Requirements Report

TEAM 24 - DIGIT

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1 Abstract

To better assist doctors with monitoring and helping patients with hand impairments, Team DIGIT will design and construct a sensory glove for the purpose of tracking real-time motion of the fingers and wrist using sensors. The glove is intended to be used in sessions with patients, who will wear the glove and be instructed to perform specific movements using their hand. A 3D model will be viewable to allow for easier viewing and analysis of data. The glove will aim to improve on prior versions, by reducing the form factor of the circuity and maintaining constant connectivity to the glove. This report provides an overview of the project's marketing and engineering requirements that will be used to design and build the glove.

2 Problem Statements

2.1 Need

There is a need to help monitor patients who have impaired motor function in their hands, such as those who have suffered a stroke, have spinal cord injuries, or other ailments that affect hand motor skills. It is important for medical professionals to be able to collect hand motion data to assess a patient's hand motor skills in real time. By utilizing hand motion data, medical professionals could assess the current condition of a patient or determine the impact of treatments or injuries. Medical professionals need the ability to instruct patients to perform certain hand motor functions and record their movements using means that minimally impact motion while simultaneously monitoring the data in real time.

2.2 Objective

The goal of project Sensory Glove V4 is to implement this glove as a medical device for doctors to use during therapy sessions for patients struggling with impairment in the hands. The design objectives include tracking motion in the hand such as fingers and wrist motion, recording and storing data for comparison in data analysis, displaying data, and prompting commands. Team DIGIT's technical solution for these design objectives will be to (1) create a PCB capable to support sensors (2) record and capture data with the sensors on the PCB then transfer data wirelessly to a secondary device (3) develop a user-friendly GUI in a GUI software development environment.

2.3 Background

It is estimated that one in four adults over the age of 25 will have a stroke in their lifetime [1] with 50% to 70% experiencing movement impairment [2]. These numbers only pertain to hand paresis from strokes and do not account for paresis caused from carpal tunnel surgery and other neurodegenerative disorders such as MS, ALS, and Parkinson's. Physical and occupational therapy is a very common practice to help patients try to regain movement, however depending on the severity of the injury/disorder, the increased out of pocket expenses can put patients in financial jeopardy. Depending on if the patient has insurance, each therapy session can be as low as $15 or up to around

$250 if uninsured [3]. Additionally, the therapist may recommend the purchase of equipment to aid in recovery at home.

There are currently some therapy gloves in the market geared toward rehabilitation of hand movement such as the MusicGlove [4], the Neofect Smart Glove [5] and the CyberGlove [6]. These products can be used to improve hand function recovery by fostering motor learning and brain reorganization. While these products can be useful, they can be very expensive, which limits their accessibility to the public.

The previous iterations of the project were inherited by Team DIGIT however they were geared to be for basketball players to improve their game. These gloves had the main objective of shot tracking to improve their game and shooting form by comparing a shot made by an individual to a previously set benchmark shot [7]. Team SCREEN in 2021 improved upon the previous iterations developed by teams S.W.I.S.H in 2019 and S.H.O.T. in 2020 by creating a glove that was smaller and less obstructive than the previous iterations and measured data in a more concise manner.

Team DIGIT's glove is meant for rehabilitation for impairment in the hands and will need to be improved to fit the needs and objectives from above. Our sponsor would like for the glove to eventually be used at the same time as an EEG cap to compare the data from movement and electrical brain activity. Since the glove will be used simultaneously with the EEG cap, the data needs to be recorded in real time to a secondary device to ensure that the two sets of data can be compared with each other. The sponsor ultimately wants a game to coincide with the glove that provides instructions for movements, feedback based on progress, and goals for patients to reach.

3 Requirements Specification

3.1 Marketing Requirements

1. **Shall** track finger, hand, and wrist motion
2. **Should** be wireless
3. **Should** include a goal-based game
4. **Should** send data to 3D modeling software
5. **Shall** display data from sensors in real time
6. **Shall** be easy to put on and remove
7. **Should** be cleanable
8. **Shall** not interfere with patient's movement
9. **Should** have a rechargeable battery

3.2 Objective Tree

The objective tree, shown in Figure 3.1, was created from the marketing requirements and corresponding engineering requirements. Weights were assigned to each grouping, using the AHP pairwise comparison tables shown in the appendix.

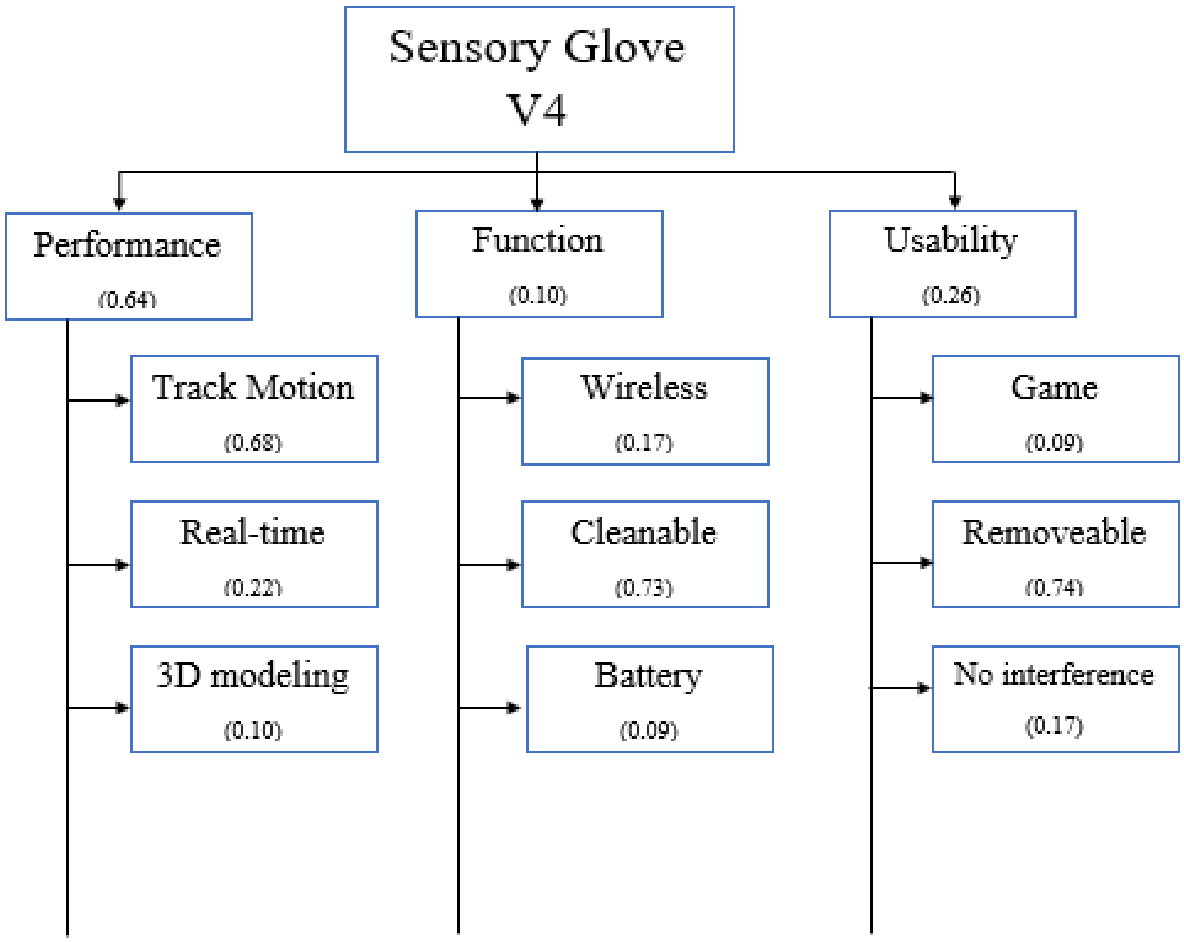

Figure 3.1 Objective Tree

3.3 Engineering Requirements

The following table defines the engineering requirements related to this project. Each engineering requirement represents an attribute of the glove and/or software which is derived from at least one of the marketing requirements (3.1). The corresponding justifications are provided to clarify the engineering requirement's importance to the overall project.

No.	Marketing Requirements	Engineering Requirements	Justification
1	2, 9	Battery **should** last 5-8 hours in idle mode	To ensure that the glove does not shut down during consecutive data collecting sessions.
2	2, 5	**Should** monitor battery level	By monitoring the battery level, the user will be able to detect low power in the battery. This is to ensure the glove does not shut down during data collection.
3	3, 4	**Should** be programmed in LabVIEW, MATLAB, or Python	The sponsor required that our code is written in either LabVIEW, MATLAB, or Python.
4	1, 5	**Should** wire sensors to analog pins	Sensors hooked up to analog pins will allow the microchip to detect changing voltage with analog to digital conversion (ADC) which then the voltage will be converted to resistance.
5	8	**Shall** contain a PCB smaller than the previous PCB design (1.95" x 2")	Designing a smaller PCB will make it easier to put on or take off the glove especially if the patient is rigid from stroke or disability.
6	8	**Shall** contain the control system and connections to all analog sensors on a single PCB	Designing a PCB to contain all the electronics and sensor connections will remove any interference that might occur to the user.
7	5	**Shall** be streamed in real time	Allows for immediate feedback based on results.
8	4, 5	**Should** be displayed in 3D motion	An easier method to view and discuss results with patient.
9	6, 7	Circuity **shall** be removable	Helps with cleaning and working with circuitry while glove is currently not being used.

10	1	**Shall** contain a minimum of 8 analog input sensors	This allows motion tracking with all 5 fingers and wrist movements.
11	4, 5	**Shall** achieve a sampling rate greater than 10 Hz	The sponsor is currently unable to achieve a sampling rate higher than 10 Hz with her prototype. She has requested that we attempt to achieve higher rates to track hand motion more precisely.
12	2, 9	**Should** use Bluetooth or Wi-Fi	Both are affordable and high-speed data transmission technologies. Either option will allow us to have a high sampling rate, as indicated in ER 11.
13	2, 9	**Should** be powered by a rechargeable battery	Using a rechargeable battery reduces our overall waste expenditure and removes the need to buy and store disposable batteries.
14	1, 3	**Should** provide positive feedback when patient follows commands correctly	Allows patient to receive quick input regarding whether they are following directions correctly.
15	6, 8	The glove **shall** be made from material that allows flexibility with different hand sizes	Allows the glove to fit over a variety of patients' hands.
16	1, 4, 5	Data from the glove **should** be sent to a secondary device	Allows the user to look at the collected data from the glove while the patient is actively using the glove. This removes interference with additional wires.
17	1, 3	**Should** display commands to instruct patient to perform specific tasks to test hand movement	Simple visual commands issued through the game will provide an easy method to communicate instructions to the patient during testing.
18	6, 8	The overall weight of the glove **shall** not be more than 4oz	A lightweight glove will allow the user to effectively use the glove and allow the user to easily remove glove from hand.
19	6, 7	The circuity **should** be encased	Allows for the circuitry to be removed from and reattached to the glove easier.

Table 3.1 Engineering Requirements

3.3.1 Verification of Engineering Requirements

Verification ensures the design meets the requirements and specifications. Table 3.2 describes how each engineering requirements will be verified for each prototype.

Engineering Requirements	Verification
1	Charge battery to full and then leave device in idle mode for up to 8 hours. Confirm after 5 hours that the glove is still functioning.
2	Confirm that the battery level can be viewed through observation by either software or hardware.
3	Confirm that all code written is in either LabVIEW, MATLAB, or Python.
4	Wiring the sensor to an analog pin and read changing voltage with the software using ADC.
5	Measure both PCB designs and compare to see if new PCB is smaller than 1.95" x 2."
6	Observing that all connections lead back to the PCB (no additional small PCB breakout boards for sensors).
7	Move sensors on the glove and see if data shows up on secondary device simultaneously.
8	Check that hand model matches the current position and orientation of the actual hand being tested.
9	The circuitry will be detached and reattached to the glove. Then the glove will be turned on and tested to see if it is working.
10	Test each sensor and be able to read the data (resistance measurement).
11	Check how many datapoints the glove can receive in one second of testing.
12	Check that glove has the capabilities to transmit data over either technology.
13	Deplete battery completely, and then charge until full again and check battery level to confirm.
14	Run an instance of the game and test that when a command followed correctly, positive feedback is issued on screen by the game.
15	Test flexibility by putting the glove on various hand sizes and flexing the fingers and rotating the wrist.
16	Test the Bluetooth/or Wi-Fi connection from the primary device to the secondary device.
17	Run an instance of the game and check to make sure commands are being issued continuously as the patient completes previous tasks.
18	Weigh the glove on a scale with all components attached.
19	Check that all circuitry except for sensors and associated connecting wires are packaged in a case.

Table 3.2 Verification of Engineering Requirements

3.4 Design Impact Statements

3.4.1 Environmental

The impact of technology on our environment is a growing issue in the modern world. To mitigate our electronic waste, we have set requirements to try and help our glove be more ecofriendly. The primary decision we are planning on implementing is to make the glove entirely wireless[1]. This will eliminate the need for wires that would normally connect the glove to other devices. In addition, we plan on using a rechargeable battery[2].This will eliminate the need to constantly dispose of old batteries and will reduce our waste.

3.4.2 Manufacturability

The sponsor and mentor have expressed their desire for the glove to be made a product in the market. The following are the constraints for manufacturability. (1) The design will consist of accessible components in the market so that future replications of the device are identical to the prototype. (2) The construction process of the design will be documented in detail for the sponsor and the mentor to have the capability to replicate the device.

3.4.3 Social

Although this sensory glove's intended use is for medical sensing by medical professionals, making this glove easy to use and easily accessible will allow a wide variety of people to take advantage of this technology. In addition to medical professionals using the glove in the office or at home for diagnosis or physical therapy, a commercial market could also be possible. For example, self-monitoring using devices such as watches is becoming very popular for health and fitness applications. If hand motion data can be demonstrated as an accurate early indicator of issues and, if appropriately priced and marketed, individuals could be motivated to collect hand motion data for themselves. While it would not necessarily be appropriate to provide a diagnosis, recommending consulting with a medical professional would be an option.

3.4.4 Standards

Standards ensure that the product works together and follows organization regulations to avoid product failure. The medical sensory glove will follow the standards from the International Electrotechnical Commission (IEC) such as standards IEC 62304 about medical device software [8] and IEC 60601-1-11 for medical electrical equipment [9]. Standards from the Institute of Electrical and Electronics Engineers (IEEE) will also be respected including the IEEE 1233 Guide for Developing System Requirements Specification [10] and IEEE 802.15.1-2005, Standard for Information technology [11]. The glove will also be created keeping in mind the standards from the

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[1] Marketing Requirement 2
[2] Marketing Requirement 9

Association for the Electronic Interconnection Industry (IPC), specifically IPC-6011, the Generic Performance Specification for Printed Boards [12] and IPC-2221A, the IPC Standards for PCBs [13]. Finally, with the intention of eventually getting FDA approval so that the glove can be sold to mass markets and used in therapy centers, the FDA standards for medical devices [14] will also be respected.

3.4.5 Economic

Healthcare equipment can be very expensive which can impact patient care. Developing a sensory glove that is inexpensive benefits both medical facilities and patients. Inexpensive equipment is accessible to greater numbers of care providers which, in turn, provides more accessibility to a greater number of patients while also reducing overall costs. Because this is medical equipment, it is important that it provide accurate and reliable data. Inexpensive sensors and materials need to be thoroughly examined to determine if they will be accurate and reliable. Another aspect to cost is repairability. If cheaper sensors are accurate but less durable, it may be possible to replace them after one or more uses.

4 References

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5 Appendix

This section explains how our group obtained the weights for each branch of the objective tree (Figure 3.1). Using the analytical hierarchy process (AHP) from Appendix B in the back of the book [15], we took our marketing requirements (3.1) and categorized them into three objectives and ranked each one according to its relative importance. The geometric mean for each row is computed and totaled using the formula $GM = \sqrt[n]{\alpha_1 \alpha_2 \ldots \alpha_n}$. The weight for each row is then computed by dividing the individual geometric mean by the sum of the means. For the weighted score, the weight from each row was multiplied by the category weight.

	Functionality	Performance	Usability	Geometric Mean	Weight
Functionality	1	1/5	1/3	0.40	0.10
Performance	5	1	3	2.47	0.64
Usability	3	1/3	1	1	0.26
Sum	9	1.33	4	3.88	1.00

Table 5.1 Sensory Glove Category AHP

Performance of the glove is most important because the overall goal of the glove is the track and record hand movements. Without performance, the project would be an ordinary glove that doesn't track hand movement. The second most important category is usability. Usability comes after performance because being able to use the glove with ease, no interference, and with a goal-based game is what makes the glove a product. The last category functionality comes after the other two because battery, wireless, and cleanable are not completely necessary for the system to operate.

Functionality	Wireless	Cleanable	Battery	Geometric Mean	Weight	Weighted Score
Wireless	1	1/7	3	0.75	0.17	0.01
Cleanable	7	1	5	3.27	0.73	0.07
Battery	1/3	1/5	1	0.40	0.09	0.00
Sum	8.33	1.2	9	4.43	1.00	0.10

Table 5.2 Functionality AHP

The cleanability of the glove is essential to ensure that our product can remain hygienic. This is especially important in a doctor/therapy setting, where the glove is planned to be primarily used. Therefore, cleanable is weighted with at least five times the importance of wireless and battery. Both designing the glove to be entirely wireless and using a rechargeable battery are goals we aim to accomplish to minimize our environmental impact. We prioritize wireless over battery due to wireless also contributing to the glove's requirement to not impair hand motion during testing. Furthermore, if the glove is not wireless, then a battery is not needed as the glove would be powered from the computer. Therefore, we weigh wireless as three times as important as battery.

Performance	Track Motion	3D Modeling	Real-time	Geometric Mean	Weight	Weighted Score
Track Motion	1	3	7	2.76	0.67	0.43
3D Modeling	1/3	1	1/5	0.40	0.09	0.06
Real-time	1/7	5	1	0.89	0.22	0.14
Sum	1.48	9	1	4.06	1.00	0.64

Table 5.3 Performance AHP

The main objective of the glove is that it tracks the motion of the hand and wrist movements. Without this, the glove is nothing more than something the patient is wearing since it would not be providing data and feedback. For this reason, tracking motion is weighted three and six times higher than real time and 3D modeling respectively. The sponsor will be using the glove simultaneously with an EEG cap, so data needs to be streamed to a secondary device in real time with little to no lag. Hence, real time is weighted about twice as much as 3D modeling. Interest was expressed by the sponsor for the movements to be streamed onto a secondary device as a 3D model so that patients and therapists can see what is happening. However, this is not necessary for the glove to work as intended so it has a weight less than 10 percent.

Usability	Game	Easy	No Interference	Geometric Mean	Weight	Weighted Score
Game	1	1/5	1/3	0.40	0.09	0.02
Easy	5	1	7	3.27	0.73	0.19
No Interference	3	1/7	1	0.75	0.17	0.04
Sum	9	1.14	8	4.43	1.00	0.26

Table 5.4 Usability AHP

When meeting with our sponsor, she emphasized that a lot of patients that use the glove, have rigid hands and such little movement that the glove needs to be easy to put on. Therefore, the category of easy/removeable is weighted about four times higher than the no interference and ten times higher than the inclusion of a game. If the circuity cannot be removed and the glove is not flexible, it can be very hard to put on and take off. In addition, the glove and its components should not get in the way of patient's movements and therapy session otherwise the data may have some error and it can make the session harder than it needs to be on the patient. Eventually it is desired that the glove will be driven by a game that is on the secondary device that is goal based and provides feedback to patients based on their progress. This is something that does not have to happen, but it would be nice if we are able to achieve this, hence why it has the lowest weight out of the three categories.