PRODUCT DESIGN SPECIFICATIONS

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Title: Assistive device to augment strength in the weak hand of a stroke patient

Team:

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Function: After stroke some patients suffer complete loss of mobility in the affected body part; however, most regain a certain degree of their original mobility and strength. There are groups working on robotic devices that sense and augment movement - this helps patient mobility, and is hypothesized to improve recovery of strength and or dexterity. The device should be glove or mitten design that could sense and augment finger movements in stroke patients.

Client requirements: Our client, Dr. Matt Jensen, would like our team to develop a glove or mitten that is able to augment finger movements in stroke patients. This device should be able to sense when a patient is opening or closing his/her hand and augment their movement based on the pressure being applied on the glove. The device should also be able to be removed from the hand with little work involved. Important areas of focus include efficiency of the design, safety regarding glove movements, and the ability to be affordable and convenient for all stroke patients. This project may involve electric, hydraulic, and various other mechanical approaches.

Design Requirements:

1. **Physical and Operational Characteristics**

   a. *Performance Requirements*

   The product should be able to improve the mobility of a stroke patient's hand while being comfortable and safe for the patient. It should be unobtrusive and be able to be worn only when the user wishes. The device must be portable and capable of being attached and worn by a patient in a home setting. It should have a significant battery life so the user can wear it for long periods of time. To add to its practicality, the device should be able to achieve average hand strength assistance, approximately 279 N.

   a. *Safety*

   If electrical power is used, electrical safety is the main concern and the device should have proper guidelines on use. Electrical components should be encased in a protective material to reduce the risk of electrical shock. If other power sources are used, proper safety should be taken and proper instruction on use of the device should be given. Device should be tested to ensure its efficiency over time. Minimal user training should be required.

   b. Accuracy and Reliability

   The device should be able to withstand prolonged use and be readily available whenever the user would like to use it. It should have lengthened battery life for continual use. It should accurately sense the amount of force the user wishes to exert and assist in the sought movement.

c. *Life In Service*

The product would ideally have a power source that would last all day, approximately 6-12 hours. Additionally, it will be capable of recharging during night, approximately 6-12 hours. The product itself should last the lifetime of the user to reduce costs for patients.

d. *Shelf Life*

If batteries or another degradable power source is used, proper storage should be noted and labeled on the device. Electrical wires and other mechanics should have proper encasing so they don't degrade over time. It should be able to be stored in a home environment so it can be near the patient.

e. *Operating Environment*

The device will have to be robust enough to function in a number of different environments. Wearers may use it in a number of different temperature and humidity environments, including the possibility of total liquid immersion (as in the case of the user spilling a glass of water on the device). The device will most likely be subject to dirty and dusty conditions. The device must withstand shock loads, as objects could be dropped on the device during daily use. Electrical interference may be encountered due to the variety of household appliances, which radiate electromagnetically.

f. *Ergonomics*

Since the product will be worn on the user's hand and potentially be used in interaction with other humans, force restrictions must be established to protect both the user and other parties who might interact with the user. In the case that the user was to shake another party's hand, for example, the device must have a force feedback mechanism in order to avoid crushing the hand. Range of motion must also be restricted to avoid hyperextension or hyper-flexion of the fingers. Also, the fingers have no ability to rotate about the long axis, so torsion forces must be minimized or eliminated. Furthermore, the device must be comfortable enough to wear for extended periods of time.

g. *Size*

The device will be worn on the hand and must not be excessively large so as to be unwieldy in daily use.

h. *Weight*

The device must not add significant weight to the user's arm. Such excessive weighting could cause stress injuries to the user over extended periods of use. Ideally the device will weigh less than 1 lb.

i. *Materials*

Materials which will come in direct contact with the skin (i.e. the glove material itself) must be non-allergenic, and also non-irritating. Mechanical materials must be strong enough to withstand shock loading. Electrical components must be protected from liquid, dirt, and dust via some protective material.

j. *Aesthetics*, *Appearance, and Finish*

The device must mimic the shape of the human hand. It must be stylish and aesthetically pleasing so that the user is not discouraged from using the device in public.

2. Production Characteristics

a. *Quantity*

One prototype is needed at the current time, however product be designed for possible mass production in the future.

b. *Target Product Cost*

The price for production of the prototype must not exceed $1000. The mass produced final design should be affordable to all stroke patients.

3. Miscellaneous

a. *Standards and Specifications*

FDA approval will be necessary. IRB approval will be necessary before any testing is done. Product must be able to be easily translated into mass production. Product must be proved beneficial to the recovery of stroke patients.

b. Customer

Stroke patients with loss of mobility in the hand. The range of patient mobility can vary from low to high, as long as some mobility is present.

c. Patient-related concerns

The product will have to undergo rigorous testing to ensure that it is safe for all patients under all circumstances. It must not have the potential to cause injury to the hand.

d. Competition

The concept of assistive movement stroke recovery therapy is new but widely known. Other devices for a wide array of body parts have been designed to assist the movement of stroke patients. To our knowledge and to the knowledge of our client no other “removable” devices have been made for the hand.