Title:

Developing an Affordable and Customizable Functional Electrical Stimulation (FES) Device for Parkinson's Tremors

An explanation of procedures and processes for product development and manufacturing

Name:
Sydney Hodge

Team Number:
6627X
Santa Ana, CA

Date:
1/29/2025

Table of Contents

1. Background Information	**3**
2. Training Program Mission Statement	**4**
3. Current Solutions	**4**
4. Our Product	**5**
5. Identifying Required Technician Competencies	**7**
6. Employee Training Process	**8**
7. Employee Recruitment Process	**12**
8. Cost-Savings Outlook	**13**
9. Conclusion	**15**

1. *Background Information*

380 million people suffer from parkinson's disease globally[1]. The struggle for these millions of people is felt personally to 6627X since one of our team member's grandmother, Joan, suffers from the disease. Although there are many methods of mitigating the symptoms of Parkinson's, these solutions are not only expensive, but often ineffective and inaccessible to older patients with heart disease. Recently, strides have been made to move away from invasive and outdated solutions, however technological solutions are still not being utilized to their greatest capabilities.

Solutions to parkinson's can be separated into three categories, surgical, pharmaceutical, and electrical. As displayed in *figure 1*, neurosurgical interventions, highly invasive deep brain surgery, and pharmacotherapy, medication linked to serious heart problems, are the only readily available solutions to treating parkinson's and essential tremors. While these solutions are relatively effective and widely available, they are not always viable options for patients like Joan, who also deal with heart disease.

Figure 1. Effectiveness and clinical availability of all major parkinson's and essential tremor treatments.

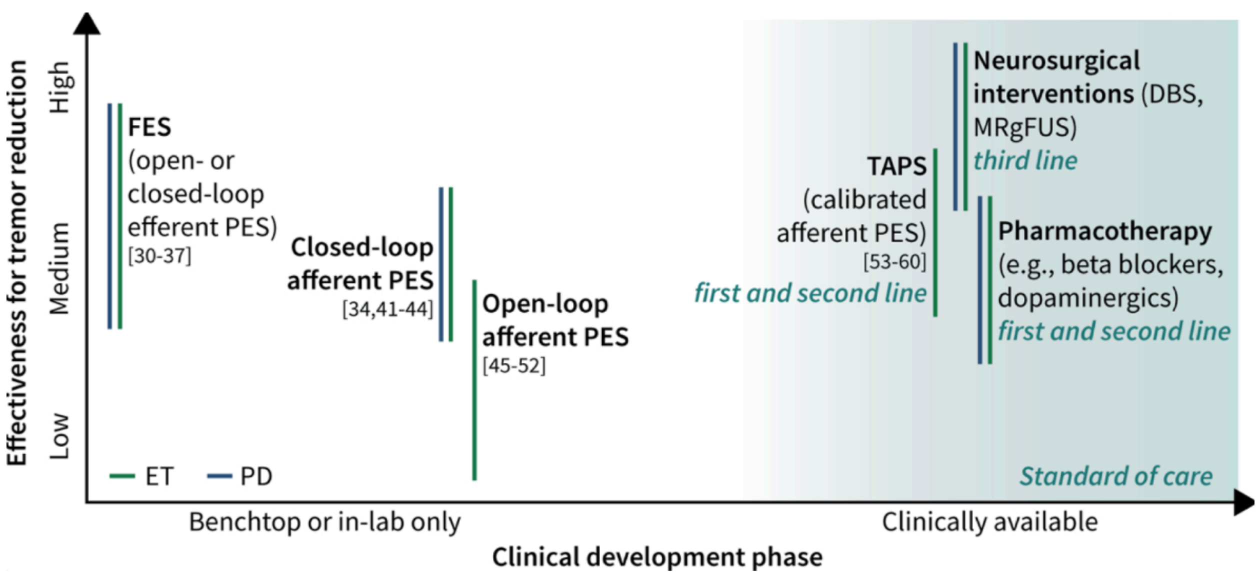


Figure 1 also displays the high effectiveness of functional electrical stimulation (FES), despite its lack of clinical availability. FES works by administering a device to a patient that is

[1] University of Michigan Health. "Essential Tremor." *Michigan Medicine*, University of Michigan Health, https://www.uofmhealth.org/conditions-treatments/brain-neurological-conditions/essential-tremor#:~:text=Essential%20tremor%2C%20also%20known%20as,tends%20to%20run%20in%20families. Accessed 28 Jan. 2025.

worn throughout the patient's daily life. The device outputs electrical pulses to the motor neurons that cause the patient's tremors. For instance, if the patient experiences ankle tremors, FES is most effective in neurons that directly control the movement of the ankle. The electrical pulses output by FES devices have shown a 70% reduction in tremors throughout extensive clinical research[2]. The only publicly available electrical option is currently peripheral electrical stimulation (PES) which offers afferent stimulation, meaning it stimulates the sensory neurons rather than motor neurons. While PES systems are less effective than FES systems, they are significantly easier to mass produce without customizing them to each patient, making them cheaper and more widely available. Overall, while effective methods of treating tremors do exist, non-invasive solutions are expensive and extremely difficult to customize for each patient.

2. Current Solutions

While non-invasive Parkinson's devices are not widely available, there are a few options currently on the market. The Gyroglove, for instance, is a device that aids in stabilizing a patient's hands. Despite its ability to be customized, however, the device costs nearly $6,000 and takes upwards of three months to ship[3].

After a thorough investigation of current US patents, we confirmed that there are currently no FES devices in development. A consultation with neurologist of over fifty years, Dr. Humberto Fernandez, revealed that the reason for the lack of development despite the wealth of research lies in the high cost of manufacturing "devices that must contain nearly entirely custom hardware and software to be effective." Through the development of this training program, our goal is to take advantage of new manufacturing technology to unlock the potential of FES research.

3. Training Program Mission Statement:

The mission of this program is to allow patients to be easily and affordably fitted for a standardized device. This will mitigate costs by allowing patients to pay for a consultation and existing device rather than the time and manpower required to purchase a fully customized treatment package.

---

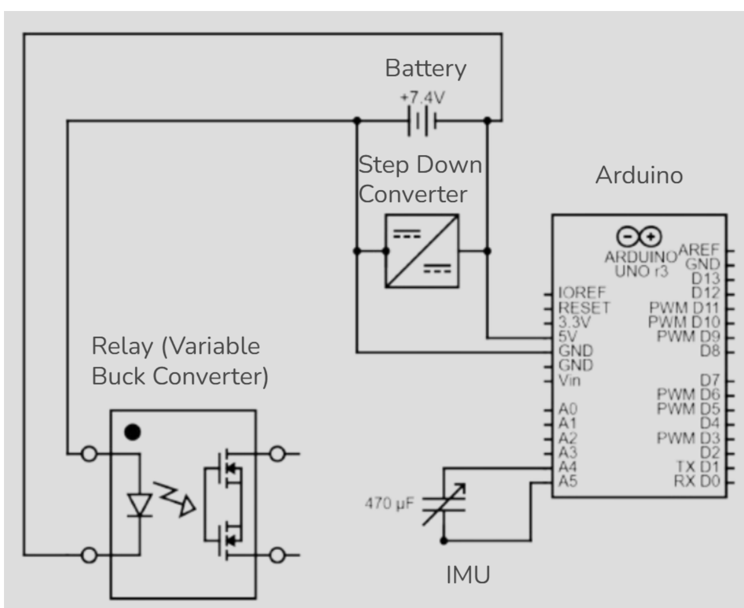
[2] Horowitz, Kristine S., et al. "Tremor: Current Concepts and Future Perspectives." *Biomedicine*, vol. 7, no. 3, 2025, doi:10.3390/biomed7030030.
[3] "Product Information." *GyroGear*, GyroGear Ltd., https://gyrogear.co/product/.

4. *Our Product*

Our product works by creating a manufacturing process that allows a closed-loop FES device to be easily customized to patients using a relatively simple and replicable process. Closed loop FES means that the device actively responds to the patient's tremor rather than outputting a predetermined frequency of electrical pulses. For instance, if the patient is experiencing a light tremor, a lighter electrical pulse will be outputted than what would be outputted for a large tremor. The components of our product include the electrical system, the sleeve, the cuff, and the software.

The electrical system is managed through the use of an Arduino Uno *(figure 2)*. The Arduino is powered by a seven volt lithium polymer battery, which is connected to a DC to DC buck converter in order to output a five volt charge to the Arduino. The battery is also directly connected to an electrode which outputs up to seven volts directly into the patient, a very safe and conservative voltage according to the medical professionals we consulted. The Arduino is also connected to an inertial sensor which collects a three dimensional force vector from the patient. This means if the patient is experiencing a tremor, the force vector reading will be analyzed by our software components in order to determine the appropriate current and voltage output to the patient. Finally, once our software determines the correct current and voltage outputs, the Arduino uses a relay to control both of these variables.

Figure 2. Electrical diagram of our product.



The sleeve and cuff are both used to align the electrode in the correct position. Since targeting the correct motor neuron is extremely important, a large portion of our focus in manufacturing this product lies in ensuring that the product properly fits the patient. The sleeve portion of the product both houses the electrical components of the device and ensures that the cuff does not slide (*figure 3)*. The cuff is a silicone wrap that houses the electrode which outputs voltage into the patient's motor neuron in order to disrupt tremors. The cuff is one of the most important components of the product to properly customize in order to achieve desired results.

Figure 3. Sleeve, cuff, and electrode properly fitted onto a patient's arm.

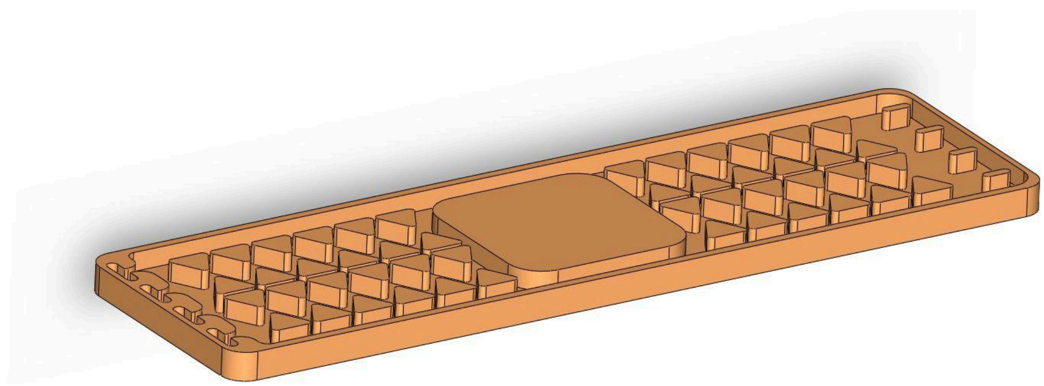
Finally, the software component of our product operates using a compressed machine learning algorithm. This means after collecting three thirty second trials of data, the machine learning algorithm will extract statistical features of a tremor versus normal movement. By simply running a python script and feeding data to our pre-coded machine learning algorithm, our device will both learn the patient's preference for maximum voltage outputs (depending on pain tolerance) and begin to differentiate between data outputted by normal movement and data outputted by tremors.

5. ***Identifying Required Technician Competencies***

With our automated system in place, device technicians will need to be trained in the following skills:

1. **Basic CAD:** Technicians will be provided with an existing "cuff" CAD that must be scaled up or down depending on measurements taken during a patient consultation. This CAD will be used to create a simple 3D printed mold for the silicone shown in *figure 4.*

Figure 4. Pre-designed cuff mold CAD that will require adjustments before technicians produce 3D printed mold.



2. **3D Printing:** After adjusting the cuff CAD, technicians will need to use a slicing software to prepare the CAD for 3D printing, print the cuff mold, and remove it from the printer (*figure 5)*.

Figure 5. Completed 3D printed mold that technicians will produce for each patient.

3. **Basic Python**: Although the code provided to technicians is designed to be user-friendly and for data collection purposes only, if the need for minor debugging arises technicians must be able to do so.

Thus, our technicians will be required to complete at least two of the following courses or similar courses (e.g. a technician finds a shorter course with the same skills) through RoboticsCareer.org before beginning their position:

1. **Advanced Manufacturing CAD:** The completion of this course certifies that technicians will be able to skillfully use CAD to alter cuff measurements to fit any patient. An advanced skill set in this area is preferred, but not necessary.
2. **Mechatronics Technology:** This course is designed to teach supply chain skills in five areas: computer programming, electrical systems, mechanical systems, robotics and additive manufacturing (3D printing). These skills encompass both programming and 3D printing skills needed for this position.
3. **Programming in Python CC:** This course is designed to teach students basic software development. The skills taught in this course are appropriate for students seeking entry level python occupations, an applicable skill level for this position.

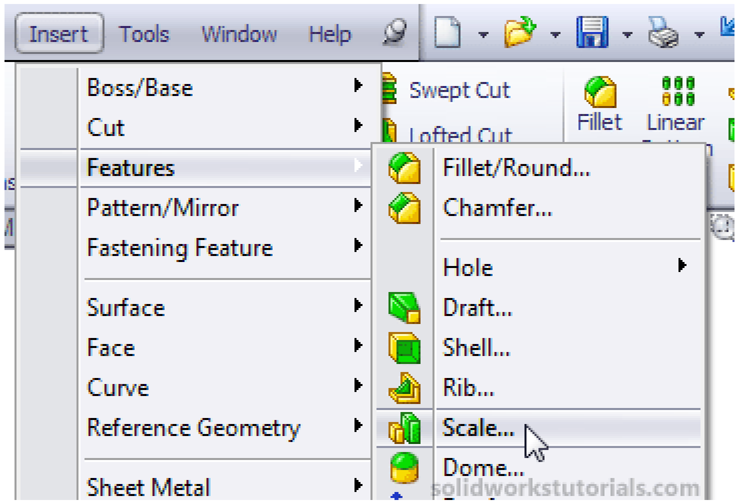
Assuming technicians complete all three courses they will begin their position with the following relevant competencies: system and process design, systems simulation/modeling, robot and system troubleshooting, electrical systems, maintenance and troubleshooting, safety (systems and procedures), electronics and controls, and computer programming. This is an exhaustive list of skills that any employer beyond our project would find extremely valuable.

6. Employee Training Process

In order to simplify processes for technicians, a clear procedure is outlined below, where technicians will apply the skills outlined in the courses above. This procedure is designed to be easily replicable for each patient. As a part of the training process, each employee must be able to replicate the following procedures:

1. The current cuff size is based on an upper forearm diameter of two inches. Begin by measuring the diameter of the patient's upper forearm using digital dial calipers. Record the diameter, then scale the forearm cuff by a factor of: the patient's upper forearm diameter divided (inches) divided by two inches (*Figure 5)*.

Figure 5. How to locate the scale tool in Solidworks.

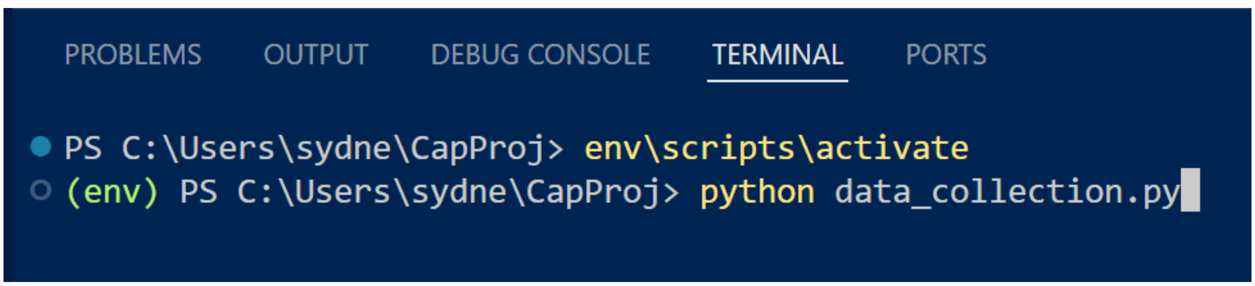


2. Save the Solidworks part file as an .stl file and open it in Cura Slicer. Lay the part flat, slice the file using default settings, then save it to an SD card and print the file.
3. While the cuff prints, assess the patient and select either a small, medium, or large cuff size. The fit of the sleeve does not need to be perfect as long as the patient is comfortable and the inertial sensor properly collects data when the patient moves. A sleeve that is too loose may move even when the patient doesn't.
4. To collect data open Visual Studio Code, and ensure the data collection code is opened. Next, use the terminal to activate the virtual environment so that the data collection script can run.

Figure 6. Type "env\scripts\activate" into the terminal and press enter in order to activate the virtual environment.

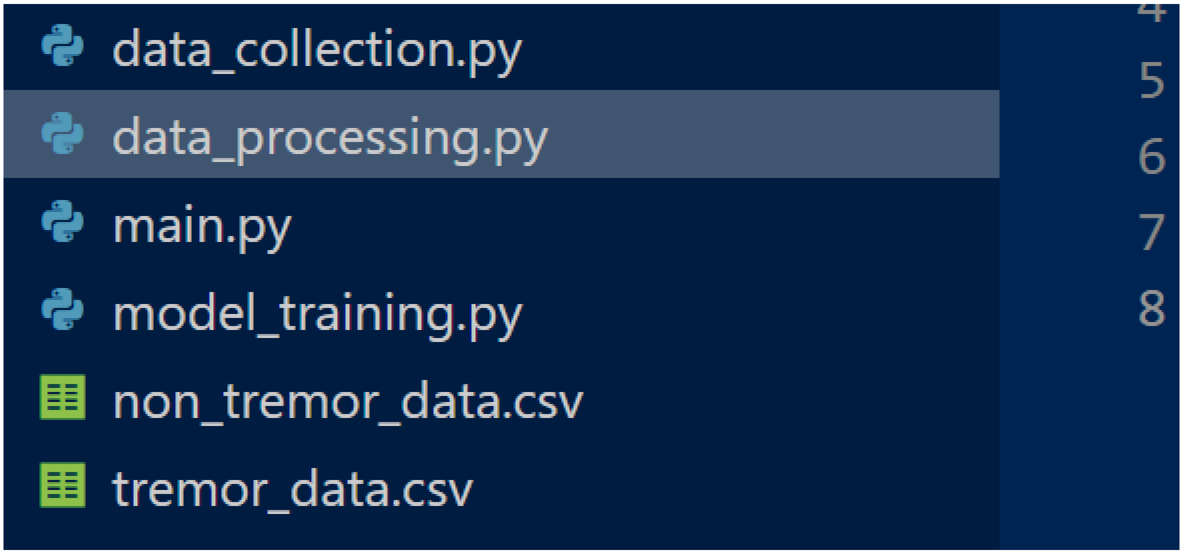
5. Next, once the patient is ready, evaluate whether the patient's current tremor state is more appropriate to conduct a non-tremor data collection or a tremor data collection. After evaluating, help the patient put on the sleeve and explain to them the test that will be taking place.
6. For a non-tremor test, instruct the patient to move normally for thirty seconds. This should include periods of no movement, periods of normal movement such as writing, stretching, or lifting objects, and any other normal maneuvers.
7. Before running the python script, ensure that the Arduino is plugged into the PC, then run the python script (*figure 7)*. Upon starting the script, start a thirty second timer, then at the end of the trial, type Ctrl+C into the terminal to end the trial. The data is time stamped so ensuring the trial ends exactly at thirty seconds is not necessary.

Figure 7. Type "python data_collection.py" into the terminal and click enter to start the script.



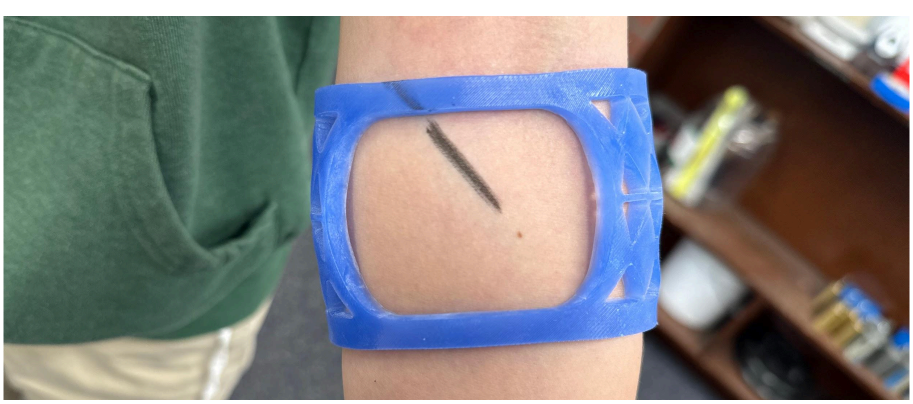
8. The data will automatically back up into an unnamed .csv file. Name the file non_tremor_1.csv. Enter files, then drag the newly created file into the folder that contains the code.
9. Repeat steps 6 through 8 two more times, naming the new files non_tremor_2.csv and non_tremor_3.csv.
10. Repeat step 7 an additional three times, but begin by ensuring that the patient is experiencing tremors as they normally do. Instruct the patient to hold their hands out in front of them (we use the term "like a zombie" for clarity) and run the script. If the patient is unable to hold their hands out in front of them for thirty seconds, allowing the patient to periodically rest their elbows on a table is acceptable.
11. Repeat steps 8 and 9 with each of the files, naming them tremor_1.csv, tremor_2.csv, etc. At this point, the files should all appear on the left of the screen (*figure 8)*.

Figure 8. Location where the .csv files should appear after running the data collection scripts.



12. Next, run the data_processing script using the method as step 7. The terminal will output a completion message when the data has finished processing.
13. Finally, run the model_training.py script. Running this script will allow the machine learning algorithm to examine and learn how to differentiate between a tremor and normal movement. There is also pre-written code in the model_training file that will allow the Arduino to control the voltage and current output using the relay. As long as the Arduino is plugged into the PC, running the model_training script will also download the code to the Arduino once it completes processing.
14. Once the cuff mold has completed printing, mix both parts of the two part silicone together, then pour it into the silicone mold.
15. Wait twenty-four hours, then remove the silicone from the mold.
16. Using a characteristic of the patient's arm, generally a vein, create a mark on the cuff that will allow the patient to properly align the cuff onto their arm (*figure 9*).

Figure 9. Create a marking to allow the silicone cuff to align. The vein in this photo is marked in black for visual clarity.



17. Next, pull the backing off an electrode and place it into the center hole in the cuff. Put the sleeve onto the patient, attach the battery, and the customization and calibration of the FES system has been completed.
18. Instruct the patient to return with any future questions or issues, and explain to them to wear it for at least six to eight hours a day for best results. Wearing the device during sleep or waking hours is acceptable.

Thanks to the relative simplicity of our procedures (considering the complexity of the product), there is no need for long-term, or month by month training. Once an employee masters the steps above, they are equipped to become a valuable member of our team. Combined with the skills gained from RoboticsCareer.org lessons, our technicians will not only be able to help administer devices, but also aid in the innovation process and ensure our company constantly stays at the forefront of parkinson's technology.

7. Employee Recruitment Process

Recruiting young engineers and medical technicians for our company requires a multifaceted approach that aligns with both short-term hiring needs and long-term workforce development. Our key strategy is implementing a marketing funnel designed to attract, engage, and convert skilled candidates. This begins with broad outreach through platforms like RoboticsCareer.org, LinkedIn, robotics competition competitors, and university career portals, ensuring visibility among aspiring engineers and medical device specialists. Hosting webinars, virtual open houses, hackathons, and events on RoboticsCareer.org focused on medical robotics can further engage potential candidates by showcasing our company's cutting-edge work in both medical and manufacturing spaces.

Beyond traditional job postings and events, leveraging social media campaigns with targeted ads can effectively draw in skilled technicians as well. By emphasizing the real-world applications of our tremor device, success stories from patients, the sleek yet effective nature of our design, and testimonials from engineers working on the project, we can create a compelling narrative that attracts mission-driven talent. Additionally, a referral incentive program can encourage current employees and industry professionals to recommend top candidates, hopefully tapping into existing networks of skilled engineers and medical technicians.

To build a sustainable talent pipeline, we plan to establish partnerships with universities, technical schools, and most importantly, RoboticsCareer.org. By sponsoring student projects, offering internships, and collaborating on research initiatives, we can cultivate a workforce that is already familiar with our technology and company culture. Hosting engineering competitions or medical device design challenges can also inspire innovation while identifying promising talent. As robotics students ourselves, we know how inspiring being challenged with an engineering problem in a competition setting can be. Lastly, creating an engaging onboarding experience, with mentorship programs and hands-on training, ensures that new hires not only integrate seamlessly but also develop long-term commitment to the company's mission.

8. Cost-Savings Outlook

Our tremor device company is designed with a lightweight, dynamic business model that prioritizes efficiency and adaptability while minimizing overhead costs. By automating key manufacturing processes, we significantly reduce the amount of time required to individually produce each device. This streamlined approach not only improves production speed but also lowers labor costs and material waste, allowing us to maintain high-quality standards without the expenses associated with traditional, labor-intensive manufacturing.

Looking toward the future, outsourcing 3D printing will further drive down costs while maintaining flexibility. By leveraging third-party 3D printing services, we eliminate the need for expensive in-house manufacturing equipment, reduce maintenance costs, and gain the ability to rapidly implement design improvements without costly retooling. This strategy enables us to scale production as demand increases while keeping upfront investment low.

Unlike companies reliant on mass production, our on-demand manufacturing model ensures that we are never burdened with outdated inventory. This approach reduces the need for large warehouse spaces, which in turn decreases storage-related expenses, including insurance costs and facility upkeep. Additionally, by avoiding mass production, we minimize financial losses from obsolete or expired technology, keeping write-offs to a minimum. Our ability to adapt dynamically to advancements in the medical field ensures that we remain at the forefront of innovation without the financial risks associated with long-term stockpiling of materials or components.

Ultimately, our cost-conscious strategy allows us to remain agile and responsive to industry changes while maintaining a lean operational structure. By combining automation, outsourced production, and an adaptive inventory model, we maximize financial efficiency while delivering cutting-edge solutions to patients in need.

9. Conclusion

Parkinson's disease affects millions of people worldwide, yet current treatments remain costly, invasive, or ineffective for many patients. Our project seeks to bridge this gap by developing an affordable, non-invasive functional electrical stimulation (FES) device that customizes treatment through a streamlined manufacturing and training process. By integrating 3D printing, machine learning, and modular electrical components, we have designed a replicable system that can be tailored to individual patients without the need for expensive, fully customized hardware.

Beyond innovation, the success of this initiative relies on equipping technicians with the necessary competencies in CAD, 3D printing, and Python programming. Our structured training program ensures that each technician gains the skills required to manufacture and deploy these devices efficiently. By reducing the cost and complexity of FES treatment, we aim to make this promising technology more accessible to those who need it most, offering new hope to individuals like Joan and the millions of others struggling with Parkinson's disease.