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To our professors:

External to the actual final report for the Brain Health Monitoring Kit, we felt it necessary to acknowledge the support and contributions of those that helped in making our project a success.

We would like to thank Dr. Leonard Trombetta (UH, Electrical Engineering) for his patience and ear whenever we encountered issues or snags in moving forward. Hopefully his life will be a little less hectic with our graduation, and he'll again enjoy students dropping by his office for what will hopefully just be small talk.

Additionally, we would like to commend Dr. Diana de la Rosa-Pohl (UH, Electrical Engineering) for ensuring we stayed on schedule and focused on the ultimate goal of completing the project on time. Hopefully our work as human test subjects in the entrepreneurship program has provided the necessary foundation to make the program an excellent addition to the Electrical Engineering senior design curriculum.

We would like to commend Dr. Hassam Panahi (UH, Red Labs) for his guiding wisdom and incomprehensible skills in somehow molding engineering students into something resembling entrepreneurs. Enjoy the patchouli and hammock-dwelling.

We'd like to thank Dr. Jose Contreras-Vidal for providing the spark that became the Brain Health Monitoring Kit, by suggesting that a seemingly inconsequential journal article on Parkinson's disease could be the foundation of a senior design project. One day we'll get to that human testing, maybe.

And finally, a special thanks goes to Dr. Chris Rorden (University of South Carolina, Neuropsychology Lab) for making himself available to assist with interfacing the TI ADS12xx chip family through both his published work and insightful email correspondence. His willingness to help struggling college students, sight unseen, cannot be lauded enough; nor would this project be where it is today without his knowledge.

Given one of the foundational aspects of the senior design curriculum is working within a team, we feel that this has been a very eye-opening lesson in team dynamics and interpersonal skills. However, we were able to advance our skills in interpersonal relationships, overcoming project hurdles, and completing objectives on schedule.

We're proud of the work we put forth and the project we were able to finish. Thank each of you for being instrumental in getting us through this process, and seeing our project become a reality.

Happy reading, this final report is only 38 pages long!



Bradley Bounds



Benjamin Madison

Brain Health Monitoring Kit

Bradley Bounds and Benjamin Madison

TABLE OF CONTENTS

Introduction.....	1
Problem.....	1
Need.....	2
Goal.....	2
Deliverables	3
Significance.....	3
Market Research	4
Market Segmentation	4
Medicine	4
Military.....	4
Gaming.....	4
Mind-body Enthusiasts	7
Education	7
Beachhead Market (BHM).....	7
Why Parkinson’s Disease?.....	7
Why not another BHM?	8
Total Addressable Market (TAM)	9
End User Profile.....	10
Full Life Cycle Use Case	10
High-Level Product Specification.....	11
Quantified Value Proposition	12
Business Model.....	13
Pricing Framework.....	14
Minimum Viable Business Product	14
Edibility	15
Methods	15
Design Overview	15
Overview Diagram.....	16
Equipment.....	17
Data Collection	19
Sensor.....	19
Smartphone	19
Server.....	19
Data Analysis.....	19
Sensor.....	19

Smartphone	20
Server.....	20
Results.....	22
EEG Sensor.....	22
Phone Application.....	26
Conclusion	29
Appendix A – Product Brochure.....	30
Appendix B – Summary of Research.....	32
Appendix C - References	39

TABLE OF FIGURES

Figure 1 – Levodopa (L-Dopa) concentration within a patient’s body over time. [2].....	2
Figure 2 – Matrix model of market segmentation analysis.....	6
Figure 3– Full Life Cycle Use Case for the BHMK	11
Figure 4– High-level product specification of the BHMK.	12
Figure 5– Quantified Value Proposition for the BHMK.....	13
Figure 6 - Overview Diagram for the Brain Health Monitoring Kit.....	17
Figure 7 – Python implemented Butterworth filters showing order 4 through 7.	21
Figure 8 – Fourier Fast transform after processing.....	22
Figure 9 – TGAM II High Alpha and High Beta wave recordings over time.....	23
Figure 10 - 8-channel output from the TI proprietary software.	24
Figure 11 – Square wave testing data received at the PC.	24
Figure 12 – Sensor data received at the phone and converted to float values.....	25
Figure 13 – Conductive fabric dry electrode prototype.	26
Figure 14 – Testing of the CFE showing excellent results.	26
Figure 15 – Live EEG sensor testing signal.....	27
Figure 16 – Final version of live graphing screen on smartphone application	28
Figure 17 – Processed bar graph data displayed on the phone application.....	28
Figure 18 – Sample brochure for the BHMK, designed to attract new users	30
Figure 19 – A sample L-dopa absorption model as shown in [2].	33

Brain Health Monitoring Kit

Bradley Bounds, Applied Electromagnetics

Ben Madison, Computer Option

INTRODUCTION

Problem

The current Parkinson's Disease (PD) treatment methods of prescribing and following uniform medication dosages are inefficient and potentially unhealthy. Dosages are prescribed by physicians based on limited interaction with, and feedback from their patients. Inaccurate dosages may not provide the full benefit of the drugs and have the potential for dangerous side effects. Even an accurately prescribed regimen does not account for an individual patient's varying daily activities and metabolic rates that can affect the efficacy of each dose.

The purpose of the Brain Health Monitoring Kit (BHMK) is to increase the quality of life for those suffering from Parkinson's disease (PD). Current treatment methods are subjectively based on limited doctor interaction, which can lead to over- or under-prescribing medication. These inaccuracies can introduce medicinal-induced side-effects and/or an increase in PD symptoms.

According to recent research, Levodopa (L-dopa) is the most commonly prescribed medication for PD. [1] [2] L-dopa is a dopaminergic replacement therapy (DRT) used to correct brain chemistry that has been adversely affected by PD. Experiments have generally shown improvement in PD patients on L-dopa, both in movement-based [3] and EEG-based [4] testing.

There are associated side-effects with continued L-dopa use. The main two are Levodopa Induced Dyskinesia (LID) and early wear-off (EWO). LID is characterized by additional motor difficulties and involuntary movements. EWO shortens the time that a L-dopa load is effective in treating the symptoms of PD. Since LID occurs at peak concentrations of the drug, it is often countered by reducing individual doses and increasing the frequency of medicine intake. [2] Conversely, EWO can be limited by increasing either the number of daily dosages or the quantity of each dose. [2] An example of these level fluctuations can be seen in Figure 1. The severity of the LID can be seen to correlate with the concentration of L-dopa interacting with the brain. Similarly, as the concentration drops, the EWO symptoms begin to appear just before the next dose is taken. With prolonged treatment, the time scale between these issues will compress. Altering dosage amounts will affect the peak level concentration. It has been shown that new patients may have a 6 to 8-hour window of improved behavior while more advanced patients may only

have a 0.5-2 hour window before faster and less-predictable wear off periods occur. [5] [6] [7] Each patient's absorption model varies depending on body chemistries and also with the length of time that the patient has been taking L-dopa. Furthermore, an individual patient's model can change daily in response to exercise levels, high protein meals and general health.

Need

Patients and doctors require constant data to ensure medication dosages and timing are properly individualized. This data will provide doctors with a timeline of dosage information, environmental factors (diet, exercise, sleep), bodily reactions to the dosage levels, and help determine a dosage plan for the individual patient. In order to provide this information, a telemedicine device is needed that will collect continuous EEG data, relate this to the concentration of drugs in the patient's brain, and allow doctors to recommend treatments based on the collected information.

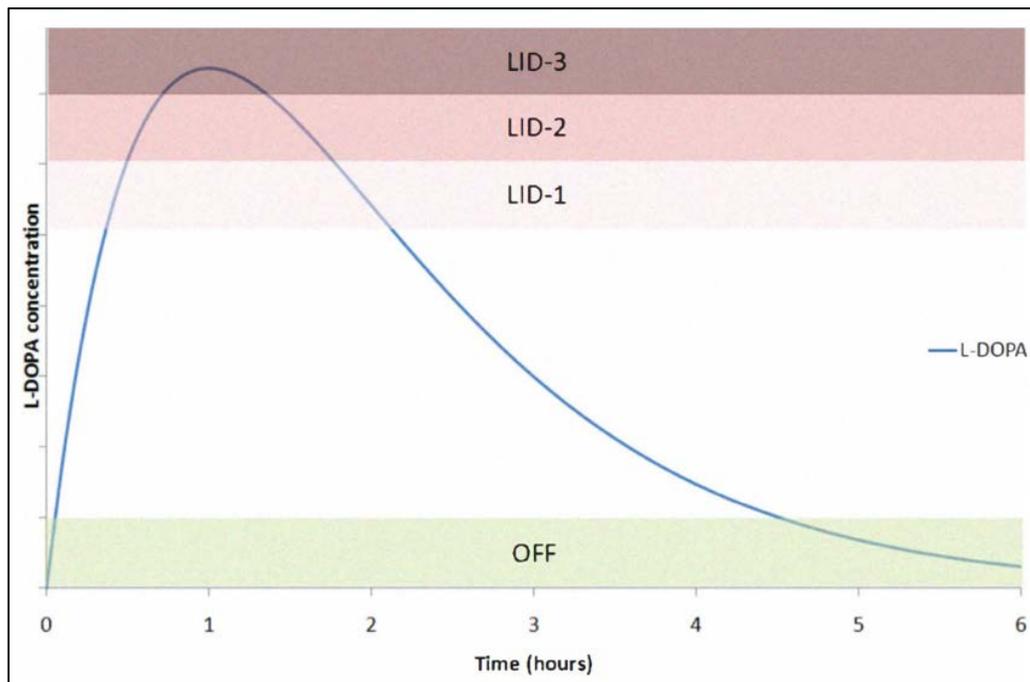


Figure 1 – Levodopa (L-Dopa) concentration within a patient's body over time. L-Dopa is metabolized within the body into catecholamine (e.g. dopamine, epinephrine). High levels of L-dopa in the system can result in L-dopa induced dyskinesia (LID), resulting in additional physical tremors beyond normal Parkinson's disease symptoms. As the medication continues to be metabolized, the concentration drops resulting in medication wear off (early wear-off), as shown in the green region at the bottom after 4.5 hours. [2]

Goal

The goal of the BHMK is to reduce the physical symptoms and additional side-effects caused by improper concentrations of L-dopa in users. The user will experience the BHMK through a discrete, wearable EEG sensor and an application on his/her smartphone. The EEG sensor will consist of a module

that rests behind the ear and a small electrode that will be held in place on the user's forehead by a circular bandage.

As long as a Bluetooth connection can be maintained, the user's brain activity can be monitored for triggers that imply oncoming side-effects (tremors, rigidity of movement). The patient's doctor can then review this data, and update their medication schedules. These notifications will then be sent to the user, with the goal of adjusting medicine intake schedules to reduce the magnitude of symptoms.

Assuming accuracy and comfort of the BHMK, neurologists who currently rely on limited and subjective data when prescribing DRT medication to their patients will appreciate this objective look on how the disease interacts with the medication. The development costs have remained under \$1,500 and production costs should remain under \$300. The cost to the end user is irrelevant given the device is to be covered by insurance companies. There are many medical devices that assist in disease management on the market that are covered by insurance/Medicare given the increased quality of life for the user, and their benefits in the context of managed disease care.

Deliverables

The final deliverable will consist of a prototype EEG sensor, smartphone application and local server for processing. The intention is for the production sensor to have a manageable form factor that will not intrude on the user's daily life, similar to a Bluetooth device used for phone calls, with the addition of an external wire and electrode, as described above. However, the project focused on proof of concept and used development components in achieving the desired functionality. The smartphone application allows the patient to manage the sensor connection and provide live and processed signal information. The server application exists on a Python server, receives raw patient EEG data and calculates the changing power levels of the user's brain activity. These changing power levels indicate L-dopa concentration levels, and specific symptoms (e.g. arm tremors, motor rigidity).

Significance

The more information that is made available to doctors, the more likely it is that an optimal medication schedule can be prescribed. This will greatly enhance the lives of PD patients by reducing symptoms and extending the time DRT can be effectively used before the negative side-effects that are introduced with continued use appear.

MARKET RESEARCH

Market Segmentation

The BHMK has the ability to collect and process individual EEG signals in a comfortable and non-invasive manner. This technology has the potential to be a player in several markets, each with a unique need and implementation. A brief summary of the top five potential markets and an accompanying matrix can be seen in Figure 2 below.

Medicine

The medical community has several potential applications for the BHMK, including PD, multiple sclerosis, ADD/ADHD, anxiety, dementia and depression. As cited above, there is sufficient research supporting that EEG signals can be used as an indicator of PD symptoms; however, for any additional disorders to be treated with the BHMK, research would need to be completed to validate the correlation of EEG activity and symptoms, determine ideal electrode placement, and adjust processing algorithms for each identified health condition. The product would need to achieve FDA approval as a medical device, and meet requirements for coverage under private and government insurance. Additionally, doctors will need to believe in the benefits and reliability of the system, in order to feel comfortable recommending it to their patients (the use of research outcomes and human testing results would be beneficial in this aspect). Currently, there are a large number of private insurers that could approve and recommend the product; however, there are also a large number of potential competitors.

Military

Soldiers in combat could potentially benefit from continuous EEG monitoring, either through providing more information to the commanding officers during combat in real-time or by monitoring the soldiers for symptoms of post-traumatic stress disorder (PTSD). It is acknowledged by the team that further research into the correlation of PTSD and EEG signal indicators would need to be conducted. The military has a large budget, but the barriers to entry in this market are extremely high. Despite this hurdle, the military is consistently on the cutting edge of new technology in the battlefield and is concerned for the well-being of soldiers, even when they are not directly engaged in combat.

Gaming

Another segment of the population that is often interested in new technology is the gaming community. There are already low-quality, inexpensive implementations of EEG monitoring that are being integrated into video games. Although the price of the BHMK may price itself out of the market, integration into virtual reality and the latest gaming trends could entice some individuals with disposable income. Where the current EEG gaming products have displayed weaknesses is in the quality of the

signal, which should not be an issue with the BHMK and its specialized integrated circuit developed specifically