The Arm Support System For Kids with Upper Limb Disability
Project Design Specifications

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Function: Many kids with upper limb muscle weakness having difficulty playing with their friends without the help of an adult because they do not have adequate muscle strength to slide their arms. Our mission is to design an arm supportive device to help a 4- year- old girl who has similar symptoms with SMA (Spinal Muscular Atrophy) move her arm to pick up game pieces. The girl has great shoulder control that is able to rotate in three directions. The design needs to include straps to hold her arm and allow her arms to move in sagittal, transverse and frontal plane by moving her shoulders.

Design Requirements:

1. Performance Requirements: The device should be able to help the girl perform some basic movements such as writing and drawing on her own.
2. Safety: The device must meet the general safety standard for medical devices and try to minimize discomfort for patients. The materials used for the device must be sterile, and mechanically as well as chemically stable, such that additional harm to the patient is avoided.
3. Accuracy and Reliability: The device dimension should well fit the 4-year-old girl and the stripes on the device should not be too strong to potentially hurt the girl's arm.
4. Life in Service: The desired device should work at least for a year and not disband.
5. Shelf-Life: 3-5 years
6. Operating Environment: The device should be operated at multiple locations, either on the floor or at the table.
7. Ergonomics: The device aims to assist the girl achieve some easy tasks without others' assistance.
8. Size: A 4-year-girl fitting dimension.
9. Weight: Less than 2 lbs.
10. Materials: PVC pipes
11. Aesthetics: Children preferred color painting on the device.

Client Requirements:

- The device should allow the girl to freely move her arms up and down.
- The girl should be able to use the device on her own.
- The device should not lead the girl in any dangers.
- The cost of the device must be under $200.

Production Characteristics:

1. Quantity: Our client has requested for 1 specific design to help the 4-year-old girl, however, in the future there is potential for mass production of the device for muscle weakness rehabilitation exercises after successful testing. Following this, the quantity might be increased.
2. Target Product Cost: Our targeted budget will be limited to 200 dollars. The current competing designs cost around $500-10k.

Standards and Consumer Characteristics:

1. Standards and Specifications:
    a. This device will be used for rehabilitation of upper limb muscle weakness under the professional occupational therapist's guidance and is classified as a class III medical device according to FDA standards [1].
    b. FDA premarket approval is required before this device can be commercially distributed.
    c. Local regulations in regards to Human Subjects or Animal Studies with this medical device will require an IRB for further studies to validate the device.
    d. Phantoms and/or computational models can be an alternative to validify this device for its current stage of development.
    e. The device specifications will have to comply with the FDA’s Federal Register, as well as the Code of Federal Regulations. The FDA also requires a number of approvals and clearances to ensure that a device is safe and effective before used on patients in hospitals. These include a 510(k) Premarketing Submission and Premarket Approval (PMA).
2. Customer: The product will be operated by trained occupational therapists and physical therapists. The product should be usable for children with upper limb muscle weakness for daily activities, play or rehabilitation purposes.
3. Patient or User-related Concerns: The device should be safe to use for both patient and operator. It should not create any discomfort for the patient. It should also have the ability to help support the weights of both arms without falling over and help her perform desired training exercises or simply play.
4. Competition

a. MIT-Manus [2]
    i. In 1998, Hogan et al. designed a direct drive, a five-bar-linkage SCARA (Selective Compliance Assembly Robot Arm) to aid in stroke rehabilitation of the upper limb. [2] The device functions in a horizontal plane and works with visual feedback to assist users to perform predefined arm movements in therapy.
b. Mirror Image Movement Enabler (MIME) [3]
    i. In 2006, a group of researchers developed the device to enable bilateral upper extremity rehabilitation for stroke patients. The MIME had 6 degrees of freedom. It involved bilateral upper extremity movement with the intent to promote neural changes within the brain to compensate for the affected hemisphere in controlling the paretic limb, and suggested feasibility of this type of design and yielded therapeutic benefits.
c. Wilmington Robotic Exoskeleton (The WREX) [4]
    i. A currently commercialized passive, pediatric, upper-limb orthosis designed to assist children with upper limb weakness. The WREX has an anthropomorphic configuration and uses parallel mechanisms with zero rest-length springs for gravity balancing. However, it has limitations including lack of countering force to allow the child to pick up objects of significant weight and difficulties for the children to raise their arm above their head due to misalignment of joints between user and devices.

References:

[1] US Food and Drug Administration (2018). Code of Federal Regulations, Title 21, Volume 8, 21CFR882. Department of Health and Human Services.

[2] Igo Krebs, H., Hogan, N., Aisen, M. L., 1998, "Robot-Aided Neurorehabilitation," IEEE Transactions on Rehabilitation Engineering, 6(1) pp. 75-87

[3] Lum, P.S., Burgar, C.G., Van, D.L., 2006, " MIME Robotic Device for Upper-limb Neurorehabilitation in Subacute Stroke Subjects: A Follow-Up Study," Journal of Rehabilitation Research and Development, 43 (5)pp. 631-642.

[4] D. D. Ragonesi, "Control of a Powered, Gravity-Balanced Orthosis for Children with Limited Upper Limb Strength." Order No. 1585176, University of Delaware, Ann Arbor, 2014.