Spinal Cord Stimulator Design Specifications (PDS)

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Preliminary Design Specifications (PDS):

Function:

Client Requirements:

- Must involve transcutaneous electrodes that are noninvasive and do not require surgery to place
- Model system of rat should be utilized before human testing
- Cannot cause excessive discomfort to patient
- Must enhance quality of life through stimulation, whether short term or long term
- Budget of $3000

Design Requirements:

1. Physical and Operational Characteristics

a. Performance Requirements: The device should be able to be able to perform under the varied location of electrodes and frequency of pulses. Current must penetrate as deep into the body as possible to reach spinal nerves. The goal of researching potentially new settings for stimulators means that our device may have capabilities outside of the realm of existing devices. The stimulator should have the the ability to change frequency of pulse without difficulty, as well as be flexible in the placement of electrodes. Since we will be using the model system of the rat, the stimulator should be able to function on a rat for the initial testing, with the knowledge that stimulation will ultimately be scaled for human use.

b. Safety: The device must not cause harm to the patient, including shocking, burning, or excessive pain. The current must be low enough that no damage is done to tissue around the electrodes. The system must not stimulate the incorrect nerves so as to cause spasms or unintended reactions.

c. Accuracy and Reliability: Each time this device is used, the electrodes should produce consistent frequency, and the device should target the same neurons/portions of the spine in order to achieve the same results. Any large deviations in these specifications could result in painful sensations for the individuals tested or even unseen adverse effects related to muscle movement/stimulation.

d. Life in Service: The spinal cord stimulator will be used at multiple intervals for testing during the span of our design, which could be extended for a couple of years. The design must be able to withstand repeated use, as well as a variety of levels of current and

voltage.

e. Shelf Life: This product will most likely be used intermittently for short periods of time throughout a given day. It should be able to withstand a wide range of electrical frequencies, as well as maintain shape and function after repeated use and removal. Any gel used should be removable for storage purposes.

f. Operating Environment: The device will need to operate at room temperature in a range from 15℃ - 25℃. The device will also be in contact with the surface of the skin of rats, which will be shaved and have gel applied topically to the electrode sites. Although the device will initially be used in a standard laboratory environment, it will eventually be used in a clinical setting.

g. Ergonomics: The device needs to be worn by a live rat, considering its weight and size. It should withstand basic maneuvering and should not inhibit normal functions such as walking, running, eating, bending, and turning.

h. Size: The wearable device will need to fit a standard rat, with the electrode system fitting tightly along its spine. The design of the device should allow for simple removal from one subject so as to allow for easy transfer to another individual.

i. Power Source: Several conventional batteries have been used: lithium-ion batteries, nuclear cells, biocells. Rechargeable batteries are excellent choices given the reusability and ease of patient maintenance. These have been used in Implantable Medical Devices [1][2]. In the future, kinetic energy from the body would be ideal since the device would be worn on the patient for potentially extended periods of time. However, due to the constraints of the project we will utilize a more conventional means of power source [3]. Additionally, biodegradable power generators are available, which could be another very biocompatible option for the future [4].

j. Weight: Most animals can conveniently carry about 10-20% of their body weight. It is clear, though, that increased strain on rat tibias results in an increase in the need for further bone formation [5]. Depending on the type and average size of the rats being used for our project, this value may vary. In general, we would like the device to weigh, at the very least, less than two pounds.

k. Materials: Most commonly, ceramics, metals, and polymers with high biocompatibility ratings are used in biomedical devices, especially when implanted. Common metals include commercial pure titanium and titanium alloys. Metals are

typically used for load-bearing devices. Polymers involved include polyurethane (usually for flexibility and its ability to conduct as an insulator). Electrodes are often made from copper, graphite, titanium, brass, silver, and platinum [6]. Many implantable spinal stimulation devices, in particular, are comprised of a wide variety of materials, including biomedical-grade silicone, various epoxies, as well as parylene C, an insulating polymer [7].

l. Aesthetics, Appearance, and Finish: The device should be insulated where necessary and have clear notation of the cathodes and anodes. Any potential triggers or current supplying components should be clearly labelled.

2. Product Characteristics:

a. Quantity: We predict that only one product will be required, as we are working on a unique electrode array for our client.

b. Target Product Cost: We were given a budget of $3,000 to complete this product. We do not anticipate surpassing this budget this semester.

3. Miscellaneous:

a. Patient-Related Concerns:

Our client has repeatedly alluded to the importance of comfort and simplicity of the design in the hopes of being able to make this product simple for consumers to use commercially. Other concerns relevant to the electrode array are the depth of the electric stimulations and how stimulating spinal nerves may also stimulate a plethora of unrelated nerves huddled within the same nerve bunch (the extent of which is currently unpredictable). The end goal of locomotion or increased bodily function may be worth some temporary discomfort to the patient if it brings long term growth, though mitigation of any discomfort is still highly prioritized.

b. Competition:

This design has many competing products from many healthcare companies across the US, including companies located within the Midwest, such as Medtronic and Boston Scientific. These companies have professionalized spinal cord stimulation (SCS) devices that can be used by Hospitals and surgeons across the country [2][8]. However, these companies focus on SCS through epidural stimulation and work on functions related to neurological mapping similar to MRIs, whereas our product will be primarily focused on SCS through transcutaneous stimulation and will have no neurological mapping capabilities. There are devices similar to our intended product that deal with

transcutaneous muscle and nerve stimulation but these devices have been specialized for pain treatment or are not as versatile as we intend our product to be [9][10][11].

4. References

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