yency and Maria	Yency and Maria	Yency and Maria	Yency and Maria	Yency and Maria
Date and Time of Collection	04/11/22 8:33pm	04/11/22 9:08pm	04/11/22 9:15pm	04/11/22 9:37pm	04/11/22 9:55pm
Frequency output (Hertz)	130.35Hz	72.84Hz	53.61Hz	129.77Hz	43.33Hz

13. ACCEPTABLE CRITERIA

The device should have an output frequency in the range of ± 10% of 20-300Hz.

14. RESULTS

The circuitry was tested by inputting a music signal to the Bluetooth receiver and connecting the SDS 1202X-E Oscilloscope probes on the TL494 chip on pins 1 (positive input of one Op Amp) and 9 (emitter of the Bipolar Junction Transistor). Two waveforms were obtained, the AC music signal and the DC converted and filtered signal being compared to one another, as well as, the frequency ranges continuously being detected.

Figure 21: Oscilloscope Test 1

Figure 22: Oscilloscope Test 2

Figure 23: Oscilloscope Test 3

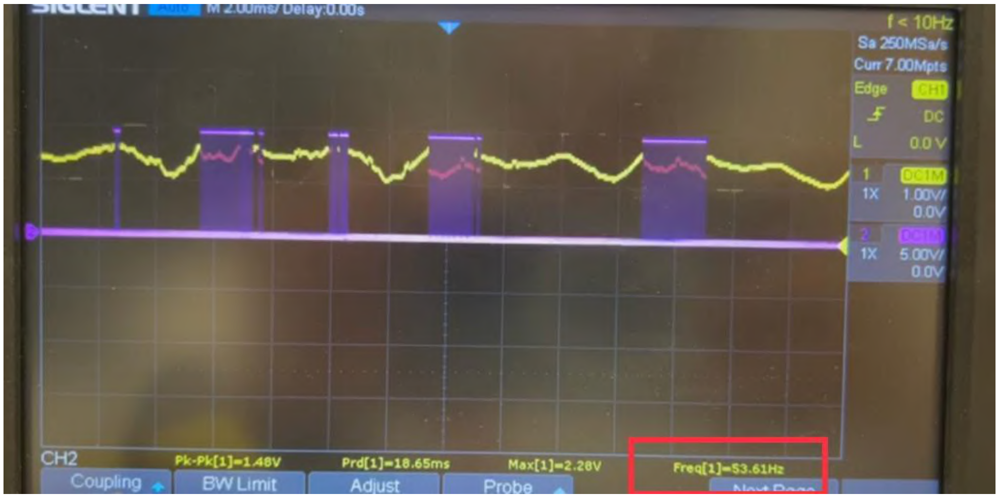


Figure 24: Oscilloscope Test 4

Figure 25: Oscilloscope Test 5

Verification Test Report 4	
Project Description: Music Vibration Device	**REVISION NO.:**
Team: Bianca Castello, Jacob Bharat, Maria Chiang, Mario Civil, Yency Perez	**Page** 1 of 2
TITLE: *The Ingress Protection Test Protocol, Vibration Device, Ensuring the device is protected against accidental spills and sweat*	

1. **PURPOSE**

The purpose of this protocol is to test if the device is resistant to moisture that it may come in *contact with, such as small splashes, spills, or sweat.*

2. SCOPE

The scope of this test determines if the device is able to resist splashes and spills with a safety factor.

3. REFERENCE DOCUMENTS

The standard that will be referenced for this type of measurement of the device is IEC 60529 IP Rating which is used to test the water resistance and determine the Ingress Protection rating of a device.

IPX4 Splashing Water Testing:

- *Defined as water splashing against the enclosure from any direction.*
- *The requirement is that the equipment under test (EUT), shall experience no harmful effects from the water being splashed against the enclosure from any direction.*
- *The test details include a test duration of at least five minutes, water volume of 10 liters per minute and pressure of 50-150 kPa.*

4. OVERVIEW/BACKGROUND

This protocol is used to decrease the number of hazards that a patient may be exposed to by mitigating the possible issue of electric shock. The vibration device contains numerous electrical components which can short circuit when exposed to water or moisture that can cause harm to the patient and damage the device. It is critical to test the moisture resistance of the device and ensure that it is properly protected against small splashes and sweat that may occur with normal use. Excessive sweating can be a consequence of damage to the autonomic nervous system as Parkinson's progresses or a side effect of anti-Parkinson's medications. To battle this possibility, having the circuitry enclosed and covered is critical. The standard IPX4 for water resistance is recommended as the minimum requirement for real durability.

5. OBJECTIVES

The first objective is that the device should be able to withstand a minimum of 50 liters of water sprayed at pressure of 50-150 kPa continuously for 5 minutes in any direction..

6. TEST EQUIPMENT

- *Water Pressure System*

- *Colored Dye*

7. MATERIAL

- *An initial prototype version of the Device Case with silicone covering.*
- *Paper Towels*
- *Water*

8. SETUP

The setup is to have a preprinted device case assembled and covered in silicone prior to the verification test.

9. EXPECTED RESULTS/HYPOTHESIS

The expected result from this protocol is that the device will be water resistant with an IPX4 rating after it is properly sprayed in silicone and the case is properly assembled.

10. PROCEDURE

1. *Place the sprayed device on a flat surface and expose it to the water pressure system such as a water sprinkler system.*
2. *Turn on the water pressure system and allow it to spray water from all directions at the case with a minimum force of 50 kilopascals. This should be with a minimum of 50 liters of water for at least 5 minutes.*
3. *After the time has elapsed, dry the device off thoroughly to ensure that there is no water or moisture on the outside.*
4. *Disassemble the case and separate the top and bottom portions.*
5. *Use new tissue to test if there was any moisture found in the inside of the case by verifying that the tissue does not contain any dye stains.*

11. DATA COLLECTION SHEET

Table 23: Ingress Protection Verification Result

	Ingress Protection Test Protocol					
	Test #1	Test #2	Test #3	Test #4	Test #5	Test #6
Data Collected by	Yency and Maria	Yency and Maria	Yency and Maria	Yency and Maria	Yency and Maria	Yency and Maria

Date and Time of Collection	04/10/22 10:40pm	04/10/22 10:50pm	04/10/22 11:05pm	04/10/22 11:20pm	04/10/22 11:32pm	04/10/22 11:46pm
Moisture Detected in Case (Yes or No)	No	No	No	No	No	No

12. ACCEPTABLE CRITERIA

The device should be able to not allow any moisture inside the device.

13. RESULTS

The device carrier was 3D printed, sprayed with black Plasti Dip, and closed. The water pressure system that was used is a sprinkler system with 104 Kpa. This was done with the purpose of making sure that no water can be absorbed when tissue paper is used to dry the inside of the case. As expected, the case did not allow splashes to pass into the case, ensuring that Parkinson's symptoms such as excessive sweating will not endanger the patient nor the device.

14. APPENDIX

Figure 26: Sprinkler Used

Figure 27: Ingress Protection Test being Performed

Figure 28: Water Pressure System Specifications

90°

12 ft.

Fixed Spray

Details | More Information

Nozzle Pattern	Quarter circle
Nozzle Radius	12 ft
Nozzle Type	Fixed spray
Nozzle Series	MPR
Specifications	Spacing: 3 to 20 feet (0,9 to 4,6 m) Pressure: 15 to 30 psi (1 to 2,1 bar) Optimum pressure: 30 psi (2,1 bar)* * Rain Bird recommends using 1800 PRS spray heads to maintain optimum nozzle performance in higher pressure situations.

Figure 29: High Pressure hose spraying device

Verification Test Report 5	
Project Description: Music Vibration Device	**REVISION NO.:**
Team: Bianca Castello, Jacob Bharat, Maria Chiang, Mario Civil, Yency Perez	**Page** 1 of 2
TITLE: *Battery Discharge & Consumption Test Protocol, Vibration Device, Ensuring the device battery capacity is enough to operate for one hour on a single charge.*	

1. **PURPOSE**

The purpose of this protocol is to test if the battery is rechargeable and able to operate for an adequate number of sessions in one week on a single charge without any external attachments.

2. **SCOPE**

The scope of this test is to determine if the battery of the vibration device is rechargeable and can operate for a certain amount of time on a single charge.

3. **REFERENCE DOCUMENTS**

The standards for that will measure how long the device can operate for while on a single charge is the IEC 60601-1. Devices with rechargeable batteries should be certified with IEC 606061-1 and comply with IEC 62133.

4. **OVERVIEW/BACKGROUND**

This protocol is to use a rechargeable power source to operate the device will reduce the risk of electric shock due to wire damage, and it will cause less noise and interference to surroundings, making it more convenient for the patient to move freely. One hour of use on a single charge allows the patient to use the device 5 sessions a day for 7 days with each session lasting about 90 seconds each. This will also make it easier for the patient to walk *and balance without anything constraining the patient's movement as they have difficulty walking and balancing already.*

5. OBJECTIVES

The first objective is that the device uses a rechargeable battery as a wireless power source with battery power to operate for 1 hour.

6. TEST EQUIPMENT

- *Multimeter*
- *Battery Analyzer and Proprietary Software*
- *Stopwatch*
- *Lithium Battery x2 (3.7V and 1100mA)*

7. MATERIAL

There are no materials required that are non-reusable.

8. SETUP

There is no setup required for the battery capacity test protocol.

9. EXPECTED RESULTS/HYPOTHESIS

The expected result from this protocol is the device will use a rechargeable battery as a wireless power source with battery power to operate for 1 hour.

10. PROCEDURE

1. *Connect the battery to the battery analyzer and prepare the software.*
2. *Ensure that the multimeter is on the voltage measurement setting to verify that it is fully charged.*
3. *Attach the battery connections to the meter probe clips.*
4. *Check the current reading after one hour and see the percentage compared to the original reading.*
5. *Calculate the battery's voltage when completely discharged .*

11. DATA COLLECTION SHEET

Table 24: Battery Discharge Result

	Battery Discharge Test Protocol				
	Trial #1	Trial #2	Trial # 3	Trial #4	Trial #5

Data Collected by	Yency	Yency	Yency	Yency	Yency
Date and Time of Collection	04/11/22 12:30pm	04/11/22 1:30pm	04/11/22 2:30pm	04/11/22 3:30pm	04/11/22 4:30pm
Current	0.55 Amps	0.55 Amps	0.55 Amps	0.55 Amps	0.55 Amps
Voltage	4.067 V	3.726 V	3.657 V	3.455 V	2.741V

Table 25: Battery Dischare Result

	Battery Consumption Test Protocol				
	Trial #1	Trial #2	Trial # 3	Trial #4	Trial #5
Data Collected by	Maria	Maria	Maria	Maria	Maria
Date and Time of Collection	04/11/22 4:30pm	04/11/22 4:45pm	04/11/22 5:00pm	04/11/22 5:15pm	04/11/22 5:30pm
Current	89.31 mAmps	89.33 mAmps	89.31 mAmps	89.29 mAmps	89.30 mAmps

Calculated hours of operation	21.990 hr.	21.986 hr.	21.990 hr.	21.996 hr.	21.993 hr.

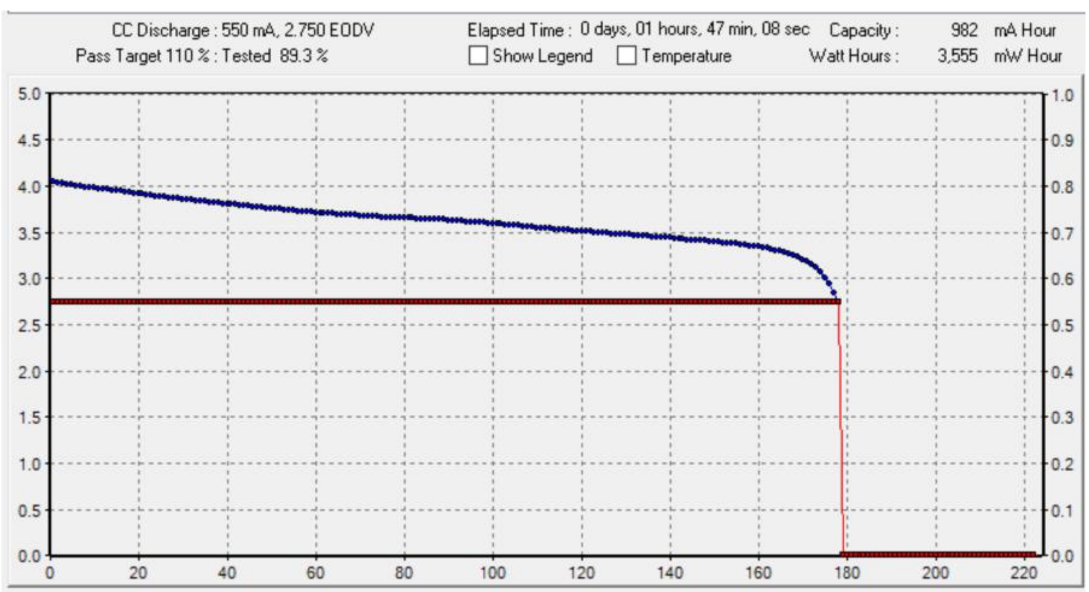
12. ACCEPTABLE CRITERIA

The battery should have a discharge time of no less than 1 hour and a calculated time of operation of at least 1hr.

13. RESULTS

The maximum voltage current that can be inputted to the TL494 chip is , the Op Amp LM358 600 mWatts, the maximum current output 250 mAmp at 15V resulting in approximately 4.25 Watts, the Bluetooth maximum current output 50 mAmp at 3.7V. The battery was connected to the battery analyzer to be discharged fully and produced a discharged curve.

Figure 30:Displayed is the discharged method line in red which represents the constant current of 550mA because the circuitry requires two batteries and the blue plot signifies the discharge curve of the battery.

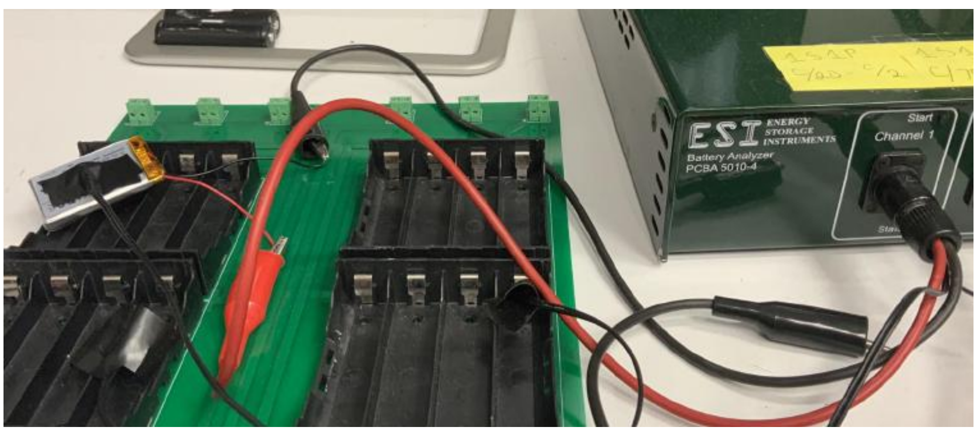


To acquire these values, the software used for analyzing the data was Matlab where charge current limit was set at 550 mAmp, charge voltage limit 4.2V, charge start voltage 2.75V, charge end rate C/22, discharge capacity limit 111%, target capacity 110%, discharge method was decided to be at constant current as seen displayed with red in the graph.

The average current the circuitry was pulling was 89.306 mA. There are 2 batteries being used with each having a capacity of 982 mAh each obtained by the battery discharge test, giving a total of 1964 mAh. By dividing the total mAh by the current readings we obtain the hours the circuitry can operate. The total average time of operation with the batteries being used for this circuitry is 21.97 hours

14. APPENDIX

Figure 31: Displays the set-up of this test where the battery's output wires are connected by the corresponding positive and negative probes of the PCBA 5010-4 Battery Analyzer.



Verification Test Report 6	
Project Description: Music Vibration Device	**REVISION NO.:**

Team: Bianca Castello, Jacob Bharat, Maria Chiang, Mario Civil, Yency Perez	
TITLE: *Biocompatibility Test Protocol, Vibration Device and Device Carrier, Ensuring the device and the device carrier are biocompatible.*	

1. PURPOSE

The purpose of this protocol is to test the materials used for the device and the device carrier to ensure it will not cause irritation to skin when used for the duration of treatment.

2. SCOPE

The scope of this test is to determine the biocompatibility of the materials using research that has already been tested and proven.

3. REFERENCE DOCUMENTS

ISO 10993-10:2010 describes the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce irritation and skin sensitization.

ISO 10993-10:2010 includes:

pretest considerations for irritation, including in silico and in vitro methods for dermal exposure;

details of in vivo (irritation and sensitization) test procedures;

key factors for the interpretation of the results.

Instructions are given for the preparation of materials specifically in relation to the above tests and several special irritation tests are described for application of medical devices in areas other than skin.

Biocompatibility

The agency has existing guidance on devices that have contact with the human body, which *will remain in effect until the draft document is finalized.*

The draft guidance applies to medical devices that contact intact skin surfaces only; have limited (24 hours or less), prolonged (24 hours to 30 days), and long-term (more than 30 days) contact durations, including repeat uses; and are composed of certain types of materials.

The materials include several synthetic polymers and a small number of fabrics.

The synthetic polymers include:

Polyethylene terephthalate (PET)

Polymethylmethacrylate (PMMA)

Polyoxymethylene (POM)

Polyphenylsulfone (PPSU)

Polypropylene (PP)

Polylactic acid (PLA)

Silicone

The fabrics include:

Polyurethane fabrics, including Lycra

Cotton fabrics

Polyamide fabrics, including nylon

Silk fabrics

4. OVERVIEW/BACKGROUND

This protocol is to test and research the materials that can be used for the material of the device to minimize the hazard and possible irritation or adverse reaction to the patient. Biocompatibility testing is part of an overall risk management process to protect humans from potential biological risks stemming from the use of medical devices. The evaluation of biocompatibility testing data for a particular device is used as evidence in establishing the *device's biological safety.*

OBJECTIVES

The first objective is that the device carrier must be biocompatible..

5. TEST EQUIPMENT

No Testing equipment is required.

6. MATERIAL

The materials that will be used include cotton, silicone, and Polyethylene Terephthalate.

7. SETUP

There is no setup required for the biocompatible test protocol.

8. EXPECTED RESULTS/HYPOTHESIS

The expected result from this protocol is the device will be biocompatible for most patients for at least 24 hours.

9. PROCEDURE

1. *This includes using research, previous data and testing to determine the biocompatibility of available materials, then choosing the most suitable material for the device and device carrier*

10. ACCEPTABLE CRITERIA

The material should be considered biocompatible by research results.

11. RESULTS

1. *There were three main materials used for the device and the device carrier which are:*
    a. *Polylactic acid (PLA)*
    b. *Cotton Fabrics*
    c. *Spandex, which is a Polyurethane Fabric*
2. *This Verification Tests passes because these materials are two fabrics and a synthetic fabric that are classified as biocompatible materials.*

6c. Test Data and Data Evaluation

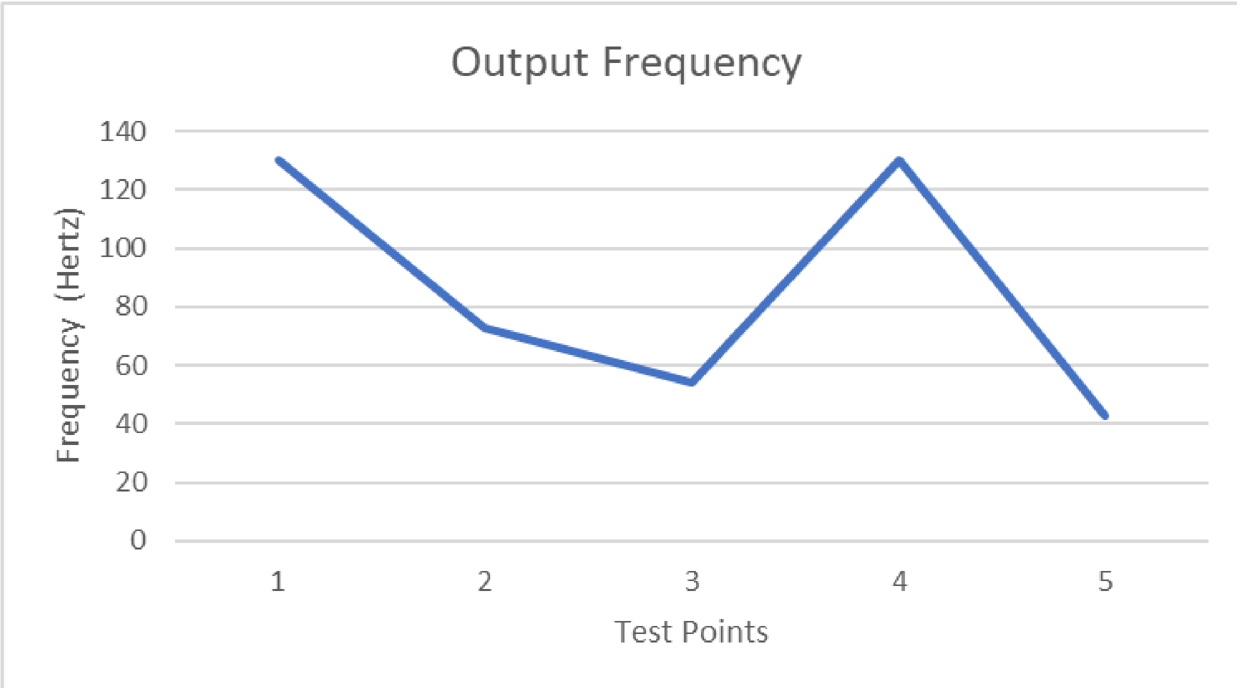
In order to develop our music vibration device we've applied many mathematical, physical and life sciences. We used our knowledge of statistics to evaluate the data collected through our verification testing of the discharged battery test. We conducted this verification test by using a multimeter, 5010-4 PCBA battery analyzer and proprietary software. A verification test of output of a frequency within the range 20-300 Hz was conducted with the use of the curve creating software which displayed the data acquisition over time. We used pathophysiology to determine the correct placement of the device, to maximize the effectiveness of the stimulation to the lower leg. Biology and neuroscience was used in research of the cause of parkinson's, understanding the mechanism that causes a decrease in dopamine and in turn a decline in motor function and freezing of gait. We used materials engineering and databases to determine the biocompatibility of the device carrier. The use of CAD software, specifically solidworks, helped to design the case with the correct dimension and perform simulations of the materials of our case (Shear Stress and Strain) through this software.

For our first verification, the dimensions and weight of the device case that contains the electrical components is within the boundary limits of 100 mm x 60. The device was measured to be 90 mm x 60 mm x 30 mm. Just reaching the border of our constraints therefore satisfying our market requirement of the device dimensions and weight. The average calculated length of the device is about 89 mm over 5 tests. The average calculated width of the device is about 58mm over 5 tests. The average calculated height of the device is 29mm over 5 tests. The average weight is about 87 grams over 5 tests. The average height range of the device carrier is 246mm to 312mm. Our acceptance criteria is the device should have dimensions of 90 mm x 60 mm x 30.15 mm and weight of less than 1 kg. The height of the stretched sock should be no less than 310 mm. Therefore, this verification test is met successfully as all the results fall within these constraints.

For our second verification, the stopwatch protocol will be used to determine the functionality of certain aspects of the device by measuring how long aspects of the device take. The average calculated time for a subject to interpret the lag time of the device music playing and vibration is 0.66 seconds or 66 milliseconds. Our acceptance criteria is the device should have latency no greater than 1 second so the delay is not noticeable. Therefore, this verification test is met successfully as all the results of lag time fall under 1 seconds.

For our third verification, the oscilloscope test protocol will be used to measure the vibrational frequency output from the vibration device. Thus, 5 tests were performed at random times throughout a song. The frequencies that were recorded are about: 130 Hz, 73 Hz, 54 Hz, 130 Hz, and 43 Hz. Our acceptance criteria is the device should have an output frequency in the range of ± 10% of 20-300Hz. Therefore, this verification test is met successfully as all the results of the frequency output were within a range of 20-300 Hz.

Figure 32: Graphed Output Frequencies



For our fourth verification, the ingress protection test protocol will be used to test if the device is resistant to moisture that it may come in contact with, such as small splashes, spills, or sweat. We determined an IPX4 rating should be met to ensure the electronics will be protected from these levels of water. A total of 6 tests were performed and the result for each was that there was no moisture detected on the paper towel. Our acceptance criteria is the device should be able to not allow any moisture inside the device. Therefore, this verification test is met successfully as there was no water detected anywhere on the paper towel during any of the tests.

For our fifth verification, the battery discharge and consumption test protocol will be to test if the battery is rechargeable and able to operate for an adequate number of sessions in one week on a single charge without any external attachments. We used a battery analyzing software called Imtec Battery Mark to set the charged current limit to 550 mAmp, charge voltage limit 4.2V, charge start voltage 2.75V, charge end rate C/22, discharge capacity limit 111%, target capacity 110% which helped us analyze and display the battery discharge represented by the blue line in the graph below.

Figure 33: Battery Discharge over time

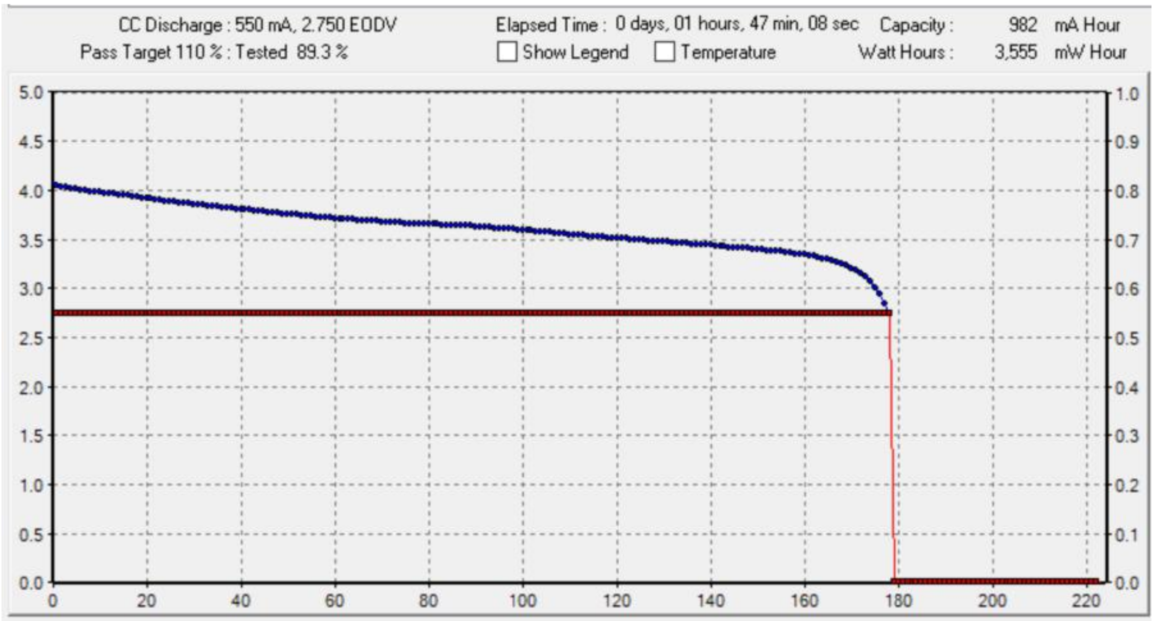
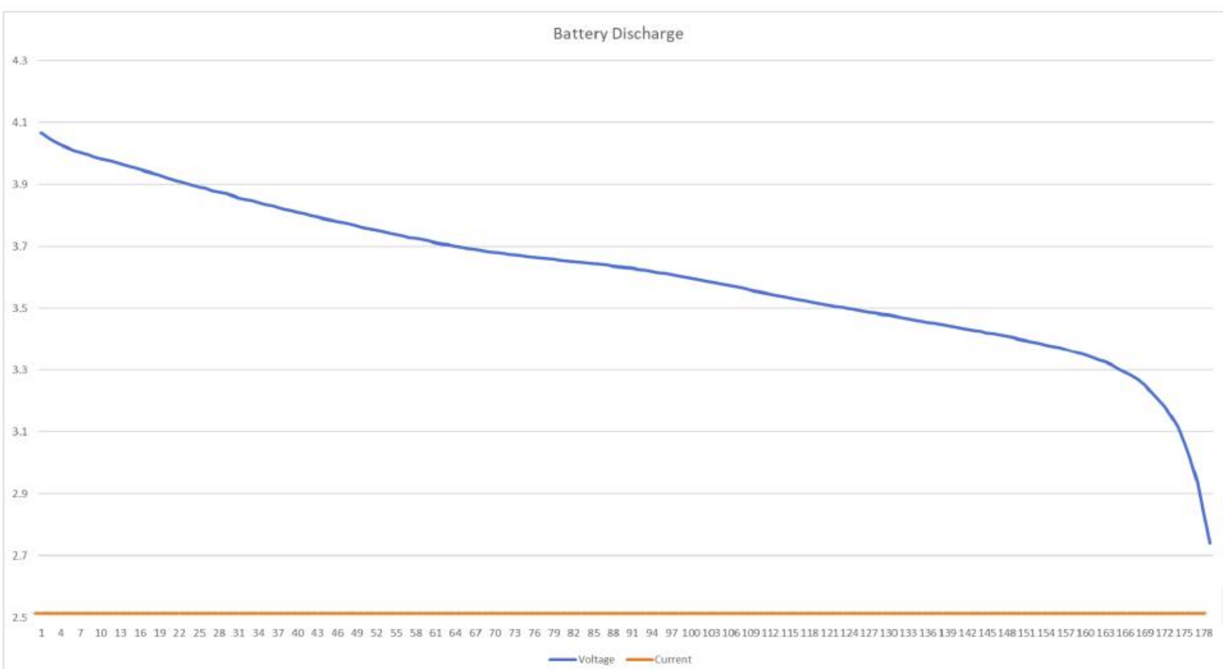


Figure 34: Battery Discharge over time



Battery Consumption Test

The average current the circuitry was pulling was 89.306 mA. There are 2 batteries being used with each having a capacity of 982 mAh each obtained by the battery discharge test, giving a total of 1964 mAh. By dividing the total mAh by the current readings we obtain the hours the circuitry can operate. The total average time of operation with the batteries being used for this circuitry is 21.97 hours. Our acceptance criteria is the battery should have a discharge time of no less than 1 hour and a calculated time of operation of at least 1hr. Therefore, this verification test is met successfully as the results of the battery consumption will take about 22 hours which highly exceed our 1 hour functionality requirement.

The sixth verification test was used to determine biocompatibility of the material of the device carrier to ensure there is no irritation to the patient's skin during the duration of the therapy session. We used the ISO 10993-10:2010 standard to research the pretested considerations for irritation of the material listed. The synthetic polymers include: Polyethylene terephthalate (PET), Polymethylmethacrylate (PMMA), Polyoxymethylene (POM), Polyphenylsulfone (PPSU), Polypropylene (PP), Polylactic acid (PLA), Silicone. The fabrics considered include: Polyurethane fabrics, including Lycra, Cotton fabrics, Polyamide fabrics, including nylon, Silk fabrics. For the procedure we researched the biocompatibilty of each material at limited (24 hours or less), prolonged (24 hours to 30 days), and long-term (more than 30 days) contact durations. Through this research and consideration we concluded that the three main materials that we will use for the device case and carrier are polylactic acid (PLA), cottom fabric and spandex. This verification test passes since the two fabrics and the synthetic fabric are all classified as biocompatible materials and would not cause irritation over an extended amount of time.

6d. Meeting Minutes

Team 6 Senior Team Meeting Minutes
Date: April 10, 2022

I. Call to Order
   A. Meeting Called to Order at: 08:00 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Absent
Jacob Bharat		Absent
Yency Perez	Minutes Taker	Present
Maria Chiang		Present
Mario Civil		Present

III. Approval of Last Meeting's Minutes
   A. Yency Motions, Maria Seconds

IV. Unfinished Business
   A. Finishing Prototype
      1. Connecting and creating the last version of the Circuit.
      2. Print and edit the final version of the case
      3. Soldering all the components
      4. Finalize one on vibration motor
      5. Idealize the circuit
      6. Connect Battery

V. New Business
   A. Verification Tests
      1. Measuring Tape: Ensure all required dimensions are met.
         a) Performed on 4/11/22
         b) Done Successfully
      2. Scale: Measure the weight of the electrical components and the device carrier ensuring less than 1 kg.
         a) Performed on 4/11/22
         b) Done Successfully
      3. Stopwatch: To measure the lag between the music playing and the vibrational rhythm to determine if the lag is within an appropriate and not noticeable range.
         a) Performed on 4/11/2022
         b) Done Successfully
      4. Oscilloscope: Measure the vibrational frequency output from the device.
         a) Performed on 4/11/22
         b) In Progress

5. The Ingress Protection Test: This test determines the exact levels that a device is able to withstand against moisture.
    a) Performed on 4/10/22
    b) Done Successfully
6. Battery Capacity Test: Accelerated cycle life testing of batteries is conducted as a means to assess whether a battery will meet its life cycle requirements.
    a) Performed on 4/11/2022
    b) In Progress
7. Biocompatibility Research: Use find materials that are already biocompatible. Find reference and evidence that supports biocompatibility.
    a) Performed on 4/10/22
    b) Passed Successfully as done by using the proper materials

VI. Due Dates/ Task
   A. How do we fill out the billing information for the poster?
   B. How do we fill out the Ferpa form?
      1. Can we get an example of how to fill each section or can we go over each section.

VII. Meeting Adjournment
   A. Meeting Adjourned at 3:27 a.m.

Team 6 Senior Team Meeting Minutes
Date: April 11, 2022

I. Call to Order
   A. Meeting Called to Order at: 05:45 p.m.

II. Roll Call

Name	Role	Attendance
Bianca Castello	Team Leader	Present
Jacob Bharat	Minutes Taker	Present
Yency Perez		Present
Maria Chiang		Present
Mario Civil		Present

III. Approval of Last Meeting's Minutes
    A. Yency Motions, Maria Seconds
IV. Unfinished Business
    A. Verification Tests
        1. Oscilloscope: Measure the vibrational frequency output from the device.
            a) Performed on 4/11/22
            b) Completed
        2. Battery Capacity Test: Accelerated cycle life testing of batteries is conducted as a means to assess whether a battery will meet its life cycle requirements.
            a) Performed on 4/11/2022
            b) Completed
V. New Business
    A. PaperWork
        1. Working on completing the DHF, DMR, Project Report, Poster, Abstract.
        2. Finalize and making last touchups
    B. Presentation
        1. Complete the powerpoints and poster
        2. Start recording
VI. Due Dates/ Task
    A. How do we fill out the billing information for the poster?
    B. How do we fill out the Ferpa form?
        1. Can we get an example of how to fill each section or can we go over each section.
VII. Meeting Adjournment
    A. Meeting Adjourned at 12:15 a.m.

FLORIDA INTERNATIONAL UNIVERSITY

BME 4908 SENIOR DESIGN PROJECT
Design Master Record

Design of VibroBeats

Submitted in partial fulfillment of the
requirements for the degree of

BACHELOR OF SCIENCE
in
BIOMEDICAL ENGINEERING

04/14/2022

Project Team 6
Bianca Castello
Jacob Bharat
Yency Perez
Maria Chiang
Mario Civil

Sponsored by: Ben Weinstock, Weinstock Physical Therapy, PC
Faculty Mentor: Dr. Zachary Danziger

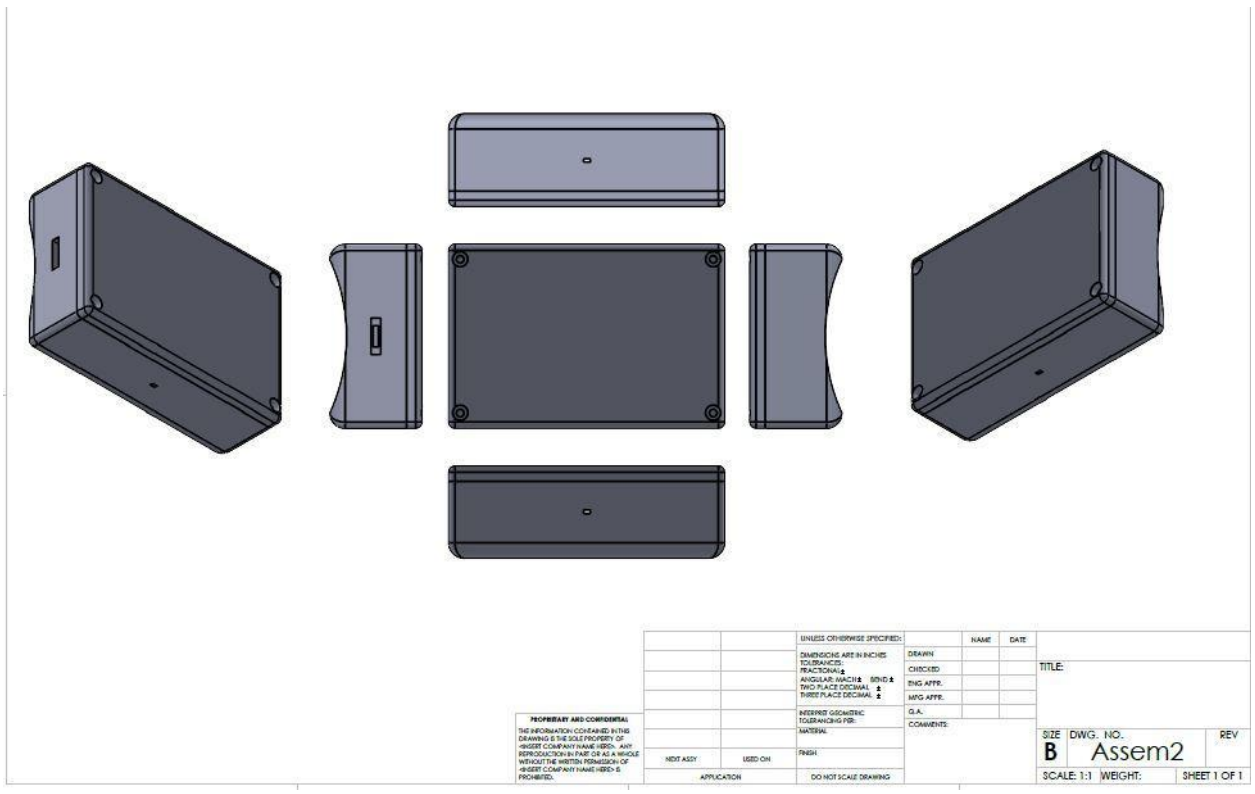
Table of Contents

Section 1: Design Specifications

1a. Engineering Drawings

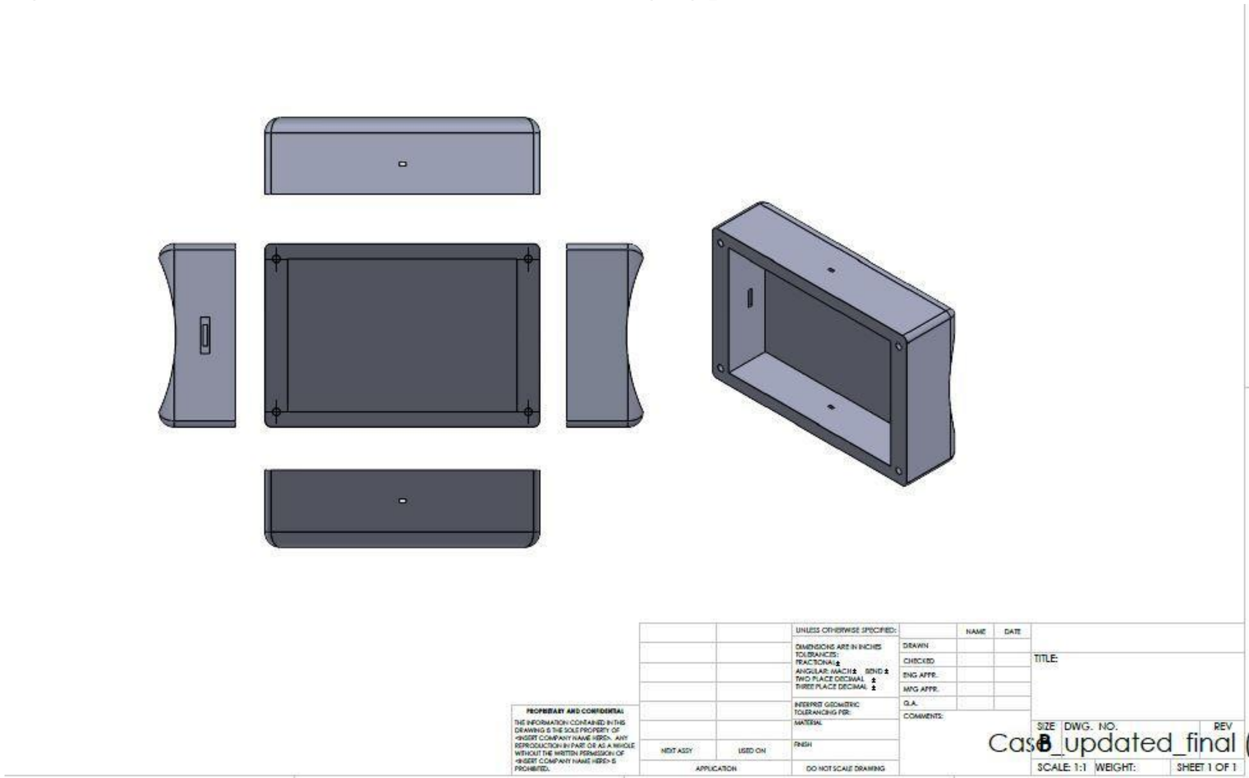
Electronics Case

Figure 1: The electronics components: the circuit board, chips, wires, vibration motors and rechargeable battery will be enclosed in the two-piece case. In addition, a charging port and a switch will extrude from the case for external access. Small screws will secure the cover and base of the device.



Base part:

Figure 2. The base of the case and microUSB charging port.



Cover:

Figure 3. The case top with 4 2.5mm holes for 3mm screws and extruded base to allow proper fixation.

Vibration Motor:

Figure 4: Side view of vibration motor with dimensions

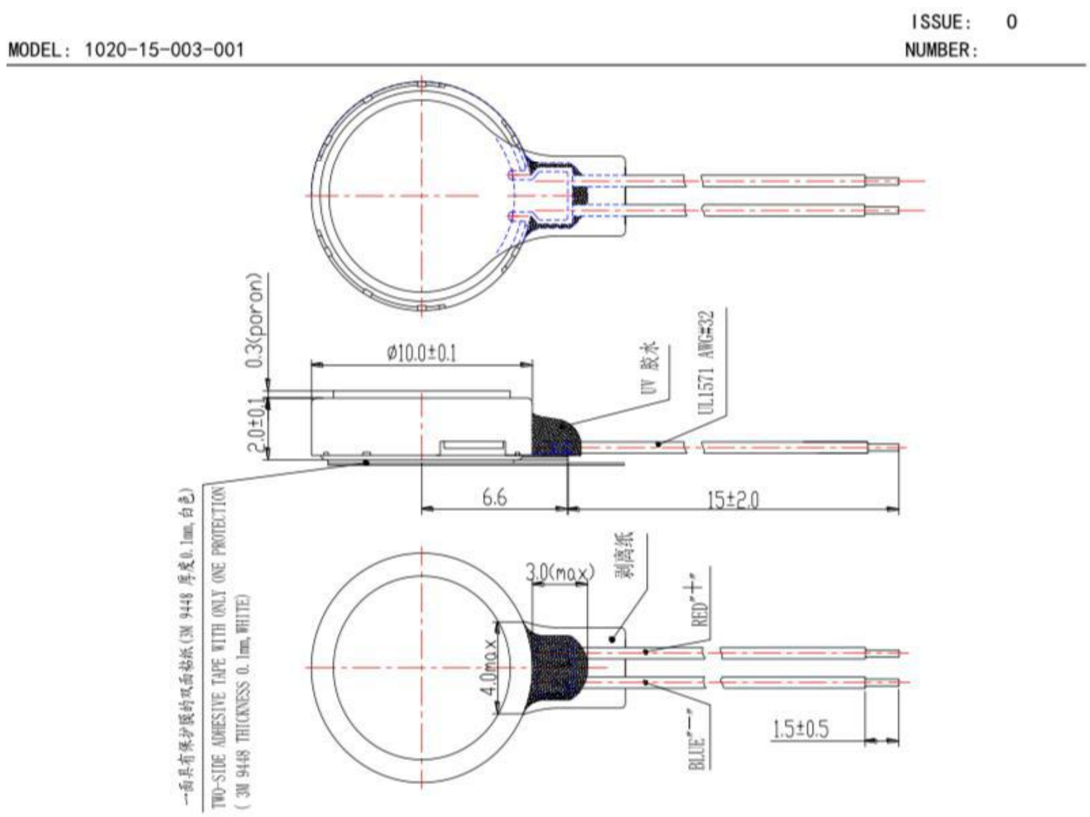
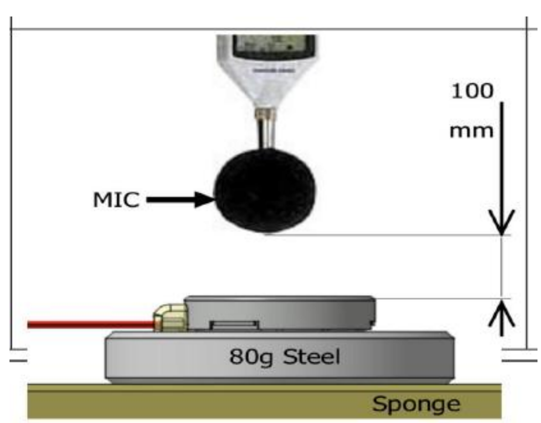
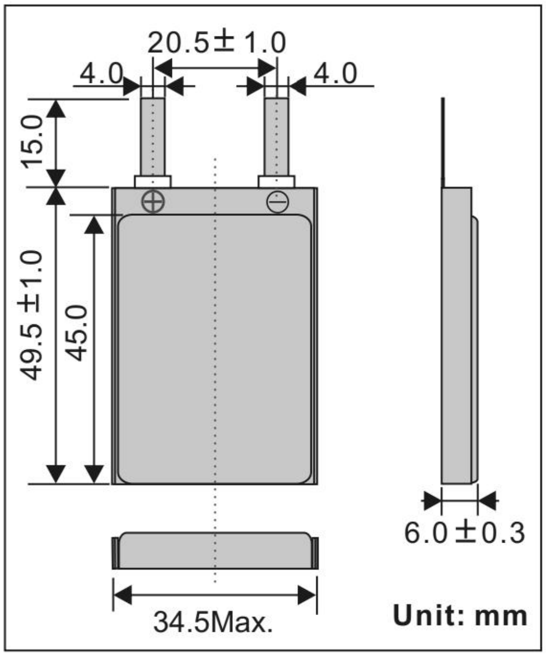


Figure 5: Vibration motor components including the sensor, accelerometer and sponge base



Li-Polymer Battery:

Figure 6: Diagram of measurements of the Li-Polymer battery



1b. Component Specifications

Table 1- TL494 Microcontroller Specifications

TL494 microcontroller	
Operating Voltage	7V
Input Voltage(Limit) (VCC)	40V
Collector output current	250 mA
Oscillator frequency	1KHz - 300 KHz
Timing capacitor	0.47 nF - 1000 nF
Timing Resistor	1.8 KΩ - 500 KΩ
Operating free-air temperature	0 C - 70 C
Width	6.35 mm

Length	19.3 mm
Weight	8 g - 10 g

TL494 Configuration

Figure 7: Schematic of the TL494 Chip

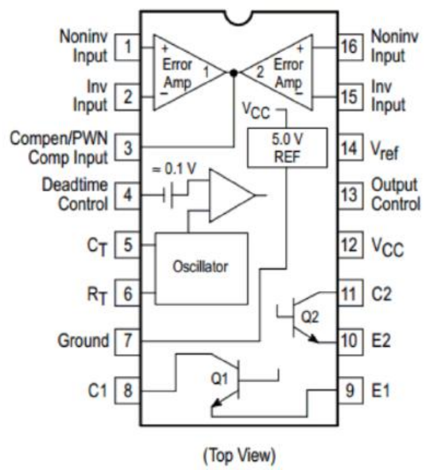
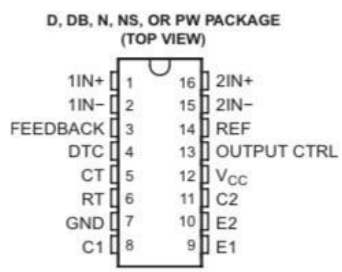


Figure 8: TL494 configuration specifications



Pin Functions

PIN		TYPE	DESCRIPTION
NAME	NO.		
1IN+	1	I	Noninverting input to error amplifier 1
1IN-	2	I	Inverting input to error amplifier 1
2IN+	16	I	Noninverting input to error amplifier 2
2IN-	15	I	Inverting input to error amplifier 2
C1	8	O	Collector terminal of BJT output 1
C2	11	O	Collector terminal of BJT output 2
CT	5	—	Capacitor terminal used to set oscillator frequency
DTC	4	I	Dead-time control comparator input
E1	9	O	Emitter terminal of BJT output 1
E2	10	O	Emitter terminal of BJT output 2
FEEDBACK	3	I	Input pin for feedback
GND	7	—	Ground
OUTPUT CTRL	13	I	Selects single-ended/parallel output or push-pull operation
REF	14	O	5-V reference regulator output
RT	6	—	Resistor terminal used to set oscillator frequency
V_{CC}	12	—	Positive Supply

Table 2. Material Specifications for the Vibration Motor

DC Vibration Motor Model : 1020-15-003-001

Operating Voltage	DC 2.5 - 3.5 V
Rated current	80 mA or less
Operational frequency	200Hz - 235 Hz
Motor construction	10-mm flat coreless
Acceleration	1.3 - 1.8 G
Allowable Temperature change	20 C - 70 C
Insulation resistance	10MΩ(Min)
Weight	0.9 g
Terminal resistance	75Ω max
Mechanical noise	50dB-A (Max)
Rated speed	10 000 rpm

Table 3. Material Specifications for the Battery

LP 603449 3.7v 1100 mAh battery

Nominal Capacity & Voltage	1100 mAh, 3.7 V
Standard Charge Method	CC/CV (CV end current 22mA)
Standard Charge current	0.2C (220mA)
Charge Max Voltage	4.200±0.020V

Standard Discharge Current	of 0.2C (220mA)
Cut-off Voltage	2.750±0.005 V
Maximum Charge Current	1C (1100mA)
Maximum Discharge Current	2C (2200 mA)
Charge Temperature	0 ~ 45 ℃/Discharge Temperature: -20 ~ +60 ℃/Storage Temperature: -20 ~ +25 ℃
Size	34.5 x 51 x 6.3mm (WxLxH)
Weight	22g

Table 4. Materials Specifications for the Device Carrier

Fabric Device Holder (Sock)	
Composition	76% Cotton, 21% Polyester, 3% Spandex
Size	Women's shoe size 7-13 and mens shoe size 6-13
Pocket width	80mm/3.3 inches across
Pocket height	110mm/4.4 inches high
Zipper	ruggedized
Manufacturer	Flippysox

1c. Material Specifications

Table 5. Material Specification for PLA

Polylactic Acid Filament (PLA)	
Composition	Polylactic Acid (PLA)
Net Weight	1 kg or 2.2 lbs
Diameter	+/- 0.05 mm

Roundness	+/- 0.07mm
Print Temperature	190-225 degrees c
Density	1.24 g/cm^3
Tensile Strength	50 MPa
Flexural Strength	80 MPa
Impact Strength(untouched) IZOD	96.1J/m

Table 6. Material Specification for Cotton

Cotton	
Strength	28-30 grams force per tex(GPT)
Fiber Diameter(Micronaire)	2.0-7.0
Elastic Recovery at 2% Extension	74%
Breaking Elongation (dry)	3-9.5
Tensile Strength (g per tex/g per denier) a. Dry b. Wet	a. 27- 44 / 3.0 - 4.9 b. 28 - 57 / 3.3 - 6.4
Water absorbing Capacity	>24 grams of water per gram of fabric
Density (g/cm3)	1.54
Degree of Polymerization	9,000-15,000
Thermal Resistance	Dry heat above 300 degrees F will cause gradual decomposition

Table 7. Material Specification for Polyester

Polyester	
Strength a. Dry b. Wet	a. 27-54 b. 27-54

Density	0.601-2.20 g/cc
Viscosity	110-180000 cP
Tensile Strength	10.0-123 MPa
Modulus of Elasticity	1.00-10.6 GPa
Flexural Yield Strength	53.8-256 MPa
Compressive Yield Strength	71.0-214 MPa
Electrical Resistivity	1.00e+12 - 1.00e+14 ohm-cm

1d. Component Schematic:

This device incorporates all the functions required in the construction of a pulse-width-modulation (PWM) control circuit on a single chip. Designed primarily for power-supply control, this device offers the flexibility to tailor the power-supply control circuitry to a specific application. The TL494 chip contains two error amplifiers, an on-chip adjustable oscillator, a dead-time control (DTC) comparator, a pulse-steering control flip-flop, a 5V, 5% precision regulator, and output-control. The oscillation provides a positive sawtooth waveform to the dead-time and PWM comparators for comparison to the various control signals. The frequency of the oscillator is programmed by selecting timing components R_T and C_T (resistor and capacitor). This chip sends out two out-of-phase signals creating DC from the AC music signal, acting as a comparator or operational amplifier.
The frequency of the oscillator becomes:

$f_{OSC} = 1/R_T \times C_T$

For the push-pull application:

$f = ½(R_T \times C_T)$

Circuit Design

Headphones with bluetooth components integrated to each earbud were obtained to satisfy the market requirement of a wireless device, to which the same soldering work was performed and the smartphone was utilized as a signal provider to the headphones. This signal travels through a low pass filter which then gets amplified (LM358) so it can pass through a peak detector that helps clean out noise from the signal. The resulting sinusoidal wave then passes through a comparator which converts it into a DC wave that a vibration motor can understand to vibrate to the beat of the music. A B20K potentiometer was determined to be the perfect component to manually establish the frequency range the device outputs and the function for this was decided to be a voltage divider. A second potentiometer was utilized, B20K, with the purpose of obtaining a variable resistance with a range of 0K Ohm to 20K Ohm. This allows the circuitry to control the DTC (dead-time control) or PWM duty-cycle. Diodes were added as flyback diodes to loop the current back to the motor, since the current would resonate otherwise and would not allow the motor to turn off when the music signal is off. The capacitor used was a 300Hz low pass filter that allowed only the bass of the signal to be input for the motor, acting as an imaginary impedance. The vibration motor was soldered to jump wires to improve board connections. After testing the vibration with the music signal, we were able to synchronize them without delay with a maximum frequency range of 0-300Hz, which concors with the low-frequency vibration therapy as indicated in literature. The music rhythm was able to be transmitted into the vibration, as well as, heard by the user using the other earbud.

While this design worked fine, the filtering of the peaks needed to be more precise. The executive decision of interveting the order of the chips used (TL494 and LM358) was made with the intention of using the latter mentioned as a peak detector, low-pass filter, and amplifier. The former chip mentioned was kept simply as the wave comparator. This fixed the precision of the filter and allowed the song "Eye of the Tiger" to vibrate accurately throughout the motor.

Figure 9: Schematic of the TL494 Chip

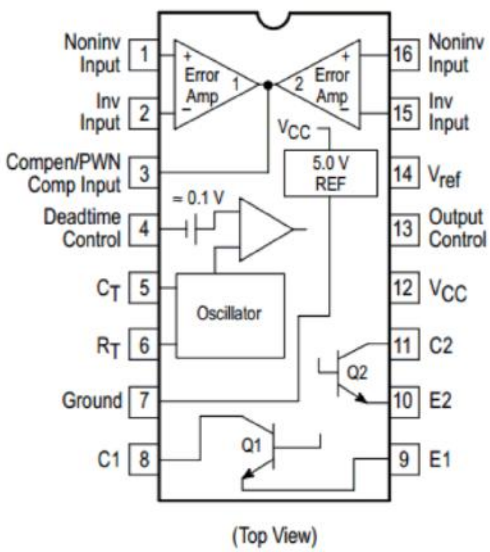
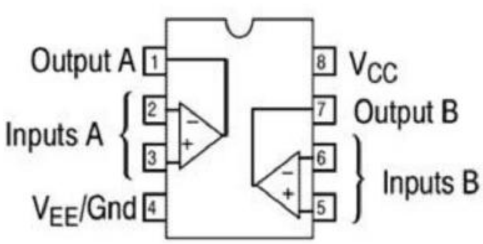


Figure 10: Schematic of the LM358



1e. Quality assurance

To ensure the device is able to effectively carry out its intended purpose, the following criteria must be met:

1. The device must be equal to or less than 100 mm x 60 mm or less in dimensions with a weight less than 1 kg.
    a. This ensures the device is able to fit in the device carrier properly and stay in place. Having the proper weight will allow normal range of motion for the patient.
    b. Results and accepted criteria can be found in the *"Measurement Test"* Protocol and verification report.
2. The device must pair to a phone through bluetooth and play music while vibration to the rhythm of the song with minimum latency
    a. This ensures the patient is able to hear and feel the music vibrations at the same time.
    b. Results and accepted criteria can be found in the *"Stopwatch Test Protocol"* Protocol and verification report
3. The device is able to deliver low frequency vibration in the range of 20-300 Hz.
    a. This ensures the device is able to accurately deliver vibrations at a frequency that is therapeutic to patients.
    b. Results and accepted criteria can be found in the "Oscilloscope Meter Test" Protocol and verification report.
4. The case is able to withstand a minimum of 50 liters of water sprayed at a pressure of 50-150 kPa continuously for 5 minutes in any direction
    a. This endures the device circuitry to be safe and not short circuit inside the case if subjected to sweat or accidental spills
    b. Results and accepted criteria can be found in the *"Ingress Protection Test"* Protocol and verification report.
5. The device must have a battery capacity to operate for at least 1 hour on a single charge.
    a. This ensures the device operates long enough to last for 5 sessions a day for 7 days, each session lasting about 90 seconds each.
    b. Results and accepted criteria can be found in the *"Battery Capacity Test"* Protocol and verification report.
6. The device must be made of biocompatible materials
    a. This ensures the device will be made of materials that have a low probability of producing a negative reaction on the skin
    b. Results and accepted criteria can be found in the *"Biocompatibility Research"* Protocol and verification report

Section 2 : Instructions

2a. Component Manufacturing

Instruction Manual:

This device is made for Parkinson's patients in Stage II-IV of the disease.

Precaution:

1. Note that this device is still in the development phase and must not be handled without proper supervision.

2. The device should not be worn in the shower or be submerged in water.

3. Ask a medical professional before use.

2b. Assembly and Disassembly

Instructions for Assembly:

Socks should be slid onto the foot with the pocket securely placed above the ankle. We recommend using a footstool or other assistive devices such as long-handled shoe horns to make putting on socks easier. The device should be removed from the charger and placed into the side pocket on the provided socks.

Instructions for Disassembly:

Turn off the device via the side button or smartphone application before removing it from the pocket. Remove the vibration device by pulling it vertically out of the pocket. The socks can be removed or worn for normal daily use.

2c. Operation and Maintenance

Instructions for Operation:

The vibration device must be used with the help of proper/certified medical staff or caregiver of the patient while in the preliminary state. The device will be charged prior to use and turned on before placing into a secured pocket located above the ankle of the patient. The device will be set to the lowest frequency and can be increased after the first session if the medical provider deems safe and beneficial. To increase frequency press the + button located on the top right side of the device before reinserting the device into the pocket. Increasing and decreasing the frequency can also be done while the device is in the pocket by pressing the + on the smartphone application linked to the device.

Device care:

The device holder ie. sock should be machine washed with cold water and dried at low temperature to prevent shrinking. The device should be stored at a safe temperature of 10-40 degrees celsius.

Instructions for Maintenance:

The electronics and case are meant for expert maintenance only, the components in the device are sensitive and can be damaged if not properly handled. The device should be checked for leaks if handled improperly or dropped. If submerged in water do not handle the device since the electrical components may cause harm.

Section 3 : Production

3a. Manufacturing and Construction

The case was manufactured by the team utilizing the Creality Ender 3 printer owned by one of the team members. The team first had to slice the design sketch in the Ultimaker Cura software to convert the design file from STL to a G-Code that the printer understands and prints. The material used was PLA (polylactic acid) which based on our project, PLA seems to work efficiently, it is affordable, and it offers an aesthetic end-product. It also has good part quality, strength, and stiffness. The top and cover of the case were printed using PLA in a process that took 12 hr 34 min to complete.

Maria Chiang was responsible for the further modifications done to both pieces, such as removing high points and deformities present in the material. The Aluminum Oxide 120J sanding paper was utilized to perfect the orifices on each side of the main body of the device to avoid significant friction when the device is placed inside the sock (device carrier).

The circuitry was assembled at the EPSi Laboratory Group of Dr. Arif Sarwat in the Electrical Engineering Department (Room 3920) where a system with a Peak Detector integrated along with a low pass filter and an amplifier on a LM358 chip, was designed to filter, amplify and detect low frequency (0-300 Hz) peaks using potentiometers and adjusting their calibration to acquire a clear and precise signal. The low frequencies are then transmitted to the second chip, TL 494, which captures the signal and acts as a comparator to convert the AC signal into the DC signal the vibration motor understands. There are 3 different potentiometers, the first one is a B20K and it acts as a variable resistor changing the ratio between two resistances (0K ohm - 20K ohm), allowing the discharge rate of the peak detector to be controlled. The second and third potentiometers are both B20K and act on the TL494. The first one as a variable resistor to change the Dead Time Control (DTC) comparator offset to 50%, shown to be the most successful and the second as a voltage divider to change the voltage reference by which affects the peaks felt by the motor. This allows for minimum delay between the music heard and the rhythm felt by the device. Many of the components needed were provided, an oscilloscope, a function generator, a DC Power supply machines were borrowed for testing and measuring critical values, such as frequency and voltage. A soldering iron, tin wire, a dremel, and a voltmeter were also utilized in the process of manufacturing. The team agreed to not split the music signal to the device and a speaker to save power. Wireless headphones were implemented because one of them was added to the circuit as a music signal transmitter and the other one left for the user to listen to the songs simultaneously.

3b. Equipment and Instruments Used

This case was 3D printed in the Ender 3 printer of one of the team members. We decided to utilize black PLA to reproduce the top and body of the case. The purpose of this double material approach was to determine the wire filament that would support stress the most in comparison with each other, this verification was obtained from a stress simulation on Solidworks to demonstrate that PLA was a better candidate for our purposes since the difference between was relatively minimal, but PLA is more affordable. Ultimaker Cura was the software employed to slice the drawing of the case and print it, a procedure that took 4 hours for the top and 7 hours for the body to be finished. Additional cleaning up was needed to eliminate extra filament residue from certain parts of the case, such as the strap opening, the interior of the main body, and all

smaller holes of the buttons and the LED feedback. Heat gun was used to melt the porous surface of the device for a better application of silicone to increase the water-resistance capabilities of the device once the circuitry is assembled.
Many of the instruments needed were provided, an oscilloscope to observe the behavior of the waveforms produced by the filtering and music signal (comparator), a function generator used for behavior verification, and a DC Power Supply machine was borrowed for testing voltage without connecting a battery. A soldering iron and tin wire were used for soldering and better all connections, a dremel was used for exposing wires and cutting the punch board to fit the casing, and a voltmeter were also utilized in the process of manufacturing to verify voltages and amperes going through the circuitry at all points. The team agreed to not split the music signal to the device and a speaker to save power. Wireless headphones were implemented because one of them was added to the circuit as a music signal transmitter and the other one left for the user to listen to the songs simultaneously.

3c. Bill of Lading

Table 8. Bill of Lading & Product Cost

Materials, Devices, and Components Purchased			
Materials/ Components	**Quantity**	**Cost**	**Total**
Coin Vibration Motor	5 units	$3.21	$16.05
Lithium Battery	1 unit	$13.00	$13.00
MT3608 DC booster module	2 units	$4.80	$9.60
TP4056 Charging port	1 unit	$1.25	$1.25
LM358 chip	1 unit	$0.50	$0.50
Fabric Device Holder	1 unit	$16.00	$16.00
PLA Filament	1 spool	$23.00	$23.00
Screw	4 units	$0.90	$3.60
TL494 chip	1 unit	$15.00	$15.00
E-Switch	1 unit	$1.15	$1.15
Misc. components (resistors, capacitors, ect.)	N/A	$5.00	$5.00
Total Material Cost			$104.15

Overhead	
40% Labor + 14% Materials cost =	$32.29

3d. Supplier Documentation

The following is documentation denoting the purchase of certain materials from our Bill of Lading, further materials shall be purchased upon finalized concept approval.

The DC vibration motor and the lithium battery were purchased from DigiKey manufacturing company and the initial prototype will be created using PLA and PETG for the top section of the case and the bottom main body of the case at FIU's Engineering Manufacturing Center. Future prototypes will be constructed utilizing the team's possession of a 3D printing, facilitating the production of the device's enclosure.

3e. Facility

The circuitry was completed at the EPSi Laboratory Group of Dr. Arif Sarwat in the Electrical Engineering Department. Their contact information:

Organization Name: Florida International University Electrical Engineering

Contact Name: Arif Sarwat

Phone Number: (305) 348 2935

Email address: asarwat@fiu.edu

Address: 10555 W. Flagler Street - Room 3920 Miami, FL 33174

3f. References:

PETG vs PLA filament: The differences. All3DP. (2021, August 13). Retrieved March 6, 2022, from https://all3dp.com/2/petg-vs-pla-3d-printing-filaments-compared/

PLA plastic / material – the ultimate guide. All3DP. (2021, October 28). Retrieved March 6, 2022, from https://all3dp.com/2/what-is-pla-plastic-material-properties/

The Online Materials Information Resource. MatWeb. (n.d.). Retrieved March 6, 2022, from http://www.matweb.com/search/datasheet.aspx?matguid=1d92ed366503454ba49b8a44099f90de&n=1&ckck=1